User Manual

Leksell Gamma Knife® Icon™

Instructions for Use

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Elekta acknowledges the trademarks and registered trademarks of other manufacturers that we use in this document.

Referenced documents

Elekta does not supply all the documents that we refer to in this document with the equipment. Elekta reserves the right to make the decision on which of the documents we supply with the equipment.

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TECHNICAL SUPPORT

Contact your local Elekta representative for technical support

Table of Contents

— Blank page —

1 Safety and regulatory information

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1.1 Intended use

Leksell Gamma Knife® Icon™ is a teletherapy device intended for stereotactic irradiation of head structures ranging from very small target sizes of a few millimeters to several centimeters.

Indications include but are not limited to; metastatic tumors, arteriovenous malformations, trigeminal neuralgia, essential tremor, meningiomas, vestibular schwannomas, pituitary adenomas and glioblastoma.

WARNING 1.1

Practitioners should be attentive to the radiation doses and potential toxicities associated with radiation delivered to adjacent structures. Side effects of stereotactic radiosurgery are generally associated with effects on critical structures that are within or nearby the treatment target. These may include effects that can be temporary or permanent (e.g. radiation necrosis). These effects can lead to edema, ischemia, brain compression, and neurological symptoms. Toxicities could include but are not restricted to motor weakness, sensory deficits, visual deficits, neurocognitive deficits, and speech deficits depending on the brain location. Rarely, serious and irreversible side effects can occur. Particular effects depend on the actual region at risk by virtue of proximity to the target, the radiation dose received and other clinical factors such as age, medical condition, the disorder irradiated, previous radiation treatment history, and other prior interventions both medical and surgical.

WARNING 1.2

For Post-surgical Pituitary Adenoma: Practitioners should be attentive to the radiation doses and potential toxicities associated with radiation delivered to adjacent structures such as the optic pathways, and should balance the risks of incidental irradiation to those structures with the benefits of treatment of the pituitary tumor. Such toxicities could include but are not restricted to motor weakness, sensory deficits, visual deficits, hormonal, neurocognitive, and speech deficits.

WARNING 1.3

For Medically Refractory Essential Tremor: Practitioners should be attentive to the radiation doses and potential toxicities associated with radiation delivered to adjacent structures such as the internal capsule and adjacent thalamus and midbrain, and they should balance the risks of incidental irradiation to those structures with the benefit of treatment to the primary lesion. Such toxicities could include but are not restricted to motor weakness, sensory deficits, visual deficits, neurocognitive, and speech deficits.

1.1.1 Intended population

The intended patients are adults and children from the age of 2 years and up.

1.2 Use of the equipment

This equipment is intended to be installed and used only in accordance with the safety procedures given within this document for the purpose for which it was designed. Nothing stated in this document reduces the user's professional responsibilities for sound judgement and best practice.

Installation and use of this equipment is subject to the law in the jurisdictions in which the equipment is being used. Users shall only install and use the equipment in such ways that do not conflict with applicable laws or regulations which have the force of law.

Use of the equipment for purposes other than those intended and expressly stated by the manufacturer, as well as incorrect use or operation, may relieve the manufacturer or his agent from all or some of the responsibility for resultant non-compliance, damage or injury.

1.3 Compliance of the equipment with international standards

Leksell Gamma Knife® Icon™ complies with the requirements of the Medical Device Directive 93/42/EEC. The product is CE marked.

1.3.1 Standards approval

Leksell Gamma Knife® Icon™ complies with the following safety standards:

- EN/IEC 60601-1 Medical electrical equipment, Part 1: General requirements for safety.
- EN/IEC 60601-1-2 Collateral standard: Electromagnetic compatibility.

Note: *Potential electromagnetic or other interference between the equipment and other devices can occur even though the device fulfills the legal requirements. To avoid such problems the possible interfering equipment could be removed from the treatment room or placed somewhere else in the room. The user should take extra care if the patient is using a pacemaker or similar device.*

- IEC 60601-2-11, Medical electrical equipment, Part 2: Particular requirements for the safety of gamma beam therapy equipment.
- AAMI ES60601-1 Medical electrical equipment: General requirements for safety.
- CAN/CSA C22.2 No. 60601-1:14 Medical Electrical Equipment, Part 1: General Requirements for Safety.
- IEC 60601-1-3: Radiation protection in diagnostic X-ray equipment.
- IEC 60601-2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis.
- IEC 60601-2-68: Particular requirements for basic safety and essential performance of X-ray based Image Guided. Radiotherapy Equipment for use with electron accelerators, light ion beam therapy systems and radionuclide beam therapy systems.

1.3.2 IEC classification

Leksell Gamma Knife® Icon™ is classified as set out in the following table.

IEC 60601-1 Type of protection against electric shock	Class I equipment
IEC 60601-1 Degree of protection against electric shock	Type B applied parts 
IEC 60601-1 Methods of disinfection recommended by the manufacturer	Disinfectable equipment (or elements). See ‘Accompanying Documentation’ for methods.
IEC 60601-1 Degree of safety of application in the presence of flammable anesthetic mixture with air or with oxygen or with nitrous oxide	Equipment NOT suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen, or nitrous oxide.

1.4 Recommendations for training

Users of the equipment shall have received adequate training on its safe and effective use before attempting to work with it.

Training requirements may vary from country to country. The user shall ensure that training is received in accordance with local laws or regulations that have the force of law. Information on training is available from Elekta or your local Elekta representative.

1.5 Important safety instructions

Elekta® products are designed to meet stringent safety standards. Every reasonable precaution has been taken during manufacture to safeguard the health and safety of patients and persons who will operate this equipment.

All medical electrical equipment requires proper installation, operation and maintenance, particularly with regard to safety.

It is vital that the user read, understand, and where applicable strictly observe all safety directions, warnings, cautions, notes and safety markings within this document and on the equipment.

WARNING 1.4

Never attempt to remove, modify or override any switches, interlocks, or other safety device on this equipment. Interfering with such safety devices could lead to death or serious injury.

This product should be installed and commissioned by Elekta® personnel or other service user approved in writing by Elekta.

The system in whole or in part may not be modified in any way without the prior written approval of Elekta.

Related Links:

Standards approval on page 9

1.5.1 Conventions for warnings, cautions, and notes

The following are samples of how warnings, cautions and notes appear throughout this document. The text within the samples explains their meaning.

WARNING 1.5

Warnings are directions which, if ignored, could constitute a health hazard, cause fatal or serious injury, or lead to clinical mistreatment.

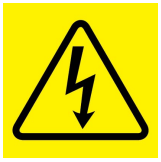
CAUTION 1.1

Cautions are directions which, if ignored, could cause damage to the equipment described in this manual, and/or any other equipment or goods, and/or could cause environmental damage.

Note: *Notes provide advice and highlight unusual points. A note can also be part of an instruction.*

1.5.2 Warning symbols found on the equipment

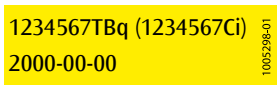
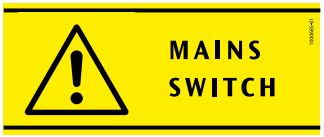
The following warning symbols may be found on the equipment:

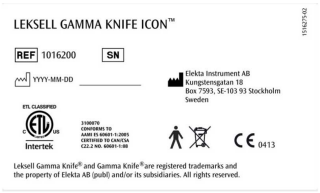
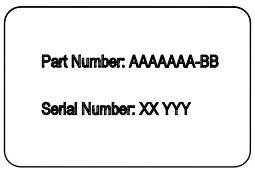
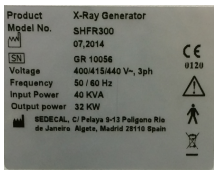
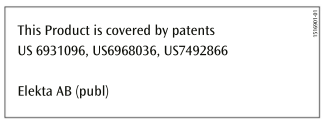
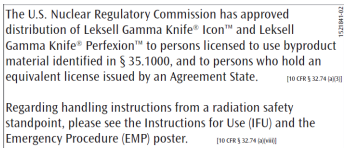
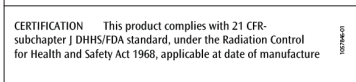
Product documentation symbol		Instructs the user to refer to the product documentation.
Warning symbol		Indicates a specific warning if displayed in conjunction with warning text. Instructs the user to refer to the product documentation if displayed without warning text.
Radiation warning symbol		Indicates the possibility of a radiation hazard.
Disposal instruction		Indicates never to dispose of the product or component into the domestic waste stream.
Mechanical hazard warning symbol		Indicates the possibility of human injury caused by scratching, squeezing, crushing, etc.
Electrical voltage hazard warning symbol		Indicates the possibility of dangerous electrical voltage.

1.5.3 Labels found on the equipment

Labeling not illustrated elsewhere in this manual are presented in this section.

Label	Found on
	Emergency alarm indicator on control panel.
	Emergency alarm indicator on control panel.

Label	Found on
	Emergency Stop button on control panel.
	Product documentation, on the control panel.
	Gantry cover
	Rear cover of radiation unit.
	Door hatch on left side cover of radiation unit.
	Release handle for X movement on patient couch.
	Release handle for Z movement on patient couch.
	Side covers of radiation unit, next to door hatch.
	Radiation unit, inside the cover.
	Activity and date label
	Rear cover of radiation unit.

Label	Found on
	Rear cover of radiation unit.
	CBCT
	X-ray tube CBCT
	X-ray tube CBCT
	kV generator
	Rear cover of radiation unit.
	Right side cover of radiation unit
	Back of the gantry cover.
	Rear cover of radiation unit.
	Warning label on Vantage Frame adapter

1.5.4 Unique Device Identification (UDI) label

On Elekta product labels the GS1 DataMatrix is introduced. This symbol represents the Unique Device Identification (UDI). It includes the unique product identification number (also known as Global Trade Item Number or GTIN). Depending on the product, other product data might be included. The use of the symbol and related product data is in compliance with the latest regulations (e.g. UDI rules issued by US FDA). See below an example:

Figure 1.1 Sample UDI label

The following GS1 Application Identifiers (AI's) might be used:

- (01) GTIN (Global Trade Item Number)
- (10) Batch or Lot number
- (11) Production date
- (17) Use by (or Expiration) date
- (21) Serial Number
- (240) Add. item identification (e.g. technical part no.)

1.5.5 Extended symbol glossary

For more information about symbols on Product Labels, see SYMBOL GLOSSARY EXTENDED (77700544) on the Elekta website: **http://www.elekta.com/services/supportplus**. The glossary lists contain applicable standards, symbol reference codes and symbol meanings, for example.

1.6 Safety precautions

1.6.1 Safety precautions for the compatibility of the equipment

Equipment described in this document shall only be used in combination with other equipment or components if these are expressly recognized by Elekta as approved and compatible. Consult Elekta for advice on compatibility with the equipment before using any equipment not supplied by Elekta.

Changes or additions to the equipment must only be performed by persons expressly authorized to do so by Elekta. Such changes must comply with best engineering practice and all applicable laws, and regulations that have the force of law within the jurisdiction.

WARNING 1.6

Changes, additions or maintenance to the equipment performed by persons without appropriate qualifications and training, and/or the use of unapproved spare parts, may lead to serious injury and/or damage to the equipment, as well as making the warranty void.

1.6.2 Safety precautions for operation of the equipment

Do not use the equipment for any application until you are sure that the procedures for care and maintenance have been satisfactorily completed.

WARNING 1.7

If any part of the equipment is known or suspected to be defective or incorrectly adjusted, DO NOT USE the equipment until a repair has been made by Elekta. Use with defective or incorrectly adjusted components or systems could expose the users and/or the patient to radiation and other safety hazards. This could lead to injury or to clinical mistreatment.

1.6.3 Radiation safety

Leksell Gamma Knife® must only be used in rooms that comply with all applicable laws, or regulations that have the force of law, concerning radiation safety for this type of equipment. Full use must be made of all radiation protection features, devices, systems, procedures, and accessories.

Any person working on this equipment must be restricted to those legally permitted to do so, and those specifically authorized by local management.

WARNING 1.8

Personnel entering the treatment room while the shielding doors are open and the sectors are not locked in the sector home position must keep their exposure time to a minimum. Overexposure to gamma radiation can endanger health.

1.6.4 Safety precautions for cardiac pacemakers, other implants or portable electronic medical devices

WARNING 1.9

Do not put the cardiac pacemaker, other implant or portable electronic medical device, in the radiation beam. If you ignore this warning, you can cause fatal injury.

WARNING 1.10

Do not deliver radiation treatment unless you continuously monitor the operation of the cardiac pacemaker, other implant or portable electronic medical device. If you ignore this warning, you can cause fatal injury.

The cardiac pacemaker, other implant or portable electronic medical device, can be damaged by very small doses of radiation. Radiation treatment can make magnetic or electric fields, or ionizing radiation, which can cause damage to these devices.

For more information on the necessary precautions, see the applicable documentation from the manufacturer of the device.

1.6.5 Final disposal of the equipment

Prior to disposal, always contact Elekta for advice.

The term final disposal means disposal of the equipment, or any part of the equipment, in such a way that the equipment or part can no longer be used for its intended purpose(s).

Never dispose of Elekta products in the domestic waste stream.

Disposal must always be executed in an environmentally sensitive manner that complies with all local and international regulations and laws. Materials hazardous to human health and the environment must be separately removed and disposed of through competent, licensed facilities. The remaining material may be recycled where facilities and local regulations permit.

WARNING 1.11

Incorrect handling or disposal of hazardous material may cause death, serious injury and environmental damage.

The recommendation is to keep the system in larger parts (RU, PPS, Gantry (if applicable), Medical cabinet) during disassembling and transport in connection with disposal.

WARNING 1.12

If the larger parts of the system are disassembled in smaller parts there is a risk for heavy parts tilting or coming loose. This may cause damage, injury or death.

WARNING 1.13

Be careful with the batteries. Batteries can cause risk of electric shock, or short circuit that may cause fire.

1.6.6 Product lifetime

Leksell Gamma Knife® Icon™ has a lifetime of 10 years.

2 Introduction

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2.1 Function of this document

The function of this document is to help users in the safe and effective operation and maintenance of the equipment described. The user includes the body with authority over the equipment and those persons who actually handle the equipment.

Before attempting to work with this equipment, the user must:

- Thoroughly read and completely understand this document.
- Keep this document with the equipment for easy access.

The most extensive configuration is described within this document, including the maximum number of options and accessories. Not every function, option or accessory described may have been purchased or licensed by the user.

2.2 Intended audience

This document is written for trained users, for Elekta service personnel, and for personnel involved in care and maintenance procedures of the product described in this manual.

2.3 Structure of this document

The information in this document has a defined structure. The structure helps the user to find the information it contains more easily. The information comes in the following chapters:

- Safety and regulatory information
- Introduction
- Product description
- Getting started
- Using Leksell Gamma Knife® Icon™
- Maintenance
- Appendix with product specifications (where applicable).

2.4 Accompanying documentation

The accompanying documentation is a list of other documents related to the product. Contact your Elekta representative for more information.

The related documents are:

- *Leksell Gamma Knife® Icon™, Emergency Procedures*
- *Leksell GammaPlan®, Online Reference Manual*

  
  LGP software

  The Online Reference Manual is available on a media together with the LGP software and is part of the system at installation. After installation, the Online Reference Manual is accessed from the Help menu within the LGP software.
- *Leksell Stereotactic System®, Instructions for Use*
- *Leksell® Vantage™ Stereotactic System, Instructions for Use*

2.5 User definitions

The different users of the system are:

Clinical users	A Clinical User is a qualified person who uses the Leksell Gamma Knife® system, and its accessories, for the treatment of patients. A Clinical User has the necessary training in the safe, clinical operation of the system and its accessories. This typically includes neurosurgeons, oncologists, nurses and physicists. In this manual, Clinical User is referred to as the user.
Service users	A Service User is a qualified person who has the necessary training to do the installation and maintenance tasks of the Leksell Gamma Knife® system and its accessories. A Service User operates the system, and its accessories, to do the necessary tests, adjustments, and repairs of the equipment. Such operation is not therapeutic.

Related Links:

User types in the system on page 65

2.6 Directional conventions

Unless explicitly stated otherwise, the directions left, right, front, and rear of the Leksell Gamma Knife® Icon™ unit are given as viewed by the patient laying on the couch in supine position. See figure below.

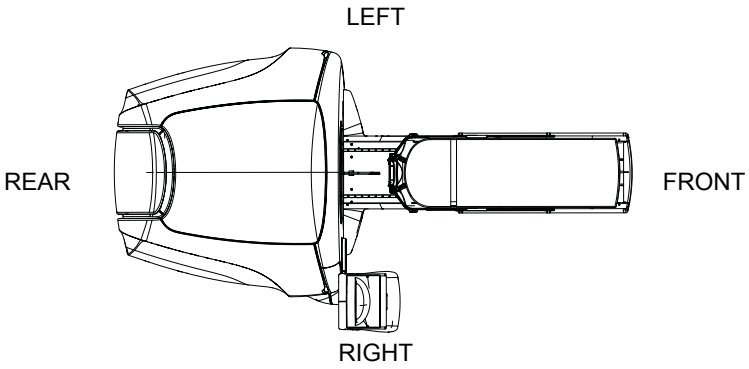

Figure 2.1 Directional conventions

2.7 Examples and illustrations

If the examples in this document refer to patients, physicists, or hospitals by name, then they are not the names of real persons or hospitals. If an example uses the name of a real person or hospital, it is accidental.

Illustrations in this document show the equipment as present. Differences may occur compared to previous models and versions of the equipment. Such differences in the illustrations are of aestethic character and not functional.

2.8 Disclaimer

- Elekta assumes no liability for use of this document if any unauthorized changes to the content or format have been made.
- Every care has been taken to ensure the accuracy of the information in this document. However, Elekta assumes no responsibility or liability for errors, inaccuracies, or omissions that may appear in this document.
- Elekta reserves the right to change the product without further notice to improve reliability, function or design.
- This document is provided without warranty of any kind, either implied or expressed, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose.

2.9 Acronyms and abbreviations

2.9.1 Glossary of terms

The following terms have this specific signification throughout this manual.

Term	Definition
Beam	A well-defined bundle of gamma rays, emitted by ^{60}Co-sources and shaped by a collimator.
Beam off	A state when the shielding doors are fully closed, all radiation sources are positioned and locked in the sector home position, and the emission of X-rays is disabled.
Beam on	During treatment, a state when the shielding doors are fully opened, the patient positioning system has reached the desired treatment target position, and the radiation sources are aligned with the desired collimators. During a CBCT scan, the state when movement of the system is enabled to emit pulses of X-rays to generate projection images.
Clearance check	A procedure performed prior to the actual treatment to ensure that no contact with the collimator cap will occur during the treatment.
Collimator	A device used to shape a beam’s outer boundaries.
Collimator cap	A cylinder-shaped cap inside the treatment cavity, used for protecting the collimators and for stopping couch movement in the case of contact during treatment.
Control panel	The actual panel of the operator console containing various indicators and push-buttons.
Frame adapter	The interface part used between the coordinate frame and the patient positioning system.
Gamma angle	The angle of which the coordinate frame is rotated around the X axis.
Home position	See PPS home position and Sector home position.
Medical cabinet	An electronic/electric cabinet in the treatment room containing control electronics and mains power supply inlet.

Term	Definition
Medical UPS	The UPS unit in the medical cabinet to back up the mains power supply to the treatment room electronics.
MOSAIQ®	MOSAIQ® is Elekta's image-enabled oncology EMR with fully integrated business features such as scheduling, billing, and management reporting and analysis.
Office cabinet	A cabinet in the control room containing the office computer, office UPS and network router.
Office UPS	The UPS unit in the office cabinet to back up the mains power supply to the control room electronics.
Operator console	The console in the control room with the control panel.
Patient couch	The couch on which the patient is placed during treatment. The couch is part of the patient positioning system.
Patient positioning system	An electro mechanical system for positioning the patient couch with the patient in the desired position.
PPS home position	The position where the patient positioning system (PPS) is in its outmost and lowest position, where the patient gets on and off the couch.
Radiological focus point	The common point where the radiation beams intersect.
Run	A sequence of shots with one gamma angle, from the point where the patient is moved into the radiation unit until the couch returns to home position.
Sector	A device used for moving the radiation sources to align with the collimators, thus achieving one of the conditions for beam on and beam off.
Sector home position	The position when the sectors are at the backmost and locked position, where the radiation sources are shielded.
Sector off position	A position between the collimators of 4 and 8 mm size where the radiation sources are shielded.
Shot	Irradiation at planned Leksell® coordinates with associated collimator setup, treatment time and gamma angle.
Target	A well-defined, circumscribed structure that is to be treated.
Target position	A preselected point within the target.
Treatment	The administration of one or more runs (from a physical point of view).
Treatment position	The position of the patient positioning system in the radiation unit where treatment is executed.

2.9.2 Short names for products

The following are short names for products referenced in this document. Other short names may occur in each section of the document and are explained where applicable.

Table 2.1 Short names for products

Short name	Definition
Clearance tool	Clearance check tool
Coordinate frame	Leksell® Coordinate Frame G, or Leksell® Vantage™ Head Frame
Coordinate Frame G	Leksell® Coordinate Frame G
Frame adapter	G-frame adapter, or Vantage frame adapter
Icon™	Leksell Gamma Knife® Icon™
Vantage Head Frame	Leksell® Vantage™ Head Frame
QA tool	QA tool Plus, or QA tool Vantage

2.9.3 Abbreviations and acronyms

The following abbreviations and acronyms may be found in this document.

Table 2.2 List of abbreviations and acronyms

Abbreviation	Definition
AI	Angiographic Image
CBCT	Cone Beam Computerized Tomography
CE	Conformité Européenne
CT	Computerized Tomography
CTDI	Computerized Tomography Dose Index
ECU	Electronic Control Unit
ESD	Electrostatic Sensitive Device
FDA	Food and Drug Administration of the United States
GUI	Graphical User Interface
HDMM	High Definition Motion Management
I/O	Input/Output
ID	Identity
IR	Infrared
LED	Light Emitting Diode
LGP	Leksell GammaPlan®
LSS	Leksell Stereotactic System®
MCU	Main Control Unit
MR	Magnetic Resonance
MRI	Magnetic Resonance Imaging
N/A	Not Applicable
PC	Personal Computer
PET	Positron Emission Tomography

Abbreviation	Definition
PPS	Patient Positioning System
QA	Quality Assurance
RF	Radio Frequency
RU	Radiation Unit
SDU	Sector Drive Unit
TPS	Treatment Planning System
UPS	Uninterruptible Power Supply
USB	Universal Serial Bus

3 Product description

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3.1 Overview of the Leksell Gamma Knife® unit

Leksell Gamma Knife® is a radiosurgery system for use in the stereotactic irradiation of intra-cranial structures. Surgery is achieved by delivering a prescribed dose as one or more shots of ionizing radiation to the exact site of the target.

Based on preoperative radiological examinations, the Leksell Gamma Knife® system provides highly accurate external irradiation of intra-cranial structures using collimated beams of ionizing radiation.

During irradiation of cobalt there are no moving parts within the unit and therefore safety, stability and accuracy are inherent features.

The system consists of several parts, physically separated into a control room and a treatment room:

- The control room contains an operator console, a Leksell GammaPlan® workstation and an office cabinet. The treatment session is controlled and monitored by the operator from the control room.
- The treatment room contains the Leksell Gamma Knife® unit, which basically consists of the radiation unit, a patient positioning system, a gantry for CBCT, an HDMM system, and a set of covers. The treatment room also contains a TV camera, patient speakers and microphone, and a treatment room monitor.

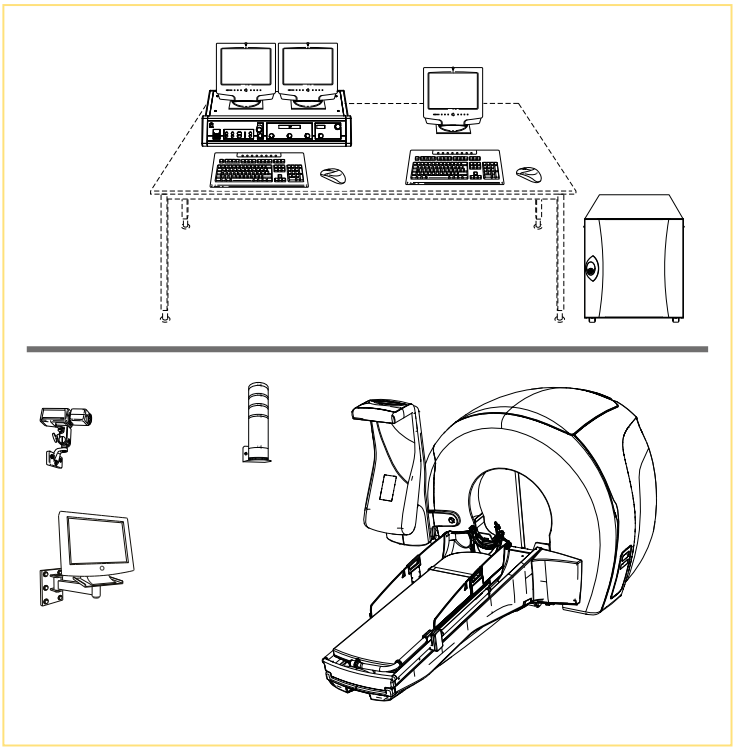

Figure 3.1 Leksell Gamma Knife® control room (top) and treatment room (bottom)

The system is electrically separated into an office side and a medical side:

- The office side consists of the equipment in the control room, as well as the following equipment in the treatment room: TV camera, patient speakers and microphone, and treatment room monitor. The office side is powered and controlled by the office cabinet in the control room.
- The medical side consists of the Leksell Gamma Knife® unit in the treatment room, and is electrically isolated from the office side. The medical side is powered and controlled by a medical cabinet, placed inside the rear cover of the radiation unit.

3.2 Description of the Leksell Gamma Knife® Icon™ unit

The main parts of the Leksell Gamma Knife® Icon™ unit are:

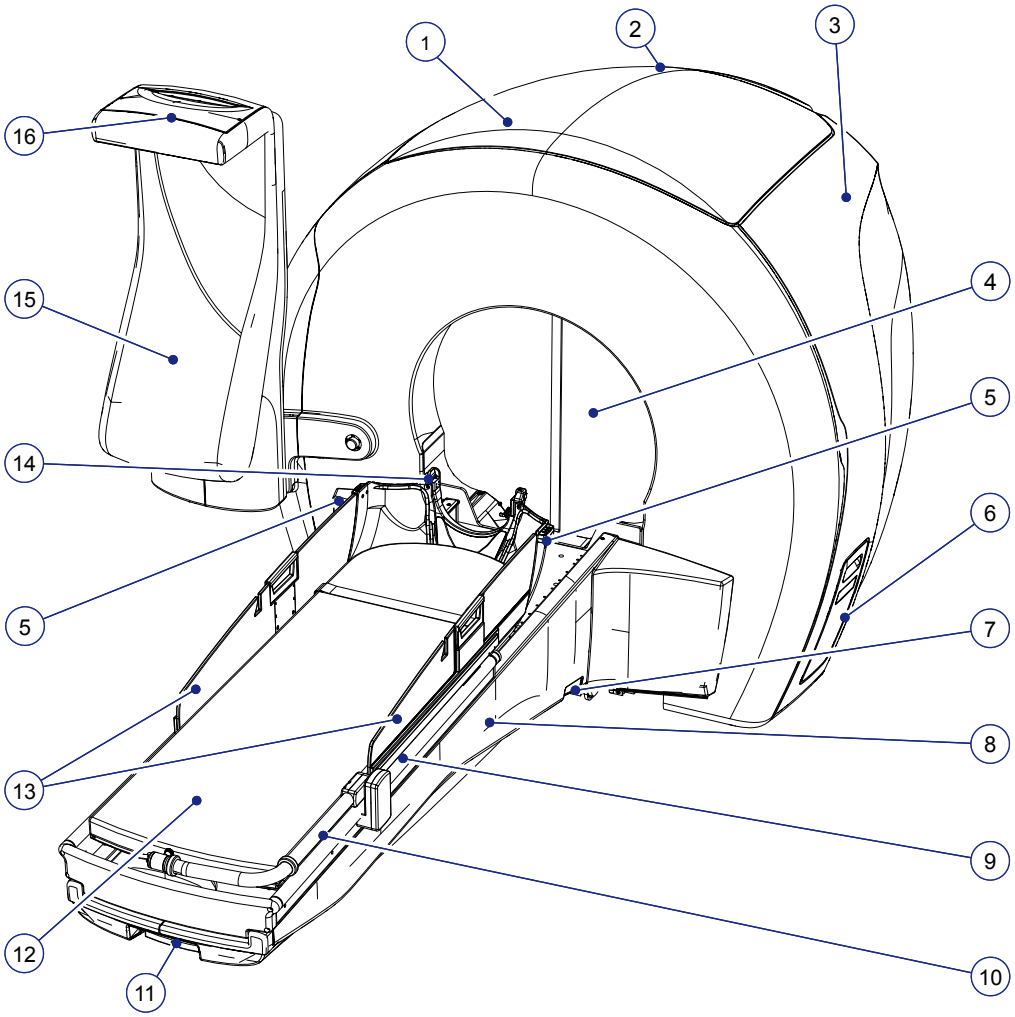

Figure 3.2 Main parts of the Leksell Gamma Knife® Icon™ unit

(1) Radiation unit (inside the cover)

(2) Medical cabinet (inside the cover at the rear end)

(3) Radiation unit cover

(4) Radiation shielding doors

(9) Patient couch (part of patient positioning system)

(10) IR camera arm

(11) Couch release handle, Z-movement

(12) Mattress

(5)	Manual controls and patient's intercom (microphone and loudspeaker)	(13)	Side protection panels (one on each side)
(6)	Door mechanism hatch	(14)	Patient docking device
(7)	Couch release handle, X-movement	(15)	Gantry with X-ray tube
(8)	Patient positioning system	(16)	Image detector

3.2.1 Description of the radiation unit

The radiation unit contains the shielded cobalt sources within the radiation body, and sector mechanism with associated units.

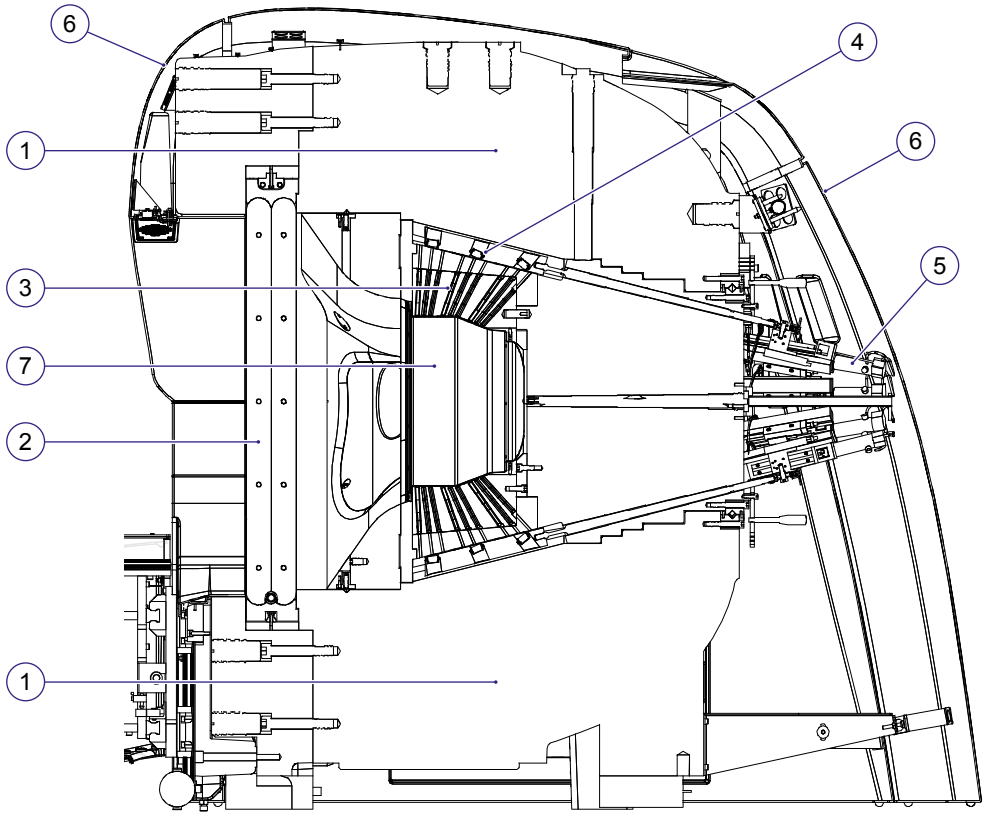

Figure 3.3 Cross-section of the radiation unit

The main parts of the radiation unit are:

- Radiation body (1)
- Shielding doors (2)
- Collimator body with collimators (3) of 4, 8 and 16 mm
- Sectors with radiation sources (4)
- Sector mechanism (5) with motors
- Radiation unit cover (6)
- Collimator cap (7)

The radiation body (1) is made of cast iron to house the cobalt sources (4) and achieve radiation protection. The sources are fixed in 8 independently movable sectors installed on the collimator body. Movement of the sectors is handled by servo controlled motors in the sector mechanism (5).

The shielding doors (2) move horizontally to the left and right to open the radiation unit and allow the patient positioning system to move the couch to the treatment position inside the radiation cavity. To ensure smooth operation, the doors are connected through gears. The mechanism is accessible via a hatch on the patient left side of the cover to enable manually closing of the shielding doors in the unlikely case of malfunction.

During treatment the sources are positioned within the radiation unit via the sector mechanism, thus achieving one of the conditions for the states Beam on or Beam off. The position sector home is where the sectors are at the backmost and locked position. The position sector off is between the collimators of 4 and 8 mm size where the sources are shielded.

The Beam on state is only possible when the sources (4) are aligned with the collimators (3). The Beam off state is only possible when the sectors with the sources are positioned and locked in the sector home position.

A sector can be blocked, meaning that no collimators are aligned with the radiation sources in that sector. Sector blocking is achieved automatically by the sector mechanism according to the treatment plan. The collimator status and possible sector blocking is shown in the application window.

Inside the treatment cavity, a cylinder-shaped collimator cap (7) covers the collimator holes. The collimator cap is used for protecting the collimators from dirt and unwanted substances, and for stopping couch movement in the case of contact during treatment.

The radiation unit is covered by a plastic cover (6) of several individual sections which are suspended on attachment points around the unit and hanging above the floor.

The sectors with the sources are positioned in the sector home position when the loading procedure is carried out as part of the installation procedure of the unit. Besides exchange at regular interval (about 5–7 years) the sources are maintenance free and cannot be reached without special equipment.

Related Links:

Closing the shielding doors manually on page 184

Body dose on page 242

Transition between Beam off and Beam on on page 235

Radiation levels around Leksell Gamma Knife® on page 237

Shutter dose on page 243

Description of the collimator status on page 69

3.2.2 Description of the patient couch

The patient couch is part of the patient positioning system of the unit which consists of a steel framework housing the electromechanical drive for the couch. The patient couch runs on rails installed on the framework.

Under normal conditions the movement is controlled by the electromechanical drive. In an emergency the couch can be manually withdrawn from the radiation unit. This requires one person to manually pull the couch towards the foot end.

There is an adjustable mattress on the couch. The mattress has a strap that you can use to safety the arms of the patient. You can move the patient vertically when you dock the patient to the docking device at the head end of the couch. You use the manual control (one unit on each side) to adjust the position of the mattress. The manual control is also used during clearance check procedures.

Transparent side protection panels are fitted on each side of the patient couch. The correct placement of these panels is confirmed by sensors and displayed in the System’s checklist on the treatment view monitor. The system will not allow treatment to commence until the panels are

fitted correctly. Each panel contains a notch (1) (see **Figure 3.4**) in its upper edge through which drip tubes or wires from monitoring equipment may be routed.

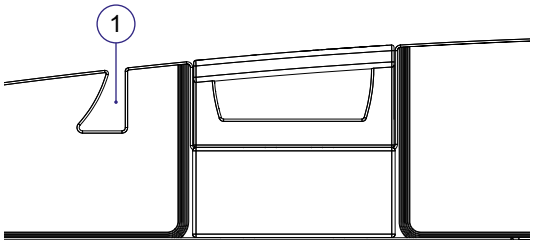

Figure 3.4 Notch in the side protection panel

Underneath the patient positioning system, at each side of the couch and close to the radiation unit, there are foot squeeze protection sensors (1) (see **Figure 3.5**). If any object gets caught between the patient positioning system and the floor during movements of the couch, the sensors trigger a system error and all movements of the couch stop.

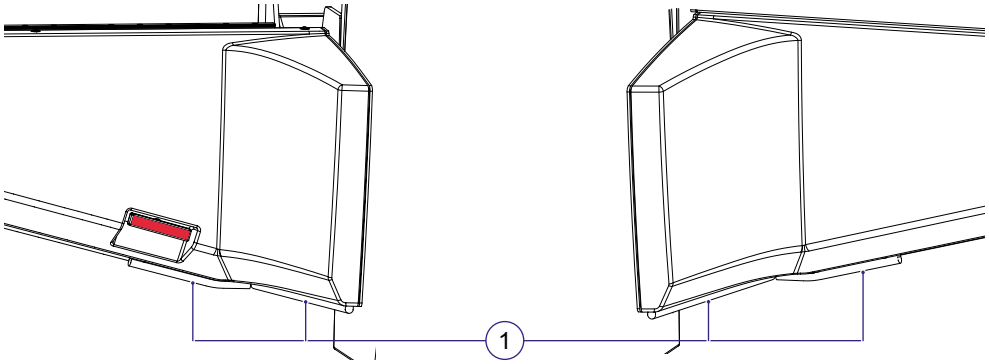

Figure 3.5 Foot squeeze protection sensors

Related Links:

Pulling out the couch on page 182

Buttons on the manual control on page 38

3.2.3 Description of the gantry

The gantry contains the parts used for CBCT. You use the CBCT for two types of scan:

- Stand alone scan: This scan is used to get the stereotactic reference for the treatment and also for treatment planning.
- CBCT for treatment: For coordinate frame the CBCT for treatment is optionally used to verify the position of the patient at the time of treatment. For Mask fixation the CBCT for treatment is used to adjust the treatment delivery of the plan according to the current patient position.

The primary parts of the gantry are:

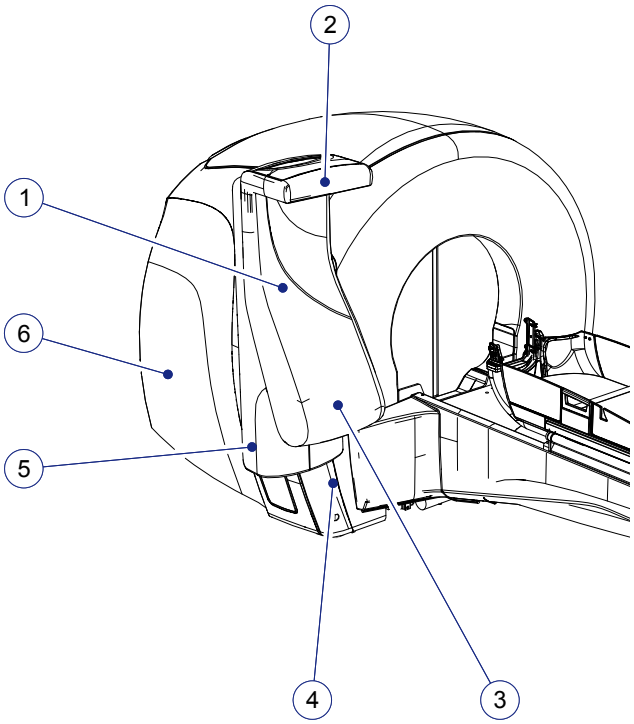

Figure 3.6 Gantry overview

(1)	C-arm	(4)	Actuator (inside the cover)
(2)	Image detector	(5)	Tilt arm
(3)	X-ray tube (inside the cover)	(6)	kV generator (inside the cover)

The rotating unit, which is called the C-arm has an X-ray tube and an image detector attached to it. The C-arm moves the head of the X-ray tube and the image detector in a circular path around the patient.

The C-arm is attached to a tilt arm. The other end of the tilt arm is attached to the RU. The tilt arm makes it possible to move the C-arm from the parked position to the scan position.

The complete gantry includes the C-arm and the tilt arm fully assembled with sensors, cabling, motor and transmission. This includes the kV generator, electronics, X-ray tube, image detector and the actuator that lifts and lowers the tilt arm.

3.2.4 Description of the HDMM

The High Definition Motion Management (HDMM) system is used to monitor movements of the patient, immobilized by mask or by Vantage head frame, during setup, CBCT for treatment, and treatment. The HDMM cannot be used for stand-alone CBCT or when the patient is immobilized with the coordinate frame G.

The HDMM system can be run in two different monitoring modes, active mode and passive mode. The active mode is the default mode when the patient is immobilized by mask. When the patient is immobilized with the Vantage Head frame, HDMM is optional and is therefore disabled by default.

WARNING 3.1

If you select passive mode, the system will not prevent dose delivery or go to treatment pause if the patient moves above the limit. This can cause treatment at incorrect position and injury to the patient.

WARNING 3.2

The patient marker is used to monitor the movement of the nose of the patient. It does not monitor the movement of the target. As the relation between marker and target motion depends on the actual clinical case, the user is expected to set the HDMM level in accordance with each specific clinical situation.

The HDMM system includes an IR camera (3), an IR camera arm (4), IR reference tool (2) and a patient marker (1), see **Figure 3.7**.

Figure 3.7 HDMM system

(1) Patient marker
(2) IR reference tool
(3) IR camera
(4) IR camera arm

The IR reference tool has four IR markers that is used to calculate the relative position of the patient marker.

A graph in the GUI shows the movements when the HDMM is on. The axis of the graph shows movements in mm and duration in seconds.

Gating means that the system automatically prevents dose delivery. Gating (8) occurs during treatment with HDMM active mode enabled (3) if an HDMM alarm is active, see **Figure 3.8**.

An HDMM alarm becomes active if:

- Patient displacement is above the HDMM alarm level
- The IR camera cannot see the patient marker or the IR reference tool for a period of more than 2 seconds.

If the HDMM alarm becomes inactive again, dose delivery automatically continues after 3 seconds (9).

Treatment pause is automatically initiated if the gating activity:

- stays for more than 30 seconds
- has occurred more than 5 times in the same shot.

If the treatment is continued after treatment pause, the above conditions apply again.

It is important that you think of the shutter dose when you do a treatment with HDMM in active mode. The system is automatically gating the dose delivery and the radiation can therefore be shut off and turned on again more times than usual for a shot.

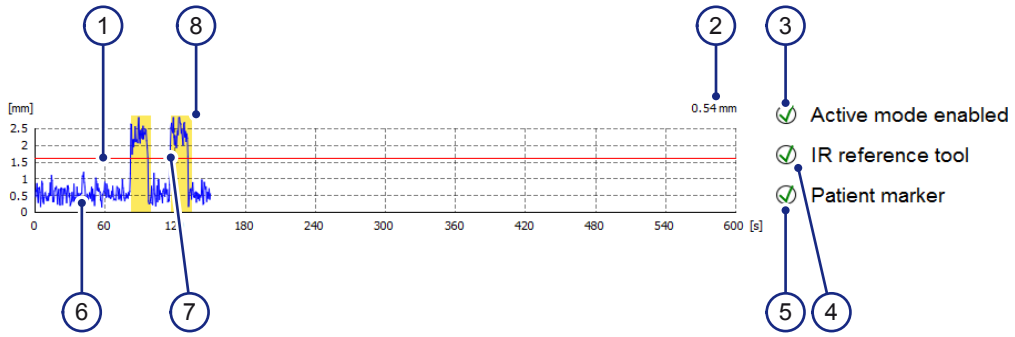

Figure 3.8 HDMM graph

(1) HDMM alarm level. You can change the HDMM alarm level in the HDMM settings.

(2) Current movement value.

(3) Active mode indicator.

(4) IR reference tool indicator. Shows that the IR camera can see the IR reference tool.

(5) Patient marker indicator. Shows that the IR camera can see the patient marker.

(6) Movement level

(7) Gating occurs when the patient moves out of position (above the HDMM alarm level) or the IR camera cannot see the reference markers for more than 2 seconds. This is shown as a yellow field in the graph.

(8) When the patient moves back into position, the dose delivery starts again after 3 seconds.

If active mode is disabled (passive mode), the HDMM area becomes dark grey in the GUI. In passive mode, HDMM alarms are not triggered and gating does not occur. In HDMM passive mode, you must look at the HDMM area to carefully monitor the patient position.

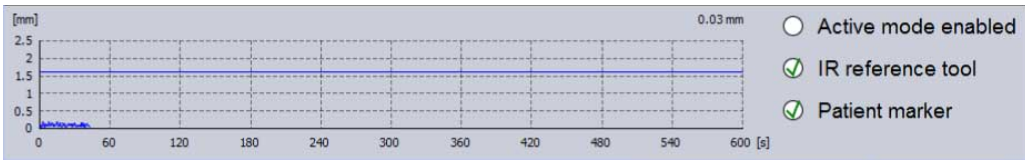

Figure 3.9 HDMM graph passive mode

Related Links:

Adjusting the HDMM settings on page 119

Shutter dose on page 243

3.2.5 Description of the medical cabinet

The medical cabinet is placed inside the radiation unit cover at the rear end. It is accessible by opening and lifting off the rear section of the cover.

Figure 3.10 Lifting off the rear cover

The cabinet consists of a mechanical chassis, a rack, containing six modules:

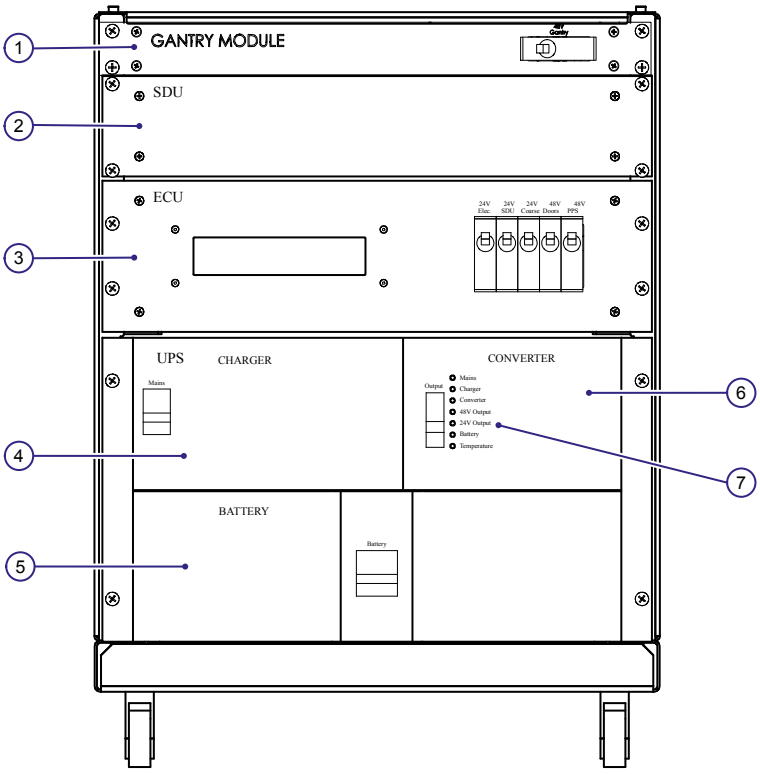

Figure 3.11 The medical cabinet

(1) Gantry module

(2) Sector Drive Unit (SDU)

(3) Electronic Control Unit (ECU)

(4) Medical UPS, charger (AC/DC converter)

(5) Medical UPS, battery section

(6) Medical UPS, converter (DC/DC converter)

(7) Medical UPS, indicators

The cabinet also includes input and output connectors and circuit breakers.

The cabinet can be pulled out to allow better access to cables and connectors.

Related Links:

Removing the rear RU cover on page 185

Routine checks of the medical UPS on page 227

Switching off the medical UPS on page 186

Description of the batteries on page 60

3.2.5.1 Description of the SDU and ECU units

The Sector Drive Unit (SDU) contains the electronics for controlling the movement of the radiation sectors.

The Electronic Control Unit (ECU) contains the control system interacting with the system software and executing the treatment sequence ordered from the control panel.

The ECU display shows the following information:

- The first 2 lines show the status of the internal processors (PPC1 and PPC2) and their software version. If the text is blinking, the processors are working. The text SDU indicates that the communication with the SDU module is established.

  ```
  PPC1 0.81.1  SDU
  PPC2 0.83.1
  ```

- The last 2 lines show information about the run being processed: the run number (**Run No**) and shot ID (**Shot ID**), the Leksell® coordinates for the shot (**X, Y, Z**), and the remaining time for the shot (**Rem T**). Example:

  ```
  Run No:1  Shot Id:A1
  X: 100.2  Y: 98.4  Z: 102.5  Rem T: 32.78
  ```

In case of failure of the MCU computer, the ECU will abort the on-going shot, and the information on the display gives the remaining time of that shot.

Note: *The ECU display is not turned off by the power key on the control panel. It can only be turned off by switching off the output of the medical UPS.*

Related Links:

Switching off the medical UPS on page 186

3.2.5.2 Description of the medical UPS

The medical UPS unit supplies the medical side of the Leksell Gamma Knife® Icon™ system (not the kV generator) with electrical power in case of failure in the mains supply. If a power failure during treatment is longer than 1 minute, a treatment pause sequence is automatically started.

The charger module includes the power input circuit breaker and feeds the +48 V output and charges the internal batteries.

The converter module has an input fuse and feeds the +24 V output.

The indicator unit contains seven green LED’s giving the following information:

- Mains – indicates that input mains voltage level is OK.
- Charger – indicates that charger output voltage level is OK.
- Converter – indicates that both DC/DC modules in the converter are OK.
- 48V Output – indicates that the 48 V output voltage level is OK.

- 24V Output – indicates that the 24 V output voltage level is OK.
- Battery – indicates that the battery voltage level and the circuit breaker is OK.
- Temperature – indicates that the temperature in the medical UPS is OK.

The battery section contains the UPS batteries and a circuit breaker. The circuit breaker will disconnect the battery if a fault occurs causing an abnormal high battery current.

3.2.6 Description of the patient intercom

The intercom has a microphone (1) at the right manual control and two loudspeakers (2) in the cover by the patient docking device. One loudspeaker is also located below the mattress.

It is possible to connect an external device to the sound system, for example a CD-player. To connect a device, you use the MUSIC IN connector behind the operator console.

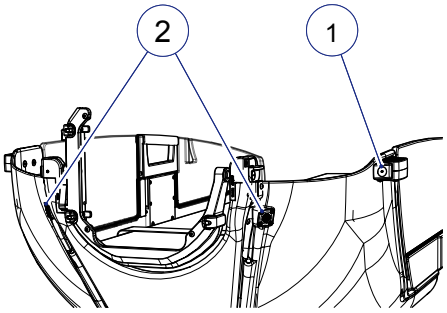

Figure 3.12 Patient microphone and loudspeakers in the PPS

The microphone and loudspeakers are switched on with the power key on the control panel.

3.2.6.1 Description of the patient alert

The patient alert (1) is connected at the front (foot end) of the PPS. When a patient is docked (during setup, imaging, and treatment), the patient can use the alert for communication.

Figure 3.13 Patient docked holding the patient alert

When the patient presses the button, a warning signal is heard.

Before a treament with mask, the operator needs to verify that the alert works properly before handling it over to the patient. If the button is pressed during treatment with mask also a warning message appears in the application window.

Related Links:

Description of the patient intercom controls on page 40

3.2.7 Buttons on the manual control

With the manual control, you can adjust the mattress. You also use the buttons during clearance check procedures and setup before treatment or CBCT scan.

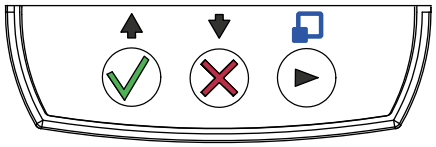

Figure 3.14 The manual control on the couch

The buttons on the manual control are:

Accept or **Up**. Moves the mattress up, or accepts a position or choice during clearance checks.

Reject or **Down**. Moves the mattress down, or rejects a position or choice during clearance checks.

Continue or **Toggle GUI**. Moves the couch into position during clearance checks and moves the couch and gantry to scan position at CBCT scan. This button also toggles the GUI of the system application between normal view and an enlarged view.

All buttons on the manual control require a dead man's switch to be activated, that is, to simultaneously press one of the buttons on the underside of the manual control.

3.3 Compatibility with MOSAIQ®

Leksell Gamma Knife® Icon™ and Leksell GammaPlan® can be connected to MOSAIQ®. The connection lets the Gamma Knife unit and Leksell GammaPlan® to interchange treatment information with MOSAIQ®. This is done before and after treatment and includes for example information about treatment plans, treatment records, and protocols.

Note: *During the treatment session, the treatment plan is always loaded from the treatment plan database.*

MOSAIQ® is a dedicated oncology information system that streamlines the full Medical Oncology or radiation oncology workflow from the first diagnosis and staging, through planning, treatment and long-term follow-up.

3.4 Description of the operator console

3.4.1 Description of the control panel

The control panel on the operator console is used to control the treatment procedure and the built-in intercom system provides communication with the patient.

The control panel contains a number of control buttons and indicators with corresponding markings. The control panel has four visually distinctive sections:

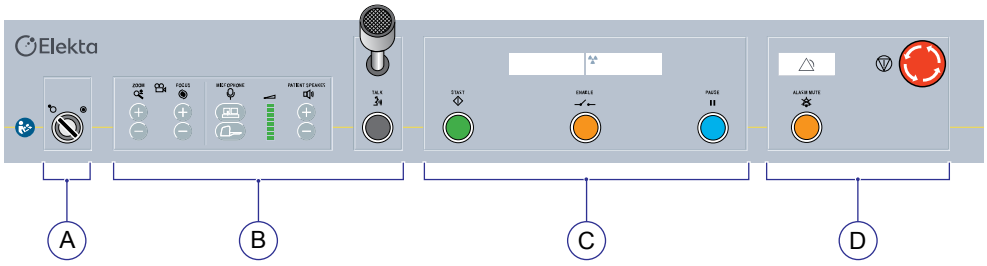

Figure 3.15 Control panel sections

(A) Power keyswitch

(B) Patient intercom controls

(C) Treatment controls and indicators

(D) Alarm controls and indicators

3.4.1.1 Description of the power key

The office side of the system is switched on and off by means of the power key in the keyswitch (2).

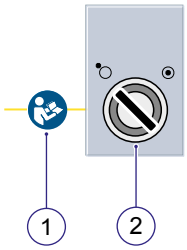

Figure 3.16 Power keyswitch

(1) Symbol indicating “Consult accompanying documents”

(2) Power keyswitch (on/off)

The power keyswitch does not directly switch on or off the electrical power. Instead, a signal is sent to the MCU computer in the office cabinet that in turn selects to switch the power on or off to the system. This means that the MCU computer must be switched on for the power key to have the desired effect.

Under normal circumstances, the power key is only turned on or off in conjunction with logging on or off the system.

- After logging on the system but before a treatment has started, the power key may be turned off. This does not power off the system or interrupt the user session, but the key must be turned on before a treatment can be started.
- If the power key is accidently turned off during treatment, the system executes a treatment pause sequence. Resumption is not possible until the key is turned on again. Use the power key to turn off the system only when the logon screen is shown.

Note: *The power key does not switch on or off power to the medical side of the system.*

Related Links:

Switching on the system on page 63

Logging on the system on page 63

Logging off the system on page 64

Switching off the system on page 64

3.4.1.2 Description of the patient intercom controls

The patient intercom provides a two-way link between the patient in the treatment room and the operator in the control room.

The intercom comprises the microphone and the gray TALK button together with the patient supervisory monitor.

The treatment room camera is controlled by the ZOOM (+/–) buttons and the FOCUS (+/–) buttons.

The volume levels are adjusted using the microphone sensitivity buttons and the PATIENT SPEAKER (+/–) buttons. The volume level is displayed by the level indicator.

Related Links:

Using the patient intercom system on page 164

Description of the patient intercom on page 37

3.4.1.3 Description of the treatment controls and indicators

The treatment controls and indicators are:

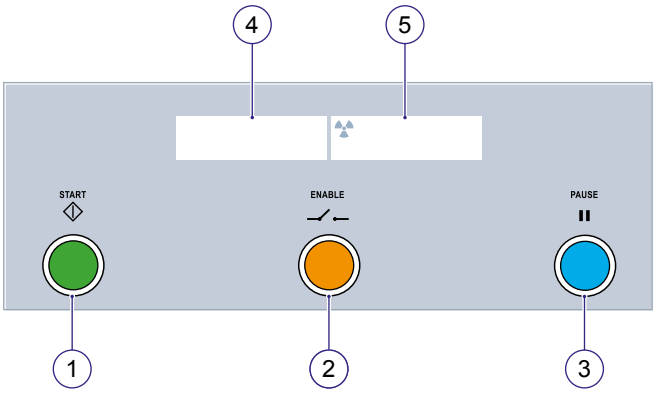

Figure 3.17 Treatment controls and indicators

	Button/indicator	Color
(1)	START	Green
(2)	ENABLE	Orange
(3)	PAUSE	Blue
(4)	Beam off	Green
(5)	Radiation (radiation in the treatment room)	Yellow

- The START button (1) (green) is used to start a treatment run or a CBCT scan. It lights up when all physical interlocks are set and when the patient couch is in the home or scan position.
- The ENABLE button (2) (orange) is used to start the actual treatment sequence. The sequence is started by simultaneously pressing the ENABLE and START buttons. For CBCT scanning, the START and ENABLE buttons must be pressed during the whole scanning procedure.
- The PAUSE button (3) (blue) is used to initiate a treatment pause sequence. When pressed, the treatment session is interrupted and the patient couch is returned to the home position.
- The Beam off indicator (4) lits green when the shielding doors are closed and the radiation sectors are locked in sector home position (radiation beams deactivated), and the emission of X-rays is disabled. No direct radiation comes out in the treatment cavity.
- The Radiation indicator (5) lits or blinks yellow whenever the Beam off state is not reached (radiation beams activated). The indicator is continuously lit when the Beam on state is reached or when movement of the system is enabled to emit pulses of X-rays to generate projection images.. The indicator blinks during transition between Beam on and Beam off, that is, during positioning, when the shielding doors are opening or closing, and when the radiation sectors are moving.

Related Links:

Description of a treatment pause sequence on page 127

Description of the Leksell Gamma Knife® Icon™ unit on page 28

3.4.1.4 Description of the alarm controls and indicators

The alarm controls and indicators are:

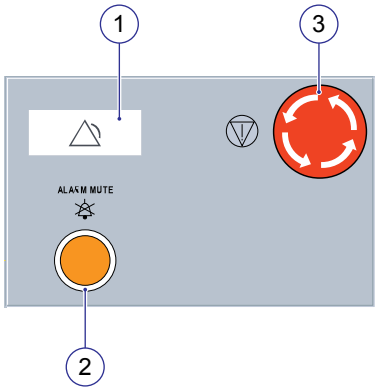

Figure 3.18 Alarm controls and indicators

	Button/indicators	Color
(1)	Emergency alarm	Red
(2)	ALARM MUTE	Orange
(3)	Emergency stop	Red

- The Emergency alarm indicator (1) flashes red if the monitoring system senses an error requiring immediate action by the operator.
- An emergency alarm is accompanied by a warning buzzer. The buzzer can be silenced for two minutes by pressing the ALARM MUTE button (2) (orange).
- The Emergency Stop button (3) is for use in an emergency. Pressing the button stops the couch, gantry and door movements immediately, and takes the sectors to the sector home position. The system remains in this state until the button is released by turning it in counter-clockwise direction as indicated by the arrows. This initiates an Emergency Exit sequence.

  A second Emergency Stop button with identical functionality may be located in the treatment room (supplied by the site and not part of the product delivery). Other emergency stop buttons may be situated according to local site and/or legal requirements.

Related Links:

Description of the Leksell Gamma Knife® Icon™ unit on page 28

Emergency Exit sequence on page 181

3.4.2 Description of the patient supervisory monitor

The patient supervisory monitor provides continuous visual monitoring of the patient, the patient couch and the shielding doors through a TV camera in the treatment room.

Controls on the monitor allow adjustment to color, brightness and contrast of the picture, as well as to the speaker volume in the control room. Zoom and focus controls for the camera are embedded in the control panel. A video recorder may be connected to the system, if required.

The monitor is switched on with the power key on the control panel.

3.4.3 Description of the treatment view monitor

The treatment view monitor provides a continuous display of the progress of the treatment session, including visual display of alarm conditions. The monitor displays the system application running on the office computer.

The monitor is switched on with the power key on the control panel.

3.5 Description of the office cabinet

The office cabinet is usually placed in the vicinity of the operator console and is connected to the operator console.

Figure 3.19 The office cabinet

(1)	LGP workstation	(4)	Router
(2)	Office computer (MCU)	(5)	Switch
(3)	Office UPS		

The office computer (MCU) (2) runs the system application used to load, check and execute the treatment plan. The power switch can be used to turn the computer on. Two USB ports are available.

Note: *The placement of switches, connectors, etc. may differ slightly depending on the model of the office computer.*

The office cabinet contains network router (4) and switch (5) for the local network.

The office UPS unit (3) supplies the office computer, network router, switch and operator console with electrical power in case of failure in the mains supply. The camera, patient speakers and microphone, and treatment room monitor (all in the treatment room) are also electrically supplied by the office UPS.

If the mains electrical supply stops, the UPS gives power for a minimum of 10 minutes. If the power failure is more than one minute, a treatment pause sequence automatically starts.

The office cabinet also holds a Leksell GammaPlan® workstation (1), that is used during treatment.

Note: *Due to different site configurations, the office cabinet may be placed up to 5 m from the operator console.*

3.5.1 Office UPS

The office UPS unit is installed at the bottom of the office cabinet. The control panel of the office UPS is available in 3 different versions. Compare the images in the sections below to identify which version you have.

Related Links:

Description of the office UPS: type 1 and 2 on page 43

3.5.1.1 Description of the office UPS: type 1 and 2

The office UPS unit is situated at the bottom of the office cabinet. The control panel of the office UPS is available in two different versions:

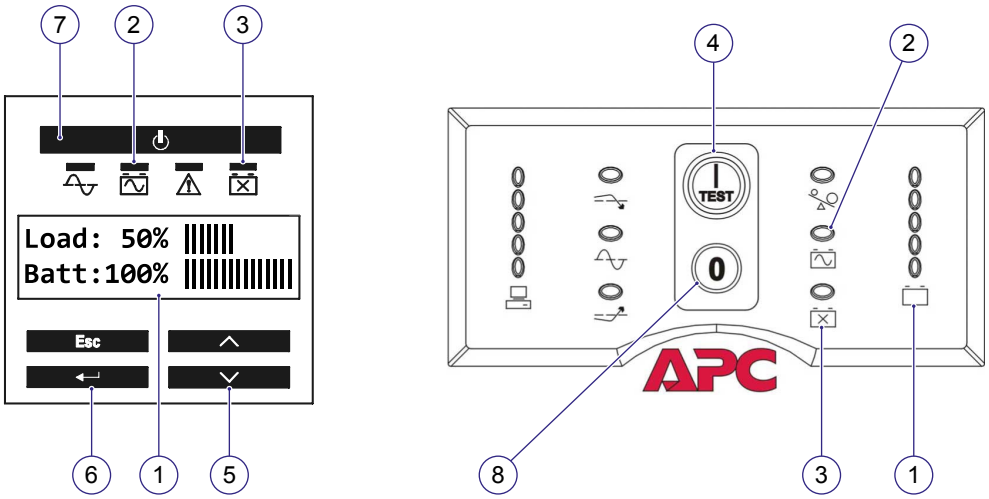

Figure 3.20 The control panel of the office UPS unit

(1) Battery level indicator
(2) On Battery indicator
(3) Replace Battery indicator
(4) Self-test/On button
(5) Up/down buttons
(6) Enter button
(7) On/Off button
(8) Off button

The office UPS performs a self-test automatically when turned on, and every 14 days thereafter. During the self-test, the UPS briefly operates the connected equipment on battery, which is indicated by the On Battery indicator (2).

If the UPS fails the self-test, the Replace Battery indicator (3) is turned on.

Related Links:

Routine checks of the office UPS: type 1 and 2 on page 228

3.5.1.2 Description of the office UPS: type 3 and 4 "Liebert"

The office UPS unit is installed at the bottom of the office cabinet. The office UPS is available in different versions.

The office UPS type 3 does an auto-battery test every 14 days. If the battery test fails, the office UPS type 3 will beep 2 seconds every minute.The office UPS type 4 does an auto-battery test every 8 weeks.

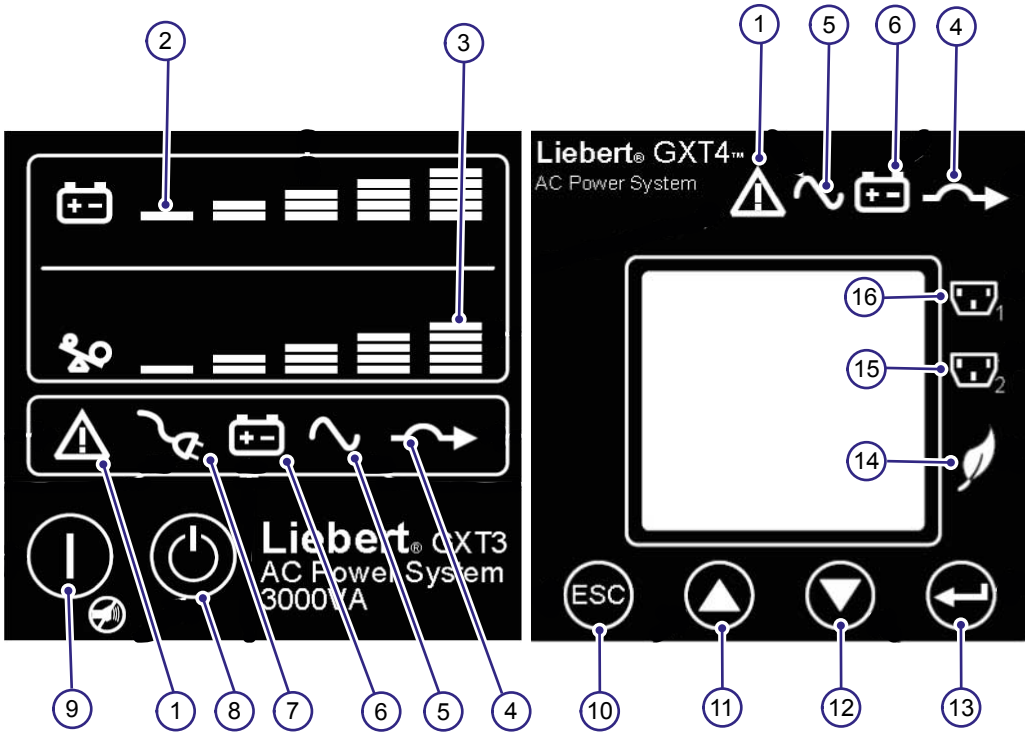

Figure 3.21 The office UPS type 3 and 4 display

(1)	Fault indicator	(9)	On/Alarm silence/Manual battery test button
(2)	Battery level indicators	(10)	ESC button
(3)	Load level indicators	(11)	Up button
(4)	Bypass indicator	(12)	Down button
(5)	Inverter indicator	(13)	Enter button
(6)	Battery indicator	(14)	ECO mode indicator
(7)	AC Input indicator	(15)	Programmable outlet2 indicator
(8)	Standby/Manual bypass button	(16)	Programmable outlet1 indicator

The bypass mode is automatically activated if the UPS has an internal error. This means that the UPS cannot operate correctly and must be replaced. The battery backup power is then disabled and if a mains failure occurs, the MCU will power off immediately without the controlled shutdown sequence. To avoid this, make sure that the bypass indicator (4) is not on before you start a treatment.

The bypass mode is indicated by an audible alarm and illuminated amber bypass indicator. If the bypass is activated stop and contact your local Elekta representative for technical support.

Note: *When you hear continuous beeps from the UPS, the unit does not operate correctly.*

If you press the standby button (8) on the office UPS type 3 for 2 seconds, the unit will go to bypass mode. If the bypass is activated on the office UPS type 3 and no indication of internal error is displayed (1), the correct mode of operation can be set if you press the on button (9) for about 1 second. The bypass indicator (4) goes off and the green inverter indicator (5) comes on.

If none of the control buttons Esc (10), Up (11), Down (12) or Enter (13) is pressed for 2 minutes on the office UPS type 4, the LCD will enter the screen saver mode. The backlight turns off. It will remain off until a control button is pressed.

Related Links:

Routine checks of the office UPS: type 3 and 4 "Liebert" on page 230

3.6 Description of the immobilization devices

3.6.1 Description of the Leksell® Vantage™ Head Frame

Leksell® Vantage™ Head Frame is the mechanical interface to the docking device of the treatment equipment. It is attached to the patient's head with fixation pins, and thereby prevents intra-operative coordinate frame displacement. The frame has an open space in front of the face area. It has three interface areas on which different tools and accessories are attached.

The frame has eight holes for the fixation pins. Normally the four outer holes are used, but if needed, for example to avoid bone flaps, the inner holes can be used.

Figure 3.22 Leksell® Vantage™ Head Frame attached to the head of the patient

Leksell® Vantage™ Head Frame is a component of Leksell® Vantage™ Stereotactic System. See the *Leksell® Vantage™ Stereotactic System, Instructions for use* for more information.

3.6.2 Description of Leksell® Coordinate Frame G

Leksell® Coordinate Frame G provides the mechanical interface to the docking device of the treatment equipment. It is rectangular with engraved, scaled rulers. It is affixed to the head by means of screws and rigid corner posts and thereby prevents intra-operative coordinate frame displacement.

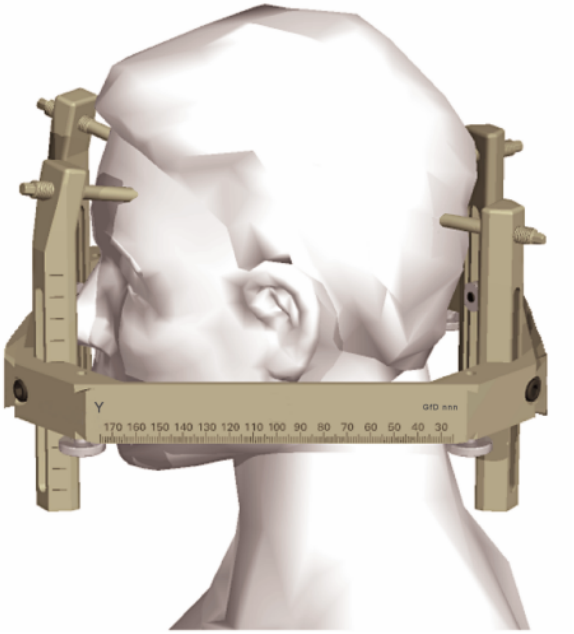

Figure 3.23 Leksell® Coordinate Frame G

Leksell® Coordinate Frame is a component of Leksell Stereotactic System®. See the *Leksell Stereotactic System®, Instructions for use* for more information.

3.6.3 Description of the Leksell® Coordinate System

The origin of Leksell® Coordinate System (where X, Y and Z are numerically zero) is located outside the fixation system at a point that is superior, lateral and posterior to the coordinate frame on the patient's right side.

The following figures show the Leksell® Coordinate System applied on the Leksell® Vantage™ Head Frame (see **Figure 3.24**), and the Leksell® Coordinate Frame G (see **Figure 3.25**). The figures also show the left (L), right (R), posterior (P), and anterior (A) side of each type of frame.

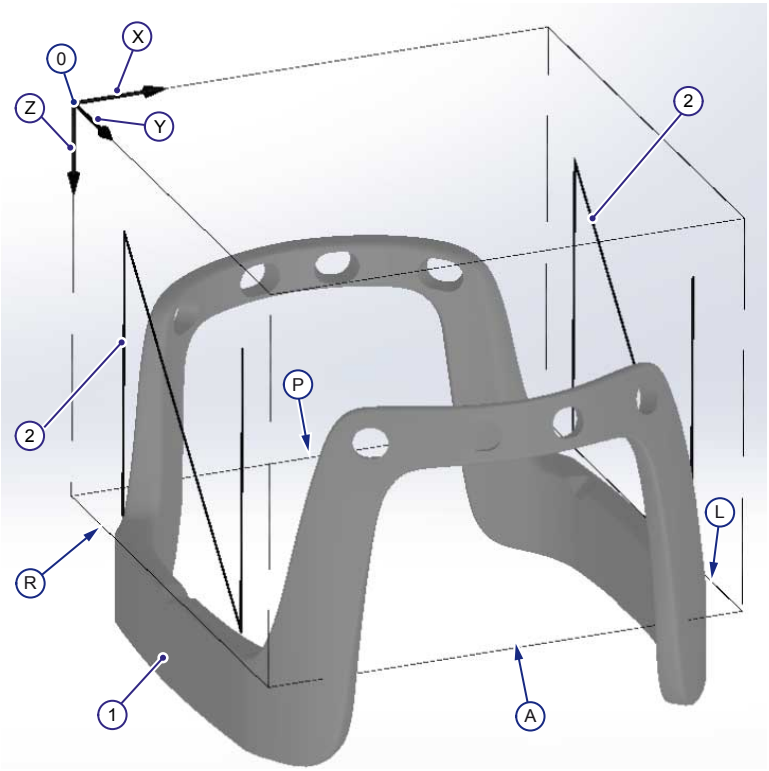

Figure 3.24 The coordinate system applied on Leksell® Vantage™ Head Frame

(0)	Origin	(1)	Vantage head frame
(2)	N shaped fiducials	(A)	Anterior
(L)	Left	(R)	Right
(P)	Posterior	(X)	X in the coordinate system
(Y)	Y in the coordinate system	(Z)	Z in the coordinate system

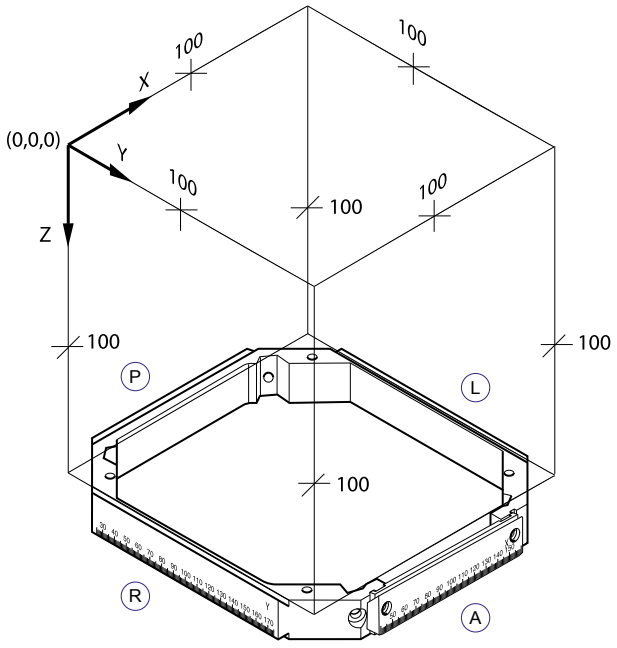

Figure 3.25 The coordinate system applied on the Leksell® Coordinate Frame G

(0)	Origin	(A)	Anterior
(L)	Left	(R)	Right
(P)	Posterior	(X)	X in the coordinate system
(Y)	Y in the coordinate system	(Z)	Z in the coordinate system

On the coordinate frame G, the coordinate scale is graduated in millimeters and conforms with the X, Y and Z directions used in CT and MR scanning.

The CBCT is calibrated to use the Leksell® Coordinate System as stereotactic reference.

The X, Y and Z coordinate settings are obtained from the patient's treatment protocol after target localization.

3.6.4 Description of the mask fixation system

The mask fixation setup includes a thermoplastic mask, a head cushion and also a mask adapter that gives the mechanical interface to the docking device of the treatment equipment. To give a fixation, both the mask and the head cushion are carefully shaped after the patient's head and then cured. For patient comfort, a knee support is used.

The patient can be removed from the fixation and re-fitted at the same position. This means that the mask fixation setup can be used for fractionated treatments over an entire treatment period.

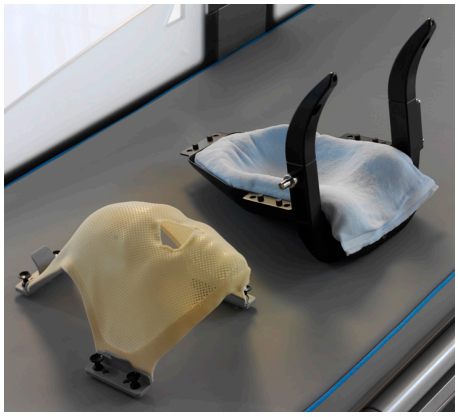

Figure 3.26 Mask fixation setup

Leksell Gamma Knife® Icon™ can be delivered with two types of head cushions, the *Moldcare* head cushion and the *Klarity* head cushion. Two workflows are given in this manual:

1. Thermoplastic mask warmed up in heated water and used together with the *Moldcare* head cushion.
2. Thermoplastic mask and the *Klarity* head cushion warmed up in an oven.

Elekta recommends a convection oven with dimensions enough to have the head cushion and the thermoplastic mask in the oven at the same time.

The thermoplastic mask is a patient specific mask used for immobilization and patient positioning during treatment. The shape of the mask is made after warm up in a temperature of 65-73 ˚C in an oven or in watherbath and then molded around the face of the patient.

When the patient is immobilized by the mask fixation system, the CBCT is used to set the stereotactic reference and the HDMM is used to monitor patient movement.

Related Links:

Description of the HDMM on page 32

3.7 Description of the safety equipment

3.7.1 Description of the emergency procedures placard

A quick reference guide of the emergency procedures is available both in the treatment room and in the control room.

Related Links:

Using emergency procedures on page 179

3.7.2 Description of the shielding door ratchet tool

The shielding door ratchet tool is used to manually close the shielding doors in case the doors do not close automatically after a treatment. The ratchet tool is placed inside the door mechanism hatch on the patient left side of the radiation unit.

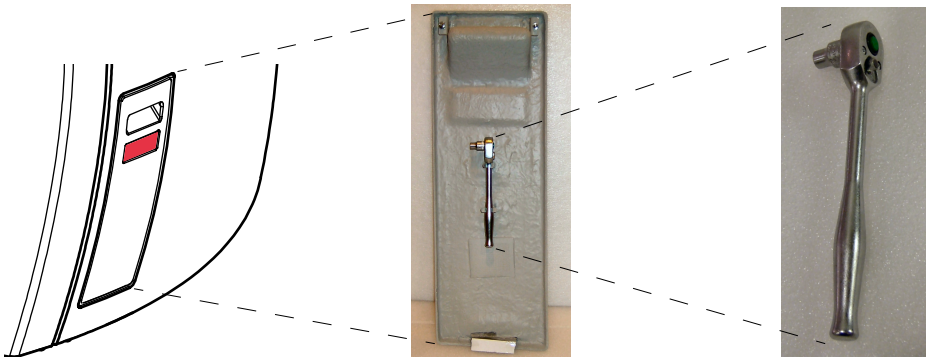

Figure 3.27 The door mechanism hatch and the ratchet tool

Related Links:

Closing the shielding doors manually on page 184

3.7.3 Description of the radiation warning lamp

A wall-mounted radiation warning lamp in the treatment room indicates the status of radiation and sectors.

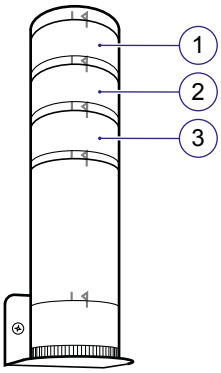

Figure 3.28 Radiation warning lamp

The three colored lamps indicate the following:

- Red (1): Radiation, that is, whenever the Beam off state is not reached (radiation beams activated) or X-ray is on.
- White (2): All sectors are locked in the sector home position.
- Green (3): Beam off (the same as the Beam off indicator on the control panel).

Related Links:

Description of the treatment controls and indicators on page 40

3.8 Description of the tools and accessories

The following tools and accessories are part of the Leksell Gamma Knife® Icon™. They are each stored in an appropriate storage place according to site preferences.

- A frame adapter for attaching the coordinate frame to the patient couch. There are two types of frame adapters:
  - G-frame adapter
  - Vantage frame adapter
- The frame cap, to use with the G-frame adapter during treatment planning.
- The clearance check tool, to do clearance checks
- A QA tool to do QA checks. There are two types of QA tools for Leksell Gamma Knife® Icon™:
  - The QA tool Plus that is used with the G-frame adapter
  - The QA tool Vantage that is used with the Vantage frame adapter
- The Phantom base plate
- The Catphan phantom
- The MR head support, to use in MR scanner with mask fixation

3.8.1 Description of the frame adapter

3.8.1.1 Description of the G-frame adapter

The frame adapter is attached to the coordinate frame positioned on the patient’s head. The frame adapter with patient is then docked to the docking device of the patient couch.

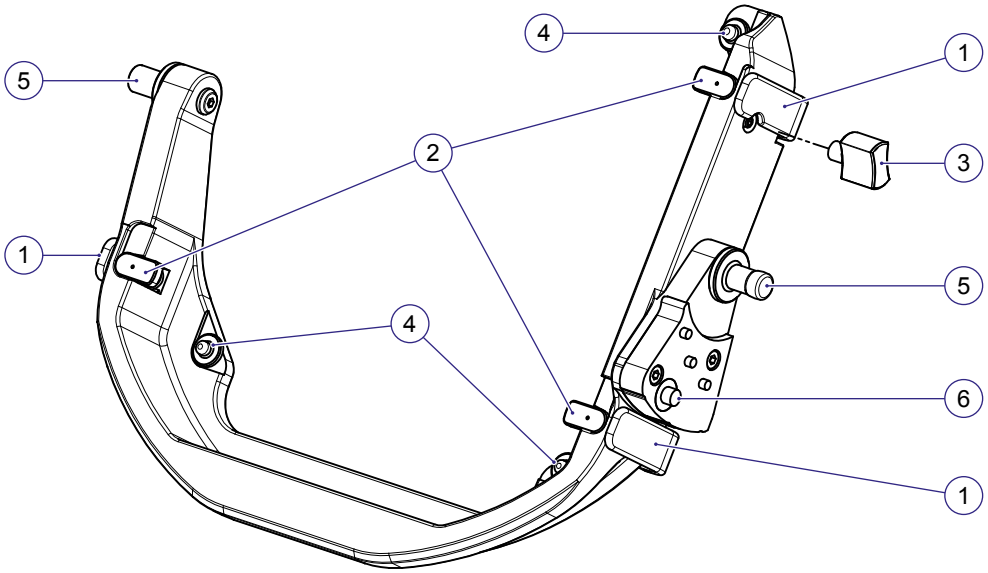

Figure 3.29 The frame adapter

(1) Fixation levers
(2) Securing plates
(3) Securing screw
(4) Locating pins
(5) Attachment pins
(6) Gamma pin

The frame adapter is attached to the coordinate frame by using 3 fixation levers (1). Each lever controls a securing plate (2) that is used to secure the coordinate frame to the frame adapter. One of the levers has a securing screw (3) that secures the lever in the locked position. In addition, 3 locating pins (4) fit into the corresponding holes in the coordinate frame. The frame adapter is then fitted to the docking device by two attachment pins (5) and guided into the correct gamma angle with a gamma pin (6).

3.8.1.2 Description of the Vantage frame adapter

The frame adapter is attached to the Vantage Head Frame that is positioned on the patient's head. The frame adapter with patient is then docked to the docking device of the patient couch.

The frame adapter is attached to the Vantage Head Frame on the three interface areas, and is locked in position by the left and right levers (1).

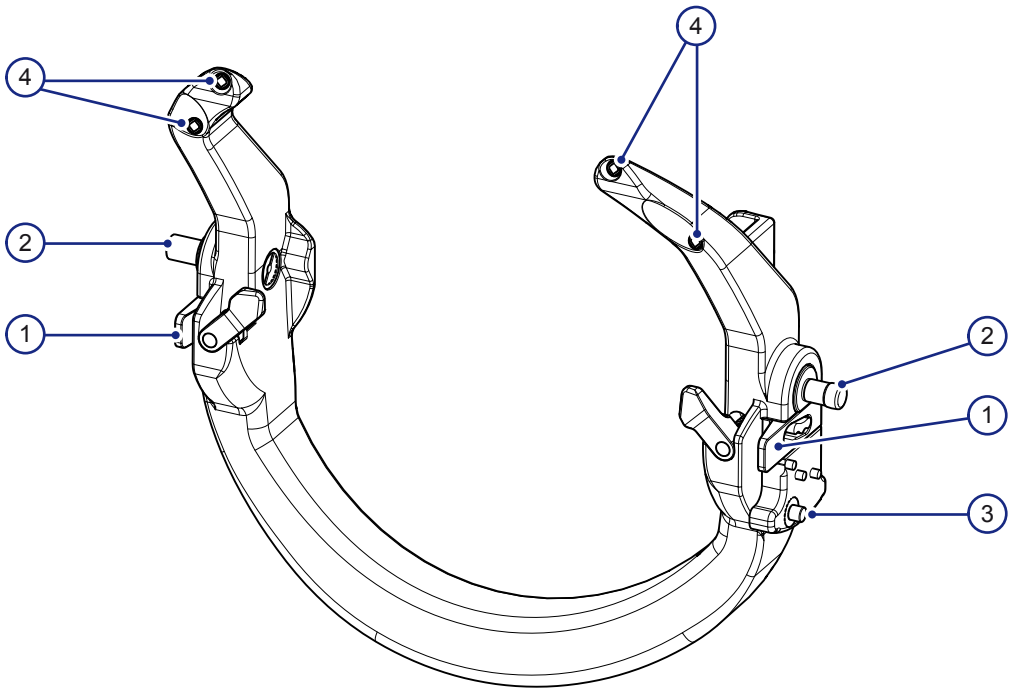

Figure 3.30 The frame adapter for Leksell® Vantage™ Head Frame

(1)	Lever	(2)	Attachment pin
(3)	Gamma pin	(4)	IR marker

The frame adapter is then fitted to the docking device by the two attachment pins (2) and guided into the correct gamma angle with a gamma pin (3). The frame adapter can be docked in three different gamma angles - 70°, 90°, and 110°.

The frame adapter has four IR markers (4) that are used to calculate the relative position of the patient marker when the HDMM system is used. HDMM system is only applicable for Leksell Gamma Knife® Icon™.

3.8.2 Description of the clearance check tool

A treatment plan may contain clearance check positions. These are positions where there is a risk for the patient's head, or the fixation posts and fixation screws of the coordinate frame, to come in contact with the collimator cap during treatment. To avoid this, a clearance check procedure must be performed for all such positions. It is not possible to start any treatment run until all of the clearance checks have been completed.

The clearance check procedure is performed by using the clearance check tool in the treatment room.

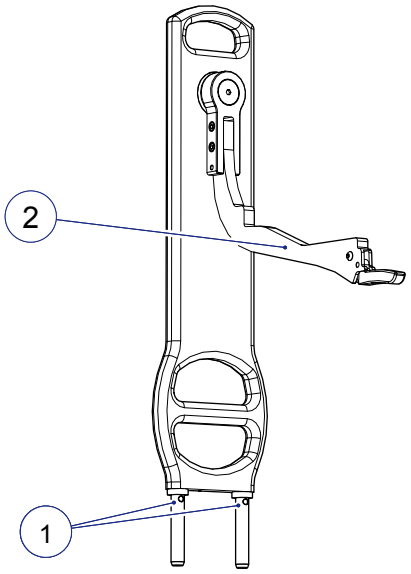

Figure 3.31 The clearance check tool

The tool is installed at the head end of the patient couch by inserting the two bars (1) into the corresponding holes in the cover just below and outside the shielding doors. The arm (2) of the tool has a form that closely follows the inner shape of the collimator cap and a part of the radiation protection within the radiation unit. When the arm is rotated a complete revolution, the whole of the cavity volume in the radiation unit is emulated.

The tool is also referred to with a shorter name, the clearance tool.

The clearance tool is used when the patient is docked to the docking device. By manually rotating the arm round the patient's head, it is possible to check that the arm passes clear of the patient's head and all parts of the coordinate frame:

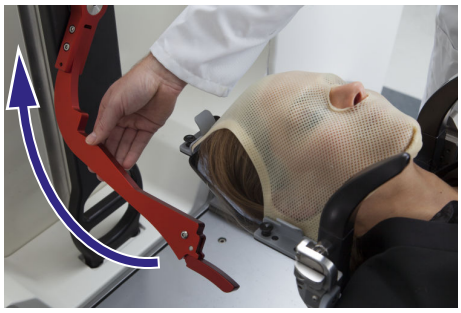

Figure 3.32 Using the clearance tool

When not used, the clearance tool is stored in an appropriate storage place according to site preferences.

Related Links:

Performing clearance checks on page 134

3.8.3 Description of the QA tools for Leksell Gamma Knife® Icon™

3.8.3.1 Description of the QA tool Plus

You can do a number of QA checks in the system application. The QA tool Plus must be used in the treatment room for these QA checks as follows:

- QA check of radiation focus precision
- QA check of clearance tool
- QA check of CBCT precision.

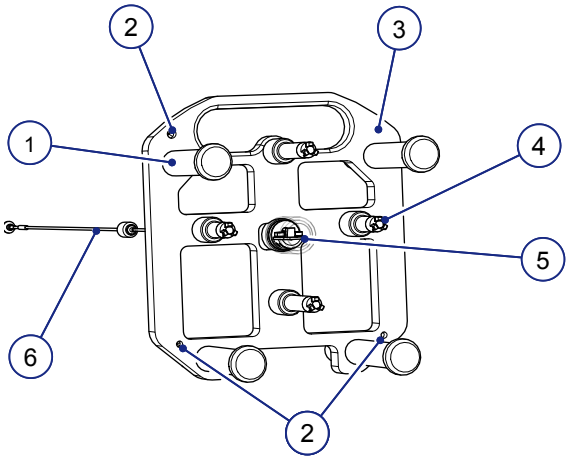

Figure 3.33 The QA tool Plus

(1)	Posts	(4)	Steel balls
(2)	Holes for locating pins	(5)	Center post
(3)	Base plate	(6)	Cable

The QA tool Plus has four cylindrical posts (1) and a center post (5), see **Figure 3.33**. The center post contains a diode sensitive to radiation. There are also four rods with steel balls (4) for CBCT QA check. The base plate (3) of the QA tool Plus has the same shape and thickness as the coordinate frame. It also has the same holes (2) for locating pins as the coordinate frame. This design makes the QA tool Plus fit in the frame adapter.

To use the QA tool Plus, the frame adapter must be attached to the QA tool Plus. The frame adapter with QA tool Plus is then docked to the docking device of the patient couch.

The cable (6) behind the QA tool Plus is attached to a special connector (1), see **Figure 3.34**:

- Below the mattresses of the couch, in the left hole in the mattress plate. The mattresses may be put back in place after the cable is connected.

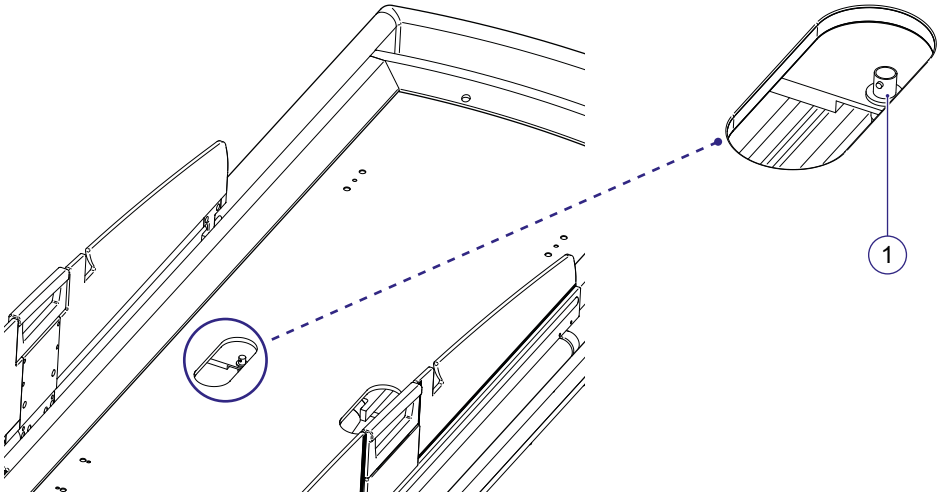

Figure 3.34 The cable connector below the mattresses

When not in use, keep the QA tool Plus in the intended storage area. Refer to the site preferences.

WARNING 3.3

Be careful when you use the tool and keep it in the intended location. If the tool gets damaged, it can have an effect on the precision of the tool, which can cause clinical mistreatment or damage to the equipment.

Related Links:

Using the QA tool to do QA checks on page 200

Doing a focus precision check on page 204

Doing a CBCT precision check on page 206

Doing a clearance tool check on page 218

3.8.3.2 Description of the QA tool Vantage

The QA tool Vantage, see **Figure 3.35** is used together with the Vantage frame adapter.

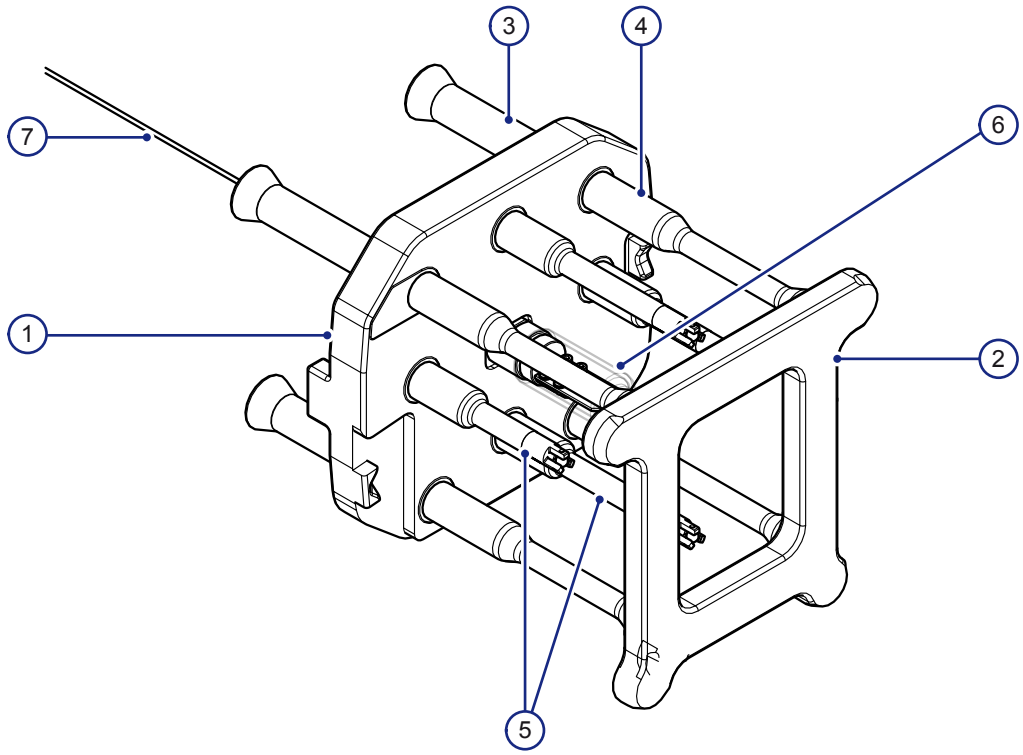

Figure 3.35 The QA tool Vantage

(1)	Tool base	(5)	Rod QA
(2)	Front plate	(6)	Radiation detector
(3)	Rod back	(7)	Cable
(4)	Shaft		

The QA tool Vantage has a tool base (1) with rods (3), a front plate (2), four rods for QA check (5), and a radiation detector (6).

The base plate has three interface areas which are used to attach the QA tool to the Vantage frame adapter. The front plate has eight interface areas which are used for QA check of the clearance check tool. The four rods are used for QA check of the CBCT precision (only applicable for Leksell Gamma Knife® Icon™). The radiation detector is used for QA check of the radiation focus precision.

The Vantage frame adapter is attached to the QA tool Vantage and then docked to the docking device of the Leksell Gamma Knife®.

The cable (7 in **Figure 3.35** is connected to a special connector (1 in **Figure 3.36**) below the mattress of the couch.

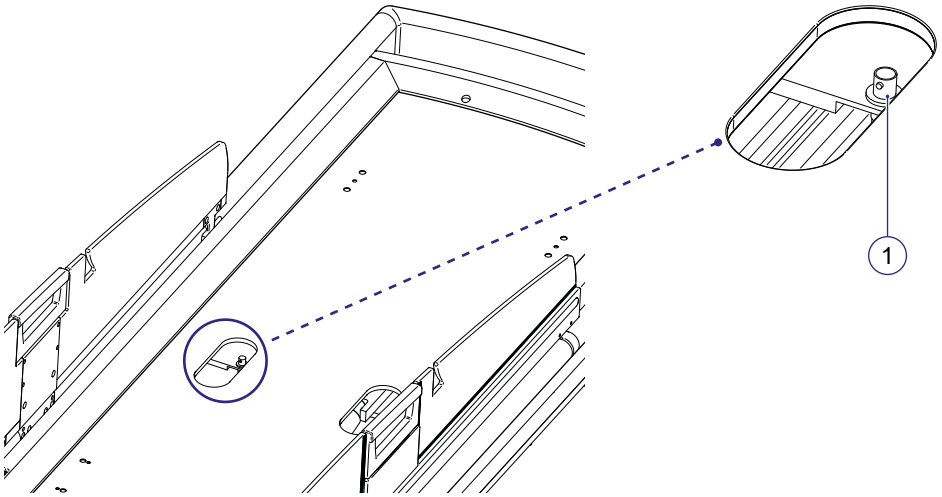

Figure 3.36 The cable connector below the mattresses

WARNING 3.4

Be careful when you use the tool and keep it in the intended location. If the tool gets damaged, it can have an effect on the precision of the tool, which can cause clinical mistreatment or damage to the equipment.

Related Links:

Using the QA tool to do QA checks on page 200

Doing a focus precision check on page 204

Doing a CBCT precision check on page 206

Doing a clearance tool check on page 218

3.8.4 Description of the frame cap

The frame cap is used during patient preparation for a treatment with the Leksell® Coordinate Frame G.

Before the dose planning is performed in Leksell GammaPlan®, a test is made to see if the frame cap can be fitted to the Leksell® Coordinate Frame G on the patient's head. The frame cap has locating pins fitting to corresponding holes in the top of the Leksell® Coordinate Frame G.

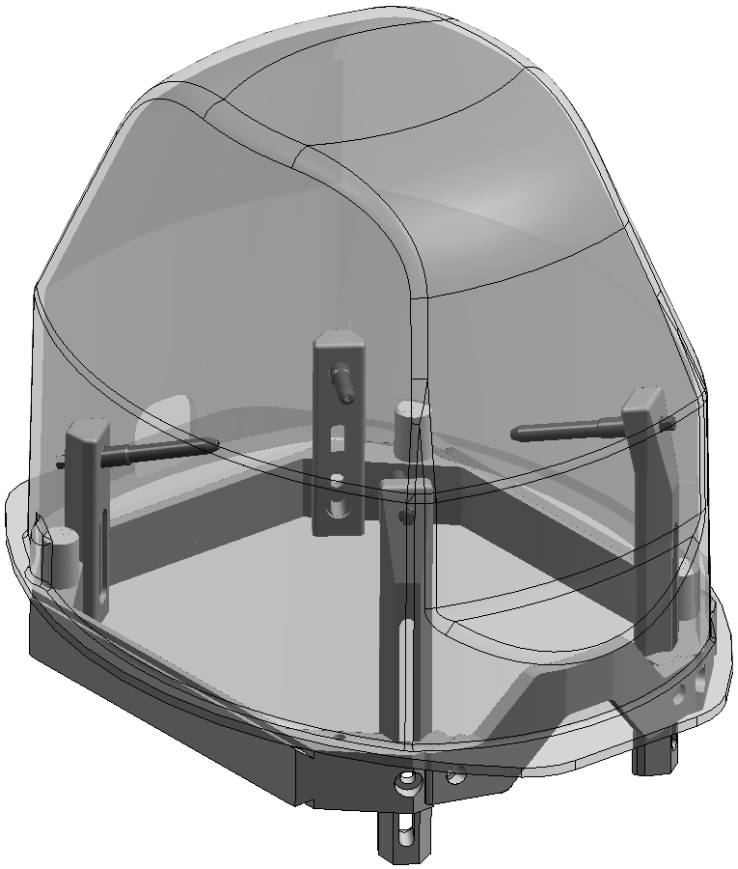

Figure 3.37 The frame cap fitted to the Leksell® Coordinate Frame G

Related Links:

Using the frame cap on page 84

3.8.5 Description of the MR head support

The MR head support (2) can be used in an MR scanner for patients immobilized by mask. It has the same shape as the mask head support and interface for mask attachment. For Philips MR scanners, there is an MR Philips interface (1).

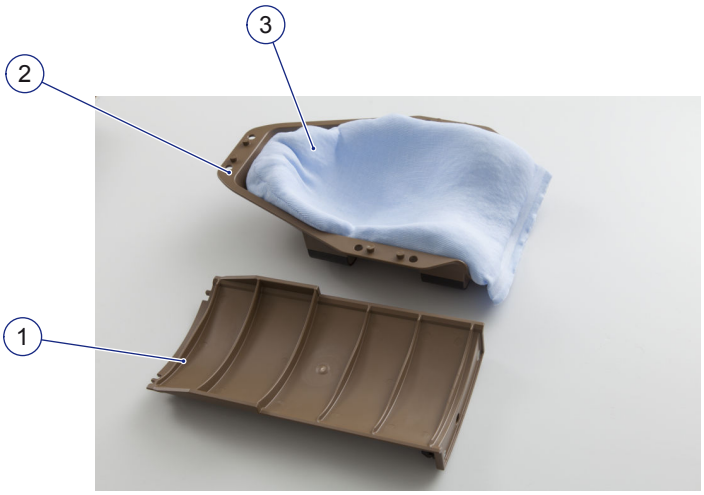

Figure 3.38 MR head support

(1) MR Philips interface

(2) MR head support

(3) Head cushion

The function of the MR head support is to help the patient to be immobilized during MR scan. This will increase the quality of the images. The MR head support is docked in the head coil of the MR scanner.

3.9 Description of the treatment room monitor and TV camera

The wall-mounted treatment room monitor provides a continuous display of the progress of the treatment session. Controls on the monitor allow adjustment of color, brightness and contrast of the picture.

The wall-mounted TV camera enables continuous visual monitoring of the patient, the patient couch and the shielding doors. The camera is controlled from the control panel with the zoom and focus buttons.

The monitor and camera are switched on with the power key on the control panel.

Related Links:

Description of the patient intercom controls on page 40

3.10 Description of the batteries

There are two UPS units containing batteries; the medical UPS and the office UPS.

- The medical UPS contains rechargeable, dry lead, maintenance-free batteries.
- The office UPS contains rechargeable, dry lead, maintenance-free batteries.

The mouse operates with two AAA / LR03 – 1.5 V alkaline type batteries that are to be replaced every six months.

Used batteries must be disposed of in accordance with local or national regulations in force.

4 Getting started

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4.1 Introductory tasks

4.1.1 Switching on the system

1 Make sure that the MCU computer in the office cabinet is on. If the power LED of the computer is not lit, use the power switch to turn the computer on.

2 Insert the key into the power keyswitch on the control panel and turn it to the on position.

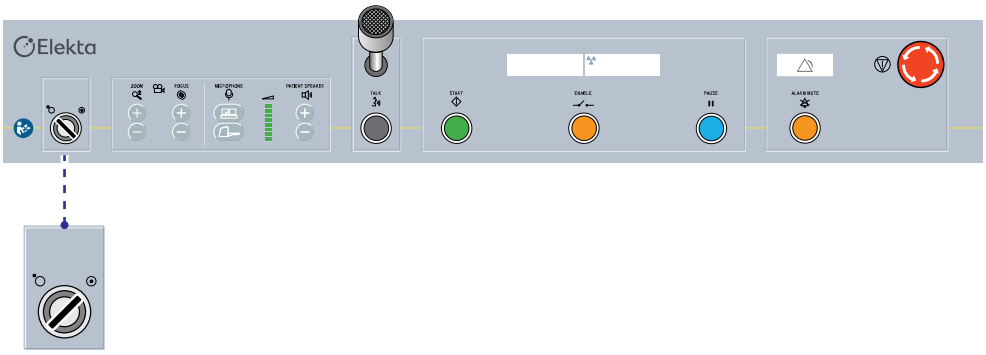


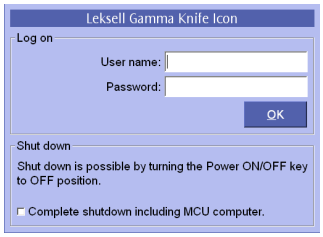
Figure 4.1 The power keyswitch on the control panel

The rest of the units in the system is powered on. The system application starts up and a logon screen is displayed on the treatment view monitor.

4.1.2 Logging on the system

Only authorized users are allowed access to the system application. The access rights defined for the user logging on determines what operating mode the application will be running and what functionality is available to the user.

When the system application starts up, a logon screen is displayed on the treatment view monitor:



1 Enter a user name and password in the text boxes of the logon screen.

For security reasons, the actual characters of the password are replaced by asterisks.

2 Click the **OK** button.

3 If the logon attempt was unsuccessful, click the **OK** button of the displayed message and try logging on again.

After successful logon, the application window is displayed.

Related Links:

User types in the system on page 65

Description of the application window on page 67

4.1.3 Initializing the system

An initialization sequence makes a check of the mechanics and electronics of the system and must be done before all functionality is available in the system application. The initialization sequence is also done in other situations, for example after you have acknowledged an emergency alarm.

A message is displayed in the system information area: **`The system must be initiated.`**

1 Click **Initiate**.

A warning message informs you that during the initialization sequence, large movements of the patient couch may occur.

If you click **Cancel**, the initialization sequence aborts. Only a few of the functions in the system application will then be available.

2 Enter the treatment room. Make sure that no items are placed on the couch or between the couch and radiation unit.

3 Click **Acknowledge** when it is safe for the couch to move.

The system is now initializing. The couch first moves to three extreme positions and then to the home position, as indicated by the blinking yellow couch indicator at the bottom left in the application window. The shielding doors are also opened slightly and then completely closed.

When the initialization is completed, an information message is displayed.

4.1.4 Logging off the system

Logging off the system can be done from the start page of the **Main** tab in the application window. Logging off the system cannot be done during system initialization.

1 Click **Log off** in the application window.

a If the power key is not in the on position when the **Log off** button is clicked, a warning message is displayed. Insert the key, turn it to the on position, and try logging off again.

b If the system is not in a safe state when the **Log off** button is clicked, a warning message is displayed. Make sure the shielding doors are closed and all the sectors are locked in the sector home position, and try logging off again.

2 Wait until the logon screen is displayed:

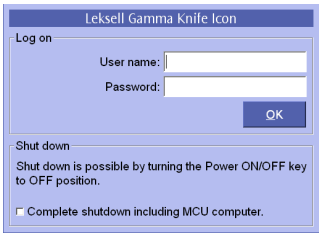


Figure 4.2 The logon screen

4.1.5 Switching off the system

When switching off the system, the default is to leave the MCU computer turned on in a stand-by state, which will speed up the process of switching on the system again. There is a choice of also turning off the MCU computer.

Switching off the system can be done when the logon screen is displayed:

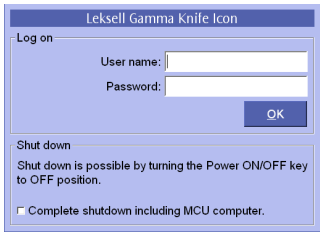


Figure 4.3 The logon screen

Note: *If the power key is accidentally turned off during treatment, the system is paused causing the patient couch to return to the home position and the shielding doors to close. Resumption is not possible until the key is turned to the on position again. Use the power key to turn off the system only when the logon screen is shown.*

1 If you want to completely shut down the system including turning off the MCU computer in the office cabinet, select the check box at the bottom of the logon screen.

2 Turn the power key on the control panel to the off position.

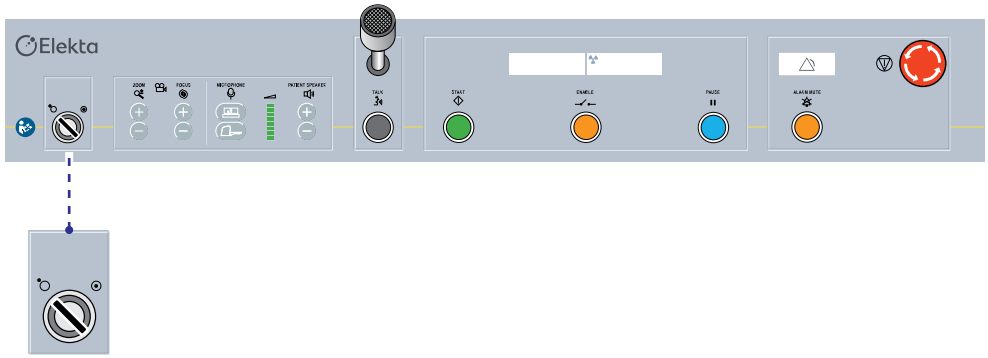


Figure 4.4 The power key on the control panel

Note: *The power key does not switch off power to the medical side of the system.*

3 Remove the power key and store it according to your site recommendations.

4.1.6 User types in the system

Only authorized users are allowed to use the system application. At start-up, a logon screen provides access for authorized users.

There are three types of authorized users in the system application:

- Certified users: Clinical user with full access to all functionality in the clinical mode, including starting a treatment.
- Non certified users: Other medical personnel with limited access to the functionality in the clinical mode. For example, they are not permitted to start a treatment or a CBCT scan.
- Service users: Elekta service personnel with full access to all functionality in the service mode.

After logon, the access rights of the user determines what operating mode the application is running and what functionality is available to the user.

Related Links:

User definitions on page 20

4.2 Understanding the interface

4.2.1 Overview of the graphical user interface

The Leksell Gamma Knife® Icon™ system application runs on the office computer and is displayed on the treatment view monitor in the control room. The treatment room monitor shows a copy of the information displayed on the treatment view monitor.

This chapter describes the design and functionality of the Graphical User Interface (GUI) of the system application. This chapter does not describe how to use the system application in a particular workflow, such as treating a patient.

There are two operating modes (versions) of the system application, one clinical mode for treatment sessions, and one service mode for service activities. The service mode is only available to Elekta® service personnel and is not described in this manual. The current operating mode is clearly identified when running the application, by the title bar of the application window.

Note: *Differences in design of the GUI may exist, depending on the system configuration. Such differences are described in separate user manuals, delivered with additional equipment.*

Once logged on, the application GUI occupies the full screen area of the monitor. The user cannot resize or minimize the application window, or gain access to the underlying Windows® operating system. However, service users can get access to the Windows® operating system by logging off the system.

Only a single application window is used, and there are very few separate dialog boxes or message boxes opened during a session. By this design, no information is obscured, and there is no need for any window management by the user.

The GUI resembles, but is not identical to, a standard Windows® interface. The user is assumed to be familiar with a standard Windows® interface operated by a mouse and keyboard.

4.2.1.1 Lists with columns

The graphical user interface uses lists with data specified in columns to present treatment plans, shots in treatment runs, etc. These lists have a title row in grey color specifying the column titles:

	Target	Shot	X	Y	Z	Gamma	Collimator	Planned time	Remaining time
○	3 - 1	A3	115.1	110.2	118.3	110	16*	0.15	0.15
○	3 - 2	A4	115.1	110.2	118.3	110	8*	0.15	0.15
○	3 - 3	A5	115.1	110.2	118.3	110	4	0.15	0.15

Figure 4.5 List with columns

A list is always sorted according to the data in one of the columns. To sort the list by another column, click the column title. A sort indicator in the form of a triangle pointing up or down is displayed in the column title, indicating whether the sorting is made in ascending or descending order. Clicking the column title toggles between ascending and descending order.

In some of the lists, the columns may be resized by dragging the vertical line between the column titles. If a column is too narrow to display all the text in the column, the text is truncated using an ellipsis (…), but the full text can be seen by resting the pointer over the truncated text. The full text then appears as a tool tip:

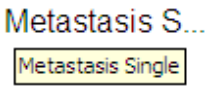


Figure 4.6 Tool tip displaying a truncated text

4.2.1.2 Navigation

It is possible to navigate the GUI, that is, to move the input focus and select or activate different interface objects, by using both the mouse and the keyboard. The object having the input focus is normally highlighted in some way, for instance by having a dotted outline.

The following keyboard functions are available:

- To move the input focus between fields, buttons and other objects, use the <Tab> key. This moves forwards between the objects in a pre-defined order. To move backwards in the order of objects, use <Shift>+<Tab>.
- In a list of objects, use the arrow keys to move up and down between them.
- The <Space> key activates the currently selected object. The meaning of activation differ between objects of different types. Activating a command button executes the action defined by the button. This is the same as clicking the button with the mouse.
- The <Esc> key aborts some operations, such as closing a drop-down menu that has been opened.
- All buttons and tabs have an associated access key, indicated by an underlined character. If no access keys are indicated, pressing <Alt> will display them. To activate a button or tab, press <Alt> together with the access key.

4.2.2 Description of the application window

After successful logon, the application window is displayed. Note that there are no window frames or window controls; the window occupies the full screen area of the monitor.

Figure 4.7 The application window after logging on

(1)	Title bar	(4)	Right tab area
(2)	Patient information area (comes into view during treatment)	(5)	Indicator area
(3)	Left tab area	(6)	Command buttons

The figure shows the start state of the application window after logging on and performing the system initialization, but before any function of the application has been chosen by the user. The different parts of the window are shortly described below.

The title bar (1) of the application window contains, from left to right:

- The product name.
- The current operating mode, **Clinical** or **Service**, determined by the type of user logged on.
- The current date and time. The format of the date and time is configurable by the user.

Below the title bar is the patient information area (2) displaying static information (during treatment) about the patient currently being treated.

Below the patient information are two areas of tabs, which occupies the largest part of the application window:

- The left tab area (3) is where the user performs most of the available functions and makes different selections. This area may contain the following different tabs: **Main**, **QA**, **Clearance**, and **Treatment**.
- The right tab area (4) is used to display important system status. Currently, this area contains the tab **Status**.

In the lower left of the application window is the indicator area (5), which displays icons indicating the physical status of the Gamma Knife unit.

At the bottom of the left tab area there are several command buttons (6) for the main functions of the system application.

Related Links:

Description of the indicator area on page 72

Description of the patient information area on page 68

Description of the Main tab on page 69

Description of the Status tab on page 69

4.2.2.1 Description of the patient information area

The patient information area displays information about the currently treated patient. The patient information is empty if a treatment plan has not been loaded. When a treatment plan has been accepted and loaded, the text boxes are filled in:

- **Patient name**: The full name of the patient.
- **Patient ID**: The identification code for the patient.
- **Date of birth**: The birth date of the patient.
- **Diagnosis**: A short description of the patient diagnosis.
- **Plan ID**: The ID of the treatment plan in the treatment plan database.
- **Max dose**: The prescribed maximum radiation dose, expressed in Gy.

The patient information text boxes cannot be edited. The function key <F2> can be used to toggle (hide or show) the patient information. When hidden, the text boxes become gray without displaying any text.

If a text is too long to fit in the corresponding text box, the text is truncated, but the full text can be seen by resting the pointer over the truncated text. The full text then appears as a tool tip.

A treatment run cannot be selected and a treatment cannot be started if the patient information is hidden. A system message is then displayed.

4.2.2.2 Description of the Main tab

The **Main** tab initially displays a start page with an image of the Gamma Knife unit and command buttons for the main functions of the system application.

Figure 4.8 The start page of the Main tab

The following command buttons are available on the start page:

- **Log off**: For logging off the system.
- **Administration**: For administrative functions, including user preferences.
- **Test**: For performing test runs.
- **QA**: For performing Quality Assurance functions.
- **Treatment**: For loading and executing a treatment plan or a stand-alone CBCT scan.

Once a function in the start page has been selected, the contents of the tab area changes. This is done in either of two ways:

- The **Main** tab changes to reflect the chosen functionality, and the command buttons disappear.
- A separate tab for the chosen functionality is added to the tab area and becomes active. The **Main** tab is then disabled.

When the chosen functionality has been executed and finished, the start page of the **Main** tab is displayed again.

4.2.2.3 Description of the Status tab

Description of the collimator status

The **Collimator status** area shows the status of the collimators used during a shot in a treatment run. There are 8 sectors of collimators, displayed in the image as they are placed within the radiation unit, as seen from the front of the Leksell Gamma Knife® Icon™ unit. The sectors are numbered from 1 to 8 in a clockwise direction.

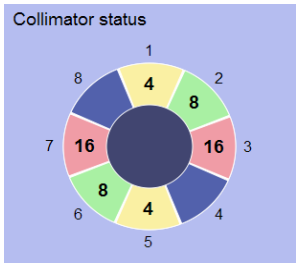


Figure 4.9 The collimator indicators

During treatment, each sector in the image shows the size of the collimators used or whether the sector is blocked. In a blocked sector, no collimators are aligned with the radiation sources in that sector. The following indicators are used for the sectors in the image:

- 4 mm collimators: light yellow sector with the number 4 within
- 8 mm collimators: light green sector with the number 8 within
- 16 mm collimators: light red sector with the number 16 within
- blocked sector: dark blue sector with no number within

Note: *The dark blue sector is also used to indicate that the corresponding sector is locked in the sector home position.*

Description of the System's checklist

The **System's checklist** area shows the status of the interlocks of the system. Before you can start a treatment, you must make sure that all hardware interlocks in the treatment room are set. When an interlock is set correctly, a green check mark appears in the circle adjacent to the interlock.

Figure 4.10 Interlock status in the System's checklist

The interlocks are:

- **Gamma angle N**: This shows the gamma angle **N** that the fixation system adapter is docked in. The value **N** is not displayed until the adapter is docked in one of the gamma angles. If the adapter is docked in a gamma angle that is different from the gamma angle specified in the selected run, a red cross appears in the circle adjacent to the interlock and a system message is displayed.
- **Docking, Mask**: Shows if the fixation system adapter is attached to the docking device on the left side of the patient, and what type of adapter (in this example, the mask).
- **Adapter docked**: Shows that the docking device is locked in position.
- **Side protection left**: Shows if the left side protection panel is closed (handle locked).
- **Side protection right**: Shows if the right side protection panel is closed (handle locked).
- **Room door**: Shows if the door to the treatment room is closed.

Description of the system information

The **System information** area is for displaying messages from the system, some of which may require an action from the user.

The system messages are of three types: error, warning and information messages, with different priorities. When no message is displayed, the system information area is colored blue and has the title **System information**. The area changes color and title to clearly indicate the type of message.

WARNING 4.1

In case of system error messages, it is essential to carefully follow any instructions given in the error messages. To not follow the instructions may lead to clinical mistreatment.

- **Error**: red colored area (highest priority)

  Informs the user of a serious problem (that is, a system error) that requires an action and user acknowledgement before any work can be resumed. These messages are always accompanied by a button **Acknowledge**. The rest of the GUI is locked and disabled (greyed-out) until the user clicks the button.

Note: *A few functions are always available, even when an error message is displayed. These are exporting log files, ending a treatment, and opening a report.*

- **Warning**: yellow colored area (medium priority)

  Informs the user of a condition that needs to be attended to before continuing. These messages may need acknowledgement or offer choices to the user, in which case one or more buttons are provided. The rest of the GUI is then locked and disabled (greyed-out) until the user clicks a button.

- **Information**: green colored area (lowest priority)

  Informs the user of system status or progress. These messages do not require acknowledgement or a choice to be made, and no buttons are provided.

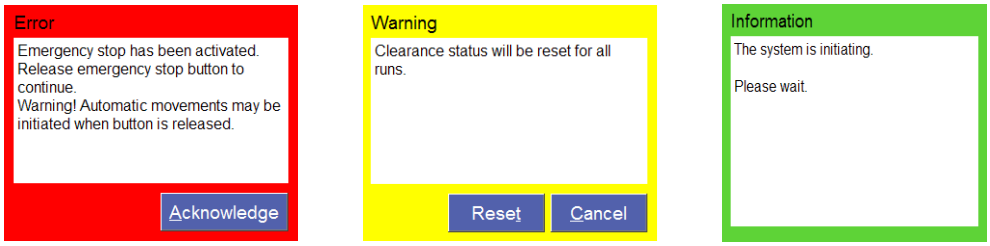


Figure 4.11 Examples of error, warning and information messages

The system messages have different priorities, as specified above. Only a single message at a time can be displayed in the system information area, the one with the highest priority. This means that some generated messages with lower priority may not be displayed, due to a message with higher priority. However, all generated system messages are saved in a system message log.

A message is cleared as soon as it has been attended to or the system state has changed.

Related Links:

Exporting log files on page 170

Viewing treatment reports on page 143

The treatment run selection page on page 158

Description of the computer security system

The system application includes a computer security system. The computer security system will stop programs that are not permitted to operate on internal and external drives. The status of the computer security system is displayed at the bottom of the **Status** tab.

The GUI uses one of two status indicator icons to show if the computer security system operates or not.

The computer security system operates.

The computer security system does not operate.

When a program is blocked by the computer security system, a button with an icon appears adjacent to the status indicator icon. No harm has been done to the system. The incident is recorded in the log files.

The computer security system has blocked a file.

Related Links:

Troubleshooting the computer security system on page 194

Blocked programs in the computer security system on page 194

4.2.2.4 Description of the indicator area

The indicator area shows four icons which give the physical status of the Gamma Knife® unit.

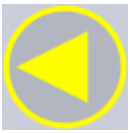
Figure 4.12 The indicator area

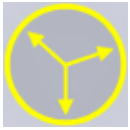
The indicators are, from left to right:

- Doors: indicates if the shielding doors to the radiation unit are closed, open or moving.
- Couch: indicates the position or movement of the patient couch in to or out from the radiation unit.
- Positioning: indicates if the patient couch is being positioned for the next shot.
- Treatment: indicates if the patient is receiving treatment (beam on).

The different states and appearances of the indicators are:

Table 4.1 States and appearances of the indicators

Indicator	Icon	Explanation
Doors	steady: 	Doors are fully closed. Treatment has not started or has finished.
	blinking: 	Doors are opening.
	blinking: 	Doors are closing.
	steady: 	Doors are fully opened.
Couch	steady: 	Couch is inactive and positioned in home position or in treatment position.
	blinking: 	Couch is moving towards the radiation unit.
	blinking: 	Couch is moving out from the radiation unit.
	steady: 	Couch is paused, either in a position just outside the radiation unit, or during treatment.
Positioning	steady: 	The system is not positioning the patient.

Indicator	Icon	Explanation
	blinking: 	The system is positioning the patient.
Treatment	steady: 	The patient is not receiving treatment.
	steady: 	The patient is receiving treatment (beam on)

4.3 Understanding the workflow

For treatment of a patient, you must use one of these fixation systems:

Leksell® Coordinate Frame G	• Treatment planning on MRI with stereotactic reference from indicator box and external MR/CT • Treatment planning on MRI with stereotactic reference from the integrated CBCT
Leksell® Vantage™ Head Frame	• Treatment planning on MRI with stereotactic reference from indicator box and external MR/CT • Treatment planning on MRI with stereotactic reference from the integrated CBCT
Mask fixation system	• Treatment planning based on stereotactic reference defined by CBCT

The HDMM system is mandatory during treatment with mask fixation. The HDMM system is optional during treatment with Vantage Head Frame.

For MOSAIQ® users the treatment plan is exported to MOSAIQ® and added to the Treatment Calendar.

4.3.1 Treatment workflow with Leksell® Coordinate Frame G and stereotactic reference defined by MR/CT

1 *Optional*: Non-stereotactic imaging MR/CT.

2 *Optional*: Pre-planning, refer to *Leksell GammaPlan®, Online Reference Manual*.

3 Create setup and coordinate frame attachment. Refer to *Leksell Stereotactic System®, Instructions for Use*.

4 Stereotactic imaging MR/CT with indicator box. These procedures are not given in this manual.

5 Treatment planning, refer to *Leksell GammaPlan®, Online Reference Manual*.

6 Treatment preparation on Leksell Gamma Knife®:

- Load the treatment
- Dock the patient and verify patient ID.

7 Do the treatment.

8 Release the patient and remove the coordinate frame.

4.3.2 Treatment workflow with Leksell® Coordinate Frame G and stereotactic reference defined by CBCT

1 Non-stereotactic imaging MR/CT.

2 *Optional*: Pre-planning, refer to *Leksell GammaPlan®, Online Reference Manual*.

3 Create setup and coordinate frame attachment. Refer to *Leksell Stereotactic System®, Instructions for Use*.

4 Treatment planning, refer to *Leksell GammaPlan®, Online Reference Manual*.

5 Stereotactic imaging CBCT:

- Request stand-alone CBCT on Leksell GammaPlan® to get the stereotactic reference for the treatment, and for the treatment planning.
- Do the CBCT preparations on Leksell Gamma Knife® Icon™:
  - Verify and accept patient data
  - Go into the treatment room.
- Dock the patient and verify ID.
- Do the scan.
- Release the patient.

6 Treatment planning, refer to *Leksell GammaPlan®, Online Reference Manual*.

7 Treatment preparation on Leksell Gamma Knife® Icon™:

- Load the treatment
- Dock the patient and verify patient ID
- *Optional:* CBCT for treatment and treatment delivery evaluation without applied correction. This can be used as a QA check.

8 Do the treatment.

9 Release the patient and remove the coordinate frame.

4.3.3 Treatment workflow with Leksell® Vantage™ Head Frame and stereotactic reference defined by MR/CT

1 *Optional*: Non-stereotactic imaging MR/CT.

2 *Optional*: Pre-planning, refer to *Leksell GammaPlan®, Online Reference Manual*.

3 Create setup and Vantage Head Frame attachment, refer to *Leksell Vantage™ Stereotactic System®, Instructions for Use*.

4 Stereotactic imaging MR/CT with indicator box. These procedures are not given in this manual.

5 Treatment planning, refer to *Leksell GammaPlan®, Online Reference Manual*.

6 Treatment preparation on Leksell Gamma Knife® Icon™:

- Load the treatment.
- Dock the patient.
- *Optional:* Activate HDMM.
- If needed, do clearance check.
- *Optional:* Do CBCT for treatment.
- If CBCT for treatment was done, do treatment delivery evaluation.

7 Do the treatment.

8 Release the patient and remove the Vantage Head Frame.

4.3.4 Treatment workflow with Leksell® Vantage™ Head Frame and stereotactic reference defined by CBCT

1 Non-stereotactic imaging MR/CT.

2 *Optional*: Pre-planning, refer to *Leksell GammaPlan®, Online Reference Manual*.

3 Create setup and Vantage Head Frame attachment, refer to *Leksell Vantage™ Stereotactic System®, Instructions for Use*.

4 Stereotactic imaging CBCT:

- Request stand-alone CBCT.
- Prepare for the CBCT.
- Dock the patient.
- Verify the patient ID.
- Do the stand-alone CBCT.
- Release the patient.

5 Treatment planning, refer to *Leksell GammaPlan®, Online Reference Manual*.

6 Treatment preparation on Leksell Gamma Knife® Icon™:

- Load the treatment.
- Dock the patient.
- *Optional:* Activate HDMM.
- If needed, do clearance check.
- *Optional:* Do CBCT for treatment.
- If CBCT for treatment was done, do treatment delivery evaluation.

7 Do the treatment for the first fraction. For subsequent fractions, it is not necessary to do step **1** -**5** again.

8 Release the patient and remove the Vantage Head Frame.

4.3.5 Treatment workflow with mask fixation and stereotactic references defined by CBCT

1. Non-stereotactic imaging MR/CT.
2. *Optional*: Pre-planning, refer to *Leksell GammaPlan®, Online Reference Manual*.
3. Create mask setup and apply the patient ID and date on the applicable patient specific equipment. Record the mattress height and other details in the setup before you release the patient. This helps you to reproduce the setup.
4. Stereotactic imaging CBCT:
   - Request stand-alone CBCT on Leksell GammaPlan® to get the stereotactic reference for the treatment, and for the treatment planning.
   - Do the CBCT preparations on Leksell Gamma Knife® Icon™:
     - Verify and accept patient data
     - Go into the treatment room.
   - Dock the patient and verify patient ID.
   - Do the scan.
   - Release the patient and keep the patient fixation equipment.
5. Treatment planning, refer to *Leksell GammaPlan®, Online Reference Manual*.
6. Treatment preparation on Leksell Gamma Knife® Icon™:
   - Load the treatment
   - Dock the patient and verify patient ID. To reproduce the setup from the stereotactic scan, refer to the protocol.
   - Activate HDMM
   - CBCT for treatment
   - Treatment delivery evaluation, also called **Online adaptive dose delivery**:
     - Co-registration
     - Virtual 6D couch correction
     - Review of updated dose delivery.
7. Do the treatment for the first fraction. For subsequent fractions, it is not necessary to do step **1** -**5** again.
8. Release the patient and keep the patient fixation equipment.

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5 Using Leksell Gamma Knife® Icon™

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5.1 Patient preparations before treatment

Before commencing the first treatment session for the day, the system must be powered on and initiated.

Before commencing a treatment session certain preparations are necessary (some of them outside the system). These procedures are only to be seen as an example and are not to be construed as complete:

- If applicable, prepare the patient in MOSAIQ®.
- Prepare the applicable immobilization, coordinate frame or mask fixation.
- If applicable, do new CT or MR scanning.
- Import the stereotactic or non-stereotactic images to Leksell GammaPlan® (LGP).
- Do the dose planning in LGP.
- Export the treatment plan from LGP.

WARNING 5.1

Practitioners should be attentive to the radiation doses and potential toxicities associated with radiation delivered to adjacent structures. Side effects of stereotactic radiosurgery are generally associated with effects on critical structures that are within or nearby the treatment target. These may include effects that can be temporary or permanent (e.g. radiation necrosis). These effects can lead to edema, ischemia, brain compression, and neurological symptoms. Toxicities could include but are not restricted to motor weakness, sensory deficits, visual deficits, neurocognitive deficits, and speech deficits depending on the brain location. Rarely, serious and irreversible side effects can occur. Particular effects depend on the actual region at risk by virtue of proximity to the target, the radiation dose received and other clinical factors such as age, medical condition, the disorder irradiated, previous radiation treatment history, and other prior interventions both medical and surgical.

WARNING 5.2

For Post-surgical Pituitary Adenoma: Practitioners should be attentive to the radiation doses and potential toxicities associated with radiation delivered to adjacent structures such as the optic pathways, and should balance the risks of incidental irradiation to those structures with the benefits of treatment of the pituitary tumor. Such toxicities could include but are not restricted to motor weakness, sensory deficits, visual deficits, hormonal, neurocognitive, and speech deficits.

WARNING 5.3

For Medically Refractory Essential Tremor: Practitioners should be attentive to the radiation doses and potential toxicities associated with radiation delivered to adjacent structures such as the internal capsule and adjacent thalamus and midbrain, and they should balance the risks of incidental irradiation to those structures with the benefit of treatment to the primary lesion. Such toxicities could include but are not restricted to motor weakness, sensory deficits, visual deficits, neurocognitive, and speech deficits.

The treatment plan database is common to LGP and the Gamma Knife system, and any treatment plan in the database can be imported and executed by the system. The transfer of the selected treatment plan between the database and the system is automatic and takes place over a local network.

In general, these procedures are not part of the Gamma Knife system and are not described in this manual. Refer to applicable procedures for your site and see respective *Instructions for Use* for each unit.

Related Links:

Switching on the system on page 63

Logging on the system on page 63

Initializing the system on page 64

5.1.1 Preparing the Coordinate Frame G

1. Prepare the coordinate frame and attach it to the head of the patient. Refer to *Leksell Stereotactic System®, Instructions for Use*.
2. *Optional:* Measure the head of the patient using the Skull Scaling Instrument, refer to *Skull Scaling Instrument, Instructions for Use*. This step is not needed if the skull shape is defined with CT, or MR, images.
3. Attach the frame cap to the coordinate frame and the head of the patient. If the frame cap do not fit, measure fixation posts and fixation screws.

   Next step is stereotactic imaging. Stereotactic imaging can either be with indicator box and external MR/CT (refer to *Leksell Stereotactic System®, Instructions for Use*), or a stand-alone CBCT.

Related Links:

Doing a stand-alone CBCT on page 99

5.1.1.1 Using the frame cap

WARNING 5.4

Handle the frame cap with care. Any damage, such as a missing locating pin, may give a false positive result of the frame cap test. This may lead to contact with the collimator cap during treatment.

1. Test if the frame cap fits by carefully placing it on top of the patient's head, fully enclosing all fixation screws and fixation posts. Make sure the locating pins are fully seated in the corresponding holes in the coordinate frame.
2. If the frame cap does not fit, this may be due to protruding fixation screws, fixation posts, or the patient skull. A treatment plan can still be devised but post configuration and detailed measurements will have to be entered in Leksell GammaPlan®.

WARNING 5.5

Do not enter a positive result of the frame cap test into Leksell GammaPlan® without performing the frame cap test correctly. The frame cap must be fully and properly attached to the coordinate frame, and the frame cap should not be made to fit by forcing or pressing it onto the coordinate frame. Otherwise the need for clearance may become undetected, leading to contact with the collimator cap during treatment.

3. Enter the result of the frame cap test in the skull and frame measurement protocol, and then in the appropriate dialog in Leksell GammaPlan®. For more information, see *Leksell GammaPlan®, Online Reference Manual*.

5.1.2 Preparing the Vantage Head Frame

1 Prepare the Vantage Head Frame and attach it to the head of the patient. Refer to *Leksell® Vantage™ Stereotactic System, Instructions for Use*.

Next step is stereotactic imaging. Stereotactic imaging can either be with indicator box and external MR/CT (refer to *Leksell® Vantage™ Stereotactic System, Instructions for Use*), or a stand-alone CBCT.

5.1.3 Setting up the mask fixation system using an oven

Prerequisites

If the patient has much facial hair, it must be shaved off to prevent bad mask fixation.

Let the hair of the patient down and try to make it as smooth as possible.

If the patient has jewelry in the face or the ears, remove them.

WARNING 5.6

Make sure that you fully monitor the patient during the full treatment from setup to the end of the treatment. If you do, you can stop the treatment if it is necessary for the patient.

The patient should be observed when docked; during setup, imaging, and treatment. It is possible to use the patient alert for communication during setup, imaging, and treament.

WARNING 5.7

Handle all Elekta equipment with care. Any damage, however slight, can reduce treatment safety, accuracy and precision. Inspect the equipment before clinical use. If you suspect that any part is damaged, contact Elekta immediately. Do not use damaged equipment for any purpose until authorized to do so by Elekta.

Note: *You must only use thermoplastic masks and head cushions supplied by Elekta. For this procedure, when you use an oven to warm up the cushion, you must use the Klarity head cushion.*

The temperatures and time given below, change with different ovens. Make sure that the head cushion is soft before you start to mold the head cushion. Elekta recommends that the head cushion is in the oven for 12-25 minutes and the thermoplastic mask for 10-15 minutes.

1 Switch on the oven and set the temperature to 73 °C.

2 Dock the mask adapter to the docking device. The mask adapter can only be attached to gamma angle 90. Lock the docking device.

Figure 5.1 Mask adapter docked

3 Remove the head cushion and thermoplastic mask from their packaging.

4 When the oven gets the correct temperature (73 °C), put the head cushion on the grid in the oven.

You can at this time also put the thermoplastic mask in the oven, together with the cushion, but the recommended time for the mask is 10-15 minutes. Make sure that the reinforcement on the mask points up and the mask attachments point down.

Figure 5.2 Head cushion in the oven

5 Make sure that the IR camera arm is folded down. Fold down the side protection panels on the couch.

6 Put the patient on the couch mattress in a sitting position.

7 When the head cushion has been in the oven for 12-25 minutes, remove it from the oven. Be careful when you remove the cushion from the oven so you do not burn your fingers.

8 Put the head cushion on the head support.

9 Adjust the head cushion to simulate the shape of a head. Make sure that you get the head cushion as thin as possible, and wide enough, in the position of the posterior head. This is to make it easier to reach the target at treatment and to get the patient in the field-of-view during CBCT scan.

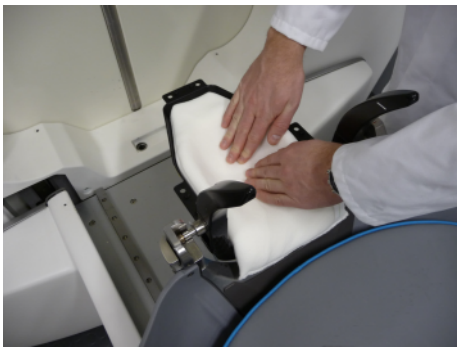


Figure 5.3 Adjusting the head cushion

WARNING 5.8

Do not let the patient use the IR camera arm, to get on or off the couch.

10 Put the patient down on the couch mattress and the head support. Think about the target and the field-of-view of the CBCT when you put the patient in position. The limits of the field-of-view in Z and Y direction are shown by white marks (1) on the mask adapter, see **Figure 5.4**.

If the patient has long hair, put the hair by the shoulders of the patient.

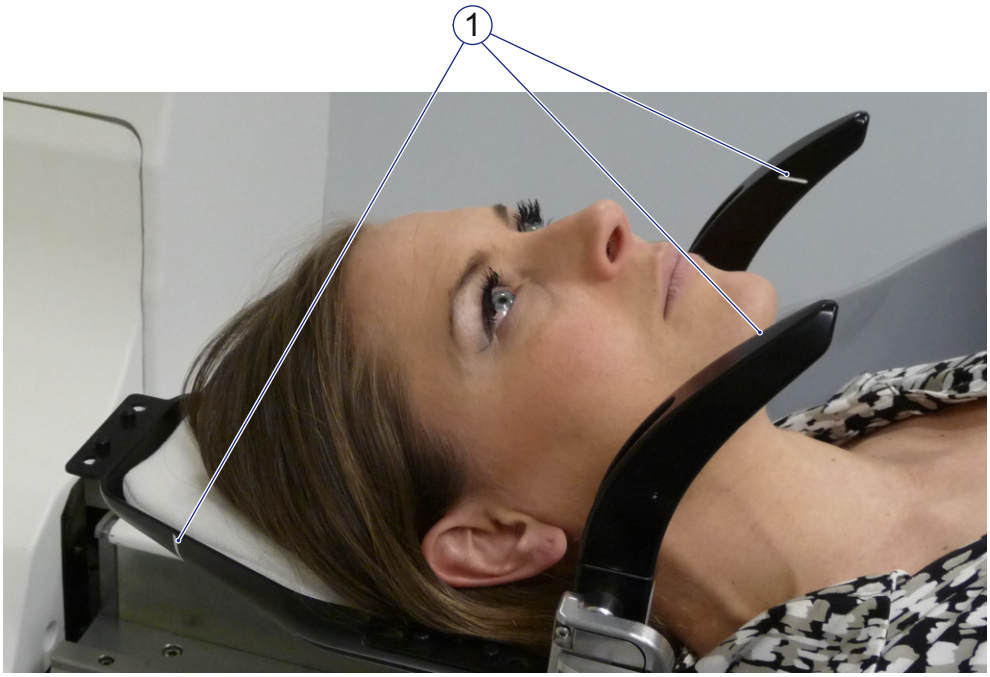


Figure 5.4 CBCT field-of-view indication

WARNING 5.9

Make sure that the head cushion is not outside the head support. If it is, it can cause a blockage of the mask attachments or a collision with the radiation unit.

11 Adjust the head cushion to let the patient have good support for the head and neck. Make sure that you put the patient in a position for maximum patient comfort to prevent movement of the patient. Tell the patient to try not to move while the head cushion is cured.

12 Put the knee support on the couch mattress and adjust it for patient comfort. Make sure that the shoulders of the patient do not press against the patient protection cover.

13 If necessary, unlock the docking device and use the Up and Down buttons on the manual control to adjust the mattress height (1), see **Figure 5.5**. Make sure that the head cushion continues to give a good support for the neck. Lock the docking device again.

Figure 5.5 Patient comfort and mattress height

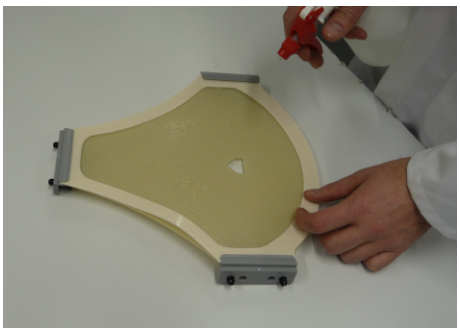
14 Close the side protection panels on the couch.

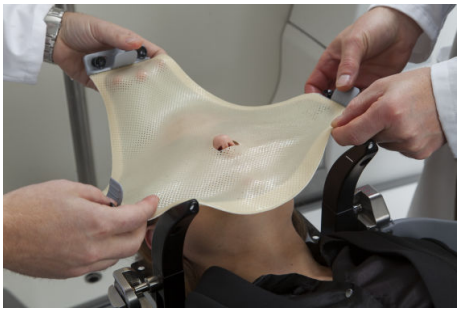
15 Make sure that the patient has maximum patient comfort to prevent movement.

16 Record the patient specific setup as follows:

- The position of the hair and hands of the patient. Make sure that the hair does not hang down.
- Mattress height (1), see **Figure 5.5**.

17 Get the mask out of the oven and spray it with water to cool down the mask before you apply it on the face of the patient. Be careful when you remove the mask from the oven so you do not burn your fingers. Immediately (in 10 seconds) put the mask on the head of the patient, see **Figure 5.6**. Make sure that you do not stretch the mask before you put it on the patient.





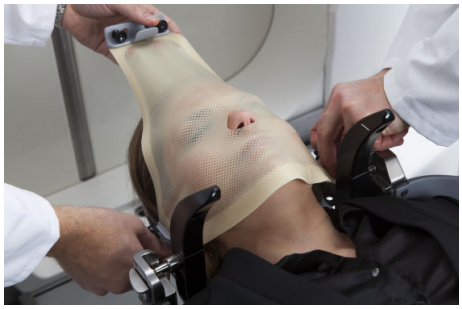


Figure 5.6 Attaching the mask to the patient

18 Attach the mask to the mask head support and lock the push pins.

Make sure that all the push pins are correctly locked. If they are not correctly locked it can cause too much movement of the patient and a risk of more CBCT scan than necessary.

19 Make a shape of the mask around the head of the patient. Make it as smooth as possible and prevent wrinkles.

20 Tell the patient to relax the jaw and fold the mask around the chin, see **Figure 5.7**.

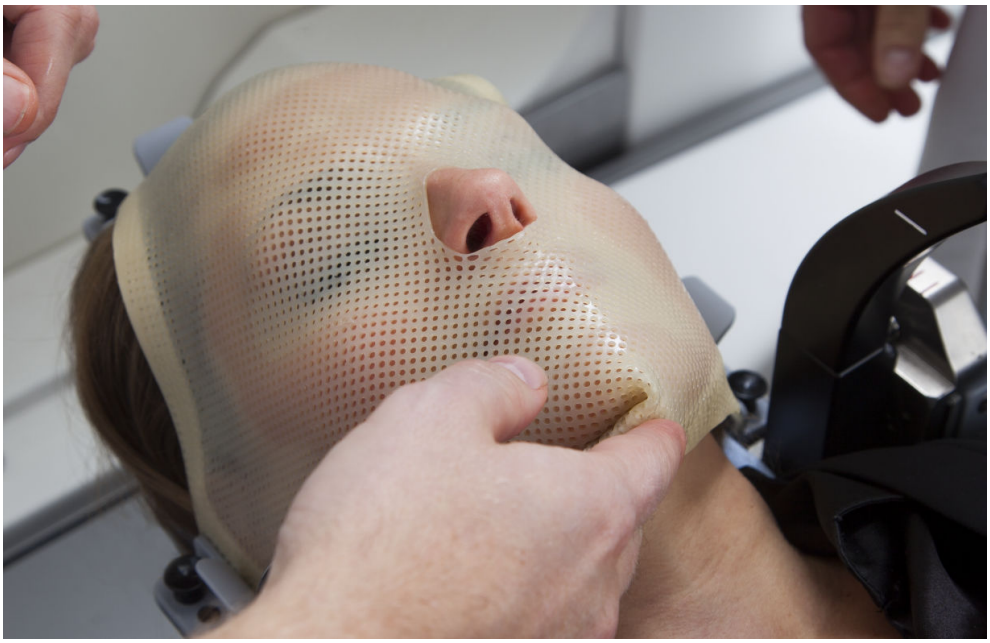


Figure 5.7 Folding the mask

21 Press carefully with your fingers around the nose bridge. Make sure that you make a free space around the nostrils.

Also make sure that the mask is opened enough to prevent contact between the mask and the nose, where you later attach the patient marker.

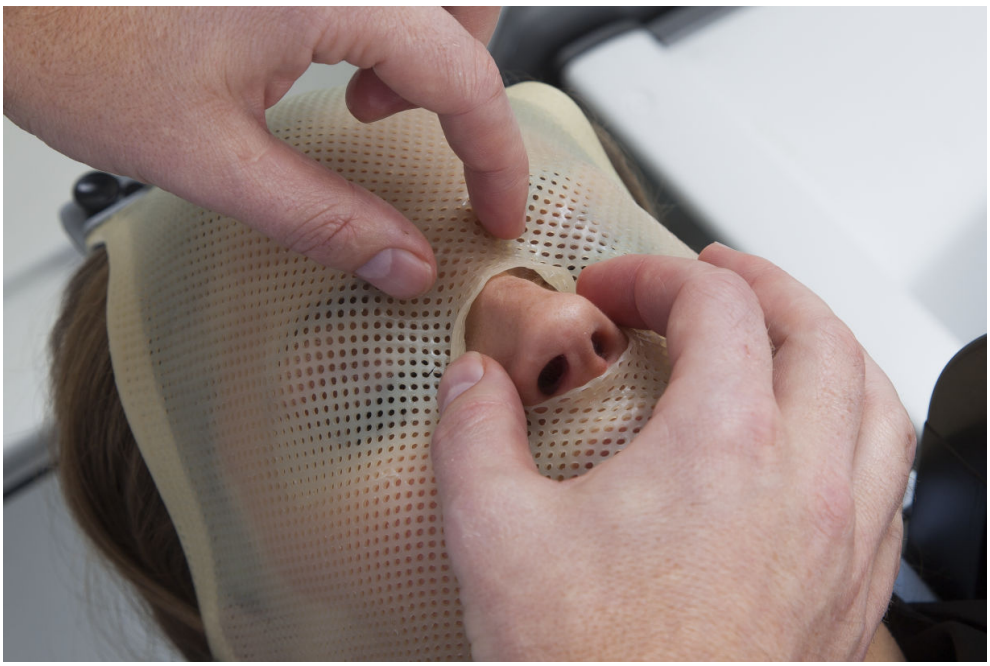


Figure 5.8 Adjusting the mask

22 If desired, do a HDMM test.

23 After minimum 12 minutes, make sure that the mask and cushion are sufficiently cured. The mask and cushion must be cool.

24 Release the patient or continue with stand-alone CBCT.

If you release the patient, tightly attach a tag or equivalent with the patient ID and the current date on the head cushion, mask and patient specific box. Make sure that the patient ID is correct.

Related Links:

Description of the patient alert on page 37

Description of the mask fixation system on page 49

Doing a stand-alone CBCT on page 99

Opening the side protection panels on page 152

Closing the side protection panels on page 152

Releasing a patient docked with a mask on page 133

Doing a HDMM test on page 97

Buttons on the manual control on page 38

5.1.4 Setting up the mask fixation system using heated water

Prerequisites

If the patient has much facial hair, it must be shaved off to prevent bad mask fixation.

Let the hair of the patient down and try to make it as smooth as possible.

If the patient has jewelry in the face or the ears, remove them.

WARNING 5.10

Make sure that you fully monitor the patient during the full treatment from setup to the end of the treatment. If you do, you can stop the treatment if it is necessary for the patient.

The patient should be observed when docked; during setup, imaging, and treatment. It is possible to use the patient alert for communication during setup, imaging, and treatment.

WARNING 5.11

Handle all Elekta equipment with care. Any damage, however slight, can reduce treatment safety, accuracy and precision. Inspect the equipment before clinical use. If you suspect that any part is damaged, contact Elekta immediately. Do not use damaged equipment for any purpose until authorized to do so by Elekta.

Note: *You must only use thermoplastic masks and head cushions supplied by Elekta. For this procedure, when you use heated water to warm up the cushion, you must use the "Moldcare" head cushion.*

1 Dock the mask adapter to the docking device. The mask adapter can only be attached to gamma angle 90. Lock the docking device.

Figure 5.9 Mask adapter docked

WARNING 5.12

Make sure that the water holds a temperature of 65-70 °C. If the temperature of the mask is too high, it can cause injury to the patient or the operator.

2 Make sure that the push pins on the thermoplastic mask are released. Hold the mask attachments as in **Figure 5.10** with the reinforcement pointing down, and put the mask in water. The water must have a temperature of 65-70 °C. The mask must be in the water for a minimum of 4 minutes but not longer than 30 minutes.

Figure 5.10 Putting the mask in water

3. Make sure that the IR camera arm is folded down. Fold down the side protection panels on the couch.
4. Put the patient on the couch mattress in a sitting position.
5. Open the foil packaging and pull out the head cushion.
6. Spray water into the head cushion to let the head cushion be cured more quickly. Spray approximately 20 times equally across the head cushion and quickly massage the water into it.

Figure 5.11 Applying water to the head cushion

7. Put the head cushion on the head support.
8. Adjust the head cushion to simulate the shape of a head. Make sure that you get the head cushion as thin as possible in the position of the posterior head. This is to make it easier to reach the target at treatment and to get the patient in the field-of-view during CBCT scan.

Figure 5.12 Adjusting the head cushion

WARNING 5.13

Do not let the patient use the IR camera arm, to get on or off the couch.

9 Put the patient down on the couch mattress and the head support. Think about the target and the field-of-view of the CBCT when you put the patient in position. The limits of the field-of-view in Z and Y direction are shown by white marks (1) on the mask adapter, see **Figure 5.13**.

If the patient has long hair, put the hair by the shoulders of the patient.

Figure 5.13 CBCT field-of-view indication

WARNING 5.14

Make sure that the head cushion is not outside the head support. If it is, it can cause a blockage of the mask attachments or a collision with the radiation unit.

10 Adjust the head cushion to let the patient have good support for the head and neck. Make sure that you put the patient in a position for maximum patient comfort to prevent movement of the patient. Tell the patient to try not to move while the head cushion is cured.

11 Put the knee support on the couch mattress and adjust it for patient comfort. Make sure that the shoulders of the patient do not press against the patient protection cover.

12 If necessary, unlock the docking device and use the Up and Down buttons on the manual control to adjust the mattress height (1), see **Figure 5.14**. Make sure that the head cushion continues to give a good support for the neck. Lock the docking device again.

Figure 5.14 Patient comfort and mattress height

13 Close the side protection panels on the couch.

14 Make sure that the patient has maximum patient comfort to prevent movement.

15 Record the patient specific setup as follows:

- The position of the hair and hands of the patient. Make sure that the hair does not hang down.
- Mattress height (1), see **Figure 5.14**.

16 After approximately 8 minutes, make sure that the head cushion is sufficiently cured. Do not start to make the shape of the mask before the head cushion is cured.

Note: *The head cushion becomes fully cured after 15 minutes.*

WARNING 5.15

Be careful when you remove the mask from the water and when you put the mask on the patient. The water is hot and can burn your fingers. Make sure that you fully wipe off the water to prevent injury to the patient.

17 Get the mask out of the water and wipe it off. Immediately (in 10 seconds) put the mask on the head of the patient, see **Figure 5.15**. Make sure that you do not stretch the mask before you put it on the patient.

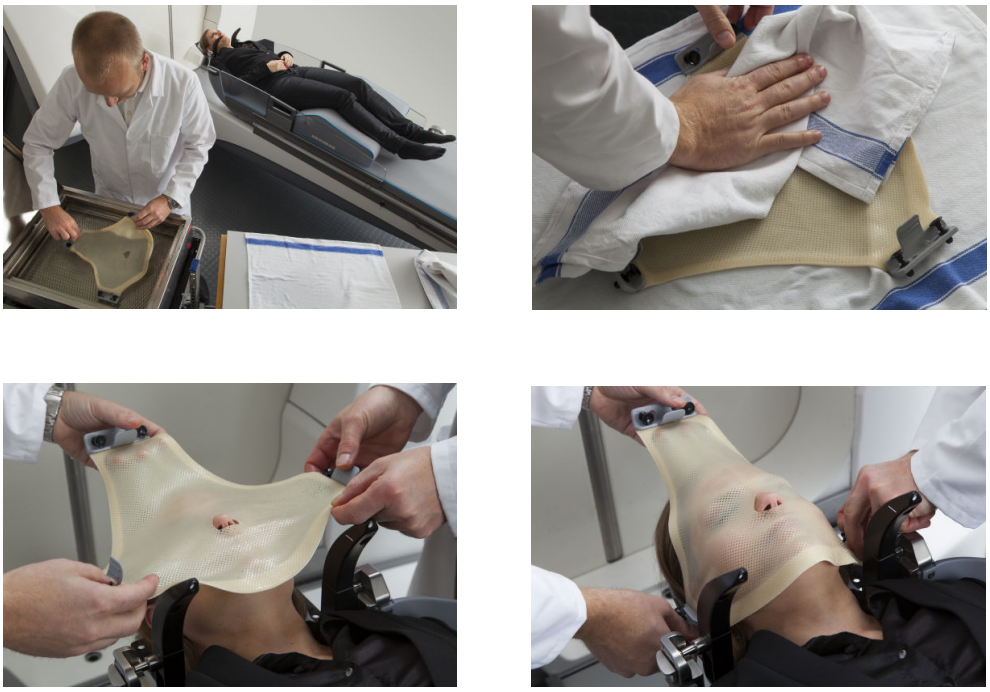


Figure 5.15 Removing the mask out of water and attaching it to the patient

18 Attach the mask to the mask head support and lock the push pins.

Make sure that all the push pins are correctly locked. If they are not correctly locked it can cause too much movement of the patient and a risk of more CBCT scan than necessary.

19 Make a shape of the mask around the head of the patient. Make it as smooth as possible and prevent wrinkles.

20 Tell the patient to relax the jaw and fold the mask around the chin, see **Figure 5.16**.

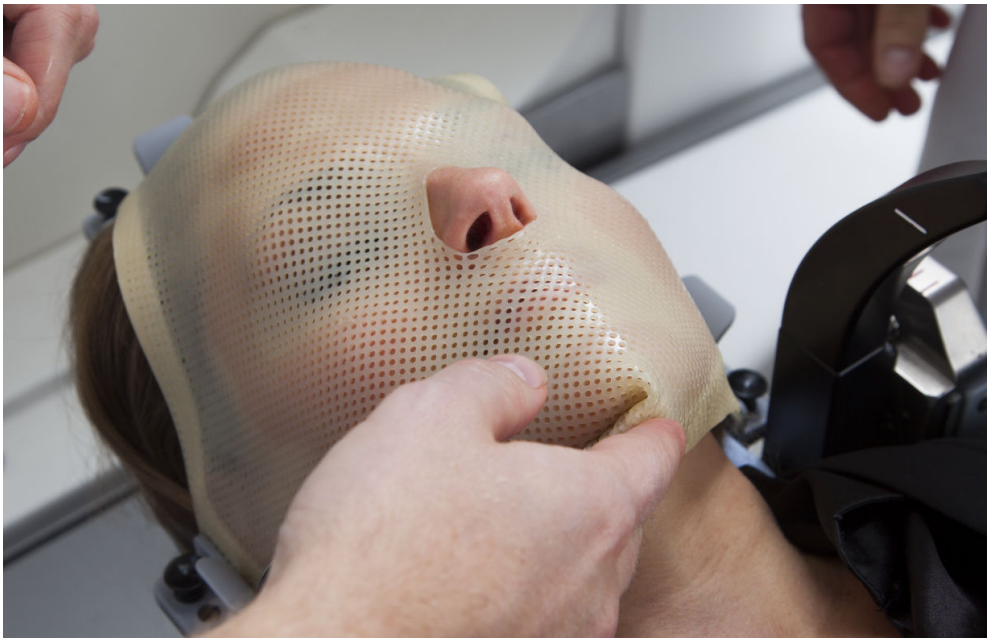


Figure 5.16 Folding the mask

21 Press carefully with your fingers around the nose bridge. Make sure that you make a free space around the nostrils.

Also make sure that the mask is opened enough to prevent contact between the mask and the nose, where you later attach the patient marker.

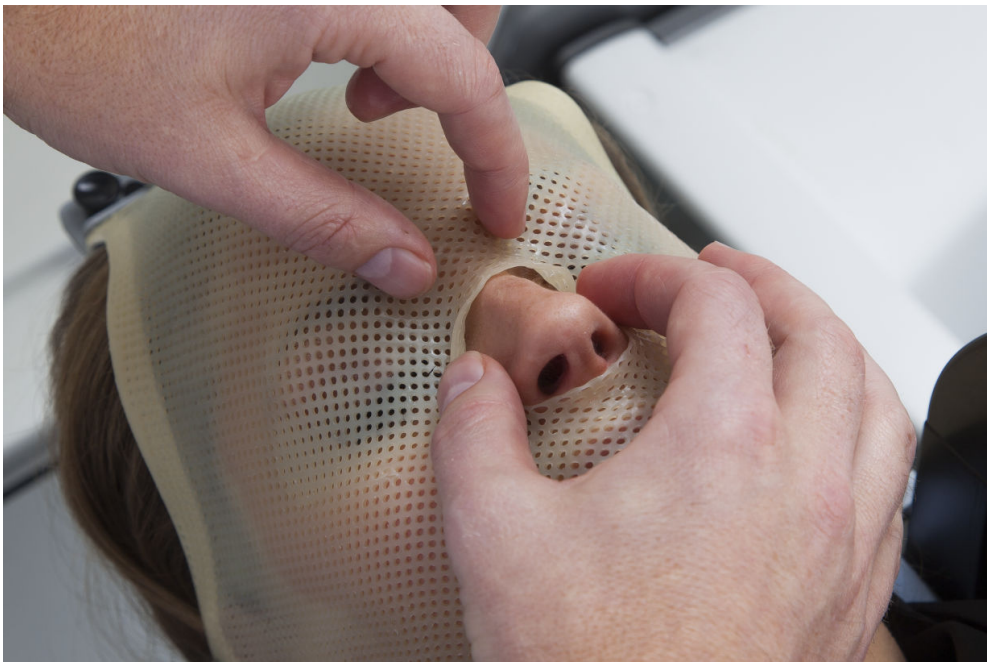


Figure 5.17 Adjusting the mask

22 If desired, do a HDMM test.

23 After minimum 10 minutes, make sure that the mask is sufficiently cured. The mask must be cool.

24 Release the patient or continue with stand-alone CBCT.

If you release the patient, tightly attach a tag or equivalent with the patient ID and the current date on the head cushion, mask and patient specific box. Make sure that the patient ID is correct.

Related Links:

Buttons on the manual control on page 38

Doing a stand-alone CBCT on page 99

Opening the side protection panels on page 152

Closing the side protection panels on page 152

Releasing a patient docked with a mask on page 133

Doing a HDMM test on page 97

Description of the patient alert on page 37

Description of the mask fixation system on page 49

5.1.5 Doing a HDMM test

Prerequisites

The patient is docked with mask or Vantage head frame.

WARNING 5.16

The patient marker is used to monitor the movement of the nose of the patient. It does not monitor the movement of the target. As the relation between marker and target motion depends on the actual clinical case, the user is expected to set the HDMM level in accordance with each specific clinical situation.

WARNING 5.17

Make sure that you fully monitor the patient during the full treatment from setup to the end of the treatment. If you do, you can stop the treatment if it is necessary for the patient.

1 Put the patient marker (1) on the nose of the patient, see **Figure 5.18**.

- Make sure that the patient marker and its attachment point on the patient are clean, for a rigid attachment.
- Try not to touch the reflective surface of the patient marker. Contamination can decrease the reflection effect.
- If mask fixation system is used, make sure that the thermoplastic mask is opened enough around the patient marker and the nose of the patient. This is to prevent contact between the mask and the marker and between the mask and the nose.
- Make sure that there is no blockage in the field-of-view between the patient marker and the IR camera.

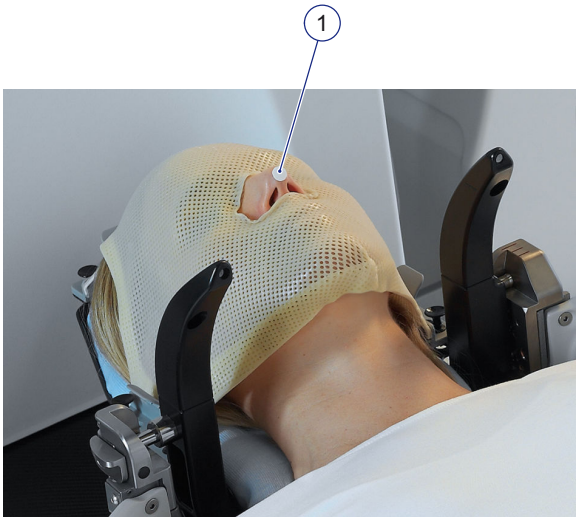


Figure 5.18 Patient marker on the patient docked with mask

2 On the start page of the **Main** tab, click the **Test** button.

3 Select **HDMM test for Vantage** or **HDMM test for Mask** in the menu.

A HDMM test view tab is displayed. The HDMM test view is used for monitoring patient movement during the mask creation.

4 Fold up the IR camera arm and release the latch (1) of the IR camera, see **Figure 5.19**. Turn the IR camera to the patient and lock the latch.

Figure 5.19 Folding up the IR camera arm

5 In the GUI, make sure that interlocks are set.

6 If the check mark for IR reference tool (1) or patient marker (2) does not appear (see **Figure 5.20**), do as follows:

- Make sure that there is no blockage in the field-of-view between the IR markers and the camera. The camera must see the markers completely to get good HDMM quality.
- Make sure that the IR camera and the arm is correctly in position.
- Make sure that the markers are clean.
- Make sure that no objects make reflections into the IR camera.

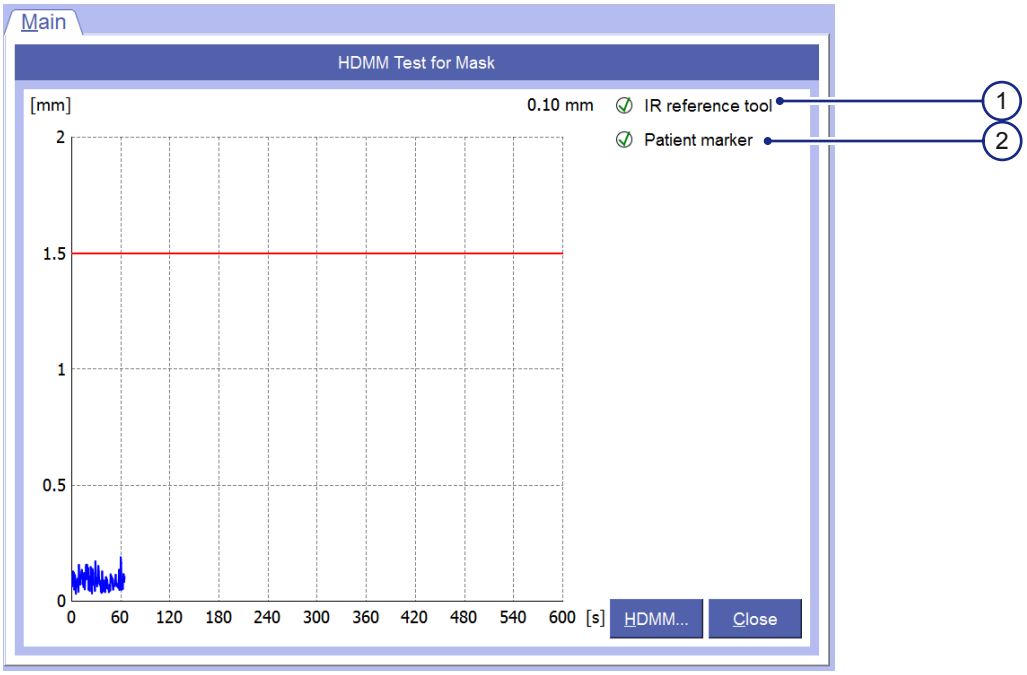


Figure 5.20 HDMM test view for mask

To reset the HDMM patient reference point, press the **Continue** button on the hand control.

5.2 Using Leksell GammaPlan®

The treatment planning, including reviewing and approval, is done in Leksell GammaPlan®. After treatment planning the plan is exported to Leksell Gamma Knife®, and the treatment session can start.

For more information about Leksell GammaPlan®, refer to *Leksell GammaPlan®, Online Reference Manual*.

5.3 Doing a stand-alone CBCT

Prerequisites

A patient file is created in Leksell GammaPlan®.

A stand-alone CBCT scan you do independently from the treatment. The patient is docked during the scan only. Independent on the number of fractions, the stand-alone CBCT only needs to be done once.

WARNING 5.18

Make sure that you fully monitor the patient during the full treatment from setup to the end of the treatment. If you do, you can stop the treatment if it is necessary for the patient.

The patient should be observed when docked; during setup, imaging, and treatment. It is possible to use the patient alert for communication during setup, imaging, and treatment.

The stand-alone scan includes:

- A request from Leksell GammaPlan®
- CBCT preparation

- Docking and verification of the patient
- The CBCT scan.

After the scan, the patient is released, and if the patient is fixated with mask, the patient specific mask is kept for subsequent operation.

This scan is used to get the stereotactic reference for the treatment and also for treatment planning.

WARNING 5.19

If the patient has long hair, make sure that the hair does not get entangled in parts of the gantry. If the hair gets entangled, it can cause injury to the patient and damage to the equipment.

WARNING 5.20

Do a CBCT QA check if you think that a part of the CBCT has hit something. A collision can have an effect on the accuracy of the equipment.

WARNING 5.21

Make sure that you select the X-ray preset to minimize the X-ray dose to the patient and at the same time get sufficient image quality.

To do a stand-alone CBCT scan, do as follows:

1 Prepare for the CBCT request in Leksell GammaPlan®.

a On the **Plan** menu, click **Fixation configuration** and select the applicable fixation type and **Reviewed for plan approved**.

b Click **Save**.

2 From the **Patient** menu, select **Request CBCT > Stand Alone**.

The **CBCT request is pending** icon appears in the menu bar. When the CBCT scan is completed by the Leksell Gamma Knife® Icon™ operator, the icon is changed to an ordinary image study icon.

*Figure 5.21 The **CBCT request is pending** icon*

3 In the Leksell Gamma Knife® application, open the CBCT request made in Leksell GammaPlan®:

a Click the **Treatment** button in the **Main** tab.

The **Select patient** page appears.

b Select the applicable CBCT scan and click the **Proceed** button, or double-click on the row.

c In the page **Verify patient data**, make sure that the patient data is correct and click the **Accept** button. If you click the **Reject** button, you get back to the **Select patient** page.

4 In the treatment room, dock the patient and press the **Accept** button on the manual control to verify the patient ID.

Note: *If docking a patient with mask fixation system, first dock the mask adapter to the docking device and lock the docking device. Then attach the mask to the mask head support and lock the push pins.*

5 Press the **Accept** button to verify the patient setup.

6 Press and hold the Continue button on the manual control, to move the couch to scan position.

7 Press and hold the Continue button to move the tilt arm to scan position. Monitor the movement to make sure that the tilt arm moves freely.

8 Press and hold the Continue button to move the C-arm to scan position. Monitor the movement to make sure that the C-arm moves freely.

9 Go out from the treatment room, and close the door.

10 In the **Image viewer** page, select **CBCT settings**. Think of the delivered dose, the age of the patient and the size of the head when you select the preset. If you put the mouse pointer over the selected preset, you can see the parameters of the preset.

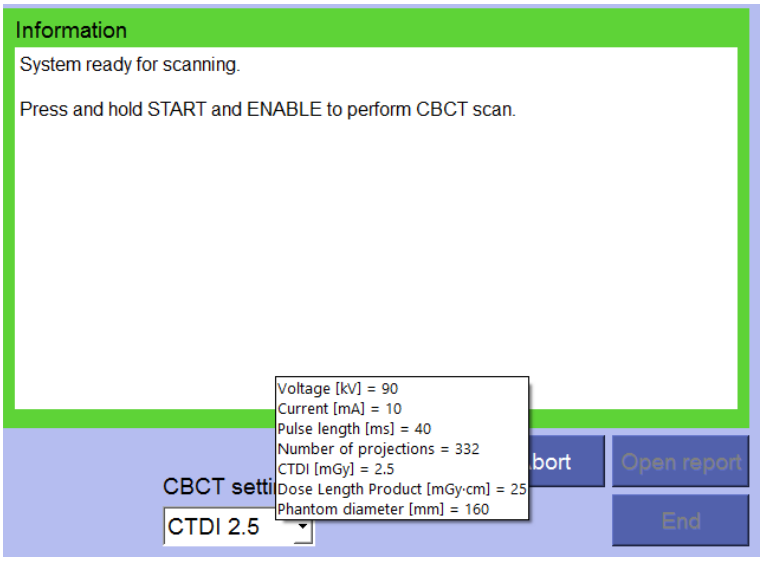


Figure 5.22 Preset parameters

11 On the control panel, press and hold the START and ENABLE buttons at the same time to start the scan. Do not release the buttons before the scan is completed. Then you have to do the scan again and the patient gets more dose than necessary. Monitor the patient during the CBCT scan.

If a message about too hot X-ray tube appears, the tube must be sufficiently cool before you continue. The required cool down time shows in the message.

12 When the CBCT scan is completed, an information message appears.

Release the START and ENABLE buttons.

13 Examine the image quality and **Accept** or **Reject** the images.

If you read out the Leksell coordinates from the images, see the section about patient weight compensation for more information.

If you accept the images, they will be automatically sent to Leksell GammaPlan®

If you click **Reject**, you must do the scan again.

14 Click **Manual** or **Automatic** to move the CBCT equipment to park position and the couch to home position.

A message appears to tell you that the CBCT sequence is completed.

15 Examine and print the reports.

16 Click **End** to complete the CBCT sequence.

For treatment planning, refer to *Leksell GammaPlan®, Online Reference Manual*.

17 Undock the patient.

If you release a patient docked with mask, tightly attach a tag or equivalent with the patient ID and the current date on the head cushion, mask and patient specific box. Make sure that the patient ID is correct.

Next step is treatment planning in Leksell GammaPlan®.

Related Links:

Troubleshooting the CBCT on page 193

CBCT predefined settings on page 163

Description of the patient alert on page 37

Description of image artifacts on page 253

Patient weight compensation and CBCT image coordinates on page 252

Using Leksell GammaPlan® on page 99

5.4 Treating a patient

5.4.1 Selecting the patient

1 Click the **Treatment** button in the **Main** tab to load the treatment plan from the treatment plan database.

The **Select patient** page appears.

If the system is configured for MOSAIQ, there are option buttons to select the treatment plan from MOSAIQ or the database.

Note: *The treatment is always loaded from the treatment plan database, although **MOSAIQ** is selected.*

2 Select the applicable treatment and click the **Proceed** button, or double-click the row.

The page **Verify treatment data** appears.

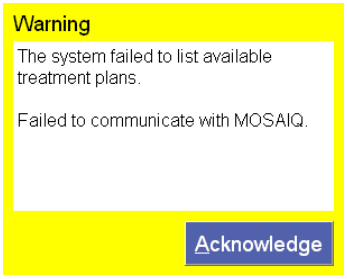
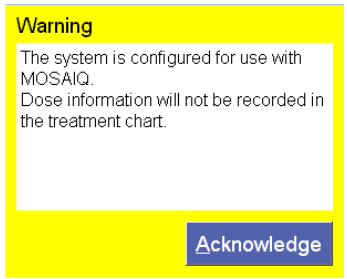
WARNING 5.22

As a user, it is your responsibility to make sure that the correct treatment plan is imported before you start the treatment.

3 In the page **Verify treatment data**, make sure that the patient data is correct and type the current date.

4 Click **Accept** to accept the treatment data and load the treatment.

For MOSAIQ users:

If	Then
The treatment plan is selected from MOSAIQ and the communication with MOSAIQ has failed, this message appears: 	– Click **Acknowledge** and click **Accept** again in the **Verify treatment data** page. – If the communication continues to fail, go back to **Select patient** page and select a treatment plan from the treatment plan database. Do steps **1** to **4** again.
The treatment plan is selected from Database, this message appears to tell you that the treatment information is not recorded in the treatment chart: 	Click **Acknowledge** to continue.

If you click the **Reject** button, you get back to the Select patient page.

5 If the treatment plan contains clearance positions, you must do a clearance check, with all clearance positions accepted.

Related Links:

Docking a patient for treatment with the mask fixation system on page 115

Performing clearance checks on page 134

The page Select patient on page 157

The treatment run selection page on page 158

The page Verify treatment data on page 160

Enlarged GUI view on page 160

The run & shot status page on page 162

5.4.1.1 Selecting a treatment run

If the treatment plan contains clearance positions, you must do a clearance check, with all clearance positions accepted, before you can do this procedure.

The tabs on the run selection page displays the gamma angles in the treatment plan. Each gamma angle contains a single treatment run.

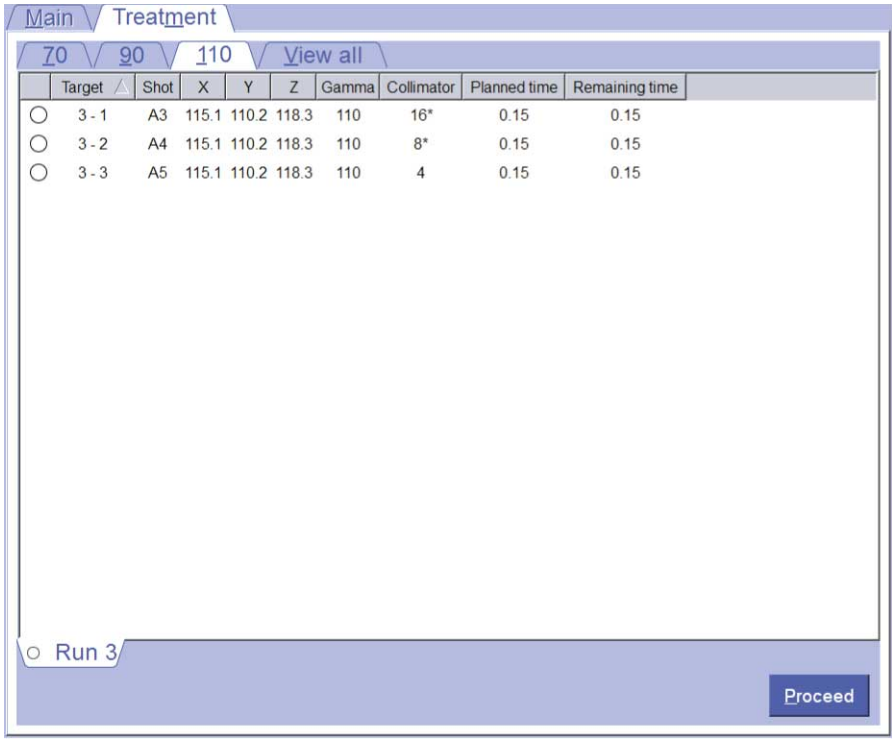


Figure 5.23 The run selection page

1 Select the tab for the gamma angle you wish to execute the run for. By default, the first gamma angle tab and its run is already selected. If clearance runs have been executed and the patient is still docked in a gamma angle, select the same gamma angle for the first treatment run to avoid undocking the patient.

   The list shows the sequence of shots in the run.

2 Click on the **Proceed** button.

   If the button is disabled, the treatment plan contains clearance runs that have not been completed.

   The GUI switches to an enlarged view, where only the most important information is displayed. This view is suited for docking the patient in the treatment room:

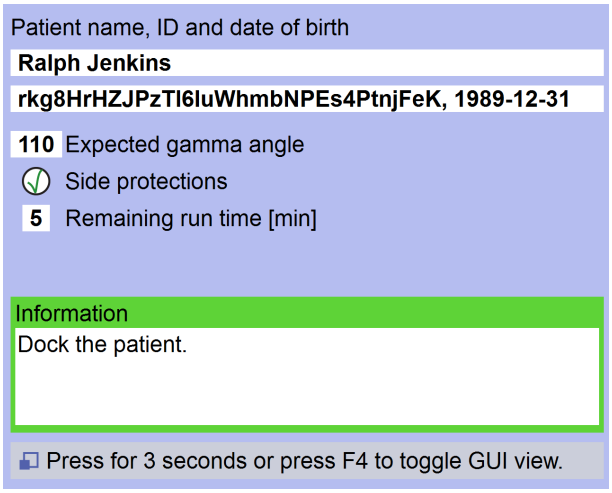


Figure 5.24 Enlarged view

3 To change the GUI to the normal view, where all information is displayed, press <F4> on the keyboard, or press and hold down the Toggle GUI button on the manual control for 3 seconds.

This displays the run & shot status page:

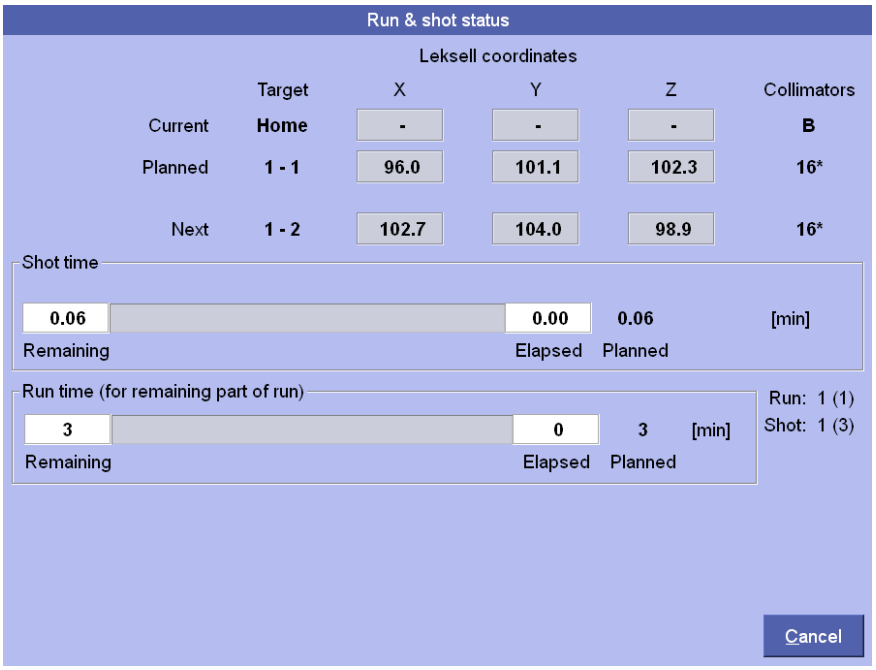


Figure 5.25 The run & shot status page

In this view, clicking **Cancel** returns to the run selection page and allows you to select another run.

Related Links:

The treatment run selection page on page 158

The run & shot status page on page 162

Troubleshooting a treatment run on page 192

Performing clearance checks on page 134

5.4.2 Docking a patient with the Coordinate Frame G

5.4.2.1 Attaching the frame adapter to the coordinate frame G

WARNING 5.23

All parts of the frame adapter must be undamaged and working. If any of the fixation levers, securing plates, locating pins, or the securing screw are missing or damaged, the frame adapter may not be correctly secured to the coordinate frame. This may lead to clinical mistreatment and/or contact with the collimator cap during treatment.

WARNING 5.24

Handle the frame adapter with care. Any damage may affect the precision of the frame adapter, which may lead to clinical mistreatment and/or contact with the collimator cap during treatment.

WARNING 5.25

If you suspect that the frame adapter may have been damaged due to a drop or other impact, the precision of the frame adapter must be verified before a treatment is started. Contact Elekta or perform a focus precision QA check.

WARNING 5.26

Make sure that there is no hair or other material between the interface areas of the coordinate frame and the frame adapter. If there is anything between the interface areas the frame adapter is not correctly attached to the coordinate frame which can have an effect on the accuracy and lead to clinical mistreatment.

To attach the frame adapter to the coordinate frame:

1 Place the patient in an upright position.

2 Release the 3 levers on the frame adapter:

a Unscrew and release the securing screw.

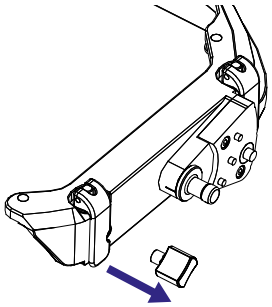


Figure 5.26 Releasing the securing screw

b Release the 3 levers by pulling them upwards.

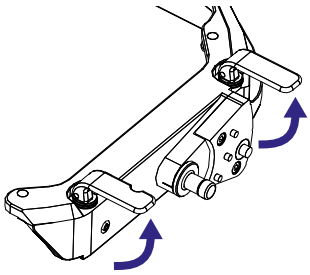


Figure 5.27 Releasing the levers

c Turn the 3 levers so that the securing plates align with the side bars.

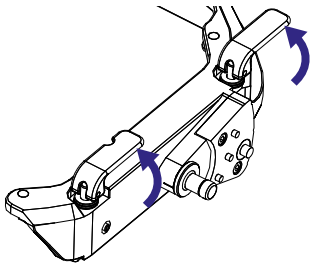


Figure 5.28 Turning the levers

3 Lower the frame adapter from above and behind the patient, and fit it to the upper surface of the coordinate frame. Make sure the locating pins (1) on the frame adapter is inserted into the corresponding holes on the coordinate frame:

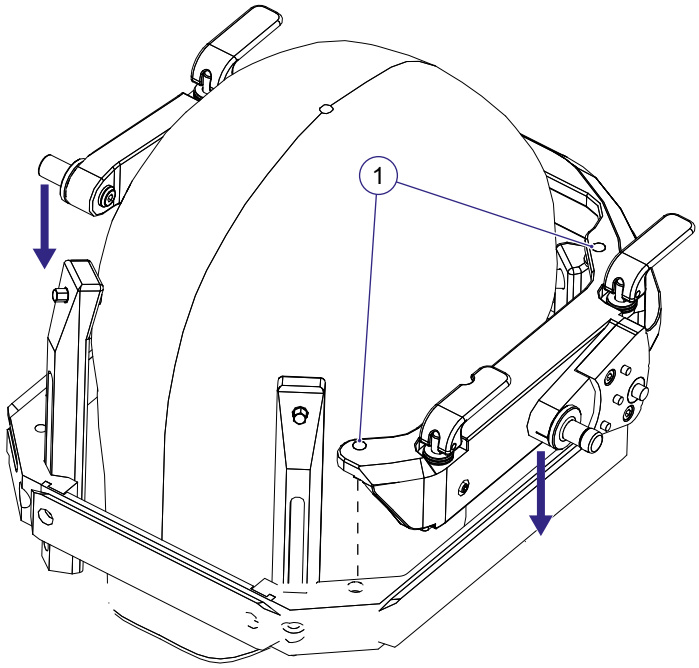


Figure 5.29 Fitting the frame adapter to the coordinate frame

4 When the frame adapter has been fitted to the coordinate frame, lock the 3 levers:

WARNING 5.27

Make sure that the securing plates are in correct position at a right angle to the frame adapter. If not, the frame adapter can be incorrectly locked to the coordinate frame, which can cause a small play. The treatment can then be made in incorrect position and cause injury to the patient.

a Turn the 3 levers so that the securing plates (1) on the underside of the frame adapter turn and secure the coordinate frame. The securing plates must be turned fully at a right angle to the frame adapter.

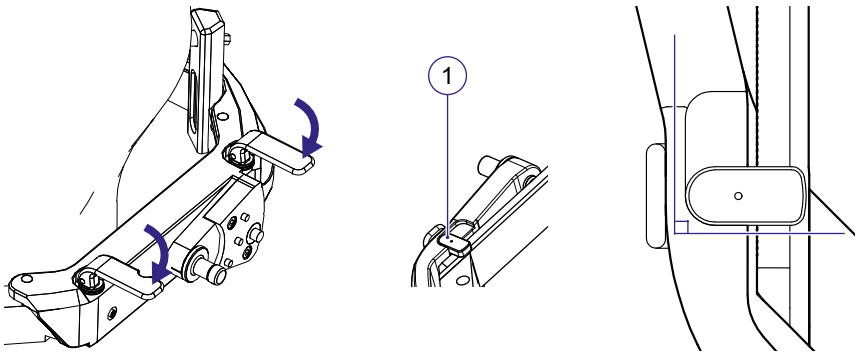


Figure 5.30 Securing the coordinate frame

b Turn the 3 levers down to lock them. Do not use force if there is much resistance when the levers are turned. When the levers are locked, make sure that they are fully flush with the frame adapter and that there is no angulation.

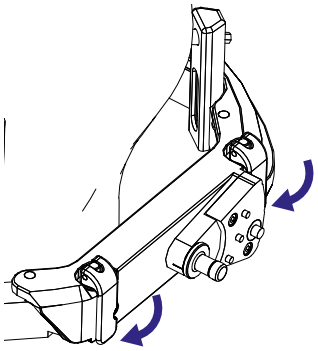


Figure 5.31 Locking the levers

c Attach and tighten the securing screw.

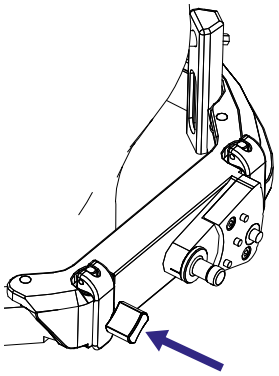


Figure 5.32 Attaching the securing screw

5 Make sure the frame adapter is secured to the coordinate frame by gently trying to lift the frame adapter by using the two attachment pins.

Related Links:

Doing a focus precision check on page 204

Releasing the frame adapter from the coordinate frame G on page 130

5.4.2.2 Docking a patient with the coordinate frame G to the patient couch

WARNING 5.28

Make sure that you fully monitor the patient during the full treatment from setup to the end of the treatment. If you do, you can stop the treatment if it is necessary for the patient.

The patient should be observed when docked; during setup, imaging, and treatment. It is possible to use the patient alert for communication during setup, imaging, and treatment.

To dock a patient at the start of a treatment session:

1. Fold down one or both side protection panels on the couch.
2. If the IR camera arm is up, fold it down to the bottom of the couch.
3. Place the patient on the couch mattress in a sitting position.
4. Attach the frame adapter to the coordinate frame on the patient's head. Lock the frame adapter to the coordinate frame by securing the fixation levers.
5. If necessary, unlock the docking device.

WARNING 5.29

Do not let the patient use the IR camera arm, to get on or off the couch.

6. Lay the patient down on the couch mattress. Carefully place the patient in the horizontal direction so that when the patient's head is lowered, the frame adapter is placed right above the docking device at the head end of the couch. Make sure to support the patient's head.

Figure 5.33 Attaching the patient to the docking device

7. If necessary, carefully move the patient so that the attachment pins on the frame adapter align with the attachment points on the docking device.

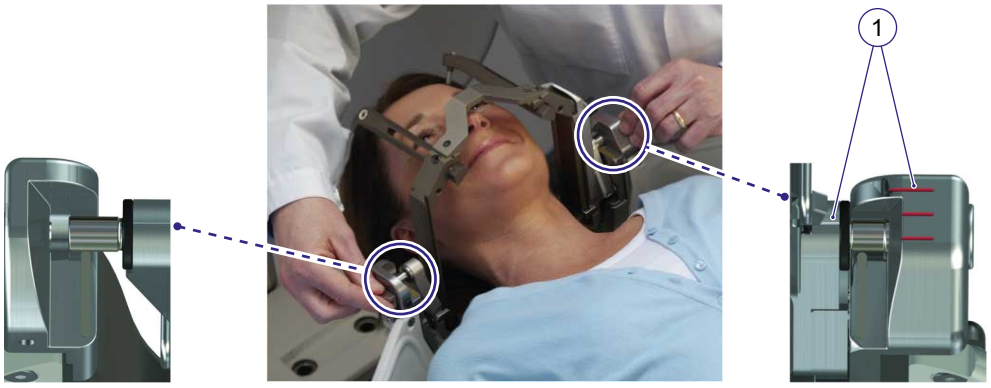


Figure 5.34 Aligning the frame adapter with the attachments points

8 Carefully adjust the patient's head so that the frame adapter will be attached in the correct gamma angle. Gently push the patient towards the patient's left side.

The guide lines (1) on the frame adapter and the docking device can be used to align the frame adapter in the correct gamma angle. Seen from the shielding doors, the red guide lines on the docking device indicate the gamma angles 70, 90 and 110.

9 Put the knee support under the patient's legs.

10 Use the Up and Down buttons on the manual control to adjust the mattress height until the patient is comfortable.

11 Lock the docking device.

Note: *This also locks the manual control functions. No further movements of the mattress can now be made.*

WARNING 5.30

Ensure that the patient's arms and hands are kept in a safe position inside the side protection panels, to prevent injury to the patient when the couch is moving in and out of the radiation unit. If necessary, use the strap on the mattress to secure the patient's arms.

12 Close the side protection panels on the couch.

Related Links:

Opening the side protection panels on page 152

Attaching the frame adapter to the coordinate frame G on page 105

Unlocking the docking device on page 154

Locking the docking device on page 153

Closing the side protection panels on page 152

Description of the patient alert on page 37

Docking and verifying the patient on page 136

5.4.3 Docking a patient with the Vantage Head Frame

5.4.3.1 Attaching the frame adapter to the Vantage Head Frame

Prerequisites

The Vantage Head Frame is attached to the head of the patient.

WARNING 5.31

Handle the frame adapter with care. Any damage may affect the precision of the frame adapter, which may lead to clinical mistreatment and/or contact with the collimator cap during treatment.

WARNING 5.32

Make sure that there is no hair or other material between the interface areas of the coordinate frame and the frame adapter. If there is anything between the interface areas the frame adapter is not correctly attached to the coordinate frame which can have an effect on the accuracy and lead to clinical mistreatment.

WARNING 5.33

If you suspect that the frame adapter may have been damaged due to a drop or other impact, the precision of the frame adapter must be verified before a treatment is started. Contact Elekta or perform a focus precision QA check.

To attach the frame adapter to the Vantage Head Frame:

1 Place the patient in the upright position.

2 Release the left and right lever on the frame adapter, see **Figure 5.35**.

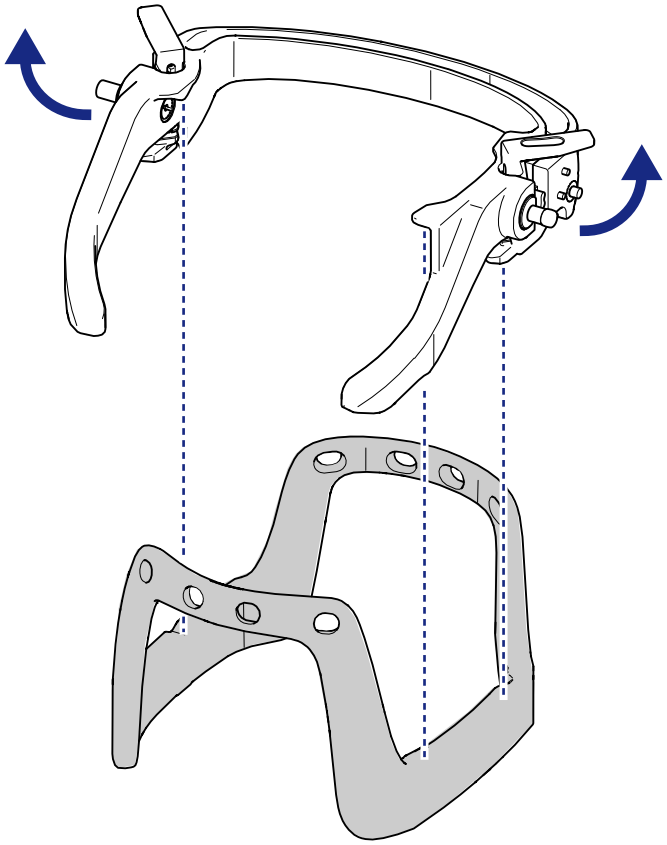


Figure 5.35 Attaching the frame adapter to the Vantage Head frame

3 Hold the frame adapter above the patient's head, with the four reflector markers pointing down.

4 Lower the frame adapter and fit it to the three interface areas on the Vantage Head Frame.

5 Turn and fold down the left and right lever at the same time to lock the frame adapter in position, see **Figure 5.36**.

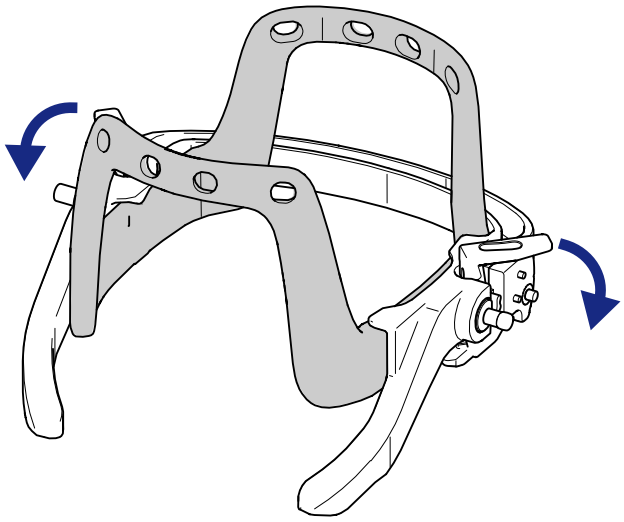


Figure 5.36 Fold down the levers to lock the adapter on the Vantage Head frame

6 Make sure that the frame adapter is correctly attached to the Vantage Head Frame.

WARNING 5.34

Make sure that the frame adapter is correctly attached to the head frame. If the frame adapter is not correctly attached, it may lead to clinical mistreatment and/or contact with the collimator cap during treatment.

5.4.3.2 Docking the patient with the Vantage Head Frame to the patient couch

To dock a patient at the start of a treatment session:

1 Fold down one or both side protection panels on the couch.
2 If the IR camera is up, fold it down to the bottom of the couch.
3 Place the patient on the couch mattress in a sitting position.
4 Attach the frame adapter to the Vantage Head Frame on the patient's head.
5 If necessary, unlock the docking device.
6 Carefully lay down the patient on the couch mattress. Make sure that you support the patient's head with one hand, and guide the patient to the docking device holding the frame adapter with the other hand. The frame adapter should be placed right above the docking device.

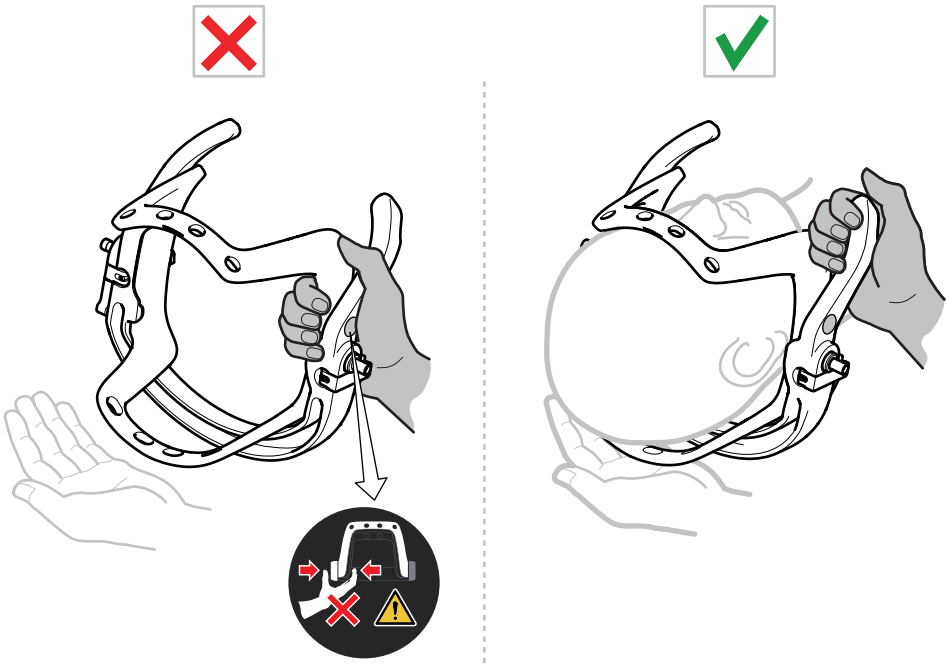


Figure 5.37 Docking the patient with Vantage Head Frame

WARNING 5.35

Do not forcefully press together or push apart the Vantage Head frame and Vantage frame adapter on the patient's right side. Forcefully pressing them together or pushing them apart on that side may have an effect on the treatment accuracy and precision.

If you suspect that this has happened, you must remove and attach the frame adapter to the head frame again.

7 If necessary, carefully move the patient so that the attachment pins on the frame adapter align with the attachment points on the docking device.

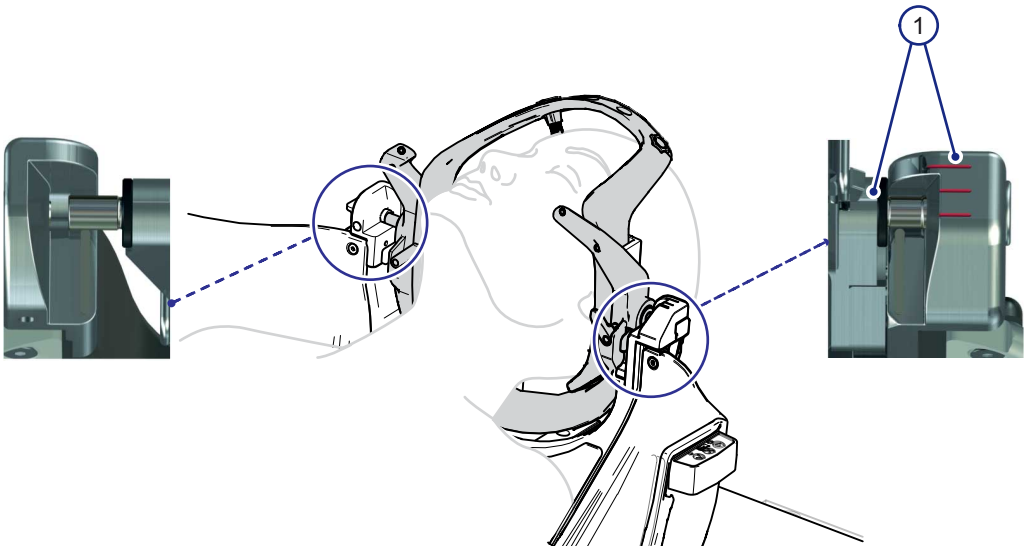


Figure 5.38 The frame adapter attached to the docking device

8 Carefully adjust the patient's head so that the frame adapter will be attached in the correct gamma angle. Gently push the patient towards the patient's left side.

The guide lines (1) on the frame adapter and the docking device can be used to align the frame adapter in the correct gamma angle. Seen from the shielding doors, the red guide lines on the docking device indicate the gamma angles 70°, 90°, and 110°.

9 Put the knee support under the patient's legs.

10 Use the UP and DOWN buttons on the manual control to adjust the mattress height until the patient is comfortable.

11 Lock the docking device.

Note: *This also locks the manual control function. No further movements of the mattress can now be made.*

12 Close the side protection panels on the couch.

5.4.4 Docking the patient in a new gamma angle

Prerequisites

This is only applicable if the patient is docked with a coordinate frame.

When changing gamma angles during a clearance check or treatment session, the patient needs to be undocked from the previous gamma angle and then docked in the new gamma angle. The patient may remain laying down on the couch during the redocking procedure.

1 On the run selection page in the **Clearance** or **Treatment** tab, select the tab for the new gamma angle you wish to execute the run for.

2 Click on the **Proceed** button.

WARNING 5.36

When docking the patient during clearance check, make sure to keep the arm of the clearance tool clear of the patient's head. Otherwise injury to the patient may result.

3 Enter the treatment room.

4 On the treatment room monitor, verify the new gamma angle.

5 Fold down one or both side protection panels on the couch.

6 Unlock the docking device.

7 Gently push the frame adapter with the patient's head towards the side of the locking lever so that the frame adapter releases from the attachment point on the left side.

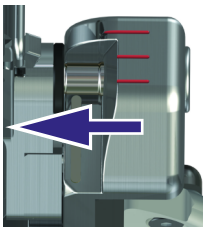


Figure 5.39 Pushing the frame adapter to release it from the attachment point

8 Carefully adjust the patient's head so that the frame adapter is attached in the new gamma angle (on the patient's left side).

9 Use the Up and Down buttons on the manual control to adjust the mattress height until the patient is comfortable in the new position.

10 Lock the docking device.

Note: *This also locks the manual control functions. No further movements of the mattress can now be made.*

11 Close the side protection panels on the couch.

12 Continue the clearance check or treatment procedure.

Related Links:

Opening the side protection panels on page 152

Unlocking the docking device on page 154

Locking the docking device on page 153

Closing the side protection panels on page 152

Executing the clearance runs on page 137

5.4.5 Docking a patient for treatment with the mask fixation system

WARNING 5.37

Make sure that you fully monitor the patient during the full treatment from setup to the end of the treatment. If you do, you can stop the treatment if it is necessary for the patient.

The patient should be observed when docked; during setup, imaging, and treatment. It is possible to use the patient alert for communication during setup, imaging, and treatment.

1 Make sure that the patient ID on the head cushion and the mask is correct.

2 Adjust the couch mattress height. Refer to the values that you recorded in the setup.

3 Dock the mask adapter with the head cushion to the docking device. The mask adapter can only be attached to gamma angle 90. Lock the docking device.

Figure 5.40 Docking the mask adapter and head cushion

4 Fold down the side protection panels on the couch. If the IR camera arm is up, fold it down to the bottom of the couch.

WARNING 5.38

Do not let the patient use the IR camera arm, to get on or off the couch.

5 Put the patient on the couch mattress in a sitting position.

6 Put the patient down on the couch mattress and the head support.

7 Put the knee support on the couch mattress.

8 Adjust the knee support and patient position for patient comfort. Try to simulate the same patient position as at the setup, for example position of the body parts, mattress height and clothing. If necessary, do more adjustments to make sure that you reproduce the patient position with maximum patient comfort.

WARNING 5.39

Ensure that the patient's arms and hands are kept in a safe position inside the side protection panels, to prevent injury to the patient when the couch is moving in and out of the radiation unit. If necessary, use the strap on the mattress to secure the patient's arms.

9 Close the side protection panels on the couch.

10 Make sure that the patient ID in the GUI agrees with the current patient and accept on the manual control. This requires that the treatment is loaded and CBCT selected.

11 Give the patient alert to the patient.

Figure 5.41 Giving the patient alert to the patient

12 Tell the patient to press the alarm button to make sure that the patient alert operates.

13 Put the mask on the head of the patient. If the mask does not fit, you must create a new patient specific mask.

14 Attach the mask to the mask head support and lock the push pins. Make sure that all six push pins are locked.

Related Links:

Opening the side protection panels on page 152

Closing the side protection panels on page 152

Setting up the mask fixation system using an oven on page 85

Setting up the mask fixation system using heated water on page 90

5.4.6 Setting up the HDMM system

Prerequisites

The patient must be in treatment position on the couch.

This procedure is applicable for treatment with the mask fixation system, or for treatment with Vantage Head frame. HDMM cannot be used during a stand-alone CBCT.

Note: *If the mask fixation system is used to fixate the patient, HDMM is mandatory and by default activated. If the Vantage Head Frame is used, HDMM is optional and by default disabled. If you want to use HDMM for Vantage Head Frame, you must activate the function, see Adjusting the HDMM settings. HDMM is not applicable for G-frame.*

WARNING 5.40

Make sure that you fully monitor the patient during the full treatment from setup to the end of the treatment. If you do, you can stop the treatment if it is necessary for the patient.

WARNING 5.41

The patient marker is used to monitor the movement of the nose of the patient. It does not monitor the movement of the target. As the relation between marker and target motion depends on the actual clinical case, the user is expected to set the HDMM level in accordance with each specific clinical situation.

1 Put the patient marker (1) on the nose of the patient, see **Figure 5.42**.

- Make sure that the patient marker and its attachment point on the patient are clean, for a rigid attachment.
- Try not to touch the reflective surface of the patient marker. Contamination can decrease the reflection effect.
- Make sure that the thermoplastic mask is opened enough around the patient marker and the nose of the patient. This is to prevent contact between the mask and the marker and between the mask and the nose.
- Make sure that there is no blockage in the field-of-view between the patient marker and the IR camera.

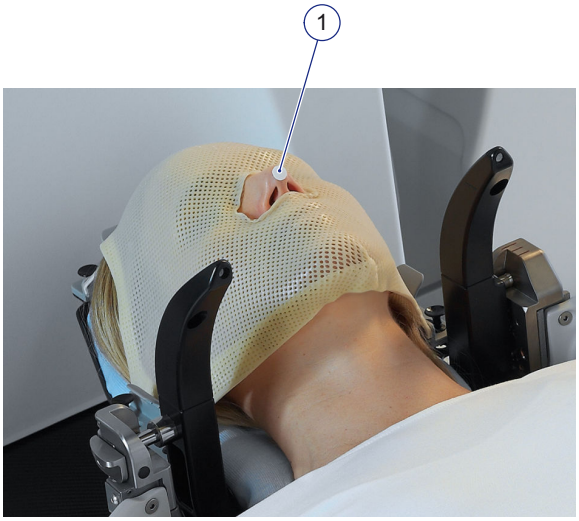


Figure 5.42 Patient marker on the patient

2 Fold up the IR camera arm and release the latch (1) of the IR camera, see **Figure 5.43**. Turn the IR camera to the patient and lock the latch.

Figure 5.43 Folding up the IR camera arm

WARNING 5.42

If you select passive mode, the system will not prevent dose delivery or go to treatment pause if the patient moves above the limit. This can cause treatment at incorrect position and injury to the patient.

3 In the GUI, make sure that the interlocks are set.

4 If the check mark for IR reference tool (4) or patient marker (5) does not appear (see **Figure 5.44**), do as follows:

- Make sure that there is no blockage in the field-of-view between the IR markers and the IR camera. The camera must see the markers completely to get good HDMM quality.
- Make sure that the IR camera and the arm is correctly in position.
- Make sure that the markers are clean.
- Make sure that no objects make reflections into the IR camera.

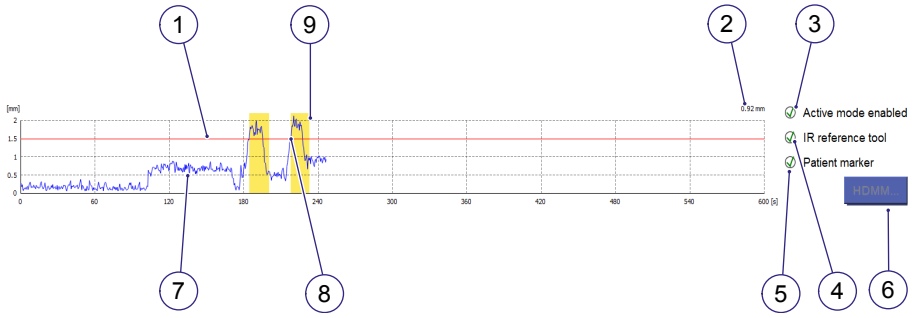


Figure 5.44 HDMM tracking graph

(1) HDMM alarm level
(2) Current movement value
(3) Active mode indicator
(6) Button for HDMM settings
(7) Movement level
(8) Gating indicator

(4) IR reference tool indicator

(5) Patient marker indicator

(9) When the patient moves back into position, the dose delivery starts again after 3 seconds.

It is important that you think of the shutter dose when you do a treatment with HDMM in active mode. The system is automatically gating the dose delivery and the radiation can therefore be shut off and turned on again more times than usual for a shot.

5 If necessary, change the HDMM alarm level in the HDMM settings.

5.4.6.1 Adjusting the HDMM settings

You can change the HDMM settings from the **Treatment** tab.

To change the HDMM settings, do as follows:

1 In the **Treatment** tab, click the **HDMM** (2) button to open the **HDMM settings** dialog.

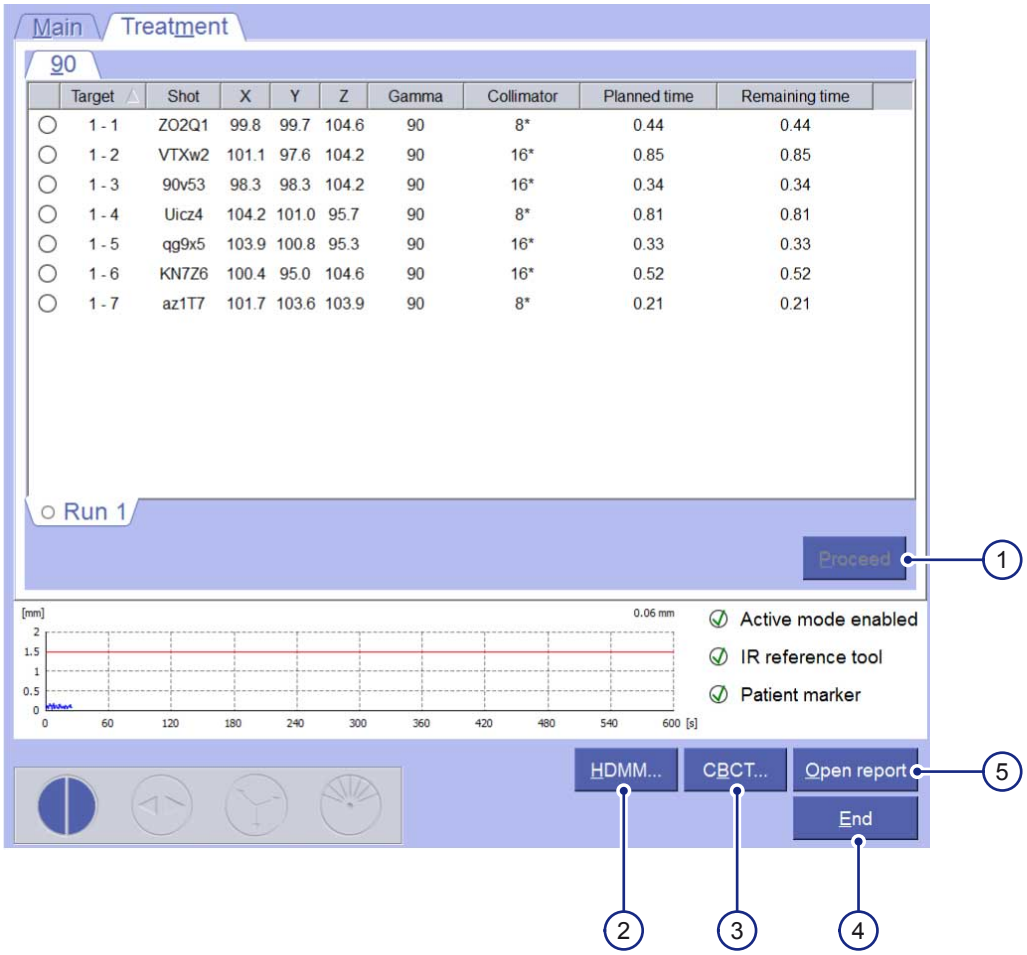


*Figure 5.45 The **Treatment** tab*

In active mode, the system stops dose delivery (gating occurs) when an HDMM alarm becomes active. An HDMM alarm is active when the patient displacement is above the HDMM alarm level or the IR camera cannot see the IR reference tool or the patient marker for more than 2 seconds. If the gating stays for more than 30 seconds or occurs more than 5 times in the same shot, a treatment pause is initiated. If the treatment is continued after treatment pause, the above conditions apply again.

WARNING 5.43

If you select passive mode, the system will not prevent dose delivery or go to treatment pause if the patient moves above the limit. This can cause treatment at incorrect position and injury to the patient.

2 Select **Active**, **Passive**, or **Disabled** mode.

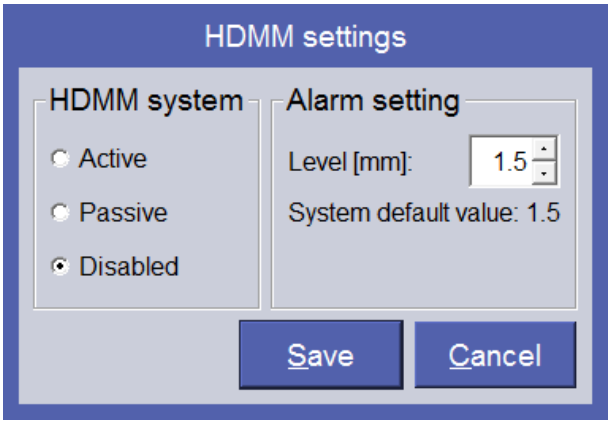


Figure 5.46 ***HDMM settings dialog for Vantage head frame***

Note: ***Disabled*** *mode is only applicable if Vantage head frame is used.*

3 Set the level of the alarm in mm. The default value is 1.5 mm but the level of the alarm can be set between 0.5 and 3.0 mm.

4 Click **Save** to save the settings or click **Cancel** to cancel the settings.

Related Links:

Description of the HDMM on page 32

Treatment delivery evaluation for Leksell Gamma Knife® Icon™ on page 123

5.4.7 CBCT for treatment

Prerequisites

The patient is docked.

WARNING 5.44

For mask fixation, make sure that the patient is correctly docked and that all six push pins are locked during the treatment. If the patient can move, incorrect treatment or treatment interruption can occur.

WARNING 5.45

Make sure that you fully monitor the patient during the full treatment from setup to the end of the treatment. If you do, you can stop the treatment if it is necessary for the patient.

If you use a mask fixation system on the patient, this procedure is mandatory. If you use the Coordinate Frame G, or the Vantage Head frame, this procedure is optional.

A CBCT scan for treatment is done when the patient is docked for treatment. That is, the patient is not released between the scan and the treatment.

The CBCT for treatment can be done before or during a pause of the treatment.

For the Coordinate Frame G, and for the Vantage Head frame, the CBCT for treatment can be used to verify the position of the patient at the time of treatment. For mask fixation, the CBCT for treatment is used to adjust the treatment delivery of the plan referred to the current patient position.

WARNING 5.46

If the patient has long hair, make sure that the hair does not get entangled in parts of the gantry. If the hair gets entangled, it can cause injury to the patient and damage to the equipment.

WARNING 5.47

Do a CBCT QA check if you think that a part of the CBCT has hit something. A collision can have an effect on the accuracy of the equipment.

WARNING 5.48

Make sure that you select the X-ray preset to minimize the X-ray dose to the patient and at the same time get sufficient image quality.

To do a CBCT scan, do as follows:

1. Enable treatment mode on the Leksell GammaPlan® workstation.
2. In the Leksell Gamma Knife® application:
   a. Click the **Treatment** button in the **Main** tab.

      The **Select patient** page appears.

   b. Select the treatment and click the **Proceed** button, or double-click on the row.

   c. In the page **Verify patient** data, make sure that the patient data is correct, type the date, and then click the **Accept** button. If you click the **Reject** button, you get back to the **Select patient** page.
3. If the Vantage Head Frame is used to fixate the patient, and if you want to use the HDMM, activate the HDMM system, see *Adjusting the HDMM settings*.

Note: *If the mask fixation system is used to fixate the patient, HDMM is mandatory and by default activated. If the Vantage Head Frame is used, HDMM is optional and by default disabled. HDMM is not applicable for G-frame.*

4. Click the **CBCT** button.
5. In the treatment room, press the Accept button on the manual control, to verify the patient ID.
6. If HDMM is used, set up the HDMM system, see *Setting up the HDMM system*.

7 If the mask fixation system is used to fixate the patient, press the patient alert to verify it works properly.

8 Press the Accept button to verify the patient setup.

9 Press and hold the Continue button on the manual control, to move the couch to scan position.

10 Press and hold the Continue button to move the tilt arm to scan position. Monitor the movement to make sure that the tilt arm moves freely.

11 Press and hold the Continue button to move the C-arm to scan position. Monitor the movement to make sure that the C-arm moves freely.

12 Go out from the treatment room and close the door.

13 In the **Image viewer** page, select **CBCT settings**. Think of the delivered dose, the age of the patient and the size of the head when you select the preset. If you put the mouse pointer over the selected preset, you can see the parameters of the preset.

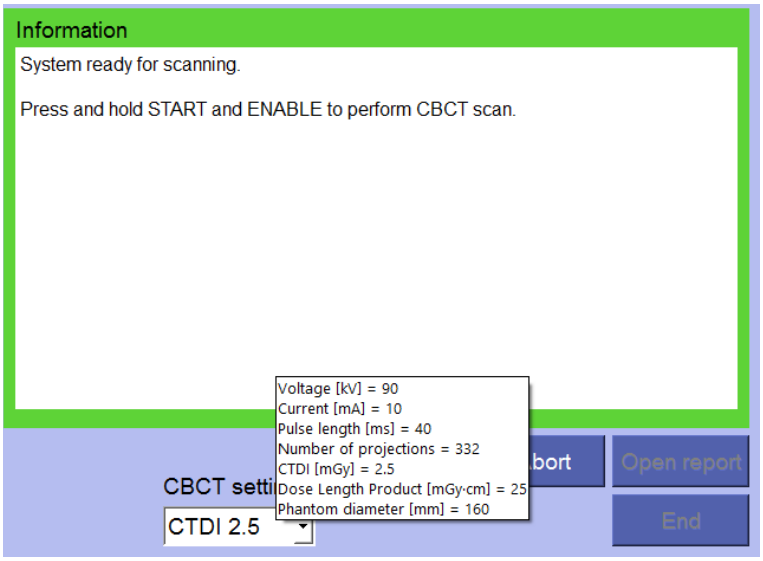


Figure 5.47 Preset parameters

14 On the control panel, press and hold the START and ENABLE buttons at the same time to start the scan. Do not release the buttons before the scan is completed. Then you have to do the scan again and the patient gets more dose than necessary. Monitor the patient during the CBCT scan.

If a message about too hot X-ray tube appears, the tube must be sufficiently cool before you continue. The required cool down time shows in the message.

15 When the CBCT scan is completed, an information message appears.

Release the START and ENABLE buttons.

16 Examine the image quality and **Accept** or **Reject** the images.

If you read out the Leksell coordinates from the images, see the section about patient weight compensation for more information.

If you accept the images, they will be automatically sent to Leksell GammaPlan®.

If you click **Reject**, you must do the scan again.

17 Click **Manual** or **Automatic** to move the CBCT equipment to park position and the couch to home position.

When the CBCT sequence is completed, you must do a treatment delivery evaluation on Leksell GammaPlan®.

Related Links:

Description of the patient alert on page 37

Description of image artifacts on page 253

Patient weight compensation and CBCT image coordinates on page 252

CBCT predefined settings on page 163

Setting up the HDMM system on page 116

Adjusting the HDMM settings on page 119

Doing a CBCT precision check on page 206

Troubleshooting the CBCT on page 193

Treatment delivery evaluation for Leksell Gamma Knife® Icon™ on page 123

Docking a patient for treatment with the mask fixation system on page 115

5.4.8 Treatment delivery evaluation for Leksell Gamma Knife® Icon™

Prerequisites

Leksell GammaPlan® is in treatment mode.

In Treatment Mode, Leksell GammaPlan® provides the functions necessary to evaluate treatment delivery of the plan based on the current patient position from CBCT images. The treatment delivery evaluation is run as an integrated part of the treatment workflow on Leksell Gamma Knife® Icon™, and should therefore be run on a workstation located next to the Leksell Gamma Knife® Icon™ operator console.

When the CBCT images are received from Leksell Gamma Knife®, Leksell GammaPlan® starts a guided workflow.

In Leksell GammaPlan®, you do as follows:

1. Perform and review co-registration of CBCT images with plan reference images.

   The system automatically recalculates dose according to the current patient position.
2. Review the dose delivery according to the current patient position compared to the planned dose.

   The treatment can continue when the review has been approved.

   The next step is doing the treatment runs.

For more information, refer to *Leksell GammaPlan®, Online Reference Manual*.

Related Links:

Doing the treatment runs on page 125

5.4.8.1 Treatment delivery evaluation for frame based fixation

To find the current patient position relative the patient position used at planning, the newly acquired CBCT image is co-registered with a suitable planning reference image study.

The relative change of the patient position is presented as a geometrical rotation and translation of the Leksell® central point (100, 100, 100). For frame based fixation, this can provide valuable information about the quality of the fixation.

For frame based fixation, the delivery of the plan is unaffected by the current patient position from CBCT images. The review and approval of delivery dose according to the current patient position from CBCT is optional, but can be performed for QA purposes.

Delivery dose can be reviewed and compared to **Planned dose**, both in image views and through dose statistics. Delivery dose takes patient position into account. Planned dose is always displayed as originally planned.

For more information, refer to *Leksell GammaPlan®, Online Reference Manual*.

5.4.8.2 Treatment delivery evaluation for mask fixation

To find the current patient position relative the patient position used at planning, the newly acquired CBCT image is co-registered with a suitable planning reference image study.

The relative change of the patient position is presented as a geometrical rotation and translation of the Leksell® central point (100, 100, 100). This can provide valuable information about the quality and repeatability of the fixation.

For the mask fixation, the delivery of the plan is always automatically corrected according to the current patient position from CBCT images, taking both translation and rotation into account. The correction is done so that the delivery of the plan preserves the planned position of each individual shot in the patient anatomy according to the current patient position.

Delivery dose can be reviewed and compared to **Planned dose**, both in image views and through dose statistics. Delivery dose takes patient position into account for both the current fraction, and for the already delivered fractions, if any. In the delivery dose, future fractions are considered to be identical to the planned dose. Planned dose is always displayed as originally planned.

For the re-locatable mask fixation, the delivery dose must be reviewed and approved before the treatment can continue.

For more information, refer to *Leksell GammaPlan®, Online Reference Manual*.

5.4.9 Doing a check of the setup

WARNING 5.49

Before the start of a treatment, make sure that there are no loose objects left on the couch or between the couch and the radiation unit. A loose object entering the radiation unit or getting stuck between the shielding doors may cause a malfunction of the equipment, and/or lead to an emergency undocking of the patient, and/or lead to injury to the patient.

WARNING 5.50

Before you start a treatment, make sure that there are no parts on the floor inside the area of the warning markers.

1 Do a visual check of the patient and the Leksell Gamma Knife® Icon™ unit. Make sure that no items are left on the couch, or between the couch and the radiation unit. Also make sure that there are no parts on the floor inside the warning markers.

WARNING 5.51

Except in an emergency situation, no one other than the patient should be in the treatment room when the shielding doors are open and the radiation sectors are not in their home position.

2 Leave the treatment room. Ensure that only the patient is present in the treatment room.

3 Close the treatment room door.

WARNING 5.52

It is necessary to verify that the patient can be heard and seen clearly in the control room before the treatment is started. The patient must be continuously observed during the treatment session. Otherwise vital information from or about the patient may be missed.

4 In the control room, communicate with the patient to verify that the patient intercom functions properly. If needed, adjust the volume and microphone sensitivity.

5 If necessary, adjust the camera zoom and focus settings so that the patient can be clearly seen on the patient supervisory monitor. Adjust the color, brightness and contrast of the monitor, as required.

5.4.10 Doing the treatment runs

Prerequisites

- If mask fixation system is used:
  - CBCT for treatment is done.
  - HDMM is activated.
- If Vantage Head frame is used:
  - *Optional:* CBCT for treatment is done.
  - *Optional:* HDMM is activated.

WARNING 5.53

For mask fixation, make sure that the patient is correctly docked and that all six push pins are locked during the treatment. If the patient can move, incorrect treatment or treatment interruption can occur.

WARNING 5.54

Exercise extreme caution at all times to ensure that the coordinate frame does not move on the patient's skull. If the coordinate frame is displaced, all treatment planning based on the coordinate frame position is invalid.

For frame fixation, and if CBCT for treatment was done, LGK receive information from LGP after the Treatment delivery evaluation about no correction applied.

For mask fixation, LGK receive information from LGP after the Treatment delivery evaluation about the applied correction.

1 Make sure that all interlocks on **System's checklist** are set.

2 Press and release the START button on the control panel (green color).

WARNING 5.55

Make sure that you fully monitor the patient during the full treatment from setup to the end of the treatment. If you do, you can stop the treatment if it is necessary for the patient.

3 At the same time, press and hold the START and ENABLE buttons. On the patient supervisory monitor, monitor the movement of the patient into the radiation unit.

4 When a message appears, release the START and ENABLE buttons.

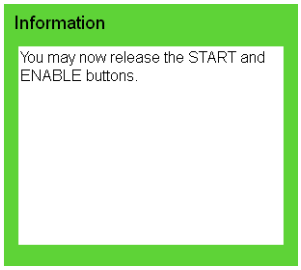


Figure 5.48 Releasing START and ENABLE buttons

At this time, the couch moves to the treatment position and the treatment run starts.

5 Monitor the patient on the patient supervisory monitor during treatment and follow the procedure of the treatment on the treatment view monitor.

For a mask fixation system or Vantage head frame, patient movements can be observed in the HDMM graph. If passive mode is selected, make sure to observe the patient movements and act accordingly.

WARNING 5.56

If you select passive mode, the system will not prevent dose delivery or go to treatment pause if the patient moves above the limit. This can cause treatment at incorrect position and injury to the patient.

6 If frame fixation with multiple angles, select the next gamma angle until the complete treatment is delivered. The treatment is not completed until all gamma angles in the treatment are delivered.

When the treatment is completed, the run status page is closed and the **Treatment** tab shows the run selection page.

7 Release the patient.

8 For mask immobilization, put the mask and the head cushion in the patient specific box. Keep the box in usual room temperature.

Figure 5.49 Patient specific box

9 Print the applicable report.

10 Close the report and click **End** to complete the treatment.

Related Links:

Releasing a patient docked with the Coordinate Frame G from the patient couch on page 129

Releasing a patient docked with the Vantage Head Frame from the patient couch on page 131

Releasing a patient docked with a mask on page 133

Viewing treatment reports on page 143

Adjusting the HDMM settings on page 119

Ending the treatment on page 128

5.4.11 Pausing a treatment

To pause a treatment, do as follows:

1 Press the PAUSE button on the control panel.

When the pause sequence is completed, the run status page shows the status of the run when it was interrupted, with the remaining treatment time.

Note: *If the remaining treatment time was 1 second or less, the run is seen as completed and cannot be continued.*

2 If necessary, you can at this time go into the treatment room to examine the patient or the equipment. If you will continue the treatment, go out from the treatment room and close the treatment room door. Make sure that only the patient is in the treatment room.

3 Select to continue or stop the current run.

- To continue the treatment run where it was interrupted, press the START button on the control panel. The interrupted run will continue, with the correct remaining time.
- To stop the treatment run, click **Cancel** in the **Treatment** tab. The run status page is closed and the **Treatment** tab displays the run selection page again. The status of the shots in the run and the run itself has been updated. The run has at this time the status of opened, meaning that it can be selected and completed.

Related Links:

Doing the treatment runs on page 125

Ending the treatment on page 128

5.4.11.1 Description of a treatment pause sequence

A treatment pause sequence can be initiated by the user at any time during an on-going treatment. The control system also initiates a treatment pause automatically if:

- The power key is turned to the off position
- The door to the treatment room is opened
- The gating activity stays for more than 30 seconds or has occured more than 5 times in the same shot
- There is a mains electrical supply failure in more than one minute.

When the treatment pause sequence is initiated, the following actions are taken by the system:

- Any on-going shot is stopped and any remaining treatment time is preserved and recorded for the run
- The sectors return to the sector home position
- The couch moves out to the home position
- The shielding doors close.

Related Links:

Description of the HDMM on page 32

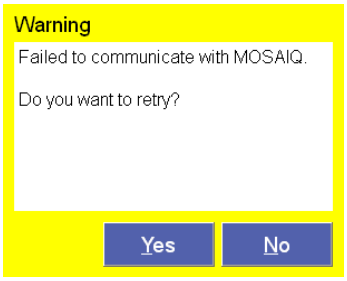
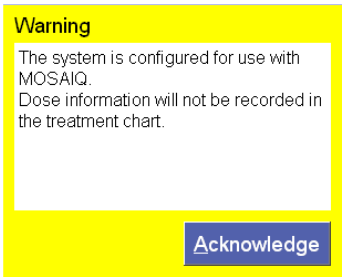
5.4.12 Ending the treatment

When you have done all the runs in the treatment plan, a message about completed treatment is displayed.

1 Click the **End treatment** button to end the treatment session.

This updates the treatment plan database (and MOSAIQ if applicable) with all data from the current treatment session.

For MOSAIQ users:

If	Then
The treatment plan was selected from MOSAIQ and the communication with MOSAIQ has failed, this message appears: 	– Click **Yes** to try again or click **No** to continue. – If you click **No**, you must update MOSAIQ manually.
The treatment plan was selected from Database, this message appears to tell you that the treatment information is not recorded in the treatment chart: 	Click **Acknowledge** to continue.

The start page of the **Main** tab is displayed, where the primary functions of the program can be selected.

Related Links:

Viewing treatment reports on page 143

5.4.12.1 Ending a treatment that is not completed

If it is necessary to end a treatment before it is completed, you can use the **End treatment** button on the run selection page. If you click the button, this message is displayed:

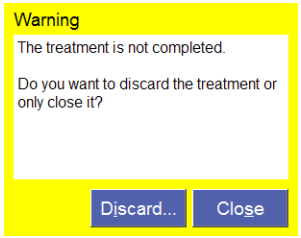


Figure 5.50 Message about not completed treatment

1 You can select to click one of the two buttons:

- Click the **Close** button to close the current treatment session. It is possible to complete the treatment at a later time.

  This updates the treatment plan database with all data from the not completed treatment session. The start page of the **Main** tab is displayed, where the primary functions of the program can be selected. In the list of treatment plans, the not completed treatment shows as open, and can be selected again.

- Click **Discard** to discard the current treatment.

  With this alternative, you cannot complete the treatment at a later time. If you select this, you must confirm the selection in one more message. In the list of treatment plans, the discarded treatment is no more available.

The treatment status for treatment plans selected in MOSAIQ® will always be updated in MOSAIQ® when you click the **End treatment** button, regardless of the treatment is completed or not.

Related Links:

Selecting the patient on page 102

5.4.13 Releasing a patient docked with the Coordinate Frame G

5.4.13.1 Releasing a patient docked with the Coordinate Frame G from the patient couch

1 Enter the treatment room.
2 Fold down one or both side protection panels on the couch.
3 Unlock the docking device.
4 Gently push the frame adapter with the patient's head towards the side of the locking lever so that the frame adapter releases from the attachment point on the left side.

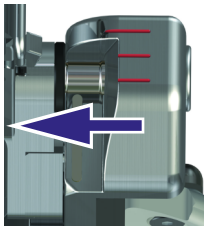


Figure 5.51 Releasing the frame adapter from the attachment point

5 While supporting the patient's head, raise the patient to a sitting position on the couch. If necessary, use the UP and DOWN buttons on the manual control to adjust the mattress height to facilitate patient movement.

Figure 5.52 Raising the patient

WARNING 5.57

Handle the frame adapter with care. Any damage may affect the precision of the frame adapter, which may lead to clinical mistreatment and/or contact with the collimator cap during treatment.

WARNING 5.58

If you suspect that the frame adapter may have been damaged due to a drop or other impact, the precision of the frame adapter must be verified before a treatment is started. Contact Elekta or perform a focus precision QA check.

6 Release the frame adapter from the coordinate frame.

WARNING 5.59

Do not let the patient use the IR camera arm, to get on or off the couch.

7 Assist the patient from the couch.

Related Links:

Opening the side protection panels on page 152

Unlocking the docking device on page 154

Releasing the frame adapter from the coordinate frame G on page 130

Doing a focus precision check on page 204

5.4.13.2 Releasing the frame adapter from the coordinate frame G

This procedure is the opposite sequence of the procedures in the attaching instruction.

WARNING 5.60

Handle the frame adapter with care. Any damage may affect the precision of the frame adapter, which may lead to clinical mistreatment and/or contact with the collimator cap during treatment.

WARNING 5.61

If you suspect that the frame adapter may have been damaged due to a drop or other impact, the precision of the frame adapter must be verified before a treatment is started. Contact Elekta or perform a focus precision QA check.

To release the frame adapter from the coordinate frame:

1 Place the patient in an upright position.
2 Release the 3 levers on the frame adapter:
   a Unscrew and release the securing screw.
   b Release the 3 levers by pulling them upwards.
   c Turn the 3 levers so that the securing plates align with the side bars.
3 Carefully lift the frame adapter to remove it from the coordinate frame.
4 Turn and lock the 3 levers on the frame adapter.
5 Attach and tighten the securing screw.

Related Links:

Attaching the frame adapter to the coordinate frame G on page 105

Doing a focus precision check on page 204

5.4.14 Releasing a patient docked with the Vantage Head Frame

5.4.14.1 Releasing a patient docked with the Vantage Head Frame from the patient couch

To release a patient that is docked with the Vantage Head Frame from the patient couch:

1 Enter the treatment room.
2 Fold down one or both side protection panels on the couch.
3 Unlock the docking device.
4 Gently push the frame adapter with the patient's head towards the side of the locking lever so that the frame adapter releases from the attachment point on the left side.

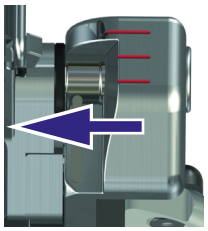


Figure 5.53 Releasing the frame adapter from the attachment point

5 While supporting the patient's head, raise the patient to a sitting position on the couch. If necessary, use the UP and DOWN buttons on the manual control to adjust the mattress height to facilitate patient movement.

WARNING 5.62

Handle the frame adapter with care. Any damage may affect the precision of the frame adapter, which may lead to clinical mistreatment and/or contact with the collimator cap during treatment.

WARNING 5.63

If you suspect that the frame adapter may have been damaged due to a drop or other impact, the precision of the frame adapter must be verified before a treatment is started. Contact Elekta or perform a focus precision QA check.

6 Release the frame adapter from the Vantage Head Frame.

7 Assist the patient from the couch.

Related Links:

Opening the side protection panels on page 152

Unlocking the docking device on page 154

Releasing the frame adapter from the Vantage Head Frame on page 132

Doing a focus precision check on page 204

5.4.14.2 Releasing the frame adapter from the Vantage Head Frame

WARNING 5.64

Handle the frame adapter with care. Any damage may affect the precision of the frame adapter, which may lead to clinical mistreatment and/or contact with the collimator cap during treatment.

WARNING 5.65

If you suspect that the frame adapter may have been damaged due to a drop or other impact, the precision of the frame adapter must be verified before a treatment is started. Contact Elekta or perform a focus precision QA check.

To release the patient from the Vantage Head Frame:

1 Place the patient in the upright position.

2 Release the left and right levers on the frame adapter.

3 Hold onto the levers and carefully lift up the frame adapter to remove it from the Vantage Head Frame.

4 Turn and fold down the left and right levers.

Related Links:

Attaching the frame adapter to the Vantage Head Frame on page 110

Doing a focus precision check on page 204

5.4.15 Releasing a patient docked with a mask

If you release a patient docked with a mask, when the treatment is paused and not completed, you must do a CBCT scan again before you continue with the treatment. If you do not, there is a risk of treatment in incorrect position. The system tells you what you have to do.

WARNING 5.66

Keep the fingers off the area between the PPS and the IR camera arm, to prevent injuries.

WARNING 5.67

Do not let the patient use the IR camera arm, to get on or off the couch.

1. If the IR camera arm is up, release the latch and turn the camera. Then fold down the arm to the bottom of the couch.
2. Fold down the side protection panels on the couch.
3. If you release the patient after a setup, make sure that the mask is cured. Unlock the push pins to release the mask from the mask head support.
4. Remove the mask from the patient.
5. Get the patient alert from the patient.
6. Remove the knee support.
7. Help the patient to get up from the couch.
8. Remove the head cushion.
9. If you release the patient after a setup, do as follows:
   a. Record the height of the couch mattress.
   b. Tightly attach a tag or equivalent with the patient ID and the current date on the head cushion, mask and patient specific box. Make sure that the patient ID is correct.
10. Put the mask and cushion in the patient specific box. Keep the box in usual room temperature.

Figure 5.54 Patient specific box

Related Links:

Opening the side protection panels on page 152

Setting up the mask fixation system using an oven on page 85

Setting up the mask fixation system using heated water on page 90

5.5 Performing clearance checks

5.5.1 Clearance check overview

A treatment plan may contain clearance positions, making it necessary to first perform a number of clearance runs. It is not possible to start any treatment run until all of the clearance runs have been completed.

The clearance check session is initiated from the control room. The actual clearance check procedure is performed by using the clearance tool in the treatment room. The manual control on the patient couch is used for moving the couch to the correct positions and for accepting or rejecting the clearance positions. All clearance positions must be accepted during the clearance checks; otherwise the treatment cannot be started.

In the GUI, the whole clearance check session takes place on the **Clearance** tab. The tab is used for selecting a gamma angle and a run, and then monitoring the run during the clearance checks.

5.5.2 Selecting a clearance run

The tabs on the run selection page displays the gamma angles that have an associated clearance run. Each gamma angle contains a single clearance run.

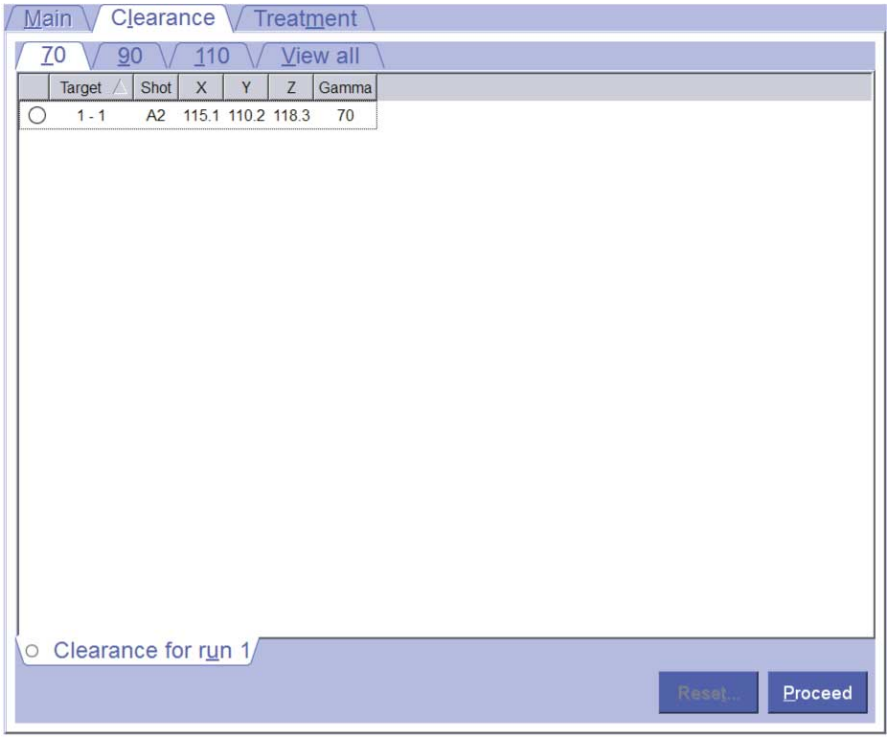


Figure 5.55 The run selection page on the Clearance tab

1 Select the tab for the gamma angle you wish to execute the clearance run for.

By default, the first gamma angle tab and its run is already selected. The list shows the sequence of shots in the run and the status of the clearance checks.

2 Click on the **Proceed** button.

The **Clearance check** page is displayed:

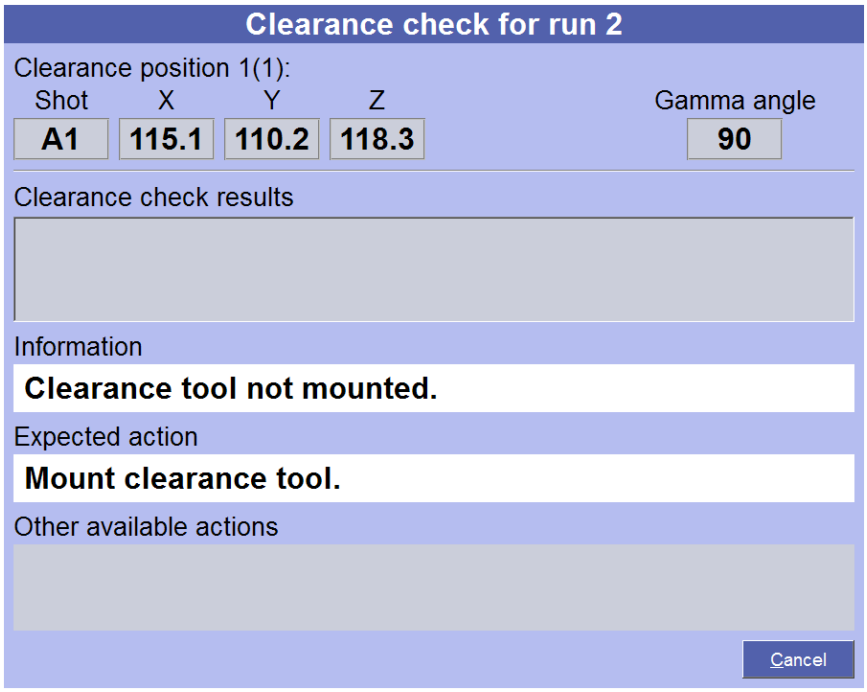


Figure 5.56 The page Clearance check

Clicking **Cancel** returns to the run selection page and allows you to select another run.

Related Links:

The clearance run selection page on page 140

The page Clearance check on page 142

Installing the clearance tool on page 135

5.5.3 Installing the clearance tool

WARNING 5.68

Be careful when you use the tool and keep it in the intended location. If the tool gets damaged, it can have an effect on the precision of the tool, which can cause clinical mistreatment or damage to the equipment.

WARNING 5.69

If you think that the tool has been damaged because of a fall or other effect, do a QA check to make sure that the precision of the tool is satisfactory.

1 Enter the treatment room. Make sure you can clearly read the instructions on the treatment room monitor when standing alongside the head end of the patient couch.

WARNING 5.70

Before you install the clearance tool, make sure that the contact surfaces near the end of the two bars are clean. Any dirt between the tool and the installing point may affect the precision of the clearance check and lead to contact with the collimator cap during treatment.

2 Install the clearance tool at the head end of the patient couch by inserting the two bars into the corresponding holes (1) in the cover just below and outside the shielding doors. Hold and lower the clearance tool by using its handle. If necessary, support or push the tool with the other hand.

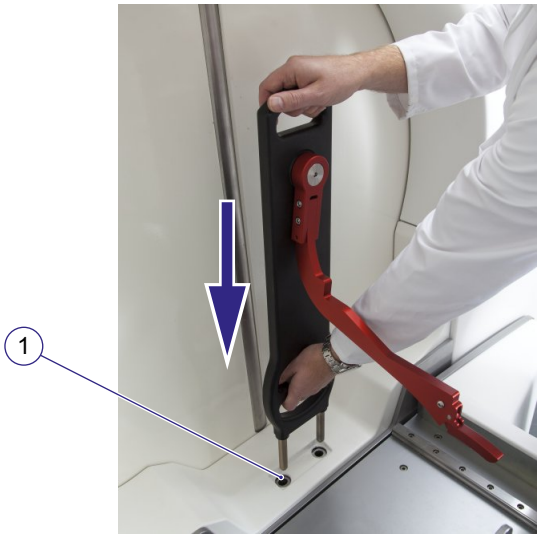


Figure 5.57 Installing the clearance tool

3 Make sure the tool is inserted all the way into the holes.

A confirmation message is then displayed in the **Information** field.

Related Links:

Cleaning the Clearance Check Tool on page 224

5.5.4 Docking and verifying the patient

1 On the treatment room monitor, verify the gamma angle of the selected run.

WARNING 5.71

When docking the patient during clearance check, make sure to keep the arm of the clearance tool clear of the patient's head. Otherwise injury to the patient may result.

2 Dock the patient.

3 Check the **System's checklist** area on the treatment room monitor. Verify that the gamma angle interlock specifies the correct gamma angle, and that all of the other physical interlocks are set, except for the treatment room door interlock:

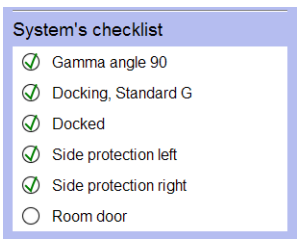


Figure 5.58 System's checklist with Room door interlock not set

Before the first clearance run can be started, the ID of the patient must be verified.

4 Verify that the static patient information is identical with the actual patient.

5 On the manual control, press the Accept button to confirm the patient ID.

Related Links:

Docking a patient with the coordinate frame G to the patient couch on page 109

5.5.5 Executing the clearance runs

Prerequisites

To do this procedure, you must first do the procedures as follows:

- Selecting a clearance run
- Installing the clearance tool
- Docking and verifying the patient.

WARNING 5.72

Be careful when you use the tool and keep it in the intended location. If the tool gets damaged, it can have an effect on the precision of the tool, which can cause clinical mistreatment or damage to the equipment.

WARNING 5.73

If you think that the tool has been damaged because of a fall or other effect, do a QA check to make sure that the precision of the tool is satisfactory.

WARNING 5.74

During all movement of the couch during clearance check, make sure to keep the arm of the clearance tool clear of the patient's head. Otherwise injury to the patient may result.

1 Press and hold down the Continue button on the manual control.

The couch starts moving to the clearance position. When the position has been reached, a signal is heard.

2 Release the Continue button.

If the Continue button is released before the position has been reached, the positioning is halted. To continue the positioning, press and hold down the Continue button again. It is also possible to abort the run.

The clearance position should now be verified by using the clearance tool.

3 Using one hand, carefully rotate the arm of the tool around the patient's head, and make sure that the arm passes **completely clear** of the patient's head and the fixation during one complete revolution of the arm. If the arm does not pass completely clear, the position must be rejected. A rejected position means that the treatment cannot be started.

Note the use of the flexible tip of the arm during the revolution:

– During the upper half of the revolution, the flexible tip of the arm must be in its unfolded position.

– During the lower half of the revolution (when the arm passes under the patient's neck), the flexible tip of the arm might need to be folded for the arm to pass clear of the couch. Any contact with the couch when the flexible tip is in its unfolded position should not cause the clearance position to be rejected.

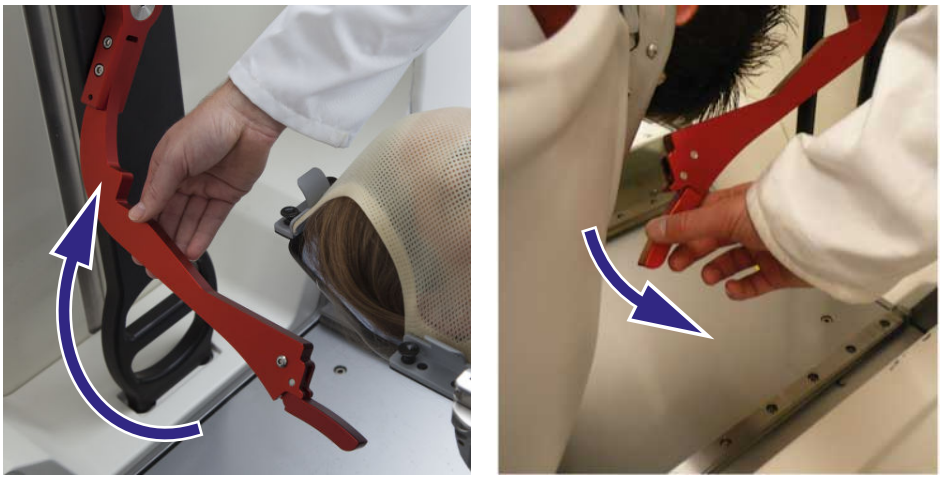


Figure 5.59 Using the clearance tool and the flexible tip

4 On the manual control, press the Accept or Reject button.

If the position was accepted, the shot identification is added to the clearance check results list with a pending (blinking) acceptance icon.

– To confirm the acceptance, press and hold down the Continue button. The couch moves to the next clearance position in the run and the procedure is repeated from step **1** . If there are no more positions in the run, continue with step **5** .

WARNING 5.75

To accept a clearance position without performing the verification procedure, or if the verification failed, may lead to contact with the collimator cap during treatment.

– To cancel the acceptance, press the Reject button. The position can now be verified again.

If the position was rejected, the shot identification is added to the clearance check results list with a pending (blinking) rejection icon.

– To confirm the rejection, press the Accept button. If there are more clearance positions in the run, the procedure is repeated from step **1** . If there are no more positions in the run, continue with step **5** . Note that a rejected position means that the treatment cannot be started.

– To cancel the rejection, press the Reject button. The position can now be verified again.

When all clearance positions in the run have been accepted or rejected, the couch is ready to move to the home position.

WARNING 5.76

During all movement of the couch during clearance check, make sure to keep the arm of the clearance tool clear of the patient’s head. Otherwise injury to the patient may result.

5 Press and hold down the Continue button.

When the couch has reached the home position, the run selection page is displayed again. The status of the clearance checks is indicated in the list of shots, and in the title for the executed run.

6 If you wish to reset the clearance status for **all** runs, click the **Reset** button.

A warning message is displayed, requesting you to confirm or cancel the status reset for all runs.

Note: *Resetting the status cannot be undone and will force you to redo all the clearance runs that have been executed.*

The clearance checks may call for clearance runs in more than one gamma angle. To complete the clearance checks, all runs must be executed:

7 Execute the clearance runs for any remaining gamma angles. On the run selection page, check the tabs to see if there are any more gamma angles that contain runs to be executed. If so, dock the patient in a new gamma angle. Do the procedure again from step **1** .

Related Links:

Selecting a clearance run on page 134

Installing the clearance tool on page 135

Docking and verifying the patient on page 136

Doing a clearance tool check on page 218

Docking the patient in a new gamma angle on page 114

5.5.6 Removing the clearance tool

When all clearance runs have been executed, you must remove the clearance tool before you can start a treatment.

WARNING 5.77

When removing the clearance tool, make sure to keep any part of the tool clear of the patient's head. Otherwise injury to the patient may result.

1 Carefully remove the clearance tool from the head end of the patient couch. Hold and lift the clearance tool by using its handle and support the tool with the other hand. Make sure to protect the patient's head when removing the clearance tool.

Figure 5.60 Removal of the clearance tool

2 Place the clearance tool back in the intended storage place.

5.5.7 Aborting the clearance run

When the clearance run has been started, the run can be aborted in the following way:

1 Press and hold down the Reject button on the manual control for 3 seconds. The abortion must then be confirmed or cancelled:

- To confirm the abortion, press the Accept button. When the couch has returned to the home position, the run selection page is displayed.
- To cancel the abortion and return to the previous action during the run, press the Reject button.

When the abortion is confirmed, all clearance positions already accepted or rejected will keep their status.

5.5.8 The clearance run selection page

The initial run selection page of the tab is for selecting a clearance run in the treatment plan. The page displays the different gamma angles as tabs. There is one clearance run for each treatment run that contains clearance positions.

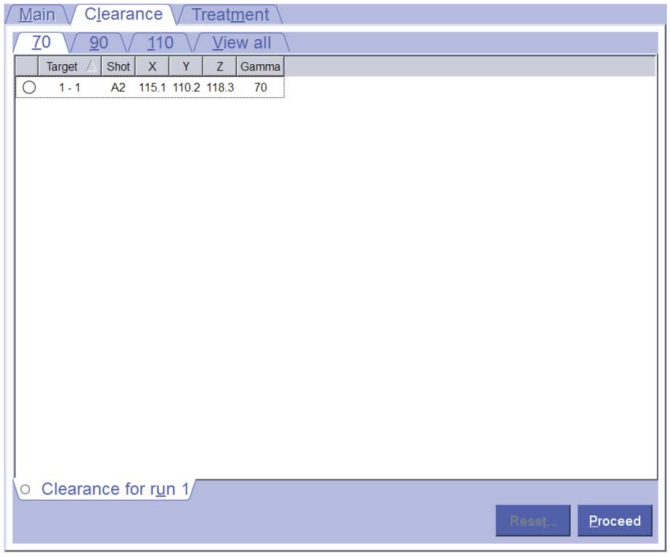


Figure 5.61 The run selection page on the Clearance tab

If the treatment plan contains more than one gamma angle, a **View all** tab is also available. This tab lists all shots in all gamma angles and all runs, but does not offer the possibility to select a run.

For each run, a list of treatment shots (with clearance positions) in the run is displayed. The list only contains the columns **Target**, **Shot**, **X**, **Y**, **Z**, and **Gamma**.

The list of shots is by default sorted by the **Target** column. To sort the list by another column, click the column title.

The status of the shots is displayed furthest to the left using the following icons:

○	Shot not started (or aborted).
✓	The position was accepted during the clearance check procedure.
⊗	The position was rejected during the clearance check procedure.

At the bottom of the page, the run title indicates which treatment run the clearance positions belong to. The run title has the same status icons as above. The status of the shots in a run determine the overall status of the run:

○ Clearance	Run not finished. (Not all shots in the run have been accepted or rejected.)
✓ Clearance	Run OK. (All positions in the run were accepted.)
⊗ Clearance	Run not OK. (One or more positions in the run were rejected.)

The following command buttons are available:

- The **Proceed** button selects the currently displayed run. A run that has been executed is still displayed, but the **Proceed** button is then disabled.
- The **Reset** button resets the clearance status for **all** runs. A warning message is displayed in the system information area, requesting confirmation of the status reset for all runs.
  - Click **Reset** to reset the clearance status.
  - Click **Cancel** to cancel the reset of status.

Note: *Resetting the status cannot be undone and will force you to redo all the clearance runs that already have been executed.*

- The **Open report** button is used for viewing reports from the treatment session.
- The **End treatment** button is used for ending the current treatment session.

Related Links:

Lists with columns on page 66

Viewing treatment reports on page 143

The treatment run selection page on page 158

5.5.9 The page Clearance check

During a clearance run, the **Clearance** tab displays the **Clearance check** page:

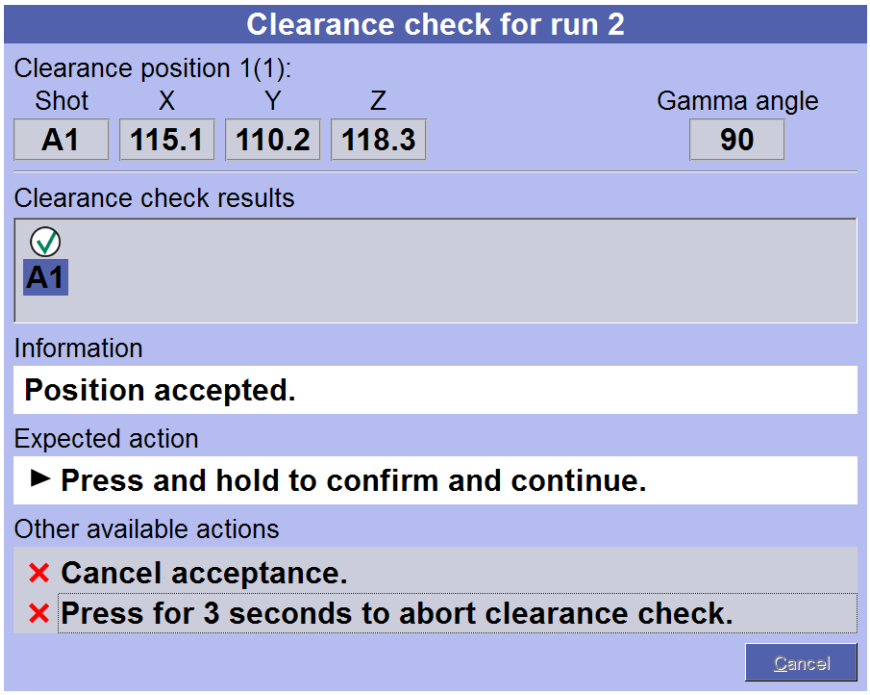


Figure 5.62 The page Clearance check

This page shows the shot status during clearance check, which is controlled from the manual control on the patient couch in the treatment room. The font size of some texts is increased, so that they can be more easily read on the treatment room monitor.

Before the run is started from the manual control, the run can be cancelled by clicking the **Cancel** button. This returns to the run selection page. Once a run has been started, it can only be aborted from the manual control.

The fields in the page are:

- **Clearance position N(T)**: The number **N** of the current clearance position, and the total number of positions **T** in the run.
- **Shot**: The identification of the shot (clearance position).
- **X, Y, Z**: The X, Y and Z coordinates for the treatment shot associated with the clearance position.
- **Gamma angle**: The gamma angle of the run (the same for all shots in a run).
- **Clearance check results**: A horizontal list of icons with shot identification, showing the status of the clearance positions:

   Position accepted.

   Position rejected.

If the list becomes full due to many completed shots, the list will be cleared if another shot is completed. The status of all shots will be shown on the run selection page when the clearance run is completed.

- **Information**: Information on the current status or action.
- **Expected action**: The action to be performed by the user in the normal case.
- **Other available actions**: Other actions that may be performed by the user at this point. This may include aborting the current clearance run.

The two action fields may contain icons for the button(s) to press on the manual control.

5.6 Viewing treatment reports

1 On the run selection page of the **Treatment** tab, click the **Open report** button.

A preview window of the report is opened:

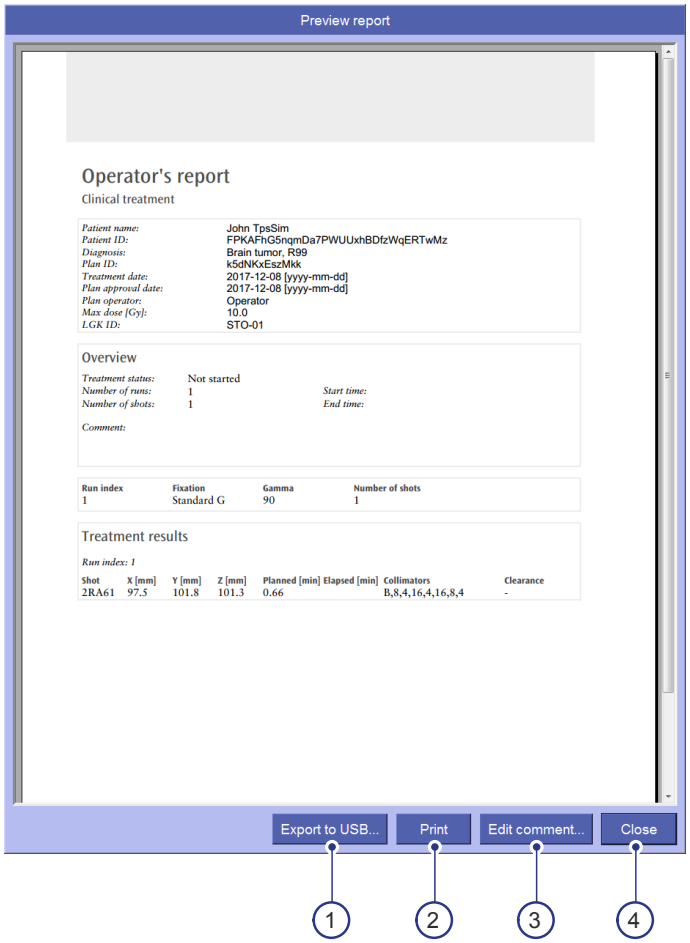


Figure 5.63 Preview window of the operator's report

(1) **Export to USB**
(2) **Print**
(3) **Edit comment**
(4) **Close**

2 In the preview window, the following choices are available:

- Click **Print** (2) to print the report or **Close** (4) to close the window.
- Click **Edit comment** (3) to open a dialog box where a comment can be edited and saved. When the comment is saved, it is added to the report, and the report is then updated in the preview window.
- Click **Export to USB** (1) to export the report as a PDF file to a USB memory stick. This makes it possible to import the report into MOSAIQ®. When you export the operator's report to USB the treatment log file is exported too.

Related Links:

Description of treatment reports on page 145

Description of the treatment log on page 147

Exporting treatment reports on page 144

5.6.1 Exporting treatment reports

To export the report:

1 Insert a USB memory stick into a USB port of the MCU computer.

2 Click **Export to USB** to export the report file to the USB memory stick.

A window is opened to allow changing some of the information that is part of the report filename:

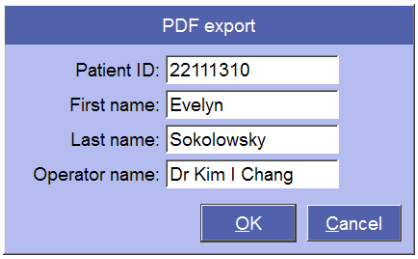


Figure 5.64 PDF export dialog box

If the export was successful, a message is displayed with the filename. If the export was unsuccessful, an explanatory message is displayed. Correct the problem and try again.

3 Remove the USB memory stick.

Related Links:

Description of the office cabinet on page 42

Description of treatment reports on page 145

5.6.2 Description of treatment reports

When all runs in a treatment plan have been executed, the reports from the treatment session should be viewed and printed from the **Treatment** tab. This should be done before the treatment session is ended.

The report contains the treatment result, see **Figure 5.65**:

Figure 5.65 Operator's report

- Summary (1): Summary including treatment plan information.
- **Overview** (2): Current treatment status and general information about each run.
- **Treatment results** (3): Detailed information about each run and shot.
- **CBCT scans** (4): Information about each CBCT scan performed for the treatment.
- **CBCT settings** (5): Detailed information about the settings used for the CBCT scans.

- **Patient position** (6): Detailed information about each successful Treatment delivery evaluation.
- **Events** (7): List of time-stamped events during treatment.

  The available events are:

  – **Treatment started**
  – **Treatment completed**
  – **Treatment paused (<reason>), shot:<shot> (<time> min)**

    The possible reasons are:

    – **HDMM alarm**
    – **Room door**
    – **System error**
    – **Operator**
    – **Power loss**
  – **Treatment resumed**
  – **Treament gating, shot: <shot> (<time> min)**
  – **HDMM system:** Active, Passive, or Disabled
  – **HDMM alarm level:** <value> [mm]
  – **HDMM reference set**

In the preview window, the following choices are available:

- **Export to USB**: Export the report as a PDF file to a USB memory stick. This makes it possible to import the report into MOSAIQ®.
  – The PDF file for the operator's report is placed in a folder named **MOSAIQ** and the filename contains the current date in YYYYMMDD format, the patient ID, the name of the patient, the name of the operator, the name of the transcriptionist, the report type, and a sequence number, for example

    MOSAIQ\20090526 -- 19200803-7777 -- Anderson, John -- Dr Jensen -- Dr Jensen -- LGK op report -- 1.pdf

    When you export the opeator's report to USB the treatment log file is exported too.
- **Print**: To print the report.
- **Edit comment**: A dialog box is opened where a comment can be edited and saved. When the comment is saved, it is added to the report, and the report is then updated in the preview window.
- **Close**: To close the window.

Related Links:

Description of the treatment log on page 147

5.6.3 Description of the treatment log

When a treatment is started the system creates a treatment log file to collect delivery events for the treatment. Each treatment log file contains a sequence of entries with a timestamp and an event, see **Table 5.1**.

Table 5.1 Delivery events

Event	Description
Treatment Events	
- **Started**	The treatment is started.
- **Completed**	The treatment is completed.
- **Gated**	Gating due to HDMM alarm
- **Resumed**	Dose delivery is resumed after gating.
- **Paused (HDMM**)	The treatment is paused due to prolonged or repeated gating.
- **Paused (Room door)**	The treatment is paused due to room door is open.
- **Paused (System error)**	The treatment is paused due to system error.
- **Paused (Operator)**	The treatment is paused by the operator.
- **Paused (Power loss)**	The treatment is paused due to power loss.
Patient Correction	Correction of the patient position is done during treatment delivery evaluation. Additonal information: • **Rotation** [degree] around the Leksell axis • **Translation** [mm] in Leksell coordinate space
Patient dock status	
- **Docked**	The patient is docked.
- **Undocked**	The patient is undocked.
Start scan	The CBCT scan is started.
End scan	The CBCT Scan is ended.
Start shot	The shot delivery is started. Additional information: • **Shot ID** • **Position** [mm] The planned shot position in Leksell coordinate space.
End shot	The shot delivery is ended. Additional information: • **Shot ID**
HDMM reference set	The HDMM reference point is set. Additional information:

Event	Description
	• **Reference type** – **NONE** No reference is set and there is no visible patient marker. – **VOLATILE** The position of the patient marker is not accurate, the patient setup is not completed. – **TEMPORARY** The patient setup is completed and confirmed by the user. – **APPROVED** Patient correction is applied and the patient marker position during the scan is used as reference point. • **Position** [mm] The reference position of the patient marker in approximate Leksell coordinate space.
HDMM alarm level	The HDMM alarm level is changed with the given displacement. Additional information: • **Displacement** [mm] The distance from the reference point to the patient marker.
Marker position	The HDMM status and measurements logged every 0.5 seconds. Additional information:

Event	Description
	• **Displacement** [mm] The distance from the reference point to the patient marker. • **HDMM status** – **NOT_TRACKING** The system is not tracking. – **TRACKING_ERROR** The sensor reports an error, or the tracking fails due to other error. – **INITIALIZING** The sensor initializes, no tracking data is reported. – **REFERENCE_TOOL_MISSING** The reference tool is not fully visible. – **NO_VISIBLE_MARKERS** The reference tool is fully visible, but no markers are visible. – **NO_MARKER_IN_BOUNDING_BOX** The reference tool is fully visible, and one or more markers are visible, but none is within the bounding box. – **TOO_MANY_MARKERS_IN_BOUNDING_BOX** The reference tool is fully visible, but there are too many markers within the bounding box. – **REFERENCE_NOT_DETERMINED** The reference tool is fully visible , and a single stray marker is visible, but no reference point is calculated. – **PATIENT_MARKER_VISIBLE** The reference tool is fully visible, and a patient marker is detected long time enough too calculate a temporary reference point. • **Position** [mm] The position of the patient marker in approximate Leksell coordinate space.
HDMM alarm	
- **Off**	The patient marker is visible and the displacement is below the alarm level.
- **Warning**	The patient marker is not visible, or the displacement is above the alarm level, but not long time enough to trigger an alarm.
- **On or restoring**	The patient marker is not visible, or the displacement is above the alarm level for too long time. Or the patient marker is restored but not long time enough to silence the alarm.
HDMM Mode	
- **Disabled**	The HDMM system is disabled.

Event	Description
- **Passive**	The HDMM system is in passive mode.
- **Active**	The HDMM system is in active mode.

Related Links:

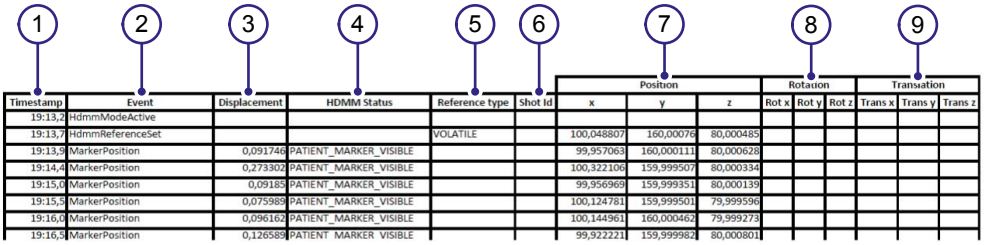
Exporting treatment log files on page 151

5.6.3.1 Exporting treatment log files

The treatment log file is exported to a USB memory stick together with the Operator's report when you select to export the Operator's report, refer to *Exporting treatment reports*.

Note: *It is recommended to export the treatment log file directly after treatment since it might be deleted after a while.*

When the treatment log files are exported to a USB memory stick they are placed in a folder named **TreatmentLog**. The filename contains the plan ID, the fraction number, and the current date in format YYYY-MM-DD. To open the treatment log file, use a tool that can handle XML, or open the treatment log file without stylesheet in MS Excel. See **Figure 5.66** for an example of exported treatment log file.



						Position			Rotation			Translation		
Timestamp	Event	Displacement	HDMM Status	Reference type	Shot Id	x	y	z	Rot x	Rot y	Rot z	Trans x	Trans y	Trans z
19:13,2	HdmmModeActive													
19:13,7	HdmmReferenceSet			VOLATILE		100,048807	160,00076	80,000485						
19:13,9	MarkerPosition	0,091746	PATIENT_MARKER_VISIBLE			99,957063	160,000111	80,000628						
19:14,4	MarkerPosition	0,273302	PATIENT_MARKER_VISIBLE			100,322106	159,999507	80,000334						
19:15,0	MarkerPosition	0,09185	PATIENT_MARKER_VISIBLE			99,956969	159,999351	80,000139						
19:15,5	MarkerPosition	0,075989	PATIENT_MARKER_VISIBLE			100,124781	159,999501	79,999596						
19:16,0	MarkerPosition	0,096162	PATIENT_MARKER_VISIBLE			100,144961	160,000462	79,999273						
19:16,5	MarkerPosition	0,126589	PATIENT_MARKER_VISIBLE			99,922221	159,999982	80,000801						

Figure 5.66 Example of an exported Treatment log file

(1) **Timestamp**
(2) **Event**
(3) **Displacement**
(4) **HDMM Status**
(5) **Reference type**
(6) **Shot Id**
(7) **Position**
(8) **Rotation**
(9) **Translation**

Note: *HDMM related information is only applicable for Leksell Gamma Knife® Icon™.*

Related Links:

Exporting treatment reports on page 144

Exporting log files on page 170

5.7 Operating the side protection panels

5.7.1 Opening the side protection panels

1 Lift up the handle of the side protection panel:

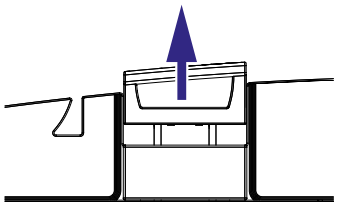


Figure 5.67 Lifting the handle of the side protection panel

CAUTION 5.1

Do not let go of the side protection panels until they are completely folded down.

2 Fold down the side protection panel all the way down:

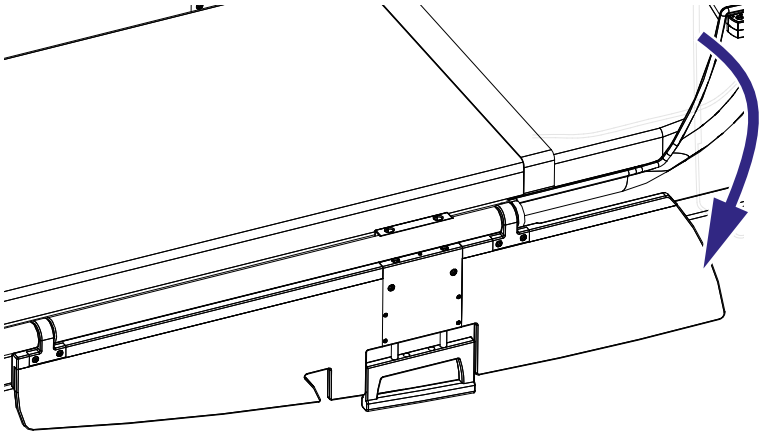


Figure 5.68 Folding down the side protection panel

5.7.2 Closing the side protection panels

1 Fold up the side protection panel to the upright position.

2 Push down the handle. Make sure the handle is properly seated in the locked position.

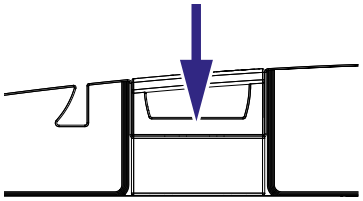


Figure 5.69 Pushing down the handle of the side protection panel

The corresponding interlock is then set in the **System's checklist** area.

5.8 Overview of the docking device

Before the immobilization device can be attached to or removed from the docking device on the couch, the docking device must be unlocked. When the immobilization device has been attached, the docking device must be locked.

The locking lever on the right side of the docking device is used for locking and unlocking the docking device.

5.8.1 Locking the docking device

To lock the docking device when the immobilization device has been attached:

1 Push the locking lever (1) all the way in from the unlocked position. Then turn the lever down to the locked position.

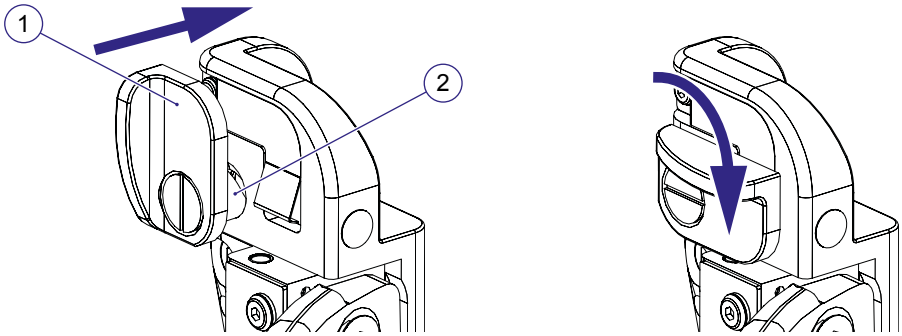


Figure 5.70 Locking the docking device

When you push the lever in, a through pin (2) meets with the attachment pin (1) (see **Figure 5.71**) of the immobilization device on the other side of the docking device. This holds the immobilization device in position.

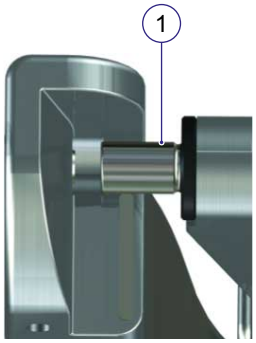


Figure 5.71 Attachment pin of the immobilization device

Note: *Locking the lever also locks the functions of the manual control on the couch. No further movements of the mattress can now be made.*

Related Links:

Unlocking the docking device on page 154

5.8.2 Unlocking the docking device

To unlock the docking device:

1 Push the lock plate (1) (see **Figure 5.72**) in and turn the locking lever (2) to the upright position.

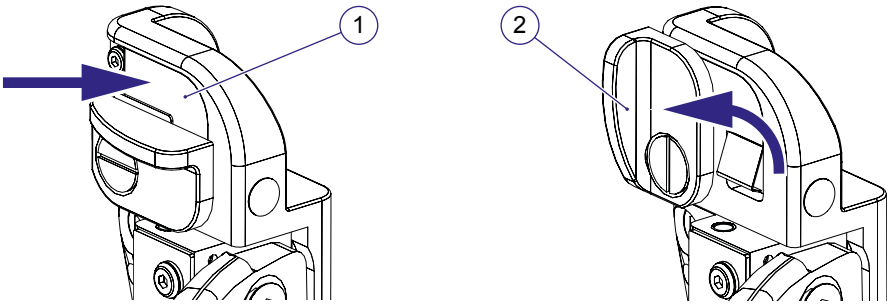


Figure 5.72 Unlocking the docking device

By means of a spring, the lever will slide out. The through pin (1) (see **Figure 5.73**) that meets with the immobilization device also slides out and releases the immobilization device, if attached.

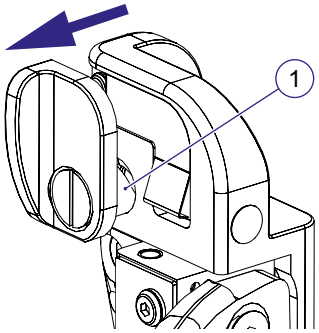


Figure 5.73 Locking lever sliding out

Related Links:

Locking the docking device on page 153

5.9 General description of the treatment

5.9.1 Description of a treatment run

When you press and release the START button on the control panel, the couch moves from the home position to the out position. That is, the X and Y position for the first shot of the run, but without moving in the Z direction. The shielding doors are then opened. These movements are indicated by the couch and door indicators at the bottom left in the GUI. The yellow Radiation indicator on the control panel starts blinking.

The START button is deactivated during the couch movement. When the couch reaches the out position and the shielding doors are fully opened, the START and ENABLE buttons become active (green and orange color).

- The START button must have been released before the START and ENABLE buttons can be pressed.
- The START and ENABLE buttons must be pressed within 60 seconds after they have become active. Otherwise a treatment pause sequence is initiated.
- If anything unexpected occurs during the transport, the movement of the couch can be stopped by releasing the START and ENABLE buttons.

When you press and hold the START and ENABLE buttons, the couch moves into the radiation unit to a position just outside the treatment cavity. When the position has been reached, a signal is heard.

When you release the START and ENABLE buttons, the final positioning to the treatment position is performed. The treatment run starts, with each shot in the run executed in turn according to the treatment plan. The control panel and the GUI shows the treatment progress:

- The setup of the collimators is displayed in the **Collimator status** area while a shot is executed.
- The treatment timer increments on the run & shot status page. The **Run time** area shows the progress of the run, and the **Shot time** area shows the progress of each shot in the run. The list of current, planned and next shots in the **Run & shot status** area scrolls to indicate the progress of the shots in the run.
- The indicator area at the bottom left of the GUI shows the status of the positioning system and treatment beams during the run.
- On the control panel, the yellow Radiation indicator emits a constant light while a shot is executed. Between the shots, the Radiation indicator is blinking.

For each shot in the run, the couch is repositioned to the next treatment position, during which the sectors are placed in the sector off position. The sectors are then repositioned to use the correct collimator sizes.

An attention triad signal sounds 20 seconds (0.33 minutes) before the end of the treatment time.

When the run is completed the patient couch is moved out of the radiation unit to the out position where it is paused. The shielding doors are closed and the couch is then moved to the home position.

Related Links:

Description of the indicator area on page 72

5.9.2 Treatment session overview

Leksell Gamma Knife® Icon™ is controlled and monitored from the control room in the shielded area outside the treatment room. The electronic and software systems in the control system execute the treatment defined in the treatment protocol by a series of control sequences.

The performance of the control sequences is continuously monitored and alarms are given in response to a number of conditions.

An ongoing treatment session can be paused at any time by pressing the PAUSE button (1) on the control panel. The session can also be interrupted using the Emergency Stop button (2), which starts an Emergency Exit sequence when the button is released.

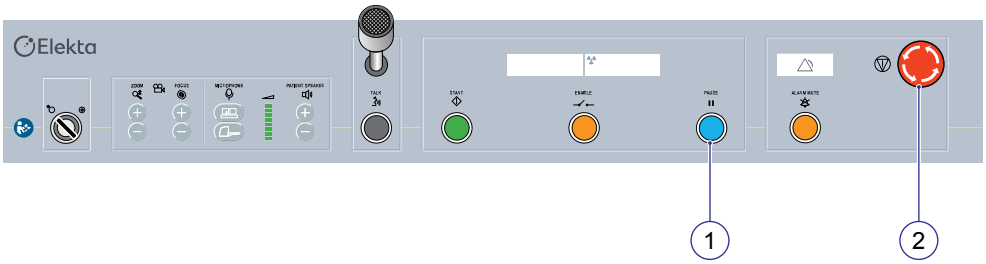


Figure 5.74 PAUSE button and Emergency Stop button

(1) PAUSE button

(2) Emergency Stop button

Related Links:

Pausing a treatment on page 127

Emergency Exit sequence on page 181

System alarm on page 192

Emergency alarm on page 192

5.9.3 Description of open treatments

A treatment that has been aborted or interrupted, manually or due to an automatic alarm condition, is recorded as an “open” treatment in the treatment plan database. Such treatments are available in the **Select patient** page together with treatments that has never been opened, and they may be (re)loaded like any other treatment.

Related Links:

The page Select patient on page 157

5.9.4 Treatment status

The status of a treatment is transferred automatically to the treatment plan database at the following occasions:

- When a treatment is paused or interrupted
- At the end of a run
- At the end of a treatment (If applicable, MOSAIQ is also updated)
- When the system is shut down.

The information on the ECU display can be used to verify treatment status.

WARNING 5.78

In case of system error messages, it is essential to carefully follow any instructions given in the error messages. To not follow the instructions may lead to clinical mistreatment.

Related Links:

Description of the SDU and ECU units on page 36

5.10 Description of different pages in the GUI

5.10.1 The page Select patient

When the **Treatment** button is clicked, the **Main** tab displays the **Select patient** page:

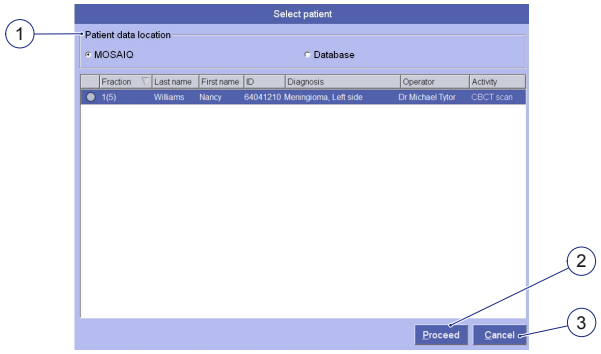


Figure 5.75 The page Select patient

(1) **Patient data location** area

(2) **Proceed** button

(3) **Cancel** button

For MOSAIQ users, the area **Patient data location** (1) shows if the treatment plan is selected from MOSAIQ or from the treatment plan database. If the system is not configured for MOSAIQ, this area does not appear.

Treatment plans are only available for treatment in a specified time since they were made in Leksell GammaPlan®:

For treatment with coordinate frame fixation	48 hours
For treatment with mask fixation	48 days

For each treatment plan in the list, the following information is given:

- Treatment status
- **Fraction**
- **Last name**
- **First name**
- **ID**
- **Diagnosis**
- **Operator**
- **Activity**.

If the treatment plan is selected from Database, the list is by default sorted by treatment plan approval date. To sort the list by another column, click the column title.

The status of the treatment plans is displayed furthest to the left using the following icons:

◯	Treatment not started.
ⓞ	Treatment opened. The treatment has been started, but has not completed.

Treatments that have been completely finished are no longer available to select in the treatment list.

To select a treatment to load, either double-click the treatment in the list, or select the treatment in the list and click the **Proceed** button (2).

To cancel the selection of a treatment, click the **Cancel** button (3). This returns to the start page of the **Main** tab, where the main functions can be selected.

Related Links:

Lists with columns on page 66

5.10.2 The treatment run selection page

The initial run selection page of the tab is for selecting a treatment run in the treatment plan. The page displays the different gamma angles as tabs, and each gamma angle contains a single run.

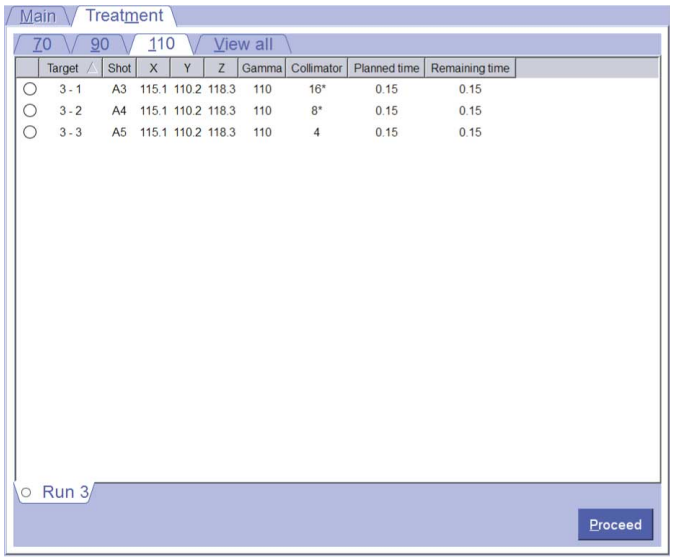


Figure 5.76 The run selection page on the Treatment tab

If the treatment plan contains more than one gamma angle, a **View all** tab is also available. This tab lists all shots in all gamma angles and all runs, but does not offer the possibility to select a run.

For each run, a list of shots in the run is displayed. The list contains the same information as in the treatment planning system.

The list of shots is by default sorted by the **Target** column. To sort the list by another column, click the column title.

In the **Collimator** column, an asterisk indicates a mix of collimator sizes in the shot, or that at least one sector is blocked. The collimator size shown is then the largest collimator size used. To get a picture of the collimator setup for a shot, right-click anywhere in the corresponding row. A pop-up image is then displayed, using the same collimator indicators as in the **Collimator status** area in the **Status** tab. To close the image, left-click anywhere outside the image or press <Esc>.

Example of collimator setup image:

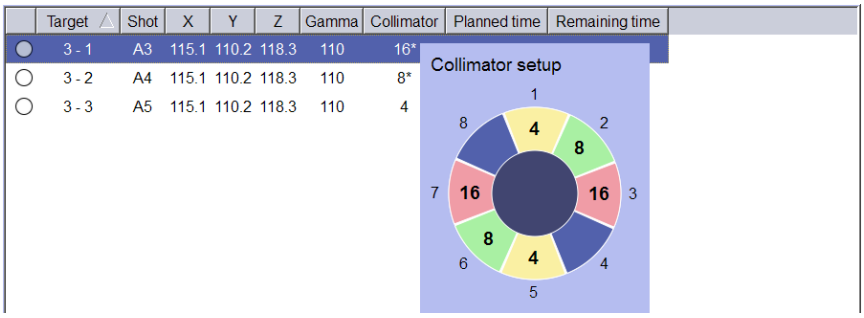


Figure 5.77 Pop-up image of collimator setup for a treatment shot

The status of the shots is displayed furthest to the left using the following icons:

○	Shot not started.
◎	Shot opened. The shot has been started, but has not completed. The column for remaining time shows how much time of the shot that remains.
✓	Shot completed.
⊗	Contact with collimator cap detected during shot.

At the bottom of the page, the run title has the same status icons as above. The status of the shots in a run determine the overall status of the run:

○ Run 3	Run not started. (No shot in the run started.)
◎ Run 3	Run opened. The run has been started, but has not completed. (One or more shots have been started or completed, but not all shots have been completed.)
✓ Run 3	Run completed. (All shots in the run completed.)
⊗ Run 3	Contact with collimator cap detected during run.

The following command buttons are available:

- The **Proceed** button selects the currently displayed run. A run that has been completed is still displayed, but the button is then disabled. It is only possible to select a run that is opened or not started.
- The **Open report** button is used for viewing reports from the treatment session.
- The **End treatment** button is used for ending the current treatment session.

Related Links:

Lists with columns on page 66

Description of the collimator status on page 69

Viewing treatment reports on page 143

5.10.3 The page Verify treatment data

After clicking the **Proceed** button, the patient and treatment data is read from the treatment plan, and the **Main** tab displays the following page:

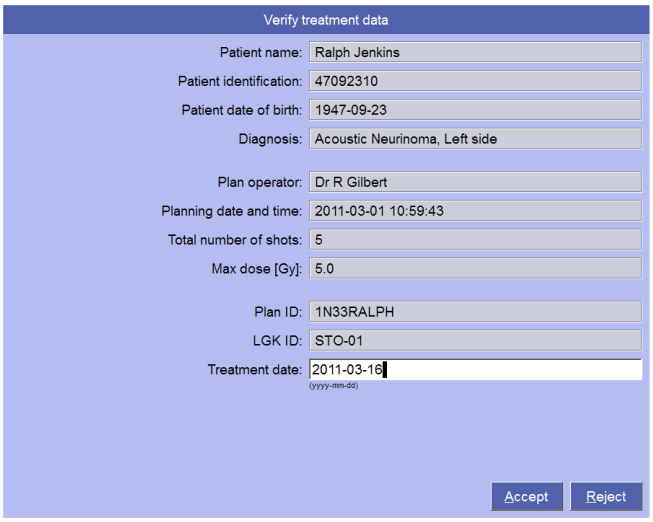


Figure 5.78 The page Verify treatment data

The most important patient and treatment data is displayed, and the data must be verified. In addition, the current date must be entered to assure that the system time is correct, when the system adjusts the radiation time for possible source decay since treatment planning.

The **Accept** button is disabled until the entered date corresponds to the system time. If the entered date is correct, but the button is still disabled, the internal MCU system clock may be incorrect. In that case, contact Elekta® service to adjust the system clock.

- Click **Accept** to accept the treatment data and load the treatment plan.
- Click **Reject** to cancel the treatment and return to the **Select patient** page.

If a text is too long to fit in the corresponding text box, the text is truncated, but the full text can be seen by resting the pointer over the truncated text. The full text then appears as a tool tip.

Once the treatment plan has been loaded, the patient information area is filled in, and the **Clearance** or **Treatment** tab becomes active. The **Main** tab is then disabled.

5.10.4 Enlarged GUI view

During docking of the patient and scan preparation, an enlarged view of the GUI is available. This view covers the entire screen and is suited for reading on the treatment room monitor.

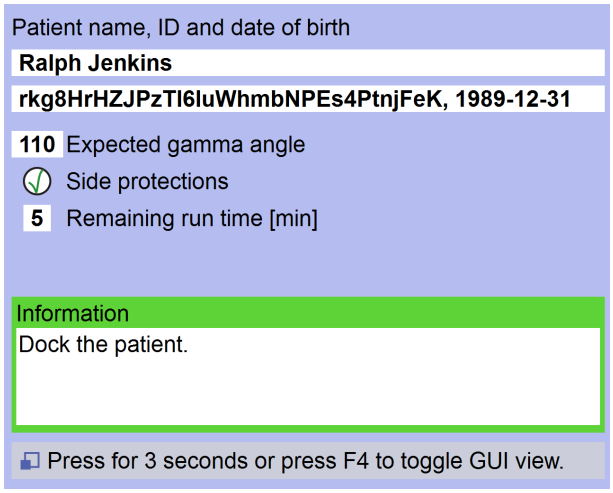


Figure 5.79 The enlarged GUI view during docking with coordinate frame G

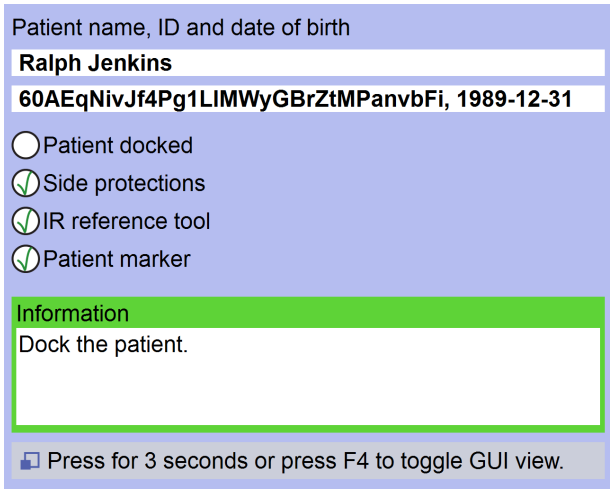


Figure 5.80 The enlarged GUI view during docking with Vantage head frame

Only the most important information is displayed in the enlarged GUI view:

- The patient's name, ID and date of birth.
- The interlocks for patient docking and side protection panels. This information vary depending on the used immobilization device, see **Figure 5.79** and **Figure 5.80**.
- The remaining time of the run.
- System messages. To be able to acknowledge error or warning messages, the GUI has to be switched to normal view.

The GUI can be switched back to the normal view, where all information is displayed, in two ways:

- in the control room, by pressing <F4> on the keyboard,
- in the treatment room, by pressing and holding down the Toggle GUI button on the manual control for 3 seconds.

This toggles the GUI between the two views.

Note: *The enlarged GUI view is only available during docking of the patient and scan preparation. Once the treatment run has been started, the enlarged view cannot be displayed.*

5.10.5 The run & shot status page

The **Treatment** tab displays the run & shot status page during the duration of a selected treatment run. During docking of the patient, an enlarged view of the GUI can be displayed instead, and the GUI can be toggled between the enlarged view and the normal view containing the run & shot status page.

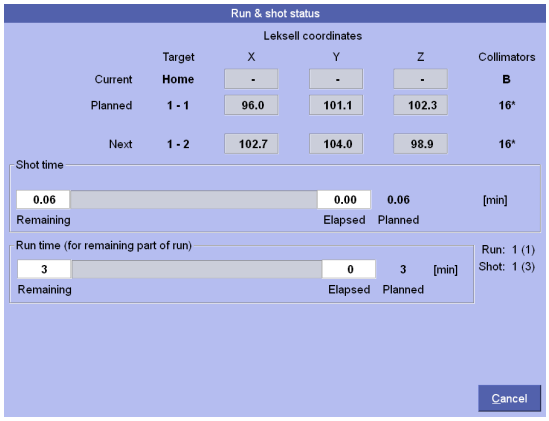


Figure 5.81 The run & shot status page on the Treatment tab

This page shows the shot and run status during treatment. Before the run is started from the control panel, the run can be cancelled by clicking the **Cancel** button. This returns to the run selection page.

Once a run has been started, it cannot be cancelled from the GUI. Except for the <F3> key described below, the GUI is disabled and locked for keyboard and mouse input until the current run is completed. A run can then only be aborted by pressing the PAUSE button or the Emergency Stop button on the control panel.

The **Run & shot status** area shows the status of the individual shots and the whole run. Information is displayed in a list-like fashion for three shots or positions: **Current**, **Planned** and **Next**. As the shots are started or completed, they are “scrolled” upwards in the list.

- **Current**: The information for the current position or shot. This information becomes identical to **Planned** when positioning for the planned shot has been completed.
- **Planned**: The information for the planned shot. This information is identical to **Current** while the shot is executed.
- **Next**: The information for the next-coming shot or position. This information moves to **Planned** when the current shot is completed.
- **Target**: The target identification. This is **Home** for the initial position, and for the final position (after the last shot).
- **Leksell coordinates**: The X, Y and Z coordinates for the shot or position.
- **Collimators**: The collimator setup for the shot. This is displayed as **B** when the sector is blocked, and as a number in the same way as for the list of shots in the run selection page.
- **Run: X(Y)**: Run number X (of total number Y).
- **Shot: X(Y)**: Shot number X (of total number Y).

- **Shot time**: A progress bar for the time of the shot, in minutes using two decimals. The following values are displayed:
  - **Remaining**: The remaining time of the shot.
  - **Elapsed**: The elapsed time of the shot.
  - **Planned**: The total planned time of the shot.
- **Run time**: A progress bar for the total time of the run, in whole minutes without decimals. This includes the time for all shots in the run, the time for positioning the patient, and the time for transporting the patient from and to the home position. The following values are displayed:
  - **Remaining**: The remaining time of the run.
  - **Elapsed**: The elapsed time of the run.
  - **Planned**: The total planned time of the run.

The elapsed time of the shot is the primary treatment timer of the system. There is a secondary treatment timer for the elapsed time, independent of the primary timer. To show (or hide) the secondary timer, press <F3>. The secondary timer is displayed to the right of the total planned time:

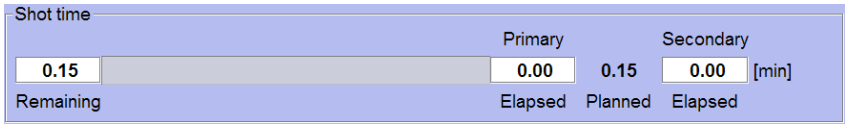


Figure 5.82 Displaying the secondary treatment timer

Note: *The secondary treatment timer may always be displayed, depending on a user preference. If so, the <F3> key is disabled.*

When a run is completed, the run selection page of the tab is displayed, where the status icons for the run and the shots have been updated.

Related Links:

Setting preferences on page 167

Enlarged GUI view on page 160

The treatment run selection page on page 158

5.11 CBCT predefined settings

A preset is a group of parameters that control how the CBCT system acquires and reconstructs the kV projection images.

When CBCT is installed, Elekta supplies a default set of presets. The system has two presets for clinical use:

- CTDI 2.5
- CTDI 6.3

Table 5.2 Data that differs between the two presets

	CTDI 2.5	CTDI 6.3
Dose CTDI	2.5 mGy	6.3 mGy

Charge/projection	0.4 mAs	1.0 mAs
Tube current	10 mA	25 mA

Table 5.3 Data shared by the two presets

Energy	90 kVp	Pulse length	40 ms
No. of projections	332	Detector pixel size	0.368 mm
Volume size	448x448x448 voxels	Voxel size	0.5 mm
Spot size	0.6 mm	Apodization filter, cut off frequency	Hamming, 0.63

The presets are optimized to get a good accuracy of the co-registration algorithm. The accuracy between the two presets are comparable. The primary difference between the preset are in the dose delivered and the noise level in the reconstructed images. The preset with the high dose gives a better image quality regarding contrast to noise ratio. This can be useful for the visual inspection of the co-registration result when you set the stereotactic reference.

The CBCT scan is not for diagnostic functions, only to set a stereotactic reference for dose planning of the treatment.

5.12 Using the patient intercom system

1 To speak to the patient, press and hold down the TALK button (8) while speaking into the microphone (7).

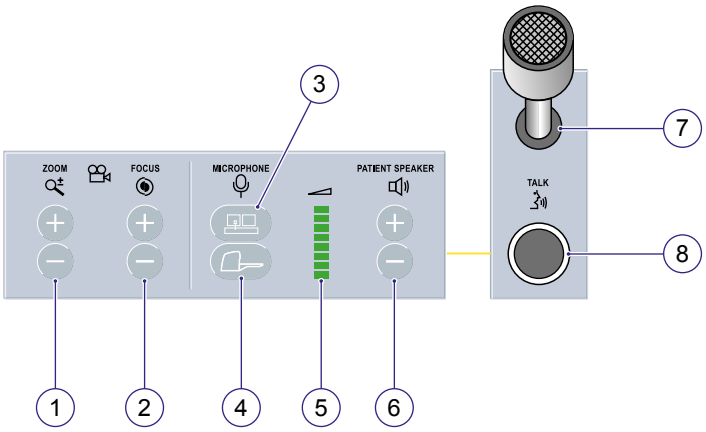


Figure 5.83 Patient intercom controls

(1) Camera zoom (ZOOM +/–)

(2) Camera focus (FOCUS +/–)

(3) Operator microphone sensitivity

(4) Patient microphone sensitivity

(5) Level indicator

(6) Patient speaker volume (PATIENT SPEAKER +/–)

(7) Operator microphone

(8) TALK button

2 To control the treatment room camera, press the ZOOM (+/–) buttons (1) and the FOCUS (+/–) buttons (2).

3 To adjust the PATIENT SPEAKER volume, press the +/– buttons (6). The volume level is displayed by the level indicator (5).

4 To adjust the speaker volume in the control room, use the volume controls on the patient supervisory monitor.

5 To adjust the operator microphone sensitivity, hold down the microphone sensitivity button (3) and simultaneously press the +/– buttons (6). The sensitivity level is displayed by the level indicator (5).

6 To adjust the patient microphone sensitivity, hold down the microphone sensitivity button (4) and simultaneously press the +/– buttons (6). The sensitivity level is displayed by the level indicator (5).

Related Links:

Description of the patient intercom on page 37

5.13 Using the user administration function

The user administration function provides activities for the setup of users and for handling their preferences and passwords. Some activities are only available to certified users and service users.

1 On the start page of the **Main** tab, click the **Administration** button and select **User administration** from the menu.

The following page is displayed:

Figure 5.84 The page User administration

2 To select an activity, click the corresponding button.

3 To leave the page, click the **Close** button. This returns to the start page of the **Main** tab.

Related Links:

Adding a user on page 166

Removing a user on page 166

Changing password on page 166

Setting preferences on page 167

Viewing all users on page 167

5.13.1 Adding a user

To add a new authorized user to the current Leksell Gamma Knife® Icon™ system:

Note: *This activity is only available for certified users and service users.*

1. On the **User administration** page, click **Add user**.
2. In the **User name** box, enter the new user name. The user name must be unique in the system.
3. From the **User type** box, select the type of user: **Non certified user** or **Certified user**.

Note: *Only service users are allowed to add a new service user.*

4. In the **Password** box, enter a password for the new user.
5. In the **Confirm password** box, enter the password again.
6. Click **Add** to add the new user, or **Close** to abort the activity.

   If the user could not be added, an explanatory message is displayed.

   When the user has been added, a list of all users is displayed.

Related Links:

User types in the system on page 65

Using the user administration function on page 165

Viewing all users on page 167

5.13.2 Removing a user

To remove an existing user from the current Leksell Gamma Knife® Icon™ system:

Note: *This activity is only available for certified users and service users.*

1. On the **User administration** page, click the **Remove user** button.
2. From the **User name** box, select the user to remove.

Note: *It is not possible to remove the user currently logged on. Only service users are allowed to remove a service user.*

3. Click **Remove** to remove the user, or **Close** to abort the activity.

   When the user has been removed, a list of all users is displayed.

Related Links:

Using the user administration function on page 165

Viewing all users on page 167

5.13.3 Changing password

To change the password of the currently logged on user:

1 On the **User administration** page, click the **Change password** button.

The **User name** box displays the name of the currently logged on user. It is not possible to select another user.

2 In the **New password** box, enter a new password. For security reasons, the actual characters of the password are replaced by asterisks.

3 In the **Confirm new password** box, enter the new password again.

4 Click **OK** to change the password, or **Close** to abort the activity.

If the password could not be changed, an explanatory message is displayed.

Related Links:

Using the user administration function on page 165

5.13.4 Setting preferences

To set the user preferences for the currently logged on user:

1 On the **User administration** page, click the **Set preferences** button.

The **User name** box displays the name of the currently logged on user. It is not possible to select another user.

2 Click the **Date format** box to select the preferred format for all dates displayed or logged by the system.

3 Click the **Time format** box to select the preferred format for all times displayed or logged by the system.

4 Click the **Preferred language** box to select the user interface language, **English** or **Local**. This box is only available if a translation of the user interface exists.

5 Click the check box at the bottom to determine if the secondary treatment timer is always visible on the run status page, instead of being manually activated with the <F3> function key.

6 Click **Set** to confirm the change of user preferences, or **Close** to abort the activity.

If the user interface language was changed, the Graphical User Interface of the application changes to display all text in the selected language.

Related Links:

Using the user administration function on page 165

The run & shot status page on page 162

5.13.5 Viewing all users

To display a list of all existing users in the current Leksell Gamma Knife® Icon™ system:

Note: *This activity is only available for certified users and service users.*

1 On the **User administration** page, click the **View all users** button.

The list of users is by default sorted by user name in ascending order. To sort the list in other ways, click a column title.

2 Click **Close** to return to the selection of activities.

Related Links:

Lists with columns on page 66

Using the user administration function on page 165

5.14 Using the patient administration function

The patient administration function lets the user view operator's reports for all treatment plans and CBCT requests in the treatment plan database, including the following type of items that no longer are available for execution:

- Discarded treatment plans and CBCT requests.
- Completed treatment plans and CBCT requests.
- Opened treatment plans and CBCT requests that are not completed in time.
- Treatments plans and CBCT requests that are not started in time.

5.14.1 The page Patient administration

When **Patient administration** is selected from the **Administration** menu, the **Main** tab displays the following page:

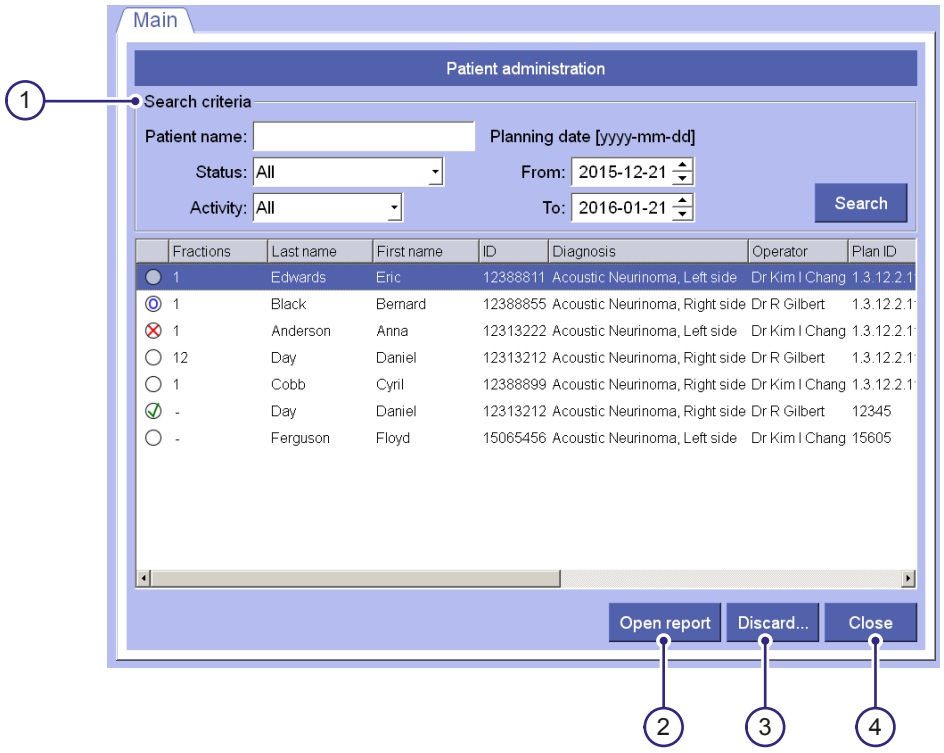


Figure 5.85 The page Patient administration

(1)	**Search criteria** area	(3)	**Discard** button
(2)	**Open report** button	(4)	**Close** button

The page lists the treatment plans and CBCT requests that fulfill the search criteria specified in the **Search criteria** area (1).

For each treatment plan or CBCT request in the list, the following information is given:

- Treatment status
- Number of **Fractions**
- **Last name**
- **First name**
- **ID**
- **Diagnosis**
- **Operator**
- **Plan ID**
- **Plan approval date**
- **Activity**

To sort the list by any of the columns, click the column title.

The status of the treatment plans and CBCT requests is displayed furthest to the left using the following icons:


Treatment or CBCT request is not started.


Treatment or CBCT request is open. The treatment or CBCT request is started, but is not completed.


Treatment or CBCT request is completed.


Treatment or CBCT request is discarded.

To leave the page. Click the **Close** button (4). This returns to the start page of the **Main** tab, where the main functions can be selected.

Related Links:

Changing the search criteria on page 169

Viewing the Operator's report on page 170

Discarding a treatment plan or CBCT request on page 170

5.14.2 Changing the search criteria

To change what items are listed on the **Patient administration** page, use the **Search criteria** area.

1. In **Patient name**, enter the first name or last name, or letters included in the first name or last name of the patient.
2. In **Status**, select the status of the treatment plans and CBCT requests:
   - **All**
   - **Opened or not started**
   - **Completed**
   - **Discarded**
3. In **Activity**, select the type of items:
   - **All**
   - **Treatments**
   - **CBCT requests**

4 In **Planning date**, select the range of planning dates for the treatment plans or CBCT requests.

5 Click **Search**.

The treatment plans and CBCT requests that fulfill the search criteria are listed.

5.14.3 Viewing the Operator's report

To view the Operator's report:

1 On the **Patient administration** page, select an item in the list and click the **Open report** button, or double-click the item in the list.

When a fractioned treatment is selected in the list, the **Open report** button changes to include a menu of all fractions. From the menu, select the fraction to view in the Operator's report. If you double-click an item in the list, the first fraction is selected.

The Operator's report for the treatment or CBCT request opens. It is possible to export the report to USB, print the report, and, for a treatment plan, edit comment on the report.

Related Links:

Viewing treatment reports on page 143

5.14.4 Discarding a treatment plan or CBCT request

To discard a treatment plan or CBCT request:

1 On the **Patient administration** page, select an item in the list and click the **Discard** button.

A warning message is displayed in the system information area, requesting to confirm discard of the item.

The selected item is discarded.

5.15 Using the export log files function

5.15.1 Exporting log files

To export log files from the current Leksell Gamma Knife® Icon™ system:

1 On the start page of the **Main** tab, click the **Administration** button and select **Export log files** from the menu.

The following page is displayed:

Figure 5.86 The page Export log files

2 Select the date from which to export the log files:

   a Select the part of the date (year, month, or day) you wish to change, by using the mouse or the <Left> and <Right> arrow keys.

   b Change the selected part of the date by using the up and down arrows at the right end of the date box, or the <Up> and <Down> arrow keys.

3 Insert a USB memory stick into a USB port of the MCU computer in the office cabinet.

4 Click **Export** to export the log files to the USB memory stick.

5 If the export was unsuccessful, an explanatory message is displayed. Correct the problem and try again.

6 Wait for the export to be completed. Then remove the USB memory stick.

7 To leave the page, click the **Close** button.

   This returns to the start page of the **Main** tab.

Related Links:

Overview of log files on page 171

Description of the office cabinet on page 42

5.15.2 Overview of log files

Log files from the Leksell Gamma Knife® Icon™ system can be exported to a USB memory stick. These log files do not constitute the treatment status that is automatically transferred to the treatment plan database at the end of a treatment. Instead, the log files contain detailed log information that may be of use primarily for service, maintenance or customer support activities. You should not need to export log files as part of the normal work flow.

Related Links:

Exporting log files on page 170

5.16 Using the test functions

5.16.1 Overview of the test functions

The **Test** button on the **Main** tab opens a menu from which a specific type of test run can be selected.

- **Clearance**
- **HDMM** (refer to *Doing a HDMM test*)
- **Physics**
- **Predefined**

Test runs can be used for various purposes, such as:

- to check various aspects of treatment runs
- to check the system after maintenance
- to demonstrate the execution of treatment runs
- to perform physics measurements.

Related Links:

Description of the physics test function on page 172

Creating and doing a clearance test run on page 176

Doing a predefined test treatment on page 178

Doing a HDMM test on page 97

5.16.2 Using the physics test function

5.16.2.1 Description of the physics test function

This function allows the user to create and perform test runs for the purpose of physics measurements. The appropriate tools must be docked instead of a patient.

WARNING 5.79

Never attempt to remove, modify or override any switches, interlocks, or other safety device on this equipment. Interfering with such safety devices could lead to death or serious injury.

When **Physics** is selected from the **Test** menu, the **Main** tab displays the following page:

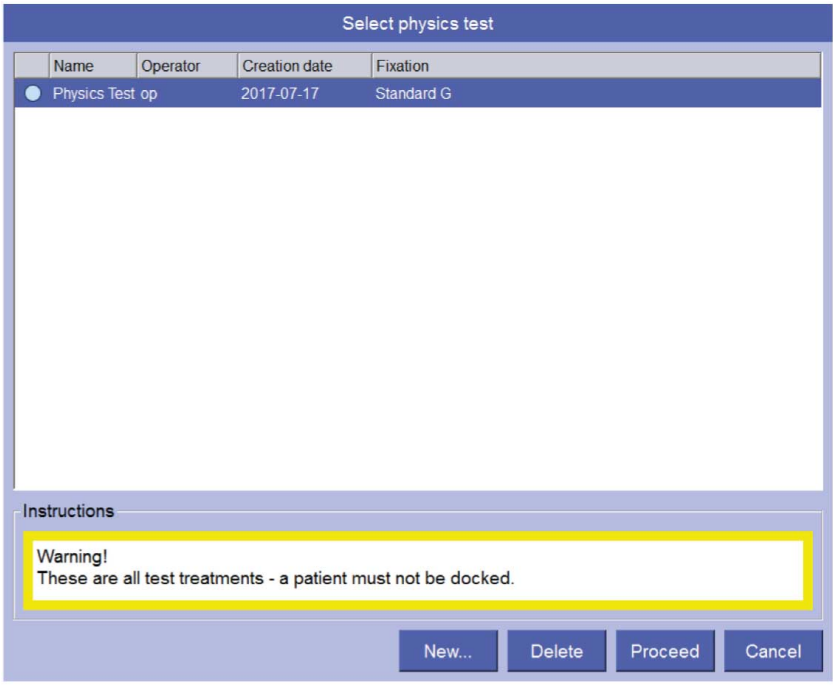


*Figure 5.87 The page **Select physics test***

The page lists the created physics tests.

For each treatment in the list, the following information is given:

- Treatment status
- **Name** of the test treatment
- **Operator** who created the test
- **Creation date**
- **Fixation** type

The list is by default sorted by the creation date. To sort the list by another column, click the column title.

A physics test is always possible to start again when it has been completed.

To leave the page, click the **Cancel** button.

5.16.2.2 Creating a physics test run

To create a physics test run:

1 On the start page of the **Main** tab, click the **Test** button and select **Physics** in the menu.

The **Select physics test** page is displayed.

2 Click the **New** button.

The **Create a physics test run** page is displayed.

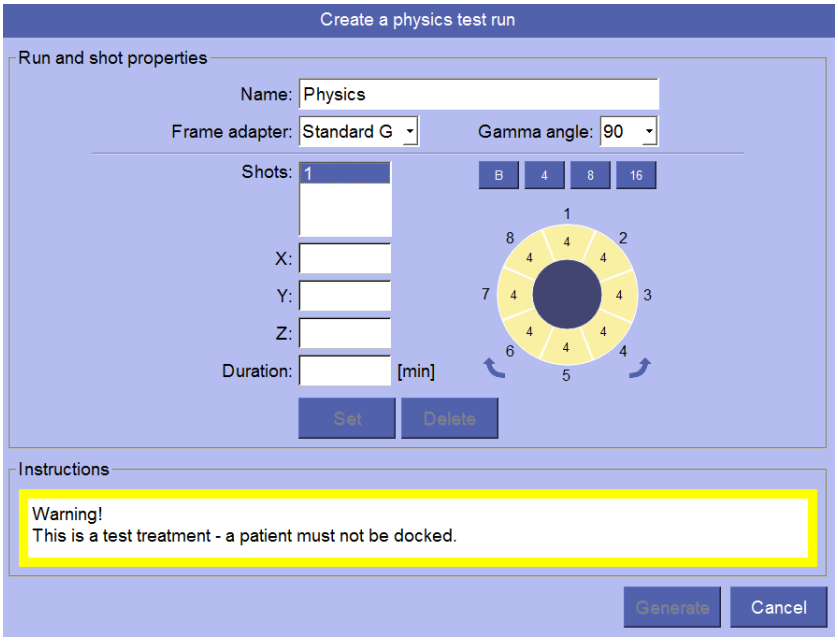


*Figure 5.88 The **Create a physics test run** page*

3 Specify the properties of the run:

a In the **Name** box, enter the name of the test run. You can have multiple tests with the same name.

b From the **Frame adapter** box, select the type of frame adapter.

c From the **Gamma angle** box, select the gamma angle of the test run.

Note: *Make sure you have selected the correct type of frame adapter, and correct gamma angle, before you continue. When the first shot is set, you cannot change the type of frame adapter, or gamma angle.*

4 Specify the properties of the shots in the run:

a In the **Shots** box, select a shot in the list to view and change its properties, or select the last shot in the list to add a new shot.

b In the **X**, **Y**, and **Z** boxes, enter the Leksell® coordinates of the shot.

c In the **Duration** box, enter the duration of the shot in minutes.

d Change the collimator setup:

- Click any of the collimator size buttons above the image to set all sectors to the same size. The button **B** is used to block a sector.
- Right-click any of the collimator size buttons above the image. The pointer changes to a pen with a collimator size indicator. Use the pen and the right mouse button to paint the collimator image with the selected size. Turn off the pen pointer by left-clicking anywhere in the collimator setup.
- When the collimator setup contains different collimator sizes, rotate the collimator setup using the curved arrows.
- Move the pointer over a section and use the scroll wheel to change the collimator size in that section.

e Click the **Set** button to add a new shot, or to confirm the changes made to an existing shot. The button is disabled if not all properties of the a shot are specificed, or if no changes are made to an existing shot.

- Click the **Delete** button to delete the current shot from the run.

5 When a test run is completely specified, click the **Generate** button to create a treatment plan containing the test run, or click the **Cancel** button to cancel the creation of the test run.

5.16.2.3 Doing a physics test

To do a physics test:

WARNING 5.80

A physics test must not be used for treatment of patients. The interface for defining a physics test cannot replace treatment planning in Leksell GammaPlan®.

1 Dock the appropriate tool in the correct gamma angle.

2 On the start page of the **Main** tab, click the **Test** button and select **Physics** in the menu.

The **Select physics test** page is displayed. The page lists the created physics test treatments.

The physics test is executed in the same way as a patient treatment.

WARNING 5.81

Before the start of a treatment, make sure that there are no loose objects left on the couch or between the couch and the radiation unit. A loose object entering the radiation unit or getting stuck between the shielding doors may cause a malfunction of the equipment, and/or lead to an emergency undocking of the patient, and/or lead to injury to the patient.

3 Select a test in the list and click the **Proceed** button, or double-click the test in the list.

a Do clearance check using the clearance tool, refer to *Performing clearance checks*.

Note: *This clearance run is only necessary to do the first time the physics test run is executed. Subsequently, the physics test run can be executed without clearance checks.*

b In the **Treatment** tab, click the **Proceed** button.

The **Run & shot status** page is displayed.

c On the control panel, press the START button to prepare for the test run.

d Press and hold the START and ENABLE buttons until an information message to release the buttons is shown.

The test run starts and the **Run & shot status** page shows the progress of the shots in the test run.

e When the test run is completed, open and print the report.

f Click **End** to complete the test run.

Note the following important aspects when you do a physics test run:

– The physics test must be done with the appropriate tool docked in the correct gamma angle. No patient is docked and no verification of patient ID is done.

– The patient information area displays the name of the test run and the creation date.

Related Links:

Treating a patient on page 102

5.16.2.4 Deleting a physics test run

To delete a physics test run:

1 Select a physics test run on the page **Select physics test**.

2 Click the **Delete** button.

The physics test is now deleted from the list. A deleted test cannot be un-deleted.

5.16.3 Using the clearance test function

5.16.3.1 Description of the clearance test function

This function allows the user to create and perform a test run for the sole purpose of checking clearance. This can be used during treatment planning in Leksell GammaPlan®, when one or more shots are placed that may cause contact with the collimator cap during treatment.

Since a rejected clearance position during clearance checks will prevent the treatment from being started, this would require a new treatment plan to be made. To avoid this, a clearance test run can be created during treatment planning, containing the shots to be verified. By executing the clearance test run with the patient docked before the treatment plan is completed, the treatment plan can be revised if a clearance position is rejected.

WARNING 5.82

Never attempt to remove, modify or override any switches, interlocks, or other safety device on this equipment. Interfering with such safety devices could lead to death or serious injury.

5.16.3.2 Creating and doing a clearance test run

1 On the start page pf the **Main** tab, click the **Test** button and select **Clearance** in the menu.

The **Create a clearance test run** page is displayed. There is no list of clearance test runs. Only a single clearance test run can be created at a time and it cannot be saved for future use.

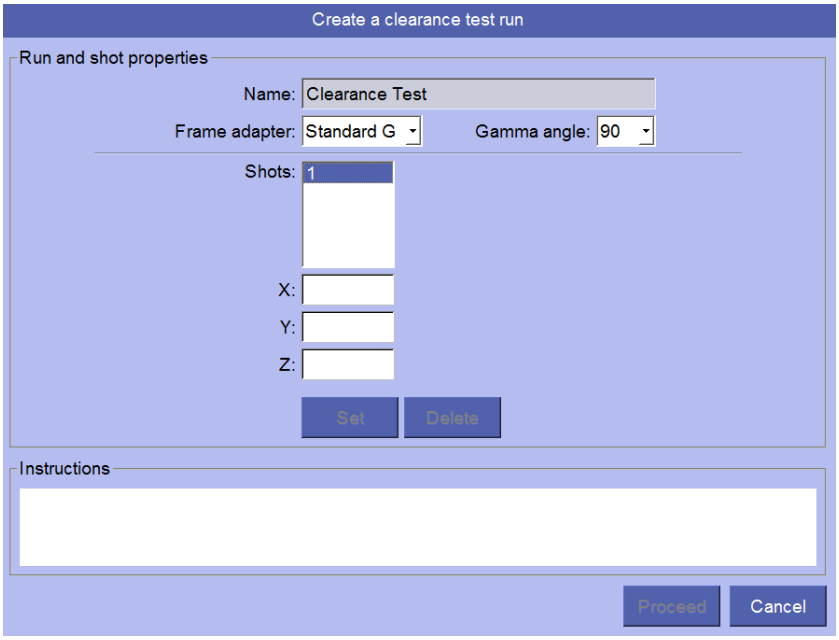


*Figure 5.89 The **Create a clearance test run** page*

2 Specify the properties of the run:

a From the **Frame adapter** box, select the type of frame adapter.

b From the **Gamma angle** box, select the gamma angle of the test run.

3 Specify the properties of the shots in the run:

a In the **Shots** box, select a shot in the list to view and change its properties, or select the last shot in the list to add a new shot.

b In the **X**, **Y**, and **Z** boxes, enter the Leksell® coordinates of the shot.

c Click the **Set** button to add a new shot, or to confirm the changes made to an existing shot. The button is disabled if not all properties of a shot are specified, or if no changes have been made to an existing shot.

– Click the **Delete** button to delete the current shot from the run.

4 When a test run is completely specified, click the **Proceed** button to execute the test.

The **Clearance** tab becomes active and shows the clearance test run.

WARNING 5.83

Be careful when you use the tool and keep it in the intended location. If the tool gets damaged, it can have an effect on the precision of the tool, which can cause clinical mistreatment or damage to the equipment.

WARNING 5.84

If you think that the tool has been damaged because of a fall or other effect, do a QA check to make sure that the precision of the tool is satisfactory.

WARNING 5.85

During all movement of the couch during clearance check, make sure to keep the arm of the clearance tool clear of the patient's head. Otherwise injury to the patient may result.

5 Execute the clearance run, refer to *Performing clearance checks*.

Note the following important aspects:

– The correct patient is docked, but no verification of patient ID is done.

– The patient information area displays the name of the test run and the creation date.

5.16.4 Using the predefined test treatment function

5.16.4.1 Description of the predefined test treatment function

This function allows the user to perform a number of predefined test treatments

Note: *A predefined test treatment must not be used for treatment of patients. Using a predefined test treatment cannot replace treatment planning in Leksell GammaPlan®.*

5.16.4.2 List of predefined test treatments

The following predefined test treatments are available:

Table 5.4 Predefined test treatments

Name	Description
1ShotLong	A single run with a single shot, but with a very long shot time.
2Shots1Run	A single run with 2 short shots in the same gamma angle, but with different collimator sizes and target locations.
3targets	A single run covering 3 target volumes, each volume covered by multiple shots.
4mm collimators	A single run with a single 4 mm shot, with a very long shot time. This run is used for dosimetry functions. The accurate shot time is given in the user interface when you press the pause button.
8mm collimators	A single run with a single 8 mm shot, with a very long shot time. This run is used for dosimetry functions. The accurate shot time is given in the user interface when you press the pause button.
16mm collimators	A single run with a single 16 mm shot, with a very long shot time. This run is used for dosimetry functions. The accurate shot time is given in the user interface when you press the pause button.
50ShotsLong	A single run with 50 long shots in the same gamma angle, but with different collimator sizes and target locations.
50ShotsShort	The same treatment as **50ShotsLong**, but with short shot times.
ClearanceToolTest(Flextip)	A special test treatment intended for use during the manual QA check of the clearance tool.
Composite	A single run with 50 short shots and different collimator setups, including collimator setups with mixed collimator sizes.
ExtremePos	A single run with 8 short shots in the same gamma angle, but with different collimator sizes. Each shot has a target that represents a fairly extreme position without any risk of contact with the collimator cap.
Mask test treatment	A single run with a single 16 mm shot. Shot time is 30 min.
MultiRunClearanceSaferoute	Multiple runs in different gamma angles, including clearance runs and saferoute positions.
Normal	Multiple runs in different gamma angles, with different collimator sizes. No clearance runs or saferoute positions.
Sector activation	A special test run that activates all sectors for all collimator sizes during some shots.
Stand alone CBCT for coordinate frame	A CBCT scan for a coordinate frame treatment.
Stand alone CBCT for Mask	A CBCT scan for a mask treatment.

5.16.4.3 Doing a predefined test treatment

To do a predefined test treatment:

1 On the start page of the **Main** tab, click the **Test** button and select **Predefined** in the menu.

A list of predefined test treatments is displayed.

2 Select a predefined test treatment in the list and click the **Proceed** button.

3 In the **Verify patient data** page, enter the current date and click the **Accept** button.

The test treatment is done in the same way as a patient treatment. Note the following important aspects:

– No patient is docked.
– The frame adapter is docked in the correct gamma angle.
– You can always start a test treatment again when it is completed.

Related Links:

Treating a patient on page 102

5.17 Viewing system information

This function displays information about the current system.

1 On the start page of the **Main** tab, click the **Administration** button and select **About** from the menu.

The following system information is displayed:

– the product name of the Leksell Gamma Knife® Icon™ system
– the manufacturer of the Leksell Gamma Knife® Icon™ system
– the overall version of the control system software
– the version of the MCU system application
– the ID of the system
– the name of the manufacturer of freeware software used in the system.

2 To leave the page, click the **Close** button. This returns to the start page of the **Main** tab.

5.18 Using emergency procedures

5.18.1 Overview of emergency procedures

The emergency procedures are to be followed when a treatment session must be aborted due to an emergency situation in which there is a risk of injury to the patient or operator.

Following the emergency procedures may also be needed after a system error or if a contact with the collimator cap has occurred, as indicated by error messages in the system information area of the treatment monitor. System errors initiate an automatic Emergency Exit sequence.

To achieve the goal of a safe state, the following procedures or actions may need to be followed in an emergency situation.

- If the emergency situation requires immediate stopping of all couch and door movements, an emergency stop should be initiated by pressing the Emergency Stop button on the control panel. By resetting the button, an Emergency Exit sequence is initiated.
- If the emergency situation requires the patient to be taken out of the radiation unit, a treatment pause should be initiated by pressing the PAUSE button on the control panel. This is the most comfortable way for the patient to be taken out of the radiation unit. If the treatment pause sequence cannot be executed, the system initiates an Emergency Exit sequence.

- If the couch does not return to the home position properly, a manual pull-out of the couch is needed in the treatment room.
- If the couch cannot be pulled out manually, an emergency undocking of the patient must be performed.
- If the shielding doors do not close automatically, they must be manually closed.
- If the sectors do not return to the sector home position automatically, they must be manually closed.

If, during treatment, any part of the patient's head or the coordinate frame comes into contact with the collimator cap, an Emergency Stop sequence is automatically initiated. A manual pull-out of the couch is then required.

Related Links:

Using the emergency stop on page 181

Pulling out the couch on page 182

Undocking the patient in case of emergency on page 183

Closing the shielding doors manually on page 184

Closing the radiation sectors manually on page 185

Emergency Stop sequence on page 180

Emergency Exit sequence on page 181

Description of a treatment pause sequence on page 127

5.18.2 Safe state and radiation

The goal of the emergency procedures is to take the patient and the system to a safe state. A safe state is achieved when:

- The patient is taken out of the radiation unit.
- The shielding doors are closed and the radiation sectors are locked in the sector home position (the Beam off state).

When the sectors have returned to the sector home position, the emitted radiation in the treatment room is greatly reduced, even if the shielding doors are open. When entering the treatment room, check if the sectors have returned to their home position by inspecting the white lamp on the wall-mounted radiation warning lamp. If the white lamp is **not** lit, it is important to perform the emergency procedures as quickly as possible.

WARNING 5.86

Personnel entering the treatment room while the shielding doors are open and the sectors are not locked in the sector home position must keep their exposure time to a minimum. Overexposure to gamma radiation can endanger health.

Related Links:

Description of the radiation warning lamp on page 50

5.18.3 Emergency Stop sequence

The Emergency Stop sequence is initiated when the Emergency Stop button is pressed, or if contact with the collimator cap occurs. The following actions are taken by the system:

- The couch and shielding doors immediately stop and hold their position.
- The sectors return to the sector home position.
- An error message is displayed in the system information area of the treatment monitor.

5.18.4 Emergency Exit sequence

The Emergency Exit sequence is initiated when the Emergency Stop button is reset, or in the case of a system alarm. The following actions are taken by the system:

- The couch returns to the outmost position, going straight out in the Z direction.
- The shielding doors close.

These actions are the same as during the treatment pause sequence. The difference is that the Emergency Exit sequence is hardware controlled, faster, and less comfortable to the patient.

Related Links:

Description of a treatment pause sequence on page 127

5.18.5 Using the emergency stop

The Emergency Stop button is located in the upper right corner of the control panel. Optionally, local regulations may require other emergency stop buttons to be installed in the treatment room or elsewhere in the control room

Use the Emergency Stop button whenever there is an urgent risk of injury to patient or operator, and the movement of the couch and shielding doors must be stopped immediately.

1 Press the Emergency Stop button (1) on the control panel, or the optional emergency stop button in the treatment room.

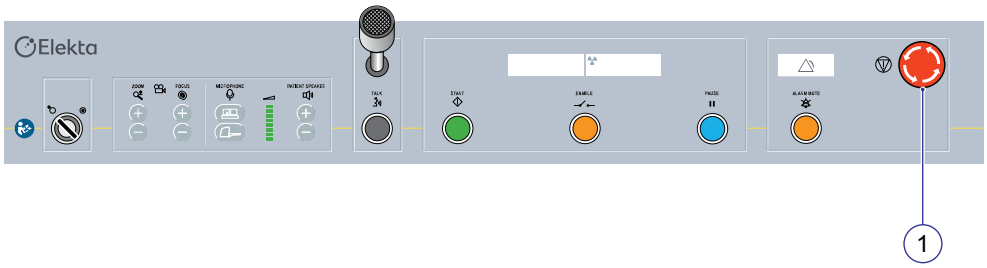


Figure 5.90 Emergency stop button on the control panel

The Emergency Stop sequence is initiated.

Related Links:

Emergency Stop sequence on page 180

5.18.6 Resetting an emergency stop

Resetting the emergency stop will initiate the Emergency Exit sequence and this will start the movement of the couch and shielding doors again.

1 Make sure that it is safe for the couch and shielding doors to move.

2 Reset the Emergency Stop button by turning it counter-clockwise as indicated by the arrows on the button.

The Emergency Exit sequence is initiated.

Related Links:

Emergency Exit sequence **on page 181**

5.18.7 Pulling out the couch

If the couch has not returned from the treatment position, or contact with the collimator cap has occurred, the patient must be withdrawn from the radiation unit as soon as possible by pulling out the couch by hand:

1 Enter the treatment room.

2 If contact with the collimator cap has occurred:

a On the left side of the couch, pull the couch release handle for X movement, labelled EMERGENCY X-RELEASE.

CAUTION 5.2

Do not pull or push the couch by using the side protection panels.

b Pull or push the couch slightly in the X direction towards the center position, so that any contact with the collimator cap is eliminated. Either **pull** the couch using the release handle, or **push** the couch by applying force to the **lower** part of the couch as indicated by the green arrows:

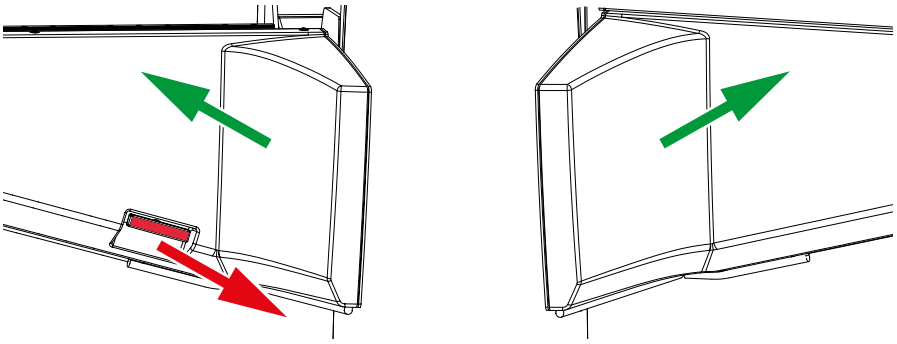


Figure 5.91 Pulling or pushing the couch in X direction

3 Pull the couch release handle for Z movement, labelled EMERGENCY Z-RELEASE.

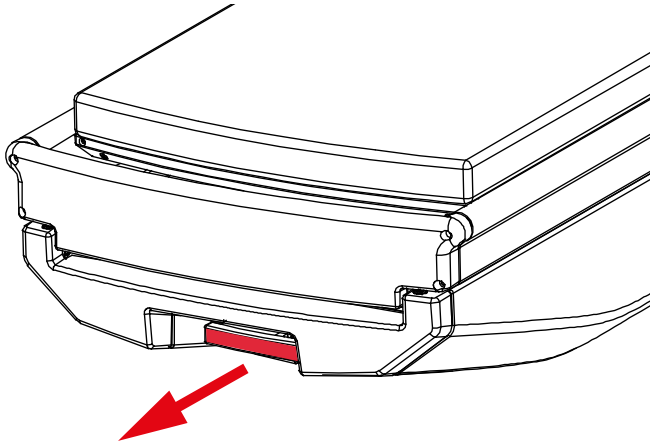


Figure 5.92 Pulling out the couch release handle for Z movement

4 Pull the couch out to the fully withdrawn position.

5 Unlock the frame adapter and assist the patient to a sitting position.

6 Assist the patient from the couch, and escort the patient out of the treatment room.

7 Push back the couch release handles into locking position (clutch engaged).

8 In the control room, acknowledge the error message. Let the system reset and execute the initialization sequence. In case a second system error occurs, acknowledge the error and let the system initialize completely.

9 If the shielding doors did not close during the initialization sequence, manually close the shielding doors.

10 Check if the radiation sectors have returned to the sector home position. This is the case if the white lamp on the wall-mounted radiation warning lamp is lit. If not, close the sectors manually.

Related Links:

Initializing the system on page 64

Closing the shielding doors manually on page 184

Closing the radiation sectors manually on page 185

Undocking the patient in case of emergency on page 183

5.18.8 Undocking the patient in case of emergency

If the couch cannot be pulled out manually, the patient must be undocked from the treatment position without withdrawal of the couch:

1 Fold down the IR camera arm and remove the knee support.

2 Go near the shielding door on the right side of the patient. If two persons, go to one side each.

3 Unlock the frame/mask adapter and release the patient from the docking position.

4 If the patient is positioned too far to the right, it may not be possible to unlock the frame/mask adapter, since the lever on the docking device cannot be moved properly. In that case, do the following and try again:

a On the left side of the couch, pull the couch release handle for X movement, labeled EMERGENCY X-RELEASE.

CAUTION 5.3

Do not pull or push the couch by using the side protection panels.

b Pull or push the couch to the left, so that it becomes possible to unlock the frame/mask adapter. Either **pull** the couch using the release handle, or **push** the couch by applying force to the **lower** part of the right side of the couch as indicated by the green arrow:

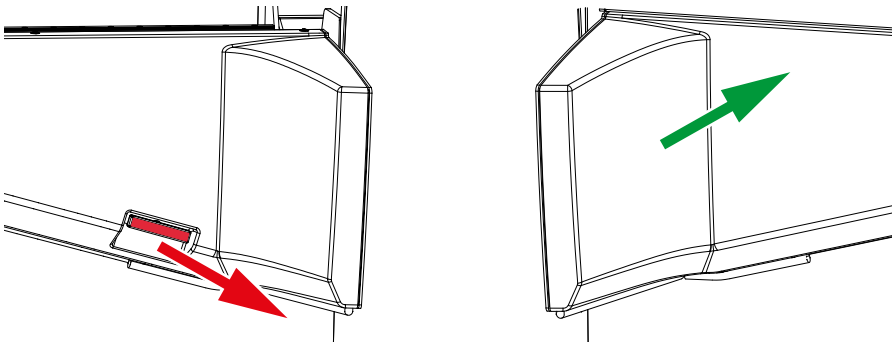


Figure 5.93 Pulling or pushing the couch to the left

5 Help the patient out of the radiation unit. Make sure that you hold the head of the patient.

6 Help the patient from the couch, and go out from the treatment room together with the patient.

7 Check if the radiation sectors have returned to the sector home position. This is the case if the white lamp on the wall-mounted radiation warning lamp is lit. If not, close the sectors manually.

Related Links:

Closing the radiation sectors manually on page 185

5.18.9 Closing the shielding doors manually

To close the shielding doors manually, proceed as follows:

1 Make sure that no objects are present in the opening of the shielding doors that would prevent the doors from completely closing.

2 On the patient left side of the radiation unit cover, open the small hatch to access the door mechanism.

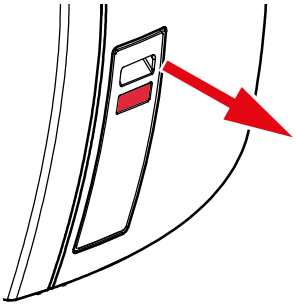


Figure 5.94 Opening the hatch to the door mechanism

3 Pull the release handle (1) outwards.

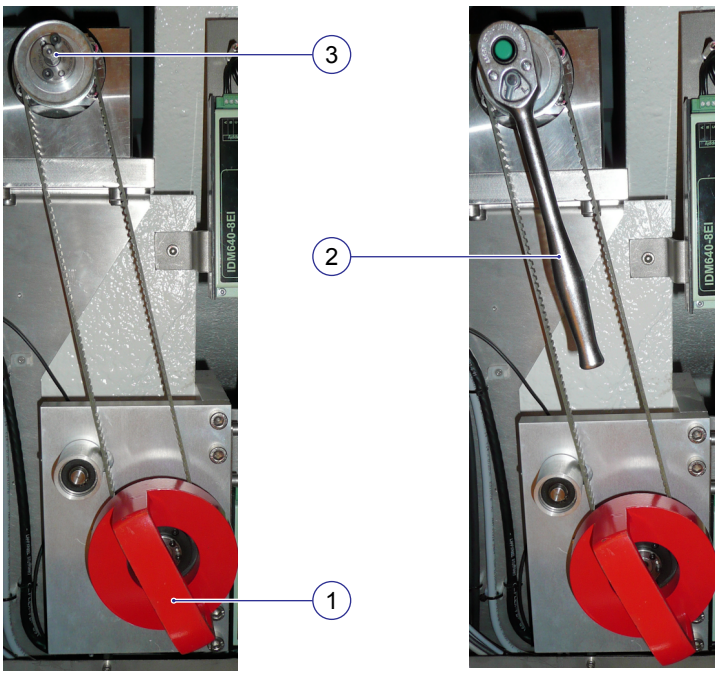


Figure 5.95 Door mechanism

4 Lift off the ratchet tool (2) placed on the inside of the door mechanism hatch and attach it to the shaft pivot (3) of the closing mechanism.

5 Turn the ratchet tool clockwise until the shielding doors are completely closed.

6 Place the ratchet tool back on the inside of the door mechanism hatch.

7 Push the release handle (1) back to the inmost position. Make sure that the handle really locks in the inmost position. If it does not, wiggle the handle at the same time as it is pushed.

5.18.10 Removing the rear RU cover

1 Carefully tilt (1) and remove (2) the rear section of the radiation unit cover.

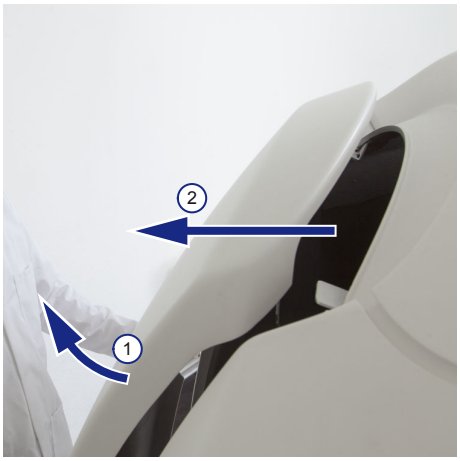


Figure 5.96 Removing the rear section of the radiation unit cover

Related Links:

Installing the rear RU cover on page 187

5.18.11 Closing the radiation sectors manually

If the radiation sectors have not returned to the sector home position, the sectors must be closed manually. The sectors' position are indicated by the white lamp on the wall-mounted radiation warning lamp. If the white lamp is not lit, close the sectors manually as follows:

1 Remove the rear section of the radiation unit cover.

2 In the ECU unit of the medical cabinet, turn off the power to the Sector Drive Unit (SDU) by using the switch (1) labelled 24V SDU.

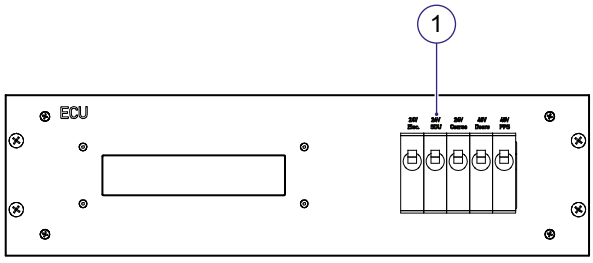


Figure 5.97 ECU with the SDU switch

At the rear of the radiation unit, the sector drive mechanics can be found. Each sector has a red handle (1) (see **Figure 5.98**) which can be used to pull the sector outwards to the end position (sector home position).

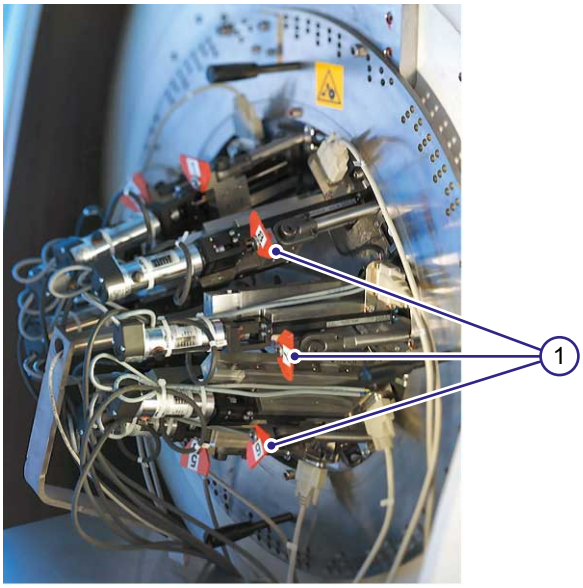


Figure 5.98 Sector Drive Unit

3 Inspect the position of each red handle. Manually pull each sector that is not in the sector home position outwards to the end position by pulling the red handle hard. When all sectors are in the sector home position, the white lamp on the wall-mounted radiation warning lamp is lit.

Note: *A certain amount of effort is required to start moving the sector handles.*

4 In the ECU unit of the medical cabinet, use the switch labelled 24V SDU to turn on the power to the Sector Drive Unit again.

Related Links:

Removing the rear RU cover on page 185

Installing the rear RU cover on page 187

5.18.12 Switching off the medical UPS

If it is necessary to fully switch off the medical UPS, do as follows:

1 Switch off the Mains circuit breaker (1).

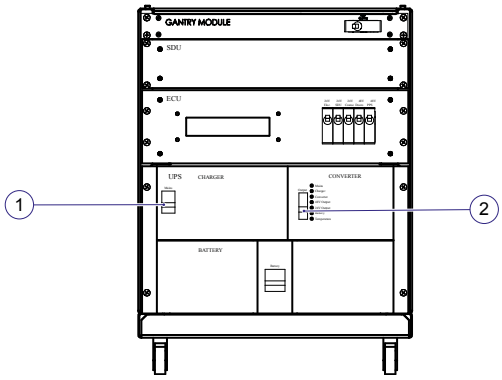


Figure 5.99 Medical UPS in the medical cabinet

2 Switch off the Output circuit breaker (2).

3 To switch on the medical UPS again, switch on the circuit breakers (1) and (2).

Related Links:

Removing the rear RU cover on page 185

5.18.13 Installing the rear RU cover

1 Carefully tilt (1) the rear RU cover and attach (2) the cover to the brackets (3) on the top cover.

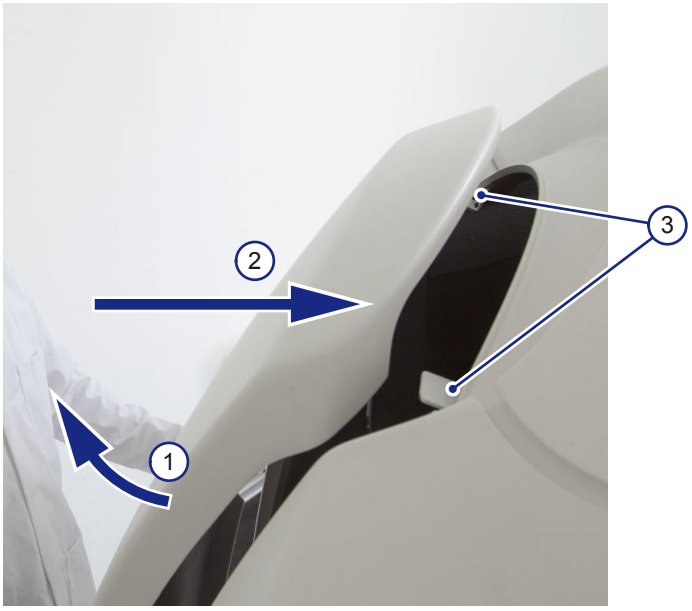


Figure 5.100 Installing the rear section of the radiation unit cover

2 Make sure that the the rear cover carriers are correctly attached to the brackets (3) on the top cover. Then lower the cover into position.

5.18.14 Switching off the office UPS: type 1 and 2

If it is necessary to fully switch off the office UPS, do as follows:

1 Press and release the Power Off button (1) or (3).

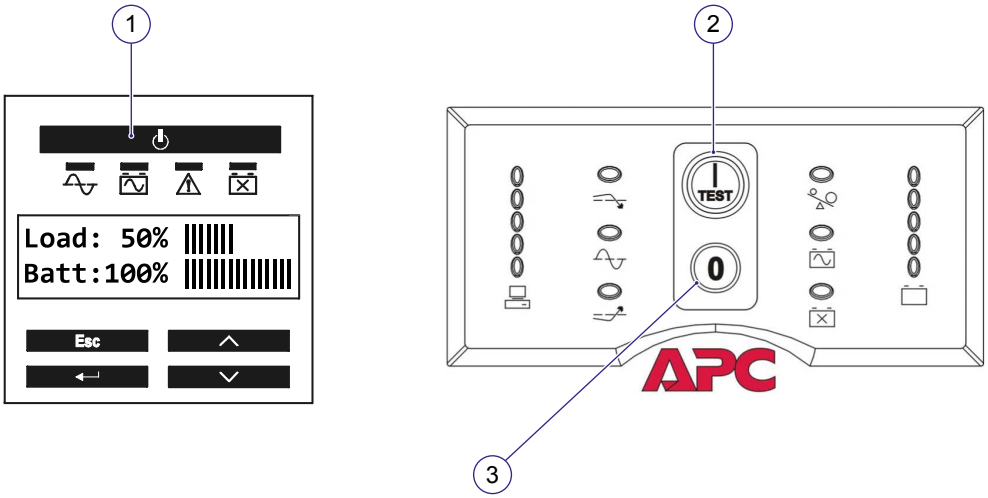


Figure 5.101 The control panel of the office UPS unit (two versions)

(1) On/Off button

(2) Self-test/On button

(3) Off button

On the office UPS version that shows to the left side in the figure, a message appears.

– Obey the instructions on the display to shut down the UPS.

2 To switch on the office UPS again, press the On button (1) or (2).

Related Links:

Description of the office UPS: type 1 and 2 on page 43

5.18.15 Switching off the office UPS: type 3 and 4 "Liebert"

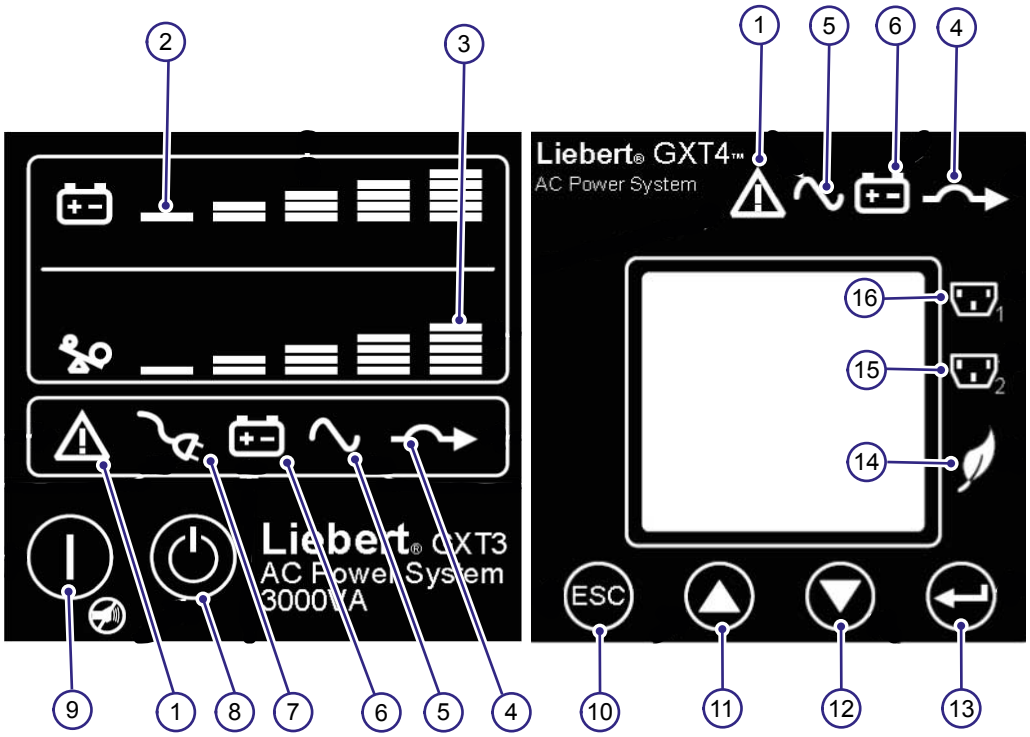


Figure 5.102 The office UPS type 3 and 4 display

(1)	Fault indicator	(9)	On/Alarm silence/Manual battery test button
(2)	Battery level indicators	(10)	ESC button
(3)	Load level indicators	(11)	Up button
(4)	Bypass indicator	(12)	Down button
(5)	Inverter indicator	(13)	Enter button
(6)	Battery indicator	(14)	ECO mode indicator
(7)	AC Input indicator	(15)	Programmable outlet2 indicator
(8)	Standby/Manual bypass button	(16)	Programmable outlet1 indicator

If it is necessary to fully switch off the office UPS type 3, do as follows:

1 Press the standby button (8) for 2 seconds. The bypass indicator (4) comes on.

2 Press the standby button (8) for 2 seconds, 2 times in less than 4 seconds.

The battery charge function and fan will be activated until the output is off and mains input is disconnected (30 seconds delay).

If it is necessary to fully switch off the office UPS type 4, do as follows:

1 Go to the Main Menu on the LCD:

   a Select CONTROL and press ENTER on the LCD.

   b Select TURN ON & OFF and press ENTER on the LCD.

   c Select TURN UPS OFF and press ENTER on the LCD.

   d Press the up button (11) or down button (12) to move the pointer and confirm the shutdown command. Press ENTER.

   You will hear an audible alarm and the power to the connected equipment is now off.

The office UPS type 4 display will illuminate because the batteries are still being charged. The office UPS type 4 display may now be disconnected from AC power and the UPS will completely shut down in approximately 15 seconds.

Related Links:

Description of the office UPS: type 3 and 4 "Liebert" on page 44

5.18.16 Switching on the office UPS: type 1 and 2

1 Press the **ON** button (7) or (4) of the office UPS unit.

The office UPS unit is installed at the bottom of the office cabinet. The control panel of the office UPS is available in two different versions:

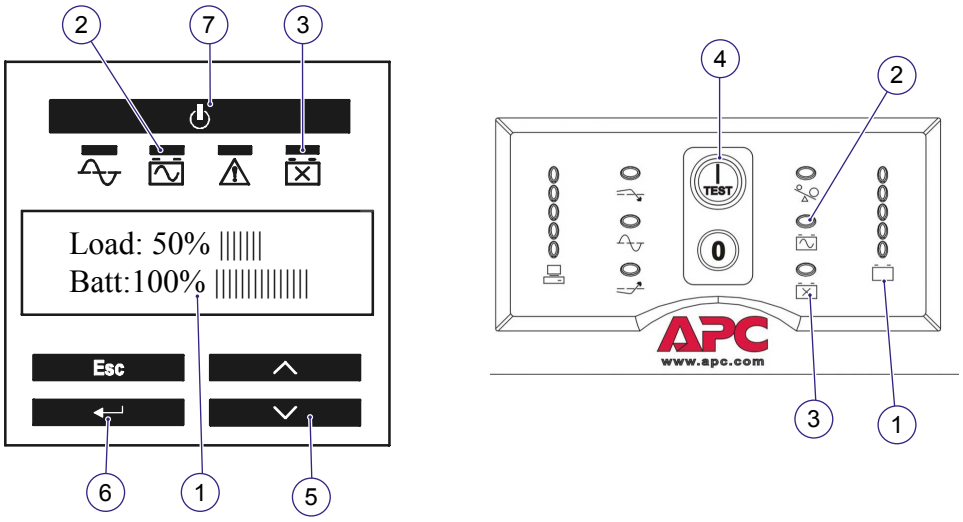


Figure 5.103 The office UPS

(1)	Battery level indicator	(5)	Up/down buttons
(2)	On Battery indicator	(6)	Enter button

(3)	Replace Battery indicator	(7)	On/off button
(4)	On and Self-test button		

Related Links:

Switching off the office UPS: type 1 and 2 on page 187

5.18.17 Switching on the office UPS: type 3 and 4 "Liebert"

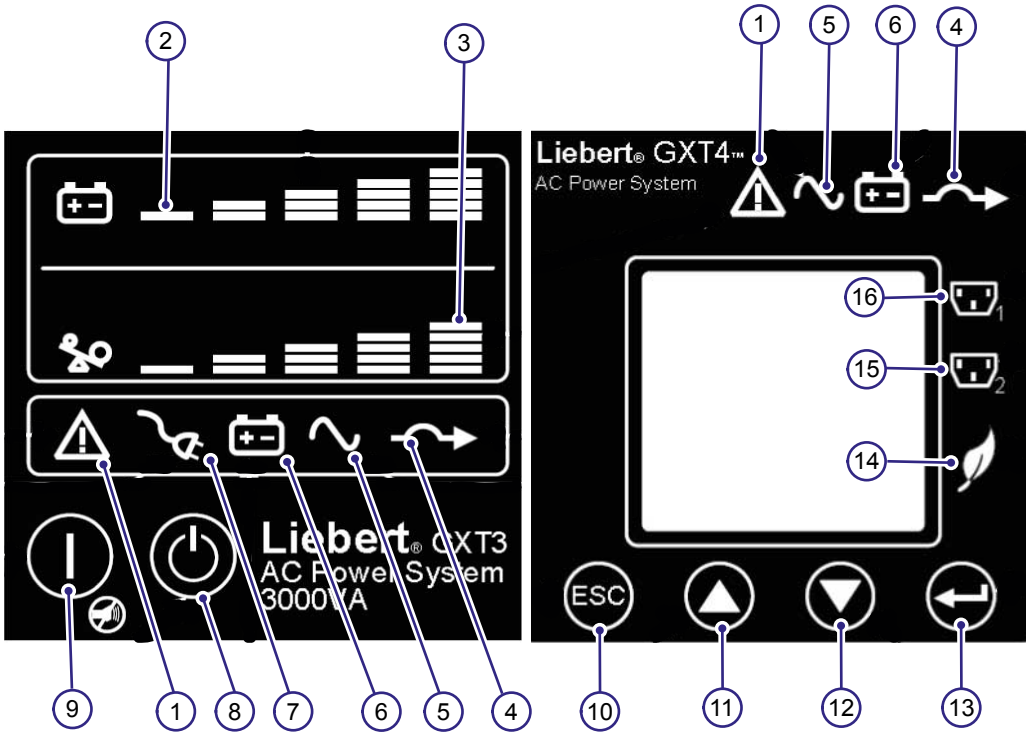


Figure 5.104 The office UPS type 3 and 4 display

(1)	Fault indicator	(9)	On/Alarm silence/Manual battery test button
(2)	Battery level indicators	(10)	ESC button
(3)	Load level indicators	(11)	Up button
(4)	Bypass indicator	(12)	Down button
(5)	Inverter indicator	(13)	Enter button
(6)	Battery indicator	(14)	ECO mode indicator
(7)	AC Input indicator	(15)	Programmable outlet2 indicator
(8)	Standby/Manual bypass button	(16)	Programmable outlet1 indicator

Start the office UPS type 3:

1 Press the on button (9) for 3 seconds.

When the inverter indicator (5) comes on, you can switch on the equipment connected to the UPS output.

2 If the UPS does not start, make sure that the input circuit breaker is pushed in. You find the circuit breaker at the rear of the UPS.

Note: *There is a delay after you have pressed the buttons until the UPS takes action.*

Start the office UPS type 4:

1 Connect the office UPS type 4 into the appropriate AC outlet.

2 When the AC power is present, the office UPS type 4 will begin the startup sequence.

You will hear an audible sound.

3 On the LCD:

a Press either the up button (11) or down button (12) once and press ENTER to switch on the office UPS type 4.

You will hear two audible sounds.

4 Make sure to examine the LCD and LED indicators so that they operate normal.

5 Examine the load percentage on the default screen to make sure that the connected equipment does not exceed the UPS rated capacity.

The office UPS type 4 now provides conditioned power to the connected load.

Related Links:

Switching off the office UPS: type 3 and 4 "Liebert" on page 188

5.19 Alarms

5.19.1 Overview of alarms

A control system monitors the operation of Leksell Gamma Knife® Icon™ and initiates alarms under certain conditions. Once an alarm has been initiated, interlocks incorporated into the system prevent a treatment from being started or continued until the alarm condition has been cleared.

There are two types of alarm, system alarms and emergency alarms. The control system initiates an Emergency Exit sequence automatically if there is a system alarm. If the Emergency Exit sequence cannot be executed, an emergency alarm is generated.

The cause or nature of the alarm is indicated on the control panel and/or in the system information area. Until the error message is acknowledged, the rest of the GUI is disabled and no functions of the system application are available.

Related Links:

Emergency Exit sequence on page 181

5.19.2 Resetting an alarm

Once the Emergency Exit sequence is completed and the cause of the alarm has been cleared, the interlocking can be reset as follows:

1 Click **Acknowledge** in the system information area.

The system then performs the initialization sequence. After the initialization sequence has completed, the **Main** tab of the GUI becomes available.

Related Links:

Initializing the system on page 64

5.19.3 Emergency alarm

An emergency alarm indicates a situation which has the potential to expose the patient or personnel to excessive radiation or some other hazard and requires immediate operator action.

The red Emergency alarm indicator on the control panel lights up and the alarm buzzer is activated. Information about the cause or nature of the alarm is shown in an error message in the system information area.

The alarm buzzer can be temporarily silenced by pressing the ALARM MUTE button on the control panel.

5.19.4 System alarm

A system alarm indicates that a fault has been found in the operation of the system. Information about the cause or nature of the alarm is shown in an error message in the system information area.

5.20 Troubleshooting

5.20.1 Troubleshooting a treatment run

A treatment may not be possible to start for the following reasons:

- If a treatment plan contains clearance runs, it is not possible to start any treatment run until all of the clearance runs have been completed.
- If any of the clearance positions were rejected during the clearance runs, you are not allowed to start the treatment.
- If one or several QA checks are overdue, it is not possible to start a treatment run.

1 If a treatment does not start, read the message in the **System information** area and obey the instructions in the table as follows:

Message	Instructions
`Complete all clearance runs in order to start treatment.`	– Complete all clearance runs.
`Clearance check failed due to rejected positions. You will not be able to perform this treatment.`	– If you think that the clearance check was not correctly done, reset all clearance runs and do the clearance check again. – If the positions were correctly rejected, you must do a new treatment plan.
`One or several QA checks are overdue. Treatments cannot be performed.`	– Do the QA check that is overdue.

Related Links:

Overview of QA checks on page 199

Performing clearance checks on page 134

5.20.2 Troubleshooting the CBCT

If a CBCT scan does not start or is stopped, you usually get a message in the **System Information** area.

1 If you have a problem with the CBCT, read the message in the **System Information** area. If applicable, obey the given instructions.

2 If the CBCT scan stops or does not start, Elekta recommend that you do a CBCT precision check before you try again with a clinical scan.

3 If the error continues, contact Elekta for more troubleshooting.

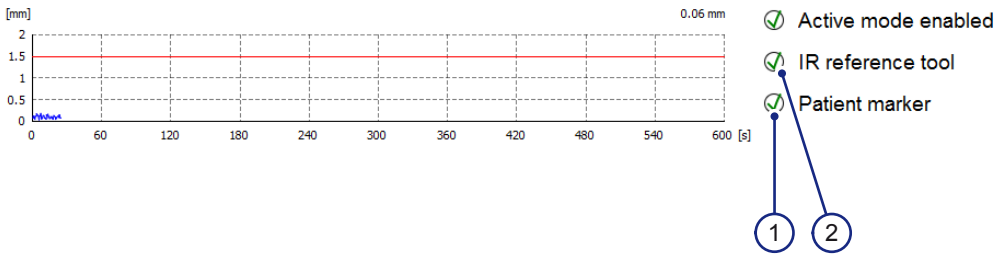
Related Links:

Doing a CBCT precision check on page 206

5.20.3 Troubleshooting the HDMM

If there is a problem with the HDMM, examine the system as follows:

1 If there are no check marks for the IR reference tool (1) or the Patient marker (2):



– Make sure that there is a clear view between the IR camera and the markers.

– Make sure that the IR camera arm is in correct position.

– Make sure that the markers are clean.

- Make sure that there are no other objects that make reflections in the view of the IR camera.
- Make sure that the lens of the IR camera is clean.
- If necessary, examine the IR camera:
  - Make sure that the two lamps are green.

If	Then
One of the lamps flashes green	The IR camera warms up
One of the lamps is yellow	Possible malfunction of the IR camera. Contact Elekta to find the cause of the malfunction.

2 If the **System Information** area shows the warning **The HDMM quality is low**, do as follows:

Note: *If the warning **The HDMM quality is low** is shown, the patient marker has moved to much, or has been invisible for the IR camera, during the calculation of the patient reference procedure. This can cause false HDMM alarms during the treatment.*

a Click **Accept**, or adjust the patient to a more comfortable position and then continue as follows:

If	Then
A CBCT scan was done	Do a new CBCT scan and continue with the treatment.
Vantage Head frame is used, and no CBCT was done	Undock the patient, and then dock the patient again and continue with the treatment.

5.20.4 Troubleshooting the computer security system

The GUI uses one of two status indicator icons to show if the computer security system operates or not.

The computer security system operates.

The computer security system does not operate.

1 If the computer security system does not operate, restart the MCU computer.

Related Links:

Switching off the system on page 64

Switching on the system on page 63

5.20.5 Blocked programs in the computer security system

When a program is blocked by the computer security system, a button with an icon appears adjacent to the status indicator icon. No harm has been done to the system. The incident is recorded in the log files.

The computer security system has blocked a file.

1 Click the button to show an information message in the system information area.

The message will be one of three types that shows the type of blocked program:

- **Windows Task Manager**
  - No action is necessary
- **File residing on an external device**
  - No action is necessary
- **File residing on an MCU internal device**
  - **Action**: Contact your Elekta® service representative.

Note: *The button is disabled during treatment and then has the tool tip: "The computer security system has blocked a file. More information is currently unavailable".*

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6 Maintenance

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6.1 User maintenance

6.1.1 Overview of QA checks

A number of QA checks must be performed by the user on a regular basis. Some of the QA checks are supported by the system application. Other QA checks must be performed manually.

WARNING 6.1

A failed QA check indicates a malfunction of the system or one of its components. Contact Elekta to determine the cause of the malfunction. No patient treatment should be started until the QA check has passed.

Table 6.1 QA checks

QA check	Type of check	Required interval	Recommended interval	Description
Focus precision	Supported by system application	1 / month[1]	2 / month	To make sure that the current location of the radiological focus point is satisfactory.
CBCT precision	Supported by system application	1 / month[2]	1 / day	To make sure that the CBCT precision is satisfactory.
CBCT image quality	Manual	2 / year	1 / month	To make sure that the CBCT image quality is satisfactory.
Emergency alarm	Supported by system application	1 / month	2 / month	An audiovisual verification of the emergency alarm in the control room.
Emergency stop	Manual	1 / month	2 / month	For verifying the function of the Emergency Stop button and the Emergency Exit sequence.
Side protection interlock	Manual	2 / year	1 / month	For verifying that the two side protection interlocks, visible in the **System's checklist** area, are working correctly.
Treatment room door interlock	Manual	2 / year	1 / month	For verifying that the treatment room door interlock, visible in the **System's checklist** area, is working correctly.
PAUSE button	Manual	2 / year	1 / month	For verifying that the PAUSE button on the control panel is working correctly.
Manual control buttons	Manual	2 / year	1 / month	For verifying that the dead man's switch on the couch manual controls is working correctly.
Clearance tool	Manual	2 / year[3]	1 / month	For verifying the accuracy of the clearance tool.

[1] And when the frame adapter or the QA tool may have been damaged.
[2] And when the frame adapter, QA tool or the gantry may have been damaged.
[3] And when the clearance tool may have been damaged.

Related Links:

Doing a focus precision check on page 204

Doing a CBCT precision check on page 206

Evaluating the CBCT image quality on page 207

Doing an emergency alarm check on page 215

Doing an emergency stop check on page 216

Examining the side protection interlocks on page 217

Examining the treatment room door interlock on page 217

Examining the pause function on page 217

Examining the manual control buttons on page 217

Doing a clearance tool check on page 218

6.1.1.1 The page QA overview

The **QA overview** page lists the QA checks that can be performed in the system application:

- **Focus precision**
- **CBCT precision**
- **Emergency alarm**.

For each QA check, the following information is given:

- the name of the check
- when the check was performed last
- the result of the check (**Passed** or **Failed**)
- the user name of the operator who performed the check
- when the check must be performed next
- a comment.

The comment can be one of the following:

- **Pending**: The QA check must be performed during the current day. Otherwise, it becomes overdue (see below).
- **Overdue**: The QA check has not been performed during the required time frame. It is not possible to perform patient treatments until the QA check has been performed with a result of **Passed**.

Note: *The columns in the list cannot be resized. If a text is too long to fit in a column, the text is truncated, but the full text can be seen by resting the pointer over the truncated text. The full text then appears as a tool tip.*

6.1.1.2 Using the QA tool to do QA checks

The QA tool is used to do the QA check Focus Precision, QA check CBCT precision, and QA check Clearance tool.

The QA tool is used together with a frame adapter. The frame adapter is attached to the QA tool, and then docked to the docking device of the patient couch.

There are two QA tools availabe for Leksell Gamma Knife® Icon™:

- QA tool Plus - to use with the G-frame adapter
- QA tool Vantage - to use with the Vantage frame adapter

When you select which QA check to do in the system application, there are two options for each QA check:

- **QA check Focus precision for Standard G**
- **QA check Focus precision for Vantage**
- **QA check CBCT precision for Standard G**
- **QA check CBCT precision for Vantage**
- **ClearanceToolTest (Flextip) for Standard G**
- **ClearanceToolTest (Flextip) for Vantage**

Related Links:

Attaching the G-frame adapter to the QA tool on page 201

Attaching the Vantage frame adapter to the QA tool Vantage on page 202

Doing a focus precision check on page 204

Doing a CBCT precision check on page 206

Doing a clearance tool check on page 218

Attaching the G-frame adapter to the QA tool

To attach the frame adapter to the QA tool is done in a way similar to attaching the frame adapter to the coordinate frame.

WARNING 6.2

Handle the frame adapter with care. Any damage may affect the precision of the frame adapter, which may lead to clinical mistreatment and/or contact with the collimator cap during treatment. If you suspect that the frame adapter may have been damaged due to a drop or other impact, the precision of the frame adapter must be verified before a treatment is started. Contact Elekta or perform a focus precision QA check.

1. Place the QA tool standing on its long posts, on the couch or other flat surface.
2. Release the securing screw and the 3 levers on the frame adapter.
3. Turn the frame adapter upside down, place it below the base plate of the QA tool, and raise it towards the base plate. Make sure the locating pins on the frame adapter is inserted into the corresponding holes on the base plate.
4. When the frame adapter has been fitted to the base plate, lock the 3 levers. Attach and tighten the securing screw.

Related Links:

Docking the G-frame adapter and QA tool to the docking device on page 201

Docking the G-frame adapter and QA tool to the docking device

Prerequisites

Before this procedure is done, the frame adapter has to be attached to the QA tool.

To dock the frame adapter with the QA tool in the docking device:

1. Unlock the docking device.

2 Make sure the posts on the QA tool point in the direction towards the radiation unit. Place the frame adapter so that the attachment pins align with the attachment points on the docking device.

3 Adjust the frame adapter so that it is attached in the correct gamma angle (90).

4 Lock the docking device.

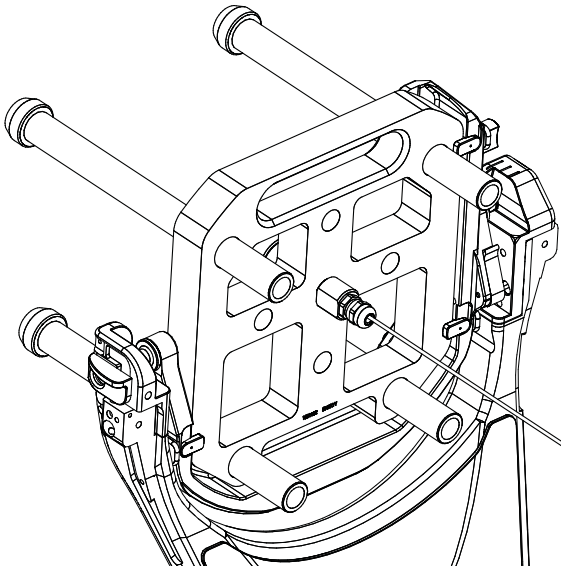

Figure 6.1 The QA tool docked to the docking device

Related Links:

Attaching the G-frame adapter to the QA tool on page 201

Unlocking the docking device on page 154

Locking the docking device on page 153

Attaching the Vantage frame adapter to the QA tool Vantage

WARNING 6.3

Before the QA tool is used, make sure that the tool has reached a stable room temperature.

To attach the Vantage frame adapter to the QA tool:

1 Put the QA tool Vantage on a flat surface.

2 Release the left and right levers on the Vantage frame adapter, see **Figure 6.2**.

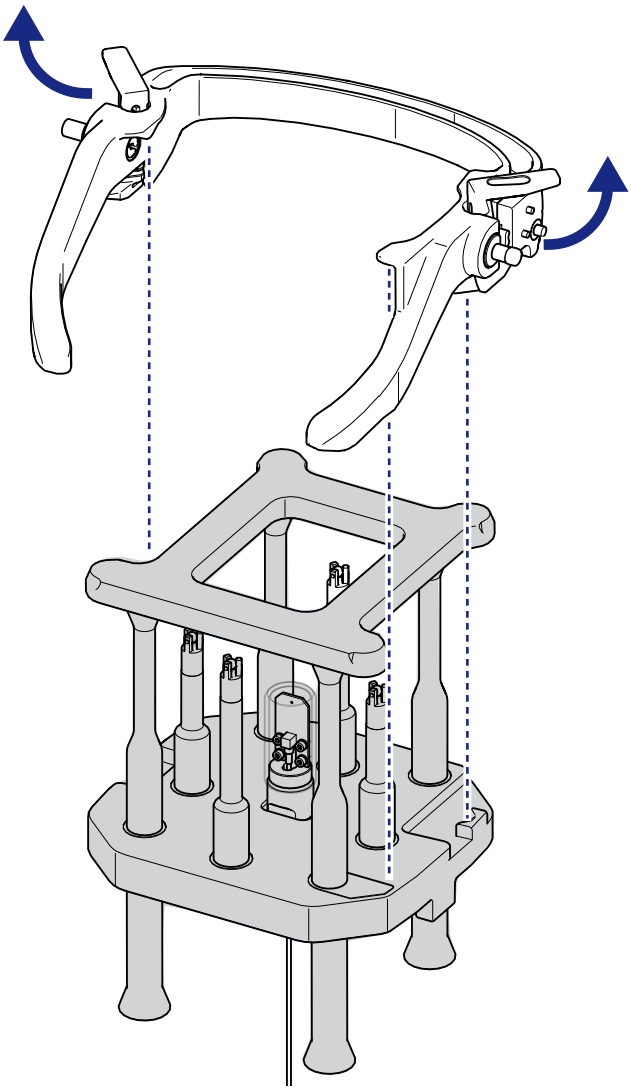

Figure 6.2 Attaching the Vantage frame adapter to the QA tool Vantage

3 Hold the Vantage frame adapter above the QA tool, with the four reflector markers pointing down.

4 Lower the Vantage frame adapter and fit it on the three interface areas on the base plate of the QA tool.

5 Turn and fold down the left and right levers to lock the frame adapter on the QA tool, see **Figure 6.3**.

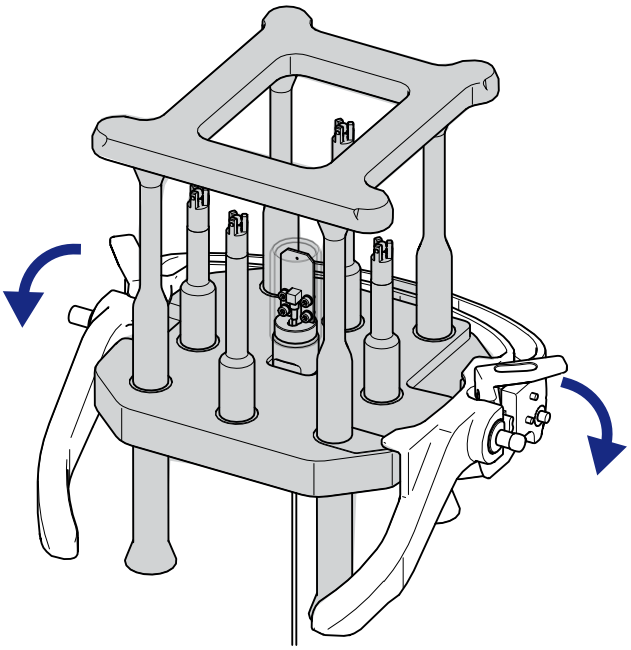

Figure 6.3 Lock the Vantage frame adapter to the QA tool Vantage

Related Links:

Docking the Vantage frame adapter and QA tool Vantage to the docking device on page 204

Docking the Vantage frame adapter and QA tool Vantage to the docking device

Prerequisites

Before this procedure is done, the Vantage frame adapter is attached to the QA tool Vantage.

To dock the frame adapter with the QA tool in the docking device:

1. Unlock the docking device.
2. Make sure the front plate on the QA tool point in the direction towards the radiation unit. Place the frame adapter so that the attachment pins align with the attachment points on the docking device.
3. Adjust the frame adapter so that it is attached in the correct gamma angle (90°).
4. Lock the docking device.

Related Links:

Attaching the Vantage frame adapter to the QA tool Vantage on page 202

Unlocking the docking device on page 154

Locking the docking device on page 153

6.1.1.3 Doing a focus precision check

This QA check is required to do once a month, or when the frame adapter or the QA tool may have been damaged. This QA check is done with the QA tool in the treatment room.

During this QA check, the system measures the position of the focus point and compare it with the calibrated position.

To do the QA check focus precision:

1 Before you start the QA check, make sure that the QA tool has reached the treatment room temperature.

2 On the start page of the **Main** tab, click the **QA** button.

A **QA** tab is added and the page **QA overview** opens.

3 Select the check **Focus precision** for the applicable frame fixation, and click the **Select check** button, or double-click the check in the list.

The page **QA focus precision check** for the applicable frame fixation opens.

4 Go into the treatment room. Make sure that you can clearly read the **Instructions** area on the treatment room monitor when standing alongside the head end of the patient couch.

WARNING 6.4

Handle the QA tool with care and store it in the intended place. Any damage may affect the precision of the tool, which may lead to incorrect results of QA checks.

If you suspect that the QA tool may have been damaged due to a drop or other impact, the precision of the QA tool must be verified. Contact Elekta for instructions on how to proceed.

5 From their storage place, take out the QA tool and the frame adapter. Attach the frame adapter to the QA tool.

6 Dock the frame adapter with the QA tool in the docking device.

CAUTION 6.1

Handle the cable for the QA tool with care and place the weight of the cable behind the base plate. During couch movement, visually check that the cable does not get stuck or stretched.

7 Connect the cable from the QA tool to the connector, which is placed either below the mattresses or in the patient intercom panel. If both connectors are present, use the connector below the mattresses.

8 In the **System's checklist** area on the treatment room monitor, make sure that the gamma angle interlock specifies the correct gamma angle, and that all of the other physical interlocks are set, except for the treatment room door interlock.

9 Go out from the treatment room and close the door.

Up to this point, you can click **Discard** to cancel the focus precision check and return to the **QA overview** page. Once the focus precision check run has been started, it can only be aborted by pressing the PAUSE button or the Emergency Stop button on the control panel.

10 Press and release the START button on the control panel (green color).

The QA check is done automatically:

- The shielding doors opens and the couch moves to predefined start position.
- When the start position is reached, you hear a signal. The couch with the QA tool moves along the three coordinate axis and the signal level of the diode is measured and displayed.
- When the measurement is done, the couch moves to home position. The shielding doors closes.
- The result of the QA check is shown in **Nominal position**, **Calculated deviation**, and **Result**. If the calculated deviation of the focus point compared to the calibrated focus point is within acceptable limits (≤0.4 mm radial), the result is **Passed**, otherwise the result is **Failed**.

11 Click **Save** to save the date and result of this QA check. Click **Discard** to discard the result of this check.

Note: *To discard a result of **Failed** is only possible if the QA check is not already overdue.*

12 On the **QA overview** page, click the **End QA** button to return to the **Main** tab.

Related Links:

Description of the QA tool Plus on page 55

Description of the QA tool Vantage on page 56

The page QA overview on page 200

Using the QA tool to do QA checks on page 200

6.1.1.4 Doing a CBCT precision check

This QA check is required to do once a month but Elekta recommends that you do it daily. You must also do this QA check when the frame adapter, QA tool or the gantry may have been damaged. The QA check is performed by using the QA tool in the treatment room.

During this QA check, the system measures the position of the steel balls on the QA tool and compare with the calibrated positions.

To do the QA check CBCT precision:

1 Before you start the QA check, make sure that the QA tool has reached the treatment room temperature.

2 On the start page of the **Main** tab, click the **QA** button.

A **QA** tab is added and the page **QA overview** opens.

3 Select the check **CBCT precision** for the applicable frame fixation, and click the **Select check** button, or double-click the check in the list.

The enlarged GUI page **QA CBCT precision check** for the applicable frame fixation opens.

4 Go into the treatment room. Make sure that you can clearly read the **Information** area on the treatment room monitor when standing alongside the head end of the patient couch.

5 From their storage place, take out the QA tool and the frame adapter. Attach the frame adapter to the QA tool.

WARNING 6.5

Handle the QA tool with care and keep it in the intended place. Any damage may affect the accuracy of the tool, which may lead to incorrect results of QA checks.

If you suspect that the QA tool may have been damaged due to a drop or other impact, the accuracy of the QA tool must be verified. Contact Elekta for instructions on how to proceed.

6 Dock the frame adapter with the QA tool in the docking device.

7 Make sure that the interlocks in the enlarged GUI view are set.

8 Obey the instructions on the treatment room monitor to move the couch and gantry to the scan position.

9 Go out from the treatment room and close the door.

Up to this point, you can click **Discard** to cancel the CBCT precision check and return to the **QA overview** page.

10 Press and hold the START and ENABLE buttons on the control panel.

Do not release the buttons before the CBCT scan is completed. If you release the buttons, the CBCT scan stops and you must manually park the CBCT equipment to be able to

continue. If you have stopped the scan, go into the treatment room and obey the instructions on the treatment room monitor to park the equipment.

The QA check is done automatically:

– The QA tool is scanned and the positions of the steel balls on the QA tool are measured. These positions are then compared to the calibrated positions.

11 When the scan is completed, release the START and ENABLE buttons.

The result of the QA check is shown in **Maximum deviation in image volume**, **Calculated fiducial deviation**, and **Result**. If the calculated deviation of the image volume compared to the calibrated measurements, is within acceptable limits (≤0.4 mm radial), the result is **Passed**, otherwise the result is **Failed**, see **Figure 6.4**

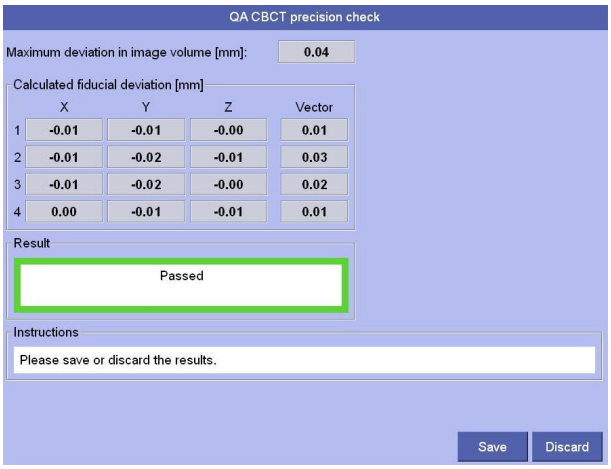

Figure 6.4 CBCT precision check values

12 In the system information area, click **Manual** (1) or **Automatic** (2) to move the CBCT equipment to park position and the couch to home position.

13 Click **Save** to save the date and result of this QA check. Click **Discard** to discard the result of this check.

Note: *To discard a result of **Failed** is only possible if the QA check is not already overdue.*

14 On the **QA overview** page, click the **End QA** button to return to the **Main** tab.

Related Links:

Description of the QA tool Plus on page 55

Description of the QA tool Vantage on page 56

The page QA overview on page 200

Using the QA tool to do QA checks on page 200

6.1.1.5 Evaluating the CBCT image quality

How to evaluate the CBCT image quality.

Installing the Catphan phantom

How to install the Catphan phantom

Note: *For temperature equalization, make sure that the tool has been removed from the packaging and stored in the room for at least four hours before usage.*

1 Install the phantom base plate (2) in 90° to the docking device in the PPS. Make sure that it is correctly docked. See **Figure 6.5**.

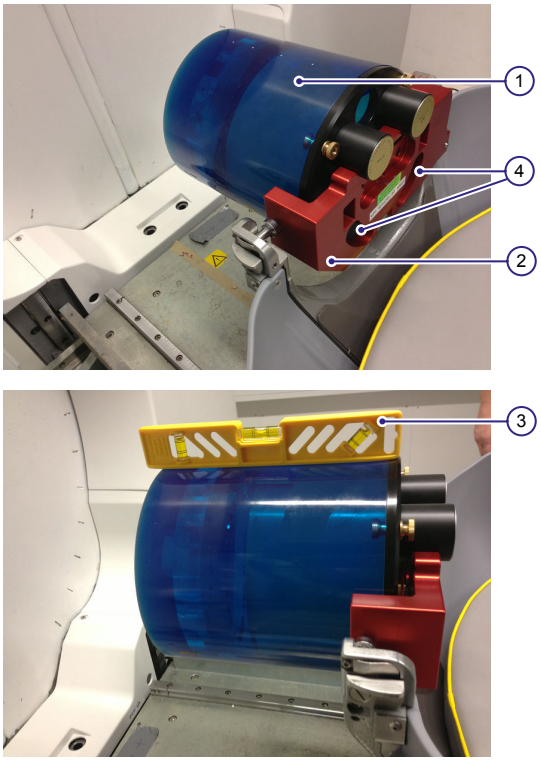

Figure 6.5 Installed Catphan phantom

(1)	Catphan phantom	(3)	Spirit level
(2)	Phantom base plate	(4)	Thumb screw x 2 (black)

2 Install the Catphan phantom (1) to the phantom base plate (2).

   a Make sure that the Catphan phantom (1) is aligned to center on the phantom base plate (2).

3 Put a spirit level (3) on top of the phantom (1).

   If the phantom is not level

   a Use the black thumb screws (4) on the side of the phantom (1) to adjust the level.

Creating a patient

1 In the Leksell GammaPlan® application, on the **Patient** menu, select **Patient Management**.
2 Click **New** and select **Create a new patient**. Click **OK**.
3 In the **New Patient** window, type and select the data for a new patient. Click **OK**.
4 On the **Plan** menu, click **Fixation configuration**.
5 Select the applicable fixation, and click **Save**.
6 On the **Patient** menu, select **Request CBCT** and then **Stand alone**.
7 In the Leksell Gamma Knife® application, click **Treatment** and select the created patient. Click **Proceed**.
8 Make sure that the patient data is correct and click **Accept**.

Doing a scan

How to do a scan

1 Obey the instructions on the screen.

a Move the PPS to scan position.

b Move the tilt arm to scan position with the controls on the PPS.

c Move the C-arm to scan position with the controls on the PPS.

WARNING 6.6

Go out from the treatment room before you activate the X-ray generator. Too much X-ray radiation exposure can cause fatal injury.

2 In the image viewer, select a **CBCT setting**. You must do the test on both settings during this evaluation.

– CTDI 2.5

– CTDI 6.3

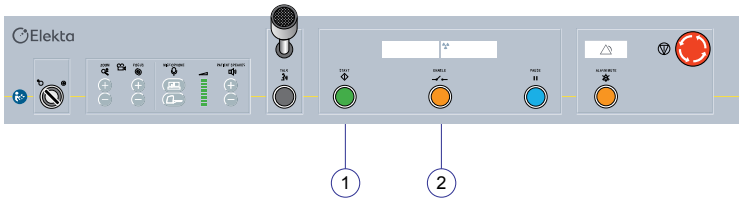

Figure 6.6 START and ENABLE buttons on the Console Panel

(1) START button (2) ENABLE button

The START and ENABLE button lights (1 and 2) come on when the system is ready for scan.

3 Press and hold down the START and ENABLE buttons (1 and 2) simultaneously on the control panel to do a scan.

The START and ENABLE buttons (1 and 2) on the control panel must be pressed and hold down until a full scan is completed.

To abort an ongoing scan before completed, release the START and ENABLE buttons (1 and 2) on the control panel.

The scan is completed when the START and ENABLE button lights (1 and 2) go off .

4 When the scan is completed, release the START and ENABLE buttons (1 and 2) on the control panel.

Measuring the spatial resolution

How to measure the spatial resolution

1 Use the scroll bars to move the image probe and find the image stack section that shows the line pairs. See **Figure 6.7** .

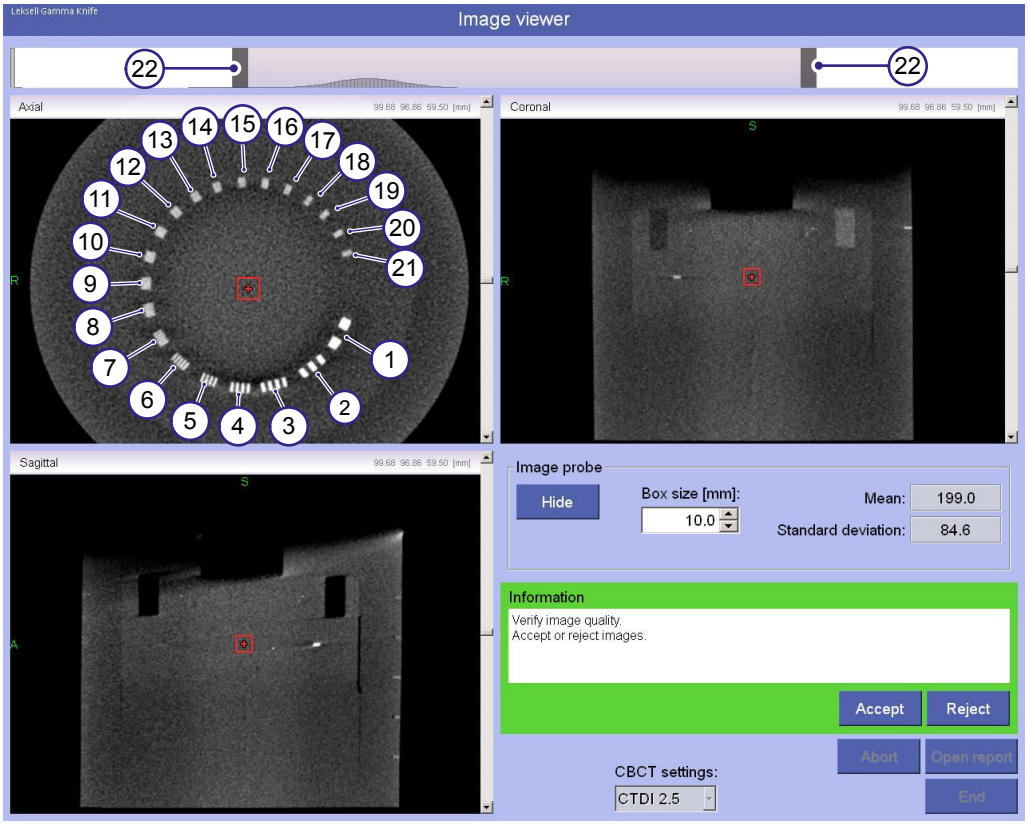

Figure 6.7 Image stack section with line pairs

(1) - (21)	1 - 21 line pair/centimeter (lp/cm)	(22)	Handle

2 Use the handles (22) at the top of the window to adjust the contrast of the images.

3 Right-click and drag to zoom in or zoom out the image until the spatial resolution module fills the image area.

4 Find the highest numbered line pair in **Figure 6.7** where each of the lines within the line pair can be seen clearly.

See **Figure 6.8** to find out more about the lines within a line pair.

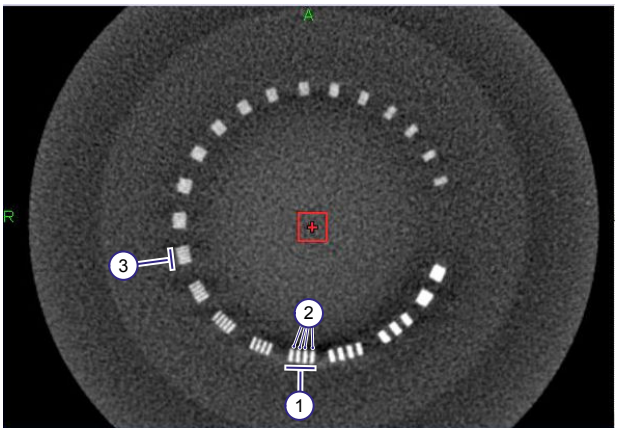

Figure 6.8 Lines within a line pair

(1) Line pair with clear lines

(2) Lines within a line pair

(3) Line pair with no clear lines

Table 6.2 Spatial resolution example values

	Example value
Spatial resolution (lp/cm) with 2.5 mGy CTDI preset	7
Spatial resolution (lp/cm) with 6.3 mGy CTDI preset	8

A minimum of 6 line pairs per centimeter (lp/cm) shows that the spatial resolution is in specification.

5 Record the result.

Measuring the contrast to noise ratio (CNR)

Measuring the contrast to noise ratio

1 Use the scroll bars to move the image probe and find the image stack section that shows the material inserts. Move to the center of the image stack section where the marker (4) is shown. See **Figure 6.9**.

2 Use the handles (5) at the top of the window to adjust the contrast of the images.

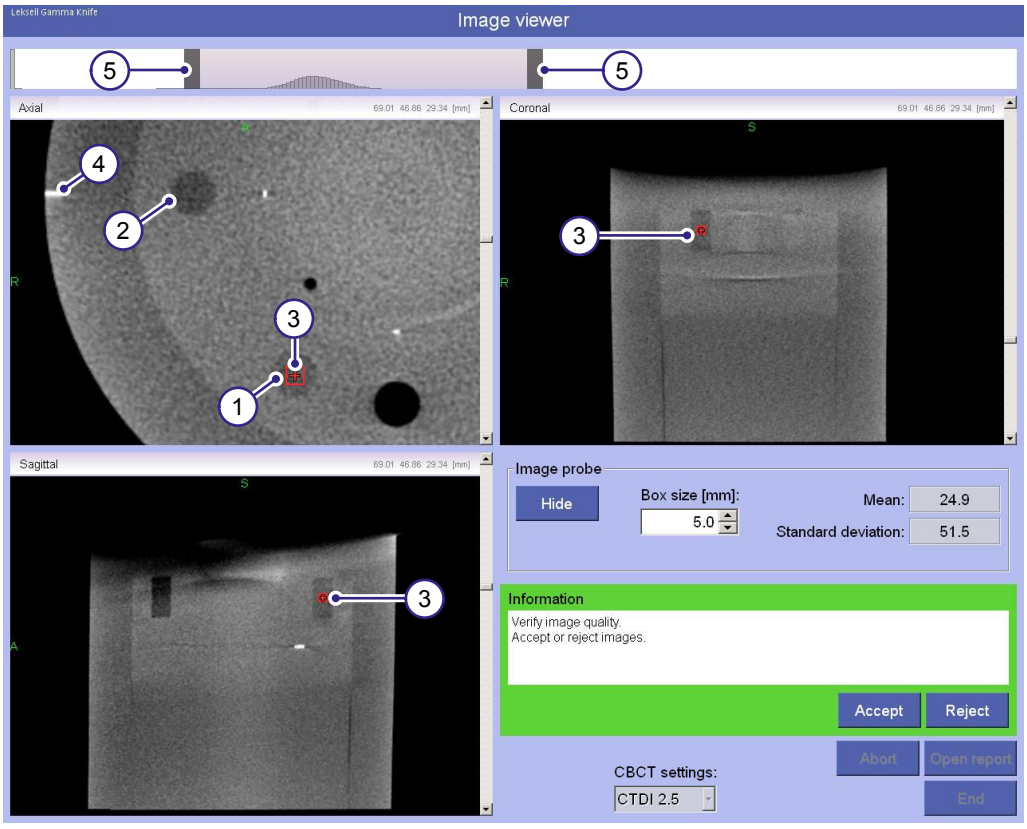

Figure 6.9 Image stack section with material inserts

(1) Polystyrene insert
(2) LDPE insert
(3) Image probe position
(4) Marker of the section center
(5) Handle

3 Right-click and drag to zoom in or zoom out the image until the polystyrene insert fills the image area.
4 Click **Show** to display the **Image probe** values.
5 Set the **Box size** for the image probe to 5.0 mm.
6 Put the image probe on the center of the polystyrene insert (1), and then click the mouse button.
7 From the **Image probe** dialog box, record the results of the **Mean** (pixel value) and **Standard deviation** of the contrast polystyrene insert.
8 Do steps 6 to 7 again for the LDPE insert (2).
9 Calculate the contrast to noise ratio (CNR) with the values from step 7 . Use the formula in Figure 6.10.

$$Contrast\ to\ noise\ ratio\ (CNR) = \frac{\bar{I}_{PS} - \bar{I}_{LDPE}}{\sqrt{\sigma_{PS}{}^2 + \sigma_{LDPE}{}^2}}$$

Figure 6.10 Formula to calculate contrast to noise ratio

Mean pixel values ($\bar{I}$) and standard deviations (σ) in the polystyrene (PS) and LDPE inserts are the variables used in the formula.

The reference values in Table 6.3 shows that the contrast to noise ratio is in specification.

Table 6.3 Reference values for the CNR result

	Reference value
Contrast to noise ratio (CNR) with 2.5 mGy CTDI preset	> 0.5
Contrast to noise ratio (CNR) with 6.3 mGy CTDI preset	> 0.8

10 Record the results.

Examples of the above formula with set values used:

Table 6.4 Example values of contrast polystyrene and LDPE insert

Insert	Mean pixel value (Mean)	Standard deviation (SD)
Polystyrene with 2.5 mGy CTDI preset	-26.8	80.2
LDPE with 2.5 mGy CTDI preset	-113.3	83.3
Polystyrene with 6.3 mGy CTDI preset	-25	48.2
LDPE with 6.3 mGy CTDI preset	-130.8	57.7

Table 6.5 Examples of CNR result

Contrast to noise ratio (CNR) with 2.5 mGy CTDI preset	0.75
Contrast to noise ratio (CNR) with 6.3 mGy CTDI preset	1.41

Measuring the uniformity

How to measure uniformity

1 Use the scroll bars to move the image probe (1) and find the image stack that shows the homogenous section. Move to the center of the image stack section where the marker (2) is shown. See **Figure 6.11**.

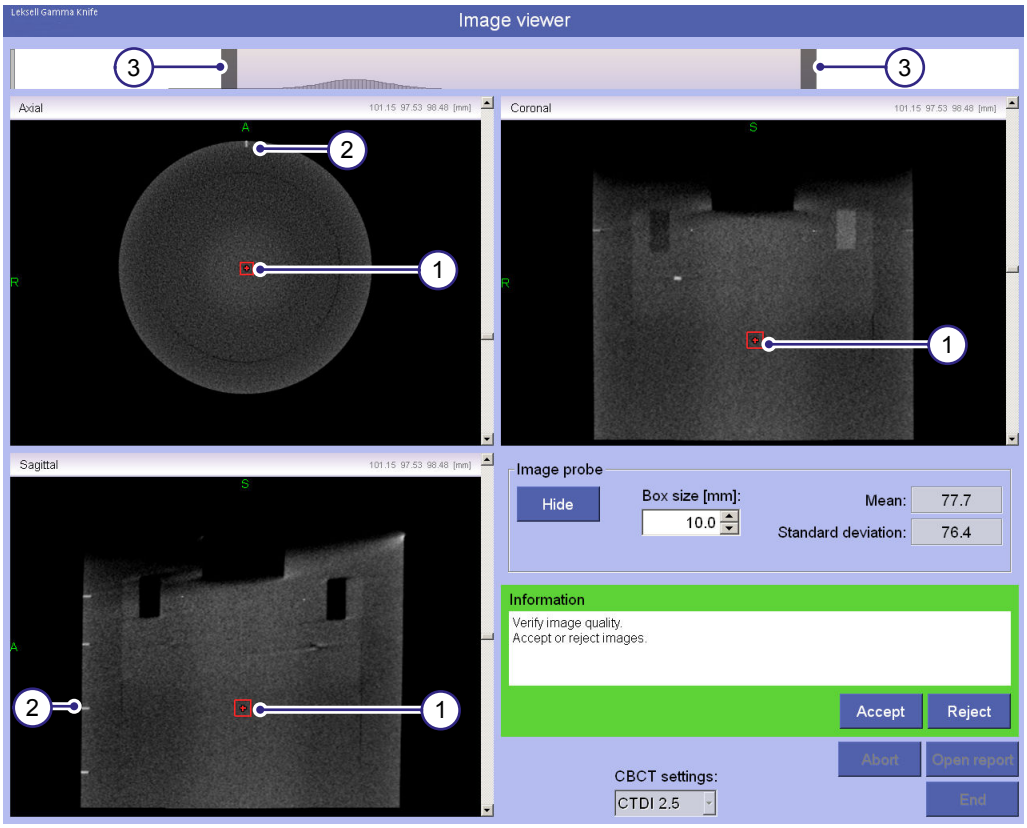

Figure 6.11 Image stack with homogenous section

(1) Image probe position

(2) Marker of the section center

(3) Handle

2 Use the handles (3) at the top of the window to adjust the contrast of the images.

3 Right-click and drag to zoom in or zoom out the image until the uniformity module fills the image area.

4 Set the **Box size** for the image probe to 10.0 mm.

5 Set the position of the image probe within ±3 mm of the phantom center (1), see **Figure 6.12**. Record the **Mean** pixel value.

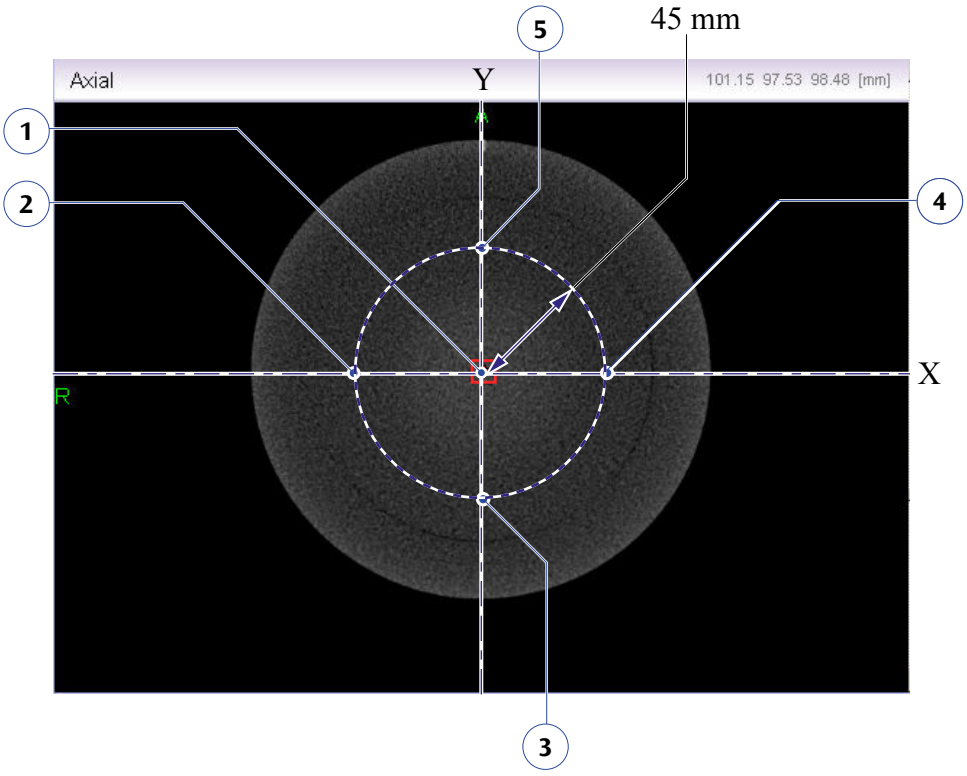

Figure 6.12 Phantom center

6 Set the image probe to a total of five different positions (1 - 5) in the image. The coordinates are shown in the upper right corner of the image.

The positions 2 - 5 must be 45 ±1 mm from the phantom center (1), see **Figure 6.12**.

7 Record the **Mean** pixel values for all selected positions 1 - 5.

8 Calculate the maximum percentage difference of the highest **Mean** pixel values recorded. Use the formula in **Figure 6.13**.

$$Percentage\ difference = \left(\frac{(\bar{I}_{high} + 1000) - (\bar{I}_{low} + 1000)}{\bar{I}_{high} + 1000} \right) x\ 100\%$$

Figure 6.13 Formula to calculate the uniformity

A value of < 21 % shows that the percentage difference is within specification.

9 Record the results.

Examples of the above formula with set values used:

Table 6.6 Example of mean and SD results with 2.5 mGy CTDI preset

Measurement Position	Coordinate position (mm)		Mean pixel value (Mean) with 2.5 mGy CTDI preset	Standard deviation (SD) with 2.5 mGy CTDI preset
	X	Y		
Position 1 - center	0	0	77.7 (used as $\bar{I}_{high}$)	76.4
Position 2	-45	0	-21.7	74.5
Position 3	0	-45	-9.6	71.4

Position 4	+45	0	-28.9	73.1
Position 5	0	+45	-39 (used as $\bar{I}_{low}$)	76.1

Table 6.7 Example of mean and SD results with 6.3 mGy CTDI preset

Measurement Position	Coordinate position (mm)		Mean pixel value (Mean) with 6.3 mGy CTDI preset	Standard deviation (SD) with 6.3 mGy CTDI preset
	X	Y		
Position 1 - center	0	0	74.6 (used as $\bar{I}_{high}$)	49.2
Position 2	-45	0	-24.8	46.3
Position 3	0	-45	-8.6	45.3
Position 4	+45	0	-33.9	46.1
Position 5	0	+45	-43.3 (used as $\bar{I}_{low}$)	48

Table 6.8 Examples of uniformity result

Percentage difference (%) with 2.5 mGy CTDI preset	10.8
Percentage difference (%) with 6.3 mGy CTDI preset	11.0

Completing the evaluation of the CBCT image quality

How to complete the evaluation of the CBCT image quality

1. Click **Accept** to accept the image quality and send the images to the Leksell GammaPlan application.
2. Click **Automatic** to move the gantry to parked position.
3. Click **End** to end the stand alone CBCT.
4. Repeat the measurings for the spatial resolution, contrast to noise ratio and uniformity with the other **CBCT setting** .
5. Remove the Catphan phantom (1) from the phantom base plate (2).
6. Remove the phantom base plate (2) from the docking device in the PPS.

Creating a patient

1. In the Leksell GammaPlan® application, on the **Patient** menu, select **Patient Management**.
2. Click **New** and select **Create a new patient**. Click **OK**.
3. In the **New Patient** window, type and select the data for a new patient. Click **OK**.
4. On the **Plan** menu, click **Fixation configuration**.
5. Select the applicable fixation, and click **Save**.
6. On the **Patient** menu, select **Request CBCT** and then **Stand alone**.
7. In the Leksell Gamma Knife® application, click **Treatment** and select the created patient. Click **Proceed**.
8. Make sure that the patient data is correct and click **Accept**.

6.1.1.6 Doing an emergency alarm check

This QA check is required to be performed once a month.

1 On the start page of the **Main** tab, click the **QA** button.

A **QA** tab is added and the page **QA overview** is displayed.

2 Select the check **Emergency alarm** and click the **Select check** button, or double-click the check in the list.

A page is displayed that shows the progress and result of the emergency alarm check. The emergency alarm check can be cancelled by clicking the **Discard** button. This returns to the **QA overview** page.

3 Click the **Activate** button.

The emergency alarm in the control room should now be activated, indicated by an audible warning buzzer and a flashing Emergency alarm indicator on the control panel. Two questions appear to confirm the functioning of the alarm.

4 Click **Yes** or **No** for each of the questions.

When both questions have been answered, the emergency alarm is deactivated and the result of the check is displayed (**Passed** or **Failed**).

5 Click **Save** to save the date and result of this emergency alarm check. Click **Discard** to discard the result of this check.

Note: *To discard a result of **Failed** is only possible if the QA check is not already overdue.*

6 On the **QA overview** page, click the **End QA** button to return to the **Main** tab.

Related Links:

The page QA overview on page 200

6.1.1.7 Doing an emergency stop check

This QA check is required to be performed once a month.

1 Select and start any of the available test treatments that includes a treatment run.

2 When a treatment run has started, press the Emergency Stop button on the control panel.

Figure 6.14 The Emergency Stop button

3 Check that the Emergency Stop sequence is executed.

4 Reset the Emergency Stop button by turning it counter-clockwise as indicated by the arrows on the button.

5 Check that the Emergency Exit sequence is performed.

6 Acknowledge the error message displayed in the system information area.

7 Initiate the system.

Related Links:

Emergency Stop sequence on page 180

Emergency Exit sequence on page 181

Overview of the test functions on page 172

Initializing the system on page 64

6.1.1.8 Examining the side protection interlocks

This QA check is required to be performed twice a year. It can be made at the same time as the physical check of the side protection panels.

1 Enter the treatment room.
2 For each of the two side protection panels on the couch:
   a Lift up the handle completely.
   b Check that the corresponding side protection interlock is cleared in the **System's checklist** area.
   c Push down the handle completely so that it is properly seated in the locked position.
   d Check that the corresponding side protection interlock is set in the **System's checklist** area.

Related Links:

Examining the side protection panels on page 225

6.1.1.9 Examining the treatment room door interlock

This QA check is required to be performed twice a year.

1 Open the door to the treatment room.
2 Check that the **Room door** interlock is cleared in the **System's checklist** area.
3 Close the door to the treatment room.
4 Check that the interlock is set in the **System's checklist** area.

6.1.1.10 Examining the pause function

This QA check is required to be performed twice a year.

1 Select and start any of the available test treatments that includes a treatment run.
2 When a treatment run has started, press the PAUSE button on the control panel.
3 Check that the treatment pause sequence is initiated.

Related Links:

Overview of the test functions on page 172

Pausing a treatment on page 127

6.1.1.11 Examining the manual control buttons

This QA check is required to be performed twice a year.

To check the function of the dead man's switch for the buttons on the couch manual controls:

1 Enter the treatment room.
2 Make sure that the docking device is unlocked.
3 For each of the two manual controls on the couch:

a Press and hold the Up button **without** simultaneously pressing the button on the underside of the manual control.

The mattress should not move.

b Press and hold the Up button **and** simultaneously press the button on the underside of the manual control.

The mattress should move upwards.

c Press and hold the Down button **without** simultaneously pressing the button on the underside of the manual control.

The mattress should not move.

d Press and hold the Down button **and** simultaneously press the button on the underside of the manual control.

The mattress should move downwards.

Related Links:

Unlocking the docking device on page 154

6.1.1.12 Doing a clearance tool check

This QA check is required to do twice a year, or when the clearance tool have been damaged. This QA check is done with the QA tool and the clearance tool.

For this QA check a predefined test treatment is used. The test treatment contains 16 clearance positions that must be verified using the normal clearance check procedure.

To do the QA check of the clearance tool:

1 On the start page of the **Main** tab, click the **Test** button and select **Predefined** in the menu.

A list of predefined test treatments is displayed.

2 Select the **ClearanceToolTest (Flextip)** for the applicable frame fixation and click the **Proceed** button.

3 In the **Verify patient data** page, enter the current date and click the **Accept** button.

4 Install the clearance tool.

5 Attach the frame adapter to the QA tool.

6 Dock the frame adapter with the QA tool.

7 Do the clearance run:

– If you use the QA tool with the G-frame adapter, do the clearance run and for each position, check if the arm of the clearance tool passes clear of the posts on the QA tool. Click the Accept or Reject buttons on the manual control.

– If you use the QA tool Vantage with the Vantage frame adapter, do the clearance run and for each position, check it the arm of the clearance tool passes clear of the front plate on the QA tool. Click the Accept or Reject buttons on the manual control.

The following should be the result of the 16 positions. Otherwise the clearance tool has not been verified.

Positions (Shot ID)	Result
CL1, CL2, CL3, CL4, CL5, CL6, CL7, CL8	Accepted
CO1, CO2, CO3, CO4, CO5, CO6, CO7, CO8	Rejected

Related Links:

Overview of the test functions **on page 172**

Using the QA tool to do QA checks **on page 200**

Performing clearance checks **on page 134**

6.1.1.13 Viewing and printing the QA report

A report in PDF format can be generated for the QA checks in the system application, giving the same information as in the **QA overview** page.

1 On the start page of the **Main** tab, click the **QA** button.

A **QA** tab is added and the page **QA overview** is displayed.

2 Click the **Open QA report** button.

A preview window with a report of all QA checks is opened.

3 Click **Print** to print the report.

4 Click **Close** to close the preview window.

Related Links:

The page QA overview **on page 200**

Exporting the QA report **on page 219**

6.1.1.14 Exporting the QA report

The QA report can be exported as a PDF file to a USB memory stick.

1 View the QA report.

2 Insert a USB memory stick into a USB port of the MCU computer.

3 Click **Export to USB** to export the QA report file to the USB memory stick.

The result is presented in a message:

– If the export was successful, a message is displayed with the filename.

– If the export was unsuccessful, an explanatory message is displayed. Correct the problem and try again.

The PDF file is placed in a folder named **QA** and the filename contains the current date in YYYYMMDD format, the current time in a 24-hour HHMMSS format, and the report type, for example:

```
QA\20120526 -- 164238 -- QA report.pdf
```

4 Remove the USB memory stick.

Related Links:

Description of the office cabinet **on page 42**

Viewing and printing the QA report **on page 219**

6.1.2 Overview of user maintenance

The table below summarizes the various regular maintenance you need to perform in order to keep your Leksell Gamma Knife® system in good working condition. The list may be expanded/ altered according to local site criteria.

Maintenance to do	Required interval	Recommended interval
Cleaning	1 / month	N/A
Safety equipment	1 / month	N/A
Frame adapter	1 / month	N/A
Medical UPS	1 / month	N/A
Office UPS	1 / month	N/A
Side protection panels	1 / month	2 / month
Couch release handles	2 / year	N/A
Check after earthquake	N/A	N/A

Related Links:

Office UPS on page 43

Examining the safety equipment on page 224

Examining the G-frame adapter on page 225

Routine checks of the medical UPS on page 227

Examining the side protection panels on page 225

Examining the Z release handle on page 226

Examining the X release handle on page 227

Examining the system after an earthquake on page 231

Cleaning the parts on page 220

6.1.2.1 Cleaning the parts

Cleaning the primary parts of the Leksell Gamma Knife® system

Periodicity: Monthly

Before cleaning any part of the system, shut down the electrical power to the system:

1. If the system application is running, log off the system. In the logon screen, select to completely shut down the system including the MCU computer.
2. On the control panel, turn the power key to the off position.
3. Perform cleaning:
   - Clean the external casing of the control panel at least monthly with a soft, damp, lint-free cloth.
   - Clean the TV camera lens at least monthly in accordance with the manufacturer's recommendations.
   - Clean the monitor screens at least monthly in accordance with the manufacturer's recommendations. It is recommended to use a special screen-cleaning tissue.

- Clean the mouse and keyboard with an approved cleaning agent suitable for peripheral computer devices.
- Clean the IR camera with a mild detergent.
- Clean the IR camera tray on the PPS.
- Clean all parts of the Leksell Gamma Knife® unit, especially the upper surfaces, by wiping them with a damp cloth with mild detergent and then drying thoroughly.

Cleaning the G-frame adapter

Periodicity: Monthly

Note: *Do not soak any part of the frame adapter.*

1 Clean the G-frame adapter as follows:

a Heavy contamination of the frame adapter with blood or body tissues must be removed at once using soft cloths.

b If more cleaning is necessary, clean the frame adapter with a clean, soft, lint-free cloth.

Cleaning the Vantage frame adapter

Periodicity: Monthly

Note: *If the frame adapter is heavily contaminated between the monthly interval, clean the frame adapter immediately.*

Material needed:

- Detergent with a recommended pH of 6 to 8
- Disinfection (70% ethanol, or 70% isopropanol)
- AESCULAP STERILIT I Drip lubricator, or an equivalent.

1 Mix the detergent, refer to the manufacturer's recommendation. Use a mild detergent with a pH between 6 and 8.

2 If the frame adapter is heavily contaminated:

a Directly flush off the particles with water.

b Soak the frame adapter for a minimum of 20 minutes in the detergent.

3 Hand clean the frame adapter with a soft brush.

4 Open the latch, see **Figure 6.15**.

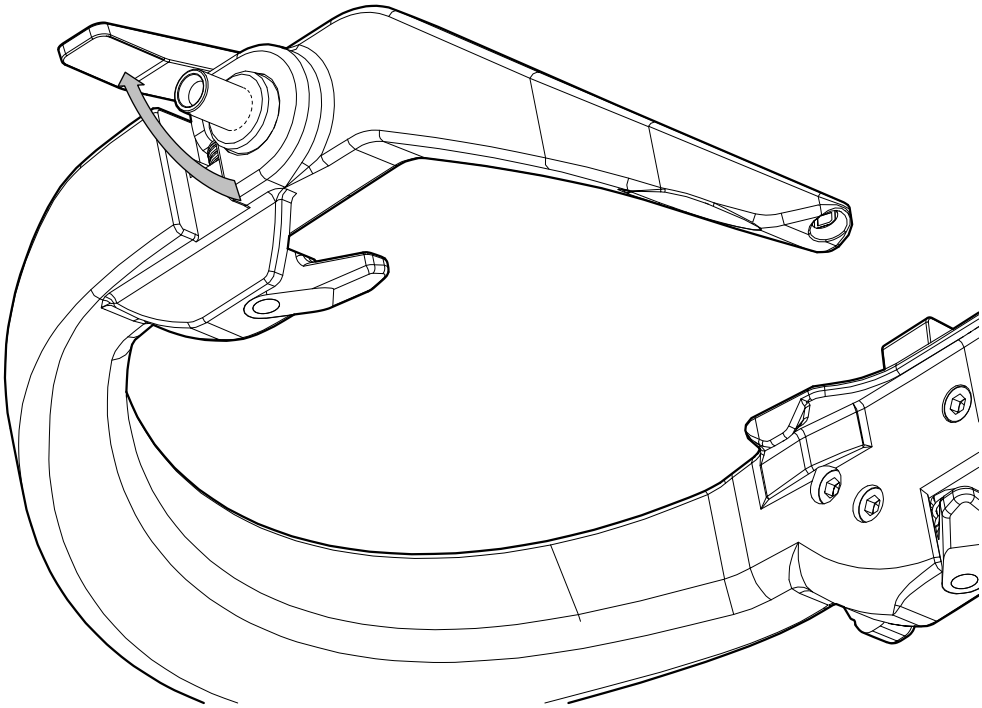

Figure 6.15 Open the latch

5 Push the shaft, see **Figure 6.16** to access the shims in the latch, and clean between the shims with a small cytology brush, see **Figure 6.17**.

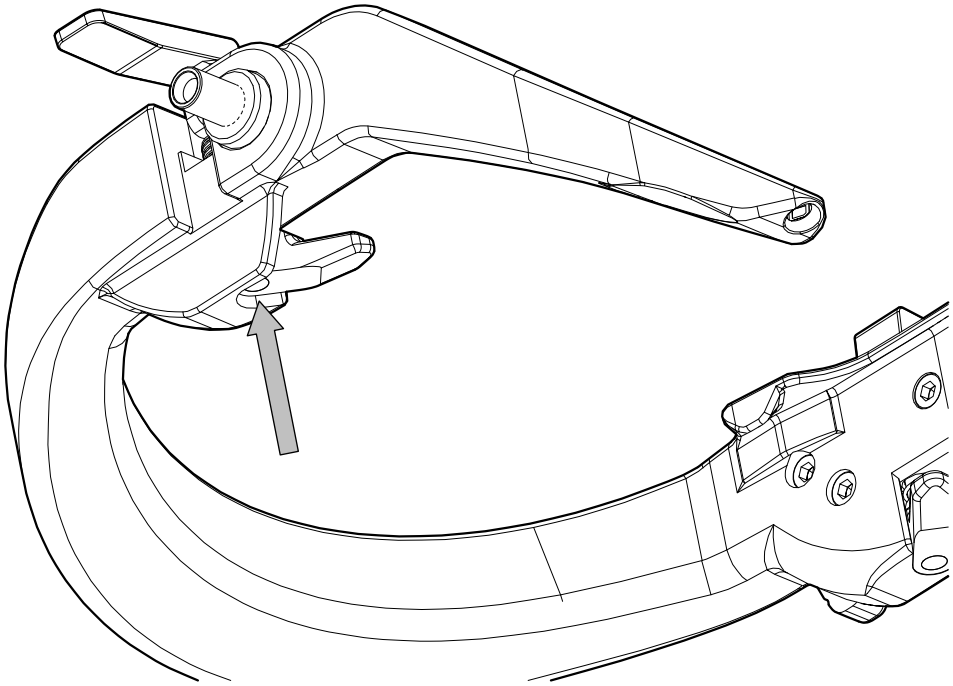

Figure 6.16 Push the shaft to access the shims in the latch

6 Release the shaft and clean the spring and the shaft with a small cytology brush, see **Figure 6.17**.

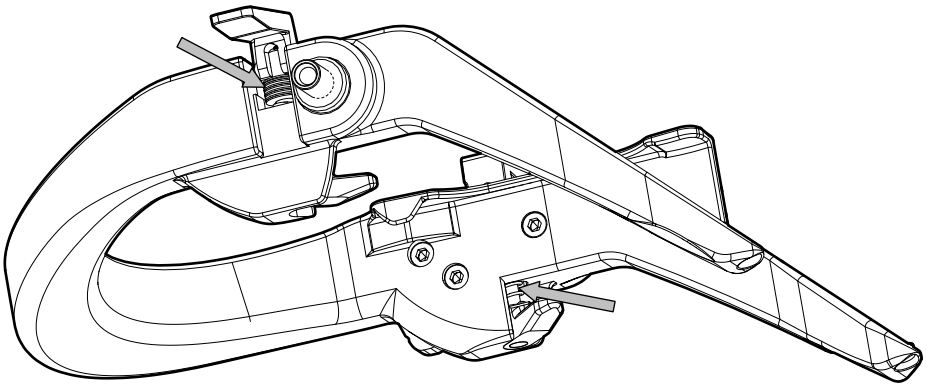

Figure 6.17 Clean between the shims

7 Flush the frame adapter fully in deionized water for a minimum of 3 minutes.

8 Fully dry the frame adapter with soft, clean, and non-shedding wipe and medically compressed air if it is necessary.

9 If disinfection is needed, wipe the surfaces of the part with a non-shedding wipe soaked with the disinfectant (70% ethanol or 70% isopropanol).

10 Carefully examine the frame adapter to make sure that all contamination is removed.

11 Lubricate the three interface areas with AESCULAP STERILIT I Drip lubricator (or an equivalent), see **Figure 6.18**. Make sure that the entire surface of each interface area is lubricated.

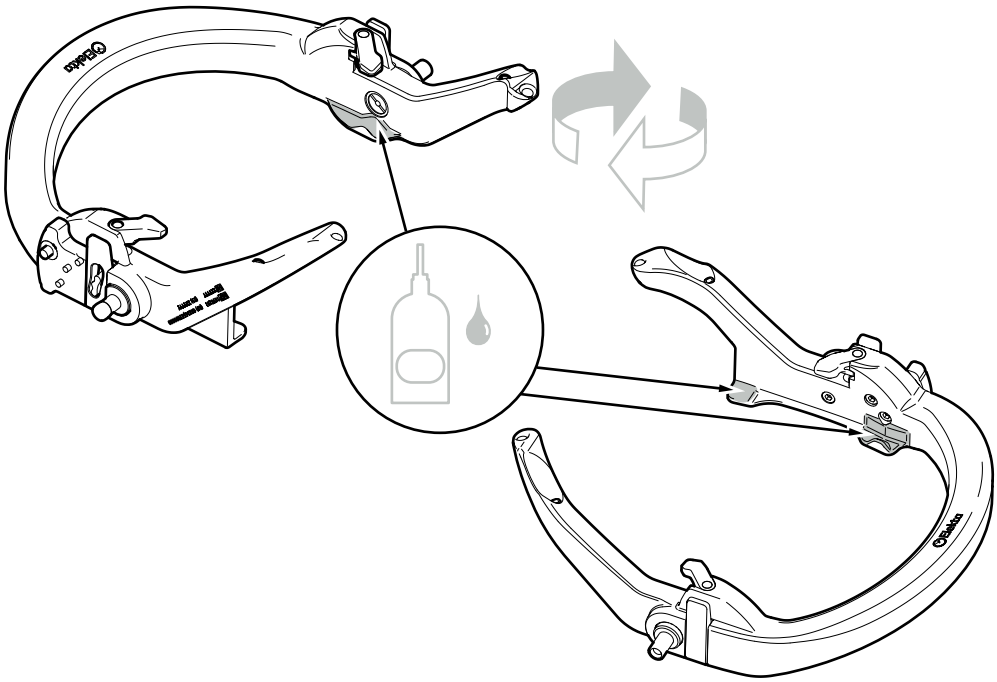

Figure 6.18 Areas for lubrication

12 Fully dry the interface areas with a clean wipe.

Cleaning Leksell® Coordinate Frame G

1 To clean the coordinate frame, refer to *Leksell Stereotactic System®, Instructions for Use*.

Cleaning the Leksell® Vantage™ Head Frame

1 To clean the Leksell® Vantage™ Head Frame, refer to *Leksell® Vantage™ Stereotactic System, Instructions for Use*.

Cleaning the mask adapter

WARNING 6.7

Do not sterilize the equipment. If sterilized, it can be damaged.

1 Heavy contamination of the equipment with blood or body tissues must be removed at once using soft cloths.

2 If more cleaning is necessary:

a Clean all parts thoroughly by hand. Use a mild detergent with a recommended pH of 6 to 8, or 70% ethanol.

b Rinse several times in distilled water.

c Dry the components with a clean, soft, lint-free cloth.

Cleaning the Clearance Check Tool

Periodicity: Monthly

1 Clean the clearance tool with a clean, soft, lint-free cloth.

It is especially important to clean the contact surfaces (1) near the end of the two bars, where the clearance tool is installed into the corresponding holes in the cover. See **Figure 6.19**.

The thinner ends (2) of the two bars that are inserted into the holes in the cover, must **not** be wiped clean, and must remain lubricated.

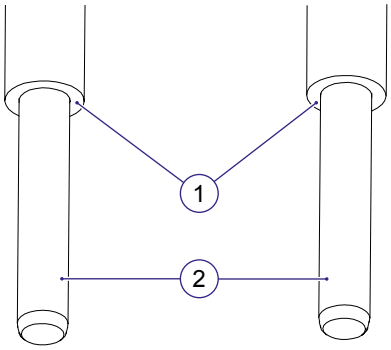

Figure 6.19 Bottom part of the clearance tool

6.1.2.2 Examining the safety equipment

Periodicity: Monthly

1 Check that the shielding door ratchet tool (used for manually closing the shielding doors) is present, undamaged and easily accessible.

2 Make sure that the crank handle for manual gantry movement is in correct position. Examine the crank handle for damage and wear.

3 Check that the Emergency Procedures placard, in both the control room and in the treatment room, is displayed in an appropriate place, clearly visible, and free from damage. If needed, order a new placard from your Elekta® service representative.

Related Links:

Description of the shielding door ratchet tool on page 50

Description of the emergency procedures placard on page 50

6.1.2.3 Examining the side protection panels

Periodicity: Monthly

1 Examine the side protection panels for damage and test the operation by folding them down and up.

This check can be made at the same time as the QA sensor check for the side protection interlocks.

Related Links:

Opening the side protection panels on page 152

Closing the side protection panels on page 152

Examining the side protection interlocks on page 217

6.1.2.4 Examining the G-frame adapter

Periodicity: Monthly

The G-frame adapter shall fit smoothly on the coordinate frame and in the docking device, if undamaged.

1 Examine the G-frame adapter for damage.
2 Check that the G-frame adapter can be easily and correctly fitted to the coordinate frame.
3 Check that the G-frame adapter can be easily and correctly fitted in the docking device.

If the G-frame adapter is damaged or after any misuse, it must be checked and verified by Elekta before using it for patient treatment. You may also perform a focus precision QA check.

Related Links:

Attaching the frame adapter to the coordinate frame G on page 105

Docking a patient with the coordinate frame G to the patient couch on page 109

Doing a focus precision check on page 204

6.1.2.5 Examining the Vantage frame adapter

Periodicity: Monthly

The Vantage frame adapter is smoothly attached on the Vantage head frame and in the docking device, if undamaged.

1 Examine the Vantage frame adapter for damage.
2 Attach the Vantage frame adapter to the Vantage head frame and make sure that it is easily and correctly attached.

3 Dock the Vantage frame adapter to the docking device and make sure that it is easily and correctly docked.

If the Vantage frame adapter is damaged or after any misuse, it must be tested and verified by Elekta before it is used for patient treatment. You can also do a focus precision QA check.

4 Make sure that warning label on the frame adapter is firmly attached and readable. If there are any signs of wear or damage, the label must be replaced. Contact your local Elekta service representative.

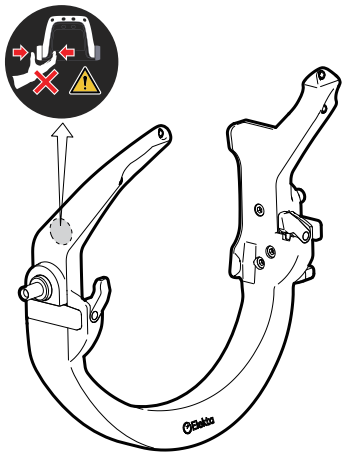

Figure 6.20 Warning label on the frame adapter

Related Links:

Attaching the frame adapter to the Vantage Head Frame on page 110

Docking the patient with the Vantage Head Frame to the patient couch on page 112

Doing a focus precision check on page 204

6.1.2.6 Examining the Z release handle

Periodicity: Every 6 months

Perform a function check and ensure that the handle is properly pushed back after the test.

1 Pull the couch release handle for Z movement, labelled EMERGENCY Z-RELEASE.

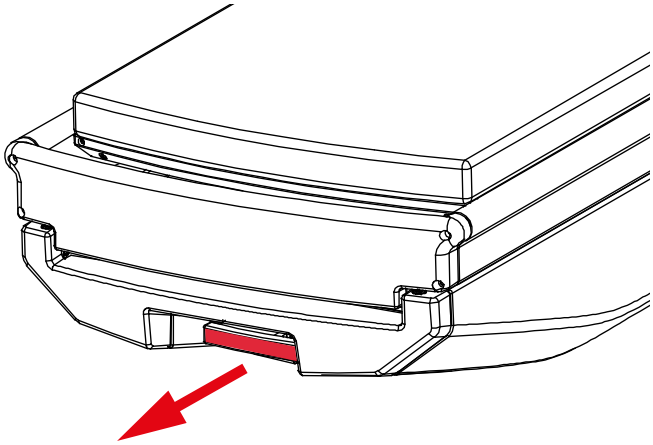

Figure 6.21 Pulling out the couch release handle

2 Push the couch inward and pull it outward to confirm that it can be moved manually.

3 Push back the couch release handle into locking position (clutch engaged).

4 Push the couch to verify that it is locked.

6.1.2.7 Examining the X release handle

Periodicity: Every 6 months

Perform a function check and ensure that the handle is properly pushed back after the test.

1 On the left side of the couch, pull the couch release handle for X movement, labelled EMERGENCY X-RELEASE.

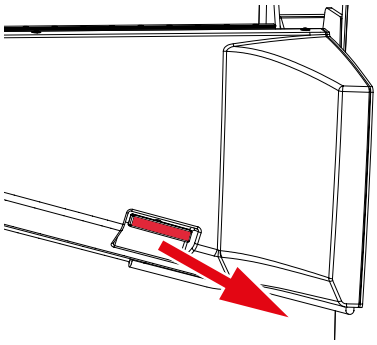

Figure 6.22 Pulling out the couch release handle

CAUTION 6.2

Do not pull or push the couch by using the side protection panels.

2 Pull or push the couch to the left and right to confirm that it can be moved manually.

3 Push back the couch release handle into locking position (clutch engaged).

4 Pull or push the couch to verify that it is locked.

6.1.2.8 Routine checks of the medical UPS

- **Periodicity**: Monthly.
- **Battery Type**: Dry lead.
- **Expected Battery Life**: 9 years.

The test should be performed at the end of the working day to not interfere with scheduled treatments, or otherwise as suitable.

1 Insert the key into the power keyswitch and turn it to the on position.

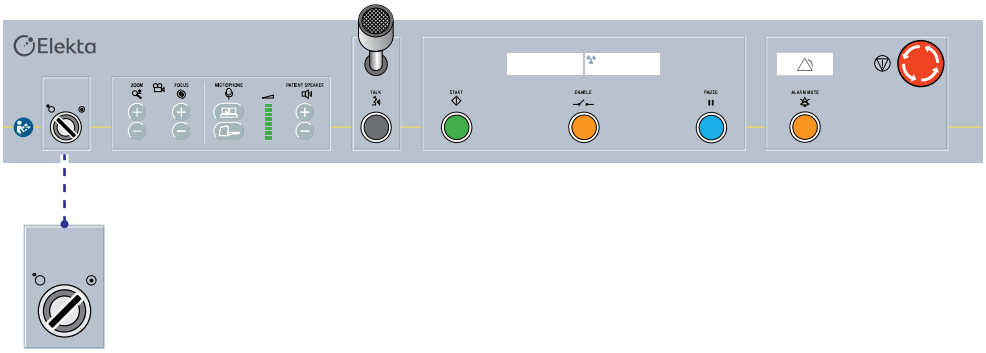

Figure 6.23 Power keyswitch on the control panel.

2 Enter the treatment room and remove the rear section of the radiation unit cover.

3 Perform a test run.

4 On the medical cabinet, switch off the mains button (1) of the UPS unit.

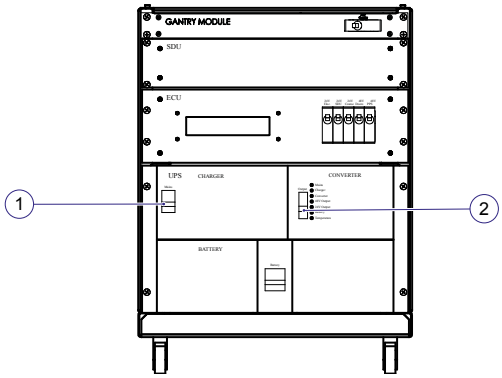

Figure 6.24 Medical UPS in the medical cabinet

The chargers are now turned off and the system is powered from the batteries as indicated by the indicator lamps of the output section (2).

5 Let the mains button be switched off for 20 minutes. The output voltage is measured over that period of time and if it falls below a preset level, a system error is generated:

- If an error is generated, contact your Elekta® service representative to arrange for the batteries to be exchanged.
- If no error is generated, the batteries are in satisfactory condition.

6 After 20 minutes, switch on the mains button (1).

If the UPS batteries have been used to power the system during a power failure they should be recharged for a minimum period of one hour before using the Leksell Gamma Knife® Icon™ unit again, when the power supply is restored.

Related Links:

Removing the rear RU cover on page 185

Overview of the test functions on page 172

6.1.2.9 Office UPS

The office UPS unit is installed at the bottom of the office cabinet. The control panel of the office UPS is available in 4 different versions. Compare the images in the sections below to identify which version you have.

Routine checks of the office UPS: type 1 and 2

Periodicity: Monthly.

If the UPS fails the self-test, the Replace Battery indicator (1) is turned on. Allow the battery to recharge for 24 hours and then perform a manual self-test. If the problem persists, the battery must be replaced.

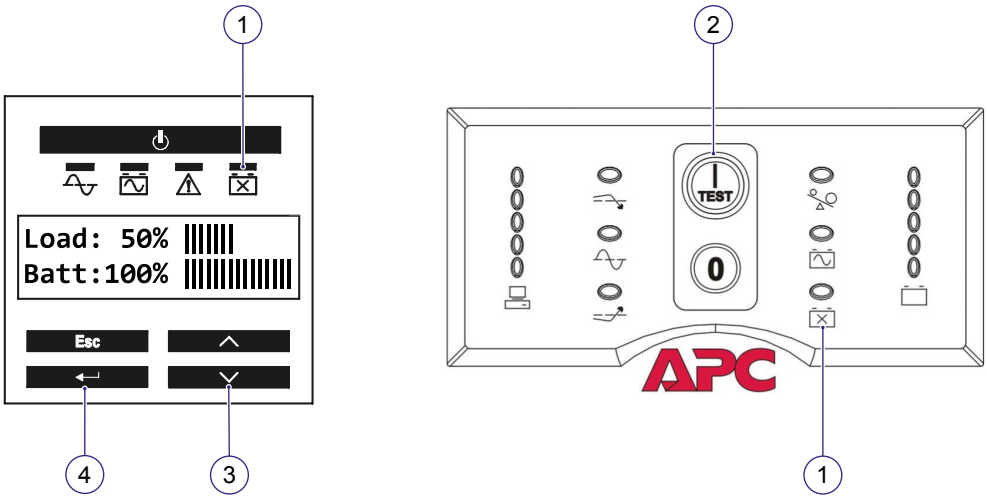

Figure 6.25 The control panel of the office UPS unit

(1) Replace Battery indicator
(2) Self-test/On button
(3) Up/down buttons
(4) Enter button

1 To perform a manual self-test:

- On the control panel with a self-test button (2), press and hold the button for a few seconds.
- On the other control panel, do as follows:

  1 Press the down or up button (3) until the message **`Main menu: Test & Diags`** appears. Then press the enter button (4).

  2 Press the down or up button until the message **`UPS Self Test:`** appears. Then press the enter button.

  3 Press the down or up button until the message **`UPS Self Test: Yes`** appears. Then press the enter button.

Related Links:

Description of the office UPS: type 1 and 2 on page 43

Routine checks of the office UPS: type 3 and 4 "Liebert"

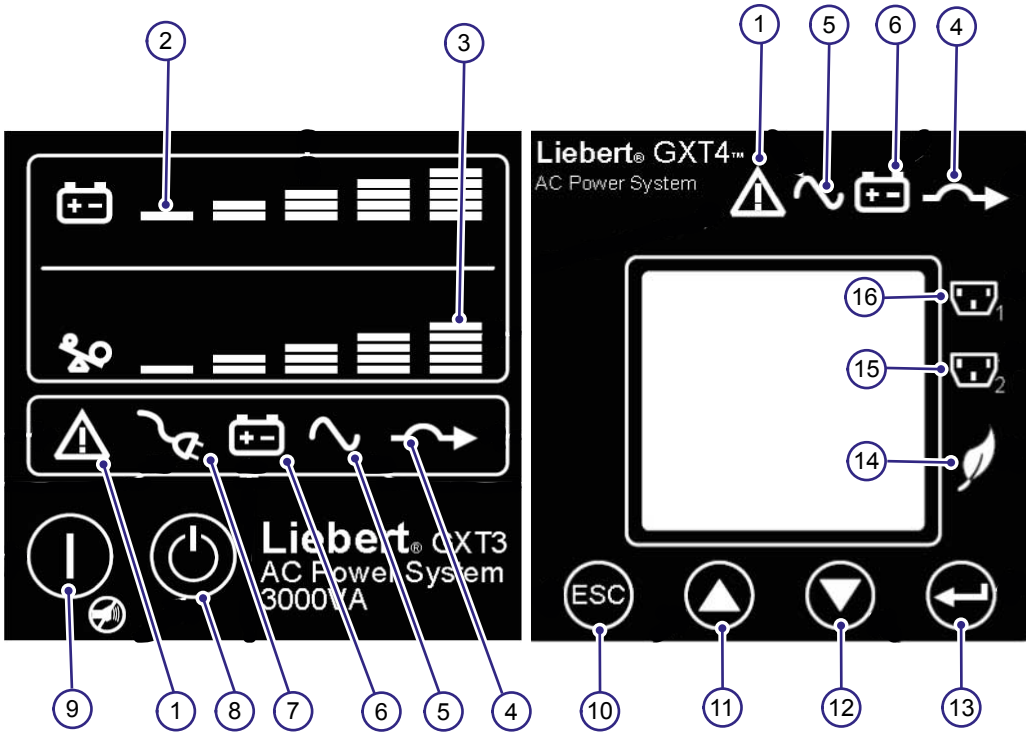

Figure 6.26 The office UPS type 3 and 4 display

(1)	Fault indicator	(9)	On/Alarm silence/Manual battery test button
(2)	Battery level indicators	(10)	ESC button
(3)	Load level indicators	(11)	Up button
(4)	Bypass indicator	(12)	Down button
(5)	Inverter indicator	(13)	Enter button
(6)	Battery indicator	(14)	ECO mode indicator
(7)	AC Input indicator	(15)	Programmable outlet2 indicator
(8)	Standby/Manual bypass button	(16)	Programmable outlet1 indicator

Manual battery test on the office UPS type 3

Periodicity: Monthly.

The office UPS type 3 will do an auto-battery test every 14 days. If the battery test fails, the UPS will beep 2 seconds every minute.

You can do a manual battery test when AC input indicator (7) is on and no alarms are active:

1 Press the on button (9) for a second.

If	Then
2 or less of the battery level indicators (2) are on after the test, the battery is defective.	Leave the office UPS connected to the mains power supply for about 24 hours. Then do the test again.

If 2 or less of the battery level indicators (2) are on after the second test, contact your local Elekta representative for technical support.

Manual battery test on the office UPS type 4

Periodicity: Monthly.

The office UPS type 4 will perform an auto-battery test every 8 week. To do a monthly manual battery test:

1 Go to the Main Menu on the LCD:

a Select CONTROL and BATT TEST.

b Press START.

If the battery test would get the result FAILED:

1 Allow the office UPS type 4 to recharge the batteries for 24 hours and do the manual battery test again.

If the battery test still shows FAILED, contact your local Elekta representative for technical support.

Related Links:

Description of the office UPS: type 3 and 4 "Liebert" on page 44

6.1.2.10 Examining the system after an earthquake

If the site has been subjected to earthquake, the Leksell Gamma Knife® Icon™ system must be checked and verified by Elekta before using it for patient treatment.

1 Contact your Elekta® service representative.

6.2 Planned maintenance

The planned maintenance of the Leksell Gamma Knife® Icon™ system contains:

- Scheduled periodic inspections performed by Elekta® service personnel or a nominated representative, under the appropriate servicing contract.

Maintenance procedures should not be undertaken by clinical users unless information is given in this manual or presented elsewhere as a specific user instruction.

Note: *Additional care and maintenance procedures may exist, depending on the system configuration. They are described in separate user manuals, delivered with the additional equipment.*

6.3 Corrective maintenance

The corrective maintenance of the Leksell Gamma Knife® Icon™ system contains:

- Repair and test of the machine in the unlikely event of a fault or malfunction, performed by Elekta® service personnel or a nominated representative, under the appropriate servicing contract.

Maintenance procedures should not be undertaken by clinical users unless information is given in this chapter or presented elsewhere as a specific user instruction.

Note: *Additional care and maintenance procedures may exist, depending on the system configuration. They are described in separate user manuals, delivered with the additional equipment.*

7 Technical data

7.1 Physical data, Leksell Gamma Knife® Icon™

Overall length, including cover	4.50 m
Overall length, including cover, gantry, and HDMM system	4.50 m
Overall width, including cover	2.23 m
Overall width, including cover, gantry, and HDMM system	2.46 m
Overall height, including cover	1.94 m
Overall height, including cover, gantry, and HDMM system	2.03 m
Total weight, including cover, gantry, and HDMM system (approximate)	20 000 kg
Maximum load on patient couch	210 kg

7.2 Radiophysical data

Maximum activity at loading	6600 Ci (approximately 244 TBq)
Number of radiation sources	192
Radiation dose rate at focal point at loading	> 3 Gy min^{-1}
Radiological accuracy	< 0.5 mm
Positioning repeatability	< 0.05 mm
CBCT accuracy	< 0.5 mm

7.3 Transition between Beam off and Beam on

The **Beam off** state is achieved when the shielding doors are fully closed, and the radiation sources are positioned and locked in the sector home position.

The **Beam on** state is achieved when the shielding doors are fully opened, the patient positioning system has reached the desired treatment target position, and the radiation sources are aligned with the desired collimators.

The transition from **Beam off** to **Beam on** starts when the operator pushes the START button on the control panel. The transition from **Beam on** to **Beam off** starts when the treatment run is finished, or when the treatment pause sequence is initiated.

Both transitions take a maximum of 75 seconds. During the transition the radiation sources are in a shielded position.

Related Links:

Description of a treatment pause sequence on page 127

7.4 Treatment timers

Accuracy of treatment timer	< 0.2%

The system is equipped with two independent treatment timers. Both the primary and the secondary timer starts when the **Beam on** state is achieved. The timers are monitored and compared continuously during the **Beam on** state.

After the time measured on the primary timer has elapsed, the radiation sectors are moved to the sector off position. The patient is then repositioned to the next shot position.

If the primary and secondary timers differ more than 0.1 minutes or 10% (whichever is reached first), the treatment is terminated, the radiation sectors are moved to the sector home position and the patient is taken out of the treatment cavity. The system then compares the primary, secondary and a third backup timer. The elapsed treatment time is set based on a majority decision of the three timers.

7.5 PPS range of movement

The maximum range of movement of the patient positioning system in Leksell® coordinates is, for each individual axis:

Maximum range of movement in X axis	20 – 180 mm
Maximum range of movement in Y axis	10 – 190 mm
Maximum range of movement in Z axis	-820 – 167 mm

The range of movement in the treatment cavity inside the radiation unit is in practice differently limited in the X and Y directions for large Z values, due to the shape of the radiation shielding. The exact range of movement is implemented and automatically handled by Leksell GammaPlan® as well as the control system for Leksell Gamma Knife® Icon™.

7.6 Electrical data

Power consumption (approximate)		Average power: 1500 VA
Mains power supply, office side	Office UPS (in office cabinet)	100 V AC, 50-60 Hz, 1500 VA (1350 W), internal circuit breaker 15 A or 120 V AC, 50-60 Hz, 1500 VA (1350 W), internal circuit breaker 15 A or 230 V AC, 50-60 Hz, 1500 VA (1350 W), internal circuit breaker 10 A Average power: 500 VA
	Input (according to country mains voltage and frequency)	
	Operator console (powered by office UPS)	100–240 V AC, 50-60 Hz, 2 × T6.3 AH / 250 V Average power: 50 VA
Mains power supply, medical side	Medical UPS in medical cabinet	Maximum power: 900 VA Average power: 300 VA

	Input	100–240 V AC, 50-60 Hz, internal circuit breaker 20 A.
	Output	24 V DC and 48 V DC
Mains power supply, kV generator		380-400 or 415/440/480 V AC, 3-phase, internal fuses 50 A Instantaneous power: 5 kVA (normal use), 25 kVA (calibration) Average power: 700 VA
Installation category		Category II

7.7 Alarm sound pressure level for the patient alert

Alarm sound pressure level is approximately 55 dBA at the operators position and 67 dBA in the treatment room.

7.8 Environmental data

Ambient temperature	+22 to +26 °C (+15 °C to +30 °C)
Relative humidity	30–55% (30–75%)
Atmospheric pressure range	700–1060 hPa

Elekta recommends that the temperature and humidity in the treatment room is as stable as possible at all times, even when the equipment is not in use for patient treatment.

7.9 Patient surveillance video system

PAL, NTSC	One wall-mounted camera in the treatment room.
	One flat screen at the operator console.

7.10 Radiation levels around Leksell Gamma Knife®

These charts show the ^{60}Co radiation levels around the Leksell Gamma Knife® unit in a treatment room. Two charts show the Beam off state and two charts the Beam on state, for 16 mm collimators. The data was measured and then rescaled for a unit with a maximum activity of 6600 Ci.

Re-scaling dose rate measurements made on a system with a given total activity to systems with other total activities is accurate in areas in the treatment room where leakage through the radiation unit dominates the measured dose rate. The accuracy of re-scaling in regions where direct scattering (e.g. in a phantom or patient) through the open shielding doors constitute a significant part of the dose rate will depend on the relative amounts of leakage and direct scattering. In case of another maximum activity, A_{max}, re-scaling is done by multiplying the values in the charts with the factor $F = A_{max} / 6600$.

At all operational phases the radiation level decreases with the distance from the treatment unit.

The uncertainties of the values given in the ^{60}Co data are as follows:

- Levels ≤ 50 µSv/h = ± 20%
- 50 µSv/h < Levels < 100 µSv/h = ± 15%
- Levels ≥ 100 µSv/h = ± 10%.

7.10.1 Radiation levels at Beam on, horizontal plane

Radiation levels at **Beam on**, with 16 mm collimator and open shielding doors, 1 m above the floor. The spacing of the grid is 0.5 m. Radiation levels are in µSv/h.

No other horizontal plane contains dose rates along the walls higher than this plane.

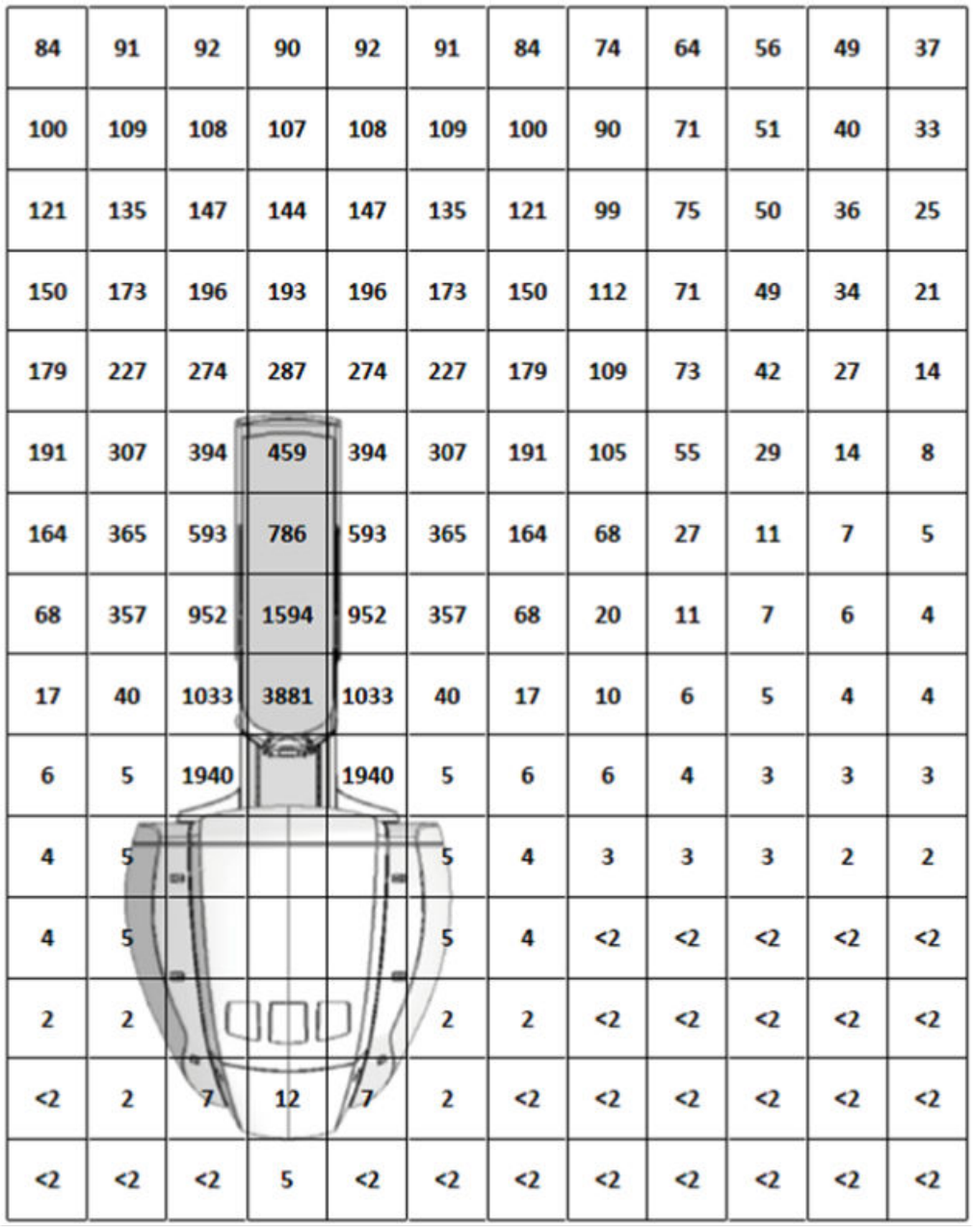

Figure 7.1 Radiation levels at Beam on, horizontal

7.10.2 Radiation levels at Beam on, vertical plane

Radiation levels at **Beam on**, with 16 mm collimator and open shielding doors, in the vertical plane through the center of the unit. The spacing of the grid is 0.5 m. Radiation levels are in µSv/h.

No other vertical plane contains dose rates along the walls, ceiling or floor higher than this plane.

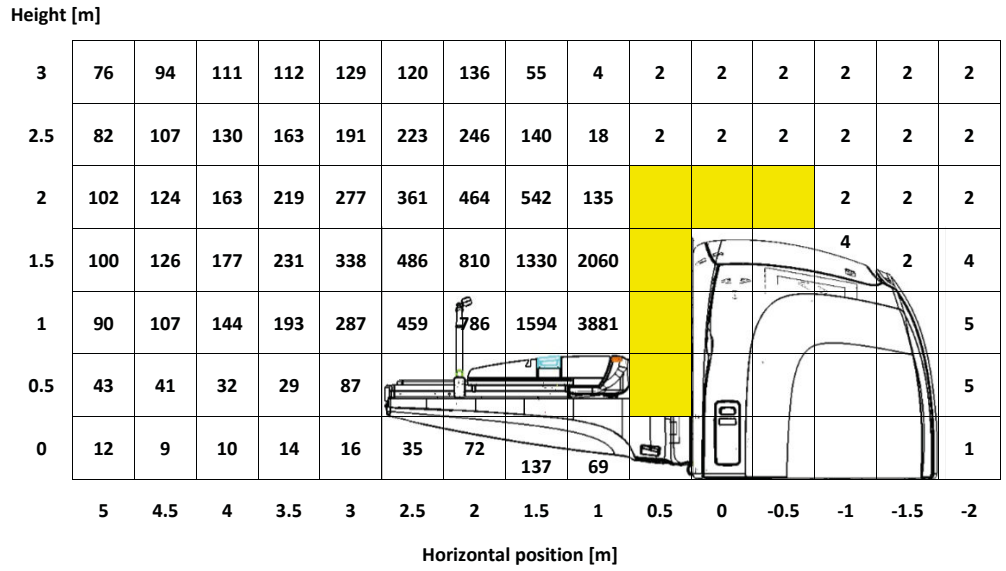

Figure 7.2 Radiation levels at Beam on, vertical

7.10.3 Radiation levels at Beam off, horizontal plane

Radiation levels at **Beam off**, shielding doors closed, 1 m above the floor. The spacing of the grid is 0.5 m.

Radiation levels are in µSv/h. No other horizontal plane contains radiation levels higher than in this plane.

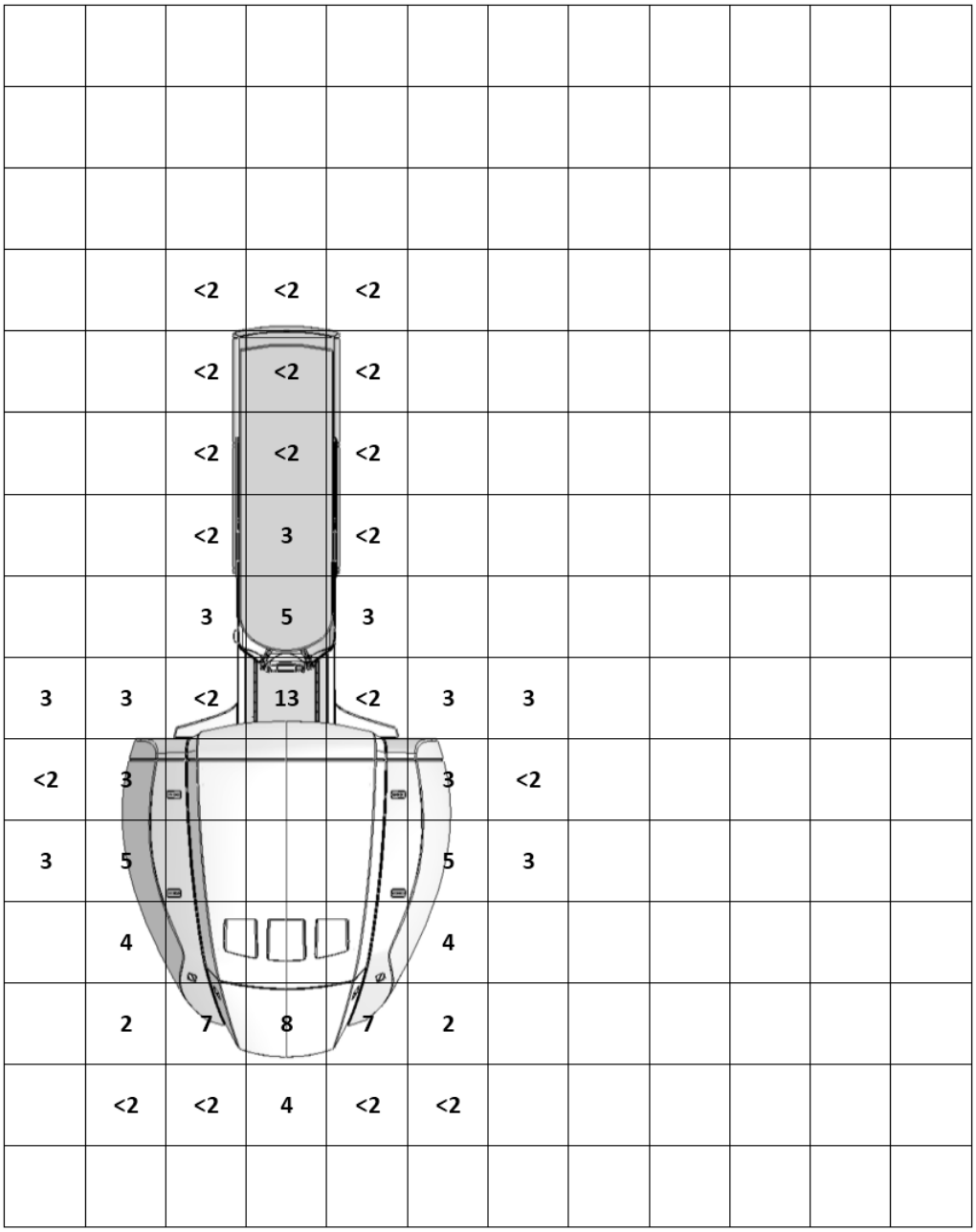

Figure 7.3 Radiation levels at Beam off, horizontal

7.10.4 Radiation levels at Beam off, vertical plane

Radiation levels at **Beam off**, shielding doors closed, 1 m above the floor. The spacing of the grid is 0.5 m.

Radiation levels are in µSv/h. No other vertical plane contains radiation levels higher than in this plane.

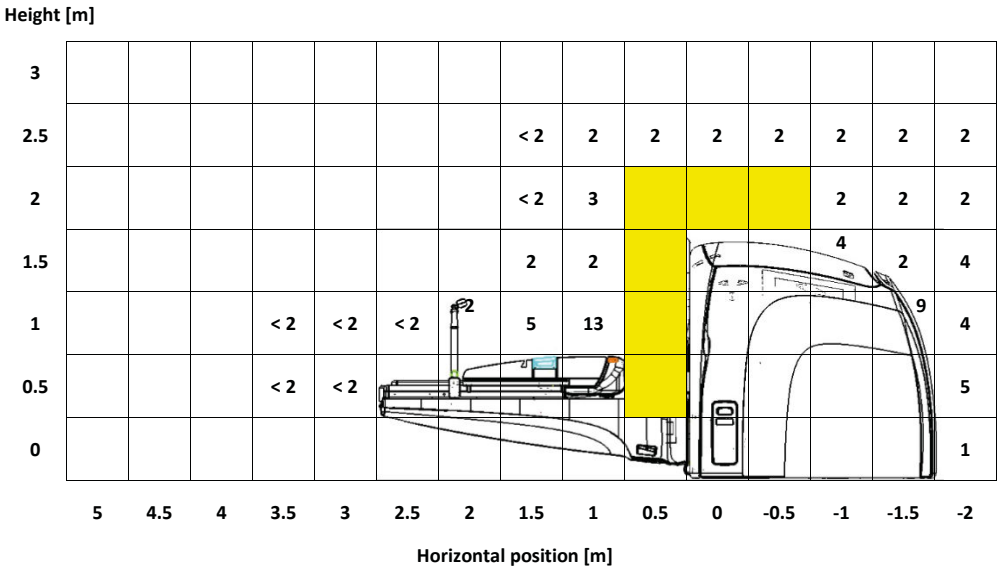

Figure 7.4 Radiation levels at Beam off, vertical

7.10.5 Radiation levels for CBCT

The figure below shows dose measurements for one high dose CBCT scan with preset 90 kV, 1 mAs. Each number in the figure represents the radiation level in µSv at a specific point in the room. The spacing of the grid is 0.5 m.

Figure 7.5 Radiation levels during a CBCT scan [µSv]

7.11 Radiation dose details

7.11.1 Body dose

The figure shows measured values of dose as a function of distance from the focus point. Dose is expressed as a percentage of the delivered dose at the focus point. The dose values in the diagram represent the average, measured doses over the cross-sections of an anthropomorphic

phantom at various distances from the focus point. The lines drawn between the measured values are intended as visual help only.

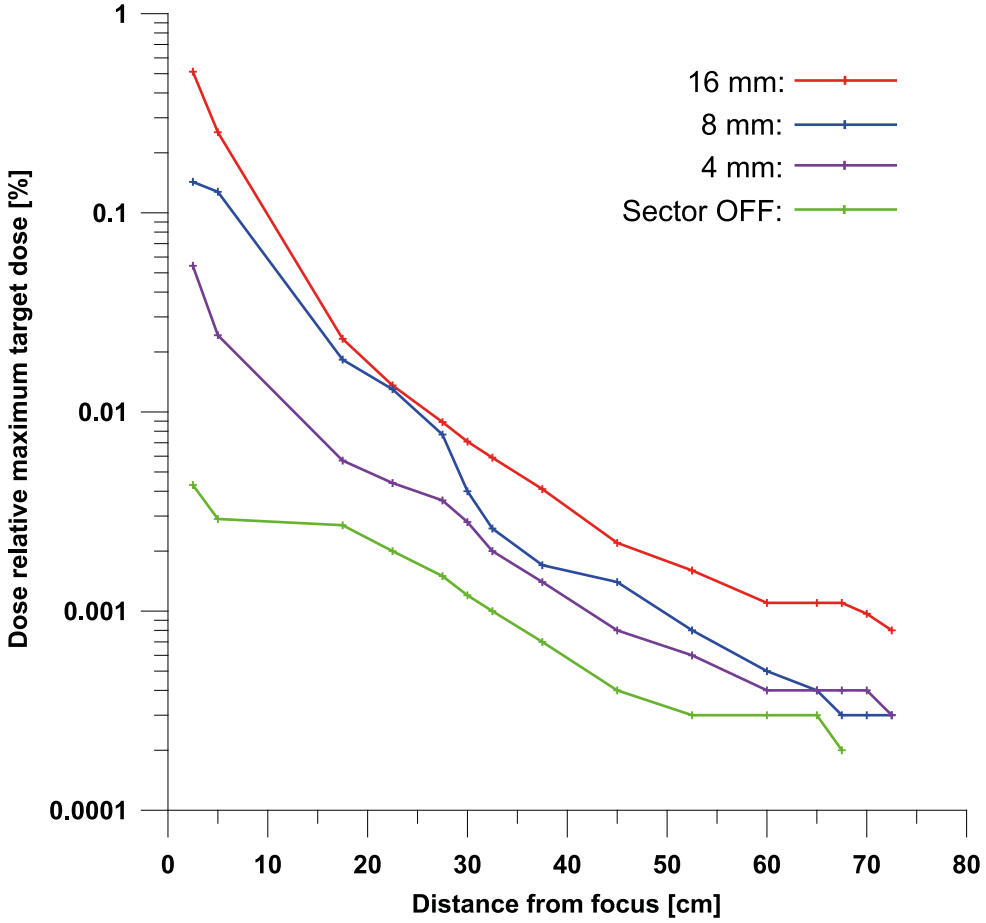

Figure 7.6 Measured values of dose from the focus point

7.11.2 Shutter dose

When the radiation sectors move towards and away from the position aligned with a collimator, some dose will inevitably be delivered to the target during the movement. This dose is known as the shutter dose.

The control system of Leksell Gamma Knife® Icon™ compensates for the shutter dose in the planned shot position so that the delivered dose becomes correct.

The procedure to compensate this is to start the timer just before the sectors reach the target position for full beam-on intensity. The position where the timer starts is optimized for each collimator size so that the dose delivered is the same, independently on the number of fractions used.

This has the effect that treatment time is measured when the dose intensity is correct, although the dose focal spot shape will be slightly distorted.

7.12 Dose build-up effect (bolus)

During treatment with Leksell Gamma Knife® Icon™, the material in the mask and head support can possibly cause a dose build-up effect and thus an increased dose near the surface of the patient's head. This bolus effect will possibly cause a reaction in the

skin of the patient, although measurements have shown that the dose that causes such an effect will be unusual.

7.13 Radiation attenuation ^{60}Co

Depending on the type of immobilization device, the gamma radiation may be slightly attenuated during treatment.

If the patient uses the mask and head support, the dose can decrease by approximately 2.5%.

If the patient uses the Leksell® Vantage™ Head Frame, the dose can decrease by approximately 1.4%.

The attenuation has been measured with a 16 mm shot in the center of a dosimetry phantom.

7.14 Radiation attenuation CBCT

If the mask and head support is used for patient fixation, the CBCT radiation is attenuated by approximately 10 %. Because of this attenuation, the image quality will be slightly degraded because of an increased noise level.

7.15 CBCT dosimetry

7.15.1 Description of a dosimetry phantom

To measure the Computed Tomography Dose Index (CTDI), you must use a dosimetry phantom.

The dosimetry phantom must be a PMMA cylinder of density 1.19 g/cm^3 with at least 160 mm in diameter for head techniques. The length of this phantom must be a minimum of 140 mm.

7.15.2 Measuring the CTDI

For this system, the $CTDI_{vol}$ = $CTDI_w$ because only one tomographic section is acquired in one rotation N=1.

The CTDI value derived in this section is approximate, because of the small size of the CTDI phantom.

1. Prepare a test patient in Leksell GammaPlan® with the applicable fixation system of the phantom.
2. Select **Request CBCT > Stand Alone**.
3. In the Leksell Gamma Knife® Icon™ system application, click **Treatment** and select the test patient.
4. Dock the selected phantom to the docking device. Use the applicable fixation system of the phantom. If necessary, align the phantom horizontally. Make sure that one of the peripheral holes are aligned with the X/Y coordinates.

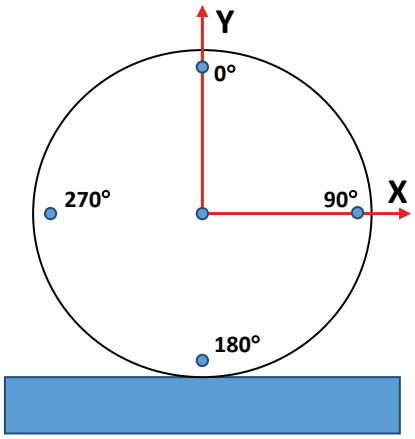

Figure 7.7 Dosimetry phantom position

5 Set up an applicable CT ionization chamber and prepare the dosimetry system to measure. Start with the center hole in the phantom.

6 Make sure that the ionization chamber is fixed in the phantom.

7 Put the plastic rods in the other 4 holes.

8 Obey the instruction on the treatment monitor to prepare the scan. Select the preset to measure.

9 Do the scan.

10 Record the result from the measurement. See **Table 7.1** on page 245. It is not necessary to save the images.

11 Go back to Leksell GammaPlan® and continue with the same test patient. Make a CBCT request again.

12 Do step **5** to **11** again for the other 4 holes. Make sure that you move the plastic rods in the phantom.

13 Do step **1** to **12** again until you get sufficient statistics.

14 Calculate the $CTDI_{100,\ Peripheral}$ as follows:

$$CTDI_{100,\ Peripheral} = ¼\ (CTDI_{100(0°)} + CTDI_{100(90°)} + CTDI_{100(180°)} + CTDI_{100(270°)})$$

15 Calculate the weighted CTDI as follows:

$$CTDI_W = 1/3\ CTDI_{100(center)} + 2/3\ CTDI_{100,\ Peripheral}$$

16 The Dose length product (DLP) for a preset is calculated by multiplying CTDI by the length of the tomographic section T = 10 cm. The number of rotations is set to N = 1.

$$DLP = CTDI_{vol} \times N \times T$$

Table 7.1 Result table

Preset Name				
Phantom	Head Phantom			
	D (mGy)			
	1st scan	2nd scan	3rd scan	Average D
$CTDI_{100(center)}$				
$CTDI_{100(0°)}$				
$CTDI_{100(90°)}$				
$CTDI_{100(180°)}$				
$CTDI_{100(270°)}$				

The deviations $CTDI_{vol}$ and DLP between different Leksell Gamma Knife® Icon™ systems, are typically less than ± 35% from the nominal stated value defined in the preset of the x-ray unit. The differences depends typically on the generator, x-ray tube output and the manufacturing of the covers of the unit.

Table 7.2 Example tables

Preset Name	2.5 mGy			
Phantom	Head Phantom			
	D (mGy)			
	1st scan	2nd scan	3rd scan	Average D
$CTDI_{100(center)}$	2.705	2.708	2.707	2.71
$CTDI_{100(0°)}$	4.086	4.087	4.086	4.09
$CTDI_{100(90°)}$	2.653	2.643	2.644	2.65
$CTDI_{100(180°)}$	0.891	0.891	0.893	0.89
$CTDI_{100(270°)}$	2.403	2.406	2.406	2.41
			$CTDI_w$ (mGy)	2.57 mGy
			DLP (10 cm)	25.7 mGy

Preset Name	6.3 mGy			
Phantom	Head Phantom			
	D (mGy)			
	1st scan	2nd scan	3rd scan	Average D
$CTDI_{100(center)}$	6.889	6.893	6.893	6.99
$CTDI_{100(0°)}$	10.43	10.43	10.43	10.43
$CTDI_{100(90°)}$	6.744	6.766	6.74	6.75
$CTDI_{100(180°)}$	2.28	2.278	2.277	2.28
$CTDI_{100(270°)}$	6.146	6.160	6.132	6.15
			$CTDI_w$ (mGy)	6.57 mGy
			DLP (10 cm)	65.7 mGy

Related Links:

Doing a stand-alone CBCT on page 99

7.15.3 Determination of $CTDI_{free, air}$

The CTDI free is determined by placing the chamber along the Z-axis (aligned with the patient) of the system. The position of the chamber is the same as the position of the chamber in the phantom.

$CTDI_{free,air}$ is determined here but is of no use for the current CBCT system. $CTDI_{free,air}$ is normally used to scale output (CTDI values) between various collimator sizes, but since the Leksell Gamma Knife® Icon™ CBCT system only have one collimator size this scaling factor is of no use.

$$CTDI_{100} = \int_{-50mm}^{+50mm} \frac{D_{ref}(z)}{(N \cdot T)} dz \cdot \frac{CTDI_{free\ air,N \cdot T}}{CTDI_{free\ air,ref}}$$

Figure 7.8 Equation for $CTDI_{free,\ air}$ measurement

The N×T is always the same and by definition $CTDI_{free\ air,\ N\times T} = CTDI_{free\ air,\ ref}$.

The CTDI dose profiles have not been measured.

The $CTDI_{free,air}$ have been measured for the 2 presets, and are included only as information about the dose output:

- $CTDI_{free,air}$ = 3.75 mGy for Preset CTDI 2.5
- $CTDI_{free,air}$ = 9.4 mGy for Preset CTDI 6.3

The deviations $CTDI_{free,air}$ and DLP between different Leksell Gamma Knife® Icon™ systems, are typically less than ± 35% from the nominal stated value defined in the preset of the x-ray unit. The differences depends typically on the generator, x-ray tube output and the manufacturing of the covers of the unit.

7.15.3.1 Measuring CTDI Free in air

CTDI free in air has been determined for the available preset Ca factor 3.

1. Prepare a test patient in Leksell GammaPlan® with the applicable fixation system of the phantom.
2. Select **Request CBCT > Stand Alone**.
3. In the Leksell Gamma Knife® Icon™ system application, click **Treatment** and select the test patient.
4. Dock the selected phantom to the docking device. Use the applicable fixation system of the phantom. If necessary, align the phantom horizontally. Make sure that one of the peripheral holes are aligned with the X/Y coordinates.
5. Set up an applicable CT ionization chamber and prepare the dosimetry system to measure. Start with the center hole in the phantom.
6. Obey the instruction on the treatment monitor to prepare the scan. Select the preset to measure.
7. Do the scan.
8. Record the result from the measurement. See **Table 7.3** on page 247. It is not necessary to save the images.
9. Go back to Leksell GammaPlan® and continue with the same test patient. Make a CBCT request again.
10. Do step **1** to **9** again until you get sufficient statistics.

    The deviations $CTDI_{free,air}$ and DLP between different Leksell Gamma Knife® Icon™ systems, are typically less than ± 35% from the nominal stated value defined in the preset of the x-ray unit. The differences depends typically on the generator, x-ray tube output and the manufacturing of the covers of the unit.

Table 7.3 Result table

Preset Name	
Phantom	Head Phantom
	D (mGy)

	1st scan	2nd scan	3rd scan	Average D
$CTDI_{100(center),\ air}$				

Related Links:

Doing a stand-alone CBCT on page 99

7.15.4 Dose profile statement

The signal were measured at different positions in the CTDI. The detector used was a PTW diode 60008 connected to an electrometer. This measurement is normalized to the dose determined at the center of the phantom using a Farmer ionization chamber (could have been normalized using the $CTDI_{100,center}$), but it will give the same answer.

The resulting dose profile within a CTDI phantom for each preset is shown in the figure:

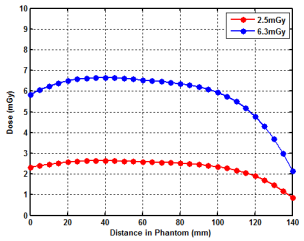

Figure 7.9 Dose profile

The dose profile is asymmetric which can be expected due to the asymmetric field, where differences in attenuation length in the phantom, effects of the inverse square law and possible heal effects.

7.15.5 Filter properties

There is a 1.2 mm aluminum equivalent and a 0.3 mm aluminum filtration built into the X-ray tube by the manufacturer. There is also a Bowtie filter with a 0.3 mm copper sheet together with a curved metal piece made of aluminum with a minimum thickness of 3 mm. This is equivalent to a minimum 11.1 mm Al-filtration. This means that the total filtration exceeds the, according to standards, minimum required filtration of 2.5 mm Al by at least 8.6 mm.

The Bowtie filter is designed as to give low intensity variation within the projections. Therefore, the filter is shaped so rays intersecting the central part of the head passes through less bowtie filter material than rays passing through non-central parts of the head. The bowtie filter significantly reduces the low energy components of the spectrum thus eliminating a large part of the radiation field that deposits dose in the head but does not contribute to information in the re-construction process.

7.15.6 Radiation levels of the CBCT

7.15.6.1 Extra focal radiation

The housing, which cover the X-ray tube and the collimator, prevent or decrease the extra-focal radiation.

7.15.6.2 Description of the leakage radiation in the loading state

The leakage radiation from the X-ray tube assembly, when in the loading state at the maximum specified power output, is not more than 1.0 mGy in one hour.

7.15.7 Image quality

Image quality can be quantified in different ways. Metrics have been chosen that are easy to measure and reflect different aspects of image quality. These are:

- Line pairs per cm counted in a well-defined geometry
- Contrast to noise ratio (CNR)
- Uniformity.

Line pairs

In order to measure resolution in CBCT images a generally accepted method is to calculate the number of visual line pairs in a well-defined phantom. In Catphan® 503 there is a section with a 1 through 21 line pair per centimeter high resolution test gauge. The gauge accuracy is ± 0.5 line pair at the 21 line pair test and even better at lower line pair tests.

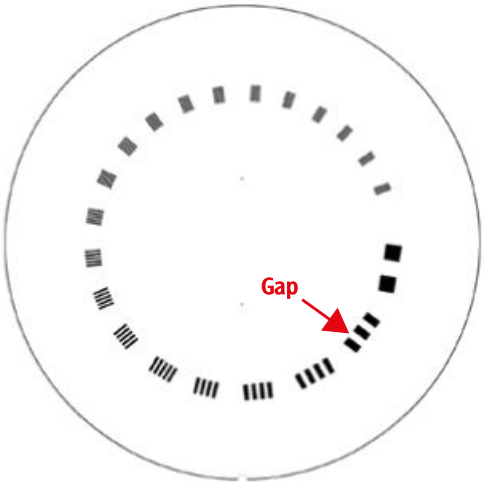

Figure 7.10 Section of Catphan® 503 containing the line pairs

There is an inverse relation between the gap size and the line pair/cm as shown in **Table 7.4** on page 249:

Table 7.4 Relation between gap size and line pair/cm

Line pair/cm	Gap size (cm)	Line pair/cm	Gap size (cm)
1	0.500	11	0.045
2	0.250	12	0.042
3	0.167	13	0.038
4	0.125	14	0.036
5	0.100	15	0.033
6	0.083	16	0.031
7	0.071	17	0.029

Line pair/cm	Gap size (cm)	Line pair/cm	Gap size (cm)
8	0.063	18	0.028
9	0.056	19	0.026
10	0.050	20	0.025

The number of line pairs/cm visually resolved is 8 for the higher preset (see **Figure 7.11** on page 250) and 7 for the lower preset.

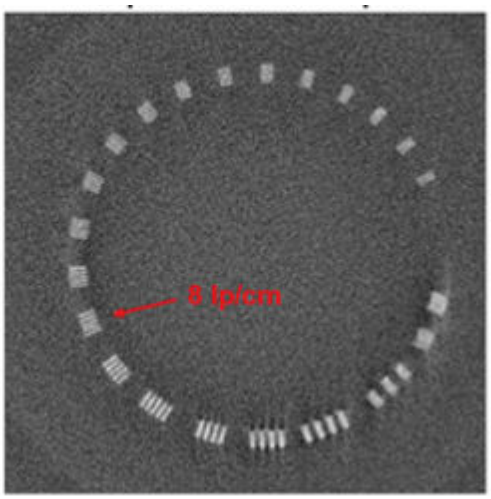

Figure 7.11 Reconstructed image of a section with line pairs

Contrast to Noise Ratio (CNR)

Contrast-to-Noise (CNR) measures contrast between two objects in reconstructed images with consideration taken to noise in each object.

The CNR may be measured in Catphan® 503 in objects of different Hounsfield Units (HU), see **Figure 7.12** on page 251. CNR is determined by calculating:

$$CNR = \frac{|S_k - S_{uniform}|}{\sqrt{\sigma_k^2 + \sigma_{uniform}^2}}$$

where S_k is signal in one of the cylindrical objects, $S_{uniform}$ is the signal in the uniform section between the objects and σ_k, $\sigma_{uniform}$ is the respectively noise.

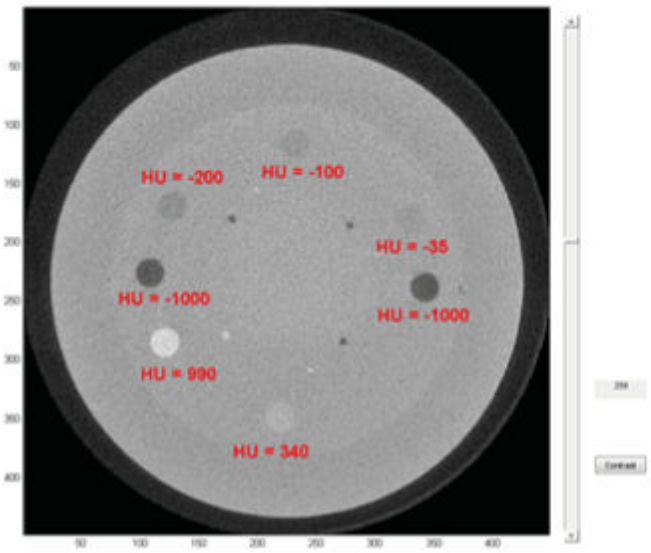

Figure 7.12 Reconstructed section in Catphan with inserts of different HU

CNR will depend on the presets (since noise is mAs dependent) as shown in **Figure 7.13** on page 251. The higher preset will show about 1.5 higher CNR compared to the lower preset.

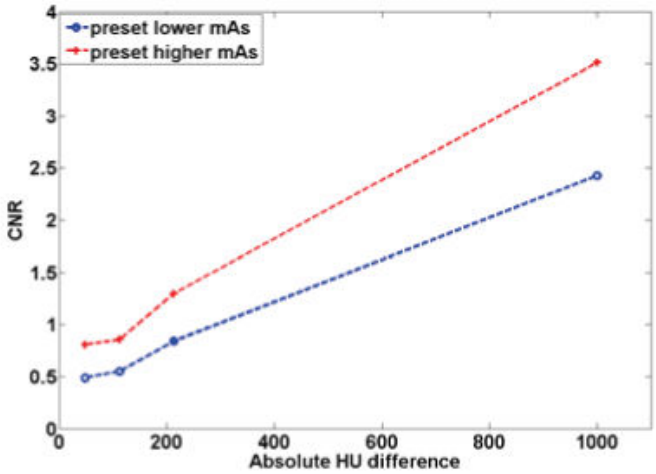

Figure 7.13 CNR as a function of HU for the two presets

Uniformity

Ideally, a reconstructed image of an object consisting of uniform material should have a constant value. But, because of scatter and beam hardening, a profile along the object will show variation.

The uniformity may be measured in the homogenous section of Catphan® 503. Measurements show variation up to 170 HU along the profile shown below.

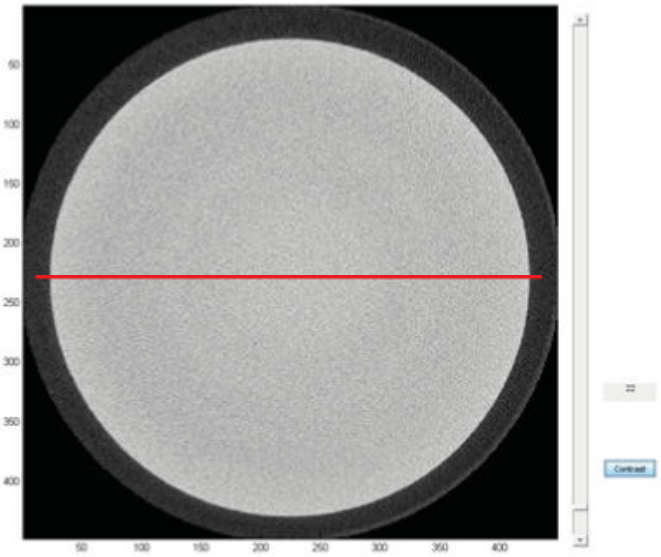

Figure 7.14 Homogenous section of Catphan

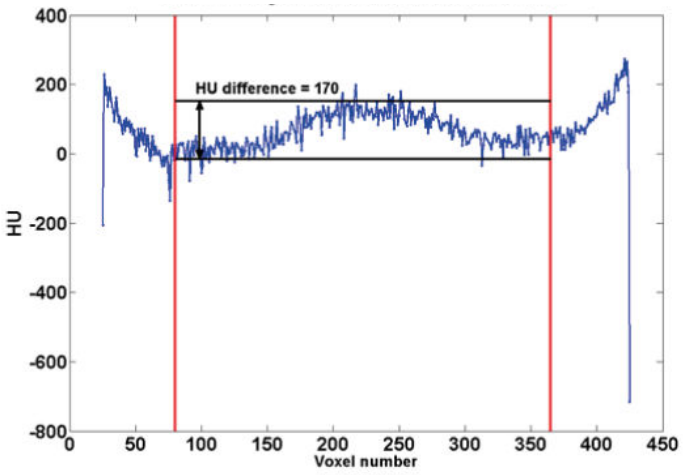

Figure 7.15 Profile along the line in previous figure

7.15.8 Patient weight compensation and CBCT image coordinates

When reading out coordinates from the CBCT images in the viewer or in Leksell GammaPlan, it is important to understand the effect of the patient weight and how it is compensated for in the system.

Inside the treatment cavity, the PPS is not sensitive to the weight of the patient. But, in the scanning position, there is a small sagging of the couch because of the patient weight. The geometric relation between scan and treatment position is calibrated without weight on the PPS. There will therefore be a small geometric deviation between stereotactic coordinates in the scan position and the treatment position when a patient is on the PPS.

The deviation is linear to patient weight and is of the order 0.08 mm for a 70 kg patient. The deviation is primarily in the Y and Z directions.

To compensate for this effect, the system applies a compensation transformation to the stereotactic coordinate definition of the reconstructed CBCT images. The compensation transform assumes a 70 kg patient on the couch.

The weight compensation is not applied during CBCT precision QA. It is not necessary since the QA examines the relative position difference since calibration and not the absolute positions. Note though, that if the CBCT images are used for a user defined precision QA, the compensation is applied in those images. It is therefore recommended to load the couch with 70 kg when you do user defined tests on accuracy.

7.15.9 Description of the reconstruction algorithm

When you acquire the projection images, Leksell Gamma Knife® Icon™ uses a reconstruction algorithm to make the 3D volume image.

The CBCT reconstruction procedure in Leksell Gamma Knife® Icon™ uses the Feldkamp-Davis-Kress (FDK) filtered back projection algorithm. Refer to *Feldkamp et al, 1984, 'Practical cone beam Algorithm', Journal of the Optical Society of America A, vol. 1, no. 6, pp. 612–619*. The implementation of the algorithm utilizes a graphics processor to give sufficient speed to reconstruct a volume image.

In conjunction with the FDK algorithm the projection images are weighted using Parker weighting to account for duplicate information due to the 197 degrees scan range of the gantry. Furthermore, to reduce noise in the volume image, a scaled Hamming apodization filter is used to filter the projection images. For details refer to *'A. C. Kak and M. Slaney, Principles of Computerized Tomographic Imaging. SIAM 2001, p. 323'*.

The FDK algorithm does not account for scattered radiation, 'beam hardening' and detector imperfections. These effects give voxel intensity values that are not easily related to Hounsfield intensities. These effects will also cause artifacts in the reconstructed volume. In the next section the resulting artifacts are discussed.

For more information on this algorithm and its limits in clinical operation, refer to:

- *Remeijer et al, 2004 'First clinical experience with cone-beam CT based setup correction protocols' Proceedings of the 8th International Workshop on Electronic Portal Imaging, EPI2K4, pp. 92–93*
- *Remeijer et al, 2004 'A comparison of patient dose from cone-beam CT scans and localization portal images', Proceedings of the 8th International Workshop on ElectronicPortal Imaging EPI2K4, pp. 88–89.*

7.15.10 Description of image artifacts

The artifacts appear because of the limits of the image acquisition or reconstruction procedure. An image artifact is a pattern that is not a part of the anatomy or an object.

7.15.10.1 Artifacts affecting Hounsfield correctness and uniformity

The reconstructed volume will not have correct Hounsfield values and homogeneous objects will not appear homogeneous in the reconstructed image. This can have several causes:

- **Scattered radiation:** The algorithm assumes that photons travel in straight paths when propagating through an object. However due to interaction (Rayleigh and Compton scatter) an additional low spatial frequency component will be added to the projection images.
- **Beam hardening:** FDK also assumes that the x-rays are monoenergetic which is not true, the x-rays have a spectra of energies. Since photons with lower energy is not as penetrable as photons with higher energy the spectrum tends have a larger amount of high energy photons after penetrating media. This is called beam hardening.
- **Ghosting and lagging:** Ghosting is the change of sensitivity in the x-ray detector and lagging is a residual signal. Both effects are due to previous exposures of the detector. These effects are smaller than beam hardening and scattering in the Leksell Gamma Knife® Icon™ system.

A bowtie filter is used to homogenize the field at the detector, reduce the dose to the patient and reduce the beam hardening and scattering artifacts. The form of the bowtie filter is optimized to give as uniform signal to the detector as possible when an idealized head is irradiated (a water cylinder). Since the image object most often differs from the idealized head and the bowtie filter itself hardens the beam, it is very hard to separate the artifacts from each other, other than in special cases. An example is the inhomogeneity of a reconstructed volume see **Figure 7.16** on page 254. This is a reconstruction of an anthropomorphical phantom for which the soft tissue is homogeneous.

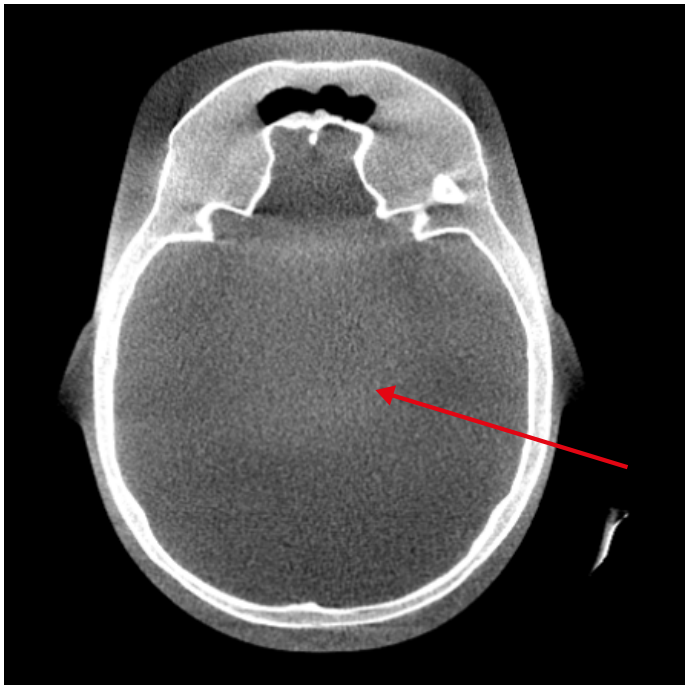

Figure 7.16 Example of non-uniformity in a uniform area of an antropomorphical phantom. There are several sources of non-uniformity for example scattered radiation, beam hardening, detector lagging and ghosting.

7.15.10.2 Cone beam artifacts

It is not possible to mathematically exact reconstruct a volume from cone beam projection images using a circular scanning path. The FDK algorithm uses an approximation to overcome this problem which results in the so called ‘Cone beam artifacts’. The artifact appear as a smearing in the axial direction of objects that are flat and parallel with the axial plane. The artifact gets larger in the axial direction away from the plane in the beam that is orthogonal to rotation axis. In the Leksell Gamma Knife® Icon™ system this plane is close to the frame plane which means that the

artifact increases higher up in the head. At the top of the head the artifact is most visible, see **Figure 7.17** on page 255:

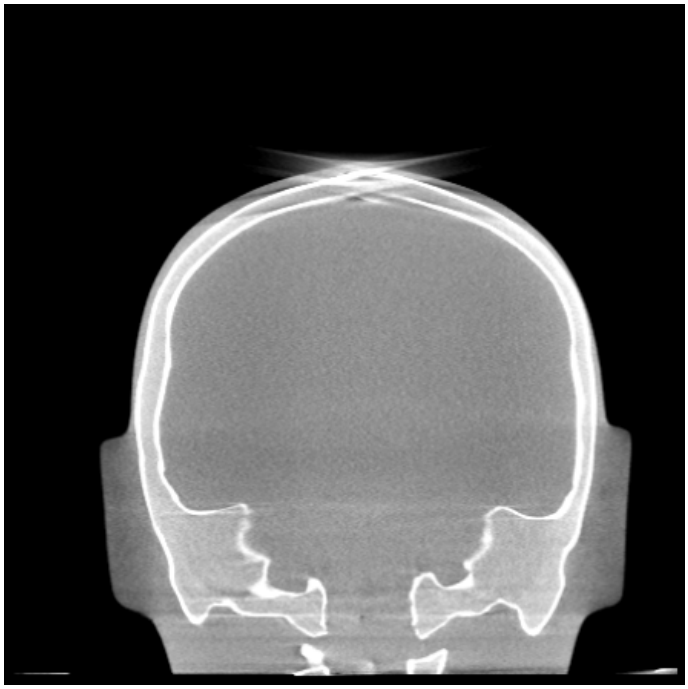

Figure 7.17 Example of a cone beam artifact at the top of the head

7.15.10.3 Streak artifacts

The streak artifacts can occur if the cone beam reconstruction is susceptible to interruptions, or if there are differences between the adjacent projection images. For example, streak artifacts can occur because of:

- Edges in the image field that are not sufficiently sampled by the small number of projections (that is, aliasing effects). An object in the FOV (or included in a subset of the projection set) that has hard high contrast edges can cause streak artifacts in the reconstructed slices. The object is possibly a part of the patient (for example, bone edges, teeth, metal objects) or a part of the equipment (for example, the edge of the table top or a part of an immobilization device). To find the cause of these artifacts, try to follow the streak artifacts to their source.
- Inconsistent beam hardening. As X-ray radiation goes through the patient, the profile of its spectrum changes as lower energy photons are absorbed (beam hardening). Where adjacent X-rays go through materials with different atomic numbers (Z), the degree of the beam hardening of these X-rays can change. This can cause the material in the ‘shadow’ of high Z material to appear to have a different density to material that is the same, but in a different area. This causes streak artifacts.

7.15.10.4 Artifacts due to non-ideal calibration

The artifacts in this section will not appear in a calibrated system.

Gain calibration: The gain calibration normalize the pixel response and the x-ray field. If the gain calibration is non ideal there will be diffuse rings in the volume image. In **Figure 7.18** on page 256 artifacts because of a bad calibration can be seen. The artifact was induced by shifting the gain calibration map, two pixels to the left.

Defect pixel: A defect pixel map is used to correct for defect pixels in the x-ray detector. If a pixel is defect and not calibrated for, a sharp ring will appear in the axial plane of the reconstructed

images. **Figure 7.19** on page 257 shows the result in the reconstructed volume of an introduced defect pixel.

In the coronal or sagittal image planes, the defect pixel bad gain calibration artifacts appear as lines, as they are of a cylinder or cone structure. The defect pixel artifact and bad gain calibration artifact will not affect the co-registration algorithm.

Geometry calibration: If the detector geometry calibration is wrong, for example if the detector is shifted after calibration, the reconstructed volume will have discontinuities. In **Figure 7.20** on page 257 the result in the reconstructed images by shifting the detector in the rotational direction of about 2 mm can be seen. This shift is detected by the QA algorithm but if the images are used there is a risk for mistreatment.

WARNING: If this artifact appears in the reconstructed volume, there is a risk for mistreatment.

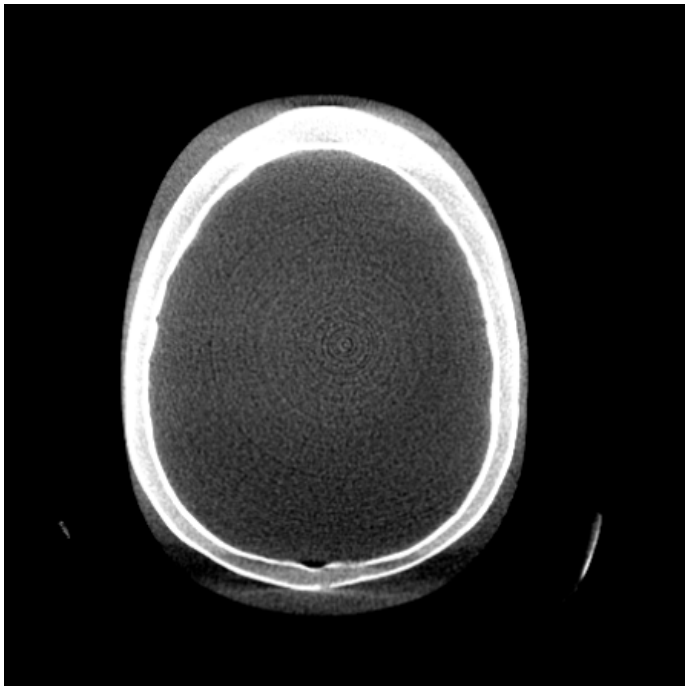

Figure 7.18 A bad gain calibration results in diffuse rings in the axial plane of the reconstructed images

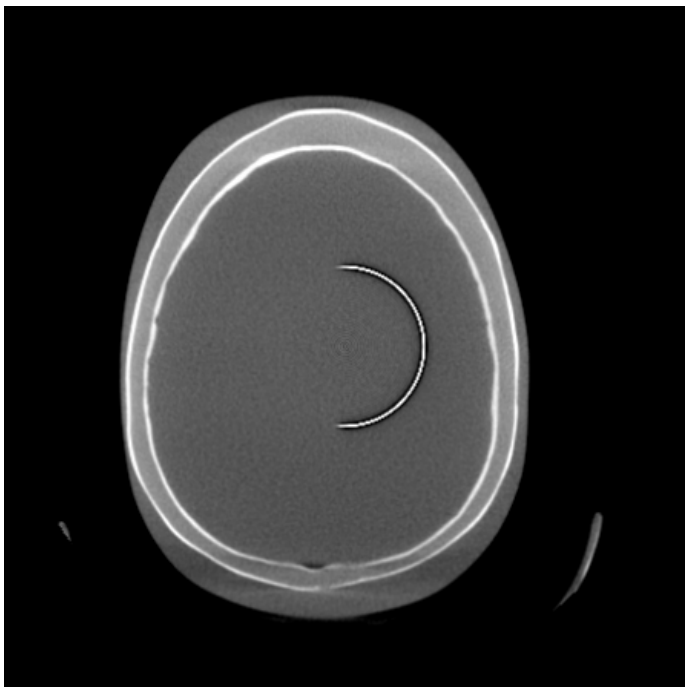

Figure 7.19 A non-corrected defect pixel will appear as a sharp ring in the axial plane of the reconstructed volume

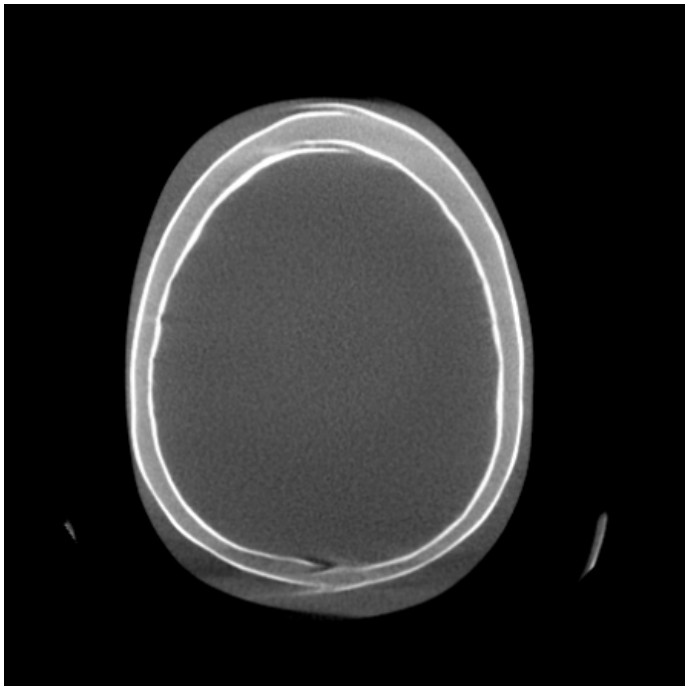

Figure 7.20 If the detector geometry calibration is erroneous, the reconstructed image will have discontinuities. This can be seen in the bone at the top of the image

7.15.11 Imaging volume and focal spot to image detector distance

The volume of the 3D imaging is 224 x 224 x 224 mm.

The distance from the focal spot of the kV X-ray beam to the image detector is 1000 mm.

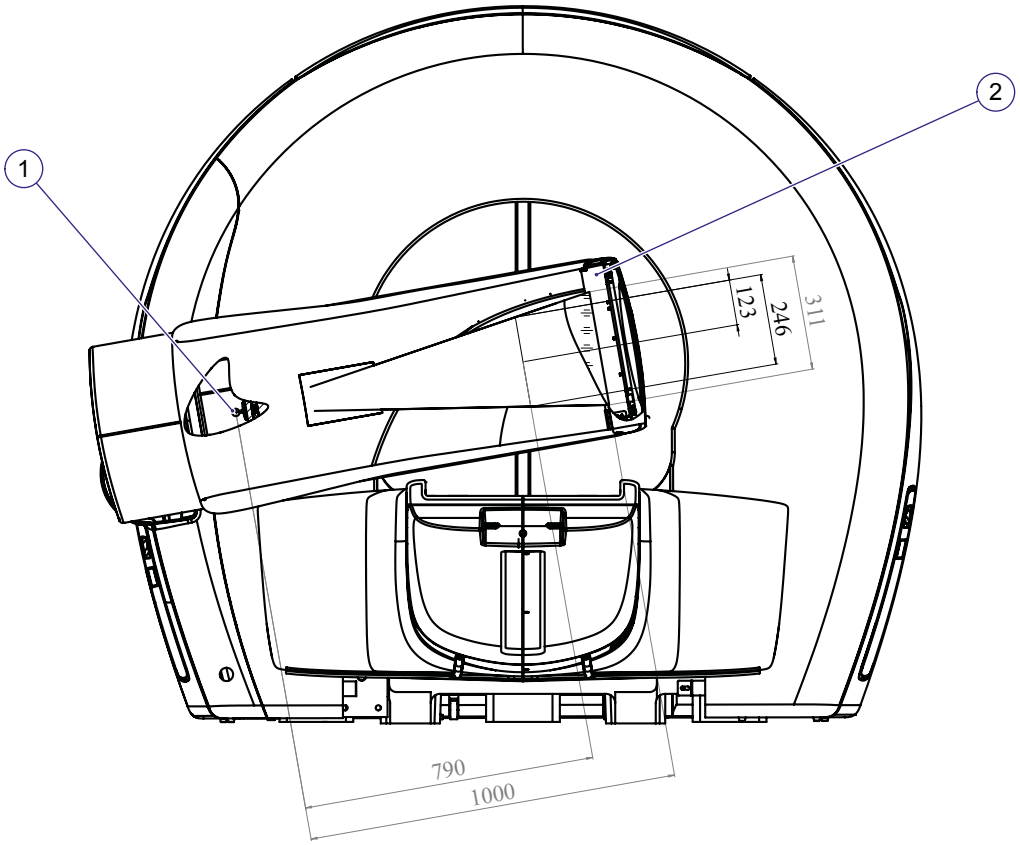

Figure 7.21 Dimensions between the kV source and the kV detector panel

(1) Focal spot of the kV X-ray beam (2) Image receptor (kV detector panel)

7.15.12 Description of the IEC 60601-1-3 compliance of the confinement of extra focal radiation

The extra focal radiation is not more than 15 cm in the superior direction to the patient of the X-ray field.

7.16 Declaration of electromagnetic emission

The Leksell Gamma Knife® unit is intended for use in the electromagnetic environment specified below. The customer or the user of the unit must make sure that it is used in such an environment.

Emission Test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group 1	The Leksell Gamma Knife® unit uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Leksell Gamma Knife® unit is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Emission Test	Compliance	Electromagnetic environment guidance
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

7.17 Electromagnetic compatibility, cable configuration

Leksell Gamma Knife® Icon™ complies with the requirements of the standard EN/IEC 60601-1-2 with the cables as follows:

Cable	Length	Used for
Cable 016	32 m	TV camera
Cable 017	32 m	TV camera
Cable 074	50 m	Treatment room monitor
Cable 082	33 m	Connect the ECU to the operator console
Cable 083	33 m	Patient microphone
Cable 084	33 m	Patient speaker
Cable 088	30 m	Connect the MCU to the X-Ray detector
Cable 089	30 m	Connect the MCU to the gantry module
Cable 136	50 m	Treatment room monitor

Shorter cables can be used if available.

The use of accessories, transducers and cables other than those specified by Elekta may result in increased emissions or decreased immunity of the equipment.

7.18 Declaration of electromagnetic immunity

The Leksell Gamma Knife® unit is intended for use in the electromagnetic environment specified below. The customer or the user of the unit must make sure that it is used in such an environment.

Immunity Test	IEC 60601-1-2 test level	Compliance	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, 4, 8, 15 kV air	±8 kV contact ±2, 4, 8, 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines 100 kHz ±1 kV for input/output lines 100 kHz	±2 kV for power supply lines 100 kHz ±1 kV for input/ output lines 100 kHz	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (100% drop in UT) for 0.5 cycles at 0º,45º, 90º,135º, 180º,225º, 270º,315º <5 % UT (100% dip in UT) for 1 cycle 70 % UT (30% dip in UT) for 25/30 cycles <5 % UT (100% drop in UT) for 5 sec	<5 % UT (100% drop in UT) for 0.5 cycles at 0º,45º, 90º,135º, 180º,225º, 270º,315º <5 % UT (100% dip in UT) for 1 cycle 70 % UT (30% dip in UT) for 25/30 cycles <5 % UT (100% drop in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. To supply the Leksell Gamma Knife® unit with continued electrical power during mains electrical supply failure, the unit has an uninterruptible power supply (UPS).
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Immunity Test	IEC 60601-1-2 test level	Compliance	Electromagnetic environment guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	6 V 150 kHz to 80 MHz, modulation 80% AM at 1 kHz 3 V/m 80 MHz to 2,7 GHz	6 V 150 kHz to 80 MHz, modulation 80% AM at 1 kHz 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of Leksell Gamma Knife® including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = \left[\frac{3.5}{3}\right]\sqrt{P}$ (150 kHz to 80 MHz) $d = \left[\frac{3.5}{3}\right]\sqrt{P}$ (80 to 800 MHz) $d = \left[\frac{7.0}{3}\right]\sqrt{P}$ (800 MHz to 2,5 GHz) where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[4] should be less than the compliance level in each frequency range.[5] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

7.19 Portable and mobile RF communications equipment

Leksell Gamma Knife® is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Leksell Gamma Knife® can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Leksell Gamma Knife® as recommended below, according to the maximum output power of the communications equipment.

[4] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Leksell Gamma Knife® is used exceeds the applicable RF compliance level above, Leksell Gamma Knife® should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating Leksell Gamma Knife®.

[5] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

WARNING 7.1

Keep all radio equipment (TETRA radios, cellular telephones, Wi-Fi devices) out of the treatment room during the treatment, and at least 30 cm from your device in the control room.

WARNING 7.2

This equipment has been tested for radiated RF immunity only at selected frequencies, and use nearby of emitters at other frequencies could result in improper operation.

Recommended separation distances between portable and mobile RF communications equipment and Leksell Gamma Knife®

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{3}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{3}\right]\sqrt{P}$	800 MHz to 2,5 GHz $d = \left[\frac{7.0}{3}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

A Appendix: Dosimetry phantom and Film Holder Tool (Optional)

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1.1 Introduction

This appendix is valid for the Dosimetry phantom and Film Holder Tool used with Vantage frame adapter.

For information on the Dosimetry phantom and Film Holder Tool used with G-frame adapter, refer to *Leksell Gamma Knife® Dosimetry phantom and Film Holder Tool, Instruction for Use*.

1.2 Dosimetry Phantom and Film Holder Tool

There are two tools available to do a check of the dosimetrical requirements of the Leksell Gamma Knife®:

- Dosimetry Phantom
- Film Holder Tool

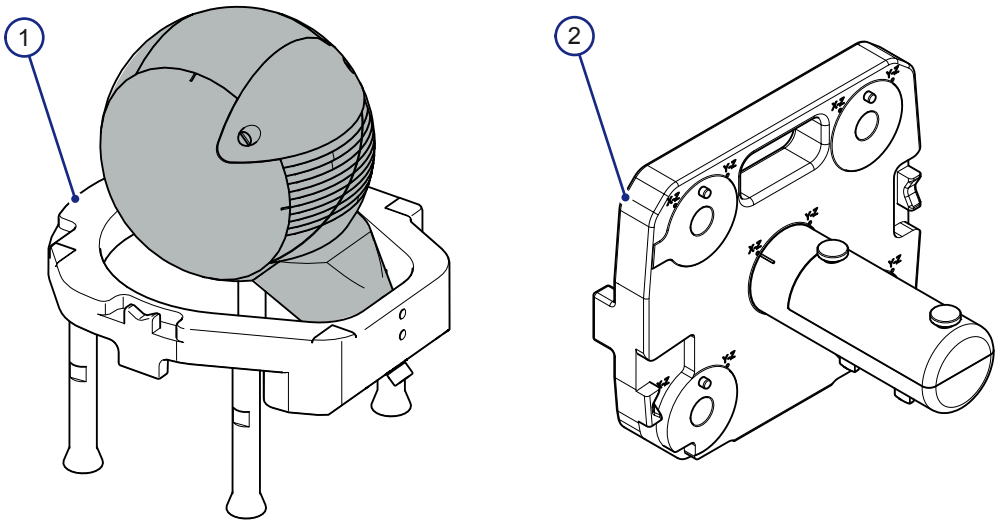

Figure 1.1 The Dosimetry Phantom (1) mounted on a base plate, and the Film Holder Tool (2)

Note: *These tools are optional and not by default delivered with the Leksell Gamma Knife®.*

The Dosimetry phantom is used for:

- Measuring the absorbed dose rate
- Measuring the precision in the dose delivery

The Film Holder Tool is used for:

- Measuring the accuracy in the dose delivery

1.2.1 The workflow to verify the radiological specifications of Leksell Gamma Knife®

The radiological specifications for the Leksell Gamma Knife® are verified in three steps:

1 **Measuring the absorbed dose rate.** In this procedure, the dose rate is measured under specified conditions. The measuring is done by an authorized person.

2 **Measuring the precision in the dose delivery.** In this procedure a comparison is done of the measured and calculated spatial dose distributions surrounding the radiological focus point.

3 **Measuring the accuracy in the dose delivery.** In this procedure the locations of the PPS calibration centre point and the radiological focus point within the treatment unit are compared.

1.3 Dosimetry phantom

1.3.1 Description of the Dosimetry Phantom

The shape and size of the Dosimetry Phantom simulate the shape and size of an adult human head. The phantom is made of Solid Water®. Solid Water responds to cobalt-60 radiation as water would do regarding absorbed dose.

The complete Dosimetry Phantom consists of the dosimetry phantom (1) mounted on a base plate (2), see **Figure 1.2**.

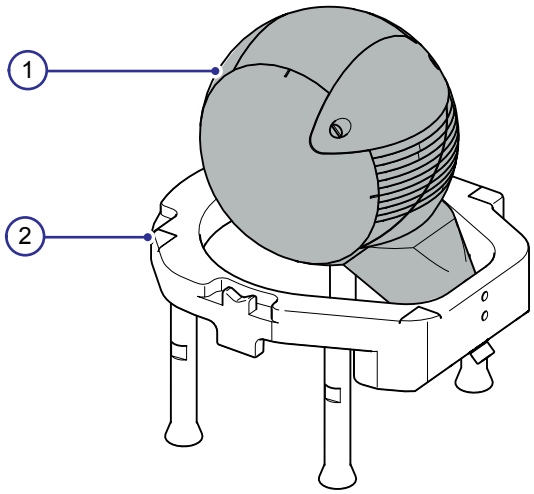

Figure 1.2 The complete Dosimetry Phantom (1) with the base plate

The complete Dosimetry Phantom can be assembled for different applications:

- Dosimetry Phantom with ionization chamber for measuring the absorbed dose rate.
- Dosimetry Phantom with film stack for measuring the precision in dose delivery.

1.3.1.1 Description of the Film perforator

The Film perforator (1), see **Figure 1.3**, is used for making positioning holes in the film. The holes make it possible to correctly position the film in the Dosimetry phantom.

The Film cassette (2) is used for fixating the film in the Film perforator.

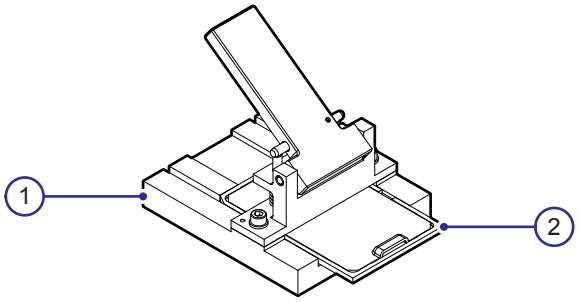

Figure 1.3 The Film perforator with a film cassette

1.3.2 Assembling the Dosimetry phantom and base plate

The Dosimetry phantom can be used with different types of base plates. It is not intended to move the Dosimetry phantom between different base plates on a regular basis. Moving the Dosimetry phantom too often could decrease the lifetime of the Dosimetry phantom.

To assemble the Dosimetry phantom and the Vantage base plate:

1 Attach the Dosimetry phantom (1) to the base plate (2). Make sure that the front clamp (4) is on the top of the Dosimetry phantom.

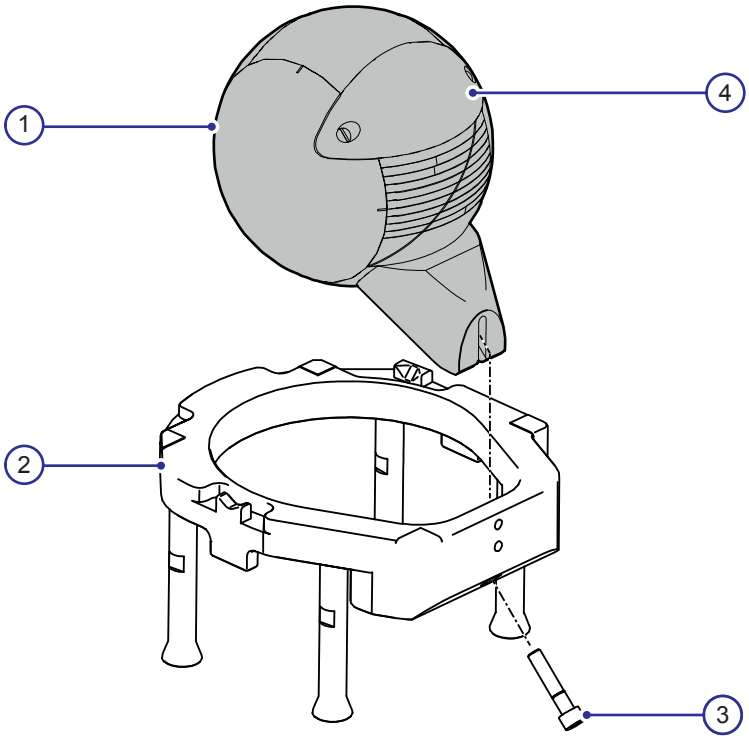

Figure 1.4 Assembling the Dosimetry phantom and base plate

2 Insert the screw (3) and tighten until the Dosimetry phantom is firmly attached to the base plate.

WARNING 1.1

Do not tighten the screw that attaches the Dosimetry phantom to the base plate, or the screws on the front clamp, too tightly. If the screws are too tightly tightened, it can cause damage to the Dosimetry phantom and screws.

1.3.3 Using the Dosimetry phantom with ionization chamber

The Dosimetry phantom with ionization chamber is used for measuring the absorbed dose rate.

1.3.3.1 Assembling the Dosimetry Phantom with the ionization chamber

To assemble the Dosimetry phantom with the ionization chamber:

1 Insert the ion chamber housing (2), with the shorter section first, into the hole at the bottom of the phantom base (1), see **Figure 1.5**. Push the ion chamber housing as far in as possible.

WARNING 1.2

Make sure that the ion chamber is in correct position in the housing. An ion chamber in incorrect position can result in incorrect measurement of the dose rate.

WARNING 1.3

If you want to drill a hole in an undrilled ion chamber housing, make sure to obey the drilling instruction that is delivered with the Dosimetry phantom. An ion chamber with an incorrectly positioned hole can result in incorrect measurement of the dose rate.

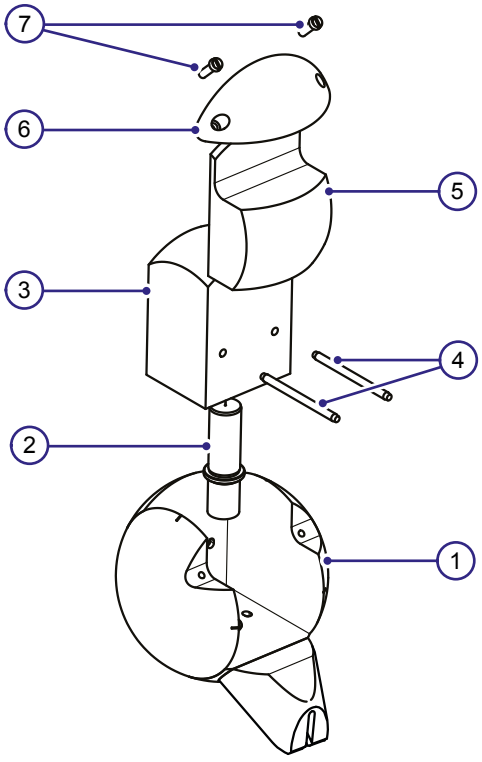

Figure 1.5 Exploded view of the Dosimetry Phantom with ionization chamber

(1)	Phantom base	(5)	Upper Film Holder
(2)	Ion chamber housing	(6)	Front clamp
(3)	Ion chamber clamp	(7)	Screws
(4)	Film Holder align rods		

2 Insert the ion chamber (1) into the ion chamber housing at the bottom of the phantom base (2), see **Figure 1.6**

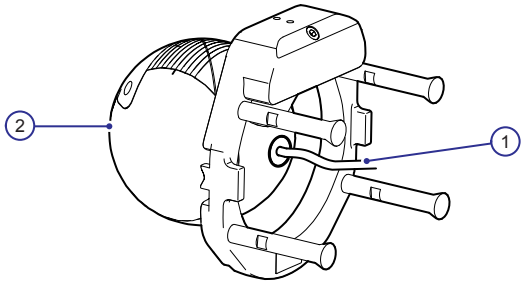

Figure 1.6 The ionization chamber inserted into the dosimetry phantom

3 Put the ion chamber clamp (3) on the ion chamber housing (2), see **Figure 1.5**. Make sure that the ion chamber clamp is tightly attached.

4 Insert the two film holder align rods (4) into the holes in the ion chamber clamp. Push the rods as far as possible into the ion chamber clamp.

5 Attach the upper film holder (5) on the ion chamber clamp.

6 Attach the front clamp (6) on the phantom base, and tighten the screws (7). Tighten the screws alternately.

WARNING 1.4

Do not tighten the screw that attaches the Dosimetry phantom to the base plate, or the screws on the front clamp, too tightly. If the screws are too tightly tightened, it can cause damage to the Dosimetry phantom and screws.

1.3.3.2 Measuring the absorbed dose rate

Prerequisites

The Dosimetry phantom is assembled with the ionization chamber.

Tools and material needed:

- Dosimetry Phantom Vantage
- Vantage frame adapter
- Ionization chamber, small

WARNING 1.5

Before starting the measurements, make sure the phantom and measuring equipment have acquired room temperature.

WARNING 1.6

Handle the Dosimetry phantom with care and keep it in the intended place. Any damage may affect the accuracy of the tool, which may lead to incorrect results of the measurement.

If you suspect that the Dosimetry phantom may have been damaged due to a drop or other impact, the accuracy of the Dosimetry phantom must be verified. Contact Elekta for instructions on how to proceed.

WARNING 1.7

Make sure that the ion chamber is in correct position in the housing. An ion chamber in incorrect position can result in incorrect measurement of the dose rate.

WARNING 1.8

Before using the Dosimetry Phantom, make sure that there is no mechanical play and that the Dosimetry Phantom base is tightly attached to the base plate.

To measure the absorbed dose rate:

1 Attach the Vantage frame adapter to the Dosimetry Phantom Vantage:

a Put the Dosimetry Phantom Vantage on a flat surface.

b Release the left and right levers on the Vantage frame adapter, see **Figure 1.7**.

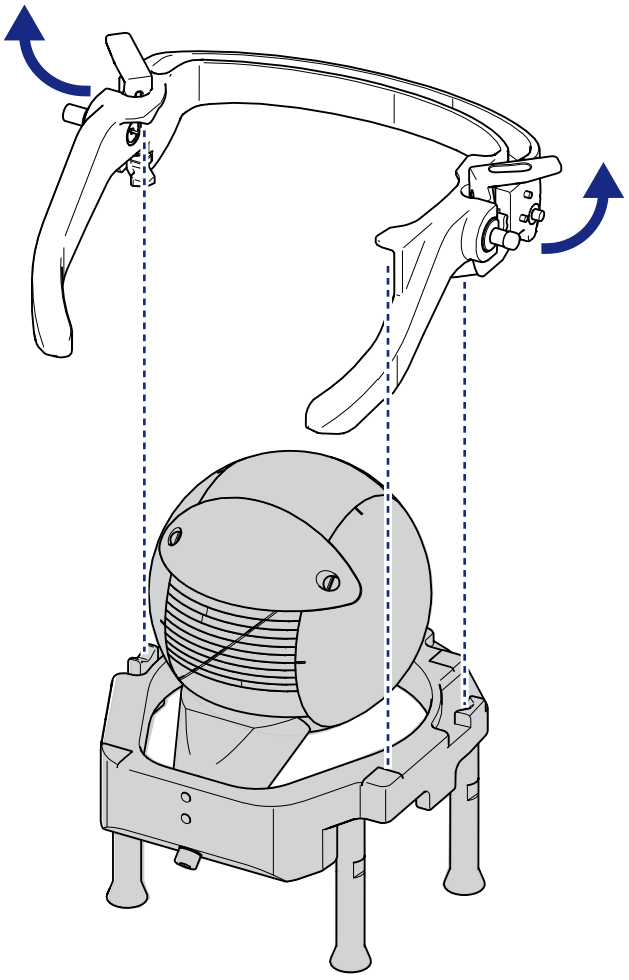

Figure 1.7 Attaching the Vantage frame adapter to the Dosimetry phantom

c Hold the Vantage frame adapter above the Dosimetry phantom, with the four reflector markers pointing down.

d Lower the frame adapter and fit it to the three interface areas on the base plate of the Dosimetry phantom.

e Turn and fold down the left and right levers to lock the frame adapter, see **Figure 1.8**.

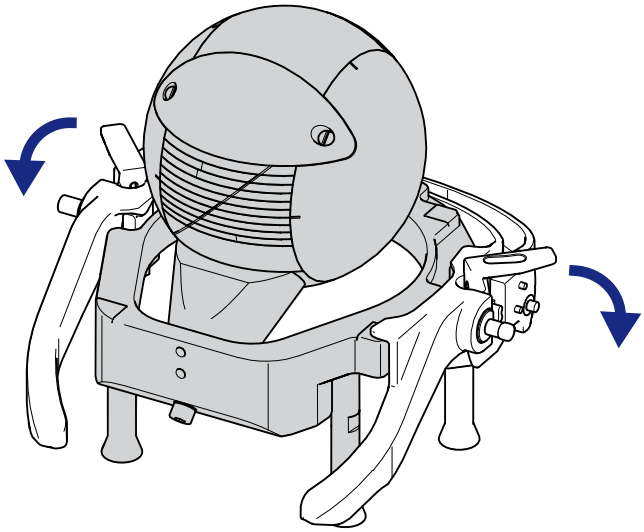

Figure 1.8 Lock the Vantage frame adapter to the Dosimetry phantom

2 Dock the Vantage frame adapter with the Dosimetry Phantom Vantage to the docking device of the patient couch.

3 Start a run with the 16 mm collimator. The run must be sufficiently long to enable measuring the dose rate according to the local dose rate protocol. When the Dosimetry Phantom is moved to treatment position, Leksell® coordinates (100, 100, 100), the measuring point of the chamber aligns with the radiological focus point.

Note: *The ionization chamber must be in treatment position during the measuring procedure to accurately measure the dose rate and to avoid unwanted shutter dose.*

4 Examine the measurements according to the local dose rate protocol.

1.3.4 Using the Dosimetry phantom with film stack

The Dosimetry phantom with film stack is used for measuring the precision in the dose delivery. The film stack is either placed vertically or horizontally in the dosimetry phantom.

1.3.4.1 Assembling the Dosimetry Phantom with the film stack

To assemble the Dosimetry phantom with the film stack:

1 Put the ion chamber plug (2) into the hole at the bottom of the phantom base (1), see **Figure 1.9**. Push the ion chamber plug as far in as possible.

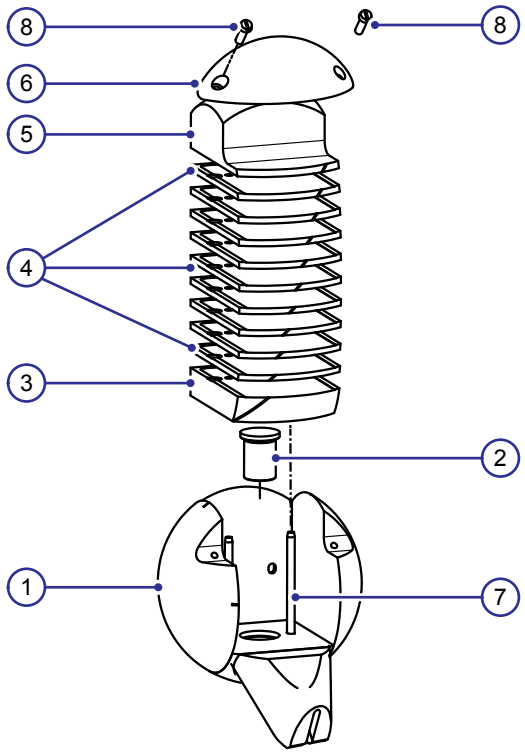

Figure 1.9 Exploded view of the Dosimetry phantom with vertical film stack

(1)	Phantom base	(5)	Upper film holder
(2)	Ion chamber plug	(6)	Front clamp
(3)	Bottom film holder	(7)	Film holder align rods
(4)	Thin film holders	(8)	Screws

2 Put a film (1) at the inner surface of a thin film holder (2) so that the positioning holes in the film and thin film holder align, see **Figure 1.10**. Repeat this for the desired number of films.

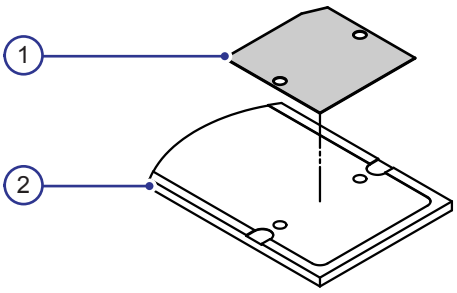

Figure 1.10 Put the film at the inner surface of a thin film holder

3 Assemble the upper film holder (5), the thin film holders (4), and the bottom film holder (3) so that the engravings on each component together create a diagonal line across the arched surface of the film holder stack, see **Figure 1.9**.

4 Insert the two film holder align rods (7) into the holes of the film stack. Push the rods as far as possible into the holes.

5 Put the film holder stack into the phantom base vertically (for measuring in the X-Y plane) or horizontally (for measuring in the X-Z plane), see **Figure 1.11**

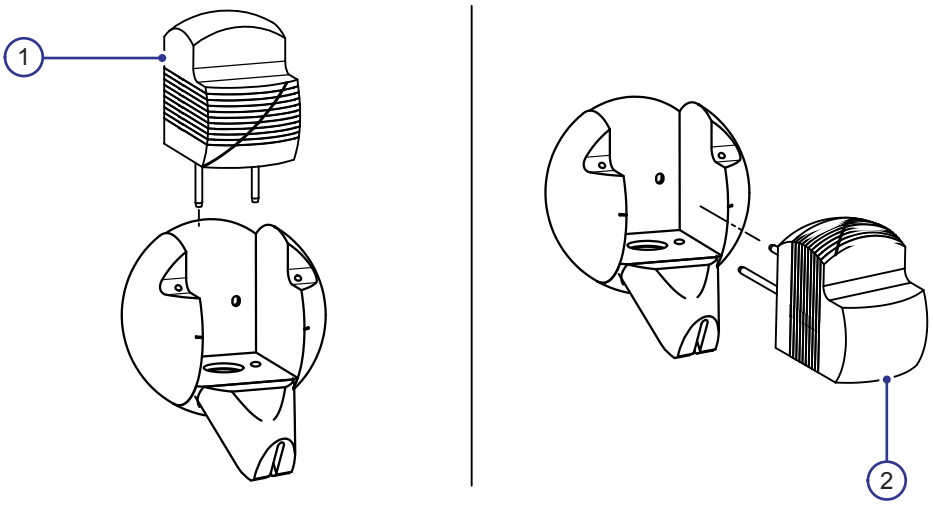

Figure 1.11 Film stack installed vertically (1), and horizontally (2)

6 Attach the front clamp (6) on the phantom base and tighten the screws (8), see **Figure 1.9**. Tighten the screws alternately.

WARNING 1.9

Do not tighten the screw that attaches the Dosimetry phantom to the base plate, or the screws on the front clamp, too tightly. If the screws are too tightly tightened, it can cause damage to the Dosimetry phantom and screws.

Preparing the film for the film stack

Tools and material needed:

- GAFCHROMIC® (EBT3) film or an equivalent
- Film perforator with film cassette
- A thin permanent pen

The scanner response of GAFCHROMIC® film depends on the orientation of the film. Therefore it is important to cut one corner and mark each film with the orientation.

To prepare the film for the dosimetry phantom:

1 Cut the films in equal-sized squares. Minimum 60 mm x 60 mm and maximum 65 mm x 65 mm. Two films for each collimator size is required.

2 Cut the corner of each film, and carefully mark the orientation of each film, see **Figure 1.12**.

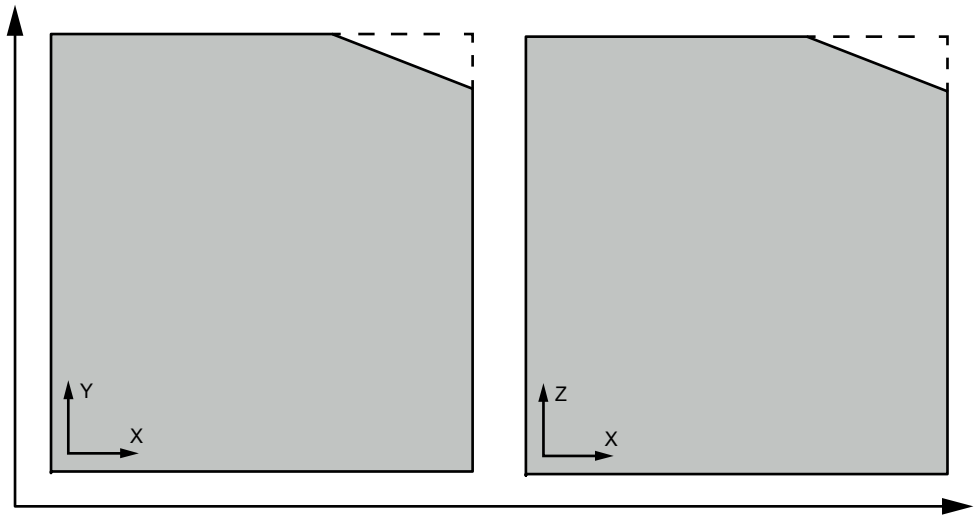

Figure 1.12 Films cut and marked with the coordinate system

3 Make holes in the films:

a Put the film in the film cassette tray, see **Figure 1.13**.

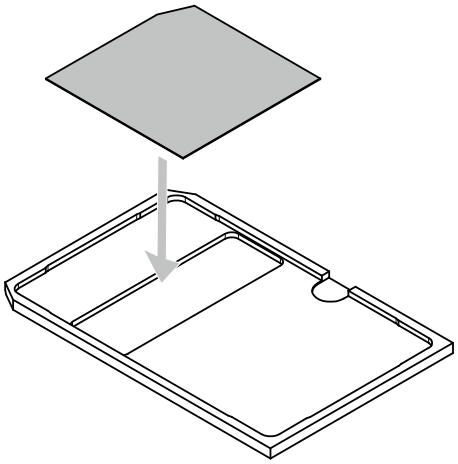

Figure 1.13 Put the film in the film cassette tray

b Put the film cassette lid on the film cassette tray so that the opening in the lid aligns with the opening in the tray, see **Figure 1.14**.

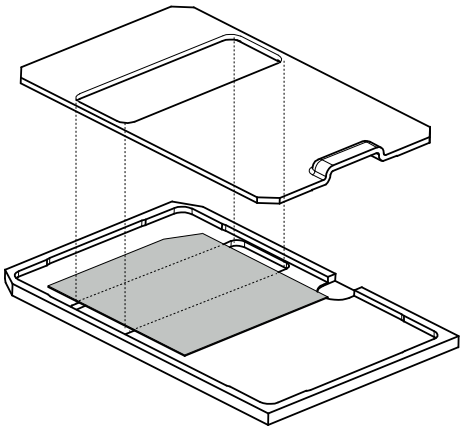

Figure 1.14 Attach the film cassette lid

c Put the film cassette tray into the Film perforator, the side with the opening first. Push until stop, see **Figure 1.15**.

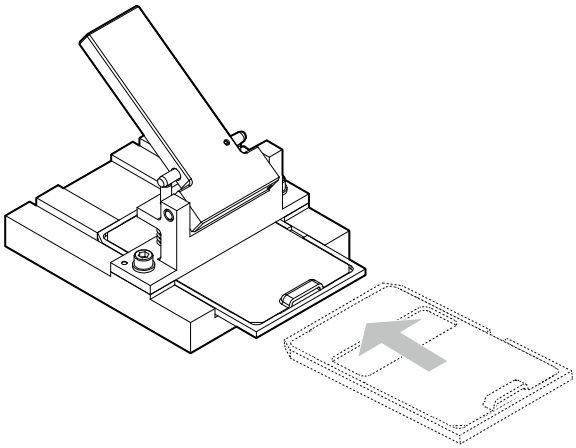

Figure 1.15 Insert the film cassette tray into the Film perforator

d Push down the Film perforator handle until stop to make holes in the film, see **Figure 1.16**.

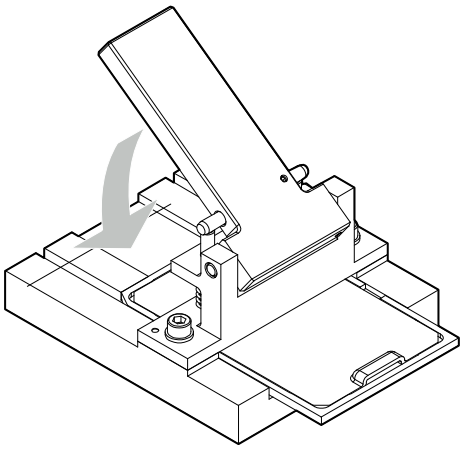

Figure 1.16 Push down the handle

Note: *Handle the film with care. Avoid scratches, and avoid long exposures to daylight and changes in temperature.*

Note: *For more information regarding film handling, refer to the information from the film manufacturer.*

1.3.4.2 Measuring the precision in the dose delivery

Tools and material needed:

- Dosimetry Phantom Vantage
- Vantage frame adapter
- Cut and marked films (two for each collimator size)

WARNING 1.10

Handle the Dosimetry phantom with care and keep it in the intended place. Any damage may affect the accuracy of the tool, which may lead to incorrect results of the measurement.

If you suspect that the Dosimetry phantom may have been damaged due to a drop or other impact, the accuracy of the Dosimetry phantom must be verified. Contact Elekta for instructions on how to proceed.

To measure the precision in the dose delivery in a Leksell Gamma Knife®:

1 Assemble the Dosimetry phantom with the film stack vertically so that the films are in the X-Y plane, refer to *Assembling the Dosimetry Phantom with the film stack*.

2 Attach the Vantage frame adapter to the Dosimetry Phantom Vantage:

a Put the Dosimetry Phantom Vantage on a flat surface.

b Release the left and right levers on the Vantage frame adapter, see **Figure 1.17**.

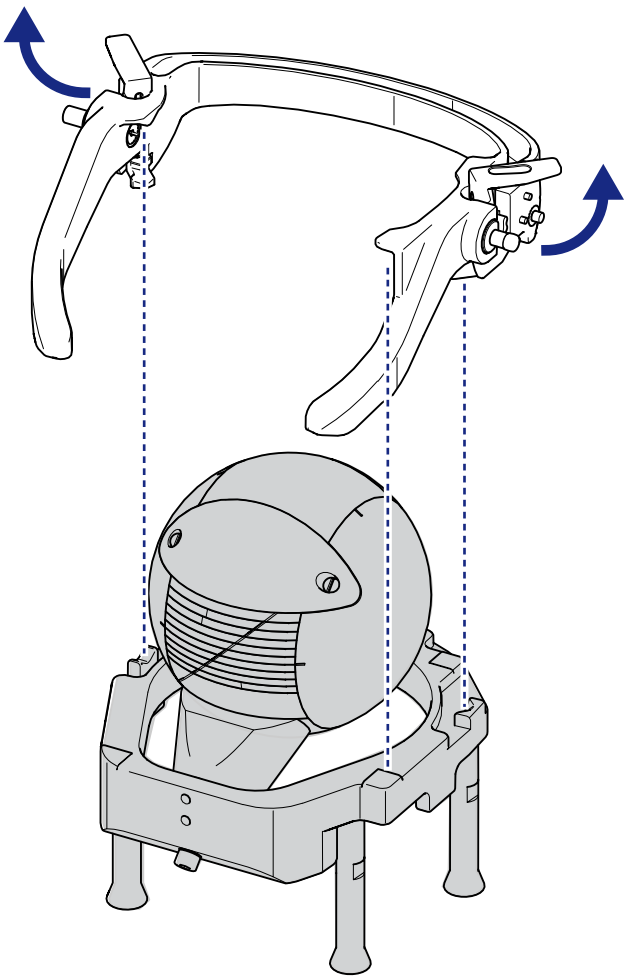

Figure 1.17 Attaching the Vantage frame adapter to the Dosimetry phantom

c Hold the Vantage frame adapter above the Dosimetry phantom, with the four reflector markers pointing down.

d Lower the frame adapter and fit it to the three interface areas on the base plate of the Dosimetry phantom.

e Turn and fold down the left and right levers to lock the frame adapter, see **Figure 1.18**.

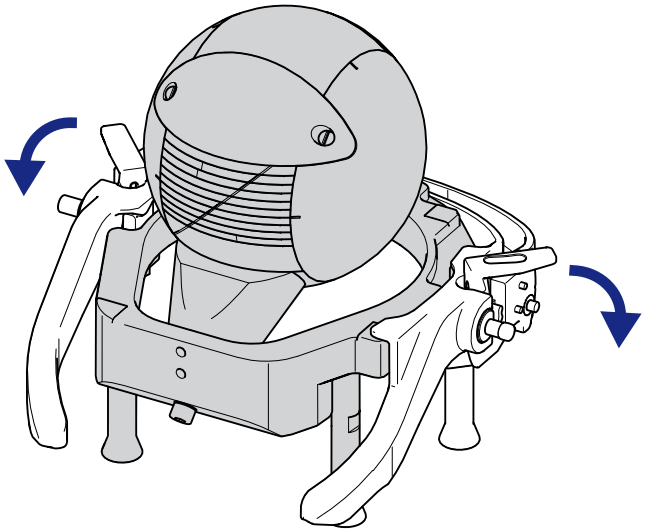

Figure 1.18 Lock the Vantage frame adapter to the Dosimetry phantom

3 Dock the Vantage frame adapter with the Dosimetry Phantom in the docking device on the patient couch.

4 Prepare a plan for the measurement at Leksell® coordinates (100, 100, 100).

5 Expose the Dosimetry Phantom for a time period corresponding to 5 Gy for EBT3 films.

6 Remove the front clamp and take out the exposed films from the thin film holder.

7 Assemble the Dosimetry phantom with new films and with the film stack horizontally so that the films are in the X-Z plane.

8 Do step **4** to step **6** for the same collimator size but in the X-Z plane.

9 Examine the films to make sure that the exposures look reasonable. If necessary, do the exposure again.

10 Save the exposed films in a dark envelope.

11 Do step **1** to step **10** again for the other collimator sizes.

Calibrating the film

Do this procedure to convert the image intensity to dose. This procedure is valid for GAFCHROMIC® film types EBT 3.

1 Cut eight films into a minimum size of 60 mm x 60 mm, maximum size 65 mm x 65 mm.

2 Use the largest collimator size. With the Dosimetry Phantom centered at the Leksell® coordinate X=Y=Z= 100, expose the films in sequence. All films shall be aligned with the X-Y plane.

3 Expose the films to these doses:

	Dose in [Gy], for film number							
Film type	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
EBT 3	0	0.5	1	2	3	4	6	8

4 Examine all films and make sure that the exposures are reasonable. If necessary, do the exposure again.

5 Save the films in a dark envelope.

1.4 Film Holder Tool

1.4.1 Description of the Film Holder Tool

The Film Holder Tool is used for doing checks of multiple points in the stereotactic treatment volume through film dosimetry, see **Figure 1.19**.

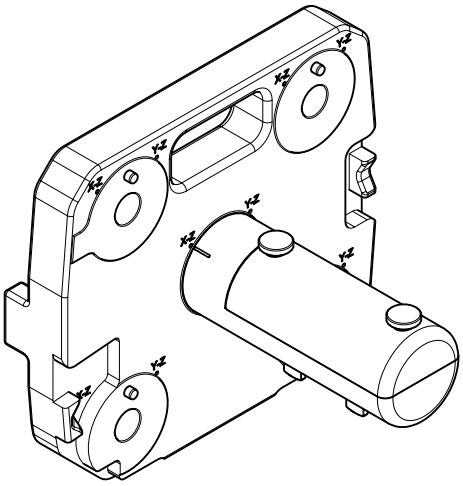

Figure 1.19 The Film Holder Tool

The Film Holder Tool is attached to the Vantage frame adapter and then docked to the docking device of the Leksell Gamma Knife®. A film is placed in the Film Holder Tool and when the tool is docked, the centre of the hole made in the film aligns with the Leksell® coordinate system (100, 100, 100).

The geometrical relationship between the radiological focus point and the Leksell® coordinate system (100, 100, 100) is determined by exposing the film to radiation and measuring the distance between the centre of the dose distribution and the centre of the hole made in the film.

In addition to measuring the dose distribution in Leksell® coordinate system (100, 100, 100), you can mount the housing and measure in these four positions too:

- (40, 40, 100)
- (160, 40, 100)
- (160, 160, 100)
- (40, 160, 100)

1.4.2 Using the Film Holder Tool

The Film Holder tool is used for measuring the accuracy in the dose delivery.

1.4.2.1 Preparing the film for the Film Holder Tool

Tools and material needed:

- GAFCHROMIC® (EBT3) film or an equivalent
- A thin permanent pen

The scanner response of GAFCHROMIC® film depends on the orientation of the film. Therefore it is important to cut one corner and mark each film with the orientation.

To prepare the film for the Film Holder Tool:

1 Cut two films to size 40 mm x 50 mm.

2 Cut the corner of each film, and carefully mark the orientation of each film, see **Figure 1.20**.

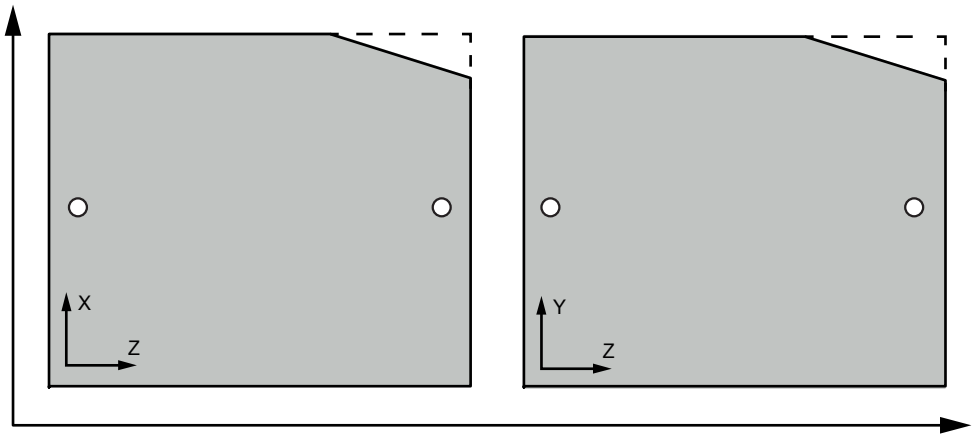

Figure 1.20 Films cut and marked with the coordinate system

Note: *Handle the film with care. Avoid scratches, and avoid long exposures to daylight and changes in temperature.*

Note: *For more information regarding film handling, refer to the information from the film manufacturer.*

1.4.2.2 Measuring the accuracy in the dose delivery

Tools and material needed:

- Film Holder Tool Vantage
- Vantage frame adapter
- Cut and marked films

To measure the accuracy in the dose delivery:

1 Attach the Vantage frame adapter to the Film Holder Tool:

a Release the left and right levers on the Vantage frame adapter, see **Figure 1.21**.

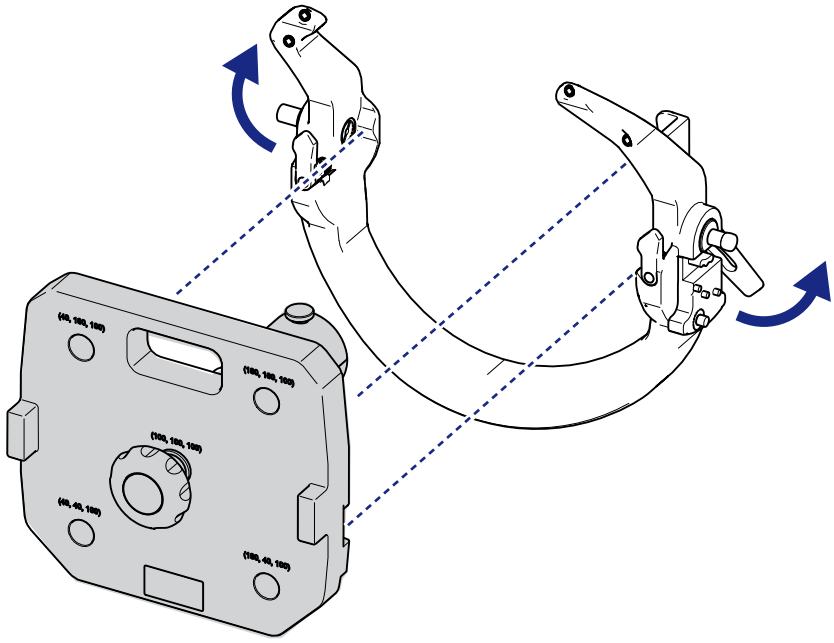

Figure 1.21 Attaching the Vantage frame adapter to the Film Holder Tool

b Fit the frame adapter to the three interface areas on the Film Holder Tool.

c Turn and fold down the left and right levers to lock the frame adapter, see **Figure 1.22**.

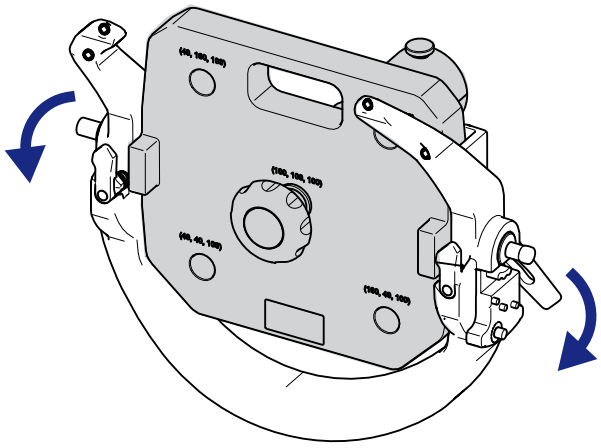

Figure 1.22 Lock the Vantage frame adapter to the Film Holder Tool

2 Dock the Vantage frame adapter with the Film Holder Tool to the docking device of the patient couch.

3 Put the Film Holder Tool housing (4) in X-Z position in the base plate (1) and tighten the knob (2), see **Figure 1.23**.

WARNING 1.11

Make sure that the knob is correctly tightened. There must be no gap between the base plate and the housing of the Film Holder Tool. If there is a gap, the needle is not in the correct position, which can lead to incorrect measurement.

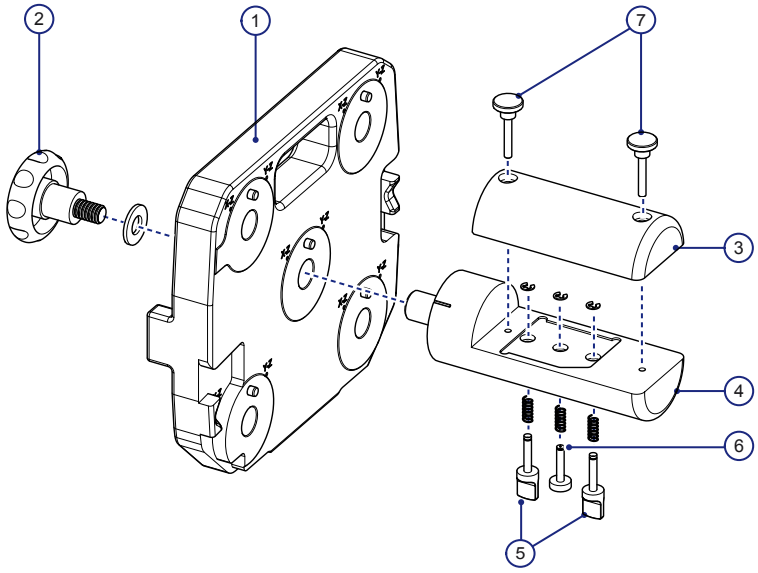

Figure 1.23 Exploded view of the Film Holder Tool

(1)	Base plate	(5)	Film markers
(2)	Knob	(6)	Needle
(3)	Clamp	(7)	Film fixation screws
(4)	Housing		

4 Place the film (1) in the Film Holder Tool housing, see **Figure 1.24**

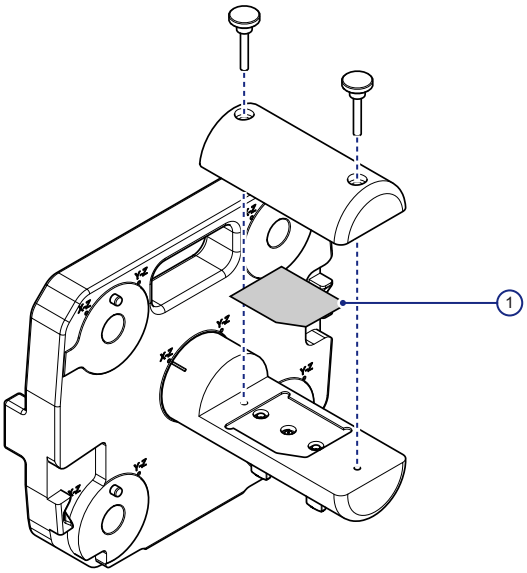

Figure 1.24 Placing the film in the housing

5 Attach the clamp (3) on the housing and tighten the two film fixation screws (7), see **Figure 1.25**. Tighten the screws simultaneously to get equal pressure on the film.

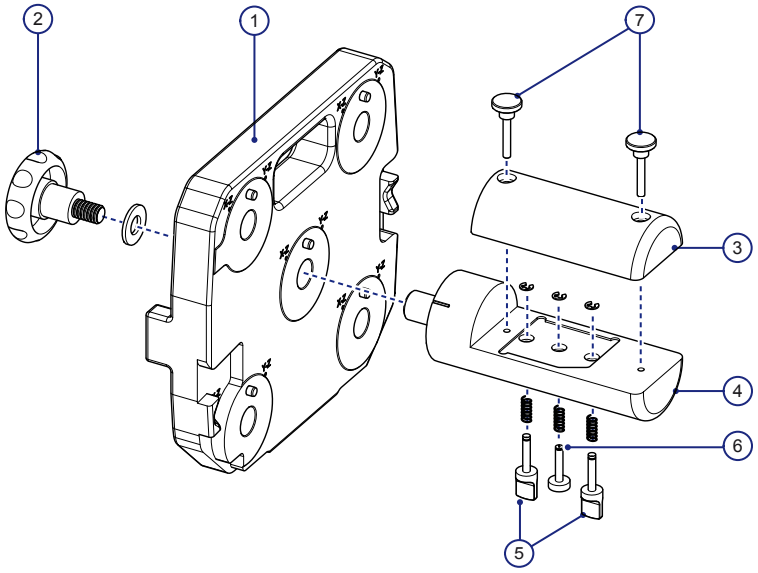

Figure 1.25 Exploded view of the Film Holder Tool

(1)	Base plate	(5)	Film markers
(2)	Knob	(6)	Needle
(3)	Clamp	(7)	Film fixation screws
(4)	Housing		

6 After tightening, make sure that the housing is in correct position by checking that the measuring plane lines (X-Z) on the base plate and the housing are aligned.

7 Use the needle (6) to make a hole in the film.

8 Push and turn the film markers (5) to make two positioning markers in the film.

9 Prepare a treatment plan for a selected collimator size that corresponds to 5 Gy for the EBT3 film.

10 Run the treatment plan to expose the film.

11 Loosen the film fixation screws and lift up the clamp.

12 Take out the film from the housing.

13 Examine the film to make sure that the exposure is reasonable. Also make sure that there is a narrow hole and two positioning markers in the film, see **Figure 1.26**. If necessary, do the measurement again.

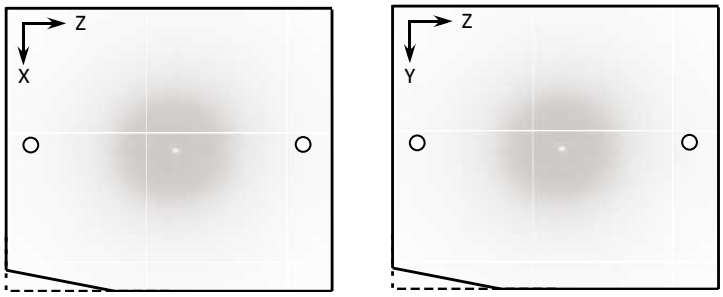

Figure 1.26 The films after the exposure, marked with orientation and positioning markers

14 Loosen the knob and rotate the housing in orientation Y-Z plane.

15 Do step **4** to **13** for orientation Y-Z.

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List of Warnings and Cautions

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We are healthcare technology innovators, specializing in radiotherapy treatments for cancer and brain disorders.

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