NEUROMODULATION MRISAFETY STATUS

July 2019

Medtronic

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Medtronic Further, Together

NEUROMODULATION MRI SAFETY STATUS JULY 2019

Go to mrisurescan.com for more information or medtronic.com/MRI for complete MRI labeling.

Always review the most current labeling prior to performing an MRI scan.

For additional assistance, contact Medtronic Technical Services at 1-800-707-0933.

a Normal Operating Mode:

- Maximum of 2.0 W/Kg Average Body SAR
- Maximum of 3.2 W/Kg Average Head SAR
- Maximum Gradient Slew Rate at 80% of PNS Limit

IEC. 60601-2-33:2010+A11:2011. Medical electrical equipment. Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis . 3rd ed. Geneva, Switzerland: International Electrotechnical Commission; 2010.

- * Under specific conditions of use. Refer to approved labeling.
- ** Medtronic data on file.
- *** Pump resumes programmed therapy after MRI scan; requires interrogation to confirm pump status.
- ‡ If pocket adapter present do not conduct full-body scans. Refer to head scan only labeling.
- [†] SureScan[™] MRI Systems that do not meet the Full Body Eligibility requirements may still be Head Scan eligible.
- No MRI if 3023 neurostimulator serial number is:
 - Less than NBV132955H
 - Between NBV133037H and NBV133063H
 - Between NBV628045S and NBV628263S
- ††† Quadrature only.

For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use.

THERAPY		PRODUCT	MODEL NUMBER	MR CONDITIONAL	STATIC MAGNET STRENGTH	MAX SPATIAL GRADIENT	RF COIL***	AVERAGE SAR (W/KG) OR B1 + rms(μT)	MAX SLEW RATE	STIMULATION STATUS FOR MRI	OTHER ELIGIBILITY CRITERIA
	SureScan™	Intellis™ SureScan™ MRI	97715/97716	Yes — Full-Body Eligible	1.5 T closed bore	≤19 T/m	Transmit: Built-in Body or Head Transmit/ Receive Coils Receive: No Restrictions	^a Normal Operating Mode	≤200 T/m/s	MRI Mode	Full Body Eligibility Report [†]
		RestoreSensor™ SureScan™ MRI	97714								
		RestoreUltra [™] SureScan MRI	97712								
		RestoreAdvanced [™] SureScan MRI	97713								
		PrimeAdvanced [™] SureScan MRI	97702								
		RestoreSensor™	37714	Yes — Head Only Eligible	1.5 T closed bore	≤19 T/m	Transmit/Receive Head Coil	^a Normal Operating Mode	≤200 T/m/s	Stim Off	No components in the head coil
		RestoreUltra™	37712								
		RestoreAdvanced™	37713								
		PrimeAdvanced™	37702								
PAIN STIMULATION*		Restore™	37711								
		Synergy™	7427								
UMI		Versitrel™	7427V								
IN S		Itrel [™] 4	37703 37704								
PA		Itrel 3	7425	No	Not Applicable						
		Activa™PC	37601	Yes — Full-Body Eligible	1.5 T closed bore	≤19 T/m	Transmit: Built-in Body or Head Transmit/ Receive Coils Receive: No Restrictions	≤ 2.0µT B1+rms or ≤ 0.1 W/kg SAR	≤ 200 T/m/s	Stim Off if unipolar Stim On or Stim Off if bipolar	Impedance check required, No pocket adapters [‡] , Abandoned system — do not conduct full-body MRI scan
		Activa [™] SC	37603								
MULATION*		Activa [™] RC	37612								
		Activa™SC	37602	Yes — Head-Only Eligible	1.5 T closed bore	**	Transmit/Receive Head Coil	≤ 0.1 W/kg SAR	≤ 200 T/m/s	Stim Off	Impedance check required, No abandoned components within 0 cm of Transmit/Receive coil
SAIN		Soletra™	7426							Stim Off, Bipolar, Settings set to 0 V	
DEEP BRAIN ST		Kinetra™	7428							Stim Off, Reed switch disabled, Cycling disabled	
TARGETED	DELIVERY*	SynchroMed [™] II***	8637	Yes — Full-Body Eligible	1.5 T 3.0T closed bore	** ≤19 T/m	See labeling for established performance	*First level Mode *Normal Operating Mode	≤ 200 T/m/s	N/A	No z-axis orientation
L MODIII 4-	NEUROMODULA- TION*	InterStim [™]	3023	Yes — Head-Only Eligible Only specific serial numbers ^{††}	1.5 T closed	≤ 19 T/m	Transmit/Receive Head Coil	^a Normal Operating Mode	≤ 200 T/m/s	Neurostimulator Off; Magnetic Reed Switch Disabled	No components in head coil
SACRAI		InterStim™ II	3058	Yes — Head-Only Eligible	bore					Neurostimulator Off	
ENTERRA		Enterra™	3116								
				No			Not Applicable -MRI Unsafe				