

CLARIA MRI™ QUAD CRT-D SURESCAN™

Model DTMA1QQ
IS4/DF-4

Product specifications

Physical characteristics

Volume ^a	35 cm ³
Mass	81 g
H x W x D	74 mm x 51 mm x 13 mm
Surface area of device can	57 cm ²
Radiopaque ID ^b	PFZ
Materials in contact with human tissue ^c	Titanium, polyurethane, silicone rubber, titanium dioxide
Battery	Hybrid CFx lithium/silver vanadium oxide

^a Volume with connector ports unplugged.

^b The radiopaque ID, which includes a Medtronic-identifier symbol, can be viewed in a fluoroscopic image of the device.

^c These materials have been successfully tested for the ability to avoid biological incompatibility. The device does not produce an injurious temperature in the surrounding tissue during normal operation.

Replacement indicators

Recommended Replacement Time (RRT)	< 2.73 V on 3 consecutive daily automatic measurements
End of Service (EOS)	3 months after RRT

Maximum energy levels and typical full energy charge times

Maximum programmed energy	35 J
Maximum delivered energy ^{a,b}	36 J
Maximum stored energy ^c	42 J
Typical charge time at Beginning of Service (BOS) ^d	8.3 s
Typical charge time at Recommended Replacement Time (RRT) ^d	12.0 s

^a Energy delivered at connector block into a 50 Ω load.

^b For 35 J programmed energy, delivered energy exceeds 35 J.

^c Energy stored at charge end on capacitor.

^d Charge time during a nonwireless telemetry session may be slightly higher.



- MR Conditional
- EffectivCRT™ Diagnostic
- EffectivCRT™ During AF Algorithm
- PhysioCurve™ Design
- AdaptivCRT™ Algorithm
- CardioSync™ Optimization
- VectorExpress™ 2.0 LV Automated Test
- Multiple point pacing
- SmartShock™ Technology
- OptiVol™ 2.0 Fluid Status Monitoring
- MVP™ Mode with Complete Capture Management™ Diagnostic (ACM, RVCM, LVCM)

Medtronic

Device parameters

Tachyarrhythmia detection parameters

Parameter	Programmable values
AT/AF Detection	On; Monitor
Zones	1 ; 2
AT/AF Interval (Rate) ^a	150; 160 ... 350 ... 450 ms
Fast AT/AF Interval (Rate) ^a	150; 160 ... 200 ... 250 ms
VF Detection ^b	On ; Off
VF Interval (Rate) ^a	240; 250 ... 320 ... 400 ms
VF Initial Beats to Detect	12/16; 18/24; 24/32; 30/40 ; 45/60; 60/80; 75/100; 90/120; 105/140; 120/160
VF Beats to Redetect	6/8; 9/12; 12/16 ; 18/24; 21/28; 24/32; 27/36; 30/40
FVT Detection	Off ; via VF; via VT
FVT Interval (Rate) ^a	200; 210 ... 240 ... 600 ms
VT Detection	On; Off
VT Interval (Rate) ^a	280; 290 ... 360 ... 650 ms
VT Initial Beats to Detect	12; 16 ... 52; 76; 100
VT Beats to Redetect	8; 12 ... 52
VT Monitor	Monitor ; Off
VT Monitor Interval (Rate) ^a	280; 290 ... 450 ... 650 ms
Monitored VT Beats to Detect	16; 20; 24; 28; 32 ... 56; 80; 110; 130
PR Logic™/Wavelet	
AF/Afl ^b	On ; Off
Sinus Tach ^b	On ; Off
Other 1:1 SVTs	On; Off
Wavelet ^b	On ; Off; Monitor
Template	[date]
Match Threshold	40; 43; 46 ... 70 ... 97%
Auto Collection	On; Off
SVT V. Limit ^a	240; 250; 260 ... 650 ms
Other enhancements	
Stability ^a	Off ; 30; 40 ... 100 ms
Onset	Off ; On; Monitor
Onset Percent	72; 75; 78; 81 ; 84; 88; 91; 94; 97%
High Rate Timeout	
VF Zone Only	Off ; 0.25; 0.5; 0.75; 1; 1.25; 1.5; 1.75; 2; 2.5; 3; 3.5; 4; 4.5; 5 min
All Zones	Off ; 0.5; 1; 1.5 ... 5; 6; 7 ... 20; 22; 24; 26; 28; 30 min
T-Wave	On ; Off
RV Lead Noise	On; On+Timeout ; Off
Timeout	0.25; 0.5; 0.75 ... 2 min
Sensitivity	
Atrial ^c	0.15; 0.30 ; 0.45; 0.60; 0.90; 1.20; 1.50; 1.80; 2.10; 4.00 mV; Off

RV ^c	0.15; 0.30 ; 0.45; 0.60; 0.90; 1.20 mV
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^a The measured intervals are truncated to a 10 ms multiple (for example, 457 ms becomes 450 ms). The device uses this truncated interval value when applying the programmed criteria and calculating interval averages.

^b The AF/Afl, Sinus Tach, and Wavelet features are automatically set to On when VF Detection is set to On.

^c This setting applies to all sensing in this chamber for both tachyarrhythmia detection and bradycardia pacing operations.

Atrial tachyarrhythmia therapy parameters

Parameter	Programmable values
Anti-Tachy Pacing (ATP)	
AT/AF Rx Status	On; Off
Therapy Type	50 Hz; Ramp; Burst+ Rx 1: Ramp ; Rx 2: Burst+ ; Rx 3: 50 Hz
Fast AT/AF Rx Status	On; Off
Therapy Type	50 Hz; Ramp; Burst+ Rx 1: Ramp ; Rx 2: Burst+ ; Rx 3: 50 Hz
Patient Activated CV	
Patient Activated CV Status	On; Off
Energy	0.4; 0.6 ... 1.8; 2; 3 ... 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35 J
Pathway ^a	AX>B; B>AX
Automatic CV	
AT/AF Automatic CV Status	On; Off
Energy	0.4; 0.6 ... 1.8; 2; 3 ... 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35 J
Pathway ^a	AX>B; B>AX
Fast AT/AF Automatic CV Status	On; Off
Energy	0.4; 0.6 ... 1.8; 2; 3 ... 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35 J
Pathway ^a	AX>B; B>AX
Shared CV	
Minimum R-R Interval ^b	400; 410 ... 500 ... 600 ms
Active Can™/SVC Coil ^c	Can+SVC On ; Can Off; SVC Off
Automatic CV Limits	
Delivery Window Start Time	00:00; 01:00; 02:00; 03:00 ... 23:00
Delivery Window Length	1 ; 2; 3; 4; 6; 8; 10; 12; 16; 20; 24 hr
Maximum Shocks per Day	1 ; 2; 3; 4; 5; No Limit
Episode Duration before Rx Delivery	
Episode Duration before CV	0; 1; 2; 3; 4; 5; 7; 10; 15; 20; 25; 30; 40; 50 min; 1; 2; 3; 4; 5; 6 ; 12; 24; 48; 72 hr; 7 days
50 Hz Burst parameters	
50 Hz Burst Duration	0.5; 1 ; 2; 3 s
# Sequences	1; 2 ... 10

Atrial tachyarrhythmia therapy parameters, cont'd.

Parameter	Programmable values
Burst+ parameters	
Initial # S1 Pulses	1; 2 ... 15 \diamond ; 20; 25
A-S1 Interval (%AA)	28; 31; 34; 38; 41 ... 59; 63; 66 ... 84; 88; 91 \diamond ; 94; 97%
S1-S2 (%AA)	28; 31; 34; 38; 41 ... 59; 63; 66; 69 ... 84 \diamond ; 88; 91; 94; 97%; Off
S2-S3 Decrement	0; 10 \diamond ; 20 ... 80 ms; Off
Interval Decrement	0; 10 \diamond ... 40 ms
# Sequences	1; 2 ... 6 \diamond ... 10
Ramp parameters	
Initial # S1 Pulses	1; 2 ... 6 \diamond ... 15; 20; 25
A-S1 Interval (%AA)	28; 31; 34; 38; 41 ... 59; 63; 66 ... 84; 88; 91 \diamond ; 94; 97%
Interval Decrement	0; 10 \diamond ... 40 ms
# Sequences	1; 2 ... 8 \diamond ; 9; 10
Stop Atria Rx After (Shared)	
Rx/Lead Suspect ...	
Disable Atrial ATP if it accelerates V. rate?	Yes \diamond ; No
Disable all atrial therapies if atrial lead position is suspect? (Atrial Lead Position Check)	Yes \diamond ; No
Duration to stop	12; 24; 48 \diamond ; 72 hr; None
Episode Duration Before Rx Delivery	
Episode Duration Before ATP	0; 1 \diamond ; 2; 3; 4; 5; 7; 10; 15; 20; 25; 30; 40; 50 min; 1; 2; 3; 4; 5; 6; 12; 24 hr
Reactive ATP™	
Rhythm Change	On \diamond ; Off
Time Interval	Off; 2; 4; 7 \diamond ; 12; 24; 36; 48 hr
Shared A. ATP	
A-A Minimum ATP Interval ^b	100; 110; 120; 130 \diamond ... 400 ms
A.Pacing Amplitude	1; 2 ... 6 \diamond ; 8 V
A. Pacing Pulse Width	0.1; 0.2 ... 1.5 \diamond ms
VVI/VOO Backup Pacing ^d	Off; On (Always); On (Auto-Enable) \diamond
VVI/VOO Backup Pacing Rate	60; 70 \diamond ... 120 bpm

^a If the Active Can™/SVC Coil parameter is set to Can Off, the Active Can™ electrode is not used as part of the high-voltage delivery pathway. If the Active Can™/SVC Coil parameter is set to SVC Off, the SVC Coil electrode is not used as part of the high-voltage delivery pathway.

^b The measured intervals are truncated to a 10 ms multiple (for example, 457 ms becomes 450 ms). The device uses this truncated interval value when applying the programmed criteria and calculating interval averages.

^c The Active Can™/SVC Coil parameter applies to all automatic, manual, and emergency high-voltage therapies. It also applies to T-Shock inductions.

^d V. Backup Pacing is delivered to the RV chamber.

Ventricular tachyarrhythmia therapy parameters

Parameter	Programmable values
VF Therapy parameters	
VF Therapy Status	On \diamond ; Off
Energy	Rx1-Rx2: 0.4; 0.6 ... 1.8; 2; 3 ... 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35 \diamond J Rx3-Rx6: 10; 11 ... 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35 \diamond J
Pathway ^a	AX>B; B>AX Rx1-Rx4: B>AX \diamond ; Rx5-Rx6: AX>B \diamond
ATP	During Charging \diamond ; Before Charging; Off
Deliver ATP if last 8 R-R \geq	200; 210 ... 240 \diamond ... 300 ms
Therapy Type	Burst \diamond ; Ramp; Ramp+
ChargeSaver™	On \diamond ; Off
Switch when number of consecutive ATP successes equals	1 \diamond ; 2; 3; 4; 6; 8; 10
Smart Mode	On \diamond ; Off
VT/FVT Therapy parameters	
VT Therapy Status	On; Off \diamond
FVT Therapy Status	On; Off \diamond
Therapy Type	CV; Burst; Ramp; Ramp+ Rx1: Burst \diamond ; Rx2-Rx6: CV \diamond
Energy	0.4; 0.6 ... 1.8; 2; 3 ... 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35 J VT Rx1-Rx2: 20 \diamond J VT Rx3-Rx6: 35 \diamond J; FVT Rx1-Rx6: 35 \diamond J
Pathway ^a	AX>B; B>AX Rx1-Rx4: B>AX \diamond ; Rx5-Rx6: AX>B \diamond
Burst therapy parameters	
Initial # Pulses	1; 2 ... 8 \diamond ... 15
R-S1 Interval = (%RR)	50; 53; 56; 59; 63; 66 ... 84; 88 \diamond ; 91; 94; 97%
Interval Dec	0; 10 \diamond ... 40 ms
# Sequences	1; 2 ... 10 VT Therapies: 3 \diamond ; FVT Therapies: 1 \diamond
Smart Mode ^b	On; Off \diamond
Ramp therapy parameters	
Initial # Pulses	1; 2 ... 8 \diamond ... 15
R-S1 Interval = (%RR)	50; 53; 56; 59; 63; 66 ... 84; 88; 91 \diamond ; 94; 97%
Interval Dec	0; 10 \diamond ... 40 ms
# Sequences	1; 2 ... 10 VT Therapies: 3 \diamond ; FVT Therapies: 1 \diamond
Smart Mode ^b	On; Off \diamond

Ventricular tachyarrhythmia therapy parameters, cont'd.

Parameter	Programmable values
Ramp+ therapy parameters	
Initial # Pulses	1; 2; 3 \diamond ... 15
R-S1 Interval = (%RR)	50; 53; 56; 59; 63; 66 ... 75 \diamond ... 84; 88; 91; 94; 97%
S1S2 (Ramp+) = (%RR)	50; 53; 56; 59; 63; 66; 69 \diamond ... 84; 88; 91; 94; 97%
S2SN (Ramp+) = (%RR)	50; 53; 56; 59; 63; 66 \diamond ... 84; 88; 91; 94; 97%
# Sequences	1; 2 ... 10 VT Therapies: 3 \diamond ; FVT Therapies: 1 \diamond
Smart Mode ^b	On; Off \diamond
Shared Settings	
V-V Minimum ATP Interval	150; 160 ... 200 \diamond ... 400 ms
V. Amplitude	1; 2 ... 6; 8 \diamond V
V. Pulse Width	0.1; 0.2 ... 1.5 \diamond ms
V. Pace Blanking	170; 180 ... 240 \diamond ... 450 ms
V. Pacing ^c	RV \diamond ; RV+LV; LV
Active Can™/SVC Coil ^d	Can+SVC On \diamond ; Can Off; SVC Off
Progressive Episode Therapies	On; Off \diamond
Confirmation+	On \diamond ; Off

^a If the Active Can™/SVC Coil parameter is set to Can Off, the Active Can™ electrode is not used as part of the high-voltage delivery pathway. If the Active Can™/SVC Coil parameter is set to SVC Off, the SVC Coil electrode is not used as part of the high-voltage delivery pathway.

^b Smart Mode is available only for Rx1–Rx4.

^c If RV+LV is selected, the ATP therapy is delivered LV→RV with a 2.5 ms delay.

^d The Active Can™/SVC Coil parameter applies to all automatic, manual, and emergency high-voltage therapies. It also applies to T-Shock inductions.

Pacing parameters

Modes, rates, and intervals

Parameter	Programmable values
Mode	DDDR; DDD \diamond ; AAIR↔DDDR; AAI↔DDD; DDIR; DDI; AAIR; AAI; VVIR; VVI; DOO; AOO; VOO; ODO
Mode Switch	On \diamond ; Off
Lower Rate ^a	30; 35 ... 50 \diamond ; 55; 60; 70; 75 ... 150 bpm
Upper Tracking Rate	80; 85 ... 130 \diamond ... 175 bpm
Paced AV ^b	30; 40 ... 130 \diamond ... 350 ms
Sensed AV ^b	30; 40 ... 100 \diamond ... 350 ms
PVARP	Auto \diamond ; 150; 160 ... 500 ms
Minimum PVARP	150; 160 ... 250 \diamond ... 500 ms
A. Refractory Period	150; 160 ... 310 \diamond ... 500 ms

^a The corresponding Lower Rate Interval can be calculated as follows:

Lower Rate Interval (ms) = 60,000/Lower Rate.

^b If CRT is adaptive, Paced AV and Sensed AV cannot be selected or programmed.

Atrial parameters

Parameter	Programmable values
Atrial Amplitude	0.5; 0.75 ... 3.5 \diamond ... 5; 5.5; 6; 8 V
Atrial Pulse Width	0.03; 0.06; 0.1; 0.2; 0.3; 0.4 \diamond ... 1.5 ms
Atrial Sensitivity ^a	0.15; 0.3 \diamond ; 0.45; 0.6; 0.9; 1.2; 1.5; 1.8; 2.1; 4.0 mV; Off

^a This setting applies to all sensing in this chamber for both tachyarrhythmia detection and bradycardia pacing operations.

RV parameters

Parameter	Programmable values
RV Amplitude	0.5; 0.75 ... 3.5 \diamond ... 5; 5.5; 6; 8 V
RV Pulse Width	0.03; 0.06; 0.1; 0.2; 0.3; 0.4 \diamond ... 1.5 ms
RV Sensitivity ^a	0.15; 0.3 \diamond ; 0.45; 0.6; 0.9; 1.2 mV
RV Pace Polarity	Bipolar; Tip to Coil
RV Sense Polarity	Bipolar; Tip to Coil

^a This setting applies to all sensing in this chamber for both tachyarrhythmia detection and bradycardia pacing operations.

LV parameters

Parameter	Programmable values
LV Amplitude	0.5; 0.75 ... 4 \diamond ... 5; 5.5; 6; 8 V
LV Pulse Width	0.03; 0.06; 0.1; 0.2; 0.3; 0.4 \diamond ... 1.5 ms
LV Pace Polarity	LV1 to RVcoil; LV2 to RVcoil; LV3 to RVcoil; LV4 to RVcoil; LV1 to LV2; LV1 to LV3; LV1 to LV4; LV2 to LV1; LV2 to LV3; LV2 to LV4; LV3 to LV1; LV3 to LV2; LV3 to LV4; LV4 to LV1; LV4 to LV2; LV4 to LV3 LV1+2 to RVcoil; LV1+3 to RVcoil; LV1+4 to RVcoil; LV2+4 to RVcoil; LV3+4 to RVcoil

CRT pacing parameters

Parameter	Programmable values
AdaptivCRT™	Adaptive Bi-V and LV \diamond ; Adaptive Bi-V; Nonadaptive CRT
V. Pacing ^a	RV; RV→LV; LV→RV \diamond
V-V Pace Delay ^a	0 \diamond ; 10 ... 80 ms
EffectivCRT™ During AF	On \diamond ; Off
Maximum Rate	80; 85 ... 110 \diamond ... 130 bpm
V. Sense Response	On \diamond ; Off
Maximum Rate	95; 100 ... 130 \diamond ... 150 bpm
Atrial Tracking Recovery	On \diamond ; Off

^a If CRT is adaptive, V. Pacing and V-V Pace Delay cannot be selected or programmed.

Atrial Capture Management™ parameters

Parameter	Programmable values
Atrial Capture Management™	Adaptive ; Monitor; Off
Atrial Amplitude Safety Margin	1.5x; 2.0x ; 2.5x; 3.0x
Atrial Minimum Adapted Amplitude	1.0; 1.5 ; 2.0; 2.5; 3.0; 3.5 V
Atrial Acute Phase Remaining	Off; 30; 60; 90; 120 ; 150 days

RV Capture Management™ parameters

Parameter	Programmable values
RV Capture Management™	Adaptive ; Monitor; Off
RV Amplitude Safety Margin	1.5x; 2.0x ; 2.5x; 3.0x
RV Minimum Adapted Amplitude	1.0; 1.5; 2.0 ; 2.5; 3.0; 3.5 V
RV Acute Phase Remaining	Off; 30; 60; 90; 120 ; 150 days

LV Capture Management™ parameters

Parameter	Programmable values
LV Capture Management™	Adaptive ; Monitor; Off
LV Amplitude Safety Margin	+ Auto ; + 0.5; + 1.0; + 1.5; + 2.0; + 2.5 V
LV Maximum Adapted Amplitude	0.5; 0.75 ... 5.0; 5.5; 6 V

Blanking periods

Parameter	Programmable values
PVAB Interval	10; 20 ... 150 ... 300 ms ^a 100; 110 ... 150 ... 300 ms ^b
PVAB Method	Partial ; Partial+; Absolute ^c
A. Blank Post AP	150; 160 ... 200 ... 250 ms
A. Blank Post AS	100 ; 110 ... 170 ms
V. Blank Post VP	170; 180 ... 230 ... 450 ms
V. Blank Post VS	120 ; 130 ... 170 ms

^a When PVAB Method = Partial+ or Absolute.

^b When PVAB Method = Partial.

^c Programming the PVAB Method to Absolute automatically resets the interval to 30 ms. If the PVAB Method is programmed to Partial or Partial+, the interval resets to 150 ms.

Rate response pacing parameters

Parameter	Programmable values
Upper Sensor Rate	80; 85 ... 120 ... 175 bpm
ADL Rate	60; 65 ... 95 ... 170 bpm
Rate Profile Optimization	On ; Off
ADL Response	1; 2; 3 ; 4; 5
Exertion Response	1; 2; 3 ; 4; 5
Activity Threshold	Low; Medium Low ; Medium High; High
Activity Acceleration	15; 30 ; 60 s
Activity Deceleration	Exercise ; 2.5; 5; 10 min
ADL Set Point	5; 6 ... 40; 42 ... 80
UR Set Point	15; 16 ... 40; 42 ... 80; 85 ... 180

Rate adaptive AV parameters

Parameter	Programmable values
Rate Adaptive AV ^a	Off; On
Start Rate	50; 55 ... 90 ... 145 bpm
Stop Rate	55; 60 ... 130 ... 175 bpm
Minimum Paced AV	30; 40 ... 100 ... 200 ms
Minimum Sensed AV	30; 40 ... 70 ... 200 ms

^a If CRT is adaptive, Rate Adaptive AV parameters cannot be selected or programmed.

Atrial rate stabilization parameters

Parameter	Programmable values
A. Rate Stabilization	On; Off
Maximum Rate	80; 85 ... 100 ... 150 bpm
Interval Percentage Increment	12.5; 25 ; 50%

Atrial preference pacing parameters

Parameter	Programmable values
A. Preference Pacing	On; Off
Maximum Rate	80; 85 ... 100 ... 150 bpm
Interval Decrement	30 ; 40 ... 100; 150 ms
Search Beats	5; 10; 15; 20 ; 25; 50

Post Mode Switch Overdrive Pacing (PMOP) parameters

Parameter	Programmable values
Post Mode Switch	On; Off
Overdrive Rate	70; 75; 80 ... 120 bpm
Overdrive Duration	0.5; 1; 2; 3; 5; 10 ; 20; 30; 60; 90; 120 min

Conducted AF response parameters

Parameter	Programmable values
Conducted AF Response	On ; Off
Response Level	Low; Medium ; High
Maximum Rate	80; 85 ... 110 ... 130 bpm

Ventricular rate stabilization parameters

Parameter	Programmable values
V. Rate Stabilization	On; Off
Maximum Rate	80; 85 ... 100 ... 120 bpm
Interval Increment	100; 110 ... 150 ... 400 ms

Post VT/VF shock pacing parameters

Parameter	Programmable values
Post VT/VF Shock Pacing	On; Off
Overdrive Rate	70; 75; 80 ... 120 bpm
Overdrive Duration	0.5 ; 1; 2; 3; 5; 10; 20; 30; 60; 90; 120 min

Post shock pacing parameters

Parameter	Programmable values
Post Shock A. Amplitude	1; 2; 3; 4 ; 5; 6; 8 V
Post Shock A. Pulse Width	0.1; 0.2 ... 1.5 ms
Post Shock V. Amplitude ^a	1; 2 ... 6 ; 8 V
Post Shock V. Pulse Width ^a	0.1; 0.2 ... 1.5 ms

^a Applies to all ventricular chambers paced.

Rate drop response parameters

Parameter	Programmable values
Rate Drop Response ^a	On; Off
Detection Type	Drop ; Low Rate; Both
Drop Size	10; 15 ... 25 ... 50 bpm
Drop Rate	30; 40 ... 60 ... 100 bpm
Detection Window	10; 15; 20; 25; 30 s 1 ; 1.5; 2; 2.5 min
Detection Beats	1; 2; 3 beats
Intervention Rate	70; 75 ... 100 ... 150 bpm
Intervention Duration	1; 2 ... 15 min

^a When Rate Drop Response is set to On, the lower rate is automatically set to 45 bpm.

Sleep parameters

Parameter	Programmable values
Sleep	On; Off
Sleep Rate	30; 35 ... 50 ; 55; 60; 70; 75 ... 100 bpm
Bed Time	00:00; 00:10 ... 22:00 ... 23:50
Wake Time	00:00; 00:10 ... 07:00 ... 23:50

Non-Competitive Atrial Pacing (NCAP) parameters

Parameter	Programmable values
Non-Comp Atrial Pacing	On ; Off
NCAP Interval	200; 250; 300 ; 350; 400 ms

MRI SureScan™ parameters

Parameter	Programmable values
MRI SureScan	On; Off
MRI Pacing Mode	DOO (Asynchronous); AOO (Asynchronous); VOO (Asynchronous); ODO (Off)
MRI Pacing Rate	60; 70; 75 ... 120 bpm

Additional pacing features

Parameter	Programmable values
PMT Intervention	On; Off
PVC Response	On ; Off
V. Safety Pacing ^a	On ; Off

^a Delivered as LV pacing when the AdaptivCRT™ operating value is LV. Otherwise, delivered as RV pacing.

Medtronic CareAlert™ parameters

Clinical management alerts

Parameter	Programmable values
OptiVol™ 2.0 Fluid Settings	
Device Tone	
OptiVol™ Alert Enable	Off (Observation only)
OptiVol™ Threshold ^a	30; 40; 50; 60 ... 180

AT/AF Burden and Rate Settings ...

Device Tone	
Alert Urgency ^b	High ; Low
AT/AF Daily Burden Alert Enable	Off (Observation only) ; On
Avg. V. Rate During AT/AF Alert Enable	Off (Observation only) ; On
Patient Home Monitor	
AT/AF Daily Burden Alert Enable ^c	Off ; On
Avg. V. Rate During AT/AF Alert Enable ^c	Off ; On

Shared (Device Tone and Patient Home Monitor)

AT/AF Daily Burden	0.5; 1; 2; 6 ; 12; 24 hours/day
Avg. V. Rate During AT/AF	90; 100 ... 150 bpm
Daily Burden for Avg. V. Rate	0.5; 1; 2; 6 ; 12; 24 hours/day

Number of Shocks Delivered in an Episode^d

Device Tone	
Alert Enable – Urgency	Off ; On-Low; On-High
Patient Home Monitor	
Alert Enable ^c	Off ; On

Shared (Device Tone and Patient Home Monitor)

Number of Shocks Threshold ^b	1 ; 2; 3; 4; 5; 6
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All Therapies in a Zone Exhausted for an Episode

Device Tone	
Alert Enable – Urgency	Off ; On-Low; On-High
Patient Home Monitor	
Alert Enable ^c	Off ; On

^a Decreasing the OptiVol™ Threshold makes the device more sensitive to changes in the patient's thoracic fluid status. Increasing the OptiVol™ Threshold could delay or prevent device observation of significant changes in the patient's thoracic fluid status.

^b This parameter is displayed only if an associated alert has been enabled.

^c Alerts are programmable and transmittable to a monitor only when Patient Home Monitor is programmed to Yes.

^d Note that VF, VT, and VVT therapies could be delivered during a single episode (from initial detection until episode termination).

Lead/Device integrity alerts

Parameter	Programmable values
RV Lead	
Device Tone	
Alert Urgency ^a	Low; High
RV Lead Integrity Enable	On ; Off
RV Lead Noise Enable	On ; Off
Patient Home Monitor	
RV Lead Integrity Enable ^b	On ; Off
RV Lead Noise Enable ^b	On ; Off
Lead Impedance Out of Range	
Device Tone	
Alert Urgency ^a	Low; High
A. Pacing Impedance Enable	On ; Off (Observation only)
RV Pacing Impedance Enable	On ; Off (Observation only)
LV Pacing Impedance Enable	On ; Off (Observation only)
RV Defibrillation Impedance Enable	On ; Off (Observation only)
SVC Defibrillation Impedance Enable ^c	On ; Off (Observation only)
Patient Home Monitor	
A. Pacing Impedance Enable ^b	Off; On
RV Pacing Impedance Enable ^b	Off; On
LV Pacing Impedance Enable ^b	Off; On
RV Defibrillation Impedance Enable ^b	Off; On
SVC Defibrillation Impedance Enable ^{b,c}	Off; On
Shared (Device Tone and Patient Home Monitor)	
A. Pacing Impedance Less than	200 ; 300; 400; 500 Ω
A. Pacing Impedance Greater than	1000; 1500; 2000; 3000 Ω
RV Pacing Impedance Less than	200 ; 300; 400; 500 Ω
RV Pacing Impedance Greater than	1000; 1500; 2000; 3000 Ω
LV Pacing Impedance Less than	200 ; 300; 400; 500 Ω
LV Pacing Impedance Greater than	800; 1000; 1500; 2000; 3000 Ω
RV Defibrillation Impedance Less than	20 ; 30; 40; 50 Ω
RV Defibrillation Impedance Greater than	100; 130; 160; 200 Ω
SVC Defibrillation Impedance Less than	20 ; 30; 40; 50 Ω
SVC Defibrillation Impedance Greater than	100; 130; 160; 200 Ω
Low Battery Voltage RRT	
Device Tone	
Alert Enable – Urgency	Off; On-Low; On-High

Patient Home Monitor	
Alert Enable ^b	Off; On
Excessive Charge Time EOS	
Device Tone	
Alert Enable – Urgency	Off; On-Low; On-High
Patient Home Monitor	
Alert Enable ^b	Off; On
VF Detection Off, 3+ VF or 3+ FVT Rx Off	
Device Tone	
Alert Enable	Off; On-High
Patient Home Monitor	
Alert Enable ^b	Off; On

^a This parameter is displayed only if an associated alert has been enabled.

^b Alerts are programmable and transmittable to a monitor only when Patient Home Monitor is programmed to Yes.

^c If an SVC lead is not implanted, the alert will not sound.

Shared parameters

Parameter	Programmable values
Patient Home Monitor	Yes; No
Alert Time ^a	00:00; 00:10 ... 08:00 ... 23:50

^a This parameter is displayed only if an associated alert has been enabled.

Data collection parameters

Parameter	Programmable values
LECG Source (Leadless ECG) ^a	Can to SVC ^{b,c} ; RVcoil to Aring; Can to Aring
LECG Range (Leadless ECG)	±1; ±2 ; ±4; ±8; ±12; ±16; ±32 mV
EGM 1 Source	RVtip to RVcoil; RVtip to RVring; Atip to RVring; Aring to RVring; Aring to RVcoil; LV3 to RVcoil; LV3 to LV4
EGM 1 Range	±1; ±2; ±4; ±8 ; ±12; ±16; ±32 mV
EGM 2 (Wavelet) Source	Can to RVcoil ; Can to RVring; RVtip to RVcoil; RVtip to RVring; Can to SVC ^{b,c} ; RVcoil to SVC ^b ; LV1 to SVC ^b ; Can to LV1; RVtip to LV1; LV1 to RVcoil; LV2 to RVcoil; LV1 to LV2
EGM 2 (Wavelet) Range	±1; ±2; ±4; ±8; ±12 ; ±16; ±32 mV
EGM 3 Source	RVtip to RVcoil; RVtip to RVring; LV1 to RVring; LV1 to RVcoil; LV2 to RVcoil; LV3 to RVcoil; LV4 to RVcoil; LV1 to LV2; LV2 to LV3; LV3 to LV4; LV1 to LV3; LV2 to LV4; LV1 to LV4
EGM 3 Range	±1; ±2; ±4; ±8; ±12; ±16; ; ±32 mV

Data collection parameters, cont'd.

Parameter	Programmable values
Monitored	EGM1 and EGM2 \diamond ; EGM1 and EGM3; EGM1 and LECCG; EGM2 and EGM3; EGM2 and LECCG; EGM3 and LECCG
Pre-arrhythmia EGM	Off \diamond ; On – 1 month; On – 3 months; On Continuous
V. Sensing Episodes	
Consecutive VS to detect \geq	5; 8; 10 \diamond ; 15; 20; 30; 40; 50; 100; 150; 200
Consecutive VP to terminate \geq	2; 3 \diamond ; 5; 10
Device Date/Time ^d	(enter time and date)
Holter Telemetry	Off \diamond ; 0.5; 1; 2; 4; 8; 16; 24; 36; 46 hr

^a This EGM channel displays far-field signals. To display an approximation of a surface ECG signal, choose the Can to SVC EGM source.

^b An SVC electrode must be present for this configuration.

^c If the Can to SVC source is selected, the EGM Range is automatically set to ± 2 mV. The EGM Range is automatically set to ± 8 mV for all other EGM Source options.

^d The times and dates stored in episode records and other data are determined by the Device Date/Time clock.

System test parameters

System test parameters

Parameter	Selectable values
Pacing Threshold Test parameters	
Test Type (LV test)	Amplitude; Pulse Width; Phrenic Nerve Stim - Amplitude; Phrenic Nerve Stim - Pulse Width
Test Type (Atrium or RV test)	Amplitude; Pulse Width
Chamber	Atrium; RV; LV
Decrement after	2; 3 ... 15 pulses
Pace Polarity (RV)	Bipolar; Tip to Coil
Pace Polarity (LV)	LV1 to RVcoil; LV2 to RVcoil; LV3 to RVcoil; LV4 to RVcoil; LV1 to LV2; LV1 to LV3; LV1 to LV4; LV2 to LV1; LV2 to LV3; LV2 to LV4; LV3 to LV1; LV3 to LV2; LV3 to LV4; LV4 to LV1; LV4 to LV2; LV4 to LV3
Mode ^a (RV or LV test)	VVI; VOO; DDI; DDD; DOO
Mode ^a (Atrium test)	AAI; AOO; DDI; DDD; DOO
Lower Rate ^b	30; 35 ... 60; 70; 75 ... 150 bpm
RV Amplitude	0.25; 0.5 ... 5; 5.5; 6; 8 V
RV Pulse Width	0.03; 0.06; 0.1; 0.2 ... 1.5 ms
LV Amplitude	0.25; 0.5 ... 5; 5.5; 6; 8 V
LV Pulse Width	0.03; 0.06; 0.1; 0.2 ... 1.5 ms
A. Amplitude	0.25; 0.5 ... 5; 5.5; 6; 8 V
A. Pulse Width	0.03; 0.06; 0.1; 0.2 ... 1.5 ms
AV Delay	30; 40 ... 350 ms
V. Pace Blanking	150; 160 ... 450 ms

A. Pace Blanking	150; 160 ... 250 ms
PVARP ^c	150; 160 ... 500 ms

VectorExpress™ LV Automated Test parameters

LV Pulse Width	0.4; 0.5 ... 1.5 ms
Test	LV1, 2, 3, 4 to RVcoil (Extended Bipolar) LV1 to LV2, LV3, LV4 LV2 to LV1, LV3, LV4 LV3 to LV1, LV2, LV4 LV4 to LV1, LV2, LV3

Sensing Test parameters

Mode ^a	AAI; DDD; DDI; VVI; ODO
AV Delay	30; 40 ... 350 ms
Lower Rate ^b	30; 35 ... 60; 70; 75 ... 120 bpm

CardioSync™ Optimization Test parameters

Sensing Lower Rate	30; 35 ... 60; 70; 75 ... 90 bpm
Pacing Lower Rate	35; 40 ... 60; 70; 75 ... 95 bpm

Wavelet Test parameters

Match Threshold	40; 43 ... 70 \diamond ... 97
Mode ^a	AAI; DDD; DDI; VVI; ODO
AV Delay	30; 40 ... 350 ms
Lower Rate ^b	30; 35 ... 60; 70; 75 ... 120 bpm

^a The selectable values for this parameter depend on the programmed pacing mode.

^b When performing the test in DDD mode, the Lower Rate must be less than the programmed Upper Tracking Rate.

^c The selectable values for this parameter depend on the programmed PVAB values.

EP study parameters

T-Shock induction parameters

Parameter	Selectable values
Chamber ^a	RV \diamond ; RV+LV; LV
Resume at Deliver	Enabled \diamond ; Disabled
Enable	Enabled; Disabled \diamond
#S1	2; 3; 4; 5 \diamond ; 6; 7; 8
S1S1	300; 310 ... 400 \diamond ... 2000 ms
Delay	20; 30 ... 300 \diamond ... 600 ms
Energy	0.4; 0.6; 0.8; 1.0 \diamond ... 1.8; 2; 3; 4 ... 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35 J
Waveform	Monophasic \diamond ; Biphasic
Pathway ^b	AX>B; B>AX \diamond

^a If the chamber selected is RV+LV, the delay is set to 2.5 ms with LV pace delivered first.

^b If the Active Can™/SVC Coil parameter is set to Can Off, the Active Can™ electrode is not used as part of the high-voltage delivery pathway. If the Active Can™/SVC Coil parameter is set to SVC Off, the SVC Coil electrode is not used as part of the high-voltage delivery pathway.

50 Hz Burst induction parameters

Parameter	Selectable values
Resume at Burst	Enabled ; Disabled
Chamber	Atrium; RV; LV
Amplitude	1; 2; 3; 4 ; 5; 6; 8 V
Pulse Width	0.10; 0.20 ... 0.50 ... 1.50 ms
VOO Backup (for atrial 50 Hz Burst) ^a	On; Off
Pacing Rate	60; 70 ... 120 bpm
V. Amplitude ^{b,c}	0.50; 0.75 ... 5.00; 5.50; 6.00; 8.00 V
V. Pulse Width ^b	0.10; 0.20 ... 1.50 ms

^a V. Backup Pacing is delivered to the RV chamber.

^b The default value for this parameter is set according to the permanently programmed settings for bradycardia pacing.

^c Crosstalk may occur when atrial pacing amplitude is greater than 6.0 V.

Fixed Burst induction parameters

Parameter	Selectable values
Resume at Burst	Enabled ; Disabled
Chamber ^a	Atrium; RV; RV+LV; LV
Interval	100; 110 ... 600 ms
Amplitude ^b	1; 2; 3; 4 ; 5; 6; 8 V
Pulse Width ^b	0.10; 0.20 ... 0.50 ... 1.50 ms
VVI Backup (for atrial Fixed Burst) ^c	On; Off
Pacing Rate	60; 70 ... 120 bpm
V. Amplitude ^{d,e}	0.50; 0.75 ... 5.00; 5.50; 6.00; 8.00 V
V. Pulse Width ^d	0.10; 0.20 ... 1.50 ms

^a If the chamber selected is RV+LV, the delay is set to 2.5 ms with LV pace delivered first.

^b Applies to all ventricular chambers paced.

^c V. Backup Pacing is delivered to the RV chamber.

^d The default value for this parameter is set according to the permanently programmed settings for bradycardia pacing.

^e Crosstalk may occur when atrial pacing amplitude is greater than 6.0 V.

PES induction parameters

Parameter	Selectable values
Resume at Deliver	Enabled ; Disabled
Chamber ^a	Atrium; RV; RV+LV; LV
#S1	1; 2 ... 8 ... 15
S1S1	100; 110 ... 600 ... 2000 ms
S1S2	Off; 100; 110 ... 400 ... 600 ms
S2S3	Off ; 100; 110 ... 400; 410 ... 600 ms ^b
S3S4	Off ; 100; 110 ... 400; 410 ... 600 ms ^b
Amplitude ^c	1; 2; 3; 4 ; 5; 6; 8 V
Pulse Width ^c	0.10; 0.20 ... 0.50 ... 1.50 ms
VVI Backup (for atrial PES) ^d	On; Off
Pacing Rate	60; 70 ... 120 bpm
V. Amplitude ^{e,f}	0.50; 0.75 ... 5.00; 5.50; 6.00; 8.00 V
V. Pulse Width ^e	0.10; 0.20 ... 1.50 ms

^a If the chamber selected is RV+LV, the delay is set to 2.5 ms with LV pace delivered first.

^b Default value when parameter is On is 400 ms.

^c Applies to all ventricular chambers paced.

^d V. Backup Pacing is delivered to the RV chamber.

^e The default value for this parameter is set according to the permanently programmed settings for bradycardia pacing.

^f Crosstalk may occur when atrial pacing amplitude is greater than 6.0 V.

Manual defibrillation parameters

Parameter	Selectable values
Energy	0.4; 0.6 ... 1.8; 2; 3 ... 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35 J
Pathway ^a	AX>B; B>AX

^a If the Active Can™/SVC Coil parameter is set to Can Off, the Active Can™ electrode is not used as part of the high-voltage delivery pathway. If the Active Can™/SVC Coil parameter is set to SVC Off, the SVC Coil electrode is not used as part of the high-voltage delivery pathway.

Manual cardioversion parameters

Parameter	Selectable values
Chamber	Atrium; RV
Energy	0.4; 0.6 ... 1.8; 2; 3 ... 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35 J
Pathway ^a	AX>B; B>AX
Minimum R-R (atrial CV only)	400; 410 ... 500 ... 600 ms

^a If the Active Can™/SVC Coil parameter is set to Can Off, the Active Can™ electrode is not used as part of the high-voltage delivery pathway. If the Active Can™/SVC Coil parameter is set to SVC Off, the SVC Coil electrode is not used as part of the high-voltage delivery pathway.

Shared manual ATP therapy parameters

Parameter	Selectable values
Minimum Interval (atrial ATP)	100; 110; 120; 130 ... 400 ms
Minimum Interval (ventricular ATP)	150; 160 ... 200 ... 400 ms
Amplitude ^a	1; 2 ... 6 ; 8 V
Pulse Width ^a	0.10; 0.20 ... 1.50 ms
VVI Backup (for atrial ATP therapy) ^b	On; Off
Pacing Rate	60; 70 ... 120 bpm
V. Amplitude ^{c,d}	0.50; 0.75 ... 5.00; 5.50; 6.00; 8.00 V
V. Pulse Width ^c	0.10; 0.20 ... 1.50 ms

^a Applies to all ventricular chambers paced.

^b V. Backup Pacing is delivered to the RV chamber.

^c The default value for this parameter is set according to the permanently programmed settings for bradycardia pacing.

^d Crosstalk may occur when atrial pacing amplitude is greater than 6.0 V.

Manual Ramp therapy parameters

Parameter	Selectable values
Chamber ^a	Atrium; RV; RV+LV; LV
Ventricular Ramp therapy parameters	
# Pulses	1; 2 ... 6 ... 15
%RR Interval	50; 53; 56; 59; 63; 66 ... 84; 88; 91; 94; 97 %
Dec/Pulse	0; 10 ; 20; 30; 40 ms
Atrial Ramp therapy parameters	
# Pulses	1; 2 ... 6 ... 15; 20; 30 ... 100
%AA Interval	28; 31; 34; 38; 41 ... 59; 63; 66 ... 84; 88; 91; 94; 97 %
Dec/Pulse	0; 10 ; 20; 30; 40 ms

^a If the chamber selected is RV+LV, the delay is set to 2.5 ms with LV pace delivered first.

Manual Burst therapy parameters

Parameter	Selectable values
Chamber ^a	RV ; RV+LV; LV
# Pulses	1; 2 ... 8 ... 15
%RR Interval	50; 53; 56; 59; 63; 66 ... 84; 88 ; 91; 94; 97%

^a If the chamber selected is RV+LV, the delay is set to 2.5 ms with LV pace delivered first.

Manual Ramp+ therapy parameters

Parameter	Selectable values
Chamber ^a	RV ; RV+LV; LV
# Pulses	1; 2; 3 ... 15
R-S1 (%RR)	50; 53; 56; 59; 63; 66 ... 75 ... 84; 88; 91; 94; 97%
S1-S2 (%RR)	50; 53; 56; 59; 63; 66; 69 ... 84; 88; 91; 94; 97%
S2-SN (%RR)	50; 53; 56; 59; 63; 66 ... 84; 88; 91; 94; 97%

^a If the chamber selected is RV+LV, the delay is set to 2.5 ms with LV pace delivered first.

Manual Burst+ therapy parameters

Parameter	Selectable values
# S1 Pulses	1; 2 ... 6 ... 15; 20; 30 ... 100
%AA Interval	28; 31; 34; 38; 41 ... 59; 63; 66 ... 84; 88; 91 ; 94; 97%
S1S2	Off; 28; 31; 34; 38; 41 ... 59; 63; 66 ... 84 ; 88; 91; 94; 97%
S2S3 Dec	Off; 0; 10; 20 ... 80 ms

Brief Statement

Claria MRI™/Claria MRI™ Quad CRT-D SureScan™ Implantable Cardioverter Defibrillator with Cardiac Resynchronization System (CRT-D MRI System)

The Claria MRI™ CRT-D SureScan™ Model DTMA1D4/DTMA1D1 and Claria MRI™ Quad CRT-D SureScan™ Model DTMA1QQ/DTMA1Q1, hereafter referred to collectively as the Claria MRI™ CRT-D device, is MR Conditional and, as such is designed to allow patients to be safely scanned by an MRI machine when used according to the specified MRI conditions for use. When programmed to On, the MRI SureScan™ feature allows the patient to be safely scanned while the device continues to provide appropriate pacing.

Indications for Use

The Claria MRI™ CRT-D system is indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias, for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk for developing atrial tachyarrhythmias and for providing cardiac resynchronization therapy in heart failure patients on stable, optimal heart failure medical therapy if indicated, and meet any of the following classifications: New York Heart Association (NYHA) Functional Class III or IV and who have a left ventricular ejection fraction $\leq 35\%$ and a prolonged QRS duration. Left bundle branch block (LBBB) with a QRS duration ≥ 130 ms, left ventricular ejection fraction $\leq 30\%$, and NYHA Functional Class II, NYHA Functional Class I, II, or III and who have left ventricular ejection fraction $\leq 50\%$ and atrioventricular block (AV block) that are expected to require a high percentage of ventricular pacing that cannot be managed with algorithms to minimize right ventricular pacing. Optimization of heart failure medical therapy that is limited due to AV block or the urgent need for pacing should be done post-implant.

A complete SureScan™ CRT-D system is required for use in the MR environment. A complete SureScan™ CRT-D system includes the following components:

- The Claria MRI™ CRT-D device
- A SureScan™ right atrial pacing lead or a Model 6725 pin plug for the right atrial port
- A SureScan™ left ventricular pacing lead
- A SureScan™ defibrillation lead

When a single coil SureScan™ defibrillation lead is used, a Medtronic DF-1 pin plug must be secured in the SVC port to make a complete SureScan™ DF-1 defibrillation system. To verify that components are part of a SureScan™ system, visit <http://www.mrisurescan.com>. Any other combination may result in a hazard to the patient during an MRI scan.

Lead Integrity Alert

The RV Lead Integrity Alert feature is intended primarily for patients who have a Medtronic ICD or CRT-D device and a Sprint Fidelis lead (Models 6949, 6948, 6931, and 6930) based on performance data. The RV LIA feature may not perform as well with a St. Jude Riata™/Durata™ lead or a Boston Scientific Endotak lead as it does when used with a Medtronic Sprint Fidelis lead. This is because different lead designs may have different failure signatures and conditions that may or may not be detected early by the RV LIA feature.

Contraindications

The Claria MRI™ CRT-D system is contraindicated for patients experiencing tachyarrhythmias with transient or reversible causes including, but not limited to, the following: acute myocardial infarction, drug intoxication, drowning, electric shock, electrolyte imbalance, hypoxia, or sepsis. The device is contraindicated for patients who have a unipolar pacemaker implanted. The device is contraindicated for patients with incessant VT or VF. The device is contraindicated for patients whose primary disorder is chronic atrial tachyarrhythmia with no concomitant VT or VF.

Warnings and Precautions

Changes in patient's disease and/or medications may alter the efficacy of the device's programmed parameters. Patients should avoid sources of magnetic and electromagnetic radiation to avoid possible underdetection, inappropriate sensing and/or therapy delivery, tissue damage, induction of an arrhythmia, device electrical reset, or device damage. Do not place transthoracic defibrillation

paddles directly over the device. Certain programming and device operations may not provide cardiac resynchronization.

Patients and their implanted systems must be screened to meet the following requirements for MRI: no implanted lead extenders, lead adaptors, or abandoned leads; no broken leads or leads with intermittent electrical contact as confirmed by lead impedance history; a SureScan™ CRT-D system implanted in the left or right pectoral region; no diaphragmatic stimulation at a pacing output of 5.0 V and at a pulse width of 1.0 ms in patients whose device will be programmed to an asynchronous pacing mode when MRI SureScan™ is programmed to On.

Additionally for pacemaker-dependent patients, it is not recommended to perform an MRI scan if the right ventricular (RV) lead pacing capture threshold is greater than 2.0 V at 0.4 ms. A higher pacing capture threshold may indicate an issue with the implanted lead.

Patients may be scanned using a horizontal field, cylindrical bore, clinical 1.5T or 3T MRI system for hydrogen proton imaging, maximum spatial gradient ≤ 20 T/m, and maximum gradient slew rate performance per axis ≤ 200 T/m/s. 1.5T scanners must be operated in Normal Operating Mode (whole body averaged specific absorption rate (SAR) ≤ 2.0 W/kg, head SAR ≤ 3.2 W/kg). 3T scanners must be operated in First Level Controlled Operating Mode or Normal Operating Mode. B_{1+RMS} must be ≤ 2.8 μ T when the isocenter (center of the bore) is inferior to the C7 vertebra. Scans can be performed without B_{1+RMS} restriction when the isocenter is at or superior to the C7 vertebra.

Continuous patient monitoring is required while MRI SureScan™ is programmed to On. While MRI SureScan™ is programmed to On, arrhythmia detection and therapies are suspended, leaving the patient at risk of death from untreated spontaneous tachyarrhythmia. In addition, if the device is programmed to an asynchronous pacing mode, arrhythmia risk may be increased.

Potential Complications

Potential complications include, but are not limited to, rejection phenomena, erosion through the skin, muscle or nerve stimulation, oversensing, failure to detect and/or terminate tachyarrhythmia episodes, acceleration of ventricular tachycardia, and surgical complications such as hematoma, infection, inflammation, and thrombosis. Other potential complications related to the lead may include lead dislodgement, lead conductor fracture, insulation failure, threshold elevation, or exit block.

Potential MRI complications for the SureScan™ system include, but are not limited to, lead electrode heating and tissue damage resulting in loss of sensing or capture or both, or induced currents on leads resulting in continuous capture, VT/VF, and/or hemodynamic collapse; spontaneous tachyarrhythmia occurring during the scan that is not detected and treated because tachyarrhythmia detection is suspended while MRI SureScan™ is programmed to On; potential for VT/VF induction when the patient is programmed to an asynchronous pacing mode during MRI SureScan™; device heating resulting in tissue damage in the implant pocket or patient discomfort or both; or damage to the functionality or mechanical integrity of the device resulting in the inability of the device to communicate with the programmer.

See the MRI SureScan™ Technical Manual before performing an MRI Scan and Device Manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult the Medtronic website at www.medtronic.com or www.mrisurescan.com.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

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