PERCEPTA™ QUAD CRT-P MRI SURESCAN™

Model W4TR01

Heart Failure Management Report

This report provides an overview of the patient's condition over the short and long term, with a focus on heart failure management. The report includes graphs that show OptiVol™ 2.0 fluid trends and trends related to heart failure over the last 14 months.

Physical characteristics

Volume[a]	19.5 cm^3
Mass	30 g
H x W x D[b]	59 mm x 46.5 mm x 11 mm
Radiopaque ID[c]	RNP
Surface area of titanium device can	34.8 cm^2
Materials in contact with human tissue[d]	Titanium, polyurethane, silicone rubber
Battery	Lithium-hybrid CFx silver vanadium oxide

[a] Volume with connector holes unplugged.
[b] Grommets may protrude slightly beyond the can surface.
[c] The radiopaque ID, which includes a Medtronic-identifier symbol, can be viewed in a fluoroscopic image of the device.
[d] 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)	180 days after 3 consecutive daily automatic measurements of ≤ 2.63 V or immediately after 3 consecutive daily automatic measurements of ≤ 2.60 V, whichever comes first
Elective Replacement Indicator (ERI)	3 months after RRT
End of Service (EOS)	3 months after ERI

- MR Conditional with SureScan™ Technology
- Bluetooth® Wireless Telemetry*
- EffectivCRT™ Diagnostic
- AdaptivCRT™ Algorithm
- EffectivCRT™ During AF Algorithm
- Multiple Point Pacing
- VectorExpress™ 2.0 LV Automated Test
- CardioSync™ Optimization
- OptiVol™ 2.0 Fluid Status Monitoring
- MVP™ Mode
- Complete Capture Management™ Diagnostic (ACM, RVCM, LVCM)

*Bluetooth® enabled CareLink™ remote monitors will be available pending FDA submission and approval.

Medtronic

Tachyarrhythmia detection 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
VT Monitor	Monitor ◆; Off
VT Monitor Interval (Rate)[a]	280; 290 ... 400 ◆... 500 ms
RV Sensitivity[b]	0.45; 0.60 mV (± 50%); 0.90; 1.20; 2.00; 2.80; 4.00; 5.60; 8.00; 11.30 mV (± 30%) Bipolar: 0.9 ◆ mV Unipolar: 2.80 ◆ mV
Atrial Sensitivity[c]	0.15 mV (± 75%); 0.30; 0.45; 0.60 mV (± 50%); 0.90; 1.20; 1.5; 1.8; 2.1; 4.0 mV (± 30%); Off Bipolar: 0.3 ◆ mV Unipolar: 0.45 ◆ mV

[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 device complies with the requirements of ISO 14708-2 when the sensitivity threshold is programmed to 2.0 mV or higher.

[c] The device complies with the requirements of ISO 14708-2 when the sensitivity threshold is programmed to 1.8 mV or higher.

Atrial tachyarrhythmia therapy parameters

Parameter	Programmable values
Antitachy Pacing (ATP)	
Fast AT/AF Rx Status	On; Off ◆
Therapy Type	Ramp; Burst+ Rx1: Ramp ◆; Rx2: Burst+ ◆; Rx3: Ramp ◆
AT/AF Rx Status	On; Off ◆
Therapy Type	Ramp; Burst+ Rx1: Ramp ◆; Rx2: Burst+ ◆; Rx3: Ramp ◆
Burst+ parameters	
Initial # S1 Pulses	1; 2; 3 ... 11 ◆ ... 15; 20; 25
A-S1 Interval (%AA)	28; 31; 34; 38; 41 ... 59; 63; 66; 69 ... 84 ◆ ; 88; 91; 94; 97%
S1-S2 (%AA)	28; 31; 34; 38; 41 ... 59; 63; 66; 69 ... 81 ◆; 84; 88; 91; 94; 97%; Off
S2-S3 Decrement	0; 10; 20 ◆ ... 80 ms; Off
Interval Decrement	0; 10 ◆; 20; 30; 40 ms
# Sequences	1; 2; 3 ... 10 ◆
Ramp parameters	
Initial # S1 Pulses	1; 2; 3 ... 13 ◆; 14; 15; 20; 25
A-S1 Interval (%AA)	
Rx1	28; 31; 34; 38; 41 ... 59; 63; 66 ... 84; 88; 91 ◆; 94; 97%
Rx2	28; 31; 34; 38; 41 ... 59; 63; 66 ... 84; 88; 91 ◆; 94; 97%
Rx3	28; 31; 34; 38; 41 ... 59; 63; 66 ... 81 ◆ ; 84; 88; 91; 94; 97%
Interval Decrement	0; 10 ◆ ... 40 ms
# Sequences	1; 2 ... 8; 9; 10 ◆
Stop Atrial Rx after (Shared)	
Rx/Lead Suspect ...	
Disable Atrial ATP if it accelerates V. rate?	Yes ◆; No
Disable all atrial therapies if atrial lead position is suspect? (Atrial Lead Position Check)	Yes ◆; No
Duration to stop	12; 24; 48 ◆; 72 hr; None
Episode Duration before Rx Delivery	
Episode Duration before ATP	0; 1 ◆; 2 ... 5; 7; 10; 15; 20; 25; 30; 40; 50 min; 1; 2; 3; 4; 5; 6; 12; 24 hr
Reactive ATP™	
Rhythm Change	On ◆; Off
Time Interval	Off ◆; 2; 4; 7; 12; 24; 36; 48 hr
Shared A. ATP	
A-A Minimum ATP Interval[a]	100; 110... 150 ◆ ... 400 ms (± 6 ms)
A. Pacing Amplitude	1; 2 V (+0.5 V -33%) 3; 4; 5; 6 ◆; 8 V (+20%/-33%)
A. Pacing Pulse Width	0.1; 0.2 ... 1.5 ◆ ms (± 25 µs)
VVI Backup Pacing	Off; On (Always); On (Auto-Enable) ◆
VVI Backup Pacing Rate	60; 70 ◆ ... 120 bpm

[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.

Pacing Parameters

Modes, rates, and intervals

Parameter	Programmable values
Mode	DDDR; DDD ◆; AAIR<=>DDDR; AAI<=>DDD; DDIR; DDI; AAIR; AAI; VVIR; VVI; DOO; AOO; VOO; ODO
Mode Switch	On ◆; Off
Lower Rate[a]	30; 35 ... 60 ◆; 70; 75 ... 150 bpm (±2 bpm)
Upper Tracking Rate	80; 85 ... 130 ◆... 175 bpm (±2 bpm); 180; 190 ... 210 bpm (+2/-11 bpm)
Paced AV[b]	30; 40 ... 130 ◆... 350 ms (± 4 ms)
Sensed AV[b]	30; 40 ... 100 ◆... 350 ms (+30; –2 ms)
Maximum AV Interval Limit	Off ◆; 250; 260 ... 500 ms

Modes, rates, and intervals, cont'd.

PVARP	Auto ◆; 150; 160 ... 500 ms (+5; –30 ms)
Minimum PVARP	150; 160 ... 250 ◆... 500 ms (+5; –30 ms)
A. Refractory Period	150; 160 ... 310 ◆... 500 ms (+5; –30 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 ... 1.25 V (+0.125 V/-33%) 1.50 ... 3.5 ◆... 5; 5.5; 6; 8 V (+15%/-33%)[a]
Atrial Pulse Width	0.03; 0.06 ms (± 10 µs); 0.1; 0.2; 0.3; 0.4 ◆... 1.5 ms (± 25 µs)
Atrial Sensitivity	Off; 0.15; 0.3; 0.45; 0.6 mV (± 60%); 0.9; 1.2; 1.5; 1.8; 2.1; 4.0 mV (± 40%) Unipolar: 0.45 ◆ mV Bipolar: 0.3 ◆ mV
Atrial Pace Polarity	Bipolar; Unipolar
Atrial Sense Polarity	Bipolar; Unipolar
Atrial Lead Monitor	Monitor Only; Adaptive
Min Limit	200 ◆; 300; 400; 500 Ω
Max Limit	1,000; 1,500; 2,000; 3,000 ◆ Ω

[a] When Atrial Amplitude is 8 V, Atrial Pulse Width must be less than 1.3 ms.

RV parameters

Parameter	Programmable values
RV Amplitude	0.5; 0.75 ... 1.25 V (+0.125 V / -33%) 1.50 ... 3.5 ◆... 5; 5.5; 6; 8 V (+15%/-33%)[a]
RV Pulse Width	0.03; 0.06 ms (±10 µs); 0.1; 0.2; 0.3; 0.4 ◆... 1.5 ms (± 25 µs)
RV Sensitivity	0.45; 0.60; 0.90; 1.20; 2.00; 2.80; 4.00; 5.60; 8.00; 11.30 mV (±55%) Unipolar: 2.80 ◆ mV Bipolar: 0.90 ◆ mV
RV Pace Polarity	Bipolar; Unipolar
RV Sense Polarity	Bipolar; Unipolar
RV Lead Monitor	Monitor Only; Adaptive
Min Limit	200 ◆; 300; 400; 500 Ω
Max Limit	1,000; 1,500; 2,000; 3,000 ◆ Ω

[a] When RV Amplitude is 8 V, RV Pulse Width must be less than 1.3 ms.

LV parameters

Parameter	Programmable values
LV Amplitude	0.5; 0.75 ... 1.25 V (+0.125 V/-33%) 1.50 ... 3.5 ◆... 5; 5.5; 6; 8 V (+15% -33%)[a]
LV Pulse Width	0.03; 0.06 ms (±10 µs); 0.1; 0.2; 0.3; 0.4 ◆... 1.5 ms (± 25 µs)
LV Pace Polarity	LV1 to LV2; LV1 to LV3; LV1 to LV4; LV1 to Can; LV2 to LV1; LV2 to LV3; LV2 to LV4;LV2 to Can; LV3 to LV1; LV3 to LV2; LV3 to LV4; LV3 to Can; LV4 to LV1; LV4 to LV2;LV4 to LV3; LV4 to Can
LV Lead Monitor	Monitor Only; Adaptive
Min Limit	200 ◆; 300; 400; 500 Ω
Max Limit	1,000; 1,500; 2,000; 3,000 ◆ Ω

[a] When LV Amplitude is 8 V, LV Pulse Width must be less than 1.3 ms.

2nd LV parameters

Parameter	Programmable values
2nd LV Amplitude	0.5; 0.75 ... 1.25 V (+0.125 V / -33%) 1.50 ... 3.5 ◆... 5; 5.5; 6; 8 V (+15% -33%)[a]
2nd LV Pulse Width	0.03; 0.06 ms (±10 µs); 0.1; 0.2; 0.3; 0.4 ◆... 1.5 ms (± 25 µs)
2nd LV Pace Polarity	LV1 to LV2; LV1 to LV3; LV1 to LV4; LV1 to Can; LV2 to LV1; LV2 to LV3; LV2 to LV4; LV2 to Can; LV3 to LV1; LV3 to LV2; LV3 to LV4; LV3 to Can; LV4 to LV1; LV4 to LV2; LV4 to LV3; LV4 to Can

[a] When 2nd LV Amplitude is 8 V, 2nd LV Pulse Width must be less than 1.3 ms

CRT/MPP pacing parameters

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

[a] If CRT is adaptive, V. Pacing 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

2nd LV Capture Management™ parameters

Parameter	Programmable values
2nd LV Capture Management™	Adaptive ◈; Monitor; Off
2nd LV Amplitude Safety Margin	+Auto ◈; +0.5; +1.0; +1.5; +2.0; +2.5 V
2nd LV Maximum Adapted Amplitude	0.5; 0.75 ... 5.0; 5.5; 6 ◈ V

Blanking periods

Parameter	Programmable values
PVAB Interval	10[a]; 20 ... 100; 110; 120 ... 150 ◈ ... 300 ms
PVAB Method	Partial ◈; Partial+; Absolute
A. Blank Post AP	150; 160 ... 200 ◈ ... 250 ms (± 5 ms)
A. Blank Post AS	100 ◈; 110 ... 170 ms (± 2 ms)
V. Blank Post VP	150; 160 ... 230 ◈ ... 320 ms (± 5 ms)
V. Blank Post VS	120 ◈; 130 ... 170; 200; 220; 250; 280; 300; 320 ms (±2 ms)

[a] If the PVAB Method is set to Partial, the minimum selectable value for the PVAB Interval is 100 ms.

Rate response pacing parameters

Parameter	Programmable values
Rates	
ADL Rate	60; 65 ... 95 ◈... 170 bpm (± 2 bpm)
Upper Sensor	80; 85 ... 120 ◈... 175 bpm (± 2 bpm)
Rate Profile Optimization	On ◈; Off
Adjust Rate Response	
ADL Response	1; 2; 3 ◈; 4; 5
Exertion Response	1; 2; 3 ◈; 4; 5
Additional Parameters	
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]	On ◈; Off
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 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; 50 ... 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

Rate drop response parameters

Parameter	Programmable values
Rate drop response[a]	On; Off ◆
Detection Type	Drop ◆; Low Rate; Both
Drop Detection	
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
Low Rate Detection	
Detection Beats	1; 2; 3 ◆ beats
Intervention	
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; AOO; VOO; ODO
MRI Pacing Rate	60; 70; 75; 80 ... 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. Delivered as RV pacing when RV only pacing is permanently programmed. Otherwise, delivered as BiV pacing.

Medtronic CareAlert™ Parameters*

Clinical Management Alerts

Parameter	Programmable values
AT/AF Burden and Rate Settings...	
AT/AF Alerts	
AT/AF Daily Burden Enable	Off ◆; On
Daily AT/AF Burden	0.5; 1; 2; 6 ◆; 12; 24 hr/24hr
Avg. V. Rate During AT/AF Enable	Off ◆; On
Daily Burden for Avg. V. Rate	0.5; 1; 2; 6 ◆; 12; 24 hr/24hr
Avg. V. Rate During AT/AF	90; 100 ◆ ... 150 bpm
Monitored VT Episode Detected	Off ◆; On
Total VP < 90%	Off ◆; On[a]
OptiVol 2.0 Fluid Settings...	Off ◆
Observation Conditions	
OptiVol Threshold[b]	30; 40; 50; 60 ◆ ... 100; 120 ... 180

[a] Alert triggered if percent of cumulative ventricular pacing is less than 90% for 7 consecutive days.
[b] 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.

Lead/Device Integrity Alerts

Parameter	Programmable values
Low Battery Voltage RRT	On ◆; Off
Lead Impedance Out of Range...	
Lead Impedance	
A. Pacing Enable	On ◆; Off
A. Pacing Less than	200 ◆; 300; 400; 500 Ω
A. Pacing Greater than	1,000; 1,500; 2,000; 3,000 ◆ Ω
RV Pacing Enable	On ◆; Off
RV Pacing Less than	200 ◆; 300; 400; 500 Ω
RV Pacing Greater than	1,000; 1,500; 2,000; 3,000 ◆ Ω
LV Pacing Enable	On ◆; Off
LV Pacing Less than	200 ◆; 300; 400; 500 Ω
LV Pacing Greater than	800; 1,000; 1,500; 2,000; 3,000 ◆ Ω
2nd LV Pacing Enable	Off ◆; On
2nd LV Pacing Less than	200 ◆; 300; 400; 500 Ω
2nd LV Pacing Greater than	800; 1,000; 1,500; 2,000; 3,000 ◆ Ω
Capture Management High Threshold	
High Threshold	
A. Capture Enable[a]	Off ◆; On
RV Capture Enable[b]	Off ◆; On
LV Capture Enable[c]	Off ◆; On
2nd LV Capture Enable[d]	Off ◆; On

*Connectivity with the Medtronic CareLink™ network is pending FDA submission and approval.
[a] If programmed to On, alert notification is sent if A. capture management has measured high thresholds for 3 consecutive days.
[b] If programmed to On, alert notification is sent if RV capture management has measured high thresholds for 3 consecutive days.
[c] If programmed to On, alert notification is sent if LV capture management has measured a high threshold for one day.
[d] If programmed to On, alert notification is sent if 2nd LV capture management has measured a high threshold for one day.

Longevity

Projected service life in years, with AdaptivCRT™ programmed to Adaptive BiV and LV

Percent Pacing			500 Ω pacing impedance		600 Ω pacing impedance	
Atrial %	RV%	LV%	2.5 V	3.5 V	2.5 V	3.5 V
0%	50%	100%	10.8	8.6	11.2	9.1
15%	50%	100%	10.5	8.2	11.0	8.8
50%	50%	100%	9.9	7.5	10.4	8.1
100%	50%	100%	9.2	6.7	9.7	7.3

Projected service life estimates are based on accelerated battery discharge data and device modeling as specified. Do not interpret these values as precise numbers.

Brief Statement
Percepta™/Percepta™ Quad, Serena™/Serena™ Quad, and Solara™/Solara™ Quad CRT-P MRI SureScan™ System (Percepta/Serena/Solara CRT-P MRI SureScan Systems) Implantable Cardiac Pacemakers with Cardiac Resynchronization Therapy

Indications
The Percepta/Serena/Solara CRT-P MRI SureScan Systems are indicated for NYHA Functional Class III and IV patients who remain symptomatic despite stable, optimal heart failure medical therapy and have a LVEF ≤ 35% and a prolonged QRS duration and for NYHA Functional Class I, II, or III patients who have a LVEF ≤ 50%, are on stable, optimal heart failure medical therapy if indicated and have 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. Rate adaptive pacing is provided for those patients developing a bradycardia indication who might benefit from increased pacing rates concurrent with increases in activity. Dual chamber and atrial tracking modes are indicated for patients who may benefit from maintenance of AV synchrony. Antitachycardia pacing (ATP) is indicated for termination of atrial tachyarrhythmias in patients with one or more of the above pacing indications.

A complete SureScan pacing system is required for use in the MR environment. A complete SureScan pacing system includes a SureScan device with Medtronic SureScan leads or a Model 6725 pin plug for the right atrial port. To verify that components are part of a SureScan system, visit http://www.mrisurescan.com.

Contraindications
The Percepta/Serena/Solara CRT-P MRI SureScan Systems are contraindicated for concomitant implant with another bradycardia device and concomitant implant with an implantable cardioverter defibrillator. There are no known contraindications for the use of pacing as a therapeutic modality to control heart rate. The patient's age and medical condition, however, may dictate the particular pacing system, mode of operation, and implant procedure used by the physician. Rate-responsive modes may be contraindicated in those patients who cannot tolerate pacing rates above the programmed Lower Rate. Dual chamber sequential pacing is contraindicated in patients with chronic or persistent supraventricular tachycardias, including atrial fibrillation or flutter. Asynchronous pacing is contraindicated in the presence (or likelihood) of competition between paced and intrinsic rhythms. Single chamber atrial pacing is contraindicated in patients with an AV conduction disturbance. Antitachycardia pacing (ATP) therapy is contraindicated in patients with an accessory antegrade pathway.

Warnings and Precautions
A complete SureScan pacing system is required for use in the MR environment. Before performing an MRI scan, refer to the MRI technical manual for MRI-specific warnings and precautions. A complete SureScan pacing system includes a SureScan device with Medtronic SureScan leads or a Model 6725 pin plug for the right atrial port. Any other combination may result in a hazard to the patient during an MRI scan. Changes in a 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. Elective Replacement Indicator (ERI) results in the device switching to VVI pacing at 65 ppm. In this mode, patients may experience loss of cardiac resynchronization therapy and/or loss of AV synchrony. For this reason, the device should be replaced prior to ERI being set. Use of the device should not change the application of established anticoagulation protocols. 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 pacing system implanted in the left or right pectoral region. Additionally, for patients whose device will be programmed to an asynchronous pacing mode when MRI SureScan is programmed to On, no diaphragmatic stimulation is present at a pacing output of 5.0 V and at a pulse width of 1.0 ms.

Potential Adverse Events or 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 arrhythmia episodes, 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 appropriate Percepta/Serena/Solara product Device Manuals for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. See the appropriate Percepta/Serena/Solara product MRI SureScan Technical Manual before performing an MRI Scan. For further information, call Medtronic at 1-800-328-2518 and/or consult Medtronic's website at www.medtronic.com or www.mrisurescan.com.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician

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