Endurity™

Single-Chamber Pacemaker

Product Highlights — Pacemaker

- Allows patients to undergo MRI scans when used with an MRI Ready lead from Abbott.*
- Physician-preferred size and physiologic shape minimize pocket size.
- Outstanding longevity provides 14,4 years of service life,[1] which is supported by a 10-year warranty.[2]
- AutoCapture™ pacing system offers the maximum in threshold adaptability and patient safety with ventricular Beat-by-Beat™ AutoCapture™ pacing systems capture confirmation. The AutoCapture pacing system automatically delivers a 5,0 V backup safety pulse when noncapture is detected, and it may be programmed to either a bipolar or unipolar configuration.
- A suite of state-of-the-art features — such as automaticity, ventricular AutoCapture™ pacing system and Sense*Ability*™ sensing algorithm technology — are designed to deliver optimal therapy for patients at implant and throughout their lives.
- Real-time electrogram (EGM) waveform, as well as the associated event markers that precede and follow a specific triggering event, can be programmed to automatically record up to 14 minutes of stored EGMs when encountering one or more programmable trigger options.
- An optional, easy-to-use handheld device (SJM MRI Activator™ device) can be used to program the device to preapproved MRI settings pre- and post-MRI scan, decreasing the number of workflow steps and increasing clinic efficiency.
- Six-month ERI-EOL interval.

*See MRI Conditional Parameters

Ordering Information

Contents: MRI Ready Pacing System

MODEL NUMBER	DESCRIPTION	DIMENSIONS (H × W × T, MM)	WEIGHT (G)	VOLUME (CC)	CONNECTOR
PM1162	Endurity Pacemaker	41 × 50 × 6	19	9.7 (± 0,5)	IS-1

Indications: Implantation is indicated in one or more of the following permanent conditions: syncope, presyncope, fatigue, disorientation due to arrhythmia/bradycardia, or any combination of those symptoms. ***Rate-Modulated Pacing*** is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity. ***Atrial Pacing*** is indicated for patients with sinus node dysfunction and normal AV and intraventricular conduction systems. ***Ventricular Pacing*** is indicated for patients with significant bradycardia and normal sinus rhythm with only rare episodes of A-V block or sinus arrest, chronic atrial fibrillation, severe physical disability.

Contraindications: ***Single-chamber pulse generators*** are contraindicated in patients with an implanted cardioverter-defibrillator. ***Rate-Adaptive Pacing*** may be inappropriate for patients who experience angina or other symptoms of myocardial dysfunction at higher sensor-driven rates. An appropriate Maximum Sensor Rate should be selected based on assessment of the highest stimulation rate tolerated by the patient. ***Single-Chamber Ventricular Demand Pacing*** is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction, or suffer a drop in arterial blood pressure with the onset of ventricular pacing. ***Single-Chamber Atrial Pacing*** is relatively contraindicated in patients who have demonstrated compromise of AV conduction. For specific contraindications associated with individual modes, refer to the programmer's on-screen help.

Potential Adverse Events: The following are potential complications associated with the use of any pacing system: arrhythmia, heart block, thrombosis, threshold elevation, valve damage, pneumothorax, myopotential sensing, vessel damage, air embolism, body rejection phenomena, cardiac tamponade or perforation, formation of fibrotic tissue/local tissue reaction, inability to interrogate or program a device because of programmer malfunction, infection, interruption of desired device function due to electrical interference, loss of desired pacing and/or sensing due to lead displacement, body reaction at electrode interface, or lead malfunction (fracture or damage to insulation), loss of normal device function due to battery failure or component malfunction, device migration, pocket erosion, or hematoma, pectoral muscle stimulation, phrenic nerve or diaphragmatic stimulation. The following, in addition to the above, are potential complications associated with the use of rate-modulated pacing systems: inappropriate, rapid pacing rates due to sensor failure or to the detection of signals other than patient activity, loss of activity-response due to sensor failure, palpitations with high-rate pacing.

Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

Endurity™
Single-Chamber Pacemaker

Product Specifications

PHYSICAL SPECIFICATIONS

Model	PM1162
Telemetry	Inductive
Dimensions (mm)	41 × 50 × 6
Weight (g)	19
Volume (cc)	9,7
Connector	IS-1

Remote Monitoring

Compatible with Merlin@home™ Transmitter

PARAMETER	SETTINGS
Rate/Timing	
Ventricular Pace/Sense Refractory (Fixed) (ms)	125; 160–400 in steps of 30; 440; 470[3]
Base Rate (min^{-1})	30–130 in steps of 5; 140–170 in steps of 10
Mode	VOO(R); VVI(R); VVT(R); Pacing Off; AOO(R); AAI(R); AAT(R)
Hysteresis Rate (min^{-1})	Off; 30[4]–150 in steps of 5
Search Interval (min^{-1})	Off; 1; 5; 10; 15; 30
Cycle Count	1–16 in steps of 1
Intervention Rate (min^{-1})	Off; 80–120 in steps of 10; Intrinsic +0; Intrinsic +10; Intrinsic +20; Intrinsic +30; Same as Base Rate
Intervention Duration (min)	1–10 in 1 minute intervals
Recovery Time	Fast; Medium; Slow; Very Slow
Rest Rate (min^{-1})	Off; 30–150 in steps of 5
Rate Responsive VREF	Off; Low; Medium; High
Shortest VREF	125–475 in steps of 25
Output/Sensing	
ACap™ Confirm[5] Feature	On; Off; Monitor
Primary Pulse Configuration	Bipolar
Backup Pulse Configuration	Bipolar
Backup Pulse Amplitude (V)	5,0[4]
Search Interval (hours)	8; 24
A or V Pulse Amplitude (V)	0,25–4,0 in steps of 0,25; 4,5–7,5 in steps of 0,5
A or V Pulse Width (ms)	0,05; 0,1–1,5 in steps of 0,1
A or V Pulse Configuration	Unipolar (tip-case); Bipolar (tip-ring)
A or V Sense Configuration	Unipolar Tip (tip-case); Bipolar (tip-ring); Unipolar Ring (ring-case)
Atrial Sensitivity (mV)	0,1–0,4[6] in steps of 0,1; 0,5; 0,75–2,0 in steps of 0,25; 2,5–4,0 in steps of 0,5; 5,0[7]
V Sensitivity (mV)	0,5–5,0 in steps of 0,5; 6-10 in steps of 1,0; 12,5[7]
Ventricular AutoCapture™ Pacing System	On; Off
Primary Pulse Configuration	Unipolar; Bipolar
Backup Pulse Configuration	Unipolar; Bipolar
Backup Pulse Amplitude (V)	5,0[8]
Search Interval (hours)	8; 24
SenseAbility™ Sensing Algorithm Technology	Off; On (Automatic sensitivity control adjustment for atrial or ventricular events)
A Max Sensitivity (mV)	0,2–1,0 in steps of 0,1
V Max Sensitivity (mV)	0,2–2,0 in steps of 0,1
Threshold Start	(Atrial and Ventricular Post-Sense) 50; 62,5; 75; 100% (Atrial Post-Pace) 0,2–3,0 in steps of 0,1 mV (Ventricular Post-Pace) Auto; 0,2–3,0 in steps of 0,1 mV
Decay Delay (ms)	(Atrial and Ventricular Post-Sense) 0; 30; 60; 95; 125; 160; 190; 220 (Atrial Post-Pace) 0; 30; 60; 95; 125; 160; 190; 220 (Ventricular Post-Pace) Auto; 0; 30; 60; 95; 125; 160; 190; 220

MRI Scan Parameters**

LOW VOLTAGE LEAD MODEL	MAGNET (TESLA)	RF POWER (SAR)	SCAN REGION
Tendril MRI™ Lead LPA1200M (46, 52, 58 cm)	1.5 T	Normal Operating Mode***	Full body
Tendril™ STS Pacing Lead 2088TC (46, 52, 58 cm)	1.5 T		
IsoFlex™ Optim™ Pacing Lead 1944 (46, 52 cm) 1948 (52, 58 cm)	1.5 T		

**Refer to the MRI Ready Systems Manual for more detailed information.
***As defined in IEC 60601-2-33, Normal Operating Mode corresponds to RF Power SAR: ≤ 2 W/kg, Head SAR ≤ 3.2 W/kg.

MRI Settings	
MRI Mode	AOO; VOO; Pacing Off
MRI Base Rate	30–120 bpm in steps of 5 bpm
MRI Atrial Pulse Configuration	Bipolar
MRI Atrial Pulse Amplitude	5,0 V; 7,5 V
MRI Atrial Pulse Width	1,0 ms
MRI RV Pulse Configuration	Bipolar
MRI RV Pulse Amplitude	5,0 V; 7,5 V
MRI RV Pulse Width	1,0 ms
AF Management[5]	
AF Suppression™ Algorithm	Off; On (Atrial implants only)
Lower Rate Overdrive (min^{-1})	10[4]
Upper Rate Overdrive (min^{-1})	5[4]
No. of Overdrive Pacing Cycles	15–40 in steps of 5
Rate Recovery (ms)	8; 12[4]
Maximum AF Suppression Rate (min^{-1})	80–150 in steps of 5; 160–180 in steps of 10
Atrial Tachycardia Detection Rate (min^{-1})	110–200 in steps of 10; 225–300 in steps of 25
Rate-Modulated Parameters	
Maximum Sensor Rate (min^{-1})	80–150 in steps of 5; 160–180 in steps of 10
Reaction Time	Very Fast; Fast; Medium; Slow
Recovery Time	Fast; Medium; Slow; Very Slow
Sensor	On; Off; Passive
Slope	Auto (-1); Auto (+0); Auto (+1); Auto (+2); Auto (+3); 1–16 in steps of 1
Threshold	Auto (-0,5); Auto (+0,0); Auto (+0,5); Auto (+1,0); Auto (+1,5); Auto (+2,0); 1–7 in steps of 0,5
Stored Electrograms	
Options	
Priority Options	Off; Low; High
Channel	1; 2; 3
Triggers	
Magnet Response	Off; Low; High
High Ventricular Rate	Off; Low; High
Rate (min^{-1})	125–300 in steps of 25
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
Advanced Hysteresis	Off; Low; High
Noise Reversion	Off; Low; High

High Ventricular Rate can alternately be High Atrial Rate; they use the same sub-parameters.

Other	
Lead Monitoring	Monitor; Auto Polarity Switch
V Low Impedance Limit (Ω)	100–500 in steps of 25
V High Impedance Limit (Ω)	750–2500 in steps of 250; 3000

Atrial limits apply when implanted in the atrium.

Lead Type	Uncoded; Unipolar; Bipolar
Magnet Response	Off; Battery Test
NIPS Options	
Stimulation Chamber	Atrial or Ventricular
Coupling Interval (ms)	100–800 in steps of 10
S1 Count	2–25 in steps of 1
S1[9]; S2; S3 and S4 Cycle (ms)	Off; 100–800 in steps of 10 (Fixed or Adaptive)
Diagnostic Trends	AT/AF Activity, Exercise; Lead Impedance; R (or P) Wave; V (or A) Threshold

1. A,V = 2,5 V @ 0,4 ms; 500 ohms; 100% VVI pacing @ 60 bpm; AutoCapture™ Pacing System OFF; SEGMs ON.
2. Terms and conditions apply; refer to the warranty for details.
3. Programming options dependent on pacing mode.
4. The highest available setting for hysteresis rate will be 5 min^{-1} below the programmed base rate.
5. Atrial Implants Only.
6. Values 0,1–0,4 not available in a unipolar sense configuration.
7. Sensitivity is with respect to a 20 ms haversine test signal.
8. This parameter is not programmable.
9. S1 Burst Cycle is applied at the preprogrammed S1 cycle length.

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St. Jude Medical is now Abbott.

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

29070-EM-END-1016-0014(3) | Information contained herein intended for audiences from outside the United States only.

Abbott

Endurity™ Core

Dual-Chamber Pacemaker

Pacemakers

MR

Product Highlights

- Allows patients to undergo MRI scans when used with MRI Ready leads from Abbott*
- Physician preferred size and physiologic shape minimize pocket size
- Outstanding longevity provides 9,7 years of service life,[1] which is supported by an 5-year warranty[2]
- AutoCapture™ pacing system offers the maximum in threshold adaptability and patient safety with ventricular Beat-by-Beat™ capture confirmation. The AutoCapture pacing system automatically delivers a 5,0 V backup safety pulse when noncapture is detected, and it may be programmed to either a bipolar or unipolar configuration
- State-of-the-art features – Ventricular Intrinsic Preference (VIP™) technology, and the AF Suppression™ algorithm, are designed to deliver optimal therapy for patients at implant and throughout their lives
- The only pacemaker with programmable AT/AF alerts specifically indicated for detecting atrial tachyarrhythmias, which have been found to be associated with an increased risk of stroke in elderly, hypertensive, pacemaker patients without prior history of AF[3]
- Real-time electrogram (EGM) waveform, as well as the associated event markers that precede and follow a specific triggering event, can be programmed to automatically record up to 2 minutes of stored EGMs when encountering one or more programmable trigger options
- An optional, easy-to-use hand-held device (SJM MRI Activator™ device) can be used to program the device to pre-approved MRI settings pre- and post-MRI scan, decreasing the number of workflow steps and increasing clinic efficiency
- Six-month ERI-EOL interval

*See MRI Conditional Parameters

Ordering Information

Contents: MRI Ready Pacing System

Model Number	Description	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector
PM2152	Endurity™ Core Pacemaker	46 x 50 x 6	19	10,4 (± 0,5)	IS-1

Indications: Implantation is indicated in one or more of the following permanent conditions: syncope, presyncope, fatigue, disorientation due to arrhythmia/bradycardia or any combination of those symptoms. ***Rate-Modulated Pacing*** is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity. ***Dual-Chamber Pacing*** is indicated for those patients exhibiting: sick sinus syndrome, chronic, symptomatic second- and third-degree AV block, recurrent Adams-Stokes syndrome, symptomatic bilateral bundle branch block when tachyarrhythmia and other causes have been ruled out. ***Atrial Pacing*** is indicated for patients with sinus node dysfunction and normal AV and intraventricular conduction systems. ***Ventricular Pacing*** is indicated for patients with significant bradycardia and normal sinus rhythm with only rare episodes of A-V block or sinus arrest, chronic atrial fibrillation, severe physical disability. AF Suppression algorithm is indicated for suppression of paroxysmal or persistent atrial fibrillation episodes in patients with one or more of the above pacing indications.

Contraindications: ***Dual-chamber pulse generators*** are contraindicated in patients with an implanted cardioverter-defibrillator. ***Rate-Adaptive Pacing*** may be inappropriate for patients who experience angina or other symptoms of myocardial dysfunction at higher sensor-driven rates. An appropriate Maximum Sensor Rate should be selected based on assessment of the highest stimulation rate tolerated by the patient. AF Suppression stimulation is not recommended in patients who cannot tolerate high atrial-rate stimulation. ***Dual-Chamber Pacing***, though not contraindicated for patients with chronic atrial flutter, chronic atrial fibrillation or silent atria, may provide no benefit beyond that of single-chamber pacing in such patients.

Single-Chamber Ventricular Demand Pacing is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction or suffer a drop in arterial blood pressure with the onset of ventricular pacing. ***Single-Chamber Atrial Pacing*** is relatively contraindicated in patients who have demonstrated compromise of AV conduction.

Potential Adverse Events: The following are potential complications associated with the use of any pacing system: arrhythmia, heart block, thrombosis, threshold elevation, valve damage, pneumothorax, myopotential sensing, vessel damage, air embolism, body rejection phenomena, cardiac tamponade or perforation, formation of fibrotic tissue/local tissue reaction, inability to interrogate or program a device because of programmer malfunction, infection, interruption of desired device function due to electrical interference, loss of desired pacing and/or sensing due to lead displacement, body reaction at electrode interface or lead malfunction (fracture or damage to insulation), loss of normal device function due to battery failure or component malfunction, device migration, pocket erosion or hematoma, pectoral muscle stimulation, phrenic nerve or diaphragmatic stimulation. The following, in addition to the above, are potential complications associated with the use of rate-modulated pacing systems: inappropriate, rapid pacing rates due to sensor failure or to the detection of signals other than patient activity, loss of activity-response due to sensor failure, palpitations with high-rate pacing.

Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

Abbott

Endurity™ Core

Dual-Chamber Pacemaker

Pacemakers

Physical Specifications

Model	PM2152
Telemetry	Inductive
Dimensions (mm)	46 x 50 x 6
Weight (g)	19
Volume (cc)	10,4[4]
Connector	IS-1

Parameter	Settings
Rate/Timing	
Atrial Pace Refractory (ms)	190-400 in steps of 30; 440; 470[5]
Atrial Sense Refractory (ms)	93; 125; 157; 190-400 in steps of 30; 440; 470[5]
Paced AV Delay (ms)	25; 30-200 in steps of 10; 225-300 in steps of 25; 350
Base Rate (min^{-1})	30-130 in steps of 5; 140-170 in steps of 10
Far-Field Protection Interval (ms)	16[6]
Hysteresis Rate (min^{-1})	Off; 30[7]-150 in steps of 5
Search Interval (min)	Off; 1; 5; 10; 15; 30
Cycle Count	1-16 in steps of 1
Intervention Rate (min^{-1})	Off; Same as Base Rate; 80-120 in steps of 10; Intrinsic +0; Intrinsic +10; Intrinsic +20; Intrinsic +30
Intervention Duration (min)	1-10 in 1 minute intervals
Recovery Time	Fast; Medium; Slow; Very Slow
Maximum Tracking Rate (min^{-1})	90-130 in steps of 5; 140-180 in steps of 10
Mode	AOO(R); AAI(R); AAT(R); VOO(R); VVI(R); VVT(R); VDD(R); DOO(R); DVI(R); DDI(R); DDD(R); Pacing Off
Post Ventricular Atrial Blanking (ms)	60-200 in steps of 10; 225; 250
PVARP (ms)	125-500 in steps of 25
Sensed AV Delay (ms)	25; 30-200 in steps of 10; 225-325 in steps of 25
Rest Rate (min^{-1})	Off; 30-150 in steps of 5
Rate Responsive AV Delay	Off; Low; Medium; High
Rate Responsive PVARP/VREF	Off; Low; Medium; High
Shortest AV Delay (ms)	25-50 in steps of 5; 60-120 in steps of 10
Shortest PVARP/VREF (ms)	125-475 in steps of 25
Ventricular Blanking (ms)	Auto, 12-52 in steps of 4
Ventricular Pace/Sense Refractory[8] (Fixed) (ms)	125; 160-400 in steps of 30; 440; 470; 500[5]
Output/Sensing	
A or V Pulse Amplitude (V)	0,25-4,0 in steps of 0,25; 4,5-7,5 in steps of 0,5
A or V Pulse Width (ms)	0,05; 0,1-1,5 in steps of 0,1
A or V Pulse Configuration	Unipolar (tip-case); Bipolar (tip-ring)
A or V Sense Configuration	Unipolar Tip (tip-case); Bipolar (tip-ring); Unipolar Ring (ring-case)
Ventricular AutoCapture™ Pacing System	On; Off
Primary Pulse Configuration	Unipolar; Bipolar
Backup Pulse Configuration	Unipolar; Bipolar
Backup Pulse Amplitude (V)	5,0[6]
Search Interval (hours)	8; 24
AutoCapture Paced/Sensed AV Delay (ms)	50/25; 100/70; 120/100
Atrial Sensitivity (mV)	0,1-0,4[9] in steps of 0,1; 0,5; 0,75-2,0 in steps of 0,25; 2,5-4,0 in steps of 0,5; 5,0[10]
Ventricular Sensitivity (mV)	0,5-5,0 in steps of 0,5; 6-10 in steps of 1,0; 12,5[10]
Rate-Modulated Parameters	
Maximum Sensor Rate (min^{-1})	80-150 in steps of 5; 160-180 in steps of 10
Reaction Time	Very Fast; Fast; Medium; Slow
Recovery Time	Fast; Medium; Slow; Very Slow
Sensor	On; Off; Passive
Slope	Auto (-1); Auto (+0); Auto (+1); Auto (+2); Auto (+3); 1-16 in steps of 1
Threshold	Auto (-0,5); Auto (+0,0); Auto (+0,5); Auto (+1,0); Auto (+1,5); Auto (+2,0); 1-7 in steps of 0,5

AF Management[8]	
AF Suppression™ Algorithm	Off; On
Lower Rate Overdrive (min^{-1})	10[6]
Upper Rate Overdrive (min^{-1})	5[6]
No. of Overdrive Pacing Cycles	15-40 in steps of 5
Rate Recovery (ms)	8; 12[6]
Maximum AF Suppression Rate (min^{-1})	80-200 in steps of 10; 225-300 in steps of 25
Atrial Tachycardia Detection Rate (min^{-1})	110-200 in steps of 10; 225-300 in steps of 25
Auto Mode Switch	Off; DDD(R) to DDI(R); DDD(R) to DDT(R); DDD(R) to VVI(R); DDD(R) to VVT(R); VDD(R) to VVI(R); VDD(R) to VVT(R)
AMS Base Rate (min^{-1})	40-170 in steps of 5
Stored Electrograms	
Options	
Priority Options	Off; Low; High
Channel	1; 2; 3
Triggers	
Advanced Hysteresis	Off; Low; High
AMS Entry/AMS Exit/ AMS Entry and Exit	Off; Low; High
AT/AF Detection	Off; Low; High
Magnet Response	Off; Low; High
High Atrial Rate	Off; Low; High
Rate (min^{-1})	125-300 in steps of 25
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
High Ventricular Rate	Off; Low; High
Rate (min^{-1})	125-300 in steps of 25
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
PMT Termination	Off; Low; High
Consecutive PVCs	Off; Low; High
No. of Consecutive PVCs	2; 3; 4; 5
Noise Reversion	Off; Low; High
Other	
A and V Lead Monitoring	Monitor; Auto Polarity Switch
A and V Low Impedance Limit (Ω)	100-500 in steps of 25
A and V High Impedance Limit (Ω)	750-2500 in steps of 250; 3000
Lead Type	Uncoded; Unipolar; Bipolar
Magnet Response	Off; Battery Test
Negative AV Hysteresis Search (ms)	Off; -10 to -120 in steps of 10
NIPS Options	
Stimulation Chamber	Atrial; Ventricular
Coupling Interval (ms)	100-800 in steps of 10[11]
S1 Count	2-25 in steps of 1
S1[12]; S2; S3 and S4 Cycle (ms)	Off; 100-800 in steps of 10 (Fixed or Adaptive)
Ventricular Support Rate (min^{-1})	Off; 30-95 in steps of 5
Sinus Node Recovery Delay (sec)	1; 2; 3; 4; 5
PMT Options	Off; Passive; Atrial Pace[5]
PMT Detection Rate (min^{-1})	90-180 in steps of 5
PVC Response	Off; Atrial Pace[5]
Ventricular Intrinsic Preference, VIP™ (ms)	Off, 50-150 in steps of 25; 160-200 in steps of 10
VIP Search Interval	30 sec.; 1; 3; 5; 10; 30 min.
VIP Search Cycles	1; 2; 3
Ventricular Safety Standby	Off; On
Diagnostic Trends	AT/AF Activity; Lead Impedance; P and R Wave; V Threshold
MRI Settings	
MRI Mode	AOO; VOO; DOO; Pacing Off
MRI Base Rate	30-120 bpm in steps of 5 bpm
MRI Paced AV Delay	25 ms; 30-120 ms in steps of 10 ms
MRI Atrial Pulse Configuration	Bipolar
MRI Atrial Pulse Amplitude	5,0 V; 7,5 V
MRI Atrial Pulse Width	1,0 ms
MRI RV Pulse Configuration	Bipolar
MRI RV Pulse Amplitude	5,0 V; 7,5 V
MRI RV Pulse Width	1,0 ms

MRI Scan Parameters*

MRI Ready Lead Model	Lead Lengths	Magnet (Tesla)	Scanner Mode	Scan Region
Tendril™ 2088TC Lead	46, 52, 58 cm	1.5 T	Normal Operating Mode	Full body
IsoFlex™ 1944 Lead	46, 52 cm	1.5 T		
IsoFlex™ 1948 Lead	52, 58 cm	1.5 T		

*Refer to the MRI Ready Systems Manual for more detailed information.

1. A,V = 2,5 V @ 0,4 ms; 500 ohms; 100% DDD pacing @ 60 bpm; AutoCapture™ Pacing System OFF; SEGMs ON.
2. Terms and conditions apply; refer to the warranty for details.
3. Healey JS, Connolly SJ, Gold MR, et al. on behalf of the ASSERT investigators. Sub-clinical atrial fibrillation and the risk of stroke: ASymptomatic atrial fibrillation and Stroke Evaluation in pacemaker patients and the AF Reduction atrial pacing Trial (ASSERT). N Engl J Med 2012; 366:120 –129.
4. ± 0,5 cc.
5. Programming options dependent on pacing mode.
6. This parameter is not programmable.
7. The highest available setting for hysteresis rate will be 5 min-1 below the programmed base rate.
8. In dual-chamber modes, the maximum ventricular refractory period is 325 ms.
9. Values 0,1-0,4 not available in a unipolar sense configuration.
10. Sensitivity is with respect to a 20 ms haversine test signal.
11. During atrial NIPS in dual-chamber modes, the shortest Coupling Interval will be limited by the programmed AV/PV delay.

Abbott
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St. Jude Medical is now Abbott.

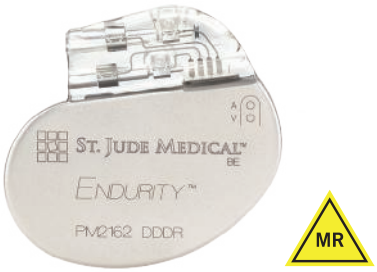
Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

27131-EM-END-1016-0018(1) | Item approved for international use only.

Abbott

Endurity™

Dual-chamber Pacemaker



Product Highlights — Pacemaker

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- Physician-preferred size and physiologic shape minimize pocket size.
- Outstanding longevity provides 9,7 years of service life,[1] which is supported by an eight-year warranty.[2]
- AutoCapture™ pacing system offers the maximum in threshold adaptability and patient safety with ventricular Beat-by-Beat™ AutoCapture™ pacing systems capture confirmation. The AutoCapture pacing system automatically delivers a 5,0 V backup safety pulse when noncapture is detected, and it may be programmed to either a bipolar or unipolar configuration.
- A suite of state-of-the-art features — complete automaticity (atrial and ventricular), Ventricular Intrinsic Preference (VIP™) technology, the AF Suppression™ algorithm and Sense*Ability*™ sensing algorithm technology — is designed to deliver optimal therapy for patients at implant and throughout their lives.
- The only pacemaker with programmable AT/AF alerts specifically indicated for detecting atrial tachyarrhythmias, which have been found to be associated with an increased risk of stroke in elderly, hypertensive, pacemaker patients without prior history of AF.[3]
- Real-time electrogram (EGM) waveform, as well as the associated event markers that precede and follow a specific triggering event, can be programmed to automatically record up to 14 minutes of stored EGMs when encountering one or more programmable trigger options.
- An optional, easy-to-use handheld device (SJM MRI Activator™ device) can be used to program the device to preapproved MRI settings pre- and post-MRI scan, decreasing the number of workflow steps and increasing clinic efficiency.
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*See MRI Conditional Parameters

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Indications: Implantation is indicated in one or more of the following permanent conditions: syncope, presyncope, fatigue, disorientation due to arrhythmia/bradycardia or any combination of those symptoms. ***Rate-Modulated Pacing*** is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity. ***Dual-Chamber Pacing*** is indicated for those patients exhibiting: sick sinus syndrome, chronic, symptomatic second- and third-degree AV block, recurrent Adams-Stokes syndrome, symptomatic bilateral bundle branch block when tachyarrhythmia and other causes have been ruled out. ***Atrial Pacing*** is indicated for patients with sinus node dysfunction and normal AV and intraventricular conduction systems. ***Ventricular Pacing*** is indicated for patients with significant bradycardia and normal sinus rhythm with only rare episodes of A-V block or sinus arrest, chronic atrial fibrillation, severe physical disability. AF Suppression™ algorithm is indicated for suppression of paroxysmal or persistent atrial fibrillation episodes in patients with one or more of the above pacing indications.

Contraindications: ***Dual-chamber pulse generators*** are contraindicated in patients with an implanted cardioverter-defibrillator. ***Rate-Adaptive Pacing*** may be inappropriate for patients who experience angina or other symptoms of myocardial dysfunction at higher sensor-driven rates. An appropriate Maximum Sensor Rate should be selected based on assessment of the highest stimulation rate tolerated by the patient. AF Suppression stimulation is not recommended in patients who cannot tolerate high atrial-rate stimulation. ***Dual-Chamber Pacing***, though not contraindicated for patients with chronic atrial flutter, chronic atrial fibrillation or silent atria, may provide no benefit beyond that of single-chamber pacing in such patients. ***Single-Chamber Ventricular Demand Pacing*** is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction or suffer a drop in arterial blood pressure with the onset of ventricular pacing. ***Single-Chamber Atrial Pacing*** is relatively contraindicated in patients who have demonstrated compromise of AV conduction.

Potential Adverse Events: The following are potential complications associated with the use of any pacing system: arrhythmia, heart block, thrombosis, threshold elevation, valve damage, pneumothorax, myopotential sensing, vessel damage, air embolism, body rejection phenomena, cardiac tamponade or perforation, formation of fibrotic tissue/local tissue reaction, inability to interrogate or program a device because of programmer malfunction, infection, interruption of desired device function due to electrical interference, loss of desired pacing and/or sensing due to lead displacement, body reaction at electrode interface or lead malfunction (fracture or damage to insulation), loss of normal device function due to battery failure or component malfunction, device migration, pocket erosion or hematoma, pectoral muscle stimulation, phrenic nerve or diaphragmatic stimulation. The following, in addition to the above, are potential complications associated with the use of rate-modulated pacing systems: inappropriate, rapid pacing rates due to sensor failure or to the detection of signals other than patient activity, loss of activity-response due to sensor failure, palpitations with high-rate pacing.
Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

Endurity™

Dual-chamber Pacemaker

Product Specifications

PHYSICAL SPECIFICATIONS — PACEMAKER

Model	PM2162
Telemetry	Inductive
Dimensions (mm)	46 × 50 × 6
Weight (g)	19
Volume (cc)	10,4[4]
Connector	IS-1
Remote Monitoring	
Compatible with Merlin@home™ Transmitter	

PARAMETER	SETTINGS
Rate/Timing	
Atrial Pace Refractory (ms)	190–400 in steps of 30; 440; 470[5]
Atrial Sense Refractory (ms)	93; 125; 157; 190–400 in steps of 30; 440; 470[5]
Paced AV Delay (ms)	25; 30–200 in steps of 10; 225–300 in steps of 25; 350
Base Rate (min^{-1})	30–130 in steps of 5; 140–170 in steps of 10
Far-Field Protection Interval (ms)	16[6]
Hysteresis Rate (min^{-1})	Off; 30[7]–150 in steps of 5
Search Interval (min)	Off; 1; 5; 10; 15; 30
Cycle Count	1–16 in steps of 1
Intervention Rate (min^{-1})	Off; Same as Base Rate; 80–120 in steps of 10; Intrinsic +0; Intrinsic +10; Intrinsic +20; Intrinsic +30
Intervention Duration (min)	1–10 in 1 minute intervals
Recovery Time	Fast; Medium; Slow; Very Slow
Maximum Tracking Rate (min^{-1})	90–130 in steps of 5; 140–210 in steps of 10
Mode	AOO(R); AAI(R); AAT(R); VOO(R); VVI(R); VVT(R); VDD(R); DOO(R); DVI(R); DDI(R); DDD(R); Pacing Off
Post Ventricular Atrial Blanking (ms)	60–200 in steps of 10; 225; 250
PVARP (ms)	125–500 in steps of 25
Sensed AV Delay (ms)	25; 30–200 in steps of 10; 225–325 in steps of 25
Rest Rate (min^{-1})	Off; 30–150 in steps of 5
Rate Responsive AV Delay	Off; Low; Medium; High
Rate Responsive PVARP/VREF	Off; Low; Medium; High
Shortest AV Delay (ms)	25–50 in steps of 5; 60–120 in steps of 10
Shortest PVARP/VREF (ms)	125–475 in steps of 25
Ventricular Blanking (ms)	Auto; 12–52 in steps of 4
Ventricular Pace/Sense Refractory[8] (Fixed) (ms)	125; 160–400 in steps of 30; 440; 470; 500[5]
Output/Sensing	
ACap™ Confirm Feature	On; Off; Monitor
Primary Pulse Configuration	Bipolar
Backup Pulse Configuration	Bipolar
Backup Pulse Amplitude (V)	5,0
Search Interval (hours)	8; 24
A or V Pulse Amplitude (V)	0,25–4,0 in steps of 0,25; 4,5–7,5 in steps of 0,5
A or V Pulse Width (ms)	0,05; 0,1–1,5 in steps of 0,1
A or V Pulse Configuration	Unipolar (tip-case); Bipolar (tip-ring)
A or V Sense Configuration	Unipolar Tip (tip-case); Bipolar (tip-ring); Unipolar Ring (ring-case)
Ventricular AutoCapture™ Pacing System	On; Off
Primary Pulse Configuration	Unipolar; Bipolar
Backup Pulse Configuration	Unipolar; Bipolar
Backup Pulse Amplitude (V)	5,0[6]
Search Interval (hours)	8; 24
AutoCapture	
Paced/Sensed AV Delay (ms)	50/25; 100/70; 120/100
Atrial Sensitivity (mV)	0,1–0,4[9] in steps of 0,1; 0,5; 0,75–2,0 in steps of 0,25; 2,5–4,0 in steps of 0,5; 5,0[10]
Ventricular Sensitivity (mV)	0,5–5,0 in steps of 0,5; 6–10 in steps of 1,0; 12,5[10]
SenseAbility™ Sensing Algorithm Technology	Off; On (Automatic sensitivity control adjustment for atrial or ventricular events)
A Max Sensitivity (mV)	0,2–1,0 in steps of 0,1
V Max Sensitivity (mV)	0,2–2,0 in steps of 0,1
Threshold Start	(Atrial and Ventricular Post-Sense) 50; 62,5; 75; 100% (Atrial Post-Pace) 0,2–3,0 in steps of 0,1 mV (Ventricular Post-Pace) Auto; 0,2–3,0 in steps of 0,1 mV
Decay Delay (ms)	(Atrial and Ventricular Post-Sense) 0; 30; 60; 95; 125; 160; 190; 220 (Atrial Post-Pace) 0; 30; 60; 95; 125; 160; 190; 220 (Ventricular Post-Pace) Auto; 0; 30; 60; 95; 125; 160; 190; 220
Rate-Modulated Parameters	
Maximum Sensor Rate (min^{-1})	80–150 in steps of 5; 160–180 in steps of 10
Reaction Time	Very Fast; Fast; Medium; Slow
Recovery Time	Fast; Medium; Slow; Very Slow
Sensor	On; Off; Passive
Slope	Auto (-1); Auto (+0); Auto (+1); Auto (+2); Auto (+3); 1–16 in steps of 1
Threshold	Auto (-0,5); Auto (+0,0); Auto (+0,5); Auto (+1,0); Auto (+1,5); Auto (+2,0); 1–7 in steps of 0,5

AF Management	
AF Suppression™ Algorithm	Off; On
Lower Rate Overdrive (min^{-1})	10[6]
Upper Rate Overdrive (min^{-1})	5[6]
No. of Overdrive Pacing Cycles	15–40 in steps of 5
Rate Recovery (ms)	8; 12[6]
Maximum AF Suppression Rate (min^{-1})	80–200 in steps of 10; 225–300 in steps of 25
Atrial Tachycardia Detection Rate (min^{-1})	110–200 in steps of 10; 225–300 in steps of 25
Auto Mode Switch	Off; DDD(R) to DDI(R); DDD(R) to DDT(R); DDD(R) to VVI(R); DDD(R) to VVT(R); VDD(R) to VVI(R); VDD(R) to VVT(R)
AMS Base Rate (min^{-1})	40–170 in steps of 5
Stored Electrograms	
Options	
Priority Options	Off; Low; High
Channel	1; 2; 3
Triggers	
Advanced Hysteresis	Off; Low; High
AMS Entry/AMS Exit/ AMS Entry and Exit	Off; Low; High
AT/AF Detection	Off; Low; High
Magnet Response	Off; Low; High
High Atrial Rate	Off; Low; High
Rate (min^{-1})	125–300 in steps of 25
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
High Ventricular Rate	Off; Low; High
Rate (min^{-1})	125–300 in steps of 25
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
PMT Termination	Off; Low; High
Consecutive PVCs	Off; Low; High
No. of Consecutive PVCs	2; 3; 4; 5
Noise Reversion	Off; Low; High
Other	
A and V Lead Monitoring	Monitor; Auto Polarity Switch
A and V Low Impedance Limit (Ω)	100–500 in steps of 25
A and V High Impedance Limit (Ω)	750–2500 in steps of 250; 3000
Lead Type	Uncoded; Unipolar; Bipolar
Magnet Response	Off; Battery Test
Negative AV Hysteresis Search (ms)	Off; -10 to -120 in steps of 10
NIPS Options	
Stimulation Chamber	Atrial; Ventricular
Coupling Interval (ms)	100–800 in steps of 10[11]
S1 Count	2–25 in steps of 1
S1[12]; S2; S3 and S4 Cycle (ms)	Off; 100–800 in steps of 10 (Fixed or Adaptive)
Ventricular Support Rate (min^{-1})	Off; 30–95 in steps of 5
Sinus Node Recovery Delay (sec)	1; 2; 3; 4; 5
PMT Options	Off; Passive; Atrial Pace[5]
PMT Detection Rate (min^{-1})	90–180 in steps of 5
PVC Response	Off; Atrial Pace[8]
Ventricular Intrinsic Preference, VIP™ (ms)	Off; 50–150 in steps of 25; 160–200 in steps of 10
VIP Search Interval	30 sec.; 1; 3; 5; 10; 30 min.
VIP Search Cycles	1; 2; 3
Ventricular Safety Standby	Off; On
Diagnostic Trends	AT/AF Activity; Exercise; Lead Impedance; P and R Wave; A and V Threshold
MRI Settings	
MRI Mode	AOO; VOO; DOO; Pacing Off
MRI Base Rate	30–120 bpm in steps of 5 bpm
MRI Paced AV Delay	25 ms; 30–120 ms in steps of 10 ms
MRI Atrial Pulse Configuration	Bipolar
MRI Atrial Pulse Amplitude	5,0 V; 7,5 V
MRI Atrial Pulse Width	1,0 ms
MRI RV Pulse Configuration	Bipolar
MRI RV Pulse Amplitude	5,0 V; 7,5 V
MRI RV Pulse Width	1,0 ms

MRI Scan Parameters**

MRI Ready Lead	Lead Lengths	Magnet (Tesla)	Scanner Mode	Scan Region
Tendril™ 2088TC Pacing Lead	46, 52, 58 cm	1,5 T	Normal Operating Mode	Full Body
IsoFlex™ Optim™ 1944 Pacing Lead	46, 52 cm			
IsoFlex™ Optim™ 1948 Pacing Lead	52, 58 cm			

**Refer to the MRI Ready Systems Manual for more detailed information.

1. A,V = 2,5 V @ 0,4 ms; 500 ohms; 100% DDD pacing @ 60 bpm; AutoCapture™ Pacing System OFF; SEGMs ON.
2. Terms and conditions apply; refer to the warranty for details.
3. Healey JS, Connolly SJ, Gold MR, et al. on behalf of the ASSERT investigators. Sub-clinical atrial fibrillation and the risk of stroke: Asymptomatic atrial fibrillation and Stroke Evaluation in pacemaker patients and the AF Reduction atrial pacing Trial (ASSERT). *N Engl J Med* 2012; 366:120–129.
4. ± 0,5 cc
5. Programming options dependent on pacing mode.
6. This parameter is not programmable.
7. The highest available setting for hysteresis rate will be 5 min^{-1} below the programmed base rate.
8. In dual-chamber modes, the maximum ventricular refractory period is 325 ms.
9. Values 0,1–0,4 not available in a unipolar sense configuration.
10. Sensitivity is with respect to a 20 ms haversine test signal.
11. During atrial NIPS in dual-chamber modes, the shortest Coupling Interval will be limited by the programmed AV/PV delay.
12. S1 Burst Cycle is applied at the preprogrammed S1 cycle length.

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St. Jude Medical is now Abbott.

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

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Information contained herein intended for audiences from outside the United States only.

Abbott

PACEMAKERS

Endurity MRI™

Dual-Chamber Pacemaker

Merlin@home™ Transmitter Compatible

Product Highlights - Pacemaker

- Allows patients to undergo 1.5 T or 3 T MRI scans when used with MRI Ready leads from Abbott*
- Physician preferred size and physiologic shape minimize pocket size
- Outstanding longevity provides 9,7 years of service life,[1] which is supported by an 8-year warranty[2]
- AutoCapture™ pacing system offers the maximum in threshold adaptability and patient safety with ventricular Beat-by-Beat™ capture confirmation. The AutoCapture pacing system automatically delivers a 5,0 V backup safety pulse when noncapture is detected, and it may be programmed to either a bipolar or unipolar configuration
- A suite of state-of-the-art features – complete automaticity (atrial and ventricular), Ventricular Intrinsic Preference (VIP™) technology, the AF Suppression™ algorithm and Sense*Ability*™ technology – is designed to deliver optimal therapy for patients at implant and throughout their lives
- The only pacemaker with programmable AT/AF alerts specifically indicated for detecting atrial tachyarrhythmias, which have been found to be associated with an increased risk of stroke in elderly, hypertensive, pacemaker patients without prior history of AF[3]
- Real-time electrogram (EGM) waveform, as well as the associated event markers that precede and follow a specific triggering event, can be programmed to automatically record up to 14 minutes of stored EGMs when encountering one or more programmable trigger options
- 6-month ERI-EOL interval
- An optional, easy-to-use hand-held device (SJM MRI Activator™ device) can be used to program the device to pre-approved MRI settings pre- and post-MRI scan, decreasing the number of workflow steps and increasing clinic efficiency

*See MRI Scan Parameters

Ordering Information

Contents: MRI Ready Pacing System

MODEL NUMBER	DESCRIPTION	DIMENSIONS (H × W × T, MM)	WEIGHT (G)	VOLUME (CC)	CONNECTOR
PM2172	Endurity MRI™ Pacemaker	46 × 50 × 6	20	10,4 (± 0,5)	IS-1

Indications: Implantation is indicated in one or more of the following permanent conditions: syncope, presyncope, fatigue, disorientation due to arrhythmia/bradycardia or any combination of those symptoms. ***Rate-Modulated Pacing*** is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity. ***Dual-Chamber Pacing*** is indicated for those patients exhibiting: sick sinus syndrome, chronic, symptomatic second- and third-degree AV block, recurrent Adams-Stokes syndrome, symptomatic bilateral bundle branch block when tachyarrhythmia and other causes have been ruled out. ***Atrial Pacing*** is indicated for patients with sinus node dysfunction and normal AV and intraventricular conduction systems. ***Ventricular Pacing*** is indicated for patients with significant bradycardia and normal sinus rhythm with only rare episodes of A-V block or sinus arrest, chronic atrial fibrillation, severe physical disability. AF Suppression™ algorithm is indicated for suppression of paroxysmal or persistent atrial fibrillation episodes in patients with one or more of the above pacing indications.

Contraindications: ***Dual-chamber pulse generators*** are contraindicated in patients with an implanted cardioverter-defibrillator. ***Rate-Adaptive Pacing*** may be inappropriate for patients who experience angina or other symptoms of myocardial dysfunction at higher sensor-driven rates. An appropriate Maximum Sensor Rate should be selected based on assessment of the highest stimulation rate tolerated by the patient. AF Suppression stimulation is not recommended in patients who cannot tolerate high atrial-rate stimulation. ***Dual-Chamber Pacing***, though not contraindicated for patients with chronic atrial flutter, chronic atrial fibrillation or silent atria, may provide no benefit beyond that of single-chamber pacing in such patients. ***Single-Chamber Ventricular Demand Pacing*** is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction or suffer a drop in arterial blood pressure with the onset of ventricular pacing. ***Single-Chamber Atrial Pacing*** is relatively contraindicated in patients who have demonstrated compromise of AV conduction.

Potential Adverse Events: The following are potential complications associated with the use of any pacing system: arrhythmia, heart block, thrombosis, threshold elevation, valve damage, pneumothorax, myopotential sensing, vessel damage, air embolism, body rejection phenomena, cardiac tamponade or perforation, formation of fibrotic tissue/local tissue reaction, inability to interrogate or program a device because of programmer malfunction, infection, interruption of desired device function due to electrical interference, loss of desired pacing and/or sensing due to lead displacement, body reaction at electrode interface or lead malfunction (fracture or damage to insulation), loss of normal device function due to battery failure or component malfunction, device migration, pocket erosion or hematoma, pectoral muscle stimulation, phrenic nerve or diaphragmatic stimulation. The following, in addition to the above, are potential complications associated with the use of rate-modulated pacing systems: inappropriate, rapid pacing rates due to sensor failure or to the detection of signals other than patient activity, loss of activity-response due to sensor failure, palpitations with high-rate pacing.

Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

Endurity MRI™

Dual-Chamber Pacemaker

Product Specifications

PHYSICAL SPECIFICATIONS

Models	PM2172
Telemetry	Inductive
Dimensions (mm)	46 × 50 × 6
Weight (g)	19
Volume (cc)	10,4[4]
Connector	IS-1

Remote Monitoring

Compatible with Merlin@home™ Transmitter

PARAMETER	SETTINGS
Rate/Timing	
Atrial Sense Refractory (ms)	93; 125; 157; 190–400 in steps of 30; 440; 4705
Paced AV Delay (ms)	25; 30–200 in steps of 10; 225–300 in steps of 25; 350
Base Rate (min^{-1})	30–130 in steps of 5; 140-170 in steps of 10
Far-Field Protection Interval (ms)	16[6]
Hysteresis Rate (min^{-1})	Off; 307–150 in steps of 5
Search Interval (min)	Off; 1; 5; 10; 15; 30
Cycle Count	1–16 in steps of 1
Intervention Rate (min^{-1})	Off; Same as Base Rate; 80-120 in steps of 10; Intrinsic +0; Intrinsic +10; Intrinsic +20; Intrinsic +30
Intervention Duration (min)	1–10 in 1 minute intervals
Recovery Time	Fast; Medium; Slow; Very Slow
Maximum Tracking Rate (min^{-1})	90–130 in steps of 5; 140–210 in steps of 10
Mode	AOO(R); AAI(R); AAT(R); VOO(R); VVI(R); VVT(R); VDD(R); DOO(R); DVI(R); DDI(R); DDD(R); Pacing Off
Post Ventricular Atrial Blanking (ms)	60–200 in steps of 10; 225; 250
PVARP (ms)	125–500 in steps of 25
Sensed AV Delay (ms)	25; 30–200 in steps of 10; 225–325 in steps of 25
Rest Rate (min^{-1})	Off; 30–150 in steps of 5
Rate Responsive AV Delay	Off; Low; Medium; High
Rate Responsive PVARP/VREF	Off; Low; Medium; High
Shortest AV Delay (ms)	25–50 in steps of 5; 60–120 in steps of 10
Shortest PVARP/VREF (ms)	125–475 in steps of 25
Ventricular Blanking (ms)	Auto, 12–52 in steps of 4
Ventricular Pace/Sense Refractory[8] (Fixed) (ms)	125; 160–400 in steps of 30; 440; 470; 5005
Output/Sensing	
ACap™ Confirm	On; Off; Monitor
Primary Pulse Configuration	Bipolar
Backup Pulse Configuration	Bipolar
Backup Pulse Amplitude (V)	5,0[6]
Search Interval (hours)	8; 24
A or V Pulse Amplitude (V)	0,25–4,0 in steps of 0,25; 4,5–7,5 in steps of 0,5
A or V Pulse Width (ms)	0,05; 0,1–1,5 in steps of 0,1
A or V Pulse Configuration	Unipolar (tip-case); Bipolar (tip-ring)
A or V Sense Configuration	Unipolar Tip (tip-case); Bipolar (tip-ring); Unipolar Ring (ring-case)
Ventricular AutoCapture™ Pacing System	On; Off
Primary Pulse Configuration	Unipolar; Bipolar
Backup Pulse Configuration	Unipolar; Bipolar
Backup Pulse Amplitude (V)	5,0[6]
Search Interval (hours)	8; 24
AutoCapture Paced/Sensed AV Delay (ms)	50/25; 100/70; 120/100
Atrial Sensitivity (mV)	0,1–0,49 in steps of 0,1; 0,5; 0,75–2,0 in steps of 0,25; 2,5–4,0 in steps of 0,5; 5,0[10]
Ventricular Sensitivity (mV)	0,5–5,0 in steps of 0,5; 6–10 in steps of 1,0; 12,5[10]
SenseAbility™ Technology	Off; On (Automatic Sensitivity Control adjustment for atrial and ventricular events)
A Max Sensitivity (mV)	0,2–1,0 in steps of 0,1
V Max Sensitivity (mV)	0,2–2,0 in steps of 0,1
Threshold Start	(Atrial and Ventricular Post-Sense) 50; 62,5; 75; 100% (Atrial Post-Pace) 0,2–3,0 in steps of 0,1 mV (Ventricular Post-Pace) Auto; 0,2–3,0 in steps of 0,1 mV
Decay Delay (ms)	(Atrial and Ventricular Post-Sense) 0; 30; 60; 95; 125; 160; 190; 220; (Atrial Post-Pace) 0; 30; 60; 95; 125; 160; 190; 220 (Ventricular Post-Pace) Auto; 0; 30; 60; 95; 125; 160; 190; 220
Rate-Modulated Parameters	
Maximum Sensor Rate (min^{-1})	80–150 in steps of 5; 160–180 in steps of 10
Reaction Time	Very Fast; Fast; Medium; Slow
Recovery Time	Fast; Medium; Slow; Very Slow
Sensor	On; Off; Passive
Slope	Auto (-1); Auto (+0); Auto (+1); Auto (+2); Auto (+3); 1-16 in steps of 1
Threshold	Auto (-0,5); Auto (+0,0); Auto (+0,5); Auto (+1,0); Auto (+1,5); Auto (+2,0); 1–7 in steps of 0,5
AF Management	
AF Suppression™ Algorithm	Off; On
Lower Rate Overdrive (min^{-1})	10[6]
Upper Rate Overdrive (min^{-1})	5[6]
No. of Overdrive Pacing Cycles	15–40 in steps of 5
Rate Recovery (ms)	8; 12[6]
Maximum AF Suppression Rate (min^{-1})	80–200 in steps of 10; 225–300 in steps of 25
Atrial Tachycardia Detection Rate (min^{-1})	110–200 in steps of 10; 225–300 in steps of 25
Auto Mode Switch	Off; DDD(R) to DDI(R); DDD(R) to DDT(R); DDD(R) to VVI(R); DDD(R) to VVT(R); VDD(R) to VVI(R); VDD(R) to VVT(R)
AMS Base Rate (min^{-1})	40–170 in steps of 5
Stored Electrograms	
Options	
Priority Options	Off; Low; High
Channel	1; 2; 3
Triggers	
Advanced Hysteresis	Off; Low; High
AMS Entry/AMS Exit/ AMS Entry and Exit	Off; Low; High
AT/AF Detection	Off; Low; High
Magnet Response	Off; Low; High
High Atrial Rate	Off; Low; High
Rate (min-1)	125–300 in steps of 25
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
High Ventricular Rate	Off; Low; High
Rate (min-1)	125–300 in steps of 25
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
PMT Termination	Off; Low; High
Consecutive PVCs	Off; Low; High
No. of Consecutive PVCs	2; 3; 4; 5
Noise Reversion	Off; Low; High
Other	
A and V Lead Monitoring	Monitor; Auto Polarity Switch
A and V Low Impedance Limit (Ω)	100–500 in steps of 25
A and V High Impedance Limit (Ω)	750–2500 in steps of 250; 3000
Lead Type	Uncoded; Unipolar; Bipolar
Magnet Response	Off; Battery Test
Negative AV Hysteresis Search (ms)	Off; -10 to -120 in steps of 10
NIPS Options	Atrial; Ventricular
Stimulation Chamber	100-800 in steps of 10[11]
Coupling Interval (ms)	2-25 in steps of 1
S1 Count	Off; 100–800 in steps of 10 (Fixed or Adaptive)
S1[12]; S2; S3 and S4 Cycle (ms)	Off; 30–95 in steps of 5
Ventricular Support Rate (min^{-1})	1; 2; 3; 4; 5
Sinus Node Recovery Delay (sec)	Off; Passive; Atrial Pace[5]
PMT Options	90–180 in steps of 5
PMT Detection Rate (min^{-1})	Off; Atrial Pace[5]
PVC Response	
Ventricular Intrinsic Preference, VIP™ (ms)	Off, 50–150 in steps of 25; 160–200 in steps of 10
VIP Search Interval	30 sec.; 1; 3; 5; 10; 30 min.
VIP Search Cycles	1; 2; 3
Ventricular Safety Standby	Off; On
Diagnostic Trends	AT/AF Activity; Exercise; Lead Impedance; P and R Wave; A and V Threshold
MRI Settings	
MRI Mode	AOO; VOO; DOO; Pacing Off
MRI Base Rate	30–120 bpm in steps of 5 bpm
MRI Paced AV Delay	25 ms; 30–120 ms in steps of 10 ms
MRI Pulse Configuration	Bipolar
MRI Pulse Amplitude	5,0 V; 7,5 V
MRI Pulse Width	1,0 ms

MRI Scan Parameters*

LEAD MODEL	MAGNET (TESLA)	SCANNER MODE	SCAN REGION
Tendril™ STS	1.5 T 3 T	Normal Operating Mode	Full-body
2088TC (lead lengths: 46 cm, 52 cm, 58 cm)			
IsoFlex™ Optim™			
1944 (lead lengths: 46 cm, 52 cm)			
1948 (lead lengths: 52 cm, 58 cm)			

*Refer to the MRI Ready Systems Manual for more detailed information.

1. A,V = 2,5 V @ 0,4 ms; 500 ohms; 100% DDD pacing @ 60 bpm; AutoCapture™ Pacing System OFF; SEGMs ON
2. Terms and conditions apply; refer to the warranty for details.
3. Healey, J., Connolly, S. J., Gold, M. R., Israel, C. W., Van Gelder, I. C., Capucci, A., . . . ASSERT Investigators. (2012). Subclinical atrial fibrillation and the risk of stroke: ASymptomatic atrial fibrillation and Stroke Evaluation in pacemaker patients and the AF Reduction atrial pacing Trial (ASSERT trial). *New England Journal of Medicine, 366*(2), 120-129..
4. ± 0,5 cc
5. Programming options dependent on pacing mode.
6. This parameter is not programmable.
7. The highest available setting for hysteresis rate will be 5 min^{-1} below the programmed base rate.
8. In dual-chamber modes, the maximum ventricular refractory period is 325 ms.
9. Values 0,1–0,4 not available in a unipolar sense configuration.
10. Sensitivity is with respect to a 20 ms haversine test signal.
11. During atrial NIPS in dual-chamber modes, the shortest Coupling Interval will be limited by the programmed AV/PV delay.
12. S1 Burst Cycle is applied at the preprogrammed S1 cycle length.

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St. Jude Medical is now Abbott.

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

29068-EM-END-1016-0013(4) | Information contained herein intended for audiences from outside the United States only.

Abbott

Allure™ RF

Cardiac Resynchronization Therapy Pacemaker

Merlin@home™ Transmitter Compatible

Product Highlights

- Angled header and physiologic tear drop shape provide better lead wrap
- CorVue™ Congestion Monitoring feature monitors the intrathoracic impedance and provides the option for both patient and physician alerts
- The DirectTrend™ Report provides a summary of three month daily, one year weekly or one year daily diagnostic trends
- Better patient utilization from day one when paired with the Merlin@home™ transmitter at point of care[1]
- AT/AF Alerts can be programmed to notify clinics when a programmed AT/AF threshold or continuous episode duration has been exceeded, or when a high ventricular rate accompanies the AT/AF episode
- Exclusive AF Suppression™ algorithm is clinically proven to suppress episodes of paroxysmal and persistent AF
- AT/AF burden trend provides a graphical representation of the percentage of time in AT/AF and the number of AT/AF episodes in the previous 52 weeks
- Up to 14 minutes of stored electrograms help identify key intrinsic and pacemaker-related events and simplify the diagnosis of complex ECG rhythms associated with heart failure
- Industry-leading longevity offers eight years of service life supported by a six-year warranty*

Ordering Information

Contents: Cardiac Pulse Generator

MODEL NUMBER	DIMENSIONS (H × W × T, MM)	WEIGHT (G)	VOLUME (CC)	CONNECTOR
PM3222	55 × 59 × 6	24	14	IS-1

1. Ren X et al. Patient adherence in remote follow-up of cardiovascular implantable electronic devices. *J Am Coll Cardiol.* 2012;59:E645, doi: 10.1016/S0735-10097(12)60646-9.

*Longevity calculated based on the following settings: 2,5V @ 0,4 ms (RA/RV/LV), 500 ohms, DDD, 60 BPM, 100% Bi-V Pacing, 100% Atrial Pacing and Stored EGMS on

Indications: Implantation of a CRT-P is indicated in one or more of the following permanent conditions: syncope, presyncope, fatigue, disorientation due to arrhythmia/bradycardia, or any combinations of those symptoms. Implantation of a CRT-P is indicated for patients who would benefit from resynchronization of the right and left ventricles of have one or more conventional indications for the implantation of a pacemaker. ***Rate-Modulated Pacing*** is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity. ***Dual-Chamber Pacing*** is indicated for those patients exhibiting: sick sinus syndrome, chronic, symptomatic second- and third-degree AV block, recurrent Adams-Stokes syndrome, symptomatic bilateral bundle branch block when tachyarrhythmia and other causes have been ruled out. ***Atrial Pacing*** is indicated for patients with sinus node dysfunction and normal AV and intraventricular conduction systems. ***Ventricular Pacing*** is indicated for patients with significant bradycardia and normal sinus rhythm with only rare episodes of A-V block or sinus arrest, chronic atrial fibrillation, severe physical disability. ***AF Suppression*** algorithm is indicated for suppression of paroxysmal or persistent atrial fibrillation episodes in patients with one or more of the above pacing indications.

Contraindications: Implanted Cardioverter-Defibrillator (ICD). Devices are contraindicated in patients with an implanted cardioverter-defibrillator. Rate-Adaptive Pacing may be inappropriate for patients who experience angina or other symptoms of myocardial dysfunction at higher sensor-driven rates. An appropriate Maximum Sensor Rate should be selected based on assessment of the highest stimulation rate tolerated by the patient. AF Suppression™ stimulation is not recommended in patients who cannot tolerate high atrial-rate stimulation. ***Dual-Chamber Pacing***, though not contraindicated for patients with chronic atrial flutter, chronic atrial fibrillation, or silent atria, may provide no benefit beyond that of single-chamber pacing in such patients. ***Single-Chamber Ventricular Demand Pacing*** is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction or suffer a drop in arterial blood pressure with the onset of ventricular pacing. ***Single-Chamber Atrial Pacing*** is relatively contraindicated in patients who have demonstrated compromise of AV conduction. ***Atrial Fibrillation.*** Allure™ devices are contraindicated in patients having chronic atrial fibrillation or intermittent atrial fibrillation that does not terminate. For specific contraindications associated with individual modes, refer to the programmer's on-screen help.

Potential Adverse Events: The following are potential complications associated with the use of any pacing system: air embolism, body rejection phenomena, cardiac tamponade or perforation, hematoma, bleeding hematoma, seroma, formation of fibrotic tissue, local tissue reaction, inability to interrogate or program due to programmer or device malfunction, infection/erosion, interruption of desired pulse generator function due to electrical interference, either electromyogenic or electromagnetic, lead malfunction due to conductor fracture or insulation degradation, loss of capture or sensing due to lead dislodgement or reaction at the electrode/tissue interface, loss of desired pacing and/or sensing due to lead displacement, body reaction at electrode interface, or lead malfunction (fracture or damage to insulation), loss of normal device function due to battery failure or component malfunction, pacemaker migration or pocket erosion, pectoral muscle or diaphragmatic stimulation, phrenic nerve stimulation, pneumothorax/hemothorax, endocarditis, excessive bleeding, induced atrial or ventricular arrhythmias, myocardial irritability, pericardial effusion, pericardial rub, pulmonary edema, rise in threshold and exit block, valve damage, cardiac/coronary sinus dissection, cardiac/coronary sinus perforation, coronary sinus or cardiac vein thrombosis.

Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

Allure™ RF

Cardiac Resynchronization Therapy Pacemaker

Product Specifications

PHYSICAL SPECIFICATIONS

Models	PM3222
Telemetry	RF
Dimensions (mm)	55 x 59 x 6
Weight (g)	24
Volume (cc)[1]	14
Connector	IS-1

PARAMETER	SETTINGS
Resynchronization Therapy	
QuickOpt™ Timing Cycle Optimization	Sensed/Paced AV Delay; Interventricular Paced Delay
RV and LV Pulse Width (ms)	0,05; 0,1–1,5 in steps of 0,1
RV and LV Pulse Amplitude (V)	0,25–4,0 in steps of 0,25; 4,5–7,5 in steps of 0,5
RV Pulse Configuration	Unipolar; Bipolar
LV Pulse Configuration	Unipolar; Bipolar; LV Tip–RV Ring; LV Ring–RV Ring
Ventricular Sense Configuration	BV Unipolar Tip; BV Bipolar; RV Unipolar Tip; RV Bipolar; Distal Tip 1–Mid 2; Distal Tip 1–Can; and Distal Tip 1–RV Tip
First Chamber Paced	Simultaneous[2]; RV; LV
SyncAV™ CRT Delta	Off; -10 to -120 in steps of 10
Shortest AV/PV Delay (ms)	25–50 in steps of 5; 60–120 in steps of 10
Output/Sensing	
Atrial ACap™ Confirm	On; Off; Monitor
Primary Pulse Confirmation	Bipolar
Backup Pulse Confirmation	Bipolar
Backup Pulse Amplitude (V)	5,0
Searchable Intervals (hrs)	8; 24
Atrial Pulse Configuration	Unipolar (tip–case); Bipolar (tip–ring)
Atrial Sense Configuration	Unipolar Tip (tip–case); Bipolar (tip–ring); Unipolar Ring (ring–case)
Atrial Sensitivity[3,4] (Fixed) (mV)	0,1–0,5 in steps of 0,1; 0,75–2,0 in steps of 0,25; 2,5–5,0 in steps of 0,5
Atrial Pulse Amplitude (V)	0,25–4,0 in steps of 0,25; 4,5–7,5 in steps of 0,5
Atrial Pulse Width (ms)	0,05; 0,1–1,5 in steps of 0,1
RVCap™ Confirm	On; Off; Monitor
Searchable Interval (hrs)	8; 24
LVCap™ Confirm	On; Off; Monitor
Searchable Interval (hrs)	8; 24
Sense*Ability*™ Technology	Off; On (Automatic Sensitivity Control adjustment for atrial and ventricular events)
A Max Sensitivity (mV)	0,2–1,0 in steps of 0,1
V Max Sensitivity (mV)	0,2–2,0 in steps of 0,1
Threshold Start	(Atrial and Ventricular Post-Sense) 50; 62,5; 75; 100% (Atrial Post-Pace) 0,2–3,0 in steps of 0,1 mV (Ventricular Post-Pace) Auto; 0,2–3,0 in steps of 0,1 mV
Decay Delay (ms)	(Atrial and Ventricular Post-Sense) 0; 30; 60; 95; 125; 160; 190; 220 (Atrial Post-Pace) 0; 30; 60; 95; 125; 160; 190; 220 (Ventricular Post-Pace) Auto; 0; 30; 60; 95; 125; 160; 190; 220
Ventricular Sensitivity (fixed) (mV)	0,5–12,5 in steps of 0,5[3,4]
Rate/Timing	
Mode	A00(R); AAI(R); AAT(R); VOO(R); VVI(R); VVT(R); DOO(R); DVI(R); DDI(R); DDT(R); DDD(R); VDD(R); Pacing Off
DDT Trigger[5]	R wave
DDT Timing[5]	DDI
Base Rate (min^{-1})	30–130 in steps of 5; 140–170 in steps of 10
Hysteresis Rate (min^{-1})	Off; 30–150 in steps of 5[6]
Search Interval (min)	Off; 1; 5; 10; 15; 30
Cycle Count	1–16
Intervention Rate (min^{-1})	Off; Same Base Rate; 80–120 in steps of 10 (Intrinsic +0; Intrinsic +10; Intrinsic +20; Intrinsic +30)
Intervention Duration (min^{-1})	1–10
Recovery Time	Fast; Medium; Slow; Very Slow
Rest Rate (min^{-1})	Off; 30–150 in steps of 5
Maximum Tracking Rate (min^{-1})	90–130 in steps of 5; 140–180 in steps of 10
Sensed AV Delay (ms)	25; 30–200 in steps of 10; 225–325 in steps of 25
Paced AV Delay (ms)	25; 30–200 in steps of 10; 225–300 in steps of 25; 350
Ventricular Pace/Sense Refractory[7] (Fixed) (ms)	125; 160–400 in steps of 30; 440; 470[8]
Atrial Pace Refractory	190–400 in steps of 30; 440; 470[8]
Atrial Sense Refractory	93; 125; 157; 190–400 in steps of 30; 440; 470[8]
PVARP (ms)	125–500 in steps of 25
Atrial Protection Interval (ms)[5]	125
Far-Field Protection Interval (ms)[5]	16
Rate-Modulated Parameters	
Rate Responsive AV/PV Delay	Off; Low; Medium; High
Rate Responsive PVARP/VREF	Off; Low; Medium; High
Shortest PVARP/VREF	125–475 in steps of 25
Sensor	On; Off; Passive
Max Sensor Rate (min^{-1})	80–150 in steps of 5; 160–180 in steps of 10
Threshold	Auto (-0,5); Auto (+0,0); Auto (+0,5); Auto (+1,0); Auto (+1,5); Auto +(2,0); 1–7 in steps of 0,5
Slope	Auto (-1); Auto (+0); Auto (+1); Auto (+2); Auto (+3); 1–16
Reaction Time	Very Fast; Fast; Medium; Slow
Recovery Time	Fast; Medium; Slow; Very Slow

AF Management	
AF Suppression™ Algorithm	Off; On
Lower Rate Overdrive (min^{-1})[5]	10
Upper Rate Overdrive (min^{-1})[5]	5
No. of Overdrive Pacing Cycles	15–40 in steps of 5
Rate Recovery (ms)	8; 12
Auto Mode Switch	Off; DDD(R) to DDI(R); DDD(R) to DDT(R); DDD(R) to VVI(R); DDD(R) to VVT(R); VDD(R) to VVI(R); VDD(R) to VVT(R)
AMS Base Rate (min^{-1})	40–170 in steps of 5
Stored Electrograms	
Options	
Priority Options	Off; Low; High
Channel	1; 2; 3
Triggers	
Advanced Hysteresis	Off; Low; High
AMS Entry/AMS Exit/ AMS Entry and Exit	Off; Low; High
AT/AF Detection	Off; Low; High
Magnet Response	Off; Low; High
High Atrial Rate	Off; Low; High
Rate (min^{-1})	125–300 in steps of 25
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
High Ventricular Rate	Off; Low; High
Rate (min^{-1})	125–300 in steps of 25
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
PMT Termination	Off; Low; High
Consecutive PVCs	Off; Low; High
No. of Consecutive PVCs	2; 3; 4; 5
Noise Reversion	Off; Low; High
Other	
Magnet Response	Off; Battery Test
Ventricular Intrinsic Preference, VIP™ (ms)	Off; 50–150 in steps of 25; 160–200 in steps of 10
VIP Search Interval	30 sec.; 1; 3; 5; 10; 30 min.
VIP Search Cycles	1; 2; 3
Atrial Tachycardia Detection Rate (min^{-1})	110–200 in steps of 10; 225–300 in steps of 25
Post Vent. Atrial Blanking PVAB (ms)	60–200 in steps of 10; 225; 250
Ventricular Safety Standby	Off; On
PVC Response	Off; Atrial Pace[8]
PMT Options	Off; Passive; Atrial Pace[8]
PMT Detection Rate (min^{-1})	90–180 in steps of 5
Lead Type	Uncoded; Unipolar; Bipolar
NIPS Options	
Stimulation Chamber	Atrial; Right Ventricular
Coupling Interval[9] *(ms)*	200–800 in steps of 10
S1 Count	2–25 in steps of 1
S1[10]*; S2; S3 and S4 Cycle (ms)*	Off; 100–800 in steps of 10 (Fixed or Adaptive)
Right Ventricular Support Rate (min^{-1})	Off; 30–95 in steps of 5
Sinus Node Recovery Delay (s)	1–5 in steps of 1
Diagnostic Trends	AT/AF Activity; Exercise; Lead Impedance; P and R Wave; A and V threshold; CorVue™ Congestion Monitoring
CorVue™ Congestion Monitoring	Off; On
CorVue Congestion Trigger	8–18 days
Patient Notifiers	
Programmable Notifiers (On; Off)	Device at ERI; Atrial Lead Impedance Out of Range; Ventricular Lead Impedance Out of Range; LV Lead ImpedanceOut of Range; AT/AF Burden; AT/AF Episode Duration; High V Rate During AT/AF; High V Rate; Percent BiV/RV Pacing Alert; CorVue Alert
Device Reset	On
Entry into Backup VVI Mode	On
Audible Duration (sec)	2; 4; 6; 8; 10; 12; 14; 16
Number of Audible Alerts per Notification	2
Number of Notifications	1–16
Time Between Notifications (hours)	10; 22

1. ± 0.5 cc
2. LV first with 10 ms interventricular delay.
3. Sensitivity is with respect to a 20 ms haversine test signal.
4. Values 0,1–0,4 not available in a Unipolar Sense Configuration.
5. This parameter is not programmable.
6. The highest available setting for hysteresis rate is 5 min^{-1} below the programmed base rate.
7. In dual-chamber modes, the maximum Ventricular Refractory Period is 325 ms.
8. Programming options dependent on pacing mode.
9. During atrial NIPS in dual-chamber modes, the shortest Coupling Interval will be limited by the programmed AV/PV Delay.
10. S1 Burst Cycle is applied at the preprogrammed S1 cycle length.

Customer Support: 46-8-474-4147
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St. Jude Medical is now Abbott.

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use. Devices depicted may not be available in all countries. Check with your Abbott representative for product availability in your country.

28347-EM-ALLU-0618-0005 | Item approved for international use only. Not for distribution in Canada.

Abbott

Neutrino™ NxT

Cardiac Resynchronization Therapy
Defibrillator (CRT-D)
CDHFA600Q

MR Compatible with myMerlinPulse™ App

Product Highlights

- Bluetooth® Low Energy (LE) communication enabling smartphone connectivity through data encryption
- MultiPoint™ pacing delivers multiple LV pacing pulses per cardiac cycle in both LV only and BiV pacing modes
- SyncAV™ *Plus* CRT technology offers dynamic AV timing with adaptive programming to ensure BiV pacing with or without MultiPoint pacing
- Improved shape with reduced volume and thickness
- 40J delivered energy safety shock option for enhanced safety margin
- DeFT Response™ technology offers noninvasive programming options to optimize rescue therapy to each patient's unique physiology and changing conditions
- VF Therapy Assurance decreases time to treatment for arrhythmias in patients who are likely to be hemodynamically unstable
- Antitachycardia pacing (ATP) while charging and prior to charging in the VF zone further extends the programming options for terminating tachyarrhythmias without a high-voltage shock
- ShockGuard™ technology with DecisionTx™ programming designed to reduce inappropriate therapy and minimize the need for programming adjustments at implant
  - SecureSense™ RV lead noise discrimination algorithm detects sustained lead noise and short bursts of oversensing that would otherwise go unnoticed or potentially lead to one or more inappropriate shocks
  - Far Field MD™ morphology discrimination and chamber onset discrimination enhances SVT and VT discrimination for reduced inappropriate therapies
- Sense*Ability*™ sensing algorithm feature provides the flexibility to fine-tune programming around T-wave oversensing without decreasing sensitivity
- The Neutrino™ NxT HF CRT-D and Quartet™ quadripolar LV lead feature four pacing electrodes and 13 pacing vectors to provide more options and greater control to address implant complications such as diaphragmatic stimulation and high pacing thresholds
- Easily test and program with Auto VectSelect Quartet™ multivector testing, offering an efficient workflow for complete results and programming
- DynamicTx™ over-current detection algorithm automatically changes shock configurations to ensure delivery of high-voltage therapy when high current is detected
- MRI Ready device tested in combination with MR Conditional leads for full-body scans using a 1,5T or 3T (Tesla) field strength MRI Scanner*
- New battery provides higher capacity than previous QHR‡ batteries to offer superior longevity/volume ratio
- DF4 connector designed to streamline defibrillation connections into a single terminal pin and reduce the number of set screws
- The CorVue™ congestion monitoring feature measures transthoracic impedance changes over time to provide additional insight into the patient's heart failure condition
- Cold can programmability provides an additional RV-SVC shock configuration to decouple the can from the shocking vector parameters in cases of lead problems
- Premature Atrial Contraction (PAC) Response to avoid pacing the atrium in a vulnerable zone
- Physiologic rate responsive AV Delay and PVARP
- QuickOpt™ timing cycle optimization provides quick and effective optimization at the push of a button
- Dual patient notification: audio notification through the device and visual notification via myMerlinPulse™ app

Ordering Information

MODEL NUMBER	DIMENSIONS (H × W × T, MM)	WEIGHT (G)	VOLUME (CC)	CONNECTOR
CDHFA600Q	74 × 51 × 12	76	34	DF-4, IS-4, IS-1

*See MRI Scan Parameters in MRI Ready Systems Manual.

Abbott

Neutrino™ NxT

Cardiac Resynchronization Therapy Defibrillator (CRT-D)
CDHFA600Q

Product Specifications

PHYSICAL SPECIFICATIONS

Model	CDHFA600Q
Telemetry	Bluetooth® LE Communication
Delivered/Stored Energy	40/45 J
Volume	34 cc
Weight	76 g
Size	74 × 51 × 12 mm
Defibrillation Lead Connections	DF4-LLHH
LV Lead Connections	IS4-LLLL
Atrial Sense/Pace Lead Connections	IS-1
High Voltage Can	Electrically active titanium can

PARAMETER	SETTINGS
Biventricular Pacing	
VectSelect Quartet™ Programmable LV Pulse Configuration	Distal Tip 1 - Mid 2; Distal Tip 1 - Proximal 4; Distal Tip 1 - Mid 3; Distal Tip 1 - RV Coil; Mid 2 - Mid 3; Mid 2 - Proximal 4; Mid 2 - RV Coil; Mid 3 - Mid 2; Mid 3 - Proximal 4; Mid 3 - RV Coil; Proximal 4 - Mid 2; Proximal 4 - Mid 3: Proximal 4 - RV Coil
MultiPoint™ Pacing	LV1, LV2
Delay MultiPoint Pacing	Delay 1: 5; 10; ... 80 ms Delay 2: 5; 10; ... 50 ms
V. Triggering	On; Off
QuickOpt™ Timing Cycle Optimization	Sensed/Paced AV delay, Interventricular pace delay
V-V Timing	Simultaneous†; RV First; LV First
Interventricular Pace Delay	RV First 10–80/LV First 15–80 ms
Ventricular Sensing	RV only (not programmable)
Ventricular Pacing Chamber	RV only; LV only; Biventricular
SyncAV™ *Plus* CRT Technology Delta	If Type = Percentage: -10; - 15;...-70% If Type = Fixed: -10; -20;...-120 ms; Off
MPP PVAB	125–260 ms
AF Management	
AF Suppression™ Pacing	On; Off
No. of Overdrive Pacing Cycles	15–40
Maximum AF Suppression Rate	80–150 min^{-1}
Sensing/Detection	
Sense*Ability*™ Sensing Algorithm	Automatic sensitivity control adjustment for atrial and ventricular events
Low Frequency Attenuation	On; Off
Threshold Start	Post-Sensed: 50; 62,5; 75; 100%; Post-Paced, Atrial: 0,2-3,0 mV Post-Paced, Ventricular: Auto, 0,2-3,0 mV
Decay Delay	Post-Sensed: 0–220 ms Post-Paced, Atrial: 0-220 ms Post-Paced, Ventricular: Auto, 0-220 ms
Ventricular Sense Refractory	125; 157 ms
Detection Zones	3 zone programming — 1 zone; 2 zones or 3 zones (VT-1; VT-2; VF)
SVT Discriminators	AV Rate Branch; Arrhythmia Onset (Chamber Onset or Sudden Onset); Interval Stability; AV Association Morphology; Discrimination (Far Field MD™ Morphology Discrimination or Original MD) with Automatic Template Update
Monitor Mode	Detection, discrimination and diagnostics, no therapy delivery (VT or VT-1 zone)
Discrimination Modes	On; Passive; Off
SVT Upper Limit	150–240 min^{-1}
SVT Discrimination Timeout	20s - 60 min; Off
Reconfirmation	Continuous sensing during charging
SecureSense™ RV Lead Noise Discrimination Algorithm	On; On with Timeout; Passive; Off
VF Therapy Assurance	On; Off
Antitachycardia Pacing Therapy	
ATP Configurations	Ramp; Burst; Scan; 1 or 2 schemes per VT zone
ATP in VF Zone	ATP While Charging; ATP Prior to Charging; Off
ATP Upper Rate Cutoff	150–300 min^{-1}
Burst Cycle Length	Adaptive (50%-100%); Fixed (200-550 ms)
Min. Burst Cycle Length	150–400 in increments of 5 ms
Readaptive	On; Off
Number of Bursts/Stimuli	1–15 with 2–20 Stimuli
Add Stimuli per Burst	On; Off
ATP Pulse Amplitude	7,5 V independent from Bradycardia and Post-Therapy Pacing
ATP Pulse Width	1,0 or 1,5 ms independently programmable from Bradycardia and Post-Therapy Pacing
High-Voltage Therapy	
DynamicTx™ Over-Current Detection Algorithm	On: Off
DeFT Response™ Technology	Programmable pulse width for P1/P2 and tilt
High-Voltage Output Mode	Fixed Pulse Width; Fixed Tilt
Waveform	Biphasic; Monophasic
RV Polarity	Cathode (-); Anode (+)
Electrode Configuration	RV to Can; RV to SVC/Can; RV to SVC
Bradycardia Pacing	
Permanent Modes	DDD(R); DDT(R); DDI(R); VVT(R); VVI(R); AAI(R); Off
Temporary Modes	DDD; DDT; DDI; VVT; VVI; AAI; AAT; DOO; VOO; AOO; Off
Activity Sensor	On; Passive; Off
Programmable Rate and Delay Parameters	Base Rate (min^{-1}); Rest Rate (min^{-1}); Maximum Tracking Rate (min^{-1}); Max Trigger Rate (min^{-1}); Maximum Sensor Rate (min^{-1}); Paced AV Delay (ms); Sensed AV Delay (ms); Rate Responsive AV Delay; Hysteresis Rate (min^{-1}); Rate Hysteresis with Search
Pulse Amplitude	0,25 - 7,5 V
Pulse Width	0,05, 0,1 - 1,5 ms
LVCap™ 1 Confirm Feature, LVCap™ 2 Confirm Feature	Setup; On; Monitor; Off
RVCap™ Confirm Feature	Setup; On; Monitor; Off
ACap™ Confirm Feature	On; Monitor; Off
Auto Mode Switch (AMS)	DDI(R); DDT(R); VVI(R); VVT(R); Off
Atrial Tachycardia Detection Rate	110–300 min^{-1}
AMS Base Rate	40; 45; ... 135 min^{-1}
PMT Detection/Termination	Atrial Pace; Passive; Off
Rate Responsive PVARP	Low; Medium; High; Off
Rate Responsive V Pace Refractory	On; Off
PAC Response	On; Off
PAC Response interval	200-400 ms
Shortest AV Delay	25–120 ms
Post-Therapy Pacing (Independently Programmable from Bradycardia and ATP)	
Post-Shock Pacing Mode	AAI; VVI; DDI; or DDD; Off
Post-Shock Base Rate	30–100 min^{-1}
Post-Shock Pacing Duration	0,5; 1; 2,5; 5; 7,5; or 10 min; Off
Device Testing/Induction Methods	
DC Fibber™ Induction Method Pulse Duration	0,5–5,0 sec
Burst Fibber Cycle Length	20–100 ms
Noninvasive Programmed Stimulation (NIPS)	2–25 stimuli with up to three extra stimuli
Patient Notifiers	
Programmable Notifiers (On; Off)	BatteryAssurance™ alert, Possible HV circuit damage, HV charge timeout, Long charge time for Capacitor Maintenance, Device at ERI, Atrial lead impedance out of range, Right ventricular pacing lead impedance out of range, Left ventricular lead impedance out of range, High-voltage lead impedance out of range, AT/AF episode duration, AT/AF Burden, High ventricular rate during AT/AF, SecureSense™ lead noise detection, Non-sustained ventricular oversensing, Biventricular/Left ventricular pacing percentage lower than limit, CorVue™ congestion monitoring
Device Parameter Reset	On
Entry into Backup VVI Mode	On
Auditory Duration	2; 4; 6; 8; 10; 12; 14; 16 sec
Number of Audio Alerts per Notification	2
Number of Notifications	1–16
Time Between Notifications	10; 22 hours
Electrograms and Diagnostics	
Stored Electrograms	30 minutes (2 user programmable + discrimination channel), up to one minute programmable pre-trigger data per VT/VF electrograms; additional triggers include lead noise detection, non-sustained ventricular oversensing, morphology template updates, atrial episode, PMT termination, PAC response, magnet reversion, noise reversion
Therapy Summary	Diagram of therapies delivered
Episodes Summary	Directory listing of up to 60 episodes with access to more details including stored electrograms
Lifetime Diagnostics	History of bradycardia events and device-initiated charging
AT/AF Burden Trend	Trend data and counts
Ventricular HV Lead Impedance Trend	Multi-Vector Trend Data
Histograms and Trends	Event Histogram; AV Interval Histogram; Mode Switch or AT/AF Duration Histogram; Peak Filtered Atrial Rate during Atrial Arrhythmia Histogram; Atrial Heart Rate Histogram; Ventricular Heart Rate Histogram; AT/AF Burden; Exercise and Activity Trending; V Rates during AMS; DirectTrend™ reports up to 1 year
PMT Data	Information regarding PMT detections
Real-Time Measurements (RTM)	Pacing lead impedances; high-voltage lead impedances; and signal amplitudes
CorVue Congestion Monitoring	On; Off
CorVue Congestion Monitoring Threshold	8–18 days

MRI Settings	Setting
Tachy Therapy	Disabled
MRI Mode	DOO; VOO; AOO; Pacing Off
MRI Base Rate	30–100 min^{-1}
MRI Paced AV Delay	25–110 ms
MRI RA and RV Pulse Amplitude	5,0 or 7,5 V
MRI RA and RV Pulse Width	1,0 ms
MRI RA and RV Pulse Configuration	Bipolar
MRI LV Pulse Amplitude	0,25-7,5 V
MRI LV Pulse Width	0,05-1,5 ms
MRI LV Pulse Configuration	D1-M2, D1-M3, D1-P4, M2-M3, M2-P4, M3-M2, M3-P4, P4-M2, P4-M3
MRI V Pacing Chamber	RV Only, LV+RV (Simultaneous)
MRI Timeout	3; 6; 9; 12; 24 hours; Off

MRI Scan Parameters§

LEAD MODEL	LEAD LENGTHS	MAGNET (TESLA)	RF TRANSMIT CONDITIONS	SCAN REGION
Quartet™ LV Lead 1456Q, 1457Q, 1458Q, 1458QL	86 cm	1,5T / 3T	Normal Operating Mode	Full-body
Durata™ Defibrillation Lead 7120Q, 7122Q	58, 65 cm	1,5T / 3T		
Optisure™ Lead LDA220Q, LDA210Q	58, 65 cm	1,5T / 3T		
Tendril™ STS Pacing Lead 2088TC	46, 52 cm	1,5T / 3T		
Tendril MRI™ Lead LPA1200M	46, 52 cm	1,5T		

†LV first with 10 ms interventricular delay.

§ For additional information about specific MR Conditional CRT-Ds and leads, including scan parameters, warnings, precautions, adverse conditions to MRI scanning, and potential adverse events, please refer to the Abbott MRI Ready Systems Manual at medical.abbott/manuals.

Brief Summary: This product is intended for use by or under the direction of a Physician. Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Customer Support: 46-8-474-4756

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Abbott

Quadra Assura™

Cardiac Resynchronization Therapy Defibrillator (CRT-D)

MR

Merlin@home™ Transmitter Compatible

Product Highlights

- MRI ready device has been tested for safe performance of an MRI scan using a 1,5 T (Tesla) field-strength MRI scanner when used in combination with MR Conditional leads[1,2]
- The Quadra Assura CRT-D and Quartet™ quadripolar LV pacing lead feature four pacing electrodes and 10 pacing vectors to provide more options and greater control to minimise implant complications such as diaphragmatic stimulation and high pacing thresholds
- Elevate response easily with Auto VectSelect Quartet™ test offering an efficient workflow for complete results and programming at the touch of a button
- SyncAV™ CRT technology dynamically adjusts AV delays based on patient's intrinsic conduction to encourage patient-tailored biventricular pacing
- DynamicTx™ over-current detection algorithm automatically changes shock configurations to ensure delivery of high voltage therapy when high current is detected
- Parylene coating for improved abrasion resistance
- Cold can programmability provides an additional RV-SVC Shock Configuration to decouple the can from the shocking vector parameters in cases of lead problems
- ShockGuard™ technology with DecisionTx™ programming designed to reduce inappropriate therapy and minimise the need for programming adjustments at implant
  - SecureSense™ RV lead noise discrimination detects sustained and short bursts of lead noise that would otherwise go unnoticed or potentially lead to one or more inappropriate shocks
  - Far Field MD™ morphology discrimination and Chamber Onset discrimination improve SVT and VT discrimination for reduced inappropriate therapies
- Antitachycardia pacing (ATP) while charging and prior to charging in the VF zone further extends the programming options for terminating tachyarrhythmias without a high-voltage shock
- Low frequency attenuation filter designed to enhance sensing performance and may reduce the possibility of oversensing T-waves
- Sense*Ability*™ feature provides flexibility to fine-tune programming around T-wave oversensing without decreasing sensitivity
- DF4 connector designed to streamline defibrillation connections into a single terminal pin and reduce the number of set screws
- Unique 40 J delivered energy safety shock option can provide a greater DFT safety margin
- DeFT Response™ technology offers the most noninvasive options for managing high DFTs
- QHR‡ chemistry battery provides greater capacity for enhanced longevity and improved charge time performance compared to previous SVO batteries
- Vibratory patient notifier enables patients with hearing problems to be alerted to a low battery, lead-related complications and more
- CorVue™ congestion monitoring feature monitors the intrathoracic impedance in multiple vectors for improved accuracy, and it provides the option for both patient and physician alerts
- QuickOpt™ timing cycle optimisation provides quick and effective optimisation at the push of a button

Ordering Information

MODEL NUMBER	DIMENSIONS (H x W x T, MM)	WEIGHT (G)	VOLUME (CC)	CONNECTOR
CD3367-40QC	75 x 41 x 14	80	38	DF-4, IS4, IS-1

Indications: The devices are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. Cardiac Resynchronisation Therapy Defibrillators (CRT-Ds) are also intended to resynchronise the right and left ventricles in patients with congestive heart failure.

Contraindications: Contraindications for use of the pulse generator system include ventricular tachyarrhythmias resulting from transient or correctable factors such as drug toxicity, electrolyte imbalance, or acute myocardial infarction.

Adverse Events: Implantation of the pulse generator system, like that of any other device, involves risks, some possibly life-threatening. These include but are not limited to the following: acute hemorrhage/bleeding, air emboli, arrhythmia acceleration, cardiac or venous perforation, cardiogenic shock, cyst formation, erosion, exacerbation of heart failure, extrusion, fibrotic tissue growth, fluid accumulation, hematoma formation, histotoxic reactions, infection, keloid formation, myocardial irritability, nerve damage, pneumothorax, thromboemboli, venous occlusion. Other possible adverse effects include mortality due to: component failure, device-programmer communication failure, lead abrasion, lead dislodgment or poor lead placement, lead fracture, inability to defibrillate, inhibited therapy for a ventricular tachycardia, interruption of function due to electrical or magnetic interference, shunting of energy from defibrillation paddles, system failure due to ionising radiation. Other possible adverse effects include mortality due to inappropriate delivery of therapy caused by: multiple counting of cardiac events including T waves, P waves, or supplemental pacemaker stimuli. Among the psychological effects of device implantation are imagined pulsing, dependency, fear of inappropriate pulsing, and fear of losing pulse capability.

Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

Quadra Assura™

Cardiac Resynchronization Therapy Defibrillator (CRT-D)

Product Specifications

PHYSICAL SPECIFICATIONS

Models	CD3367-40QC
Telemetry	RF
Delivered/Stored Energy (J)	40/45
Volume (cc)	38
Weight (g)	80
Size (mm)	75 × 41 × 14
Defibrillation Lead Connections	DF4-LLHH
LV Lead Connections	IS4-LLLL
Sense/Pace Lead Connections	IS-1
High-Voltage Can	Electrically active titanium can
MR Conditional	Yes, MRI Ready

PARAMETER	SETTINGS
Biventricular Pacing	
VectSelect Quartet™ LV	Distal Tip 1 - Mid 2, Distal Tip 1 - Proximal 4, Distal Tip 1 - RV Coil; Pulse Configuration Mid 2 - Proximal 4; Mid 2 - RV Coil; Mid 3 - Mid 2; Mid 3 - Proximal 4; Mid 3 - RV Coil; Proximal 4 - Mid 2; Proximal 4 - RV Coil
V. Triggering	On; Off
QuickOpt™ Timing Cycle Optimization	Sensed/paced AV delay, interventricular pace delay
V-V Timing	Simultaneous[3]; RV First; LV First
Interventricular Pace Delay (ms)	RV First 10–80 / LV First 15–80 in increments of 5
Ventricular Sensing	RV only (not programmable)
Ventricular Pacing Chamber	RV only; biventricular
SyncAV™ CRT Delta	Off; -10 to -120
Shortest AV Delay (ms)	25–120
AF Management	
AF Suppression™ Pacing algorithm	On; Off
No. of Overdrive Pacing Cycles	15–40 in steps of 5
Maximum AF Suppression Rate	80–150 min^{-1}
Sensing/Detection	
Sense*Ability*™ Technology	Automatic Sensitivity Control adjustment for atrial and ventricular events
Low Frequency Attenuation	On; Off
Sense Filter	(Post-Sensed; Atrial) 50; 62,5; 75; 100%; (Post-Paced; Atrial) 0,2–3,0 mV; Threshold Start (Post-Sensed; Ventricular) 50; 62,5; 75; 100%; (Post-Paced; Ventricular) Auto; 0,2–3,0 mV
Decay Delay	(Post-Sensed/Post-Paced; Atrial/Ventricular) 0–220
Ventricular Sense Refractory (ms)	125; 157
Detection Zones	3 zone programming - 1 zone, 2 zones or 3 zones (VT-1, VT-2, VF)
SVT Discriminators	AV Rate Branch; Arrhythmia Onset (Chamber Onset or Sudden Onset); Interval Stability; AV Association; Morphology Discrimination (Far Field MD™ or Original MD) with Manual (original MD only) or Automatic Template Update
Monitor Mode	Detection, discrimination and diagnostics, no therapy delivery (VT or VT-1 zone)
Discrimination Modes	On; Passive; Off
SVT Threshold	150–240 min^{-1}
SVT Timeout	0; 25–5 min
Reconfirmation	Continuous sensing during charging
Lead Noise Discrimination	SecureSense™ RV lead noise discrimination (On; On with Timeout; Passive; Off)
Antitachycardia Pacing Therapy	
ATP Configurations	Ramp; Burst; Scan; 1 or 2 schemes per VT zone
ATP in VF Zone	ATP While Charging; ATP Prior to Charging; Off
ATP Upper Rate Cutoff	150–300 min^{-1}
Burst Cycle Length	Adaptive; Readaptive or Fixed
Min. Burst Cycle Length (ms)	150–400 in increments of 5
Number of Bursts/Stimuli	1–15 with 2–20 Stimuli
Add Stimuli per Burst	On; Off
ATP Pulse Amplitude (V)	7,5 Independent from Bradycardia and Post-Therapy Pacing
ATP Pulse Width (ms)	1,0 or 1,5 Independently programmable from Bradycardia and Post-Therapy Pacing
High-Voltage Therapy	
DynamicTx™ Algorithm	On; Off
DeFT Response™ Technology	Programmable pulse width for P1/P2 and tilt
High-Voltage Output Mode	Fixed Pulse Width; Fixed Tilt
Waveform	Biphasic; Monophasic
RV Polarity	Cathode (-); Anode (+)
Electrode Configuration	RV to Can; RV to SVC/Can; RV to SVC
Bradycardia Pacing	
Permanent Modes	Off; DDD(R); DDT(R); DDI(R); VVT(R); VVI(R); AAI(R)
Temporary Modes	Off; DDD; DDT; DDI; VVT; VVI; AAI; AAT; DOO; VOO; AOO
Rate-Adaptive Sensor	On; Off; Passive
Programmable Rate and Delay Parameters	Off; Base Rate (min^{-1}); Rest Rate (min^{-1}); Maximum Tracking Rate (min^{-1}); Maximum Sensor Rate (min^{-1}); Paced AV Delay (ms); Sensed AV Delay (ms); Rate Responsive AV Delay; Hysteresis Rate (min^{-1}); Rate Hysteresis with Search
BiVCap™ Confirm; LVCap™ Confirm; RVCap™ Confirm	Setup; On; Monitor; Off
ACap™ Confirm	Setup; On; Monitor; Off
QuickOpt™ Timing Cycle Optimization	Interventricular Pace Delay
Auto Mode Switch (AMS)	Off; DDI(R); DDT(R); VVI(R); VVT(R)
Atrial Tachycardia Detection Rate (min^{-1})	110-300
AMS Base Rate (min^{-1})	40; 45; ... 135
Auto PMT Detection/Termination	Atrial Pace; Off; Passive
Rate Responsive PVARP/VREF	Off; Low; Medium; High
Ventricular Intrinsic Preference (VIP™)	Off; On (50–200)
Post-Therapy Pacing (Independently programmable from Bradycardia and ATP)	
Post-Shock Pacing Mode	Off; AAI; VVI; DDI; or DDD
Post-Shock Base Rate (min^{-1})	30–100 in increments of 5
Post-Shock Pacing Duration (min)	Off; 0,5; 1; 2,5; 5; 7,5; or 10
Patient Notifiers	
Programmable Notifiers (On; Off)	Device at ERI; Charge Time Limit Reached; Possible HV Circuit Damage; Atrial Lead Impedance Out of Range; RV Lead Impedance Out of Range; LV Lead Impedance Out of Range; High-Voltage Lead Impedance Out of Range; AT/AF Burden; V Rate During AT/AF; AT/AF Episode Duration; % V Pacing; CorVue™ Congestion Trigger, SecureSense algorithm — lead noise detected, nonsustained lead noise detected
Device Parameter Reset	On
Entry into Backup VVI Mode	On
Vibration Duration (sec)	2; 4; 6; 8; 10; 12; 14; 16
Number of Vibrations per Notification	2
Number of Notifications	1–16
Time Between Notifications (hours)	10; 22
Electrograms and Diagnostics	
Stored Electrograms	Up to 25 minutes; including up to 1 minute programmable pre-trigger data per VT/VF diagnosis; detection; electrograms; triggers include diagnosis; therapy; atrial episode; PMT termination; PC shock delivery; noise reversion; magnet reversion; morphology template verification; lead noise detected, nonsustained lead noise detected, NSVT/NSVF
Therapy Summary	Diagram of therapies delivered
Episodes Summary	Directory listing of up to 60 episodes with access to more details including stored electrograms
Lifetime Diagnostics	History of bradycardia events and device-initiated charging
AT/AF Burden Trend	Trend data and counts
Ventricular HV Lead Impedance Trend	Multi-Vector Trend Data
Histograms	Event Histogram; AV Interval Histogram; Mode Switch Duration Histogram; Peak Filtered Rate Histogram; Atrial Heart Rate Histogram; Ventricular Heart Rate Histogram; AT/AF Burden; Exercise and Activity Trending; V Rates During AMS, DirectTrend™ reports up to 1 year
PMT Data	Information regarding PMT detections
Real-Time Measurements (RTM)	Pacing lead impedances; high-voltage lead impedances; and signal amplitudes
CorVue™ Congestion Monitoring	On; Off
CorVue Congestion Trigger	8–18 days
MRI Scan Parameters	

If the implanted system is comprised of a combination of leads that have differing RF Power (SAR), scan region and/or additional considerations, use the most restrictive of each to determine the overall set of scan conditions applicable for the total system.

LEAD MODEL	LEAD LENGTHS	RF POWER (SAR)	SCAN REGION
Tendril™ STS Pacing Lead		Normal Operating Mode*	Full-body
2088TC	46, 52 cm		
IsoFlex™ Optim™ pacing leads			
1944	46, 52 cm		
Durata™ Defibrillation Lead			
7122Q, 7120Q	58, 65 cm		
Optisure™ Lead			
LDA210Q, LDA220Q	58, 65 cm		
Quartet™ LV Lead			
1456Q; 1457Q; 1458Q; 1458QL	86 cm		

*As defined in IEC 60601-2-33, Normal Operating Mode corresponds to RF Power SAR: ≤ 2 W/kg, Head SAR ≤ 3.2 W/kg

1. MR Conditional Field Strength: 1,5 Tesla
2. See MRI-Ready Systems Manual for approved MR Conditional Systems Device/Lead combinations and scan parameters
3. LV first with 10 ms interventricular delay

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing indications, contraindications, warnings, precautions, potential adverse events and directions for use.

30025-SJM-QD-1015-0027(5) | Item approved for international use only.

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Unify Assura™

Cardiac Resynchronization Therapy Defibrillator (CRT-D)

Merlin@home™ Transmitter Compatible

Product Highlights

- Parylene coating for improved abrasion resistance
- DynamicTx™ Over-Current Detection Algorithm automatically changes shock configurations to ensure delivery of high voltage therapy when high current is detected
- Cold Can programmability provides an additional RV-SVC Shock Configuration to decouple the can from the shocking vector parameters in cases of lead problems
- ShockGuard™ technology with DecisionTx™ programming designed to reduce inappropriate therapy and minimise the need for programming adjustments at implant
- SecureSense™ RV lead noise discrimination detects sustained and short bursts of lead noise that would otherwise go unnoticed or potentially lead to one or more inappropriate shocks
- Far Field MD™ morphology discrimination and Chamber Onset discrimination improve SVT and VT discrimination for reduced inappropriate therapies
- Antitachycardia pacing (ATP) while charging and prior to charging in the VF zone further extends the programming options for terminating tachyarrhythmias without a high-voltage shock
- Low frequency attenuation filter designed to enhance sensing performance and may reduce the possibility of oversensing T-waves
- Sense*Ability*™ feature provides flexibility to fine-tune programming around T-wave oversensing without decreasing sensitivity
- DF4 connector designed to streamline defibrillation connections into a single terminal pin and reduce the number of set screws
- Unique 40 J delivered energy safety shock option can provide a greater DFT safety margin
- DeFT Response™ technology offers the most noninvasive options for managing high DFTs
- QHR‡ chemistry battery provides greater capacity for enhanced longevity and improved charge time performance compared to previous SVO batteries
- Vibratory patient notifier enables patients with hearing problems to be alerted to a low battery, lead-related complications and more
- CorVue™ congestion monitoring feature monitors the intrathoracic impedance in multiple vectors for improved accuracy, and it provides the option for both patient and physician alerts
- QuickOpt™ timing cycle optimisation provides quick and effective optimisation at the push of a button

Ordering Information

Contents: Cardiac Pulse Generator

MODEL NUMBER	DIMENSIONS (H x W x T, MM)	WEIGHT (G)	VOLUME (CC)	CONNECTOR DEFIBRILLATION	CONNECTOR SENSE/PACE
CD3361-40C	79 x 40 x 14	78	36	DF1	IS-1
CD3361-40QC	73 x 40 x 14	77	36	DF4	DF4; IS-1

Indications: The devices are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. Cardiac Resynchronisation Therapy Defibrillators (CRT-Ds) are also intended to resynchronise the right and left ventricles in patients with congestive heart failure.

Contraindications: Contraindications for use of the pulse generator system include ventricular tachyarrhythmias resulting from transient or correctable factors such as drug toxicity, electrolyte imbalance or acute myocardial infarction.

Adverse Events: Implantation of the pulse generator system, like that of any other device, involves risks, some possibly life-threatening. These include but are not limited to the following: acute hemorrhage/bleeding, air emboli, arrhythmia acceleration, cardiac or venous perforation, cardiogenic shock, cyst formation, erosion, exacerbation of heart failure, extrusion, fibrotic tissue growth, fluid accumulation, hematoma formation, histotoxic reactions, infection, keloid formation, myocardial irritability, nerve damage, pneumothorax, thromboemboli, venous occlusion. Other possible adverse effects include mortality due to: component failure, device-programmer communication failure, lead abrasion, lead dislodgment or poor lead placement, lead fracture, inability to defibrillate, inhibited therapy for a ventricular tachycardia, interruption of function due to electrical or magnetic interference, shunting of energy from defibrillation paddles, system failure due to ionising radiation. Other possible adverse effects include mortality due to inappropriate delivery of therapy caused by: multiple counting of cardiac events including T waves, P waves, or supplemental pacemaker stimuli. Among the psychological effects of device implantation are imagined pulsing, dependency, fear of inappropriate pulsing and fear of losing pulse capability.

Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

Unify Assura™

Cardiac Resynchronization Therapy Defibrillator (CRT-D)

Product Specifications

PHYSICAL SPECIFICATIONS

Models	CD3361-40C	CD3361-40QC
Telemetry	RF	RF
Delivered/Stored Energy (J)	40/45	40/45
Volume (cc)	36	36
Weight (g)	78	77
Size (mm)	79 x 40 x 14	73 x 40 x 14
Defibrillation Lead Connections	DF1	DF4
Sense/Pace Lead Connections	IS-1	IS-1; DF4
High-Voltage Can	Electrically active titanium can	Electrically active titanium can
Coating	Parylene	Parylene

PARAMETER	SETTINGS
Biventricular Pacing	
V. Triggering	On; Off
QuickOpt™ Timing Cycle Optimization	Sensed/paced AV delay, interventricular pace delay
V-V Timing	Simultaneous*; RV First; LV First
Interventricular Pace Delay (ms)	RV First 10–80/LV First 15–80 in increments of 5
Ventricular Sensing	RV only (not programmable)
Ventricular Pacing Chamber	RV only; biventricular
Negative AV Hysteresis/ Search (ms)	Off; -10 to -120
Shortest AV Delay (ms)	25–120
VectSelect™ Programmable LV Pulse Configuration	LV tip to RV coil; LV bipolar; LV ring to RV coil
AF Management	
AF Suppression™ Pacing	On; Off
No. of Overdrive Pacing Cycles	15–40 in steps of 5
Maximum AF Suppression Rate	80–150 min^{-1}
Sensing/Detection	
Sense*Ability*™ Technology	Automatic Sensitivity Control adjustment for atrial and ventricular events
Low Frequency Attenuation	On; Off
Sense Filter	(Post-Sensed; Atrial) 50; 62,5; 75; 100%; (Post-Paced; Atrial) 0,2–3,0 mV;
Threshold Start	(Post-Sensed; Ventricular) 50; 62,5; 75; 100%; (Post-Paced; Ventricular) Auto; 0,2–3,0 mV
Decay Delay	(Post-Sense/Post-Pace; Atrial/Ventricular) 0–220
Ventricular Sense Refractory (ms)	125; 157
Detection Zones	3 zone programming - 1 zone, 2 zones or 3 zones (VT-1, VT-2, VF)
SVT Discriminators	AV Rate Branch; Arrhythmia Onset (Chamber Onset or Sudden Onset); Interval Stability; AV Association; Morphology Discrimination (Far Field MD™ or Original MD) with Manual (original MD only) or Automatic Template Update
Discrimination Modes	On; Passive; Off
SVT Threshold	150–240 min^{-1}
SVT Timeout	0,25–5 min
Lead Noise Discrimination	SecureSense™ RV lead noise discrimination (On; On with Timeout; Passive; Off)
Monitor Mode	Detection, discrimination and diagnostics, no therapy delivery (VT or VT-1 zone)
Reconfirmation	Continuous sensing during charging
Antitachycardia Pacing Therapy	
ATP Configurations	Ramp; Burst; Scan; 1 or 2 schemes per VT zone
ATP in VF Zone	ATP While Charging; ATP Prior to Charging; Off
ATP Upper Rate Cutoff	150–300 min^{-1}
Burst Cycle Length	Adaptive; Readaptive or Fixed
Min. Burst Cycle Length (ms)	150–400 in increments of 5
Number of Bursts/Stimuli	1–15 with 2–20 Stimuli
Add Stimuli per Burst	On; Off
ATP Pulse Amplitude (V)	7,5 Independent from Bradycardia and Post-Therapy Pacing
ATP Pulse Width (ms)	1,0 or 1,5 Independently programmable from Bradycardia and Post-Therapy Pacing
High-Voltage Therapy	
DynamicTx™ Algorithm	On; Off
DeFT Response™ Technology	Programmable pulse width for P1/P2 and tilt
High-Voltage Output Mode	Fixed Pulse Width; Fixed Tilt
Waveform	Biphasic; Monophasic
RV Polarity	Cathode (-); Anode (+)
Electrode Configuration	RV to Can; RV to SVC/Can; RV to SVC
Bradycardia Pacing	
Permanent Modes	Off; DDD(R); DDT(R); DDI(R); VVT(R); VVI(R); AAI(R)
Temporary Modes	Off; DDD; DDT; DDI; VVT; VVI; AAI; AAT; DOO; VOO; AOO
Rate-Adaptive Sensor	On; Off; Passive
Programmable Rate and Delay Parameters	Off; Base Rate (min^{-1}); Rest Rate (min^{-1}); Maximum Tracking Rate (min^{-1}); Maximum Sensor Rate (min^{-1}); Paced AV Delay (ms); Sensed AV Delay (ms); Rate Responsive AV Delay; Hysteresis Rate (min^{-1}); Rate Hysteresis with Search
LV Cap™ Confirm; RV Cap™ Confirm	Setup; On; Monitor; Off
ACap™ Confirm	On; Monitor; Off
QuickOpt™ Timing Cycle Optimization	Interventricular Pace Delay
Auto Mode Switch (AMS)	Off; DDI(R); DDT(R); VVI(R); VVT(R)
AMS Detection Rate (min^{-1})	110–300
Atrial Tachycardia Base Rate	40; 45; ... 135
Auto PMT Detection/Termination	Atrial Pace on PMT; Off; Passive
Rate Responsive PVARP/VREF	Off; Low; Medium; High
Ventricular Intrinsic Preference (VIP™)	Off; On (50–200)
Post-Therapy Pacing (Independently programmable from Bradycardia and ATP)	
Post-Shock Pacing Mode	Off; AAI; VVI; DDI; or DDD
Post-Shock Base Rate (min^{-1})	30–100 in increments of 5
Post-Shock Pacing Duration (min)	Off; 0,5; 1; 2,5; 5; 7,5; or 10
Device Testing/Induction Methods	
DC Fibber™ Pulse Duration (sec)	0,5–5,0
Burst Fibber Cycle Length (ms)	20–100
Noninvasive Programmed Stimulation (NIPS)	2–25 stimuli with up to three extra stimuli
Patient Notifiers	
Programmable Notifiers (On; Off)	Device at ERI; Charge Time Limit Reached; Possible HV Circuit Damage; Atrial Lead Impedance Out of Range; RV Lead Impedance Out of Range; LV Lead Impedance Out of Range; High-Voltage Lead Impedance Out of Range; AT/AF Burden; V Rate During AT/AF; % V Pacing; CorVue™ Congestion Trigger; SecureSense lead noise detected; nonsustained lead noise detected
Device Parameter Reset	On
Entry into Backup VVI Mode	On
Vibration Duration (sec)	2; 4; 6; 8; 10; 12; 14; 16
Number of Vibrations per Notification	2
Number of Notifications	1–16
Time between Notifications (hours)	10; 22
Electrograms and Diagnostics	
Stored Electrograms	Up to 45 minutes including up to 1 minute programmable pre-trigger data per VT/VF diagnosis/detection; electrograms; triggers include: diagnosis; detection; therapy; atrial episode; PMT termination; PC shock delivery; noise reversion; magnet reversion; morphology template verification; lead noise detected; non-sustained lead noise detected; NSVT/NSVF
Therapy Summary	Diagram of therapies delivered
Episodes Summary	Directory listing of up to 60 episodes with access to more details including stored electrograms
Lifetime Diagnostics	History of bradycardia events and device-initiated charging
AT/AF Burden Trend	Trend data and counts
Ventricular HV Lead Impedance Trend	Multi-Vector Trend Data
Histograms	Event Histogram; AV Interval Histogram; Mode Switch Duration Histogram; Peak Filtered Rate Histogram; Atrial Heart Rate Histogram; Ventricular Heart Rate Histogram; AT/AF Burden; Exercise and Activity Trending; V Rates During AMS; DirectTrend™ reports up to 1 year
PMT Data	Information regarding PMT detections
Real-Time Measurements (RTM)	Pacing lead impedances; high-voltage lead impedances; and signal amplitudes
CorVue™ Congestion Monitoring	On; Off
CorVue Congestion Trigger	8–18 days

* LV first with 10 ms interventricular delay.

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St. Jude Medical is now Abbott.

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

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Information contained herein intended for audiences from outside the United States only. Not approved for use in Canada.

Abbott

Quadra Assura MP™

Cardiac Resynchronisation Therapy Defibrillator (CRT-D)

Merlin@home™ Transmitter Compatible

Product Highlights

- MultiPoint™ pacing delivers multiple LV pacing pulses per cardiac cycle and is designed to improve hemodynamic and clinical response
- The Quadra Assura MP CRT-D and Quartet™ quadripolar LV pacing lead feature four pacing electrodes and 10 pacing vectors to provide more options and greater control to minimise implant complications such as diaphragmatic stimulation and high pacing thresholds
- VectSelect Quartet™ multivector testing feature offers a streamlined workflow to identify, test and program the patient's pacing vector
- Parylene coating for improved abrasion resistance
- DynamicTx™ Over-Current Detection Algorithm automatically changes shock configurations to ensure delivery of high voltage therapy when high current is detected
- Cold Can programmability provides an additional RV-SVC Shock Configuration to decouple the can from the shocking vector parameters in cases of lead problems
- ShockGuard™ technology with DecisionTx™ programming designed to reduce inappropriate therapy and minimise the need for programming adjustments at implant
- SecureSense™ RV lead noise discrimination detects sustained and short bursts of lead noise that would otherwise go unnoticed or potentially lead to one or more inappropriate shocks
- Far Field MD™ morphology discrimination and Chamber Onset discrimination improve SVT and VT discrimination for reduced inappropriate therapies
- Antitachycardia pacing (ATP) while charging and prior to charging in the VF zone further extends the programming options for terminating tachyarrhythmias without a high-voltage shock
- Low Frequency Attenuation filter designed to enhance sensing performance and may reduce the possibility of oversensing T-waves
- Sense*Ability*™ feature provides the flexibility to fine-tune programming around T-wave oversensing without decreasing sensitivity
- DF4 connector designed to streamline defibrillation connections into a single terminal pin and reduce the number of set screws
- Unique 40 J delivered energy safety shock option can provide a greater DFT safety margin
- DeFT Response™ technology offers the most noninvasive options for managing high DFTs
- QHR™* chemistry battery provides greater capacity for enhanced longevity and improved charge time performance compared to previous SVO batteries
- Vibratory patient notifier enables patients with hearing problems to be alerted to a low battery, lead-related complications and more
- CorVue™ congestion monitoring feature monitors the intrathoracic impedance in multiple vectors for improved accuracy, and it provides the option for both patient and physician alerts
- QuickOpt™ timing cycle optimisation provides quick and effective optimisation at the push of a button

Ordering Information

Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector
CD3371-40C	83 x 41 x 14	83	40	DF1, IS4, IS-1
CD3371-40QC	75 x 41 x 14	80	38	DF4, IS4, IS-1

Indications: The devices are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. Cardiac Resynchronisation Therapy Defibrillators (CRT-Ds) are also intended to resynchronise the right and left ventricles in patients with congestive heart failure.

Contraindications: Contraindications for use of the pulse generator system include ventricular tachyarrhythmias resulting from transient or correctable factors such as drug toxicity, electrolyte imbalance, or acute myocardial infarction.

Adverse Events: Implantation of the pulse generator system, like that of any other device, involves risks, some possibly life-threatening. These include but are not limited to the following: acute hemorrhage/bleeding, air emboli, arrhythmia acceleration, cardiac or venous perforation, cardiogenic shock, cyst formation, erosion, exacerbation of heart failure, extrusion, fibrotic tissue growth, fluid accumulation, hematoma formation, histotoxic reactions, infection, keloid formation, myocardial irritability, nerve damage, pneumothorax, thromboemboli, venous occlusion. Other possible adverse effects include mortality due to: component failure, device-programmer communication failure, lead abrasion, lead dislodgment or poor lead placement, lead fracture, inability to defibrillate, inhibited therapy for a ventricular tachycardia, interruption of function due to electrical or magnetic interference, shunting of energy from defibrillation paddles, system failure due to ionising radiation. Other possible adverse effects include mortality due to inappropriate delivery of therapy caused by: multiple counting of cardiac events including T waves, P waves, or supplemental pacemaker stimuli. Among the psychological effects of device implantation are imagined pulsing, dependency, fear of inappropriate pulsing, and fear of losing pulse capability.

Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

*QHR is a trademark of Greatbatch Medical

ST. JUDE MEDICAL

Quadra Assura MP™

Cardiac Resynchronisation Therapy Defibrillator (CRT-D)

Product Specifications

PHYSICAL SPECIFICATIONS		
Models	**CD3371-40C**	**CD3371-40QC**
Telemetry	RF	RF
Delivered/Stored Energy (J)	40/45	40/45
Volume (cc)	40	38
Weight (g)	83	80
Size (mm)	83 x 41 x 14	75 x 41 x 14
Defibrillation Lead Connections	DF1	DF4-LLHH
LV Lead Connections	IS4-LLLL	IS4-LLLL
Sense/Pace Lead Connections	IS-1	IS-1
High-Voltage Can	Electrically active titanium can	Electrically active titanium can
Coating	Parylene	Parylene

PARAMETER	SETTINGS
Biventricular Pacing	
VectSelect Quartet™	Distal Tip 1 - Mid 2, Distal Tip 1 - Proximal 4, Distal Tip 1 - RV Coil; Pulse Configuration Mid 2 - Proximal 4; Mid 2 - RV Coil; Mid 3 - Mid 2; Mid 3 -Proximal 4; Mid 3 - RV Coil; Proximal 4 - Mid 2; Proximal 4 - RV Coil
MultiPoint Pacing	LV1; LV2
Delay MultiPoint Pacing	Delay 1: 5; 10; …80 ms Delay 2: 5; 10; … 50 ms
V. Triggering	On; Off
QuickOpt™ Timing	
Cycle Optimisation	Sensed/paced AV delay, interventricular pace delay
V-V Timing	Simultaneous*; RV First; LV First
Interventricular Pace Delay (ms)	RV First 10-80 / LV First 15-80 in increments of 5
Ventricular Sensing	RV only (not programmable)
Ventricular Pacing Chamber	RV only; biventricular
Negative AV Hysteresis/Search (ms)	Off; -10 to -120
Shortest AV Delay (ms)	25-120
AF Management	
AF Suppression™ Pacing	On; Off
No. of Overdrive Pacing Cycles	15-40 in steps of 5
Maximum AF Suppression Rate	80-150 min^{-1}
Sensing/Detection	
Sense*Ability*™ Technology	Automatic Sensitivity Control adjustment for atrial and ventricular events
Low Frequency Attenuation	On; Off
Threshold Start	(Post-Sensed; Atrial) 50; 62,5; 75; 100%; (Post-Paced; Atrial) 0,2-3,0 mV; (Post-Sensed; Ventricular) 50; 62,5; 75; 100%; (Post-Paced; Ventricular) Auto; 0,2-3,0 mV
Decay Delay	(Post-Sense/Post-Pace; Atrial/Ventricular) 0-220
Ventricular Sense Refractory (ms)	125; 157
Detection Zones	3 zone programming - 1 zone; 2 zones or 3 zones (VT-1; VT-2; VF)
SVT Discriminators	AV Rate Branch; Arrhythmia Onset (Chamber Onset or Sudden Onset); Interval Stability; AV Association; Morphology Discrimination (Far Field MD or Original MD) with Manual (original MD only) or Automatic Template Update
Monitor Mode	Detection, discrimination and diagnostics, no therapy delivery (VT or VT-1 zone)
Discrimination modes	On; Passive; Off
SVT Threshold	150-240 min^{-1}
SVT Timeout	0,25-5 min
Reconfirmation	Continuous sensing during charging
Lead Noise Discrimination	SecureSense™ RV lead noise discrimination (On; On with Timeout; Passive; Off)
Antitachycardia Pacing Therapy	
ATP Configurations	Ramp; Burst; Scan; 1 or 2 schemes per VT zone
ATP in VF Zone	ATP While Charging; ATP Prior to Charging; Off
ATP Upper Rate Cutoff	150 - 300 min^{-1}
Burst Cycle Length	Adaptive; Readaptive or Fixed
Min. Burst Cycle Length (ms)	150-400 in increments of 5
Number of Bursts/Stimuli	1-15 with 2-20 Stimuli
Add Stimuli per Burst	On; Off
ATP Pulse Amplitude (V)	7,5 Independent from Bradycardia and Post-Therapy Pacing
ATP Pulse Width (ms)	1,0 or 1,5 Independently programmable from Bradycardia and Post-Therapy Pacing
High-Voltage Therapy	
DynamicTx™ Algorithm	On; Off
DeFT Response™ Technology	Programmable pulse width for P1/P2 and tilt
High-Voltage Output Mode	Fixed Pulse Width; Fixed Tilt
Waveform	Biphasic; Monophasic
RV Polarity	Cathode (-); Anode (+)
Electrode Configuration	RV to Can; RV to SVC/Can; RV to SVC
Bradycardia Pacing	
Permanent Modes	Off; DDD(R); DDT(R); DDI(R); VVT(R); VVI(R); AAI(R)
Temporary Modes	Off; DDD; DDT; DDI; VVT; VVI; AAI; AAT; DOO; VOO; AOO;
Rate-Adaptive Sensor	On, Off, Passive
Programmable Rate and Delay Parameters	Off; Base Rate (min^{-1}); Rest Rate (min^{-1}); Maximum Tracking Rate (min^{-1}); Maximum Sensor Rate (min^{-1}); Paced AV Delay (ms); Sensed AV Delay (ms); Rate Responsive AV Delay; Hysteresis Rate (min^{-1}); Rate Hysteresis with Search
BiVCap™ Confirm; LVCap™ Confirm; RVCap™ Confirm	Setup; On; Monitor; Off
ACap™ Confirm	On; Monitor; Off
QuickOpt™ Timing Cycle Optimisation	Interventricular Pace Delay
Auto Mode Switch (AMS)	Off; DDI(R); DDT(R); VVI(R); VVT(R)
Atrial Tachycardia Detection Rate (min^{-1})	110-300
AMS Base Rate (min^{-1})	40; 45; ... 135
Auto PMT Detection/Termination	Atrial Pace; Off; Passive
Rate Responsive PVARP/VREF	Off; Low; Medium; High
Ventricular Intrinsic Preference (VIP™)	Off; On (50-200)
Post-Therapy Pacing (Independently programmable from Bradycardia and ATP)	
Post-Shock Pacing Mode	Off; AAI; VVI; DDI; or DDD
Post-Shock Base Rate (min^{-1})	30-100 in increments of 5
Post-Shock Pacing Duration (min)	Off; 0,5; 1; 2,5; 5; 7,5; or 10
Device Testing/Induction Methods	
DC Fibber™ Pulse Duration (sec)	0,5-5,0
Burst Fibber Cycle Length (ms)	20-100
Noninvasive Programmed Stimulation (NIPS)	2-25 stimuli with up to three extrastimuli
Patient Notifiers	
Programmable Notifiers (On; Off)	Device at ERI; Charge Time Limit Reached; Possible HV Circuit Damage; Atrial Lead Impedance Out of Range; RV Lead Impedance Out of Range; LV Lead Impedance Out of Range; High-Voltage Lead Impedance Out of Range; AT/AF Burden; V Rate During AT/AF; AT/AF Episode Duration; % V pacing; CorVue Congestion Trigger; SecureSense — lead noise detected, non-sustained lead noise detected
Device Parameter Reset	On
Entry into Backup VVI Mode	On
Vibration Duration (sec)	2; 4; 6; 8; 10; 12; 14; 16
Number of Vibrations per Notification	2
Number of Notifications	1-16
Time Between Notifications (hours)	10; 22
Electrograms and Diagnostics	
Stored Electrograms	Up to 45 minutes; including up to 1 minute programmable pre-trigger data per VT/VF diagnosis; detection; electrograms; triggers include diagnosis; therapy; atrial episode; PMT termination; PC shock delivery; noise reversion; magnet reversion; morphology template verification; lead noise detected, non-sustained lead noise detected, NSVT/NSVF
Therapy Summary	Diagram of therapies delivered
Episodes Summary	Directory listing of up to 60 episodes with access to more details including stored electrograms
Lifetime Diagnostics	History of bradycardia events and device-initiated charging
AT/AF Burden Trend	Trend data and counts
Ventricular HV Lead Impedance Trend	Multi-Vector Trend Data
Histograms	Event Histogram; AV Interval Histogram; Mode Switch Duration Histogram; Peak Filtered Rate Histogram; Atrial Heart Rate Histogram; Ventricular Heart Rate Histogram; AT/AF Burden; Exercise and Activity Trending; V Rates during AMS; DirectTrend™ reports up to 1 year
PMT Data	Information regarding PMT detections
Real-Time Measurements (RTM)	Pacing lead impedances; high-voltage lead impedances; and signal amplitudes
CorVue™ Congestion Monitoring	On; Off
CorVue Congestion Trigger	8-18 days

* LV first with 10 ms interventricular delay

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use. Devices depicted may not be available in all countries. Check with your St. Jude Medical representative for product availability in your country.

Item GMCRM1076EN

GMCRM1076EN

ST. JUDE MEDICAL™

SJM Confirm™

Implantable Cardiac Monitor

Implantable Cardiac Monitors

Product Highlights

- Smallest device of its kind in both size and volume
- Manual and auto activated triggers for EGM storage
- Programmable data storage options to maximize episode capture
- 3-year implant life
- The SJM Confirm ICM can be scanned in patients under the following conditions:
  - Closed bore, cylindrical magnet
  - Static magnetic field strength of 1.5 Tesla (T) only
  - Maximum gradient slew rate 200 T/m/s per axis
  - Whole body Specific Absorption Rate (SAR) less than or equal to 4.0 W/kg
  - The uninterrupted duration of active scanning (when radio frequency (RF) and gradients are on) over the chest during MRI must not exceed 60 minutes
  - Confirmation of absence of other contraindicated implantable devices and/or leads, including abandoned leads, lead extenders and lead adaptors

In non-clinical testing, the Abbott MR Conditional SJM Confirm ICM produced a temperature rise of less than 3C at a maximum MR system-reported whole body averaged specific absorption rate (SAR) of 3.9 W/Kg as displayed on the MR scanner console for 60 minutes of MR scanning in a 1.5T closed bore MR scanner (manufacturer Philips, model Intera 1.5, Software version: 9.5.2). MR Conditional- Please refer to the SJM Confirm ICM User's Manual.

Ordering Information

Contents: Implantable Cardiac Monitor

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)
DM2100 (Syncope)	56,3 x 18,5 x 8	12	6,5 (± 0,5)
DM2102 (AF Detection)	56,3 x 18,5 x 8	12	6,5 (± 0,5)

Separately Available Accessories

Contents: SJM Confirm™ External Patient Activator device

Model Number	Description
DM2100A	External Patient Activator

Indications: The SJM Confirm™ ICM is indicated for the monitoring and diagnostic evaluation of patients who experience unexplained symptoms such as: dizziness, palpitations, chest pain, syncope, and shortness of breath, as well as patients who are at risk for other cardiac arrhythmias.

The SJM Confirm ICM Model DM2102 is also indicated for patients who have been previously diagnosed with atrial fibrillation or who are susceptible to developing atrial fibrillation.

Contraindications: There are no known contraindications for the implantation of the SJM Confirm™ ICM. However, the patient's particular medical condition may dictate whether or not a subcutaneous, chronically implanted device can be tolerated.

Adverse Events: Possible adverse events (in alphabetical order) associated with the device, include, but are not limited to the following: Allergic reaction, Bleeding, Chronic nerve damage, Erosion, Excessive fibrotic tissue growth, Extrusion, Formation of hematomas or cysts, Infection, Keloid formation

Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

Abbott

Product Specifications

Physical Specifications

Models	DM2100	DM2102
Sampling Rate (Hz)	128	128
Dimensions (mm)	56,3 x 18,5 x 8	56,3 x 18,5 x 8
Volume (cc)	6,5	6,5
Weight (g)	12	12
Electrode Spacing (mm)	39	39
Electrode Minimum Surface Area (mm^2)	30	30

Parameter	Settings	
Features		
Longevity	3 years	3 years
Patient Trigger	Yes	Yes
Auto Activation Trigger	Yes	Yes
Tachycardia Trigger	Yes	Yes
Tachycardia Cycle Count	Yes	Yes
Bradycardia Trigger	Yes	Yes
Asystole (duration) Trigger	Yes	Yes
EGM Storage	48 minutes	48 minutes
Patient Trigger	Yes, Programmable	Yes, Programmable
Auto Activation	Yes, Programmable	Yes, Programmable
Activity Response	Inhibit, Monitor, Off	Inhibit, Monitor, Off
Noise Response	Inhibit	Inhibit
Programmable AF episode duration	N/A	>30 sec., >1 min., 2 min., >5 min., >10 min.
Diagnostics		
Episodal Diagnostics	Yes	Yes
Heart Rate Histogram	Yes	Yes
Mean Heart Rate	No	No
Remote Monitoring	Transtelephonic monitoring (TTM)*	Transtelephonic monitoring (TTM)*
Patient Activator (PA)	Battery-powered PA	Battery-powered PA

* Connectivity depends upon country and use of a compatible receiver unit.
Please contact your Abbott sales representative for more details.

Customer Support: 46-8-474-4756

Abbott
One St. Jude Medical Dr., St. Paul, MN 55117 USA, Tel: 1 651 756 2000
SJM.com
St. Jude Medical is now Abbott.

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

27112-SJM-CFM-1115-0007(1) | Item approved for international use only.

Abbott

INSERTABLE CARDIAC MONITOR

Jot Dx™

Model DM4500
Insertable Cardiac Monitor

Abbott's Jot Dx™ insertable cardiac monitor (ICM) with SharpSense™ technology is designed to detect arrhythmias and wirelessly transmit data to the Merlin.net™ Patient Care Network (PCN) for the following patients:

- Patients who experience symptoms that may be associated with a cardiac arrhythmia
- Patients who are at risk for abnormal cardiac rhythms
- Patients who have been previously diagnosed with atrial fibrillation (AF) or who are susceptible to developing AF

Jot Dx™ ICM utilizes the key episode feature on Merlin.net™ to reduce monitoring burden. This includes the ability to toggle the feature on or off at facility or patient level.

Product Highlights

Device

- SharpSense™ technology improves the detection of AF, Bradycardia and Pause, with high relative sensitivity
- Electrogram (EGM) scatterplots to easily identify relationships between variables
- Small size (~ 1.4 cc) with slim profile
- Simple insertion procedure requiring minimal time and resources
- Intuitive one-touch programming on the Merlin™ Patient Care System
- Remote monitoring ready
- Patient-activated and auto-activated triggers for EGM storage
- Programmable data storage options to ensure capture of significant events while reducing the risk of missing unexpected events
- Proven Abbott SenseAbility™ sensing algorithm feature designed to allow accurate sensing over a wide range of signals
- 1.5T and 3T MR Conditional

Mobile App and Connectivity

- Bluetooth® wireless technology between ICM and myMerlin™ app, which patients can download onto their mobile device. No need for a separate bedside transmitter or patient activator
- ICM continuously monitors rhythm, and myMerlin™ app proactively transmits data per schedule and alerts set by the clinic
- App features integrated activator functionality, allowing patients to privately record and transmit EGMs during symptoms. No separate activator hardware required
- Notifications inform patients of daily device checks and scheduled transmissions to promote remote monitoring adherence without burdening the clinic
- App available in 35+ languages to engage patients and provide a personalized experience
- Transmissions are sent to the Merlin.net™ PCN, providing clinicians with data and reports
- Abbott mobile transmitters are available for patients without their own compatible mobile device

Ordering Information

Jot Dx™ ICM

NAME	MODEL NUMBER	DESCRIPTION	MRI STATUS	X-RAY ID MODEL CODE
Jot Dx™ ICM	DM4500	Insertable cardiac monitor	1.5T and 3T MR Conditional	CC

Jot Dx™
Model DM4500
Insertable Cardiac Monitor

Product Specifications

PHYSICAL SPECIFICATIONS

Model	DM4500
Volume	1.4 cc
Length	49 mm
Width	9.4 mm
Thickness	3.1 mm
Weight	3.0 g

PARAMETER	SETTINGS
Features	
Longevity	2 years†
Detection Sampling Rate	512 Hz
Patient Trigger	Yes
Symptom Alert	Off On (All Symptoms) On (with Detection)
Remote Monitoring	myMerlin™ app via Bluetooth® wireless technology
Patient Activator	myMerlin™ app via Bluetooth® wireless technology
Tachycardia Trigger and Alert	Yes
Bradycardia Trigger and Alert	Yes
Pause Trigger and Alert	Yes
AF Trigger and Alert	Yes
Programmable AF Episode Duration	30 seconds, 1, 2, 6, 10, 20, 30, 60 minutes
AF Burden Alert	Off, 30 minutes, 1, 3, 6, 9, 12, 24 hours
AF Continuous Episode Alert	Off, 10, 20, 30, 60, 180 minutes
Ventricular Rate during	Off
AF Alert	Rate Threshold: 90, 100, 110, 120, 130, 140, 150, 175, 200 bpm Total Time: 1, 3, 6, 9, 12 hours
Activity Inhibits Auto Detection	Programmable, On or Off
Noise Response Inhibits Auto Detection	Yes
Diagnostics	
Episodal Diagnostics	Yes
Total EGM Storage	60 minutes
Symptom EGM Duration	Pre-trigger — 4, 6, 8, 10, 12, 14 minutes Post-trigger — 30, 40, 50, 60 seconds
Auto Detected EGM Duration	AF Pre- and Post-trigger — 10, 20, 30, 60, 90, 120 seconds Other (Tachy, Brady, Pause) Pre- and Post-trigger — 10, 20, 30, 40, 50, 60 sec
EGM Sampling Rate	128 Hz
Heart Rate Histogram	Yes
AF Diagnostics	Yes
AF Burden Trend	Yes

†Two years under the following usage scenarios:
- Average of one auto-detected episode per day
- Average of one patient-activated symptom per month
- Up to six-month shelf storage time

NOTE: At a maximum shelf storage time of 18 months, longevity is reduced by approximately five months.

Security Measures

- The ICM encrypts its wireless communication using Advanced Encryption Standard (AES) 128-bit encryption and is designed to limit communications to only a single authenticated and paired myMerlin™ app at any given time
- The ICM uses the pairing procedure specified in Bluetooth® wireless technology low energy protocols and a proprietary pairing protocol as an added security measure. Pairing requests are authenticated using cloud-based public key cryptography authentication
- The ICM creates a unique 128-bit key for the paired mobile app and verifies it at the onset of every communication. If the unique key is not verified, the monitor denies access
- The ICM uses an authorization protocol, which limits a paired mobile app's access based on clinician settings
- The myMerlin™ app encrypts wireless communication to the Merlin.net™ Patient Care Network (PCN) through a secure Transport Layer Security connection using SHA256 cryptographic protection
- The Merlin.net™ PCN is housed in a secured data center and is ISO27001:2013 certified. Access to patient data in the Merlin.net PCN is restricted to authorized users as set by the clinic administrator. ICM data is encrypted using AES 128-bit encryption

Abbott
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Abbott.com

Rx Only
Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

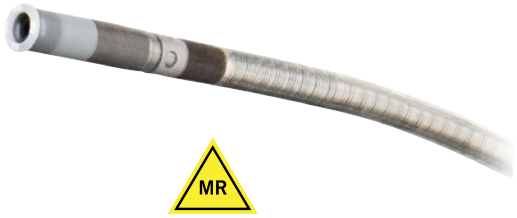
MAT-2202749 v1.0 | Item approved for use outside of the United States.

Abbott

PACING LEADS

Tendril™ STS

Pacing Lead



Product Highlights - Pacing Leads

- The Tendril™ STS lead allows patients to undergo 1.5 T or 3 T MRI scans when used in conjunction with an MRI Ready device from Abbott*
- Soft silicone tip offers more compliance and less tip pressure at the lead tip-endocardium interface
- Small diameter lead offers improved ease of venous passage, reduced risk of venous thrombosis or rib-clavicle crush and ability to accommodate additional leads more easily
- Optim™ lead insulation — a chemical co-polymer that blends the best features of polyurethane and silicone for improved handling and increased durability
- Titanium nitride (TiN) fractal coating on the tip and ring electrodes is designed to promote precise sensing and to provide improved contact with the myocardium
- Lubricious Fast-Pass™ coating facilitates lead insertion through the introducer and veins to ease implantation
- Fits through a 6 F introducer

Ordering Information

MODEL NUMBER	DESCRIPTION	INSULATION	FIXATION	MIN. INTRODUCER (F)	CONNECTOR	LENGTH (CM)
2088TC	Tendril™ STS Pacing Leads	Optim™	Ext/Ret helix	6	IS-1 bipolar	46**; 52**; 58**; 65; 100

*See MRI conditional parameters.
**Indicates lead lengths that are MRI conditional.

Indications: Tendril™ STS Lead is designed for permanent sensing and pacing in either the right atrium or the right ventricle, in combination with a compatible device. Active leads such as the Tendril STS lead may be indicated for patients where permanent fixation of passive leads is suspected to be unstable.

In atrial applications, the use of screw-in leads such as Tendril STS lead may be indicated in the presence of an abnormal, surgically altered or excised atrial appendage.

Contraindications: Tendril STS lead is contraindicated: in the presence of tricuspid atresia, for patients with mechanical tricuspid valves, in patients who are expected to be hypersensitive to a single dose of one milligram of dexamethasone sodium phosphate.

Adverse Events: Potential complications associated with the use of Tendril STS lead are the same as with the use of other active fixation leads and include: cardiac tamponade, diaphragmatic stimulation, embolism, excessive bleeding, induced ventricular ectopy, infection, loss of pacing and/or sensing due to dislodgment or mechanical malfunction of the pacing lead, phrenic nerve stimulation, thrombosis. Complications reported with direct subclavian venipuncture include pneumothorax, hemothorax, laceration of the subclavian artery, arteriovenous fistula, neural damage, thoracic duct injury, cannulation of other vessels, massive hemorrhage and, rarely, death.

Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

Tendril™ STS

Pacing Lead

Product Specifications

PHYSICAL SPECIFICATIONS

Models	2088TC
Minimum Introducer Size	6 F
Type of Lead	Active-fixation, steroid-eluting, endocardial, straight pacing lead
Lead Connector	IS-1 bipolar
Lead Lengths	46**; 52**; 58**; 65; 100 cm
Fixation Mechanism	Extendable/Retractable helix
Typical Number of Rotations for Helix Extension	6–11 (straight stylet)
Lead Body Diameter	1,9 mm (max)
Tip-to-Ring Spacing	10 mm
Lead Tip Electrode (Cathode)	Active Titanium-nitride-coated Pt/Ir helix (2,0 mm extension)
Tip Electrode Surface Area	6,9 mm^2
Ring Electrode (Anode)	Titanium-nitride-coated Pt/Ir
Ring Electrode Surface Area	16 mm^2
Mapping	Capable with Titanium-nitride-coated Pt/Ir helix
Steroid	< 1 mg dexamethasone sodium phosphate
Inner Conductor/Outer Conductor	MP35N™* coil
Inner Insulation	Silicone rubber
Outer Insulation	Optim™ lead insulation
Lead Body Coating	Fast-Pass™ coating

In-Pack	
Straight stylets	1 x-soft in lead, 1 x-soft, 1 soft
J-shaped stylets	2 soft
Helix extension/retraction clip-on tools	2 clip-on tools

Accessory Kits Available Separately	Model Number	Compatible Lenghts	Description
Stylet Kit	DSO6003 with appropriate length designation	46; 52; 58; 65; 100 cm	1 clip-on tool, 1 J-shaped soft, 1 x-soft, 1 soft, 1 firm, 1 x-firm
Locator™ Plus Deflectable Stylet	1281 with appropriate length designation	46; 52; 58 cm	Disposable implant tool to facilitate precise lead positioning and manipulation with one hand
	1292 with appropriate length designation	46; 52; 58 cm	

MRI Conditional Parameters

MRI scan parameters vary depending on the MRI Ready device used. Consult the MRI Ready System Manual for specific product combinations and associated MRI scan parameters.

MP35N is a trademark of SPS Technologies, LLC

MR

*See MRI conditional parameters.

**Indicates lead lengths that are MRI conditional.

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

26022-SJM-TND-0914-0002(7) | Item approved for international use only.

Abbott

QuickFlex™ µ

Left-Heart Lead

Product Highlights

- Superb deliverability combined with exceptional stability and performance
- Low profile - 4,3 F lead body; 4,0 F lead tip
- Optim™ lead insulation – a chemical co-polymer that blends the best features of polyurethane and silicone for improved handling and increased durability
- Steerable tip - distal tip angle can be controlled to maneuver through venous anatomy
- Flexible lead body
  - Tip-to-ring electrode spacing of 20 mm
  - Shorter tip and ring electrodes reduce the length of rigid portions of the lead body
- Allows Direct-To-Target™ placement through CPS Aim™ SL inner catheter to deliver leads to small, acute venous anatomies that may have been unreachable in the past
- Compatible with over-the-wire or stylet approaches

Ordering Information

Contents: Left-heart lead

Model Number	Insulation	S-Curve Height (mm)	Minimum Introducer (F)	Connector	Lengths (cm)
1258T	Optim™	16	5	IS-1 bipolar	75; 86; 92

Indications and Usage: The QuickFlex lead has application as part of a St. Jude Medical biventricular system.
Contraindications: The use of QuickFlex leads is contraindicated in patients who:
- Are expected to be hypersensitive to a single dose of 1,0 mg of dexamethasone sodium phosphate.
- Are unable to undergo an emergency thoracotomy procedure.
- Have coronary venous vasculature that is inadequate for lead placement, as indicated by venogram.

Customer Support: 46-8-474-4756

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

QuickFlex™ µ

Left-Heart Lead

Product Specifications

PHYSICAL SPECIFICATIONS

MODEL	1258T
Parameter	**Description**
Connector	IS-1 Bipolar
Lead Length	75 cm; 86 cm; 92 cm
Lead Body Size	4,3 F (1,42 mm/0,056")
Tip Electrode Size	4,0 F (1,33 mm/0,052")
LV Lead Delivery System Introducer Size	Minimum 5 F ID
Minimum S-Curve Height	16 mm
Tip Electrode	Pt/Ir; TiN coated; ring-shaped; two grooves
Steroid	Dexamethasone sodium phosphate
Tip Electrode Surface Area	5,0 mm^2
Ring Electrode Surface Area	7,4 mm^2
Tip-to-Ring Electrode Spacing	20 mm
Lead Body Insulation	Optim™ insulation
Lead Body Coating	Fast-Pass™ coating
Conductors*	
Distal (coil)	MP35N™
Proximal (cables)	MP35N™
Suture Sleeve	Attached

*MP35N is a trademark of SPS Technologies, Inc.

GMCRM772EN

Customer Support: 46-8-474-4756

Item GMCRM772EN

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

OptiSense™

Pacing Lead

Product Highlights

- OptiSense™ pacing lead technology offers optimal tip-to-ring spacing for more precise atrial sensing without inappropriately sensing extra-atrial signals:
  - Unique 1,1 mm tip-to-ring spacing enables sensing of even the finest atrial arrhythmia signals (standard atrial leads typically have a tip-to-ring spacing of 10 mm or more)
  - Accurate atrial sensing enables appropriate atrial diagnostics and therapies
- Less far-field R-wave interference with innovative far-field signal reduction technology
- Optim™ lead insulation — a chemical copolymer that blends the best features of polyurethane and silicone for improved handling and increased durability
- Thin lead body diameter of 5,8 F can be inserted using a 7 F introducer
- Steroid elution and titanium nitride fractal coating on electrodes for low thresholds
- Includes three different J-shaped stylets providing options for different patient anatomies and handling preferences

Ordering Information

Contents: Cardiac Pacing Lead

MODEL NUMBER	INSULATION	FIXATION	MINIMUM INTRODUCER (F)	CONNECTOR	LENGTHS (CM)
1999	Optim	Ext/Ret helix	7	IS-1 bipolar	40; 46; 52

Indications: The OptiSense™ lead is designed for permanent sensing and pacing in the atrium with a compatible pulse generator. An active lead, such as the OptiSense™ lead, may be indicated for patients where permanent fixation of passive leads is suspected to be unstable. In atrial applications, the use of a screw-in lead, such as the OptiSense™ lead, may be indicated in the presence of an abnormal, surgically altered or excised atrial appendage.

Contraindications: The OptiSense™ lead is contraindicated: In the presence of tricuspid atresia, for patients with mechanical tricuspid valves, in patients who are expected to be hypersensitive to a single dose of one milligram of dexamethasone sodium phosphate.

Adverse Events: Potential complications associated with the use of OptiSense™ leads are the same as with the use of other active fixation leads and include: cardiac tamponade, diaphragmatic stimulation, embolism, excessive bleeding, induced ventricular ectopy, infection, loss of pacing and/or sensing due to dislodgment or mechanical malfunction of the pacing lead, phrenic nerve stimulation, thrombosis. Complications reported with direct subclavian venipuncture include pneumothorax, hemothorax, laceration of the subclavian artery, arteriovenous fistula, neural damage, thoracic duct injury, cannulation of other vessels, massive hemorrhage and, rarely, death.

Refer to the User's manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

OptiSense™
Pacing Lead

Product Specifications

PHYSICAL SPECIFICATIONS

Model	1999
Minimum Introducer Size	7 F
Type of Lead	Active-fixation; bipolar; steroid-eluting; endocardial: atrial pacing lead
Lead Connector	IS-1 bipolar
Lead Lengths	40; 46; 52 cm
Fixation Mechanism	Extendable/retractable helix
Lead Body Diameter	0,076"/1,9 mm (5,8 F)
Tip-to-ring Spacing	1,1 mm
Lead Tip Electrode (Cathode)	Active titanium-nitride-coated Pt/Ir helix (1,8 mm extension)
Tip Electrode Surface Area	6,4 mm^2
Ring Electrode (Anode)	Titanium-nitride-coated titanium ring
Ring Electrode Surface Area	17 mm^2
Mapping	Capable with titanium-nitride-coated Pt/Ir helix
Steroid	< 1 mg dexamethasone sodium phosphate
Inner Conductor/ Outer Conductor	MP35N‡ coil
Inner Insulation	Silicone rubber
Outer Insulation	Optim™ lead insulation
Lead Body Coating	Fast-Pass™ coating

IN PACK

Straight Stylets	1 x-soft in lead; 1 x-soft; 1 soft
J-curved Stylets	1 standard; 1 wide; 1 narrow
Helix Extension/ Retraction Clip-on Tools	2 clip-on tools

ACCESSORY KITS

Available Separately	Model Number	Compatible Lengths	Description
Stylet Kit	DS06000 with appropriate length designation	52 cm	1 fixation tool; 1 clip-on tool; 1 standard J shape; 1 wide J shape; 1 narrow J shape
	DS06001 with appropriate length designation	46; 52 cm	1 clip-on tool; 1 standard J shape; 1 wide J shape; 1 narrow J shape
	DSO6002 with appropriate length designation	46; 52 cm	1 fixation tool; 1 clip-on tool; 1 J-shaped soft; 1 x-soft; 1 soft; 1 firm; 1 x-firm
	DSO6003 with appropriate length designation	40; 46; 52 cm	1 clip-on tool; 1 J-shaped soft; 1 x-soft; 1 soft; 1 firm; 1 x-firm
Locator™ Plus Deflectable Stylet	1281 with appropriate length designation	46; 52 cm	Disposable implant tool that facilitates precise lead positioning and allows manipulation with one hand
	1292 with appropriate length designation	52 cm	

LIMITED LIFETIME WARRANTY

Terms and conditions apply; refer to the warranty for details.

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St. Jude Medical is now Abbott.

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

28817-SJM-CAG-1115-0058(1) | Information contained herein intended for audiences from outside the United States only.

Abbott

Durata™

Defibrillation Lead

MR

Product Highlights

- Allows patients to safely undergo an MRI scan when used in combination with an Abbott MRI Ready device.*,†
- Optim™ lead insulation is a chemical copolymer that offers superior handling and durability.[1]
- Two innovative designs are intended to help prevent tissue ingrowth — flat-wire technology provides a low profile for the defibrillation coils, and silicone backfilling completely fills the shock coil space.
- Redundant conductors serve as a backup system in the unlikely event of a conductor failure.
- Symmetrically aligned cables within the lead body and centrally located coil provide for additional protection to the inner coil.[2]
- The DF4 connector is designed to simplify implants by streamlining defibrillation connections into a single terminal pin and reducing the number of set screws.

Ordering Information

Contents: Defibrillation Lead

REORDER NUMBER	INSULATION	FIXATION	MINIMUM INTRODUCER (F)	SHOCK CONFIGURATION	SENSING	TIP-TO-PROXIMAL COIL (CM)	CONNECTOR§	LENGTH (CM)
7120	Optim	Ext/Ret Helix	7	Dual-coil	True bipolar	17	DF1; IS-1	60; 65
7120Q	Optim	Ext/Ret Helix	7	Dual-coil	True bipolar	17	DF4	52; 58+; 65+
7121	Optim	Ext/Ret Helix	7	Dual-coil	True bipolar	21	DF1; IS-1	60; 65; 75
7121Q	Optim	Ext/Ret Helix	7	Dual-coil	True bipolar	21	DF4	52; 58; 65
7122	Optim	Ext/Ret Helix	7	Single-coil	True bipolar	N/A	DF1; IS-1	60; 65; 75
7122Q	Optim	Ext/Ret Helix	7	Single-coil	True bipolar	N/A	DF4	52; 58+; 65+
7170	Optim	Tines	7	Dual-coil	True bipolar	17	DF1; IS-1	60; 65; 75
7170Q	Optim	Tines	7	Dual-coil	True bipolar	17	DF4	52; 58; 65
7171	Optim	Tines	7	Dual-coil	True bipolar	21	DF1; IS-1	60; 65; 75
7171Q	Optim	Tines	7	Dual-coil	True bipolar	21	DF4	52; 58; 65
7172Q	Optim	Tines	7	Single-coil	True bipolar	N/A	DF4	52; 58; 65

Indications for Use: The Durata™ transvenous leads are indicated for use with compatible pulse generators (refer to the applicable defibrillator manual for system indications). They provide pacing and sensing and deliver cardioversion/defibrillation therapy to the heart. A transvenous lead system may offer the patient the benefit of avoiding a thoracotomy for lead implantation. If the initial lead configuration is not effective, repositioning of the lead or other lead configurations should be attempted. In some patients, a nonthoracotomy lead configuration may not provide reliable conversion of arrhythmias, and the use of subcutaneous or epicardial patch defibrillation leads should be considered.

Contraindications: Contraindications for use of the Durata leads with an implantable pulse generator include ventricular tachyarrhythmias resulting from transient or reversible factors such as drug toxicity, electrolyte imbalance, or acute myocardial infarction. Transvenous lead systems are contraindicated for patients with tricuspid valvular disease or a mechanical heart valve. Durata leads are contraindicated for patients for whom a single dose of 1.0 mg of dexamethasone sodium phosphate is contraindicated. The Durata leads are contraindicated for extra firm (red color knob) stylets. The lead is not designed, sold, or intended for use other than as indicated.

Potential Complications: Possible complications of the use of transvenous lead systems include, but are not limited to, supraventricular or ventricular arrhythmias, conduction disturbances, cardiac perforation, cardiac tamponade, loss of contractility, air embolism, heart wall rupture, myocarditis, post-operative heart failure, chronic mechanical stimulation of the heart, tricuspid valve dysfunction, lead fracture necessitating surgical removal, pneumothorax, hemothorax, infection, tissue necrosis and erosion of the skin. Specific events and effects are summarised below:

WARNING: Implanted cardiac leads are subjected to a hostile environment within the body due to constant, complex flexural and torsional forces, interactions with leads and/or the pulse generator, or other forces associated with cardiac contractions and patient physical activity, posture and anatomical influences. Cardiac leads' functional lifetimes can be affected by these and other factors.

Refer to the defibrillator manual for additional complications and precautions specific to the pulse generator.

Durata™

Defibrillation Lead

Product Specifications

TRUE BIPOLAR, ACTIVE-FIXATION DEFIBRILLATION LEADS

Models	7120	7120Q	7121	7121Q	7122	7122Q
Fixation	Ext/Ret Helix	Ext/Ret Helix	Ext/Ret Helix	Ext/Ret Helix	Ext/Ret Helix	Ext/Ret Helix
Shock Configuration	Dual-Coil	Dual-Coil	Dual-Coil	Dual-Coil	Single-Coil	Single-Coil
Sensing Configuration	True Bipolar	True Bipolar	True Bipolar	True Bipolar	True Bipolar	True Bipolar
Min. Size Introducer	7 F	7 F	7 F	7 F	7 F	7 F
Lengths (cm)	60; 65	52; 58; 65	60; 65; 75	52; 58; 65	60; 65; 75	52; 58; 65
Connector	DF1; IS-1	DF4	DF1; IS-1	DF4	DF1; IS-1	DF4
Body Diameter	6,8 F	6,8 F	6,8 F	6,8 F	6,8 F	6,8 F
Tip-to-Anode Spacing	11 mm	11 mm	11 mm	11 mm	11 mm	11 mm
Tip-to-Proximal Coil	17 cm	17 cm	21 cm	21 cm	N/A	N/A
Tip Electrode Area	6 mm^2	6 mm^2	6 mm^2	6 mm^2	6 mm^2	6 mm^2
Steroid Plug	Yes	Yes	Yes	Yes	Yes	Yes
Distal Shock Coil Area	367 mm^2	367 mm^2	367 mm^2	367 mm^2	367 mm^2	367 mm^2
Proximal Shock Coil Area	588 mm^2	588 mm^2	588 mm^2	588 mm^2	N/A	N/A
MRI Conditional	No	Yes, MRI Ready (lengths: 58 and 65 cm)	No	No	No	Yes, MRI Ready (lengths: 58 and 65 cm)
MRI Whole-body SAR	N/A	2 W/kg	N/A	N/A	N/A	58 cm = 2 W/kg 65 cm = 1.6 W/kg

TRUE BIPOLAR, PASSIVE-FIXATION DEFIBRILLATION LEADS

Models	7170	7170Q	7171	7171Q	7171Q
Fixation	Tines	Tines	Tines	Tines	Tines
Shock Configuration	Dual-Coil	Dual-Coil	Dual-Coil	Dual-Coil	Single-Coil
Sensing Configuration	True Bipolar	True Bipolar	True Bipolar	True Bipolar	True Bipolar
Min. Size Introducer	7 F	7 F	7 F	7 F	7 F
Lengths (cm)	60; 65; 75	52; 58; 65	60; 65; 75	52; 58; 65	52; 58; 65
Connector	DF1; IS-1	DF4	DF1; IS-1	DF4	DF4
Body Diameter	6,8 F	6,8 F	6,8 F	6,8 F	6,8 F
Tip-to-Anode Spacing	11 mm	11 mm	11 mm	11 mm	11 mm
Tip-to-Proximal Coil	17 cm	17 cm	21 cm	21 cm	N/A
Tip Electrode Area	3.5 mm^2	3.5 mm^2	3.5 mm^2	3.5 mm^2	3.5 mm^2
Steroid Plug	Yes	Yes	Yes	Yes	Yes
Distal Shock Coil Area	367 mm^2	367 mm^2	367 mm^2	367 mm^2	367 mm^2
Proximal Shock Coil Area	588 mm^2	588 mm^2	588 mm^2	588 mm^2	N/A
MRI Conditional	No	No	No	No	No
MRI Whole-body SAR	N/A	N/A	N/A	N/A	N/A

*MRI Conditional Field Strength, 1,5 Tesla.
†See MRI Procedure Information for approved MR Conditional Systems Device/Lead combinations and scan parameters
§Abbott DF1 lead connectors conform to the international connector standard ISO 11318/Amd. Abbott IS-1 lead connectors conform to the international connector standard ISO 5841. Abbott DF4 lead connectors conform to the international connector standard ISO 27186: 2010 (E).
+Indicates lead lengths that are MRI Conditional.*,†

1. Jenney C, Tan J, Karicherla A, Burke J, Helland J. A New Insulation Material for Cardiac Leads with Potential for Improved Performance. *Heart Rhythm*. 2005;2:S318-S319.
2. Abbott. Engineering Report: Tension and Cable Shortening Comparison. Report 60032635.

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Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

28818-SJM-DUR-1114-0001(2) | Information contained herein intended for audiences from outside the United States only.

Abbott

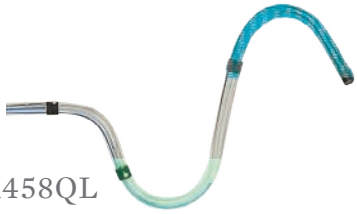
Quartet™ Family

Left-heart Leads

1458Q

1456Q

1457Q



1458QL

Product Highlights

- Proven Quartet™ LV lead performance with the most Quadripolar lead options to match a patient's anatomy
- The Quartet™ Family of LV leads offers more distal shape options including the Large-S, Small-S and Double Bend and more total electrode spacing options including 40, 47 and 60 mm
- Allows patients to safely undergo an MRI scan when used in combination with an Abbott MRI Ready device[1,2]
- Four pacing electrodes to provide more options and greater control in pacing vector selection
- Superb deliverability with exceptional stability and performance
- Low profile—4,7 F lead body; 4,0 F lead tip
- Optim™ lead insulation—a chemical co-polymer that blends the best features of polyurethane and silicone for improved handling and increased durability
- Steerable tip—distal tip angle can be controlled to maneuver through venous anatomy
- Flexible lead body—narrow ring electrodes provide lead tip flexibility
- Allows Direct-To-Target™ delivery placement through CPS Aim™ SL slittable inner catheter to deliver leads to small, acute venous anatomies that may have been unreachable in the past
- Compatible with over-the-wire or stylet approaches

Ordering Information

Contents: Left-heart Lead

MODEL NUMBER	SHAPE	TT	INSULATION	MINIMUM CURVE HEIGHT	MINIMUM INTRODUCER (F)	CONNECTOR	LENGTHS (CM)
1458Q	Large-S	47	Optim™	16	5	IS4-LLLL	75; 86*; 92
1456Q	Small-S	40	Optim™	8	5	IS4-LLLL	75; 86*
1457Q	Double Bend	47	Optim™	16	5	IS4-LLLL	75; 86*
1458QL	Large-S	60	Optim™	16	5	IS4-LLLL	75; 86*

*Indicates models that are MRI conditional.[1,2]

Indications and Usage: The Quartet LV lead has application as part of an Abbott biventricular system.

Contraindications: The use of the Quartet LV lead is contraindicated in patients who:

- Are expected to be hypersensitive to a single dose of 1,0 mg of dexamethasone sodium phosphate.
- Are unable to undergo an emergency thoracotomy procedure.
- Have coronary venous vasculature that is inadequate for lead placement, as indicated by venogram.

Quartet™ Family
Left-heart Leads

Physical Specifications

PARAMETER	DESCRIPTION	DESCRIPTION	DESCRIPTION	DESCRIPTION
Models	**1458Q**	**1456Q**	**1457Q**	**1458QL**
Connector	IS4-LLLL	IS4-LLLL	IS4-LLLL	IS4-LLLL
Lead Length	75; 86; 92 cm	75; 86 cm	75; 86 cm	75; 86 cm
Maximum Lead Size	5,1 F (1,70 mm/0,067″) at the ring electrode	5,1 F (1,70 mm/0,067″) at the ring electrode	5,1 F (1,70 mm/0,067″) at the ring electrode	5,1 F (1,70 mm/0,067″) at the ring electrode
Lead Body Size	4,7 F (1,57 mm/0,062″)	4,7 F (1,57 mm/0,062″)	4,7 F (1,57 mm/0,062″)	4,7 F (1,57 mm/0,062″)
Tip Electrode Size	4,0 F (1,3 mm/0,052″)	4,0 F (1,3 mm/0,052″)	4,0 F (1,3 mm/0,052″)	4,0 F (1,3 mm/0,052″)
LV Lead Delivery System Introducer Size	Minimum 5 F ID	Minimum 5 F ID	Minimum 5 F ID	Minimum 5 F ID
Minimum Curve Height	16 mm	8 mm	16 mm	16 mm
Tip Electrode	Pt/Ir; TiN coated; ring-shaped; two grooves	Pt/Ir; TiN coated; ring-shaped; two grooves	Pt/Ir; TiN coated; ring-shaped; two grooves	Pt/Ir; TiN coated; ring-shaped; two grooves
Steroid	Dexamethasone sodium phosphate	Dexamethasone sodium phosphate	Dexamethasone sodium phosphate	Dexamethasone sodium phosphate
Tip Electrode Surface Area	4,9 mm^2	4,9 mm^2	4,9 mm^2	4,9 mm^2
Ring Electrode Surface Area	7,4 mm^2	7,4 mm^2	7,4 mm^2	7,4 mm^2
Electrode Spacing				
Distal Tip 1 – Mid 2	20 mm	20 mm	20 mm	20 mm
Distal Tip 1 – Mid 3	30 mm	30 mm	30 mm	47 mm
Distal Tip 1 – Proximal 4	47 mm	40 mm	47 mm	60 mm
Lead Body Insulation	Optim™ lead insulation	Optim™ lead insulation	Optim™ lead insulation	Optim™ lead insulation
Lead Body Coating	Fast-Pass™ coating	Fast-Pass™ coating	Fast-Pass™ coating	Fast-Pass™ coating
Conductors				
Distal (coil)	MP35N‡ LT	MP35N‡ LT	MP35N‡ LT	MP35N‡ LT
Proximal (cables)	ETFE; MP35N LT	ETFE; MP35N LT	ETFE; MP35N LT	ETFE; MP35N LT
Suture Sleeve	Attached	Attached	Attached	Attached
MRI Conditional	Yes, MRI Ready (length: 86 cm)	Yes, MRI Ready (length: 86 cm)	Yes, MRI Ready (length: 86 cm)	Yes, MRI Ready (length: 86 cm)

1. MRI conditional parameters: 1,5 Tesla, 2 W/Kg SAR.
2. See MRI Ready Systems Manual for approved MR conditional systems device/lead combinations and scan parameters.

Customer Support: 46-8-474-4756

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Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

28905-SJM-QRT-1015-0011(3)
Information contained herein intended for audiences from outside the United States only.

Abbott

CPS Direct™ SL II

Slittable Outer Guide Catheter

Product Highlights

- Integrated hub and hemostasis valve
- Increased curve retention and optimized catheter body structure for improved kink resistance
- Soft tip to lessen risk of traumatic insertion

Ordering Information

Contents: Dilator and Two Valve Bypass Tools

MODEL NUMBER	CURVE SHAPE	AVAILABLE LENGTH (CM)	OVERALL LENGTH (CM)	INNER DIAMETER (F/MM)	OUTER DIAMETER (F/MM)
DS2C001	Straight	47	50,7	7/2,44	9/3,00
DS2C002	115º	47	50,7	7/2,44	9/3,00
DS2C003	135º	47	50,7	7/2,44	9/3,00
DS2C004	Wide	47	50,7	7/2,44	9/3,00
DS2C005	X-Wide	47	50,7	7/2,44	9/3,00
DS2C006	Right Side	47	50,7	7/2,44	9/3,00
DS2C011	Straight	54	57,7	7/2,44	9/3,00
DS2C012	115º	54	57,7	7/2,44	9/3,00
DS2C013	135º	54	57,7	7/2,44	9/3,00
DS2C014	Wide	54	57,7	7/2,44	9/3,00
DS2C015	X-Wide	54	57,7	7/2,44	9/3,00

Straight 115º 135º Wide Extra Wide Right Side

Separately Available Accessories

MODEL NUMBER	NAME	TYPE
DS2A003	CPS™ Universal Slitter	Slitter
DS2A004	CPS Direct™ SL Valve Bypass Tool	Valve bypass tool

Customer Support: 46-8-474-4756
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Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

28047-SJM-CPS-1115-0005(2) | Item approved for international use only.

Abbott

CPS Direct™ PL

Peelable Outer Guide Catheter

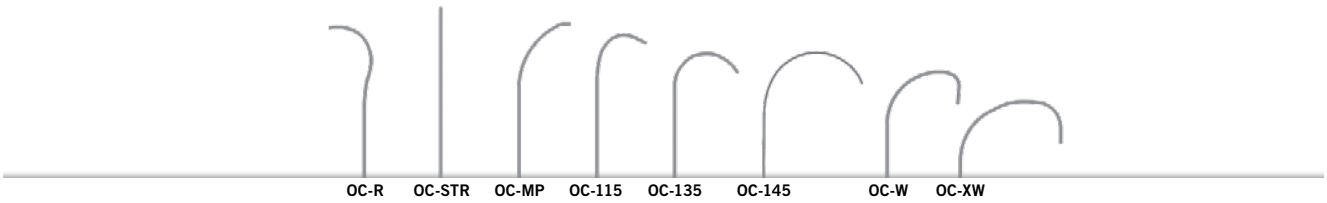
Product Highlights

- Unique SiteMark™ tungsten marker stripes provide superior fluoroscopic visibility to verify torque transfer
- Compatible with CPS Aim™ inner catheter and CPS Luminary™ bideflectable catheter with lumen to modify shape and extend reach if necessary
- EvenPeel™ stripes provide more smooth and reliable peeling for worry-free sheath removal

Ordering Information

Contents: Sheath with hemostasis valve attached, dilator and 2 valve bypass tools

MODEL NUMBER	CURVE SHAPE	AVAILABLE LENGTH (CM)	OVERALL LENGTH (CM)	INNER DIAMETER (F/MM)	OUTER DIAMETER (F/MM)
410210	Straight (OC-STR)	47	50,7	7/2,44	9/3,00
410211	Multipurpose (OC-MP)	47	50,7	7/2,44	9/3,00
410212	115° (OC-115)	47	50,7	7/2,44	9/3,00
410213	135° (OC-135)	47	50,7	7/2,44	9/3,00
410214	Wide (OC-W)	47	50,7	7/2,44	9/3,00
410215	Extra Wide (OC-XW)	47	50,7	7/2,44	9/3,00
410216	Right Sided (OC-R)	47	50,7	7/2,44	9/3,00
410224	145° (OC-145)	47	50,7	7/2,44	9/3,00
410217	Straight (OC-STR)	54	57,7	7/2,44	9/3,00
410218	Multipurpose (OC-MP)	54	57,7	7/2,44	9/3,00
410219	115° (OC-115)	54	57,7	7/2,44	9/3,00
410220	135° (OC-135)	54	57,7	7/2,44	9/3,00
410221	Wide (OC-W)	54	57,7	7/2,44	9/3,00
410222	Extra Wide (OC-XW)	54	57,7	7/2,44	9/3,00
410223	Right Sided (OC-R)	54	57,7	7/2,44	9/3,00
410225	145° (OC-145)	54	57,7	7/2,44	9/3,00



Separately Available Accessories

MODEL NUMBER	NAME	TYPE
410194	CPS Direct™ PL Valve Bypass Tool (Pack of 2)	Valve bypass tool
410195	CPS Direct™ PL Inner Catheter SafeSheath™ Sealing Adapter	Self-sealing valve
410190	CPS™ Implant Kit (Includes Needle, Syringe and 0,035″ Guidewire)	Implant Kit

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Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

28810-SJM-CPS-1115-0004(1)

Information contained herein intended for audiences from outside the United States only.

Abbott

CPS Courier™

Guidewires

Product Highlights

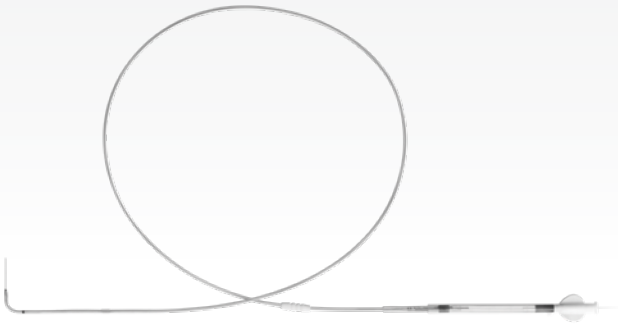
- Helps physicians more easily subselect the target coronary branch vein and deliver the LV lead to its preferred destination

Ordering Information

Model Number	Distal Support	Length (cm)	Units per box	Diameter (in)
DS2G001	Soft	195	5	0,014
DS2G002	Medium	195	5	0,014
DS2G003	Firm	195	5	0,014
DS2G004	Extra Firm	195	5	0,014

CPS Duo™

Stylet Guidewire System



Product Highlights

- Enables optimal subselection of the branch vein and offers greater maneuverability and control of the LV lead

Ordering Information

Model Number	Type	Length (cm)	Diameter (in)
DS2M001	CPS Duo™ Stylet	75; 86	OD: 0,014" LV lead lumen compatible ID: 0,012" compatible
DS2M006	CPS Duo™ Guidewire	195	0,012"

Customer Support: 46-8-474-4756

Abbott
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Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

27099-SJM-CPS-1115-0003(1) | Item approved for international use only.

Abbott

Merlin™ Pacing System Analyzer (PSA) Resterilizable Cable Model EX3150 is Obsolete

Purpose:

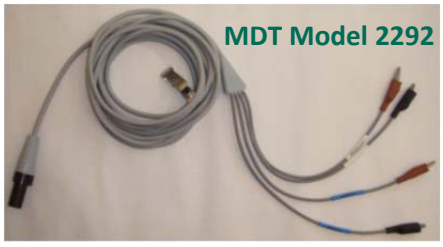
The purpose of this memo is to inform you that the Model EX3150 resterilizable PSA cable inventory is depleted and the product is now obsolete. We have decided to leverage the resources to develop the next generation PSA and accessories.

Model EX3150

Replacement Adapters and Cables:

For centers that are committed to using resterilizable cables we offer an adapter Model EX3180 that is compatible with the Medtronic Model 2292 resterilizable cable

Model EX3180



MDT Model 2292

For other centers, please start ordering adapters and disposable cables as a substitute for the resterilizable PSA Cable. There are two available adapters EX3170 Merlin™ PSA Cable Adapter (3-chamber) and 4053 Merlin™ PSA Cable Adapter (2-chamber).

Model EX3170

Model 4053

The disposable cable is available to order in multiples of 1 each. The Model 4051L is the alligator style cable that is compatible with all leads, including the IS4/DF4 with the testing sleeve.

The testing sleeve is available in Optisure leads packaging and is planned to be including in other IS4 leads when globally approved. The IS4/DF4 testing sleeve (Model EX3151) is available through customer service as an accessory in multiples of 1 each.

Model 4051L

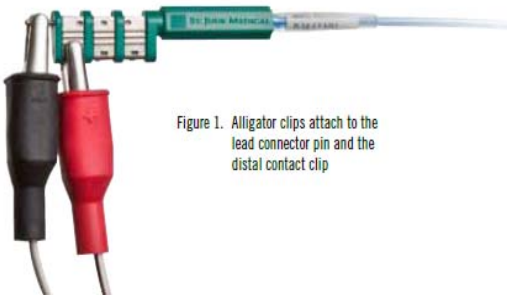
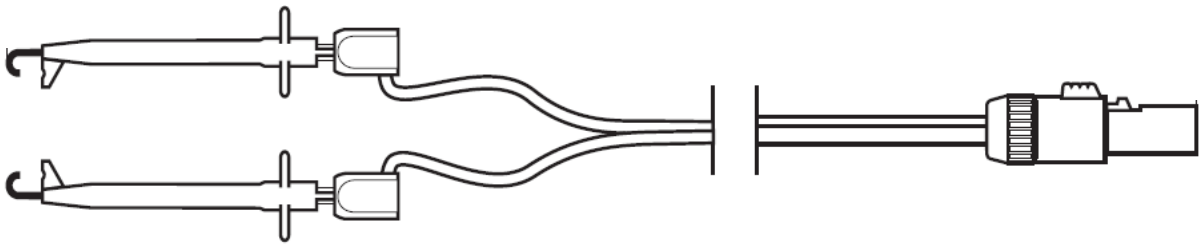


Figure 1. Alligator clips attach to the lead connector pin and the distal contact clip

The 4161 is another option of disposable cables but has a hook instead of an alligator connection.



Model 4161

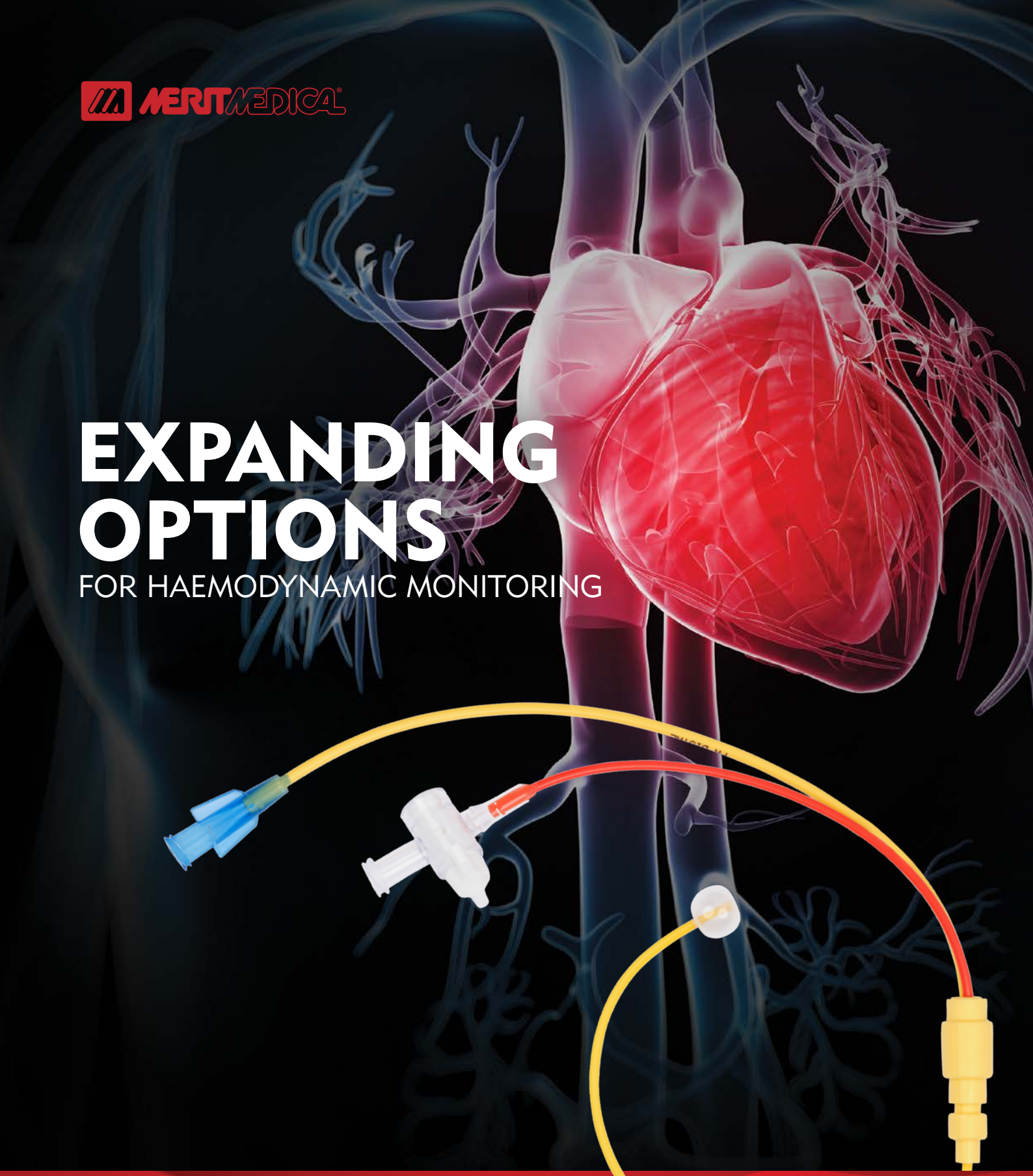
Please contact Technical Service Support for clarification on the PSA cable options that are available

- **Phone:** +46 8 474 4147
- **Email:** technical.support@sjm.com

MERIT MEDICAL®

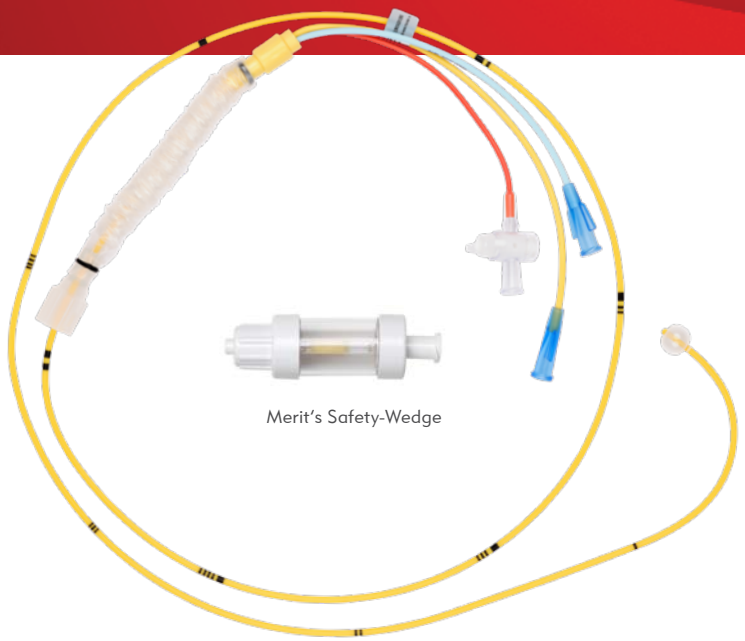
EXPANDING OPTIONS

FOR HAEMODYNAMIC MONITORING



Merit Pulmonary Artery and Thermodilution Catheters

Merit Pulmonary Artery and Thermodilution Catheters



Merit's Safety-Wedge

Monitoring Life™

- Utilize multiple lumens to meet advanced monitoring needs.
- Merit's unique Safety-Wedge prevents over-pressurization and potential pulmonary artery rupture.
- Contamination shield provides additional barrier for infection control.
- Available in 5–7.5 French catheters, with 2–5 lumens.

THERMODILUTION CATHETERS

Product Code	French Size	Lumens	Length	Accepted Guide Wire	Special Features	Units per Box
Polyurethane Material/Standard						
TD2504NDXF	5F	4	90 cm	.018" Wire	Safety Wedge	5
TD2604NDXF	6F	4	110 cm	.025" Wire	Safety Wedge	5
TD2604NXF	6F	4	110 cm	.025" Wire	-	5
TD2704NDF	7F	4	110 cm	.025" Wire	Safety Wedge/ Sleeve	5
TD2704NXF	7F	4	110 cm	.025" Wire	-	5
TD2755NDF	7.5F	5	110 cm	.025" Wire	Safety Wedge/ Sleeve	5
TD2755NDPXF	7.5F	5	110 cm	.025" Wire	Safety Wedge/ Paceport	5
TD2755NXF	7.5F	5	110 cm	.025" Wire	-	5
Polyurethane Material/S-Curve Tip						
TD2704NCXF	7F	4	110 cm	.025" Wire	-	5
Polyurethane Material/Soft Body						
TD2755NX	7.5F	5	110 cm	.025" Wire	-	5

PULMONARY ARTERY CATHETERS

Product Code	French Size	Lumens	Length	Accepted Guide Wire	Units per Box
Polyurethane Material					
TD2502NXF	5F	2	90 cm	.018" Wire	5
TD2602NXF	6F	2	110 cm	.025" Wire	5
TD2702NXF	7F	2	110 cm	.025" Wire	5
CL2702NXF	7F	2	110 cm	.025" Wire	5
TD2703NF	7F	3	110 cm	.025" Wire	5

CRITIKIT™ ICE/ROOM TEMPERATURE INJECTATE SYSTEMS AND ACCESSORIES

Product Code	Description	Sterile	Box/Case Content (Units)
680000	Ice/Room temperature Injectate Critikit (with in-line sensor, control syringe & cooling coil)	Yes	4/8
680006	In-line injectate sensor housing	Yes	25/250
680178	Ice/Room temperature Injectate Critikit (with in-line sensor and control Syringe, without cooling coil)	Yes	5/20
682252	10 mL control syringe	Yes	10/50

CRITICATH® PULMONARY ARTERY CATHETERS

Product Code	Model	Size	Length	No. of Lumens	PA Wedge Pressure	CV Pressure	Cardiac Output	CVP Medic Port	Aditional Information	Box/Case Content (units)
680372	SP5325	5F	80 cm	2	Yes	No	No	No	Monitoring Catheter	5/20
680373	SP5325L	5F	110 cm	2	Yes	No	No	No	Monitoring Catheter	5/20
680374	SP5327	7F	110 cm	2	Yes	No	No	No	Monitoring Catheter	5/20

CRITICATH® THERMODILUTION CATHETERS

Product Code	Model	Size	Length	No. of Lumens	PA Wedge Pressure	CV Pressure	Cardiac Output	CVP Medic Port	Aditional Information	Box/Case Content (units)
680349	SP5105	5F	80 cm	4	Yes	Yes	Yes		PVC Catheter Material	5/20
680103	SP5107U	7F	110 cm	4	Yes	Yes	Yes			5/20
680381	SP5107U–14	7F	110 cm	4	Yes	No	No		Pre-mounted Luer-Lok™ AC shield	5/20
680382	SP5107U + SP5045	7F	110 cm	4	Yes	Yes	Yes		Pre-mounted In-Line Inject, sensor	5/20
680378	SP5507U	7.5F	110 cm	5	Yes	Yes	Yes	Yes		5/20
680379	SP5507U–14	7.5F	110 cm	5	Yes	Yes	Yes	Yes	Pre-mounted Luer-Lok™ AC shield	5/20
680380	SP5507U + SP5045	7.5F	110 cm	5	Yes	Yes	Yes	Yes	Pre-mounted In-Line Inject, sensor	

Before using refer to Instructions for Use for indications, contraindications, warnings, precautions, and directions for use.

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