CRM PRODUCT CATALOG

CRT-D

Abbott

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CRT-D

Quadra Assura MP™

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]
- MultiPoint™ pacing delivers multiple LV pacing pulses per cardiac cycle and is designed to improve haemodynamic 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
- 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
- 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 is 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
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.

Product Specifications

PHYSICAL SPECIFICATIONS

Models	CD3371-40QC
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
Coating	Parylene
MR Conditional	Yes, MRI Ready

PARAMETER	SETTINGS
Biventricular Pacing	
VectSelect Quartet™ LV pulse configuration	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 Optimization	Sensed/paced AV delay, interventricular pace delay
V-V Timing	Simultaneous3; 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; (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;	Setup; On; Monitor; Off
RVCap™ Confirm	On; Monitor; Off
ACap™ Confirm	Interventricular Pace delay
QuickOpt™ Timing Cycle Optimization	Off; DDI(R); DDT(R); VVI(R); VVT(R)
Auto Mode Switch (AMS)	
Atrial Tachycardia Detection Rate (min^{-1})	110-300 40; 45; ... 135
AMS Base Rate (min^{-1})	Atrial Pace; Off; Passive
Auto PMT Detection/Termination	Off; Low; Medium; High
Rate Responsive PVARP/VREF	Off; On (50–200)
Ventricular Intrinsic Preference (VIP™)	
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 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, 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
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

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.

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

Unify Quadra™

Cardiac Resynchronisation Therapy Defibrillator (CRT-D)

Merlin@home™ Transmitter Compatible

Product Highlights

- The Unify Quadra CRT-D and Quartet™ quadripolar LV 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
- Downsized device for a smaller footprint
- The 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
- ShockGuard™ technology with DecisionTx™ programming designed to reduce inappropriate therapy and minimise the need for programming adjustments at implant
- 40 J delivered energy provides unsurpassed energy for defibrillation
- Streamlined header connectors (IS4-LLLL/DF4-LLHH) reduce pocket bulk
- QHR‡ chemistry battery provides greater capacity for enhanced longevity and improved charge time performance

Ordering Information

Contents: Cardiac Pulse Generator

MODEL NUMBER	DIMENSIONS (H × W × T, MM)	WEIGHT (G)	VOLUME (CC)	CONNECTOR
CD3251-40	83 × 41 × 14	83	40	DF1, IS4, IS-1
CD3251-40Q	75 × 41 × 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, death, 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.

Product Specifications

PHYSICAL SPECIFICATIONS

Models		
Telemetry	RF	RF
Delivered Energy (J)	40	40
Volume (cc)	40	38
Weight (g)	83	80
Size (mm)	83 × 41 × 14	75 × 41 × 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

PARAMETER	SETTINGS
Biventricular Pacing	
VectSelect Quartet™ Programmable LV Pulse Configuration	Distal Tip 1 - Mid 2; Distal Tip 1 - Proximal 4; Distal Tip 1 - RV Coil; 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 (BiV Trigger Mode)	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™ Algorithm Pacing	On; Off
No. of Overdrive Pacing Cycles	15-40 in steps of 5
Maximum AF Suppression Rate	80-150 min^{-1}
SenseAbility™ 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	VT-1; VT-2; VF
SVT Discriminators	AV Rate Branch; Sudden Onset; Interval Stability; Morphology Discrimination (MD) with Manual or Automatic Template Update
Reconfirmation	Continuous sensing during charging
Antitachycardia Pacing Therapy	
ATP Configurations	Ramp; Burst; Scan; 1 or 2 schemes per zone
ATP in VF Zone	ATP While Charging; ATP Prior to Charging; Off
ATP Upper Rate Cutoff	200-400 ms
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
High-Voltage Therapy	
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
Permanent Modes	Off; DDD(R); DDT(R); DDI(R); VVT(R); VVI(R); AAI(R)
Temporary Modes	Off; DDD(R); DDT(R); DDI(R); VVT(R); VVI(R); AAI(R); 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
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; 50-200 (50-150 in increments of 25; 160-200 in increments of 10)
BiVCap™ Confirm; LVCap™ Confirm Feature	Setup; On; Monitor; Off
RVCap™ Confirm Feature	Setup; On; Monitor; Off
ACap™ Confirm Feature	On; Monitor; Off
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
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 3 extra stimuli
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 Monitoring Trigger
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
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; and morphology template verification
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
PMT Data	Information regarding PMT detections
Real-time Measurements (RTM)	Pacing lead impedances; high-voltage lead impedances; signal amplitudes
CorVue™ Congestion Monitoring	On; Off
CorVue Congestion Trigger	8-18 days

*LV first with 10 ms interventricular delay

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.

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.

Unify™

Cardiac Resynchronisation Therapy Defibrillator (CRT-D) with CorVue™ Congestion Monitoring

Product Highlights

- Advanced Biventricular (BiV) Pacing options.
  - VectSelect™ programmable LV pulse configuration (LV ring — RV coil, LV tip — RV coil or LV bipolar) may be adjusted noninvasively via the programmer.
  - Triggered Pacing with BiV Trigger Mode helps maintain a high percentage of BiV pacing by triggering pacing in both the left and right ventricles in response to a sensed ventricular event.
  - Negative AV hysteresis with search promotes ventricular pacing by automatically reducing the AV delay when intrinsic activity is present, thereby promoting a high degree of ventricular pacing.
- The 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.
- Unique 40 J Safety Shock option, delivered energy, provides a greater DFT safety margin and may minimise the need for multiple DFT tests at implant.
- The DF4 connector is designed to simplify implants by streamlining defibrillation connections into a single terminal pin and reducing the number of set screws.
- QHR‡ chemistry battery provides greater capacity for enhanced longevity and charge times.
- The addition of antitachycardia pacing (ATP) while charging and prior to charging in the VF zone further extends the programming options for converting tachyarrhythmias before or during charge.
- The % BiV-Pacing alert notifies patients and their clinics when percent biventricular pacing is less than the programmed threshold.
- The Low Frequency Attenuation filter is designed to enhance sensing performance and may reduce the possibility of oversensing T waves.
- BiVCap™, LVCap™, RVCap™ and ACap™ Confirm features promote patient safety by automatically ensuring capture of the myocardium in response to pacing stimuli in the left ventricle, right ventricle and right atrium.
- DeFT Response™ technology tools provide more clinically proven, noninvasive options for managing high DFTs.
  - Programmable pulse widths allow the user to tailor the shock to the individual patient, making shocks more efficacious.[1]
  - SVC shocking electrode can be quickly and noninvasively activated or deactivated with the press of a button.
  - 40 J delivered energy provides unsurpassed energy for defibrillation.
  - Four programmable tilt options are available to accommodate variances among patients.[2]
- Unique Sense*Ability*™ sensing algorithm feature, with Decay Delay and Threshold Start, provides the flexibility to fine-tune sensing to individual patient needs.
- QuickOpt™ Timing Cycle Optimisation provides quick and effective optimisation for more patients at the push of a button.[3]
- Unique Morphology Discrimination plus AV Rate Branch SVT discrimination feature helps reduce the risk of inappropriate ICD shocks and is intended to promote fast, accurate diagnosis and delivery of therapy. Clinical data states that this combination resulted in a sensitivity of 100% with a specificity of 85%.[4]
- Unique AF Suppression™ algorithm is clinically proven to suppress episodes of paroxysmal and persistent AF.
  - Studies show a 25% decrease in symptomatic AF burden.[5]
- AT/AF Alerts notify patients and their 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.
- Up to 45 minutes of continuous, fully annotated stored electrograms, including up to 60 seconds of pretrigger information per electrogram.
- Unique Vibratory Patient Notifier allows even patients with hearing problems to be alerted to a low battery, lead-related complications and more.
- Automatic Daily High-Voltage (HV) Lead Integrity Test is designed to automatically test the HV lead on a daily basis to ensure therapy delivery for optimal patient safety.
- Multiple hardware and software system safeguards are included for added security and patient comfort.
- Decreased device footprint and volume with the most narrow (40 mm) design available for greater patient comfort and range of motion during activity.

Ordering Information

Contents: Cardiac Pulse Generator

MODEL NUMBER	DIMENSIONS (H × W × T, MM)	WEIGHT (G)	VOLUME (CC)	CONNECTOR DEFIBRILLATION	CONNECTOR SENSE/PACE
CD3235-40	79 × 40 × 14	78	36	DF1	IS-1
CD3235-40Q	73 × 40 × 14	77	36	DF4	IS-1; DF4

Unify™

Cardiac Resynchronisation Therapy Defibrillator (CRT-D) with CorVue™ Congestion Monitoring

Product Specifications

PHYSICAL SPECIFICATIONS

Models	CD3235-40	CD3235-40Q
Telemetry	RF	RF
Delivered/Stored Energy (J)	40/45	40/45
Volume (cc)	36	36
Weight (g)	78	77
Size (mm)	79 × 40 × 14	73 × 40 × 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

PARAMETER	SETTINGS
Biventricular Pacing	
V. Triggering (BiV Trigger Mode)	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
VectSelect™ LV Programmable Pulse Configuration	LV tip to RV coil; LV bipolar; LV ring to RV coil
AF Management	
AF Suppression™ Algorithm Pacing	On; Off
No. of Overdrive Pacing Cycles	15–40 in steps of 5
Maximum AF Suppression Algorithm Rate	80–150 min^{-1}
Sensing/Detection	
Sense*Ability*™ Sensing Algorithm 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	VT-1; VT-2; VF
SVT Discriminators	AV Rate Branch; Sudden Onset; Interval Stability; Morphology Discrimination (MD) with Manual or Automatic Template Update
Reconfirmation	Continuous sensing during charging
Antitachycardia Pacing Therapy	
ATP Configurations	Ramp; Burst; Scan; 1 or 2 schemes per zone
ATP in VF Zone	ATP While Charging; ATP Prior to Charging; Off
ATP Upper Rate Cutoff	150–300 bpm
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
High-Voltage Therapy	
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
Bradycardia Pacing	
Permanent Modes	Off; DDD(R); DDT(R); DDI(R); VVT(R); VVI(R); AAI(R)
Temporary Modes	Off; DDD(R); DDT(R); DDI(R); VVT(R); VVI(R); AAI(R); 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
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; 50–200 (50–150 in increments of 25; 160–200 in increments of 10)
LVCap™ Confirm; RVCap™ Confirm	Setup; On; Monitor; Off
ACap™ Confirm Features	On; Monitor; Off
Post-Therapy Pacing (Independently Programmable from Bradycardia and ATP)	
Post-Shock Pacing Mode	Off; AAI; VVI; DDI; 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 Monitoring Trigger
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 pretrigger data per VT/VF diagnosis/detection electrograms; triggers include: diagnosis; therapy; atrial episode; PMT termination; PC shock delivery; noise reversion; magnet reversion; and morphology template verification
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
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 Trigger	8–18 days

*LV first with 10 ms interventricular delay.

1. Mouchawar G, Kroll M, Val-Mejias JE et al. ICD waveform optimization: a randomized prospective, pair-sampled multicenter study. *PACE* 2000;23 (Part II):1992-1995.
2. Sweeney MO, Natale A, Volosin KJ et al. Prospective randomized comparison of 50%/50% versus 65%/65% tilt biphasic waveform on defibrillation in humans. *PACE* 2001;24:60-65.
3. Baker JH, Mckenzie J, Beau S et al. Acute evaluation of programmer-guided AV/PV and VV delay optimization comparing an IEGM method and echocardiogram for cardiac resynchronization therapy in heart failure patients and dual-chamber ICD implants. *Journal of Cardiovascular Electrophysiology* 2007;18:185-191.
4. Sperzel J, Meine M et al. A new automatic update function of the morphology template used for SVT/VT discrimination in an ICD. *Europace Supplements* 2002;3:A131, #1515.
5. Carlson MD et al. A new pacemaker algorithm for the treatment of atrial fibrillation: results of the Atrial Dynamic Overdrive Pacing Trial (ADOPT). *JACC* 2003;42:627-633.

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.

Warnings and Precautions:
Implantation Procedure. The physician should be familiar with all components of the system and the material in this manual before beginning the procedure. Ensure that a separate standby external defibrillator is immediately available.

Implant the pulse generator no deeper than 5 cm to ensure reliable data transmission. For patient comfort, do not implant the pulse generator within 1,25 cm of bone unless you cannot avoid it.

Device Replacement. Replace the pulse generator within three months of reaching the ERI indication. Replace the pulse generator immediately upon reaching ERI if there is frequent high-voltage charging and/or one or more of the pacing outputs are programmed above 2,5 V.

Battery Incineration. Do not incinerate pulse generators as they contain sealed chemical power cells and capacitors that may explode. Return explanted devices to Abbott.

High-Voltage Can. Ensure that tachyarrhythmia therapy is programmed Off before handling the pulse generator to avoid any risk of accidental shock. Do not program tachyarrhythmia therapies On until the pulse generator is inserted in the pocket. For effective defibrillation, perform all defibrillation testing with the can in the pocket.

Magnetic Resonance Imaging (MRI). Avoid MRI devices because of the magnitude of the magnetic fields and the strength of the radiofrequency (RF) fields they produce.

Device Storage. Store the pulse generator at temperatures between 10° and 45°C. Do not subject it to temperatures below -20° or over 60°C. After cold storage, allow the device to reach room temperature before charging the capacitors, programming, or implanting the device because cold temperature may affect initial device function.

Device Communication. Communication with the device can be affected by electrical interference and strong magnetic fields. If this is a problem, turn off nearby electrical equipment or move it away from the patient and the programmer. If the problem persists, contact Abbott.

Lead Impedance. Do not implant the pulse generator if the acute defibrillation lead impedance is less than 20 ohms or the lead impedance of chronic leads is less than 15 ohms. Damage to the device may result if high-voltage therapy is delivered into an impedance less than 15 ohms.

Suboptimal RF Communication. The Merlin™ Patient Care System (PCS) indicates the quality of the RF communication by the telemetry strength indicator LEDs on both the programmer and the Merlin™ Antenna.

Disconnecting Leads. Connecting or disconnecting sense/pace leads can produce electrical artifacts that can be sensed by the pulse generator. To prevent detection of artifacts, reprogram the pulse generator to tachyarrhythmia therapy

Off: before disconnecting the leads from a pulse generator in the operating room; before a post-mortem examination; whenever there are no leads connected to it; when sense/pace leads are connected but are not implanted in a patient.

If a programmer is not available, use a magnet to prevent delivery of tachyarrhythmia therapy in response to detected disconnection artifacts. Place the magnet over the pulse generator before disconnecting the leads. Do not remove it until the leads are reconnected.

External Equipment for Arrhythmia Induction. If external equipment is used for arrhythmia induction through the pulse generator header and leads, apply rectified AC current through the high-voltage ports, not the sense/pace ports, to avoid damaging the sense/pace function: disconnect the external equipment from the pulse generator before any therapy is delivered; otherwise, damage to the device is likely to occur. Place a magnet over the device until the external equipment can be disconnected.

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.

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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.

35827 MAT-1901389 v1.0 | Information contained herein intended for audiences from outside the United States only.

Abbott

CRM PRODUCT CATALOG

CRT-P

Abbott

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CRT-P

Quadra Allure MP™

Cardiac Resynchronization Therapy Pacemaker

MR

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
- Allows patients to undergo MRI scans when used with MRI Ready leads from Abbott*
- The Quadra Allure MP™ CRT-P and Quartet™ quadripolar LV pacing lead feature four pacing electrodes and 14 pacing vectors to provide more options and greater control to address complications at and post implant to improve CRT response
- SyncAV™ CRT technology dynamically adjusts AV delays based on patient's intrinsic conduction to encourage patient-tailored biventricular pacing
- Elevate Response Easily with Auto VectSelect Quartet™ Test offering an efficient workflow for complete results and programming at the touch of a button
- 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
- Longevity offers 8,2 years of service life supported by a six year warranty*†

Ordering Information

Contents: Cardiac Pulse Generator

MODEL NUMBER	DIMENSIONS (H x W x T, MM)	WEIGHT (G)	VOLUME (CC)	CONNECTOR
PM3562	56 x 59 x 6	26	15	1S4-LLLL, 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/SO735-10097(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

†Battery impact of MultiPoint™ Pacing is dependent upon the output of the LV2 Pulse (for example LV2 = 2,5 V 0,4 ms results in an approximate 18% longevity impact.)

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.

Product Specifications

PHYSICAL SPECIFICATIONS

Models	PM3562
Telemetry	RF
Dimensions (mm)	56 x 59 x 6
Weight (g)	27
Volume (cc)[1]	15
Connector	IS4-LLLL, IS-1
MRI Conditional	Yes, MRI Ready

PARAMETER	SETTINGS
Resynchronization Therapy	
VectSelect Quartet™ LV Pulse Configuration	Distal Tip 1–Mid 2; Distal Tip 1–Proximal 4; Distal Tip 1–RV Ring; Mid 2–Proximal 4; Mid 2–RV Ring; Mid 3–Mid 2; Mid 3–Proximal 4; Mid 3–RV Ring; Proximal 4–Mid 2; Proximal 4–RV Ring; Distal Tip 1–Can; Mid 2–Can; Mid 3–Can; Proximal 4–Can
MultiPoint™ pacing Settings	LV1; LV2
Delay MultiPoint pacing	Delay 1: 5; 10; ...80ms Delay 2: 5; 10; ...50ms
V. Triggering options	On; Off
QuickOpt™ Timing Cycle Optimization	Sensed/Paced AV Delay; Interventricular Paced Delay
Intraventricular pace delay	10–80 in steps of 5
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
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
SenseA*bility*™ 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
MRI Scan Parameters*	

MRI READY LEAD MODEL	LEAD LENGTHS	MAGNET (TESLA)	SCANNER MODE	SCAN REGION
Quartet™ LV Lead		IsoFlex Optim and Tendril STS: 1,5 T and 3 T	Normal Operating Mode*	Full Body
1456Q, 1457Q, 1458Q, 1458QL	86 cm			
IsoFlex™ Optim™ Lead				
1944	46 cm, 52 cm			
1948	52 cm, 58 cm			
Tendril™ STS Pacing Lead				
2088TC	46 cm, 52 cm, 58 cm			

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

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.

Quadra Allure™

Cardiac Resynchronization Therapy Pacemaker

MR

Merlin@home™ Transmitter Compatible

Product Highlights

- Allows patients to undergo MRI scans when used with MRI Ready leads from Abbott*
- The Quadra Allure™ CRT-P and Quartet™ quadripolar LV pacing lead feature four pacing electrodes and 14 pacing vectors to provide more options and greater control to address complications at and post implant to improve CRT response
- SyncAV™ CRT technology dynamically adjusts AV delays based on patient's intrinsic conduction to encourage patient-tailored biventricular pacing
- Elevate Response Easily with Auto VectSelect Quartet™ Test offering an efficient workflow for complete results and programming at the touch of a button
- 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 their 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
- Longevity offers 8,2 years of service life supported by a six year warranty*

Ordering Information

Contents: Cardiac Pulse Generator

MODEL NUMBER	DIMENSIONS (H x W x T, MM)	WEIGHT (G)	VOLUME (CC)	CONNECTOR
PM3542	56 x 59 x 6	26	15	1S4-LLLL, 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/SO735-10097(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 switched on vs. switched off.

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.

Product Specifications

PHYSICAL SPECIFICATIONS

Models	PM35
Telemetry	RF
Dimensions (mm)	56 x 59 x 6
Weight (g)	27
Volume (cc)[1]	15
Connector	IS4-LLLL, IS-1
MRI Conditional	Yes, MRI Ready

PARAMETER	SETTINGS
Resynchronization Therapy	
VectSelect Quartet™ LV Pulse Configuration	Distal Tip 1–Mid 2; Distal Tip 1–Proximal 4; Distal Tip 1–RV Ring; Mid 2–Proximal 4; Mid 2–RV Ring; Mid 3–Mid 2; Mid 3–Proximal 4; Mid 3–RV Ring; Proximal 4–Mid 2; Proximal 4–RV Ring; Distal Tip 1–Can; Mid 2–Can; Mid 3–Can; Proximal 4–Can
V. Triggering options	On; Off
QuickOpt™ Timing Cycle Optimisation	Sensed/Paced AV Delay; Interventricular Paced Delay
Intraventricular pace delay	10–80 in steps of 5
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
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
MRI Scan Parameters	

MRI READY LEAD MODEL	LEAD LENGTHS	MAGNET (TESLA)	SCANNER MODE	SCAN REGION
Quartet™ LV Lead		1,5 T	Normal Operating Mode*	Full Body
1456Q, 1457Q, 1458Q, 1458QL	86 cm			
IsoFlex™ Optim™ Lead				
1944	46 cm, 52 cm			
1948	52 cm, 58 cm			
Tendril™ STS Pacing Lead				
2088TC	46 cm, 52 cm, 58 cm			

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

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.

Quadra Allure MP™ RF

Cardiac Resynchronisation Therapy Pacemaker

MERLIN@HOME™ TRANSMITTER COMPATIBLE

MR

Product Highlights

- MultiPoint™ Pacing delivers multiple LV pacing pulses per cardiac cycle and is designed to improve hemodynamic and clinical response
- The Quadra Allure MP™ RF CRT-P and Quartet™ quadripolar LV pacing lead feature four pacing electrodes and 14 pacing vectors to provide more options and greater control to address complications at and post implant to improve CRT response
- SyncAV™ CRT technology dynamically adjusts AV delays based on patient's intrinsic conduction to encourage patient-tailored biventricular pacing
- Elevate response easily with Auto VectSelect Quartet™ Test offering an efficient workflow for complete results and programming at the touch of a button
- Angled header and physiologic teardrop 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 patients and their 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
- Longevity offers 8,2 years of service life supported by a five- year warranty*

Ordering Information

Contents: Cardiac Pulse Generator

MODEL NUMBER	DIMENSIONS (H × W × T, MM)	WEIGHT (G)	VOLUME (CC)	CONNECTOR
PM3262	56 × 59 × 6	27	15	1S4-LLLL, IS-1

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.

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/SO735-10097(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.

Quadra Allure MP™ RF

Cardiac Resynchronisation Therapy Pacemaker

Physical Specifications

Model	PM3262
Telemetry	RF
Dimensions (mm)	56 × 59 × 6
Weight (g)	27
Volume (cc)[1]	15
Connector	IS4-LLLL, IS-1
Resynchronisation Therapy	
VectSelect Quartet™ Programmable LV Pulse Configuration	Distal Tip 1 — Mid 2; Distal Tip 1 — Proximal 4; Distal Tip 1 — RV Ring; Mid 2 — Proximal 4; Mid 2 — RV Ring; Mid 3 — Mid 2; Mid 3 — Proximal 4; Mid 3 — RV Ring; Proximal 4 — Mid 2; Proximal 4 — RV Ring; Distal Tip 1 — Can; Mid 2 — Can; Mid 3 — Can; Proximal 4 — Can
MultiPoint™ Pacing Settings	LV1; LV2
Delay MultiPoint Pacing	Delay 1: 5; 10; ... 80 ms Delay 2: 5; 10; ... 50 ms
V. Triggering Options	On; Off
QuickOpt™ Timing Cycle Optimisation	Sensed/Paced AV Delay; Interventricular Paced Delay
Intraventricular Pace Delay	10–80 in steps of 5
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
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 Technology 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 Feature	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 Feature	On; Off; Monitor
Searchable Interval (hrs)	8; 24
LVCap™ Confirm Feature	On; Off; Monitor
Searchable Interval (hrs)	8; 24
Sense*Ability*™ Sensing Algorithm 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 Impedance Out of Range; AT/AF Burden; AT/AF Episode Duration; High V Rate During AT/AF, High V Rate, Percent BiV/RV Pacing Alert CorVue Congestion Monitoring 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.

Allure Quadra™ RF

Cardiac Resynchronisation Therapy Pacemaker

Merlin@home™ Transmitter Compatible

Product Highlights

- The Allure Quadra™ CRT-P and quadripolar LV pacing lead features four pacing electrodes and 14 pacing vectors to provide more options and greater control to address complications at and post implant to improve CRT response.
- Angled header and physiologic teardrop 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 unitilization from Day 1 when paired with the Merlin@home™ transmitter at point of care.
- AT/AF alerts can be programmed to notify patients and their 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 over seven and a half 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
PM3242	56 × 59 × 6	27	15	IS4-LLLL, IS-1

*Longevity calculated based on the following settings: 2.5 V, 500 Ohm, 60 BPM, 100% DDD-BiV Pacing, 0.4 ms, Cap Confirm Off, and Stored EGM On.

Indications: Implantation of Allure and Allure RF devices is indicated for: maintaining synchrony of the left and right ventricles, implantation of Assurity™, Endurity™ and Allure™ family of devices is indicated in one or more of the following permanent conditions: syncope, presyncope, fatigue, disorientation, 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: 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***. Anthem 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 Quadra™ RF

Cardiac Resynchronisation Therapy Pacemaker

PHYSICAL SPECIFICATIONS

Model	PM3242
Telemetry	RF
Dimensions (mm)	56 × 59 × 6
Weight (g)	27
Volume (cc)[1]	15
Connector	IS4-LLLL, IS-1

PARAMETER	SETTINGS
Resynchronisation Therapy	
QuickOpt™ Timing Cycle Optimisation	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
VectSelect Quartet™	Unipolar; Bipolar; Distal Tip 1 - Mid 2; Distal Tip 1 - Proximal 4; Distal Tip
LV Pulse Configuration	1 - RV Ring; Mid 2 - Proximal 4; Mid 2 - RV Ring; Mid 3 - Mid 2; Mid 3 - Proximal 4; Mid 3 - RV Ring; Proximal 4 - Mid 2; Proximal 4 - RV Ring; Distal Tip 1 - Can; Mid 2 - Can; Mid 3 - Can; Proximal 4 - Can
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
Interventricular Pace Delay (ms)	10–80 in steps of 5
Output/Sensing	
Negative AV Hysteresis Search (ms)	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
Atrial ACap™ Confirm Feature	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 Feature	On; Off; Monitor
Searchable Interval (hrs)	8; 24
LVCap™ Confirm Feature	On; Off; Monitor
Searchable Interval (hrs)	8; 24
Sense*Ability*™ Sensing Algorithm 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	
Rate Responsive AV/PV Delay	Off; Low; Medium; High
Rate Responsive PVARP/VREF	Off; Low; Medium; High
Shortest PVARP/VREF (ms)	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
of the 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 Monitoring 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 Impedance Out of Range; AT/AF Burden; AT/AF Episode Duration; High V Rate During AT/AF, High V Rate, Percent BiV/RV Pacing Alert CorVue Congestion Monitoring 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.

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/SO735-10097(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.

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); AA1(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[6]	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.

Allure™

Cardiac Resynchronization Therapy Pacemaker

Product Highlights

- Angled header and physiologic teardrop 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
- 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 8.2 years of service life supported by a six-year warranty*

Ordering Information

Contents: Cardiac Pulse Generator

MODEL NUMBER	DIMENSIONS (H x W x T, MM)	WEIGHT (G)	VOLUME (CC)	CONNECTOR
PM3120	55 x 59 x 6	24	14	IS-1

*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 or 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.

Product Specifications

PHYSICAL SPECIFICATIONS

Models	PM3120
Telemetry	Inductive
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; LV Unipolar Tip; LV Bipolar; RV Unipolar Ring; LV Tip–RV Tip BV; RV only; LV only (temporary mode)
First Chamber Paced	Simultaneous[2]; RV; LV
Interventricular Pace Delay (ms)	10–80 in steps of 5
Output/Sensing	
Negative AV Hysteresis Search (ms)	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
Atrial ACap™ Confirm Feature	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 Feature	On; Off; Monitor
Searchable Interval (hrs)	8; 24
LVCap™ Confirm Feature	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[6]	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 Impedance; Out 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.

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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.

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