CRM PRODUCT CATALOG

ICD

Abbott

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ICD

Ellipse™ VR

Single-chamber Implantable Cardioverter Defibrillator (ICD)

MR

Merlin@home™ Transmitter Compatible

Product Highlights

- MRI Ready device has been tested for safe performance of an MRI scan using a 1,5 Tesla field-strength MRI scanner when used in combination with an MR Conditional lead[1,2]
- Improved shape with reduced volume and thickness
- 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 algorithm 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 improves SVT and VT discrimination for reduced inappropriate therapies
- Low frequency attenuation filter designed to enhance sensing performance and may reduce the possibility of oversensing T waves
- Sense*Ability*™ sensing algorithm 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
- 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
- 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
- ST monitoring capability provides unprecedented, continuous insight into significant ST shift events and associated ventricular arrhythmias through enhanced monitoring of iEGM and ST-segment as a diagnostic tool to help guide appropriate clinical action
- 36 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

Ordering Information

Contents: Single-chamber Implantable Cardioverter Defibrillator (ICD)

MODEL NUMBER	DIMENSIONS (H × W × T, MM)	WEIGHT (G)	VOLUME (CC)	CONNECTOR DEFIBRILLATION	CONNECTOR SENSE/PACE
CD1377-36C	68 × 51 × 12	66	31	DF1	IS-1
CD1377-36QC*	66 × 51 × 12	67	30	DF4	DF4

*Indicates models that are MR Conditional[1,2]

Indications: The devices are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

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

Adverse Events: Implantation of the implantable cardioverter defibrillator, 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.

Ellipse™ VR

Single-chamber Implantable Cardioverter Defibrillator (ICD)

Product Specifications

PHYSICAL SPECIFICATIONS

Models	CD1377-36C	CD1377-36QC
Telemetry	RF	RF
Delivered/Stored Energy (J)	36/39	36/39
Volume (cc)	31	30
Weight (g)	66	67
Size (mm)	68 × 51 × 12	66 × 51 × 12
Defibrillation Lead Connections	DF1	DF4
Sense/Pace Lead Connections	IS-1	DF4
High Voltage Can	Electrically active titanium can	Electrically active titanium can
Coating	Parylene	Parylene
MR Conditional	No	Yes-MRI Ready

PARAMETER	SETTINGS
Sensing/Detection	
Sense*Ability*™ Sensing Algorithm Technology	Automatic sensitivity control adjustment for ventricular events
Low Frequency Attenuation	On; Off
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; 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	Sudden Onset; Interval Stability; Sinus Interval History; Morphology Discrimination (Far Field MD™ Morphology Discrimination or Original MD) with Manual (Original MD) or Automatic Template Update
Discrimination Modes	On; Passive; Off
SVT Threshold	150–240 min^{-1}
SVT Timeout	0,25–5 min
Monitor Mode	Detection, discrimination and diagnostics, no therapy delivery (VT or VT-1 zone)
Reconfirmation	Continuous sensing during charging
Lead Noise Discrimination	SecureSense™ RV lead noise discrimination algorithm (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	1–15
Number of Stimuli	2–20
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™ Over-current Detection Algorithm	On; Off
DeFT Response™ Technology	Programmable pulse width for P1/P2 and tilt
High Voltage Output Mode	Fixed Pulse Width; Fixed Tilt
Waveform	Biphasic; Monophasic
RV Polarity	Cathode (-); Anode (+)
Electrode Configuration	RV to Can; RV to SVC/Can; RV to SVC
Bradycardia Pacing	
Permanent Modes	Off; VVI(R)
Temporary Modes	Off; VVI; VOO
Rate-Adaptive Sensor	On; Off; Passive
Programmable Rate Parameters	Off; Base Rate (min^{-1}); Rest Rate (min^{-1}); Maximum Sensor Rate (min^{-1}); Pulse Amplitude (RV) (V); Pulse Width (RV) (ms); Hysteresis Rate (min^{-1}); Rate Hysteresis with Search
Ventricular AutoCapture™ Pacing System	On; Off
Post-Therapy Pacing (Independently Programmable from Bradycardia and ATP)	
Post-Shock Pacing Mode	Off; VVI
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 3 extra stimuli
Patient Notifiers	
Programmable Notifiers (On; Off)	Device at ERI; Charge Time Limit Reached; Possible HV Circuit Damage; Ventricular Lead Impedance Out of Range; High Voltage Lead Impedance Out of Range; %V pacing; CorVue™ Congestion Monitoring Trigger; SecureSense lead noise detected, non-sustained lead noise detected, ST Episodes (Type I only)
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 one minute programmable pre-trigger data per VT/VF diagnosis/detection electrograms; triggers include: diagnosis; detection; therapy; 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
Ventricular HV Lead Impedance Trend	Multi-Vector Trend Data
Histograms	Event Histogram; Ventricular Heart Rate Histogram; Exercise and Activity Trending; DirectTrend™ reports up to 1 year
Real-Time Measurements (RTM)	Pacing lead impedances; high voltage lead impedances; and signal amplitudes
ST Monitoring	ST Histogram Data; Long-term ST Deviation Trend; ST Episode Log; ST Episode Details; 24-Hour ST and HR Trend; ST EGM Baseline and Snapshots prior to ST Episode; VT/VF; Interrogation (Snapshots and 24-hour trend at time of interrogation)
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
Durata™ Defibrillation Lead 7120Q, 7122Q	58, 65 cm	Normal Operating Mode**	Full Body
Optisure™ Lead LDA210Q, LDA220Q	58, 65 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.

Ellipse™ DR

Dual-chamber Implantable Cardioverter Defibrillator (ICD)

Merlin@home™ Transmitter Compatible

Product Highlights

- MRI Ready device has been tested for safe performance of an MRI scan using a 1,5 Tesla field-strength MRI scanner when used in combination with MR Conditional leads[1,2]
- Improved shape with reduced volume and thickness
- 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 algorithm 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
- Low frequency attenuation filter designed to enhance sensing performance and may reduce the possibility of oversensing T waves
- Sense*Ability*™ sensing algorithm 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
- 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
- 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
- ST monitoring capability provides unprecedented, continuous insight into significant ST shift events and associated ventricular arrhythmias through enhanced monitoring of iEGM and ST segment as a diagnostic tool to help guide appropriate clinical action
- 36 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

Ordering Information

Contents: Dual-chamber Implantable Cardioverter Defibrillator (ICD)

MODEL NUMBER	DIMENSIONS (H × W × T, MM)	WEIGHT (G)	VOLUME (CC)	CONNECTOR DEFIBRILLATION	CONNECTOR SENSE/PACE
CD2377-36C	69 × 51 × 12	66	31	DF1	IS-1
CD2377-36QC*	70 × 51 × 12	68	31	DF4	IS-1; DF4

*Indicates models that are MR Conditional[1,2]

Indications: The devices are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

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

Adverse Events: Implantation of the implantable cardioverter defibrillator, 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.

Ellipse™ DR

Dual-chamber Implantable Cardioverter Defibrillator (ICD)

Product Specifications

PHYSICAL SPECIFICATIONS

Models	CD2377-36C	CD2377-36QC
Telemetry	RF	RF
Delivered/Stored Energy (J)	36/39	36/39
Volume (cc)	31	31
Weight (g)	66	68
Size (mm)	69 × 51 × 12	70 × 51 × 12
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
MR Conditional	No	Yes-MRI Ready

PARAMETER	SETTINGS
AF Management	
AF Suppression™ Pacing	On; Off
No. of Overdrive Pacing Cycles	15–40 in steps of 5
Maximum AF Suppression Rate	15–40 in steps of 5
Sensing/Detection	
Sense*Ability*™ Sensing Algorithm Technology	Automatic sensitivity control adjustment for atrial and ventricular events
Low Frequency Attenuation	On; Off
Threshold Start	(Post-Sensed; Atrial) 0,2; 0,3; 0,45; 0,6; 0,9; 1,2; 1,5; 1,8; 2,4; 3,0; 3,6; 4,5; 5,7; 7,2; 9,0; 11,2; 13,5; 15,8; 18,0 mV; (Post-Sensed; Ventricular) 0,9; 1,2; 1,5; 1,8; 2,4; 3,0; 3,6; 4,5; 5,7; 7,2; 9,0; 11,2; 13,5; 15,8; 18,0 mV; (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™ Morphology Discrimination 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 algorithm (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	1–15
Number of Stimuli	2–20
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™ Over-current Detection Algorithm	On; Off
DeFT Response™ Technology	Programmable pulse width for P1/P2 and tilt
High Voltage Output Mode	Fixed Pulse Width; Fixed Tilt
Waveform	Biphasic; Monophasic
RV Polarity	Cathode (-); Anode (+)
Electrode Configuration	RV to Can; RV to SVC/Can; RV to SVC
Bradycardia Pacing	
Permanent Modes	Off; DDD(R); DDI(R); VVI(R); AAI(R)
Temporary Modes	Off; DDD; DDI; VVI; AAI; AAT; DOO; VOO; AOO
Rate-Adaptive Sensor	On; Off; Passive
Programmable Rate and Delay Parameters	Base Rate (min^{-1}); Rest Rate (min^{-1}); Maximum Tracking Rate (min^{-1}); Off; Maximum Sensor Rate (min^{-1}); Paced AV Delay (ms); Sensed AV Delay (ms); Rate Responsive AV Delay (Atrial and RV) (ms); Hysteresis Rate (min^{-1}); Rate Hysteresis with Search
Ventricular AutoCapture™ Pacing System	On; Off
ACap™ Confirm Feature	On; Monitor; Off
QuickOpt™ Timing Cycle Optimisation	Sensed/Paced AV delay
Auto Mode Switch (AMS)	Off; DDI(R); VVI(R)
Atrial Tachycardia Detection Rate (min^{-1})	110–300
AMS Base Rate (min^{-1})	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; 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; Ventricular 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; non-sustained lead noise detected; ST Episodes (Type I only)
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 one 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
ST Monitoring	ST Histogram Data; Long-term ST Deviation Trend; ST Episode Log; ST Episode Details; 24-Hour ST and HR Trend; ST EGM Baseline and Snapshots prior to ST Episode; VT/VF; Interrogation (Snapshots and 24-hour trend at time of interrogation)
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 MRI™ Lead LPA1200M	46, 52, 58 cm	Normal Operating Mode**	Full Body
Tendril™ STS Pacing Lead 2088TC	46, 52 cm		
IsoFlex™ Optim™ Pacing Leads 1944	46, 52 cm		
Durata™ Defibrillation Lead 7120Q, 7122Q	58, 65 cm		
Optisure™ Lead LDA210Q, LDA220Q	58, 65 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. MRI Conditional Field Strength: 1,5 Tesla.

2. See MRI-Ready Systems Manual for approved MR Conditional systems device/lead combinations and scan parameters.

Fortify Assura™ Single-chamber ICD

CD1359-40C and CD1359-40QC

Parylene Coated

MR

Merlin@home™ Transmitter Compatible

Product Highlights

- MRI Ready device has been tested for safe performance of an MRI scan using a 1,5 Tesla field-strength MRI scanner when used in combination with an MR Conditional lead[1,2]
- 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 algorithm 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 improves SVT and VT discrimination for reduced inappropriate therapies
- Low frequency attenuation filter designed to enhance sensing performance and may reduce the possibility of oversensing T waves
- Sense*Ability*™ sensing algorithm 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
- 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
- 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
- ST monitoring capability provides unprecedented, continuous insight into significant ST shift events and associated ventricular arrhythmias through enhanced monitoring of iEGM and ST segment as a diagnostic tool to help guide appropriate clinical action
- 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

Ordering Information

Contents: Single-chamber Implantable Cardioverter Defibrillator (ICD)

MODEL NUMBER	DIMENSIONS (H × W × T, MM)	WEIGHT (G)	VOLUME (CC)	CONNECTOR DEFIBRILLATION	CONNECTOR SENSE/PACE
CD1359-40C	73 × 40 × 14	76	35	DF1	IS-1
CD1359-40QC*	71 × 40 × 14	75	35	DF4	DF4

*Indicates models that are MR Conditional[1,2]

Indications: The devices are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

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.

Fortify Assura™ Single-chamber ICD

CD1359-40C and CD1359-40QC Parylene Coated

Product Specifications

PHYSICAL SPECIFICATIONS

Models	CD1359-40C	CD1359-40QC
Telemetry	RF	RF
Delivered/Stored Energy (J)	40/45	40/45
Volume (cc)	35	35
Weight (g)	76	75
Size (mm)	73 × 40 × 14	71 × 40 × 14
Defibrillation Lead Connections	DF1	DF4
Sense/Pace Lead Connections	IS-1	DF4
High Voltage Can	Electrically active titanium can	Electrically active titanium can
Coating	Parylene	Parylene
MR Conditional	No	Yes — MRI Ready

PARAMETER	SETTINGS
Sensing/Detection	
Sense*Ability*™ Sensing Algorithm Technology	Automatic sensitivity control adjustment for ventricular events
Low Frequency Attenuation	On; Off
Sense Filter	(Post-Sensed; Ventricular) 50; 62,5; 75; 100%; (Post-Paced; Ventricular) Auto; 0,2–3,0 mV
Decay Delay	(Post-Sense/Post-Pace; 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	Sudden Onset; Interval Stability; AV Association; Morphology Discrimination (Far Field MD™ Morphology Discrimination or Original MD) with Manual (Original MD) or Automatic Template Update
Discrimination Modes	On; Passive; Off
SVT Threshold	150–240 min^{-1}
SVT Timeout	0,25–5 min
Monitor Mode	Detection, discrimination and diagnostics, no therapy delivery (VT or VT-1 zone)
Reconfirmation	Continuous sensing during charging
Lead Noise Discrimination	SecureSense™ RV lead noise discrimination algorithm (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	1–15
Number of Stimuli	2–20
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™ Over-Current Detection Algorithm	On; Off
DeFT Response™ Technology	Programmable pulse width for P1/P2 and tilt
High Voltage Output Mode	Fixed Pulse Width; Fixed Tilt
Waveform	Biphasic; Monophasic
RV Polarity	Cathode (-); Anode (+)
Electrode Configuration	RV to Can; RV to SVC/Can; RV to SVC
Bradycardia Pacing	
Permanent Modes	Off; VVI(R)
Temporary Modes	Off; VVI; VOO
Rate-Adaptive Sensor Programmable	(Post-Sense/Post-Pace; Ventricular) 0–220
Rate Parameters	Off; Base Rate (min^{-1}); Rest Rate (min^{-1}); Maximum Sensor Rate (min^{-1}); Pulse Amplitude (RV) (V); Pulse Width (RV) (ms); Hysteresis Rate (min^{-1})
Rate Hysteresis with Search Ventricular AutoCapture™ Pacing System	On; Off
Post-Therapy Pacing (Independently Programmable from Bradycardia and ATP)	
Post-Shock Pacing Mode	Off; VVI
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; Ventricular Lead Impedance Out of Range; High Voltage Lead Impedance Out of Range; %V pacing; CorVue™ Congestion Monitoring Trigger; SecureSense RV lead noise discrimination algorithm; non-sustained lead noise detected; ST Episodes (Type I only)
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 one minute programmable pre-trigger data per VT/VF diagnosis/detection electrograms; triggers include: diagnosis; detection; therapy; 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
Ventricular HV Lead Impedance Trend	Multi-Vector Trend Data
Histograms	Event Histogram; Ventricular Heart Rate Histogram; Exercise and Activity Trending; DirectTrend™ reports up to one year
Real-Time Measurements (RTM)	Pacing lead impedances; high voltage lead impedances; and signal amplitudes
ST Monitoring	ST Histogram Data; Long-term ST Deviation Trend; ST Episode Log; ST Episode Details; 24-Hour ST and HR Trend; ST EGM Baseline and Snapshots prior to ST Episode; VT/VF; Interrogation (Snapshots and 24-hour trend at time of interrogation)
CorVue™ Congestion Monitoring	On; Off
CorVue™ Congestion Monitoring Trigger	8–18 days

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.

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 MRI™ Lead LPA1200M	46, 52, 58 cm	Normal Operating Mode**	Full Body
Tendril™ STS Pacing Lead 2088TC	46, 52 cm		
IsoFlex™ Optim™ Pacing Lead 1944	46, 52 cm		
Durata™ Defibrillation Lead 7120Q, 7122Q	58, 65 cm		
Optisure™ Lead LDA220Q, LDA210Q	58, 65 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.

Fortify Assura™ Single-chamber ICD

CD1359-40 and CD1359-40Q Non-coated

MR

Merlin@home™ Transmitter Compatible

Product Highlights

- Allows patients to undergo MRI scans when used with MRI Ready leads from Abbott
- 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 minimize the need for programming adjustments at implant
  - SecureSense™ RV lead noise discrimination algorithm 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 improves SVT and VT discrimination for reduced inappropriate therapies
- Low frequency attenuation filter designed to enhance sensing performance and may reduce the possibility of oversensing T waves
- Sense*Ability*™ sensing algorithm 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
- 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
- ATP while charging and prior to charging in the VF zone further extends the programming options for terminating tachyarrhythmias without a high voltage shock
- ST monitoring capability provides unprecedented, continuous insight into significant ST shift events and associated ventricular arrhythmias through enhanced monitoring of IEGM and ST-segment as a diagnostic tool to help guide appropriate clinical action
- 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

Ordering Information

Contents: Single-chamber Implantable Cardioverter Defibrillator (ICD)

MODEL NUMBER	DIMENSIONS (H × W × T, MM)	WEIGHT (G)	VOLUME (CC)	CONNECTOR	CONNECTOR SENSE/PACE
CD1359-40	74 × 40 × 14	76	35	DF1	IS-1
CD1359-40Q*	71 × 40 × 14	75	35	DF4	DF4

*See MRI Scan Parameters.

Indications: The devices are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

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.

Fortify Assura™ Single-chamber ICD

CD1359-40 and CD1359-40Q Non-coated

Product Specifications

PHYSICAL SPECIFICATIONS

Models	CD1359-40	CD1359-40Q
Telemetry	RF	RF
Delivered/Stored Energy (J)	40/45	40/45
Volume (cc)	35	35
Weight (g)	76	75
Size (mm)	74 × 40 × 14	71 × 40 × 14
Defibrillation Lead Connections	DF1	DF4
Sense/Pace Lead Connections	IS-1	DF4
High Voltage Can	Electrically active titanium can	Electrically active titanium can
MR Conditional	No	Yes — MRI Ready

PARAMETER	SETTINGS
Sensing/Detection	
Sense*Ability*™ Sensing Algorithm Technology	Automatic sensitivity control adjustment for ventricular events
Low Frequency Attenuation	On; Off
Sense Filter	(Post-Sensed; Ventricular) 50; 62,5; 75; 100%; (Post-Paced; Ventricular) Auto; 0,2–3,0 mV
Decay Delay	(Post-Sense/Post-Pace; 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	Sudden Onset; Interval Stability; AV Association; Morphology Discrimination (Far Field MD™ Morphology Discrimination or Original MD) with Manual (Original MD) or Automatic Template Update
Discrimination Modes	On; Passive; Off
SVT Threshold	150–240 min^{-1}
SVT Timeout	0,25–5 min
Monitor Mode	Detection, discrimination and diagnostics, no therapy delivery (VT or VT-1 zone)
Reconfirmation	Continuous sensing during charging
Lead Noise Discrimination	SecureSense™ RV lead noise discrimination algorithm (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	1–15
Number of Stimuli	2–20
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™ Over-Current Detection Algorithm	On; Off
DeFT Response™ Technology	Programmable pulse width for P1/P2 and tilt
High Voltage Output Mode	Fixed Pulse Width; Fixed Tilt
Waveform	Biphasic; Monophasic
RV Polarity	Cathode (-); Anode (+)
Electrode Configuration	RV to Can; RV to SVC/Can; RV to SVC
Bradycardia Pacing	
Permanent Modes	Off; VVI(R)
Temporary Modes	Off; VVI; VOO
Rate-Adaptive Sensor	(Post-Sense/Post-Pace; Ventricular) 0–220
Programmable Rate Parameters	Off; Base Rate (min^{-1}); Rest Rate (min^{-1}); Maximum Sensor Rate (min^{-1}); Pulse Amplitude (RV) (V); Pulse Width (RV) (ms); Hysteresis Rate (min^{-1})
Rate Hysteresis with Search	On; Off
Ventricular AutoCapture™ Pacing System	
Post-Therapy Pacing (Independently Programmable from Bradycardia and ATP)	
Post-Shock Pacing Mode	Off; VVI
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; Ventricular Lead Impedance Out of Range; High Voltage Lead Impedance Out of Range; %V pacing; CorVue™ Congestion Monitoring Trigger; SecureSense RV lead noise discrimination algorithm; non-sustained lead noise detected; ST Episodes (Type I only)
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 one minute programmable pre-trigger data per VT/VF diagnosis/detection electrograms; triggers include: diagnosis; detection; therapy; 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
Ventricular HV Lead Impedance Trend	Multi-Vector Trend Data
Histograms	Event Histogram; Ventricular Heart Rate Histogram; Exercise and Activity Trending; DirectTrend™ reports up to one year
Real-Time Measurements (RTM)	Pacing lead impedances; high voltage lead impedances; and signal amplitudes ST Histogram Data; Long-term ST Deviation Trend; ST Episode Log; ST Episode Details; 24-Hour ST and HR Trend; ST EGM Baseline and Snapshots prior to ST Episode; VT/VF; Interrogation (Snapshots and 24-hour trend at time of interrogation)
CorVue™ Congestion Monitoring	On; Off
CorVue™ Congestion Monitoring Trigger	8–18 days

MRI Scan Parameters**

LEAD MODEL	LEAD LENGTHS	RF POWER (SAR)	SCAN REGION
Tendril MRI™ Lead LPA1200M	46, 52, 58 cm	Normal Operating Mode**	Full Body
Tendril™ STS Pacing Lead 2088TC	46, 52 cm		
IsoFlex™ Optim™ Pacing Leads 1944	46, 52 cm		
Durata™ Defibrillation Lead 7120Q, 7122Q	58, 65 cm		
Optisure™ Lead LDA210Q, LDA220Q	58, 65 cm		

**Refer to the MRI-Ready Systems Manual for additional information.

Fortify Assura™ Dual-chamber ICD

CD2359-40C and CD2359-40QC with Parylene Coating

Merlin@home™ Transmitter Compatible

MR

Product Highlights

- MRI Ready device has been tested for safe performance of an MRI scan using a 1,5 Tesla field-strength MRI scanner when used in combination with an MRI conditional lead[1,2]
- 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 algorithm 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 improves SVT and VT discrimination for reduced inappropriate therapies
- Low frequency attenuation filter designed to enhance sensing performance and may reduce the possibility of oversensing T-waves
- Sense*Ability*™ sensing algorithm 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
- 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
- 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
- ST monitoring capability provides unprecedented, continuous insight into significant ST shift events and associated ventricular arrhythmias through enhanced monitoring of iEGM and ST segment as a diagnostic tool to help guide appropriate clinical action
- 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

Ordering Information

Contents: Dual-chamber Implantable Cordiverter Defibrillator (ICD)

MODEL NUMBER	DIMENSIONS (H × W × T, MM)	WEIGHT (G)	VOLUME (CC)	CONNECTOR DEFIBRILLATION	CONNECTOR SENSE/ PACE
CD2359-40C	74 × 40 × 14	76	35	DF1	IS-1
CD2359-40QC*	71 × 40 × 14	75	35	DF4	IS-1; DF4

*Indicates models that are MR Conditional[1,2]

Indications: The devices are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

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.

Fortify Assura™ Dual-chamber ICD

CD2359-40C and CD2359-40QC with Parylene Coating

Product Specifications

PHYSICAL SPECIFICATIONS

Models	CD2359-40C	CD2359-40QC
Telemetry	RF	RF
Delivered/Stored Energy (J)	40/45	40/45
Volume (cc)	35	35
Weight (g)	76	75
Size (mm)	74 × 40 × 14	71 × 40 × 14
Defibrillation Lead Connections	DF1	DF4
Sense/Pace Lead Connections	IS-1	IS-1; DF4
High Voltage Can Coating	Electrically active titanium can Parylene	Electrically active titanium can Parylene
MRI Conditional	No	Yes – MRI Ready

PARAMETER	SETTINGS
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*™ Sensing Algorithm Technology	Automatic sensitivity control adjustment for atrial and ventricular events
Low Frequency Attenuation	On; Off
Threshold Start	(Post-Sensed; Atrial) 50; 62,5; 75; 100%; (Post-Paced; Atrial) 0,2–3,0 mV; 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 ms
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™ Morphology Discrimination 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 Discrimination Timeout	0,25–5 min
Reconfirmation	Continuous sensing during charging
Lead Noise Discrimination	SecureSense™ RV lead noise discrimination algorithm (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	200–400 ms
Burst Cycle Length	Adaptive; Readaptive or Fixed
Min. Burst Cycle Length (ms)	150–400 in increments of 5
Number of Bursts	1–15
Number of Stimuli	2–20
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™ Over-current Detection Algorithm	On; Off
DeFT Response™ Technology	Programmable pulse width for P1/P2 and tilt
High Voltage Output Mode	Fixed Pulse Width; Fixed Tilt
Waveform	Biphasic; Monophasic
RV Polarity	Cathode (-); Anode (+)
Electrode Configuration	RV to Can; RV to SVC/Can; RV to SVC
Bradycardia Pacing	
Permanent Modes	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 (Atrial and RV); Hysteresis Rate (min^{-1}); Rate Hysteresis with Search
Ventricular AutoCapture™ Pacing System	On; Off
ACap™ Confirm Feature	On; Monitor; Off
QuickOpt™ Timing Cycle Optimisation	Sensed/Paced AV Delay
Auto Mode Switch (AMS)	Off; DDI(R); VVI(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 ms)
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; Ventricular 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 Monitoring Trigger; SecureSense — lead noise detected; non-sustained lead noise detected; ST Episodes (Type I only)
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 one 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
ST Monitoring	ST Histogram Data; Long-term ST Deviation Trend; ST Episode Log; ST Episode Details; 24-Hour ST and HR Trend; ST EGM Baseline and Snapshots prior to ST Episode; VT/VF; Interrogation (Snapshots and 24-hour trend at time of interrogation)
CorVue™ Congestion Monitoring	On; Off
CorVue™ Congestion Trigger	8–18 days

1. MRI Conditional Field Strength: 1,5 Tesla.
2. See MRI-Ready Systems Manual for approved MR Conditional systems device/lead combinations and scan parameters.

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 MRI™ Lead LPA1200M	46, 52, 58 cm	Normal Operating Mode**	Full Body
Tendril™ STS Pacing Lead 2088TC	46, 52 cm		
IsoFlex™ Optim™ Pacing Lead 1944	46, 52 cm		
Durata™ Defibrillation Lead 7120Q, 7122Q	58, 65 cm		
Optisure™ Lead LDA220Q, LDA210Q	58, 65 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.

Fortify Assura™ Dual-chamber ICD

CD2359-40 and CD2359-40Q Non-coated

MR

Merlin@home™ Transmitter Compatible

Product Highlights

- Allows patients to undergo MRI scans when used with MRI Ready leads from Abbott*
- 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 algorithm 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 improves SVT and VT discrimination for reduced inappropriate therapies
- Low frequency attenuation filter designed to enhance sensing performance and may reduce the possibility of oversensing T waves
- Sense*Ability*™ sensing algorithm 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
- 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
- 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
- ST monitoring capability provides unprecedented, continuous insight into significant ST shift events and associated ventricular arrhythmias through enhanced monitoring of IEGM and ST segment as a diagnostic tool to help guide appropriate clinical action
- 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

Ordering Information

Contents: Dual-chamber Implantable Cordiverter Defibrillator (ICD)

MODEL NUMBER	DIMENSIONS (H × W × T, MM)	WEIGHT (G)	VOLUME (CC)	CONNECTOR DEFIBRILLATION	CONNECTOR SENSE/PACE
CD2359-40	74 × 40 × 14	76	35	DF1	IS-1
CD2359-40Q*	71 × 40 × 14	75	35	DF4	IS-1; DF4

*See MRI Scan Parameters.

Indications: The devices are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

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.

Fortify Assura™ Dual-chamber ICD

CD2359-40 and CD2359-40Q Non-coated

Product Specifications

PHYSICAL SPECIFICATIONS

Models	CD2359-40	CD2359-40Q
Telemetry	RF	RF
Delivered/Stored Energy (J)	40/45	40/45
Volume (cc)	35	35
Weight (g)	76	75
Size (mm)	74 × 40 × 14	71 × 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
MRI Conditional	No	Yes — MRI Ready

PARAMETER	SETTINGS
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}
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 Star (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™ Morphology Discrimination 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 algorithm (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	1–15
Number of Stimuli	2–20
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™ Over-current Detection Algorithm	On; Off
DeFT Response™ Technology	Programmable pulse width for P1/P2 and tilt
High Voltage Output Mode	Fixed Pulse Width; Fixed Tilt
Waveform	Biphasic; Monophasic
RV Polarity	Cathode (-); Anode (+)
Electrode Configuration	RV to Can; RV to SVC/Can; RV to SVC
Bradycardia Pacing	
Permanent Modes	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 (Atrial and RV); Hysteresis Rate (min^{-1}); Rate Hysteresis with Search
Ventricular AutoCapture™ Pacing System	On; Off
ACap™ Confirm Feature	On; Monitor; Off
QuickOpt™ Timing Cycle Optimisation	Sensed/Paced AV Delay
Auto Mode Switch (AMS) Atrial Tachycardia	Off; DDI(R); VVI(R)
Detection Rate (min^{-1})	110–300
AMS Base Rate (min^{-1})	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; Ventricular 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 Monitoring Trigger; SecureSense — lead noise detected; non-sustained lead noise detected; ST Episodes (Type I only)
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 one 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
ST Monitoring	ST Histogram Data; Long-term ST Deviation Trend; ST Episode Log; ST Episode Details; 24-Hour ST and HR Trend; ST EGM Baseline and Snapshots prior to ST Episode; VT/VF; Interrogation (Snapshots and 24-hour trend at time of interrogation)
CorVue™ Congestion Monitoring	On; Off
CorVue™ Congestion Trigger	8–18 days

MRI Scan Parameters**

LEAD MODEL	LEAD LENGTHS	RF POWER (SAR)	SCAN REGION
Tendril MRI™ Lead LPA1200M	46, 52, 58 cm	Normal Operating Mode***	Full Body
Tendril™ STS Pacing Lead 2088TC	46, 52 cm		
IsoFlex™ Optim™ Pacing Lead 1944	46, 52 cm		
Durata™ Defibrillation Lead 7120Q, 7122Q	58, 65 cm		
Optisure™ Lead LDA220Q, LDA210Q	58, 65 cm		

**Refer to the MRI-Ready Systems Manual for additional information.

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

Fortify™ VR

Implantable Cardioverter Defibrillator (ICD)
with CorVue™ Congestion Monitoring

Product Highlights

- 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 % V-Pacing alert notifies patients and their clinics when percent ventricular pacing is greater than the programmed threshold.
- The low frequency attenuation filter is designed to enhance sensing performance and may reduce the possibility of oversensing T waves.
- 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 touch 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.
- Unique morphology SVT discrimination feature helps reduce the risk of inappropriate ICD shocks and is intended to promote fast, accurate diagnosis and delivery of therapy.
- Up to 45 minutes of continuous, fully annotated stored electrograms, including up to 60 seconds of pre-trigger 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.
- AutoCapture™ Pacing System offers the maximum in threshold adaptability and patient safety with ventricular Beat-by-Beat™ AutoCapture™ pacing systems confirmation. The AutoCapture Pacing System automatically delivers a 5,0 V backup safety pulse when noncapture is detected.
- 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: Implantable Cardioverter Defibrillator (ICD)

MODEL NUMBER	DIMENSIONS (H × W × T, MM)	WEIGHT (G)	VOLUME (CC)	CONNECTOR DEFIBRILLATION	CONNECTOR SENSE/PACE
CD1233-40	73 × 40 × 14	76	35	DF1	IS-1
CD1233-40Q	71 × 40 × 14	75	35	DF4	DF4

Fortify™ VR

Implantable Cardioverter Defibrillator (ICD) with CorVue™ Congestion Monitoring

Product Specifications

PHYSICAL SPECIFICATIONS

Models	CD1233-40	CD1233-40Q
Telemetry	RF	RF
Delivered/Stored Energy (J)	40/45	40/45
Volume (cc)	35	35
Weight (g)	76	75
Size (mm)	73 × 40 × 14	71 × 40 × 14
Defibrillation Lead Connections	DF1	DF4
Sense/Pace Lead Connections	IS-1	DF4
High Voltage Can	Electrically active titanium can	Electrically active titanium can

PARAMETER	SETTINGS
Sensing/Detection	
Sense*Ability*™ Sensing Algorithm Technology	Automatic sensitivity control adjustment for atrial and ventricular events
Low Frequency Attenuation	On; Off
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; Ventricular) 0–220
Ventricular Sense Refractory (ms)	125; 157
Detection Zones	VT-1; VT-2; VF
SVT Discriminators	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 VT 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	1–15
Number of Stimuli	2–20
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	
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	VVI(R); Pacer Off
Temporary Modes	Off; VVI; VOO
Rate-Adaptive Sensor	On; Off; Passive
Programmable Rate Parameters	Off; Base Rate (min^{-1}); Rest Rate (min^{-1}); Maximum Sensor Rate (min^{-1}); Hysteresis Rate (min^{-1}); Rate Hysteresis with Search
Ventricular AutoCapture™ Pacing System	On; Off
Post-Therapy Pacing (Independently Programmable from Bradycardia and ATP)	
Post-Shock Pacing Mode	Off; VVI
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; Ventricular Lead Impedance Out of Range; High Voltage Lead Impedance Out of Range; %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 25 minutes including up to one minute programmable pre-trigger data per VT/VF diagnosis/detection electrograms; triggers include: diagnosis; therapy; 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
Ventricular HV Lead Impedance Trend	Multi-Vector Trend Data
Histograms	Event Histogram; Ventricular Heart Rate Histogram; Exercise and Activity Trending
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

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.

Indications: The devices are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

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°C and 45°C. Do not subject it to temperatures below -20°C 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.

Fortify™ DR

Implantable Cardioverter Defibrillator (ICD)
with CorVue™ Congestion Monitoring

Product Highlights

- 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 % V-Pacing alert notifies patients and their clinics when percent ventricular pacing is greater than the programmed threshold
- The low frequency attenuation filter is designed to enhance sensing performance and may reduce the possibility of oversensing T waves
- 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 touch 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 SenseAbility™ 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 touch 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 pre-trigger 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
- AutoCapture™ Pacing System offers the maximum in threshold adaptability and patient safety with ventricular Beat-by-Beat™ capture confirmation. The AutoCapture Pacing System automatically delivers a 5,0 V backup safety pulse when noncapture is detected
- ACap™ Confirm Pacing System periodically completes a threshold search and automatically adjusts amplitude to address patients' changing atrial thresholds
- Designed to reduce unnecessary right ventricular pacing, the Ventricular Intrinsic Preference (VIP™) algorithm allows intrinsic conduction when possible and provides optimised ventricular support when needed

Ordering Information

Contents: Implantable Cardioverter Defibrillator (ICD)

MODEL NUMBER	DIMENSIONS (H × W × T, MM)	WEIGHT (G)	VOLUME (CC)	CONNECTOR DEFIBRILLATION	CONNECTOR SENSE/PACE
CD2233-40	74 × 40 × 14	76	35	DF1	IS-1
CD2233-40Q	71 × 40 × 14	75	35	DF4	DF4

Fortify™ DR

Implantable Cardioverter Defibrillator (ICD) with CorVue™ Congestion Monitoring

Product Specifications

PHYSICAL SPECIFICATIONS

Models	CD2233-40	CD2233-40Q
Telemetry	RF	RF
Delivered/Stored Energy (J)	40/45	40/45
Volume (cc)	35	35
Weight (g)	76	75
Size (mm)	74 × 40 × 14	71 × 40 × 14
Defibrillation Lead Connections	DF-1	DF4
Sense/Pace Lead Connections	IS-1	DF4
High-Voltage Can	Electrically active titanium can	Electrically active titanium can

PARAMETER	SETTINGS
AF Management	
AF Suppression™ Pacing	On; Off
No. of Overdrive Pacing Cycles	15–40 in steps of 5
Maximum AF Suppression Rate	80–150 min^{-1}
Sensing/Detection	
Sense*Ability*™ Technology	Automatic Sensitivity Control adjustment for atrial and ventricular events
Low Frequency Attenuation	On; Off
Threshold Start	(Post-Sensed; Atrial) 50; 62,5; 75; 100%; (Post-Paced; Atrial) 0,2–3,0 mV; (Post-Sensed; Ventricular) 50; 62,5; 75; 100%; (Post-Paced; Ventricular) Auto; 0,2–3,0 mV
Decay Delay	(Post-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 VT 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	1–15
Number of Stimuli	2–20
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	
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	DDD(R); DDI(R); VVI(R); AAI(R); Pacer Off
Temporary Modes	Off; DDD; DDI; 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
QuickOpt™ Timing Cycle Optimisation	Sensed/Paced AV delay
Auto Mode Switch (AMS)	Off; DDI(R); VVI(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)
Ventricular AutoCapture™ Pacing System	On; Off
ACap™ Confirm	On; Monitor; Off
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; Ventricular 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
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; 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 Trigger	8–18 days

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.

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.

Abbott
The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem, Belgium
Tel: +32 2 774 68 11
cardiovascular.abbott

Customer Support: 46-8-474-4756

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

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