CRM PRODUCT CATALOG



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Ellipse[™] VR

Single-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 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

- SenseAbility[™] 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	$68 \times 51 \times 12$	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, thromboenholi, 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, 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.

EllipseTM VR

Single-chamber Implantable Cardioverter Defibrillator (ICD)

Product Specifications

Models	CD1377-36C	CD1377-36QC	
5	RF	RF	
	36/39	36/39	
	31 56	30 67	
	58 × 51 × 12	66 × 51 × 12	
	DF1	DF4	
High Voltage Can	IS-1 Electrically active titanium can	DF4 Electrically active titanium can	
Coating	Parylene	Parylene	
MR Conditional	No	Yes-MRI Ready	
PARAMETER	SETTINGS		
Sensing/Detection			
SenseAbility [™] Sensing	Automatic	sensitivity control adjustment for	
Algorithm Technology	ventricular		
Low Frequency Attenuation	On; Off		
Threshold Start		ed; Ventricular) 50; 62,5; 75; 100%;	
Dogay Dolay		l; Ventricular) Auto; 0,2–3,0 mV	
Decay Delay Ventricular Sense Refractory (m		e/Post-Pace; Ventricular) 0–220	
Detection Zones		ramming – 1 zone, 2 zones or 3	
		I, VT-2, VF)	
SVT Discriminators		set; Interval Stability; Sinus Interval	
		orphology Discrimination (Far Field	
		phology Discrimination or Original	
	Template U	Manual (Original MD) or Automatic	
Discrimination Modes	On; Passive		
SVT Threshold	150-240 m		
SVT Timeout	0,25-5 min		
Monitor Mode		discrimination and diagnostics, no	
Reconfirmation		ivery (VT or VT-1 zone) sensing during charging	
Lead Noise Discrimination		se [™] RV lead noise discrimination	
Beau Holde Biber miniation	algorithm		
	(On; On wit	h Timeout; Passive; Off)	
Antitachycardia Pacing Therapy	7		
ATP Configurations		st; Scan; 1 or 2 schemes per VT zone	
ATP in VF Zone		ATP While Charging; ATP Prior to Charging;	
ATP Upper Rate Cutoff	150-300 m		
Burst Cycle Length Min, Burst Cycle Longth (mc)		eadaptive or Fixed increments of 5	
Min. Burst Cycle Length (ms) Number of Bursts	1-15	increments of 5	
Number of Stimuli	2-20		
Add Stimuli per Burst	On; Off		
ATP Pulse Amplitude (V)		dent from Bradycardia and Post-	
	Therapy Pa		
ATP Pulse Width (ms)		dependently Programmable from a and Post-Therapy Pacing	
High Voltage Therapy			
DynamicTx [™] Over-current Detection Algorithm	On; Off		
DeFT Response [™] Technology	Programma	able pulse width for P1/P2 and tilt	
High Voltage Output Mode	Fixed Pulse	Width; Fixed Tilt	
Waveform	Biphasic; M		
RV Polarity	Cathode (-)		
Electrode Configuration	кv to Can;	RV to SVC/Can; RV to SVC	
Bradycardia Pacing			
Permanent Modes	Off; VVI(R)		
Temporary Modes Rate-Adaptive Sensor	Off; VVI; V On; Off; Pas		
Programmable Rate Parameters		ate (min ⁻¹); Rest Rate (min ⁻¹); Maxi-	
-	mum Senso (V); Pulse V	r Rate (min ⁻¹); Pulse Amplitude (RV) Vidth (RV) (ms); Hysteresis Rate	
Ventricular AutoCapture [™] Pacing System	On; Off	e Hysteresis with Search	
Post-Therapy Pacing (Independ	ently Programma	ble from Bradycardia and ATP)	
Post-Shock Pacing Mode	Off; VVI	- ,	
Post-Shock Base Rate (min ⁻¹) Post-Shock Pacing Duration (mi	30–100 in i	ncrements of 5 ,5; 5; 7,5; or 10	
Device Testing/Induction Meth	ods		
Device Testing/Induction Meth DC Fibber [™] Pulse Duration (sec)			
	0,5-5,0 20-100	li 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
Notification 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

f 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 letermine 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**	n lin d
Optisure™ Lead LDA210Q, LDA220Q	58, 65 cm		Full Body

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

MR Conditional Field Strength: 1,5 Tesla.

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

Ellipse[™] DR

Dual-chamber Implantable Cardioverter Defibrillator (ICD)

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



- SenseAbility[™] 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	$69\times51\times12$	66	31	DF1	IS-1
CD2377-36QC*	$70 \times 51 \times 12$	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.

Ellipse™ DR

Dual-chamber Implantable Cardioverter Defibrillator (ICD)

Product Specifications

PHYSICAL SPECIFICATIONS

PHYSICAL SPECIFICATIO			 Post-Shock Post-Shock 	
Models	CD2377-36C	CD2377-36QC	_ Post-Shock	
Telemetry Delivered/Stored Energy (J)	RF 36/39	RF 36/39	Device Tes	
Volume (cc)	31	31		
Weight (g) Size (mm)	66 69 × 51 × 12	$\begin{array}{c} 68\\ 70\times51\times12 \end{array}$	Burst Fibbo Noninvasiv	
Defibrillation Lead	DF1	DF4	Stimulation	
Connections	10.1	IS 1 DE4	Patient No	
Sense/Pace Lead Connections	IS-1	IS-1; DF4	Programm	
High Voltage Can		um can Electrically active titanium can		
Coating MR Conditional	Parylene No	Parylene Yes-MRI Ready		
PARAMETER	SETTINGS		_	
AF Management			Device Par	
AF Suppression [™] Pacing	On; Off	6 -	Entry into	
No. of Overdrive Pacing Cy- Maximum AF Suppression			Vibration I	
Sensing/Detection			Number of Notificatio	
	Automatic consi	tivity control a division out for stais!	Number of	
SenseAbility [™] Sensing Algorithm Technology	and ventricular	tivity control adjustment for atrial events	Time Betw (hours)	
Low Frequency Attenuatio				
Threshold Start		trial) 50; 62,5; 75; 100%; (Post-Paced; 1V; (Post-Sensed; Ventricular) 50; 62,5;		
D D. l	75; 100%; (Post-	Paced; Ventricular) Auto; 0,2-3,0 mV		
Decay Delay Ventricular Sense Refractor		st-Pace; Atrial/Ventricular) 0–220		
Detection Zones	3 zone program	ming – 1 zone, 2 zones or 3 zones		
SVT Discriminators	(VT-1, VT-2, VF AV Rate Branch			
Sv i Discriminators	Onset or Sudde	; Arrhythmia Onset (Chamber n Onset); Interval Stability; AV	Therapy Su	
	Association; M Field MD [™] Mor	orphology Discrimination (Far phology Discrimination or Original	Episodes S	
	MD) with Man	al (original MD only) or Automatic	Lifetime D	
Monitor Mode	Template Upda Detection, discu	te imination and diagnostics, no	Elicenne	
Discrimination Made	therapy delivery	v (VT or VT-1 zone)	AT/AF Bur Ventricula	
Discrimination Modes SVT Threshold	On; Passive; Off 150–240 min ⁻¹	0n; Passive; 0n 150–240 min ⁻¹		
SVT Timeout	0,25–5 min		Impedance Histogram	
Reconfirmation		sing during charging		
Lead Noise Discrimination		V lead noise discrimination algorithm meout; Passive; Off)		
Antitachycardia Pacing Th				
ATP Configurations		an; 1 or 2 schemes per VT zone	PMT Data	
ATP in VF Zone		rging; ATP Prior to Charging; Off	Real-Time (RTM)	
ATP Upper Rate Cutoff Burst Cycle Length	150–300 min ⁻¹ Adaptive; Reada	uptive or Fixed	ST Monito	
Min. Burst Cycle Length (n				
Number of Bursts Number of Stimuli	1-15			
Add Stimuli per Burst	2–20 On; Off		CorVue [™] Co	
ATP Pulse Amplitude (V)	7,5 Independent	from Bradycardia and Post-Therapy	CorVue Co	
ATP Pulse Width (ms)	Pacing	endently Programmable from		
ATT T uise width (iiis)		l Post-Therapy Pacing	MDISA	
High Voltage Therapy			MRI Sc	
DynamicTx [™] Over-current	On; Off		If the impla	
Detection Algorithm DeFT Response [™] Technolog	y Programmable	pulse width for P1/P2 and tilt	(SAR), scan determine t	
High Voltage Output Mode				
Waveform RV Polarity	Biphasic; Mono		LEA	
Electrode Configuration	Cathode (-); And RV to Can: RV to	o SVC/Can; RV to SVC	Tendril MR	
Bradycardia Pacing	, , , , , , , , , , , , , , , , , , , ,	, ,	LPA1200M	
Permanent Modes	Off; DDD(R); DI	DI(R); VVI(R); AAI(R)	Tendril™ ST	
Temporary Modes	Off; DDD; DDI;	VVI; AAI; AAT; DOO; VOO; AOO	2088TC	
Rate-Adaptive Sensor Programmable Rate and De	On; Off; Passive); Rest Rate (min-1); Maximum	IsoFlex [™] Oj	
Parameters	Tracking Rate (nin ⁻¹); Off; Maximum Sensor Rate	Leads 1944	
	(min ⁻¹); Paced A' Rate Responsive	V Delay (ms); Sensed AV Delay (ms); AV Delay (Atrial and RV) (ms);	1944	
	Hysteresis Rate	(min ⁻¹); Rate Hysteresis with Search	Durata™ De	
Ventricular AutoCapture [™] Pacing System	On; Off		7120Q, 7122Q	
ACap [™] Confirm Feature	On; Monitor; Of		Optisure™ L	
QuickOpt [™] Timing Cycle Optimisation	Sensed/Paced A	V delay	LDA210Q, LI	
Auto Mode Switch (AMS)	Off; DDI(R); VV	I(R)		
Atrial Tachycardia Detectio Rate (min ⁻¹)	on 110–300		**As defined in Head SAR ≤ 3.2	
AMS Base Rate (min ⁻¹)	40; 45;135		11eau 5AR ≤ 3.2	
	nation Atrial Pace on P	MT; Off; Passive	1. MRI Conditi	
Auto PMT Detection/Termin Rate Responsive PVARP/V Ventricular Intrinsic Prefer	REF Off; Low; Mediu	ım; High	2. See MRI-Res scan parameter	

Post-Therapy Pacing (Independe	ntly 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 Metho	ds
DC Fibber [™] Pulse Duration (sec) Burst Fibber Cycle Length (ms)	0,5-5,0 20-100
Noninvasive Programmed	2–25 stimuli with up to three extra stimuli
Stimulation (NIPS)	
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) Number of Vibrations per	2; 4; 6; 8; 10; 12; 14; 16 2
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
Lifetime Diagnostics	more details including stored electrograms 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"
PMT Data	reports up to 1 year Information regarding PMT detections
Real-Time Measurements	Pacing lead impedances; high voltage lead
(RTM)	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)
$\operatorname{CorVue}^{\text{\tiny TM}}\operatorname{Congestion}\operatorname{Monitoring}$	On; Off
CorVue Congestion Trigger	8–18 days

can Parameters

lanted system is comprised of a combination of leads that have differing RF Power n region and/or additional considerations, use the most restrictive of each to 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		
Tendril™ STS Pacing Lead 2088TC	46, 52 cm		
IsoFlex [™] Optim [™] Pacing Leads 1944	46, 52 cm	Normal Operating Mode**	Full Body
Durata™ Defibrillation Lead 7120Q, 7122Q	58, 65 cm		
Optisure™ Lead LDA210Q, LDA220Q	58, 65 cm		

in IEC 60601-2-33, Normal Operating Mode corresponds to RF Power SAR: \leq 2 W/kg, 3.2 W/kg.

litional Field Strength: 1,5 Tesla.

Ready Systems Manual for approved MR Conditional systems device/lead combinations and ters.

Fortify Assura[™] Single-chamber ICD

CD1359-40C and CD1359-40QC Parylene Coated

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	$73 \times 40 \times 14$	76	35	DF1	IS-1
CD1359-40QC*	$71 \times 40 \times 14$	75	35	DF4	DF4

"Indicates models that are MR Conditional^{1,7}

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.

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 73 × 40 × 14	75 71 × 40 × 14
Size (mm) Defibrillation Lead Connections	73 × 40 × 14 DF1	71 × 40 × 14 DF4
Sense/Pace Lead Connections	IS-1	DF4 DF4
High Voltage Can	Electrically active titanium	Electrically active titanium
	can	can
Coating	Parylene	Parylene
MR Conditional	No	Yes - MRI Ready
PARAMETER	SETTINGS	
Sensing/Detection SenseAbility [™] Sensing Algorithm	Automatic sensitivity control ad	iustment for ventricular events
Technology	rutomate sensitivity control ac	distinctic for ventricular events
Low Frequency Attenuation	On; Off	
Sense Filter	(Post-Sensed; Ventricular) 50; 62	2,5; 75; 100%;
	(Post-Paced; Ventricular) Auto;	
Decay Delay	(Post-Sense/Post-Pace; Ventricu	ılar) 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™	
	or Original MD) with Manual (O	riginal MD) or Automatic
	Template Update	
Discrimination Modes	On; Passive; Off	
SVT Threshold	150-240 min ⁻¹	
SVT Timeout Monitor Mode	0,25-5 min	amostics no thereas 1.1
wonitor Mode	Detection, discrimination and di	agnostics, no therapy delivery
Reconfirmation	(VT or VT-1 zone) Continuous sensing during char;	ring
Lead Noise Discrimination	SecureSense™ RV lead noise dis	
Lead Noise Discrimination	(On; On with Timeout; Passive;	
Antitachycardia Pacing Therapy	(on, on white Endeoue, Easive, e	511)
ATP Configurations	Damp. Pupet Saan 1 on 2 saham	a non VT gono
ATP in VF Zone	Ramp; Burst; Scan; 1 or 2 scheme ATP While Charging; ATP Prior	
ATP Upper Rate Cutoff	150-300 min ⁻¹	to charging, on
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 Bradycard	lia and Post-Therapy Pacing
ATP Pulse Width (ms)	1,0 or 1,5 Independently Program	
	Post-Therapy Pacing	
High Voltage Therapy		
DynamicTx [™] Over-Current	On; Off	
Detection Algorithm		
DeFT Response [™] Technology	Programmable pulse width for I	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; Ventricu	
Programmable	Off; Base Rate (min ⁻¹); Rest Rate	
Rate Parameters	(min ⁻¹); Pulse Amplitude (RV) (V); Pulse Width (RV) (ms);
Data Huntanasis with C	Hysteresis Rate (min ⁻¹)	
Rate Hysteresis with Search Ventricular AutoCapture™	On; Off	
Pacing System		
	hr Duoguommahl - f D 1	rdia and ATD)
Post-Therapy Pacing (Independent Post-Shock Pacing Mode	Iy Programmable from Bradyca Off; VVI	ruia anu ATP)
Post-Shock Pacing Mode 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		
Device Testing/Induction Methods DC Fibber™ Pulse Duration (sec)	0,5–5,0	
Burst Fibber Cycle Length (ms)	20–100	
Noninvasive Programmed	2–25 stimuli with up to three ex	tra stimuli
Stimulation (NIPS)		
Patient Notifiers		
	Dorrigo at EDL Channer Time T	it Dooghod, Doogil-1- TTV
Programmable Notifiers (On; Off)	Device at ERI; Charge Time Lin Circuit Damage: Vontrigular Log	
	Circuit Damage; Ventricular Lea	
	High Voltage Lead Impedance (
	CorVue [™] Congestion Monitorin	
	lead noise discrimination algorit	
Device Parameter Reset	detected; ST Episodes (Type I or On	my)
Entry into Backup VVI Mode	On On	
Vibration Duration (sec)	2; 4; 6; 8; 10; 12; 14; 16	
Number of Vibrations per	2	
Notification		
Number of Notifications	1 14	

 Number of Notifications
 1–16

 Time Between Notifications (hours)
 10; 22

Electrograms and Diagnostics Up to 25 minutes including up to one minute programmable pre-trigger data per VT/VF diagnosis/detection electrogramma Stored 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 Diagram of therapies delivered Therapy Summary Episodes Summary Directory listing of up to 60 episodes with access to more details including stored electrograms Lifetime Diagnostics Ventricular HV Lead History of bradycardia events and device-initiated charging Multi-Vector Trend Data Impedance Trend Histograms Event Histogram; Ventricular Heart Rate Histogram; Exercise and Activity Trending; DirectTrendr™ reports up to one year Pacing lead impedances; high voltage lead impedances; and signal amplitudes Real-Time Measurements (RTM) ST Histogram Data; Long-term ST Deviation Trend; ST Episode Log; ST Episode Details; 24-Hour ST and HR Trend; ST Monitoring ST EGM Baseline and Snapshots prior to ST Episode VT/ VF; Interrogation (Snapshots and 24-hour trend at time of interrogation) CorVue™ Congestion Monitoring CorVue™ Congestion Monitoring On; Off 8-18 days Trigger

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		
Tendril™ STS Pacing Lead 2088TC	46, 52 cm		
IsoFlex™ Optim™ Pacing Lead 1944	46, 52 cm	Normal Operating Mode**	Full Body
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: \leq 2 W/kg, Head SAR \leq 3.2 W/kg.

Fortify Assura™ Single-chamber ICD

CD1359-40 and CD1359-40Q Non-coated

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



Merlin@home™ Transmitter Compatible

- 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	$74 \times 40 \times 14$	76	35	DF1	IS-1
CD1359-40Q*	$71 \times 40 \times 14$	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.

Fortify Assura[™] Single-chamber ICD CD1359-40 and CD1359-40Q Non-coated

Product Specifications

Models	CD1359-40	CD1359-40Q
elemetry	RF	RF
elivered/Stored Energy (J)	40/45	40/45
olume (cc)	35	35
eight (g) ze (mm)	76 74 × 40 × 14	75 71 × 40 × 14
fibrillation Lead Connections		71 × 40 × 14 DF4
nse/Pace Lead Connections	DF1 IS-1	DF4 DF4
igh Voltage Can	Electrically active titanium	Electrically active titanium
ight voltage can	can	can
R Conditional	No	Yes — MRI Ready
ARAMETER	SETTINGS	
nsing/Detection		
nseAbility™ Sensing Algorithm	Automatic sensitivity control	adjustment for ventricular events
echnology		aujustment for ventricular events
ow Frequency Attenuation	On; Off	(25 55 1000) (D + D - 1
ense Filter	(Post-Sensed; Ventricular) 50 Ventricular) Auto; 0,2–3,0 mV	
ecay Delay	(Post-Sense/Post-Pace; Ventr	
entricular Sense Refractory (ms)	125; 157	
tection Zones	3 zone programming – 1 zone VT-2, VF)	e, 2 zones or 3 zones (VT-1,
'T 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	
iscrimination Modes	On; Passive; Off	
T Threshold	150-240 min ⁻¹	
T Timeout	0,25-5 min	
onitor Mode	Detection, discrimination and diagnostics, no therapy delivery (VT or VT-1 zone)	
econfirmation	Continuous sensing during ch	arging
ad Noise Discrimination		discrimination algorithm (On; On
ntitachycardia Pacing Therapy	with finebul, fusive, ony	
P Configurations	Ramp; Burst; Scan; 1 or 2 sche	mes per VT zone
P in VF Zone	ATP While Charging; ATP Pr	
P Upper Rate Cutoff	150–300 min ⁻¹	ior to onlinging, on
urst Cycle Length	Adaptive; Readaptive or Fixed	1
in. Burst Cycle Length (ms)	150-400 in increments of 5	
imber of Bursts	1–15	
imber of Stimuli	2-20	
ld Stimuli per Burst	On; Off	
TP Pulse Amplitude (V)		ardia and Post-Therapy Pacing
TP Pulse Width (ms)	1,0 or 1,5 Independently Progr Post-Therapy Pacing	rammable from Bradycardia and
gh Voltage Therapy		
/namicTx™ Over-Current etection Algorithm	On; Off	
eFT Response™ Technology	Programmable pulse width fo	r P1/P2 and tilt
gh Voltage Output Mode	Fixed Pulse Width; Fixed Tilt	
aveform	Biphasic; Monophasic	
Polarity	Cathode (-); Anode (+)	
ectrode Configuration	RV to Can; RV to SVC/Can; R	V to SVC
adycardia Pacing	Off MAR(D)	
rmanent Modes	Off; VVI(R)	
emporary Modes	Off; VVI; VOO (Bost Sama /Bost Base Ventr	igular) 0, 220
ate-Adaptive Sensor rogrammable	(Post-Sense/Post-Pace; Ventr Off: Base Bate (min ⁻¹): Best Ba	icular) 0–220 ite (min ⁻¹); Maximum Sensor Rate
ate Parameters	(min ⁻¹); Pulse Amplitude (RV) Hysteresis Rate (min ⁻¹)	

(Post-Sense) Post-Pace; Ventricular) 0–220 Off; Base Rate (min³); Rest Rate (min³); Maximum Sensor Rate (min³); Pulse Amplitude (RV) (V); Pulse Width (RV) (ms); Hysteresis Rate (min³)

IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) DEVICES

ate Hysteresis with Search entricular AutoCapture™ acing System	On; Off
0,	ly Programmable from Bradycardia and ATP)
ost-Shock Pacing Mode	Off: VVI
ost-Shock Base Rate (min ⁻¹)	30–100 in increments of 5
ost-Shock Pacing Duration (min)	Off; 0,5; 1; 2,5; 5; 7,5; or 10
evice Testing/Induction Methods	
C Fibber™ Pulse Duration (sec)	0,5-5,0
urst Fibber Cycle Length (ms)	20-100
oninvasive Programmed timulation (NIPS)	2–25 stimuli with up to three extra stimuli
atient Notifiers	
rogrammable 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)
evice Parameter Reset	On
ntry into Backup VVI Mode	On
ibration Duration (sec)	2; 4; 6; 8; 10; 12; 14; 16 2
umber of Vibrations per otification	-
umber of Notifications	1-16
ime Between Notifications (hours)	10; 22
lectrograms and Diagnostics	
tored 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
herapy Summary	Diagram of therapies delivered
pisodes Summary	Directory listing of up to 60 episodes with access to more details including stored electrograms
ifetime Diagnostics	History of bradycardia events and device-initiated charging
entricular HV Lead Impedance rend	Multi-Vector Trend Data
listograms	Event Histogram; Ventricular Heart Rate Histogram; Exercise and Activity Trending: DirectTrend™ reports up to one year
iistograms eal-Time Measurements (RTM)	Event Histogram; Ventricular Heart Rate Histogram; Exercise and Activity Trending; DirectTrend™ reports up to one year 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;
-	and Activity Trending; DirectTrend™ reports up to one year Pacing lead impedances; high voltage lead impedances; and signal amplitudes ST Histogram Data; Long-term ST Deviation Trend; ST
-	and Activity Trending; DirectTrend™ reports up to one year 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/
-	and Activity Trending; DirectTrend™ reports up to one year 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

Scan Parameters**

LEAD MODEL	LEAD LENGTHS	RF POWER (SAR)	SCAN REGION
Tendril MRI™ Lead LPA1200M	46, 52, 58 cm		
Tendril™ STS Pacing Lead 2088TC	46, 52 cm		
IsoFlex™ Optim™ Pacing Leads 1944	46, 52 cm	Normal Operating Mode**	Full Body
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

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



Merlin@home™ Transmitter Compatible



- SenseAbility[™] 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	$74 \times 40 \times 14$	76	35	DF1	IS-1
CD2359-40QC*	$71 \times 40 \times 14$	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.

Fortify Assura[™] Dual-chamber ICD

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

Product Specifications

Models		59-40C	CD2359-40QC		
Telemetry Delivered /Stored Energy (1)	RF		RF		
Delivered/Stored Energy (J) Volume (cc)	40/45 35		40/45 35		
Weight (g)	76		75		
Size (mm)		0 × 14	71 × 40 × 14		
Defibrillation Lead	DF1		DF4		
Connections					
Sense/Pace Lead	IS-1		IS-1; DF4		
Connections					
High Voltage Can			Electrically active titanium car Regularia		
Coating MRI Conditional	Paryle No	ene	Parylene Yes – MRI Ready		
with conditional	140		res – with Ready		
PARAMETER		SETTINGS			
AF Management					
AF Suppression [™] Pacing		On; Off			
No. of Overdrive Pacing Cy	cles	15-40 in steps of 5			
Maximum AF Suppression		80–150 min ⁻¹			
Sensing/Detection					
SenseAbility [™] Sensing			ntrol adjustment for atrial		
Algorithm Technology		and ventricular events			
Low Frequency Attenuation	n	On; Off			
Threshold Start			; 62,5; 75; 100%; (Post-Paced;		
		Atrial) 0,2–3,0 mV; Thre Ventricular) 50; 62,5; 75;	shold Start (Post-Sensed;		
		Ventricular) Auto; 0,2-3			
Decay Delay		(Post-Sense/Post-Pace; Atrial/Ventricular) 0-220 ms			
Ventricular Sense Refractor	ry (ms)				
Detection Zones		3 zone programming – 1	l zone, 2 zones or 3 zones		
SVT Discriminators					
SVI Discriminators	SVT Discriminators		AV Rate Branch; Arrhythmia Onset (Chamber Onset or Sudden Onset); Interval Stability; AV		
		Association; Morpholog	y Discrimination (Far Field		
		MD [™] Morphology Disci	rimination or Original MD)		
		with Manual (original I Template Update	MD only) of Automatic		
Monitor Mode		Detection; discrimination	on and diagnostics; no		
		therapy delivery	0 ,		
Discuinination Modes		(VT or VT-1 zone)			
Discrimination Modes SVT Threshold		On; Passive; Off 150–240 min ⁻¹			
SVT Discrimination Time	11 1	0,25-5 min			
Reconfirmation	<i>,</i>	Continuous sensing during charging			
Lead Noise Discrimination	1	SecureSense [™] RV lead no	oise discrimination algorithm		
		(On; On with Timeout; F	Passive; Off)		
Antitachycardia Pacing Th	ierapy				
ATP Configurations		Ramp; Burst; Scan; 1 or			
ATP in VF Zone ATP Upper Rate Cutoff		ATP While Charging; A 200–400 ms	TP Prior to Charging; Off		
Burst Cycle Length		Adaptive; Readaptive or	Fixed		
Min. Burst Cycle Length (ms)	150-400 in increments			
Number of Bursts		1–15			
Number of Stimuli			2-20		
Add Stimuli per Burst			On; Off		
ATP Pulse Amplitude (V)			radycardia and Post-Therapy		
* • •		Pacing	D 11.0		
ATP Pulse Width (ms)		1,0 or 1,5 Independently Bradycardia and Post-T	herapy Pacing		
High Voltage Therapy					
DynamicTx [™] Over-current	:	On; Off			
Detection Algorithm		Decomony able autores:	deh fon D1 /D2 and eile		
DeFT Response [™] Technolo High Voltage Output Mode		Programmable pulse wi Fixed Pulse Width; Fixe			
High Voltage Output Mode Waveform	-	Biphasic; Monophasic	a mit		
RV Polarity		Cathode (-); Anode (+)			
Electrode Configuration		RV to Can; RV to SVC/C	an: RV to SVC		
Bradycardia Pacing		,,			

On; Monitor; Off Sensed/Paced AV Delay Off; DDI(R); VVI(R)

Atrial Pace; Off; Passive

110-300

40: 45: ... 135

RV Polarity Electrode Configuration Bradycardia Pacing Off; DDD(R); DDT(R); DDI(R); VVT(R); VVI(R); AAI(R) Off; DDD; DDT; DDI; VVT; VVI; AAI; AAT; DOO; VOO; AOO Permanent Modes Temporary Modes VOO; AOO On; Off; Passive 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 Re-sponsive AV Delay (ms); Sensed AV Delay (ms); Rate Re-sponsive AV Delay (Atrial and RV); Hysteresis Rate (min⁻¹); Rate Hysteresis with Search On; Off

Rate-Adaptive Sensor Programmable Rate and Delay Parameters

Ventricular AutoCapture™ Ventricular AutoCapture Pacing System ACap[®] Confirm Feature QuickOpt[®] Timing Cycle Optimisation Auto Mode Switch (AMS) Atrial Tachycardia Detection Rate (min⁻¹) AMS Base Rate (min⁻¹) Auto PMT Detection/ Termination Rate Responsive PVARP/VREF Off; Low; Medium; High Ventricular Intrinsic Preference Off; On (50–200 ms) (VIP^{**}) IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) DEVICES

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 Method	ls
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 Episoo 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 verificatio lead noise detected; non-sustained lead noise detected; NSVT/NSVF
Therapy Summary Episodes Summary	Diagram of therapies delivered Directory listing of up to 60 episodes with access to
Lifetime Diagnostics	more details including stored electrograms History of bradycardia events and device-initiated
ATT /ATT Days days Thread	charging
AT/AF Burden Trend Ventricular HV Lead	Trend data and counts Multi-Vector Trend Data
Impedance Trend	
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 Trenc ST Episode Log; ST Episode Details; 24-Hour ST an 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	On; Off
Monitoring	

sy 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			
Tendril™ STS Pacing Lead 2088TC	46, 52 cm			
IsoFlex [™] Optim [™] Pacing Lead 1944	46, 52 cm	Normal Operating Mode**	Full Body	
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: \leq 2 W/kg, Head SAR \leq 3.2 W/kg.

Fortify AssuraTM Dual-chamber ICD

CD2359-40 and CD2359-40Q Non-coated





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
- SenseAbility[™] 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	$74 \times 40 \times 14$	76	35	DF1	IS-1
CD2359-40Q*	$71 \times 40 \times 14$	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

Fortify Assura[™] Dual-chamber ICD CD2359-40 and CD2359-40Q Non-coated

Product Specifications

Models	CD2359-40	CD2359-40Q	DC Fibber [™] Pulse Du	ration (sec)
Telemetry	RF	RF	Burst Fibber Cycle Le	
Delivered/Stored Energy (J)	40/45	40/45	Noninvasive Program Stimulation (NIPS)	nmed
Volume (cc)	35	35		
Weight (g)	76	75	Patient Notifiers	
Size (mm)	74 × 40 × 14	71 × 40 × 14	Programmable Notifi	ers (On; Off)
Defibrillation Lead Connections Sense/Pace Lead Connections	DF1 IS-1	DF4 IS-1; DF4		
High Voltage Can	Electrically active titanium can	Electrically active titanium can		
MRI Conditional	No	Yes — MRI Ready		
PARAMETER	SETTINGS		Device Parameter Re	set
AF Management			Entry into Backup VV	
AF Suppression [™] Algorithm Pacing	g On; Off		Vibration Duration (s	
No. of Overdrive Pacing Cycles	15-40 in steps of 5		Number of Vibrations Notification	-
Maximum AF Suppression Rate	80–150 min ⁻¹		Number of Notification Time Between Notific	
Sensing/Detection				
SenseAbility [™] Sensing Algorithm Technology	Automatic sensitivity contro ventricular events	adjustment for atrial and	Electrograms and Dia	
Low Frequency Attenuation	On; Off		Stored Electrograms	
Sense Filter	0,2-3,0 mV; Threshold Star	5; 75; 100%; (Post-Paced; Atrial) (Post-Sensed; Ventricular) 50; Ventricular) Auto; 0,2–3,0 mV		
Decay Delay	(Post-Sense/Post-Pace; Atria			
Ventricular Sense Refractory (ms)	125; 157		m1 -	
Detection Zones	3 zone programming – 1 zon (VT-1, VT-2, VF)	ne, 2 zones or 3 zones	Therapy Summary Episodes Summary	
SVT Discriminators	AV Rate Branch; Arrhythmi or Sudden Onset); Interval S	tability; AV Association;	Lifetime Diagnostics	;
	Morphology Discrimination Discrimination or Original M only) or Automatic Templat	(Far Field MD [™] Morphology MD) with Manual (original MD	AT/AF Burden Trenc	
Monitor Mode	Detection; discrimination and delivery (VT or VT-1 zone)		Ventricular HV Lead Trend Histograms	Impedance
Discrimination Modes	On; Passive; Off		Histograms	
SVT Threshold	150-240 min ⁻¹			
SVT Timeout	0,25-5 min			
Reconfirmation Lead Noise Discrimination	Continuous sensing during of SecureSense [™] PV lead noise		PMT Data	
	SecureSense [™] RV lead noise discrimination algorithm (On; On with Timeout; Passive; Off)		Real-Time Measuren	nents (RTM)
Antitachycardia Pacing Therapy	Dama, Dunat, Caan, Lon 2 cabo	mas non VT gono	ST Monitoring	
ATP Configurations ATP in VF Zone	Ramp; Burst; Scan; 1 or 2 sche ATP While Charging; ATP Pr			
ATP Upper Rate Cutoff Burst Cycle Length	150–300 min ⁻¹ Adaptive; Readaptive or Fixed	1	C - N/™ C +i	Manitanian
Min. Burst Cycle Length (ms)	150–400 in increments of 5	1	CorVue [™] Congestion CorVue [™] Congestion	
Number of Bursts	1–15		confue congestion	11.6861
Number of Stimuli	2-20			
Add Stimuli per Burst	On; Off 7.5 In dama dama from Durador	and is and Deat Theman Deaters	MRI Scan Par	ameters
ATP Pulse Amplitude (V) ATP Pulse Width (ms)	1,0 or 1,5 Independent from Bradyc and Post-Therapy Pacing	ardia and Post-Therapy Pacing rammable from Bradycardia		1
High Voltage Therapy			LEAD MODEL	LEAD LENG
DynamicTx [™] Over-current Detection Algorithm	On; Off		Tendril MRI™ Lead LPA1200M	46, 52, 58 cm
Defection Algorithm DeFT Response [™] Technology	Programmable pulse width fo	or P1/P2 and tilt	Tendril™ STS	
High Voltage Output Mode	Fixed Pulse Width; Fixed Tilt		Pacing Lead	46, 52 cm
Waveform DV D-lastic	Biphasic; Monophasic		2088TC	
RV Polarity Electrode Configuration	Cathode (-); Anode (+) RV to Can; RV to SVC/Can; R	V to SVC	IsoFlex™ Optim™ Pacing Lead	46, 52 cm
Bradycardia Pacing			1944 Durata ^{тм}	
Permanent Modes	Off; DDD(R); DDT(R); DDI(F		Defibrillation Lead	58, 65 cm
Temporary Modes Rate-Adaptive Sensor	Off; DDD; DDT; DDI; VVT; V On; Off; Passive	VI; AAI; AAT; DOO; VOO; AOO	7120Q, 7122Q	
Programmable Rate and Delay	Off; Base Rate (min-1); Rest Ra	ate (min-1); Maximum Tracking	Optisure [™] Lead LDA220Q, LDA210Q	58, 65 cm
Parameters	Rate (min ⁻¹); Maximum Senso (ms); Sensed AV Delay (ms); 1	or Rate (min ⁻¹); Paced AV Delay Rate Responsive AV Delay (Atrial n ⁻¹); Rate Hysteresis with Search	**Refer to the MRI-Ready	Systems Manua
Ventricular AutoCapture [™] Pacing System	On; Off		***As defined in IEC 6060	1-2-33, Normal (
ACap [™] Confirm Feature QuickOpt [™] Timing Cycle	On; Monitor; Off Sensed/Paced AV Delay		Head SAR \leq 3.2 W/kg.	
Optimisation 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; Pass	ive		
Rate Responsive PVARP/VREF	Off; Low; Medium; High			
Ventricular Intrinsic Preference (VIP™)	Off; On (50–200)			
Post-Therapy Pacing (Independe		cardia and ATP)		
Post-Shock Pacing Mode	Off: A AI: VVI: DDI: or DDD			

 Post-Shock Pacing Mode
 Off; AAI; VVI; DDI; or DDD

 Post-Shock Base Rate (min⁴)
 30-100 in increments of 5

 Post-Shock Pacing Duration (min)
 Off; 0,5; 1; 2,5; 5; 7,5; or 10

er™ Pulse Duration (sec) 0,5-5,0 ober Cycle Length (ms) sive Programmed ion (NIPS) 20–100 2–25 stimuli with up to three extra stimuli otifiers

Programmable Notifiers (On; Off)	Device at ERI; Charge Time Limit Reached; Possible HV Circuit Damage; Atrial Lead Impedance Out of Range; Ven- tricular 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

Scan Parameters**

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

ne MRI-Ready Systems Manual for additional information.

ed in IEC 60601-2-33, Normal Operating Mode corresponds to RF Power SAR: \leq 2 W/kg, 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	$73 \times 40 \times 14$	76	35	DF1	IS-1
CD1233-40Q	$71 \times 40 \times 14$	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) Size (mm)	76 73 × 40 × 14	75 71 × 40 × 14
Defibrillation Lead Connections	75×40×14 DF1	DF4
Sense/Pace Lead Connections	IS-1	DF4 DF4
High Voltage Can	Electrically active titanium can	Electrically active titanium can
PARAMETER	SETTINGS	
Sensing/Detection		
SenseAbility™ Sensing Algorithm	Automatic sensitivity control ac	ljustment for atrial and
Technology Low Frequency Attenuation	ventricular events On; Off	
Threshold Start	(Post-Sensed; Ventricular) 50; 6	2 5: 75: 100%:
Threshold Start	(Post-Paced; Ventricular) 50, 0	0.2-3.0 mV
Decay Delay	(Post-Sensed/Post-Paced; Vent	
Ventricular Sense Refractory (ms)	125; 157	
Detection Zones	VT-1; VT-2; VF	
SVT Discriminators	Sudden Onset; Interval Stability	
	(MD) with Manual or Automat	
Reconfirmation	Continuous sensing during cha	rging
Antitachycardia Pacing Therapy	n n	X 100
ATP Configurations	Ramp; Burst; Scan; 1 or 2 schen	
ATP in VF Zone ATP Upper Rate Cutoff	ATP While Charging; ATP Price	r to Charging; Off
Burst Cycle Length	150–300 bpm 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 bradycard	
ATP Pulse Width (ms)	1,0 or 1,5 independently program	nmable from bradycardia and
	post-therapy pacing	
High Voltage Therapy	n' in i writi n' imit	
High Voltage Output Mode Waveform	Fixed Pulse Width; Fixed Tilt 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); Hysteresis Rate (min ⁻¹);	Rate Hysteresis with Search
	On; Off	
Pacing System	,	ordia and ATP)
Pacing System Post-Therapy Pacing (Independent	y Programmable from Bradyca	urdia and ATP)
Pacing System Post-Therapy Pacing (Independent Post-Shock Pacing Mode	,	urdia and ATP)
Pacing System Post-Therapy Pacing (Independent Post-Shock Pacing Mode Post-Shock Base Rate (min ⁴)	Programmable from Bradyca Off; VVI	urdia and ATP)
Pacing System Post-Therapy Pacing (Independent Post-Shock Pacing Mode Post-Shock Base Rate (min ⁴) Post-Shock Pacing Duration (min)	y Programmable from Bradyca Off; VVI 30–100 in increments of 5	urdia and ATP)
Pacing System Post-Therapy Pacing (Independent Post-Shock Pacing Mode Post-Shock Base Rate (min ⁻¹) Post-Shock Pacing Duration (min) Device Testing/Induction Methods DC Fibber TM Pulse Duration (sec)	y Programmable from Bradycs Off; VVI 30–100 in increments of 5 Off; 0,5; 1; 2,5; 5; 7,5; or 10 0,5–5,0	urdia and ATP)
Pacing System Post-Therapy Pacing (Independent Post-Shock Pacing Mode Post-Shock Base Rate (min ⁺¹) Post-Shock Pacing Duration (min) Device Testing/Induction Methods DC Fibber™ Pulse Duration (sec) Burst Fibber Cycle Length (ms)	y Programmable from Bradyce Off; VVI 30–100 in increments of 5 Off; 0,5; 1; 2,5; 5; 7,5; or 10 0,5–5,0 20–100	
Pacing System Post-Therapy Pacing (Independent Post-Shock Pacing Mode Post-Shock Base Rate (min ⁴) Post-Shock Pacing Duration (min) Device Testing/Induction Methods DC Fibber™# Pulse Duration (sec) Burst Fibber Cycle Length (ms) Noninvasive Programmed	y Programmable from Bradycs Off; VVI 30–100 in increments of 5 Off; 0,5; 1; 2,5; 5; 7,5; or 10 0,5–5,0	
Pacing System Post-Therapy Pacing (Independent) Post-Shock Pacing Mode Post-Shock Pacing Duration (min) Post-Shock Pacing Duration (min) Device Testing/Induction Methods DC Fibber [™] Pulse Duration (sec) Burst Fibber Cycle Length (ms) Noninvasive Programmed Stimulation (NIPS)	y Programmable from Bradyce Off; VVI 30–100 in increments of 5 Off; 0,5; 1; 2,5; 5; 7,5; or 10 0,5–5,0 20–100	
Pacing System Post-Therapy Pacing (Independent Post-Shock Pacing Mode Post-Shock Base Rate (min ⁻¹) Post-Shock Pacing Duration (min) Device Testing/Induction Methods DC Fibber ⁻¹² Pulse Duration (sec) Burst Fibber Cycle Length (ms) Noninvasive Programmed Stimulation (NIPS) Patient Notifiers	y Programmable from Bradyce Off; VVI 30–100 in increments of 5 Off; 0,5; 1; 2,5; 5; 7,5; or 10 0,5–5,0 20–100 2–25 stimuli with up to three er	ttra stimuli
Pacing System Post-Thotrapy Pacing (Independent) Post-Shock Pacing Mode Post-Shock Base Rate (min ¹) Post-Shock Base Rate (min ¹) Post-Shock Pacing Duration (min) Device Testing/Induction Methods DC Fibber ^{my} Pulse Duration (see) Burst Fibber Cycle Length (ms) Noninvasive Programmed Stimulation (NPS) Patient Notifiers	y Programmable from Bradyce Off; VVI 30–100 in increments of 5 Off; 0,5; 1; 2,5; 5; 7,5; or 10 0,5–5,0 20–100 2–25 stimuli with up to three er Device at ERI; Charge Time Lii Circuit Damage; Ventricular Le High Voltage Lead Impedance	tra stimuli nit Reached; Possible HV ad Impedance Out of Range; Out of Range; %V Pacing;
Pacing System Post-Therapy Pacing (Independent) Post-Shock Pacing Mode Post-Shock Base Rate (min ⁻¹) Post-Shock Base Rate (min ⁻¹) Post-Shock Pacing Duration (min) Device Testing/Induction Methods De Fibber ^{MP} Pulse Duration (sec) Burst Fibber Cycle Length (ms) Noninvasive Programmed Stimulation (NIPS) Patient Notifiers Programmable Notifiers (On; Off)	y Programmable from Bradyce Off; VVI 30-100 in increments of 5 Off; 0,5; 1; 2,5; 5; 7,5; or 10 0,5-5,0 20-100 2-25 stimuli with up to three e: Device at ERI; Charge Time Lit Circuit Damage; Ventricular Le	tra stimuli nit Reached; Possible HV ad Impedance Out of Range; Out of Range; %V Pacing;
Ventricular AutoCapture™ Pacing System Post-Therapy Pacing (Independent Post-Shock Pacing Mode Post-Shock Pacing Duration (min') Post-Shock Pacing Duration (min') Dost-Shock Pacing Duration (sec) Burst Fibber™ Pulse Duration (sec) Burst Fibber Cycle Length (ms) Noninvasive Programmed Stimulation (NIPS) Patient Notifiers Programmable Notifiers (On; Off) Device Parameter Reset Entry into Backup VVI Mode	y Programmable from Bradyce Off; VVI 30–100 in increments of 5 Off; 0,5; 1; 2,5; 5; 7,5; or 10 0,5–5,0 20–100 2–25 stimuli with up to three er Device at ERI; Charge Time Lin Circuit Damage; Ventricular Le High Voltage Lead Impedance CorVue™ Congestion Monitori On	tra stimuli nit Reached; Possible HV ad Impedance Out of Range; Out of Range; %V Pacing;
Pacing System Post-Therapy Pacing (Independent Post-Shock Pacing Mode Post-Shock Pacing Mode Post-Shock Pacing Duration (min) Device Testing/Induction Methods DC Fibber ^{***} Pulse Duration (sec) Burst Fibber Cycle Length (ms) Noninvasive Programmed Stimulation (NIPS) Patient Notifiers Programmable Notifiers (On; Off) Device Parameter Reset Entry into Backup VVI Mode Vibration Duration (sec)	y Programmable from Bradyce Off; VVI 30–100 in increments of 5 Off; 0,5; 1; 2,5; 5; 7,5; or 10 0,5–5,0 20–100 2–25 stimuli with up to three e: Device at ERI; Charge Time Lin Circuit Damage; Ventricular Le High Voltage Lead Impedance CorVue™ Congestion Monitori On On 2; 4; 6; 8; 10; 12; 14; 16	tra stimuli nit Reached; Possible HV ad Impedance Out of Range; Out of Range; %V Pacing;
Pacing System Post-Therapy Pacing (Independent Post-Shock Pacing Mode Post-Shock Base Rate (min ⁻¹) Post-Shock Pacing Duration (min) Device Testing/Induction Methods DC Fibber ⁻¹²⁴ Pulse Duration (sec) Burst Fibber Cycle Length (ms) Noninvasive Programmed Stimulation (NIP8) Patient Notifiers Programmable Notifiers (On; Off) Device Parameter Reset Entry into Backup VVI Mode Vibration Duration (sec) Number of Vibrations per	y Programmable from Bradyce Off; VVI 30–100 in increments of 5 Off; 0,5; 1; 2,5; 5; 7,5; or 10 0,5–5,0 20–100 2–25 stimuli with up to three er Device at ERI; Charge Time Lin Circuit Damage; Ventricular Le High Voltage Lead Impedance CorVue™ Congestion Monitori On	tra stimuli nit Reached; Possible HV ad Impedance Out of Range; Out of Range; %V Pacing;
Pacing System Post-Therapy Pacing (Independent Post-Shock Pacing Mode Post-Shock Base Rate (min ⁻¹) Post-Shock Pacing Duration (min) Device Testing/Induction Methods DC Fibber ⁻¹² Pulse Duration (sec) Burst Fibber Cycle Length (ms) Noninvasive Programmed Stimulation (NIPS) Patient Notifiers Programmable Notifiers (On; Off) Device Parameter Reset	y Programmable from Bradyce Off; VVI 30–100 in increments of 5 Off; 0,5; 1; 2,5; 5; 7,5; or 10 0,5–5,0 20–100 2–25 stimuli with up to three e: Device at ERI; Charge Time Lin Circuit Damage; Ventricular Le High Voltage Lead Impedance CorVue™ Congestion Monitori On On 2; 4; 6; 8; 10; 12; 14; 16	tra stimuli nit Reached; Possible HV ad Impedance Out of Range; Out of Range; %V Pacing;

Electrograms and Diagnostics Stored Electrogram Up to 25 minutes including up to one minute programmable 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 Diagram of therapies delivered Therapy Summary

Directory listing of up to 60 episodes with access to more details including stored electrograms History of bradycardia events and device-initiated charging Episodes Summary Lifetime Diagnostics Ventricular HV Lead Impedance Trend Multi-Vector Trend Data Event Histogram; Ventricular Heart Rate Histogram; Exercise and Activity Trending Pacing lead impedances; high voltage lead impedances; and signal amplitudes Real-Time Measurements (RTM)

CorVue Congestion Monitoring On: Off CorVue Congestion Monitoring Trigger 8-18 days

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.
 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:

Histograms

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 standbly 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 is inserted in the pocket. For effective defibrillation, perform all defibrillation testing with the can in the pocket. For effective defibrillation, perform all defibrillation testing with the can in the pocket. Boy Generators 20°C on over 00°C. After Cold Storage, allow the device to reach room temperatures before charging the capacitors, programming, or implanting the device for effective defibriling the device because cold temperature before charging the capacitors, programming, or implanting the device because cold temperature may affect initial device function. Device Replacement. Replace the pulse generator within three months of reaching the ERI

Device Communication. Communication with the device can be affected by electrical interference

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. B 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.

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 bedar 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. Merlin Antenna

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 rissue 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 fluction 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 cardica cevents 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.

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 efficacious¹
 - 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 patients²
- 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 button³



- 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 burden⁵
- 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	$74 \times 40 \times 14$	76	35	DF1	IS-1
CD2233-40Q	$71 \times 40 \times 14$	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) Weight (g)	35 76	35 75
Size (mm)	70 74 × 40 × 14	73 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	0.00	
AF Suppression™ Pacing No. of Overdrive Pacing Cycles	On; Off 15–40 in steps of 5	
Maximum AF Suppression Rate	80–150 min ⁻¹	
Sensing/Detection		
SenseA <i>bility</i> ™ Technology	Automatic Sensitivity Control a	adjustment for atrial and
	ventricular events	
Low Frequency Attenuation Threshold Start	On; Off (Post-Sensed; Atrial) 50; 62,5; 7	75: 100%:
	(Post-Paced; Atrial) 0,2-3,0 mV	<i>V</i> ;
	(Post-Sensed; Ventricular) 50;	
Decay Delay	(Post-Paced; Ventricular) Auto (Post-Sensed/Post-Paced; Atria	
Ventricular Sense Refractory (ms)	125; 157	ii/ventricular/o 220
Detection Zones	VT-1; VT-2; VF	
SVT Discriminators		; Interval Stability; Morphology
	Discrimination (MD) with Mai Update	nuai or Automatic Template
Reconfirmation	Continuous sensing during cha	rging
Antitachycardia Pacing Therapy	gg cita	
ATP Configurations	Ramp; Burst; Scan; 1 or 2 schen	nes per VT zone
ATP in VF Zone	ATP While Charging; ATP Price	or to Charging; Off
ATP Upper Rate Cutoff	150-300 bpm	
Burst Cycle Length Min. Burst Cycle Length (ms)	Adaptive; Readaptive or Fixed 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 Bradycar	
ATP Pulse Width (ms)	1,0 or 1,5 independently progra Post-Therapy Pacing	mmable from Bradycardia and
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 Temporary Modes	DDD(R); DDI(R); VVI(R); AAI Off; DDD; DDI; VVI; AAI; AAT	
Rate-Adaptive Sensor	On; Off; Passive	, 000, 100, 400
Programmable Rate and	Off; Base Rate (min-1); Rest Rat	e (min-1); Maximum Tracking
D-l D	Rate (min ⁻¹);	Devel AV Deless (max) Coursed
Delay Parameters	Maximum Sensor Rate (min ⁻¹); AV Delay (ms); Rate Responsiv	
	(min ⁻¹); Rate Hysteresis with Se	
QuickOpt™ Timing Cycle	Sensed/Paced AV delay	
Optimisation Auto Mode Switch (AMS)	Off; DDI(R); VVI(R)	
Atrial Tachycardia Detection Rate	110-300	
(min ⁻¹)		
AMS Base Rate (min ⁻¹)	40; 45; 135	
Auto PMT Detection/Termination Rate Responsive PVARP/VREF	Atrial Pace; Off; Passive Off; Low; Medium; High	
Ventricular Intrinsic Preference	Off; 50–200 (50–150 in increme	ents of 25; 160–200 in
(VIP™)	increments of 10)	
Ventricular AutoCapture™ Pacing System	On; Off	
ACap™ Confirm	On; Monitor; Off	
Post-Therapy Pacing (Independent		ardia 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	2-25 stimuli with up to three e	xtrastimuli
Stimulation (NIPS)		
Patient Notifiers Programmable Notifiers (On; Off)	Device at ERI; Charge Time Li	mit Paachad, Pacsible LIV
Programmable Notiners (On; On)	Circuit Damage; Atrial Lead In	npedance Out of Range; out of Range; High-Voltage Lead
	AF; % V Pacing; CorVue™ Con	
Device Parameter Reset	On	
Entry into Backup VVI Mode Vibration Duration (sec)	On 2; 4; 6; 8; 10; 12; 14; 16	
Number of Vibrations per	2; 4; 0; 8; 10; 12; 14; 10 2	
Notification		
Number of Notifications	1-16	
Time Between Notifications (hours)	10; 22	

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

- prospective, pair-sampled multicenter study. *PACE* 2000;23 (Part ID:1992-1995.
 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.
 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.
 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.
 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.

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 immediately upon reaching ERI if there is frequent high-voltage charging and/or one or more of the pacing outputs are programmed dove 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 Of before handling 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 Communication. Communication with the device are a beaffected by electrical network representations and a 5°C. Do not subject it to temperature before charging the Capolic. The problem, turn of nearby electrical actimeter ference and strong magnetic fields. If this is a problem, turn of nearby electrical actimeter ference and strong magnetic fields. If this is norblem, turn of nearby electrical actimates the evice strange any of the programmer. If the problem persists, contact Abbott.</l

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Customer Support: 46-8-474-4756

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

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