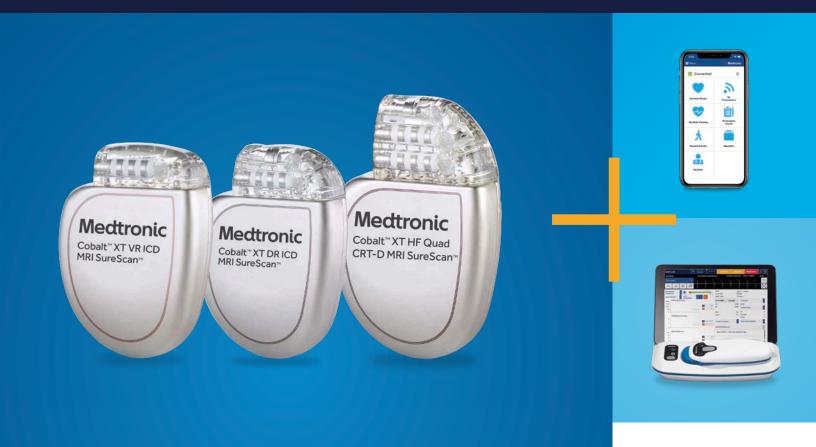
THE FUTURE IS HERE

Meet Cobalt™ XT ICDs and CRT-Ds



Medtronic



- Extended longevity and higher output, while maintaining exclusive PhysioCurve[™] size and shape
- Exclusive technology to reduce shocks
- Exclusive algorithms to optimize CRT
- Exclusive algorithms to manage atrial fibrillation (AF)

THE FUTURE ISHERE



BlueSync[™] technology that enables tablet-based programming and app-based remote monitoring





STREAMLINED WORKFLOWS & HEART FAILURE MANAGEMENT

- Simplified, integrated heart failure risk assessment with TriageHF[™] technology
- Manage alerts of clinically relevant events with additional CareAlert[™] notifications

UNMATCHED FEATURE SUITE

Extended Longevity

Mean longevity projections based on CareLink[™] patient data.*

8.3
YEARS
Claria MRI™
Quad and
Amplia™ MRI
Quad CRT-Ds¹¹

Mean longevity projection
based on real-world
programming of U.S.
national CareLink network
patients. January 2019.

Mean longevity
projection based on
median CareLink
settings in the
Cobalt XT
HF Quad
CRT-Ds¹²

11.9 YEARS 10.5 Cobalt XT Dual Chamber Evera MRI™ XT ICDs4 and Evera MRI[™] S **Dual Chamber** ICDs³ $Mean \, long evity \, projection$ Mean longevity projection based on median CareLink based on real-world programming of U.S. settings in the Cobalt XT manual. national CareLink network patients. January 2019.

12.0
YEARS
Visia AF MRI™
Single Chamber ICDs⁵

Mean longevity projection based on real-world programming of U.S. national CareLink network patients. January 2019.

13.6
YEARS
Cobalt XT Single Chamber ICDs⁵

Mean longevity projection based on median CareLink settings in the Cobalt XT manual.

*These values should not be interpreted as precise numbers. Individual patient results may vary based on their specific programming and experience.
†With AdaptivCRT™ programmed to BiV and LV.

Option for 40 J Energy Delivery on All Shocks (including first shock)^{2,4,6}

MAXIMUM PROGRAMMED ENERGY

40 J

MAXIMUM DELIVERED ENERGY**

40 J

MAXIMUM STORED ENERGY^{††}

47 J

UNMATCHED FEATURE SUITE

PhysioCurve Design

PhysioCurve showed a 30% reduction in overall skin pressure compared to noncontoured devices.⁷

- Tapered at the head and bottom of device to reduce skin pressure and promote patient comfort
- Smaller footprint for a smaller incision
- Designed with lead wrap in mind landing area to minimize additional stresses on the lead⁸





SmartShock[™] 2.0 Technology

Lowest inappropriate shock rate*9

SmartShock 2.0 includes six exclusive algorithms that discriminate true lethal arrhythmias from other arrhythmic and nonarrhythmic events.^{†10}

1.5%
Inappropriate shock rate in dual and triple chamber patients at one year9

2.5%
Inappropriate
shock rate in single
chamber patients
at one year⁹

†PR Logic™ does not apply to VR devices.

Exclusive Technology to Reduce Shocks

SmartShock 2.0+ technology combines the proven discrimination algorithms in SmartShock 2.0 with the exclusive Intrinsic ATP algorithm to provide a robust shock reduction suite.

^{*}A controlled, head-to-head study evaluating the comparative performance of device algorithms has not been done. Comparison of inappropriate shock rates based on survey of published literature.



Intrinsic ATP™ (iATP) Algorithm

iATP is the only **automated and smart** ventricular antitachycardia pacing (ATP) algorithm that provides individualized therapy in real time.



On/Off



INDIVIDUALIZED THERAPY

ATP designed for each VT

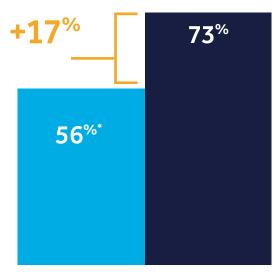


REAL-TIME RESPONSE

If VT is redetected, iATP automatically adjusts the next ATP sequence

In a virtual modeling study, Intrinsic ATP's termination rate was 17 percentage points higher than traditional ATP (burst) with no difference in acceleration rate.¹¹

- Traditional ATP
- iATP



% Termination

UNMATCHED FEATURE SUITE

Exclusive Algorithms to Optimize CRT Delivery

AdaptivCRT[™] Algorithm adapts to patients' changing needs by optimizing CRT pacing minute-to-minute.

EffectivCRT[™] Diagnostic verifies effective CRT delivery, offering insights on the quality of the reported % ventricular pacing.

IMPROVEMENT IN CRT RESPONSE

12%

Improvement in CRT patient response with AdaptivCRT*13

RELATIVE REDUCTION IN MORTALITY

29%

AdaptivCRT is associated with a 29% relative reduction in mortality^{†14}

REDUCTION IN HOSPITALIZATIONS

59%

Reduction in a patient's odds of 30-day HF readmission with AdaptivCRT¹⁵

EFFECTIVE CRT PACING

EffectivCRT Diagnostic verifies effective pacing using a unipolar electrogram to evaluate morphology, looking for a negative deflection.

^{*}Comparing AdaptivCRT to Echo-optimized BiV pacing in patients with normal AV conduction, percentage of patients improved in Packer clinical composite score (CCS) at 6-month follow-up. CCS is a composite measure of mortality. HF hospitalizations, and symptomatic changes.

[†]Patients who received AdaptivCRT were associated with a 29% relative reduction in all-cause mortality vs. conventional CRT (after adjusting for other potential risk factors including age, gender, LVEF, NYHA class, QRS duration, AF, CAD, hypertension, AV block, and LBBB).



Exclusive Algorithms to Manage AF

DETECT

Single Chamber

TruAF[™] Detection Algorithm can detect AF in single chamber ICD patients using a traditional lead.

Dual Chamber and CRT-D

Highest published AF episode detection accuracy (PPV).*†16-19

REDUCE

CRT-D

46% reduction in AF risk with AdaptivCRT Algorithm.**20

Dual Chamber and CRT-D

36% relative reduction in AT/AF episodes \geq 7 days with Reactive ATP[™] Algorithm. ††21

RESPOND

CRT-D

EffectivCRT during AF is an exclusive feature to improve effective CRT delivery in the presence of AF.

Up to a **16**% increase in effective CRT delivery during AF.²²

 $^{^*\!}A$ controlled, head-to-head study evaluating the comparative performance of device algorithms has not been done.

AF detection accuracy rates determined from independent clinical trials are presented for reference.
†Detection accuracy is compared using PPV, which is the percentage of all AT/AF episodes detected by the individual device detection algorithm that were adjudicated as true AT/AF.

^{**}Most of the reduction in AF occurred in subgroups with prolonged AV conduction at baseline and with significant left atrial reverse remodeling.

^{††}Compared to matched control group.

REIMAGINED CONNECTIVITY

BlueSync Technology

Cobalt XT ICDs and CRT-Ds with BlueSync technology enable secure, wireless communication.











Tablet-based CareLink SmartSync™ device manager Cobalt XT ICDs and CRT-Ds MyCareLink Heart™ mobile app or MyCareLink Relay™ Home Communicator CareLink network

Supported by the Get Connected service

Security Measures^{2,4,6}

BlueSync Technology

BlueSync technology security was designed to protect the device, patient data, and connectivity.

Device Protection

- BlueSync devices do not accept programming from unauthorized sources.
- BlueSync devices are not connected to internet.
 Devices do not have an IP address, unlike other connected consumer products.

Data Privacy

End-to-end encryption

Data are encrypted in BlueSync technology using NIST* government standard for security before being transmitted to the CareLink network.

Please go to **medtronic.com/security** for up-to-date security information.



Increase Patient Adherence, Save Lives

Cardiac device patients who are not adherent with remote monitor transmissions will miss out on the following benefits:

50%

potential increase in survival rate of patients²³⁻²⁵

35%

potential reduction in ER visits^{26,27}

18%

potential reduction in length of hospital stay²⁸





MyCareLink Heart results in 94.6% patient adherence to transmission schedule compared to 77% patient adherence for bedside monitors.²⁹

Alternative Monitoring Option

MyCareLink Relay Home Communicator

A Bluetooth home communicator offers your patients an alternative option for easy and reliable monitoring.

- No manual pairing required
- Requires little to no user interaction

For patients who prefer not to use a smartphone.



MyCareLink Relay must be plugged in and patients must be within communication range for successful transmissions. Requires Wi-Fi or cellular connection.

STREAMLINED WORKFLOWS & HEART FAILURE MANAGEMENT

TriageHF Technology*

TriageHF automates patient triage for clinicians to easily identify which patients are at the highest risk of heart failure decompensation.

TriageHF will generate a patient's risk level by assessing³⁰:

- OptiVol[™]
- Patient Activity
- AT/AF Burden
- Ventricular Rate during AT/AF
- % Ventricular Pacing
- Shocks
- Treated VT/VF
- Night Ventricular Rate
- Heart Rate Variability



Risk of an HF hospitalization in the next 30 days³¹

HIGH

Hazard Ratio **10x**

MEDIUM

Hazard Ratio 2.1x

LOW

Neg Pred Value 99.4%





TriageHF-enabled clinics[†] can leverage the technology for all ICD & CRT patients with OptiVol, with backward compatibility.



Automated notifications to enable clinical action.

^{*}TriageHF is not an alarm. The TriageHF assessment does not replace heart failure assessments in standard clinical practice. Medical treatment should not be modified remotely based solely on the TriageHF assessment. Interpretation of the TriageHF assessment requires clinical judgment by a medical professional. The TriageHF assessment should be used in conjunction with professional guidelines for patient management decisions.

[†]TriageHF requires clinic activation. Contact your local Medtronic sales representative for activation requirements.



Additional CareAlerts

Tachyarrhythmia Status:

- Monitored VT
- Weekly ATP delivered
- Daily VT/VF episodes

Bradyarrhythmia Status:

- Right ventricular pacing > 40%
- High capture thresholds

Heart Failure Status:

- Ventricular pacing < 90%
- OptiVol 2.0 Fluid Status Monitoring

- on U.S. CareLink™ transmission data as of January 2019; UC201802366 EN
- ² Medtronic Cobalt™ XT HF Quad MRI SureScan™ Model DTPA2QQ device manual
- ³ Medtronic Evera MRI[™] XT DR SureScan[™] and Evera MRI[™] S DR SureScan[™] Mean Projected Service Life based on U.S. CareLink™ transmission data as of January 2019; UC201802366 EN.
- ⁴ Medtronic Cobalt™ XT DR ICD MRI SureScan™ Model DDPA2D4 device manual.
- ⁵ Medtronic Visia AF[™] VR Mean Projected Service Life based on U.S. CareLink[™] transmission data as of January 2019; UC201802366 EN.

 ⁶ Medtronic Cobalt™ XT VR ICD MRI SureScan™ Model DVPA2D4 device manual.
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Brief Statements

Cobalt[™]/Crome[™] MRI SureScan[™] ICD and CRT-D Systems

Indications: The Cobalt™XT, Cobalt™, and Crome™HF CRT-D MRI SureScan™ systems are indicated for use in patients who are at significant risk of developing atrial and/or life-threatening ventricular arrhythmias and who have heart failure with ventricular arrhythmias. Heart failure patients must have experienced one or more of the following conditions:

- NYHA Functional Class III or IV patients who remain symptomatic despite stable, optimal medical therapy and have LVEF \leq 35% and a prolonged QRS duration
- NYHA Functional Class II patients who have left bundle-branch block (LBBB) with a QRS duration ≥ 130 ms and a left ventricular ejection fraction ≤ 30%
- NYHA Functional Class I, II, or III who are on stable, optimal medical therapy (if indicated), and have LVEF ≤ 50%, atrioventricular block (AV block), and are expected to require a high percentage of ventricular pacing that cannot be managed with algorithms to minimize right ventricular pacing

The Cobalt XT, Cobalt, and Crome VR and DR ICD MRI SureScan systems are indicated for the automated treatment of patients who have experienced, or are at significant risk of developing, atrial and/or life-threatening ventricular arrhythmias through the delivery of antitachycardia pacing, cardioversion, and defibrillation therapies.

MRI Conditions for Use: Medtronic SureScan ICD and CRT-D systems are MR Conditional, and as such are designed to allow patients to undergo MRI under the specified conditions for use. ICD and CRT-D SureScan system patients may be scanned using a horizontal field, cylindrical bore, clinical 1.5T or 3T MRI system for hydrogen proton imaging. When programmed to On, the MRI SureScan feature allows the patient to be safely scanned while the device continues to provide appropriate pacing. A complete SureScan defibrillation system, which is a SureScan device with appropriate SureScan lead(s), is required for use in the MR environment. To verify that components are part of a SureScan system, visit http://www.mrisurescan.com/. Any other combination may result in a hazard to the patient during an MRI scan.

 $\textbf{Contraindications:} \ \ \textbf{The Cobalt XT, Cobalt, and Crome VR and DR ICD and CRT-DMRI SureScan systems are contraindicated for use in the following situations:$

- If implanted with a unipolar pacemaker
- If incessant VT or VF exists
- \bullet If the primary disorder is chronic atrial tachyarrhythmia with no concomitant VT or VF
- If tachyarrhythmias with transient or reversible causes exist, including the following known issues: acute myocardial infarction, drug intoxication, drowning, electric shock, electrolyte imbalance, hypoxia, and sepsis.

Warnings and Precautions: Changes in a patient's disease and/or medications may alter the efficacy of the device's programmed parameters. Patients should avoid sources of magnetic and electromagnetic radiation to avoid possible underdetection, inappropriate sensing and/or therapy delivery, tissue damage, induction of an arrhythmia, device electrical reset, or device damage. Do not place transthoracic defibrillation paddles directly over the device. Patients and their implanted systems must be screened to meet the following requirements for MRI: no lead extenders, lead adaptors, or abandoned leads present; no broken leads or leads with intermittent electrical contact as confirmed by lead impedance history. The device must be operating within the projected service life, and the system must be implanted in the left or right pectoral region.

Potential Adverse Events: Potential adverse events include, but are not limited to, the following events: allergic reactions, atrial fibrillation, bradyarrhythmia, cardiac arrest, device migration, discomfort, dizziness, dyspnea, erosion, excessive fibrotic tissue growth, heart failure or loss of CRT (for CRT-D patients), hematoma, hemorrhage, inability to deliver therapy, inappropriate shock, infection, lead migration/dislodgement, lethargy, loss of pacing, mental anguish, necrosis, nerve damage, oversensing, palpitations, seroma, syncope, tachyarrhythmia, tissue damage due to heating of the device, undersensing, and wound dehiscence. Potential MRI complications include, but are not limited to, lead electrode heating and tissue damage resulting in loss of sensing or capture or both, spontaneous tachyarrhythmia, potential for VT/VF induction, device heating that results in tissue damage, stimulation of the leads that results in continuous capture, VT/VF, hemodynamic collapse, damage to the device or the leads, causing the system to fail or treat the patient's condition incorrectly, and movement or vibration of the device or the leads, resulting in dislodgement.

See the device manuals for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and adverse events. See the MRI SureScan Technical Manual before performing an MRI Scan. For further information, call Medtronic at 1-800-328-2518 and/or consult the Medtronic website at medtronic.com or mrisurescan.com.

 $\textbf{Caution:} \ \ \text{Federal law (USA)} \ \ \text{restricts these devices to sale by or on the order of a physician.}$

TriageHF™

Intended Use: The TriageHF feature can be used with commercially available Medtronic CRT-D, CRT-P, and ICD devices that have the OptiVol™ Fluid Status Monitoring feature. The indications for use of these devices do not change. The TriageHF feature gives physicians another source of information to use in managing their patients. It does not replace assessments that are part of standard clinical practice or override recommended guidelines for treatment of heart failure patients. Clinicians should not rely exclusively on the TriageHF information to assess a patient's heart failure risk. The TriageHF information is available to clinicians who monitor their device patients on the Medtronic CareLink™ network.

Contraindications: There are no known contraindications for the use of TriageHF information.

See the device manual for detailed information regarding the intended use, contraindications, warnings, precautions, and potential complications/adverse events. For further information, call Medtronic Technical Services at 1-800-328-2518 and/or consult the Medtronic website at medtronic.com.

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

Medtronic Model 24970A CareLink SmartSync™ Device Manager Base and Associated Apps

Indications: The base is intended to be used as part of the CareLink SmartSync Device Manager system. Clinicians use the base to analyze the electrical performance of cardiac leads during device implant or invasive troubleshooting. Clinicians use the base's ECG connections along with the app display to view, measure, and record live cardiac waveforms. The base is intended to be used by healthcare professionals only in operating environments under direct medical supervision.

Contraindications: The base is not intended for use as an external pulse generator (EPG) outside of the implant procedure. In addition, the patient's age and medical condition may dictate the lead analyses appropriate for the patient. See the device manual for detailed information regarding the intended use, contraindications, warnings, precautions, and potential complications adverse events. For further information, call Medtronic Technical Services at 1-800-328-2518 and/or consult Medtronic's website at medtronic.com.

 $\textbf{Caution:} \ \ \text{Federal law (USA)} \ \ \text{restricts these devices to sale by or on the order of a physician.}$

Medtronic Model 24967 Patient Connector and Associated Apps

Indications: The patient connector is intended to be used with Medtronic apps to interrogate, analyze, and/or program implantable Medtronic devices. The patient connector uses Bluetooth® technology to transmit that data to a Medtronic app for further processing. The patient connector is intended to be used by healthcare personnel only in a clinical or hospital environment.

Precautions: Security — Maintain adequate physical security of the patient connector to prevent unauthorized use that could lead to harm to patients. Bluetooth communication in the patient connector is encrypted for security. Medtronic inductive telemetry uses short-range communication to protect patient information. If the patient connector should fail, there is no risk of patient harm. See the 24967 Patient Connector Technical Manual before using the CareLinkSmartSync Device Manager for detailed information regarding the procedure, indications or intended uses, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult the Medtronic website at medtronic.com.

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

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