

# ENGINEERED FOR THE FUTURE OF CONNECTED HEALTH

Azure™ with  
BlueSync™ Technology



<sup>1</sup> Medtronic Azure XT DR MRI SureScan™ Device Manual. M964338A001B. 2016-10-22.

<sup>2</sup> Orega M. Azure longevity Increase Compared to Advisa™. September 2017. Medtronic data on file.

<sup>3</sup> Hudnall H. Reactive Atrial-based Antitachycardia Pacing Therapy to Slow Progression of Atrial Fibrillation. August 2017, Medtronic data on file.



Completely  
Redesigned



Secure Wireless  
Communication  
with BlueSync  
Technology<sup>1</sup>



Improved  
Longevity<sup>2</sup>

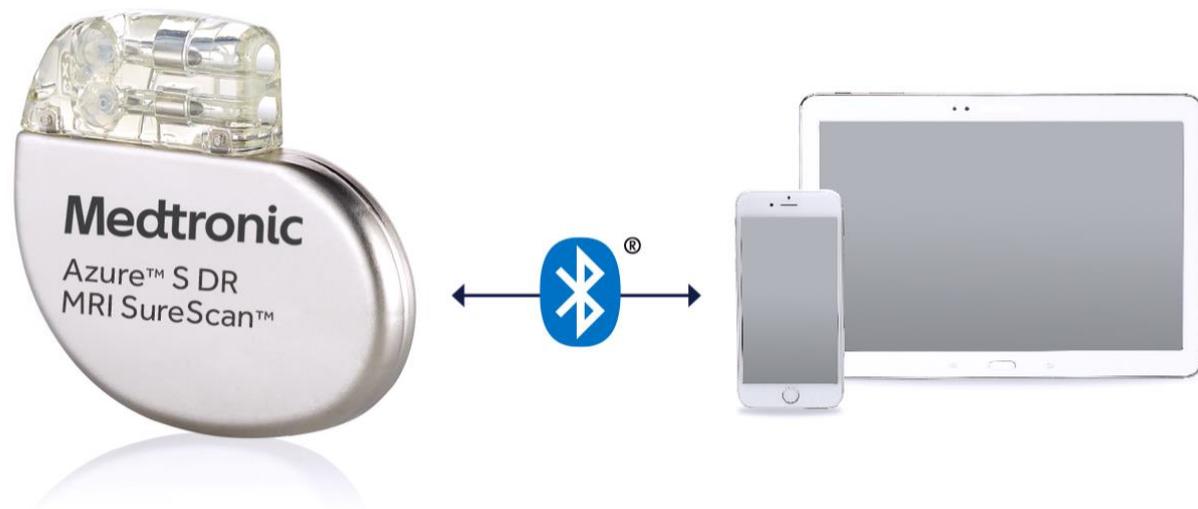


AF Detection  
and Reduction<sup>3</sup>

**Medtronic**  
Further, Together

# COMPLETELY REDESIGNED

With BlueSync™ Technology for Secure<sup>1</sup> Wireless Communication via Bluetooth® Low Energy without Compromising Longevity<sup>2</sup>



<sup>1</sup> Medtronic Azure™ XT DR MRI SureScan™ Device Manual. M964338A001B. 2016-10-22.

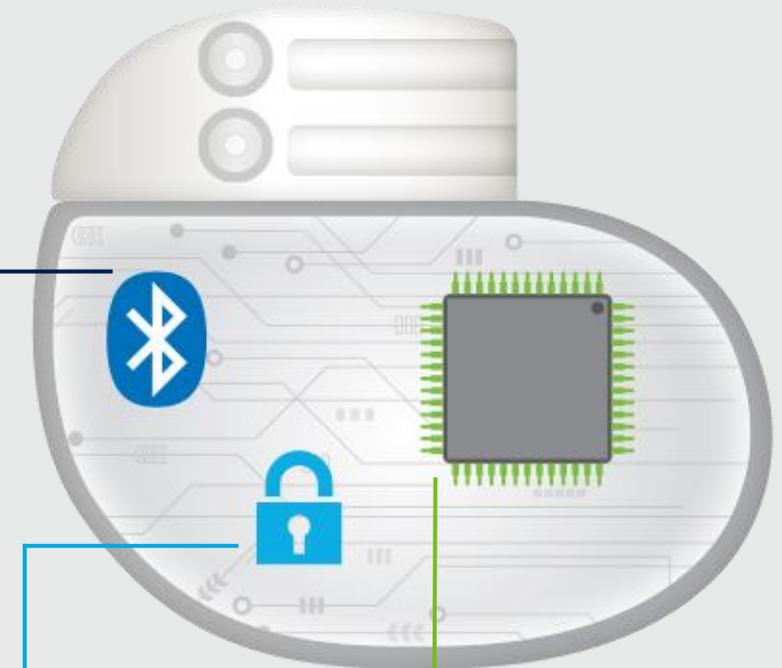
<sup>2</sup> Orenga M. Azure longevity Increase Compared to Advisa™. September 2017. Medtronic data on file.

## Key Design Changes

**Bluetooth® Low Energy (BLE)**  
enabled to automatically and securely<sup>1</sup> communicate with BLE smartphones or tablets

**Encryption Module**  
Data are encrypted in the pacemaker using NIST\* standard encryption

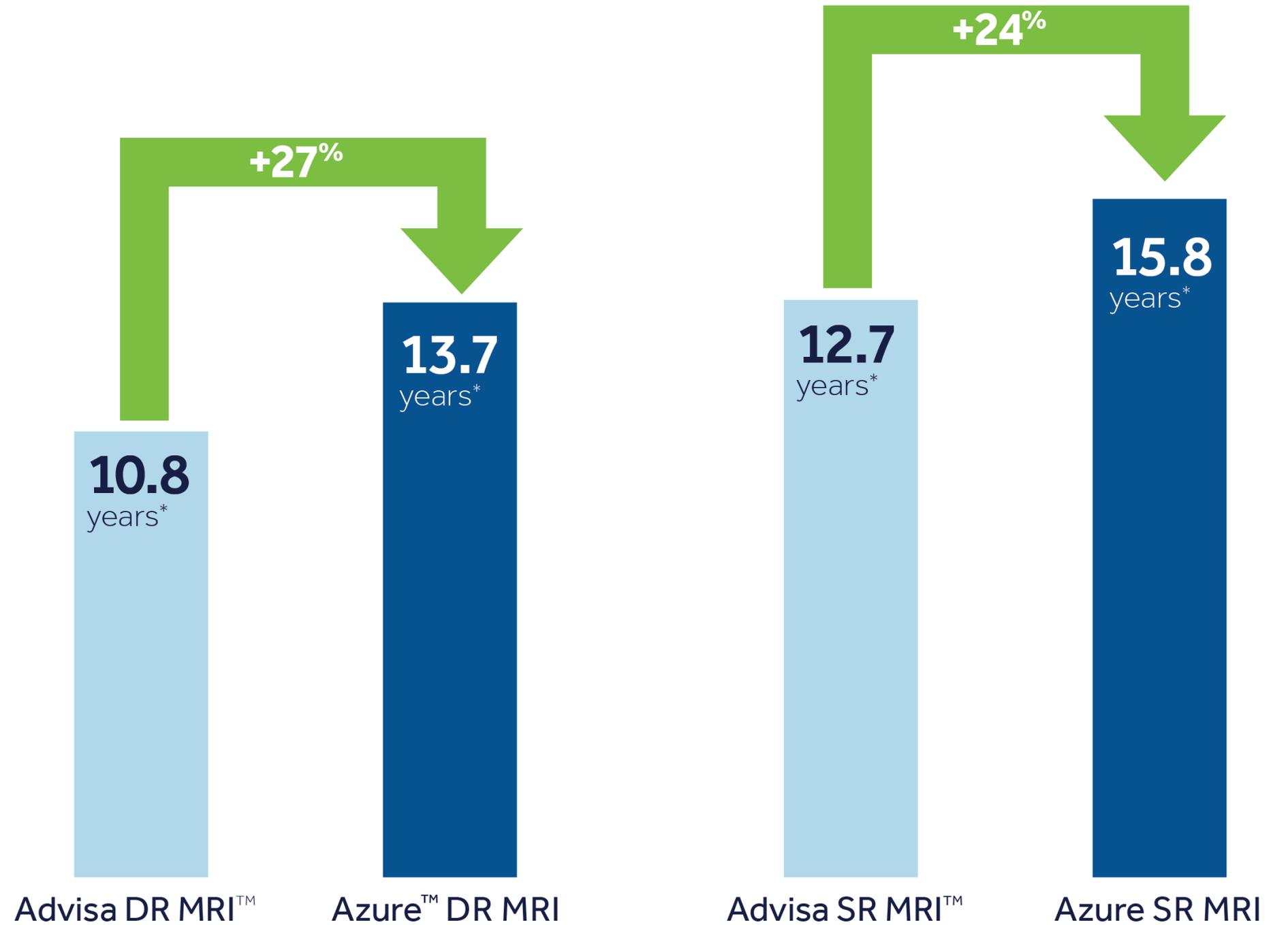
**High Density Integrated Circuit**  
reduces current drain for increased longevity



\*NIST: National Institute of Standards and Technology.

# IMPROVED LONGEVITY

New hardware architecture optimizes circuitry to reduce current drain and improve longevity<sup>1</sup>



<sup>1</sup> Oren M. Azure™ longevity Increase Compared to Advisa™. September 2017. Medtronic data on file.

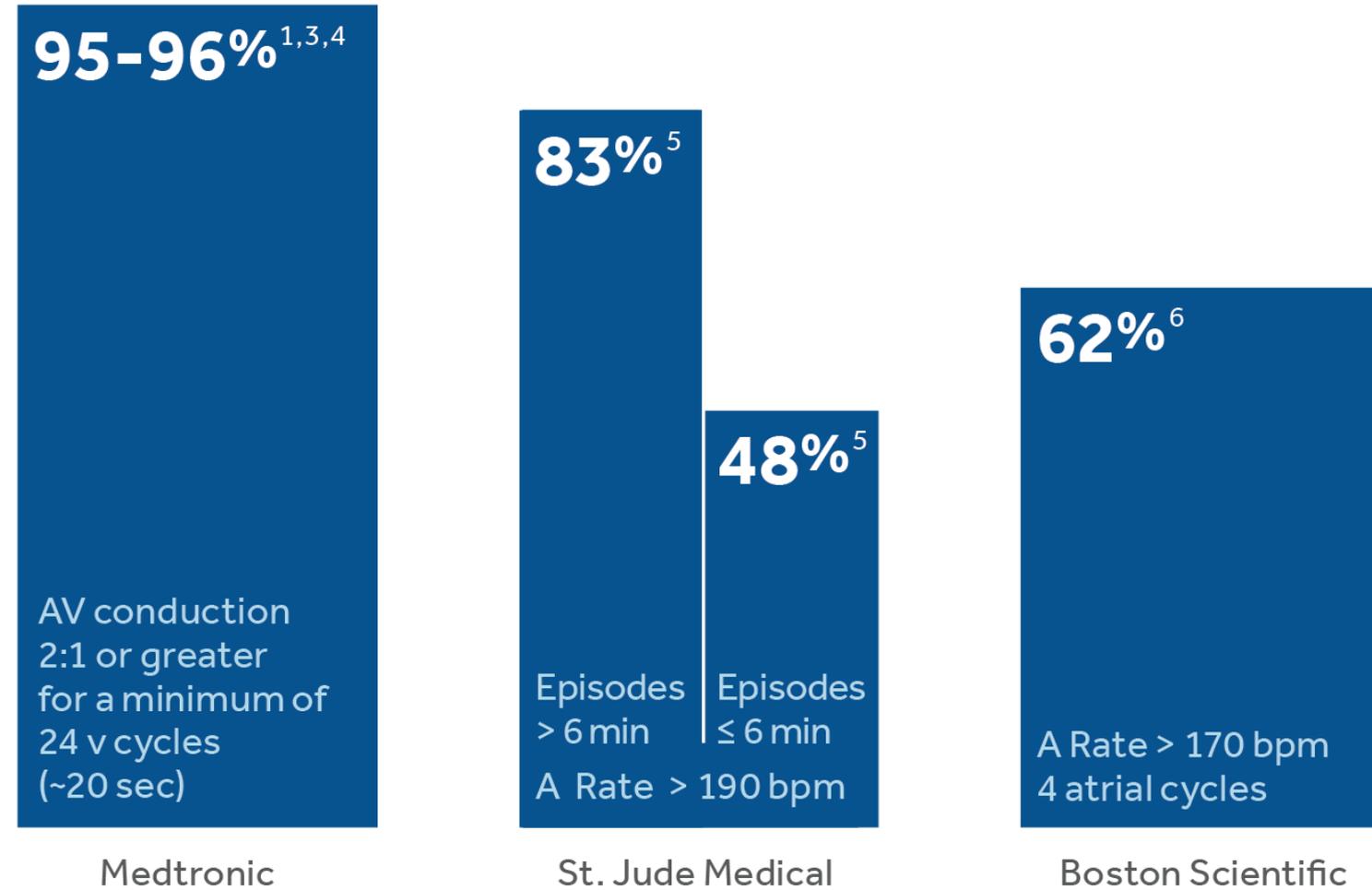
\*DR: MVP™, SR: VVI 50%, 500 ohm, 2.5 V, pre-storage EGM off.

# DETECT AF

## AF Episode Detection Accuracy (PPV)<sup>2\*</sup>

### Accurate AF Detection

Reduce AT/AF false positives  
with PR Logic™<sup>1</sup> Algorithms



\*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.

<sup>1</sup> Purerfellner H, et al. *Pacing Clin Electrophysiol.* 2004;27:983-992.

<sup>2</sup> Sprenger M. Comparison of Manufacturer's AT/AF Detection Accuracy across Clinical Studies. January 2015. Medtronic data on file.

<sup>3</sup> Ziegler PD. Accuracy of Atrial Fibrillation Detection in Implantable Pacemakers. *Heart Rhythm.* 2013;10:S147 [PO02-08].

<sup>4</sup> Medtronic Data on File. QADoc DSN026170, Version 2.0, "AT/AF Duration Performance Comparison."

<sup>5</sup> Kauffman ES, et al. *Heart Rhythm.* 2012;9:1241-1246.

<sup>6</sup> Nowak B, et al. *Pacing Clin Electrophysiol.* 2005;28:620-629.

# TIMELY ALERTS OF CLINICALLY RELEVANT EVENTS<sup>1,2</sup>

CareAlert™ notifications can be programmed and viewed only by the clinician:

- AT/AF Burden Notification
- Lead Impedance
- Low Battery Voltage @ RRT
- VT Episodes
- Fast V. Rate During AT/AF
- Capture Management™
- % V. Pacing

<sup>1</sup> Medtronic Azure™ XT DR MRI SureScan™ Device Manual. M964338A001B. 2016-10-22.

<sup>2</sup> Howard K. Alert Notification Timing. September 2017. Medtronic data on file.



Wireless alerts can now be transmitted via Bluetooth® using the MyCareLink Heart™ mobile app, providing patient monitoring — even outside the home.

# REDUCE AF

## Reduce Unnecessary RV Pacing

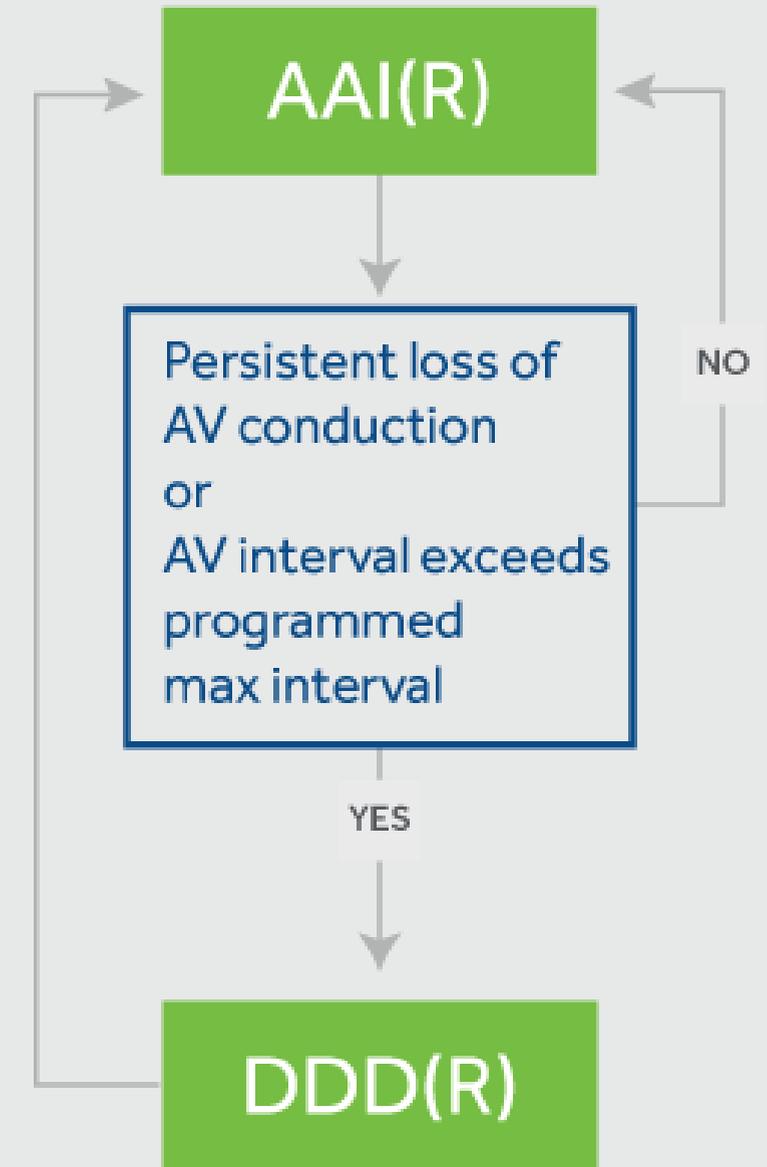
With MVP™<sup>1</sup>

### Now updated with the option to control maximum AV interval

- RV pacing is associated with an increased risk of HF hospitalization.<sup>2</sup>
- RV pacing is associated with a 1% increase in risk of AF for each 1% increase in cumulative RV pacing.<sup>2</sup>
- MVP algorithm reduces unnecessary RV pacing by 99%.<sup>1</sup>

<sup>1</sup> Gillis AM, et al. Reduction of unnecessary right ventricular pacing due to the managed ventricular pacing (MVP) mode in patients with symptomatic bradycardia. Benefit for both sinus node disease and AV block indications. Presented at HRS 2015 (Abstract AB21-1).

<sup>2</sup> Sweeney MO, et al. *Circulation*. 2003;107:2932-2937.



# CAPTURING THE POWER OF SMART TECHNOLOGY

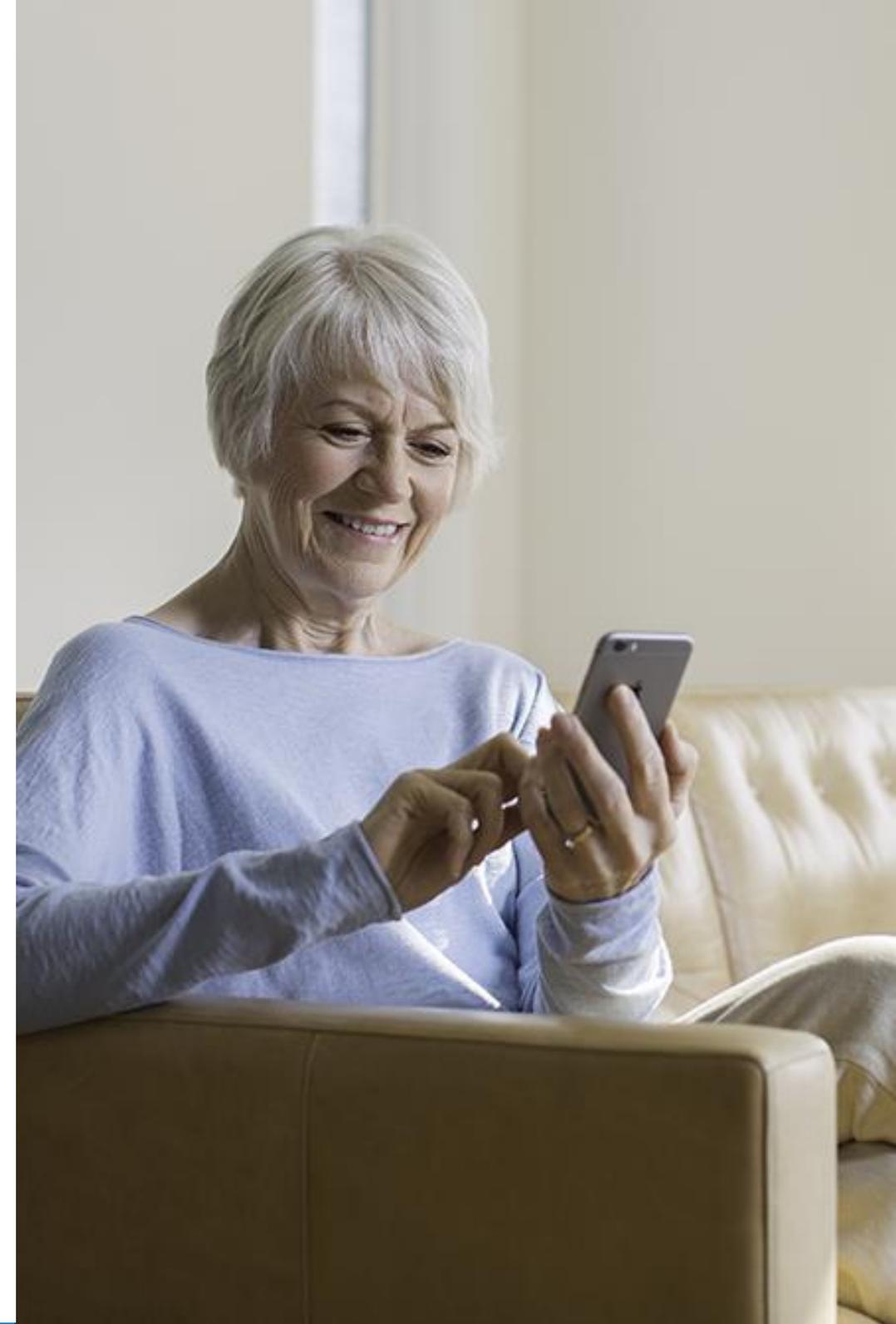
Adoption of smart technology is increasing

- **73%** of Americans 60 years and older own a smartphone.<sup>1</sup>
- **62%** of consumers use their phones to look up health information.<sup>2</sup>
- **83%** of payers and providers believe that consumers need to take more control of their health in a value-based system.<sup>3</sup>

<sup>1</sup> Anderson GO, AARP. Technology Use and Attitudes among Mid-Life and Older Americans. December 2017.

<sup>2</sup> Pew Research Center. US Smartphone Use in 2015. April 1, 2015.

<sup>3</sup> Xerox Corporation. New Insights on Value-based Care Healthcare, Attitudes 2016.



Our first generation of smart technology\* in the hands of our patients resulted in the following:

USE OF  
SMART

> 95,000

patients have adopted  
MyCareLink Smart™  
monitor globally.<sup>1</sup>

PATIENT  
SATISFACTION

85%

of over 2,300 patients  
said they would recommend  
MyCareLink Smart monitor  
to other patients.<sup>2</sup>

ADHERENCE

90%

of 1,291 patients — and 89%  
of 444 patients over 70 years  
of age — using MyCareLink  
Smart monitor remained  
adherent to HRS guidelines  
after 12 months of use.<sup>3</sup>

This spurred Medtronic's continued innovation in remote monitoring by enabling the Azure™ pacemaker with BlueSync™ technology to communicate directly with a patient-owned mobile platform.

\*MyCareLink Smart is not compatible with BlueSync-enabled devices.

<sup>1</sup> Wells P. Medtronic data on file. MyCareLink Smart Global Adoption. December 2017.

<sup>2</sup> MyCareLink Smart Patient Website Satisfaction Survey. February 2017. Medtronic data on file.

<sup>3</sup> Khaldoun G, et al. MPH, FHRS; Success of CIED Remote Monitoring Using App Based Smart Technology: Does Age Matter? Presented at HRS 2017 (Abstract 17-A-8995 HRS).

# ENGINEERED FOR THE FUTURE OF CONNECTED HEALTH



New tablet-based CareLink SmartSync™ device manager pacing system analyzer (not yet broadly available)



Azure pacemaker engineered with BlueSync technology



MyCareLink Heart™ mobile app on patient's smartphone or tablet



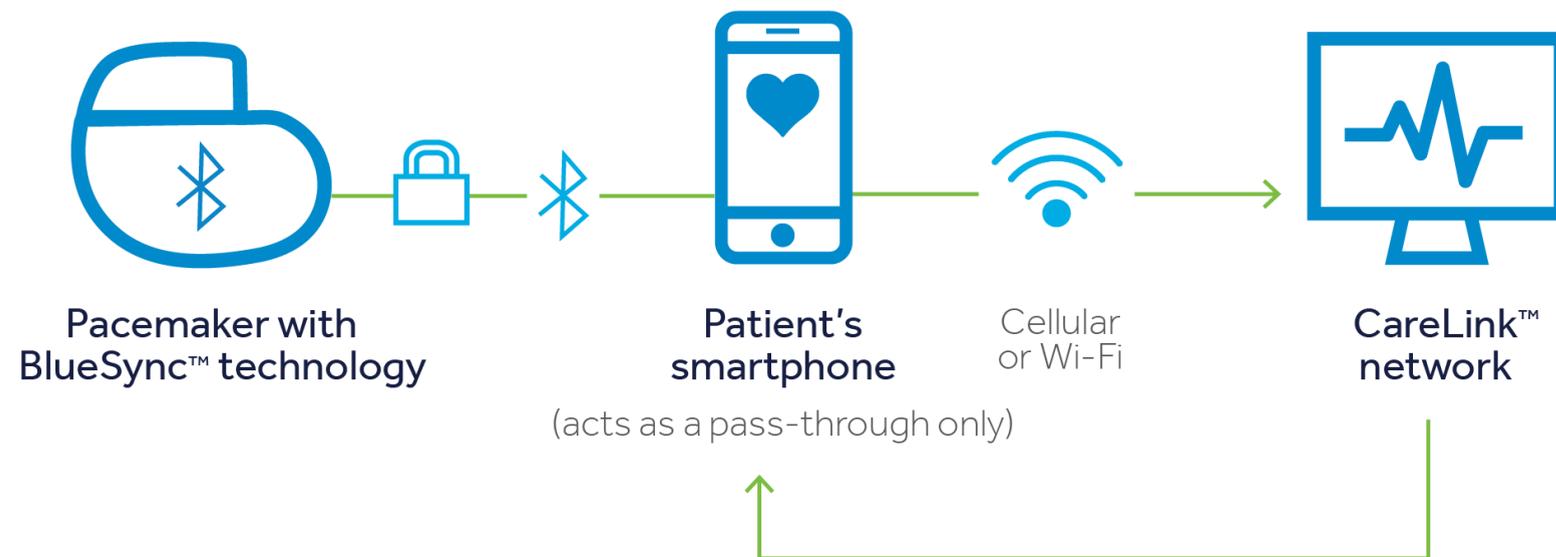
CareLink™ network

**Azure™ with BlueSync™ Technology**  
Innovation in consumer digital tools is creating new opportunities in healthcare. BlueSync technology allows Medtronic to innovate and connect with the patients and clinicians in new and exciting ways.

# INTRODUCING

## MyCareLink Heart™ Mobile App

- Patients can now use their smartphone\* to transfer heart device data via the app — even outside the home — replacing the bedside monitor.
- Patients can now view select pacemaker data, including model name and battery longevity.



MyCareLink Heart™ allows the patient to view select data (content of transmissions and alerts is not visible to the patient)



Enhanced security with data encryption and pacemaker protection<sup>1</sup>



Use of Bluetooth® Low Energy is designed to minimize battery drain of the pacemaker.<sup>1</sup>



Automatic notifications inform patients of transmission status.



Upgradeable throughout lifetime of device

<sup>1</sup> Medtronic Azure™ XT DR MRI SureScan™ Device Manual. M964338A001B. 2016-10-22.

\*Please visit [www.MCLHeart.com](http://www.MCLHeart.com) for a list of compatible smartphones and tablets.

# BENEFITS

**MyCareLink Heart™ mobile app is designed to offer the following benefits:**



## Patient Engagement Promotes Patient Satisfaction<sup>1</sup>

- Integrate remote monitoring into your patient's daily life using a patient-owned smartphone and eliminate the need for a bedside monitor.
- Provide patient peace of mind with the MyCareLink Heart app which allows patients to view select data, such as transmission status.
- Activated patients are significantly more likely to engage in healthy behaviors.<sup>2</sup>



## Patient Compliance Results in Increased Clinic Efficiencies<sup>3</sup>

- Patient monitoring — even outside the home — helps deliver quality of care in line with HRS guidelines.
- Reduce clinic time spent on follow-up activities.
- Push notifications help patients stay connected, transmit on time, and verify that transmissions were sent.



## Upgradeability Sets the Foundation for Future Technologies

Similar to consumer apps, as technology advances, so will MyCareLink Heart — throughout the life of the pacemaker.

<sup>1</sup> Varma N. *Cont Cardiol Educ*. 2016;2:198-204.

<sup>2</sup> Fowles JB, et al. *Patient Educ Couns*. 2009;77:116-122.

<sup>3</sup> Cronin EM, et al. *Heart Rhythm*. 2012;9:1947-1951.



# OVERVIEW

MyCareLink Heart™ mobile app allows patients to easily view select data — intended to provide peace of mind of patients living with a pacemaker.

Home

MY VITALS TRACKING

NOTE: Vitals information is stored ONLY in the app and is NOT sent to your clinic.

DAY WEEK MONTH

< TODAY MAR 15, 2018 >

Weight lbs **135** >  
+1 Since yesterday +2 Since last week

Systolic mmHg **151** >

Diastolic mmHg **97** >

Heart Rate bpm **85** >

Symptom **1**

This information is only stored on the patient's phone; it is not sent to the clinic.

Home

MY PACEMAKER

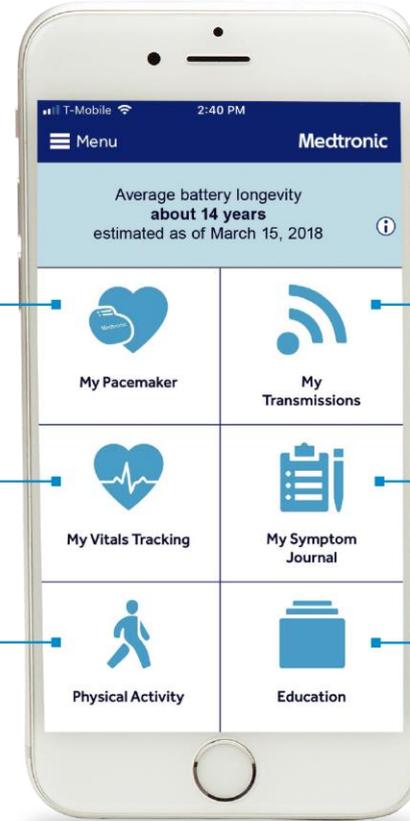
Implanted 01/01/2017 Model Number W1DR01

Serial Number PRFxxxxxH Device Name Azure™ XT DR MRI SureScan™

MY CLINIC

Care East Clinic  
James Circle N., Suite # 115  
St Paul, MN 55555  
555-555-5555

Office Hours:  
Monday- Friday 8:00 am to 5:00 pm  
555-555-5555



Home

MY TRANSMISSIONS

Special Transmission Request  
Did your clinic request an unscheduled transmission? If approved, send now.  
**SEND TRANSMISSION**  
Not a substitute for calling Emergency.

UPCOMING TRANSMISSION

Monday, July 6, 2018  
Transmission will be automatically sent.

PAST TRANSMISSIONS

Monday, January 5, 2018  
Transmission Successful

Tuesday, August 14, 2017  
Transmission Successful

Home

SYMPTOM JOURNAL

Record symptoms in the app to review with your doctor on your next visit.

**RECORD NEW SYMPTOMS**

RECORDED SYMPTOMS

Today  
Shortness of Breath, around 3:00 pm >

Monday, February 24, 2018  
Heart fluttering, Feeling faint, I was cookin... >

Friday, January 18, 2018  
Shortness of Breath, I was watching TV at... >

Monday, July 5, 2017  
Palpitations, Heart fluttering, I was walkin... >

This information is only stored on the patient's phone; it is not sent to the clinic.

Home

PHYSICAL ACTIVITY

DAY WEEK MONTH

**1:15**  
Hours Minutes  
Of walking and running activity yesterday

**+45**  
Minutes  
You were more active yesterday than the previous day

Home

Expand All

- + WHAT IS REMOTE MONITORING?
- + HOW DOES REMOTE MONITORING WORK?
- + DOES MY DEVICE AFFECT HOW ACTIVE I CAN BE?
- + DO I NEED TO DO ANYTHING SPECIAL WHEN I GO THROUGH AIRPORT SECURITY?
- + IS IT SAFE FOR ME TO USE HOUSEHOLD APPLIANCES?
- + WILL MAGNETS AFFECT MY DEVICE?
- + CAN MEDICAL PROCEDURES AFFECT MY DEVICE?
- + CAN I GET AN MRI WITH MY DEVICE?
- + WILL MY DEVICE NEED TO BE REPLACED?

Information on this app should not be used as a substitute for talking with your doctor. Always talk with your doctor about diagnosis and treatment information.

ADDITIONAL INFORMATION

To learn more about Medtronic and its mission, please visit us at [www.medtronic.com](http://www.medtronic.com).

All patient and clinical data are fictitious and are for demonstration purposes only.

# SECURITY MEASURES<sup>1</sup>

Security for BlueSync™ connectivity and features was **designed** to protect the device, patient data, and connectivity. In addition to Medtronic's extensive internal product security **testing**, Medtronic has also engaged outside specialized security testing firms.



## Pacemaker Protection

- **Pacemaker doesn't accept programming** from unauthorized sources. It only accepts programming from Medtronic programmers in close proximity.
- **Device not connected to Internet**  
Pacemaker does not have an IP address, unlike connected consumer products.



## Data Privacy

### **End-to-end encryption:**

Data are encrypted in the pacemaker using NIST\* government standard for security (used in critical applications like banking) before it is transmitted to CareLink™ network via the app.

<sup>1</sup> Medtronic Azure™ XT DR MRI SureScan™ Device Manual. M964338A001B. 2016-10-22.

\*NIST: National Institute of Standards and Technology.

# UNMATCHED MRI ACCESS

With Azure™ MRI, patients have access to 1.5T and 3T full body scanning<sup>1</sup>

## Built to be scanned

- Our SureScan™ devices and leads work in any combination.\*
- Scanning conditions are simple: no MRI exclusion zone, no patient height restriction, no MRI duration restriction.<sup>1</sup>

<sup>1</sup> M964377A001 Azure™ MRI SureScan™/Astra™ MRI SureScan™ pacing systems MRI Technical Manual.

\*For complete list of approved device and lead combinations, please visit [www.mrisurescan.com](http://www.mrisurescan.com).



## Brief Statement

### Azure™ MRI SR and DR IPG

**Indications:** The Azure DR MRI and Azure SR MRI SureScan™ systems are indicated for the rate adaptive pacing in patients who may benefit from increased pacing rates concurrent with increases in activity. Accepted patient conditions warranting chronic cardiac pacing include symptomatic paroxysmal or permanent second- or third-degree AV block, symptomatic bilateral bundle branch block, symptomatic paroxysmal or transient sinus node dysfunctions with or without associated AV conduction disorders, or bradycardia-tachycardia syndrome to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias. The Azure DR MRI devices are also indicated for dual chamber and atrial tracking modes in patients who may benefit from maintenance of AV synchrony. Dual chamber modes are specifically indicated for treatment of conduction disorders that require restoration of both rate and AV synchrony, which include various degrees of AV block to maintain the atrial contribution to cardiac output, VVI intolerance (for example, pacemaker syndrome) in the presence of persistent sinus rhythm, or vasovagal syndromes or hypersensitive carotid sinus syndromes. Antitachycardia pacing (ATP) is indicated for termination of atrial tachyarrhythmias. In bradycardia patients with one or more of the above pacing indications.

**MRI Conditions for Use:** Medtronic SureScan pacing systems are MR conditional, and as such are designed to allow patients to undergo MRI under the specified conditions for use. Pacemaker 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 pacing 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.

**Contraindications:** The Azure DR MRI and Azure SR MRI SureScan systems are contraindicated for concomitant implantation with another bradycardia device or with an implantable cardioverter defibrillator. Rate-responsive modes may be contraindicated in those patients who cannot tolerate pacing rates above the programmed Lower Rate. Dual chamber sequential pacing is contraindicated in patients with chronic or persistent supraventricular tachycardias, including atrial fibrillation or flutter. Asynchronous pacing is contraindicated in the presence (or likelihood) of competition between paced and intrinsic rhythms. Single chamber atrial pacing is contraindicated in patients with an AV conduction disturbance. ATP therapy is contraindicated in patients with an accessory antegrade pathway.

**Warnings and Precautions:** Changes in 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. Use of the device should not change the application of established anticoagulation protocols. 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 or Potential Complications:** Potential complications include, but are not limited to, rejection phenomena, erosion through the skin, muscle or nerve stimulation, oversensing, failure to detect and/or terminate arrhythmia episodes, acceleration of tachycardia, and surgical complications such as hematoma, infection, inflammation, and thrombosis. Potential lead complications include, but are not limited to, valve damage, fibrillation, thrombosis, thrombotic and air embolism, cardiac perforation, heart wall rupture, cardiac tamponade, pericardial rub, infection, myocardial irritability, and pneumothorax. Other potential complications related to the lead may include lead dislodgement, lead conductor fracture, insulation failure, threshold elevation, or exit block. Potential MRI complications include, but are not limited to, lead electrode heating and tissue damage resulting in loss of sensing or capture or both, or induced currents on leads resulting in continuous capture, VT/VF, and/or hemodynamic collapse.

*See the device manuals before performing an MRI Scan for detailed information regarding the implant procedure, indications, MRI conditions of use, contraindications, warnings, precautions, and potential complications. For further information, call Medtronic at 1-800-328-2518 and/or consult the Medtronic website at [medtronic.com](http://medtronic.com).*

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

### Medtronic CareLink™, MyCareLink™, MyCareLink Smart™ Patient Monitors, MyCareLink Smart™ Application, Medtronic CareLink™ Network, CareLink™ Mobile Application, and Medtronic MyCareLink Connect™ Patient Website

**Intended Use:** The Medtronic CareLink, MyCareLink, MyCareLink Smart patient monitors, MyCareLink Smart application, CareLink network, and the CareLink mobile application are indicated for use in the transfer of patient data from some Medtronic implantable cardiac devices to the Medtronic CareLink network based on physician instructions and as described in the product manual. Medtronic CareAlerts are not intended to be used as the sole basis for making decisions about patient medical care. These products are not a substitute for appropriate medical attention in the event of an emergency and should only be used as directed by a physician. The CareLink mobile application is intended to provide current CareLink network customers access to CareLink network data via a mobile device for their convenience. The CareLink mobile application is not replacing the full workstation, but can be used to review patient data when a physician does not have access to a workstation. The CareLink mobile application and the MyCareLink Smart mobile application have minimum requirements for the mobile device and operating system. The minimum requirements for the mobile device and operating system are expected to change over time. Periodically, the patient may need to update their mobile device's operating system, or replace their mobile device to continue to use the app to transfer data to the CareLink network. The MyCareLink Connect patient site is intended to provide patients, their friends/family, and caregivers messages regarding transmission status of patient device diagnostic data to the CareLink network. The MyCareLink Connect patient website is dependent on certain browser software, and that software is expected to change over time. Patients that are experiencing technical issues with the MyCareLink Connect patient website should contact Medtronic Patient Services at the number below. Data availability, alert notifications and patient messages are subject to Internet connectivity, access, and service availability. The CareLink and MyCareLink patient monitors and the MyCareLink Smart reader must be on and in range of the device. The MyCareLink Smart reader must also be within range of the patient's mobile device. The CareLink network and mobile device accessibility to the CareLink network may be unavailable at times due to maintenance or updates, or due to coverage being unavailable in your area. Mobile device access to the Internet is required for the CareLink mobile app and the MyCareLink Smart monitoring system and subject to coverage availability. Standard data and text message rates apply. Message frequency depends on account settings and clinic scheduling.

**Contraindications:** There are no known contraindications.

**Warnings and Precautions:** The CareLink, MyCareLink and MyCareLink Smart patient monitors must only be used for interrogating compatible Medtronic implantable devices. While using the CareLink or MyCareLink patient monitor, do not use a cellular phone while the antenna is positioned over the implanted device. The CareLink and MyCareLink monitors are intended for use within the prescribing country. The MyCareLink Smart patient monitors may be used internationally. Standard mobile device availability and rates apply.

*See the device manuals for detailed information regarding the instructions for use, indications or intended uses, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-800- 929-4043 and/or consult the Medtronic website at [medtronic.com](http://medtronic.com).*

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

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