THE FUTURE IS HERE

Meet Azure™ Pacemaker with BlueSync™ Technology
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UNMATCHED FEATURE SUITE

- Exclusive algorithms to manage atrial fibrillation (AF) in pacemaker patients
- Reduce unnecessary RV pacing with MVP™ feature
- Improved longevity — updated hardware architecture optimizes circuitry (to reduce current drain)
- Unmatched MRI access — 1.5T and 3T full body scanning

REIMAGINED CONNECTIVITY

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

STREAMLINED WORKFLOWS

- Manage alerts of clinically relevant events with additional CareAlert™ notifications
- MyCareLink Heart™ mobile app is designed to increase clinic efficiencies through patient compliance

Atrial Fibrillation (AF) Is Prevalent and Clinically Challenging

- 1 in 3 CIED patients will develop new onset AF within the first 2.5 years of implant1

Increases the risk of heart failure greater than 3-FOLD2

5-FOLD increase in ischemic stroke risk for AF patients3

Detect

Highest published AF episode detection accuracy (PPV)*†4-7

95–96% AF episode detection accuracy (PPV)

Reduce

Exclusive algorithms demonstrated to reduce the risk and duration of AF

36% relative reduction in AT/AF episodes ≥ 7 days with Reactive ATP™ Algorithm†8

* 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.
Atrial Fibrillation (AF) Is Prevalent and Clinically Challenging

1 in 3 CIED patients will develop new onset AF within the first 2.5 years of implant\(^1\)

Increases the risk of heart failure greater than 3-\(\text{FOLD}\)^2

5-\(\text{FOLD}\) increase in ischemic stroke risk for AF patients\(^3\)

Exclusive Algorithms to Manage AF in Patients

**DETECT**

Highest published AF episode detection accuracy (PPV)*\(^{14-7}\)

95–96% AF episode detection accuracy (PPV)\(^{5-7}\)

**REDUCE**

Exclusive algorithms demonstrated to reduce the risk and duration of AF

36% relative reduction in AT/AF episodes \(\geq 7\) days with Reactive ATP™ Algorithm\(^{18}\)

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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.
Exclusive Algorithms to Manage AF in Patients

Reduce duration of AF\(^8\) with Reactive ATP
Reactive ATP provides an opportunity to terminate an ongoing AF episode by delivering ATP during those times when the rhythm has organized and/or slowed.

Analysis design
An analysis design of 8,032 patients in the Medtronic CareLink™ database assessed the impact of Reactive ATP across pacemakers, ICDs, and CRT devices.\(^8\)

RESULTS
Reactive ATP is associated with a reduction in the duration of AT/AF\(^8\):
- \(\geq 1\) day by 19%
- \(\geq 7\) days by 36%
- \(\geq 30\) days by 44%

36% reduced risk of persistent AF\(^8\)

Simple programming nominals updated to MINERVA\(^8\) settings.

*Compared to matched control group; matched components included age, sex, baseline AF and percent VP, pacing mode, and device type.
Reduce Unnecessary RV Pacing\textsuperscript{10} with MVP Feature

Now updated with the option to control maximum AV interval

- RV pacing is associated with an increased risk of HF hospitalization.\textsuperscript{11}
- RV pacing is associated with a 1\% increase in risk of AF for each 1\% increase in cumulative RV pacing.\textsuperscript{11}
- MVP algorithm reduces unnecessary RV pacing by 99\%.\textsuperscript{10}

\begin{figure}
\centering
\includegraphics[width=\textwidth]{chart.png}
\caption{Diagram showing the process of determining pacing mode.}
\end{figure}

* Compared to matched control group; matched components included age, sex, baseline AF and percent VP, pacing mode, and device type.
With Azure MRI, Patients Have Access to 1.5T and 3T Full Body Scanning.

Built to be scanned SureScan™ devices were specifically engineered for the MRI environment, with enhancements that ensure patient safety during an MRI scan.*

Scanning conditions are simple: no MRI exclusion zone, no patient height restriction, no MRI duration restriction.13

UNMATCHED FEATURE SUITE

Improved Longevity

Updated hardware architecture optimizes circuitry to reduce current drain and improve longevity.12

15.8 YEARS* 13.7 YEARS†
Azure XT SR MRI Azure XT DR MRI

12.7 YEARS† 10.8 YEARS†
Advisa SR MRI™ Advisa DR MRI™

+24% +27%

*Projected service life estimates assume device configuration at VVI 50%, 2.5V, 500 Ohm lead impedances, Pre-storage EGM off. Projected service life estimates are based on accelerated battery discharge data and device modeling. The values calculated based on this information should not be interpreted as precise numbers. Individual patient results may vary based on their specific programming and experience.

†Projected service life estimates assume device configuration at MVP 50% AP, 5% VP, 2.5V in both chambers, 500 Ohm lead impedances, Pre-storage EGM off. Projected service life estimates are based on accelerated battery discharge data and device modeling. The values calculated based on this information should not be interpreted as precise numbers. Individual patient results may vary based on their specific programming and experience.

*For a complete list of approved device and lead combinations, please visit mrisurescan.com.
With Azure MRI, Patients Have Access to 1.5T and 3T Full Body Scanning.\textsuperscript{13}

**Built to be scanned**

- SureScan\textsuperscript{™} devices were specifically engineered for the MRI environment, with enhancements that ensure patient safety during an MRI scan.\textsuperscript{*}

- Scanning conditions are simple: no MRI exclusion zone, no patient height restriction, no MRI duration restriction.\textsuperscript{13}

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REIMAGINED CONNECTIVITY

BlueSync Technology
Azure with BlueSync technology enables secure, wireless communication.

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

Device Protection
- Pacemaker doesn’t accept programming from unauthorized sources.
- Device 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 the pacemaker using NIST* government standard for security before being transmitted to the CareLink network.

Key Components of BlueSync Technology

- **Encryption Technology**
  Data are encrypted in the pacemaker using NIST* standard encryption.

- **Bluetooth**
  Low Energy enabled to securely communicate with Bluetooth Low Energy smartphones or tablets.

- **High-density Integrated Circuit**
  Reduces current drain for increased longevity.

Please go to [medtronic.com/security](http://medtronic.com/security) for up-to-date security information.

*NIST: National Institute of Standards and Technology.
MyCareLink Heart Mobile App

Patients can now use their smartphone to automatically transfer device data via the MyCareLink Heart mobile app, even outside the home (where cellular or Wi-Fi connectivity is available). *

- **My Heart Device**
  Displays battery longevity, implant date, heart device name, serial number, and patient’s clinic information.

- **Physical Activity**
  The app uses data from patient’s heart device to create daily, weekly, and monthly views of physical activity.

- **My Transmissions**
  Has information about transmissions sent from a patient’s heart device to their clinic.

- **Education**
  Provides information about living with a heart device.

Patients are required to keep their smartphone/tablet up to date to use the app.

- **Connectivity Status**
  Green check mark confirms Bluetooth® is ON and the app was connected recently.

Available on iOS and Android™.

*Please visit MCLHeart.com for a list of compatible smartphones and tablets.

Alternative Monitoring Option

**MyCareLink Relay Home Communicator**

MyCareLink Relay offers a monitoring alternative to patients who prefer not to use a smartphone.

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

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

Timely Alerts of Clinically Relevant Events$^{14,15}$

Time to a clinical decision was $\sim 7x$ faster with the use of Medtronic CareAlert notifications compared to standard office follow-up.$^{16}$

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

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

MyCareLink Heart mobile app was designed to offer the following benefits:

**Patient Engagement Promotes Patient Satisfaction**¹⁷
- 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.¹⁸

**Patient Compliance Results in Increased Clinic Efficiencies**¹⁹
- 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.
Indications: 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 tachycardia using 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 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 transattacheryardia 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: MRI or MR to not extend lead electrodes or implanted devices, nor 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 tissue, infection, oversensing, failure to detect and/or terminate arrhythmia episodes, acceleration of tachyarrhythmia, and surgical complications such as hematoma, infection, inflammation, and thrombosis. Potential lead complications include, but are not limited to, vascular damage, fibrillation, thrombosis, and thoracic and abdominal, 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.

Brief Statements: Azure MRI™, MRi SR MRI™ and MRi 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 rate adaptability include symptomatic paroxysmal or permanent second- or third-degree AV block, symptomatic bilaterally 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 paroxysmal atrial fibrillation. 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 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 pacemaker indications.

MRI Conditions for Use: Medtronic SureScan pacing systems are MR conditional, and assuch 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 1.5 T or 3 T MRI system for hydrogen proton imaging. When programmed to the MRi DR/MRI SureScan feature, the patient is 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.

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References


Medtronic

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.