THE FUTURE IS HERE

Meet Azure™
Pacemaker with BlueSync™ Technology

Medtronic

THE FUTURE IS HERE

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

Meet Azure™ Pacemaker with BlueSync™ Technology

UNMATCHED FEATURE SUITE

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-FOLD[2]

5-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)*†[4-7]

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 ≥ 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.

UNMATCHED FEATURE SUITE

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]:

- ≥ 1 day by 19%
- ≥ 7 days by 36%
- ≥ 30 days by 44%

36%

reduced risk of persistent AF*[8]

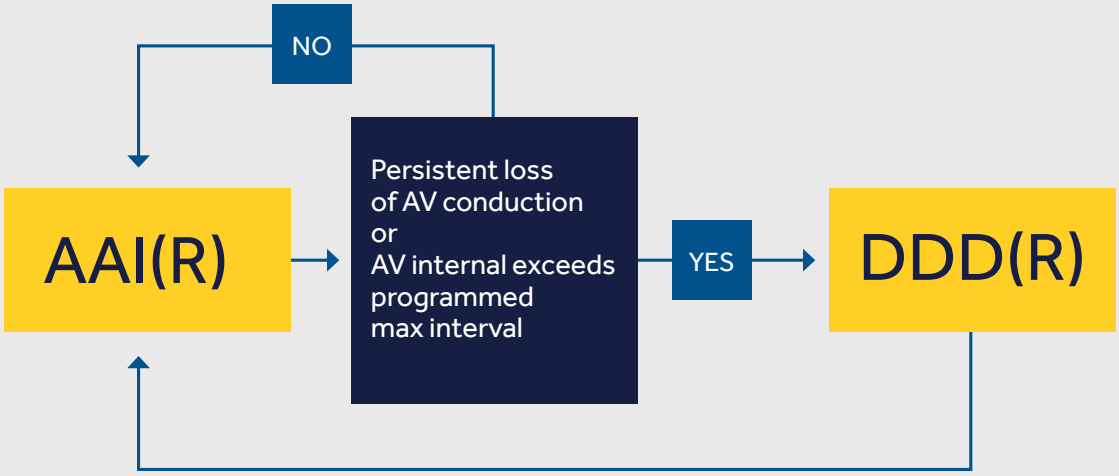
Simple programming nominals updated to MINERVA[9] settings.

*Compared to matched control group; matched components included age, sex, baseline AF and percent VP, pacing mode, and device type.

Reduce Unnecessary RV Pacing[10] with MVP Feature

Now updated with the option to control maximum AV interval

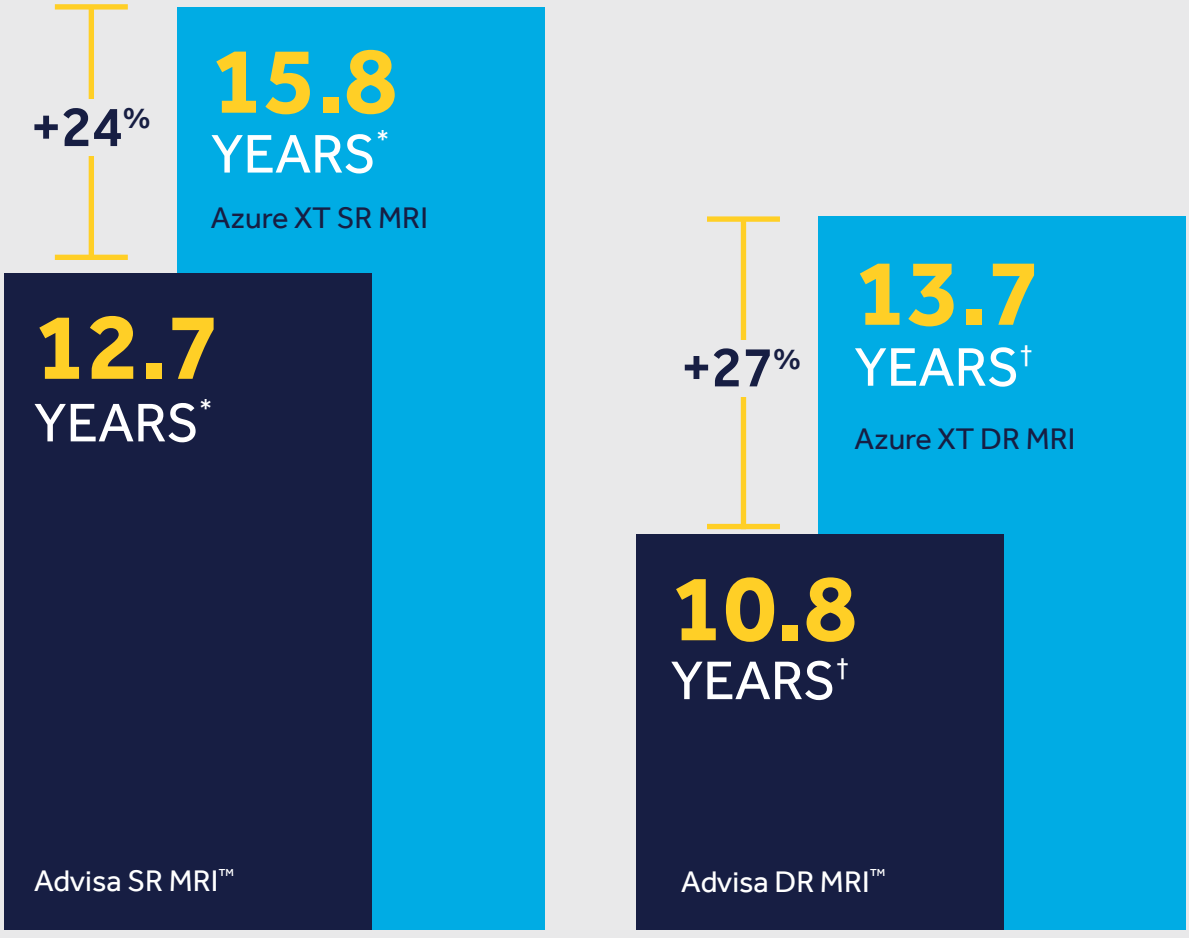
- RV pacing is associated with an increased risk of HF hospitalization.[11]
- RV pacing is associated with a 1% increase in risk of AF for each 1% increase in cumulative RV pacing.[11]
- MVP algorithm reduces unnecessary RV pacing by 99%.[10]



UNMATCHED FEATURE SUITE

Improved Longevity

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



*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.

UNMATCHED MRI ACCESS

With Azure MRI, Patients Have Access to 1.5T and 3T Full Body Scanning.[13]

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]

*For a complete list of approved device and lead combinations, please visit mrisurescan.com.

REIMAGINED CONNECTIVITY

BlueSync Technology

Azure with BlueSync technology enables secure, wireless communication.

Tablet-based CareLink SmartSync™ device manager

Azure™ pacemaker engineered with BlueSync technology

MyCareLink Heart mobile app or MyCareLink Relay™ Home Communicator

CareLink network

Supported by the Get Connected service

Security Measures[14]

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

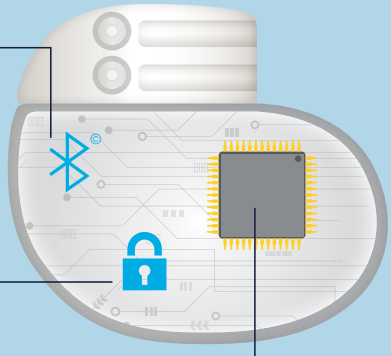
End-to-end encryption

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

Key Components of BlueSync Technology

Bluetooth® Low Energy enabled to securely[14] communicate with Bluetooth Low Energy smartphones or tablets.

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



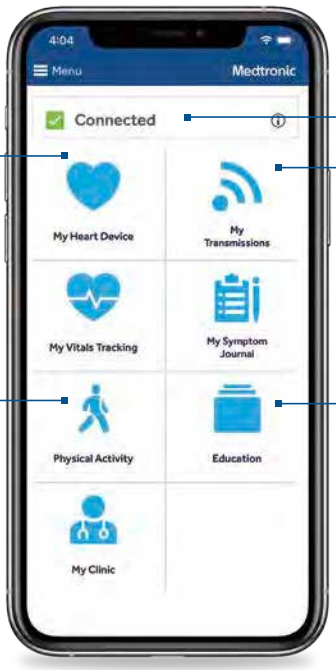
High-density Integrated Circuit reduces current drain for increased longevity.

Please go to **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).*



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

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

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

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

Education
Provides information about living with a heart device.

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

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 **~7x faster** with the use of Medtronic CareAlert notifications compared to standard office follow-up.[16]

CareAlert notifications can be programed 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.

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Brief Statements

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 bradycardiatachycardia 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 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 1.5T 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 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. 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.

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 CareLink SmartSync 24970A and Technical Manual and 24967 Patient Connector Technical Manual before using the CareLink SmartSync 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.

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 CareLink SmartSync 24967 Patient Connector Technical Manual before using the CareLink SmartSync 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.

See the device manual for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative 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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