ENGINEERED TO ENABLE THE FUTURE OF CONNECTED HEALTH

Introducing Azure™ with BlueSync™ Technology

- Completely Redesigned
- Improved Longevity¹
- AF Detection and Reduction²
- Secure Wireless Communication with BlueSync Technology³

Medtronic
COMpletely REDESIGNED

With BlueSync™ Technology for Secure Low Energy (BLE) enabled to automatically and securely communicate with BLE smartphones or tablets

Key Design Changes

Bluetooth® Low Energy (BLE) enabled to automatically and securely 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

*DR: MVP™, SR: VVI 50%, 500 ohm, 2.5 V, pre-storage EGM off.
ACCU R A T E  
AF DETECTION
Reduce AT/AF false positives with PR Logic™ algorithms

<table>
<thead>
<tr>
<th>Device</th>
<th>Positive Predictive Value%</th>
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<tr>
<td>MDT</td>
<td>96.2%</td>
</tr>
<tr>
<td>BSX</td>
<td>62%</td>
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<tr>
<td>STJ</td>
<td>59.7%</td>
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AF detection accuracy rates determined from independent clinical trials are presented for reference.

*A controlled head-to-head study evaluating the comparative performance of device algorithms has not been done.

TIMELY ALERTS
OF CLINICALLY RELEVANT EVENTS

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 are transmitted via Bluetooth monitor (currently available)
REDUCE THE LIKELIHOOD OF PATIENTS EXPERIENCING AT/AF²

With Reactive ATP™
- rATP provides an opportunity to terminate an ongoing AF episode by delivering ATP during those times when the rhythm has organized and/or slowed.
- rATP is associated with a reduction* in the progression of AF to ≥ 1 day, ≥ 7 days, and ≥ 30 days events across all device types (p < 0.001).²

<table>
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<th>≥ 1 day by</th>
<th>≥ 7 days by</th>
<th>≥ 30 days by</th>
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<tbody>
<tr>
<td>21%</td>
<td>40%</td>
<td>49%</td>
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Analysis of 8,032 U.S. patients in the Medtronic CareLink™ database assessed the impact of rATP across pacemakers, ICDs, and CRT devices.²

*Model components included group, age, sex, baseline AF, and device type. Frailty model results were consistent with those from Cox proportional hazards models (P > 0.0001 for all).

REDUCE UNNECESSARY RV PACING

With MVP™¹¹

Now updated with the option to control maximum AV interval
- RV pacing is associated with an increased risk of HF hospitalization.¹²
- RV pacing is associated with a 1% increase in risk of AF for each 1% increase in cumulative RV pacing.¹²
- MVP algorithm reduces unnecessary RV pacing by 99%.¹¹
CAPTURING THE POWER OF SMART TECHNOLOGY

Use of smart technology is becoming more prevalent

- Smartphone adoption in U.S. by users 65 and older has nearly quadrupled in the last five years.\(^\text{13}\)
- 62% of consumers use their phones to look up health information.\(^\text{14}\)
- 83% of payers and providers believe that consumers need to take more control of their health in a value-based system.\(^\text{15}\)
Our first generation of smart technology* in the hands of our patients resulted in the following:

<table>
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<tr>
<th>USE OF SMART</th>
<th>PATIENT SATISFACTION</th>
<th>ADHERENCE</th>
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<tr>
<td>&gt;77,000</td>
<td>85%</td>
<td>90%</td>
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</table>

patients have adopted MyCareLink Smart™ monitor globally.\(^{16}\)
of over 2,300 patients said they would recommend MyCareLink Smart monitor to other patients\(^{17}\)
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\(^{18}\)

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.
BLUESYNC-ENABLED DEVICES SET THE FOUNDATION FOR THE FUTURE OF CONNECTED HEALTH

Innovation in consumer digital tools is creating new opportunities in healthcare. BlueSync technology will allow Medtronic to innovate and connect with the patients and clinicians in new and exciting ways.

- New tablet-based CareLink SmartSync™ device manager pacing system analyzer (not yet broadly available)
- Azure pacemaker engineered with BlueSync Technology
- Patient-owned mobile platform
- CareLink network
BLUESYNC-ENABLED DEVICES

are designed to transfer heart device data via Bluetooth Low Energy (BLE) to the CareLink network from anywhere — even outside the home

Enhanced security with data encryption and pacemaker protection

Use of Bluetooth Low Energy is designed to minimize battery drain of the pacemaker.

Automatic notifications inform patients of transmission status

Upgradeable throughout lifetime of device

*Not presently available for use with a patient-owned mobile platform.
SECURITY MEASURES

Security for the new 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.
- Device not connected to Internet
  Pacemaker does not have an IP address, unlike connected consumer products.

Data Privacy
Encryption: Data are encrypted in the pacemaker using NIST* government standard for security (used in critical applications like banking) before they are transmitted to CareLink via the app.

*NIST: National Institute of Standards and Technology.

UNMATCHED MRI ACCESS

With Azure MRI, patients have access to 1.5T and 3T full body scanning.

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.19

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

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: primary or secondary bradycardia, 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 (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 arrhythmias with bradycardia-tachycardia syndrome to prevent symptomatic bradycardia in 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 freely scan while the device continues to provide appropriate pacing. A complete SureScan 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.mruiserscan.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 flutter or fibrillation. 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 antrage pathway.

Warnings and Precautions: Changes in patient’s disease and/or medications may alter the device’s programming. Patients should not change the application of established anticoagulation protocols. Patients and their implantated systems must be screened to meet the following requirements for MRI: no lead extenders, lead adaptors, or abandoned leads present. Patients should not leave the room with electromagnetic 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, or failure to detect/sense arrhythmias. Contraindications apply to 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.

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