

# MORE TIME TO FOCUS ON PATIENT CARE

Reveal LINQ™ ICM System  
with TruRhythm™ Detection

The world's smallest, most accurate ICM system<sup>1,2</sup> also provides innovative ways to allow you to focus on what matters most — patient care.



**Medtronic**

# MORE TIME TO FOCUS ON PATIENT CARE



Reveal LINQ™ ICM System  
with TruRhythm™ Detection

## UNMATCHED ACCURACY

Reduce false episode review burden while maintaining high sensitivity.<sup>3</sup>

## PROVEN ICM TECHNOLOGY

Continuously monitor patients for up to 3 years.\*

## EXCLUSIVE SERVICES & SOLUTIONS

Designed to get you back to caring for patients.



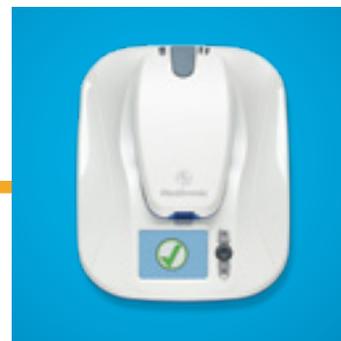
## STREAMLINE DEVICE PROGRAMMING AND INTERROGATION

Reveal LINQ™ Mobile  
Manager



## WORLD'S SMALLEST, MOST ACCURATE ICM<sup>1,2</sup>

Reveal LINQ ICM with  
TruRhythm Detection



### World's Smallest ICM<sup>1</sup>

One-third the size of a AAA battery (1.2 cc)

### World's Most Accurate ICM Algorithm<sup>2</sup>

TruRhythm Detection inside Reveal LINQ insertable cardiac monitor (ICM)

### 3-year Longevity\*

Device longevity that optimizes diagnostic yield

### 700+ Published Clinical Articles & Abstracts<sup>4</sup>

Reveal™ family of ICMs

### 1.5T & 3T MRI Conditional

No post-insertion wait time or patient positioning restrictions†



Actual Size

\*Reference the Reveal LINQ ICM Clinician Manual for usage parameters.

†Reveal LINQ has demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use. Please see the Reveal LINQ MRI Technical Manual for more details.



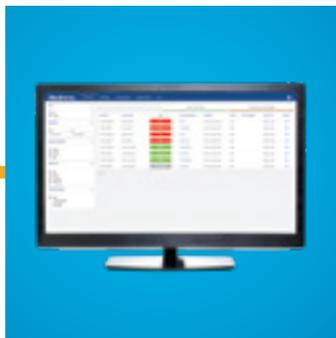
**DIRECT SUPPORT FOR PATIENT MONITOR CONNECTIVITY ISSUES**

**Medtronic Stay Connected™ Service**



**CUSTOMIZE ALERTS FOR CLINICALLY ACTIONABLE REPORTS**

**CareLink™ Network**



**EXPERT OPERATIONAL SUPPORT TO HELP MANAGE PATIENTS**

**Medtronic FocusOn<sup>SM</sup> Monitoring Service\*\***

\*\*Medtronic FocusOn<sup>SM</sup> Monitoring Service is provided by Medtronic Monitoring Inc., a wholly owned subsidiary of Medtronic.

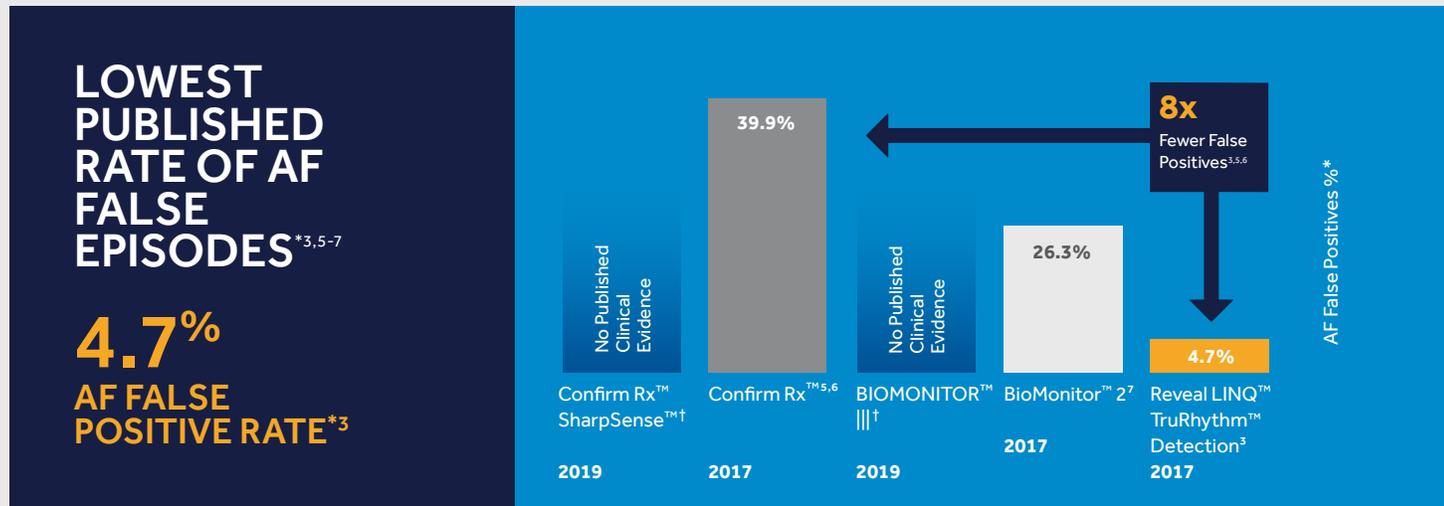
# UNMATCHED ACCURACY

Reduce false episode review burden while maintaining high sensitivity.<sup>3</sup>



## TRURHYTHM DETECTION INSIDE REVEAL LINQ ICM

Experience Fewer False Alerts<sup>3</sup>



Maintain High Sensitivity<sup>3</sup>

**HIGHEST PUBLISHED AF DETECTION ACCURACY**<sup>\*\*3,5-7</sup>

**98.9%**

**AF DURATION SENSITIVITY**<sup>\*\*3</sup>

	Confirm Rx SharpSense (2019)	Confirm Rx (2017)	BIOMONITOR III (2019)	BioMonitor 2 (2017)	Reveal LINQ TruRhythm Detection (2017)
AF Duration Sensitivity	No Published Clinical Evidence†	83.8% <sup>5,6</sup>	No Published Clinical Evidence†	No Published Clinical Evidence†	98.9% <sup>3</sup>

**Disclaimer: A controlled, head-to-head study evaluating the comparative performance of these devices has not been done.**

\*Based on AF episodes ≥ 2 minutes and in known AF patients. % of false positives = (1 – episode PPV). AF episodes PPV may vary between gross and patient average.

†Confirm Rx™ with SharpSense™ technology & BIOMONITOR III have no published clinical evidence showing AF episode PPV or AF sensitivity. BioMonitor 2 has no published clinical evidence showing AF Sensitivity.

\*\*Based on AF episodes ≥ 2 minutes and in known AF patients. AF sensitivity may vary between gross and patient average.

# PROVEN ICM TECHNOLOGY

Continuously monitors patients for up to 3 years.\*

	30 Days Is Not Enough	2 Years Is Not Enough	Superior Diagnostic Yield	Informed Treatment Decisions
Cryptogenic Stroke (CRYSTAL-AF Study) <sup>†</sup>	<b>88%</b> of patients who had AF would have been missed if only monitored for 30 days <sup>**8</sup>	<b>30%</b> of cryptogenic stroke AF diagnoses occur between years 2 and 3 <sup>8</sup>	<b>8.8x</b> more AF detected at 36 months with ICM vs. conventional follow-up <sup>††8</sup>	<b>97%</b> of patients in whom AF was detected received oral anticoagulants at 12 months <sup>8</sup>
Syncopal Episodes	ICM recommended for syncopal episodes > 30 days apart <sup>9</sup>	<b>20%</b> of syncope diagnoses occur between years 2 and 3 <sup>11</sup>	<b>3.6x</b> more likely to reach a syncope diagnosis with ICM vs. conventional care <sup>***12</sup>	<b>82%</b> of Reveal™ ICM guided diagnoses led to treatment <sup>14</sup>
Suspected AF (REVEAL AF Study) <sup>†††</sup>	<b>84.5%</b> of patients with AF would have been missed if only monitored for 30 days <sup>10</sup>	<b>16%</b> of patients with ICM-detected AF would be missed if monitoring stopped at 2 years <sup>10</sup>	<b>4.3x</b> more likely to reach a diagnosis with ICM in 12 months vs. one-time, 30-day monitor <sup>13</sup>	<b>76%</b> of patients with ICM-detected AF had a change in clinical management <sup>10</sup>

\*Reference the Reveal LINQ ICM Clinician Manual for usage parameters.

<sup>†</sup>The CRYSTAL-AF Study was a randomized, controlled study conducted on 441 patients to assess whether long-term monitoring with Reveal XT is more effective than conventional follow-up (control) for detecting atrial fibrillation in patients with cryptogenic stroke.

<sup>\*\*</sup>Based on Kaplan-Meier estimates.

<sup>††</sup>In the CRYSTAL-AF study, the control group included 88 conventional ECGs, 20 24-hour Holters, and 1 event recorder.

<sup>\*\*\*</sup>2018 ESC Guidelines for Diagnosis and Management of Syncope defined conventional testing as undefined physician discretion for monitoring excluding ICM, External Loop Recorder, Tilt Test, EP Study, Recurrent 12-lead ECG, or 7-day Holter monitor.

<sup>†††</sup>The REVEAL AF Study was a prospective, single-arm, multicenter study to quantify the incidence of AF in patients at high risk for but without previously known AF using an ICM (Reveal LINQ or Reveal XT).

## AF MANAGEMENT

Reveal LINQ ICM provides physicians with longitudinal data to objectively determine both asymptomatic and symptomatic AF.<sup>15,16</sup>

This data results in the measure of AF burden and accurate characterization of the AF type to effectively guide therapy decisions.<sup>15,16</sup>



# EXCLUSIVE SERVICES & SOLUTIONS

Designed to get you back to caring for patients.



## STREAMLINE DEVICE PROGRAMMING AND INTERROGATION

### Reveal LINQ Mobile Manager

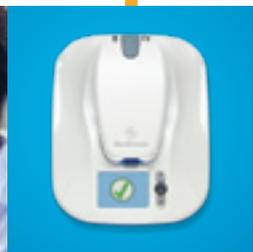
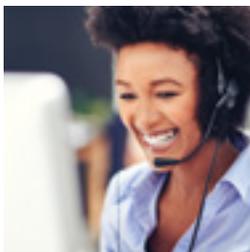
A single, app-based solution for managing:

- Mobile convenience
- Guided workflow animations
- Integrated patient education



## WORLD'S SMALLEST, MOST ACCURATE ICM<sup>1,2</sup>

### Reveal LINQ ICM with TruRhythm Detection

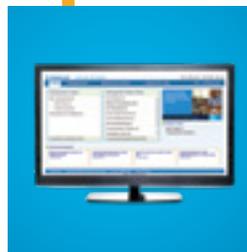
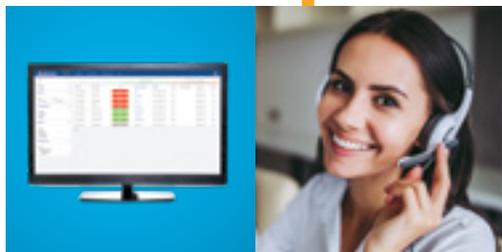


## DIRECT SUPPORT FOR PATIENT MONITOR CONNECTIVITY ISSUES

### Medtronic Stay Connected Service

A specialized patient service for monitor troubleshooting, connectivity issues, and other questions:

Direct patient line for fast service (1-866-470-7709)



## EXPERT OPERATIONAL SUPPORT TO HELP MANAGE PATIENTS

### Medtronic FocusOn Monitoring Service\*

A remote monitoring service that helps optimize your time:

- Ensures data transmissions through patient management and communication
- Patient cardiac data review by certified technicians
- Clinically actionable reporting to inform treatment decisions

\*Medtronic FocusOn<sup>SM</sup> Monitoring Service is provided by Medtronic Monitoring Inc., a wholly owned subsidiary of Medtronic.

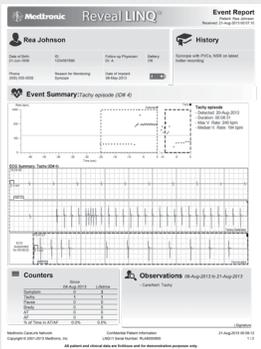
## CUSTOMIZE ALERTS FOR CLINICALLY ACTIONABLE REPORTS

### CareLink Network

A remote monitoring network that enables data-driven care decisions:

- CareAlert<sup>TM</sup> notifications allow for customized reports by clinic and/or individual patient
- Cardiac Compass<sup>TM</sup> report provides a 90-day view of patient cardiac data

# CLINICALLY ACTIONABLE REPORTS AVAILABLE ON THE CARELINK NETWORK



## Event Reports Prioritize Critical Alerts

- Customize to be generated daily with CareAlerts at the clinic- and/or patient-level
- Completely optional



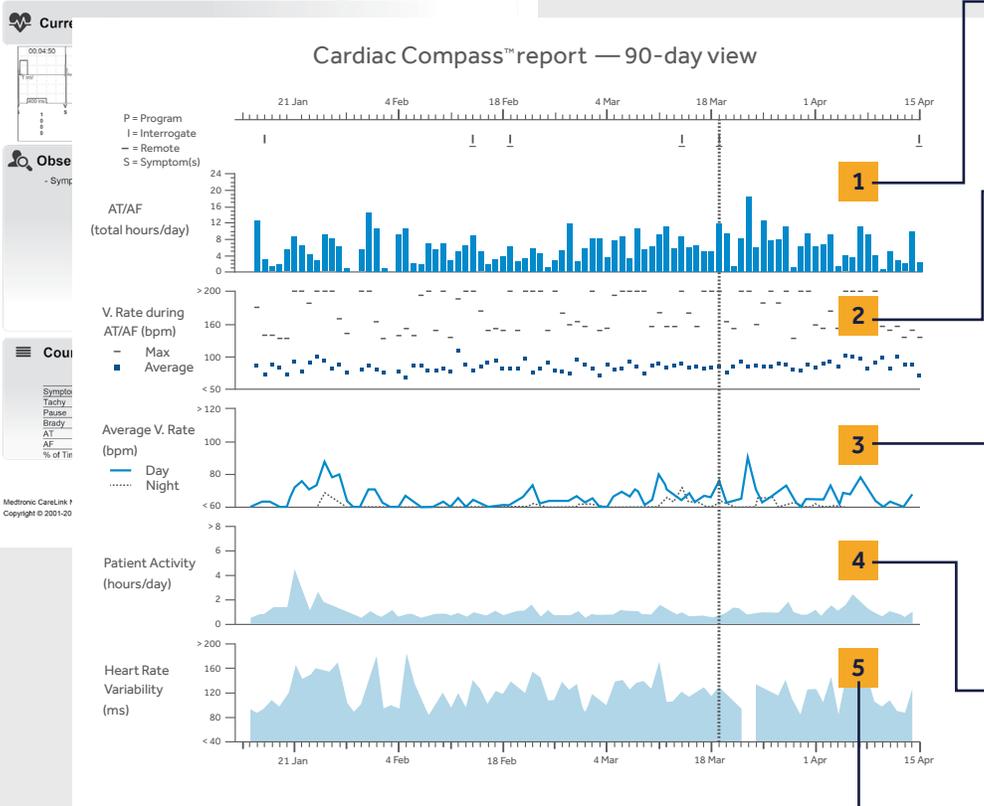
## Full Reports Get the Full Picture

- Generated when patient performs manual transmission
- Detailed reporting of data collected since last manual transmission, including detailed episode data



## Summary Reports with Cardiac Compass Inform Medical Treatment

Customize to be generated for patient diagnostic trends and to match billing cycles.



### AT/AF total time per day

This trend data is based on a count of 2-minute periods when an AT/AF episode is detected or in progress.

### Ventricular rate during AT/AF

The daily average ventricular rate is derived from the number of ventricular beats during AT/AF episodes and the total time in AT/AF for that day.

### Average ventricular rate

The average day and night heart rates are derived from the sum and number of R-R intervals during the periods defined as "day" and "night."

### Patient activity

The sum of patient activity in hours per day.

### Heart rate variability

Median ventricular interval calculated every 5 minutes.

Clinical and patient data are fictitious and for demonstration purposes only.

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No post-insertion wait time or patient positioning restrictions<sup>†</sup>



Actual Size

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<sup>†</sup>Reveal LINQ has demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use. Please see the Reveal LINQ MRI Technical Manual for more details.

### Brief Statement

#### Reveal LINQ™ Insertable Cardiac Monitor, Reveal LINQ™ Mobile Manager System, and Patient Assistant

**Indications:** The Reveal LINQ insertable cardiac monitor (ICM) is an implantable patient-activated and automatically activated monitoring system that records subcutaneous ECG and is indicated in the following cases: ■ Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias ■ Patients who experience transient symptoms such as dizziness, palpitation, syncope, and chest pain, that may suggest a cardiac arrhythmia. The device has not been tested specifically for pediatric use.

**Reveal LINQ Mobile Manager System:** The Reveal LINQ Mobile Manager app is intended for programming and interrogating the Reveal LINQ ICM LNQ11. The Medtronic 24965 patient connector is a portable electronic device using low frequency inductive telemetry to communicate with the Reveal LINQ ICM. The patient connector uses Bluetooth® technology to transmit implantable heart device data to the Reveal LINQ Mobile Manager app for further processing. The patient connector is intended to be used by healthcare personnel only in a clinical or hospital environment.

**Patient Assistant:** The Patient Assistant is intended for unsupervised patient use away from a hospital or clinic. The Patient Assistant activates the data management feature in the Reveal™ insertable cardiac monitor to initiate recording of cardiac event data in the implanted device memory. **Contraindications:** There are no known contraindications for the implant of the Reveal LINQ ICM or for the Reveal LINQ Mobile Manager system. However, the patient's particular medical condition may dictate whether or not a subcutaneous, chronically implanted device can be tolerated.

#### Reveal LINQ™ Insertable Cardiac Monitor

**Warnings/Precautions:** Patients with the Reveal LINQ ICM should avoid sources of diathermy, high sources of radiation, electrosurgical cautery, external defibrillation, lithotripsy, therapeutic ultrasound and radiofrequency ablation to avoid electrical reset of the device, and/or inappropriate sensing as described in the medical procedure and EMI precautions manual. MRI scans should be performed only in a specified MR environment under specified conditions as described in the Reveal LINQ MRI Technical Manual.

#### Reveal LINQ Mobile Manager System

Before inserting the Reveal LINQ ICM, verify that the patient connector and mobile device are fully charged. The patient connector and mobile device may run out of power during the insertion procedure if they are not fully charged. You will not be able to program or interrogate the patient's Reveal LINQ ICM until the patient connector and the mobile device have power. Only use the patient connector to communicate with the intended implanted device. Do not use the patient connector to communicate with other implanted devices. Using the patient connector to communicate with other implanted devices can interfere with those devices, potentially affecting the other implanted device's functionality or therapy delivery. **Use of wireless devices** — The patient connector incorporates radiofrequency (RF) communications components which may affect other devices and equipment in the medical environment. The use of wireless devices in the medical environment must be evaluated and authorized by the responsible organization. RF interference may affect device performance. Electromagnetic Compliance (EMC) testing shows that the patient connector provides reasonable protection against harmful interference and provides EMC immunity in a typical medical installation. The use of wireless devices in the medical environment must be evaluated and authorized by the responsible organization. However, there is no guarantee that interference will not occur in a particular installation. If the patient connector does cause harmful interference to other devices or is negatively impacted by

other devices, correct the interference by one or more of the following measures: reorient or relocate the patient connector and other devices; increase the separation between the patient connector and other devices by at least two meters (approximately 6 feet); and/or turn off any interfering equipment. **Radiofrequency (RF) interference** — Portable and mobile RF communications equipment can interfere with the operation of the patient connector. There is no guarantee that it will not receive interference or that any particular transmission from this system will be free from interference. To avoid interference, do not use the patient connector and mobile device within 2 m (6 feet) of other wireless communications equipment. Using the patient connector near these devices could interfere with communication between the Reveal LINQ ICM and the patient connector.

**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. **Environmental precautions** — To ensure safe and effective operation, use the device with care to avoid damage to the patient connector from environmental factors that may impair its function. Care is exercised in design and manufacturing to minimize damage to devices under normal use. However, electronic devices are susceptible to many environmental stresses. Specifically, the patient connector may be affected by electrostatic discharge (ESD). In an environment likely to cause ESD, such as a carpeted floor, discharge any charge collected on your body before touching the device. **Patient Assistant:** Operation of the Patient Assistant near sources of electromagnetic interference, such as cellular phones, computer monitors, etc., may adversely affect the performance of this device. **Potential Complications:** Potential complications of the Reveal LINQ device include, but are not limited to, device rejection phenomena (including local tissue reaction), device migration, infection, and erosion through the skin.

#### Medtronic MyCareLink™ Patient Monitor, Medtronic CareLink™ Network and CareLink™ Mobile Application

**Intended Use:** The Medtronic MyCareLink patient monitor and CareLink network are indicated for use in the transfer of patient data from some Medtronic implantable cardiac devices based on physician instructions and as described in the product manual. 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. 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. CareLink network availability and mobile device accessibility 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 and subject to coverage availability. Standard text message rates apply. **Contraindications:** There are no known contraindications. **Warnings and Precautions:** The MyCareLink patient monitor must only be used for interrogating compatible Medtronic implantable devices.

See the device manuals for detailed information regarding the implant procedure, indications, 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.

### References

- <sup>1</sup> ICM Size Comparison Guide. Medtronic data on file. 2019.
- <sup>2</sup> ICM Accuracy Comparison Guide. Medtronic data on file. 2019.
- <sup>3</sup> Pürerfellner H, et al. *Europace*. 2018;20:f321-f328.
- <sup>4</sup> Medtronic Reveal™ Publications. Medtronic data on file. 2019.
- <sup>5</sup> Confirm Rx™ ICM DM3500 FDA Clearance Letter. 2017.
- <sup>6</sup> Nölker G, et al. *J Cardiovasc Electrophysiol*. 2016;27:1403-1410.
- <sup>7</sup> Biotronik BioMonitor 2 Technical Manual. 2017.
- <sup>8</sup> Sanna T, et al. *N Engl J Med*. 2014;370:2478-2486.
- <sup>9</sup> Writing Committee Members, et al. *Heart Rhythm*. 2019;16:e227-e279.
- <sup>10</sup> Reiffel JA, et al. *JAMA Cardiol*. 2017;2:1120-1127.
- <sup>11</sup> Furukawa T, et al. *J Cardiovasc Electrophysiol*. 2012;23:67-71.
- <sup>12</sup> Brignole M, *Eur Heart J*. 2018;39:1883-1948.
- <sup>13</sup> Reiffel JA, et al. *Am Heart J*. 2020;219:128-136.
- <sup>14</sup> Edvardsson N, et al. *Europace*. 2011;13:262-269.
- <sup>15</sup> Wechselberger S, et al. *Europace*. 2018;20:f312-f320.
- <sup>16</sup> Verma A, et al. *JAMA Intern Med*. 2013;173:149-156.

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