EXPERIENCE THE REVEAL LINQ™ ADVANTAGE

REVEAL LINQ™ INSERTABLE CARDIAC MONITOR
AN OVERVIEW
# REVEAL™ ICM PRODUCT EVOLUTION

**OVER 20 YEARS OF DEVELOPMENT EXPERIENCE IN ICMS**

<table>
<thead>
<tr>
<th>Year</th>
<th>Model</th>
<th>Features</th>
</tr>
</thead>
</table>
| 1998 | Reveal | - World’s first implantable loop recorder  
- 14-month battery |
| 2000 | Reveal Plus | - World’s second implantable loop recorder  
- 14-month battery  
- MR-conditional |
| 2007 | Reveal DX | - 3-year battery  
- Added to the Medtronic CareLink™ Network  
- MR-conditional |
| 2009 | Reveal XT | - 3-year battery  
- AF detection algorithm  
- Cardiac Compass diagnostics |
| 2011 | Fullview Software | - Improved data viewing and collection  
- Improved noise discrimination algorithm  
- Improved AF detection algorithm |
| 2014 | Reveal LINQ ICM | - World’s smallest insertable cardiac monitor  
- Simplified insertion procedure  
- New AF detection algorithm with increased accuracy  
- Simplified and streamlined reporting and patient management  
- Most studied ICM on the market with 500+ publications¹ |
Indications for use

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 SYSTEM ADVANTAGES
POWERFUL CARDIAC MONITORING

ICMs are underutilized

ICMs are recommended by clinical guidelines\(^2,3\) — yet significantly underutilized

Up to

3 in 4

Patients who met appropriate criteria for ICM implantation did not receive one\(^4\)
REVEAL LINQ SYSTEM ADVANTAGES
AN ADVANCED MONITORING SOLUTION

Solution Enablers

Insertion Tools
Patient Assistant
NEW app-based Reveal LINQ™ Mobile Manager
NEW Monitoring Service Solutions*

*Available in select U.S. markets.
REVEAL LINQ SYSTEM ADVANTAGES
REVOLUTIONIZING CARDIAC MONITORING

The smallest, most powerful insertable cardiac monitor

- One-third the size of a AAA battery (1.2 cc)
- Up to a 3-year longevity for long-term monitoring
- MR Conditional at 1.5 and 3.0 Tesla
- Minimally invasive, simplified insertion procedure
- 96.7% of patients very satisfied or satisfied with Reveal LINQ ICM after insertion
REVEAL LINQ SYSTEM ADVANTAGES
SIMPLE INSERTION PROCEDURE

Best location: 45 degrees to sternum over 4th intercostal space, 2 cm from left edge of sternum

97% Of physicians found the insertion tool simple and intuitive.\(^6\)

Requires minimal procedure time and clinical resources
REVEAL LINQ SYSTEM ADVANTAGES
SMART ECG DATA STORAGE

ECG data storage: 59 minutes total
Patient-activated: up to 30 minutes

Patient Assistant

4 episodes @ 7.5 minutes each
- 6.5 min prior  
  Patient-activated

3 episodes @ 10 minutes each
- 9 min prior  
  Patient-activated

2 episodes @ 15 minutes each
- 14 min prior  
  Patient-activated

Reveal LINQ™ Insertable Cardiac Monitoring System
**REVEAL LINQ SYSTEM ADVANTAGES**

**SMART ECG DATA STORAGE**

**ECG data storage: 59 minutes total**
Automatically detected: 27 minutes

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2 minutes of longest AF episode stored since last interrogation in addition to the 27 minutes of automatically detected episodes.

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Pause, Brady, Tachy

AT/AF

Start of episode

30 sec

27 sec

End of episode

Automatic detection
Transforming your ability to diagnose and treat even the most difficult-to-detect arrhythmias

Evidence superiority.\textsuperscript{1,8-11}
Real-world impact. \textsuperscript{8,12,13}

Proven arrhythmia detection.\textsuperscript{8,14,15}
Informed clinical decisions.

Innovative solutions.
Simplified experience.
REVEAL LINQ SYSTEM ADVANTAGES
PROVEN ARRYTHMIA DETECTION.
INFORMED CLINICAL DECISIONS.

99.4%
Reveal LINQ is proven to find AF
Highest published AF detection accuracy on the market, at 99.4%, streamlines data review

63%
63% fewer false positives than shown in other ICM published data

50+
As the most clinically-validated ICM, with 50+ detection performance papers, Reveal LINQ is the reliable choice for arrhythmia management
PROVEN ACCURACY
DURATION-BASED PERFORMANCE METRICS

Reveal LINQ AF monitoring
Duration-based performance metrics

98.4% SENSITIVITY
99.5% SPECIFICITY
97.2% PPV
99.7% NPV
99.4% ACCURACY

Comparison of AF burden detected by ICM and Holter

r = 0.995
PROVEN ACCURACY
PATIENT AND EPISODE-BASED PERFORMANCE METRICS

Reveal LINQ AF monitoring
Patient- and episode-based performance metrics\(^8\)

<table>
<thead>
<tr>
<th></th>
<th>Patient-based</th>
<th>Episode-based</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>97.4%</td>
<td>97.1%</td>
</tr>
<tr>
<td>Specificity</td>
<td>97.0%</td>
<td></td>
</tr>
<tr>
<td>PPV</td>
<td>92.5%</td>
<td>97.1%</td>
</tr>
<tr>
<td>NPV</td>
<td>99.0%</td>
<td>90.4%</td>
</tr>
<tr>
<td>Accuracy</td>
<td>99.4%</td>
<td></td>
</tr>
</tbody>
</table>
PROVEN ACCURACY
AF FALSE POSITIVE COMPARISON

fewer false positives with Reveal LINQ™ than shown in other ICM published data14

63%

Confirm-AF16
40.9%

BioMonitor 2-AF17
26.3%

Reveal LINQ8
9.6%

False Positive Rate*

50%

25%

0%

*% of False Positives = (1 – Episode PPV). Episode PPV may vary (gross, patient average).
PROVEN ACCURACY
AT/AF SUMMARY REPORT

Provides an overview of all atrial arrhythmias detected, including:

- % of time in AT/AF
- Average time in AT/AF per day
- Number of episodes at a given duration

All patient and clinical data are fictitious and for demonstration purposes only.
All patient and clinical data are fictitious and for demonstration purposes only.
With an evidence portfolio of 500+ published clinical articles and abstracts\(^1\)

Across Cryptogenic Stroke, Syncope, and Atrial Fibrillation patient populations\(^8-10\)

Published in multiple premier journals, including *Heart Rhythm*, *The New England Journal of Medicine* and *JACC* \(^8,9,11\)
Diagnosis of AF in stroke patient changes treatment protocol

- **3 million** patients in the US have AF\(^\text{18}\)
  - AF increases the risk of stroke 5\(\times\).\(^\text{18}\)
  - Treatment with Oral Anti-coagulation (OAC) Therapy reduces the likelihood of experiencing stroke by 67%.\(^\text{19}\)
  - Stroke is the predominant cause of mortality and morbidity in patients with AF.\(^\text{18}\)

### Distribution of Ischemic Strokes

<table>
<thead>
<tr>
<th>Type</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardioembolic</td>
<td>20%</td>
</tr>
<tr>
<td>Cryptogenic Stroke</td>
<td>30%</td>
</tr>
<tr>
<td>Large Vessel</td>
<td>30%</td>
</tr>
<tr>
<td>Small Vessel</td>
<td>15%</td>
</tr>
<tr>
<td>Other</td>
<td>5%</td>
</tr>
</tbody>
</table>

1/3 of Ischemic Strokes are Cryptogenic\(^\text{20}\)

61% of patients who had both AF and a stroke did not know they had AF prior to their stroke\(^\text{18}\)
Clinical impact of Reveal ICM in stroke
Detection of AF allows for treatment with OAC therapy

Landmark Crystal-AF Study, published in the *NEJM*[^9]

[^9]: More patients with AF detected at 12 months with Reveal ICM[^9]

Median number of days to AF detection over 12 months[^9]

Percent of patients prescribed OAC once AF was detected[^9]
Real-world practice with Reveal LINQ ICM
Superiority of Reveal LINQ system to detect AF in Cryptogenic Stroke patients

Real-world practice validates superiority of the Reveal LINQ System to detect AF in cryptogenic stroke (CS) patients

Everyday use of Reveal LINQ confirms findings in landmark CRYSTAL AF study (NEJM, 2014), and emphasizes need for long-term monitoring in CS patients

72% of AF patients would be missed if monitoring ends at 30 days
## CLINICAL RIGOR

### SYNCOPE

40% of the population will experience syncope\(^{21}\)
Cardiac syncope doubles the risk of death

<table>
<thead>
<tr>
<th>MORTALITY</th>
<th>MAGNITUDE</th>
<th>UNDIAGNOSED</th>
<th>FRUSTRATION</th>
</tr>
</thead>
</table>
| Cardiac condition doubles the risk of death and increases the 6-month mortality rate by 10%\(^{22}\) | - 3-5% of all ER visits\(^{23}\)  
- 1-3% of all hospitalizations\(^{23}\) | 50% of all patients leave the hospital without a diagnosis\(^{24}\) | - 13 different tests during diagnosis period\(^{10}\)  
- Syncope patient visits 3 specialists on average\(^{10}\) |
Limited yield of many diagnostic tests
Diagnostic yield of non implantable diagnostic tests is less than 50%

*Based on mean diagnosis time of 5.1 mos.
Guidelines for the diagnosis and management of syncope (version 2009)

The Task Force for the Diagnosis and Management of Syncope of the European Society of Cardiology (ESC)

Developed in collaboration with European Heart Rhythm Association (EHRA), Heart Failure Association (HFA), and Heart Rhythm Society (HRS)

Monitoring Choice by Frequency of Symptoms

<table>
<thead>
<tr>
<th>Frequency of symptoms</th>
<th>Suggested ECG monitoring technique</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daily</td>
<td>24 h Holter, in-hospital telemetric monitoring</td>
</tr>
<tr>
<td>Every 2-3 days</td>
<td>48-72 h Holter, in-hospital telemetric monitoring</td>
</tr>
<tr>
<td>Every week</td>
<td>7 days Holter or external loop recorder</td>
</tr>
<tr>
<td>Every month</td>
<td>14-30 days external loop recorder</td>
</tr>
<tr>
<td>Less than once per month</td>
<td>Implantable loop recorder</td>
</tr>
</tbody>
</table>

Monitoring Choice by Patient Risk

- TLOC—suspected syncope
- TLOC—non-syncopal

Initial evaluation
- Syncope
- Uncertain diagnosis
- Risk stratification*

Certain diagnosis
- High risk**
- Early evaluation and treatment
- Delayed treatment guided by ECG documentation
- Cardiac or neurally-mediated tests as appropriate
- No further evaluation
- TLOC—confirmed syncope

Low risk, recurrent Syncope
- ILR
- Confirm with specific test or specialist's consultancy

Low risk, single or rare
- Confirm with specific test or specialist's consultancy

Reveal LINQ™ Insertable Cardiac Monitoring System

Medtronic
Suspected AF Monitoring
Continuous monitoring can reveal AF

- Symptoms are not a good indicator for presence of AF\cite{30-34}
- Continuous monitoring with ICMs can identify AF in patients at high risk\cite{35, 36}

<table>
<thead>
<tr>
<th>Study</th>
<th>Method of Monitoring</th>
<th>% Asymptomatic AF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Page et al. 1994\cite{30}</td>
<td>External monitors: 1 day/week (5×)</td>
<td>92.3% of episodes</td>
</tr>
<tr>
<td>Strickberger et al. 2005\cite{31}</td>
<td>Implantable Pacemakers</td>
<td>94% of episodes</td>
</tr>
<tr>
<td>Quirino et al. 2009\cite{32}</td>
<td>Implantable Pacemakers</td>
<td>81% of episodes</td>
</tr>
<tr>
<td>Orlov et al. 2007\cite{33}</td>
<td>Implantable Pacemakers</td>
<td>94.7% of episodes</td>
</tr>
<tr>
<td>Verma et al. 2013\cite{34}</td>
<td>Implantable Loop Recorders</td>
<td>79% of episodes</td>
</tr>
</tbody>
</table>

22% of a patient population at high risk was found to have > 6min of AF within 12 months\cite{36}
AF MANAGEMENT
Optimize decisions pre- and post-ablation

PRE
- Document Baseline AF burden.
  - Provide objective data for follow-up comparisons.
  - Data to optimize pre/post management + re-ablation
- Case Planning
  - PVI when Paroxysmal AF is documented?
  - PVI + additional lines if substrate ablation is needed
- Work Flow Planning
  - Minimize days with difficult back-to-back cases.
  - Triage patients on your waiting list.

POST
- Monitor patients for up to 3 years.
- Optimize medical therapy.
  - Discontinue OAC?
- Re-ablate to disrupt substrate conduction with additional lines.

REVEAL ICM
Reliably identifies AF and confirms the absence of AF.\textsuperscript{37,38}
Features proven AF detection algorithm and published evidence that provides information to make informed decisions.
Proven AF algorithm accurately detects AF 99.4% of the time.\textsuperscript{8}
ADVANCED MONITORING
INNOVATIVE SOLUTIONS.
SIMPLIFIED EXPERIENCE.

STREAMLINED INSERTION WORK FLOW

Simple, minimally invasive outpatient insertion procedure

New app-based device management with the Reveal LINQ Mobile Manager

ACTIONABLE REPORTS

- Supported by an enhanced Medtronic CareLink Network
- Industry’s highest diagnostic yields, with actionable reports\textsuperscript{10,39-41}

SIMPLIFIED PATIENT MANAGEMENT

Resources to support clinic efficiency and data review

- New Medtronic Academy Learning Plan
- New Patient Education Resources
- New Reveal LINQ\textsuperscript{SM} Monitoring Service*

*Available in select U.S. markets.
Simplify device management with the NEW Reveal LINQ Mobile Manager, an innovative app-based programming system.

IT’S EASY TO GET STARTED

The Reveal LINQ Mobile Manager can only be used with the Reveal LINQ ICM and the Medtronic patient connector, available from Medtronic.
ADVANCED MONITORING
CLINICALLY ACTIONABLE REPORTS

Easy-to-use, clinically actionable reports
The information you need when you need it, supported by an enhanced CareLink Network

Comprehensive
- Get the full picture with diagnostic trends on simplified reports.

Customizable
- Optional CareAlert™ notifications with auto-generated reports

The Medtronic MyCareLink Patient Monitor and the Medtronic CareLink Network are indicated for use in the transfer of patient data from Medtronic implantable cardiac devices. These products are not a substitute for appropriate medical attention in the event of an emergency. Data availability and alert notifications are subject to Internet connectivity and access, and service availability. The MyCareLink Patient Monitor must be on and in range of the device. Alert notifications are not intended to be used as the sole basis for making decisions about patient medical care.

95% of physicians found the Reveal LINQ reports easy to use and clinically actionable

96.7% of patients say it is very easy to use the MyCareLink Patient Monitor to transmit data to the CareLink Network
ADVANCED MONITORING
CLINICALLY ACTIONABLE REPORTS

Easy-to-use, clinically actionable reports
The information you need when you need it

Event Report
Data may help in timely management of patients.

Summary Report
Data may help in routine management of patients.

Full Report
Manual transmission from patient when you need to know more.

Completely OPTIONAL
✓ Event Reports create work for your clinics.
✓ Reserve only for most critical information.
ADVANCED MONITORING
NEW CLINICIAN LEARNING PLAN

New clinician learning plan on Medtronic Academy
Supports streamlined Reveal LINQ patient management

- **Tailored** to meet your needs for easier data and patient management. Integrates best practices from 100+ clinicians nationwide.

  - Master Use of Reports.
  - Optimize Alert and Data Collection.
  - Standardize Work Flows.
  - Maximize Patient Engagement.

Access learning plan at: MedtronicAcademy.com/LINQMonitoring

Course completion provides up to 6 CEU hours.*

*Provider approved by the California Board of Registered Nursing. Provider Number 13145, for 1 contact hour per course.
New patient education system
Helps ensure patients get the right information at the right time

We revamped the materials we offer to educate patients, in order to make the flow of information more helpful and clear.
ADVANCED MONITORING
NEW REVEAL LINQ MONITORING SERVICE

The Reveal LINQ Monitoring Service*
A virtual extension of your clinical team, helping you streamline patient management and cardiac data review.

Optimize Your Time

Data is transmitted and then analyzed by certified technicians at the Medtronic Monitoring Center. Only the most clinically-relevant, actionable information is sent to the clinician.

Extra support to feel assured patients are transmitting regular automatic and manual transmissions as needed.

*Available in select markets. Connect with your Diagnostics Representative to learn more about the service.
Debbie’s story
Reveal ICM used to discover a rare form of AT

After Debbie fainted the first time, she didn't think much about it. As a cardiac nurse, she knew there were many reasons people faint. But the fainting continued, and within a couple of months she was passing out three times a day. Her cardiologist decided to give Debbie a Medtronic Reveal Insertable Cardiac Monitor (ICM).

Based on the information from the Reveal ICM, her doctors determined Debbie had a rare, aggressive form of atrial tachycardia (AT) that was very resistant to treatment. She tried new medications. Debbie’s doctors also relied on the Reveal ICM to monitor how her heart responds to the therapy.

With her fainting under better control, Debbie got back to practicing ballet.

She encourages people who experience fainting episodes to make a doctor appointment right away.
Scott’s story
Reveal ICM used to discover AF in 22-year-old stroke patient

On his way to a soccer game, 22-year-old Scott suddenly began wobbling. His head started throbbing. What he thought was dehydration turned out to be much worse. The college student had suffered a stroke. Surgeons removed a blood clot in his brain, but a looming question remained: What caused the stroke in this seemingly healthy young man?

Scott’s doctors suspected it was the result of atrial fibrillation (AF). So Scott’s doctors turned to the Reveal LINQ ICM, which, within a few months, confirmed he had AF.

The diagnosis not only gave Scott’s doctors the information they needed to prescribe stroke-preventive blood thinners; it gave Scott the peace of mind to live life fully again.

Actual patient photo. This story reflects one person’s experience. Not every person will receive the same results.
Debbie’s story
Reveal ICM finds AF and Guides EP
Treatment Plan

When Debbie started experiencing an uncomfortable heart fluttering, she tried to ignore it. When the episodes became more frequent, she could no longer deny something was wrong. That’s when she made an appointment with a cardiologist.

Debbie’s doctor suggested an insertable cardiac monitor to determine the cause of her episodes. The Reveal ICM discovered that the upper chambers of Debbie’s heart were beating very fast and irregularly.

She was referred to an EP, who used the Reveal ICM data to guide the development of a treatment plan.

Eventually, Debbie regained her old energy and enthusiasm. “I was so excited that it captured an abnormal heart rhythm. It wasn’t in my head after all,” Debbie said.
ECONOMIC VALUE
ICM OVERVIEW

- Reduce healthcare utilization through prevention of a second stroke

- Effectively diagnose cardiac arrhythmias in Syncope patients, leading to treatment

- Positive procedural and downstream economics with flexibility of procedure location
MORE AF DETECTED at 12 months with Reveal™ ICM in cryptogenic stroke patients

OAC therapy SIGNIFICANTLY REDUCES the risk of stroke

ANNUAL COST of stroke-related care is $64,629
Clinical impact of Reveal ICM in syncope patients

13
Median number of inconclusive tests before ICM was implanted\textsuperscript{10}

78%
Patients that receive a diagnosis following a syncopal event with Reveal™ ICM \textsuperscript{10}

75%
of Reveal-guided diagnoses were found to be cardiac related\textsuperscript{10}

25%
Reveal ICM patients that receive device therapy within 36 months\textsuperscript{44}

Accurately Diagnose

Effectively Treat
ECONOMIC VALUE
REVEAL LINQ ICM AND THE CARE CONTINUUM

Long-term benefits of Reveal LINQ ICM
Accurate diagnosis and defined care continuum

PATIENT CARE CONTINUUM

NO ICM IMPLANTED
- Care continuum is variable or unknown
- Further diagnostic testing, with mixed results
- Increased costs and inefficient use of resources
- Potential loss of patient to follow-up
- A ‘revolving door’ experience for patients

ICM IMPLANTED
- Accurate diagnosis of cardiac arrhythmia
- Timely and informed treatment decisions
- Potential long-term patient care within hospital system
- Broad benefits from remote monitoring with MyCareLink™ Patient Monitor
- Identify indicated patients with treatment needs

VS.
## Opportunity for procedural efficiencies with Reveal LINQ ICM

### Cath Lab vs. Procedure Room Costs
- Reduced overhead and less expensive equipment outside of the cath lab\(^45\)

### Patient Recovery Location
- Choice of implant location may require alternate patient recovery location\(^45\)

### Staffing Requirements
- Location of procedure may allow for flexibility in required staff\(^45\)

### On average, savings ranged from $0 – $681 per implant by moving procedure location\(^45\)
REFERENCES

5. Reference the Reveal LINQ ICM Clinician Manual for usage parameters.
REFERENCES


**Brief Statement**

Medtronic MyCareLink™ Patient Monitor, CareLink™ Network, CareLink™ Mobile Application, Reveal LINQ™ Insertable Cardiac Monitor, Patient Assistant, and Reveal LINQ™ Mobile Manager

The Medtronic MyCareLink Patient Monitor and the Medtronic CareLink Network are indicated for use in the transfer of patient data from Medtronic implantable cardiac devices. These products are not a substitute for appropriate medical attention in the event of an emergency. Data availability and alert notifications are subject to Internet connectivity and access, and service availability. The MyCareLink Patient Monitor must be on and in range of the device. Alert notifications are not intended to be used as the sole basis for making decisions about patient medical care.

**Brief Statement**

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

**Indications: The Reveal LINQ Insertable Cardiac Monitor (ICM)**

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.

**Warnings/Precautions**

**Reveal LINQ Insertable Cardiac Monitor**

Patients with the Reveal LINQ ICM should avoid sources of diathermy, high sources of radiation, electrosurgical cautery, external defibrillation, lithotripsy, therapeutic ultrasound, and radio frequency 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 radio frequency (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.
**BRIEF STATEMENT**

**MEDTRONIC MYCARELINK™ PATIENT MONITOR, CARELINK™ NETWORK, CARELINK™ MOBILE APPLICATION, REVEAL LINQ™ INSERTABLE CARDIAC MONITOR, PATIENT ASSISTANT, AND REVEAL LINQ™ MOBILE MANAGER, CONT’D.**

**Radio frequency (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.
BRIEF STATEMENT
MEDTRONIC MYCARELINK™ PATIENT MONITOR, CARELINK™ NETWORK, CARELINK™ MOBILE APPLICATION, REVEAL LINQ™ INSERTABLE CARDIAC MONITOR, PATIENT ASSISTANT, AND REVEAL LINQ™ MOBILE MANAGER, CONT’D.

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 www.medtronic.com.

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