### Device Characteristics

**Size and Mass**
- **Volume:** 1.2 cm³
- **Dimensions:** 44.8 mm x 7.2 mm x 4.0 mm
- **Mass:** 2.5 g ± 0.5
- **Distance between electrodes:** 37.7 mm

**Compatibility and Identification**
- **MR Compatibility:** MR Conditional
- **Radiopaque ID:** “M” shape identifier on the header

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**Battery**
- **Chemistry:** Lithium carbon monofluoride
- **Projected Longevity:**
  - **Sensing:** 3 Years
  - **Programmable:**
    - Brady detection
      - Parameter: Brady Detection
        - Programmable values: On; Off
      - Parameter: Brady Interval (Rate)
        - Programmable values: 1,000; 1,200; 1,500; 2,000 ms (± 10 ms)
      - Parameter: Brady Duration
        - Programmable values: 4; 8; 12 beats
    - Tachy detection
      - Parameter: Tachy Detection
        - Programmable values: On; Off
      - Parameter: Tachy Detection Interval (Rate)
        - Programmable values: 270; 280; … 340; … 520 ms (± 10 ms)
      - Parameter: Tachy Duration
        - Programmable values: 5; 12; 16; 24; 32; 48 beats
    - Symptomatic Episode Duration
      - Parameter: Symptomatic Episode Duration
        - Programmable values: Four 7.5 min episodes; three 10 min episodes; two 15 min episodes
    - Reason for Monitoring
      - Programmable values: Syncope; Palpitations; Seizures; Ventricular Tachycardia; Suspected AF; AF Ablation; AF Management; Stroke; Other
    - Device Date/Time...
      - Externally entered: 00:00; 01:00; 02:00 … 11:00; 12:00; 13:00 … 23:00
    - Wireless Data Priority
      - Programmable values: Brady, Tachy, Pause; Brady Pause, Tachy; Tachy, Brady Pause; Tachy, Pause, Brady, Pause, Brady; Pause, Brady, Tachy
  - **Programmable:**
    - **Device Data Collection:**
      - On
      - After being turned on, Device Data Collection cannot be turned off.

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**Sensing**
- **Sampling Rate:** 256 Hz
- **Sampling Resolution:** 16 bits/sample
- **Bandwidth:** 0.5 – 95 Hz

### Programmable Parameters

**R-wave sensing**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Programmable values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>0.025; 0.035; 0.05; 0.075; 0.1 … 0.2 mV ± 20% of the programmed value + 0.005 mV</td>
</tr>
<tr>
<td>Sensing Threshold Decay Delay</td>
<td>130; 150; 200; 300; 400; 500 ms (±10 ms)</td>
</tr>
<tr>
<td>Blank after Sense</td>
<td>130; 150; 170; 200; 250; 300; 400 ms (±10 ms)</td>
</tr>
</tbody>
</table>

**Pause detection**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Programmable values</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Asystole) Detection</td>
<td>On; Off</td>
</tr>
<tr>
<td>(Asystole) Duration</td>
<td>1.5; 3.0; 4.5 s (± 10 ms)</td>
</tr>
</tbody>
</table>

**AT/AF detection**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Programmable values</th>
</tr>
</thead>
<tbody>
<tr>
<td>AT/AF Detection</td>
<td>On; AT/AF; On - AF only; Off</td>
</tr>
<tr>
<td>AF Detection Sensitivity</td>
<td>Least Sensitive; Less Sensitive; Balanced Sensitive; More Sensitive</td>
</tr>
<tr>
<td>Ectopy Rejection</td>
<td>Off; Nominal; Aggressive</td>
</tr>
<tr>
<td>AT/AF Recording Threshold</td>
<td>All episodes: ≥ 6 min; ≥ 10 min; ≥ 20 min; ≥ 30 min; ≥ 60 min; Only longest episode</td>
</tr>
<tr>
<td>Detect Very Regular AT Rhythms</td>
<td>Off; On - Rates ≥ 67 bpm; On - Rates ≥ 100 bpm; On - All Rates</td>
</tr>
</tbody>
</table>

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*Under the following usage scenarios:
- Average of 1 auto-detected episode per day
- Average of 1 patient-activated episode per month
- Less than or equal to 6 months shelf life (between device manufacture and insertion).

Note: Under maximum shelf storage time (12 months), longevity is reduced by approximately 3 months.

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*The Reveal LINQ™ insertable cardiac monitor (ICM) has been demonstrated to pose no known hazards in a specified MR environment with the conditions of use specified in the Reveal LINQ™ ICM Clinical Manual. Please see the Reveal LINQ™ ICM Clinical Manual for additional details.

*Reason for Monitoring is used to set arrhythmia detection parameters to pending automatically.
*Tachy Detection based on 230 – Date of Birth.
*The times and dates stored in episode records and other data are determined by the Device Date/Time clock.
*Wireless Transmission Time programming is based on the Device Date/Time clock.
*Turning on Device Data Collection enables sensing and data collection (all episode types). After being turned on, Device Data Collection cannot be turned off.

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Reveal LINQ™ Insertable Cardiac Monitoring System

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Medtronic
Patient Assistant Model PA96000

1. **Record Symptom Button**
   Pressed by patient to record ECG when symptomatic

2. **Searching Light**
   Flashes blue indicating the patient should hold the Patient Assistant over the Reveal LINQ™ ICM

3. **Success Light**
   Illuminates green when the symptom is successfully marked

4. **Connection Slot**
   Allows patient to attach the Patient Assistant to a key chain, lanyard, or other personal item

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**Reveal LINQ™ ECG Data Storage**

Up to 30 minutes of patient-activated episodes

- Four episodes at 7.5 minutes each ................. 6.5 min
- Three episodes at 10 minutes each ............. 9 min
- Two episodes at 15 minutes each .......... 14 min

27 minutes of automatically detected episodes

Episode types: Pause, Brady, Tachy

Atrial episodes: AT/AF

Two minutes (included in the 27 minutes of automatically detected episodes) of ECG data recorded before detection

Two minutes of longest AF episode stored since last interrogation in addition to the 27 minutes of automatically detected episodes
Rate Histogram

The Rate Histogram report is based on a continuous recording of ventricular rates since the last patient session. The Rate Histogram report presents heart rate data in 2 types of histograms:

- Ventricular rate
- Ventricular rate during AT/AF

The report includes data from the current (since last session) collection period.

AT/AF Summary

AT/AF Summary report provides an overview of all atrial arrhythmias detected, including percentage of time in AT/AF, average time in AT/AF per day, and number of episodes at a given duration.

Cardiac Compass™ Trends

Cardiac Compass™ report provides trending data, which includes daily AT/AF burden, V. rate during AT/AF, average day and night V. rate, daily activity, and heart rate variability.

All patient and clinical data are fictitious and for demonstration purposes only.
**Reveal LINQ™ LNQ11 Insertable Cardiac Monitor and Patient Assistant**

**Indications: Reveal LINQ™ LNQ11 Insertable Cardiac Monitor**
The Reveal LINQ™ insertable cardiac monitor 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

This device has not been specifically tested for pediatric use.

**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™ insertable cardiac monitor. However, the patient’s particular medical condition may dictate whether or not a subcutaneous, chronically implanted device can be tolerated.

**Warnings/Precautions:**

**Reveal LINQ™ LNQ11 Insertable Cardiac Monitor**
Patients with the Reveal LINQ™ insertable cardiac monitor 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.

**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 include, but are not limited to, device rejection phenomena (including local tissue reaction), device migration, infection, and erosion through the skin.

See the device manual 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.

**Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician.