CONFIRM Rx™ ICM
with SharpSense™ Technology

CAPTURING THE RHYTHM OF LIFE
DIAGNOSIS IS EMPOWERING.

SharpSense™ Technology delivers the necessary information you need to clearly and confidently diagnose arrhythmias.

DOUBT IS DEBILITATING.

Confirm Rx™ Insertable Cardiac Monitor (ICM) identifies difficult to detect arrhythmias, including atrial fibrillation (AF).

REMOTE MONITORING HAS NEVER BEEN SO ENGAGING.

Remote monitoring via smartphone connectivity with an easy-to-use app encourages patient compliance.

DELIVER CONVENIENTLY
Remote monitoring via smartphone connectivity with an easy-to-use app encourages patient compliance.

DETECT ACCURATELY
New SharpSense™ Technology significantly reduces false detection of AF, Bradycardia and Pause episodes.

DECIDE CONFIDENTLY
Deeper patient insights can guide a better diagnosis. Decide confidently on the best course of action with Confirm Rx™ ICM.
DELIVER CONVENIENTLY

Confirm Rx™ ICM uses smartphone connectivity and the easy-to-use myMerlin™ for Confirm Rx™ mobile app to remotely monitor patients.

SMARTER CONNECTIVITY

No home-based transmitter or patient activator necessary.

STREAMLINED INTERACTION

From procedure to follow-up, Confirm Rx™ ICM is easy to manage. Enrollment and transfer to a follow-up clinic is simple for procedure staff. Clinicians can then customize alerts with our easy-to-use interface.

MERLIN.NET™ PATIENT CARE NETWORK

The myMerlin™ for Confirm Rx™ mobile app engages patients, because they can:

- Better describe their symptoms with keywords, e.g., fainting, fluttering, to provide you additional insight for a confident diagnosis.
- Send symptom transmissions to the clinic without the need to wait for a nightly sync with a traditional transmitter, when appropriate.
- View transmissions and symptom history without having to contact the clinic to confirm successful data transfers.
- Receive automatic notifications when they miss device checks or scheduled transmissions.
- Better describe their symptoms with keywords, e.g., fainting, fluttering, to provide you additional insight for a confident diagnosis.
- Send symptom transmissions to the clinic without the need to wait for a nightly sync with a traditional transmitter, when appropriate.
- View transmissions and symptom history without having to contact the clinic to confirm successful data transfers.
- Receive automatic notifications when they miss device checks or scheduled transmissions.

ENCOURAGES COMPLIANCE

97% of registered myMerlin™ mobile app users transmitted at least once.

1.6 DAYS average time between transmissions.
DETECT ACCURATELY

Accurate information helps with decision-making. Confirm Rx™ ICM with SharpSense™ Technology significantly refines AF, Bradycardia and Pause detection to supply you with actionable information that supports your diagnosis.

IMPROVED VISUALIZATION

Scatterplots allow better visualization of AF, Bradycardia and Pause episodes.

97% REDUCTION IN FALSE DETECTION*

More discerning—better sensing. SharpSense™ Technology harnesses the power of extra discriminators to improve accuracy. False detection of potential events is now reduced by 97%.

AF

- Actively reviews the previous 30 seconds for P-wave detection to discern an AF episode.
- AF RHYTHM RELATIVE SENSITIVITY
  - AF 97.2%

BRADYCARDIA

- Dynamically evaluates multiple R-waves and P-waves to create customized thresholds to detect true Bradycardia episodes.
- BRADYCARDIA RHYTHM RELATIVE SENSITIVITY
  - BRADYCARDIA 98.6%

PAUSE

- Analyzes P-wave and R-wave characteristics during the previous 6 seconds, based on customized secondary thresholds, to detect true Pause episodes.
- PAUSE RHYTHM RELATIVE SENSITIVITY
  - PAUSE 98.1%

* Determined by evaluation of real-world episodes in previously identified devices, using SharpSense™ Technology.
DECIDE CONFIDENTLY

When you see the big picture, people live fuller lives. Decide confidently with Confirm Rx™ ICM with SharpSense™ Technology.


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RX ONLY

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Indications: The Confirm Rx™ ICM is indicated for the monitoring and diagnostic evaluation of patients who experience unexplained symptoms such as: dizziness, palpitations, chest pain, syncope, and shortness of breath, as well as patients who are at risk for other cardiac arrhythmias. It is also indicated for patients who have been previously diagnosed with atrial fibrillation or who are susceptible to developing atrial fibrillation. The Confirm Rx ICM has not been specifically tested for pediatric use.

Contraindications: There are no known contraindications for the implantation of the Confirm Rx™ ICM. However, the patient’s particular medical condition may dictate whether or not a subcutaneous, chronically implanted device can be tolerated.

Adverse Events: Possible adverse events (in alphabetical order) associated with the device, include the following: Allergic reaction, Bleeding, Chronic nerve damage, Erosion, Excessive fibrotic tissue growth, Extrusion, Formation of hematomas or cysts, Infection, Keloid formation and Migration. Refer to the User’s Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

Precautions: Clinicians must log onto Merlin.net™ Patient Care Network to view transmissions from patients' Confirm Rx™ ICM. On Merlin.net™ ICM they can configure transmission schedule and enable or disable features on patient's myMerlin™ mobile app. Review of transmissions is dependent on the clinician and may not happen immediately following delivery of such transmissions.

Limitations: Patients may use their own or Android™ or Apple™ mobile digital device to transmit information from their Confirm Rx™ ICM using the myMerlin™ mobile app. To do so the device must be powered on, app must be installed, Bluetooth® wireless technology connection enabled and data coverage (cellular or Wi-Fi™) available. The myMerlin™ app provides periodic patient monitoring based on clinician configured settings. Transmission data is resent if not sent successfully. However there are many internal and external factors that can hinder, delay, or prevent acquisition and delivery of ICM and patient information as intended by the clinician. These factors include: patient environment, data services, mobile device operating system and settings, ICM memory capacity, clinic environment, schedule/configuration changes or data processing.

An Abbott mobile transmitter is available for patients without their own compatible mobile device.

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