

CONFIRM Rx™ ICM
with SharpSense™ Technology



EXPERIENCE THE
LATEST EVOLUTION
IN ICM





EXPERIENCE ADVANCED DETECTION ACCURACY

EXPERIENCE ENHANCED PATIENT COMPLIANCE

EXPERIENCE SIMPLIFIED DATA MANAGEMENT

EXPERIENCE A FASTER TIME TO DIAGNOSIS



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

With a suite of solutions, Confirm Rx™ ICM improves accuracy in arrhythmia detection, encourages patient compliance and simplifies remote patient management for a faster time to diagnosis.¹⁻³

EXPERIENCE ADVANCED **DETECTION ACCURACY**

Capture arrhythmia episodes correctly by significantly reducing false detections.



97%

REDUCTION IN FALSE DETECTION²

SharpSense™ technology harnesses the power of extra discriminators to confirm or reject detections—improving accuracy.

AF

Actively reviews the previous 30 seconds for the presence of P-waves to discern an AF episode.

RELATIVE SENSITIVITY

97.2%⁴

BRADYCARDIA

Dynamically evaluates multiple R-waves and P-waves to create customized thresholds to detect true Bradycardia episodes.

RELATIVE SENSITIVITY

98.6%⁴

PAUSE

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

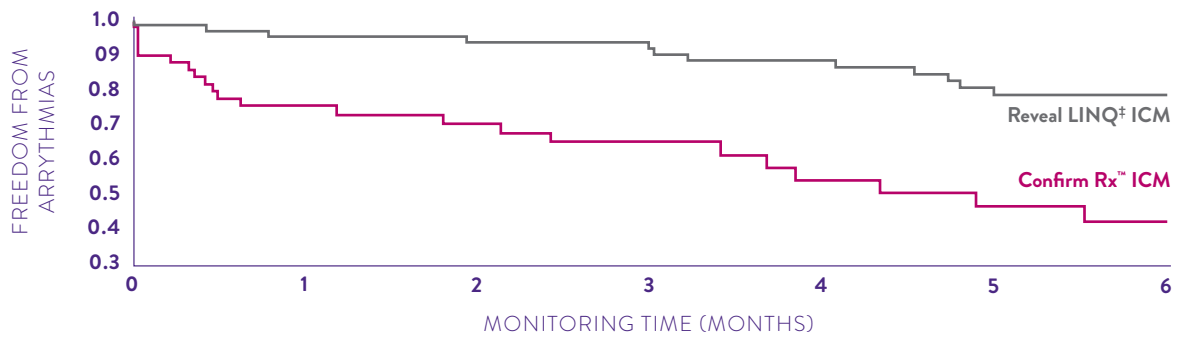
RELATIVE SENSITIVITY

98.1%⁴

CONFIRM Rx™ ICM IS THE ONLY ICM AVAILABLE WITH AN AF INDICATION.

Kaplan-Meier: Confirm Rx™ ICM vs. Reveal LINQ[‡] ICM

P=0.006



At Risk	0	1	2	3	4	5	6
Confirm Rx:	49	35	27	19	15	13	9
Reveal LINQ:	63	60	57	52	47	40	38

KAPLAN-MEIER ANALYSIS SHOWED THAT THE **CONFIRM Rx DEVICE DETECTED SIGNIFICANTLY MORE TRUE ARRHYTHMIC EPISODES IN MORE PATIENTS—AND DID SO SOONER.¹**

EXPERIENCE ENHANCED PATIENT COMPLIANCE

The myMerlin™ mobile app keeps patients connected to encourage compliance.

MARKET-DEFINING CONNECTIVITY

No home-based transmitter or patient activator needed.
The patient simply uses a smartphone.



Data transmission for arrhythmic events with Confirm Rx™ ICM is **significantly faster** than the Reveal LINQ⁺ ICM, specifically the patient-activated symptom events.¹

Confirm Rx™ ICM data transmission is approximately

20x

FASTER than
Reveal LINQ⁺ ICM¹

Mean time to data transmission is significantly faster with Confirm Rx™ ICM¹

ABBOTT
CONFIRM Rx™ ICM

24 ± 103 min.

MEDTRONIC
REVEAL LINQ⁺ ICM

475 ± 426 min.

P-value (P<0.0001)

97%

OF PATIENTS WERE COMPLIANT with myMerlin™ mobile app.³

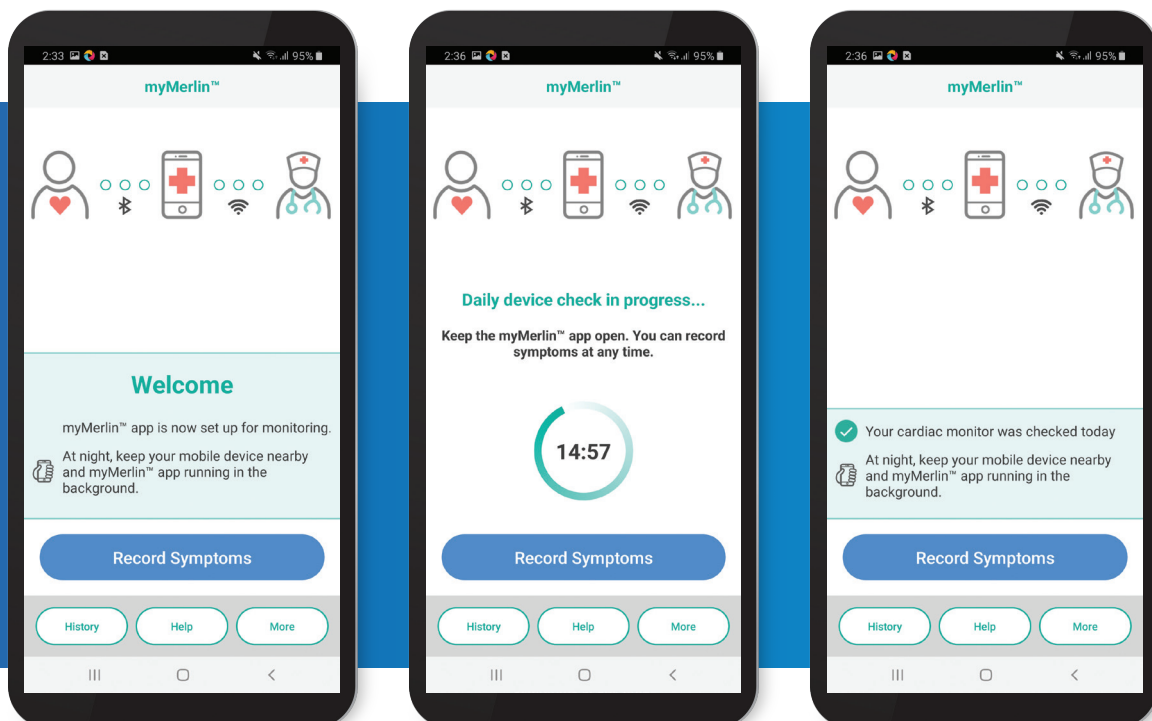
NEXT-GENERATION APP ENHANCEMENTS

Improved compatibility with iOS⁺ and Android⁺ operating systems for enhanced connectivity that keeps patients connected to your care:

- Active scanning for consistent engagement between Merlin.net™ patient care network (PCN) and myMerlin mobile app.
- Improved pairing divided into three discrete processes to accommodate variable internet connection or pauses in connectivity.

Your patients can enjoy peace of mind with automatic daily checks. The myMerlin app lets patients know that information from their device is being sent to their clinic daily.

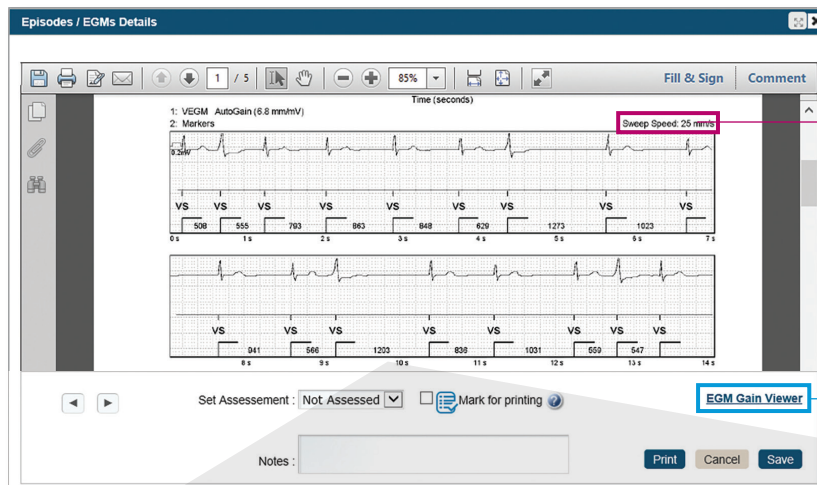
The intuitive interface engages patients with the familiarity of their smartphone.



EXPERIENCE SIMPLIFIED DATA MANAGEMENT

Make fast sense of the rich data flow Confirm Rx™ ICM provides with greater P-wave visibility, customized reporting and more robust data management tools.

GREATER P-WAVE VISIBILITY



Presenting rhythm sweep speed is standardized to 25 mm/s.

Gain up to clearly see P-waves in the EGMs to verify your diagnosis.



Use the digital caliper to measure and identify arrhythmic behavior.

EXPERIENCE SIMPLIFIED DATA MANAGEMENT

CUSTOMIZED REPORTING FOR DIAGNOSTIC REVIEWS AND TIMELY BILLING

Customize the report timeframe based on your need.

Clinical summary for easier diagnostic review of rhythm trends or episodes.

Quickly identify patients who are ready for billing, based on your clinic thresholds, to easily generate a customized summary report for simplified billing.

Abbott Merlin.net™ Patient Care Network

Signed in as *s 4492_id_vv1* Help Switch to Sign Out

Recent Transmissions Patient List Tools Clinic Administration

Patient profile Transmission All Transmissions Patient Summary Clinical Comments

Smith Joseph Patient ID: Station8
Confirm Rx™ ICM, DM3500
Patient List > Patient Summary

Patient Summary Report

From: 09-08-2020 To: 10-09-2020 Date Range: 31 days

Transmission summary

Episodes count	This report period	Since enrolled in Merlin.net	Remote Transmissions
AT/AF	101	250	Scheduled: 12
Tachy	8	40	Patient initiated: 8
Brady	0	32	Alert initiated: 0
Pause	0	51	
Symptom	0	5	
Symptom (with Detection)	8	37	

Note: Calculations are based on the episodes that were sent to Merlin.net. It does not include episodes marked as "Inappropriate".

AF Burden (12 months)

From: 10-10-2019 To: 10-09-2020

Note: Transmissions more than a 120 days apart will result in a gap in the trend.

Mark as Billed on: 10-04-2020

Last Billed: 10-04-2020 Next Billed: 11-04-2020

Next Transmission: 10-12-2020

Patient's schedule can be changed by selecting the [Schedule](#) link.

Note: The next transmission is before the next billable date or has not been scheduled.

Cancel Save

EXPERIENCE THE **POWER OF FASTER**

Confirm Rx™ ICM with SharpSense™ technology delivers the information needed to diagnose arrhythmia faster with greater certainty and ease.

Abbott continues to advance ICM technology—empowered by smartphone remote monitoring—to provide the solutions that meet the evolving needs of your practice. That commitment has never been as important as it is in today's environment that puts a priority on flexibility in care.



CONTACT YOUR ABBOTT REPRESENTATIVE FOR MORE INFORMATION ABOUT **CONFIRM Rx™ ICM WITH SHARPSense™ TECHNOLOGY.**

1. Ip J, Jaffe B, Castellani M, et al. Arrhythmia Detection in Implantable Cardiac Monitor Randomized Clinical Trial Comparing Reveal LINQ™ and Confirm Rx™. PACE. Sept. 24, 2020. <https://doi.org/10.1111/pace.14076>
2. Evaluation of Clinic Impact of Confirm Rx 1.2 Algorithm Enhancements. Abbott document 60098828. April 2019.
3. Priorkowski C, et al. Early real-world adoption of mobile remote monitoring using the Confirm Rx Insertable Cardiac Monitor. Poster presented at: APHRS; 2018.
4. Design Validation Report and Trace Matrix, Insertable Cardiac Monitor (ICM) System document 60076435. Rev E. March 2019.

Abbott

One St. Jude Medical Dr., St. Paul, MN 55117 USA, Tel: 1 651 756 2000
Abbott.com

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 insertion of the Confirm Rx™ ICM. However, the patient's particular medical condition may dictate whether or not a subcutaneous, chronically inserted 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™ PCN 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.

™ Indicates a trademark of the Abbott group of companies.

‡ Indicates a third-party trademark, which is property of its respective owner.

Bluetooth and the Bluetooth logo are registered trademarks of Bluetooth SIG, Inc.

© 2020 Abbott. All Rights Reserved.

MAT-2010085 v2.0 | Item approved for Global use.

