Confirm Rx™ ICM
Clinical Compendium

PROVEN RELIABILITY AND **PERFORMANCE**

Confirm Rx™ Insertable Cardiac Monitor
with SharpSense™ Technology

Abbott

Insertable cardiac monitors are becoming a widely used diagnostic tool to detect arrhythmias. The Confirm Rx™ ICM has been updated with SharpSense™ technology to further improve the performance of the device. This is a collection of product and clinical data to help clinicians make informed decisions for their patients.

DETECT **ACCURATELY**

Performance of SharpSense™ Technology

Retrospective analysis of a Global Registry demonstrates SharpSense™ technology **significantly reduces false detection** of AF, Bradycardia, and Pause episodes.

97.9%

OVERALL REDUCTION IN FALSE POSITIVES[1]

- 76,403 episodes from 356 devices were analyzed using a simulation of the validated SharpSense technology discriminators[1]
- Enhanced arrhythmia detection algorithms in SharpSense technology significantly decreases incidents of false Pause, Bradycardia, and AF episodes while maintaining high sensitivity[1]

NUMBER OF EPISODES BEFORE AND AFTER SHARPSENSE™ TECHNOLOGY DISCRIMINATORS[1]

	ALL EPISODES	FALSE POSITIVE EPISODES
BASE ALGORITHM INITIAL DETECTIONS	76,403	52,431
	72.1% reduction	97.9% reduction
AFTER SHARPSENSE™ TECHNOLOGY DISCRIMINATORS	21,301	1,119

FALSE POSITIVE (FP) REDUCTION & RELATIVE SENSITIVITY PERFORMANCE OF SHARPSENSE™ TECHNOLOGY[1]

	FALSE POSITIVE REDUCTION	RELATIVE SENSITIVITY
PAUSE	98.6%	99.2%
BRADY	98.8%	97.9%
AF	42.4%	94.6%

* Relative sensitivity = $\frac{\text{True positive detections after SharpSense technology}}{\text{True positive detections by the base algorithm}}$

Algorithm enhancement **reduced episode rate**

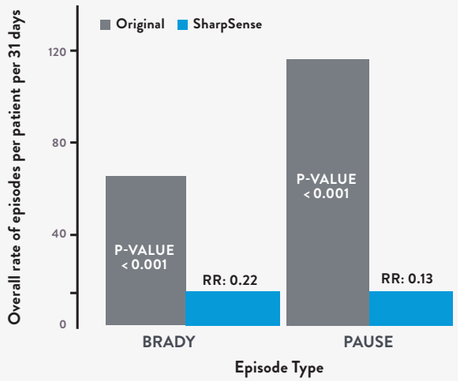
78%
LOWER RATE OF BRADY EPISODES[2]

87%
LOWER RATE OF PAUSE EPISODES[2]

Patients with SharpSense™ technology were associated with an 78% lower rate of brady episodes and a 87% lower rate of pause episodes in the first four months post implant. SharpSense technology improves the data management of ICM detected episodes by reducing false positive episodes and decreasing overall episode count[2]

6,810 patients were included in the retrospective simulation comparing algorithm performance among similar patient types[2]

REDUCTION IN OVERALL EPISODE RATE WITH SHARPSENSE™ TECHNOLOGY[2]



Multi-center analysis demonstrates a **consistent improvement in performance**

97.8%
OVERALL REDUCTION IN FALSE POSITIVES[3]

76%
REDUCTION IN ALL EPISODES[3]

- 294,416 episodes from 8 centers were retrospectively analyzed using a simulation from the validated SharpSense™ technology discriminators[3]
- A median follow-up period of 317 days[3]
- SharpSense technology significantly reduces false Pause, Bradycardia, and AF episodes with minimal reduction in true episode detection[3]

NUMBER OF EPISODES BEFORE AND AFTER SHARPSENSE™ TECHNOLOGY DISCRIMINATORS[3]

	ALL EPISODES	FALSE POSITIVE EPISODES
WITHOUT SHARPSENSE™ TECHNOLOGY	215,775	167,799
	76.0% reduction	97.8% reduction
WITH SHARPSENSE™ TECHNOLOGY	51,732	3,756

FALSE POSITIVE REDUCTION & RELATIVE SENSITIVITY PERFORMANCE OF SHARPSENSE™ TECHNOLOGY[3]

	FALSE POSITIVE REDUCTION	RELATIVE SENSITIVITY
PAUSE	98.8%	99.6%
BRADY	94.9%	99.9%
AF	45.7%	98.6%

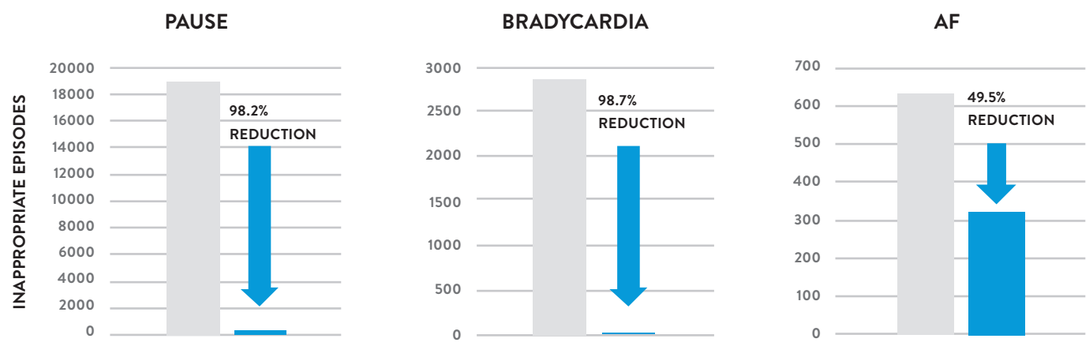
Arrhythmia detection improves in devices with reported sensing issues

96.9%
REDUCTION IN FALSE POSITIVES[4]

86%
REDUCTION IN DETECTED EPISODES[4]

- 25,359 Pause, Brady, and AF episodes were analyzed using a simulation of the validated SharpSense™ technology discriminators over a median device follow-up period of 116 days[4]
- SharpSense technology significantly reduces false pause, bradycardia, and AF episodes with minimal reduction in true episode detection[4]

INAPPROPRIATE PAUSE, BRADYCARDIA, AND AF DETECTIONS BEFORE AND AFTER SHARPSENSE™ TECHNOLOGY DISCRIMINATORS[4]



Implementation of SharpSense™ technology may reduce episode review burden, improve clinical workflow and improve patient management.[5]

PERFORMANCE OF DISCRIMINATORS IN THE VALIDATION TESTING DATA[5]

	FALSE POSITIVE REDUCTION	RELATIVE SENSITIVITY
PAUSE	99%	98%
BRADY	99%	100%
AF	58%	100%

Arrhythmia detection improves in Heart Failure Patients

SHARPSENSE™ TECHNOLOGY ALGORITHM ENHANCEMENTS REDUCE FALSE POSITIVES BY

97.9%

IN PATIENTS WITH HEART FAILURE[6]

- 313,051 Pause, Bradycardia, and AF episodes triggered by conventional algorithms were transmitted between August 2017 and May 2019 (follow-up duration 258 ± 159 days)[6]
- Confirm Rx™ ICM with SharpSense™ technology significantly reduces false positive detection of Pause, Bradycardia, and AF episodes while maintaining sensitivity. This may reduce the requirement for human review of arrhythmic episodes and thus improve clinic workflow.[6]

PERFORMANCE OF ALGORITHM ENHANCEMENTS IN SHARPSENSE™ TECHNOLOGY[6]

	FALSE POSITIVE REDUCTION	RELATIVE SENSITIVITY
PAUSE	98.5%	99.3%
BRADY	96.1%	99.5%
AF	30.4%	98.0%

	ALL EPISODES	FALSE POSITIVE EPISODES
WITHOUT SHARPSENSE™ TECHNOLOGY	313,051	193,370
	↓ 63% reduction	↓ 97.9% reduction
WITH SHARPSENSE™ TECHNOLOGY	116,691	4,012

Early generation ICM shows **Atrial Fibrillation can be accurately detected**

The 90-patient DETECT-AF study compared Confirm™ ICM to a Holter monitor and found:[7]

94%

AF EPISODE SENSITIVITY[7]

97.3%

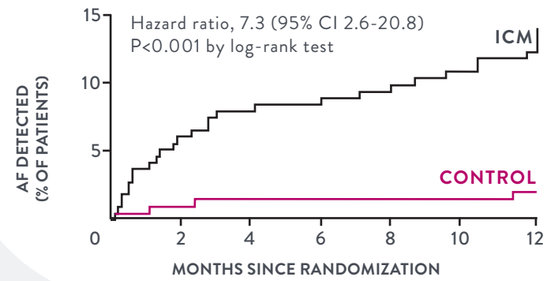
POSITIVE PREDICTIVE VALUE (PPV)[7]

Confirm™ ICM can accurately and repeatedly detect paroxysmal AF episodes of at least 2 minutes in duration[7]

Continuous monitoring using an ICM **better detects** AF in cryptogenic stroke patients vs. standard monitoring[8]

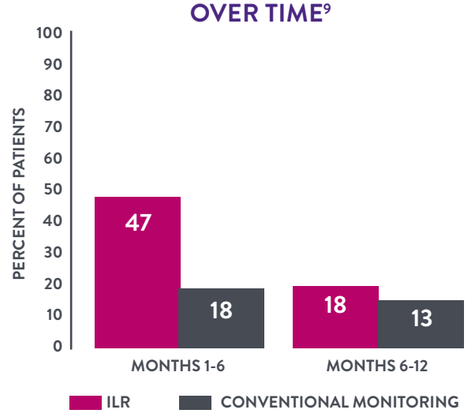
- AF detection using an ICM was 84 days (median)[8]
- At one year, an ICM detected AF in 7.3 times more patients than standard monitoring[8]

DETECTION OF AF BY 12 MONTHS[8]



More Atrial Fibrillation properly detected and more decisions made with Implantable Loop Recorder after catheter ablation[9]

DIFFERENCES IN AF DETECTION OVER TIME[9]



- 44 patients received implants
- In the first six months, conventional monitoring missed AF in 29% of patients where ILRs accurately detected AF[9]
- As many as 84% of AF recurrences were asymptomatic
- Rate control and anti-arrhythmic drugs were discontinued more in the ILR arm[9]

OUTCOMES ARE A MATTER OF TIME:

Time to diagnosis and intervention can impact overall care and cost of care.

Confirm Rx™ ICM uses smartphone connectivity and myMerlin™ mobile app to remotely monitor patients.

94%

OF ICM PATIENTS WERE REGISTERED WITH THE APP[10]

97%

OF REGISTERED PATIENTS HAD AT LEAST ONE TRANSMISSION[10]

All worldwide implants of Confirm Rx™ ICM between March 2017 to July 2018 were included:

- 13,323 patients enrolled[10]
- Episodes were transmitted to Merlin.net™ PCN in minutes to hours and were viewed by the clinician within 1-2 days[10]

EPISODE TRANSMISSION AND VIEW TIMES[10]

EPISODE TYPE	TIME FROM EPISODE UNTIL MERLIN.NET™ PCN	TIME FROM MERLIN.NET™ PCN UNTIL CLINICIAN VIEW
Patient-Initiated	3.6 [2.5, 11.7] minutes	1.3 [0.6, 3.6] days
Device-Initiated	19.3 [11.5, 49.1] hours	1.2 [0.7, 3.3] days

A **COMPARISON**

Between Reveal LINQ‡ and Confirm Rx™ ICM[11]

Enrolled 50 patients with 117 arrhythmic episodes transmitted over a mean follow-up of 4.3±1.6 months[11]

Confirm Rx™ ICM data transmission is approximately

20x

FASTER than Reveal LINQ‡ ICM[11]

Mean time to data transmission is significantly faster with Confirm Rx™ ICM[11]

ABBOTT **CONFIRM Rx™ ICM**	MEDTRONIC **REVEAL LINQ‡ ICM**
24 ± 103 min	475 ± 426 min

P-value (P<0.0001)

Medtronic LINQ‡ ICM

ADJUDICATION OF TRANSMISSIONS COSTS TIME AND RESOURCES[12]

695

CareLink‡ Remote Monitoring Transmissions

Average time to review one transmission was

30 to 45 min

minutes

Adjudication of CareLink‡ network transmissions required a considerable time commitment given a false positive incidence rate ranging **FROM 46% TO 86%**[12]

CLINICAL DECISION MAKING

with an ICM

THE RHYTHM EVALUATION FOR ANTICOAGULATION WITH CONTINUOUS MONITORING (REACT.COM)

Continuous rhythm assessment with an ICM allows for targeted anticoagulation (30 day dosage for AF episode ≥ 1 hour) without compromising stroke risk:[13]

94% **REDUCTION IN TOTAL TIME ON NOVEL ORAL ANTICOAGULANTS (NOACS)[13]**

References

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2. Piorkowski C, Shaik NA, Tilz RR, et al. Episode Rates with Confirm Rx SharpSense Technology using a Real-World Monitoring Database. Presented at Asia Pacific Heart Rhythm Society (APHRS); Bangkok, Thailand; Oct 27-29, 2019.
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6. Beggs, S, Jiang C, Qu F, et al. Evaluation of SharpSense algorithm enhancements in patients with heart failure. Presented at Asia Pacific Heart Rhythm Society (APHRS); Bangkok, Thailand; Oct 27-29, 2019.
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13. Passman R, Leong-Sit P, Andrei AC, et al. Targeted anticoagulation for atrial fibrillation guided by continuous rhythm assessment with an insertable cardiac monitor: the Rhythm Evaluation for Anticoagulation with Continuous Monitoring (REACT.COM) pilot study. J Cardiovasc Electrophysiol. 2016; 27(3):264-70.

TO LEARN MORE ABOUT **CONFIRM RX™ ICM WITH SHARPSENSE™ TECHNOLOGY,** SPEAK WITH YOUR ABBOTT REPRESENTATIVE.

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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 episodes 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 Episodes: Possible adverse episodes (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 episodes.

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 prepisode 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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