



PROVEN RELIABILITY,
INCREASED CONTROL

Abbott Insertable Cardiac Monitors with
SharpSense™ Technology

Insertable cardiac monitors are becoming a widely used diagnostic tool to detect arrhythmias. Abbott ICMs have been updated with SharpSense™ technology to further improve their performance. 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 POSITIVES¹

- 76,403 episodes from 356 devices were analyzed using a simulation of the validated SharpSense technology discriminators¹
- Enhanced arrhythmia detection algorithms in SharpSense technology significantly decreases incidents of false Pause, Bradycardia, and AF episodes while maintaining high sensitivity¹

NUMBER OF EPISODES BEFORE AND AFTER SHARPSENSE™ TECHNOLOGY DISCRIMINATORS¹

	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™ TECHNOLOGY¹

	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 EPISODES²

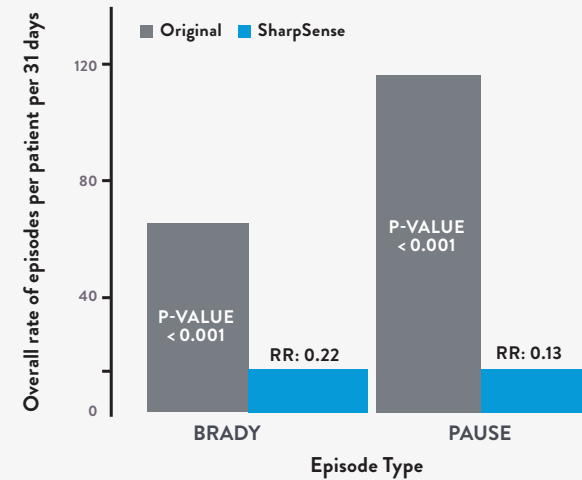
87%

LOWER RATE OF PAUSE EPISODES²

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 count²

6,810 patients were included in the retrospective simulation comparing algorithm performance among similar patient types²

REDUCTION IN OVERALL EPISODE RATE WITH SHARPSENSE™ TECHNOLOGY²



Arrhythmia detection improves in devices with reported sensing issues

96.9%

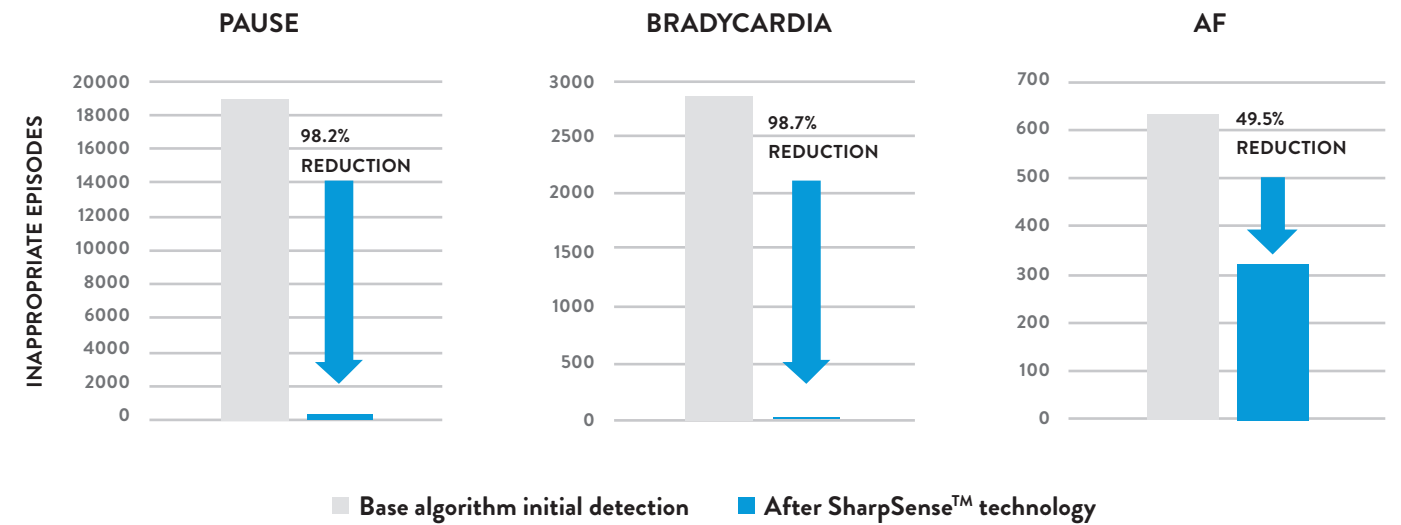
REDUCTION IN FALSE POSITIVES⁴

86%

REDUCTION IN DETECTED EPISODES⁴

- 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 days⁴
- SharpSense technology significantly reduces false pause, bradycardia, and AF episodes with minimal reduction in true episode detection⁴

INAPPROPRIATE PAUSE, BRADYCARDIA, AND AF DETECTIONS BEFORE AND AFTER SHARPSENSE™ TECHNOLOGY DISCRIMINATORS⁴



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

97.8%

OVERALL REDUCTION IN FALSE POSITIVES³

76%

REDUCTION IN ALL EPISODES³

- 294,416 episodes from 8 centers were retrospectively analyzed using a simulation from the validated SharpSense™ technology discriminators³
- A median follow-up period of 317 days³
- SharpSense technology significantly reduces false Pause, Bradycardia, and AF episodes with minimal reduction in true episode detection³

NUMBER OF EPISODES BEFORE AND AFTER SHARPSENSE™ TECHNOLOGY DISCRIMINATORS³

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

76.0% reduction in All Episodes and 97.8% reduction in False Positive Episodes.

FALSE POSITIVE REDUCTION & RELATIVE SENSITIVITY PERFORMANCE OF SHARPSENSE™ TECHNOLOGY³

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

PERFORMANCE OF DISCRIMINATORS IN THE VALIDATION TESTING DATA⁵

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

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

Arrhythmia detection improves in Heart Failure Patients

SHARPSENSE™ TECHNOLOGY
ALGORITHM ENHANCEMENTS
REDUCE FALSE POSITIVES BY

97.9%

IN PATIENTS WITH HEART FAILURE⁶

- 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
- Abbott ICMs 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™ TECHNOLOGY⁶

	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 SENSITIVITY⁷

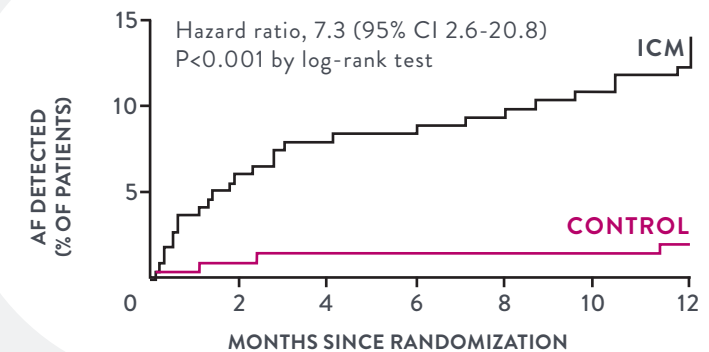
97.3%
POSITIVE PREDICTIVE VALUE (PPV)⁷

Confirm™ ICM can accurately and repeatedly detect paroxysmal AF episodes of at least 2 minutes in duration⁷

Continuous monitoring using an ICM better detects AF in cryptogenic stroke patients vs. standard monitoring⁸

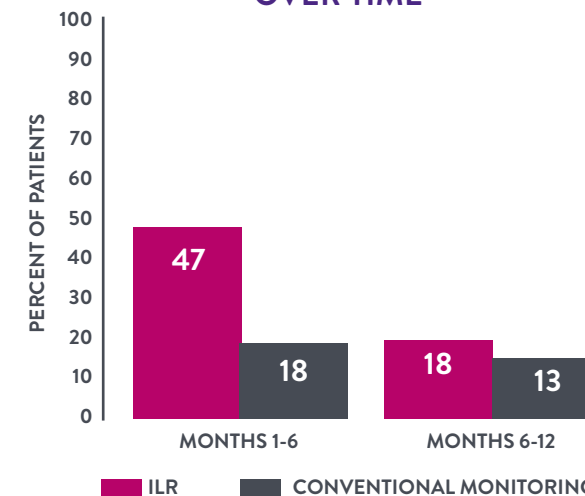
- AF detection using an ICM was 84 days (median)⁸
- At one year, an ICM detected AF in 7.3 times more patients than standard monitoring⁸

DETECTION OF AF BY 12 MONTHS⁸



More Atrial Fibrillation properly detected and more decisions made with Implantable Loop Recorder after catheter ablation⁹

DIFFERENCES IN AF DETECTION OVER TIME⁹



- 44 patients received implants
- In the first six months, conventional monitoring missed AF in 29% of patients where ILRs accurately detected AF⁹
- As many as 84% of AF recurrences were asymptomatic
- Rate control and anti-arrhythmic drugs were discontinued more in the ILR arm⁹

OUTCOMES ARE A MATTER OF TIME:

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



Abbott ICMs use smartphone connectivity and the myMerlin™ mobile app to remotely monitor patients.

*Patients can use an Abbott-provided mobile transmitter if they do not have a smartphone

A COMPARISON

Between Reveal LINQ[‡] and Confirm Rx™ ICM¹¹

Enrolled 50 patients with 117 arrhythmic episodes transmitted over a mean follow-up of 4.3±1.6 months¹¹

Confirm Rx™ ICM data transmission is approximately

20x

FASTER than Reveal LINQ[‡] ICM¹¹

Mean time to data transmission is significantly faster with Confirm Rx™ ICM¹¹

ABBOTT
CONFIRM Rx™ ICM

24 ± 103 min

P-value (P<0.0001)

MEDTRONIC
REVEAL LINQ[‡] ICM

475 ± 426 min

94%

OF ICM PATIENTS WERE REGISTERED WITH THE APP¹⁰

97%

OF REGISTERED PATIENTS HAD AT LEAST ONE TRANSMISSION¹⁰

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

- 13,323 patients enrolled¹⁰
- Episodes were transmitted to Merlin.net™ PCN in minutes to hours and were viewed by the clinician within 1-2 days¹⁰

EPISODE TRANSMISSION AND VIEW TIMES¹⁰

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

Medtronic LINQ[‡] ICM

ADJUDICATION OF TRANSMISSIONS COSTS TIME AND RESOURCES¹²

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 \geq 1 hour) without compromising stroke risk:¹³

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

MANAGE WITH FLEXIBILITY TO GET ALL EPISODES

For hard-to-detect arrhythmias you can toggle to view all episodes for a specific patient, rather than three key episodes. You can also view all episodes facility-wide.



POTENTIAL STAFF TIME SAVINGS FROM REDUCED DATA BURDEN

All patients¹⁴

Hours/year reduction

120 **36**

Clinic Personnel
(100 patients)

Electrophysiologists
(100 patients)

Top 25th percentile patients¹⁴

Hours/year reduction

300 **96**

Clinic Personnel
(100 patients)

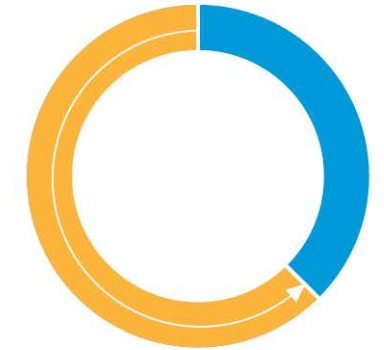
Electrophysiologists
(100 patients)

FOCUS YOUR DIAGNOSTIC DATA

Choose to view three key episodes for a patient or facility.

Decrease your data burden on average by

63%¹⁵



With Key Episodes* turned on and pause algorithm improvements

*Key episodes is a feature of Merlin.net compatible with Jot Dx Only

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TO LEARN MORE ABOUT **ABBOTT ICMS 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 events and directions for use.

Indications: Abbott Insertable Cardiac Monitors (ICMs) are 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 cardiac arrhythmias. Abbott ICMs are also indicated for patients who have been previously diagnosed with atrial fibrillation or who are susceptible to developing atrial fibrillation. Abbott ICMs have not been specifically tested for pediatric use.

Contraindications: There are no known contraindications for the insertion of Abbott ICMs. 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 these devices, 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 preepisode 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.

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