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 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%

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

Algorithm enhancement **reduced episode rate**
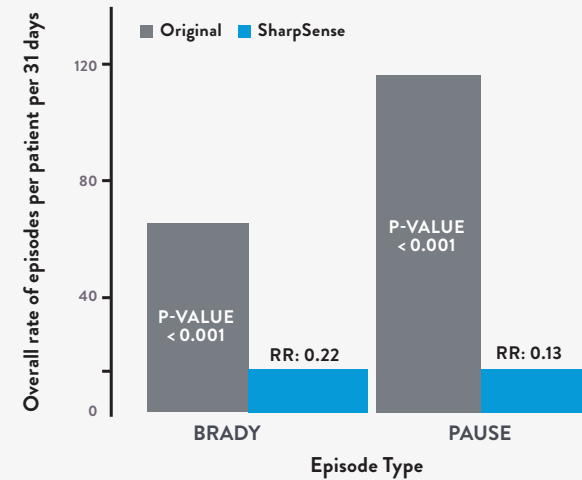
78%
LOWER RATE OF BRADY EPISODES[2]

87%
LOWER RATE OF PAUSE EPISODES[2]

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

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

■ Original ■ SharpSense

Overall rate of episodes per patient per 31 days

P-VALUE < 0.001 — BRADY — RR: 0.22
P-VALUE < 0.001 — PAUSE — RR: 0.13

Episode Type

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
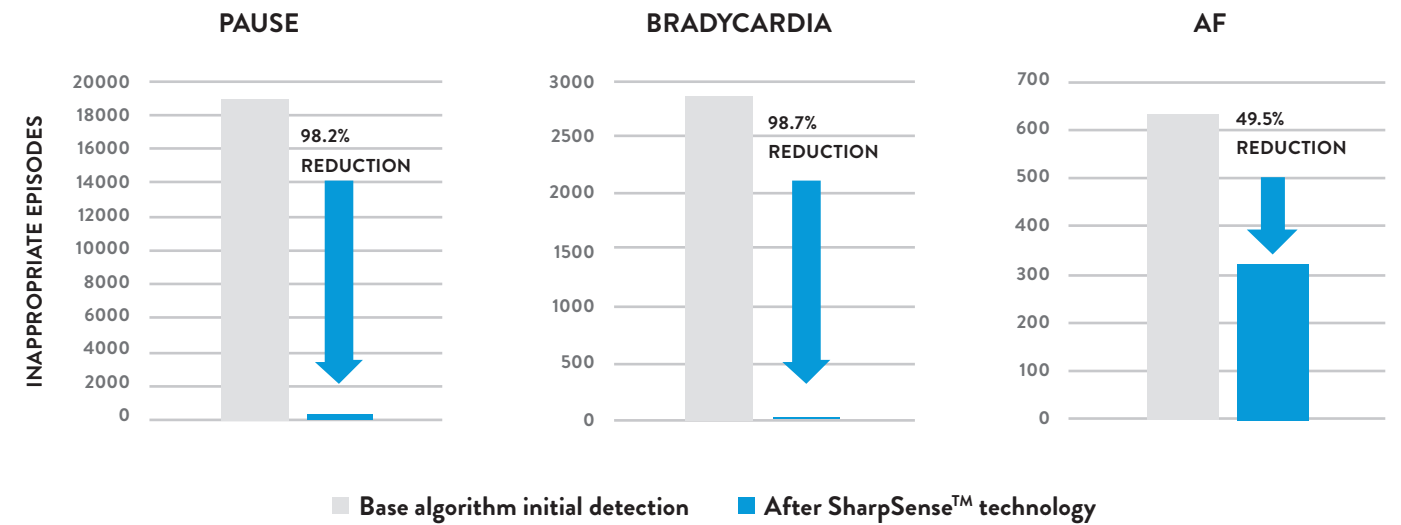
96.9%
REDUCTION IN FALSE POSITIVES[4]

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]

PAUSE — 98.2% REDUCTION
BRADYCARDIA — 98.7% REDUCTION
AF — 49.5% REDUCTION

INAPPROPRIATE EPISODES

■ Base algorithm initial detection ■ After SharpSense™ technology

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]

- 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™ 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]
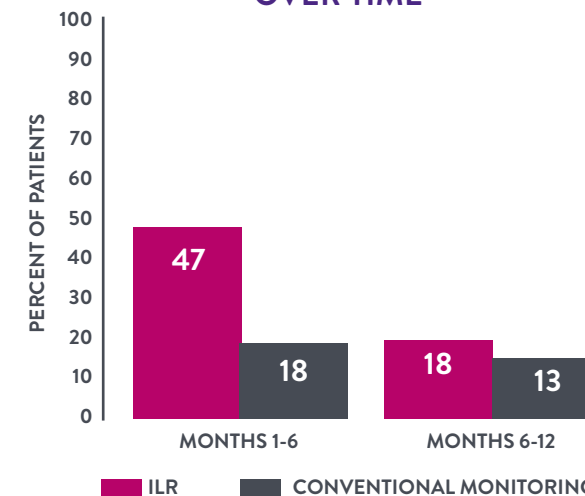
- AF detection using an ICM was 84 days (median)[8]

- At one year, an ICM detected AF in 7.3 times more patients than standard monitoring[8]

DETECTION OF AF BY 12 MONTHS[8]

Hazard ratio, 7.3 (95% CI 2.6-20.8) P<0.001 by log-rank test

ICM

CONTROL

AF DETECTED (% OF PATIENTS)

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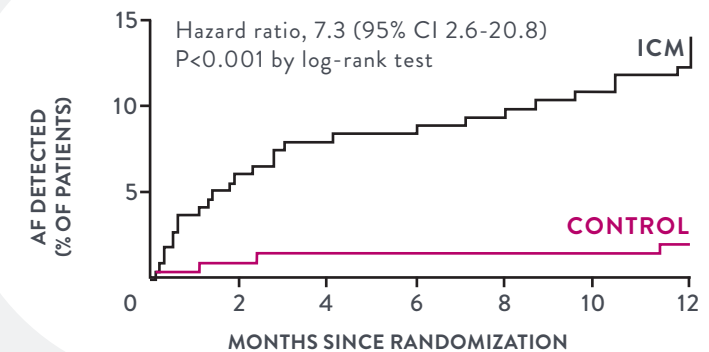
More Atrial Fibrillation properly detected and more decisions made with Implantable Loop Recorder after catheter ablation[9]

DIFFERENCES IN AF DETECTION OVER TIME[9]

PERCENT OF PATIENTS

MONTHS 1-6: ILR 47, CONVENTIONAL MONITORING 18
MONTHS 6-12: ILR 18, CONVENTIONAL MONITORING 13

■ ILR   ■ CONVENTIONAL MONITORING

- 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.

ABBOTT ICM → **PATIENT SMARTPHONE*** → **CLINICIAN PORTAL**

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

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]

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.

[ALL] EPISODES ← → [3 KEY] EPISODES

POTENTIAL STAFF TIME SAVINGS FROM REDUCED DATA BURDEN

All patients[14]		Top 25th percentile patients[14]	
Hours/year reduction		Hours/year reduction	
120	36	300	96
Clinic Personnel (100 patients)	Electrophysiologists (100 patients)	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]
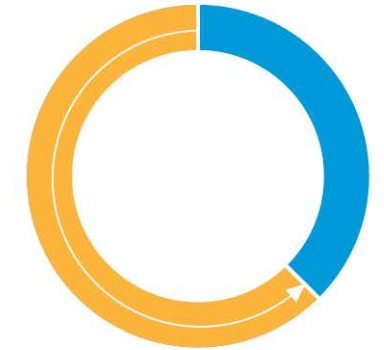
With Key Episodes* turned on and pause algorithm improvements

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

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15. HRS 2021 Poster - Reducing Clinical Review Burden of Insertable Cardiac Monitors In Patients with Frequent Arrhythmia Detections

TO LEARN MORE ABOUT **ABBOTT ICMS WITH SHARPSENSE™ TECHNOLOGY,**
SPEAK WITH YOUR ABBOTT REPRESENTATIVE.