CONFIRM Rx™ ICM
with SharpSense™ Technology

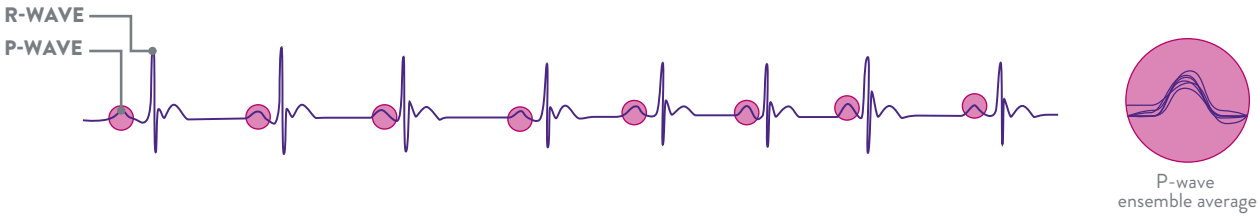
CAPTURING THE **RHYTHM OF LIFE**

Abbott

ACCURATELY DISCERN **AF**

Before logging an AF event, SharpSense™ Technology analyzes the previous 30 seconds for the presence or absence of P-wave characteristics.

97.2%
RELATIVE SENSITIVITY FOR AF[2]



AF DETECTION

BASE ALGORITHM

Evaluates regularity, variance and onset

ENHANCEMENT

Verifies absence of P-waves

- No P-waves → **STORE EPISODE**
- P-waves detected → **REJECT EPISODE**

Confirm Rx™ ICM base algorithm analyzes a 64-beat window based on R-R variability to evaluate:

REGULARITY: Regular or irregular rhythm pattern
VARIANCE: Variance of R-R intervals
SUDDEN ONSET: How the rhythm initiates

If an AF episode occurs, SharpSense™ Technology will check for P-waves by:

1

Scanning 30 seconds prior to initial AF trigger to determine qualified beats

- SharpSense™ Technology identifies beats that are within a range of pace (40–100 bpm)—Beat Selection
- SharpSense™ Technology layers the selected beats on top of each other to look for consistent P-wave morphology and significance of P-wave amplitude—Ensemble Average

2

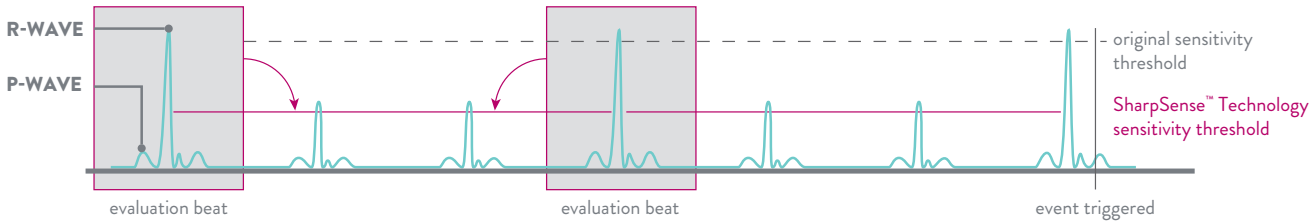
Verifies the absence of P-waves

- Stores AF episode if P-waves are not detected
- Rejects AF episode if P-waves are detected

CORRECTLY CAPTURE **BRADYCARDIA**

SharpSense™ Technology confirms Bradycardia episodes by dynamically increasing sensitivity between Bradycardia beats and applying a secondary threshold based on P-wave, R-wave and T-wave characteristics.

98.6%
RELATIVE SENSITIVITY FOR BRADYCARDIA[2]



BRADYCARDIA DETECTION

BASE ALGORITHM

Bradycardia detection occurs

ENHANCEMENT

Bradycardia undersensing discriminator applied

Calculates new intervals based on any new beats found with secondary threshold

If 3 of 4 initially detected Bradycardia beats are Bradycardia beats

STORE EPISODE

If 2 of 4 detected Bradycardia beats are NOT Bradycardia beats

REJECT EPISODE

After Bradycardia is indicated, SharpSense™ Technology confirms an event by:

1

Opening 4 pre-trigger EGM windows

- One prior to each of the 4 Bradycardia beats detected
- Each window extends to the prior sensed beat
- Calculates customized secondary threshold based on P-wave, R-wave and T-wave characteristics

2

Applying a secondary threshold to each window

3

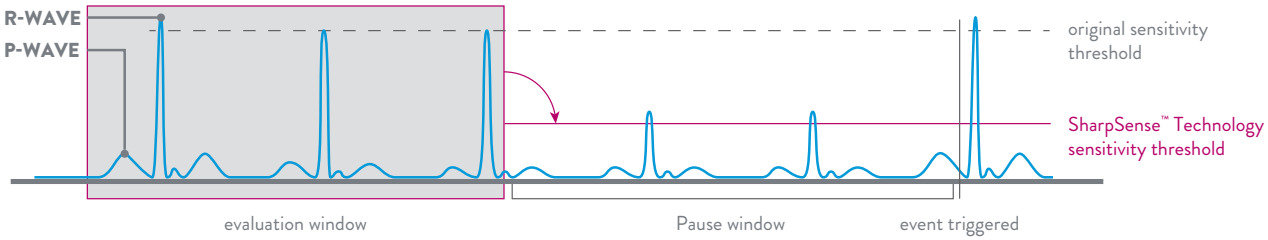
Determining the presence of undersensed beats

- Stores Bradycardia event if 3 of 4 detected beats meet Bradycardia criteria
- Rejects episode if 2 of 4 detected beats do not meet Bradycardia criteria

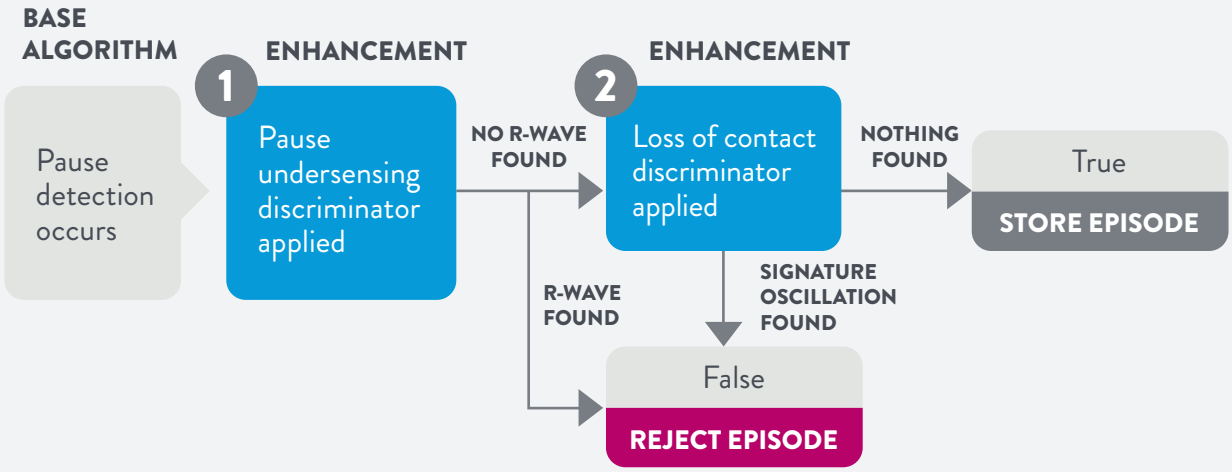
PRECISELY DETECT **PAUSE**

To accurately identify Pause episodes, SharpSense™ Technology dynamically increases sensitivity by applying a secondary threshold, based on P-wave and R-wave characteristics, and evaluating evidence of loss of tissue contact.

98.1%
RELATIVE SENSITIVITY FOR PAUSE[2]



PAUSE DETECTION



After a Pause detection is triggered, SharpSense™ Technology evaluates and confirms a Pause event by:

1

Analyzing 6 seconds of EGM data prior to the last sensed beat

- Calculates customized secondary threshold based on P-wave and R-wave characteristics

2

Applying a secondary threshold to Pause window

3

Determining the presence of undersensed beats

4

Checking for loss of contact

- If no undersensed beats are identified, SharpSense™ Technology searches for the presence of signature oscillation
- Stores Pause episode if no signature oscillation is found
- Rejects Pause episode if oscillation is found

GREATER SPECIFICITY, GREATER CERTAINTY

Confirm Rx™ ICM with SharpSense™ Technology uses additional discriminators to confirm or reject detections made by existing Confirm Rx™ ICM algorithms—significantly improving the accuracy of Atrial Fibrillation (AF), Bradycardia and Pause detected 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%.[1]

By maintaining a high relative sensitivity and improving the Positive Predictive Value (PPV),[2] Confirm Rx™ ICM with SharpSense™ Technology monitors and stores true arrhythmic events.

Greater specificity means greater certainty—allowing you to decide clearly and confidently on a diagnosis, and enabling more patients to live fuller lives.

1 ALGORITHM

Base algorithm initial detection

2 DISCRIMINATOR

Analysis by SharpSense™ Technology

- True → **STORE EPISODE**
- False → **REJECT EPISODE**

ENHANCEMENT GOALS

1. Maintain base algorithm high sensitivity
2. Improve specificity of device performance

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

HOW **SHARPSENSE™ TECHNOLOGY** DISCERNS

ARRHYTHMIA	SHARPSENSE™ TECHNOLOGY
ATRIAL FIBRILLATION (AF)	• Base AF algorithm is published in DETECT AF to have 100% patient sensitivity • SharpSense™ Technology builds on base AF algorithm to improve specificity with minimal impact on sensitivity • Analyzes 30 seconds of pre-trigger rhythm • Calculates ensemble average to detect P-waves
BRADYCARDIA	• Calculates customized secondary threshold based on beats in 4 windows • Considers R-wave variability and accounts for P-wave, R-wave and T-wave characteristics
PAUSE UNDERSENSING	• Calculates customized threshold based on beats in 6-second pre-trigger window (from last sensed beat) • Considers R-wave variability and accounts for P-wave and R-wave characteristics
PAUSE LOSS OF CONTACT (LOC)	• Evaluates 2-second pre-trigger window for presence of signature noise pattern

1. Evaluation of Clinic Impact of Confirm Rx 1.2 Algorithm Enhancements. Abbott Document 60098828. April 2019.
2. Design Validation Report and Trace Matrix, Insertable Cardiac Monitor (ICM) System. Abbott Document 60076435 Rev. E. March 2019.

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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 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.

Additional information: 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 schedules and enable or disable features on a patient's myMerlin™ for Confirm Rx™ ICM 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 Apple‡ or Android‡ mobile device to transmit information from their Confirm Rx™ ICM using the myMerlin™ for Confirm Rx™ ICM mobile app. To do so the device must be powered on, app must be installed, Bluetooth® wireless technology enabled and data coverage (cellular or WiFi‡) available. The myMerlin™ for Confirm Rx™ ICM mobile app provides periodic patient monitoring based on clinician configured settings. Data is resent if the transmission was 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.

SJM-CFM-0419-0128 | Item approved for U.S. and OUS use.

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