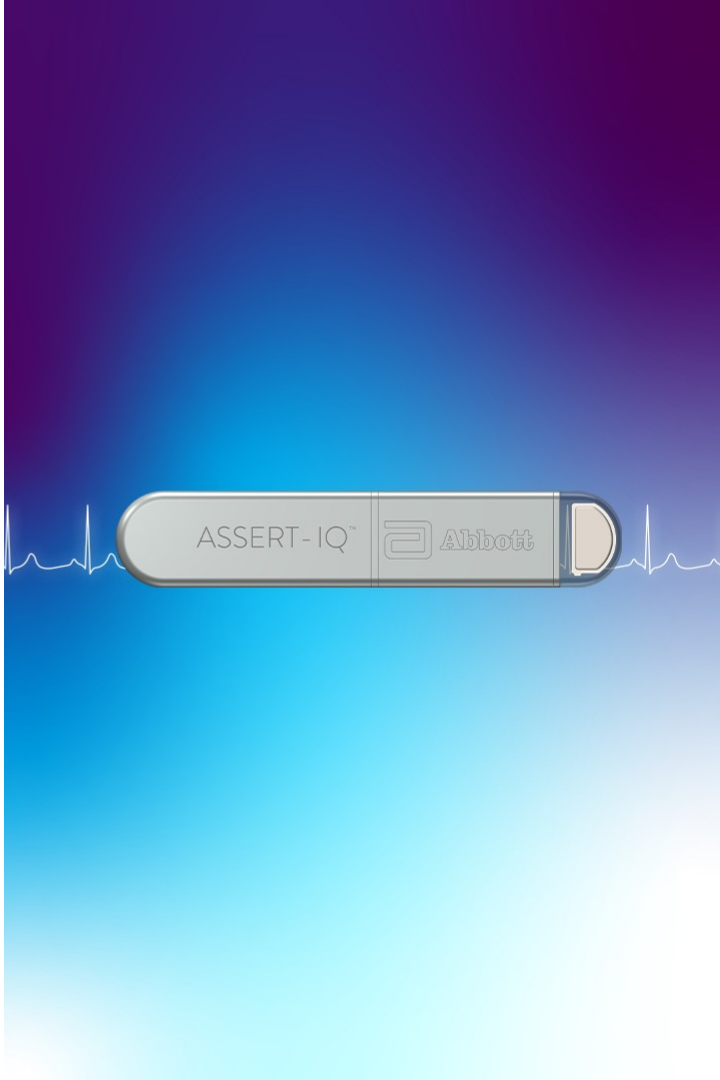
Assert-IQ™
Insertable Cardiac Monitor (ICM)

Assert-IQ™ ICM

Clinical Compendium

Abbott

CONTENTS



Assert-IQ™ ICM is designed to focus on generating data that matters — data that is clinically actionable.

CLINICALLY ACTIONABLE DATA FOR PHYSICIANS AND PATIENTS

ADVANCED ALGORITHMS provide industry-leading accuracy[1,2] for arrhythmia detection that:

- Builds user confidence in transmitted data;
- Provides reassurance to patients who need a diagnosis.

KEY EPISODE TECHNOLOGY provides flexibility for data management while maintaining time-to-diagnosis for patients.[3,4]

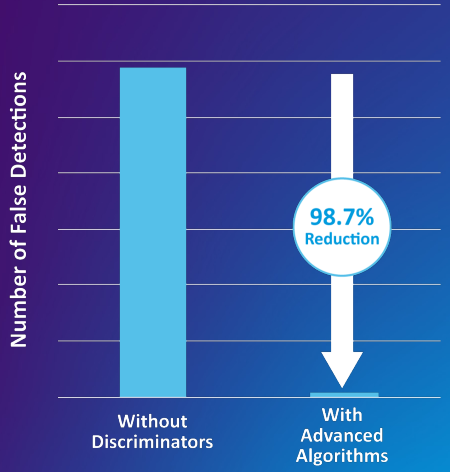
LEARN MORE

DETECT ARRHYTHMIAS MORE ACCURATELY WITH FEWER FALSE POSITIVES AND LESS DATA BURDEN

Assert-IQ™ ICM's enhanced algorithms reduce false detections by 98.7% for AF and Pause while maintaining 97.7% of true EGMs.[1,2,5]

Assert-IQ ICM's AF algorithm reduces data burden by 21% compared to LINQ II‡ with AccuRhythm‡ AI while maintaining sensitivity.*[,1,9,10]

AF and Pause False Detections



Total EGMs/Patient/Month Transmitted to Clinic

*As of 12.31.22, LINQ II‡ with AccuRhythm‡ AI. EGM burden comparison is based on two independent, random, real-world data sets. Patient characteristics and device programming may differ.

LEARN MORE

KEY EPISODES^ - OPTIMIZED FOR EACH ARRHYTHMIA TYPE

Key Episode technology sets Abbott's Assert-IQ™ ICM apart from others by allowing clinicians the ability to see All Episodes or 3 Key Episodes, depending on the needs of the patient or clinic.[11]

	Assert-IQ™ ICM	Medtronic Reveal LINQ‡	Medtronic LINQ II‡
Arrhythmia Type	**Key Episode Selection:** Up to 3 EGMs per day, per arrhythmia type[4]	**Selection:** One EGM per day based on wireless data priority[5]	**Selection:** Three auto episode EGMs per day, per arrhythmia type[6]
Atrial Fibrillation	1. Longest episode 2. Second longest episode **3. Fastest mean rate**	**One EGM per day sent wirelessly** Patient manual transmission optional to see all information[5]	**Same standard criteria set for all arrhythmia types** 1. First episode 2. Second episode 3. Longest episode
Tachycardia	1. Longest episode 2. Second longest episode **3. Fastest maximum rate**		
Bradycardia	1. Longest episode 2. Second longest episode **3. Fastest minimum rate**		
Pause	1. Longest episode 2. Second longest episode **3. Shortest episode**		

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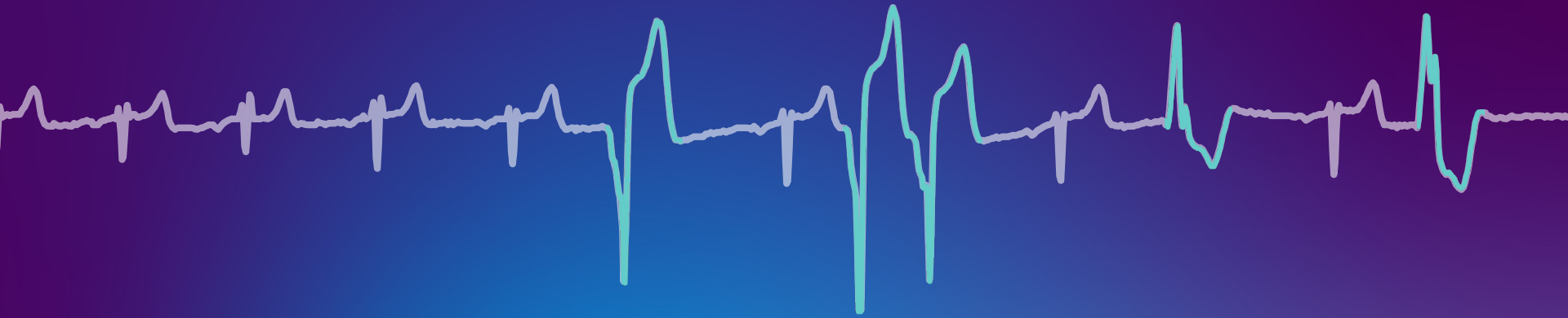
^ Key Episodes is a feature of Merlin.net™ Patient Care Network (PCN)

NEW IQ INSIGHTS CAPTURE PREMATURE VENTRICULAR CONTRACTION DIAGNOSTICS

Leading PVC detection algorithm offers the ability to capture consecutive events **including couplets and triplets.**[12]



Patient PVC counts vary over 24-hour periods; **longer monitoring** has been shown to double the identification of patients with a PVC burden of >10%.[13]

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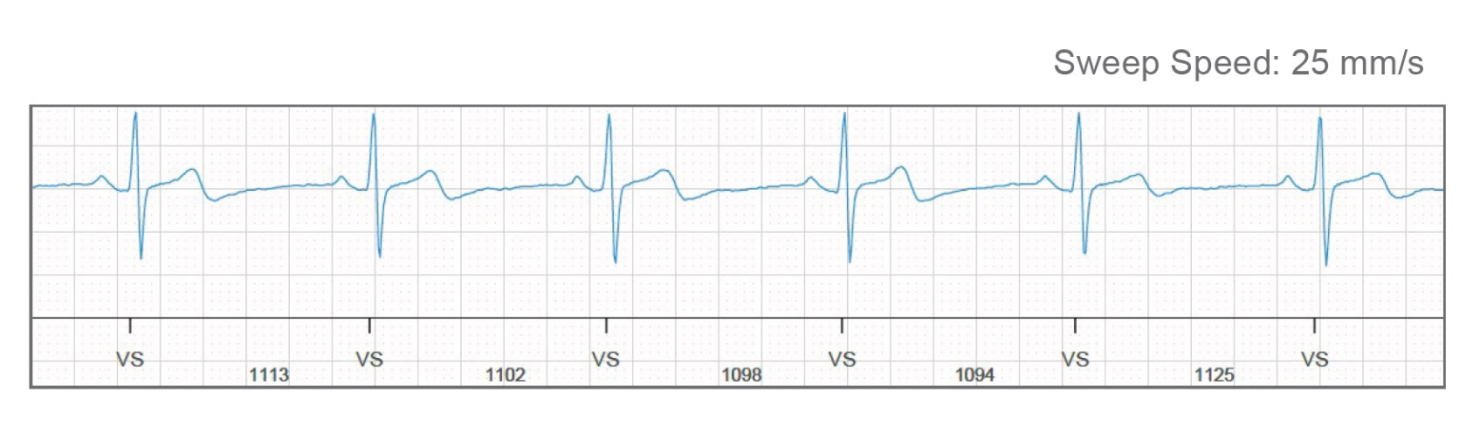
ASSERT-IQ™ ICM OFFERS CLEAR ECG/EKG SIGNAL QUALITY

Consistent P-waves were visible in newly designed clinical reports across all patients.[14]



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Assert-IQ™
Insertable Cardiac Monitor (ICM)

PERFORMANCE BY THE NUMBERS

ADVANCED ALGORITHMS

Abbott

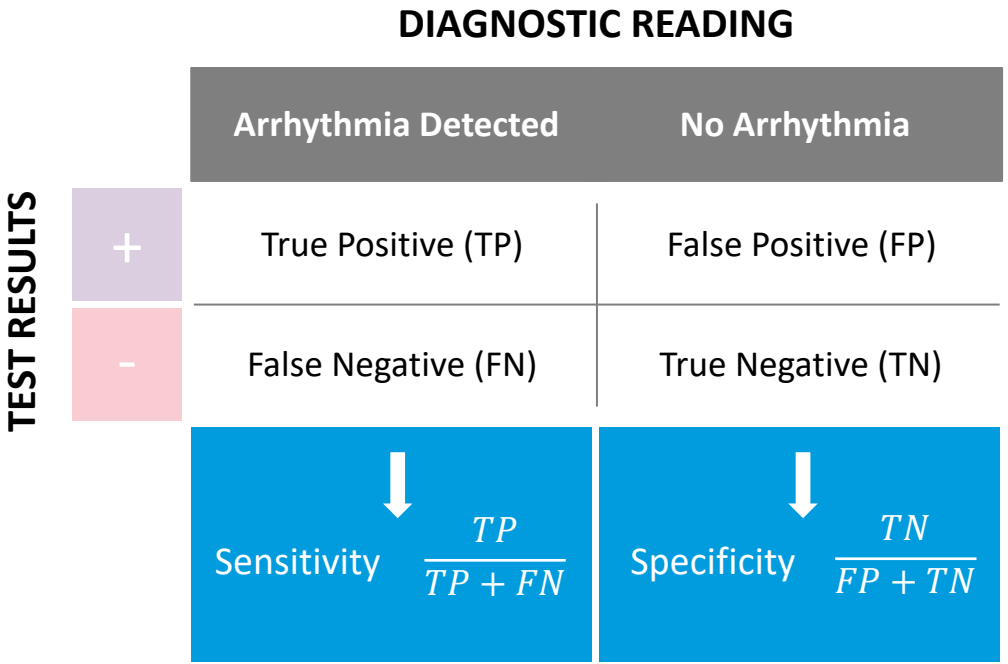
Vocabulary Review for Evaluating Diagnostic Device Accuracy

Sensitivity

- Ability of the test to identify the presence of a condition, aka true positive rate

Specificity

- Ability of the test to identify the absence of a condition correctly, aka true negative rate



Improving the Specificity of Atrial Fibrillation and Tachycardia Detection in an ICM

GOPINATHANNAIR ET AL. HRS POSTER 2022[1]

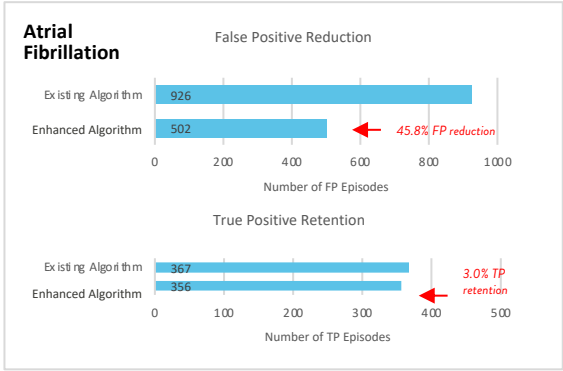
KEY FINDING

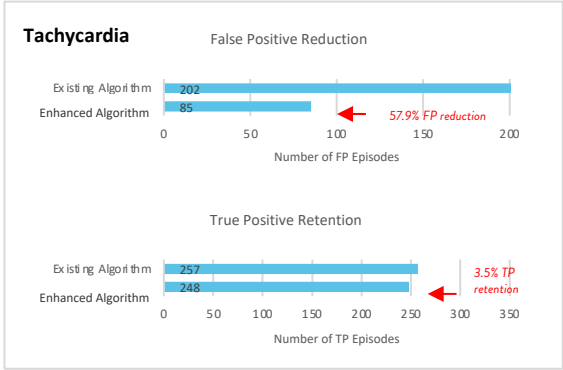
New AF and Tachy detection enhancements significantly reduced false detections while maintaining sensitivity.

- Enhanced algorithms **retained true positives** with minimal reduction.
- Reduction in false detections may **reduce the clinical cost and time for diagnosis**.

RESULTS

1) AF enhancements achieved **45.8% FP reduction with 97.0% sensitivity.**
2) Tachy enhancements achieved **57.9% FP reduction with 96.5% sensitivity.**





STUDY DESIGN

The existing AF detection algorithm in SharpSense™ technology was enhanced with discriminators to reject episodes that exhibit any of the following phenomena: 1) R-R intervals (RRI) display a repeated pattern, 2) RRI irregularity due to R-wave undersensing or AV block, 3) RRI irregularity due to T- or P-wave oversensing, 4) Consistent P-waves in the signal.

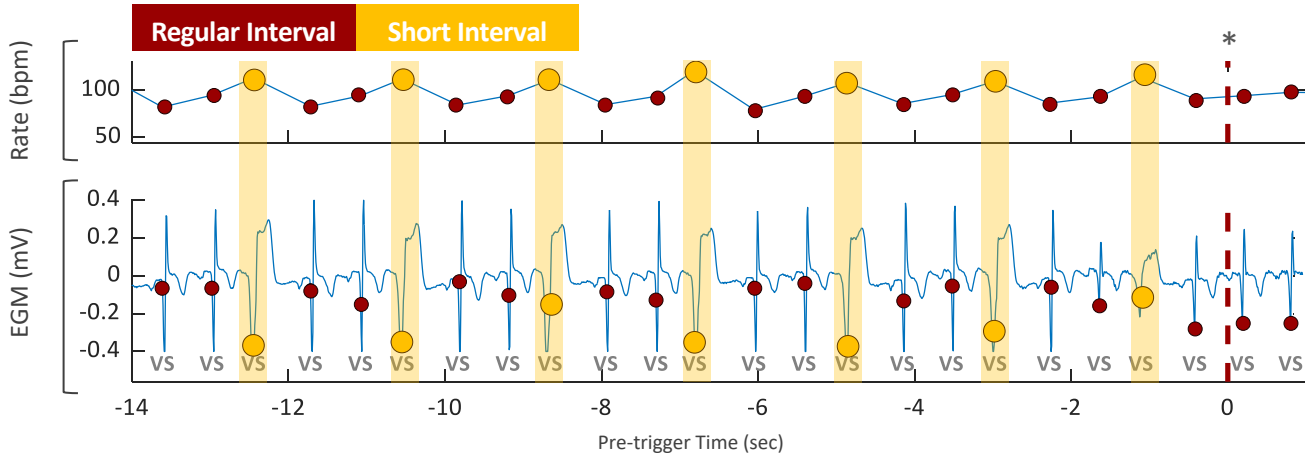
The existing Tachy detection algorithm in SharpSense technology was enhanced to reject episodes that exhibit any of the following phenomena: 1) High rate due to T- or P-wave oversensing, 2) Sudden onset due to R-wave undersensing or AV block.

EGMs were manually adjudicated as true or false positives and divided into independent algorithm training and testing datasets.

Improving the Specificity of Atrial Fibrillation and Tachycardia Detection in an ICM

GOPINATHANNAIR ET AL. HRS POSTER 2022[1] (CONTINUED)

NEW AF Pattern Recognition Discriminator

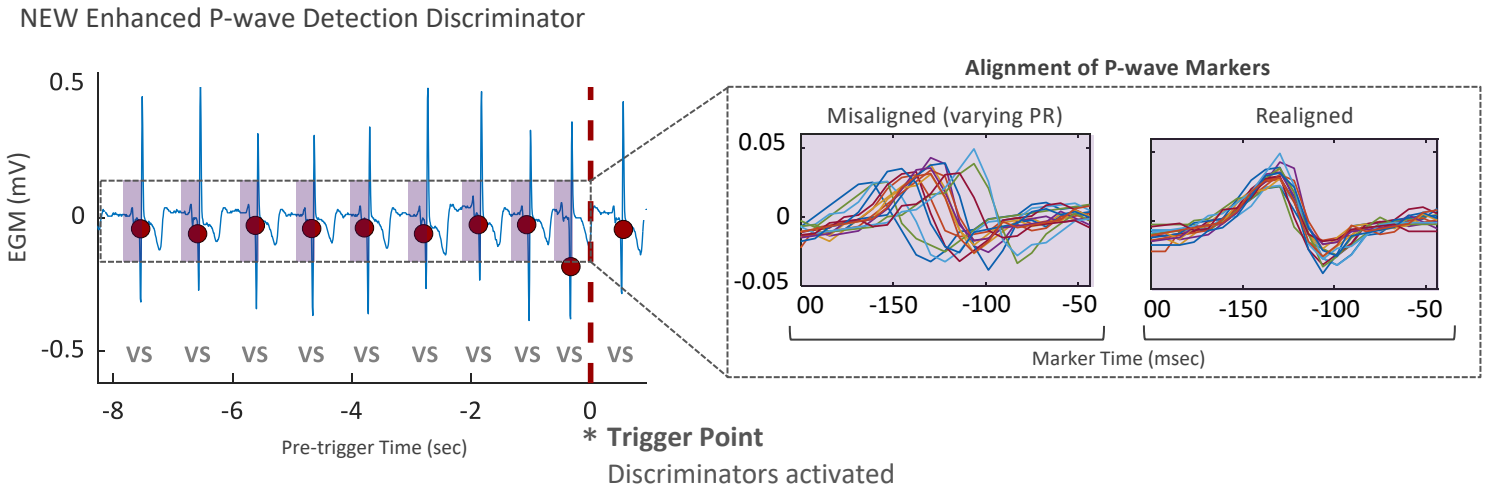


AF algorithm enhancement designed for intelligent pattern recognition of irregular R-R intervals can create recognizable regular-regular-short-regular-regular-short patterns**.** The enhancement detects the RRI pattern and rejects false AF detection.

*AF and Tachy discriminators analyze 30 seconds of data pre-trigger

Improving the Specificity of Atrial Fibrillation and Tachycardia Detection in an ICM

GOPINATHANNAIR ET AL. HRS POSTER 2022[1] (CONTINUED)



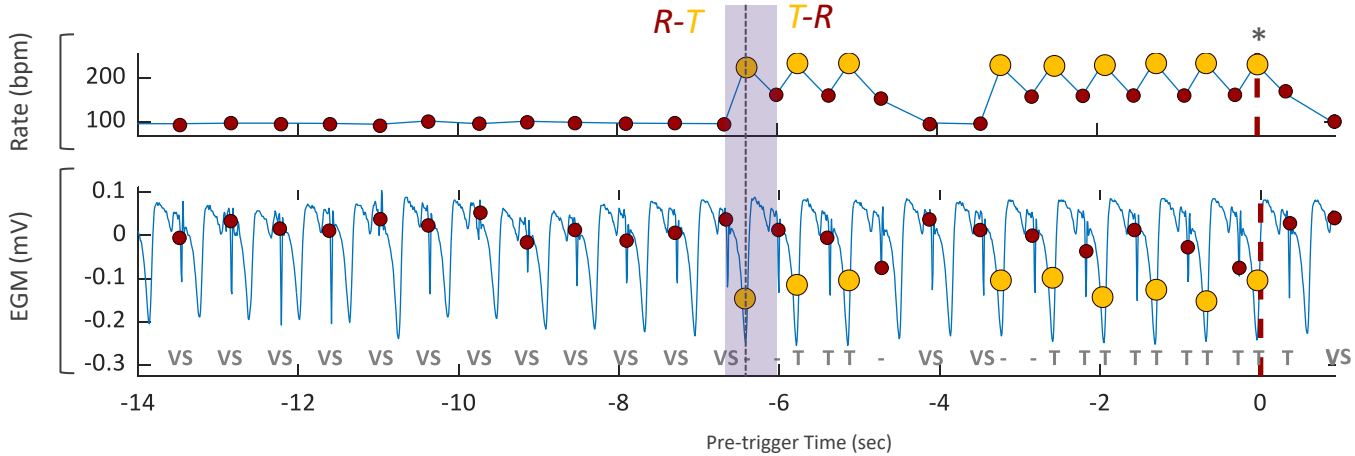
AF algorithm enhancement detects consistent P-waves more accurately amid varying P-R intervals.
The enhancement helps reject false AF detection by realigning R-wave markers before calculating an ensemble average for P-wave analysis.

*AF and Tachy discriminators analyze 30 seconds of data pre-trigger

Improving the Specificity of Atrial Fibrillation and Tachycardia Detection in an ICM

GOPINATHANNAIR ET AL. HRS POSTER 2022[1] (CONTINUED)

NEW T-wave Oversensing Discriminator



* **Trigger Point**
Discriminators activated

Consistency of sequential R-T intervals is more consistent than heart rate for pattern recognition

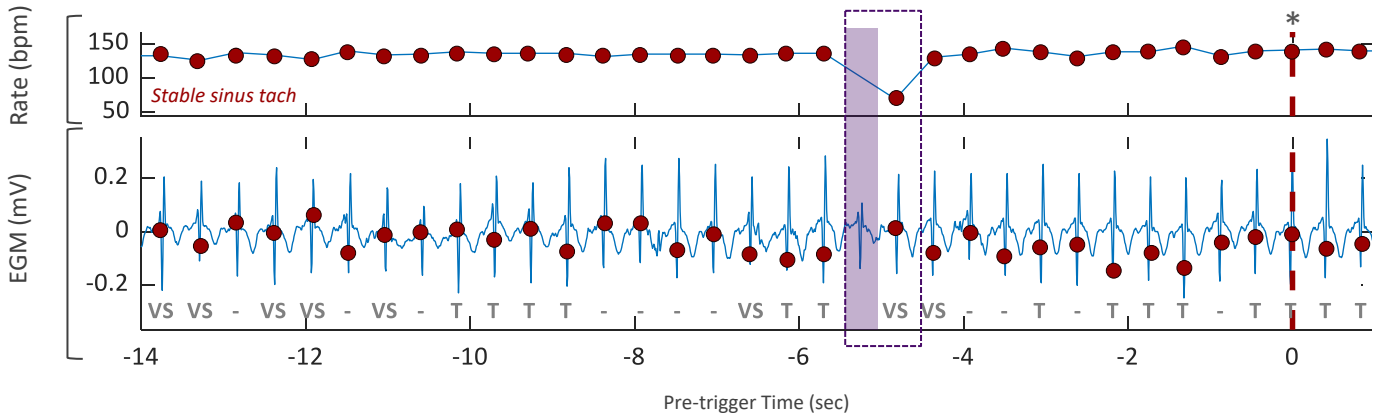
Tachy algorithm enhancement designed for intelligent recognition of T-wave oversensing and sequential R-T internals. An oversensed T-wave breaks up an R-R interval into two short intervals: R-T and T-R. The interval combination can be recognized by a short-long-short-long pattern because R-T is typically shorter than T-R.

*AF and Tachy discriminators analyze 30 seconds of data pre-trigger

Improving the Specificity of Atrial Fibrillation and Tachycardia Detection in an ICM

GOPINATHANNAIR ET AL. HRS POSTER 2022[1] (CONTINUED)

NEW R-wave Undersensing Discriminator



***Trigger Point**
Discriminators activated

The long R-R interval due to undersensing causes false sudden onset of a high ventricular rate (HVR)

Tachy algorithm enhancement designed for intelligent recognition of R-wave undersensing.
The enhancement detects R-wave undersensing and rejects false sudden onset detection. Enhanced discriminators prevent storing multiple EGM episodes during a stable tachycardia event, which ensures only clinically actionable data is captured.

*AF and Tachy discriminators analyze 30 seconds of data pre-trigger

Development and Evaluation of a New Algorithm Enhancement to Improve Specificity of Pause Detection in an ICM

AFZAL ET AL. HRS POSTER 2022[2]

KEY FINDINGS

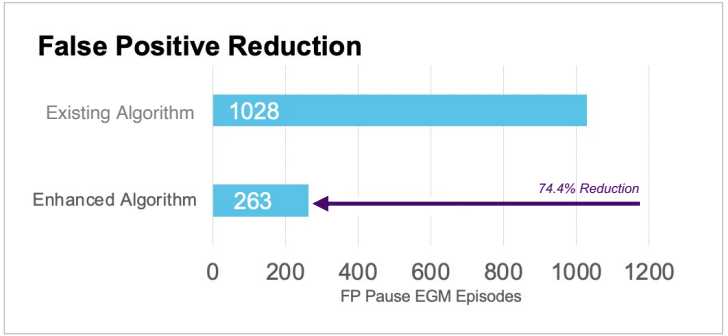
Advanced algorithm detection enhancements **reduced false Pause detections by 74.4%** while **maintaining 99.3% relative sensitivity** and may **improve efficiency in device clinic**.

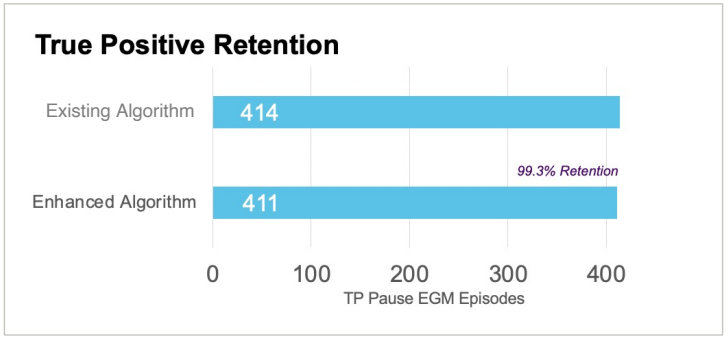
STUDY DESIGN

Existing algorithm for Pause discrimination was enhanced to reject false pause detections that exhibit any of the following phenomena:

- **Extremely small R-waves**
- **Signal baseline drift**
- **Signal saturation**
- **Fast ventricular rhythm (tachycardia) during undersensing**

STUDY METHOD
- Algorithm enhancements were trained on 7,178 consecutive EGMs from 1,490 ICM devices over 478 patient months of monitoring.
- The enhanced algorithm was subsequently tested on 1,442 consecutive EGMs from 349 devices over 87 patient-months of monitoring.





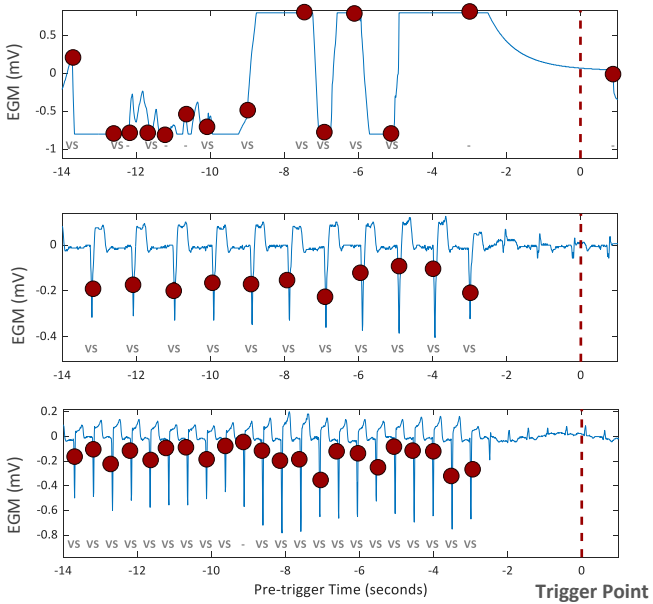
Development and Evaluation of a New Algorithm Enhancement to Improve Specificity of Pause Detection in an ICM

AFZAL ET AL. HRS POSTER 2022[2] (CONTINUED)

KEY FINDINGS, CONTINUED

Advanced algorithm detection enhancements **reduced false Pause detections by 74.4%** while **maintaining 99.3% relative sensitivity** and may **improve efficiency in device clinic**.

To the right are 3 examples of false positives handled by algorithm enhancements:



New Pause enhancement rejects false detection due to non-physiological interruption and signal saturation.

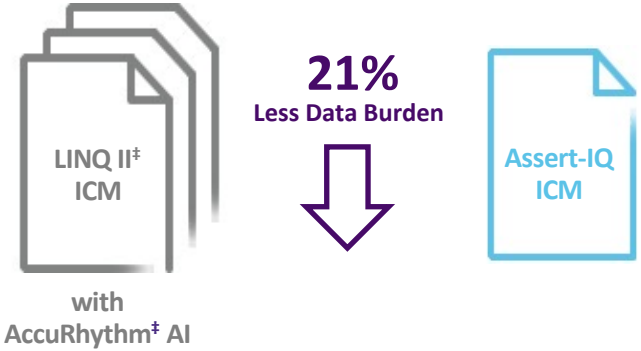
New Pause enhancement rejects false detection due to severe sudden drop of R-wave amplitude.

New Pause enhancement rejects false detection during tachycardia.

- Pause enhancement designed for rate adaptive R-wave and P-wave amplitude analysis for more appropriate secondary threshold search.
- Enhancement rejects false pause detection during tachycardia with sudden drop of R-wave amplitude.

Less Atrial Fibrillation Data Burden

Total EGMs per Patient per Month Transmitted to Clinic



	LINQ‡ II ICM with AccuRhythm‡ AI[9]	Assert-IQ ICM with Key Episodes turned On[10]
ICM Patients	434	509
AF EGMs	3,609	10,836
Total Months	3	9.5
AF Data Burden (AF EGMs/patient/month)	**2.8**	**2.2**

KEY FINDING

Assert-IQ™ ICM's AF algorithm **reduces data burden by 21% compared to LINQ II‡ with AccuRhythm‡ AI** while maintaining sensitivity.*,1,9,10

ANALYSIS METHOD

- AF EGM data burden in LINQ II‡ with AccuRhythm‡ AI was calculated from an HRS abstract.[9]
- AF EGM data burden in Assert-IQ ICM was calculated by applying new algorithm enhancements and key episode selection on AF EGMs triggered by predicate Abbott ICMs in a retrospective analysis.[10]
- Performance was evaluated by identifying total AF EGMs per patient over reported months.

*As of 12.31.22, LINQ II‡ with AccuRhythm‡ AI. EGM burden comparison is based on two independent, random, real world data sets. Patient characteristics and device programming may differ.

Evaluating the Impact of New Arrhythmia Detection Algorithms in an ICM

SHEHATA ET AL. APHRS POSTER 2022[4]

KEY FINDINGS

New advanced algorithms improved specificity of episodes while maintaining time-to-diagnosis of predicate ICMs.

- New algorithms reduced total EGMs by **35.6%.**

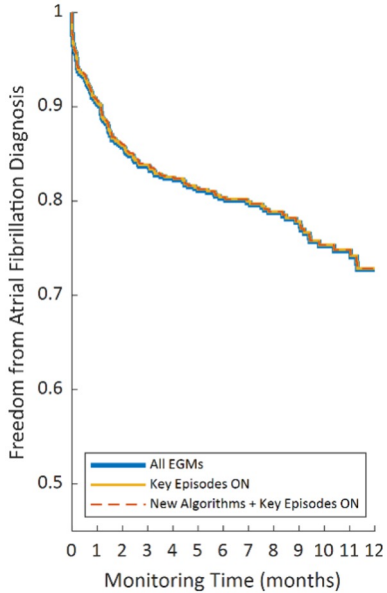
STUDY DESIGN

- Retrospective analyses of ***randomly selected*** Abbott ICM devices and their respective episode EGMs.
- Reduction in EGM review burden and time-to-diagnosis were compared with **Key Episodes** feature.

STUDY METHOD

In 821 ICMs, over a total of 469 patient-year remote follow-up duration, a total of 60,156 EGMs (35,723 AF; 12,194 Pause; and 12,239 Tachycardia) were transmitted.

Enhanced Algorithms Maintain AF Time-to-Diagnosis



New **Advanced Algorithms** achieved overlapping freedom from diagnosis in all three Kaplan Meier curves (AF, Pause, Tachycardia).

Evaluating the Impact of New Arrhythmia Detection Algorithms in an ICM

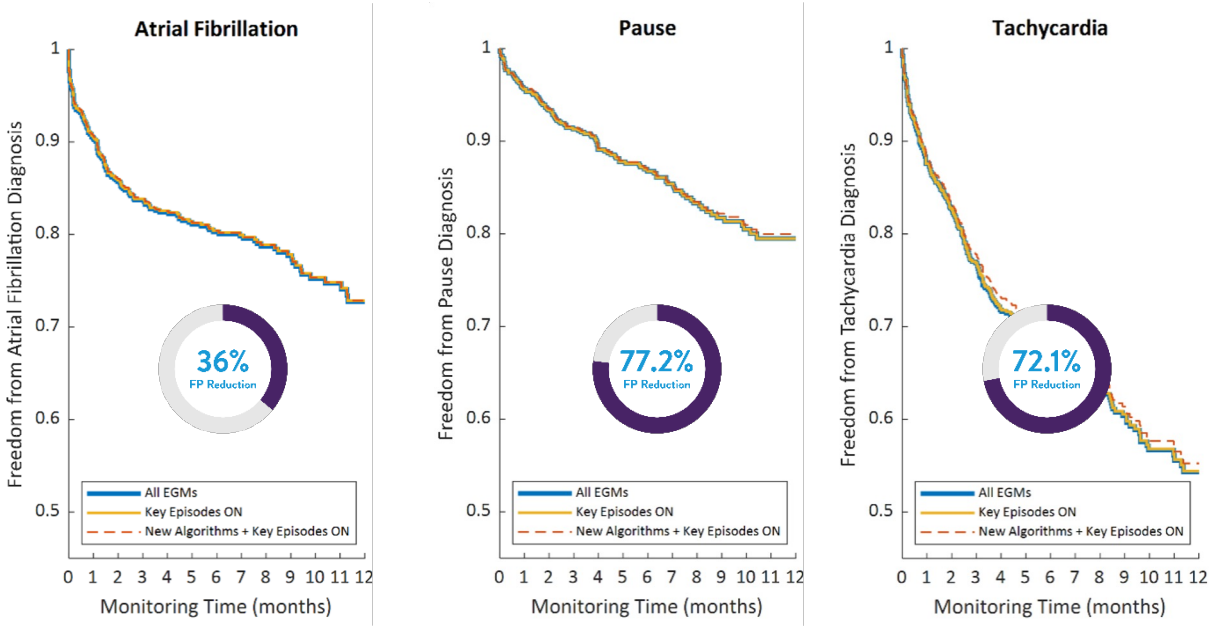
SHEHATA ET AL. APHRS POSTER 2022[4] (CONTINUED)

KEY FINDINGS, CONTINUED

Enhanced algorithms improved specificity:

- 36% FP Reduction for AF
- 77.2% FP Reduction for Pause
- 72.1% FP Reduction for Tachy

New algorithms reduced total EGMS by **35.6%** while maintaining time-to-diagnosis of predicate ICMs.



New **Advanced Algorithms** achieved overlapping freedom from diagnosis in all three Kaplan Meier curves (AF, Pause, Tachycardia).

Assert-IQ™
Insertable Cardiac Monitor (ICM)

PERFORMANCE BY THE NUMBERS

NEW IQ INSIGHTS

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Evaluation of a Novel Premature Ventricular Contraction (PVC) Detection Algorithm in an ICM

MANYAM ET AL. HRS POSTER 2022[12]

KEY FINDING

The novel PVC detection algorithm achieved **99.7% specificity** of consecutive events including couplets and triplets while detecting **75.8% of true PVCs** in the ICM sensed signal.

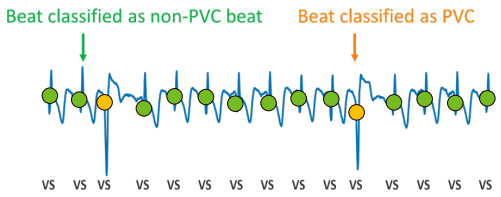
NOVEL ALGORITHM DESIGN

PVC detection tracks R-R interval (RRI) changes at each beat to identify premature beats, and then compares QRS morphologies to a self-updating template to verify the premature excitations are originated from the ventricles.

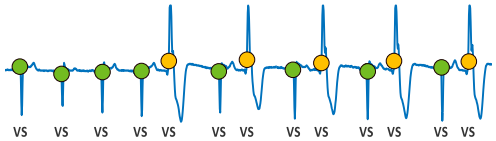
STUDY DESIGN

The PVC detection algorithm was trained on EGMs from 94 ICM devices, with a total duration of 832 minutes; and testing on EGMs from 100 independent devices, with a total duration of 864 minutes.

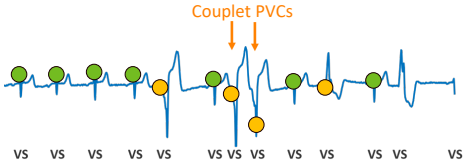
Isolated PVCs



Ventricular Bigeminy



Couplet PVCs and Isolated PVCs w/ Different Morphology



PVC Detection Performance on all Annotated PVC Beats

	Training	Testing
Sensitivity	78.6%	75.8%
Specificity	99.5%	99.7%
Positive Predictive Value	70.8%	82.7%
Negative Predictive Value	99.7%	99.5%

PVC detection performance demonstrating **99.7% specificity.**

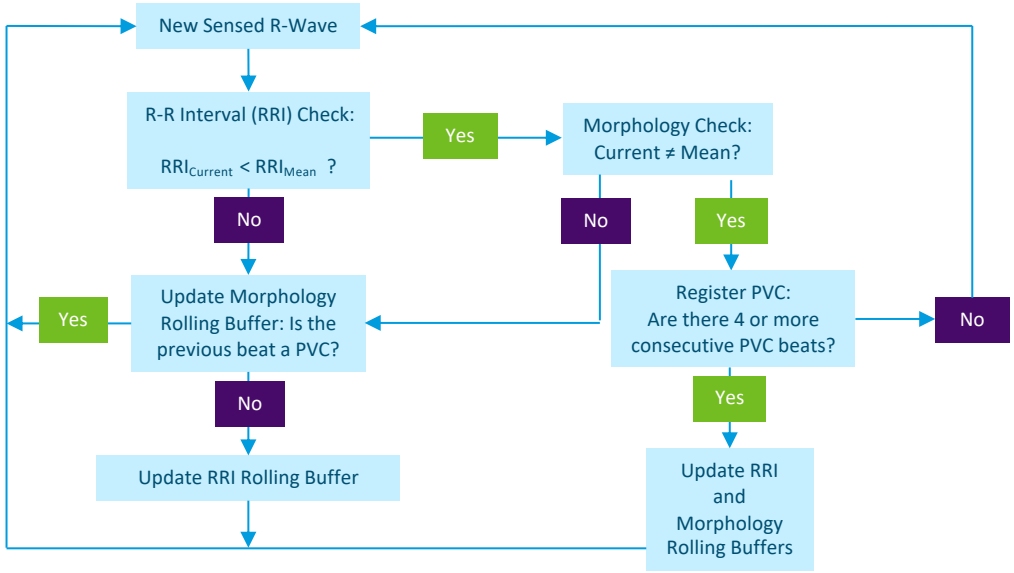
Evaluation of a Novel Premature Ventricular Contraction (PVC) Detection Algorithm in an ICM

MANYAM ET AL. HRS POSTER 2022[12] (CONTINUED)

ALGORITHM DESCRIPTION

- PVC detection accounts for fluctuations in heart rate and EGM signal amplitude changes by maintaining an RRI and QRS morphology rolling buffer.
- Rolling buffers consist of the most recent 3 intrinsic beats, which are updated on a first-in first-out fashion.
- QRS morphology comparison uses area under the curve, peak amplitudes, and polarity changes to identify beats that are significantly different from intrinsic beats and classifies them as PVCs.

Diagram of PVC Detection Algorithm



Assert-IQ™
Insertable Cardiac Monitor (ICM)

ECG/EKG

CLEAR, CRISP P-WAVES

Abbott

ICM P-wave Visibility in a New Clinical Report

SHEHATA ET AL. APHRS POSTER 2022[14]

KEY FINDING

P-waves were visible in 89.8% of analyzed beats.

- 90.9% of EGMs reviewed had P-waves visible in >50% of heart beats (see table on right).

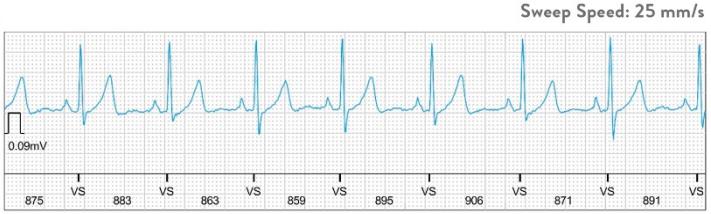
P-wave visibility could:

- **Reduce clinic burden and time to review ICM data.**
- Facilitate rhythm interpretation and increase confidence in rhythm diagnosis.

STUDY DESIGN
All presenting rhythm EGMs were displayed in vector-graphic PDF reports and reviewed by two independent reviewers to count beats with P-waves visible in each EGM. PVC complexes were excluded.

STUDY METHOD
Merlin.net™ Patient Care Network (PCN) in December 2021 identified 101 sequential patients with remote transmissions at 30, 60, and 90 days post implant.

Example of Presenting Rhythm EGM



Presenting rhythm example from a vector-graphic PDF displaying NSR.

P-wave Visibility Summary

Post-implant time	Total beats analyzed (n)	Beats with visible P-wave (%)	EGMs with visible P-wave in >50% of beats (%)
Day 30	1429	89.1%	90.4%
Day 60	1459	90.8%	92.0%
Day 90	1500	89.4%	90.3%

P-wave visibility was consistent over time (day 30: 89.1%; day 60: 90.8%; day 90: 89.4%). No patient had zero P-wave visibility.

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IMPORTANT SAFETY INFORMATION

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 for Use: The Assert-IQ™ ICM is indicated for the monitoring and diagnostic evaluation of patients who experience unexplained symptoms that may be cardiac-related such as: dizziness, palpitations, chest pain, syncope, and shortness of breath, as well as patients who are at risk for cardiac arrhythmias such as bradycardia, tachycardia, and sinus pauses.

The Assert-IQ ICM is also indicated for patients who have been previously diagnosed with atrial fibrillation (AF) or who are susceptible to developing AF. The Assert-IQ ICM is intended to be inserted subcutaneously in the left pectoral region, also described as the left anterior chest wall. The Assert-IQ ICM has not been specifically tested for pediatric use.

Intended Use: The Assert-IQ ICM is intended to help physicians and clinicians monitor, diagnose and document the heart rhythm in patients who are susceptible to cardiac arrhythmias and unexplained symptoms by detecting arrhythmias and transmitting data for review.

Contraindications: There are no known contraindications for the insertion of the Assert-IQ ICM. However, the patient's particular medical condition may dictate whether or not a subcutaneous, chronically inserted device can be tolerated.

Potential 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 for use, contraindications, warnings, precautions and potential adverse events.

An Abbott mobile transmitter is available for patients without their own compatible mobile device.

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