

**CONFIRM Rx™ ICM**  
with SharpSense™ Technology



CAPTURING  
THE **RHYTHM**  
**OF LIFE**



## OVERVIEW AND SHARPSense™ TECHNOLOGY ENHANCEMENTS



## PAIRING AND CONNECTIVITY



## FOLLOW-UP ON MERLIN.NET™ PCN



# Topics Covered

- Introduction to Cardiac Monitoring
- Advantages and Challenges
- Recent Enhancements

# CRM Devices at a Glance

**Insertable  
Cardiac Monitors**

**Monitors  
heartbeat**

**Pacemakers**

**Heartbeat  
is too slow**

**Defibrillators**

**Heartbeat  
is too fast**

**Cardiac  
Resynchronization  
Therapy**

**Heartbeat is  
out-of-sync**

# What is a Cardiac Monitor?

## RECORDING DEVICE

- Records EKGs
- Used to identify and diagnose cardiac arrhythmias

## USED TO IDENTIFY PATIENTS WITH SLOW, FAST OR IRREGULAR HEART RATES

- Pacemaker/ICD implantation requires documentation of arrhythmia ***correlating*** with patient symptoms
- Cardiac monitors provide the documentation (EKG) and the ability for the patient to document symptoms

# Who Needs a Cardiac Monitor?

**SYNCOPE/  
PRE-SYNCOPE**  
(Fainting)

**SUSPECTED  
ARRHYTHMIA**

**ATRIAL  
FIBRILLATION**

# What is Syncope?

## **FAINTING. CAUSES INCLUDE:**

- Reflex syncope
- Orthostatic syncope
- Cardiac arrhythmias
- Structural cardiopulmonary disease

## **CARDIAC MONITORS HELP PHYSICIANS**

- Correlate patient symptoms with cardiac arrhythmias
- Rule out cardiac arrhythmia as the cause of syncope



# What is a Suspected Arrhythmia?

## **PATIENT DESCRIBES SYMPTOMS AS HEART RELATED**

- Palpitations
- Chest pain
- Shortness of breath

## **CARDIAC MONITORS HELP PHYSICIANS**

- Document cardiac arrhythmias
- Correlate patient symptoms



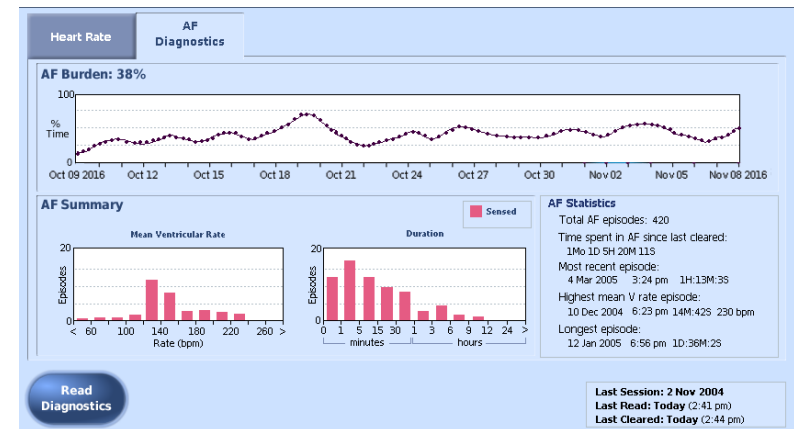
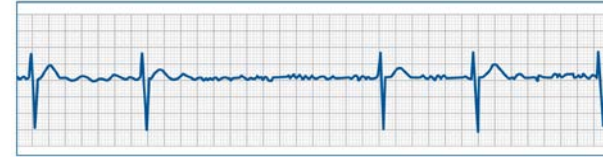
# What is AF?

## ATRIAL FIBRILLATION (AF, Afib)

- Upper chambers of the heart beat fast and erratically (300–400 bpm)
- Can lead to blood clots, stroke, heart failure

## CARDIAC MONITORS HELP PHYSICIANS

- Diagnose AF as it may be undiagnosed
- Quantify AF burden
- Correlate patient symptoms

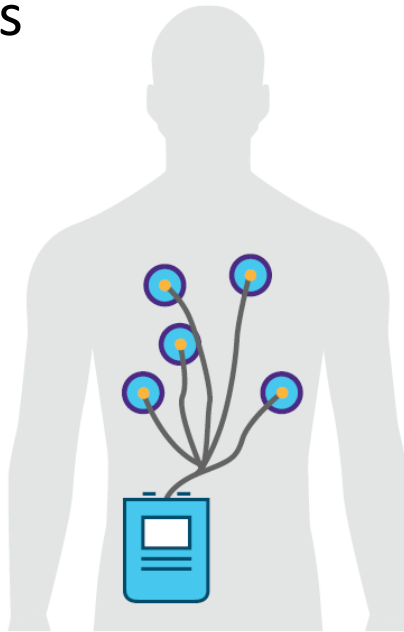




# Types of Cardiac Monitors

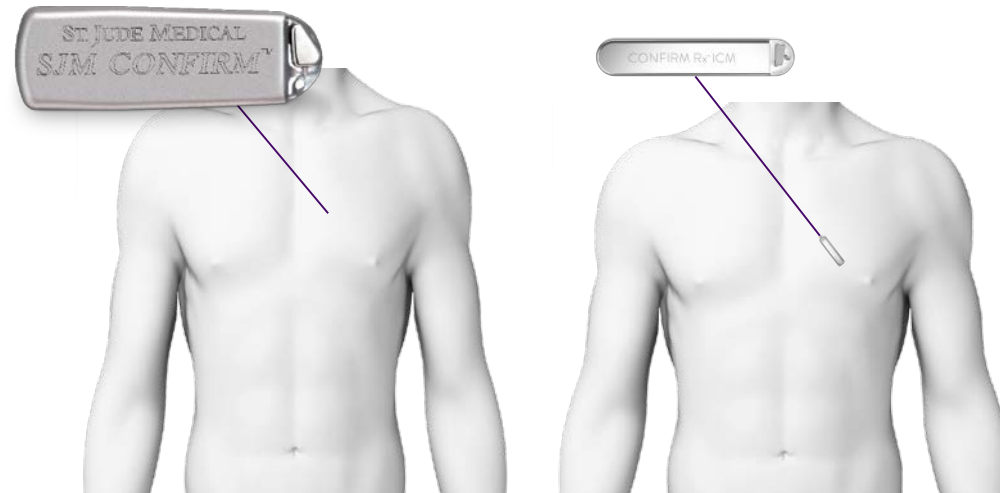
## EXTERNAL

- Holter Monitors
- Event Recorders
- Wearables



## INTERNAL

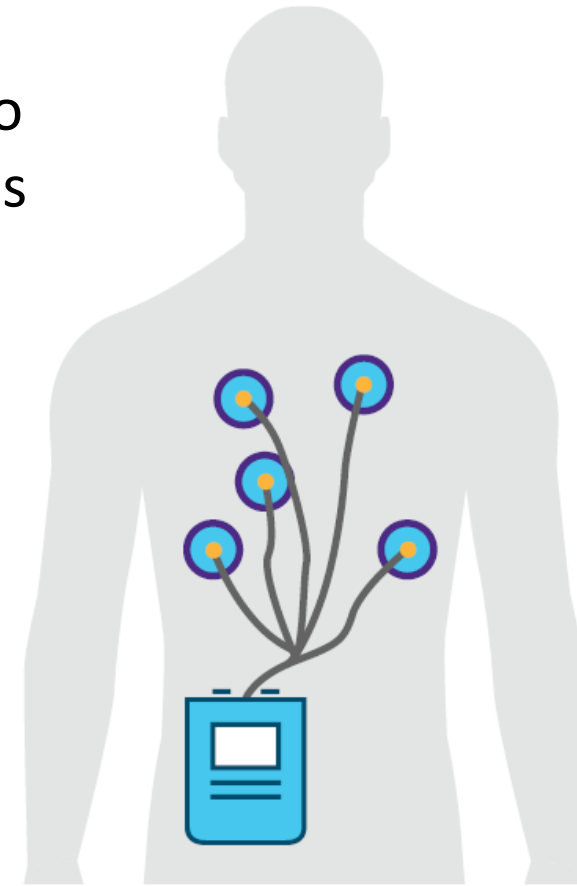
- Implantable/Insertable



# Limitations of EXTERNAL Cardiac Monitors

## HOLTER MONITORS, EVENT RECORDERS, WEARABLES

- A recorder you can use for up to 30 days that attaches to the skin. The patient can press when they feel symptoms
- Patient compliance issues
  - Cumbersome wires
  - Difficulty operating/transmitting
  - Skin irritation
  - Interference with work, activities or travel
  - Forget to transmit data
  - Charging required, so monitoring is not continuous
  - Noticeably visible, conspicuous



Rothman, S. A., et al. The Diagnosis of Cardiac Arrhythmias: A Prospective Multi-Center Randomized Study Comparing Mobile Cardiac Outpatient Telemetry Versus Standard Loop Event Monitoring (2007). *Journal of Cardiovascular Electrophysiology*, 18(3):241-247.

CSS Insight. Success of Apple Watch Means More Growth in Sales of Wearable Technology <https://www.ccsinsight.com/press/company-news/3695-success-of-apple-watch-means-more-growth-in-sales-of-wearable-technology>. Accessed June 26th, 2019.

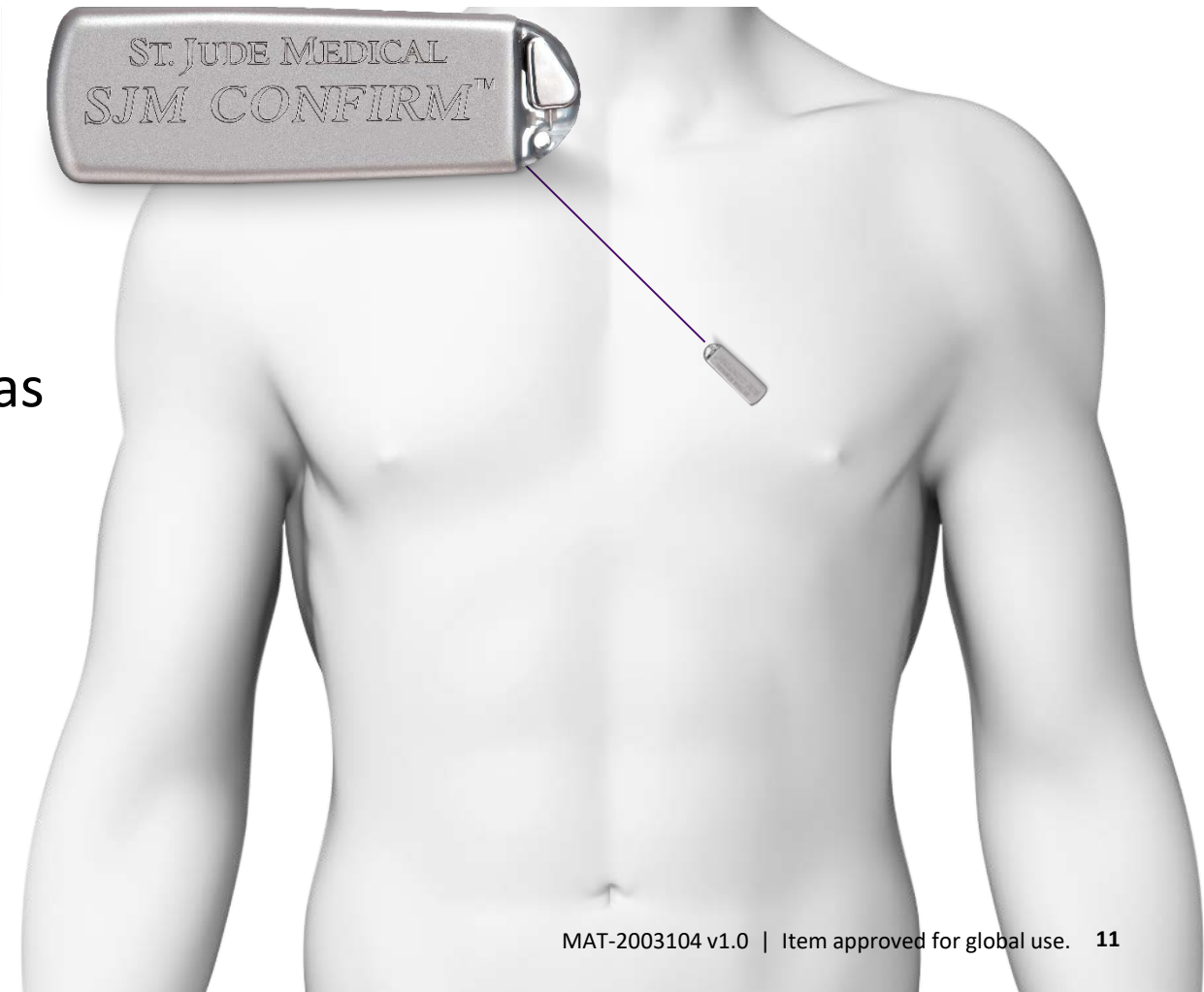
# Advantages of IMPLANTABLE/INSERTABLE Cardiac Monitors

## CAPTURE VALUABLE DIAGNOSTIC INFORMATION

- Documentation doesn't require patient compliance

## ALLOW PHYSICIANS TO

- Accurately diagnose infrequent arrhythmias
- Provide appropriate patient care
  - Identify indicated patients for treatment: (pacemaker or defibrillator implant)



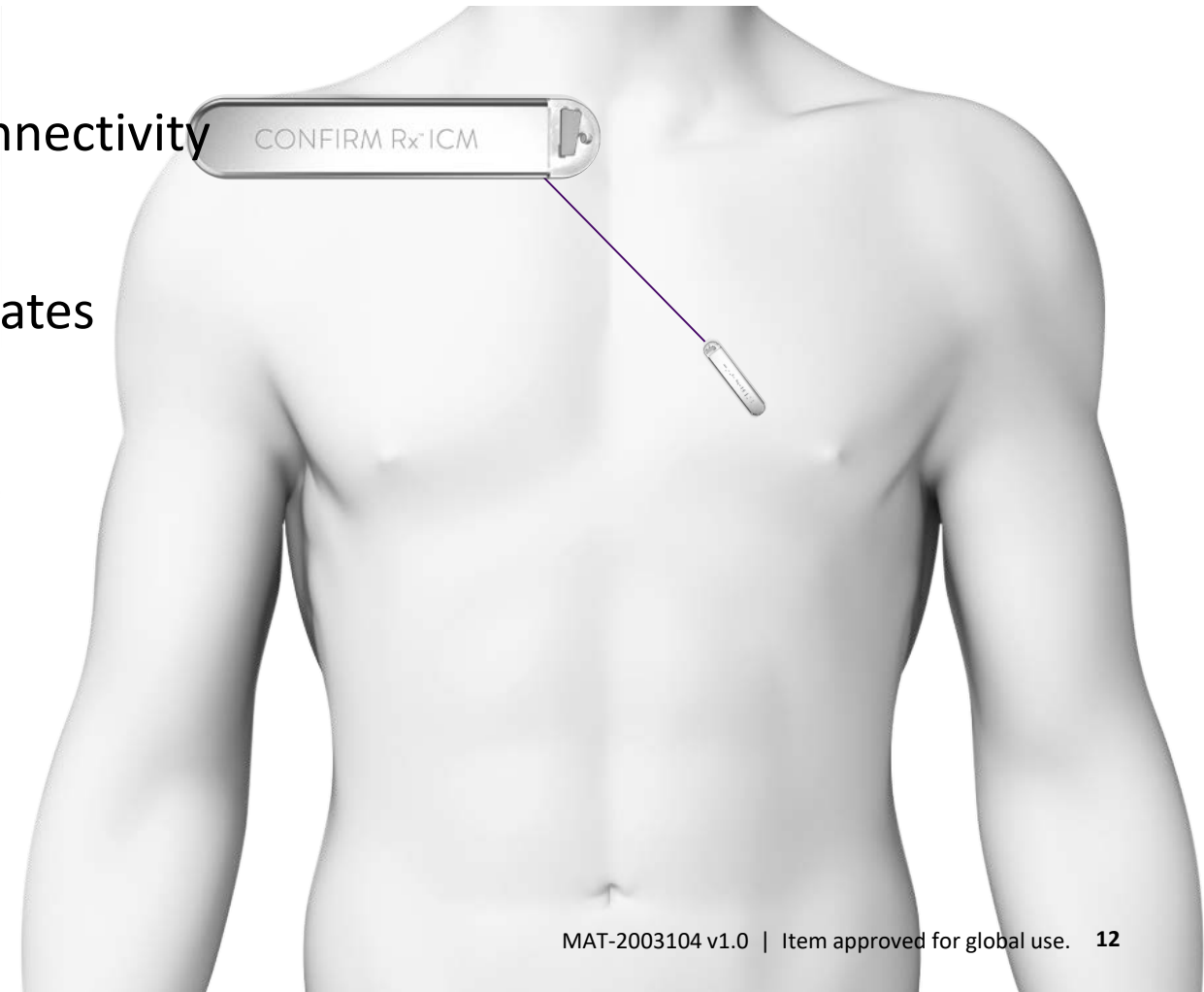
# INSERTABLE Cardiac Monitors

## MINIATURIZED CARDIAC MONITORS

- Less invasive, simple insertion procedure
- Bluetooth® wireless technology or wireless connectivity
- Inconspicuous/discreet
- Still provide continuous monitoring for heart rates (too slow, too fast or irregular)

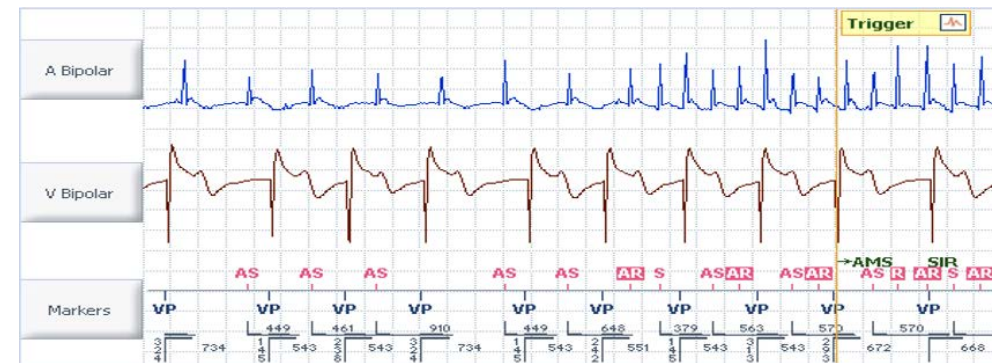
## CHALLENGES

- Managing data burden
  - Clinical relevance of short episodes
  - EKG interpretation without atrial lead
- Managing patient expectations



# Challenges with INSERTABLE Cardiac Monitors

## AF DETECTION with ICMs versus traditional CRM devices



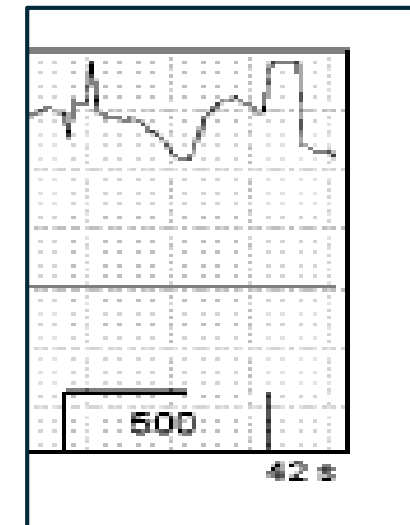
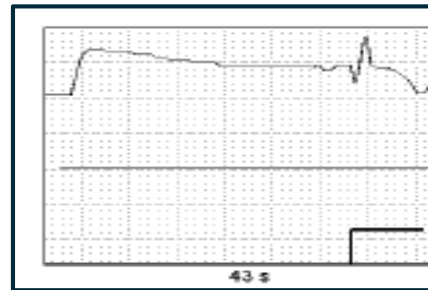
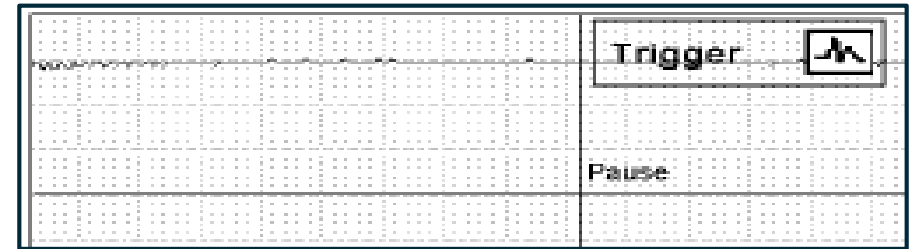
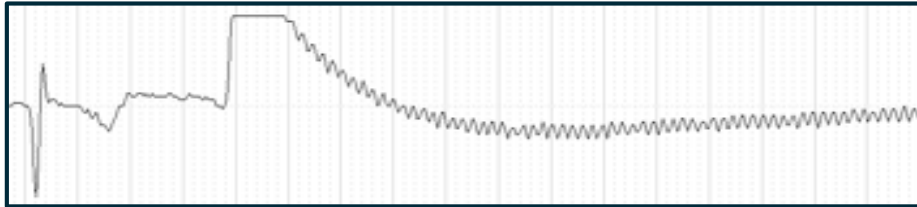
### POSSIBLE CAUSES:

- Only two electrodes versus leads in the top and bottom chambers of the heart
- Dependent on visualization of P-waves
- Oversensing/undersensing

# Challenges with INSERTABLE Cardiac Monitors

## LOSS OF CONTACT

ELECTRODE LOSES CONTACT WITH PATIENT TISSUE

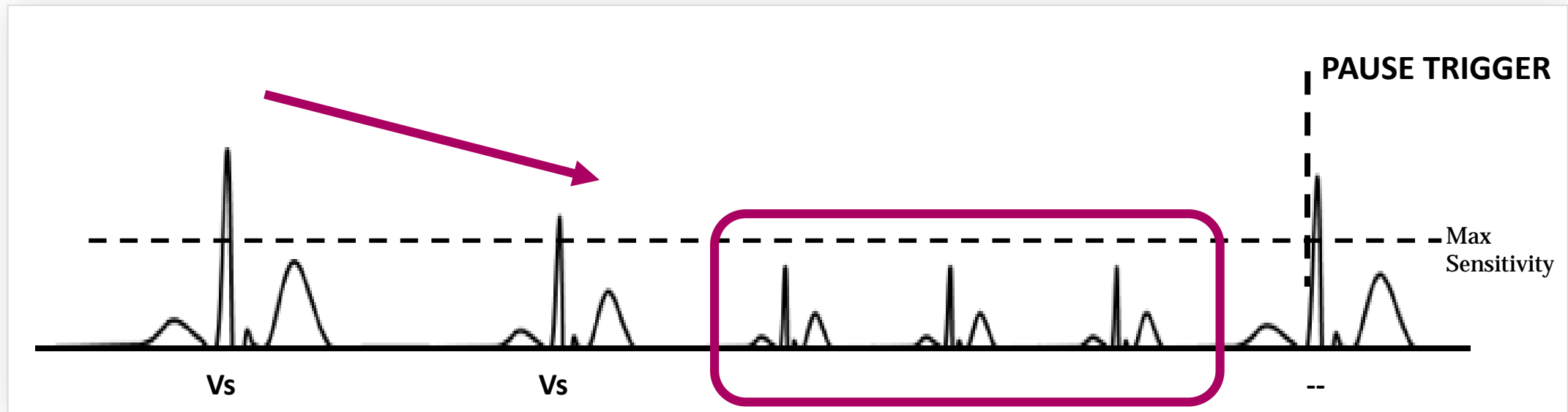


### POSSIBLE CAUSES:

- Loose pocket
- Hematoma, air entrapment at time of implant
- Positional changes (e.g., side sleeping)

# Challenges with INSERTABLE Cardiac Monitors

## DECLINING, VARIABLE or SMALL R-WAVES



### POSSIBLE CAUSES:

- Loose pocket
- Positional changes

# Sensitivity and Specificity: THE CONCEPTS

## WHAT ARE THEY AND WHAT DO THEY MEAN IN MEDICAL DEVICES?

**SENSITIVITY** measures actual positives that are correctly identified as positives.

- **FOR EXAMPLE:** *An AF episode identified by the ICM that REALLY is an AF episode*

**SPECIFICITY** measures actual negatives that are correctly identified as negatives.

- **FOR EXAMPLE:** *If the patient is not in AF but is in Sinus Rhythm and the device does identify it as Sinus Rhythm*



**SENSITIVITY THEREFORE QUANTIFIES THE AVOIDING OF FALSE NEGATIVES, AND SPECIFICITY DOES THE SAME FOR FALSE POSITIVES. FOR ANY TEST, THERE IS USUALLY A TRADE-OFF BETWEEN THE MEASURES.**



# Sensitivity and Specificity: THE CONCEPTS

Measure of the **number** of real episodes that are correctly identified as episodes in both the ICM and Holter

EPISODE  
SENSITIVITY



EPISODE  
SPECIFICITY



Measures the duration (minutes) of real AF that are correctly identified as AF from the onset to the end

DURATION  
SENSITIVITY



DURATION  
SPECIFICITY



Sensitivity of the ICM for diagnosing patients with any AF

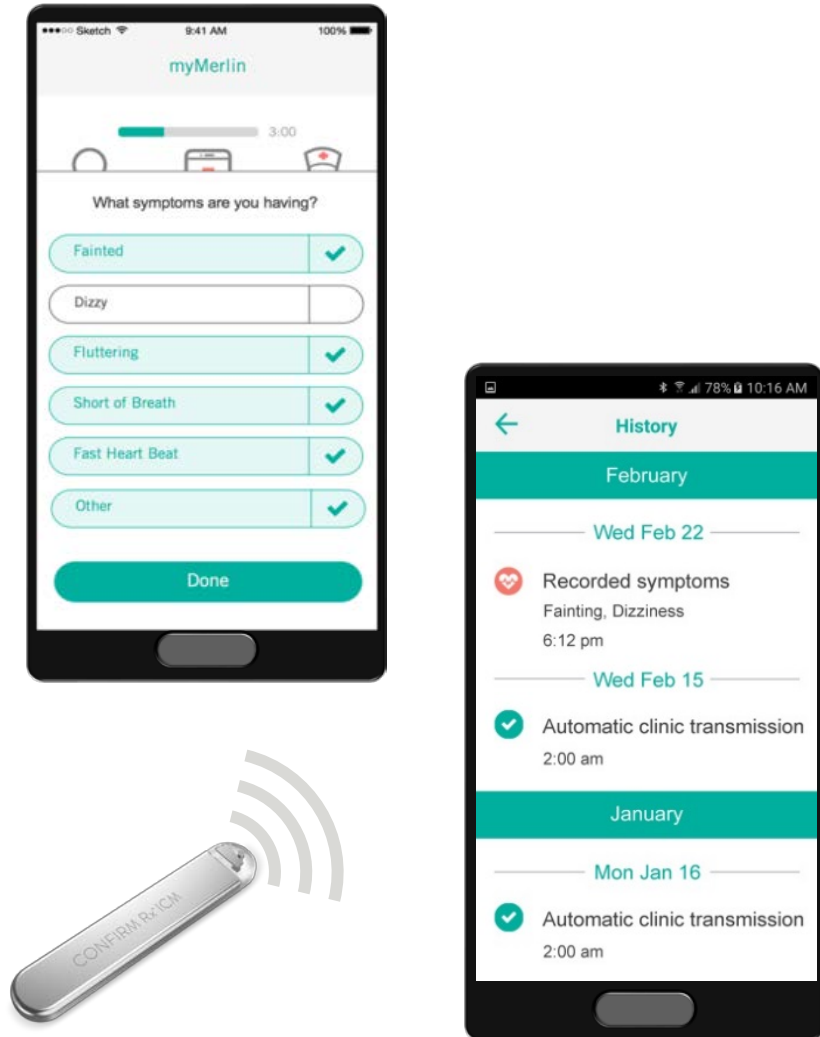
PATIENT  
SENSITIVITY



Measure of the **number** of non-AF episodes recorded by the Holter and not detected by the ICM

Measures the duration (minutes) of the false positive recorded out of all minutes the patient was not in AF

# Confirm Rx™ ICM Firsts



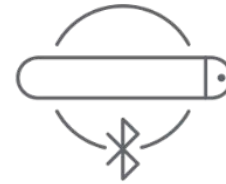
- App-based recording of patient-initiated symptomatic events
- Patients can annotate symptomatic events with specific keywords, such as **“fainted”** or **“fast heart rate”**
- Enables the patient to verify and view past transmissions, including recorded symptoms, and access troubleshooting resources, both of which may reduce clinic burden
- Notification of daily device checks and scheduled transmissions allows patients to stay compliant to remote monitoring while reducing clinic follow-up burden

# CONFIRM Rx™ ICM

with SharpSense™ Technology



**DELIVER  
CONVENIENTLY**



**DETECT  
ACCURATELY**

**DECIDE  
CONFIDENTLY**

# SharpSense™ Technology Represents Abbott Learnings and Customer Feedback

## KEY TECHNOLOGY UPDATES

### PAUSE ALGORITHM ENHANCEMENTS

Pause Undersensing and Loss of Contact Discriminators

### BRADYCARDIA ALGORITHM ENHANCEMENT

Bradycardia Undersensing Discriminator

### AF ALGORITHM ENHANCEMENT

P-wave Discriminator

## SETTINGS AND DATA PRESENTATION

### NEW NOMINAL SETTINGS

Bradycardia Cutoff Rate 30 bpm | Max Sensitivity 0.125 mV

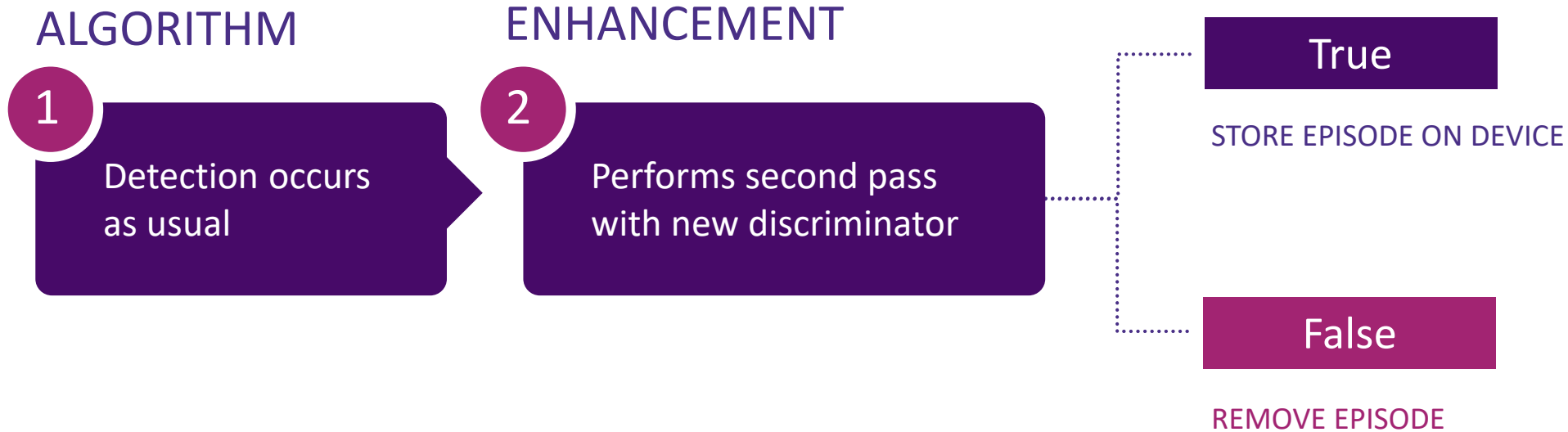
### SCATTERPLOT REPORTS

New Heart Rate vs. Time Graphs

# DETECT ACCURATELY

# DETECT Accurately with SharpSense™ Technology

SHARPSENSE TECHNOLOGY OFFERS NEW DISCRIMINATORS THAT VERIFY THE ACCURACY OF POTENTIAL EVENTS



# DETECT Accurately with SharpSense™ Technology

## FOUR NEW DISCRIMINATORS ENHANCE CURRENT ALGORITHMS

### BRADYCARDIA UNDERSENSING DISCRIMINATOR

Bradycardia Algorithm

### PAUSE UNDERSENSING DISCRIMINATOR

Pause Algorithm

### P-WAVE DISCRIMINATOR

AF Algorithm

### LOSS OF CONTACT DISCRIMINATOR

Pause Algorithm

# DETECT Accurately with SharpSense™ Technology

## RELATIVE SENSITIVITY

BRADYCARDIA	99% <sup>1</sup>
PAUSE	98% <sup>1</sup>
AF	97% <sup>1</sup>

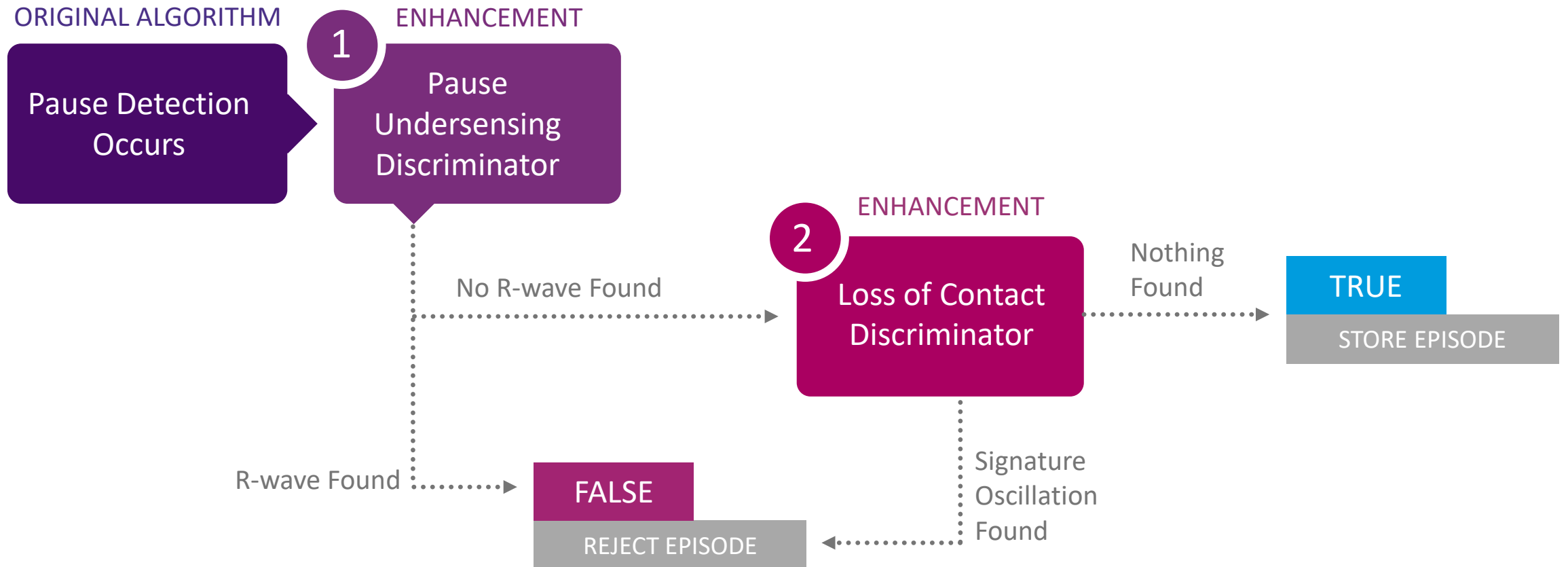
97%

REDUCTION IN FALSE  
DETECTION OF  
EVENTS\*<sup>2</sup>

\*Determined by evaluation of real-world episodes in previously identified devices, using SharpSense™ technology.  
1. Design Validation Report and Trace Matrix, Insertable Cardiac Monitor (ICM) System DOC 60076435 Rev. E. March 2019.  
2. Evaluation of Clinic Impact of Confirm Rx 1.2 Algorithm Enhancements. Abbott document 60098828. April 2019.



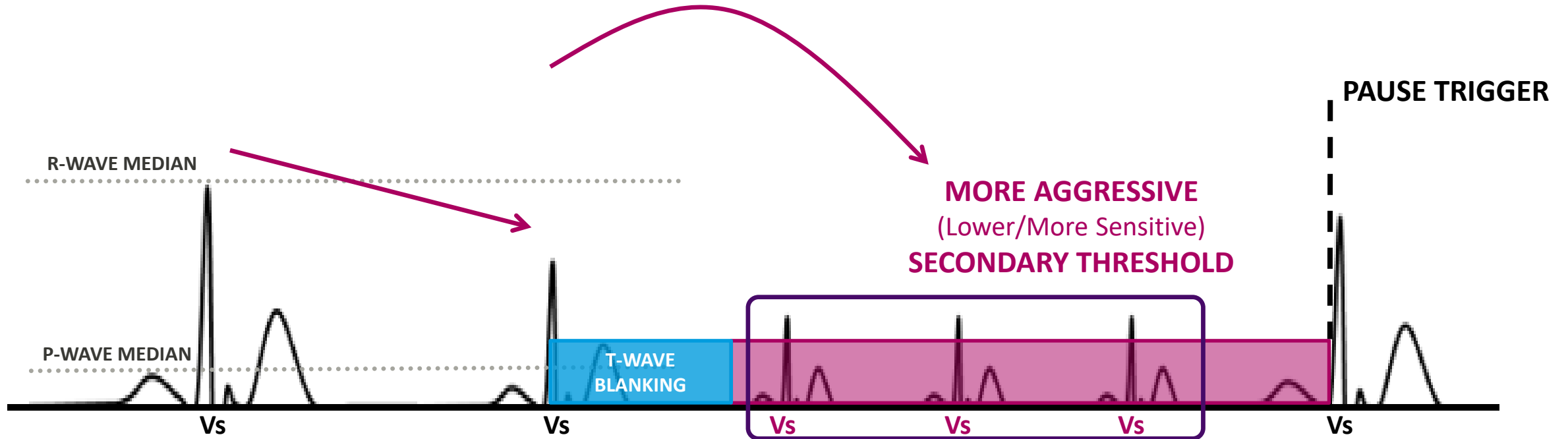
# PAUSE EPISODE Detection Uses Two Enhancements



# Calculating SECONDARY THRESHOLD Pause Discriminator

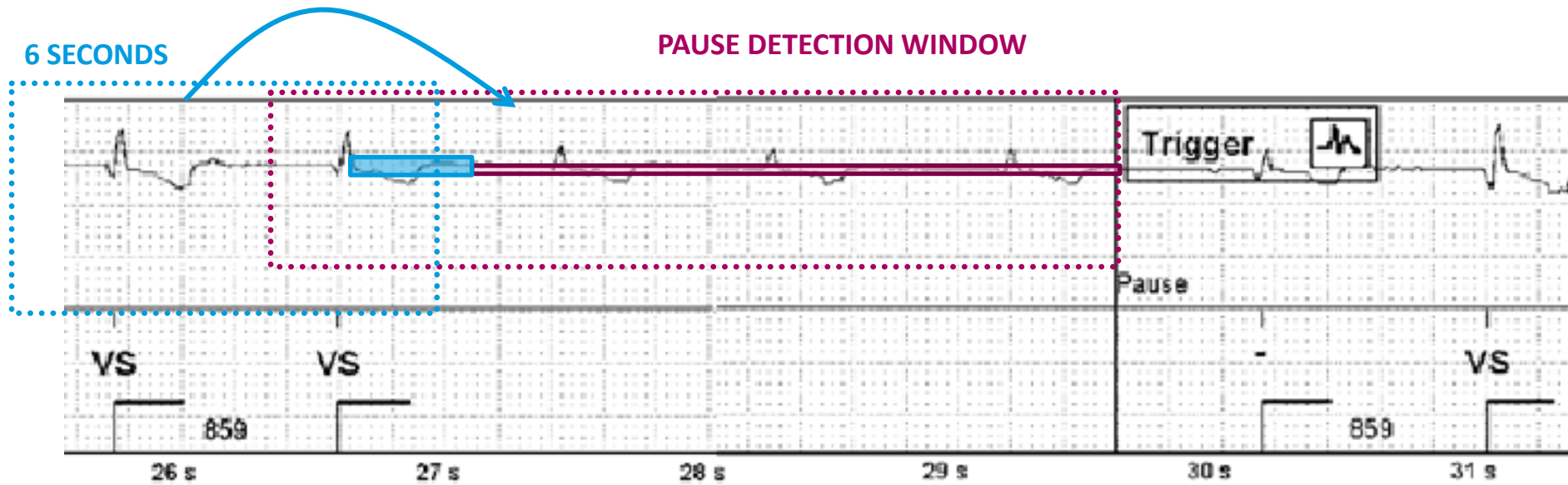
DECLINING, VARIABLE or SMALL R-WAVES?



UNDERSENSED BEATS FOUND?  
Remove Pause Episode



# SharpSense™ Technology In Action

ANALYZES P-/R-WAVES IN WINDOW PRIOR TO THE PAUSE TO DETERMINE OPTIMAL SECONDARY THRESHOLD TO APPLY IN PAUSE DETECTION WINDOW



-  T-WAVE BLANKING applied to last sensed beat before the Pause
-  SECONDARY THRESHOLD applied to Pause window to search for undersensed beats

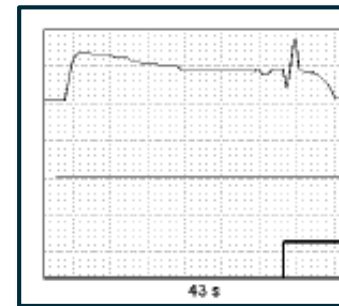
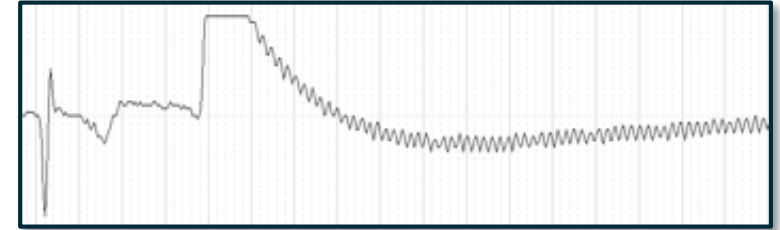
# Loss Of Contact Discriminator

## BACKGROUND:

All false Pause detections due to Loss of Contact observed a small characteristic noise signal

**NOTE:** May not be apparent in the PDF

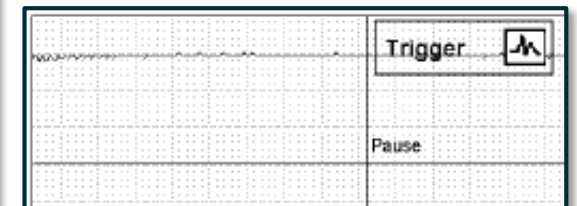
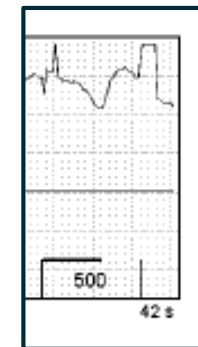
The small characteristic noise signal is not always readily visible on stored EGMs



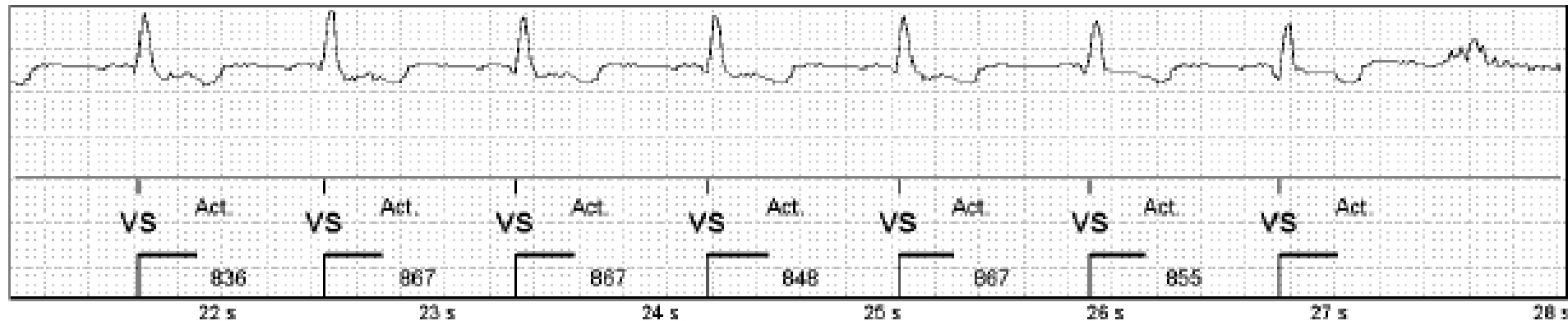
## THE SOLUTION:

Loss of Contact Discriminator will:

- Look for the small noise signal in the VEGM signal when the existing algorithm detects a Pause episode
- Reject the original Pause detection if the analyzed EGM section shows a characteristic signature oscillation



# Loss Of Contact



If a CHARACTERISTIC SIGNATURE OSCILLATION IS PRESENT during 2 seconds prior to trigger, EPISODE IS REJECTED

# BRADYCARDIA Discriminator Decision Tree

ORIGINAL ALGORITHM

Bradycardia  
Detection Occurs

ENHANCEMENT

Bradycardia  
Undersensing  
Discriminator

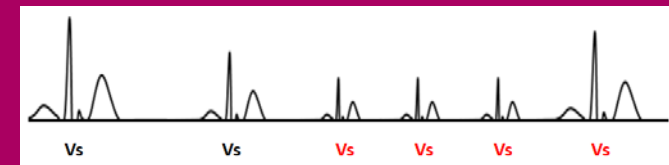
Calculates new intervals based on any new  
beats found with Secondary Threshold

If 3 of 4 initially detected Bradycardia  
beats are truly Bradycardia beats  
(no undersensing found)



STORE EPISODE

If 2 of 4 initially detected Bradycardia  
beats are **NOT** in fact Bradycardia beats  
(undersensing found)



REJECT EPISODE

# BRADYCARDIA Discriminator in Action

## IF UNDERSENSED BEATS ARE FOUND

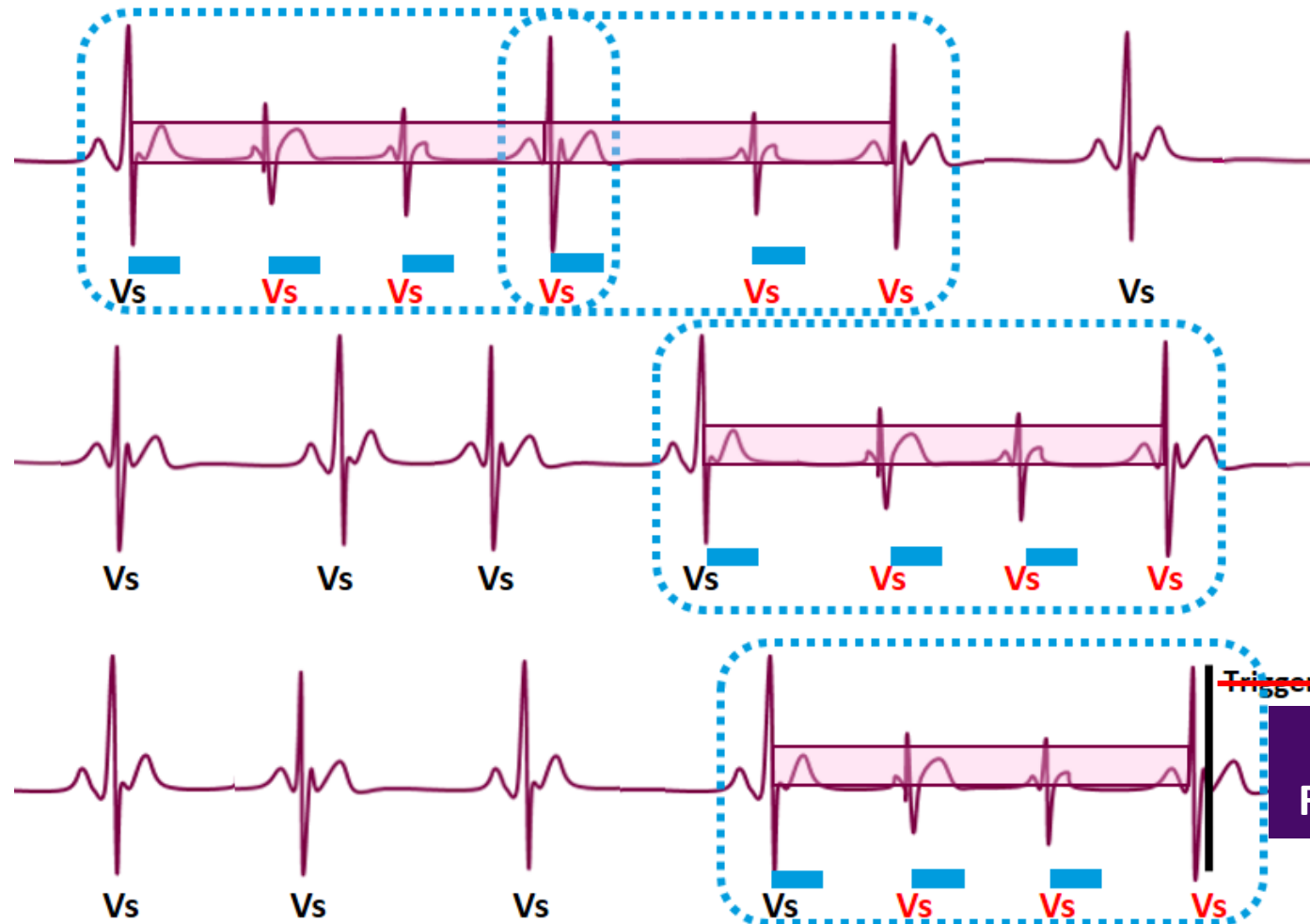
the device recalculates the intervals in each window

## ACCEPTS

if **3 of 4** initially detected Bradycardia beats are truly Bradycardia beats

## REJECTS

if **2 of 4** detected Bradycardia beats are NOT in fact Bradycardia beats



# AF DETECTION Algorithm Overview

## ALGORITHM TESTS

**REGULARITY** — evaluates the rhythm pattern to determine whether it is regular or irregular

**VARIANCE** — evaluates the variance of R-R intervals; the larger the variance, the more likely the rhythm is AF (vs. patterned rhythms such as bigeminy)

**SUDDEN ONSET** — evaluates how the rhythm initiates

**ALL 3 TESTS MUST INDICATE AF FOR AN EPISODE TO BE TRIGGERED**

- 64-BEAT EVALUATION WINDOW
- 3 TESTS EVALUATE RHYTHM

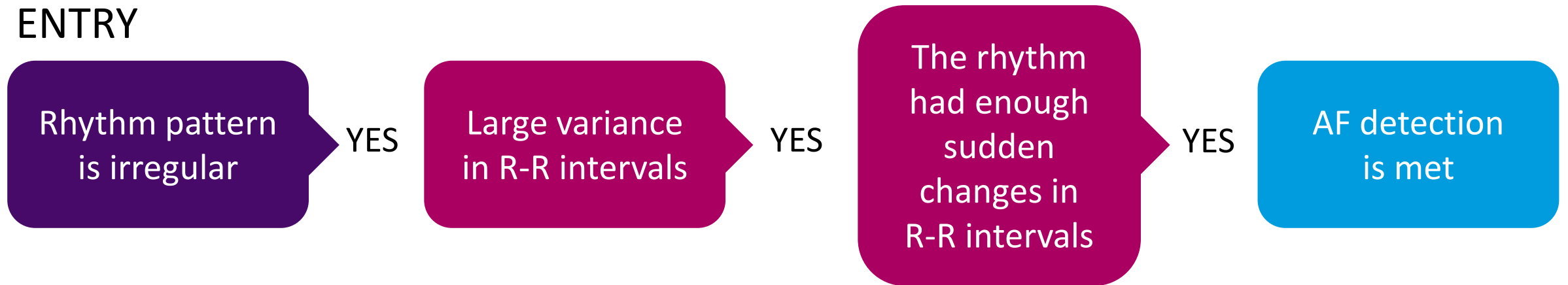
ALGORITHM TEST	ALGORITHM DETERMINATION	
Regularity	✓ Irregular	✗ Irregular
Variance	✓ Large Variance	✗ Large Variance
Sudden Onset	✓ Yes	✗ No
Algorithm Response	Trigger AF Episode	No Trigger

✓ Indicates rhythm is AF ✗ Indicates rhythm is not AF

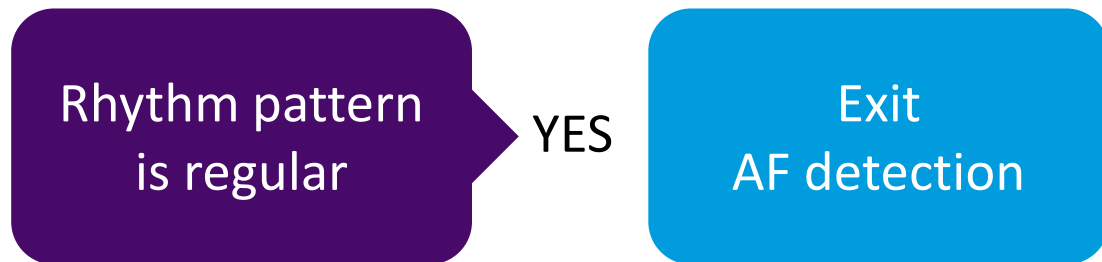


# AF EPISODE Entry and Exit

## ENTRY



## EXIT



# AF DETECTION Decision Tree

## ORIGINAL ALGORITHM

AF detection occurs

## ENHANCEMENT

AF undersensing discriminator

Searches for consistent P-waves presence in 30 seconds prior to detection

If consistent P-waves are not found

STORE EPISODE

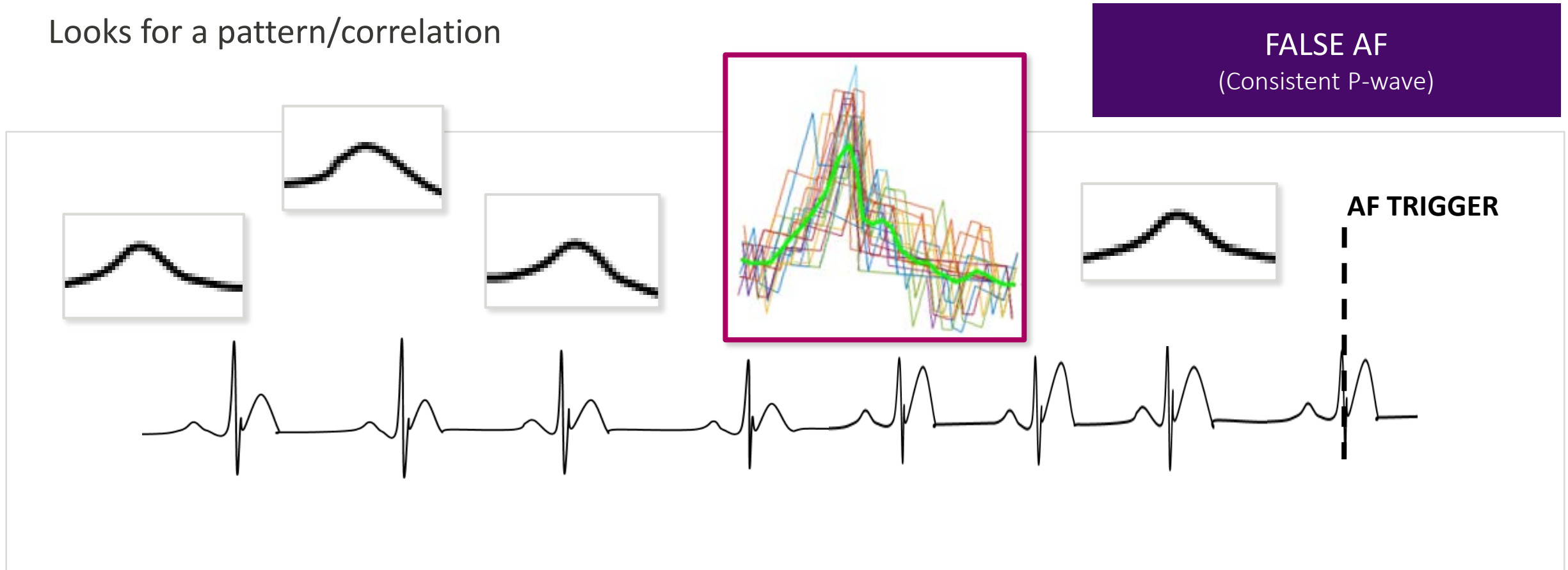
If consistent P-waves are found

REJECT EPISODE

# The P-Wave Discriminator

## STACKS P-WAVE SEGMENTS OF SELECTED BEATS

Looks for a pattern/correlation

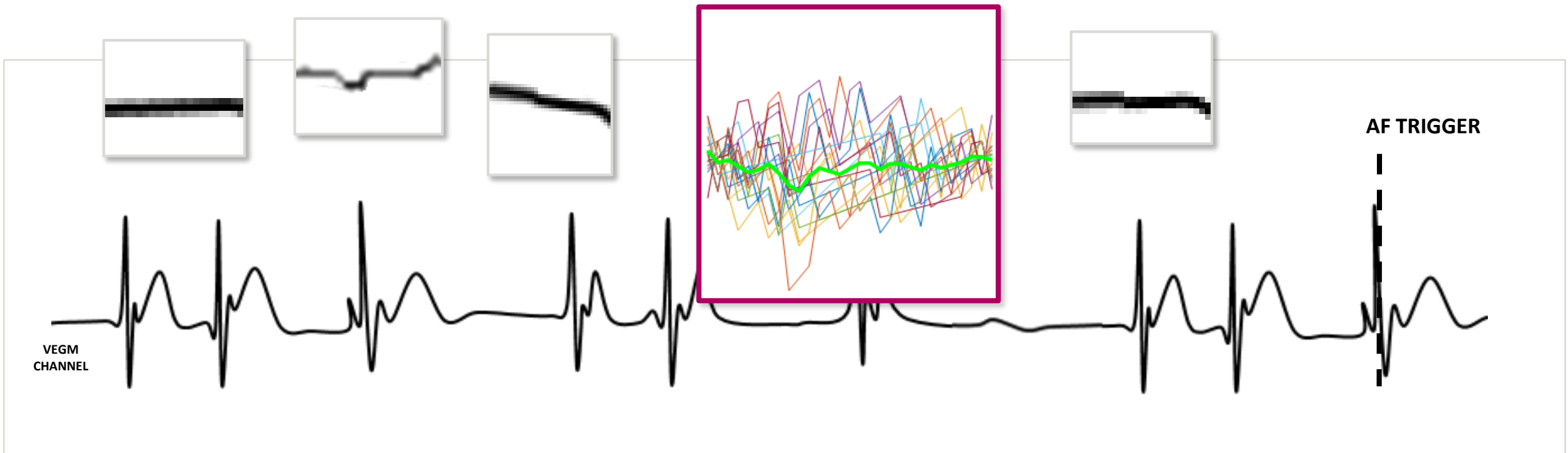


# The P-Wave Discriminator

STACKS P-WAVE SEGMENTS OF QUALIFIED BEATS  
TOGETHER TO GET AN AVERAGED P-WAVE

Evaluates correlation, morphology and amplitude

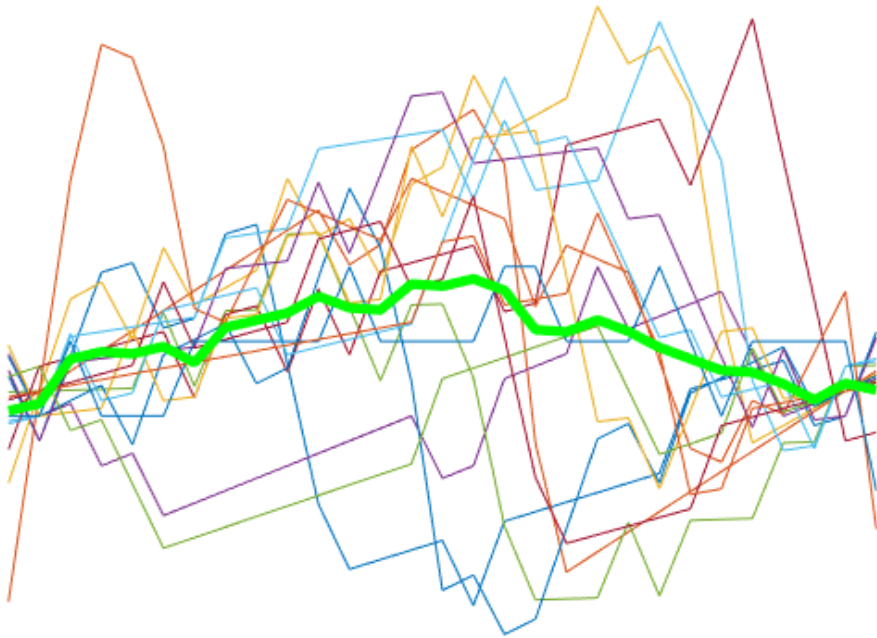
TRUE AF  
(No consistent P-wave)



# Individual and Ensemble Averaged P-waves

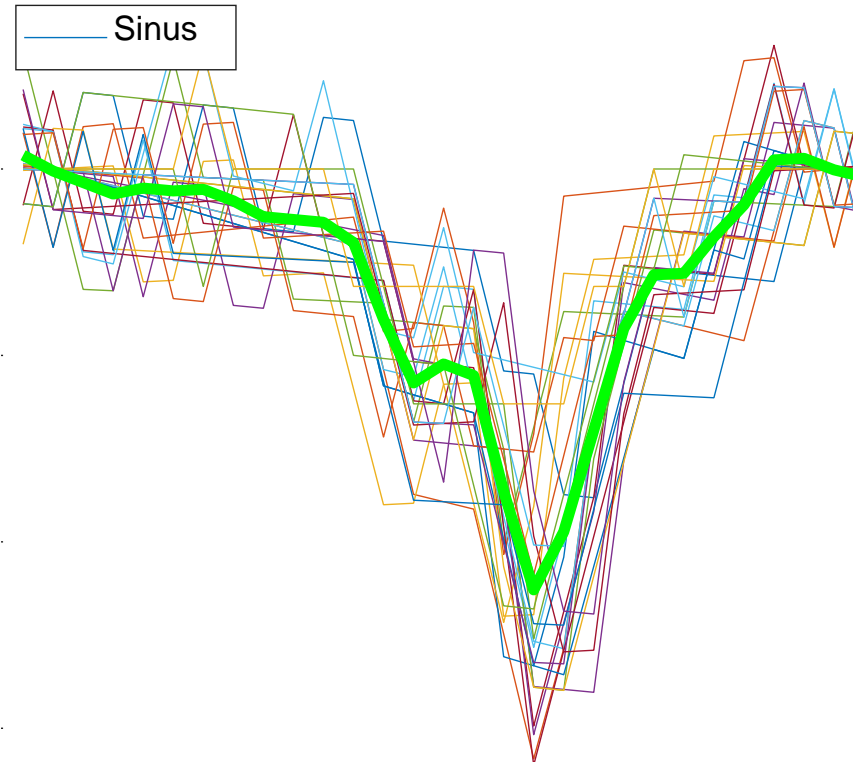
## TRUE AF

No consistent P-wave pattern



## FALSE AF

Consistent P-wave pattern



# DETECT ACCURATELY with SharpSense™ Technology

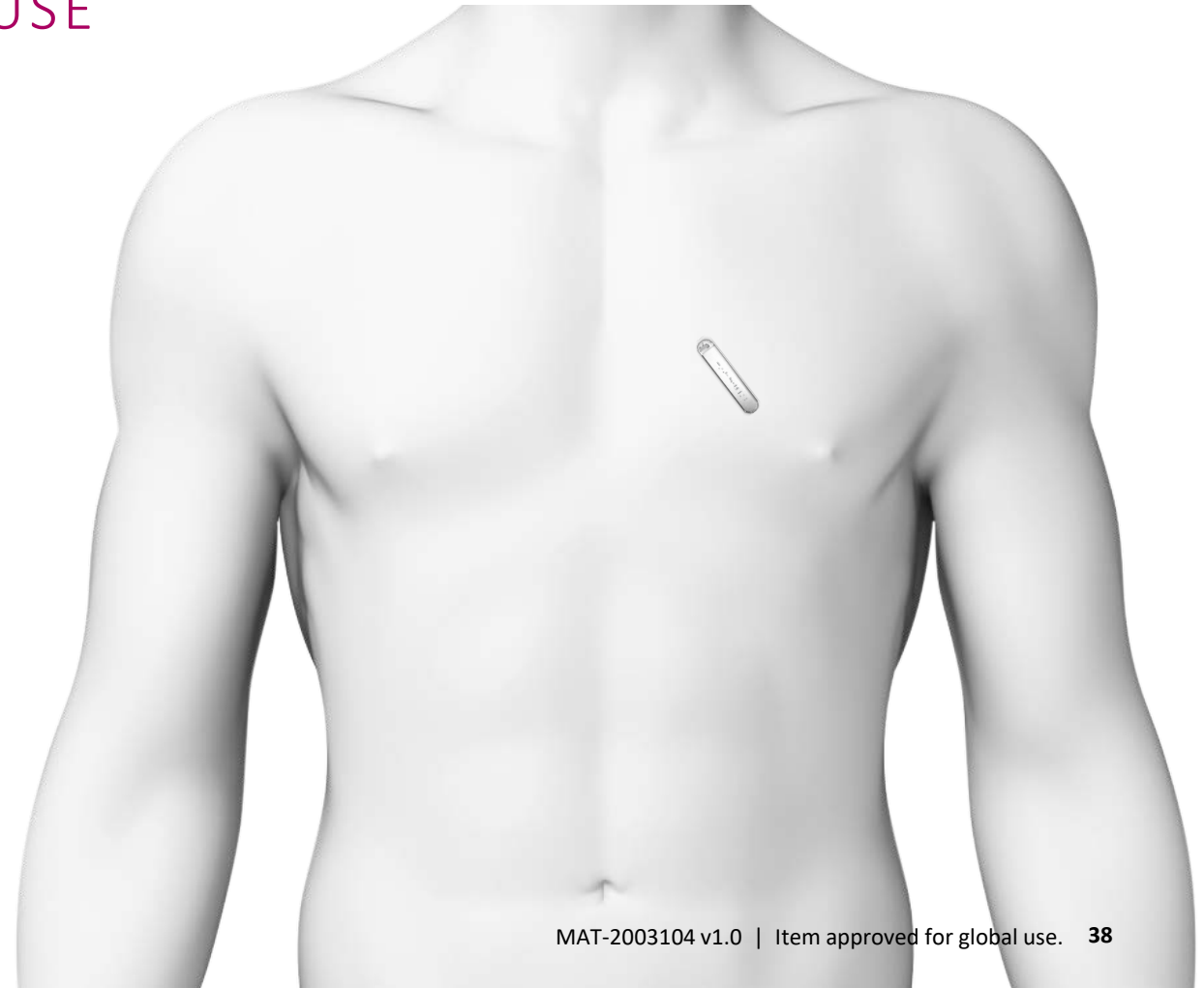
NEW NOMINAL SETTINGS  
BETTER PERFORMANCE AND EASE OF USE

## BRADYCARDIA

Cutoff rate adjusted to **30 bpm**  
per industry standards

## MAX SENSITIVITY

Increased from 0.15 to **0.125 mV**

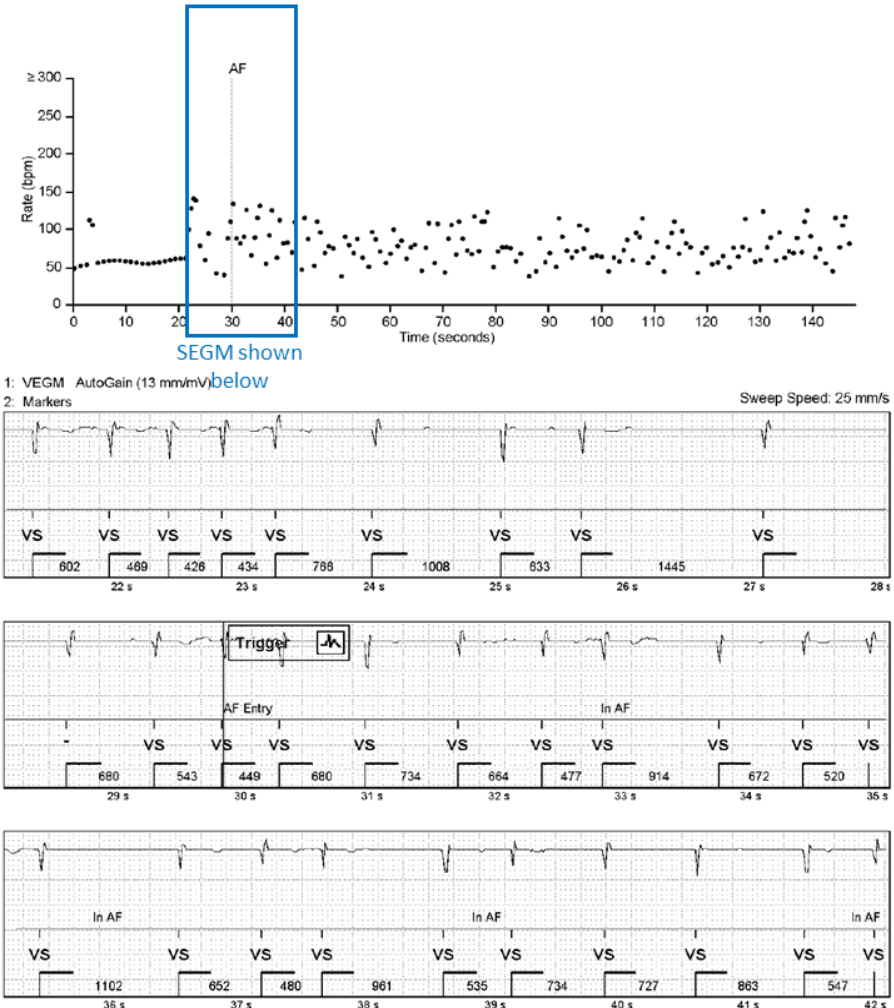


# DETECT ACCURATELY with SharpSense™ Technology

## NEW SCATTERPLOTS

## HEART RATE VS. TIME GRAPHS ADDED TO EXISTING EPISODE REPORTS

- Improves visualization of events
- Available for all episode types on Merlin.net™ PCN and programmer
- Shows programmed Bradycardia and Tachycardia zones, Episode Triggers and Exit Flags



DELIVER CONVENIENTLY



# Confirm Rx™ ICM Firsts



## BLUETOOTH® WIRELESS TECHNOLOGY COMMUNICATION BETWEEN ICM AND MOBILE APP



# DELIVER Conveniently with Smartphone Connectivity

EMPOWER AND ENGAGE PATIENTS WITH AN  
INTEGRATED TRANSMITTER AND SYMPTOM RECORDER

myMerlin™ mobile app  
**ELIMINATES**

SEPARATE  
HANDHELD  
ACTIVATOR



SEPARATE  
BEDSIDE  
TRANSMITTER



# Bluetooth<sup>®</sup> Low Energy Wireless Technology

A LOW-ENERGY, SHORT-RANGE RF TECHNOLOGY

## KEY BENEFITS

- Low power consumption
- Connectivity to mobile phones
- Global availability, license free
- Secure 128-bit AES encryption\*

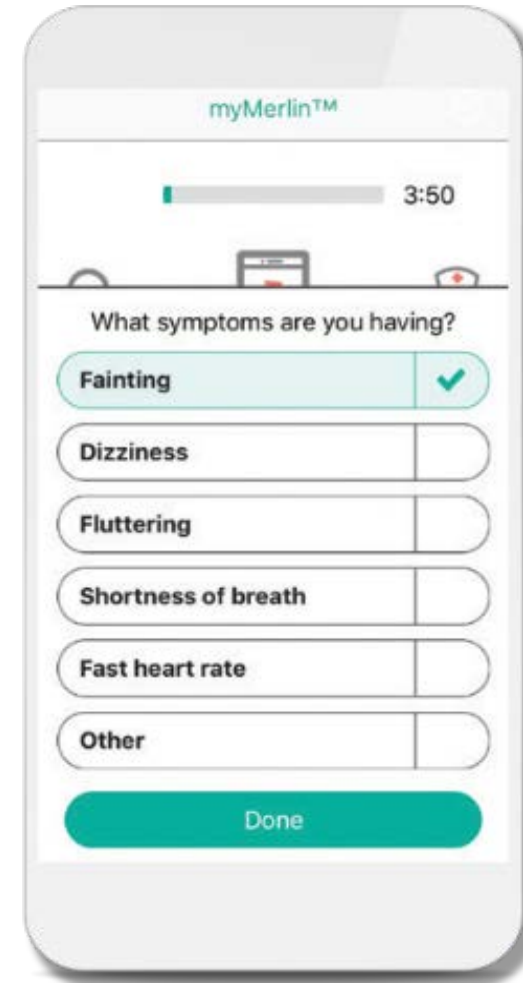
## EXAMPLES OF DEVICES USING BLUETOOTH<sup>®</sup> LOW ENERGY WIRELESS TECHNOLOGY

- Heart rate monitors
- Blood pressure monitors
- Fitness devices

# DELIVER Conveniently with Smartphone Connectivity

## ENHANCE PATIENT COMPLIANCE

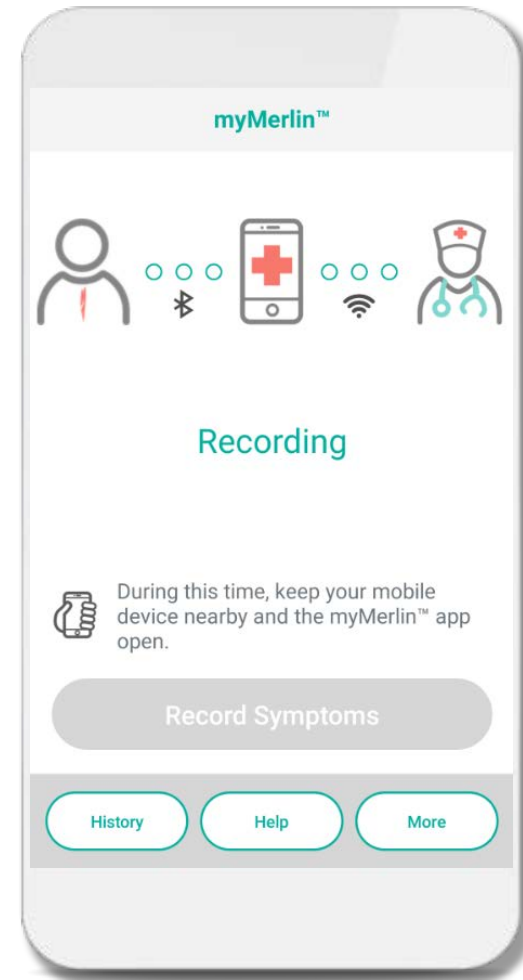
PATIENTS CAN DESCRIBE THEIR SYMPTOMS USING KEYWORDS  
(e.g., **fainting**)



# DELIVER Conveniently with Smartphone Connectivity

## ENHANCE PATIENT COMPLIANCE

**PATIENTS CAN SEND SYMPTOM TRANSMISSIONS INSTANTLY,\***  
without waiting to connect with a bedside transmitter or going to an in-person interrogation

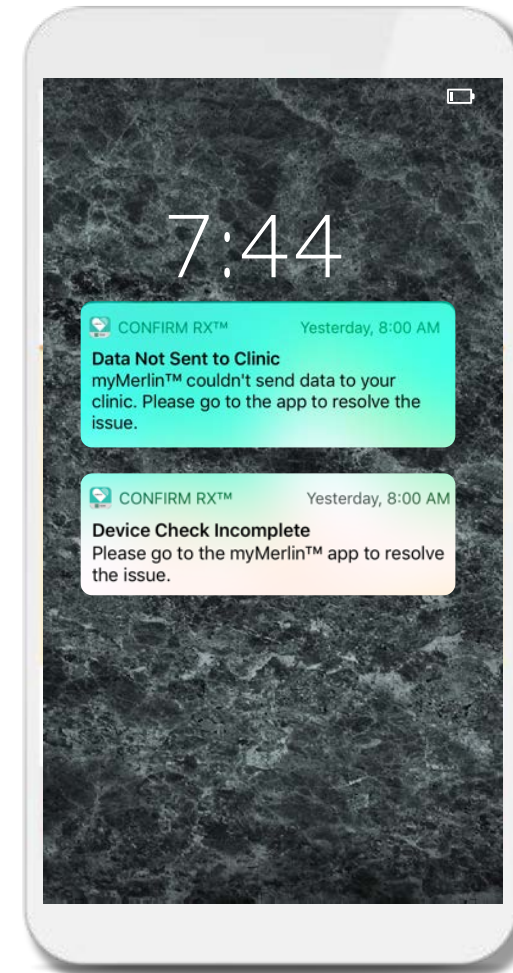


\*Where data service is available.

# DELIVER Conveniently with Smartphone Connectivity

## ENHANCE PATIENT COMPLIANCE

**PATIENTS CAN RECEIVE  
AUTOMATIC NOTIFICATIONS**  
when they miss device checks  
or scheduled transmissions

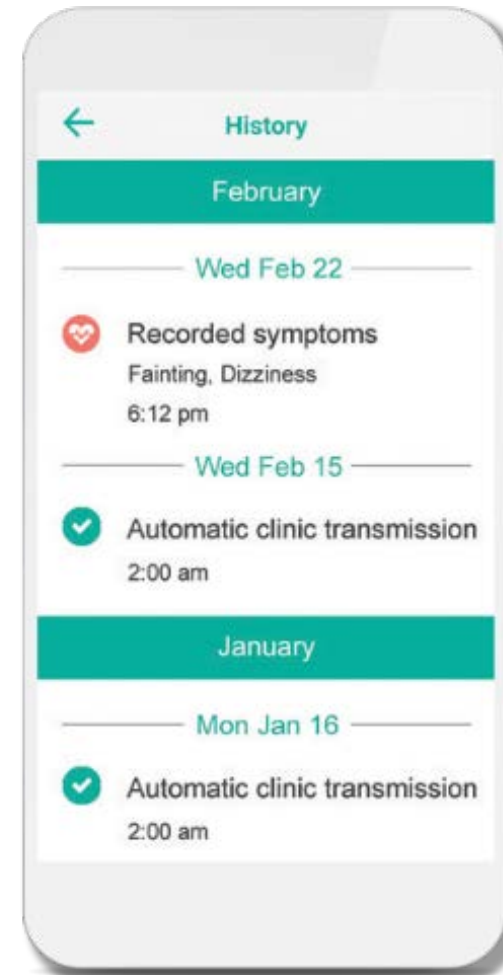


# DELIVER Conveniently with Smartphone Connectivity

## ENHANCE PATIENT COMPLIANCE

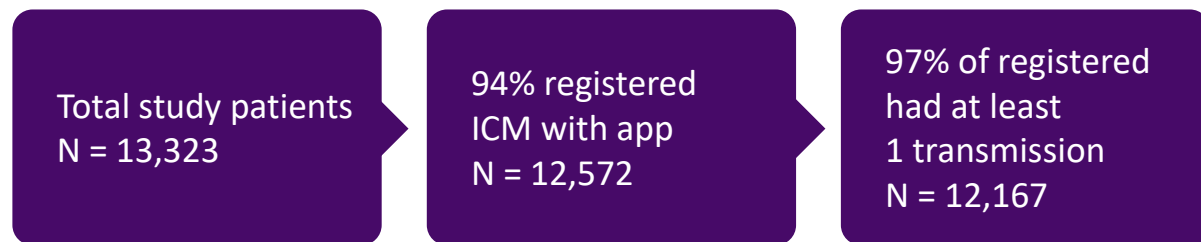
### PATIENTS CAN VIEW A HISTORY OF SCHEDULED TRANSMISSIONS AND SYMPTOM RECORDINGS

without having to contact the clinic to confirm successful data transfers



# DELIVER Conveniently with Smartphone Connectivity

## COMPLIANCE WITH APP-BASED REMOTE MONITORING



## EPISODE TRANSMISSION AND VIEW TIMES

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

## STUDY DETAIL<sup>1</sup>

### METHODS

Worldwide, multicenter, non-randomized database of Confirm Rx™ ICM implants from March 2017 through July 2018. N = 13,323

### RESULTS

- 94% OF ICM PATIENTS REGISTERED for the myMerlin™ mobile app
- 97% OF APP-REGISTERED PATIENTS USED IT
- REMOTE MONITORING CONNECTIVITY occurred every 1.6 DAYS OR 4.4 TIMES PER WEEK
- EPISODES WERE TRANSMITTED to the Merlin.net PCN in minutes to hours and WERE VIEWED BY CLINICIAN WITHIN 1 TO 2 DAYS

## CONCLUSION

Study findings suggest suitability of app-based Bluetooth® wireless technology for future cardiac implantable devices

1. Piorkowski C, et al. Early real-world adoption of mobile remote monitoring using the Confirm Rx Insertable Cardiac Monitor. Poster presented at: APHR; 2018.



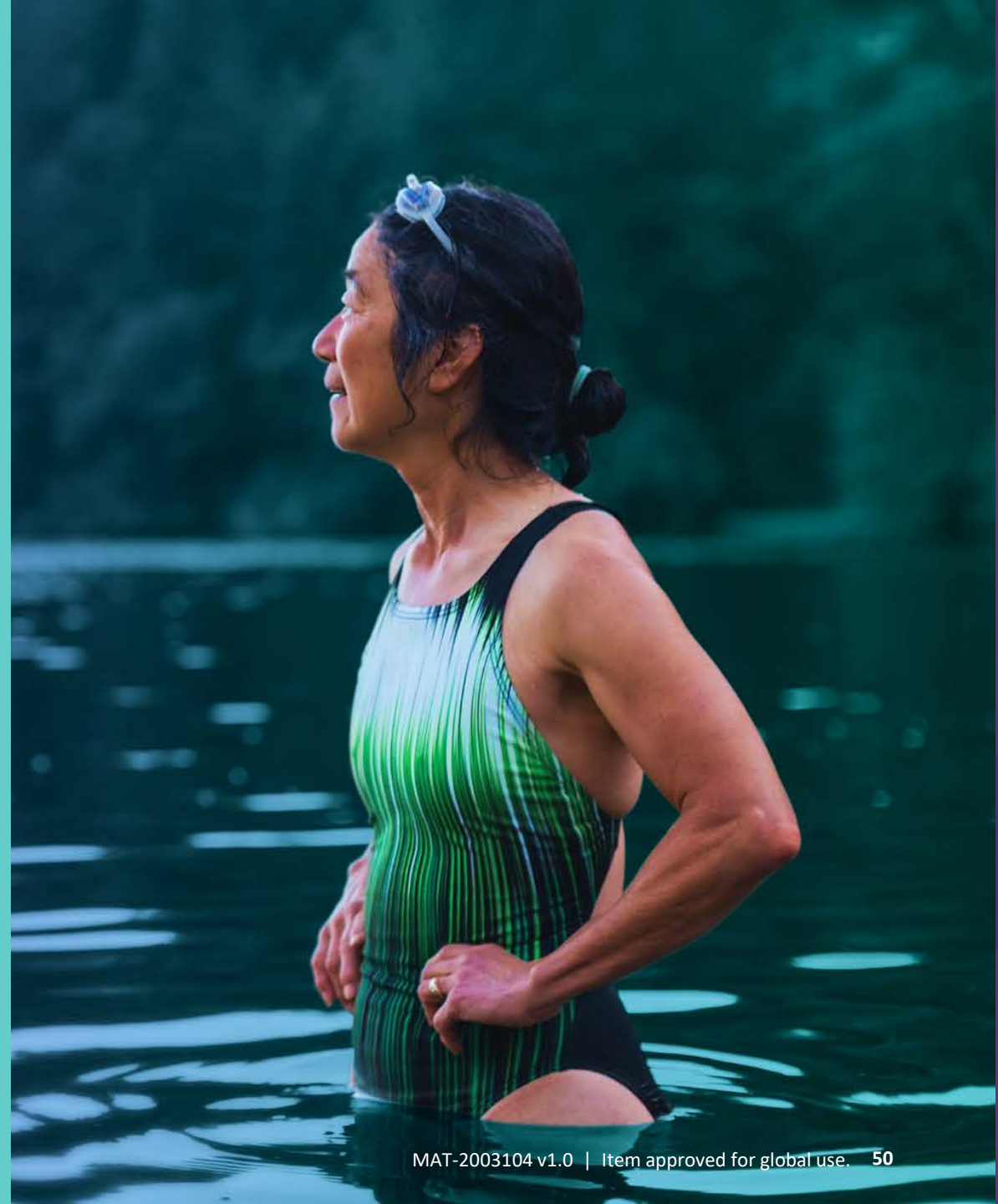
DECIDE CONFIDENTLY

## DOUBT IS DEBILITATING

Confirm Rx™ ICM identifies difficult-to-detect arrhythmias, including AF

## DIAGNOSIS IS EMPOWERING

SharpSense™ Technology delivers the necessary information you need to clearly and confidently diagnose arrhythmias



# DECIDE Confidently with Confirm Rx™ ICM with SharpSense™ Technology

## ICM MONITORING | BY THE NUMBERS

84  
DAYS

The median time to detect an AF episode in patients with cryptogenic stroke when using an implantable loop recorder<sup>1\*</sup>

134  
DAYS

The median time for diagnosis in patients with unexplained syncope when using an implantable loop recorder<sup>2\*</sup>

730  
DAYS

Confirm Rx ICM offers up to 730 days of continuous heart monitoring, providing ample time to diagnose the most difficult-to-detect arrhythmias<sup>3</sup>

\*This information was not collected with the Confirm Rx ICM device and is meant to provide information to the broader class of devices.

1. Sanna, T., et al., (2014). Cryptogenic Stroke and Underlying Atrial Fibrillation. The New England Journal of Medicine, 370(26), 2478-2486. doi:10.1056/NEJMoa1313600.
2. Solbiati, M., et al, (2017). The diagnostic yield of implantable loop recorders in unexplained syncope: A systematic review and meta-analysis. International Journal of Cardiology, 231, 170-176.
3. Data on file, Confirm Rx User's Manual. ARTEN10169974 A 2019-03 (EU) and ARTEN100170023 A 2019-03 (US)

# DECIDE Confidently

## ICM MONITORING | THE ACCURACY OF ICMS

	DETECT-AF* (SJM CONFIRM™ DM2102) <sup>1**</sup>	LINQ USABILITY STUDY*** (REVEAL LINQ‡) <sup>2</sup>
Episode Sensitivity	94.0%	97.3%
Duration Sensitivity	83.9%	98.4%
Episode Specificity	96.7%	Not Available
Duration Specificity	99.4%	99.5%
Patient Sensitivity	100%	97.4%

There are no head-to-head studies comparing the Medtronic Reveal LINQ and the Confirm Rx ICM.

\*Numbers calculated using a GEE.

\*\*The SJM Confirm™ ICM DM2102 and the Confirm Rx™ ICM DM3500 prior to SharpSense™ Technology use the same algorithms for the identification of AF.

\*\*\*Numbers shown are gross calculations.

1. Nölker, et al. (2016). Performance of an Implantable Cardiac Monitor to Detect Atrial Fibrillation: Results of the DETECT AF Study. *Journal of Cardiovascular Electrophysiology*. . 10.1111/jce.13089.
2. Sanders, et al. (2016). Performance of a New Atrial Fibrillation Detection Algorithm in a Miniaturized Insertable Cardiac Monitor: Results from the Reveal LINQ Usability Study. *Heart Rhythm*. 13.10.1016/j.hrthm.2016.03.005.

### STUDIES CURRENTLY AVAILABLE ON THE ACCURACY OF ICMS

- Have very different patient populations
- Did not compare different ICM devices
- Did not evaluate the Confirm Rx™ ICM device

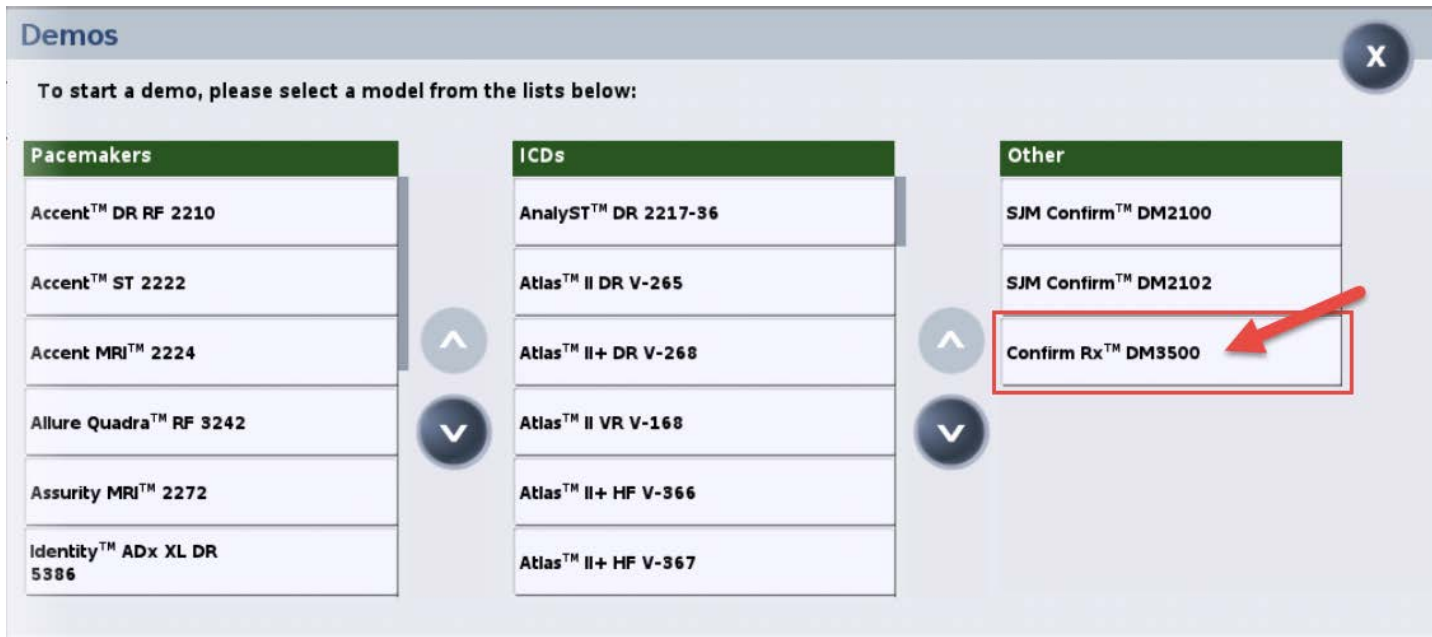
BREAKOUT #1

# PROGRAMMING CONSIDERATIONS AND EGM EXAMPLES



# Start Demo on Merlin™ PCS Programmer

**TOOLS → EDUCATION MATERIALS → DEMOS → Confirm Rx™ DM3500**



**WHEN PROMPTED, SELECT  
“Follow-up Demo”**

# Programming Considerations

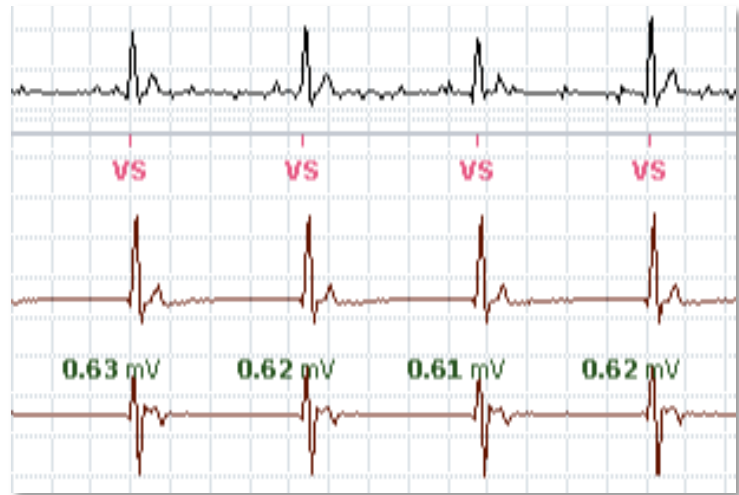
## PROPER DETECTION RELIES ON APPROPRIATE SENSING

1. Measure R-wave
2. Verify Dynamic Range
3. Program appropriate Max Sensitivity

# Programming Considerations

## STEP #1: MEASURE R-WAVE

Tests Button → Measure Amplitude



The screenshot shows the ECG software interface. On the left, a sidebar contains a 'Tools' menu, a Bluetooth icon, a 'Detection is ENABLED' status, a 'Followup Demo' section for 'Confirm Rx™ ICM Syncopal', and a note: 'Note: This is a demo application.' The main display area shows an ECG strip with four channels (I, II, VEGM, VSENSE) and a 'Markers' section with 'VS' labels. A 'Measure Amplitude' button is highlighted with a red box. Below it, the 'R-Wave Amplitude' is shown as 0.62 mV (Jul 8, 2019 10:31 am) and the 'Sweep Speed' is 25 mm/s. The right sidebar includes a heart rate display of 70 bpm, PDF export options, and a navigation menu with 'Tests' highlighted in red. Other menu items include 'FastPath™ Summary', 'Episodes', 'Diagnostics', 'Parameters', and 'Wrap-up™ Overview'. At the bottom, there are 'Restore Channels', 'Print', and 'End Session' buttons.

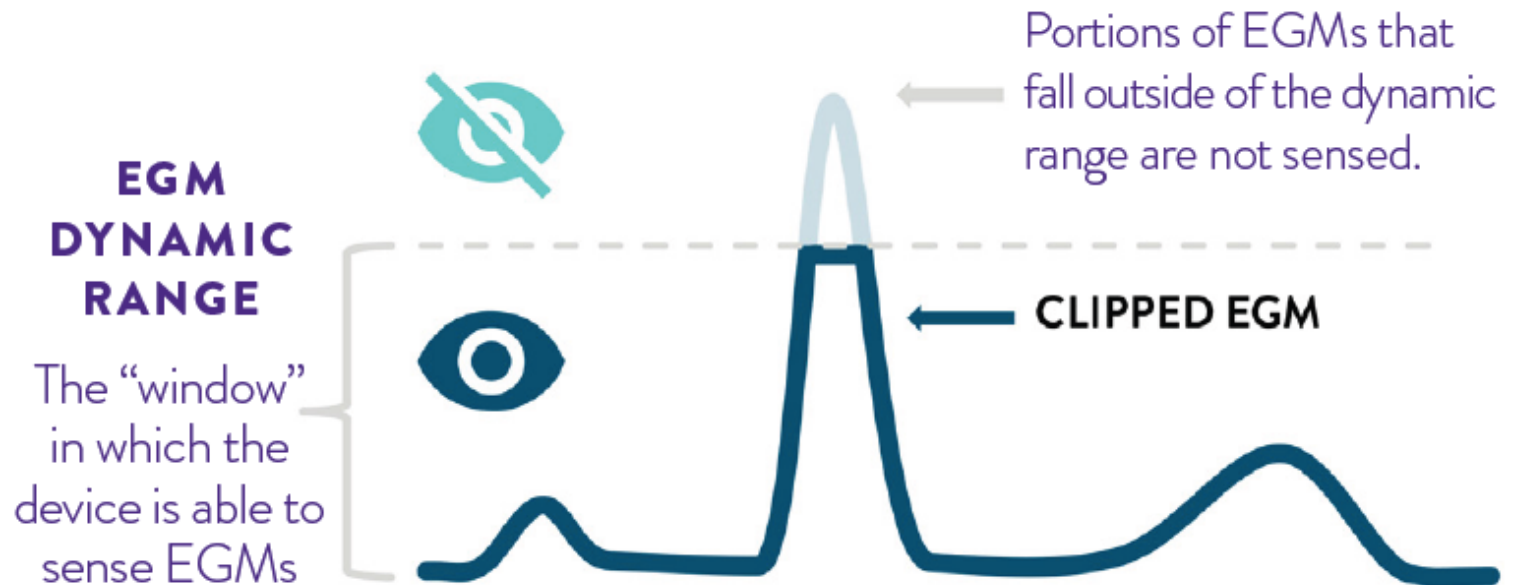
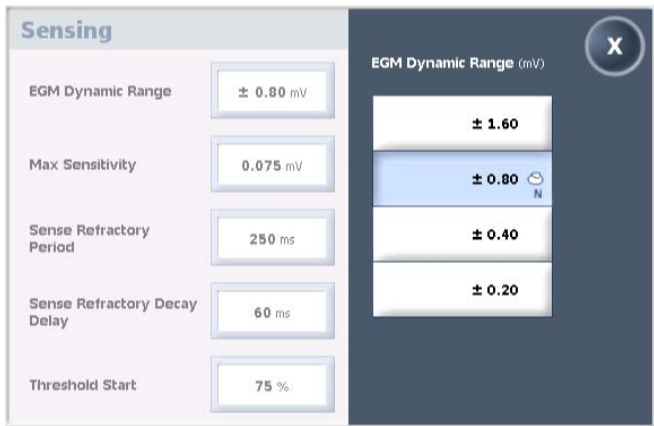


# Programming Considerations

## STEP #2: VERIFY DYNAMIC RANGE

Parameters Button → Sensing

Program Dynamic Range close to the R-wave value



# Programming Considerations

## STEP #3: PROGRAM MAX SENSITIVITY

Parameters Button → Sensing

R-wave  $\geq 0.45$  mV?

NO

Calculate  
Max Sensitivity

$$\frac{\text{R-wave Amplitude}}{3} \approx \text{Max Sensitivity}$$

YES

Use nominal  
Max Sensitivity  
(0.125 mV)

$$\frac{0.31 \text{ mV}}{3} = 0.103 \text{ mV} \approx \mathbf{0.10 \text{ mV}}$$



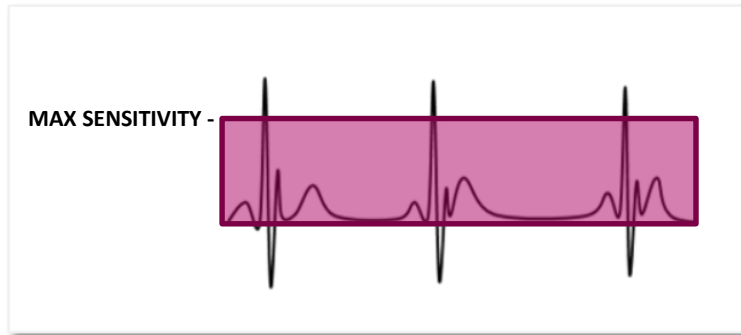
### REMINDER

If oversensing occurs, adjust Max Sensitivity until sensing is appropriate\*

\*Be cautious when programming Max Sensitivity to 0.05 mV. Oversensing may occur and cause noise reversion, which inhibits episode recording.

# Max Sensitivity: Less Sensitive versus More Sensitive

**LESS SENSITIVE** (larger Max Sensitivity value)



**MORE SENSITIVE**  
(smaller Max Sensitivity value)



# How Would You Interpret This EGM?

## P-WAVE OVERSENSING Causing False AF Detection

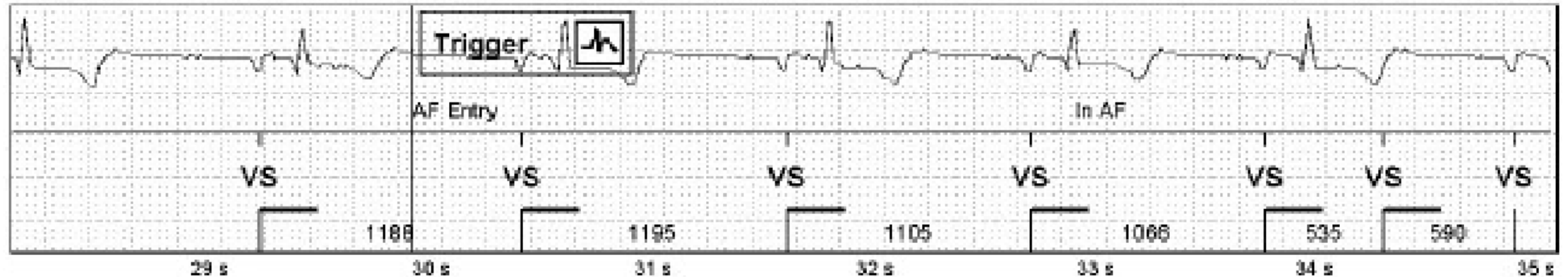
### AF Episode

Page 2 of 5

1: VEGM AutoGain (28 mmV/mV)

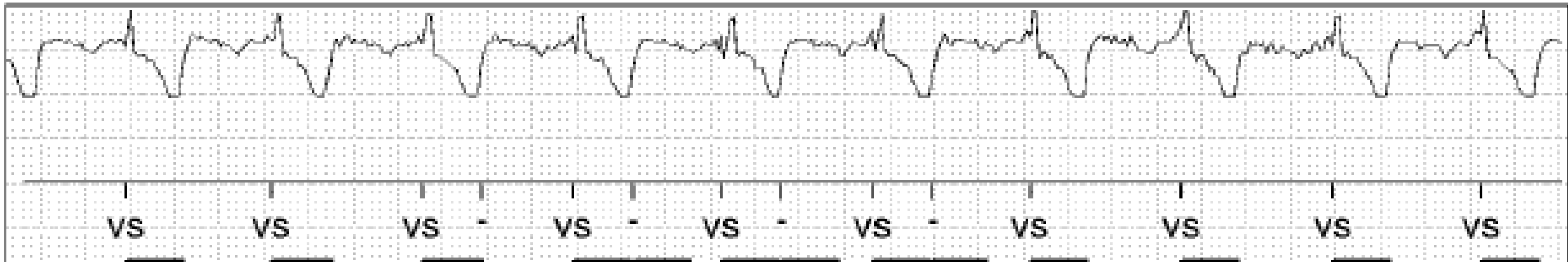
2: Markers

Sweep Speed: 25 mm/s



# How Would You Interpret This EGM?

**T-WAVE OVERSENSING** Causing False AF Detection



# Assess Programmed Cutoff Rates

## PARAMETERS → EPISODE & ALERT TYPE

The screenshot shows the 'Detection' settings screen with a table of episode and alert types. The table has four columns: 'Episode & Alert Type', 'Detection', 'EGM Trigger Priority', and 'Merlin.net DirectAlerts™'. The 'Detection' column contains checkmarks for all listed items. The 'EGM Trigger Priority' column shows 'Low' for 'AF Episode (6 min)' and 'High' for 'Tachy Episode (180 min<sup>-1</sup>, 12 intervals)', with 'n/a' for the others. The 'Merlin.net DirectAlerts™' column is empty for all items. To the right of the table is a 'Stored EGM Settings' box with a list of settings and their values: AF Pre-Trigger Duration (30 sec), AF Post-Trigger Duration (120 sec), Other Pre-Trigger Duration (30 sec), Other Post-Trigger Duration (30 sec), Symptom Pre-Trigger Duration (8 min), and Symptom Post-Trigger Duration (60 sec). Below the table are 'Preview' and 'Program' buttons, and a note: 'Merlin.net DirectAlerts™ are customizable only through the Merlin.net™ portal.'

Episode & Alert Type	Detection	EGM Trigger Priority	Merlin.net DirectAlerts™
AF Episode (6 min)	✓	Low	
Continuous AF Alert (30 min)	✓	n/a	
AF Burden Alert (6 hours, Daily)	✓	n/a	
V Rate During AF Alert (100 min <sup>-1</sup> for 6 hours, Daily)	✓	n/a	
Tachy Episode (180 min <sup>-1</sup> , 12 intervals)	✓	High	

Stored EGM Settings

- AF Pre-Trigger Duration: 30 sec
- AF Post-Trigger Duration: 120 sec
- Other Pre-Trigger Duration: 30 sec
- Other Post-Trigger Duration: 30 sec
- Symptom Pre-Trigger Duration: 8 min
- Symptom Post-Trigger Duration: 60 sec

Merlin.net DirectAlerts™ are customizable only through the Merlin.net™ portal.

## NOMINAL EPISODE SETTINGS

- AF: 2 minutes
- Tachy: 12 intervals at 180 bpm
- Brady: 30 bpm
- Pause: 3 seconds

Device-detected episodes are scheduled to transmit every night at 2 a.m. (non-programmable).

# Assess Programmed Cutoff Rates

Click boxes in this column to edit parameters

Episode & Alert Type	Detection	EGM Trigger Priority	Merlin.net DirectAlerts™
AF Episode (6 min)	<input checked="" type="checkbox"/>	Low	<input type="checkbox"/>
Continuous AF Alert (30 min)	<input checked="" type="checkbox"/>	n/a	<input type="checkbox"/>
AF Burden Alert (6 hours, Daily)	<input checked="" type="checkbox"/>	n/a	<input type="checkbox"/>
V Rate During AF Alert (100 min <sup>-1</sup> for 6 hours, Daily)	<input checked="" type="checkbox"/>	n/a	<input type="checkbox"/>
Tachy Episode (180 min <sup>-1</sup> , 12 intervals)	<input checked="" type="checkbox"/>	High	<input type="checkbox"/>

Stored EGM Settings

AF Pre-Trigger Duration	30 sec
AF Post-Trigger Duration	120 sec
Other Pre-Trigger Duration	30 sec
Other Post-Trigger Duration	30 sec
Symptom Pre-Trigger Duration	8 min
Symptom Post-Trigger Duration	60 sec

Merlin.net DirectAlerts™ are customizable only through the Merlin.net™ portal.

Preview 0 Program

Scroll down to see all options

# When Do You Want to Store an EGM?

Uncheck boxes to turn detection or EGM triggers off

Episode & Alert Type	Detection	EGM Trigger Priority	Merlin.net DirectAlerts™
AF Episode (6 min)	<input checked="" type="checkbox"/>	Low	<input type="checkbox"/>
Continuous AF Alert (n/a)	<input checked="" type="checkbox"/>	n/a	n/a
AF Burden Alert (n/a, n/a)	<input checked="" type="checkbox"/>	n/a	n/a
V Rate During AF Alert (100 bpm for 6 hours, Daily)	<input checked="" type="checkbox"/>	n/a	<input type="checkbox"/>
Tachy Episode (180 bpm, 12 intervals)	<input checked="" type="checkbox"/>	High	<input type="checkbox"/>

**Stored EGM Settings**

AF Pre-Trigger Duration	30 sec
AF Post-Trigger Duration	120 sec
Other Pre-Trigger Duration	30 sec
Other Post-Trigger Duration	30 sec
Symptom Pre-Trigger Duration	8 min
Symptom Post-Trigger Duration	60 sec

Merlin.net DirectAlerts™ are customizable only through the Merlin.net™ portal.

Preview 4 Program



# Which EGMs are Most Important?

## EGM TRIGGER PRIORITY (Low, High, Off)

**LOW PRIORITY:** Overwrites old episodes with equal or higher priority when storage is full.

Episode & Alert Type	Detection	EGM Trigger Priority	Merlin.net DirectAlerts™
AF Episode (6 min)	<input checked="" type="checkbox"/>	Low	<input type="checkbox"/>
Continuous AF Alert (30 min)	<input checked="" type="checkbox"/>	n/a	<input type="checkbox"/>
AF Burden Alert (6 hours, Daily)	<input checked="" type="checkbox"/>	n/a	<input type="checkbox"/>
V Rate During AF Alert (100 min <sup>-1</sup> for 6 hours, Daily)	<input checked="" type="checkbox"/>	n/a	<input type="checkbox"/>
Tachy Episode (180 min <sup>-1</sup> , 12 intervals)	<input checked="" type="checkbox"/>	High	<input type="checkbox"/>

Stored EGM Settings

AF Pre-Trigger Duration	30 sec
AF Post-Trigger Duration	120 sec
Other Pre-Trigger Duration	30 sec
Other Post-Trigger Duration	30 sec
Symptom Pre-Trigger Duration	8 min
Symptom Post-Trigger Duration	60 sec

Merlin.net DirectAlerts™ are customizable only through the Merlin.net™ portal.

Preview 0 Program

**Off:** No EGMs will be stored

**Low and High:** At least one EGM is stored for an episode trigger

**HIGH PRIORITY:** Additional EGMs are stored if space is available. Once storage is full, new EGMs replace oldest stored EGM.

# Customize Episode Storage

PARAMETERS → EPISODE & ALERT TYPE → Stored EGM Settings

**Detection**

Episode & Alert Type	Detection	EGM Trigger Priority	Merlin.net DirectAlerts™
AF Episode (6 min)	<input checked="" type="checkbox"/>	Low	<input type="checkbox"/>
Continuous AF Alert (30 min)	<input checked="" type="checkbox"/>	n/a	<input type="checkbox"/>
AF Burden Alert (6 hours, Daily)	<input checked="" type="checkbox"/>	n/a	<input type="checkbox"/>
V Rate During AF Alert (100 min <sup>-1</sup> for 6 hours, Daily)	<input checked="" type="checkbox"/>	n/a	<input type="checkbox"/>
Tachy Episode (180 min <sup>-1</sup> , 12 intervals)	<input checked="" type="checkbox"/>	High	<input type="checkbox"/>

**Stored EGM Settings**

AF Pre-Trigger Duration	30 sec
AF Post-Trigger Duration	120 sec
Other Pre-Trigger Duration	30 sec
Other Post-Trigger Duration	30 sec
Symptom Pre-Trigger Duration	8 min
Symptom Post-Trigger Duration	60 sec

Merlin.net DirectAlerts™ are customizable only through the Merlin.net™ portal.

Preview 0 Program

# Stored EGM Settings

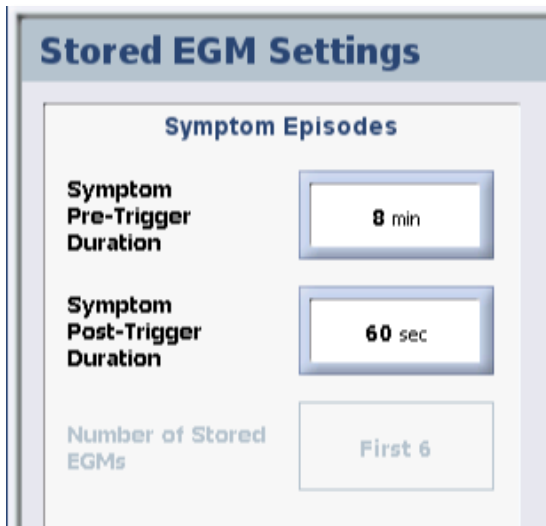
Determine how much time is recorded  
**BEFORE AND AFTER EPISODES ARE TRIGGERED**

The screenshot displays the 'Stored EGM Settings' interface, which is organized into three main columns: Symptom Episodes, AF Episode, and Tachy, Brady & Pause Episodes. Each column contains specific duration settings for pre-trigger and post-trigger periods. A 'Number of Stored EGMs' setting is located at the bottom left. A close button (X) is visible in the top right corner of the settings panel.

Category	Setting	Value
Symptom Episodes	Symptom Pre-Trigger Duration	8 min
	Symptom Post-Trigger Duration	60 sec
	Number of Stored EGMs	First 6
AF Episode	AF Pre-Trigger Duration	30 sec
	AF Post-Trigger Duration	120 sec
Tachy, Brady & Pause Episodes	Other Pre-Trigger Duration	30 sec
	Other Post-Trigger Duration	30 sec

# Managing EGM Storage

**A SYMPTOM EPISODE RECORDS 8 MINUTES (nominally)** before the patient hits the “Record Symptoms” button and one minute after.



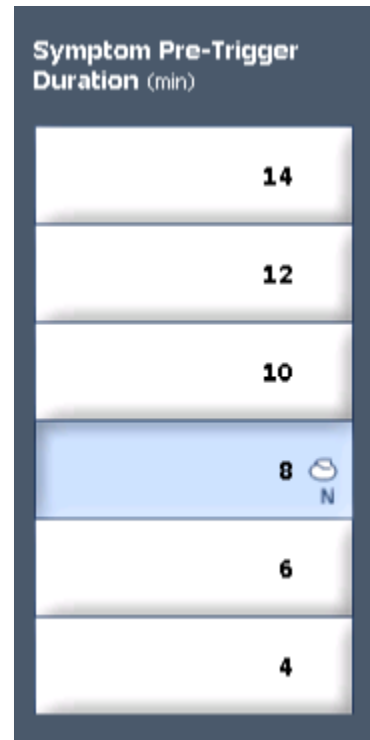
**Stored EGM Settings**

**Symptom Episodes**

Symptom Pre-Trigger Duration: 8 min

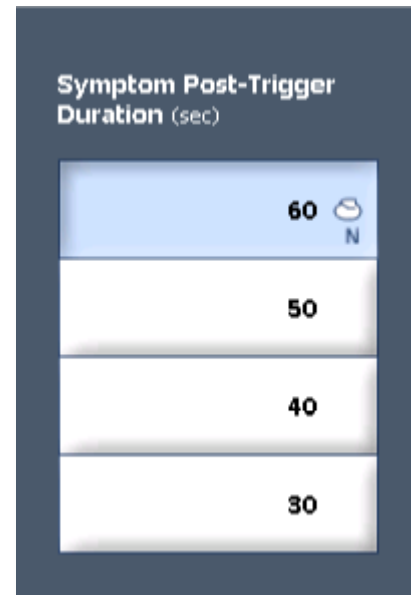
Symptom Post-Trigger Duration: 60 sec

Number of Stored EGMs: First 6



**Symptom Pre-Trigger Duration (min)**

14
12
10
8 N
6
4



**Symptom Post-Trigger Duration (sec)**

60 N
50
40
30

- Consider shortening the pre-trigger duration if the patient is able to record symptoms within a shorter timeframe or if more EGM space is desired.
- Consider lengthening the pre-trigger duration if the patient has difficulty pressing “Record Symptoms” in a timely fashion (e.g., can’t find their phone).

# Managing EGM Storage


**STORED EGM SETTINGS FOR AF EPISODES** can be as short as 10 seconds before and after, or as long as 2 minutes before and after.

**AF Episode**


AF Pre-Trigger Duration

AF Post-Trigger Duration

**AF Pre-Trigger Duration (sec)**

120
90
60
30  N
20
10

**AF Post-Trigger Duration (sec)**

120  N
90
60
30
20
10

# Managing EGM Storage


**TACHY, BRADY AND PAUSE EPISODE STORAGE ARE PROGRAMMED TOGETHER** and can be as short as 10 seconds before and after, or as long as 1 minute before and after.

**Tachy, Brady & Pause Episodes**


Other Pre-Trigger Duration

Other Post-Trigger Duration

**Other Pre-Trigger Duration (sec)**

60
50
40
30  N
20
10

**Other Post-Trigger Duration (sec)**

60
50
40
30  N
20
10

# Managing Alerts: What Do They Mean?

## SET THE CONDITIONS FOR MONITORING AF

**AF Episode & Alert Detection**

AF Episode	Continuous AF Alert	AF Burden Alert	V Rate During AF Alert
AF Duration: 6 min	Continuous AF Threshold: 30 min	AF Burden: Total Time in AF: 6 hours	High V Rate Threshold: 100 min <sup>-1</sup>
		Evaluation Period: Daily	Total Time in High V Rate: 6 hours
			Evaluation Period: Daily

**AF Duration (min)**

- 20
- 10
- 6
- 2
- 1
- 0.5

60

0.5

AF Duration: The shortest AF episode that will be stored.

# Managing Alerts: What Do They Mean?

## SET THE CONDITIONS FOR MONITORING AF

**AF Episode & Alert Detection**

**AF Episode**

AF Duration: 6 min

**Continuous AF Alert**

Continuous AF Threshold: 30 min

**AF Burden Alert**

AF Burden: Total Time in AF: 6 hours

Evaluation Period: Daily

**V Rate During AF Alert**

High V Rate Threshold: 100 min<sup>-1</sup>

Total Time in High V Rate: 6 hours

Evaluation Period: Daily

**Continuous AF Threshold (min)**

- 180
- 60
- 30
- 20
- 10

**Continuous AF Threshold:** Triggers an alert if a single episode lasts the programmed duration.



# Managing Alerts: What Do They Mean?

## SET THE CONDITIONS FOR MONITORING AF

**AF Episode & Alert Detection**

**AF Episode**

AF Duration: 6 min

**Continuous AF Alert**

Continuous AF Threshold: 30 min

**AF Burden Alert**

AF Burden: Total Time in AF: 6 hours

Evaluation Period: Daily

AF Burden: Total Time in AF

- 12 hours
- 9 hours
- 6 hours (selected)
- 3 hours
- 1 hour
- 30 min

24 hours

30 min

**AF Burden:** Triggers an alert if the total time in AF that day exceeds the programmed value (multiple episodes).

# Managing Alerts: What Do They Mean?

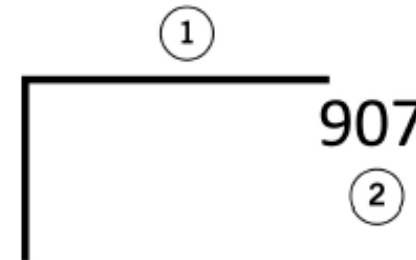
## SET THE CONDITIONS FOR MONITORING AF

AF Episode & Alert Detection			
<b>AF Episode</b>	<b>Continuous AF Alert</b>	<b>AF Burden Alert</b>	<b>V Rate During AF Alert</b>
AF Duration: 6 min	Continuous AF Threshold: 30 min	AF Burden: Total Time in AF: 6 hours	High V Rate Threshold: 100 min <sup>-1</sup>
		Evaluation Period: Daily	Total Time in High V Rate: 6 hours
			Evaluation Period: Daily

**V Rate During AF Alert:** Triggers an alert if the ventricular rate during AF that day exceeds the programmed rate for the programmed duration.

# Basic Event Markers

Marker	Description
AF Entry	AF entry
In AF	AF ongoing
AF Exit	AF exit
T	Binned interval: Tachycardia
B *	Binned interval: Bradycardia
A or P	Binned interval: Asystole or Pause
VS	Ventricular sensed event
Episode Exit	Episode exit
Tachy	Tachy episode diagnosis
Brady	Brady episode diagnosis
Asystole or Pause	Asystole or pause episode diagnosis
Patient Activated or Symptom	Patient activated or symptom EGM storage



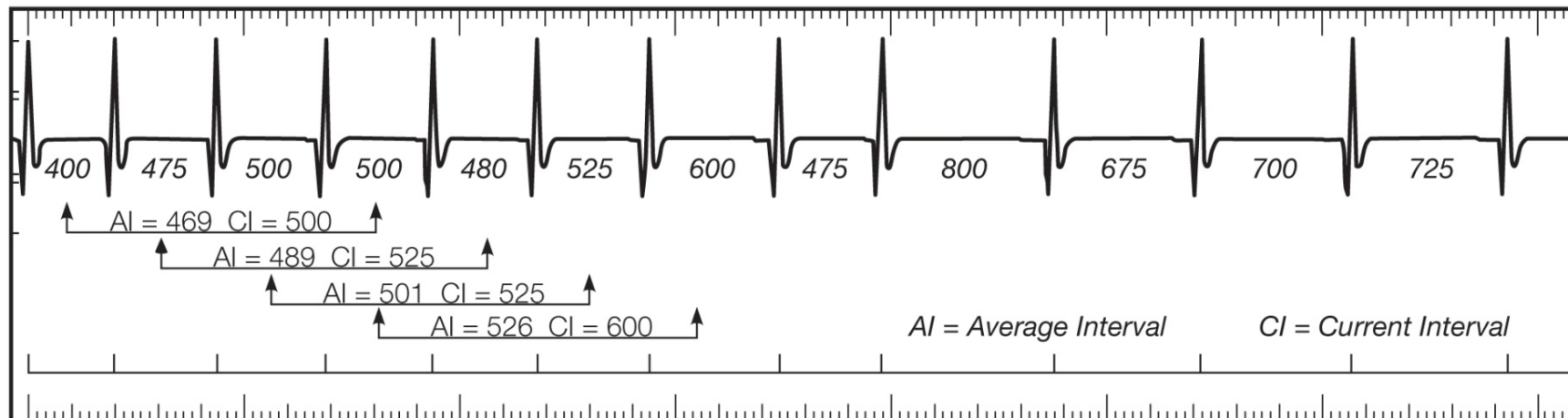
1. Refractory Period (Line)
2. R-R Interval

\*A/Asystole is used for SJM Confirm™ implantable cardiac monitor; P/Pause is used for Confirm Rx™ ICM.

# Current Interval And Interval Average

**THE CURRENT INTERVAL (CI)** is the interval the device is measuring now

**THE INTERVAL AVERAGE (IA)** is the CI plus the last three intervals before that, divided by four



CONFIRM Rx™ ICM

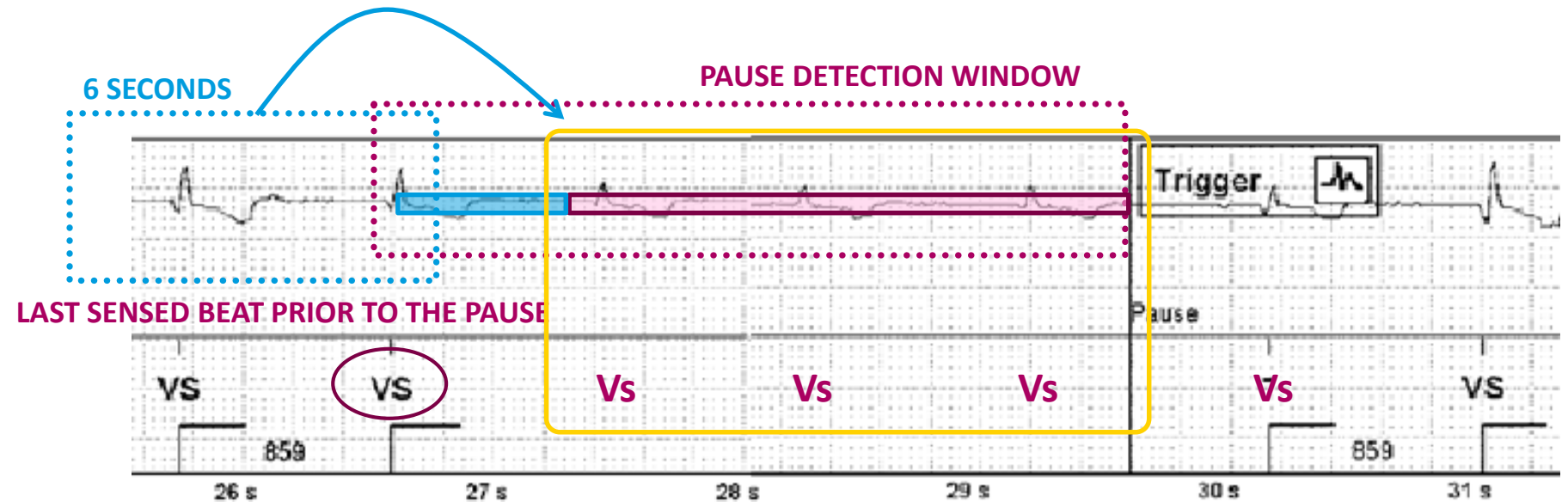
# EGM EXAMPLES





# FALSE PAUSE

- **ANALYZES R- AND T-WAVES** immediately prior to detection
- Applies new **SENSITIVITY THRESHOLD** to Pause window based on this information
- **UNDERSENSED BEATS FOUND**

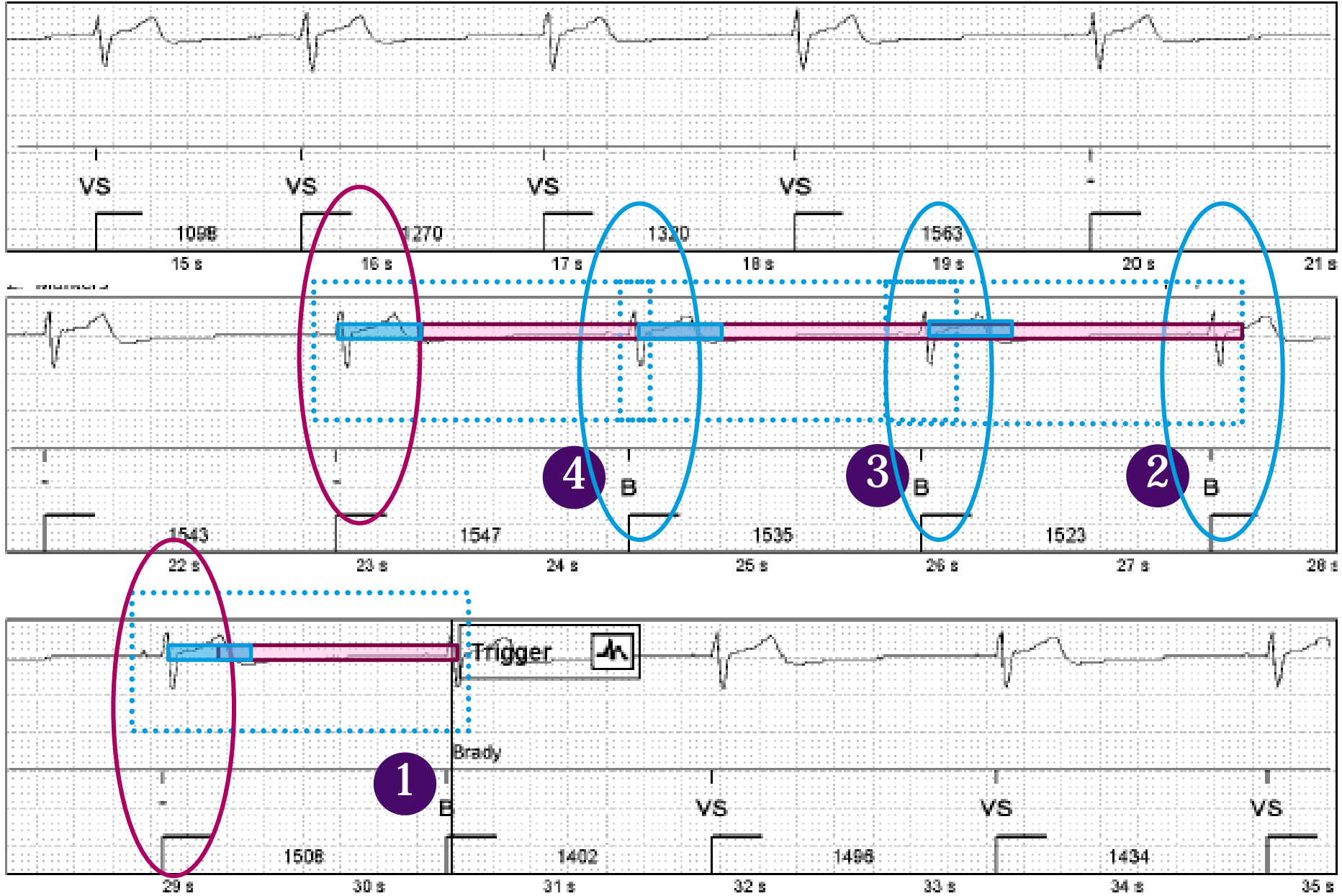


**T-WAVE BLANKING** applied to last sensed beat before the Pause

**SECONDARY THRESHOLD** applied to Pause window to search for undersensed beats

# TRUE BRADY

- Analyzes P-, R- and T-waves from **SELECT BEATS** leading up to detection
- Looks for undersensed beats in all **FOUR BRADY WINDOWS**
- **NO UNDERSENSED BEATS FOUND?**  
Stores Brady episode





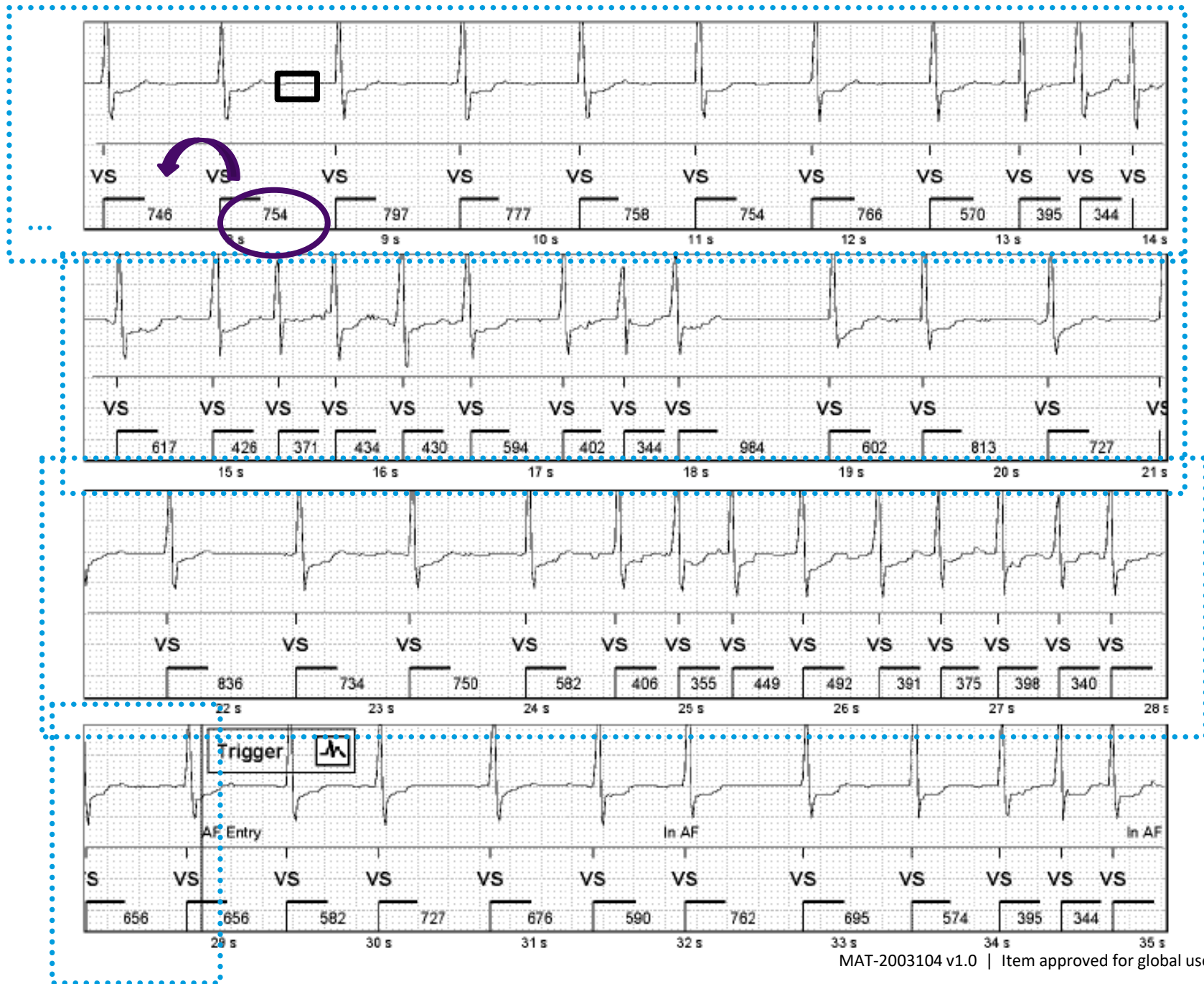


# TRUE AF

NO VISIBLE  
P-WAVES

- 40–100 bpm?
- No abrupt shortening?
- If so, looks for P-wave and **COMPARES TO OTHER QUALIFIED SEGMENTS**

30 SECONDS PRE-TRIGGER

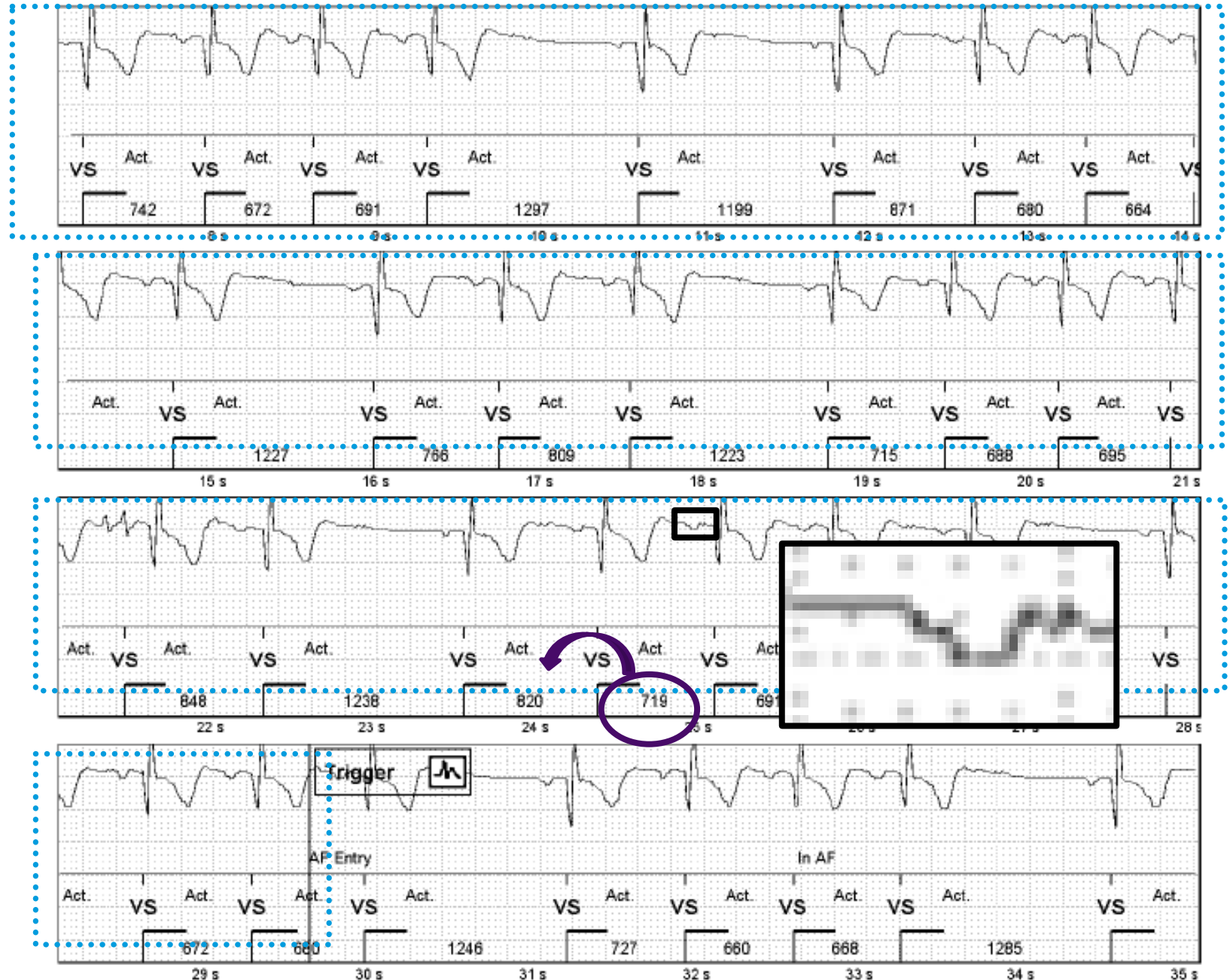


# FALSE AF

VISIBLE  
P-WAVES

- 40–100 bpm?
- No abrupt shortening?
- If so, looks for P-wave to **COMPARE IN ENSEMBLE AVERAGE**

30 SECONDS PRE-TRIGGER

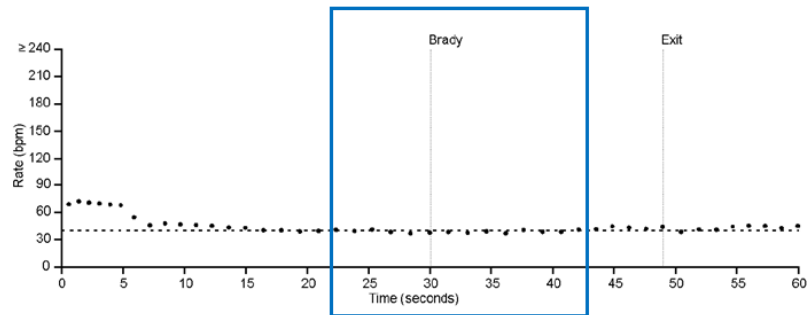


# Scatterplot Examples

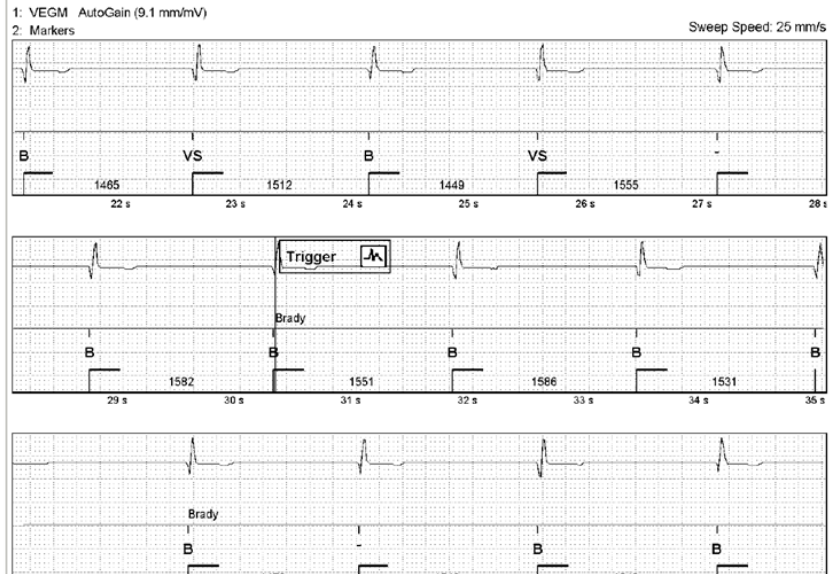
## Brady Episode

Page 1 of 3

Date & Time Apr 18, 2017 4:00 am  
 Duration 19s  
 Min Rate 37 bpm  
 Average Rate At Detection 38 bpm



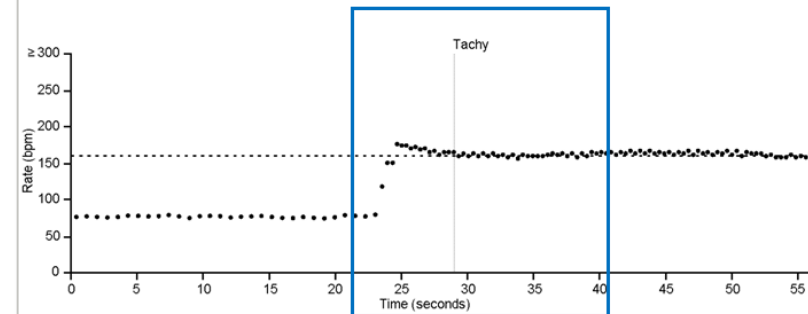
SEGM shown below



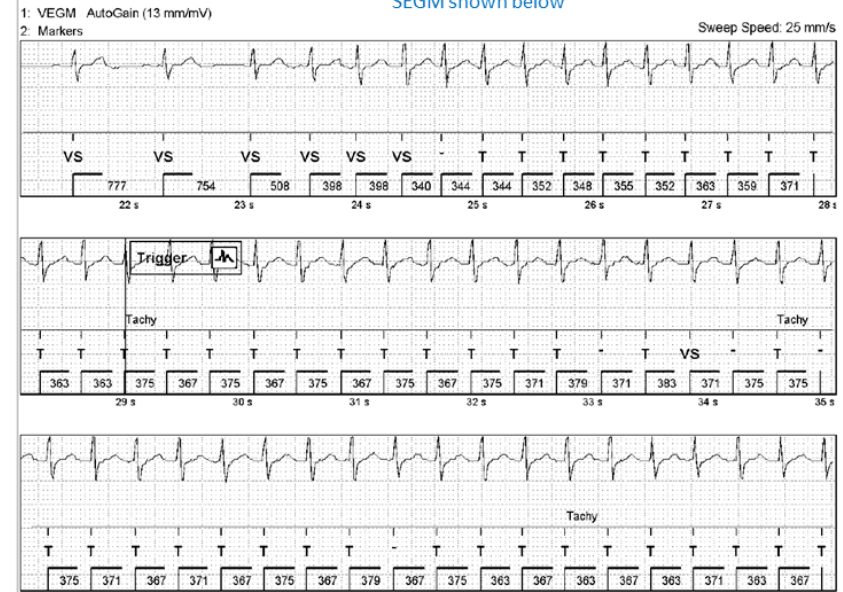
## Tachy Episode

Page 1 of 2

Date & Time Jan 15, 2019 2:46 am  
 Duration 36s  
 Max Rate 166 bpm  
 Average Rate At Detection 164 bpm



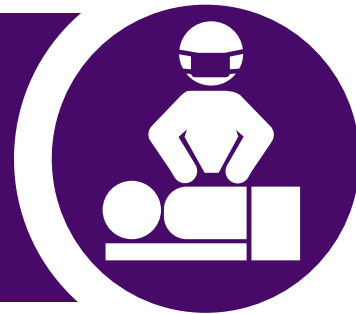
SEGM shown below



OVERVIEW AND  
SHARPSense™ TECHNOLOGY  
ENHANCEMENTS



PAIRING AND CONNECTIVITY



FOLLOW-UP ON  
MERLIN.NET™ PCN



# Topics Covered

- Workflow
- Pairing with the myMerlin™ Mobile App
- Staying Connected

# WORKFLOW, PAIRING AND CONNECTIVITY



# End-to-End Workflow



## INITIAL CONSULT

- Physician prescribes Confirm Rx™ ICM
- Clinic staff provides patient with brochure containing instructions on how to download the myMerlin™ mobile app to their personal smartphone



## BEFORE PROCEDURE

- Patient downloads myMerlin mobile app to their personal smartphone
- Patient views interactive demo tutorial to learn about the app



## REMOTE FOLLOW-UP

Follow-up staff reviews scheduled and unscheduled transmissions on Merlin.net™ PCN



## PROCEDURE

1. Initial Programming
2. Device Insertion
3. Check Sensing
4. Close Incision
5. Enroll Patient in Merlin.net PCN
6. Pair ICM to Patient's Smartphone
7. Educate Patient
8. Discharge Patient

### \*IMPORTANT NOTE:

The ICM should not be paired prior to implant. Pairing should only occur after the ICM has been successfully implanted.

myMERLIN™ MOBILE APP

# PAIRING TO THE CARDIAC MONITOR

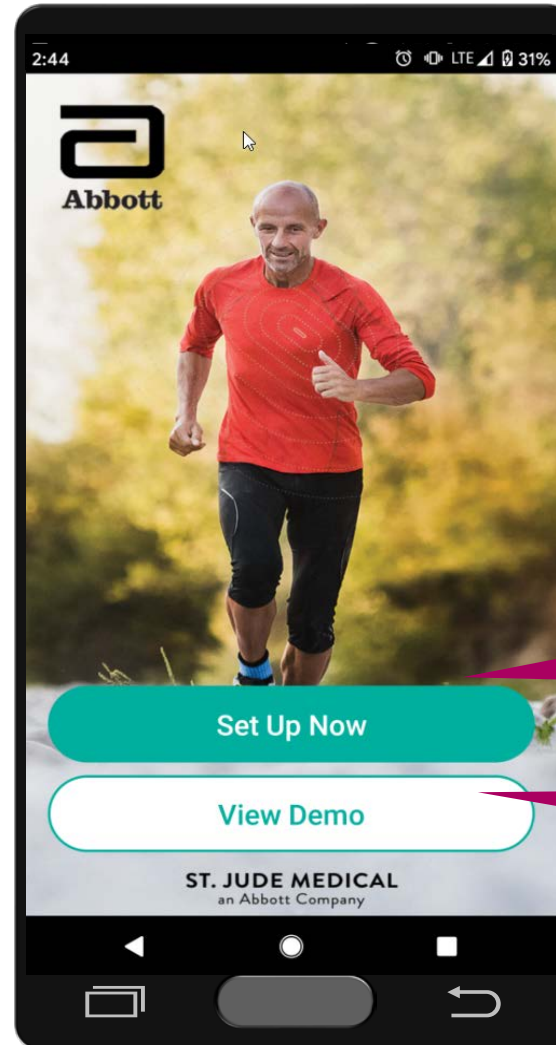




# myMerlin™ Mobile App

## SPLASH SCREEN

- Only visible when a patient's mobile device is not paired to their cardiac monitor



**SET UP NOW**  
Starts the pairing process.

**VIEW DEMO**

Opens the tutorial menu.

# Setup

## PAIR AFTER THE INSERTION PROCEDURE

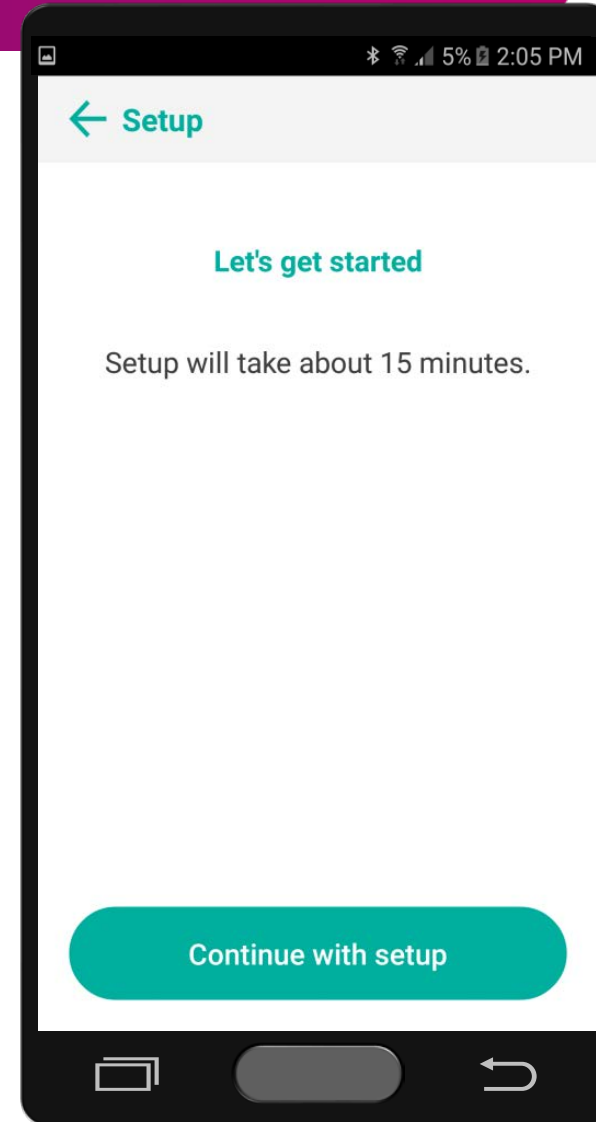
- Process should take just a few minutes if done at this time, but can take up to 15 minutes to complete.

### **\*IMPORTANT NOTE:**

The ICM should not be paired prior to implant. Pairing should only occur after the ICM has been successfully implanted.

## INTERNET CONNECTION IS REQUIRED

- Wi-Fi<sup>†</sup> or
- Cellular data connection



# Patient Info

- Patient information required to pair to cardiac monitor
- Must be entered correctly and match the patient's profile in Merlin.net™ PCN
- Authentication information required for device security

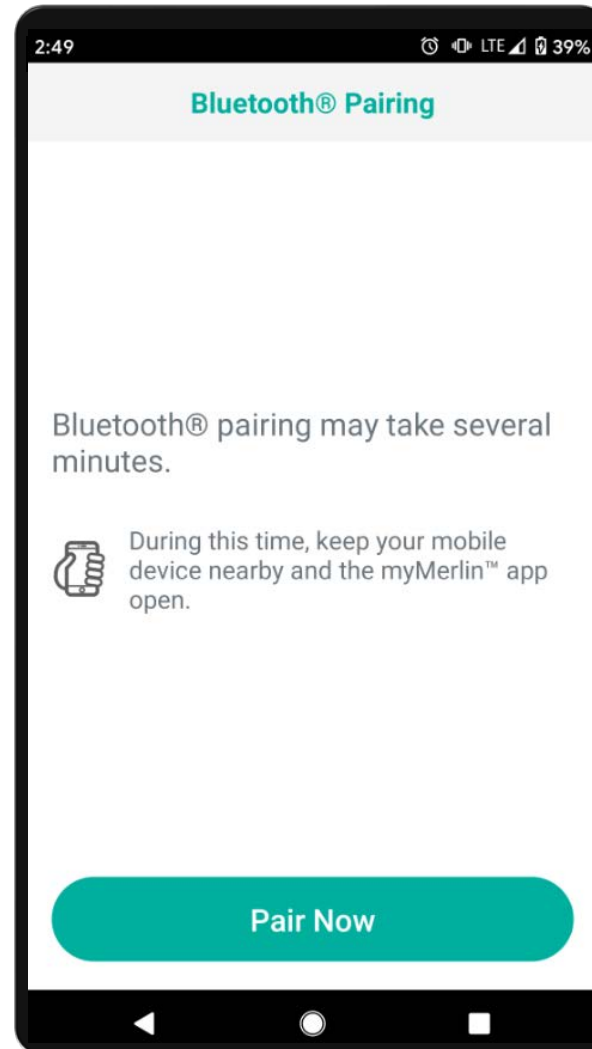
**MESSAGE**  
Depending on the country, this message may be displayed. For help, please call your local Abbott representative.

The image shows a smartphone screen with a 'Patient Info' form. At the top, there is a back arrow and the title 'Patient Info'. The form has two input fields: 'Date of Birth' with the value '4/1/00' and 'Confirm Rx™ Serial Number' with the value '8006724'. Below the form, there is a teal 'Next' button. At the bottom of the screen, there is contact information for Remote Care Technical Support: 'For help, please call: Remote Care Technical Support 1-877-MY-MERLIN or +1-877-696-3754'. The phone's status bar at the top shows 5% battery and 2:05 PM.

**PATIENT INFO**  
Enter patient date of birth and Confirm Rx™ ICM serial number.  
  
The implanted device serial number is located on the patient ID card.

# Bluetooth® Wireless Technology Pairing

- Patient's device is ready to pair to their cardiac monitor
- Mobile device must be within 1.5 m (5 ft) of the patient



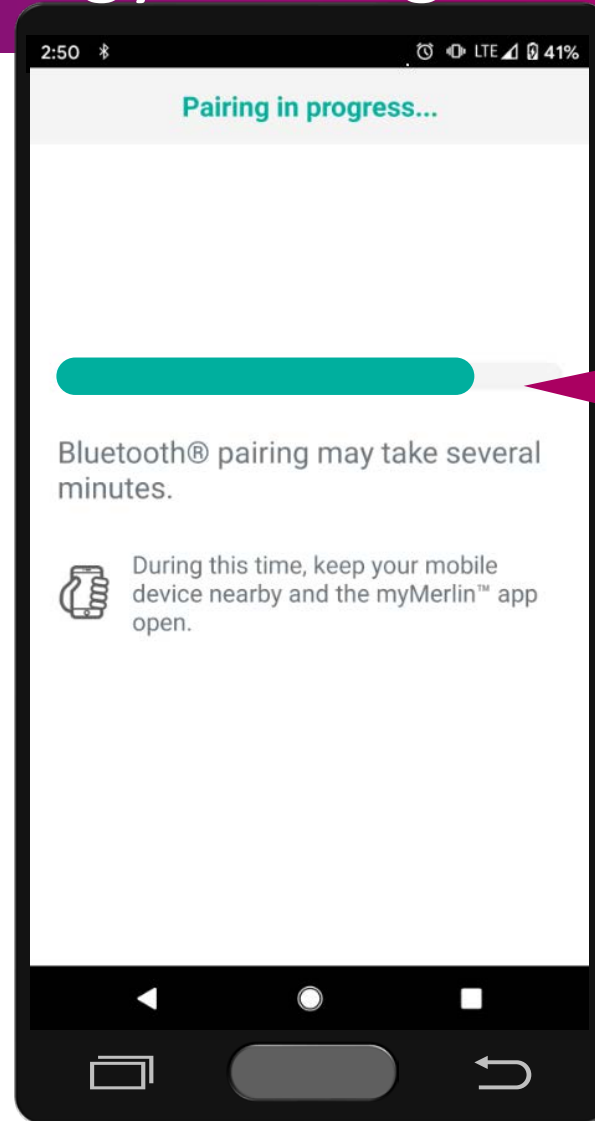
**READY TO PAIR?**  
Keep the patient's mobile device within 1.5 m (5 ft) of the implanted device.

# Bluetooth® Wireless Technology Pairing

- Progress bar indicates status
- Mobile device must be within 1.5 m (5 ft) of the patient
- This step is the longest and may take several minutes to complete

## IF PAIRING FAILS:

- Ensure data connection (Cellular/Wi-Fi<sup>†</sup>)
- Confirm patient's Merlin.net™ information is correct



**PROGRESS BAR**  
Indicates status.

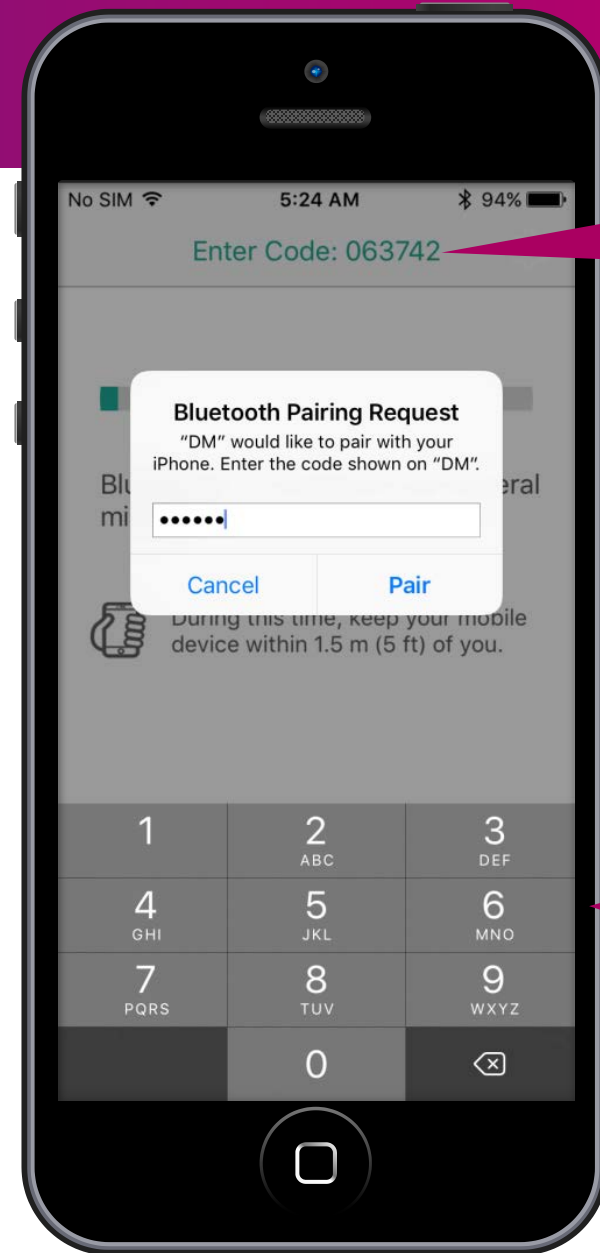
# iOS<sup>†</sup> Software Devices

## BLUETOOTH<sup>®</sup> WIRELESS TECHNOLOGY PAIRING REQUEST

- Prompt appears shortly after pressing

Pair Now

- Code is displayed in the background
- iOS software requires the code to be entered within approximately **30 seconds**



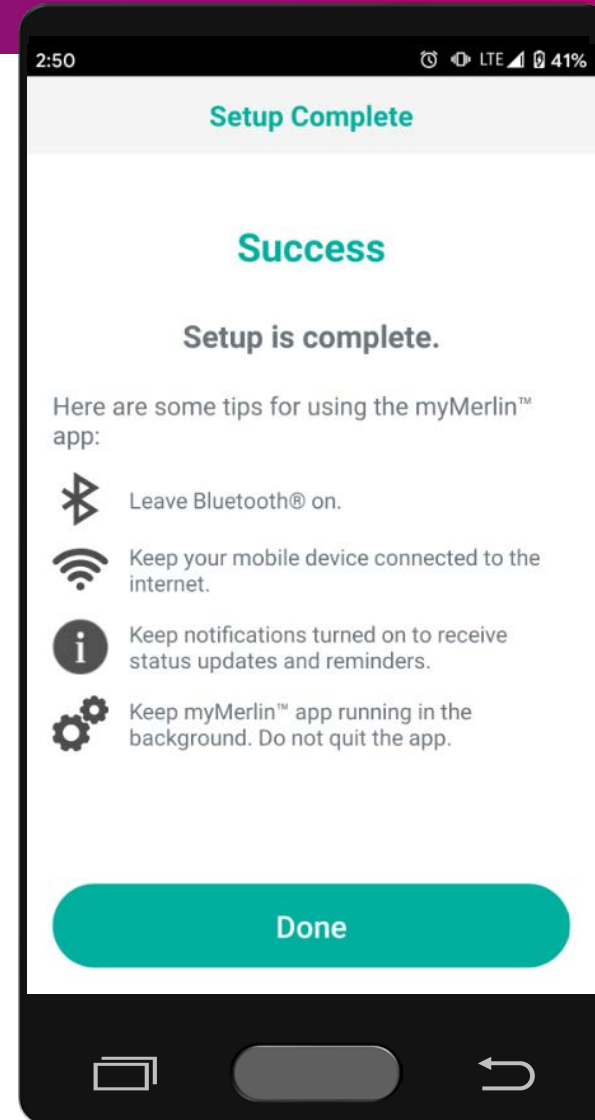
**CODE** is displayed  
in the background.

**ENTER CODE**  
using keypad

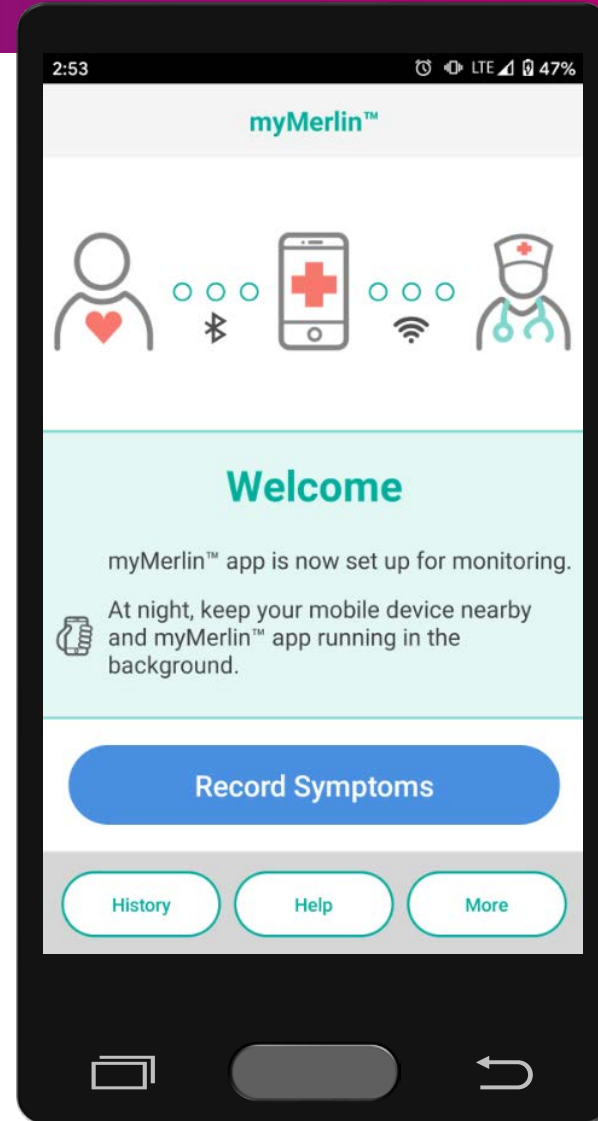
# Setup Complete

## PATIENT INSTRUCTIONS

- Leave Bluetooth® wireless technology ON
- Keep mobile device connected to the internet
- Keep notifications turned ON
- Keep myMerlin™ app running in the background. Do not quit app.



# Home Screen





# Activation Code

**REQUIRED IF THE PATIENT'S CARDIAC MONITOR HAS BEEN PAIRED PREVIOUSLY WITH ANY SMARTPHONE**

- Additional authentication required for device security

## EXAMPLES OF WHEN THIS IS REQUIRED

- The patient purchases or exchanges their mobile device for a new one
- The patient needs to wipe their existing mobile device
- The patient unpairs their Confirm Rx™ ICM from their mobile device via the Bluetooth® wireless technology settings menu

Activation Code Delivery

You will need to enter an activation code.

How would you like to receive it?

Email: t\*\*\*\*r@abbott.com

Text: \*\*\*\*\*8655

I already have a code

For help, please call:  
Remote Care Technical Support  
1-877-MY-MERLIN or  
+1-877-696-3754

Next

## ACTIVATION CODE DELIVERY

Select how you want to receive your activation code.

Email and phone number are obtained from the Merlin.net™ PCN.

# Operating System Updates



- Apple<sup>‡</sup> and Google<sup>‡</sup> periodically update the OS for their devices
- The myMerlin™ mobile app will undergo assessment upon release of OS updates
- On rare occasions, certain OS updates may impact the functionality of the myMerlin mobile app
- Compatibility warning messages are turned on by Abbott **only** if compatibility testing is not complete **or** if a compatibility issue is discovered
- Notifications informing patients of compatibility issues will automatically be pushed to the myMerlin mobile app by Abbott

## TWO COMPATIBILITY MESSAGES

**WARNING:** App is still allowed to be used

**BLOCK:** App is not able to be used until compatibility issue is resolved

myMERLIN™ MOBILE APP

# RECORDING A SYMPTOM EPISODE




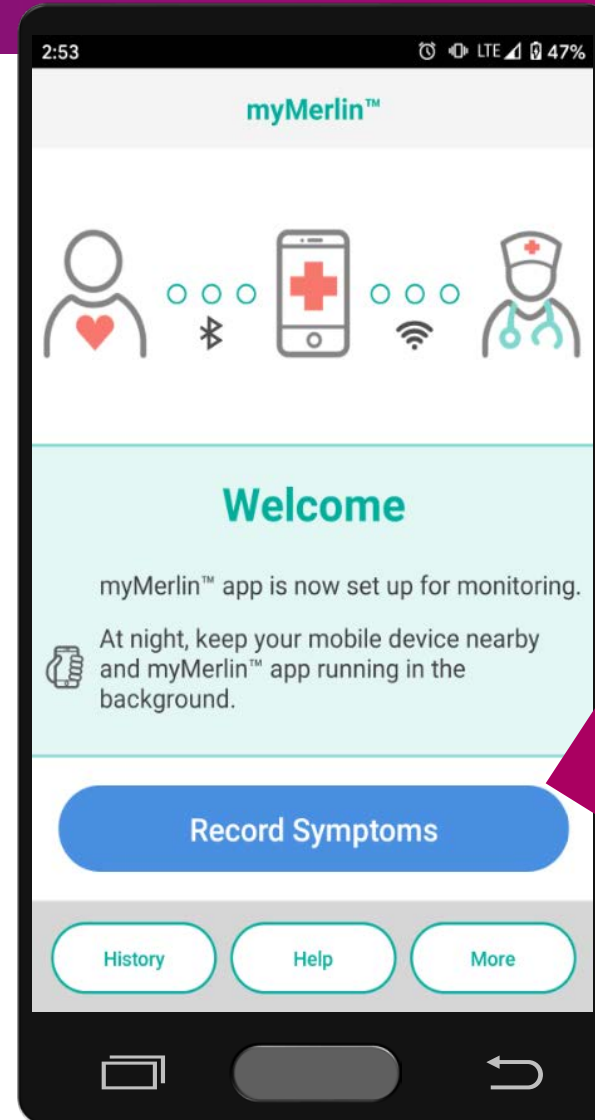
# Home Screen

## BUTTONS

- Record Symptoms
- History
- Help
- More

**NOTE: THE RECORD SYMPTOMS BUTTON IS ONLY DISPLAYED** if the option is selected in the patient's Merlin.net™ PCN settings.

Record Symptom using Patient App 



Based on the patient's indication, a clinician may request that a patient perform a symptom recording in their cardiac monitor when they are feeling symptomatic.

These recordings are sent to the follow-up clinic for review. It is important to remind patients that this is only to be used when they are symptomatic.

# Select Symptoms

## PREDEFINED SYMPTOM LIST

- Select none, one or multiple
- Mobile device initiates connection with the patient's ICM in the background while this screen is displayed

myMerlin™

What symptoms are you having?

Fainting

Dizziness

Fluttering

Shortness of breath

Fast heart rate

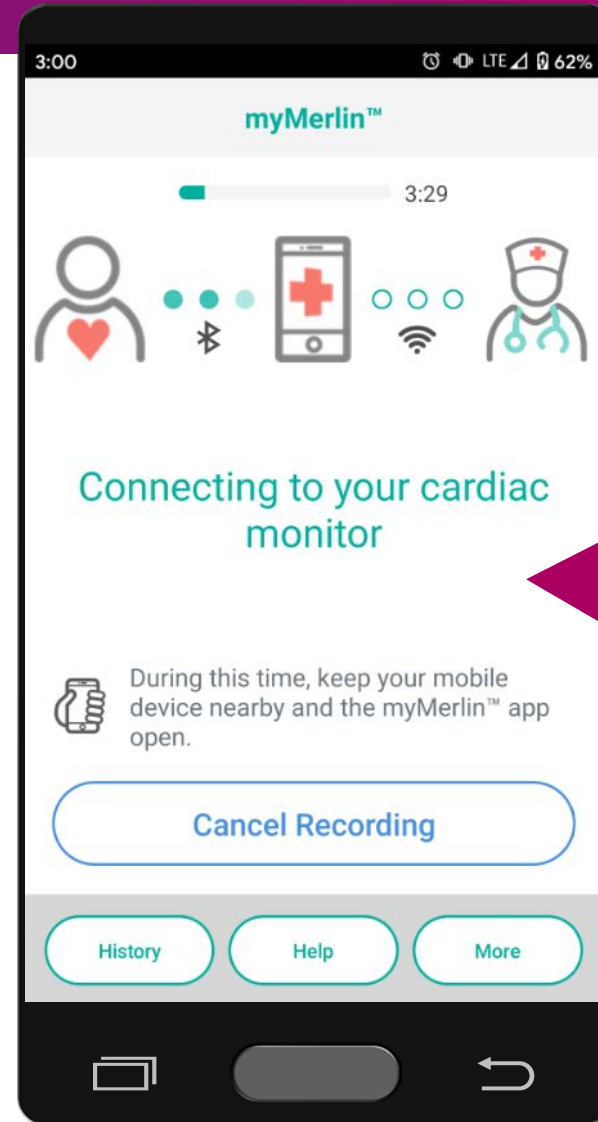
Other

Done

Which symptom is the patient experiencing?

# Connecting

- Bluetooth® wireless technology connection initiated with cardiac monitor
- Upon connection, episode recording is initiated in the ICM

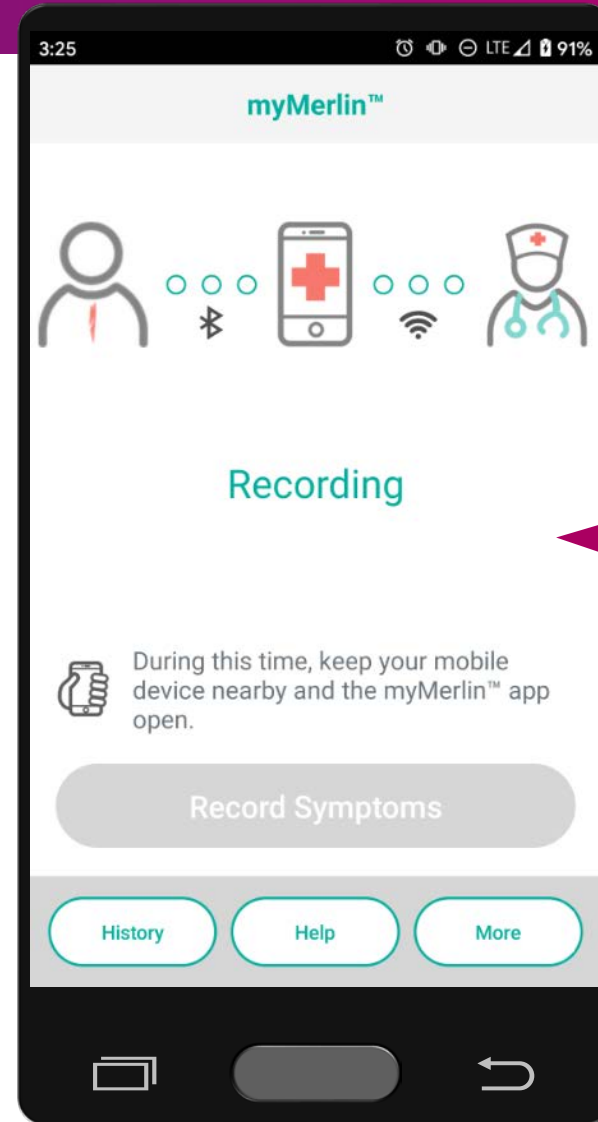


Once this process has started, the patient may put their mobile device away in their pocket while it automatically progresses through the next few steps.

# Recording

## SYMPTOM EPISODE

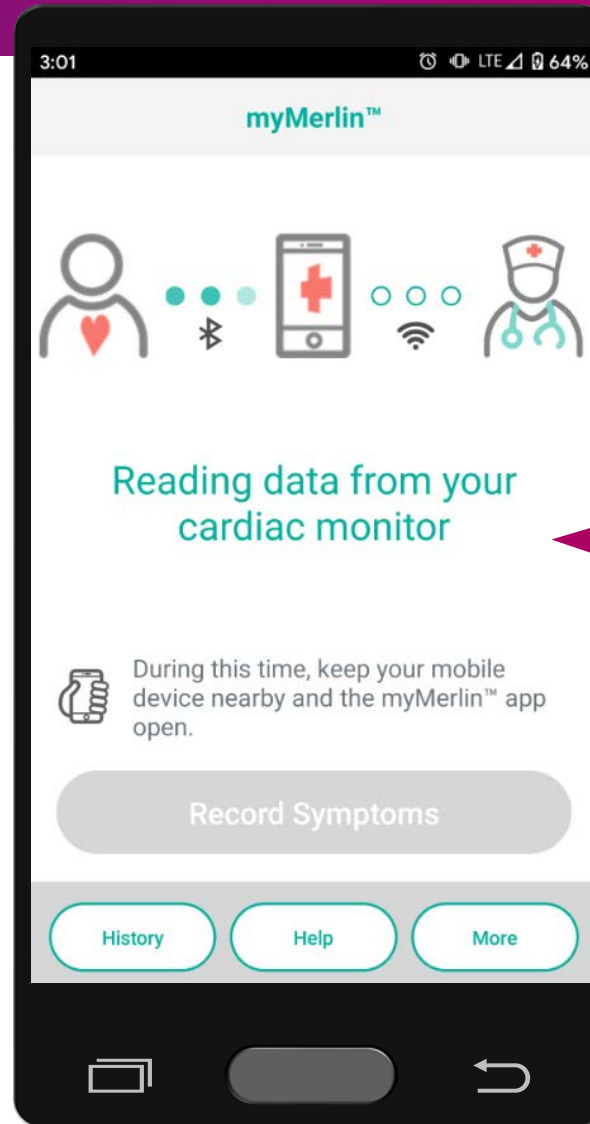
is recorded within the  
Confirm Rx™ ICM



The patient's cardiac monitor is now recording information.

# Reading Data

**AFTER THE SYMPTOM EPISODE HAS BEEN RECORDED,** the myMerlin™ mobile app will download the episode



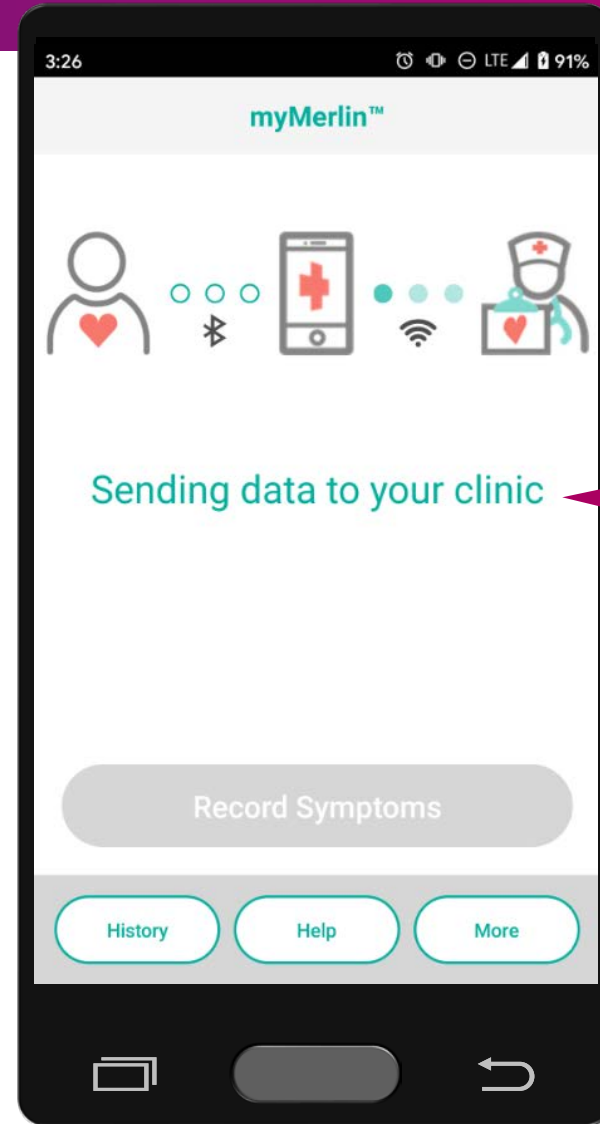
The mobile app is now downloading information from the cardiac monitor.



# Sending Data

**AFTER THE SYMPTOM EPISODE HAS BEEN RECORDED,** the myMerlin™ mobile app will download the episode

**ONLY** displayed in Merlin.net™ PCN Recent Transmissions if the patient's DirectAlert™ settings have symptom episodes configured as  red or  yellow alerts



The app will now send data to the patient's device clinic.

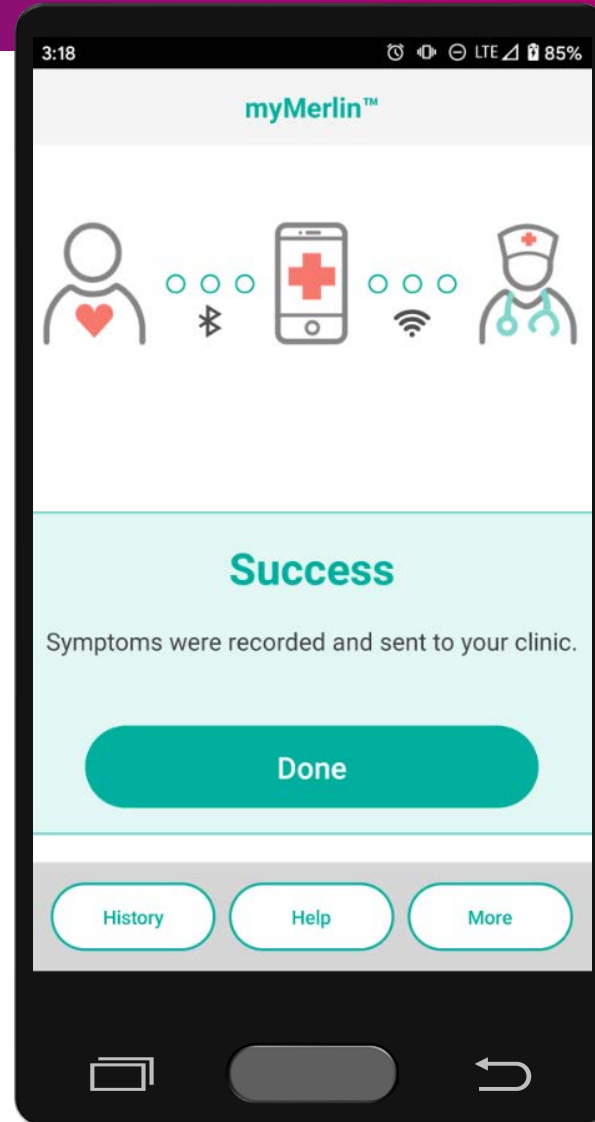


Average Monthly Data Usage

**< 10 MB** PER MONTH WITH NORMAL USAGE

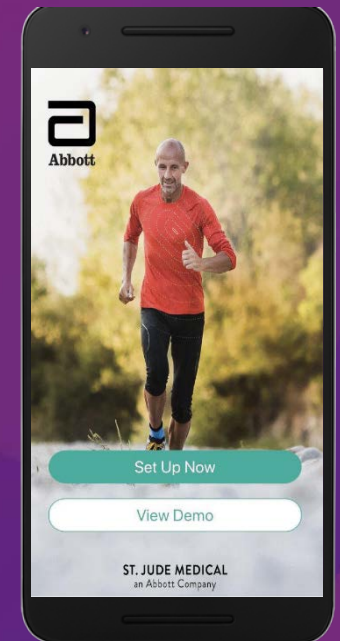
# Success

**DATA SUCCESSFULLY TRANSMITTED** to  
the Merlin.net™ Patient Care Network



ENHANCEMENTS TO myMERLIN™ MOBILE APP

# Confirm Rx™ ICM



# 4 Major Improvements to the myMerlin™ Mobile App

## THE myMERLIN™ MOBILE APP

ENSURES PATIENTS ARE CONNECTED WHEN IT MATTERS MOST

The new mobile app enhancements include:

1

Updates to patient notifications and prompts, helping patients stay connected

2

Improved compatibility with new Android<sup>‡</sup> and iOS<sup>‡</sup> operating systems

3

Optimized workflow for a better patient experience

4

The look and feel of some screens within the myMerlin™ app have been updated

# Patient Notifications and Prompts

1

2

3

4

## **UPDATES TO THE PATIENT NOTIFICATIONS AND PROMPTS HELPING PATIENTS STAY CONNECTED**

- Improved frequency of app notifications.
- More automatic retries of incomplete transmissions and device checks.
- Requests to keep the app open or running.
- New notifications to assist with maintaining appropriate battery optimization settings.

# Patient Notifications and Prompts

1

2

3

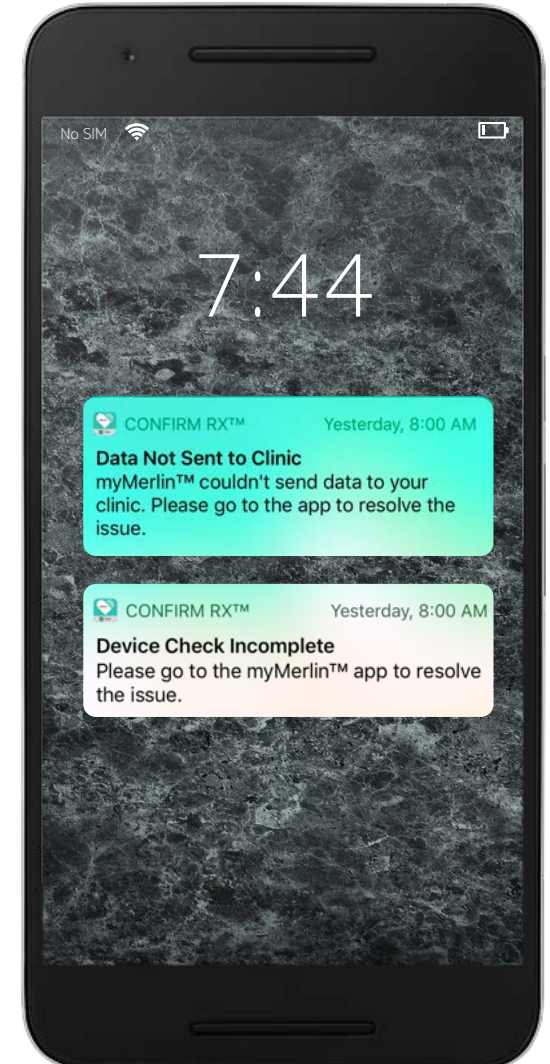
4

**The myMerlin™ mobile app will now display local notifications to the patient whenever an activity is not completed as scheduled.**

For example:

1. If data is not sent to clinic for two consecutive days.
2. If app is not able to connect to the device to perform a daily device check for two consecutive days.
3. These notifications will appear even if the patient has “force closed” the app!

**If multiple issues occur, the notifications will appear concurrently on the same screen.**



# Patient Notifications and Prompts

1

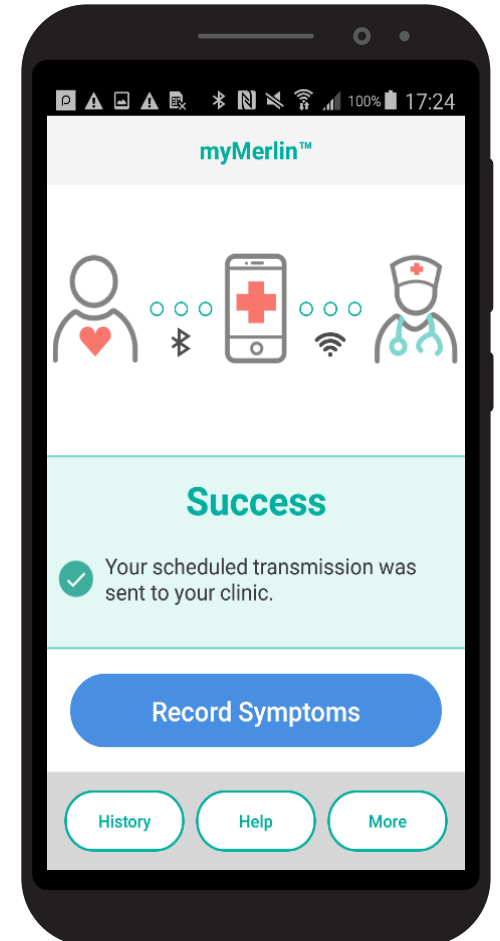
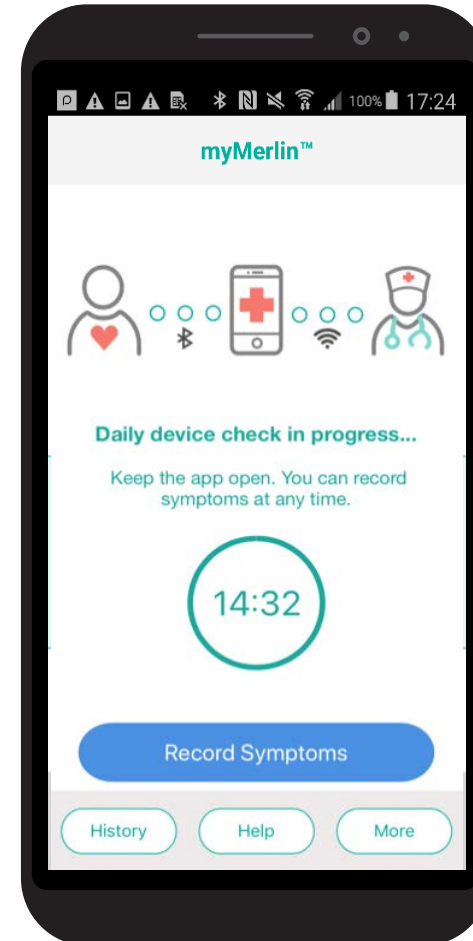
2

3

4

The local notification appears on the 2nd day after the problem was identified and will appear daily until resolved – even if the app is not running in the background!

- Upon seeing the notification, the user should tap it to open the myMerlin™ app.
- When the user taps the local notification, this will launch the myMerlin™ app.
- When the app is launched, it will automatically attempt to complete any overdue workflows.
- This new behavior, called “Automatic Retry”, will perform the same functions that previously required the user to tap the “Try Now” or “Send Data Now” buttons.



# Patient Notifications and Prompts

1

2

3

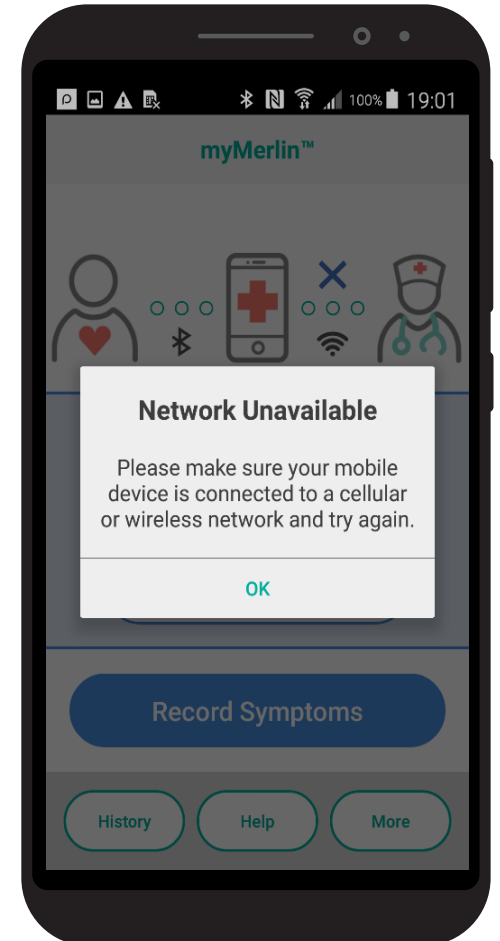
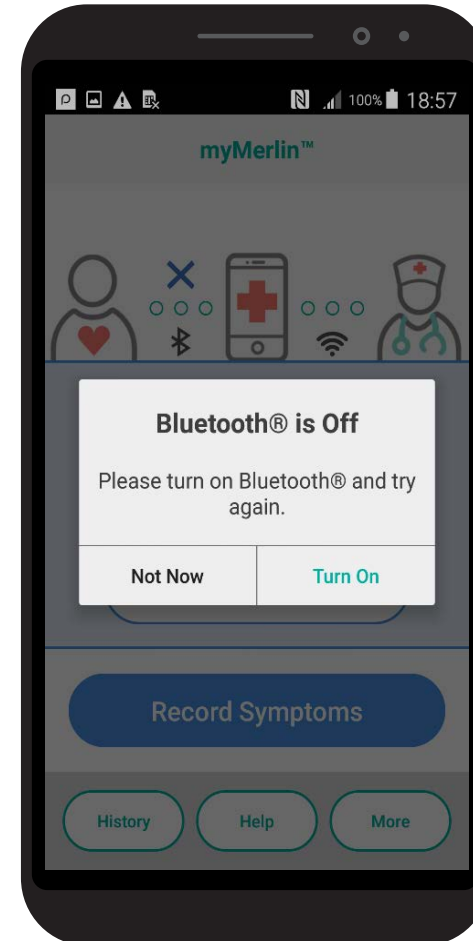
4

**Before attempting to automatically connect to the device, the app will also check to ensure the phone is set up correctly.**

If the phone's Bluetooth® or Wi-Fi<sup>±</sup> (internet connectivity) is turned OFF when the app attempts to automatically connect to the device, it will prompt the user to address the set-up issue.

As a reminder:

- Bluetooth® must be “ON.”
- Internet/Wi-Fi must be connected





# Patient Notifications and Prompts

1

2

3

4

## With the app enhancements, there are new notifications to assist with maintaining appropriate battery optimization settings.

Ensure battery optimization is disabled for Android<sup>‡</sup> devices (Android 6.0 and later).

- If battery optimization is enabled, a dialog notification is generated by the Android phone.
- The dialog will re-appear every 24 hours while the setting remains enabled!

### Do not optimize battery usage.

Confirm Rx™ will be able to run in the background and its battery usage will stop being optimized.

NO

YES

### Stop optimizing battery usage?

Confirm Rx™ will be able to run in the background. Its battery usage won't be restricted.

NO

YES

### Let app always run in background?

Allowing Confirm Rx™ to always run in the background may reduce battery life.

You can change this later from Settings > Apps & notifications.

Deny

Allow

If battery optimization is enabled, a dialog notification is generated by the Android phone, and text may vary, depending on the phone.

# Operating System Compatibility

1

2

3

4

## Improved compatibility with new Android<sup>‡</sup> and iOS<sup>‡</sup> operating systems.

- Better connection via Bluetooth<sup>®</sup> wireless technology.
- More frequent requests to wake up the myMerlin<sup>™</sup> app by Merlin.net<sup>™</sup> Patient Care Network.



# Operating System Compatibility

1

2

3

4

**Merlin.net™ PCN now sends hourly “silent push notifications” to each iOS<sup>‡</sup> app from approximately 2 a.m. –7 a.m. every day.**

The goal is to “wake up” the app and to give it more opportunities to try to complete the overnight activities.

(The previous behavior was one nightly push notification at 4 a.m. to each iOS<sup>‡</sup> app.)



# Workflow Improvements

1

2

3

4

## **The workflow has been optimized for a better patient experience.**

- In the new app software, if the last step in pairing the device to the myMerlin™ mobile app is unsuccessful, it can be re-attempted once internet connectivity is more reliable without repeating the entire set-up process from the beginning.
- There is also now a six-hour window to complete the set-up process.

# Workflow Improvements

1 2 3 4

The setup and pairing of the myMerlin™ mobile app now completes in three main phases:

## 1. VALIDATION

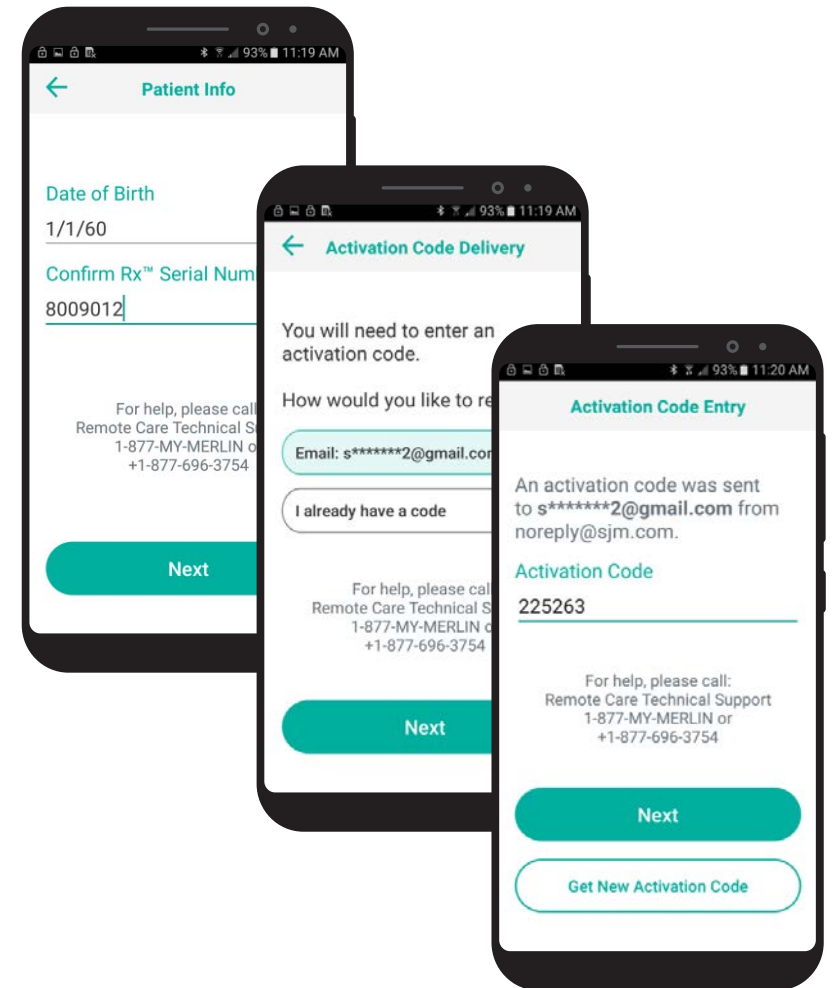
- The user enters date of birth and serial number in the myMerlin™ mobile app.
- The app receives validation and secure credentials back from Merlin.net™ PCN.

## 2. BONDING

- The app uses secure credentials to create a Bluetooth® bond with the Confirm Rx™ ICM.

## 3. PROFILE SYNC

- The app receives profiles (follow-up schedules, DirectAlert™ settings, etc.) from Merlin.net™ PCN.
- The app configures the DirectAlert™ settings in the ICM device.

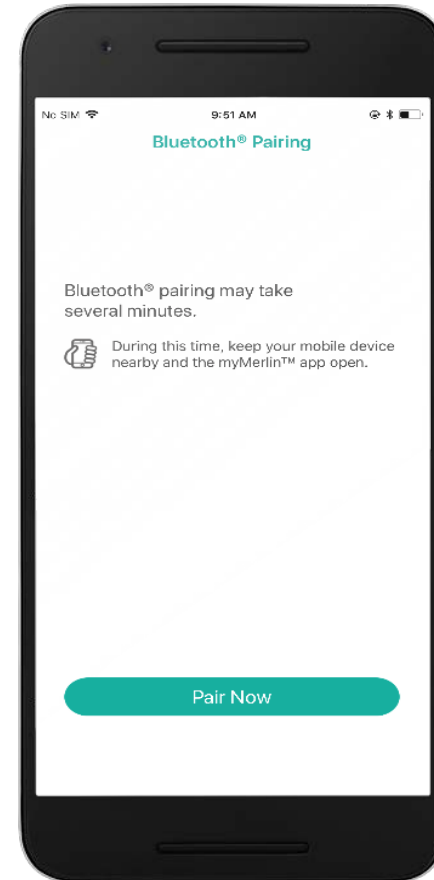


# Workflow Improvements



## The setup and pairing of the myMerlin™ mobile app now completes in three main phases:

- Once any stage successfully completes it does not need to be repeated.
- The third stage can now be completed outside the hospital. It fails most frequently with one of the following errors:
  - “Connection Problem”
  - “Network Problem”
  - “Unable to Complete Set-up”
- You now have 6 hours to complete the pairing process once it has been initiated.
  - If unable to connect within the 6-hour window the app will go back to the “Set-Up Now” screen.



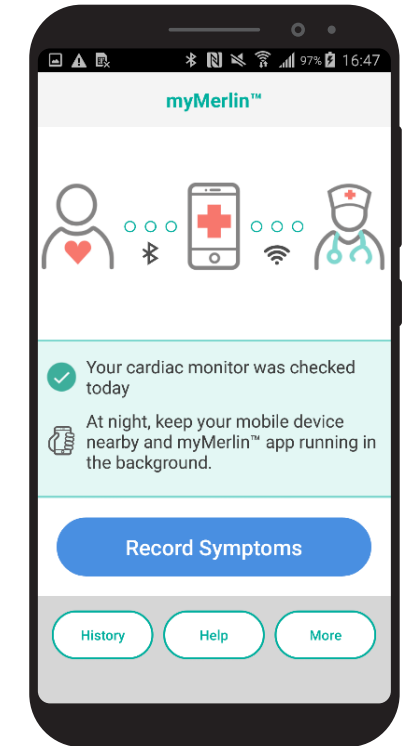
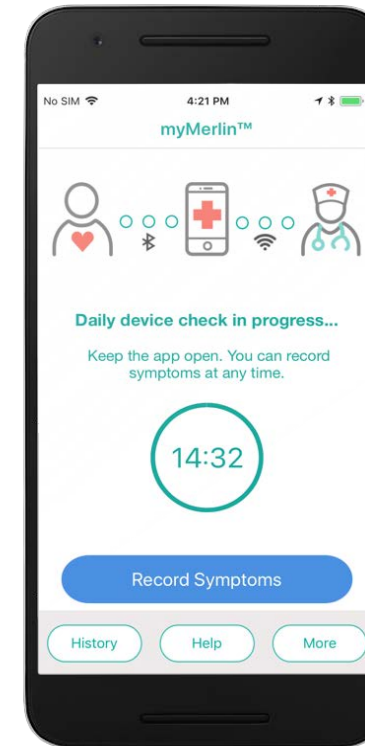
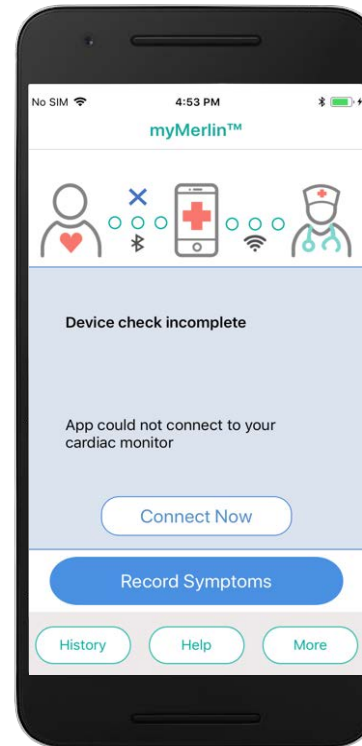
If you are unable to complete pairing at the clinic, instruct the patient to select the “Pair Now” button, when they are in an area of good internet connectivity. They will have 6 hours to complete the process.

# Improving the Look and Feel of the App



## The look and feel of some screens within the myMerlin™ app have been updated.

- The look and feel of some screens has been updated and the user interface is now optimized for an even better patient experience.
- Friendlier language of app notifications.



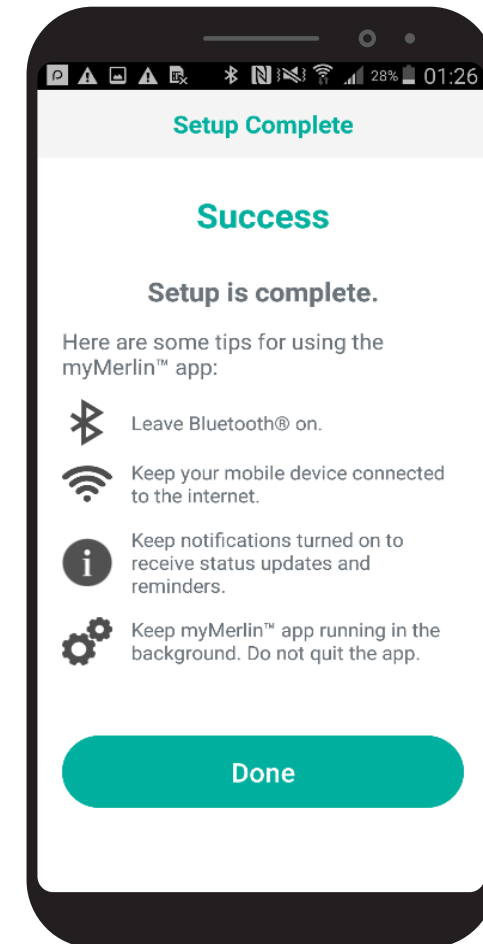
# Tips and Tricks for Successful Use of the myMerlin™ App

## TIPS AND TRICKS

- Do not disable app permissions for the myMerlin™ mobile app.
- Allow notifications from the myMerlin™ mobile app.
- Stay connected to the internet.
- Do not force quit the app.
- Keep app running in the background.

## KEEP THE APP OPEN DURING ACTIVITIES SUCH AS:

- “Set-Up”
- “Pair Now”
- “Connect Now”
- “Automatic Retry”





OVERVIEW AND  
SHARPSense™ TECHNOLOGY  
ENHANCEMENTS



PAIRING AND CONNECTIVITY



FOLLOW-UP ON  
MERLIN.NET™ PCN



# Topics Covered

- Remote Follow-up with Merlin.net PCN
  - Patient Enrollment
  - Scheduling
  - DirectAlerts™ Notification Feature
  - Episode Types
- Additional Features/Smart Tools

MERLIN.NET™ PCN

# PATIENT ENROLLMENT



# Patient Enrollment Workflow



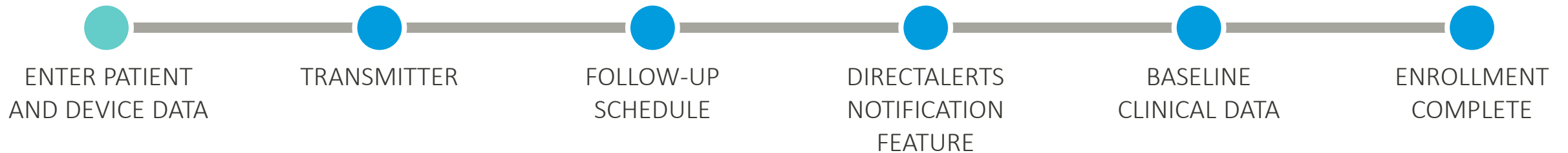
## PROCEDURE STAFF

- Enroll patient in Merlin.net™ PCN
- Release/transfer patient to the referring (follow-up) clinic

## REFERRING (FOLLOW-UP) CLINIC STAFF

Follow-up clinic finishes enrollment by completing the following steps:

- Follow-up schedule
- DirectAlerts™ notification settings
- Baseline clinical data on Merlin.net PCN



# Merlin.net™ Patient Care Network (PCN)

## What is an Implant-Only Account?

### WHAT'S THE DIFFERENCE BETWEEN CLINIC TYPES?

- Implant-only accounts have a simplified workflow for enrolling and transferring patients
- Will not receive clinical data from the myMerlin™ mobile app

### HOW IS AN IMPLANTING-ONLY ACCOUNT SET UP?

1. Complete a Merlin.net PCN clinic enrollment form (implanting-only account section)
2. List all associated clinics (clinics that the implant-only account will transfer patient profiles to after the procedure)
3. Submit the form to [syconnectivity@abbott.com](mailto:syconnectivity@abbott.com)

#### CLINIC ENROLLMENT FORM FOR MERLIN.NET™ PATIENT CARE NETWORK (PCN)

Email: [syconnectivity@abbott.com](mailto:syconnectivity@abbott.com)

Fax To: 1-800-918-8111

DATE: / /

Thank you for your interest in the St. Jude Medical Merlin.net™ Patient Care Network (PCN). In order to enroll, please complete this form with your Merlin.net™ PCN Field Representative.

##### CLINIC INFORMATION

NAME OF CLINIC OR GROUP (30 Char. Limit): \_\_\_\_\_  
PRIMARY ADDRESS: \_\_\_\_\_  
CITY: \_\_\_\_\_ STATE: \_\_\_\_\_ ZIP: \_\_\_\_\_  
TELEPHONE: \_\_\_\_\_ FAX: \_\_\_\_\_

##### CLINIC TYPE

PLEASE SELECT THE TYPE OF CLINIC:  IMPLANTING ONLY  REFERRING

Allows procedure staff at 'Implanting Only' centers to:

1. Enroll newly implanted patients without receiving transmissions or alerts.
2. Transfer patients to respective referring centers after implant.

Allows Referring Centers to:

1. Enroll new patients, receive transmissions and alerts
2. Request routine patient transfers into their account from implanting centers.
3. View patients awaiting transfer into their Merlin.net PCN clinic from another account.

##### ASSOCIATED SITES

Site associations allow easy transfer of patients to other sites. If this site is to be associated with others, include a site name and Merlin.net PCN user from the associated account.

1. MERLIN.NET PCN CLINIC NAME: \_\_\_\_\_ MERLIN.NET PCN USER ID: \_\_\_\_\_  
2. MERLIN.NET PCN CLINIC NAME: \_\_\_\_\_ MERLIN.NET PCN USER ID: \_\_\_\_\_  
3. MERLIN.NET PCN CLINIC NAME: \_\_\_\_\_ MERLIN.NET PCN USER ID: \_\_\_\_\_

##### MERLIN.NET PCN SYSTEM ADMINISTRATOR

MERLIN.NET PCN SYSTEM ADMINISTRATOR: \_\_\_\_\_  
TELEPHONE: \_\_\_\_\_ EMAIL: \_\_\_\_\_

Note: The Merlin.net PCN system administrator will be emailed a username and password, and will be responsible for adding additional clinic users.

FIELD REPRESENTATIVE: \_\_\_\_\_ REP NUMBER: \_\_\_\_\_  
TELEPHONE: \_\_\_\_\_ EMAIL: \_\_\_\_\_

PLEASE FAX OR EMAIL THIS CLINIC ENROLLMENT FORM TO THE CONTACT INFORMATION PROVIDED ABOVE.

##### Rx Only

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. Unless otherwise noted ™ indicates that the name is a trademark of, or licensed to, St. Jude Medical or one of its affiliates.

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SJM-MER-117-011(S) Item approved for U.S. use only.

# Merlin.net™ Patient Care Network (PCN)

## Overview

## Managing Cardiac Monitor Patients With Merlin.net PCN

### ENHANCEMENTS FOR CARDIAC MONITORS

- Enrolling Cardiac Monitor Patients
- Implant-only Account Type for Procedure Staff
- DirectAlerts™ Notification Settings for ICM

### ADDITIONAL MERLIN.NET PCN FEATURES

- Connectivity Column
- Disconnected Transmitter Thresholds
- Transferring Patient Profiles

The screenshot displays the Merlin.net Patient Care Network interface. At the top, the Abbott logo is on the left, and user information 'Signed in as E Cunningham' with 'Help', 'Switch to', and 'Sign Out' options is on the right. Below this is a navigation bar with tabs for 'Recent Transmissions', 'Patient List', 'Tools', and 'Clinic Administration'. The main content area shows a table of patients with the following columns: Patient, Transmission, Schedule, Device, DirectAlerts™, and Alerts List. A search bar is located above the table. On the right side, there is a 'Quick Links' sidebar with various metrics and a 'Patient Management' section.

Patient	Transmission	Schedule	Device	DirectAlerts™	Alerts List
Craft (VT w/ ATP), Mr.	07-06-2012 09:08 AM Patient initiated	09-17-2012 73 days	Current™ VR RF, 1207-36 : 60391	🚩	Successful ATP; Alert Episodes 2
Aybar (AT/AF burden), Mr.	07-06-2012 09:16 AM Scheduled	05-21-2014 684 days	Accent™ DR RF, 2210 : 60351	🚩	AT/AF burden; PMT detection;
Craft (VT w/ ATP), Mr.	07-06-2012 02:40 AM	09-17-2012 73 days	Current™ VR RF, 1207-36 : 60391	🚩	Successful ATP; Alert Episodes 2
Harris (VT), Mrs.	07-28-2012 06:40 AM Alert initiated	10-16-2012 80 days	Fortify™ DR, 2231-40 : 60371	🚩	Successful ATP;
Harris (VT), Mrs.	07-24-2012 06:00 AM	10-16-2012 84 days	Fortify™ DR, 2231-40 : 60371	🚩	Successful ATP;
Harris (VT), Mrs.	07-21-2012 06:38 AM	10-16-2012 87 days	Fortify™ DR, 2231-40 : 60371	🚩	Successful ATP;
Miller (VT/VF Shock), Mr.	07-30-2012 04:50 AM Alert initiated	10-22-2012 84 days	Current™ VR RF, 1207-36 : 60401	🚩	HV therapy;

# Merlin.net™ PCN Patient Enrollment

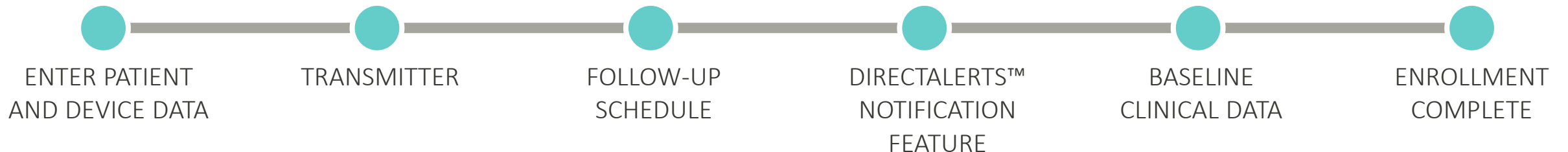
## WHAT'S UNIQUE FOR ICM DEVICES?

- New Required Field: Implanting Physician
- Follow-up schedule default: 31 days for life for ICM patients

## HAS THE ENROLLMENT PROCESS CHANGED?

No, but ICM patients need to be **MANUALLY ENROLLED**

## WHAT IS THE MANUAL ENROLLMENT PROCESS?



**Enroll a Patient**

**Patient & Device Data**

**Device Data**

\* Serial #: 1234567

\* Device name: Confirm Rx™ ICM, DM3500

\* Implant Date: 04-23-2020

\* Implanting Physician: -- Select a Physician -- **NEW**

transmit every 31 Days for life

**NEW**

- 31 Days
- Week
- 2 Weeks
- 13 Weeks (91 days)
- 26 Weeks (182 days)
- Month
- 2 Months
- 3 Months
- 4 Months
- 6 Months

# Patient Enrollment

## Accessible from Quick Links Menu

Signed in as E Cunningham | Help | Switch to | Sign Out  
Merlin.net™ Patient Care Network

Recent Transmissions | Patient List | Tools | Clinic Administration

My Patients | All | Search by Name, ID, Dv | Archive | Print | More Actions

Patient	Transmission	Schedule	Device	DirectAlerts™	Alerts List
Craft (VT w/ ATP), Mr.	07-06-2012, 09:08 AM Patient initiated	09-17-2012 73 days	Current™ VR RF, 1207-36 : 60391	🚩	Successful ATP, Alert Episodes 2
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Craft (VT w/ ATP), Mr.	07-06-2012, 02:40 AM	09-17-2012 73 days	Current™ VR RF, 1207-36 : 60391	🚩	Successful ATP, Alert Episodes 2
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Harris (VT), Mrs.	07-24-2012, 06:00 AM	10-16-2012 84 days	Fertily™ DR, 2231-40 : 60371	🚩	Successful ATP,
Harris (VT), Mrs.	07-21-2012, 06:38 AM	10-16-2012 87 days	Fertily™ DR, 2231-40 : 60371	🚩	Successful ATP,
Miller (VT/VF Shock), Mr.	07-30-2012, 04:50 AM Alert initiated	10-22-2012 84 days	Current™ VR RF, 1207-36 : 60401	🚩	

Quick Links

- Unviewed Transmissions: 8
- Transmissions with alerts: 20
- Patients with overdue follow-up: 0
- Patients with no future schedule: 1
- Patients with pending transmissions due today: 0
- Disconnected Transmitters: 5
- Messages: 0
- Patient Management
- My Active Patients: 14
- Enroll Transferred Patients: 0
- Release Requests from another clinic: 0

Enroll a new patient

**ENROLL NEW PATIENT**

Recent Transmissions | Patient List | Tools | Clinic Administration

## Enroll a Patient

### Enroll Patient by Device

Try this option first for auto enroll or transferring a patient

\* Device name:

\* Device Serial #:

\* Date of birth:

**Enroll**

### Enroll Patient by Merlin.net™ Number

\* Merlin.net™ number:

**Enroll**

### Enroll Manually

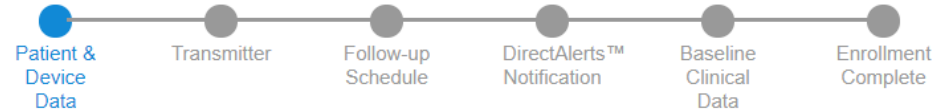
Use this option for manual enrollment.

**Enroll**

**ENROLL MANUALLY**

# Merlin.net™ PCN Patient Enrollment

## Enroll a Patient



### Patient & Device Data

#### Device Data

\* Serial #:

\* Device name:

\* Implant Date:

\* Implanting Physician:



#### Patient Details

\* First name:

Middle name:

\* Last name:

\* Date of birth:

\* Patient ID:

Merlin.net™ number:

Clinic location:

Clinic enrollment:

Race:

Gender:

Patient language:



#### Address and Contact [Emergency Contact](#)

\* Address 1:

Address 2:

Address 3:

\* City:

\* State/Prov.:

\* Zip/Postal code:

Country:

\* Primary/Mobile phone:

Email:



USED for myMerlin™ Mobile App Pairing

USED for Activation Code Delivery

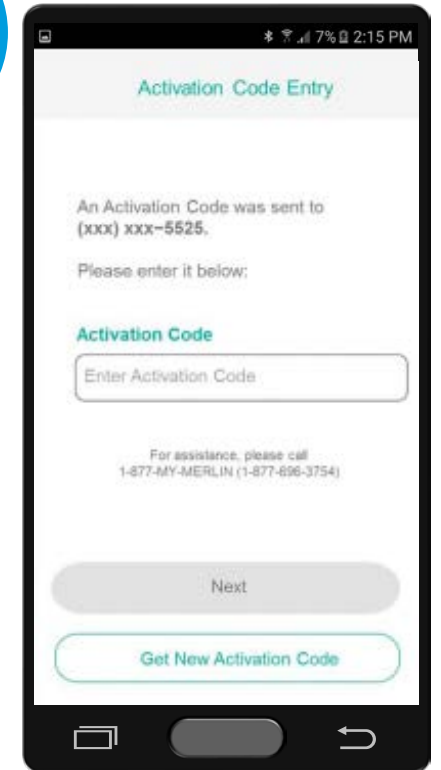


# Merlin.net™ PCN Activation Codes

## REQUIRED TO PAIR WITH PHONE ANYTIME AFTER THE FIRST (INITIAL) PAIRING

- Can be texted or emailed to the patient
- If there is no email address for the patient in the profile, the email option will not be available

**IF THE PHONE NUMBER IN THE PATIENT'S PROFILE IS A LANDLINE, THEY WILL NOT RECEIVE THE TEXT MESSAGE.** Please ensure the primary/mobile phone can receive text messages (or enter an email address).



### Address and Contact [Emergency Contact](#)

\* Address 1:

Address 2:

Address 3:

\* City:



\* State/Prov.:

\* Zip/Postal code:

Country: USA

\* Primary/Mobile phone: 1



Email:

USED for Activation Code Delivery

# Merlin.net™ PCN

## SmartSchedule™ Calendar

Enroll a Patient

Patient & Device Data Transmitter Follow-up Schedule DirectAlerts™ Notification Baseline Clinical Data Enrollment Complete

### Follow-up Schedule

**Schedule Type**

SmartSchedule™ calendar:  Manual entry calendar:  None:

**Permanent schedule:**

Starting on  MM-DD-YYYY   the  of

transmit every 31 Days for life

Switch to temporary schedule

Starting on:  MM-DD-YYYY   the  of

transmit every  for

then revert to permanent schedule:

Clear

Diagnostics and Episodes (including Stored EGMs)

Back Cancel Save and Close Continue

When checked, the Confirm Rx™ ICM will only clear during *scheduled* transmissions

# Merlin.net™ PCN

## DirectAlerts™ Notification Feature

### CHOOSE WHEN TO RECEIVE INFORMATION

#### Alert Type

##### Device Alerts

- Battery Low
- Parameter Errors
- Monitor at End Of Service
- Device Reset
- Monitoring Disabled



##### Clinical Alerts

- AF Episode
- Continuous AF
- AF Burden
- V. Rate during AF
- Tachy Episode
- Brady Episode
- Pause Episode
- Symptom Alert

Record Symptom using Patient App ⓘ

ALL alerts can always be seen in Recent Transmissions.

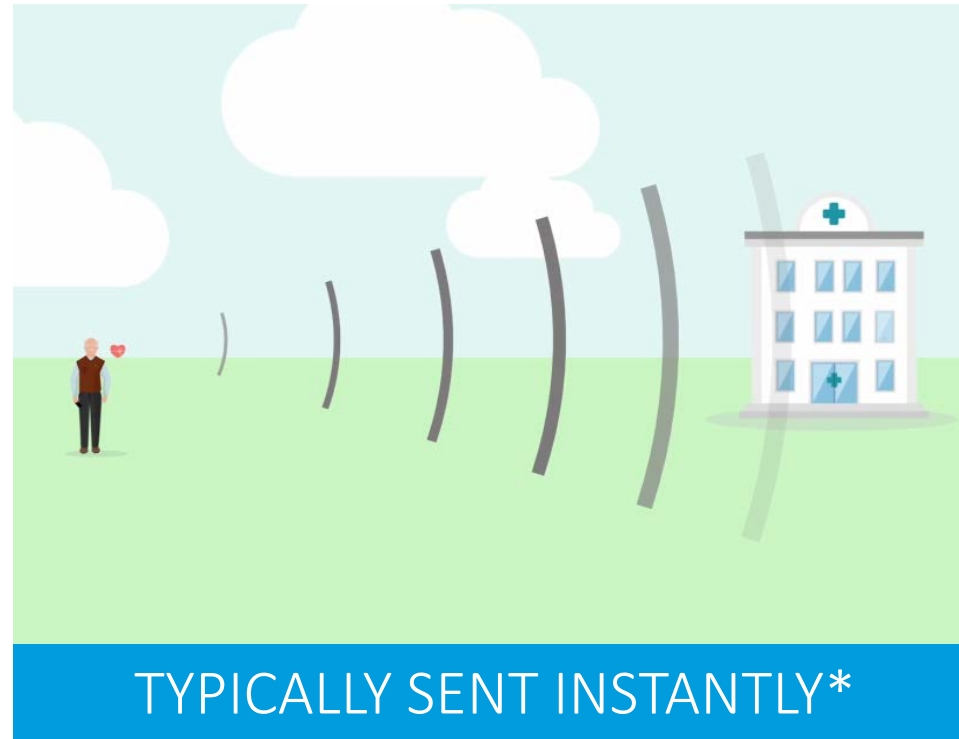
#### Alert Classification

 Red  Yellow Off

Alert Type	Red	Yellow	Off
<b>Device Alerts</b>			
Battery Low	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Parameter Errors	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Monitor at End Of Service	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Device Reset	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Monitoring Disabled	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
<b>Clinical Alerts</b>			
AF Episode	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Continuous AF	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
AF Burden	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
V. Rate during AF	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Tachy Episode	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Brady Episode	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Pause Episode	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Symptom Alert	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
<b>IMMEDIATELY</b>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
<b>DAILY CHECK</b>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
<b>SCHEDULED FOLLOW-UP</b>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

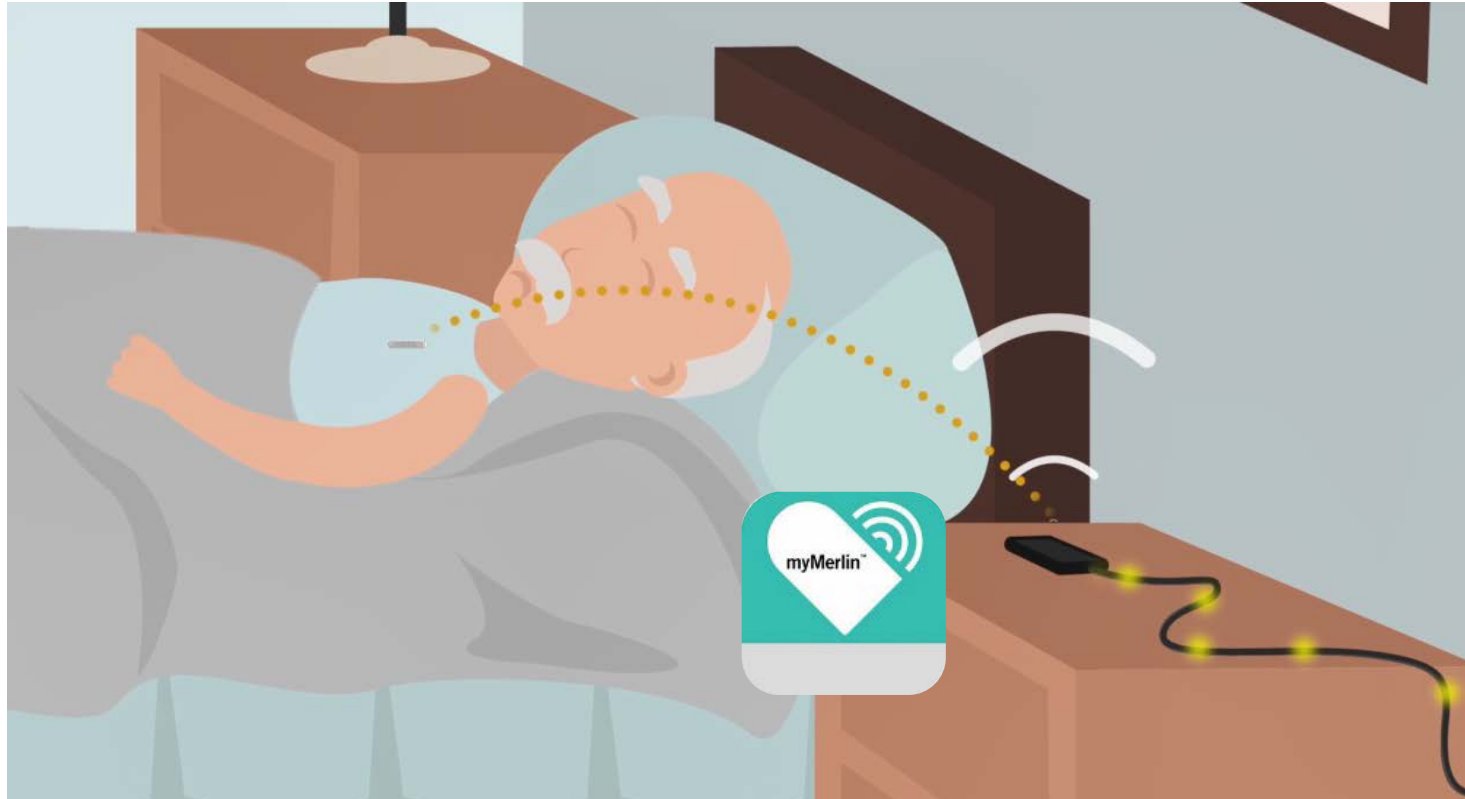
Make sure this is checked if the patient will be recording symptoms!

# Patient-Initiated Transmissions (Symptom Episodes)



\*Based on internet connection.

# Device-Detected Transmissions



DirectAlert™ checks are scheduled daily at 2:00 a.m. Device-detected episodes are also transmitted with the scheduled follow-up (default is every 31 days).



MERLIN.NET™ PCN

# ADDITIONAL FEATURES



# Transfer Patients — PULL WORKFLOW

(Requesting a Patient from Another Clinic)

## 1 SELECT ENROLL A PATIENT

## 2 FIND THE PATIENT PROFILE BY SEARCHING:

- Device Name OR Merlin.net™ PCN Number
- Device Serial Number
- Date of Birth

## 3 A RELEASE REQUEST IS SENT TO THE PATIENT'S CURRENT FOLLOW-UP CLINIC

## 4 REQUEST APPROVED BY PATIENT'S CURRENT FOLLOW-UP CLINIC

## 5 PATIENT'S PROFILE IS MADE AVAILABLE FOR ENROLLMENT (patient will move to the new clinic's "Enroll Transferred Patients" list)

The screenshot shows the Abbott Patient List interface. The 'Enroll a Patient' section is active, with sub-sections for 'Enroll Patient by Device' and 'Enroll Patient by Merlin.net™ Number'. The 'Enroll Patient by Device' section includes a dropdown for 'Device name', input fields for 'Device Serial #' and 'Date of birth' (MM-DD-YYYY), and an 'Enroll' button. The 'Enroll Patient by Merlin.net™ Number' section includes an input field for the 'Merlin.net™ number' and an 'Enroll' button.

Quick Links	
Unviewed Transmissions	8
Transmissions with alerts	20
Patients with overdue follow-up	0
Patients with no future schedule	1
Patients with pending transmissions due today	0
Disconnected Transmitters	5
Messages	0
Patient Management	
My Active Patients	14
Enroll Transferred Patients	0
Release Requests from another clinic	0
<a href="#">Enroll a new patient</a>	

PENDING REQUESTS

TRANSFERRED PATIENTS

# Transfer Patients — PUSH WORKFLOW

(Releasing a Patient from Your Clinic)

**Abbott** Signed in as *E Cunningham* Help ▾ Switch to Sign Out  
**Merlin.net™ Patient Care Network**

Recent Transmissions **Patient List** Tools Clinic Administration

Active Clinic Patients ▾ All ▾  Enroll a new patient **More Actions** ▾

Patient	Device	Implant Date	All Transmissions	Latest Transmission	Next Transmission	Latest Comments	<input type="checkbox"/>
ANDERSON STANLEY	Accent® DR RF, 2210:656565	04-23-2020	0 Remote 0 In-clinic		04-30-2020 --		<input type="checkbox"/>
Aybar (AT/AF burden) Mr.	Accent® DR RF, 2210:60351	12-04-2009	0 Remote 0 In-clinic		05-21-2014 --	On vacation until September 20th and leaving transmitter at ...	<input type="checkbox"/>
Baur Jake	Promote Quadra®, 3237-40:204490		0 Remote 0 In-clinic		none		<input type="checkbox"/>
Bennett Tony	Ellipse□ DR, 2411-36:128810	10-10-2011	0 Remote 0 In-clinic		04-02-2014 --		<input type="checkbox"/>
Bickford (AT/AF Episodes) Ms.	Accent® DR RF, 2210:60421	06-03-2010	10 Remote 4 In-clinic	07-06-2012 04:23 AM	08-30-2012 55 days		<input type="checkbox"/>
Childs (Shock) Mr.	Promote® RF, 3207-36:60311	07-09-2008	3 Remote 1 In-clinic	07-28-2012 10:39 PM	03-28-2014 608 days	11-16-2011 02:18 PM dljkfaslkdjgkgl	<input type="checkbox"/>
Craft (VT w/ ATP) Mr.	Current® VR RF, 1207-36:60391	01-06-2010	1 Remote 1 In-clinic	07-06-2012 09:08 AM	09-17-2012 73 days	07-06-2012 02:40 AM syncopal episode	<input checked="" type="checkbox"/>
Doe Jane ID:Post Ablation	Confirm RX™ ICM, DM3500:8009001	09-01-2016	1 Remote 0 In-clinic	01-20-2017 04:07 PM	10-28-2017 281 days		<input type="checkbox"/>





# Transfer Patients — PUSH WORKFLOW

**4**

**Release Patient**

Patient has Unarchived Transmissions and cannot be released. Go to Recent transmissions list to archive your transmission

Patient  
Mr. Craft (VT w/ ATP)

\* Reason for Release

Select a clinic below to release patient(s) to the clinic.

Clinic Name	Address	Phone Number	
Fontana Lake Heart Clinic (Treating)	4376 Fames St., Waycross, OHIO, USA, 98961	1 552 962 8489	<input type="radio"/>
Not Assigned			<input type="radio"/>

\* Required

- Transferred to another clinic
- Explanted
- Removed from Merlin.net™
- Expired

**Release Patient**

Patient has Unarchived Transmissions and cannot be released. Go to Recent transmissions list to archive your transmission

Patient  
Mr. Craft (VT w/ ATP)

\* Reason for Release







Select a clinic below to release patient(s) to the clinic.

Clinic Name	Address	Phone Number	
Fontana Lake Heart Clinic (Treating)	4376 Fames St., Waycross, OHIO, USA, 98961	1 552 962 8489	<input checked="" type="radio"/>
Not Assigned			<input type="radio"/>

**5**

**6**

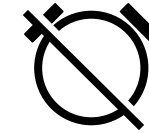
# Merlin.net™ PCN Connectivity Column

Connectivity	
	Inductive Not monitored
	Not Paired
	No Communication >30 days
	Snoozed 1 days remaining
	
	Disabled

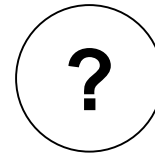
**QUICKLY VIEW  
CONNECTIVITY  
STATUS** of all  
patients from  
Patient List page



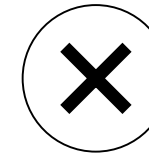
Connectivity OK



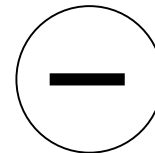
Snoozed \_\_\_ Days  
Remaining



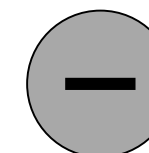
Not Paired



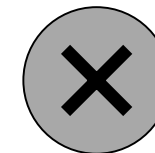
Disabled



No Communication  
\_\_\_ Days



No Alert Checks  
\_\_\_ Days



Inductive  
Not Monitored

**7 CONNECTIVITY STATES**

# Merlin.net™ PCN — Adding Connectivity and Last Transmitter Communication Columns



Signed in as *E Cunningham* Help Switch to Sign Out

Merlin.net™ Patient Care Network

Recent Transactions Patient List Tools Clinic Administration

1

Active Clinic Patients All Search by Name, ID, Device

Patient	Device	Implant Date
ANDERSON STANLEY	Accent® DR RF, 2210:656565	04-23
Aybar (AT/AF burden) Mr.	Accent® DR RF, 2210:60351	12-04
Baur Jake	Promote Quadra®, 3237-40:204490	
Bennett Tony	Ellipse DR, 2411-36:128810	10-10
Bickford (AT/AF Episodes) Ms.	Accent® DR RF, 2210:60421	06-03
Childs (Shock) Mr.	Promote® RF, 3207-36:60311	07-09
Craft (VT w/ ATP) Mr.	Current® VR RF, 1207-36:60391	01-06

2

### Add or Remove Columns

Visible Columns

- Patient Status
- Device
- Advisory: - Premature Battery Depletion (ICD Battery)
- Implant Date
- Transmitter Software Version
- All Transmissions
- Latest Transmission
- Next Transmission
- Connectivity
- Last Transmitter Communication
- Latest Comments

3

Enroll a new patient More Actions

Selected Rows

- Release Patient
- Re-activate Patient
- Mass change process
- Send a DirectCall™

Full List

- Print
- Download Spreadsheet
- Add or Remove Columns

4

**CHECK THESE BOXES**

Cancel Done

# Merlin.net™ Patient Care Network

## Disconnected Transmitter Thresholds

There are **TWO CONNECTIONS** that can be verified on Merlin.net PCN

### ① TRANSMITTER CONNECTION

myMerlin™ Mobile App → Merlin.net PCN  
(Cellular or Wi-Fi<sup>‡</sup> Connection)



### ② DIRECTALERT™ CHECK CONNECTION

myMerlin Mobile App → Confirm Rx™ ICM  
(Bluetooth® Wireless Technology Connection)



# Merlin.net™ Patient Care Network

## Disconnected Transmitter Thresholds

### CLINIC CONFIGURATION STEPS

- 1 Select **Clinic Administration**
- 2 Select **Scheduling and Messaging**
- 3 Select **Edit**
- 4 Scroll down to **Disconnected Transmitter Thresholds** section
- 5 Scroll back to the top and click **Save**

The screenshot displays the Abbott Merlin.net Patient Care Network interface. The top navigation bar includes 'Recent Transmissions', 'Patient List', 'Tools', and 'Clinic Administration'. The 'Clinic Administration' tab is selected, and the 'Scheduling & Messaging' sub-tab is active. The left sidebar shows a menu with 'Scheduling & Messaging' selected. The main content area shows the 'Scheduling & Messaging' settings, including 'Preferred scheduling method' (SmartSchedule™ calendar, Manual entry calendar, None) and 'DirectCall™ Messaging'. A modal window titled 'Disconnected Transmitter Thresholds' is open, showing the following settings:

- Patients with Mobile App transmitters:**
  - Monitor patient's transmitter communication status:
    - Notify if transmitter does not communicate for: 3 days ▼  
*(Transmitters communicate with Merlin.net daily.)*
  - Monitor patient's DirectAlert™ Check status:
    - Notify if DirectAlert™ Checks are not performed for: 8 days ▼  
*(DirectAlert™ Checks are performed daily. DirectAlert™ Check status information is based upon data provided from the last transmitter communication.)*

# Merlin.net™ Patient Care Network

## Disconnected Transmitter Thresholds

### CONFIGURABLE BASED ON TRANSMITTER TYPE

- Cardiac monitors use Mobile App transmitters

### PATIENT TRANSMITTER COMMUNICATION STATUS

- Transmitter communication status with Merlin.net PCN

### DIRECTALERTS™ CHECK STATUS

- Transmitter communication status with patient's device
- Disconnected threshold can be set as short as 1 day

#### Disconnected Transmitter Thresholds

Here are your clinic's thresholds for receiving Disconnected Transmitter notifications on the website.

##### Patients with Mobile App transmitters:

- Monitor patient's transmitter communication status:  
Notify if transmitter does not communicate for:  ▼  
*(Transmitters communicate with Merlin.net daily.)*
- Monitor patient's DirectAlert™ Check status:  
Notify if DirectAlert™ Checks are not performed for:  ▼  
*(DirectAlert™ Checks are performed daily.  
DirectAlert™ Check status information is based upon data provided from the last transmitter communication.)*

##### Patients with Merlin@home transmitters:

- Monitor patient's transmitter communication status:  
Notify if transmitter does not communicate for:  ▼  
*(Transmitters communicate with Merlin.net weekly.)*
- Monitor patient's DirectAlert™ Check status:  
Notify if DirectAlert™ Checks are not performed for:  ▼  
*(DirectAlert™ Checks are performed daily.  
DirectAlert™ Check status information is based upon data provided from the last transmitter communication.)*

# Merlin.net™ Patient Care Network Disconnected Transmitter Thresholds

## INDIVIDUAL PATIENT CONFIGURATION STEPS

- 1 Select **Patient List**
- 2 Locate the Patient Profile and select their name
- 3 Select **Transmitter**
- 4 Select **Edit**
- 5 Scroll down to configure **Disconnected Transmitter Threshold**
- 6 Scroll back to the top and click **Save**

The screenshot displays the Merlin.net Patient Care Network interface. The top navigation bar includes 'Recent Transmissions', 'Patient List', 'Tools', and 'Clinic Administration'. Below this, a sub-navigation bar shows 'Patient profile', 'Transmission', 'All Transmissions', and 'Clinical Comments'. The main content area is divided into two columns. The left column, titled 'Patient profile', contains a list of sections: 'Patient & Device Data', 'Transmitter' (highlighted with a purple box and arrow labeled '3'), 'Follow-up Schedule', 'DirectAlerts™ Notification', and 'Baseline Clinical Data'. The right column, titled 'Transmitter Details', contains an 'Edit' button (highlighted with a purple box and arrow labeled '4') and a message: 'This information populates once a patient's transmitter has had a successful connection to Merlin.net.' Below this, the following details are listed: 'Transmitter Model: myMerlin™ APP1001', 'Patient App Software Version: 1.0.1003', and 'Patient App Registration Date: 04-27-2020'. At the bottom of the page, there are two configuration options, each with a checked checkbox and a dropdown menu set to '7 days' (highlighted with a purple box and arrow labeled '5'). The first option is 'Monitor patient's transmitter communication status: Notify if transmitter does not communicate for: (Transmitters communicate with Merlin.net daily.)'. The second option is 'Monitor patient's DirectAlert™ Check status: Notify if DirectAlert™ Checks are not performed for: (DirectAlert™ Checks are performed daily. DirectAlert™ Check status information is based upon data provided from the last transmitter communication.)'. At the very bottom, there is a table with columns for 'Patient Name/ID' and 'Device Model Number', with the first row showing 'Henry (Innap Md Switch) M...' and 'Jenkins Carl'.

# MERLIN.NET™ PCN REPORTS





# FastPath™ Summary Screen

PAGE 1

Reason for Monitoring:  
**Post AF Ablation**

Last Clinic Session: Oct 3, 2016  
Last Remote Session: Nov 3, 2016  
Last Cleared: Nov 3, 2016

Clinical alerts (3)

Remaining Battery Capacity



## Episode Counts

	Since Nov 3, 2016	Since Nov 3, 2016
AF	2	2
Tachy	0	0
Brady	0	0
Pause	0	0
Symptom (All)	1	1
Symptom (with Detection)	1	1

**FastPath® Summary**

Reason for Monitoring: **Post AF Ablation**

Last Clinic Session: Oct 3, 2016  
Last Remote Session: Nov 3, 2016  
Last Cleared: Nov 3, 2016

Implant Date: Mar 1, 2016

Remaining Battery Capacity:

R-Wave Amplitude: 0.29 mV (Oct 3, 2016 5:03 pm)

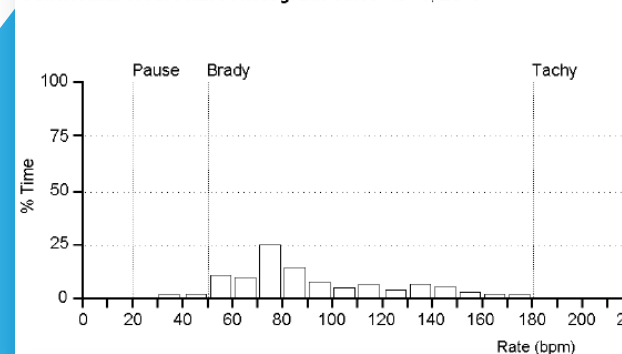
Presenting Rhythm:

Episode Counts	Since Nov 3, 2016	Since Nov 3, 2016
AF	2	2
Tachy	0	0
Brady	0	0
Pause	0	0
Symptom (All)	1	1
Symptom (with Detection)	1	1

Key Parameters	Value
AF Episode	✓ 6 min
Tachy Episode	n/a
Brady Episode	n/a
Pause Episode	n/a
Patient Activated Episode	✓
EGM Dynamic Range	± 0.80 mV
Max Sensitivity	0.15 mV

Ventricular Heart Rate Histogram Since Nov 3, 2016

Ventricular Heart Rate Histogram Since Nov 3, 2016



## Alerts



Clinical

AF Episode Detected Nov 10, 2016

Symptom Episode with Device Detection Nov 10, 2016

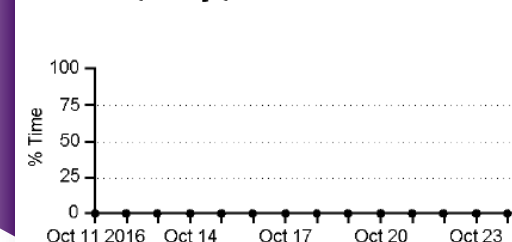
Exceeded Continuous AF Episode Threshold Nov 10, 2016

PAGE 2

## AF Statistics Since Nov 3, 2016

Total AF Episodes: 2  
Total AF Burden since last cleared: 0% (41m 8s)  
Most recent episode: Nov 10, 2016 7:55 am 6m 20s  
Highest mean V rate episode: 111bpm Nov 10, 2016 4:37 am 34m 48s  
Longest episode: Nov 10, 2016 4:37 am 34m 48s

## AF Burden (31 Days)



# Episodes Summary



**Doe, Jane** ID Post AF Ablation  
**Confirm Rx™ ICM 3500** 7768881  
Following Physician: Dr. Nancy Drew 1111111111

**Nov 10, 2016**  
**8:04 am (PST)**  
Remote

## Episodes Summary

Page 1 of 1

Last Clinic Session Oct 3, 2016  
Last Cleared Nov 3, 2016  
Last Remote Session Nov 3, 2016

### Episode Counts

	Since Nov 3, 2016	Since Nov 3, 2016	Since Mar 1, 2016
AF	2	2	2
Tachy	0	0	0
Brady	0	0	0
Pause	0	0	0
Symptom (All)	1	1	1
Symptom (with Detection)	1	1	1

### Episode Directory

Type	Date & Time	Duration (D:H:M:S)	Additional Info.	Status
Symptom (with Detection)	Nov 10, 2016 8:01 am	n/a	Dizzy, Fluttering	
AF	Nov 10, 2016 7:55 am	6:20	91 bpm avg.	
AF	Nov 10, 2016 4:37 am	34:48	111 bpm avg.	



BREAKOUT #2

# IMPLANT DEMONSTRATION AND MERLIN.NET™ PCN BEST PRACTICES



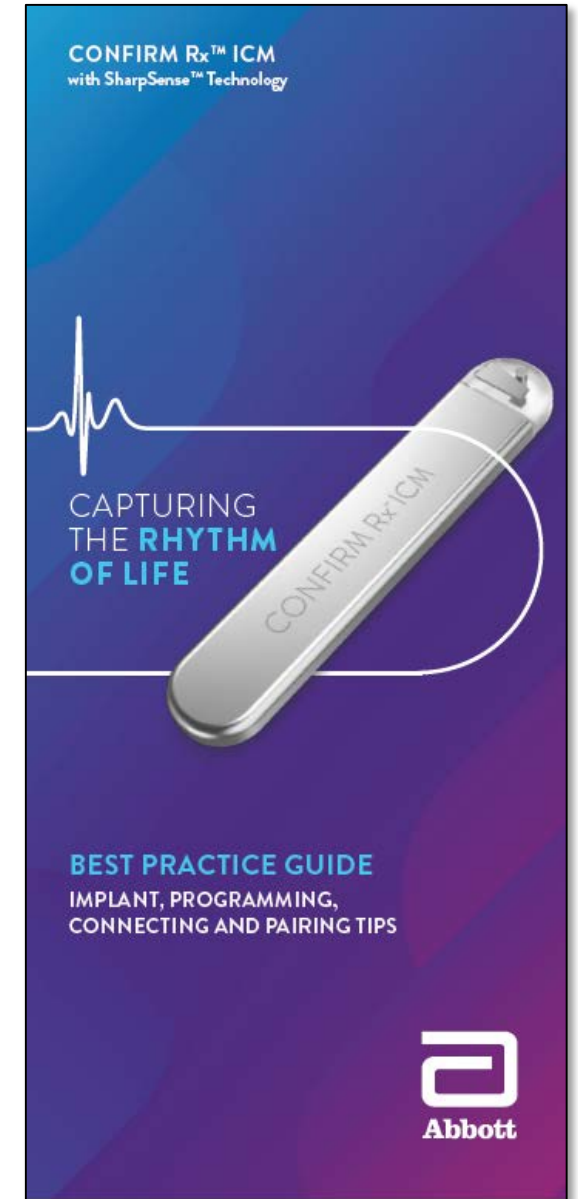
# Confirm Rx™ ICM Best Practice Guide

## Tips & Tricks

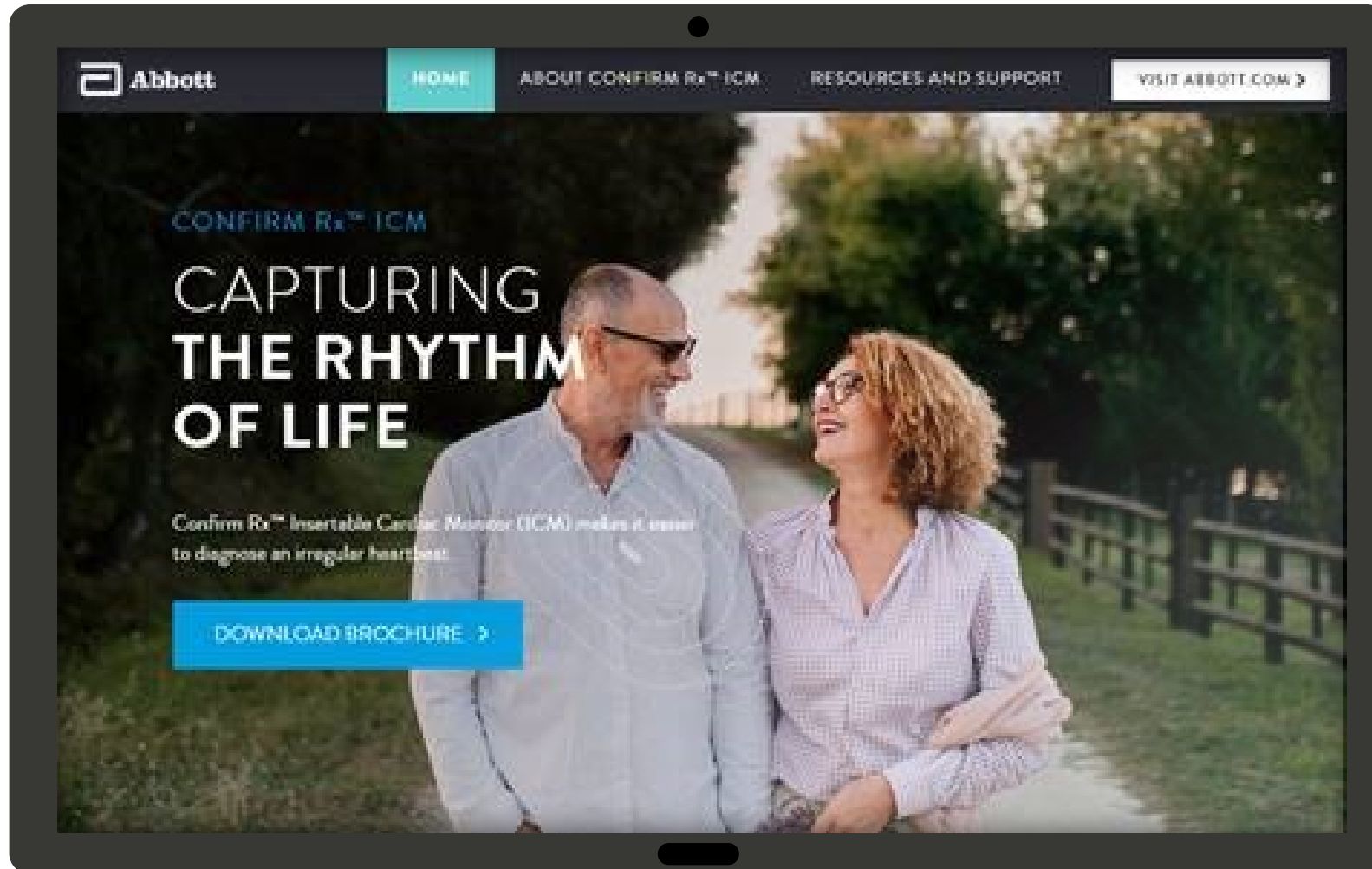
- Implant
- Programming
- Connectivity
- Pairing

🍏 = iPhone® settings  
🤖 = Android® settings

🍏 Bluetooth®, cellular data/Wi-Fi†	ON
🤖 Bluetooth®, location services & cellular data/Wi-Fi†	ON
🍏 Background app refresh	ON
🤖 Background data usage	ON
🍏 Automatically update apps	ON
🤖 Automatically update apps	ON
🍏 Font size STANDARD	ON
🤖 Font size NORMAL	ON
🍏 Battery Low Power Mode	OFF
🤖 Battery Saver	OFF
🍏 Offload unused apps	OFF
🤖 Battery optimization for "Confirm Rx™" app	OFF

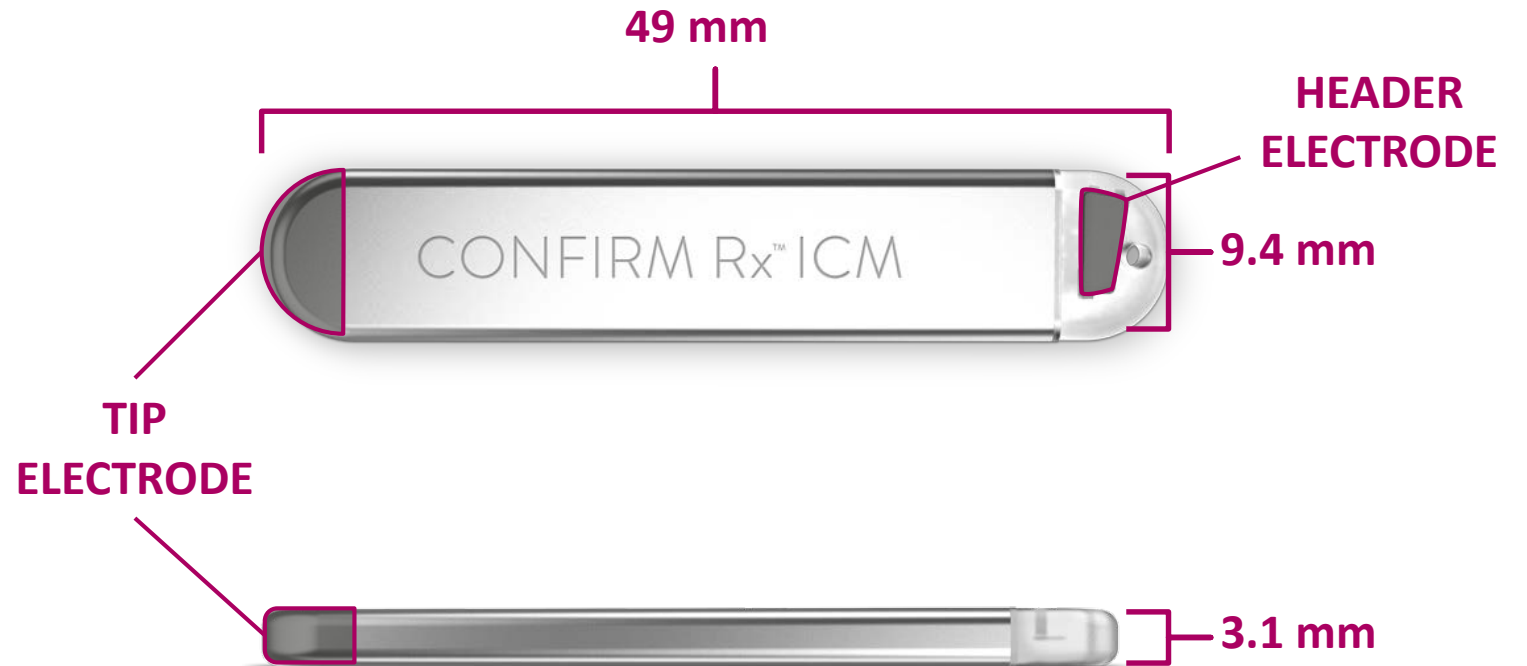


Patient Website: [www.ConfirmYourRhythm.com](http://www.ConfirmYourRhythm.com)



# Confirm Rx™ ICM Specifications

SPECIFICATION	VALUE
Volume	1.4 cc
Mass	3.0 g
Length	49 mm
Width	9.4 mm
Thickness	3.1 mm
Longevity	2 years



# MERLIN.NET™ PCN BEST PRACTICES





# Disconnected Transmitter Thresholds

## Transmitter Communication Status

### “NO COMMUNICATION FOR X DAYS”



Refers to the connection between the myMerlin™ mobile app and Merlin.net™ PCN

Will display the **current number of days since communication** (up to a maximum of 30 days after which it will show > 30 days)

Monitor patient's transmitter communication status:  
Notify if transmitter does not communicate for: 3 days  
*(Transmitters communicate with Merlin.net daily.)*

CONFIGURE SETTINGS IN  
MERLIN.NET PCN

- Programmable 3–7 days

# Disconnected Transmitter Thresholds

## Troubleshooting Transmitter Communication Status

**“NO COMMUNICATION FOR X DAYS”** refers to the connection between the myMerlin™ mobile app and Merlin.net™ PCN



### DOES THE PATIENT'S PHONE HAVE AN INTERNET CONNECTION?

- Is cellular data (LTE/3G/4G) or Wi-Fi<sup>†</sup> present?
- Is the phone in airplane mode? Battery saver mode?

### IS THE APP ON THEIR PHONE?

- Paired to the device?
- Running in the background at all times?
- Has the patient reached the data limit on their cellular phone plan?\*

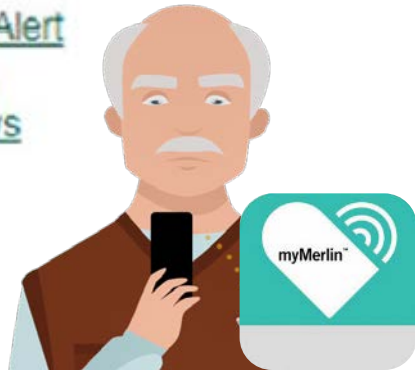
\*Does not apply to the Abbott-provided mobile transmitter (MTX1000)

# Disconnected Transmitter Thresholds

## DirectAlert™ Check Status

### “NO ALERT CHECKS IN X DAYS”

⊖ No Alert  
Checks  
>3 days



Refers to the **Bluetooth® wireless technology connection** between the myMerlin™ mobile app and Confirm Rx™ ICM

Monitor patient's DirectAlert™ Check status:  
◆ Notify if DirectAlert™ Checks are not performed for *(DirectAlert™ Checks are performed daily. DirectAlert™ Check status information is based upon data provided from the last transmitter communication.)* 1 day

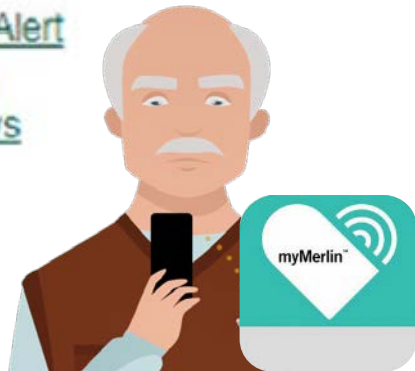
CONFIGURE SETTINGS IN  
MERLIN.NET™ PCN

- Programmable 1–14 days

# Disconnected Transmitter Thresholds

## Troubleshooting DirectAlerts™ Check Status

⊖ No Alert  
Checks  
>3 days



IS THE MYMERLIN™  
MOBILE APP RUNNING  
IN THE BACKGROUND?

IS THE APP ON THEIR  
PHONE?

- Paired to the device?
- Running in the background at all times?

DOES THE PATIENT  
SLEEP WITHIN 5 FEET  
OF THEIR PHONE?

IS BLUETOOTH® WIRELESS  
TECHNOLOGY ON?

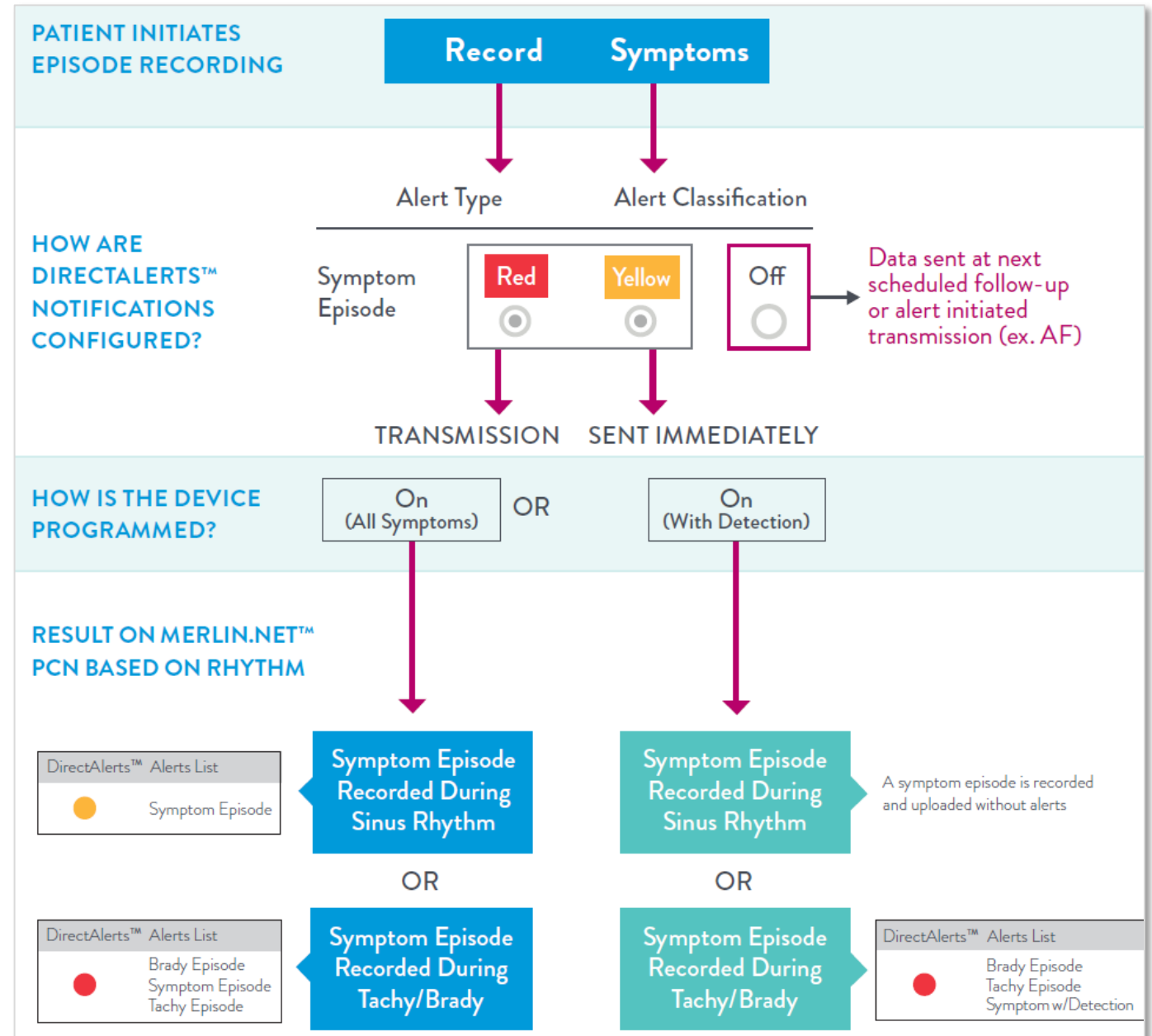
- Is the phone in airplane mode?
- Battery saver mode?

# Symptom Episode Programmability

The Confirm Rx™ ICM Can Be Programmed:

- On (All Symptoms)
- On (with Detection) (nominal setting)

REFER TO THE CHART HERE (also in the Best Practice Guide) for the various results based on device programming and DirectAlert™ settings in Merlin.net™ PCN.





**THANK YOU**

## ACRONYM DEFINITIONS

AES	Advanced Encryption Standard	ICD	implantable cardioverter defibrillator
AF	atrial fibrillation	ICM	insertable cardiac monitor
AVD	atrioventricular delay	NSA	National Security Agency
CI	current interval	OS	operating system
CRT-D	cardiac resynchronization therapy defibrillator	PCN	Patient Care Network
EGM	electrogram	PCS	Patient Care System
EKG	electrocardiogram	PPV	positive predictive value
FP	false positive	RF	radio frequency
GEE	generalization estimating equation	TF	true positive
IA	interval average	VEGM	ventricular intracardiac electrogram

## RX ONLY

**Brief Summary:** This product is intended for use by or under the direction of a physician. 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 patient's Confirm Rx™ ICM. On Merlin.net™ PCN they can configure transmission schedules and enable or disable features on a 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 Apple<sup>®</sup> or Android<sup>®</sup> mobile 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<sup>®</sup> wireless technology enabled and data coverage (cellular or WiFi<sup>®</sup>) available. The myMerlin™ 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.

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APPENDIX

# REFERENCE MATERIALS



# Sensing

The Confirm Rx™ ICM uses the SenseAbility™ sensing algorithm — the same as Abbott ICDs and CRT-Ds

The SenseAbility sensing algorithm provides programmable options to reduce oversensing and undersensing issues

Sensing	
EGM Dynamic Range	± 0.80 mV
Max Sensitivity	0.15 mV
Sense Refractory Period	250 ms
Sense Refractory Decay Delay	60 ms
Threshold Start	75 %

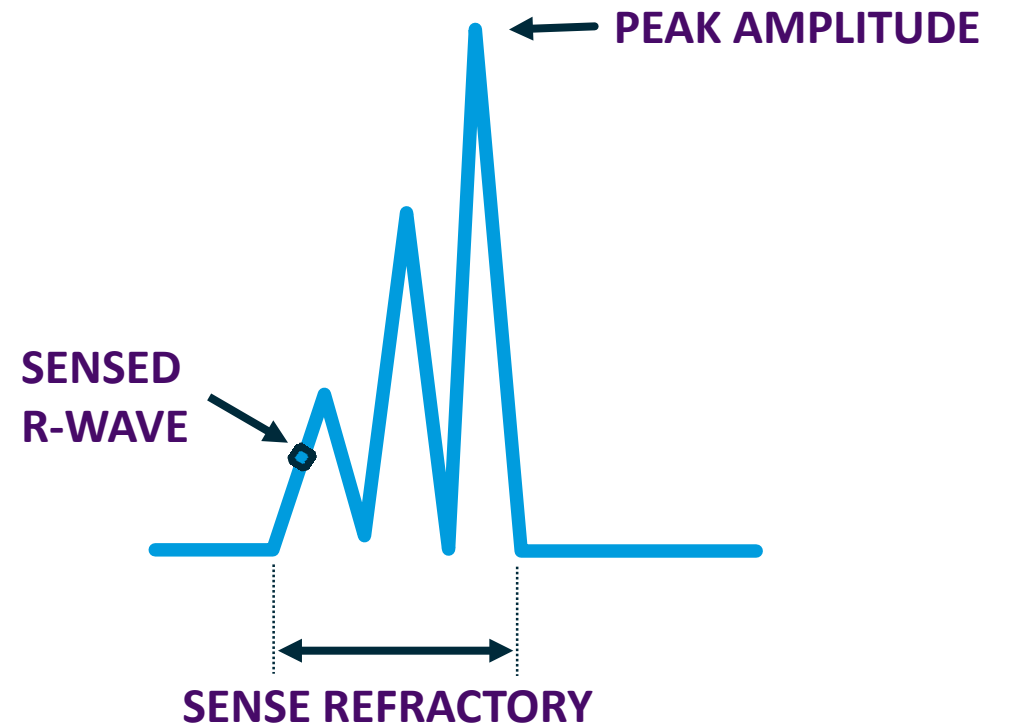
# Sense Refractory Period

- Begins as soon as an R-wave is detected by the sensing filter
- All events falling within the sense refractory window will be considered “one event” by the device
- Longer settings may be used for patients with wide intrinsic QRS complexes

## PROGRAMMABLE PARAMETER

**SETTINGS:** 125; 150 ... 400 ms

**NOMINAL:** 250 ms



# Threshold Start

- Calculated off of the measured peak amplitude
- Used to begin the linear decay

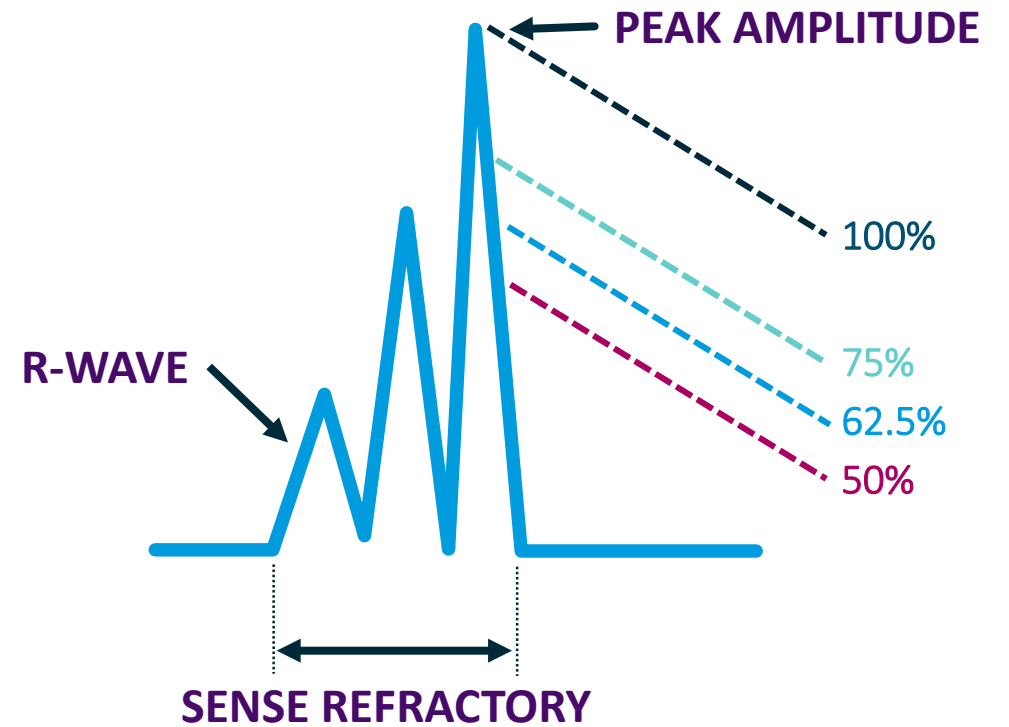
## PROGRAMMABLE PARAMETER

**SETTINGS:** 100%; 75%; 62.5%; 50%

**NOMINAL:** 75%

## EXAMPLES

Dynamic Range (mV)	MAX THRESHOLD START (mv)			
	100%	75%	62.5%	50%
± 1.60	1.6	1.2	1.0	0.8
± 0.80	0.8	0.6	0.5	0.4
± 0.40	0.4	0.3	0.25	0.2
± 0.20	0.2	0.15	0.125	0.1



# Decay Delay

- Delays the time before the linear decay occurs

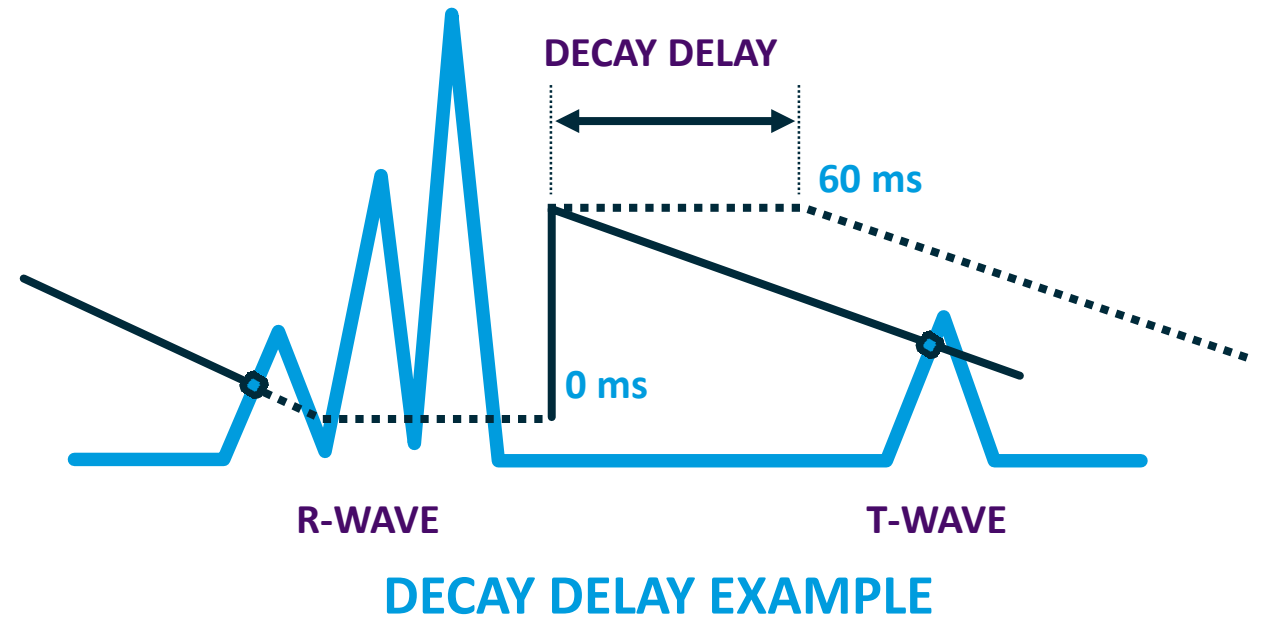
## PROGRAMMABLE PARAMETER

**SETTINGS:** 0; 30; 60; 95; 125; 160; 190; 220 ms

**NOMINAL:** 60 ms

## DECAY DELAY EXAMPLE

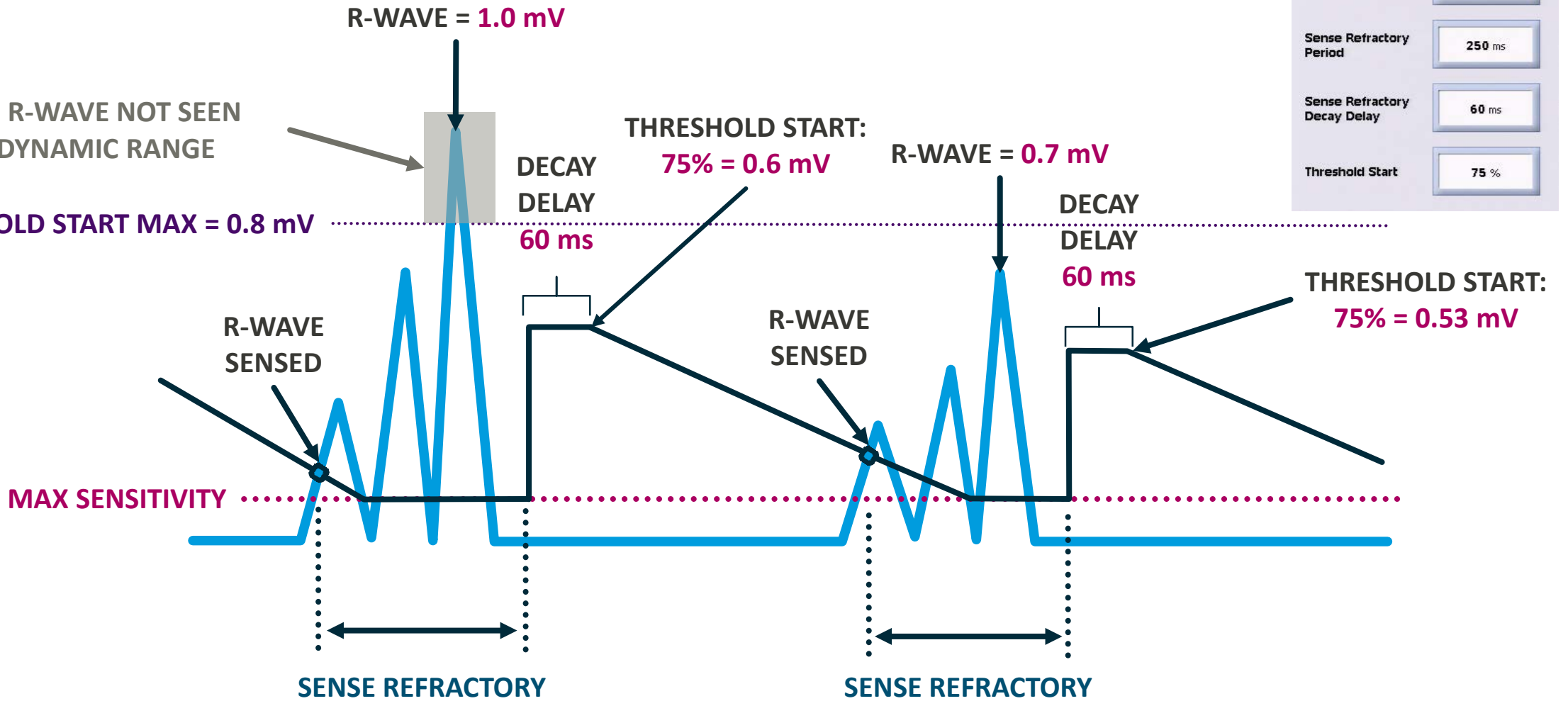
- If no Decay Delay had been programmed, the ICM would have oversensed the T-wave
- A 60 ms Decay Delay allows the insertable cardiac monitor to not sense the T-wave



# SenseAbility™ Sensing Algorithm

PEAK OF R-WAVE NOT SEEN DUE TO DYNAMIC RANGE

THRESHOLD START MAX = 0.8 mV



Sensing	
EGM Dynamic Range	$\pm 0.80$ mV
Max Sensitivity	0.15 mV
Sense Refractory Period	250 ms
Sense Refractory Decay Delay	60 ms
Threshold Start	75 %

# Stored EGM Configurations

## AF EPISODES

### TRIGGERS

- PRE: 10–120 sec
- POST: 10–120 sec

## OTHER EPISODES

**TYPES:** TACHY, BRADY, PAUSE

### TRIGGERS

- PRE: 10–60 sec
- POST: 10–60 sec

## PATIENT-ACTIVATED EPISODES

### TRIGGERS

- PRE: 4–14 min
- POST: 30–60 sec

Will an episode be triggered?

Episode & Alert Type	Detection	EGM Trigger Priority	Merlin.net DirectAlerts™
AF Episode (6 min)	<input checked="" type="checkbox"/>	High	<input type="checkbox"/>
Continuous AF Alert (30 min)	<input checked="" type="checkbox"/>	n/a	<input type="checkbox"/>
AF Burden Alert (6 hours, Daily)	<input checked="" type="checkbox"/>	n/a	<input type="checkbox"/>
V Rate During AF Alert (100 bpm for 6 hours, Daily)	<input checked="" type="checkbox"/>	n/a	<input type="checkbox"/>
Tachy Episode (180 bpm, 12 intervals)	<input checked="" type="checkbox"/>	High	<input type="checkbox"/>

Merlin.net DirectAlerts™ are customizable only through the Merlin.net™ portal.

Stored EGM Settings

AF Pre-Trigger Duration	30 sec
AF Post-Trigger Duration	120 sec
Other Pre-Trigger Duration	30 sec
Other Post-Trigger Duration	30 sec
Symptom Pre-Trigger Duration	8 min
Symptom Post-Trigger Duration	60 sec

Preview 0 Program

Patient-activated episodes are **ALWAYS** high priority.

# Other Episodes

EPISODE TYPE	PROGRAMMABLE PARAMETER	DESCRIPTION	PARAMETER SETTINGS/NOMINALS
Brady	Brady Cutoff Rate	Four intervals below this rate trigger episode storage	<b>SETTINGS:</b> 30; 40; 50 bpm <b>NOMINAL:</b> 30 bpm
Tachy	Tachy Cutoff Rate	The rate that must be exceeded for a programmed number of intervals (Tachy count) triggers episode storage  If patient date of birth is entered at insertion, Tachy cutoff rate = 230 – (patient age)	<b>SETTINGS:</b> 120; 125 ... 250 bpm <b>NOMINAL:</b> 180 bpm*
	Tachy Count	The number of intervals where the rate is faster than the Tachy cutoff rate triggers episode storage	<b>SETTINGS:</b> 8; 9 ... 25; 30 ... 50 intervals <b>NOMINAL:</b> 12 intervals
Pause	Pause Duration	No detection of intrinsic rhythm for more than this duration triggers episode storage	<b>SETTINGS:</b> 2; 3 ... 8 s <b>NOMINAL:</b> 3 s

\*Nominal value if patient date of birth is not programmed.



# Episode Priority (Low vs. High)

## PATIENT-ACTIVATED EPISODES

**Protected Episode(s):** ALL episodes

NO other episode type can overwrite a **PATIENT-ACTIVATED** episode.

## TACHY, BRADY, PAUSE AND AF EPISODES

**Protected Episode:** Most recent (of each)

Each episode type has a protected episode that will never be overwritten.

Episodes become unprotected once read by the myMerlin™ mobile app and uploaded to the Merlin.net™ PCN.





A **LOW** priority episode will never overwrite a **HIGH** priority episode.

A **HIGH** priority episode will never overwrite a **PATIENT-ACTIVATED** episode.

# Transmissions and Clearing

## FOLLOW-UP SCHEDULE OPTIONS:

- Week
- 31 Days
- 2 Weeks
- 13 Weeks (91 days)
- 26 Weeks (182 days)
- Month
- 2 Months
- 3 Months
- 4 Months
- 6 Months
- 9 Months
- 12 Months

EPISODE TYPE	DIRECTALERTS™ NOTIFICATION FEATURE	TRANSMITTED* TO MERLIN.NET™ PCN AT	AFTER TRANSMISSION*, CAN BE OVERWRITTEN BY	EPISODES CLEARED UPON TRANSMISSION
AUTO-ACTIVATED AF, Tachy, Brady, Pause	 Red	Daily Check	SAME or HIGHER Priority Episodes	NO
	 Yellow			
	OFF	Scheduled Follow-up (default every 31 days)		YES (if enabled)
PATIENT-ACTIVATED	 Red	Immediately**	ONLY Patient-activated Episodes	NO
	 Yellow			
	OFF	Scheduled Follow-up (default every 31 days)		YES (if enabled)

\*Episodes become “unprotected” in device (can be overwritten) after they have been transmitted to the Merlin.net PCN.

\*\*Transmission will also include any new (untransmitted) auto-activated episodes.

# Detection Qualifiers

**DETECTION QUALIFIERS** are additional parameters that can be enabled to reduce the occurrence of false-positive episode recordings

DETECTION QUALIFIER	ON	OFF
Arrhythmia Detection during Activity	Allows episode recording while the patient is active	Inhibits episode recording while the patient is active
Bigeminy Qualifier	Bigeminy avoidance ON; if bigeminy is detected, episode recording is inhibited	Bigeminy avoidance OFF; all Tachy episodes recorded
Sudden Onset	Tachy episode recorded ONLY if onset is sudden	ALL Tachy episodes recorded



# AF Diagnostics

## STORED EGMs

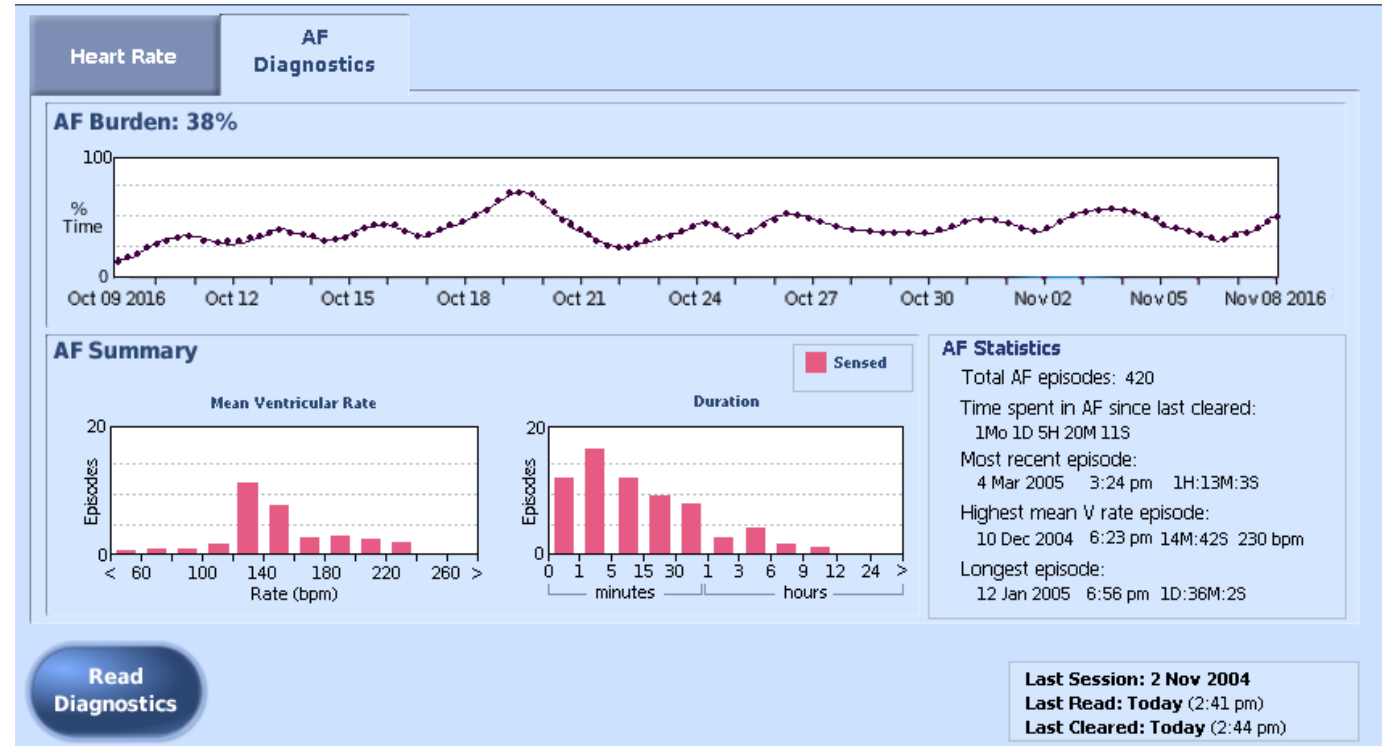
- AF Episode Entry

## TREND AND HISTOGRAMS

- AF Burden Trend — 30 or 31 Days
- Histogram — Mean Ventricular Rate
- Histogram — AF Episode Durations

## OTHER STATISTICS

- Total AF Episodes
- Time Spent in AF since Last Cleared
- Most Recent Episode
- Highest Mean V Rate Episode
- Longest Episode



# AF Detection Algorithm — OVERVIEW

64-beat evaluation window

3 tests to evaluate if rhythm is AF

## ALGORITHM TESTS

**REGULARITY** — evaluates the rhythm pattern to determine whether it is regular or irregular

**VARIANCE** — evaluates the variance of R-R intervals; the larger the variance, the more likely the rhythm is AF (vs. patterned rhythms such as bigeminy)

**SUDDEN ONSET** — evaluates how the rhythm initiates

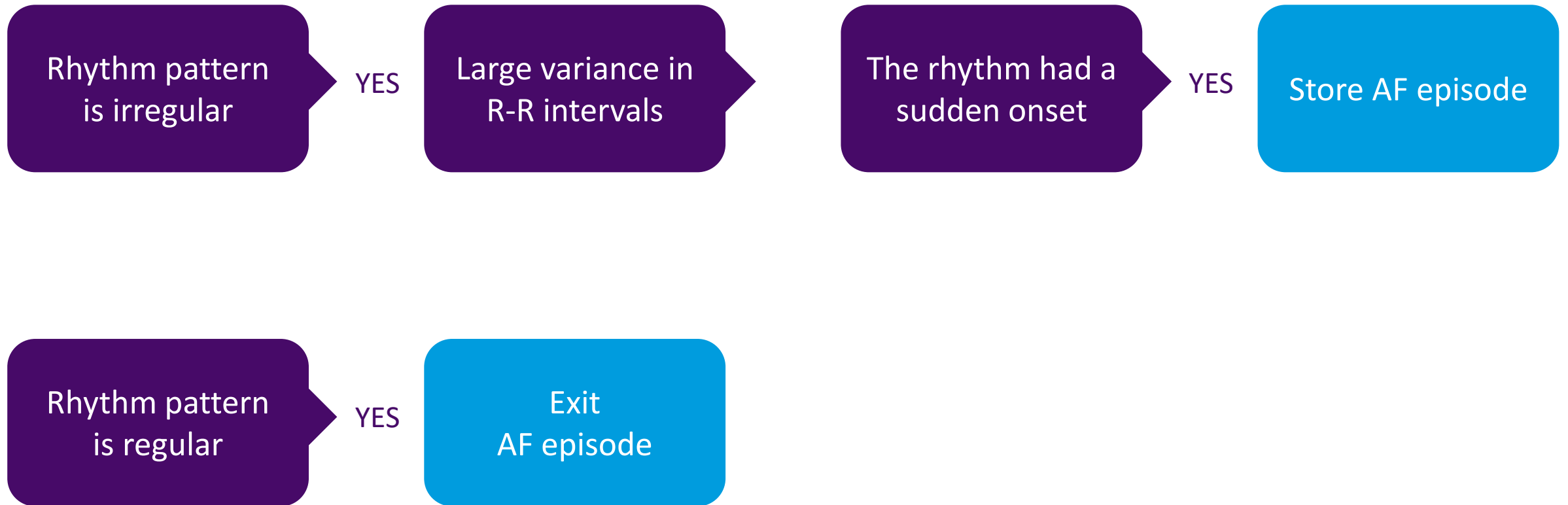
**ALL 3 TESTS MUST INDICATE AF FOR AN EPISODE TO BE TRIGGERED**

ALGORITHM TEST	ALGORITHM DETERMINATION	
Regularity	✓ Irregular	✗ Regular
Variance	✓ Large Variance	✗ Small Variance
Sudden Onset	✓ Yes	✗ No
<b>Algorithm Response</b>	Trigger AF Episode	No Trigger

✓ Indicates rhythm is AF

✗ Indicates rhythm is not AF

# Episode Entry and Exit





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