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

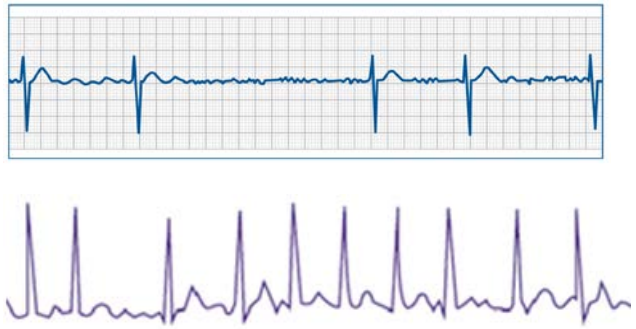
CARDIAC MONITORS HELP PHYSICIANS

- Document cardiac arrhythmias
- Correlate patient symptoms

What is AF?

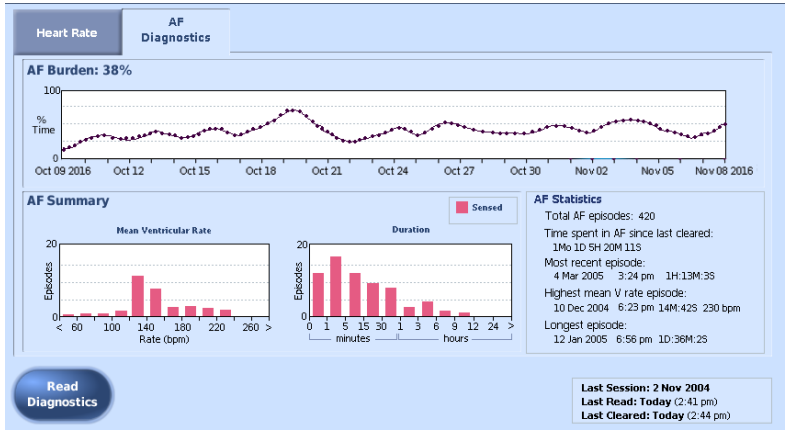
ATRIAL FIBRILLATION (AF, Afib)

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



CARDIAC MONITORS HELP PHYSICIANS

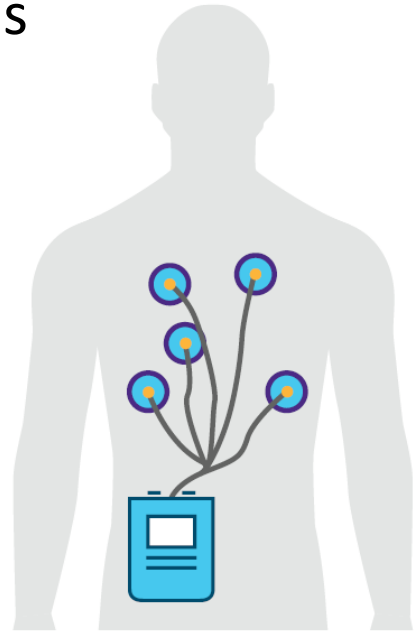
- Diagnose AF as it may be undiagnosed
- Quantify AF burden
- Correlate patient symptoms



Types of Cardiac Monitors

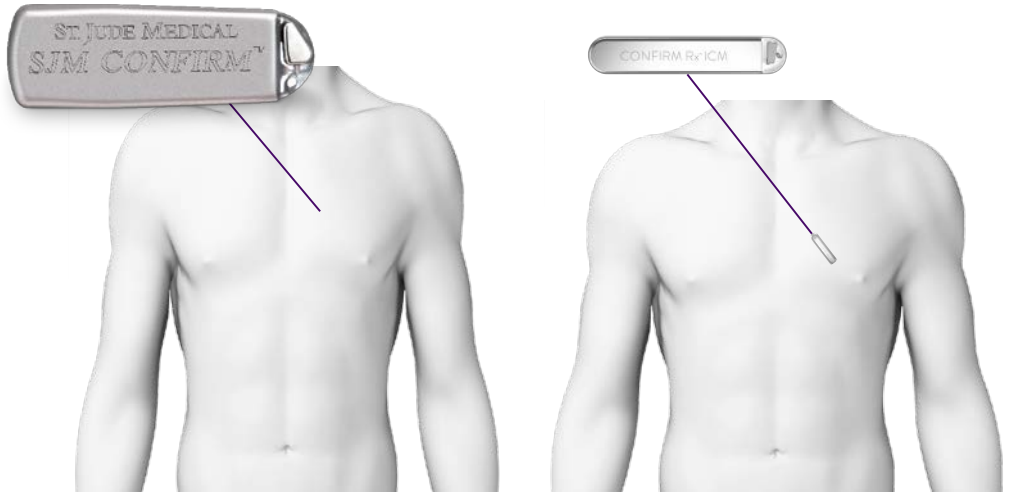
EXTERNAL

- Holter Monitors
- Event Recorders
- Wearables



INTERNAL

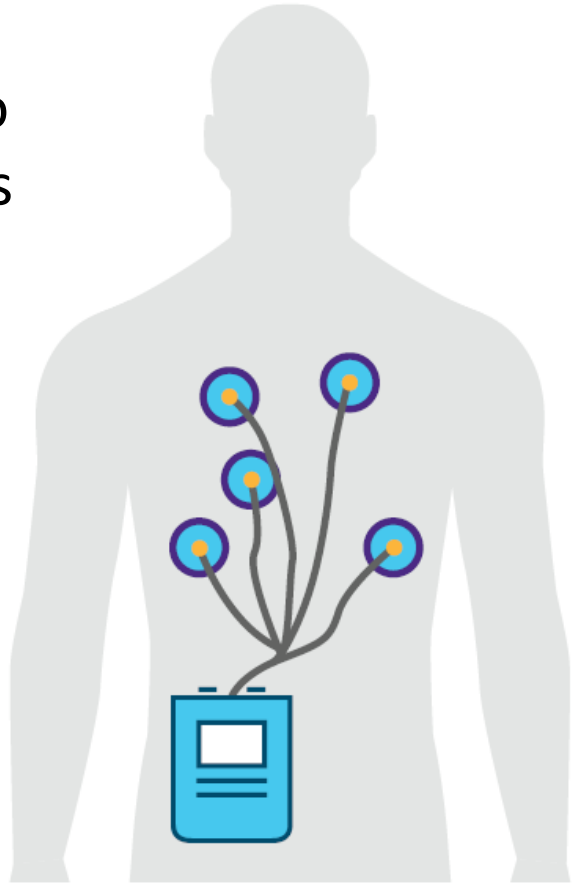
- Implantable/Insertable



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.

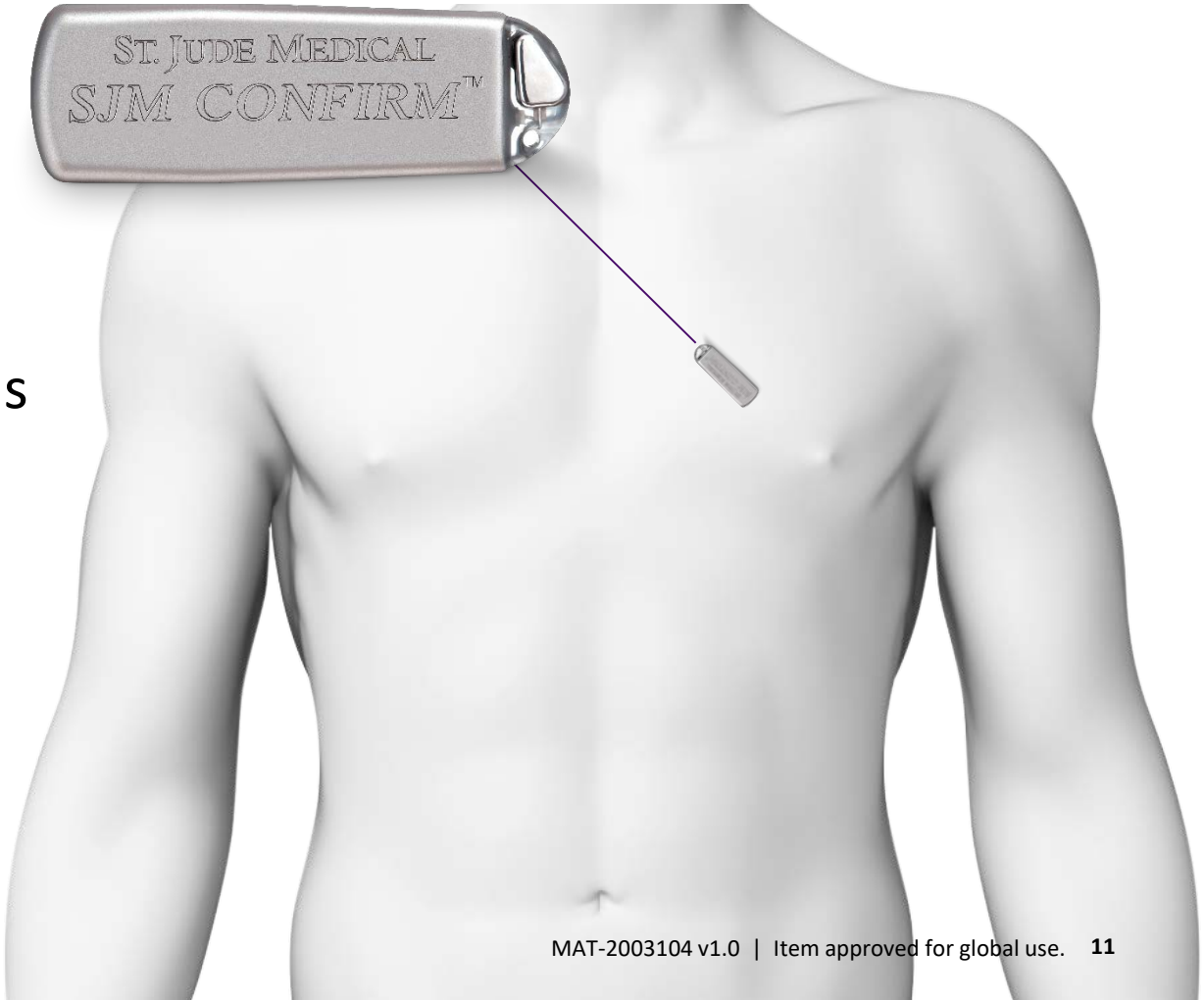
Advantages of **IMPLANTABLE/INSERTABLE** Cardiac Monitors

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)



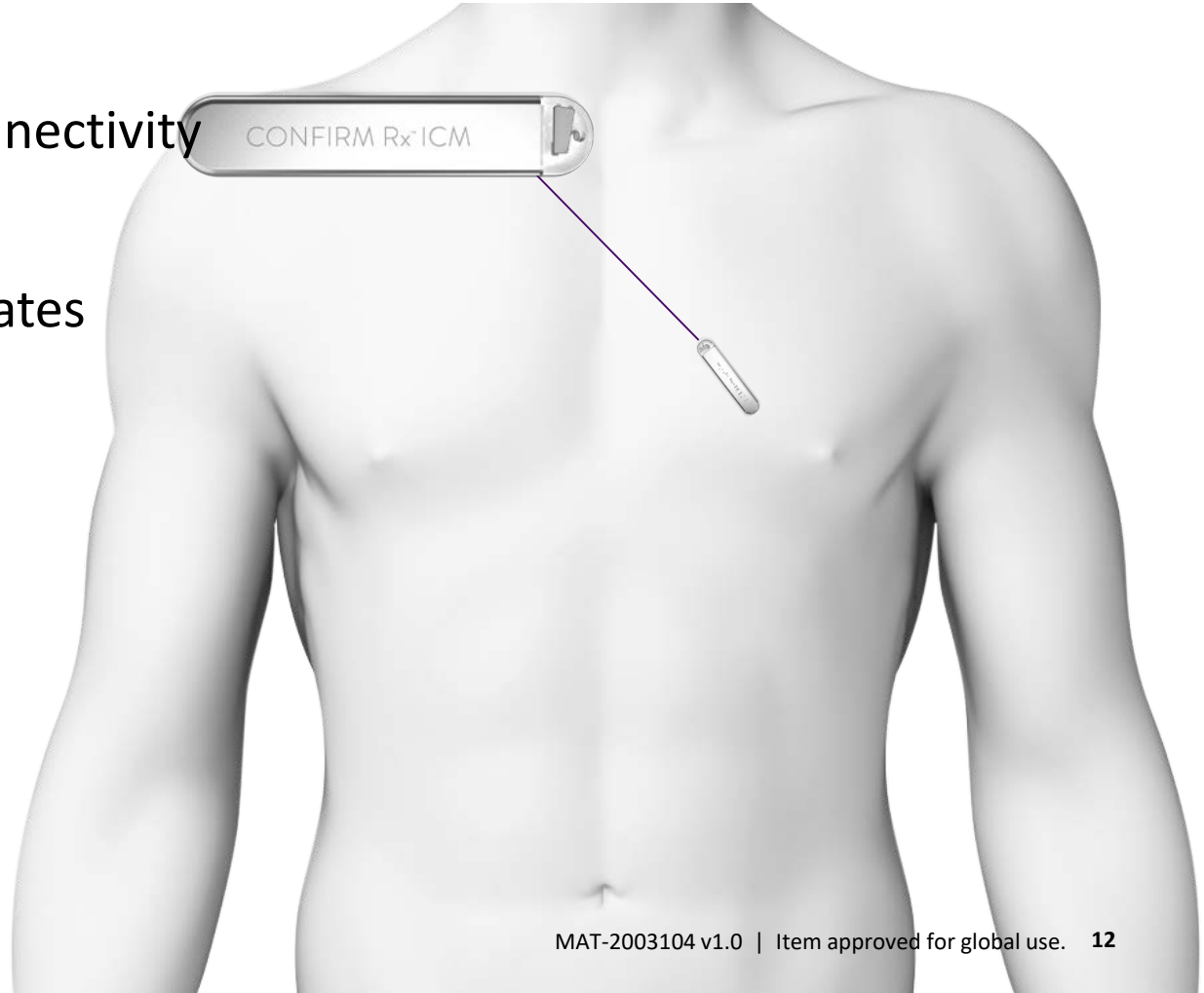
INSERTABLE Cardiac Monitors

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)

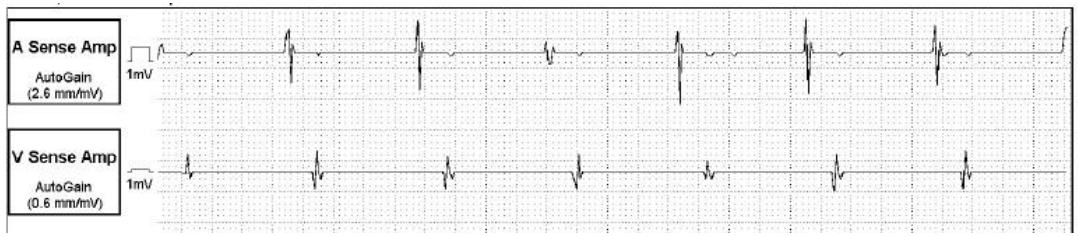
CHALLENGES

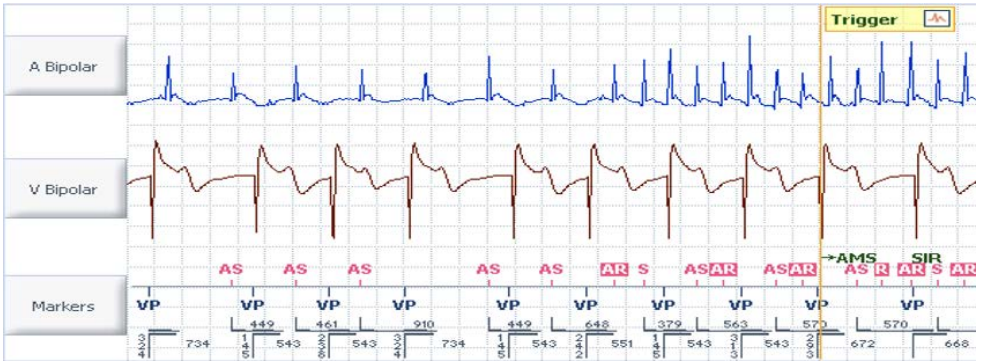
- Managing data burden
  - Clinical relevance of short episodes
  - EKG interpretation without atrial lead
- Managing patient expectations



Challenges with **INSERTABLE** Cardiac Monitors

AF DETECTION with ICMs versus traditional CRM devices





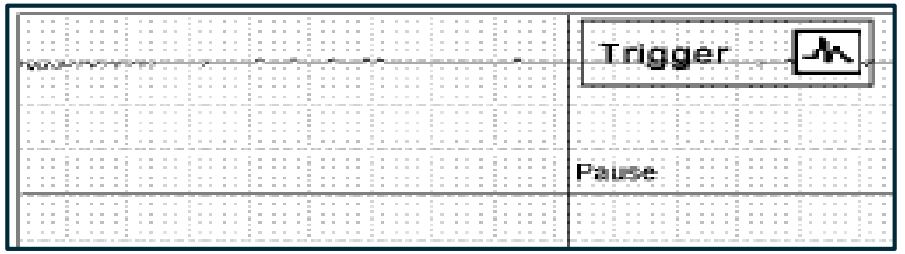
POSSIBLE CAUSES:

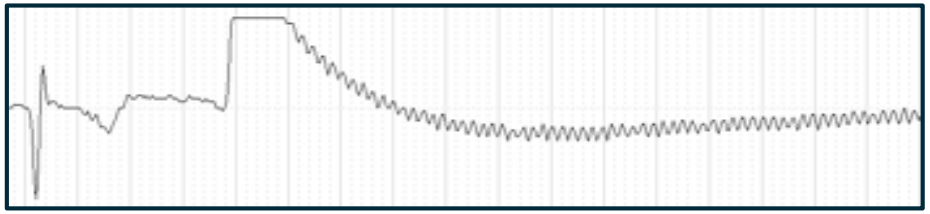
- Only two electrodes versus leads in the top and bottom chambers of the heart
- Dependent on visualization of P-waves
- Oversensing/undersensing

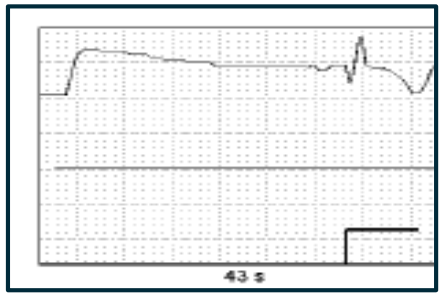
Challenges with **INSERTABLE** Cardiac Monitors

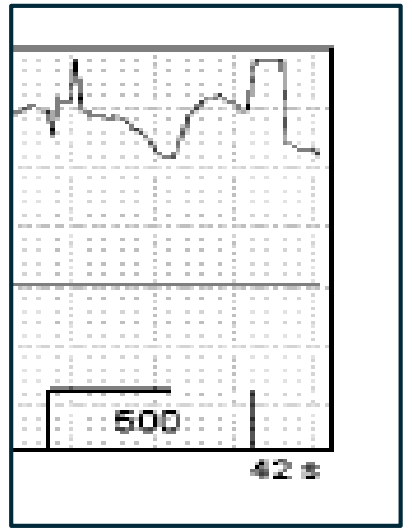
LOSS OF CONTACT

ELECTRODE LOSES CONTACT WITH PATIENT TISSUE







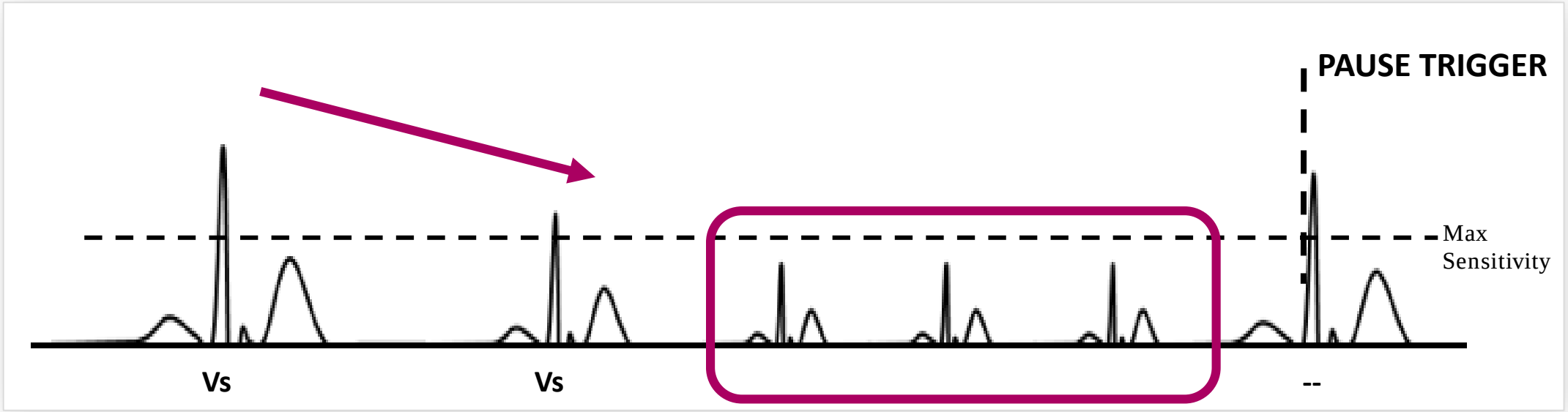


POSSIBLE CAUSES:

- 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**

EPISODE SENSITIVITY

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

EPISODE SPECIFICITY

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

DURATION SENSITIVITY

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

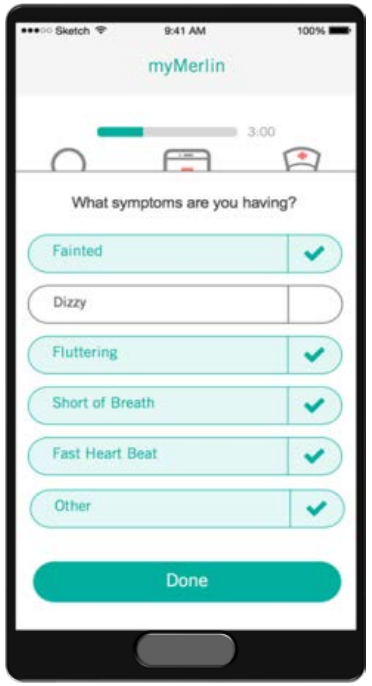
DURATION SPECIFICITY

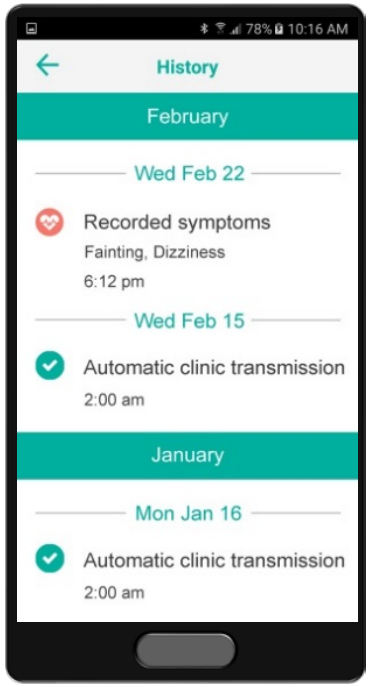
Measures the duration (minutes) of the false positive recorded out of all minutes the patient was not in AF

PATIENT SENSITIVITY

Sensitivity of the ICM for diagnosing patients with any 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

ALGORITHM

1. Detection occurs as usual

ENHANCEMENT

2. Performs second pass with new discriminator

- **True** → STORE EPISODE ON DEVICE
- **False** → REMOVE EPISODE

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%[1]
PAUSE	98%[1]
AF	97%[1]

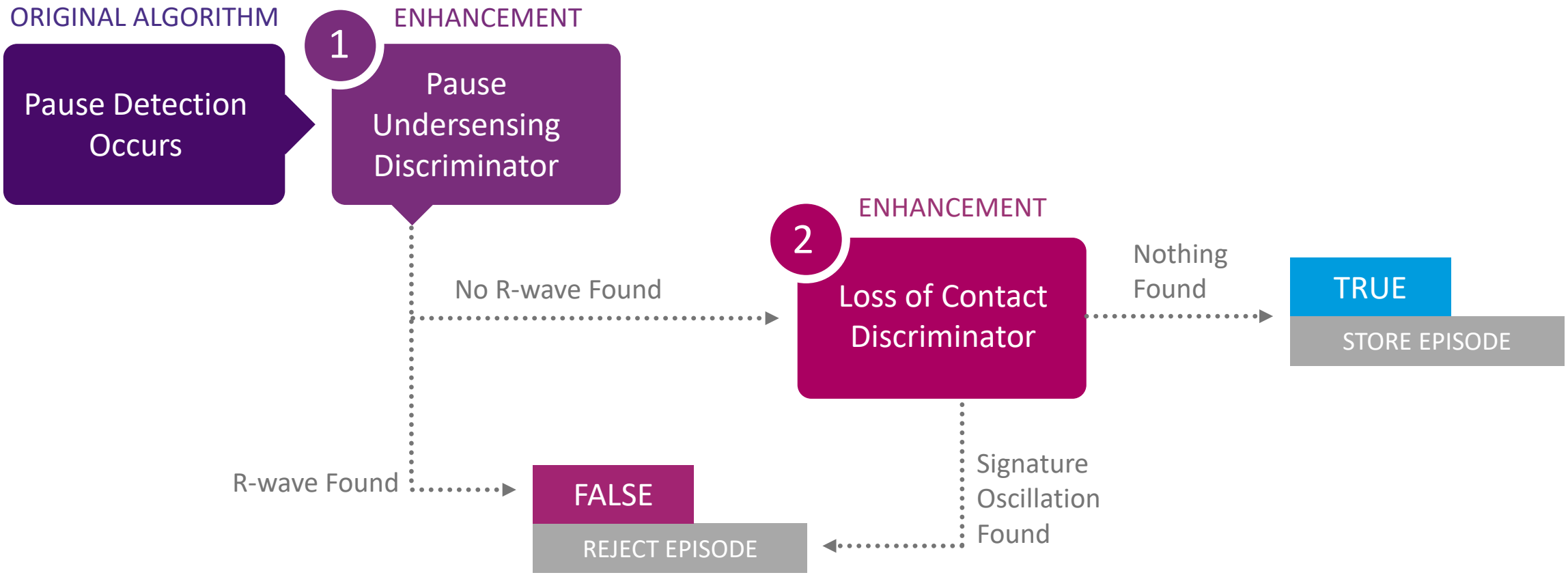
97%

REDUCTION IN FALSE DETECTION OF EVENTS*[2]

*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.

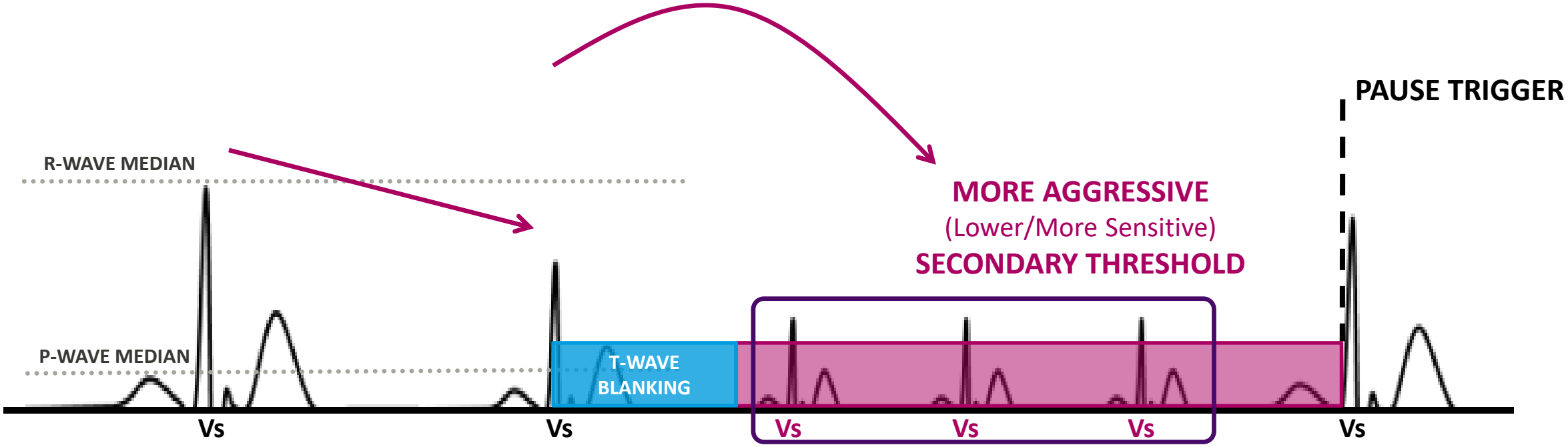
PAUSE EPISODE Detection Uses Two Enhancements



Calculating SECONDARY THRESHOLD
Pause Discriminator

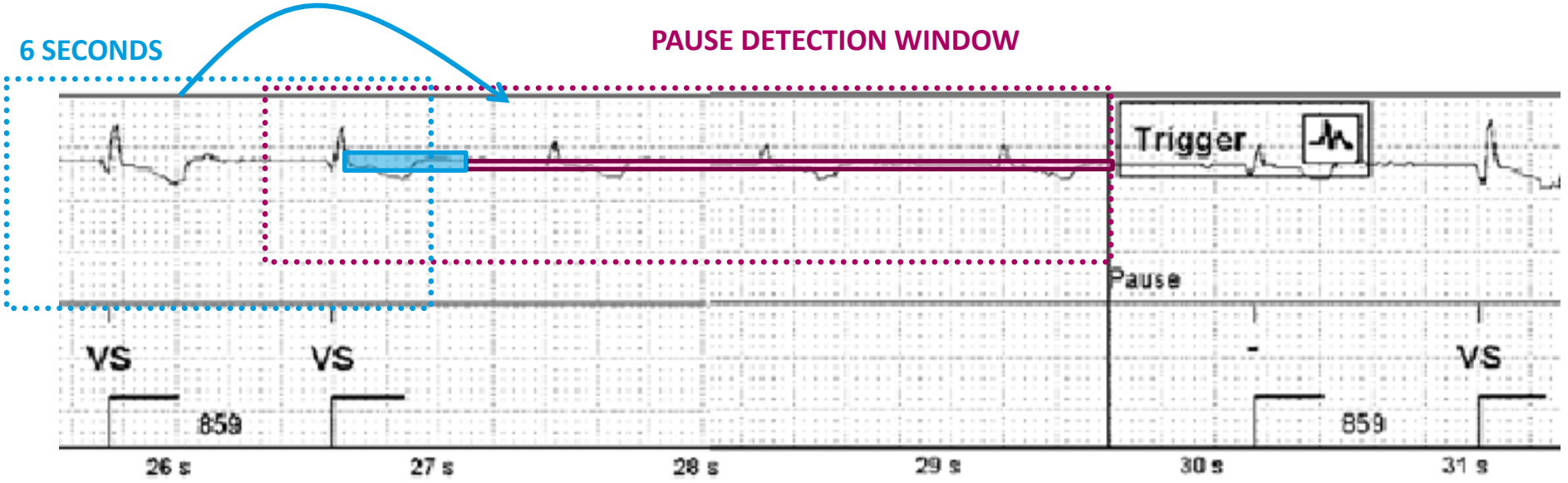
DECLINING, VARIABLE or SMALL R-WAVES?

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

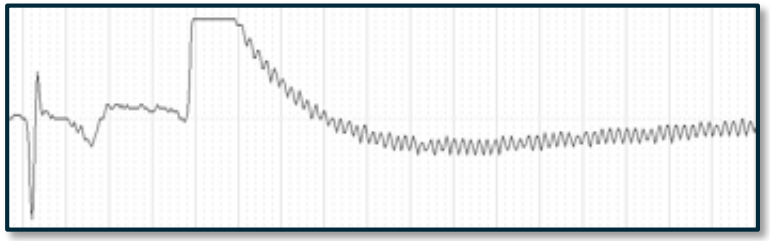
Loss Of Contact Discriminator

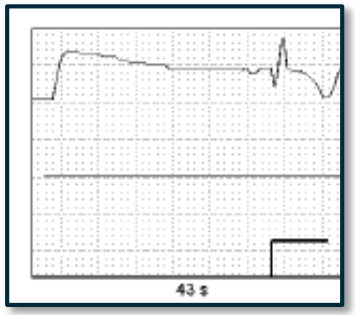
BACKGROUND:

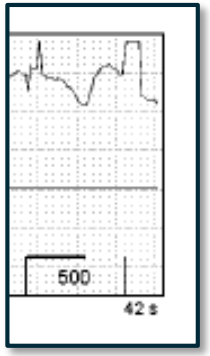
All false Pause detections due to Loss of Contact observed a small characteristic noise signal

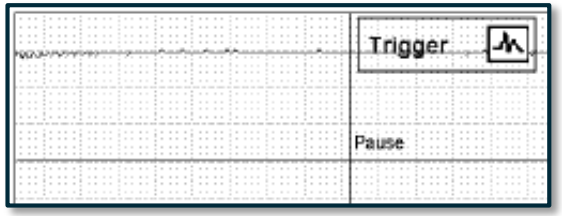
NOTE: May not be apparent in the PDF

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







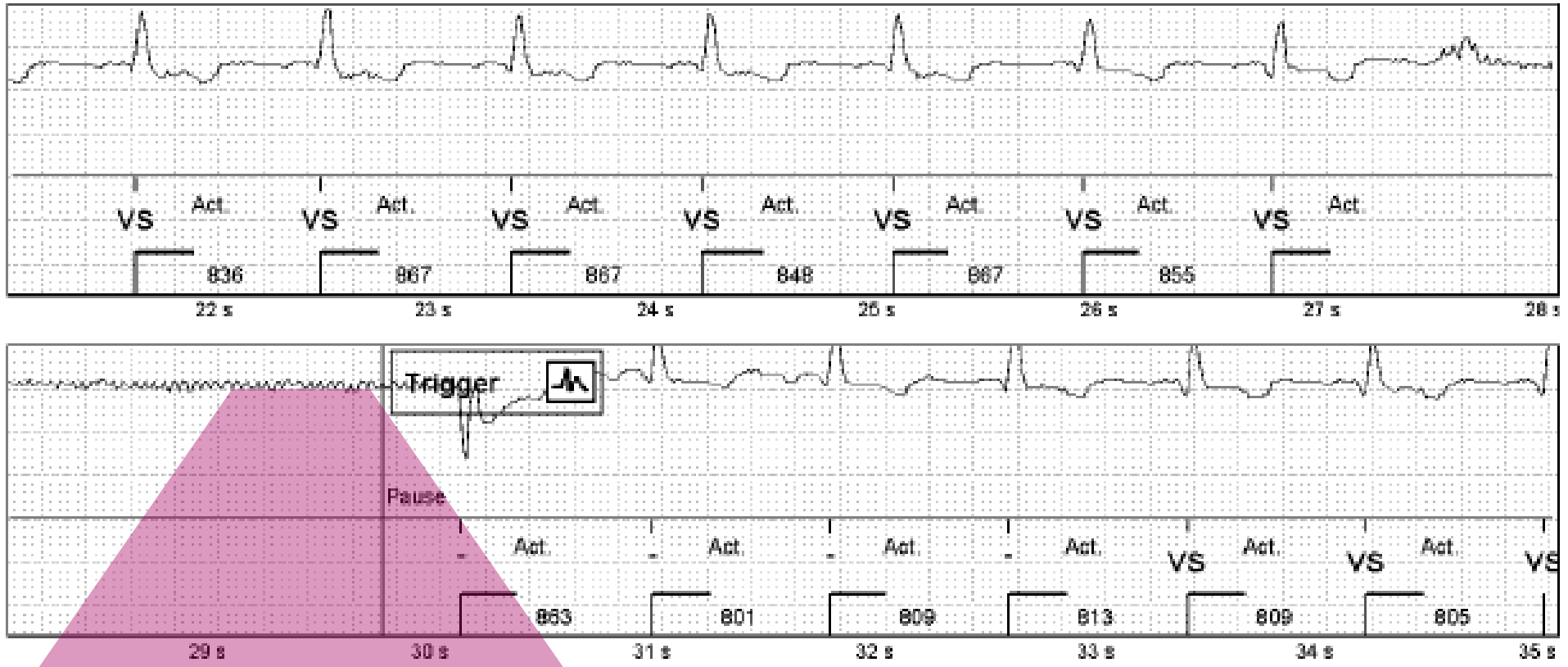


THE SOLUTION:

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

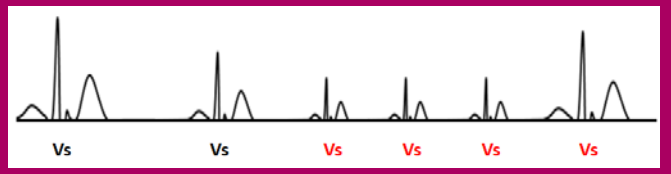
Bradycardia **Undersensing Discriminator**

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

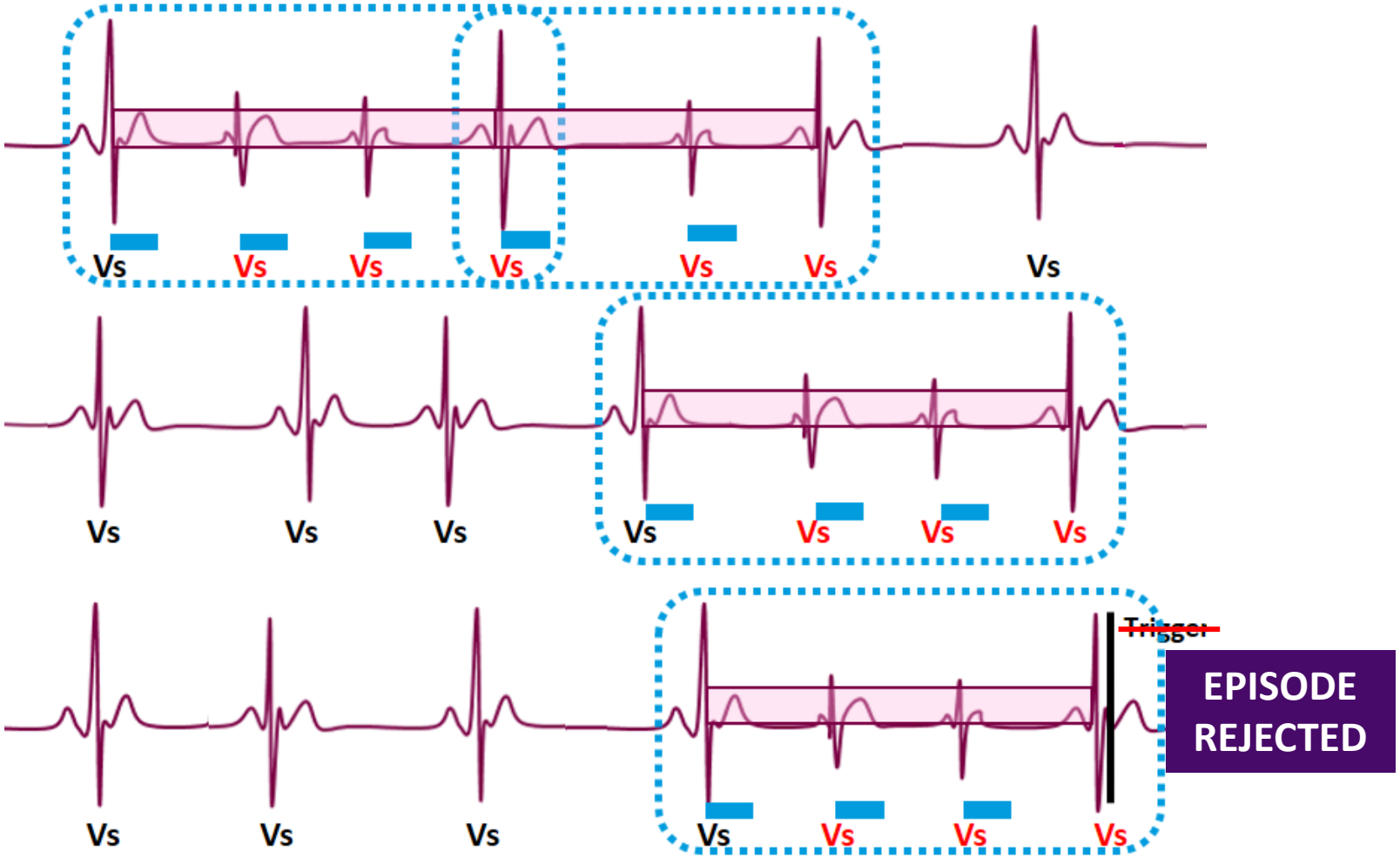
the device recalculates the intervals in each window

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

Rhythm pattern is irregular → YES → Large variance in R-R intervals → YES → The rhythm had enough sudden changes in R-R intervals → YES → AF detection is met

EXIT

Rhythm pattern is regular → YES → Exit AF detection

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

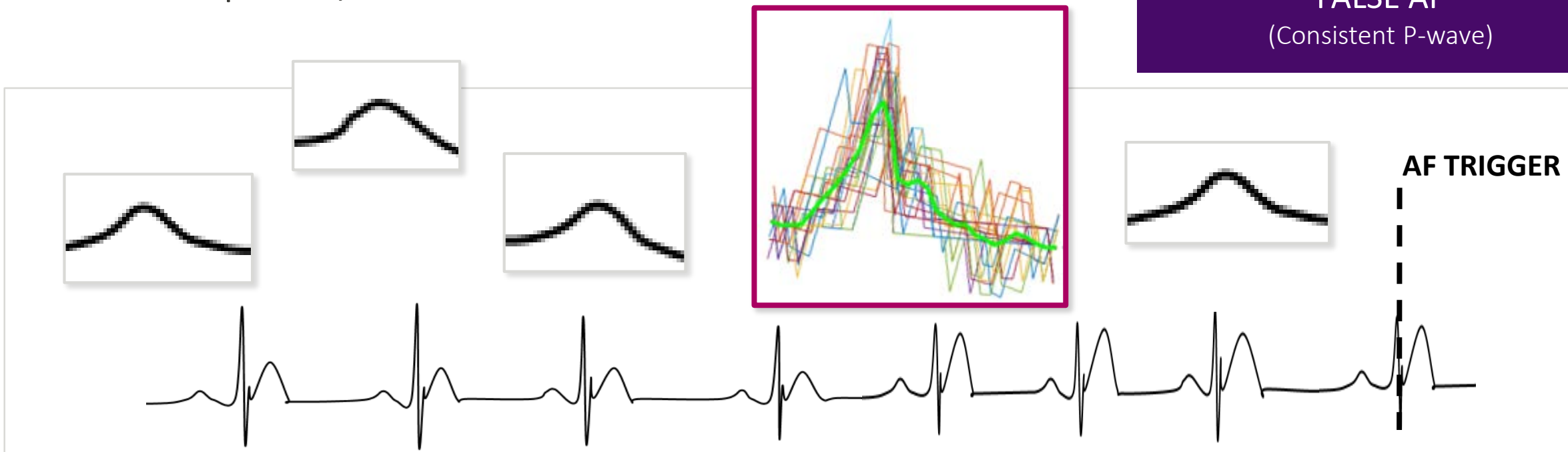
REJECT EPISODE

The P-Wave Discriminator

STACKS P-WAVE SEGMENTS OF SELECTED BEATS

Looks for a pattern/correlation

FALSE AF
(Consistent P-wave)

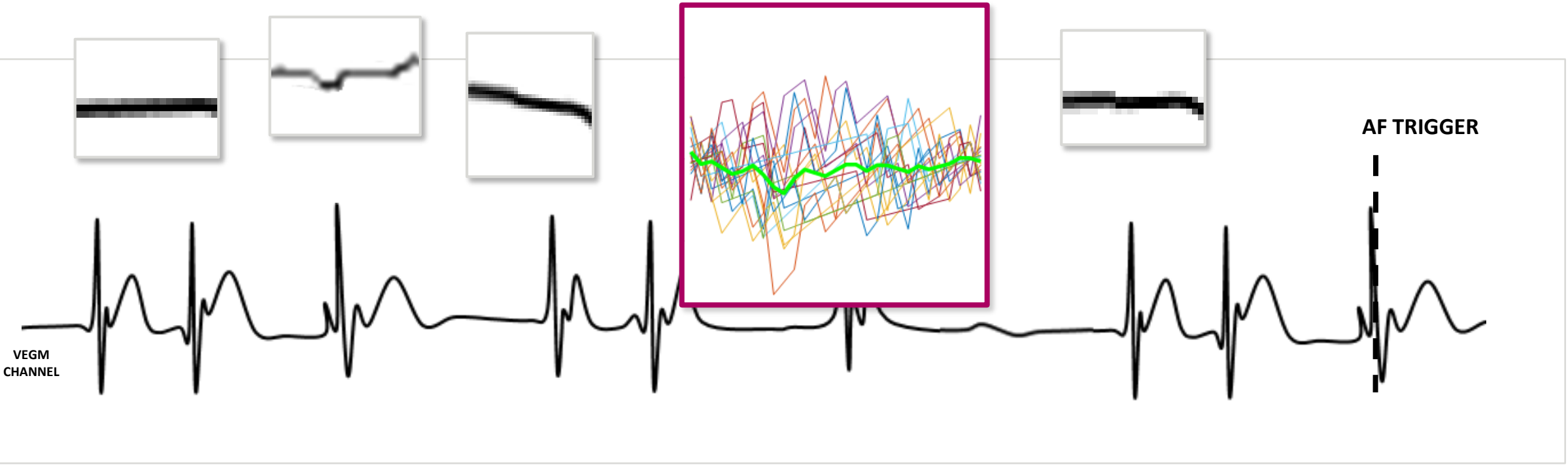


The P-Wave Discriminator

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

Evaluates correlation, morphology and amplitude

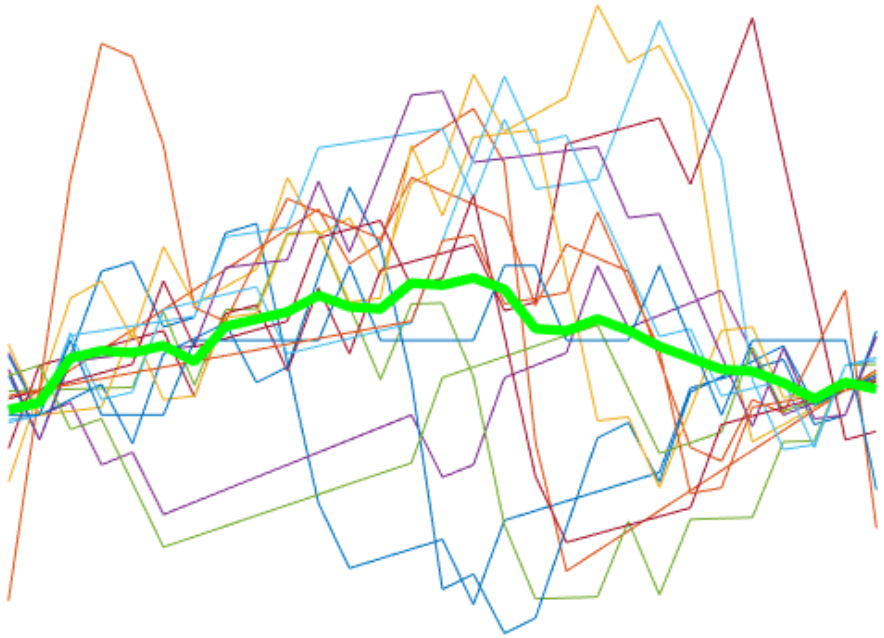
TRUE AF
(No consistent P-wave)



Individual and Ensemble Averaged P-waves

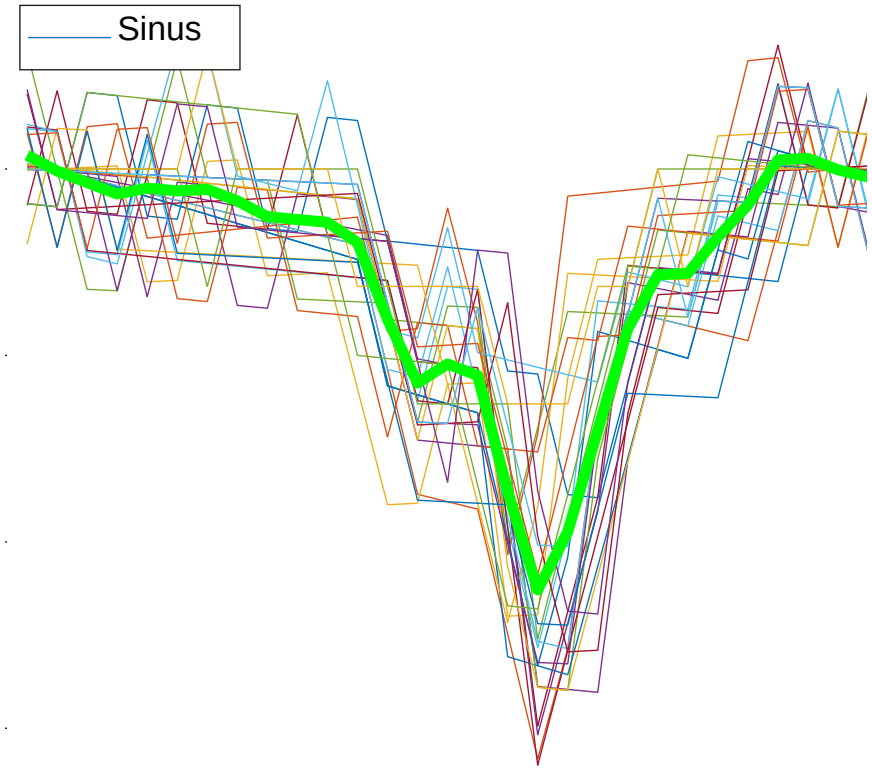
TRUE AF

No consistent P-wave pattern



FALSE AF

Consistent P-wave pattern



DETECT ACCURATELY with SharpSense™ Technology

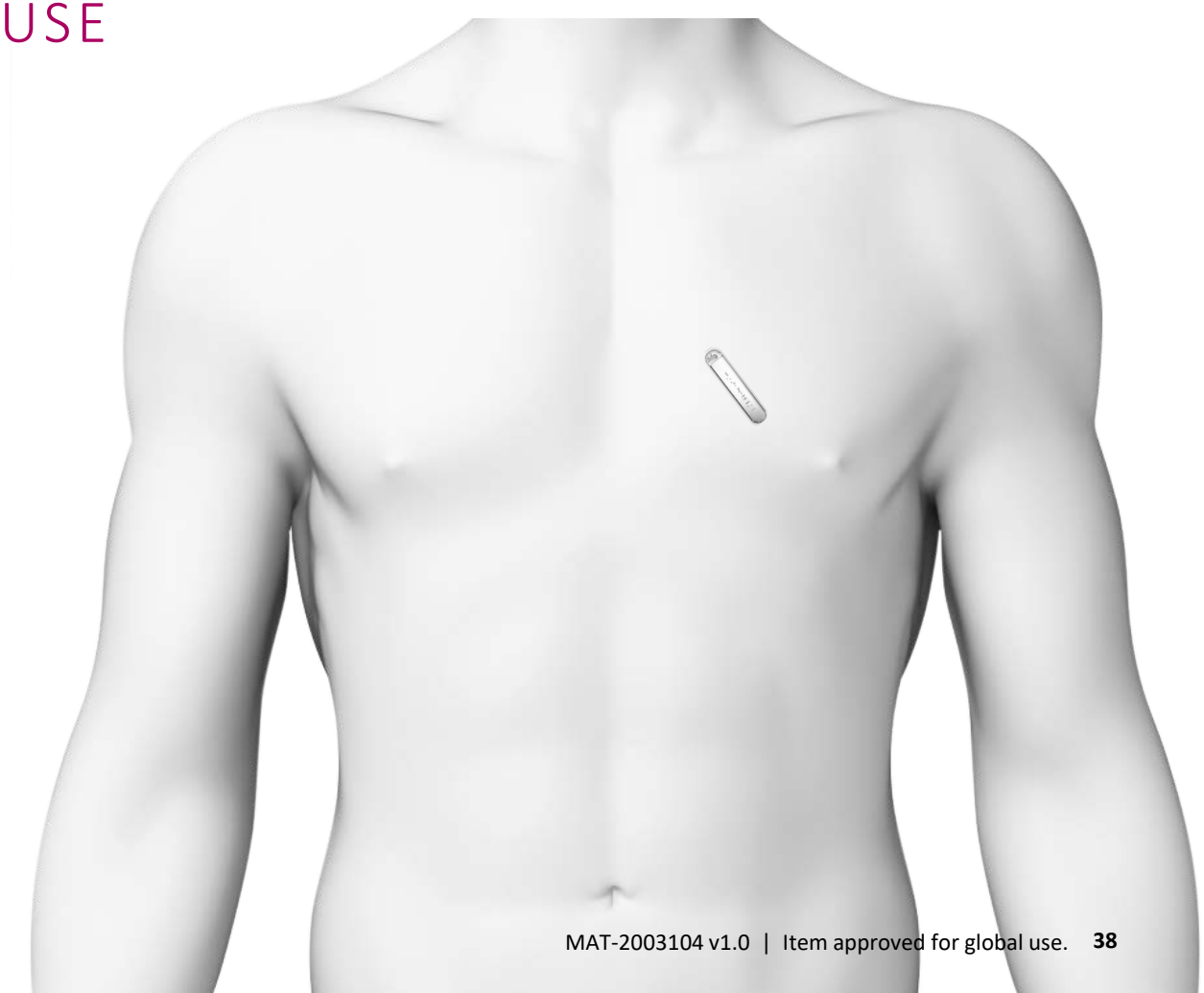
NEW NOMINAL SETTINGS
BETTER PERFORMANCE AND EASE OF USE

BRADYCARDIA

Cutoff rate adjusted to 30 bpm
per industry standards

MAX SENSITIVITY

Increased from 0.15 to 0.125 mV

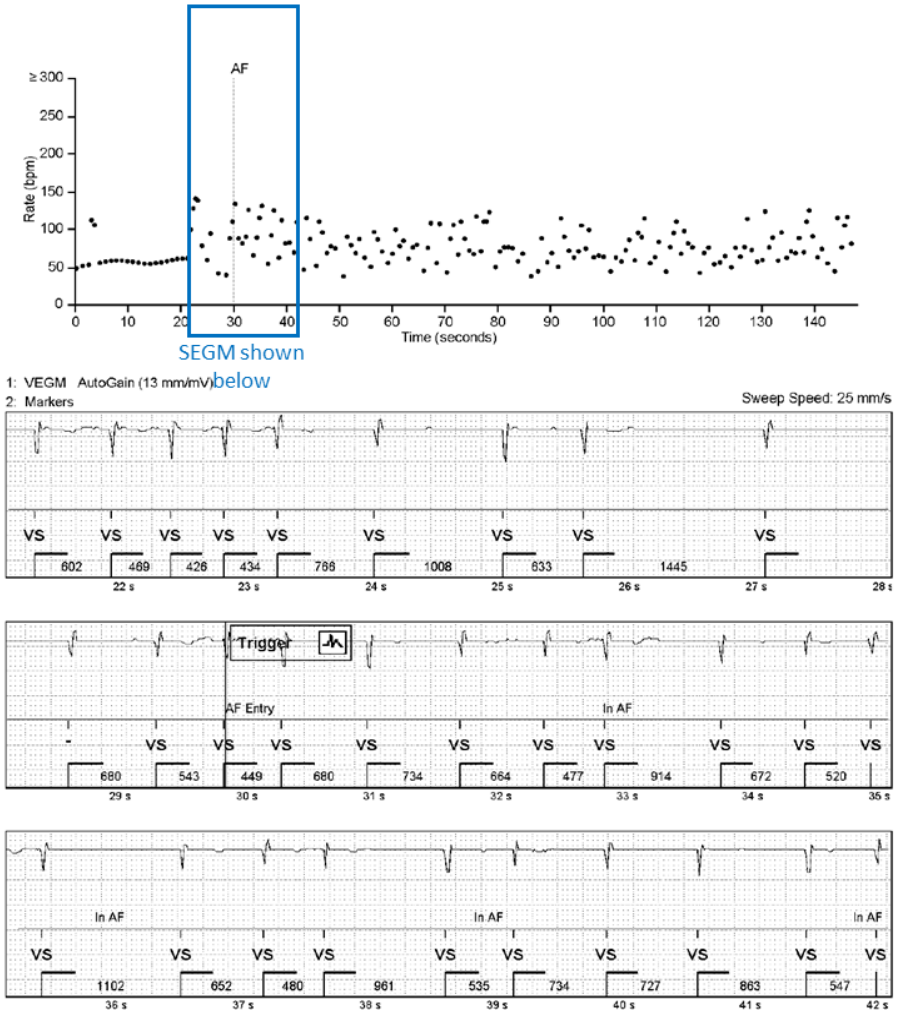


DETECT ACCURATELY with SharpSense™ Technology

NEW SCATTERPLOTS

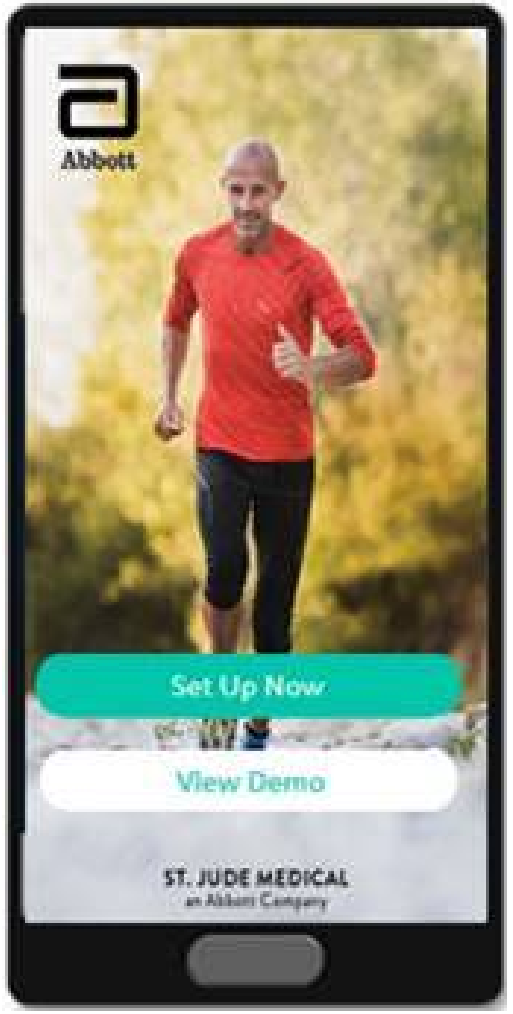
HEART RATE VS. TIME GRAPHS ADDED TO EXISTING EPISODE REPORTS

- 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® 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® LOW ENERGY WIRELESS TECHNOLOGY

- Heart rate monitors
- Blood pressure monitors
- Fitness devices

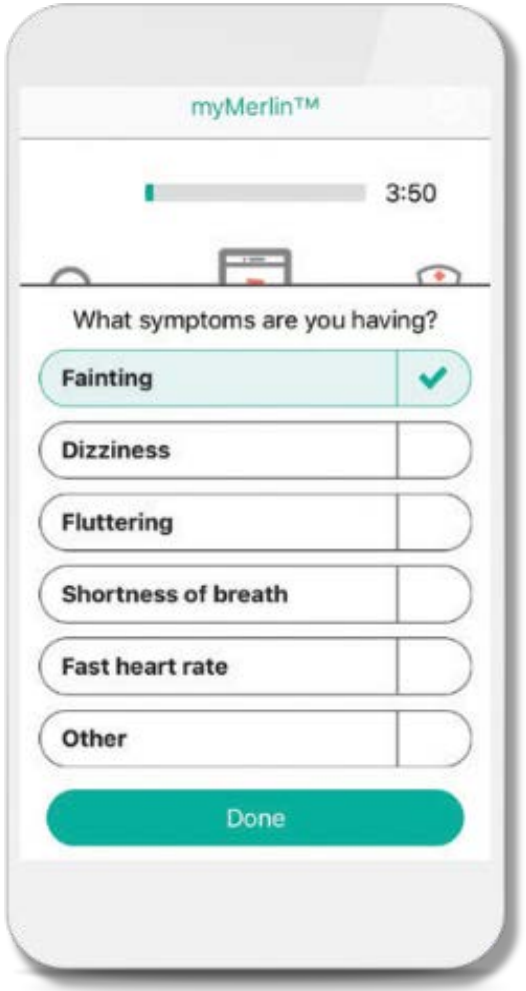
*NSA-approved encryption standard deemed suitable for Classified documents.

DELIVER Conveniently with Smartphone Connectivity

ENHANCE PATIENT COMPLIANCE

PATIENTS CAN DESCRIBE THEIR SYMPTOMS USING KEYWORDS

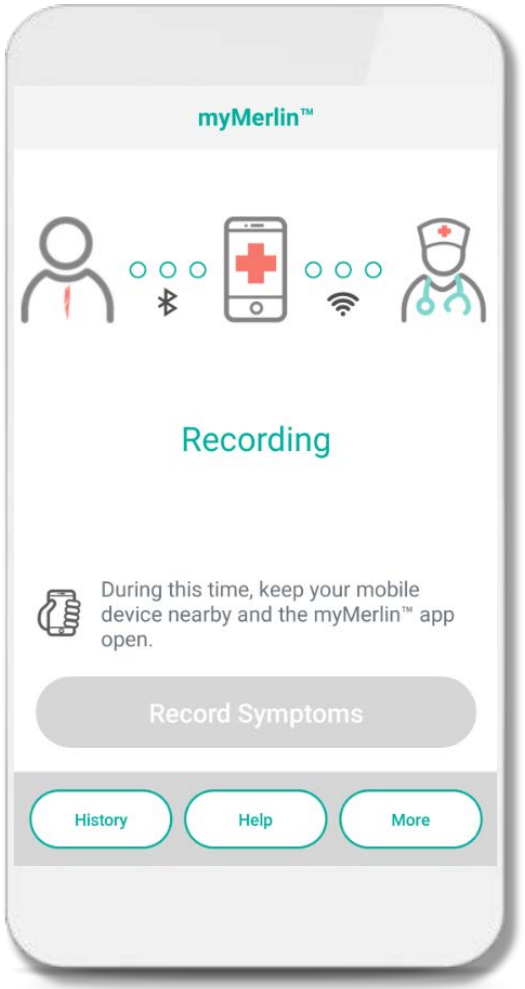
(e.g., fainting)



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



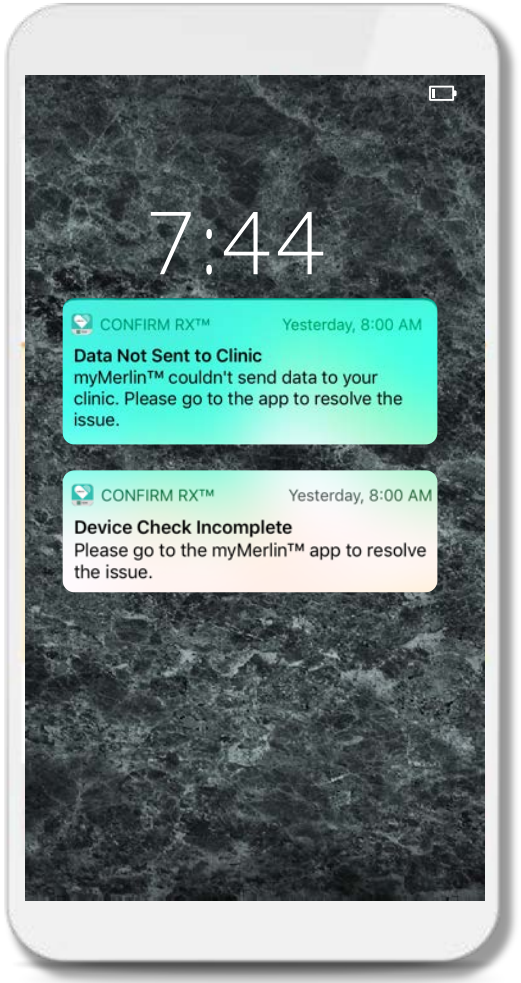
*Where data service is available.

DELIVER Conveniently with Smartphone Connectivity

ENHANCE PATIENT COMPLIANCE

PATIENTS CAN RECEIVE AUTOMATIC NOTIFICATIONS

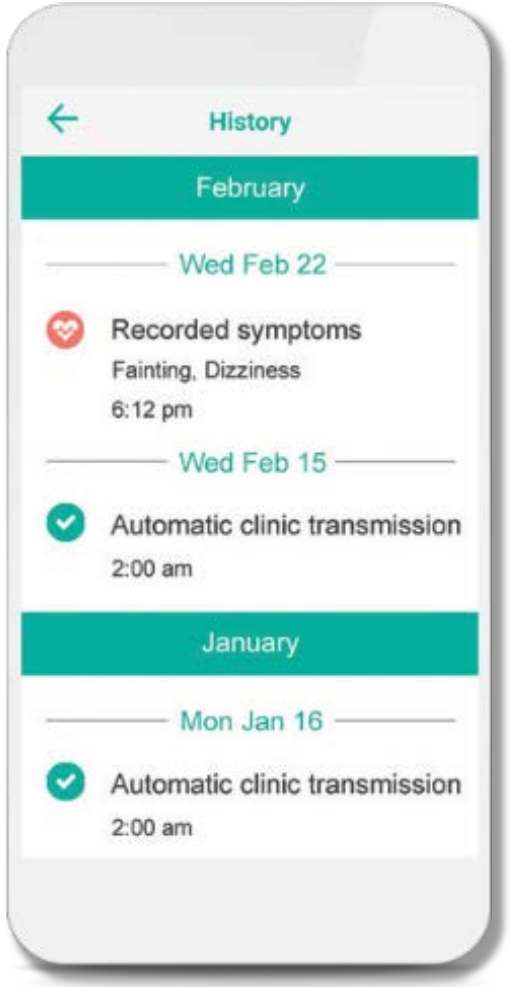
when they miss device checks or scheduled transmissions



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

Total study patients
N = 13,323

94% registered ICM with app
N = 12,572

97% of registered had at least 1 transmission
N = 12,167

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

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

STUDY DETAIL[1]

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

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[1*]

134 DAYS

The median time for diagnosis in patients with unexplained syncope when using an implantable loop recorder[2*]

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[3]

*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)[1]**	LINQ USABILITY STUDY*** (REVEAL LINQ‡)[2]
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

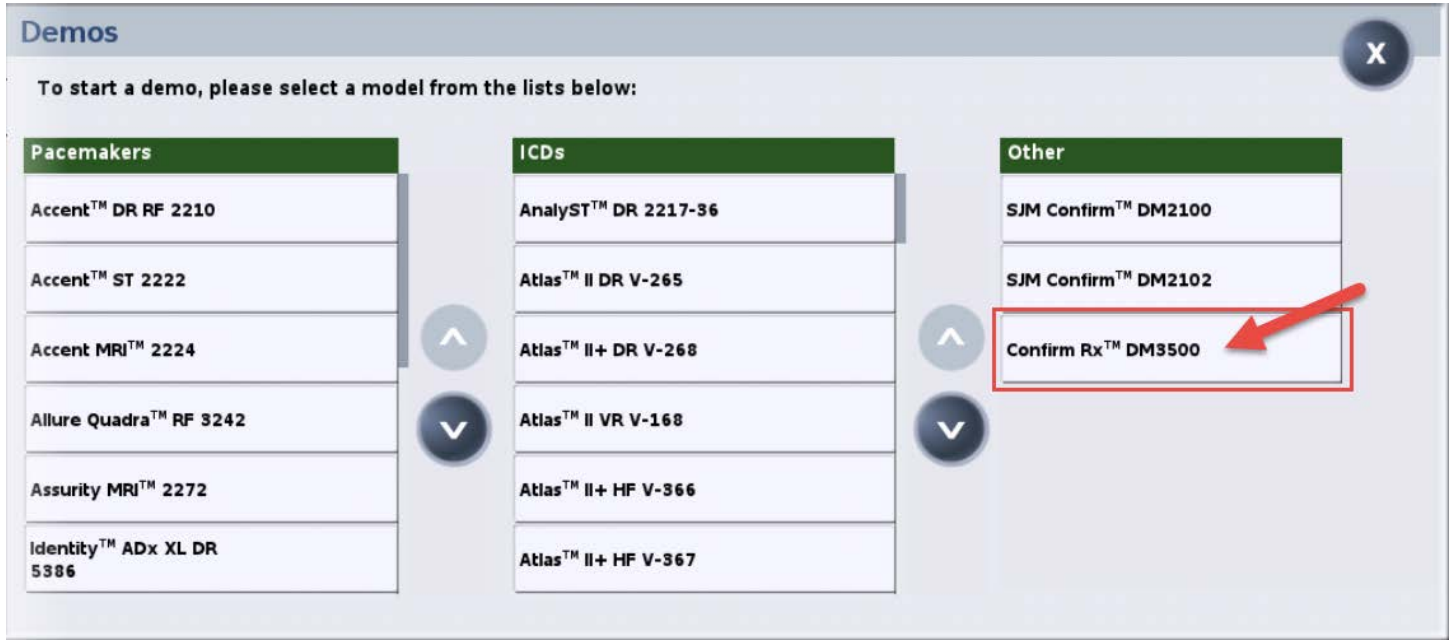
- Have very different patient populations
- Did not compare different ICM devices
- Did not evaluate the Confirm Rx™ ICM device

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

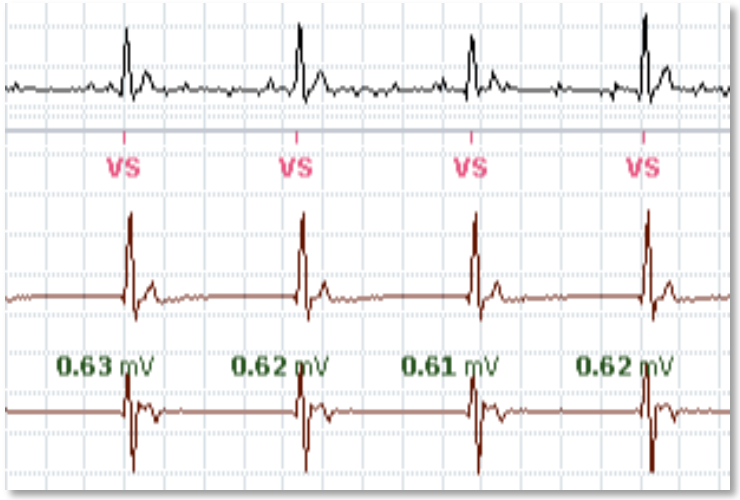
PROPER DETECTION RELIES ON APPROPRIATE SENSING

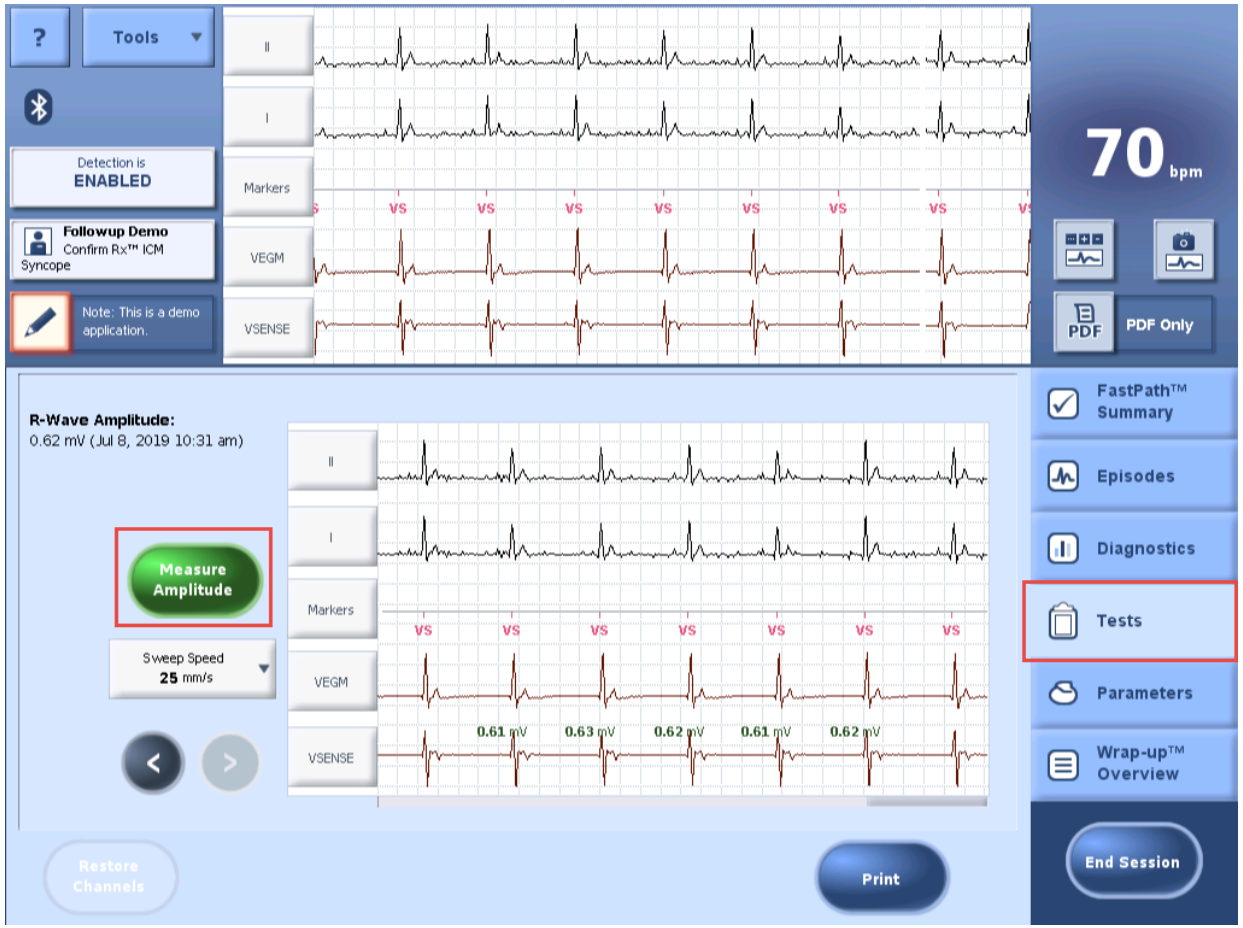
1. Measure R-wave
2. Verify Dynamic Range
3. Program appropriate Max Sensitivity

Programming Considerations

STEP #1: MEASURE R-WAVE

Tests Button → Measure Amplitude



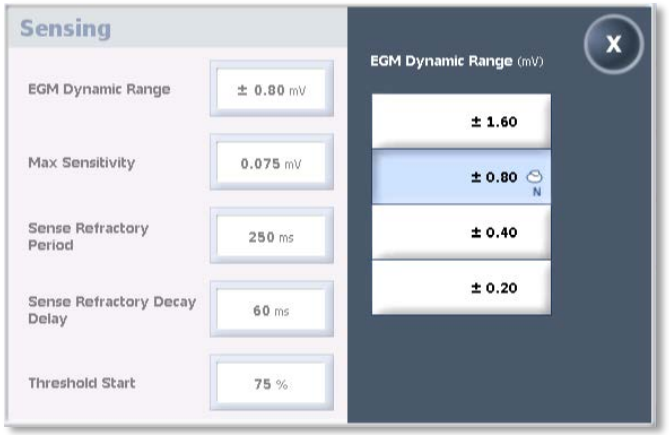


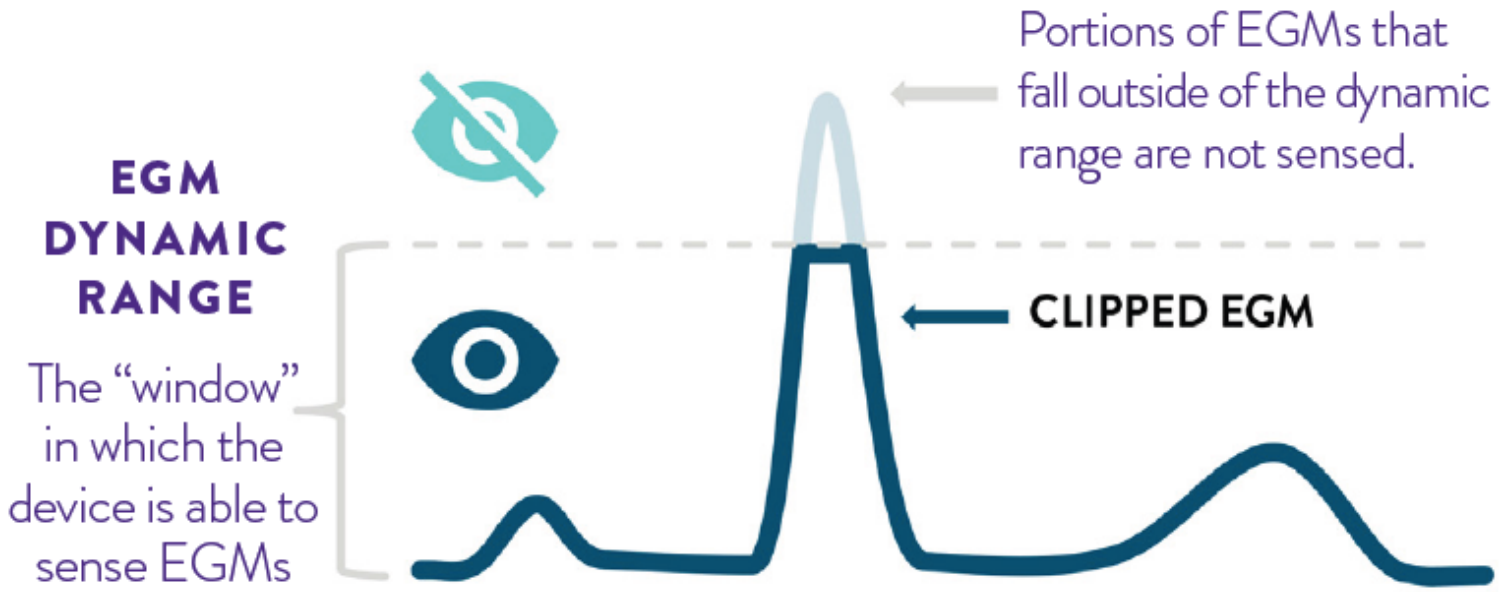
Programming Considerations

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 ≥ 0.45 mV?

NO

Calculate Max Sensitivity

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

YES

Use nominal Max Sensitivity

(0.125 mV)

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

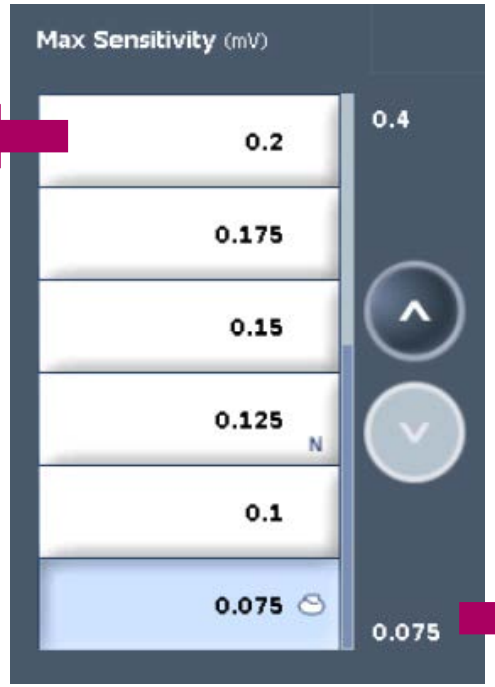
REMINDER

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

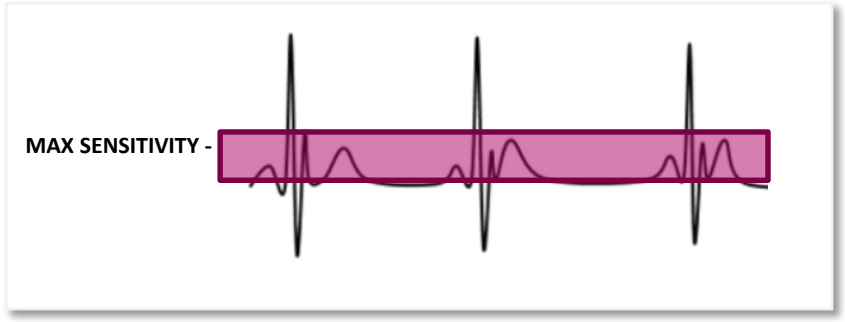
*Be cautious when programming Max Sensitivity to 0.05 mV. Oversensing may occur and cause noise reversion, which inhibits episode recording.

Max Sensitivity: Less Sensitive versus More Sensitive

LESS SENSITIVE (larger Max Sensitivity value)

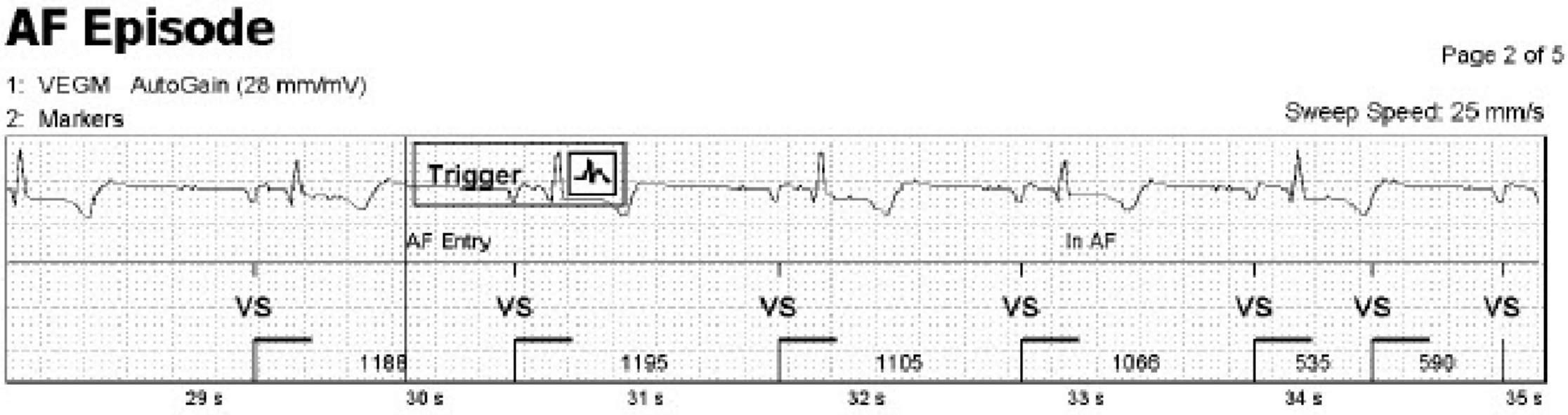


MORE SENSITIVE
(smaller Max Sensitivity value)



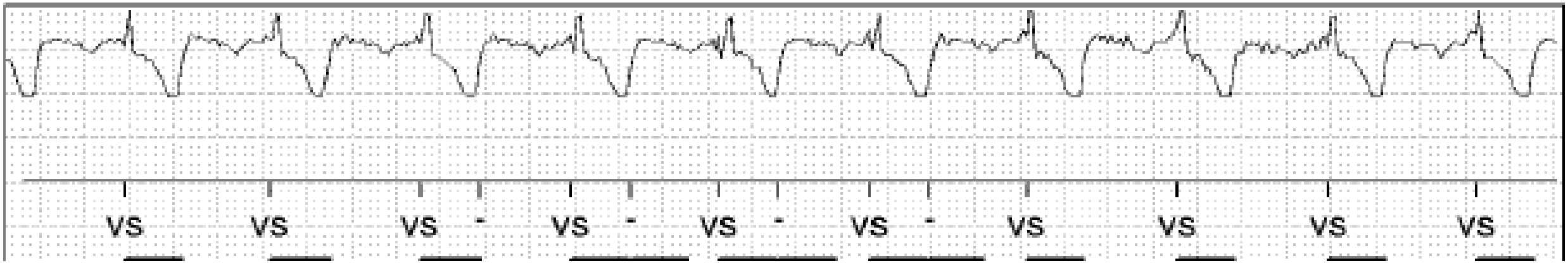
How Would You Interpret This EGM?

P-WAVE OVERSENSING Causing False AF Detection



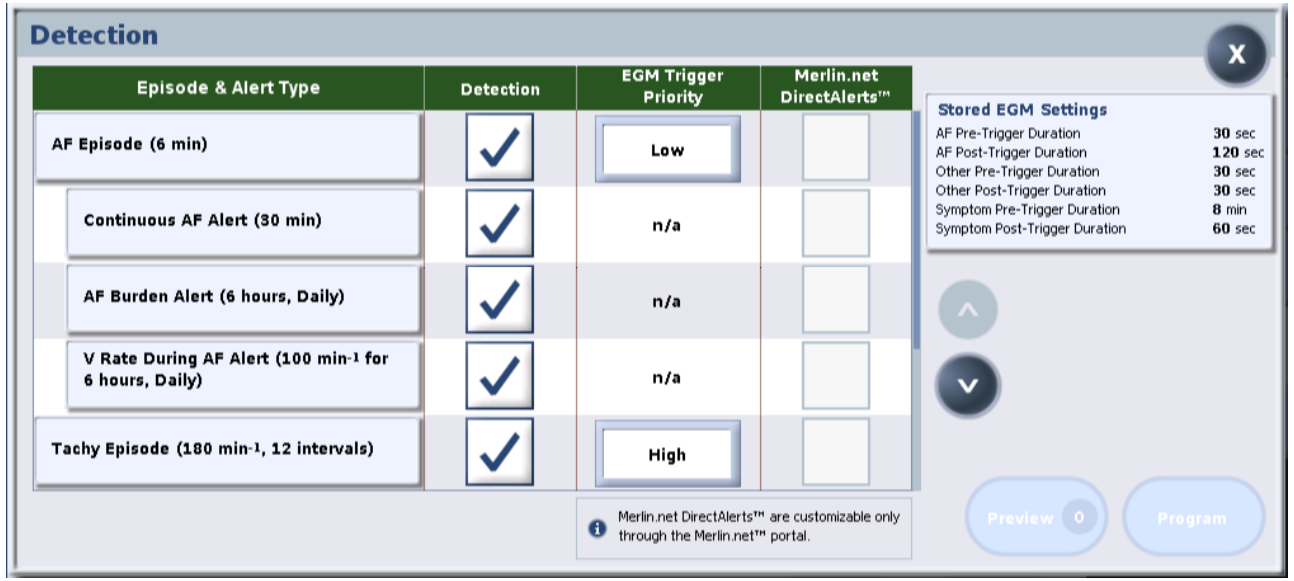
How Would You Interpret This EGM?

T-WAVE OVERSENSING Causing False AF Detection



Assess Programmed Cutoff Rates

PARAMETERS → EPISODE & ALERT TYPE

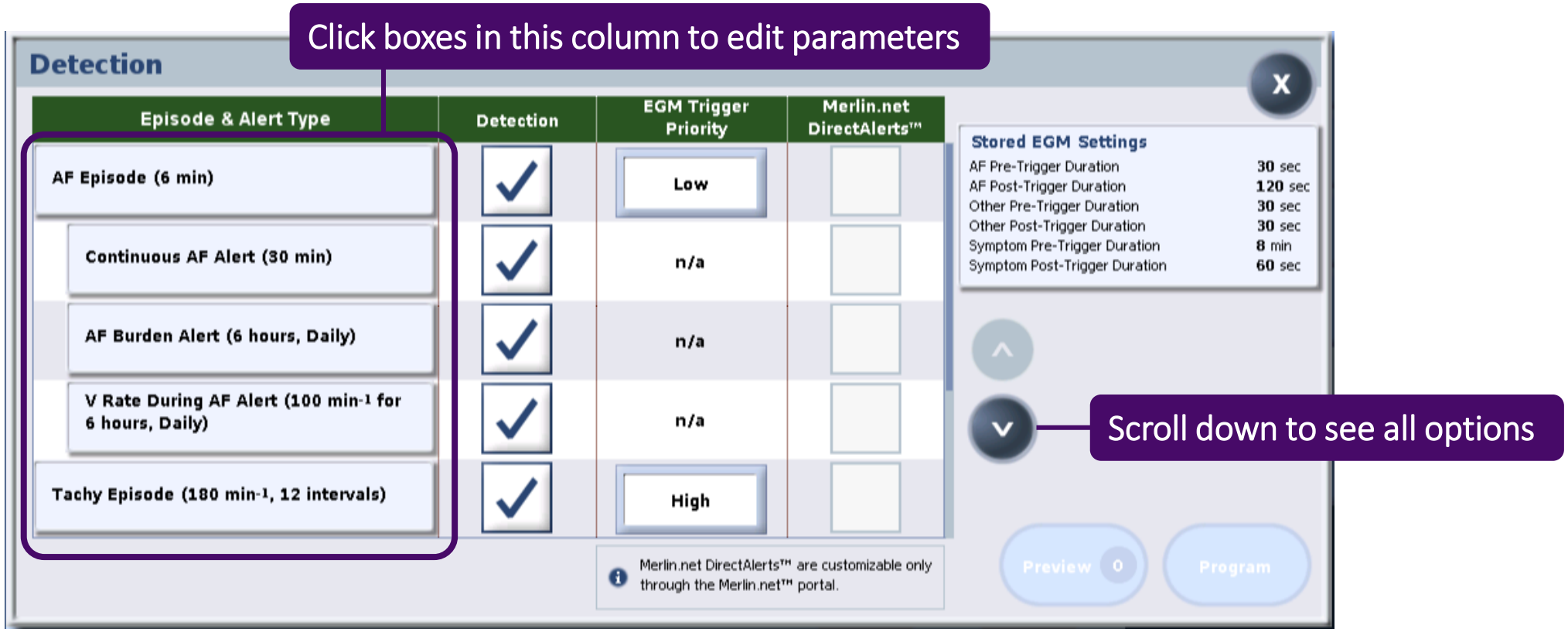


NOMINAL EPISODE SETTINGS

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

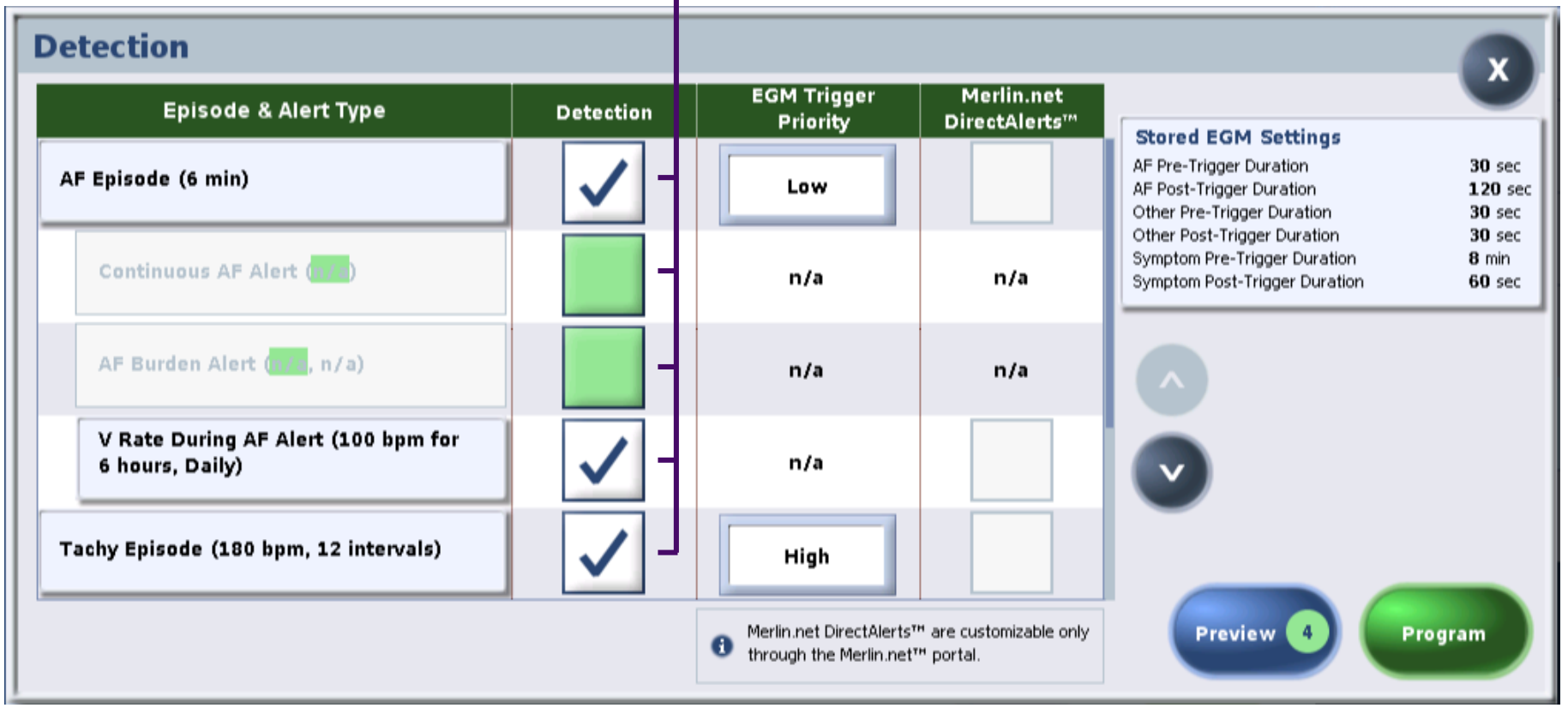
Device-detected episodes are scheduled to transmit every night at 2 a.m. (non-programmable).

Assess Programmed Cutoff Rates



When Do You Want to Store an EGM?

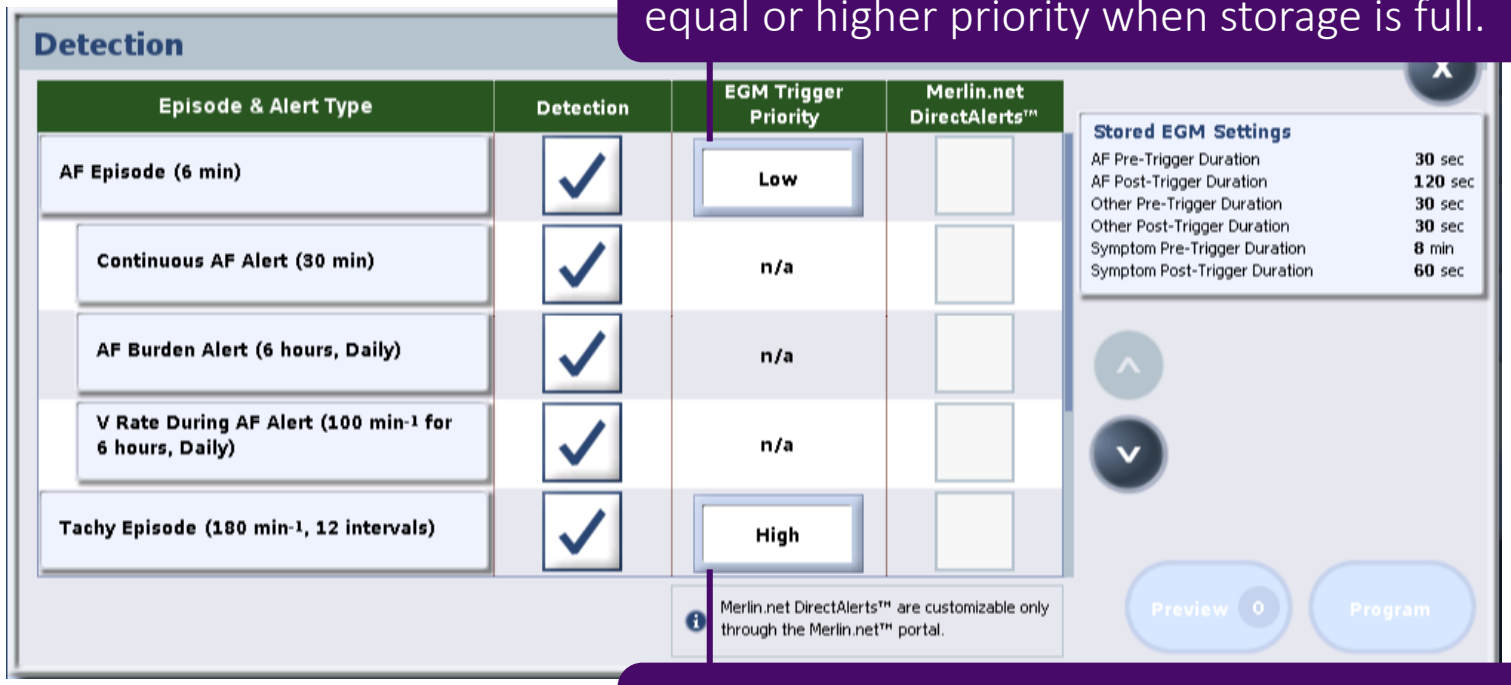
Uncheck boxes to turn detection or EGM triggers off



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.



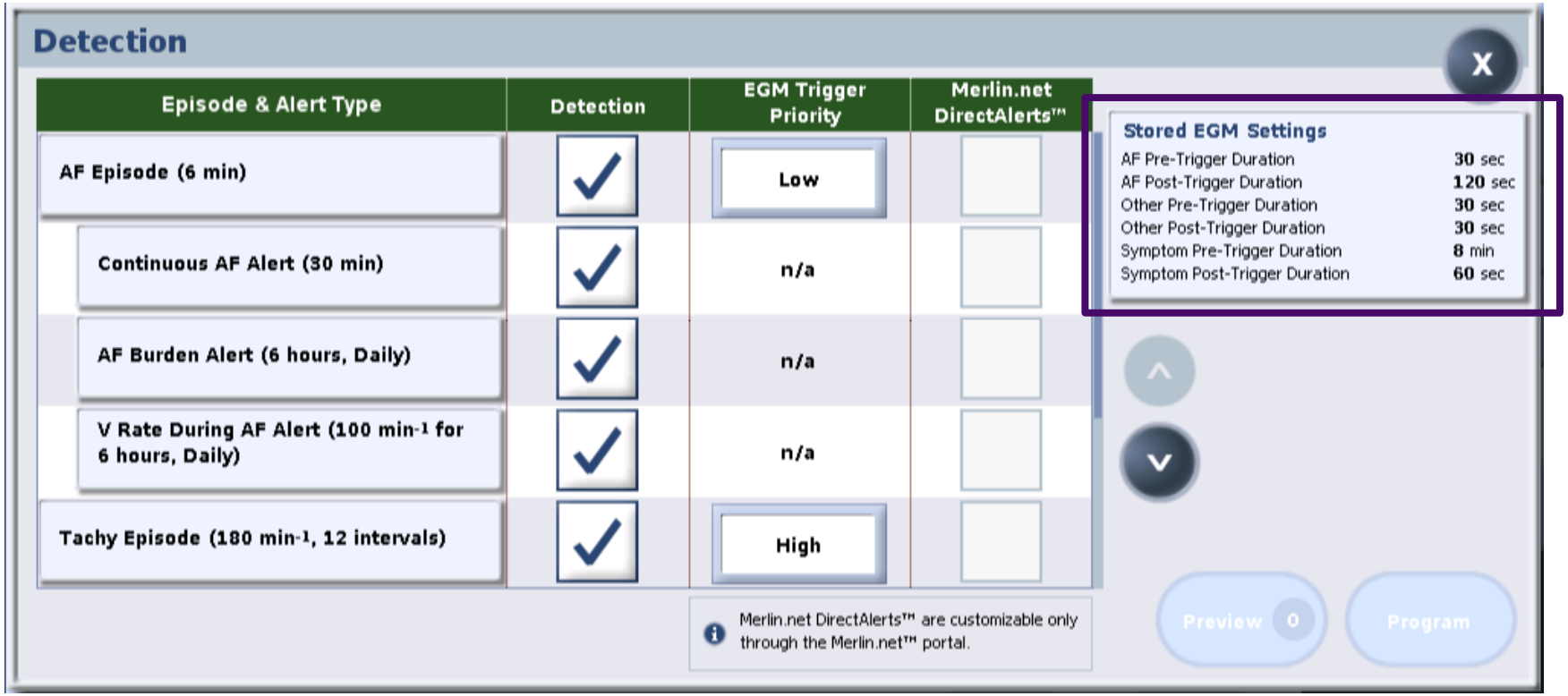
HIGH PRIORITY: Additional EGMs are stored if space is available. Once storage is full, new EGMs replace oldest stored EGM.

Off: No EGMs will be stored

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

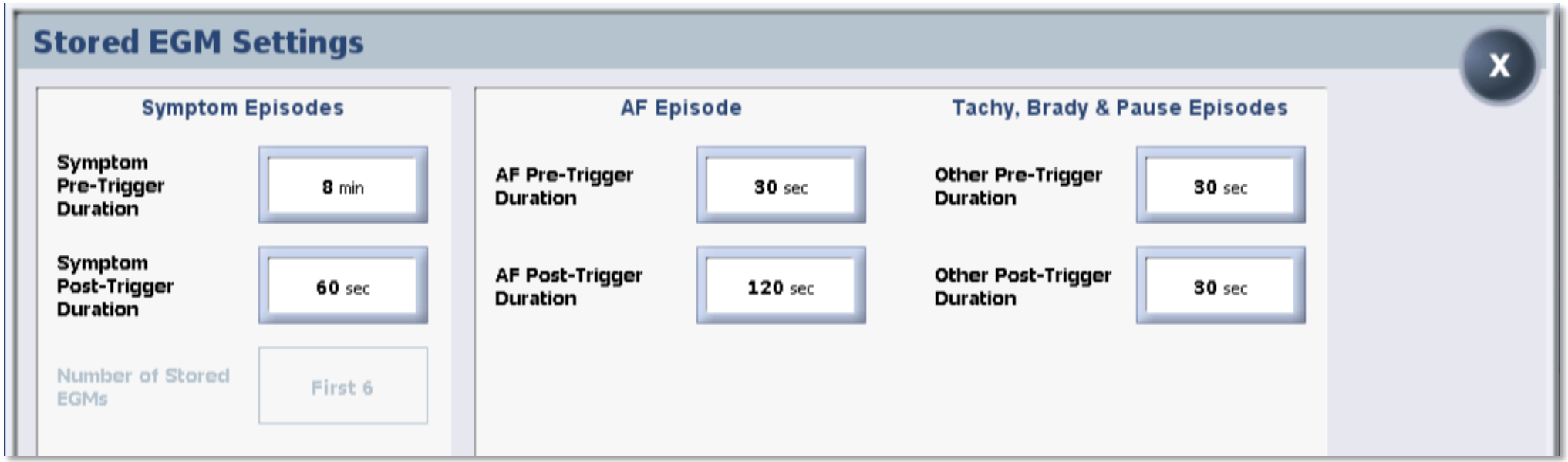
Customize Episode Storage

PARAMETERS → EPISODE & ALERT TYPE → Stored EGM Settings



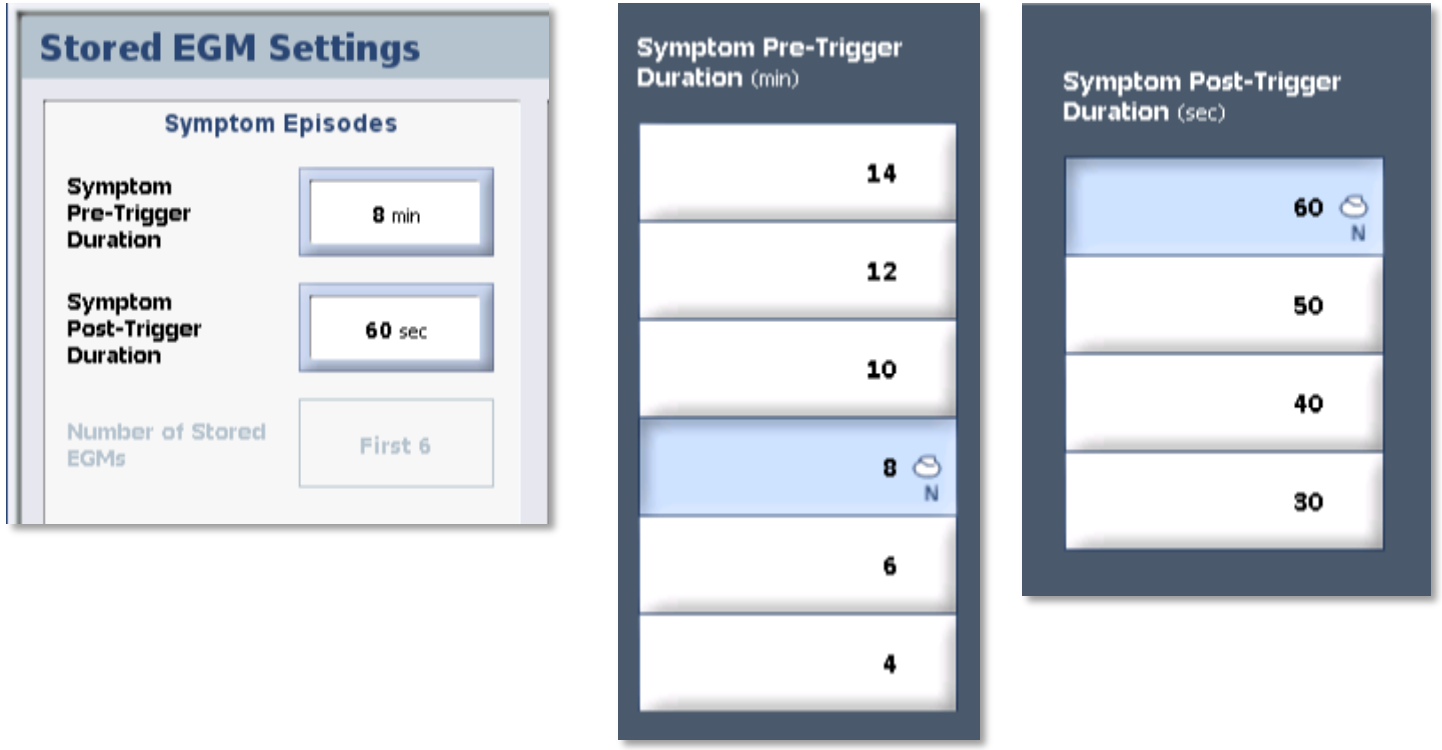
Stored EGM Settings

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



Managing EGM Storage

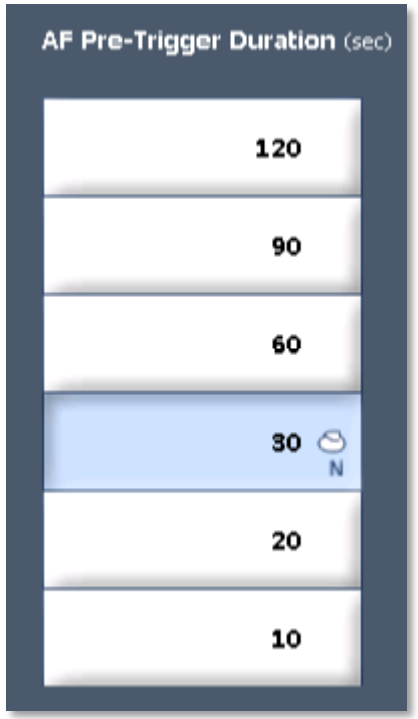
A SYMPTOM EPISODE RECORDS 8 MINUTES (nominally) before the patient hits the "Record Symptoms" button and one minute after.

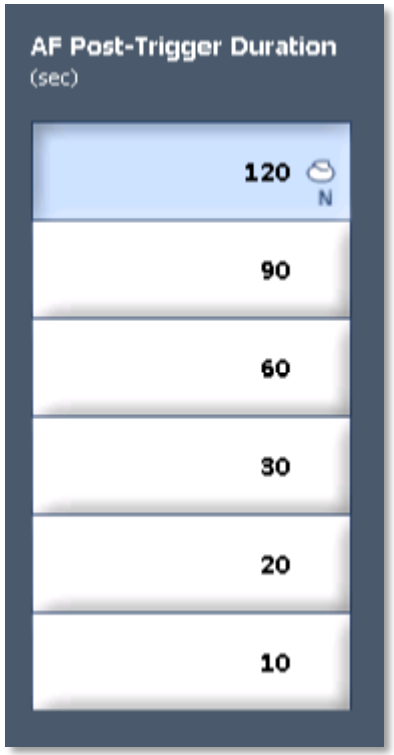


- **Consider shortening the pre-trigger duration** if the patient is able to record symptoms within a shorter timeframe or if more EGM space is desired.
- **Consider lengthening the pre-trigger duration** if the patient has difficulty pressing "Record Symptoms" in a timely fashion (e.g., can't find their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

Managing EGM Storage

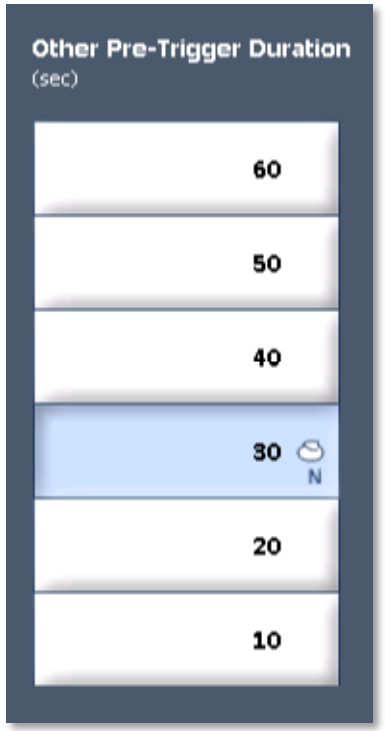
STORED EGM SETTINGS FOR AF EPISODES can be as short as 10 seconds before and after, or as long as 2 minutes before and after.

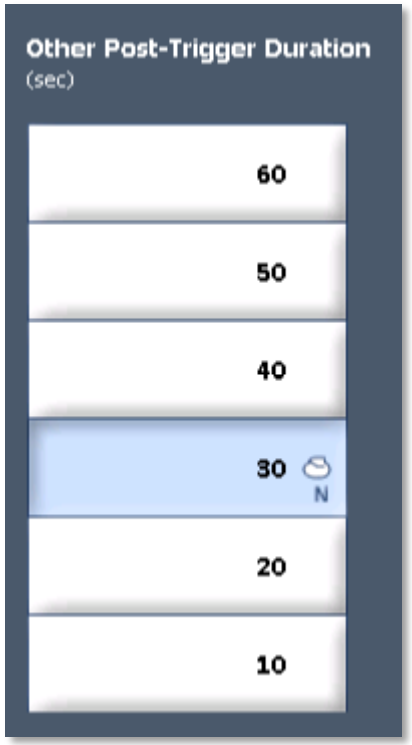




Managing EGM Storage

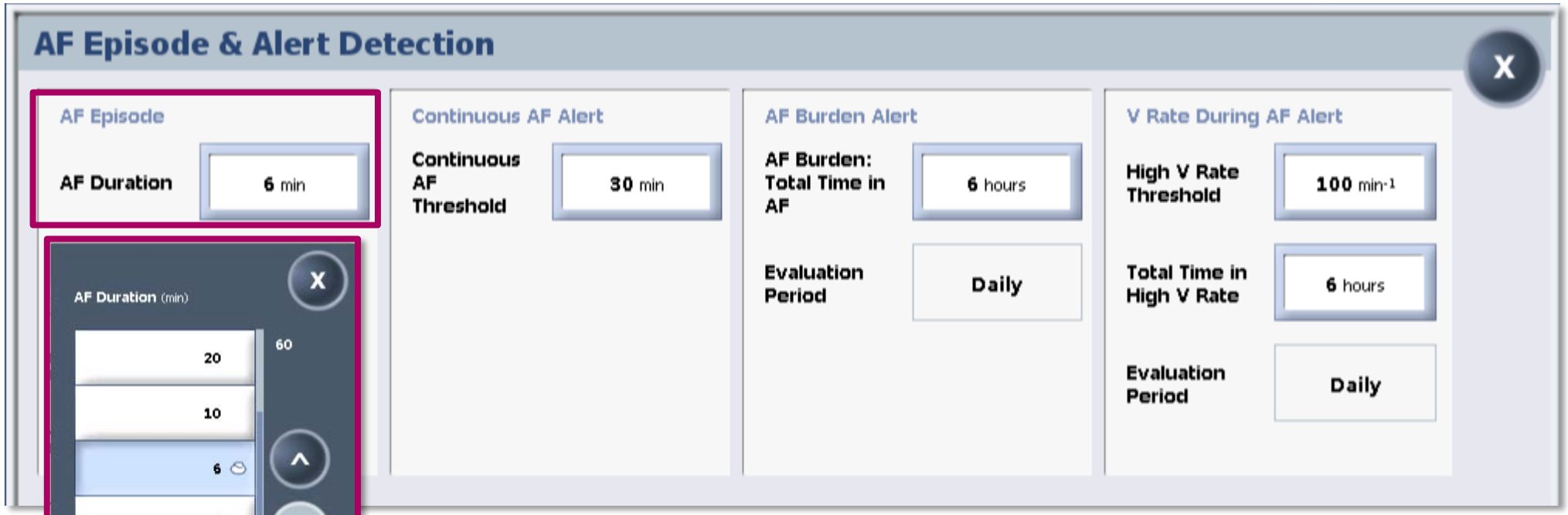
TACHY, BRADY AND PAUSE EPISODE STORAGE ARE PROGRAMMED TOGETHER and can be as short as 10 seconds before and after, or as long as 1 minute before and after.





Managing Alerts: What Do They Mean?

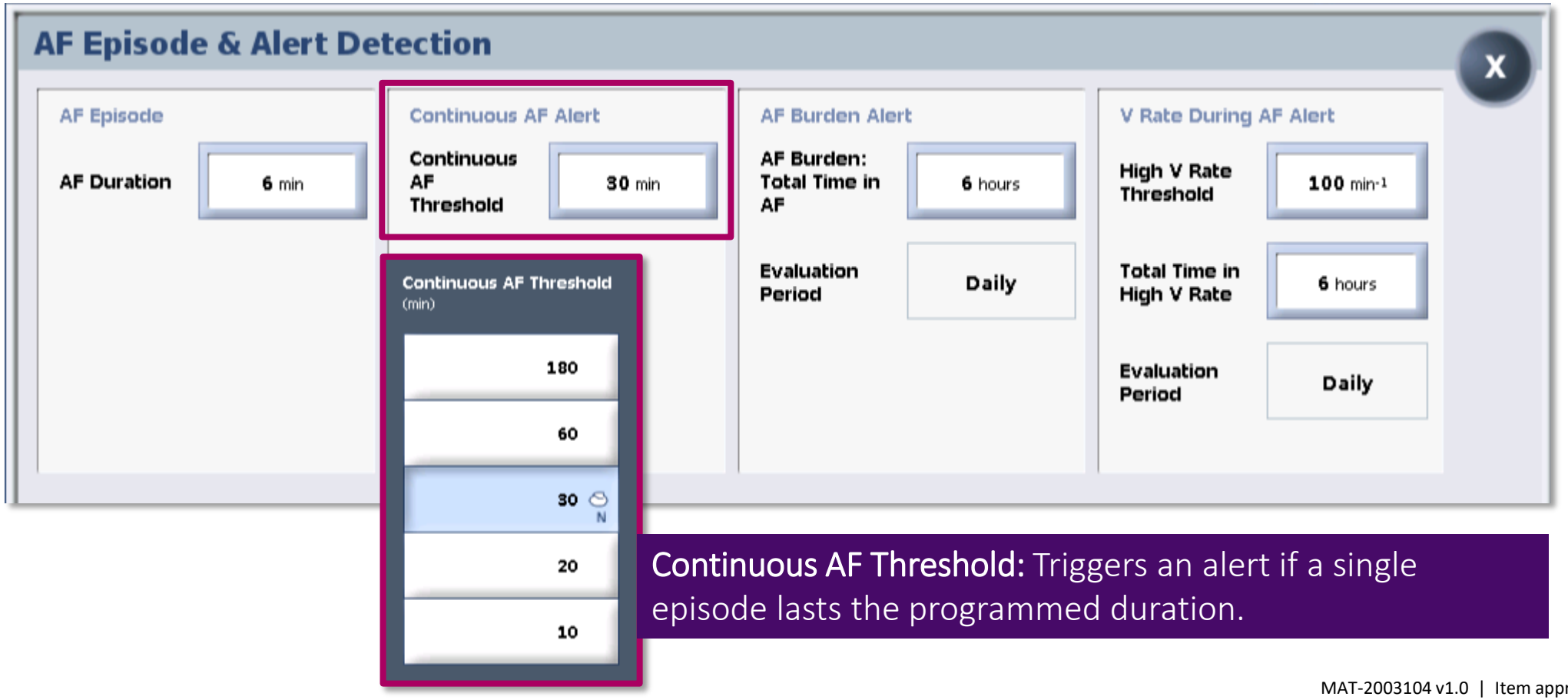
SET THE CONDITIONS FOR MONITORING AF



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

Managing Alerts: What Do They Mean?

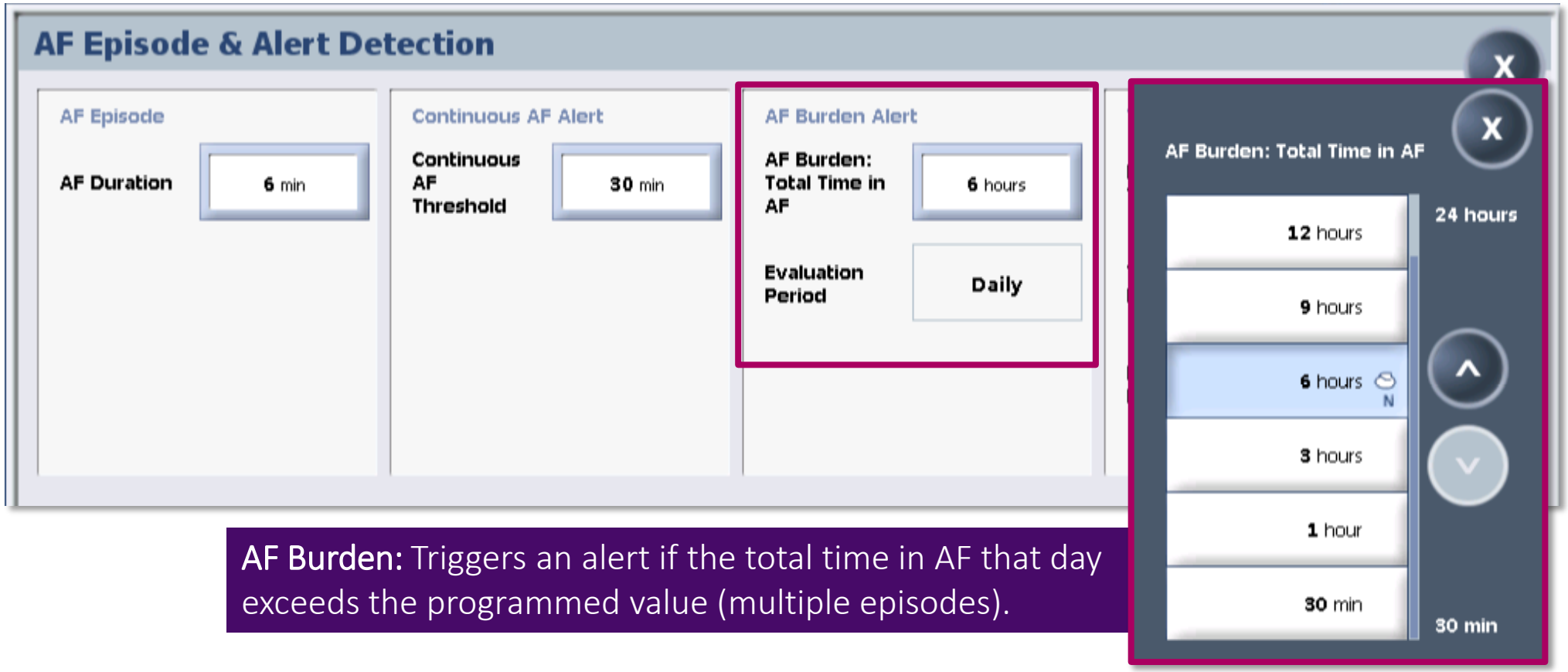
SET THE CONDITIONS FOR MONITORING AF



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

Managing Alerts: What Do They Mean?

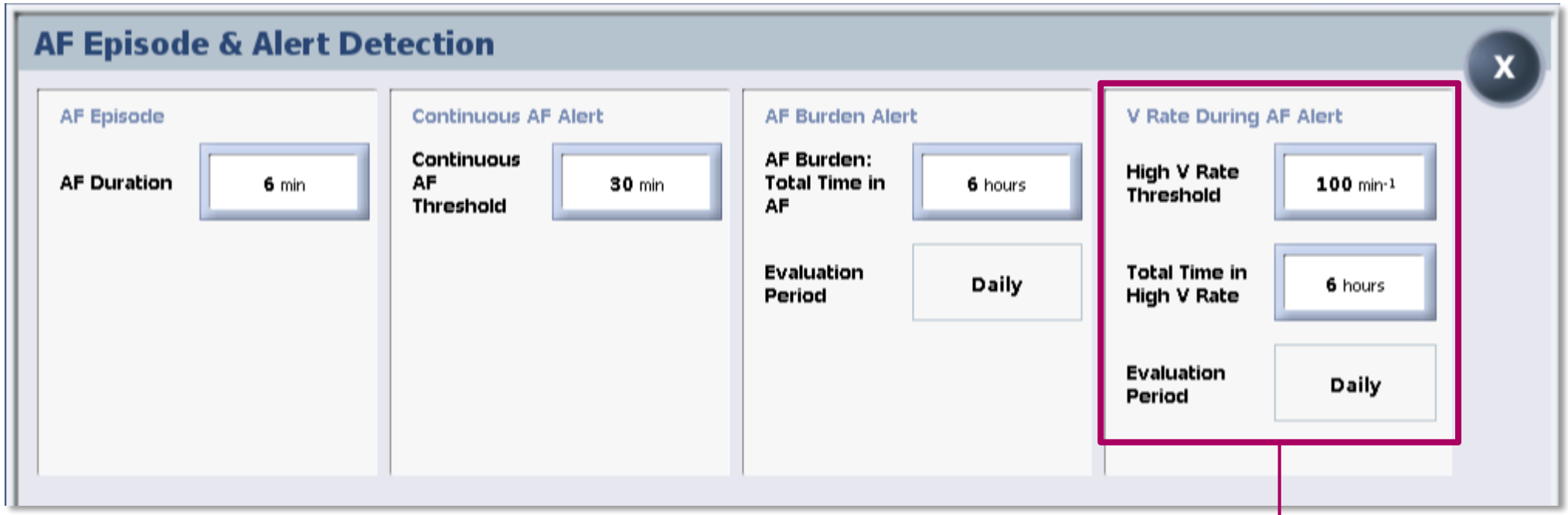
SET THE CONDITIONS FOR MONITORING AF



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

Managing Alerts: What Do They Mean?

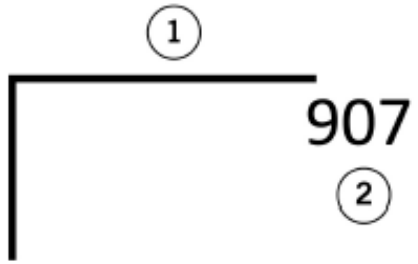
SET THE CONDITIONS FOR MONITORING AF



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

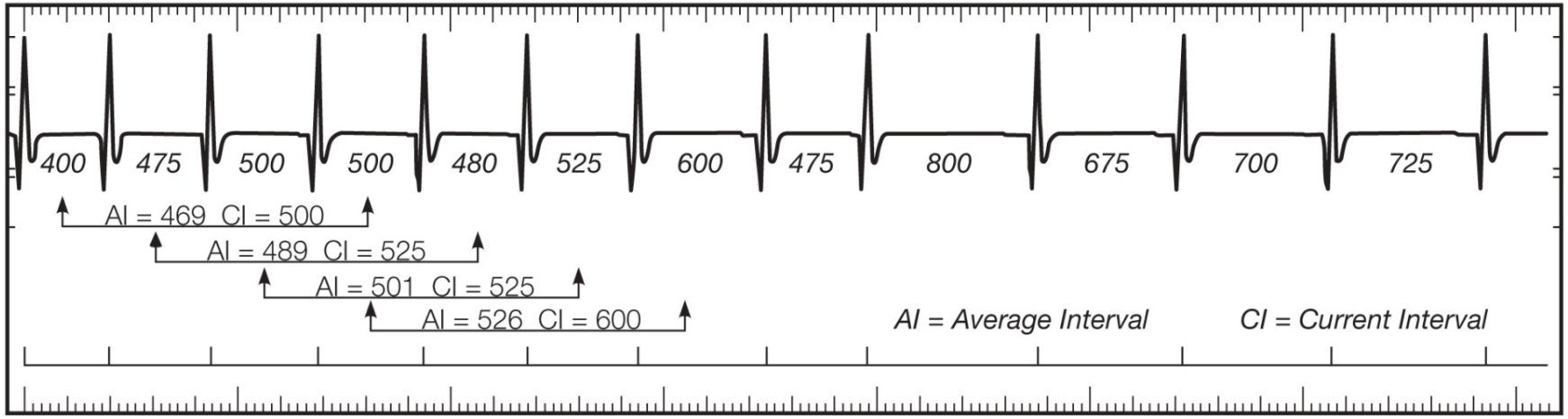
*A/Asystole is used for SJM Confirm™ implantable cardiac monitor; P/Pause is used for Confirm Rx™ ICM.

Confirm Rx ICM Help Manual

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

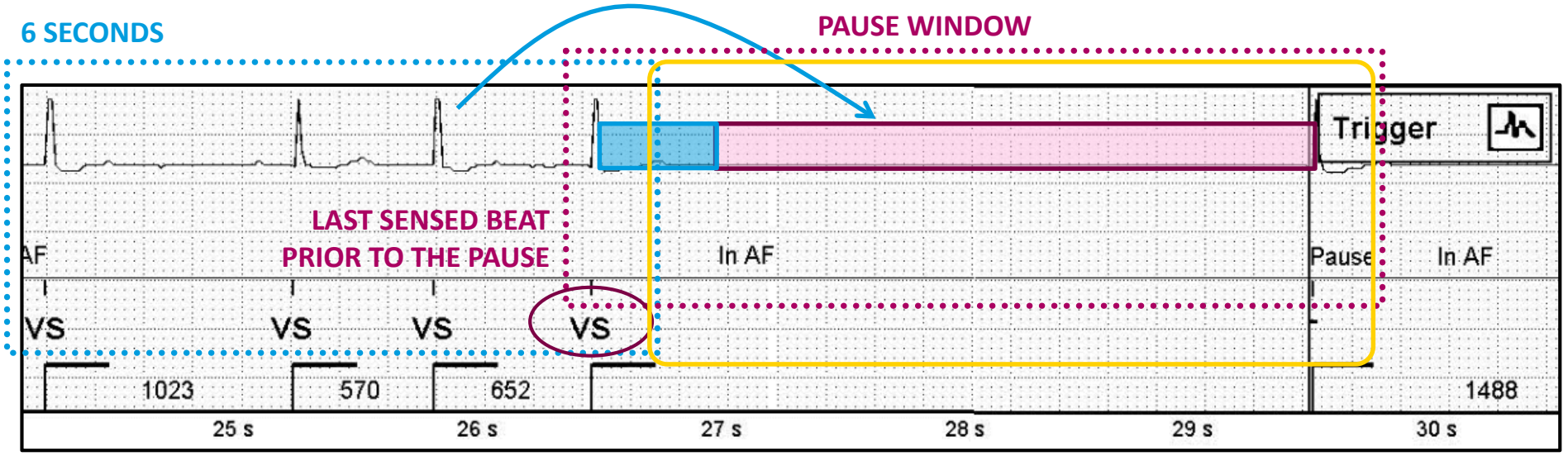


CONFIRM Rx™ ICM

EGM EXAMPLES

TRUE PAUSE

- **ANALYZES R- AND T-WAVES** immediately prior to detection
- Applies new **SENSITIVITY THRESHOLD**
- **NO UNDERSENSED BEATS FOUND?** Stores Pause episode

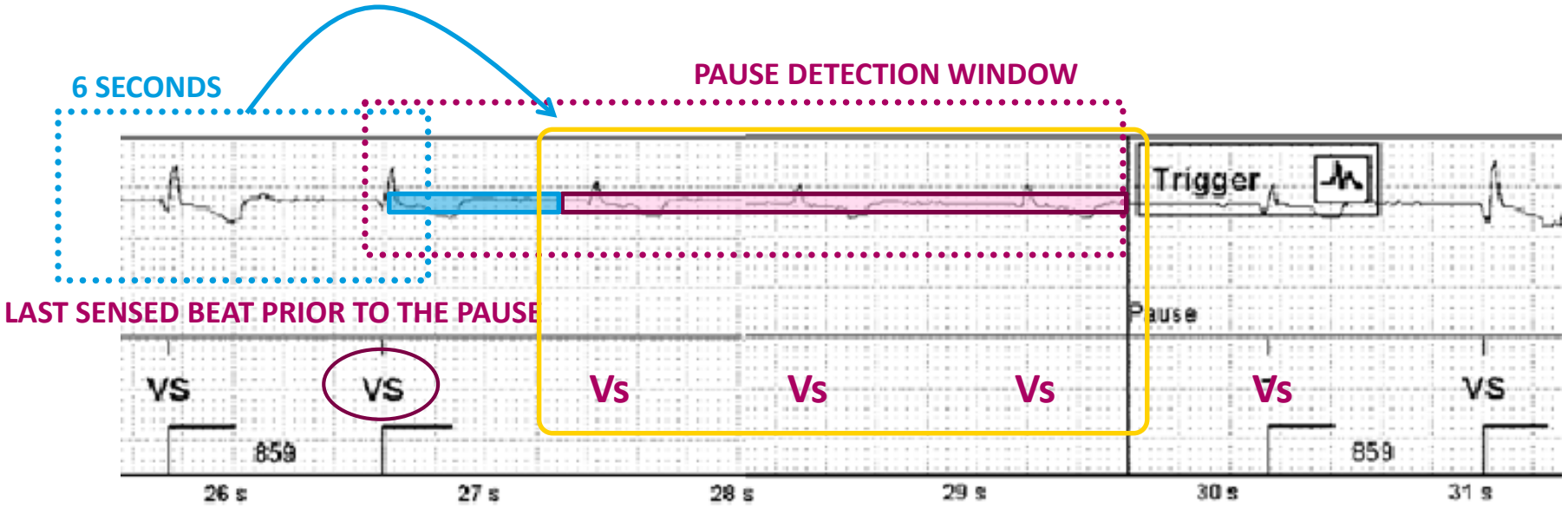


T-WAVE BLANKING applied to last sensed beat before the Pause

SECONDARY THRESHOLD applied to Pause window to search for undersensed beats

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**

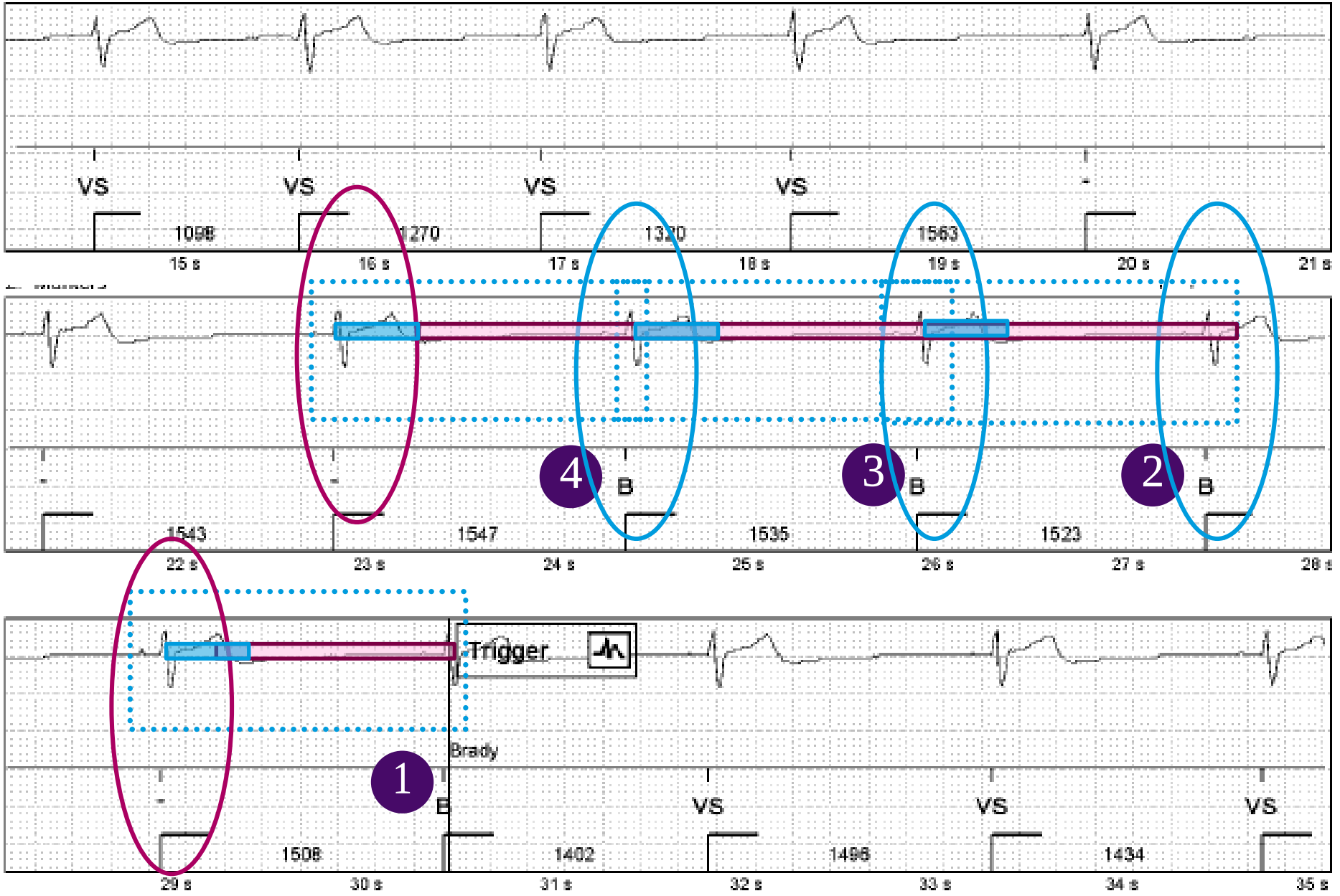


T-WAVE BLANKING applied to last sensed beat before the Pause

SECONDARY THRESHOLD applied to Pause window to search for undersensed beats

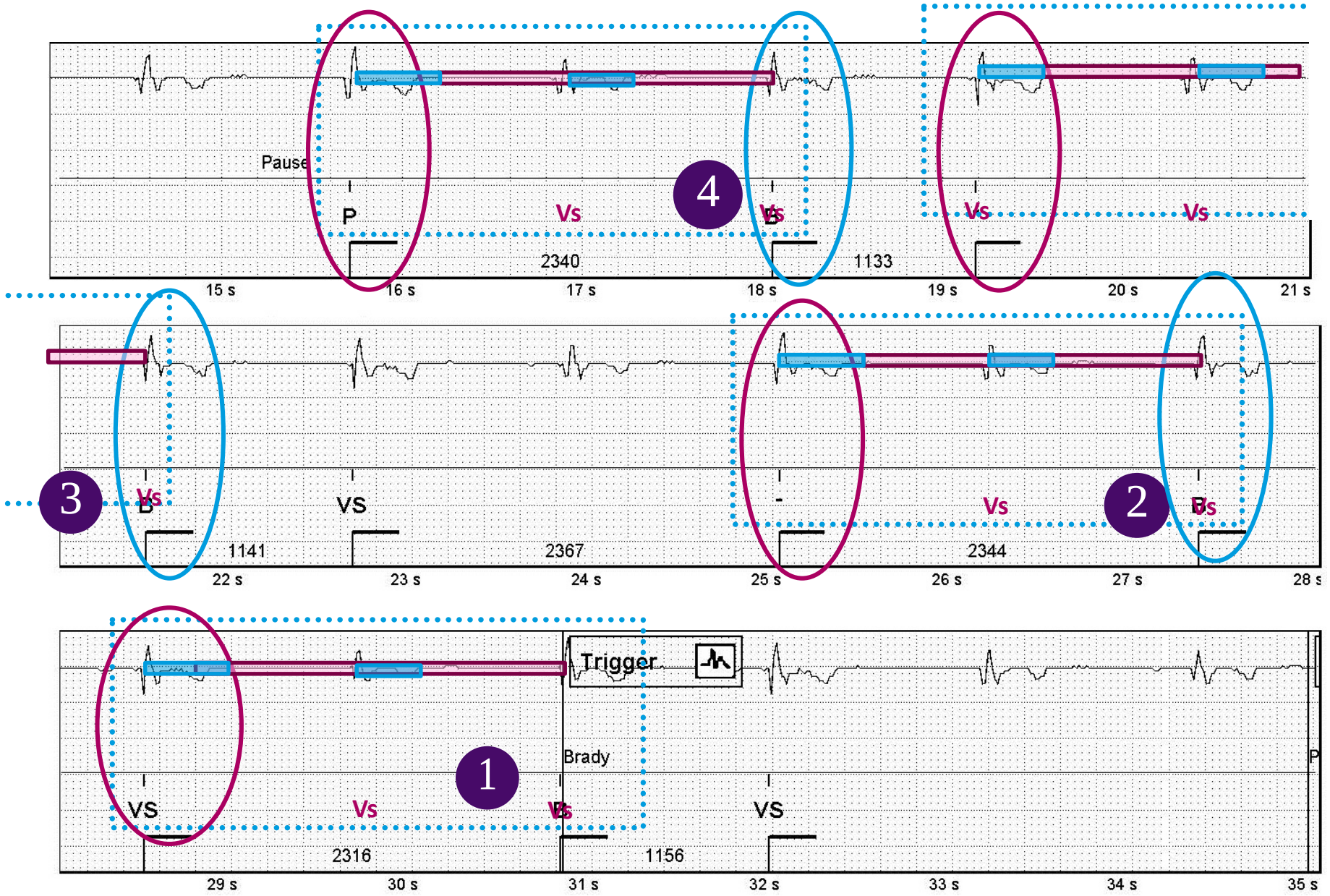
TRUE BRADY

- 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



FALSE BRADY

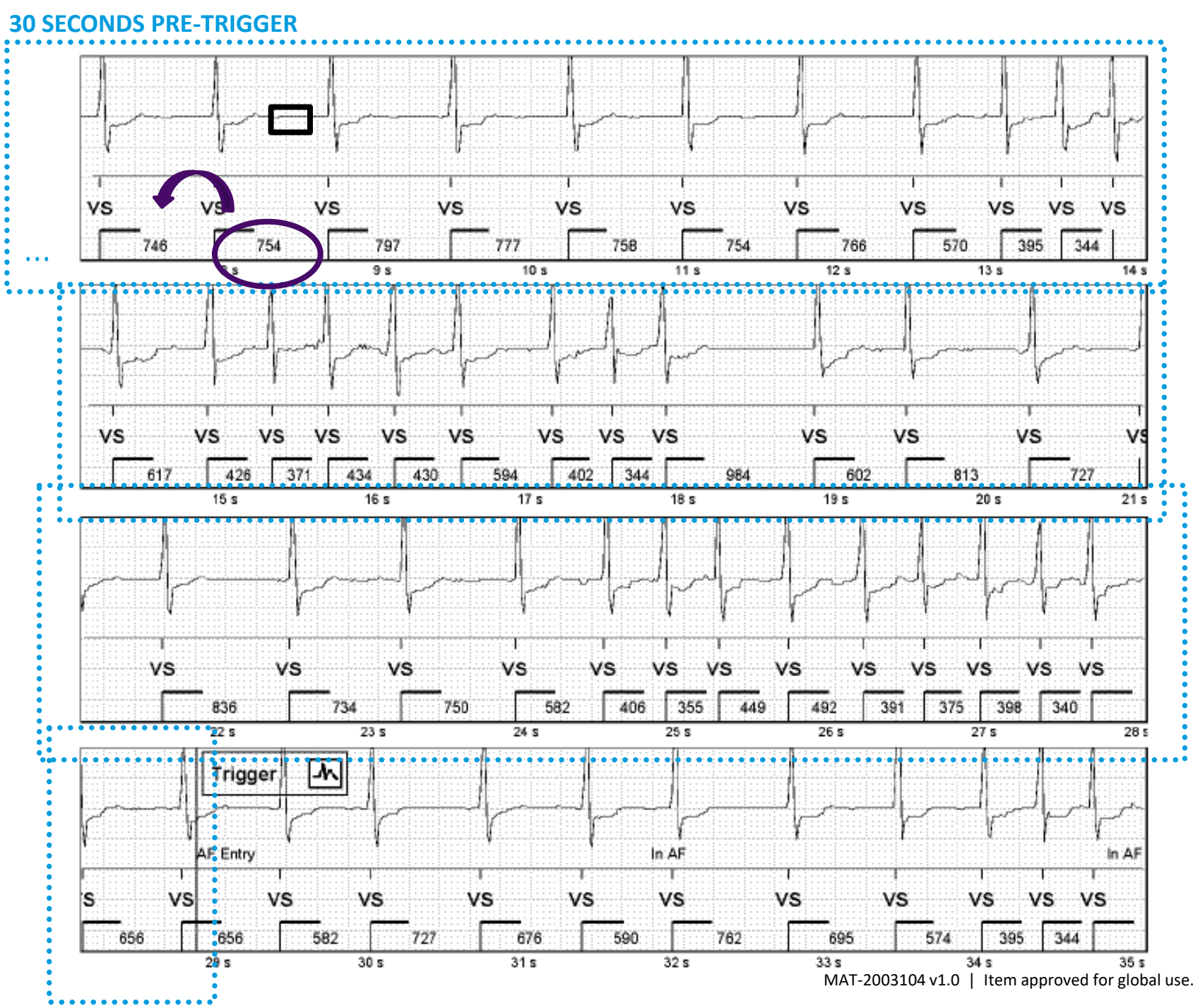
- Analyzes P-, R- and T-waves from **SELECT BEATS** leading up to detection
- Looks for undersensed beats in all **FOUR WINDOWS**
- Recalculates intervals based on undersensed beats that are found
- **REMOVES BRADY EPISODE**



TRUE AF

NO VISIBLE P-WAVES

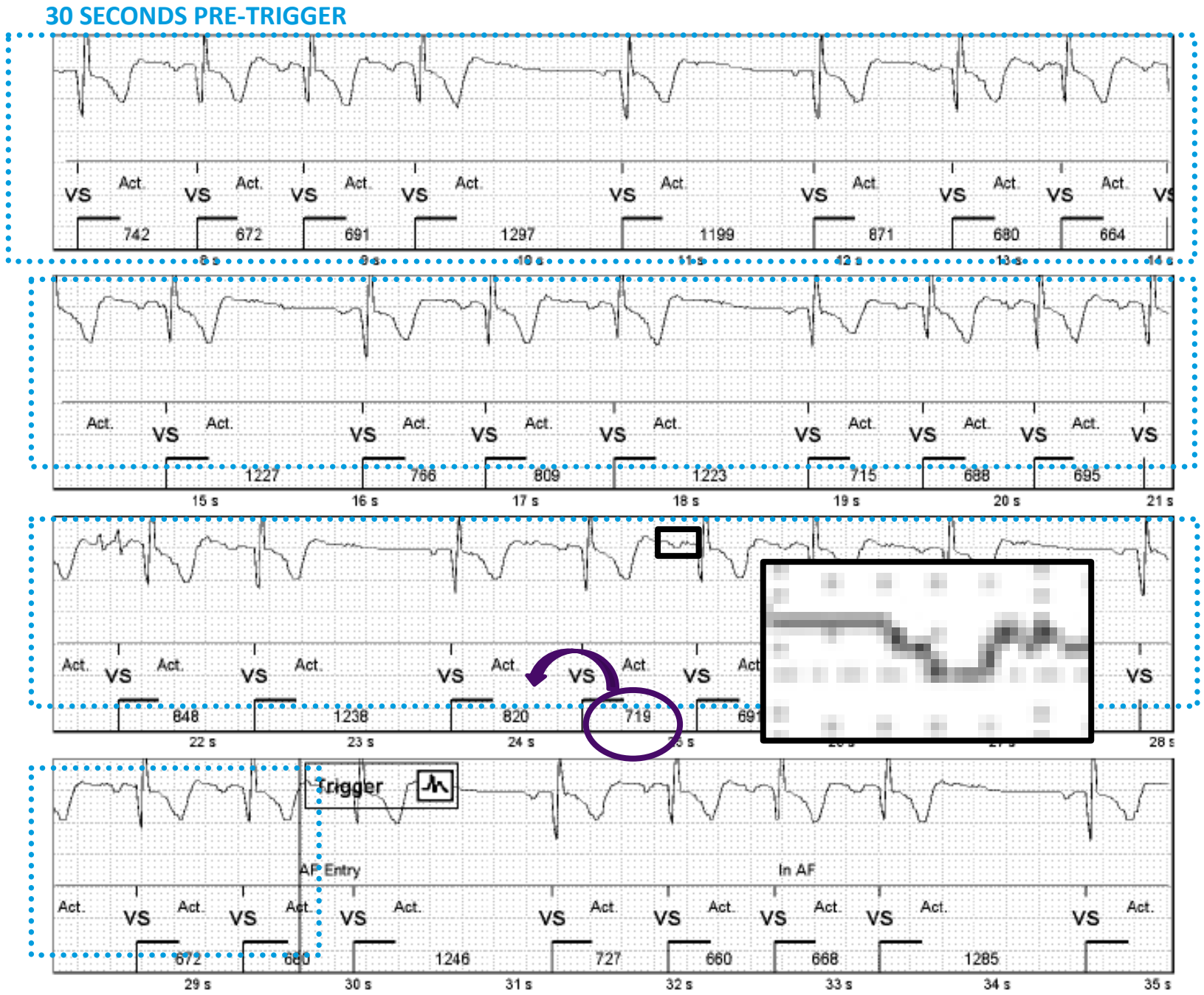
- 40–100 bpm?
- No abrupt shortening?
- If so, looks for P-wave and **COMPARES TO OTHER QUALIFIED SEGMENTS**



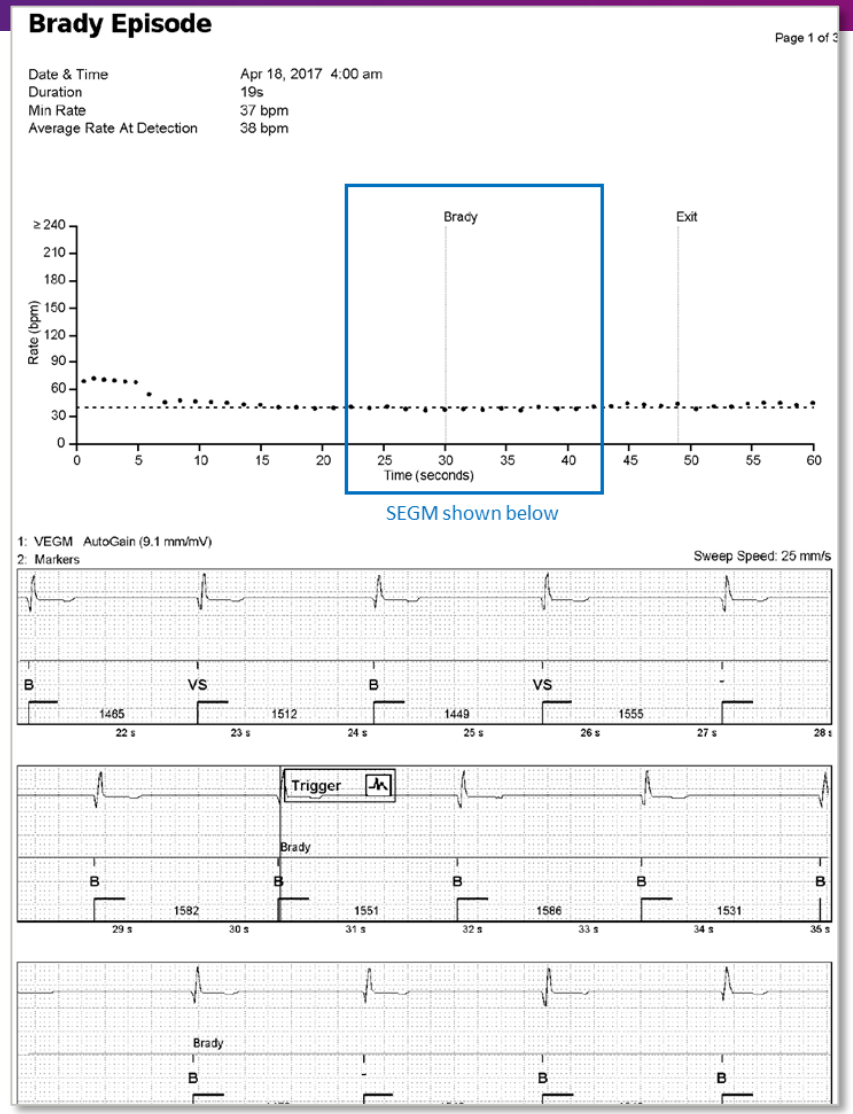
FALSE AF

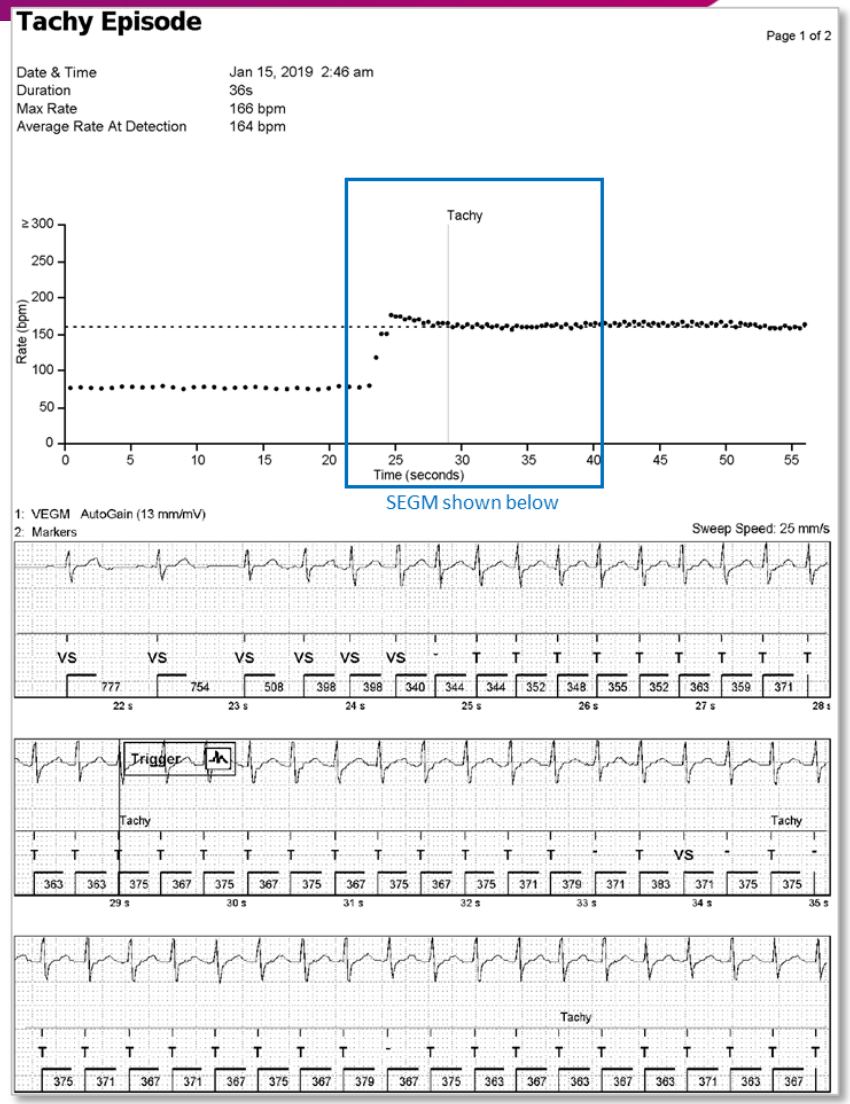
VISIBLE P-WAVES

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



Scatterplot Examples





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

GET IT ON Google Play | Download on the App Store

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.

REMOTE FOLLOW-UP

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

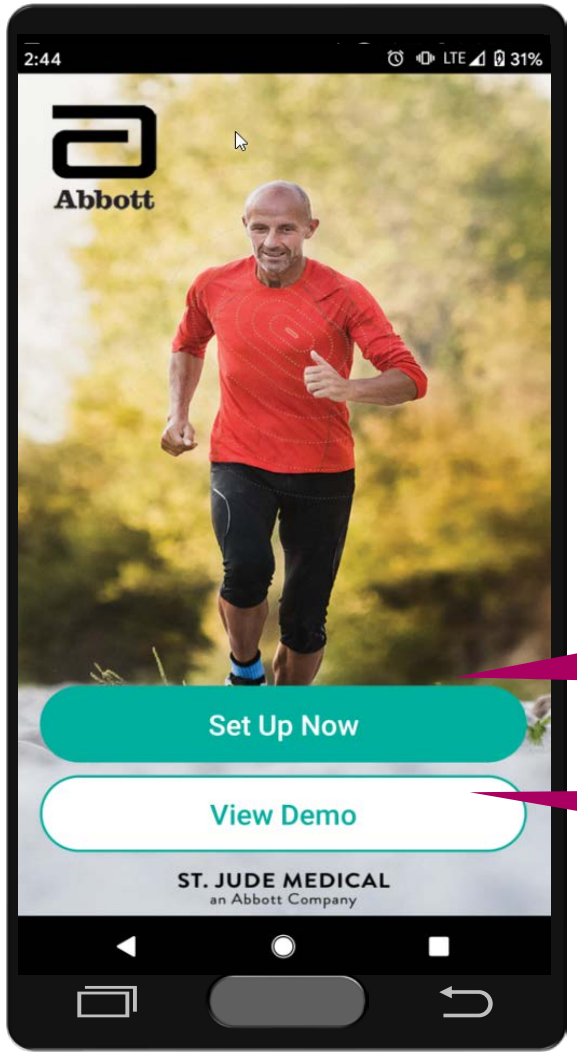
myMERLIN™ MOBILE APP

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

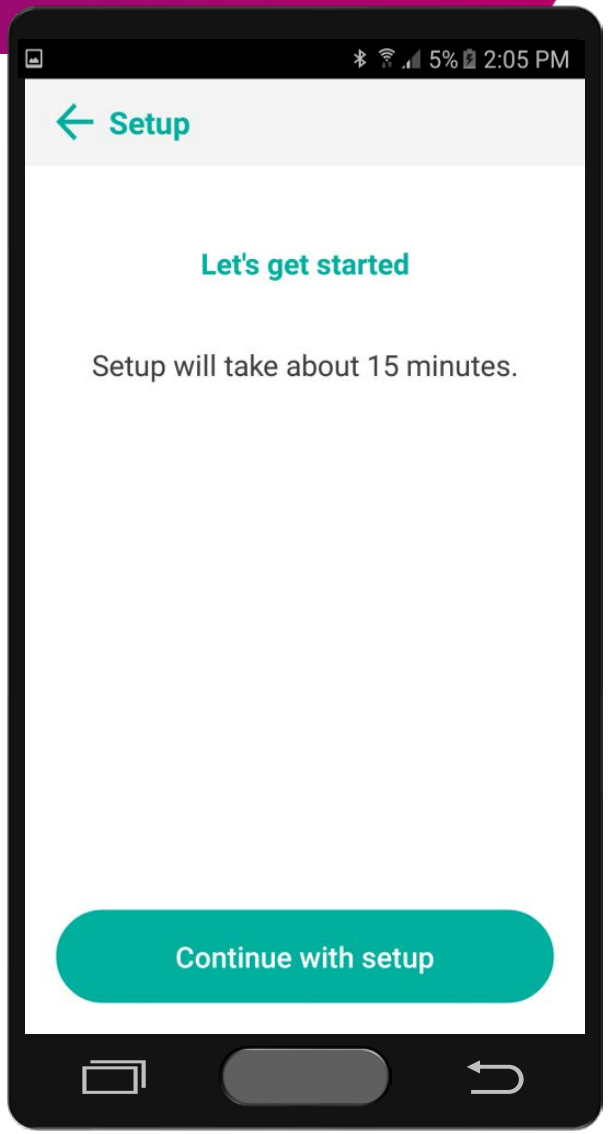
PAIR AFTER THE INSERTION PROCEDURE

- 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.

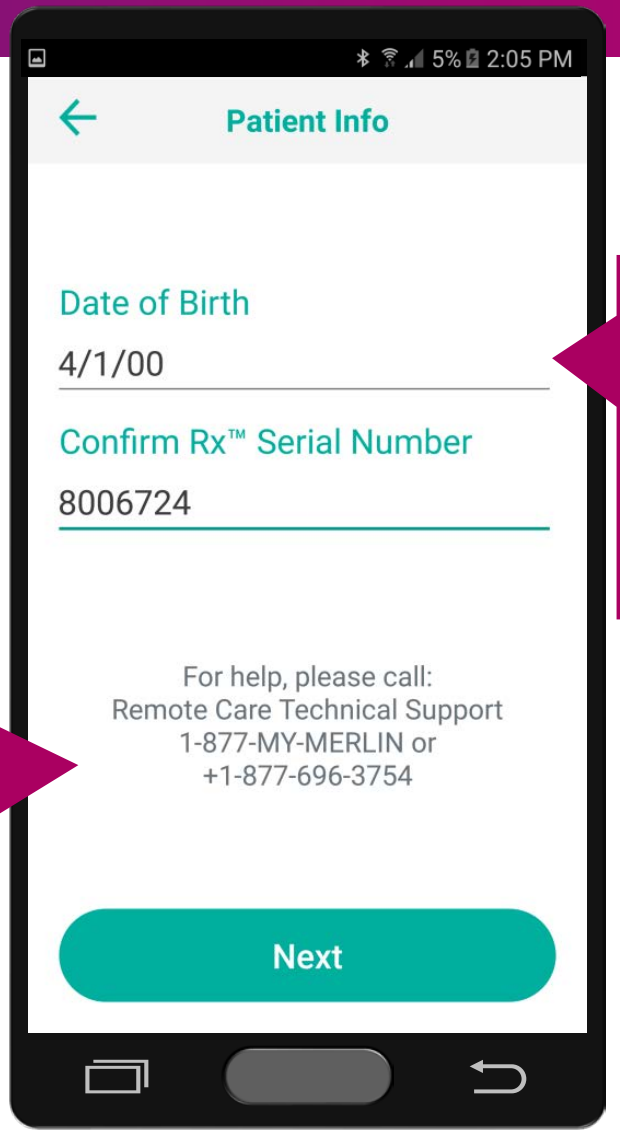
INTERNET CONNECTION IS REQUIRED

- Wi-Fi‡ 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



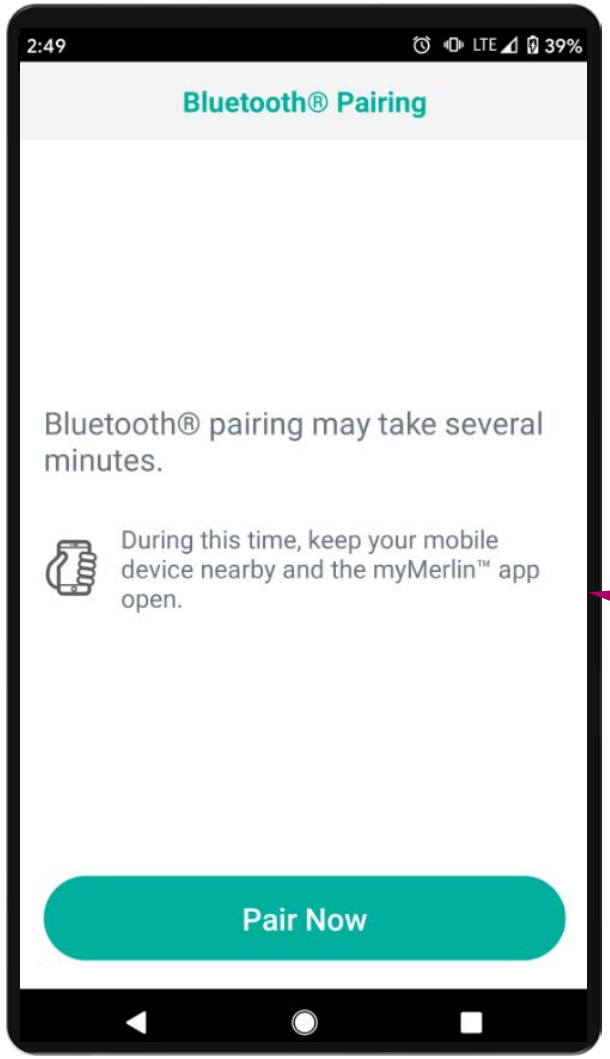
MESSAGE
Depending on the country, this message may be displayed. For help, please call your local Abbott representative.

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



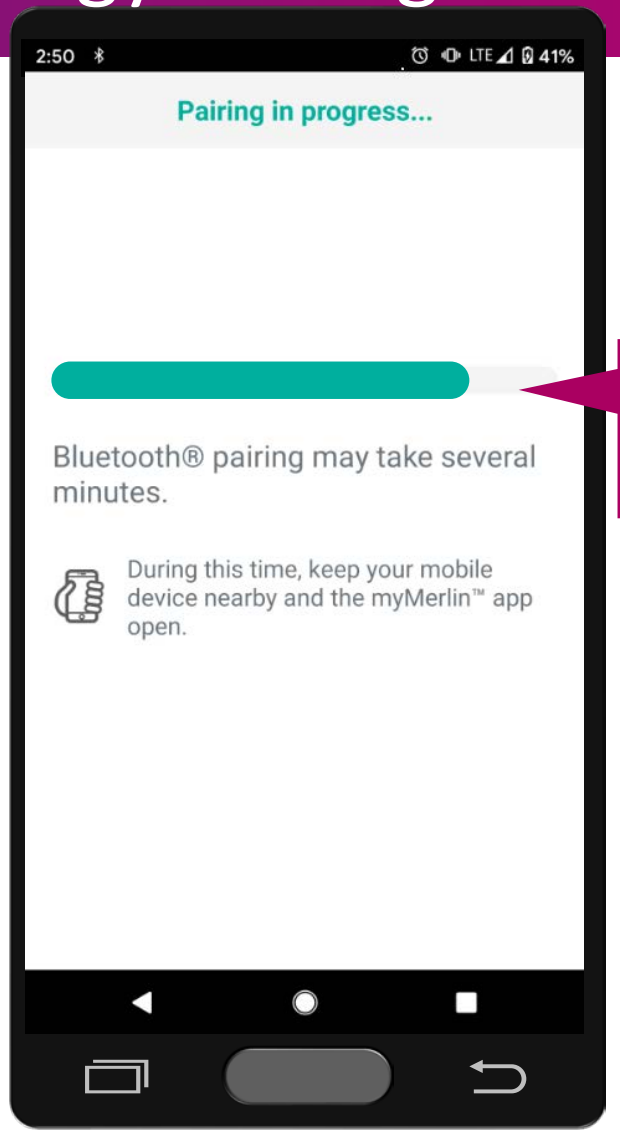
READY TO PAIR?
Keep the patient's mobile device within 1.5 m (5 ft) of the implanted device.

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‡)
- Confirm patient's Merlin.net™ information is correct



PROGRESS BAR
Indicates status.

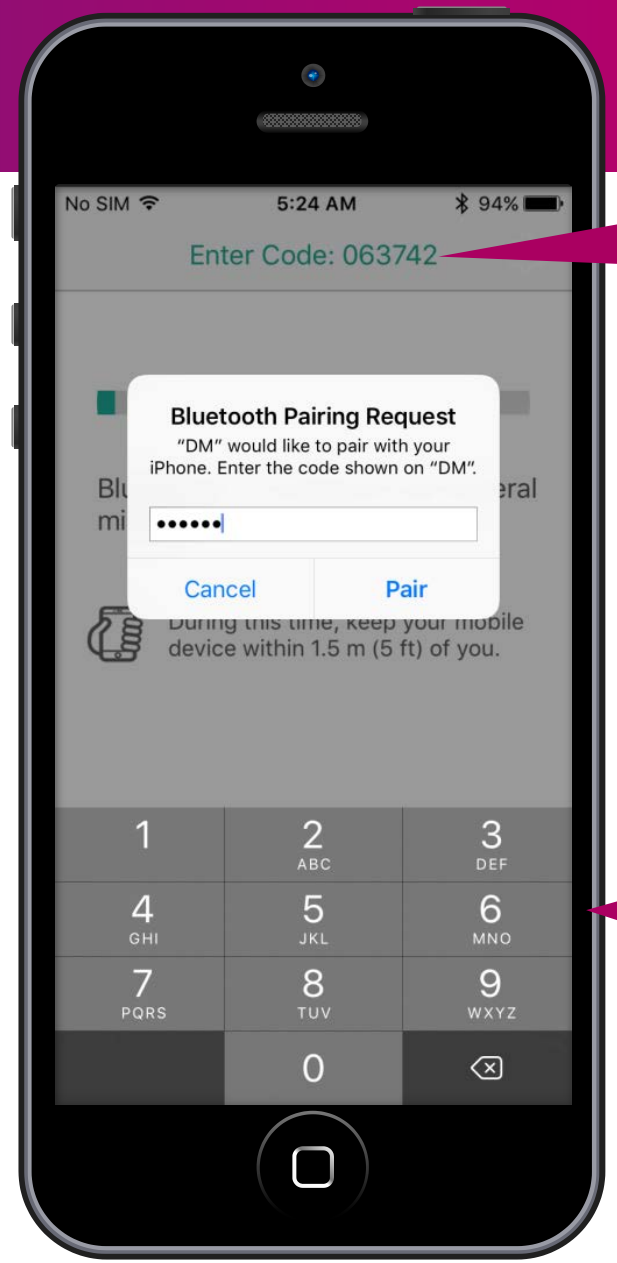
iOS‡ Software Devices

BLUETOOTH® 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**



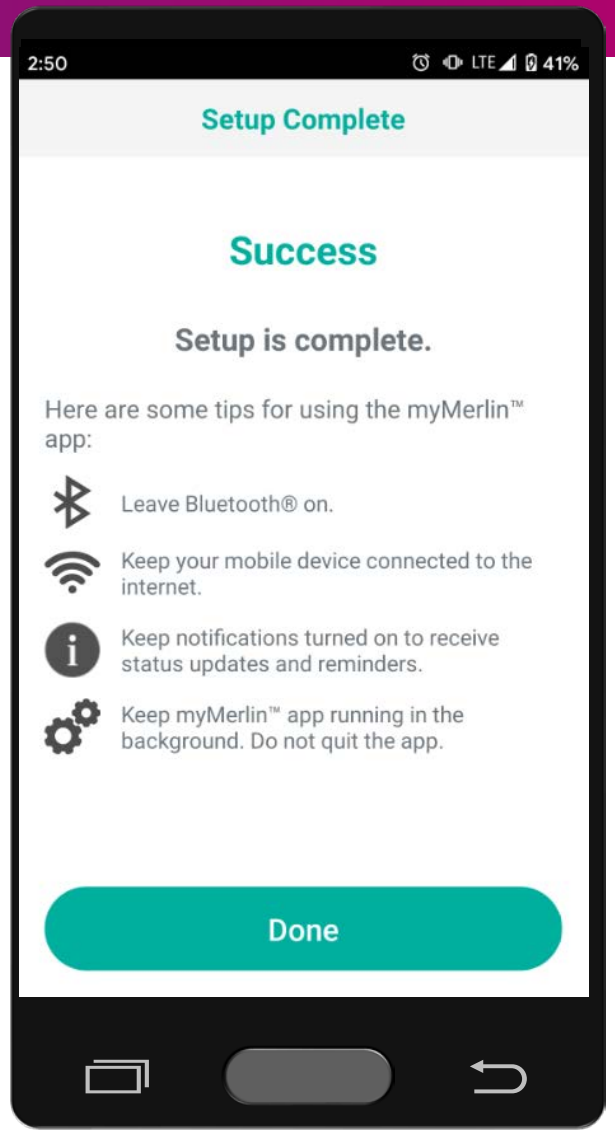
CODE is displayed in the background.

ENTER CODE using keypad

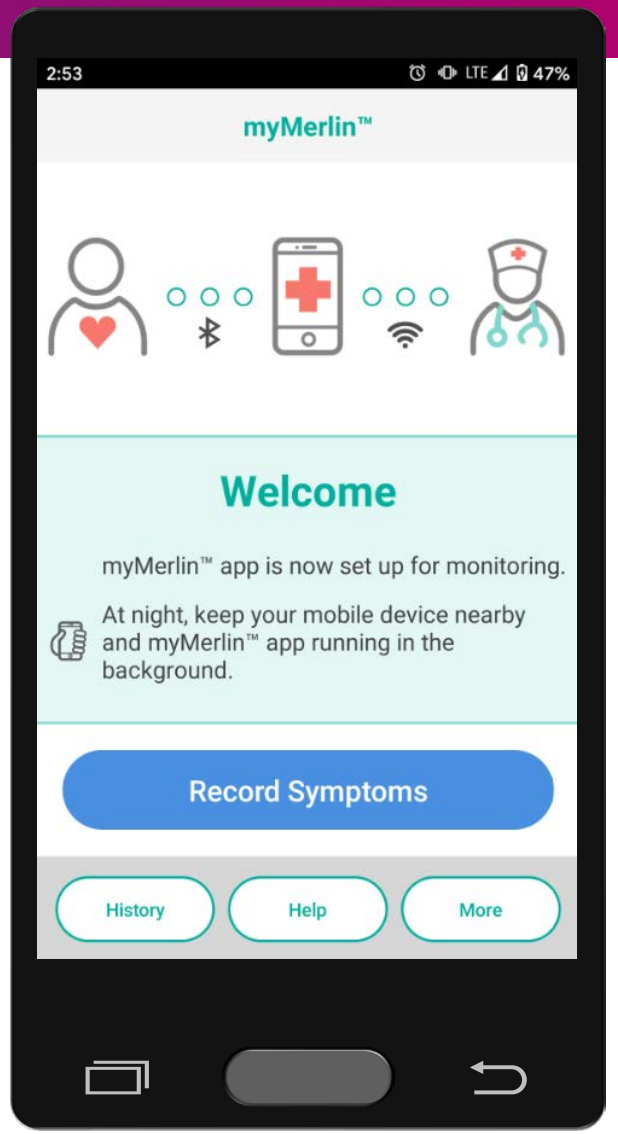
Setup Complete

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


2:53
LTE 47%
myMerlin™
Welcome
myMerlin™ app is now set up for monitoring.
At night, keep your mobile device nearby and myMerlin™ app running in the background.
Record Symptoms
History
Help
More

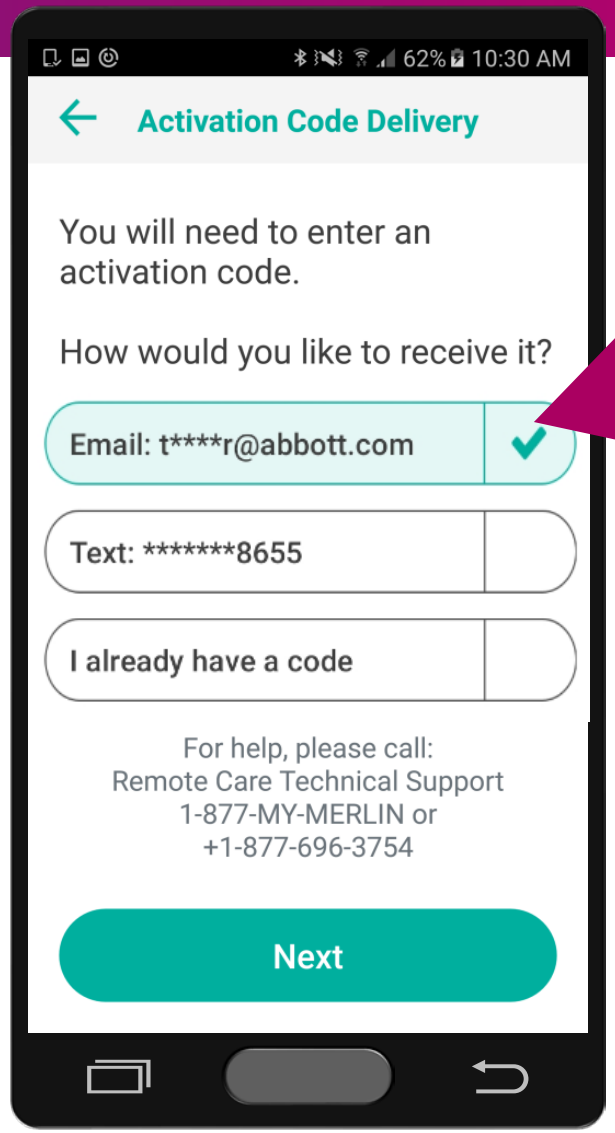
Activation Code

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

Select how you want to receive your activation code.

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

Operating System Updates

- Apple‡ and Google‡ 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

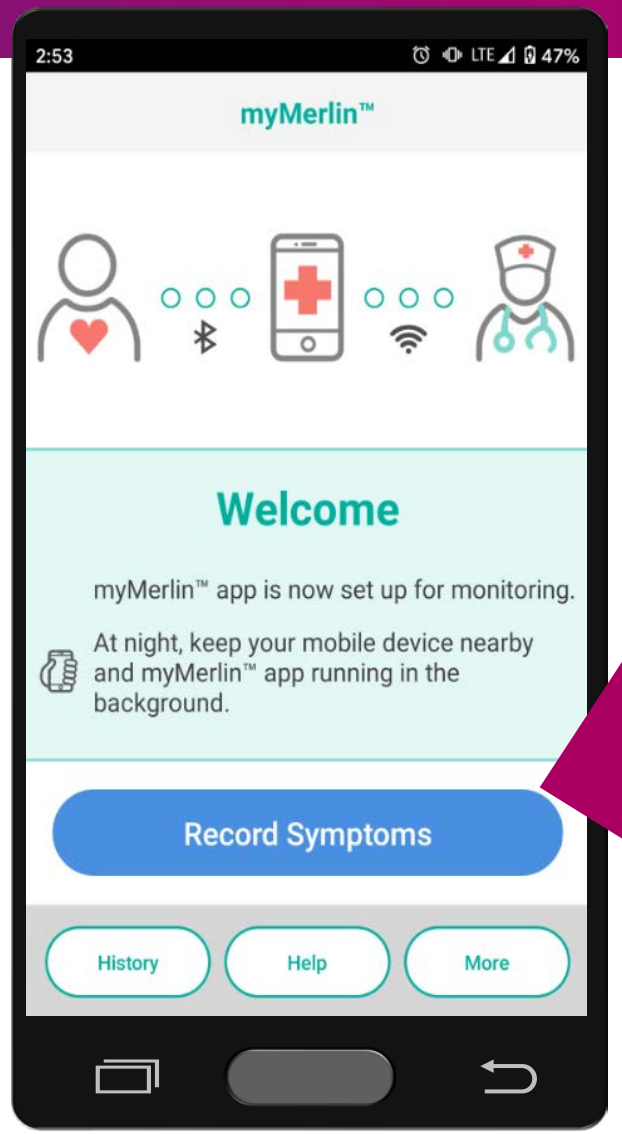
RECORDING A SYMPTOM EPISODE

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.



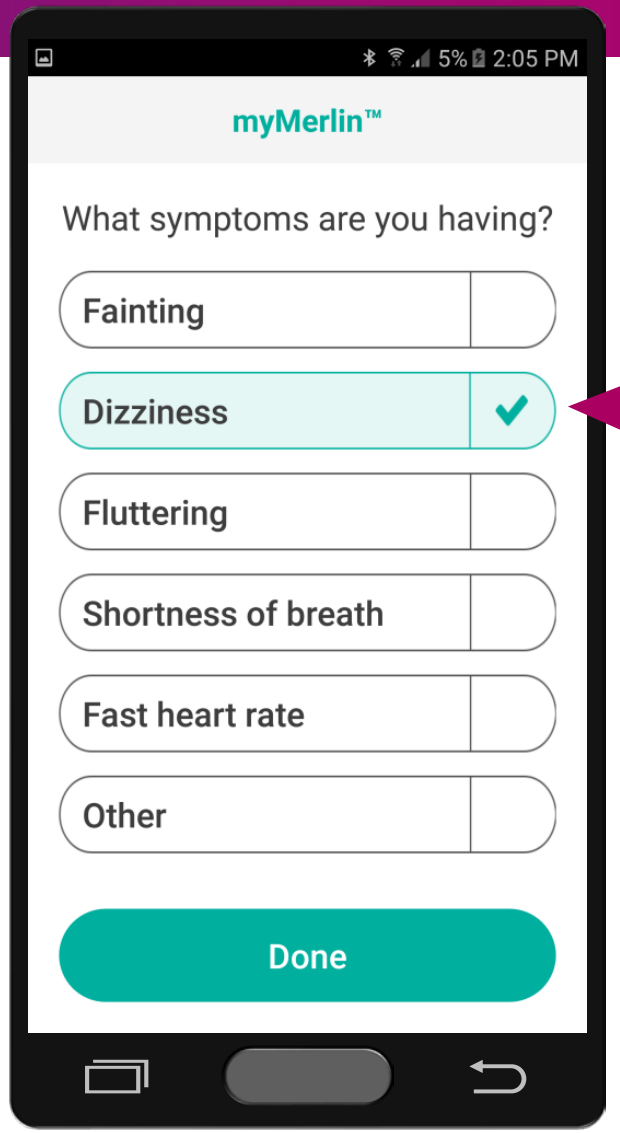
Based on the patient's indication, a clinician may request that a patient perform a symptom recording in their cardiac monitor when they are feeling symptomatic.

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

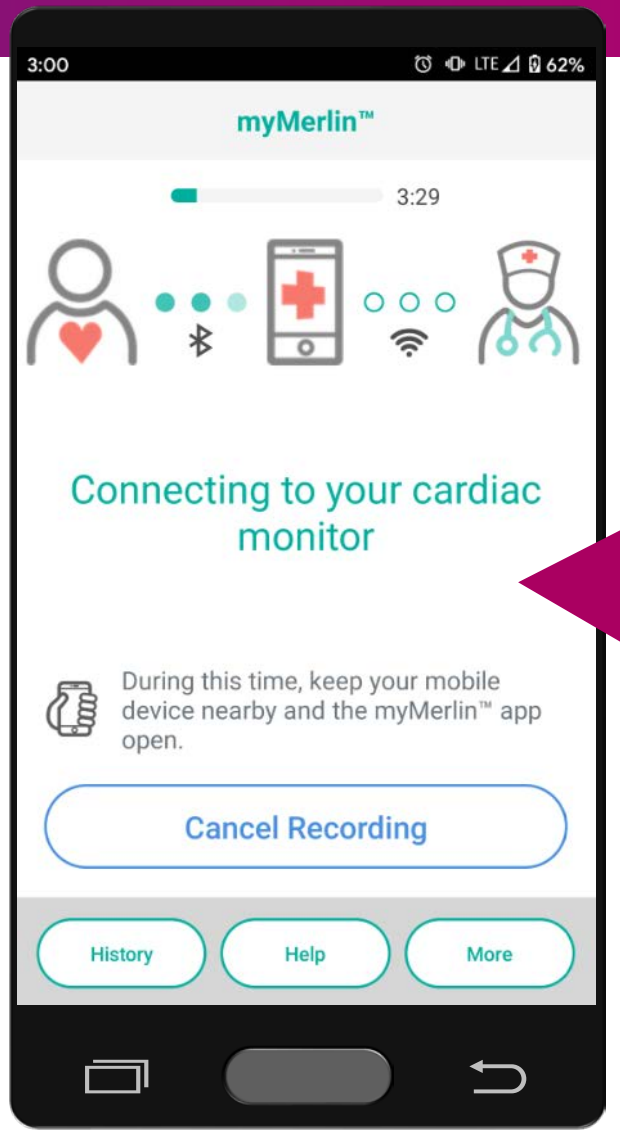
- Select none, one or multiple
- Mobile device initiates connection with the patient's ICM in the background while this screen is displayed



Which symptom is the patient experiencing?

Connecting

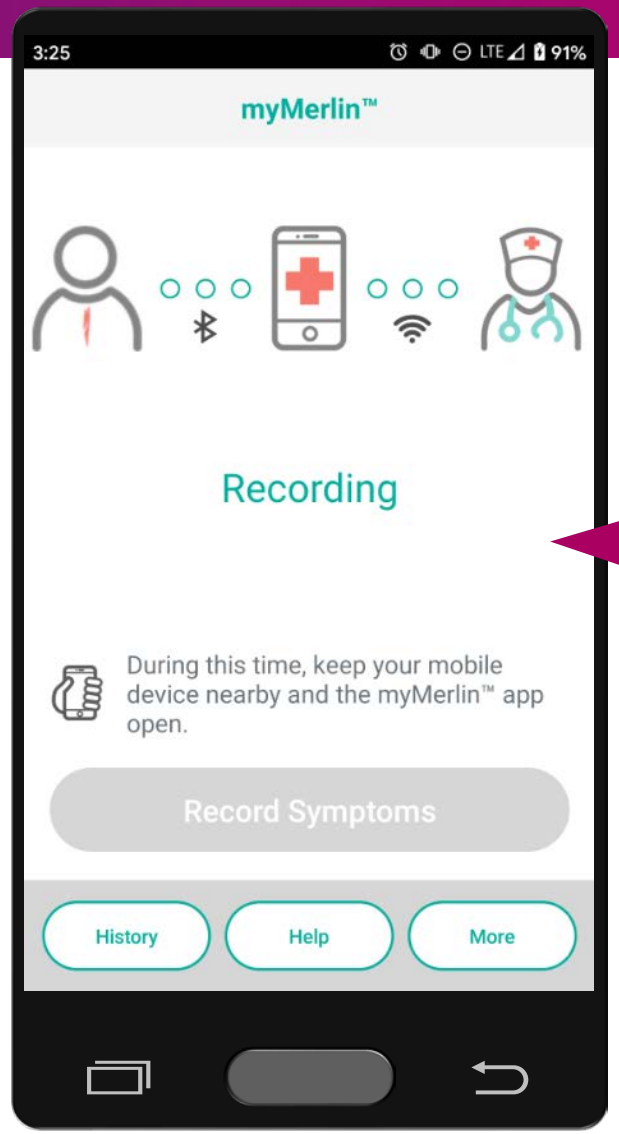
- Bluetooth® wireless technology connection initiated with cardiac monitor
- Upon connection, episode recording is initiated in the ICM



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

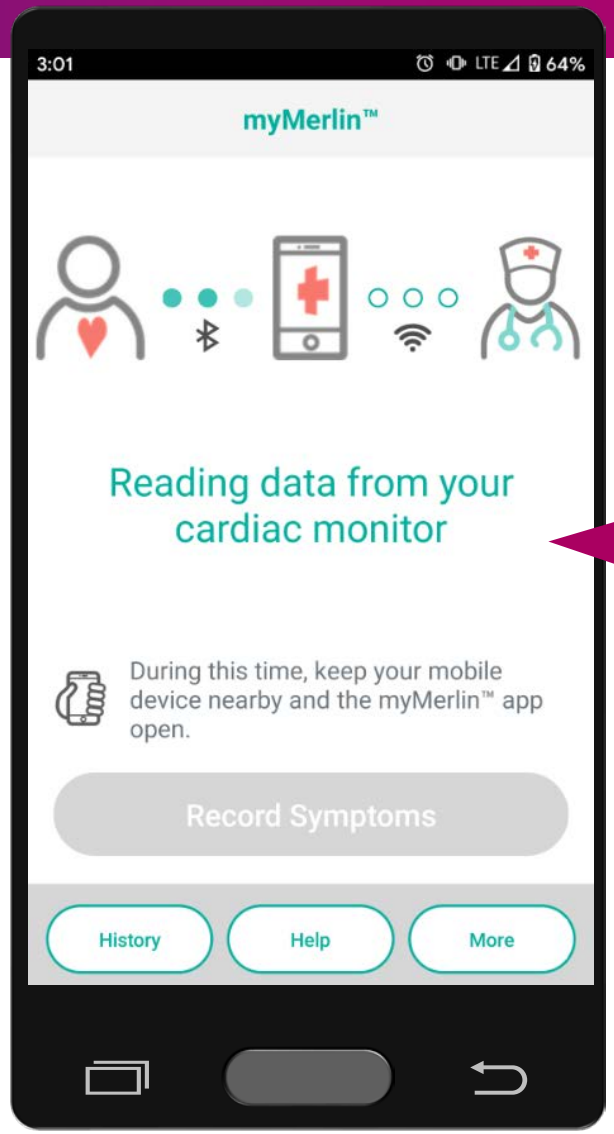
SYMPTOM EPISODE
is recorded within the Confirm Rx™ ICM



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

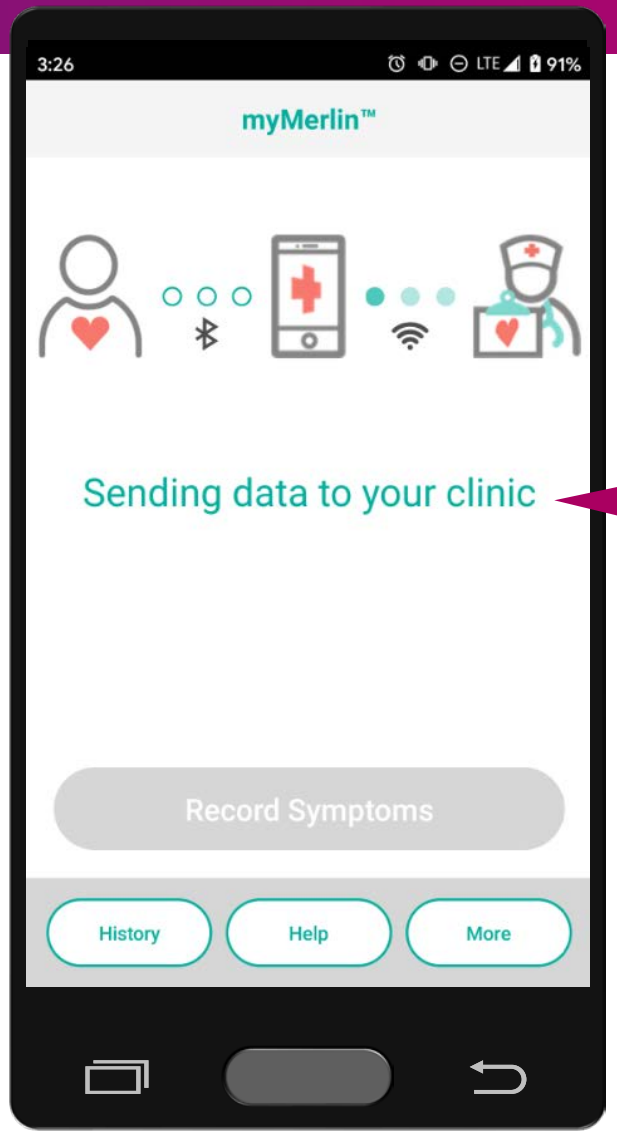


The mobile app is now downloading information from the cardiac monitor.

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



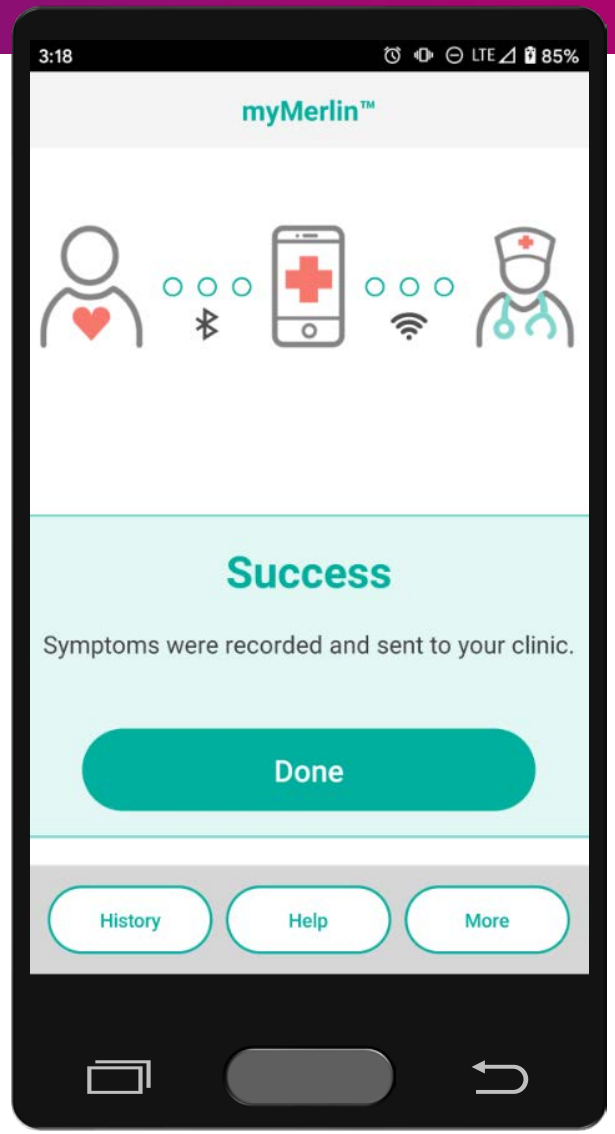
The app will now send data to the patient's device clinic.

Average Monthly Data Usage

< 10 MB PER MONTH WITH NORMAL USAGE

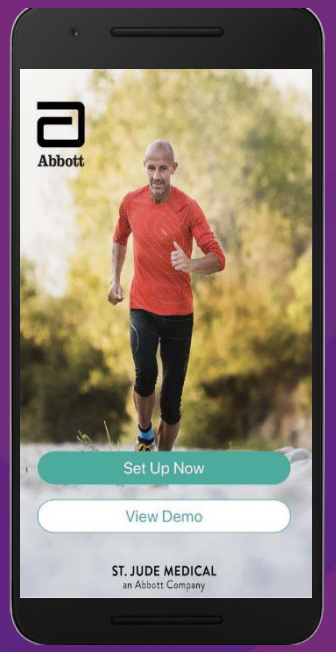
Success

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



ENHANCEMENTS TO myMERLIN™ MOBILE APP

Confirm Rx™ ICM



MAT-2003104 v1.0 | Item approved for global use.

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‡ and iOS‡ 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

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.

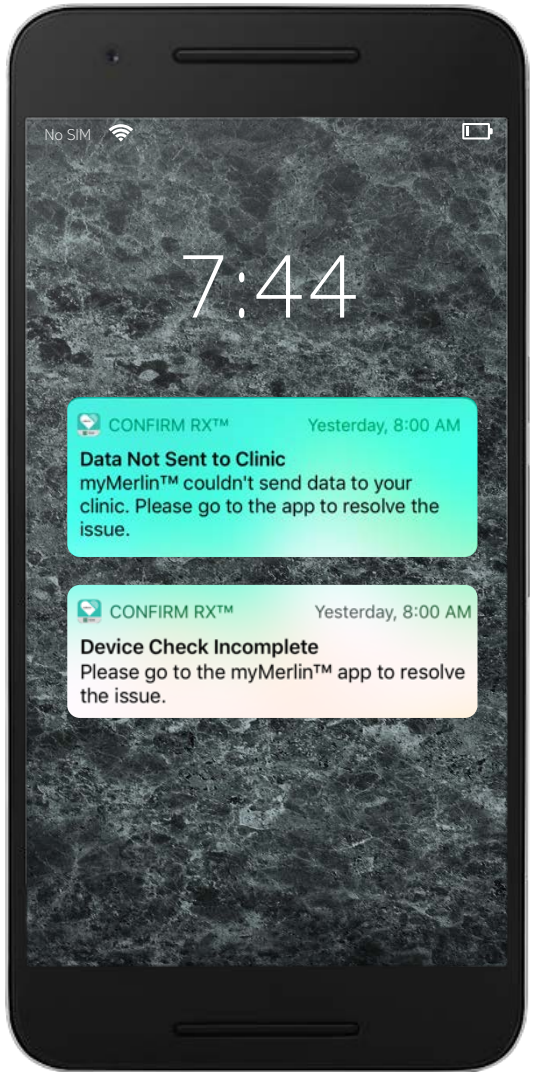
Patient Notifications and Prompts

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!

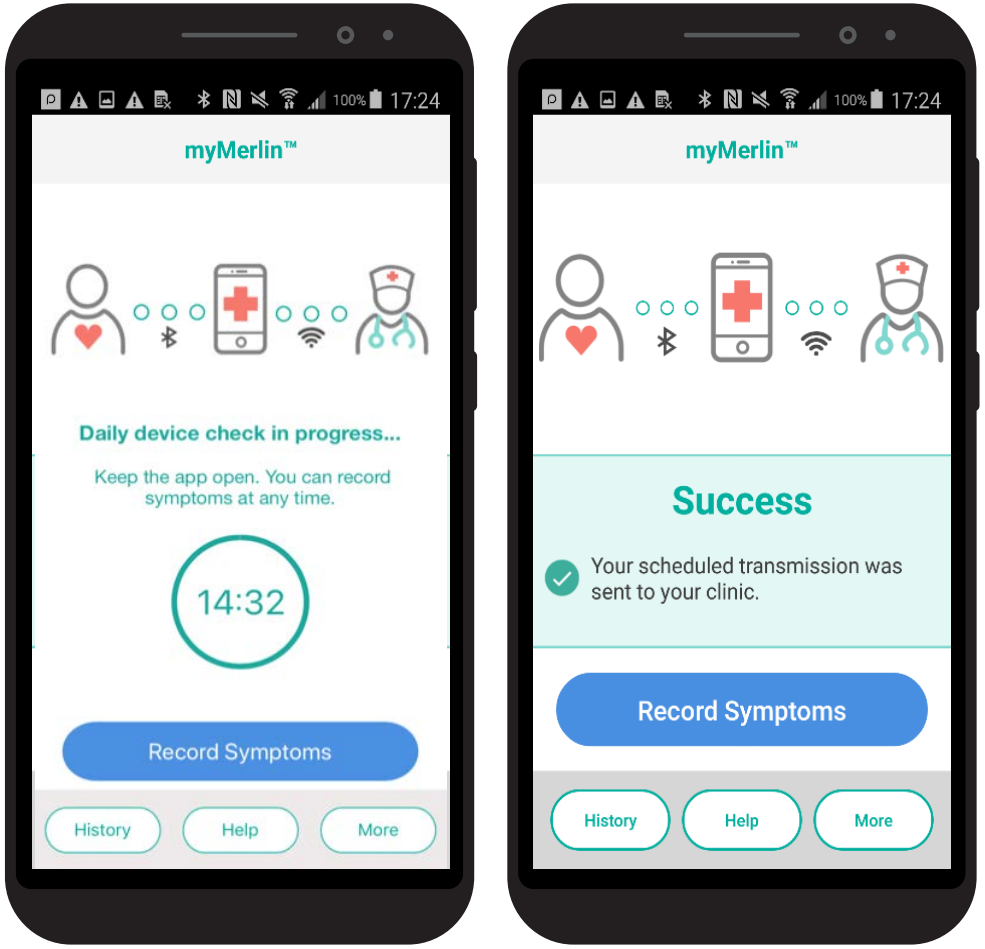
If multiple issues occur, the notifications will appear concurrently on the same screen.



Patient Notifications and Prompts

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.



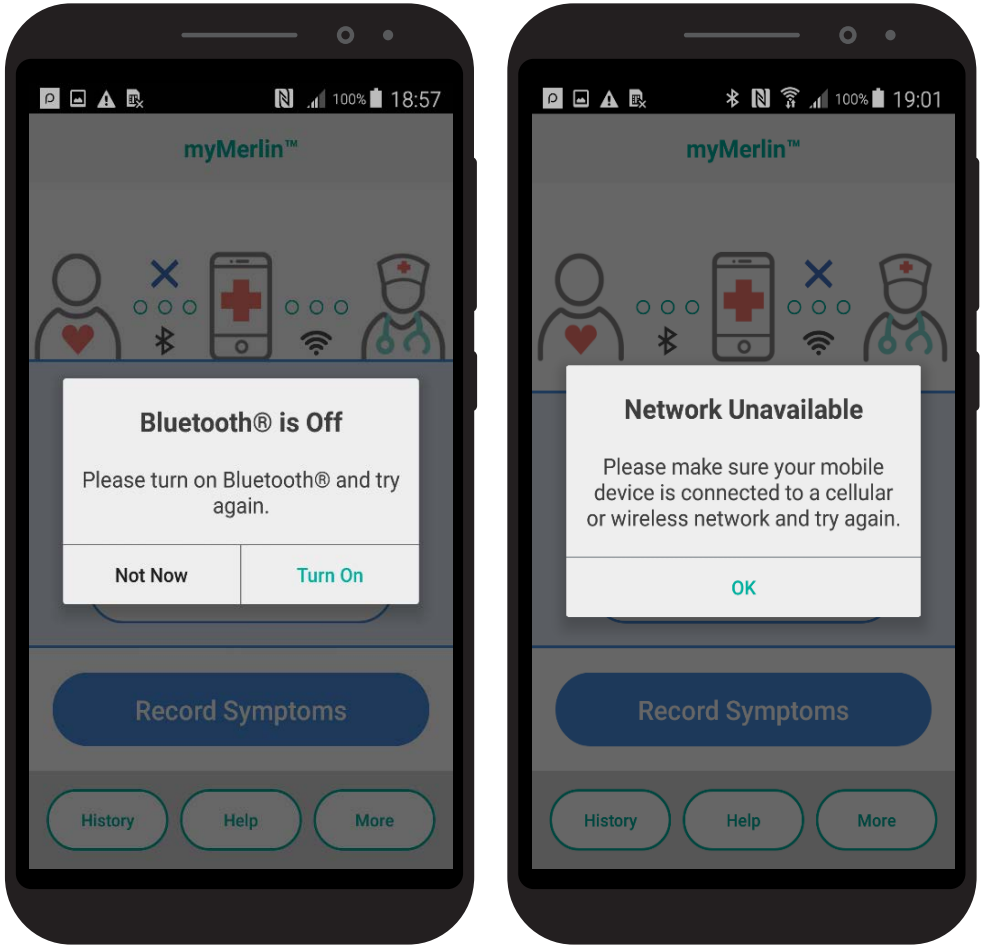
Patient Notifications and Prompts

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‡ (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

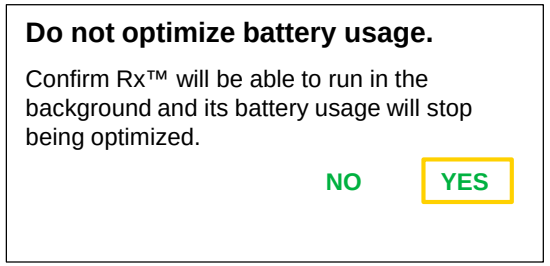


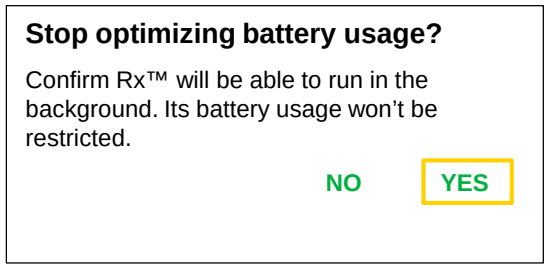
Patient Notifications and Prompts

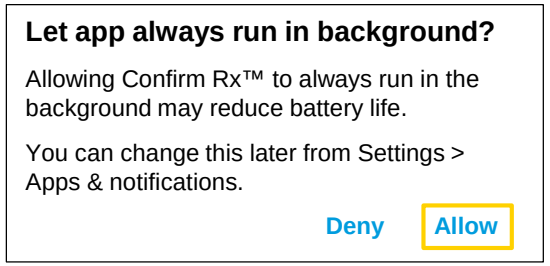
With the app enhancements, there are new notifications to assist with maintaining appropriate battery optimization settings.

Ensure battery optimization is disabled for Android‡ 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!







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

Improved compatibility with new Android‡ and iOS‡ operating systems.

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

Operating System Compatibility

Merlin.net™ PCN now sends hourly “silent push notifications” to each iOS‡ 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‡ app.)

Workflow Improvements

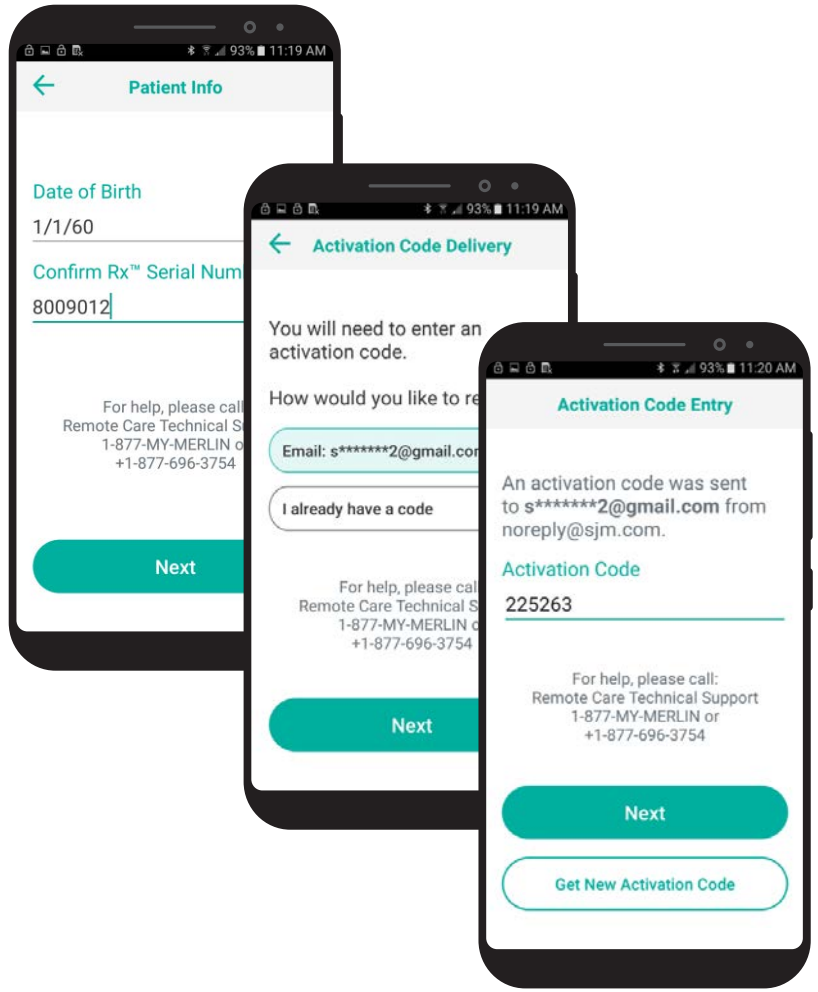
The workflow has been optimized for a better patient experience.

- 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

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

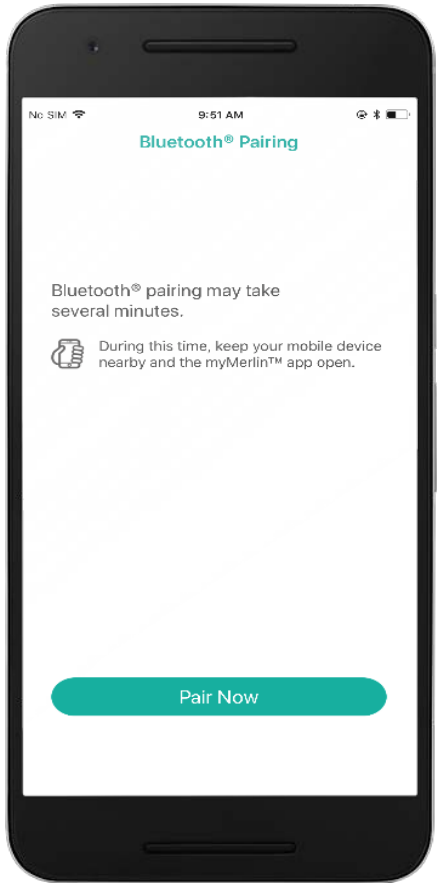
1. VALIDATION
   - The user enters date of birth and serial number in the myMerlin™ mobile app.
   - The app receives validation and secure credentials back from Merlin.net™ PCN.
2. BONDING
   - The app uses secure credentials to create a Bluetooth® bond with the Confirm Rx™ ICM.
3. PROFILE SYNC
   - 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.

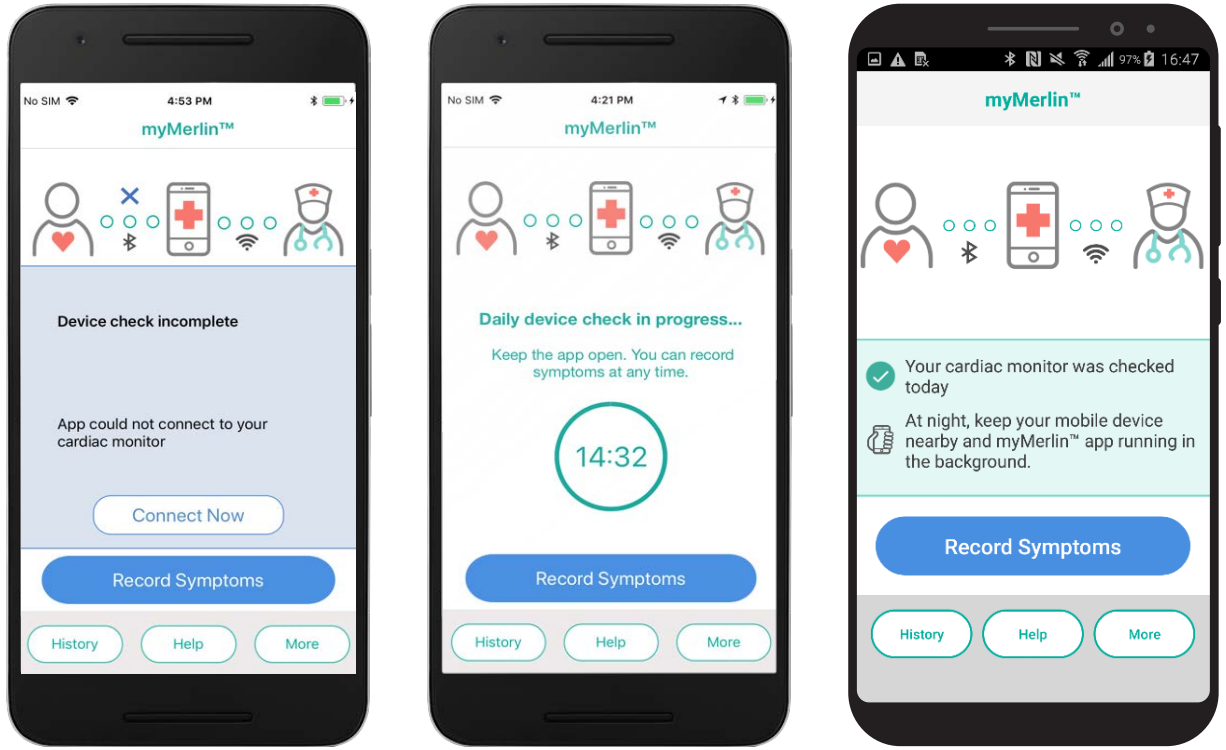


If you are unable to complete pairing at the clinic, instruct the patient to select the "Pair Now" button, when they are in an area of good internet connectivity. They will have 6 hours to complete the process.

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.



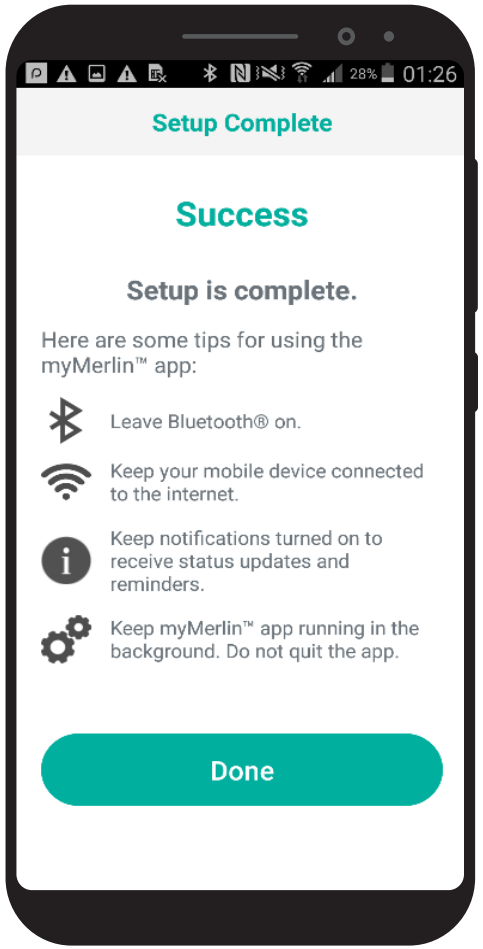
Tips and Tricks for Successful Use of the myMerlin™ App

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

ENTER PATIENT AND DEVICE DATA

TRANSMITTER

FOLLOW-UP SCHEDULE

DIRECTALERTS NOTIFICATION FEATURE

BASELINE CLINICAL DATA

ENROLLMENT COMPLETE

Merlin.net™ Patient Care Network (PCN)

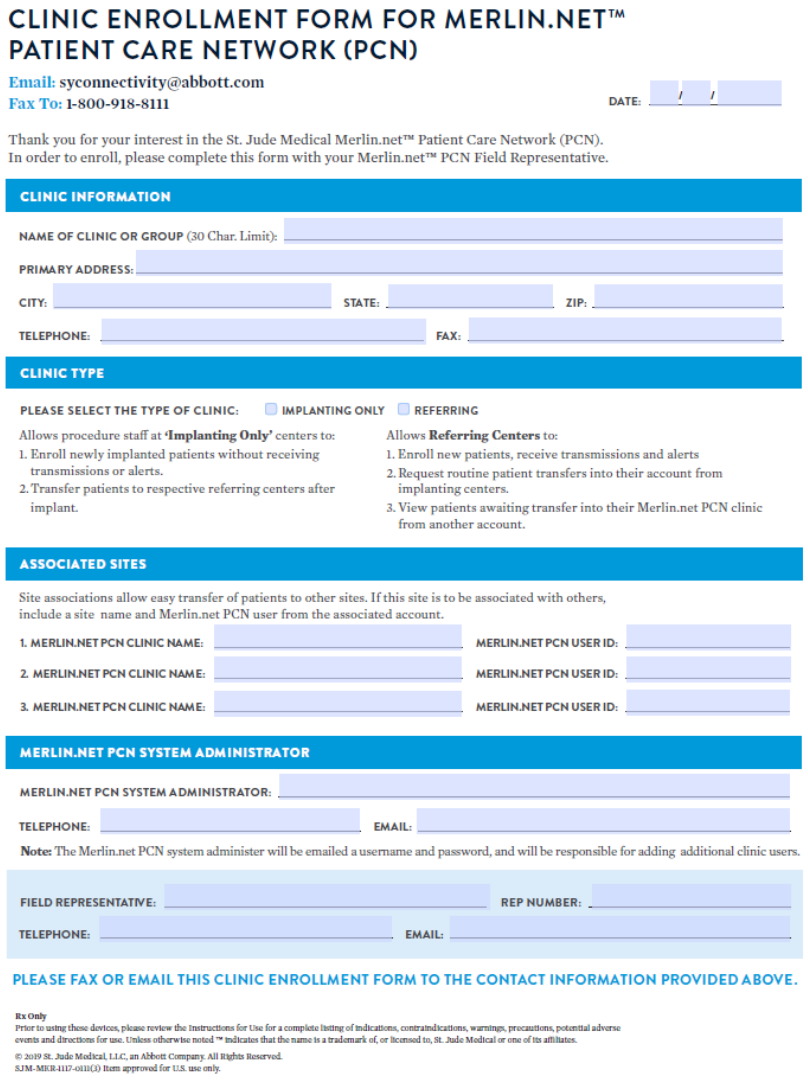
What is an Implant-Only Account?

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**



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

Email: 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 administer 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.

SJM-MER-1117-0111(3) Item approved for U.S. use only.

Merlin.net™ Patient Care Network (PCN)
Overview

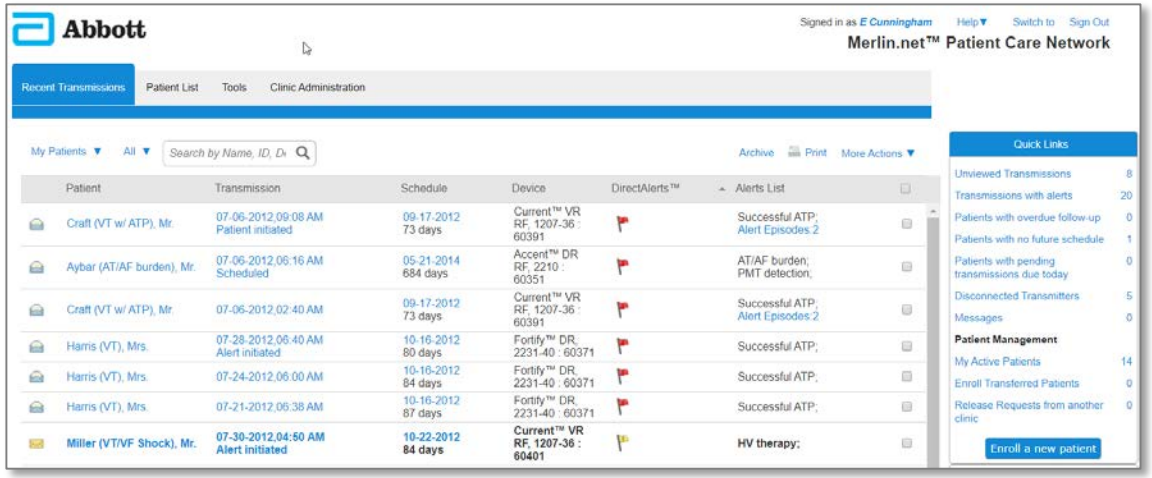
Managing Cardiac Monitor Patients With Merlin.net PCN

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

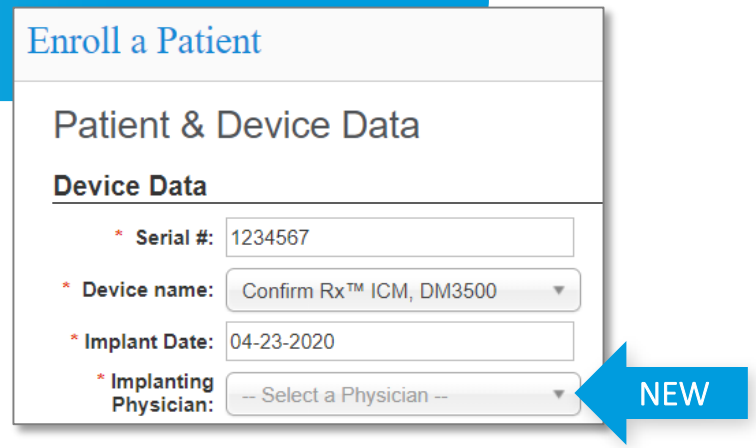
- Connectivity Column
- Disconnected Transmitter Thresholds
- Transferring Patient Profiles

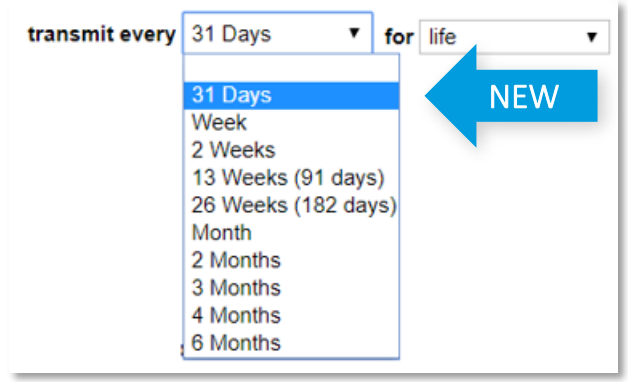


Merlin.net™ PCN
Patient Enrollment

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?

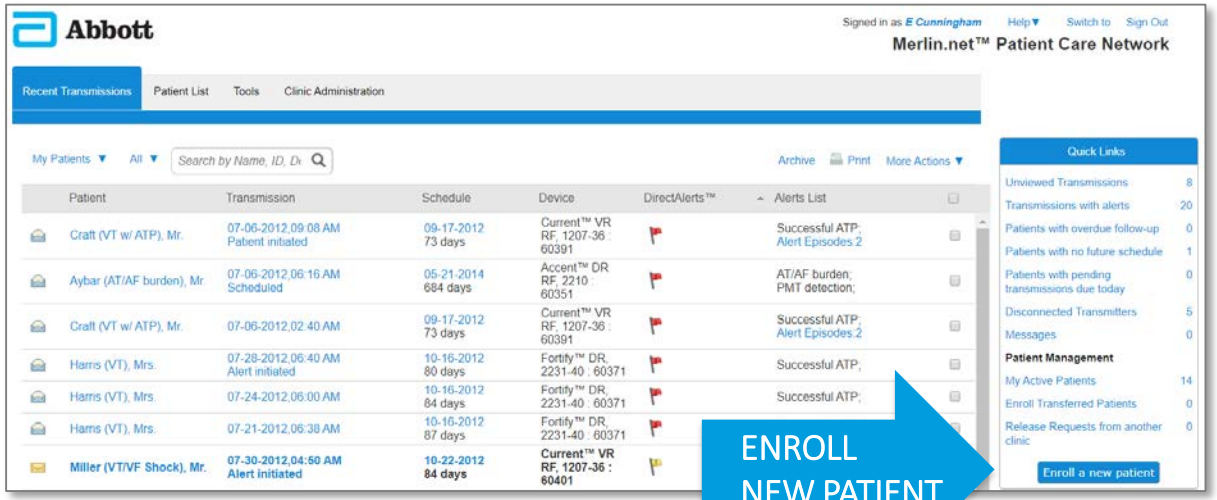
No, but ICM patients need to be **MANUALLY ENROLLED**

WHAT IS THE MANUAL ENROLLMENT PROCESS?

1. ENTER PATIENT AND DEVICE DATA
2. TRANSMITTER
3. FOLLOW-UP SCHEDULE
4. DIRECTALERTS™ NOTIFICATION FEATURE
5. BASELINE CLINICAL DATA
6. ENROLLMENT COMPLETE

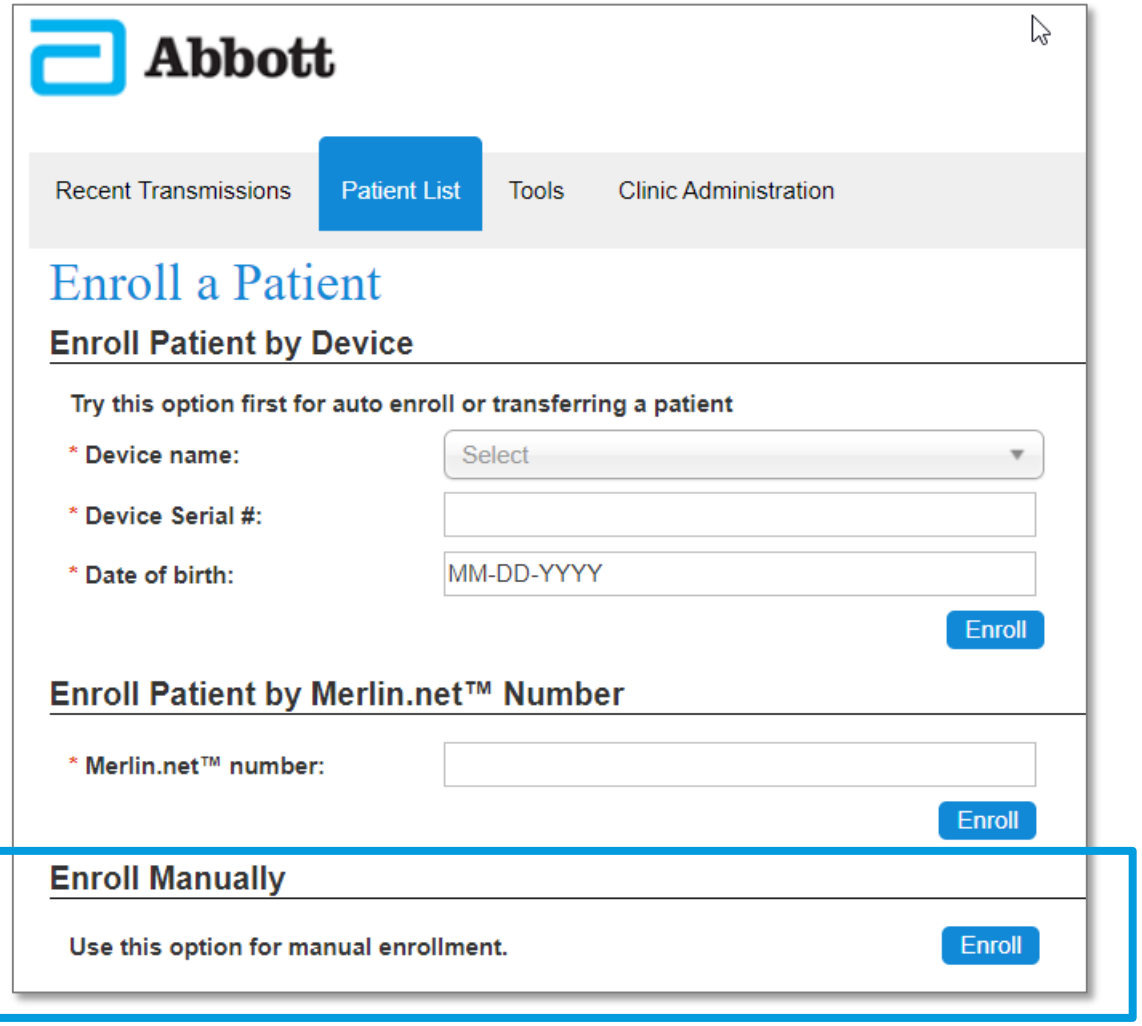
Patient Enrollment

Accessible from Quick Links Menu

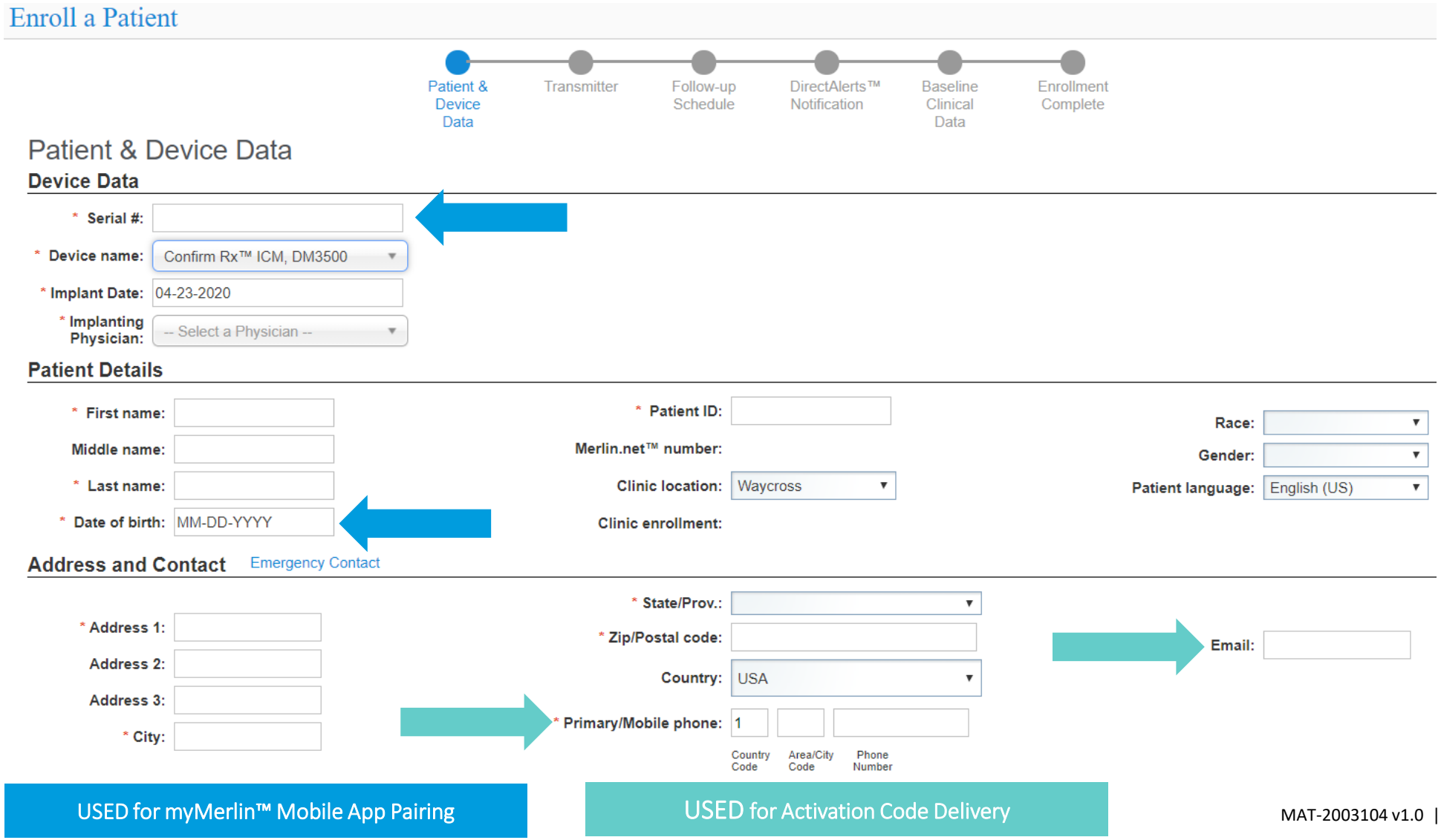


ENROLL NEW PATIENT

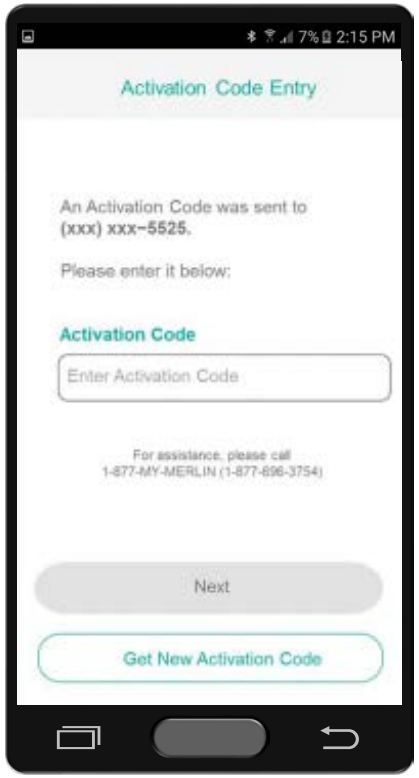
ENROLL MANUALLY



Merlin.net™ PCN
Patient Enrollment



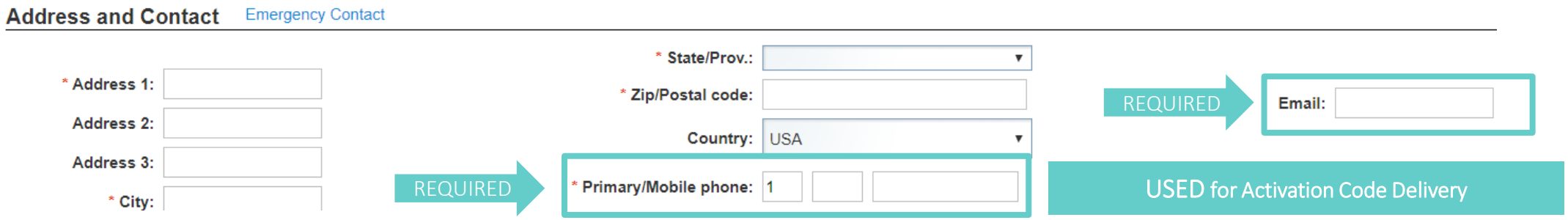
Merlin.net™ PCN
Activation Codes



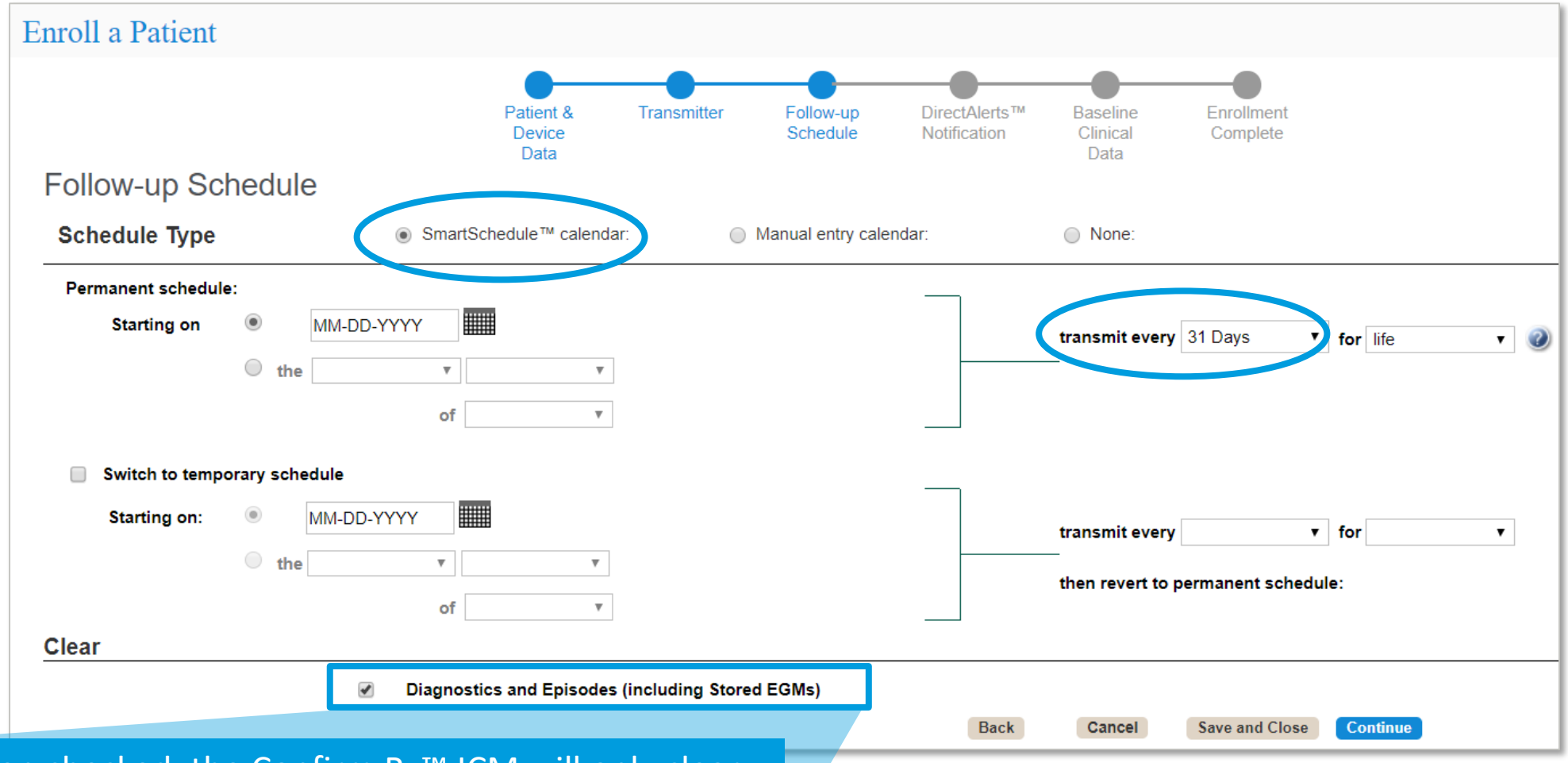
REQUIRED TO PAIR WITH PHONE ANYTIME AFTER THE FIRST (INITIAL) PAIRING

- 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).



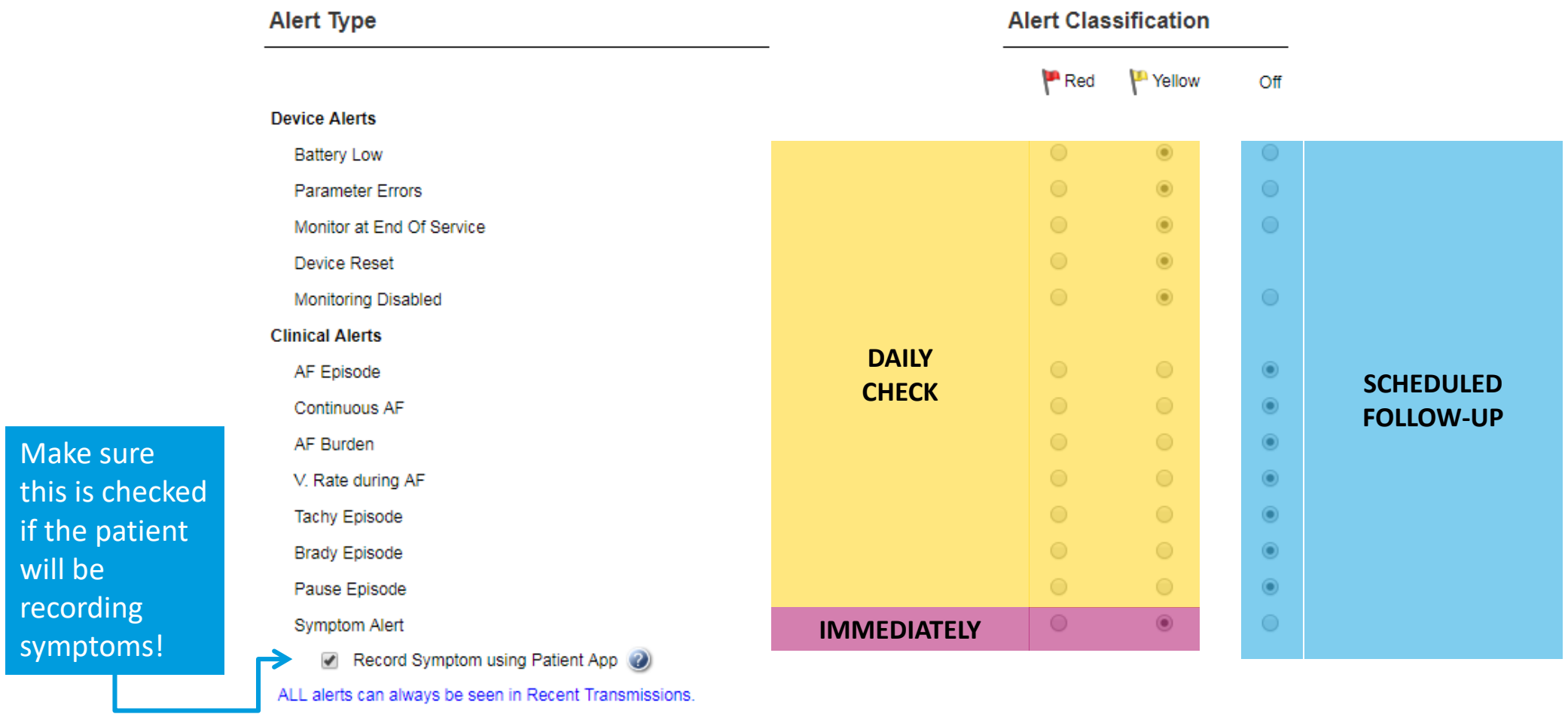
Merlin.net™ PCN
SmartSchedule™ Calendar



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

Merlin.net™ PCN
DirectAlerts™ Notification Feature

CHOOSE WHEN TO RECEIVE INFORMATION

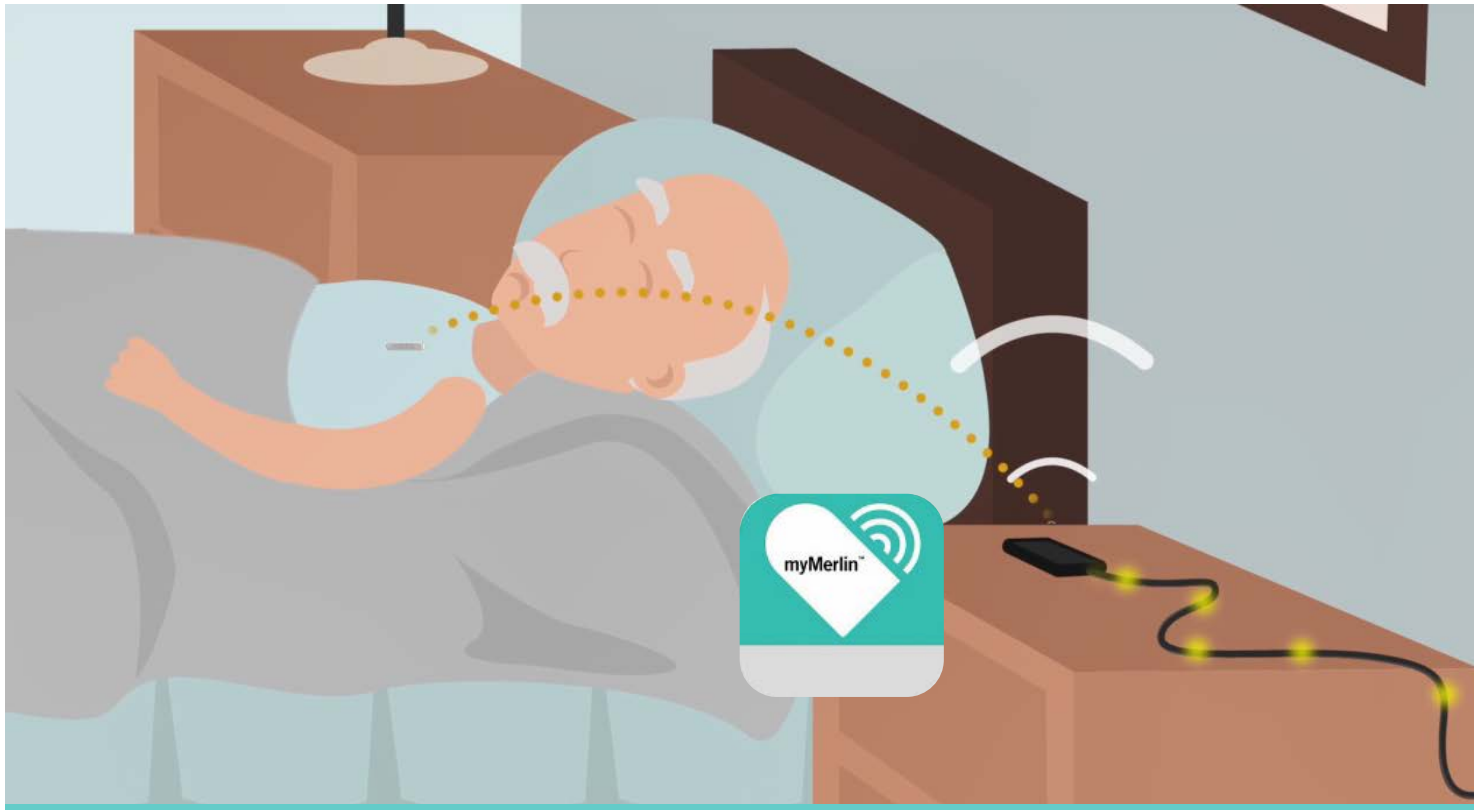


Patient-Initiated Transmissions (Symptom Episodes)

TYPICALLY SENT INSTANTLY*

*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).

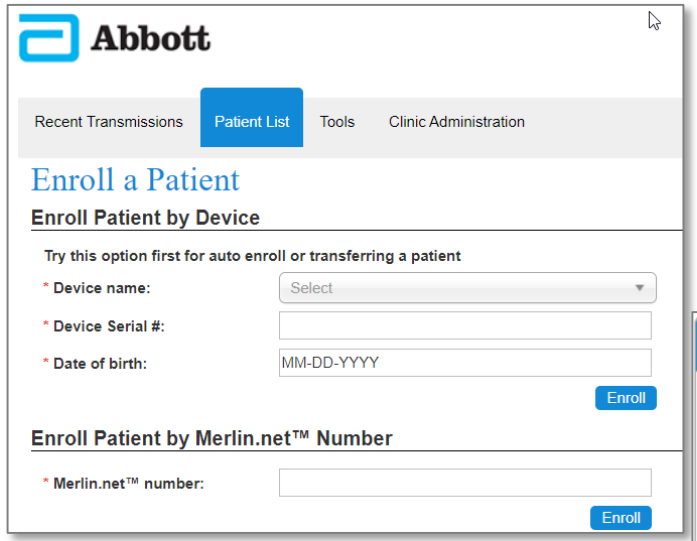
MERLIN.NET™ PCN

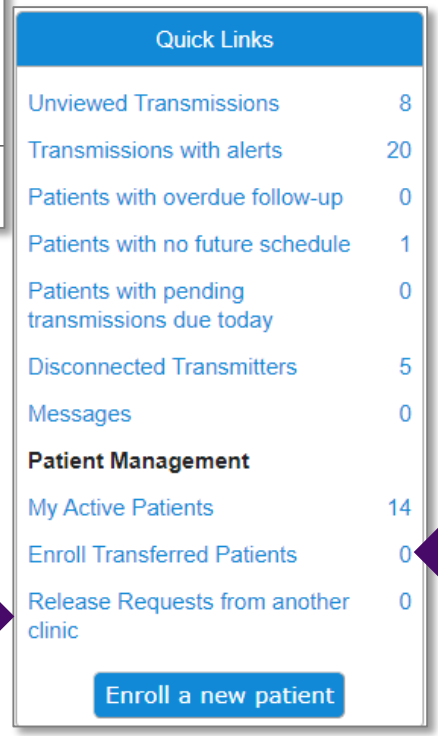
ADDITIONAL FEATURES

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)



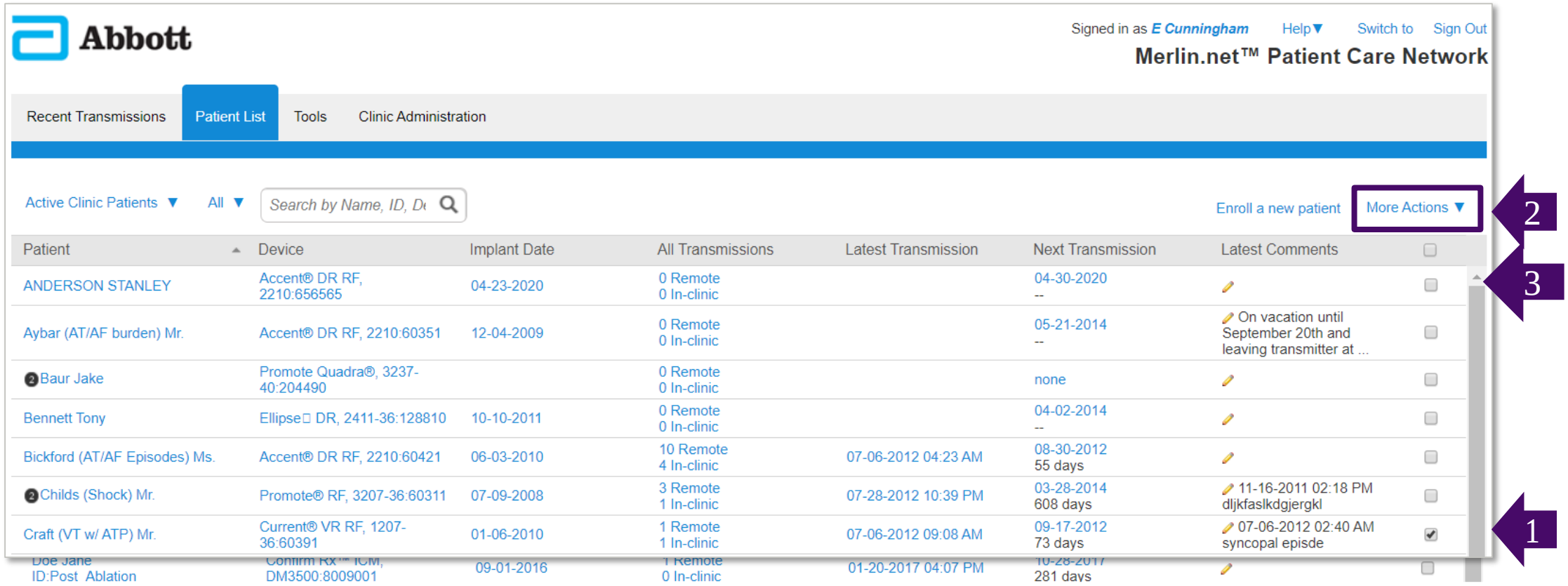


PENDING REQUESTS

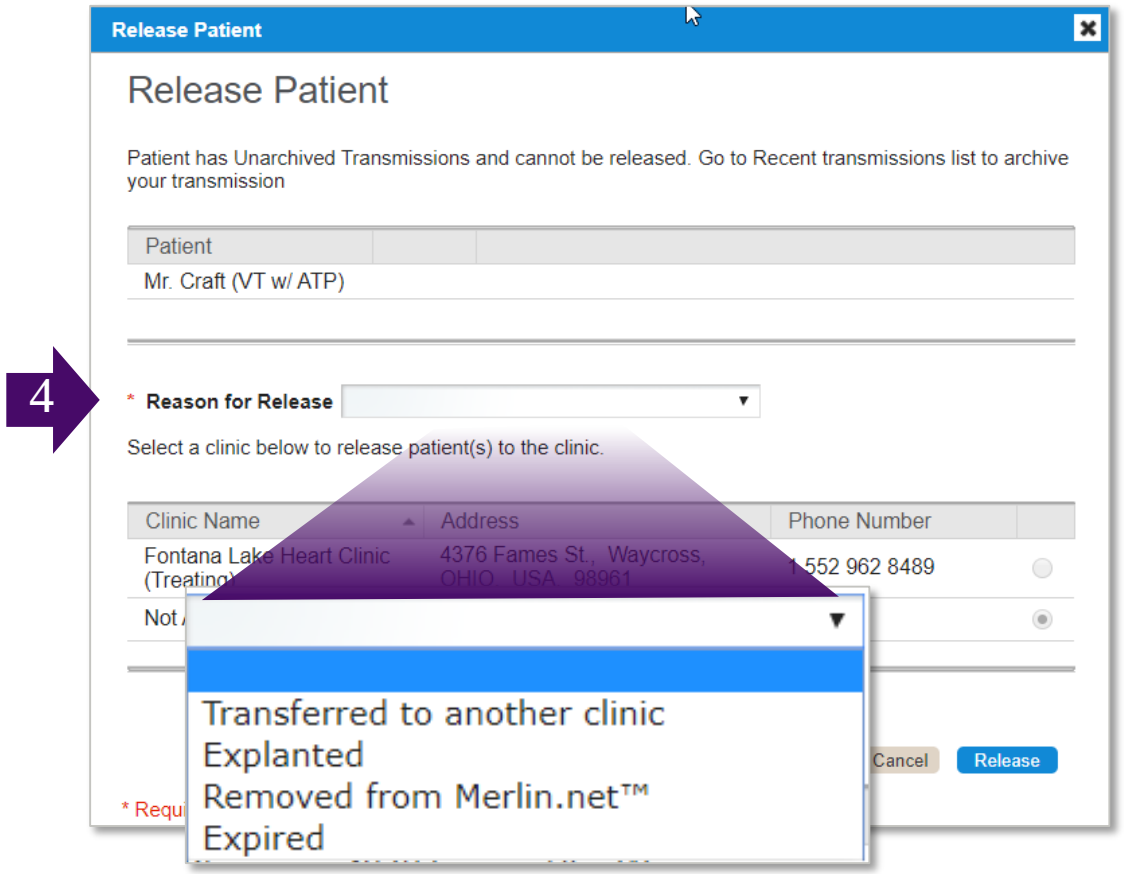
TRANSFERRED PATIENTS

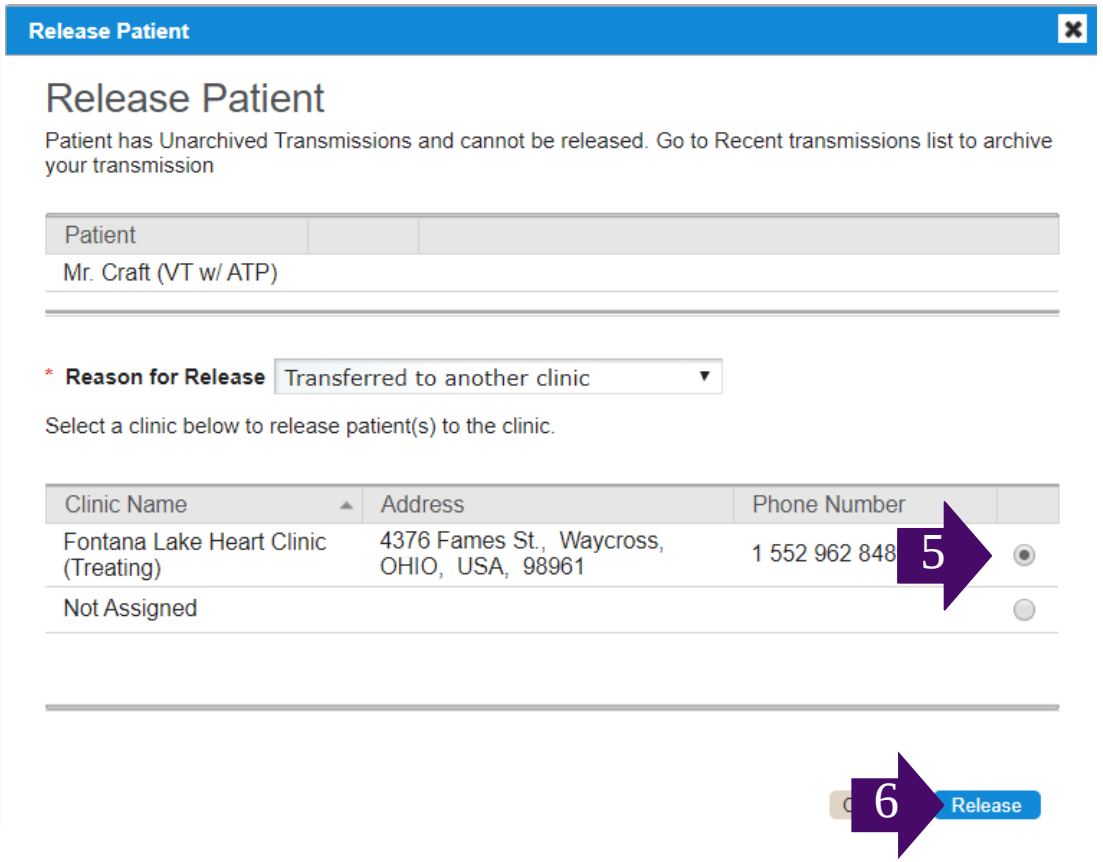
Transfer Patients — **PUSH WORKFLOW**

(Releasing a Patient from Your Clinic)

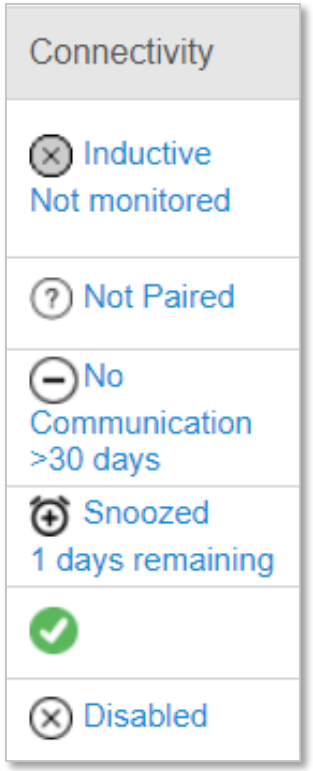


Transfer Patients — **PUSH WORKFLOW**

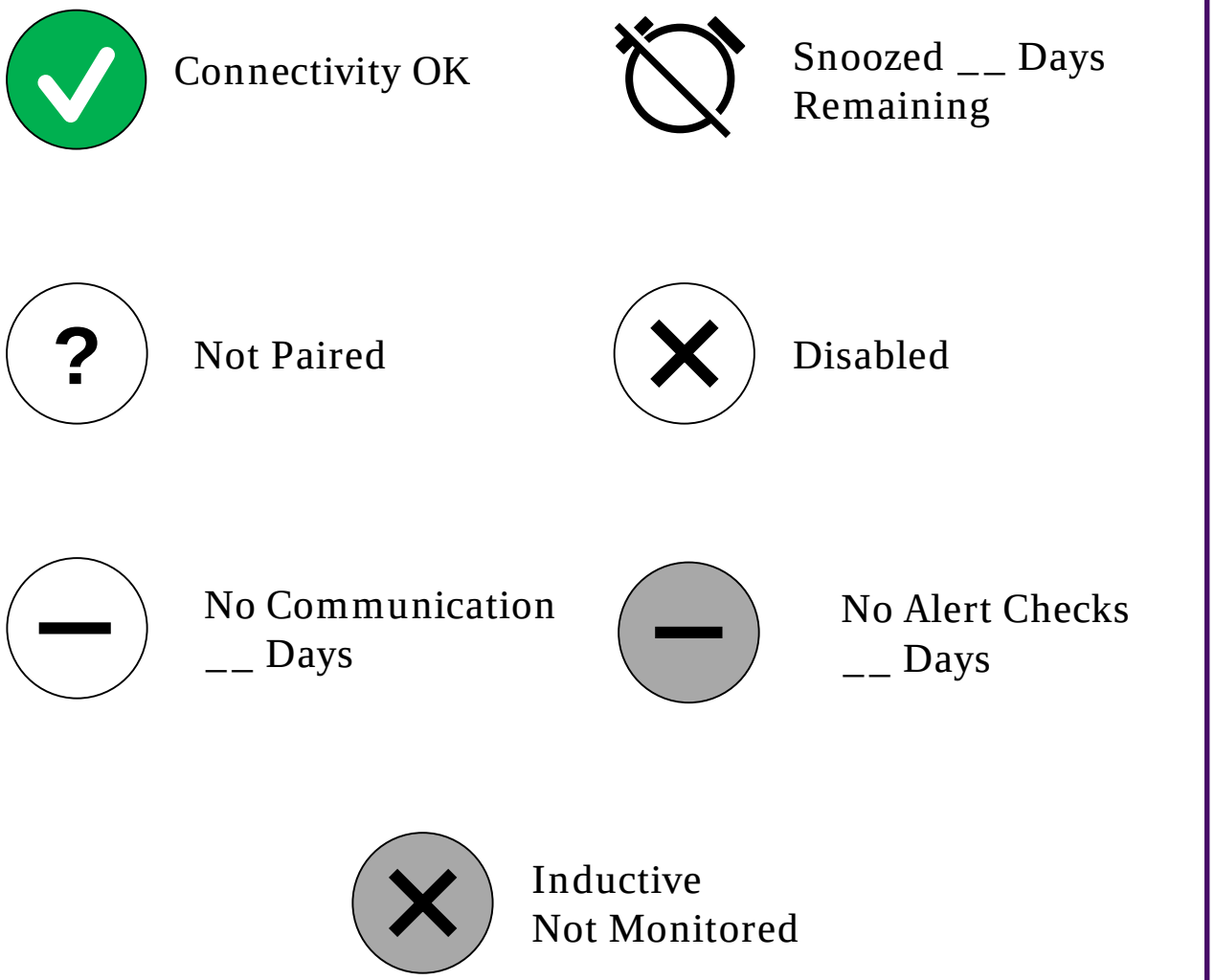




Merlin.net™ PCN
Connectivity Column

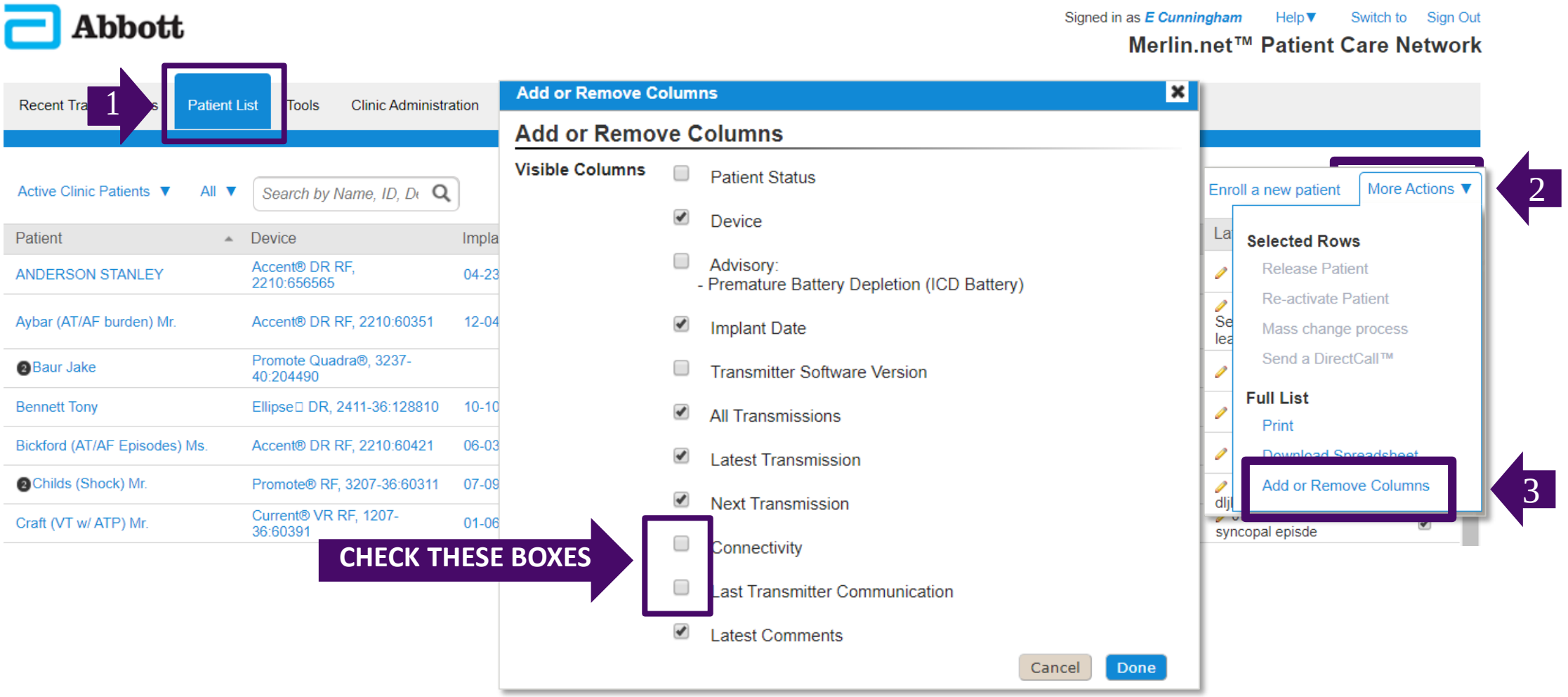


QUICKLY VIEW CONNECTIVITY STATUS of all patients from Patient List page



7 CONNECTIVITY STATES

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



Merlin.net™ Patient Care Network
Disconnected Transmitter Thresholds

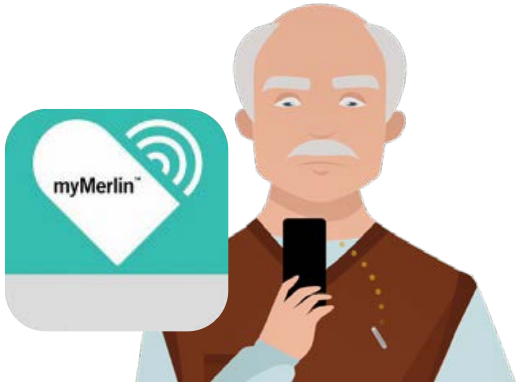
There are **TWO CONNECTIONS** that can be verified on Merlin.net PCN

1 TRANSMITTER CONNECTION

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

2 DIRECTALERT™ CHECK CONNECTION

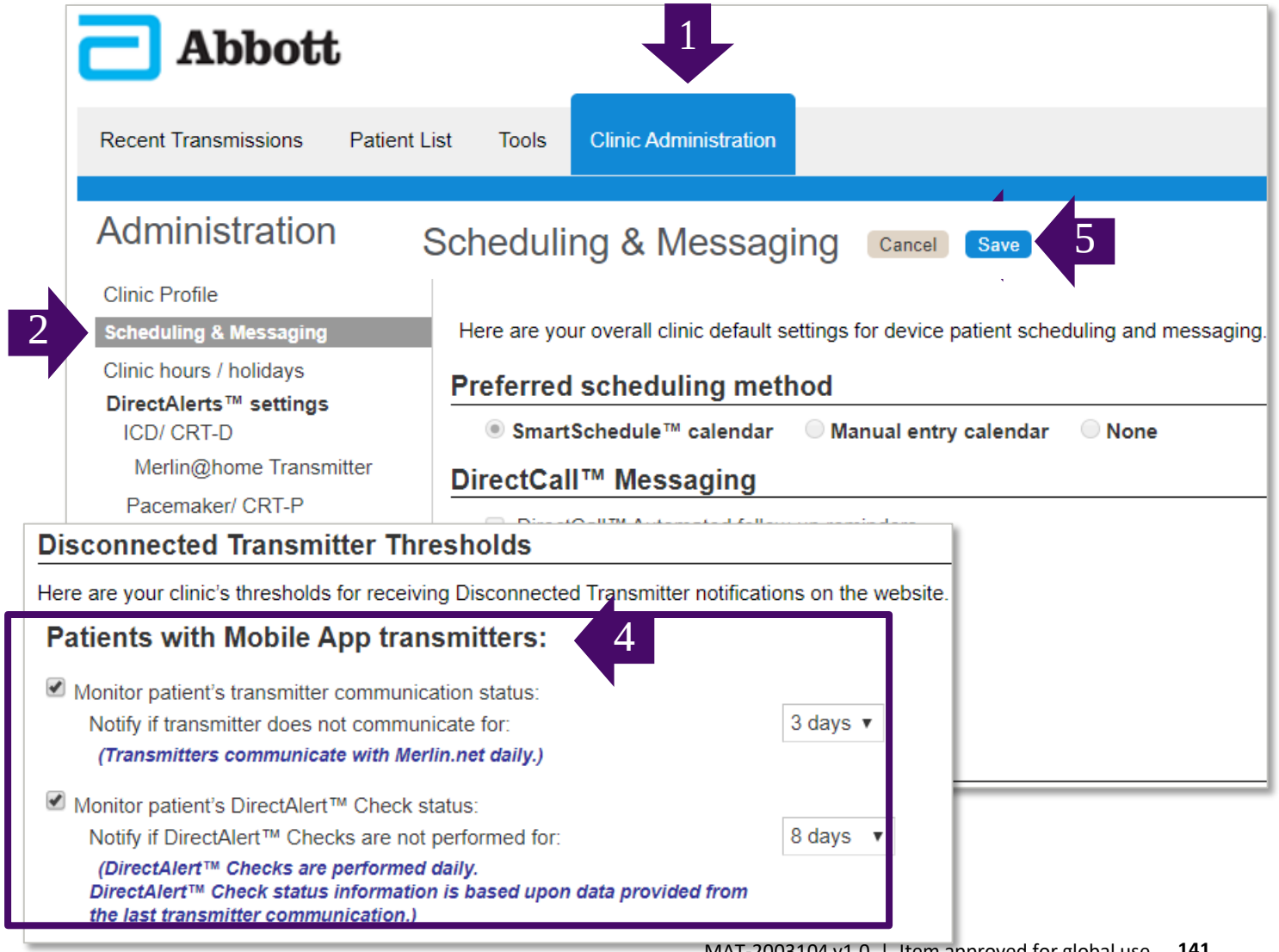
myMerlin Mobile App → Confirm Rx™ ICM
(Bluetooth® Wireless Technology Connection)



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**

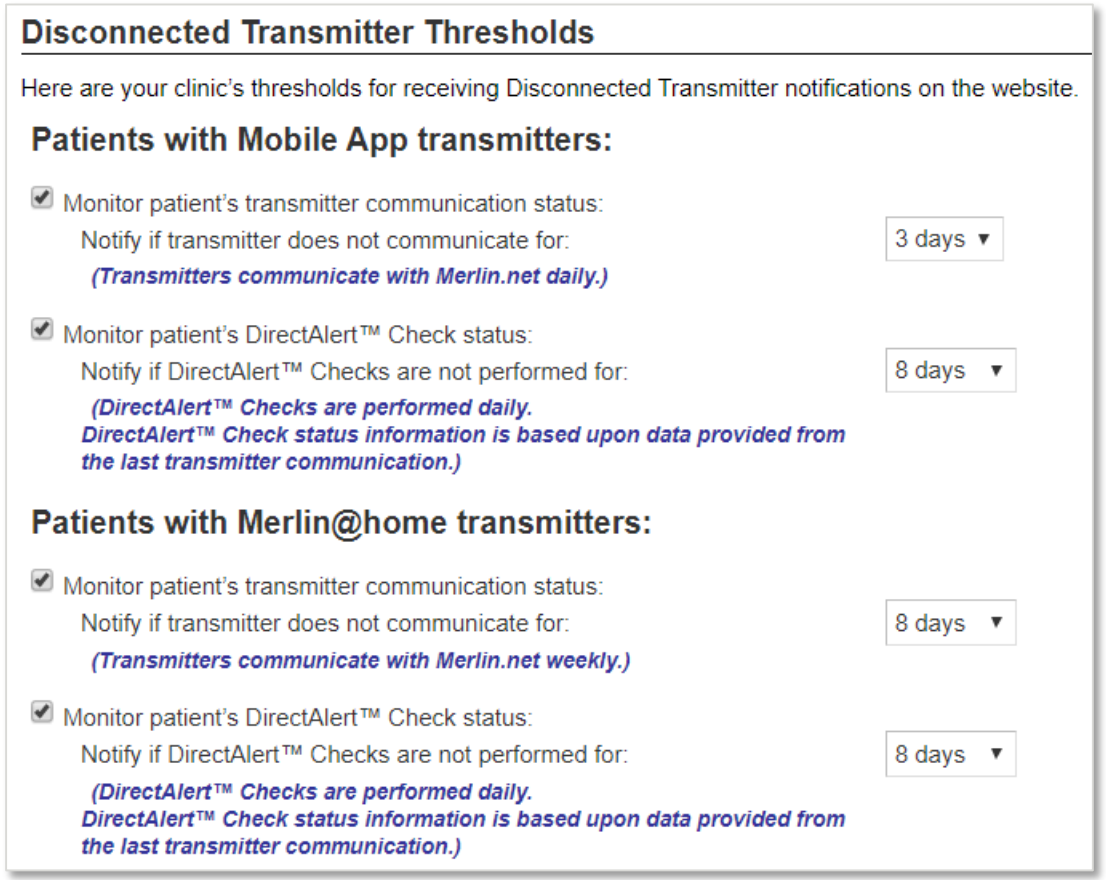


Merlin.net™ Patient Care Network
Disconnected Transmitter Thresholds

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



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**

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)

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

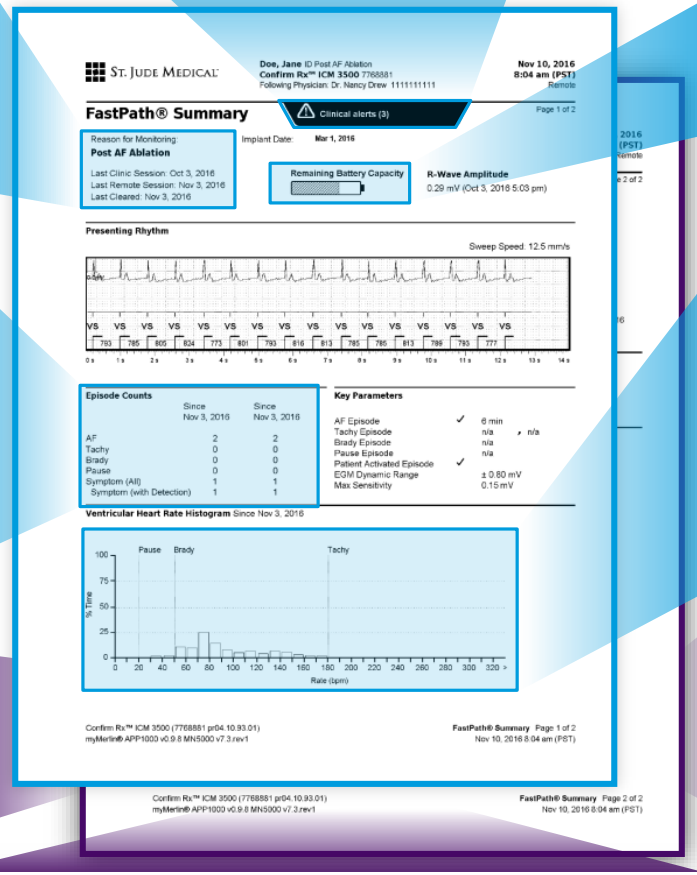
Alerts

Clinical

AF Episode Detected Nov 10, 2016

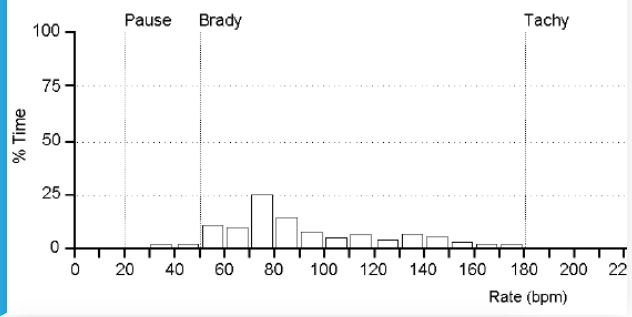
Symptom Episode with Device Detection Nov 10, 2016

Exceeded Continuous AF Episode Threshold Nov 10, 2016

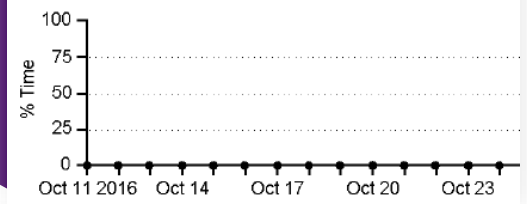


Remaining Battery Capacity

Ventricular Heart Rate Histogram Since Nov 3, 2016



AF Burden (31 Days)



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

Episodes Summary

ST. JUDE MEDICAL

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

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.	

EGM Retrieved

Example Episode

ST. JUDE MEDICAL

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

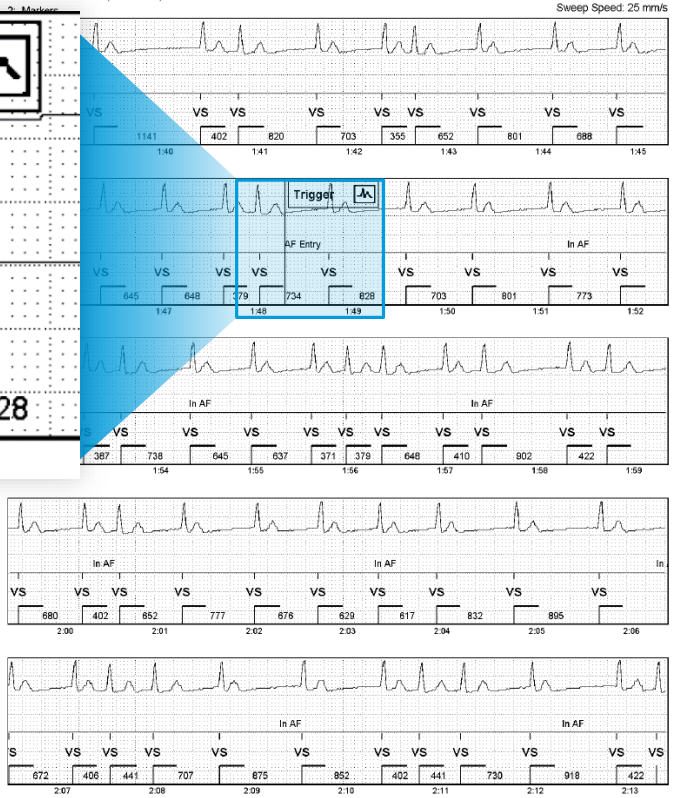
Nov 10, 2016
8:04 am (PST)
Remote

Symptom (with Detection) Episode

Page 4 of 16

1: VEGM AutoGain (26 mm/mV)
2: Markers

Sweep Speed: 25 mm/s



Confirm Rx™ ICM 3500 (7768881 pr04.10.93.01)
myMerlin® APP1000 v0.9.8 MN5000 v7.3.rev1

Symptom (with Detection) Episode Page 4 o...
Nov 10, 2016 8:04 am (PST)

ST. JUDE MEDICAL

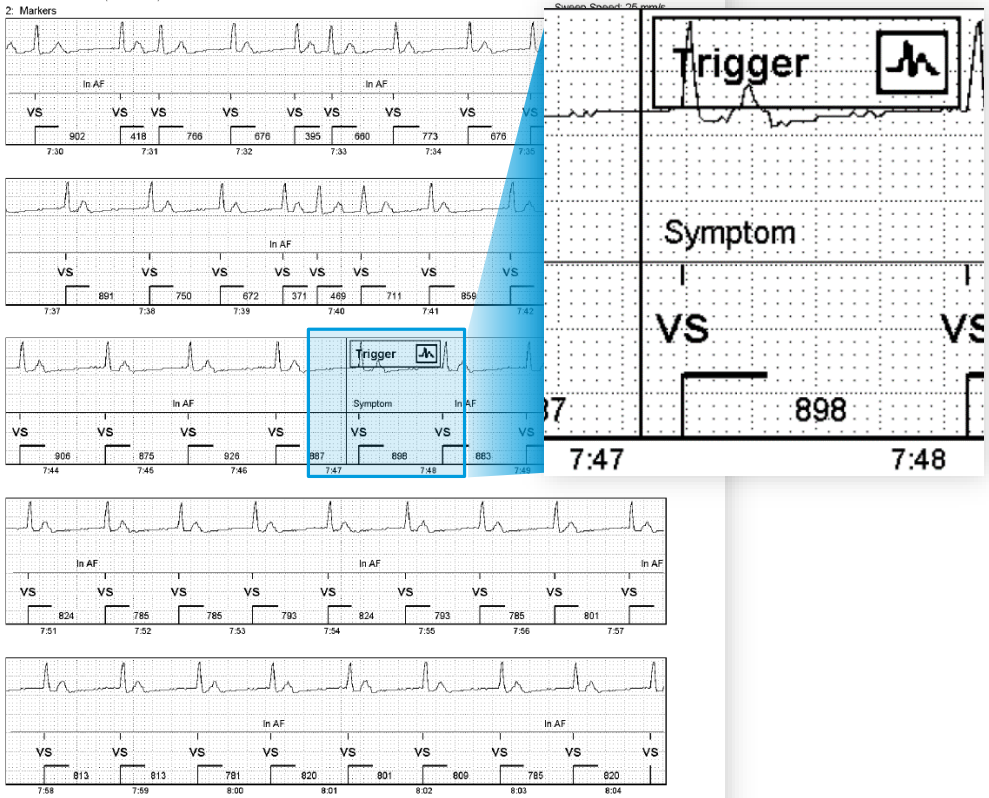
Doe, Jane ID Post AF Ablation
Confirm Rx™ ICM 3500 7768881
Following Physician: Dr. Nancy Drew 1111111111

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

Symptom (with Detection) Episode

Page 14 of 16

1: VEGM AutoGain (26 mm/mV)
2: Markers



Confirm Rx™ ICM 3500 (7768881 pr04.10.93.01)
myMerlin® APP1000 v0.9.8 MN5000 v7.3.rev1

Symptom (with Detection) Episode Page 14 ...
Nov 10, 2016 8:04 am (PST)

BREAKOUT #2

IMPLANT DEMONSTRATION AND MERLIN.NET™ PCN BEST PRACTICES

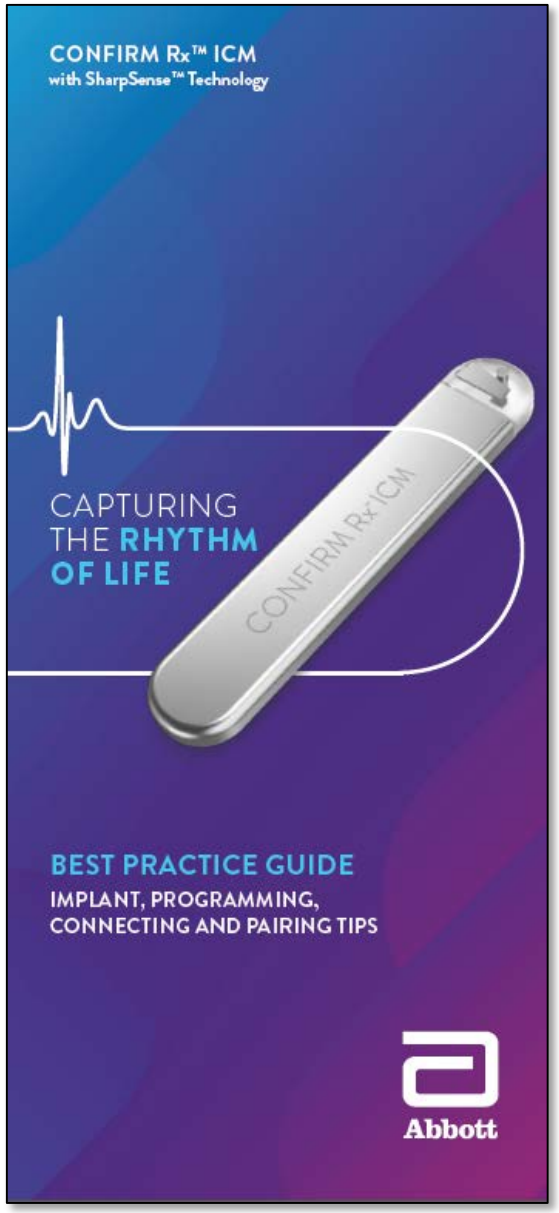
Confirm Rx™ ICM Best Practice Guide

Tips & Tricks

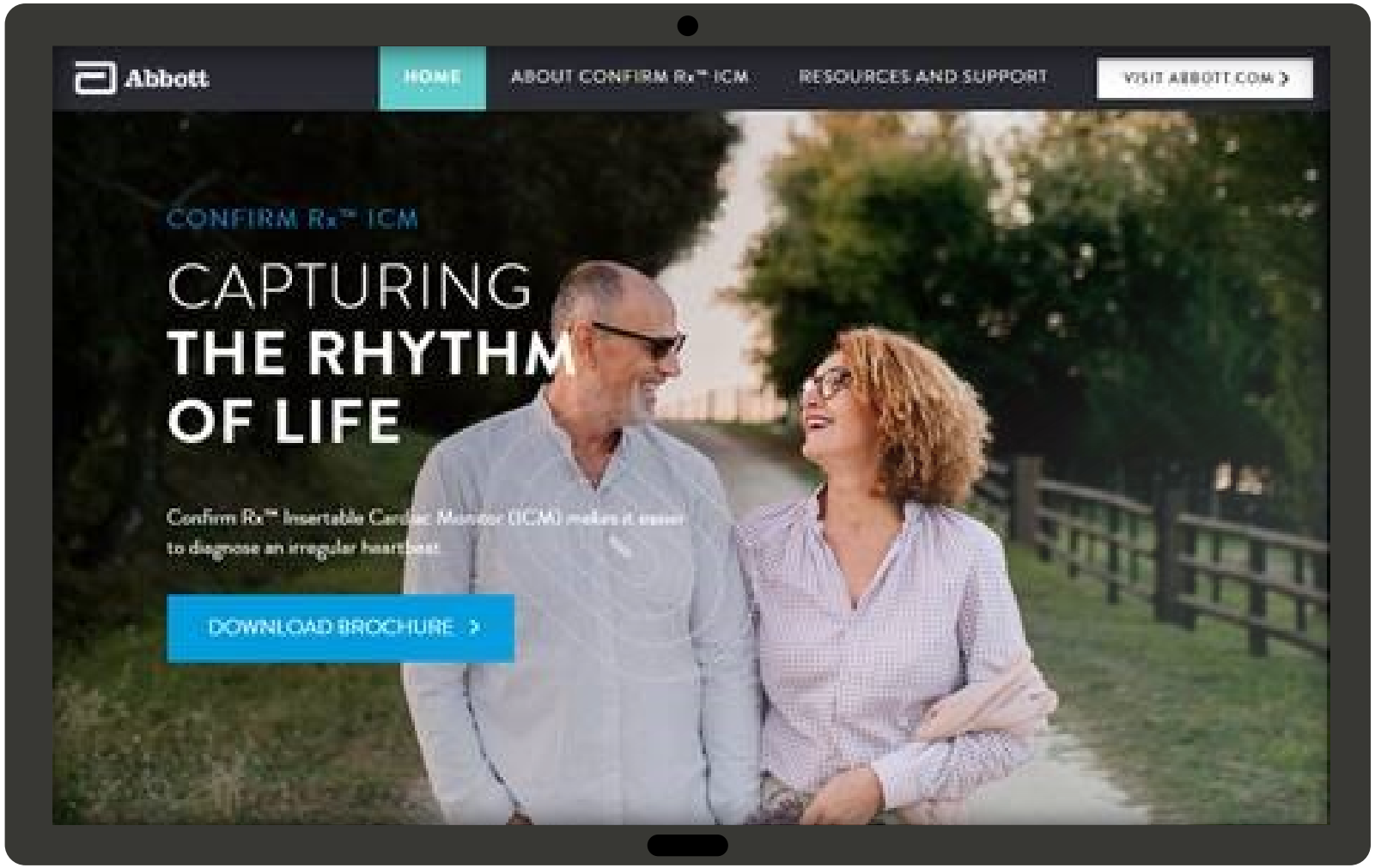
- Implant
- Programming
- Connectivity
- Pairing

= iPhone† settings
= Android† settings

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

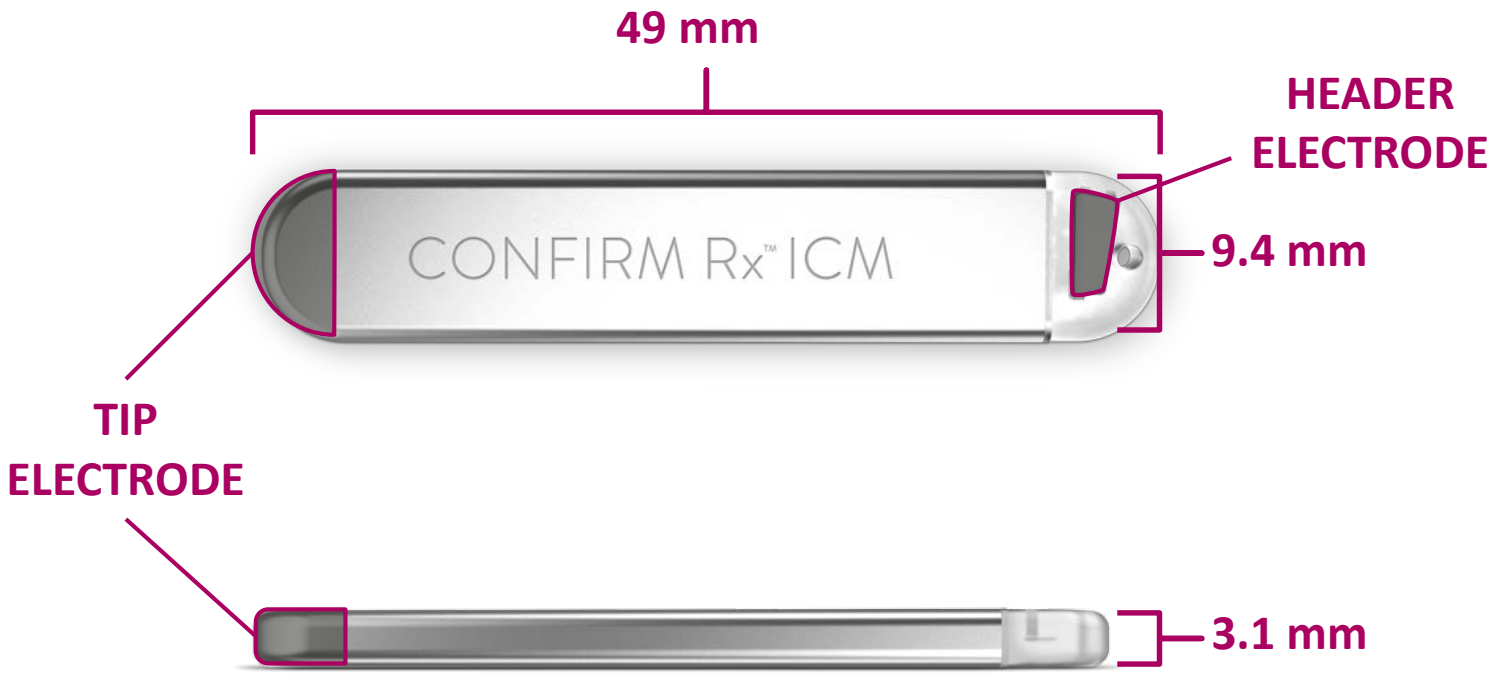


Patient Website: www.ConfirmYourRhythm.com



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

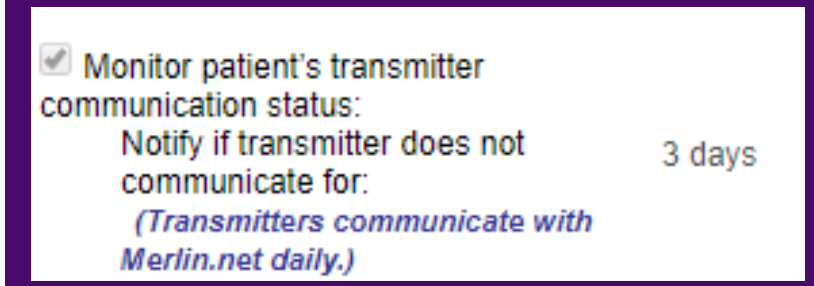
Disconnected Transmitter Thresholds
Transmitter Communication Status

“NO COMMUNICATION FOR X DAYS”

No Communication 8 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)



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

IS THE APP ON THEIR PHONE?

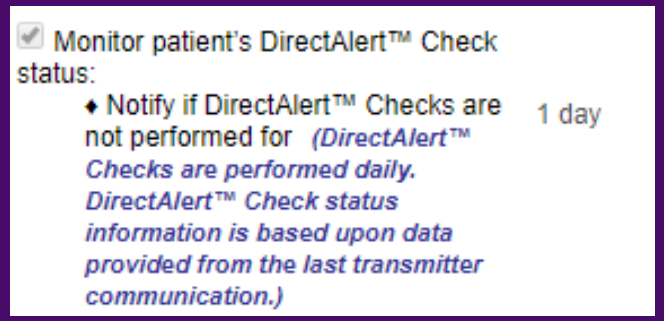
- Paired to the device?
- Running in the background at all times?
- Has the patient reached the data limit on their cellular phone plan?*

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

Disconnected Transmitter Thresholds
DirectAlert™ Check Status

“NO ALERT CHECKS IN X DAYS”

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

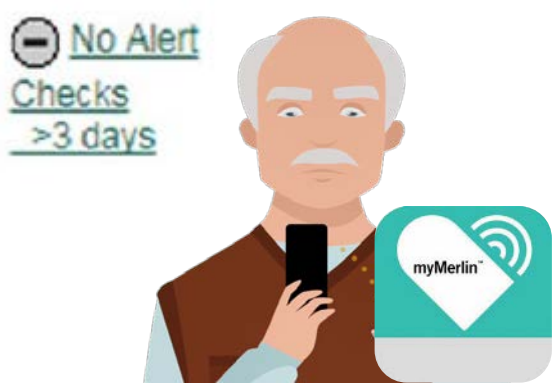


CONFIGURE SETTINGS IN MERLIN.NET™ PCN

- Programmable 1–14 days

Disconnected Transmitter Thresholds

Troubleshooting DirectAlerts™ Check Status



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?

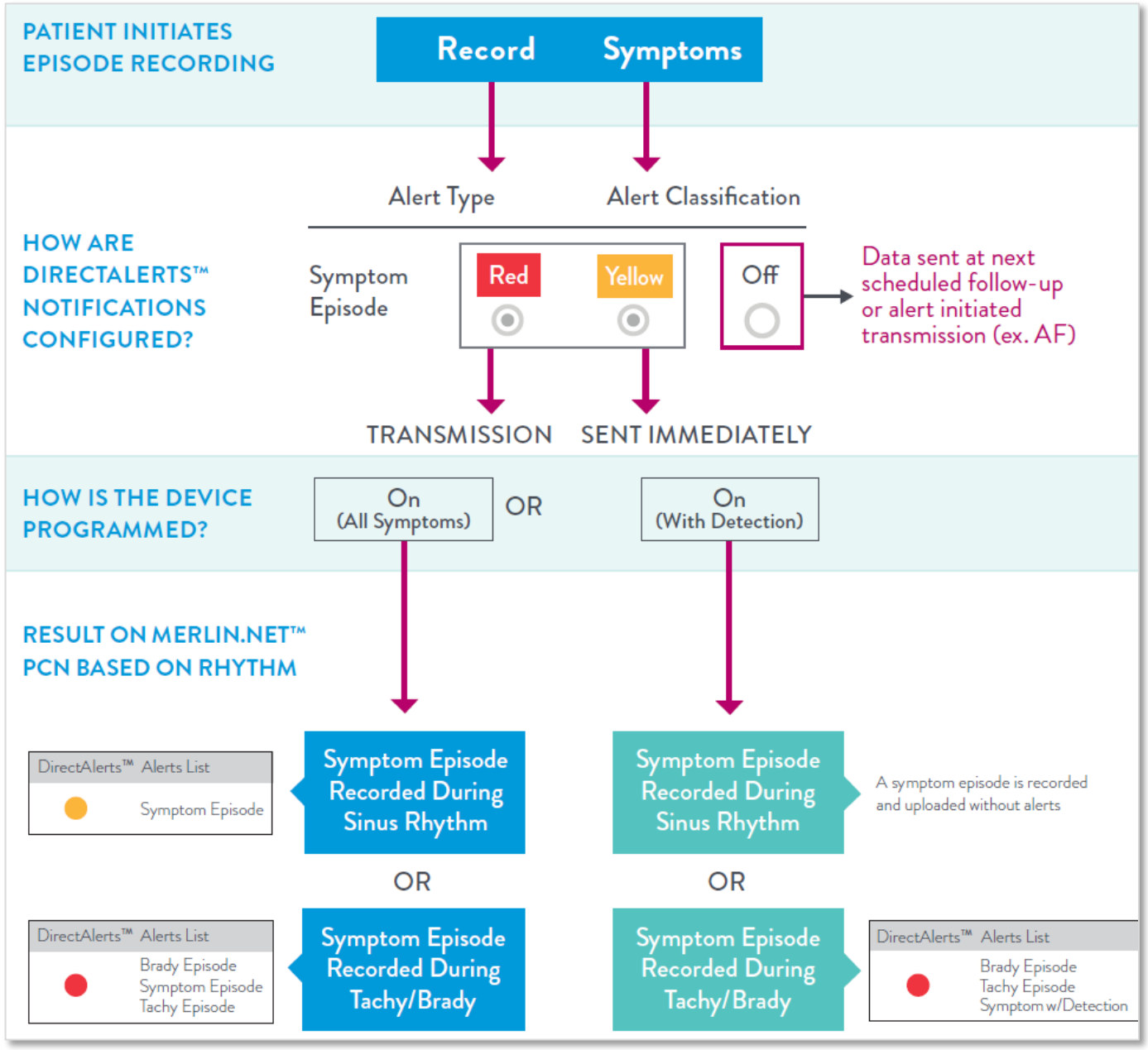
- Is the phone in airplane mode?
- Battery saver mode?

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
AF	atrial fibrillation
AVD	atrioventricular delay
CI	current interval
CRT-D	cardiac resynchronization therapy defibrillator
EGM	electrogram
EKG	electrocardiogram
FP	false positive
GEE	generalization estimating equation
IA	interval average
ICD	implantable cardioverter defibrillator
ICM	insertable cardiac monitor
NSA	National Security Agency
OS	operating system
PCN	Patient Care Network
PCS	Patient Care System
PPV	positive predictive value
RF	radio frequency
TF	true positive
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‡ or Android‡ 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® wireless technology enabled and data coverage (cellular or WiFi‡) 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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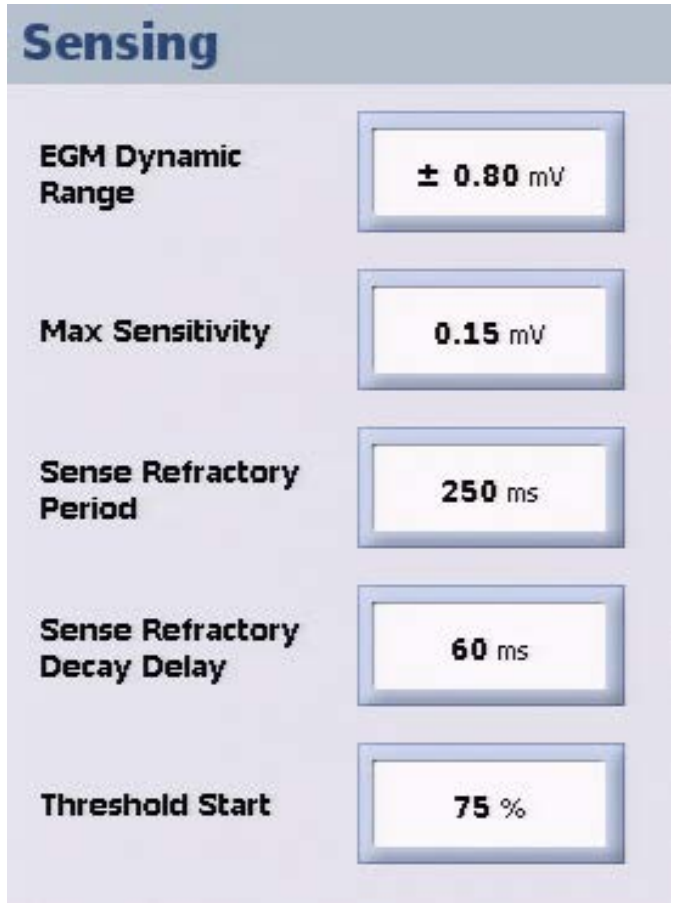
APPENDIX

REFERENCE MATERIALS

Sensing

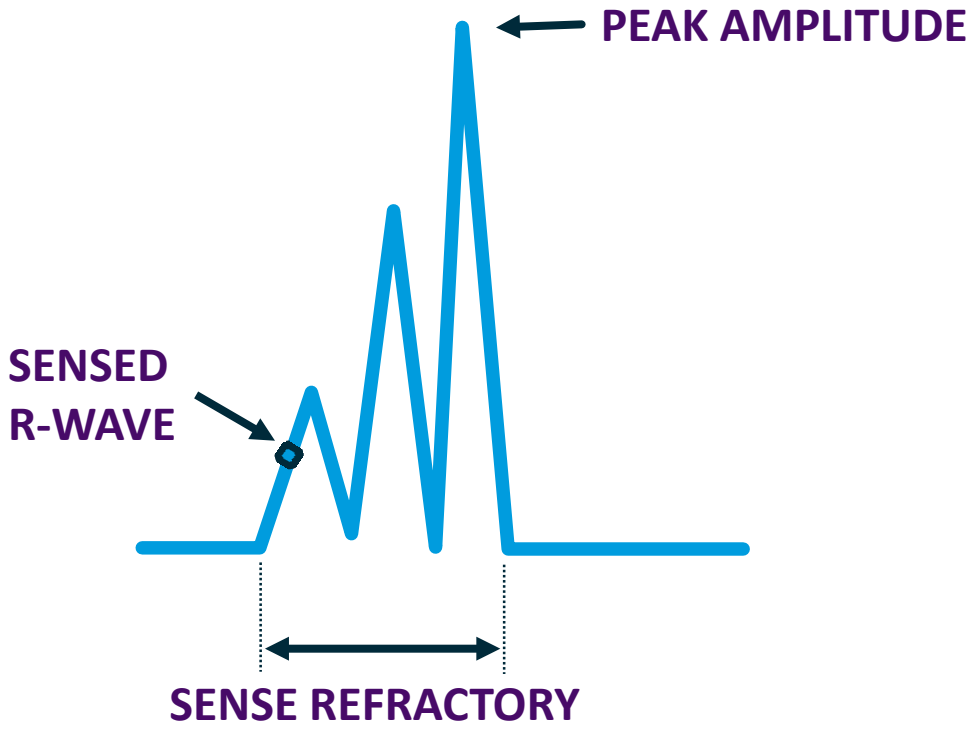
The Confirm Rx™ ICM uses the Sense*Ability*™ sensing algorithm —
the same as Abbott ICDs and CRT-Ds

The Sense*Ability* sensing algorithm provides programmable options to reduce oversensing and undersensing issues



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

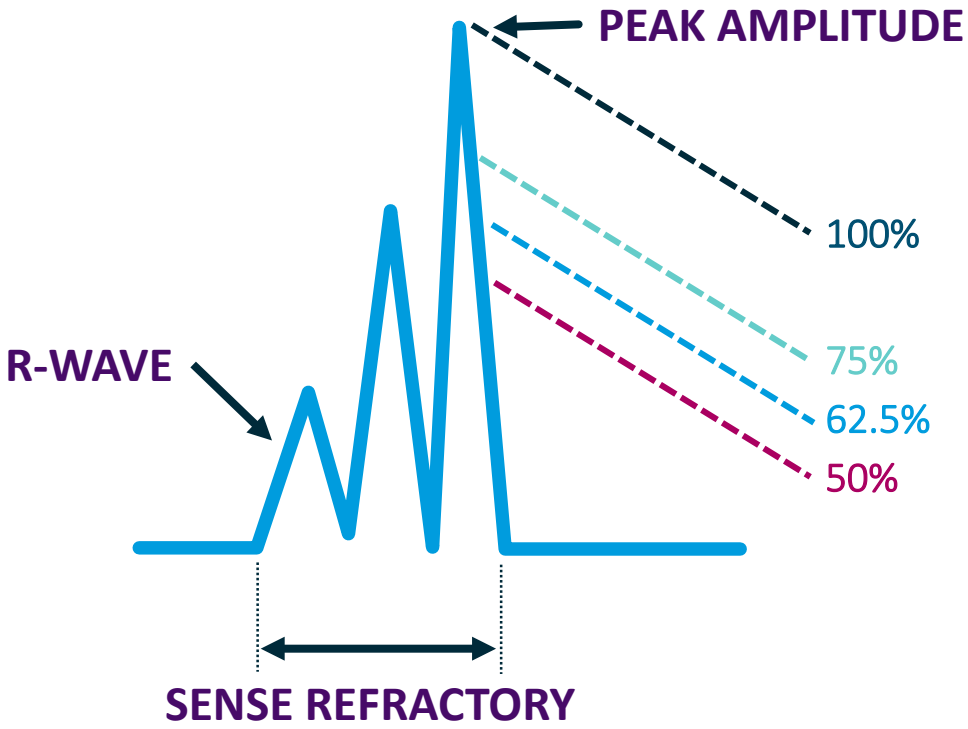
PROGRAMMABLE PARAMETER

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

NOMINAL: 75%

EXAMPLES

	MAX THRESHOLD START (mv)			
Dynamic Range (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

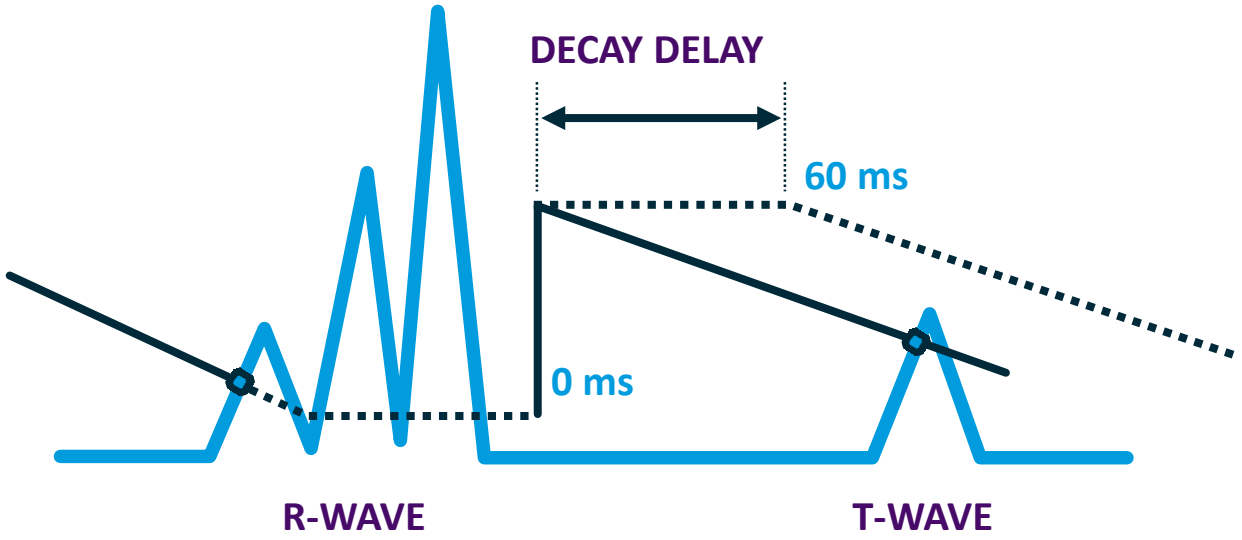
PROGRAMMABLE PARAMETER

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

NOMINAL: 60 ms

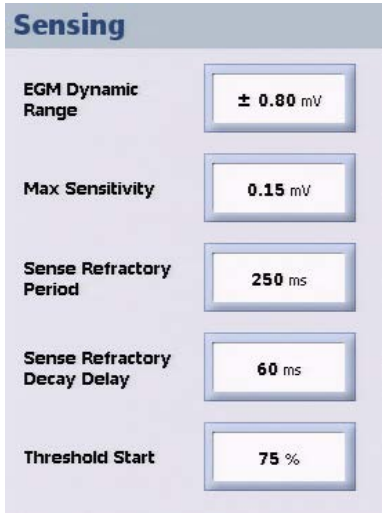
DECAY DELAY EXAMPLE

- 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



DECAY DELAY EXAMPLE

Sense*Ability*™ Sensing Algorithm



R-WAVE = 1.0 mV

PEAK OF R-WAVE NOT SEEN DUE TO DYNAMIC RANGE

THRESHOLD START MAX = 0.8 mV

DECAY DELAY 60 ms

THRESHOLD START: 75% = 0.6 mV

R-WAVE = 0.7 mV

DECAY DELAY 60 ms

THRESHOLD START: 75% = 0.53 mV

R-WAVE SENSED

R-WAVE SENSED

MAX SENSITIVITY

SENSE REFRACTORY

SENSE REFRACTORY

Stored EGM Configurations

AF EPISODES

TRIGGERS

- **PRE:** 10–120 sec
- **POST:** 10–120 sec

OTHER EPISODES

TYPES: TACHY, BRADY, PAUSE

TRIGGERS

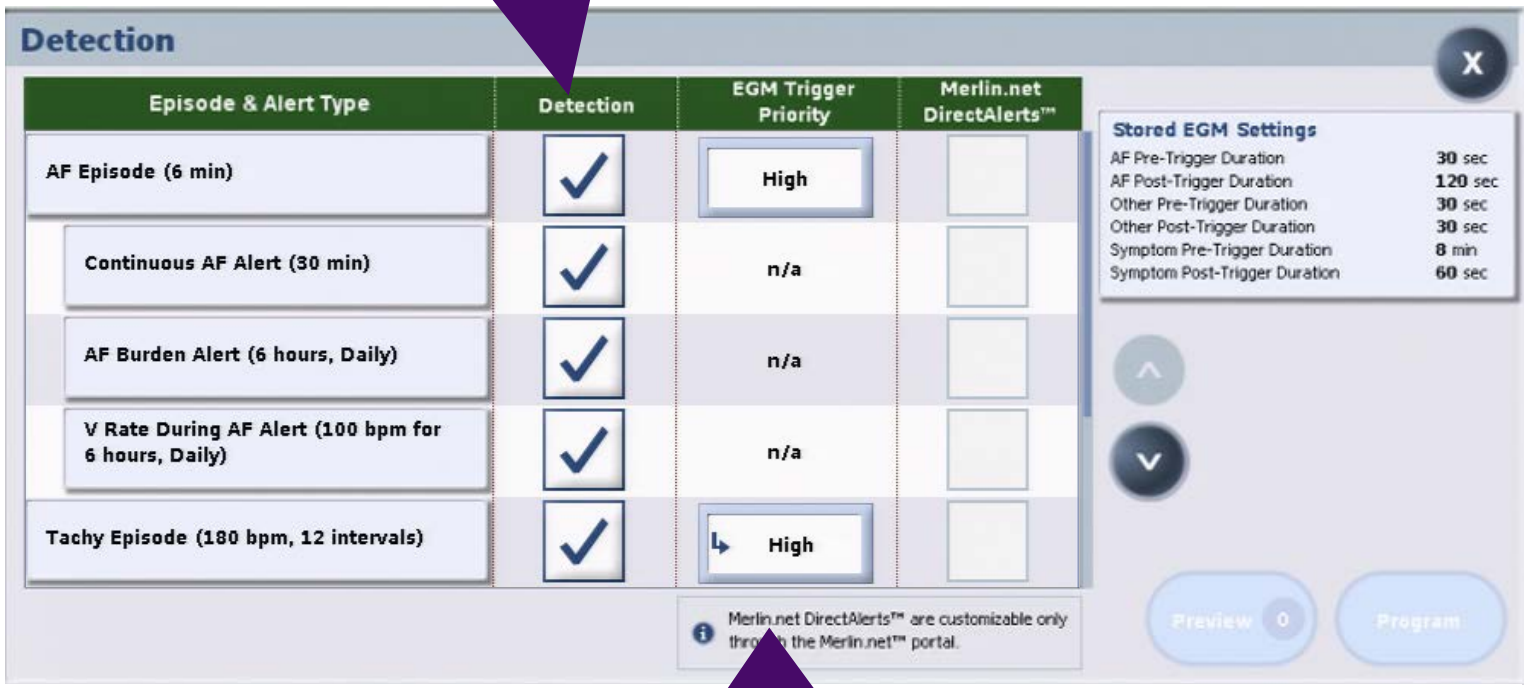
- **PRE:** 10–60 sec
- **POST:** 10–60 sec

PATIENT-ACTIVATED EPISODES

TRIGGERS

- **PRE:** 4–14 min
- **POST:** 30–60 sec

Will an episode be triggered?



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	**SETTINGS**: 30; 40; 50 bpm **NOMINAL**: 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)	**SETTINGS**: 120; 125 … 250 bpm **NOMINAL**: 180 bpm*
	Tachy Count	The number of intervals where the rate is faster than the Tachy cutoff rate triggers episode storage	**SETTINGS**: 8; 9 … 25; 30 … 50 intervals **NOMINAL**: 12 intervals
Pause	Pause Duration	No detection of intrinsic rhythm for more than this duration triggers episode storage	**SETTINGS**: 2; 3 … 8 s **NOMINAL**: 3 s

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

Episode Priority (Low vs. High)

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 Yellow	Daily Check	SAME or HIGHER Priority Episodes	NO
	OFF	Scheduled Follow-up (default every 31 days)		YES (if enabled)
PATIENT-ACTIVATED	Red Yellow	Immediately**	***ONLY*** Patient-activated Episodes	NO
	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

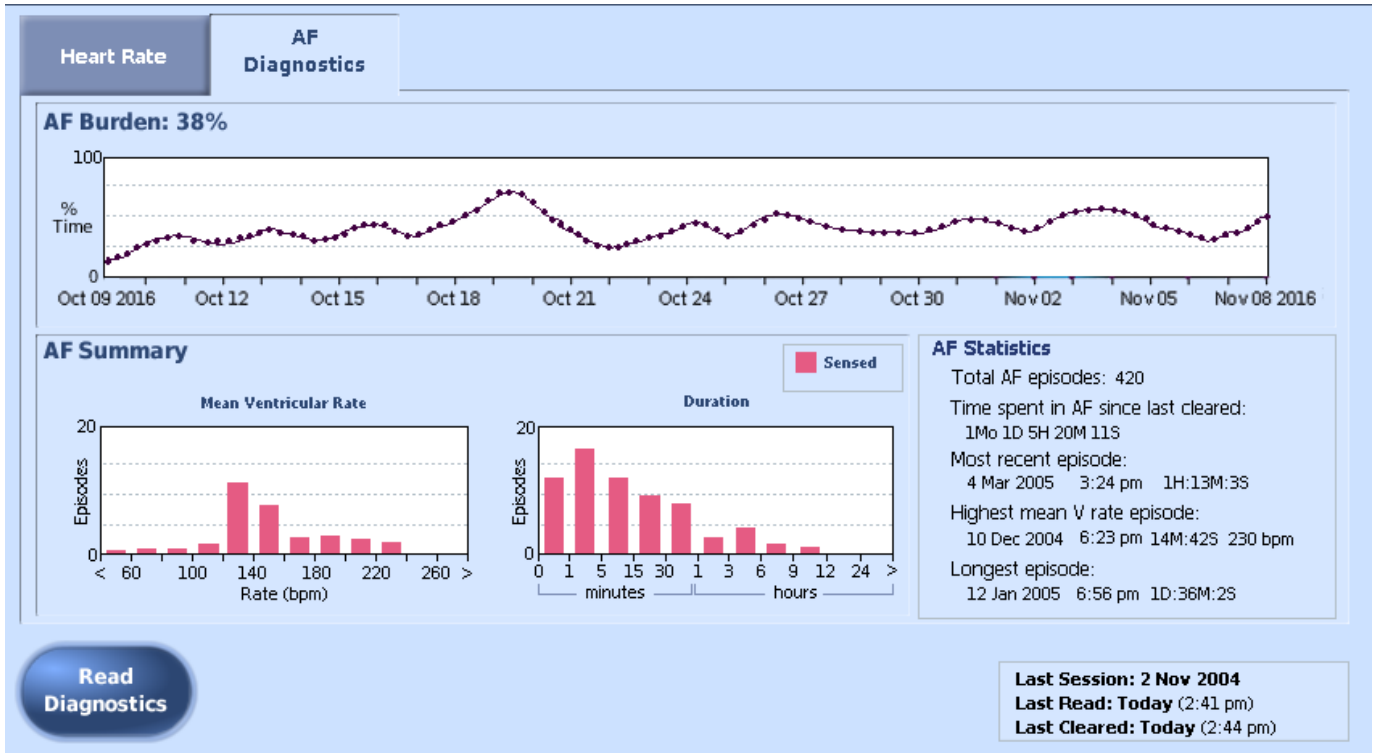
- AF Episode Entry

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)

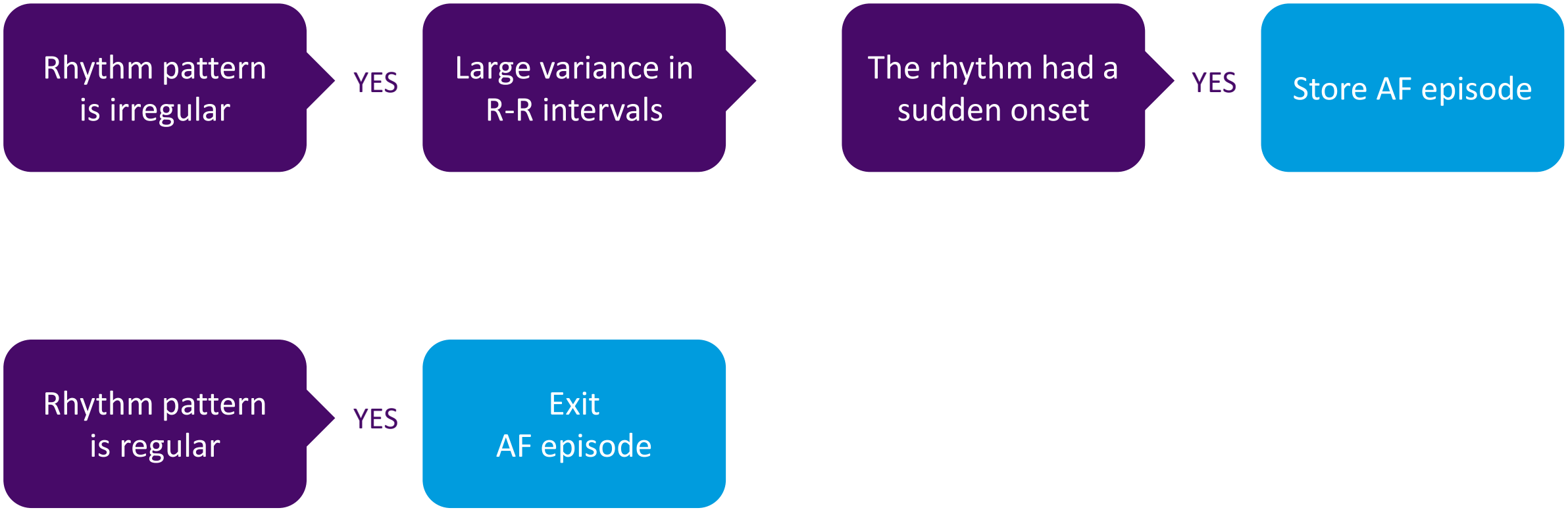
SUDDEN ONSET — evaluates how the rhythm initiates

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
Algorithm Response	Trigger AF Episode	No Trigger

✓ Indicates rhythm is AF
× Indicates rhythm is not AF

Episode Entry and Exit



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