Medtronic

Reveal LINQ™

INSERTABLE CARDIAC MONITOR

Enhanced Features and Algorithms Guide

POWERFUL CARDIAC MONITORING

SMALL. SIMPLE. CONNECTED. PRECISE.

Introduction

This Interactive PDF guide is designed to give you the basic technical details on the Reveal LINQ™ Insertable Cardiac Monitor (ICM) enhanced features and algorithms.

At the completion of this guide, you will be able to:

- Identify Reveal LINQ ICM enhanced features and algorithms
- Describe the clinical need that each feature addresses and list the benefits for each feature
- Describe the benefits of the new P-SENSE detection enhancement

The Evolution of Reveal® ICM

From a Diagnostic Device to a Patient Management Tool

1998: Reveal ICM

2000: Reveal Plus ICM

2007: Reveal DX ICM

- 3-year battery
- Added to the Medtronic CareLink®Network
- MR-Conditional

2009: Reveal XT ICM

- AF detection
- Cardiac Compass®

2011: FullView®

Powered by

FullView Software

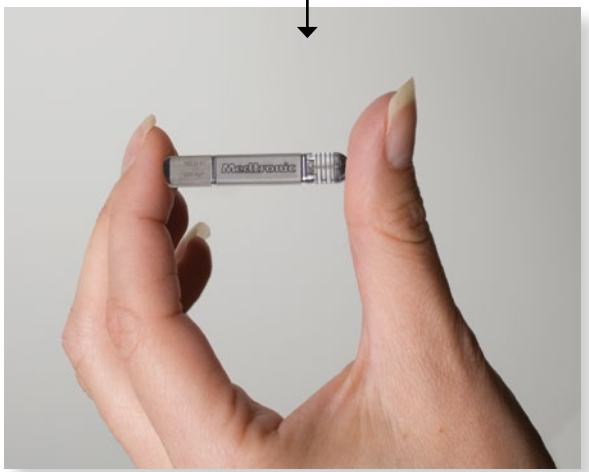
- Improvements for viewing and collecting data

Miniaturized Reveal® ICM Device

Breakthrough Technology

3-year monitoring
remote management*

87% smaller and
wireless transmissions



* Under the following usage scenarios:
- Average of 1 auto-detected episode per day
- Average of 1 patient-activated episode per month
- Less than or equal to 6 months shelf life (between device manufacture and insertion)

Note: Under maximum shelf storage time (12 months), longevity is reduced by approximately 3 months.

Introducing…

Reveal LINQ™ ICM System

Powerful Cardiac Monitoring

Powerfully Small
87% smaller than Reveal® XT ICM, with 20% more data memory

Reveal LINQ ICM

Powerfully Simple
Simplified insertion procedure with < 1 cm incision provides the most discreet cardiac monitoring option, with improved cosmetic appearance for greater patient acceptance

Insertion Tool

Powerfully Connected
Only wireless insertable cardiac monitoring system that continuously collects and trends data for up to 3 years, with automatic CareAlert® Notifications

Patient at Home Monitor

Powerfully Precise
Clinically actionable, easy-to-read CareLink® reports reduce the data management burden

Actionable Information

Feature Overview

A miniaturized device that is powered by Reveal® performance

New Features

- 1.2 cc
- 59 min ECG storage
- Wireless one-way telemetry
- Titanium nitride coated electrodes to improve sensing
- Enhanced atrial arrhythmia detection
- Nominals customized by patient type
- Incision and insertion tools for a minimally invasive insertion
- Medtronic CareAlert® notifications

Leveraging Reveal XT ICM Capabilities

- 3-year longevity*
- MR-Conditional
- Daily trended diagnostics via Cardiac Compass®

* Under the following usage scenarios:
  - Average of 1 auto-detected episode per day
  - Average of 1 patient-activated episode per month
  - Less than or equal to 6 months shelf life (between device manufacture and insertion)

Note: Under maximum shelf storage time (12 months), longevity is reduced by approximately 3 months.

Reveal LINQ™ ICM Provides More Customized Solutions

ECG Data Storage: 59 Minutes Total

Clinical Goal

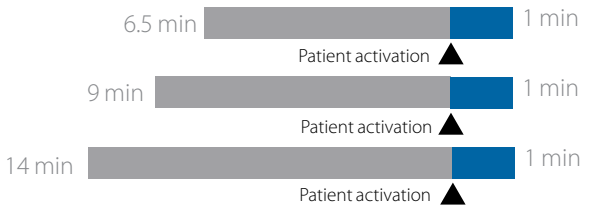
Increased patient-activated ECG memory options to provide additional time, where needed, for patients to use their Patient Assistant to help establish a symptom-rhythm correlation.

Up to 30 minutes of patient-activated episodes.

4 episodes @ 7.5 min. each

3 episodes @ 10 min. each

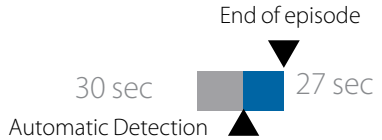
2 episodes @ 15 min. each



27 minutes of automatically detected episodes

Episode types: Pause, Brady, Tachy

- Up to 27 episodes: 30 seconds of ECG data recorded before detection and up to 27 seconds prior to the end of the episode

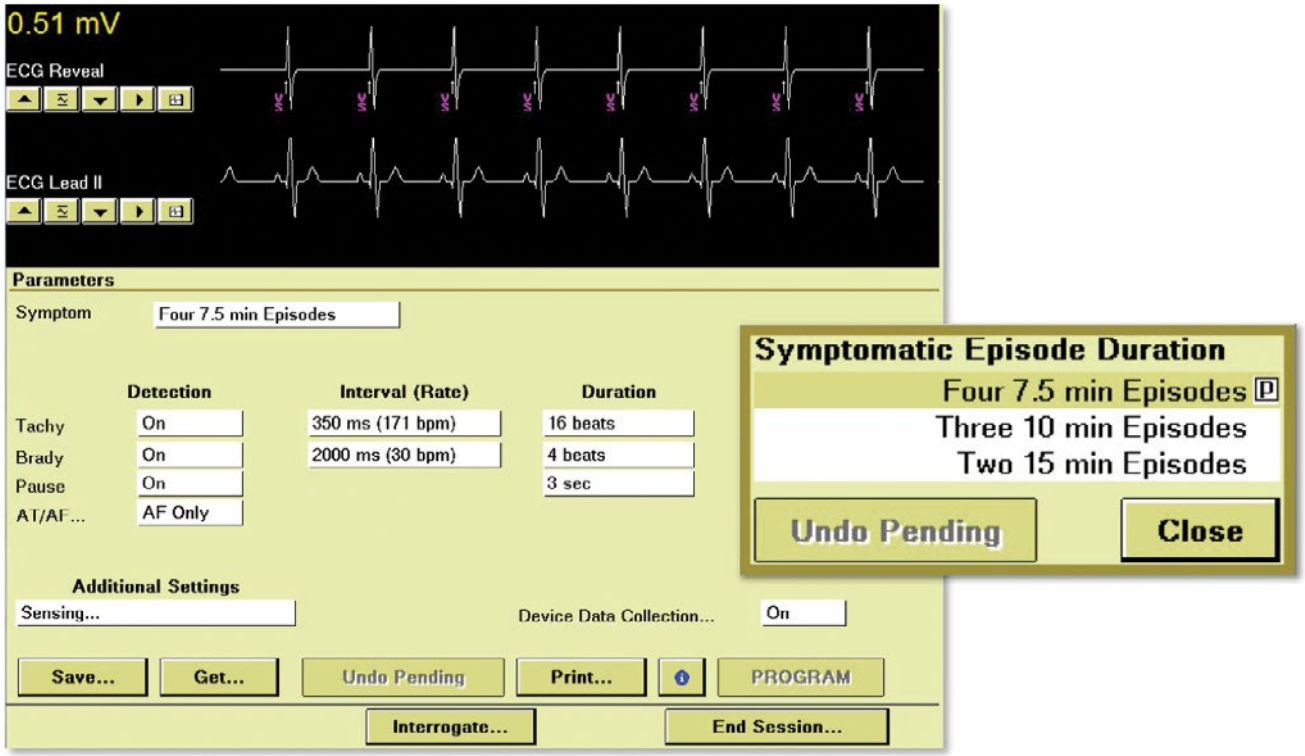


Atrial episodes: AT/AF

- Two minutes of ECG data recorded before detection

Two minutes of longest AF episode stored since last interrogation *in addition* to the 27 minutes of automatically detected episodes.

Symptomatic Episode Duration

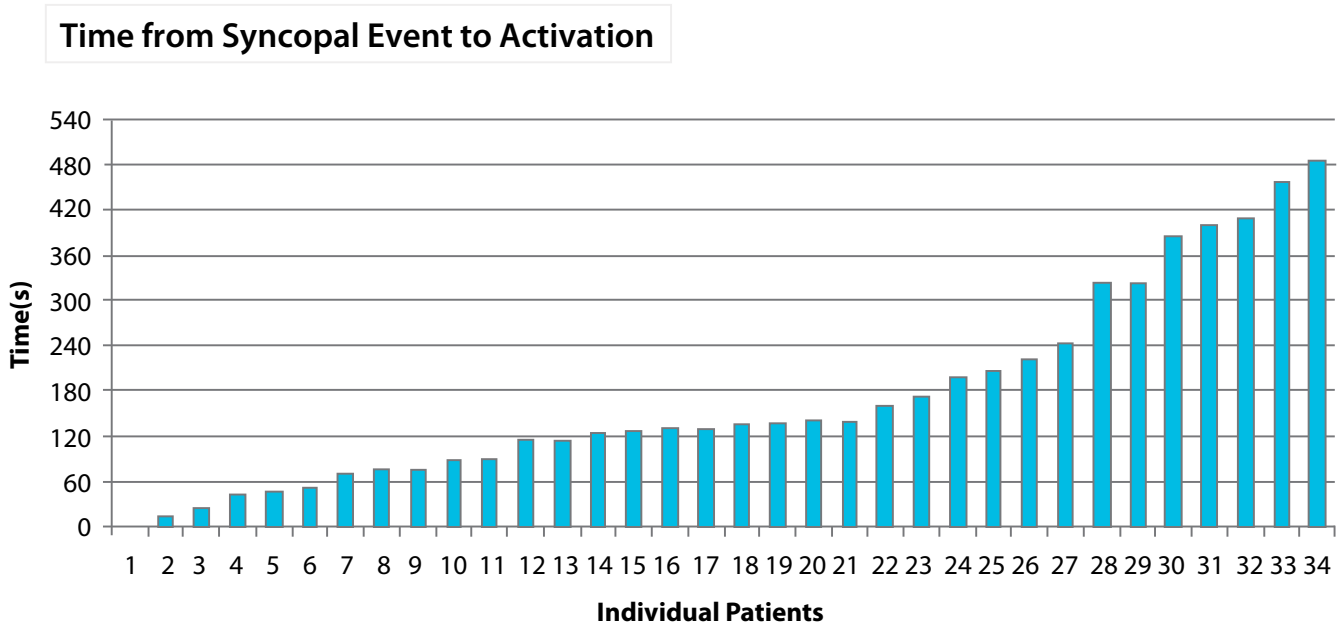


All patient and clinical data are fictitious and for demonstration purposes only.

NOTE: Stored symptomatic events will be cleared in reprogramming Symptomatic Episode Duration.

Value of Increased and Flexible Patient-Activated Event Memory Storage

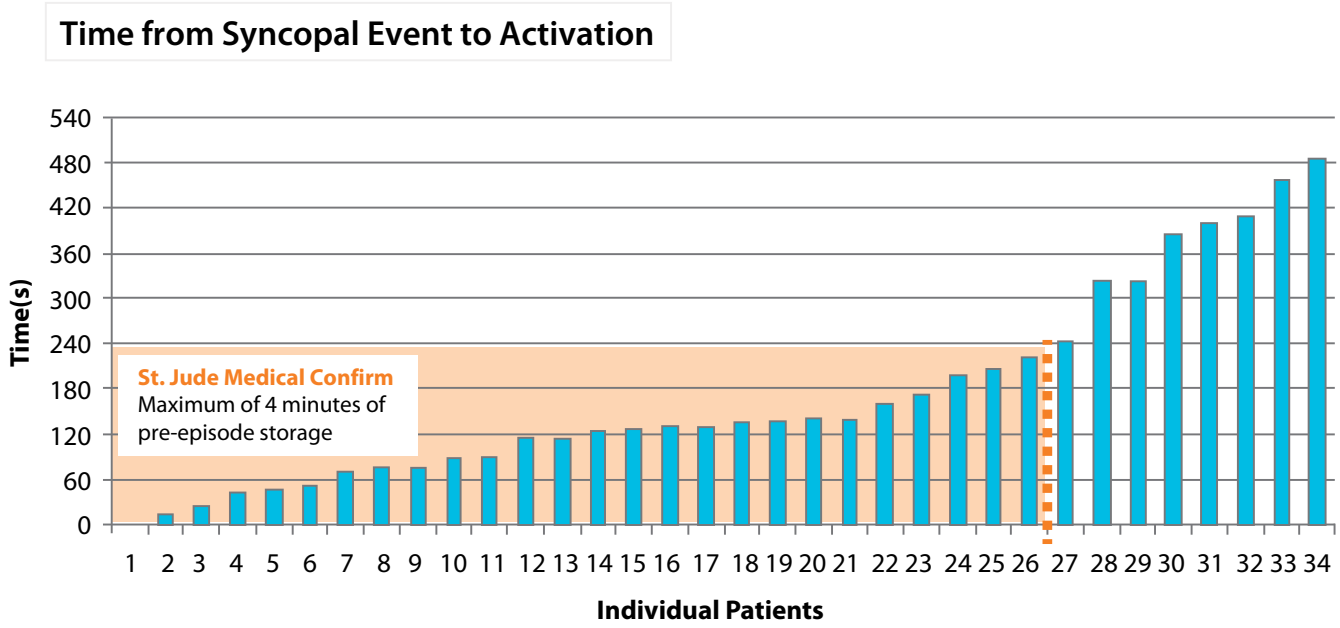
Clinical Data



Source: Turley AJ, Tynan MM, Plummer CJ. Time to manual activation of implantable loop recorders – implications for programming recording period: a 10-year single-centre experience. *Europace*. October 2009;11(10):1359-1361.

Value of Increased and Flexible Patient-Activated Event Memory Storage

Clinical Data



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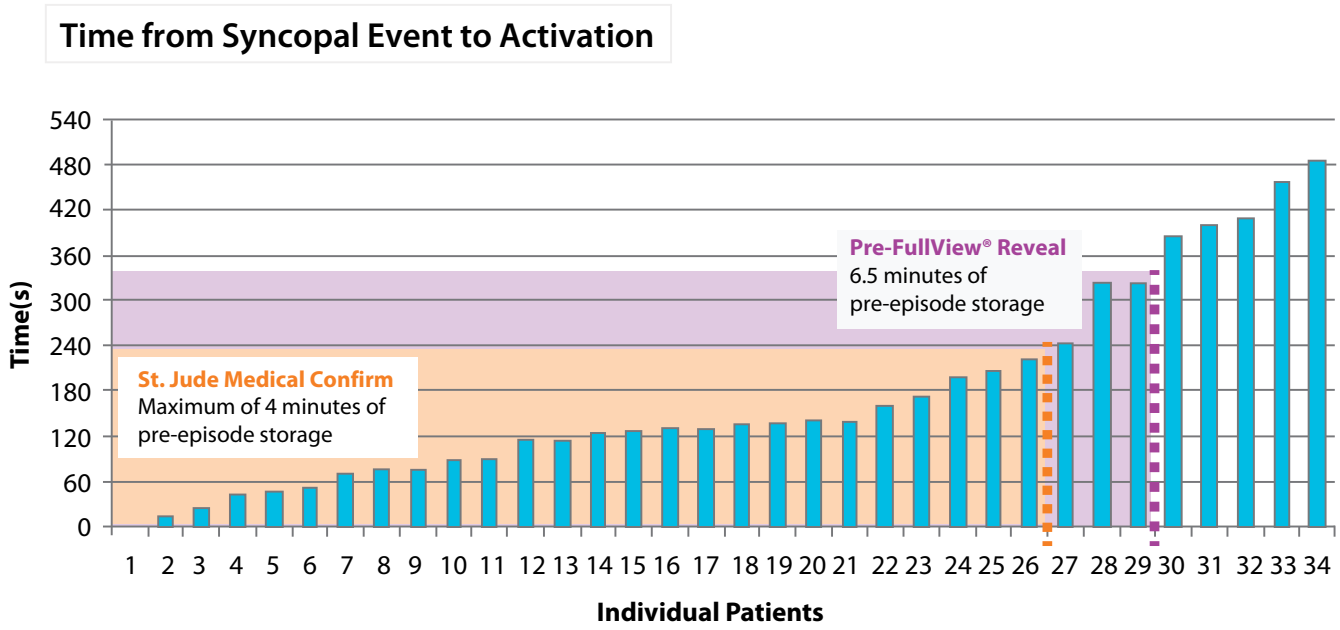

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Value of Increased and Flexible Patient-Activated Event Memory Storage

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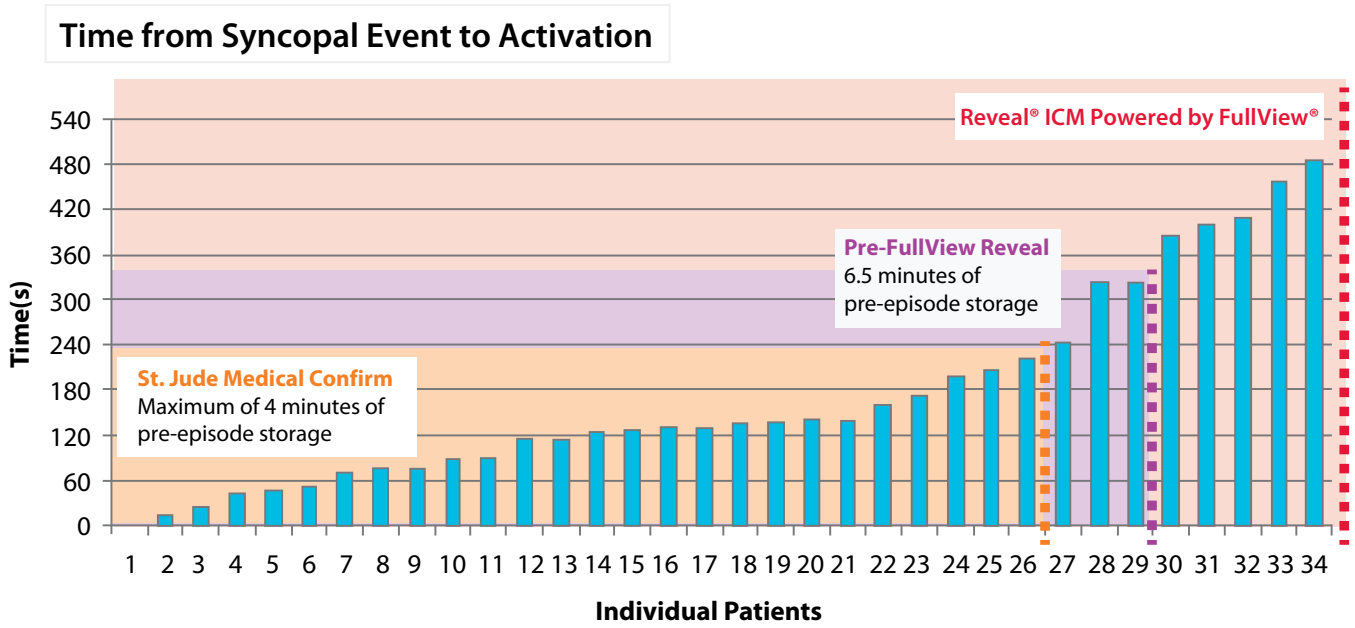

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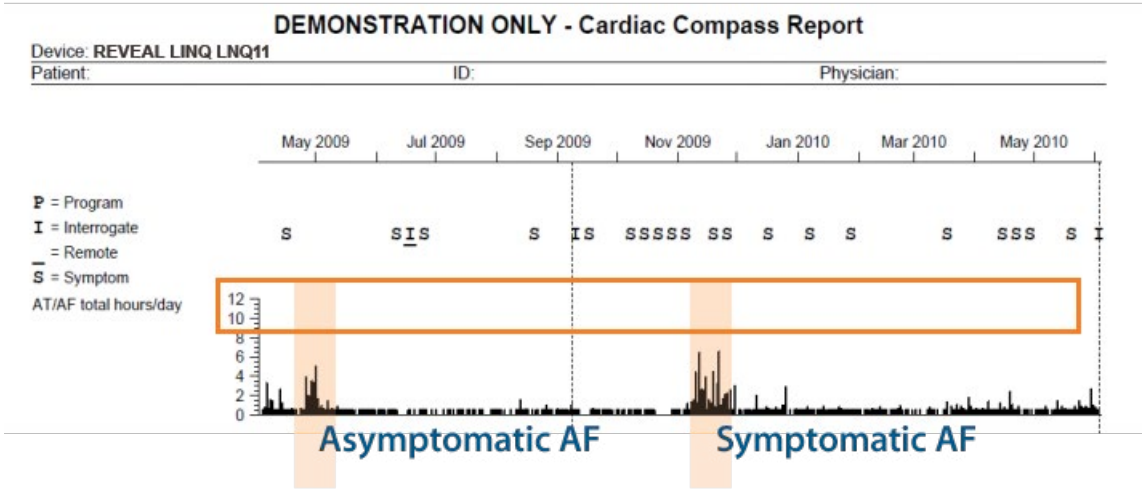
Customized Solutions

Patient-Activated Episodes Marked with "S" on Cardiac Compass®

To help correlate symptomatic events with other clinical data.



Automatic and Optimized Programming

Clinical Goal

Arrhythmia detection parameters can be set up automatically when patient's Date of Birth and clinician's Reasons for Monitoring are entered on the programmer during device setup.

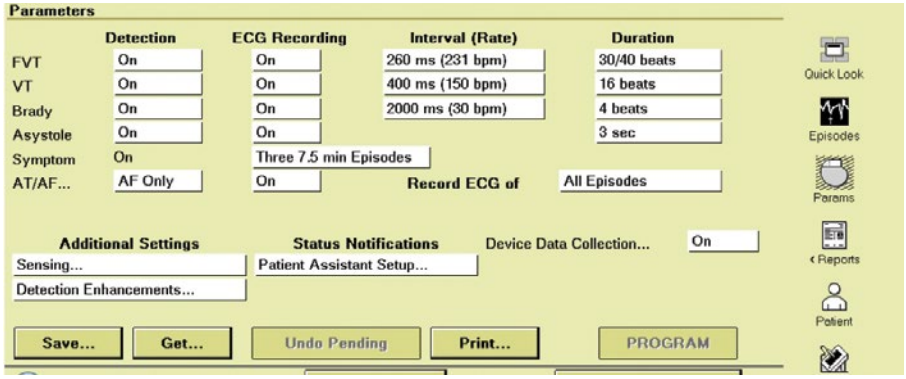
Reason for Monitoring: Programmed Value	Parameter			
	AF Detection Sensitivity	Ectopy Rejection	Episode Recorded Storage Threshold for AF Episode	Episode Priority
Syncope	Least	Aggressive	Longest AF Only	Pause, Tachy, Brady
Palpitations	Less	Nominal	≥ 6 min	Tachy, Pause, Brady
Seizures	Least	Aggressive	≥ 10 min	Pause, Tachy, Brady
Ventricular Tachycardia	Least	Aggressive	≥ 10 min	Tachy, Pause, Brady
Suspected AF	Less	Nominal	≥ 6 min	Tachy, Pause, Brady
AF Ablation Monitoring	Balanced	Nominal	All	Tachy, Pause, Brady
AF Management	Balanced	Nominal	All	Tachy, Pause, Brady
Cryptogenic Stroke	Balanced	Aggressive	All	Tachy, Pause, Brady
Other	Less	Aggressive	≥ 10 min	Pause, Tachy, Brady

Simplified Setup

Removed the following Programming options:

- ECG Recording ON/OFF
- VT Stability and Onset programming
- FVT Interval (Rate), FVT Duration (non-programmable)*

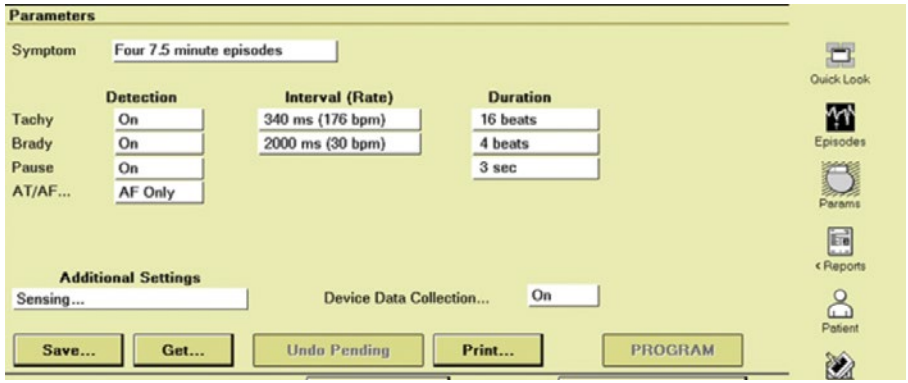
* **NOTE:** FVT zone fixed at 260 ms with NID 30/40



Reveal® XT ICM FullView®

Renamed:

- Asystole to "Pause"
- VT/FVT to "Tachy"



Reveal LINQ™ ICM

Detection/Termination Criteria

Episode Type	Detection	Termination
Pauses	No R-waves for *3 sec	12 R-waves
Tachy	*16 consecutive beats > programmed rate	8 consecutive beats slower than the detection rate
	FVT: non-Programmable 30/40 beats > 231 bpm (260 ms)	
Brady	*4 beats < *30 bpm (2,000 ms)	4 beats faster than the detection rate
AT/AF	Must be > recording threshold • Evaluate R-R intervals every 2 min	Evaluate R-R intervals every 2 min
Symptom	Patient Activation (button press) using their Patient Assistant	1 min post-activation

* Programmable parameters

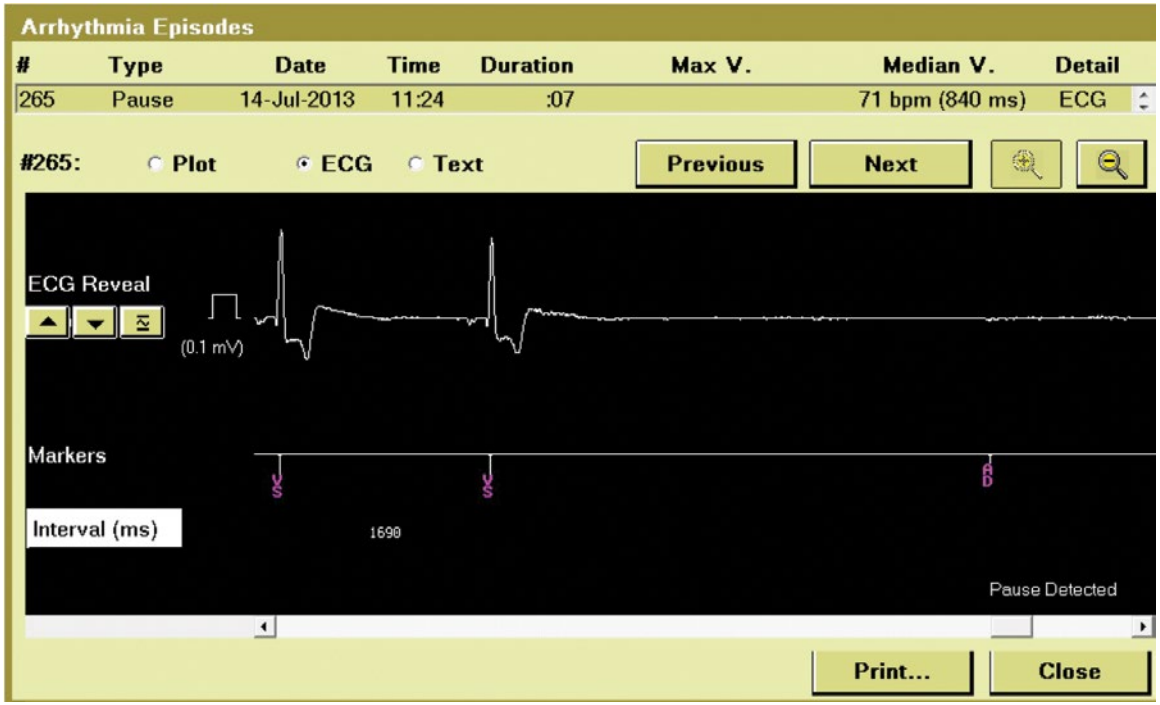
Pause | Tachy | AT/AF

Click on each one of these three options for more details.

Pause Detection

Clinical Goal

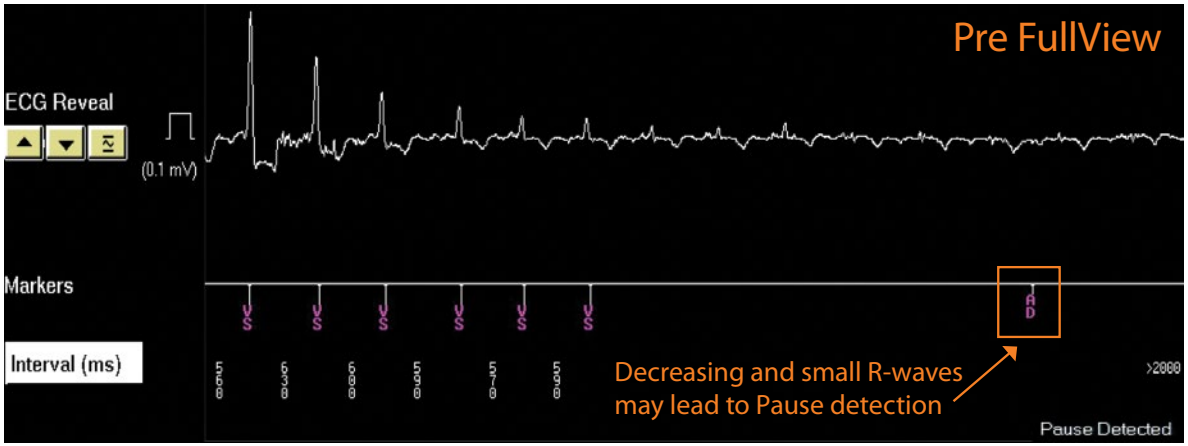
Reveal LINQ™ ICM's ability to continuously monitor if the patient's heart rhythm stops and no ventricular events are sensed for a programmable period of time.

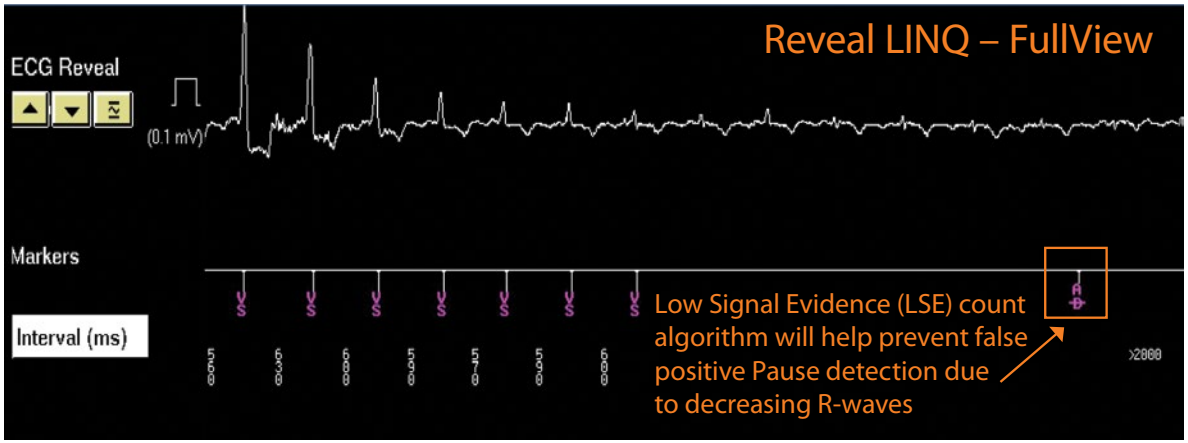


All patient and clinical data are fictitious and for demonstration purposes only.

Pause Detection

Detected Pause Due to Diminishing R-Waves: Identification and Rejection





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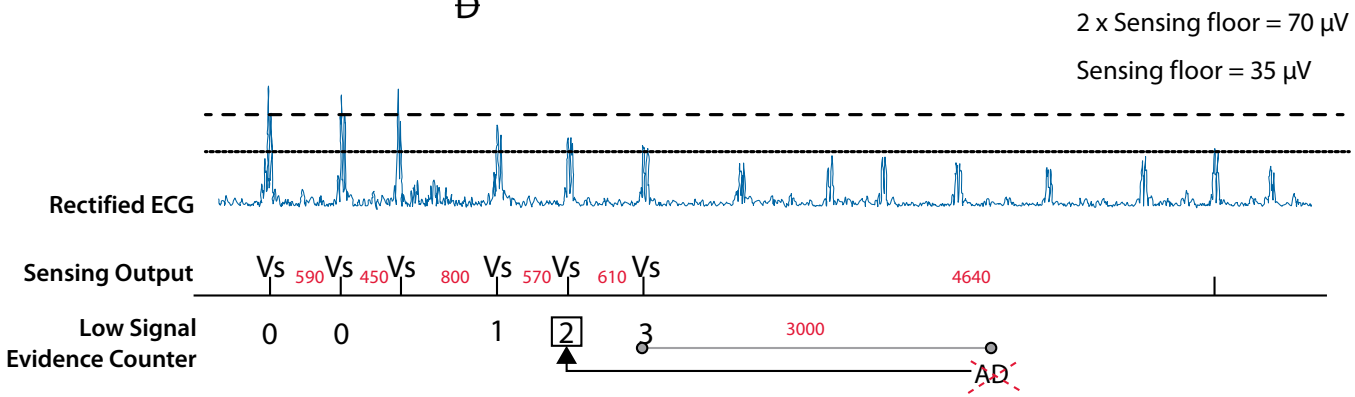
Detected Pause due to Diminishing R-Waves

Identification and Rejection Details

Reveal LINQ™ ICM's ability to distinguish between diminishing R-waves and a true asystolic pause.

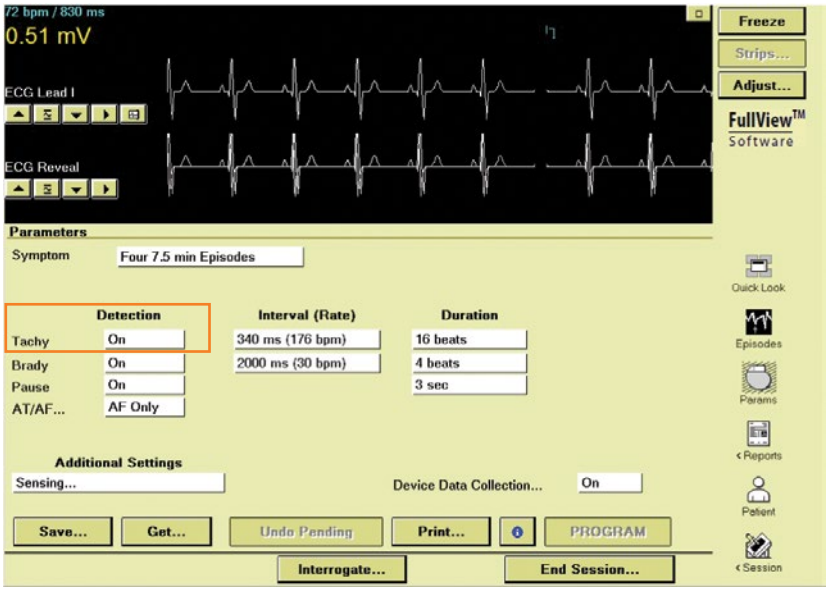
Algorithm identifies diminishing R-waves before detection:

- "Low Signal Evidence" counter is incremented by sensed R-waves prior to the pause which are < 2X the minimum sensing threshold, and decremented by signals above it
- Pause detection is rejected if the Low Signal Evidence > 0 on the beat before the long pause
- Pause reject-episode marker: $\frac{A}{\not{D}}$



Note: This algorithm is only active if sensing is programmed to 25, 35, or 50 µV

Tachy Detection

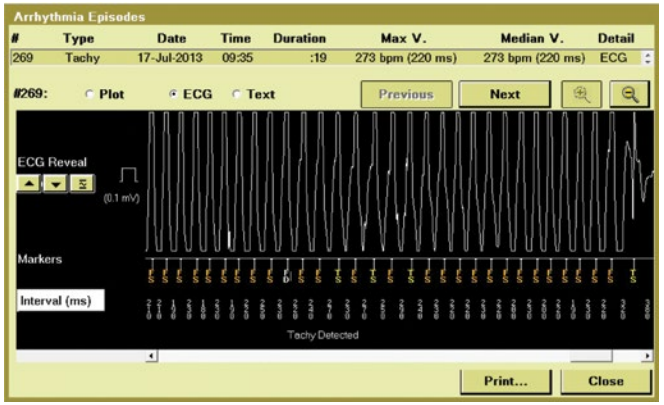


FVT Zone

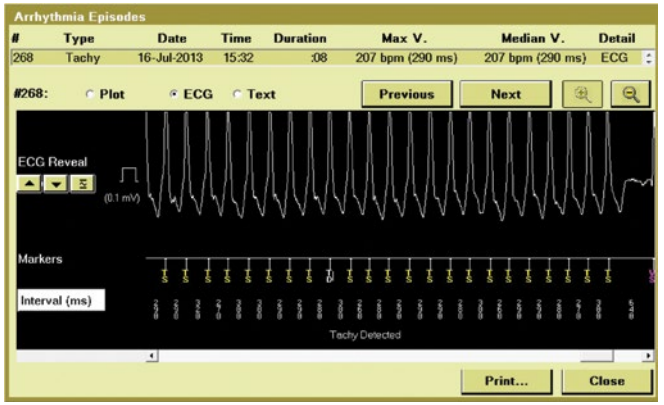
Non-programmable

Rate: > 231 bpm (260 ms)

Duration: 30/40 beats



FVT



VT

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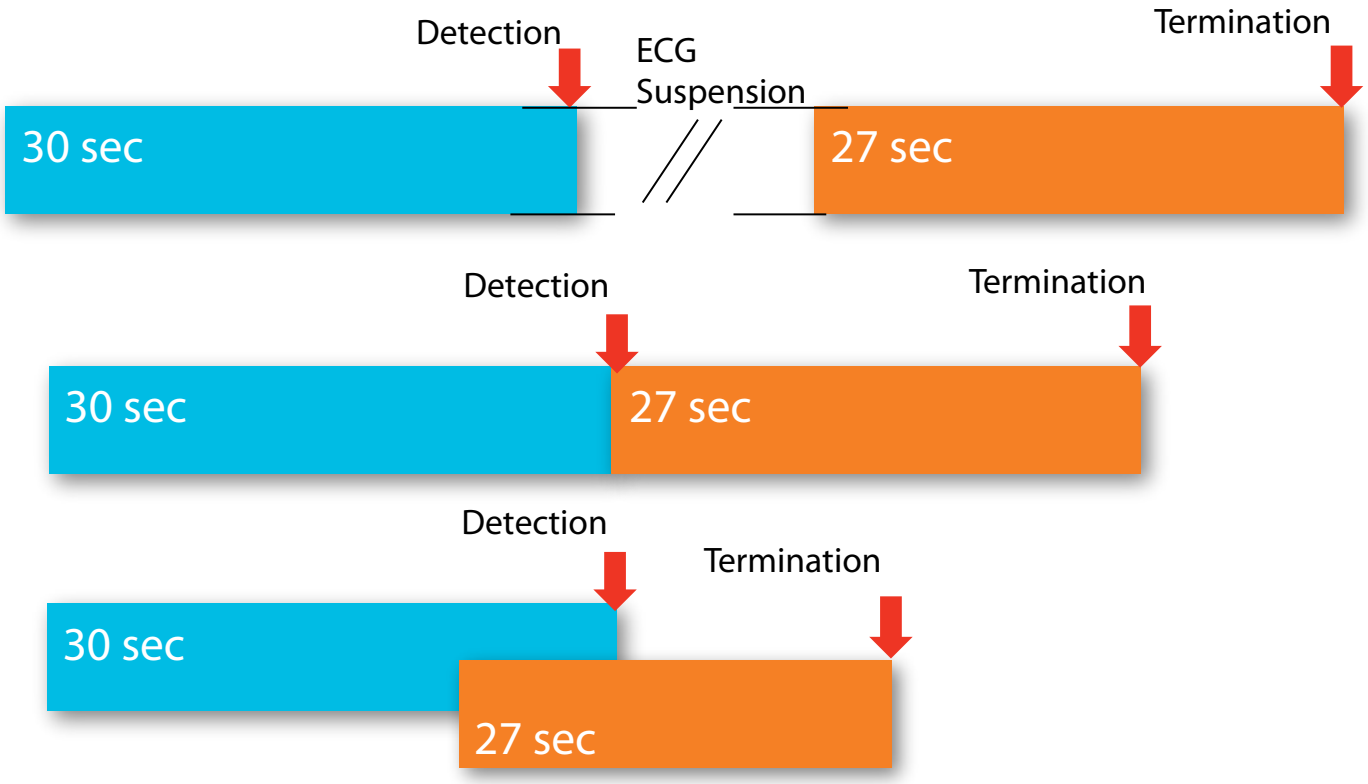
Detection/Termination Ventricular Episode Storage

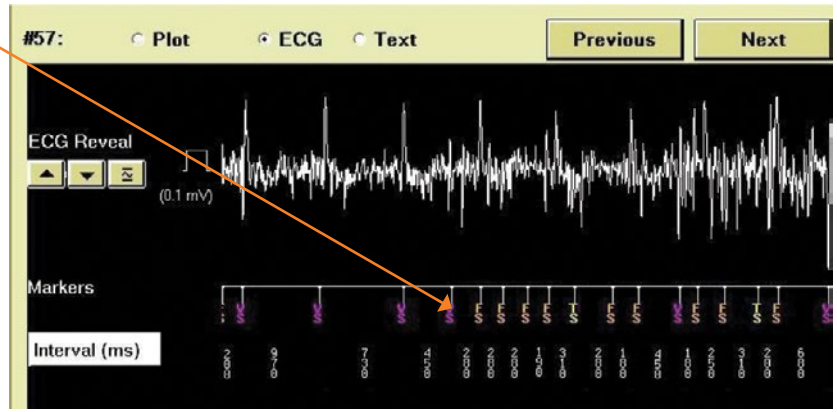


Tachy Detection – Noise Rejection Algorithm

Clinical Goal

Reveal LINQ™ ICM's ability to recognize and ignore noise that may trigger Tachy detection.

- 150 ms blanking only scheme



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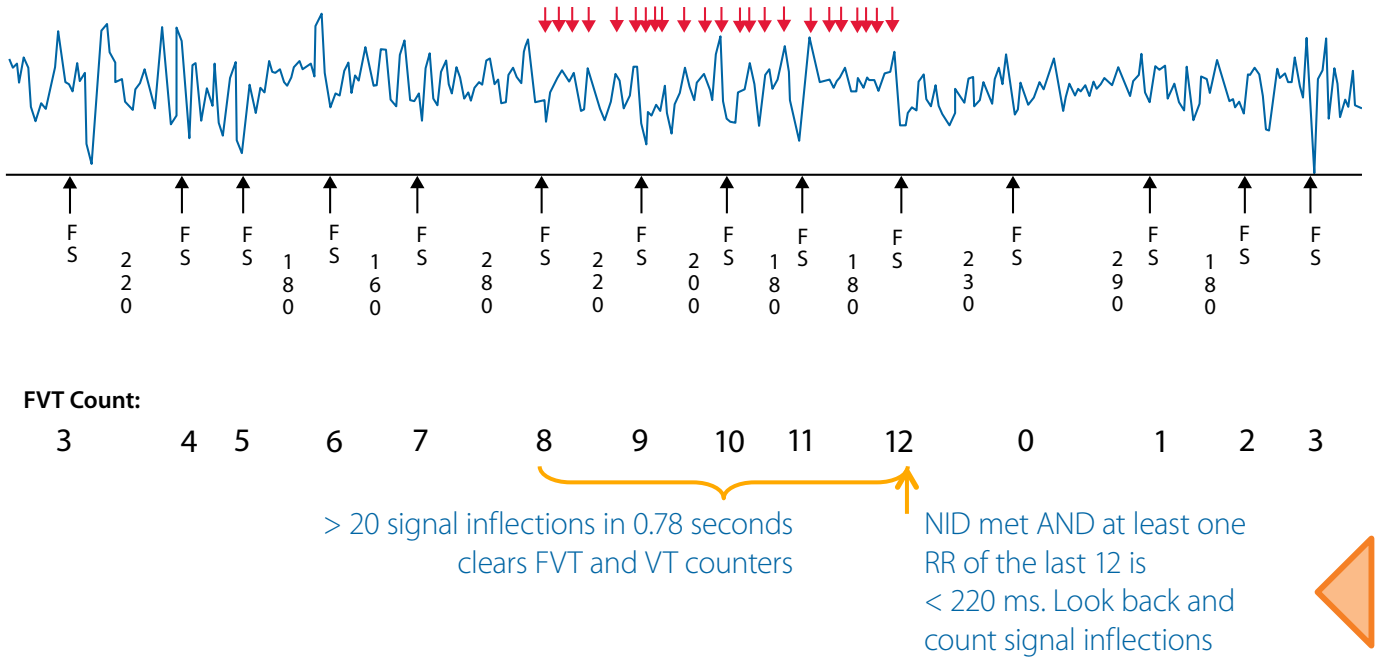
Tachy Detection – Noise Rejection Algorithm

Noise Rejection Algorithm

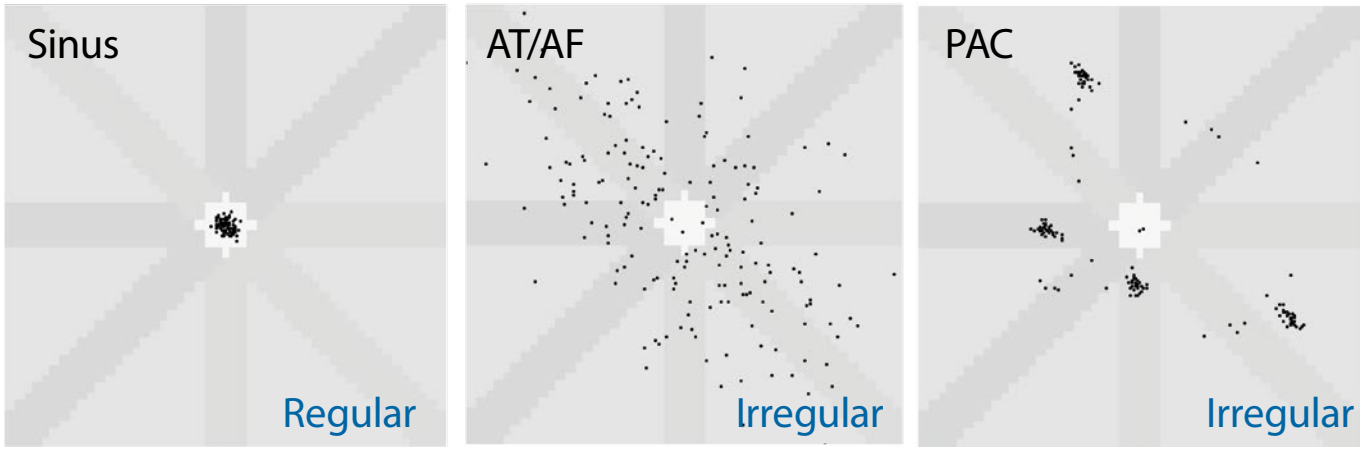
- At the FVT detection point, if at least one R-R is < 220 ms in the last 12 beats then Reveal LINQ™ ICM counts the number of signal deflections in the prior 0.78 seconds (> 20 signal inflections clears the FVT counters)
- Adds episode marker for FVT Rejection ($\frac{F}{\not{D}}$)



AF Detection

Clinical Goal

Specificity of AF detection through discrimination of true AF from other irregular rhythms.

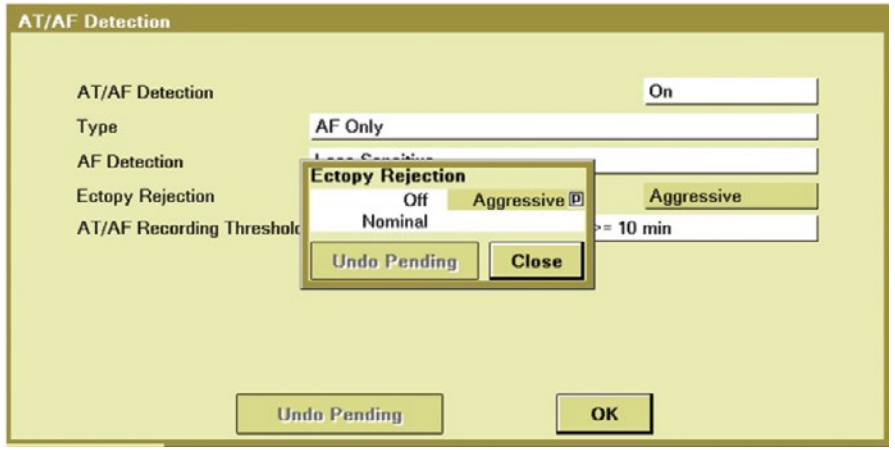


Two minute Lorenz Plots of RR intervals. Lorenz plots are a way to graphically represent correlation structures in an RR interval time series.

Overall Goal for AF Detection Enhancements

- Preserve AF burden accuracy
  - Preserve Sensitivity to AF detection
- Reduce episode review burden
  - Detection is optimized for accurate detection, fast and simple follow-up
  - Nominal programming based on patient type
  - Enhanced episode storage scheme

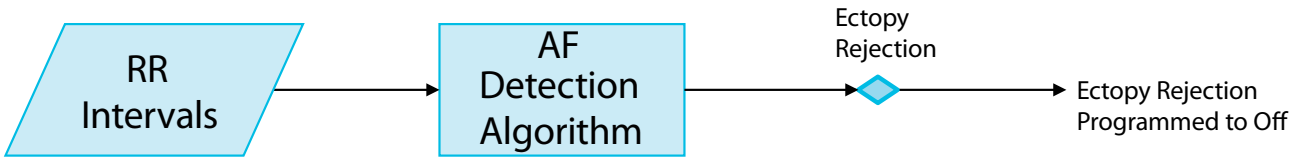
P-SENSE Detection Enhancement



The P-SENSE detection enhancement is programmed through the Ectopy Rejection.

Algorithm Enhancement

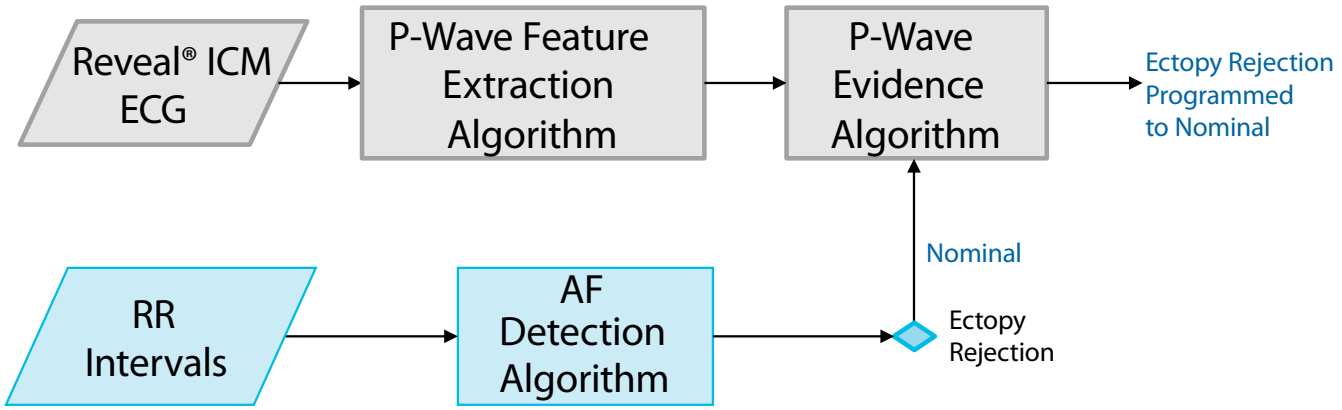
P-SENSE



NOTE: This is the current operation of the AF detection algorithm in Reveal® XT with FullView®.

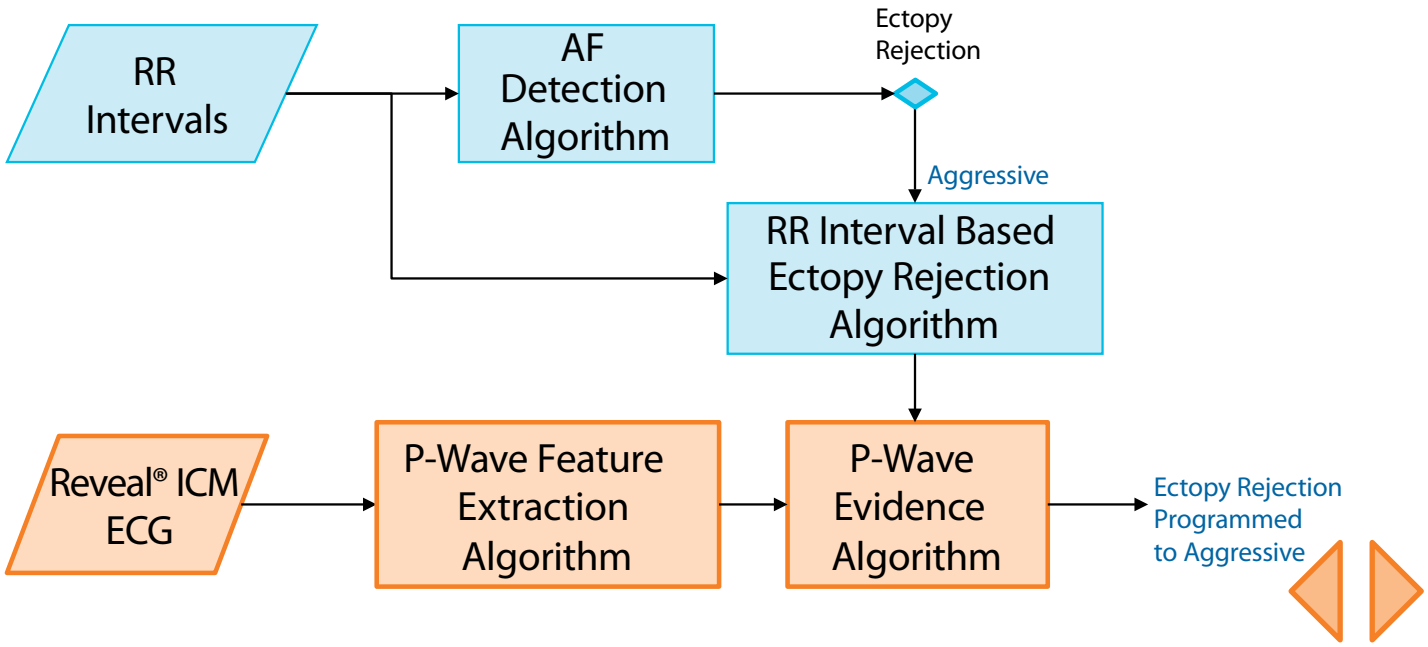
Algorithm Enhancement

P-SENSE

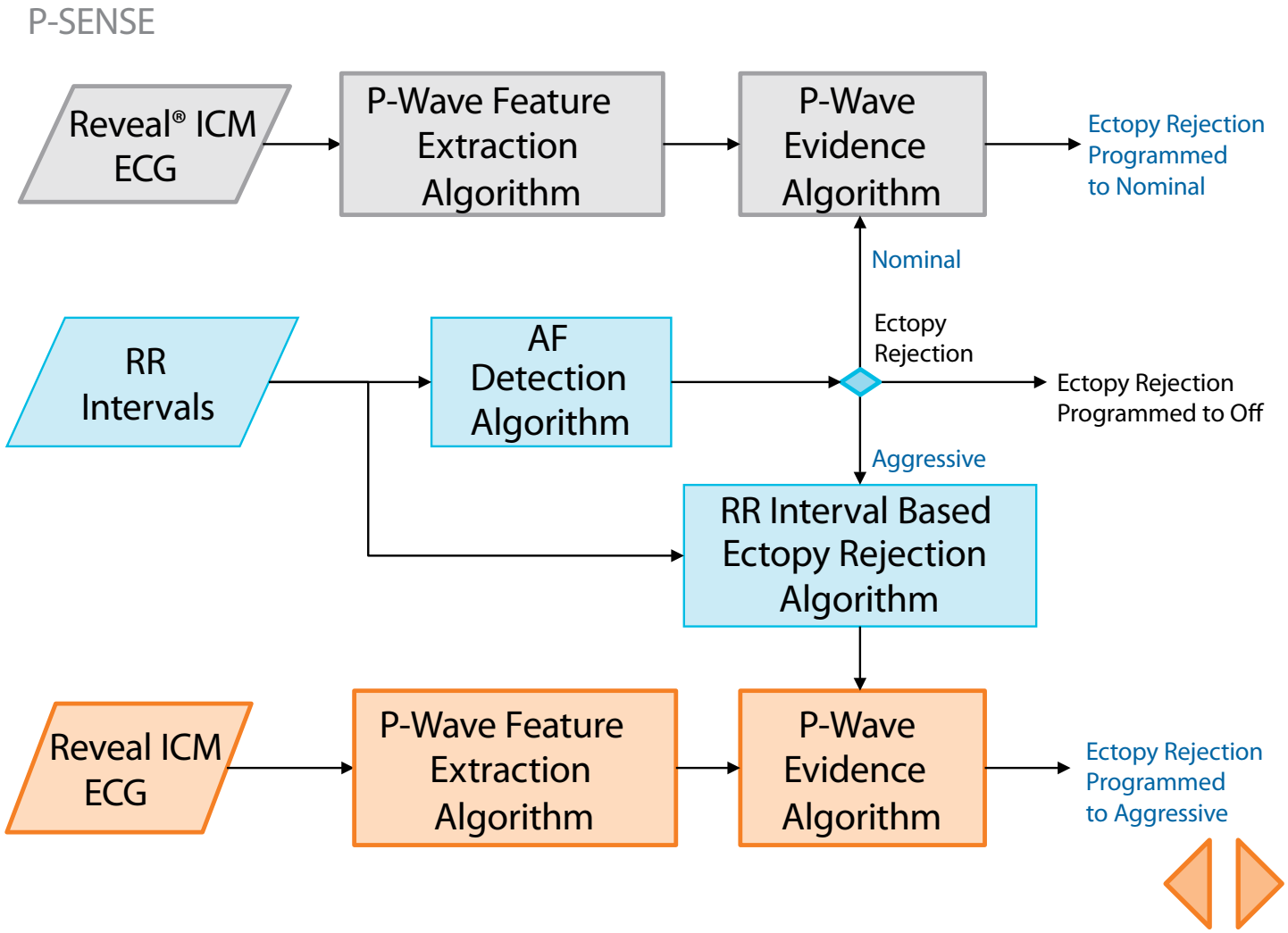


Algorithm Enhancement

P-SENSE

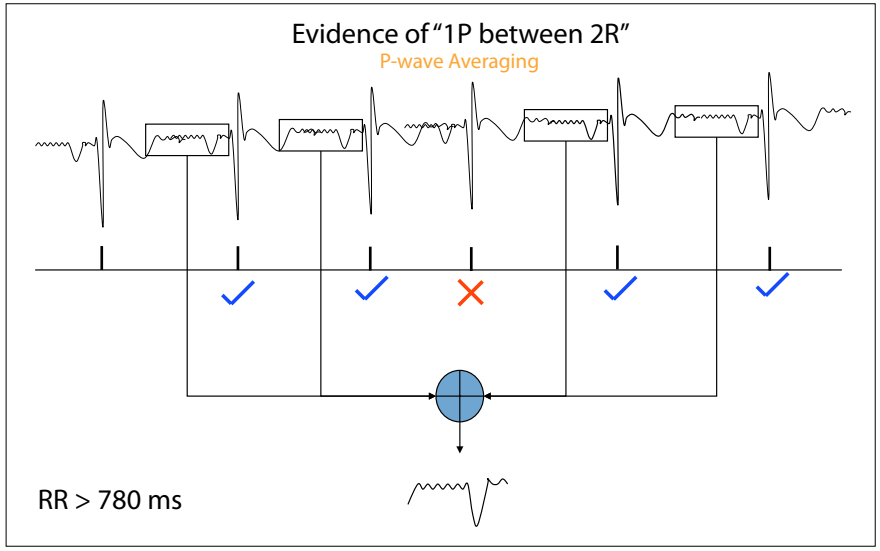


Algorithm Enhancement



P-SENSE Details

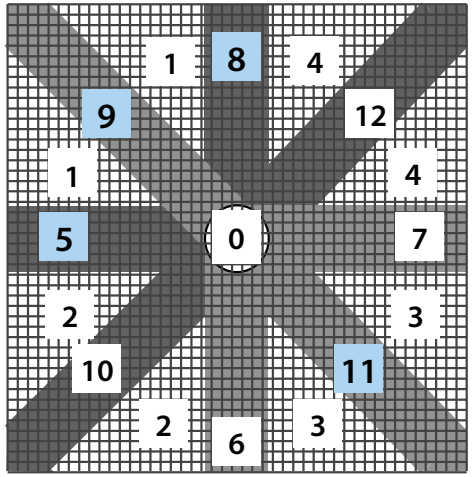
- P-wave feature extraction algorithm includes:
  - Averaging ECG for a set of 4 beats meeting rate and regularity criteria (dependent of ectopy rejection setting)
  - Identifying p-wave, atrial flutter waves, and noise from morphologic features of average ECG
  - Identifying p-wave evidence if there is one p-wave and absence of atrial flutter waves or noise

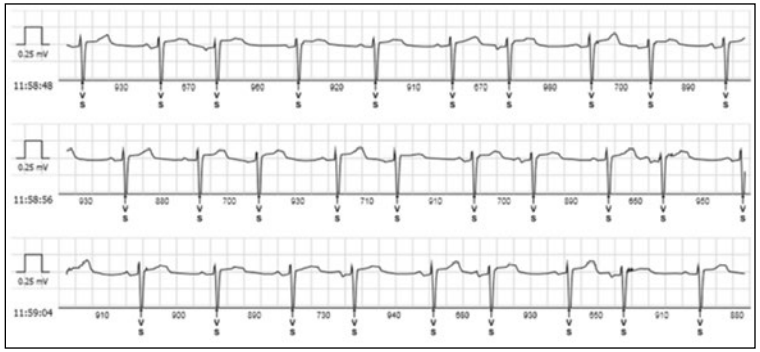


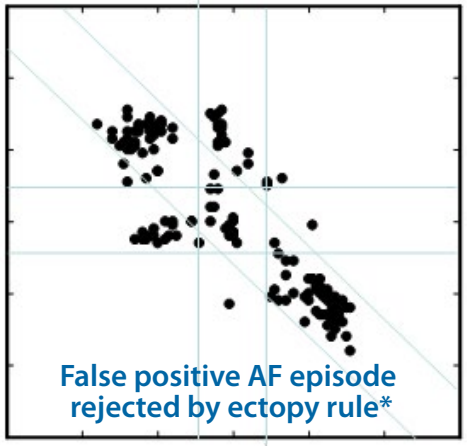
- P-wave evidence algorithm includes:
  - Accumulation of P-wave evidence over two-minute detection period
  - Reduction of AF evidence, computed from Lorenz plot based algorithm, by P-wave evidence prior to detection

RR Interval Based Ectopy Rejection Algorithm

- "Ectopy Rejector" better discriminates true AF episodes from episodes of bigeminy and trigeminy
- Runs of bigeminy or trigeminy (see ECG below) commonly translate into a density of points in segments 5, 9, 8, and 11 of the Lorenz plot
- AF will not be detected if the evidence of ectopy is great enough at the end of each two-minute detection window







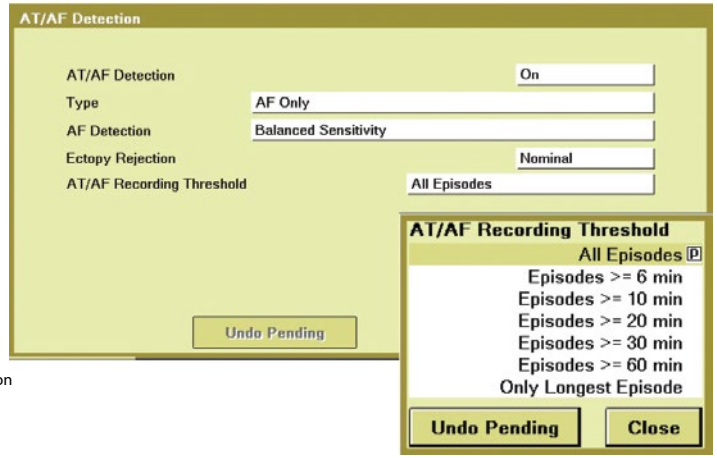
* Same Ectopy Rejection in FullView®.

AF Detection

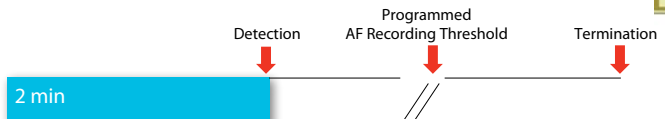
Enhanced Episode Storage Scheme

New: Longest AF Only storage option (default for syncope patients)

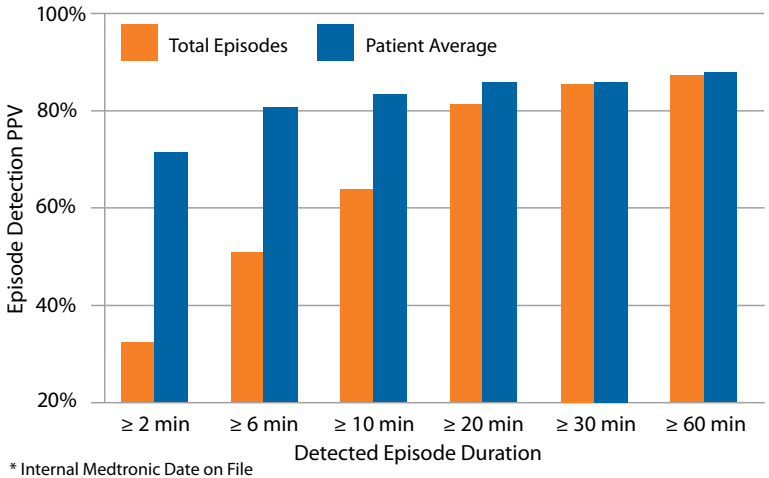
Only AF episodes that meet the minimum duration setting will create an AF log entry.



Atrial Episodes



Episode Detection PPV for AF Monitoring Setting (AF-only; Balanced Sensitivity; Ectopy Rejection Nominal) First 150 Patients from XPECT study*



* Internal Medtronic Date on File

Optimizing AF Detection

Purpose: Reduce burden of episode review

Reason for Monitoring: Programmed Value	Parameter			
	AF Detection Sensitivity	Ectopy Rejection	Episode Recorded Storage Threshold for AF Episode	Episode Priority
Syncope	Least	Aggressive	Longest AF Only	Pause, Tachy, Brady
Palpitations	Less	Nominal	≥ 6 min	Tachy, Pause, Brady
Seizures	Least	Aggressive	≥ 10 min	Pause, Tachy, Brady
Ventricular Tachycardia	Least	Aggressive	≥ 10 min	Tachy, Pause, Brady
Suspected AF	Less	Nominal	≥ 6 min	Tachy, Pause, Brady
AF Ablation Monitoring	Balanced	Nominal	All	Tachy, Pause, Brady
AF Management	Balanced	Nominal	All	Tachy, Pause, Brady
Cryptogenic Stroke	Balanced	Aggressive	All	Tachy, Pause, Brady
Other	Less	Aggressive	≥ 10 min	Pause, Tachy, Brady

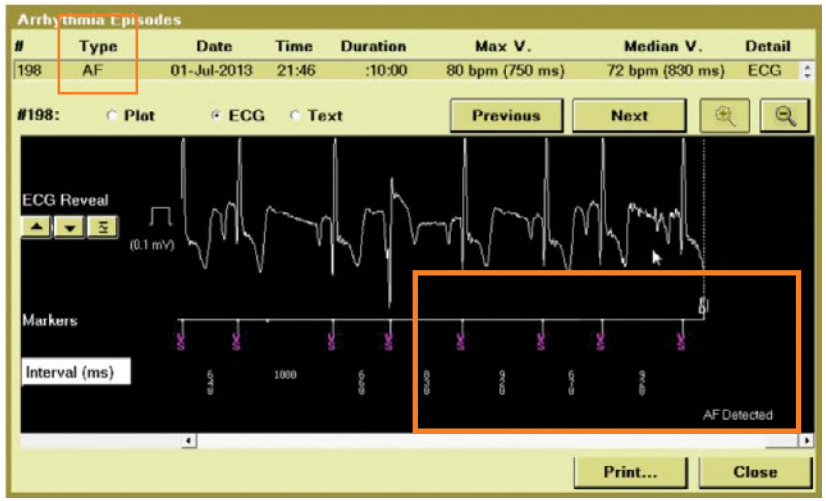
P-SENSE Performance

First 150 patients from XPECT study; 5,937 hours of Holter monitoring; 52 patients with 752 hours of AF in 303 episodes

	FullView® Nominal	AF Monitoring	AF Diagnosis	Non-AF
Duration Sensitivity (% of time of true AF detected)	98.0%	97.9%	97.6%	95.9%
Duration Specificity (% of time of non-AF not over-detected)	97.4%	98.8%	99.0%	99.5%
Duration PPV (% of time of detection being true AF)	84.4%	92.1%	93.5%	96.3%
Episode Sensitivity (% of true AF episodes detected)	91.8%	91.1%	90.8%	88.1%
Episode PPV (% of detected episodes with true AF)	66.6%	71.6%	73.2%	84.3%

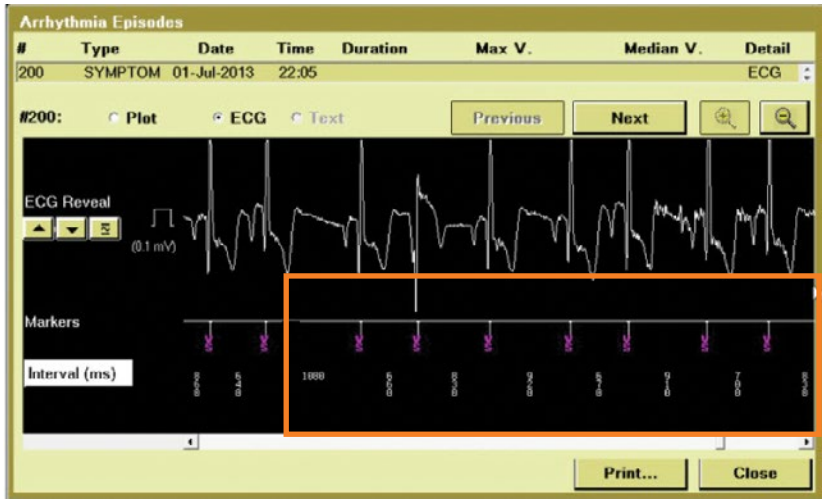
Improved Arrhythmia Detection

P-SENSE Performance Comparative Analysis



Reveal® XT

AF false positive episode detected based on R-R variability only (FullView® AF Detection algorithm)



Reveal LINQ™ ICM P-SENSE

Enhanced rhythm discrimination in the presence of R-R irregularity

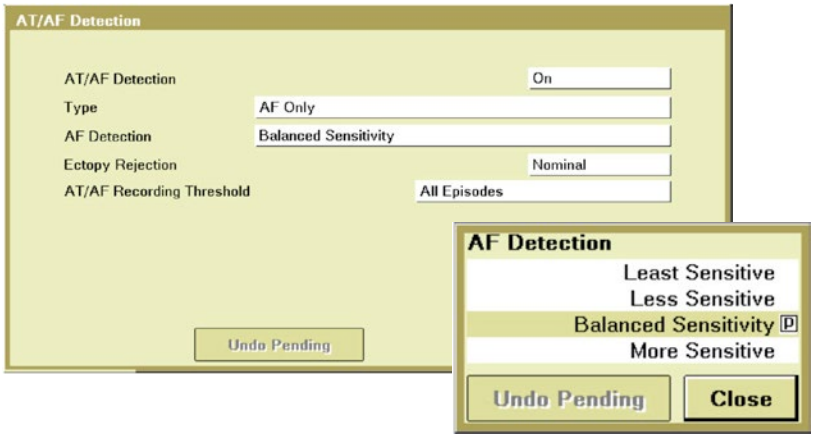
All patient and clinical data are fictitious and for demonstration purposes only.

Programming AT/AF Detection Parameters

AF Only Detection

To program AT/AF detection parameters:

1. Select Parameters
2. Select AT/AF Detection

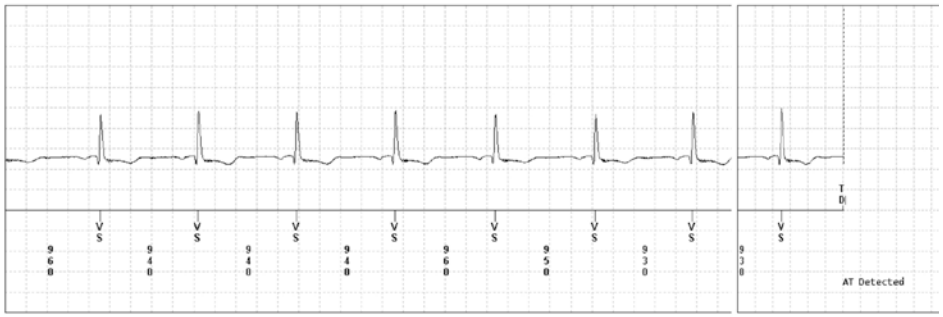


AT/AF Detection type in AF Only, AF Detection in Balanced Sensitivity, and Ectopy Rejection in Nominal setting will work best for the majority of patients. Medtronic recommends these settings for optimal atrial fibrillation burden detection.*
If false positives are noted in AF Only mode (for example: irregular sinus rhythm or sinus with frequent PACs), consider reprogramming detection to a less sensitive value, and Ectopy Rejection to "Aggressive".
If it is desired to increase sensitivity to detecting atrial fibrillation, consider reprogramming detection to a more sensitive value.

Only if it is suspected or known that the patient has atrial tachycardia or atrial flutter does Medtronic recommend programming AT/AF Detection type to ATAF for a short duration of time, and after diagnosis of AT reprogram back to AF Only mode.

* Burden is defined as the cumulative time in AT/AF. Time in AT/AF (Quick Look™ screen, Cardiac Compass®, and AT/AF Summary) will report total time of AF episodes when programmed to AF Only. When programmed to AT/AF time in AT/AF is reported as the combined total time of AT and AF episodes.

AT Detection



To discriminate very regular AT rhythms from very regular sinus rhythm, selectable lower rate cutoffs can be added to the "Detect Very Regular AT Rhythms" algorithm.

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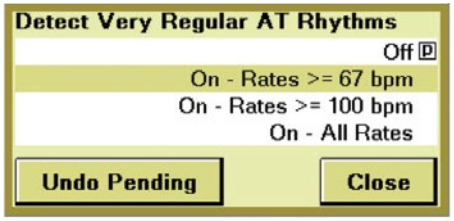
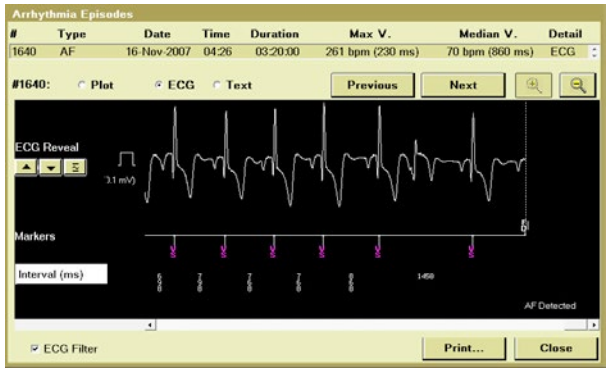
Consider the following if very regular sinus rhythms are being detected as AT:

- Intrinsic intervals > 900 ms program "On-Rates ≥ 67 bpm" *(see above ECG strip and intervals example)*
- Intrinsic intervals < 900 ms program "On-Rates ≥ 100 bpm"
- Intrinsic intervals < 600 ms program "Off"



AF False Positive Detection

Due to ectopy rhythms (i.e., sinus arrhythmia, PACs, PVCs, bigeminy, trigeminy)



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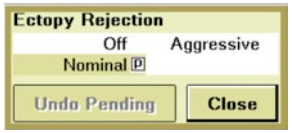
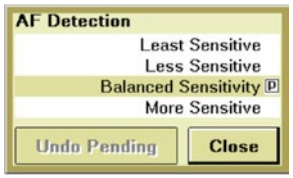
If false positive detections due to ectopy rhythms: Consider one, two, or all three options below:



1. If Ectopy Rejection is currently Off – consider programming to "Nominal"; If Ectopy Rejection is currently Nominal – consider programming to "Aggressive"

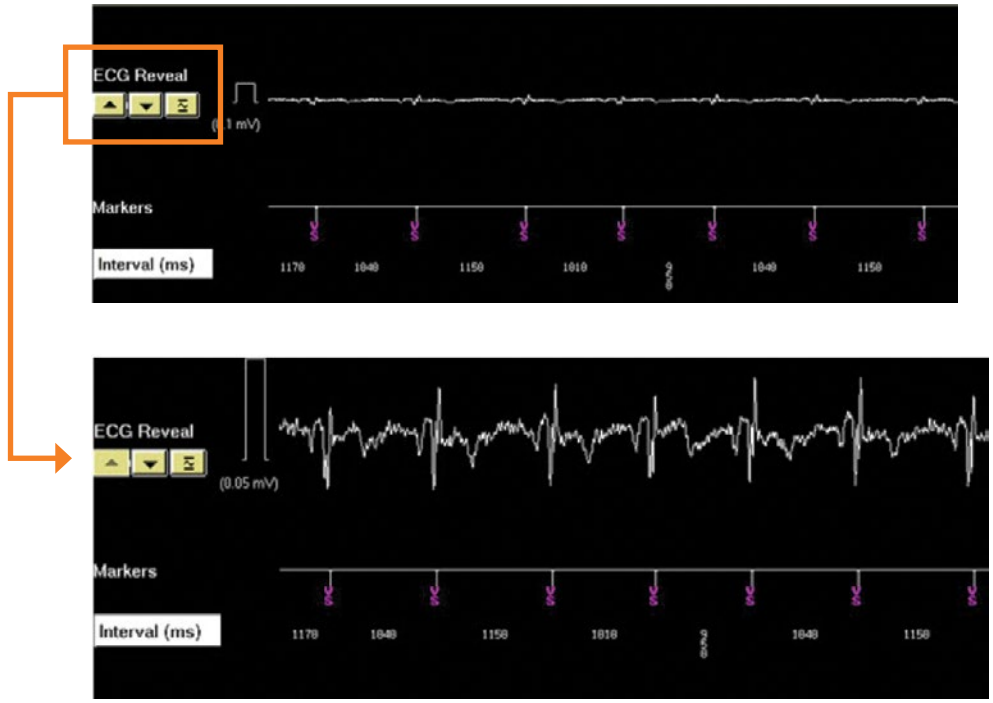
2. Program AT/AF ECG Recording Threshold to a longer ECG.



3. Consider programming AF Detection to "Less" or "Least" Sensitive.

Zoom Capability

- Zoom function to analyze stored ECGs at appropriate scale and amplitude
- Calibration pulse to quickly visualize R-wave signal amplitude/quality during stored ECG analysis
- P-Wave Zoom Capability



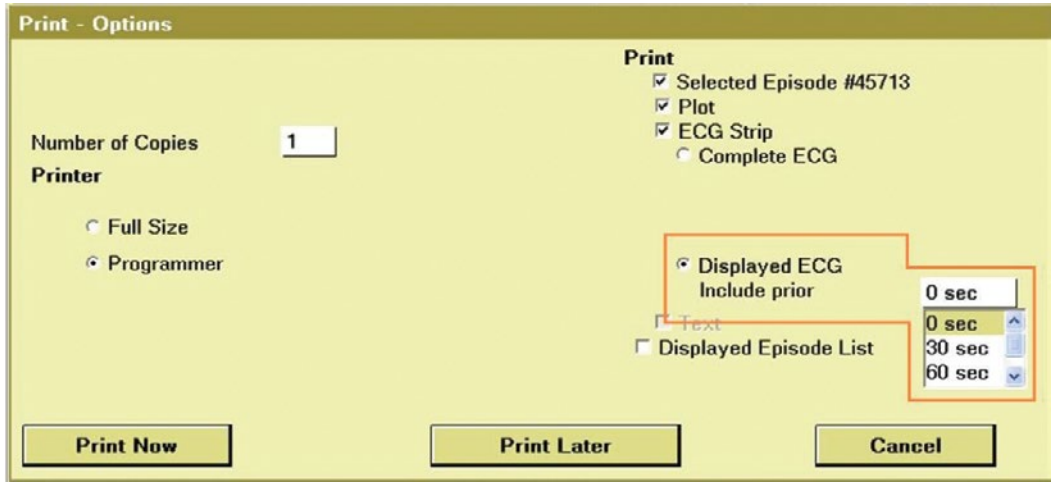
Note: ECG Gain ranges from ± 0.05mV to ± 2.0mV (with ± 0.5mV the default)

Flexible Printing Options

Clinical Goal

Flexibility in how much of a stored episode is printed from the 2090 Programmer (to alleviate too much, or too little, data being printed).

- Option allows you to print the "Displayed ECG" plus the prior 0, 30, 60 or 120 seconds for stored episodes



Note: This printing function is available for internal strip-chart-recorder, external printer and print to PDF file function.

Medtronic MyCareLink Patient Monitor and the Medtronic CareLink® Network are indicated for use in the transfer of patient data from Medtronic implantable cardiac devices. These products are not a substitute for appropriate medical attention in the event of an emergency. Data availability and alert notifications are subject to Internet connectivity and access, and service availability. The MyCareLink Patient Monitor must be on and in range of the device. Alert notifications are not intended to be used as the sole basis for making decisions about patient medical care.

Brief Statement

See the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events.

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