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Learning Objectives

- List the indications for insertable cardiac monitor (ICM)
- Describe implant programming
- Verbalize the components of the Sensing Consult found on the BIOTRONIK programmer
- Identify sensing status: normal sensing, over-sensing, and under-sensing
- List steps for troubleshooting potential BIOMONITOR sensing issues
- Verbalize the components of SmartECG

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This slide has a decorative background on the left side consisting of a series of vertical, wavy lines that create a sense of depth and movement. The main content is a list of learning objectives. The Biotronik logo and tagline are located in the bottom right corner.

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ICM Indications

ICM Indication Implant % (N=62, single center)	Diagnostic Finding	% Rhythm detected (N=62, single center)
Syncope (90.3%)	<ul style="list-style-type: none"> • AV conduction disorder • Sinus node disorder • Paroxysmal SVT • Atrial fibrillation 	19.6% 16.1% 7.1% 1.8%
Palpitations (8.1%)	<ul style="list-style-type: none"> • Atrial fibrillation 	100%
Ischemic Stroke (1.6%)	<ul style="list-style-type: none"> • Atrial fibrillation 	100%

Silveira I, Sousa MJ, Antunes N, Silva V, Roque C, Pinheiro-Vieira A, Lagarto V, Hipólito-Reis A, Luz A, Torres S. Efficacy And Safety Of Implantable Loop Recorder: Experience Of A Center. J Atr Fibrillation. 2016 Aug 31;9(2):1425. doi: 10.4022/jafib.1425. PMID: 27909534; PMCID: PMC5129687.



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BIOMONITOR IV

Indication-based Programming – Program Consult

The screenshot displays the BIOMONITOR IV software interface. At the top, there is a rhythm strip showing a regular sinus rhythm with a rate of 60 bpm and a mean amplitude of 1.53 mV. Below the rhythm strip, there are tabs for 'Diagnostics/Home Monitoring', 'Sensing', and 'Patient'. The 'Diagnostics/Home Monitoring' tab is active, showing a 'Send test message' button and a table with columns for 'Home Monitoring', 'Last message type', and 'Event message'. A 'Program sets' menu is open, listing various indications: Atrial fibrillation, Syncope, Tachycardia [bpm], Palpitations, Bradycardia [bpm], AF monitoring, Sudden rate drop [bpm], Cryptogenic stroke, Pause [s], Symptom, Resting rate period, Start resting period, and Resting period duration. The 'Program sets' option is highlighted with a red box. On the right side of the interface, there are several buttons: 'Follow-up', 'Parameters', 'Tests', 'Recordings', 'Diagnostics', 'Status', 'LiveSupport', 'More', 'Preferences', and 'End'.

*Please refer to BMIV Technical Manual for the full list of Indications

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BIOMONITOR IV

Indication-based Programming – Program Consult

- Program Consult nominal settings for:
 - Syncope
 - Palpitations
 - AF Monitoring
 - Cryptogenic Stroke

Parameter	Syncope	Palpitations	AF Monitoring	Cryptogenic Stroke
Atrial fibrillation (AF)	ON	ON	ON	ON
AF sensitivity	Low	Medium	Medium	Medium
RR variability limit [%]	12	12	12	12
Confirmation time [min]	10	6	6	2
Bigeminy rejection	Aggressive	Aggressive	Standard	Aggressive
Ectopy Rejection	ON	ON	ON	ON
AF transmission	ON	ON	ON	Detect only
Tachycardia	ON	ON	ON	ON
Tachy limit [bpm]	160	180	180	180
Tachy counter	16	32	48	48
Bradycardia	ON	ON	ON	ON
Brady zone limit [bpm]	35	30	30	30
Brady duration [s]	20	30	30	30
Sudden Rate Drop (SRD)	ON	OFF	OFF	OFF
SRD rate decrease [%]	50	-	-	-
SRD sensitivity	Low	-	-	-
Pause	ON	ON	ON	ON
Pause duration [s]	3	5	5	5

*Please refer to BMIV Technical Manual for the full list of Indications

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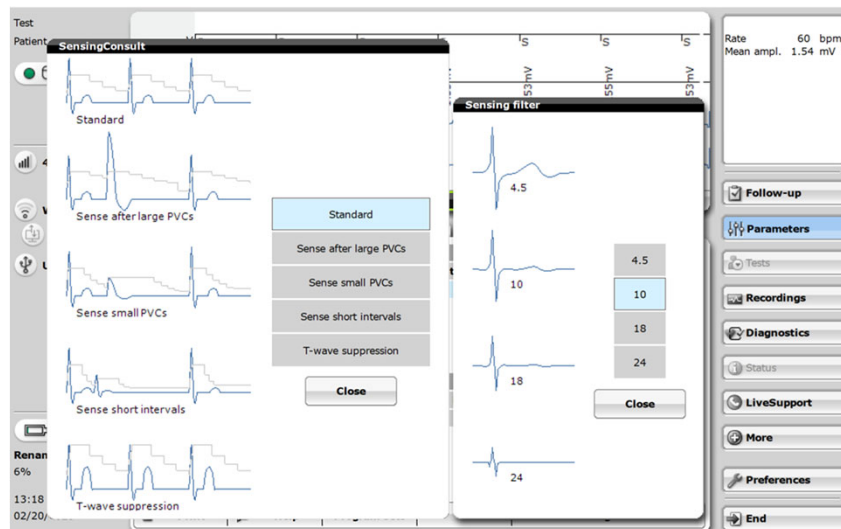
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Sensing and Troubleshooting

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Sensing Consult Overview



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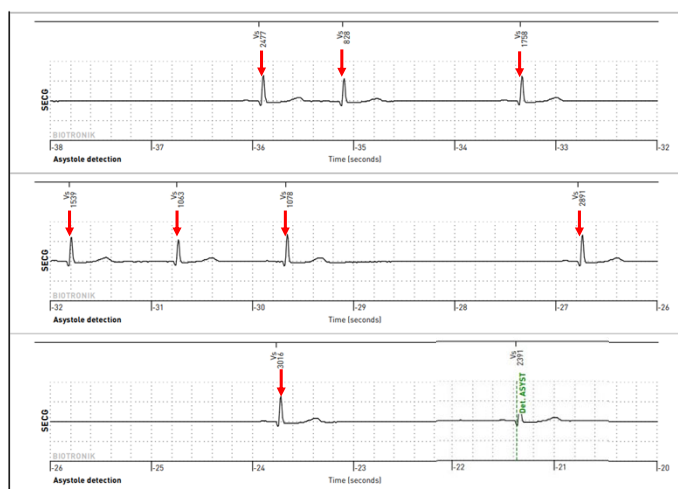
Evaluating Recordings for Appropriate Sensing and Triggers

Line up marker channels

- Is sensing appropriate?

Recording Trigger annotation

- What is the recording Trigger?



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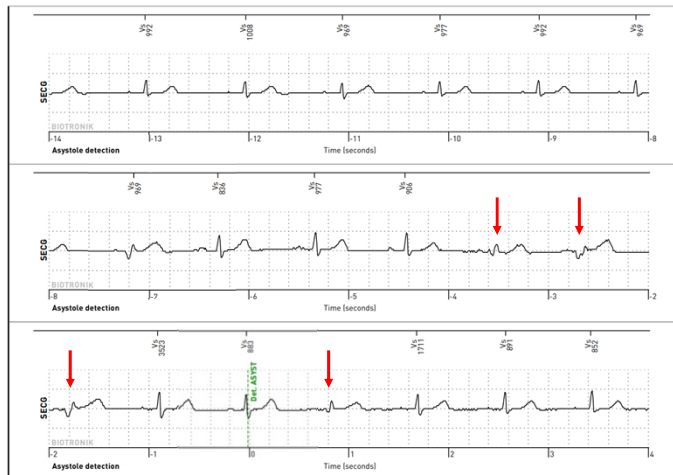
Evaluating Recordings for Appropriate Sensing and Triggers

Note the lack of a marker channel for the QRS

This is an example of:

- Under-sensing?
- Over-sensing?
- Normal sensing?

Under-sensing



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Evaluating Sensing Systematic Process

Event Data: Findings/Recordings

- What is the episode trigger?
- Is sensing appropriate?
- Was the recording a true event or a false positive?
- Suggested device re-programming if applicable
 - **Sensing Consult**



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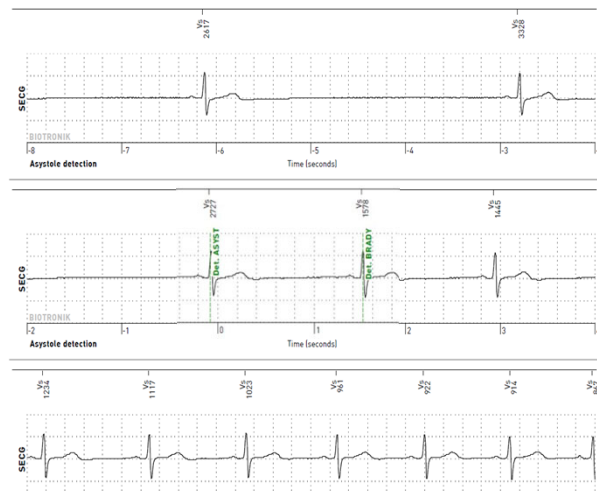
10

Case Study #1

Event Data: Findings/Recordings

- What is the episode trigger?
- Is sensing appropriate?
- Was the recording a true event or a false positive?
- Suggested device re-programming if applicable
 - **Sensing Consult**

Conclusion: Normal sensing true Asystole and Bradycardia episode



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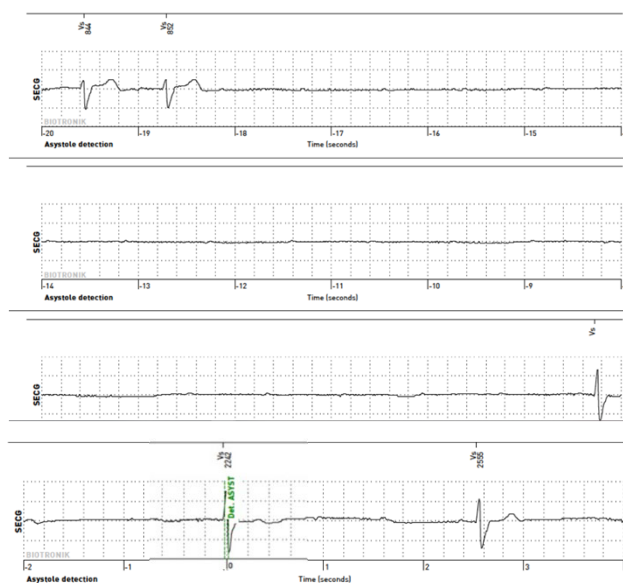
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Case Study #2

Event Data: Findings/Recordings

- What is the episode trigger?
- Is sensing appropriate?
- Was the recording a true event or a false positive?
- Suggested device re-programming if applicable
 - **Sensing Consult**
 - **Event trigger criteria**

Conclusion: Normal sensing true Asystole episode



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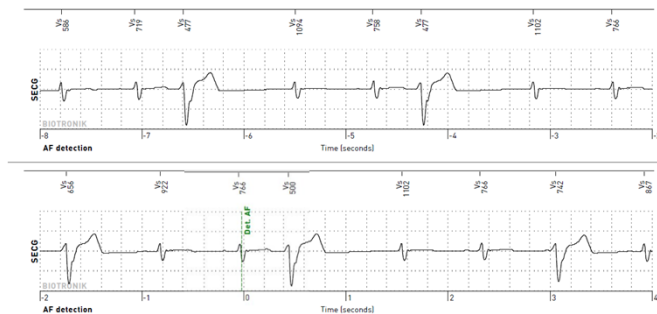
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Case Study #3

Event Data: Findings/Recordings

- What is the episode trigger?
- Is sensing appropriate?
- Was the recording a true event or a false positive?
- Suggested device re-programming if applicable
 - **Sensing Consult**

Conclusion: False positive detection for AF due to PVCs



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Case Study #3

Programming Recommendations

BIOMONITOR IV

- Bigeminy rejection
 - Change to Aggressive
- RhythmCheck-Ectopy Rejection
 - 72% reduction in false positive AF detections due to ectopy¹

Trigger type	Detection	Recording	Transmission
Atrial fibrillation	Atrial fibrillation (AF)	ON	OK
Tachycardia [bpm]	AF sensitivity	Medium	
Bradycardia [bpm]	RR variability limit [%]	12	Cancel
Sudden rate drop [%]	Confirmation time [min]	6	
Symptom	Bigeminy rejection	Standard	Help
Resting rate period	Ectopy rejection	ON	

1. BIOTRONIK Data on file: Performance of BIOMONITOR IIIIm Ectopy Rejection Parameter in Patients with Ectopy.



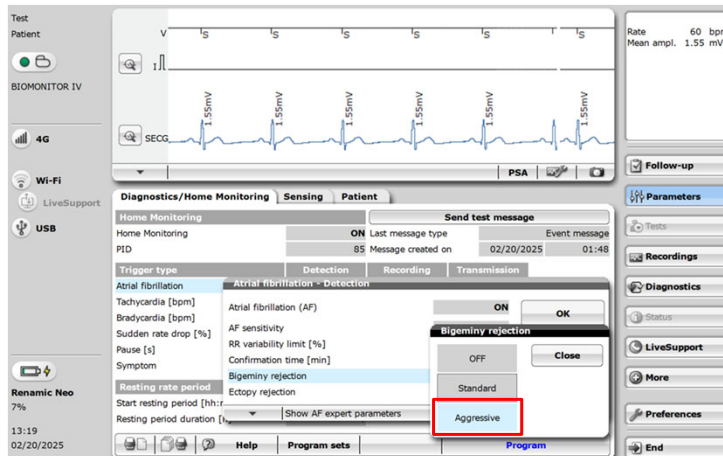
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Case Study #3

Programming Recommendations

BIOMONITOR IV

- Bigeminy rejection
 - Change to Aggressive
- RhythmCheck-Ectopy Rejection
 - 72% reduction in false positive AF detections due to ectopy¹



1. BIOTRONIK Data on file: Performance of BIOMONITOR IIIIm Ectopy Rejection Parameter in Patients with Ectopy.



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Case Study #4

Event Data: Findings/Recordings

- What is the episode trigger?
- Is sensing appropriate?
- Was the recording a true event or a false positive?
- Suggested device re-programming if applicable
 - **Sensing Consult**

Conclusion: Under-sensing small PVCs



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Case Study #4

Programming Recommendations

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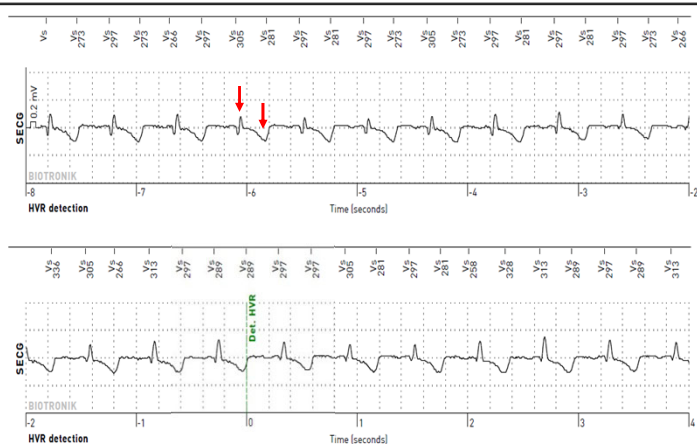
Case Study #5

Event Data: Findings/Recordings

- What is the episode trigger?
- Is sensing appropriate?
- Was the recording a true event or a false positive?
- Suggested device re-programming if applicable
 - **Sensing Consult**
 - **Sensing filter [Hz]**

Conclusion: T-wave oversensing

Last received episode: High ventricular rate (Nov 11, 2020 8:51:26 PM)



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Case Study #5

Programming Recommendations

The screenshot shows the 'SensingConsult' window with the following elements:

- Left Panel:** Patient information (BIOMONITOR IV, 4G, Wi-Fi, LiveSupport, USB) and device status (Renamic Neo).
- Top Right:** Rate: 60 bpm, Mean ampl.: 1.54 mV.
- Center:** Five ECG traces labeled: Standard, Sense after large PVCs, Sense small PVCs, and Sense short intervals.
- Right Panel:** A list of sensing options: Standard, Sense after large PVCs, Sense small PVCs, Sense short intervals, and T-wave suppression (highlighted with a red box). A 'Close' button is at the bottom.
- Bottom Right:** A vertical menu with buttons for Follow-up, Parameters, Tests, Recordings, Diagnostics, Status, LiveSupport, and More.



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Case Study #5

Programming Recommendations

The screenshot shows the 'Sensing filter' window with the following elements:

- Left Panel:** Patient information (BIOMONITOR IV, 4G, Wi-Fi, LiveSupport, USB) and device status (Renamic Neo).
- Top Right:** Rate: 60 bpm, Mean ampl.: 1.54 mV.
- Center:** Four ECG traces labeled: 4.5, 10, 18, and 24.
- Right Panel:** A list of sensing filter options: 4.5, 10, 18 (highlighted with a red box), and 24. A 'Close' button is at the bottom.
- Bottom Right:** A vertical menu with buttons for Follow-up, Parameters, Tests, Recordings, Diagnostics, Status, LiveSupport, and More.



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Sensing Algorithm-Troubleshooting Guidelines

APS Troubleshooting suggestions

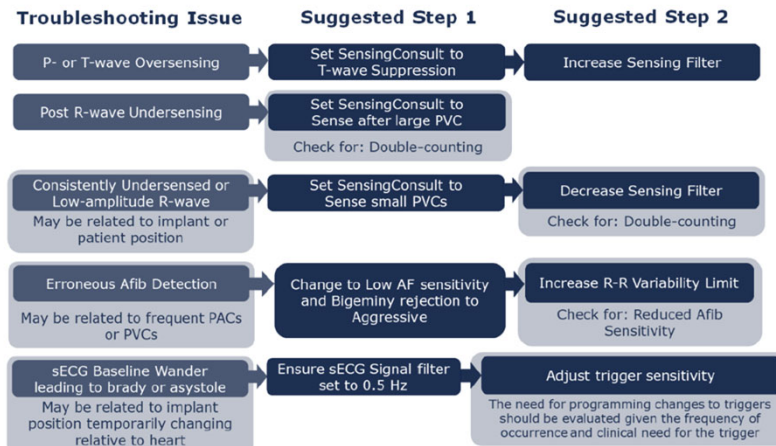


Figure 1. Troubleshooting suggestions and guidelines



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SmartECG: How does it work?

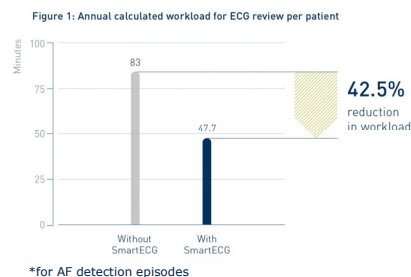


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BIOMONITOR IV: SmartECG with Artificial Intelligence* and Advanced Algorithms to Focus on Actionable Data

Cloud-based computing feature

- Reduced false positive episodes across all major arrhythmia types by 86%¹
- Reduced ECG review workload by 42.5%²
- Evaluates each transmitted episode
- Trigger alerts for only true events and displays in the Home Monitoring Service Center
- Provides **all** transmitted episodes in the Home Monitoring Service Center to clinicians for full disclosure (programmable)



1. Data on file. Sensitivity and specificity provided is relative to performance without SmartECG.
 2. Bisignani G, Cheung JW, Rordorf R, et al. Implantable cardiac monitors: artificial intelligence and signal processing reduce remote ECG review workload and preserve arrhythmia detection sensitivity. Front Cardiovasc Med. 2024;11:1343424. Published 2024 Jan 23. doi:10.3389/fcvm.2024.1343424.



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SmartECG

What is it?

SmartECG is an advanced algorithm that incorporated Artificial Intelligence (AI) for AF that works on the HMSC.

What are the benefits?

Designed to improve workflows for clinicians by reducing the number of false positives.



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The Purpose Of SmartECG

SmartECG runs on HMSC, and:

- Applies AI technology and advanced algorithms to **reduce false positives***
- Allows customers to focus only on the **actionable** data



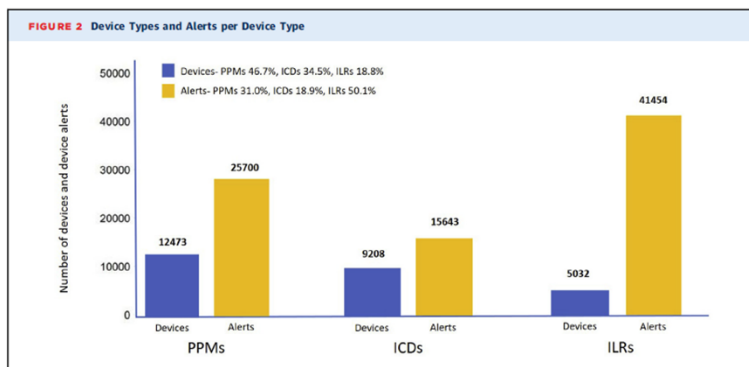
* For AF only

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The Purpose Of SmartECG

FIGURE 2 Device Types and Alerts per Device Type



From this study on more than 26,000 patients across all device manufacturers¹:

- ILRs are responsible for the **highest** number of alerts/episodes
- From other publications, we know that around **50-70%** of these are false positives^{2,3}

SmartECG is designed to **reduce** false positive alerts, helping customers **reduce their workload and review burden.**

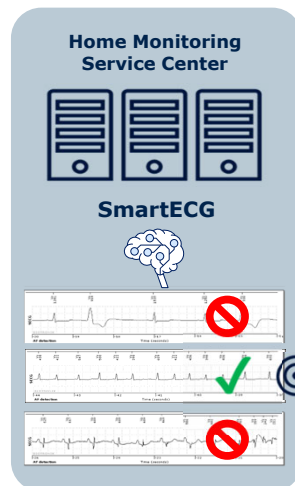
1 – O’Shea CJ, Middeldorp ME, Hendriks JM, et al. Remote Monitoring Alert Burden: An Analysis of Transmission in >26,000 Patients. JACC Clin Electrophysiol. 2021;7(2):226-234. doi:10.1016/j.jacep.2020.08.029
 2 – O’Shea CJ, Middeldorp ME, Hendriks JM, et al. Remote Monitoring of Implantable Loop Recorders: False-Positive Alert Episode Burden. Circ Arrhythm Electrophysiol. 2021;14(11):e009635. doi:10.1161/CIRCEP.121.009635
 3 – Afzal et al. Incidence of false-positive transmissions during remote rhythm monitoring with implantable loop recorders, <https://doi.org/10.1016/j.hrthm.2019.07.015>

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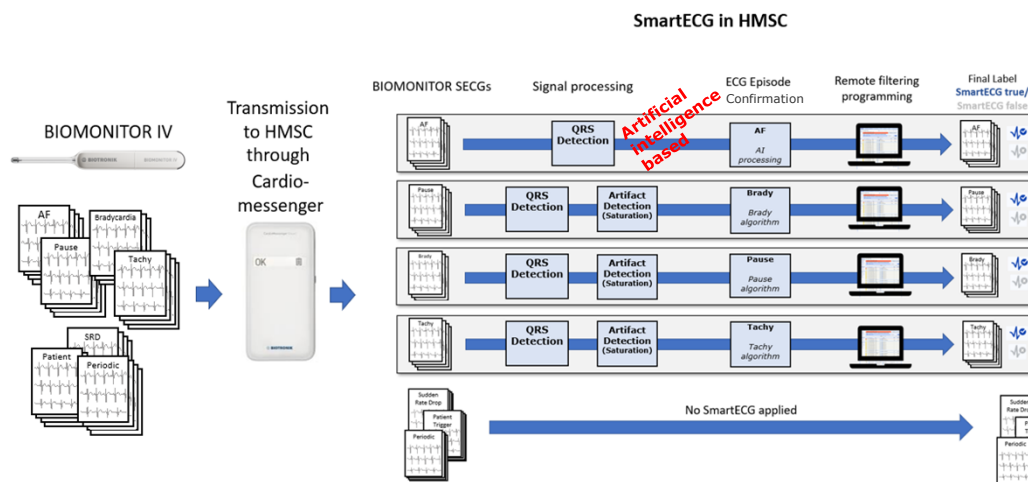
What episode-types are filtered by SmartECG?

- AF (with AI-based processing)
 - Pause*
 - Bradycardia
 - Tachycardia*
- *For BIOMONITOR IV, Pause and Tachycardia replace Asystole and HVR from previous BIOMONITOR generations.



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SmartECG: Big Picture

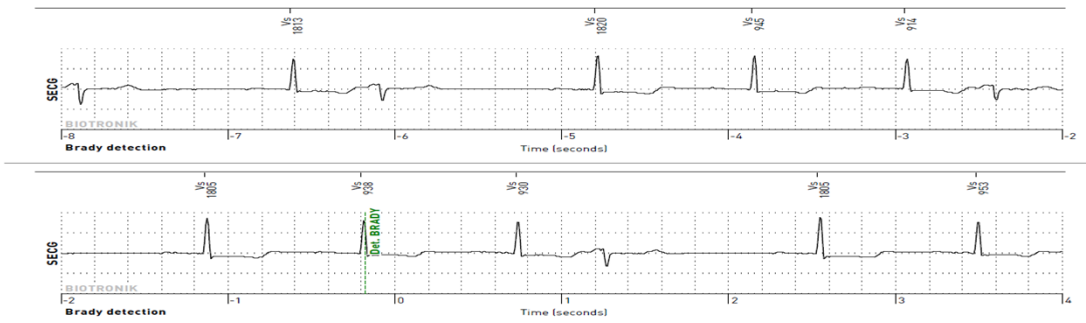


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SmartECG

How does it work?

Step 1: Recording from implanted device sent to the HMSC



Brady Episode detected due to under-sensing of small QRS complexes



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SmartECG

How does it work?

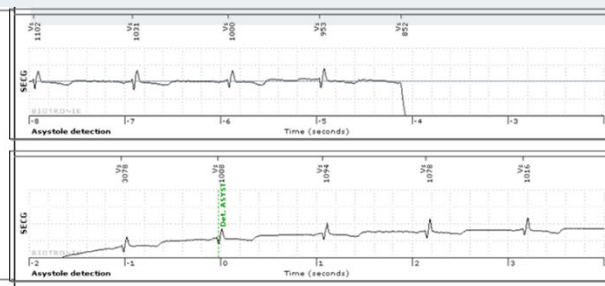
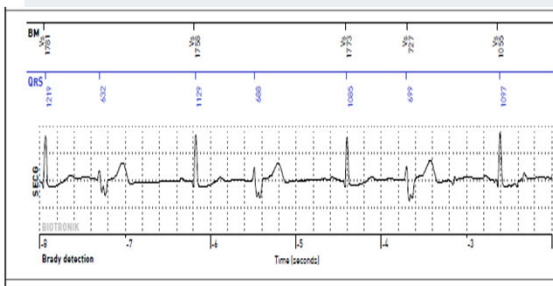
Step 2: SmartECG redetects QRS and applies Artifact detection

QRS Redetection

- Better recognition of smaller amplitude QRS peaks
SmartECG markers in blue
Device markers in grey

Artifact Detection

- Detects SECG segments showing signal loss (due to signal saturation) in order to reduce false detection. This phase applies to Brady, Pause, and Tachy only.

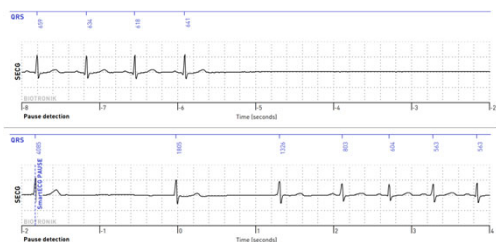


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SmartECG

How does it work?

Step 3: Episode Classification based on SmartECG redetected QRS



SmartECG	
Criteria	>= 3 s
Result	4.1 s - SmartECG true
Remark	
	none

Brady, Tachy, Pause episodes

- Episode classified based on programmed device detection criteria
- Labeled as true or false by the same algorithms found in the device

Atrial Fibrillation (AF) episodes

- AI applied to AF onset episodes
- AF onset episodes with improved QRS detections are labeled by the AI algorithm as true or false



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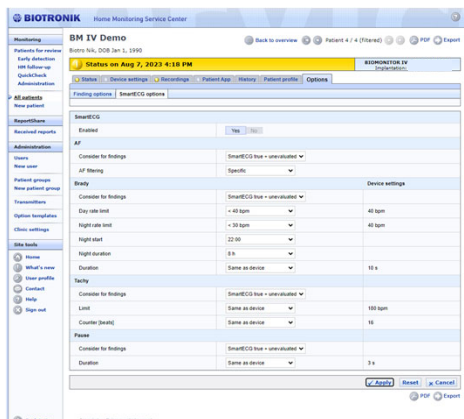
SmartECG

How does it work?

Step 4: Episode classified as True or False based on remote filtering options

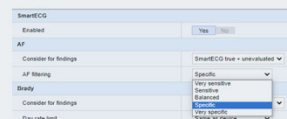
SmartECG Remote Filtering Options applied

Note: These settings apply only to the HMSC, not the device



SmartECG Remote filtering options

- Applied to the classified episodes to improve workload
- Set criteria for AF onset episodes to customize sensitivity and specificity



- Episode classified as True or False

Blue icon = SmartECG True

Grey icon = SmartECG False




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Home Monitoring Service Center (HMSC)

SmartECG Navigation




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Thank you!

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