ICM Programming and Troubleshooting

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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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ICM Indications

ICM Indication Implant % (N=62, single center)	**Diagnostic Finding**	**% Rhythm detected** (N=62, single center)
Syncope (90.3%)	• AV conduction disorder • Sinus node disorder • Paroxysmal SVT • Atrial fibrillation	19.6% 16.1% 7.1% 1.8%
Palpitations (8.1%)	• Atrial fibrillation	100%
Ischemic Stroke (1.6%)	• 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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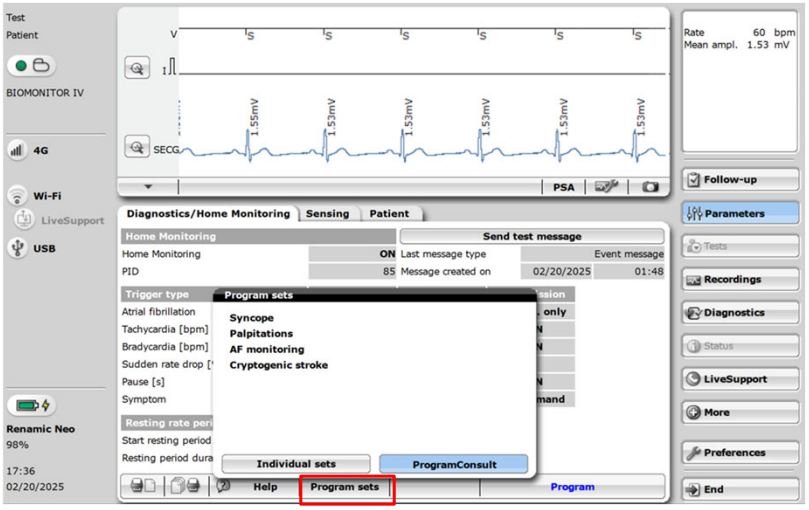
BIOMONITOR IV

Indication-based Programming – Program Consult



*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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Sensing and Troubleshooting

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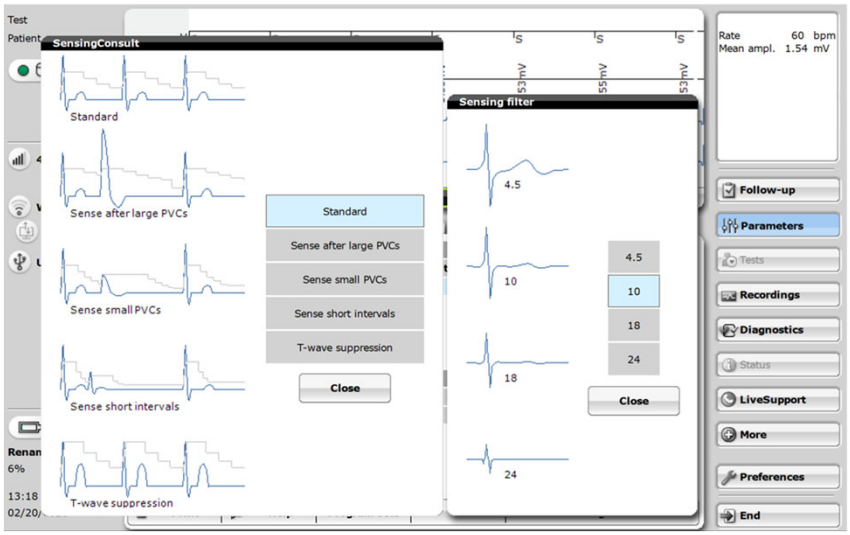
Sensing Consult Overview



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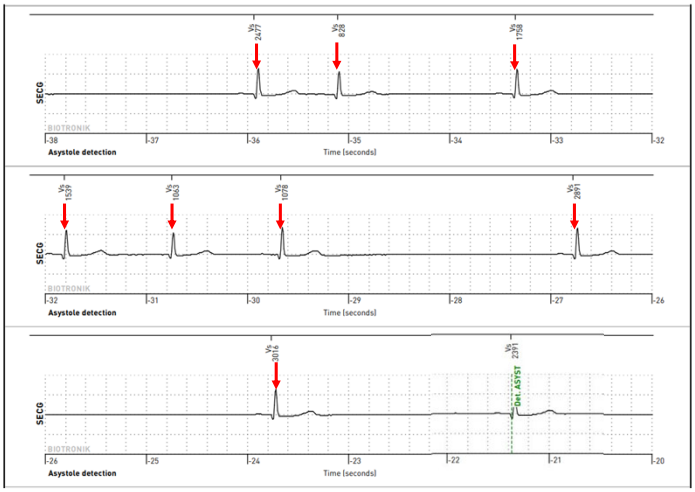
Evaluating Recordings for Appropriate Sensing and Triggers

Line up marker channels
- Is sensing appropriate?

Recording Trigger annotation
- What is the recording Trigger?



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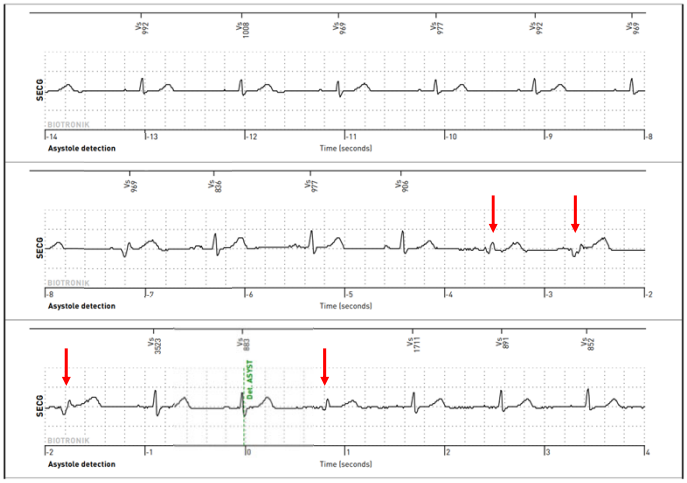
Evaluating Recordings for Appropriate Sensing and Triggers

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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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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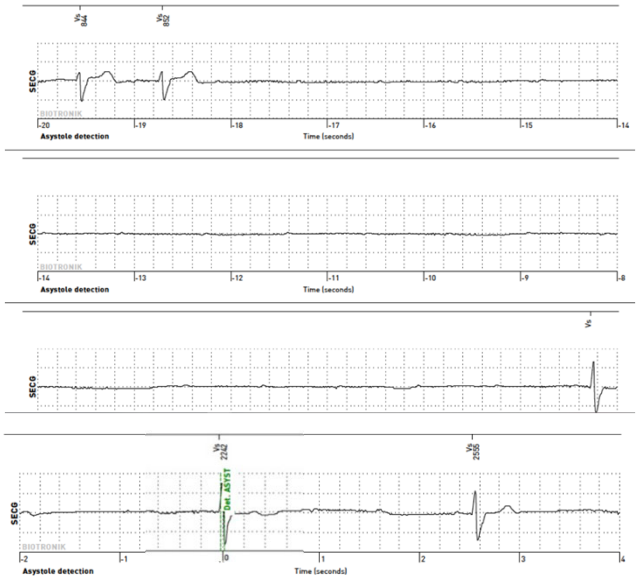
Case Study #2

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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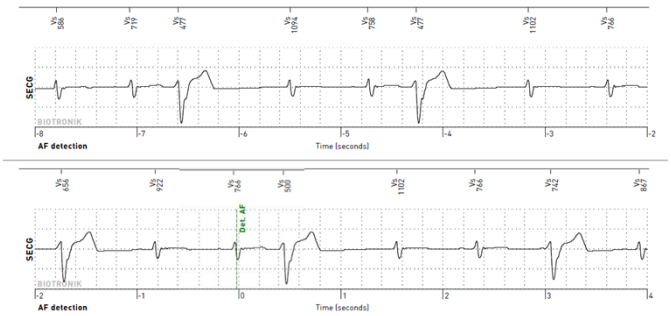
Case Study #3

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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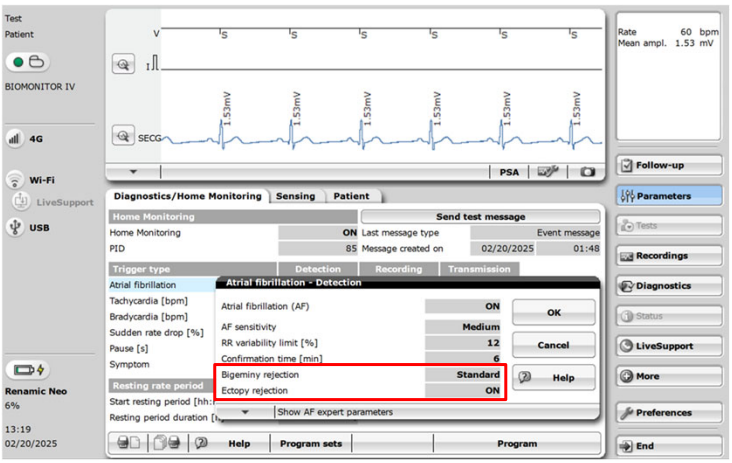
Case Study #3

Programming Recommendations

BIOMONITOR IV

- Bigeminy rejection
  - Change to Aggressive
- RhythmCheck-Ectopy Rejection
  - 72% reduction in false positive AF detections due to ectopy[1]



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

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Case Study #3
Programming Recommendations

BIOMONITOR IV

- Bigeminy rejection
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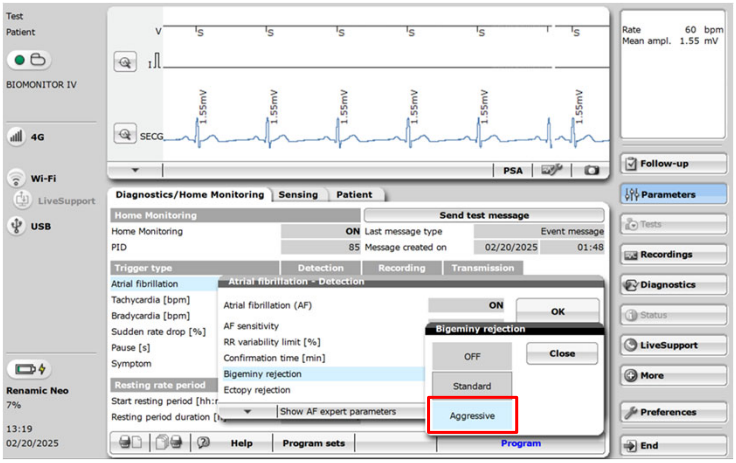

1. BIOTRONIK Data on file: Performance of BIOMONITOR IIIm Ectopy Rejection Parameter in Patients with Ectopy.

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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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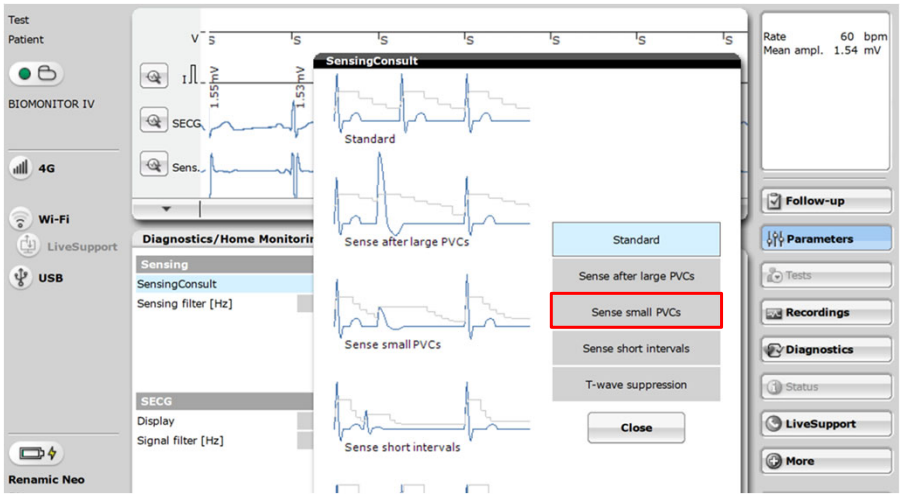
Case Study #4

Programming Recommendations



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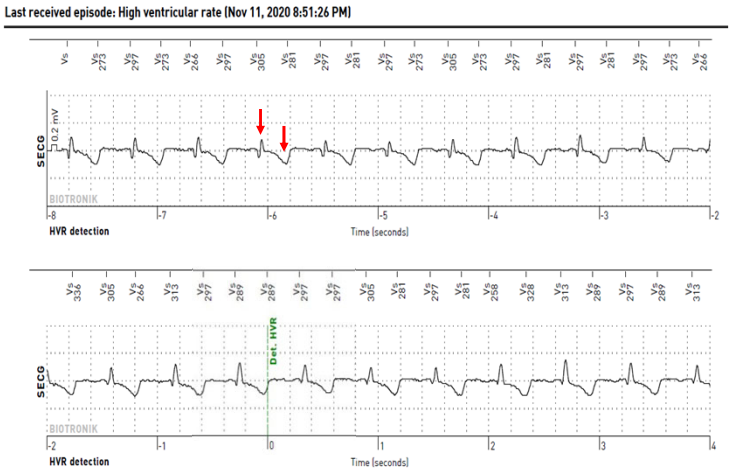
Case Study #5

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



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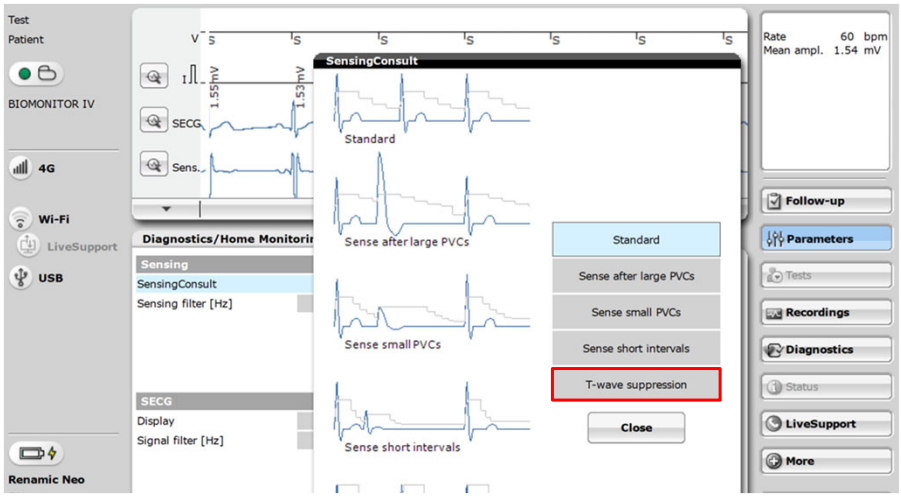
Case Study #5
Programming Recommendations



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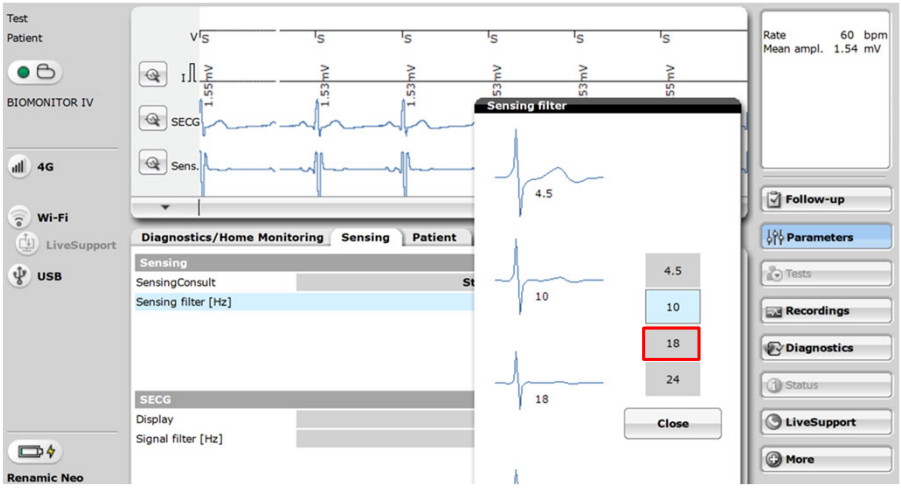
Case Study #5
Programming Recommendations



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Sensing Algorithm-Troubleshooting Guidelines

APS Troubleshooting suggestions

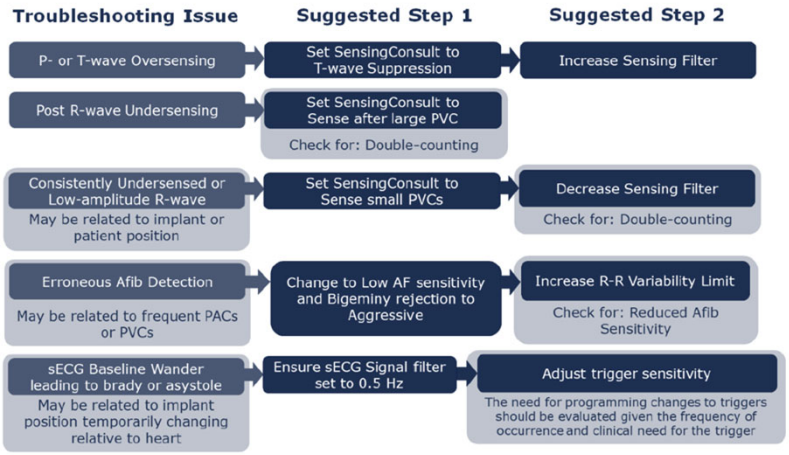

Figure 1. Troubleshooting suggestions and guidelines

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SmartECG: How does it work?

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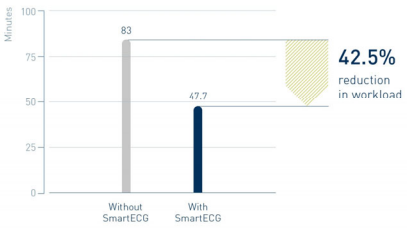
BIOMONITOR IV: SmartECG with Artificial Intelligence* and Advanced Algorithms to Focus on Actionable Data

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)

86%
Overall False Positive Reduction[1]

Figure 1: Annual calculated workload for ECG review per patient



*for AF detection episodes

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?	What are the benefits?
SmartECG is an advanced algorithm that incorporated Artificial Intelligence (AI) for AF that works on the HMSC.	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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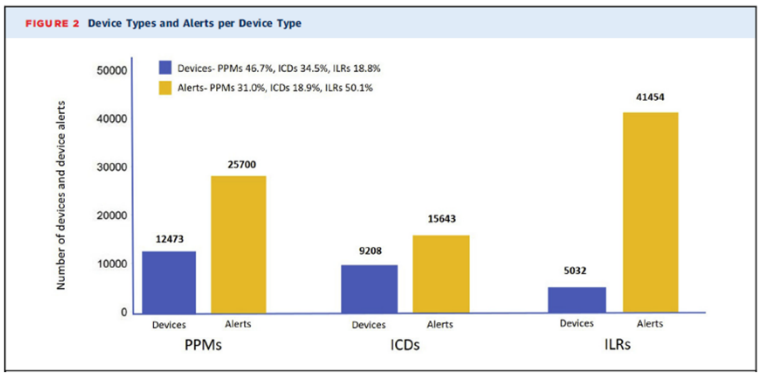
The Purpose Of SmartECG



From this study on more than 26,000 patients across all device manufacturers[1]:

- 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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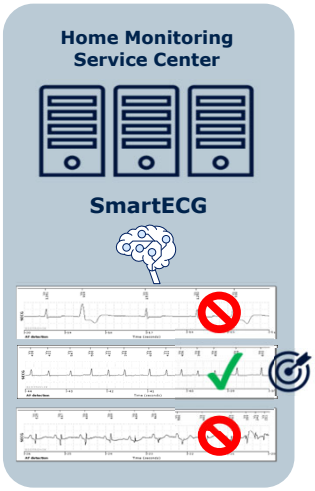
What episode-types are filtered by SmartECG?

- 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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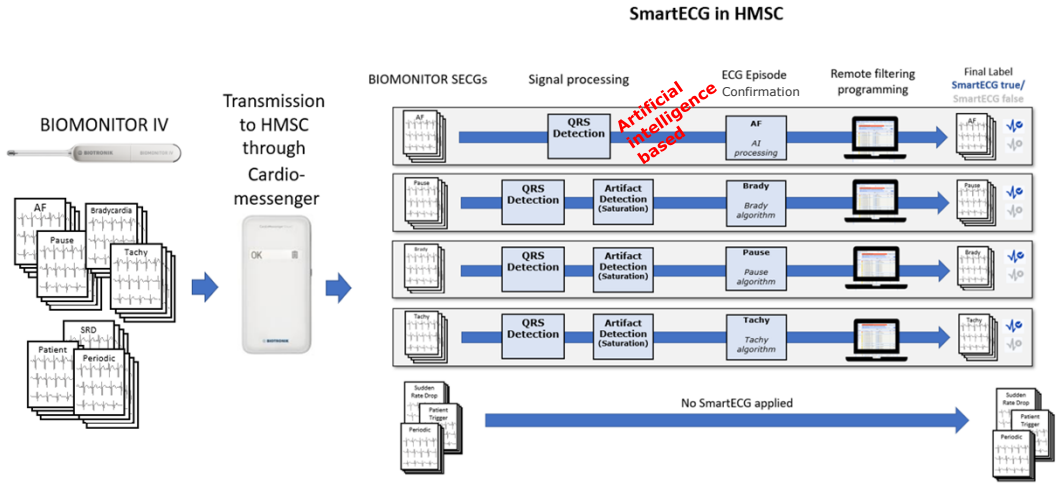
SmartECG: Big Picture



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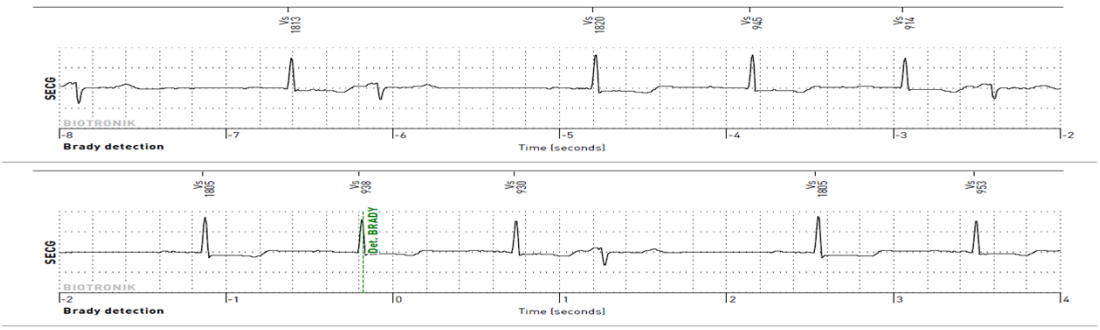
SmartECG
How does it work?

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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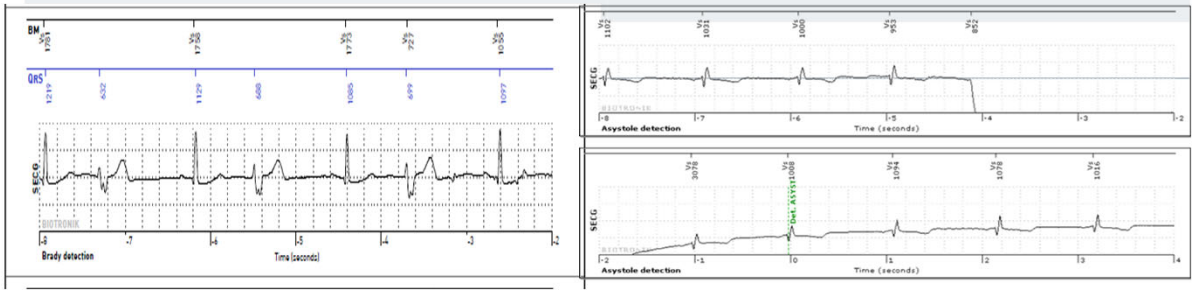
SmartECG
How does it work?

Step 2: SmartECG redetects QRS and applies Artifact detection

QRS Redetection	Artifact Detection
• Better recognition of smaller amplitude QRS peaks *SmartECG markers in blue* *Device markers in grey*	• 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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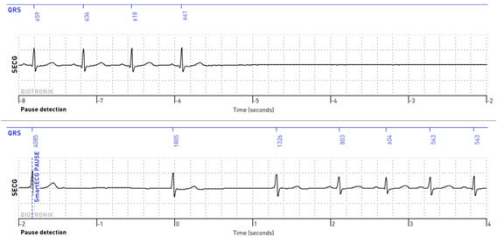
SmartECG
How does it work?

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	Atrial Fibrillation (AF) episodes
• Episode classified based on programmed device detection criteria • Labeled as true or false by the same algorithms found in the device	• 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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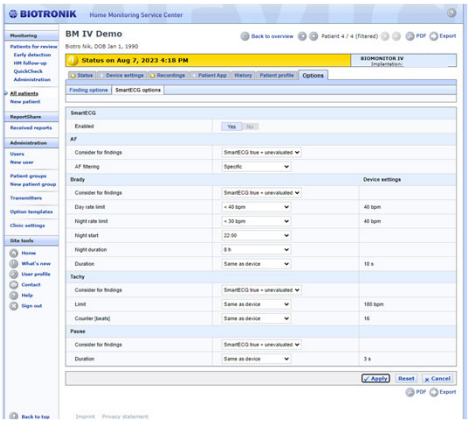
SmartECG
How does it work?

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

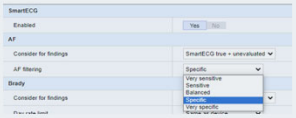
SmartECG Remote Filtering Options applied

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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