



**MAM 2017**

MULTIDISCIPLINARY ARRHYTHMIA MEETING

NOVEMBER 2 - 3, 2017

ZURICH, SWITZERLAND

# Biomonitor 2: Accurate arrhythmia detection

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# How does Biomonitor 2 detects AF?

- FA is detected when R-R intervals vary at least of a programmed value (RR variability limit [%])
- R-R variability must remain over the variability limit for a programmable duration (Confirmation Time)

# Parameters of AF detection

**Diagnostics** | **Home Monitoring** | **Patient**

**Detection settings**

Atrial fibrillation (AF)	<b>Medium</b>
High ventricular rate (HVR)	<b>ON</b>
Bradycardia	<b>ON</b>
Sudden rate drop (SRD)	<b>OFF</b>
Asystole duration [s]	<b>3</b>
Patient trigger	<b>ON</b>

**Atrial fibrillation (AF)**

Atrial fibrillation	<b>ON</b>	<b>OK</b>
AF sensitivity	<b>Medium</b>	<b>Cancel</b>
		<b>Help</b>

▼ Show AF expert parameters

**Atrial fibrillation (AF)**

Atrial fibrillation	<b>ON</b>	<b>OK</b>
AF sensitivity	<b>Medium</b>	<b>Cancel</b>
RR variability limit [%]	<b>12.5</b>	<b>Help</b>
Onset/resolution window	<b>8 / 16</b>	
Onset intervals	<b>5</b>	
Resolution intervals	<b>1</b>	
Confirmation time [min]	<b>6</b>	

▲ Hide AF expert parameters

- Sensitivity to AF has 3 pre-set: low, medium and high
- Advanced personalized parameters are available

# Parameters of AF detection

**Atrial fibrillation (AF)**

Atrial fibrillation  ON

AF sensitivity  **Medium**

RR variability limit [%]  12.5

Onset/resolution window  **8/16**

Onset intervals  5

Resolution intervals  1

Confirmation time [min]  6

**AF sensitivity**

Low

**Medium**

High

**RR variability limit**

6.25  **CI**

12.5

18.75

Preset sensitivity

AF sensitivity	Low	Medium	High
RR variability limit [%]	18.75	12.5	6.25
Onset/resolution window	16/24	8/16	8/16
Onset intervals	9	5	5
Resolution intervals	3	1	1

**Confirmation time**

1	2	3
4	5	<input type="checkbox"/> 6
10	20	30

**Onset/resolution window**

8/16

16/24

24/32

**Onset intervals**

<input type="checkbox"/> 5	<input type="checkbox"/> 7
<input type="checkbox"/> 9	<input type="checkbox"/> 11
<input type="checkbox"/> 13	<input type="checkbox"/> 15
<input type="checkbox"/> 17	<input type="checkbox"/> 19
<input type="checkbox"/> 21	<input type="checkbox"/> 23

**Resolution intervals**

1

3

5

7

# AF algorithm: Main features

1. Evaluation of R-R variability in every **ONSET WINDOW (8 R-R intervals)**

Stability threshold = Mean interval \* **Variability Limit (12.5%)**

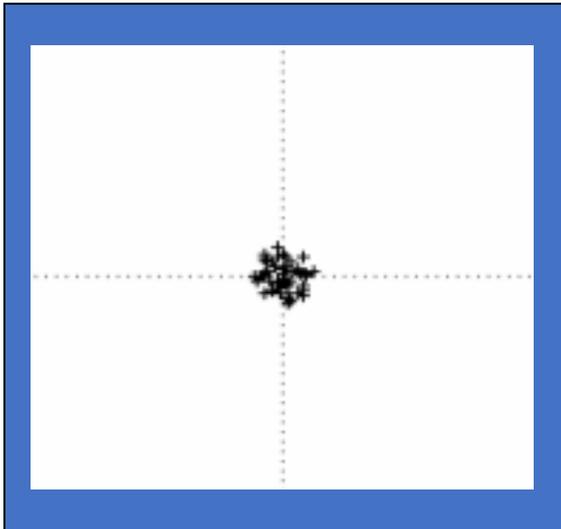
2. Unstable R-R intervals are counted in an “instability counter”
3. When this counter reaches the **Onset Interval Values (5)** an AF window is declared
4. Two consecutive AF windows elicit a “Possible AD status” (presumed AF)
5. If the condition of “presumed AF” lasts for the **Confirmation Time (6 minute)** an AF episode is recorded.
6. The **Resolution Window (16 intervals)** is stable when no more than 1 (or a programmed value) of **resolution intervals (1)** are unstable.
7. AF episode is declared as “ended” when two consecutive Resolution Windows are stable.

RED: Programmable parameters

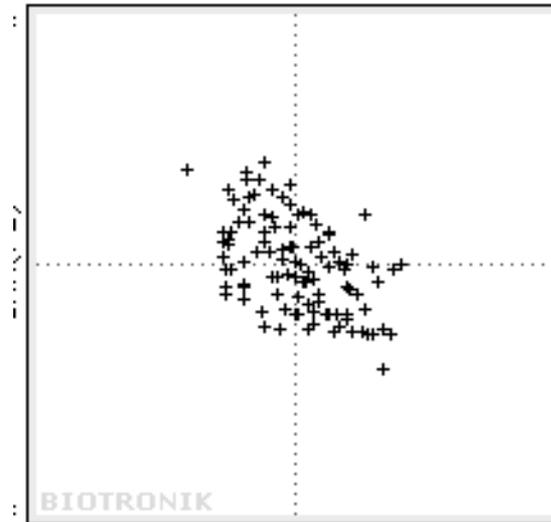


# How to interpretate the Lorenz Plot?

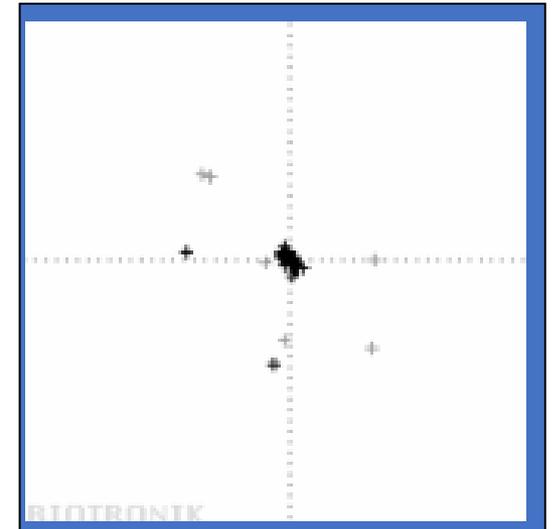
Sinus rhythm



Atrial fibrillation



HVR  
(High Ventricular Rate)





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**CLINICAL RESEARCH**

# Atrial fibrillation detection using a novel three-vector cardiac implantable monitor: the atrial fibrillation detect study

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# AF- Detect Study

**Table 1** Patient characteristics

	<b>Overall (n = 66)</b>
Mean age, years	60.4 ± 9.4
Male gender, n (%)	57 (86.4)
Mean body mass index (BMI), kg/m <sup>2</sup>	28.2 ± 4.2
LA dimension, mm	44.1 ± 5.4
Ejection fraction, %	54.1 ± 6.1
Hypertension, n (%)	41 (62.1)
Diabetes, n (%)	11 (16.7)
Heart failure, n (%)	0 (0)
Coronary artery disease, n (%)	3 (4.5)
History of stroke/TIA, n (%)	3 (4.5)
Valvular heart disease, n (%)	37 (56.1)
Dysthyroidism, n (%)	13 (19.7)
Number of previous AADs, n	1.4 ± 0.6

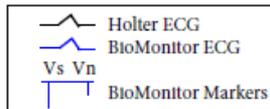
Data are expressed in mean ± standard deviation or absolute number and percentage.

TIA, transient ischaemic attack; AF, atrial fibrillation; AAD, anti-arrhythmic drug.

# AF-Detect Study - Results

- In 63 Holter recordings, 2878 h of data were analysed, from which 146 AF episodes were identified.
- In the ICM memory, a total of 654 episodes were stored and analysed, 513 of them (78.4%) were classified as TP<sub>ICM</sub> and 141 (21.6%) as FP.
- The FP episodes were incorrectly classified as AF, due to PACs or PVCs (102 of 141), signal noise (29 of 141), and irregular atrioventricular conduction (10 of 141).
- **The total per-episode sensitivity was 95.5%.**
- **The total per-episode predictive positive value (PPV) was 76.3%.**

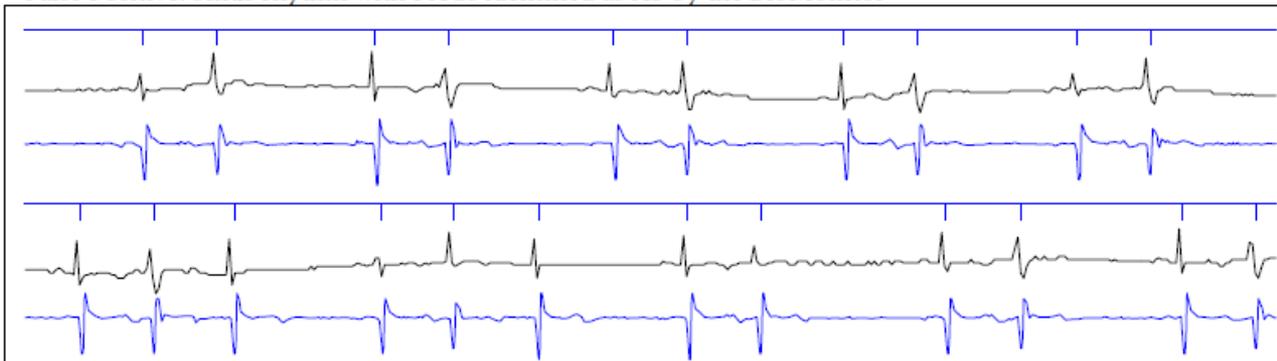
# AF-Detect Study Examples



True Positive: Real AF identified as AF by the BioMonitor



False Positive: Sinus rhythm with PACs identified as AF by the BioMonitor



# AF-Detect Study

## Conclusions

- Continuous monitoring using the novel ICM, equipped with a dedicated AF detection algorithm, accurately detected AF episodes with 95.4% mean episode sensitivity and 76.3% mean episode PPV.
- The BioMonitor ICM is a promising and reliable tool in the accurate AF detection, potentially guiding clinicians to tailor individual AF patient's management.
- Further long-term prospective studies are needed to evaluate the clinical benefits of this novel device.