A Novel Algorithm to Improve Atrial Fibrillation Detection in Implantable Cardiac Monitors

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Disclosures: **M. Richards:** A- Compensation for Services; Boston Scientific; B - Speaker's Bureau; Boston Scientific, Janssen, Medtronic, Biotronik; **D. Perschbacher:** C - Equity Interests/Stock Options – Non-Public; Boston Scientific Corp.. K - Salary; Boston Scientific Corp; **K. Herrmann:** C - Equity Interests/Stock Options – Non-Public; Boston Scientific Corp.. K - Salary; Boston Scientific Corp; **K. Siejko:** C - Equity Interests/Stock Options – Non-Public; Boston Scientific Corp.. K - Salary; Boston Scientific Corp; **S. Saha:** C - Equity Interests/Stock Options – Non-Public; Boston Scientific Corp.. K - Salary; Boston Scientific Corp;

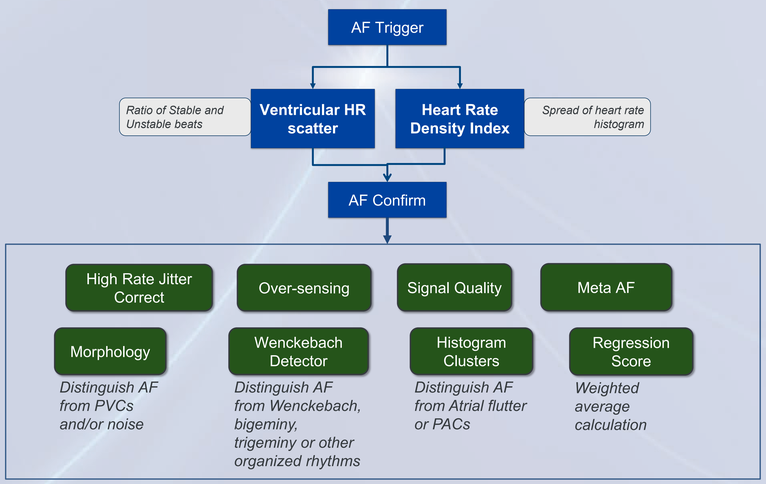
BACKGROUND

Implantable cardiac monitors (ICM) are commonly used to automatically detect atrial fibrillation (AF). Existing AF detection algorithms focus on R-R interval variability and are associated with a high percentage of false positive episodes. Real-world evaluations of AF algorithms in ICMs have reported positive predictive values (PPV) ranging from 26% to 84% for episodes ≥2 minutes.[1]

The objective of this work was to evaluate an AF detection algorithm with particular focus on maintaining acceptable detection sensitivity while reducing false positives due to confounding factors, including ectopic beats, bigeminal rhythms, AV block, and signal noise and artifact.

METHODS

An AF algorithm, based on R-R variability, signal morphology, and novel rhythm identification features, was developed and tested on a wideband, high resolution, 12-lead Holter ECG data set from 6 different clinical studies from the Telemetric and Holter ECG Warehouse (THEW). The V2-V3 vector was used to simulate the implanted ICM signal and was evaluated using a software model of ICM sensing hardware.



RESULTS

The AF detection algorithm was run under two settings: 1) based solely on R-R variability (AF Trigger only), and 2) with additional novel confirmation evaluations (AF Trigger & Confirm) at three sensitivities: balanced, least, and most.

Data from 485 patients (35 AF, 7.2% AF prevalence) was evaluated by the AF algorithm under the two settings. Patient data ranged from 10 min to 24 hours (total 60.1 days, 1.8% AF), and data with noise and artifact was not excluded.

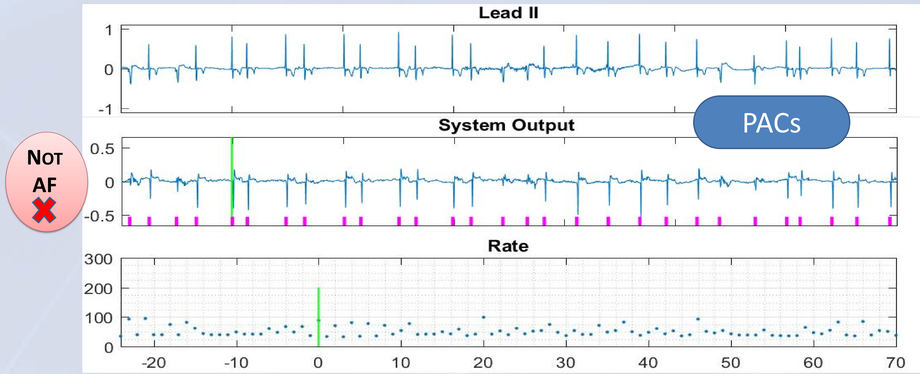
	AF Trigger	AF Trigger + Confirm (Balanced Setting)	AF Trigger + Confirm ([Less - More Sensitive Settings])
Sensitivity	99.74	99.49	98.07 - 99.61
Specificity	98.47	99.96	99.99 - 99.95
PPV	54.38	97.97	99.22 - 97.12
NPV	100.00	99.99	99.96 - 99.99
Accuracy	98.49	99.95	99.95 - 99.94

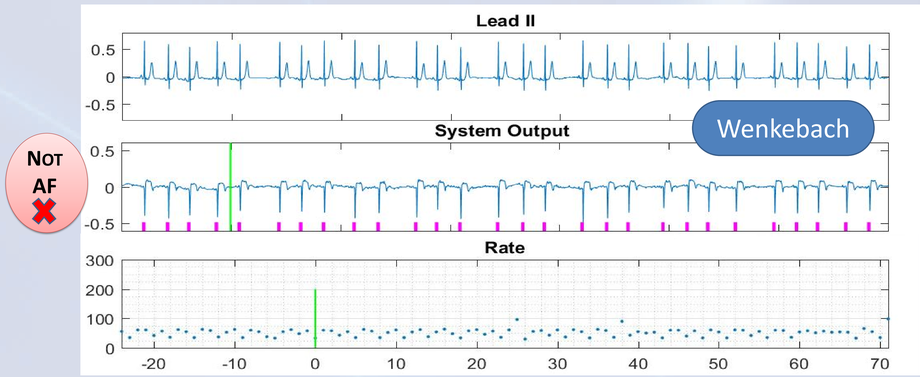
Algorithm PPV improved from 54.4% with R-R variability alone (AF Trigger only) to 97.1%, 98.0%, and 99.2% with confirmation evaluations at most, balanced, and least sensitivities, respectively. In exchange, the sensitivity to detect 2-minute AF episodes dropped only 0.1%, 0.3% and 1.7%, respectively.

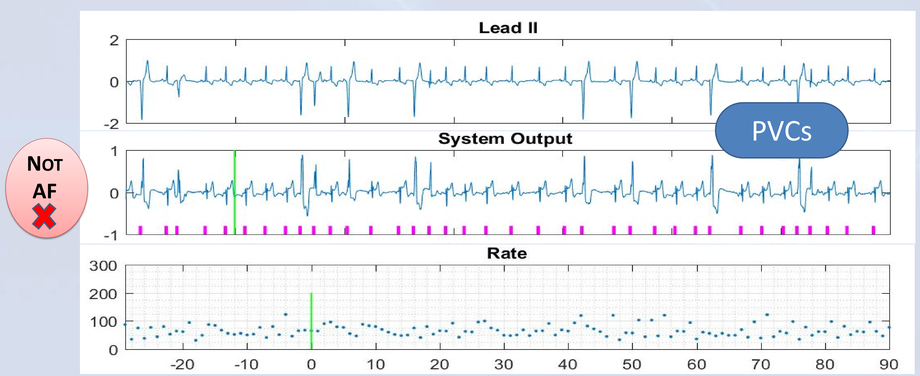
CONCLUSIONS

Clinical rhythms which often cause false positive alerts for AF, such as AV Wenckebach and frequent PVC are rejected by the combination AF Trigger & Confirm algorithm.

- The addition of rhythm confirmation steps markedly improves false positive rates
- This could easily translate to improved accuracy and efficiency in the device clinic.
- Evaluation of the in vivo performance of this algorithm in ICM implanted in humans is the subject of current investigation







[1]. Mittal et al. Real-world Performance of an Enhanced Atrial Fibrillation Detection Algorithm in an Insertable Cardiac Monitor. Heart Rhythm Society, 2016: 13 (8): 1624-1630.

CRM-549606-AA

Data used for this research was provided by Telemetric and Holter ECG Warehouse (THEW), University of Rochester, NY.

LUX-Dx™ Insertable Cardiac Monitor System

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "User's Manual" for more information on Indications, Contraindications, Warnings, Adverse Events, and Operator's Instructions.

INDICATIONS
The LUX-Dx™ Insertable Cardiac Monitor (ICM) is intended to monitor and record subcutaneous ECG (S-ECG). The recorded S-ECG is used for the clinical evaluation and diagnosis of cardiac arrhythmias. The LUX-Dx is indicated for use in patients that have a known heart condition and are at risk of developing an abnormal heart rhythm, or have symptoms that may suggest a cardiac arrhythmia, such as dizziness, palpitations, syncope, chest pain, and/or shortness of breath.
The LUX-Dx has not been tested specifically for pediatric use.

CONTRAINDICATIONS
There are no known contraindications for the insertion of the LUX-Dx insertable cardiac monitor. However, the patient's particular medical condition may dictate whether or not they can tolerate a subcutaneous, chronically-inserted device.
LATITUDE Clarity is contraindicated for use with any device other than a compatible Boston Scientific device.

WARNINGS
Concomitant use of the ICM system and implanted electro-mechanical devices [for example implantable neuromodulation/neurostimulation systems, ventricular assist device (VAD), or implantable insulin pump or drug pump] can result in interactions that could compromise the function of the ICM, the co-implanted device, or both. Electromagnetic interference (EMI) or therapy delivery from the co-implanted device can interfere with ICM sensing and/or rate assessment, resulting in failure to monitor or record when needed. Verify sensing configuration, operation modes, surgical considerations and existing placement of all involved devices prior to any co-implant. To help prevent undesirable interactions, test the ICM system when used in combination with the co-implanted device.
Do not expose a patient with an ICM system to diathermy. The interaction of diathermy therapy with an insertable cardiac monitor can damage the device and cause patient injury.
The influence of medical equipment on implanted devices varies considerably according to the type of unit and energy levels employed. In situations where the risks are known, always interrogate the device and save data before the procedure, and check device function afterwards.
Magnet model 6386 has been tested for use with the ICM system. Use of any other magnets has not been tested and could result in failure to initiate communication with the device.
The magnet provided with the ICM system may cause interference with devices sensitive to magnetic fields such as hearing aids, pacemakers, and other implanted devices. It can also permanently disable some magnetic strip cards. Keep the magnet at least 15 cm (6 inches) away from items sensitive to magnetic fields, including the ICM device when the magnet is not being used to initiate communication between the device and the patient or clinic app.
The mobile devices and magnet are MR Unsafe and must remain outside the MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document for Safe MR Practices.
Unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the inserted device, and significant harm to or death of the patient and/or damage to the inserted device may result.
Scanning patients who have other MR Conditional devices is acceptable if all the MR Conditional requirements for each of the implanted devices are met. Do not conduct an MRI scan if any conditions or implants prohibit it.
Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients.

PRECAUTIONS
For specific information on precautions, refer to the following sections of the product labeling: General, Clinical Considerations, Sterilization and Storage, Insertion, Magnet, Device Programming, Environmental and Medical Hazards, Follow-up, Device Removal and Disposal.

POTENTIAL ADVERSE EVENTS

Potential adverse events related to insertion of the device may include, but are not limited to, the following:

- Device migration
- Erosion
- Foreign body rejection phenomena
- Formation of hematomas or seromas
- Infection
- Local tissue reaction
- Tissue damage

For a list of potential adverse events associated with MRI scanning, refer to the MRI Technical Guide.

If any adverse events occur, invasive corrective action and/or ICM system modification or removal may be required.

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