

# Can Machine Learning Be Used to Optimize a Tachycardia Detection Algorithm in an Implantable Cardiac Monitor?

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Disclosures: S.Mittal: 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; D. Perschbacher: C - Equity Interests/Stock Options - Non-Public; Boston Scientific Corp.. K - Salary; Boston Scientific Corp.

## BACKGROUND

- Implantable cardiac monitors (ICMs) are increasingly being implanted for long-term ECG monitoring, including for detection of tachyarrhythmias.
- To date, two important challenges persist – eliminating false detection due to oversensing of "noise" and distinguishing supraventricular from ventricular tachycardia (SVT, VT).
- Resolution of these challenges would greatly enhance the clinical utility of ICMs and reduce the time spent on adjudicating detected events.

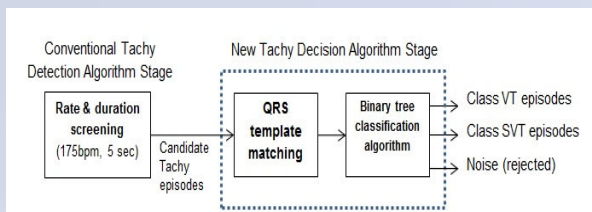
**Purpose:** Evaluate a new machine learning-based binary decision tree algorithm that utilizes QRS template-based morphology and RR interval variability descriptors to categorize ICM detected tachy episodes as either:

- SVT (sinus tach; regular SVT; atrial fib/flutter with rate in "tachy" zone),
- VT (mono or polymorphic VT; Vfib),
- or rejected as noise

## METHODS

- Decision tree training was performed with data derived from pre-existing surface 3-lead and 12-lead ECG databases.
- Tachy episodes (n=340; VT 265/SVT 75) were recorded at the time of an EP study; Holter recordings acquired during exercise stress testing were used to study noise episodes (n=603; 375 pts).
- A multivector linear transform was used to map the signals to the nominal ICM electrode position.
- An independent test set included tachy episodes acquired from subcutaneous ICDs (n=233 from 92 pts; VT 232/SVT 1) and additional Holter recordings with noise and artifacts (n=879; 500 pts).

Figure: Schematic of 2-stage tachycardia algorithm



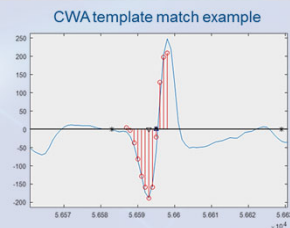
The decision tree uses the following metrics to reject noise and determine VT/VF vs. SVT rhythms:

- Heart Rate
- Morphology
- QRS complex characteristics

## RESULTS

- As shown in the table, training and test set performance was comparable
- Notable was the minimal loss of sensitivity (1.2% and 0.9%) imposed by the tachy decision tree
- Most of the noise (96%) was correctly rejected, which improved the PPV from 23% to 86%

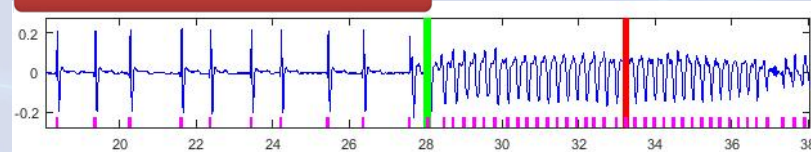
	Training Set	Test Set
Candidate Episode counts	n=340 tachy, 603 noise	n=233 tachy, 879 noise
Conventional 8/10 tachy detection PPV	37.9%	23.4%
Enhanced tachy detection PPV	94.4%	86.2%
<b>Decision tree performance:</b>		
Relative sensitivity	98.8%	99.1%
Correct VT vs. SVT classification rate	97.5%	97.3%
Correct Noise Rejection	97.8%	96.0%



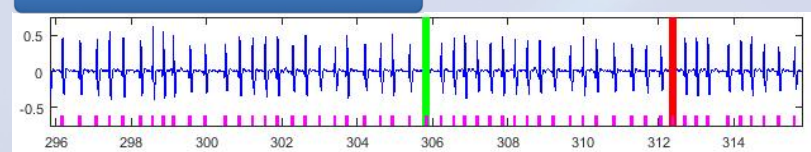
Enhanced template-matching techniques based on those in the Subcutaneous ICD (S-ICD)

- Beat-to-beat morphology match
- Morphology match to a normal sinus rhythm template

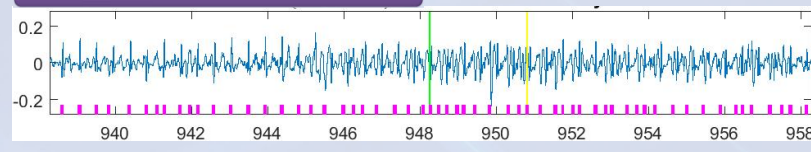
Classified as VT/VF



Classified as SVT



Rejected as Noise



## CONCLUSIONS

- Addition of a classification algorithm trained with morphologically descriptive features to an ICM can enable prioritization of VT over SVT episodes, and substantially reject false episodes due to oversensing, noise, and artifact with only a small loss in sensitivity.
- This may help to triage alerts by substantially reducing the number of tachy episodes that require immediate adjudication.
- Further evaluation on implanted ICM device signals is recommended. This algorithm will be incorporated into a novel ICM under development.

## **LUX-Dx™ Insertable Cardiac Monitor System**

### **INDICATIONS**

The LUX-Dx™ Insertable Cardiac Monitor (ICM) is intended to monitor and record subcutaneous electrocardiogram (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.  
92496928 (Rev. B)

***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.