Consistent visibility in P-waves observed in patients implanted with LUX-Dx Insertable Cardiac Monitor

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Disclosures: C. Frazier-Mills: Consultant - Boston Scientific Corp; **A. Rajan:** Salary - Boston Scientific Corp; **D. Mahajan:** Equity Interests/Stock Options – Boston Scientific Corp.; Salary - Boston Scientific Corp; **D. Perschbacher:** Equity Interests/Stock Options – Boston Scientific Corp.; Salary - Boston Scientific Corp; **D. Bohn:** Equity Interests/Stock Options – Boston Scientific Corp.; Salary - Boston Scientific Corp; **K. Herrmann:** Equity Interests/Stock Options – Boston Scientific Corp.; Salary - Boston Scientific Corp;

Background

- Insertable Cardiac Monitors (ICM) are implanted for long-term ECG monitoring and detection of atrial arrhythmias
- The visibility (or absence) of P-waves in the ICM ECG is an important feature in the diagnosis of atrial arrhythmias

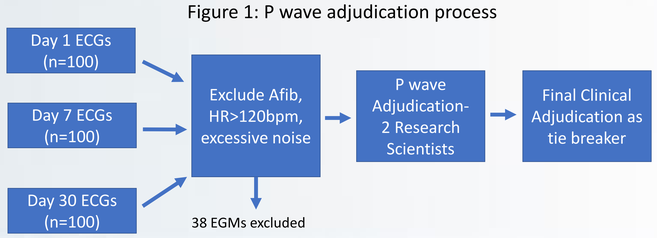
Objective

- Evaluate the visibility of P-waves in patients with the recently approved LUX-Dx ICM.

Methods

- The P-wave visibility was evaluated from the first 100 patients implanted with LUX-Dx ICM.
- The daily presenting ECG (10 second rhythm) on Day 1, Day 7 and Day 30 from the day of implant were reviewed to calculate the percentage of beats with clearly visible P-waves
- Of 300 presenting ECG, 38 rhythms were excluded which included atrial fibrillation (AF burden >50%), high HR (>120 bpm), excessive noise and unavailable data. None of the patients had excessive noise or high HR on all three days.
- 2 research scientists adjudicated the number of visible P waves in each presenting rhythm and in cases of a disagreement, a nurse practitioner (with clinical experience) was used as the tie breaker.
- The rhythms were adjudicated on simulated view of the official patient data management system (Latitude Clarity™). A nominal voltage and time scale was utilized on the simulations, to view the ECG rhythms for all patients, though both the scales are adjustable in Latitude Clarity™ system which can further improve visibility of P waves.

Figure 1: P wave adjudication process



Results

Figure 2: Overall P wave visibility

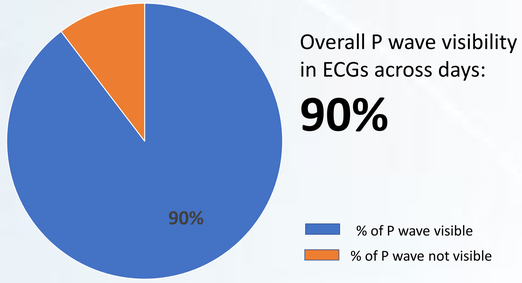


Table 1: P wave visibility data characteristics

	Total Beats	Visible P waves	%visibility	%Pts >50% visibility
Day 1	946	826	**87%**	90%
Day 7	1075	989	**92%**	96%
Day 30	1011	906	**90%**	89%

Figure 3: Comparison of P wave visibility distribution across days

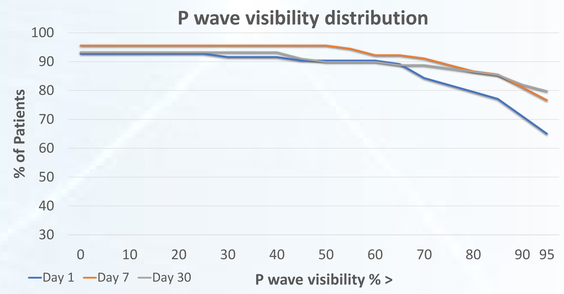


Figure 4: Examples of the presenting ECG display in the patient data management system **LATITUDE Clarity™**

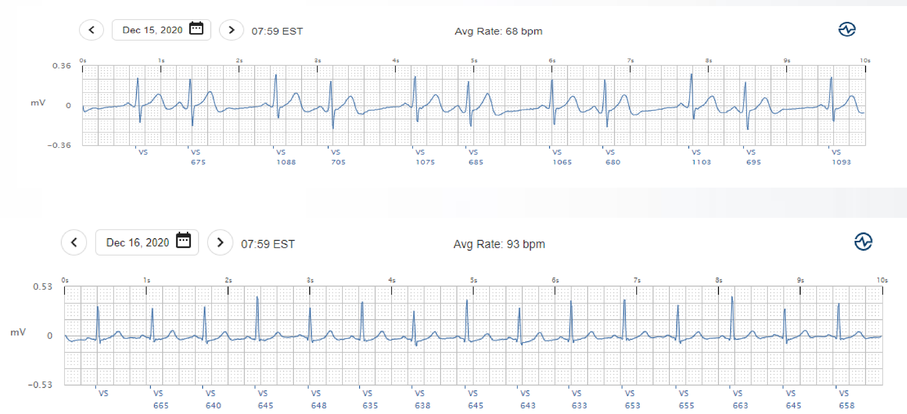
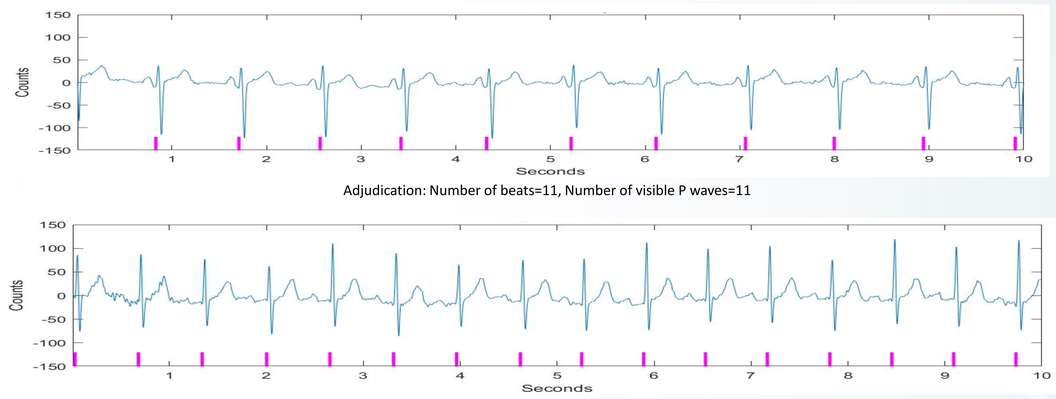


Figure 5: Examples of the presenting ECG display in the **simulated view** used for P wave adjudication process



- A repeated measures analysis showed that there was no statistical difference in the visibility of P-waves across days (p=0.25)
- At a patient level, 83% of patients had greater than 50% visibility on all three days.
- 7%, 4% and 7% patients had no P wave visible at Day-1, Day-7 and Day-30 respectively. Only 3% patients had no P wave visible for all three days

Conclusions

- The LUX-Dx showed consistent visibility of P waves across a wide range of patients which is an important clinical feature in diagnosing atrial arrhythmias.
- Adequate p wave visibility, may lessen analysis time and improve clinic workflow

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.

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