Boston Scientific
Advancing science for life™

Accuracy of Implantable Loop Recorders:

A Multi-Centre, Multi-Device Comparison of False Positive Alert Burden in Remote Transmissions[1]

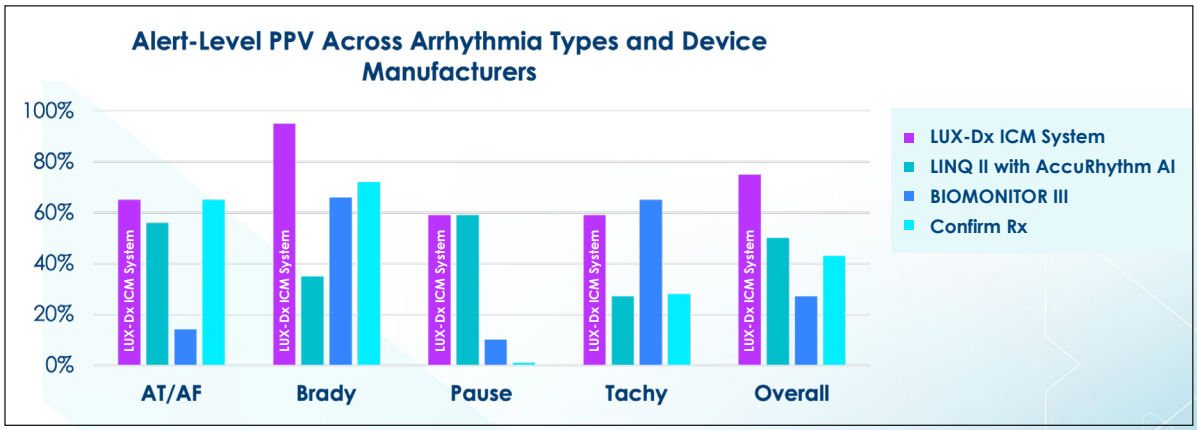
Authored by: Kamsani S, Middeldorp M, Evans S, Russo A, Jayakumar M, Deering T, Shahmohamadi E, Baykaner T, Fitzgerald J, Gopinathannair R, Abbas M, Varma N, Freeman J, Mittal S, Sanders P.

Abstract Overview

An abstract presented by Dr. Suraya Hani Kamsani at Heart Rhythm 2024 evaluated real-world arrhythmia detection accuracy across all manufacturers. The abstract specifically evaluated the following ICMs:

- Boston Scientific's first-generation LUX-Dx™ ICM System (M301)
- Medtronic's LINQ II™ with AccuRhythm™ AI
- Biotronik's BIOMONITOR III™ with RhythmCheck
- Abbott's Confirm Rx™ with SharpSense™

A total of 652 patients with 18,665 alerts were randomly selected across multiple centers and analyzed for rates of true and false positive transmissions according to device and episode type.



The study found that Boston Scientific's first generation ICM, the LUX-Dx ICM System (M301), had the highest overall PPV of all the ICMs evaluated.

Learn more about the findings by reading the full abstract here

LUX-Dx II+™ ICM System: Algorithm Enhancements

Focused on what matters.

The LUX-Dx II+ ICM System builds upon the advanced dual-stage algorithms and unparalleled signal quality of the groundbreaking first generation LUX-Dx ICM device – adding enhanced detection algorithms and programming options to reduce false positives and prioritize clinically actionable events.

Algorithm enhancements to reduce false positives:

- The enhanced Pause Algorithm includes an additional verification step that further rejects false positives due to low signal-to-noise ratios.
  - This enhancement was found to reduce false positives by 49% while maintaining 100% relative sensitivity.[2]*
- The enhanced AF Algorithm includes an additional verification step that identifies sequential heart rate patterns.
  - This enhancement demonstrated a 38% reduction in AF false positives while maintaining high relative sensitivity (>98%).[3]*

Algorithm enhancements to improve clinic efficiency:

- The LUX-Dx II+ ICM System is the only ICM to offer nighttime programming for both the Brady and Pause Algorithms†, allowing you to tailor detection parameters separately for daytime and nighttime (applied from 11:00 pm – 7:00 am).
  - Tailored settings for nocturnal episodes were found to reduce 75% of Brady and 57% of Pause S-ECG episodes for review.[4]*
- The enhanced AF Algorithm merges adjacent AF episodes, reducing the number of episodes for review, which may improve clinic workflow and expedite clinical decision making.
  - Merging adjacent AF episodes was found to reduce 26% of AF S-ECG episodes for review.[4]*

Sources

1. Kamsani S, Middeldorp M, Evans S, et al. Accuracy of Implantable Loop Recorders: A Multi-Centre, Multi-Device Comparison of False Positive Alert Burden in Remote Transmissions. Heart Rhythm Journal. 2024; PO-01-021. DOI: https://doi.org/10.1016/j.hrthm.2024.03.635
2. Burke M, Ravikumar V, Siejko K, Bohn D, Verdino R. Enhanced Pause Algorithm for Insertable Cardiac Monitor Reduces Clinical Review Burden. Poster presented at 2023 Heart Rhythm Society; May 2023; New Orleans, LA
3. Richards M, Frost K, Mahajan D, Saha S, Herrmann K, Perschbacher D. Novel Run-Test Algorithm for Improved AF Detection in Insertable Cardiac Monitors. Poster presented at 2022 Heart Rhythm Society; April 2022; San Francisco, CA
4. Rajan A, Perschbacher D, Mahajan D, et al. Improving Clinic Workflow and Diagnosis for the LUX-Dx Insertable Cardiac Monitor. Poster Presented at Heart Rhythm Society; April 2022; San Francisco, CA

*Simulated performance tested on real-world LUX-Dx ICM events

†As of 7.20.23: REVEAL LINQ™ Clinician Manual, LINQ II™ Clinician Manual, BIOMONITOR III™ Technical Manual, BIOMONITOR IIIm™ Technical Manual, BIOMONITOR IV™ Technical Manual, Merlin Patient Care System for SJM Confirm™ ICM, Confirm Rx™ ICM and Jot Dx™ ICM Help Manual, Merlin Patient Care System Assert-IQ™ ICM Help Manual

LUX-Dx II™ and LUX-Dx II+™ Insertable Cardiac Monitor Systems

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 Insertion and usage of this product may result in adverse events which may lead to injury, death, or other serious adverse reactions. If any adverse events occur, invasive corrective action and/or ICM system modification or removal may be required. 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. Potential adverse events related to device operation may include, but are not limited to, the following: Premature battery depletion, Sensing issues, Error codes, Loss of telemetry. Transient procedural adverse events are expected in some patients. These include, but are not limited to discomfort, pain, anxiety, and other systemic symptoms that might be related to medications or other interventions performed during implant. For a list of potential adverse events associated with MRI scanning, refer to the bostonscientific-elabeling.com. MRI Technical Guide at www.bostonscientific-elabeling.com Any serious incident that occurs in relation to this device should be reported to Boston Scientific and to the relevant local regulatory authority. 97104968 (Rev. A)

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner trained or experienced in device implant.

Boston Scientific
Advancing science for life™

Cardiology
4100 Hamline Avenue North
St. Paul, MN 55112-5798
www.bostonscientific.com

Patients and Families:
1.866.484.3268
Medical Professionals:
1.800.CARDIAC (227.3422)

CRM-1910504-AA