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Advancing science for life™

LUX-Dx II+™

ICM System

Focused on what matters

You don’t have time to be distracted by extraneous data

The LUX-Dx II+™ ICM System builds upon the advanced dual-stage algorithms and unparalleled signal quality of the original LUX-Dx™ system, while also adding enhanced detection algorithms and monitoring capabilities to help reduce false alerts, encourage patient compliance, and prioritise clinically actionable events.

The LUX-Dx II+™ ICM system is focused on what matters:

Meaningful alerts

Clear S-ECG signals

Seamless patient experience

Efficient workflows

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Meaningful alerts

Reduce false positives without missing a beat

Powered by enhanced detection algorithms, the LUX-Dx II+™ ICM System is focused on providing clinically actionable event alerts and rejecting false positives.

Detect

Verify

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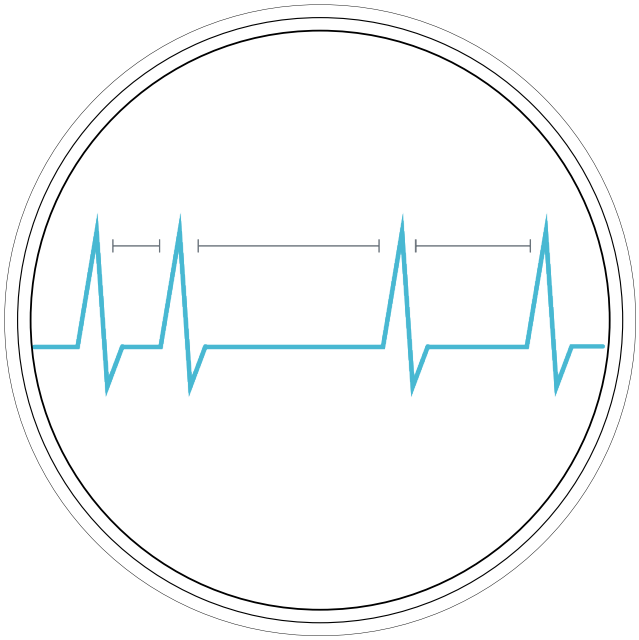
Meaningful alerts

Enhanced atrial fibrillation algorithm

Continues to use R-R variability to detect potential AF rhythms and merge adjacent episodes, which was found to reduce 26% of AF S-ECG episodes for review.[1†]

The algorithm also includes an additional verification step to identify repeating sequential patterns and reduced false positives by 38% while maintaining high relative sensitivity.[2†]



Enhanced where it matters most

The original LUX-Dx™ ICM set the standard in monitoring with dual-stage algorithms that automatically detect and verify events before sending alerts.

The LUX-Dx II+™ ICM is equipped with enhanced versions of those powerful algorithms, further improving its ability to reject false positives across multiple arrhythmia types.

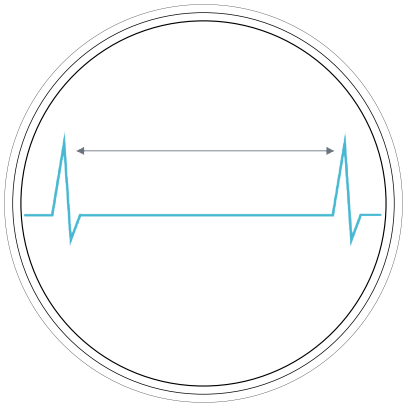
38% reduction in false positives while maintaining high relative sensitivity[2†]

26% fewer AF S-ECG episodes for review[1†]

Meaningful alerts

Enhanced pause algorithm

Continues to use R-R interval to detect pause episodes, and the enhanced verification step further rejects false positives due to undersensing of low amplitude signals.

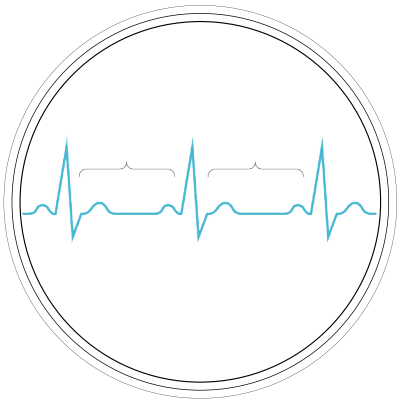


49% fewer false positives with 100% relative sensitivity[3†]

Bradycardia algorithm

Uses rate and duration parameters during the detection stage to identify potential brady episodes, with separate programmable parameters for daytime and nighttime.

During the verification stage, episodes are further examined and rejected if undersensing is identified.



The difference is night and day

Advanced night-time programming can detect, differentiate and record only specified night-time brady and pause events between 11pm–7am. The LUX-Dx II+™ ICM is the only ICM with night-time pause programming*.

75% reduction in nighttime brady S-ECG episodes for review[1†]

57% reduction in nighttime pause S-ECG episodes for review[3†]

Meaningful alerts

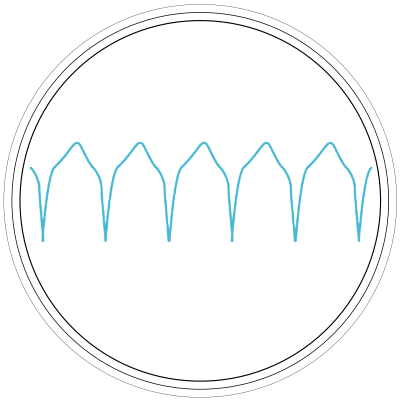
Atrial tachycardia algorithm

Uses rate, duration and built-in flexibility to detect high-rate rhythms sustained over time or short-duration AT/atrial flutter.

The LUX-Dx II+™ ICM is the only ICM with separate AT programming.

Tachycardia algorithm

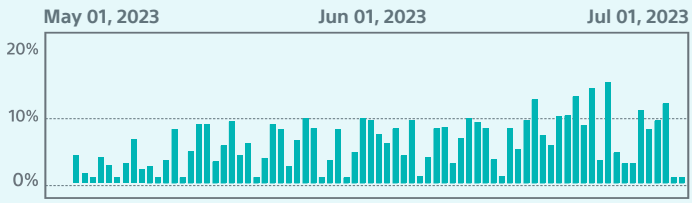
Uses a machine-learning decision tree to identify potential tachy episodes and reject events outside rate zone.



Novel PVC burden algorithm

Uses a patient-specific morphology assessment in the verification step that enables detection of PVC sequence types like couplets and triplets. The LUX-Dx II+ ICM provides a daily burden percentage with advanced programming and is the **only ICM with an actionable alert***.

85.4% PPV in detecting singlet, couplet and triplet PVCs[4†]



11.2% daily value July 2nd, 2023

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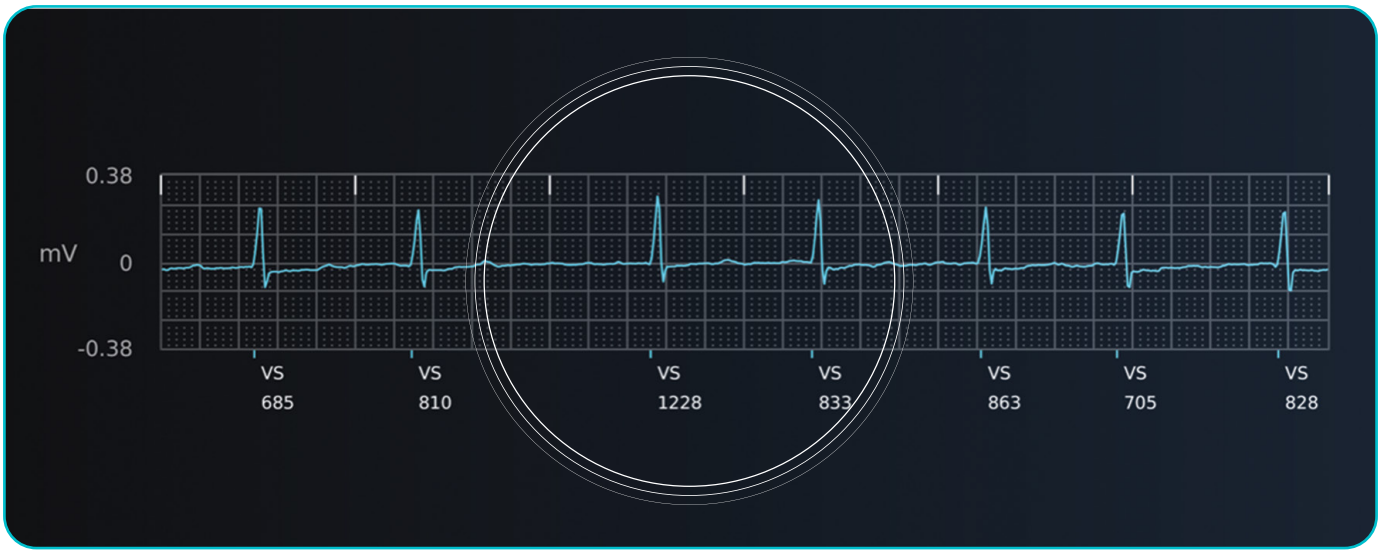
Clear S-ECG signals

Visible P-waves. It's as clear as that.

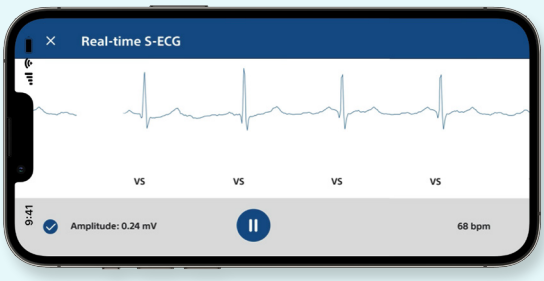
The LUX-Dx II+™ ICM System is focused on reducing analysis time by providing astoundingly clear S-ECG signals from day one.

90% of P-waves visible in heart cycles over time[5]**



Clinic Assistant app

With the LUX-Dx™ Clinic Assistant app, you only need one device to connect to and interrogate devices, minimising the need for additional monitoring.

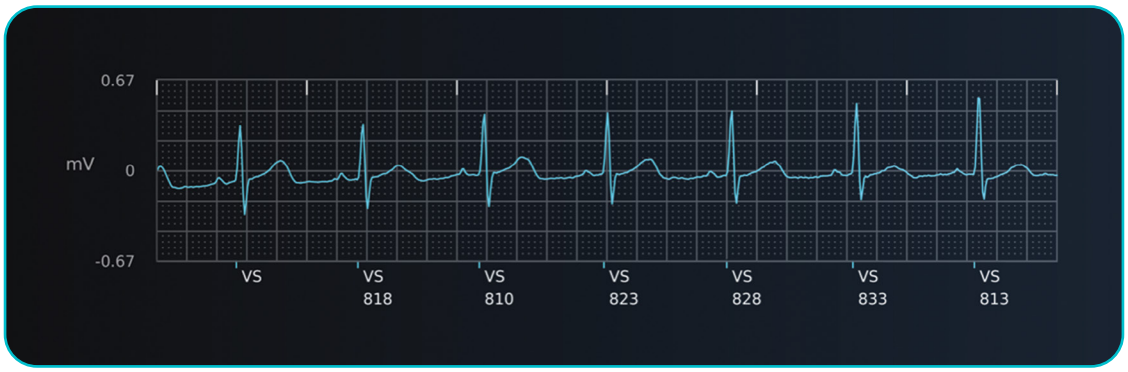


Clarity from day one

Right from the start, the LUX-Dx II+ ICM makes it easy to verify correct placement and connection confidence by transmitting real-time S-ECGs in sharp resolution.

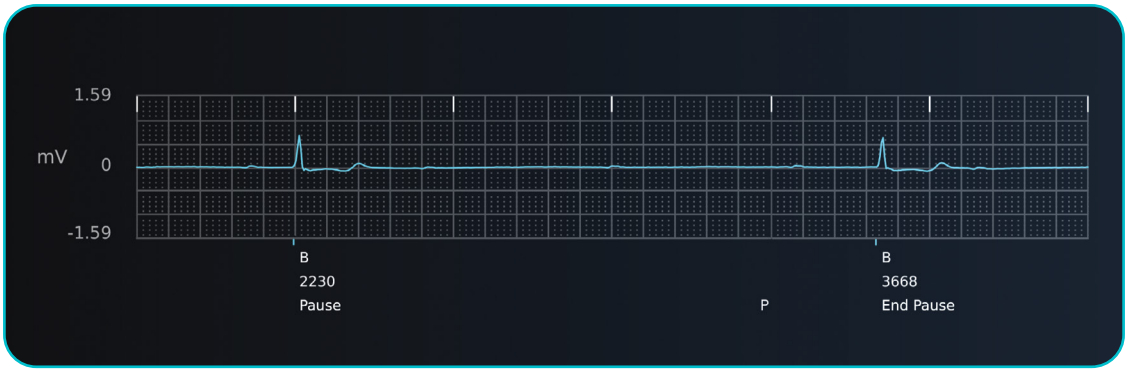
- View real-time patient S-ECGs
- Interrogate any LUX-Dx ICM**
- Apply LATITUDE Clarity™ parameter changes

Clear S-ECG signals



Presenting S-ECG

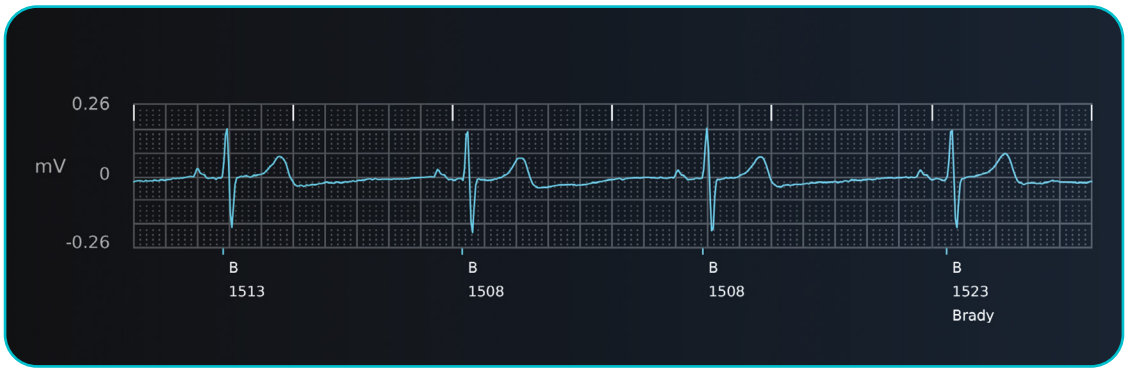
S-ECG from Atrial Fibrillation alert



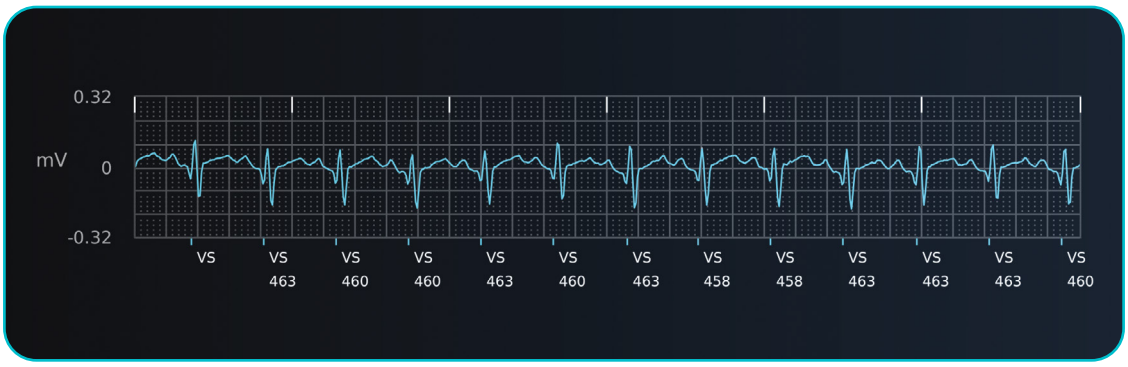
S-ECG from Pause alert

Cases shown are from real LUX-Dx™ ICM patients.

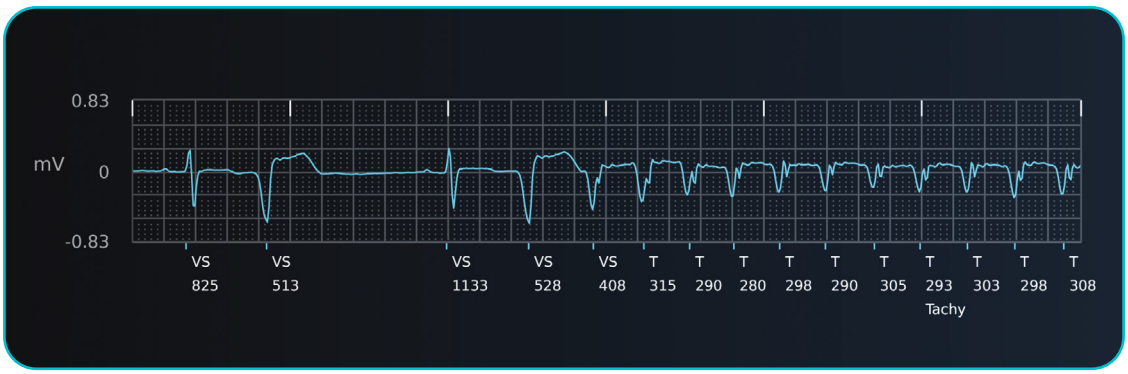
Clear S-ECG signals



S-ECG from Bradycardia alert



S-ECG from Atrial Tachycardia alert



S-ECG from Tachycardia alert

Cases shown are from real LUX-Dx™ ICM patients.

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Seamless patient experience

Simple choices for seamless connectivity

The LUX-Dx II+™ ICM System is focused on supporting every step along the cardiac monitoring journey – for both physicians and patients alike.

Flexible patient monitoring

The LUX-Dx II+ ICM system now offers a choice for patients to use their own mobile phone with the downloadable myLUX™ patient app for monitoring.

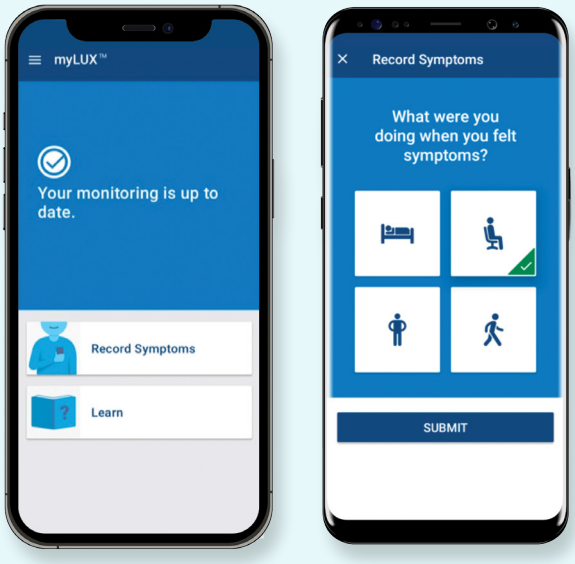
Available on the App Store

Android app on Google Play

myLUX Patient app

The primary connection point between a patient's LUX-Dx II+ ICM device and the LATITUDE Clarity™ server, the user-friendly myLUX Patient App helps empower patients to play an active role in recording symptoms and connecting their device.

- Current monitoring status
- One-way clinic messaging
- Programmable symptom tracking
- Patient education tools



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Efficient workflows

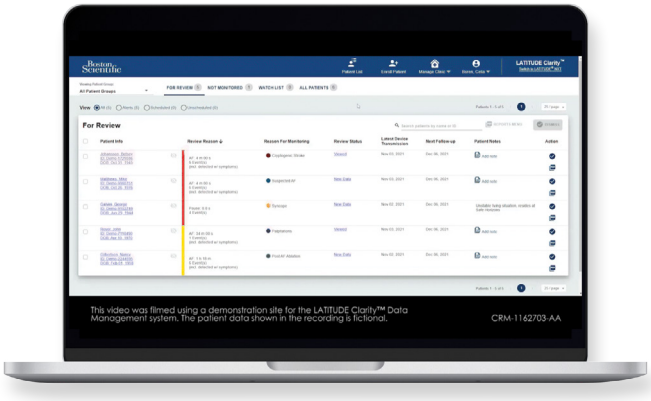
Designed to accelerate clinical decision-making

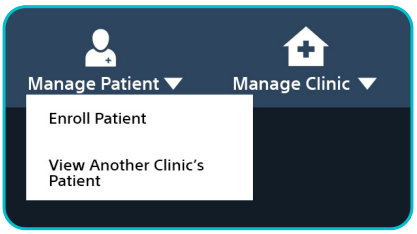
The LUX-Dx II+™ ICM System is focused on maximising workflow efficiency by streamlining data management and simplifying common review procedures.

Efficient workflows

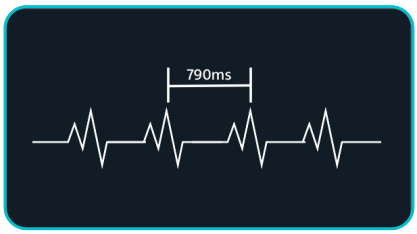
LATITUDE Clarity™ Data Management System

Built specifically to meet the needs of ICM management teams, LATITUDE Clarity helps to increase efficiencies, enhance workflows and fine-tune monitoring. It's equipped with powerful tools to help you see the bigger data picture – without losing the detail to back it up.

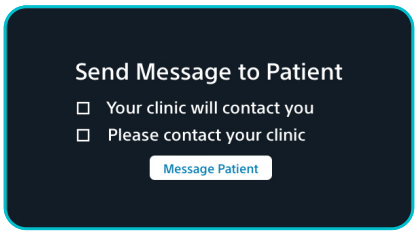




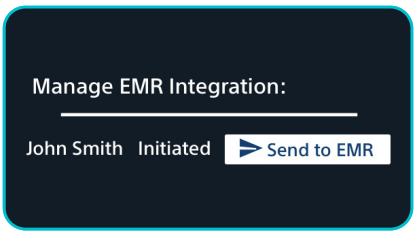
Temporary read-only access



Intuitive S-ECG review tools

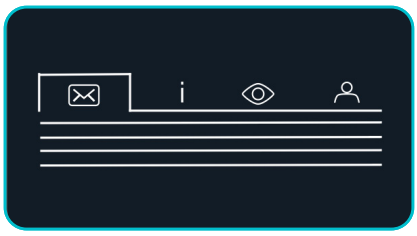


One-way patient messaging

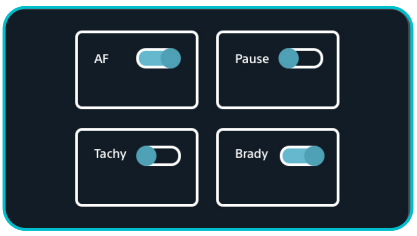


Easy EMR integration

Customisable patient reports



Organised dashboard view



Efficient remote programming

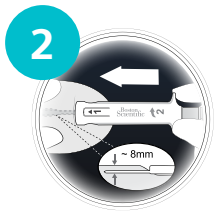
Efficient workflows

Efficiency is a familiar feeling

The intuitive insertion process of the LUX-Dx II+™ ICM is designed for reliable placement, rapid validation, and confident completion.

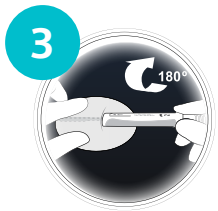
Incision

Create a small incision using the included LUX-Dx™ Incision Tool.



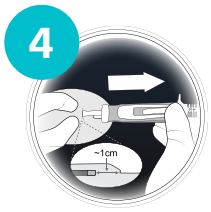
Tunnel

Insert the included LUX-Dx insertion tool into opening.



Rotate

Twist the insertion tool 180 degrees to create a pocket.

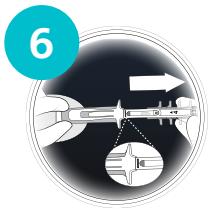


Pull back

Pull back on insertion tool plunger to the pre-marked blue line.

Insert

Push in the insertion tool plunger all the way to place device in pocket.



Remove

Remove insertion tool and close using standard surgical techniques.

Insertion tools

The LUX-Dx II+™ ICM includes a reloadable, all-in-one insertion tool and incision tool to simplify the device insertion procedure.

1. 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.
2. Richards M, Frost K, Mahajan D, *et al.* Novel run-test algorithm for improved AF detection in insertable cardiac monitors. Poster presented at 2022 Heart Rhythm Society; April 2022; San Francisco, CA.
3. Burke M, Ravikumar V, Siejko K, *et al.* Enhanced pause algorithm for insertable cardiac monitor reduces clinical review burden. Poster presented at 2023 Heart Rhythm Society; May 2023; New Orleans, LA.
4. Nair D, Herrmann K, Mahajan D *et al.* Novel PVC burden algorithm for insertable cardiac monitors (ICMs) detects all PVC sequence types. Poster presented at: 2021 Heart Rhythm Society; July 2021; Boston, MA.
5. Frazier-Mills C, Rahan A, Saleeby R, *et al.* Consistent visibility in P-waves observed in patients implanted with LUX-Dx Insertable Cardiac Monitor. Poster presented at: 2021 Heart Rhythm Society; July 2021; Boston, MA.

† 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.

** Evaluated using the LUX-Dx ICM System.
References to "LUX-Dx ICMs" Includes LUX-Dx, LUX-Dx II™ and LUX-Dx II+™ ICM Systems.

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