LUX-Dx™ ICM Systems

Clinical Compendium

LUX-Dx™ ICM Systems

Timeline

Publications

2017
- Improved AF Rhythm Discrimination Using QRS Morphology[1]

2018
- A Novel Algorithm Reduces False Positives For Pause Detection In Implantable Cardiac Monitors[2]
- A Novel Algorithm To Improve Atrial Fibrillation Detection In Implantable Cardiac Monitors[3]
- Can Machine Learning Be Used To Optimize A Tachycardia Detection Algorithm In An Implantable Cardiac Monitor?[4]

2019
- A Novel Algorithm Improves Detection Of Arrhythmias with Regular RR Intervals In Implantable Cardiac Monitors[5]
- Artificial Neural Network Algorithm Improves Atrial Fibrillation Detection[6]
- Improved AF Rhythm Discrimination With An Implantable Cardiac Monitor Using QRS Morphology[7]
- Performance Of A New Implantable Cardiac Monitor Pause Detection Algorithm In The Presence Of Low-amplitude R-waves[8]

2020
- Clinical performance of a novel remote programming system for insertable cardiac monitors; results of the CARMEL study[9]

Launch! LUX-Dx™ ICM System

2021
- A Novel Adaptive Insertable Cardiac Monitor Algorithm Improves The Detection Of Atrial Fibrillation and Atrial Tachycardia In Silico[10]
- Consistent Visibility Of P-waves Observed In Patients Implanted With LUX-Dx Insertable Cardiac Monitor (ICM)[11]
- Improved Detection Of Atrial Arrhythmias With Regular R-R Intervals In Patients With The LUX-Dx Insertable Cardiac Monitor[12]
- Novel PVC Burden Algorithm For Insertable Cardiac Monitors Detects All PVC Sequence Types[13]

2022
- Improving Clinic Workflow And Diagnosis For The LUX-Dx Implantable Cardiac Monitor[14]
- Novel Algorithm For Improved AF Detection In Insertable Cardiac Monitors[15]
- Real-world Characterization And Use Of Insertable Cardiac Monitor Remote Programming[16]

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2023
- Does Optimized Daytime/Nighttime Programming Reduce Insertable Cardiac Monitor Event Burden?[17]
- Enhanced Pause Algorithm For Insertable Cardiac Monitor Reduces Clinical Review Burden[18]
- Evaluation Of The Insertable Cardiac Monitor Placement And Safety In The LUX-Dx PERFORM Study[19]
- Interim Evaluation Of Insertable Cardiac Monitor Signal Quality In The LUX-Dx PERFORM Study[20]
- Preliminary Results From The LUX-Dx PERFORM Study[21]

2024
- ***Independent Abstract!*** Accuracy of Implantable Loop Recorders: A Multi-Centre, multi-Device Comparison of False Positive Alert Burden in Remote Transmissions[22]
- Implantation Of A Novel Insertable Cardiac Monitor: Preliminary Multicenter Experience In Europe[23]
- ***Independent Abstract!*** Monitoring of Remotely Reprogrammable Implantable Loop Recorders With Algorithms to Reduce False-positive Alerts[24]
- Preliminary Implantation Experience In Europe With A Novel Insertable Cardiac Monitor[25]
- ***Independent Abstract!*** Reduction in Implantable Loop Recorder Alert Burden: A Targeted Approach to Slash Transmission Volume Using Patient Specific Programming Beyond Vendor Reason For Monitoring Nominals[26]

2025
- Artificial Intelligence Versus Electrophysiologists Adjudication Of Atrial Arrhythmias: A Validation Study[27]
- Detection Of New Atrial Fibrillation In Patients With Heart Failure By An Insertable Cardiac Monitor: Preliminary Analysis Of The LUX-Dx TRENDS Study[28]
- Initial Real-world Usage of a Novel PVC Burden Feature with Programmable Alerts in an Insertable Cardiac Monitor[29]
- Physician Disagreement When Adjudicating Atrial Fibrillation Episodes Detected By Insertable Cardiac Monitor[30]
- Premature Ventricular Contraction Detection And Estimation Of Daily Burden By An Insertable Monitor[31]
- Real-world Use Of Insertable Cardiac Monitor Remote Programming[32]

Sources on following page

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Timeline

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15 Richards M, Pershbacher D, Mahajan D, Saha S, Herrmann K, Frost K. Heart Rhythm. 2022;19(5):S289-S290. Doi: 10.1016/j.hrthm.2022.03.336
16 Mahajan D, Frost K, Herrmann K, McGee-Taylor R. Innovations in Cardiac Rhythm Management. 2022;13(11):5230-5235. doi: 10.19102/icrm.2022.13112
17 Burke M, Rajan A, Pershbacher D, Mahajan D, Herrmann K. EP Europace. 2023;25:S1. Doi: 10.1093/europace/euad122.249
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- Section 1: Summary of Clinical Data
  - Signal Quality
  - Remote Programming
  - Insertion Procedure
- Section 2: Recent Publications
- Section 3: LUX-Dx II+™ Algorithm Performance
- Section 4: Clinical Trials
- Section 5: Terminology

Focused on what matters.

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Boston Scientific

Section 1

Summary of Clinical Data

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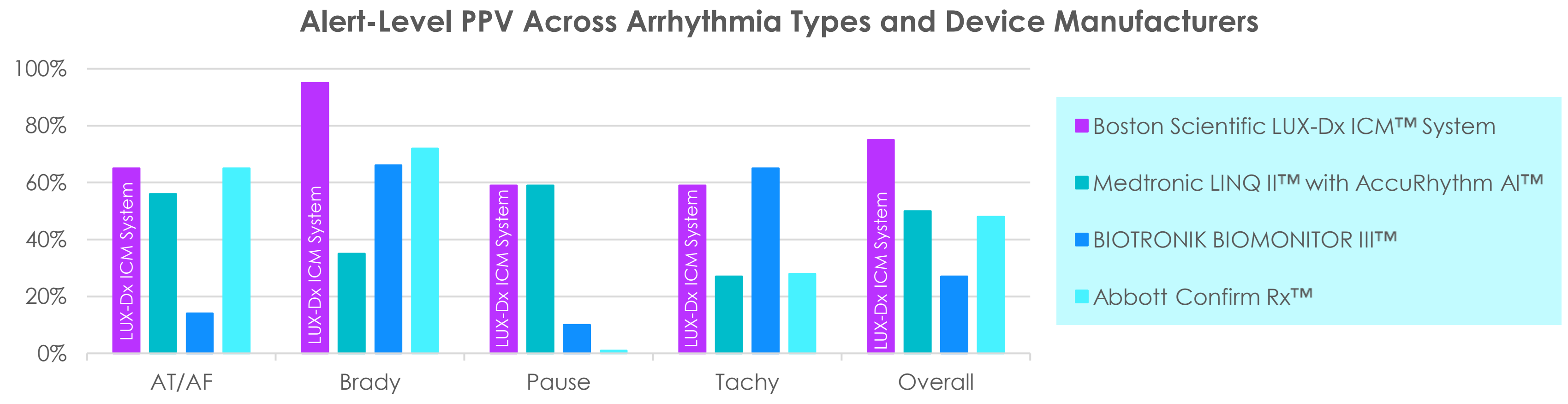
Real World Performance

Section 1: Summary of Clinical Data

An independent abstract presented at HRS 2024 evaluated real-world arrythmia detection accuracy across all ICM manufacturers[1]

- **652 patients with 18,665 alerts**
- **Randomly selected across multiple centers**



The first-generation LUX-Dx ICM system had the highest overall Positive Predictive Value (PPV) across all ICMs evaluated[1]

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;21(5):PO-01-021. doi: 10.1016/j.hrthm.2024.03.635

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LUX-Dx II+™ Algorithm Performance

Section 1: Summary of Clinical Data

KEY DATA		
Algorithm	Description	Results
AF	Repeating sequential patterns verification step	38% reduction in AF false positives while maintaining high relative sensitivity (>98%)[1*]
	Merging adjacent AF episodes	Reduced 26% of the AF S-ECG episodes for review[2*]
AT	Improved detection of AT by decoupling AT and AF durations	Combined AF and AT detection PPV improved to 97% when AT programmed with both higher rates and longer durations[3†]
TACHY	Machine learning used to optimize tachycardia detection algorithm	Correctly rejected noise 96% of the time[4†]
		PPV improved from 23% to 86%[4†]
PAUSE	Low signal-to-noise ratio enhancement	Reduced false positives by 49% while maintaining 100% relative sensitivity[5*,‡]
NIGHTTIME BRADY & PAUSE DETECTION	Optimized settings for nocturnal episodes	Reduced 75% of Brady and 57% of Pause S-ECG episodes for review[2*]
PVC BURDEN	Capable of detecting singlets, couplets, and triplets	100% PPV and 84% sensitivity for identifying patients with PVC burdens ≥10%[6¶,‡]

* Simulated performance tested on real-world LUX-Dx ICM events. † Bench Test results may not necessarily be indicative of clinical performance ‡ Also applicable to LUX-Dx II™ ICM System ¶ *in silico* testing of algorithm performance on 12-lead Holter data

1. Richards M, Perschbacher D, Mahajan D, Saha S, Hermann K, Frost K. Novel Algorithm for Improved AF Detection in Insertable Cardiac Monitors. Heart Rhythm. 2022;19(5):S289-S290. doi: 10.1016/j.hrthm.2022.03.336 **2.** Rajan A, Perschbacher D, Mahajan D, et al. Improving Clinic Workflow and Diagnosis for the LUX-Dx Insertable Cardiac Monitor. Heart Rhythm. 2022;19(5):S235. doi: 10.1016/j.hrthm.2022.03.206. **3.** Richards M, Perschbacher D, Frost K, Herrmann K. Improved Detection of Atrial Arrhythmias with Regular R-R Intervals in Patients with the LUX-Dx Insertable Cardiac Monitor. Heart Rhythm. 2021;18(8):S389. doi: 10.1016/j.hrthm.2021.06.964 **4.** Mittal S, Siejko K, Saha S, Perschbacher D. Can Machine Learning be Used to Optimize a Tachycardia Detection Algorithm in an Implantable Cardiac Monitor? European Heart Journal. 2018;39:Suppl_1. Doi: doi.org/10.1093/eurheartj/ehy564.P1033. **5.** Burke MC, Ravikumar V, Siejko K, Bohn D, Verdino RJ. Enhanced pause algorithm for insertable cardiac monitor reduces clinical review burden. Heart Rhythm. 2023;20(5):S723. Doi: 10.1016/j.hrthm.2023.03.1498. **6.** Siejko KZ, Kupfer M, Rajan A, Herrmann K, Nair D. Premature ventricular contraction detection and estimation of daily burden by an insertable cardiac monitor. *Heart Rhythm O2*. 2025. doi: https://doi.org/10.1016/j.hroo.2025.01.004

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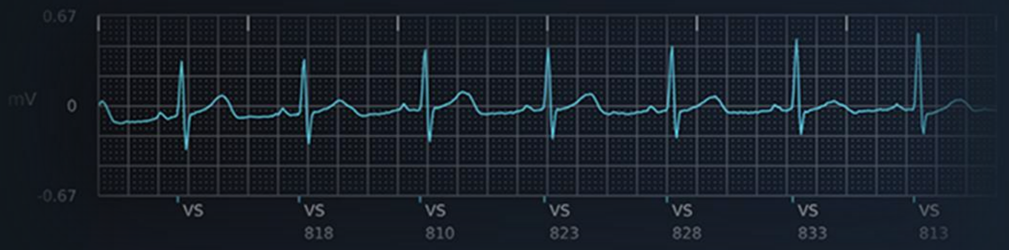
LUX-Dx II+™ Algorithm Performance

Section 1: Overall Performance

KEY DATA		
Characteristic	Description	Results
Signal Quality	Clear S-ECG signals	90% of heart cycles had clearly visible P-waves[1*]
		P-wave visibility is consistent over time[1*,2*]
Remote Programming	Reliable remote programming	92% of programming changes were applied within 48 hours[3*]
	Seamless connectivity	The median percentage of days with a data transmission for patients was 94%[3*]
Safety	Quick insertion, in both hospital and clinic settings	4-minute median procedure time[4*]
	Safe procedure	ICM system complication free rate was 99.4% for in-clinic procedures and 99.8% for hospital procedures[4*]

* Evaluated using the LUX-Dx™ ICM System

1. Frazier Mills C, Raja A, Saleeby RC, et al. Consistent visibility of P-waves observed in patients implanted with LUX-Dx Insertable Cardiac Monitor (ICM). Heart Rhythm. 2021;18(8):S398. doi: 10.1016/j.hrthm.2021.06.985 **2.** Richards M, Mahajan D, Simon T, et al. Interim evaluation of insertable cardiac monitor signal quality in the LUX-Dx PERFORM study. EP Europace. 2023;25:S1. Doi: https://doi.org/10.1093/europace/euad122.612 **3.** Stolen C, Rosman J, Manyam H, et al. Preliminary results from the LUX-Dx insertable cardiac monitor remote programming and performance (LUX-Dx PERFORM) study. Clinical Cardiology. 2023;46(1):100-107. Doi: doi.org/10.1002/clc.23930 4. Richards M, Mahajan D, Simon T, et al. Interim evaluation of insertable cardiac monitor signal quality in the LUX-Dx PERFORM study. EP Europace. 2023;25:S1. Doi: https://doi.org/10.1093/europace/euad122.612



Signal Quality

Section 1: Summary of Clinical Data

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Signal Quality Overview

Section 1: Summary of Clinical Data

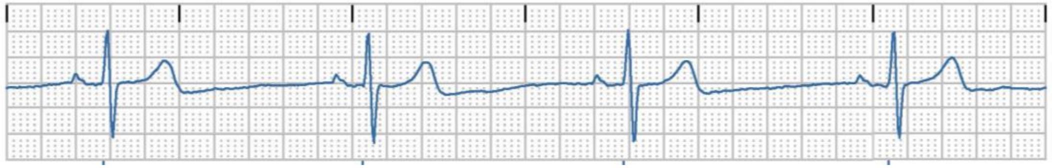
Adequate P-wave visibility may reduce analysis time & improve clinic workflow

90%

of P-waves clearly visible in heart cycles[1*]

97%

of patients had at least one presenting ECG with visible P-waves[1*]



P-wave visibility is **consistent over time**[1*, 2*]

* Evaluated using the LUX-Dx™ ICM System

1 Frazier Mills C, Raja A, Saleeby RC, et al. Consistent visibility of P-waves observed in patients implanted with LUX-Dx Insertable Cardiac Monitor (ICM). Heart Rhythm. 2021;18(8):S398. Doi: 10.1016/j.hrthm.2021.06.985 2 Richards M, Mahajan D, Simon T, et al. Interim evaluation of insertable cardiac monitor signal quality in the LUX-Dx PERFORM study. EP Europace. 2023;25:S1. Doi: https://doi.org/10.1093/europace/euad122.612

LUX-Dx™ ICM Systems

Signal Quality: P-Wave Visibility

Section 1: Summary of Clinical Data

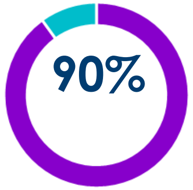
Visibility or absence of P-waves in the ICM ECG is an important feature in the diagnosis of atrial arrhythmias

Adequate P-wave visibility may reduce analysis time and improve clinic workflow

Study Overview

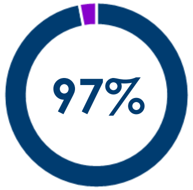
- Presenting ECGs were reviewed for first 100 LUX-Dx ICM patients 1, 7 and 30 days from insertion
- Of 300 presenting ECGs, 38 rhythms were excluded which included:
  - AF (AF burden >50%)
  - High HR (>120 bpm)
  - Excessive noise and unavailable data
- None of the patients had excessive noise or high HR on all three days

Results



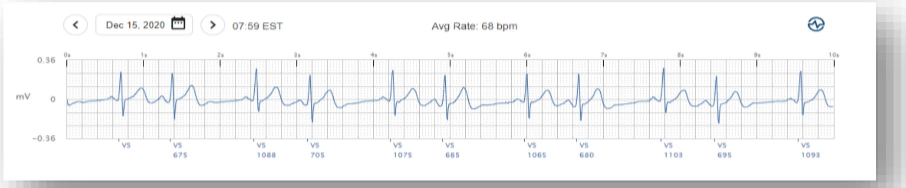
P-waves were clearly visible **in 90% of heart cycles** and consistent over time[1*]

P-waves visible in **97% of patients** on at least one presenting ECG[1*]



	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%

Examples of the presenting ECG display in the patient data management system LATITUDE Clarity™



* Evaluated using the LUX-Dx™ ICM System

1 Frazier Mills C, Raja A, Saleeby RC, et al. Consistent visibility of P-waves observed in patients implanted with LUX-Dx Insertable Cardiac Monitor (ICM). Heart Rhythm. 2021;18(8):S398. Doi: 10.1016/j.hrthm.2021.06.985

LUX-Dx PERFORM: Signal Quality

Section 1: Summary of Clinical Data

Visibility or absence of P-waves in the ICM ECG is an important feature in the diagnosis of atrial arrhythmias

Adequate P-wave visibility may reduce analysis time and improve clinic workflow

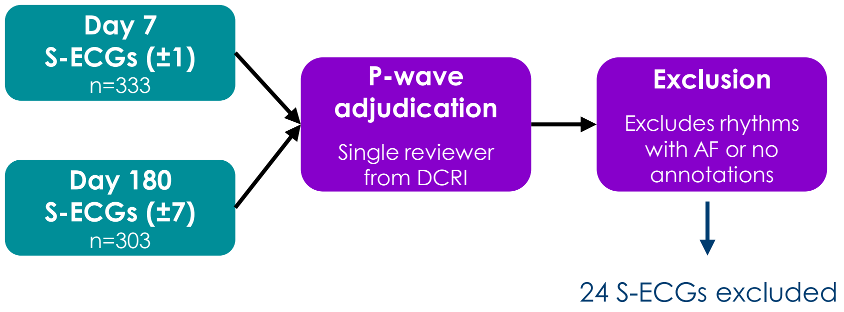
Study Overview

- P-wave visibility evaluated from first 356 patients enrolled in the LUX-Dx PERFORM study
  - Daily presenting rhythms used for assessment
- P-waves were blindly adjudicated by independent electrophysiologists from Duke Clinical Research Institute (DCRI)

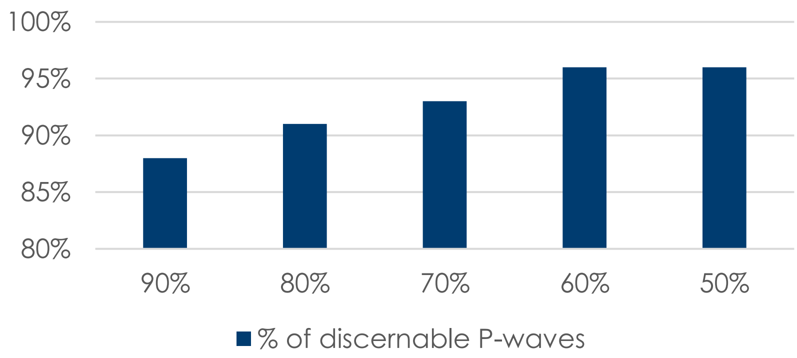
Results

Preliminary data from an interim evaluation of the LUX-Dx PERFORM study found LUX-Dx provided **consistent P-wave visibility through 180 days post insertion** with most patients having a clearly defined P-wave in most beats within a 10 second ECG strip[1*]

P-wave adjudication process



P-wave Visibility in At Least One ECG at a Patient Level



* Evaluated using the LUX-Dx™ ICM System

1 Richards M, Mahajan D, Simon T, et al. Interim evaluation of insertable cardiac monitor signal quality in the LUX-Dx PERFORM study. EP Europace. 2023;25:S1. Doi: https://doi.org/10.1093/europace/euad122.612

Remote Programming

Section 1: Summary of Clinical Data

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LUX-Dx™ ICM Systems

LUX-Dx PERFORM: Remote Programming

Section 1: Summary of Clinical Data

Evaluation of remote programming in the LUX-Dx PERFORM Study

Preliminary data from the LUX-Dx PERFORM study demonstrated high transmission rates and showed the feasibility of remote programming to optimize arrhythmia detection and improve clinical workflow

Study Overview

- Multicenter, prospective, single-arm, post-market, observational study (NCT04732728)
- First 369 patients enrolled used for interim evaluation

Results

- Successful daily data transmission from the ICM to LATITUDE Clarity™ Data Management System occurred 86% of the time[1*]
- Median % days with a data transmission for individual patients was 94%[1*]
- 43 reprogramming sessions in 34 subjects[1*]
  - 36 reprogramming sessions in 24 patients were completed using the **myLUX™ Patient App**[1*]
  - **92% of the changes were applied within 48 hours**[1*]

92%
of programming changes were applied within 48 hours[1*]
Real-world data!

94%
median % of days with a data transmission for individual patients[1*]
Real-world data!

Learn more about the downloadable myLUX Patient App, available for the LUX-Dx II/II+ ICMs!

Not available for M301

* Evaluated using the LUX-Dx™ ICM System

1. Stolen C, Rosman J, Manyam H, et al. Preliminary results from the LUX-Dx insertable cardiac monitor remote programming and performance (LUX-Dx PERFORM) study. Clinical Cardiology. 2023;46(1):100-107. Doi: doi.org/10.1002/clc.23930

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Robust Remote Programming

Section 1: Summary of Clinical Data

Robust programming to fine-tune patient alerts

Making remote programming adjustments to adapt to patient-specific considerations can be done without the need to bring the patient into the clinic and can enhance workflow by substantially decreasing episodes for review.

An ***independent study*** looked at the impact of remote reprogramming on alert transmissions across manufactures

	Medtronic	Abbott	Boston Scientific	Biotronik	Totals
# Patients	25	22	23	24	94
# Recommendations	24	21	22	24	91
# Response/ Changes Made	13	4	12	4	34
# Initial Transmissions	691	495	545	493	2,224
# Follow Up Tranmsssions	385	346	272	464	1,467
Total decrease in transmissions	306	149	273	29	757
Percentage	**44%**	**30%**	**50%**	**6%**	**34%**
Decreased transmission from remote recommendations	203	89	252	1	545
Decrease transmissions from programmer recommendations	57	66	N/A	30	153

Most changes made to BSC ICMs were done remotely. 12 programming changes were made across 23 BSC patients. This led to a **50% decrease in BSC transmissions.**[1]

Post reprogramming, the LUX-Dx ICMs had the lowest number of transmissions out of all manufactures.[1]

In an ***independent study***, the LUX-Dx ICM delivered alerts per day that were in-line with Medtronic's LINQ II™ ICMs†

0.15 median alerts/day for LUX-Dx[2*]
0.13 median alerts/day for LINQ II[2*]

After remotely programming the ICMs, LUX-Dx ICM alerts per day were substantially decreased and inline with LINQ II

0.01 median alerts/day for LUX-Dx[2*]
0.03 median alerts/day for LINQ II[2*]

* Evaluated using the LUX-Dx™ ICM System † All trademarks are the property of their respective owners

1 Kerns RV, Davish SF, Leahy RA, Flowers S. Reduction in Implantable Loop Recorder Alert Burden: A Targeted Approach to Slash Transmission Volume Using Patient Specific Programming Beyond Vendor Reason For Monitoring Nominals. Heart Rhythm. 2024;21(5):S159. doi: 10.1016/j.hrthm.2024.03.575 2 Neiman ZM, Raitt MH, Rohrbach G, Dhruva SS. Monitoring of remotely reprogrammable implantable loop recorders with algorithms to reduce false-positive alerts. Journal of the American Heart Association. 2024;13(5). Doi: doi.org/10.1161/JAHA.123.032890

LUX-Dx™
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Real-world Remote Programming

Section 1: Summary of Clinical Data

Real-world Remote Programming experience

Remote programming capabilities of the LUX-Dx ICM may improve the clinical experience of device programming optimization

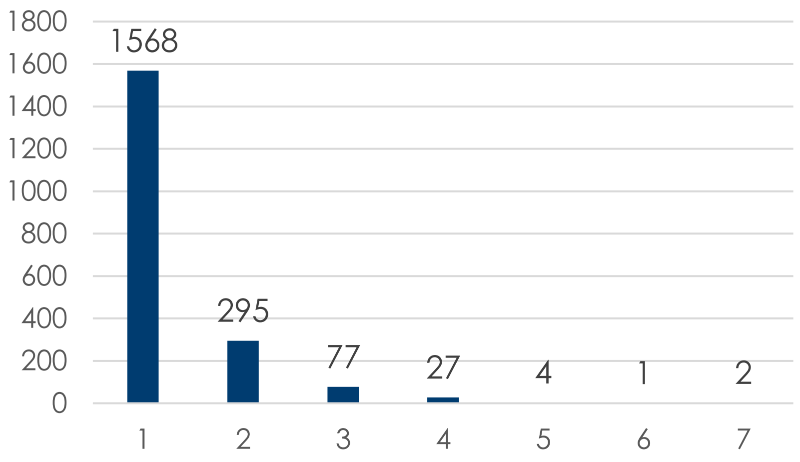
Study Overview

- Analysis included all patients in the US implanted with the LUX-Dx ICM between July 2020 and June 2021 (N=8,238)

Results

- 1,974 (24%) devices were reprogrammed
  - 1,025 patients had first reprogramming event within 10 days following insertion[1*]
    - 87% (891) remote
    - 13% (134) in-clinic
- Most patients (1,568, 79.4%) underwent **only 1 reprogramming event**[1*]

Frequency of Reprogramming Events



* Evaluated using the LUX-Dx™ ICM System

1. Mahajan D, Frost K, Herrmann K, McGee-Taylor R. Real-world characterization and use of insertable cardiac monitor remote programming. Innovations in Cardiac Rhythm Management. 2022;13(11):5230-5235. doi: 10.19102/icrm.2022.13112

Real-world European Experience

Section 1: Summary of Clinical Data

Real-world Remote Programming experience in European patients

Reprogramming reduces transmission review workload and remote reprogramming can help to optimize device management

Study Overview

- 506 patients across 20 European centers

Results

- 287 reprogramming events occurred in 153 patients
  - 101 events (35%) performed remotely[1*]
  - Within 30 days post-insertion, 18% of LUX devices were reprogrammed[1*]
  - Median transmission rate reduction of 23% after reprogramming[1*]

Transmission Types[1*]	
Alert	65% (8,290)
Scheduled	30% (3,829)
Patient-initiated transmissions	4% (481)
Clinician initiated interrogations	1% (92)

* Evaluated using the LUX-Dx™ ICM System

1. Fareh S, Argenziano L, Scala F, et al. Real-world use of insertable cardiac monitor remote programming. EP Europace. 2025;27(suppl_1). Doi: 10.1093/europace/euaf085.037

Insertion Experience

Section 1: Summary of Clinical Data

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LUX-Dx PERFORM: Preliminary Results

Section 1: Summary of Clinical Data

Evaluation of device insertion and safety in the LUX-Dx PERFORM Study

Preliminary data from the LUX-Dx PERFORM study found that the LUX-Dx ICM can be inserted quickly, in both hospital and clinic settings, with a very low complication rate

Study Overview

- 727 patients enrolled at 24 centers in the US from March 2021 to May 2022
  - 717 patients had successful device insertions
  - 9 patients withdrew prior to insertion
- ICM system-related complication-free rate (CFR) was calculated using Kaplan-Meier methodology
  - 97.5% one-side lower confidence limit (LCL) was compared to prespecified performance target of 94%
  - All ICM system-related adverse events were adjudicated by independent physicians

Results

- 76% of the insertions occurred in-hospital and 24% occurred in-clinic[1*]
- Several closure techniques were used with surgical glue being used most often (62%) [1*]
- Median procedure time was 4 minutes[1*]
- ICM system-related complications were low in both clinic (99.8% CFR) and hospital (99.8% CFR) settings[1*]

ICM INSERTIONS	PROCEDURES (n=718)
Setting	
Hospital	547 (76%)
Clinic	171 (24%)
Closure Technique	
Surgical glue	441 (62%)
Adhesive strips	321 (45%)
Sutures	298 (42%)
Staples	61 (9%)

* Evaluated using the LUX-Dx™ ICM System

1. Richards M, Stolen C, Simon T, et al. Evaluation of insertable cardiac monitor placement and safety in the LUX-Dx PERFORM study. EP Europace. 2023;25;S1. Doi: https://doi.org/10.1093/europace/euad122.654

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European Insertion Experience

Section 1: Summary of Clinical Data

Preliminary data from the EU shows the implantation of the LUX-Dx as fast and uncomplicated

Positive feedback was received from the operator and patient

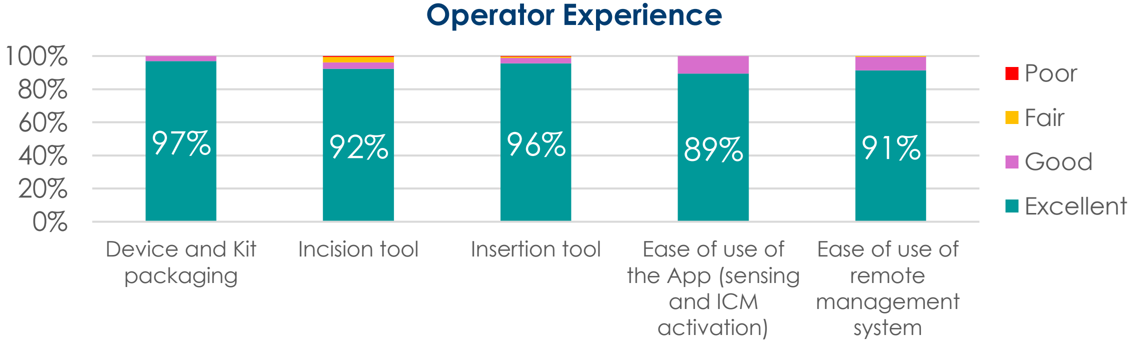
Study Overview

- 368 implantation procedures
  - From 23 EU centers
- System includes:
  - Incision tool
  - Single-piece insertion tool with pre-loaded LUX-Dx ICM
- Following implantation, patients provided mobile device with preloaded App to connect to their ICM
- Data and feedback taken at time of implant

Results

PROCEDURE DETAILS	N=368
Electrophysiology labs	92%
Use of local anesthesia	97%
Use of systemic or local antibiotics	56%
Surface ECG mapping performed	30%
ICM implantation in left parasternal region	100%
ICM implantation with an orientation of 45°	88%
Median time from skin incision to suture	4 min (25%-75%: 2-7)

- Device repositioning was required in 2% (n=9) patients
- **Majority of patients didn't report any pain or paresthesia** either at implant (91% and 98%, respectively) or discharge (98% and 99%, respectively)[1*]
- Median time from skin incision to suture was **4 minutes**[1*]
- Operator experience rated all insertion procedure components as "**Excellent**" a majority of the time (≥ 89%)[1*]



* Evaluated using the LUX-Dx™ ICM System.

1. Fareh S, Nardi S, Argenziano L, et al. Implantation of a novel insertable cardiac monitor: preliminary multicenter experience in Europe. J Interventional Cardiac Electrophysiology. 2024;67(9):2117-2125. doi: 10.1007/s10840-024-01821-y

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Section 2
Recent Publications

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LUX-Dx™ ICM Systems

AI vs. EP Adjudication

Section 2: Recent Publications

AI is as good as expert EPs when adjudicating atrial arrhythmia ICM episodes*

Expert EP adjudicators demonstrated high agreement with each other when adjudicating atrial arrhythmia (AA) events recorded from LUX-Dx ICMs. An AI algorithm classification of the same rhythms compared against the consensus of the EPs yielded similar high agreement.

Study Overview

- 316 LUX-Dx ICM* AF and AT episodes, as well as patient triggered events
- Rhythms adjudicated by:
  - 3 certified EPs
  - AI, which included BeatLogic™
- Rhythm classification did not distinguish between AF, AFlut, and other AAs
- Agreement assessment used Cohen's Kapa

Results

- Expert EP adjudicators demonstrated high agreement with each other (mean pairwise Kappa = 0.89)[1,*]
- **Comparison of the AI classification vs. the expert EP consensus yielded similarly high agreement** (Kappa = 0.89)[1,*]

	AI vs Consensus EP	EP A vs EP B	EP A vs EP C	EP B vs EP C	EP Mean
Kappa	0.89	0.91	0.88	0.88	0.89
Upper CL	0.94	0.95	0.93	0.93	--
Lower CL	0.84	0.86	0.82	0.82	--

** Concept device or technology. Not available for sale on the LUX-Dx ICMs*

1 Andrade J, Stucky M, Wold N, et al. Artificial Intelligence versus Electrophysiologists adjudication of atrial arrhythmias: a validation study. Abstract presented at: Heart Rhythm 2025; April 25, 2025; San Diego, CA; CE-499645-004. doi: 10.1016/j.hrthm.2025.03.065

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EP Adjudication of AF Episodes

AF is a complex arrhythmia and can cause disagreement with adjudication

This observation highlights the need for a more accurate and consistent way to adjudicate ICM S-ECG.

Study Overview

- To evaluate the adjudication agreement between EPs reviewing LUX-Dx detected AF episodes, 3 types of analyses were performed:
  - Single EP vs. 7-EP's expert consensus using 117 episodes
  - Clinicians vs. 2-EP's expert consensus using 1268 episodes
  - Inter-rater agreement (EP vs. EP, EP vs. Clinic) using 1493 episodes
- All inter-rater comparisons were quantified using Cohen's Kappa and percentage agreement

Results

- There was a **sizeable observed disagreement among physicians** in the adjudication of ICM-detected AF/Aflutter episodes[1]
- A trend of **higher sensitivity and lower specificity** was observed; this might reflect a more conservative approach to avoid missing true episodes[1]
- The observed 12-18% disagreement between reviewers has implications for both patient care and new algorithm development, which relies on adjudication as a reference standard[1]

	# LUX-Dx AF Episodes	Agreement %	Cohen's Kappa	Sensitivity	Specificity
Single EP vs. EP Expert Consensus	117	82.2%	0.68	93%	77%
Clinic vs. EP Expert Consensus	1268	87.8%	0.76	98.2%	78%
EP vs. EP	1493	88.2%	0.77	NA	NA

1 Pokorney S, Rajan A, Mahajan D, et al. Physician disagreement when adjudicating atrial fibrillation episodes detected by insertable cardiac monitor. Poster presented at: Heart Rhythm 2025; April 25, 2025; San Diego, CA; PO-02-121. doi: 10.1016/j.hrthm.2025.03.603

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New AF in a HF Population

Section 2: Recent Publications

High prevalence of newly detected AF in the LUX-Dx TRENDS study population*

Patients predominately classified with persevered or moderately reduced EFs were observed to have a high rate of AF that was previously undiagnosed.

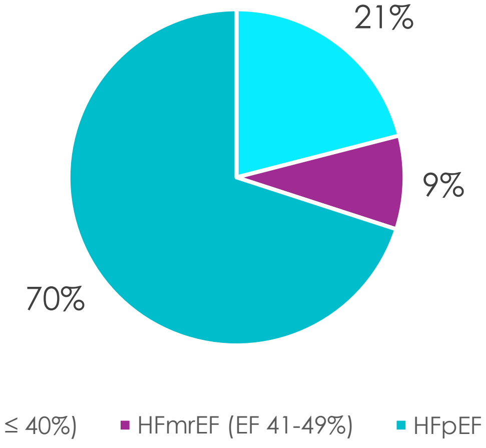
Study Overview

- In this preliminary analysis, 132 LUX-Dx TRENDS patients who did not have a previous atrial arrhythmia (AA) diagnosis were assess for detection of new AF
- An AI algorithm was used to classify ICM-detected AF episodes
  - Down-selected to the first, longest, and fastest episodes
  - Resultant episodes were adjudicated by an EP
- Time to occurrence of true AF calculated using Kaplan-Meier methodology

Results

- Estimated detection of newly evident AF:[1]
  - 29% at 1 year
  - 41% at 1.5 years
- Majority of patients (70%) had an EF ≥ 50% (HFpEF)[1]

HF Patients with no prior history of AA (N=132)



** Concept device or technology. Not available for sale on the LUX-Dx ICMs*

1 Pokorney S, Rajan A, Mahajan D, et al. Physician disagreement when adjudicating atrial fibrillation episodes detected by insertable cardiac monitor. Poster presented at: Heart Rhythm 2025; April 25, 2025; San Diego, CA; PO-02-121. doi: 10.1016/j.hrthm.2025.03.603

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Section 3

LUX-Dx II+ Algorithm Performance

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Atrial Fibrillation (AF) Algorithm

Section 3: LUX-Dx II+™ Algorithm Performance

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AF Algorithm: Legacy Data

Section 3: LUX-Dx II+™ Algorithm Performance

Applicable to LUX-Dx™

The LUX-Dx II+ ICM leverages the AF algorithm from the first-generation LUX-Dx, with two additional enhancements discussed on the next pages to further reduce false positives and the number of AF S-ECGs for review.

A robust first-generation LUX-Dx™ AF algorithm

Episodes are verified using an adaptive morphology assessment and R-R variability to reduce false positives. The LUX-Dx ICM System allows for tailored sensitivity settings through the programmable response settings.

R-R Variability and Morphology Assessment

Based on S-ICD technology, AF episodes are verified in using an adaptive morphology assessment, which rejects non-AF windows by comparing each beat to an **adaptive patient-specific template**, discriminating noise and PVCs from AF.

Study Overview[1*]

- Surface ECG from 2,040 patients (77 AF, 3.8% AF prevalence)
- 161,306 2-min windows (3872 AF)
- Assessed by the AF algorithm under 5 settings

Results

Inclusion of the morphology assessment at the 'Least' AF Sensitivity Setting **resulted in a 53.1% reduction** in false positive AF detection while maintaining sensitivity.[1*,†]

AF burden PPV using morphology ranged from **73%-99%**[1‡*]

Programmable sensitivity response settings

Response settings provide important flexibility, enabling you to **fine-tune a patient's ICM settings** and titrate events

Study Overview[2*]

- Simulated reprogramming the first 100 LUX-Dx patients
- 1,028 adjudicated AF episodes

Results

Episode Level Reduction

Simulated Reprogramming	True Positive (TP)	False Positive (FP)
More → Balanced	-23%	-60%
Balanced → Less	-11%	-57%
Less → Least	-17%	-57%

Simulated reprogramming to a lesser sensitivity setting in simulation resulted in no loss in patient-level sensitivity & a higher reduction in FP than TP episodes[2*,‡]

*Evaluated using the LUX-DxTM ICM System † Bench Test results may not necessarily be indicative of clinical performance. ‡ As of 3/3/2025: 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™ and JOT Dx™ ICM Help Manual, Merlin Patient Care System Assert-IQ™ ICM Help Manual.

1 Mittal S, Saha S, Pershbacher D, Siejko KZ. Improved AF rhythm discrimination with an implantable cardiac monitor using QRS morphology. Heart Rhythm. 2019;16(5):S256-257. **2** Boston Scientific Internal Data on File. 1,028 AF episodes were reviewed and adjudicated by a panel of electrophysiologists to calculate PPV. Average monitoring time was 144 days.

LUX-Dx™ ICM Systems

AF Algorithm: Novel Pattern Detection

Section 3: LUX-Dx II+™ Algorithm Performance

38% reduction in false positives while maintaining high relative sensitivity [1*]

LUX-Dx II+ ICMs feature enhanced AF algorithm to further minimize false positives

Enhanced AF detection algorithm incorporates novel pattern detection features.

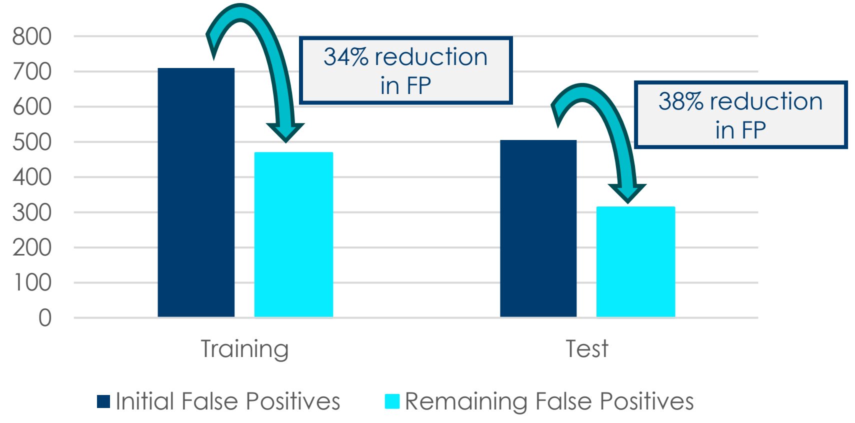
Study Overview

- AF enhancement utilizes a run test theory for randomness (AF) or non-randomness (Not AF)
- Trained using Holter ECG data from THEW database (Telemetric Holter and ECG Warehouse, Univ. of Rochester, NY, assigned per database) as well as *in vivo* episodes from the LUX-Dx™ ICM (independently adjudicated)
- Tested *in silico* against independent set of LUX-Dx episodes (121 patients, limited to ≤5 episodes per patient, at any programmed AF sensitivity setting and duration)

Results

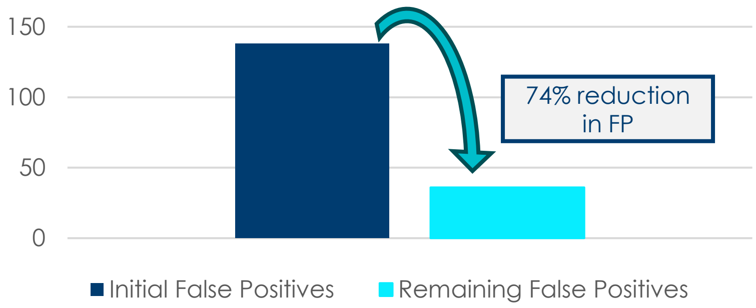
Implementation of this algorithm enhancement demonstrated a **38% reduction in AF false positives** while maintaining high relative sensitivity (>98%)[1*]

Change in False Positive AF Episodes



Subsequent analysis of 135 adjudicated episodes showed a dramatic **74% reduction in false positives while maintaining 100% relative sensitivity** when restricted to episodes of a 4-minute duration and More response settings[1*]

AF False Positive Reduction of 4 Minute Episodes When Programmed to More Sensitive



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

1. Richards M, Perschbacher D, Mahajan D, Saha S, Herrmann K, Frost K. Novel Algorithm for Improved AF Detection in Insertable Cardiac Monitors. Heart Rhythm. 2022;19(5):S289-S290. Doi: 10.1016/j.hrthm.2022.03.336

Applicable to LUX-Dx II+™ ICM System only

LUX-Dx™ ICM Systems

AF Algorithm: Episode Merging

Section 3: LUX-Dx II+™ Algorithm Performance

The LUX-Dx II+ ICM features an enhanced AF algorithm that merges adjacent AF episodes

Merging adjacent AF episodes reduced 26% of AF S-ECGs for review, which may improve clinic workflow and expedite clinical decision making[1*]

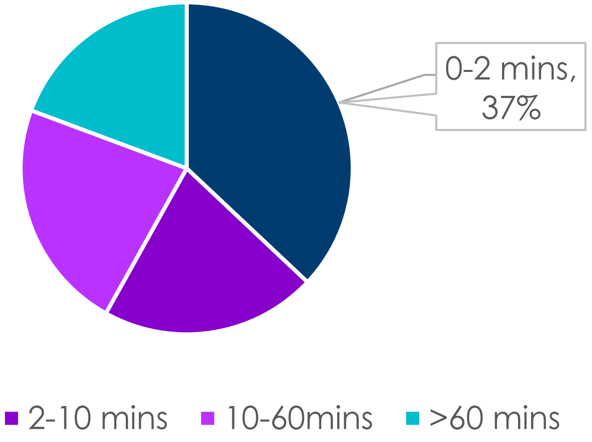
Study Overview

- 1,423 LUX-Dx ICM patients, and detected Bradycardia, Pause, or AF episode
- 18,025 AF episodes (n=246)
- Clinically non-actionable AF episodes defined as:

  Consecutive AF episodes (any time of day) separated by ≤ 2 mins and are considered a continuation of the same AF event

Results

AF Episode Gaps



Detected AF episodes were found to be in proximity with a previously detected AF episode[1*]:

36% at episode level

18% at patient level

26% reduction in AF S-ECGs for clinical review[1*]

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

1. Rajan A, Perschbacher D, Mahajan D, et al. Improving Clinic Workflow and Diagnosis for the LUX-Dx Insertable Cardiac Monitor. Heart Rhythm. 2022;19(5):S235. Doi: 10.1016/j.hrthm.2022.03.206

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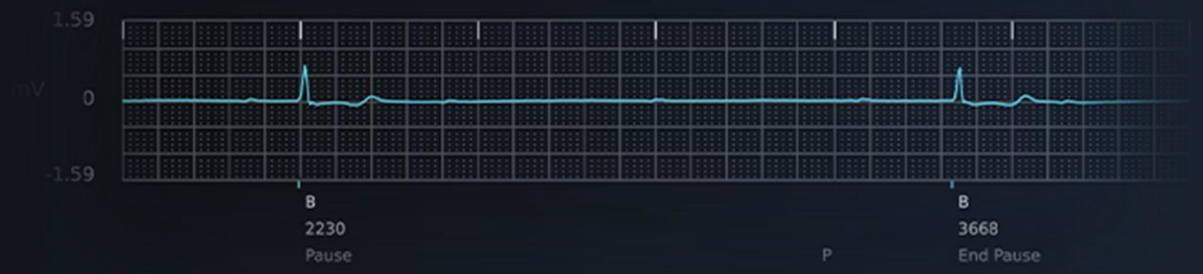

Pause Algorithm

Section 3: LUX-Dx II+™ Algorithm Performance

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Pause Algorithm: Signal-to-Noise

Section 3: LUX-Dx II+™ Algorithm Performance

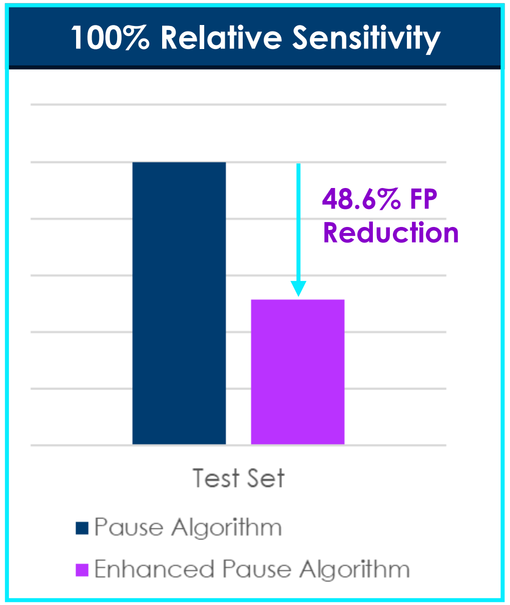
Enhanced Algorithm to decrease the review burden in ICM device clinics

Rejecting false positives due to very low signal-to-noise ratios substantially reduces false pause episodes. This can potentially lead to reduced clinic review burden.

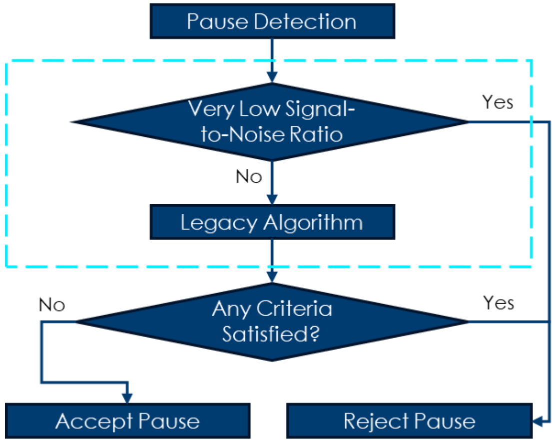
Study Overview

- BSC internal adjudication of development test set
  - 347 patients, 1033 episodes
- Independent test set adjudicated by two experts (third expert resolved disagreements)
  - 93 patients, 728 episodes

Results



The enhanced Pause algorithm for very low signal-to-noise ratio **reduced false positives by 49%** while maintaining 100% relative sensitivity[1*]



	Number of Patients	Number of Episodes	Relative Sensitivity (%)	Reduction in FP episodes (%)	Reduction in patients with FP events (%)
Development	347	1033	100	62.5	74.1
Test	93	728	100	48.6	31.3

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

1. Burke MC, Ravikumar V, Siejko K, Bohn D, Verdino RJ. Enhanced pause algorithm for insertable cardiac monitor reduces clinical review burden. Heart Rhythm. 2023;20(5):S723. Doi: 10.1016/j.hrthm.2023.03.1498

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Nighttime Programming

Section 3: LUX-Dx II+™ Algorithm Performance

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Nighttime Programming: Pause & Brady

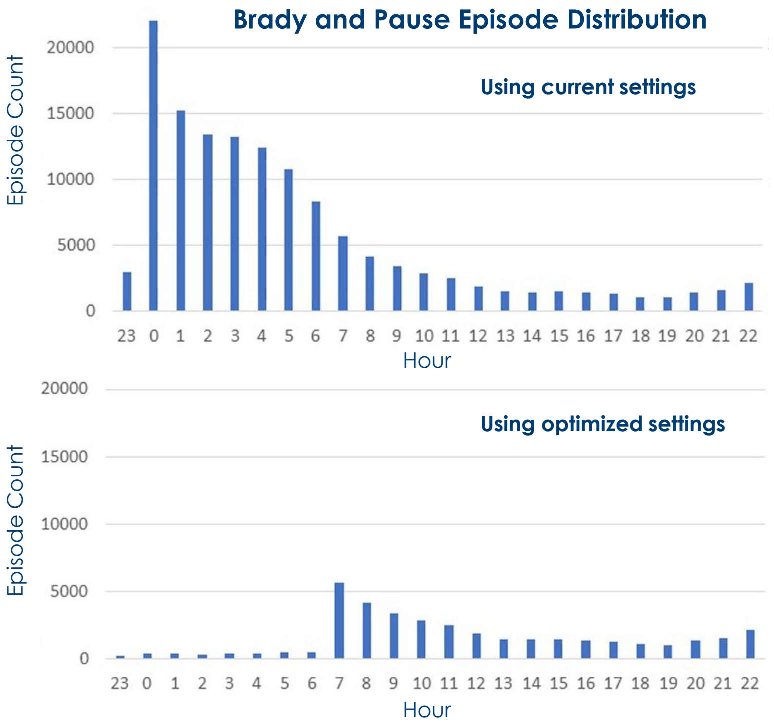
Section 3: LUX-Dx II+™ Algorithm Performance

LUX-Dx II+ ICMs feature advanced nighttime programming capabilities to detect and differentiate personalized nighttime brady and pause events for review

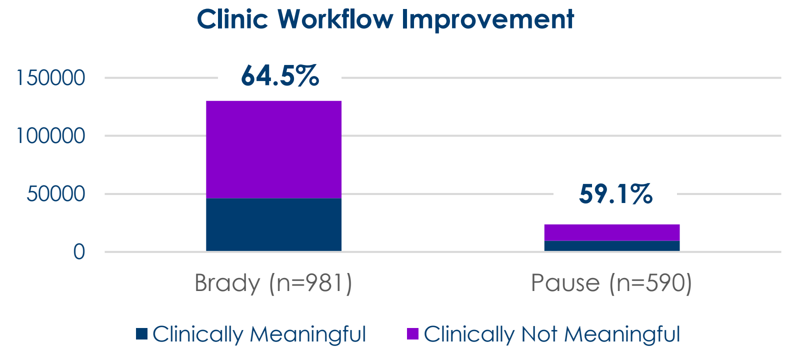
Study Overview

- 1,423 LUX-Dx ICM patients, and detected Bradycardia, Pause, or AF episode
- 130941 Brady episodes (n=981) and 24993 pause episodes (n=590)
- Clinically non-actionable pause and brady episodes defined as:
    - Nocturnal (11 pm – 7 am) bradycardia episodes with HR > 30 BPM
    - Nocturnal pause episodes with episode duration < 5s

Results



- At an episode level, 65% and 59% of brady and pause episodes were nocturnal, respectively[1*]
- Removing nocturnal episodes defined as clinically non-actionable **resulted in a reduction of 75% of Brady and 57% of Pause S-ECGs episodes for review**[1*]



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

1. Rajan A, Perschbacher D, Mahajan D, et al. Improving Clinic Workflow and Diagnosis for the LUX-Dx Insertable Cardiac Monitor. Heart Rhythm. 2022;19(5):S235. Doi: 10.1016/j.hrthm.2022.03.206

Image taken from: Burke M, Rajan A, Pershbacher D, Mahajan D, Herrmann K. Does optimized daytime/nighttime programming reduce insertable cardiac monitor event burden? EP Europace. 2023;25:S1. Doi: 10.1093/europace/euad122.249

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Premature Ventricular Contractions (PVC) Burden Algorithm

Section 3: LUX-Dx II+™ Algorithm Performance

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LUX-Dx™ ICM Systems

PVC Burden: Performance

Section 3: LUX-Dx II+™ Algorithm Performance

The LUX-Dx II+ ICM PVC Burden algorithm capable of detecting multiple PVC sequences, including couplets and triplets

Study Overview

- Beat-level PVC detection performance evaluated by replaying patient-triggered ECG recordings from the predecessor LUX-Dx ICMs
- Burden-level was assessed *in silico* against real-world Holter data
- Software model used to compare performance of the ICM algorithm directly to other PVC algorithms using an established benchmark dataset

Results

- Patients' PVC burdens
  - 38 patients had true PVC burdens >10%[1*]
    - **100% PPV, 85% sensitivity, 100% specificity**
  - For select patients with high PVC burdens, PVC sequences account for a high % of their overall PVC count--**failure to detect would lead to a significant underestimation of true burden**
    - 20 ICM patients had adjudicated PVC couplets or triplets (28% of total true PVC tally)
    - 8/20 patients had true PVC burdens of ≥5%,
      - Detected PVC sequences comprised on average 16% of all ICM PVC counts
- Comparison to Benchmark
  - Linear correlation of r2 = 0.988 vs true PVC burden with a RMSE of 0.95%[1*]

Dataset	No. patients	Average PVC burden	% PVC couplets & triplets
ICM patient-triggered episodes	183	0.84%	11.6%
24-Hr Holter	89	11.6%	11.2%
MIT-BIH arrhythmia	22	6.5%	9.6%

Beat-level PVC Detection Performance[1†]

	Metric	Gross Performance	Patient Average	GEE & CI
Software Model	Sensitivity	81.0%	73.3%	73.7% (67.7-79.0)
	Specificity	99.8%	88.7%	99.7% (99.5-99.8)
	PPV	74.4%	44.3%	44.5% (38.0-51.2)

* in silico testing of algorithm performance on 12-lead Holter data. † Simulated performance tested on real-world LUX-Dx ICM events

1. Siejko KZ, Kupfer M, Rajan A, Herrmann K, Nair D. Premature ventricular contraction detection and estimation of daily burden by an insertable cardiac monitor. Heart Rhythm O2. 2025. doi: https://doi.org/10.1016/j.hroo.2025.01.004

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PVC Burden: Real-World Usage

Section 3: LUX-Dx II+™ Algorithm Performance

Flexible Dual-Stage Algorithm

The LUX-Dx II+ ICM offers unique and flexible programming capability that allows clinicians to tailor settings to meet the needs of their patients

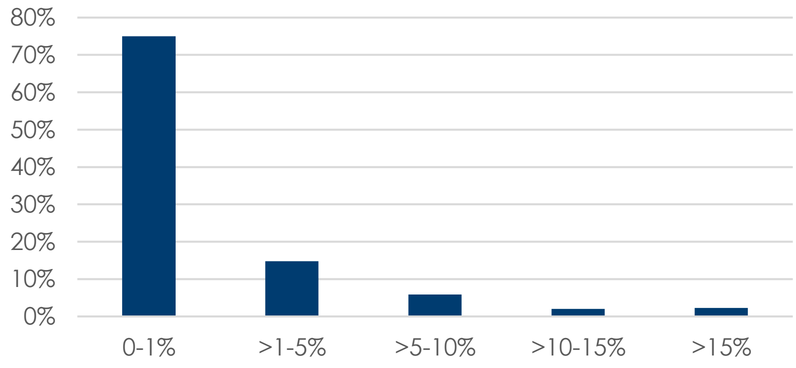
Study Overview

- Daily PVC burden trends were obtained from 6,729 US patients monitored with the LUX-Dx II/II+ ICMs (M302, M312) in the LATITUDE Clarity™ Data Management System

Results

- Patients' PVC burdens
  - PVC Burden algorithm turned ON in 1,177 patients (17.5%)[1]
  - Majority of patients had PVC Burden ≤1%[1]
  - **> 4% of patients had PVC burdens >10%**[1]
- PVC burden alert programming
  - Most commonly programmed combination for PVC burden alerts was a 15% threshold for 5 days[1]
  - **17 of 24 possible alert configurations were utilized**[1]
- Clinicians' PVC Programming and Monitoring
  - In patients with PVC Burden turned ON, **50.5% utilized Continuous monitoring, and 50.0% utilized Short-Term periodic monitoring**[1]

Distribution of Mean Daily PVC Burden by Patient



Programming Mode (N=6,729)		
	Patients (n)	Patients (%)
PVC Burden ON	1,177	17.5%
Continuous Mode	588	50.0%
Short-term Periodic Mode	589	50.5%

1. Herrmann K, Mahajan D, Fuhs M, Siejko K, Kupfer M. Initial real-world usage of a novel PVC burden feature with programmable alerts in an insertable cardiac monitor. Heart Rhythm. 2025;22(4):s681. doi: https://doi.org/10.1016/j.hrthm.2025.03.1655

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Atrial Tachycardia (AT) Algorithm

Section 3: LUX-Dx II+™ Algorithm Performance

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AT Algorithm: Longer Durations

Section 3: LUX-Dx II+™ Algorithm Performance

Longer Durations Yield Higher PPVs

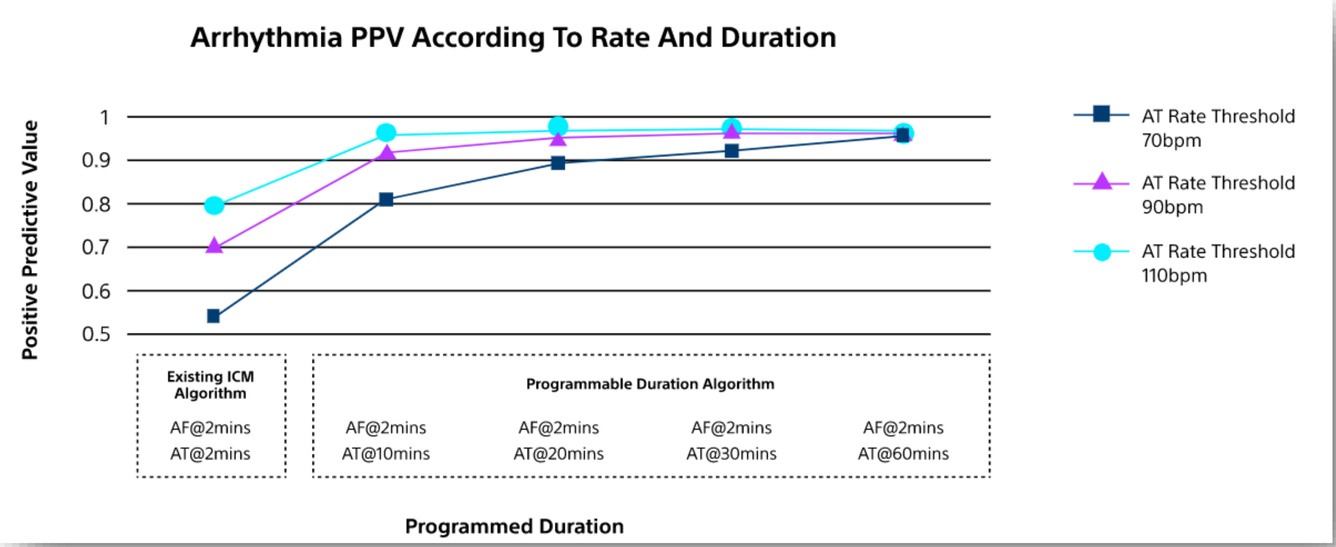
The flexibility of this AT algorithm allows for short duration AF monitoring with longer duration AT monitoring, which may improve capture of atrial tachycardias when compared to devices with inflexible AT duration settings.

Study Overview

- Surface ECGs from 2,010 patients
- 77 AF patients
- 6 AT patients

Results

- A high PPV for AT can be achieved while maintaining detection sensitivity for short durations
  - **PPV improved from 54% to 97%** with higher rates and longer durations[1*,†]



* Bench Test results may not necessarily be indicative of clinical performance. † Evaluation using the LUX-Dx™ ICM System

1. Richards M, Pershbacher D, Saha S. A novel algorithm improves detection of arrhythmias with regular RR intervals in implantable cardiac monitors. Heart Rhythm. 2019;16(5):S447-S448.

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AT Algorithm: Longer Durations

Section 3: LUX-Dx II+™ Algorithm Performance

Longer Durations Yield Higher PPVs

The flexibility of this AT algorithm allows for short duration AF monitoring with longer duration AT monitoring, which may improve capture of atrial tachycardias when compared to devices with inflexible AT duration settings

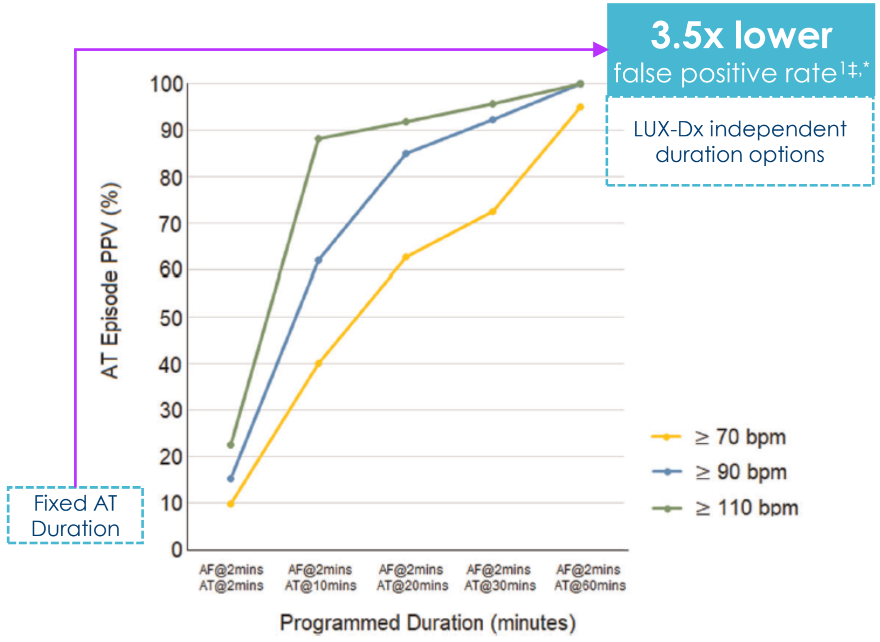
Study Overview

- Surface ECG from 1,966 patients using THEW Library
- Adjudicated episodes of atrial flutter
  - N=6, 82 hours total
- AT algorithm programmed to different combinations of rate and duration while AF algorithm was programmed and held constant at a 2-min duration and AF Response set to More

Results

AT Algorithm PPV increased to 100% when programed to longer durations

- When the AF and AT algorithms were both programmed to a 2-min duration (fixed settings typical of other existing ICMs), AT algorithm episode-level PPV was 22% at ≥110 bpm[1*,†]
- When the AF algorithm was programmed to a 2-min duration and the AT algorithm was programmed to a 60-min duration, the AT algorithm episode-level PPV was 100% at ≥110 bpm[1*,†]



* Bench Test results may not necessarily be indicative of clinical performance † Evaluation using the LUX-Dx™ ICM System ‡ False Positive Rate = 100% PPV. 3.5x lower false positive rate at 110bpm, the nominal LUX-Dx AT duration = ((100%-22%)/22%)

1 Saha S, Perschbacher D, Jones P, Frost K, Sharma A, Mittal S, Richards M. A novel adaptive insertable cardiac monitor algorithm improves the detection of atrial fibrillation and atrial tachycardia in silico. Journal of Cardiovascular Electrophysiology. 2021;32(9):2536-2543. Doi: doi.org/10.1111/jce.15178

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AT Algorithm: AT without AF

Section 3: LUX-Dx II+™ Algorithm Performance

A population of patients have AT and do not have AF

When patients had the presence of both AT and AF, when AT was detected first, it was detected 26 days prior to AF[1]

Study Overview

- In vivo analysis
  - 40 patients (avg 49 days/patient)
- AT algorithm: programmed to 4 hours for 24 patients and 2 hours for 16 patients
  - All were programmed to > 110bpm

Results

In 14% of cryptogenic stroke patients, the LUX-Dx™ AT algorithm identified AT in patients who had no AF episodes[1*]

	All Patients Pts (Episodes)	Cryptogenic Stroke Pts (Episodes)	Syncope Pts (Episodes)	Rhythm Mgmt Pts (Episodes)
Patients	40	14	4	19
AF Total	10 (534)	3 (90)	0(0)	7 (444)
AT Total	10 (47)	3 (17)	1 (1)	6 (29)
AT and No AF	6 (26)	2 (13)	1 (1)	3 (12)
% AT Only Detected	15%	14%	25%	16%

Study Overview

- Deidentified LUX-Dx patient data from LATITUDE Clarity, 3,736 patients
- 1,705 episodes, not adjudicated

Results

A larger data set broken down by indication shows a **significant number of stroke and syncope patients with AT alone**[1*]

% of patients who had AT and no AF[1*]

	Patients (#)	Patients (%)
Stroke Patients	**93/147**	**63.3%**
Syncope Patients	122/175	69.7%
Rhythm Management Patients	31/209	14.8%

In LUX-Dx patients with AT episodes who also had the presence of AF, **when AT was detected first, AT was detected 26 days prior to AF**[1*]

* Evaluation using the LUX-Dx™ ICM System

1 Richards M, Perschbacher D, Frost K, Herrmann K. Improved Detection of Atrial Arrhythmias with Regular R-R Intervals in Patients with the LUX-Dx Insertable Cardiac Monitor. Poster presented at Heart Rhythm 2021;18(8):S389. Doi: 10.1016/j.hrthm.2021.06.964

Tachycardia Algorithm

Section 3: LUX-Dx II+™ Algorithm Performance

LUX-Dx™
ICM Systems

Tachy Algorithm: Dual-Stage Algorithm

Section 3: LUX-Dx II+™ Algorithm Performance

Patient adaptive machine learning Tachy algorithm

Patient adaptive machine learning is used to optimize the verification stage of the tachycardia detection algorithm and updates regularly. The morphology assessment in the verification stage is based on Boston Scientific's S-ICD technology.

Study Overview

- Tachy episodes were recorded at the time of an EP study
  - n=340; VT 265/SVT75
- Holter recordings acquired during exercise stress testing were used to study noise
  - n=603; 375 pts
- An independent test set included tachy episodes from S-ICDs and additional Holter recordings with noise and artifacts
  - SICD test set: n=233; 93 pts; VT 232/SVT 1
  - Holter test set: n=879; 500 pts

Results

In bench testing, the tachy algorithm:

- **Improved PPV to 86%** compared to 23% for conventional 8 out of 10 beat tachy detection [1*,†]
- **Correctly rejected noise 96% of the time**[1*,†]
- Correctly **classified VT v. SVT 97.3%** of the time [1*,†]

	Training Set (%)	Test Set (%)
Candidate Episode Counts	340 tachy, 603 noise	233 tachy, 879 noise
Conventional 8/10 Tachy Detention PPV	37.9	23.4
Enhanced Tachy Detention PPV	94.4	86.2
Decision Tree Performance:		
Relative sensitivity	98.8	99.1
Correct VT vs. SVT Classification Rate	97.5	97.3
Correct Noise Rejection	97.8	96.0

** Bench Test results may not necessarily be indicative of clinical performance* † Evaluation using the LUX-Dx™ ICM System

1 Mittal S, Siejko K, Saha S, Herrmann K, Perschbacher, D. Can Machine Learning be Used to Optimize a Tachycardia Detection Algorithm in an Implantable Cardiac Monitor. Poster presented at: 2018 European Society of Cardiology; August, 2018; Munich, Germany

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Section 4

Clinical Trials

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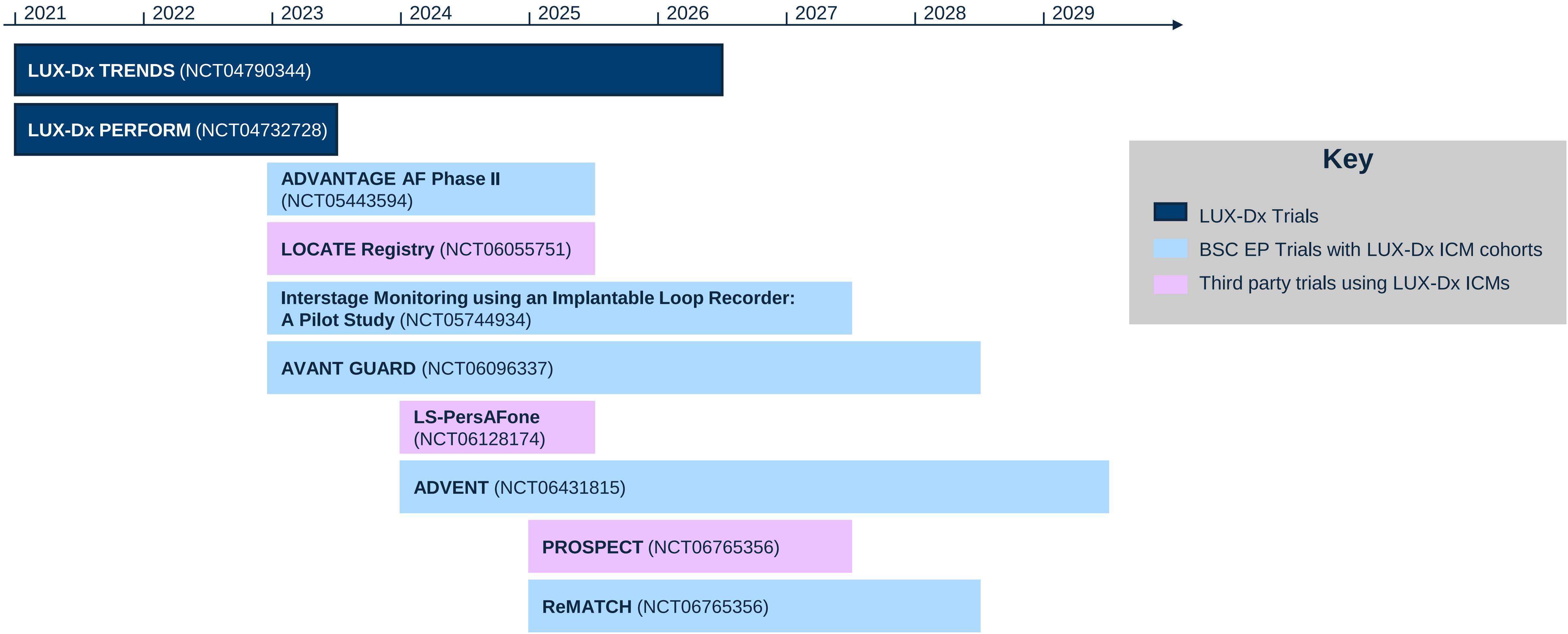
LUX-Dx™ ICM Systems

Timeline of US Clinical Trials

Section 4: Clinical Trials



LUX-Dx™ ICM Systems

LUX-Dx™ PERFORM Study

LUX-Dx™ Insertable Cardiac Monitor Remote Programming and Performance Study

PURPOSE

The LUX-Dx PERFORM clinical trial will characterize use of the remote programming feature of the LUX-Dx insertable cardiac monitor (ICM) as well as its arrhythmia detection performance and system-related safety events.

DESIGN ELEMENTS

This is a prospective, multi-center, single-arm, post-market, observational study with the goal of characterizing and summarizing data collected from the LUX-Dx ICM System.

- **Participants:** Approximately 600-800 adults will be enrolled and implanted with the LUX-Dx ICM within 30 days post-enrollment. Participants must be indicated for the LUX-Dx ICM and monitored for cryptogenic stroke, syncope, AF management, post-AF ablation or suspected AF.
- **Duration:** Approximately 12 months for each participant with an overall study duration of 3.5 years
- **Timeline:** Enrollment began March 2021

CLINCIAL RELEVANCE

This study will support evidence-based recommendations regarding the use of remote programming and the LUX-Dx ICM system by characterizing its use, performance and safety in a broad range of people indicated for an ICM.

ClincialTrials.gov identifier NCT04732728

LUX-Dx™ Heart Failure Sensors in an Insertable Cardiac Monitor System (LUX-Dx TRENDS)

PURPOSE

The LUX-Dx TRENDS clinical trial will collect sensor and heart failure event data that will be used in the development of new insertable cardiac monitoring (ICM) systems.

DESIGN ELEMENTS

This is a prospective, multi-center, single-arm, non-significant risk, investigational device study that will collect clinical data as well as device data using an investigational version of the LUX-Dx™ ICM. A portion of data will also be collected using a wearable cardiac monitor.

- **Sub-studies:** Participants will contribute to at least one of the two sub-studies involving echocardiography and exercise.
- **Participants:** Approximately 300-500 adults with NYHA Class II or III heart failure will be enrolled and implanted with the investigational version of the LUX-Dx ICM.
- **Duration:** All participants will be followed until their device is inactivated, explanted, or the batter is exhausted. The overall study duration is expected to be 4.5 years.
- **Timeline:** Enrollment began March 2021

CLINCIAL RELEVANCE

Development of new ICM diagnostic features and sensors may expand the population of patients who benefit from this device. The LUX-Dx TRENDS study will provide data supporting the next generation of ICM devices by specifically investigating the potential benefit for patients with heart failure.

ClincialTrials.gov identifier NCT04790344

The device used in this study is an investigational version of the LUX-Dx™ ICM.
CAUTION: Investigational device. Limited by federal Law to investigational use only.
Not available for sale.

LUX-Dx™ ICM Systems

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Section 5

Terminology

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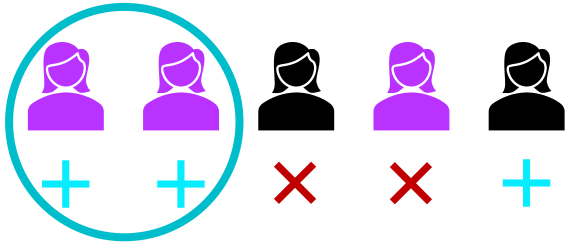
LUX-Dx™ ICM Systems

Clinical Terms

Section 5: Terminology

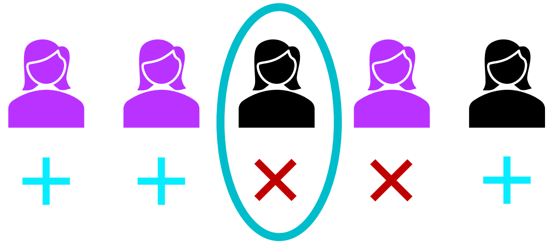
True Positive (TP)

Correctly identified positive condition as positive



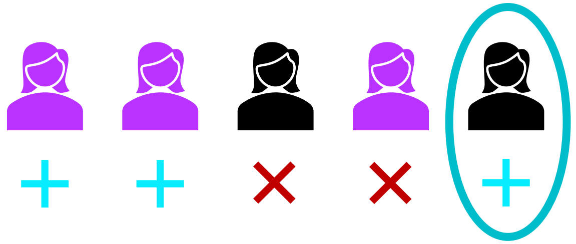
True Negative (TN)

Correctly identified negative condition as negative



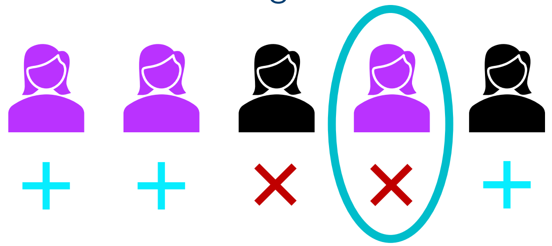
False Positive (FP)

Incorrectly identified negative condition as positive.



False Negative (FN)

Incorrectly identified positive condition as negative



KEY

- Positive Condition
- Negative Condition
- Positive Identification
- Negative Identification

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Clinical Terms

Section 5: Terminology

Sensitivity	How well can the test identify patients with a specified condition.	$$\text{Sensitivity} = \frac{TP}{(TP + FN)}$$
Specificity	How well can the test identify patients without a specified condition.	$$\text{Specificity} = \frac{TN}{(FP + TN)}$$
PPV **(Positive Predictive Value)**	Proportion of detected events being true positives.	$$\text{PPV} = \frac{TP}{(TP + FP)}$$

Inversely related (Sensitivity ↔ Specificity)

Relative Sensitivity? Using a fictitious example – a 98% relative sensitivity means an algorithm is correctly retaining 98% of the true events from the previous algorithm; but mistakenly rejecting 2% of those true events. Relative sensitivity applies when you're comparing a new algorithm to a prior algorithm.

FN, false negative; FP, false positive; TN, true negative; TP, true positive.

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[LUX-Dx II™ and LUX-Dx II+™ Insertable Cardiac Monitor Indications, Safety, and Warnings]