LUX-Dx™ ICM Systems*

# Publications and Clinical Trials

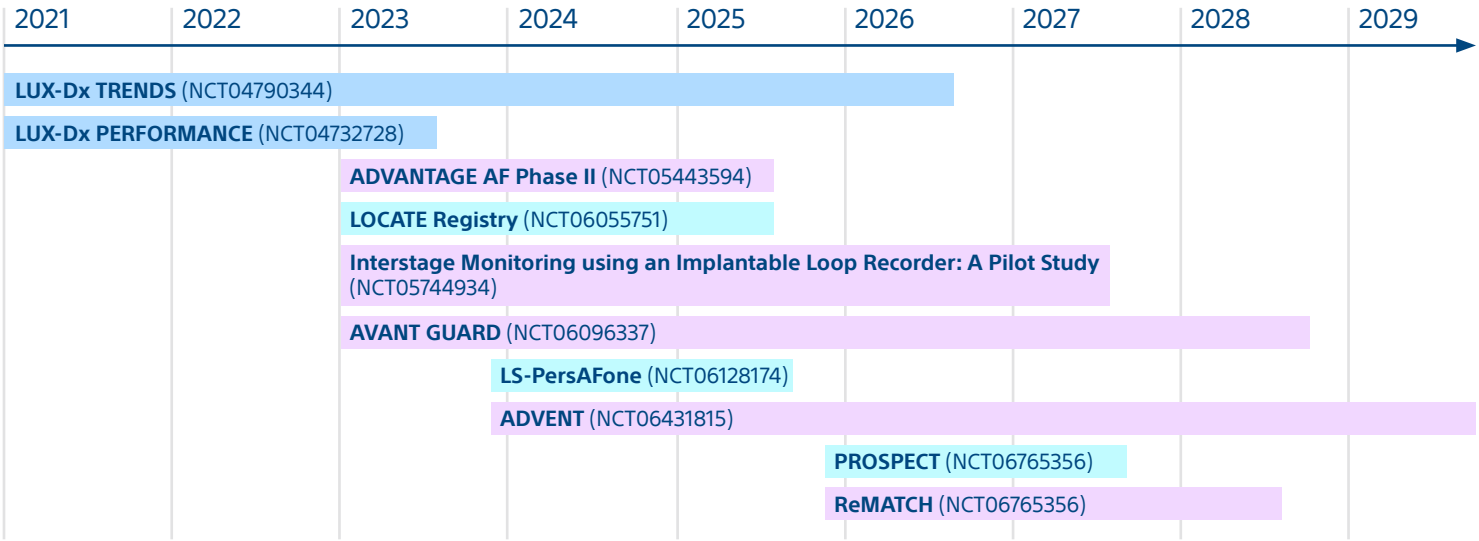
Boston Scientific
Advancing science for life™

## 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]<br>• A Novel Algorithm To Improve Atrial Fibrillation Detection In Implantable Cardiac Monitors[3]<br>• 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]<br>• Artificial Neural Network Algorithm Improves Atrial Fibrillation Detection[6]<br>• Improved AF Rhythm Discrimination With An Implantable Cardiac Monitor Using QRS Morphology[7]<br>• Performance Of A New Implantable Cardiac Monitor Pause Detection Algorithm In The Presence Of Low-amplitude R-waves[8] |
| **2020 – LAUNCH! LUX-Dx™ ICM System** | • Clinical performance of a novel remote programming system for insertable cardiac monitors; results of the CARMEL study[9] |
| **2021** | • A Novel Adaptive Insertable Cardiac Monitor Algorithm Improves The Detection Of Atrial Fibrillation and Atrial Tachycardia In Silico[10]<br>• Consistent Visibility Of P-waves Observed In Patients Implanted With LUX-Dx Insertable Cardiac Monitor (ICM)[11]<br>• Improved Detection Of Atrial Arrhythmias With Regular R-R Intervals In Patients With The LUX-Dx Insertable Cardiac Monitor[12]<br>• 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]<br>• Novel Algorithm For Improved AF Detection In Insertable Cardiac Monitors[15]<br>• Real-world Characterization And Use Of Insertable Cardiac Monitor Remote Programming[16] |
| **2023 – LAUNCH! LUX-Dx II+™ ICM System** | • Does Optimized Daytime/Nighttime Programming Reduce Insertable Cardiac Monitor Event Burden?[17]<br>• Enhanced Pause Algorithm For Insertable Cardiac Monitor Reduces Clinical Review Burden[18]<br>• Evaluation Of The Insertable Cardiac Monitor Placement And Safety In The LUX-Dx PERFORM Study[19]<br>• Interim Evaluation Of Insertable Cardiac Monitor Signal Quality In The LUX-Dx PERFORM Study[20] |
| **2024** | • Preliminary Results From The LUX-Dx PERFORM Study[21]<br>• Independent Abstract! Accuracy of Implantable Loop Recorders: A Multi-Centre, multi-Device Comparison of False Positive Alert Burden in Remote Transmissions[22]<br>• Implantation Of A Novel Insertable Cardiac Monitor: Preliminary Multicenter Experience In Europe[23]<br>• Independent Abstract! Monitoring of Remotely Reprogrammable Implantable Loop Recorders With Algorithms to Reduce False-positive Alerts[24]<br>• Preliminary Implantation Experience In Europe With A Novel Insertable Cardiac Monitor[25]<br>• 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]<br>• Detection Of New Atrial Fibrillation In Patients With Heart Failure By An Insertable Cardiac Monitor: Preliminary Analysis Of The LUX-Dx TRENDS Study[28]<br>• Initial Real-world Usage of a Novel PVC Burden Feature with Programmable Alerts in an Insertable Cardiac Monitor[29]<br>• Physician Disagreement When Adjudicating Atrial Fibrillation Episodes Detected By Insertable Cardiac Monitor[30]<br>• Premature Ventricular Contraction Detection And Estimation Of Daily Burden By An Insertable Monitor[31]<br>• Real-world Use Of Insertable Cardiac Monitor Remote Programming[32] |

*References to "LUX-Dx ICMs" Includes LUX-Dx™, LUX-Dx II™ and LUX-Dx II+™ ICM Systems

# US Clinical Trials




**KEY:** LUX-Dx Trials | BSC EP Trials with LUX-Dx ICM cohorts | Third party trials using LUX-Dx ICMs


1 Pershbacher D, Saha S, Siejko K. Improved AF rhythm discrimination using QRS morphology. Journal of Electrocardiology. 2017;50(6):867. doi: doi.org/10.1016/j.jelectrocard.2017.08.065
2 Richards M, Pershbacher D, Herrmann K, Saha S, Siejo K. A novel algorithm reduces false positives for pause detection in implantable cardiac monitors. Heart Rhythm. 2018;15(5):S123.
3 Richards M, Pershbacher D, Herrmann K, Saha S. A novel algorithm to improve atrial fibrillation detection in implantable cardiac monitors. Heart Rhythm. 2018;15(5):S123.
4 Mittal S, Siejko K, Saha S, Pershbacher 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 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.
6 Richards M, Pershbacher D, Herrmann K, Lu C, Mahajan D. Artificial Neural network algorithm improves atrial fibrillation detection. Heart Rhythm. 2019;16(5):S659-S60. doi: 10.1016/j.hrthm.2019.04.013
7 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.
8 Toquero J, Saha S, Pershbacher D, Siejko K, Herrmann K. P1089 Performance of a new implantable cardiac monitor pause detection algorithm in the presence of low-amplitude R-waves. Heart Rhythm. 2019;21(suppl_2):ii251. Doi: doi.org/10.1093/europace/euz095
9 Saha S, Pershbacher D, Jones PW, et al. Clinical performance of a novel remote programming system for insertable cardiac monitors; results of the CARMEL study. 2020;17(5):S199. doi: 10.1016/j.hrthm.2020.04.006
10 Saha S, Pershbacher 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
11 Frazier Mills C, Raja A, Saleeby RC, et al. PO05-065 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
12 Richards M, Pershbacher D, Frost K, Herrmann K. PO05-044 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
13 Nair D, Herrmann K, Mahajan D, Siejko K. PO04-035 Novel PVC burden algorithm for insertable cardiac monitors detects all PVC sequence types. Heart Rhythm. 2021;18(8):S293. doi: 10.1016/j.hrthm.2021.06.731
14 Rajan A, Pershbacher D, Mahajan D, et al. PO-647-08 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
15 Richards M, Pershbacher D, Mahajan D, Saha S, Herrmann K, Frost K. PO-662-03 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
16 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
17 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
18 Burke MC, Ravikumar V, Siejko K, Bohn D, Verdino RJ. PO-05-085 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
19 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: doi.org/10.1093/europace/euad122.654
20 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: doi.org/10.1093/europace/euad122.612
21 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
22 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
23 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
24 Kamsani S, Middeldorp M, Evans S, et al. PO-01-021Accuracy of Implantable Loop Recorders: A Multi-Centre, Multi-Device Comparison of False Positive Alert Burden in Remote Transmissions. Heart Rhythm Journal. 2024;21(5). Doi: doi.org/10.1016/j.hrthm.2024.03.635
25 Fareh S, Diamante A, Nardi S, et al. Preliminary implantation experience in Europe with a novel insertable cardiac monitor. Europace. 2024;26(supp_1),euae102.665. Doi: 10.1093/europace/euae102.665
26 Kerns RV, Davish SF, Leahy RA, Flowers S. PO-01-003 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
27 Andrade JG, Stucky MJ, Wold N, et al. Artificial Intelligence versus electrophysiologists adjudication of atrial arrhythmias: a validation study. Heart Rhythm. 2025;22(4):S31. doi: doi.org/10.1016/j.hrthm.2025.03.065
28 Wan EY, Pershbacher D, Mahajan D, et al. Detection of new atrial fibrillation in patients with heart failure by an insertable cardiac monitor: Preliminary analysis of the LUX-Dx TRENDS study. Heart Rhythm. 2025;22(4):S311-S312. doi: 10.1016/j.hrthm.2025.03.653
29 Herrmann K, Mahajan D, Fuhs M, Siejko K, Kupfer M. PO-06-108 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: doi.org/10.1016/j.hrthm.2025.03.1655
30 Pokorney S, Rajan A, Mahajan D, et al. Physician disagreement when adjudicating atrial fibrillation episodes detected by insertable cardiac monitor. Heart Rhythm. 2025;22(4):S287. doi: doi.org/10.1016/j.hrthm.2025.03.603
31 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: doi.org/10.1016/j.hroo.2025.01.004
32 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




LUX-Dx II and LUX-Dx II+ ICM
Indications, Safety, and Warnings

Boston Scientific
Advancing science for life™

**Cardiology**
300 Boston Scientific Way
Marlborough, MA 01752-1234
**www.bostonscientific.com**

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



CRM-2220605-AA