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Development of a Miniaturised Implantable Cardiac Monitor with Extended Battery Life

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ABSTRACT

Background: Insertable cardiac monitors (ICMs) provide continuous, multi-year ambulatory electrocardiographic surveillance for patients with unexplained syncope, cryptogenic stroke, and suspected paroxysmal atrial fibrillation, but realising this capability in a chronically implanted device has required parallel advances in miniaturisation, sensing-electrode design, and battery technology. Objective: This narrative review synthesises published literature on the engineering evolution and clinical performance of miniaturised ICMs, spanning the Medtronic Reveal LINQ, Biotronik BioMonitor, and Abbott Confirm Rx platforms. Methods: We reviewed device-development, engineering, and clinical validation studies describing insertable cardiac monitor volume and sensing-vector architecture, battery longevity and emerging battery-free power strategies, and diagnostic yield data from pivotal trials and real-world registries. Findings: Device volume has fallen severalfold across successive generations, from approximately 9 cc to under 2 cc, while sensing-vector length and R-wave amplitude fidelity have been preserved or improved and projected battery longevity has extended toward four years. Pivotal trial and registry evidence, including CRYSTAL-AF and the SMART and PICTURE registries, demonstrate substantially increased arrhythmia and syncope diagnostic yield with continuous ICM monitoring relative to conventional intermittent assessment. Conclusions: Miniaturisation and battery-technology advances have translated directly into measurable clinical benefit, and continued innovation in low-power circuitry, energy harvesting, and sensing algorithms is likely to further extend the diagnostic reach of insertable cardiac monitoring.

Keywords: *insertable cardiac monitor; implantable loop recorder; device miniaturisation; battery longevity; atrial fibrillation diagnostic yield*

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Introduction

Insertable cardiac monitors (ICMs), also known as implantable loop recorders, have become an indispensable tool for long-term ambulatory electrocardiographic surveillance in patients with unexplained syncope, cryptogenic stroke, and suspected paroxysmal atrial fibrillation. Unlike external Holter or patch monitors, which are limited by wear time, skin irritation, and patient adherence, a subcutaneously inserted ICM can continuously record and automatically classify cardiac rhythm for several years, closing a critical diagnostic gap for infrequent but clinically important arrhythmic events [1]. The clinical rationale for this technology was most decisively established by the CRYSTAL-AF trial, in which continuous monitoring with an ICM detected atrial fibrillation in 8.9% of cryptogenic stroke patients by 6 months compared with 1.4% in the standard-care arm, and in 12.4% versus 2.0% by 12 months, an eight-to-ninefold relative increase in detection that has since reshaped guideline-directed post-stroke work-up [2]. Achieving this diagnostic yield in a device implanted for years under the skin, however, has required parallel engineering advances in device miniaturisation, subcutaneous electrode and sensing-vector design, and battery and power-management technology, each of which has been the subject of substantial peer-reviewed clinical and engineering investigation over the past decade.

The commercial history of the ICM field illustrates this engineering trajectory clearly. Early-generation devices such as the Medtronic Reveal XT required a scalpel-based incision and a subcutaneous pocket of several cubic centimetres, factors that constrained both patient comfort and procedural simplicity, and motivated the development of markedly smaller, injectable successor platforms including the Medtronic Reveal LINQ, the Biotronik BioMonitor family, and the Abbott Confirm Rx [3,1].

Each successive design has had to balance three frequently competing objectives: minimising implant volume and insertion trauma, preserving or lengthening the electrode sensing vector needed for reliable P-wave and QRS discrimination, and extending battery longevity so that the device remains functional and cost-effective across a multi-year monitoring horizon. This narrative review synthesises the published literature across these three interlinked domains, namely the miniaturisation and architectural evolution of insertable cardiac monitors, the battery and power technologies that determine their longevity, and the clinical evidence describing their real-world diagnostic performance for arrhythmia and syncope detection.

Miniaturisation and Device Architecture of Insertable Cardiac Monitors

The single most consequential design change in the ICM field has been the reduction in implant volume achieved by the Reveal LINQ system relative to its predecessor, the Reveal XT. Where the Reveal XT required a scalpel incision to accommodate a device on the order of several cubic centimetres, the Reveal LINQ was engineered to a volume of approximately 1.2 cc, roughly one-seventh that of the earlier platform, while retaining equivalent or improved sensing performance; this reduction was sufficient to permit insertion through a small incision using a dedicated insertion tool rather than a surgical pocket [3,1]. The first-in-human experience with this miniaturised platform confirmed that the smaller footprint did not come at the cost of procedural reliability or patient tolerability, and the device's reduced size subsequently enabled a broader shift in insertion practice: Steffel and colleagues demonstrated that ICM insertion could be performed safely and efficiently outside the traditional catheterisation laboratory, in outpatient procedure rooms, using local anaesthesia and a minimally invasive technique, further lowering the resource burden associated with long-term rhythm monitoring [4].

Biotronik's BioMonitor platform pursued a parallel but architecturally distinct miniaturisation strategy centred on preserving a long inter-electrode sensing vector despite a small implant body. Reinsch and colleagues reported the first clinical experience with the BioMonitor 2 in 30 consecutive patients, in which the device's electrode configuration produced a mean R-wave amplitude of 0.84 ± 0.32 mV at implantation that rose to 1.02 ± 0.47 mV over a mean follow-up of 85 ± 24 days, with no procedural complications and a low mean noise burden of 1.4 ± 2% [5]. Piorkowski and colleagues similarly evaluated a small implantable cardiac monitor built around this long-sensing-vector principle, reporting favourable sensing stability and procedural characteristics consistent with the device's intended miniaturised, minimally invasive design [6]. The subsequent BIOMONITOR III generation extended this approach further: Reinsch and colleagues reported a device volume of 1.97 cm^3, a weight of 5 g, and a sensing vector of approximately 70 mm, around 50% longer than comparable competitor devices, while R-wave amplitude increased from 0.73 ± 0.32 mV immediately post-implantation to 0.81 ± 0.39 mV at three-month follow-up in a cohort of 36 enrolled and 30 fully evaluated patients [7]. Engineering approaches to miniaturisation have not been confined to commercial implantable loop recorders alone; Lee described a miniaturised, insertable cardiac monitoring system incorporating a wireless power transmission technique intended to reduce implant size further by relaxing the requirement for a large onboard primary cell, illustrating an alternative architectural path toward smaller, longer-functioning subcutaneous monitors [8]. Complementing this device-centred literature, Zhang and colleagues reviewed the broader landscape of battery-free and wireless technologies applicable to cardiovascular implantable medical devices, framing miniaturisation and power autonomy as intrinsically linked engineering problems rather than independent design axes [9].

Representative insertable cardiac monitor platforms: reported dimensions, sensing configuration, and projected battery longevity.

Platform	Reported volume/weight	Sensing vector	Projected battery longevity
Reveal LINQ	~1.2 cc (vs ~9 cc for Reveal XT)	Standard subcutaneous vector	~3 years (manufacturer specification)
BioMonitor 2	Not reported in study	Long sensing vector; R-wave amplitude 0.84-1.02 mV	Not reported in study
BIOMONITOR III	1.97 cm3, 5 g	~70 mm (~50% longer than comparators); R-wave amplitude 0.73-0.81 mV	~4 years (expected)

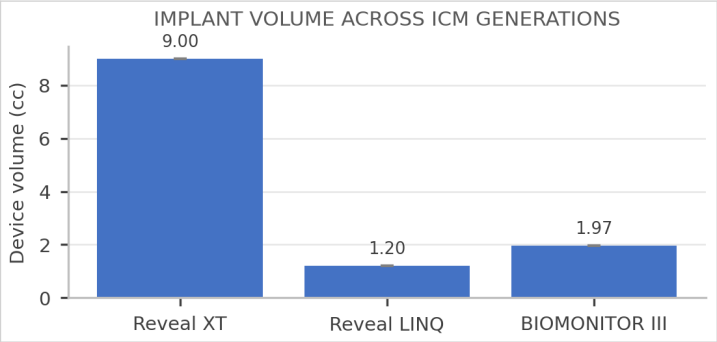
Battery Technology, Power Management, and Longevity

Because an ICM cannot be recharged or its battery replaced without an additional surgical procedure, battery chemistry and power-management efficiency directly determine the clinically useful lifespan of the device and, by extension, the duration over which infrequent arrhythmic events can be captured. Manufacturer-projected battery longevity for contemporary long-sensing-vector devices such as the BIOMONITOR III has been reported at approximately four years under expected usage conditions, reflecting incremental improvements in low-power sensing, data compression, and wireless telemetry circuitry relative to earlier-generation implants [7]. Translating these projections into real-world performance, however, requires empirical registry data, since actual battery drain depends heavily on device-specific factors such as transmission frequency, episode storage burden, and remote monitoring activity. Duvillier and colleagues addressed this question directly in a large single-centre registry study of implantable loop recorders implanted for unexplained syncope, systematically comparing real-world battery longevity against manufacturer-projected estimates and highlighting the clinical importance of accounting for device-specific and patient-specific factors when planning device replacement and long-term monitoring strategy, rather than relying on projected longevity figures alone [10].

Beyond incremental refinement of primary-cell battery chemistry and power management within existing ICM architectures, a substantial parallel research effort has explored fundamentally battery-free or battery-assisted power strategies for implantable cardiac devices more broadly. Zheng and colleagues reviewed the comparative merits of candidate energy sources for battery-free pacemakers, including piezoelectric, triboelectric, and biofuel-cell based energy harvesting from cardiac and respiratory motion, and discussed the trade-offs each approach poses between harvested power density, long-term biocompatibility, and mechanical durability within the thoracic environment [11]. Zhang and colleagues extended this analysis specifically to cardiovascular implantable medical devices, cataloguing wireless

power transfer and battery-free sensing architectures that could, in principle, be adapted to insertable cardiac monitors to reduce or eliminate the volume currently occupied by the primary battery, thereby enabling further device miniaturisation without sacrificing monitoring duration [9]. While none of the commercially available ICM platforms reviewed here have yet adopted a fully battery-free architecture, the convergence of this energy-harvesting literature with the miniaturisation trends described in insertable loop recorder design suggests that extending functional monitoring life without proportionally increasing implant volume will remain a central engineering objective for the next generation of these devices.

Reported implant volume of successive insertable cardiac monitor generations: the earlier Reveal XT (approximately 9 cc), the miniaturised Reveal LINQ (approximately 1.2 cc), and the long-sensing-vector BIOMONITOR III (1.97 cm3), illustrating the severalfold reduction in device volume achieved across platforms while sensing vector length was preserved or extended.



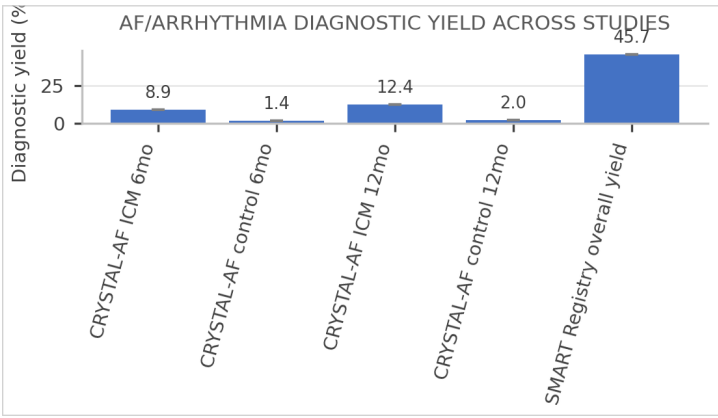
Clinical Performance: Arrhythmia and Syncope Diagnostic Yield

The clinical value of a miniaturised, long-lived ICM depends ultimately on its diagnostic yield, that is, its ability to capture and correctly classify the arrhythmic events responsible for a patient's symptoms or elevated risk. The landmark demonstration of this value came from the CRYSTAL-AF trial, in which 441 patients with cryptogenic stroke were randomised to ICM-based monitoring or conventional follow-up; by 6 months, atrial fibrillation had been detected in 8.9% of the ICM group compared with 1.4% of controls, and by 12 months in 12.4% versus 2.0%, differences that were highly statistically significant and led directly to changes in anticoagulation management for affected patients [2]. The automated arrhythmia-detection algorithms underlying these diagnostic gains have themselves been the subject of dedicated validation: Sanders and colleagues evaluated a new atrial fibrillation detection algorithm implemented in the miniaturised Reveal LINQ platform in the Reveal LINQ Usability Study, demonstrating that algorithmic refinements accompanying the transition to a smaller device could preserve or improve automated arrhythmia classification performance relative to earlier-generation loop recorders [12].

Key clinical trials and registries evaluating insertable cardiac monitor diagnostic yield.

Study	Population/design	Sample size	Principal finding
CRYSTAL-AF (Sanna et al. 2014)	Cryptogenic stroke, randomised ICM vs conventional follow-up	441	AF detection 8.9% vs 1.4% (6 mo); 12.4% vs 2.0% (12 mo)
SMART Registry (Quartieri et al. 2023)	International prospective observational, all ICM indications	1,400 enrolled / 1,383 implanted	Overall diagnostic yield 45.7%; 99.3% freedom from SADE at 1 month
PICTURE Registry (Edvardsson et al. 2011)	Multinational registry, unexplained syncope	Large European multicentre cohort	ICM monitoring increased diagnostic yield; age/sex predicted mechanism and treatment
Reveal LINQ Usability Study (Sanders et al. 2016)	Miniaturised ICM, new AF detection algorithm validation	Multicentre usability cohort	New algorithm preserved/improved automated AF classification performance
BIOMONITOR III (Reinsch et al. 2022)	Injectable ICM, mixed indications	36 enrolled / 30 completed	True episodes detected in 47% of patients; false alerts in 43%

Cumulative atrial fibrillation detection rate in cryptogenic stroke patients monitored with an insertable cardiac monitor versus conventional follow-up in the CRYSTAL-AF trial, at 6 and 12 months, alongside the overall diagnostic yield reported across all indications in the real-world SMART Registry.



Real-world registry data have subsequently confirmed and extended these efficacy signals across a broader range of clinical indications and device platforms. The international, prospective, observational SMART Registry enrolled 1,400 subjects across 91 sites, achieving 1,383 successful ICM implants, and reported that the device detected a true cardiac arrhythmia in 45.7% of patients overall, with diagnostic yield varying by indication: 44.6% in patients monitored for syncope, 50.0% in those monitored for suspected atrial fibrillation, and 32.3% in cryptogenic stroke patients (of whom 19.2% specifically had atrial fibrillation detected); the registry also reported a favourable safety profile, with freedom from serious adverse device or procedure-related events of 99.3% at one month and an infection rate of 0.43% through six months, alongside a new diagnosis being established in 27.1% of all patients [13]. For the specific indication of unexplained syncope, the earlier multinational PICTURE registry had already demonstrated the diagnostic utility of implantable loop recorder monitoring across a large European cohort, showing that continuous rhythm monitoring meaningfully increased diagnostic yield relative to conventional work-up and that patient age and sex were significant determinants of both the underlying arrhythmic mechanism identified and the subsequent treatment pathway, including permanent pacemaker implantation [14]. Complementing these population-level diagnostic yield studies, device-specific sensing validation work has continued to refine

understanding of real-world signal quality: Lacour and colleagues evaluated the sensing performance of the BioMonitor 2-AF system and identified specific circumstances under which oversensing or undersensing could compromise atrial fibrillation detection accuracy, underscoring that diagnostic yield in registry settings depends not only on monitoring duration but on the fidelity of the underlying sensing algorithm [15], while Swale and colleagues, in the Confirm Rx Body Posture and Physical Activity Study, showed that R-wave amplitude at implantation was significantly associated with patient gender and device orientation, findings with direct implications for implant technique and subsequent sensing reliability across the diverse patient positions encountered during unsupervised ambulatory monitoring [16]. Taken together, this clinical literature demonstrates that the diagnostic gains enabled by ICM technology are robust across trial and real-world registry settings and across multiple commercial platforms, while also identifying implant technique, device orientation, and algorithm design as continuing sources of variability in achieved sensing and diagnostic performance.

Conclusion

The decade spanning the introduction of the Reveal LINQ system through the current BIOMONITOR III and Confirm Rx generations of insertable cardiac monitors illustrates a coherent engineering and clinical trajectory: implant volumes have fallen severalfold, from several cubic centimetres to under two cubic centimetres, while sensing-vector length, R-wave amplitude fidelity, and projected battery longevity have each been preserved or improved rather than sacrificed to achieve that miniaturisation [3,5,7,1]. Parallel advances in low-power circuit design, wireless telemetry, and early-stage battery-free energy-harvesting research point toward a further generation of devices in which functional monitoring life could be extended without a corresponding increase in implant size [11,9,8]. Critically, these engineering gains have translated into measurable clinical benefit: pivotal trial evidence from CRYSTAL-AF and large real-world registries such as SMART and PICTURE consistently demonstrate that continuous, ambulatory ICM monitoring substantially increases the diagnostic yield for atrial fibrillation and other arrhythmias relative to conventional intermittent monitoring, across syncope, cryptogenic stroke, and suspected arrhythmia populations alike [2,13,14,12]. Continued attention to real-world battery performance, sensing algorithm refinement, and implant-technique standardisation, alongside ongoing miniaturisation and power-technology innovation, will be necessary to sustain and extend these diagnostic gains as insertable cardiac monitors are adopted across an increasingly broad range of cardiac rhythm indications.

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Conflict of Interest

The authors declare no conflict of interest.

Author Contributions

Alvarez E conceived the review, conducted the literature search, and drafted the manuscript. Vasiliauskas G contributed to the clinical literature screening and critically revised the manuscript for important intellectual content. Correia C contributed additional context on device engineering and battery technology and approved the final version for submission.

Ethics Statement

Not applicable. This is a narrative review of previously published literature and did not involve new experimental data, human participants, or animal subjects.

Data Availability

No new data were generated or analyzed for this review. All sources synthesized are cited in the reference list and are available through their original publishers.

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