Res Intell Manuf Assem, 2025, 4(1): 144-167
DOI: 10.25082/RIMA.2025.01.002

RESEARCH ARTICLE

Pacemaker Interrogation Reports: Comparing Diagnostics, Lead Impedance, Pacing Thresholds and Battery Performance

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Received: January 6, 2025;
Accepted: March 23, 2025;
Published: March 27, 2025.

Citation: Neupane S, Goswami T. Pacemaker Interrogation Reports: Comparing Diagnostics, Lead Impedance, Pacing Thresholds and Battery Performance. *Res Intell Manuf Assem*, 2025, **4**(1): 144-167. https://doi.org/10.25082/RIMA.2025.01.002

Abstract: Pacemakers are critical in managing cardiovascular arrhythmias, yet device malfunctions remain a significant clinical challenge, impacting patient safety and outcomes. This study presents a structured comparison of pacemaker interrogation reports from three leading manufacturers: Abbott referred to as Manufacturer A/A Devices, Boston Scientific as Manufacturer B/B Devices and Medtronic as Manufacturer C/C Devices focusing on battery performance, lead functionality, pacing modes, and arrhythmia management. By analyzing the interrogated data, device reliability, longevity, and diagnostic capabilities of the devices are understood. Data were categorized and compared with each other to assess performance trends and clinical usability. Results revealed significant variations in battery longevity, lead performance monitoring, and arrhythmia detection capabilities among the devices. Manufacturer C interrogation reports provide trend analysis and battery life management whereas Manufacturer A provide real-time diagnostics and alerts, and Manufacturer B reports demonstrated long-term stability and efficiency. The findings highlight the need for standardized reporting practices across manufacturers to enhance data consistency, comparability, and clinical utility. Such standardization would streamline clinician workflows, improve decision-making, and ultimately higher patient outcomes. This study underscores the importance of real-world data to optimize pacemaker management and calls for collaborative efforts among manufacturers, clinicians, and regulators to develop unified reporting frameworks. By integrating predictive analytics and remote monitoring capabilities, future advancements in pacemaker achieve higher patient care and device performance.

Keywords: pacemakers, cardiovascular arrhythmias, interrogation reports, medtronic, Abbott, Boston Scientific

1 Introduction

Cardiovascular arrhythmias, characterized by irregular heartbeats, are a significant global health concern, affecting millions of individuals and leading to severe complications such as stroke, heart failure, and sudden cardiac death [1]. Pacemakers, which deliver electrical stimulation to regulate heart rhythms and restore normal cardiac function, have become indispensable in managing these conditions. Since their inception as external devices in the late 1950s, pacemakers have evolved into sophisticated implantable systems capable of adaptive pacing and real-time monitoring [2]. Despite these advancements, device malfunctions ranging from minor operational irregularities to critical failures remain a persistent clinical challenge, posing serious risks to patient safety and outcomes [3].

Modern pacemakers consist of several critical components, including the pulse generator, leads, electrodes, and sensors, all of which work in concert to ensure effective cardiac stimulation. The pulse generator, housing the battery and electronic circuitry, serves as the control unit, while the leads and electrodes transmit electrical impulses to the heart [4]. Advanced pacemakers also incorporate sensors that enable adaptive pacing based on the patient's physiological needs, offering personalized therapy. However, these devices are not immune to failure. Hardware malfunctions, software anomalies, lead defects, and battery depletion are among the common issues that can compromise pacemaker performance, underscoring the need for a deeper understanding of failure mechanisms and the implementation of preventive measures [5–7].

Leading manufacturers have significantly advanced pacemaker technology, integrating innovations such as leadless designs, smart device connectivity, and enhanced battery longevity to improve patient outcomes [8]. Comparative studies have demonstrated that leadless pacemakers reduce complication rates compared to traditional transvenous devices, highlighting their potential for improved safety and reliability [9]. However, despite these technological advancements, the lack of standardized reporting formats across manufacturers complicates data interpretation and clinical decision-making [10]. Pacemaker interrogation reports provide essential insights into battery longevity, lead performance, and pacing thresholds, enabling proactive device management, yet differences in data presentation and proprietary formats create challenges for direct comparisons [11]. Addressing these disparities through standardized reporting and improved interoperability could enhance clinical assessment and optimize pacemaker management.

This study aims to address this gap by presenting a structured comparison of pacemaker interrogation reports from the three leading manufacturers, with a focus on diagnostic data, lead impedance, pacing thresholds, and battery longevity. From the performance data, this research seeks to uncover patterns in battery efficiency, pacing effectiveness, and device durability. A deeper understanding of these factors can enhance clinical decision-making, enabling personalized device selection based on patient-specific needs. Furthermore, this study may help identify the strengths and limitations of specific device, contributing to future advancements in pacemaker technology.

Ultimately, the findings of this research will provide valuable insights for the medical community, aiding in informed decision-making regarding pacemaker management and selection. By expanding our understanding of long-term pacemaker performance, this study seeks to improve patient outcomes and contribute to the ongoing discourse on optimizing pacemaker technology.

Through a comprehensive analysis of interrogation reports, this research underscores the importance of standardized reporting practices and highlights the potential for innovation in device monitoring and management.

1.1 Materials in Pacemaker

The biomaterials needed for the implantable pacemaker are alloplastic, that is, not biological in origin [12]. They include metals, ceramics or glasses, and polymers. From a physical point of view, the main difference between these groups of materials is the type of chemical bond which holds the materials together [13].

1.2 The Pathophysiological Understanding

A pulse generator and one or more transvenous or epicardial leads that link the generator to the myocardium make up the pacing system [14]. While actual pulse generator failure is extremely uncommon, pacing system malfunction does happen from time to time. A malfunctioning lead, electrode-tissue interface, or pulse generator can cause a malfunctioning pacing system. When a lead malfunctions, more issues arise than when a pulse generator malfunctions [15].

The majority of these issues can be fixed with simple device reprogramming. In actuality, most malfunctions are caused by the pacemaker's normal programmed function. Correct diagnosis and treatment of malfunctions depend critically on having a good understanding of their cause [16].

1.3 Etiology

The following categories apply to causes of pacing system malfunctions [17]:
(1) Sensing (under sensing or oversensing)
(2) Pacing (loss of capture, loss of output, failure to output)
(3) Rate (inappropriate rate, pacemaker-mediated tachycardia)
(4) Inappropriate lead position
(5) Inappropriate mode
(6) Extracardiac stimulation
(7) True pulse generator failure
(8) Pacemaker syndrome
(9) Twiddler syndrome

1.4 Key Parts of Pacemaker

Pulse Generator: The pulse generator forms the main component of the pacemaker. It contains functions, electronic circuitry, and a battery that powers the device. The pacemaker

operates on battery power, which is supplied by the battery [18].

Leads: Built-in leads are used to connect the heart muscle to the pulse generator. Electrical impulses are transmitted from the ganglion to regulate the rhythms of the heart [19]. The implants can be inserted into the ventricles, atria, or both, depending on the type of pacemaker.

Electrodes: Electrodes touch the heart muscles directly. They appear at the edge of the front. They enable the heart and pacemaker to conduct the electricity, which helps the heart beat faster.

Sensors: Some pacemaker come with sensors to monitor body activity levels and adjust the pacing rate of the pacemaker accordingly. Rate responsiveness is a characteristic that allows the pacemaker to adapt to the physiological requirements of the patient [20].

1.5 Potential Failure Modes

There are many ways a pacemaker can malfunction, including hardware problems, software errors, lead errors, and low battery levels [21]. Understanding the specific failure mechanisms is important for a failure focused analysis [22]. For example, if the battery runs out, the machine may stop moving, and if the copper breaks, the electrical stimulator may stop working.

Battery Depletion: Pacemakers have limited battery life; It usually lasts between five and fifteen years, depending on usage. One common failure condition that causes loss of pacing output is battery loss.

Lead Malfunction: Over time, lead insulation can crack, leak or cause insulation to fail. Lead defects can interfere with electrical output, causing pacing problems [19].

Software Faults: For optimal performance, pacemakers have complex software algorithms built into them. While rare, malfunctions can occur due to software errors preventing the device from operating.

Hardware Issues: Hardware problems can occur in the electronic circuits or connections that are part of the pulse generator. These can cause irregular pacing or other problems.

Understanding these potential failure factors is important for a comprehensive assessment of pacemaker deficiencies, as each component is essential for the device to effectively control the heart rhythm [17].

2 Literature review

A comprehensive literature search was conducted to evaluate the performance, management, and clinical implications of cardiac implantable electronic devices (CIEDs), including pacemakers, implantable cardioverter-defibrillators (ICDs), and cardiac resynchronization therapy (CRT) devices. The review focused on key aspects such as quality of life (QoL) impact, technological advancements, battery longevity, lead performance, pacing modes, arrhythmia management, and device interrogation practices. The study also examined variations in reporting formats, diagnostic capabilities, and clinical usability across leading manufacturers, highlighting the need for standardized practices to enhance data consistency and patient outcomes. By synthesizing findings from multiple studies, this review aims to provide insights into optimizing CIED management, improving device reliability, and addressing gaps in current research to guide future advancements in cardiac care. (see Table 1)

This table provides a comprehensive overview of various aspects related to cardiac implantable electronic devices (CIEDs), including pacemakers, ICDs, and CRT devices. It highlights key findings, clinical implications, and recommendations for improving patient outcomes, such as the importance of QoL assessments, advancements in device technology, and strategies for optimizing battery life and device management. However, the table also underscores significant gaps in the literature, such as the lack of long-term data on device performance, patient outcomes, and the broader application of emerging technologies. These limitations highlight the need for more extensive research, standardized reporting, and real-world evidence to guide clinical decision- making and enhance the safety and efficacy of CIEDs.

3 Methods

3.1 Data Collection

The data for this study were collected from pacemaker interrogation reports from three manufacturers. These interrogation reports included critical performance metrics such as:

Table 1 Summary of Literature review on Pacemaker Performance, Management and Clinical Implications

Aspect	What This Paper Provides	What This Paper Does Not Provide	Recommendations	Clinical Implications
QoL Impact [23]	Shows significant QoL improvement with pacemakers, LVADs, and ICDs.	Lacks long-term QoL data across different patient groups.	Study QoL variations by device type, manufacturer, and demographics.	Emphasizes the need for QoL assessments in device selection and patient counseling.
Pacemaker Development [24]	Reviews the evolution of pacemakers, from external devices to leadless, MRI-compatible pacemakers, and highlights key technological milestones.	Lacks detailed discussion on recent experimental pacemaker technologies or long-term clinical outcomes.	Incorporate more case studies and long-term performance data to enhance understanding of newer pacemaker technologies.	Provides historical context and future insights, assisting clinicians in understanding the trajectory of pacemaker technology and its potential impact on patient care.
Pacemaker Programming History [25]	Traces the evolution of pacemaker programming from invasive methods to non-invasive techniques like magnetic programming and RF communication, culminating in bidirectional telemetry and multiprogrammable devices.	Does not provide current or future advancements in pacemaker programming beyond the 1970s.	Explore recent innovations in pacemaker programming and their real-world applications.	Highlights the transformative impact of programming advances, which has shaped modern pacemaker management and personalized patient care.
Pacemaker Implantation & Management [26]	Discusses patient selection, complex pacing modes (MVP, CRT), procedural risks, and post-implant care including infection prevention, troubleshooting, and remote monitoring.	Does not delve into specific patient outcomes or long-term follow-up data on device performance	Include long-term patient outcome data and case studies to guide clinicians in decision-making.	Highlights the importance of individualized care through vigilant monitoring, optimal device programming, and infection prevention to enhance patient outcomes and reduce complications.
Pacemaker Battery Life [6]	Examines factors affecting battery life, such as pacing rate, pulse duration, voltage, lead impedance, and the impact of high-impedance leads on current drain.	Does not provide extensive data on the real-world impact of pacing reductions or algorithm optimizations over time.	Explore more extensive clinical data on the long- term effects of pacing reductions and device algorithm optimizations.	Emphasizes the importance of optimizing pacing parameters and device algorithms to enhance battery longevity, helping clinicians improve device efficiency and patient outcomes.
Battery Depletion Prediction [27]	Explains methods for predicting battery depletion in pacemakers using an oscilloscope to study impulse curves, enabling extended pacemaker lifespan.	Does not provide data on the impact of these methods in modern pacemaker designs or technologies.	Investigate the application of these predictive methods in current pacemaker technologies and explore improvements in battery management.	Highlights the value of active battery management in extending pacemaker lifespan and reducing premature replacements, optimizing device efficiency and patient care.
Variability in CIED Durability [28]	Highlights significant differences (up to 44%) in battery duration among pacemakers, ICDs, and CRT-Ds, with factors like battery chemistry, capacity, and current drainage influencing device longevity.	Does not provide data on the specific factors that influence these differences across individual manufacturers.	Encourage the development of standardized industry reporting on device durability and features to improve transparency and informed decision- making.	Emphasizes the importance of standardized reporting to guide clinicians in selecting devices, ensuring better long- term patient outcomes, and reducing healthcare costs.
Postmortem CIED Interrogation [29]	Describes a 15-year study on postmortem interrogation of pacemakers, defibrillators, and loop recorders, revealing a 98.5% success rate for retrieving useful data on device malfunction, cause of death, time of death, and patient identification.	Does not explore the broader application of postmortem CIED interrogation across different patient populations or device types.	Advocate for the routine use of postmortem CIED interrogation to enhance both clinical knowledge and forensic investigations.	Highlights the value of postmortem CIED interrogation in identifying device- related failures and improving both clinical outcomes and forensic investigations.
Pacemaker Battery Depletion and Diagnosis [30]	The paper emphasizes the gradual depletion of pacemaker batteries and its potential to cause serious morbidity, particularly in the Elective Replacement Indication (ERI) and End of Life (EOL) stages. It presents two case studies: one of pacemaker syndrome triggered by automatic reprogramming during ERI, and another of torsade de pointes and complete atrioventricular block due to complete battery depletion. The paper introduces the "Rules of Ten" as an ECG-based method for early detection of battery depletion.	The paper does not explore in- depth pathophysiology behind battery depletion or provide specific management protocols for patients. It also doesn't compare the "Rules of Ten" with other ECG methods.	Regular monitoring and follow-up for pacemaker patients, especially at the ERI and EOL stages, to prevent delayed diagnoses. The "Rules of Ten" ECG-based method can be implemented as a practical diagnostic tool for early detection of battery depletion.	Delayed diagnosis of pacemaker battery depletion can result in serious conditions like pacemaker syndrome and torsade de pointes. Regular monitoring and timely intervention using the "Rules of Ten" method can improve patient outcomes by detecting battery depletion early, preventing life- threatening arrhythmias, and ensuring better management of pacemaker patients.
Objective [31]	Investigates longevity of VVI-pacemakers, with CPI Microlith 605 showing median lifespan of 19.2 years, one lasting 26.3 years.	Does not consider patient- specific factors (e.g., age or health conditions), pacing frequency, electrode-lead combinations, or dual-chamber pacemakers.	Future studies should include factors such as pacing frequency, patient demographics, electrode-lead combinations, dual- chamber pacemakers, and clinical outcomes.	Findings suggest using pacemakers with longer battery lives, such as CPI Microlith 605, for patients requiring extended therapy, reducing frequent replacements and improving care.
Study Objective [32]	Investigates the incidence and outcomes of premature battery depletion (PBD) in Abbott ICDs and CRT devices.	Does not investigate non- Abbott devices or long-term battery life beyond the advisory period.	Further studies needed to evaluate PBD rates in non- Abbott devices and long-term follow-up beyond advisory period.	Provides insights into the reliability of Abbott devices and the potential risks of premature battery depletion.
Premature Battery Depletion in Abbott Pacemakers: A Case Report [33]	Detailed case reports of premature battery depletion in Abbott pacemakers (models PM1152, PM1160, PM1172, PM1240, PM1272, PM2152, PM2160, PM2172, PM2240, PM2260, PM2272). (1) FDA Class I recall advisory and its clinical relevance. (2) Evidence of failure due to loss of radiofrequency transmitting capabilities. (3) Clinical presentation, diagnosis, and intervention for affected patients. (4) Highlights the failure of remote monitoring systems in detecting sudden pacemaker failures.	Specific numerical data on pacemaker battery life for all affected models. - In-depth statistical analysis of the recall's broader impact.	Close monitoring and prophylactic generator replacement for pacemaker- dependent patients. - Proactive generator changes should be considered for patients with affected devices, particularly those who are pacemaker-dependent.	Failure of remote monitoring systems calls for enhanced patient safety measures and more robust protocols. - Immediate generator replacement should be considered to avoid complications, especially for older patients.
CIED management [34]	It provides methods for identifying CIED type and manufacturer, guidance on interpreting ECGs for pacemaker status, and recommendations for using a "doughnut magnet" to ensure asynchronous pacing.	It does not provide detailed device programming instructions or long-term care protocols for CIED patients during the pandemic.	The paper recommends using remote CIED monitoring when available, applying ECG interpretation rules like the "Rules of Ten" to assess battery depletion or reset, and consulting with electrophysiologist s for urgent device reprogramming or surgery.	The paper highlights the importance of timely identification and management of CIED issues, ensuring that urgent consultations and interventions are conducted despite limited resources during a healthcare crisis.
ED staff performing device interrogation for cardiac implants [35]	It shows that ED staff can perform cardiac device interrogations faster than traditional methods while maintaining safety.	It does not discuss long- term outcomes or broader impacts on patient management beyond the ED.	ED staff should be trained to perform cardiac device interrogations in emergency settings to improve efficiency.	This study suggests that ED staff can safely and efficiently conduct cardiac device interrogations, potentially improving emergency care workflows.
Diagnostic Yield of Pacemaker Interrogation Reports [36]	A retrospective analysis of 88 patients with implanted pacemakers or ICDs to assess the diagnostic yield of device interrogation in unexplained syncope cases.	Definitive evidence supporting the routine use of device interrogation as a primary diagnostic tool for syncope in patients with previously implanted pacemakers or ICDs.	Device interrogation should not be routinely performed in all cases of unexplained syncope unless supported by concerning exam findings, telemetry, or ECG abnormalities.	The study highlights that patient history and orthostatic vital signs provide higher diagnostic value than device interrogation, suggesting a more targeted approach to evaluating syncope in these patients.
PMT diagnosis and management [37]	A detailed case report on the identification and treatment of PMT using pacemaker interrogation/programming in the emergency department.	In-depth exploration of alternative treatment options for PMT or other arrhythmias in pacemaker patients.	Incorporating pacemaker interrogation as a standard part of ED management for patients with pacemaker-related arrhythmias.	Demonstrates the effectiveness of pacemaker interrogation/programming in ensuring patient stability in the ED. resolving PMT and
Electromagne tic interruption [38]	A case report on EMI interference between a Micra VR leadless pacemaker and an LVAD after conversion from HeartMate II to HeartMate 3.	A generalized solution applicable to all cases of EMI between LVADs and leadless pacemakers.	Positioning the programmer head on the patient's back can facilitate successful pacemaker interrogation when EMI is present.	Awareness of potential EMI issues during LVAD conversion is crucial, and alternative interrogation strategies should be considered to ensure proper device function.
CIED Management [39]	Overview of Boston Scientific pacemakers, CRT devices, ICDs, programming, and perioperative care	No direct comparison with other manufacturers, lacks step-by- step programming guidance, and omits rare surgical scenarios	Training on interrogation, programming, emergency management, and institutional education	Improves clinician expertise in device management, optimizing perioperative safety and cardiac function
Pacemaker Safety Mode [40]	It provides a detailed case study of a pacemaker failure due to Safety Mode activation and battery impedance.	It does not provide definitive solutions for preventing pacing inhibition during Safety Mode activation.	The paper recommends considering early pacemaker replacement for pacemaker- dependent patients at risk of Safety Mode complications.	Clinically, it emphasizes the importance of evaluating pacemaker function and considering preventive replacement to avoid risks of pacing inhibition in pacemaker- dependent patients.
Pacemaker replacement rates based on device longevity, patient survival, and demographic factors [41]	Estimates of pacemaker replacement rates by age, gender, and primary indication, along with cost implications of device longevity changes.	Real-world long- term data on device longevity or replacement rates beyond projections and simulations.	Focus on optimizing device longevity for younger patients and consider demographic factors when selecting pacemaker models.	Longer device longevity reduces replacement surgeries, complications, and healthcare costs, particularly for older patients.
Survival and failure rates of implantable defibrillator leads [42]	Comparative analysis of lead survival and failure rates across manufacturers, impact of recalled leads, and predictors of lead failure.	Mechanisms of death in patients with recalled leads or long- term follow-up beyond 2011.	Focus on lead construction improvements, avoid recalled leads, and consider patient-specific factors in lead selection.	Boston Scientific and St. Jude Medical leads outperform Medtronic leads; recalled leads are associated with higher failure rates and increased mortality, emphasizing the need for careful lead selection and monitoring.

Battery Status: Remaining battery capacity, voltage levels, and predicted replacement dates.

Lead Impedance: Electrical resistance measured across the leads to monitor their integrity.

Pacing Thresholds: The minimum electrical stimulus required to consistently elicit a cardiac response.

Arrhythmia Detection Logs: Information on the detection and management of arrhythmias.

Event Logs: Records of pacing events, lead failures, software anomalies, and other notable occurrences.

The interrogation data were obtained from clinical settings where pacemaker devices were retrieved posthumously. Data was anonymized to protect patient identity, and all reports were de-identified prior to analysis to comply with ethical standards and patient confidentiality protocols.

3.2 Data Processing

Anonymization: All patient-identifiable information was removed to comply with ethical guidelines and privacy standards.

Standardization: The reports from the three manufacturers had varying formats. These were standardized into a unified format for comparative analysis.

Data Cleaning: Outliers, incomplete records, and erroneous data were identified and removed using threshold-based filtering and domain expertise.

3.3 Key Metrics for Comparison

The key metrics evaluated in this analysis included:

Battery performance: Comparison of remaining battery life estimates from each manufacturer.

Lead performance: Lead impedance, pacing thresholds, and capture thresholds.

Pacing Modes and Rates: Comparison of pacing strategies, including pacing modes, pacing rates, and the pacemaker's ability to adapt to arrhythmias and varying physiological demands across different manufacturers.

Interrogation report layout: Comparison of the structure and presentation of pacemaker interrogation data, including how manufacturers organize and display key metrics like battery status, lead performance, pacing rates, and arrhythmia management.

4 Data Analysis

4.1 Categorization of Metrics

The interrogation reports were categorized based on several performance parameters:

Battery Status: Classified as "Optimal", "Monitor", and "Replace Soon" based on remaining battery life.

Lead Impedance: Analyzed to identify any degradation or failure patterns.

Pacing Thresholds: Analyzed over time to detect increasing trends, which might indicate lead issues or increased energy consumption.

Arrhythmia Events: Reviewed to evaluate device response accuracy and consistency.

Data were further categorized by device age, type, patient demographics, and specific device settings (such as pacing modes) to provide context for performance comparisons.

4.2 Device Specific Comparisons

Each manufacturer's pacemaker models were compared based on: 1) Battery Longevity; 2) Lead Performance; 3) Pacing Mode Efficiency; 4) Report layout.

Differences in proprietary technologies, such as adaptive pacing modes or algorithms, were taken into account when interpreting the results. Manufacturer-specific innovations were noted to assess their impact on device reliability and patient outcomes. This methodology ensures a rigorous comparative analysis of pacemaker performance, allowing for the identification of key strengths and weaknesses across different manufacturers and their devices.

5 Results

5.1 Battery Performance

5.1.1 Voltage Behavior and Remaining Life

The battery performance of pacemakers from three leading manufacturers A, B, and C was evaluated based on the key factors such as Elective Replacement Indication (ERI) thresholds, voltage ranges, magnet rates, battery longevity, End of Service (EOS) indicators, Recommended Replacement Time (RRT), and remaining life estimates. The findings are summarized in Table 2.

Table 2 Battery Performance Compariso

Factor	Manufacturer A	Manufacturer B	Manufacturer C
ERI Threshold	2.60 V	Not provided	2.83 V
Voltage range	2.45 V – 2.90 V	Indirectly inferred from time to explant	2.63 V – 2.94 V
Magnet Rate	8.6 ppm – 98.1 ppm	90 ppm (shorter life), 100 ppm (longer life)	Not provided
Battery Longevity	Near ERI 2.60 V	Shorter life at 90 ppm, longer life at 100 ppm	Approaching ERI (2.83 V)
EOS and RRT	Close to ERI 2.60 V	Indirectly suggested via remaining life estimates	EOS at 2.82 V, RRT at 2.83 V
Remaining Life	Not directly provided	Shorter life at 90 ppm, longer life at 100 ppm	8 months - 8.6 years (varying stages)

(1) Manufacturer A:

A. Voltage range**:** 2.45 V to 2.90 V; voltage approaches ERI (2.60 V).

B. The pacemaker is nearing the end of life, especially with 2.45 V approaching the 2.60 V ERI threshold.

C. Remaining life isn't explicitly stated, but it can be inferred that the pacemaker is getting close to requiring replacement as its voltage dips closer to the ERI. (see Figure 1)

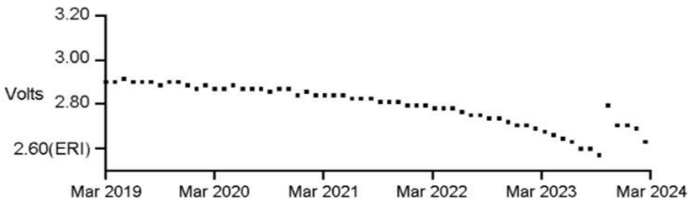

Figure 1 Voltage trend (Manufacturer A)

This report includes a waveform that represents the voltage and impedance levels of the pacemaker battery. Monitoring these parameters ensures timely replacement or maintenance of the device. A stable voltage curve indicates a healthy battery status, while a declining trend suggests that the battery is nearing the end of its life, requiring predictive maintenance to avoid interruptions in device performance.

(2) Manufacturer B:

A. Voltage is not provided but inferred from magnet rate and time to explant.

B. 90 ppm generally correlates with a shorter remaining life (e.g., 0.25 years to $<$ 3 months).

C. 100 ppm correlates with a longer remaining life (e.g., 6.5 years to 14.5 years).

In this report, battery performance trends are inferred from static data points and associated metrics, as direct battery voltage trend graphs are not provided. Instead, the performance is evaluated using static voltage values at interrogation, such as those related to Elective Replacement Indicator (ERI) and pacing thresholds, which are influenced by battery status. Additional insights are derived from the magnet rate, where a 90-ppm rate correlates with a shorter battery life ($<$ 3 months) and 100 ppm indicates longer battery life (up to 14.5 years).

(3) Manufacturer C:

A. Voltage range: 2.63 V to 2.94 V.

B. 2.83 V is marked as ERI, and 2.82 V as EOS (End of Service).

C. Remaining life varies from 8 months to 8.6 years, depending on the stage of the battery life:

a. At 2.88 V, the remaining life is 8 months.

b. At 2.82 V (EOS), the pacemaker is near replacement.

c. 2.63 V indicates a longer remaining life (8.6 years), suggesting that the pacemaker is still functional and needs some time before replacement.

In this report, battery performance trends can be inferred from specific data points and alerts related to battery voltage, remaining longevity, and battery-related thresholds—though there's no direct battery voltage trend graph. Instead, battery performance is evaluated through static voltage values at key points, such as Elective Replacement Indicator (ERI) and End of Service (EOS), alongside calculated longevity estimates

5.1.2 Magnet Rate and Battery Longevity

Manufacturer A: Magnet rates vary between 78.6 ppm to 98.1 ppm, with 78.6 ppm observed at 2.45 V, suggesting reduced performance as the battery approaches end-of-life.

Manufacturer B: 90 ppm correlates with shorter battery life, while 100 ppm suggests a longer battery life.

Manufacturer C: No magnet rate data provided, but the battery voltage can be used to infer the remaining life.

5.1.3 Remaining Life and Replacement Timing

(1) A Devices:

A. The battery is nearing the end of its useful life based on the voltage approaching ERI.

B. Exact remaining life isn't directly provided but inferred from voltage.

(2) B Devices:

Magnet rate data allows an estimate of remaining life: A. 100 ppm correlates with a long life (e.g., 6.5 years**,** 14.5 years).

B. 90 ppm correlates with a short life (e.g, 0.25 years, $<$ 3 months).

(3) C Devices:

Remaining life varies significantly based on voltage:

A. At 2.88 V, the pacemaker is expected to last 8 months.

B. At 2.94 V, the remaining life is 3 years.

C. At 2.63 V, the pacemaker can last up to 8.6 years, indicating it is still in a relatively healthy state.

D. At 2.82 V (EOS), it needs to be replaced immediately.

Key Insights:

(1) Voltage

A. A Devices typically show voltages near 2.60 V (ERI threshold), indicating that their batteries are near the end of life.

B. B Devices doesn't provide specific voltage data, but their magnet rate correlates with battery life: 90 ppm indicates a shorter battery life, and 100 ppm indicates a longer battery life.

C. C Devices has a higher ERI threshold (2.83 V), and their battery voltages are higher, suggesting longer remaining life in some cases (up to 8.6 years).

Remaining Life:

Manufacturer A: Battery is nearing the end of its life, and replacement is imminent based on voltage approaching the ERI threshold.

Manufacturer B: The magnet rate is a reliable indicator, with 90 ppm showing shorter remaining life and 100 ppm showing longer life.

Manufacturer C: Remaining life can range from 8 months to 8.6 years, depending on the battery's voltage, with 2.63 V showing the longest remaining life.

Summary:

A. A Devices show a low voltage range, with many readings approaching the ERI, signaling imminent replacement.

B. B Devices uses magnet rate and time to explant as proxies for battery life, with 90 ppm indicating shorter remaining life and 100 ppm indicating longer life.

C. C Devices have more detailed data on voltage and remaining life, with 2.82 V marking the EOS and 2.63 V indicating a longer lifespan.

5.2 Lead Performance

The lead performance of pacemakers from three leading manufacturers was evaluated based on key parameters such as lead impedance, capture thresholds, sensing issues, pacing impedance, battery voltage, remaining life, and overall lead integrity monitoring. The findings are summarized in Table 3.

Table 3 Lead Performance Comparison

Parameter	Manufacturer A	Manufacturer B	Manufacturer C
Lead Impedance	High lead impedance warnings, particularly for RV and Atrial leads for more than 3000 ohms.	High pacing impedance warnings for more than 3000 ohms, less frequent than Manufacturer C.	Frequent warnings for unipolar lead and bipolar lead impedance. High impedance and polarity switches noted for more than 3000 ohms as per interrogation report.
Capture Threshold	High capture thresholds observed, similar to Manufacturer C.	Lower capture thresholds, but warnings still issued for high thresholds.	High capture thresholds frequently observed, indicating poor lead performance.
Sensing Issues	Reports of sensing issues, but fewer compared to Manufacturer C.	Short V-V intervals and sensing issues, similar to Manufacturer C, but fewer reported incidents.	Frequent reports of short V-V intervals, lead fractures, and double- counted R-waves.
Pacing Impedance	High pacing impedance alerts for more than 3000 ohms as per interrogation report., similar to Manufacturer C.	High pacing impedance and performance issues indicated with lead degradation.	High pacing impedance warnings for more than 3000 ohms as per interrogation report., indicating potential lead failure.
Battery Voltage & Remaining Life	Battery voltage monitored with remaining life alerts, but typically provides more lead-time before replacement recommendation.	Battery voltage monitored, but provides longer timelines for device replacement.	Battery voltage monitored with warnings on low voltage affecting pacing performance. Remaining life alerts provided.
Lead Integrity & Alerts	Fewer lead integrity issues reported, but still some impedance and threshold alerts.	Less frequent lead impedance alerts; focuses more on pacing efficiency and therapy success.	More detailed and frequent lead impedance and capture threshold alerts.
Overall Lead Performance Monitoring	Good monitoring of lead integrity, though fewer detailed alerts.	Monitors lead performance well, but may give less frequent warnings than Manufacturer C.	Proactive with detailed warnings about lead issues and battery life.

5.2.1 Lead Impedance

(1) A Devices:

A Devices also report lead impedance values, with similar warnings like “high lead impedance” or “lead impedance low” indicating potential issues. Lead impedance warnings, particularly related to the RV lead and Atrial lead, signal possible electrical contact issues or lead mispositioning, similar to what we observe in Manufacturer C’s systems.

(2) B Devices:

B Devices’ report impedance data too, although the specifics of the impedance threshold warnings may vary slightly. In their data, high impedance values also suggest lead dysfunctions, but Manufacturer B tends to have more specific guidance for interpreting impedance values (e.g., “high pacing impedance”, which indicates lead degradation or failure).

(3) C Devices:

A. Impedance values in C devices can show warnings when impedance values are too high or abnormal, which suggests potential issues like lead fractures or poor contact. For example, C devices have specific logs for unipolar lead impedance warning and bipolar lead impedance warning (e.g., RV unipolar lead impedance warning), which are critical for identifying lead performance problems.

B. Impedance warnings across different periods (e.g., “RV polarity switch”, “high RV threshold”) provide a clear signal of degraded lead performance. Manufacturer C data indicates high and fluctuating lead impedance as a warning sign.

5.2.2 Capture Threshold

(1) Manufacturer A:

These devices monitor capture thresholds too, with alerts when thresholds exceed expected levels. High thresholds can also be an issue in Manufacturer A devices, similar to Manufacturer C, and could indicate ineffective pacing due to lead-related issues.

(2) Manufacturer B:

These devices monitor and alert when capture thresholds become too high, although these

thresholds are generally lower compared to the other manufacturers, meaning the pacing function might degrade at lower energy levels.

(3) Manufacturer C:

These devices generally have high capture thresholds as a warning indicator. This indicates that the device might be unable to consistently stimulate the heart at lower energy levels, possibly due to lead issues such as dislodgement or insulation damage. For example, Manufacturer C reports high RV thresholds on several patients, suggesting potential lead or electrode issues.

5.2.3 Sensing Issues

(1) A Devices:

These devices also report sensing issues, although they tend to have fewer reported problems. However, sensing issues still include high thresholds and improper lead contact.

(2) B Devices:

These devices include sensing alerts for issues like short V-V intervals, and the device often recommends troubleshooting for lead integrity and electrical noise interference. Like Manufacturer C, sensing issues are primarily linked to lead problems or device malfunction.

(3) C Devices:

These devices report a range of sensing issues, including short V-V intervals and irregularities in signal detection (e.g., double-counted R waves). These issues can arise due to lead fractures, poor contact, or signal interference. For example, sensing issues were reported in Manufacturer C data for multiple patients, leading to recommendations to check for lead fractures or loose set screws.

5.2.4 Pacing Impedance

(1) Manufacturer A:

These devices also report pacing impedance, with high values similarly indicating lead dysfunction. Manufacturer A devices provide alerts when pacing impedance is abnormally high, suggesting an issue with the lead or electrode.

(2) Manufacturer B:

These devices also report pacing impedance and provide warnings when it exceeds acceptable thresholds, indicating a possible lead problem.

(3) Manufacturer C:

These devices report pacing impedance, and high values in this parameter suggest poor pacing lead performance. For instance, high pacing impedance in Manufacturer C data can indicate problems like lead dislodgement, fracture, or insulation damage.

5.2.5 Battery Voltage and Remaining life

(1) A Devices:

These devices similarly monitor battery health, and remaining life is critical for ensuring pacing continuity. Low battery levels can affect lead performance, though Manufacturer A tends to give more lead-time warnings before a replace device recommendation.

(2) B Devices:

These devices also track battery voltage, but battery alerts are less frequent, often giving longer timelines for device replacement. Low battery voltage in Manufacturer B devices can sometimes result in pacing failures if it affects lead functionality.

(3) C Devices:

These devices report battery voltage and remaining life**,** which are crucial for lead performance. As the battery voltage decreases, it can affect the device's ability to properly power the leads and maintain effective pacing. A low battery voltage is often linked to lead degradation or the need for device replacement.

In the Manufacturer C pacemaker reports, lead performance is evaluated primarily through written data points, without direct waveform analysis. The reports indicate frequent warnings for unipolar and bipolar lead impedance, which could suggest issues such as poor contact or lead degradation. Additionally, the reports highlight high capture thresholds, which are frequently observed and may indicate suboptimal lead function. These high thresholds suggest that more energy is needed to achieve effective pacing, potentially due to poor lead performance. Furthermore, C devices report document sensing issues such as short V-V intervals, lead fractures, and double-counted R-waves. These issues could affect the accuracy and effectiveness of pacing, leading to potential therapy interruptions. The reports also provide high pacing

impedance warnings, which may indicate lead failure or degradation, thereby affecting the efficiency of the pacing system. While no waveform data is provided, these written metrics serve as the primary means of assessing lead performance, offering insights into both immediate and potential issues that may require attention.

Manufacturer A provide detailed analyses of lead performance through metrics like the Atrial Capture Test, Atrial Sense Test, and Atrial Sense Amplitude Trend. (see Figure 2)

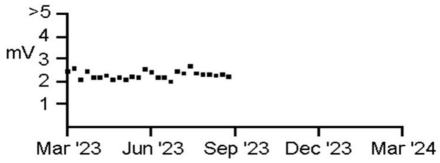

Figure 2 Atrial Sense Amplitude Trend (Manufacturer A)

Atrial Capture Test

Atrial Capture Test tests the energy threshold needed for the pacemaker to stimulate the atrium effectively and achieve capture. This guides programming of the atrial pacing output, ensuring reliable atrial activation while conserving battery life.

Atrial Sense Test and Amplitude Trend

Atrial Sense Test measures the pacemaker's sensitivity to natural atrial electrical activity and monitors changes in detected signal amplitude over time and ensures the pacemaker accurately detects atrial signals, avoiding misinterpretation that could lead to unnecessary pacing (oversensing) or missed pacing opportunities (under sensing). (see Figure 3)

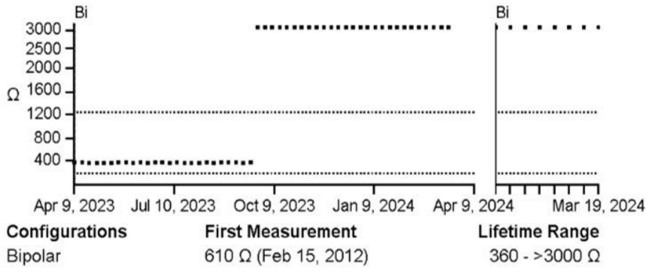

Figure 3 Lead Impedance trend (Manufacturer A)

Atrial Lead Impedance

Atrial lead Impedance measures the electrical resistance of the atrial lead to check its integrity and function and detects potential lead problems, such as dislodgement, insulation damage, or fracture, ensuring uninterrupted and effective pacing.

Ventricular Capture Test, Sense Test, and Auto Capture Trend

These test tests the pacemaker's ability to stimulate and sense ventricular activity while optimizing pacing output through auto-capture technology and guarantees effective ventricular pacing with minimal energy consumption and verifies that natural ventricular activity is being detected accurately. (see Figure 4, 5 and 6)

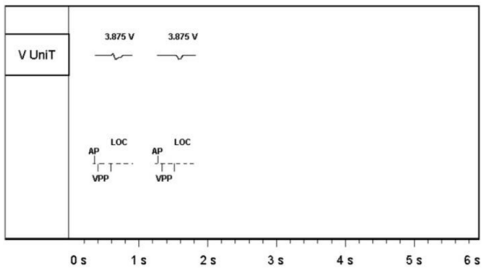

Figure 4 Ventricular Capture test (Manufacturer A)

B devices reports focus on specific metrics like P Wave Amplitude and Impedance Trends, which track the electrical signal from the atrium to assess lead performance and identify potential

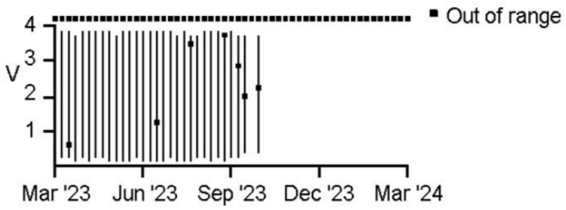

Figure 5 Auto Capture Trend (Manufacturer A)

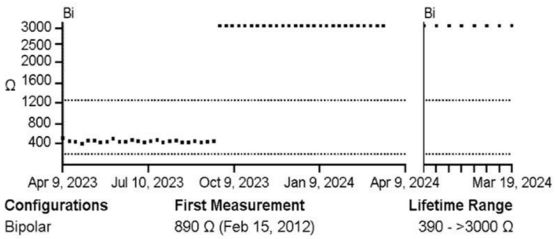

Figure 6 Ventricular Lead Monitoring (1 year trend) (Manufacturer A)

issues such as insulation damage or poor contact. Similarly, the R Wave Amplitude and Ventricular Pacing Threshold measure ventricular signal strength and pacing energy requirements, balancing effective capture with energy efficiency to extend battery life.

P Wave Amplitude and Impedance Trends

Tracks the electrical signal from the atrium and the performance of the atrial lead. It ensures effective sensing and pacing while identifying potential lead-related issues.

R Wave Amplitude and Ventricular Pacing Threshold

Measures the electrical signal from the ventricles and the energy needed for consistent pacing. It balances effective ventricular capture with energy efficiency, extending the device's longevity. (see Figure 7)

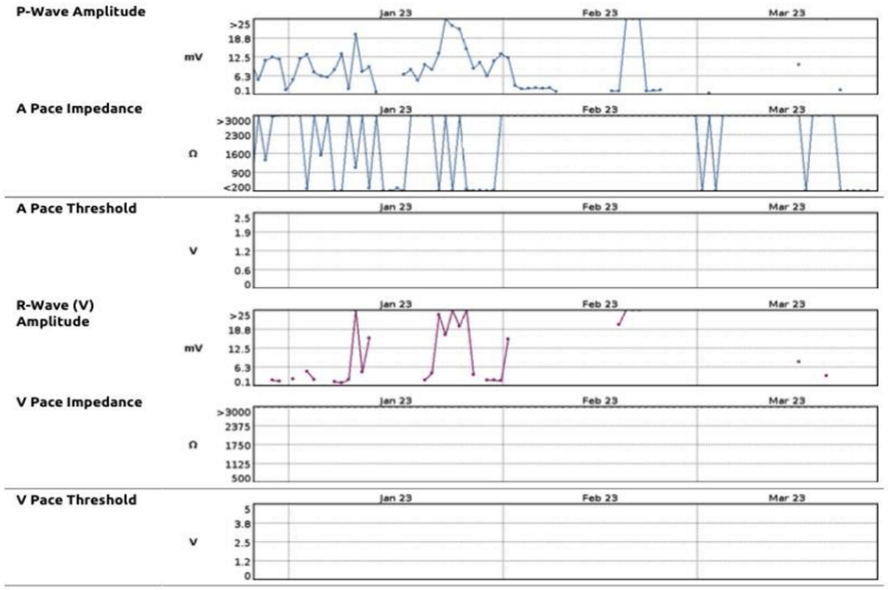

Figure 7 Amplitude and Impedance trend (Manufacturer B)

5.3 Pacing Modes and Rates

(1) A Devices:

Predominantly DDD (dual-chamber pacing) modes, with a few operating in DDI or DDDR. The base rates range from 50–70 bpm, and maximum sensor rates range from 120–140 bpm.

(2) B Devices:

Devices support various pacing modes (VVIR, DDD, DDDR) with lower rate limits around 60 ppm and upper sensor rates between 110-130 ppm. These settings are standard for maintaining optimal heart rates based on patient activity.

(3) C Devices:

Modes vary significantly, with AAIR, DDDR, VVIR, and VVI configurations. Some devices have mode switching capabilities (e.g., AAIR<=>DDDR). Base rates generally range from 60–70 bpm, with upper sensor rates reaching 130 bpm. Manufacturer C might also utilize adaptive rates to adjust based on activity

Summary: All manufacturers offer comparable pacing modes and rate limits, although individual device models and patient needs lead to variations in the programmed rates.

(1) Manufacturer A

Manufacturer A reports focus on AT/AF Burden, displaying the duration of atrial arrhythmias and the corresponding ventricular response. This metric evaluates the pacemaker's ability to manage arrhythmias effectively and maintain safe ventricular rates, thereby reducing the risk of complications like stroke or tachycardia.

AT/AF Burden with v rated during AT/AF (see Figure 8)

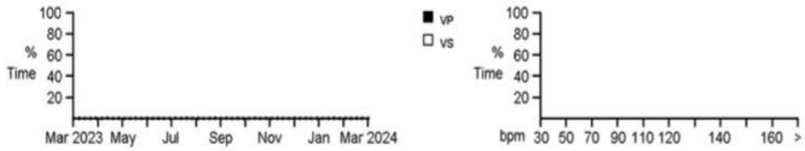

Figure 8 AT/AF Burden with V rated in Manufacturer A

AT/AF Summary (see Figure 9)

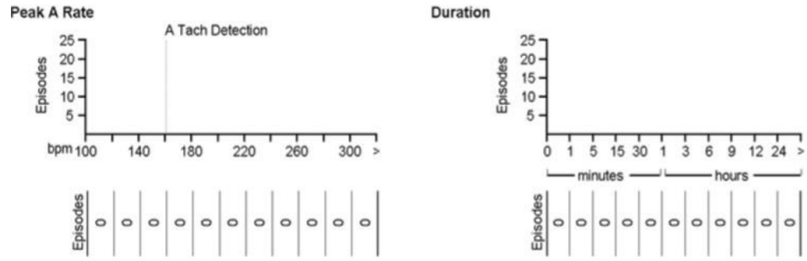

Figure 9 AT/AF summary in Manufacturer A

The waveform displays the duration the patient experiences atrial arrhythmias (AT/AF) and how the ventricles respond (paced or intrinsic). Here it is 0% AT/AT burden. This evaluates the pacemaker's ability to manage arrhythmias and maintain a safe ventricular rate, reducing risks like stroke or tachycardia.

Heart Rate Histogram with atrial and ventricular waveforms (see Figure 10)

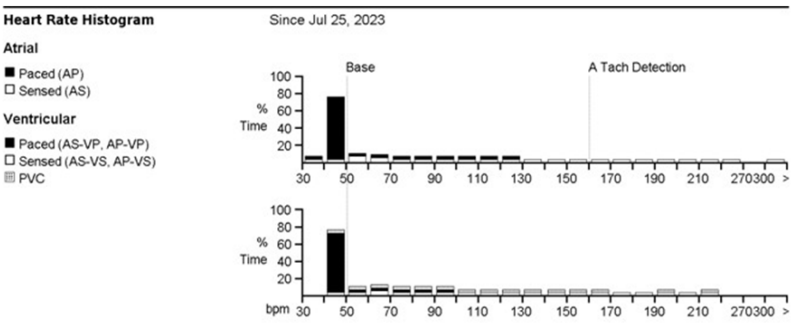

Figure 10 HR Histograms in Manufacturer A

The histogram tracks heart rates, distinguishing between intrinsic cardiac beats and those paced by the device in both atrial and ventricular chambers. This ensures the pacemaker

is appropriately pacing when needed, monitoring the patient's natural cardiac activity and determining how often pacing support is required.

(2) Manufacturer B

These devices integrate additional features like AT/AF Burden and Mode Switch, which monitor arrhythmia episodes and adapt pacing modes accordingly to prevent rapid ventricular pacing during atrial arrhythmias. (see Figure 11)

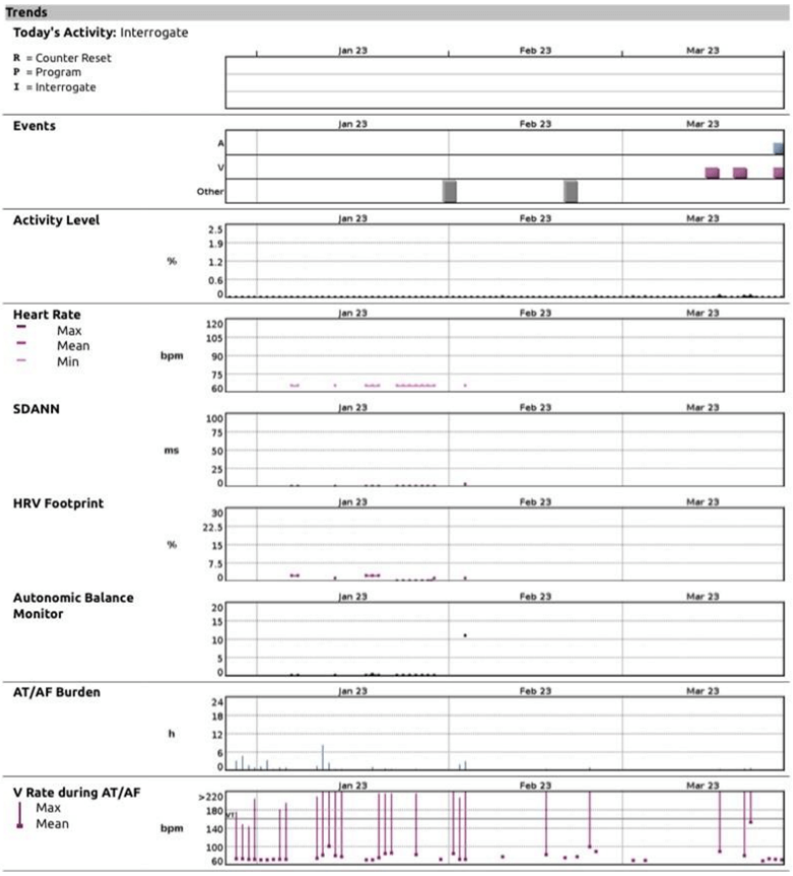

Figure 11 Trends in Manufacturer B

Other notable metrics include:

A. Pacing Percent indicates the proportion of time the pacemaker actively paces the atrial or ventricular chambers. It helps evaluate dependency on the pacemaker and informs whether therapy adjustments are needed, such as reducing unnecessary pacing.

B. Respiratory Rate uses thoracic impedance monitoring to estimate the patient's breathing rate. It provides additional physiological data for rate-responsive pacing, where the pacemaker adjusts heart rate based on physical activity or breathing patterns. (see Figure 12)

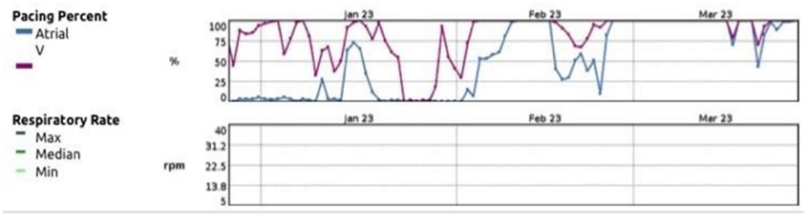

Figure 12 Pacing and Respiratory rate in Manufacturer B

Histograms

ATR Mode Switch, V detection (see Figure 13)

Heart rate variability waveform measures the variability in the time intervals between heartbeats (R-R intervals). Heart rate variability (HRV) is a key indicator of autonomic nervous

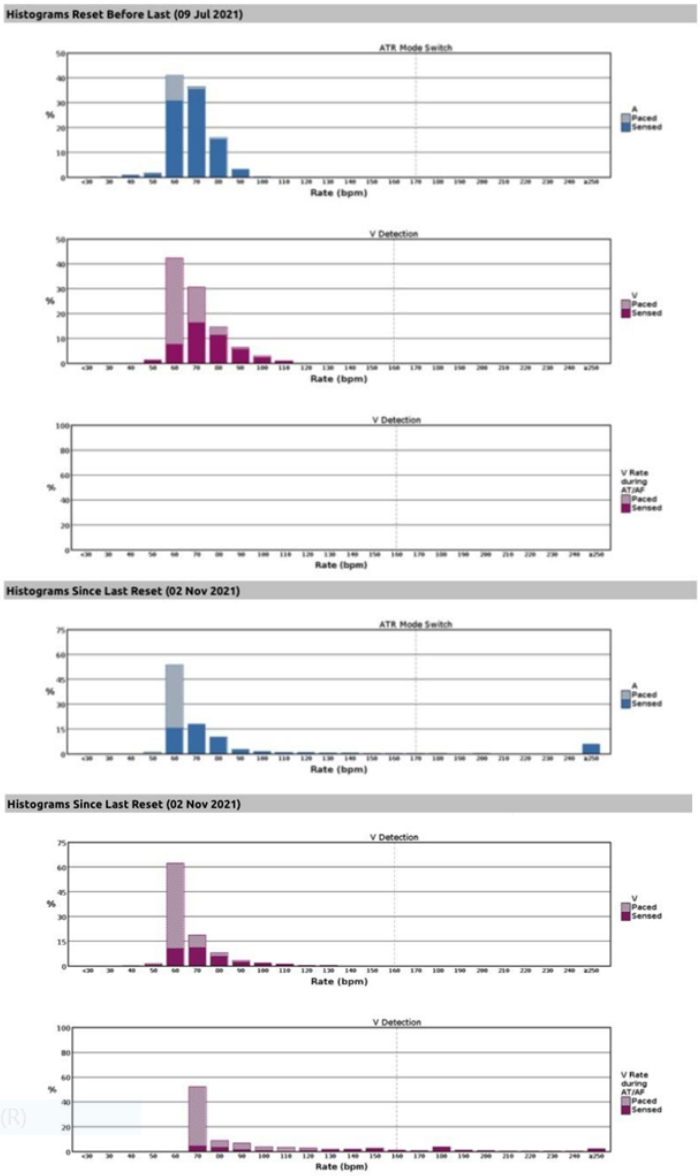

Figure 13 ATR mode switch and V detection in Manufacturer B

system activity and cardiac health. It is used for assessing stress, recovery, and potential arrhythmias. Low HRV may indicate an increased risk of cardiac events, while high HRV is generally a sign of good health. (see Figure 14)

(3) Manufacturer C

These devices leverage Cardiac Compass Trends to monitor pacing performance andphysiological adaptability.

This section provides daily or monthly trends for various parameters, such as:

A. AT/AF episodes per day: Graphs show time spent in atrial fibrillation or atrial tachycardia, which reflects how well the pacemaker manages arrhythmias over time. (see Figure 15)

B. Patient Activity and Heart Rate Variability: These trends track the patient's daily activity level and heart rate variability, which relate to how the pacemaker adjusts to changing physical demands. By analyzing the patient activity graph, adaptive rate functionality across different devices can be discussed. (see Figure 16)

Rate Histograms:

The histograms summarize the distribution of atrial and ventricular pacing rates. For example: Atrial and Ventricular Rate Distribution: This histogram shows the frequency of different heart rates, which helps assess the consistency and efficacy of the device's pacing under various conditions.

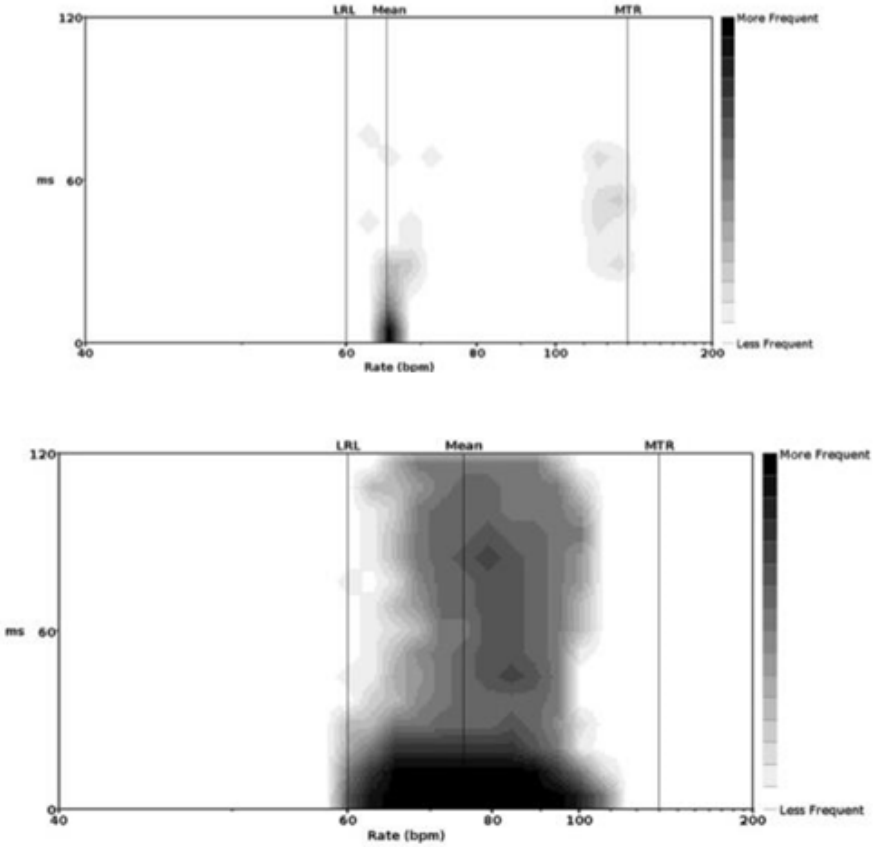

Figure 14 HR variability in Manufacturer B

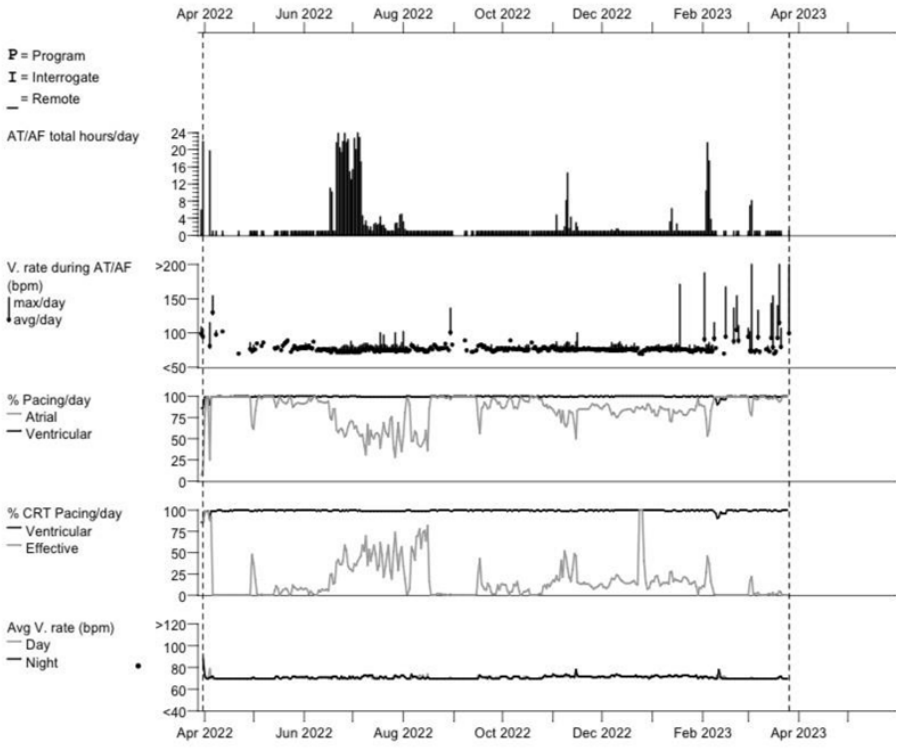

Figure 15 Trends in Manufacturer C

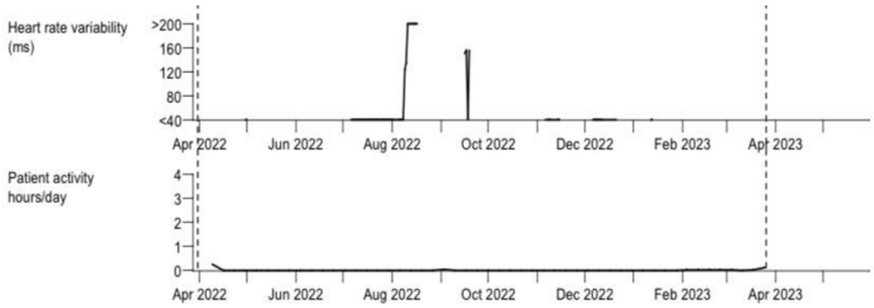

Figure 16 Patient activity and HR variability in Manufacturer C

Time in AT/AF: There are also pacing distributions specific to time spent in arrhythmia states like AT/AF, which can be used to evaluate the device's efficiency in maintaining normal sinus rhythm compared to other brands. (see Figure 17)

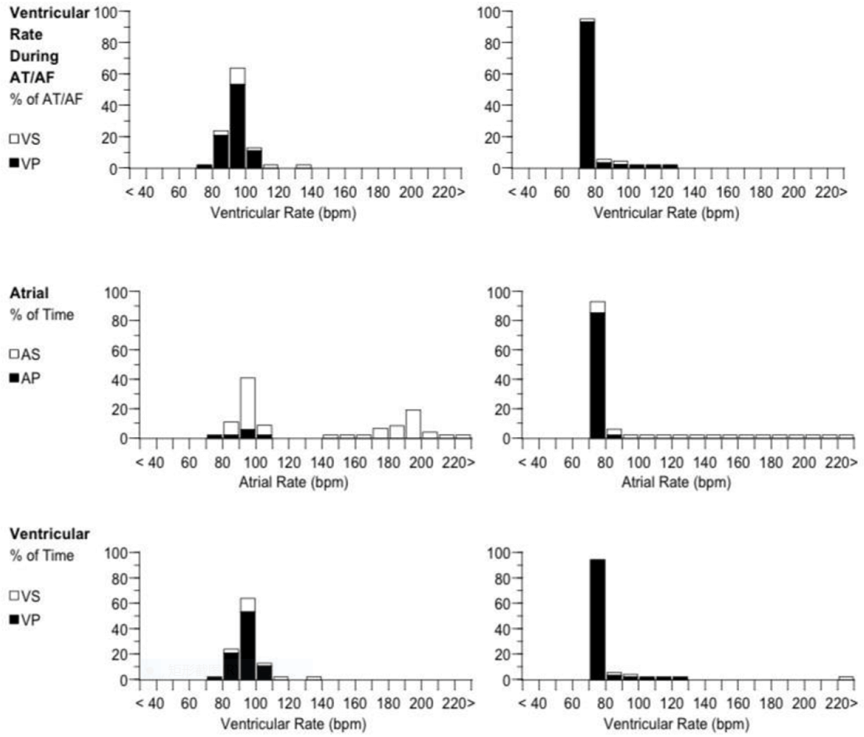

Figure 17 Rate Histograms in Manufacturer C

This comparison highlights the strengths and unique diagnostic tools each manufacturer offers for evaluating battery performance**,** lead functionality, and pacing modes. While Manufacturer C provides detailed trend-based diagnostics, Manufacturer A emphasizes reliable real-time performance monitoring, and Manufacturer B focuses on patient adaptability and long-term stability.

5.4 Interrogation report

When comparing pacemaker interrogation reports from the three manufacturers we should look at several aspects of these reports that affect clinical usability, data clarity, and comprehensiveness. Here's an in-depth comparison of these reports:

5.4.1 Report Layout and Readability

A Devices: These reports are designed with an intuitive layout that's relatively easy to follow, though they may not be as data-heavy as Manufacturer C's. Manufacturer A focuses on presenting critical information in a straightforward way, often including trend lines but with less detail in each section compared to Manufacturer C. Manufacturer A's reports are known for

real-time data visibility, prioritizing recent events.

B Devices: These reports are concise and straightforward, which can benefit clinicians looking for a quick overview. They offer key metrics on battery life, pacing activity, and any recent arrhythmia events, although they may not have as many detailed graphical elements as Manufacturer C's. The reports are easy to read, with well-highlighted alerts and action items.

C Devices: These interrogation reports are well-organized and tend to be comprehensive, covering a broad range of data points. The layout is generally modular, allowing clinicians to view sections on battery life, lead performance, and arrhythmia episodes independently. The reports are known for including graphical trends and tables, making it easier for clinicians to spot changes over time.

5.4.2 Battery Status and Longevity Tracking

Manufacturer A: These reports provide accurate battery status with a remaining life estimation based on recent usage. The report may not be as granular in terms of predictive analytics compared to Manufacturer C but gives reliable information for typical clinical needs.

Manufacturer B: Known for strong battery management, These reports also include an estimated time until replacement but focus more on efficiency metrics, such as battery drain trends. Their reports provide a clear view of battery life expectancy but may lack the intricate projections seen in C Devices.

Manufacturer C: These reports provide detailed battery status information, including an estimated time until replacement that adjusts based on device usage. They use data-driven projections to predict battery depletion, which helps in planning replacement procedures. This section is typically detailed, with clear warnings when the battery approaches its end-of-life.

5.4.3 Lead Performance Monitoring

A Devices: These reports cover essential lead parameters, including pacing thresholds and impedance measurements, but with a greater focus on real-time diagnostics. The reports include alerts if the leads show signs of performance degradation, though trend analysis may be less detailed than in Manufacturer C reports.

B Devices: These reports also emphasize lead performance, providing data on lead impedance and pacing thresholds. They include historical data on lead status, which is valuable for tracking long-term stability, but might offer fewer real-time alerts compared to Manufacturer A.

C Devices: These reports provide detailed lead diagnostics, including impedance measurements, sensing thresholds, and pacing thresholds. Their reports often include trend graphs showing lead impedance over time, which is critical for early detection of lead issues like fractures or insulation breaches.

5.4.4 Arrhythmia Detection and Event Logging

Manufacturer A: These reports also monitor arrhythmias, with a focus on frequency and type of episodes. The reports provide a summary of recent arrhythmia events and may include some real-time data if the patient is enrolled in remote monitoring. However, Manufacturer A may not provide as extensive historical trend data as Manufacturer C.

Manufacturer B: These reports provide event logging for arrhythmias, with concise details on episode frequency and duration. Their focus is more on actionable insights, flagging significant arrhythmia events rather than providing exhaustive historical data.

Manufacturer C: These reports are particularly robust in terms of arrhythmia monitoring. They include a detailed history of arrhythmia episodes, categorized by type (e.g., atrial fibrillation, ventricular tachycardia), with timestamps, episode durations, and treatment provided (like ATP). The reports also feature algorithms for trend analysis, allowing clinicians to identify patterns.

5.4.5 Remote Monitoring Capabilities

A Devices: Manufacturer A's Merlin.net remote monitoring platform is known for its user-friendly interface and effective remote data transmission. Interrogation reports from Merlin.net provide real-time insights, particularly useful for tracking recent changes. However, the data in Manufacturer A reports might be slightly more simplified compared to Manufacturer C.

B Devices: The LATITUDE platform by Manufacturer B offers remote monitoring but is often praised for simplicity rather than depth. LATITUDE can provide alerts and event

notifications, but reports might be more condensed, focusing on high-level information rather than exhaustive details.

C Devices: Manufacturer C's CareLink network is highly integrated with their interrogation reports. CareLink enables continuous remote monitoring, automatically updating clinicians on device status, arrhythmias, and lead performance. Reports pulled from CareLink are usually detailed and updated with the latest patient data, which is beneficial for proactive management.

5.4.6 Customization and User Controls

Manufacturer A: These reports are straightforward with minimal customization options. Their goal is simplicity and speed, providing clinicians with essential information without a lot of user-specific tailoring.

Manufacturer B: These reports provide limited customization but do allow clinicians to filter alerts and focus on key metrics. While customization options may not be as detailed as Manufacturer C's, they still offer enough to make the reports useful in varied clinical contexts.

Manufacturer C: These reports are highly customizable, allowing clinicians to prioritize sections based on specific needs. This flexibility is advantageous in situations where certain metrics, such as arrhythmia episode logs or battery life, are more relevant to the patient's condition.

5.4.7 Alerts and Notifications

A Devices: These devices provide effective alerts in their reports, particularly for battery status and lead performance. Their alerts are well-placed and make use of color-coding or symbols to quickly draw attention to any urgent issues.

B Devices: These reports include alerts, but they focus on critical issues only, providing a streamlined experience. This approach makes the reports easy to read, though some clinicians may find the alerts less frequent or detailed than those in Manufacturer C reports.

C Devices: These reports contain robust alert systems that flag issues like low battery, abnormal lead impedance, and arrhythmia episodes. Their reports often highlight warnings prominently, making them hard to miss for clinicians.

The interrogation reports from three leading manufacturers: Manufacturer A, Manufacturer B, and Manufacturer C were evaluated based on key aspects such as report layout, battery status, lead performance, arrhythmia detection, remote monitoring capabilities, customization options, and alert systems. The findings are summarized in Table 4.

Table 4 Fornell-Lecker criterion

Aspect	Manufacturer A	Manufacturer B	Manufacturer C
Report Layout	Intuitive, real-time focus	Concise, action- oriented	Modular, detailed, graphical
Battery Status	Accurate, reliable estimations	Focus on efficiency, basic projections	Predictive, data- driven projections
Lead Performance	Real-time monitoring	Emphasis on long- term stability	In-depth diagnostics, trend analysis
Arrhythmia Detection	Recent episode summary	Focused on actionable events	Detailed episode history, trends
Remote Monitoring	Simple and effective (Merlin.net)	Efficient and streamlined (LATITUDE)	Advanced, real-time updates (CareLink)
Customization	Limited customization	Moderate customization	Highly customizable
Alerts and Notifications	Clear, real-time alerts	Minimal but essential alerts	Prominent alerts, comprehensive

5.5 Visualization Report

The graphs developed for A, B, and C devices display a comparative analysis of different parameters such as voltage, battery life, pulse amplitude, lead impedance, and sensor rates between different models of pacemakers. A bar is taken for every parameter for a given device so that an easy comparison of how devices of these companies compare on different parameters can be done. The data is also presented in a long format, where each parameter is plotted along the y-axis and the device model along the x-axis. The difference in hue between each parameter

simplifies the identification and comparison of values for all the pacemaker devices. With this analysis, the varying performance and nature of pacemakers by the three major manufacturers are made evident. (see Figure 18, 19 and 20)

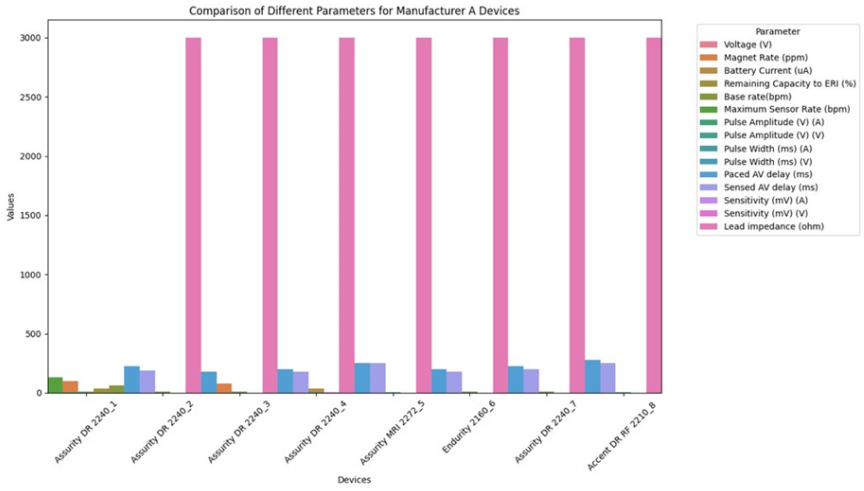

Figure 18 Comparison of different parameters for Manufacturer A devices

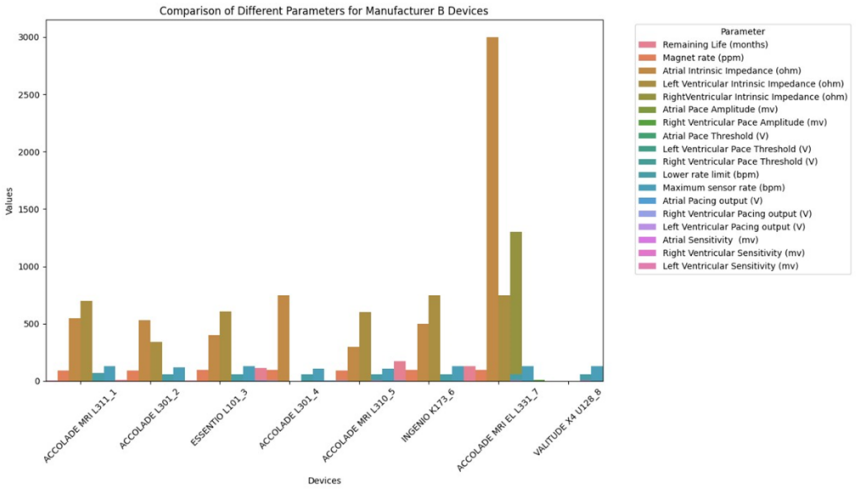

Figure 19 Comparison of different parameters for Manufacturer B devices

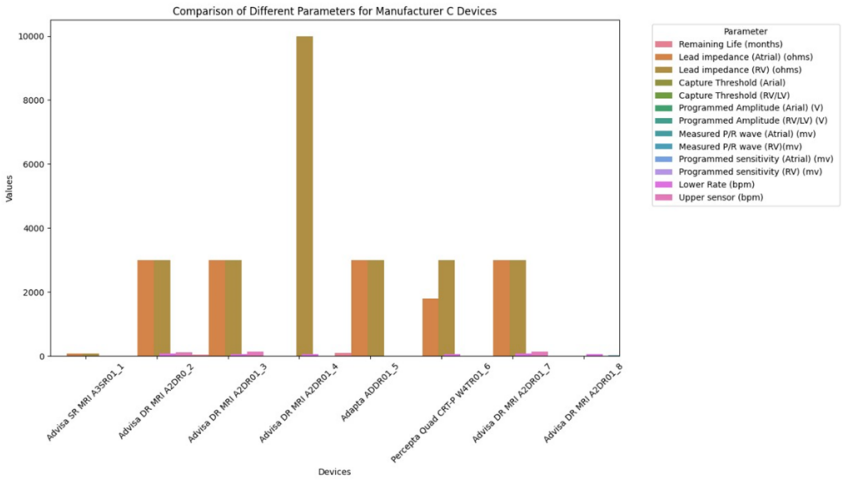

Figure 20 Comparison of different parameters for Manufacturer C devices

6 Discussion

The performance, reliability, and usability of cardiac implantable electronic devices (CIEDs) can be well evaluated on the basis of an analysis of pacemaker interrogation reports of three companies. The reports have structured data, focusing on key aspects such as battery performance, lead diagnostics, pacing modes, arrhythmia monitoring, and usability. However, differences in data presentation and reporting structures reflect distinct clinical decision-making approaches, highlighting the necessity for standardized practices to ensure consistency and optimize patient management [43].

6.1 Battery Performance

Manufacturer C's reporting is better in highlighting voltage trends and forecast analysis so that clinicians can plan and prepare battery replacements. Devices A likes real-time efficiency metrics with true battery status notifications but lacks a predictive function. B focuses more on simple battery life estimation, where efficiency metrics are the priority, possibly at the expense of using it for long-term planning. These variations highlight the need for uniform battery life estimation methodologies across manufacturers to ensure reliability in clinical decision-making [44, 45]. Standardized reporting of device longevity is essential to facilitate accurate comparisons and prevent premature or delayed replacements [46].

6.2 Lead Performance

Lead diagnostics play a crucial role in ensuring effective pacing and minimizing complications. C Devices leads the way in lead performance monitoring with full diagnostics including impedance measurements, sensing thresholds, and pacing thresholds, along with trend graphs to review historically. Device A emphasizes more real-time lead diagnostics with instantaneous alerts for likely problems. Manufacturer B emphasizes long-term stability by using historical lead performance data but gives fewer instantaneous alerts. Integrating both real-time and historical diagnostics into a standardized framework would improve lead monitoring strategies across manufacturers [46, 47].

6.3 Pacing Modes and Arrhythmia Management

The approach to pacing and arrhythmia management varies across manufacturers. C Devices provide in-depth pacing mode and arrhythmia control information through advanced diagnostics and trend analysis of history. Manufacturer A prioritizes real-time arrhythmia detection and pacing mode optimization with prompt clinical action alerts. B Devices prioritizes pacing stability over the long term and arrhythmia trends, but its real-time monitoring capabilities are less robust. These are clinical priority distinctions, wherein A and C Devices are best in real-time data utilization, and B Devices is best for historic data in longitudinally managing patients. These differences underscore the need for interoperable data sharing and harmonization of pacing and arrhythmia diagnostics across different systems to enhance clinical decision-making [48, 49].

6.4 Report Layout and Usability

Variations in report design impact how clinicians interpret and utilize interrogation data. C devices reports provide rich data on pacing modes and arrhythmia control with the assistance of advanced diagnostics and historical trend monitoring. Manufacturer A highlights real-time detection of arrhythmia and pacing mode optimization with timely clinical action alerts. B Devices highlights long-term pacing stability and arrhythmia trends, though its real-time monitoring is weaker. These are differences in clinical priorities, where Devices A and C lead in the utilization of real-time data and B focuses on historical data for longitudinal patient management. These differences in usability suggest that standardizing report structures while preserving critical manufacturer- specific innovations could improve clinician workflow efficiency [50].

6.5 Remote Monitoring and Customization

Remote monitoring solutions further distinguish the three manufacturers. Manufacturer C's CareLink network merges remote monitoring and interrogation reports, providing predictive

analytics and easy data integration. Manufacturer A's Merlin.net system emphasizes simplicity of interface and real-time data transmission optimized. B's LATITUDE system provides remote monitoring optimized with a focus on operational efficiency. C Devices allows for greater levels of customization, with the ability for reports to be specific to clinical needs,

while A and B provide more standardized reporting systems. Standardizing remote monitoring protocols while allowing some degree of customization could enhance patient management without sacrificing clinical flexibility [43, 51].

Overall, the interrogation reports are all unique in terms of data presentation, usability, and clinical usefulness. The variance in reporting design and functionality points to the need for standardization of device reporting in order to provide consistency, efficiency in clinician workflow, and optimal patient outcomes. Standardization of these reporting practices should be the goal of future endeavors with the retention of the innovative elements that set each company apart.

7 Conclusion

The research provides a comprehensive comparative evaluation of pacemaker interrogation reports by the leading manufacturers in terms of key features of battery performance, lead status, pacing modes, arrhythmia detection, and reportability. The research focuses on different aspects of device management to benefit clinical decision-making. These differences in reporting formats and diagnostic performance emphasize the potential advantages of adopting standardized reporting practices, which would enhance data consistency, comparability, and clinical utility across manufacturers.

In terms of battery performance, C Devices provides trend analysis and predictive insights, Manufacturer A focuses on real-time efficiency metrics and notifications, B emphasizes straightforward battery life estimations with long-term stability, reflecting distinct priorities. For lead performance, C Devices offers comprehensive diagnostics and historical trends, Manufacturer A delivers real-time alerts, B prioritizes long-term stability with fewer immediate alerts, highlighting the need for balanced monitoring. Regarding pacing modes and arrhythmia management, C provides advanced diagnostics and historical trends, Device A focuses on real- time detection and actionable alerts, and B emphasizes long-term pacing stability and trends, showcasing differing clinical priorities. These variations underscore the importance of integrating diverse functionalities to optimize patient care and outcomes.

Finally, pacemaker selection and its associated interrogation system must be resolved according to the patient's individual clinical needs and the practice environment of the healthcare organization. By leveraging the unique strengths of each device reporting system and demanding higher levels of standardization, clinicians can maximize the efficient utilization of pacemakers and improve cardiac care and patient outcomes. This study focuses on the necessity of collaboration among manufacturers, clinicians, and regulators in creating standard reports that will stimulate innovation.

Conflicts of interest

The authors declare no conflicts of interest.

References

[1] American Heart Association. "Why would I need one?", 2021. https://www.heart.org

[2] Aquilina O. A brief history of cardiac pacing. Images in paediatric cardiology. 2006, 8(2): 17. https://pmc.ncbi.nlm.nih.gov/articles/PMC3232561

[3] Shivi A, Shinde RK. Smart Pacemaker: A Review. Cureus. 2022, 14(10). https://doi.org/10.7759/cureus.30027

[4] Ward C, Henderson S, Metcalfe NH. A short history on pacemakers. International Journal of Cardiology. 2013, 169(4): 244-248. https://doi.org/10.1016/j.ijcard.2013.08.093

[5] Kalra J, Lightner NJ, Taiar R. (Eds.). Advances in Human Factors and Ergonomics in Healthcare and Medical Devices: Proceedings of the AHFE 2021 Virtual Conference on Human Factors and Ergonomics in Healthcare and Medical Devices, July 25–29, 2021, USA. Springer. https://doi.org/10.1007/978-3-030-80744-3

[6] Shepard RK, Ellenbogen KA. Leads and longevity: how long will your pacemaker last? Europace. 2008, 11(2): 142-143. https://doi.org/10.1093/europace/eun359

[7] Maisel WH, Moynahan M, Zuckerman BD, et al. Pacemaker and ICD generator malfunctions: analysis of Food and Drug Administration annual reports. Jama. 2006, 295(16): 1901-1906. https://doi.org/10.1001/jama.295.16.1901

[8] Ferrick AM, Raj SR, Deneke T, et al. 2023 HRS/EHRA/APHRS/LAHRS expert consensus statement on practical management of the remote device clinic. Heart Rhythm. 2023, 20(9): e92-e144. https://doi.org/10.1016/j.hrthm.2023.03.1525

[9] Piccini JP, El-Chami M, Wherry K, et al. Contemporaneous Comparison of Outcomes Among Patients Implanted With a Leadless vs Transvenous Single-Chamber Ventricular Pacemaker. JAMA Cardiology. 2021, 6(10): 1187. https://doi.org/10.1001/jamacardio.2021.2621

[10] Burri H, Senouf D. Remote monitoring and follow-up of pacemakers and implantable cardioverter defibrillators. Europace. 2009, 11(6): 701-709. https://doi.org/10.1093/europace/eup110

[11] Slotwiner D, Varma N, Akar JG, et al. HRS Expert Consensus Statement on remote interrogation and monitoring for cardiovascular implantable electronic devices. Heart Rhythm. 2015, 12(7): e69-e100. https://doi.org/10.1016/j.hrthm.2015.05.008

[12] Shanmugam DK, Anitha SC, Souresh V, et al. Current advancements in the development of bionic organs using regenerative medicine and 3D tissue engineering. Materials Technology. 2023, 38(1). https://doi.org/10.1080/10667857.2023.2242732

[13] Schaldach M. Electrotherapy of the heart: technical aspects in cardiac pacing. Springer Science & Business Media, 2012.

[14] Salih A M. Characterization of in-vivo damage in implantable cardiac devices and the lead residual properties. Wright State University, 2019. https://corescholar.libraries.wright.edu/etd_all

[15] Marras E, Sciarra L, Bocchino M, et al. Pacemaker malfunctions in Danon's disease. Pacing and Clinical Electrophysiology, 2008, 31(1): 125-128. https://doi.org/10.1111/j.1540-8159.2007.00937.x

[16] Atlee JL. Pacemaker Malfunction in Perioperative Settings. In: Atlee, J.L., Gombotz, H., Tscheliessnigg, K.H. (eds) Perioperative Management of Pacemaker Patients. Springer, Berlin, Heidelberg, 1992. https://doi.org/10.1007/978-3-642-76531-5_18

[17] Sabbagh E, Abdelfattah T, Karim M, et al. Causes of Failure to Capture in Pacemakers and Implantable Cardioverter-defibrillators. Journal of Innovations in Cardiac Rhythm Management. 2020, 11(2): 4013-4017. https://doi.org/10.19102/icrm.2020.110207

[18] Goswami T. Investigation of Retrieved Cardiac Devices. Biomedical Journal of Scientific & Technical Research. 2019, 23(4). https://doi.org/10.26717/bjstr.2019.23.003924

[19] Salih A, Goswami T. Residual properties of silicone (MED-4719) lead with leads from retrieved devices. Materials Engineering Research. 2022, 4(1): 236-244. https://doi.org/10.25082/mer.2022.01.005

[20] Mulpuru SK, Madhavan M, McLeod CJ, et al. Cardiac pacemakers: function, troubleshooting, and management: part 1 of a 2-part series. Journal of the American College of Cardiology. 2017, 69(2): 189-210. https://doi.org/10.1016/j.jacc.2016.10.061

[21] Rockland R, Parsonnet V, Myers GH. Failure modes of American pacemakers—in vitro analysis. American Heart Journal. 1972, 83(4): 481-492. https://doi.org/10.1016/0002-8703(72)90039-7

[22] Sabbagh E, Abdelfattah T, Karim M, et al. Causes of Failure to Capture in Pacemakers and Implantable Cardioverter-defibrillators. Journal of Innovations in Cardiac Rhythm Management. 2020, 11(2): 4013-4017. https://doi.org/10.19102/icrm.2020.110207

[23] Willy K, Ellermann C, Reinke F, et al. The Impact of Cardiac Devices on Patients' Quality of Life — A Systematic Review and Meta-Analysis. Journal of Cardiovascular Development and Disease. 2022, 9(8): 257. https://doi.org/10.3390/jcdd9080257

[24] Mulpuru SK, Madhavan M, McLeod CJ, et al. Cardiac pacemakers: function, troubleshooting, and management: part 1 of a 2-part series. Journal of the American College of Cardiology. 2017, 69(2): 189-210. https://doi.org/10.1016/j.jacc.2016.10.061

[25] Mond HG. The Development of Pacemaker Programming: Memories From a Bygone Era. Heart, Lung and Circulation. 2021, 30(2): 233-239. https://doi.org/10.1016/j.hlc.2020.08.006

[26] Paglia E, Carter J. Cardiac Pacemakers. Hospital Medicine Clinics. 2017, 6(3): 374-396. https://doi.org/10.1016/j.ehmc.2017.04.007

[27] Davies G, Siddons H. Prediction of battery depletion in implanted pacemakers. Thorax. 1973, 28(2): 180-182. https://doi.org/10.1136/thx.28.2.180

[28] Davies G, Siddons H. Prediction of battery depletion in implanted pacemakers. Thorax. 1973, 28(2): 180-182. https://doi.org/10.1136/thx.28.2.180

[29] Munawar DA, Mahajan R, Linz D, et al. Predicted longevity of contemporary cardiac implantable electronic devices: A call for industry-wide "standardized" reporting. Heart Rhythm. 2018, 15(12): 1756-1763.
https://doi.org/10.1016/j.hrthm.2018.07.029

[30] Paratz ED, Block TJ, Stub DA, et al. Postmortem Interrogation of Cardiac Implantable Electronic Devices. JACC: Clinical Electrophysiology. 2022, 8(3): 356-366.
https://doi.org/10.1016/j.jacep.2021.10.011

[31] Olabi AG, Abdelghafar AA, Soudan B, et al. Artificial neural network driven prognosis and estimation of Lithium-Ion battery states: Current insights and future perspectives. Ain Shams Engineering Journal. 2024, 15(2): 102429.
https://doi.org/10.1016/j.asej.2023.102429

[32] Katz D, Akiyama T. Pacemaker longevity: the world's longest lasting VVI pacemaker. Annals of Noninvasive Electrocardiology. 2007, 12(3): 223-226.
https://doi.org/10.1111/j.1542-474X.2007.00165.x

[33] Davis J, Thibault B, Mangat I, et al. Canadian Registry of Electronic Device Outcomes (CREDO): The Abbott ICD Premature Battery Depletion Advisory, a Multicentre Cohort Study. CJC Open. 2021, 3(1): 48-53.
https://doi.org/10.1016/j.cjco.2020.09.008

[34] Melman YF, Steinberg BA, Lancaster J, et al. Limitations of manufacturer-recommended remote monitoring in the St. Jude Assurity/Endurity battery recall. HeartRhythm Case Reports. 2021, 7(12): 791-794.
https://doi.org/10.1016/j.hrcr.2021.09.013

[35] Sinha SK, Akinyele B, Spragg DD, et al. Managing cardiac implantable electronic device patients during a health care crisis: Practical guidance. Heart Rhythm O2. 2020, 1(3): 222-226.
https://doi.org/10.1016/j.hroo.2020.05.005

[36] Neuenschwander JF, Peacock WF, Migeed M, et al. Safety and efficiency of emergency department interrogation of cardiac devices. Clinical and Experimental Emergency Medicine. 2016, 3(4): 239-244.
https://doi.org/10.15441/ceem.15.118

[37] D'Angelo RN, Pickett CC. Diagnostic yield of device interrogation in the evaluation of syncope in an elderly population. International Journal of Cardiology. 2017, 236: 164-167.
https://doi.org/10.1016/j.ijcard.2017.02.121

[38] Sobel RM, Donaldson PR, Dhruva N. Pacemaker-mediated tachycardia: Management by pacemaker interrogation/reprogramming in the ED. The American Journal of Emergency Medicine. 2002, 20(4): 336-339.
https://doi.org/10.1053/ajem.2002.33780

[39] Kawase K, Yamagata K, Ishibashi K, et al. Leadless pacemaker interrogation interference after conversion of a left ventricular assist device. HeartRhythm Case Reports. 2023, 9(1): 25-27.
https://doi.org/10.1016/j.hrcr.2022.10.005

[40] Cronin B, Birgersdotter-Green U, Essandoh MK. Perioperative Interrogation of Boston Scientific Cardiovascular Implantable Electronic Devices: A Guide for Anesthesiologists. Journal of Cardiothoracic and Vascular Anesthesia. 2019, 33(4): 1076-1089.
https://doi.org/10.1053/j.jvca.2018.05.005

[41] Burgemeestre GM, Timmer SAJ. Syncope due to pacemaker failure to capture after device transition into Safety Mode. HeartRhythm Case Reports. 2022, 8(7): 482-484.
https://doi.org/10.1016/j.hrcr.2022.04.008

[42] Boriani G, Bertini M, Saporito D, et al. Impact of pacemaker longevity on expected device replacement rates: Results from computer simulations based on a multicenter registry (ESSENTIAL). Clinical Cardiology. 2018, 41(9): 1185-1191.
https://doi.org/10.1002/clc.23003

[43] Varma N, Braunschweig F, Burri H, et al. Remote monitoring of cardiac implantable electronic devices and disease management. Europace. 2023, 25(9).
https://doi.org/10.1093/europace/euad233

[44] Alam MB, Munir MB, Rattan R, et al. Battery longevity in cardiac resynchronization therapy implantable cardioverter defibrillators. Europace. 2013, 16(2): 246-251.
https://doi.org/10.1093/europace/eut301

[45] Censi F, Calcagnini G, Mattei E, et al. Estimate and reporting of longevity for cardiac implantable electronic devices: a proposal for standardized criteria. Expert Review of Medical Devices. 2021, 18(12): 1203-1208.
https://doi.org/10.1080/17434440.2021.2013199

[46] Kusumoto FM, Schoenfeld MH, Wilkoff BL, et al. 2017 HRS expert consensus statement on cardiovascular implantable electronic device lead management and extraction. Heart Rhythm. 2017, 14(12): e503-e551.
https://doi.org/10.1016/j.hrthm.2017.09.001

[47] Karnik AA, Helm RH, Gaskill MD, et al. High impedance alert with safety switching: An unreported hazard of hybrid pacing systems. Journal of Cardiovascular Electrophysiology. 2019, 30(7): 1102-1107.
https://doi.org/10.1111/jce.13941

[48] Diamond J, Varma N, Kramer DB. Making the Most of Cardiac Device Remote Management. Circulation: Arrhythmia and Electrophysiology. 2021, 14(3).
https://doi.org/10.1161/circep.120.009497

[49] Slotwiner DJ, Abraham RL, Al-Khatib SM, et al. HRS White Paper on interoperability of data from cardiac implantable electronic devices (CIEDs). Heart Rhythm. 2019, 16(9): e107-e127. https://doi.org/10.1016/j.hrthm.2019.05.002

[50] Daley C, Coupe A, Allmandinger T, et al. Clinician use of data elements from cardiovascular implantable electronic devices in clinical practice. Cardiovascular Digital Health Journal. 2023, 4(1): 29-38. https://doi.org/10.1016/j.cvdhj.2022.10.007

[51] Slotwiner DJ, Serwer GA, Allred JD, et al. 2024 HRS perspective on advancing workflows for CIED remote monitoring. Heart Rhythm O2. 2024, 5(12): 845-853. https://doi.org/10.1016/j.hroo.2024.09.012