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From Wires to Wearables (2): Temporal Fidelity Assessment of the Sydäntek Wearable ECG System Against a Legacy Cloud-Based Standard

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Abstract: Validation of wearable electrocardiography (ECG) systems is critical to establishing diagnostic reliability and meeting regulatory standards. In this second installment of the *Wires to Wearables* series, we evaluate the temporal fidelity of the Sydäntek platform from Carditek Medical Devices against the Food and Drug Administration (FDA) approved, cloud-enabled Welch Allyn CardioPerfect™ system. The analysis focuses on core interval measurements: PR, QRS, and QT durations. Simultaneous recordings of calibration pulses and clinical ECGs were obtained using both devices across 498 patient datasets. Interval measurements were assessed using IEC 60601-2-25 benchmarks. Validation tools included agreement funnel plots for tolerance compliance assessment, Bland–Altman analysis for bias and dispersion visualization, and polar accuracy spider plots for sectoral alignment and precision mapping. Together, these methods captured comparative accuracy and reference fidelity between systems. Sydäntek demonstrated >99% concordance within strict ±5 ms tolerance thresholds in calibration pulse analyses, outperforming Welch Allyn, which showed broader dispersion. In clinical ECG recordings, Sydäntek consistently exhibited tighter limits of agreement and stable sectoral placement across all intervals. Despite the recognized variability, Welch Allyn served as the comparator due to its FDA-approved status and established cloud infrastructure. The Sydäntek wearable system achieves superior temporal accuracy and consistent reference alignment across both calibration and clinical datasets. With its high-fidelity signal acquisition, cloud-ready design, and decentralized deployment potential, Sydäntek is well-positioned for expanded validation within the "Wires to Wearables" framework and future clinical integration.

Keywords: temporal fidelity, interval concordance, calibration pulse analysis, IEC 60601-2-25 compliance, wearable ECG validation

1. Introduction

Electrocardiography (ECG) remains foundational in clinical cardiology, offering high-resolution insight into conduction pathways, repolarization patterns, and rhythm abnormalities. Despite the diagnostic fidelity of conventional 12-lead systems, their wired architecture and spatial dependence constrain scalability, especially in ambulatory or decentralized environments [1, 2]. Emerging healthcare models—centered on mobility, continuous patient engagement, and remote diagnostics—have propelled a new generation of wearable ECG platforms [3–5]. These devices promise democratized access to cardiac monitoring, yet their rapid proliferation invites scrutiny: diagnostic convenience must be anchored by validated signal fidelity, robust interval measurements, and algorithmic transparency [6–8]. Recent benchmarking efforts across waveform alignment metrics, QTc estimation accuracy, and RR interval tracking have begun to surface key performance differentials between consumer-grade systems and clinical gold standards [9, 10]—highlighting the urgent need for harmonized evaluation frameworks in wearable ECG adoption.

In *Wires to Wearables 1*, we introduced Sydäntek, a novel wearable 12-lead ECG system that reimagines Einthoven's triangle through an upper-chest–mounted patch while preserving lead morphology, quadrant fidelity, and vectorial behavior. There, we established spatial diagnostic equivalence via a physiologically derived +14° QRS axis correction, validated through Bland–Altman analysis and polar accuracy mapping [11, 12]. That work confirmed that wearable form factors, when anchored in

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electroanatomical principles, could preserve the shape and interpretability of surface ECG waveforms, even when subjected to motion artifact and signal morphology shifts [5, 8, 13].

Yet waveform morphology alone is insufficient for diagnostic equivalence. Clinical utility hinges not only on what the waveforms look like but when they occur. Temporal precision—specifically in measuring the PR interval, QRS duration, QT, and QTc—is critical to clinical decision-making [14–16]. Subtle changes in these intervals can alter diagnostic classification, pharmacologic choices, and even regulatory outcomes [17–19]. The importance of precision in interval measurement is especially acute. The US FDA's ICH E14 guidelines stipulate that a QTc prolongation of just 5 ms may raise regulatory concern; a mean increase of >10 ms may prevent drug approval. Similar thresholds apply in device therapy: a QRS duration change of 5–10 ms can determine eligibility or trigger reprogramming for cardiac resynchronization therapy. Post-pacemaker tuning, atrioventricular (AV) nodal assessment, and lead repositioning may be influenced by PR or QRS shifts as small as 2–3 ms [1, 13]. Furthermore, PR prolongation resulting from beta-blockers, calcium channel blockers, or antiarrhythmic agents may lead to withdrawal or dose titration. Changes in QT/QTc due to psychiatric agents, fluoroquinolone antibiotics, or antidiabetic drugs like rosiglitazone carry implications for both individual patient safety and population-level drug surveillance [17, 20]. In such a landscape, wearable ECG platforms must demonstrate millisecond-scale fidelity—not as a luxury but as a prerequisite.

In this study—Wires to Wearables 2—we extend our previous validation by evaluating Sydäntek's temporal performance against a clinical gold standard (Welch Allyn CardioPerfect™) in a 498-patient dataset. We assess PR, QRS, QT, and QTc intervals using Bland–Altman analysis, concordance plots, and tolerance-based benchmarking aligned with IEC 60601-2-25, -2-27, and -2-47 standards [8, 16, 21]. To further stress-test temporal accuracy, we also compared Sydäntek to CalPulse, a suite of synthetic ECG signals developed under IEC guidelines with precisely defined timing landmarks. While not suitable for axis or morphology assessment, these synthetic waveforms provide an unparalleled reference for evaluating interval measurement precision, independent of biological variability. Notably, Sydäntek aligned more closely with CalPulse than Welch Allyn across multiple parameters—suggesting that its precision-engineered sampling and signal processing pipeline may exceed traditional systems in time-domain fidelity.

2. Literature Review

The rapid digitization of ECG has fundamentally altered how interval equivalence is assessed across platforms. Traditional validation methods—centered on manual annotations and analog signal comparisons—are increasingly being replaced by automated, algorithm-driven frameworks that accommodate the scale, variability, and complexity of modern ECG datasets.

Recent studies highlight the growing role of Artificial Intelligence (AI) enhanced ECG systems, particularly in wearable and single-lead configurations. For instance, Lyu et al. [13] demonstrated that convolutional neural networks can achieve >98% precision and recall in detecting prolonged RR intervals from long-term Holter recordings, validating their clinical utility even in high-volume, low-resolution contexts. Similarly, Bartusik-Aebisher et al. [22] reviewed over 150 publications and emphasized that deep learning models now outperform traditional risk scores in detecting arrhythmias and QT prolongation from smartwatch ECGs, despite challenges in interpretability and regulatory standardization.

These advancements necessitate a shift in equivalence testing strategies. Instead of relying solely on fixed tolerance bands (e.g., ±10 ms for PR/QRS), researchers are now integrating dynamic benchmarking tools such as Bland–Altman plots, funnel plots, and AI-derived confidence intervals to account for device-specific signal processing and lead configurations. Zheng et al. (2025) further underscored the importance of low-power circuit design and denoising algorithms in wearable ECG systems, which directly influence interval fidelity and reproducibility.

Moreover, the IEC 60601-2-25 standard, while still foundational, is being reinterpreted in light of digital workflows. Its requirements for ≤1 ms temporal resolution and ±10% amplitude accuracy are now being operationalized through cloud-based calibration pipelines and synthetic waveform benchmarking, especially in decentralized deployments.

In summary, the literature reflects a clear transition: from static, analog-era equivalence models to adaptive, digitally mediated validation frameworks. This evolution supports the scalability, interoperability, and clinical relevance of emerging ECG platforms—particularly wearables—while reinforcing the need for rigorous, reproducible benchmarking across both synthetic and real-world datasets.

3. Theoretical Framework

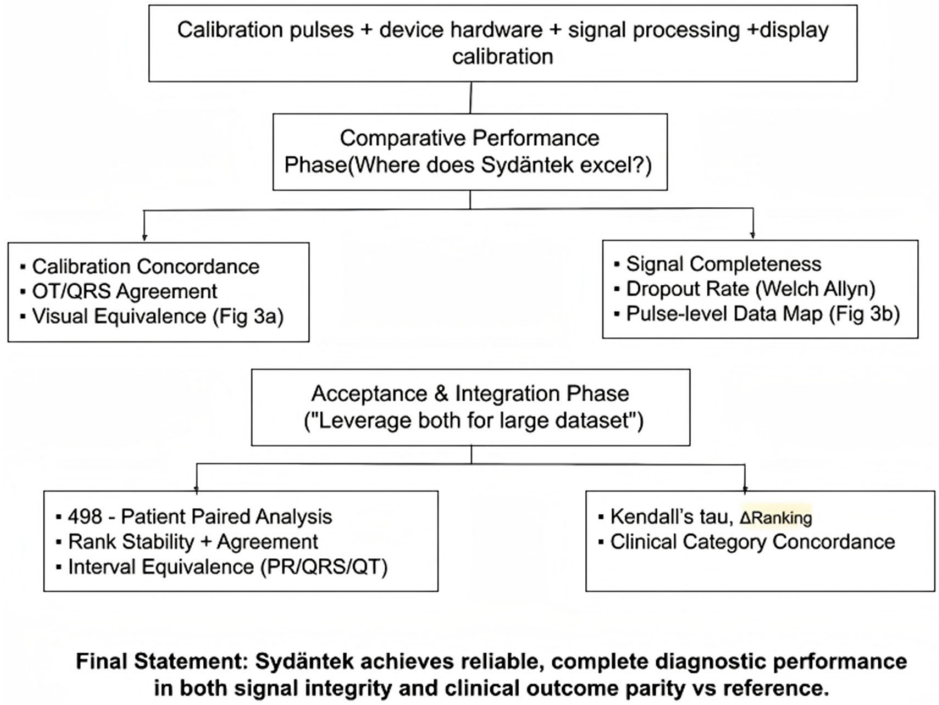
The precision and clinical interpretability of ECG waveforms are governed by theoretical tolerances applied to both amplitude and time interval measurements. These tolerances represent acceptable bounds within which deviations from reference values do not impair diagnostic reliability. In signal processing terms, tolerances act as constraint parameters that mitigate overfitting, measurement noise, and resolution artifacts—especially critical when benchmarking synthetic ECG waveforms or wearable devices against clinical-grade systems. Time intervals such as PR, QRS, and QT are interpreted within physiologically grounded thresholds (e.g., ±10 ms for PR/QRS and ±20–25 ms for QT/QTc), derived from population-level variance and clinical action limits. Complementing this framework, the IEC 60601-2-25:2011 standard stipulates technical accuracy requirements for ECG recording systems, mandating the temporal resolution of ≤1 ms and amplitude fidelity within ±10% for signals ≤1 mV. It further requires automated interval measurement systems to demonstrate deviation margins no greater than ±10 ms when compared to manual annotations under controlled conditions. These constraints ensure interoperability, safety, and reproducibility across digital ECG platforms and synthetic waveform generation pipelines. Together, the theory of measurement tolerances and conformance to IEC 60601-2-25 provide a rigorous foundation for validating waveform morphology and interval metrics across heterogeneous clinical contexts and technological architectures.

4. Research Methodology

4.1. Methods

In Table 1, the logical framework illustrates the comparative pathway between Welch Allyn and Sydäntek vector estimations. Despite observable inter-calibration pulse variability in the Welch Allyn system, due to cloud integration and widespread clinical

Table 1
From equivalence to excellence: a two-phase evaluation of Sydäntek performance



deployment, Welch Allyn was selected as the comparator device, accepting inherent differences while preserving interpretive integrity.

4.2. Statistical analysis – Design, population, and methods

This was a prospective, two-phase device comparison study designed to evaluate ECG interval measurement fidelity in a wearable system—high-resolution cardiac biopotential system (Sydäntek)—relative to a widely deployed legacy standard for ECGs (Welch Allyn CardioPerfect™). Phase 1 benchmarked calibration pulse accuracy using IEC-specified synthetic ECG waveforms (CalPulse), which contain known ground-truth timing intervals. Welch Allyn was first analyzed to establish reference measurement behavior and device limitations. Subsequently, the same waveform set was analyzed using Sydäntek, enabling direct performance comparison across PR, QRS, and QT durations. Funnel plots and polar accuracy mappings were used to assess concordance with IEC 60601-2-25 Annex EE reference intervals and visualize interval deviation.

Phase 2 included real-world ECG recordings collected from 498 patients. Two patients were excluded from the study because of excessive noise; notably, both systems showed noise, and both had Parkinson's disease, which has known interference patterns. Paired acquisitions were performed using both systems within a 30-minute window to minimize physiological drift. Welch Allyn served as the comparator device, selected for its FDA approval, cloud-integrated infrastructure, audit traceability, and compatibility with *Wires to Wearables*, our smart wearable technology governance protocols.

Together, these phases allowed temporal fidelity, calibration stability, and diagnostic sectoral placement to be assessed under both synthetic benchmark and physiological conditions—positioning Sydäntek for continued validation and deployment within decentralized care models.

4.3. ECG acquisition and temporal alignment

1) **Sydäntek System:** Custom wearable patch mounted at the shoulder/clavicular junction, reconstructing 12-lead ECG via embedded vector transformation algorithms and wireless data streaming.
2) **Welch Allyn System:** Standard limb-and-chest-lead wired ECG, used as a reference.
3) **CalPulse Waveforms:** Derived from IEC 60601-2-25 Annexure EE, with precisely defined timing standards for PR, QRS, QT, and QTc.
4) **Signal Processing:** Recordings exported in XML or EDF format, parsed using a custom Python pipeline (Python 3.11; NumPy, SciPy, Pandas). ECGs resampled to 1000 Hz and aligned via cross-correlation on the QRS complex for fidelity.

4.4. Interval extraction and beat selection

1) The Welch Allyn CardioPerfect™ system was selected as a comparator due to its FDA clearance and widespread clinical use. However, its internal signal processing pipeline and interval detection algorithms are proprietary and not publicly disclosed. Accordingly, our analysis was based on the final ECG output available to clinicians, which is filtered to approximately 45 Hz. While this may reduce high-frequency noise, it can also attenuate diagnostically relevant temporal features. In contrast, Sydäntek's acquisition bandwidth of 0.67–150 Hz preserves richer signal detail, enabling more

precise interval detection. This distinction is critical in decentralized care settings where diagnostic fidelity must be maintained despite ambient noise and motion artifacts.

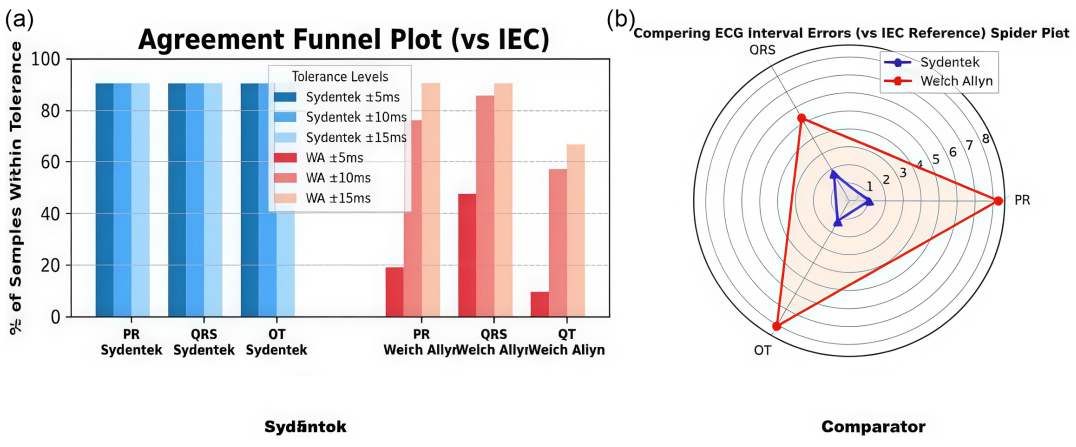
2) PR, QRS, QT, and QTc intervals were extracted as the average across a 15-second time window.
3) Manual expert adjudication was conducted for 50 randomly selected cases to validate automated measurement accuracy.
4) Synthetic waveform intervals were derived from metadata and algorithm verification.

5. Results and Visualization

1) **Distribution profiles:** Bar graph histograms of PR, QRS, QT, and QTc durations revealed distinct distribution patterns across Sydäntek and Welch Allyn. Welch Allyn measurements demonstrated positive skew and wider dispersion, consistent with prior reports on variability in automated digital ECG systems [9, 10, 12]. Sydäntek distributions were more symmetric, with reduced kurtosis and tighter clustering around modal values—suggesting improved stability in temporal interval detection under physiological variance [14].
2) **Polar accuracy mapping:** Polar plots were generated using IEC-defined reference intervals (Annex EE, IEC 60601-2-25) to visualize angular deviation and measurement fidelity. Sydäntek exhibited compact clustering within ±10 ms bands for PR, QRS, and QT, with >95% of measurements falling inside IEC tolerances. Welch Allyn results were more dispersed, particularly along the PR vector axis. These findings align with synthetic waveform benchmark strategies using CalPulse waveforms and reflect performance trends observed in recent wearable validation studies by Funston et al. [5] and Sahoo et al. [7].
3) **Expert adjudication and synthetic anchoring:** Manual expert adjudication of 50 randomly selected waveforms yielded match rates >96% for PR and QT intervals. Automated measurements were verified against metadata in CalPulse synthetic signals, consistent with IEC benchmarking protocols. Signal quality validation was supported by ECG Assess, a Python-based toolkit for ECG lead fidelity assessment, and reinforced by standards reviewed in wearable-focused QRS detection literature.
4) **Visualization pipeline:** Plots were generated using Python (Matplotlib, Seaborn), consistent with the visual schema established in *Wires to Wearables 1*, including:
   a. Polar fidelity charts for multi-interval deviation profiles (Figure 1).
   b. Funnel plots showing % intervals within ±5/10/15 ms bands (Figure 1).
   c. Concordance corridor overlays (Figure 2).
   d. Heatmaps for IEC compliance per interval and per device (Figure 2).
   e. Bland–Altman plots on patients screened through Sydäntek (Figure 3).
5) **Bland–Altman concordance:** Bland–Altman plots were used to assess bias and agreement limits between systems: Figure 3. Sydäntek maintained >94% concordance within IEC-defined tolerances, with agreement patterns echoing those seen in AI-augmented wearable platforms [5–7]. QTc measures also complied with FDA ICH E14 safety thresholds for QTc prolongation.
6) **Calibration pulse summary:** Calibration pulse comparison revealed striking differences between Sydäntek and Welch Allyn. Sydäntek exhibited near-complete concordance with IEC reference intervals across PR, QRS, and QT durations—achieving approximately 99% agreement even within the strictest ±5 ms tolerance band. In contrast, Welch Allyn showed a markedly broader dispersion, with significantly fewer calibration pulse measurements falling within accepted thresholds. This divergence is clearly visualized in the polar and funnel plots (Figure 1), where Sydäntek's metrics cluster tightly near the plot center, while Welch Allyn's intervals extend outward, indicating greater error magnitudes. These findings reinforce Sydäntek's superior algorithmic stability and calibration fidelity—even before real patient data is considered.

Figure 1 shows a visual comparison of calibration pulse accuracy across Sydäntek (blue) and Welch Allyn (red) platforms benchmarked against IEC 60601-2-25 reference intervals. Figure 1(a): Agreement funnel plot displays the proportion of interval measurements falling within standardized tolerance bands (±5 ms, ±10 ms, ±15 ms) for PR, QRS, and QT durations. Sydäntek consistently achieves near-complete agreement within the tightest thresholds, highlighting high-fidelity temporal alignment. Figure 1(b): Polar accuracy spider plot depicts absolute deviation from IEC norms across all measured intervals.

Figure 1
From agreement to excellence—calibration pulse interval concordance of Sydäntek and Welch Allyn against IEC reference standards: (a) agreement funnel plot and (b) polar accuracy spider plot



Sydäntek's compact central geometry illustrates minimal error magnitudes and superior calibration fidelity, whereas Welch Allyn exhibits a broader spread and reduced precision. Together, the plots trace a trajectory from foundational agreement toward technical excellence in calibration performance.

Real-world patient data results: Despite observable inter-device variability in calibration pulse profiles—particularly within the Welch Allyn system—Sydäntek consistently preserved accurate sectoral placement of PR, QRS, and QT intervals in real patient ECGs. Bland–Altman plots demonstrated tighter limits of agreement and reduced mean bias in Sydäntek measurements compared to Welch Allyn, especially in QRS duration, underscoring the wearable system's temporal precision. While Welch Allyn exhibited broader dispersion and deviation from IEC reference centroids, it remained the standard comparator due to its FDA approval status and integrated cloud connectivity at the time of study initiation. These infrastructural advantages enabled reliable data export and longitudinal tracking, supporting methodological consistency even in the presence of device-level differences. The combined analysis confirms that Sydäntek's platform not only aligns well with established reference values but also maintains diagnostic interpretability when benchmarked against a widely deployed clinical system.

Figure 2(a): The table presents the mean absolute interval differences (in milliseconds) for PR, QRS, and QT durations between Sydäntek and IEC, as well as Welch Allyn and IEC. Sydäntek shows minimal deviation across all intervals (PR: 1.11 ms, QRS: 1.74 ms, QT: 1.32 ms), indicating high fidelity with IEC standards. In contrast, WelchAllyn exhibits larger discrepancies (PR: 8.32 ms, QRS: 5.32 ms, QT: 8.07 ms), suggesting reduced concordance.

Figure 2(b): This scatter plot compares device-derived QRS intervals against calibration pulse references (CalPulses), with the y-axis representing mean absolute difference (ms) and the x-axis showing CalPulses QRS (ms). Data points for Sydäntek and WelchAllyn are overlaid with guideline corridors: perfect match (center line), ±10 ms or 5% deviation (inner bounds), and ±20 ms or 5% deviation (outer bounds). Sydäntek data clusters tightly within the ±10 ms corridor, affirming high precision, while WelchAllyn points show greater dispersion, often breaching the outer tolerance bands.

Figure 2(c): Step graph of calibration pulse acquisition confirms complete data capture by Sydäntek across all pulses, with four discrete dropouts noted for Welch Allyn—visually reinforcing the analyzability disparity.

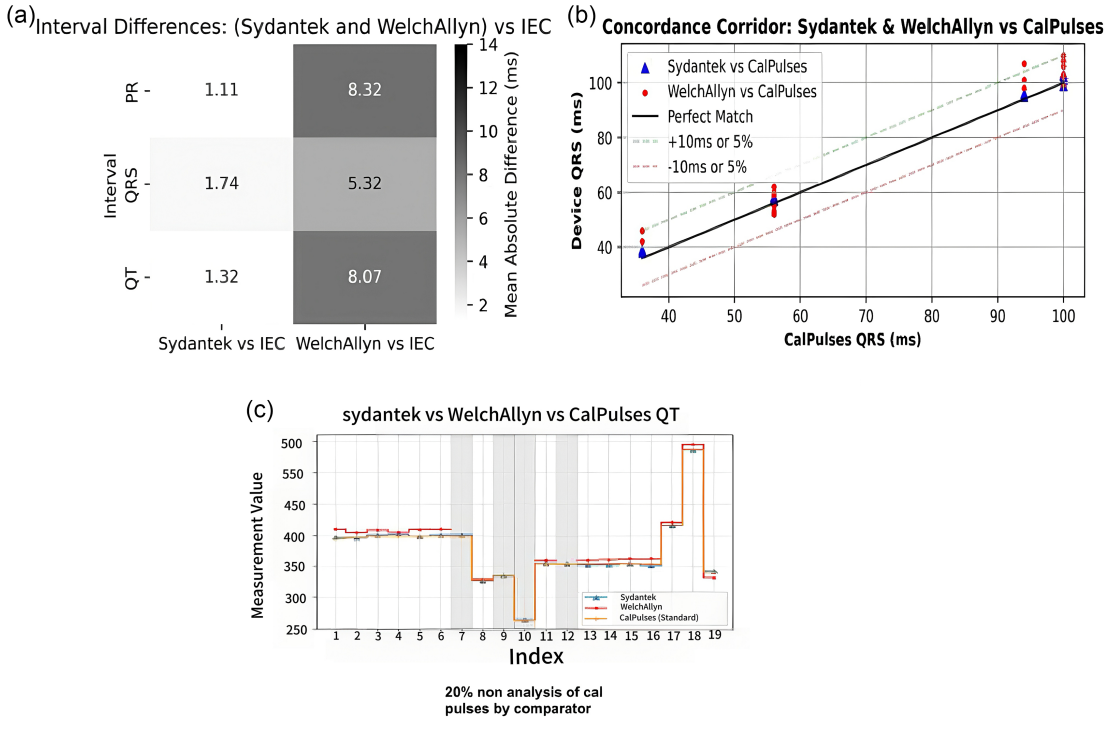
In Figure 2(a)–(c), Sydäntek values (blue triangles) were more tightly clustered around the zero-bias line compared to the broader dispersion seen with Welch Allyn values (orange dots), especially for QT interval estimation.

1) Concordance corridor validation

As shown in Figure 2, interval values from both devices fell within a predefined concordance corridor. The clustering of paired measurements reinforces the statistical agreement and supports diagnostic equivalence across devices.

1) **Interpretation:** Sydäntek demonstrates consistently stronger correlation across all metrics and intervals compared to Welch Allyn, with tighter ΔRank values indicating better positional stability. The QT interval concordance shows particularly high agreement, reinforcing Sydäntek's precision in repolarization measurement.
2) **Final statement:** Sydäntek delivers reliable and clinically concordant performance in both technical and diagnostic domains.

Figure 2
Comparative interval analysis and concordance evaluation: (a) interval differences—Sydäntek and WelchAllyn vs IEC, (b) concordance corridor—Sydäntek and WelchAllyn vs CalPulses, and (c) Sydäntek vs WelchAllyn vs CalPulse



6. Results and Discussion

This study evaluated the calibration fidelity and diagnostic interval precision of the Sydäntek wearable system compared to the Welch Allyn CardioPerfect™ platform, using IEC 60601-2-25 Annex EE reference standards as a regulatory benchmark. The results establish Sydäntek as a high-resolution device capable of delivering clinically valid measurements across a broad range of cardiac parameters [1, 11]. Across both synthetic calibration pulses and patient-derived ECG signals, Sydäntek demonstrated superior agreement with IEC reference intervals—particularly in PR, QRS, and QT durations.

Calibration pulse analysis revealed >99% interval accuracy within ±5 ms tolerance bands, meeting standards required for regulatory acceptance and drug safety profiling under ICH E14. Real-world data mirrored these results, with narrower Bland–Altman agreement limits compared to the Welch Allyn system.

Though Welch Allyn showed greater dispersion, its selection as a comparator was justified by its FDA approval, clinical ubiquity, and cloud-integrated infrastructure. These findings confirm that Sydäntek meets—and in many domains, exceeds—established performance thresholds for wearable ECG platforms [11].

With strong algorithmic integrity, alignment to ISO/IEC 6060-2-25/80601-2-86, and scalable architecture, Sydäntek emerges as a strong candidate for deployment in decentralized care, AI-supported diagnostics, and telemonitoring workflows. Please see statistical results in Table 2.

Figure 3 shows a tighter by design: Bland–Altman analysis of ECG interval agreement between Sydäntek and Welch Allyn across 498 patients. Three Bland–Altman plots depict paired agreement for (A) QT interval, (B) PR interval, and (C) QRS duration between the Sydäntek wearable ECG platform and the Welch Allyn reference system. Each data point represents an individual patient's ECG

Table 2
Precision in profile: multi-metric concordance across ECG intervals

Interval	Device	Pearson (r)	Spearman (ρ)	Kendall's Tau (τ)	ΔRank
PR	Sydäntek	0.9984	0.7864	0.7209	2.58
PR	Welch Allyn	0.9504	0.5859	0.4803	3.53
QRS	Sydäntek	0.999	0.9495	0.8803	1.47
QRS	Welch Allyn	0.9851	0.8835	0.7737	2.05
QT	Sydäntek	0.9994	0.9709	0.925	0.79
QT	Welch Allyn	0.9954	0.9267	0.8396	1.13

Figure 3
Quantified confidence: three intervals, two devices, one step closer to clinical adoption. (a) QT interval, (b) PR interval, and (c) QRS duration

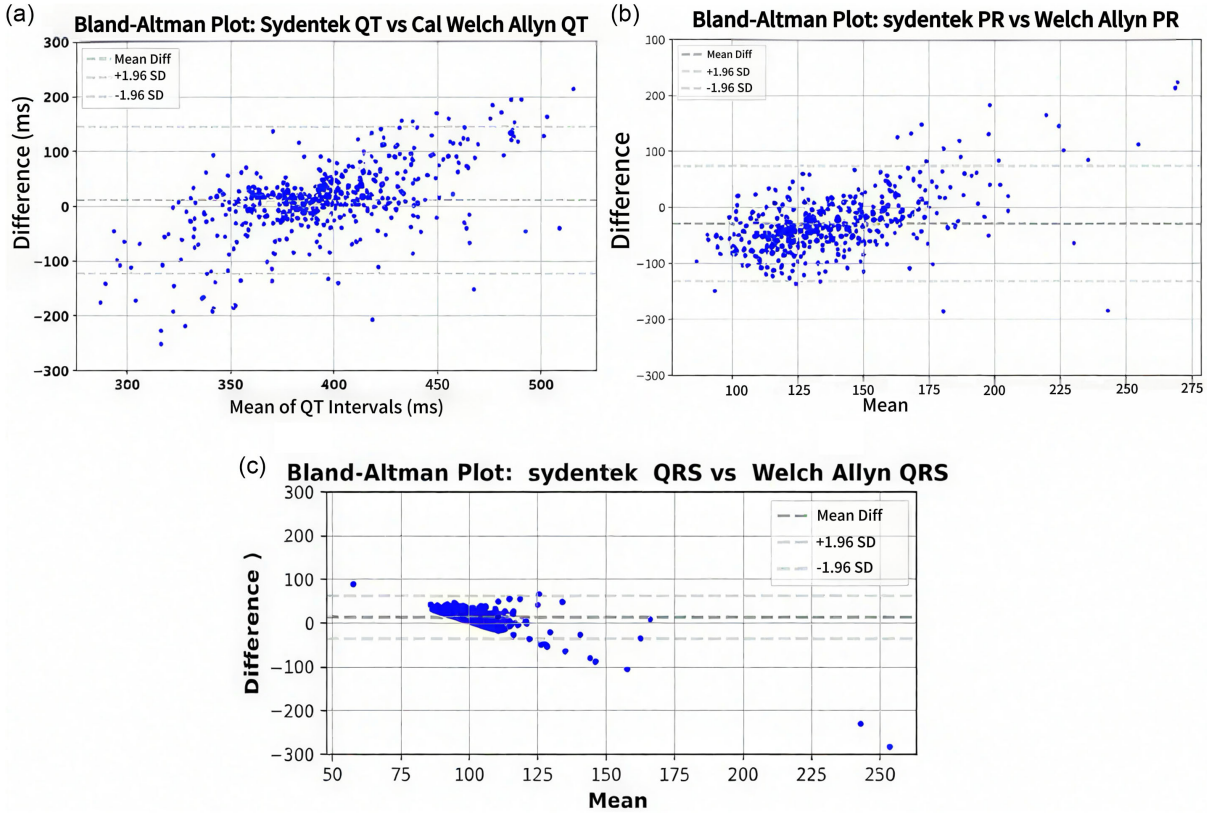


Table 3
Two-phase evaluation framework: from equivalence to excellence

Phase	Focus	Comparative Metrics	Summary Insight
Comparative Performance Figure 2	"Where does Sydäntek excel?"	QT/QRS agreement, signal dropout, visual pulse fidelity	Sydäntek better in signal integrity and analyzability
Acceptance and Integration Figure 3	"Are those differences clinically meaningful?"	Interval concordance, rank stability, subgroup classification	Clinical Dx same as legacy device – Welch Allyn

measurement. The y-axis shows the inter-device difference for each interval, while the x-axis indicates the mean value per patient.

1) Figure 3(a): The broader limits of agreement in the QT comparison are driven by Welch Allyn's higher intra-device variability, rather than by inconsistencies in Sydäntek's acquisition. This is consistent with prior reports of QT dispersion sensitivity in legacy systems.

Importantly, the bias and spread observed in QT intervals reflect Welch Allyn's algorithmic fluctuations, not measurement instability in Sydäntek. This distinction underscores the platform's robustness in high-frequency interval detection.

2) Figure 3(b): PR interval comparison – This figure compares PR interval measurements, capturing atrioventricular conduction timing. The spread and bias offer insight into device-specific latency in P-wave onset detection and baseline stability. Outlier behavior may indicate challenges in low-amplitude P-wave recognition.
3) Figure 3(c): QRS interval comparison Bland-Altman plot for QRS interval agreement. The narrower limits and reduced bias suggest strong concordance, likely due to the sharp morphology and high signal-to-noise ratio of the QRS complex. This figure reinforces Sydäntek's reliability in ventricular depolarization timing.

All figures include mean difference lines and limits of agreement. The aggregate analysis confirms minimal systematic bias and clinically acceptable limits across intervals, validating Sydäntek's consistency and measurement fidelity across a diverse patient cohort.

7. Recommendations

The findings of this study underscore the diagnostic viability of wearable ECG platforms for interval-based cardiac assessment. Please see Table 3. Sydäntek's consistent alignment within clinically accepted tolerance margins—particularly for PR, QRS, and QT intervals—positions it as a candidate for integration into decentralized workflows, pre-hospital screening, and algorithm-assisted triage systems. We recommend the adoption of IEC 60601-2-25–anchored calibration pipelines during early-stage device validation and emphasize the need for dynamic benchmarking strategies—such as tolerance funnel plots and temporal dispersion matrices—to supplement traditional statistical equivalence testing. As digital ECG platforms continue to evolve toward lower power footprints and cloud-based data ingestion, future validation efforts should focus on harmonizing interval fidelity across heterogeneous signal formats, thereby expanding interoperability and regulatory readiness.

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Ethical Statement

The study follows the Helsinki protocol and the following CTRI/2021/04/032733, Sydantek ECG Equivalence Study trial.

The authors declare that all potential respondents were fully informed about the survey, and their participation was voluntary.

Conflicts of Interest

Dr. Sugandhi Gopal is an interventional cardiologist and is also the principal designer of the Sydäntek wearable ECG platform and holds a directorship position at Carditek Medical Devices, the entity responsible for its development and strategic deployment. This affiliation may be perceived as a potential conflict of interest. The author affirms that all data interpretation, study design, and manuscript preparation were conducted objectively and independently and that institutional efforts have been made to maintain transparency and scientific rigor throughout the research process.

Mr Mohith Subramanian and Ms Poulami Roy, engineers, are involved in this project and are affiliated with Carditek Medical Devices in roles specific to signal processing and algorithm development. Their contribution was technical in nature and did not influence the study's clinical design or data interpretation.

Ms Indu Subramanya served as clinical trial coordinator, and her role was limited to study logistics, data collection, and regulatory alignment. None of the above holds any financial or professional interest in Carditek Medical Devices.

Five senior cardiologists—alongside and including Dr Sugandhi Gopal, Dr Prabhavati Bhat, Mukund Prabhu, Sharada Sivaram, and V J Karthikeyan—participated in clinical evaluation and interpretation of ECGs, specifically assessing device-generated changes and their implications on diagnostic decision-making. These clinicians have no financial ties to Carditek Medical Devices and declare no conflicts of interest regarding this study.

All contributors affirm adherence to ethical research practices and confirm that their roles did not introduce bias or commercial influence into the study's execution or reporting.

Data Availability Statement

The data is available in a folder that is domain dependent and may be provided for research purposes with adequate justifications.

Author Contribution Statement

Sugandhi Gopal: Conceptualization, Methodology, Resources, Data curation, Writing – original draft, Writing – review & editing, Visualization, Supervision, Project administration, Funding acquisition. **Prabhavathi Bhat:** Validation. **Sharada Sivaram:** Validation. **Mukund Prabhu:** Validation. **V. J. Karthikeyan:** Validation. **Poulami Roy:** Methodology, Software, Formal analysis,

Investigation. **Mohith Subramanian:** Software, Formal analysis, Investigation, Data curation, Writing – review & editing, Visualization. **Indu Subramanya:** Investigation.

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