Review of cloud computing services for analysis and reporting of ECG-related data

VitalSignum Oy

Group 9

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Introduction

Electrocardiograms (ECGs) have been a key diagnostic tool in cardiac care for over a century and are critical for monitoring and assessing heart function. According to World Health Organization (2021), cardiovascular diseases are the leading cause of death worldwide, representing 32% of all deaths globally. Of these, 85% are due to heart attack and stroke. (World Health Organization, 2021) Detecting heart events that predispose, foreshadow, or indicate cardiovascular diseases is, therefore, an essential preventative strategy. Advances in wearable technology and cloud computing are transforming the healthcare sector concerning data collection, analysis, and reporting. (Li et al. 2019; Tahir et al. 2020). Nowadays, cloud computing for the analysis of the electrocardiogram (ECG) data enables real-time and remote cardiac monitoring, leading to cost and time savings in health care through diminished need for visits to the health care facility and early detection and intervention of heart events (VitalSignum n.d; Kamga et al. 2022).

VitalSignum Oy is operating within the trend of integrating wearable technology and cloud-computing analysis, developing easy-to-use solutions and services for remote cardiac health monitoring. Their product Beat2Phone ECG is a wireless wearable medical-grade sensor that can be used to measure both short- and long-term 1-lead ECG signals. The device is paired with a phone application used by the patient, and the application can also be connected to a cloud service used by healthcare professionals. Healthcare professionals have immediate access to the ECG recordings in the VitalSignum cloud and can view and analyze the recordings with the help of an algorithm provided by a cloud computing platform, Cardiolyse Oy. The VitalSignum interface uses anomaly annotations from the cloud computing algorithm provided by Cardiolyse. The VitalSignum service can also generate aggregated reports in their own cloud from multiple ECG reports. (VitalSignum n.d.)

In this report, we will review alternative cloud-based ECG solutions to Cardiolyse by comparing their performance, accessibility, AI/ML integration, and regulatory compliance. The report aims to answer the following research questions:

1. What are the existing cloud computing solutions for ECG data analysis and reporting, beyond the one used by VitalSignum?
2. How do these solutions compare to each other? What are the associated challenges and benefits?
3. Could AI-driven solutions enhance the accuracy, speed, or efficiency of these cloud-based ECG analysis services?

State-of-the-art review

The potential benefits of AI in cardiology are vast, including improved diagnostic accuracy, risk prediction, and treatment outcomes. ECG analysis is the most developed application of machine learning (ML) methods in cardiology, owing mostly to publicly available databases for training and testing. (Itchhaporia 2022). However, wearable data differs from the clinical standardized measurements, mainly because of the noise arising from factors such as poor electrode contact with the skin, movement and muscle contraction during the ECG, and external electrical interference. Utilizing AI-based interpretation and screening of data obtained from wearable devices is mainly hindered by these artefacts in the ECG signal and lack of labelled datasets of wearable ECGs. (Khunte et al. 2023). AI models and algorithms most commonly rely on the I-lead signal of clinical 12-lead ECG measurements as signal from 1-lead wearable devices simulate this lead the most (Duarte 2019). The 12-lead standardized clinical measurements, by nature, are not demonstrative of measuring artefacts. Therefore, noise-adaptive AI solutions for ECG interpretation are a point of interest in this report.

A few novel applications of utilizing AI in wearable ECG analysis include detection of conditions not derived from but manifested in the heart such as hypoglycemic events, training tailored AI models for individuals and predicting cardiac events before they occur. Convolutional neural network (CNN) and recurrent neural network (RNN) models together have been shown to reliably be able to detect hypoglycemia from 200 heartbeats extracted from a 5-minute wearable night-time ECG recording, based on heartbeat morphology and beat sequences (Porumb et al. 2020). Recently, AI has been successfully shown to predict atrial fibrillation, which can predispose to a stroke, 30 minutes before the onset of this arrythmia (Gavidia et al. 2024). To account for interpatient heterogeneity of ECG signals, a generic and simple CNN model has been proposed already in 2016 to train AI for an individual with their own patient-specific data, allowing for tailored, highly accurate and very fast detection of even subtle changes in their ECG. The CNN solution could learn to extract patient-specific features and was trained on the patient’s own data rather than large complex datasets. The proposed solution was shown to surpass many state-of-the-art methods in both efficiency and accuracy. (Kiranyaz et al. 2016). We hypothesize that even today, the use of this kind of a ‘precision medicine’ AI solution faces issues with high cost, high resource needs, and data collection, all of which hinder the up-scaling possibilities and generalization of personal AI models.

The novel applications mentioned above have not yet been adapted to commercial cloud-based ECG analysis services as extensive work for optimization, clinical validation and generalization needs to be done. We think that in the future, if regulatory compliance is achieved, the predictive capabilities combined with personalized AI models will be valuable in wearable ECG technology, where continuous data collection over extended periods allows AI to analyze trends and patterns in an individual’s ECG signal. This would enhance personalized healthcare and also facilitate timely alerts to healthcare providers, enabling early interventions in cardiac care.

Key standards guiding the analysis of patient data in a cloud computing environment include ISO 27799:2016 together with ISO/IEC 27002, providing healthcare-specific protocols for information security, cybersecurity and privacy protection. A CE mark indicates the product conforms to all relevant European Medical Device Regulation requirements and as such is required to place a device on the market in the EU. The General Data Protection Regulation (GDPR) is another framework governing the collection, storage, and handling of patient data. GDPR emphasizes patient consent, data minimization, and the right to data access and deletion. All of these standards and regulations directly influence the practices used to ensure privacy and security while working with third-party cloud computing services and patient data.

Method and solution architecture

Methods

This section outlines the approach and process adapted for conducting this review.

Initially, an interview was conducted with the company, VitalSignum Oy, to understand their needs for their cloud computing platform and current status. After the needs were identified, we proceeded to identify similar cloud computing platforms that are available for remote ECG monitoring. Publicly available data such as reports, websites, user manuals, patents, legal documents and short articles were utilized to identify and analyze cloud-based platforms for ECG analytics. Moreover, different platforms were contacted via email to collect more information about their technical specifications, performance, certifications, pricing and security measures.

The platform's availability for ECG monitoring, compliance with European Union (EU) regulations, amount of information available, compatibility with I-lead ECG and device agnosticism served as the inclusion criteria for this review.

We were able to identify 11 cloud computing platforms for remote ECG monitoring. Out of these, 6 were discarded for not fulfilling our inclusion criteria. Some other reasons that prevented their inclusion are addressed in the results. After the identification, the platforms were evaluated in the following aspects: data storage, performance, cost-effectiveness, scalability, user accessibility and interface, integration with artificial intelligence (AI) or machine learning (ML), and regulatory compliance.

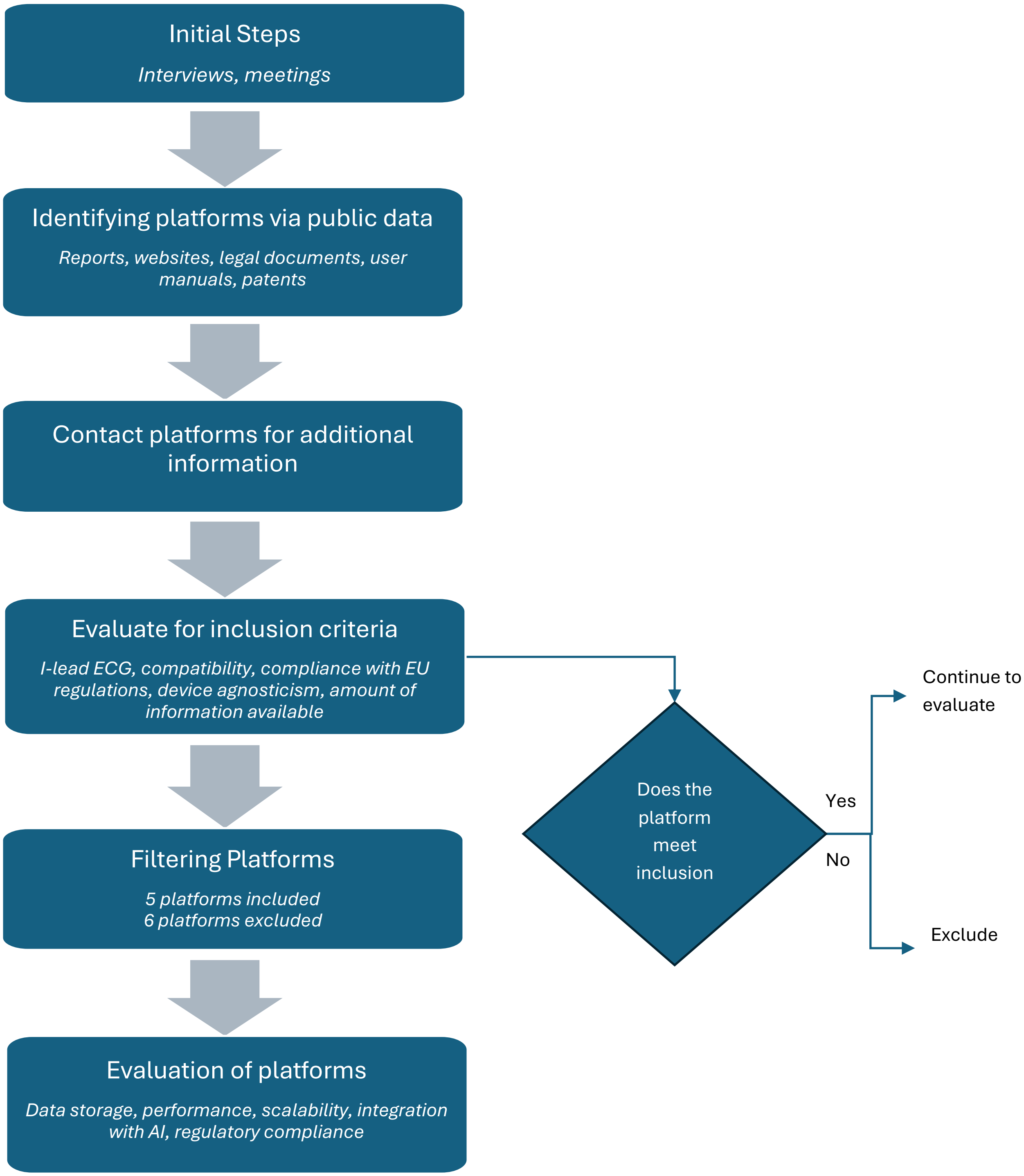

Figure 1. *Process to conduct the review.*

Key standards

Implementing a cloud-based ECG data processing and reporting system requires strict compliance with healthcare IT standards. This is required to assure interoperability, data security, and regulatory compliance requirements. These standards may be categorized based on their primary functions: interoperability and data interchange, data security and privacy, medical device compliance, and AI governance and ethics. Therefore, these standards address the technological, security, and regulatory requirements for managing sensitive ECG data across healthcare systems. These requirements demonstrated below can be incorporated into the system's architecture (Figure 2.) to provide consistent data transit, secure storage, easy analysis, and regulatory compliance.

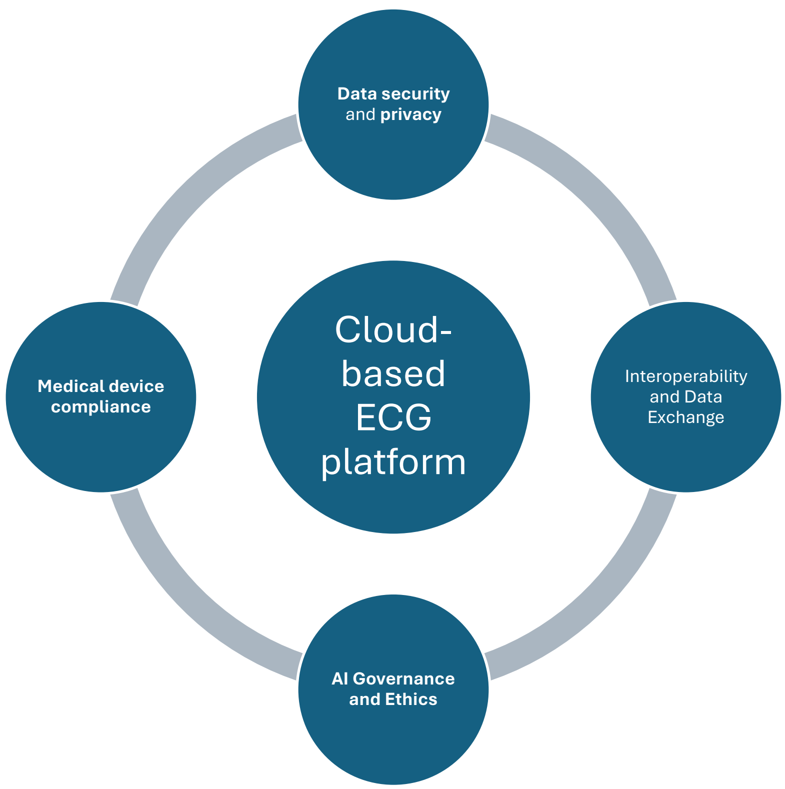

Figure 2. *Key components of an ECG cloud computing platform*

Interoperability and Data Exchange

Interoperability is a key component of healthcare information systems, allowing seamless exchange and comprehension of data across devices and platforms. The following standards are crucial to address issues related to data transfer and interoperability in a cloud-based ECG system:

1. **Health Level Seven (HL7):**

HL7 establishes standardized frameworks for the exchange, retrieval, integration and sharing of medical data. In a cloud-based ECG system, HL7 facilitates precise analysis and efficient workflows through the structured transmission of data from ECG devices to cloud platforms and electronic health records (EHRs).

2. **Fast Healthcare Interoperability Resources (FHIR):**

FHIR is another HL7 standard that is designed for web-based healthcare applications and offers a RESTful approach to data exchange. FHIR facilitates the organization of ECG data and metadata, enabling efficient retrieval and display through APIs, particularly for web and mobile applications.

3. **Digital Imaging and Communications in Medicine (DICOM):**

DICOM is known for its specialty in the processing, storage, and transmission of medical waveforms and images, including ECG data. To maintain compatibility with a variety of analysis tools and storage systems inside the cloud architecture, DICOM ensures that waveform data is stored in a standardized, interoperable format.

4. **ISO/IEEE 11073-10406:**

ISO/IEEE 11073-10406 establishes interoperability standards for ECG devices, especially their communication protocols. The standard ensures consistent acquisition, formatting, and transmission of data, facilitating seamless integration of ECG devices with cloud-based infrastructures. Additionally, it offers standardized data interchange that adheres to safety criteria, aligning with broader compliance objectives for the functionality and interoperability of medical devices.

Data security and privacy

Due to the sensitivity of patients' ECG data, strict security and privacy measures are essential to mitigate threats including data breaches, unauthorized access, and information misuse. The following standards establish robust foundations for the protection of this type of data:

1. **ISO/IEC 27001 along with ISO 27799:2016 and ISO/IEC 27002**

ISO/IEC 27001 functions as a fundamental security standard by offering guidelines for the establishment, implementation, maintenance, and ongoing enhancement of an information security management system (ISMS). It is particularly critical in healthcare as it protects sensitive patient data, including ECG records. ISO/IEC 27001 establishes key requirements for data encryption, access controls, and audit traces, ensuring the security of ECG data during transmission and storage in the cloud. These standards, in conjunction with ISO 27799:2016 and ISO/IEC 27002, which offer healthcare-specific and general information security controls, collaborate to provide a secure environment that reduces the risks associated with data loss, data breaches, and unauthorized access. The architecture guarantees that only authorized personnel have the ability to access or modify patient ECG data by setting up encryption protocols and robust access control mechanisms.

2. **The General Data Protection Regulation (GDPR)**

With a focus on patient permission, data minimization, and the right to access and erase personal information, GDPR regulates how personal data is managed inside the EU. GDPR compliance guarantees patient sovereignty over data in cloud-based ECG systems while requiring responsibility and openness in data processing procedures.

Medical device compliance

1. **IEC 62304**

IEC 62304 establishes the lifetimes for software used in medical devices. This framework offers a systematic approach for the development, testing, and risk management of software utilized in cloud-based services and ECG devices, ensuring performance and safety.

2. The CE Mark

A CE mark certifies that a medical device complies with the safety, health, and environmental standards established by the European Union (EU). For cloud-based ECG solution, acquiring a CE certification validates compliance with the European Medical Device Regulations (MDR), thereby allowing legal distribution and utilization of the solution within the EU.

AI Governance and Ethics

Ethical and regulatory challenges must be addressed when AI is implemented in healthcare solutions. For AI applications in healthcare, the EU Artificial Intelligence Act proposes guidelines for ethical and safe use of AI. Within this act, healthcare AI is classified as a high-risk use case. The act emphasizes transparency, data quality, and machine learning bias prevention, ensuring that AI algorithms in patient care remain reliable and interpretable.

Security requirements

In a cloud-based ECG data solution that handles sensitive health information, the effective execution of security protocols is crucial. Therefore, the system must adapt its functionality to meet the needs of healthcare professionals and patients, enabling efficient connections with healthcare operations (Nawaz & Ahmed, 2022). The solution addresses security concerns and complies with regulatory standards, thereby safeguarding sensitive data and enhancing clinical processes, which leads to swift and precise decision-making (Meingast et al., 2006). The security requirements outlined below are considered necessary to achieve effective risk protection and regulatory compliance.

1. Protection Against Hardware Failures

To defend against unexpected hardware malfunctions such hard disk failures, the system employs redundant data storage solutions such as cloud-based replication across geographically distributed servers and RAID (Redundant Array of Independent Disks) (Kachhala & Gangarde, 2016). The deployment of disaster recovery systems and frequent backups ensures that in the case of a loss, data is restored quickly. The risks associated with hardware failures are further reduced by using cloud services, which provide built-in fault tolerance and redundancy.

2. **Protection Against Unauthorized Access and Tampering**

According to Evans and Brown (2001), advanced encryption techniques, such as AES-256, are utilized to enable the system to encrypt data at rest to ensure system data security. Multi-factor authentication (MFA) and role-based access control (RBAC) regulate access exclusively for authorized personnel (Fareed & A. Yassin, 2022). For data transit, TLS/SSL is preferred as is a secure communication technology utilized by the system to protect data during transmission (Kumar et al., 2024). Wisnu Uriawan et al. (2024) stated that cryptographic hash systems, such as SHA-256, serve to verify data integrity, thereby preventing data manipulation. Robust firewall systems and secure APIs restrict unauthorized access to communication pathways.

3. **Patients' Right to Access Data**

Chiruvella and Guddati (2021) stated that the right of patients to access their own data is a fundamental factor in selecting the appropriate solution. Apparently, patients can securely access their health data through a user-friendly portal compliant with FHIR. Strict data separation is maintained when patients access their ECG data through the provided login credentials. Compliance with laws (HIPAA, GDPR) ensure that patients' rights to access, modify, and manage their data are fully protected.

4. **Logging and Audit Trails**

For logging and audit trails, user interactions with ECG data are recorded in immutable audit logs that encompass details such as user identity, timestamps, and actions performed. The logs are securely stored and periodically reviewed to detect unauthorized access or suspicious activities (Rule et al., 2019). This measure ensures compliance with the regulatory framework HIPAA and ISO/IEC 27001, which requires audit trails for sensitive data.

5. **Protection Against Ransomware Attacks**

To protect against ransomware attacks, the system employs frequent software updates, endpoint security, and advanced network monitoring tools to mitigate ransomware threats by identifying and preventing malicious activities. Encrypted backups are maintained in different environments in order to ensure data recovery in the case of a ransomware attack. Moreover, threat detection mechanisms are used to observe unusual access patterns and isolate systems upon the identification of anomalies (CISA, 2020).

6. **Long-Term Preservation of Health Information**

Health records need to be stored in standardized formats (HL7, DICOM) to guarantee extended preservation requirements, ensuring long-term interoperability and accessibility. A data migration strategy has been developed to enable the transfer of archived records to new platforms in response to technological advances. Additionally, ensuring safe and secure support of data throughout the product's life cycle needs to be considered (Corn, 2009).

Results

This section includes our findings of the current landscape of cloud computing platforms that facilitate remote ECG monitoring. The full list of parameters for which information was gathered for all of the companies included key regulatory elements (CE, MDR, GDPR), standards (ISO), device agnosticism, suitability for 1-lead ECG signal processing, type of analysis (algorithm/AI/Human), turn-around time and mode of reporting (continuous stream or batch analysis), scalability, paying scheme, number of reported anomalies and diagnostic performance metrics, risk scoring as an output, proof of diverse validation cohorts, EHR integration, and viability for Business to Business commerce transaction (B2B).

The compared solutions are presented in this section as a concise description of each solution that was found to be a possible cloud computing platform service provider for VitalSignum. The results also emphasize any possible unique features or characteristics as well as their limitations.

Cardiolyse (current service provider):

Our review will start with analyzing Cardiolyse as this is the cloud computing platform for remote cardiac monitoring currently utilized by Vital Signum Oy. It is mainly located in Finland but provides global B2B software as a service (SaaS) solution. They store data on CE certified cloud platform (any other ISO required?), analyze and interprets ECG data with at least 148 ECG parameters including heart rate variability (HRV), detect 20 types of arrhythmias, atrial fibrillation, myocardial infarction, ischemia, ventricular hypertrophy, provide cardiac risk scores and prognosis for up to two months for critical cardiac events using a traffic light system, all while using their innovative machine learning algorithm. The cloud-based algorithm also detects extra beats, conduction times, conduction disorders, and stress index. Cardiolyse can integrate data from various sources such as ECG devices (device-agnostic) and smartwatches indicating its interoperability. There is no evidence of the accuracy or performance level of the platform. However, their patent (Methods of ECG evaluation based on universal scoring system, US10512412B2) suggests that their method of analysis increases the accuracy of the reported outcomes.

Willem™ by Idoven AI:

The Madrid-based Idoven AI offers a robust ECG analysis platform called Willem™ designed for healthcare providers, featuring MDR, GDPR and CE compliance and adherence to ISO standards (27001, 27017, 27018, and 27701, 13485). The platform is device-agnostic and supports 1-lead ECGs. It uses machine learning analysis algorithms to provide predictive and diagnostic insights, with a current sensitivity and specificity of 97% and global accuracy of 95%. The service delivers batch analysis with scalable cloud infrastructure and promises the ability to integrate with EHRs. According to Quartieri et al. (2023) Idoven's models appear to be validated with diverse and inclusive global cohorts for both healthy and diagnosed patients, with 1 234 207 hours of ECG data and 47 035 patients. In addition, Idoven AI is able to provide 85 output classes within 22 cardiac patterns and 4 intervals (eg. QT-interval) (Quartieri et al. 2023, Idoven 2024). They offer risk scoring and are developing more predictive capabilities, notably with models aimed at forecasting atrial fibrillation risk within a six-month timeframe. With its high accuracy (95% globally) and real-time capabilities, Idoven supports B2B solutions for continuous ECG monitoring and risk prediction.

Willem™ is also used in initiatives like the ASSIST project consortium and the FAITHFUL consortium, both of which focus on advancing cardiovascular care. In the ASSIST Consortium focuses on improving triage and diagnosis of acute coronary syndromes, including STEMI and NSTEMI. The FAITHFUL Consortium leverages Willem to enhance early detection of heart failure in primary care, aiming to improve patient outcomes and reduce hospitalizations by up to 40%. The participation of Willem™ in these kinds of collaborations demonstrates trust within the cardiac care community. Other consortiums where Willem™ is used include WILLEM, ARISTOTELES, MAESTRIA, REDO-FIRM, and UMBRELLA. (Idoven, 2024).

HES® RTM used in COR.Cloud by Corscience:

HES® combined with COR.cloud is a Germany-based ECG analysis platform compliant with MDR, GDPR, and CE standards, demonstrating adherence to high regulatory and privacy standards. It is device-agnostic, supports 1-lead ECG with the HES® RTM algorithm, and offers a scalable Corscience cloud infrastructure. HES® RTM is an algorithm and does not utilize AI or Human assisted analysis. The platform delivers real-time analysis, possibly with a continuous stream analysis, providing a set of 18 output metrics, including 6 beat types, 8 event types, and detailed information on ventricular tachycardia, fibrillation, atrial fibrillation, and R-wave location. The platform is designed for B2B utilization with a pay-per-use pricing model. However, no information was found for algorithm validation cohorts or studies. Specific details on sensitivity, specificity, and accuracy also remain unreported. An interesting feature they claim to provide is signal filtering and noise reduction, although these were not further described. COR.Cloud and HES® solutions for 12-lead ECG analysis were recently adapted by Taiwanese BriteMED operating in the Asia-Pacific region. (HES Hannover ECG System, n.d., Monitoring, n.d.)

Cardiomatics:

Cardiomatics is a Poland-based service providing a scalable cloud platform. The solution complies with MDR, GDPR, and CE standards, ensuring regulatory adherence. No information is publically provided about adherence to ISO standards. Cardiomatics supports B2B applications, and multiple clinics have applied their services in practice. The paying scheme is volume based but contracts are highly negotiable for companies and businesses. The platform claims to be device-agnostic, but compatibility with Beat2Phone would need to be confirmed. One of the key requirements for Beat2Phone remains unanswered, as there is no mention of the data they can analyze; suitability for 1-lead data would be the first thing to confirm with this company.

Cardiomatics uses AI for batch analysis and does not support continuous streaming analysis or real-time processing (minimum of 5 hours turn-around time but is negotiable for enterprises). The output includes at least 26 cardiac patterns and arrhythmias while also providing insights such as the heart rate variability and AFib burden statistics. However, it does not currently include risk scoring. There is no mention of EHR integration. Two case studies are available through their website, along with 2 published peer-reviewed articles, 7 studies and 2 clinical trials on their way, including one with pediatric patients demonstrating strong incentive for more diverse use cases and development. (Krzowski et al. 2022; Cardiomatics - Advanced AI for Fast ECG Interpretation, n.d.)

InstaECG from Tricog:

Tricog is an Indian company which developed InstaECG an artificial intelligence-based ECG analysis web application. InstaECG is a MDR, GDPR and CE compliant which means European country's hospitals, clinics, diagnostic centers, and healthcare professionals can use. InstaECG follows business to business policy for commercialization. There is no available information found about the 1-led ECG support, but InstaECG supports 12-led ECG. Human analysis has been used to process the ECG data besides AI driven analysis. Batch analysis is used rather than continuous stream analysis. EHR integration can be possible by InstaECG. There is also risk scoring available on this platform. Scalability and diverse validation cohort is also offered by the InstaECG. The sensitivity is 95% and specificity is 95.25% found from the InstaECG but the accuracy is not available. ISO 13485:2016 and ISO 27001 standards are followed by InstaECG. A payment scheme is also available from InstaECG of Tricog.

Cardiologs from Philips:

The well-known company Philips offered MDR, GDPR and CE complaint AI based platform Cardiologs. It follows business to business model. So, it provides services to hospitals, clinics, health professionals but not individual people. Cardiologs has device agnostics properties which helps to connect different manufacturer machines. Besides AI analysis, Cardiologs takes consideration of human analysis before presenting the result to its customers. There are no options for real time analysis and continuous stream analysis. EHR integration can be implemented with Cardiologs. It is scalable, which means any size of input data can be analyzed with diverse validation cohorts. The sensitivity, specificity and accuracy for atrial fibrillation are 98%, 91% and 96% - 98% respectively. For ventricular tachycardia, the sensitivity, specificity and accuracy of Cardiologs are 97%, 68% and 97% respectively. The number of reported anomalities of Cardiologs is 14 cardiac arrythmias. Paysing scheme is also available in Cardiologs. It follows standard ISO 13485.

CloudBeat Software from Cardiodiagonostics:

United States of America is the founding location of CardioDiagnostics. It is a cloud-based solution provider. Even though there is no direct information found about the MDR, GDPR and CE compliance but CardioDiagnostics is HIIPA and FDA compliant. The cloud-based software from Cardiodiagonostics is Cloud Beat supports monitoring ECG and creates reports for the user. This scalable software uses human analysis with AI analysis, which makes the report more credible. CloudBeat is a device agnostics software which supports 1-lead ECG. EHR integration can be possible with CloudBeat. It is a sclable software where the user can use any number of patients ECG. The paying scheme is also available for the CloudBeat but there is no information found about the sensitivity, specificity, number of reported anomalies and accuracy.

Excluded platforms

The following cloud computing analysis services for ECG reporting were excluded from further comparison with other solutions. The most usual reasons for exclusion were lack of regulatory compliance relevant in the EU region, lack of ability to process 1-lead ECG data and high customization. They are briefly mentioned or described here in case they make improvements that allow them to be considered valid service providers in the future.

Cardiolearn™ by Heartvoice:

Cardiolearn™ is a China-based ECG analysis solution lacks documented compliance with EU regulatory standards like MDR, GDPR, CE, and ISO (心之声(‘*HeartVoice*’), 2024, [partly Google Translated]), greatly limiting its viability in Europe and resulting in exclusion for further comparison.

PMCardio by PowerfulMedical:

PMCardio looks robust and promising when it comes to published research, ECG analysis output metrics, accuracy, data security and regulatory compliance (Himmelreich & Harskamp 2023; PMcardio: AI-Powered ECG Interpretation n.d.) However, an e-mail reply was received from the company representative where they confirmed they only support 12-lead data, which resulted in the exclusion of PMCardio for further analysis and comparison with other solutions.

AccurECG by AccurKardia:

This platform appeared to be promising due to its characteristics such as device-agnosticism, compatibility with 1-lead ECG and ability to detect 13 different types of arrythmia. The problem arises with its compliance with EU regulations as it is only approved by the Food and Drug Administration (FDA) currently that limits its usage in Europe.

Tempus ECG-AF by Tempus:

Tempus ECG-AF is a US-based platform that analyzes ECG data and detects atrial fibrillation or atrial flutter (AF) in patents. It was found to be compatible with only 12-lead ECG recording. Since it is only approved by FDA, its usage in Europe was unclear.

Amazon Web Health Services:

Services like Amazon SageMaker, Amazon Web Services (AWS) Lambda, AWS Health Analytics, Amazon HealthLake support ECG data including 1-lead ECG. However, high customization and integration of different services are required to achieve the results required for Beat2Phone. Moreover, not all AWS services are available in Europe to be used.

Cardio Diagnostics:

By 2017 Cardio diagnostics was founded (Cardio Diagnostics). This AI driven ECG platform is not compatible with 1-lead ECG. There is no information found about MDR, GDPR and CE compliance of this platform. This platform also works in a business-to-business model. There are also uses of human analysis besides AI analysis. It is also scalable with a prediction model. Cardio Diagnostics offers a pay scheme with 79% sensitivity, 76% specificity and 77.5% accuracy. There is a lack of information about EHR integration, diverse validation cohort following ISO standards and number of reported anomalies. Response is not found from the Cardio Diagnostics for inquiry email.

Discussion

This review was able to highlight a few key platforms that can be considered an alternative to Cardiolyse cloud computing platform. Cardiologs by Phillips, and Willem by Idoven AI emerged as other competitive platforms to incorporate real time ECG monitoring and AI powered analysis. These platforms provide high accuracy, specificity and sensitivity with capabilities to detect diverse cardiac patterns and arrhythmias. However, when comparing with Cardiolyse, they offer less comprehensive long term predictive ECG analysis insights such as lack of detailed risk scoring. For diagnostic precision, Willem is more robust adhering to comprehensive regulatory standards indicating robust privacy and security measures. Additionally, Willem and Cardiologs both excel in large-scale data handling due to its advanced EHR interoperability and batch analysis capabilities, making it ideal for hospital, clinical and research applications. Moreover, Cardiologs also offers human review which means that it does not completely rely on its AI algorithm but includes human validation of the result as a mandatory step in the process.

Other platforms that stood out were HES COR.cloud, that is an algorithm-based analysis software, and Cardiomatics. The former appears to be relatively expensive as it offers pay-per-use services, depending on the scale of usage, while the volume-based prices of the latter offer flexibility for negotiable contracts for businesses. The disadvantage of Cardiomatics is that it does not support real time analysis which can hinder the purpose and objective of Beat2Phone that is to provide continuous monitoring, early detection of heart abnormalities and improved patient outcome. HES COR.cloud has a strong cloud infrastructure indicating its potential for scalability and handling large datasets, however, EHR integration may be a challenge.

One of the main challenges faced during this review was the limited access to technical documentation, patents, and research studies that provide complete and in-depth details of the platform. Moreover, it was difficult to obtain the required support from the platform providers to gather information. These challenges hindered the process of conducting comprehensive comparative analysis. As a result, this review heavily relies on publicly available marketing materials and other general information, which serves as a limitation. This means that the comparison may be influenced by incomplete or promotional content, that introduces some bias in representing the platform's capabilities. Additionally, there were not adequately reported validation studies and other metrics to ensure that these platforms perform well in the real-world, across different patient populations or healthcare settings. Therefore, while this review offers a preliminary comparison, it is difficult to draw final conclusions about the true strengths and weaknesses of each platform and requires further inquiry by collaborating with the favorite service providers as a potential user.

Conclusion

This report addresses a significant challenge in the identification and evaluation of cloud-based solutions for the analysis and reporting of data from wearable ECG devices. The primary challenge involved finding alternative platforms to the current provider, Cardiolyse, that could improve the accuracy, efficiency, and scalability of remote cardiac monitoring while complying with strict regulatory standards.

The main users of the proposed solutions are healthcare professionals who rely on accurate ECG analysis for diagnosis, monitoring, and clinical decision-making. Furthermore, patients benefit from improved diagnostic precision, timely interventions, and personalized care strategies.

The evaluated solutions demonstrate potential in improving cardiac care by enabling real-time or near-real-time monitoring, facilitating early detection of arrhythmia, and utilizing predictive analytics for the management of long-term risks. The improvements result in better clinical outcomes, including reduced hospitalizations, heightened patient safety, and a more effective use of healthcare resources. Additionally, the effectiveness of these solutions can be assessed using metrics such as diagnostic accuracy, sensitivity, specificity, patient outcomes, and healthcare cost savings.

The assessed platforms highlight several noteworthy features, including the device-agnostic architectures, advanced AI-driven analytics for arrhythmia detection and risk prediction, compliance with critical regulatory frameworks (MDR, GDPR, CE), and the capability to scale for handling large datasets. As a result, Willem™ by Idoven, HES® RTM used in COR.Cloud by Corscience, Cardiomatics, InstaECG from Tricog, Cardiologs from Philips and CloudBeat Software from Cardiodiagonostics are evaluated platforms that demonstrated remarkable capabilities, illustrating their high accuracy, robust AI algorithms, and efficient integration EHRs.

To implement these solutions effectively, further actions and research are necessary, including validation in real-world environments, negotiation of contracts with providers, and integration into Beat2Phone. The steps should correspond with the specific needs of healthcare institutions and end-users to ensure usability and reliability.

The research revealed significant findings, emphasizing the advantages of platforms in terms of diagnostic performance and regulatory compliances. However, there are obstacles remaining, including limited access to technical documentation, reliance on promotional materials, and an absence of adequate validation studies. The identified gaps emphasize the importance of direct engagement with providers and the implementation of thorough trials to confirm suitable solutions across various healthcare settings.

In summary, although various platforms demonstrate promises for improving remote ECG monitoring and analysis, additional scientific validation and practical implementation efforts are essential. These efforts will ensure that the selected solution fulfills the demanding requirement of accuracy, scalability, and security required for substantial influence in cardiac care.

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Appendices

Appendix 1

	1	2	3	4	5	6	7	8	9	10	11	12	13
MDR Compliant	Y	Y	Y	X	Y	N	X	Y	X	X	X	Y	N
GDPR Compliant	Y	Y	Y	X	Y	N	X	Y	X	Y	X	Y	N
CE Compliant	Y	Y	Y	X	Y	N	X	Y	X	X	X	Y	N
B2B	Y	Y	Y	Y	Y	Y	X	Y	X	Y	Y	Y	Y
Device agnostic	Y	Y	Y	Y	Y	Y	X	Y	X	Y	Y	Y	Y
Supports 1-lead ECG	Y	Y	N	Y	Y	Y	X	X	X	N	Y	Y	Y
Uses AI analysis	Y	Y	Y	Y	Y	Y	X	Y	X	Y	Y	N	Y
Uses Human analysis	X	N	Y	N	Y	N	X	N	X	Y	Y	N	X
Continuous stream analysis	Y	N	N	N	N	X	X	N	X	Y	N	X	N
Batch analysis	Y	Y	Y	Y	Y	Y	X	Y	X	X	Y	X	Y
Risk scoring	Y	N	Y	N	Y	X	X	N	X	X	N	N	N
Scalable	Y	Y	Y	Y	Y	Y	X	Y	X	Y	Y	N	Y
EHR integration	X	Y	Y	N	Y	X	X	X	X	X	Y	N	Y
Diverse validation cohort	Y	Y	Y	Y	Y	X	X	Y	X	X	X	X	X
Prediction models	Y	Y	Y	Y	Y	N	X	N	X	Y	Y	X	X
Real time	Y	Y	Y	X	N	Y	X	N	X	N	Y	Y	X
Paying scheme	X	X	Y	X	Y	Y	X	Y	X	Y	Y	Y	X
Sensitivity	X	97	90	70% - 99%	98% (AF) and 97% (VT)	96%	X	X	X	X	X	X	X
Specificity	X	97	95.25	82%-99%	91% (AF) and 68% (VT)	99%	X	X	X	X	X	X	X

	1	2	3	4	5	6	7	8	9	10	11	12	13
Accuracy	X	95	X	96%-98%	96%-98% (AF) and 97% (VT)	X	X	X	X	X	X	X	X
Number of reported anomalies	20	22	140	21	14	13	X	26	X	X	X	18	X
ISOs (written form list here)	SX 6014 5511 0001 class 2a	ISO 27001, 27017, 27018, 27701, 13485	13485:2016, GDPR and ISO 27001	X	ISO 13485	HIPAA	X	X	X	ISO13485	ISO13485	HIPAA	HIPAA

Platform Name:

1 = Cardiolyse

2 = WillemTM (Idoven AI)

3 = InstaECG (Tricog)

4 = CardiolearnTM (Heartvoice)

5 = Cardiologs (Philips)

6 = AccurECG

7 = Tempus ECG-AF

8 = Cardiomatics

9 = PMCardio

10 = Cardio Diagnostics (https://cdio.ai/)

11 = CloudBeat Software (https://cardiodiagnostics.net/)

12 = HES RTM (initially COR.cloud + HES)

13= Amazon HealthLake

Y = Yes

N = No

X = Not Found

Appendix 2

Completed task or *topic* in report	**Team Members**
Short progress report for the course	Fizra Khan
Guidelines for information mining & report outline	Fizra Khan
Introduction	Teemu Syrjälä
State of the art review	Teemu Syrjälä
Methods	Fizra Khan
Vitalsignum contact person	Fizra Khan
Cardiolyse	Fizra Khan
Exploration of service providers	Teemu Syrjälä
Reaching out to cloud computing platforms & company contact	Teemu Syrjälä
Willem™ by Idoven AI	Teemu Syrjälä
HES® RTM used in COR.Cloud by Corscience	Teemu Syrjälä
Cardiolearn™ by Heartvoice (exluded service)	Teemu Syrjälä
PMCardio by PowerfulMedical (excluded service)	Teemu Syrjälä
Cardiomatics	Teemu Syrjälä
Key Standards	Hien Tran
Security Requirements	Hien Tran
Conclusion	Hien Tran
Figure 2	Hien Tran
Formatting report template	Hien Tran
Tempus ECG-AF by Tempus (excluded service)	Fizra Khan
AccurECG by AccurKardia	Fizra Khan
Amazon Web Health Services (excluded service)	Fizra Khan
Discussion	Fizra Khan
InstaECG from Tricog	Md Tanvirul Kabir Chowdhury
Cardiologs from Philips	Md Tanvirul Kabir Chowdhury
CloudBeat Software from Cardiodiagonostics	Md Tanvirul Kabir Chowdhury
Cardio Diagnostics (excluded service)	Md Tanvirul Kabir Chowdhury
Appendix 1 Table transferred from the service_table.xls	Md Tanvirul Kabir Chowdhury