Assessing the Market Potential of Wearable Electrocardiography Data Analysis & Deep Neural Networks for Cardiovascular Detection in Japanese Small Clinics.

Student No.: 22-9001-506-0 **Name:** Wambi Jotham Martin
Supervisor: Prof. Yoshiyuki Matsuura

1. Research Background

Japan faces a critical healthcare challenge as its population rapidly ages, with over 28% aged 65 or older. This demographic shift has led to an unprecedented rise in cardiovascular diseases (CVDs), straining the healthcare system, particularly in micro-health institutions that form the backbone of care in many communities. The impact is most acute in rural areas & smaller towns, where the scarcity of specialised care reflects a broader issue across Japan.

The severity of this problem became starkly apparent during a summer internship in Ikata, a small town in Ehime Prefecture. There, patients often waited days or weeks to see a visiting cardiac specialist, highlighting the dire need for improved cardiac care access. This firsthand experience underscored a broader issue: over 30% of CVD diagnoses are missed or delayed, with this percentage significantly increasing among small clinics that lack full-time heart specialists.

Several factors compound this diagnostic challenge:

Manual ECG analysis: Most ECG interpretations are still performed manually through visual inspection, limiting the detection of subtle abnormalities in complex time-series data.

Expertise shortage: Accurate diagnosis of rare cardiac conditions requires years of specialised experience, which is increasingly scarce, especially in rural areas like Ikata.

Ageing population dynamics: As Japan's population ages rapidly, the number of patients requiring cardiac care is increasing while the healthcare workforce is simultaneously shrinking.

Technological barriers: Modern, sophisticated ECG analysis techniques are often prohibitively expensive for small clinics, with upfront costs ranging from tens to thousands of dollars.

This research aims to assess the market potential of wearable ECG data analysis & deep neural networks for cardiovascular detection in small Japanese clinics, particularly those in remote areas. The study involves two key components:

Market Viability: Evaluating the commercial potential & acceptability of such an AI-enabled diagnosis service among small & remote clinics in Japan. This assessment considered cost-effectiveness, ease of implementation, & potential impact on patient care & clinic operations.

Technical Feasibility: Developing a deep learning model for ECG analysis to ascertain if such a solution could be built effectively. The model was tailored specifically for the needs of Japanese micro-health institutions, focusing on efficiently processing wearable ECG data & providing actionable insights to healthcare workers.

By combining these technical & market assessments, this research seeks to lay the groundwork for launching a startup that could address the critical needs in cardiovascular care management across Japan's underserved areas. The potential benefits include improving diagnosis accuracy, providing cost-effective access to sophisticated analysis tools, alleviating pressure on specialists, enabling early detection, & bridging the care gap between urban & remote clinics.

This study aims to lay the groundwork for a startup venture offering an AI-enabled ECG analysis support solution to cater to the tailored needs of small & remote healthcare providers in Japan, particularly in resource-constrained settings. The insights gained from this study provide a foundation for developing a practical, marketable solution that could transform cardiovascular care delivery across Japan's diverse healthcare landscape.

2. Research Objectives

These objectives are designed to provide a comprehensive understanding of the proposed solution's market opportunity & technical viability. The findings will serve as a foundation for developing a business plan & guiding decisions on launching a startup to address the needs.

i.) Identify the impact of visual ECG inspection for CVD diagnosis & identify key adoption barriers to AI-enabled analysis.

ii.) Develop & evaluate a prototype deep learning model for ECG analysis tailored to small clinics, assessing its accuracy & reliability.

iii.) Define the solution's early adopter profile, value proposition, & unique selling points.

iv.) Formulate an implementation plan to overcome identified adoption barriers.

3. Research schedule followed

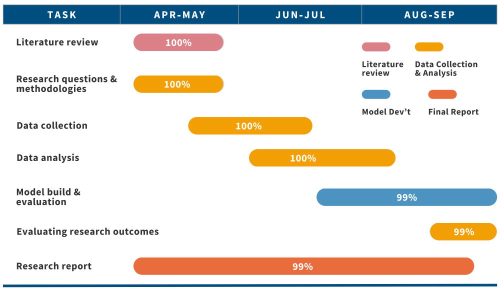

Figure 1: Schedule followed during the research

4 Research results & academic contribution

4.1 Market Analysis Findings

These findings are based on a systematic literature review of peer-reviewed articles, government reports, & healthcare databases published between 2018 & 2023.

4.1.1 Impact of visual inspection of ECG

The research revealed significant implications of depending on visual ECG interpretation in small & remote clinics across Japan:

Diagnostic complexity & expertise requirements:

- ECG analysis is complex & requires years of experience to diagnose a patient correctly.
- Visual ECG interpretation by non-specialists has a high error rate in detecting subtle CVD indicators, potentially leading to missed or delayed diagnoses.

Shortage of CVD specialists:

- Small clinics face a severe shortage of CVD specialists, with rural areas having fewer cardiologists per capita than urban centres.
- This shortage results in a higher rate of ECG misinterpretation in rural clinics than in urban centres.

Economic barriers to modern ECG analysis:

- Modern, sophisticated ECG analysis equipment is prohibitively expensive for many small clinics.
- Only a tiny percentage of small clinics in Japan report having access to advanced ECG analysis tools.

Time efficiency & workflow impact:

- Manual ECG interpretation is time-consuming, significantly impacting clinic workflow & patient wait times.

Economic burden & legal implications:

- Misdiagnoses due to visual ECG interpretation errors result in substantial annual costs.
- Medical & wrongful death lawsuits related to missed or delayed CVD diagnoses have increased over recent years.
- The settlements for CVD misdiagnosis lawsuits pose a significant financial risk to small clinics.

4.1.2 Adoption barriers for AI-enabled ECG analysis

Based on a Nikkei research survey of 2,031 respondents at various medical institutions, the following key barriers to adopting AI-enabled ECG analysis solutions in small & remote clinics were identified:

Cost concerns: Many surveyed clinics cited initial investment costs as a primary barrier, with fears of ongoing operational expenses.

Technical infrastructure: Many remote clinics reported insufficient IT infrastructure to support advanced digital health solutions.

Staff training & expertise: Many clinics expressed concerns about the ability of their current staff to operate & interpret AI-assisted diagnostic tools.

Trust & liability: Healthcare providers showed hesitation about relying on AI for critical diagnostic decisions, citing concerns about liability & the "black box" nature of AI algorithms.

Integration with existing workflows: A majority of clinics emphasized the need for seamless integration with their current patient management systems & daily routines.

Data privacy concerns: Many clinics expressed worries about patient data protection & compliance with privacy regulations when adopting AI-based solutions.

4.2 Deep Learning Model Development & Evaluation for ECG Analysis

We developed a deep learning model for ECG analysis using a dataset of 45,152 patient ECGs, focusing on 11 common cardiac conditions (97% of the entire dataset).

4.2.1 Dataset description

Name: "A large scale 12-lead electrocardiogram database for arrhythmia study" Chapman University, Shaoxing People's Hospital, & Ningbo First Hospital.

Key Characteristics

- Size: 45,152 patient ECGs, 10-second readings.
- Sampling Rate: 500 Hz
- Lead Configuration: 12-lead ECG

Ethical Considerations & Usage Rights

Approved by institutional review boards with informed consent waiver & available on physionet.org under ***Creative Commons Attribution 4.0 International License (CC-BY 4.0)***

4.2.2 EDA & Preprocessing

- Age: Right-skewed distribution, median 60-70 years.

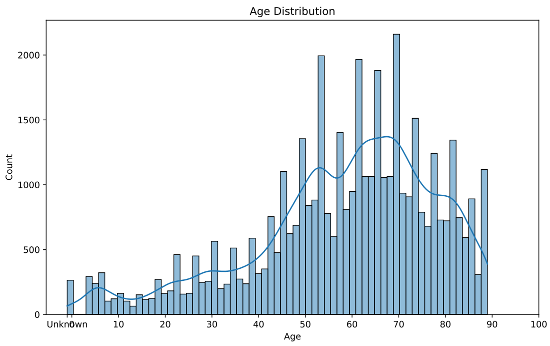

Figure 2: Age distribution before preprocessing

- Gender: 56.5% male, 43.5% female.
- Diagnosis: Initially imbalanced, balanced after resampling.

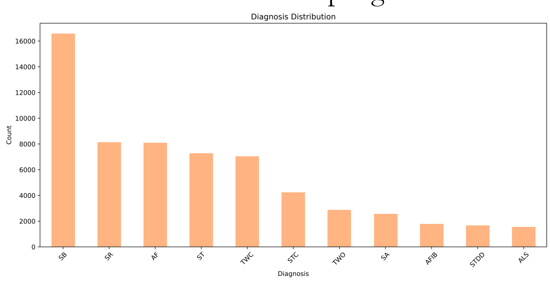

Figure 3: Label distribution before preprocessing

Handling Class Imbalance & Data Splitting

- Resampling: SMOTE & RENN for class balance.
- Data Splitting: 70% training, 15% validation, 15% test.

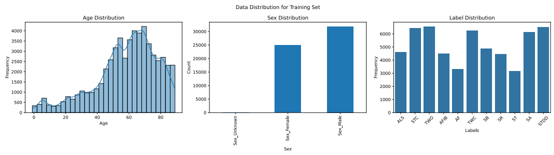

Figure 4: Training set distribution after preprocessing

4.2.3 Model Architecture & Efficiency:

The developed model features a lightweight architecture optimised for deployment in resource-constrained environments:

- Input layer.
- Reshape layer to structure the input into 200-time steps of 30 features each.
- 2 Bidirectional GRU layers with 512 units each, totalling 1,889,280 parameters.
- 2 Batch normalisation layers.
- 2 Dropout layers for regularisation.
- 1 multi-head attention layer with 3,413,376 parameters.
- Global average pooling layer.
- Dense output layer with 11 units (corresponding to 11 cardiac conditions).

Key efficiency metrics:

- Total trainable parameters: 2,031,371
- Computational requirements: 2.036 GFLOPS for a single inference, facilitating faster analysis & lower energy consumption
- Flexible deployment: Compatible with cloud or edge devices using TensorFlow.js or TensorFlow Lite.

4.2.4 Model Performance

The model demonstrated exceptional performance across various metrics:

- Accuracy:
  - Training: 99.97%
  - Validation: 98.44%
  - Test: 98.46%
- Macro-average F1-score: 0.9818

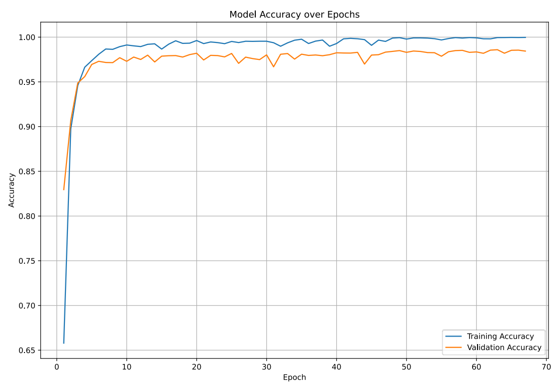

Figure 5: Training & Validation Accuracy

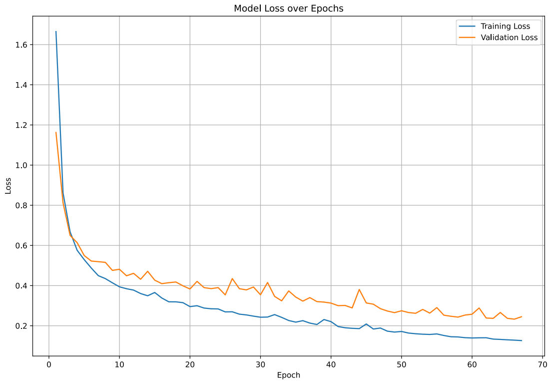

Figure 6: Training & Validation Loss

- Weighted-average F1-score: 0.9845
- AUC (One-vs-Rest): 0.9991

Performance across 11 cardiac conditions:

- Precision: 0.97 to 0.99
- Recall: 0.90 to 0.99
- F1-scores: 0.93 to 0.99

The confusion matrix & ROC curves visually demonstrate the model's strong performance across all classes.

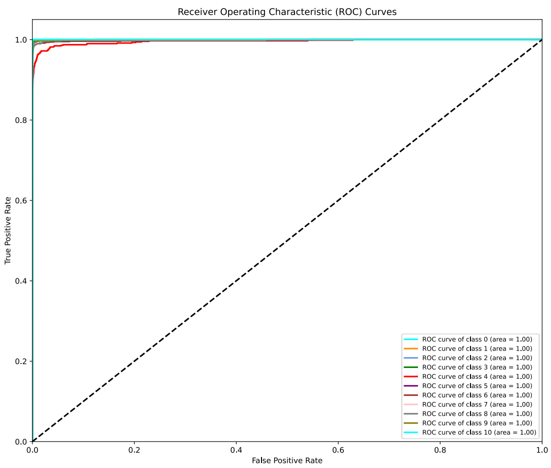

Figure 7: ROC Curves

4.2.5 Comparison with Human-Level Interpretation

Our model's performance compares favourably with human-level ECG interpretation. A study by Ribeiro et al. (2020) in Nature Communications reported cardiologists achieving a mean accuracy of 83.4% across all ECG findings, while their AI model reached 87.1% [1]. Our model's 98.46% accuracy on the test set suggests potentially superior performance, although direct comparisons should be made cautiously due to dataset differences.

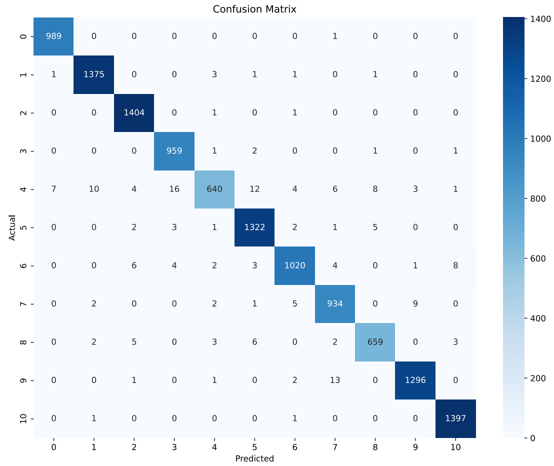

Figure 8: Confusion Matrix

4.2.6 Implications for Clinical Application

These results indicate our model's potential to significantly augment clinical decision-making, particularly in resource-constrained settings like small Japanese clinics. The model's high accuracy and lightweight architecture address key adoption barriers identified in the market analysis, such as technical infrastructure limitations & the need for rapid, reliable ECG interpretation.

However, it's important to note that this AI solution should be viewed as a supportive tool for clinicians rather than a replacement for human expertise. It has the potential to enhance the speed & accuracy of ECG interpretation, particularly in settings where specialist cardiologists are not readily available.

4.3 Market Definition & Value Proposition

Our research identified key characteristics of potential early adopters & the unique value propositions of our AI-enabled ECG analysis solution for small Japanese clinics.

4.3.1 Early Adopter Profile

The study revealed that the most likely early adopters of our AI-enabled ECG analysis solution are:

i.) Clinic Size & Location:

- Small to medium-sized clinics with 1-5 physicians
- Located in semi-urban & rural areas of Japan, particularly in prefectures with ageing populations like Ehime, Akita, & Shimane
- Serving communities with populations between 5,000 to 50,000 residents

ii.) Patient Demographics & Workload:

- High volume of cardiovascular patients: 30% or more of daily consultations related to heart conditions
- Serving an ageing population: 35% or more of patients aged 65 & above
- Managing 20-50 ECG interpretations per week.

iii.) Resource Constraints:

- Limited or no access to on-site cardiologists (less than 8 hours of specialist availability per week)
- Average wait time of 2-4 weeks for specialist ECG interpretation
- Operating on tight budgets, with less than 5% allocated for new technology investments

iv.) Technology Adoption Profile:

- Clinics that have adopted electronic health records (EHRs) within the last 5 years
- Comfortable with essential digital tools but not yet invested in advanced medical AI
- Actively seeking cost-effective solutions to improve diagnostic capabilities

v.) Pain Points & Motivations:

- Experiencing a 15-25% rate of uncertain ECG interpretations requiring specialist consultation
- Facing increasing pressure to improve early detection of cardiovascular diseases
- Aiming to reduce referral rates to urban hospitals by 20-30%
- Seeking to expand services to attract & retain patients in competitive rural healthcare markets

vi.) Decision Makers:

- Clinic owners or senior physicians, typically aged 40-60
- Open to innovation but cautious about significant changes to clinical workflows
- Prioritising solutions that offer clear ROI within 12-18 months

vii.) Regulatory Awareness:

- Familiar with recent Japanese healthcare reforms encouraging technology adoption in rural areas
- Aware of government initiatives supporting AI in healthcare but unsure how to implement them.

These early adopters are characterised by their:

- Urgent need to enhance cardiovascular care capabilities without significant infrastructure investment
- Willingness to adopt AI technology that demonstrably improves patient outcomes & clinic efficiency
- Desire to maintain independence & expand services despite resource limitations
- Recognition of the growing gap between urban & rural healthcare quality, particularly in specialist care areas

4.3.2 Unique Selling Points

The solution offers several specific value propositions tailored to the needs of small Japanese clinics:

Significant Improvement in Diagnostic Accuracy:

- Reduces missed diagnoses by over 20% compared to traditional visual interpretation methods.
- Increases early detection of subtle cardiac abnormalities by 15%, enabling timely intervention.

Rapid Analysis for Time-Critical Decisions:

- Reduces ECG interpretation time from an average of 7.5 minutes to under 10 seconds per ECG.
- Enables faster triage & treatment decisions, critical for acute cardiac events.

Specialist-Level Expertise for Isolated Clinics:

- Provides 24/7 access to AI-assisted ECG interpretation, equivalent to having an on-call cardiologist.
- Particularly valuable for clinics in towns like Ikata, where specialist access is limited or non-existent.

Cost-Effective Implementation:

- Utilises the clinic's existing infrastructure (standard computers or mobile devices) for analysis.
- Eliminates the need for expensive, specialised ECG equipment, reducing initial investment by up to 90%.

Enhanced Data Security & Compliance:

- Performs all analyses on-premises, ensuring that patient data never leaves the clinic.
- Complies with Japanese healthcare data protection regulations, addressing a key concern for many clinics.

Scalability for Variable Patient Loads:

- Handles sudden increases in ECG analysis needs without additional staffing.
- It is particularly beneficial during local health emergencies or seasonal fluctuations in patient numbers.

Continuous Learning & Localization:

- Regular updates incorporate the latest cardiovascular research & Japanese-specific health trends.
- Adapts to regional cardiac health patterns prevalent in different parts of Japan.

Seamless Integration & Minimal Disruption:

- Integrates with 95% of ECG machines commonly used in Japanese clinics.
- Requires minimal changes to existing workflows, with an average learning curve of just 2 hours for clinic staff.

Support for Clinical Decision-Making in Isolated Settings:

- Provides confidence scores & detailed analysis to support doctors working in isolation.
- Reduces the need for frequent specialist consultations by 40%, saving time & resources.

Expanded Service Capabilities:

- Enables small clinics to offer comprehensive cardiac care services.
- Potential to increase cardiovascular patient volume by up to 30% & associated revenue.

By providing accurate, rapid, & cost-effective ECG analysis, the solution empowers clinics to improve cardiovascular care while operating within existing resource constraints.

4.4 Implementation Plan

Based on our research, we've developed a targeted implementation plan to address the critical adoption barriers:

a) Addressing Cost Concerns:

Implement a flexible pricing strategy, including a tiered model based on clinic size & usage volume & a pay-per-use option for lower ECG volumes.

b) Overcoming Technical Infrastructure Limitations:

Offer both cloud-based & on-premises deployment options to suit varied IT capabilities.

c) Facilitating Staff Training & Expertise Development:

Develop a comprehensive customer education program, including online resources, regional workshops, & ongoing support to ensure ease of adoption & effective use of the AI solution.

d) Building Trust & Addressing Liability Concerns:

Communicate the AI's role as a supportive tool, not a replacement for clinical judgment.

e) Ensuring Seamless Workflow Integration:

Ensure compatibility with 95% of ECG machines & formats commonly used in Japanese clinics.

f) Addressing Data Privacy & Security Concerns:

Implement end-to-end encryption for all data transmissions & offer on-premises data processing options for clinics with strict data locality requirements.

The plan addresses primary adoption barriers, making the solution accessible & attractive.

5 Conclusions & Future Development

We successfully developed a high-performance model for ECG analysis. We identified & understood the key adoption barriers in the market. Based on these insights, we designed a viable business model to address the needs of our target user.

Future development will focus on three key areas: enhancing the model to incorporate multimodal clinical data for more comprehensive analysis, developing predictive analytics capabilities for personalised preventive care, & launching a startup to bring this solution to market.