THE UNIVERSITY OF
SYDNEY

Design Report

Gluxco

Non-invasive method for blood glucose monitoring

Tutorial 05 Group 12

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1. Executive Summary

Current glucose level monitoring methods for type 1 diabetic patients, specifically children, are solely reliant on invasive needle-based measurements that are painful and inconvenient. Gluxco has targeted this gap in the market through the proposal of a unique, non-invasive sensor seamlessly integrated into smart watches that measures glucose level through electromagnetic (EM), photoplethysmography (PPG) and thermal sensing system.

Gluxco's venture from initial planning to final market release has been guided by the mitigation of key risks which include the potential operational challenges of the software, non-compliant data security, financial insecurity from capital funding and subsidisation approval. Through stringent and detailed control plans, Gluxco can confidently move forward to implement the solution.

To ensure the success of our smart device, the primary stakeholders that must be managed have been identified as the selected manufacturer and healthcare providers such as doctors providing management plans to diabetic patients. Due to their direct influence on the success and delivery of the product, these stakeholders must be closely communicated with through regular meetings and consultations.

Estimated total timeframe of the project is ~1.5 years, spanning from 2026-01-01 to 2027-05-09, including ISO and TGA regulatory approval.

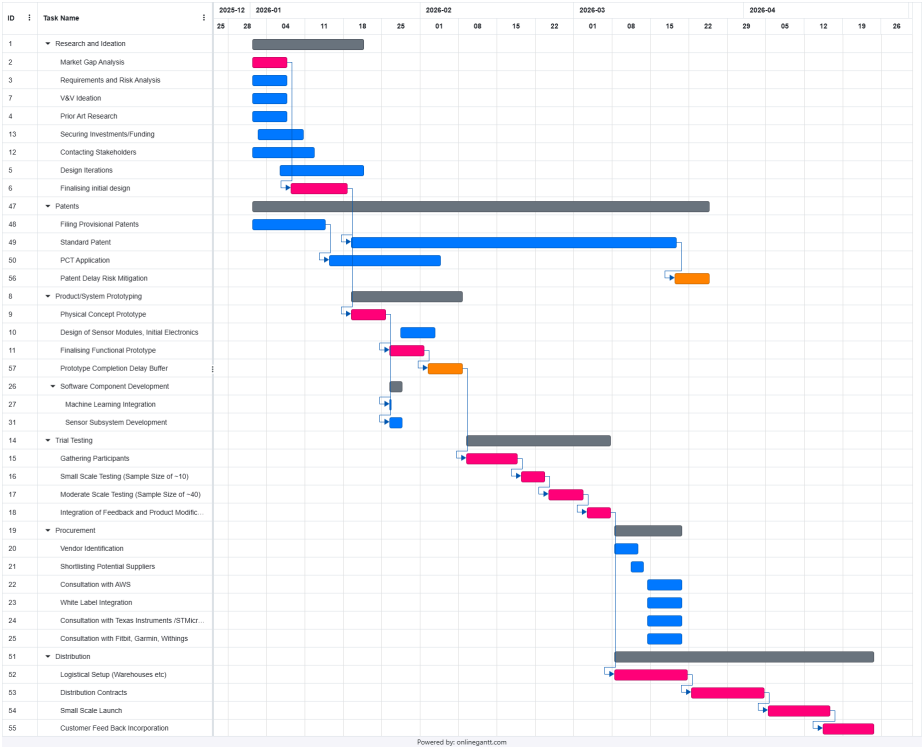

Figure 1. High-level Gantt (TGA and ISO 15197 regulatory approvals are not shown in this chart but are included in the detailed Gantt).

After careful consideration of all associated costs, our smart device has been projected to be profitable after two years post launch, with a gross margin of 50.75% and demonstrating feasibility of strong revenue stability amidst entering an established market. Gluxco intends to source funding from venture capitals such as Uniseed and Brandon Capital, NSW Health Medical Devices Fund, CSIRO, Australian Diabetes Society, and industry partners.

2. Our Proposed Solution

2.1 Problem Statement

Poor diabetes management among Australian children, particularly those with Type 1 diabetes, due to invasive, inconvenient and costly procedures of traditional finger-prick glucose monitoring estimated to be $750 per user annually, acts as a deterrent for regular self-monitoring resulting in non-compliance with regular glucose monitoring by approximately 67% of the diabetic user community [1], [2]. Additionally, the inaccuracy of manual administration which suffers from error rates of up to 20%, has led to preventable long-term health complications, including early-onset neuropathy, retinopathy, and increased cardiovascular risk in adolescence [3], [4], [5]. With an anticipated increase in the global diabetic population to 10.2% by 2030, the need to address the limitations of current methods by introducing a painless, passive, automatic monitoring system with reduced parental supervision is crucial to ensuring better health outcomes [6].

2.2 Engineering Requirements

Table 1. *Engineering Requirements*

#	Requirement	Statement	Description/Elaboration
User			
R1.1	Convenience	System required to be convenient for both the user and any supervisors.	The system shall employ non-invasive sensors to measure blood glucose levels [7]. The process of each measurement should require no more than two user interventions, and less than one hour of total maintenance per day on average. This represents a significant reduction compared to existing CGM devices that necessitate multiple finger prick calibrations daily. Furthermore, efficiency of the system will be validated through a time-and-motion study, and should reflect similar time taken as standard daily chores or activities.

R1.2	Intuitive	System is accessible with short and simple training times.	The smart room interface shall achieve a System Usability Scale (SUS) score of at least 75 when evaluated by caregivers, with users demonstrating proficiency in all essential functions after no more than 180 minutes of initial training and maintaining this proficiency without additional instruction for at least 24 months; verification shall be conducted through standardized usability testing with a representative sample of 15 - 20 caregivers of diverse technical backgrounds, with longitudinal follow-up evaluations at 6, 12, and 24-month intervals.
Function			
R2.1	Accuracy	Systems must be required to have a high ratio of true positives with relation to total number of predictions.	The proposed glucose sensing technology shall demonstrate measurement precision within ± 15% deviation from reference laboratory blood analysis when evaluated against identical samples, adhering to TGA classification requirements for Class IIa medical devices [8], [9], [10], [11]. Testing methodology shall comply with the specific provisions outlined in ISO 15197 and undergo evaluation through the conformity assessment procedures detailed in Schedule 3 of the Therapeutic Goods Regulations 2002 [12].
R2.2	Battery Life	The standard operation time of each charge cycle should be reasonably long.	This requirement shall be verified through automated battery life testing under standard operating conditions (20°C ± 5°C, 30-70%) relative humidity. The device shall operate for a minimum of 500 testing cycles on a single battery charge/replacement.
R2.3	Low Environmental impact	System must optimise the consumption of energy in general	The device shall generate no more than 10 kg CO_2 equivalent during its operational lifetime of 5 years, as calculated according to the NGER Technical Guidelines [13]. This shall be verified through a life cycle assessment conducted by an independent certified environmental assessor.
R2.4	Data Transmission	Low latency transmission of accurate data must be required for a real-time detection device.	The sensor must transmit real-time blood glucose data and automated glucose trend analysis to a paired device app within at least 1 minute of measurement with a mean absolute relative difference (MARD) ≤ 10% including remote devices for caregivers or healthcare providers [14].
R2.5	Feasibility	Development of the system must be financially feasible.	System must retain a reasonable net present value of within 20% of $2500. The expected return for the investment should be around 8 - 10%, and the system can be expected to generate cash flow for 4 - 5 years (expected lifespan) [15], [16].
R2.6	Manufacturing Cost	System must seek a minimum cost of manufacturing to improve financial accessibility.	For houses requiring a room, the addition of the smart room should cost no less than $1,300 and no more than $3,900 per square meter for the basis of the room [17]. The manufacturing cost of smart additions should not exceed the average monthly

			income of a low-mid family, based on a $45,000 annual income as defined by the Australian Government [18].
Compliance			
R3.1	Safety	System must not cause harm under intended use.	The testing, methods and function of the system shall eliminate or mitigate potential physical hazards that could cause bodily injury - ranging from minor cuts to serious trauma requiring medical attention - through appropriate design safeguards.
R3.2	Legal Compliance	System must comply with all relevant legal standards and policies.	The system should encrypt user data at a minimum AES-256 level to comply with Australian Privacy Act 1988. The device must be manufactured in Good Manufacturing Practice (GMP)-compliant facilities. The device must comply with ISO 13485 (Medical device QMS), ISO 15197 (glucose monitoring), and IEC 62304 (software). Relevant components and devices within the smart room should be classified as a class **IIa** medical device and comply with TGA regulations affecting this class of devices [11].
R3.3	Public Healthcare Policy	System must comply with all public healthcare policies.	System must comply with public healthcare programs to ensure accessibility for users in low-income households. The system must integrate with Medicare and NDSS programs where applicable.

2.3 Proposed Solution

Our company proposes a non-invasive, smart wearable device (see Figure 2) that implements a multi-sensor fusion system that measures real-time, accurate glucose levels to overcome the limitations of current methods and ensure user health and longevity. The measurement unit comprises three sensors which are electromagnetic (EM), photoplethysmography (PPG) and thermal. The EM sensor uses bioimpedance electrodes to detect changes in tissue dielectric properties, which are influenced by the glucose concentration in interstitial fluids [19], [20].The PPG sensor measures blood volume and optical absorption patterns, which can fluctuate with glucose-driven changes in vascular behavior [21].

To ensure robustness and reliability of glucose measurements and eliminate any impact of external disturbances, a thermal sensor is included to provide real-time calibrated data [22]. These temperature metrics help the smart system evaluate signal reliability, allowing it to distinguish between genuine glucose-driven changes and environmental or physiological noise. Thus, all data is processed using a machine learning model which dynamically assigns weights to each input based on real-time signal quality, delivering a stable and accurate glucose measurement.

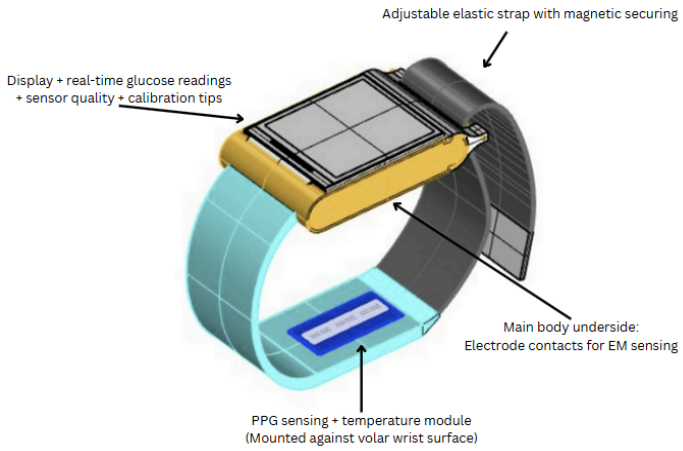

Figure 2. CAD model of the wearable device showing sensor layout, display interface, and strap design for stable wrist contact.

The data is processed and stored entirely within the onboard unit, eliminating the need for external connectivity such as SIM cards or cloud servers. The device is self-contained, featuring onboard memory (NOR flash) capable of holding up to 24 hours of glucose measurements. To ensure both independence and clinical accuracy, the system requires a **one-time calibration period** during setup. This involves wearing a continuous glucose monitor (CGM) for 10–14 days to collect labelled ground truth data, enabling personalised model training. After this supervised setup phase, the device operates autonomously, delivering reliable non-invasive glucose readings without the need for finger-prick tests, implanted sensors, or internet access. This approach maintains user comfort and minimizes risks such as skin irritation or inflammation from repeated needle-based procedures.

3. Solution Development

Our core innovation is an **adaptive fusion architecture** that learns, at each prediction, **how much to trust** the outputs of PPG and bio-impedance (EM) sensors, guided by their internal **confidence scores** and contextual **temperature input.**

We use an adaptive fusion architecture to decide, in real time, how much to trust each sensor

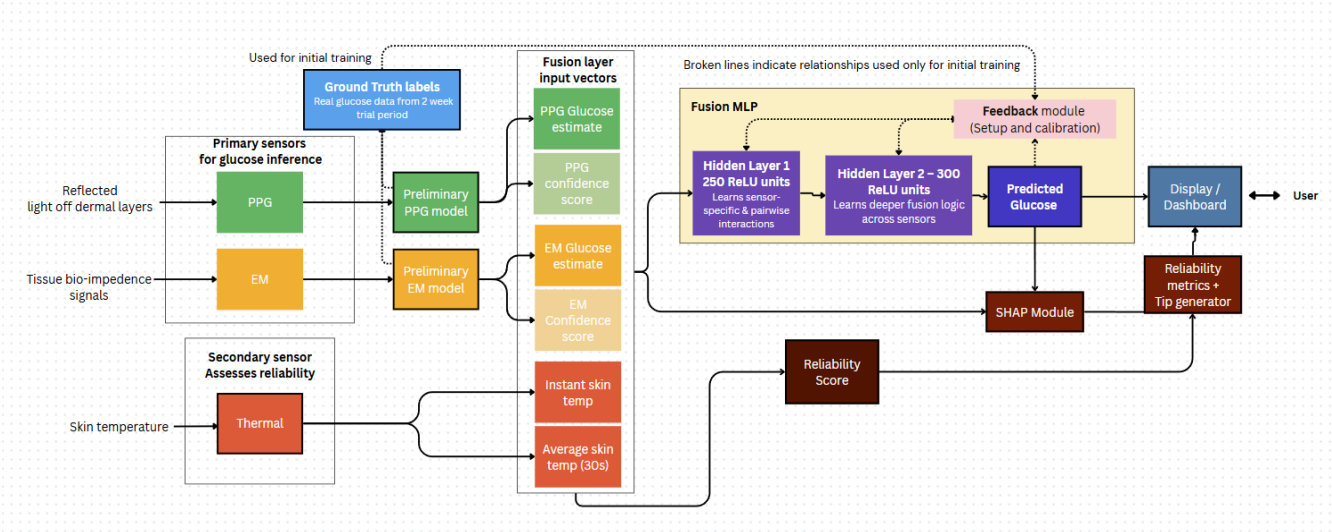

Figure 3. System overview. Confidence scores are calculated from signal quality and are not learned. SHAP is used only for explaining predictions. See Appendix A.1 for details.

Post-inference SHAP (SHapley Additive Explanations) identifies which inputs most influenced each prediction. While not used for confidence estimation, SHAP improves transparency by exposing model dependency — even when signals are degraded. This addresses a core limitation of many non-invasive systems, which often lack explainability under poor signal conditions. The system runs fully on-device with no cloud dependency.

Signal Conditioning

To mitigate motion artifacts, thermal drift, and electrical noise, raw PPG and EM signals undergo modality-specific preprocessing based on best practices from prior work [23], [24]. These steps ensure reliable feature extraction and stable model input.

- **PPG:** Follows Zeynali et al.'s segmentation and feature extraction scheme, with smoothing via Savitzky–Golay filtering (2nd order, 21-point window), followed by a 0.5–8 Hz 3rd-order Butterworth filter. Signals are segmented into 1-second windows centered on systolic peaks (detected using amplitude and spacing thresholds) [24]. Extracted features include waveform statistics (mean, std, skewness, kurtosis), sample entropy, and systolic/diastolic area ratios.
- **EM**: As per Yen et al. (2022), impedance is captured across 11 frequencies (50–100 kHz). PCA reduces this to the top 3 principal components (explaining ~90–95% of variance), ensuring efficient input without major information loss [23].
- **Skin Temperature:** Not a glucose predictor, but a contextual reliability cue. Sudden drops (e.g., <32 °C) indicate peripheral vasoconstriction, which dampens PPG pulsatility and alters impedance.Instantaneous and 30 s rolling averages are included as inputs to help the fusion model down-weight unreliable sensors.

Ground Truth and Supervised Training

To ensure accurate and personalized glucose estimation, the system requires a supervised calibration phase using reference glucose values from a commercial Continuous Glucose Monitor (CGM). This process enables the model to learn individual-specific physiological baselines and improve prediction reliability.

Calibration Protocol [See appendix A.2 for training pipeline]

- Duration: 10–14 days of continuous CGM wear alongside the non-invasive prototype.
- Sampling:
    - CGM: 5-minute intervals
    - PPG & EM: Continuous, downsampled to align with CGM timestamps
- Data Pairing: Each training sample includes:
    - Extracted PPG and EM features
    - Contextual temperature data
    - CGM ground-truth glucose value

Each session yields ~2,000–4,000 labeled samples per user for model training.

Model Training during calibration protocol

Training occurs in two stages: first, each sensor stream is calibrated independently; then a fusion model learns to combine their outputs under contextual modulation. [See appendix A.3 for training vs deployment pipelines]

Stage 1: Sensor-Specific Regression Models

PPG Sub-model
Our PPG regression model is based on the signal processing and segmentation framework proposed by Zeynali et al. (2025), but we implement a lightweight MLP in place of their ResNet34 architecture to meet embedded inference constraints [24].

EM Sub-model
Following the DUAL framework, we apply PCA to 11-frequency impedance signals and input the top 3–5 components into a similar two-layer MLP [23]. Confidence is computed from spectral coherence, phase consistency, and PCA reconstruction error.

Both sub-models are trained using mean squared error (MSE) loss against CGM values, with early stopping and per-user normalization. To further mitigate overfitting, we apply 5-fold cross-validation during calibration, and include a dropout layer ($p = 0.3$) in each sub-model.

Stage 2: Fusion Model Training

The fusion model learns to combine both sensor estimates, their confidence scores, and the temperature context to predict final glucose values. The fusion layer is trained during calibration to optimize

prediction using both sensor estimates and their engineered confidence scores. During deployment, **these fusion weights remain fixed**, allowing stable, real-time inference without retraining.

Input Composition

- **PPG Estimate**: A preliminary glucose prediction generated from ~30 time-domain features extracted from 1-second peak-aligned PPG segments.
- **EM Estimate**: A glucose prediction based on 3–5 principal components extracted from 11-frequency complex bioimpedance signals.
- **Skin-Temperature (instant)**: instantaneous skin temperature detects acute vasoconstriction
- **Skin-Temperature (30-s avg):** A 30-second rolling average of skin temperature for thermal drift
- **PPG Confidence Score**: A scalar trust value derived from signal quality metrics such as peak detection consistency, signal-to-noise ratio, and entropy stability.
- **EM Confidence Score**: A scalar trust metric calculated from phase smoothness, spectral coherence, and PCA reconstruction error

All confidence metrics are normalized to a 0–1 range using min-max scaling over the training dataset. These scores are **engineered**, not learned, and are fixed at inference time.

Fusion layer Architecture

The fusion model detailed in Figure 3 is a 2-layer MLP optimized for embedded inference, balancing non-linear flexibility with compactness for real-time use.

Sensor Attribution and Confidence Evaluation (SHAP)

SHAP is applied *post-inference* to visualise which inputs most influenced a prediction; it does **not** assess raw signal quality. Real-time trust bars are driven by independent metrics (signal-to-noise ratio, phase coherence, entropy stability)

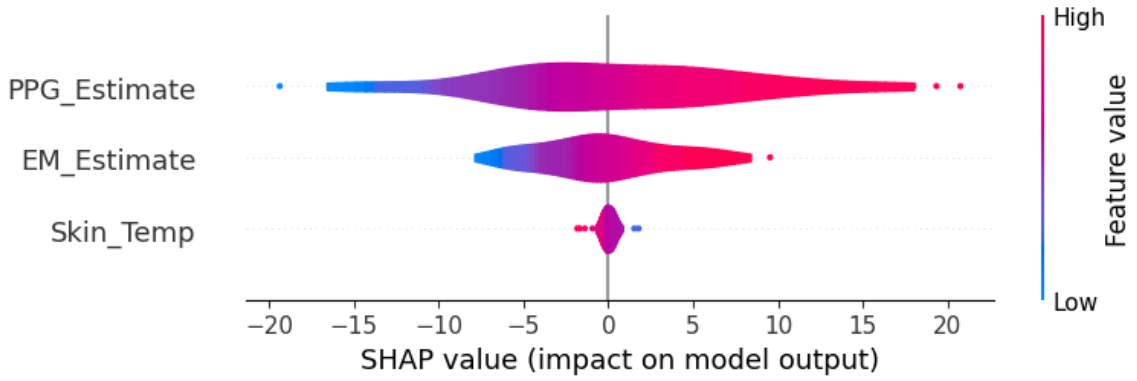

Figure 4. A simulated SHAP summary plot showing relative feature attribution for a given glucose prediction. In this example, *PPG_Estimate* shows the highest influence on model output, followed by

EM_Estimate. These SHAP values reflect model dependency, not input reliability. Confidence scores are used separately to assess signal trustworthiness (see Appendix A.4 for simulation code).

SHAP values are used to interpret which sensor streams the model relied on most in a specific prediction. While confidence scores determine whether a sensor is reliable, SHAP helps contextualize that reliability — especially if the model heavily depended on a low-confidence input. In such cases, user-facing tips may escalate in urgency to reflect this influence-aware guidance:

- "Model relied heavily on PPG input — ensuring the strap is tight and skin is dry."
- "Model ignored the EM signal due to low influence — no action required."

These tips do not indicate sensor failure but highlight the model's current dependency, helping users improve signal conditions when necessary. SHAP is never shown directly to users but may be used internally to prioritize or contextualize alerts driven by confidence degradation. See Appendix A.5 for a simulated workflow of tip generation.

Prediction Output (See figure 5)

- **Primary Output**:
  A continuous glucose estimate in mg/dL, updated at configurable intervals (e.g., every 5 minutes).
- **Auxiliary Output**:
  A low-confidence flag is triggered when internal signal-quality metrics (e.g., signal-to-noise ratio, waveform entropy, or phase stability) indicate insufficient reliability for a trustworthy reading. SHAP values are used separately for interpretability and indirectly support reliability tips by identifying which inputs the model relied on most in a given prediction.
- **Prediction Latency:** Estimated at ~2.5 seconds per inference on an ESP32-C3 microcontroller (80 MHz), executing from external QSPI flash. This figure is projected from TensorFlow Lite Micro and CMSIS-NN benchmarks for int8 models on similar resource-constrained hardware, and may vary depending on flash wait-states and cache hit rates. With an active power draw of ~33 mW, total energy per inference is estimated between 83–150 mJ, remaining well within a duty-cycled budget for 5-minute updates.

Figure 5. Example UI for a wearable implementing the fusion system

Embedded Implementation and Deployment

Our design targets real-time, on-device glucose estimation using ESP32-C3 hardware, enabling offline operation without requiring external computation or connectivity. This supports fully portable, battery-efficient wearable use.

Model Optimization for Wearable Deployment

The final model is designed to operate entirely offline, using only onboard resources, making it ideal for continuous use in real-world settings. Deployment contingencies and system limitations are detailed in Appendix A.6.

We applied three key optimization strategies:

- **Quantization:**
  Post-training 8-bit quantization, followed by structural pruning, reduces the model from ~22 MB to **~3.5 MB**, with minimal accuracy degradation (<2 mg/dL RMSE increase). This estimate aligns with typical compression ratios achieved by TensorFlow Lite for Microcontrollers.
- **Pruning:**
  Low-importance neurons are removed to reduce both storage and computation load.
- **External Flash Execution:**
  The model is stored in external QSPI NOR flash and executed directly from it, freeing internal memory for sensing and user interface tasks.

The system is optimized for fully autonomous, offline operation, but can optionally transmit results via Bluetooth for mobile logging or remote alerts.

Validation Strategy and Design Justification

Our validation approach combines simulation-driven testing with design decisions grounded in proven research. A supervised per-user calibration protocol is assumed over a 10–14 day window of paired CGM and sensor data. Key evaluation metrics include RMSE, MARD, Clarke Error Grid coverage, and inference latency. Target thresholds—RMSE < 15 mg/dL, MARD < 10%, and ≥ 85% of

predictions in Clarke Zone A—are selected in alignment with ISO 15197 and TGA clinical accuracy standards. The fusion system is designed to maintain prediction robustness under degraded sensor conditions by leveraging confidence-weighted signal estimates. While no formal ablation or dropout experiments were conducted, such stress-testing is outlined in the planned validation roadmap (Appendix A.7) as part of future simulation and clinical evaluation phases.

Early and Mid-Fusion Architectures

The DUAL framework (Yen et al., 2022) combines PPG and EM signals via a fixed mid-fusion layer and achieves 100% Zone-A accuracy under lab conditions [23], but it fails when inputs degrade, lacking adaptability. Our method retains DUAL's late-fusion strengths but introduces a confidence-weighted fusion layer: each sensor outputs a glucose estimate and trust score, allowing dynamic re-weighting at inference. SHAP then reveals which inputs influenced the prediction, enabling transparency without modifying model weights.

PPG-Only Glucose Estimation Models

Zeynali et al. (2025) showed that PPG alone, processed with ResNet34, could estimate glucose with RMSE of 19.7 mg/dL and 76.6% Zone A accuracy [24]. Their results were based on stable, fasted surgical patients and do not reflect typical wearable conditions. We use their 1-second peak-aligned segmentation but improve robustness by integrating EM and temperature inputs to handle cases where PPG is unreliable due to vasoconstriction or noise.

Fixed Sensor Importance and Static Fusion

Gong et al. (2025) relied on fixed-weight regression for EM data, which performed well in typical subjects but degraded when physiology changed (e.g., low BMI, dehydration) [27]. We address this by using a learned fusion layer that ingests each sensor's glucose estimate, its confidence score, and temperature context. During training, the fusion network automatically adjusts the relative influence of PPG, EM, and temperature for every sample, enabling robust predictions even when one modality is compromised.

Limitations of Monolithic End-to-End Models

ResNet and LSTM-based models perform well but are too large and rigid for low-power embedded systems.We use a modular design: each sensor is processed independently, and a lightweight fusion layer combines their outputs. SHAP is applied after prediction to show which inputs mattered. This structure is compact, explainable, and optimized for real-time use on wearable hardware.

This system architecture demonstrates a functional and scalable pathway toward explainable, on-device glucose monitoring. While further clinical validation is needed, our modular design, paired with interpretability mechanisms like SHAP, represents a step forward in user-informed non-invasive glucose sensing

4. Risk Management Plan

This section outlines the risk management strategy for our non-invasive glucose monitoring device for children with Type 1 diabetes. The plan identifies, analyses, and establishes risk controls across technical, operational, financial, stakeholder, environmental, legal/policy, and ethical domains under the Australian Regulatory Framework.

The technical and operational risk analysis is primarily guided by the Australian Therapeutic Goods Administration (TGA) Essential Principles for medical devices. The device must comply with the essential principles outlined in Schedule 1 of the Therapeutic Goods (Medical Devices) Regulations, which establishes the fundamental safety and performance requirements all medical devices must meet before they can be supplied in Australia.

Stakeholder risks are addressed through our stakeholder management plan, which identifies key individuals and groups—including young users, their families, healthcare providers, investors and regulatory authorities—and outlines engagement strategies to ensure their needs are met throughout the project lifecycle.

Environmental risks, particularly those related to device end-of-life management, are significant considerations. Our approach includes designing for recyclability, implementing a take-back program for proper disposal of electronic components and batteries, and minimising packaging waste.

Legal and ethical risks are inherent components of all technical, operational, and environmental aspects of the project. The TGA legally and ethically stipulates TGA principles related to safety, performance, and privacy as the administrative body for the Therapeutic Goods Act 1989. Our compliance strategy addresses these requirements while maintaining data security and user confidentiality.

Financial risk analysis identifies several key vulnerabilities, including capital resource depletion, manufacturing cost overruns, unexpected regulatory compliance expenses, and lower-than-projected market adoption. Mitigation strategies include incorporating comprehensive insurance coverage, strategic supplier contracts, phased investment approaches, and Medicare reimbursement pathways.

This Risk Management Plan demonstrates our commitment to delivering a safe, effective medical device that meets all TGA requirements while protecting our users, supporting their care providers, and ensuring the financial sustainability of the project through prudent risk mitigation strategies. The Plan balances cost management with essential investment in quality and safety, ensuring both project viability and user welfare while protecting shareholder value.

Refer to Appendix B for Risk Matrix and Risk Management Framework

4.1 Risk Register

Risk Category	Risk	Probability (1-5)	Impact (1-5)	Inherited Risk Level (= PxI)	Risk Liability	Risk control/mitigation plan	Responsible party for risk control/ mitigation	Residual risk level
Operational	Malfunction of the device component	**Possible P = 3**	**Severe I = 5** Recall of defective products with significant time and cost implications.	**Very High PI = 15**	The manufacturing Team Suppliers	Implement quality assurance procedures for outsourced components and internal production.	Production Management Team	**High R = 10**
Operational	Supply Chain Disruption to Key Device Components	**Possible P = 3**	**Major I = 4** Cause production delays and financial risk	**High PI = 12**	The company	Maintain at least two suppliers for critical components	Production Management Team	**Medium to low R = 6-8**
Operational	Inaccurate readings due to software malfunction	**Possible P = 3**	**Major I = 4** The device would be non-operational during software rectification.	**High PI = 12**	Software developers and designers	Routine maintenance of the software system and thorough testing.	Software integration team	**Medium R = 8**
Technical: Cybersecurity	Leakage of confidential data (location, diabetes trends, condition) Cyber-Attacks	**Possible. P = 2**	**Moderate I = 3** Non- compliance with Australian Privacy Principles and the Privacy Act 1988	**Medium PI = 6**	The target users. Children with type 1 diabetes	Local-only logging and access auditing | **No external-facing API**	Basic security managed by embedded O	**Low R = 5**

Technical: Safety	Structural Failure due to unintended use	**Possible P = 3**	**Moderate I = 3** Sharp edges, toxic material exposure inflicting injury to users	**High PI = 9**	Guardian/Supervisor	Increase structural integrity, remove redundant hazardous components and provide warming and risk from unintended use to users	Design Team Safety Lead	**Medium** **R = 6**
Technical: Safety	Catastrophic Battery Failure	**Rare P = 1**	**Severe I = 5**	**Medium** **PI = 5**	Manufacture of Battery	Add redundancies for restricted battery charging. Alerts user of extreme temperatures	Design Team	**Low** **R = 4**
Stakeholder	Rejection or limited support for the product by the end-user	**Unlikely P = 2**	**Severe I = 5** Loss of capital and Bankruptcy	**High** **PI = 10**	Company and financial supporters	Rigorous client research Trial testing with repeated iterations for feedback	Design Team	**Medium** **R = 8**
Legal/policy	Delayed regulatory approval from the TGA	**Unlikely P = 2**	**Major I = 4** significant delays to product release	**High** **PI = 8**	Company and financial supporters	Engage TGA early through pre -submission meetings to clarify requirements and avoid costly resubmissions	Software development and design team	**Low** **R = 6**
Environmental	Improper disposal of electronic components, circuit boards, and batteries releasing hazardous materials.	**Likely P = 3**	**Minor I = 2** Potential soil and water contamination from heavy metals (lead, mercury) and other toxic substances	**Medium** **PI = 6**	The company: Environmental Compliance team	Design for disassembly to facilitate the separation of components Clearly labels of hazardous materials and components Partner with certified e-waste recyclers in Australia	Design Team	**Low** **R= 4**

Environmental	Plastic housing and components add to Australia's plastic waste problem	**Likely** **P = 4**	**Minor** **I = 2** Long-term environmental persistence of non-biodegradable materials.	**High** **PI = 8**	The company: Environmental Compliance team	Use recyclable or biodegradable plastics where possible Minimise packaging materials Include recycling symbols and instructions Consider implementing a circular economy approach	Design Team	**Low** **R= 6**
Ethical	User data breach Non-compliance with the Privacy Act 1988	**Rare** **P = 1**	**Moderate;** **I = 3** Emotional distress to stakeholders and reputational damage to the company	**Low** **PI = 3**	Company	Data encryption, regular software updates and auditing	Software development and design team	**Low** **R =2**
Financial	Depletion of capital resources due to poor financial planning and budgeting, or unexpected financial costs.	**Possible** P = 3	**Major** I = 4 Halt to project progression with potential for premature closure	**High** **PI = 12**	Financial supporters such as capital institutions, Diabetes Australia	Predetermine all expected costs and secure supplier costs. Conduct monthly financial reviews and implement corrective action Acquire a wide variety of capital funding	Project manager Finance management team	**Medium** **R = 6**
Financial	Product Liability Claims	**Unlikely** **P=2**	**Severe** **I=5**	**High** **PI = 10**	Company and Insurer	Obtain comprehensive product liability insurance (minimum $10M coverage)	Production Manage	**Medium** **R = 6**

			Medical device liability claims in Australia averaged $3.2M per incident in 2022 (Australian Medical Association Insurance Report, 2023			Implement a Robust quality management system with documented testing	ment Team	
Financial	Delayed Medicare Reimbursement approval	**Possible** **P = 3**	**Major** **I = 4** Disrupt a business's ability to meet financial obligations	**High** **PI= 12**	Company	Secure bridge funding to cover the 12-month reimbursement gap (The Medical Technology Association of Australia reports an average of 9 months for new diabetes to attain Medicare Approval)	Finance Management Team	**Medium** **R = 6**
Financial	Recall or field correction expense	**Unlikely** **P = 2** 606 recall actions by TGA in 2019-20 (Recalls annual report 2019-20)	**Severe** **I = 5** **Can cost $310K** TGA Recall Action Database, 2022	**High** **PI = 10**	Company	Obtain product recall insurance coverage Implement a serialised tracking system for targeted recall	Production Management Team	**Medium** **R = 8**
Financial	Post-launch Software update costs exceeding projections	**Possible** **P = 3**	**Moderate** **I = 3**	**High** **PI= 9**	Company	Implement a Modular Software architecture to reduce complexity Establish fixed-price maintenance contracts	Software team Financial Team	**Medium** **R = 8**

Figure 6: Risk Register and Management Plan

5. Stakeholder Management

Following a thorough, exhaustive analysis of all involved stakeholders a clear direction of the allocation of the company's time and resources towards high priority stakeholders has been finalised. These results have been determined using a balanced consideration of both the interest and influence of the stakeholder as shown in figure 7. Level of interest has been defined as how much a stakeholder cares about or is invested in the project's outcome whilst influence is defined as how much power stakeholders have over project decisions, resources, direction.

According to analysis shown in figure 8 the key, primary stakeholders include the expected manufacturer, and doctors who require full engagement from the company. The manufacturer of our smart device is responsible for the final production and delivery of the product. Clear communication of product specifications and quality standards maintained through regularly scheduled meetings and consultations from delivery of the product until the end of sales period is vital for the success of the company. Similarly, significant stakeholder engagement with doctors who facilitate the endorsement of the smart device will directly influence the profitability and success of the company. As they are involved in direct user interaction, this primary stakeholder will be involved from the beginning planning phase with consistent engagement throughout development, delivery and launch. Consultations with doctors in major hospitals will allow the company to build trust and foster strong relationships as well as identify opportunities for growth in future market expansion

Secondary to these primary stakeholders include venture capitals, research institutions, Diabetes Australia, who provide valuable financial support or technical advice. As a startup company, significant capital investment is essential to initiate the research, planning and technological development of the solution. Through regular progress meetings on device performance development and financial forecasting, the company will be able to secure funding and support for the product solution as well as build mutually beneficial relationships. The company is confident in delivering these expectations to the stakeholder through promising pitches that demonstrate a strong base foundation grounded in market research and clear benchmarks.

Figure 7. Stakeholder interest and Influence Matrix

		Influence	
		Low	High
Interest	High	Keep Informed (e.g. email update lists, town hall information events)	Full engagement (E.g. one-on-one consultation, small group meetings, regular 2-way communication)
	Low	Little effort required (e.g. information on request or access to public announcements)	Keep satisfied (E.g. address interests, keep well informed, incorporate views where offered)

Figure 8. Stakeholder Management Table

Stakeholder	*Nature of interest*	*Level of interest*	*Level of influence*	*Engagement level (see matrix)*	*Engagement method(s)*	*Engagement timeframe*	*Anticipated outcomes*
Diabetes affected Children	The primary target user	High; design and costing decisions directly influences user experience and proclivity for long term usage [28]	Low; they may give feedback on ease of use but do not have a significant influence	Keep informed	Surveys, advertisements, consultations with carers, trade shows in schools	From start to finish of project and should be engaged for reiteration and improvement	Better versions of the device, more streamlined usage, more normalised usage of device
Diabetes Australia	Administration and delivery of subsidised products for diabetes management, potential source of funding	High; Diabetes Australia has high involvement in funding new diabetes technologies [29](e.g. seed funding of $250,000 in 2024 for research program)	Medium; dependent on whether funding is provided. They may give feedback on ease of use but do not have a significant influence	Manage closely	Information sharing through email updates	From start to finish of project, to incorporate any possible feedback with respect to user usability	Subsidization of proposed product would be beneficial for widespread implementation
Therapeutic Goods Administration (TGA)	Main regulatory body over medical products in Australia	Low; not concerned with the success of this product, only relevant for approval of safety and fitness of product	High; any unmet requirements can potentially result in project shutdown and major capital loss	Keep Satisfied, meet requirements	Information sharing, applications, compliance with regulatory standards	During initial stages of regulatory compliance	As long as requirements are met, this stakeholder should be satisfied

Internet Providers	Supplier	Low; not concerned with the success of this product, stakeholder mostly concerned with own external sales	High; impacts the live data processing of user data which is essential for glucose monitoring	Keep Informed	Information sharing, Annual update on service loads	Engage throughout the planning, delivery, as well as ongoing maintenance and operation	Ensures that a key capability of the product can be delivered to consumers.
Australian government department of health and aged care	Regulatory and policy maker	Low; not concerned with success of product, stakeholder does not reap any direct benefit	High; they control what devices, services, and tests get subsidised under Medicare.	Keep satisfied	Formal regulatory submissions, occasional reporting and audits.	During regulatory phase (pre-launching during TGA submission) and ongoing (after product launching)	Device subsidy through Medicare
(Delivery Stage) Expected Manufacturer (Stryker, J&J etc.)	Expected delegated production of device	High ; As long as financial incentive is high, with an estimated profit margin of roughly 20.8% [30] (based on Garmin Ltd., one of the largest players in the wearable device market)	High ; Full Cooperation necessary for completion and successful product delivery.	Full engagement required.	Regular meetings, information sharing and progress updates	From the delivery, production of the device until the end of the maturity of sales period	Depending on manufacturer, stakeholder could be difficult. Conflicts of interest are possible, and may require reallocation of production services.

(Developmental Stage) Expected Manufacturer (Stryker, J&J etc.)	Expected delegated delivery of device	Low; due to unproven concepts and financial incentive.	Low; Little influence over design and development of product	Little effort Required	Newsletters, emails and progress updates when requested	During initial stages of design, can consult for requirements with regards to delivery stage.	Satisfying needs will be required for cooperation during the delivery stage.
Schools	Primary supervisor during school hours	Medium; school staff are legally responsible for implementing student's diabetes management plan and must undergo training for necessary education [31]	Low, no significant impact on decisions made during the project	Keep informed	Information sharing, Annual update on service loads	Towards the end of the project, when the product design is finalised and manufactured	Acceptance of new product and willingness to acquire familiarity with product
Hospitals	Potential purchase of product, support integration in care systems	Medium; interest in implementing improved measures of blood glucose level for increased efficiency [32]	Low; no significant impact on decisions made during the project	Keep informed	Procurement outreach, clinical training sessions	Launch, procurement stage	Institutional support, bulk orders

Pharmacies / Therapeutic device retailers	Retailers	Low; a high influence product would greatly boost revenue but its success or failure doesn't significantly impact the business	High; directly impacts distribution and selling. If retailers do not purchase the device from wholesalers, its demand drops	Keep satisfied	Demonstration of profit and influence. Promote smart device by sharing weekly marketing content	Towards the end of the project, when the product design is finalised and manufactured	Integration of product into merchandise. Instore promotion of products to boost sales.
Doctors	First point of contact for diabetes diagnosis and management	High; Interested in solutions that improve user's management of diabetes and overall well being of their patients.	High; success of smart devices depends on endorsement from doctors to their users. Lack of support may lead to loss in revenue.	Full engagemen t	Consultation with major hospitals. Representative pitches and q&a sessions in workplaces.	Consultation during planning phase, keeping engaged throughout, development, delivery and launch	Ease of access to the wider public, Provides a primary source of income
Advocacy groups (e.g. s network groups)	Potential source of charitable funding, advocating power and minor influence	Medium; interested in novel methods of glucose measurement that improve user wellbeing and management plans [33]	Low, depending on size of group and nature of the individuals within it.	Keep Informed	Regular general updates on device performance, development progress. (Newsletters, emails.)	During stakeholder engagement, and throughout the rest of the product life span.	Fairly variable and volatile stakeholder group. Some conflict of interest is possible, but the overall influence of each individual group is low.

Research Institutions (e.g. universities, Diabetes Australia Research Program)	Focused on research on diagnosis, prevention and treatment of diabetes	High; interested in technical product development and improvement of glucose measurement technologies	Medium, may suggest crucial technical information for technological development	Manage closely	Regular general updates on device performance, development progress. (Newsletters, emails.) With potential for consultations.	During initial stages of product planning and research	Mutually beneficial relationship in the interests of improving healthcare for users. Potential source of funding
Venture capital	Provides financial banking to startups, looking for high-return investments in exchange for equity in the company	Medium; successful market integration of the product provides direct financial benefit but is contingent on the decision to invest or not.	High; hold high influence over certain decisions to protect their financial investment.	Manage closely	Regular progress reports and meetings to secure funding rounds, financial statements, sales forecasts, risk management discussion	Pre-launch and growth phase - initial R&D, clinical trials, early commercialisation	Funding for development and commercialisation, strategic support for business scaling, significant equity taken in exchange for investment
Smartwatch companies (Garmin, fitbit, apple)	Lifestyle enhancing tech companies interested in integrating the technology	Medium; integrating health monitoring features into smartwatches is a growing trend [34]	Low; no significant impact on decisions made during the project	Keep informed	Q&A panels, emails, product pitches and partnership discussions	Launch and growth phase	A wider and more robust platform integrating the technology, more widespread acceptance of the product

Delivery/device recall service	Proper handling and safe delivery of the device to the healthcare facilities/users (directly) without compromise to their function and longevity	Low; not concerned with the success of this product, stakeholder mostly concerned with own external sales	Low; no significant impact on decisions made during the project	Little effort required; however must maintain strong relationship for operational success	Regular communication on delivery timelines and packaging requirements, development of a recall protocol and safety plans, performance metrics for on-time delivery and incident reporting	Pre-launch and ongoing post-launch	Reliable delivery system to ensure device integrity and timely delivery, a clear recall system for safe device return and replacement, customer satisfaction
Project team members (Yujin, Glora, Jun, Elvis, and Michael)	Each student brings expertise from their specific engineering discipline (civil, biomedical, software, and chemical).	High	Medium	Manage closely	active engagement throughout the project, regular team meetings for collaboration and problem solving	Throughout the entire project duration	Interdisciplinary knowledge sharing for innovative solutions, Potential for PhD progression based on project outcomes

6. Project Implementation Plan

6.1 Gantt Chart

Please refer to Appendix C for the detailed Gantt Chart.

Task	Justification
Research and Ideation [35]	Understanding market trends, target market requirements and strong foundational research into investment sources and various stakeholder needs is a fundamental task that must be undertaken to ensure long-term success and minimise potential future disruptions.
Patents [36]	Patenting our novel solution is essential in protecting our company integrity and long term revenue, especially due to competing brands that are undergoing research and development.
Product/system Prototyping [37]	Initial prototypes allow iterative refinement and early validation of core functionality. This identifies critical technical challenges before scaling to later stages of manufacturing or certification.
Trial Testing [38]	Clinical evaluation through small (n=10) and moderate (n=40) participant studies is used to validate system performance, usability, and reliability under semi-controlled conditions. This stage assesses user interaction, ease of use, and functional robustness.
Procurement	Engaging vendors and securing components (e.g sensors, microcontrollers) ensures hardware consistency and allows time for negotiation, delivery delays and integration testing
Software Component Development	Coding of core system logic, external integrations with third-party APIs like (Fitbit, AWS, apple). Requires rigorous unit, system, regression and user acceptance testing to meet functional and non functional software requirements
Machine Learning Development	Machine learning is a key component of the functional system, and through rigorous training and implementation carried out by an experienced engineering team, time must be invested into this task to ensure the model is fully developed.
Sensor Subsystem Development	Involves calibration and analog signal processing. Critical for optimising the conversion of raw data into actionable insights (e.g glucose readings or sensor reliability scores)
ISO 13485 Approval [39]	Certification ensures compliance with international medical device quality standards, covering audits, document control and clinical safety. A prerequisite for market entry and TGA certification.
TGA Approval [40]	The product must be approved by the TGA and included on the

	Australian Register of Therapeutic Goods (ARTRG) before they can be distributed in the market. In accordance with TGA classification requirements as a Class IIa medical device, approval processing time is approximately 6 months [41].
Distribution [42]	The launch of our product must be carefully monitored to adjust for feedback and ensure its overall success in the market. Dedicating time to streamline distribution and efficient transport methods will improve customer satisfaction.

Although most initial development stages are leaning towards more optimistic approaches to the time frame, buffers have been included as minor contingencies for potential delays in these processes. Of all early stage tasks, patenting is the most time consuming due to the legal complexity, dependencies in technical development and responses from regulatory bodies. Furthermore, several different patents need to be filed in order to guarantee the intellectual property rights of our product, including a preliminary provisional patent, followed by a PCT patent. This is then followed by the application of a standard patent. Although this process is time consuming, the development of our product can continue whilst this is going on, as it is not a critical path.

In addition, of the entire development process, the approvals from TGA and ISO 13485 are most time consuming. The process of approval from ISO 13485 generally takes 6-12 months if a quality management system is already in place, but 12-24 months if it is not. This gantt chart assumes a period of roughly 12 months for the ISO 13485 process, with a 30 day buffer for potential delays. Regarding the TGA approval process, over 90% of Class IIa medical devices were approved within 188 days or less in the past, which is reflected in this gantt chart with an additional 30 days buffer to mitigate delays.

Although these buffers are time consuming, dependent tasks can proceed if no delays occur, skipping the time allocated to these buffers entirely. They are also highlighted in orange for visual clarity. Tasks that are deemed critical for the development process have been highlighted in red for visual clarity. It should also be noted that the approval processes have been highlighted green, but are considered critical.

7. Cost Analysis

The financial sustainability and commercial viability of our non-invasive glucose monitoring device for children with Type I diabetes (T1D) is critically dependent on a robust and realistic cost analysis. This section presents a comprehensive overview of the estimated costs associated with development, regulatory approval, manufacturing, and ongoing operation of the device, as well as the projected revenue streams and break-even analysis.
The cost estimation plan is informed by the risk management framework outlined in figure 6.. Recognising the technical, regulatory, financial, and market uncertainties inherent to medical device

development under the Therapeutic Goods Administration (TGA) guidelines, we have incorporated a contingency reserve and dynamic cost monitoring processes to ensure prudent financial management. Each major cost component has been carefully benchmarked against industry standards and adjusted to reflect identified risks, such as potential regulatory delays, manufacturing overruns, and evolving market adoption rates.

By integrating risk mitigation strategies into our financial planning, we aim to balance essential investment in safety, quality, and compliance with the need to maintain cost-effectiveness and shareholder value. This approach not only strengthens our business case for investors and funding organisations but also ensures that our device can be delivered to market efficiently, sustainably, and in full compliance with all regulatory requirements.

The following analysis details our fixed and variable cost structure, unit economics, early-stage financial projections, and market comparison, providing a transparent foundation for ongoing financial decision-making and stakeholder engagement.

7.1 Cost Estimation

A comprehensive and realistic cost estimation is crucial for the financial sustainability and commercial viability of our non-invasive glucose monitoring device, Gluxco. The following tables detail the anticipated fixed and variable costs associated with the development, regulatory approval, manufacturing, and ongoing operation of the device. All estimates include appropriate contingencies to address technical, regulatory, and financial uncertainties as identified in the risk management plan.

7.1.1 Fixed Costs

The fixed costs represent the foundational investments required to bring the device to the market. These costs are incurred largely upfront or on an annual basis, regardless of the number of units produced. The costs include all research and development, regulatory compliance and quality management. The total fixed costs is projected to be $804,265 AUD, including 10% contingency for unforeseen technical, regulatory, or financial uncertainties [see Appendix D].

7.1.2 Variable Costs

Variable costs are incurred for each device produced and sold. These include the manufacturing cost per unit - which is a fixed, predictable amount for each device - as well as operational costs such as packaging, logistics, warranty, and customer support. These costs scale directly with production volume. To account for operational risks, a contingency reserve is included to accommodate potential fluctuations in supply chain or unexpected operational expenses. Overall, the variable cost is projected $172. 36 AUD [see Appendix E].

7.1.3 Break Even Analysis

To assess the financial viability of the project, a break-even analysis was performed using the cost estimates. The fixed costs for the first year which include all development, regulatory, and manufacturing setup expenses, are projected to be $804,265 AUD. Each device produced incurs a

variable cost of $172.36 AUD per unit, covering all core hardware components, assembly, packaging, logistics, calibration, and warranty. The planned selling price for the device is $350 AUD per unit. The break-even point is determined by calculating how many units must be sold so that total revenue equals the sum of fixed and variable costs. This is achieved by first finding the contribution margin per unit, which is the difference between the selling price and the variable cost. In this case, each device sold contributes $177.64 towards covering the fixed costs, after accounting for the variable expenses. By dividing the total fixed costs by the contribution margin per unit, we find that approximately 4,527 units must be sold for the business to break even in the first year [see Appendix F]. This means that once 4,527 devices have been sold, all initial investments and production costs will have been recovered, and any additional sales will generate profit. The total revenue required to reach this break-even point is $1,585,150 AUD.

Figure 9 shows Gluxco's projected revenues, costs, and profit over three years. The business is expected to reach profitability in year 2, with strong profit growth by year three.

Figure 9. *Gluxco Three-Year Revenue and Profit Projection*

Year	Units Sold	Revenue	Variable Costs	Fixed Costs	Total Costs	Net Profit/Loss
1	3,000	$1,050,000	$517,080	$804,265	$1,321,345	- $271,345
2	8,000	$2,800,000	$1,378,880	$300,000	$1,678,880	$1,121,120
3	15,000	$5,520,000	$2,585,400	$300,000	$2,885,400	$2,364,600

Additionally, a gross margin for the product will be 50.75%, highlighting a strong profitability profile for the product. Achieving the break-even sales volume will be a key milestone, after which the business can focus on scaling and generating sustainable profits. The break-even analysis thus provides a clear financial target and supports strategic planning for pricing, production, and market entry.

7.2 Long-term comparison with existing CGM devices

Over the long term, Gluxco offers a fundamentally different value proposition compared to established continuous glucose monitoring (CGM) devices such as the Dexcom G6 which is a current market leader in Australia and globally with a user base of approximately 2.8 - 2.9 million worldwide as of 2024 [50]. While both devices provide continuous, real-time glucose data for diabetic patients, their approaches to measurement, cost structure, and user experience diverge significantly.

Gluxco uses non-invasive technologies to eliminate the need for needles, adhesives, and frequent sensor changes. This not only greatly improves user comfort but also removes the ongoing burden of consumable costs. In contrast, Dexcom G6 requires regular sensor insertions and transmitter replacements, resulting in substantial recurring expenses and potential discomfort or skin irritation over time.

Financially, the difference is striking. Gluxco is expected to have a one-time cost of approximately $350, with a potential replacement every two years, leading to a five-year total cost of about $700

AUD. Dexcom G6, however, incurs a five-year cost of around $20,000 AUD due to the need for new sensors every 10 days and transmitters every three months. This ongoing cost can be a significant barrier for many users and healthcare systems, despite reimbursement options. Moreover, Gluxco's non-invasive approach generates far less medical waste, supporting environmental sustainability goals. However, it is important to note that Gluxco, as a new technology, must still demonstrate equivalent accuracy, reliability, and regulatory approval to match the clinical trust established by Dexcom. If validated, Gluxco could dramatically improve access, adherence and affordability for people with diabetes, especially in pediatric and cost-sensitive populations, while also reducing the environmental footprint of diabetes care.

Figure 10. *Long-Term Comparison: Gluxco vs Dexcom G6*

Aspect	Gluxco	Dexcom G6 (CGM)
Measurement method	Non-invasive: PPG, EM, temperature sensors	Invasive (subcutaneous sensor with needle)
Upfront device cost	$350 AUD (one time)	$350 - $500 AUD (starter kit)
Ongoing consumables	None	Sensor: ~ $100 (10 days) Transmitter: ~$300 (3 months)
5-year total cost	$700 (if replaced every 2 years)	~$20,000 AUD
User comfort	High (no insertion and adhesives)	Moderate (needle insertion, adhesive)
Pediatric suitability	Excellent	Good (approved for ages 2+)
Regulatory status	In development	TGA, FDA, CE approved
Reimbursement	Not yet	Yes (Medicare, NDSS, private insurance)
Environmental impact	Low (minimal disposables)	High (frequent sensor/transmitter waste)
Long-term value	Very high if validated (low cost, comfortability)	High, but with significant ongoing costs
Potential risks	Needs to prove accuracy and reliability	Sensor adhesion, ongoing cost burden

7.3 Funding/Investment Resources

Securing adequate funding is essential for the successful development, validation, and commercialisation of the Gluxco non-invasive glucose monitoring device. In Australia, a wide array of funding resources is available to support innovative medical technologies, ranging from government grants and research partnerships to venture capital and industry collaborations.

1. **Venture Capital**

Venture capital (VC) is a primary source of funding for medtech start-ups aiming to scale their operations, achieve regulatory approval, and enter new markets. Australian medtech-focused VCs, such as Uniseed and Brandon Capital, provide capital as well as commercialisation expertise and industry connections [51], [52]. These funds often invest in early-stage companies with strong research foundations and the potential for high-impact clinical outcomes. Engaging with VC investors can open doors to later-stage private equity and strategic acquirers.

2. **The NSW Health Medical Devices Fund**
   The NSW Health Medical Devices Funds provides substantial non-dilutive grants - between $500,000 and $5,000,000 per application - to support proof-of-concept, clinical studies, and early commercialisation of the product [53].
3. **Australian Government - Medical Device Partnering Program (MDPP)**
   The MDPP provides up to 250 hours of technical expertise, including research, prototyping, verification and validation and small-scale clinical evaluation [54]. Additionally, it helps connect start-ups with well-known manufacturers and commercial partners, making it an ideal resource for early-stage development and de-risking of new medical devices [54].
4. **CSIRO Kick-Start**
   CSIRO Kick-Start offers matched funding for research and development, typically between $10,000 and $50,000 [55]. This program is particularly valuable for proof-of-concept work and enables collaboration with CSIRO researchers, providing both technical and financial support to accelerate innovation [55].
5. **The Australian Diabetes Society and Clinical Partnerships**
   Organisations such as the Australian Diabetes Society can be valuable partners, offering opportunities for clinical trial funding or pilot studies, especially for paediatric and innovative diabetes technologies. Collaborating with clinical and academic institutions can also unlock additional grant opportunities and facilitate real-world validation.
6. **Industry Partners**
   Strategic collaborations with established medtech companies - such as Johnson & Johnson or Stryker - can provide non-dilutive funding, access to manufacturing infrastructure, regulatory expertise, and global distribution networks.

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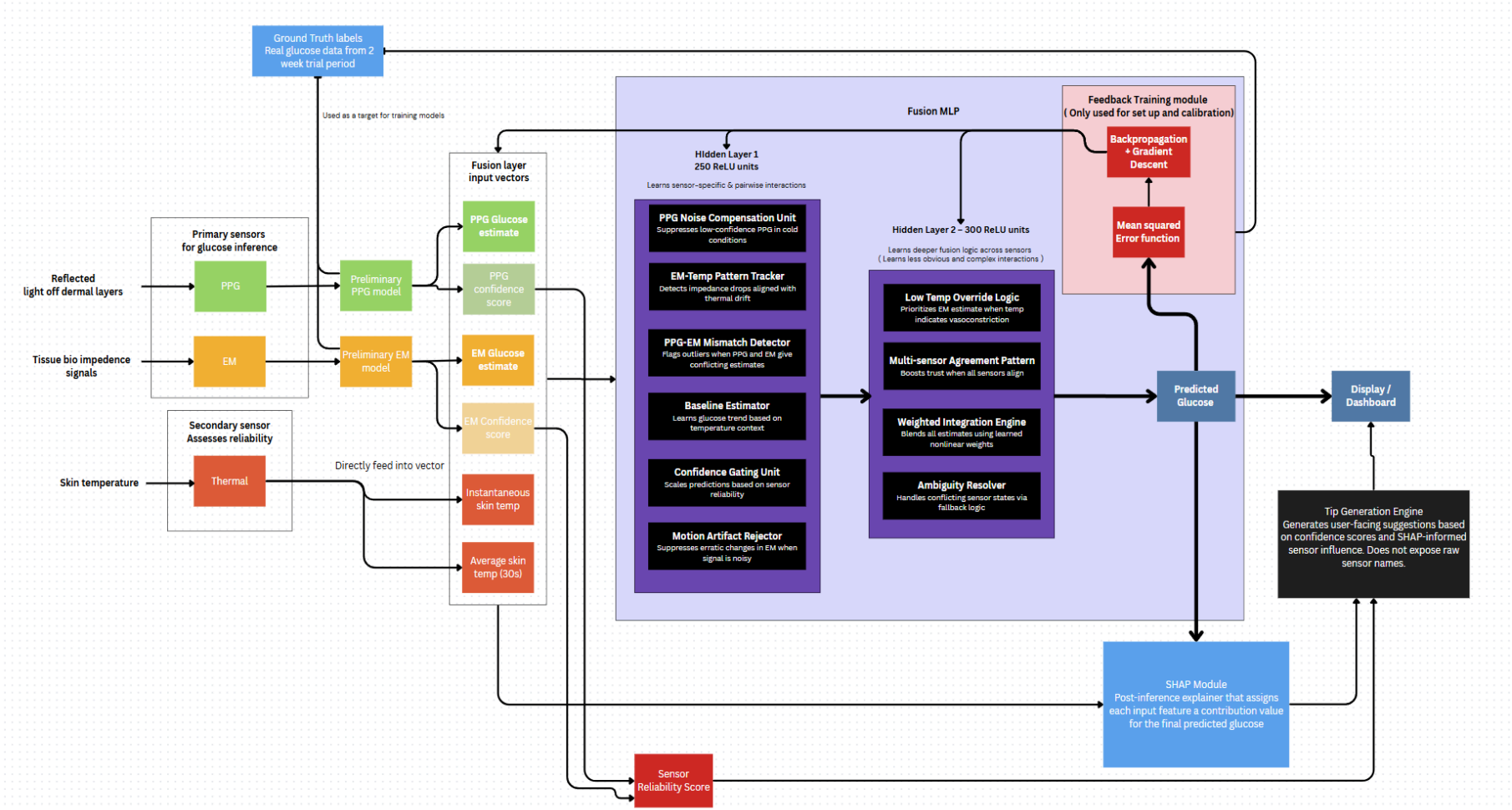
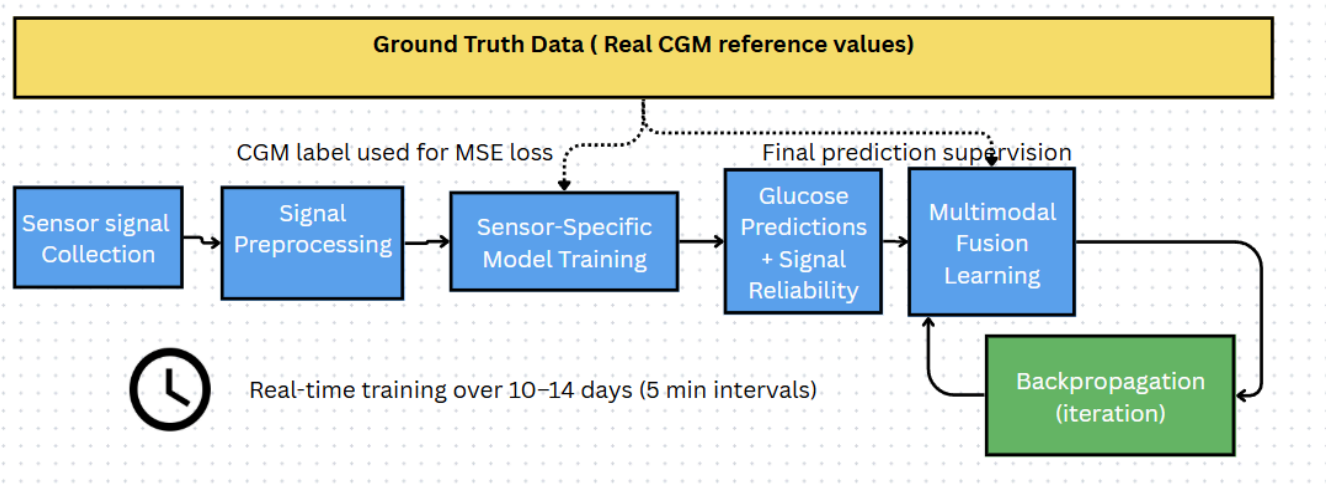
Appendix A.

A.1 Detailed system overview diagram

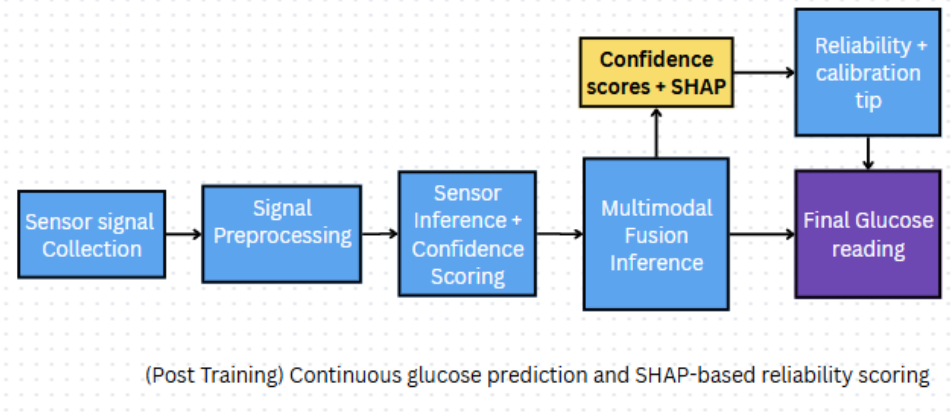


A.2 Supervised training pipeline over 10–14 days

Sensor features are aligned with CGM labels to train submodels and a fusion network with confidence weighting.



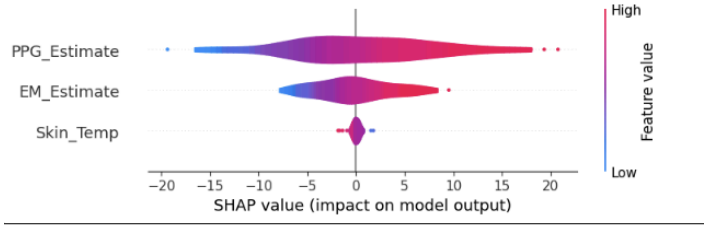
A.3 Deployment pipeline Diagram (Model becomes entirely independent post-training)



A.4 SHAP Value Illustration Using Simulated Sensor Data

```python
import numpy as np
import pandas as pd
from sklearn.ensemble import RandomForestRegressor
from sklearn.model_selection import train_test_split
import shap
import matplotlib.pyplot as plt

# --- Curated data generation ---
np.random.seed(42)
N = 500

# Bimodal skin temperature: most normal, some very cold
normal_temp = np.random.normal(36.5, 0.3, int(N * 0.8))
low_temp = np.random.normal(32.5, 0.5, int(N * 0.2))
skin_temp = np.concatenate([normal_temp, low_temp])
np.random.shuffle(skin_temp)

# EM stable predictor
em_estimate = np.random.normal(100, 10, N)

# PPG affected by low temp
ppg_base = np.random.normal(100, 12, N)
ppg_noise = np.where(skin_temp < 34.0, np.random.normal(0, 10, N), 0)
ppg_estimate = ppg_base + ppg_noise

# True glucose = weighted sum + noise
true_glucose = (
    0.6 * ppg_estimate +
    0.4 * em_estimate +
    np.random.normal(0, 4, N)
)

# Assemble DataFrame
df = pd.DataFrame({
    'PPG_Estimate': ppg_estimate,
    'EM_Estimate': em_estimate,
    'Skin_Temp': skin_temp,
    'True_Glucose': true_glucose
})

# --- Modeling and SHAP ---
X = df[['PPG_Estimate', 'EM_Estimate', 'Skin_Temp']]
y = df['True_Glucose']
X_train, X_test, y_train, y_test = train_test_split(X, y, test_size=0.3, random_state=1)

model = RandomForestRegressor(n_estimators=100, random_state=1)
model.fit(X_train, y_train)

explainer = shap.Explainer(model)
shap_values = explainer(X_test)

# --- Plot ---
shap.summary_plot(shap_values, X_test, plot_type="violin")
```

```
C:\Users\Elvis\AppData\Local\Temp\ipykernel_26336\1455846166.py:53: FutureWarning: The NumPy global RNG was see
bal RNG. Pass `rng` explicitly to opt-in to the new behaviour and silence this warning.
  shap.summary_plot(shap_values, X_test, plot_type="violin")
```



A.5: Confidence-Based Tip Generation and SHAP Attribution

Purpose:

The below examples demonstrate a mock example using randomly generated confidence scores from sensors and shap scores to simulate the system's real-time tip generation logic based on **engineered sensor confidence scores** and **SHAP feature attributions**. The system interprets sensor input quality and assigns actionable user feedback, while SHAP values provide insight into the influence of each sensor on the current glucose prediction.

```python
import matplotlib.pyplot as plt
import random

# === Randomly generate confidence scores between 0 and 1 ===
conf_scores = {
    'PPG_Estimate': round(random.uniform(0.0, 1.0), 2),
    'EM_Estimate': round(random.uniform(0.0, 1.0), 2),
    'Skin_Temp_Stability': round(random.uniform(0.0, 1.0), 2),
    'Motion_Stability': round(random.uniform(0.0, 1.0), 2)
}

# === Randomly generate SHAP scores to indicate feature importance ===
shap_scores = {
    key: round(random.uniform(0.5, 5.0), 2) for key in conf_scores
}

# === Tip suite logic ===
tips = []

# PPG Logic
ppg = conf_scores['PPG_Estimate']
if ppg < 0.4:
    tips.append("PPG unstable — tighten strap and reduce hand motion.")
elif ppg < 0.7:
    tips.append("PPG moderate — keep hand still during reading.")

# EM Logic
em = conf_scores['EM_Estimate']
if em < 0.4:
    tips.append("EM signal weak — ensure tight skin contact and dry surface.")
elif em < 0.7:
    tips.append("EM signal moderate — check sensor alignment.")

# Skin temp stability
temp = conf_scores['Skin_Temp_Stability']
if temp < 0.4:
    tips.append("Temperature unstable — wait for device to acclimate.")
elif temp < 0.7:
    tips.append("Moderate temperature variation detected — avoid abrupt environment changes.")
```

```python
# Motion stability
motion = conf_scores['Motion_Stability']
if motion < 0.4:
    tips.append("High motion detected — sit still for accurate measurement.")
elif motion < 0.7:
    tips.append("Moderate movement — reduce motion if possible.")

# === Visualization ===
def plot_confidence_and_shap(conf_scores, shap_scores):
    sensors = list(conf_scores.keys())
    conf_vals = list(conf_scores.values())
    shap_vals = list(shap_scores.values())

    conf_colors = ['green' if v > 0.8 else 'orange' if v > 0.5 else 'red' for v in conf_vals]

    fig, (ax1, ax2) = plt.subplots(2, 1, figsize=(8, 6))

    ax1.barh(sensors, conf_vals, color=conf_colors)
    ax1.set_xlim(0, 1)
    ax1.set_title("Sensor Confidence Scores")
    ax1.set_xlabel("Confidence (0–1)")
    for i, v in enumerate(conf_vals):
        ax1.text(v + 0.02, i, f"{v:.2f}", va='center')

    ax2.barh(sensors, shap_vals, color='steelblue')
    ax2.set_title("SHAP Feature Attribution")
    ax2.set_xlabel("SHAP Value (Impact on Prediction)")
    for i, v in enumerate(shap_vals):
        ax2.text(v + 0.2, i, f"{v:.2f}", va='center')

    plt.tight_layout()
    plt.show()

# === Output tips and plot ===
tips_output = "\n".join(f"• {tip}" for tip in tips)
plot_confidence_and_shap(conf_scores, shap_scores)

tips_output
```

Components Shown:

1. **Confidence Scores (Top Bar Chart):**
   Engineered trust scores for each sensor input (range 0–1), color-coded by quality:
   - Green: High (≥ 0.8)
   - Orange: Medium (0.5–0.8)
   - Red: Low (< 0.5)
     These scores determine whether a sensor is considered reliable in the current prediction.

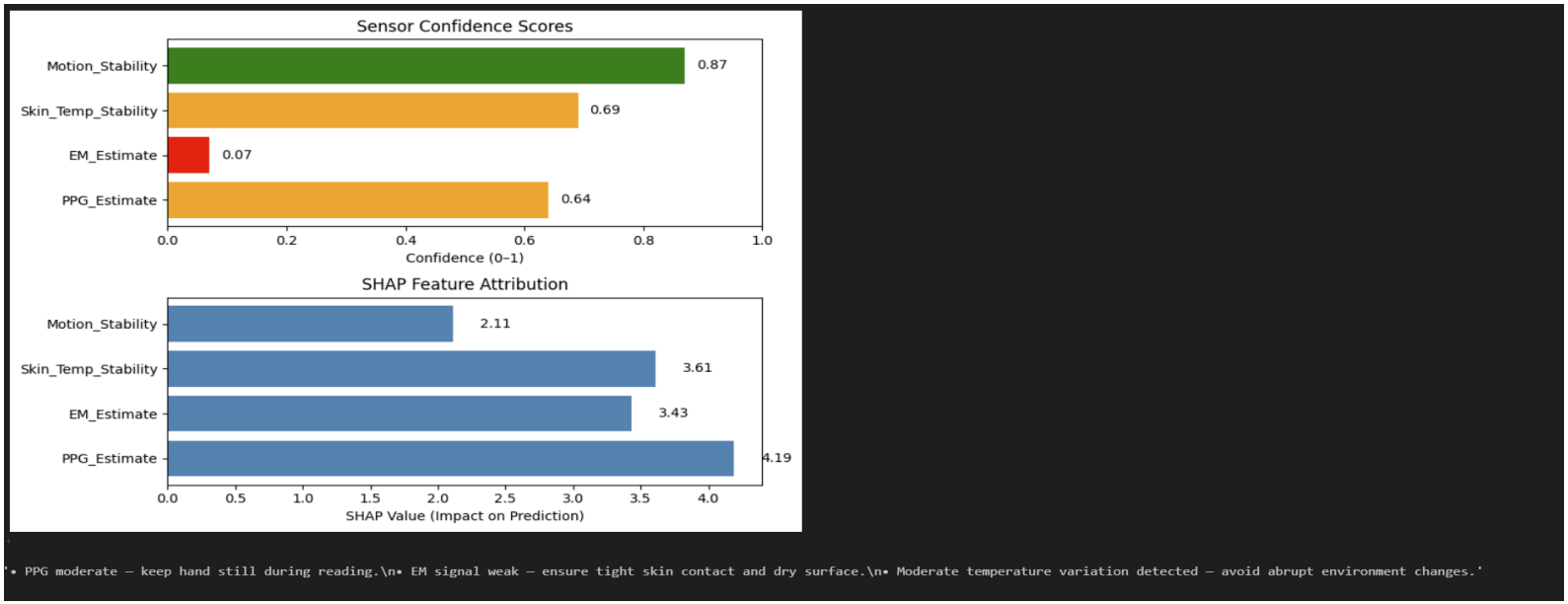
2. **SHAP Attribution (Bottom Bar Chart):**
   Reflects how much each sensor influenced the model's final output. While not used for confidence estimation, SHAP helps contextualize the model's dependency. For example, the model may prioritize PPG, EM, or both equally — even if confidence varies.

3. Tip Output (Printed):
Tips are generated by combining confidence scores (for signal trust) with SHAP attribution (to assess model reliance). If the model strongly relied on a signal that was weak or marginal in quality, the system escalates that tip. These internal cues are not shown directly to the user, but are translated into natural, actionable advice.

These cues allow the system to adapt its guidance based on both signal quality and model behavior — improving transparency without exposing raw sensor names or attribution values to the user.

System Cue (SHAP-informed)	Translated Tip for User
PPG prioritized **Moderate PPG confidence** **Low EM confidence**	**"Tighten the band and remain still during measurement."**
EM prioritized **Moderate EM confidence** **Low PPG confidence**	**"Ensure full skin contact with the device."**

Both sensors moderately relied on Moderate confidence	**“Minimize motion and avoid large temperature shifts.”**
Low-confidence sensor ignored by model (low SHAP)	***(No tip shown — model compensated)***
High-confidence sensor relied on (high SHAP)	***(No action required — model used clean input)***



A.6 Contingencies & Future-Proofing

To ensure robustness beyond the initial prototype scope, several contingency measures are planned or under investigation:

- Data generalisation: While current calibration uses ~2 000–4 000 samples per user over 10–14 days, future versions will support optional augmentation via pretraining on public photoplethysmography datasets, followed by per-user fine-tuning. A hold-out group of participants will be retained to validate generalisation beyond the training set.

- Confidence calibration: Current confidence scores are engineered from signal features (e.g., entropy, coherence), not learned. We plan to bin predictions by these scores and evaluate RMSE monotonicity. If misalignment is detected, we will explore conformal prediction or uncertainty heads for calibrated trust estimation.

- Security hardening: Firmware will enforce AES-128 secure boot and encrypted model storage on NOR flash. All Bluetooth communication will use LE Secure Connections with AES-CCM. Signal spoofing resilience will be addressed via spectral sanity checks and glucose rate-of-change clamping.

- Demographic fairness: PPG confidence will be monitored against Fitzpatrick skin-tone categories and BMI quintiles. If systematic bias is found, the fusion model will increase EM weighting or trigger rebalancing at runtime.

- Energy and latency margin: Performance numbers are based on benchmarked inference profiles. A 30 % guard band has been reserved to accommodate runtime variance due to flash latency, instruction cache misses, and future firmware extensions.

- Evaluation thresholds: Our design targets are RMSE < 15 mg/dL, MARD < 10 %, and ≥ 85 % in Clarke Zone A. Final deployment models will be validated on an unseen cohort to verify alignment with ISO 15197 standards.
- Energy & Latency Caveats: Latency (2.5 s) and energy (83–150 mJ) are projected from vendor benchmarks (CMSIS-NN, Espressif XIP); actual values may vary with memory access patterns and runtime conditions. Including LED drive (~45 mJ/min average) and optional BLE advertising (~0.3 J/day), the total daily energy usage remains under 5% of a 200 mAh 3.7 V cell. A 15% guard band is reserved to account for firmware growth and cryptographic overhead.

A.7 Validation Roadmap

- To transition from a design-stage prototype to a deployable, clinically relevant system, we propose a four-phase validation roadmap. Each phase is structured to progressively increase system realism, empirical grounding, and deployment confidence.
- **Phase 1: Simulation and Architecture Validation**
  Initial validation will focus on simulation-level testing and architectural benchmarking. This includes verifying model convergence and performance using synthetic or replayed biosignal data (PPG, EM, and skin temperature). We will deploy the model on embedded hardware such as the ESP32-C3 to confirm that latency, memory usage, and power consumption fall within wearable constraints. Fusion robustness will be assessed by simulating degraded inputs (e.g., dropout or noise in a sensor stream) and observing system behavior. SHAP attributions will be inspected post-inference to ensure that the interpretability layer correctly reflects feature importance under known input conditions.
- **Phase 2: Individual Calibration Testing**
  Following architectural validation, the system will be tested using supervised calibration sessions with individual users. Each user will provide 10–14 days of data, pairing CGM glucose values with multi-sensor inputs. We will compute RMSE, MARD, and Clarke Error Grid performance, comparing these to ISO 15197 and TGA thresholds. Confidence scores will be binned, and average error will be evaluated across bins to confirm that trust scores align with actual prediction reliability.
- **Phase 3: Generalisation and Stress Testing**
  A subset of users will be reserved as a hold-out group for cross-user generalisation testing. To assess fusion reliability, we will simulate various failure modes such as sensor dropout, motion artifacts, and ambient temperature shifts. Ablation studies will be conducted by selectively disabling one modality (PPG or EM) and measuring impact on performance. We also plan to evaluate fairness across skin-tone categories (e.g., Fitzpatrick scale) and body mass index (BMI) ranges to identify demographic sensitivity.
- **Phase 4: Embedded Field Trials**
  Finally, field trials will validate the system in real-world use. The model will run fully on-device, collecting data over 24-hour sessions to observe real-time behavior. BLE communication, data retention strategy (e.g., FIFO buffers), and energy usage will be evaluated under natural use patterns. Live SHAP attributions will be logged and compared to expected behavior to confirm that the model remains interpretable and stable when deployed.

Appendix B.

Risk Management Framework

Risk Management Process

Our risk management process follows these key steps in alignment with TGA expectations:

1. **Risk Identification**: Through system analysis and expert consultation
2. **Risk Analysis**: Assessment of probability and impact of each identified risk
3. **Risk Evaluation**: Determination of risk level using our risk matrix
4. **Risk Control**: Implementation of mitigation strategies and controls
5. **Residual Risk Assessment**: Evaluation of remaining risk after controls
6. **Risk Monitoring**: Ongoing assessment throughout the product life cycle

Risk Acceptance Criteria

Severity Categories:

- **Not significant (1)**: Minimal consequences; will not significantly delay project, cost implications easily managed
- **Minor (2)**: Temporary impacts requiring some effort to rectify
- **Moderate (3)**: Temporary impact requiring significant effort to rectify
- **Major (4)**: Permanent impact requiring significant redesign or revision
- **Severe (5)**: Total loss, potentially leading to project cancellation

Probability Categories:

- **Rare (1)**: Could happen, but probably never will
- **Unlikely (2)**: Not likely to occur in normal circumstances
- **Possible (3)**: May occur at some time
- **Likely (4)**: Expected to occur at some time
- **Almost certain (5)**: Expected to occur regularly under normal circumstances

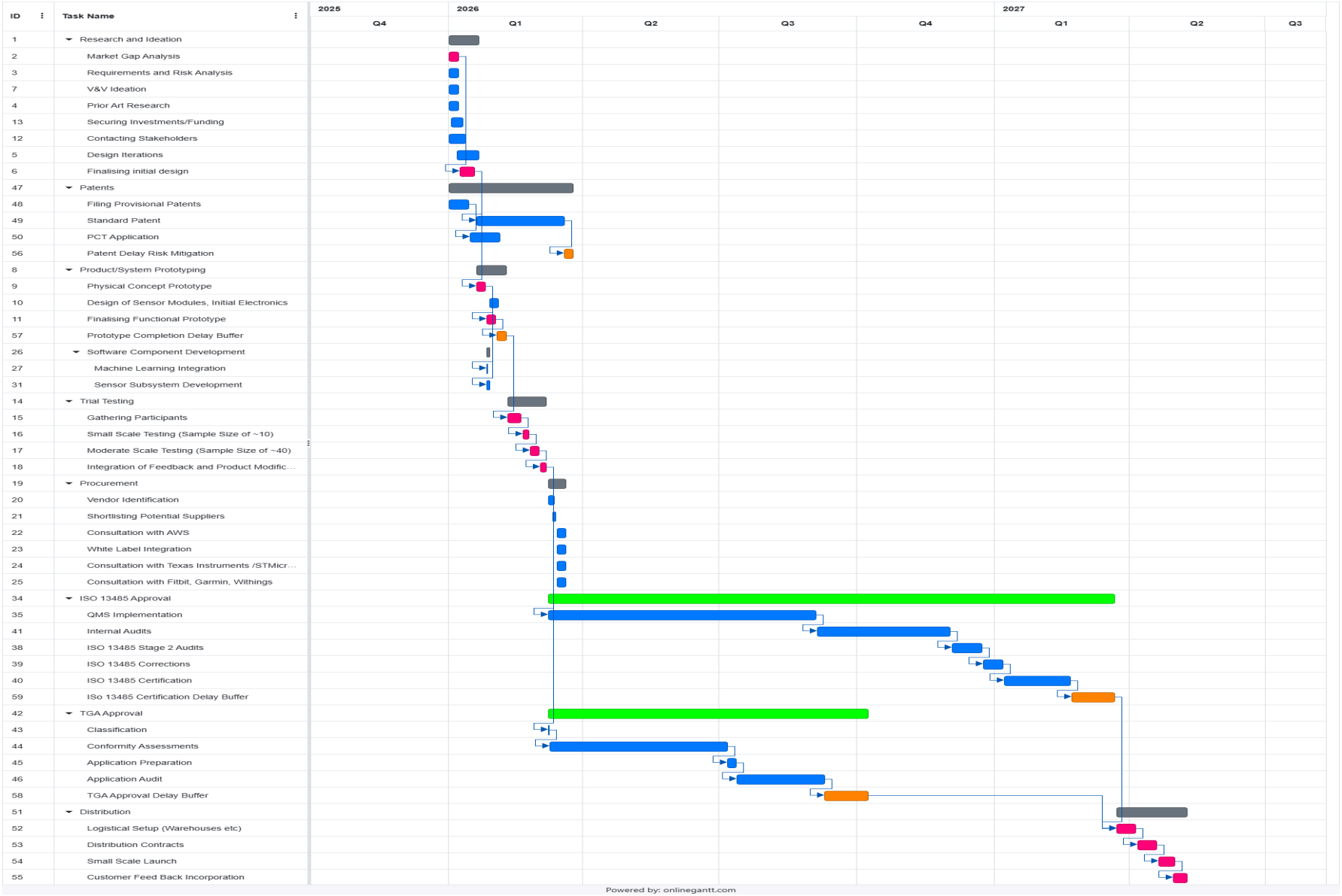
Risk Acceptability Matrix:

- **Low Risk (1-4)**: Acceptable with routine monitoring
- **Medium Risk (5-9)**: Acceptable with enhanced monitoring and controls
- **High Risk (10-14)**: Requires significant mitigation before proceeding
- **Very High Risk (15-25)**: Unacceptable without major redesign or control

Risk Matrix

			Potential consequences				
			Minimal consequences. (E.g. Will not significantly delay project, cost implications easy to manage)	Temporary impacts requiring some effort to rectify (E.g. Project delays, deferral of work, require design revisions)	Temporary impact requiring significant effort to rectify	Permanent impact (E.g. requires significant redesign, revision of project scope, requirement to source more funding)	Total loss (E.g. project cancellation)
			Not significant = 1	**Minor = 2**	**Moderate = 3**	**Major = 4**	**Severe = 5**
Likelihood	Expected to occur regularly under normal circumstances	**Almost certain = 5**	**Medium**	**High**	**Very high**	**Very high**	**Very high**
	Expected to occur at some time	**Likely = 4**	**Medium**	**High**	**High**	**Very high**	**Very high**
	May occur at some time	**Possible = 3**	**Low**	**Medium**	**High**	**High**	**Very high**
	Not likely to occur in normal circumstances	**Unlikely = 2**	**Low**	**Low**	**Medium**	**Medium**	**High**
	Could happen but probably never will	**Rare = 1**	**Low**	**Low**	**Low**	**Low**	**Medium**

Appendix C. Gantt Chart



Appendix D. Fixed Cost Table

Fixed Cost Table

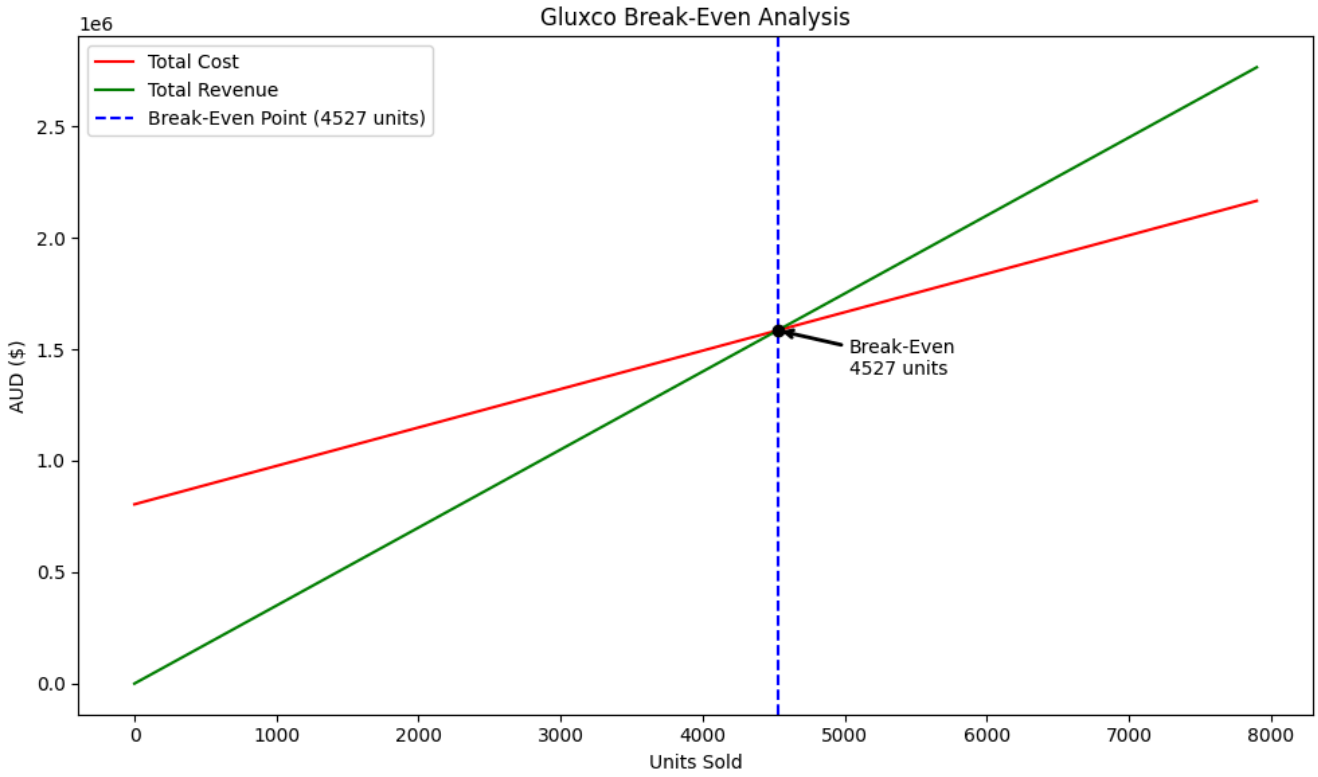
	Category	Cost (AUD)	Details
Research and Development	Electronic design & engineering	$150,000	Circuit design, PCB layout, Sensor integration, Component selection
	Embedded firmware development	$100,000	Firmware for sensor data acquisition, Signal processing, Device control, BLE integration
	Software development	$100,000	Cross-platform app, Bluetooth, Data visualisation, Alerts
	Algorithm/ML model development	$70,000	Sensor fusion, Glucose estimation, Pediatric calibration
	Prototype fabrication	$60,000	2 - 3 prototype iterations, 3D printing, PCB assembly, Initial bench testing
	Verification & validation (V&V)	$50,000	Functional, safety, and reliability testing, Iterative improvements
	Regulatory consultation, documentation, risk, submission	$50,000	Consultant support, Technical file prep, Risk management file, Clinical evaluation, Submission report prep
	TGA application fee	$1,150	Application fee for Class IIa device [43]
	QMS implementation	$100,000	ISO 13485 - Medical device QMS ISO14971 - Medical device risk management IEC62304 - Medical device software IEC60601 - Medical electrical equipment performance
Manufacturing	Initial manufacturing setup/technology transfer	$50,000	Technology transfer to J&J or Stryker, process adaptation, pilot runs, integration with partner's validated manufacturing systems, and quality assurance alignment.
Subtotal cost		$731,150	
Contingency (10%)		$73,115	Reserve for unforeseen technical, regulatory, or financial uncertainties
Total fixed costs (Year 1)		$804,265	

Appendix E. Variable Cost Table

Variable Cost Table (Including Contingency)

Component	Cost (AUD)	Details
Photoplethysmography (PPG) sensor module	$9.81	**MAX86150**, a multi-wavelength PPG sensor - ideal for wearables due to small size (3.3 x 5.6 mm) [44].
Electromagnetic (EM) sensor	$10.50	**ADS1292R**, a low-power biopotential analogue front end (AFE) optimised for wearable applications, leverages bioimpedance measurement to detect subtle physiological changes such as those in tissue hydration and dielectric properties [45].
Thermal sensor	$10.08	**MAX30205**, a clinical grade thermal sensor with ±0.1°C accuracy [46].
Microcontroller with Bluetooth function	$10.43	**ESP32-C3-MINI-1-N4**; energy efficient, integrated with Bluetooth [47].
Temporary data storage	$1.14	**Winbond W25Q32JVSSIQ**; prevents data loss during processing or connectivity interruptions and supports device update and troubleshooting [48].
Battery and charging	$5.40	Lithium battery USB-C Charger [49].
PCB & assembly	$30	Custom PCB ($10), professional assembly ($20).
Enclosure & housing	$15	Custom enclosure, 3D printed or moulded plastics.
Packaging & logistics	$10 - 30	Packaging materials, shipping, logistics handling.
Calibration	$40	Calibration tools and procedures.
Warranty	$5 - 10	Allowance for return, replacement, repairs.
Total Variable Cost Per Unit	$172.36	

Appendix F. Break-Even Analysis for Gluxco



Break-Even Analysis for Gluxco