

# Clinical Integration of Wearables Health Data



## Table of Contents

CLINICAL INTEGRATION OF WEARABLES HEALTH DATA .....	1
.....	1
EXECUTIVE SUMMARY .....	3
<b>1. BACKGROUND.....</b>	<b>4</b>
<b>2. OBJECTIVES OF THIS REPORT .....</b>	<b>4</b>
<b>3. CURRENT WEARABLE LANDSCAPE .....</b>	<b>4</b>
<b>4. DATA ECOSYSTEMS &amp; INTEGRATION PATHWAYS .....</b>	<b>6</b>
4.1 HOW WEARABLE DATA ECOSYSTEMS WORK .....	6
4.2 THE 4 -STAGE DATA PIPELINE TO CLINICAL RECORDS .....	7
<b>5. CLINICAL UTILITY &amp; LIMITATIONS.....</b>	<b>8</b>
5.1 CORE VITAL SIGNS .....	8
5.2 EXTENDED VITAL SIGNS .....	9
<b>6. AUSTRALIAN HEALTHCARE CONTEXT.....</b>	<b>11</b>
6.1 INTEGRATION MODELS FOR WEARABLE DATA IN AUSTRALIAN HEALTHCARE .....	11
6.2 READINESS TO INTEGRATE WEARABLE DATA .....	12
<b>7. RISK , GOVERNANCE &amp; DATA CONSIDERATIONS .....</b>	<b>12</b>
7.1 REQUIRED FHIR ATTRIBUTES FOR WEARABLE DATA .....	12
7.2 HANDLING MISSING OR UNRELIABLE DATA .....	13
7.3 INTEGRATION WITH THE AUSTRALIAN PRIVACY FRAMEWORK .....	13
7.4 INTEGRATION WITH MYHEALTH RECORD .....	15
7.5 TGA DEVICE CLASSIFICATION AND REGULATORY CONSIDERATIONS.....	16
7.6 DATA GOVERNANCE CHECKLIST FOR WEARABLE DATA INTEGRATION .....	17
<b>8. KEY FINDINGS.....</b>	<b>18</b>
<b>9. IMPLEMENTATION CONSIDERATION .....</b>	<b>18</b>
<b>10. RECOMMENDATIONS .....</b>	<b>18</b>
<b>11. ACKNOWLEDGMENT.....</b>	<b>19</b>
<b>12. ABOUT JR ANALYTICS .....</b>	<b>19</b>
<b>13. REFERENCES.....</b>	<b>19</b>

## Executive Summary

Wearable health technologies have rapidly expanded in capability and adoption, offering continuous or near-continuous monitoring of physiological parameters such as heart rate, activity, sleep, respiratory rate, and, in some devices, electrocardiography and blood oxygen saturation. This growth has generated increasing interest in their potential role within healthcare systems, particularly in remote patient monitoring and longitudinal health assessment.

This white paper evaluates commonly available wearable devices and their associated data ecosystems, with a focus on data accessibility, integration pathways, and clinical applicability within the Australian healthcare context.

A key finding is that, while wearable devices provide a broad range of physiological data, direct integration into clinical systems is not currently available. All integration pathways require intermediary layers, typically smartphone applications and middleware platforms to aggregate, standardise, and transform data into clinically usable formats such as HL7 FHIR. As a result, integration is technically feasible but operationally complex.

The analysis also highlights that wearable data is best suited to longitudinal monitoring rather than acute clinical decision-making. Core metrics such as heart rate and activity trends demonstrate relatively consistent performance and may support patient engagement and chronic disease monitoring. In contrast, parameters such as blood oxygen saturation, temperature, and single-lead ECG are more variable and require cautious interpretation, particularly in dynamic or clinical environments.

Within the Australian healthcare system, additional challenges arise from fragmented electronic medical record (EMR) systems and the structure of national platforms such as My Health Record, which are designed for document-based uploads rather than continuous data streams. These limitations reinforce the need for middleware-driven approaches and the transformation of raw wearable data into summarised, clinically relevant insights.

From a governance perspective, wearable data introduces important considerations around data quality, consent, security, and clinical responsibility. As consumer devices are not classified as medical-grade monitoring systems, their use within clinical workflows requires clear labelling as patient-generated data and appropriate clinician oversight.

This report finds that wearable technologies offer meaningful opportunities to extend healthcare beyond traditional settings, particularly through trend analysis and remote monitoring. However, their safe and effective use depends on appropriate integration models, clinical governance, and careful interpretation of data.

This report outlines a practical clinically safe, and scalable pathway for integrating wearable health data into Australian healthcare systems, with a focus on real world implementation rather than theoretical capability.

## 1. Background

Wearable devices have evolved from consumer fitness tools into platforms capable of capturing a wide range of physiological data. Advances in sensor technology, mobile computing, and cloud-based analytics have enabled continuous monitoring outside traditional healthcare environments. This shift aligns with broader trends in healthcare toward remote monitoring, preventative care, and patient-centred data ownership. However, despite technological progress, integration of wearable data into clinical systems remains limited and fragmented. In Australia, the digital health ecosystem includes a mix of general practice systems, hospital EMRs, and national platforms such as My Health Record. These systems are not uniformly designed to ingest continuous, patient-generated data, creating barriers to integration.

## 2. Objectives of This Report











This report aims to:

- Evaluate ten commonly available wearable devices and their capabilities
- Examine how wearable data is accessed and managed across platforms
- Identify integration pathways into healthcare systems
- Assess clinical utility and limitations of wearable-derived data
- Explore feasibility within the Australian healthcare context

## 3. Current Wearable Landscape

A range of consumer wearable devices were assessed, including smartwatches, fitness trackers, and sensor-based devices. Across devices, core metrics include heart rate, activity and movement and sleep patterns. Extended metrics available on selected devices include blood oxygen saturation (SpO<sub>2</sub>), respiratory rate, skin or wrist temperature and Electrocardiography (ECG). Data collection varies between continuous monitoring, periodic sampling, and user-initiated measurements. Many devices also provide derived metrics such as stress scores, readiness indices, and activity summaries.

Table 1

	Apple Watch Series 9	Apple Watch Ultra 2	Huawei Watch GT 4	Garmin Venu 3	COROS Pace 3	Samsung Galaxy Watch 6	Google Pixel Watch 2	Fitbit Sense 2	Whoop Strap 4.0	Oura Ring Gen 3
										
<b>Metrics- Core</b>										
HR	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
ECG	✓	✓	✗	✗	✗	✓	✓	✓	✗	✗
Activity	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
<b>Metrics- Extended</b>										
SpO2	✓	✓	✓	✓		✓	✓	✓		
Resp Rate	✓	✓	✗	✗	✓				✓	✓
Temp	✓	✓	✓	✗		✓		✓		✓
Sleep	✓	✓		✓	✓	✓	✓	✓	✓	✓
<b>Data Access Type</b>										
Processed data	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
(user-authorized)	✓	✓								
<b>Integration Readiness</b>	Moderate	Moderate	Moderate	Moderate	Low	Moderate	Moderate	Moderate	Low	Moderate
<b>Key Limitations</b>	iPhone required; limited raw	Expensive, iPhone only	Limited API	Limited clinical validation	Limited health metrics	Battery life	Fewer features vs Apple	Google dependency	Subscription required	Limited real-time data
<b>Key Strengths</b>	Comprehensive features, strong ecosystem	Rugged, advanced sensors	Long battery life	Fitness + health balance	Lightweight, performance focused	Android integration	Google ecosystem	Wellness insights	Recovery-focused analytics	Sleep + recovery insights
<b>Overall Suitability</b>	High for remote monitoring, limited direct clinical integration	High for remote monitoring	Moderate	Moderate–High	Low–Moderate	Moderate–High	Moderate	Moderate	Low (research/recovery use)	Moderate (longitudinal tracking)

## 4. Data Ecosystems & Integration Pathways

### 4.1 How Wearable Data Ecosystems Work

Wearable health data is managed within platform-specific ecosystems that control how health data is collected, stored, and accessed. These ecosystems act as intermediaries between the device and any downstream applications, including potential clinical systems. Two dominant ecosystems were identified: Apple HealthKit and Google Health Connect. Both platforms enable aggregation of wearable data and provide developer access through APIs and SDKs. However, neither platform supports direct integration with clinical systems in Australia. Instead, data must pass through additional layers, typically requiring custom applications or middleware solutions.

Feature	Apple HealthKit (iOS)	Google Health Connect (Android)
Supported Data Types	100+ health data types (HR, ECG, SpO <sub>2</sub> , RR, sleep, temp)	50+ health data types (HR, activity, sleep; no ECG currently)
Device Compatibility	Apple devices only	Multiple Android devices
Data Access	Via HealthKit SDK (Xcode/Swift)	Via Health Connect API
Data Storage	On-device (user-controlled)	On-device (user-controlled)
Data Retention	User-managed	Default ~30 days (extendable)
Third-party Integration	Extensive (HealthKit ecosystem)	Growing ecosystem (500+ apps)
EMR Integration	Not available	Not available
FHIR Compatibility	Possible via HealthKitOnFHIR (open source)	Requires middleware / custom mapping
Regulatory Status	Consumer wellness platform	Consumer wellness platform

Both Apple HealthKit and Google Health Connect present structural limitations when considered for clinical integration. Data within these platforms is primarily stored locally on the user's device and is only shared when explicitly requested by an application, creating a dependency on user consent and app-level access. This architecture, while privacy-preserving, introduces challenges for continuous and automated clinical data flow.

Integration into clinical systems is not natively supported and typically requires custom-built solutions or third-party middleware platforms. At present, there are no certified or standardised connections between these wearable ecosystems and Australian electronic medical record (EMR) systems. As a result, data integration pathways are often fragmented, involving multiple intermediaries, additional processing layers, or manual steps.

These limitations highlight a fundamental gap between consumer health ecosystems and established clinical interoperability frameworks. While wearable platforms are effective for personal health tracking and data aggregation, significant technical and governance enhancements are required to enable safe, scalable, and clinically meaningful integration into healthcare systems.

### Key Insights

- Both ecosystems act as data gateways rather than clinical systems, requiring additional layers for healthcare integration
- No direct integration exists with Australian EMRs or My Health Record, necessitating middleware solutions
- Apple HealthKit offers broader data coverage, including ECG, while Google Health Connect supports wider device diversity
- FHIR compatibility is indirect, relying on third-party tools or custom development
- Data remains user-controlled, requiring explicit consent and application-level access

### 4.2 The 4 -Stage Data Pipeline to Clinical Records

Integration of wearable data into clinical systems follows a multi-stage pipeline involving device capture, platform aggregation, data transformation, and eventual entry into electronic medical records (EMRs). This process is not direct and requires multiple intermediary steps to ensure data standardisation, validation, and secure transmission. The pipeline highlights the key technical and operational requirements for wearable integration, including the role of middleware and the importance of interoperability standards such as HL7 FHIR.

Stage	Component	Description
Stage 1	Wearable Device	Data captured via sensors (HR, ECG, SpO <sub>2</sub> , accelerometers); transmitted via Bluetooth to smartphone <b>Key Considerations</b> Continuous vs on-demand capture; limited on-device storage (3–7 days); data accuracy varies
Stage 2	Smartphone Application	Manufacturer apps (Apple Health, Samsung Health, Garmin Connect) aggregate and store data <b>Key Considerations</b> Platform-dependent; sync latency (seconds–minutes); user-controlled data sharing
Stage 3	Cloud / Middleware	Platforms (Azure Health Data Services, Validic) convert raw data into HL7 FHIR format with LOINC coding <b>Key Considerations</b> Data standardisation; validation checks; encryption (TLS 1.2+); dependency on third-party systems
Stage 4	Clinical System (EMR)	FHIR-formatted data integrated into EMR via API; clinician review required before use <b>Key Considerations</b> Requires workflow integration; governance and validation essential; alerts may be configured

For wearable data to be clinically usable, it must first be converted into standardised, interoperable formats. This is typically achieved through middleware platforms that map raw or processed wearable data into HL7 FHIR Observation resources using established coding

systems such as LOINC. For example, heart rate can be mapped to LOINC 8867-4, oxygen saturation (SpO<sub>2</sub>) to 59408-5, blood pressure to 85354-9, temperature to 8310-5, and respiratory rate to 9279-1. In addition to standardisation, validation processes are essential to identify physiologically implausible values and ensure data quality prior to clinical use. Secure data transmission and storage must also be implemented, commonly using encryption protocols such as TLS 1.2 or higher.

Even when technically integrated, wearable data must be incorporated into clinical workflows in a safe and usable manner. This requires clinician oversight of patient-generated data before it influences decision-making, clear labelling of such data as non-clinical grade, and the use of alerts or thresholds to highlight clinically relevant changes. Importantly, systems must avoid data overload by prioritising summarised outputs and trend-based insights rather than continuous raw data streams.

### Key Insights

- Middleware platforms provide the most practical current solution, enabling multi-device integration and alignment with clinical systems
- Custom builds are suitable for early pilots, but are resource-intensive and difficult to scale
- National standards pathways (FHIR / AU Core) represent the most future-ready approach, but require longer timelines and specialised expertise
- Manual approaches are useful for proof-of-concept only and are not appropriate for routine clinical use
- Integration strategy should align with intended scale, with different approaches suited to pilot, multi-site, and enterprise deployment

## 5. Clinical Utility & Limitations

The clinical value of wearable health data depends on both the reliability of measurements and the context in which they are used. Wearable devices provide access to a range of physiological parameters that have potential clinical relevance. However, the utility of these measurements varies depending on the type of metric, measurement conditions, and intended use. For practical purposes, wearable-derived data can be broadly categorised into core vital signs, which demonstrate higher reliability, and extended vital signs, which provide additional insights but carry greater variability and uncertainty.

### 5.1 Core Vital Signs

Core vital signs represent the most reliable and clinically useful parameters available from wearable devices. These metrics support continuous, non-invasive monitoring and are most suitable for longitudinal assessment.

#### **Heart Rate (HR)**

- Measured in beats per minute (BPM) using optical sensors
- Most reliable wearable-derived metric, particularly at rest
- Widely used in cardiovascular monitoring and trend analysis

## **Respiratory Rate (RR)**

- Measured in breaths per minute, typically derived during rest or sleep
- Most accurate during low-motion conditions
- Useful for identifying respiratory trends and early deterioration

These parameters form the foundation of wearable-based monitoring and are best suited for trend analysis rather than isolated measurements.

## 5.2 Extended Vital Signs

Extended vital signs provide additional physiological insights but are associated with higher variability and technical limitations.

### **Blood Oxygen Saturation (SpO<sub>2</sub>)**

- Reflects oxygen levels in the blood
- Useful for respiratory monitoring and trend detection
- Accuracy may be reduced during motion or poor sensor contact

### **Skin or Wrist Temperature**

- Tracks peripheral temperature trends rather than core body temperature
- Useful for illness detection and recovery monitoring
- Not a direct substitute for clinical temperature measurement

### **Electrocardiography (ECG) / Heart Rhythm**

- Single-lead ECG available in selected devices
- Can detect rhythm abnormalities such as atrial fibrillation
- Requires user activation and does not provide continuous monitoring

### **Blood Pressure (where available)**

- Typically estimated using calibration-based methods
- Less reliable than clinical-grade measurements
- Better suited for trend observation rather than diagnostic use



## Vital Signs accuracy summary table

Device	Core vitals accuracy	Extended vitals accuracy	Key accuracy limitations
Apple watch series 9	High (HR, RR at rest)	Moderate (ECG, BP, temperature)	Interval sampling (not continuous), reduced accuracy during movement, battery-based sensor throttling
Apple watch ultra 2	High	Low - moderate	Motion filtering may miss short changes, reduced accuracy in cold/tattoos, low-power mode disables sensors
Samsung galaxy watch 6	Moderate-high	Moderate	BP requires calibration, HR less accurate in HIIT, reduced sampling for battery
Google pixel watch 2	Moderate	Moderate	Software instability (sensor dropouts), reduced reliability, battery limits continuous tracking
Fitbit sense 2	Moderate - high	Moderate	Data gaps during sleep, requires good skin contact, inconsistent sensor availability
Garmin venu 3	High	Moderate	ECG is manual only, temperature only during sleep, misses short activities
Whoop strap 4.0	Moderate	Moderate	HR noise from movement, delayed calibration (7 days), no real-time SpO <sub>2</sub> /temp
Oura ring gen 3	High (resting)	Moderate	Poor accuracy during movement (HIIT), ring rotation causes gaps, temperature is baseline-only
Huawei watch GT 4	Moderate - high	Moderate	No ECG/BP, relies on optical sensing (affected by environment), manual tracking needed
<u>Coros</u> pace 3	High	Moderate	Small HR deviation, SpO <sub>2</sub> limited, GPS variance affects contextual accuracy

## Key Insights

- Core vital signs (HR, RR) demonstrate the highest reliability, particularly under resting conditions
- Extended metrics (SpO<sub>2</sub>, temperature, ECG) show greater variability and are influenced by external factors
- Most wearable-derived data is suitable for trend monitoring rather than point-of-care decision-making
- Accuracy varies significantly across devices, reinforcing the need for validation and clinical oversight

## 6. Australian Healthcare Context

The integration of wearable health data in Australia is shaped by a fragmented EMR landscape, limited interoperability, and reliance on intermediary systems.

### 6.1 Integration Models for Wearable Data in Australian Healthcare

Approach	Estimated Cost (AUD)	Timeline	Best Use Case	Key Features	Advantages	Limitations / Risks
Custom Build (App-based)	\$50,000–\$150,000	3–6 months	Single-site pilot / proof of concept	Custom iPhone app using Apple HealthKit; collects and displays patient-consented data	Full control over design and workflow; suitable for early pilots	Not scalable; high development effort; no direct EMR integration
Middleware Platform	\$30,000–\$100,000 + subscription	2–4 months	Multi-site / scalable deployment	Platforms (e.g. Azure Health Data Services, Validic, Open Wearables); device connectivity + FHIR conversion	Scalable; supports multiple devices; enables EMR integration	Vendor dependency; ongoing costs; Australian EMR connectors may need customisation
National Standards Pathway (AU Core / FHIR)	\$80,000–\$200,000+	6–12 months	Enterprise / government-scale deployment	Alignment with AU Core Data for Interoperability (AUCDI); integration with My Health Record (future-ready)	Most future-proof; aligns with national strategy; enables system-wide interoperability	Longest timeline; requires FHIR expertise; dependent on national infrastructure readiness
Manual Upload (Proof of Concept)	\$0–\$20,000	Immediate	Early validation / low-cost pilot	Patient exports data (PDF/CSV); clinician reviews manually	Fastest and lowest cost; no technical integration required	Not scalable; no automation; no audit trail; patient compliance

## 6.2 Readiness to integrate wearable data

The readiness of Australian EMR systems to integrate wearable data varies:

Best Practice (General Practice)	Integration points available (e.g., Halo Connect), but limited native support
Medical Director / Helix (Telstra Health)	API-based integration possible via third-party platforms
Sunrise (SA Health)	Requires middleware for FHIR-to-HL7 conversion
Epic (select Australian sites)	Most advanced integration capability; supports external data ingestion, with existing connections (e.g., Apple Health via MyChart)

Without a standardised national integration pathway, middleware-based solutions remain the most realistic approach for near-term implementation.

## 7. Risk , Governance & Data Considerations

For wearable data to be safely integrated into clinical systems, it must meet minimum standards for data quality, traceability, and interoperability. This requires not only technical mapping to interoperability standards such as HL7 FHIR, but also the implementation of validation and governance frameworks to ensure clinical reliability. Wearable data differs from traditional clinical data in that it is patient-generated, non-clinical-grade, and subject to variability. As such, additional metadata and validation rules are required before it can be incorporated into electronic medical records (EMRs).

### 7.1 Required FHIR Attributes for Wearable Data

1. To ensure clinical traceability and safe interpretation, each wearable-derived data point should include key FHIR attributes:

#### **Device Identification**

- Device name and model → mapped to FHIR Device resource (deviceName)
- Firmware or software version → FHIR Device (version)

#### **Temporal Accuracy**

- Measurement timestamp (time of capture, not upload) → FHIR Observation (effectiveDateTime)

### Clinical Semantics

- Standardised coding using LOINC:
  - Heart Rate → 8867-4
  - SpO<sub>2</sub> → 59408-5
  - Respiratory Rate → 9279-1
  - Temperature → 8310-5
- Units standardised using UCUM:
  - bpm, %, °C

### Regulatory and Data Classification

- Data flagged as patient-supplied
- Device classification (wellness vs medical device) clearly identified

### 7.2 Handling Missing or Unreliable Data

When a wearable device fails to provide valid measurement, the FHIR Observation Resource must be populated with the following codes:

- Sensor offline or battery throttled → not performed
- Technical error or implausible value → error
- Data not available for unknown reason → unknown

### Key Insights

- Wearable data requires additional metadata and validation compared to traditional clinical data
- FHIR provides a structured framework, but implementation requires careful mapping and governance
- Data quality is variable, necessitating automated plausibility checks
- Clear labelling as patient-generated data is essential for safe clinical use
- Validation systems are critical to prevent erroneous data influencing clinical decision
  
- Fragmentation of EMR systems
- Lack of direct integration pathways
- My Health Record limitations (document-based system)

### 7.3 Integration with the Australian Privacy Framework

The integration of wearable health data into clinical systems must comply with the Australian Privacy Principles (APPs) under the *Privacy Act 1988*. As wearable data is classified as sensitive health information, its collection, use, storage, and sharing require strict governance and transparency. Unlike traditional clinical data, wearable data is patient-generated and often stored across consumer platforms, including international cloud services. This introduces additional considerations for consent, data quality, and cross-border data handling

## Key Privacy Principles for Wearable Data Integration

<b>Domain</b>	<b>APP Reference</b>	<b>Key Requirements</b>	<b>Practical Implications</b>
<b>Data Collection</b>	APP 3 – Sensitive Information	Explicit patient consent required prior to data collection; consent must be informed, voluntary, and specific	Patients must clearly understand how wearable data will be collected and used within their care
<b>Use and Disclosure</b>	APP 6	Data can only be used for the primary purpose for which it was collected; secondary uses require additional consent	Separate consent required for analytics, research, or commercial use of wearable data
<b>Data Quality</b>	APP 10	Data must be accurate, up-to-date, and relevant	Wearable data should be clearly labelled as patient-generated and non-clinical-grade within clinical systems
<b>Data Security</b>	APP 11	Data must be protected from unauthorised access, loss, or misuse	Encryption (in transit and at rest), secure APIs, and role-based access controls are essential, particularly for real-time data streams
<b>Transparency</b>	APP 1 – Open & Transparent Management	Organisations must clearly communicate data collection, use, and sharing practices	Privacy policies must include details of third-party platforms (e.g., cloud providers, wearable ecosystems)
<b>Access and Correction</b>	APP 12 & 13	Patients must be able to access and correct their data	Systems must provide user-friendly mechanisms for data access and correction
<b>Cross-border Data Transfer</b>	APP 8	Organisations remain responsible for data stored overseas	Must ensure equivalent privacy protections; vendor compliance and data-sharing agreements are critical

## Key Insights

- Wearable data is classified as sensitive health information, requiring strict compliance with privacy laws
- Explicit, informed patient consent is essential for both collection and use
- Data ownership and control remain with the patient, requiring transparent data flows
- Cross-border data storage introduces additional regulatory risk, particularly with global wearable platforms
- Clear labelling and governance frameworks are required to safely integrate wearable data into clinical systems

## 7.4 Integration with MyHealth Record

Integrating the health data with platforms such as My Health Record allows it to become part of the clinical record for the patient. This increases legal responsibility, data accuracy expectations, and governance requirements.

### How the integration works

- Personal wearable device collects data.
- Vendor platform stores raw data and performs basic processing.
- Data is filtered, aggregated, interpreted, and converted to clinically meaningful insights. iv) Selected documents are uploaded to My Health Record.

### What can be uploaded on My Health Record

- Patient's overall health status
- Include long-term trends
- Significant clinical events
- Summarised physiological data

### What cannot be uploaded on My Health Record

- Continuous real-time data streams
- Raw wearable datasets
- Unverified consumer data

### Challenges with the integration

- Personal wearable devices generate massive datasets, causing data overload.
- The wearables are not always clinically accurate, causing data reliability concerns.
- No authority is responsible for validating the data.
- Multiple systems are involved, causing privacy risks.

### What can be done to bridge these gaps

- Converting wearable data into trends, alerts, and clinical summaries.
- Include a clinician in the loop, to review and validate information and data before it is uploaded.
- Using scheduled uploads.
- Defining upload criteria, so that only clinically significant changes are uploaded


## 7.5 TGA Device Classification and Regulatory Considerations

Most consumer wearable devices are not classified as medical devices under the Australian Therapeutic Goods Administration (TGA) when used for general wellness, fitness tracking, or lifestyle monitoring. In these cases, they are not included on the Australian Register of Therapeutic Goods (ARTG) and are considered low-risk, non-regulated products.

However, classification is determined by how the data is used, rather than the device itself. When wearable data is used to support clinical monitoring or inform healthcare decisions, the system may be considered a Software-based Medical Device (SaMD) and become subject to regulatory requirements.


### **Class I (Low Risk)**

- Data is used for general wellness or informational purposes only
- No clinical decisions are made based on the data
- Suitable for self-monitoring, patient engagement and trend visualisation

 Not suitable for diagnosis or clinical alerts

### **Class IIa (Low–Medium Risk)**

- Data supports clinical monitoring and may be reviewed by healthcare professionals
- Suitable for chronic disease monitoring and remote patient monitoring programs

 Requires increased validation, governance, and oversight

### **Class IIb (Medium–High Risk)**

- Data is used for continuous monitoring and directly influences clinical decision-making
- Suitable for higher-risk patient populations and near real-time monitoring environments

 Not typical for consumer wearables unless integrated into regulated clinical systems

### **Implications for Wearable Data Integration**

The regulatory classification of wearable systems is driven by use case and clinical context, not simply by the device.

- Most consumer wearable applications currently operate within Class I (non-regulated or low-risk use)
- When integrated into healthcare systems and used for clinical decision-making, systems may transition to Class IIa or higher
- This shift introduces requirements for clinical validation, risk management frameworks and regulatory compliance and documentation

## 7.6 Data Governance Checklist for Wearable Data Integration

Effective integration of wearable data into healthcare systems requires a structured governance framework to ensure privacy, security, data quality, and regulatory compliance. The following checklist summarises key governance domains and recommended actions.

Domain	Key Requirements	Recommended Actions
<b>Governance &amp; Accountability</b>	Clear ownership and oversight	Assign data owner and steward; define roles for access and sharing; establish governance framework; conduct periodic reviews
<b>Consent &amp; Patient Control</b>	Informed and ongoing consent	Obtain explicit consent; clearly explain data use; enable opt-out and withdrawal; allow patient access to their data
<b>Data Collection &amp; Minimisation</b>	Collect only relevant data	Limit to clinically relevant data; define data types and frequency; avoid unnecessary data capture; document purpose
<b>Data Classification &amp; Labelling</b>	Proper identification of data type	Classify as sensitive health data; label as “Patient-Generated Health Data (PGHD)” and “Non-clinical grade”; separate from clinical data
<b>Data Quality &amp; Integrity</b>	Ensure reliability and traceability	Define accuracy thresholds; implement validation checks; flag unreliable data; maintain timestamps and device metadata
<b>Security Controls</b>	Protect data from breaches	Encrypt data in transit and at rest; implement role-based access and MFA; secure APIs; conduct regular security testing
<b>Data Storage &amp; Location</b>	Manage data residency and retention	Prefer Australian-based storage; ensure cross-border compliance; define retention and deletion policies
<b>Data Sharing &amp; Integration</b>	Controlled and standardised sharing	Share minimum necessary data; use FHIR standards; integrate via EMRs/My Health Record; establish data-sharing agreements
<b>Clinical Use Boundaries</b>	Safe use in clinical settings	Ensure clinician oversight; avoid fully automated decisions based solely on wearable data
<b>Audit &amp; Monitoring</b>	Track access and compliance	Maintain audit logs; monitor for breaches; report incidents per regulatory requirements
<b>Regulatory Compliance</b>	Align with TGA requirements	Assess device classification; restrict consumer devices to low-risk use; ensure compliance if used clinically
<b>Data Lifecycle Management</b>	End-to-end data handling	Define processes for collection, transmission, storage, use, sharing, archival, and deletion
<b>Documentation &amp; Training</b>	Organisational readiness	Maintain policies (privacy, governance, incident response); train staff on safe use of wearable data

## Key Insights

- Governance is essential for safe and scalable integration of wearable data
- Patient consent and transparency are central requirements across all stages
- Data quality and validation must be actively managed, not assumed
- Security and compliance obligations increase significantly once data enters clinical systems
- Wearable data should be integrated within controlled, clinician-supervised frameworks

## 8. Key Findings

- No direct integration exists between wearable devices and clinical systems
- Middleware is essential for any integration pathway
- Wearable data is best suited for trend monitoring, not acute care
- Data accuracy varies across parameters and devices
- Australian integration is limited by system fragmentation
- Clinical governance is critical for safe implementation

## 9. Implementation Consideration

- While the technical pathways for integrating wearable data are increasingly well defined, real-world implementation requires consideration of additional clinical and system-level factors.
- The introduction of continuous patient-generated data may increase clinician workload and contribute to alert fatigue if not appropriately filtered and summarised. Integration models should therefore prioritise clinically meaningful insights rather than raw data streams.
- Financial sustainability is another important consideration, particularly in primary care settings where reimbursement models for remote monitoring remain limited. In addition, reliance on consumer wearable devices raises potential concerns around equity of access and digital inclusion.
- Finally, medico-legal responsibility in the context of wearable data remains an evolving area. Clear governance frameworks will be required to define accountability when such data is incorporated into clinical workflows.

## 10. Recommendations

- Begin with pilot implementations in controlled settings
- Focus on summarised data rather than raw data streams
- Adopt middleware-based integration approaches
- Prioritise clinician-reviewed workflows
- Develop clear governance and data validation frameworks
- Align with national standards (FHIR, AU Core) for future scalability

## 11. Acknowledgment

JR Analytics acknowledges the contribution of the student team from the University of Sydney Applied Engineering Projects Through Practera program who conducted the study on wearable health data integration. Their work provided a valuable foundation for this report.

## 12. About JR Analytics

JR Analytics is a clinician-led digital health company focused on developing innovative solutions to improve healthcare delivery, data integration, and clinical decision-making. The organisation specialises in digital health platforms, prehospital and acute care systems, and emerging applications of data and artificial intelligence in healthcare.

## 13. References

### Technical and Interoperability Standards

- Health Level Seven International (HL7). *Fast Healthcare Interoperability Resources (FHIR) Release 4*.
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### Australian Regulatory and Legal Frameworks

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- Therapeutic Goods Administration (TGA). *Regulatory guidelines for Software-based Medical Devices (SaMD)*.
- Australian Digital Health Agency (ADHA). *My Health Record System Documentation*.
- HL7 Australia. *Australian Core Data for Interoperability (AUCDI)* and AU Core FHIR Implementation Guide

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- Google LLC. *Health Connect API Documentation*.
- Microsoft Corporation. *Azure Health Data Services*. Technical documentation for cloud based FHIR conversion and data standardization.
- Validic. *Digital Health Platform Integration Documentation*.