EXAMPLES OF
APPROVED WEARABLE MEDICAL DEVICES
FOR CLINICAL USE

PhD Project: Quality Management of Patient Generated Health Data from Wearables for Clinical Use

By:
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Background

Advances in medical technologies are increasing remote patient monitoring programs. These technologies enable healthcare professionals to monitor the health status of patients outside clinical settings. Depending on patients’ health conditions, clinicians may prescribe devices such as blood pressure monitor, Glucometers, etc., then use the collected data help them with decisions about patient care.

However, before being ready for use, like any other medical devices, these wearables must be evaluated and approved by a regulatory agency. The approval means that both patients and clinicians can make treatment decisions based on data reported by the device. Some of the well-known medical device agencies are Therapeutic Goods Administration (TGA) in Australia, Food and Drug Administration (FDA) in the USA, The European Medical Device Regulation (MDR), Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK, The Therapeutic Products Directorate (TPD) in Canada, and the Asian Harmonisation Working Party (AHWP).

We are conducting a PhD project on the quality of data collected by these new regulated wearable medical devices. We aim to understand the data flow from when collected by patients, to finally used by clinicians; how they are recorded, stored, transferred, analysed, represented, also whether they integrate with clinical information systems. Throughout the flow of these data how they are managed to be clinically valuable and fit the purpose for which they have been developed.

As a clinician (doctor, nurse, allied health practitioner) or a health information professional (chief information officer, health IT manager, health information manager) who is involved in the management practices of data from wearables, we are studying your experience and point of view on how the data could potentially be valuable in your patient care.

Methods

We searched through the mentioned regulatory agencies websites for a cross-section of wearable devices approved to be used by patients.

The keywords used for search are “wearable”, “remote monitor”, “home monitor”, “sensor”, “portable device”, “ambulatory device”, and “outpatient monitor”. Also, the mentioned terms used in combination with the health condition-related terms. For example, “Glucose remote monitor” to retrieve more relevant results.

Inclusion criteria:

In this project, we are looking for wearables medical devices which are:

- Non-invasive
- Mobile; collect data continuously at anywhere and any time
- Used outside clinical setting

Exclusion criteria:

- Invasive devices
- Non-mobile devices; do not collect data continuously
- Only used within clinical settings
In this report we have provided some examples of the approved wearable medical devices for illustrative purposes to assist with our research.

**Diabetes wearable medical devices**

<table>
<thead>
<tr>
<th>Device name</th>
<th>TGA (Australia)</th>
<th>FDA (USA)</th>
<th>Canada (TPD)</th>
<th>MDR (EU)</th>
<th>MHRA (UK)</th>
<th>AHWP Asia Pacific</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. FreeStyle Libre Pro Flash Glucose Monitoring System Sensor</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>2. Medtronic Enlite Sensor</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>3. Animas Vibe&lt;sup&gt;TM&lt;/sup&gt;</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>4. Dexcom G5 Mobile Continuous Glucose Monitoring System</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>5. Guardian REAL-Time Continuous Glucose Monitoring System, in vivo</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
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<tr>
<td>6. Eversense</td>
<td></td>
<td></td>
<td>✓</td>
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</tbody>
</table>

**Cardiovascular disease-related wearable medical devices**

<table>
<thead>
<tr>
<th>Device name</th>
<th>TGA (Australia)</th>
<th>FDA (USA)</th>
<th>Canada (TPD)</th>
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</tr>
</thead>
<tbody>
<tr>
<td>1. eMotion Faros-Electrocardiographic long-term ambulatory recorder</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. AVIVO&lt;sup&gt;TM&lt;/sup&gt; Mobile Patient Management (MPM) System</td>
<td></td>
<td>✓</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
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<tr>
<td>3. TelePatch Cardiac Monitor</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. VitalPatch&lt;sup&gt;®&lt;/sup&gt; VitalConnect Platform</td>
<td></td>
<td>✓</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. HealthSTAT Blood Pressure and Central Aortic Systolic Pressure Monitoring</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>6. Icentia CardioSTAT</td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
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<tr>
<td>7. Bioflux</td>
<td>✓</td>
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<tr>
<td>8. Kardia Band System</td>
<td></td>
<td></td>
<td>✓</td>
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</table>
## Motion disorder-related wearable medical devices

<table>
<thead>
<tr>
<th>Device name</th>
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<th>AHWP Asia Pacific</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. ViMove</td>
<td>✔</td>
<td>✔</td>
<td></td>
<td></td>
<td>✔</td>
<td></td>
</tr>
<tr>
<td>2. Neuromuscular motion disorder long-term ambulatory recorder-analyser</td>
<td>✔</td>
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</tr>
</tbody>
</table>
Device name: FreeStyle Libre Pro Flash Glucose Monitoring System
Manufacturer: Abbott Australasia Pty Ltd
Health Condition: Diabetes type 1 & 2
Intended purpose: The Sensor measures and stores glucose readings when worn on the body. The Sensor has a small, flexible tip that is inserted just under the skin. When used with The Libre Pro Reader, the Health Care Professional is able to review a patient's ambulatory glucose profile over the last 14 days. The FreeStyle Libre Pro Flash Glucose Monitoring system is a glucose monitoring device indicated for detecting trends and tracking patterns in persons (age 18 and older) with diabetes. The system is intended for use by health care professionals.

Device name: Animas Vibe System
Manufacturer: Animas Corporation
Health Condition: Diabetes type 1 & 2
Intended purpose: The Animas Vibe System is a continuous glucose monitor (CGM) and insulin pump combination for people with diabetes. The CGM is an externally-worn device with an internal sensor that continuously measures glucose values in the fluid around the cells (interstitial glucose) for up to seven days (the life of the sensor). The insulin pump delivers insulin as a single dose (bolus) when needed or continuously throughout the day (basal insulin). The insulin pump displays glucose values from the CGM along with glucose trending information, alerts and alarms, and insulin pump data and information. The CGM sensor is a small wire that is inserted under the skin of the abdomen and measures interstitial glucose values. These values are sent through the transmitter to the insulin pump. Glucose trends, alerts and alarms help users stay within their target glucose ranges.
**Device name:** Dexcom G5 Mobile Continuous Glucose Monitoring System  
**Manufacturer:** Dexcom, Inc.  
**Health Condition:** Diabetes type 1  
**Intended purpose:** This device uses a small flexible metal wire (sensor) that is inserted just below the skin where it generates a small electrical signal in response to the amount of sugar that is present (interstitial glucose). This electrical signal is converted into a blood glucose reading and transmitted wirelessly every 5 minutes to a dedicated receiver and/or compatible mobile device (smart phone, tablet, etc.) for display to a user. The system must be calibrated at least two times per day by testing a fingertip blood sample with a blood glucose meter. People with diabetes can use the information from this device to make diabetes treatment decisions (for example, administer insulin or carbohydrates). Information from the device can also be used to help determine patterns in glucose levels and make long-term adjustments to diabetes treatment plans to keep blood glucose levels in a safe range. The system can alert users when glucose values are approaching potentially dangerously high (hyperglycaemic) and/or dangerously low (hypoglycaemic) levels.
**Device name:** Guardian REAL-Time Continuous Glucose Monitoring System, in vivo  
**Manufacturer:** Medtronic Australasia Pty Ltd  
**Health Condition:** Diabetes type 1 & 2  
**Intended purpose:** An assembly of portable, electronic devices used to periodically/continuously measure and record interstitial-fluid glucose concentrations in diabetic patients. It typically includes an electrochemical sensor, a transmitter, and a receiver that captures, stores, and converts the sensor signals to glucose concentrations for display. The system aids in the detection of episodes of hyperglycaemia and hypoglycaemia. Data recorded may be used for later analysis by physicians using dedicated software.

**Device name:** eMotion Faros - Electrocardiographic long-term ambulatory recorder, telemetric  
**Manufacturer:** Network Optimiser Solutions Pty Ltd  
**Health Condition:** Cardiovascular disease  
**Intended purpose:** The eMotion Faros is an ambulatory recorder and transmitter for ECG and motion (accelerometer) data. Faros can perform EKG measurement, R-R interval data measurement and capture patient motion. The eMotion Faros is indicated for adult and paediatric patients who require vital sign monitoring inside or outside hospital or healthcare facility environment. The eMotion Faros does not provide interpretative statements. Final interpretation and diagnosis is the responsibility of a physician.
**Device name:** AVIVO™ Mobile Patient Management (MPM) System  
**Manufacturer:** Medtronic, Inc.  
**Health Condition:** Cardiac Arrhythmia  
**Intended purpose:** The AVIVO™ MPM System is a wearable, wireless physiological monitoring and arrhythmia detection system that is used by patients to aid clinicians in the identification, diagnosis and management of various clinical conditions, events and/or trends. It consists primarily of the Wearable Sensor (monitoring device) and the Transmitter (portable data transmission device). In combination with interpretation services provided by Medtronic Monitoring, Inc.’s Monitoring Centre, as well as secure online review of data by healthcare providers, the AVIVO™ MPM System enables patient- and physician-friendly physiological monitoring and arrhythmia detection for extended periods of time.

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**Device name:** TelePatch Cardiac Monitor  
**Manufacturer:** Medicomp, Inc.  
**Health condition:** Cardiac arrhythmia  
**Intended purpose:** TelePatch Cardiac Monitor PM750 is a small, auto triggered, device, prescribed by physicians for patients who are experiencing symptoms that may be attributable to cardiac arrhythmia. Shortness of breath and palpations are examples of these symptoms. This device may be worn for a period of days or weeks - whatever time is necessary to capture and record the ECG. The PM750 has two operating modes to allow for event analysis of the recorded ECG or in Holter mode to allow for full disclosure analysis of the recorded ECG. The device is comprised of the function contained within the CardioPAL SAVI (Model PM410) ECG loop recorder and the SAVI Wireless (Model PM500) event monitor and an off the shelf cellular phone. The device can be used with a break-away lanyard and has interaction with a PC interface cable.
**Device name:** VitalPatch® VitalConnect Platform  
**Manufacturer:** Vital Connect, Inc.  
**Health condition:** -  
**Intended purpose:** VitalPatch is a wearable biosensor which may be used as part of the VitalConnect Platform. The device is a disposable, battery-powered, adhesive patch containing sensors used to gather patients’ physiological data, which are transmitted wirelessly. The wear duration for the VitalPatch wearable biosensor is from 96 hours to 120 hours. The VitalConnect Platform is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of physiological data in home and healthcare settings. This can include heart rate, electrocardiography (ECG), heart rate variability, R-R interval, respiratory rate, skin temperature, activity (including step count), and posture (body position relative to gravity including fall). Data are transmitted wirelessly from the VitalConnect Sensor for storage and analysis. The VitalConnect Platform can include the ability to notify healthcare professionals when physiological data fall outside selected parameters. The device is intended for use on general care patients who are 18 years of age or older as a general patient monitor, to provide physiological information. The data from the VitalConnect Platform are intended for use by healthcare professionals as an aid to diagnosis and treatment. The device is not intended for use on critical care patients.
**Device name:** HealthSTAT Blood Pressure Monitoring Device  
**Manufacturer:** HealthSTAT Australia  
**Health Condition:** Hypertension  
**Intended purpose:** The device is intended to measure systolic and diastolic blood pressure and pulse rate, and to utilize the radial pulse waveform to derive the central aortic systolic pressure (CASP). It is for use on patients who are eighteen (18) years or older, have a palpable radial pulse, and do not have common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation. The results are intended for use by qualified healthcare personnel as an aid to diagnosis and treatment.

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**Device name:** CardioSTAT  
**Manufacturer:** Icentia  
**Health condition:** Cardiac disease  
**Intended purpose:** CardioSTAT is a new cardiac monitor designed for long-term continuous ECG recording. Compact, light and comfortable, it ensures optimal patient compliance and high-quality recordings.  

With better detection of atrial fibrillation and faster ECG reports, CardioSTAT provides clinicians with the ideal tool for accurate cardiac rhythm diagnosis.
**Device name:** Bioflux  
**Manufacturer:** Biotricity, Inc.  
**Health condition:** Cardiac disease  
**Intended purpose:** The bioflux system consists of the bioflux device and the server. The bioflux device is a portable, battery-powered, wireless cardiac monitor which may be worn by a patient to record ECG and activity level data for up to 30 consecutive days. The device can capture patient activated and auto-triggered events such as Bradycardia, Tachycardia, pause and Atrial Fibrillation as identified by an embedded arrhythmia detection algorithm. The device is designed to automatically deliver the data to the server. The data is delivered to the server wirelessly via mobile cellular dedicated network connection. A medical professional, using the server, can adjust and program the device configuration and auto-triggering parameters. Bioflux device is not a life-supporting or life-sustaining system. Clinical judgment and experience are used to check and interpret the data.

**Device name:** Kardia Band System  
**Manufacturer:** AliveCore, Inc.  
**Health condition:** Cardiac disease  
**Intended purpose:** The Kardia Band System is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The Kardia Band System also displays ECG rhythms and detects the presence of atrial fibrillation and normal sinus rhythm (when prescribed or used under the care of a physician). The System is intended for use by healthcare professionals, adult patients with known or suspected heart conditions and health conscious individuals. The Kardia Band System consists of the Kardia Band Hardware (watchband), the Kardia watch app software (installed on the Apple Watch), and the Kardia phone app software (installed on the Apple iPhone). The Kardia Band System transmits the ECG signal from its electrode to the Kardia watch app on the Apple Watch to be analyzed and presented to the user. All ECGs are synced with the user’s account.
Device name: ViMove™
Manufacturer: dorsaVi, Inc.
Health condition: Movement disorders
Intended purpose: ViMove, developed by dorsaVi, uses wireless sensor technology to accurately and objectively measure movement and muscle activity of the lower back. This effectively removes the guesswork from clinical assessments and allows health experts to obtain a better understanding of the unique features of your movements and postures that may be contributing to your back pain.

Device name: Neuromuscular motion disorder long-term ambulatory recorder-analyser
Manufacturer: CKG Manufacturing Pty Ltd
Health Condition: Parkinson
Intended purpose: The Parkinson's Kinetigraph (PKG) System is intended to monitor physical motion and activity, to quantify kinematics of movement disorder symptoms, such as tremor, and assess activity in any instance where quantifiable analysis of motion and activity is desired.