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Technology Review of Remote Patient Monitoring Devices

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North East London **NHS**
NHS Foundation Trust



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1 Introduction

With aging populations, the increasing incidence of chronic diseases and the need to control health care costs, connected health technologies are becoming increasingly important for remote patient monitoring. While it has long been accepted that for patients living with chronic heart failure, monitoring is necessary, the traditional model has been to arrange periodic clinical reviews in either primary or secondary care or via nurse-led monitoring through a combination of telephone contact, clinic reviews and occasional home visits.¹ However remote patient monitoring has developed rapidly in the past 10 years, enabling physiological measurements to be taken from patients who are not at the same location as the healthcare provider. Such systems can take a number of forms, from patient initiated measurements that are carried out with devices that are used a set number of times a day, and where measurements might be stored and taken to periodic meetings with the healthcare provider, to more recent data acquisition methods from on-body or implanted devices, such as a sensing patch or pacemaker, where measurements can often be taken and transmitted without the active involvement of the patient. Such data is communicated with relevant health care professionals who can then decide whether to take any further action. The ability to monitor patients more closely at a range of time points and activity levels is intended to achieve a better understanding of the patient's condition and more timely attention that may facilitate the earlier detection of clinical deterioration, reduce the need for subsequent emergency hospitalization and achieve better disease management.

There are typically a number of elements of hardware and communication protocols used as part of a remote patient monitoring system, whose activities can be divided up into a number steps. There is firstly the sensing devices that collect a patient's physiological data, the subsequent transmission of this data from the patient's environment to a remote location, the subsequent processing and evaluation of the data collected to make it available to healthcare professionals for review and finally the possibility of alerting parties to health status concerns who can then intervene for possible corrective action. The standard set of peripherals for monitoring a patient with cardiovascular disease typically includes ECG and blood pressure monitors, weight scales and a pulse oximeter. Such systems and devices that are either currently available or that are coming onto the market show a range of technology development trends, which this review will consider in the following sections:

1. Data acquisition and communication technology developments
2. Portability
3. Technology Developments Associated with Specific Peripheral Monitoring Devices

A component of this technology review has involved capturing details on 142 relevant products developed by 83 companies (see Appendix I) and 2,224 patents (see Appendix II).

2 Data Acquisition and Communication Technology Developments

2.1 Physiological Measurement Devices

The first step after a remote monitoring device has taken a patient's reading is either to store and/or transmit the data. Improvements in memory capabilities and cost now allow for storage of significant amounts of high-quality physiologic data locally on devices.² For example, the Zio Patch from iRhythm continuously monitors and records an up to 20,000 minutes worth of patient heart beats.³

Where a device transmits data, most cases this will be first to a transmitter-receiver that is located near to the patient. This transmission of data can take place in a wired fashion or, increasingly, in a wireless manner, often using low-energy, short-range communication protocols.

Wireless communication offers many ease-of-use advantages to patients and, where the device can be carried with or on the patient as they carry out their daily activities, it can help in obtaining more accurate physiological signal measurements. Sensors may themselves be able to act as transmitter-receivers, allowing bi-directional communication with their paired transmitter-receiver (as with Biotronik cardiac implants) or act solely as transmitters. Important aspects of wireless communication protocols for such systems include the data bit rates, data transmission error frequency, the distance of communication and power consumption.

The emergence in recent years of a number of low-energy wireless communication standards, has been a highly important driver in developing remote monitoring capabilities, particularly for on-body or implanted sensing devices that have strict power consumption and size restraints, however such restraints restrict the distance over which these devices can transmit to their paired transmitter-receiver:

1. Devices may communicate with transmitter-receivers via a body area network (BAN); such protocols are used by medical devices that are located on or in the patient's body. Methods may apply infrared light, microwave radio or near-field coupling through skin conduction.⁴ These types of communication methods have a very short transmission range, with inductive technologies requiring the external transmitter-receiver to touch the skin of the patient. Developments in this area include new communication methods, such as the use of ultrasonic FM sound communication.⁵
2. Alternatively, devices may use a wireless personal area network (WPAN), which applies short-range radio frequency transmission technologies such as the Bluetooth,⁶ Bluetooth Low Energy (BLE),⁷ ANT⁸ or ZigBee^{9,10} specifications or the 402-405 MHz frequency band as specified by the Medical Implant Communication Service (MICS).¹¹ Such methods have a communication range of between 2 to 10 meters. Although the Bluetooth Low Energy protocol was only released in 2011, it has been widely adopted by many manufacturers of wireless medical devices.¹²

The requirements of having a patient-side transmitter-receiver that communicates using a method with low energy consumption can also result in a device limited in its frequency of communication with its transmitter-receiver. While this might not be an issue with measurement devices that are worn intermittently at set times during the day for the taking and transmission of patient readings (such as the Tunstall myclinic¹³ or Honeywell Hommed Genesis systems¹⁴), issues do arise where continual patient monitoring is desirable. For instance, data suggests that the usefulness of non-invasive monitors in identifying arrhythmias lies largely in the duration of the monitoring.¹⁵

One example that combines different radio communication methods is a patent from Cardiac Pacemakers Inc. that proposes the use of two communication systems in implantable medical devices (IMDs), where one is used for short-range distances, when the patient is at home within 9-12 feet of the repeater communicating with the Advanced Patient Management system but there is additionally a wireless transmitter-receiver in the implant that can communicate over a wider distance with the repeater or host computer using either wireless WANs or LANs or the cellular telephone network to ensure that at least a notification of the significant event(s) can be sent. A second rechargeable battery dedicated to communicating over long distances would be used so to not compromise the functioning of the IMD to provide therapy to the patient.¹⁶

In this context, antenna development is also significant research interest for use with both in-body and on-body devices, especially as such components additionally suffer from energy absorption, reflection, diffraction or shadowing and multipath fading due to body movements. Furthermore antennas located in implants are affected by severe signal decay and shortening effects due to the surrounding biological tissue, and antennae design is an active field of research by device manufacturing companies.¹⁷ Such systems are increasingly applying multiple antennae ('antenna diversity') to improve the quality and reliability of communication^{18,19}, methods to apply multiple communication systems and switching systems (such as frequency hopping) to improve data transmission rates and communication coverages,^{20,21} as well as investigating ways to effectively improving antennae size and structure, without increasing its size, for optimal signal transmission.^{22,23,24}

Battery Life

Power consumption is of critical importance for portable physiological sensing devices, which are expected to be small and provide long and uninterrupted operation. Low power consumption is important both for the long-term performance of devices and, in the case of implantable devices, for the safety of the patient.²⁵ Therefore a range of research and development activities have been undertaken to maximize battery life. Many such developments have been focused towards efficiently transmitting data, which uses a large proportion of total power consumption:

1. Energy efficient signal processing algorithms. Many sensing devices carry out calculations within the processing unit that is integrated with the sensor to reduce the size of transmitted data readings²⁶. For instance the Lifetouch ECG sensor has a 72 hr operating time due to the calculations it carries out within its processor in the sensor chip thus reducing the amount of data it needs to send wirelessly.
2. Low power sensor-chip components, such as low power amplifiers.²⁷

3. Onyx II, Model 9560 has a power saving feature that automatically adjusts transmitted power based on distance from the main unit. This unique feature allows for approximately 600 spot checks on 2 AAA batteries.
- 3 Efficient power usage by turning the transmissions from device on and off at appropriate points^{28,29}.

Other examples of current developments includes research work focused towards miniaturizing batteries,³⁰ power-scavenging techniques where energy harvested from natural or artificial power sources surrounding the patient could be used directly to power the device.^{31,32}

2.2 Transmitter-Receiver Communication

There has been a general move from use of stored values in measurement devices which are uploaded periodically by a clinician to be evaluated (such as the Opti24-hour ABPM blood pressure monitor from QRS Diagnostic³³), to measurement devices that are paired transmitter-receivers that are in constant communication with the device and can regularly or continually transmit readings onto the remote clinician database through wired or wireless communication methods, with wireless methods utilising cellular phone networks (GPRS or UMTS³⁴), wireless wide area networks (WiMAX³⁵) and or local area networks (GSM³⁶, WiFi³⁷).

While many sensing devices are paired with an external transmitter-receiver due to the size restrictions of a measuring device and the size of the unit needed to be able to communicate using long distance communication protocols, some devices have an integrated transmitter-receiver, such as the CardioSen'C from SHL-Telemedicine, which features a built-in cellular modem.³⁸

The transmitter-receiver paired with a patient's measuring sensor might be in the form of a mobile handset, personal digital assistant or other monitoring device. Such set ups often include a processor which controls operation of the wireless sensing device, memory which provides instructions and data to the processor and also performs logical and arithmetic operations, and centrally, a transmitter and receiver to allow long-distance transmission of data between the patient and a remote medical database.³⁹

The wireless capability of such transmitter-receivers has significantly risen in the last few decades due to the enormous growth in internet traffic and widespread use of cellular communication systems and the scaling of integrated circuits at a manageable cost, power, and size.^{40,41}

The use of smart phones as a patient-side transmitter-receiver is being increasingly used in such telehealth systems as patient-side transmitter-receivers, exploiting both the computational and communication capabilities of these widespread devices, which can result in an inexpensive personal monitoring device. The ways companies have used smart phone technologies as part of such a system fall into a number of categories:

1. Measurement devices that can be physically attached to a patient's phone, able to take an ECG or blood pressure reading and then, using the installed app on the patient's phone, process the data and use the mobile phone or Wi-Fi network to send the data onwards.

Examples include the AliveCor mobile heart monitor with single-lead ECG that snaps onto iPhone⁴² and Android phones as well as the Kenek blood pressure monitor from LionsGate Technologies⁴³ which plugs into the audio port of a patient's smart phone.

2. Adapted mobile phones that are designed as dedicated healthcare devices, able to take and transmit readings, such as the LifeWatch V from LifeWatch AG which is a modified Android-based phone that has a number of integrated sensors "combined with wellness-related applications and cloud-based services",⁴⁴ or the CarePortal from Docobo,⁴⁵ which is a modified Android tablet that includes a 1 lead ECGs and bio-impedance sensor.
3. Most commonly, however, device developers have been pairing a separate medical device and an existing patient's smart phone, often communicating wirelessly through Bluetooth or BLE protocols. Examples of such devices include the smartheart from SHL-Telemedicine; a 12 lead ECG device that uses Bluetooth to send digitally encoded ECG data to a patient's smartphone or tablet,⁴⁶ or the Body Analyser Bluetooth Smart Scales from Aseptika, that uses the patient's phone to automatically record readings via an installed App.⁴⁷

At this point in the remote patient monitoring system, there is also a need to manage the communication challenges that appear where there are multiple medical devices that are generating readings from a patient, as well as the additional pre-programmed data such as patient identifiers, alarm thresholds and device settings. Also data needs to be managed effectively by a patient-located transmitter-receiver to reduce network traffic and therefore power usage.^{48,49}

2.3 Clinician-side Remote Data Collection

Once readings have been transmitted from the measuring device to the patient-side transmitter-receiver, they then need to be relayed onto a remote data collection point. At this point in the system there needs to be a method of efficient data storage, modelling, triage and appropriate presentation of data to medical personnel. Such data processing may be carried out entirely through algorithms and automatically-generated data displays which a clinician then reviews, or the data may be initially reviewed by medically-trained staff at a medical data centre, to provide third party clinical decision support (as in the myclinic system, supplied by Tunstall, where a central monitoring center undertakes the technical and clinical triage, and operators notify clinicians if necessary⁵⁰). Often additional clinical support is required for such data analyses due to the additional workload created by this influx of data. As an example, algorithms used by implantable devices are known to generate a high rate of inappropriate arrhythmia diagnoses.⁵¹

In this field is active research undertaken with regards to providing sophisticated algorithms to provide both patient and carers with a better understanding of a patient's current condition and any likely health concerns. Examples of such innovations include, methods to present to clinicians accurate and meaningful information rather an infinite set of data points, therefore trends and spikes in data need to be provided, as well as alerts if patients aren't checking their biometrics as often as needed.^{52,53} Such presentation work can involve involve classifying patients according to patient states and calculating a real-time risk assessment of the patient to provide a real-time clinical decision support system⁵⁴, as well as improved graphical representations of electrocardiogram data to enable simple programming of an implantable medical device.⁵⁵ Devices that display goal

indicators to provide information on the amount of time that physiological data was within the predetermined goal limit.⁵⁶ Furthermore as remote monitoring increases the risks of identity fraud, it is important that any data communication is carried out securely, that data communication only occurs when devices are authenticated to one another, that data is encrypted⁵⁷ to ensure secure data transfer. While such secure transmission is often achieved through the sending of unique crypto keys, researchers are also considering the use of biometric signals to extract unique characteristics to allow discrimination of users.^{58,59,60}

As storage and computation becomes increasingly cloud based, health monitoring systems using cloud architecture are being offered, bringing with it advantages of cost, platform-independence, location-independence for the clinician to review the data and fast deployment.⁶¹

3 Portability

The developments in communication strategies described in section 2 have enabled greater portability for telehealth measurement devices. These have allowed a greater number of patient readings to be taken, with wearable "on-body" and implanted "intra-body" sensors offering the potential for continuous physiological monitoring.

Increasingly, remote patient monitoring systems use set-ups that allow patients to carry out their daily activities while the measuring devices are being worn by the patient connected. However there is a range of portability capabilities; those that can easily be carried with the patient, fitting into a pocket or bag for intermittent, but which are designed to take on-the-go readings and as well as those that are "on-body" or "in-body" devices. Furthermore while some devices allow the patient to move freely around the home while the device is being worn, the patient can still be restricted in their movements as they will need to be within signalling distance of the patient-side receiver-transmitter for readings to be transmitted to the clinicians data view. In contrast where there are also measuring systems that can be considered fully portable, using wireless and cellular mobile technologies to allow patients to move outside of the home while still transmitting data onto the clinician-side database.

3.1 Transiently-worn measuring sensor systems with a dedicated home-based transmitter-receiver

Transiently-worn peripherals paired with a static patient-side receiver-transmitter are one of the most established telehealth systems on the market. Many such systems started to appear on the market from 2006 onwards. Such measurement sensor devices are characterised by being regularly but intermittently used by the patient to provide the patient's transceiver-transmitter with readings at particular times of the day with devices interacting with a central patient-side transmitter-receiver that communicates data onwards to the remote clinical database. Such systems require a relatively high degree of patient compliance for such readings to be taken. The transmitter-receiver can include a patient-facing interface that offers the opportunity for clinicians to ask patients questions regarding their perception of their own health via customizable patient surveys (for example the myclinic system from Tunstall, and the Motiva Telestation from Philips), enabling further remote compliance with care protocols. Furthermore, with the use of unique patient identifiers with such telemonitoring systems means that one system can be used by a collection of patients (e.g. in a nursing home situation).

The cost of a dedicated patient-side transmitter-receiver can be replaced by a PC-implemented platform (such as the HeathAnywhere system from BioSign⁶²), however it appears that the use of mobile phones or tablets as the patient-side receiver-transmitter (as outlined in section 2.2), is being adopted by such systems, as these can aggregate of readings taken from multiple Bluetooth enabled devices, carry out the required signal processing and transmission of such data, but with greater flexibility and portability than that provided by traditional systems and at lower cost.

Many medical sensing devices used in such home-based systems now have integrated Bluetooth, both to allow simple transmission of data to the patient-side transmitter-receiver (for instance the Bluetooth-enabled weight scales from Beurer GmbH⁶³) and to improve patient mobility while measurements are being taken (such as the Onyx II Model 9560 pulse oximeter, which just needs to be within 100 meters of the home-based transmitter-receiver for transmission of measurements⁶⁴).

Other developments for such systems include an increase in the number of multi-measurement devices that more fully utilizes the time window of patient interaction with a medical diagnostic device, therefore requiring fewer individual readings to be taken, such as the Omron weight scale that measures weight, body fat percentage, BMI, resting metabolism, and visceral fat.⁶⁵ Newer versions of such static home monitoring systems boast minimal setting up requirements, often companies offer either to carry out the installation of the remote patient monitoring system at the patient's home, or provide a 'plug and play' installation experience with remote configuration of devices and software updates. These measures are designed to reduce or remove entirely any burden on the healthcare staff for the monitoring system set up.

Devices identified



MyMedic II (Tunstall)



Genesis™ DM Pro/DM Pro BP monitor (Honeywell Hommed)



Central Communication Module (SHL-Telemedicine)



Health Guide (Intel)

- Motiva Telestation system from Philips
- HeathAnywhere system from BioSign
- Healthcare Access packages from BL Healthcare
- Health Guide system from Intel
- Genesis Touch, Genesis DM Pro/DM Pro from Honeywell Hommed, to be used with the peripherals such as the A&D Medical Digital Blood Pressure Monitor, ChoiceMed Fingertip Pulse Oximeter, Honeywell Scales, Contec CMS50E SpO₂ monitor, Noin Onyx II SpO₂ monitor
- icp mymedic II, icp myclinic healthcare systems from Tunstall Healthcare Ltd
- Central Communication Module from SHL-Telemedicine that can be used with the TelePress, TelePulse Oximeter, TeleWeight, CardioBeeper 12/12 and Cardio'B devices

3.2 Portable Spot-Check Devices

Portable spot-check devices offer the patient the capability of taking physiological measurements throughout the day, at any location, thus increasing compliance. Such are often available for direct consumer purchase and offered at relatively low price points. These devices are cordless, of compact design and light-weight in order to be easily carried. They offer the opportunity of long-term monitoring with a high degree of ease of use. For instance, HeartScan from Omron⁶⁶ has a dry finger electrode and an electrode that is held against the chest during the taking of ECG measurements that last 30 seconds. Devices feature good memory capabilities, such as the Nellcor Portable SpO2 monitor from Covidien that offers 80 hours of storage capability.⁶⁷

While the mobility aspect of such devices can be seen to enhance patient compliance, it should be noted that patients are expected to transfer measurement data via their computer once they return home.

Devices identified

			
Nellcor Portable SpO2 patient monitoring system (Covidien)	ME80 blood pressure monitor from Beurer GmbH	Heart Check Pen (CardioComm)	HeartScan (Omron)

- Nellcor Portable SpO2 patient monitoring system from Covidien
- HeartCheck ECG and Heart Check Pen devices from CardioComm
- HeartScan from Omron
- ME80 blood pressure monitor from Beurer GmbH

3.3 Portable Spot-Check Devices paired with Smart Phones

It may seem a little technological development to move from an intermittent measurement device described in the previous section, which must be plugged into a computer to upload measurements, to one which can either communicate to a smartphone or tablet located on a patient (QardioArm blood pressure monitor from Qardio), or which has a GPRS modem integrated into the device itself (such as the Thumb ECG device from Zenicor⁶⁸ and the HealthHUB from Docobo include a built-in GPRS modem). However such devices offer the patient the capability of sending real-time measurements to their clinician if they sense an abnormal event. However, such devices still require patients to remember to take the measurements, and will not be able to capture any pre-event information.

Many such devices are considered by clinicians to have limited sensing capabilities, for example 1 lead ECGs, and as such many devices have issues associated with gaining widespread clinical acceptance.

These devices are often paired with consumer-friendly analysis software and do offer patients with considerable empowerment to self-manage their health.

Devices identified

			
impulse ECG monitor from Plessey Semiconductors	CarePortal (Docobo) Includes standard lead I ECG which is operated by simply holding the device in your hands, as well as bio-impedance measurements	Mobile ECG Telemetry Solution (METS) from MegaKoto	Blood Pressure Monitor from Withings

- HealthHub and CarePortal from Docobo
- CardioSen'C, SmartHeart, Cardiobeeper 12/12 from SHL Telemedicine
- AliveCor mobile heart monitor from AliveCor
- HeartView P12/8 Mobile from Aerotel
- Mobile ECG Telemetry Solution (METS) from MegaKoto
- H'andy sana 210 from Medxhealth
- Activ8rlives Blood Presssure Bluetooth 4.0 monitor from Aseptika
- Kenek Edge pulse oximeter and blood pressure monitor from LionsGate Technologies
- impulse ECG monitor from Plessey Semiconductors
- Blood Pressure Monitor from Withings
- BodyGuardian from Preventice

3.4 Wearables

Most wearables currently designed to capture physiological measurements are not classified as medical devices, but are instead aimed at the direct-to-consumer health and wellness sector. However the market for medical device wearable technologies is expected to grow to more than \$5 billion by 2018.⁶⁹

In contrast to devices that are worn intermittently for the purpose of spot-checks, these “on-body” devices allow the harvesting of patient data on demand or continually, while requiring little or zero patient interaction. Such measurement devices tend to be discrete and non-disruptive for the patient, as they are often small, lightweight and worn in a manner familiar and therefore acceptable to the patient – such as a wristband.⁷⁰

One of the major hurdles to the adoption of sensing technology has been the size of the sensors and front-end electronics that, in the past, have made the hardware required to gather physiological and movement data too obtrusive to be suitable for long-term monitoring applications. In addition, the increased period of time that the wearable is used has generated additional power consumption issues. However recent developments in micro-electro-mechanical systems (MEMS) technology have allowed researchers to develop ultra-low power miniature circuits that have integrated sensing capability, front-end amplification, microcontroller functions, and radio transmission into one chip, thus resulting in System-on-Chip (SoC) implementations.^{71,72} The AMIS-52100 is an example of such a low-cost, ultra low-power transmitter-receiver that has been developed for developers of portable remote patient monitoring devices.⁷³ This development, alongside the use of batch fabrication techniques, have resulted in significant reductions in the size and cost of sensors.

There are a number of categories of wearables:

3.4.1. Single Use Wearables

An increasing range of patch or bandage-styled wearables are now available for use in remote patient monitoring. These devices are intended for single-use, short-term, continual monitoring applications, most commonly designed to obtain ECG measurements. The devices are highly miniaturized, requiring no recharging of batteries, but will typically be able to take readings for 7 to 14 days (as with the iRhythm Zio Patch⁷⁴) and therefore generate patient benefits in comparison with the traditional Holter monitor that is worn for only 24 hours. Such patients can be seen to provide patients with the opportunity to be released early from hospital while continuing to be closely monitored by their health care providers.

No patient interaction is required with such the devices, which are placed on the patient by healthcare professionals, ensuring correct placement for optimal readings. In comparison to spot-check measurement devices, wet electrodes are applied in such devices to ensure good sensor to skin contact.

The single use nature of such devices reduces concerns regarding infection that can result from incomplete sterilization of shared devices. However these patches are also increasingly recyclable, enabling valuable electronics to be retained.

Devices identified

			
The HealthPatch MD from Vital Connect	Zensor from Intelesens	NUIVANT Mobile Cardiac Telemetry (MCT) System from Medtronic	Zio Patch from iRhythm

- HealthPatch MD from Vital Connect
- Zensor and V-Patch from Intelesens
- NUIVANT Mobile Cardiac Telemetry (MCT) System from Medtronic
- 3-lead ECG Dyna-Vision telemonitoring Patch from TeleMedic International
- Lifetouch from Isansys Lifecare Ltd
- Zio Patch from iRhythm
- BioPatch from Zephyr
- OxiPatch from OxiRate
- SeniumVitals from Toumaz Technology
- ECG patch from CardioNet
- Syna-Vision System from TeleMedic International

3.4.2 Belt-worn

Belt-worn devices tend to be apply dry electrodes for heart rhythm measurement. These devices offer advantages such as ease of wear: with no prepping of the skin required and no use of adhesives to attach the sensors – instead patients can don the belts themselves. The design of such belts mean they are not intended to be worn constantly, with most of these devices providing patients with transient spot-readings. However the format of the belt enables far more leads to be included in the device, for instance the smartheart belt from SHL-Telemedicine includes a hospital-grade set of 12 ECG leads⁷⁵. These devices will then transmit readings wirelessly to a patient’s smart phone (such as the QardioCore), or require upload of the data by the patient.

Devices identified

		
SmartHeart from SHL-Telemedicine	Cardio'B from SHL-Telemedicine	QardioCore from Qardio

- Smartheart, Cardio'B and CardioBeeper 12/12 from SHL-Telemedicine
- Polar Transmitter from Polar USA
- QardioCore from Qardio
- BBHRM1 from BeetsBlu
- W183 from Alutech International Ltd
- CS010, SC009 from Alatech Technology

3.4.3 Smart Watches

Smart watches are measurement devices in the form of a computerized wristwatch. Such devices provides sensors in a design that already has high patient acceptance, that can be worn discretely and is of a size that enables enhanced data processing functionality. These device formats are on the increase due to the increase in smart watches coming onto the market from the health and wellness

sector,⁷⁶ as well as technological advances in sensor design enabling blood oxygen sensing to occur at the wrist for oximeter devices.

Devices identified

			
Visensia Mobile from OBS Medical	Blood Pressure Watch, HealthSTATS International	WristPx2, Model 3150 Wrist-worn Pulse Oximeter from Nonin	WristClinic SpO ₂ Continuous from TelcoMed

- Visensia Mobile from OBS Medical
- Blood Pressure Watch, HealthSTATS International
- WristPx2, Model 3150 Wrist-worn Pulse Oximeter from Nonin
- WristClinic SpO₂ Continuous Monitor, Wrist Clinic Bluetooth and Watch Me from TelcoMed
- Oxitone pulse oximeter from OxiRate
- Wearable Health Monitor from Sotera Wireless
- Quest Wrist Oximeter
- Check Mate II Pulse oximeter
- Fingertip Pulse Oximeter A-50F
- WristOx2 digital Pulse Oximeter by Invacare
- NatureSpirit Wearable Wrist Pulse Oximeter
- Simband from Samsung (under development)
- Basis B1 wrist band from Basis

3.4.4 Smart Garments

Advances in material science have enabled the development of e-textile based systems that integrate sensing capability into garments. These offer a 'wear and forget' functionality,⁷⁷ with the capability of reading physiological parameters in real time. In contrast to earlier wearable technology devices, these have electronic elements integrated with textile fibres.

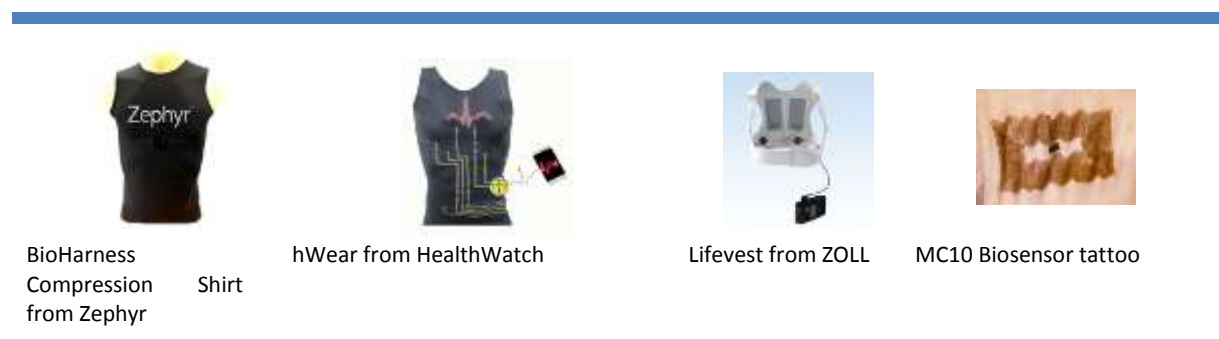
In the early days of such networks, integration was achieved by running wires in pockets created in garments to connect up the sensors, such as the MITHril system.⁷⁸ However recently developed wearable systems integrate individual sensors that use wireless communication methods, forming intelligent body sensor networks (BSNs), making them far more suitable for long-term health monitoring. The majority of smart garments on, or coming onto the market apply wearable electrodes consisting either of metal fibres that have been woven directly into the fabric (hWear line from HealthWatch Ltd, AiQ Smart Clothing Inc⁷⁹), electrodes which have been stitched into the fabric (BioHarness shirts from Zephyr⁸⁰) or where conductive materials have been deposited onto the fabric at the appropriate locations.

Most smart fabric products are beginning to enter the market in the health and wellness sector for direct consumer purchase to add biometric monitoring capabilities to wearable fitness gear. Few

smart garments are available aimed at remote patient monitoring. One product that is designed for the medical device market is the LifeVest wearable defibrillator from ZOLL Medical Corporation, which can be worn by patients at risk from sudden cardiac arrest. The LifeVest continuously monitors the patient's heart using dry, non-adhesive sensing electrodes and if a life-threatening heart rhythm is detected, the device alerts the patient before releasing a conductive gel prior to delivering a treatment shock to restore normal heart rhythm.⁸¹ Companies with intentions to enter this market include BlueLibris and At&T⁸² and Shimmer Sensing.⁸³

However most prototypes with smart functionality do not have a high level of integration, which means that several system parts, such as processing capabilities and energy supply, are placed in external devices.⁸⁴ For example, for the Zephyr BioHarness Shirt, the OMSignal SmartWear,⁸⁵ the smart wear from Equival⁸⁶ and the LifeVest from ZOLL, all have separate data modules that connect with the shirt. Development to such products will benefit from new electronic devices that are more textile compatible: flexible, organic, lightweight, low-cost and low power. Numerous patents claiming methods for creation of conductive textiles⁸⁷ or those which integrate optical threads for pulse oximetry⁸⁸ have been filed. And further developments in flexible components such as batteries,^{89,90} antennae,⁹¹ and screens⁹² are additionally supported by the increase in interest in flexibility by smartphone manufacturers.⁹³ More futuristic wearable monitors are also being investigated, such as temporary epidermal sensors or tattoos, as developed by MC10, that can measure a patient's blood pressure, temperature and heart rate.⁹⁴

Devices identified



- BioHarness Compression Shirt from Zephyr
- Biometric SmartWear from OMSignal
- BioMan from AiQ Smart Clothing
- hWear from HealthWatch
- LifeVest from ZOLL
- MC10 Biosensor Tattoo
- Smart wear from Equival
- SmartVest from OMSignal
- Oxsys cloth disposable Pulse Oximeter from Info Solutions

3.5 Developments in Wearable Technologies

3.5.1 Methods of Device Attachment

The wide range of devices in the above categories have differently applied both adhesive and non-adhesive methods to ensure both good patient to sensor contact and to enable patient mobility.

Adhesive methods have the capability of having better attachment to the skin and therefore can result in a superior measurement signal, however they have traditionally had the drawback that the might may result in skin discomfort or irritation, especially where the such a device is worn for a long time. A range of adhesives meeting different patient-activity levels, skin types and device size are being developed, including hydrocolloids and silicon-based adhesives.⁹⁵

Alternatively methods describing specialized microblades or microneedles for use with bioelectrical patches (among others) are also being investigated.⁹⁶

Non-adhesive methods have issues regarding increased signal noise, and to enable a good fit, patent applications have been made that include a tissue contact sensor, to sense the temperature sensor to determine whether the sensor is on the tissue of a patient.⁹⁷

3.6 Implantable Medical Devices (IMDs)

While non-invasive monitoring is an attractive approach for patients that require short term monitoring of a period of weeks to months, invasive methods can provide longer-term monitoring for patients that are suffering from unexplained symptoms, along with technologies that can capture with greater sensitivity the measured parameters predicting worsening heart failure. This monitoring format also reduces even further the need for patient interaction with the remote monitoring system.⁹⁸

With regards cardiovascular treatments, implantable sensors include right ventricular (RV), pulmonary artery (PA), and left atrial (LAP) pressure or oxygen saturation sensors (such as the hemodynamic monitor Model 10440 from Medtronic⁹⁹).¹⁰⁰ In addition, new therapeutic technologies are becoming available, such as Cardiac Contractility Modulation (CCM), which supplies non-excitatory electrical pulses during the absolute refractory period of the heart cycle, improving contractility by increasing the heart's force of contraction (as supplied by the implantable Optimizer IV device from Impulse Dynamics¹⁰¹), and Baroreflex Activation Therapy (BAT) (as provided by the Barostim neo Hypertension system from CVRx¹⁰²).

Furthermore some implantable devices can combine both therapy delivery with monitoring technologies, including implantable cardiac resynchronization therapy (CRT) and implantable cardioverter defibrillator (ICD) devices. CRT devices resynchronizes the contractions of the heart's ventricles, whereas ICDs can restore normal cardiac rhythms by delivering electrical shock therapy for cardioverting or defibrillating the heart (such as the Biotronik Ileo ICD¹⁰³). All of the above devices consist of an electronic controller placed subcutaneously like a pacemaker in a minimally invasive procedure, with two to three leads that are placed transvenously with tips embedded in the endocardium of the desired chamber, pulmonary vein or aortic artery (depending on the measurement type required), that both monitor the heart rate to detect irregularities, those signals back to the pulse generator that causes the electrodes to additionally to emit tiny pulses of electricity to correct them.

Once implanted, IMDs function autonomously by relying on pre-programmed operation and control of the therapeutic and monitoring functions. The IMDs communicate with external devices, such as programmers, repeaters and similar devices, which can re-program, troubleshoot and download data. Wireless communication has long been an essential component of such implants, as wired links

from an external electronic unit to an implanted unit inside the body are prone to infection in the long term.¹⁰⁴

3.6.1 Developments in Implant Remote Monitoring Technologies

Power Consumption

Battery power requirements, as described previously in section 2.1.1, is of critical importance to implantable devices, with current devices on the market having a longevity from 3¹⁰⁵ up to 11¹⁰⁶ years after which they need to be replaced.¹⁰⁷ Alternatively, battery-free approaches are becoming available, including the CardioMEMs battery-free implantable sensor,¹⁰⁸ which uses an inductor coil to enable the resonant frequency of the inductor-capacitor circuit to be measured remotely. Alternatively rechargeable batteries are be used, where an implant can have power transmitted to it via an exterior-transmitting and an implantable-receiving coil, negating the need for invasive battery replacements.¹⁰⁹

Communication Methods

Traditionally, clinicians have communicated with IMDs though a near-field form of communication such as inductive coupling. This involves an induction coil (often in the form of a wand) placed within centimeters of the implanted device at periodic in-clinic visits, and therefore the data only becomes available to clinicians periodically.

However most implants are now are equipped with bidirectional radio communication. With this data are automatically sent from the IMD to a local transmitter-receiver in the direct proximity of the patient.¹¹⁰ Such developments have resulted in a range of IMDs with differing communication capabilities; with the CardioMEMs HF system, the patient must use a pillow containing an antenna to take sensor readings for 18 seconds in duration (daily or upon clinical request),¹¹¹ whereas with Biotronik implantation devices, users have the option of using a static transmitter-receiver (CardioMessenger I or CardioMessenger S) or portable (CardioMessenger II) receiver-transmitter. The CardioMessenger II transmitter must not be less than 8 inches (20 cm) away from the patient and no more than 6 feet (2 meters) away from the place where they sleep.¹¹²

All such devices require patient co-operation to stay within proximity of a transmitter, if a medically significant event occurs while the implanted device is out of range of the repeater, there is the chance that it may not be possible to transmit this information at that time. No smart phone or tablet-based transmitter-receivers are available for this class of sensor.

It should also be noted that in contrast to in-hospital continuous cardiac rhythm monitoring, while the remote monitoring the implantable device collects data continually, its transmitter will only communicates with the transmitter at scheduled times, for instance once a day, unless special events are detected by the device where upon non-scheduled transmissions will be sent to the server.¹¹³ This arrangement is related to battery consumption concerns.

Miniaturization

Size is an important consideration for IMDs, the smaller the device the less invasive the surgery required for implantation and the less discomfort or inconvenience felt by the patient. Advances in miniaturization, particularly micro-electro-mechanical systems (MEMS) has been key, as size of such

devices requires a System on Chip (SoC) approach, with the sensor, antenna, signal processing electronics and energy source integrated in a single platform.¹¹⁴ In February 2014, Medtronic released the smallest cardiac monitor that has FDA clearance and CE marked; the Reveal LINQ Insertable Cardiac Monitor, which is about 1 cubic centimeter in size.¹¹⁵ Further developments in miniaturization include research at Stanford where an ECG monitor has been designed that is only one millimeter on a side and 0.1 mm thick, whose signals can be measured using an external device.¹¹⁶

There are advanced implant devices in development, such as wireless endocardial pacing and sensing, wireless probing of the heart – creating an intracardiac electrogram and even CHIC (Chip In Cell)¹¹⁷ where an autonomous wireless, implantable sensor could provide active, continuous-time monitoring of cellular activity.¹¹⁸ With these developments, the application of nano- and molecular-scale technologies for design and fabrication of the implantable circuitry is expected to lead to advances in integration density and dynamic power dissipation in implants, enabling neuro-electronic interfacing and nano-bio-robotics. However, current biomedical nanotechnologies are still faced with many challenges, such as lower reliability, relatively high stand-by power consumption, and electron leakage due to insufficient insulation.¹¹⁹

Devices identified



Evia ProMRI pacemaker
DR-T, SR-T (Biotronik)



Sorin Remote Monitoring
System for the PARADYMRF
ICD



Evera MRI SureScan
implantable cardioverter-
defibrillator (ICD)
(Medtronic)



CardioMEMS Battery-free
Implantable sensor

- Medtronic (REVEAL XT Insertable Cardiac Monitor, Reveal LINQ ICM)
- Sorin (SmartView Remote Monitoring System for PARADYMRF implanted cardiac devices)
- Biotronik (CardioMessenger for families of Biotronik Pacemakers and ICDs)
- CardioMEMs (CardioMEMs HF System)
- St Jude Medical (implantable devices with Merlin@Home)
- hemodynamic monitor Model 10440 from Medtronic
- Optimizer IVs from Impulse Dynamics
- Real LINQ Insertable Cardiac Monitor from Medtronic
- SJM Confirm implantable cardiac surveillance monitor from St Jude Medical

4 Technology Developments Associated with Specific Peripheral Monitoring Devices

A medical sensor device typically consists of three parts: the sensing and data collection hardware that obtains physiological data, the communication hardware and software to relay this data to a remote centre and thirdly the data analysis techniques to extract clinically relevant information. This

section will review developments in remote monitoring specifically for devices that provide ECG readings, blood pressure measurements, blood oxygen saturation levels as well as patient weight.

Such products on the market over-whelmingly have features directed towards ease of use, such as LCD measurement displays or audio features that offer guidance to patients where their cooperation is required, or alternatively require zero patient interaction (for instance, once fitted, the Lifetouch from Isansys is active with a pull tab, after which all else is automatically handled by the system). Such features are important considering the chronic heart failure patient demographics, who tend to be elderly or frail.

4.1 ECG Monitors

Electrocardiography is widely used in the recording of the electrical activity of the heart via the impulses generated by the polarization and depolarization of cardiac tissue. Electrocardiogram (ECG) recordings are translated into a waveform to determine heart rate, heart rate variability, and duration of PQ and QT intervals. Traditionally this is in the form of a transthoracic interpretation of the electrical activity of the heart over a period of time, as detected by electrodes attached to the surface of the skin and recorded or displayed by a device external to the body. A typical ECG monitoring system consists of electrodes an amplifier and a transmitter. ECG monitors typically use chloride electrodes coupled to the skin with gel. In clinical settings, 12 electrodes are used, allowing the heart's activity to be viewed from 12 different angles.

The clinical need to monitor outpatients has resulted in advances in technology that allows remote monitoring of through a wide variety of devices, including ambulatory external monitors, implantable event recorders, pacemakers, and cardioverter-defibrillators. Devices that are available can record cardiac rhythm continuously or intermittently, can be worn externally or can be implanted subcutaneously.

A key validation of new technologies coming onto the market for the clinical setting has been demonstrating the equivalence or improvement of the device against the traditional Holter monitor, an ambulatory electrocardiography device used in hospitals that is worn by patients for 24-48 hours for continuous monitoring purposes (see Figure 1). Holter electrodes are stuck to the patient's chest, with 3 or 5 leads running from the electrodes to the monitor that is carried by the patient in a pocket or pouch. Although newer Holter monitors now have up to 2 weeks of recording capability, the relatively short duration of monitoring can be inadequate for patients if symptoms are infrequent.¹²⁰ Studies demonstrating equivalence of new devices will encourage insurance companies to identify the device as an acceptable Holter monitor replacement suitable for clinical placement, instead of simply an experimental or investigational device.¹²¹



Figure 1 Photograph of a patient wearing a Holter Monitor by Misscurry, available under a GNU Free Documentation Licence.

Newer devices generally offer advantages according to their size, their ability to allow ECG monitoring for longer time periods and can provide nearly real-time data analysis when the patient transmits a recording in proximity to a symptomatic event.

Intermittent recorders are the largest category of ECG devices, and appear in the form of either continuous looping or non-looping monitors. Continuous looping monitors automatically record heart rhythms that reach a programmed threshold of slow or fast heart rate, or can be designed to only record data when activated by the patient, once activated the data is stored on the device. Such devices are attached to the patient through chest electrodes or a wrist band. An example is the Watch Me wrist-worn device from Telecomed.¹²² Non-looping monitors are suited for patients with sustained cardiac rhythm episodes that last for more than one minute. The monitor is placed against the chest wall or pressed by the patient's hands for measurements to be made, an example is the AliveCor heart monitor, supplying a single lead ECG tracing. The drawback of such devices is that they have no data on the initiation of the arrhythmia that might provide information on the arrhythmic mechanisms, and short arrhythmias that end before the device is applied will not be recorded.

In contrast portable cardiac monitoring systems can automatically record and transmit arrhythmic event data from ambulatory patients as well as recording data from patient-triggered activations. An example of such devices include the BodyGuardian from Preventive released in 2013, which has a sensor that adheres to the skin and records and wirelessly transmits data to a remote monitoring site.¹²³ There is a real value of continual monitoring in real time, with 60% of cardiac events occurring without noticeable symptoms to the patient.¹²⁴

Implantable loop monitors (such as the St Jude Confirm loop monitor¹²⁵ or the Medtronic Reveal Loop) are implanted under the breastbone along with an internal battery and microchip for recording and storage of heart rhythm tracings to provide a continuous recording of a patient's heart rhythms. These record a single-lead ECG signal through two electrodes and can be triggered automatically or by patient activation via placement of an activator over the device.¹²⁶ This is a particular advantage for patients who have infrequent symptoms. Furthermore, the issue of patient compliance in tolerating bulky external monitors is eliminated.

Pacemakers and ICDs can also function as continuous monitoring devices and include algorithms to detect arrhythmias, and these can provide detailed arrhythmia logs including the number, duration and data of arrhythmia episodes as well as the trends over time for the patient in suffering these events. Ventricular tachyarrhythmia episodes can also be recorded by ICDs, also enabling detailed evaluation of each device therapy to determine its appropriateness and success.

A major issue with the provision of long-lived wireless ECG monitoring involves the power consumption, and this issue is particularly pertinent for devices that offer fast ECG reading collection and transmission.

ECG Electrodes

Usually two or more electrodes are used in ECG devices, which can be combined into a number of pairs. The output from each pair is known as a lead, with each lead looking at the heart from a different angle. Different types of ECGs can be referred to by the number of leads that are recorded. There is a balance between ease of taking a reading and the provision of a hospital-grade reading, which is traditionally achieved using 12 lead ECG transmitters. A single lead tracing while having the capability of being a very simply used, intermittent ECG reader (such as the Docobo HealthHUB¹²⁷

and AliveCor ECG reader¹²⁸) has the potential to miss many ischemic events thus questioning their usefulness in a clinical setting.¹²⁹

However innovations in placement of electrodes have enabled a greater range of measurements to be made with simpler devices applying fewer electrodes, for instance the Siemens Medical Solutions TruST m12lead ECG uses 9 true leads and interpolates 4.¹³⁰ Whereas now ECGs can be constructed which apply just three differential leads to generate a 12-lead ECG measurement.¹³¹

4.1.2 Electrode Attachment Methods

The most common method to attach sensors onto a patient's skin is to use adhesive electrodes, to ensure good contact between the sensor and the skin gel (as used with the bandage-style BodyGuardian ECG from Preventice¹³² or the adhesive patches used in the V-Patch from Intelesens¹³³). While such attachment methods work for stationary patients, this approach suffers from several problems. First, the material used to construct the electrode or the paste can cause skin irritation and discomfort, especially if the subject is performing rigorous physical exercise and may be sweating. Another problem is that, during motion, the electrodes may become loose, breaking electrical contact and causing high noise spikes in the data.¹³⁴

While one approach has been to develop the electrode assembly to allow a large range of movement of the subject while minimizing problems associated with the electrodes becoming detached or giving inaccurate results,¹³⁵ in recent years, much effort has been focused on the development of dry and non-contact electrodes, which are designed to operate without a dedicated electrolyte. These tend to be more comfortable for a patient and so are seen as better suited for long-term monitoring, requiring no skin preparation. Equally, short-term devices benefit from dry electrodes as these are far more simple and durable where short-infrequent use over longer periods of time is expected.¹³⁶ However such electrode forms are more difficult to secure against the patient, suffering from greater skin-electrode impedance, and being more subject to more noise inference, particularly from motion artefacts and power lines.¹³⁷ There is a need to develop dry electrodes that are flexible, biostable and able to provide a high-quality signal acquisition without the need for electrolyte gel or adhesive. Numerous variations of dry electrodes exist from simple stainless steel discs, flexible rubber or foam¹³⁸ structures to products with surface micro-features that improve the electrode/skin interface¹³⁹ and micro-fabricated silicon structures with built-in amplifier circuitry.¹⁴⁰ Equally important is the ability for a device to improve the signal to noise ratio to product a robust heart rhythm monitor that can cope with artefacts introduced by motion or variable electrode impedance, as achieved with the IMEC ECG necklace.¹⁴¹

However devices that require even less bodily contact are currently in development. Plessey Semiconductors launched the Electric Potential Integrated Circuit (EPIC) sensor in 2011, which measures changes in an electric field using a highly-sensitive impedance sensor, requiring no physical or resistive contact to make measurements, therefore devices that are simply held close to a patient's chest will be able to generate a detailed ECG reading.¹⁴² Companies such as Shimmer Sensing¹⁴³ are also increasingly interested in developing wearable ECG sensor technology where the use of a flexible garment that includes conductive threads stitched into the garment portion to

provide a signal transmission pathway will be able to replace cumbersome electrode leads and therefore reduces the discomfort experienced by the subject.¹⁴⁴

Devices identified

			
ECG patch from Toumaz Technology Ltd	BioHarness from Zephyr	HeartScan from Omron Healthcare	QardioCore from Qardio

1 lead ECG provided in the Tunstall myclinic monitoring package	NUIVANT Mobile Cardiac Telemetry (MCT) System (Medtronic)
Atrial Fibrillation Monitor (Melys AFS)	Polar Transmitter (Polar USA)
Bioharness (Zephr)	RhythmPadGP (CardioCity)
Biopatch (Zephr)	SeniumVitals (Toumaz Technology Ltd)
BodyGuardian (Preventice)	Sensium Life Pebble (Toumaz Technology Ltd)
Cardio'B (SHL-Telemedicine)	Smart shirt (OMsignal)
CardioBeeper 12/12 (SHL-Telemedicine)	SmartHeart (SHL-Telemedicine)
CardioDefender (Everist Genomics)	Thumb ECG device (Zenicor)
CardioSen'C (SHL-Telemedicine)	TruST 12-Lead (Siemens Medical Solutions)
ECG Rhythm Strip Recorder (Philips)	V-Patch (Intelesens)
ECG monitor (Qardio)	WatchBP (Microlife)
ECG necklance (IMEC)	WatchMe (Telcomed)
H'andy sana 210 (Medxhealth)	Zensor (Intelesens)
HealthHUB (Docobo)	Zio Patch (irhythm)
HealthPatch(VitalConnect)	
HeartCheck ECG device (CardioComm)	
HeartCheck Pen (CardioComm)	
HeartScan (Omeron)	
HeartView P12/8 Mobile (Aerotel)	
hWear (Healthwatch)	
imPulse (Plessey Semiconductors)	
Lifetouch (Isansys Lifecare Ltd)	
Mobile ECG Telemetry Solution (METS) (MegaKoto)	
Mobile heart monitor (AliveCor Inc)	

4.2 Blood Pressure Monitors

The ability to measure blood pressure within the human heart and its vasculature provides critical information regarding the organ's functions. A traditional blood pressure meter, known as a sphygmomanometer, comprises an inflatable cuff to restrict blood flow and a mercury or mechanical manometer to measure the pressure using either acoustic sensors that detect "Korotkoff" sounds, or using pressure sensors. Automated electronic phygmanometers have been available for the last ten years and these tend to be highly user-friendly, requiring nothing more than the patient correctly put on the arm cuff of the device and push a start button for automatic inflation and measurement taking (such as the A&D Medical blood pressure monitor¹⁴⁵). Devices intended to be used at home tend to be mobile connected, such as the Kenek BP from LionsGate Technologies.

In an attempt to simplify the cuff even more, some companies have created small cuffs that fit a patient's wrist and have adapted their algorithms for calculating blood pressure to account for the differences sensors obtain when reading the pressure at the wrist rather than the arm (Model HEM-637 sold by Omron Healthcare¹⁴⁶).

However, cuff-based blood-pressure measurements only determine the systolic and diastolic blood pressures; they do not measure dynamic, time-dependent blood pressure, and such continual blood pressure monitoring has a diagnostic value as blood pressure varies at different times of the day. Blood pressure can also become elevated due to anxiety, leading to 'white coat hypertension', where anxiety in the doctor's surgery causes a reading that is higher than normal.¹⁴⁷

4.2.1 Cuff-less Blood Pressure Monitors

An example of a cuff-less blood pressure monitor is the continuous blood pressure monitoring device offered by the Visi Mobile from Sotera Wireless where sensors worn around the thumb and placed on the chest are connected to the ViSi Mobile worn on the wrist¹⁴⁸. This device in part uses a photo-plethysmographic method where an infrared photo-plethysmograph is used to detect changes in the volume of blood within the finger with each cardiac cycle along with a cuff placed around the finger which changes in pressure to keep the blood volume of the finger constant, such cuff oscillations are closely correlated to the intra-arterial pressure wave, giving an estimate of the changes of systolic and diastolic pressure.^{149,150,151}

The Danish company Sense A/S is also developing a continuous blood pressure monitor called ContiPress that uses patch with electrodes that sense the changing impedance of tissue around a vessel, to convert to a blood pressure reading.¹⁵² Another device coming onto the market, that offers ease of use advantages, although not continuous monitoring, is the H2 smartband from Korean company H2 Care, uses an oscillometric blood pressure sensor, requiring users to simply press a thumb or finger onto the device for 20 seconds.¹⁵³

Concerns, however, regarding the accuracy of such new measurement methods used in such devices is indicated by IEEE Standards association approving the "Standard for Wearable Cuffless Blood Pressure Measuring Devices." (IEEE 1708) in August 2014.¹⁵⁴

4.2.2. Implants

The barostim neo Hypertension system from CVRx¹⁵⁵ is indicated for patients with a systolic blood pressure ≥ 140 mmHg despite being on 3 or more antihypertensive medications. The device is implanted under the skin and acts by electrically activating baroreceptors located in the carotid

artery, which are the body's pressure sensors that regulate cardiovascular function. These receptors are able to send signals to the brain to activate the body's blood pressure regulation system, with effects including relaxation of blood vessels, slowing the heart and reducing body fluid via the kidneys resulting in lowering blood pressure and workload on the heart. The device wirelessly communicates with an external programmer system that adjusts and customizes the device's settings.

New generations of implantable microelectronic sensors using thin film technology are expected to provide advances in the range of implantable devices, such as their use in implanted stents, which are intended to assist in monitoring signs of restenosis. These sensors are likely to be formed using thin film technology, forming capacitor plates in parallel wafers that can be capable of converting pressure measurements into capacitance and then with the integrated antenna, communicating a radio frequency signal.^{156,157}

Devices identified



H2 smartband from H2 Care



EW2153W from Philips



MicroLife WatchBP



Blood Pressure Monitor from Withings

- H2 smartband from H2 Care
- Checkme, Viatom
- EW2153W from Philips
- QardioArm from Qardio
- WatchBP from MicroLife
- Kenek BP from LionsGate Technologies
- BP102 Wireless Blood Pressure Monitor, TELcomed
- Latitude Blood Pressure Monitor from Boston Scientific
- Blood Pressure Monitor from Withings
- Activ8lives Blood Pressure Bluetooth 4.0 monitor from Aseptika
- Pulsewave health monitor, from BioSign
- Model HEM-637 by Omron Healthcare
- Opti 24-hour ABPM from QRS Diagnostic
- TelePress from SHL-Telemedicine
- Blood Pressure Watch from HealthSTATS International
- Blood Pressure. Pulse Unit Meter from Philips
- A&D Digital Blood Pressure Monitor from Honeywell Hommed
- Blood Pressure Monitor from Tunstall

4.3 Pulse Oximeters

Pulse oximetry is used to measure various blood flow characteristics, such as the blood-oxygen saturation of haemoglobin in arterial blood, the volume of individual blood pulsations supplying the tissue, and/or the rate of blood pulsations corresponding to each heartbeat of a patient. A pulse oximeter measures the absorption and/or reflectance of light sent at 660nm and 940nm wavelengths (haemoglobin has a different absorption spectra depending on whether it is oxygenated or deoxygenated), through tissue that has a high perfusion rate of blood, usually at the finger or earlobe.

Traditionally, oximeters have focused the infrared wavelengths onto the human nail tip using a 'crocodile clip' fingertip sensor.¹⁵⁸ However innovations in single-sided reflective pulse oximetry, where incident light is passed through the skin and is reflected off the subcutaneous tissue and bone, has enabled development of devices that can be sited in non-traditional body locations, offering advantages for continuous reading methods as they are less likely to interfere with the user's daily activities. Reflective sensors are offered by ASTRI.¹⁵⁹ And a more comfortable wearable device that would use reflectance technology is also envisaged by Intelesens, where a chest-based oximeter applies an infra-red radiation onto the chest, and detects reflectance.¹⁶⁰

The Oxitone bracelet is an example which uses oxygen saturation measurements to be taken at the wrist, enabling a more patient-friendly wearable device. Measurements can be taken at the wrist due to the company's novel blood flow sensor that applies light speckle technology along with light absorption sensors to measure light absorption rates, resulting in a method resistant to motion artefacts¹⁶¹. It should be noted however that wrist-monitoring devices tend to use far more power due to the increased intensity of light required.

Nonin's oximeter boasts of further developments to the light sensor technology, where the use of high-intensity pure light spectrum LEDs are used to improve the accuracy of measurements, but avoiding any secondary spectrum emission that can occur with common red LEDs.¹⁶²

Furthermore, the SPO 6000 pulse oximeter from SPO Medical features AutoSpot technology, that varies the light intensity to improve the signal noise to signal ratio that can be an issue where a patient's pulses are of low amplitude (i.e. the patient has a low perfusion index), or where the patient is moving.¹⁶³

Looking further into the future, developments in the area of smart garments with integrated optic fibres could provide 'out-coupling' and 'in-coupling' of light to enable spectroscopic characterization of human tissue.¹⁶⁴ However, developers are also looking at reusing existing capabilities of smart phones; as more recent models incorporate a camera that is now capable of accurately analysing color signals of a fingertip placed in contact with its optical sensor to provide oxygen saturation measurements.¹⁶⁵

Devices identified



Onyx II Model 9560
(Nonin)



Nellcor Portable SpO2 patient
monitoring system (Covidien)



WristOx2 Model
3150 (Nonin)



Wrist Oximeter from Oxitone

- Nellcor Portable SpO2 patient monitoring system (Covidien)
- TelePulse Oximeter (SHL Telemedicine)
- WristOx2 Model 3150 (Nonin)
- Onyx II Model 9560 (Nonin)
- Pulse Oximeter Bluetooth 4.0 (Aseptika)
- WristClinic SpO2 Continuous (Telcomed)
- Spirodoc (Medical International Research)
- Kenek Edge Pulse Oximeter (LionsGate Technologies)
- Wrist-worn pulse oximeter (Oxitone)
- Spo Medical Spo 6000 Finger Pulse Oximeter (SPO Medical)
- PulseOX 7500 (SPO Medical)
- Pulse Oximeter DC300C318T (MedChoice)
- iHealth wireless Pulse oximeter
- ChoiceMed Fingertip Pulse Oximeter from A&D
- Clontec CMS50E SpO2
- Philipos Pulse Oximeter
- Oximeter from Oxitone
- Wearable wrist pulse oximeter from NatureSpirit
- WristOx2 digital Pulse Oximeter from InvaCare

4.4. Weight and Body Composition Devices

Weight scales tend to be the most established of the monitoring technologies examined in this review and are often available for consumer purchase as the data produced is of interest also for the health and wellness categories.

Ease of use and accuracy improvements are key innovation drivers for these devices. While there is a lower need for these to be mobile devices, there is an increasing use of Bluetooth or WiFi technologies integrated into such devices, enabling automatic upload of data directly to patient's smartphone or tablet (such as the Body Analyser by Aseptika¹⁶⁶).

Additional features being integrated to improve ease-of-use include 'no-button' scales, where just stepping onto the scales automatically turns the device on and generates the reading, and stepping off unsurprisingly turns the device off, prompts and weight readings can be provided audibly, with visual displays providing large numbers. Handle bars are also available for those who are frail or who have balance issues (Philips Steady Scale¹⁶⁷).

A key requirement of scales used in home monitoring is a high degree of accuracy of weight measurements. Supporting this function, innovations have appeared in on-the-market devices where using four load cells remove the need for 'special levelling procedures'¹⁶⁸ as well as the inclusion body position detectors¹⁶⁹ or motion tolerance¹⁷⁰. Similarly, devices boasting the measurement of up to 400lbs enable monitoring of a broad range of patient types.

Most recent versions are Bluetooth enabled and/or WiFi communication. Increasingly, scales aim to measure a wide range of metrics including: weight, bioelectrical impedance analysis and body fat percentage, resting metabolism, water, muscle composition, visceral fat levels, bone % and BMI.¹⁷¹

As scales are often a family-used device, scales used in remote patient monitoring set ups often either incorporate patient recognition capabilities (the Withings Body Analyser recognises up to 9 users), and will cancel out readings which are unexpected.¹⁷²

Devices identified



Body Analyser (Aseptika)



Body Analyser (Withings)



Weight Scales (Boston Scientific)

- Scales (Tunstall)
- Honeywell Scale (Honeywell Hommed)
- HRS-305 Accuro Handrail Scale (NCI Technologies)
- Scales, Steady Scales (Philips)
- TeleWeight (SHL-Telemedicine)
- Body Analyser Bluetooth Smart Scales (Aseptika)
- Smart Body Analyser (Withings)
- Scales (Boston Scientific)
- UC-321PBT-C (A&D Medical)

- HBF-206IT (Omron)
- Pally Smart Health Scale (Ace Sensor Inc)
- BF800 (Beurer GmbH)
- WS-210 Wireless Weight Scales (Telcomed)

5 Supporting Sensor Sets

5.1 Sensors integrated to Support Physiological Measurements

The miniaturisation of sensor sets has enabled an increasingly sophisticated set of sensor sets in a device, providing supporting data on a patient's movement, position, temperature, as well as sensors that can measure the internal structure of the device, as described below.

Where a device is intended to be portable, continual monitoring readings must take into account the patient's movement, allowing devices to be incorporated into athletic activity. Devices increasingly have incorporated tri-axial accelerometers to improve the quality of data, understanding physiological measurements as a function of physical activity to mitigate any artefacts from these biophysical signals. For instance, Spirodoc from Medical International Research has incorporated a tri-axial motion sensor to correlate the saturation level with physical activity, featuring a walk counter, movement analysis and activity counts via vector magnitude units (VMU). During the single six-minute walk test, Spirodoc estimates the level of oxygen therapy required by the patient.¹⁷³

Furthermore, body position sensors are also being incorporated into devices, such as the BodyGuardian from Preventice, applying accelerometers, magnetoresistive sensors and electromagnetic tracking systems (ETSS) to understand the patient's posture preceding abnormal measurements.

Temperature sensors are additionally integrated – whether to determine the extent of contact of the sensor with the patient or as an indicator of wellness of a patient (very mild hypothermia is an indicator of imminent death in CHF patients), such as with the Visensia mobile device from OBS Medical.¹⁷⁴

Sensors to provide additional information on implanted devices are also increasingly used to improve patient safety, for instance a housing integrity indicator from St Jude Medical that applies an electrical conductor along the main portion of an implantable medical lead, along with a closed channel and a detection substance.¹⁷⁵

Other cardiovascular implantable sensors are additionally being developed to become capable of measuring, monitoring and reporting blood constituent levels. This enables, in real time or close to real time, to detect sudden changes in analyte concentration in the subject, and enables healthcare professionals to early detect a severe medical condition even though the subject is not visiting a healthcare facility.¹⁷⁶ Implantable devices may additionally become more active in this area with a number of patents claiming the facility to dispense doses of medication.¹⁷⁷

5.2 Multi-device Monitors

One issue with many remote monitoring systems has been that many they are only able to carry out one specific physiological measurement, a situation which can necessitate a patient or healthcare provider purchasing three, four, or five different devices. The Philips' collection of blood pressure, pulse oximeter, ECG, and diabetes monitoring devices are is an example. And as the number of sensors available for patient monitoring increases, the number of devices supplied to patients could increase correspondingly especially for patients suffering from multiple chronic conditions.

However devices more recently introduced onto the market are designed to more fully utilize the time window of patient interaction, such as the HealthPatch MD from VitalConnect that measures ECG, temperature, blood pressure, respiration rate and blood oxygen¹⁷⁸ and the WristClinic SpO₂ continuous model that measures blood pressure, respiratory rate and oxygen saturation.¹⁷⁹

Multi-sensor sets provide further monitoring and analysis opportunities, an example being the Toumaz group¹⁸⁰ whose Sensium device allows signals to be wirelessly collected, synchronized, processed and transmitted from a body network.¹⁸¹

Furthermore, technology available in a standard mobile phone camera is being shown to have the potential to be used as an accurate multi-parameter physiological monitor.^{182,183} By applying independent component analysis on the colour channels in video recordings, such devices can extract the blood volume pulse from the facial regions. Heart rate (HR), respiratory rate, and HR variability (HRV, an index for cardiac autonomic activity) can be quantified.

Devices identified



Wrist Clinic Bluetooth from Telcomed, which can monitor heart rate and rhythm, blood pressure, respiratory rate, blood oxygen saturation,



The OxiPatch from OxiRate that can monitor heart rate, blood oxygen saturation, respiratory rate, physical activity



The Smart Body Analyser from Withings that can analyse body fat via bioelectrical impedance, heart rate, air quality, temperature and carbon dioxide



HealthPatch MD from Vital Connect. That can measure heart rate, temperature, blood pressure, respiration rate and blood oxygen.

6 Cardiac Telemetry Patent Set

A set of 2224 patents were identified (1270 families) that describe a range of innovations in telemedicine sensor technology and communication methods. This patent set was then analysed in terms of the distribution of assignee companies, predominant IPC classification and country of filing.

All patents are listed in Appendix II.

Patents were retrieved from the Thomson Innovation database using the following search strings:

CTB=(telemetr* AND (cardiac OR heart)) AND ALL=(home) AND DP>=(19940101);

CTB=(electrode AND implant AND heart AND wireless AND monitor) AND DP>=(19940101);

CTB=(antenna* same body) AND ALL=(monitor* AND home) AND DP>=(19940101) AND IC=((A61));

CTB=(encryption AND telemetr* AND (cardiac OR heart OR blood)) AND DP>=(19940101);

CTB=(body ADJ analyser) OR CTB=(body ADJ analyzer) AND CTB=(monitor*) AND DP>=(19940101) AND IC=((A61));

CTB=(monitor* AND oximet*) AND DSC=(home) AND DP>=(19940101) AND IC=((A61B) OR (A61N));

CTB=(wearable near5 ECG) AND DP>=(19940101);

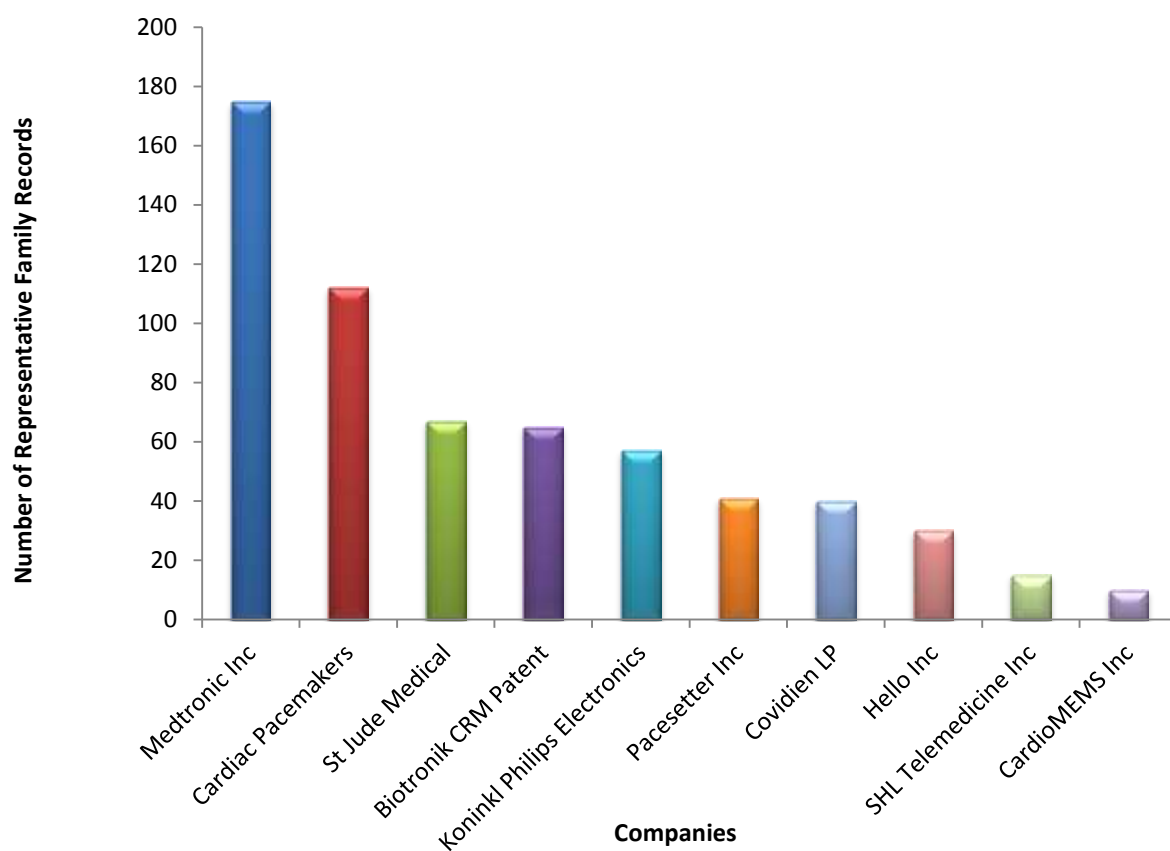
TAB=(telehealth ADJ cardiovascular) AND DP>=(19940101);

ALL=(wearable AND worn AND (sens! OR monit!)) AND DP>=(20090101);

TAB=(telehealth OR telemonitor* OR "remote patient monitor*" AND oximeter) AND DP>=(20090101);

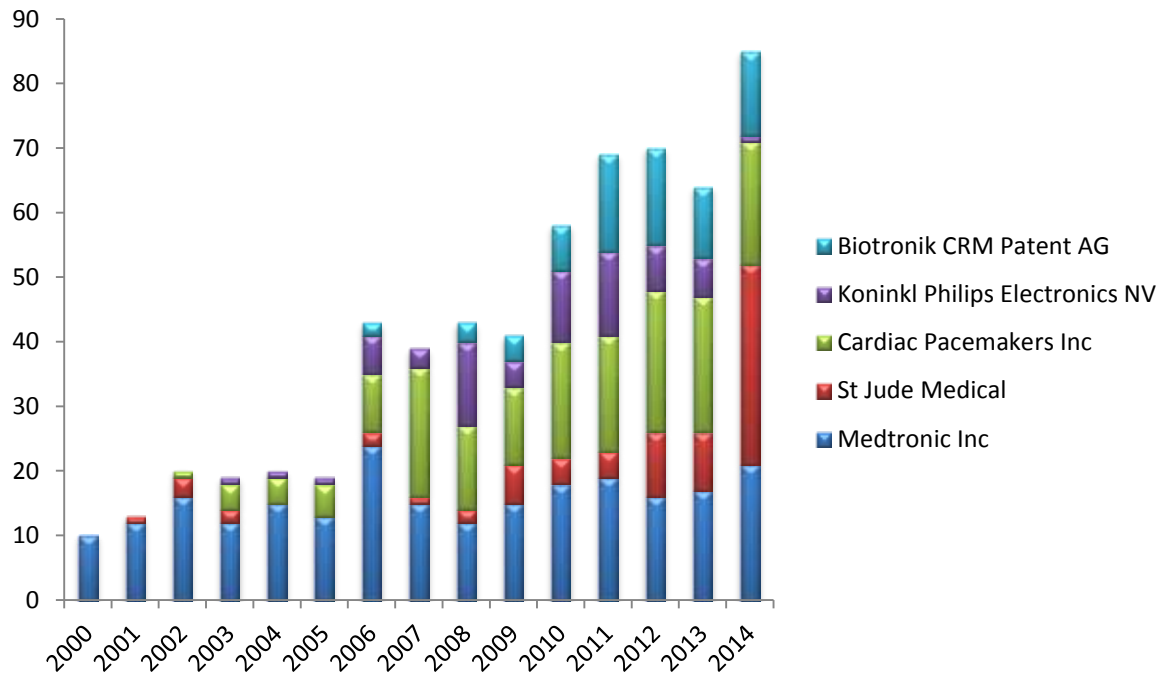
CTB=(antenna AND monitor* AND telemetr* AND medical) AND DP>=(19940101);

6.1 Top Assignees



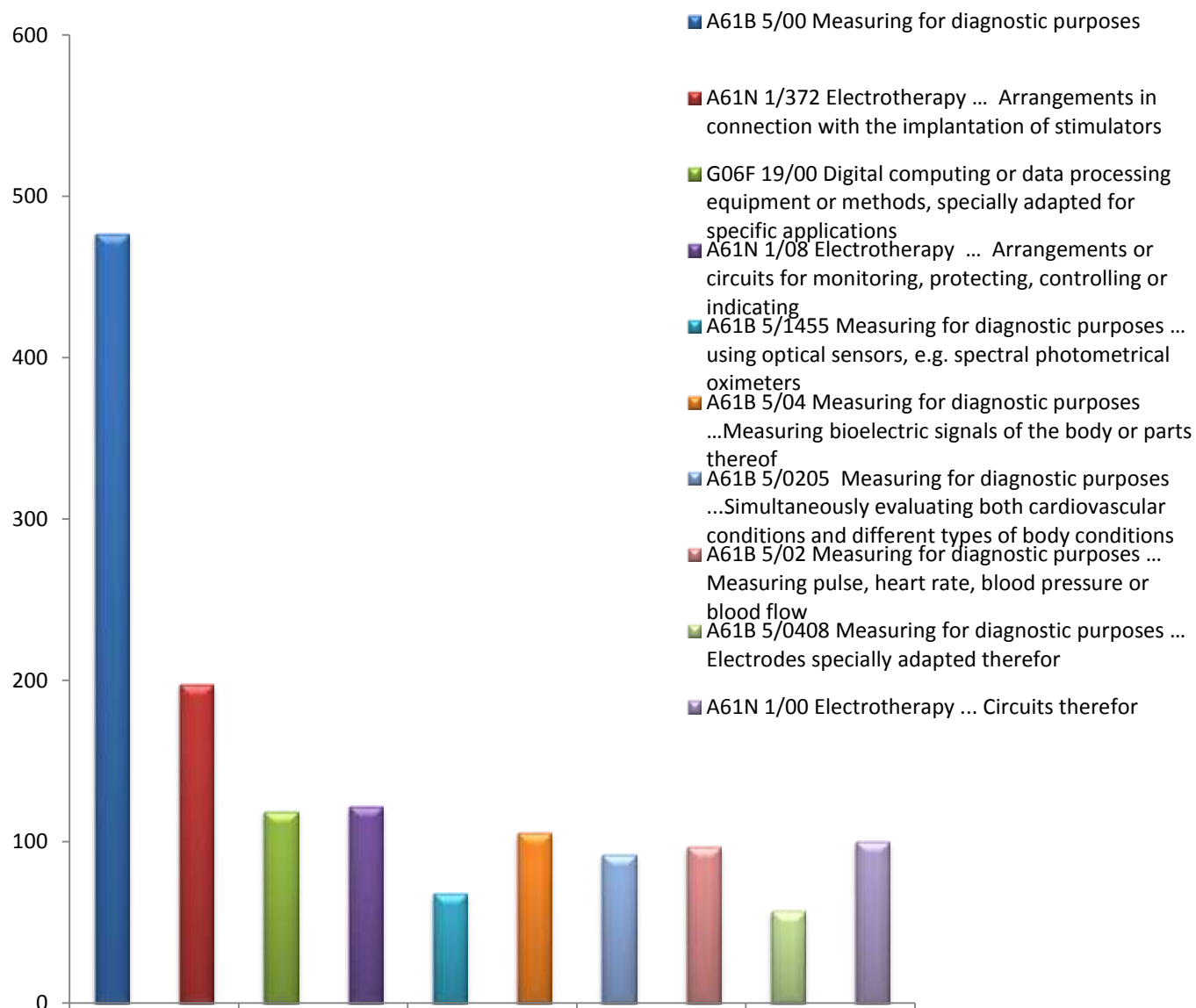
Although many assignees are present in the patent set, the graph above indicates most patent families are assigned to companies developing cardiac implant devices, which is perhaps unsurprising considering the complexity of such devices and associated systems.

6.2 Top Assignees by Year



The graph above highlights the growth in some of the larger companies in the medical telemetry field. Cardiac Pacemakers Inc and St Jude Medical have greatly increased their presence in this field.

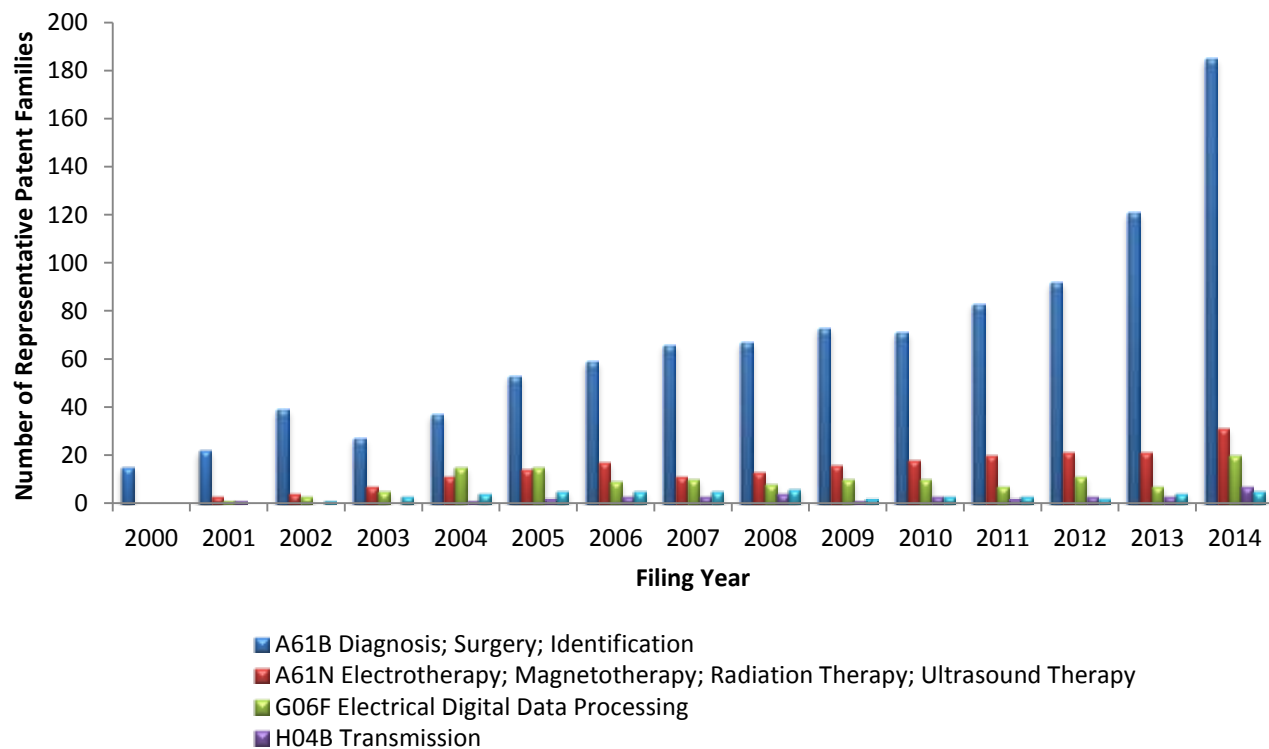
6.3 Most frequent International Property Classifications



Note that A61B 5/00 is a parent classification to many of the other IPC codes displayed and therefore should be viewed independently.

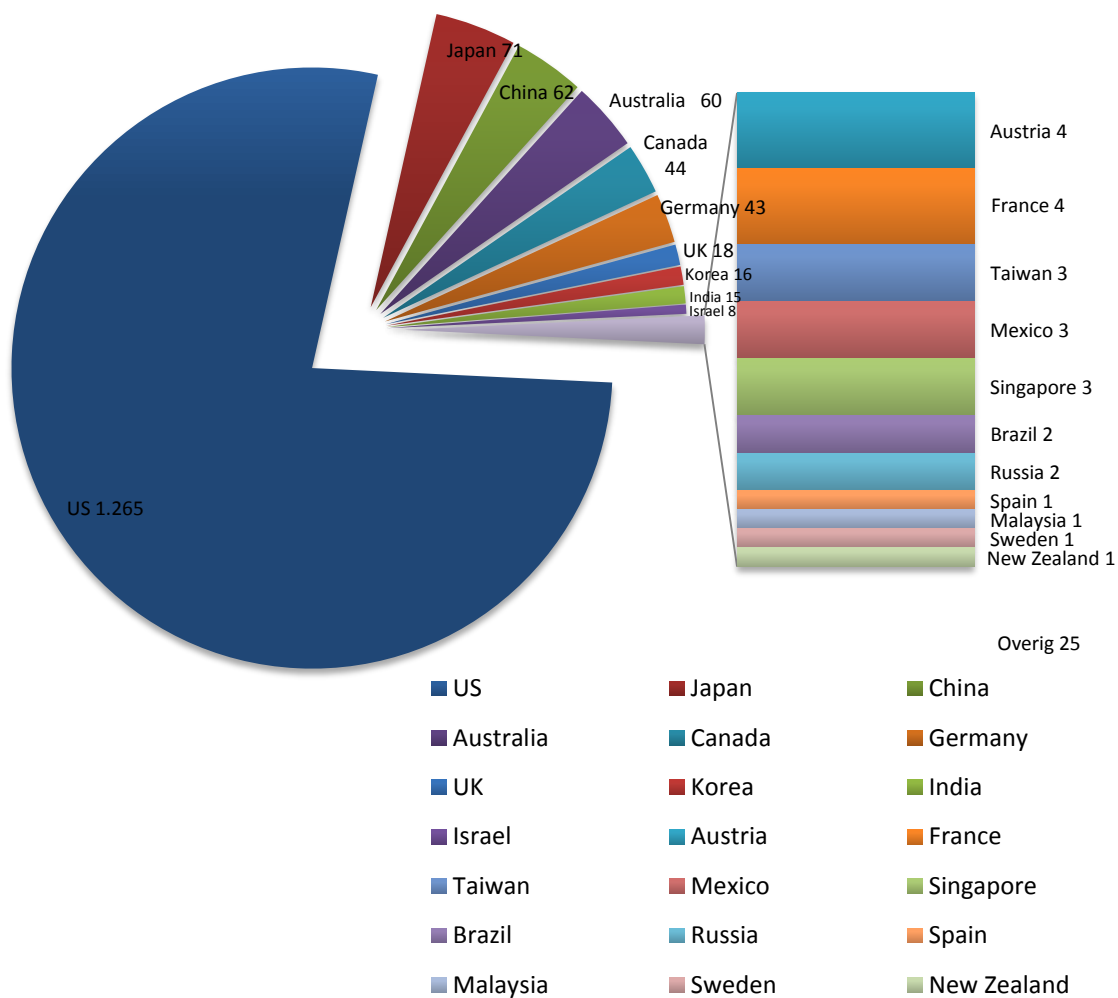
Many of the patents have been classified with regards to devices relating to ECG monitors, which reflects also the number and range of such monitors found on the market, as described in section 4.1.

6.4 Most frequent International Property Classifications by Year of Patent Filing



Key fields in medical telemetry are indicated by the classifications in this graph, with the general classification for devices involved in diagnosis growing year by year, with rapid growth in evidence from 2011 onwards.

6.5 Top Countries for Patent Filing



The importance of the US market in telemetry is highlighted in the above chart. In contrast total of 90 patents have been filed in EU countries.

7 Conclusion

The different devices reviewed in this report indicate a growing trend in providing portable and wearable products for patients, to improving ease of use and patient compliance. Such product releases are being supported by intensive research and development in RF communication strategies, device miniaturization and battery technologies.

The overall mobile health market is growing substantially. Research and analysis firm GlobalData expects the market to grow in value from an estimated \$0.5 billion in 2010 to over \$8 billion by 2018.¹⁸⁴ Such growth can also be seen in the growth in patents describing developments in different aspects of remote monitoring systems (see section 6.4).

Developments of new sensor devices have been enabled by advances in semiconductor technology including embedded processing, low power management and wireless connectivity. This has enabled monitoring technologies to becoming smaller, lower-cost, low-power, non-invasive and unobtrusive, offering real-time assessments that depend less and less on the patient transmitting their own data. The use of smart phones has been key in spreading adoption and shaping developments, by providing both wireless communication and computation capacities within a patient owned device.

Further developments with regards battery, antennae and communication strategy are also moving devices towards being able to remove the need for the 'middle man' transceiver-receiver device that is currently being required for long-distance data transfer.

Biosensor development and cost and patient acceptance of such devices has been supported by the parallel growth in equivalent products for the health and wellness sector,¹⁸⁵ such as Google Glass and the Fitbit wristband. Contributions to sensor quality by the health and wellness sector is demonstrated by some companies who recognise the importance of establishing the quality of their sensors within a medical setting before marketing products towards the health and wellness sector.¹⁸⁶ However, the stringent CE requirements for marking a device as being a Medical Device or an In Vitro Diagnostic Medical Device, does mean that companies intending to develop a device focused towards healthcare usage need to have a very different software development and data handling strategy. Furthermore, to gain clinical acceptance new technologies will not only need to have their clinical accuracy validated, but also their real benefit for a healthcare setting.¹⁸⁷

It should also be recognised that remote monitoring devices can be directed at quite specific patient populations. There are those relatively active patients who will benefit from a device that provides high portability alongside having access to their measurements to increase their own management of their disease. For this population, the increasing number of wearable, or miniaturized portable devices that can offer continual, unobtrusive monitoring offers many benefits. There are also patients who are more vulnerable, who have limited mobility and therefore devices that can offer more continuous and accurate monitoring will enable them to remain at home, while being closely monitored by their healthcare providers.

Furthermore, as increasing amounts of data are streamed from such devices, there are challenges both in systems being able to operate such devices as lesser time will be available to carry out the computations while the volume of computations goes on increasing¹⁸⁸ and also in assisting the

cardiologist and allied professionals in being able to handle this ever increasing amount of data in a timely and appropriate way.¹⁸⁹

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