

Horizon Scan Report 0027

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Diagnostic Technology: iPhone, iPod and iPad add-on or plug-in medical devices

Clinical Question:

- What is the accuracy and utility of the newly available plug-in iPhone, iPad and iPod medical diagnostic devices?

Background, Current Practice and Advantages over Existing Technology:

Since the introduction of the iPhone by Apple in January 2007 the device has become hugely popular with over 72 million sold in the 2011 fiscal year alone (1). A large number of medical applications (“apps”) have been developed and many of the inherent functions of the iPhone, iPad and iPod have been adapted for diagnostic purposes (2,3). More recently, plug-in accessories that convert the Apple devices into diagnostic tools have been developed, combining ubiquitous smartphone and medical technology. As healthcare awareness and the use of smartphones increases, it is important to assess the accuracy, cost effectiveness and usability of these devices to see if they have a place in the primary care setting. There are many advantages of iPhone, iPad and iPod medical devices. Firstly, these devices provide a means of self-monitoring in the home, allowing patients to be more involved in the control of their health and may reduce the number of GP consultations required, especially when combined with the associated ‘apps’ that allow patients to analyse and communicate their results directly with their general practitioner. Secondly, if a number of these devices are used in conjunction it reduces the amount of equipment required by patients and GPs, particularly of use during home visits.

Temperature

Temperature is one of the vital measurements used by clinicians, patients and carers to assess acute illness episodes. It is conventionally measured using an infrared thermometer (tympanic), electronic contact thermometer (rectal, oral and axillary) or chemical thermometer (axillary or forehead). Recently, non-contact infrared temporal artery thermometers have been developed as they pose no risk of injury for the patient, the site for measurement is readily accessible without the need for disrobing and there is no risk of cross contamination whilst obtaining a measurement, reducing the need for sterilisation or disposable covers (4).

Blood pressure

Blood pressure is measured using a mercury sphygmomanometer or automated blood pressure monitor. It is traditionally measured by medical practitioners, but the availability of automated blood pressure monitors means that patients are increasingly monitoring their own blood pressure at home.

Blood glucose

Capillary blood glucose is measured using a blood glucose meter, in the primary care and hospital settings and at home.

Dermoscopy

Dermoscopy is a useful technique for the analysis of potentially malignant skin lesions, increasing the likelihood that featureless melanomas are not overlooked. It is rarely performed in general practice with most patients referred directly to a dermatologist.

Details of Technology:

This report summarises the evidence for plug-in medical devices that convert an Apple device into a diagnostic tool. It does not include medical applications which merely record or represent data, use the inherent functions or sensors of the iPhone, iPod or iPad for diagnostic purposes, or those which transmit data wirelessly to a smartphone.

Table 1 summarises the characteristics of currently available iPhone, iPad and iPod devices.

Table 1: iPhone, iPad and iPod devices – summary of characteristics

Name of device	Manufacturer	Description	Approximate cost	CE approval	FDA approval	Software required	Compatible devices
ThermoDock®	Medisana	Infrared non-contact temporal artery probe	£71	Yes	No	VitaDock®	Apple (iOS 3.0 or higher) devices (iPhone 3G, 3GS, 4G / iPod touch 2nd, 3rd, 4th generation / iPad / iPad 2).
CardioDock®	Medisana	Measures BP and pulse via a 22-32 cm cuff (30-42 cm available)	£109.95	Yes	No	VitaDock®	Apple (iOS 3.0 or higher) devices (iPhone 3G, 3GS, 4G / iPod touch 2nd, 3rd, 4th generation / iPad / iPad 2).
iHealth BP3 Fully Automatic Arm Cuff Electronic Blood Pressure Dock	Andon Health Cp., Ltd	Measured BP and pulse via a 22-32 cm cuff (30-42 cm available)	£89.99	Yes	Yes (based on substantially equivalent predicate) ¹	iHealth	iPhone4, iPod touch and iPad2
Withings Blood Pressure Monitor, Upper Arm Type: BP-800	Withings	Measures BP and pulse via a standard 22-42 cm cuff	£119.95	Yes	Yes (based on substantially equivalent predicate) ²	Withings	Apple (iOS 3.0 or higher) devices (iPhone 3G, 3GS, 4G / iPod touch 2nd, 3rd, 4th generation / iPad / iPad 2)
GlucuDock®	Medisana	Measures blood glucose level	£79.95	Yes	No	VitaDock®	Apple (iOS 3.0 or higher) devices (iPhone 3G, 3GS, 4G / iPod touch 2nd, 3rd, 4th generation / iPad / iPad 2)
iBGStar® Blood Glucose Monitoring System	Sanofi-Aventis	Measures blood glucose level	£48	Yes	Yes (based on substantially equivalent predicate) ³	iBGStar® Diabetes Manager	iPhone 3G, 3GS, 4G / iPod touch 4th generation / iPad / iPad 2
Handyscope	FotoFinder Systems, Inc	Digital dermatoscope attachment	£695	Yes	FDA 510(K) exempt ⁴	Handyscope	iPhone 4 and 4S

¹ http://www.accessdata.fda.gov/cdrh_docs/pdf10/K102939.pdf

² http://www.accessdata.fda.gov/cdrh_docs/pdf11/K110872.pdf

³ http://www.accessdata.fda.gov/cdrh_docs/reviews/K103544.pdf

⁴ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRsearch.cfm?FR=880.6350>

Temperature

The Medisana ThermoDock® (5) connects via a dock connector and enables the measurement of body temperature, typically 5cm away from the body, above the eyebrow between the forehead and the temple. The ThermoDock® can also be used to measure the temperature of objects (e.g. fluids, surfaces and ambient temperature) within a range of 0-100°C.

The ThermoDock® requires the associated VitaDock® software (free ‘app’) which stores and displays data from 4 Medisana medical devices (CardioDock®, GlucoDock®, TargetScale® and ThermoDock®). It also provides statistical analysis of the results and allows results to be emailed to a healthcare professional. According to the ThermoDock® instruction manual it has met the American Society for Testing and Materials (ASTM) E1965 Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature and complies with the European Standards EN 60601 (medical electrical equipment) and EN 12470-5 (clinical thermometers, performance of infra-red ear thermometers).

Blood pressure

The Medisana CardioDock® (5) measures blood pressure and pulse via a 22-32 cm cuff. The iPhone or iPod touch is inserted into the CardioDock® which can be charged via a mains adapter (mini-USB). According to the CardioDock® instruction manual it complies with the EU standard 93/42/EEC for non-invasive blood pressure monitors and complies to the European Standards EN 60601 and EN 1060 (non-invasive sphygmomanometers).

The Andon Health iHealth BP3 Fully Automatic Arm Cuff Electronic Blood Pressure Dock (6) measures blood pressure and pulse via a 22-48 cm cuff. The iPhone, iPod or iPad is inserted into the iHealth Dock which can be charged via a mains adaptor (mini-USB). According to the manufacturer it complies with the Association of Medical Instrumentation (AAMI) SP-10 (manual, electronic, or automated sphygmomanometers) and European Standard EN 1060 certifications (communication with the manufacturer).

The Withings Blood Pressure Monitor, Upper Arm Type (BP-800) (7) measures blood pressure and pulse via a 22-42 cm cuff. It plugs into the dock connector and is powered by AAA non-rechargeable batteries. It has been certified EC medical and has been validated according to the European Society of Hypertension test protocol (communication with the manufacturer).

Blood glucose

The Medisana GlucoDock® (5) is intended for the quantitative measurement of blood glucose levels with results relayed to the VitaDock® ‘app’ for display and graphical representation. It connects via a dock connector. According to the GlucoDock® instruction manual it complies with European Standard EN 60601. The monitor is certified in accordance with the requirements of EU guidelines 98/79 (in vitro diagnostic devices) and the lancets and lancing device correspond to the requirements of EC Directive 93/42 (medical products).

The iBGStar® Glucose Monitoring System (8) consists of the iBGStar® Blood glucose meter, BGStar test strips and BGStar control solution. It is similarly intended for the quantitative measurement of blood glucose levels in fresh capillary whole blood samples and also connects via a dock connector. It is unclear what certification the iBGStar® has achieved.

Dermoscopy

The FotoFinder Handyscope (9) is a digital handheld dermatoscope that the iPhone (4 and 4S) can be plugged into. It requires the associated Handyscope ‘app’ which provides a magnified and polarised view and allows photos to be uploaded via a secure connection to the online-platform where they can be stored and rated by skin cancer specialists.

Patient Group and Use:

Temperature

- Measuring temperature in patients who present with fever or acute illness especially during disease outbreaks (e.g. influenza season).
- Self-monitoring of temperature in patients being managed at home during an acute illness episode.
- The ThermoDock® is not suitable for measuring the temperature of new-born infants up to 100-days old or in children under 3 years old who have a weakened immune system (ThermoDock® instruction manual).

Blood pressure

- Assessment of cardiovascular risk in the general population and in specific patient groups, including those with diabetes and renal impairment.

- Monitoring anti-hypertensive treatment.
- Routine monitoring of blood pressure in pregnancy.

Blood glucose

- Patients with type 1 or type 2 diabetes mellitus to monitor glycaemic control.

Dermoscopy

- Diagnosis and monitoring of melanocytic lesions, enabling general practitioners to understand naevus morphology beyond what is possible by naked eye examination alone.

Importance:

Temperature

Fever is a commonly seen sign in general practice with one study showing that 5% of all patients visiting a surgery in a 4 week period were febrile, including 36% of all children below the age of 7 years old. However, the majority of temperature readings occur in the home (10). Measuring body temperature is vital for the diagnosis of fever, which is frequently associated with infection, immunological diseases and drug reactions, and can act as a red flag for serious infections such as meningitis, pneumonia and septicaemia in populations where the prevalence of serious infection is low (11). Temperature can also have a profound effect on heart rate and respiratory rate measurements as so must be factored in by clinicians when interpreting their significance (12).

Blood pressure

Blood pressure is the most commonly performed measurement in general practice with hypertension the most common chronic disease in primary care affecting at least one quarter of adults in the UK (13). The importance of monitoring blood pressure can be seen in the relationship between raised blood pressure and morbidity and mortality from a number of diseases including cardiovascular disease, peripheral arterial disease and end stage renal disease (14).

Blood glucose

There are thought to be over 2.6 million people in the UK diagnosed with diabetes (15). The Diabetes Control and Complication Trial (DCCT) (US and Canada) (16) and the United Kingdom Prospective Diabetes Study (UKPDS) (17) showed long-term health and economic benefits from tight glycaemic control. This was supported by a 2009 meta-analysis of randomised controlled trials that showed that intensive control of blood glucose significantly reduce the number of coronary events in diabetic patients (18).

Dermoscopy

24% of primary-care consultations in England and Wales are related to the diagnosis and management of skin conditions, including skin lesions (1.7%) (19), with 1777 people are thought to die each year from melanoma (20). Early detection is the most reliable strategy to reduce the mortality rate of melanoma (21) but general practitioners in the UK miss up to a third of skin malignancies (22).

Previous Research:

Temperature

Accuracy compared to existing technology

A recent Horizon Scanning Report (4) found that non-contact thermometers provide an accurate means of measuring children's temperature in the community compared to axillary and rectal (23) temperatures (23,24). However, this report did not include details of the ThermoDock[®], which uses similar technology. According to the manufacturers the accuracy of the ThermoDock[®] is +/- 0.2-0.3°C and varies according to temperature with the greatest accuracy in the range 36.0-39.0°C (+/- 0.2°C). We did not find any published or registered studies regarding the accuracy of the ThermoDock[®].

Impact compared to existing technology

A recent study showed that non-contact thermometers caused less discomfort to children than traditional mercury in-glass axillary thermometers (24). In adults, they have also shown to be of more practical use than contact thermometers in a number of settings including during sleep studies (25) and during exercise (26).

Guidelines and Recommendations

The NICE guideline on feverish illness in children (27) recommends that in children aged 4 weeks to 5 years, temperature should be measured using an electronic or chemical dot thermometer in the axilla or an infrared tympanic thermometer. We did not find any guidelines on the measurement of temperature in adults or recommendations for non-contact thermometers.

Blood pressure

Accuracy compared to existing technology

The iHealth and Withings blood pressure monitoring systems are both based on substantially equivalent predicate devices. The Withings blood pressure monitor has been validated according to the European Hypertension Society protocol (28) (communication with manufacturer). The iHealth blood pressure dock has been validated according to the European Hypertension Society Protocol and the Association for the Advancement of Medical Instrumentation (AAMI) protocol (29) (communication with the manufacturer).

We did not find any predicate for the Medisana CardioDock® or existing published studies.

Guidelines and Recommendations

Blood pressure can be measured manually or automatically unless there is a pulse irregularity in which case blood pressure must be measured manually using direct auscultation over the brachial artery (13). In health adults blood pressure should be measured at least every 5 years and should be measured more frequently if the patient's blood pressure is close to 140/90 mmHg or the patient is on antihypertensive drugs.

Blood glucose

Accuracy compared to existing technology

The iBGStar® is substantially equivalent to a predicate device which was shown to exceed the International Organization for Standardisation (ISO) 5197 minimum system accuracy requirements (30). The iBGStar® blood glucose measuring system and Diabetes Manager Application were also studied 'in house' and in a clinical setting by a person with diabetes. These studies demonstrated the ease of operating the iBGStar® blood glucose monitoring system as intended (30).

We did not find a predicate or any existing published studies for the GlucoDock®.

Dermoscopy

Accuracy compared to existing technology

Two meta-analyses have confirmed that using a dermatoscope increases diagnostic accuracy by 5-30% when compared to clinical visual inspection, depending on the experience of the physician and the type of skin lesion (31,32). However, we did not find any evidence of the accuracy of the Handyscope as compared to traditional dermatoscopes.

Cost-effectiveness and economic impact:

There is no literature on the cost-effectiveness or economic impact of using any iPhone, iPad or iPod medical devices.

Research Questions:

- How accurate are the iPhone, iPad or iPod medical devices compared to conventional devices?
- How acceptable is the use of the iPhone, iPad or iPod medical devices to health care professionals, patients and carers?
- Are these devices cost effective in the medical setting?

Suggested next step:

- Studies validating the use of iPhone, iPad or iPod medical devices against currently used conventional devices in primary care.
- Studies comparing the accuracy of the 3 available models of blood pressure monitors
- Studies comparing the accuracy of the 2 available models of blood glucose monitors
- Studies evaluating the acceptability of the iPhone, iPad or iPod medical device amongst health care professionals, patients and carers.
- Studies evaluating the cost-effectiveness of the iPhone, iPad or iPod medical devices for use in primary care settings.

Expected outcomes:

- The potential benefits or harms from implementation are currently unclear.

Additional note:

The AliveCor ECG plug-in device is not currently for sale but may be available by summer 2012, pending FDA approval. It provides a single lead ECG recording (lead I) and has been shown to be accurate (33) and easy to use (34) in 2 small scale studies. Several other plug-in medical devices have been identified but these are not currently for sale, including ultrasound probes, microscopes and spectrometers.

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This report was prepared by the Primary Care Diagnostic Horizon Scanning Centre Oxford

Authors: Miriam Thake, Annette Plüddemann, Jane Wolstenholme, Christopher P Price, Matthew Thompson, Carl Heneghan.

Contact details: Dr. Annette Plüddemann; Email: horizonscanning@phc.ox.ac.uk