An Ethical Analysis of Personal Health Monitoring in the UK

A Case Study

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Abstract: Recent years have seen an influx of medical technologies capable of remotely monitoring the health and behaviours of individuals to detect, manage and prevent health problems. Known collectively as ‘Personal Health Monitoring’ (PHM), these systems are intended to supplement medical care with health monitoring outside traditional care environments such as hospitals. In the face of ageing demographics across the EU, such technologies are seen as a promising way to close the predicted gap between healthcare demand and resources. Medical care and monitoring currently provided by humans may be supplemented by technological monitoring, creating new ways of delivering healthcare to the elderly, homebound, chronically ill and healthy alike. However, the implications of introducing technological monitoring into healthcare need to be considered in greater detail before the technologies are widely used. PHM allows for greater collection of personal health data about users, which may raise ethical concerns. As an emerging technology with the potential for widespread usage across Europe and beyond, the opportunity remains for PHM to be developed and deployed responsibly by adhering to the principles of Responsible Research & Innovation (RRI). To contribute to this process an interview study with potential users and healthcare professionals was carried out in the UK. Twenty-one stakeholders were interviewed from patient groups and healthcare professionals representing medical conditions targeted by PHM: diabetes mellitus, hypertension and dementia. A series of recommendations on how to address the ethical implications and concerns of stakeholders are provided for members of industry responsible for developing PHM devices and services. Nine recommendations were identified:

- Offer devices and services with user feedback and recommendations for better health
- Limit user access to raw monitoring data
• Offer multiple levels of summarised feedback to users
• Create open channels of communication with users
• Do not view monitors as a replacement for staff
• Give users control over their devices
• Capture contextual information to support monitoring data
• Take a minimal approach to contextual data
• Discuss the extent and implications of monitoring with users

The work described here is a first broad step in the RRI process which can contribute to the development and deployment of any PHM devices and services. The study can be understood as a broad ethical foresight study achieved through engagement with PHM stakeholders, including patients, doctors and healthcare organisations. Each of the five RRI principles described by the European Commission was adhered to (see: Appendix 1), providing an example of how development and deployment can be performed responsibly with the involvement of stakeholders.

**Keywords:** Personal Health Monitoring, RRI, healthcare.

**Citation:** The full citation information will be inserted here once the paper is accepted.

**Field of Research or Industry**

As PHM describes a number of different technologies, its development and usage is relevant to a broad range of research fields and industries. PHM, defined as any electronic device or system with the capability to collect, store and transmit data about a health-related aspect of an identified user’s life outside a hospital or similar medical environment, is designed to operate within private spaces (e.g. home, car) and collect personal health data via wearable, implantable and environmental sensors. In other words, PHMs are devices which monitor a person’s health at home. PHM broadens the scope and availability of data pertaining to a person’s health.
The primary focus of PHM lies in the support of patients with long term chronic conditions such as chronic pulmonary obstructive disease, diabetes, asthma and heart disease, as well as general home care and assistance for the elderly and infirm. However, potential applications are broad, and can also include physiological monitoring in healthy people, for example, for monitoring the body’s response to sports activities. Devices that can be considered PHM may elsewhere be called ambient intelligence, assistive technology, fitness monitors (see: Figure 1), telehealth and telecare. Relevant industries therefore include healthcare, home and social care, assisted living facilities, and wellness monitoring services. Devices are being developed both by industry and academic researchers. Similarly, monitoring and care services are being provided both by public health bodies as well as the private sector.

Beyond catering to personal interest in health and wellbeing, these industries are currently responding to demographic challenges which mean that a greater number of patients will be cared for at home than ever before. New methods and technologies which allow for home monitoring and care are required to ease the burdens of increasing healthcare costs and ageing demographics which threaten to overwhelm the existing budgets and personnel available for healthcare across Europe. Monitoring devices are seen as a way to fill this gap between available healthcare resources and increasing demand for and cost of healthcare. Home monitoring devices may allow for sufficient care to be provided at a lower cost or to a greater number of patients, for example by allowing multiple patients to be monitored simultaneously by a single carer. Monitoring can allow health professionals to check up on patients without a face-to-face interaction, up to and including conducting remote consultations.

PHM can also provide always-on well-being monitoring to individuals susceptible to health emergencies or conditions, meaning needless trips to the hospital or GP may be avoided. PHM is thus intended not only to provide an efficient way of delivering healthcare to chronic patients, but also as a safety net for growing elderly populations across Europe through emergency alerts and early recognition of health problems. PHM is seen as a promising way to allow patients to ‘age-at-home’ as opposed to in a full-time care facility, which will ideally both reduce the costs of care for the healthcare industry while increasing the patient’s satisfaction with their surroundings. PHM, in particular telecare and telehealth, has achieved a prominent status amidst strategies for “healthy ageing” throughout the EU and beyond (Cardona, 2008). In the UK, PHM is thought to
be a more efficient means of providing certain kinds of healthcare, particularly chronic illness management, home care and other information-intensive practices\textsuperscript{1,2}.

A range of PHM systems are currently available to consumers or exist within research and development settings. General distinctions can be drawn between mobile and wearable monitors, environmental sensors and in-vivo monitors. Mobile monitors are devices which are worn on the body or carried by the user for the purpose of monitoring health parameters, including vital signs, stress, and blood quality. Such devices may be used both to track the progress of a specific health condition as well as for preventative and lifestyle purposes, such as detecting deviance in health parameters at an early stage, which may be used to try to detect the onset of a medical condition requiring treatment. The range of mobile monitors is broad and includes wrist and arm bands (see: Figure 2), clothes with woven-in sensors, body area networks, global positioning system (GPS) trackers and smart phone devices.

Environmental monitors provide information about a patient’s private space, such as the home, car or workplace. They do not require the patient to wear, carry or implant sensing devices, but instead use sensors embedded into an environment, although combinations of wearable and environmental sensors are foreseeable. Applications of environmental monitors include smart homes devices (see: Figure 3), fall detectors, pressure pads, activity and sleep monitors.

In-vivo monitors require implantation in the user to provide real-time monitoring of physiological parameters, such as blood chemistry and pressure. Examples include in vivo glucose monitoring chips built on radio-frequency identification (RFID) technology which may eventually be coupled with in vivo insulin dispenser systems, or implantable stents monitoring the constitution of blood useful for chemotherapy or early detection of heart attacks.

The emergence of PHM is not without its pitfalls and problems for users. The potential of PHM to change how medical care is provided by expanding the aspects of patient life

\textsuperscript{1} Department of Health. Innovation Health and Wealth: Accelerating Adoption and Diffusion in the NHS 2011.

\textsuperscript{2} Department of Health. The power of information: Putting all of us in control of the health and care information we need. 2012.
open to medical scrutiny needs to be recognised. PHM allows for increasing amounts of personal health data to be collected about users. While this may allow for more efficient forms of medical care, it may likewise lead to new ethically problematic forms of medicine. Much of the acceptability of PHM in these regards rests upon the expectations of the user, concerning for example the degree to which monitoring in a private space is found acceptable for the sake of medical care. To begin to understand the ethical acceptability of PHM in these terms and develop devices and services which are accepted by users, engagement with users and other stakeholders throughout the R&I processes leading to these devices is necessary.

**Event or Activity**

To explore the potential ethical issues raised by PHM, interviews were conducted with potential users of PHM in the UK. Participants were based at two NHS Trusts and one Clinical Commissioning Group in the East Midlands which have piloted telehealth devices for chronic illness management, although participants did not necessarily have direct experience with these pilot programmes. The sample consisted of healthcare professionals working for the three NHS sites, patients accessing their care, and family carers providing support to these patients. Human research ethics clearance was granted by De Montfort University and the NHS’ National Research Ethics Service (ref: 12/EM/0160).

The concept of a user was interpreted broadly to include not only patients, but individuals who will potentially have access to data recorded by PHM devices which may be used in providing clinical or informal treatment, or for strategic purposes such as care commissioning. The range of participants was chosen to engage a broad range of stakeholder groups affected by PHM, while remaining focused enough to allow for in-depth interviews.

The sample consisted of 21 people, including fifteen patients and six healthcare professionals. A gender balance was sought among participants (see: Appendix 1): in the end, thirteen participants were women and eight men, aged between 36 and 82 years old, with a median age of 63. For the “patient” participants, five were recruited with diabetes mellitus and five with hypertension. A further five individuals were recruited who cared for someone with dementia. For the healthcare professionals recruited, three were care commissioners currently involved with the pilot programmes. A further three were clinicians specialising in diabetes mellitus and hypertension treatments. These illnesses were targeted to reflect how monitoring is currently being employed by the NHS. Devices for monitoring glucose levels and blood pressure are currently being piloted in the Whole System Demonstrator Programme in the UK. Dementia monitoring devices are used across the UK by individual NHS institutions, city/county councils and
charitable organisations, particularly fall detectors, door sensors and GPS tracking devices.

Interviews focused on the responses of potential users to PHM systems currently in development or available to consumers/health services in the UK. A review of such PHM systems was conducted prior to the interviews. Systems were identified from academic literature addressing the ethics of PHM (Mittelstadt et al., 2014), existing monitoring programmes administered by the aforementioned NHS bodies, councils and charities, and a review of online and high street shops selling PHM directly to consumers.\

**Why does it fall under Responsible Research and Innovation (RRI)?**

As a whole, this case study is an example of ethics foresight through public engagement. Rather than being tied to a particular device or development cycle, the study covers a range of technologies by focusing on technological features and their ethical implications. Potential users of monitoring devices were engaged through interviews to generate recommendations for industry that can impact on the design of future devices and the ways in which existing devices are used. In this way the “values, needs and expectations” of society and particular stakeholder groups were explored to influence the outcomes of R&I. The study is thus an example of how stakeholder engagement occurs in RRI, as it provides recommendations from stakeholders relevant to both the development and deployment of PHM systems. It remains the responsibility of system developers and monitoring service providers to consider these recommendations and implement them on a case-by-case or device-by-device basis.

**Examples of engagement activities**

Three types of engagement activities were conducted: recruitment sessions, interviews and conference presentations.

**Recruitment Sessions:** Patients were recruited to the study through presentations and discussions with patient and carer support groups and charities. Three such groups were approached, with five recruitment sessions occurring at monthly group meetings. Each session involved a brief presentation describing PHM, its potential uses for the relevant

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3 A table outlining the latter can be found in Appendix 2

disease (e.g. diabetes), and some initial ethical concerns. Members of the group were then invited to ask questions and provide initial reactions to the technology, before being invited to participate in interviews.

**Conference Presentations:** To raise awareness of the issues and recommendations identified in the interviews (see below), three presentations were made during the study at academic conferences. These presentations provided an opportunity for feedback from researchers and developers of PHM systems on the findings and recommendations of the interviews, while raising awareness of the ethical dimensions of PHM. These presentations provided a further channel for engagement with stakeholders in the development and use of PHM in the UK.

**Interviews:** 32 semi-structured interviews were completed. Interviews lasted from 25 to 75 minutes, with most between 45 and 50 minutes. Each patient participant was invited to complete two interviews, with the first introducing the technology, the patient’s background, and initial reactions, and the second exploring concerns in more depth and probing for changed views. Recognising that healthcare professionals had prior knowledge of telehealth and telecare, they completed one interview. All interviews were conducted in the home or office of the participant.

Interviews were loosely structured around an interview guide focusing on the participant’s reaction to particular technological features and proposed uses. Systems were hypothetically augmented with additional features or restrictions (for example, on how data is collected and used by carers) at different stages of each interview based on the concerns expressed by each participant. Questions focused on how the participant’s reactions addressed the ethical acceptability of the systems, and how the systems needed to be modified, restricted or used to make them acceptable to users. Images of systems and mock-up charts reflecting the type of data and health patterns that can be created by PHM were presented to participants to help explain the potential ethical implications of monitoring (see: Figures 4 and 5).
**Figure 4: Blood pressure chart**

**Recommendations from the Interviews**

Participants raised a number of concerns that suggest issues to be given attention by PHM developers and service providers and specific actions to be taken. Recommendations presented below are based upon these concerns. Several participants suggested that data collected needs to be used to improve a patient’s care.

It was suggested that data collection is only justified insofar as the data is subsequently analysed and used to improve the user’s care. For example, several participants suggested that monitoring is justified because it provides clinicians with a better picture of the patient’s health. These participants expected that service providers are using collected data to improve their service or the user’s care, as opposed to only passively monitoring for emergency situations. This expectation suggests that proactive monitoring involving feedback and interventions for developing health conditions may be valued or expected by users. This type of monitoring likely involves greater burdens for service providers due to the additional costs of analysing data and contacting users outside of emergency situations. Put simply, preventative monitoring that is more complex than existing emergency monitoring (e.g. fall detection) and feeds more information back to users is seen as valuable. Hence, developers and service providers should be encouraged to offer PHM devices and services that offer users personalised feedback and
recommendations to improve their health, both to chronically ill patients and healthy individuals.

Figure 5: Blood glucose chart with activity log

Following from this, one healthcare professional suggested that monitoring can help users “take control” of their illness through self-monitoring. However, a care team is still required to provide feedback, assist the user in understanding their measurements, and to arrange care when a problem arises. This view assumes that PHM provides meaningful data and a practical method of contact between service providers and users. It must be remembered that PHM makes it possible for care and feedback to be provided to the user without a healthcare professional or carer being involved (at all times). In these situations users may misunderstand the meaning or implications of the measurements taken by the device. For developers and service providers it is thus crucial to find appropriate levels of feedback and data provided directly to users to avoid
misunderstandings and anxiety. Similarly, how the device allows the user to communicate with their care team also needs to be considered. It is important that users be given opportunities to ask questions about the device and their data to prevent avoidable anxiety and thus provide a better monitoring service for users.

How data is presented to users was also raised in the sense that PHM may cause obsession with health among users. This was seen as likely if users are given access to raw data collected by the device. Developers and service providers need to consider how and when data is provided to users to minimise the possibility of obsession while providing meaningful data that users can refer to when communicating with their care team. A simplified daily or weekly summary may be preferable to raw data. With that said, users are diverse in terms of care needs and values. Some may feel “the less you know, the better,” while others feel they have a right to data about themselves. It is therefore desirable to offer multiple levels of feedback from which the users can choose on a case-by-case basis. Such an approach respects the user’s autonomy while creating an opportunity to explain the hazards of misinterpreting data.

PHM systems monitor a variety of conditions as well as health parameters and behaviours. Despite this, a potential for PHM to provide a limited view of a user’s health condition was recognised by healthcare professionals. Monitors provide an objective account of the user’s condition, but one which is limited to the parameters or behaviours being monitored. The patient may have conditions or symptoms unrelated to cause for monitoring which can affect how physiological and behavioural readings are interpreted. Without this information readings can be misinterpreted. To put this data into context and provide better care and feedback to the user, it may be necessary to combine measurements with additional information.

For example, users can be asked to provide additional information about their behaviour at the time a reading is taken, access to the user’s medical history can be granted to service providers, or a human carer can visit to check for problems not captured by PHM systems.

It is worth noting that a related ethical issue is left unaddressed by this approach. Some users will ask for as much data as possible due to anxiety over their health. Providing multiple levels of data to choose from does nothing to address possible obsession among such users. Health professions that were interviewed seemed to suggest that limiting the data given to all users was desirable due to this possibility. However, this requires adopting strong normative positions on the issues of user access rights and the responsibility of health professionals to choose what is best for their patients. A clear recommendation cannot therefore be provided beyond recommending multiple access levels which are deemed more or less appropriate on an individual basis.
monitoring. Alternatively, systems can be designed to capture a greater range of parameters and behaviours. How to solve this complex issue of a loss of context when monitoring a patient needs to be addressed at the level of particular devices and monitoring services. Developers and service providers will need to strike a balance between the effectiveness of the readings and the user’s privacy. At a minimum information should only be shared when an explanation of its relevance to interpreting measurement data is provided. Unlimited access to a patient’s complete medical history or electronic health records is ethically unjustifiable if the user’s privacy is to be preserved.

Relating to this, patients mentioned several necessary limitations for PHM to be acceptable to them. Monitoring in private or embarrassing locations or situations, such as when the user is in the bathroom, was seen as unjustifiable. The need for an on-off switch was also frequently mentioned to allow the user to switch off monitoring at any problematic moments. However, in some cases reducing the user’s control over the monitoring system can be justified. For example, dementia carers viewed an on-off switch as problematic as they felt the carer, rather than the patient, should be in control of the system.

Finally, several healthcare professionals felt that service providers from the private sector will need to see themselves as care providers when offering monitoring services to consumers. Medicine was seen as involving a sort of bargain between patients and healthcare professions in which the patients give up some privacy or access to their bodies to receive care. Service providers will need to remind users that they are entering into a medical relationship when using monitoring: “We have a negotiation that goes on when we introduce the device...there probably needs to be some kind of conversation.” Practically speaking, when offering devices and services a negotiation appears to be required with users to inform them of the extent and implications of the data being collected. Broadly speaking this negotiation is a form of RRI which should occur throughout the R&I process and also with individual users at the time of purchase or use.

**Any impact achieved?**

To date little measurable impact has been achieved. The type of impact to be expected from this sort of overview study is difficult to measure compared with, for instance, the development of a particular monitoring device. With that said, participants in the recruitment sessions and interviews have reported speaking with family and colleagues about PHM. Awareness of ethical issues has therefore been raised to some degree among potential users of the devices.

Ideally the dissemination presentations and this case study report will influence developers and service providers in the UK and beyond to consider issues and make changes to systems and services to improve their acceptability to users. The interviews were based around existing PHM devices and proposed uses in the UK, meaning the
recommendations produced are directly relevant and can impact upon the usage of PHM in the UK.

Lessons learned
A number of issues and recommendations requiring further consideration by PHM developers and service providers can be drawn from the engagement activities discussed above. Below is a summary of the issues that have also been described above.

- **Offer devices and services with user feedback and recommendations for better health.** Monitoring devices and services which offer preventative care and feedback in addition to emergency alerts should be offered to healthy individuals in addition to chronically ill and homebound individuals.

- **Limit user access to raw monitoring data.** Doing so minimises opportunities for misinterpretation and health obsession among users. However, access should not be prohibited, but rather discouraged.

- **Offer multiple levels of summarised feedback to users.** Doing so can accommodate those who wish to remain “happily ignorant” about their health, as well as highly motivated patients interested in self-care.

- **Create open channels of communication with users.** Provide a clear method for users to communicate with service providers to ask questions about their data, feedback and monitoring devices.

- **Do not view monitors as a replacement for staff.** Ensure sufficient support staff are made available and trained to help users interpret their data and feedback before making any changes to their lifestyle or care.

- **Give users control over their devices.** When not being used in a professional care setting or for patients lacking the capacity to consent, PHM devices should allow users to disable monitoring temporarily. For example, by including an ‘on-off’ switch. Doing so respects the user’s autonomy by providing control over when monitoring is allowed into their home (or other private space).

- **Capture contextual information to support monitoring data.** Additional contextual information needs to be considered in analysing PHM data to ensure accurate interpretation. This can be achieved by accessing the user’s medical record, requiring the user to input additional information at the time of a reading, or including occasional visits from a human carer to check up on the patient.

- **Take a minimal approach to contextual data.** Only request access to a
user’s medical history when clear justification can be offered for its relevance to the interpretation of monitoring data. Doing so helps preserve the user’s privacy.

- **Discuss the extent and implications of monitoring with users.** Service providers are de facto healthcare providers, and must act as such. A negotiation is required with users to ensure they understand the extent of the data collected and services offered.

Responsibility to protect users from unacceptable uses of personal health data currently rests with system developers and service providers. The scope of data collected and transmitted by PHM raises significant concerns over bodily surveillance and novel misuses of personal health data which are not curtailed by current EU data protection legislation. An analysis of existing UK and NHS policy conducted in parallel with the case study showed that few ethical constraints are placed on these devices and the data they generate beyond the existing legal frameworks (Mittelstadt, 2013). The recommendations made here are thus all the more important.

Plans are in place to increase the impact of the study through further publications in peer-reviewed academic journals targeted at industry and developers. Presentations at industry conferences are also planned, focusing on the need for stakeholder engagement in designing PHM systems, and particular issues to be considered in the process.

This case study has thus provided an example of how giving attention to the implications of PHM mediating medical relationships can help assess the ethical acceptability of such technologies and hopefully contribute to practical changes in system design and deployment strategy in the future.

**References**


**Funding:** This case study was conducted for the “Responsible Industry” project. The “Responsible Industry” project has received funding from the European Union’s Seventh Framework Programme for research, technological development and demonstration under grant agreement no 609817.

**Acknowledgements:** This case study was conducted for the EU-funded project “Responsible Industry” and was originally published on the project’s website. A link to the page where the case study was published can be found [here](#).

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Appendix 1 – Relevance to RRI Action Points

The case study addresses the Science with and for Society unit of the European Commission’s five RRI action points as follows:

1. **Engage society more broadly in its research and innovation activities**
   The study can be considered as an example of ethical foresight conducted through stakeholder engagement. It identified and conceptualised ethical issues of an emerging technology to facilitate discussion and amelioration of these aspects in future developments. Stakeholders including potential patient users, clinicians and care commissioners were engaged.

2. **Increase access to scientific results**
   Conference presentations and plans for further industry-oriented dissemination will provide greater access to the results of the interview study.

3. **Ensure gender equality, in both the research process and research content**
   A gender equal sample was sought. Although the resulting sample was not equally representative of males and females (13 females, 8 males), this is not attributed to failures in the recruitment methodology but rather reflects the demographics of the support groups and charities from which patient participants were recruited.

4. **Take into account the ethical dimension**
   As mentioned above, the case study is a form of ethical foresight. Interviews focused on ethical dimensions of the concerns expressed by participants with particular technological features or proposed uses of PHM data. This type of stakeholder engagement and ethical foresight undertaken in the study provides an example to be followed by developers and service providers in designing their offerings for specific subsets of users.

5. **Promote formal and informal science education**
   Informal education has been promoted among participants through the recruitment sessions and interviews. Participants reported that they found themselves thinking about and discussing the implications of PHM with family and colleagues following participation in the study.

### Appendix 2 – Commercially Available PHM

<table>
<thead>
<tr>
<th>PHM Category</th>
<th>Examples (Brand – Device Type/Name)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activity Monitor (wearable)</td>
<td>Tanita – Pedometer</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Category</th>
<th>Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fitbit – Various Wireless Activity and Sleep Trackers</td>
<td>Soleus Go – Activity Tracker</td>
</tr>
<tr>
<td>Glucose Monitor</td>
<td>Medisana – Blood Glucose Monitor</td>
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<td></td>
<td>OneTouch – VerioSync</td>
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<tr>
<td>Blood Pressure Monitor</td>
<td>iHealth – BP5 Wireless Blood Pressure Cuff Monitor</td>
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<tr>
<td></td>
<td>Omron – Upper Arm Blood Pressure Monitor</td>
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<tr>
<td></td>
<td>Boots – Blood Pressure Wrist Monitor</td>
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<td></td>
<td>Kinetik – Blood Lowering Device</td>
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<tr>
<td></td>
<td>Withings – Blood Pressure Monitor</td>
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<tr>
<td></td>
<td>Kinetik – Wrist Fully Automatic Blood Pressure Monitor</td>
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<tr>
<td></td>
<td>Prestigio – Smart Blood Pressure and Heart Rate Monitor</td>
</tr>
<tr>
<td>Smart Thermometer</td>
<td>Boots – Non-Contact Thermometer</td>
</tr>
<tr>
<td>Body Analyser/Persomal</td>
<td>Omron – Digital Personal Scale</td>
</tr>
<tr>
<td>Scale</td>
<td>Medisana – VitaDock Target Scale</td>
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<td></td>
<td>Salter – Slim Analyser Scale</td>
</tr>
<tr>
<td></td>
<td>Kinetik – Body Composition Monitor</td>
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<tr>
<td>Heart Rate Monitor</td>
<td>Prestigio – Smart Blood Pressure and Heart Rate Monitor</td>
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<tr>
<td></td>
<td>Polar – Heart Rate Monitor (with GPS)</td>
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<tr>
<td></td>
<td>Samsung – Galaxy S5</td>
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<tr>
<td>Fertility Monitor</td>
<td>DuoFertility – Fertility Monitor</td>
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