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1 Title:

Not all Sensors are Created Equal: A Framework for Evaluating Human **Performance Measurement Technologies** Authors: *Brian Caulfield (Corresponding Author), The Insight Centre for Data Analytics, O'Brien Centre for Science, University College Dublin, Dublin 4, Ireland and Applied Research for Connected Health, NexusUCD, Belfield Office Park Block 9/10, Clonskeagh, Dublin 4, Ireland. Email: b.caulfield@ucd.ie Telephone: 01 7166515. *Brenda Reginatto, Applied Research for Connected Health, NexusUCD, Belfield Office Park Block 9/10, Clonskeagh, Dublin 4, Ireland *Patrick Slevin, The Insight Centre for Data Analytics, O'Brien Centre for Science, University College Dublin, Dublin 4, Ireland. *These authors contributed equally to this work.

25 Abstract

26 Recent years have witnessed an explosion in the number of wearable sensing devices and associated 27 apps that target a wide range of biomedical metrics, from actigraphy to glucose monitoring to lung 28 function. This offers big opportunities for achieving scale in the use of such devices in application 29 contexts such as telehealth, human performance and behaviour research and digitally enabled 30 clinical trials. However, this increased availability and choice of sensors also brings with it a great 31 challenge in optimising the match between the sensor and a specific application context. There is a 32 need for a structured approach to first refining the requirements for a specific application, and then evaluating the available devices against those requirements. In this paper we will outline the main 33 34 features of such an evaluation framework that has been developed with input from stakeholders in 35 academic, clinical and industry settings.

36 1. Introduction

37 The market availability of digital devices that measure different aspects of human performance and 38 behaviour has significantly increased in recent years. Human performance and behaviour 39 measurement technology refers to consumer and medical grade health and wellbeing devices across 40 a number of fields such as wearable, digital health and remote monitoring technologies. It is 41 estimated that the number of connected wearable devices worldwide will increase from 325 million in 2016 to 929 million by 2021¹. Similarly, the digital health consumer base is growing in tandem, it 42 43 is forecasted that by 2021, the number of people availing of remote monitoring programmes will 44 grow to 52 million globally². Although the increased availability of such devices is leading to greater research and commercial opportunity, it can also create significant confusion, especially for 45 professionals who are attempting to select appropriate technologies that meet the requirements of 46 47 their specific application, whether it is clinical trial, a research study, or a digital health service. To 48 the authors' knowledge, there are currently no standardised methods to help professionals identify, 49 evaluate and compare the numerous human performance devices available with respect to their

50 specific application requirements. In the absence of such a method, several issues exist for 51 professionals who are undertaking device evaluations.

52 The first of these issues is the need for a tool that helps professionals identify devices that satisfy 53 their application requirements. In many cases, when technologies are chosen and later evaluated, it 54 is often not the device that emerges as the problem per se. It is that the device was, at the time of 55 selection, not appropriate given the specific needs and requirements of the service provider and/or 56 the user. Therefore, to address such an outcome, the authors would argue, that the application 57 requirements should be the driver of the process (i.e. device identification, evaluation and 58 comparison). This creates a fresh emphasis for the professional to understand the nuances of their 59 specific application.

Though there are fuzzy boundaries between them, it is useful to consider three primary application contexts for human performance devices: Wellness/Fitness; Healthcare; and Clinical Trials/Research each with different use cases, depending on the primary motivation for use (Figure 1). Each application will have their own particular set of requirements to consider when deciding upon the type of device to deploy there within.

To help demonstrate the diverging requirements that can exist between applications in relation to a specific device, Figure 2 compares the potential high-level requirements for deploying a wearable activity tracker as part of an employee wellness programme versus those of a clinical trial endpoint.

It is evident from this example that the requirements of an application can be more nuanced and complex than one might imagine. The requirements appear similar in both use cases, yet even at this high level there are some critical differences and even more would be likely to emerge on a detailed analysis of the discrete requirements for each use case. This raises an issue for professionals while attempting to choose an appropriate device due to the difficulty of accounting for the plethora of requirements within an application context. For example, professionals may not be familiar with establishing a set of requirements? Or more importantly, they may have questions about the various

criteria that are important to define when choosing a device? To help address questions like these, the authors would argue that a process to thoroughly guide professionals through the definition of their application requirements could decrease the risk of selecting a device that does not fully account for the needs of the service or user, and are, therefore, not fit-for-purpose.

79 Another issue facing professionals in this space is the lack of a holistic tool for evaluating human 80 performance devices. Several tools are available to help professionals evaluate digital health 81 technologies but these tools are heavily biased towards measuring human factors criteria. A reason 82 for this is that many of these tools have been developed within the discipline of human-computer interaction where the evaluation of user-interfaces associated with web applications and mobile 83 84 technologies are a core focus ^{3–9}. Elsewhere, tools have also been developed to evaluate the 85 acceptance, user-experience and usability of both the hardware and the software aspects of digital 86 systems, products and services ^{10–15}. However, while these tools can be useful, there is a need to also 87 evaluate aspects such as regulatory compliance, technical specifications and capabilities and scientific evidence supporting the use of a given device. These evaluation domains can be 88 89 particularly relevant in highly regulated applications such as clinical trials. Once more, the availability 90 of a holistic evaluation tool, which takes all such aspects in consideration, could support 91 professionals to determine more effectively whether a device is indeed fit-for-purpose, according to 92 their specific application requirements.

A final issue that should be highlighted is the lack of a tool to evaluate human performance devices prior to their implementation. As mentioned above, the available evaluation tools are primarily focused on measuring human factors criteria. Because of their nature, as tools that are focused on the outcome of a person's interaction with a product, they are frequently administered postimplementation. Yet, it is not until a post-implementation evaluation is conducted, that the devices' appropriateness to the service provider and the end-user is discovered, at which time the device could emerge as not fit-for-purpose. Long before this point however, a decision to invest in a device,

or several devices, was made. Such scenarios illustrate that an opportunity exists for a tool that can help mitigate the risk of spending resources on devices that are not appropriate, by extending the evaluation process to the pre-purchase phase where discrete devices are identified and evaluated against the application requirements so that the most appropriate device can be selected in a systematic and informed manner.

105 The aim of this paper is to address the gaps highlighted above by describing a framework for 106 evaluating human performance technologies. The framework guides professionals through the 107 processes of defining application requirements, searching for and selecting candidate devices, and 108 finally performing a structured evaluation of these devices against application requirements – all 109 with a view to helping them determine if a device is fit-for-purpose and worthy of field testing based 110 on their specific requirements. Whether these requirements are in the context of a clinical trial, a 111 pilot study, or a digital health service, the outcome should reflect a systematic and rigorous 112 evaluation.

113 2. Results

114 The evaluation framework follows a three-step process, (1) Requirements Definition, (2) Device 115 Search and (3) Device Evaluation (Figure 3). Each step of this framework is supported by relevant 116 templates, which guide the user through the process and to allow for the clear documentation of the 117 rationale for their choice. In this regard the user is defined as the person/group responsible for 118 selecting the device for deployment in the specified application. Though it is recommended that the 119 framework be employed in a systematic manner, the steps could be applied in sequence or users 120 could elect to apply isolated elements of the framework if constrained by resources and time. For 121 example, there may be situations where one or more devices of interest have already been identified as part of an ad-hoc process. In this case, the user could complete step one (Requirements 122 123 Definition), skip step two (Device Search) and proceed to step three (Device Evaluation) to 124 determine which of the pre-selected devices is most fit-for-purpose and / or worthy of field testing,

- according to their specific requirements. On the other hand, some users may not have the resources
- 126 or time to enable completion of a formal field-testing phase, and therefore, this could limit the
- 127 application of the framework to a desk-based
- 128 evaluation of identified devices.

129 Step 1 – Requirements Definition

130 Defining the application requirements at the beginning of the process enables the user to conduct a 131 more systematic and efficient device search and evaluation. The template provided by the 132 framework guides the user through this process, prompting the consideration of different aspects including: application description and goals, device requirements (e.g. what data needs to be 133 134 collected through the device) and user profile (i.e. who are the people expected to use the device 135 and any specific design requirements they may have). Other aspects to reflect upon include: budget, 136 setting (e.g. home, hospital), geographical location (e.g. urban or rural area), technical requirements 137 (e.g. operational system preferences, compatibility with other equipment and connectivity 138 requirements) and any ethical dilemmas associated with the use of the device (e.g. users are part of 139 a vulnerable population or device is likely to place undue burden or stress on users). Figure 4 offers 140 an excerpt from the requirements definition template.

Finally, the user is encouraged to categorize requirements as essential or secondary, according to how critical they are to the achievement of the application goals. This is important because it helps users remain grounded in those aspects that are most important, which can be often challenging when evaluating and comparing devices that offer multiple features and functionalities. Additionally, the essential requirements form the basis for the device search strategy, as described below.

146 It is important to note, that the extent and intricacy of the requirements list is at the discretion of 147 the user. A more intricate requirements list will, in general, reduce the pool of devices unearthed in 148 the search, while a high-level requirements list will, in general, broaden the scope of the devices 149 identified.

150 Step 2 – Device Search

The second step of the framework aims to help the user identify available devices that match their essential application requirements in an efficient and yet comprehensive manner. Firstly, the user is guided through the process of generating keywords based upon the essential application requirements and using such keywords to conduct a systematic web search. Several recommendations are also provided on how to optimise the search, for example, by using particular words or symbols to widen or restrict results, and reviewing the search engine settings to avoid biased results (e.g. based on the user's location or previous search history).

The user is then prompted to use a comparison matrix template to shortlist devices worthy of a comprehensive desk-based evaluation. It is recommended that only those devices which satisfy all essential requirements are taken to the third step of the framework (Device Evaluation). Figure 5 presents an example of the comparison matrix. In this case, only Devices 2 and 3 satisfy all essential requirements and are deemed worthy of a comprehensive desk-based evaluation.

163 Step 3 – Device Evaluation

The third step of the framework allows the user to conduct a comprehensive desk-based device evaluation and determine whether one or more devices are worthy of field testing. The template provided prompts the user to answer a number of questions and scrutinize each device according to six domains: 1) Background Information; 2) Cost and Supply Information; 3) Regulatory Compliance; 4) Scientific Evidence; 5) Technical Evaluation and 6) Human Factors. Figure 6 offers an excerpt of the device evaluation template for illustrative purposes. A description of each domain is discussed below.

171 Background Information

The user is prompted to gather background information on the company supplying the device. This may include, for example, information on the size of the organisation, number of years they have been operating, where the company is based and whether they have experienced any product recalls in the past. The goal of this section is to give the user a sense of trust in the company behind the device and clarify whether they possess the required infrastructure to support the use of the device for the purpose specified by the user. Such knowledge can be of critical importance if the application requires a steady supply of a large number of devices.

179 Cost and Supply Information

This section allows the user to determine whether the device is affordable and available. It covers the costs of the device (including the need for additional or recurrent purchases, shipping fees, or technical support subscription charges), as well as relevant supply information, such as availability in the target country, minimum order requirements and the possibility of obtaining a free sample.

184 Regulatory Compliance

This domain requires the user to consider whether the device evaluated complies with relevant regulatory standards, with due regard to the territory or territories in which the device will be deployed. This includes not only safety and performance standards, but also data protection regulation applicable to the target location where the device will be used.

189 Scientific Evidence

190 The user is encouraged to examine the scientific evidence supporting the intended use of the device. 191 This includes, but is not limited to, evidence demonstrating the validity and accuracy of the device's 192 target measurement in comparison to the gold standard, data quality under field conditions (as opposed to highly controlled, in-lab environments), clinical safety and performance, technical 193 194 feasibility and usability. Where the intended use stated by the manufacturer differs from the user 195 application, it is important to investigate whether there is evidence supporting the latter. For 196 instance, if the user wishes to use an activity tracker originally designed for athletes with a cohort of 197 geriatric patients, it would be important to determine whether there is any data published on the 198 use of the device by older people.

199 Technical Evaluation

This domain scrutinizes the device's technical specifications and capabilities. The intention is to give the user a deep understanding of how the device operates and what technical infrastructure may be required. Examples of sub-sections within this domain include device dimensions, battery life and charging methods, calibration requirements, operational system compatibility, connectivity requirements (e.g. wired, Wi-Fi, BT), data access and storage (e.g. is it possible to access raw data from the device? Where is the data stored?), data security (e.g. how is user data protected?) and data visualisation (e.g. does the device provide feedback? In this case, where is it displayed?).

207 Human Factors

The final domain of the evaluation template relates to the device usability and other human factors. The questions in this section help the user examine the level of end-user interaction required, as well as any obvious design issues, which may hinder usability and user experience. Other aspects to consider include the device material (e.g. is it washable? Is it durable? Could it cause allergy or skin irritation?) and the quality of educational materials provided.

213 Data Gathering and Interpretation

214 The user may refer to a variety of sources to obtain the information required to complete the device 215 evaluation process. These might include the supplier's website, news outlets, blogs, scientific 216 journals, discussion forums and communication with the supplier. Where information regarding a 217 query cannot be located, it is recommended that this is clearly stated (e.g. 'information not found'), 218 instead of making assumptions around the device features and capabilities. Documenting the access 219 date and source of information is also highly encouraged as there may be discrepancies depending 220 on when and where information is garnered (e.g. different resellers may offer different prices). 221 Documenting the information source is also particularly beneficial when revisiting the decision-222 making process in the future.

223 Once all queries have been answered, the columns on the right-hand side of the template prompt 224 the user to compare the devices. This can be seen on the 'Requirements Fulfilled?' column 225 presented in Figure 6. For each query the user should try to determine whether the relevant 226 application requirement is fulfilled for each device. It is recommended to clearly document if the 227 query is not relevant to the user requirements or if further information is required to finalise a 228 decision. Once more, this is beneficial when revisiting the decision-making process in the future.

By comparing how well the devices satisfy the application requirements under each domain, the user should be in a much more informed position to determine which device or devices are worthy of field testing. It is recommended to clearly document the rationale for the decision made, as well as any specific areas that require further investigation through field testing. In the case where a conflict between two devices emerges, and the user is satisfied that they have obtained all the information they can to help inform their desk-based evaluation, it is recommended that the user field tests both devices to determine the most fit-for-purpose device.

3. Discussion

The evaluation framework presented in this paper was developed as a collaboration between academic, industry and clinical stakeholders to address the lack of an existing structured approach to help professionals evaluate human performance technologies. The framework provides a comprehensive tool which enables the user to define their specific requirements, conduct a systematic web search and complete a holistic desk-based evaluation, to determine whether one or more devices are fit-for-purpose and / or worthy of field testing.

The first two steps of the framework, Requirements Definition and Device Search, are unique in comparison to existing resources. To the authors' knowledge, this is the first tool to prompt users to thoroughly reflect upon and prioritise their requirements prior to selecting a device. It is believed that this will enable users to conduct a more efficient search and grounded evaluation, decreasing

the risk of selecting devices that fail to fully account for the specific needs of their application.
Similarly, no other resources have been found to support professionals in conducting a systematic
web search to identify devices that match such requirements.

While existing tools may help users evaluate specific aspects of a digital health device, these resources are not conducive of a holistic evaluation. The six domains presented on the third step of the framework, address this gap by allowing users to conduct a comprehensive desk-based evaluation regardless of their own area of expertise. It is also expected that this exercise may help users identify areas where they require specialist input to help them decide whether a device matches their application requirements.

Finally, it is important to note that the desk-based evaluation process described in this paper is not expected to replace the need for field testing of selected devices. It is, however, believed that it will greatly help users identify critical issues in a timely manner, i.e. before significant time or resources are spent on implementing devices that are not fit-for-purpose. This offers a significant advantage over existing resources, which mainly focus on evaluating devices post-implementation.

4. Methods

The three-step evaluation process outlined above was developed using an iterative participatory design approach, as described by Simonsen and Hertzum ¹⁶. This is a hybrid design approach that emphasises the involvement of potential future end-user's expertise and experiences primarily for the design of technologies, businesses and social innovative products and services ^{16,17}. Moreover, as well as being an inclusive design process it is also iterative, where researchers and potential future end-users work collaboratively to discover, explain, reflect and integrate knowledge at various timepoints in the process to aid in the productive development of the design ¹⁸.

The approach was felt to be most appropriate considering the cross-collaborative nature of the research which required the input of various types of expertise in the health technology field, from

both research and industry, throughout the design process of the evaluation framework. Two industry collaborators were involved at different points throughout the process. In both cases, selection of human performance measurement technologies was a critical issue for their business, one company being involved in tele-health service provision, and the other being a clinical research organisation. Figure 7 illustrates the main project stages including the point at which each stakeholder group were involved.

277 Defining the Device Search and Requirements Definition Processes

The initial phase of the project aimed to define the Device Search Process (Step 2 in Results). Early iterations of this process were trialled by the researchers (BR and PS) using two discrete smart blood pressure monitors as the focus for the desk-based web search. These searches were unstructured but did entail the formulation of keyword searches. When all keyword sequences were saturated, the researchers reconvened to critically evaluate the process used.

The core aspect to emerge from this early work, was that though the process made sense in terms of formulating keyword sequences to identify potential devices, without the requirements of a specific use case, the web search findings were too expansive. For instance, a plethora of smart blood pressure monitors were identified but without contextual information such as, a set budget per device, there was no early mechanism to filter down the large number of devices garnered from the web search.

Through further consensus, the researchers decided that hypothetical applications with specific requirements should be developed first, one academic in nature and one from a health technology industry perspective. Doing so would allow the researchers to assess the flexibility of the tool in relation to the diverse needs of potential end users. Crucially, the specific application requirements would help focus the identification process while providing the device evaluation with a more purposeful direction. A hypothetical academic application, concerning a diabetes self-monitoring

study requiring the use of a smart glucometer, was then developed, forming the basis for theRequirements Definition Process (Step 1 in Results).

297 Industry Workshop 1

298 A one-hour workshop with the two industry collaborators was then arranged with the aim of (a) 299 gaining feedback regarding the overall project design and trajectory and (b) defining an industry-led 300 hypothetical application. During the workshop, the collaborators were presented with the 301 hypothetical academic application use case. Based on this example, they were then given the task of 302 developing an industry-led application use case that reflected the requirements of a provider style 303 study. The primary outcome of the workshop was the development of industry-led hypothetical use 304 case namely a medication adherence programme, requiring the use of a smart pill adherence 305 tracking device

306 Expert Consultation 1: Specification of Device Evaluation Template

The aim of this phase was to develop the specifications for the device evaluation template. To align with the iterative participatory approach, the research centre's existing in-house healthcare technology expertise was leveraged to identify the specifications. To provide the basis for the feedback sessions with the expert group (n=7), the authors developed an alpha version of the device evaluation template, using a list of device evaluation criteria that had originally been used by one of them (BC) as a teaching tool.

Each expert was invited to participate in a 30-minute brainstorming session with researchers (BR and PS). The experts came from a variety of digital health backgrounds including biomedical, software and systems engineering, human factors, regulatory, clinical and digital health expertise. Each expert was provided with a copy of the alpha version at the beginning of the session. They were asked for their feedback regarding the domain content in the context of using it to evaluate a digital health and wellbeing device. Notes were taken by the researchers regarding the relevant points made by each expert. Upon completing the feedback sessions, the notes gathered were collated and examined for patterns. As patterns were identified, they were cross checked for consistency and
 compiled into iteration additions. The researchers then refined the domains and the alpha template
 was subjected to its first iteration.

323 Expert Consultation 2: Domain Question Development

324 The aim of this phase was to develop the questions within each domain. To ensure these iterations 325 complied with initial feedback and comments, the same experts (n=7) were invited to partake in a 326 follow-up 30-minute feedback session with two researchers (BR and PS). The experts received a copy 327 of the iterated template at the beginning of the session and asked for their feedback regarding the 328 domains and questions there within. As the expert critiqued the iterated template, notes were 329 taken, and afterwards collated and examined for patterns. If patterns were identified, they were 330 cross checked for consistency and compiled into iteration additions. The insights gathered informed 331 the final iteration. The researchers now had a beta version of the template ready for testing.

332 Pre-Evaluation Template Testing

In this phase, the researchers (BR and PS) aimed to define the devices, per hypothetical use case, that would be allocated to the external researchers for testing the device evaluation template. To explain how the devices were chosen for the testing phase, it will be instructive to provide an example using the smart pill box hypothetical use case. The researchers followed the first two steps of the process: Requirements Definition and Device Search. Leveraging the requirements defined by the industry collaborators (Figure 8), the researchers conducted the device web search based on these criteria:

smart or connected device; ability to track medication (pill / tablet) adherence; portable device;
offline use enabled (i.e. store and forward); potential ability for other services to access; monitoring
data (near) real time; currently available for purchase; distributed in Ireland; and compliance with
EU regulations (CE marking, EU Data Protection Directive).

Using the Google search engine, a search was conducted to identify potentially suitable devices. The researchers went 4 pages deep into the Google search engine (10 results displayed per page) for each keyword permutation. In each case, the first 40 results were examined to search for relevant devices. Once new search combinations were not yielding any new device search information within the 40 results, the researchers concluded that saturation had been reached and ceased the search. The following keywords were used: smart / connected / wireless / Bluetooth; monitor / track; medication / pill / tablet; and adherence / compliance.

A number of keyword permutation combinations were tested. One researcher (BR) tested combinations using the keyword 'monitor' (e.g. smart + monitor + medication + adherence + device) while another researcher (PS) tested combinations containing the word 'track' (e.g. smart + track + medication + adherence + device).

The following combinations retrieved the largest number of new results: (smart + monitor + medication + adherence + device); (smart + monitor + pill + adherence + device; wireless + monitor + medication + adherence + device); (Bluetooth + monitor + medication + adherence + device); and (Bluetooth + monitor + medication + compliance + device). A record was not kept of the number of unique devices that were found using each search combinations.

360 From this search, 21 devices were initially identified. All smartphone apps, connected blister packs 361 and smart ingestible pills, totalling 5, were excluded since they were outside the scope of this 362 medication adherence programme. A further 2 devices were excluded because they were not 363 focused on pill or tablet adherence monitoring. Another 2 devices were excluded because they were 364 bound to a service that did not allow integration with external services. The remaining 12 devices 365 were subjected to the requirements comparison matrix. Based on this comparison, 9 devices were excluded because they didn't meet one or more criteria or not enough information was available 366 367 despite contacting manufacturing company and three devices were shortlisted as suitable to allocate 368 to the evaluation template testing phase as seen in Figure 9.

The same process was followed by researchers to determine the devices to be allocated to the those testing the evaluation template based on the smart glucometer hypothetical use case. In total, 10 devices were identified of which 2 were found to be suitable for the testing phase.

372 Evaluation Template Testing

373 For this phase, the aim was to finalise the device evaluation template in terms of its usability and 374 general experience. To ensure objectivity, external researchers (n=5) from a range of digital health 375 and wellbeing backgrounds, other than those used in the specification of the device evaluation 376 template, were recruited to test the beta version. Both hypothetical application use cases were 377 tested; two participants were allocated the smart glucometer academic use case, and three were 378 allocated the smart pill-box industry use case. Each participant was emailed a copy of the beta 379 version template, a copy of the application requirements plus an outline of the devices to be 380 evaluated. No parameters were defined for the testing other than to test the device evaluation 381 template using the devices allocated to them. The testing was completed at their convenience.

Upon completion, comments were received via email from the participants in relation to the usability, user-experience and perceived usefulness of the evaluation template. Their feedback was collated and examined for patterns. When patterns were identified, they were cross checked for consistency and compiled into iteration additions. These concluding insights informed the final iteration of the beta version device evaluation template.

387 Industry Workshop 2

A final one-hour workshop was conducted with the two industry collaborators. The aim was to present the framework and garner final feedback. Particularly, the authors wanted to explore if they felt (a) that the three-step framework process was a useful and relevant guide and (b) that the device evaluation template was flexible enough to meet their specific needs. Notes were taken and feedback was incorporated to the final version of the evaluation framework.

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397 6. Competing Interests

398 The authors have no competing interests to declare.

399 7. Contributions

BR and PS contributed to study design, data collection and analysis and writing/reviewing the manuscript. BC supervised the project, contributed to study design, provided the list of device evaluation criteria which formed the basis for the alpha version of the device evaluation template and critically reviewing the manuscript. All authors have approved the final version of this manuscript and take accountability for all aspects of the manuscript.

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- 455 10. Figure Legends
- 456 Figure 1: Three Primary Application Contexts for Human Performance Devices
- 457 Figure 2: Example of High Level Requirements for Deploying a Wearable Tracker in Different
- 458 Application Contexts
- 459 Figure 3: Evaluation Framework's Three Step Process
- 460 Figure 4: Excerpt from the Requirements Definition Template
- 461 Figure 5: Example of Comparison Matrix in Practice
- 462 Figure 6: Excerpt from the Device Evaluation Template
- 463 Figure 7: Main Project Stages and Stakeholder Input
- 464 Figure 8: Application Requirements
- 465 Figure 9: Device Shortlisting