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A maturity grid assessment tool for environmentally conscious design in the medical device industry

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ABSTRACT

The medical device industry is growing increasingly concerned about environmental impact of products. Whilst there are many tools aiming to support environmentally conscious design, they are typically complex to use, demand substantial data collection and are not tailored to the specific needs of the medical device sector. This paper reports on the development of a Maturity Grid to address this gap. This novel design tool was developed iteratively through application in five case studies. The tool captures principles of eco-design for medical devices in a simple form, designed to be used by a team. This intervention tool provides designers and product marketers with insights on how to improve the design of their medical devices and specifically allows consideration of the complex trade-offs between decisions that influence different life-cycle stages. Through the tool, actionable insight is created that supports decisions to be made within the realm of design engineers and beyond. The tool highlights areas which are influenced by design decisions taken, some of which are perceived to be outside of the direct control of designers.

1. Sustainable design and medical devices

The medical device sector globally has a significant impact on the environment. Products in this sector typically have very short lifecycles of 18–24 months,[1] and, as a result, it is a sector with a fast rate of change and innovation. More patents are filed in this sector per annum than in computer technology, transport or digital communication.[1] In the EU, there are around 25,000 medical technology firms, with the majority (95%) being SMEs. In the US, the medical device market was estimated to be worth USD125.4 bn in 2013.[2]

Despite the rapid rate of innovation, investment to develop new products is large and the environmental impact of devices is substantial. In an industry which is already highly regulated, further pressures on environmental design are not universally welcomed. As a result, it has been noted that this is a sector in which sustainable design has been slow to take hold.[3] However, it is evident that the medical device industry is increasingly concerned about the environmental impact of their products and processes (Deval, 2007), as these are significant. For example, approximately 90% of medical device waste consists of either disposable or one-time use products/components.[3] Indeed, Kadamus (2008) reported that 6600 tons (approximately 600,000 kg) of medical waste are generated every day by healthcare facilities in the US. Much of this waste has been in contact with the bodily fluids of patients and roughly 12% is non-hazardous plastic.

In addition, to comply with regulations on hygiene and cleanliness, and meet performance requirements, there are many 'non-desirable' materials used. These might be potentially harmful to humans in use, such as phtahalate plasticizers in plastic products (Hill, 2003) or result in harmful toxic emissions during disposal (Marshall et al., 2009a,b). Materials might also be scarce or more widely harmful. For example, healthcare is the fourth largest contributor of mercury to the environment and a significant contributor of dioxins, another serious environmental pollutant

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[1] http://www.eucomed.org/uploads/Modules/Publications/the_emti_in_fig_broch_12_pages_v09_pbp.pdf.

[2] http://www.espicom.com/usa-medical-device-market.html (accessed 24-3-15).

[3] http://www.mddionline.com/article/sustainability-medical-device-design (accessed 24-3-15).

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(Zimmer and McKinley, 2008). Despite these risks, the sector is perceived as having lagged behind other industries in the design of environmentally responsible products (Karlsson and Ohman, 2005).

To make a significant change, opportunities for reducing environmental impact must be considered early in the design phase of product development (Sutcliffe et al., 2009). Indeed, there is a growing body of research which is seeking to provide guidance to designers (e.g. Pigosso et al., 2013; Bhamra et al., 2011; Keitsch, 2012). To date, this guidance for designers aims to be of relevance across all industry sectors. However, there are specific industrial sectors, such as the medical device sector, which have a substantial environmental impact and which might benefit from more targeted advice (Sutcliffe et al., 2009).

To address this significant issue, the responsibility falls into the hands of designers of medical devices. But, when reviewing academic literature on environmentally conscious design, there is little attention paid to medical devices. Thus, there is a genuine need for methods which enable the assessment of designs and provide guidance to designers in this high-impact sector (Deval, 2007). This paper reports on the development of a new design tool that seeks to address this gap. Recognising the importance of information in supporting sustainable design (Aschehoug et al., 2013), this tool aims to present information for designers in a useful, easily accessible and usable form. This is especially important, recognising the dominance of SMEs in this sector.

This paper is structured as follows. Firstly, a case will be made for the need for a new design tool, based on a review of existing tools. This will focus specifically on 'maturity grids' as a method for addressing this gap. Next, the research methods will be described. This will be followed by a description of the development and testing of a new tool, building on evidence from case study application and literature. The paper concludes with opportunities for further research in this area.

1.1. The medical device sector

Definitions of medical devices vary among different geographical areas, but in general they include articles manufactured specifically for diagnostics, monitoring, treatment, or modification of the human body, that are not solely pharmaceutical goods.

In the USA, medical devices are controlled and regulated by the Food and Drug Administration. In Europe, the definition of a medical device is provided by the EU, but individual countries take on the task of approving devices for use inside their own borders. USA and European definitions for medical devices are given below, since these are the two largest markets for medical devices (Espicom, 2011a,b).

- EU: "Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; investigation, replacement or modification of the anatomy or of a physiological process; control of conception and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means" (European Union, 2007a,b).
- USA: "An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them; intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment or prevention of disease in man or other animals; or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes" (FDA, 2011a).

The EU and USA definitions are broadly similar and this gives us the basis for understanding of what is meant by a medical device within the context of research. The definition is, however, necessarily broad, and covers a wide range of complexity; from simple tongue depressors, through syringes, blood pressure monitors, surgery tools up to large X-ray or Magnetic Resonance Imaging machines.

2. The need for a new tool to support sustainable design of medical devices

For firms wishing to improve their eco-credentials, there are a range of product assessment and eco-design tools currently available. Comprehensive reviews eco-design tools are available in Pigosso and Rozenfeld (2010, 2012) and Knight and Jenkins (2009). Pigosso for example examined over 100 such methods is available in Pigosso and Rozenfeld (2012). These include: Life Cycle Assessment (LCA) (Hauschild et al., 2004; Tischner et al., 2000; Donnelly et al., 2006; Stevels, 2001); the Materials Energy and Toxicity matrix (van Berkel et al., 1997); Environmental impact assessment (Senecal et al., 1999); Eco communication matrix (Stevels, 2001); Multi-criteria analysis (Mendoza and Prabhu, 2003); Hierarchy of focussing (Hauschild et al., 2004); Eco-concept spiderweb (Tischner et al., 2004); Eco-roadmap (Donnelly et al., 2006); Carbon footprinting (Weidema et al., 2008); and various eco-design guidelines and checklists (Knight and Jenkins, 2009). Given the plethora of tools aimed at eco-design, why is a new tool to address eco-design in medical devices needed? To answer this, it is first necessary reflect on the scope and objectives of some of existing methods in a little more detail.

Many of these tools are used to provide objective, detailed and quantitative data regarding impact, based on a comprehensive analysis of materials, processes, and emissions (e.g. carbon footprinting). In addition, many of these tools are time-consuming to use and depend upon having a 'final design' to analyse. They also do not necessarily provide any direct indication of how improvements might be made. To be of use to designers, eco-design tools need to be: "simple to use, do not require comprehensive quantitative data and are not too time demanding" (Byggeth and Hochschorner, 2006, p. 1423). Byggeth and Hochschorner (2006) reviewed 15 such eco-design tools, which they believed satisfied these criteria. They concluded that existing tools do not provide sufficient support in trade-off situations, which is important in the design process, and that tools should beneficially include a life-cycle perspective.

In a similar analysis, Knight and Jenkins (2009) listed a range of eco-design tools, including checklists, eco-ideas maps, environmental effect analysis, guidelines, MET matrix (Materials, Energy, Toxicity), impact assessment, life cycle assessment, eco-compass and 'environmental Quality Function Deployment (QFD)'. The application of QFD to sustainability is interesting, as it is explicitly intended to be used during design, rather than to analyse the

results of design activity (Wimmer et al., 2008). A large number of eco-design heuristics or guidelines are provided (Masui et al., 2001), to enable direct comparison between 'engineering metrics' and 'environmental voice of customer (VOC)'. However, as noted by Masui et al. (2001), these are 'intended for general use, not for a specific product'.

Thus, there are a plethora of tools available. Some of the more dominant, as identified by the authors, are listed below to demonstrate the need for a new tool focused on medical devices. It is recognised that this list is not exhaustive, but we believe the issues raised are indicative and representative of the wider set of tools listed above.

- *Life cycle assessment (LCA)*: used to quantify the potential environmental impact of a product over its full life cycle. LCA is generally viewed as the leading approach to assessing a product's environmental credentials. However, a full LCA of a design is, by its nature, time consuming and labour intensive (and as a result expensive). These assessments can be objective and thorough and provide indications of opportunities for improvement. However, they are difficult to apply at the design stage and again do not inherently provide any structured guidance for designers.
- *Design guidelines*: form the most basic form of eco-design tool (Knight and Jenkins, 2009), in which a heuristic rule of 'good design' is presented. Such tools do not necessarily direct designers towards improved outcomes. It would be possible to generate guidelines specific to the medical device industry, but the static nature of the statements found in guidelines means that this type of tool may do not provide any real guidance to designers in moving towards better outcomes.
- *Carbon foot-printing*: is a technique that involves quantifying the environmental impact of a product (or process) by converting those impacts to carbon dioxide equivalents. Many different tools are available, some at little or no cost. They produce an output that is specific to the challenge of carbon consumption and thus do not address a wider set of issues regarding eco-design.
- *Multi-criteria analysis*: enables the assessment of multiple options in the face of varying stakeholder opinions, and can deal with mixed (qualitative and quantitative) data sets. This is a thorough, but data intensive methodology which gives complex numerical outputs (Mendoza and Prabhu, 2003). Choi et al. (2008) provide an example of the application of this type of analysis to charcoal barbeques; the output is highly specific and it is difficult to interpret the figures in terms of directed guidelines for improving environmental credentials.
- *Environmental impact assessment*: is a well-established technique for evaluating the direct impacts on the environment, considering alternatives and attempting to mitigate any deleterious effects (Senecal et al., 1999). However, the technique is not specific to product development, and thus would be difficult to customise for the medical device industry.
- *Checklists*: Knight & Jenkins noted that checklists are viewed by firms as "easy to understand and are often the first tool a company starts to use when getting into eco-design" (p.37) However, they tend to result in a binary (yes/no) response, offering simplicity, but a lack of detail in enabling improvement. They also noted the risk that they provide 'common sense' without specificity.
- *Eco-design maturity model*: Pigosso et al. (2013) adopted the principles of capability maturity to propose an 'eco-design maturity model'. This model comprises a set of eco-design practices which are described at different levels of 'maturity'. Here, 'maturity' relates to a set of successive stages of incorporation of eco-design issues into product development processes. The underpinning logic is to determine whether eco-design is treated systematically as a phenomenon and is incorporated within processes, strategies and systems. As a tool, it is comprehensive but generic. It does not aim to address the needs of more specific sectors, such as the medical device sector. The focus of the tool is also on processes, rather than the products that emerge.

Considering these various approaches, it is possible to infer a number of reasons why a new tool is needed. Firstly, many existing tools are not intended to be applicable at the design stage of a new product, but provide a means for assessing the credentials of an existing offering (Telenko et al., 2008). Many existing tools rely upon the collection of data, and as a result are time consuming and complex to use (e.g. Carbon foot-printing). Where assessments are made, they are either at a highly detailed level, or the tool might provide a 'scale' against which core elements can be scored. However, in the majority of cases, there is no specificity around what a high or a low score might be. As a result, it is not possible to easily identify how a design might be improved or what objectively characterises poor performance. In conclusion, tools are either highly specific, aiming to address in detail a single sector or issue or tend towards being superficial, providing generic heuristic advice, but with insufficient specificity to be helpful.

It is worth restating the main gap presented by this analysis; whilst many of these tools might be used in the medical device sector, none are tailored to the specific needs of this sector. This latter point is important, as the medical device sector has specific characteristics, such as safety, efficacy and reliability, set in a context of high regulation explicitly targeted at medical devices (e.g. FDA[4]), very high throughput of materials and a demand for hygiene and cleanliness. Together, these pose particular issues for sustainable product development.

There are a number of sectors where tools have been created specifically to meet the needs of that sector. For example, the ENDAMI and LEAF tools from the Fraunhofer Institute for Building Physics[5] provide enable life cycle analysis in the aviation sector.

In Section 1, we explained that the medical device sector has specific characteristics and that there is a need for methods which enable the assessment of designs and provide guidance to designers in this high-impact sector (Deval, 2007). Whilst there are a plethora of existing tools which could be used, none of them are specifically targeted at this important sector. Thus, there is an opportunity for a new tool to address this clear and critical gap to focus on sustainable design specifically in the medical devices sector.

Whilst there may be many possible routes to providing a solution, this study chose to develop a 'maturity grid' based tool, which will enable designers to assess the 'maturity' of a design and identify opportunities for improvement. Such an approach has the advantages of 'checklists' in simplicity, but with further details on how a progression might be made towards improved performance.

2.1. Maturity grid based tools

Byggeth and Hochschorner (2006) made a distinction between tools supporting analysis, comparison and prescription, which

[4] http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm373750.htm.

[5] http://www.ibp.fraunhofer.de/content/dam/ibp/de/documents/Informationsmaterial/Geschaeftsfelder/Flyer_FraunhoferIBP_CleanSky_EDS_ENDAMI_web.pdf (accessed 24-3-15).

seems to suggest that a tool might not be effective at addressing all three goals simultaneously. However, a commonly used tool in other domains is the Maturity Grid (Maier et al., 2012), which provides a structure in which performance is described at increasing levels of 'maturity' for a range of criteria; albeit in a simpler fashion than the more complex Capability Maturity Model.

The underlying logic of this approach is to both enable assessment, but also to provide specific guidance on what improved performance might look like.

Maturity grids originated in the quality control domain (Crosby, 1979), and define a number of levels of "maturity" for a processes in a given topic area. For example, Crosby's early example examines six components of quality management with five levels of maturity described for each component. This structure allows a company to assess how mature a company is with respect to each of the aspects or processes contained within the maturity grid. Since their origin, approaches based on maturity assessments and analyses have been applied in a variety of areas, including those relevant to this study, such as the design process (e.g. Maier et al., 2011; Maier et al., 2009), healthcare albeit connected to patient safety rather than medical devices, and new product development (for a review see Maier et al., 2012). It has been suggested by Kirkwood et al. (2011) that a maturity type approach could be usefully applied with a sustainability brief.

Typically, maturity grids have been conceived to address organisational 'processes' (e.g. Chiesa et al., 1996; Pigosso et al., 2013) with a view that a mature process will naturally result in a successful outcome. To date, this approach has not been applied to the analysis and improvement of *products*, either within or outside of the medical device sector. Thus, by focussing on the characteristics of a product, the adoption of a maturity grid approach provides an original application for maturity grid assessments.

3. Research approach

The approach taken to creating an 'eco-design maturity grid' follows the model suggested by Maier et al. (2012). Maier et al. proposed that the development of new maturity grids should follow four phases: planning, development, evaluation and maintenance. This investigation covers the first three of these phases, from planning through to evaluation, as summarised below:

- *Planning*: This tool is aimed at medical device designers, with the aim of allowing and encouraging them to design more environmentally conscious medical devices. The scope of the tool is restricted to the life cycle of a medical device and aims to be useful for all types of medical device. Success is defined as the ability of the tool to provide useful information and direction for medical device designers in creating more environmentally conscious medical devices.
- *Development*: The content of the tool is structured around five separate product life cycle phases, each with its own Maturity Grid. Maturity levels were selected to be "as good as the designer could make it" at the most mature level and "the worst case scenario" at the least mature level. From here, literature, and discussion with designers was used to formulate the text for each cell in the grid.
- *Evaluation*: The tool was evaluated and refined through a series of case studies with medical device designers. This process was highly iterative with the initial development phase.

The maturity grids for the tool were initially populated from literature and prototype versions of the tool were then taken to companies, who were asked to use it, in a session lasting between 60 and 90 minutes. In each case, participants were asked to use the design to analyse and identify possible design changes to a product which was currently in development.

Results fed an iterative design process, whereby suggestions and feedback from each case study were built into the next version of the tool. Changes were tracked using a change log, and version control. Perhaps surprisingly, at each subsequent application, participants only added content, and at no point did suggestions from a company contradict suggestions which had been made previously. Four case studies were conducted during this development phase, where content continued to be enriched from the literature and from the iterative process of application. When no further suggestions for improvement were being suggested by participants, a further validation case study was undertaken. Here, the tool was used in a company, with as little input as possible from the researcher (Fig. 1).

3.1. Planning: semi-structured interviews

To inform the initial creation of the assessment tool, 8 semi-structured interviews were conducted with key opinion leaders in healthcare design and use. Four of these were medical device designers, each with a personal interest in eco-design and one of whom sat on many relevant committees. Three were in the UK National Health Service (NHS) with a remit to consider sustainability and thus took a wider view on policy, regulation and the overall healthcare system. The final interviewee was responsible for sustainability in a major outreach organisation. Thus, participants were selected to represent a wide range of perspectives.

These interviews are not reported in detail in this paper, but provided an important starting point for the planning of the new tool, both in terms of overall approach and also content. The interviews confirmed that Design for Environment (DfE) in the medical device industry is still in its infancy and demonstrated the need for a simple tool that addresses issues more widely than just product packaging. DfE for medical devices is especially problematic as it is extremely difficult to justify apparently higher costs to the purchasing agencies. Overall awareness of DfE is patchy both at a detailed level and in terms of the wider product-service system. Even where there is awareness, good intentions are not necessarily translating into action either by designers.

These interviews had implications for the design of a new tool. The tool must enable the translation of these simple ideas into practice and must also focus attention more broadly on the underlying business model. The tool must fit within the business context, and be simple to use. Several respondents noted that if the

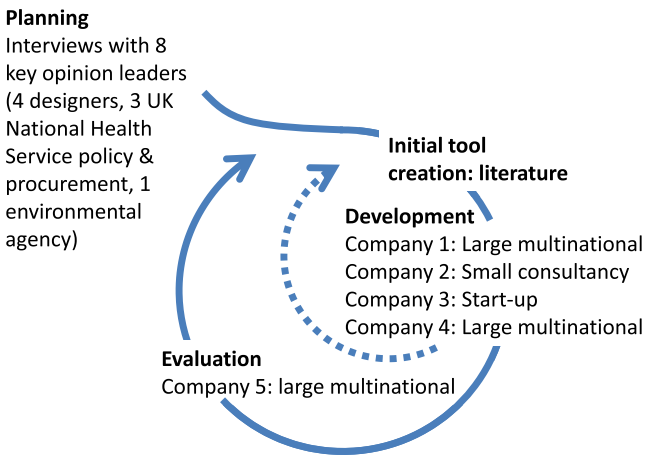

Fig. 1. Tool development cycle.

tool demands significant time or expense in use, then it is unlikely to be tolerated. Finally, the tool must provide designers with guidance on how to improve designs and it must address topics of specific to the medical device industry, such as single use items.

3.2. Initial tool creation

The initial set of maturity grids were populated from literature, following the process described by Maier et al. (2012) and used in similar cases (e.g. Moultrie et al., 2006). At this stage, the tool's underpinning structure and logic was established.

- *Selecting process areas*: A leading principle in developing the tool was that it should retain the idea of life cycle thinking. That is to say that it should address the impacts of the product throughout its life cycle from raw material sourcing, through manufacturing, distribution, use and end of life. Thus, in this case, the equivalent of a 'process area' is each stage of the product life cycle. This resulted in five separate maturity type grids, one for each life cycle phase, each of which contained design issues relevant to that particular life cycle phase.
- *Selecting maturity levels*: Within each grid anchor phrases were used along a scale of 1–5, allowing designers to choose the phrase that most closely corresponded with the situation for the device that they were analysing. This process is referred to from here forward as "scoring". 1 represented situations that were considered the worst outcomes environmentally, and 5 represented situations that were considered the best outcomes environmentally. This is slightly at odds with the idea that being environmentally conscious generally consists of minimising and reducing where possible, but is closely tied with the idea that higher scores signal improvement, and is in line with the qualitative approach taken by De Jonge (2006). In some cases, a "Not Applicable" option was also provided, giving a score of zero. The need for this option emerged early in the interviews, as some design issues were deemed to be relevant for some devices, but not necessarily all. For example, a manual device, such as a traditional scalpel, should not be able to score a 5 (the best score) for power consumption simply because it is unpowered.

In addition to the grid itself, spaces were provided so that designers using the tool could answer two extra questions: whether they had influence over the issue that they were scoring and whether they would need extra evidence in order to provide a score that they felt confident about. For example, would they need to go and ask colleagues or factory managers in order to provide the information needed? The layout of an 'unpopulated' maturity grid is illustrated in Fig. 2.

3.3. Tool development and validation

A decision was taken early on that this should be a paper-based, rather than software tool. Software tools are most effective in enabling detailed analysis, typically when used by a designer working alone or sequentially with other designers (Moultrie and Maier, 2014). They have an advantage in 'detail', but tend to inhibit the involvement of a wider set of stakeholders and team members who might provide important insights. As this tool is envisaged to be used by a small team, and is designed to encourage debate and discussion, it was felt that a paper-based solution was most appropriate. It was also felt that this would enable iteration and evaluation before expending resources in coding. This does not preclude a software based tool being implemented at a later date.

In total five companies were recruited for this part of the study, four in the development group and one for validation. To ensure anonymity, these companies are given the identifiers 1 through 5.

Companies were recruited in a variety of ways. Participants were identified based on personal contacts and the industrial databases of the host research organisation. Researchers in similar domains were also asked if there were aware of any companies who may wish to participate. Participating designers were asked to nominate any colleagues in other firms. Finally, the NHS Sustainable Development Unit offered some possible contacts. Potential participants were approached by email with an explanation of the research and a request to participate. In most cases, a telephone call was also needed to outline the research in more detail. Table 1 provides an overview of the 5 case companies.

In companies 1–4, the session was split into two distinct parts; firstly a semi-structured interview with the designers and secondly an application of the emerging Maturity Grid in order to evaluate its effectiveness. The semi-structured interview sought specifically to capture insights regarding the critical issues in medical device design. This was conducted before applying the tool in order that the concepts contained within the tool did not lead the discussion.

In order to ensure that participants could use the tool without intervention from the researcher, a set of instructions was provided in the form of a booklet that accompanied the worksheets. This booklet briefly outlined the structure of the tool, and offered step by step instructions on scoring and on using the Summary, Analysis

Issue	0	1	2	3	4	5	Issue score	Do you need more evidence to score reliably?	Can you influence this as a designer?
e.g. packaging weight	N/A	Description for level 1 – worst case	Description for level 2	Description for level 3	Description for level 4	Description for level 5 – best case			
Issue 2									
Issue 3									
Issue 4									
Issue n									
						Total life cycle phase score	X		

Fig. 2. An unpopulated maturity grid.

Table 1
Case companies.

Company identifier	Organisation type
1	Large multinational
2	Small but established medical device design consultancy
3	Start-up medical device firm
4	Large multinational
5	Large multinational

and Ideas Worksheet. It also offered additional information for completing the scoring for every individual design issue on every grid. Specifically, participants were asked to circle the statement that most closely resembled the current state of affairs for the product currently being designed; selecting 0 if the issue did not apply to their medical device. They then wrote this score into the "score" column and commented on wither they could score reliably and whether this issue was one that they felt they could influence by design. Finally, they summed the score for the overall worksheet.

Having used the worksheets, participants were asked to assess the tool's feasibility, usability and utility and whether using it produced useful outcomes for the designers, as described by Platts (1993). Designers assessed the design of a medical device that they had provided. By using the maturity grids to assess a real product, they became familiar with the layout and contents, in order to subsequently answer the following questions:

- Whether the instructions and guidance provided with the tool were clear and unambiguous.
- Whether the wording in the tool itself was clear and unambiguous.
- Whether designers felt there were any issues that were included unnecessarily.
- Whether designers felt there were any issues that had been missed.
- Whether they thought the tool would bring any benefits to their work.
- If the tool was seen as being beneficial, how it might be used.

Thus, the participants contributed to the development of the grids and ensured that there was 'member validation' of the tool (Bloor, 1997). An example of a completed Maturity Grid is provided in Fig. 3. Participants were specifically asked to comment on the descriptions of each maturity level and add or change any content they felt would aid clarity and accuracy. After the session, participants were asked to review any written comments made by the author to check for common understanding, and all participant companies were offered access to the finished tool.

In company 5, the pre-application interviews were not conducted, as at this point, the tool had reached a point of comparative saturation; where no new concepts had been introduced in the previous interviews. At this point, the tool was delivered in a workshop with multiple designers to consider the design of an existing product. As in companies 1–4, this was followed with a series of questions regarding the completeness, usability and benefits of the tool.

The prototype tool thus evolved continuously as new literature was identified and feedback was received from participants. As a result, the tool became more 'complete' as the development cycle progressed. There are clear drawbacks to this approach, as evidence gained in the earlier interviews was by default less complete than the later ones. However, this was viewed as necessary, and it is our view that this ongoing cycle of development enhanced the quality of the tool. This follows the same rationale as other examples of tool development (e.g. Lofthouse, 2006; Moultrie et al., 2007).

4. A new tool for assessing sustainable design of medical devices

Because of the iterative nature of the development of this tool, the detailed content and reflection from case studies is presented simultaneously. In some cases, this content is primarily defended through literature. In other cases, there is little literature as the ideas are predominantly influenced by responses from the case companies.

	Issue	0	1	2	3	4	5	Issue score	Do you need more evidence to score reliably?	As a designer, can you influence this?
Packaging for the primary product (do not include supplies delivered subsequently)	**Space efficiency of packaging**	N/A option not available for this design issue	Obvious unaddressed inefficiencies in shape,amount or type packaging, e.g. trays that could easily be replaced with flexiform packs	Easily achievable shape, amount or type modifications available, but only on a small scale	One or two of shape, efficiency or type addressed, but inefficiencies remain	Packaging efficiency maximised via shape, amount and type, of one or two of: primary, secondary and tertiary packaging	Packaging efficiency maximised via shape, amount and type of all packaging	3	N	Y
	Structure of packaging	N/A option not available for this design issue	Material thickness could be reduced, and one or more unnecessary layer of packaging remains	Material thickness reduced as far as possible, but more than one unnecessary layer of packaging remains	Material thickness reduced as far as possible, but one unnecessary layer of packaging remains	Multiple layer packaging eliminated where possible, but material thickness could still be reduced	Material thicknesses reduced and multiple layer packaging eliminated as far possible	4	Y	Y
	Recycled, reused or remanufactured content of packaging	N/A option not available for this design issue	No recycled, reused or remanufactured content in packaging	25% of packaging is recycled, reused or remanufactured	50% of packaging is recycled, reused or remanufactured	75% of packaging is recycled, reused or remanufactured	All of the packaging is recycled, reused or remanufactured	1	N	Y
	Recyclability, Reusability, remanufacturability and compostability of packaging	N/A option not available for this design issue	None of the packaging is recyclable, reusable, remanufacturable or compostable through conventional pathways	25% of the packaging is recyclable, reusable, remanufacturable or compostable through conventional pathways	50% of the packaging is recyclable, reusable, remanufacturable or compostable through conventional pathways	75% of the packaging is recyclable, reusable, remanufacturable or compostable through conventional pathways	All of the packaging is recyclable, reusable, remanufacturable or compostable through conventional pathways	5	N	Y
	PVC content of packaging	N/A option not available for this design issue	Packaging contains PVC that could easily be replaced, low molecular weight phthalates (e.g. DEHP) used as plasticisers	Packaging contains PVC that could easily be replaced, no low molecular weight phthalates (e.g. DEHP) used as plasticisers	PVC present but essential, with low molecular weight phthalates e.g. DEHP used as plasticisers	PVC present but essential, with no low molecular weight phthalates used as plasticisers	Packaging contains no PVC	5	N	Y
Transport of finished goods (do not include supplies delivered subsequently)	**Distance of transport from production site to end user**	N/A option not available for this design issue	International - between continents	International - between countries within a single continent	National - long distances (over 100 miles)	National - short distances (20-100 miles)	Local (within 20 miles)	1	N	N
	Method of transport from production site to end user	N/A option not available for this design issue	Aeroplane	Light goods vehicle	Heavy goods vehicle	Sea or rail; road vehicles with efficiency modifications (e.g. tear drop shaped trucks)	Minimal impact transport (e.g. bicycle, solar powered)	1	N	N
							Overall score for distribution (out of 35)	20		

Fig. 3. A completed worksheet for the distribution phase of the product life cycle (note, the uncompleted sheet is in the Appendix).

Table 2
Anchor phrases for worksheet 1 – raw material sourcing.

Item	Rationale for anchor phrases
1.1 Scarcity of materials	Low scores are for products containing the rarest substances as defined by the U.S. Geological Survey (2002). The scale is graded to reflect the relative inclusion of scarce substances, with a goal of no scarce substances.
1.2 Diversity of materials	Low scores are for products containing a diverse array of materials, including paints, lacquers and coatings which are hard to remove and plastics of a similar density (e.g. Coulter et al., 1998). The scale is graded to reflect the relative inclusion of a diverse array of materials, with a goal of minimal diversity.
1.3 Recycled, reused or remanufactured content	Low scores are for designs containing no recycled, reused or remanufactured content. The scale is graded through 25%, 50%, 75% and 100% content by weight.
1.4 Mercury	This is a binary choice (yes/no), given the move to phase out all mercury in medical devices (EU, 2007a). Low scores are for products containing mercury. A good design should include no mercury.
1.5 PVC	Low scores are for designs containing PVC which contains dioxins and which could be easily replaced. The scale is graded to reflect the ease with which PVC can be replaced by more benign materials.
1.6 Transport: origin to production site distance	Products with low scores include materials transported internationally. Better designs include a greater proportion of raw materials transported within 20 miles.
1.7 Transport: origin to production site method	Anchor phrases are based on the Borken-Kleefeld et al. (2010) analysis of transportation methods. Transportation methods are grouped in descending order of impact, with transportation by aeroplane resulting in the lowest scores.
1.8 Major energy sources in material conversion	Anchor phrases present a continuum to reflect the impact of each energy source on emissions, with coal producing the most carbon, sulphur dioxide, nitrous oxides and airborne mercury (Grübler et al., 1999). Petroleum results in fewer emissions (Gaffney and Marley, 2009) and renewable sources are the most benign.

Responses from companies are in italics. Quotes or opinions from interviewees are attributed just to the company and are noted as "Company 1", "Company 2" etc. All worksheets are reproduced in full in the Appendix. For each worksheet, the rationale for the selection of anchor phrases is presented below, along with any specific commentary from respondents on elements of the worksheet.

4.1. Worksheet 1: raw material sourcing

The rationale for each anchor phrase in this worksheet is described in Table 2.

Respondents felt that a goal to included more recycled/reused/remanufactured content to be contentious, given current limitations due to legislation which discourages this practice. However, they recognised the potential here for reducing impact on the environment. Respondents also acknowledged the desirability of reducing mercury and PVC content, and especially PVC containing dioxins. In general, they agreed that it is desirable that both PVC and mercury are eliminated from medical devices (Health Care Without Harm, 2011b). Designers in Company 2 specifically commented that they did not include PVC in their products.

A designer from company 5 noted that it is difficult to either know or define the true point of origin for raw materials, and the group concluded that they would score their device one link backwards in the supply chain (i.e. to include their immediate suppliers). They also commented that this is an issue over which they feel they have little influence. Similarly, designers felt that the mode of transport was outside of their direct influence, despite this being an important issue.

The most contentious issue in this worksheet was the sources of energy used in material conversion. Participants from Company 5 questioned the helpfulness of this item as it was deemed both difficult to answer, and not within scope for their ability to effect change. However, others noted its importance despite this difficulty.

4.2. Worksheet 2: manufacture and assembly

The rationale for each anchor phrase in this worksheet is described in Table 3. All of these items were 'compulsory', as they apply to all products.

When considering production processes, a designer in Company 2 noted that injection moulding was cheap as well as a comparatively low energy process; and as a result is used widely. However, this has negative repercussions at the end of the device's life however, since it made disassembly much more difficult. Company 3 said: "We're using injection moulding and we're replacing glass that needs to be heated to around 1300° with plastic that needs to be heated up to around 200°, so it's a much lower energy process than the current market." The interviewee also commented that although this saved energy, the primary reasons for this material choice were related to product function. These comments highlight the complicated relationship between items, and that achieving a sustainable design requires complex trade-offs.

Designers in Company 2 and 3 acknowledged the importance of considering energy sources, but again commented that it was difficult to provide a confident answer to this question as energy sources might vary depending on location of production.

Solid and liquid waste were acknowledged as important in this sector, and Company 4 stated that they had explicit targets in this area. Company 2 noted that the amount of waste depends on specific practices in factories and thus can be difficult for a designer to influence. Designers in Company 4 noted similarly, but Company 5 answered these questions with no difficulties.

Two other concerns were raised in discussions with designers, but these both proved difficult to translate into 'objective' maturity scales. These related to the toxicity of manufacturing processes and toxicity of waste water. These are both important environmental concerns (e.g. Seuring and Muller, 2008), but designers felt that they were not necessarily within their control. To address this, they have been included within the tool, but a more generic scoring approach has been used, where designers might rate their impact from 'very severe' through to 'no impact'. It was felt that this was a suitable way of ensuring the issue was not ignored.

4.3. Worksheet 3: packaging and distribution

Product packaging was encapsulated entirely within the Distribution worksheet to enable it to be considered separately from the main product production. When scoring, "Not Applicable" was not available since all of the issues could be applied to medical devices, regardless of specific characteristics. In the UK manufacturers must comply with The Packaging (Essential Requirements) Regulations 2009 (SI 2009/1504), which in turn ensures compliance with The European Union Directive on Packaging and Packaging Waste 1994 (94/62/EC).[6] This legislation dictates that other European countries

[6] In the UK, manufacturers must also comply with The Producer Responsibility Obligations (Packaging Waste) Regulations (SI 2010/2849), which requires companies over a certain size to pay towards the recycling of packaging at the end of its life.

Table 3
Anchor phrases for worksheet 2 – manufacture and assembly.

Item		Rationale for anchor phrases
2.1	Dominant processes in product assembly	Anchor phrases are based on Gutowski et al.'s (2006) model of energy use in common manufacturing processes. The most efficient processes are low in energy consumption, but also high in throughput. The scales reflect Gutowski et al.'s ranking of these processes.
2.2	Major energy sources used in product assembly	Anchor phrases are identical to those in 1.8 above, but as applied during manufacture and production.
2.3	Solid waste associated with the production of one unit	Low scores are for designs resulting in 100% solid waste by weight during production. The scale is graded through 25%, 50%, 75% and 100% content by weight. A design goal is to achieve zero solid waste.
2.4	Waste water discharged to environment with the production of one unit	Production of medical devices can result in the discharge of polluted (waste) water (Eagan and Joeres, 2002). Low scores are for designs resulting in 100% waste water by weight during production. The scale is graded through 25%, 50%, 75% and 100% content by weight. A design goal is to achieve zero waste water.

are subject to similar local laws, and compliance with these laws has been used to define the lower end of the scale for the purposes of the tool. These standards are summarised by the industry organisation INCPEN (The Industry Council for Packaging and the Environment) (2008). Firstly, packaging volume and weight must be the minimum necessary for safety, hygiene and acceptability of the packaged product for the purchaser and end-user. Secondly, packaging must be suitable for recycling, composting or energy recovery and suitable for re-use if re-use is intended or claimed. Finally, any noxious or hazardous constituents of packaging must be minimised to reduce the impact on the environment when it is finally recycled, composted, incinerated or land-filled. Specifically, the combined concentrations of lead, cadmium, mercury and hexavalent chromium must not exceed 100 ppm except in plastic crates and pallets used in a closed loop system or in containers made from lead crystal or recycled glass.

With this context in mind, the rationale for each anchor phrase in this worksheet is described in Table 4. All of these items were 'compulsory', as they apply to all products.

Respondents were particularly interested in how the packaging design might be improved, but noted that legislation was a barrier to making these improvements. A designer in company 1 noted that its single-use components tended to be somewhat over-packed out of cautiousness and that this was "just to cover all eventualities". This cautiousness results in excess packaging, particularly through the use of multiple layers.

When considering the use of recycled/reused or remanufactured content in packaging, a designer in Company 4 noted that the design decisions are "often process driven […] transport, or what is required for storing." Company 5 noted that in order to create the most effective packaging solution, the entire system had to be considered: "We know that it [packaging] blows up into the pallet and the transportation and the energy that it takes to move and freight it around the world."

What happens to the packaging after use was believed to be outside of the designer's direct influence. Company 2 commented that it can be difficult for medical device designers to influence packaging choice: "We can push for something, but it doesn't always necessarily lead to the solution we would have chosen". This view was supported by Company 1 whose marketing department had a heavy influence and Company 4 who stated "Marketing requirements sometimes mean that things have to be done a particular way." As a result, designers were able to answer this question clearly, but acknowledged that they did not always have as much control as they would like over packaging materials. They did note that changes in technology mean that what is not currently recyclable, may become so in future as systems are put in place that allow for the sorting, collection and processing of materials that are currently incinerated or landfilled.

Transportation of finished goods was also felt to be difficult to influence, but the design of the packaging might have an impact. It was noted by Company 1 that the answer to this question would change as the product was rolled out; at first transport would only be within one country. Later, the product would become available overseas, resulting in differing transport methods, potentially with greater impact. Company 5 commented that "We have international users but only one manufacturing location … we could send things by boat but it would require weeks."

4.4. Worksheet 4: product use

The rationale for each anchor phrase in this worksheet is described in Table 5. All of these items were 'compulsory', as they apply to all products.

Designers felt again that they were not really able to influence the energy sources used during product use, although they might be able to make an informed guess. However, several of them stressed that while they felt there was little they could do about changing energy sources, they appreciated the importance of the issue.

Designers also confirmed that the challenge of making devices reusable is a critical one in this sector. Company 2 had contemplated making a device that performed the same function but was reusable but: "There is always a worry about it from a hygiene point of view." All designers recognised re-use as an important but controversial issue.

The complexity of company supply chains means it is difficult for designers to be certain about distances travelled for consumable supplies. Company 4's product went via a complex warehousing and storage system, adding to the total distance travelled, whereas others shipped in a much more direct way. However, they also acknowledge that these issues are influenced by the underlying logic for the product. Designers were more knowledgeable about transport at this stage in the product life cycle than for earlier stages.

As with 'Manufacture and Assembly', three important issues were raised where performance were not easy to measure objectively. Firstly, quantifying the relative merits of cleaning and sterilisation procedures is difficult because this is contingent on the clinical setting; but it is apparent that the use of harsh chemicals should be avoided where possible. Secondly, it is beneficial to reduce the number of journeys needed between home and healthcare facilities, but again, this is difficult to quantify. Furthermore, it is not always the case that more journeys are necessarily more detrimental to the environment. Finally, serviceability is another area where meaningful ways of analysing what is desirable and what is not are lacking, since the range of medical devices is so large. Where there are opportunities to prolong the lifespan of devices by increasing the ease of maintenance and upgrade, this can generate positive environmental outcomes. For these issues, a generic scale has been included from 'very severe impact' through to 'no impact'.

Table 4
Anchor phrases for worksheet 3 – packaging and distribution.

Item		Rationale for anchor phrases
3.1	Packaging: Space Efficiency	Anchor phrases are based on INCPEN, with low scores representing unaddressed problems that could be easily solved. Better designs have packaging which is optimised. We have avoided prescribing 'a best solution' based on feedback from respondents.
3.2	Packaging: Structure	As in 3.1, but with an emphasis on material thickness and the number of layers. Low scores are for solutions with thick materials and multiples layers of packaging.
3.3	Packaging: recycled, reused or remanufactured content	Anchor phrases are identical to those in 1.3 above, but as applied to packaging
3.4	Packaging: recyclability, reusability, re-manufacturability, compostibility	Low scores are for packaging designs resulting in 100% content which cannot be recycled/reused/remanufactured or composted. The scale is graded through 25%, 50%, 75% and 100% content by weight. A design goal is to recycle (etc.) 100% of packaging content.
3.5	Packaging: PVC	Anchor phrases are identical to those in 1.5 above, but as applied to packaging
3.6	Transport of finished goods: distance	Anchor phrases are identical to those in 1.6 above, but as applied to distribution of finished goods
3.7	Transport of finished goods: method	Anchor phrases are identical to those in 1.7 above, but as applied to distribution of finished goods

Table 5
Anchor phrases for worksheet 2 – product use.

Item		Rationale for anchor phrases
4.1	Energy consumption during use	A low scoring device is one which is always on, with opportunities for increased energy efficiency. A design goal is to power down when not in use and use efficient components. This pragmatic approach recognises that some products (e.g. X-ray machine) are consumer more power than a blood pressure monitor.
4.2	Major energy sources used to provide power during use	Anchor phrases are identical to those in 1.8 above, but as applied during product use.
4.3	Waste water produced over the lifetime of one unit	Anchor phrases are identical to those in 2.4 above, but as applied during product use.
4.4	Lifetime	Low scores are for single use products. High scores are for multiple use products.
4.5	Transport of disposable components: distance	Anchor phrases are identical to those in 1.6 above, but as applied to distribution of disposable components.
4.7	Transport of disposable components: method	Anchor phrases are identical to those in 1.7 above, but as applied to distribution of disposable components.

4.5. Worksheet 5: end of life

The rationale for each anchor phrase in this worksheet is described in Table 6.

Several designers noted that they were familiar with the issue of designing for disassembly with respect to the environment "Absolutely, we could optimise that. The team would do that if it was a requirement" (Company 4). Company 3 were also confident that designing for disassembly presented no problem, but were sceptical about how much value it might add: "It would be quite easy to make it dis-assemble-able but the amount you would gain would be very, very small". Others commented that they met some of the goals of disassembly but this was co-incidental rather than intentional. Company 2, for example said that they had tried to make everything out of the same plastic, which can aid end of life processing, but that this was for performance and aesthetic reasons rather than fulfilling environmental goals.

Designers noted that there was very little that couldn't be recycled given sufficient infrastructure, but that such systems are not always in place. They acknowledged that scoring this as 'potential' was therefore sensible. Company 2 commented that they had contemplated the idea of making part of the device reusable "You have to explore all the avenues … we said it would be nice if you could take it apart and autoclave some of it". Ultimately, though, the desire for a single use device had won out. Similarly, Company 5 commented that a disposable device was "a market requirement for the product" in the case of that particular medical device type.

Designers were surprisingly lacking in knowledge about this subject: "I would say I'm totally oblivious … sad but true!" (Company 4). There was acknowledgement, though, that this issue needed to be addressed: "There is, within the patient population, a discomfort with chucking away some of this stuff" (Company 3).

As with manufacturing, the issue of toxicity was viewed as important, but difficult to measure objectively and thus, generic scales have been used.

5. Discussion and conclusions

A new tool to improve environmentally-conscious design of medical device is proposed that has been developed iteratively based on literature and insights from application in five medical device firms. These firms represent a range of medical devices from neurosurgery to urology, demonstrating the tool to be robust in its application. The tool is the first of its kind to specifically address environmentally-conscious design in the medical device development sector. In particular, the tool allows consideration of the complex trade-offs between decisions that influence different life-cycle stages.

Building the tool required balancing the inclusion of a broad range of issues for completeness, but trying to eliminate issues over which designers had little control. Areas where this balance was difficult included issues such as power sources for material conversion, and transport methods.

A major goal in developing the tool was to provide designers with a method to allow them to assess their product, whilst also directing environmental improvements, not just providing a 'score'. This meant that the tool aimed to induce discussion (amongst the design team) and support idea generation for possible improvements. Whilst using the grids, no adverse comments were made on the usability of this format, from which we inferred that the tool was straightforward to use. Indeed, responses were positive towards the collation of key issues in a simple format. Company 5 indicated that this goal was fulfilled, at least for their business context: "This tool facilitates conversation better than anything we use today". Company 4 commented that in using the tool, and

Table 6
Anchor phrases for worksheet 2 – end of life.

Item		Rationale for anchor phrases
5.1	Ability to disassemble	Anchor scales are based on the works of Navin-Chandra (1994) and Bryant et al. (2004) which aim to quantify everything from the time needed to remove fasteners to the number of other parts opened up when the fastener is removed. This has been simplified here, to enable the designer to state how easy the process would be overall, whether there is a need for mechanical assistance in disassembly.
5.2	Potential to recycle materials	Material recycling is complex in medical devices, since much waste is classed as hazardous once it has been in contact with patients. Anchor phrases aimed to explore the *potential* to recycle some or all of the device and whether infrastructure changes would need to be implemented in order to achieve this.
5.3	Potential to re-process	For medical devices, reuse and remanufacture (e.g. Kang and Wimmer, 2008; Knight and Jenkins, 2009) are generally treated as "reprocessing". For medical devices, this is complex due to the need to remove all biological debris (blood, other fluids, tissue etc.) and also any chemicals used in reprocessing the device (which can cause irritation or worse in the next patient) (www.fda.gov/Medical Devices, FDA, 2011b). As in 5.2, the anchor phrases reflect the proportion of the product that might be re-process-able.
5.4	Landfill/incineration at end of useful life	This is complementary to 5.1, 5.2 and 5.3 which deal with the potential to design for non-landfill outcomes. This item seeks to assess the gap between what actually happens to the device, and whether it could be designed so that more environmentally sound paths became feasible. Anchor phrases again reflect the relative proportion (by weight) of the devices which goes to landfill or incineration.

discussing ways of improving the environmental credentials of their products, they would adapt the tool to suit their processes and ways of conducting business, and that the tool's structure meant that this was possible.

The tool highlights the importance of taking a whole-system view, and issues such as disassembly at the product's end of life can only be achieved if a wider system is available to make this happen (Waage, 2007). The tool also recognises that whilst the designer has a key role to play in reducing environmental impact (e.g. Luttropp and Lagerstedt, 2006), the designer might not have control of the whole system. However, for issues such as 'transport methods', a designer can design to reduce the negative impact they have (for example by not designing something that can only be air freighted), even if they cannot guarantee the best outcome when all other factors are considered. For this reason, issues such as power sourcing and transport modes remained an important component of the assessment tool.

The issue of 'system boundaries' recurred in several firms. There are blurred boundaries between product and enterprise level efforts to address sustainability, even though the tool aimed to restrict analysis solely to the product itself. Company 5 commented that boundaries also need to be clear within the tool itself; either set by the users before the attempting to use the tool, or predefined. The type of system boundaries the interviewee was referring to included issues such as how many steps back in the supply chain should be examined in raw material sourcing (especially if a device uses preformed components). The tool purposely did not define how many levels back users should aim to look, because the aim was that they chose the issues over which they had control, but the tool could potentially be improved by making this policy more explicit.

Scoring the devices in question was relatively straightforward; that is to say that discussions over which 'score' should be chosen were usually resolved fairly swiftly, but occasional questions arose over whether a score of 5 in one issue equated with a score of 5 in another. Due to the nature of the tool, it is not the case that they are numerically equivalent in terms of environmental impact, as measured in units such as carbon dioxide equivalents, or tonnes of carbon dioxide. A score of 5 aims to represent the best that a designer could aim for and a score of 1 the worst type of design. This means that it is difficult to compare individual scores. However, the tool does enable users can prioritise areas where the score seems poor relative to their priorities and expectations.

The issues in the tool represent environmental issues with varying levels of interconnectedness. Some are closely related, such as packaging type and structure. Others potentially oppose each other, such as if an object is designed to be disassembled and used again, it may not be optimised for recycling. This means that not only is it unlikely that a designer could produce a medical device that scored a 5 for everything, but also that scoring a 5 for everything is not necessarily the outcome that yields the best environmental results overall. There are plenty of examples of activities which have been pursued as they are seen to be more environmentally friendly than alternatives, but upon examination have turned out to be red herrings. For example, in 2005, the UK Environment Agency published evidence that despite campaigns to get the mother's of infants to use washable (i.e. reusable) rather than disposable nappies, for environmental reasons, the environmental impacts of home laundered, commercially laundered and disposable nappies were not significantly different to each other. For this reason, the tool deliberately leaves the prioritisation of areas for improvement to the tool user, since the actual impact of a particular course of action is likely to vary device by device. In other words the tool can promote DfE activity, but it is not on its own a recipe for an environmentally perfect medical device.

This issue of trade-offs in design has previously been highlighted as an important issue (Byggeth and Hochschorner, 2006) and that existing tools do not provide sufficient support in trade-off situations. By addressing the whole life-cycle in a comparatively concise manner, the maturity grid allows these trade-offs to be more clearly seen.

5.1. Limitations

Maier et al. (2012) suggest that the creation process for maturity grids should include a maintenance phase to ensure it continues to be relevant. Since the type of maturity grid developed here looks at characteristics of the product, rather than of 'process maturity', its contents may date as technology moves forward. This means that, for example, some manufacturing processes that are considered less desirable now, could become much more environmentally benign in future. The implication is that the tool will need to be updated periodically, to reflect these changes. In addition, extra issues may need to be added future research reveals that, for example, particular substances are more harmful than previously thought.

Inevitably there are issues that may be relevant to some areas of medical device design that may not be included here. In the review process for this paper, one reviewer noted that the reuse of production residues might be usefully included. Whilst this did not emerge as an issue in the specific case studies, we would expect this and other issues to arise and to be included through further case

study work. In terms of the research process, the case studies yielded rich data, but this is set against their being few in number. A detailed case study approach was considered the best way of improving the tool and evaluating it in use. This comes at the cost of engagement with a wider number of companies.

Finally, engagement was, for the most part, with companies that had some level of interest in environmentally conscious design, which was necessary to see the tool in use and to facilitate discussion. This means, however, that this research may lack perspective from companies for whom environmentally conscious design is not a priority.

5.2. Further work

The tool as described appears robust and useful in the design of medical devices. However, it would be beneficial to extend the application through further cases to specifically explore its general applicability across a wider variety of medical devices. There may be more nuanced version of this tool that might apply in different contexts.

Whilst many elements of the tool are specifically targeted at medical devices, there are others that may apply more generally. Further work might seek to tease out the issues which are applicable across industry sectors and those which are bespoke to different sectors. A more complex tool could thus be derived which is of value across a wide range of sectors. This would also enable insights into those detailed design issues which might be of specific relevance in different sectors.

Related to this, it is evident through applications in different firms that there are complex trade-offs to be made between different elements. What might optimise design for environment in materials use might be at odds with the optimal solution for distribution. These complex trade-offs are at the heart of any design exercise. Furthermore, trade-offs are inherent in design for environment are further complicated by design decisions made for other purposes. For example, an effective design for ease of assembly might be sub-optimal for sustainability. How firms handle these trade-offs might provide fruitful opportunities for research.

Finally, assessing the environmental credentials of current products is only part of the story. To be effective in the long term, changes to design processes and practices need to be more formally institutionalised. There is thus work to be done in better understanding how such changes can be implemented and good practices anchored as part of a company's design activity.

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Appendix. Tool for assessing environmentally conscious design in medical devices

Worksheet 1 – Raw material sourcing

	Issue	0	1	2	3	4	5	Issue score	Do you need more evidence to score reliably?	As a designer, can you influence this?
Material selection	**Scarcity of materials**	N/A option not available for this design issue	Materials used include the rarest metals: Gold, Platinum, Iridium, Osmium, Rhenium, Tellurium, Palladium, Rhodium and Ruthenium	Product is composed mainly of materials known to come from finite sources	Product is composed of a mixture of materials known to be from finite sources, and those known to be plentiful	Only plentiful materials used, although not all are renewable	Only plentiful and renewable materials used			
	Diversity of materials	N/A option not available for this design issue	Wide range of materials used, including multiple polymers of similar density, multiple paints and lacquers used as coatings	Diverse range of raw materials used but consolidated use of paints, lacquers and other substances that inhibit material reuse and recycling	Some use of lacquers and paints, raw material list could be reduced further	Range of materials pared down, some non-recyclables, or materials that are difficult to separate used	Range of materials reduced to absolute minimum, paints and lacquers used minimally, polymers separated by density and any metals used are			
	Recycled, reused or remanufactured content	N/A option not available for this design issue	No recycled, reused or remanufactured materials used	25% of materials are recycled, reused or remanufactured	50% of materials are recycled, reused or remanufactured	75% of materials are recycled, reused or remanufactured	All materials used are recycled, reused or remanufactured			
	Mercury	N/A option not available for this design issue	Contains mercury				Contains no mercury			
	Pvc	N/A option not available for this design issue	Contains PVC that could easily be replaced, low molecular weight phthalates (e.g. DEHP) used as plasticisers	Contains PVC that could easily be replaced, no low molecular weight phthalates (e.g. DEHP) used as plasticisers	PVC present but essential, with low molecular weight phthalates e.g. DEHP used as plasticisers	PVC present but essential, with no low molecular weight phthalates used as plasticisers	Product contains no PVC			
Transportation of raw materials and components to production site	**Distance from point of origin of raw materials to production site**	N/A option not available for this design issue	International - between continents	International - between countries within a single continent	National - long distances (over 100 miles)	National - short distances (20-100 miles)	Local (within 20 miles)			
	Method of transport from point of origins of raw materials to production site	N/A option not available for this design issue	Aeroplane	Light goods vehicle	Heavy goods vehicle	Sea or rail; road vehicles with efficiency modifications (e.g. tear drop shaped trucks)	Minimal impact transport (e.g. bicycle, solar powered)			
Processing	**Major energy sources used in raw material extraction**	N/A option not available for this design issue	Coal provides the primary source of energy	Petroleum products provide the primary source of energy	A combination of non-renerwable and renewable energy sources used	Only renewable energy sources used, but some combustion is invluved (e.g. of bui-fuels)	All energy used is from renewable sources without combustion (e.g. geothermal, hydroelectic, solar, wind)			
							Overall score for Raw Material Sourcing (out of 40)			

Worksheet 2 – Manufacture and assembly

	Issue	0	1	2	3	4	5	Issue score	Do you need more evidence to score reliably?	As a designer, can you influence this?
Manufacturre and assembly	**Dominant processes in product assembly**	N/A option not available for this design issue	Oxidation, Drill Electrical Discharge Machining	Sputtering, Chemical Vapour Deposition	Wire Electrical Discharge Machining, Finish Machining, Laser Direct Material Deposition	Abrasive Waterjet, Grinding	Injection Moulding, machining			
	Major energy sources used in product assembly	N/A option not available for this design issue	Coal provides the primary energy source	Petroleum products provide the primary energy source	A combination of non-renewable and renewable energy sources used	Only renewable energy sources are used, but some combustion is involved (e.g.of biofuels)	All energy used in processing from renewable sources without combustion e.g. geothermal, hydroelectric, solar, wind			
	Solid waste associated with the production of one unit	N/A option not available for this design issue	100% or more of finished product weight produced in solid waste during manufacture	75% of finished product weight produced in solid waste during manufacture	50% of finished product weight produced in solid waste during manufacture	25% of finished product weight produced in solid waste during manufacture	No net solid waste produced			
	Waste water discharged to environment associated with the productino of one unit	N/A option not available for this design issue	100% or more of finished product weight produced in waste water during manufacture	75% or more of finished product weight produced in waste water during manufacture	50% or more of finished product weight produced in waste water during manufacture	25% or more of finished product weight produced in waste water during manufacture	No net waste water during manufacture			
Toxicity of processes: note, there is no objective scale for this item	**Toxicity of air emissions from production processes**	Select this if there are no air emissions	Very severe impact	Severe impact	Mild impact	Minimal impact	No impact			
	Toxicity of water emissions from production processes	Select this if there are no water emissions	Very severe impact	Severe impact	Mild impact	Minimal impact	No impact			
							Overall score for manufacture and assembly (out of MAX 30, MIN 20)			

Worksheet 3 – Distribution

	Issue	0	1	2	3	4	5	Issue score	Do you need more evidence to score reliably?	As a designer, can you influence this?
Packaging for the primary product (do not include supplies delivered subsequently)	**Space efficiency of packaging**	N/A option not available for this design issue	Obvious unaddressed inefficiencies in shape,amount or type packaging, e.g. trays that could easily be replaced with flexiform packs	Easily achievable shape, amount or type modifications available, but only on a small scale	One or two of shape, efficiency or type addressed, but inefficiencies remain	Packaging efficiency maximised via shape, amount and type, of one or two of: primary, secondary and tertiary packaging	Packaging efficiency maximised via shape, amount and type of all packaging			
	Structure of packaging	N/A option not available for this design issue	Material thickness could be reduced, and one or more unnecessary layer of packaging remains	Material thickness reduced as far as possible, but more than one unnecessary layer of packaging remains	Material thickness reduced as far as possible, but one unnecessary layer of packaging remains	Multiple layer packaging eliminated where possible, but material thickness could still be reduced	Material thicknesses reduced and multiple layer packaging eliminated as far possible			
	Recycled, reused or remanufactured content of packaging	N/A option not available for this design issue	No recycled, reused or remanufactured content in packaging	25% of packaging is recycled, reused or remanufactured	50% of packaging is recycled, reused or remanufactured	75% of packaging is recycled, reused or remanufactured	All of the packaging is recycled, reused or remanufactured			
	Recyclability, Reusability, remanufacturability and compostability of packaging	N/A option not available for this design issue	None of the packaging is recyclable, reusable, remanufacturable or compostable through conventional pathways	25% of the packaging is recyclable, reusable, remanufacturable or compostable through conventional pathways	50% of the packaging is recyclable, reusable, remanufacturable or compostable through conventional pathways	75% of the packaging is recyclable, reusable, remanufacturable or compostable through conventional pathways	All of the packaging is recyclable, reusable, remanufacturable or compostable through conventional pathways			
	PVC content of packaging	N/A option not available for this design issue	Packaging contains PVC that could easily be replaced, low molecular weight phthalates (e.g. DEHP) used as plasticisers	Packaging contains PVC that could easily be replaced, no low molecular weight phthalates (e.g. DEHP) used as plasticisers	PVC present but essential, with low molecular weight phthalates e.g. DEHP used as plasticisers	PVC present but essential, with no low molecular weight phthalates used as plasticisers	Packaging contains no PVC			
Transport of finished goods (do not include supplies delivered subsequently)	**Distance of transport from production site to end user**	N/A option not available for this design issue	International - between continents	International - between countries within a single continent	National - long distances (over 100 miles)	National - short distances (20-100 miles)	Local (within 20 miles)			
	Method of transport from production site to end user	N/A option not available for this design issue	Aeroplane	Light goods vehicle	Heavy goods vehicle	Sea or rail; road vehicles with efficiency modifications (e.g. tear drop shaped trucks)	Minimal impact transport (e.g. bicycle, solar powered)			
							Overall score for distribution (out of 35)			

Worksheet 4 – Use

	Issue	0	1	2	3	4	5	Issue score	Do you need more evidence to score reliably?	As a designer, can you influence this?
Packaging for the primary product (do not include supplies delivered subsequently)	**Energy consumption during use**	Select this if the device has NO power requirements during use	Device is always on,some components could be replaced with less power-hungry alternatives (e.g. display type)	Device is always on, but optimised for low energy consumption	Device has low energy standby mode but cannot be switched off completely	Device has lowest energy components available, and can be switched off completely when not required	Device has lowest energy components available and automatically powers down to zero when not required			
	Major energy sources used to provide power to product during use (including re-charging where appropriate)	Select this if the device has NO power requirements during use	Coal provides the primary energy source	Petroleum products provide the primary energy source	A combination of non-renewable and renewable energy sources used	Only renewable energy sources are used, but some combustion is involved (e.g.of biofuels)	All energy used in processing from renewable sources without combustion e.g. geothermal, hydroelectric, solar, wind			
	Waste water produced over the lifetime of one unit (e.g. used in cooling)	Select this if the device produces NO waste water during use	100% or more of device weight produced in waste water over the lifetime of the	75% or more of device weight produced in waste water over the lifetime of the device	50% or more of device weight produced in waste water over the lifetime of the device	25% or more of device weight produced in waste water over the lifetime of the device	Less than 1% of device weight produced in waste water over the lifetime of the device			
	Product life	N/A option not available for this design issue	Entire product is single use	Majority of product is made from single use components	Majority of the product can be reused, but with single use consumables	Entire product can be used more than once, but fewer than ten times	Entire product can be reused more than ten times			
Transport of disposable supplies	**Distance of transport for disposable components**	Select this if there are NO disposable components	International - between continents	International - between countries within a single continent	National - long distances (over 100 miles)	National - short distances (20-100 miles)	Local (within 20 miles)			
	Method of transport for disposable components	Select this if there are NO disposable components	Aeroplane	Light goods vehicle	Heavy goods vehicle	Sea or rail; road vehicles with efficiency modifications (e.g. tear drop shaped trucks)	Minimal impact transport (e.g. bicycle, solar powered)			
General issues. Note, there is are no objective scoring criteria for these items	**Cleaning and sterilisation procedures**	Select this if there is no requirement for cleaning and	Very severe impact	Severe impact	Mild impact	Minimal impact	No impact			
	Eliminating journeys between home and healthcare facilities	Select this if there is no requirement for journeys	Very severe impact	Severe impact	Mild impact	Minimal impact	No impact			
	Serviceability	Select this if there is no requirement for service	Very severe impact	Severe impact	Mild impact	Minimal impact	No impact			
							Overall score for distribution (out of MAX 30, MIN 5)			

Worksheet 5 – End of life

	Issue	0	1	2	3	4	5	Issue score	Do you need more evidence to score reliably?	As a designer, can you influence this?
End of life	**Ability to disassemble**	Select this if the device consists of only one component	Disassembly not possible	Disassembly possible only via shredding	Disassembly possible, only with mechanisation, excluding shredding	Manual disassembly possible with some effort	Easy manual disassembly (can be achieved in less than one minute)			
	Potential to recycle materials	Select this if all parts of the device will be entirely bio-hazardous after use	Recycling not possible - too complex, no appropriate technology, or recyclable portions not separable from other parts	Some recycling theoretically possible, but major infrastructure changes would be needed	Some parts recyclable using established processes, the rest is theoretically recyclable, but major infrastructure changes would	Majority of device recyclable through established processes	Device is fully recyclable through established processes			
	Potential to reprocess (i.e. reuse, remanufacture) as the same or a simliar medical device	N/A option not available for this design issue	No reusable/ reprocessable components	25% of device reusable/ reprocessable where facilities exist	50% of device reusable/ reprocessable where facilities exist	75% of device reusable/ reprocessable where facilities exist	Device is fully reusable/ reprocessable where facilities exist			
	Landfill/incineration at the end of useful life	N/A option not available for this design issue	Entire product to landfill or incineration	75% by weight of product to landfill or incineration	50% by weight of product to landfill or incineration	25% by weight of product to landfill or incineration	No waste, landfill or incineration			
Toxicity: note, there is no objective scale for this item	**Toxicity of landfilled wasst**	Select this if there is no landfill waste	Very severe impact	Severe impact	Mild impact	Minimal impact	No impact			
	Toxicity of products from incineration processes	Select this if there is no incineration	Very severe impact	Severe impact	Mild impact	Minimal impact	No impact			
							Overall score for distribution (out of MAX 30, MIN 10)			

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