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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