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A Dual Verification Model for Designing Home Use Medical Devices

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Increasingly, medical devices are being used by lay people outside the clinical environment (FDA, 2010; Gardner-Bonneau, 2011). These are frequently called home use medical devices (HUMD). A HUMD is defined as "a medical device intended for users in a non-clinical or transitory environment, is managed partly or wholly by the user, requires adequate labelling for the user, and may require training for the user by a licensed health care provider in order to be used safely and effectively" (FDA, 2010).

The process of designing a HUMD differs from consumer products, because although these devices are used by lay people, they are medical devices which are safety critical and subject to regulatory requirements (Gupta, 2007; FDA, 2012). On the other hand, as lay users differ significantly from professionals in terms of their needs and capabilities, the design process of HUMD requires a different approach than medical devices designed for professional use (Wiklund & Wilcox, 2005). Despite many generic design process models (e.g. Pugh, 1991; French, 1999; Stanton, 2004; Clarkson et al, 2007; Pahl et al, 2007) and guidance and models for medical device (e.g. FDA, 1997; Alexander, et al., 2001; Alexander & Clarkson, 2002), little information was identified regarding the design process for HUMD.

In order to support designers, a new model was developed which involves five stages, i.e. discovering the needs, task clarification, design, testing and final validation. The model highlights the importance of understanding regulatory requirements and lay user requirements, and also emphasises the validation and verification activities. It is called the "Dual Verification Model for Designing Home Use Medical Devices" (Figure 1).

This paper will discuss how the regulatory requirements and lay user requirements were captured, how the model was developed, and what potential value it might have to designers.

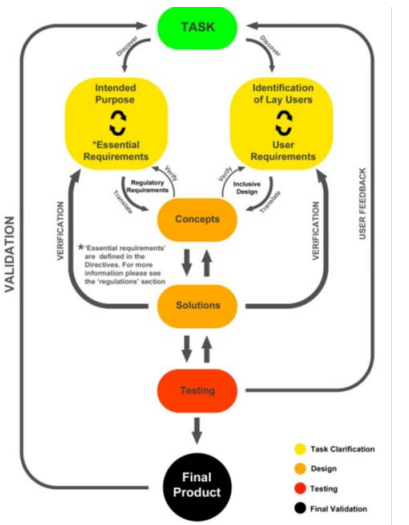

Figure 1: The 'Dual Verification Model for Designing Home Use Medical Devices'

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