Author’s response to reviews

Title: The Role of the User within the Medical Device Design and Development Process: Medical Device Manufacturers’ Perspectives

Authors:

Arthur G Money (arthurmoney@yahoo.com)
Julie Barnett (julie.barnett@brunel.ac.uk)
Jasna Kuljis (jasna.kuljis@brunel.ac.uk)
Michael P Craven (michael.craven@nottingham.ac.uk)
Jennifer L Martin (jennifer.martin@nottingham.ac.uk)
Terry Young (terry.young@brunel.ac.uk)

Version: 3 Date: 17 February 2011

Author’s response to reviews: see over
Dear Dr Norton,

Re: The Role of the User within the Medical Device Design and Development Process: Medical Device Manufacturers’ Perspectives

Please find herewith an updated copy of the above paper, which I would be grateful if you would consider for publication in BMC Medical Informatics and Decision Making. I can confirm, that in line with your journal submission policy, this manuscript has not been submitted elsewhere. Furthermore, in line with the editorial requests, informed consent has been documented in the Methods section on page 10, and the manuscript and associated files conform with the specified journal style.

The authors were pleased to see such minor revisions requested to the manuscript. Nevertheless, we have made every effort to address these comprehensively and believe the manuscript is much improved as a result of this.

Appended to this letter are the reviewers’ comments and our responses to each of these respectively. Changes to the manuscript that reflect these changes are highlighted in yellow for your convenience.

If you require anything further, please do not hesitate to contact me.

In the meantime, thank you very much for your time and attention, and I look forward to hearing from you in due course.

Sincerely,

Dr Arthur G. Money
Reviewer's report #1

**Title:** The Role of the User within the Medical Device Design and Development
**Process:** Medical Device Manufacturers' Perspectives
**Version:** 1  **Date:** 16 December 2010
**Reviewer:** Mary Beth Privitera

**Reviewer's report:**

Authors,
This article is very much needed within industry practices. Your findings are on target with common attitude and belief within the US medical device development industry. My only criticism is in sample size- while the information you present is in well organized and in an appropriate depth more subjects (device manufacturers) should be included. I am recommending this as a discretionary revision as even without this addition, the article is directive and helpful.

_Thank you for your positive comments and sharing your valuable recommendations that will undoubtedly improve the manuscript. We have included a statement in the first paragraph of the Concluding discussion section (highlighted in yellow for your convenience) emphasising that the results of this study should be considered as provision, given the sample size. Nevertheless given the limited existing research in this area, the findings provide an important point of reference for further work._

Further, I recommend clarification in the conclusion section as I am not clear as to what HF principles/practices can be modified to better accommodate the MDDD industry partners. Rather I believe the intent of the authors are to make industry developers more aware of truly utilizing HF practices. My rational is simple that HF techniques have been developed over time and are proven successful- the same can be said of engineering practices and techniques, yet engineering is never ignored while HF can be not utilized, misrepresented and/or in contrary fully integrated.

_Thank you, we have now updated our discussion on page 25 to reflect and re-align our rational in light of these suggestions. We have also added an extended discussion on pages 8/9 to highlight that the perception of human factors engineering methods, held by some developers, is that their primary function is to be used as part of a ‘cake-frosting’ exercise (Boivie 2006, 2007). We discuss how this misrepresentation may be overcome in order to fully realise the value of such methods within the medical device development process. Furthermore, the recommendations on pages 26/27 have now been updated to reflect the need to make industry developers more aware of the processes and advantages of fully utilising human factors engineering methods._
Many thanks for taking time to write this article.

_The authors would like to thank the reviewer once again for taking the time to review our work and provide such valuable and thoughtful comments. We believe the manuscript of much improved as a result of auctioning these recommendations._

**Level of interest:** An article of importance in its field  
**Quality of written English:** Acceptable  
**Statistical review:** No, the manuscript does not need to be seen by a statistician.  
**Declaration of competing interests:**  
I declare that I have no competing interests'
Reviewer's report #2

Title: The Role of the User within the Medical Device Design and Development Process: Medical Device Manufacturers' Perspectives
Version: 1 Date: 1 February 2011
Reviewer: Sylvia PELAYO

Reviewer's report:

Very interesting topic for people interested in human factors engineering and user centred design. To my knowledge, there is very few studies focusing on the manufacturers point of view and the difficulties they have to deal with. Very clear paper, well-written.

Minor Essential Revisions:
- The reader is a bit disappointed in the following part: “The challenge for industry”. A lot of results of others studies are given but the authors make few comments/analysis on these results. They do not question the elements.

   Thank you for these extremely valuable comments. An analysis of the results has now been included on pages 8/9 (highlighted in yellow for your convenience).

- Two elements are missing in the paper: (1) the question of the understanding of the concepts and methods of the user centred design by the manufacturers which consider them as “frosting a cake” (Boivie et al., 1997) and

   This is a very useful and appropriate insight, we have now included within the discussion on pages 8/9 references to two of Boivie’s recent research outputs. We emphasise that the ‘cake-frosting’ perception of human factors engineering methods by developers influences the level of engagement and application of these methods.

(2) the question of the role of human factors experts: can the manufacturers be able to apply all the methods? (Concepts and principles are sometimes difficult to grasp and are based on a theoretical background that must be acquired).

   Thank you, we agree that this point required more emphasis and attention within the manuscript. Consequently, we have added a discussion on pages 8/9 and on page 25 in the Concluding discussion section, to consider whether there is a need for experts to offer human factors engineering methods as a service, change methods to better suit the developers needs, or educate and increase awareness of developers.
Discretionary Revisions:
- no title to the figures

  *Titles to figures are provided after the References section of the manuscript.*

- Figure 1: usability tests during the stage one??

  *Thank you, a clarification has now been made to clearly state that usability tests may only be appropriate when testing legacy systems as a means of identifying which improvements may be made in a revised/new system.*

- p.6 "the challenge for industry" : the authors have not "demonstrated", take another formulation, e.g. "although a large number of HF methods are available...."

  *Wording has now been amended to reflect above comment.*

- comments in the text of the figures are sometimes redundant with the figures themselves

  *Text in Figure 2 has now been reduced to avoid redundancy and repetition within the text.*

  *The authors would like to thank the reviewer for the extremely valuable and insightful comments, we believe the manuscript is much improved as a result of incorporating these.*