Reviewer's report

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

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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.
- 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 (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).

Discretionary Revisions:
- no title to the figures
- Figure 1: usability tests during the stage one??
- 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...."
- comments in the text of the figures are sometimes redundant with the figures themselves
- p.11: define "AED"
- reference 9 : a letter is missing in the title "Cost"

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a
statistician.

Declaration of competing interests:

The reviewer declare that she has no competing interests