Risk Assesment

Zuzanna Parnicka, Yiheng Liu

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This Risk Assesment is based on Standards applicable for medical devices. Which relates to the project that is report is about. Below mentioned standards are taken into account.

1 Standards to be satisfied

1. ISO 14971 (ISO 14971:2012) The development team may self access and discard any negligible risks for the purpose of the risk assesment.
2. Directive 93/42/EEC This standard is above ISO 14971 in order of application.
   All risks must be minimized, regardless of size, and balance against benefit of the divice. Only nonacceptable risks need to be accounted in ISO 14971.
3. Risk Reduction
   (a) I14 - risks need to be reduced "As Low as Reasonably Practicable", with economic considerations permitted (ALARP).
   (b) D93 - risks reduced "As Far as Possible", and no economic considerations permitted.
   (c) I14-6.5 - If residual risks are not acceptable and further risk control not practicable, assess: Does benefit outweigh risks.

2 Risk Management

1. For the prupose of this project, the only applicable part of the life cycle where any risks are great enuogh to warrant thw application of this plan will be during the "intended use time". this time is defined as from the begging to the end of te demonstartion of the project, whether digitally recorded or live.
   The process: the device is meant to be a life saving boat that helps the lifeguard to take the drowning/injured person in the water back to the shore. The boat is called by a lifeguard's bracelet, comes to the lifeguard position and collects them and the injured back to the shore.
2. Responsibilities and authorities of the project. All group memebers are meant to work on each part of the project at least in very low level. Each person is resposible for explaining their done tasks to other group members. Each part of the project has a supervisor, that is resposible for giving tasks and checking:
   (a) Management: Vojtech Ilcik, Zuzanna Parnicka
   (b) Electronics: Al Muthanna Almoslem
   (c) Programming: Hritik Roy Chowdhury
   (d) Mechnical: Yieng Liu
3. Reviewing tasks Each risk is assesed on rolling basis as new and possible hazardous situations are indentified throughout the project design and testing phases. The risk's acceptability will be assesed using the criteria matrix from Appendix (Figure X).

(a) risk 1

(b) risk 2

4. Risk Acceptability, including risks with unpredictable probability of occurence and those of which harm cannot be estimated. The criteria is based on the matrix (Figure X) in Appendix.

   (a) risk 1

   (b) risk 2

5. Verification activities. Verification of the above data is done via data from manufacturer, data from typical operations of similar purpose and calibre, as well as data generated while testing the device itself. Figure X in Appendix.

6. Review of production and postproduction information. Because the product has a very short life cycle, this section is not applicable. However, data retained from any testng during the design and prototyping phase will be reviewed and used for risks.