# Risk Assessment

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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 assessment.

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 (including risks with unpredictable probability of occurence and those of which harm cannot be estimated) will be assesed using the criteria matrix from Appendix (Figure X).

   (a) Waterproofing failure.
   Primary compartment water leakage can cause boat drowning, loss of integrity and secondary compartment water leakage which would cause electronic components damage. The primary compartment water leakage is not neccessary to cause harm to the user. However, the secondary compartment water leakage would be a harm to the user, and could result in temporary impairment requiring professional medical intervention, due to electronics having contact with water.
   Solution to prevent water leakage:

      i. Use of silicon on all the posible water leakage corners, holes.
      ii. Testing the primary and secondary compartment in different conditions and times to see if/how the water leakage is changing or is it even apeparing.
      iii. Choosing as many waterproof components as possible.

   Risk Assessment: Occasional - Serious.

   (b) Navigation system failure.
   Navigation system consists of: GPS module, magnetometer and accelometer. The failure could be caused by interfeering magnetic fields, which could cause the magnetometer to not calibrate properly.
   Solution to prevent the navigation system failure:

      i. Putting navigation components as far as possible from devices creating magnetic fields.
      ii. Findign a solution for distance beetwen servo and magnetometer.
      iii. Testing in environments with different magnetic fields and noticing impact on the system.

   Risk Assessment: Occasional - Negligible.

   (c) Communication failure.
   RF module in the project is meant to send and receive coordinates of the bracelet. The problem could be the distance. The module specifications need to fulfill the product requirements. If there was a problem with distance it might be that the boat does not receive location it should go to. Another problem could be that the RF signal is interrupt by environment.
   Solution to prevent communication failure:

      i. Choosing RF module in respect to user requirements.
      ii. Testing RF in different circumstances.

   Risk Assessment: Occasional - Negligible.

   (d) Motor failure.
   If the motor fails, the boat is not able to drive. Therefore, the goal of the project is not satisfied. The boat cannot get to the bracelet location or help to get back to the shore. The motor failure can cause damage to limbs, which is harmfull to the user. Motor failure can be caused by overheat, kelp/rocks, seaweed getting stuck in the propellers.
   Solution to motors failure:

      i. One of the best solutions is choosing motors that will be able to satisfy product requirements and at the same time, choosing the motors that are less possible to fail.

   Risk Assessment: Remote - Minor.

   (e) Battery overheating or explosion.
   Battery overheating or explosion can be caused by overcharging, damage, exposure to high temperature. Battery overheating or explosion could be a harm to the operator. It could cause serious injury or less serious harm. However, it is hazardous to life of the product or the user.
   Solution to battery overheating or explosion:

i. The battery will be cooled by being in the water.
ii. Overcharging the battery needs to be taken into account, while preparing and testing the boat.
iii. Overall damage can be prevented by being carefull with all the electronics components.

Risk Assessment: Remote - Serious/Critical.

(f) Unexpected electronic components failure.
Unexpected electronics component failure can be anything. E.g. overheating, damaging the component by accident. It is not possible to find solutions for this problem. In the testing phase, components can be replaced or repaired. However, when something happens while the working process, only the emergency stop can help. However, this issue is possible to prevent/make it less possible to appear thanks to many tests. Risk Assessment: Remote/Occasional - Negligible.

(g) Failure of safety features.
Safety features for the project are: emergency stop, handle for the user. It might be that the emergency stop does not work for unknown reason during the work cycle, even though it worked while testing. The same can happen with the handle. The handle is made to let the program know, if the user is holding the boat, if the handle is not held the boat stops moving and waits for the signal. If this feature stops working, the boat could drive without the user and leave them somewhere on the water, or harm the user.
Solution to failure of safety features:

i. Having more than one safety feauture.
ii. Testing safety feautures in different environments.
iii. Waterproofing safety features.

Risk Assessment: Remote/Occasional - Minor/Serious.

(h) Managment problems.
Managment problems can appear as not sufficient time managment, uneven tasks distribution, miscommunication in the group, budget overrun, need to wait for some tasks to be done to be able to start other tasks.
Solution to managment problems:

i. Choosing group leader.
ii. Choosing leader of each project part (electrical, mechanical, programming).
iii. Making a timeplan in the begging and adjusting it during the project work.
iv. Making a budget plan.
v. Using recycled components from university, home, companies.

Risk Assessment: Probable - Negligible.

4. 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.

5. 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.