Ambient Assisted Living Joint Programme

Project full title:
Development of a non-invasive CAPactive sensor oral MOUSE interface for the disabled elderly
(CAPMOUSE, AAL-2008-1-203)

Deliverable report:
D1.3: Risks

and Safety

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General

This document gives an overview of the risks involved in the development of the capacitive sensor oral mouse device – the CapMouse.

This project is mainly focused on development activities to provide a proof of concept of using one or more capacitive sensors worn on the head and controlled by the tongue, and a prototype. This project is novel and innovative in the sense that there are no such solutions available on the market so far.

We need to research if the proposed solution is realistic and competitive compared to other solutions already in the market. This investigation is not something that finishes here; it continues throughout the project.

Only when all risks are mapped, assessed and mitigated the product will have the potential to be successful in the market.

This deliverable mainly contains:

- Description of the risk management methodology used
- The electronic and software risks
- Physical design risks of the headset
- User and usage risks of different target groups
- Conclusions

1. Used methodology at HMC, product risk analysis for product development

HMC uses a methodology that is inherited from the mother company Permobil. It is mainly used during design and maintenance of the product, the aim is to produce a safe product, the method is devised in a way that it complies with all the rules set foreword by the FDA, EN and ISO regulations for wheelchairs including mechanical/electronic accessories.

Risk management hereafter means the identification, assessment, and prioritization of risks followed by coordinated and economical application of resources to minimize, monitor, and control the probability and/or impact of any unfortunate events or to maximize the realization of opportunities.

Risk management covers much more than just risks analysis. However at this stage of the project we will specially target product safety. Economic issues, supplier/production reliability will be left out for further stages of development. Production methods and production verification tools will also not be covered.

At HMC we have worked on a Risk Management Manual for quite some time (with the help of our mother company Permobil). Because such a document is very valuable and important for the company we cannot make it public here. Because the rules and our understanding over the matter continuously changes the document needs constant follow-up and editing. It also covers a larger area than the CapMouse project needs. Therefore, we will customize and use the parts that apply to CapMouse to the best of our knowledge.

2.1 PURPOSE/SCOPE

Total or partial risk management is mandatory to MDD/93/42/EEC and FDA 21 CFR 820.30. This risk management manual is applicable to all stages of the life cycle of a device, such as powered wheelchairs, accessories etc., and complies, as far as possible, with the harmonized standard EN ISO 14971.

This manual is part of our quality management system.
The risk management manual defines organization, responsibilities and work processes for the risk management process. This includes identifying, analyzing and evaluating risks for persons, property and environment as well as measures for reducing the risks to acceptable levels.

2.2 DEFINITIONS, ABBREVIATIONS

Hereby an important list of definitions and abbreviations, it is of capital importance to use the terms correctly and only terms from the list!

Definitions

English	English definition
Accident	Hazard causing injury or death
Consequence	
Failure	Loss of ability to function normally
Failure Probability Density	
Fault Effect, Fault Consequence	
Fault Mode	
Harm	Physical injury or damage to the health of people, or damage to property or the environment
Hazard	Potential source of harm
Hazard event	
Incident	An undesirable event which, under slightly different circumstances, could result in harm to people, damage to property or harm to the environment
Item	
Life cycle	All phases in the life of a medical device, from the initial conception to final decommissioning and disposal
Personal Safety	
Probability of Failure	
Product Safety	
Product Safety Work	
Risk	Combination of probability of occurrence of harm and the severity of that harm
Risk Analysis	Systematic use of available information to identify hazards and to estimate the risk
Safety Analysis	

English	English definition
Safety defect	
Safety	Freedom from unacceptable risk.
Serious Defect	
Validation	Establishing by objective evidence that device specifications conform with user needs and intended use
Verification	Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled

Abbreviations

Abbreviation	English explanation
RMM	Risk Management Manual
RMP	Risk Management Plan
RAC	Risk Analysis Chart
RCC	Risk Control Chart
RMR	Risk Management Report
CAPA	Corrective And Preventive Action
FTA	Fault tree analysis
FMEA	Failure mode and effect analysis
RPN	Risk Priority Number
PDM	Product Data Management

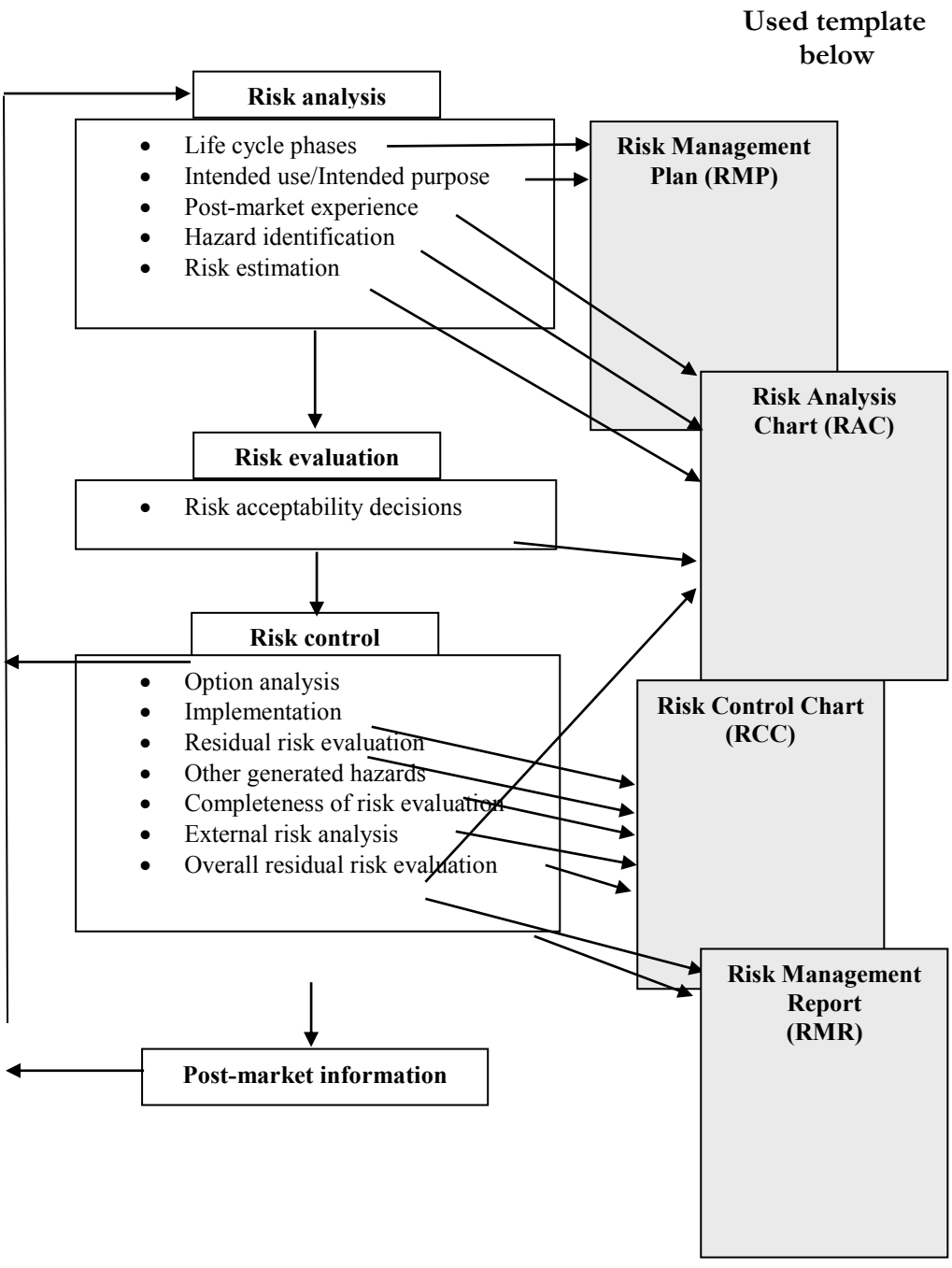
2.3 Risk management DOCUMENTS

The risk management work within a development project uses at least the document templates presented below.

RMP	Risk Management Plan	This template is the plan for the risk management work within the project.
RAC	Risk Analysis Chart	This template is a tool for the work involving risk identification, estimation, evaluation and elimination. All according to this manual.
RCC	Risk Control Chart	This template is a tool for the work involving risk evaluation and elimination. All according to this manual.
RMR	Risk Management Report	This template is used to describe the result of risk management activities in the project. The report must also include references to all measures taken during the risk management process.

2.4 *Risk management process STEPS*

CapMouse risk management process during development/engineering test and product use.



2.4.1 RMP

Life cycle phases
Life cycle phases for the device are to be specified in the "Risk Management Plan".
Intended use/Intended purpose identification
A complete specification of Intended use/Intended purpose identification for the device is made in the "Market Requirement Specification".

2.4.2 RAC

Hazard identification or failure mode identification.
If Failure mode method is used, all failure modes shall be specified.

Historic and Post-market experience
When performing risk analysis work, it is important to use experiences from prior similar work. It is essential to use experience that can be extracted from the company's post-market database. The project manager is responsible to engage the quality group to assist with this research. The project manager should also consult more experienced project managers when appropriate.

Feedback from tests and pre-series
Feedback/experience from all tests provides important information about hazards and must be used as input in the "Risk Analysis Chart".
Risks reduced to an acceptable level by verifying tests according to harmonized standards must also be included and handled in the risk analysis work.

Reasonably foreseeable misuse
The risk analysis must also take into account and consider reasonably foreseeable misuse.
Lifetime, maintenance and checks
The risk analysis must also take into consideration lifetime limitation, need for maintenance and the need for regular control.

Consequences must be minimized
It is also important to design the device in such a way that the consequences are minimized if a fault occurs.

2.4.3 Risk estimation

To be specified in the "Risk Analysis Chart".
Once a hazard or failure mode has been identified, a risk estimation is made including probability "Po", severity "S" and probability to detect "Pd".

The tables for Po, S and Pd cannot be made public.

Estimation of the risk(s) for each hazard
RPN=Po*S*Pd
Risk Priority Number = Probability *Severity * Detect ability

A snapshot of a RAC for the CapMouse USB Interface Board (full document cannot be made public).

Analyzed device module or system: **CapMouse USB Interface**	Participants in risk analysis: Rob Matthys, Marijn Lamers, Hans Fraeyman
Identification of analyzed object: **Will be used in different projects**	

Abbreviation keys

Rating: Po= Probability. **S**= Severity. **Pd**= Possibility to **D**etect. **Po * S * Pd =RPN** **Mark cell RPN with:** **RPN>44: red** **RPN19-44: yellow** **RPN<19: green**

		Characteristics of risk/				Rating			Evaluation	
No	**Identification, part no**	**Hazard/Failure mode**	**Causes of failure**	**Effect**	**How to detect**	**Po**	**S**	**Pd**	**RPN**	**Accept/Not accept**
1	Power supply	5V output too high	Voltage divider resistors out of specs	Damage/failure of components connected to 5V	Place a zenerdiode of 5V6 to protect 5V – see remark no 1	2	2	1	4	A
2	Power supply	5V output too low	Voltage divider resistors out of specs or power node defect	Malfunctioning of device	BOD of 4V on ATmega644P processor	2	2	1	4	A
3	Power supply	24V-IN Input voltage too high	Easyrider / Omni output voltage circuit defect	Property damage	Place a schottkydiode of 28V to protect 24V – see remark no 2	2	2	1	4	A
4	Power supply	24V Input voltage too low	Easyrider / Omni output voltage circuit defect	Malfunctioning of device	BOD of 4V on ATmega644P processor	2	2	1	4	A
					Place a zenerdiode of 15V					

3 *Electronic technology development risks.*

3.1 Sensor technology

The used sensor technology in the CapMouse project is based on a capacitive measurement. The capacitance formed between the sensor and the detecting surface (cheek of the head) is measured and fluctuations on this capacitor value are analyzed and taken as input.

Capacitive sensors as such exit already long time, the technology is not new and these kinds of sensors are often used in the industry and consumer products. They work well in controlled environments and where there is a considerable variation on the capacitor value is considerable they also work reliable (examples: counting boxes or cans on a production line, bringing the finger close to the sensor).

In the CapMouse application however the conditions in which the sensor will be used are not always that clear. The variation on the distance between sensor and body are minute. Environmental changes (humidity, temperature, vibration of the sensor to the cheek etc.) all will have an influence on the behavior. Also the headset that will be used can have some effects (e.g. conductivity of the materials used).

There are different methods to measure the capacitance all with their advantages and disadvantages. Selecting the correct method is crucial in this project. All different methods need to be investigated and the right solution needs to be selected.

In other words many tests will be needed to determine if the sensor will work correct under all conditions. The sensor can be calibrated at start but it needs be investigated how stable the sensor is in time. At this stage it is almost sure novel calibration and signal processing will be necessary to achieve a good result.

Furthermore we will group multiple sensors on close to each other, potentially creating crosstalk.

This project is built around the sensor, if the sensor does not perform as expected it could potentially jeopardize the whole project.

3.2 Interface to device

The electronic interface between the sensor and the device to be controlled, is of lower risk. The aim is to use standard communication protocols like USB, Bluetooth or RS232. These communication links are often used and have shown their fitness.

3.3 Solution specific risks

Because this device will potentially be used to control devices used by handicapped people the device needs be safe and usable under most conditions. The user will depend on this device for most of his activities and failure of the device could have serious consequences for the user or his environment.

4. *Physical design risks of the headset:*

4.1 Sensor head fixation in position

A lot of effort will be put into making the sensor positioning as fix as possible during use. The issue is in conflict with the demand for great flexibility in adjusting the headset to fit various persons. Using wear ability gear (headset) with more goods and less adjustment possibilities may enable a more fix position for the sensor head, but will increase stigma for the user, affecting acceptance and the need to fit different persons anatomy.

4.2 Adjustability

Adjustability is a main concern and also affects usability and fixation of the sensor head in its position in front of the users mouth. Adjustability ads to the complexity of the product, demands more advanced production methods and increases production cost. With less adjustability one may develop thinner and lighter headsets that reduces stigma which is an acceptance issue
Measures will be taken to identify concepts that reduce adjustability to a minimum, maintaining usability to different anatomies.

4.3 Material tolerance and plastic memory (fit to head)

Tolerances and plastic memory may loosen up the fit to, for example the scull; resulting in an un-tight fit and an unpleasant user experience. This issue is in conflict with. Adjustability of the head set will somewhat reduce this risk.

4.4 Cost

Depending on the market segment cost will determine the possible success.
If the CapMouse is sold as a simple accessory used by elderly people where no funding is available, the sales price needs to be low, therefore a certain volume will need to be in place to have any return on investment.

In the rehabilitation or handicapped market, in most countries funding is available for medical justified devices. So if the CapMouse delivers a sufficient and unique value to the user (compared to other solutions) the price will be of less importance. Medical justified solutions and devices are under limited price pressure; however volume is almost always low.

4.5 Produce ability

The production of such a headset could quickly turn into a very expensive exercise. The use of specific plastics, miniature mechanical joints and fixtures has a high set-up cost (molds, pressing tools etc.).
Volume is of importance, at HMC we have some experience with production in low cost countries and a major hurdle is always the low volumes. Most manufacturers only serve high volume customers because they do not have skilled staff that can handle product shifts quickly. In other words it takes a long time before they master to produce a new product and then they want to produce it as long as possible.

4.6 Competing products.

There are a lot of input devices on the market today. The strength of the cap mouse product is that it uses no ordinary physical movements to produce input and input will therefore not be made when not wanted.

The weakness is the position in the face.

Cap mouse might best be in conjunction with other input devices, such as laser pointers, where CapMouse will work as a clicker, confirming commands. This will speed up user input as they today uses scanning and time factors to confirm.

5 User and usage risks of different target groups:

5.1 Acceptance

The user willingness to accept wearing a headset or other wear ability concept is crucial for the success of the Cap Mouse product. The main concern is the stigma that user might experience wearing something odd on their head and having something weird in front of the mouth. Stigma is reduced because similar technical devices are used frequently and are considered life style products. A light and seamless design will probably level the user acceptance

Due to the result of sensor development the user might not want to accept using cap mouse because of the large sensors. Stigma is increased when you need to have something large in front of the mouse. The area around the eyes nose and mouse are areas of personal integrity and users are picky when it comes to allowing a product to interfere in that area. Take glasses as an example.

5.2 Ability to comprehend

The user ability to comprehend might not be a big issue, but might affect the willingness to use the CapMouse at all if the advantages are not clearly communicated in the industrial design.

5.3 Chafing

Some users will use the CapMouse all day and some will use it only for a short while. For the first user group (all day users) chafing will be an issue that needs to be addressed in the concept developed for them. This user group is also particularly hard to mount a head set on since the use headrests that prevents a headset that goes around the back of the head to be used. In this case a head set that runs over the head might be a solution, but will add stigma. Another design that is considered is a head set hanging down from a stabile position on the mandibular bone in front of the ears. Choosing a concept that is closer the consumer electronics, such as Bluetooth headsets or stereo head phones might reduce stigma

5.4 Pain through pressure

Pain through pressure is an issue, mainly in in-ear concepts, where some of the headset stability is gained by fixating it in the ear of the user. This might not be accepted if it's not combined with a loudspeaker and might also conflict with hearing aids of some patients

5.5 Ability to put on/take off

The ability to put on and take off is a small issue for the slightly disabled elderly. Concepts will be developed addressing this problem. The gravely disabled will have assistance and is not addressed in this risk to the same extent.

5.6 Functionality expectations.

The complexity of the product must be in line with the added functionality. If we produce a headset that only clicks, the design must communicate the low functionality degree in the design.

5.7 Allergy

Allergy is to be address using non allergic materials close to skin, mainly around the sensor head since this is a sensitive part of the face concerning skin irritation. The investigation into non allergic materials is also a deliverable in the project

6 *Risk analysis table.*

6.1 Focus

The focus of this risk assessment is elderly handicapped user group.

6.2 Guidelines

Guidelines for acceptance of risks defined in this method, a product of consequence and likelihood is the risk and acceptance criteria provided on the following scale:

- 1-2 = No action
- 3-7 = measures to avoid consequence should be addressed
- 8-16 = measures to avoid consequence Must always be addressed

Severity / **Probability**	Major (3)	Moderate (2)	Minor (1)
Large (3)	9	6	3
Small (2)	6	4	2
Tiny (1)	3	2	1

6.3 CapMouse risk analysis table

Risk description	Probability	Consequence	Risk	Is measure required (yes/no)	How to manage situation
stigma	3	3	9	Yes	Design work is ongoing to reduce stigma. Further evaluation will be done in user test 2.
Electrical hazard	1	1	1	Yes	
Chafing	2	2	2	Yes	Design work is ongoing to reduce chafing by avoiding headset contact with sensitive parts of the skin
Pain through pressure	2	2	4	yes	Long time tests wearing CapMouse should be performed in test round 2
Pain putting on taking off	1	2	2	yes	Avoid hinges and joints in hair area. Conflicts with adjustability. Long time use for some users, have to be taken in to account and long-time testing is to be performed in to consideration.
Ability to put on device	2	2	4		Raising hands above head is a problem for some users. There are concepts addressing this, ear hung and shoulder hung concepts. If none of these concepts are chosen for production, assistance in putting on the device is the only feasible solution. For the very disabled this is not an issue since assistants will do the putting on
Ability to take off device	2	2	4		Raising hands above head is a problem for some users. There are concepts addressing this, ear hung and shoulder hung concepts. If none of these concepts are chosen for production, assistance in putting on the device is the only feasible solution. For the very disabled this is not an issue since assistants will do the taking off.
Low value for selected user groups	2	3	6	No. Not within AAL	Add value by using good quality materials, high level of fit and finish, added functionality (possibly microphone and ear piece)
Interference with other hearing aid	2	3	6	yes	Elderly do use both glasses to a large extent and also hearing aids. Glasses is a minor problem and may also be used to fixate the CapMouse headset, but hearing aids will most defiantly interfere with the CapMouse
Interference with glasses	1	2	2	no	Is solved with ear worn and shoulder worn CapMouse carrier
Interference from other electrical devices					This is a technical risk
Hygiene(risk due to placement close to	2	3	6	yes	Using material that is, and is experienced as, hygienic. The hair and top of head is an aggressive environment for a product and action will be taken to design it in a way and with materials that it does not visually

mouth and in hair)					degenerate.
Disadvantage to looks (mess up hair=lower degree stigma)	2	3	6	yes	Is solved with ear worn and shoulder worn CapMouse carrier
Material fade (fit to head)	2	3	6	yes	Material fade may loosen up the fit to, for example the scull; resulting in an un tight fit and an unpleasant user experience. materials and hinges will designed in such a way that plastic memory is addressed
Material tolerance and plastic memory (fit to head)	2	3	6	yes	Tolerances and plastic memory may loosen up the fit to, for example the scull; resulting in an un tight fit and an unpleasant user experience. This issue is in conflict with
Comprehend CapMouse functionality	2	1	2	yes	This is a cognitive matter. The shape (design) of Cap Mouse carrier (i.e. some kind of headset) should be describing the use in an obvious way
Ability to use CapMouse functionality	3	2	6	yes	Low entry level when it comes to comprehensiveness. Distinct and ease of use clicking with tongue
User reluctance to use CapMouse					Communicate obvious advantages to user. Un-intrusive industrial design that encourages use, I.e the user wants to wear it because it adds to their looks in a positive way. Like glasses
Ability to install and start using USB CapMouse	1	1	1	no	Plug and play. Instruction video?
Wireless CapMouse may add difficulty, especially to inexperienced users.	3	2	6	no	If wireless will need some kind of charging, matching could be physical and be performed when charging, instead of by pressing buttons on both sender and receiver
Other solutions that may attract user group.	3	2	6	no	The" tongue solution" is not the only solution for this user group, and other may be accepted more easily due to that they are not head or body worn. Stigma and complexity is reduced. Added functionality may under some circumstances reduce this risk.

6.4 Conclusions from an industrial design perspective.

1. Ability, understanding how, and wanting to use the CapMouse is probably the largest risk in terms of specified user group, where understanding probably holds first place.

2. The ”tongue solution” is not the only solution for this user group, and other may be accepted more easily due to the fact that they are not head or body worn. Stigma and complexity is reduced. Added functionality may under some circumstances reduce this risk.

7 Overall conclusions

7.1 Technical Design

The main in the technical development is certainly the capacitive sensor head.

Extensive lab data and user tests needs to bring the proof the sensor is working according to the specifications set out in the EN norms EN 121 82 (Technical aids for disabled persons. General requirements and test methods) and EN 121 84 (Electrically powered wheelchairs, scooters and their chargers. Requirements and test methods).

If the sensor fails the risk exists the final product will not be accepted in the market or will not compete against available solutions in the market.

The design of the hardware interface (part between sensor and computer) can be considered as a low risk development. The interface is using state of the art components which have been frequently used in other designs.

7.2 Headset Design

- Ability, understanding how, and wanting to use the CapMouse is probably the largest risk in terms of specified user group, where wanting to use the CapMouse probably is the most serious issue.

- The" tongue solution" is not the only solution for this user group, and other may be accepted more easily due to that they are not head or body worn. Stigma and complexity is reduced. Added functionality may under some circumstances reduce this risk.

- Fixation of the sensor head is a serious issue due to the length the arm needs to have in order for the sensor head to reach the mouth. Enabling such a fix position demands a individually customized headset in order for the headset to not become too bulky.

- There is a conflict of concepts when it comes to the demands of different user groups. The solution to this is a highly modularized concept that may be fixated in different ways or two to three different mechanical designs.

7.3 Cost - Produce ability

The risk exists that the design requests complicated and therefore expensive production methods. If we cannot reach a certain production volume the return on investment could fail. Maybe it would be wise to involve a production company at an early stage, ask for some guidance and maybe request some quotations.