iToilet

Deliverable D1.5

Ethics, legal issues and safety in iToilet project

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Abstract

This document is the first version of Deliverable D1.5 "Ethics, legal issues and safety in iToilet project" of the iToilet (ICT-enhanced Toilet Supporting Active Life) project within Call 2015 of the Ambient Assisted Living Joint Programme und will be updated in PrM10 (January 2017) and in PrM20 (November 2017).

Deliverable D1.5 deals with the ethical, legal and safety issues which are of high importance for successful user involvement and evaluation in general.

The iToilet project is Co-funded by the European AAL Joint Programme and national funding agencies in Austria, Hungary, Italy and Slovenia.

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Content

1 Executive Summary

The iToilet DoW describes Task 1.4 “Ethics, legal issues and safety” within WP1 as follows: “This task handles the ethical, legal and safety issues which are of high importance for successful user involvement and evaluation in general. This task will be organised in close cooperation with the ethical governance in WP5.”

This deliverable D1.5 is a first overview report on methodologies related to ethical, legal and safety issues. The D1.5 is planned to be available in 3 versions during the project, due first in ProjectMonth3 (June 2016) with updates in PrM10 (January 2017) and PrM20 (November 2017).

The principles laid out in this document are recommended reading for all persons working in the project and establish a common framework which will be updated and monitored over the project time.

2 Introduction

The aim of this deliverable is to discuss the ethics, legal and safety related aspects of the user involvement and the human-machine interaction in the iToilet project. Resulting from this analysis a proposed methodology for the design and realisation process of the iToilet prototype will be given, which will be evaluated and adapted in upcoming updates of this deliverable D1.5.

This document contains recommendations for the following areas:

- Ethical considerations
- Legal implications
- Safety aspects in the iToilet project

2.1 Ethics

The approach to addressing ethics issues in iToilet can be based on several years of hands-on experience of the partner TUW/AAT in performing ethics management in international assistive technology and AAL RTD cooperation projects. Moreover, TUW successfully managed the ethics issues in the Friendly Rest Room (FRR/FP5) project which was based on extensive user involvement in laboratory and field settings. The experience of appropriately involving a potentially vulnerable user group in a sensitive area of research – personal hygiene and toileting – will be transferred to and refined in iToilet. TUW integrates research ethics in the work practice of this project in two significant ways: first, by translating relevant formal ethical and legal requirements into useful normative guidelines in the specific context of iToilet and, second, by going beyond traditional normative ethics and checklist of do's and don'ts. This will be done by continuously identifying and addressing any emerging issues during the course of the research.

In addition, the internal ethical procedures at the user test sites of partners NIMR and CS will govern the user related work and formal ethical approval will be sought for user related activities in the Austrian and Hungarian test sites.

This document gives an overview of the ethical guidance and governance in the iToilet project. There is a first version in PrM3 with updates planned at PrM10 and PrM30 to cover issues throughout the project, responding to potentially new ethical issues that may emerge during the project. Guidance in this document centers on user involvement, its ethical dimensions and privacy. This focus can be considered justified as the potential users of the iToilet product may include users who may be on an average more vulnerable than mainstream technology

users today and the work area is kind of a taboo matter. For long-term research this creates the need to focus on appropriate research methods, a well-planned process of informed consent, and carefully handled issues of privacy. Sample documents for informed consent confirmation and an information letter for the users are provided in this deliverable. While this document deals with implementation related best practice planning another separate task in the project is dedicated to independently monitoring ethical issues.

2.2 Legal background

The main relevant legal frameworks that are drawn upon during the project work involving end users are the EU and derived Austrian and Hungarian privacy and data protection legislation (based on Directive 95/46/EC), to change in the next years, and, where applicable, the Clinical Trials Directive 2001/20/EC and concretisation in Commission Directive 2005/28/EC. It has to be noted that iToilet primarily targets non-medical applications, except in case of special conditions given by the environment of use.

Privacy is a fundamental human right laid down in many significant international treaties and declarations, including the UN Declaration of Human Rights and the Charter of Fundamental Rights of the European Union (2000/C364/01), which article 8 on Protection of personal data reads the following:

> *Article 8: Protection of personal data*
>
> *1. Everyone has the right to the protection of personal data concerning him or her.*
>
> *2. Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law. Everyone has the right of access to data which has been collected concerning him or her, and the right to have rectified.*
>
> *3. Compliance with these rules shall be subject to control by an independent authority. (Council of the European Union 2001)*

In the frame of a research project that collects information from voluntary test persons adequate attention must be paid to privacy aspects.

2.3 Safety

The goal of iToilet is to promote the quality of life for elderly people through an ICT-enhanced assistive toilet which can be considered a form of (stationary) assistive robot. This target will be achieved in the project by developing an assistive toilet that is able to adjust its height and tilt according to user preferences, to physically support the user in sitting down and standing up, and to ensure safe sitting by a sensory monitoring and info-communication system to prolong independent living in a safe and user friendly way.

Comprising of a motorised assembly according to the basically applicable EC "Directive for Machinery" a system like iToilet*" … must be designed and constructed so that it is fitted for its function, and can be operated, adjusted and maintained without putting persons at risk when these operations are carried out under the conditions foreseen but also taking into account any reasonably foreseeable misuse thereof.*" There also exist several standards dealing with risk assessment. A more specialised recent standard EN ISO 13482 "Robots and robotic devices -- Safety requirements for personal care robots", category "Physical assistant robot: Personal care robot that physically assists a user to perform required tasks by providing supplementation or augmentation of personal capabilities" can be applied by analogy with respect to the risk management procedures which closely follow principles established in the ISO 12100:2010 and related standards.

The physical safety of technology is the main concern when involving users in testing, a FMEA study therefore will be conducted. If, like in iToilet, physical interaction between humans and machinery is implied, risks can be minimized by applying appropriate test designs.

To ensure safety of test participants in a formal way, it is planned to have insurance in place to cover participants in the laboratory and field trial phases.

2.4 Suggested Readers

This deliverable (with its updates) aside from more specific deliverables on requirements and technical concepts forms a baseline to follow during the project work. Its guidelines are intended to be genuinely considered by all project partners throughout the development and evaluation process and especially whenever users are directly involved, and as background information for other audience.

2.5 Relationship to other documents

The deliverable D1.5 relates to D1.1 and D1.2 and the upcoming reports D1.3, D2.x and D5.1.

3 Ethics

In what follows, the focus is on the more formal aspects of the approach to ethics that must be addressed in the context of iToilet as already contained in the proposal. To ensure that ethics issues are given sufficient attention in this project the following structures are in place: an ethics manager (TUW) is integrated in the consortium; sufficient resources are allocated in WP1 and WP5 for continuously addressing ethics issues; and deliverables are dedicated to ethics (D1.5 Ethics, legal issues and safety in iToilet project; D5.1 Ethical Guidelines and Legal Implications, D5.4 Ethical Guidelines for Lab and Field Trials including Informed Consent, and Final Remarks on Ethics to be included in the Final Report D5.6). A close cooperation between the ethics manager and the partners leading user involvement is foreseen. An internal working group on ethics, which will call attention to and discuss emerging ethics issues under the leadership of the ethics manager, will be formed to deliberate emerging ethics issues during the course of the project.

An upcoming tool for elaborating the ethics issues in such AAL projects is the MEESTAR toolkit. MEESTAR is useful as an instrument of ethical evaluation and it provides ethical-normative guiding principles for the use of ambient assisted living (AAL) systems. The consortium will explore its applicability for iToilet in more details. (Manzeschke at al. 2013, Manzeschke 2015)

In Hungary the ethics approval process to clinical trials involving humans consists of two steps: as the first step the approval of the institutional Ethics Committee has to be gained. The investigation plan, the patients' information brochure and text of the consent, technical documentation, users' manual and a number of specified certificates must be submitted. As the second step, the permission for starting the trial should be gained from the National Public Health and Medical Office Service (ÁNTSZ) in case of non-medical devices. If the device is considered as a medical device, the permission has to be gained from the National Registration and Training Center (ENKK). In both cases the authority has to obtain the opinion of the National Scientific and Research Ethics Committee (TUKEB). The whole process requires 3-6 months. In summary, the local Ethics Committee of NIMR does not grant the research permission, instead it controls whether the research is executed according to the permit of the authorities (ENKK).

In Austria, ethics approval is attained through the following process: The approval of the institutional Ethics committee (Ethikkernteam [ethics core team]; Head: Sr Karin Weiler) has to be gained for the entire project period. The investigation plan, patient's information

brochure, text of consent and other ethically significant documents have to be submitted and are discussed by the Ethikkernteam. Additionally, it needs to be judged whether the development of this specific product needs further national approval. This could be approved by following institutions: ethic commission of Medical University Vienna or ethic commission of government of Vienna. Along their outlined guidelines their focus does not emphasize the development of new products. An attempt for ethic approval by these institutions should be used to confirm this assumption.

One of the major ethics-related challenges in inviting users to actively participate in a project in toileting is overcoming the taboo effect of addressing personal hygiene in a research setting. A significant effort will be invested in creating conditions for user involvement that enable users to contribute to the emerging product in a way that makes them feel confident, competent, and safe throughout the process without compromising their dignity. The Partner TUW will take the lead and draw on its experience from the successfully run earlier FP5 project FRR (Friendly Rest Room) in removing the taboo effect of toileting and constructing ethically appropriate user participation.

The iToilet project is set up around continuous input from a participatory design process. The active involvement of potential users in the project's research activities and trials therefor plays an essential role. The recruitment of real users will concentrate on people who could potentially benefit from the finished iToilet concept, which practically means the involvement of potentially vulnerable persons calling for sensitivity to ethical issues. There exist a number of widely accepted instruments to guide research involving human subjects. Of central importance in this context are the Helsinki Declaration of the World Medical Association and The International Guidelines for Biomedical Research of the Council for International Organizations of Medical Sciences (CIOMS) in guiding the conduct of biomedical research involving human subjects. This deliverable attempts to deal in a practicable way with the concrete ethical issues that researchers may face in a technology research and development project with focus on the needs of the ageing population. In what follows, the ethical aspects of user involvement and guidelines for involving users in the context of a technology research and technology project are summarised.

Ethics emphasises two basic central principles when human beings are involved in research. The first is the complete *voluntariness* of participation under full understanding of the background. It has to be avoided that users are coerced or tricked into participating in research where coercion can occur in different and subtle ways. Patients recruited for research at facilities where they also receive treatment can easily be led to believe that their treatment is somehow dependent on their consent to participate. It may therefore be necessary that the recruitment is done by persons not involved in regular treatment.

Secondly, the participation of volunteers should also be as safe as possible. *Safety* here refers to both physical and mental safety, which means that researchers have the responsibility to actively protect the participants from all kinds of potential harm. In medical research, the principle of minimal risk is common in describing research and it should be analogously applied in AAL projects with user involvement. This means in practice that the anticipated probability for and the possible magnitude of harm or discomfort caused by involvement in the research are not significantly higher than those during daily life or during equivalent routine treatment. See also chapter Safety Issues.

3.1 Recommended Procedures

In the following some recommendations are summarised.

If compensation for participation is offered it should not be so extensive that it would overrule

the free and voluntary consent. Typically compensation is offered for extra costs like travel costs to the test site. If other incentives are given they should be limited to the non-material (idealistic) kind. As far as the two test sites (NIMR in Hungary and CS in Austria) are concerned no compensation for the participation are offered to participants at NIMR. Travel costs of the participants are not linked with their participation in the trial. Also at CS financial compensation for the participation in the trial is not applied. In Austria, travel from and to the test side is not included in the trial setting itself. This belongs to the general day care center attendance.

To cater also for the unexpected events insuring participants for the duration of the trials is recommended, which may well include the travel to and from the test site. In general the principle of minimal risk is applied. According to Hungarian rules the trial cannot begin until a liability insurance contract is made among others for these unexpected events. Also at Austrian test site the formal process for setting up an insurance has been started.

Different user involvement methods and techniques may be used, from formal questionnaires to active participation of users, open interviews, workshops, trials in laboratory and real life settings, etc. Care should be taken to choose those methods for user needs elicitation and user feedback collection which are likely to deliver the best quality of input from the specific users for which they are applied, carefully observing that not all methods are suited for all users.

An equal representation of men and women in the trials is recommended as technologies may be perceived differently by men and women and despite the fact that because of the age related gender statistics it will be easier to recruit older women than older men to participate in technology trials.

Attention needs to be paid to the fact that users who are participating may somehow benefit while others are excluded from such subjectively felt benefits which may be seemingly simple things like visits to other places, being listened to, trying out a new technology, having something to speak of, etc. This includes the need to communicate reasons for inclusion/exclusion in an open way.

Ethics also applies to internal project communication. There should be regular and open exchange established between all project parties, the developers, care or user institutions, and users to ensure that ethical issues that may come up during the project can be identified and addressed earliest possible. Attention such should be taken to any unspoken feeling of uneasiness developing on the user side and the fitting of the research tasks and testing at the test sites so that they do not disrupt normal work routines of the staff.

Aspects of privacy play an important role in activities where data is collected and especially in a project dealing with personal needs in a taboo area. This needs to be covered also in the informed consent procedure and is based on the legal aspects discussed in a separate chapter.

Though not fully applicable to the iToilet system autonomously acting machinery broadly summarised as “robots” opens up an ethical field of “roboethics” which deals with the code of conduct that designers implement in such tools or machines that are unaware of choices made by their human creators. Human beings bear the moral responsibility for the actions of the developed systems [Veruggio et al 2011].

3.2 Informed consent procedure

A sound and documented procedure for informed consent is a basic requirement for any researchers in projects involving human participants in their work and a special requirement in the AAL calls, therefore also the case in iToilet. Furthermore, the national (the Hungarian

and the Austrian in iToilet) ethics approval procedures described in section 3 and sub-section 3.1 also set the requirements for the informed consent. In iToilet the informed consent will have a continuous aspect, as users are not only invited to contribute at the beginning of a new cycle of trials but wherever possible throughout the project. On the one hand this will provide the participants a lot of possibilities to stop their cooperation if they no longer wish to continue it. On the other hand the form of cooperation throughout the project will change which cannot be easily and finally covered by one initial agreement. The informed consent in iToilet will therefore consist of information provided to the potential participant about the complete participation plans from user requirements, participatory design to final trials and the confirmation of the informed consent will testify that the participants are knowingly and voluntarily taking part in the proposed research process. Additionally, special emphasis will be put on continuous feedback from users and frequent informal renewal of their willingness to contribute further in the project.

At the beginning of the iToilet project an information and informed consent draft has been produced and delivered to the lead funding agency as a required precondition. The information provided to the mainly older adults to be recruited into the project is kept as non-technical and easy to understand as possible. The basic information is provided in written and will be repeated in oral form during recruiting and it serves the function of preparing the participant for giving consent to and performing the planned tasks as well as possible. At the beginning of every phase of user involvement more details will be given on the concrete tasks so there should be no unpleasant surprises on the day of the trials, interviews, or workshops. The drafted information letter provides basic information on the project and its aims; reasons for the need for user participation; names and contact details of contact persons; an explanation of the project's data protection policy; clarification of the use of the kind of documentation/recording (audio, video recordings, still photography).

The informed consent which the participants confirm with their signature, date and place, documents that they have read, or they have been read to, and understood all the information provided, that all their questions have been sufficiently answered, and that they give their free and voluntary consent to participating in the project. They can be asked separately to consent to different modes of participation and documentation.

Because the user participation in iToilet can be over a longer time span and it will take place in institutions for users with according needs it is possible that some users could develop a dependency on the system. During the user involvement it is therefore essential to communicate openly to the potential participants that the prototypes might not be available after the project, as this depends also on the institutions, and the system may be available on the market only after some years. In fact, in iToilet we plan to have the users tested the iToilet prototype only few weeks, the likelihood of developing dependency therefore can be considered low.

From good experiences with regard to ensuring that the study design is acceptable for the users principles developed in the similar 'Friendly Rest Room' (FRR) project (QLK6-CT-2001-00458), in which three of the iToilet partners participated in, are recommended [1,2]. It was

[1] http://www.is.tuwien.ac.at/fortec/reha.e/projects/frr/frr.html

[2] For user-centered research in the FRR project, see also, C. Dayé and M. Egger der Campo. (2011). User-Driven Research – How to Integrate Users' Needs and Expectations in a Research Project. In: J.F.M. Molenbroek, J. Mantas & R. de Bruin

found in FRR that the users benefited in terms of increased confidence from the information packages provided for them at the time of recruitment and from the research team's careful rehearsal of the user tests. These packages included photos and texts that laid out the details about the participation and tasks.

This means that informed consent in the iToilet project will be considered a carefully planned process that starts well before any actual recruitment or participation takes place, making use of written, videotaped, and demonstration ("show-and-tell") elements that can help users become prepared for the tasks at hand. The informed consent process is renewed not only for different test cycles but also continuously during the particular kind of participation.[3]Usual practice in testing advanced technology especially with elderly subjects, that participants are allowed to try the test prototypes before giving their consent. Once enrolled to the trial, sufficient time will be devoted to the participants for being trained for using safely and efficiently the test prototype before the actual trial period. Users' opinions, recommendations and approvals during training will be noted.

3.3 Informed consent information letter and consent draft

The following shows the draft of the proposed information and consent form in English. National versions for Austria and Hungary will be developed following this draft.

Information Sheet iToilet

You are invited to join a research study to look at improvements by an ICT enhanced toilet. In the following we have collected a short summary on the project for your information. **If you have any questions or want to talk about your participation, please feel free to contact the**

Responsible Contact Person:

Ms. XY
Phone:

(Eds.). A Friendly Rest Room: Developing Toilets of the Future for Disabled and Elderly People. Amsterdam: IOS Press, pp. 60-68.

[3] Details in setting up ethically acceptable user participation in the context of an international R&D project involving potentially vulnerable persons have been reported, for example, in M. Rauhala. (2011). When Ethical Guidance Is Missing and Do-It-Yourself is Required: The Shaping of Ethical Peer Review and Guidance in the FRR Project. In: In: J.F.M. Molenbroek, J. Mantas & R. de Bruin (Eds.). A Friendly Rest Room: Developing Toilets of the Future for Disabled and Elderly People. Amsterdam: IOS Press, pp. 49-59.

Available Monday-Friday 8:00-16:00

What is iToilet?

iToilet is a research project funded by the EU and national research funding organisations. There are (3 Austrian)(2 Hungarian) and (4)(5) other European parties involved. End users like you are participated in Austria and Hungary.
The goal of the project is the development and test of a toilet system able to support easier usage of a toilet.
The project is scheduled for the time from 1 April 2016 to 30 September 2018.

How does iToilet work?

The basis is formed by a motorized, height adjustable and tilt-able toilet seat and a few sensors which detect your presence and the position of the seat. Commands for adjusting the toilet can be given by speech control and buttons.
You will get a small identification card to signal your presence to the toilet and to hold your personal preferred settings.
The following functionalities will be part of the evaluation:

- Detecting your presence in the toilet
- Adjustment of the seat position by speech or buttons
- Measurement of the seat position
- Storing of usage and timing information
- Detection of emergencies like e.g. falls

IMPORTANT: The iToilet-system also comprises an emergency call function but for your safety in case of an emergency you still can use the traditional nurse call also!!!

How is your participation planned?

At first, ideas and information from all participants will be collected in an interview to gain prioritised requirements for the development.
In the course of the project you will be asked several times to discuss and assess some particular functions to help guide the development.
Finally, in early 2018, the functional toilet system will be available for testing over a test period of some weeks in the institution. We ask you to make use of the new toilet when staying in the institute.
Before and after the test period you will be asked again some questions to help us evaluate the developed solution.
All activity will take place in the institution.

Will there be any costs involved for me?

Your participation will not cause any costs for you. On the other hand we are, unfortunately, not able to pay for your effort.

What happens with the recorded data?

All data recorded during your participation will be kept strictly confidential. Your personal data will be used only in anonymised format and for scientific purposes.
You can at any time have a look on the data by addressing the above mentioned contact person and also request its deletion.

Can I stop my participation whenever I want?

Yes. You are participating on a totally voluntary basis and you can withdraw at any time – without the need to give a reason and without further consequences for you.

Are there any foreseeable risks?

The base toilet is a medically certified product (See the declaration of conformity in 9.) and the whole iToilet prototype was assessed for safety before the tests are started. This study involves the mechanical adjustment of the toilet seat position while sitting during the testing. If you feel uneasy about this you should not participate. There may also be other risks that we cannot predict but we expect no increased risk compared to using a standard toilet.

Who is involved in the iToilet project?

TU Wien – Technical University, Centre for Applied Assistive Technology (Austria)
CS Caritas Socialis– an MS day-care centre (Austria)
CareCenter Software GmbH – a company delivering care documentation (Austria)
Santis Kft. – the company producing the toilet (Hungary)
Smart Com d.o.o. – a company producing computers (Slovenia)
Országos Orvosi Rehabilitációs Intézet – rehabilitation clinic, here the tests are done (Hungary)
Synthema srl – a company producing the speech recognition (Italy)

Informed Consent

1. I, _____, agree to participate in the research project "**iToilet**" for the purpose of designing and testing an ICT enabled toilet.
2. I have been given sufficient information about this research project and its goals. The purpose of my participation as an interviewee and test person in this project has been explained to me and is clear.
3. I know that I can contact at any time the responsible person, whose address is on the information sheet I got, with any questions about the project and my participation.
4. My participation in this project is voluntary. There is no explicit or implicit coercion whatsoever to participate. I have the right not to answer any of the questions. If I feel uncomfortable in any way during my participation, I have the right to withdraw at any time by a simple notice to the responsible person, mentioned in the information sheet, without consequences for me.
5. I understand and accept that I will not be paid for my participation.
6. My participation will not cause any costs for me.

		Addon:
YES o	NO o	I allow the recording (by audio/video tape) and taking photographs of the interview and tests. This material will only be used for scientific purposes within the project and not used for any other purpose without my permission.

_____ _____

Place and Date Signature of Subject

4 Legal aspects

4.1 General considerations

In iToilet the research tries to respect the participants' privacy in the best way although the need to collect private data cannot be completely avoided. All work with collected data will be performed based on assigned codes for the users so their identity remains unknown. This is to ensure that data collected cannot be connected with specific persons by researchers or even other persons not involved in iToilet unless strictly required and in a controlled and documented way. The use of real names of participants in any documents circulated within the project will be altogether avoided, so that they do not accidentally become part of reports or publications and using pseudonyms is encouraged. As a principle only those data that are really necessary for the project should be collected. All data collected are to be stored on a secured server with controlled access within the area of applicability of the European data protection law. Also hardcopies of documents with user-related data and audio-visual materials should be kept in locked facilities. Access to personal data and to audio-visual materials showing participants should be made possible only for designated persons as far as needed at each research site, all other access to data should be only possible to already anonymised data. Special consent is asked from users for the use of video and audio recording and photo documentation of user involvement where it is deemed necessary. Any use of photo or video material for publication purposes has to be separately agreed to by the users concerned.

Note that participatory design tasks where users actively contribute to design work might on the other hand create ownership rights and the right to be named as contributor.

4.2 National and EU legislation

The iToilet project partners are responsible for taking into account any further special requirements of their respective national privacy legislation.

In Austria, the current privacy legislation is laid down in the Federal Act Concerning the Protection of Personal Data (Datenschutzgesetz 2000 – DSG 2000) (available at www.dsk.gv.at).

Similarly in Hungary the Hungarian Data Protection Act (Act No. CXII of 2011) covers relevant regulations.

Except for the two user test sites no need to store personal data shall arise for other partners.

In future new regulations based on the recently agreed EC Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) are to be expected to enter into force in their national implementations in 2018. As far as can be said today there will be no important changes required to the currently observed principles in iToilet, the strengthened

rights to review the stored personal data and to request its deletion has been already included in the informed consent draft.

5 Safety Issues

5.1 Physical Interaction

The iToilet system with the toilet seat (and optionally armrests) has central mechanically moving motorised parts as part of the solution. These parts will move either according to an explicit command by the user via the user interface (UI) in form of a speech command or pressing a command button, or because of an automatic function of the system.

Physical interaction between user and iToilet can be grouped into two classes: intended interaction and unintended interaction. During use of the iToilet system, direct physical interaction between user and the seat is implied and intended, though no interaction in the form of collisions should occur. The risk of such collisions but also loss of balance can be reduced by avoiding sudden movement of the seat in any form surprising to the user. One method to achieve this will be the use of acoustic announcements to inform the user of any action autonomously taken by the iToilet system. Another measure will be the limiting of the range of movement to smaller and slower steps but also the possibility for the user to stop any movement by command. Here especially the cases where the iToilet system acts autonomously without explicit command by the user via the UI have to be considered.

Another possible collision might take place when the user is colliding with the not-moving seat. Such kind of collision cannot be avoided by the iToilet safety system – hazard related to this kind of collision should be reduced by appropriate design (e.g. no sharp edges, handles, etc.).

The third possibility for collisions can occur when any objects in the environment (placed there by the user or by staff) are in the way of moving parts of the iToilet system. There will only be limited possibilities to detect such events by monitoring force and positions of the system parts for “normal” values.

5.2 Emergency detection

iToilet has included dedicated emergency detection components. This is important because iToilet is thought of providing the users independence from personal assistance and therefore they are “on their own” also in emergency situations.

A special component is therefore planned for the detection of falls, where a user ends up lying on the floor or at least in such a low position that it is unlikely to be intended and safe. Detection of such an event will automatically trigger an alarm procedure with the user being given the possibility to stop the alarm by confirming that he/she is OK.

Furthermore, throughout the design procedures will be implemented to detect uncommon behaviour of the user, mostly based on time related use patterns. Such events will cause prompting of the user to confirm that he/she is OK.

5.3 Safety and Risk assessment

ISO 13482:2014 takes particular care about the fact, that personal service robot systems require close human-robot-interaction and collaboration as well as physical human-robot contact. This aspect before adoption of this standard had been only handled in the context of industrial robots where simply put interaction had to be avoided for safety reasons.

ISO 13482 basically focuses on "moving within its environment" machinery (robots) for personal care aspects going beyond the various more general standards on "Safety of Machinery". A *service robot* is defined as "… actuated programmable mechanism … performing useful tasks for humans …". The best fitting category in ISO 13482 is named *restraint-free type physical assistant robot* and its function is described as "physically assists a user to perform required tasks by providing supplementation or augmentation of personal capabilities". Examples given for this class are powered assisted devices or walking aids, "devices to assist elderly/tired persons to and from chair, bed etc." and "aiming to provide more ease and comfort in daily life for independent living".

An upcoming standard ISO/TS 15066:2016 specifies safety requirements for collaborative industrial robot systems and the work environment, and supplements the requirements and guidance on collaborative industrial robot operation given in ISO 10218-1 and ISO 10218-2. It only applies to industrial robot systems, although the safety principles presented can be useful to other areas of robotics where there is intentional collaboration between humans and robotic devices.

As a summary over several at least partly applicable standards the following list of important requirements which observation will help to avoid risks is formulated. They are not covering the use as a medical device though some principles are derived from the medical risk area. The base toilet is a medically certified product (See the declaration of conformity in Annex 9.1) and the whole iToilet prototype will be assessed for safety before the tests are started.

5.3.1 Basic Requirements

- Intended use or foreseeable misuse

Clarity about the principle of *intended use* as referenced e.g. in ISO 14971 ("Medical devices — Application of risk management to medical devices") is an important aspect to be observed. During design and when producing the instruction manual, the intended use of iToilet and also any reasonably foreseeable misuse thereof should be considered. The construction should be in such a way as to "naturally" suggest the correct use and prevent as much as possible any abnormal use if such use would cause additional risk. The instructions always should draw the attention of the user to proper ways of use which help avoid risks.

- Safety principles

Solutions in iToilet must conform to safety principles based on the generally acknowledged state of the art. As consequence in general, the system (and its parts) must be designed and manufactured in a way that any harm of the user(s) caused by mechanical risks, electrical risks, electro-magnetic risks, and thermal risks is being reduced to the lowest possible level. This shall include risks of use error under consideration of the technical knowledge, experience, and training of intended users (especially when thinking of safety design for mentally/cognitive/physically impaired users).

- Power supply

If the safety of the user(s) depends on the functioning of the power supply, the system must be equipped with a means of permanently monitoring the state of the power supply and bringing the system into a safe state in case of insufficient power supply.

Any interruption, re-establishment or instability of the power supply must not lead to dangerous situations. As examples, movements in such case must not start unexpectedly, parameters must not change in an uncontrolled way, stopping on command must not be prevented if the command has already been given, any mechanical parts must not lose their supporting function and basic emergency call functions must remain effective.

- Cleaning, cleanness during use

For use in both private and institutional environment, particular requirements regarding cleaning and cleanness respectively hygiene need to be considered. The system parts must be designed and constructed in such a way that they can be regularly and easily cleaned. The surfaces must be smooth and avoid harvesting of deposits which also applies to all accessible joints. This is of specific concern because iToilet is related to an area where hygiene is an important factor.

- Safety and reliability of control system

Control systems must be designed and constructed in such a way as to withstand the intended operating stresses and external influences and prevent hazardous situations from arising as much as possible. Any fault in the components (hardware or software) must not lead to hazardous situations. In case of human misuse or error reasonable measures should be taken to limit possible hazards. Periodic self-checks for proper system state and the limits of parameters shall be implemented, leading to safe shutdown if necessary.

- Control elements

Mechanical control elements must be clearly visible and identifiable or marked to communicate their function, positioned such that they can be safely and ergonomically operated, and prevent unintentional activation. Any activation should be followed by a clear signal, either mechanical (in case of buttons) or audible.

Where control is not done via mechanical elements e.g. for commands given by speech some form of audible response has to be provided and a help function to list the recognised command should be available.

Any initiation of an automatic function with prolonged duration should be properly announced. The mechanical control elements as well as all forms of *stop* command in general should always override any automatic function in progress.

- Stop and emergency call

The system must be fitted with at least one mechanical control element which when activated brings any movement to a complete stop regardless of the current state and other conflicting commands. Additionally there at least must be one emergency call device which is clearly identifiable, visible and easily accessible to trigger an alarm call procedure.

- Logging

If not disallowed by the user use statistics and any errors should be logged to the linked care documentation system to support failure detection and analysis.

5.3.2 Risk Management Process

As standard obligation for the manufacturer of a technological system a risk assessment must be carried out in order to determine the health and safety requirements which apply. The machinery then has to be designed and constructed under consideration of the results of the risk assessment.

This should be implemented as an iterative process of risk assessment and actions for risk reduction, defining the limits of the system under intended use and foreseeable misuse, the hazards and risks as well as protective measures and instructions for use.

The Risk Analysis process is often performed by the use of an FMEA (“Failure Mode and Effects Analysis”) of which several versions exist. Also other alternative methods (e.g. the expert brain storming methods) can be used. The consortium will discuss most suitable methods for

iToilet.

In iToilet a safety report of the developed prototypes will be produced to analyse and circumvent hazards for the users.

6 Conclusions

This first version of deliverable D1.5 contains the recommended procedures for the project work in the iToilet project with regard to ethical, legal and safety issues commonly encountered in research projects. They are based on established state of the art and experience from earlier projects.

The principles laid out in this document are recommended reading for all persons working in the project and establish a common framework which will be updated and monitored over the project time.

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8 Definitions, Acronyms and Abbreviations

AAL	Ambient Assisted / Active and Assisted Living
CC	Project partner Carecenter
CMU	Central Management Unit (for AAL programme, located in Brussels)
CS	Project partner Caritas Socialis
DoW	Description of Work of the iToilet project
ICT	Information and Communication Technologies
iToilet	AAL Project, ICT-enhanced Toilet Supporting Active Life

MCI	Mild Cognitive Impairment
NCP	National Contact Person (usually at NFA)
NFA	National Funding Agency
NIMR	Project partner Országos Orvosi Rehabilitációs Intézet
PrM	ProjectMonth (PrM1=April 2016)
PU	Primary User, old persons or persons with a disability (see also SU, TU)
SAN	Project partner Santis
SmCo	Project partner Smart Com
SU	Secondary User, informal and professional care persons (see also PU, TU)
SYN	Project partner Synthema
TU	Tertiary User, e.g. institutions, insurance, … (see also PU, SU)
TUW	Project coordinator TU Wien (Vienna University of Technology)
UI	User Interface
URB	User Research Base (URBs are located at the two user test sites NIMR and CS)
WP	Work package of the iToilet project

9 Annex

9.1 Declaration of Conformity regarding toilet stand up support Devices

EG - Konformitätserklärung

EC – Declaration of Conformity

Wir erklären hiermit, das der Produkt

This is to certify that the

Toiletten Aufstehhilfe R2D2

Toilet stand up support R2D2, BC65 und MMC

den Anforderungen der europäische Richtlinie entspricht.

Confirms to the European requirements.

Medizinprodukte Richtlinie 93/42/EWG - Produktklasse 1

Medical device directive 93/42/EEC –productclass 1

unter Beachtung der Referenznorm(en)

considering to the reference standard(s)

DIN EN ISO 12182
DIN EN ISO 10535

Santis Kft
Pipohegyutca 16
4034 Debrecen

Debrecen, 2008.10.01 Rist Atilla /Geschäftsführer ----------

Ort und Datum der Ausstellung Name und Funktion Unterschrift

Place and date of issue Name and function Signature

9.2 FMECA – A short overview

This section provides some basic information about FMEA which is a risk analysis process often used. Note, that alternative methods (e.g. the expert brain storming methods) are also available. The consortium will discuss most suitable methods for iToilet.

FMEA ("Failure Mode and Effects Analysis") is a systematic approach developed by NASA which tries to analyse the possible failures for each component, sub-system or function together with the possible reasons for such a failure as well as the severity when occurring. The process estimates the associated risk and lists possible mitigation measures leading to improvements of the system safety. An FMEA serves to identify potential failure modes in a forward logic attempt based on past experience or common failure logic before resources are wasted or risks emerge as hazards in reality. It is based on a system diagram of components, roles and their functions, thus is performed in between system design and application.

Several process descriptions and read-made worksheets for FMEA are available. The basic elements on FMEA worksheets are (cf. Wikipedia):

- **Item Description, Mode, Effect and Cause**

For each item in the system diagram it is necessary to look at the cause of a failure mode and the likelihood of occurrence. This can be done by analysis, calculations, looking at similar items or processes and the failure modes that have been documented for them in the past. A failure cause is primarily looked upon as a design weakness. All the potential causes for a failure mode should be identified and documented. This should be formulated in technical terms. Examples of causes are: Human errors in handling, manufacturing induced faults, fatigue, creep, abrasive wear, erroneous algorithms, excessive voltage or improper operating conditions or use (depending on the used ground rules).

- **Probability (P)**

A failure mode is given a Probability Ranking.

Rating	Meaning
A	Extremely Unlikely (Virtually impossible or No known occurrences on similar products or processes, with many running hours)
B	Remote (relatively few failures)
C	Occasional (occasional failures)
D	Reasonably Possible (repeated failures)
E	Frequent (failure is almost inevitable)

- **Severity (S)**

This rating determines the severity for the worst-case scenario adverse end effect (state). It is convenient to write these effects down in terms of what the user might see or experience in terms of functional failures. Examples of these end effects are: full loss of function x, degraded performance, functions in reversed mode, too late functioning, erratic functioning, etc. Each end effect is given a Severity number (S) from, I (no effect) to VI (catastrophic), based on cost and/or loss of life or quality of life. These numbers prioritize the failure modes (together with probability and detectability). Below a typical classification in form of a Severity Rating is given.

Rating	Meaning
I	No relevant effect on reliability or safety
II	Very minor, no damage, no injuries, only results in a maintenance action (only noticed by discriminating customers)
III	Minor, low damage, light injuries (affects very little of the system, noticed by average customer)
IV	Moderate, moderate damage, injuries possible (most customers are annoyed, mostly financial damage)
V	Critical (causes a loss of primary function; Loss of all safety Margins, 1 failure away from a catastrophe, severe damage, severe injuries, max 1 possible death)
VI	Catastrophic (product becomes inoperative; the failure may result in complete unsafe operation and possible multiple deaths)

- **Detection (D)**

The means or method by which a failure is detected, isolated by operator and/or maintainer and the time it may take until detection. This is important for maintainability control (Availability of the system) and it is especially important for multiple failure scenarios. This may involve dormant failure modes (e.g. No direct system effect, while a redundant system / item automatic takes over or when the failure only is problematic during specific mission or system states) or latent failures (e.g. deterioration failure mechanisms, like a metal growing crack, but not a critical length). It should be made clear how the failure mode or cause can be discovered by an operator under normal system operation or if it can be discovered by the maintenance crew by some diagnostic action or automatic built in system test. A dormancy and/or latency period may be entered.

Rating	Meaning
1	Certain – fault will be caught on test
2	Almost certain
3	High
4	Moderate
5	Low
6	Fault is undetected by Operators or Maintainers

- **Dormancy or Latency Period**

The average time that a failure mode may be undetected may be entered if known.

- **Indication**

If the undetected failure allows the system to remain in a safe / working state, a second failure situation should be explored to determine whether or not an indication will be evident to all operators and what corrective action they may or should take.

After these basic steps the Risk level may be calculated.

- **Risk level (P*S and D), Risk Priority Number (RPN=P*S * D)**

Risk is the combination of effect probability and severity where probability and severity includes the effect on non-detectability (dormancy time). This may influence the end effect probability of failure or the worst case effect severity. The exact calculation may not be easy in all cases and it has been shown that mathematically this "multiplication" is problematic because it is not well defined for ordinal scales and can cause rank reversals. Nevertheless, the tools with all its limitations is accepted to be able to identify major failure modes and hazards in a system, though not guaranteeing comprehensive coverage when applied in isolation.

- **Recommended Actions**

For the items with high (or unacceptable) risk level recommended actions to address potential failures that have a high RPN. These actions could include specific inspection, testing or quality procedures; selection of different components or materials; de-rating; limiting environmental stresses or operating range; redesign of the item to avoid the failure mode; monitoring mechanisms; performing preventative maintenance; and inclusion of back-up systems or redundancy.