AXO-SUIT: Assistive exoskeleton suitable for elderly persons

AXO-SUIT DELIVERABLE

Work Package WP1:
End Users

Deliverable 1.2:
Ethical Procedure of Testing and Validation (Part 2)

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Ambient Assisted Living Joint Programme: National Funding Agencies for AXO-SUIT

Ambient Assisted Living Joint Programme

AXO-SUIT: Assistive exoskeleton suitable for elderly persons

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AXO-SUIT Partnership:

Participant no.	Participant organisation name	Participant short name	Organisation type	Country
1 (Coordinator)	Aalborg University	AAU	Univ, End user	Denmark
2	University of Gävle	UGAV	Univ, End user	Sweden
3	University of Limerick	UoL	Univ, End user	Ireland
4	Welldana A/S	WELL	End user, IND	Denmark
5	Bioservo Technologies AB	BIOT	IND, business	Sweden
6	MTD Precision Engineering Ltd	MTD	IND, business	Ireland
7	Hjälpmedelsteknik Sverige	HJALP	End user	Sweden
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1. Executive summary

Background

End users are being involved throughout the design, development, testing and validation of AXO-SUIT across four European countries: Belgium, Denmark, Ireland and Sweden. Therefore, ethical issues surrounding their involvement in these research activities must be considered. Part 1 of D1.2 outlined the ethics requirements in each of the four countries listed, and described the procedures undertaken from M1 to M16 to ensure that these ethics requirements were fulfilled, for activities that included both non-physical and physical involvement.

Our Goals

- To formulate and adopt ethical procedures in the engagement of end users throughout the AXO-SUIT project.
- To ensure that ethical procedures continue to be adopted during the testing, validation and system evaluation activities that are scheduled for Year 3 of the AXO-SUIT project.

Our Approach and Course of Action

- As Part 2 of a two-part deliverable, this document briefly summarises activities related to ethics that have been carried out during the project to date.
- This document also describes the preparations underway to ensure that AXO-SUIT testing and evaluation activities involving end users, scheduled for Year 3 of the project, will be ethically sound and will receive approval from the necessary authorities prior to commencement.

Our Findings and Results

- Approval from the relevant ethics authorities was successfully obtained for all research involving AXO-SUIT end users to date.
- Research conducted in Belgium to date has been covered by COM employees' contracts and insurance. An application for research ethics approval has also been submitted to cover end user research activities in Belgium during Year 3 of the project.
- Current ethics approval applies to upcoming AXO-SUIT research activities in Denmark, thus on additional applications are required in that country.
- Any planned research in Ireland will require approval from the University of Limerick Science and Engineering Research Ethics Committee prior to commencing the activity.
- Approval has been obtained for research to date in Sweden, however further ethics applications will be required for any additional testing and evaluation activities.

Impact of the Deliverable

Knowledge of the requirements for obtaining research ethics in each country will help to minimise the risk of potential delays in receiving end user feedback on AXO-SUIT designs and prototypes, and in testing and validation.

Planned Dissemination and Exploitation

The information contained in this document will inform ethical considerations throughout the remainder of the AXO-SUIT project.

2. Introduction

The AXO-SUIT project aims to incorporate a strong focus on user-centred design, in order to ensure that a successful system is developed [1]. As such, the project will engage with end users across all partner countries (Belgium, Denmark, Ireland and Sweden) to obtain information on their needs and feedback on AXO-SUIT designs and prototypes. Human participants will also be involved in the testing and evaluation of the AXO-SUIT modules.

The involvement of human participants in any form of research means that ethical issues will be encountered. These issues can be considered according to the four fundamental principles of research ethics [2]:

- Respect for autonomy – respecting the decision-making capacities of autonomous individuals;
- Beneficence – providing benefits, and balancing benefits against risks and costs;
- Non-maleficence – avoiding the causation of harm;
- Justice – distributing benefits, risks and costs fairly.

These principles are being used as guiding strategies for end user engagement throughout the AXO-SUIT project.

D1.2 Part 1 introduced the procedures being adopted to ensure that all engagement with end users and/or other human participants in the AXO-SUIT project is ethically sound. These procedures are being implemented as part of Work Package 1 (WP1). D1.2 Part 1 also outlined the specific ethical issues that are defined within the AAL Programme [3], along with an outline of how these ethical issues are being addressed within the AXO-SUIT project.

As Part 2 of a two-part deliverable, the aim of this document is to provide updates on ethics-related activities already described and undertaken during the AXO-SUIT project, as well as plans for future activities during the remainder of the project.

Section 4 includes updates on ethics procedures in each partner country relating to current AXO-SUIT activities, and project activities that have already been completed. Section 5 describes the research ethics requirements and preparations that are underway to ensure that AXO-SUIT testing and evaluation activities involving end users and other human participants – scheduled for Year 3 of the project – will be ethically sound, and will receive approval from the necessary authorities prior to commencement. Section 6 provides an outline of the updated schedule for testing and evaluation, with a brief discussion of the ethical implications and requirements that must be taken into account to ensure that this schedule is met without issues or delay.

3. Vocabulary and abbreviations

Term	Explanation
AAL	Active and Assisted Living
ADLs	Activities of Daily Living
DDPA	Danish Data Protection Agency
ECRN	Ethics Committee for Region Nordjylland
EUG	End User Group
FB	Full Body: test-rig or exoskeleton containing all components: LB, UB and TB.
LB	Lower Body: part of the test-rig or exoskeleton containing the legs.
Primary End User	The person who actually uses an AAL product or service, a single individual, "the well-being person". This group directly benefits from AAL by increased quality of life.
S&E REC	University of Limerick Science and Engineering Research Ethics Committee
Secondary End User	Persons or organisations directly being in contact with a primary end-user, such as formal and informal care persons, family members, friends, neighbours, care organisations and their representatives. This group benefits from AAL directly when using AAL products and services (at a primary end user's home or remote) and indirectly when the care needs of primary end-users are reduced.
Tertiary End User	Institutions and private or public organisations that are not directly in contact with AAL products and services, but who somehow contribute in organising, paying or enabling them. This group includes the public sector service organisers, social security systems, insurance companies. Common to these is that their benefit from AAL comes from increased efficiency and effectiveness which result in saving expenses or by not having to increase expenses in the mid and long term.
UB	Upper Body: part of the test-rig or exoskeleton: containing the arms and, in some setups, the glove.
WP	Work Package

4. Ethics Approval Obtained for Current and Completed Activities

The AXO-SUIT project incorporates end user involvement across four European countries (Belgium, Denmark, Ireland and Sweden), each with its own individual regulations and authorities relating to research ethics. Outlines of the ethics requirements in each AXO-SUIT partner country have been described in Part 1 of D1.2. D1.2 Part 1 also provided details of ethics applications made in each country during the first sixteen months of the project – including descriptions of participant recruitment and data protection measures – and proof of ethics approval obtained, where applicable.

Section 4.1 to 4.4 provide brief updates on matters related to ethics for end user activities which have been completed within the AXO-SUIT project since M16, and/or are currently in progress. For further information on previous ethics-related activities up to M16 of the project, please refer to D1.2 Part 1.

4.1. Belgium

In Belgium, COM – in collaboration with colleagues from UZ Gent – is responsible for the involvement of end users in the AXO-SUIT project. For the Questionnaire 1 study, no formal ethical approval was required, as questionnaires were distributed to COM and UZ Gent employees only, and are covered by employees' contracts and insurance. Similarly, approval was not required for basic usability testing in Hasselt, December 2016 since only COM employees took part. All participants chose to take part of their own volition, and written informed consent was provided by all participants prior to testing, in keeping with principles of research ethics [2].

4.2. Denmark

In Denmark, AAU is responsible for the involvement of end users, including seeking approval from the relevant ethics committees. Data protection and privacy issues are governed by the Danish Data Protection Agency (DDPA) via a working committee at Aalborg University, while ethical issues related with experimental testing are governed by the Ethics Committee for Region Nordjylland (ECRN).

As noted in D1.2 Part 1, the Danish Data Protection Agency (DDPA) has granted permission to gather and store data concerning personal health condition throughout the entire AXO-SUIT project period (application included in Appendix A). Since all end user activities which have taken place in Denmark have included non-physical involvement of end users only (e.g. questionnaire study, focus group), this DDPA approval has covered all AXO-SUIT work to date.

4.3. Ireland

UoL is responsible for seeking approval for all AXO-SUIT end user activities which take place in Ireland. Approval for such activities is sought via the University of Limerick's research ethics procedures, specifically the Faculty of Science & Engineering Research Ethics Committee (S&E REC).

As described in D1.2 Part 1, approval was obtained from S&E REC for a previous study of end users' functional requirements (i.e. Questionnaire 1), and a small laboratory study of human movement during a selection of these functional tasks . No additional ethics applications have been submitted since the completion of D1.2 Part 1.

4.4. Sweden

In Sweden, UGAV is responsible for overseeing research ethics within the AXO-SUIT project. As described in D1.2 Part 1, approval was obtained from the Ethical Board Uppsala for all project activities which consist of non-physical involvement of end users. UGAV is securely storing all signed consent forms obtained from end users in Sweden to date.

5. Research Ethics: Future End User Activities

As part of the user-centred design process, further activities incorporating end users are planned throughout Year 3 of the project. These activities will include additional activities seeking end user opinions on AXO-SUIT prototype designs and commercialisation opportunities, and also activities which will allow end users to physically interact with and test AXO-SUIT prototypes.

For methods which involve physical participation of end users, additional ethical considerations must be taken into account e.g. full understanding of participant roles for informed consent, safety, injury risks, potential for physical discomfort or embarrassment. Since the upper and lower-body prototypes are currently in development, planning for such end user involvement is underway. Advance planning for such activities is crucial, since applying for and receiving approval from the relevant ethics committees can be a lengthy process.

The following sections will outline current plans for ethical procedures in relation to physical involvement of end users in the AXO-SUIT project.

5.1. Belgium

COM, in collaboration with UZ Gent, has submitted an application for ethics approval which includes both future end user testing and focus groups. Approval of this application is currently pending.

5.2. Denmark

Physical testing with AXO-SUIT exoskeleton prototypes in Denmark will be conducted at the robotics lab at AAU. It is proposed to create a 'Living Lab'-style environment for late-stage testing and evaluation, to recreate the intended use scenarios as closely as possible in a laboratory environment. The precise protocol(s) for all testing are in preparation, and have yet to be agreed by the AXO-SUIT consortium.

The ECRN was contacted in mid-2016 to determine their requirements for end user testing of AXO-SUIT. The AXO-SUIT team at AAU submitted information about the nature and purposes of AXO-SUIT to the ECRN. Following this correspondence, in August 2016, the ECRN indicated that AXO-SUIT prototypes are not considered as medical devices from their perspective, and provided clearance to proceed with physical testing of AXO-SUIT prototypes at AAU.

For all upcoming end user activities in Denmark, participant recruitment and data storage will follow the procedures previously agreed with the DDPA, as outlined in D1.2 Part 1 (Appendix A). As with all research throughout the AXO-SUIT project, research procedures involving end users will be designed to conform with the main principles of research ethics, as outlined in Section 2 of this document [2].

5.3. Ireland

The schedule for AXO-SUIT testing and evaluation campaigns during Year 3 of the project is presented in Section 6. Should any testing and evaluation activities involving human participants take place in Ireland, further applications to S&E REC will be made relating to each specific study protocol. Testing will not commence until S&E REC approval has been obtained.

5.4. Sweden

An approval for physical end-user test in a controlled environment was obtained from the Ethical Board Uppsala, but for the testing protocol of the previous EXO-LEGS project. Once a test protocol of AXO-SUIT is made and agreed in the consortium, detailed documents on risk assessment with mitigation, hazard notification, briefing sheet, and test procedures will need to be submitted to the ethical board to obtain approval for testing in Sweden.

6. Schedule of end user testing during Year 3

The proposed schedule for testing and evaluation during Year 3 of the AXO-SUIT project is displayed in the table below.

Table 1. Gantt chart outlining the schedule for end user testing and evaluation during Year 3 of the AXO-SUIT project.

	Oct 25	**Nov 26**	**Dec 27**	**Jan 28**	**Feb 29**	**Mar 30**	**Apr 31**	**May 32**	**June 33**	**Jul 34**	**Aug 35**	**Sept 36**
UB Test rig: Basic usability testing												
LB Test Rig: Basic usability testing												
Assess Basic Mechanical Integration (D4.1)												
UB Test Rig with DPM: Basic usability testing (powered)												
End user focus groups: Prototype v01 (Denmark)												
UB Prototype v01: Usability Testing									**?**			
LB Prototype v01: Usability Testing									**?**			
UB Prototype: Structured evaluation												
LB Prototype: Structured evaluation												
Full system final evaluations												
End user final system evaluations												

Key:

- UB
- LB
- FB
- End user involvement

6.1. Ethical Considerations for Future Testing and Validation

As already outlined in this document, numerous ethical considerations must be taken into account when planning for end user involvement in the physical testing and evaluation of AXO-SUIT. Closer interaction of users with AXO-SUIT test-rigs and/or prototypes necessitates more detailed consideration of potential hazards and identification of ways to mitigate risks.

The next end user involvement scheduled is another focus group study (Focus Group 2) which will take place in Denmark, and will be coordinated by HJALP, WELL and AAU. In this study, primary end users will be invited to view images and a physical prototype of the updated UB AXO-SUIT module. The aim of this second focus group is to obtain user feedback on the updated designs of the UB module, and to gain further user opinions on commercialisation prospects for AXO-SUIT. As with Focus Group 1, this will be a low-risk activity. Current ethics approval from the DDPA and ECRN applies to this activity also; therefore no additional applications will be required for this study.

Formal usability testing and structured evaluations of UB and LB prototypes will involve human users physically interacting with AXO-SUIT. Eligibility criteria for participants must be carefully considered for these activities to minimise risk to participants. Clear and concise information will also need to be drawn up regarding the testing procedures for all participants, to ensure that fully informed consent to participate can be provided. Equally, detailed testing protocols will need to be devised so as to ensure the collection of high-quality relevant data, while minimising participant discomfort and fatigue.

Detailed testing protocols will be developed for the specific UB and LB subsystems, and for the FB AXO-SUIT. These protocols will build upon the basic usability testing protocol adopted in Hasselt in December 2016 (see D4.4 for full description and protocol) to further investigate technical issues (e.g. functioning of motors and sensors), as well as user-centred issues e.g. usability and user acceptance. Where required, these protocols will be submitted as part of the research ethics application for consideration by the relevant research ethics authority, and will be amended in response to ethics authority feedback, as required.

7. Conclusions

The overall aim of Deliverable 1.2 is to formulate and implement ethical procedures in the engagement of end users throughout the AXO-SUIT project, specifically relating to end user involvement in the design, testing and validation stages. This document has described measures taken to address all ethical considerations and requirements which have been of relevance from M15 to M28 of the AXO-SUIT project.

Ethics procedures that will apply to all research activities involving AXO-SUIT end users in all partner countries throughout Year 3 of the project have been identified. Updates on ethics-related activities for research conducted to date have also been described. In addition, this document has outlined the preparations being undertaken to address ethical considerations in further research involving AXO-SUIT end users.

The contents of this document will guide research ethics procedures during the final year of the AXO-SUIT project, particularly in relation to the requirements and timelines for obtaining approval for proposed future studies which will include physical involvement of human participants. In this way, AXO-SUIT will continue to implement timely and appropriate ethical procedures in the engagement of end users and other participants throughout the remainder of the project.

8. References

1. Röcker, C., *User-Centered Design of Intelligent Environments: Requirements for Designing Successful Ambient Assisted Living Systems*, in *Proceedings of the Central European Conference of Information and Intelligent Systems (CECIIS'13)*. 2013. p. 4-11.
2. Beauchamp, T.L. and J.F. Childress, *Principles of biomedical ethics*. 2001: Oxford University Press, USA.
3. AAL Programme *Guide for Applicants - Active and Assited Living Programme Call 2015*. 2015.