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REACH

Deliverable D32: Detailed set of privacy guidelines and schemata: Summarization of the outcome of the development of necessary data privacy and security schemata to (1) protect sensed data; (2) ascertain computational anonymity; (3) ensure privileged intervention access (associated with task T.7.5).

Abstract: This deliverable report examines the outcomes of the REACH research project with regard to data privacy and data security, associated with **Task T7.5**. This document gives an overview of our analyses involving ethics and privacy concerns in terms of the individual touchpoints and shows how these findings guided the project towards the determination of the medical purpose and intended use – cornerstones to on the path to market entry. In addition, we provide a brief overview of how the guidelines regarding data protection and encryption influenced the technical design and implementation of project components. Furthermore, we provide an update on the management of legal implications (and the implications resulting from this for system requirements and business strategy) of the use of machine learning and artificial intelligence in the context of REACH solutions, incorporating an external expert opinion. Finally, this deliverable report contains a summary of our approach towards risk governance and standardization in this regard: our work in REACH on privacy and security schemata, culminated in a CEN Workshop Agreement (guideline) that generalizes REACH outcomes and makes them accessible and usable beyond the REACH consortium.

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Tasks of the involved partners with respect to the deliverable (and respective tasks) presented in this report:

Partner	Short task description
DTU	• Lead of conceptual strategy around privacy and security • Lead of technical privacy and security aspects around the data platform • Technical implementation of privacy and security schemata around TP4 • Lead of transfer of learnings/outcomes into formalized schemata and guidelines
CU	• Contribution to clarification of acceptability related privacy aspects in the context of TP4
TUM	• Strategy and structure for the deliverable • Support with formalization and integration of input for this deliverable • Co-lead of transfer of learnings/outcomes into formalized schemata and guidelines • Technical implementation of privacy and security schemata around TP2
SK	• Coordination of clarification of legal aspects around the use of machine learning in TP2 • Support with the clarification of the implications of privacy, security, ethical, and legal implications for a medical device submission strategy • Support with implementation of privacy and security schemata around TP2 • Contribution to transfer of learnings/outcomes into formalized schemata and guidelines
SC	• Technical implementation of privacy and security schemata around TP2 • Contribution to transfer of learnings/outcomes into formalized schemata and guidelines
TU/e	• Privacy and security schemata around TPs 1 and 3 • Contribution to transfer of learnings/outcomes into formalized schemata and guidelines
DIN	• Facilitation of transfer of learnings/outcomes into formalized schemata and guidelines
FIAIS	• Support with implementation of privacy and security schemata around TP2 • Contribution to transfer of learnings/outcomes into formalized schemata and guidelines

Contents

Key expressions

Abbreviations for partners:

- **AH**: ArjoHuntleigh
- **AM**: Alreh Medical
- **CU**: University of Copenhagen
- **DTU**: Technical University of Denmark
- **EPFL**: École Polytechnique Fédérale de Lausanne
- **HUG:** Hôpitaux Universitaires de Genève
- **SC:** SmartCardia
- **SK**: Schön Klinik
- **TU/e:** Eindhoven University of Technology
- **TUM:** Technical University of Munich
- **ZZ**: ZuidZorg

Activation: Physical and cognitive activation before an incident or way to keep patient as long as possible in a good baseline health state.

Activities of Daily Living (ADLs): Activity categories (e.g. dressing, bathing, feeding, etc.) which are necessary to maintain care independent living.

Ambient sensors: Sensors not worn on the body but integrated into the environment, everyday objects, PI²Us, etc., primarily supply in REACH the context and labelling.

D: Deliverable report.

End-user: Elderly citizen that are supposed to profit from reach services and products.

M: Project month within the project duration (e.g. M19 refers to project month 19, namely August 2017)

Modularization: As defined, for example by (Baldwin & Clark, 2000), modularization can be considered as a means to control the internal complexity of a system e.g. by reducing and clarifying the interfaces between system elements.

Personalized Intelligent Interior Units (PI²Us): Smart furniture which is used to integrate the REACH concepts and functionality seamlessly into the different REACH use case settings. In a broader sense, Touchpoints will mainly materialize as “furniture”, i.e., elements that can be placed and moved within a particular environment or setting (e.g., beds, bathroom furniture, mobile walkers/standers, large-scale interfaces, smart flooring tiles, smart tables, etc.). Additionally, the Touchpoints will also appear as ambient sensor add-on modules and wearables.

Physical Activity: Target condition of REACH. The systemized early detection and intervention-based prevention of physical inactivity and sedentary behavior in a variety of care settings such as homes and everyday life, day care centers, and other geriatric facilities will not only significantly reduce the risk of LTC admissions and re-admissions (and thus as targeted by REACH reduce overall healthcare cost) but also increase the elderly’s functional performance, social participation, independence, and quality of life.

Stakeholders: In REACH the term “stakeholders” refers to the entire network and the diversity of players, partners, shareholders, stakeholders, end users, organizations, companies, institutions, and others that relate to, act in, are impacted by, and/or are interested in the activities, developments, and goals of the project.

T: Task defined in the project proposal.

Touchpoints/Engine concept: structures the envisioned REACH product-service-system architecture, into manageable research and development clusters.

Touchpoints: The "Touchpoints" will act as "graspable" front ends towards the end users (elderly). The Touchpoints will serve as data gathering devices and as mediators of services and interventions coordinated by the Engine towards the end user. Each Touchpoint is modular and made up of several subsystems which allow adapting the system both for a particular person or setting, as well as over time.

TRLs, IRLs, SRLs: The concepts of Technology Readiness Levels (TRLs; see, for example, **(NASA, 2012)**, and System and Integration Readiness Levels (SRLs/ IRLs, see, for example, **(Sauser, et al., 2006)**) can be used to track the maturity of the implemented sub-systems and their interfaces and integration with each other. In addition, project management can facilitate a successful system integration.

Use case setting: Use case setting refers to the four solution operators, and this report refers to them as use case settings since they reflect concrete application scenarios.

WP: Work package defined in the project proposal.

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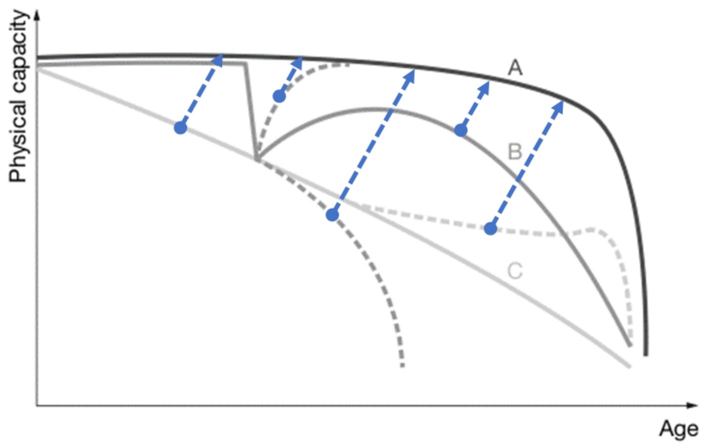
1 Introduction

REACH creates new market opportunities for European industry, including SMEs to capitalize on European high-tech-knowhow, to make Europe a market leader in prevention technologies, meanwhile tackling the ultimate cause of rising healthcare expenditures.

1.1 REACH overall hypotheses and goals

REACH develops, matures, and integrates products, processes, and solutions that seek to prevent older citizens from loss of function and decline as a major cause of physical inactivity. As such, the REACH system transforms clinical and care environments such as homes and everyday life, day care centers and other forms of care into highly personalized and data-driven early intervention systems that engage older people in preventative and rehabilitative activity, primarily physical activity but also with regard to cognitive, mobility, social and nutritional aspects (see **Figure 1-1**).



— A. Optimal trajectory, intrinsic capacity remains high until the end of life.

— B. Interrupted trajectory, an event causes a decrease in capacity with some recovery.

— C. Declining trajectory, capacity declines steadily until death.

The dashed lines represent alternative trajectories

Figure 1-1: REACH solutions help to modify and optimize trajectories of physical capacity (image adapted from WHO "World Report on Ageing and Health")

1.2 REACH toolkit and Touchpoints

The REACH toolkit guides the technical implementation of REACH. The toolkit comprises a series of partially independent components or "raw elements" developed by the partners, which can be classified into 11 categories (sensors, analytics and ML-tools, devices, smart furniture, exercise and behavior change schematics, human-machine-interfaces, data storage platforms etc.). REACH has developed and refined a design methodology (Sensing-Monitoring-Intervention/SMI workflow) for the use case specific combination and integration of these elements (see **Figure 1-2**).

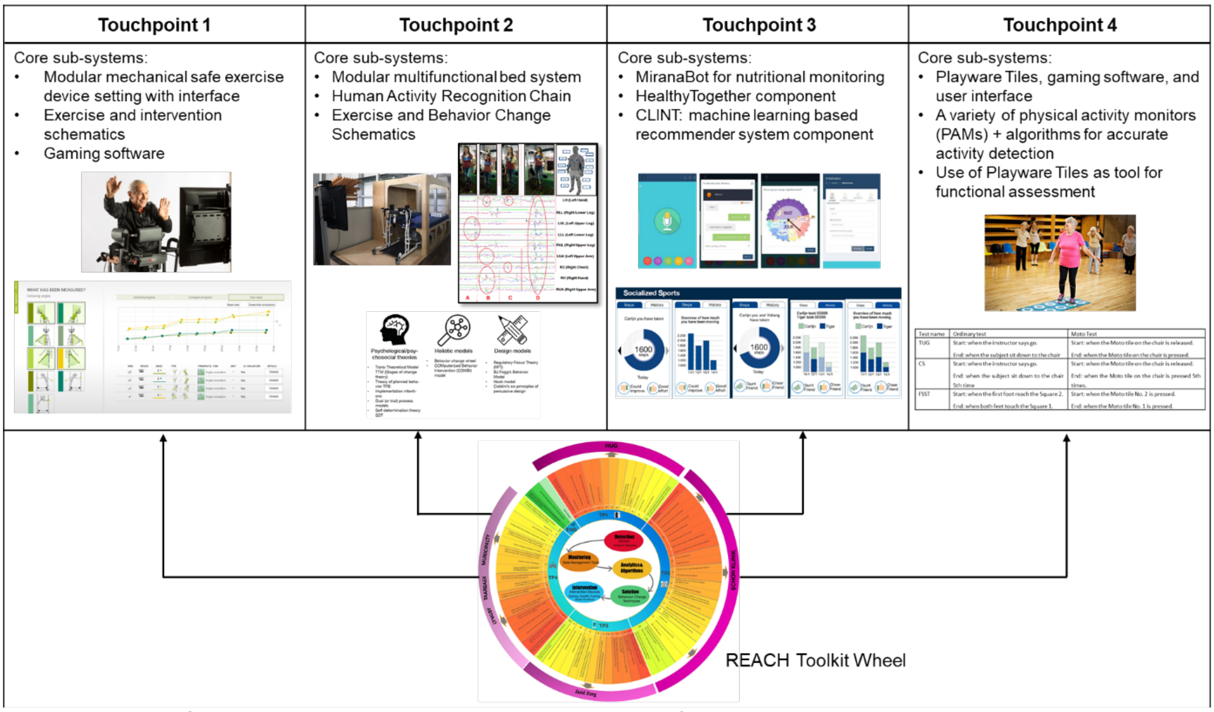


Figure 1-2: REACH Toolkit Wheel and its connection to the four Touchpoints

The REACH toolkit approach allows the tailoring of solutions that create value for end-users, care providers and health care payers alike. It does so through the combination, integration and adaptation/re-design of its elements towards the different contexts of different countries, different payment and reimbursement structures (e.g., insurance or tax-based), specific use case settings and processes and, most importantly, individual end-user needs and capabilities. (SK/Schön Klinik, HUG/Geneva Hospital, ZZ/Zui-dZorg, Lyngby/Lyngby Municipality). In this context, REACH demonstrates its ability to integrate, cross-integrate, share and interchange its elements (e.g. several Touch-points share standard elements that were, to a certain extent, adapted to the use case setting) and co-create (REACH believes that the ability to identify, incorporate and de-sign / develop new case-specific elements for each use case setting is important to the achievement of useful and appropriate solutions.).

1.3 Ecosystem approach and system verification and validation by trials

REACH achieves its objectives through highly integrated sensing-monitoring-interven-tion chains representing comprehensive solutions that are exemplarily and iteratively adapted in the project to the ecosystems of a series of care settings throughout Europe (homes, hospitals, care homes, day care facilities, communities, etc.) for older individ-uals. REACH implements, demonstrates, tests, and validates (by more than 27 small- to medium-sized trials) through those settings, customized and personalized instances of this chain. A unique feature of REACH is the integrated utilization of personalized behavior change and engagement techniques informing about the development of the products and solutions (sensors, interfaces, devices, etc.).

REACH implements a combination of wearable and ambient sensors for each Touch-point along with a set of co-adapted Machine Learning elements. Machine Learning is used as a core element in multiple ways, e.g. to predict Activities of Daily Living (ADLs), recognize physical activity and behavior trends, detect deviations of patterns and critical situations, cluster and profile people, and inform the effectiveness of the assignment of certain interventions. Personalized Intelligent Interior Units (PI²Us; smart furniture devices) are used to seamlessly integrate the above described functional elements into daily life in the different target use case settings. Last but not least, REACH has developed practices and schematics to assess the implications of the use of its solutions with regard to privacy, legal, and ethical aspects in order to ensure technology acceptance by end-users, caregivers, and other care and medical professionals (see **Figure 1-3**).

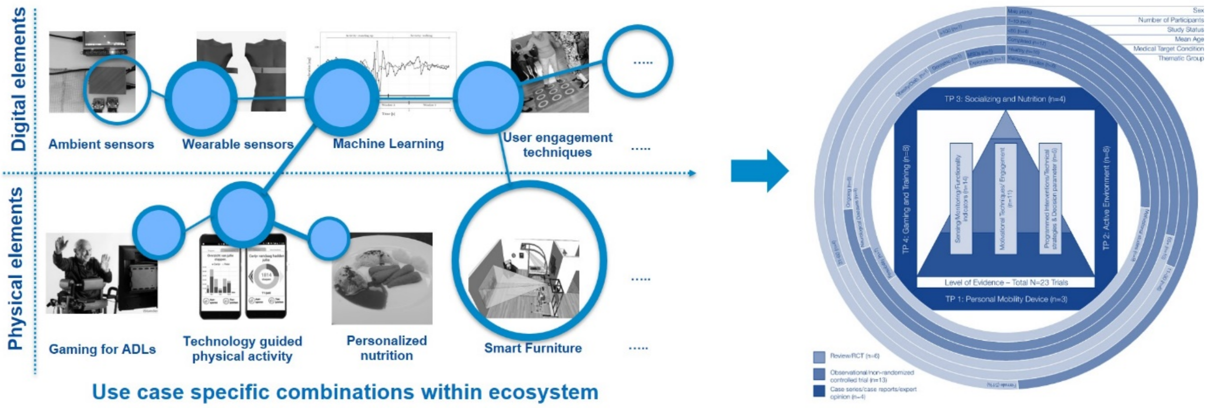


Figure 1-3: Ecosystem approach and system verification and validation by trials

1.4 REACH to market: a simplified structure

In order to work towards market implementation REACH needed to clarify and sharpen the medical purpose of its solutions, develop a regime for market segmentation, facilitate the preparation of medical certification and IPR protection activities, and define concrete business and marketing procedures.

1.4.1 Medical purposes

- **Touchpoint 1:** System: Prevent, maintain, and restore balance, muscle strength, and muscle endurance. Patients: Patients who already have mild to moderate limitations due to polyneuropathy, stroke, advanced age, incomplete cross sections, or mild cognitive impairment. Environment: Care homes, rehabilitation institutions, day care environments, offices of occupational and physical therapists, etc. Use under the supervision of instructed personnel; no 1:1 care necessary.
- **Touchpoint 2:** System: The system is intended to facilitate patient mobilization and help monitor vital signs and potentially dangerous situations. Simultaneously, it should recognize when a patient needs stronger nursing or therapeutic support and then support him or her in the partial takeover of activities. Patients: Patients with moderate to high restrictions of self-care (Activities of Daily Living) and / or with motor and / or cognitive impairment due to a neurological, medical or other disabling disease. Environment: Hospital or other nursing environments. System is able to alert a specialist, care professionals, or other skilled or semi-skilled personnel. Use in the absence of skilled or semi-skilled personnel, which only has to be available nearby.
- **Touchpoint 3:** System: App for behavior detection/monitoring, analysis, and modification. Patient: Healthy or not seriously ill people, especially in adulthood.

The system can also be used under medical supervision to improve the treatment of chronic diseases (diabetes, sedentary lifestyle, obesity, etc.). Environment: Everyday environment up to assisted living. Use if necessary, on the recommendation of a doctor.

- **Touchpoint 4:** System: A training guide to improve walking movement capability, gait safety, stability, endurance, and selective leg movements. The system is also able to capture and monitor parameters of gait safety (balance), walking speed, and endurance for functional assessment purposes and to detect physical activity trends and critical situations. Patient: People with gait and stability limitations while still able to walk. Environment: For groups of older people in sports groups and in day care facilities and for self-training. Can also be used for input measurement for allocation to suitable programs and groups.

1.4.2 Market segmentation

For business and marketing purposes, a simplified REACH structure includes and scales down the solutions developed as part of the Touchpoints in four major target market segments (see Figure 1-4):

- For developers of new products
- For health care institutions
- For homes
- For communities

Techniques from the field of motivational segmentation and behavior change are used to further sub-classify these segments and link them to REACH solutions.

Figure 1-4: Preliminary draft of the REACH consultancy firm website

1.4.3 Technology management

REACH develops products that are allocated at the intersection between medical and non-medical products. REACH therefore evaluates the market potential for each solution, classifies its solutions and develops associated roadmaps and regimes for medical certification. These activities are supported by REACH's active involvement and lead in numerous standardization frameworks on national, European (CEN), and worldwide (ISO) levels.

1.4.4 Business and marketing

REACH is currently preparing the formation of a "REACH Active Ageing GmbH" which will serve beyond the project as an integrator of REACH partner's individual products and services and a solution provider to above named market segments.

1.5 Tasks and goals of this deliverable

This deliverable report provides a summary on how data protection and privacy-related issues were addressed in REACH2020 research project (associated with **Task T7.5**). The main content of this report is structured as follows.

1. **Ethics, privacy, acceptability and legal aspects in the context of REACH:** In this chapter, we give an overview of the development of our ethics and privacy-related guidelines over the course of the project, and on how these aspects were addressed in the respective Touchpoints.
2. **Brief summary of the consideration and implementation of privacy and security schemata in key REACH system components:** This Chapter provides a brief summary of the technical implementation of the privacy and data security aspects.
3. **Legal aspects in the context of Machine Learning/HAR in TP2 – ensure privileged intervention access:** We examined the legal dimension of machine learning and artificial intelligence (AI) in the context of the REACH research project with support from an external expert. A summary of the results is provided in this chapter.
4. **Risk governance: guidelines for introducing ambient and wearable monitoring technologies balancing privacy protection against the need for oversight and care:** Our pioneering efforts to establish ambient and wearable monitoring technology in the healthcare sector led to the creation of risk governance guidelines in the form of a CEN Workshop Agreement. The outcome is reported in this chapter.

This deliverable addressed the reviewer recommendations outlined in Appendix X as follows:

- R12 Innovation management towards practicability and acceptability of REACH solutions
- R16 technical maturation of Touchpoint 2 with business aspects in mind
- R19 Development of a medical device submission strategy

Regarding the issues of ethics, privacy and legal aspects, we were able to establish a set of guidelines already early in the projects, that we elaborated with regard to the respective Touchpoints, in order to inform and guide the technical implementation of the REACH solution. REACH is pioneering efforts to establish privacy standards for the use of digital monitoring technology in the healthcare field.

2 Ethics, privacy, acceptability and legal aspects in the context of REACH

2.1 Ethics and privacy as a guiding principle of REACH

The dimensions of privacy and ethics are a fundamental element all activities within the REACH research project. We laid out these principles in **Deliverable D43**, where we reported on the core elements of our privacy guidelines. This comprehensive overview encompasses issues related to 1) studies and trials, 2) general ethics compliance, 3) data protection, and 4) data management, and led to the development of internal standards, code of conducts and common practices. We devised a number of checklists in order to facilitate compliance. In addition, the REACH Data Management Plan was first presented.

2.2 In-depth analysis of ethics, privacy and legal issues for the respective Touchpoints

On the basis of the aforementioned efforts, we were able to perform an in-depth analysis of ethical, privacy, security and legal-related considerations. These aspects were examined with regard to the patient journey within the respective Touchpoints. Such a patient journey, in this case for Touchpoint 2, is depicted in **Figure 2-1** (see **Appendix of Periodic Report No. 1** for more details on the other TPs). An overview of the outcomes of this analysis is provided in **Table 2-1 Table 2-5** on the following pages.

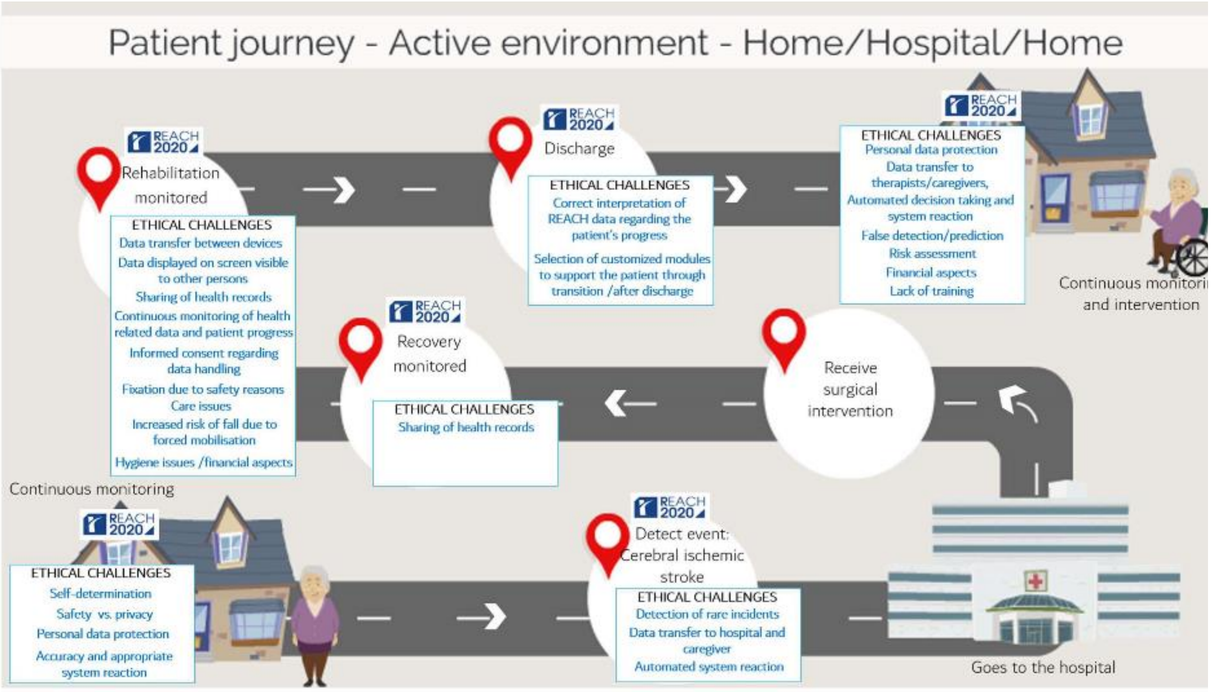


Figure 2-1. Privacy issues plotted along the TP2 patient journey (see Appendix of Periodic Report No. 1 for more details on the other TPs).

Table 2-1. General, integrated overall REACH view.

	Ethical, social, and inclusion dimensions	Privacy aspects	Legal and liability aspects	Usability, accessibility and acceptability
Key aspects to be considered (in TPs and overall REACH level)	• Ethical feasibility of screening-like sensor based early detection • Avoid stigmatization • Combat loneliness and facilitate socializing and community-based solutions • Selective/differential automation/assistance: amount of technical assistance provided or (intentionally) not provided needs to be carefully adapted to the situation • Understand ecosystem and context in which REACH solution is inserted • Choice, adaptability, personalization • Adhere to user-driven design and user + stakeholder co-creation principles • Interoperability of REACH with existing and other solutions • Adapt (i.e. minimize) number of sensors used and data generated to the specific goals • Transparency and fairness of data collection and ML pipelines • Possibility to object to, influence, or revise the automated processing of data. • Use of proper and non-stigmatizing wording both during development and for communication of the results and developments.	• Compliance with the GDPR • Avoid uncontrollable centralized “data oceans” (a la US and China) and create flexible local, distributed, and goal/use specific platforms • Application of privacy by design principles • Informed consent • Responsible handle data re-use • Apply proper pseudonymization (i.e. codification)/anonymization • Regulate accountability and data/information access • Minimize the amount of data generated and processed by integrating need for sensor readings and algorithm design • Balance data need for personalization and user profiling vs. privacy needs • Enhance digital literacy of elderly	• Support later CE certification through systematic and well documented development processes • Consider legal and liability aspects arising from REACH Engine/analytics components and automated or semi-automated ways of decision-making regarding detection and intervention • Assessment of potential risks (harm and negative consequences) for elderly or patient through REACH solutions • Application of risk management techniques • Development of appropriate user manuals and training instructions for use of REACH solutions in the different environments needed.	• Co-creation and user participation: involvement of users into the requirements engineering and development process needs to be ensured. • Systematic requirements engineering • Usability: use of proper metrics to assess the capability to properly use the devices (e.g. NASA task load index) • Systematic verification and validation: technical, professionals, users, stakeholders, etc.) • Acceptability: Emphasizing elderly needs and requirements that each REACH concept is trying to answer • Acceptability: Understanding how the whole REACH concept fit into the elderly environment (home, care home, clinical environment) • Acceptability: iterative testing needed to assess the circumstances/condition of acceptance of functions and designs of the furniture. • Use of qualitative and Ethnographic studies • Accessibility: employment of concepts such as “design for all”, “personalization”, and “accessibility” •
Documents that provide guidance	a) ISO 26000 Social Responsibility b) WHO Screening criteria and good practices (e.g. Wilson and Jungner and updated versions) c) CWA 17145-1:2017 (WI=WSSAT001) Ethics assessment for research and innovation - Part 1: Ethics committee d) ISO/ DTS 17033 Ethical claims and supporting information – principles and requirements e) IWA 18:2016 Framework for integrated community-based life-long health and care services	a) REACH Deliverable D10.1/ D43: Ethics, Privacy, and Data Management b) The EU’s General Data Protection Regulation (GDPR) c) The OECD privacy framework d) CEN/CLC/JTC 8 Privacy protection by design and by default e) ISO/IEC 20889:2018 Privacy enhancing data de-identification terminology and classification of techniques f) ISO/NP 31700 Consumer protection — privacy by design for consumer goods and services	a) ISO14155:2011 Clinical investigation of medical devices for human subjects – good clinical practice b) IEC/ISO 31010:2009 Risk management - Risk assessment techniques. c) ISO 31000:2009 Risk management - Principles and guidelines. d) ISO 13485:2016 Medical devices - Quality management systems -- Requirements for regulatory purposes e) National medical devices laws (e.g. German Medizinproduktegesetz: MPG) f) European MDD (Medical Device Directive), 93/42/EEC -includes regulations on medical CE marking, etc.	a) EN ISO 9241-161:2016 (WI=00122208) Ergonomics of human-system interaction - Part 161: Guidance on visual user-interface elements (ISO 9241-161:2016) b) EN ISO 9241-11:2018 (WI=00122223) Ergonomics of human-system interaction - Part 11: Usability: Definitions and concepts (ISO 9241-11:2018) c) ISO 21542:2011 Building construction -- Accessibility and usability of the built environment d) ISO TC 136 Furniture e) ISO/IEC JTC 1/SC 35 User Interfaces + user interface accessibility cultural and linguistic adaptability and accessibility

	f) ISO TC 314 Ageing societies: WG1 – age inclusive work environments; WG2 - dementia inclusive communities g) ISO/TR 2222:2006 Health informatics — good principles and practices for clinical data warehouses	g) ISO/AWI 22697 Health informatics – application of privacy management to personal health information h) ISO/IEC 29100:2011 Information technology – security technologies – privacy framework i) ISO/IEC 29101:2013 Information technology – security techniques privacy architecture frameworks j) ISO/TR 18638:2017 Health informatics – guidance on health information privacy education in health care organizations k) ISO/IEC AWI 27030 Information technology – security techniques – guidelines for security and privacy in internet of things	g) Clinical Evaluation Report (CER) according to MEDDEV 2.7/1 rev4 and MDD (or MDR)	f) ISO/TS 20282-2:2013 Usability of consumer products and products for public use -- Part 2: Summative test method g) ISO/TR 16982:2002 Ergonomics of human-system interaction -- Usability methods supporting human-centered design h) IEC 62366-1:2015 Medical devices -- Part 1: Application of usability engineering to medical devices i) ISO 9241-960:2017 Ergonomics of human-system interaction -- Part 960: Framework and guidance for gesture interactions j) ISO/IEC TR 29138-3:2009 Information technology -- Accessibility considerations for people with disabilities -- Part 3: Guidance on user needs mapping k) ISO/DIS 21801 General guidelines on cognitive accessibility l) ISO/CD 24552 Ergonomics -- Accessible design -- Accessibility of digital information visually displayed on small consumer products m) ISO/IEC 29138-1:2018 Information technology -- User interface accessibility -- Part 1: User accessibility needs

Table 2-2. Touchpoint 1: Acceptability drivers in the context of the Smart Walker (ActivLife).

System components		Ethical, social, and inclusion criteria	Privacy aspects	Legal and liability aspects	Usability, accessibility and acceptability
Item	**Application**				
PI²Us/Modular mechanical setting and devices:	People at risk of falls are enabled to perform alone safe training in a device that holds and guides them. The device states a training stander with a novel kinematic and mechanical structure that allows the safe and independent execution of a wide ADL-focused training programs	• The safe training device and the training settings (including games) shall be designed/set up in a way that avoids stigmatization. • To facilitate social and cognitive activities the training sessions should be designed for being administered and performed in groups rather than alone • The device shall allow to control the level of assistance (e.g. secure holding) provided	--- *not applicable*	• What certification processes (CE, medical CE, Safety, etc.) would be required for what type of environments (physical therapy practices, elderly activity centers, clinical environments, etc.)? • Development of appropriate user manuals and training instructions for use in the different environments needed. • Document proper requirements engineering from the beginning to facilitate later CE certification. • Assessment of potential risks (harm and negative consequences) for elderly patients and people administering the trainings	• Co-creation and user participation: involvement of users into the requirements engineering and development process needs to be ensured. • Systematic requirements engineering • Usability: use of proper metrics to assess the capability to properly and safely use the ActivLife devices (e.g. NASA task load index)
Sensing/ Sensing and data gathering sub-system:	Groups at risk of a) Fall & Frailty, b) Neurodegenerative diseases, or c) cardiac issues are given a wearable to further verify high risk (screening). If the risk is verified there are administered training with TP1 elements. TP1 sensors: wearable sensor, step count, EMG, gesture tracking and feedback about games performed. Linked platform: CARP	• The sensor based early intervention strategy of this TP equals a screening procedure: is it ethically feasible in this context (e.g. does the reduction of risk of falls outweigh the fact that it may also have negative consequences, e.g. induce fear and turn elderly into "unhealthy" people at risk of falls or even patients. Are sufficient enough treatments (i.e. trainings) available to really counteract the diagnosed risk of falls?	• The sensor used in the screening context should be simple and obtain as less health values and data as possible, i.e. only those needed to generate a minimal viable analytics result. • Ensure that data storage and processing for the screening is done in a local, secure silo (e.g. by creating local instances for CARP or HSDP) by the institution (e.g. a practice of a general practitioner) administering it. • The use of ML to provide feedback and modulate trains should in a top down manner ideally decide type and number of sensors needed.	• Consider the available CE/medical CE certifications of the sensor to be used for screening. • Consider the available CE/medical CE certifications for the sensing and data collection system used to administer and modulate trainings.	• Use of qualitative and Ethnographic studies to determine under what circumstances the users accept the monitoring by the sensors
Analytics/ Software and Algorithms:	ML (unsupervised learning) is used to classify elderly into	• Ensure that neither clustering algorithms nor training data sets facilitate discrimination.	• Compliancy with the GDPR needed and the national data protection regulations	• How can we ensure that the ML modules (or the software through which they will be deployed) meets	• Systematic verification and validation (technical, professionals, us-

	groups and assign the right training schemes. During the training ML (supervised learning) is used to intelligently modulate the trainings.	• Ensure that despite use of ML at various stage in the detection-analytics process, there is enough room for choice and human interaction.	• Informed consent needed • Does the ML-system require a re-use of the data for other purposes? • Supervised learning requires as many (multivariate) parallel sensor readings in parallel – to what extent does this conflict with privacy regimens asking to obtain only the necessary data?	all safety/certification/clinical requirements and will be allowed for use in hospital (clinical) and care home/home care (non-clinical) use. • Who is liable if based on the ML and the trainings provided negative consequences/health outcomes for an individual elderly are the result? • Can the patient object to any use of ML in the context of contact with the screening or training system?	ers, stakeholders, etc.) of the performance of the ML-based system components

Intervention/ Schematics for engagement, behaviour change, and physical/cognitive training:	Modular training schemes (ADLs, falls, cognitive, cardiac, etc.) embedded into software games that can be played through the ActivLife device. In the games a variety of behaviour change techniques are integrated, such as gamification, goal setting, peer pressure, etc.	• Patient empowerment to more self-training with the Active Life device should not lead to less social contact.
		• In the context of personalized behaviour change elements embedded into trainings and games to performed with the ActivLife device:
		  • how are the "goals" set?
		  • how is it ensured that the system nudges and not manipulates?
		  • how is it ensured that the system still provides choice?
			• Handling of data and information obtained in the context of the development of personalized trainings with ActivLife
			• Both elderly and the providers of the personalised trainings (sports coaches, physical therapists, etc.) should be trained in using the systems in a privacy preserving manner
				• What certification processes (CE, medical CE, Safety, etc.) would be required (in particular for the modular physical) for the training/gaming software for what type of environment?
				• Training and behaviour change schematics: validation and liability requirements for administering them in in home, care home, and clinical environments?
				• Assessment of potential risks (harm and negative consequences) for elderly patient
				• Ensure that people do not over exercise.
					• Acceptability: iterative testing needed to assess the circumstances/condition of acceptance of functions and designs of the training functionality
					• Acceptability: the designed intervention (games) should be personalized to the user needs, ability and preferences.
					• Use co-creation and user participation to develop the underlying concepts (e.g. goal setting and behaviour change mechanism) of the personalisation regimens

User interfaces:	Software that allows to play the games, select specific games, display progress over time, etc.	• Interfaces should be designed in a way that they do not disadvantage any user group (male/female; skilled/un-skilled), and allow for broad accessibility (elderly, care givers, physio therapists, younger people, etc.)	• Management of data obtained through gaming (e.g. screen time, games played, performance). • Allow users through the interface to set/adjust their privacy preferences • Interfaces and data sharing with higher level systems and platforms (e.g. Philips HSDP) • Privacy by design, e.g. according to ISO/PC 317	• Consider medical CE certification for clinical context use/adaptation	• Ensure broad Accessibility: employment of concepts such as "design for all", "personalisation", and "accessibility"

Table 2-3. Touchpoint 2 Acceptability drivers in the context of the Smart Care/Patient Room.

System components		Ethical, social, and inclusion criteria	Privacy aspects	Legal and liability aspects	Usability, accessibility and acceptability
Item	**Application**				
PI²Us/Modular mechanical setting and devices: adaptable modular physical care/patient room environment (frame around PI²U-Bed, PI²U-MiniArc, PI²U-SilverArc, etc., i.e. Total Room Kit); adaptable to various care scenarios: home/smart home, care home, rehabilitation hospital.	Modular smart rehabilitation room for rehabilitation (clinical setting) and activation purposes (home); Modular system that a) integrates existing elements (e.g. existing beds), b) serves as carrier for unobtrusive sensing, c) allows flexible adding/removing of integrated training functionality, and d) can be adapted to a variety of settings.	• Adaptability: the integration of REACH solutions through PI²Us shall be highly context sensitive, adapted to a community's/institution's ecosystem (e.g. through modular combinations of toolkit elements) and individual users and their situations (personalisation) • Is the amount of physical support, assistance, and comfort provided suitable for the need and the context (i.e. not too much and not to less assistance or automation provided) so that enough assistance can be provided while still challenging people • Shall PI²Us make the integrated functionality "visible" or "in-visible/hidden"? • PI²Us shall follow a user-driven design and co-creation principles • The deployment of PI²Us in any environment shall not lead to any kind of stigmatisation • principles of social and public interest design could be taken into account	*--- not applicable*	• What certification processes (CE, medical CE, safety, declaration of conformity etc.) would be required for what type of environments (home, care homes, clinical environments, etc.) allow fast modular adaptation. • Development of appropriate user manuals and training instructions for use in the different environments needed. • Assessment of potential risks (harm and negative consequences) for elderly patient	• Co-creation and user participation: involvement of users into the requirements engineering and development process needs to be ensured. • Usability: where proper metrics used to assess the capability to properly use the devices (e.g. NASA task load index)? • Acceptability: iterative testing needed to assess the circumstances/condition of acceptance of functions and designs of the furniture. • Acceptability: how does it fit to the user's environment? • Accessibility: it needs to be ensured that the furniture/room elements can easily be used by a variety of users (elderly with different capabilities, care personnel, family members, etc.); therefore, employment of concepts such as "design for all", "personalisation", and "accessibility" (e.g. ISO TC 59 accessibility of the built environment, ISO TC 136 furniture, etc.)
Sensing/ Sensing and data gathering sub-system: network of a variety of ambient and wearable sensors (pluggable to CARP and HSDP) for use in context of HAR	Network of a variety of ambient and wearable sensors (for HAR); Human Activity Recognition requires a tailor-made set of ambient and wearable sensors.	• Is the type of sensors used appropriated and indirect enough to guarantee the users privacy and dignity? • The number of sensors used in the HAR environment shall not be excessive but minimised and tailored to what is necessary to perform the needed ML-tasks. • The deployment of wearable sensors as well as ambient sensors in	• Do the sensors and the components used (e.g. the wireless sensor network) in it ensure that unwanted access (e.g. through hacking) is prevented? • Does the data collection pipeline ensure that the data are handed over safely from process step to process step (e.g. from the sensors to the sub-serves to the platform)	• Consider the available CE/medical CE certifications of the sensors and the software part of the total room kit in the context of data collection and storage • Declaration of conformity • Suitable intended purpose	• Acceptability: In case of wearable sensors: to what extent it is feasibly that elderly wear or have attached a specific sensor continuously. • How do on board storage capacity and battery power affect efficient use in the clinical environment. • Accessibility: can then sensors easily be deployed and intuitively

		the environment shall be done in a way that avoids over stigmatisation • Interoperability: is the deployed sensing and data collection solution compatible with existing digital and non-digital systems in the environment in question (e.g. home and building automation systems, sensors/clouds of other products needed by the user or the care givers, etc.)	• When and how are data pseudonymized (i.e. codification)/anonymised. • How is access to the data controlled and is accountability clearly regulated (e.g. who is the data controller) • What are advantages/disadvantages of a locally (e.g. at SK) deployed HDSP version and a CARP platform located in Copenhagen. • How much access and control are the elderly user (patient) given over the data?		be used by the care givers, nurses, and the end-users alike?
Analytics/ Software and Algorithms: Human Activity Recognition Chain (HAR)	The automated ML-based recognition/prediction of Human Activities can serve as the basis for advanced and proactive interventions in any care environment.	• Does the training data set accurately represent the source/target population? • Are the logics/mechanics of the algorithm transparent? • Is it possible and ethically viable to obtain the necessary permissions (Ethics approval) for the obtaining of training data sets? • To what extent have elderly/patients the possibility to gain knowledge about, object to, or influence the automated processing of their data?	• Compliancy with the GDPR needed and the national data protection regulations • Informed consent needed • Does the ML-system require a re-use of the data for other purposes? • HAR requires as many (multivariate) parallel sensor readings in parallel – to what extent does this conflict with privacy regimens asking to obtain only the necessary data?	• How can we ensure a legally correct obtaining, use, and reuse of training data and data sets (ideally obtained in the same institution) needed to build up and train ML algorithms? • How can we ensure that the ML modules (or the software through which they will be deployed) meets all safety/certification/clinical requirements and will be allowed for use in hospital (clinical) and care home/home care (non-clinical) use. • Who is liable if based on the ML components output and the decisions made based on it negative consequences/health outcomes are the result? • Can the patient object to any use of ML in the context of his hospital stay or treatment?	• To what extent are key acceptability drivers considered: ○ Transparency of the whole data collection and processing pipeline and right to object or withdraw or determine privacy settings ○ Is the value for the user high enough to justify and outweigh the case specific data collection and processing intensity? ○ Is data security ensured?
Intervention/ Schematics for engagement, behaviour change, and physical/cognitive training: Activation through room integrated mobilisation (verticalization,	Activation through room integrated mobilisation (verticalization, mobility, training, etc.) strategies and devices. Integration into everyday furniture and environments allows for better self-use and in-	• The smart training room should prioritise the administration of training ADLs and social training) and empowerment solutions best able to stimulate further social inclusion. • Patient empowerment to more self-training should not lead to less social contact.	• Handling of data and information obtained in the context of the development of personalised trainings and therapies	• What certification processes (CE, medical CE, safety, declaration of conformity, etc.) would be required (in particular for the modular physical) training functions and elements of the bed for what type of environments (home, care homes, clinical environments, etc.) to allow fast modular adaptation.	• It is difficult to test and validate more than 1 or 2 behaviour change strategies in combination • General behaviour change regimens should be developed and fined tuned in an iterative manner including at several stages direct user feedback and user co-creation elements

mobility, training, etc.) strategies and devices	dependence and lowers accessibility and barrier of use (patient empowerment)	• The seamless inclusion of training into the care/patient room should not lead to less social contact and more retraction. • Empowerment and assistive solutions (e.g. in the form of the iStander toileting function) must be carefully balanced against and adapted to the user's capabilities as of still to provide enough stimuli and not make sedentary behaviour to easy.		• Training and behaviour change schematics: validation and liability requirements for administering them in home, care home, and clinical environments • Assessment of potential risks (harm and negative consequences) for elderly patient	
User interfaces: Room management software	Room management software. By an appropriate GUI, the user can intuitively control the REACH system.	• Interfaces should be designed in a way that they do not disadvantage any user group (male/female; skilled/un-skilled), etc. • Can the interface be designed in a way that it facilitates the inclusion and activities of informal caregivers?	• Management of data obtained through its use (e.g. screen time and similar) • Interfaces and data sharing with higher level systems and platforms (e.g. Philips HSDP) • Privacy by design, e.g. according to ISO/PC 317	• Consider medical CE certification for clinical context use/adaptation • Declaration of conformity • Suitable intended purpose	• The user interface shall facilitate broad accessibility and inclusion; e.g. according to ISO/IEC JTC 1/SC 35 User Interfaces (which includes provisions on user interface accessibility cultural and linguistic adaptability and accessibility ISO/IEC JTC 1/SC 35)

Table 2-4. Touchpoint 3: Acceptability drivers in the context of Socializing and Nutrition.

System components		Ethical, social, and inclusion criteria	Privacy aspects	Legal and liability aspects	Usability, accessibility and acceptability
Item	**Application**				
B1: PI²Us/ Modular mechanical setting and devices: Smart table Kooktafel, PI²U-Silver Arc, ActivLife	People at risk of falls are enabled to perform independent safe training in a device that holds and guides them. The device states a training stander with a novel kinematic and mechanical structure that allows the safe and independent execution of a wide ADL-focused training programs	• Does the seamless integration of digital technology into day care centres/care homes by PI²Us lead to an unwanted blurring of the boarders between real and digital world? • PI²Us (Smart Table, PI²U-Silver Arc, Active Life) shall follow a user-driven design and co-creation principles • The deployment of Smart Table, PI²U-SilverArc, ActivLife in any environment shall not lead to any kind of stigmatization	• The physical environment and devices are in this Touchpoint designed to facilitate activities in the community, however these devices shall also ensure that people can still retract and keep certain activities and data private	• What kind of certifications are required for the installation of PI²Us as furniture in day care centres? • Are the PI²U furniture elements designed for on-site installation by professionals or non-professionals (i.e. whom do we expect to install the elements)? Who is liable in case malfunction/harm due to incorrect installation? • PI²Us are complex types of furniture – are user manuals enough or are systematic training briefings needed?	• Does the smart cooking table allow to keep physical and cognitive stress levels (e.g. according to NASA TLX) low in order to ensure safe and intuitive use? • To facilitate socialising and the use in a community, all elements of this touchpoint must in particular ensure very broad accessibility (e.g. according to ISO standards or similar deign guides)
B2: Sensing/ Sensing and data gathering sub-system: Ecosystem of sensing and interface elements Mirana Bot, HealthyTogether App, SMAAK concept for a social eating platform, and FitBit	The HealthyTogether user interface (that allows tracking and social- or self-reflection based on PA data from FitBit) can be combined flexibly with a module for food tracking and a module for social eating and communication around food.	• From the available ecosystem of sensing elements, provided by this touchpoint, only those elements shall be selected which are really needed in a specific context. The minimization of sensing elements states a key privacy by design element.	• Both elderly and the care givers should be trained in using the systems in a privacy preserving manner • The system implies functionality of social platforms such as Facebook or similar, however the information obtained (about eating habits, steps, physical activity, etc.) are much more personal • Systems should be designed in a way which limits user's risks of unwanted or accidental data sharing	• Sensors may wrongly detect the input or fail to detect the input (e.g. in case of Mirana Bot or FitBit). Therefore, the accuracy performance of the sensors needs to be specified.	• Acceptability: In case of wearable sensors: to what extent it is feasible that elderly wear, or are otherwise continuously attached to, a specific sensor? • Acceptability: In case of application (Mirana Bot), to what extent it is feasible that the elderly can describe their nutrition habits (prompt with notification in case they forgot) / how easy it is to log their nutrition habits? • How do on-board storage capacity and battery power affect efficient use in the community in question? • Accessibility: can sensors be easily deployed and intuitively be used?
B3: Analytics/ Software and Algorithms: Philips dashboard and machine learning based personalization	Modularly combinable set of tools for interpretation of health and life style data in the context of behaviour change/engagement	• Does the training data set accurately represent the source/target population? • Are the logics/mechanics of the algorithm transparent? • Since the solution for this TP involves the use of high-dimensional neural networks and similar	• The use of data dashboards and ML in the community context must be made transparent to everyone taking part in the community activities) elderly, caregivers, and professionals, etc.) • Possibility to opt out or limit data collection by the system must be	• Who is liable in case a by the algorithm selected and recommended action, training, intervention leads to negative outcomes/consequences?	• To what extent are key acceptability drivers considered: ○ Transparency of the whole data collection and processing pipeline and right to object or withdraw or determine privacy settings

		techniques: can it be ensured that the decision logics of the algorithms at work can be comprehended and retraced? • Is it possible and ethically viable to obtain the necessary permissions (Ethics approval) for the obtaining of training data sets? • To what extent have elderly/patients the possibility to gain knowledge about, object to, or influence the automated processing of their data?	possible without being excluded from the community activities the system shall facilitate		○ Is the value for the user high enough to justify and outweigh the case specific data collection and processing intensity? ○ Is data security ensured?
B4: Intervention/ Schematics for engagement, behaviour change, and physical/cognitive training: Personalised engagement regimens in combination with personalised food receipts and cooking guidance, and gamified social training at activity centre	Schemata and guidance for the implementation of engagement and behaviour change regimens in the context of socialising and nutrition	In the context of personalised behaviour change: • how are the “goals” set? • how is it ensured that the system nudges and not manipulates? • how is it ensured that the system still provides choice?	• Very personal data about food preferences, health states, friends, etc. are generated: users shall stay in control with regard to sharing, cross integration, and sharing of this data.	• Who is liable if people are nudged into a certain behaviour with negative consequences?	• Behaviour change and personalisation regimens should be developed and fined tuned in an iterative manner including several stages direct user feedback and user co-creation elements
B5: User interfaces: HealthyTogether App	A novel app based on HealthyTogether to collect step data, identify activity patterns, derive personalisation strategies	• In particular in the community centre context, the interfaces should be designed in a way that they do not disadvantage any user group (male/female; skilled/un-skilled), etc.	• How is consent obtained when data are shared for motivation purposes (e.g. gamification) with peers?	---	• The user interface shall facilitate broad accessibility and inclusion; e.g. according to ISO/IEC JTC 1/SC 35 User Interfaces (which includes provisions on user interface accessibility cultural and linguistic adaptability and accessibility ISO/IEC JTC 1/SC 35)

Table 2-5. Touchpoint 4: Acceptability drivers in Gamified Engagement Environments.

System components		Ethical, social, and inclusion criteria	Privacy aspects	Legal and liability aspects	Usability, accessibility and acceptability
Item	Application				
B1: Pl²Us/ Modular mechanical setting and devices: Combination of Pl²U-MiniArc furniture with playware tiles	Novel combination of playwear tiles with a standing table allows for a variety of trainings	• Does the training-furniture setting allow that the elderly also conduct other, more natural ways of activity, e.g. does the training setting empower them so that they visit more often friends or shops or similar, since balance and walking speed increase.	---	• Who is liable if accidents happen during self- or supervised training sessions?	• Co-creation and user participation: involvement of users into the requirements engineering and development process needs to be ensured. • Usability: where proper metrics used to assess the capability to properly use the devices (e.g. NASA task load index)? • Acceptability: iterative testing needed to assess the circumstances/condition of acceptance of functions and designs of the furniture. • Accessibility: it needs to be ensured that the furniture/room elements can easily be used by a variety of users (elderly with different capabilities, care personnel, family members, etc.); therefore, employment of concepts such as “design for all”, “personalisation”, and “accessibility” (e.g. ISO TC 59 accessibility of the built environment, ISO TC 136 furniture, etc.)
B2: Sensing/ Sensing and data gathering sub-system: Set of playware tiles and ambient and wearable sensors for the upgrade of smart homes for the elderly	Co-adapted set of ambient and wearable sensors	• Is the type of sensors used in the smart homes for elderly appropriate and indirect enough to guarantee the users privacy and dignity? • The number of sensors used in the used in the smart homes for elderly shall not be excessive but minimised and tailored to what is necessary to perform the needed ML-tasks. • Interoperability: is the deployed sensing and data collection solution compatible with existing digital and non-digital systems in the environment in question (e.g. home and building automation systems, sensors/clouds of other	• Do the sensors and the components used in the smart home (e.g. the wireless sensor network) in it ensure that unwanted access (e.g. through hacking) is prevented? • Does the data collection pipeline ensure that the data are handed over safely from process step to process step (e.g. from the sensors to the sub-serves to the platform) • When and how are data pseudonymized/anonymised. • How does Carp ensure data privacy and security?	• What kinds of certifications are for the smart home sensors needed in the Danish context?	• Acceptability: In case of wearable sensors: to what extent it is feasibly that elderly wear or have attached a specific sensor continuously. • How do on board storage capacity and batter power affect efficient use in the clinical environment. • Accessibility: can then sensors easily be deployed and intuitively be used by the care givers, nurses, and the end-users alike?

		products needed by the user or the care givers, etc.).	• How is access to the data on CARP controlled and is accountability clearly regulated (e.g. who is the data controller) • How much access and control is the elderly user (patient) given over the data through CARP?		
B3: Analytics/ Software and Algorithms: ML for early detection (on device ML for accurate steps recognition for elderly + trends prediction) + device (playware) integrated functional assessment	The setting allows to perform assessment of functional ability using the gamified device	• The developed ML algorithms should consider the specifics of the user group (elderly) • On device assessment shall not lead to a loss of social contact e.g. with doctors of care givers.	• Does the ML-system require a re-use of the data for other purposes?	• How accurate is the on-device assessment of functional ability and who administers it? > what types of validation and certification needed. • Who is liable if the functional assessment was wrong and led to the inappropriate actions, suggestions, or trainings with negative consequences?	• To what extent are key acceptability drivers considered: ○ Transparency of the whole data collection and processing pipeline and right to object or withdraw or determine privacy settings ○ Is the value for the user high enough to justify and outweigh the case specific data collection and processing intensity? Is data security ensured?
B4: Intervention/ Schematics for engagement, behavior change, and physical/cognitive training: Training plans and games for activation of elderly with playware tile	Training schemata provide target-oriented ADL trainings in gamified, fun inducing manner enhancing medical outcomes	• There are indications that more active elderly may actually consume more health care services. • How can we distinguish between activity stimulating "nudging" and "manipulation"	Very personal data about trainings and how certain interventions work for a certain person are generated.	• Who is liable if people are nudged into a certain behaviour with negative consequences? • How can over-exercising be avoided?	• It is difficult to use (as well as test and validate) more than 1 or 2 behaviour change strategies in combination • General behaviour change regimens should be developed and fined tuned in an iterative manner including at several stages direct user feedback and user co-creation elements
B5: User interfaces: Data collection and visualisation through DTU CARP and Philips data dashboard	Dashboard summarize and visualize the different datasets of importance to the researchers for behaviour research	• Can the interface be designed in a way that it facilitates the inclusion and activities of informal carers?	• Interfaces and data sharing with higher level systems and platforms (e.g. Philips HSDP)? • Privacy by design, e.g. according to ISO/PC 317	• What certifications are required for use in what context?	• The user interface shall facilitate broad accessibility and inclusion; e.g. according to ISO/IEC JTC 1/SC 35 User Interfaces (which includes provisions on user interface accessibility cultural and linguistic adaptability and accessibility ISO/IEC JTC 1/SC 35)

2.3 Alignment of the REACH strategy and goals

Building on these previous achievements, we were able to refine the strategy and goals of the REACH project as a whole. In particular, it was possible to define medical purpose and intended use in **Reporting Period 3** (see **Figure 2-2**, see also **Deliverable D37, Appendix**). This determination is the basis of the classification of a product as a medical device (MD) and its certification – and therefore a cornerstone for market entry. The classification is based on the potential risks associated with the use of this device and therefore highly dependent on the results of the aforementioned efforts regarding ethics, privacy and legal risks.

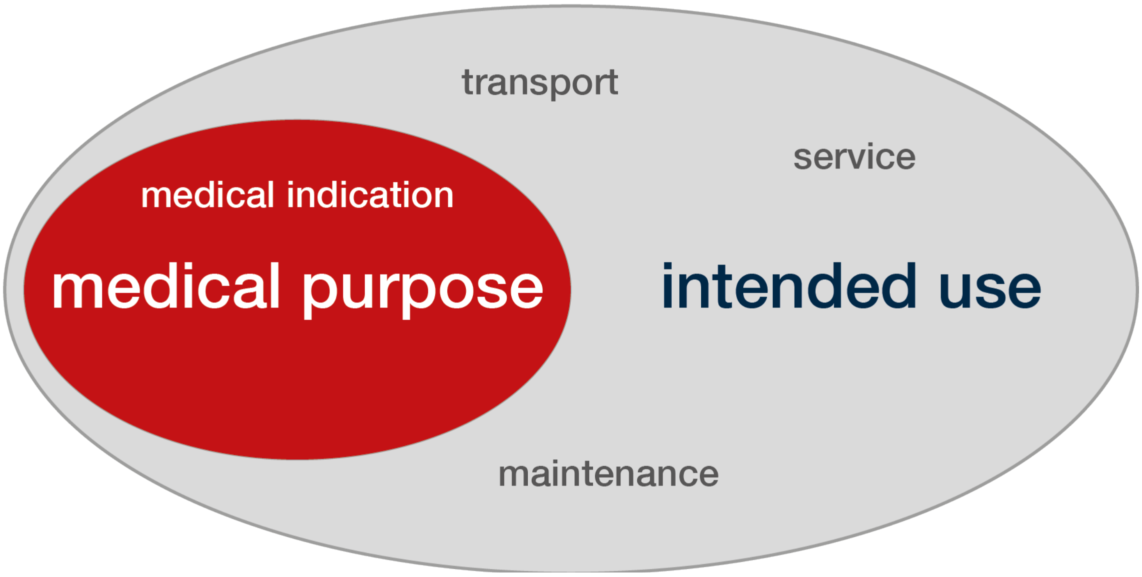


Figure 2-2. Determination of the medical purpose and intended use.

3 Brief summary of the consideration and implementation of privacy and security schemata in key REACH system components

3.1 Overview of the technical implementation strategy for privacy and security related considerations

All of the considerations related to ethics, privacy and legal issues, that are discussed in this deliverable report, require an appropriate technical implementation in order to be effective. The following three points can be considered as the guiding principles for the technical implementation of privacy and security related concerns:

1. **Protect sensed data**
2. **Ascertain computational anonymity**
3. **Ensure privileged intervention access**

These principles have been fundamental to the design, development and implementation of all technical aspects of the REACH solution. We reported these efforts in particular and in great detail in **Deliverable D7**. The following provides a brief overview of the technical solutions that were implemented in the context of specific aspects of REACH.

3.2 TP 2 – protected sensed-data

The protection of the data that is collected with sensors is highly important. The implementation of this aspect is showcased in **TP2**. A general overview of the data security strategy on the technical level is depicted in the **Figure 3-1**.

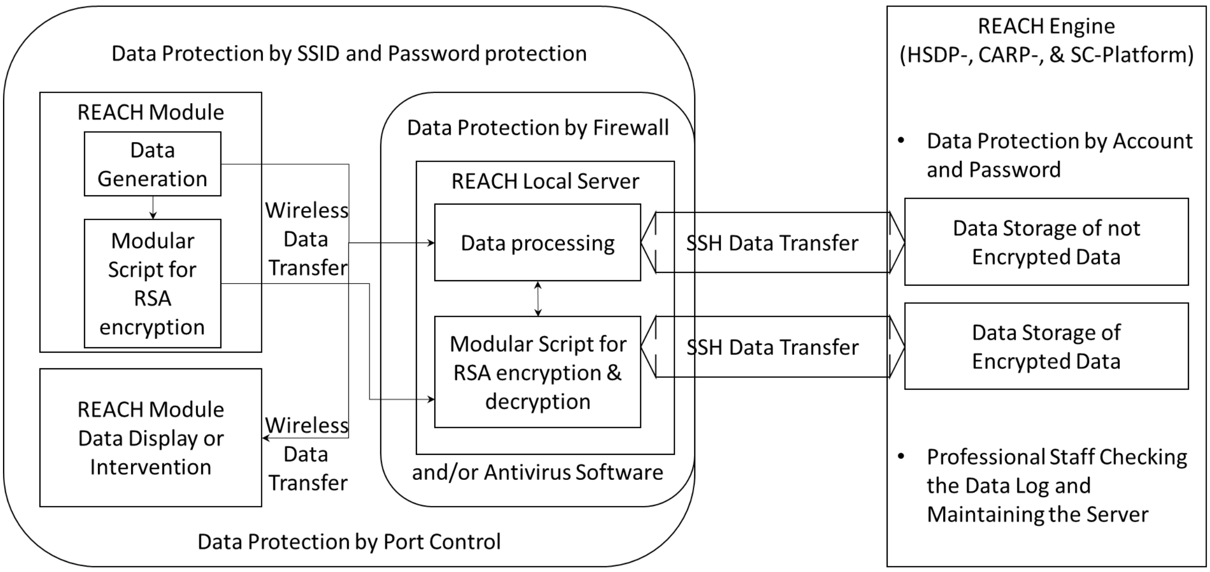


Figure 3-1. General overview of the technical data security and general communication schema.

The different prototypes in REACH generate various data. In the first instance, this data is saved locally on the respective device. The prototypes are part of a local area network (LAN) in which they communicate with a local server. The network is password protected in order to allow only authorized access and the server runs a firewall and anti-malware software. In addition, an encryption module utilizing an RSA cryptosystem for secure data transmission can be implemented which serves as a second protective layer in case the local network is compromised to prevent access to plaintext data. The transmission of data from the LAN environment to the REACH engine is utilizing the Secure Shell (SSH) network protocol. The data transferred to the REACH engine can be encrypted as well by the RSA encryption module. The only disadvantage is additional time for encryption, due to the secure 4096-bit encryption key.

3.3 Data platforms CARP and/or SmartCardia – ascertain computational anonymity

The data platforms CARP and SmartCardia also make use of data protection strategies in order to ensure privacy.

CARP

The data management backend of CARP is based on SQLite and makes use of open source libraries. CARP applies the following state-of-art security mechanism; Authentication, Authorization, and Encryption.

The CARP Portal is used to issue a token for collecting data from the registered users in the study. An enrolled researchers and participants are assigned with user ID, role, and scopes. This provides valuable information required by researchers and studies.

Communication with CARP Platform is secured using the Open Authentication 2.0 (OAuth2) workflow, which is the state-of-art in RESTful authentication and data source integration.

The communication in CARP is secured using Secure Sockets Layer (SSL) and Transport Layer Security (TLS) as a standard security technology for establishing encrypted endpoint between the CARP platform and its clients.

SmartCardia

The data from the device are stored in an encrypted custom format in the cloud database. The data stored is anonymous in nature (without patient name and features that could allow inferring with the identity).

All the personal computers and servers of the Company must have their hard drives fully encrypted. In Windows, the allowed tool is BitLocker. In OS X is FileVault. In Linux, the hard drive must be encrypted during the installation process. The key manager is the responsible of setting up the hard drive encryption and storing the recovery keys of each computer. The hard drive encryption must be done using a strong password (mixing uppercase, lowercase, numbers and symbols) only known by the employee and the key manager.

The servers of the Company used for hosting Web applications and services must have installed the corresponding SSL/TLS certificates, which must be created by a trusted Certificate Authority (CA) because of the request of the key manager, to establish secure connections.

The information transported by Wi-Fi between different application/services must be also encrypted using SSL/TLS certificates. If encryption is not possible, due to hardware limits, it is mandatory to obfuscate the data before sending them across communications lines. In particular, the connection from the mobile phone to the server to store information in the cloud is performed using a secure communication based on SSL.

4 Legal aspects in the context of Machine Learning/HAR in TP2 – ensure privileged intervention access

4.1 Legal aspects regarding the use of AI in healthcare

There is a broad variety of ethical and legal issues associated with using AI in healthcare. AI can be used to diagnose diseases applying algorithms to process a multitude of biological markers, provide alerts from behavioral data to suggest urgent interventions – or inversely, to suggest that no critical changes have taken place. Here we focus on liability when AI suggests an action (a procedure or an intervention) or a “wait-and-see” inaction perhaps and when this leads to patient harm. The following table (Price et al., 2019) sums up situations when patient harm may lead to liability.

Table 4-1. Examples of potential legal outcomes related to AI use in clinical practice.

Scenario	AI recommendation	AI accuracy	Physician action	Patient outcome	Legal outcome (probable)
1	Standard of care	Correct	Follows	Good	No injury and no liability
2			Rejects	Bad	Injury and liability
3		Incorrect (standard of care is incorrect)	Follows	Bad	Injury but no liability
4			Rejects	Good	No injury and no liability
5	Nonstandard care	Correct (standard of care is incorrect)	Follows	Good	No injury and no liability
6			Rejects	Bad	*Injury but no liability*
7		Incorrect	Follows	Bad	*Injury and liability*
8			Rejects	Good	No injury and no liability

In his summary table, two scenarios involving patient harm are flagged as raising liability. The first (scenario 2) is a special case where the clinician may be liable simply by deviating from standard care procedures. The fact that the clinician may have used – and has rejected to follow the advice of - an AI application that also suggested using standard care procedures might possibly exacerbate the liability. However, the second case (scenario 7) is much more acute. Here the AI system goes beyond and against standard of care and suggests an incorrect procedure (including possibly a non-action) – that leads to patient harm.

In general, AI algorithms will often (typically) have a complexity that does not allow clinical staff unravel and track the reasoning from possibly massive amounts of data to a conclusion. This issue of “black box medicine” is the subject of a rapidly growing field of studies of legal, management and medical aspects, e.g. (Challen et al., 2019; Emanuel & Wachter, 2019; Price et al., 2019). Similarly, studies and documents prepared for the European Parliament have dealt with the issues in depth (Kritikos, 2019; Yeung, 2019). The non-profit organization PHG, located in Cambridge, UK, also contains several sources and resources relevant to liability of AI-based interventions: https://www.phgfoundation.org/briefing/legal-liability-machine-learning-in-healthcare

With the maturing of the REACH system the following key concerns (the authors state that this list is not meant to be comprehensive) should be addressed in depth by ethicists and technical experts (Stahl & Coeckelbergh, 2016):

Implications for society and healthcare:

- Replacement and its implications for care giver.

- Replacement and its implications for the quality of care: de-humanization and ‘‘cold’’ care.

Implications for human-robot interaction:

- Autonomy of the robotic system.
- Role and tasks: role of the robot in the particular care process
- Moral agency: dealing with ethically problematic situations.
- Responsibility: ethical, legal, social responsibilities
- Deception: robots as social companions, social-emotional involvement
- Trust: how trustworthy can a robotic system be?

Key concerns of ICT involving human users:

- Privacy and data protection
- Safety and avoidance of harm

Both issues have been addressed in the previous chapters.

Furthermore, the principles stated in the H2020 Responsible Research and Innovation (RRI) concept were used as guidance document in the REACH project (European_Commission, 2019).

Table 4-2. Scaffolding questions of the framework for RRI in ICT (Stahl & Coeckelbergh, 2016).

Scaffolding questions of the framework for RRI in ICT.

	Process – Speed of innovation and diffusion	Product – Ubiquity and pervasiveness – Applied and fundamental research	Purpose – Logical malleability	People –Problem of many hands
Anticipate	Is the planned research methodology acceptable?	Will the products be socially desirable? How sustainable are the outcomes?	Why should this research be undertaken?	Have we included the right stakeholders?
Reflect	Which mechanisms are used to reflect on process? Alternatives:	How do you know what the consequences be? What might be the potential use? What don't we know about? How can we ensure societal desirability? –Alternatives:	Is the research controversial? –Alternatives:	Who is affected? –Alternatives:
Engage	How to engage a wide group of stakeholders?	What are viewpoints of a wide group of stakeholders?	Is the research agenda acceptable?	Who prioritises research? For whom is the research done?
Act	How can your research structure become flexible? What training is required? What infrastructure is required?	What needs to be done to ensure social desirability? What training is required? What infrastructure is required?	How do we ensure that the implied future is desirable? What training is required? What infrastructure is required?	Who matters? What training is required? What infrastructure is required?

It could be assumed that during the further development and in extended use in practice cases and near operational environment a refined analysis regarding ethical requirements will be evaluated. This would be one of the tasks to be covered by the spin-off company from REACH in the process of bringing REACH to the market.

4.2 REACH Workshop on legal aspects of machine learning and AI

In addition to the written expert opinion on legal issues, we held a workshop on legal aspects of machine learning and AI in healthcare. The workshop took place on December 3, 2019 at TUM. The main take home messages that we developed in the workshop are as follows.

1. **Responsibility of the doctor/prescriber and negligence:** ML/AI or another highly autonomous assistive device is for the time being considered as a “tool” and the doctors/prescribers remain responsible. Doctors/prescribers must consider this

when they base their decision making on highly complex ML/AI outputs. In particular with regard to criminal law a doctor may be held accountable for negligence offences (although it may then be determined in a civil law process that the technology and its provider contributed to the mistake/incident).

2. **Claims:** Claims made by the system provider correlate with rate of potential liability. The through the producer claimed „confidence“ (i.e. confidence/accuracy of the predictions made by the system) may play a big role. If the producer claims a low confidence of its systems predictions the low liability for him/her but probably less doctors will then want to use it, then they are liable. On the other hand, high confidence claimed means an incredible high liability for the producer, but doctors probably will very willing to adopt.

3. **Focus**: Focus on structured institutionalized environments and narrow task to control use and limit risk.

4. **Training**: Like with a complex medical device a system provider my specify that the doctor/care personnel requires some sort of training to ensure that the system is used correctly and minimizes risks. (nor: the product manual is non-binding; a specific contract must be made between the user and the provider to specify what the product and do and what not and how it must be used/handled/maintained/etc.)

5. **Ensure quality of training data**: Quality and non-bias of training data/data input: Quality of the data with which the system is trained matters.

6. **In the future**: Consider rethinking the legal framework: In the future, when decision-making by ML/AI systems gets more complex and sophisticated the legal framework may have to be revised.

5 Risk governance in the context of privacy and security: guidelines for introducing ambient and wearable monitoring technologies balancing privacy protection against the need for oversight and care

The introduction of ambient and/or wearable monitoring technology in the healthcare environment entails risks related to privacy and data protection. These risks need to be balanced against the intended effect of improved oversight and care. With the research conducted in the REACH, the project can be considered to be at the frontier of the developments. As a result, the project was able to make a substantial contribution to the groundwork for new regulatory frameworks and standardization activities.

Our efforts culminated in the development of a CEN Workshop agreement (CWA) with the title *"Privacy of monitoring technology — Guidelines for introducing ambient and wearable monitoring technologies balancing privacy protection against the need for oversight and care"*. A CWA is an agreement developed and approved in a Workshop by the European Committee for Standardization (CEN). It can be considered as a "pre-standard", i.e. a document preceding a binding international or European standard. The CEN CWA will be published in February 2020 and cannot be made part of this deliverable report due to confidentiality.

With the CEN CWA, we aim to offer a practical, structured guidelines to care organizations, in order to balance the need and the right for privacy with the need for care. The guidelines may also benefit additional stakeholders, such as relatives, technology providers, regulatory bodies and administrations. Therefore, we outlined a governance model, including the informed consent process, in order to facilitate the use of ambient and wearable technology in a healthcare setting for monitoring purposes.

In this context, one of the main challenges is the weighing of needs for privacy and care in an ethically responsible way (see **Figure 5-1**). Our risk governance model makes use of the proven process of informed consent.

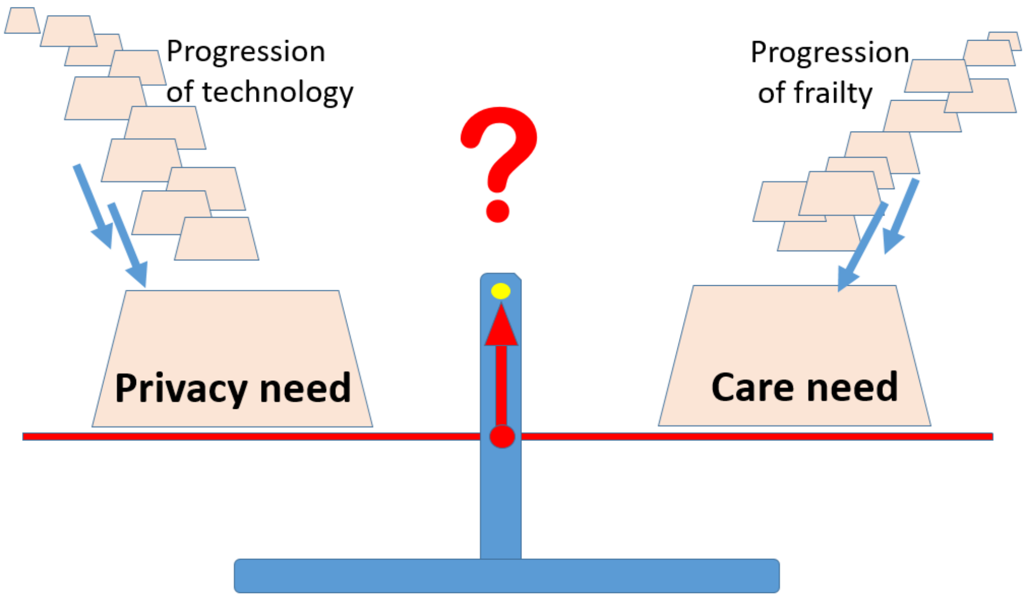


Figure 5-1. Balancing the need for privacy and the need for care and their drivers.

This process relies on the realistic communication of risks and benefits. In order to ensure the validity of this process, the following criteria has to be fulfilled: a) information has to be disclosed, b) the individual (or a representative) has to be capable to make a decision, c) the information needs to be comprehended by the addressee, and d) the nature of the decision has to be voluntary. The monitoring system therefore has to be implemented and operated in a way that ensures the adherence to the process described above. In order to illustrate the procedure, we developed a number of use cases with exemplary personas which is part of the Annex of the CWA.

The development of the CEN CWA was based on our previous work with regard to standardization activities, which have been reported in great detail in **Deliverable D38**, and the REACH ethics wrap-up, which was provided in **Deliverable D44**.

6 Conclusion

In this deliverable report, we were able to provide a comprehensive overview of the outcomes of the REACH research project with regard to data privacy and data security, associated with **Task T7.5**. Ethics and privacy concerns are a core aspect of the REACH research project from the very beginning. From a set of initial guidelines, we were able to differentiate these principles for the respective Touchpoints in order to analyze primary concerns. This provides not only the groundwork for a future certification as a medical device (MD), but also guided the technical development and implementation of the project, in order to make privacy and data security a core feature of the solution. We are also involved with the exploration of the legal dimension of machine learning and artificial intelligence which is still a relatively novel topic. Our efforts finally culminated in preparing a CEN Workshop Agreement for the European Committee for Standardization, breaking ground for an international standard on risk governance in terms of weighing privacy concerns against the need for care.

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Appendix I – Legal expert opinion on machine learning and AI in healthcare

Leibniz Universität Hannover

REACH2020

Short expert opinion on the legal situation - selected topics

FOR INTERNAL USE ONLY

DANIELA SPRENGEL

Short expert opinion on the legal situation: REACH2020
Daniela Sprengel

D) Basic literature

I. Literature used

Bamberger, Heinz Georg / Roth, Herbert / Hau, Wolfgang / Poseck, Roman

Beck´scher Online-Kommentar, 52. Edition, Stand 01.11.2019
(cited: Beck´scher Online Kommentar/*author*)

Gsell, Beate / Krüger, Wolfgang / Lorenz, Stephan / Reymann, Christoph (Gesamtherausgeber für das Zivilrecht)

Beck-Online Großkommentar, Stand 01.10.2019, München, 2017
(cited: Beck Online Großkommentar BGB/*author*)

Palandt, Otto (Begründer)

Bürgerliches Gesetzbuch, 79. Auflage, München, 2020
(cited: Palandt/*author*)

II. Judgments used, which are merely exemplary

OLG Düsseldorf, judgement from 24. 1. 1978 - 4 U 154/77, NJW 1978, 1693 (1693)

BGH, judgement of 31-01-1995 - VI ZR 27/94 (Frankfurt a.M.), NJW 1995, 1286 ff.

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Appendix II – Presentation by the legal expert

REACH 2020

Diligence, standard of care

Ass. iur. Daniela Sprengel

Outline

- General Information
- Research / Development
- Use
- Recommendations

I. General Information
Good to know…

1. The Law as such
2. Possible (criminal) offences, claims

   Civil Law

   Crime Law

   Product liability Law

3. Standard of diligence

I. General Information
Good to know…

1. The Law as such

   Problems:

   Very abstract, no concrete information

   Assume: An action is based a human decision

   Lawmakers did not think about robots!

I. General Information
Good to know…

2. Possible (criminal) offences, claims

a) Civil law: Contractual claims

b) Crime law:

Negligent homicide

Negligent personal injury

Omission e.g. homicide

c) Product liability law

I. General Information
Good to know…

3. Standard of diligence

???

objective rating

always related to a single case

Legal obligations are binding!

But: they're rarely concrete.

→ What may the concerning parties expect?

II. Research / Development

Development: Different workpackages

Research:

Technical tests less legally complicated

Research with humans

Problems with the standard of care

III. Use

Different responsibilities

The producer

The User

IV. Recommendations

1. User manual
2. Contractual regulations
3. Consent of parties / probands
4. Documentation

Leibniz Universität Hannover

Thank you very much for your attention.

COMMENTS, QUESTIONS, DISCUSSION…

Appendix III – Design of an interface for remote monitoring of critical deviations in the daily activities of frail elderly home-dwelling family members

Design of an interface for remote monitoring of critical deviations in the daily activities of a frail elderly home-dwelling family member

DTU

Andreas Villadsen s143994
Ditte Jørgensen s145327

MSc thesis Design and Innovation
January 26th 2020

Design of an interface for remote monitoring of critical deviations in the daily activities of a frail elderly home-dwelling family member

This thesis is the final project of the MSc programme in Design & Innovation. The thesis is conducted with DTU management at the Technical University of Denmark, in fulfilment of the requirements to obtain a M.Sc.Eng. The project was carried out in the 5 months' period from August 26, 2019 to January 26 2020.

Students:
Andreas Villadsen
Ditte Jørgensen

Supervisor:
Henning Boje Andersen

Andreas Villadsen
s143994

Ditte Jørgensen
s145327

Abstract

Lack of oversight of a frail home-dwelling elderly can in some cases lead to critical events going unnoticed. Consequences of which are often costly, irreversible, or even fatal. Thus, many relatives of frail elderly persons living alone, often experience feelings of worry and are burdened by concerns related to the well-being of the elderly. Existing research proposes to alleviate these problems by use of in home monitoring technologies. However, most of the proposed monitoring systems target healthcare professionals and not the relatives as main users. Therefore, this thesis strives to explore the design of a user interface, of an in home monitoring system, targeting relatives as the main users.

Particularly, the thesis adopts a user centric design thinking approach, to investigate how a UI and its underlying sensor-system should be designed, in order to alleviate the worries and concerns experienced by the relatives and the elderly. Through semi-structured interviews with 7 relatives and 14 elderlies, user needs and requirements were investigated. The focus being to empathize with users through their stories, worries and perceptions of the proposed monitoring system. Additionally, three loops of prototype-facilitated user tests were conducted to uncover UI specific user needs and requirements.

The resulting UI design proposal, is a minimalistic teal coloured user interface for smartphones, named SenseFriend. The UI revolves around a dashboard with a status indicator, communicating the level of deviation in behavioural trends. Furthermore, the UI contains a log of the latest activities and an overview of the weekly and monthly trends in specific activities. Based on 3 rounds of evaluation and testing with users, it is safe to assume that the proposed UI design represents the test participants' essential needs and requirements. However, whether or not, the proposed UI design encapsulates the average relatives' needs and requirements, cannot be concluded from this project.

Acknowledgements

We would like to thank our thesis supervisor Henning Boje Andersen, Professor emeritus, Senior Researcher at DTU Management engineering, for providing inspiration, feedback and guidance throughout the project.

We would also like to acknowledge everyone that participated in interviews or user tests, thank you for setting time aside to meet and talk to us. Without you, this project would not have been possible.

A special thank you to Gitte Ifergan, Group leader of the care centre Bonderupgård, as well as the staff and users of the care centre. Thanks for giving us a unique opportunity and taking good care of us while we were your guests.

Lastly we would also like to thank Lars Nørh, chief consultant of quality and innovation in the elder care sector of Aalborg municipality, for sharing his thoughts and experiences with us.

Reading guide

The thesis consists of 7 chapters in total. In the first chapter, *intro*, the thesis project is introduced and outlined and in the last chapter, *outro*, the thesis project is concluded and reflected upon. The 5 chapters in between are structured according to the process of the project, where each chapter represent a specific phase. Each chapter has its own specific colour, and in the beginning of each chapter a model will indicate the phase of the process. In the end of each chapter, the particular phase are wrapped up with a discussion, reflection and a sub-conclusion.

Throughout the thesis, appendices are referenced with a simple code in square brackets, indicating the number of chapter and sequence. Eg. [A 3.2] will reference the second appendix in the third chapter. The appendices are compiled in a separate document, enabling the reader to investigate the appendices alongside the reading. We will encourage the reader to do so, as it can enhance the understanding of the process. Though, it is still possible to read and understand the thesis without the appendices.

External literature is referenced using the citation style American Psychological Association 6th edition (APA). The author and year are referenced in brackets directly in the text, like: (Norman, 2013).

In the following, a glossary of the used terms and abbreviations are presented, and can be used throughout the reading to support the reader's comprehension.

Regarding figures and tables, if they do not contain a source reference in the figure/table text, the content is original work from the thesis team.

Terms

Relative
The relative to an elderly family member or a friend that is providing care to the elderly. (caregiver, next of kin)

Elderly family member
The elderly person, whom the relative is worried about. It could also be a friend. (care receiver)

Fall alarm
A device that enables the elderly to notify emergency services with the click of a button. (Fall pendant, faldalarm, nødkald)

Safety visit/call
A home care service offered to check up on elderly people worried about falling or other critical events. It can both be in the form of a visit or a phone call.
(tryghedsbesøg/tryghedsopkald)

Multimodality
Refers to the use of more than one mode. In the context used in this thesis, it refers to the use of more than one sensor/sensor type collaborating for the same specific purpose.

Abbreviations

AAL / Ambient Assisted Living

UI / User Interface

REACH / Responsive Engagement of elderly promoting Activity and Customized Healthcare

UX / User Experience

ADL / Activities of Daily Living

IADL / Instrumental Activities of Daily Living

FOF / Fear of falling

ICT / Information and Communication Technologies

RAM / Remote Activity Monitoring

PIR / Passive Infrared

EMG / Electromyography

ECG / Electrocardiography

IRC / Infrared Radiation Changes

SPC / Statistical Process Control

EWS / Early Warning Score

IoT / Internet of Things

USM / User Story Map

MVP / Minimum Viable Product

Lo-Fi / Low fidelity

Hi-Fi / High fidelity

Content

1. INTRODUCTION

In this chapter the thesis project will be introduced and clarified. In the following, the project origin, scope and research questions will be presented. Furthermore, the thesis process and plan will be presented.

1.1. Project origin

The project idea originates from a thesis proposal put forward by the thesis supervisor, Henning Boje Andersen. The proposal arose based on his work carried out in the EU funded project, Responsive Engagement of elderly promoting Activity and Customized Healthcare (REACH). The REACH project revolves around the idea of a remote monitoring system developed to be used by professional caregivers (REACH 2020, n.d.). However, while working on the REACH project, it became clear to him that there might also be a user need and a market potential for a system targeted the relatives of frail elderly people instead of healthcare professionals. This resulted in the following thesis proposal:

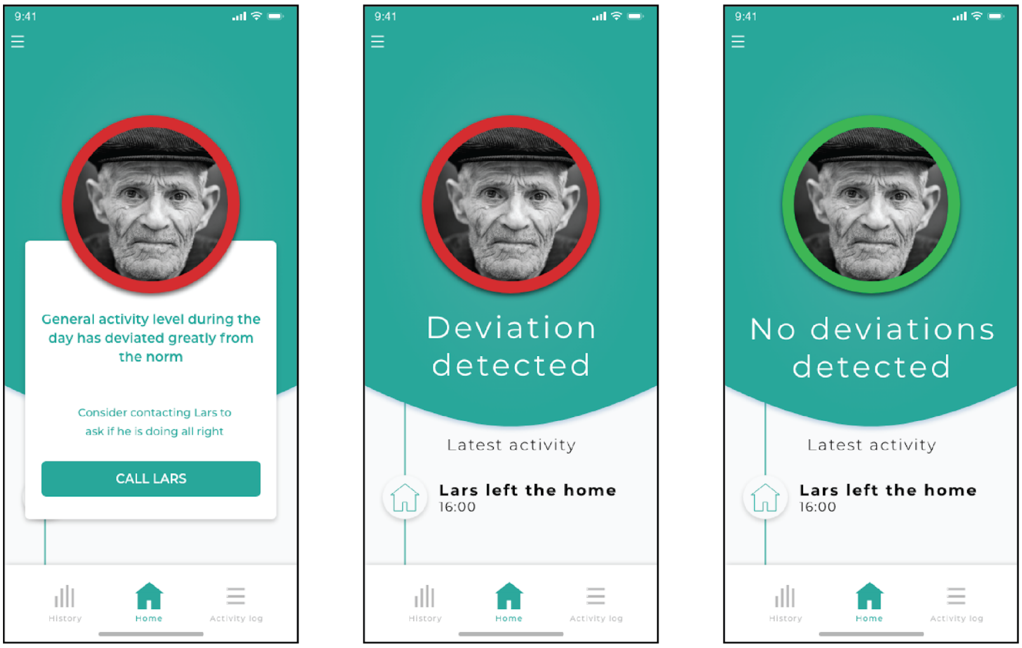
Design of a dashboard to monitor remotely daily activities of a frail elderly home-dwelling family member.

For us as students, the thesis proposal was especially interesting, as one of the main goals for our thesis project was that it should be people centred. Furthermore, we found the proposal relatable as lack of oversight of an elderly family member has caused problems in our own families. Therefore, we found it obvious to seize the opportunity and adopt the thesis proposal. Additionally, most of the research focused on monitoring systems for elderly is targeted healthcare professionals or home care. This makes monitoring systems targeted the relatives a relatively under-explored, but dynamic, and promising area. Therefore, going into the project we were motivated by both academic curiosity, and strong empathy towards the context of the problem. Ultimately, we also saw the project as a unique opportunity to investigate and potentially add to this relatively novel area.

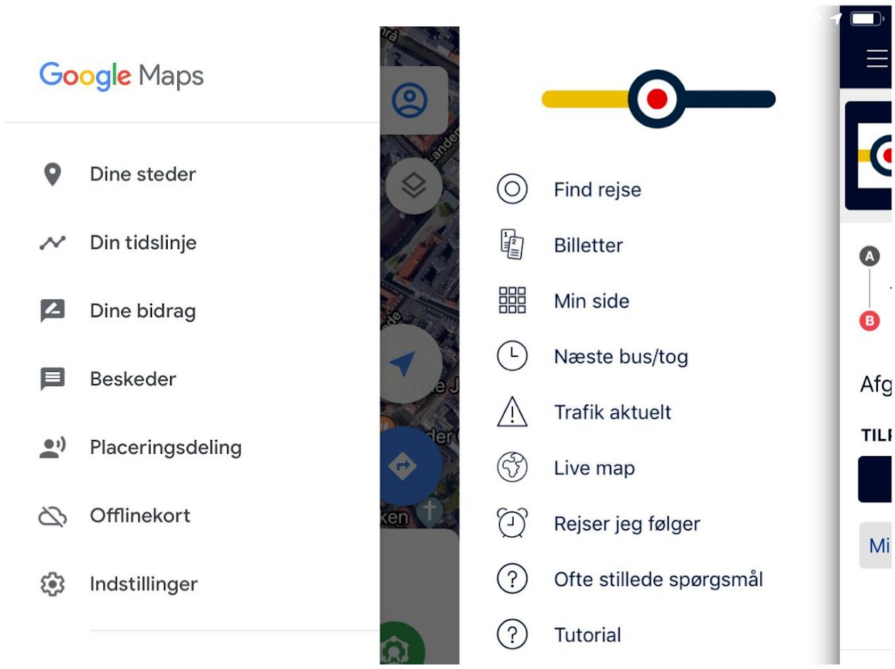
1.2. Project scope

The main purpose of the project is to explore the design of a user interface (UI), exploiting ambient in-home sensors, aiming to provide peace of mind for relatives worrying about a frail elderly family member living alone. In other words, the purpose is to explore the design of a UI and the underlying sensor system, of an ambient assisted living system (AAL system) able to monitor and detect critical events and deviations in behavioural trends of a frail elderly person living alone. In this regard, the main focus of the project is on the user needs, requirements, and user experience of said

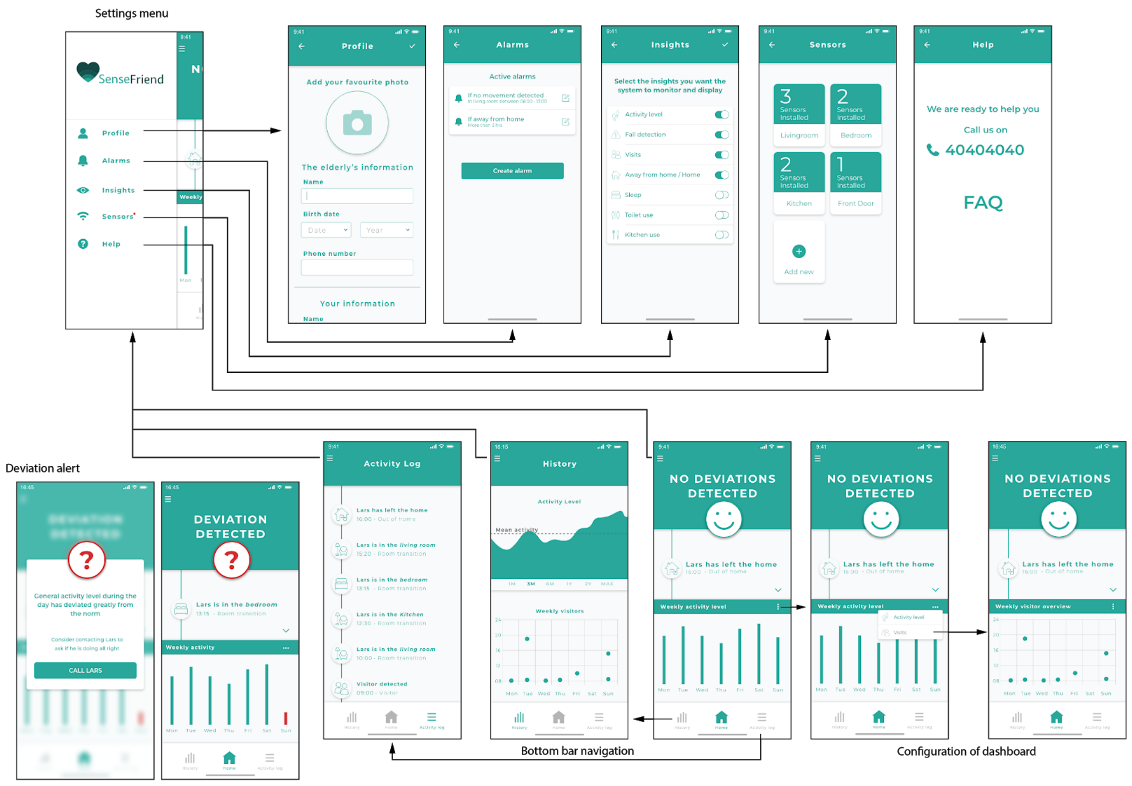
Variation 2



A 5.15: Menu inspiration - loop 3



A 5.16: Prototype overview - loop 3



A 5.16 p. 1/1

A 5.17: Test guide - Loop 3

AIM	PLAN	FOLLOW UP QUESTIONS
1. Investigate the user's preferences for the content and the visual design of the main dashboard. 2. Investigate the navigation and usability of the main dashboard and the setting menu. 3. Validate the overall visual look and color choice with a high fidelity prototype.	1. View the prototype on a smartphone and hand it out to the participants 2. Ask them to click around and investigate the interface while observing and taking notes 3. Show them the deviation view 4. Ask follow up question 1 5. Show them dashboard 2 including the deviation view 6. Ask follow up question 2	After random navigation 1. What do you think about the design? After showing both dashboards 2. Which one do you prefer? and why? 3. Do you like the idea about having a picture?

A 5.17 p. 1/1

A 5.18: Test results loop 3

In this appendix the feedback from the tests in loop 3 are compiled in order to gain an overview. Positive comments are highlighted with green, negative with red and specific ideas with yellow.

Feedback 1:

Visual design

- The text in the bottom bar menu is too difficult to read. I don't think I am the only one who will struggle with that.
- Like the color and the simplicity

History view

- I don't care about visits

Setting menu

- The alarm settings are really nice, just what I want
- I don't understand the movement detected alarm, when would you use that?
- There should be a red mark on the sensor, so you know which one it is about
- How would it be if we were many siblings who should enter the App? - then we could make changes all the time if we don't agree

General

- Smart that it stores the data and learn from it. I would be able to use my own intuition if I get an alarm a day where I know my mom is very tired or sick and if I don't know already it is good that I can check up on her.

Variant 1

- I like the smiley and the question mark. It is good that it is different so you can notice that something have changed.
- I would prefer to get the pop up view straight away when I open the app, because it is valuable information

Variant 2

- I like the simplicity, I would prefer this look but with the smiley and question mark from variant 1.
- I don't like the picture, I don't think my mother would either. She would be annoyed if we had to take a picture of her. I know who I am looking after… but maybe if I was monitoring two persons, you know, that could be a situation, but then a name would be enough. Maybe if the home care were using something similar a picture would be good to remember who it was

Regarding the use of the app

- I imagine that I would use the app a lot if I am traveling. Otherwise I will probably check it once a week so it fits with 2-3 days after I have visit her.

Feedback 2:

Visual design

- The simplicity and the clarity of the design makes it universally applicable.
- The colors are pretty fine, very nordic, but they can be changed depending on where the app is sold.
- It looks like a real product, you get the feeling that you use a real app that you have bought.
- It is difficult to see the text in the bottom bar menu and in the last activity. There should be more contrast. Remember that a big part of the user group will have problem with their sight
- Like the simplicity of the bottom bar menu - easy and intuitive navigation between views

Activity log

- Cute icons

History view

- A really long perspective for that age group: would prefer if it starts with the weekly overview, that's the first thing you will need
- Use total instead of max
- An overview of leave from home should also be present if it is turned it on in the insights settings - then you can see how much he is getting out

Deviation detected view

- What if I am checking the app an early sunday morning? when will it push this view? how does the algorithm work?
- I would like to get an insight on what the deviation is, for instance if he has not been in the bathroom for a long time.

Overview of sensors

- You should take a picture of where they are placed in order to remember where they sit, when you need to change battery
- The battery level should have color code of yellow and red
- There could also be an indication/notification if something is wrong with the sensor. If it is not measuring.

Variant 1

- I like the status about the current activity
- I don't need the history view on the main view when I can access it anyway

Variant 2

- I like this view the best. The picture is more personal and you are not in doubt where the focus should be. It is the same when your children call and you see a photo of them, it is cosy.
- Good that the picture is so big. It is like the search area on google it is also big because it is the most important part.
- Maybe the ring around the picture should be yellow instead of red. Then the really important parts are red, when you get a fall alarm for instance.

Regarding the use of the app
When can you imagine to check the App?
- It will differ from person to person. I think my wife will check every day maybe 2 times a day. I would not do it that often.
- I would prefer to make the settings so I receive a notification if there is a deviation. The fall alarm should be pushed automatically with a loud noise as a default setting. Otherwise I would like to decided when I get notifications that are not as important. So I don't get disturbed in a meeting

Would you trust the algorithm?
- It depends how many false alarms you recieve
- It is important that you get information about the lack of precision in the beginning, maybe you can give some discount in that period.

Test 3:
Visual design
- It looks good, like a real app you can buy in the Appstore
- The menu icon is too small
- The simpler the better

Variant 1:
- I like the variant 2 more.
- It is too much informations with a history overview also. I am afraid that I will overinterpret and get nervous if I get too much informations.

Variant 2:
- I like that it is so simple. I just need to know if there is something I should act on - if there is then I can take a closer look. If there isn't then I don't have to.
- I like the red or green indication. I don't know if I would understand an yellow indicator, then I should interpret again. Either there is something wrong or otherwise there is not.
- The picture is not important for me, it could also be the smiley on this one if I don't have a good picture.

Test 4:
Visual design
- I like that it is so simple and clear

Variant 1:
- It is not that clear if it is bad or good with the smiley and the question mark as it is with the green and red color.
- The visual expression is more messy in this one

Variant 2:
- The visual expression is better here, more simple and the important thing is in focus.
- For me it would make sense to also have a yellow color. Then you would know that something is different, but it is not alarming, but something you should check up on tomorrow again. Then if it is still yellow or turns red, then you would act on it.

A 5.19: List of requirements - Updated 3

The requirements marked with green are new requirements added, based on the learnings from design loop 3.

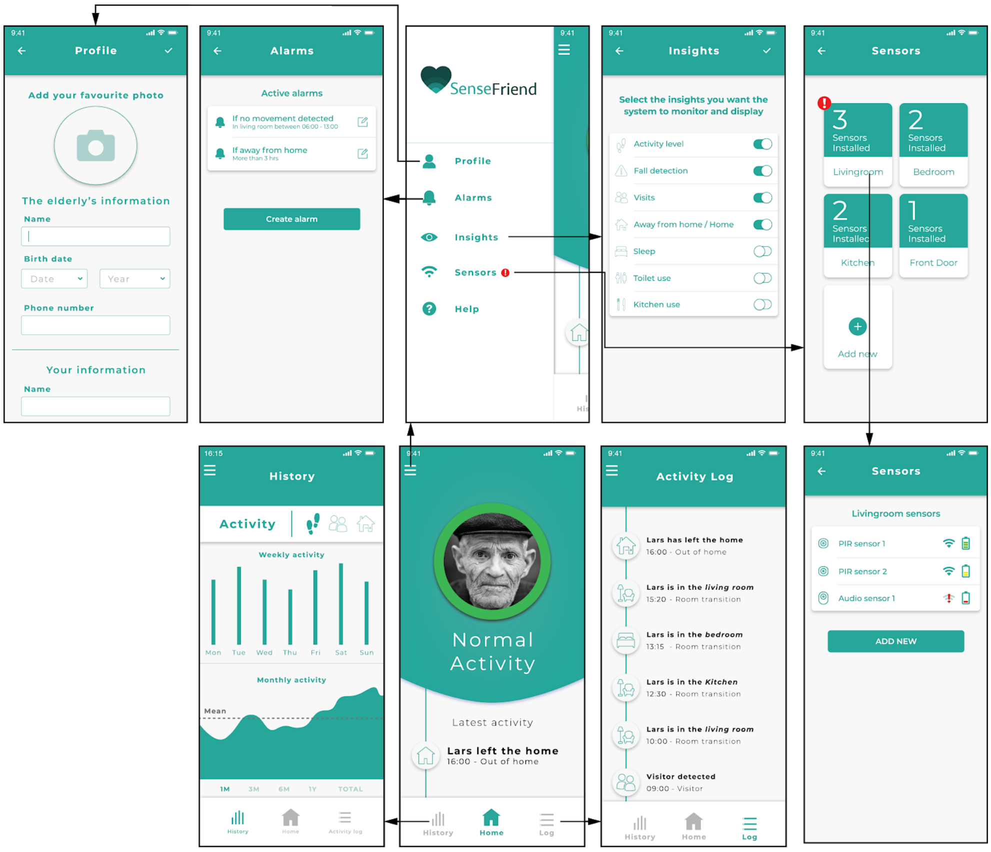
Relatives	
Requirement	**Comment**
The system should allow personalised alarms to be created.	From the user research it was learned that users would like to set up personal alarms.
The system should be able to function with varying amounts of sensors.	Some users expressed that they would prefer to have a sensor system with very low amounts of sensors, where other users wanted to have as many sensors needed to have the best coverage.
The data collected should be configurable.	Users expressed a need to be able to pick and choose between what data was collected.
The system should at minimum enable the user to monitor: - If the elderly have gotten out of bed - If the elderly have fallen - Indication of general activity level - If the elderly has left the home - Indicate if there have been visitors	The listed information were all requested by relatives in the user research.
The system should not require manual collaboration from the elderly in order to function.	Some of the surveyed relatives expressed worries about the elderly's ability to operate such a system.

The data interpretation system should enable the relative to receive interpreted information.	It was learned from the user research that some of the relatives would not feel comfortable to interpret the data themselves.
Requirements related to the UI design	
The main dashboard view should contain an indication of the latest activity of the elderly.	The users found this feature highly valuable, as it gave them an idea of what was going on in the exact moment.
The dashboard should contain both a weekly and a monthly historical overview of the behavioral trends.	The users liked the idea of having an overview of the bigger picture, giving a hint if the behavioral trend have been declining over a longer period of time
The indication of the status of deviation should be accompanied with a easy understandable line of text describing the status.	It was found that a well being indicator bar and an activity score were too ambiguous, while a simple positive/negative indication together with a text was easy to understand.
The dashboard should make it possible for the user to view an activity log where all the latest activities are shown.	The users explained that this could give them a better idea of the context of a potential decline in the behavioral trend. Furthermore it could be used as a ticket to talk, giving the opportunity to discuss the activities of the day.
It should be possible for the user to deselect insights/views, such as toilet use.	It was learned that not all users had the same need to see specific insights.
Setup or configuration options should not be given without guidance text or examples.	Some users were confused about configuration options and choices, saying they did not fully understand what they were configuring.
Text boxes with no clickable options should not share visual design with buttons that are clickable.	Some users were observed trying to click on information boxes with no intended clickable interaction.

Clickable lists should not share visual design with non clickable lists.	Some users did not think to click on a list entry because it resembled another list shown earlier that was not clickable.
Visual feedback should be given to the user after a successful configuration or setup action has been performed.	
The interface should indicate the status of deviations in behavioral trends from the home view in a resolution of 3: *Normal, Minor & Critical.*	The users requested that it would be nice to have there should be an in between status improving the resolution of the deviation detection Resolution of deviation detection on the main dashboard could be increased by adding an indication of minor deviation
Historical graphs should be kept only to the history view of the interface.	Users did not want to have historical graphs on the Home view of the interface.
An option for showing a profile picture should be included in the interface.	Some users liked the idea of having a profile photo, other users would prefer not to have it.
Font size must be no less than size 14 (minimum 9 px height on smallest font entry).	For some users it was hard to read the small text on the interface.
Contrast between text and background should be high.	To increase readability.
Elderly	
Requirement	**Comment**

The system should detect falls and other critical events autonomously.	The surveyed elderly saw the automation of the system as a big advantage.
The sensors should be as small and discreet as possible.	When the sensors are installed in the elderly's home it is important that it fit into the interior etc.
The sensors used should not violate the privacy of the elderly.	Based on knowledge from the background investigation, video and cameras should be avoided.
Relatives and Elderly	
Requirement	**Comment**
The installation of the system should not require major reconstruction of the house.	Some of the relatives stated that if the installation of the system would require craftsmen, it would be too much for the elderly.
It should not be possible for anyone to recreate pictures, video or audio from the sensor data collected.	Both the relatives and the elderly expressed concerns related to data safety.

A 5.20: Prototype - final UI proposal

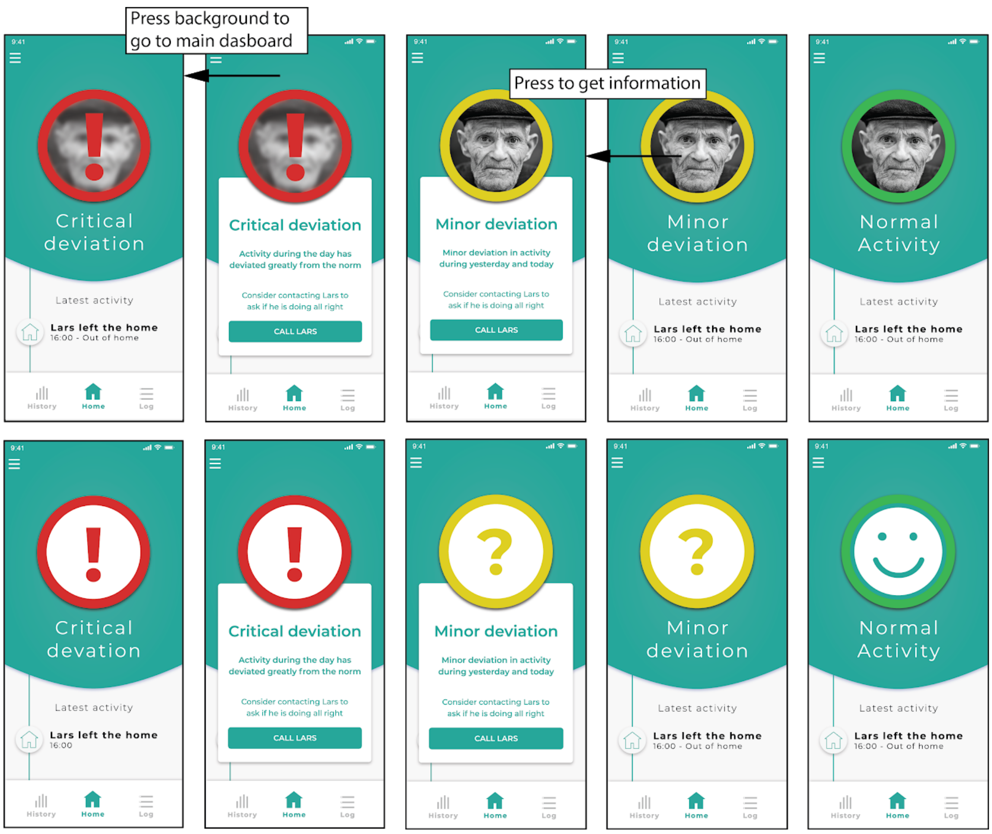


A 5.20 p. 1/2

A 5.20: Prototype - final UI proposal

Dashboard states with picture

Dashboard states without picture



A 5.20 p. 2/2

Appendix IV – Abstracts of related publications

EFFECTS OF PLAYFUL EXERCISE OF OLDER ADULTS ON BALANCE AND PHYSICAL ACTIVITY: A RANDOMIZED CONTROLLED TRIAL

Humira Ehrari,
Rasmus Tolstrup Larsen,
Henning Langberg &
Henning Boje Andersen

Journal of Population Ageing **(2020)**

Abstract

There is evidence that one of the most important approaches to improving the healthy ageing of older adults is for them to carry out daily physical activity. However, motivation to engage in physical activity is often low in old age. This study investigated the potential of engaging older adults in playful exercise to increase physical activity and balance. A randomised control trial (RCT) was performed with 26 independently living older adults (initially 38, but 12 were lost to illness or death during the course of the project), mean age 83.54 (SD: 7.12), 19 women. Participants were randomly allocated to intervention (n = 16) or control (n = 12) (originally 19 in each group). The intervention consisted of playful exercise on Moto tiles 6 * 2 min twice a week over 10 weeks, while control group participants engaged in normal daily activities.

The intervention group participants improved functional balance (Berg's Balance Score) by an average of 5.02 points, and the control group by 2.58 points ($p = 0.11$). No between-group difference was observed in physical activities outside exercise sessions ($p = 0.82$). The difference in gain of balance as measured by BBS was below statistical significance, as a result of the sample size being too small. However, trial results suggest that older pre-frail and frail adults who engage in a moderate playful exercise programme over at least 10 weeks may potentially experience a modest gain in balance. Moreover, the playful exercise created a joyous social atmosphere among the participants who spontaneously remarked that the play sessions were much more fun than their standard light exercise programme of one hour twice a week. This motivational outcome is important for adherence to any exercise programme and indeed for general well-being.

CONCERNS AND TRADE-OFFS IN INFORMATION TECHNOLOGY ACCEPTANCE: THE BALANCE BETWEEN THE REQUIREMENT FOR PRIVACY AND THE DESIRE FOR SAFETY

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ABSTRACT

This paper constructs a new model of motivation in the unified theory of acceptance and use of technology (UTAUT) to explore the trade-off between privacy and safety. Using an explorative approach, we used Self-determination theory (SDT) to explore how human motivational determinants influence the trade-off between safety and privacy in technology acceptance. We take the Scandinavian healthcare context as our empirical outset by exploring how older Danish adults perceive sensor-based E-health monitor technology that is designed to monitor their health status. Danish municipalities aim to use these technologies to identify early warning signs and thereby improve the quality of care and life by making people more self-reliant and reducing unnecessary hospitalisation. However, ethical issues concerning privacy versus safety need to be taken into consideration when implementing these technologies. After monitoring 21 respondents (mean age: 85) living independently at home over 9 weeks, we interviewed them about their concerns regarding privacy and safety. Our findings show that the respondents were willing to compromise their privacy if their autonomy and personal integrity were respected and if the benefits of sensor-based monitoring outweighed health-related threats. We used these findings and the theoretical outset to create a novel model that considers human motivation when using UTAUT.

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