AHEAD – Augmented Hearing Experience and Assistance for Daily life

D5-2 First Business Development Strategy and Plan

Date 2014-07-29

Version 1.0

Dissemination Level: Public

Legal Notice

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Document control page

Code	D5 2_First Business Development Strategy and Plan_v1
Version	1.0
Date	2014-07-29
Dissemination level	PU
Category	R
Document Owner	Johanniter
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Work Package	WP5
Fragment	No
Abstract	This deliverable contains an overview of the first approach to define the necessary actions for a business strategy. Considerations that came up during the first reporting period were taken into account to form a first idea of how to make a business of the project results. This leads to ongoing steps for the consortium and functions as guidance through exploitation. As the grade of detail cannot be too narrow because it is very early in the project for this, a clarification in a later phase – pronounced as Deliverable 5.6 in Month 36 – is necessary for later uptake of actions. This document provides a first direction for business modelling.
Status	Draft Ready for internal review X Task leader accepted X WP leader accepted X Project Coordinator accepted X
Previous Versions	none

Version Notes

Version	Author(s)	Date	Changes made
0.1	Jürgen Braun	2013-07-17	First content

	0.2	Gudrun Haider, Georg Aumayr	2014-05-02	Structure, content design
	0.3	Georg Aumayr	2014-05-08	input request
	0.4	Jürgen Braun	2014-05-26	input
	0.5	Gudrun Haider	2014-05-28	Revision
	0.6	Gudrun Haider	2014-07-09	Revision
	0.7	Georg Aumayr	2014-07-11	Revision and input refinement
	0.8	Georg Aumayr	2014-07-22	Revision and input refinement
	1.0	Georg Aumayr	2014-07-29	
	1.0			Final version submitted to the European Commission
Internal review history	Reviewed by		Date	Comments made
	Gudrun Haider		2014-07-29	
	Robert Brandstetter		2014-07-29	

Executive summary

Deliverable 5.2 provides a first strategy development for the business case AHEAD. By this it is necessary to define the market relevant background and the interpretation of user requirements and results of the field trial to a business relevant level. This supports the definition of a business development approach which is initialized by a definition of potential and target groups of AHEAD. So principle decisions on direction can be done and business branches are spread out.

To give the upcoming ideas a better foundation, the background services are stated in the steps of development from standards and risk managements up to regulatory processes. This can be just strived but is necessary to give a background.

The market analysis is dealing with the upcoming competitors of Wearables and Smartwatches. They are the most threatening developments since the project started, as they are providing some functions already.

A short overview of the results of the first meeting of the market advisory panel are presented to show the outer perspective on AHEAD by stakeholders and to secure the objective view of the consortium.

From this point it is clear what has to be done next and what the strategies main points and direction are.

Introduction

AHEAD provides health-related and communication services on a hearing glasses system for elderly people with hearing impairments. The main goal of the AHEAD project is the integration of a voice-user-interface (VUI) supported by a graphical-user-interface (GUI) on a smartphone into a hearing glasses system to support elderly people in their everyday life management. The hearing glasses system consists of traditional eye glasses and hearing aids - two devices elderly people are already used to. Voice-based interaction allows the elderly user to interact naturally with the system without the need to learn new and complex interaction techniques.

Purpose and scope of this deliverable

For developing a product, that is supposed to win recognition after market launch (in different EU countries with different health systems and cultures at optimum), it is necessary to generate a business development strategy or plan, that defines aims as well as possible barriers and approaches to overcome those in an early stage. On the stage of development factors like costs, usability, usefulness and product's appeal in addition to the quality of the product must be taken into account.

D5.2 is based on D5.1 (Business Development Model Analysis) that contains a critical review of current business models and analyses their success in the target markets for the AHEAD technology at national and international level, and conduces as preliminary to D5.3 (Intermediate Business Development Strategy).

Background

Stakeholder Analysis

At the beginning of the project AHEAD a stakeholder analysis concerning tertiary end users has delivered an overview of capabilities within the community and provided a first insight in the dynamic of the market. This stakeholder analysis is documented in D2.2 p.41-46. Referring to the dynamic between different stakeholder groups and end user groups it is necessary to point out that care organizations are acting as SME's and are focused on covering costs and maximizing the value gain. As stated in D5.1, this value is not just a financial aspect but a social value as well.

User Requirements and Context Analysis

Document D2.2 (User requirement and context analysis) summarizes the results of the user requirements and context analysis.

AHEAD has to deal with primary users (seniors) and secondary users (formal and informal caregivers). Devices to be used in interaction with AHEAD are the hearing glasses system and a smartphone which is connected with the hearing glasses system. The expected health-related and communication services are: emergency calls (triggered by the user or by vital signs), vital parameter measuring, phone calls, reminder functions (medicine intake, drinking), warning system (oven/windows), finding assistant (lost keys), public transport assistant (navigation and timetables of public transport), weather information, etc. Although voice based interaction is preferred, a text or graphical user interface should be in place to allow for monitoring and/or controlling the interaction process.

Lab and Field Trials

As in D4.1 (Assessment and Evaluation Plan) is discussed, the whole phase of technical development (WP 3) of the AHEAD system goes along with three lab trials and one field trial. This will ensure that

the AHEAD system, its functions and usability will meet the acceptability of elderly people within real life scenarios.

Business Development Model Analysis

A business analyse contains several tasks. Summarized it means to identify and manage stakeholders' requirements, to describe chances as well as barriers, to define aims, to disclose potential new products/ services and to develop business strategies for their implementation. Business strategy has many definitions, but generally it involves the definition of long-term goals, determining actions to achieve the goals and mobilizing resources to execute the actions. A strategy describes how the ends (goals) will be achieved by the means (resources). Strategic planning for business of the finished AHEAD product is a process and thus has inputs, activities, and outputs. It may be formal or informal and is typically iterative with feedback loops throughout the process. Some elements of the process may be continuous and others may be executed as discrete projects with a definitive start and end during a period. Strategic planning provides inputs for strategic thinking, which guides the actual strategy formation. The end result is the organization's strategy, including a diagnosis of the environment and competitive situation.

Taking into account that the finished AHEAD product could be declared as medical device we can make use of traditional business models but must consider rules and guidelines from medical devices. Additionally organisations like health care insurances and other potential funding institutions must be involved – first in participating countries, further bit by bit in foreign markets. As the AHEAD system is based on a hearing aid it will be also necessary to contract collaborations with located professionals whose confession is the adjustment of hearing aid systems and similar devices (e.g. audiologists, acousticians).

This means, that the health care and funding system as well as potential partners in the country, where the system should be brought on the market, must be analysed. Questions that should be answered are:

- How are medical devices handled in this country?
- What documents are needed for the opening of the market in this country?
- Are potential partners in this country located?

Further, for developing a traditional business plan several aspects regarding to the product/service must be figured out. To make it concrete, that means for the AHEAD system (first draft):

Key Activities:

Hardware

Software/apps

Services: internet-downloads

training program for the customers (acoustician)

hotline for the customers?

Labelling (CE)

Key partners:

Audiologists, acousticians and acoustician shops

Health care insurances and further funding institutions

Resources:

Available products, software, apps, services and infrastructures we use

Value proposition:

Benefits for the costumer

Benefits for partners (e.g. acousticians)

Customer relationships

User instructions/ information materials in national language

Training for the customers

Hotline

Further interaction?

Customer segments

Audiologists, acousticians, opticians

Further?

Channels

Sales, marketing and distribution

Cost structure

Calculation of total costs: product/ production

Profit margin

Revenue model

Revenue from shops, acousticians and other partners

Concerning the findings of D5.1, it is necessary to include potential stakeholders for a broader approach. Johanniter are dealing with a first service model for AHEAD as a full system but parts of AHEAD are a potential market for itself. So this allows classical business models as well as social business models, which are suited for NPOs like most care organizations are. Also it is necessary to define the term value also as a construct of financial value, shareholder value and social value. This gives a special perspective to the stated key features of the business model analysis as the definitions of certain criteria has to be widened (e.g. revenue model, value proposition or channels).

Another approach is to propose a market and give an overview over this, coming from the perspective of key competences of the main product of AHEAD – hearing glasses, sensors and adjusting hearing aids.

Market Overview

In general glasses are well accepted by customers/ users, but not hearing aids. Persons in need of hearing aids don't recognize their improving hearing loss, negate their hearing impairment and/ or feel ashamed. Additionally hearing aids are more expensive than glasses, but often don't support the user in an effective way. Finally, almost relatives and/ or home care professionals give the initial impulse for buying a hearing aid.

At present behind-the-ear-hearing-aids are the most appealed hearing aids on the market and are recommended by several stakeholders (e.g. ENT-doctors, ENT-hospitals, audiologists, hearing aid acousticians). The total market of hearing aids combined with glasses is only less than 1%.

Devices that measure medical health data are already available on the market too. But the great advantages of the AHEAD-system are

- the combination of glasses, a hearing aid, a device that monitor vital parameters and comprises tasks of an smartphone and further assistive functions
- voice based bidirectional interaction
- and therefore users obtain unobtrusively support.

Business Development Approach

Principle Decisions

At the partner meeting in Copenhagen, a primary decision had to be made if AHEAD would be commercialized by single partners, a consortium as a whole or by a company funded and shared by partners. This brings up the question if there is going to be one strategy for the consortium or several strategies for the partners to commercialize finding of AHEAD for themselves.

The decision fell to a consortium wide strategy but with the freedom to follow additional aims for commercialization.

Definition of target group

By this decision, it is possible to define the target group by the similarities of all partners' target groups. So we are aiming for people with hearing impairments without a limitation to age. This divergence to the typical market for AAL projects has its reasons. First of all, younger people are more affine to technological support than seniors are. And some features are not just interesting for people with impairments but also for fit people as a lifestyle product. Sportive people like to measure their vital signs during training, some young people start to gather information about them (self-monitoring), seniors are profiting from the hearing aid in several ways as well. The target group has to be opened to make success of a product possible. The markets to start with are lifestyle products for younger people. So these younger people can show the elderly how the new technology works. This is a well-known paradigm from the time of VCRs to the smart phone age.

So we defined three major target groups with several sub groups:

1. Hearing impaired people

   1.1 No age restriction

   1.2 Most effect because of nearly no limitations because of bone conduction instead of air tubes

2. Sportive people

   2.1 No age restriction

   2.2 Support of personal training

   2.3 Monitoring of vital signs throughout the day

3. Persons with the need of assistance

   3.1 No age restriction

   3.2 Alert-system

   3.2 Adherence and Compliance Support System

Branches for Business

This split of target groups allows addressing different primary strategies for the partners. As the target group for hearing impaired people is directly addressed by Audit Data and Bruckhoff, the target group of sportive people is addressed by Cosinuss and Innovationsmanufaktur. Also the persons with the need of assistance are addressed by ATOS and Johanniter. Each of these exploitation strategies follow an own path but are connected by the idea of AHEAD as a system as a whole. The need of each branch is also differing. As the hearing impaired people are more into hardware support, sportive people are looking for a lifestyle product. And people in need of assistance are having a need of social and health-related support services.

For the work with impaired people, it is necessary to follow the standards for medical devices and to have the certificates. This is necessary because of the refunding by national health insurances. This reduces the costs for the client dramatically and increases the market potential and acceptance. As an example, the background of medical products shall be describes, as it is the most complex of branches, which are going to be addressed.

Background service development

Medical device

Classification of medical devices

A medical device has its own rules, guidelines and directives depending on its classification. The classification of medical devices in the European Union is outlined in Annex IX of the Council Directive 93/42/EEC. There are basically four classes, ranging from low risk to high risk.

- Class I (including Is & Im)
- Class IIa
- Class IIb
- Class III

The European classification depends on rules that involve the medical device's duration of body contact, invasive character, use of an energy source, effect on the central circulation or nervous system, diagnostic impact or incorporation of a medicinal product. Certified medical devices should have the CE mark on the packaging, insert leaflets, etc.. The packaging should also show harmonised pictograms and EN standardised logos to indicate essential features such as instructions for use, expiry date, manufacturer, sterile, don't reuse, etc.

Declaration of conformity

The authorization of medical devices is guaranteed by the Declaration of Conformity. This declaration is issued by the manufacturer itself, but for products in Class Is, Im, IIa, IIb or III it must be verified by a Certificate of Conformity issued by a Notified Body. A Notified Body is a public or private organisation that has been accredited to validate the compliance of the device to the European Directive.

Medical devices that pertain to Class I (on condition they do not require sterilization or do not measure a function) can be marketed purely by self-certification.

EC-certificate

The manufacturer of a Class IIa product needs an EC-certificate according to DIN EN ISO 13485 or EC certificate (like bruckhoff hannover).

EC-CERTIFICATE

Production Quality Assurance System
(Annex V of the Directive 93/42/EEC on Medical Devices)
No. G2 10 09 14760 011

Manufacturer: bruckhoff hannover gmbh
Herrenstraße 6
30159 Hannover
GERMANY

Facility(ies): bruckhoff hannover gmbh
Herrenstraße 6, 30159 Hannover, GERMANY

Product Category(ies): Hearing aids and their accessories (HdO-Anpassset, easy-clip set, BTE set) as well as tinnitus masker

Figure 1: bruckhoff's EC-Certificate

The ISO 13485 is a Quality Management-System. It fixes how a company has to work, all processes are well-defined and the organization structure is clear.

If a company brings a medical device into the market, the declaration of conformity as an output file is needed. The declaration of conformity includes:

- Certificate from a notify body, that makes him able to handle with hearing aids for example QM-system ISO 13485
- Technical documentation incl. essential requirements (checklist >=26 pages)
- The proof that the company is able to measure the hearing aid
- List of all used standards and guidelines
- EMC-safe test (EN 60118-13)
- Test report technical data from the DHI-Germany (German hearing aid institute)
- Report of the used material with skin contact (ISO 10993)
- Risk management folder for the device (ISO 14971)
- Final declaration that the manufacturer assumes the responsibility for the product.

The risk management folder accords to DIN EN ISO 14971. The risk management files for the AHEAD-system are the following:

- *Essential requirements for Class IIa Medical products*
- *Risk management to ISO 14971 incl. a risk analyse*
    - *output file risk analyse*

- *risk evaluation in table form based on the analyse control of the risk from 2.2 (What to do to minimized the risk)*

The ISO 14971 also contains the chapter 7 product realization. The steps of design and development according to the ISO 14971 are specified in the chapter 7.3. The procedure starts with the planning on the development and ends with what to do with modification in the development process (please see Risk management.).

Furthermore, a market observation needs to be conducted: what happened with other hearing aids (defects or risks) in the market?

All these aspects are integral parts of the main-product-folder.

CE label

In the EU, all medical devices must be identified with the CE label. For ensuring a high level of protection of human health and safety and the good functioning of the Single Market directives were developed.

The core legal framework consists of following 3 directives:

- Directive 90/385/EEC regarding active implantable medical devices
- Directive 93/42/EEC regarding medical devices
- Directive 98/79/EC regarding in vitro diagnostic medical devices

These 3 main directives have been supplemented over time by several modifying and implementing directives, including the last technical revision brought about by Directive 2007/47 EC.

The national governments of EU member states must have appointed a competent authority (CA) responsible for medical devices. The competent authority is a body with authority to act on behalf of the member state government to ensure that the member state government transposes requirements of medical device directives into national law and applies them. The CA has to report to the minister of health. The CAs have no jurisdiction in other state than its own, but information are exchanged and tried to reach common positions. In the UK, for example, the Medicines and Healthcare products Regulatory Agency (MHRA) acts as a CA. In Italy it is the Ministero Salute (Ministry of Health).

In September 2012, the European Commission proposed new legislation aimed at enhancing safety, traceability, and transparency.

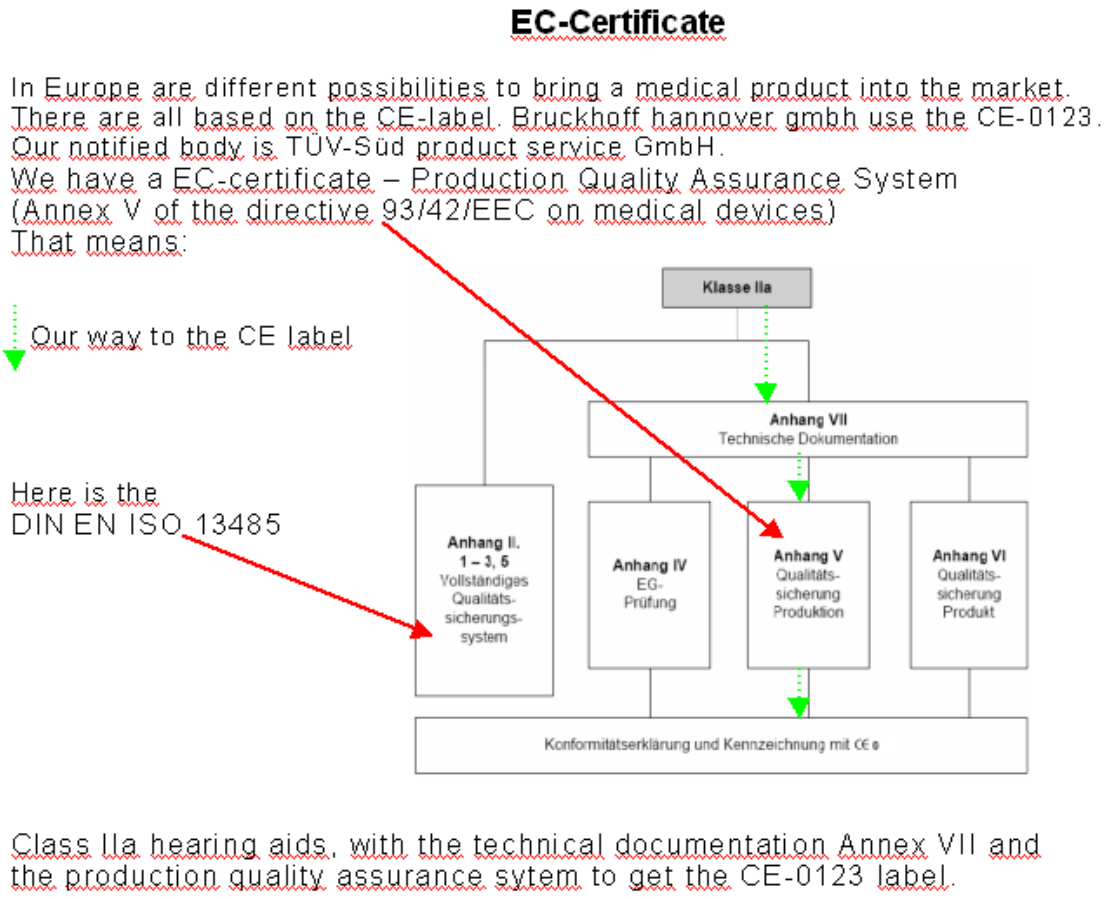


Figure 2: AHEADs way to its CE-label.

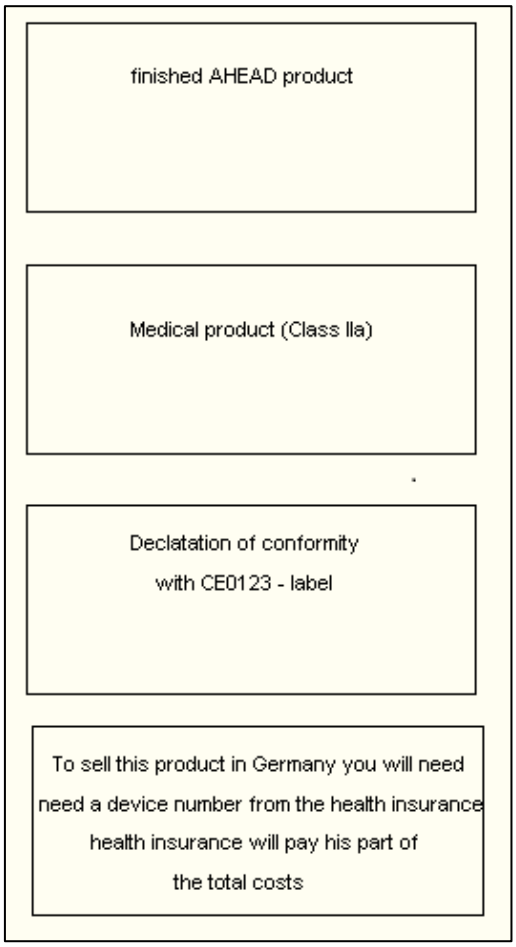


Figure 3: Figure 2 AHEADs way to come into market

Risk management

Our risk management files are the following:

The manufacturer shall establish, document and maintain throughout the life cycle an on-going process for identifying hazards associated with the AHEAD medical devices, i.e. hearing devices, and physiological sensors, as well software under MDD, estimating and evaluating the associated risks, controlling these risks, and monitoring the effectiveness of the controls. This process shall include the following elements (ISO 14971:2007):

- risk analysis
- risk evaluation
- risk control
- production and post-production information

The risk analysis process is started with a description of the intended use and characteristics related to the safety of the medical device. In the next step potential hazards are identified and its risks are estimated for hazardous situations.

Both components of a risk, probability and consequence, are analysed separately for the estimation of a hazard. For risk control there will be a stepwise approach to reduce risks:

1. inherent safety by design
2. protective measures in the medical device itself or in the manufacturing process
3. information for safety

This means that if practicable, the medical device should be designed to be inherently safe. If this is not practicable, then protective measures such as barriers or alarms are appropriate. The least preferred protective measure is a written warning or contra-indication. It is recognized that one possible result of the risk control option analysis could be that there is no practicable way of reducing the risk to acceptable levels. In this case, a risk/benefit analysis can be carried out to determine whether the benefit of the medical device outweighs the residual risk. All the documentation is performed in the risk management file.

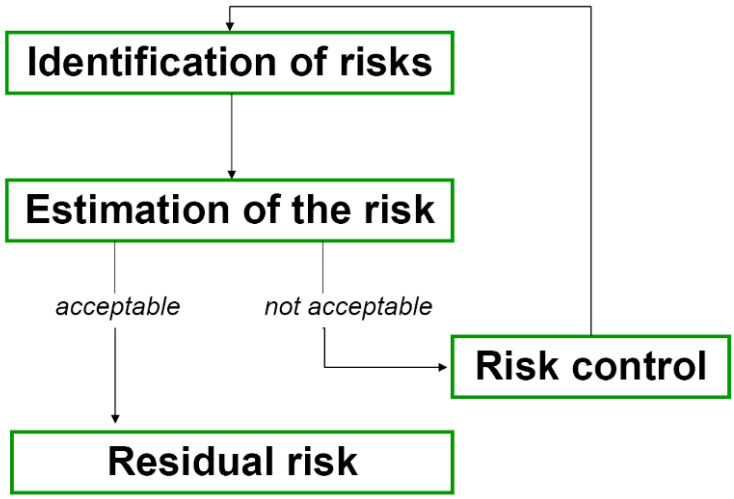


Figure 14: Process of risk analysis, evaluation and control

Development Process

- According to EN 62304
- Development versus documentation model (V-Model, waterfall, …)
- Software development plan
- Architecture and Detailed Design

Problem Solving/Deviation Management

- According to EN 62304
- Identifying reasons for problem
- Identifying proper changes and their side effects
- Maintaining the consistency of the software configuration
- Verifying that changes were implemented
- Related to change and risk management process

Software Maintenance

- According to EN 62304
- Informing regulatory authorities about security problems

- Releasing changed software only after validation
- Considering if other products may be affected
- related to change and risk management process

Configuration Management/Change Management

- According to EN 62304
- Control of
    - documents (SOPs, technical documentation, etc.)
    - source code
    - SOUPs1, Tools2, Environment
- Risk evaluation
- Approval of changes

Verification and Validation

- According to EN 62304
- Verification: proof that development process was performed as planned
- To be verified: user requirements, functional specifications, architecture, detailed design, software implementation, etc.
- Verification: via review of technical documentation, software testing (unit-, integration-, system tests)
- Validation: proof that the final product meets the user requirements
- Validation: via (user) acceptance tests, usability tests, clinical studies

[1] Software of unknown pedigree

[2] Testing tools, development tools, building tools

Traceability

Figure 5 shows the traceability map implemented at the software quality management system of AHEAD

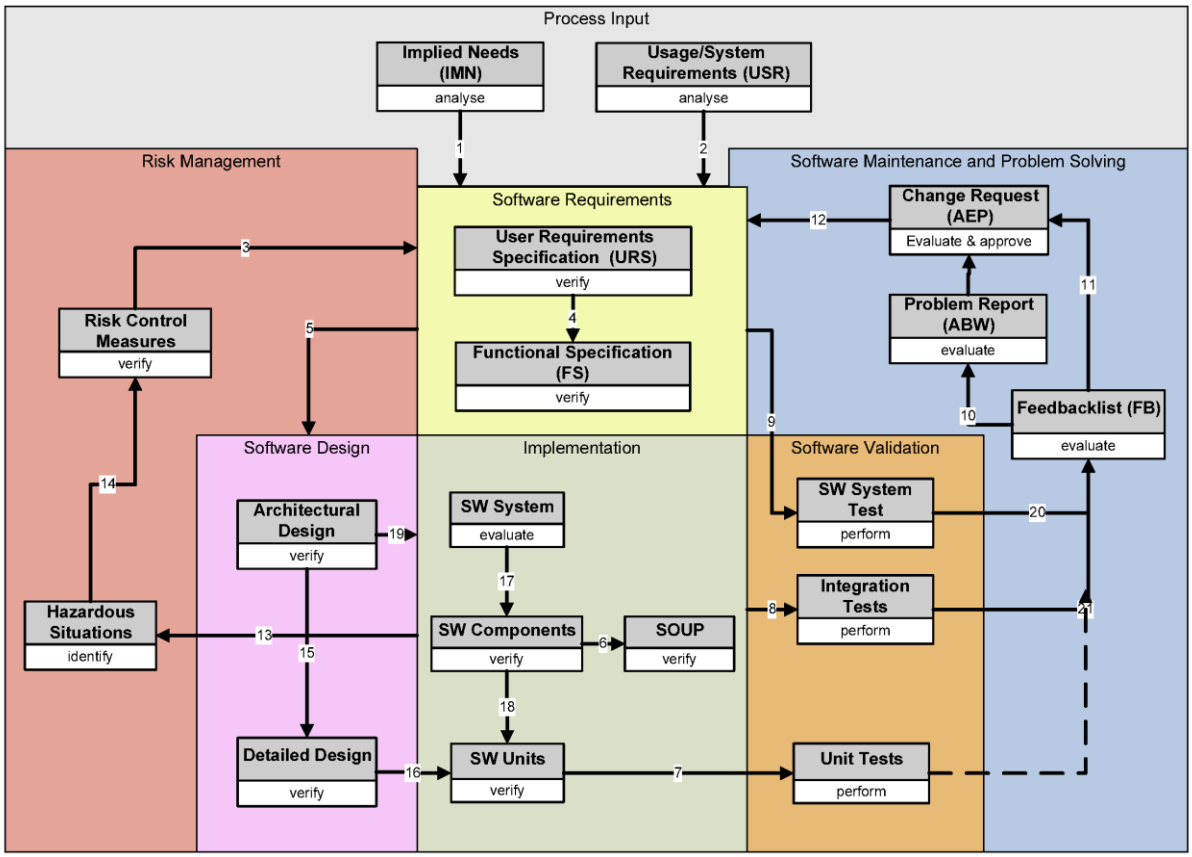


Figure 5: Traceability map

Practical Requirements related to mobile devices

- Provide remote maintenance/helpdesk functions
- Domain integration
- Software inventory
- Software distribution, in-house App-Market
- Access Control Management and Enforcement
- User Authentication and Profiles
- 3rd Party Solutions: AirWatch, SAP Afaria, MobileIron, etc.

Regulatory Process and Clinical Data

Confirmation of conformity with the requirements under the intended use of the device, and the evaluation of the side-effects and of the acceptability of the benefit/ risk ratio must be based on clinical data.

- Relevant scientific literature
- Critical evaluation of the results of all clinical investigations made
- Critical evaluation of the combined clinical data provided above

For the performance of a clinical trial ethics committee and legal authorities could ask for documents:

- Conformance to the essential requirements of the MDD
- Risk analysis
- Declaration of conformity (if the product is already certified)
- User Manual

ISO 14155 addresses good clinical practice for the design, conduct, recording and reporting of clinical investigations carried out in human subjects to assess the safety or performance of medical devices for regulatory purposes.

ISO 14155 specifies general requirements intended to

- Protect the rights, safety and well-being of human subjects,
- Ensure the scientific conduct of the clinical investigation and the credibility of the results,
- Define the responsibilities of the sponsor and principal investigator, and assist sponsors, investigators, ethics committees, regulatory authorities and other bodies involved in the conformity assessment of medical devices.

Typical Pitfalls

When implementing a Quality Management System for providing documentation of compliance with the Medical Device Directive, it is important that it envelops the entire organization. Some of the typical pitfalls that may be encountered are:

- No clear commitment to QM from the management
- Non-involvement of all employees (developer, team leader, …)
- Missing specific QM Know-How in-house or external (via coaching)
- No critical assessment of current internal processes
- Establishment of QM processes is more than establishment of tools
- Risk management starts too late
- Underestimation of needed time QM is necessary prior to clinical studies (“fulfilment of the essential requirements”)

3.4 CE-label

The manufacturer is able to put the CE label on the product, if he is able to print and sign the declaration of conformity. The technical documentation is send to the notified body, so they know there is a new medical product in the market.

The manufacturer must have the complete main-product-folder. This folder contains all about the product incl. all tests and the points under 3.1 and a risk management.

The CE label must be placed direct on the product. Also the name of the manufacturer must be placed on the packaging and on the user instruction.

For a medical product we have to use a special user instruction.

AHEAD and CE-Marking

Timeline for AHEAD processing through getting the CE marking:

Internal Audit (December, 2014)

- software development
- successfully completed

Certification Audit (May, 2015)

- QM-System Upgrade for Software (EN ISO 13485)
- Technical documentation of Hearing glasses and physiological sensors
- Successfully completed

CE Certificate Hearing glasses + sensors (September, 2015)

If manufacturers wish to place a new medical device on the European Market the design, manufacture and testing of the product in question will likely have to comply with the EU framework on medical devices. Given that the AHEAD platform is likely to employ hearing devices and they fall under MMD, the existence of the Medical Device Framework (MDF) is of importance. The Medical Device Framework is extremely complex and, given its flexibility, is of an ever evolving application. It can represent a significant regulatory barrier to those wishing to innovate in the area of medical devices.

As with other areas of its intervention into healthcare regulation the MDF acts primarily so as to protect the internal market, i.e., the free movement of goods3 within the Union.4 Prior to the introduction of the EU framework on Medical Devices in the 1990s, the regulation of medical devices was subject to the differing regimes of each member state. This created barriers to the functioning of the single market and the free circulation of medical devices. As a consequence, the Commission decided to harmonize regulation in the area of medical devices so as to remove obstacles to the internal market. In addition the Medical Device Framework also aims to provide users in the European Single Market with a higher degree of protection than that which existed previously. This occurs by requiring that the same basic safety requirements are present throughout Europe. This was effectuated by the harmonization of essential requirements and certification and inspection procedures.5 The three EU directives, which represent the Medical Device Framework lay down numerous different requirements and basic safety standards which a product must meet before it can receive approval to be placed upon the European market. For AHEAD services only applies The Medical Devices Directive (MDD) 93/42/EEC amended by Directive 2007/47/EC.

[3] The main treaty provisions related to the freedom of movement for goods are Articles 34–36 TFEU

[4] The recitals of the Medical Devices Directive (MDD) 93/42/EEC begin by referring to the Single Market as a justification for action.

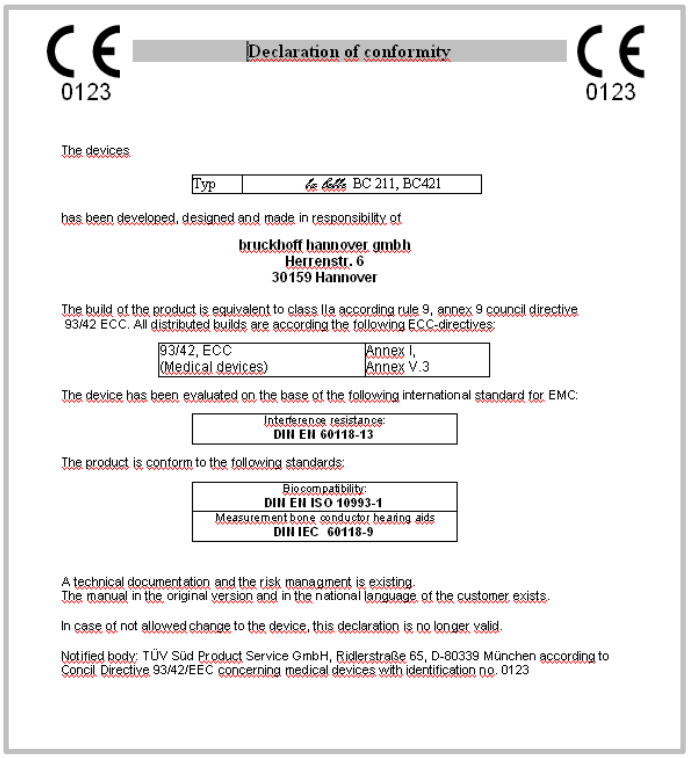
[5] Institute for Prospective Technological Studies Seville (2000). Single Market Regulation on Innovation: Regulatory Reform and Experiences of Firms in the Medical Device Industry.

The MDD is applicable to most medical devices, with the AIMD6 The MDD will therefore likely apply to hearing (plus glasses plus sensors for physiological data acquisition) devices in AHEAD that are to be placed on the market in Europe. In order to be placed on the market, all products that fall within the scope of the directive and meet its requirements are required to bear an EC conformity mark to show compliance with the directive. The aim of this is to allow products that conform to the directive's requirements to be sold freely throughout the EU without hindrance from national governments. The Medical Device Framework is important for the AAL sector, especially for those projects, as AHEAD, that aims to provide health support.

Essential requirements for Class IIa Medical products

According to the MDD Annex IX the hearing device and sensors connected to glasses to be used in AHEAD is of Class IIa (active device for diagnosis, allowing direct diagnosis/ monitoring of a vital physiological process).

1. *Risk management to ISO 14971 incl. a risk analyse*
   a. *output file risk analyse*
   b. *risk evaluation in table form based on the analyse*
   c. *control of the risk from 2.2 (What to do to minimized the risk)*
   d. *risk report und final declaration*
3. *Risk management review once per year – if there are new risks to have a look at?*



CE 0123 CE 0123

Declaration of conformity

The devices

Typ	BC 211, BC421

has been developed, designed and made in responsibility of

bruckhoff hannover gmbh
Herrenstr. 6
30159 Hannover

The build of the product is equivalent to class IIa according rule 9, annex 9 council directive 93/42 ECC. All distributed builds are according the following ECC-directives:

93/42, ECC (Medical devices)	Annex I, Annex V.3

The device has been evaluated on the base of the following international standard for EMC:

Interferenes resistance:
DIN EN 60118-13

The product is conform to the following standards:

Biocompatibility:
DIN EN ISO 10993-1
Measurement bone conductor hearing aids
DIN IEC 60118-9

A technical documentation and the risk managment is existing.
The manual in the original version and in the national language of the customer exists.

In case of not allowed change to the device, this declaration is no longer valid.

Notified body: TÜV Süd Product Service GmbH, Ridlerstraße 65, D-80339 München according to Concil Directive 93/42/EEC concerning medical devices with identification no. 0123

[6] This Directive covers all powered medical devices implanted and left in the human body, such as pacemakers, implantable defibrillators, implantable infusion pumps, cochlear implants and implantable neuromuscular stimulators. The Directive also covers implanted passive parts of active devices such as pacemaker leads and adapters, and external parts that are an essential part of the systems, e.g. pacemaker programmers.

Marketanalysis

The European market

In 2010 approx. 71 million people with deafness or problems in hearing live in in Europe. Only 20% of them use a hearing aid. The problem is the image of the hearing aid in society.

The European hearing aids and audiology devices market shows in 2012 14,5 % of the European population suffered from hearing impairments, which amounted to 60 million candidates who would benefit from using a hearing device.

The retail European hearing aid and audiology device market was valued at over €3.8 billion in 2010, while the wholesale market was valued at almost €1.3 billion. The retail market is expected to grow rapidly by 2017 due to aggressive growth strategies among local and international retail chains and the adoption of new technologies such as wireless Bluetooth® hearing aids and receiver-in-canal models. In addition, the European market for hearing devices exhibits high market potential as the penetration of hearing aid users in Europe is only 18.5%. Growth of the hearing device market is largely dependent on the reimbursement policies of each country, the technological innovations that are offered by the manufacturers and the distribution of hearing aids by the retailers to the end users.

The European markets include:

- Austria,
- Belgium,
- Denmark,
- Finland,
- France,
- Germany,
- Italy,
- The Netherlands,
- Norway,
- Portugal,
- Spain,
- Sweden and
- Switzerland

Phonak, Oticon, Siemens, GN ReSound and Widex lead the almost €1.3 billion wholesale market, while Cochlear and MED-EL lead the cochlear implant market.

In process are the following important questions:

What are the benefits of AHEAD in comparison to Smartwatches?

Analyze of competitors in measure medical health data. Some competitors are using Smartwatches (e.g. Samsung Galaxy Gear Neo 2) or wearables with a sensor for heartbeat and SpO2 (Withings Pulse O2 Activity- and Health Tracker); and the possibilities are increasing.

It will be a big market, but not based on a hearing aid and the use of a smart phone because this is covered already.

- Analyze market size and development of the market.
- Analyze the potential of this market.
- Analyze of the potential customer.
- Analyze on utility models and patents in this medical health market.

The past few decades have witnessed a significant increase in the population suffering from hearing problems. However, advancements in science and technology have successfully taken up the challenge and produced hearing aid devices addressing the complex medical needs of hearing loss patients. This has enabled millions of people suffering from hearing loss to lead a safer and happier life. The global market for hearing aids has continued to gain strength in terms of volume since past many years. As the incidence of hearing loss continue to rise, the demand for hearing aids will keep on increasing in the coming years.

The market for implantable hearing aids is also gaining ground, further strengthening the overall hearing device market. A major share of sale of hearing aids is carried out thorough public distribution channels with the US Veteran Affairs market registering high positive growth in the first half of fiscal 2011 as against negative growth in the previous quarter. The principal markets of the global hearing aid industry include Europe, North America, and Asia-Pacific.

The market is characterized by certain clear features which are indicative of the trends likely to affect the market. One major trend is still low market penetration of hearing aids which in turn provides significant opportunity for further growth. In addition, the industry is responding to the diverse market need with new product innovations.

The opponents: Wearables and Smartwatches

Opportunities

Another market AHEAD has to face is the market of consumables like wearables and Smartwatches. Especially facing the lifestyle market, it is necessary to look at these consumables as an alternative. Also for the market of assisting technology this is. Wearables are providing sensors and software to analyze health parameters. Today the can count steps and measure SpO2. Also they are able make a sleeping tracker and activity tracker. With a reasonable small sensor power, they are already achieving success on the fitness market. This is also the case for Smartwatches. Smartwatches bring also the benefit to have a display and a high compatibility with certain smartphones. But this compatibility is just given for a small number of phones and looking for a high end market including a customer binding process.

Limitations

Wearables and Smartwatches are bound to physical vibrations as an alert signal and physical interaction. There is no way available to use speech commands at this time. Also the interaction patterns are not manifested until now and not part of the socio-technical establishment. The target group is a lifestyle oriented, sportive group of people, who like to track themselves and monitor their life. They like to be in control.

Chances for AHEAD

The interaction modus of AHEAD with using speech commands and getting acoustic feedback by hearing glasses as well as visual and physical by the smartphone, provides the possibility for natural, humanlike interaction. Also AHEAD is supporting on a software base, not a hardware base. It is compatible to more than one brand of Smartphones. This opens the market for cheaper brands like Wiko or Huawei and increases the acceptability for people with a lower income – like seniors. AHEAD is using in-hear health sensors. This is a benefit as you use them, when you want them to use and are not bound to it. This comes in handy in comparison with Smartwatches that include a heart rate sensor. The heart rate can be detected permanently by the Smartwatch and could be used for non-health related purposes like biosensory-marketing. AHEAD does not have to use the medical sensors every time. It is working without it as well. When people do not want to have the medical tracking, they just put it out of their ear and it is not possible to monitor anything anymore. This makes the control easier and absolute. This kind of control increases trust in AHEAD as a system.

The Aim

A major aim is to increase the social acceptance. This project is an opener for this technology to a market that is not yet directly addressed. Also a lot of people don't know about the fixed amount from the health insurance that is given to support the buy of a hearing aid and think hearing aids are too expensive and it takes a long time to get such a hearing aid. Another aspect is the compatibility between smartphone, health sensor and hearing aid or high quality head set. Existing products do not have the compatibility between Wearables and every android smartphone. A supportive platform is the medical market for hearing aids. This is a lever for entering a market; hold tight by giants like Samsung.

Concerning the hearing market, a market, Smartwatches and Wearables cannot address, number of sale are impressive. For Germany in 2012 906.000 hearing aids (846.000 therefrom was BTE-hearing aids) were sold.

The guiding principle for hearing aids could be the following

It is important to get a hearing aid

- in a simple way
- quick in time
- not expensive (because of the health insurance)
- in a good quality

Also the additional value has to be pointed out.

Market Advisory Panel

During the first session of the Market Advisory Panel, several issues have been discussed with the Panel in Munich. This section should give a short overview of the advice AHEAD got from the outer perspective.

Interest of MAP in AHEAD

It is interesting for the MAP how AHEAD is trying to approach usability and acceptance for the customers. Also they are interested in early experiments and results of the use of AHEAD, especially concerning the use of several devices as a whole system. The potential of the core technology of bone conduction and the idea of hearing glasses was a positive point of discussion. This boosts the potential of audio feedback and lingual system interaction. Also the idea of a Market Advisory Panel was positively awed.

Remarks for AHEAD

During the discussion of the MAP, several remarks have come up that could support the further actions of AHEAD. This form of criticism and stimulation for the consortium was very fruitful. Some remarks were dealing with the quality of studies as they are not representative. Also the market insight from the MAP was interesting as they proposed that people do not want to focus on health but rather only receive medical data if absolutely necessary. Also it was pointed out that elderly mostly have two pairs of glasses – one for near sight, one for far sight. This could become a problem, if only one AHEAD device would be available. Also a result of one of the AHEAD studies was that family members would offer their voice for the speech output. But other studies in Austria showed that elderly didn't choose the avatars resembling relatives.

A major advice was about the potential of AHEAD. It cannot solve all problems. Therefore it must become more focused.

The **proposed values** of AHEAD were, following the MAP:

Safety, Quality of Life, Comfort, Support for AdL, Agglomeration of dispersed information, intuitive usage and attention enhancement.

AHEAD is up to **solving problems** as:

Hearing deficits, loss of orientation, forgetfulness, reduces the distraction in AdL and can provide a learning support.

Potential **distribution channels** could be:

Opticians, Audiologists, Care Providers, Medical supply stores, technic discounters and pharmacies.

As possible **additional functionalities** were stated:

Orientation and direction support, providing individualized news and information, reading emails and social media news, assisting with names of people in the surroundings and supporting blind people.

Conclusion

AHEAD has a great potential for all business partners. By this the strategy for further business development has to be split up to the expertise of partners. The approaches can be very different in respect to the needs of the target groups. The potential is there for a lot of people but for a start, there has to be a focus on one topic. This is going to be the support and assistance of people. Especially the reminder functionality and orientation/ navigation is a feature to be extended. Also the reading of vital signs for safety reason is important in combination with an alert system to it that provides adequate response to emergencies and social needs. AHEAD has to be a socio-technical system. The devices and the social transformation of the potentials in a real use have to be the major aim.

To support this aim the consortium will start to increase the contact to stakeholders and strengthen the MAP. Also the service development will be essential for the upcoming period. Services for care providers and service for adjustment and customization of AHEAD will be a challenge to conquer for the consortium but boost the outcome. With the focus on support and the inclusion of more stakeholders, the market potential can be defined more precisely. The hearing aid market is promising enough to go for a specialized, supportive solution, especially as the prices are insurance supported. The idea to give a hearing aid a benefit to support people in keeping up their health and living longer on their own, is not only a benefit for the primary end user but for insurances as well as their long-time costs are reduced and health care is not going to be so expensive on the long run. This can bring an additional asset to AHEAD. A hearing aid that reduces costs to a health system! This refunding option is giving an argument to estimated higher prices.

First Business Development Strategy – next steps

The first business development strategy states following points:

- Focus on a supportive system
- Increasing of stakeholder involvement
- Open product tests with as many test users as possible in the project
- Presentation and testing on community fairs
- Establishing contact to private and governmental insurances
- Estimation of product development costs

There is also the need of further, detailed descriptions of:

- Distribution channels
- Manufacturing
- Logistics on productions
- Supply chain for services
- Service models for emergency alert handling
- National laws and standards for medical devices
- Communication plan
- Calculation for product and setting the price

Final Comment:

This deliverable was originally in the hands of Bruckhoff. Due to special reasons, it was not possible for Bruckhoff to provide a full version of D.5.2. As the contact between Johanniter and Bruckhoff is very positive, they declared to accept the lead for this Deliverable. By this, the focus also changed from a hard fact deliverable to a more open, confirmative style. Johanniter are not a classical SME but a social organization from non-profit-area. The aim of Johanniter was to create a value that is going beyond the financial figures and to support the tiny blossom of social business. For Johanniter it was also a learning process to start business development strategies from the scratch in a market, where do not have the core competences. With the support of our partners, we mastered this challenge! We want to thank all partners of the consortium who supported us to make this Deliverable to the guidepost it is now.