SIFEM

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Semantic Infostructure interlinking an open source Finite Element tool and libraries with a model repository for the multi-scale Modelling and 3d visualization of the inner-ear

Deliverable D2.2

User Requirements and Data Availability Analysis

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Abstract:	The aim of this deliverable is to identify the problem that needs to be solved, specify the user requirements that have been gathered and specify the desired output of the R&D activities and the SIFEM Semantic Infostructure. These requirements and the respective analysis provided in this document will lead the design and the implementation of the system. Moreover, this deliverable includes a section, where the requirements associated to VPH Network of Excellence have identified and reported in order to link the project outcomes and activities to existing and future research directions. Mainly, the potential clinical users of the system are involved in this task (UoA and UCL), contributing to the acquisition of the experts opinions, as well as ICCS,

	ISVR and LiU representing the research users. Through the detailed analysis of the state of the art presented in another deliverable (D2.1), the identification of experts' needs and the constraints deriving from the available resources, the approach for the deployment of the system was defined: the SIFEM Semantic Infostructure will be a web-based application, interlinking an open source Finite Element tool and libraries with a model repository for the multi-scale modelling and 3D visualization of the inner-ear.
Keyword List:	Inner ear, multi-scale modelling, usage scenarios, users and stakeholders, normal cochlear, Meniere

Document revision history

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		Modified By	Brief Description of Changes
v0.1	12/02/2013	ICCS	First draft of the Table of Contents (ToC)
v0.2	04/03/2013	UoA, ICCS, UCL, ISVR	Final ToC
v1	01/04/2013	UoA	Contribution
v2	17/06/2013	UoA, UCL	Contribution
v3	28/06/2013	UoA	Contribution
v4	01/07/2013	ICCS	1st Draft Version
v4.1	01/07/2013	ICCS	ICCS forwarded the deliverable for internal reviewing
v5	08/07/2013	ISVR	Comments by ISVR
v6	10/07/2013	ICCS	Updated version
v7	15/07/2013	UoA	Contribution
v8	17/07/2013	ISVR	Contribution
v9	18/07/2013	ICCS	Merged version
v10	22/07/2013	UoA	Contribution
v11	22/07/2013	ICCS	Final Version before internal review
v11.1	26/07/2013	DERI	Internal Review
v12	29/07/2013	ICCS	Final Version

1 GUIDELINES

Overview

The following report denotes the draft version of the Table of Contents (ToC) for the deliverable D2.2 User Requirements and Data Availability Analysis.

Prerequisites

D2.1 State of the Art: The research conducted during this deliverable is necessary to identify state of the art inner ear modelling techniques.

No Other Prerequisites are needed.

Responsibilities

Responsibilities have been assigned according to the expertise of each of the involved partners and the effort each one of the partners has dedicated to WP2 Design of the SIFEM system.

Each one of the partners is responsible to provide its own contribution (indications of responsibilities are presented at the titles of each chapter).

ICCS as the Task 2.2 leader is responsible for the circulation of the ToC and final version of the consolidated deliverable.

2 TABLE OF CONTENTS

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Definitions, acronyms and abbreviations

Acronym	Title
Cochlear Structure and Modelling	
BM	Basilar membrane
TM	Tectorial membrane
RM	Reissner's membrane
OHCs	Outer hair cells
IHC	Inner hair cell
St	Stereocilia
C	Cortilymph
SV	Scala vestibuli
ST	Scala tympani
SM	Scala media
OC	Organ of Corti
HC	Hensen's cell
DC	Deiter's cell
RL	Reticular lamina
IS	Inner sulcus
HS	Hensen's stripe
IP	Inner pillar cell
OP	Outer pillar cell
Mod	Modiulus
BC	Bone Conduction
ENT	ear, nose, and throat
OAE	Otoacoustic emissions

DPOAE	Distortion product otoacoustic emissions
Other Methods and Processes	
FE	Finite Element
FEM	Finite Element Method
SNHL	Sensorineural hearing loss
PTA	percutaneous transluminal angioplasty
TTS	temporary threshold shift
RTAE	Requirements and Technology Assessment Exercise
PACS	Picture archiving and communication system
DICOM	Digital Imaging and Communications in Medicine
Project Management	
CB	Consortium Board
CCB	Change Control Board
CO	Confidential, only for members of the consortium (including the Commission Services)
CR	Change Request
D	Demonstrator
DL	Deliverable Leader
DM	Dissemination Manager
DMS	Document Management System
DoW	Description of Work
Dx	Deliverable *(where x defines the deliverable identification number e.g. D1.1.1)*
EC	Ethical Committee
EM	Exploitation Manager
EU	European Union
FM	Financial Manager

FP	Framework Programme
MS-	Microsoft Corporation
MSx	project Milestone *(where x defines a project milestone e.g. MS3)*
Mx	Month *(where x defines a project month e.g. M10)*
O	Other
P	Prototype
PC	Project Coordinator
PM	partner Project Manager
PO	Project Officer
PP	Restricted to other programme participants (including the Commission Services)
PU	Public
QA	Quality Assurance
QAP	Quality Assurance Plan
QDF	Quality Function Deployment
QM	Quality Manager
R	Report
RE	Restricted to a group specified by the consortium (including the Commission Services)
RUP	Rational Unified Process
s/w	Software
STEP	Standard Technology Evaluation Process
STM	Scientific and Technical Manager
TL	Task Leader
WP	Work Package
WPL	Work Package Leader
WPS	Work Package Structure

3 EXECUTIVE SUMMARY

This document is the second deliverable of WP2 "Design of the SIFEM system" and represents the result of task "T2.2: Requirements Analysis" which runs the first semester of the project (M1-6). In this task, according to DoW:

"During this task a user requirement analysis will be conducted so as to identify and classify the potential SIFEM stakeholders. The clinical partners as well as the researchers will play key role in the identification of the requirements of the final users. The requirements elicitation is a crucial phase in order to identify the stakeholders and users of the system as well as the usage scenarios that will set the directions for the analysis of functional and non-functional specifications.

The study will also examine the legal and ethical aspects of the SIFEM system, while the questionnaires distributed to experts will be supervised by the SIFEM Ethical Committee so as to account for all relevant legislation in EU."

The deliverable contains five (5) main sections:

- The first main section, comprising Chapter 4, provides an overview of the adopted methodology, including the identification of the users and systems' stakeholders, description of the expert panel that was used to collect requirements and final the questionnaires, generic and user-specific, that were structured to gather the requirements are attached.
- Afterwards, during Chapter 5, the legal and ethical issues are identified that are correlated to the research activities of the project and the ethical committee is presented that has the responsibility to observe the compromise to the legal and ethical requirements during the whole project duration.
- During Chapter 6, there are reported the Experts' feedback and there is performed an analytical evaluation and assessment of the clinical and biomedical experts requirements. Users' needs are then analysed and the target user group choice is made and justified. Finally the adopted approach for the system based on all the above factors along with the related benefits and impacts are presented. Moreover, it deals with the identification of the modelling parameters and system specifications and performs an initial identification of the clinical models and scenarios as well preliminary suggestions on the interface design. Analytical system specification and use cases will be presented in D2.3 SIFEM System Architecture.

- Finally, the deliverable includes a section reporting the link to the VPH Network of Excellence requirements. However, activities related to building a bridge with the VPH requirements and current and future research directions are foreseen to be included during Task 6.4 VPH Bridge Implementation: *"Design and development of the SIFEM bridge to the VPH technical for achieving semantic and technical interoperability among the data and the models of the proposed project's infrastructure and the VPH Data and Models Repository. The first release of the VPH Bridge will be available by month M30 and integrated in the 2nd release of the SIFEM Infrastructure (D6.2b), while the final release of the VPH Bridge will be available at the end of the project (M36) and fully integrated with the final infrastructure release (D6.3)"*.

4 METHODOLOGY

4.1 PRELIMINARY KNOWLEDGE OF THE STATE OF THE ART

The Technical Annex reports that: *"The number of people with all levels of hearing impairment is rising mainly due to a growing global population and longer life expectancies. It is estimated that 278 million people worldwide have moderate to profound hearing loss in both ears, according to the World Health Organization[1] (WHO) requiring rehabilitation. The implications of this number include unprecedented demands on public health services and the health-care system. Understanding the exact pathophysiological consequences and mechanisms through which diverse causative factors give rise to hearing impairment in humans requires a thorough understanding of the normal function of the cochlea. Despite significant progress, more work is needed to develop novel approaches to restore hearing".*

Also, it is reported that[2,3] "*The study of the normal function and pathology of the inner ear has unique difficulties as it is inaccessible during life and so, conventional techniques of pathologic studies such as biopsy and surgical excision are not feasible, without further impairing function. Hence, insight into the pathologic basis of ear disease can be obtained only by post-mortem studies of the cochlea and by developing credible animal models. Mathematical modelling is therefore particularly attractive as a tool in researching the cochlea and its pathology. Mathematical models have been recently introduced into the study of cochlear physiology and pathology, giving insight into the system's behaviour and attributes that would have been impossible to have with human in-vivo studies. Finite element models can serve as a powerful platform to study the structure-function relationship in normal and pathological ears as well as give insights into the planning of novel surgical procedures for the rehabilitation of Sensorineural hearing loss"*.

[1] http://www.who.int/mediacentre/factsheets/fs300/en/index.html

[2] Arts HA. Sensorineural hearing loss in adults. In: Cummings CW, Flint PW, Haughey BH, et al, eds. Otolaryngology: Head & Neck Surgery. 5th ed. Philadelphia, Pa: Mosby Elsevier;2010:chap 149

[3] Bauer CA, Jenkins HA. Otologic symptoms and syndromes. In: Cummings CW, Flint PW, Haughey BH, et al, eds. Otolaryngology: Head & Neck Surgery. 5th ed. Philadelphia, Pa: Mosby Elsevier;2010:chap 156

It is shown in the deliverable D2.1 “State of the Art” that mathematical modelling can play a key role in understanding the biomechanical processes involved in hearing. The power of such a model is not only its ability to explain current concepts and account for empirical (experimental and clinical) observations, but also its ability to incorporate future data, as they become available in the literature. It is safe to say that the complete solution for the transformation of basilar membrane motion to hair cell excitation for the entire cochlea has yet to be attained.

In general, models of the cochlea should have to have the ability to simulate current concepts of physiology of hearing as well as well as account for the phenomenology of Sensorineural hearing loss.

4.2 METHODOLODY DESCRIPTION

Even though some basic principles and methodologies (such as questionnaires, focus groups, interviews) can be applied for eliciting user requirements from an application such as the one designed and developed as part of SIFEM project, in truth a combination of methods is needed for fully understanding users’ expectations and build an application that will be really useful.

In SIFEM a questionnaire for defining the basic principles of the final SIFEM outcomes was prepared. The questionnaire was in practice used as a basis for an open exchange of views, a brainstorming procedure, through which the user needs were acquired and further analyzed. In fact in the following this feedback that was received from clinical and biomedical experts is presented.

The SIFEM vision is to develop an Infostructure to semantically interlink a Finite Element (FE) tool and open-source supportive tools and libraries with the clinical knowledge, the available clinical and experimental data and a Model Repository in order to obtain more elaborate and reusable multi-scale models of the inner-ear.

The long-term outcome of the SIFEM project is to accelerate the understanding of the physiology and pathology of the cochlea and support the diagnosis and management of Sensorineural hearing loss paving the way for individualized assessment decision making and treatment planning resulting to more personalized healthcare.

A crucial phase is the requirements elicitation in order to identify the experts' needs for such a system and define the usage scenarios that will set the directions for the analysis of functional and non-functional specifications. In order to efficiently record the experts’ requirements, we conducted an anonymous survey (http://tinyurl.com/sifem-quest).

Users' requirements were captured through:

- analysis of the state of the art (see D2.1);
- interviews with experts and questionnaires; As already mentioned above the adopted methodology is a combination of user requirements acquisition and analysis methodologies (questionnaire, interview, and brainstorming) and follows a two steps approach:
    - Discussion in order to identify the basic principles the application should have (such as the type of knowledge, skill, attitudes, or behaviour addressed, the clinical procedures, the kind of feedback for the user etc.)
    - Analysis of the feedback received through the abovementioned discussion, determination of requirements along with a feasibility study taking into consideration limitations such as budget, time, technology and any other resources in order to determine the approach to be followed for the implementation of SIFEM Semantic Infostructure and modelling activities.

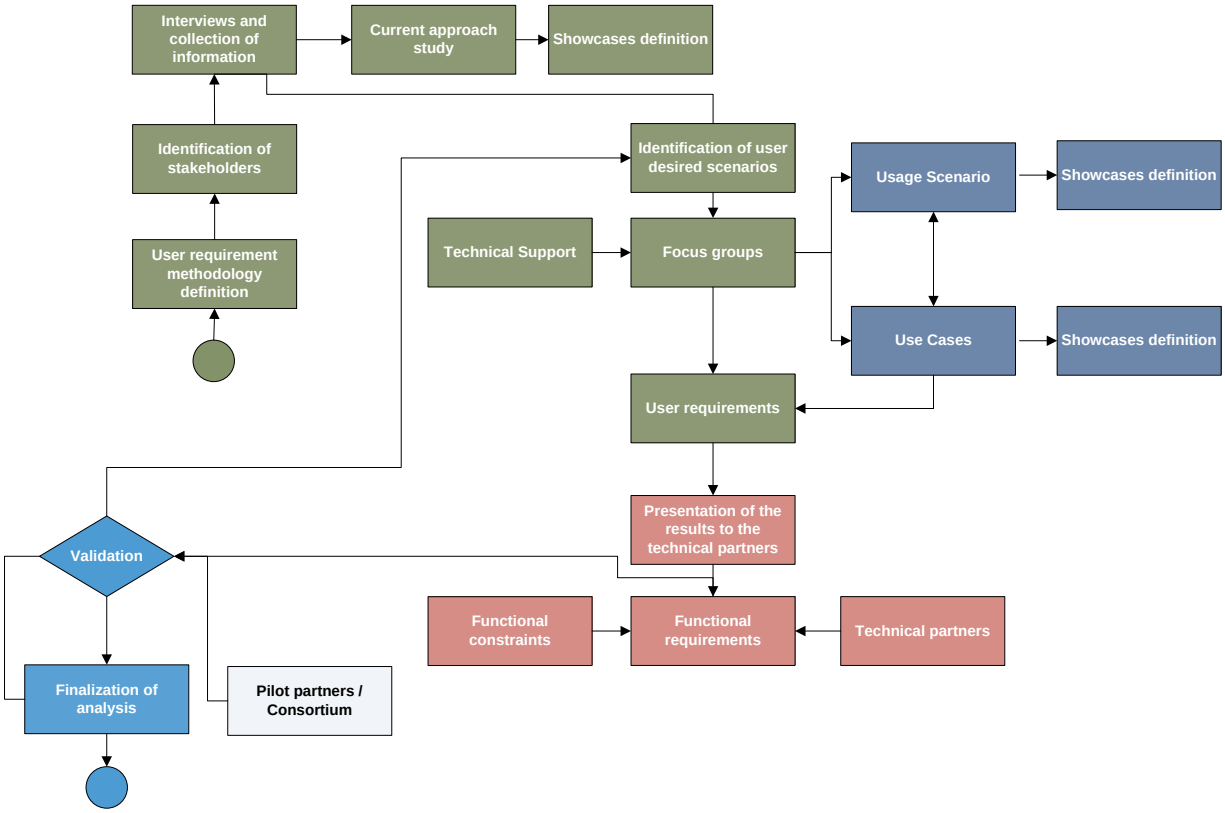


Figure 1 – Steps of the user requirements collection and analysis methodology

In this deliverable the aim is to define the approach adopted for the application and not the definition of the technologies, specifications and architecture (details for these will be provided in D2.3). For this aim the "red" tasks are not included in this deliverable. Moreover, for the "blue" tasks there will be presented in this deliverable an overview of the analysis but the details use cases and system scenarios will be included in the D2.3.

As it is evident from the diagram, the user requirements analysis defines the approach. Once the approach is defined and agreed there is no way back concerning the basic principles of the application. The development and the evaluation is a more dynamic procedure, but the approach to be adopted is a much more straightforward decision.

The main steps of the User Requirements gathering methodology that was followed can be summarized in the following:

- User requirement methodology definition
- Identification of stakeholders
- Interviews and collection of information

- Current approach study and Showcases definition
- Identification of user desired scenarios
- Focus groups to identify the Use Cases
- Presentation of the results to the technical partners
- Functional and non-functional requirements and Functional constraints of the system
- Validation by the Pilot partners / Consortium and finalization of analysis

There were formed two different questionnaires in order to better analyse the responses and collect valuable information on the system design and functionality:

- Generic Questionnaire, further divided in three main categories:
  - Generic Questions
  - Functional Aspects
  - Exploitation Aspects
- User-specific Questionnaire (Clinical users, Researchers/Software Engineers and Educational Groups (Biomedical Engineers)).

The questionnaires were formed according to the following dimensions:

Dimension 1: The purpose and aims of the application

The experts were asked about the purpose and aims of the application and the following alternatives were proposed:

1. Education (conceptual knowledge, basic skills, and an introduction to the actual work)
2. Clinical rehearsal
3. Research

Dimension 2: The unit addressed by the application

The second important issue that needs to be clarified is the target unit and the complexity of the end user:

1. Individual (teaching knowledge and basic skills)
2. Team, addressed first to ‘‘single discipline teams’’, consisting of multiple individuals from a single discipline, and then to ‘‘multidisciplinary teams’’

3. Work unit, for example, a specific surgical team
4. Organisation, how the organisation reacts in specific tasks

Dimension 3: The experience level of application users

Another question that is closely related to the previous:

1. College, University
2. Initial professional education
3. Biomedical Researchers
4. Software Engineers
5. Educational Groups (Biomedical Engineers)

Dimension 4: The clinical procedure addressed by the application

Clinical procedures are in most cases very complex and involve difficult decisions taking into consideration various factors. The procedure addressed by the application is a very important dimension of the provided solution.

Dimension 5: The technology applicable or required for the application

While previous dimensions are common in software user requirements this one is specific for the scope of the application.

Dimension 7: Exploitation Aspects of the system

According to this dimension, there were inserted in the questionnaire, specific questions about the licenses of the final product, the potential stakeholders and audience as well as additional potential exploitation aspects (i.e. CE marking).

4.3 USERS AND STAKEHOLDERS IDENTIFICATION

The definition of stakeholders involves all different categories of individuals, groups or organizations directly or indirectly involved in the planning and decision making process. The important issue to be determined for each stakeholder is to which extent their involvement will take place and at which phase of the project.

In order to identify the project's stakeholders it is needed to be considered which individuals and organizations are primarily involved in the project. There is also a section of stakeholders that relates to those that may be affected by the outcome of the project. These may be separated into individuals, groups or organizations. Therefore, the stakeholders may be identified in the following categories.

1. Project outcome stakeholders
   These can be identified as the project team that provides the execution of the project. Therefore, it can be deduced that the main areas of interest are universities, university hospitals, research teams and private or public companies with specific R&D interest.
2. Product Usage stakeholders
   This is the most important category of stakeholders. It refers to the end users of the system that will be produced. A further separation may be done at this point. There can be identified as the business end of the users and the customer end. At the business end category there are hospitals, private clinics, private clinicians and research laboratories. The customer end involves a much broader spectrum and it is difficult to assume all descriptions. The main areas involve patients and research scientists, who may directly use the product.
3. Funding stakeholders
   This category is directly related to category 1. The only addition to that part is the European commission in the sense that major funding comes from their resources. Since they approve the release of funding and provide major part of the resources, they are also accountable for the results of the project.
4. Contributors stakeholders
   This category refers to the level of commitment of groups or individuals. Their contribution is not directly associated with the success of the project. Such individuals may be identified as clinicians and research scientists with this specific field of expertise.
5. Review stakeholders
   In this category we refer primarily to the individuals assigned by the European commission to review or audit the project. Their main interest is to ensure the success of the outcome of the project. This is done through the review of the quality

of the deliverables (reviewers), the general management of the project that involves guidelines and intra- and post- project reviews (project officer) and the review of the project's expenditures (auditors). It is clear that there is overlapping of stakeholders in different categories. The issue of consideration though is the level of commitment of each stakeholder. This may vary greatly between different individuals, groups or organizations. In that way the stakeholders may be identified in four categories depending on the level of commitment.

Categories	Stakeholders
Primary	• Private/Public Hospitals • Clinicians
Secondary	• University hospitals • Universities • Educational purposes
Tertiary	• Research teams/scientists • Research laboratories
Quaternary	• Reviewers/Auditors • Private/Public R&D companies • Cochlear Implant and Cochlear Aids manufacturers • Funding partners

Probably the most important users' category is the cochlea research community, especially since there are many grey areas in the field and great proportion of the current knowledge is based on animal studies, since it is practically impossible to perform in vivo studies in human. The platform could be both a benchmark for common research and advances exchange and a tool to extend and verify novel research ideas. The final Infostructure, especially since it will be open source, could be the future point for the entire research community. Since it will both give access to multilevel data repository regarding to cochlea anatomy and function and allow its elaboration, it could be adapted by different research groups.

Regarding to clinicians, the project could be found useful in two ways. The first is patient-oriented. Results of the platform could be used to aid the diagnosis of the individual patient, although it is highly uncertain to define that during the life time of this project, a valuable clinical tool could be achieved. Data from the platform could help in diagnostic decisions and fine tuning of the treatment. Apart from this, the platform could be used as a basis for future development of a new laboratory test. Linking between clinics and hospital could enrich data repository and achieve faster and more reliable progress of the platform in this direction.

Educational institutions are another important stakeholder category. The platform could be used both by pre- and postgraduate students, with or without special interest on the field. Given the fact that cochlea anatomy is a difficult field, the platform or at least a small and easy to use edition could be used as an interactive educational tool. More advanced educational purposes will be adapted by ENT residents and audiology trainees. Overall, universities and university hospitals either with or without relevant research activity could use the platform for educational purposes.

Finally, hearing aid and cochlear implants industry could use the platform for future development and improvement of products. It is known that almost 25% of hearing aids bought are never used due to technical or rehabilitation insufficiencies. In addition to this, satisfaction after cochlear implantation is highly variant. The platform could eliminate need for clinical testing through modelling some of the devices outcome and improve personalized fine tuning of the devices.

4.4 EXPERT PANEL DESCRIPTION

In order to identify users' requirements, a questionnaire was built. The questionnaire consisted of a common body and three different parts, dedicated to clinicians, educational stuff and software developers and technicians respectively.

The questionnaire was sent to memberships of all these expert communities, in order to record all potential needs, remarks and feedback. Whoever could identify his/herself in more than one category (i.e. clinician and professor) could answer more than one sections of the questionnaire.

The questionnaire was sent in tens of clinicians with special interest in Audiology from many countries. Mail lists of Audiology Societies were used. Clinicians included Audiologists, ENT doctors with special interest in ear disorders and ear surgeons, known for their clinical experience or/and their clinical research. ENT doctors without special focus and advanced knowledge and clinical and research interest were not invited to fill the questionnaire. Useful information about their approach from the clinical point of view was gathered.

Apart from clinicians, the questionnaire was sent to researchers who have published studies focused on cochlea function and especially on cochlea modelling. This group of experts includes mechanics, bioengineers and basic researchers. They were approached by members of the consortium who had collaborated in the past, or via their relevant publications.

Finally, the questionnaire was sent to universities and other educational institutes, in order to have some feedback on the depth of knowledge required and the appropriate interface. Both university professors and Audiology Department Directors, responsible for students and ENT residents' education, were asked.

The questionnaire was sent in the mail list of the Politzer Society, the biggest and most prestigious international community for otologic surgery and science. Politzer Society organises annually the most important otology meetings focused on clinical and research advances.

5 LEGAL AND ETHICAL ISSUES

The Ethics Committee of the consortium has been set during the First Plenary Meeting and includes three members from three different Institutes.(A. Sismanis, UoA, A.Bibas, UCL, S. Stenfeld, LiU). All of them are clinical oriented and experienced researchers. The Committee will have the responsibility of decision regarding to Legal and Ethical issues. It will discuss and decide regarding to ethical and legal issues such as patients' data protection, confidentiality, regulation compliance and consent need. In any case required, and before any crucial decision, they will contact and collaborate as necessary with the relevant legal departments of their institutes.

The only part of the project where ethical and legal issues may arise is the validation procedure, since it will be the only one including patient data. Initial planning of the validation procedure does not involve recruitment of patients or volunteers. Retrospective, already possessed data will be used for validation according to current estimation at this phase of the project.

The validation protocol will be approved by the responsible Ethics Committee of the Hospital where the patients' data will be extracted from medical records. This obligation will of course be a second official level of safeguard regarding to Ethical Issues preservation and compliance to relevant regulations.

Validation procedure will not include any kind of interventional procedures. This means that treatment plan and safety of any of the patients involved will not be changed or influenced in any level. Additionally, no diagnostic or monitoring procedures will be performed in the patients included, apart from them already applied according to current clinical practice and their specialized clinical needs according to current guidelines and standard clinical care. Therefore, according to current regulations, there will be no need of personalized consent.

Data will be actively protected with use of anonymised records, so that patients will not be identifiable at any phase of the procedure. Records will be protected by passwords and only authorized medical personnel will have access.

Results of this research may be presented or published for use by the medical or scientific community, but confidentiality will be protected at all times. No identifying information or medical records will be made available to other physicians, research, insurance companies, or any other individual or agency.

According to model development and needs, the above initial planning for validation protocol might change and include some kind of patients' involvement or new data recorded prospectively. In this case, it is obvious that the ethics committee approval will be obtained and that personalised consent forms will be filled by every patient. Further actions as required will take place as soon as a potential change of the initial plan appears.

In any case, the following regulations will be addressed the validation procedure will be subject to them:

- Article 8 of the European Convention on Human Rights and the judgments of the European Court of Human Rights.
- Article 7 & 8 of the Charter of Fundamental Rights of the European Union.
- OECD 1980 Guidelines on Privacy.
- Council of Europe 1981 Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data.
- Council of Europe, Recommendation on human rights and biomedicine, concerning biomedical research, Strasbourg 25th of January 2005.
- Recommendation (97) 5 of the Council of Europe on the protection of medical data.
- Recommendation (83) 10 of the Council of Europe on the protection of personal data used for scientific research and statistics.
- DIRECTIVE 95/46/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 24 OCTOBER 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.
- Directive 2002/58 concerning the processing of personal data and the protection of privacy in the electronic communications sector.
- Opinion no. 13 of the European Group on Ethics on Ethical Issues of Healthcare in the Information Society.
- DIRECTIVE 95/46/EC Section 4, Article 11: Information where the data have not been obtained from the data subject.

6 EVALUATION AND ASSESMENT OF THE CLINICAL AND BIOMEDICAL EXPERTS REQUIREMENTS

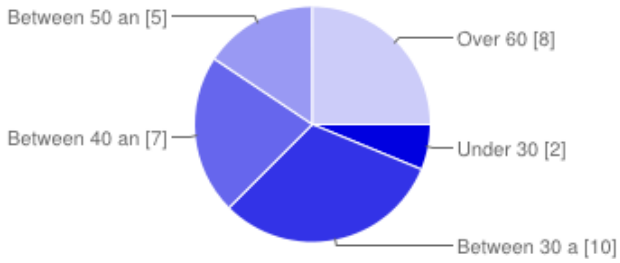
6.1 USERS' NEEDS ANALYSIS

Thirty five responses from questionnaires have been collected. 55% were collected from Clinical users, 30% from Researchers/Software Engineers and 15% from Educational Groups.

The responses were analyzed in order to extract valuable conclusions upon the functionalities of the system in order to design the system architecture and specify the functional specifications that will be reported in D2.3.

The cochlea research community is characterized by great level of expertise and specialization. Thus, its size is restricted and the potential target group of the questionnaire would not transcend some hundreds of people worldwide. Despite this fact, the questionnaire was sent to more than 150 experts, from the communities already described in section 6.4 (expert panel description). Response rate was average. Still, the number of responses in the questionnaire is proportional to the size of the experts' community and gives the opportunity for useful conclusions.

Please specify your age



Company, Organization

Over 15 academic institutes from three different continents were represented in the origin of the experts who answered the questionnaire, including Chapman University, STH, UoA, Stanford University, The Cleveland Hearing and Balance Center, UC Irvine etc. On top of this, some answers were collected by private practicians, which means that the sample was representative of different types of approach.

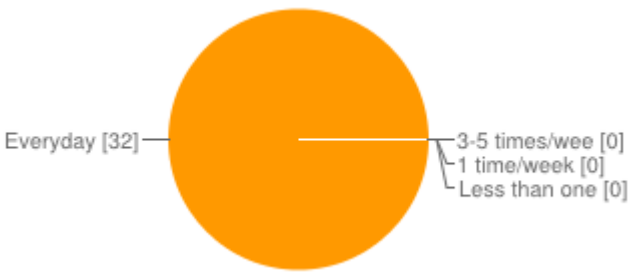
Country

Over 10 countries from three different contents were represented, giving the opportunity to collect feedback from different research environments, with great variations in technological background and consequently needs and expectations. This fact strengthens the quality and the representativeness of the answers, since the platform is designed to be universal and should be eligible for use in a spectrum of countries and corresponding technical and knowledge background.

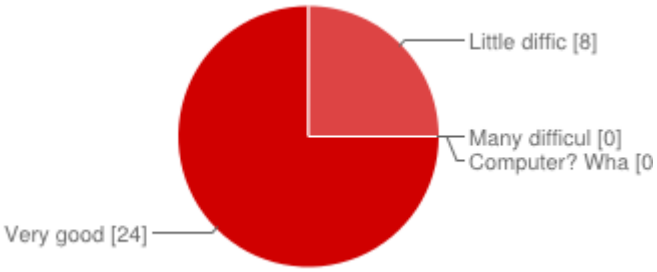
Countries of origin of the researchers answered are listed below:

- Greece
- Cyprus
- Iraq
- USA
- UK
- Serbia
- Switzerland
- Philippines
- Turkey
- Slovakia
- Jordan

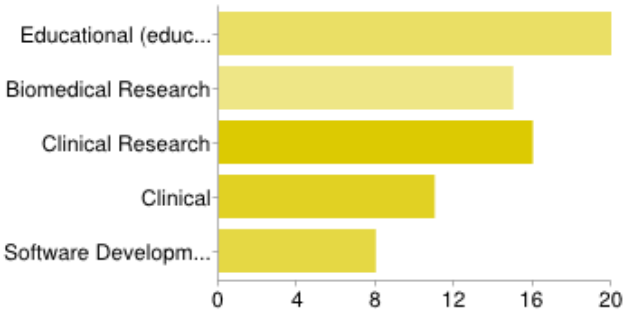
How often do you use your Computer?



Computer skills

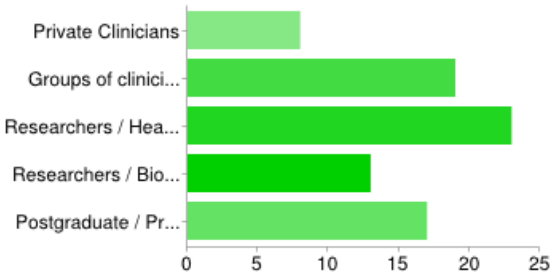


The main functionality of the system and the domain that the SIFEM should mainly target is:



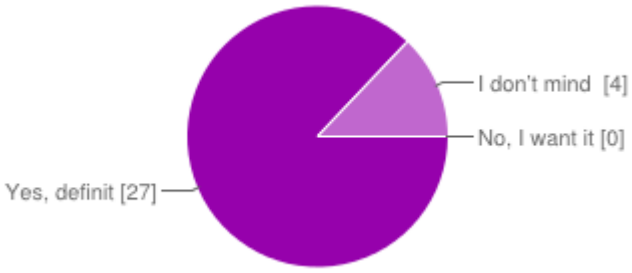
The results of this question are very important and useful regarding to the overall direction of the project. Despite the project is at the initial stage, it is still clear to the majority of the correspondents that research direction is predominant. The sum of the responses given for clinical and biomedical research is first by far (35 vs. 20), while educational purposes rank second. Additionally, it is clear that direct outcomes of this project will not be easily included in every day medical practice, at least at this phase of development. This fact is something that the consortium already had discussed and the compatible feedback from the relevant scientific community will help to determine the main final directions of the project as mainly research-oriented and intermediate in terms of clinical usability.

Who are the final users of the system?



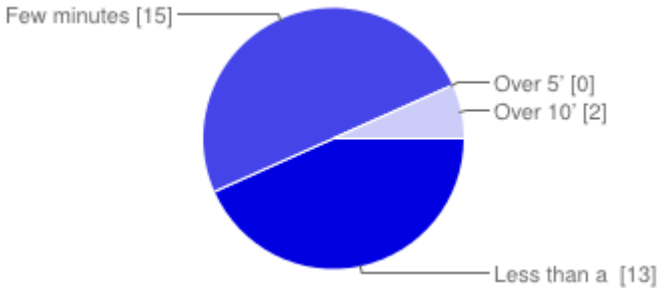
The results of this question are similar to the last one. Again, the research community ranks clearly first as final user of the system, especially if groups of clinicians are included, while students are second by far. This feedback ensures that main target group of the project outcome is the research community, and secondly educational purposes.

The final SIFEM platform should be published on the web;

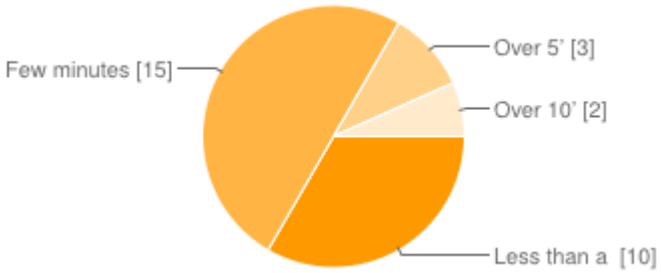


Great majority of answers confirms the initial open source and web based orientation of the project. Future users wish a web based platform, suitable for data repository and exchange, quick and real time communication, research ideas establishment and development. The major policy choice for open source, compatible with EU directions, is being rewarded by the experts' community.

Please select the maximum acceptable response time for the 3D visualization.



Please select the maximum acceptable response time for the FEM solver.



These two questions should be very well considered during the whole FEM solver and interface planning. Great majority of the correspondents does not appear willing to use a platform which will take more than a few minute to present results. Of course this contrasts realistic time needed for this kind of calculations. These solutions could be the development of different editions which will be suitable for different uses and needs (i.e. educational or oriented to particular elements), or the division of the calculations in smaller parts in order to be represented in less time.

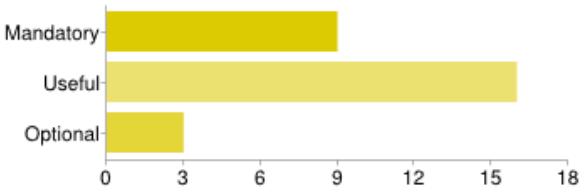
Which additional functionalities are necessary to be included in the final product?

A simple collaboration environment where I can chat with other researchers/clinicians and exchange data/knowledge	**12**	22%
Communication with the Hospital's Electronic Health Record (EHR ready to acquire DICOM images or other clinical information directly from the patient's EHR)	**10**	18%
Bidirectional communication with the Hospital's Electronic Health Record (EHR ready to acquire DICOM images or other clinical information directly from the patient's EHR and store information exported by SIFEM modelling activities directly to EHR)	**13**	24%
Address specific standardization policies (i.e. Health Level Seven International (HL7 v2)	**4**	7%
Interoperability and connection to picture archiving and communication system (PACS). PACS is a medical imaging technology which provides economical storage of, and convenient access to, images from multiple modalities (source machine types). Electronic images and reports are transmitted digitally via PACS; this eliminates the need to manually file,	**16**	29%

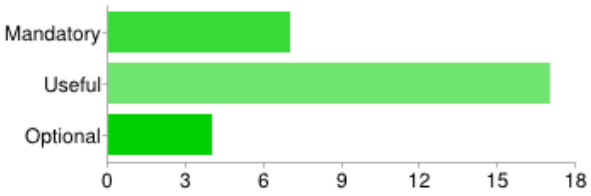
retrieve, or transport film jackets. The universal format for PACS image storage and transfer is DICOM (Digital Imaging and Communications in Medicine).		

The importance of this answer is in two levels. Firstly, it indicates the most popular format of data to be stored. Secondly, it confirms that the initial development of a platform or a specific format, like DICOM, can be the reference point for all future extensions and applications. SIFEM can be such a milestone, in the field of cochlea research, since there is not another similar platform. It also confirms the value of the platform as a quick and on-site communication tool between research groups, since the answer that ranks second is the connection between departments and hospitals. As mentioned in the stakeholders section, mobility of knowledge and connection of groups of experts are a main target of the project and this seems to find correspondence to the experts who fulfilled the questionnaire.

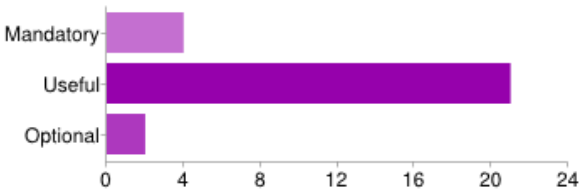
Hair Bundle capacitance [Apex of the cochlea: LUMPED ELEMENT model of electrical coupling]



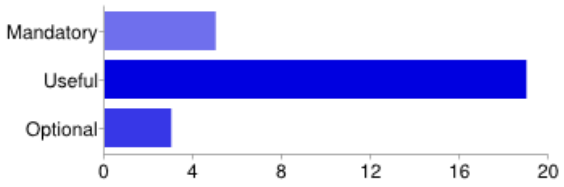
Hair Bundle resistance [Apex of the cochlea: LUMPED ELEMENT model of electrical coupling]



Sensitivity to displacement of the RL [Apex of the cochlea: LUMPED ELEMENT model of electrical coupling]



Sensitivity to velocity of RL [Apex of the cochlea: LUMPED ELEMENT model of electrical coupling]



There are many parameters associated with any model of electrical behavior in the cochlea. Four of those parameters are taken to be representative of the interest of the survey participants in the electrical aspects of the model:

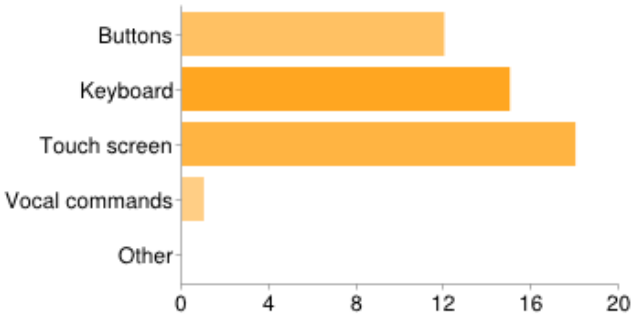
- hair bundle capacitance
- hair bundle resistance
- sensitivity to displacement of the RL
- sensitivity to velocity of the RL

We can conclude from the responses that a significant majority of the participants see the electrical aspects of the model as being useful, and some see these aspects as mandatory.

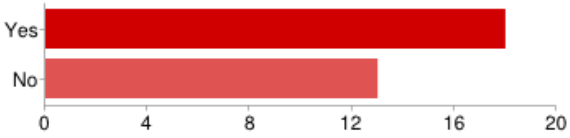
It is thus important that these aspects are incorporated into the model, and important that the parameters used are as realistic as possible.

The four parameters selected also happen to be significant for any model of the cochlea that includes active outer hair cells. Of the four, the parameter considered by the most participants to be mandatory is the hair bundle capacitance, which is widely known to have a significant effect on the time constant of outer hair cell response.

What is the more immediate and easier type of interface for the experts' interaction with SIFEM (mainly consider the 3D Visualization and properties editing?

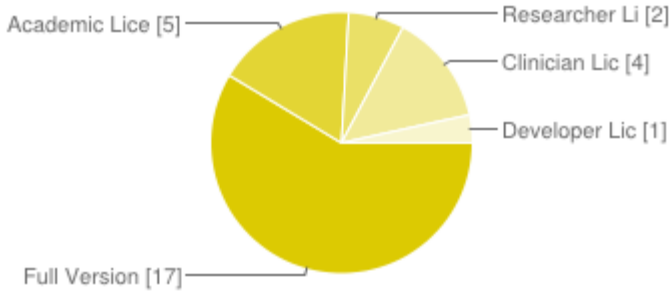


Do you believe there should be different versions of interface for researchers, clinicians and educational stuff?



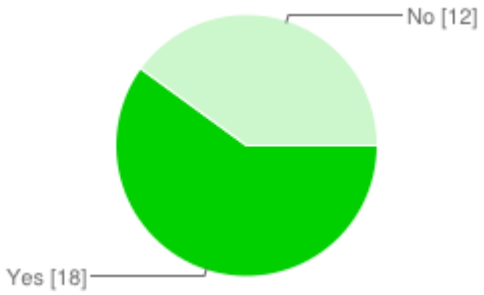
One more question that verifies the necessity for two different types of interface, regarding to different user profiles and needs.

Should we distribute the SIFEM solution under different licenses and different functionalities?



Here the answers are divided, since the majority prefers the spread of a full version for all users, but a strong minority is divided between some partial solutions. The important message is that most of the users might not need access for the full version, but maybe a potential access on demand would be useful for everybody, given that the full version would be time and memory consuming.

Would you use the SIFEM system in case it won't be CE certified?

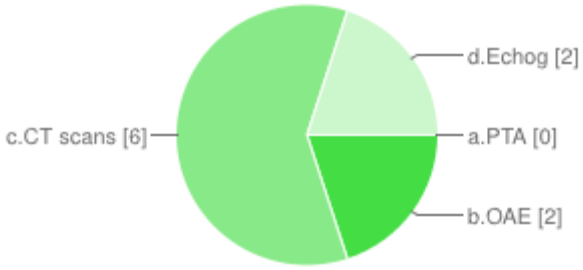


Which clinical use do you think SIFEM will provide?

a. Diagnosis	23%
b. Design of a new hearing test	19%
c. Hearing aid design improvement	19%
d. Cochlear implant design improvement	23%
e. Cochlear implant rehabilitation	15%

The answers to this question verify the main direction of the project. 51% of the answers agree that the main use of the platform will be the either directed to hearing aids and cochlear implants improvement, while only 23% believe that the direct outcome could be used for diagnosis of the particular patient.

Which clinical data would you be interested in feeding?



a. PTA	**0**	0%

b. OAE **2** 20%

c. CT scans **6** 60%

d. Echog **2** 20%

A very interesting conclusion, generated by the answers provided to this question is that none of the participants believes that the platform could be so developed that PTA (Pure Tone Audiogram) could be used as input. This would demand generic and at the same time reliable and translation of the clinical outcome (PTA) to exact pathology of the cochlea elements. The total agreement, in lack of PTA usability, is not only useful for the design of the parameters used, but also ensures that the experts who answer the questionnaire are aware of the difficulties and limitations of the project. Consequently, this type of answer is a good indicator for. In contrary, CT scans which rank first, are maybe the best input choice for the development of the platform, but not for its final use.

Would it be helpful in designing a clinical or research protocol?

Yes **10** 100%

No **0** 0%

The agreement in the potential usefulness in developing new research protocols is total.

As a summary, the answers to the questionnaire are considered as both reliable and helpful for users requirement determination. All experts categories were proportionally represented and information was gathered by different points of view. Answers to specific technical questions and correct approaches to prediction of parameters used and outcomes expected regarding to limitations and restrictions of the project show that the choice of the experts user panel was correct. Experts, who answers showed a deep knowledge of the field and an understanding of the project structure.

According to the questionnaire feedback, some conclusions about users requirements can be made.

- Firstly, the platform will be oriented to different user needs and will be structured in different forms in order to serve **research, educational and clinical** needs.
- According to the majority of the answers, researchers will be the main category of users benefited.
- The platform will be web based and will provide the necessary environment for data exchange and collaboration between research teams for ideas exploitation or common projects development. This will satisfy EU policy for research collaboration.
- Time needed for FEM solving should be restricted as possible (preferably not exceeding a few minutes). This could lead to segmentation of the procedures.
- Patient specific clinical use is not expected during the lifetime of this project.
- The platform could be used for cochlear implants and hearing aids development.
- Different versions (extended and brief) of the platform should be available regarding to different needs.

These conclusions, together with some specific remarks made by members of the experts' society, will be seriously taken into account during the planning of the platform, the services provided and the interface design.

6.2 USAGE SCENARIOS DEFINITION AND SYSTEM CASES

At this phase of development of the cochlea FEM, is very difficult to predict the final structure. As a consequence, most likely the majority of the clinical scenarios that will be described in this section will not be applicable. Thus, these scenarios show both the complexity of the problem and the potential levels of verification of the model produced. In any case, these are initial plans and the final usage scenarios will have differences and will be subject to several assumptions and restrictions.

On top of this, this section includes potential scenarios and approaches, based both on physiological function and mechanisms of hearing loss and lesions of several elements of the cochlea. This does not mean that these scenarios will be available or used at the validation procedure and as a consequence, their confirmation is not a success indicator of the project. Moreover, these scenarios are potential pathways of the development of the platform, based on current state of the art of the cochlea function, the pathophysiology of hearing loss and existing models.

Normal hearing

The response of the BM to sounds of different frequencies is strongly affected by its mechanical properties, which vary progressively from base to apex. At the base the BM is relatively narrow and stiff. This causes the base to respond best to high frequencies. At the apex the BM is wider and much less stiff, which causes the apex to respond best to low frequencies. Each point on the BM is tuned; it responds best (with greatest displacement) to a certain frequency, called the characteristic frequency [1]. Lopez-Poveda et al [2] (2007) proved clinically with phsychoacoustic measures that this frequency sites shifts upwards (from apical to basal area) as the stimulus level increases, unlike the rest mammals.

It is believed that the tuning of the BM arises from two mechanisms. One is known as the passive mechanism. This depends on the mechanical properties of the BM and surrounding structures, and it operates in a roughly linear way. The other is the active mechanism. This depends on the operation of the OHCs, and is nonlinear. The active mechanism depends on the cochlea physiological condition.

Sounds of different frequencies produce maximum displacement at different places along the BM, that is, there is a frequency-to-place transformation. If two or more sinusoids with different frequencies are presented simultaneously, each produces maximum displacement at its appropriate place on the BM. In effect, the cochlea behaves like a frequency analyser, although with less than perfect resolution. The resolution is often described in terms of the sharpness of tuning. This refers to the 'narrowness' of the response patterns on the BM. The whole phenomenon is called tonotopy.

Most of the pioneering work on patterns of vibration along the BM was done by von Bekesy (1960) [3]. A rough first-line validation of the model could be based on the findings of this study.

Regarding to the active mechanism, the nonlinear processing of acoustic signals by the ear has been verified by psychoacoustical observations, electrophysiological examinations and the analysis of the saturating behaviour of evoked otoacoustic emissions, but the sources of the nonlinearities remained unidentified. Possible sources include: material, geometrical (the dependence of the stiffness on the displacement) and state-dependent nonlinearities of mechanical structures, the nonlinear mechanoelectrical transduction process of auditory hair cells and nonlinear neural coding of information, e.g. rate intensity functions. A mixture of all these nonlinearities is effective in vivo and it is difficult to distinguish separate causes [4].

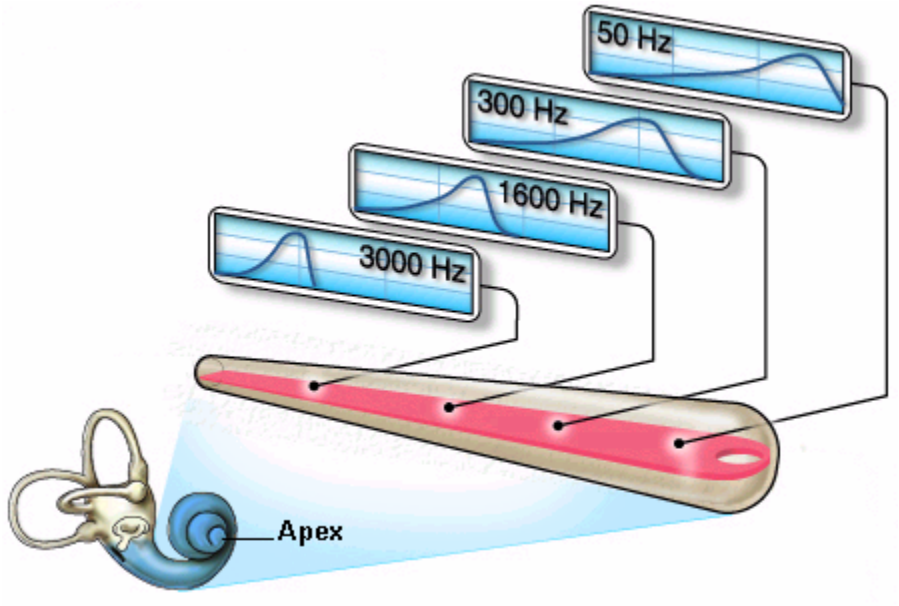


Figure 2: Differences between normal cochlea and Mondini [5]

Ménière disease

Meniere disease is a frequent cause of sensorineural hearing loss. It has an episodic course, with vertigo attacks, tinnitus, aural fullness and fluctuating hearing loss. The course is prolonged and majority of the patients ends up with severe to profound sensorineural hearing loss. The pathophysiology of Meniere disease consists of endolymphatic hydrops. This means that the quantity of endolymph is increased due to unknown causes. Consequently, the pressure of the enolymph is increased and potentially this fact is the causative agent.

According to post mortem temporal bone findings 93% of patients suffering from Meniere's disease [6], while the size of stria vascularis is significantly smaller compared to healthy individuals. Thus, some researchers give a causative relation between hydrops and stria vascularis degeneration at the initial stages and between stria degeneration and hearing loss at the clinical level, since stria vascularis produces the endolymph and is responsible for the endocohlear potential. Disturbance of its function, (as a "battery" of the cochlea) leads to electomechanical coupling dysfunction.

In a potential clinical scenario, the basis of validation would be the detection of volume increase. Secondly, the effect of endolymph volume increase could be checked. A potential verification of sensorineural hearing loss by the platform demonstrated by OAEs absence could be an initial validation of the platform.

According to a recent study, [7] cyclic DPOAE modulation is different in subjects with Ménière's syndrome when compared to the patterns in normal subjects and in other control subjects with non-Ménière's SNHL and/or vestibular disorders. The DPOAEs of normal and non-Ménière's ears were suppressed more during negative ear canal pressure than during positive ear canal pressure. This literature data could be used for validation.

Otherwise, electrocohleography data could be used, since correlation between SP/AP ratio increase in Meniere patients (summating and action potential respectively) are well established in the literature.

More detailed results in the future could include endolymph volume-related response and stria vascularis size change regarding to hydrops. A potential future benefit in both research and clinical level would be the determination of hydrops threshold level, above which hearing loss begins.

Presbycusis/ Noise induced hearing loss

Presbycusis effects great majority of population over 65. Clinically, it consists of progressive hearing loss with accompanying tinnitus and sometimes lack of discrimination. Noise induced hearing loss has a similar clinical outcome (progressive hearing loss and tinnitus), but occurs earlier and in individuals after ongoing or acute noise exposure.

In terms of pathophysiology, both conditions correlate with degeneration of OHC/IHC. Presbycusis occurs with predominantly OHC loss, fractures or scattering, according to the majority of temporal bone studies especially at the basal end. This explains the fact, that hearing loss primarily and most severely occurs at high frequencies. IHC are mostly affected in noise induced hearing loss. Other elements affected in various degrees are spiral ganglion cells, nerve degeneration and basilar membrane (thickness).

Otoacoustic emissions production would be the milestone of a potential validation procedure. A first step would be the lack of detection, especially in the basal turn. Theoretically, a distinction between noise induced hearing loss and presbycusis would be achievable, due to OAE detection, regarding to different pathophysiologic basis. Obviously, this direction of platform use would be valuable in the field of relevant clinical research.

Mondini Deformity

This type of malformation has been described as a flattened cochlea with development only of the basal coil. Instead of two and one-half turns in the bony cochlea, there may be only one and one-half turns, with the middle and apical turns occupying a common space. The agenesis is rarely symmetrical, but both ears always show some degree of malformation. Mondini deformity can cause varying degrees of sensorineural hearing loss, although most individuals have profound hearing loss [8].

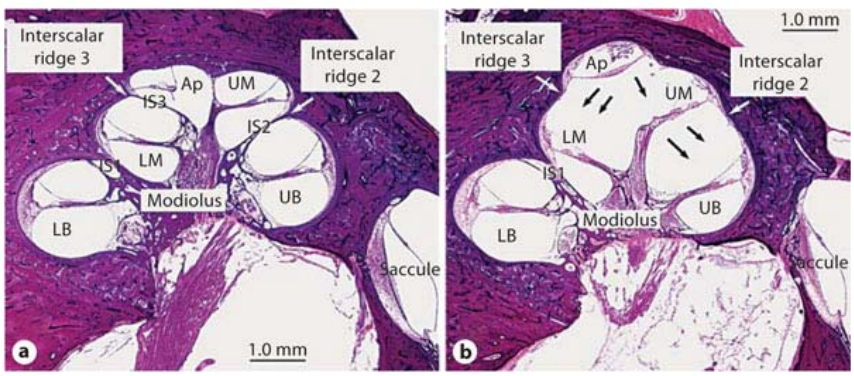


Figure 3: Differences between normal cochlea and Mondini [5]

This lesion could be a basic valistaion model, since there should be no OAE signal at all on the apical turn of the cochlea, since it is completely absent.

Acoustic trauma

Acoustic trauma is an acute hearing loss, after exposure to intense noise (i.e. explosion, burst). It is often accompanied by tinnitus and the sensorineural hearing loss is most commonly more severe circa one octave above the frequency sound.

Recent studies have shown that hair cells can die through different pathways (Bohne et al., 2007; Hu et al., 2002). Some cells die through apoptosis, an active mode of cell death that requires a persistent energy supply, whereas others die from necrosis, a passive mode of cell death due to early disintegration of cells.

The usage scenario in this case could include stimulation of both the stimuli and the response, in order to examine the origin of hearing loss in both types. This means that sound frequency and sound volume could be recorded and produced virtually in the model, after analyzing recorded noises. Then, this input could be fed in the model and detects the output. Given that OHC are mainly affected, lack of detection of DPOAEs could be the validation tool, according to the findings of Moussavi et al (2012), who published a study validating that DPOAEs are affected before PTA.

Nordman et al (2000) published one of the few studies that compare the pathological findings in temporary and permanent threshold shift. They concluded that moderate levels of noise exposure, buckling of the supporting cells results in an uncoupling of the OHC stereocilia from the tectorial membrane which results in a TTS. On top of this, differences between permanent and temporary threshold shift could be studied by repeated scenarios of acoustic trauma.

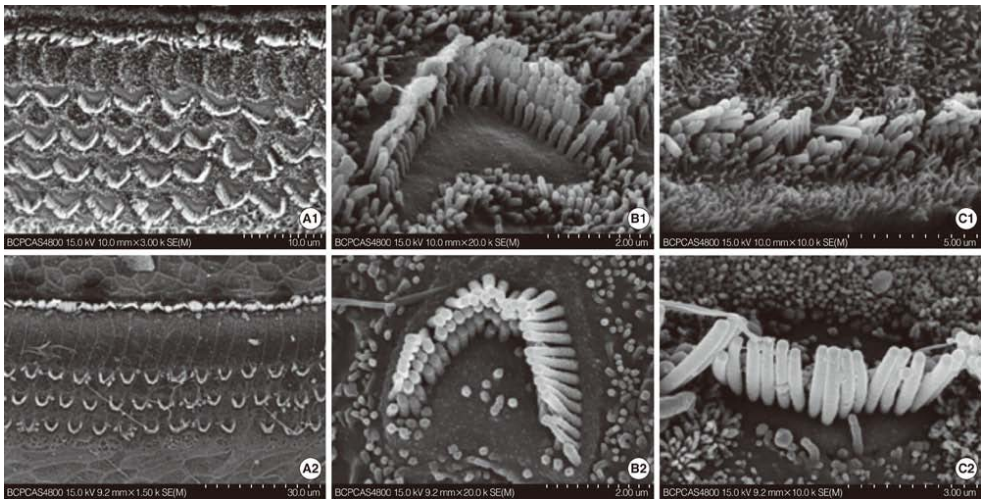


Figure 4: OHC before and after noise exposure with more severe lesions in the apical part [9].

Cochlear implant

Cochlear implant is at the time a surgically implanted device suitable for patients with profound hearing loss or deafness due to hair cell loss. Classic cochlear implants consist of external (microphone, speech processor and transmitter) and internal (receiver and stimulator and an array of up to 22 electrodes that stimulates) parts.

It is estimated that over 200,000 patients have been implanted nowadays (Semen of 2012), outcomes vary from almost full rehabilitation to normal activity to rejection, depending on time of hearing loss (post- or prelingual), patients; expectations, surgical insertion, number of channels and of course quality of the device. Consequently, technology and development of cochlear implantation is cutting edge.

Although the cochlear implants have been successfully developed to restore near-to-normal hearing for profoundly deaf people, several studies have reported severe damage by the implants to the delicate cochlear basilar membrane. In each implant system, a microphone above the external ear receives sound, which is sent to a microprocessor and then converted to electrical currents travelling through an electrode array (consisting of platinum wires embedded in Silastic) inserted into the scala tympani (the lower tubular space of the cochlea), A finite element model was developed by Kha et al (2012) for predicting: 1) frequency of contact between the proximal section of the electrode array on the scala tympani's upper wall, and 2) magnitude of the associated shear stresses at the contact areas.

Cochlea models are one of the main tools for the improvement and development of CI. In fact, the majority of FEM models published in the literature are oriented to CI and more specifically to insertion techniques and lesion caused (Zhang 2011, Kha 2012, Kha 2007, Lim 2005, Chen 2003).

Potential modeling of the active mechanism in the future could be the milestone of improvement of the electrodes activation and CI function and outcomes.

Physiology of Normal cochlea	***Model requirements (dependent on physiology)***	***Validation test***	***Usage scenarios***
Place coding of Frequency across basilar membrane	Mass-stiffness gradient of basilar membrane	Data from literature for expected area along the basilar membrane to be stimulated (peak of	Understand physiology of place coding and cochlea amplifier. Educational

		travelling wave)	purposes
Loudness coding at the level of the basilar membrane	Define minimum and maximum	Increase of the peak of the travelling wave with increasing input signal	Understand physiology. Define maximum BM durability
Pathology of Cochlea	Pathophysiology	Potential validation	Usage scenarios
Mondini deformity	Reduced coiling of the cochlea	Hearing from literature	Model Validation
Meniere	Increased volume/pressure of the fluids.	OAE,Echog	Understand and distinguish role of
Presbycusis	Predominantly OHC loss	OAE, dead regions	Confirm scenarios based on athological findings
Acoustic trauma	OHC cells	OAEs	Explore pathophysiology, distinct PTS/TTS
Cohlear impantation	Lesions in BM	BM vibration patterns	Improve CI outcome

Table 1: Model requirements dependent on physiology of normal cochlea

Engineering & Scientific usage

The identified scientific usage scenarios, which will be analytically defined and presented in D2.3 “SIFEM System Architecture” could be summarized to the following:

- To compare the response of a fully coupled 3D model with simple straight box models, in order to understand the limitation of the box model. The box model is widely used because of its simplicity and computational speed and it is important to understand its strengths and weaknesses.
- To predict micromechanical motion in the active cochlea, which cannot be directly measured using current techniques.

- To individually model the different mechanism of bone conduction hearing and, thus, rank their importance as a function of excitation position and frequency. Several diagnostic methods are based on bone conduction hearing and a better understanding of the mechanisms would throw light on the range of application of these methods.

6.3 SUGGESTIONS ON THE INTERFACE DESIGN

Interface should be practical and user friendly, considering that users will belong to different groups, with different expectations, needs and degrees of konowledge. Consequently, the interface should be designed cleverly in order to be simple enough and attractive for pregraduate students and analytic and detailed for highly sophisticated first line research. A propostion to this direction is that a **basic screen** should be designed covering basic, mainly educational needs. Advanced users with sophisticated needs could seek more detailed information by entering according to their choice in particularly designed parts of the interface which will open specific windows performing more detailed information.

The main screen should have an outline of the basic user categories. In this way it is easy to separate the individual needs of each group. Each category then should have an individual menu board. It is necessary to try and accommodate in the same screen view as much information as possible. It is not at all practical to move through a number of screenshots until the main application is set.

Any type of calibration should be done **automatically** upon entering the software. The same should be done with the initial settings and parameters of the system. There should exist a unique entrance in order to alter these settings. It is difficult to estimate in advance the level of knoweledge of the user.

Visual performance of data is essential. The model output could perform geometry, fluid dynamics, hair cell number and movement, electrical coupling visually both in 2-D and 3-D scale. The schemes and the animations produced would be much more helpful ig they could be rotated 360^{o} in order to give full impression to the users. The input of the tests required should provide a direct output in the same screenshot. It is highly necessary to be able to manipulate the results and provide the ability for data storage and alterations through the test. The data storage should be done in hard and soft copy (depending on the will of the user) and it should be able to be translated in the basic formats.

An added value would be the coloured visualisation of fluid dynamics and electric mobility. Coloured visualisation of all elements is essential in terms of comprehension. Therefore, colour identification should run through the entire simulation process. This should include the type of simulation that needs to be run, the parameters, the results etc.

Another important issue is the access in detailed anatomy data and explanation both of the modelling basis and results. A user should have automatic and efficient explanation of the antomic and physiologic backgrounds and the procedures performed for any output.

Depending on the number of degrees of freedom of the model, the FEM solving could last several minutes or more, which could be helpful if during this time relevent information about cochlea functionulity would be presented. Additionally, at the same time quick multiple choice tests could be performed for educational purposes. Finally, the program could ask the user during computation time for his/her expectation for the particular output. This could be a control mechanism both for users and the platform.

Data collection and overall descpriptive statistics should be automatically present on demand. In order to do so, a multi-tasking menu is required in order to acquire different screenshots at different times. This multi-tasking concept proposes that there should be the capability to run different of altered simulations at the same time. The identification and production of results is secondary but highly necessary. It is expected that users will seek for different results regarding to altered parameters. This means that it should easy for the user to run the application with different parameters and compare the results quicklly and graphically.

The normal presentation of the interface will be in a standard pc format. It is advisable to be able to create a tablet version. The touch screen concept exists in most new software developments.

Overall, the interface shpould be user-friendly and multi-oriented, covering needs of all user categories. It should be simple enough for educational purposes of pregraduate students and at the same time extending to the ability of easy on line data repository exchange between research groups. This means that interface should be flexible and gradually demanding.

7 REQUIREMENTS ASSOCIATED TO VPH NETWORK OF EXCELLENCE

In this section, we summarize the requirements that were identified by the analysis performed by the Virtual Physiological Human (VPH) Network of Excellence[4] (NoE) consortium and presented in their Deliverable (D3.2 VPH Requirements and Technology Assessment Exercise[5]). In addition, this section includes the correlation between the identified requirements by the VPH NoE and the elicited requirements of SIFEM.

The majority of VPH researchers that responded to the Requirements and Technology Assessment Exercise (RTAE) questionnaire expressed *"a need to access computational resources to be able to conduct their research. With access to resources secured, the NoE has to be able to migrate VPH researchers from the desktop workstations that they are currently using to the grid. In the past, many researchers have found the barrier to entry too high when trying to switch to using the grid, so the NoE toolkit must provide tools to lower this barrier to entry. The range of different grid middleware tools employed by various grids means that researchers typically have to learn a number of different client tools and interoperation mechanisms to be able to address all of the resources that they need to use."*

Moreover, respondents to the RTAE questionnaire expressed *"a need to access compute power in a number of different ways, including via the command line, via a portal and via a PDA."*

The above issues are addressed by the SIFEM project, utilizing a GRID infrastructure and a web-based platform that provides access to the SIFEM system and its results. The GRID infrastructure is being used by the FEM solver to perform accurate and quick Finite Element equations solving. In addition, the SIFEM system is being embedded to a web-based platform, providing easy access to modelling tools and the SIFEM outcomes.

In addition, the ability to define workflows was also highlighted as a significant requirement by many RTAE respondents. "*Due to the wide range of research projects represented, a number of different ways to define workflows are required. These included GUI tools and web interfaces and script based workflow tools.*" The SIFEM project overcomes the standardization problem by semantically interlink the Finite Element (FE) tool that will be developed and the open-source supportive tools and libraries with the clinical knowledge as well as the available clinical and experimental data.

[4] http://www.vph-noe.eu/

[5] Available Online:

https://www.google.gr/url?sa=t&rct=j&q=&esrc=s&source=web&cd=2&cad=rja&ved=0CD8QFjAB&url=http%3A%2F%2Fwww.vph-noe.eu%2Fvph-repository%2Fdoc_download%2F51-vph-noe-requirements-and-technology-assessment-exercise&ei=bqbKUaaIFcnlswao74DACg&usg=AFQjCNG0Esl8yMdBUCJVf2q7diO_UAHVwQ&sig2=kZWbl5TMXMyBJBPiU-Abdw&bvm=bv.48340889,d.Yms

Finally, as part of the VPH NoE D3.2 VPH Requirements and Technology Assessment Exercise[6], is included a section on collaborative tools concluding that "*many projects fail or are less successful than anticipated due to poor communication and with a disparate team across Europe and the differences in language and culture apparent, we would look to utilise such tools to overcome difficulties encountered with utilising just emails and teleconferencing. With the move towards reducing travel and lowering our carbon footprint, this opposes the needs of projects where interaction is essential to determine solutions to problems or to establish trust between partners.*"

Therefore, the SIFEM consortium performs a state of the art analysis at the beginning of the project (i.e. D2.1) in order to identify tools and services that could be re-used for segmenting medical images, while open source libraries will be facilitate and extended for constructing the visualization tools (i.e. VTK).

[6] Available Online:

https://www.google.gr/url?sa=t&rct=j&q=&esrc=s&source=web&cd=2&cad=rja&ved=0CD8QFjAB&url=http%3A%2F%2Fwww.vph-noe.eu%2Fvph-repository%2Fdoc_download%2F51-vph-noe-requirements-and-technology-assessment-exercise&ei=bqbKUaaIFcnlswao74DACg&usg=AFQjCNG0Esl8yMdBUCJVf2q7diO_UAHVwQ&sig2=kZWbl5TMXMyBJBPiU-Abdw&bvm=bv.48340889,d.Yms

8 CONCLUSIONS

This deliverable records the requirements of the SIFEM users and guides activities that will be undertaken during Task 2.4 System Architecture and Functional Specifications and reported in D2.3 SIFEM System Architecture. The activities performed during Task 2.2 and recorded in this deliverable mainly conclude to the following:

- The main outcome of the project and the developed Semantic Infostructure mainly targets the clinical and biomedical research and less the educational directions.
- Additionally, it should be noted that direct outcomes of this project cannot be included in every day medical practice.
- The final Semantic Infostructure will be open source and web based. Future users wish a web based platform, suitable for data repository and exchange, quick and real time communication, research ideas establishment and development.
- The main clinical scenarios that were preliminary identified and will be targeted by the project activities are the following:
    - Normal hearing
    - Meniere disease
    - Presbycusis/ Noise induced hearing loss
    - Mondini Deformity
    - Acoustic trauma
    - Cochlear implant
- The main engineering and scientific scenarios could be summarized to the following:
    - To compare the response of a fully coupled 3D model with simple straight box models, in order to understand the limitation of the box model
    - To predict micromechanical motion in the active cochlea, which cannot be directly measured using current techniques
    - To individually model the different mechanism of bone conduction hearing and thus rank their importance as a function of excitation position and frequency

9 APPENDIX: QUESTIONNAIRES

In this sub-section, the questions are reported that were structured in the form of an online Questionnaire, using Google forms powered by Google Drive.

(Fill in the questionnaire writing or ticking in the block. You can give more than an answer.)

1 Generic Questions

1.1 General Aspects

Background	
Date	

1. Age

Under 30	
Between 30 and 40	
Between 40 and 50	
Between 50 and 60	
Over 60	

2. Company, Organization	
3. Country	
4. Role	

5. Computer Use	*Everyday*	*3-5 times/week*	*1 time/week*	*Less than one time/week*
6. Computer skills	*Very good*	*Little difficulties*	*Many difficulties*	*Computer? What is it?*

System Usage Scenarios

Please consider the SIFEM project as a final solution:

7. The main functionality of the system and the domain that the SIFEM should mainly target is:

Educational (education and training)	
Research	
Clinical	

8. Who are the final users of the system?

Private Clinicians	
Groups of clinicians (i.e. public or private bodies such as a Hospitals, Healthcare Institutes)	
Researchers / Healthcare Professionals	
Researchers / Biomedical Engineers	
Postgraduate / Pregraduate Students	

Additional Comments

1.2 Functional Aspects

General Issues

9. The final SIFEM platform should be published on the web;

Yes, definitely since I want platform-independence and terminal-independence	
I don't mind about the modelling but I want the results to be stored in my computer	
No, I want it installed only on my computer	

10. Please select the maximum acceptable response time for the 3D visualization;

Less than a minute	
Few minutes	
Over 5'	
Over 10'	

11. Please select the maximum acceptable response time for the FEM solver;

Less than a minute	
Few minutes	
Over 5'	
Over 10'	
Interoperability and connection to PACS	

12. Which additional functionalities are necessary to be included in the final product;

A simple collaboration environment where I can chat with other researchers/clinicians and exchange data/knowledge	
Communication with the Hospital's Electronic Health Record (EHR ready to acquire DICOM images or other clinical information directly from the patient's EHR)	
Bidirectional communication with the Hospital's Electronic Health Record (EHR ready to acquire DICOM images or other clinical information directly from the patient's EHR and store information exported by SIFEM modelling activities directly to EHR)	
Address specific standardization policies (i.e. Health Level Seven International (HL7 v2)	
Interoperability and connection to picture archiving and communication system (PACS). PACS is a medical imaging technology which provides economical storage of, and convenient access to, images from multiple modalities (source machine types). Electronic images and reports are transmitted digitally via PACS; this eliminates the need to manually file, retrieve, or transport film jackets. The universal format for PACS image storage and transfer is DICOM (Digital Imaging and Communications in Medicine).	
Please report any other functionality (i.e. include ICD-10 terminology, etc.)	

13. What is the more immediate and easier type of interface for the experts' interaction with SIFEM (mainly consider the 3D Visualization and properties editing)?

Buttons	
Keyboard	
Touch screen	
Vocal commands	
Other	

14. Do you believe there should be different versions of interface for researchers, clinicians and educational stuff?

a. Yes
b. No

Additional Comments

1.3 Exploitation Aspects

Financial Aspects

Please consider the SIFEM project as a final open-source solution:

15. Should we distribute the SIFEM solution under different licenses and different functionalities?

Full Version	
Academic License (system cases with dump data for demonstration)	
Researcher License (focusing mainly on the FE geometry and mechanical modelling)	
Clinician License (focusing mainly on the 3D visualization and the pathologies)	
Developer License (mainly the SDK for the FEM tools)	

16. Would you use the SIFEM system in case it won't be CE certified;

Yes	
No	

17. In your opinion, who should download and use the system?

Private Clinics	
Public Hospitals	
University Hospitals	
Universities	
Research Organizations	
Other	

Additional Comments

2 Clinician-Specific Questions

1. Which clinic-pathological scenarios would you be interested in predicting a model response?

a. Increase endolyph volume in the scala media and predict the travelling wave response
b. Change mechanical properties of the cochlea (mass/stiffness of the basilar membrane etc)
c. Dead regions of the cochlea
d. Stimulation of 3rd window effect

e. Inner/Outer Hair Cell loss
f. Mechanical fatigue after continuous overload (noise exposure)
g. Other (open).....

2. Which outputs of the model would you be interested in?

a. Travelling wave visualisation
b. Transfer function of the cochlea (stapes volume/velocity)
c. Input/output function of otoacoustic emissions
d. Fluid dynamics visualisation

3. Would you intent to use SIFEM as a personalised model to be used as a clinical tool for individual patients?

a. No
b. Depends on speed
c. Depends on how easy is to use the platform
d. Depends on reliability of data
e. Depends on clinical usefulness of data

4. Based on the abbreviations indicated below please indicate the material properties that should be used the FE cochlear model:

Name	Abbreviation	Name	Abbreviation
Basilar membrane	BM	Henson cell	HC
Tectorial membrane	TM	Deiters's cell	DC
Reissner's membrane	RM	Reticular lamina	RL
Outer hair cells	OHCs	Inner sulcus	IS
Inner hair cell	IHC	Hensen's stripe	HS
Stereocilia	St	Inner pillar	IP
Cortilymph	C	Outer pillar	OP
Scala vestibuli	SV	Scala media	SM
Scala tympani	ST	Modiulus	Mod
Organ of Corti	OC		

		Base of the cochlea			Apex of the cochlea		
Name	**Value and unit**	**Mandatory**	**Useful**	**Optional**	**Mandatory**	**Useful**	**Optional**
Fluid density	1×10^{3} kg/m^{3}						
BM density	1×10^{3} kg/m^{3}						
TM density	1×10^{3} kg/m^{3}						
OC density	1×10^{3} kg/m^{3}						
Fluid viscosity	1×10^{-3} kg/(m s)						
BM damping	6×10^{3} N s/m^{2}						
TM damping	3×10^{-2} N s/m^{2}						
OC damping	1×10^{-3} N s/m^{2}						

BM thickness	1.5×10^{-6} m						
BM Young's modulus	2×10^{8} Pa						
TM Young's modulus	1×10^{3} Pa						
OC Young's modulus	40 Pa						
IHC Young's modulus	4×10^{3} Pa						
OHC Young's modulus	6×10^{3} Pa						
DC Young's modulus	1×10^{4} Pa						
PC Young's modulus	4×10^{4} Pa						
RL Young's modulus	3×10^{4} Pa						
TM Poisson's ratio	0.49						
OC Poisson's ratio	0.49						
BM width	2.5×10^{-4} m						
Hair bundle stiffness	10^{-3} N/m						
Longitudinal coupling parameter	0.1						

		Base of the cochlea			**Apex of the cochlea**		
Material properties (human)	**Value and unit**	**Mandatory**	**Useful**	**Mandatory**	**Useful**	**Mandatory**	**Useful**

Fluid density	1×10^3 kg/m^3						
Sound speed in the fluid	$(1.5+0.10i)\times10^3$ m/s						
Bone density	5.4×10^3 kg/m^3						
Bone Poisson's ratio	0.3						
Bone Young's modulus	2.1×10^{15} Pa						
Round window density	2×10^3 kg/m^3						
Round window Poisson's ratio	0.3						
Round window Young's modulus	7×10^4						
Round window loss factor	0.857						

5. LUMPED ELEMENT model of electrical coupling

Longitudinal resistances

		Base of the cochlea			Apex of the cochlea		
Name	**Value and unit**	**Mandatory**	**Useful**	**Optional**	**Mandatory**	**Useful**	**Optional**
Scala Vestibule (SV)	3×10^{6} Ω/m						
Scala Media (SM)	5×10^{6} Ω/m						
organ of Corti (OC)	150×10^{6} Ω/m						
Scala Tympani (ST)	15×10^{4} Ω/m						
Stria Vascularis	0 Ω/m						

Transverse resistances to ground

		Base of the cochlea			Apex of the cochlea		
Name	**Value and unit**	**Mandatory**	**Useful**	**Optional**	**Mandatory**	**Useful**	**Optional**
SV	10 Ω.m						
SM	27 Ω.m						
OC	4 Ω.m						

Hair bundle parameters

			Base of the cochlea			Apex of the cochlea		
Name	**Base**	**Apex**	**Mandatory**	**Useful**	**Optional**	**Mandatory**	**Useful**	**Optional**
Hair Bundle capacitance	5.6×10^{-8} F/m	3.16×10^{-7} F/m						
Hair Bundle	10000	10000						

resistance	Ω.m	Ω.m						
Sensitivity to displacement of the RL	2×10^{-3} A/m	2.5×10^{-4} A/m						
Sensitivity to velocity of RL	5.23×10^{-6} C/m	8.18×10^{-7} C/m						

OHC soma parameters

			Base of the cochlea			**Apex of the cochlea**		
Name	**Base**	**Apex**	**Mandatory**	**Useful**	**Optional**	**Mandatory**	**Useful**	**Optional**
OHC membrane capacitance	2.8×10^{-7} F/m	1.58×10^{-6} F/m						
OHC membrane resistance	550 Ω.m	1500 Ω.m						
OHC piezoelectric constant	2.4×10^{6} m/C	2.4×10^{6} m/C						

6. Which clinical use do you think SIFEM will provide?.

a. Diagnosis
b. Design of a new hearing test
c. Hearing aid design improvement
d. Cochlear implant design improvement
e. Cochlear implant rehabilitation

7. Which clinical data would you be interested in feeding?

a. PTA
b. OAE
c. CT scans
d. Echog

8. Would it be helpful in designing a clinical or research protocol?

a. Yes
b. No

Additional Comments

3 Researchers/Software Engineers-specific questions

1. The boundary conditions should be:

Default by the system	
Manually entered	
Default with the possibility of manually editing	

2. Please specify the input format to the FEM modelling;

DICOM	
Other image format (.jpg, .png)	
Other format type	

3. Which are the necessary output formats of the FEM modelling and 3D geometrical data?

.XML	
.OBJ	
.3DS	
.MAX	
ANSYS format	
OpenFOAM format	
FEMAP format	
Fluent format	
Other	

4. Which stimulations would you be interested to see in a cochlea model?
   a. Graphically view the output of the travelling wave
   b. Pathological scenarios (e.g. Meniere, presbyacousis, sudden hearing loss) by changing mechanical properties like hair cells
   c. Input of single tones and combination
   d. Input of musical theme and corresponding cochlear implant

5. Do you think a cochlea model would be useful in
   a. designing new cochlear implants
   b. designing middle ear implants
   c. designing new speech strategies in cochlear implants

4 Educational Groups (Biomedical Engineers)-specific questions

1. Which will be the main educational group to benefit from SIFEM
   a. Medical students
   b. Biology students
   c. ENT residents
   d. PhD students
   e. Computer science students

2. Do you think SIFEM could be educationally useful without previous consultation?

f. Yes
a. No
b. Depends on interface

3. SIFEM could be used to integrate innovative research ideas?

a. Yes
b. No

5 Other Possible parameter values for the electrical coupling

On the macroscopic level:

For a LUMPED ELEMENT model of electrical coupling, we have longitudinal resistances [Ohm/metre] for the:

- scala vestibuli,
- scala media
- organ of Corti
- scala tympani.
- stria vascularis (usually assumed to be zero)

In addition we have transverse resistances to ground [Ohms . metres] from the:

- scala vestibuli,
- scala media
- scala tympani.

- The longitudinal resistances vary from base to apex with the cross-sectional area of the various structures. Hence for a FINITE ELEMENT model, which would already include the geometry for the mechanical parts of the model, it should only be necessary to know the conductance [Siemen/metre] of:
- perilymph
- endolymph
- stria vascularis material (not sure if it has a name)

For the longitudinal resistances, it would then be necessary to know:

- surface resistance of Reissner's membrane [Siemen/metre^2]
- and an analogous surface resistance for the interfaces between the stria vascularis and the scala media, and between the scala tympani/vestibuli and the spiral limbus.

We also need:

- resting potentials of the scala media versus scala vestibuli/tympani

At the microscopic level:

Hair bundle:

- hair bundle capacitance + hair cell apical capacitance
- hair bundle resistance
- sensitivity of hair bundle resistance to displacement
- sensitivity of hair bundle resistance to velocity. (It would be nice to include adaptation kinetics to the model, but for anything but the simplest model, this would require including Ca ion transport and the action of myosin molecules in the model, which is really beyond the scope of the project. A gating-spring model may be useful, but anything but the simplest model could require mechanical modelling at the tip-link level, which (I think) is also beyond the scope of the project)
- saturation MET channel current - in general this will be asymmetric

Hair cell:

- - hair cell membrane capacitance
- - hair cell membrane resistance
- - hair cell piezoelectric constant
- - Nerst K+ ion hair cell membrane potential

It is usually assumed that these parameters do not vary longitudinally from base to apex. However, they are different for outer and for inner hair cells.

Of interest to the cochlear implant community may be:

- neural membrane capacitance
- nerve fibre conductance
- bone conductivity

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