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Next Generation Earplugs

A Deep Insert Solution

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Preface

This master's thesis was written at the Norwegian University of Science and Technology as part of the study program at the *Department of Mechanical and Industrial Engineering*. It was carried out for *SINTEF Digital* during the spring semester of 2018, as a continuation of my project course work. I got to know the people at SINTEF through the NTNU course Experts in Teamwork during the spring semester of 2017, and contacted them in the search for an exciting product development project. The idea of developing a deep insert earplug was part of an early phase project that SINTEF had barely initiated, and was tailored to my specialization field, Product Development and Materials Engineering, as a topic for the project and master's thesis.

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Jørgen Amundsen

Acknowledgment

First of all, I'd like to express my sincere gratitude for the consultancy by my supervisor, Associate Professor *Knut Aasland*, and SINTEF co-supervisor, *Olav Kvaløy*. Additionally, I want to thank *Odd K. Pettersen* and *Audun Solvang* at *SINTEF Digital* for initiating the project and providing technical guidance along the way.

I appreciate all the support and assistance I have gotten throughout the project. Without the goodwill from both the *Department of Mechanical and Industrial Engineering* at NTNU and *SINTEF Digital*, the project would not have been executable.

J.A.

Abstract

Noise-induced hearing loss can in most cases be prevented with conscious use of hearing protection devices. Even though there seems to be much more attention directed towards attenuation levels of these devices, there are several indications of comfort being just as - if not more - important. A lot of the commercially available hearing protection devices seem to be a compromise between degree of sealing and comfort. The present work was conducted to explore possibilities for, and develop concepts to, a *deep insert earplug* solving these compromise issues. An extensive literature study laid the foundation for the conceptual designs that were developed. As a result, a water-filled deep insert earplug with a controllable sealing part was developed through rapid prototyping and the wayfaring design model. The progression was driven by continuous testing of comfort and functionality, eventually leading to the final deep insert earplug concept. An automated test method, *New Early Warning Test*, was utilized to indicate the attenuation levels of the prototypes. The deep insert earplug was tested at different ear canal depths and compared with commercially available hearing protection devices. Attenuation levels at well over 30 dB were shown to be yielded by the prototypes. The benefits of an earplug sealing deep in the ear canal have been indicated. Moreover, the advantages of utilizing water as a medium for both attenuation and hydraulic control of the sealing part in hearing protection applications have been revealed.

Sammendrag

Hørselstap som følge av støy kan i de fleste tilfeller unngås med bevisst bruk av hørselvern. Til tross for at veldig mye fokus rettes mot hørselsvernets dempeevne, er det mye som tyder på at komfort er minst like viktig, om ikke viktigere. Det kan derimot virke som om mange av variantene på markedet er et kompromiss mellom tetning og komfort. Arbeidet i dette prosjektet hadde som formål å uforske mulighetene for, og utvikle konsepter til, en dyptsittene (deep insert) ørepropp som kan forbedre både tetning og komfort. Et omfattende litteraturstudium la grunnlaget for de konseptuelle løsningene som ble utviklet. En vann-fylt, dyptsittende ørepropp med en kontrollerbar tettedel ble utviklet gjennom prototyping og wayfaring-metoden. Utviklingen i prosjektet ble drevet fremover ved kontinuerlig testing av komfort og funksjonalitet, noe som førte til det endelige konseptet for en deep insert ørepropp. En automatisert testmetode, *New Early Warning Test*, ble benyttet for å anslå dempeevnen til prototypene. Ørepluggen ble testet på flere ulike dybder av øregangen, og sammenlignet med andre kommersielle varianter av hørselvern. Testingen viste lovende resultater, med en dempingsevne på godt over 30 dB for prototypene. Fordelene med et hørselvern som tetter mot den benede delen av øregangen, i tillegg anvending av vann som medium for både lyddemping og hydraulisk kontroll av tettedelen, har blitt indikert.

Acronyms

ANR Active noise reduction

CIC Completely in the canal

DI Deep insert

EAC External auxiliary canal

GUI Graphical user interface

HA Hearing aid

HL Hearing level

HP Hearing protection

HPD Hearing protection device

MLE Maximum likelihood estimation

NEWT New Early Warning Test

NIHL Noise-induced hearing loss

NPD New product development

PLA Polylactic acid

PD Product development

PVA Polyvinyl alcohol

REAT Real-ear attenuation at threshold

RTV Room temperature vulcanizing

SBD Set-Based design

SBPD Set-based product development

SD Standard deviation

SNR Single number rating

TM Tympanic membrane

Contents

Chapter 1

Introduction

This chapter sets the scene for this Master's thesis and state the motivation for developing a *Next Generation Earplug*. Background and motivation is briefly presented, before the actual problem is defined. Scope of Work includes previous work, objectives and delimitations, and sets the framework for the project. Lastly, the rest of the report is summarized in Structure of the Report.

1.1 Background and Motivation

Earplugs are widely used as hearing protection (HP), both for personal, military, and industrial purposes. The awareness of hearing health seems to be steadily increasing among people, and with good reason. Noise-induced hearing loss (HIHL) is a common problem, and despite being challenging to estimate with precise numbers it is reported to be the second most common occupational illness recorded in the U.S. (Murphy et al., 2011). These illnesses are almost always preventable if wearing hearing protection devices (HPDs) properly. However, HPDs are avoided by many individuals because of discomfort or conflicting equipment. Davis (2008) outlines previous research and explores issues related to hearing protector comfort, stating the importance of comfort pretty clearly:

> "The most effective hearing protector is the one that is worn consistently and correctly."
>
> *Davis (2008)*

The background for this Master's thesis, in addition to a somewhat promising market potential, was an idea brought up by the acoustics department of *SINTEF Digital* of a *deep insert* earplug. Groundwork, benchmarking and a brief exploration of such a concept was conducted through the Project thesis work preliminary to this study. Consequently, a set of outlines were set to formulate the problem description for this thesis and direct the development process in a certain direction.

1.2 Problem Description

Both hearing protection devices and earphones need to seal the ear canal properly to attenuate sounds from the surroundings. They will all be a compromise between degree of sealing and comfort. The project aims at developing an earplug that yields better sealing and better comfort than existing solutions. This is accomplished by using entirely new ideas for sealing the ear canal.

1.3 Scope of Work

The ear and ear canal, much like any other part of our body, differs from person to person. These differences are also seen across genders and populations. Ultimately, this directly affects comfort and protection levels of any hearing protection device. There are several products that are supposed to serve the market for hearing protection, but no single type of device is optimal for every situation or individual. Therefore, it is desirable, and a scope of this work, to develop

a uni-ear, deep insert earplug that yields great comfort and usability, with a high level of attenuation.

1.3.1 Previous Work

During the project thesis work, the concepts of a deep insert earplug were explored quite briefly. Literature on human ear canal anatomy and HP attenuation was extensively studied, making up for a solid foundation for the literature reviewed in this thesis. Some benchmarking was done to map out the existing market of similar products. However, the project thesis was only scraping the surface regarding concept generation and development. A few concepts were explored through prototyping, but the lack of target specifications and explicit purposes resulted in a somewhat vague physical outcome. Different concepts on foam variants with controllable cross-sections were mainly focused on, in which a sealed surface foam plug that was shrunken down by vacuum yielded the best results. However, the prototypes were only tested with respect to functionality, and not comfort or attenuating effect. Among the recommendations for further work, there were particularly two points that had been taken into account beforehand the development work in this master's thesis. Firstly, a proper list of target specifications will be created to have a defined framework to develop within. Secondly, the research and discussion done on using liquids as an attenuating medium will be central in the extended work of this project. The concept of taking advantage of the attenuating effect from sound transmission in air-liquid interfaces will be put under scrutiny, and certainly indicates benefits too promising not to investigate further.

1.3.2 Objectives

The main objectives of this Master's thesis, listed in a tentative order order of execution, are:

1. To investigate and enlighten literature on the human ear canal and other research relevant for designing a properly fitting deep insert earplug.
2. To generate conceptual solutions to a comfortable, easy-to-use, well sealing deep insert earplug.
3. To explore and verify concepts through prototyping and testing, using acknowledged design methodologies.
4. To test the attenuating abilities of the final concept in the acoustics laboratory at *SINTEF*.

1.3.3 Delimitations

Findings in the previous work and more newly discovered literature indicate that liquids can make up for great attenuating media. Consequently, this research will set out to explore concepts with these particular assumptions in mind. Being a new product development (NPD) project, the work strategy is going to empathize with a front-loaded approach to the design and development journey. The confidentiality agreement made with *SINTEF Digital* is assumed to delimit the methods of investigation to some extent. Most design methodologies highlight teamwork and interlaced knowledge as one of the requirements for solving engineering problems efficiently and effectively. Although the supervisors provide expertise in both the acoustics field and the product development field, the multidisciplinary nature of this earplug development project is considered slightly delimited by the one-man, homogeneous developer team. Time limits will always play a significant role concerning the results, and is especially threatening for a development project with such high uncertainties. First and foremost, the work will be aiming at developing a sealing part of the plug that can reach proper ear canal depths to be a deep insert plug. In other words, the functionality and comfort will be the aspects most focused upon, and any attenuation testing is considered a bonus.

1.4 Structure of the Report

The thesis will be structured in a fairly classical way, in terms of scientific reports. Literature review, method, results, discussion and conclusion are all presented in order, but divided slightly differently. Firstly, a literature review is presented in *Chapter 2* to set the foundation for anatomical terms and dimensional studies published on the ear canal. Additionally, some different aspects of sound attenuation is presented here. In *Chapter 3* a product specification is defined through customer understanding, a full-system concept outline and target specifications. *Chapter 4* presents the design methodologies used for the development and prototyping. Concept generation and ideation for the deep insert earplug is presented in *Chapter 5*, making up for the solutions explored and developed in *Chapter 6*. Attenuation measurements of the final full-system earplug concept are presented in *Chapter 7*. All results from the work - both physical and empirical - are discussed in *Chapter 8*, as a basis for the given further work recommendations. Lastly, an overall conclusion is made in *Chapter 9*. Appendices are placed at the end of the report.

Chapter 2

Literature Review and Groundwork

This chapter presents most of the literature relevant for this master's thesis. Being an extension of the somewhat more vague and exploring work done in the project thesis, major parts of the literature study are still of high relevance. Several sections therefore remain rather untouched as they will be referred to in the thesis, including ear canal anatomy, dimension studies and bone conduction. The chapter will furthermore enlighten the principles of sound transmission between different media, as a key phenomenon and basis for the development of the next generation deep insert earplug.

2.1 The Anatomy of the Human Ear Canal

The book *The Human Ear Canal* by Ballachanda (2013) has been one of the main sources in the process of getting to know the human ear canal, which is especially important to fit a deep insert earplug. This brings up a question that should be defined and explained:

> *What defines a deep insert earplug, and why is this preferable?*

Ballachanda (2013) defines a deep canal hearing aid as "*. . . a device that terminates beyond the second bend and makes contact with the bony portion of the external auditory canal.*" See Figure 2.1. This definition will also be applicable in the case of an earplug, as the term "deep canal" is referring to how deep the tip of the product fits into the ear.

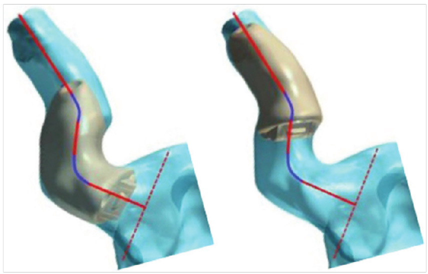


Figure 2.1: Two completely-in-the-canal (CIC) products, where the deep fitting CIC product is shown to the right. Illustration by Starkey Laboratories (Ballachanda, 2013).

Figure 2.2 illustrates the anatomical basics of the human ear canal, which is part of the outer ear. The ear canal has a two-part skeletal structure. Firstly, it has a lateral part, the *cartilaginous* canal, consisting of elastic cartilage. Secondly, it has a medial part, the *osseous* canal, consisting of bone. The ear canal is not straight, but has a rather complicated geometrical appearance as it moves from the entrance (*concha*) and in towards the tympanic membrane (TM), also known as the eardrum. As can be seen in Figure 2.2 it has two bends, creating a twisted cavity with dimensional alterations along the length. The canal bends upwards at the first bend, before it turns downwards at the second bend, towards the eardrum. To get the maximum attenuating effect from a

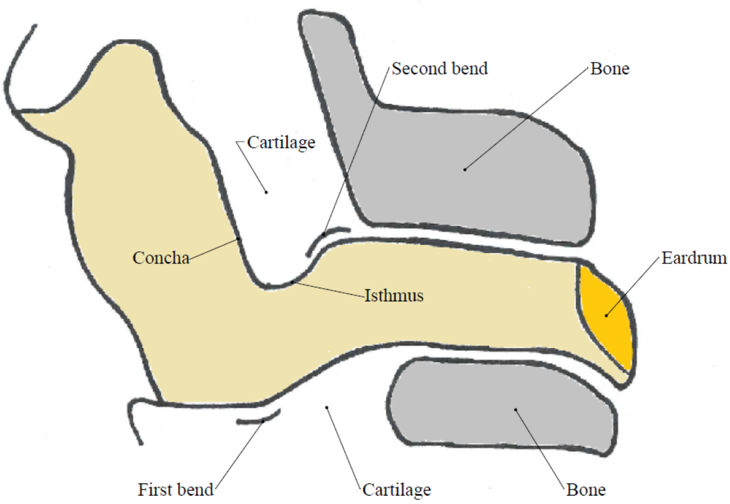


Figure 2.2: Simple anatomical illustration of the human ear canal.

hearing protection device like an earplug, it is desirable to seal the ear canal at the bony part, so that it is only bone conduction transmission paths that are restrictive concerning attenuation. As a reference to the level of attenuation, Berger et al. (2003) showed through real-ear attenuation at threshold (REAT) measurements that deeply inserted foam plugs can yield maximum attenuation levels at 500Hz frequencies of 47.8 dB. Another possible benefit with deep insertion is that the bony part of the external auxiliary canal (EAC) will probably be less in play than in the cartilaginous in the case of movements (e.g., moving the jaw). The catch with plugging the bony part is the thin and easily irritable skin of the osseous canal. Ballachanda (2013) state that the thickness of the osseous canal skin measures approximately 0.1-0.2 mm in thickness, down to as little as one-fifth of the cartilaginous canal skin thickness. A journal article by Staab et al. (2000) points out that even a pressure of 0.5 g/mm^2 in the bony canal, equal to the weight of a piece of paper, is reported to cause pain. This proves the kind of sensitivity that deep insert HPDs are dealing with.

2.2 Ear Canal Dimensions

Physical dimensions of the ear canal are key for developing a deep insert HPD. This is fundamental in determining size and shape of the device, both radially and axially. It has to be small enough to get into the osseous canal, but with no danger of going too close to the tympanic membrane. The narrowest portion of the canal, *isthmus*, is stated by Ballachanda (2013) to be located right in the junction between the cartilaginous and osseous canal, which will have to be passed to accomplish a deep insert earplug. Several methods have been developed throughout the years on dimensional analyzing of the ear canal, and some of the results are presented in Table 2.1. These measurements are done on cadavers, not live individuals, and thus there may be some minor aberrations from reality. The measuring endpoints are also not directly specified.

Parameters	**Total** (n=280) [mm]	**Male** (n=160) [mm]	**Female** (n=120) [mm]
Length	23.5 ± 2.5	25.2 ± 2.6	22.5 ± 2.3
Longest diameter	9.3 ± 0.9	9.7 ± 1.1	8.5 ± 0.7
Shortest diameter	4.8 ± 0.5	5.1 ± 0.7	4.4 ± 0.3

Table 2.1: External ear canal measurements gathered from 280 silicone impression molds of 140 cadavers. Adapted from Staab et al. (2000).

The results presented by Stinson and Lawton (1989) from studying 14 individual ear canals seem to be a more practical approach for this exact purpose. These measurements are illustrated in Figure 2.3 by an axis starting at the inferior part of the eardrum, going concentrically within the ear canal, and extend 2 to 3 mm into the concha. The results on the EAC lengths are reported to range between 27 and 35 mm. It is important to point out that these lengths are measured over a curved concentrical axis, and will realistically be 3 to 4 mm shorter when measured along a straight line.

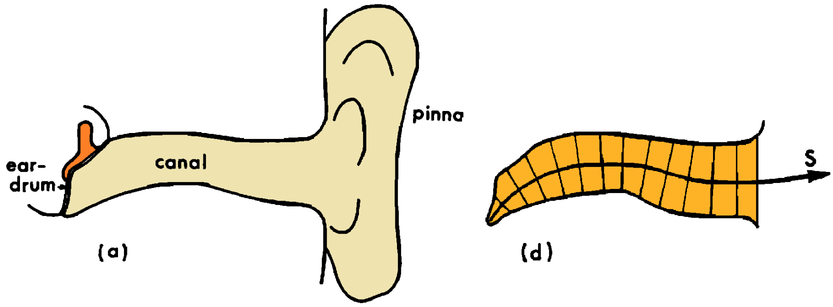


Figure 2.3: Illustrations from Stinson and Lawton (1989) and how their measurements was done from the inferior point of the tympanic membrane, following center line S.

In addition to the ear canal lengths, Stinson and Lawton (1989) also gathered cross-sectional areas. The results from these measurements have been charted in Figure 2.4, as a function of position along the curved S-axis. Even though the cross-section of an ear canal has more of a random oval-like shape, these measurements can be used as a guideline for how a uni-ear plug could be designed. For the sake of simplicity, if assuming a circular shape along the S-axis and using the same measurements for the cross-sectional area, the diameter of the cross-section is given by $d = 2\sqrt{A/\pi}$, and calculated in Table 2.2.

Diameter	**Position, S [mm]**						
	0	5	10	15	20	25	30
Mean [mm]	0	5.6	7.0	8.0	7.8	8.6	9.8
Min. [mm]	0	4.5	5.3	6.0	5.9	6.7	8.0
Max. [mm]	0	6.4	8.3	9.2	9.1	10.5	11.0

Table 2.2: Mean, min., and max. diameter along the S-curve, based on area data from Stinson and Lawton (1989).

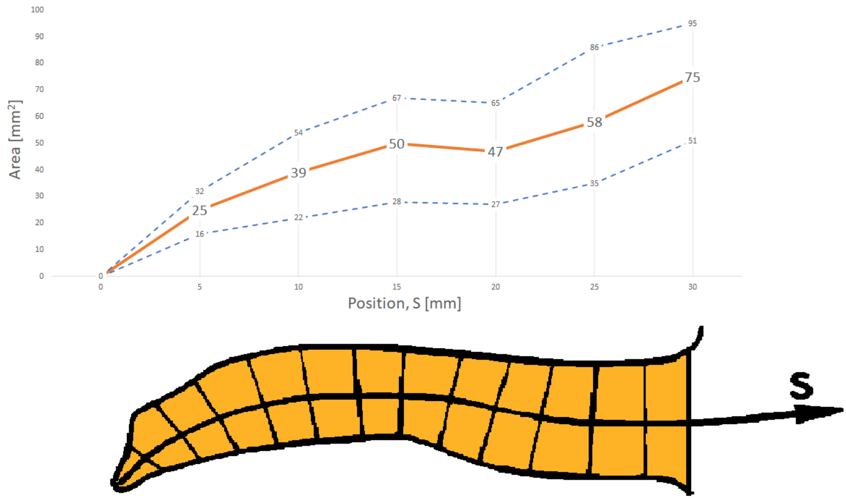


Figure 2.4: Measurements gathered from Stinson and Lawton (1989), showing the average cross-sectional area from a study of 14 individual ear canals. The dashed curves show the range of variation.

2.3 Bone Conduction

When the earplugs are properly inserted and penetrating deeply into the ear canal, what limits the attenuation is bone conduction (BC). Berger et al. (2003) provide indication that BC limits the achievable attenuation to a mean value range of 40 to 60 dB, depending on the frequencies. REAT values from measuring the limiting attenuation levels of conventional foam earplugs are further reviewed in Section 2.4.

2.4 Foam Earplug Attenuation

The obtainable attenuation by a foam earplug is dependent on several factors. Choice of material is affecting this, but one of the most determining factors will be the insertion of the plug. A deeply inserted (DI) foam plug is by Berger et al. (2003) stated to reach about 80 to 100% of the ear canal depth. *3M E-A-R® Classic® Plus* high-attenuation foam plugs, with a length of 24 mm, was in this study used to get REAT values and obtain the BC limits of humans. It was done by measuring the maximum attenuating effect of these plugs when deeply inserted. The results are shown in Table 2.3 across the frequency range.

Value	Frequency [Hz]						
	125	250	500	1k	2k	4k	8k
Mean [dB]	39.9	44.4	47.8	43.7	37.4	44.4	47.0
SD [dB]	5.5	4.8	3.5	4.2	2.9	3.7	4.7

Table 2.3: Mean REAT and standard deviation values for *3M E-A-R® Classic® Plus* by Berger et al. (2003).

2.5 Sound Transmission In Air-Liquid Interfaces

Transmission of sound over boundaries between different media has been extensively studied over the years. Kinsler et al. (2000) explains the phenomenon of boundary losses with how reflected and transmitted sound waves are generated for acoustic waves travelling over such a boundary, as illustrated in Figure 2.5. The transmitted and reflective waves depend on the characteristic acoustic impedances and speeds of sound of the two media, and can be denoted as ratios of pressure amplitudes and pressure intensities. An extract of relevant physical properties for media of interest is condensed into Table 2.4.

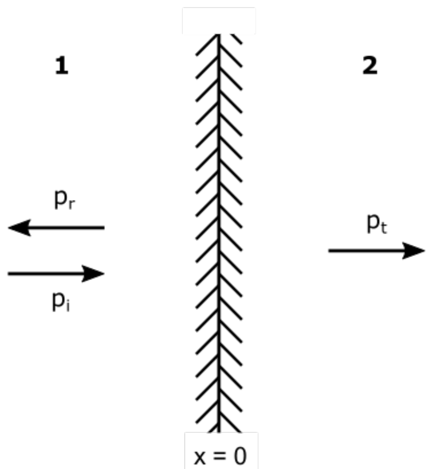


Figure 2.5: Pressure amplitudes of the incident (P_i), reflected (P_r) and transmitted (P_t) wave for a normal incident over a boundary (x=0) between two media of different characteristic impedances.

Kinsler et al. (2000) further reveals that whenever the two media have strongly dissimilar values of characteristic impedance, the coefficient for sound intensity transmission is small. A small intensity transmission also implies a small pressure transmission. This will be the case for an air-water transmission, for instance, with the vast dissimilar-

Medium	Temperature (°C) T	Speed of Sound (m/s) c	Density (kg/m3) ρ	Characteristic Imp. (Pa*s/m) r
Air	20	343	1.21	415
Water (fresh)	20	1481	998	$1.48x10^6$
Castor oil	20	1540	950	$1.45x10^6$
Glycerin	20	1980	1260	$2.5x10^6$
Rubber (soft)	N/A	1050*	950	$1.0x10^6$

Table 2.4: Physical properties of matter, adapted from Kinsler et al. (2000). *Bulk speed of sound.

ities of the respective medias characteristic impedances. It is also shown that the sound intensity coefficient is the same independently of what side of the boundary the incident wave is coming from. In other words, a wave travelling over an air-water interface will have the same loss as for a wave travelling over a water-air interface. Oblique incidence, where the waves make an angle of incidence that is not normal to the boundary, is likely to be the case, depending on the final earplug design. Figure 2.5 is therefore considered a fairly simplified model. Also, a thin partition surface separating the two media is going to be present, and thus make it even more impossible to predict the sound wave loss in decibels in a general manner. For this thesis, as a project of concept and development, the exact mathematics behind these phenomena are not investigated any further.

2.6 Synopsis

The exploration and findings from the project thesis have led up to a slightly more definite idea on how the next generation deep insert earplug should perform. The idea of using liquids as attenuating medium in a flexible bulb was quite heavily focused upon in the recommendations for further work in the project thesis, and is something that will be extensively explored during this master's thesis. With the literature study now also presenting the phenomena of acoustical dampening from sound transmission over different media, a scope of work will be to investigate how well these principles will perform in real-life hearing protection applications.

Chapter 3

Product Specification

Product specification is aiming at understanding the customers to map out some of the crucial requirements of a deep insert HPD. Based on this, rough outlines of such a concept are presented, before functional requirements and target specifications for the product are concretized.

3.1 Customer Understanding

The deep insert earplug is aiming at end customers using traditional earplugs for hearing protection, which will appeal to everything from sleeping purposes to light industry and military services. In addition to serving the market of HPDs, the sealing part of this earplug will also be applicable for hearables.

This HPD is supposed to give the end customer added value through a design that meets the following three requirements:

- Comfort
- Enhanced noise reduction
- Usability

Inserting an earplug is not necessarily a straightforward process, and it requires both right sized earplugs and the right technique. By not inserting the plug correctly, chances of getting inadequate protection are high. Studies reviewed by Murphy et al. (2011) indicate that real-world attenuation from earplugs used by workers is typically 20 dB less than the attenuation ratings from the manufacturer. This proves the problems with conventional earplugs when used by untrained or inexperienced users. It is therefore desirable to have an alternative earplug that is easier inserted to proper depths than existing variants. Easily insertable deep insert options are obtainable with custom moulded impressions, but then again the usability is massively decreased regarding the initial moulding process. The price will also be a considerable setback with customized options.

The skin in the ear canal is thin and easily irritated. Irritated skin is often the case for long time use, where pressure and minor movements of the earplug causes discomfort or pain. Insertion of the earplug causes friction that also contributes to lack of comfort. This is especially problematic with an already irritated ear canal, which can be the case for long time use or several insertions of the plug. Discomfort is not just a problem in itself, but it can lead to reluctant users and avoidance of using hearing protection.

The attenuating part of the product is expected to achieve attenuation of magnitudes almost as high as with an active noise reduction (ANR) system, but with considerably lower average sales prices. Consequently, there is no need for battery changes or recharging, and the physical size of the device can be considerably smaller. Physical size is a parameter that that affects the comfort of an earplug. By reducing the external part of the plug, the plug will be much more suitable for sleeping purposes or any situation where additional safety equipment, such as helmets and glasses, can be a conflicting issue.

The concepts of this deep insert HPD are also supposed to yield properties that reduce the risk of blocking the ear canal with cerumen, which can be a problem with conventional earplugs.

3.2 Next Generation Earplug - The Big Picture

Through the process of developing concepts for a deep insert earplug in the preliminary work, some rough outlines of what could be the *Next Generation Earplug* were highlighted. The big picture of this new concept is fairly simple: a bulb-shaped sealing part and an exterior part that controls the contraction and expansion of it. They are connected by a flexible stem, and the system as a whole is filled with a liquid. Figure 3.1 illustrates how the concept can be divided into the following four subfunctions:

1. **The Sealing Part**
2. **The Exterior Part**
3. **The Stem**
4. **The Attenuating Medium**

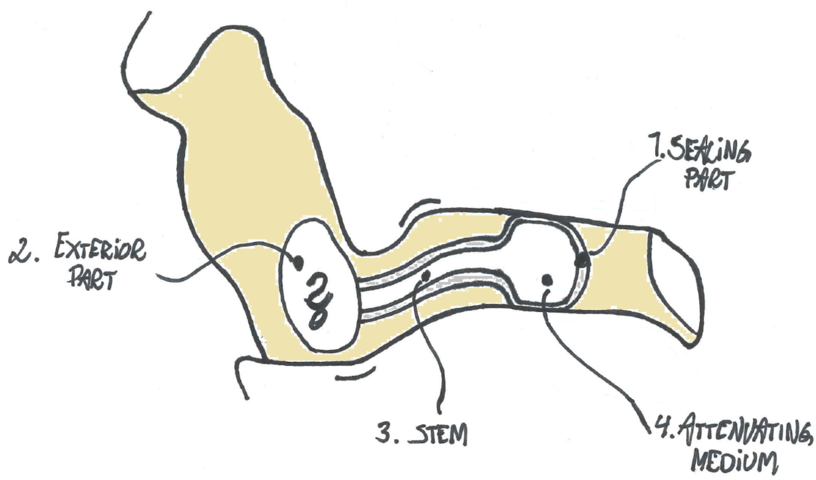


Figure 3.1: Concept outline of the next generation earplug and its four vital parts, inserted beyond the second bend of the EAC.

3.3 Functional Requirements

3.3.1 The Kano Model - A Brief Overview

It is useful to have some proper guidelines when classifying and organizing a product's functional requirements in relation to customer needs. To easily cope with this, the *Kano model* has been used, described by Emery (2006) and illustrated in Figure 3.2. This model is used as a brief overview on how the earplug has to perform, and sets the basis for further definition of product specifications. The model addresses three types of requirements for satisfying the customer:

- Basic needs
- Performance needs
- Delighters

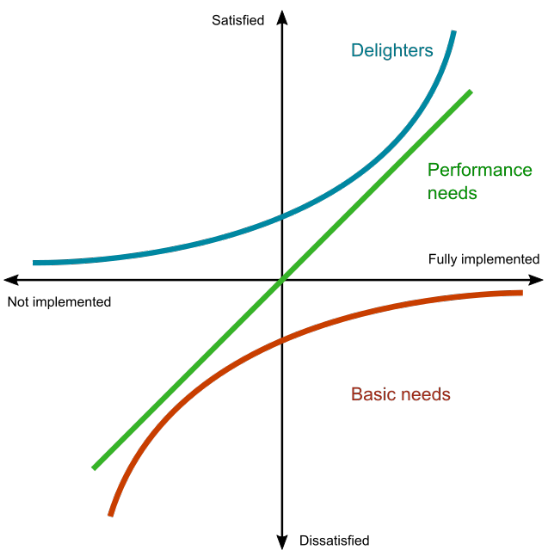


Figure 3.2: The Kano model.

Basic needs refer to the bare minimum of what is expected of the product. A product not satisfying these requirements will lead to dissatisfied customers. *Performance needs* are the types of characteristics that increases or decreases customer satisfaction by their degree. *Delighters* are attributes that not necessarily are expected of the product, but will lead to increased customer satisfaction. The three categories are presented in Table 3.1 with presumed features of a deep insert HPD.

Feature	Basic need	Per. need	Delighter
Attenuating	x		
Uni-ear sized	x		
Biocompatible	x		
Easy insertion		x	
Easy removal		x	
Comfortable long-term wear		x	
Soil-resistant		x	
Reusable			x
Available as corded pairs			x
Visibility for compliance check			x
Uniform attenuation across frequencies			x

Table 3.1: Functional requirements matrix in accordance to the characteristics of the Kano model.

3.3.2 Target Specifications

The development of *target specifications* is extensively described by Ulrich and Eppinger (2012) and defined as an extended list of specifications, where relevant metrics are presented with weighted importance and target values. The metrics are supposed to reflect the customer needs that have been established in *Customer Understanding*, and discretize them as precisely as possible. Each metric should ideally correspond to a certain customer need, but several metrics will in many cases be necessary to satisfy one need in practice. The target values of the metrics are denoted with two useful types of measures: *ideal values* and *marginal values*. The ideal values represent what the designer is aiming at achieving, while marginal values represent the marginally acceptable values of the respective metrics. These values can be expressed in several ways, and are often either exact values or indicating a range in which the metric should be. The metrics of this deep insert earplug are specified in Table 3.2. This is ultimately setting the boundaries of a competitively viable product space in which the designer is left to work, and further development is accordingly carried out by the best approach possible. It is important to note that the earplug target specifications in this table are preliminary guidelines, as concepts and trade-offs have yet to be known, and will consequently be worked out as part of the concept generation and development process.

No.	Metric	Importance (1-5)	Units	Marginal Value	Ideal Value
1	Noise reduction	5	dB	>32	N/A*
2	Pressure to the EAC	5	g/mm^2	N/A	<0.5
3	Stem diameter	2	mm	<5.3	<4.3
4	Total length	4	mm	<25.0	22.0
5	Max. dia., sealing part	4	mm	>8.3	9.0
6	Min. dia., sealing part	4	mm	<5.3	<4.3
7	Length, sealing part	2	mm	<8	<5
8	Max. dia, exterior part	2	mm	<20	15
9	Max. depth, exterior part	4	mm	<12	<6
10	Insertion time	2	s	<30	<5
11	Comfortable wearing time	4	h	>2	>8

Table 3.2: Target specifications.
*There is no thing such as ”Ideal value” concerning noise reduction of an HPD, as the recommended noise reduction is based on the noise environment in which the hearing protection aims at operating.

Chapter 4

Design Methodology

Design methodologies used to approach the development process in this work were chosen considering the high degree of uncertainties and unknowns associated with the earplug. An HPD specifically classified as a uni-ear deep insert earplug with liquids as an attenuating medium seems never to have been developed, making this a new product development (NPD) process. Methods particularly suitable for driving such a development process have been utilized. More specifically, elements from both Set-Based Design (SBD) and Wayfaring has been important for the progression, and will be more closely presented in this chapter.

4.1 Set-Based Design

With the constraints and target specifications of the earplug defined, a set-based design approach is considered a good way to start generating ideas within the subfunction solution spaces. Being an NPD process, it is unfavorable to eliminate any possible solutions in the early phase. The earplug is decomposed into four subfunctions, as discussed in Chapter 3, that all have a set of constraints. Each set contains countless solutions to the design. This is exactly where SBD is an appropriate way of attacking the design process; an approach that was first seen in Toyota's development line and documented by Ward et al. (1995).

Figure 4.1 illustrates the early progression of concept creation in this project pretty well. As the four subfunctions of the earplug are defined with, more or less, isolated functionalities, a set-based approach will be started out with. All four subfunctions have a certain space of solutions, only constrained by the target specifications defined in Chapter 3. As discussed by Smith (2007), such spaces narrow down as discoveries are accomplished and typically progress to a few parallelly developing distinct options that eventually merge into a complete system design.

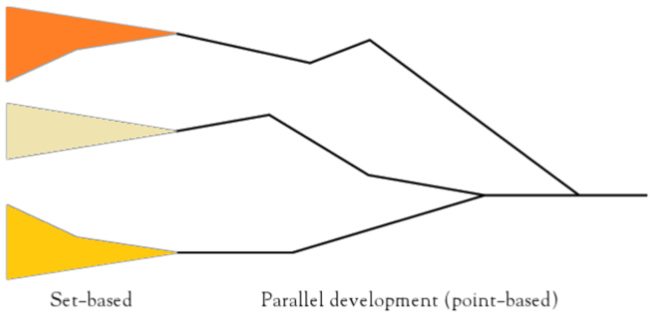


Figure 4.1: The time line of a process, progressing from a Set-Based Development to a Parallel Development. Illustration from Smith (2007)

SBD, as a way of increasing flexibility while reducing the amount of rework throughout a development process, yields favorable properties for this project. However, being a one-man team in a highly time-limited project, decisions cannot be deferred for too long. When the solution spaces narrow down as part of the concept and ideation phase, a slightly more driving methodology, *Wayfaring*, can be implemented to accelerate further concept development.

4.2 Wayfaring

Wayfaring has the advantage of tackling unsolved engineering and design problems when no solutions are present. The method was first presented by Steinert and Leifer (2012) as a way of *hunting for the next big idea*. Gerstenberg et al. (2015) explore this methodology further, utilizing it as an appropriate approach to early-stage concept creation in the process of solving such problems. As a first step, wayfaring is about taking an initial direction based on best guesses. In this earplug development process this is where the prototyping journey towards functional concepts is starting, and thus overlapping with the set-based ideation phase earlier described. The wayfaring method is all about fast learning and front-loading by developing low-resolution prototypes. Still, the exact product requirements are not fixed but are dynamically developing through this fuzzy front-end phase of the product development. The hunt for what Gerstenberg et al. (2015) have referred to as "unknown unknowns", is illustrated in Figure 4.2 as a journey of wayfaring-inspired PD.

The wayfaring starts in point A, imagining that this is a known point in the concept

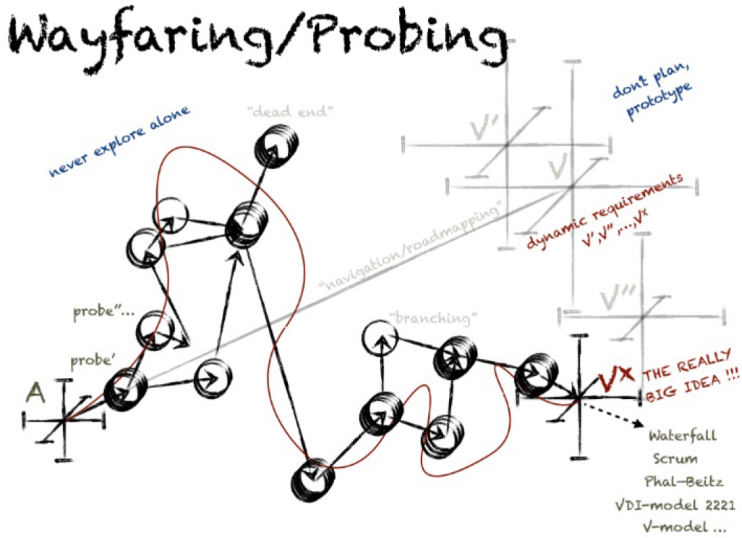


Figure 4.2: The Wayfaring journey. Illustration from Gerstenberg et al. (2015).

discovery space. The axes around the point represent the space of uncertainties. V, V' and V" represent the 'next big ideas' on the journey towards the 'really big idea' in point V^x. Every stage of a 'big idea' has its own dimensions of uncertainties which are investigated through one or more prototypes. Testing and learning from these prototypes increases understanding of the solution space and the overall problem. The wayfaring is continually progressing by probing ideas to discover the unexpected. As illustrated in Figure 4.3, new knowledge is gained by building and testing prototypes, each prototype represented by a single probe.

The aim is to make the probing as fast, cheap and low-risk as possible to choose the next step by abductive reasoning and continuously feed to the understanding of the problem. The intention of the low-resolution prototypes is to find critical functions or avoid unnecessary directions of development. Therefore, the prototypes are intended to be built with the option of failing before planning the process too much. Gerstenberg et al. (2015) further reveals the importance of merging system components as soon as possible, as part of making the wayfaring journey more efficient. This is highly relatable to the earplug development, as the process would strongly benefit from early compatibility between subsystems, especially concerning the sealing and external part. Therefore, integration should be tested while integration issues and changes to the system are still easily manageable. To ensure that the components can be merged, quasi-simultaneous prototyping across the different subsystems of the earplug will be emphasized during the development phase of this work.

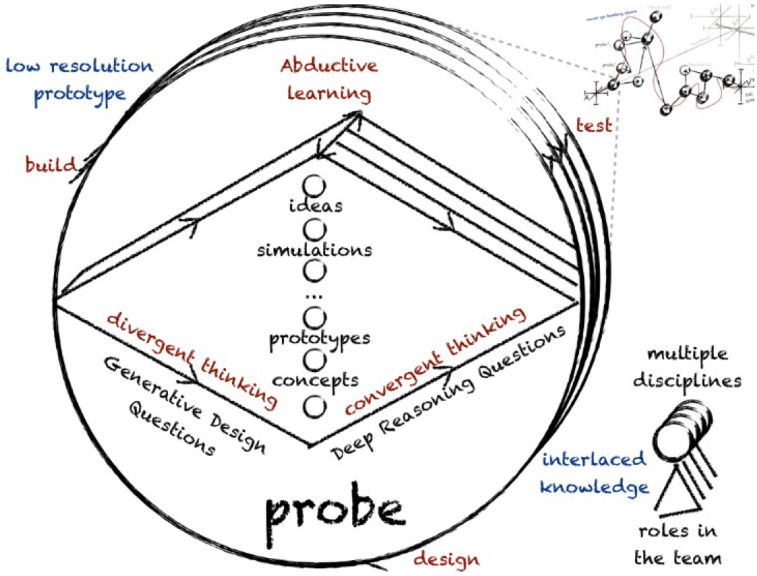


Figure 4.3: Probing cycle. Illustration from Gerstenberg et al. (2015).

Chapter 5

Concept and Ideation

With respect to *'the big picture'* of this deep insert earplug and tentative functional requirements established in Chapter 3, the phase of ideation and concept generation was entered. By a set-based approach - working within solution spaces defined by the target specifications - this chapter presents and discusses different concepts to the four defined subfunctions of the earplug.

5.1 Subfunctions

This section is presenting possible solutions to the different subfunctions, illustrated in Figure 3.1, that were generated throughout the ideation phase of the project. All subfunctions are independent to a certain degree, enabling for some concurrent development. However, the choice of sealing part will affect the choice of external part and vice versa. This is discussed more deeply as part of the development process in Chapter 6.

5.1.1 The Sealing Part

The first, and arguably the most vital, part of the earplug is the *sealing part*. This is the tip of the earplug, which is supposed to deeply penetrate the ear canal and seal against the osseous part. As pointed out in the literature review, the osseous canal is thin-skinned and rather sensitive to pressure. By having to pass *isthmus*, the narrowest part of the EAC, to reach into the bony part of the canal, the cross-section of the sealing part should be dimensionally controllable. In other words, this subfunction has to perform in two states: *contracted* and *expanded*. Some kind of thin-walled flexible bladder quickly became subject to the sealing part, enabling for cross-sectional contraction, evenly spread pressure and containable of liquids. Two ways of contracting and expanding this bladder were considered as possible concepts to this subfunction: *mechanically* and *hydraulically*. This chapter will only present brief concepts on form and function, whereas Chapter 6 will investigate dimensions and other specifications more deeply as part of the development and prototyping process.

Hydraulically controlled

The idea of controlling the state of the sealing part by controlling the internal pressure is promising for a couple of reasons. It excludes the need for a mechanical system inside the plug, and consequently keeps the flexibility in other subfunctions, such as the stem. However, it requires a fine-tuned system for distributing the pressure.

There are really two principal ways of managing the bladder hydraulically. It can either be in an initially contracted state, which is expanded by injecting the liquid with a positive pressure, as illustrated in Figure 5.1. This solution is great for the insertion of the plug, because of the shrunken cross-section of the initial state (1). However, it requires holding a constant pressure to keep the sealing in the expanded state (2), which can potentially cause leakages over time. Another idea to this way of controlling the bladder is using a thin, stretchy material, such as latex, and expand the cross-section of the bladder, again by using overpressure. As illustrated in Figure 5.2 an approach like that can make the sealing part deform like a balloon, rather than by folding in the initial state of equilibrium pressure.

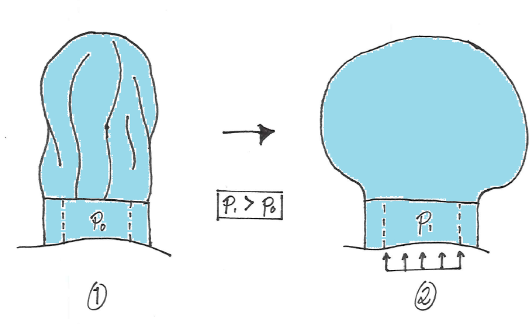


Figure 5.1: The bladder contracted in the initial state, expanded by injecting the liquids with a positive pressure in state two.

The other principal way of handling the bladder is an opposite variant of the latter two, with an initial state of complete expansion. As illustrated in Figure 5.3, the bladder can be contracted with vacuum for insertion and removal of the plug. This idea will require some neat solution on how to increase container volume of the plug, to create

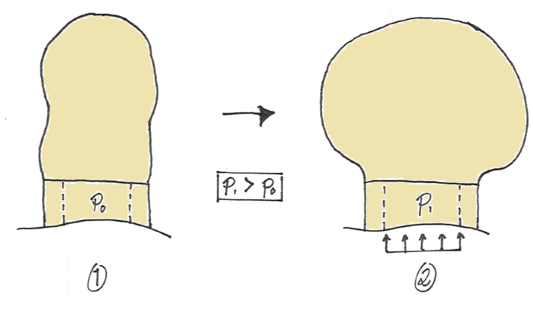


Figure 5.2: The thin bladder blown up and expanded by injecting the liquids with overpressure, from state one to state two.

the vacuum needed and to keep the liquids drained from the bladder. While the first two solutions in require an overpressure to function in the sealing state, this concept is sealing against the ear canal under atmospheric pressure.

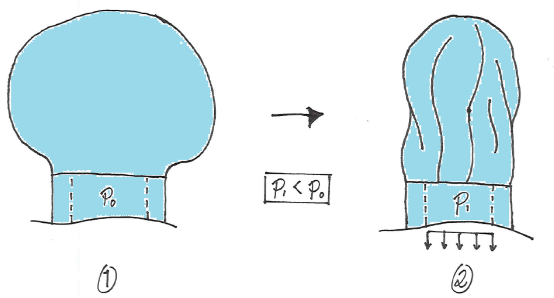


Figure 5.3: The bladder fully expanded in initial state, shrunken in by evacuating the liquids through the stem in state two.

Mechanically controlled

The cross-section of the bladder can also be controlled mechanically. Being made of some kind of flexible material such as silicone rubber, the bladder will contract diametrically upon elongation. The idea is that a rod is running through the inside of the plug, and able to move axially to push the bladder tip with some force *F*, as illustrated in Figure 5.4. This does not exclude the principal of using liquids as an attenuating medium, but it needs to be able to drain away some of the liquids as the volume of the bladder decreases. A solution like this will have to be structurally compliant with transferring the axial load to the bladder tip, while at the same time remaining flexible for the sake of

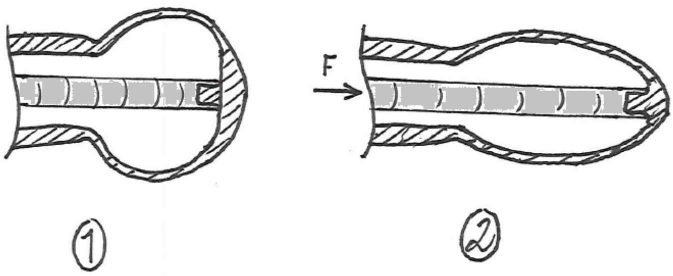


Figure 5.4: State 1: The bladder in a sealing state, unaffected by the rod. State 2: The bladder is elongated by the load of the rod, resulting in a contracted cross-section.

comfort. The nature of an elastic material such as silicone rubber will make it go back to the initial sealing state by itself.

5.1.2 The Stem

The *stem* is the part of the plug that connects the sealing and the exterior part. Consequently, these subfunctions are the driving forces of how the stem needs to perform. The stem has to sit comfortably in the EAC without conflicting the anatomical nature of the canal. Two main variants were brought up as potential takes on a uni-ear design for the stem: a flexible pipe with a uniform circular cross-section, and a pre-moulded variant shaped to the typical EAC. A flexible and uniform pipe, like the one illustrated in Figure 5.5a, is easy to manufacture and somewhat easy to dimension, with the minimum diameter of *isthmus* being the driving factor. The lack of sealing from such a stem will, however, be enhanced with a pre-moulded stem shaped to the EAC, as illustrated in Figure 5.5b. Even though a stem shaped to the EAC invites several additional dimensional variances to the shape, this way of constructing an in-ear device has been proven successful before, like the *Songbird Disposable Hearing Aid* reviewed in Staab et al. (2000).

5.1.3 The Exterior Part

The purpose of the *exterior part* is to manage the shape of the sealing part and ensuring a deep insert fit when placed towards the outer ear. By all means, the solutions to this part of the earplug very much depend on the sealing part. Physically, it is a question of how it should rest in the outer ear and how to prevent the plug from poking the eardrum while still reaching deep enough. Regarding functionality, it is simply a matter of how

(a) A flexible, uniform pipe.

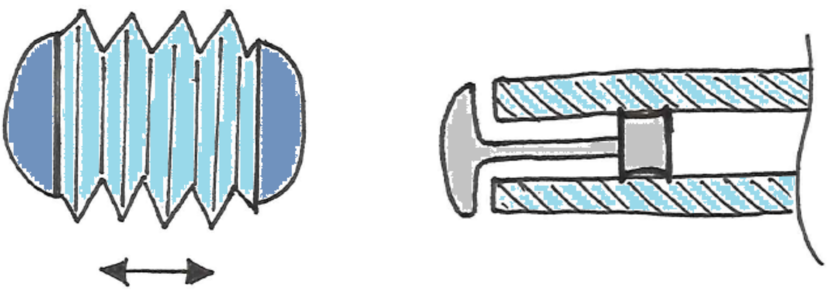
(b) A pre-moulded shape.

Figure 5.5: Two conceptual takes on the stem.

the cross-section of the sealing part is going to be controlled. The possible solutions are depending on choices made for the sealing part, and are categorized in the following subsections based on the required functionality from the sealing part.

Hydraulic control

A sealing part that is fully expanded in a neutral state, as illustrated in Figure 5.3, can be contracted by the use of a vacuum. In cases where using a pump is not an optional solution, a vacuum can be created by increasing the volume of a closed container.



(a) Accordion concept.

(b) Piston concept.

Figure 5.6: Two hydraulic control concepts.

Three concepts on increasing the container volume to obtain vacuum were investigated in the conceptual phase. Figure 5.6a shows a well-known principle of changing the volume of a cavity by using a flexible bellow, much like the way an accordion works. By operating the side pieces as the arrow is visualizing, the volume can be increased/decreased, and vacuum can be created. The challenge with such a concept may be to manage the bellow by using just one hand. The reason is that it is preferable to reach over with the second hand to lift the ear and straighten out the canal as the

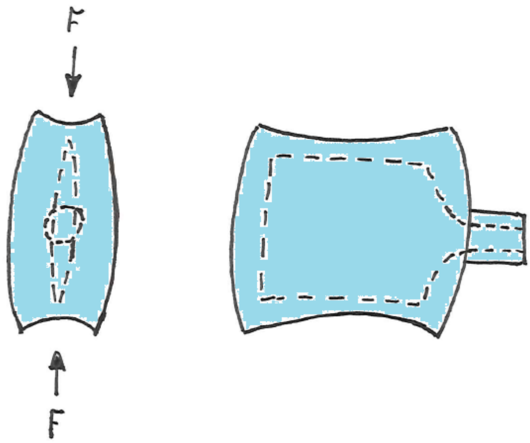


Figure 5.7: Bellow concept.

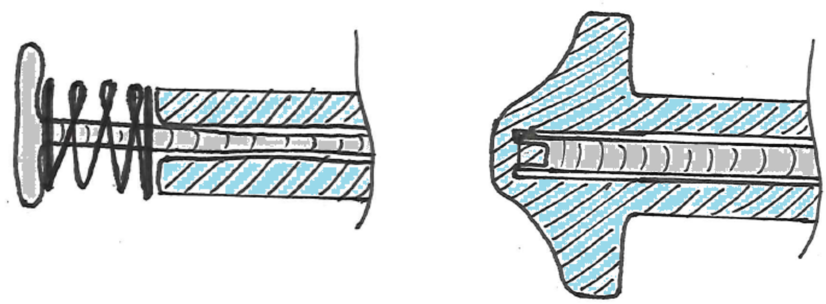
earplug is inserted; a method well described by earplug manufacturers and in Murphy et al. (2011). After the evacuated sealing part is correctly placed in the osseous canal, the bellow will have to be released to an equilibrium pressure state so that the sealing part sits tightly against the EAC. Figure 5.6b illustrates the principle of a piston and a cylinder. The idea is that the exterior part is working similarly as a syringe, where the liquids are sucked out of the sealing part, and thus shrinking the cross-section by the evacuating effect. This is a well-proven way of evacuating liquids but needs to keep a complete seal between the moving parts to prevent leakages. Much like the bellow, this is a design that might be somewhat troublesome to control only with one hand.

A third idea is illustrated in Figure 5.7 as some other kind of bellow. This concept is simply a flexible pillow with an internal cavity that increases in volume when squeezed. As shown by the dotted lines on the drawing, the cavity is initially shaped like a narrow oval-like pocket. “F” and appurtenant arrows denote the way of squeezing the bladder, and the narrow pocket is supposed to turn into a cylinder with increased volume, which evacuates the liquids from the sealing part. When the bellow is squeezed together, and containing most of the liquids, the vacuum will ensure a contracted earplug tip.

For the case of inflating the bladder to expand it towards a sealing state, all of the concepts mentioned above are more or less applicable. The piston and the bellows described in Figure 5.6a, Figure 5.6b and Figure 5.7 can be used for this purpose if only reversed. This will then require something that keeps the pressure and prevents it from leaking. Overpressure will naturally be somewhat trickier to handle and hold than in the case of a system in equilibrium pressure state. The concepts illustrated in Figure 5.8a and Figure 5.8b can work the same way as pressurized syringes, but again some locking mechanism is required to keep the overpressure.

Mechanical control

As discussed in the subsection for the sealing part of the earplug, the cross-section of the bladder can be contracted by elongating its length. The prerequisites for such a solution is either having some push/pull system or a suspended system. The latter was the most contiguous to contemplate as this would enable for a self-sealing system. As illustrated in Figure 5.8a the system can be suspended by an ordinary spring. When the rear part is pushed, a flexible shaft is moving axially inside the stem. The shaft is connected to the tip of the sealing part, like in Figure 5.4, and contracting the cross-section upon pushing. The spring resets the system when the rear part is released, and the sealing part expands towards the EAC. Whereas this concept might be struggling from leakages between the shaft and the stem, Figure 5.8b illustrates a completely closed system. The idea behind this is somewhat similar to the spring concept, but with the shaft sitting in the center of a silicone rubber sheath. The elastic properties of silicone rubber are then supposed to reset the system back to initial state after being pushed, again making the bladder seal against the EAC.



(a) Spring concept. (b) Closed sheath concept.

Figure 5.8: Two conceptual takes on a suspended push-system.

5.1.4 The Attenuating Medium

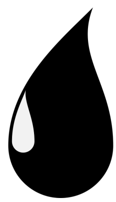
Besides the small attenuating effects from the earplug material itself, it is preferable to introduce some liquid to benefit from the attenuating effects of sound transmission over different media, reviewed in Chapter 2. The use of a liquid is the essence of this *next generation earplug* concept. In addition to being acoustically appropriate, the liquid is preferred to be biocompatible, preventing it from harming the skin in case of leakages. Also, the attenuating medium has to be compatible with the chosen earplug material to prevent any chemical degradation of the earplug.

Water

Water is an obvious medium to consider, with its completely natural and biocompatible appearance. It yields some of the best acoustical properties in terms of being an attenuating medium but has the disadvantage of freezing at temperatures below 0 °C. Its availability, combined with the relatively high characteristic impedance, will make water an great choice for the early concept and prototyping phases.

Oils (vegetable)

Olive oil is a commonly used substance for softening up the earwax and decreasing the need for ear irrigation. As stated by Kraszewski (2008), this is an effective and harmless way of cleaning the ear, with no associated irritation to the skin. Acoustically speaking, it is clear from Table 2.4 in the literature review that the physical properties of such oils are close to the properties of water, at least in the case of castor oil. Consequently, the attenuating effect from using oil will differ minimally from using water. Nevertheless, some of these oils seem to yield freezing points way lower than for water.



Glycerin

The literature study presented in Chapter 2 revealed some highly promising characteristics for the liquid *glycerin*, probably most known as *glycerol*. This liquid yields characteristic impedances almost twice as high as for water and castor oil. Glycerin is a biologically harmless substance, being used for everything from food to personal care products. Mario (2017) further discusses the great properties of glycerin in antifreeze

appliances, with its freezing point quickly dipping down towards -40 °C in mixtures with just 30% water.

Other media

Based on acoustical and biochemical properties, both water, vegetable oils and glycerin have been brought up as potential attenuating mediums for the earplug. Other mediums might be subjects of investigation, like gel type materials. These are typically jelly-like materials with more viscous properties than the latter three variants, and assumably yielding some totally different acoustical properties. Another way of increasing the attenuating effect of the mediums is by introducing inhomogeneities to the liquid. This could typically be particles of some solid, causing scattering and backscattering of the incident sound wave. Investigation of this kind of compositions will probably be subject for further work.

5.2 Morphology Matrix

A *morphology matrix* was created as a tool for further concept generation in the following phases of the development process, as illustrated in Figure 5.9. The matrix puts the four subfunctions of the next generation deep insert earplug up against the respective, presented conceptual solutions.

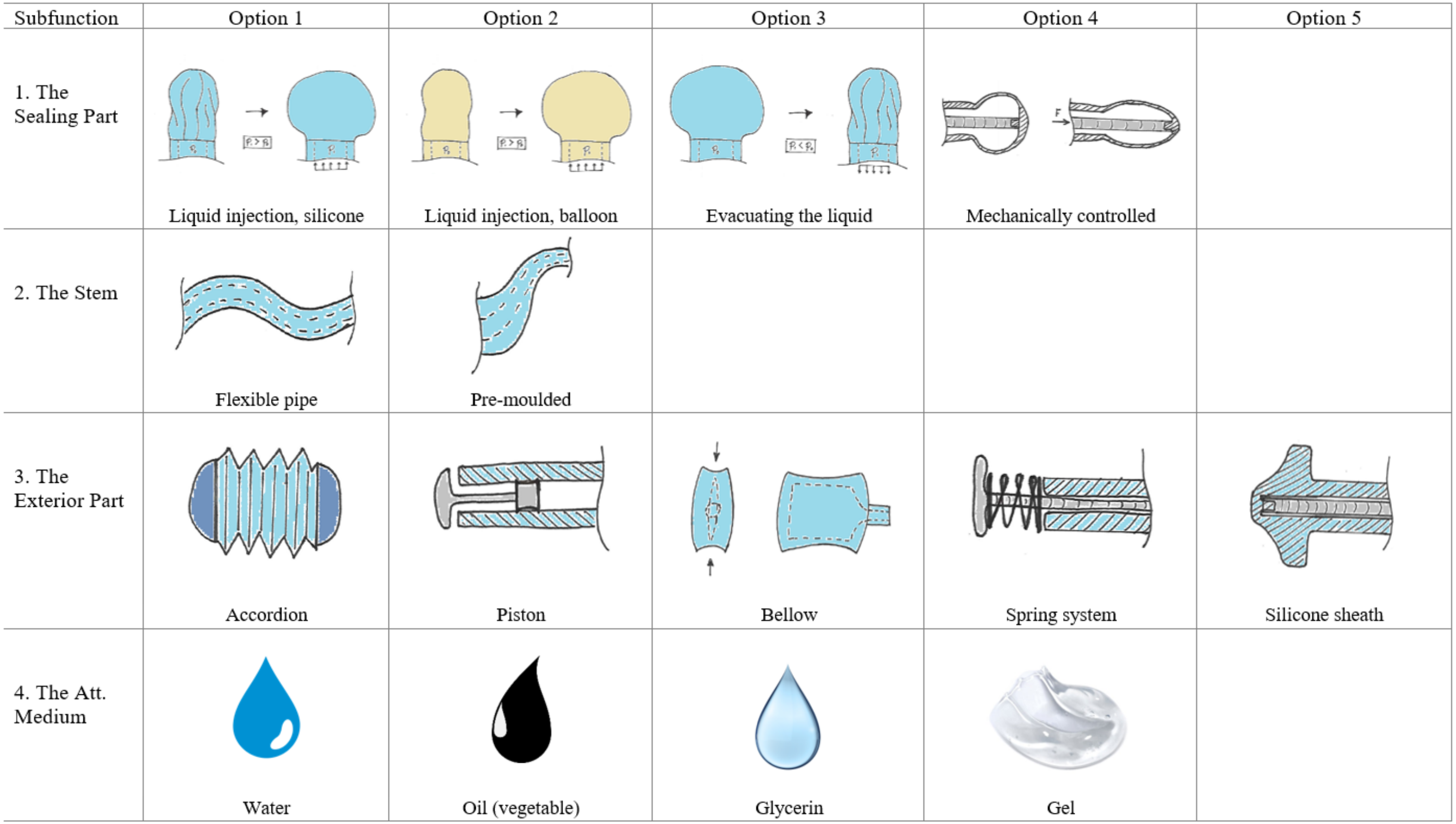


Figure 5.9: All the conceptual solutions to the four subfunctions of the earplug condensed into a morphology matrix.

Chapter 6

Development of The Next Generation Earplug

This chapter contains a description of the design and production methods used, in addition to condensing the whole development process of the deep insert ear plug. The development process is documented with all relevant steps of designing, exploring and producing prototypes of the different subsystems. Discussion of the iterative decisions and testing of the prototypes is also documented. The final concepts and prototypes for the respective subsections are presented in the last section, containing a final morphology matrix, illustrations of the final full-system prototype and a conceptual model of a more ideal and refined prototype.

6.1 Design and Production Method

The concepts described in Chapter 5, with rather intricate shapes that require a fine level of detail, rely on some proper production processes to be explored and tested. Concerning this, finding ways of producing such prototypes is considered one of the significant milestones in this project. Among the lessons learned from the preliminary work, the knowledge gained on different types of silicone materials - how they behave and how they are handled - is considered one of the most important. Another considerable advantage from this preparatory work has been the familiarity with appropriate ways of making moulds and performing successful high fidelity mouldings. This section will present the primary methods and materials that underlie the following development and prototyping phases of the earplug.

6.1.1 Moulding and 3D-Printed Tools

A simplified type of injection moulding is being used for most of the prototyping. As earlier stated, the preparatory work has resulted in an excellent understanding of how small and detailed shapes can easily be modeled with addition vulcanizing silicone and 3D-printed moulds. The combination of Polylactic acid (PLA) plastics and this type of silicone has proven to work seamlessly together in moulding applications, with no need for release agents. A considerable concern in this production has been obtaining the internal cavities of many of the concepts presented. The outer shape of these models is easy to obtain, and can in most cases be solved with a two-piece split-mould. However, since these parts have to be thin-walled and with non-uniform cavities, the tricky part is moulding with negative draft angle cores. Draft angles are traditionally applied to the mould geometry for easier disassembly of the cured mould. The idea of making the cores from Polyvinyl alcohol (PVA) plastics has been a significant breakthrough for the prototyping process in this project. PVA plastics can also be used as a filament for 3D printing, and has the benefit of being water-soluble. Consequently, using PVA filament instead of PLA for the cores enables for the cores to be decomposed and washed out after the mould has cured. The relevant materials used for these processes are more closely described in Subsection 6.1.2.

The evolvement of the exact moulding processes has indeed been part of the development process of the earplug itself, and the discoveries related to production will be presented along with the product development in Section 6.2. However, the outlines on how these concepts could be prototyped have pretty much remained unchanged. A schematic illustration of a typical mould setup can be seen in Figure 6.1. This setup consists of a two-piece injection mould that is clamped together onto a mould base by the use of guide pins. The mould has a traditional design, including the mould cavity, a core, a sprue as an inlet for the silicone, a runner, and a riser at the top.

All of the printed parts in this project was printed with an *Original Prusa i3 MK2* printer. Despite being a relatively simple desktop printer, the Prusa printer yields consistent and sufficient results for prototyping purposes, with properties like automatic bed leveling, skew axis compensation, and heated bed. *PrusaControl* was the software used for generating printable G-codes from the Solidworks .sldprt-files. This is a simple software with just a handful of adjustable parameters. The settings that were mostly used within the two categories of 3D-prints in this project are presented in Table 6.1.

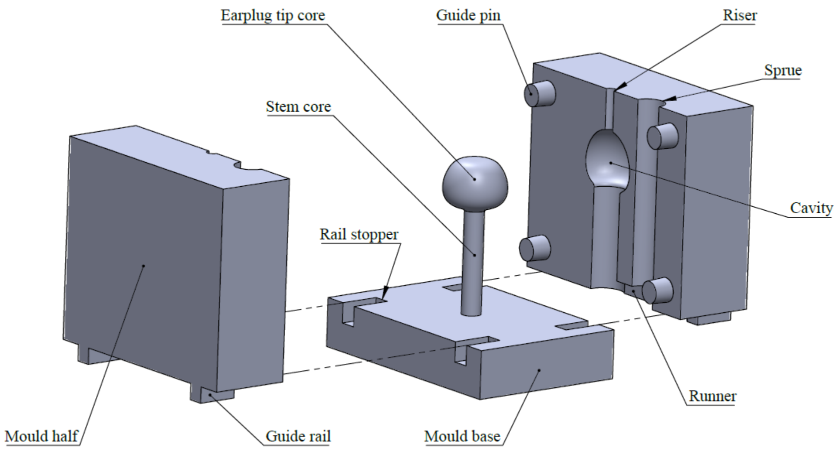


Figure 6.1: A schematic presentation of the general mould setup. This exact mould is from making an early prototype of the sealing part and stem.

PrusaControl settings	**Outer mould pieces**	**Moulding cores**
Material	Prusa PLA	Primavalue PVA
Quality	0.1 - 0.2 mm	0.1 mm
Infill	15 - 20 %	20 - 30 %
Support	None	None
Brim	On	On
Manual printer settings		
Nozzle temp.	220 °C	205 - 210 °C
Bed temp.	60 °C	60 °C
Printing speed	100 %	40 - 60 %
Printing surface	Clean	Glued

Table 6.1: Prusa 3D-printer settings.

6.1.2 Materials

By now, it is no secret that the EAC makes up for a challenging region to develop for. The dimensional variances, combined with easily irritated and sensitive areas, favor material choices that yield properties like being flexible, elastic and harmless to the skin. From the work done in the project thesis, a couple of materials have shown to be exceptionally great for these kind of applications, and will frequently be used in the prototyping process.

Dreve Biopor® AB 25 Shore silicone

Dreve Biopor® AB 25 Shore[1] is a room-temperature-vulcanizing (RTV), also known as addition vulcanizing, silicone that is a two-component silicone rubber explicitly used in the application of making earmoulds. The Biopor silicone cures at room temperatures with setting times at approximately 30 min., and can cure under relatively oxygen-deficient conditions. As a result, there is no thermoplastic shrinkage during the curing process. This makes it great for moulding, and enables for rapid prototyping. Another beneficial property of this exact material is its poor adhesion to PLA plastics, making the preparation of moulds easy, with no need for any release agent. The required equipment for working with Dreve Biopor® AB is illustrated in Figure 6.2.

Figure 6.2: Injector gun, with silicone dispenser and mixing nozzle.

Dreve Lacquer B

Dreve Lacquer B is a liquid silicone lacquer used in the application of coating earmoulds. This lacquer is a moisture-cured lacquer used as a coating for robustness and easier cleaning. Not only will the lacquer give the mould a glossy finish, but it has proven particularly helpful as a surface conditioner for moulds with pores and rugged finishes. This medium is rather easy in use and can be applied by dipping the silicone part in the liquid, followed by curing at room temperature (and under the influence of air humidity) for approximately 15-20 min. The lacquer is identified with some hazards and was therefore used under strict precautions, with proper storing, handling and use of protective equipment.

[1] Technical data sheet can be found in *Appendix B.1*

3D Printer Filament

PLA filament is arguably the most used filament material for 3D printing and was used for making the moulds in this project. This is a relatively cheap, non-toxic material which has proven to be great in the application of moulding with the Dreve silicone. PVA filament is a dissolvable material that is commonly used as support material in complex 3D-printed models. Despite being dissolvable in water, PVA has similar printing temperatures as PLA and is therefore easily used with the same printer settings and in combination with PLA. Its sensitivity to moisture makes it important to keep the PVA in a dry environment. Relevant specifications on the filament materials used in the project are listed in Table 6.2.

Filament material	**3DNet PLA 1.75**	**3DNet PVA 1.75**
Diameter	$1.75mm \pm 0.02mm$	$1.75mm \pm 0.02mm$
Nozzle temp.	190 - 240 °C	190 - 210 °C
Bed temp.	0 - 70 °C	0 - 70 °C
Rec. dissolving temp. (water)	N/A	30 - 40 °C

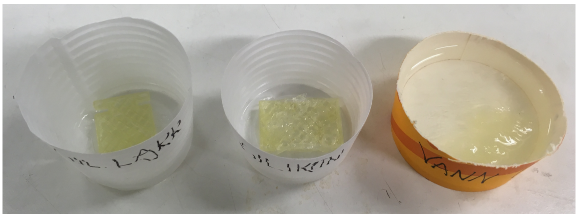
Table 6.2: Filament specifications. Adapted from 3DNet (2018a) and 3DNet (2018b).

6.2 Development and Prototyping

6.2.1 Experimenting with the Materials

With the materials discussed in the previous subsection as a starting point for the prototyping phase, some experiments were done at an early stage to see how they worked together. One of the main concerns was how the PVA cores would react during the moulding process, being so sensitive to moisture. Some simple experiments were conducted to get to know the sensitivity of PVA, and how it reacted in contact with other materials of interest. As illustrated in Figure 6.3a, 3D printed PVA specimens were put in three separate containers. The specimens were exposed to, from left to right, Dreve Lacquer B, Dreve Biopor RTV-silicone, and water. The experiment was run for one hour and showed promising results for further development. As Figure 6.3b is indicating, the water container made up for the only case of dissolved PVA. The other two containers just showed a cured silicone layer on top of an unaffected PVA specimen. Conclusively, the PVA seems to work well in the application of a moulding process with this silicone material.

(a) Before experiment.



(b) 1 hour later.

Figure 6.3: Experimenting with PVA in contact with the two silicone materials and water.

6.2.2 The Sealing Part and Stem

The Bladder Design

The bladder, effectively the sealing part, is in many ways key for developing a working deep insert HPD. With three out of four bladder concepts based on a moulded bulb shape, the development phase set out to explore just that. Based on the anatomical research and literature reviewed in Chapter 2, the dimensions of this part were estimated. Figure 2.4 illustrates how the sealing part should be penetrating approximately 20 mm in from the ear canal opening, concha, to ensure sealing against the bony part of the canal. In this figure, such a depth corresponds to a mean diameter of 7.0 mm, seen in Table 2.2. Staab et al. (2000) also indicate measurements of mean longest diameter at 9.3 mm, presented in Table 2.1. Taking the oval-like shaped nature of the EAC into consideration, in addition to these two diameter measurements, some compromise had to be done when dimensioning the bladder. Consequently, the bladder was designed with a maximum diameter of 8.6 mm as a starting point for the prototyping process. The height was set to 7.5 mm as an estimate on not being too bulky, but at the same time enable for enough sealing area to minimize the EAC pressure and prevent pain when expanded.

As illustrated in Figure 6.4, the bladder was designed with a cavity that is supposed to complement a radial contraction of the bladder. It was designed with a 0.4 mm wall thickness, and slightly more robust top and bottom shoulders to structurally achieve

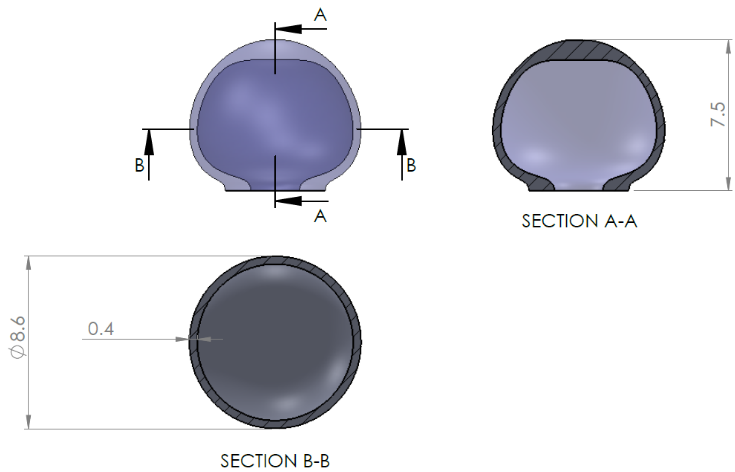


Figure 6.4: The bladder design.

this. Ideally, the walls should be as thin as possible to minimize forming of folds and maximize the attenuating effect of the liquid. Therefore, the wall thickness was a compromise between this and mouldability.

The Stem Design

There were never particularly good reasons not to make stem in the same mould as the bladder, and it quickly became part of the same process. By completely relying on the attenuating effect of a liquid-containing bladder sealing against the osseous canal, the idea of a flexible uniform pipe became the way to go from early on. The narrowest part of the EAC, isthmus, is positioned between the first and second bend and is the driving parameter for the outer dimensions of the stem. Based on the calculations done in Table 2.1 the diameter of the stem was designed with a diameter of 5 mm. The initial design also had a length of 12.5 mm making the total length of the plug about the same as conventional foam plugs.

Prototyping Section 1

Based on the bladder and stem design described in the subsection above, a mould was designed in SolidWorks. The mould cavity mirrors a perfect representation of this shape, as illustrated in Figure 6.6. This two-piece mould consists of all the technical features needed, including the sprue, riser, runner and guide pins.

Next up was figuring out the making of the cores that would create the internal

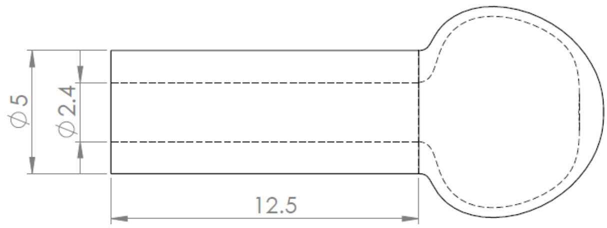


Figure 6.5: The stem design.

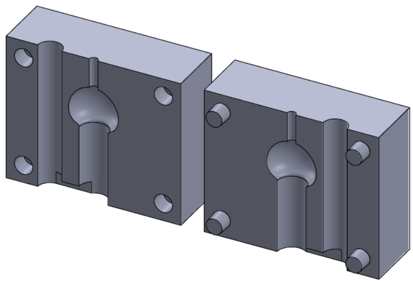
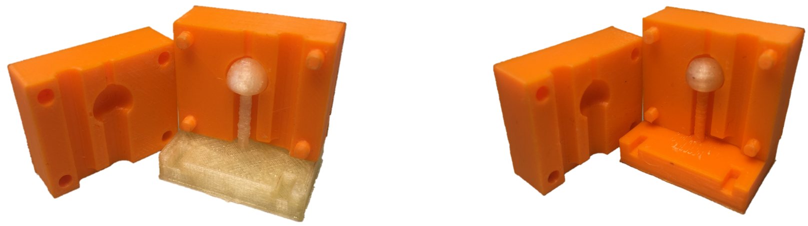


Figure 6.6: 1st bladder and stem mould.

cavity of the earplug. The technical challenge regarding this issue was getting the 3D printer to create the stem core with the bladder core on top of it. The first version was designed as a one-piece PVA core, with the mould base, stem core, and bladder core, as illustrated in Figure 6.7a. This was executed after some fine tuning of the printer, and used for the first prototype of the plug. The way of printing the core for the stem and bladder in one piece enabled for great dimensional control and ensured a perfectly concentric fit in the mould. However, it implied a lot of wasted PVA, in addition to a stem core that was technically challenging to print regarding its small diameter. The next revision to this core was making the mould base and stem core as one piece of PLA, and the bladder core printed separately with PVA, as illustrated in Figure 6.7b. Since the stem core had a uniform shape, there was no need for a dissolvable core, and using PLA was therefore sufficient. The bladder core was then printed with the same dimensions, but with an extruded cut making it easy to mount onto the stem core. Both of the latter two ways of making cores yielded the same results.

The first prototypes were then produced with the mould parts discussed above. As illustrated in Figure 6.8, the moulds were first clamped together, before the silicone was injected into the sprue until all air bubbles had come out of the riser. The mould cured



(a) 1^{st} ver. of the core (All PVA).

(b) 2^{nd} ver. of the core (PLA and PVA).

Figure 6.7

after about 30 minutes, and the mould was taken apart.

(a) Clamping.

(b) Injecting.

(c) Taken apart.

Figure 6.8: The moulding process.

After the mould had cured, the silicone part was pulled off of the stem core, leaving just the PVC bladder core inside. The excess material, shown in Figure 6.8c, was then trimmed away. The level of detail in the printed mould pieces left a grainy-like texture to the surface of the plug. The earplug was given two layers of silicone lacquer through a dipping process to minimize the chance of tearing apart the bladder when removing the core. The process of getting the bladder core out of the mould happened to be slightly more cumbersome than initially assumed. Because of the narrow stem canal, all the air had to be squeezed out manually to let the water hit the PVA core. Then the plug was lying in water of 30-40 °C for a couple of hours. Even though this is the time of dissolution stated by the manufacturer, the PVA needed some work to dissolve. The bladder was then massaged and poked at by a tiny screwdriver through the stem. Bit by bit the bladder core eroded through the stem before it eventually was just the bladder cavity left. This was a project breakthrough at this point. The method of using PVA as material for the bladder core might not be the most efficient way of producing these prototypes, but it certainly gets the job done. The first prototype of the stem and bladder is illustrated in Figure 6.9. A small lobe of the runner was left in the trimming process for easier handling of the plug during testing.

Figure 6.9: 1st prototype of the bladder and stem.

In the spirit of rapid prototyping, the plug was mounted onto a syringe to see how it contracted upon evacuation. As shown in Figure 6.10, a simple evacuation test with a syringe showed some structural weaknesses with the bladder. Instead of contracting laterally, it buckled down in the longitudinal direction. Such deformation will not decrease the cross-section of the bladder, and thus not making insertion of the plug very easy. This kind of design flaw is something that needs to be figured out in further development.

Figure 6.10: 1st prototype with simulation of bladder contraction when evacuated.

Despite the result from the contraction test, the plug was mounted onto a setup that enabled for testing fit, comfort and, to some extent, attenuation. As illustrated in Figure 6.11 the stem was blocked off with a plastic pipe and some *Blu Tack*.

In the first test, the prototype was entered approximately 18-19 mm into the EAC of the developer before the Blu Tack was attached to block the pipe, as shown in Figure 6.11b. The testing was conducted for 1.5 hours. The second test was conducted in a meeting with SIINTEF Digital, where the design was reviewed. The plug was also tested in the EAC by one of the SINTEF supervisors for about 15 minutes and was compared

(a) (b)

Figure 6.11: Testing the 1st prototype of the bladder and stem in the EAC.

to a regular foam plug in the other EAC. The comments from the tests are reported in Table 6.3.

Test subject	Comments
Developer	• Comfort seems okay after 1.5 hour, no signs of getting worse during the test. • The plastic pipe introduced some uncomfortableness in the case of bigger jaw movements.
Sintef employee	• "Surprisingly comfortable!" • Attenuation seems to be good, considering that it only contains air. • Would like to see a prototype with double length stem for easier testing. • Would like to see it tested when containing liquids. • Would like to see the bladder volume being controlled by an exterior part.

Table 6.3: Notes from testing the 1st bladder and stem prototype.

The testing seemed to indicate a promising level of comfort yielded by this type of plug. It had not yet been tested as deep as it might be expected to be but was undoubtedly lying in the region of the bony part of the ear canal at 18-19 mm depths. It was not too surprising that the plastic pipe made it slightly uncomfortable, but this would not be a case with the external part attached. This kind of discomfort is exactly what the concept of a flexy stem is supposed to prevent in an ideal earplug. The comments were significant contributions to further development of the earplug.

Prototyping Section 2

What is here referred to as *Prototyping Section 2*, is a set of designs and prototypes developed with respect to the comments on the previous design. First and foremost, the stem was elongated by 20 mm to make room for a deeper fit and easier handling during testing. The remaining dimensions were unchanged, but new mould pieces were printed with the elongated cavity. At this point, some changes had to be made for the stem core, as this would not be printable with the new height. As illustrated in Figure 6.12, a threaded M3 screw with the PVA bladder core screwed onto it makes up for the internal cavity of the earplug. This solution was much more robust, making the production of the prototypes easier and more consistent.

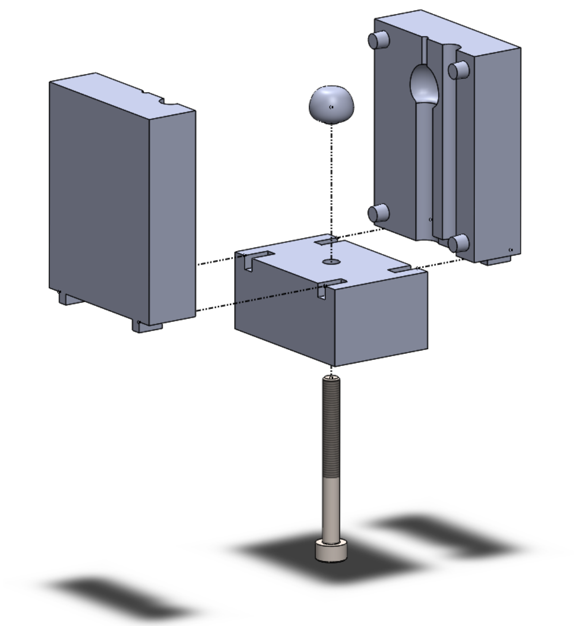


Figure 6.12: The 2nd bladder and stem mould setup.

Another concern with the previous prototypes was the deformation pattern of the bladder. A new core was designed to prevent the bladder from collapsing longitudinally when evacuated. As illustrated in Figure 6.13 the bladder core was designed to give the moulded bladder longitudinal braces for stiffening up in this direction, forcing the bladder to deform laterally by folding. The braces were designed, as shown in Figure 6.13a, as four arrow-shaped braces. The arrow-like shape had the intention of forcing the braces to meet in the center of the bladder when wholly deformed. The number of braces was a choice compromising between keeping the volume as big as possible for the liquids and having enough braces to prevent it from flattening out when evacuated. With this design, most of the thin-walled area of the bladder was preserved by putting the braces on a thinner stem towards the peripheral part of the core. Concerning the new mould design with an M3 screw as the stem core, the bladder core was 3D printed with an extruded cut to enable it for being easily screwed onto the stem core.

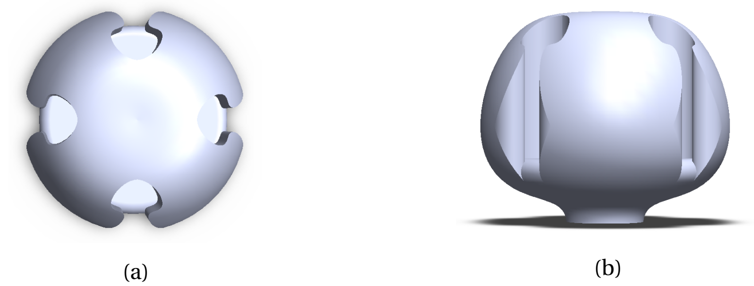


Figure 6.13: The revised bladder core design, giving laterally stiffening braces to the silicone mould.

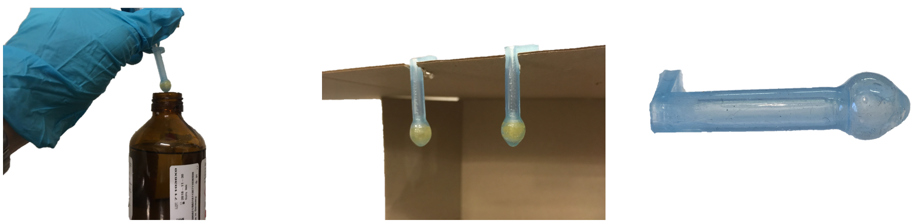
The new bladder core was slightly more troublesome from a printing perspective. The Prusa printer seemed to struggle with the fine details of the new bracing design, creating strings of PVA over the bracing holes. The printer was set up with a 0.1 mm detail level and a 40% printing speed to cope with this. Even with the finest level of detail, the printer could not manage to print the bracing design precisely. As can be seen in Figure 6.14, the shape of the bracing turned out a little different than the actual design.

Figure 6.14: 3D-printed bladder core (PVA), with cavities creating laterally stiffening braces to the finished silicone mould.

The new way of screwing the bladder core onto the M3 screw introduced some challenges to the positioning of the bladder core. By default, the bladder core would be slightly angled as a result of the screw pitch. With as little as 0.4 mm of a wall-thickness, this angle created an offset big enough almost to close the gap between the mould-pieces and the core. In production, the misalignment was compensated for by sanding down one side of the core with a fine piece of sandpaper. The process of sanding down the bladder core turned out to be a sensible procedure as it smoothened out the grains from the print. As illustrated in Figure 6.15, the mould was mounted with a reasonable gap between the core and the mould half.

Figure 6.15

With the bladder core adequately mounted with a reasonable gap all around, prototypes with elongated stems and braced bladders were made with the same production method as used earlier. The mould-pieces were clamped together before silicone was injected through the sprue. After the silicone had cured, the silicone was screwed off of the stem core, leaving just the bracing PVC core inside the bladder. The excess material was trimmed away before the plugs were dipped in silicone lacquer and hanged for curing. As can be seen in Figure 6.16b, the elongated stem implied more lacquer to be dripping off during the curing process. Consequently, the drops had to be manually removed as they built up.



(a) Dipping. (b) Curing. (c) Finished prototype.

Figure 6.16: Postliminary work after the moulding process.

A simple test was again conducted by using a syringe to see how the new design yielded concerning the deformation pattern. As illustrated in Figure 6.17, the air was evacuated from the bladder, showing how it would deform upon contraction. The bracing turned out to be affecting the contraction just the way it was supposed. When evacuated, the bladder deformed laterally while keeping the length unchanged. Several specimens of the same design were produced and tested, in which all of them yielded roughly the same results. Ideally, the bladder walls should have folded more uniformly around the center line. Some minor changes in the bracing design would have probably been able to better this, either by adjusting the design or number of braces. This design was passed on to further in-ear testing, being aware of the 3D printer issues with printing details at this scale.

(a) Side view.

(b) Front view.

Figure 6.17: 2nd prototype with simulation of bladder contraction when evacuated.

Similarly to the shorter prototypes earlier presented, an in-ear test was conducted for this prototype as well. The plug was mounted onto a plastic pipe and contracted by hand. The entrance of the pipe was kept closed to hold the contraction before the plug was inserted in the ear canal. Some saliva was applied to the bladder for easier insertion. When the earplug tip reached approximately 18-19 mm deep, the bladder was expanded by opening up the entrance of the pipe. Lastly, a clod of Blu Tac was attached to seal the stem entrance. The test was conducted for 1.5 hours and is documented in Figure 6.18.

(a)

(b)

Figure 6.18: Testing the 2nd prototype of the bladder and stem in the EAC.

Not too surprisingly, the comfort of this prototype did not differ very much from the first prototypes. Both the outer dimensions of the plug and the testing depth remained the same. However, it was interesting to note how little of a comfort change in which the bladder bracing resulted. Even though the braces are stiffening up the bladder to some extent, they seem to affect comfort minimally when oriented in the longitudinal direction. A couple of prototypes were also presented to the supervisors at SINTEF, and with positive feedback on the improvements on the new design. Responses and notes from the testing process are condensed into Table 6.4.

Test subject	Comments
Developer	• Comfort seems okay after 1.5 hour - consistent throughout the test. • Stem length gives room for deep insert testing and better handling. • Plastic pipe introduced some uncomfortableness in the case of bigger jaw movements or when touched/poked. • Promising effect from the bracing. The bladder deforms laterally when evacuated. • Much easier to insert when in the contracted state. • Despite the folds being a bit bulky and concentrically not completely uniform, the silicone is soft enough to slither through Isthmus.
Sintef supervisor	• Very usable stem length with respect to further testing. • The concept of using longitudinal bracing in the bladder walls seems to be a promising way to go. • Could consider making the wall thickness of the bladder gradually thinner towards the middle of the bladder length to achieve the right deformation.

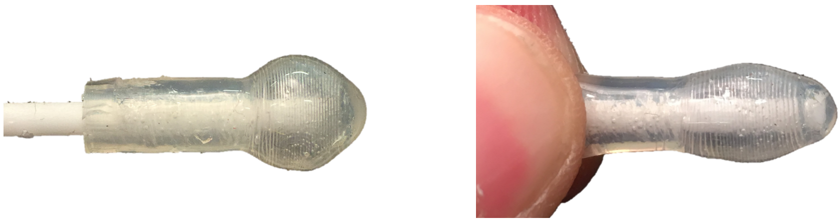
Table 6.4: Notes from testing the 2$^{\text{nd}}$ bladder and stem prototype.

6.2.3 The External Part

The external part was developed in parallel with the bladder and stem and was therefore tested in combination with the bladder prototypes. Most of the full system prototypes are presented in the section for *Final Concept*, while this subsection is going to present the choice and evolvement of the external part.

Choice of design

As described in the ideation chapter, two ways of controlling the bladder size were essentially brought up; either by mechanical elongation of the bladder, or by using hydraulics. When the first prototype of the bladder and stem was made, the mechanical variant was tried out. As illustrated in Figure 6.19, this concept seemed to work out. One great benefit of this design is how the push mechanism enables for inserting the earplug with just one hand. However, a big concern was how to retain the flexibility of the stem with the shaft inside. Some narrow spring could have been a solution to this issue but was never explored as other concepts were considered better options. As discussed earlier, the hydraulic concepts would have eliminated this kind of problem. Based on these assumptions, an elimination process took place to find a starting point in the set of hydraulic concepts. Both the accordion and piston are well-known ways of changing the volume but has the drawback of being troublesome to manage with one hand. However, the bellow concept was a promising idea at this point, appearing to deal with all of the above-mentioned challenges. Consequently, the bellow became subject for development of the external part, which will be presented in the next subsection.

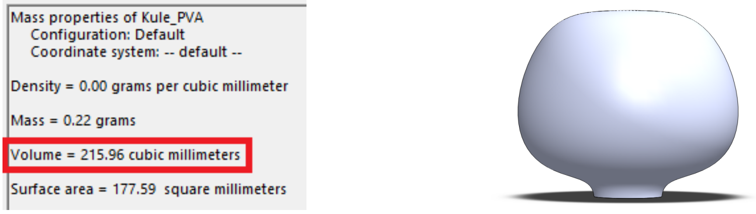


(a) (b)

Figure 6.19: Testing cross-sectional contraction of the bladder by mechanical elongation.

Bellow development

As described in the ideation chapter, and illustrated in Figure 5.7, the bellow is basically a hollow pillow that is supposed to be mounted onto the stem. When the bellow is squeezed, the internal cavity is expanding. The idea is that the increase in bellow volume will create a vacuum and suck the liquid into the bellow while the bladder is collapsing. A closed system is required for this to work. Firstly, the bladder cavity was inspected in Solidworks to find the volume needed to contract the bladder sufficiently. As illustrated in Figure 6.20, the bladder will contain a volume of approximately 216 mm^3.



(a) (b)

Figure 6.20: Volume of the bladder cavity captured from Solidworks.

In reality, a sufficiently contracted bladder will probably contain about 20-30% of the original volume, which was the basis for the first bellow prototype. Firstly, an outer shape of the bladder was modeled in Solidworks, as illustrated in Figure 6.21. Its geometry is designed to be easily squeezable with the scooped top and bottom. The side walls have a bulged out shape that follows the internal cavity, to force the right deformation upon squeezing. The cavity is designed to be a narrow oval-like pocket in the initial state. When squeezed the oval cavity is supposed to widen out towards a perfectly circular cylinder. The bellow cavity was designed with respect to the volume of the bladder cavity. Assuming that the bellow cavity becomes a circular cylinder when squeezed, this design yields a potential volume increase of 186 mm^3. The cavity is connected to a pipe that is supposed to be joined with the stem. The first bellow design is sketched out in Figure 6.22.

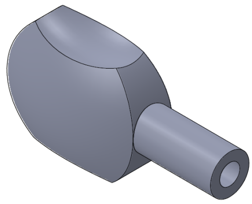


Figure 6.21

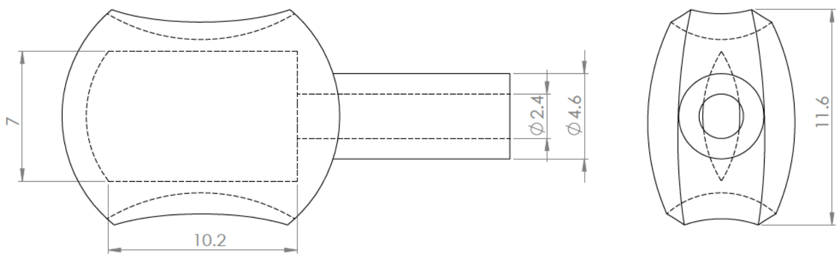


Figure 6.22: 1st bellow design.

By the same procedure as with the bladder and stem, the model illustrated above was used to make a two-piece mould in Solidworks. The modularity from the earlier mould designs enabled for reusing the mould bases, just by switching the stem cores.

As illustrated in Figure 6.23, the only changes done to the mould design is a new guide pin system. The guiding bar on the one was partly designed because of the tight space outside the sprue. However, it turned out to be a much better design regarding assembling and disassembling the moulds.

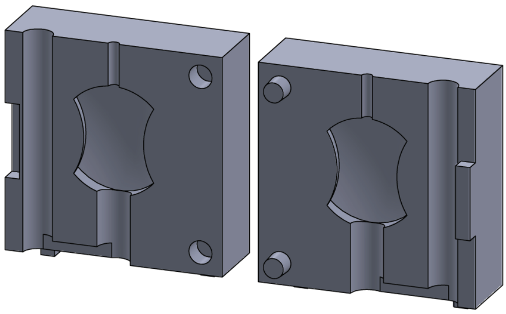


Figure 6.23: 1st bellow mould.

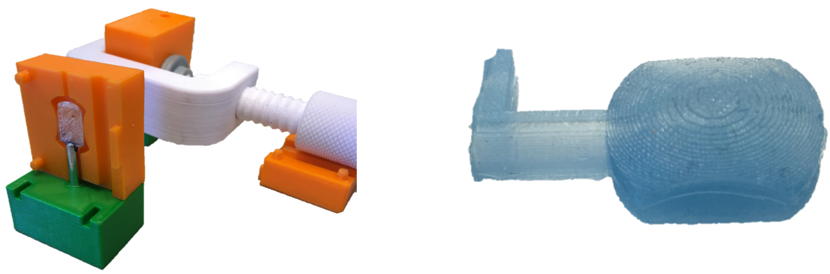
An entirely new way of doing the core was necessary at this point. As with the bladder development, a lot of the effort in prototyping the bladder was focused on creating a well-working core. The challenge was designing the core to sit tightly on the stem core while still keeping the size down, being such a tiny, narrow chip. As illustrated in Figure 6.24, several designs were tried out to deal with these issues. Again, the small-sized geometries introduced some difficulties with getting high-resolution 3D-prints. The first bellow core was designed as a fork that would mount tightly around the top of the stem core. Printing this core in an upright position was not doable, so it was printed horizontally at the expense of a poorer stem core fit. With the first version yielding poor fit and inconsistent moulding results, a second bellow core was designed, shown in Figure 6.24b. This core was designed with a bottom sleeve, tightly attaching to the stem core. This design would negatively affect the volume increase as it widens out the bellow cavity by a fair amount. Bellows moulded with the second core proved these assumptions, yielding no noticeable suction effect when squeezed. The third and final bellow core was designed as a result of a revised stem core. To retain as much potential for volume increase as possible the stem core was cut at the center of the top to enable for mounting the bellow core without having to wrap around the stem core. The third bellow core could then be printed as a completely flat chip, and thus make the initial cavity as narrow as possible.

Productionwise, the bellow was moulded with the same methods as with the bladder and stem. The bladder core was carefully wedged into the stem core top before the mould was clamped together and injected with silicone. After dissolving and washing

(a) 1^{st} Bellow core. (b) 2^{nd} Bellow core. (c) 3^{rd} Bellow core.

Figure 6.24: The evolvement of the bellow moulding core.

out the PVA core, the bladder turned out as the one illustrated in Figure 6.25b.



(a) (b)

Figure 6.25: Production of the first bellow design.

The bellow was first mounted directly to the first bladder prototype to test its suction properties. The two stems were connected with a small plastic pipe and properly sealed. As a starting point, the bellow was tested just by using air inside the assembly. In this test, the bladder was not affected at all upon squeezing the bellow, probably due to the air suspension from the compressibility properties of air. Nevertheless, a system containing water was prototyped to test the bellow in an application more true to the concept.

Figure 6.26

As illustrated in Figure 6.26, both the bladder and the bellow was mounted onto a T-connector, with the third opening blocked off by a screw. The system was assembled in water, ensuring that no air bubbles were kept inside. The squeezing seemed to work fine, by forcing the side walls out and increasing the cavity volume. Despite feeling quite like expected, the bellow seemed to have little affection on the bladder volume, even when filled with water. Since the cavity was flat in the initial condition, it might not deform quite as expected. Also, the squeezing will concurrently decrease the stem volume by narrowing down at the bellow entrance, because of the small-sized bellow. A revision of the bellow design, based on the test report tabulated in Table 6.5, had to be made for this concept to work.

Test subject	**Comments**
Developer	• Reacts as expected upon squeezing, with the walls bulging out and cavity widening up. • Good size with respect to sitting in concha. • Small evacuating effect on the bladder.

Table 6.5: Notes from testing the 1st bellow prototype.

A completely new design was drawn to improve the volume increase of the bladder, as illustrated in Figure 6.27. The second bellow was designed with increased length and height of the cavity, compromising slightly on the overall size. A more uniform deformation of the cavity over the whole length was ensured by straightening up the outer geometries, designing them to go along with the internal geometries. The pocket was still kept as narrow as possible, but with more of an oval shape than the bellow core used for the previous prototypes. Designing the core with a straight cut on the stem side also enabled for 3D-printing the core in upright position, and thus achieve the desired shape. The new core was a lot easier to print than the previous cores, yielding much more consistent results.

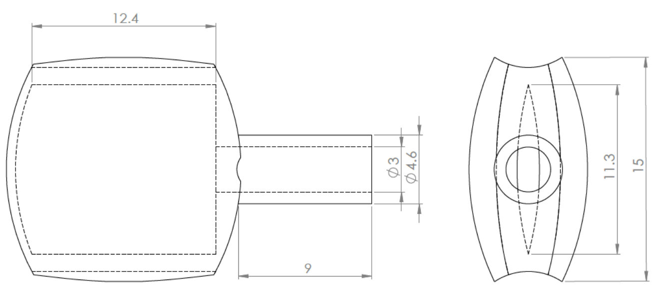


Figure 6.27: 2nd bellow design.

A new set of moulds and cores were constructed with the enhanced design, as illustrated in Figure 6.28. Once again the mould halves were made to fit the already printed mould bases, and with the same features as previously used moulds.

Production of the second bellow was executed the same way as with the first. After

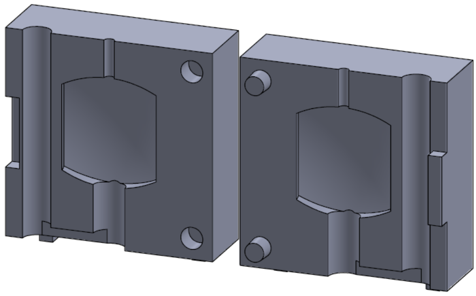
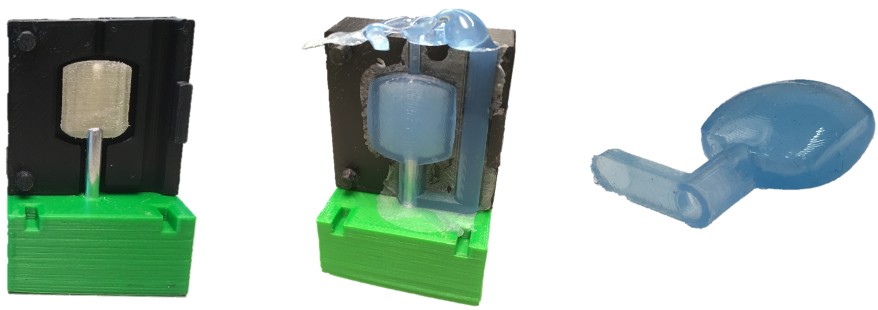


Figure 6.28: 2nd bellow mould.

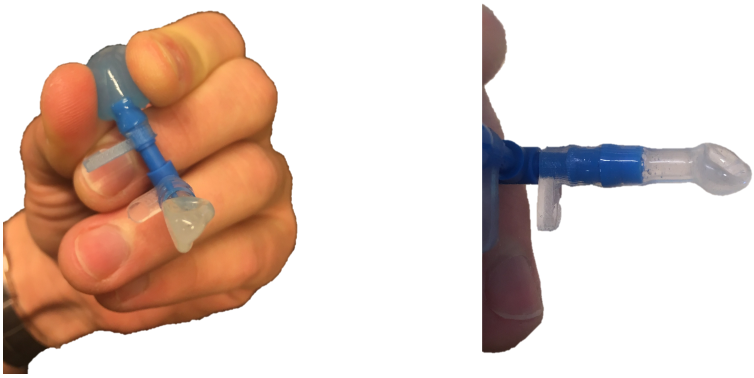
printing, the bellow cores were sanded down at the bottom sides to follow the outer shape of the bellow, as can be seen in Figure 6.29a. The bellow core was then hammered onto the stem core for a wedged and tight fit, followed by silicone injection, curing and trimming. The new PVA core was much easier to get out, being slightly longer and wider relative to the depth. Contrary to the moulding cores previously experimented with, this could easily be broken into pieces and pushed out through the stem even before completely dissolved. Finally, two layers of silicone lacquer were applied to the bellow, before the second version was ready for testing.



(a) Mould assembly. (b) After curing. (c) Finished bellow.

Figure 6.29: Production of the 2nd bellow prototype.

A new assembly was prepared using the second prototype of the bladder and stem to test the evacuating effect of the new bellow prototype. A T-connector was used to connect the two pieces, with the third connection blocked off. After filling the T-connector, bellow, bladder, and stem entirely with water, the system was assembled under water. As illustrated in Figure 6.30, the bladder contracted the same way as with the syringe when the bellow was squeezed. The bladder immediately reacted to the bellow squeeze and shrunk up to a certain point. Continued squeezing after the bellow cavity had reached its maximum volumemade the bladder start expanding again. Notes from testing the second bellow prototype are tabulated in Table 6.6.



(a) (b)

Figure 6.30: Testing the 2nd prototype of the bellow in application with the bladder.

Test subject	**Comments**
Developer	• Immediate contraction of the bladder when squeezed. • Able to evacuate the bladder almost to the full extent. • Still fits okay in concha, despite the increase in size. • Can be hard to hold at the exact point for maximum bladder contraction without tipping over. • The increased width makes this bellow slightly harder to squeeze without twisting. Some structural improvements might be done to prevent this. • Could need a mechanism to stop the squeeze when the cavity is fully expanded.

Table 6.6: Notes from testing the 2nd bellow prototype.

6.2.4 The Attenuating Medium

Water was the only liquid used as attenuating medium in this projects prototypes. As described in the literature chapter, water yields great attenuating properties in comparison with topical mediums like oils, gel, and glycerine. Being the most available and easily handled among the considered mediums, water became a first choice for the prototyping and testing.

6.3 Final Concept

This section will condense all the presented prototyping and development into status quo for the full-system deep insert earplug. The concept choices related to each subsystem will be enlightened through the previously discussed morphology matrix, to get an overview of the final concept of this next generation earplug. Some of the most prevailing full-system prototypes will be presented, representing the prototypes tested in Chapter 7. Lastly, some concepts will be presented as more ideal models of this earplug.

6.3.1 Final Morphology Matrix

The final morphology matrix, Figure 6.31, illustrates the conceptual path taken within the different subsystems and makes up for the full-system concept used for the prototypes tested in Chapter 7.

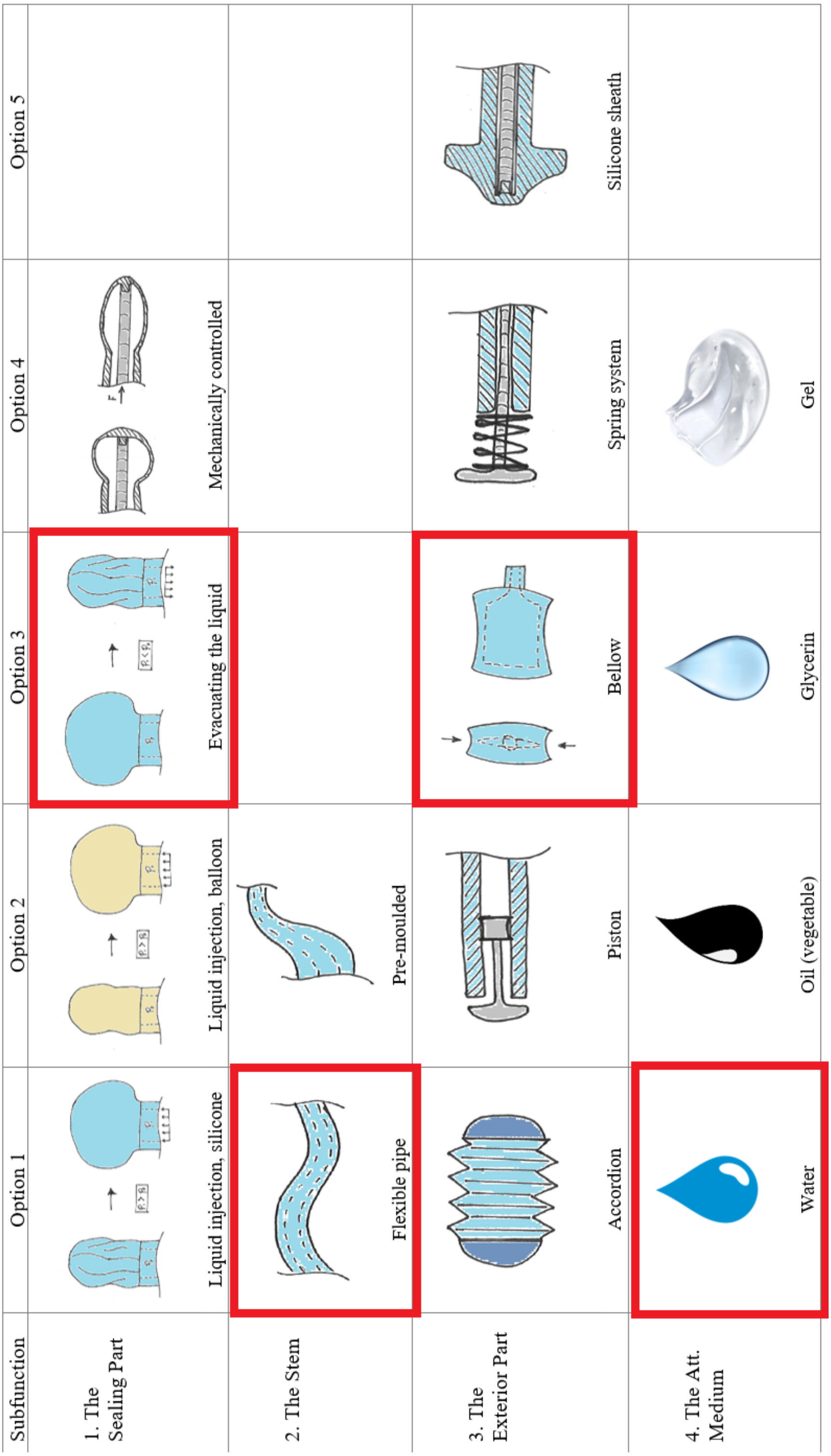


Figure 6.31: Final morphology matrix.

6.3.2 Full-system Prototype

The final full-system prototype of the deep insert earplug is an assembly of the latest subsystem revisions. These prototypes are the ones used for the attenuation measurements in Chapter 7.

Parts List

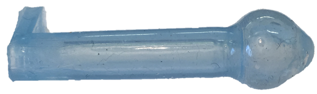
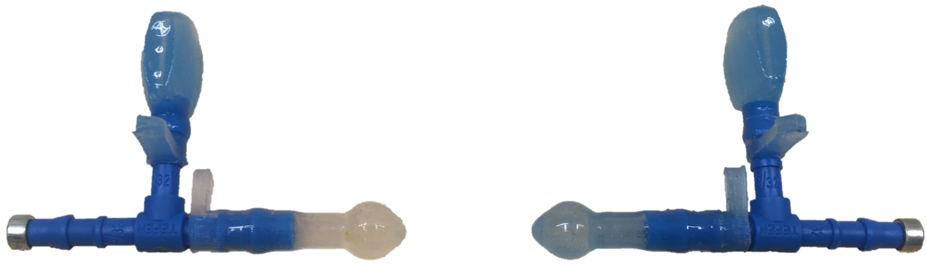
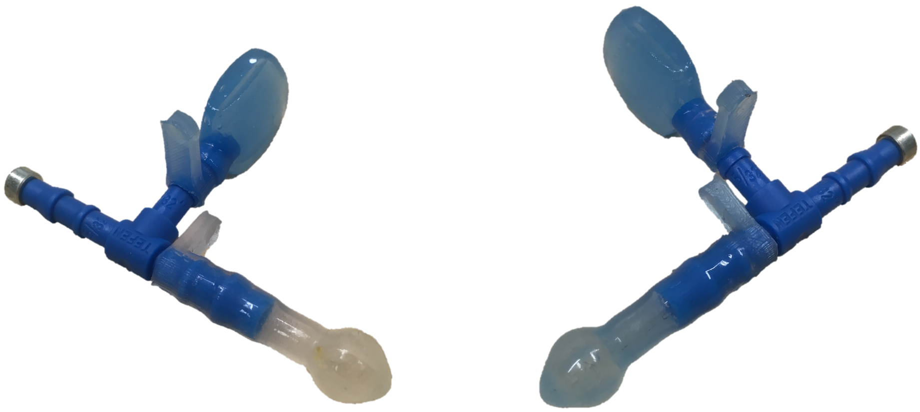
Part	
Bladder/Stem (*v2*)	
Bellow (*v2*)	
5/32" T-connector	
M3 Hex socket screw	

Table 6.7: Parts list for the final assembly.

Illustrations



(a)



(b)

Figure 6.32: Final prototypes.

Testing

The final prototype was inserted into the EAC on several occasions, with the purpose of testing comfort and overall feel. The first test was conducted for approximately 45 minutes, with the earplug inserted at a 20 mm depth. Pictures from this test are illustrated in Figure 6.33. The plug was slightly troublesome to insert the first time but got in with the help of a mirror and saliva as lubricant. With some light pushing, the bladder slipped through isthmus. No pain or discomfort was reported during the insertion. When the bellow was released, the bladder immediately sealed tightly against the ear canal. The earplug felt comfortable throughout the test period and proved to be very little sensitive to jaw movements, indicating a proper fit in the osseous canal. The protruding exterior part is not the tidiest, but this is not the scope of the prototype. After testing, the bladder was contracted by squeezing the bellow, and taken out without problems.

(a) (b)

Figure 6.33: 1st test of the full-assembly prototype with respect to comfort and convenience.

Some smaller prototypes with chopped off T-connectors were also assembled but proved not to be as easily handled as the larger versions. For the purpose of testing the subsystem concepts, the larger prototypes were used for the most part. The REAT-measurements presented in Chapter 7 were conducted with these exact prototypes and revealed some new things about them. The comfort was reported to be good, but the bellows proved to be too fragile for several insertions. A few of them had to be replaced after about 30-40 insertions because of tearing apart. All incidents of tearing happened right in the transition between the short side wall and the stem at the bellow, as illustrated in Figure 6.34. This would be easily dealt with by designing the bellow with slightly thicker walls in this area. Notes from testing and using the full-system prototype are condensed into Table 6.8.

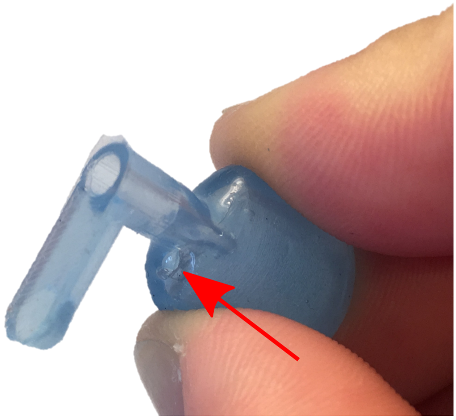


Figure 6.34: Torn apart bellow from several insertions of the full-system prototype.

Test subject	Comments
Developer	• Comfortable and feels good. • No pain or discomfort, even after several inserts within a short time span. • Takes some practise to control and manage with ease. • Bellow is easily twisted if squeezing with an offset. Need some structural stiffening to prevent this. • Bellow tears apart in the transition to the stem after several uses. • A more compact and user-friendly prototype might be sensible when testing on other subjects. • Difficult to know exactly how deep it penetrates, especially for outsiders.

Table 6.8: Notes from testing the full-system prototype.

6.3.3 The Next Generation Earplug - Concept Model

The subsystem concepts developed for the deep insert earplug have yielded promising results also when implemented on a system level. It is therefore contiguous to start developing a full system design, and not just a functional prototype. The subsystems certainly all have a potential for improvement concerning form an function, but they all fulfill with respect to the expected functionalities of the earplug at this stage. Up to now, testing and development have been focusing on achieving just that. A conceptual model was designed to illustrate the ideas for a full-system with all of the components seamlessly implemented. The design brings in all the best from subsystem development, but at the same time empathizing on functionality and feel from a user perspective.

Figure 6.35: Concept model.

The concept model, illustrated in Figure 6.35, is based on the final prototype from the development chapter. Instead of positioning the stem inlet at the short side bellow wall, it is placed on the bulging side. This way the bellow would rest against the concha, without protruding, when correctly inserted. The stem length is designed to give a 22 mm deep fit in this case. Also, the bladder and stem is mounted to the bellow with an offset, ensuring that the bellow is not conflicting with other parts of the outer ear.

By now, it is known that the bladder would benefit from getting a structural improvement to prevent it from twisting and bending the wrong way upon squeezing. However, placing the stem on the bigger side wall of the bellow, as well illustrated in

Figure 6.36: Concept model (sideview).

Figure 6.36, is likely to be positively affecting this issue. When inserting the earplug, the bladder and stem will contribute with a moment of force counteracting to the potential twist movement. Additionally, the fillet supporting the bellow-stem connection for structural integrity is assumed to improve the bellow behavior quite drastically. More concept model illustrations are to be found in *Appendix A*.

Chapter 7

Attenuation Measurements

As part of exploring the full-system earplug concept, some testing of the actual noise reduction was preferred. With promising results on both functionality and comfort, the next step was doing REAT-measurements to verify - or at least seek indications on - the attenuating effect of the next generation earplug concept. The following chapter presents the method and results from testing attenuation of the prototype in the acoustics laboratory at *SINTEF Digital*, Trondheim. The scope of experiments in this chapter was not only to investigate the actual attenuating abilities of water in the application of a deep insert earplug but also to test its attenuation at different ear canal depths and compare it with commercially available HPDs.

7.1 The NEWT Method

The measurements in this thesis were conducted by using an automated test method, known as the New Early Warning Test (NEWT). The NEWT method, presented by Vinay et al. (2014), is a method originally designed to automatically monitor auditory threshold in individuals exposed to high levels of noise. An adaptive maximum likelihood estimation (MLE) psychophysical procedure, first proposed by Green (1990), makes up for the basis of the NEWT method. In this application, the MLE procedure essentially aims at finding the most probable hearing level (HL) for the subject being tested. The HL estimates from these procedures are shown by Vinay et al. (2015) to be at least accurate as normal audiometry.

A total set of seven frequencies is played in a randomly generated order during the test, with each frequency trial consisting of six sound stimuli. The test frequencies are 125, 250, 500, 1k, 2k, 4k and 8k Hz. A push button is connected to the test system, and the subject is asked to respond to hearable sounds. The test subject has a 2 s interval in which the push button can be pressed before a new stimulus is played. After the test subject has given a response, an additional random pause between 0 and 3 s is given. In the exact software version used for these measurements, the sounds are changed to 1/1 octave band-pass filtered noise. The method for test attenuation is carried out in accordance with the standard for REAT-measurements, *ISO 4869-1*.

7.2 Test Setup

A schematic presentation of the test setup is illustrated in Figure 7.1. In one room, the *control room*, all the software and sound processing is being controlled. This includes a PC running the NEWT software, a *D-Audio* USB Audio Reference Sound Card and a *NAD 312* stereo integrated amplifier driving the speakers. A second room, the *acoustics room*, is a sound isolated room separated from the control room for a completely sterile listening environment. The acoustics room has four speakers placed at a head level height in each corner of the room. The test person sits in a chair right in the middle, and the sounds are presented binaurally to the listener through the four speakers. A push button is placed in the middle for the test person to respond to the sounds. Realistic pictures of the test setup are illustrated in Figure 7.2b.

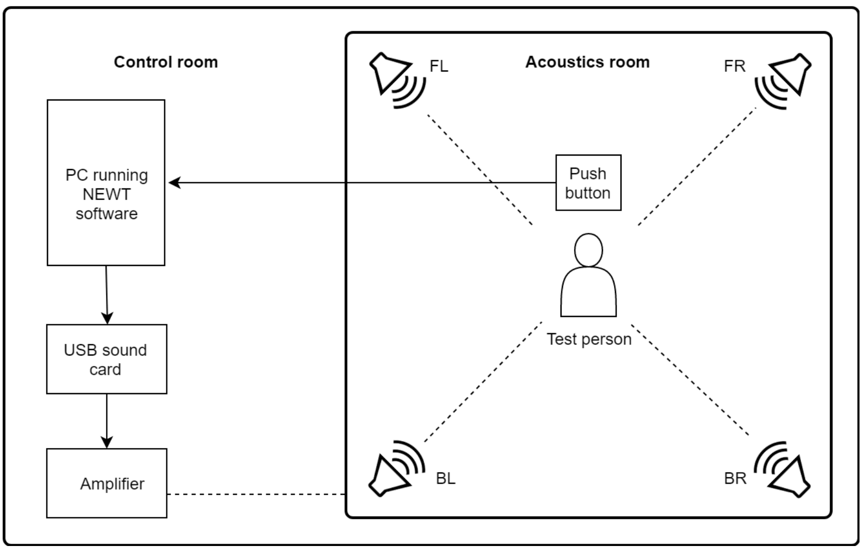
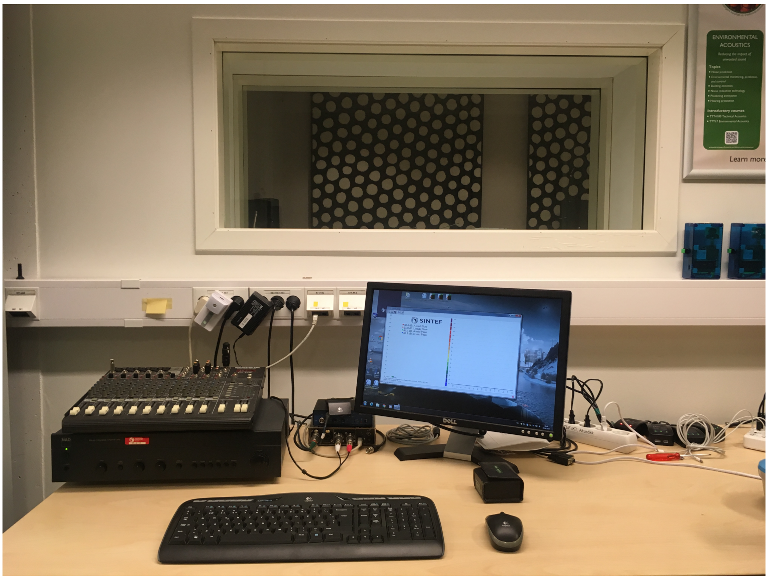


Figure 7.1: Schematic REAT test setup.



(a) Control room.

(b) Acoustics room.

Figure 7.2: REAT test setup.

7.3 Procedure

A test is initiated by starting the NEWT from the control room. When the subject presses the push button, the test starts. The button shall be pressed by the subject every time noise is clearly heard. A fanfare is played when the test is finished. The test data can be exported to an excel document from the NEWT software, and categorized within the selected "earplug type" and "test subject". The data is easily trackable, with results on the measured threshold at the respective frequencies, and marked with date and time.

The NEWT graphical user interface (GUI) is illustrated in Figure 7.3.

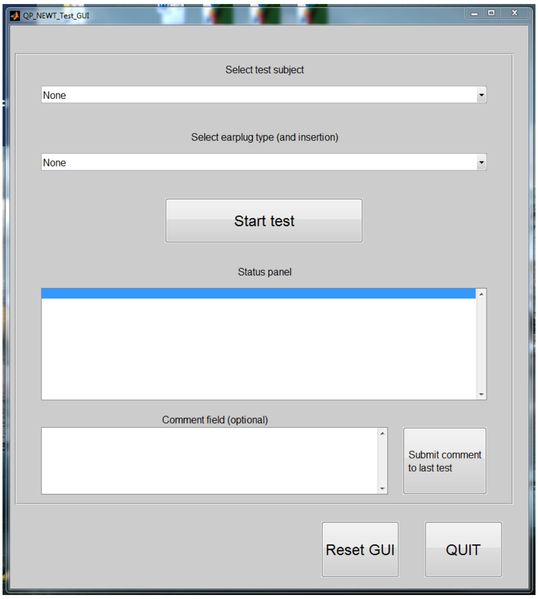


Figure 7.3: The NEWT GUI.

To be able to calculate the noise reduction of an HPD it is necessary to have an open threshold reference value. Therefore, the test session is opened by conducting the NEWT without an HPD. The noise reduction of the tested HPDs is then calculated by finding the difference to these reference values. Firstly, it is preferred to tweak the parameters of the MATLAB script to get the open threshold values as close to zero as possible across the whole frequency spectrum. This is due to a limited dynamic range of the system, and getting as much room for attenuation as possible without exceeding these limits. The script is tuned by adjusting the parameters in accordance with the first reference value test.

The noise reduction yielded by the HPDs is calculated by using REAT. As stated by Berger and Casali (2007) REAT is defined as the difference between occluded threshold values, from wearing an HPD, and open threshold values, from not wearing an HPD:

$$REAT = Threshold_{occluded} - Threshold_{open} \tag{7.1}$$

7.4 Participant

Due to limited resources and time, the tests were only conducted on the developer. The test participant had normal hearing range (<25 dB hearing loss) from 125Hz through 8kHz and was tested by pure-tone audiometry. The participant is not experiencing any discharge, pain or tinnitus in the ears. A few test runs with guidance from a SINTEF supervisor were initially conducted before testing started. Consequently, the test subject knew the testing procedures.

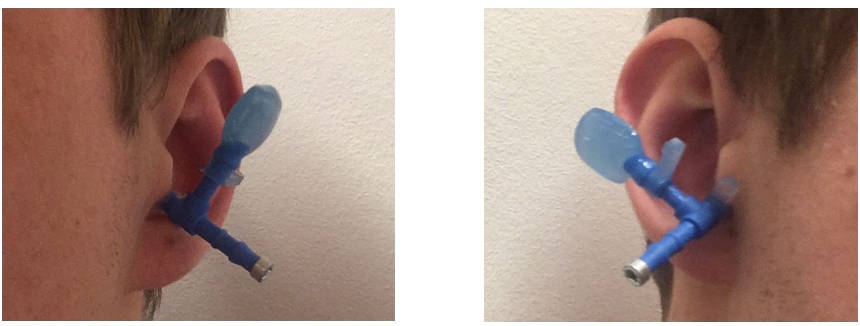
7.5 Design of Experiments

The testing was essentially conducted with the intention of exploring three things:

1. Attenuation of a deeply inserted full-system prototype.
2. Change in the attenuating effect of the prototype at different EAC depths.
3. DI Prototype attenuation compared to commercially available HPDs.

7.5.1 The Full-system Prototype - Deep Insert

First and foremost, the attenuating effect of the full-system prototype deeply inserted, approximately 23 mm deep, was measured. The prototype was tested at this depth for two insertions, in which one of the insertions were tested twice. Testing them twice at the same insert was done to cope with some of the measurement uncertainties. Inserting the plugs twice was done to take account of the variation from insertion. A deeply inserted set of plugs is illustrated in Figure 7.4.

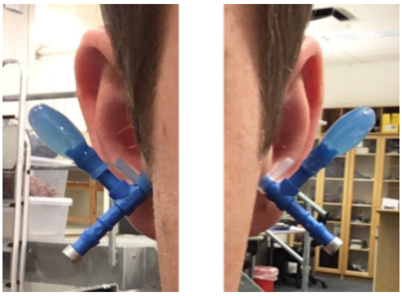


(a) Left ear. (b) Right ear.

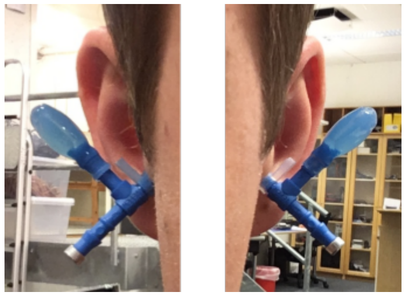
Figure 7.4: The full-system prototype inserted 23 mm deep in the EAC.

7.5.2 The Full-system Prototype - Various EAC Depths

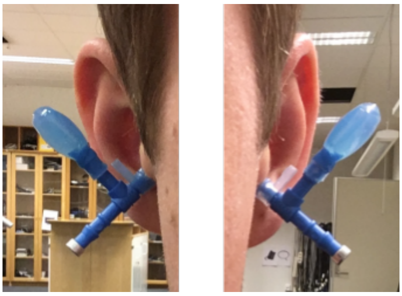
To further investigate the effect of a deep insert fit, the prototype was tested at different depths of the EAC. These measurements were conducted by inserting the full-system prototypes 23 mm deep in the EAC and running the NEWT. The plugs were moved out approximately 2 mm between each measuring. As with the testing discussed above, the test was run twice for each depth to even out the uncertainty of measurement. The depths are highly approximated and are documented in Figure 7.5.



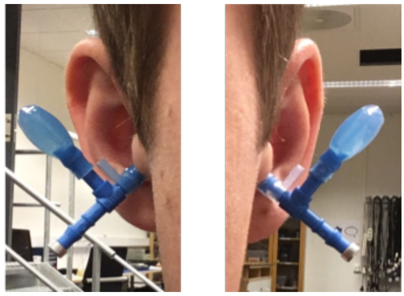
(a) 23 mm.



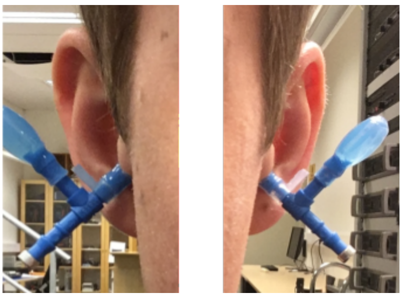
(b) 21 mm.



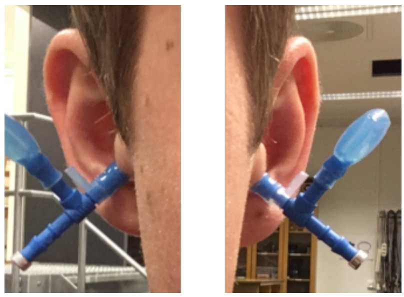
(c) 19 mm.



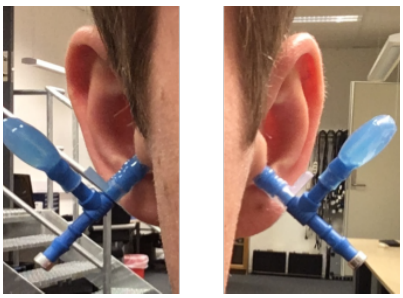
(d) 17 mm.



(e) 15 mm.



(f) 13 mm.



(g) 11 mm.

Figure 7.5: Testing the full-system prototype at various depths.

7.5.3 Comparison with Commercially Available HPDs

Two commercially available HPDs were tested in the same manner as the DI prototype, to have some reference values of known devices. The *3M E·A·R Classic* and *3M Peltor Optime III* were the choices for comparison, being two of the most commonly used HPDs on the market. These reference devices could then be used to indicate "lay of the land" for the prototype in comparison with both foam earplugs and earmuffs. Technical data sheets for the 3M HPDs can be found in *Appendix B.2*, with the relevant 3M laboratory attenuation data condensed into Table 7.1. Note that 3M Peltor Optime H10A is the equivalent to 3M Peltor Optime III in the laboratory attenuation data. These values are just presented as a reference to the NEWT results.

Device	Lab. att. [dB]	Frequency [Hz]						
		125	250	500	1k	2k	4k	8k
3M E·A·R Classic	Mean	37.4	40.9	44.8	43.8	36.3	42.6	47.3
	SD	5.7	5.0	3.3	3.6	4.9	3.1	2.7
3M Peltor H10A	Mean	21.0	26.0	36.6	40.6	38.0	42.7	41.3
	SD	1.9	2.3	2.3	2.4	2.5	1.8	2.5

Table 7.1: Laboratory Attenuation Data from 3M™.

As discussed in Chapter 2, the *3M E·A·R Classic Plus* was shown by Berger et al. (2003) to reach the BC limits of humans, and is therefore considered one of the most effective HPDs when deeply inserted. For the tests in this research, the *3M E·A·R Classic* was the variant being used. Compared to the "Plus" variant, these plugs are slightly shorter but are assumed to reach just over 20 mm when deeply inserted.

(a) 3M E·A·R Classic.

(b) 3M Peltor Optime III.

Figure 7.6: Two commercially available 3M HPDs for comparison.

The earplugs were inserted two times and tested twice for each insert. Testing them twice at the same insert was again done to cope with some of the measurement uncertainties while inserting the plugs twice was done to take account of the variation of insertion. The same procedure was used for the earmuffs, which were tested in an over-the-head position. As illustrated in Figure 7.7, the earplugs were deeply inserted with minimal protrusion outside concha.

(a) 3M E·A·R Classic deeply inserted.

(b) 3M Peltor Optime III onset.

Figure 7.7

7.6 Results

7.6.1 The Prototype at Various Depths

Results from measuring REAT for the full-system prototype are condensed into Table 7.2, and graphically presented in Figure 7.8. These results include measurements of the prototypes both deeply inserted (23 mm) and for various EAC depths. All the data of which the mean REAT-values are based on can be found in *Appendix C.1*.

Depth [mm]	Value [dB]	Frequency [Hz]						
		125	250	500	1k	2k	4k	8k
23	Mean REAT	39.5	39.8	42.8	43.5	45.5	33.8	36.0
21	Mean REAT	32.8	28.0	33.8	36.8	34.8	32.8	33.0
19	Mean REAT	36.5	31.0	36.8	41.8	38.8	36.8	33.0
17	Mean REAT	31.0	29.0	33.8	41.8	36.8	38.8	31.0
15	Mean REAT	30.0	29.0	30.8	41.8	34.8	39.8	33.0
13	Mean REAT	13.5	10.0	13.3	26.5	30.8	28.3	26.5
11	Mean REAT	9.5	6.0	11.8	15.5	22.0	19.0	8.0

Table 7.2: Mean REAT-values for various depths.

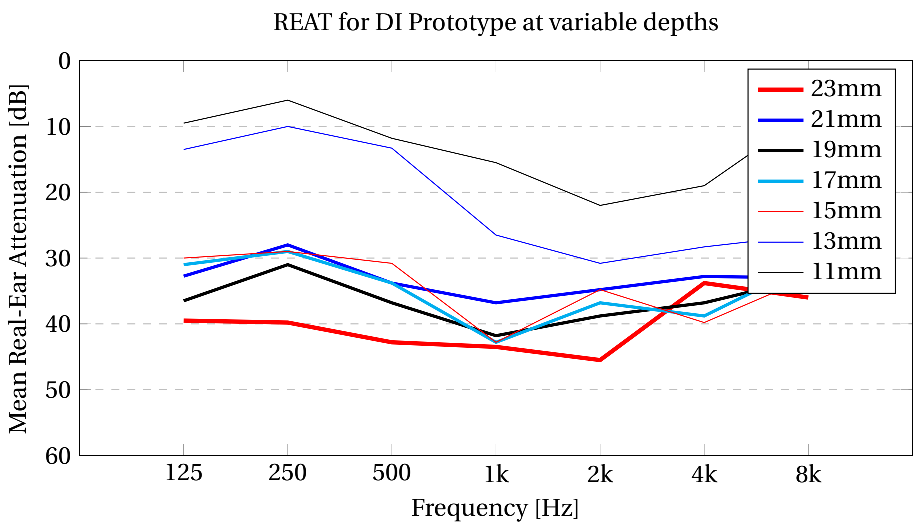


Figure 7.8: REAT for the final prototype at variable depths.

7.6.2 Comparison with Commercially Available HPDs

Results from measuring the 3M earplugs and earmuffs are condensed into Table 7.3, and graphically presented in Figure 7.9. The mean REAT measurements are here compared to the prototype measurements at a 23 mm depth. All the data of which the mean REAT-values are based on can be found in *Appendix C.2*.

Device	**Value [dB]**	**Frequency [Hz]**						
		125	250	500	1k	2k	4k	8k
DI Prototype	REAT	39.5	39.8	42.8	43.5	45.5	33.8	36.0
3M E·A·R Classic DI	REAT	37.5	37.0	39.8	43.1	40.3	40.3	38.5
3M Peltor Optime III	REAT	18.4	26.6	40.8	41.3	37.8	36.8	30.1

Table 7.3: Mean REAT values from comparison tests.

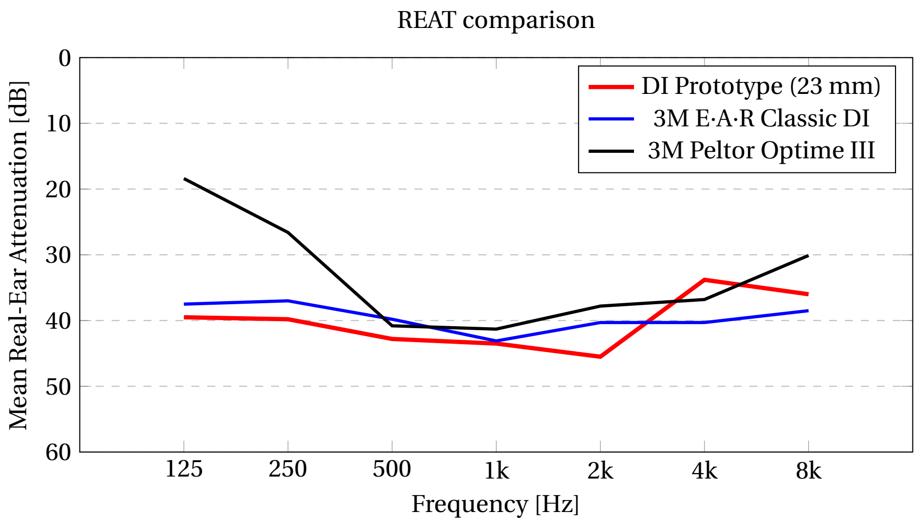


Figure 7.9: Comparison of mean REAT values for the final DI Prototype, *3M E·A·R Classic* foam plugs, and *3M Peltor Optime III* earmuffs.

Chapter 8

Discussion and Study Limitations

This chapter discusses the findings from developing and testing the deep insert earplug. The results are analyzed and interpreted while limitations to the study are highlighted. Lastly, a set of bullet points are listed as recommendations for further work.

8.1 The Deep Insert Earplug

This project set out with the goal of finding new ideas to an earplug that yields better sealing and better comfort than existing solutions, without compromising on attenuation levels. The preliminary work contributed to a delimitation of the problem, narrowing down the space of investigation to some deep insert, liquid-filled earplug. The objectives were made to be as specific as possible, without excluding potential solutions to the problem. Objective one was achieved by conducting a literature review, including an extensive investigation of ear canal anatomy and previous dimensional research. The second objective was achieved by approaching the concept generation in a set-based manner, with solution spaces well constrained by the defined product requirements. The choice of applying wayfaring and probing as a design methodology is considered an important factor for arriving at the final concept. Especially the sealing part and external part were results of learning from rapid prototyping cycles, fulfilling the third objective for this work. The result of a promisingly comfortable and well attenuating deep insert earplug certainly seems to resonate with the initial goals of this project. Some discussion has been included in the ideation and development chapters as a natural part of progression in a development process like this, but major findings will be discussed more deeply in this section. Regarding the functional requirements addressed through the Kano model, the final prototype has shown to fulfill all of the basic needs. Most of the performance needs are also fulfilled, except comfortable long-term wear, which has not been tested yet. Despite some weaknesses in the bellow design, the final prototype is also reusable, being one the delighters.

The Sealing Part and Stem

Based on the literature review, the goal was to come up with the most universal design to the sealing part. As described in the development chapter, the sealing part was designed with the best approximation between findings from Staab et al. (2000) and Stinson and Lawton (1989). Front-loading and spending much time to interpret and combine such studies resulted in a bladder that yielded complete sealing in the osseous canal without reported discomfort. It is important to note that these sealing results are only based on testing in a small population of males - the developer's and a Sintef employee's ear canals - and cannot be considered perfectly significant. However, the population is including ear canals of individuals in both their twenties and sixties and thus imply some degree of universality of the dimensional design.

Developing a clever solution to the sealing part has been a critical factor for obtaining solutions to the overall problem. As stated in the introduction, hearing protection devices will always be compromising between the degree of sealing and comfort, and the final prototypes from this work indeed seem to empathize on both. Comfort was highly focused on, not only by an adequately calculated bladder design but also by keeping the flexibility of the stem. The way of controlling the bladder contraction by hydraulics is considered crucial for obtaining the reported comfort. Probing cycles and low-resolution prototypes drove the bladder design towards what it is today. Badly deforming bladders quickly became subject to development of this subsystem, but the longitudinal bracing inside the bladder managed to cope with this problem. Despite still deforming in a slightly non-uniform manner concentrically, the bracing showed evidence of working purposely. The latest bladder design, deforming laterally upon evacuation, slithered through isthmus without problems and was considered proof of concept good enough to focus on further testing and developing other subsystems. As reported by Casali and Park (1990) large jaw movements have shown to reduce the protection levels for earplugs generally. Earplugs that seal against the ear canal over the whole penetration length will typically be affected by such movements because of propagating into - and thus moving - the cartilaginous canal. Unlike these types of earplugs, the bladder concept from this work only seals against the osseous canal when deeply inserted, causing little to no movement of the plug in the case of large jaw movements. This is assumably one of the main reasons for the reportedly promising comments on comfort. However, the small sample sizes of test subjects are considered a limiting factor to the results concerning comfort. More time and resources to produce enough prototypes would have allowed for testing in a larger population. At least a convenience sample of 20 or more subjects would have been preferable to test the prototypes with respect to usability and comfort.

The External Part and Concept Model

Even though the sealing part was the determinant in this development process, it was useful to engineer the different subsystems concurrently. Development of the external part was accelerating after the reported discomfort from testing the earplug with a sealing plastic pipe inside. The initial choice of a bellow concept for the external part was based on best guesses. The bellow concept yielded features that were convenient with the bladder design that was already in progression, in addition to the benefit of controlling the bladder completely without mechanical transmission. After a few iterations, the bellow proved to work exactly as expected, shrinking down the bladder by vacuum when squeezed. With water being essentially incompressible, using this as an attenuating medium resulted in a highly reactive connection between the bellow and the bladder. As pointed out during testing, the bellow design shows some structural weaknesses in application with the full-system prototypes. When mounted to the stem at the short side wall, the bellow tended to twist around if not squeezed the right way, especially in the hands of inexperienced users. However, testing with respect to functionality and comfort showed proof of concept for the full-system concept presented in the final morphology matrix. A concept model of the full system deep insert earplug has been illustrated at the end of Chapter 6, showing how all of these proven subsystem concepts ideally can be implemented into one complete earplug. As briefly discussed, this model is assumed to improve the integrity of the bellow by the new placement of the stem and bladder. A moment of force from the stem and bladder is assumed to counteract the potential twist movement when inserting this earplug, in addition to the fillet supporting the connection between stem and bellow.

The Attenuating Medium

Water quickly became subject for the attenuating medium, with its great availability, biocompatibility and and acoustical properties. Not only did water serve as an attenuating medium, but more importantly it became key for controlling the sealing part hydraulically with the external part. Additionally, it proved to be compatible with the RTV-silicone used for the prototypes, with no signs of chemical degradation. A concern with using water is its relatively high freezing point. The prototypes were never tested in environments with temperatures down towards or below 0°C. Consequently, the case of a frozen earplug was not experienced. As discussed in the concept generation there are several media that are able to cope with the freezing issues, where especially glycerol might seem to be strong candidate.

Method

The production methods used for making prototypes in this work has proven to be rather sub-optimal. Despite resulting in finely detailed prototypes, the process is very time-consuming. The moulding process itself is quick, but the prework and supplementary work is not. The process of getting the PVA core out of the moulded parts is particularly time-consuming, often taking several hours to complete. The injection moulding was great for making a few prototypes for iterative learning but did not allow for making enough devices for a typical preferred sample size of twenty test subjects or more. Mass production of these earplugs would require an enhanced and more efficient production method. Looking at alternative core materials could solve a lot of the addressed production problems.

It is plausible to assume that the results from the development process have some limitations, regarding the limited time and human resources. The prototyping and testing was intended just to indicate some proof of concepts, leaving lots of room for polishing and refining the solutions. Comfort and functionality have been the key areas of focus during the development process, but the intentions of adequately testing a full-system prototype's attenuating properties in the acoustics laboratory have been continuously driving the project forward. Being one developer in this project, making up for a rather homogeneous team, is undoubtedly one of the limiting factors of this work. Even though acoustics expertise from the SINTEF co-supervisors and PD expertise from the supervisor have been available throughout the project, the process is likely to have been halted to some extent by the one-man developer team. Homogeneity can easily affect decision making, efficiency, and multidisciplinarity in ways that are not necessarily serving an NPD process like this.

8.2 Attenuation Measurements

The choice of using the NEWT method turned out to be useful for this work, and a necessity for being able to achieve the fourth objective. With limited time after the product development phases, such an automated test method was just efficient enough to get sufficient measurements to predict the attenuating effect of the concept. The fact that the NEWT method does not require any audiologist to be conducted was also a crucial factor for execution of the measurements.

By the standards for subjective method of measuring sound attenuation, *ISO-4869-1*, sixteen subjects shall be used for each test. In this research, time and resources did not allow for that. The measurements are highly intended to be indicators that support - or inhibit - the concepts from the development phase, rather than proving anything. However, the repeatedly consistent results from testing the prototype certainly indicate the concepts' attenuating effect with high plausibility. As a reference point for the validity of the test, the measured mean REAT-values for the 3M E·A·R Classic earplugs are sitting within the standard deviation data from 3M (*Appendix B.2*) for all frequencies except two. The measured values for 500Hz and 8kHz lie slightly outside the standard deviation of the 3M laboratory attenuation data. The measurements for 3M Peltor Optime III are also lying in the same range as the laboratory attenuation data from 3M, but also here with some values slightly outside the given standard deviations, especially for the higher frequencies. However, the curves seem to follow the same pattern. A comparison of the mean REAT data measured in this work and the laboratory attenuation data from 3M is graphically presented in *Appendix C.3*. The lower measured attenuation values for the Optime III earmuffs might be due to a slightly looser headband, as they were not new. As specified in *ISO-4869-1*, application force of the earmuffs shall ideally be measured and reported, but this was not empathized for the scope of this testing. Standard deviations would be preferred to have in the presented DI prototype data, but the limited test frame did not allow for sample sizes big enough for SDs to be valid. The fact that the test subject is biased to some extent, being the developer of the earplug, is not to be circumvented. With that being said, the NEWT method, with randomly ordered frequency bands for each test, is able to appease this to a considerable degree. The random order makes it almost impossible to cheat and purposely repeat the response at every test. The small variation in the test results presented in *Appendix C* undergirds this.

For a first attenuation test of the full-system concept, the results are rather strong when compared to the other commercially available HPDs tested. The prototype yields better attenuation than both the deeply inserted 3M E·A·R Classic foam plugs and the 3M Peltor Optime III earmuffs in the frequency range of 125Hz to 2kHz. The dip in attenuation for the prototype at 4kHz is somewhat hard to explain, but the variable depth measurements indicate that this is a special case for the 23 mm depth. When looking at the raw data presented in *Appendix C.1*, the mean REAT values for 4kHz seem to follow a pattern of increasing when moving from 23 to 15 mm depths, before it decreases. There are no signs of any outstanding deviations in the data at 23 mm depth, and this frequency might just be a weaker spot for this prototype. As discussed in Chapter 2, BC limits typically range between 40 and 60 dB depending on the frequencies. With the DI prototype yielding attenuation levels around the magnitude of 40 dB for all octave bands, it is certainly pushing these limits. It is especially interesting to note how consistent the attenuation is for the depths from 15 mm to 21 mm. Measurements in this region are only varying within a 5dB window. When moving further out of the EAC, the level of attenuation drops drastically. However, the deepest insert at 23 mm yields particularly great sound attenuation, indicating the benefits of a deep insert fit sealing against the osseous canal. The discovery of a relatively low drop of noise reduction from 23 mm to 15 mm depths might reveal the options for a shorter length version of the DI prototype. A 30 dB level of attenuation will in most practical cases be more than sufficient. The 15 mm deep insert, measuring attenuation levels of 30 dB or more for the full frequency spectrum, indicates that a 15 mm version of the prototype would be a variant to consider for an optional model.

If comparing the attenuation results from measuring the prototype and the 3M earplug, the level of sealing yielded by the prototype is rather promising considering the difference in lengths of sealing area between the two. The prototype has a much shorter sealing area, with the 7.5 mm long bladder, contrary to the foam plug that seals along its whole length. This undergirds the assumed benefits of utilizing liquids, in this case water, as attenuating media. Moreover, no previous research or patents considering or mentioning water - or liquids, for that matter - as attenuating medium in the application of hearing protective earplugs have been found through this study. Also, the way of hydraulically controlling the sealing part of an HPD, for easier insertion and better sealing, is radically new and innovative. Taking these findings into consideration, this could possibly be groundbreaking research in the field of HPDs.

8.3 Recommendations for Future Work

The study limitations have been highlighted and discussed earlier in the discussion chapter and set the basis for the recommendations for future work. Several processes throughout this development work could have been extended for more generation and exploration of different concepts, especially with respect to verifying the findings with statistically significant data. Recommendations for further work on developing this deep insert earplug are listed below:

- Revise the bladder design and try out different configurations of the bracing idea.
- Design the bellow mould with a thicker short side wall to prevent it from tearing apart after several uses.
- Produce the bellow with a side-mounted stem, as illustrated in the concept model (Chapter 6 and *Appendix A*), to prove/refute the assumptions that this will solve a lot of the integrity problems with squeezing the bellow.
- Gather empirical data on comfort and convenience by testing the prototype within a larger group of subjects. Convenience sampling would probably be sufficient as this can be classified as pilot testing. A suggestion for an appropriate experiment design and a constituent questionnaire, inspired by the research of Park and Casali (1991) and Byrne et al. (2011), has been made for this project and is presented in *Appendix D*.
- Conduct the NEWT method with at least sixteen subjects to get statistically significant data derived from the sound attenuation measurements, in accordance with *ISO 4869-1*.
- Test the full-system prototype with other attenuating media. Especially glycerol, as discussed in the ideation phase, appears to be a great replacement medium with its biocompatible, acoustic and near anti-freeze properties.
- Look at alternative core materials, e.g., making the cores by using ice and let the mould cure in temperatures below the freezing point. This way the core can be easily removed by defrosting the cured earplug.

Chapter 9

Conclusion

This master's thesis set out with the intentions of developing nothing less than the *Next Generation Earplug*. Through achieving all of the four initially stated objectives, a solution for a water-filled, highly controllable deep insert earplug has been developed in this work. The solutions were developed by empathizing on front-loading and properly specifying the product requirements based on an extensive literature study. The final prototype has been able to show the benefits of a deep insert solution, especially with the groundbreaking use of water to hydraulically control the shape of the sealing part in an HPD. Both the results from testing and the feedback from supervisors at *SINTEF* indicate that the concepts developed in this project have significant commercial potential. Not only does it compromise minimally between sealing and comfort, but it yields exceptionally great attenuation in testing. With attenuation levels way above 30 dB, the deep insert earplug prototype is already competing with well established HPDs by one of the most prominent prosecutors on the market. There are findings in this work that are completely new to the field of HPDs - and candidates for intellectual property (IP) protection - making this research not unlikely to be a first step towards the actual *Next Generation Earplug*.

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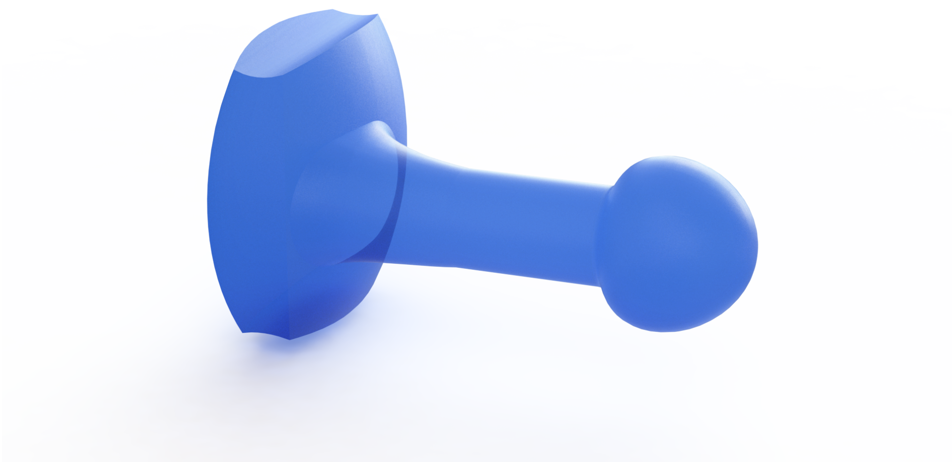
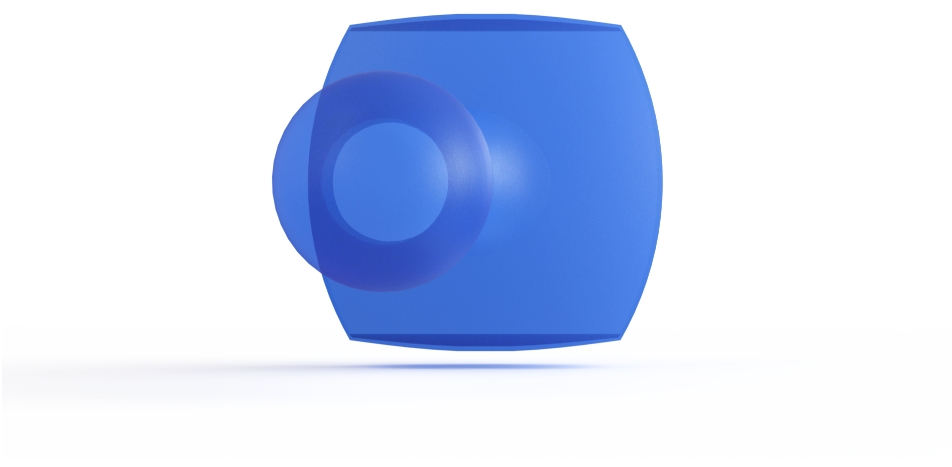
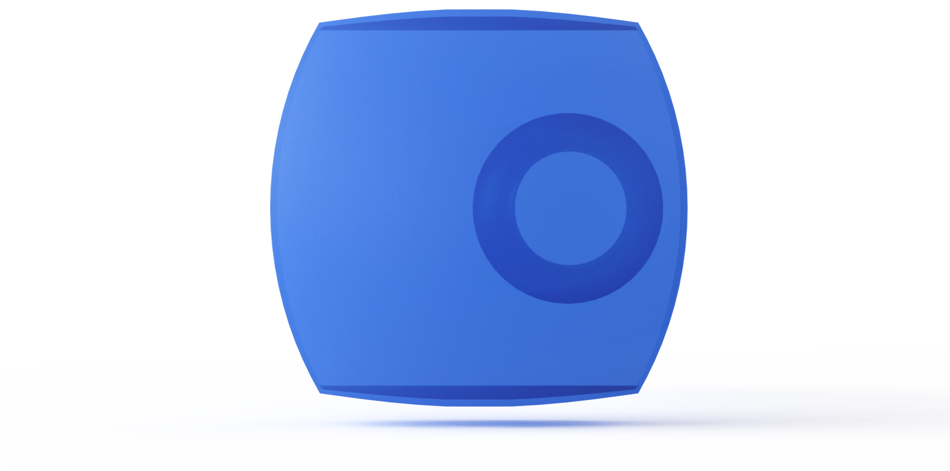
Appendix A

Concept Model Renderings







Appendix B

Technical Data Sheets

B.1 Biopor AB 25 Shore - Technical Data Sheet

Dreve

Biopor® AB

(DE) Gebrauchsanleitung

(GB) Directions for use

(FR) Mode d'emploi

(ES) Instrucciones de uso

(IT) Istruzioni per l'uso

(NL) Gebruiksaanwijzing

18°C 64°F – 28°C 82°F

CE 0044

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(DE) Gebrauchsanleitung

Produktbeschreibung

Biopor® AB ist ein additionsvernetzendes Zwei-Komponenten-Silikon mit einer Härte von 25, 40 oder 70 Shore A. Dieses Material eignet sich zur Herstellung von HdO (CE)- und Lärmschutzotoplastiken.
Biopor® AB light ist ein additionsvernetzendes, schwimmfähiges Zwei-Komponenten-Silikon mit einer Endhärte von 25 Shore A zur individuellen Anfertigung von HdO (CE)- und Schwimmschutzotoplastiken.
Biopor® AB fluoreszent ist ein additionsvernetzendes, schwimmfähiges Zwei-Komponenten-Silikon mit einer Härte von 40 Shore A. Dieses Material eignet sich zur Herstellung individueller HdO (CE)- und Lärmschutzotoplastiken sowie für die Herstellung von Schwimmschutzotoplastiken.
Biopor® AB, Biopor® AB light und Biopor® AB fluoreszent vulkanisieren bei Raumtemperatur und werden in Doppelkartuschen geliefert, mit dem Injector oder Injector control A verarbeitet und sind in vielen attraktiven Farben lieferbar. Die Verarbeitung von Biopor® AB 400 erfolgt mit dem Injector 400 pneumatic.

Verarbeitung

a) in Gips
b) in Fotogel
c) indirekte digitale Herstellung mit FotoCast® SL

1. a, b) Die Abformung möglichst wie eine fertige Otoplastik bearbeiten und mit Silon oder Abdruckwachs beschichten.
c) Empfang der Scan-Datei der Abformung.
2. a) Die Abformung in Gips einbetten. Ausgehärteten Gips mit Seifenwasser isolieren. Küvette schließen und Gegenguss herstellen. Nach der Aushärtung des Gipses die Küvette öffnen, Abformung entfernen und Gipsform mit Isolat isolieren.
b) Die Abformung in Gel einbetten und nach der Aushärtung des Gels wieder entnehmen. Isolierung der Negativform aus Gel ist nicht erforderlich.
c) Modellation der Otoplastiken und digitale Erstellung der Form-Modelle.
3. a) Die Form mit Biopor® AB aus der Doppelkartusche mit Hilfe des Injectors blasenfrei füllen. Küvette schließen und unter einer Presse zusammendrücken.
b) Die Negativform aus Gel mit dem Biopor® AB Material befüllen und in einen Drucktopf (Polymax 1) stellen, damit blasenfreie Otoplastiken entstehen.
c) Herstellung der FotoCast® SL Form im Stereolithographie-Verfahren. Nach der Herstellung wird das Biopor® AB in die Form appliziert.
4. a, b) Die Aushärtung des Biopor® AB erfolgt bei Raumtemperatur. Nach der Aushärtung die Ohrstücke aus der Form entfernen.
c) Aushärtung des Biopor® AB Material erfolgt bei Raumtemperatur. Nach der Aushärtung wird die FotoCast® SL Form zerstört.
5. a, b, c) Das Ohrstück mit Fräsen für weiche Materialien bearbeiten.
6. a, b, c) Biopor® AB Otoplastiken können optimalerweise mit dem raumtemperaturhärtenden Biopor® AB RT Lack oder dem lichthärtenden Biopor® AB UV Lack veredelt werden. Diese Lacke werden in Doppelkartuschen geliefert, die Lackierung erfolgt im Pinsel-Verfahren. Sie können ebenfalls für Biopor AB 25 und 40 Shore A Biopor® Lack verwenden oder Lack B für alle Biopor® AB Materialien. Biopor® Lack und Lack B werden im Tauchverfahren aufgebracht und gut abgeschlagen, damit keine Bläschen entstehen.

Wichtige Hinweise

Zur korrekten Anwendung und Vermeidung von Vulkanisationsstörungen sollten folgende Hinweise beachtet werden:

- Nach Gebrauch Mischkanüle als Verschluss auf Doppelkartusche belassen.
- Die Polymerisation von additionsvernetzenden Silikonen kann z. B. durch Cerumen, Gummihandschuhe, Cremes, Kunststoffe, usw. inhibiert werden.

Hautreizungen und Allergien sind bis heute im Zusammenhang mit additionsvernetzenden Silikonmaterialien unbekannt.

Anmischung

Mit der Mischkanüle erfolgt genaue 1:1 Mischung der beiden Komponenten.

Lagerung

Lagerung bei Raumtemperatur 18 °C – 28 °C (64 °F – 82 °F).

Lieferform

Packung mit 8 Doppelkartuschen 48 ml à 2 x 24 ml
Packung mit 1 Doppelkartusche 400 ml à 2 x 200 ml

Zubehör

150	Injector für Doppelkartuschen
150P	Injector pneumatic für Doppelkartuschen
15151	Injector control A
321	Mischkanülen geeignet für Biopor® AB 25 und 40 Shore A, Biopor® AB light und Biopor® AB fluoreszent, Ø 5,4 mm, 100 Stück
327	Mischkanülen geeignet für Biopor® AB 70 Shore A, Ø 6,3 mm, 100 Stück
323	Kanülenspitzen, 50 Stück
1504P	Injector 400 pneumatic
3214	Mischkanülen geeignet für Biopor® AB 400, Ø 6,3 mm, 100 Stück
448	Fotogel
3429	Polymax 1, 230 V 50/60 Hz
3429-A	Polymax 1, 115 V 50/60 Hz

Chargennummer / Haltbarkeitsdatum

Die Chargennummer und das Haltbarkeitsdatum befinden sich auf der Außenverpackung und auf jeder Doppelkartusche. Bei Beanstandungen des Produktes bitte immer die Chargennummer des Produktes angeben. Verwenden Sie das Produkt nach Ablauf des Mindesthaltbarkeitsdatums nicht ohne Prüfung.

Technische Daten siehe letzte Seite.

Die Dreve Otoplastik GmbH haftet nicht für Schäden, die durch fehlerhafte Anwendung des Materials hervorgerufen werden.

Stand der Information: Januar 2011

(GB) Product description

Product description

Biopor® AB is an addition-vulcanising 2-component silicone with a hardness of 25, 40 or 70 Shore A. It can be used for the production of BTE earmoulds (CE)- and hearing protection.
Biopor® AB light is an addition-vulcanising floatable 2-component silicone with a final hardness of 25 Shore A for the individual production of BTE earmoulds (CE)- and swim protection.
Biopor® AB fluorescent is an addition-vulcanising, floatable 2-component silicone with a hardness of 40 Shore A. It can be used for the production of individual BTE earmoulds (CE), hearing and swim protection.
Biopor® AB, Biopor® AB light and Biopor® AB fluorescent are available in many different colours in double cartridges and are used by means of the Injector or Injector control A. Biopor® AB 400 is used with the Injector 400 pneumatic.

Working process

a) in plaster
b) in Fotogel
c) indirect digitale production with FotoCast® SL material

1. a, b) If possible process the impression as far as the final form is achieved and coat it with Silon or impression wax.
c) Reception of the scan data of the earmould.
2. a) Embed the impression into the plaster. Isolate the cured plaster with soap water. Close the flask and produce the counterpart. After curing of the plaster open the flask, take out the impression and isolate plaster form with Isolat.
b) Embed the impression into the gel and after curing take it out of the gel. Isolation of gel form is not necessary.
c) Modelling of the earmould and digital production of the form model.
3. a) Fill the plaster form with Biopor® AB from double cartridges free of air bubbles with the help of the Injector. Close the flask and put together by means of a press.
b) In order to assure earmoulds free from bubbles the negative mould made of gel together with the Biopor® AB material has to be placed into a pressure polymerisation unit (Polymax 1).
c) Manufacturing of the FotoCast® SL form by the sterelithography process. After the manufacturing of the form the Biopor® AB material can be filled into it.
4. a, b) Biopor® AB cures out at room temperature. After curing take the earmoulds out of the form.
c) The material cures at room temperature. After curing tear the FotoCast® SL form.
5. a, b, c) Process the earmoulds with cutting tools for soft materials.
6. a, b, c) Biopor® AB earmoulds can be lacquered with Biopor® AB RT Lacquer which cures at room temperature or with the UV curing Biopor® AB UV Lacquer. The lacquers, packaged in double cartridges, will be applied by brush. For Biopor® AB 25 and 40 Shore A you can also use the Biopor® Lacquer or for all Biopor® AB materials Lacquer B. Biopor® Lacquer and Lacquer B will be applied by dipping. Shake earmould after dipping in order to avoid bubbles.

Important Notes

For correct use and in order to avoid problems during vulcanisation of the material the following instructions should be followed:
- Leave mixing canula on the cartridge for sealing effect.
- Polymerisation of addition-vulcanising silicones can be inhibited by cerumen, rubber gloves, creams, resins, etc.

Until today, skin irritations or allergies are not known in connection with addition-vulcanising silicone materials.

Processing

Exact mixing ratio of 1:1 of both components.

Storage

Keep at room temperature 18 °C – 28 °C (64 °F – 82 °F).

Form of delivery

Package containing 8 double cartridges 48 ml à 2 x 24 ml
Package containing 1 double cartridge 400 ml à 2 x 200 ml

Auxiliaries

150	Injector for double cartridges
150P	Injector pneumatic for double cartridges
151151	Injector control A
321	Mixing canulas for Biopor® AB 25 and 40 Shore A, Biopor® AB light and Biopor® AB fluorescent, Ø 5,4 mm, 100 pieces
327	Mixing canulas for Biopor® AB 70 Shore A, Ø 6.3 mm, 100 pieces
323	Canula tips, 50 pieces
1504P	Injector 400 pneumatic
3214	Mixing canulas for Biopor® AB 400, Ø 6.3 mm, 100 pieces
448	Fotogel
3429	Polymax 1, 230 V 50/60 Hz
3429-A	Polymax 1, 115 V 50/60 Hz

Lot number / Best before date

The lot number and the best before date are indicated on the external packaging and on each double cartridge. In case of claims please always indicate the lot number of the product. Do not use the product after expiry of the best before date without examination.

For technical data please refer to the last page.

Dreve Otoplastik GmbH is not liable for any damages caused by improper application of the material.

Date of information: January 2011

(FR) Description du produit

Description du produit

Biopor® AB est une silicone en deux composants, vulcanisant par addition avec une dureté de 25, 40 ou 70 Shore A. Ce matériel peut être utilisé pour la production des embouts contour (CE 0044) ou pour des embouts anti-bruits.
Biopor® AB light est une silicone flottable en deux composants vulcanisant par addition avec une dureté finale de 25 Shore A pour la production des embouts contour (CE 0044) et des embouts anti-eaux individuels.
Biopor® AB fluorescent est une silicone flottable en deux composants vulcanisant par addition avec une dureté de 40 Shore A. Ce matériel peut être utilisé pour la production des embouts contours (CE 0044) et des anti-bruits individuels ainsi que pour des anti-eaux.
Biopor® AB, Biopor® AB light et Biopor® AB fluorescent vulcanisent à température ambiante, sont disponibles en cartouche double et sont utilisés avec l'Injector ou l'Injector Control A. Le Biopor® est livrables en plusieurs couleurs attractives. Biopor® AB 400 est utilisé avec l'Injector 400 pneumatique.

Le traitement

a) en plâtre
b) en Fotogel
c) fabrication digitale, indirecte avec FotoCast® SL

1. a,b) Travaillez l'empreinte le plus possible comme un embout tout prêt. Recouvrez l'empreinte avec „ Silon " ou cire d'empreinte.
c) Réception des fichiers avec le scan d'empreinte.
2. a) Encastrez l'empreinte dans plâtre ou gel et isolez le plâtre durci avec de l'eau savonneuse. Fermez le moule et créez le contre moule. Ouvrez le moule après le durcissement du plâtre, écartez l'empreinte et isolez le moule avec »Isolat«. Une isolation du moule négatif en gel, n'est pas nécessaire.
b) Encastrez l'empreinte au gel en reprenez le après le durcissement. Une isolation du moule négatif en gel n'est pas nécessaire.
c) Modellation d'embouts et création digitale du modèle forme.
3. a) Remplissez le moule sans bulles, avec Biopor® AB en cartouche double, à l'aide de l'injector. Fermez le moule et comprimez le en dessous une presse.
b) Remplissez le moule négatif en gel avec le Biopor® AB et mettez le dans un pot de pression (Polymax 1) afin que des embout sans bulles se produisent.
c) Production du moule FotoCast® SL avec le processus de stéréo-lithographie. Après la production le Biopor® AB est appliqué dans le moule.
4. a,b) Le Biopor® AB durcit à température ambiante. Prélevez les embouts après le durcissement.
c) Le durcissement a lieu à température ambiante. Après durcissement le moule en FotoCast® SL est détruit.
5. a,b,c) Traitez l'embout avec les fraises pour les matéraux souples.
6. a,b,c) Les embouts en Biopor® peuvent être laqué avec le laque vulcanisant par température ambiante Biopor® AB RT ou bien avec le laque vulcanisant par lumière Biopor® AB UV. Ces laques sont fournis en double cartouche et le laquage à lieu avec un pinceau. Vous pouvez aussi laquer les embouts Biopor® AB 25 et 40 Shore A avec le laque Biopor® vulcanisant par chaleur ou bien le laque B vulcanisant par température ambiante pour tous les Biopor® AB matériaux. Laque B et laque Biopor® sont utilisés en trempant. Les embouts sont bien secoués pour qu'aucune bulle ne puisse pas surgir.

Notes importantes

Pour une utilisation correcte et pour éviter des problèmes pendant la vulcanisation les renseignements suivants doivent être respectés:
- Après usage, laisser le bec mélangeur sur la cartouche comme bouchon.
- La polymérisation des silicones vulcanisant par addition peut être arrêtée par cérumen, des gants en caoutchouc, des crèmes, des résines, etc.

Jusqu'à aujourd'hui, des irritations de peau ou des allergies en fonction des silicones vulcanisant par addition sont inconnues.

Procédure

Le mélange exacte 1:1 des deux composantes résulte par le bec mélangeur.

Stockage

Garder à température ambiante 18 °C – 28 °C (64°F – 82 °F).

Conditionnement

Paquet de 8 cartouches double 48 ml chacune de 2x24 ml
Paquet de 1 cartouche double 400 ml chacune de 2x200 ml

Accessoires

150	Injector pour des cartouches doubles
150P	Injector pneumatique pour des cartouches doubles
151151	Injector control A
321	Becs mélangeur approprié pour Biopor® AB 25 et 40 Shore A, Biopor® AB light, Biopor® AB fluorescent, Ø 5,4 mm, 100 pièces
327	Becs mélangeur approprié pour Biopor® AB 70 Shore A, Ø 6,3 mm, 100 pièces
323	pointes, 50 pièces
1504	Injector 400
1504P	Injector 400 pneumatique
3214	Bec mélangeur approprié pour Biopor® AB 400, Ø 6,3 mm, 100 pièces
448	Fotogel
3429	Polymax 1, 230 V 50/60 Hz
3429-A	Polymax 1, 115 V 50/60 Hz

Numéro de lot / Date de péremption

Le numéro de lot et la date de péremption sont indiqués sur l'emballage extérieur et sur chaque cartouche double. En cas de plainte, veuillez toujours informer le numéro de lot du produit. N'utilisez plus le produit après la date de péremption sans l'examiner d'abord.

Pour des données techniques, veuillez regarder sur la dernière page.

Dreve Otoplastik GmbH n'est pas responsable pour aucuns dommages causés par une application non-appropriée du matériel.

État de l'information : janvier 2011

(ES) Descripción del producto

Descripción del producto

Biopor® AB es una silicona bicomponente de reticulación por adición con una dureza de 25, 40 ó 70 Shore A. Este material es adecuado para la producción de moldes retroauriculares (CE) y de prevención de ruidos.
Biopor® AB light es una silicona bicomponente flotante de reticulación por adición con una dureza final de 20 Shore A para la producción individual de moldes retroauriculares (CE) y moldes de natación.
Biopor® AB fluorescente es una silicona bicomponente de reticulación por adición, flotante, con una dureza de 40 Shore A. Este material es adecuado para la producción individual de moldes retroauriculares (CE) y de prevención de ruidos, así como para la producción de moldes de natación.
Biopor® AB, Biopor® AB light y Biopor® AB fluorescente vulcanizan a temperatura ambiente y se suministran en cartuchos dobles, se procesan con el Inyector o el Inyector control A, y están disponibles en muchos colores atractivos. El procesamiento de Biopor® AB 400 se realiza con el Inyector 400 o el Inyector 400 neumático.

Procesamiento

a) con yeso
b) con Fotogel
c) producción digital indirecta con FotoCast®

1. a, b) La impresión debe procesarse a ser posible como un molde auditivo acabado y recubrirse con Silon o cera de impresión.
c) Recepción de los archivos escaneados del molde.

2. a) Poner la impresión en yeso. Aislar el yeso endurecido con agua jabonosa. Cerrar la cubeta y crear un contramolde. Una vez endurecido el yeso, abrir la cubeta, extraer la impresión y aislar el molde de yeso con Isolat.
b) Poner la impresión en gel y volver a retirarla una vez endurecido el gel. No es necesario aislar el molde negativo de gel.
b) Modelación de los moldes auditivos y producción digital de los modelos.

3. a) Llenar el molde con Biopor® AB del cartucho doble sin burbujas con la ayuda del Inyector. Cerrar y comprimir la cubeta con una prensa.
b) Para garantizar moldes auditivos sin burbujas se tiene que rellenar el molde negativo de gel con el material Biopor® AB en un aparato de presión (Polymax 1).
c) Producción del molde FotoCast® mediante estereolitografía. Una vez obtenido, se aplica el Biopor® AB en el molde.

4. a, b) El Biopor® AB se endurece a temperatura ambiente. Tras el endurecimiento, retirar las piezas auditivas del molde.
c) El material Biopor® AB se endurece a temperatura ambiente. Tras el endurecimiento se destruye el molde de Fotocast® SL.

5. a, b, c) Procesar la pieza auditiva con fresas para materiales blandos.

6. a, b, c) Los moldes auditivos de Biopor® AB se pueden refinar de forma óptima con Laca Biopor® AB RT, que endurece a temperatura ambiente, o con Laca Biopor® AB UV fotoendurecible. Estas lacas son disponibles en cartuchos dobles, el proceso de lacado se efectua con pincel. Se puede utilizar tambien la laca Biopor® para el Biopor® AB 25 y 40 Shore A o la laca B para todos los materiales Biopor® AB. Laca Biopor® y laca B se emplea mediante inmerson y la agita buen para evitar la formacion de burbujas.

Advertencias importantes

Para la aplicación y eliminación correctas de fallos de vulcanización, deben observarse las advertencias siguientes:

- Tras el uso, dejar la cánula de mezcla puesta como tapón en el cartucho doble.
- La polimerización de siliconas de reticulación por adición puede verse inhibida, por ejemplo, por cerumen, guantes de goma, cremas, plásticos, etc.

Hasta el momento, no se conocen irritaciones cutáneas y alergias producidas por materiales de silicona de reticulación por adición.

Elaboración

Con la cánula de mezcla se realiza una mezcla exacta 1:1 de ambos componentes.

Almacenaje

Almacenar a temperatura ambiente 18 °C – 28 °C (64 °F – 82 °F).

Presentación

Caja con 8 cartuchos de 48 ml dobles de 2 x 24 ml
Caja con 1 cartucho de 400 ml doble de 2 x 200 ml

Accesorios

150	Inyector para cartuchos dobles
150P	Inyector neumático para cartuchos dobles
15151	Inyector control A
321	Cánulas de mezcla adecuadas para Biopor® AB 25 y 40 Shore A, Biopor® AB light y Biopor® AB fluorescente, Ø 5,4 mm, 100 uds.
327	Cánulas de mezcla adecuadas para Biopor® AB 70 Shore A, Ø 6,3 mm, 100 uds.
323	Puntas de cánula, 50 uds.
1504P	Injector 400 neumático
3214	Cánulas de mezcla adecuadas para Biopor® AB 400, Ø 6,3 mm, 100 uds.
448	Fotogel
3429	Polymax 1, 230 V 50/60 Hz
3429-A	Polymax 1, 115 V 50/60 Hz

Número de lote / Fecha de caducidad

El número de lote y la fecha de caducidad constan en la caja y en cada cartucho doble. En caso de reclamación, por favor indique siempre el número de lote del producto. No utilice el producto tras la expiración de la fecha de caducidad sin controlarlo.

Los datos técnicos véanse en la última página.

Dreve Otoplastik GmbH queda exonerada de toda responsabilidad en caso de daños imputables a la aplicación o al empleo incorrecto del material.

Versión de la información: gennaio 2011

(IT) Descrizione del prodotto

Descrizione del prodotto

Biopor® AB è un silicone bicomponente reticolante per addizione con durezza di 25, 40 o 70 Shore A. Questo materiale è adatto alla preparazione di retroauricolari (CE) e tappi di protezione contro il rumore.
Biopor® AB light è un silicone bicomponente, con buone caratteristiche di galleggiabilità, reticolante per addizione, con durezza finale di 25 Shore A per la realizzazione di retroauricolari (CE) e chiocciole galleggianti individuali.
Biopor® AB fluorescente è un silicone bicomponente galleggiabile, reticolante per addizione con durezza finale di 40 Shore A che vulcanizza a temperatura amiente. Questo materiale si qualifica per la realizzazione di chiocciole (CE) e tappi antirumore individuali come anche la produzione di chiocciole galleggianti individuali.
Biopor® AB, Biopor® AB light e Biopor® AB fluorescente, vulcanizzano a temperatura ambiente e vengono forniti in doppie cartucce e lavorabili con l'iniettore, sono disponibili in vari colori. La lavorazione di Biopor® AB 400 avviene per mezzo di un iniettore 400 oppure un iniettore 400 pneumatico.

Lavorazione

a) con gesso
b) con Fotogel
c) con indiretta digitale produzione con materiale FotoCast® SL

1. a, b) Consigliamo di lavorare l'impronta fino a renderla il più simile possibile alla forma definitva della chiocciola. Ricoprire l'impronta con Silon oppure cera.
c) Ricevimento del file scannerizzato della impronta

2. a) Posare l'impronta nel gesso. Isolare il gesso indurito con acqua saponata (detersivo). Chiudere la muffola in ottone e produrre un controstampo. Dopo l'indurimento del gesso, aprire la muffola, prelevare l'impronta e isolare il modello di gesso con Isolat.
b) Posare l'impronta in gel e dopo l'indurimento del gel prelevare l'impronta. Non è necessario di isolare una forma negativa prodotta di gel.
c) Modellare le chiocciole e realizzare in digitale delle forme.

3. a) Applicare il Biopor® AB della doppia cartuccia con l'aiuto di un iniettore nella forma di gesso senza creare delle bolle. Chiudere la muffola e premerla sotto una pressa.
b) Per ottenere delle chiocciole senza bolle bisogna depositare la forma negativa di gel con il materiale Biopor® AB in una macchina a pressione (Polymax 1).
c) Produzione della forma FotoCast® SL con il processo della stereolithografia. Dopo che la forma è stata prodotta applicare il Biopor® AB.

4. a, b) Biopor® AB vulcanizza a temperatura ambiente. Dopo l'indurimento estrarre le chiocciole dal gesso.
c) Biopor® AB vulcanizza a temperatura ambiente. Dopo l'indurimento la FotoCast® SL forma va distrutta.

5. a,b,c) La chiocciola va rifinita con le frese per materiale morbido.

6. a,b,c) Le chiocciole prodotte di Biopor® AB possono essere laccate con la lacca Biopor® AB RT che vulcanizza all'aria oppure la lacca Biopor® AB UV che polimerizza con la luce. Queste lacche sono disponibili in cartucce doppie, la laccatura risulta con un pennello. Naturalmente si può utilizzare anche la lacca Biopor® per il Biopor® AB 25 und 40 Shore A oppure la lacca B per tutti i materiali siliconici. Lacca Biopor® e lacca B vanno utilizzati ad immersione e agitate opportunamente per evitare la formazione di bolle.

Note importanti

Per un corretto utilizzo e per evitare difetti di vulcanizzazione, è necessario attenersi alle seguenti istruzioni:

- Dopo l'utilizzo, lasciare la cannula di miscelazione sulla doppia cartuccia come dispositivo di chiusura.
- La polimerizzazione di siliconi reticolanti per addizione può essere inibita, ad esempio, da cerume, guanti in gomma, creme, resine, ecc.

Non sono finora note irritazioni cutanee ed allergie connesse a materiali siliconici reticolanti per addizione.

Lavorazione

Con la cannula di miscelazione si realizza una mescolazione esatta di 1:1 con le due componenti.

Conservazione

Conservare a temperatura ambiente 18 °C – 28 °C (64 °F – 82 °F).

Forma di consegna

confezione da 8 cartucce doppie 48 ml, 2 x 24 ml
confezione da 1 cartuccia doppia 400 ml, 2 x 200 ml

Accessori

150	Iniettore con cartucce doppie
150P	Iniettore pneumatico con cartucce doppie
151151	Controllo iniettore A
321	Cannule di miscelazione adatti per Biopor® AB 25 e 40 Shore A, Biopor® AB light, Biopor® AB fluorescente, Ø 5,4 mm, 100 pezzi
327	Cannule di miscelazione adatti per Biopor® AB 70 Shore A, Ø 6,3 mm, 100 pezzi
323	Punte per cannula di miscelazione, 50 pezzi
1504	Injector 400
1504P	Injector 400 pneumatico
3214	Cannule di miscelazione adatti per Biopor® AB 400, Ø 6,3 mm, 100 pezzi
448	Fotogel
3429	Polymax 1, 230 V 50/60 Hz
3429-A	Polymax 1, 115 V 50/60 Hz

Numero di partita / Data di inalterabilità

Il numero di partita e la data di inalterabilità sono riportati sia sulla confezione esterna che su ogni cartuccia doppia. In caso di reclami del prodotto, indicare sempre il numero di partita del prodotto. Non utilizzare il prodotto dopo la data di scadenza senza controllarlo.

I dati tecnici vedi l'ultima pagina.

Dreve Otoplastik GmbH declina qualsiasi responsabilità per danni causati dall'utilizzo scorretto del materiale.

Stato delle informazioni: gennaio 2011

(NL) Productbeschrijving

Productbeschrijving

Biopor® AB is een additief-verbindend, 2-componenten silikoon met een eindhardheid van 25, 40 of 70 shore A. Dit materiaal is geschikt voor de productie van "achter-het-oor"oorstukjes (CE) en lawaaibeschermers.

Biopor® AB light is een additief-verbindend, 2-componenten silikoon met een eindhardheid van 25 Shore A, welk op het water drijft, voor de individuele productie van "achter-het-oor"oorstukjes (CE) en zwemdopjes.

Biopor® AB fluorescent is een additief-verbindend, 2-componenten silikoon met een eindhardheid van 40 Shore A, welk op het water drijft. Dit materiaal is geschikt voor de productie van individuele "achter-het-oor"oorstukjes (CE) en lawaaibeschermers alsook voor de productie van zwemdopjes.

Biopor® AB, Biopor® AB light en Biopor® AB fluorescent worden in dubbele cartouches geleverd, met een Injector of Injector Control A verwerkt en zijn in vele attraktieve kleuren leverbaar. De verwerking van Biopor® AB 400 gebeurt met een Injector 400 pneumatic.

Verwerking

a) met gips
b) met Fotogel
c) indirecte digitale productie met FotoCast® SL

1. a), b) De afdruk, voor zover mogelijk, bewerken zoals een kant-en-klaar oorstukje. De afdruk van een laag "Silon" of afdrukwas voorzien.
c) Ontvangen van het scan-bestand van de oorafdruk.

2. a) De afdruk in gips of gel inbedden. Uitgeharde gips met zeepwater isoleren. De mal sluiten en een contra-mal maken. Na het uitharden van de gips de mal openen, de afdruk verwijderen en de gipsmal met "Isolat" isoleren. Een isolatie van de negatief mal uit gel is niet vereist.
b) de afdruk in gel inbedden en na uitharding van het gel terug ontnemen. Een isolering van de mal uit gel is niet noodzakelijk.
c) Modellatie van het oorstukje en het digitale maken van het vormmodel.

3. a) De mal met Biopor® AB uit de dubbele cartouche met behulp van de injector zonder luchtbellen vullen. Mal sluiten en onder een drukpers samendrukken.
b) De negatief mal uit gel met het Biopor® AB vullen en in een stoompot stellen, zodat blazenvrije oorstukjes ontstaan.
c) Productie van de FotoCast® SL vorm door middel van het stereolithographie proces. Na de productie wordt het Biopor® AB in de vorm geappliqueerd.

4. a, b) Het uitharden van het Biopor® AB gebeurt bij kamertemperatuur. Na het uitharden de oorstukjes uitbedden.
c) Het uitharden van het Biopor® AB gebeurt bij kamertemperatuur. Na het uitharden wordt de FotoCast® SL vorm vernietigd.

5. a), b), c) Het oorstukje met frezen voor soepele materialen bewerken.

6. a, b, c) Biopor® oorstukjes worden idealiter met de aan kamertemperatuur verhardende Biopor® AB RT lak of met de door licht verhardende Biopor® AB UV lak afgewerkt. Deze lakken worden in een dubbele cartouche geleverd. Het lakken gebeurt met een penseel. U kunt het Biopor® AB 25 en 40 Shore A eveneens met de door hitte verhardende "Biopor® lak" lakken. Alle Biopor® AB materialen kunnen met de door lucht verhardende "lak B" gelakt worden. Deze lakken worden door middel van dompelen opgebracht en worden goed afgeslagen, zodat geen luchtblaasjes ontstaan.

Belangrijke opmerking

Voor een correcte aanwending en het vermijden van storingen tijdens het vulkaniseren moeten volgende aanwijzingen in acht genomen worden:

- na gebruik de mengkanule als afsluitdop op de dubbele cartouche laten zitten.
- de polymerisatie van additief-verbindende silikonen kan door bv. cerumen, rubberhandschoenen, crèmes, kunststoffen, enz. gestoord worden.

Huidprikkelingen en allergieën in verband met additief-verbindende silikonen zijn tot heden onbekend.

Verwerking

Met de mengcanule gebeurt een precieze 1:1 vermenging van de twee componenten.

Bewaren

Bewaren bij kamertemperatuur 18 °C – 28 °C (64 °F – 82 °F).

Levering

Pak met 8 cartouches S 48 à 2 x 24 ml
Pak met 1 cartouche S 400 à 2 x 200 ml

Toebehoor

150	Injector voor dubbele cartouches
150P	Injector pneumatic voor dubbele cartouches
151151	Injector Control A
321	Mengcanules geschikt voor Biopor® AB 25 en 40 Shore A, Biopor® AB light, Biopor® AB fluorescent, Ø 5,4mm, 100 stuk
327	Mengcanules geschikt voor Biopor® AB 70 Shore A, Ø 6,3 mm, 100 stuk
323	Canulespitsen, 50 stuk
1504	Injector 400
1504P	Injector 400 pneumatic
3214	Mengcanules geschikt voor Biopor® AB 400, Ø 6,3 mm, 100 stuk.
448	Fotogel
3429	Polymax 1, 230 V 50/60 Hz
3429-A	Polymax 1, 115 V 50/60 Hz

Batchnummer / Houdbaarheidsdatum

Het batchnummer en het houdbaarheidsdatum staan zowel op de buitenverpakking als op elke cartouche genoteerd. Gelieve bij bezwaren altijd het batchnummer van het product te willen aangeven. Gebruik het product niet meer na afloop van het houdbaarheidsdatum zonder voorafgaande controle.

Technische details, zie laatste bladzijde.

Dreve Otoplastik GmbH kan niet verantwoordelijk gesteld worden voor schade die door foutief gebruik van het materiaal onstaat.

Laatste wijziging: januari 2011

Technische Daten / Technical data / Données techniques / Datos técnicos / Dati tecnici / Technische gegevens

	Biopor® AB 70 Shore A	Biopor® AB 40 Shore A	Biopor® AB 25 Shore A
Gesamtverarbeitungszeit Total processing time Temps total de procédure Tiempo total de procesamiento Tempo complessivo di lavorazione Totale verwerkingsduur	2 min 30 sec ± 30 sec	2 min 30 sec ± 30 sec	2 min 30 sec ± 30 sec
Abbindezeit Setting time Temps de prise de forme Tiempo de endurecimiento Tempo di presa Verhardingstijd	25 min ± 5 min	25 min ± 5 min	25 min ± 5 min
Endhärte Final hardness Dureté finale Dureza final Durezza finale Eindhardheid	70 ± 5 Shore A	40 ± 2 Shore A	25 ± 2 Shore A
Verformung unter Druck Strain in compression Déformation sous pression Deformación bajo presión Deformazione sotto pressione Vervorming onder druk	7,5 % ± 0,5 %	7,5 % ± 0,5 %	8,5 % ± 0,5 %
Rückstellung nach Verformung Elastic recovery Reprise de la forme initiale Reposición tras deformación Ripristino dopo deformazione Terugvorming na vervorming	> 99,9	> 99,9	> 99,9
Lineare Maßänderung Linear dimensional change Changement dimensionnel linéair Cambio dimensional lineal Modifica dimensionale lineare Lineaire maatverandering	< 0,1 %	< 0,1 %	< 0,1 %
Konsistenz Consistency Consistance Consistencia Consistenza Consistentie	mittelfließend - Typ 2 medium-bodied - type 2 médium - Type 2 viscosidad media - tipo 2 fluidità media - Tipo 2 matig vloeibaar - Typ 2	mittelfließend - Typ 2 medium-bodied - type 2 médium - Type 2 viscosidad media - tipo 2 fluidità media - Tipo 2 matig vloeibaar - Typ 2	mittelfließend - Typ 2 medium-bodied - type 2 médium - Type 2 viscosidad media - tipo 2 fluidità media - Tipo 2 matig vloeibaar - Typ 2

Die Anmisch- und Verarbeitungszeiten beziehen sich auf eine Raumtemperatur von 23 °C ± 1 °C (73,4 °F ± 1,8 °F) und eine relative Luftfeuchtigkeit von 50 %. Bei additionsvernetzenden Silikonen können durch Kühlung (z. B. Lagerung im Kühlschrank) diese Zeiten verlängert, durch Erwärmung verkürzt werden. Technische Daten nach DIN EN ISO 4823.

The mixing and processing times refer to a room temperature of 23 °C ± 1 °C (73.4 °F ± 1.8 °F) and a relative air humidity of 50 %. Regarding addition-vulcanising silicones these times can be prolonged by cooling (e. g. storage in the refrigerator) and shortened by heating. Technical data according to DIN EN ISO 4823.

Le temps de procédure se réfère à une température ambiante 23 °C ± 1 °C (73,4 °F ± 1,8 °F) et à une humidité relative de 50 %. Une température plus basse ralentit et une température plus élevée accélère la procédure. Données techniques conformément à DIN EN ISO 4823.

El tiempo de procesamiento se refiere a una temperatura ambiente de 23 °C ± 1 °C (73,4 °F ± 1,8 °F) y una humedad atmosférica relativa de 50 %. Los tiempos de procesamiento y endurecimiento aumentan o disminuyen en función de la temperatura. Las temperaturas bajas prolongan los procesos, las altas los acortan. Datos técnicos según DIN EN ISO 4823.

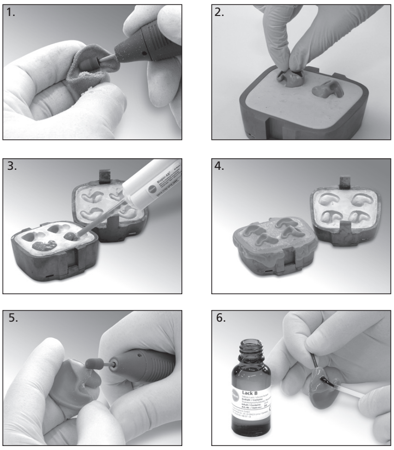
Technische Daten / Technical data / Données techniques / Datos técnicos / Dati tecnici / Technische gegevens

	Biopor®AB fluoreszent	Biopor®AB light
Gesamtverarbeitungszeit Total processing time Temps total de procédure Tiempo total de procesamiento Tempo complessivo di lavorazione Totale verwerkingsduur	2 min 30 sec ± 30 sec	2 min 30 sec ± 30 sec
Abbindezeit Setting time Temps de prise de forme Tiempo de endurecimiento Tempo di presa Verhardingstijd	25 min ± 5 min	25 min ± 5 min
Endhärte Final hardness Dureté finale Dureza final Durezza finale Eindhardheid	40 ± 2 Shore A	25 ± 2 Shore A
Verformung unter Druck Strain in compression Déformation sous pression Deformación bajo presión Deformazione sotto pressione Vervorming onder druk	3,7 % ± 0,5 %	9,5 % ± 0,5 %
Rückstellung nach Verformung Elastic recovery Reprise de la forme initiale Reposición tras deformación Ripristino dopo deformazione Terugvorming na vervorming	> 99,9	> 99,9
Lineare Maßänderung Linear dimensional change Changement dimensionnel linéair Cambio dimensional lineal Modifica dimensionale lineare Lineaire maatverandering	< 0,1 %	< 0,1 %
Konsistenz Consistency Consistance Consistencia Consistenza Consistentie	mittelfließend - Typ 2 medium-bodied - type 2 médium - Type 2 viscosidad media - tipo 2 fluidità media - Tipo 2 matig vloeibaar - Typ 2	mittelfließend - Typ 2 medium-bodied - type 2 médium - Type 2 viscosidad media - tipo 2 fluidità media - Tipo 2 matig vloeibaar - Typ 2

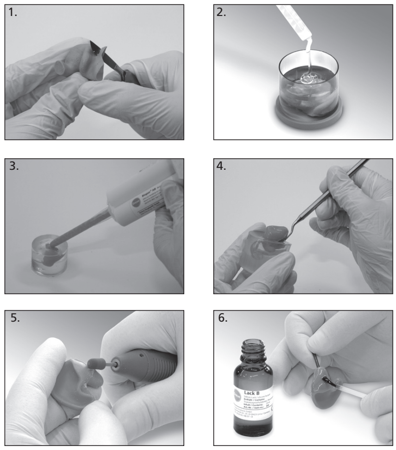
I tempi di lavorazione si riferiscono a temperature ambiente di 23 °C ± 1 °C (73,4 °F ± 1,8 °F) e ad un'umidità relativa dell'aria del 50 %. Le temperature inferiori prolungano i tempi di lavorazione e di posa, mentre le temperature superiori li abbreviano. Dati tecnici in conformità a DIN EN ISO 4823.

De meng- en verwerkingstijd heeft betrekking op een kamertemperatuur van 23 °C ± 1 °C (73,4 °F ± 1,8 °F) en een relative luchtvochtigheid van 50 %. Lagere temperaturen verlengen, en hogere temperaturen verkorten deze tijden. Technische gegevens volgens DIN EN ISO 4823.

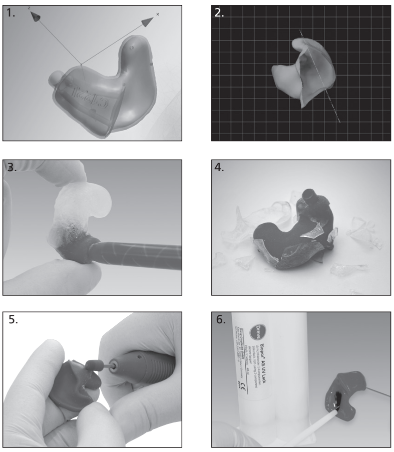
Verarbeitung in Gips, Processing in plaster, Traitement avec plâtre, Elaboración con yeso, Elaborazione con gesso, Verwerking met gips



Verarbeitung in Fotogel, Processing in Fotogel, Traitement avec Fotogel, Elaboración con Fotogel, Elaborazione con Fotogel, Verwerking met Fotogel



Verarbeitung mit FotoCast® SL, Processing with FotoCast® SL, Traitement avec FotoCast® SL, Elaboración con FotoCast® SL, Elaborazione con FotoCast® SL, Verweking met FotoCast® SL



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B.2 3M™ Laboratory Attenuation Data

Laboratory Attenuation Data for 3M™ Hearing Protection Products (Tested in Accordance with ANSI S3.19-1974)

*3M recommends fit testing of hearing protectors. If the NRR is used to estimate typical workplace protection, 3M recommends that the NRR be reduced by 50% or in accordance with applicable regulations.

Disposable Roll Down Earplugs

			Octave Band Attenuation Data (dB)									
Device	**NRR***	**CSA Class**	**Frequency (Hz)**	125	250	500	1000	2000	3150	4000	6300	8000
E•A•R™ Classic™	29 dB	AL	Mean Attenuation	37.4	40.9	44.8	43.8	36.3	41.9	42.6	46.1	47.3
			Standard Deviation	5.7	5.0	3.3	3.6	4.9	3.0	3.1	3.5	2.7
E•A•R™ Classic™ Small	29 dB	AL	Mean Attenuation	32.9	37.5	41.4	40.0	36.4	43.9	45.2	48.2	48.1
			Standard Deviation	4.2	4.4	4.2	4.3	4.0	3.0	2.5	2.6	4.4
E•A•R™ Classic™ Plus	33 dB	AL	Mean Attenuation	37.7	43.0	47.0	43.7	38.2	44.5	45.4	49.1	48.4
			Standard Deviation	4.9	4.7	3.3	3.4	3.6	2.8	3.6	4.4	4.4
E•A•R™ Classic™ Plus Metal Detectable	33 dB	AL	Mean Attenuation	37.7	43.0	47.0	43.7	38.2	44.5	45.4	49.1	48.4
			Standard Deviation	4.9	4.7	3.3	3.4	3.6	2.8	3.6	4.4	4.4
E•A•R™ Classic Soft ™	31 dB	AL	Mean Attenuation	35.7	41.5	46.2	42.4	37.7	42.5	44.7	47.2	46.4
			Standard Deviation	7.4	8.5	6.2	5.3	2.4	3.7	3.5	5.4	4.5
E•A•R™ E-Z-Fit™	28 dB	AL	Mean Attenuation	35.6	36.9	39.0	37.5	35.1	42.3	44.9	47.7	48.7
			Standard Deviation	5.8	5.0	4.6	5.9	3.0	2.6	3.3	3.4	4.5
E•A•R™ TaperFit™ 2 (2 size earplug)	32 dB	AL	Mean Attenuation	36.4	39.1	41.7	40.7	38.1	44.5	45.9	48.4	48.1
			Standard Deviation	3.6	2.9	3.4	3.5	2.8	2.0	2.3	3.2	3.7
E•A•R™ Classic™ SuperFit™ 30	30 dB	AL	Mean Attenuation	32.9	37.5	41.4	40.0	36.4	43.9	45.2	48.2	48.1
			Standard Deviation	4.2	4.4	4.2	4.3	4.0	3.0	2.5	2.6	4.4
E•A•R™ Classic™ SuperFit™ 33	33 dB	AL	Mean Attenuation	37.7	43.0	47.0	43.7	38.2	44.5	45.4	49.1	48.4
			Standard Deviation	4.9	4.7	3.3	3.4	3.6	2.8	3.6	4.4	4.4
3M™ 1100 and 1110	29 dB	AL	Mean Attenuation	33.9	37.7	39.8	38.5	37.0	41.9	42.7	45.5	44.6
			Standard Deviation	4.7	5.5	5.6	4.8	3.1	3.8	3.4	4.0	3.4
E•A•Rsoft™ Yellow Neons™ (2 size earplug)	33 dB	AL	Mean Attenuation	38.4	40.3	43.2	41.8	38.6	45.0	45.7	49.6	47.3
			Standard Deviation	4.8	4.8	5.0	4.0	2.6	3.3	3.3	4.0	3.5
E•A•Rsoft™ Yellow Neon™ Blasts (2 size earplug)	33 dB	AL	Mean Attenuation	38.4	40.3	43.2	41.8	38.6	45.0	45.7	49.6	47.3
			Standard Deviation	4.8	4.8	5.0	4.0	2.6	3.3	3.3	4.0	3.5
E•A•Rsoft™ SuperFit™ (2 size earplug)	33 dB	AL	Mean Attenuation	38.4	40.3	43.2	41.8	38.6	45.0	45.7	49.6	47.3
			Standard Deviation	4.8	4.8	5.0	4.0	2.6	3.3	3.3	4.0	3.5
E•A•Rsoft™ Yellow Neons™ Metal Detectable Regular size only	32 dB	AL	Mean Attenuation	36.1	37.4	39.7	38.6	38.5	44.6	45.4	47.4	48.0
			Standard Deviation	3.6	4.9	4.3	3.1	2.7	3.2	4.1	3.2	3.2
3M™ Nitro™	32 dB	AL	Mean Attenuation	36.1	37.4	39.7	38.6	38.5	44.6	45.4	47.4	48.0
			Standard Deviation	3.6	4.9	4.3	3.1	2.7	3.2	4.1	3.2	3.2
3M™ Tattoo™	32 dB	AL	Mean Attenuation	36.1	37.4	39.7	38.6	38.5	44.6	45.4	47.4	48.0
			Standard Deviation	3.6	4.9	4.3	3.1	2.7	3.2	4.1	3.2	3.2
E•A•Rsoft™ Grippers ™	31 dB	AL	Mean Attenuation	38.9	38.7	42.9	41.9	39.2	45.6	47.4	50.9	48.2
			Standard Deviation	4.6	5.4	5.7	5.3	3.4	3.8	3.8	5.3	5.2
E•A•Rsoft™ FX ™	33 dB	AL	Mean Attenuation	40.8	40.8	43.6	41.8	37.9	45.2	47.6	49.0	46.8
			Standard Deviation	2.9	3.5	4.0	3.8	2.6	2.8	3.5	3.8	4.3

NOTE: The Noise Reduction Rating (NRR) shown for 2 size products are based on laboratory testing of regular and large sizes of the earplug.

10/21/2015

Laboratory Attenuation Data for 3M™ Hearing Protection Products (Tested in Accordance with ANSI S3.19-1974)

*3M recommends fit testing of hearing protectors. If the NRR is used to estimate typical workplace protection, 3M recommends that the NRR be reduced by 50% or in accordance with applicable regulations.

3M™ PELTOR™ Earmuffs

Device	NRR*	CSA Class	Octave Band Attenuation Data (dB) Frequency (Hz)	125	250	500	1000	2000	3150	4000	6300	8000
Optime™ 105 - H10A	30 dB	AL	Mean Attenuation	21.0	26.0	36.6	40.6	38.0	41.8	42.7	41.7	41.3
Over the Head Position			Standard Deviation	1.9	2.3	2.3	2.4	2.5	2.7	1.8	2.1	2.5
Optime™ 105 - H10B	29 dB	AL	Mean Attenuation	21.0	26.4	37.1	40.0	36.9	40.4	42.1	41.6	42.2
Behind the Head Position			Standard Deviation	2.7	2.6	3.0	3.6	2.4	3.4	2.8	2.9	2.5
Optime™ 105 - H10P3	27 dB	AL	Mean Attenuation	20.7	25.5	36.2	38.3	35.7	39.3	41.3	42.1	41.3
Hard Hat Attached			Standard Deviation	3.0	3.3	3.9	3.4	2.9	3.5	3.4	2.5	3.1
Optime™ 101 - H7A	27 dB	A	Mean Attenuation	15.5	24.5	35.3	40.0	36.9	39.9	37.5	37.7	38.1
Over the Head Position			Standard Deviation	3.0	2.0	2.4	2.8	2.6	2.8	3.2	2.7	3.9
Optime™ 101 - H7B	26 dB	A	Mean Attenuation	16.8	23.5	34.8	39.7	36.5	35.8	36.2	40.1	40.1
Behind the Head Position			Standard Deviation	3.4	2.6	2.1	2.6	2.3	2.2	2.4	2.4	3.0
Optime™ 101 - H7P3*	24 dB	A	Mean Attenuation	15.3	21.8	33.7	40.0	36.2	35.5	34.7	37.2	35.5
Hard Hat Attached			Standard Deviation	2.6	2.5	2.6	3.3	3.8	3.0	2.7	3.1	3.2
Optime™ 98 - H9A	25 dB	A	Mean Attenuation	15.5	22.0	33.7	39.7	36.5	42.7	40.1	39.8	40.6
Over the Head Position			Standard Deviation	2.7	3.5	2.6	2.4	2.6	2.6	2.8	2.7	2.5
Food Industry Earmuff - H9A-02	26 dB	A	Mean Attenuation	15.1	21.7	31.2	38.6	35.6	40.5	43.0	40.9	41.8
Over the Head Position			Standard Deviation	2.8	1.9	2.7	2.0	3.0	3.5	3.2	2.0	2.7
Optime™ 98 - H9P3*	23 dB	A	Mean Attenuation	14.8	20.2	30.5	38.7	36.4	38.9	36.3	39.4	38.3
Hard Hat Attached			Standard Deviation	2.5	3.1	3.4	2.6	3.0	2.9	3.0	3.7	2.9
Optime™ 95 - H6A	21 dB	B	Mean Attenuation	12.4	15.0	26.2	35.2	35.2	30.9	33.3	36.0	37.5
Over the Head Position			Standard Deviation	2.6	1.8	2.5	3.2	2.5	3.0	2.0	4.5	3.2
Optime™ 95 - H6B	21 dB	B	Mean Attenuation	13.2	14.2	25.1	34.2	35.4	30.4	35.1	37.0	38.5
Behind the Head Position			Standard Deviation	2.9	1.6	2.6	2.6	3.0	2.8	2.1	4.0	2.8
Optime™ 95 - H6F	21 dB	B	Mean Attenuation	12.4	15.0	26.2	35.2	35.2	30.9	33.3	36.0	37.5
Over the Head Position			Standard Deviation	2.6	1.8	2.5	3.2	2.5	3.0	2.0	4.5	3.2
Optime™ 95 - H6P3E	21 dB	B	Mean Attenuation	12.3	17.2	27.8	32.8	33.9	36.5	36.0	36.5	36.8
Hard Hat Attached			Standard Deviation	2.7	3.0	2.5	2.8	2.9	4.1	3.0	4.3	4.6
H31A	24 dB	A	Mean Attenuation	13.2	20.4	30.8	35.8	37.0	41.3	37.1	34.1	35.5
Over the Head Position			Standard Deviation	2.6	2.5	2.7	2.6	3.2	2.5	2.5	2.9	2.2
H31P3*	23 dB	A	Mean Attenuation	12.2	18.9	29.7	34.8	37.2	37.0	35.8	35.0	37.4
Hard Hat Attached			Standard Deviation	2.1	2.6	2.3	2.7	3.6	2.9	2.4	4.0	3.9
H505B Welding Helmet Earmuff	17 dB	B	Mean Attenuation	12.7	13.2	22.9	21.6	31.9	40.2	39.5	37.6	38.6
Behind the Head Position			Standard Deviation	5.5	2.1	2.6	2.3	2.5	3.4	3.5	3.6	3.5
X1A	22 dB	A	Mean Attenuation	16.0	18.3	27.7	37.6	35.1	42.2	41.4	39.4	39.3
Over the Head Position			Standard Deviation	5.2	3.1	3.0	3.5	2.8	2.8	2.6	2.6	3.8
X1P3E	21 dB	B	Mean Attenuation	13.8	17.3	27.4	35.6	34.5	41.8	40.1	36.8	36.1
Hard Hat Attached			Standard Deviation	4.5	3.2	2.9	2.8	2.9	2.9	2.9	3.7	4.1
X2A	24 dB	A	Mean Attenuation	14.9	21.6	31.8	41.0	36.7	39.1	38.5	39.0	39.0
Over the Head Position			Standard Deviation	4.2	3.3	2.3	2.5	3.0	2.4	2.0	2.8	3.4
X2P3E	24 dB	A	Mean Attenuation	15.2	21.3	32.6	39.2	35.9	37.7	37.1	38.6	37.3
Hard Hat Attached			Standard Deviation	4.2	3.1	2.8	3.2	3.3	2.8	2.1	2.5	3.0
X3A	28 dB	AL	Mean Attenuation	23.4	27.7	29.4	42.5	38.8	39.3	42.3	39.5	39.5
Over the Head Position			Standard Deviation	3.0	2.1	3.1	2.6	2.7	4.0	3.3	2.6	2.8
X3P3E	25 dB	AL	Mean Attenuation	19.6	24.1	29.7	39.1	35.7	38.2	40.3	37.1	35.4
Hard Hat Attached			Standard Deviation	3.3	3.1	2.5	3.9	3.1	4.7	3.5	4.4	4.9
X4A	27 dB	AL	Mean Attenuation	20.5	24.1	32.8	40.7	37.6	44.5	45.4	42.4	42.3
Over the Head Position			Standard Deviation	4.6	3.4	1.9	2.8	2.9	3.1	2.5	3.1	3.0
X4P3E	25 dB	A	Mean Attenuation	18.1	21.6	32.4	40.1	36.5	44.2	46.2	43.7	43.3
Hard Hat Attached			Standard Deviation	4.9	2.6	2.0	2.3	3.2	3.9	2.7	2.4	3.0
X5A	31 dB	AL	Mean Attenuation	23.9	30.5	41.1	43.0	38.0	43.1	44.0	41.1	40.3
Over the Head Position			Standard Deviation	4.1	2.2	2.8	2.9	2.7	2.9	2.4	2.6	2.2
X5P3E	31 dB	AL	Mean Attenuation	21.6	29.3	41.0	42.4	37.5	41.7	42.5	40.6	40.5
Hard Hat Attached			Standard Deviation	3.2	2.5	2.8	3.1	2.2	2.3	2.5	2.9	2.6

Appendix C

Data from REAT-measurements

C.1 REAT Data - Prototype at Variable Depths

Table C.1 contains all data and calculations from testing the prototype at various depths. Mean threshold (Mt) is the mean value of measured thresholds for two tests per depth. For the deepest insert test the prototypes were tested once (Test 0) before it was reinserted and tested twice, as with the rest of the depths. Test 1 and Test 2 represents the Mt value at this depth. Mean REAT values are calculated for each depth using Equation 7.1.

Table C.1: REAT Data - Prototype at Variable Depths
(T = Threshold, Mt = Mean threshold, MR = Mean REAT)

Device	**Test no.**	**Measure [dB]**	**Frequencies [Hz]**						
			125	**250**	**500**	**1k**	**2k**	**4k**	**8k**
Reference	Test 1	T (open)	-0.5	9.0	1.5	1.5	3.0	1.5	5.0
	Test 2	T (open)	-0.5	5.0	3.0	5.0	1.5	3.0	3.0
		Mt	-0.5	7.0	2.3	3.3	2.3	2.3	4.0
23mm	Test 0	T	41.0	45.0	47.0	45.0	47.0	39.0	41.0
	Test 1	T	39.0	45.0	45.0	45.0	48.5	35.0	39.0
	Test 2	T	39.0	48.5	45.0	48.5	47.0	37.0	41.0
		Mt (T1 & T2)	39.0	46.8	45.0	46.8	47.8	36.0	40.0
		MR	39.5	39.8	42.8	43.5	45.5	33.8	36.0
21mm	Test 1	T	33.0	35.0	35.0	43.0	39.0	33.0	35.0
	Test 2	T	31.5	35.0	37.0	37.0	35.0	37.0	39.0
		Mt	32.3	35.0	36.0	40.0	37.0	35.0	37.0
		MR	32.8	28.0	33.8	36.8	34.8	32.8	33.0
19mm	Test 1	T	35.0	37.0	39.0	45.0	41.0	41.0	37.0
	Test 2	T	37.0	39.0	39.0	45.0	41.0	37.0	37.0
		Mt	36.0	38.0	39.0	45.0	41.0	39.0	37.0
		MR	36.5	31.0	36.8	41.8	38.8	36.8	33.0
17mm	Test 1	T	29.5	35.0	37.0	45.0	37.0	39.0	35.0
	Test 2	T	31.5	37.0	35.0	45.0	41.0	43.0	35.0
		Mt	30.5	36.0	36.0	45.0	39.0	41.0	35.0
		MR	31.0	29.0	33.8	41.8	36.8	38.8	31.0
15mm	Test 1	T	29.5	37.0	33.0	43.0	35.0	43.0	37.0
	Test 2	T	29.5	35.0	33.0	47.0	39.0	41.0	37.0
		Mt	29.5	36.0	33.0	45.0	37.0	42.0	37.0
		MR	30.0	29.0	30.8	41.8	34.8	39.8	33.0
13mm	Test 1	T	11.0	17.0	22.0	31.5	33.0	31.5	31.5
	Test 2	T	15.0	17.0	9.0	28.0	33.0	29.5	29.5
		Mt	13.0	17.0	15.5	29.8	33.0	30.5	30.5
		MR	13.5	10.0	13.3	26.5	30.8	28.3	26.5
11mm	Test 1	T	13.0	13.0	13.0	17.0	28.0	22.0	15.0
	Test 2	T	5.0	13.0	15.0	20.5	20.5	20.5	9.0
		Mt	9.0	13.0	14.0	18.8	24.3	21.3	12.0
		MR	9.5	6.0	11.8	15.5	22.0	19.0	8.0

C.2 REAT Data - HPDs for Comparison

Table C.2 contains all data and calculations from testing the two commercially available HPDs. Mean threshold (Mt) is the mean value of measured thresholds for two tests per insert/onset. Overall mean threshold (M(Mf)) is the mean value of the two different insertions/onsets. Mean REAT values are calculated for each HPD using Equation 7.1.

Table C.2: REAT Data - Conventional HPDs
(T = Threshold, Mt = Mean threshold, M(Mt) = Overall mean threshold, MR = Mean REAT)

Device	Test no.	Meas. [dB]	Frequencies [Hz]						
			125	250	500	1k	2k	4k	8k
Reference	1	T (open)	-0.5	5.0	3.0	3.0	5.0	3.0	3.0
	2	T (open)	1.5	7.0	5.0	5.0	3.0	3.0	3.0
		Mt (open)	0.5	6.0	4.0	4.0	4.0	3.0	3.0
3M E·A·R Classic	1 (1st ins.)	T	35.0	43.0	41.0	45.0	43.0	45.0	43.0
	2 (1st ins.)	T	37.0	43.0	37.0	45.0	41.0	43.0	43.0
		Mt	36.0	43.0	39.0	45.0	42.0	44.0	43.0
	1 (2nd ins.)	T	37.0	47.0	45.0	47.0	45.0	43.0	41.0
	2 (2nd ins.)	T	39.0	43.0	45.0	48.5	41.0	39.0	43.0
		Mt	38.0	45.0	45.0	47.8	43.0	41.0	42.0
		M(Mt)	37.0	44.0	42.0	46.4	42.5	42.5	42.5
		MR	36.5	38.0	38.0	42.4	38.5	39.5	39.5
3M Peltor Optime III	1 (1st ons.)	T	17.0	35.0	43.0	43.0	37.0	37.0	33.0
	2 (1st ons.)	T	20.5	31.5	41.0	45.0	43.0	41.0	31.5
		Mt	18.8	33.3	42.0	44.0	40.0	39.0	32.3
	1 (2nd ons.)	T	17.0	35.0	43.0	45.0	39.0	41.0	35.0
	2 (2nd ons.)	T	17.0	33.0	45.0	45.0	41.0	37.0	37.0
		Mt	17.0	34.0	44.0	45.0	40.0	39.0	36.0
		M(Mt)	17.9	33.6	43.0	44.5	40.0	39.0	34.1
		MR	17.4	27.6	39.0	40.5	36.0	36.0	31.1

C.3 Measured Data Compared to 3M Data

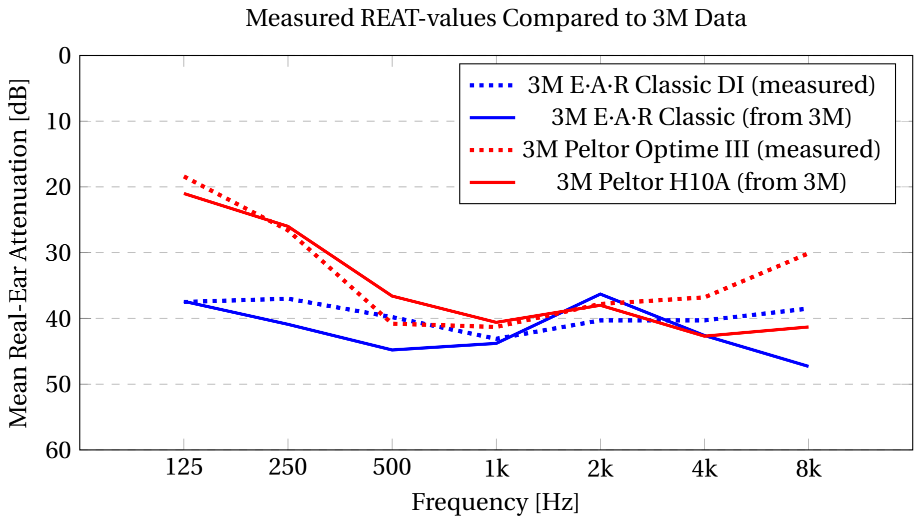

Figure C.1: Comparison of measured Mean REAT and 3M laboratory attenuation data for *3M E·A·R Classic* foam plugs and *3M Peltor Optime III* earmuffs.

Appendix D

Questionnaire

The following questionnaire was inspired by the research of Park and Casali (1991) and Byrne et al. (2011), and is supposed to supplement with empirical data on comfort and convenience among a significantly sized number of subjects. The idea is to test the deep insert prototype up against a commercially available foam plug (e.g., the commonly used *3M E·A·R Classic*); one in each ear at the same time. The hearing protection The test will typically be conducted for an hour, after instructions on insertion, and preferably in a controlled noise environment. Test participants are given one questionnaire each and are asked to fill it out after the one hour of testing. As illustrated in the following document, a set of parameters related to comfort and convenience are listed. The test subjects are asked to check the boxes on the scale that best matches their experience, to get index scores. A resolution of at least five points should be considered for the scale. Any less than five points might be slightly uninformative, while too many points are considered to be confusing and possibly counterproductive. Anyhow, an odd number of scale-points is recommended in this application, enabling for a neutral midpoint.

Deep Insert Earplug

1. Age group

- ○ 19 and under
- ○ 20 - 29
- ○ 30 - 39
- ○ 40 - 49
- ○ 50 – 59
- ○ 60 +

1. Gender

- ○ Male
- ○ Female

2. In terms of your current occupation(s), how would you characterize yourself?

- ❑ Writer
- ❑ Administrative Assistant
- ❑ Journalist
- ❑ Secretary
- ❑ Academic
- ❑ Professional
- ❑ Technical Expert
- ❑ Student
- ❑ Designer
- ❑ Administrator/Manager
- ❑ Other

3. Overall, how satisfied are you with existing hearing protection devices?

- ○ Very satisfied
- ○ Somewhat satisfied
- ○ Neither satisfied nor dissatisfied
- ○ Somewhat dissatisfied
- ○ Very dissatisfied

4. How many times have you used hearing protection the past six months?

- ○ < 5 times
- ○ 5 – 15 times
- ○ > 15 times
- ○ Not sure

5. Are you right-handed or left-handed?

○ Left-handed

○ Right-handed

6. The following questionnaire is aiming at determining the level of comfort for the hearing protection devices you are currently wearing. Check the box along the line of word pairs that most precisely represent how the earplug feel right now.

Deep Insert Earplug

Painful	❑	❑	❑	❑	❑	**Painless**
Comfortable	❑	❑	❑	❑	❑	**Uncomfortable**
Uncomfortable pressure	❑	❑	❑	❑	❑	**Not uncomfortable pressure**
Tolerable	❑	❑	❑	❑	❑	**Intolerable**
Loose	❑	❑	❑	❑	❑	**Tight**
Bothersome	❑	❑	❑	❑	❑	**Not bothersome**
Light	❑	❑	❑	❑	❑	**Heavy**
Not cumbersome	❑	❑	❑	❑	❑	**Cumbersome**
Hard	❑	❑	❑	❑	❑	**Soft**
Hot	❑	❑	❑	❑	❑	**Cold**
Rough	❑	❑	❑	❑	❑	**Smooth**
No feeling of complete isolation	❑	❑	❑	❑	❑	**Feeling of complete isolation**
Ear blocked	❑	❑	❑	❑	❑	**Ear open**
Ear full	❑	❑	❑	❑	❑	**Ear empty**

"Reference foam plug"

Painful	❑	❑	❑	❑	❑	**Painless**
Comfortable	❑	❑	❑	❑	❑	**Uncomfortable**
Uncomfortable pressure	❑	❑	❑	❑	❑	**Not uncomfortable pressure**
Tolerable	❑	❑	❑	❑	❑	**Intolerable**
Loose	❑	❑	❑	❑	❑	**Tight**
Bothersome	❑	❑	❑	❑	❑	**Not bothersome**
Light	❑	❑	❑	❑	❑	**Heavy**
Not cumbersome	❑	❑	❑	❑	❑	**Cumbersome**
Hard	❑	❑	❑	❑	❑	**Soft**
Hot	❑	❑	❑	❑	❑	**Cold**
Rough	❑	❑	❑	❑	❑	**Smooth**
No feeling of complete isolation	❑	❑	❑	❑	❑	**Feeling of complete isolation**
Ear blocked	❑	❑	❑	❑	❑	**Ear open**
Ear full	❑	❑	❑	❑	❑	**Ear empty**

7. The following questionnaire is aiming at determining the level of convenience for the hearing protection devices you are currently wearing. Check the box along the line of word pairs that most precisely represent the convenience of the earplug.

Deep Insert Earplug

Easy to apply	❑	❑	❑	❑	❑	**Difficult to apply**
Unacceptable	❑	❑	❑	❑	❑	**Acceptable**
Good fit	❑	❑	❑	❑	❑	**Poor fit**
Stable	❑	❑	❑	❑	❑	**Unstable**
Unattractive	❑	❑	❑	❑	❑	**Attractive**
Simple	❑	❑	❑	❑	❑	**Complicated**
Easily loosens	❑	❑	❑	❑	❑	**Doesn't loosen**

"Reference foam plug"

Easy to apply	❑	❑	❑	❑	❑	**Difficult to apply**
Unacceptable	❑	❑	❑	❑	❑	**Acceptable**
Good fit	❑	❑	❑	❑	❑	**Poor fit**
Stable	❑	❑	❑	❑	❑	**Unstable**
Unattractive	❑	❑	❑	❑	❑	**Attractive**
Simple	❑	❑	❑	❑	❑	**Complicated**
Easily loosens	❑	❑	❑	❑	❑	**Doesn't loosen**

ADDITIONAL COMMENTS