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Development of shell for next generation ultrasound probe

Utvikling av skall for neste generasjons ultralydprobe

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Maskin, prosess- og produktutvikling

Development of shell for next generation ultrasound probe

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Preface

This master thesis is the last part of my two yearlong study for the master's in mechanical engineering and product development at the Norwegian University of Life Sciences, where I will graduate spring 2019. From previous I have a bachelor's degree in Product development from the University of South – Eastern Norway, graduate spring 2016.

From I was 16 until I was 22 I worked as a sales assistant in a local hardware store. During my time here, I came across thousands of different products, often two or more similar products from different suppliers. I saw the importance of using the right materials and design to get a successful product. This experience aroused my interest in how things are made and the importance of good design and led me later into the direction of mechanical engineering and product development.

My primary motivation for completion of this thesis is to increase my own knowledge within the theory of ultrasound, the usage of the ultrasound probes, thermodynamics, ergonomics and the use of rapid prototyping to create new innovative design without the limitations of traditional production methods. The thesis is written in cooperation with GE Vingmed Ultrasound. I have been working as a consultant at GE Vingmed Ultrasound since 2016 which has given me experience with projects and product development of plastics, sheet metal parts, and molded parts to be used on their ultrasound scanners. This thesis deals with the development of the shell for next generation ultrasound probe and possibilities of using rapid prototyping to optimize the ergonomics and the thermal characteristics of the shell.

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Anders S Wangensteen, Mechanical Engineer/ Value Engineering, Ole Blytt, Hardware Manager, Thea H Ottesen, Systems Test Engineer, Madeleine Eng Jiun Yi, Ultrasound test engineer, Glenn Reidar Lie, Global Product Manager, Gunnar Hansen, Global Clinical Research Manager, Jan Yee, Global Clinical trainer/educator, Trym Eggen, Senior Engineer, Jan Halvor Lie, Lead Program Integrator,

Ås,15.05.2019

Fredrik Stokvik

Sammendrag

Teknologien for ultralyd blir bedre og bedre etter hvert som elektronikken og programvare utvikler seg. En oppgradering i elektronikken krever ofte mer plass grunnet større komponenter. Denne oppgaven ser på mulighetene som finnes for å løse framtidens problemer med plass, ergonomisk utforming og varmegenerering i probeskall. Oppgaven er skrevet i samarbeid med GE Vingmed Ultrasound, og tar for seg utforming og utvikling av skallet til neste generasjons ultralydprobe.

Målet for prosjektet har vært å utvikle en prototype for nytt probeskall med mulighet for videre tekniske løsninger som kan tas med tilbake til bedriften. Målet for oppgaven har vært å komme frem til ett design som har gode varmeledningsegenskaper, plass til all nødvendig elektronikk, og et godt ergonomisk grep.

Prosjektet er bygd opp i henhold til Pugh sin metode for oppbygning av et utviklingsprosjekt og IPD metoden er brukt for å sikre god dataflyt igjennom hele prosjektet. SCAMPER metoden og modulisering metoden er brukt for generering av ideer og konsepter. Utviklingen av det endelige konseptet har gått i iterasjoner, hvor det først ble sett på eksisterende løsninger, før egne ideer ble generert. Ideene ble vektet opp imot hverandre og på grunnlag av dette ble forskjellige konsepter generert. De forskjellige konseptene ble 3D-printet, testet og det ble innhentet tilbakemeldinger fra fagpersonell. Fra den første konseptfasen som førte frem til to ulike konseptretninger, disse ble igjen testet med brukerscreening og analyser. Fra denne konseptutviklingen ble resultatene fra testingen og brukerscreeningen tatt med videre for å utvikle ett endelig konsept.

Det har blitt benyttet forskjellige dataprogrammer for CAD modellering, FEM og termiske analyser. Det har blitt gjort en utredning om teknologien og hvordan ultralyd fungerer, samt sett på eksisterende løsninger for varmeledning og ergonomi. Valgene som har blitt tatt igjennom oppgaven er basert på teori og egen screening av konsepter. Forskjellige ideer og konsepter har blitt testet ut og 3D-printing er benyttet som et verktøy for testing av ideer. Valg og vurderinger er også tatt på bakgrunn av erfaringer gjort igjennom ett tidligere prosjekt på 3D-printing gjort høsten 2018 [1].

Det endelige konseptet har ett godt ergonomisk grep med de gitte rammebetingelsene, basert på teori om ergonomi og tilbakemeldinger fra fagpersonell. Den totale lengden på proben er 140 mm og den har en bredde på 53 mm. Vekten på det nye skallet er sirka 37 gram. Skallet har plass til all nødvendig elektronikk og temperaturen på overflaten mot operatør er 23,6 °C, temperatur mot pasient er 37,6 °C. Den nye proben består av tre deler, en nesedel og to skalldeler.

For videre arbeid vil det i første rekke produseres opp en liten serie, der all elektronikk settes inn i skallet for å se at geometrien passer. Deretter innhente mer data for de termiske simuleringene for å få en endelig bekreftelse på at temperaturene er innenfor de gitte grensene før termisk testing gjennomføres. Med dette på plass, vil godkjenning i henhold til ISO60601 måtte gjennomføres og verifisere at skallet og proben oppfyller alle nødvendige krav. Dernest må det ses nærmere på markedsmessige utfordringer.

Abstract

The ultrasound technology improves continuously with the development of electronics and software. An upgrade in the electronics often requires more space due to larger components. This thesis investigates the possibilities to solve problems of the time to come regarding space, ergonomics, and heat generation in probe shells. The thesis is written in cooperation with GE Vingmed Ultrasound, and deals with design and development of the shell for the next generation ultrasound probe.

The goal for the project was to develop a new shell with the possibilities for further technical solutions that could be brought back to the company. The goal for the thesis has been to achieve a design with good thermal properties, that fits all necessary electronics and has a good ergonomic grip.

The project is built up according to Pugh's method for structure of a development project, while the IPD method was used to secure good dataflow through the project. The SCAMPER method and the modularity method has been used for generating ideas and concepts. The development of the final concept has been done in iterations, where existing solutions first was analyzed, before own ideas was generated. The ideas were weighted and compered against each other and based on these ideas different concepts was made. The different concepts were 3D printed, tested and feedback from professionals was obtained. From the early concept generation there was reached two different concept directions, that was tested with user screening and analyzes. From the further concept development, the results from the testing and the user screening was used to form the final concept.

Different computer programs were used for CAD models, FEM and thermal analyzes. An investigation was done on technology and how ultrasound works, and existing solutions for heat conduction and ergonomics. The decisions made through the thesis is based on theory and own screening of concepts. Different ideas and concepts have been tested and 3D printing is used as a tool for testing of ideas. Choices and assessments are also made on the experiences done in an earlier project on 3D printing done in autumn 2018 [1].

The concept which emerged have a good ergonomic grip given the framework, based theory on ergonomics and feedback from professionals. The total length of the probe is 140 mm and the width are 53 mm. The weight of the new shell is approximately 37 grams. The shell fits all necessary electronics and the temperature towards the operator is 23,6 °C the temperature towards the patient is 37,6 °C. The new probe consists of the three parts, one nose-piece and two shell parts.

For further work a small series needs to be produced, where all the electronics should be placed to see that the electronics fits. Then it should be collected more data for the thermal simulations to get a final confirm that the surface temperatures are within the given limits. With this in place approvals according to ISO60601 needs to be carried out and verify that the shell and probe fulfills all requirements. Then, it must be looked more closely at market related challenges.

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1. INTRODUCTION

To get an overview of the project and the healthcare business, various information about the company and the market needs to be obtained.

1.1 Marked background

Norway is one of the countries in Europe that spends the most money per citizen on healthcare. In 2015 4,681 Euros per citizen. Cardiac diseases, cancer, Chronic obstructive pulmonary disease and diabetes are the most common non-contagious diseases and the Norwegian government has committed to the WHO to reduce the mortality of these diseases by 25% per 2025. In Norway the strategy to reduce the mortality of the non-contagious diseases is to diagnose and treat patients making their life easier. In the age spend between 30-69 in Norway the mortality of cardiac diseases in 2015 was “82,4 for men and 31,6 for women per 100 000 citizens” [2]. For high-income countries and low- and middle-income countries cardiovascular diseases is one of the leading causes of mortality, with one-third of total deaths for high income countries and one-fourth for low- and middle income. It is projected that by 2030 cardiovascular diseases will be the leading cause of death worldwide [3].

1.2 Business background

The Cardiovascular ultrasound market is a million-dollar business market. GE Vingmed Ultrasound A/S is part of GE Healthcare. GE Vingmed Ultrasound roots back to the 1970’s and started with a research group at NTNU. It was later industrialized in Horten by local investors before it was acquired by GE in 1998. GE Healthcare is multinational company with over 50 000 employees worldwide. GE Healthcare is divided into different branches within Diagnostic imaging & service, Clinical Care Solutions, IT & digital solutions and Life Sciences. GE Vingmed Ultrasound is part of the Clinical Care Solutions branch which has different focus areas such as Cardiovascular imaging (heart and veins), Women’s health (infants and mammography) and General imaging. GE Vingmed Ultrasound is located just outside of downtown Horten and has approximately 200 employees, working within probes, cardiovascular ultrasound and primary care ultrasound. The employees are split in to three branches; supply chain, research and development (R&D) and other (management and administration). The supply chain with the assembly of the ultrasound scanners and the R&D department focusing on bringing the technology forward. GE Vingmed Ultrasound is working mostly against the high-end market of cardiovascular imaging, with a revenue of approximately 1.8 billion NOK per year and a marked share of approximately 40%. Everyday more than 200, 000 patients are diagnosed with scanners from GE Vingmed Ultrasound.

Figure 1: GE Vingmed Ultrasound Strandpromenaden 45 [4]

1.3 The importance of ultrasound in healthcare

Ultrasound is a nondestructive way of setting diagnostics on patient, "*since the 1950s no sustained cases of harm from imaging have been found*" [5]. Using this method allows the sonographers and doctors to see inside the body of the patient, to get the right diagnostics and helping to save lives or spearing the patient for painful surgeries. With the technology moving forward probes are also used to guide the surgeons during operations removing the necessity of open-chest surgery.

1.4 Potential of new technologies

The shells of the probes that already exists on the market are usually produced using the injection molding method. The problem with this method is the limitations within geometrical shapes. There are different design rules that needs to be followed when designing for injection molding. If 3D printing is used as production method, the designer is free from these boundaries and has possibility of more ergonomic shapes. The probes are used many hours through the day and the shape of the probe is important for the operator. 3D printing can also be used to potentially create new thermal solutions, controlling the heat leaking out of the probe. With the 3D printing technology rushing forward it is a possibility that this method will replace many of the traditional production methods. In production of parts for aircraft engines GE is pushing the technology forward and are using 3D printing of titanium to reduce the number of parts.

1.5 Competitors

There are many competitors in the ultrasound marked. Some competitors, such as Phillips, Siemens and Esaote, deliver full scanning systems with various probes for cardiac and vascular scanning, while some competitors such as Clarius delivers wireless solutions to be used with handheld solutions.

1.6 Terms of reference

The thesis is done in cooperation with GE Vingmed ultrasound, where the goal is to design a shell for the next generation ultrasound probes. The thesis will be divided into three different parts mechanical-, thermodynamic- and ergonomics design.

1.7 Mission statement

The mission in this thesis is to investigate, develop and design the most suitable design for next generation ultrasound probe. The project goal is to increase the knowledge of the author with the use of rapid prototyping as a potential production method of probe shells. The new product shall be designed to be able to contain all necessary electronics, control the heat in the probe and have an ergonomic shape. FEM analysis, thermal analysis and external concept testing shall be used to test the concepts and ideas generated through this thesis. The marked goal is to create a new design that has equivalent or better ergonomic design than the already existing probes on the market.

1.8 Problems and focus points

The following problems and focus point will be emphasized:

- Ergonomics probe such as: Length of the probe, diameter of the probe, ergonomic grip and fitting for different hand sizes
- Heat control in the probe: Emission of heat and thermal solutions and choice of materials with right thermal properties
- Fitting of electronics: Length of the probe and diameter of the probe complies with the size of the electronics

1.9 Technological and functional bottlenecks

- For the thermal study there are limited data available for the electronics such as heat generation and placement of heat sources
- For the ergonomics the shape of the probe would be limited by the electronics, this could interfere for a good ergonomic grip
- The material data from the resin and filaments for 3D printer’s suppliers are limited, hence data needed for simulations might not be available or adequate

2. PROJECT PLAN

To get an overview over the project and tasks that needs to be completed a project plan must be developed.

2.1 Project goals

To get a direction of where the project is going, goals must be set.

2.1.1 Main goal

The product developed through the project shall be delivered to GE Vingmed Ultrasound, but it is also the master thesis for the student as a final delivery completing the master's degree.

For GE Vingmed Ultrasound the main goal is:

> To develop a concept for a new probe shell with best combination possible of thermal heat control, mechanical and ergonomic fitting.

For the student the main goal is:

> To develop a finished prototype with further technical recommendations to present for GE Vingmed Ultrasound and write the thesis according to the guidelines provided by NMBU with method and complete description.

2.1.2 Part goals

To achieve the main project goal, the following partial goals must be fulfilled.

- Plan the project and establish relevant methodology
- Examine and get an overview over existing technology
- Find solo solutions for all tree topics
- Develop new concepts combining the solo solutions
- Perform testing of the concepts, thermal, structural and ergonomics
- Investigate materials
- Develop a final concept with technical specifications
- Complete, finish and deliver the thesis

2.2 Work and milestone plan

The full work schedule can be seen in appendix B. Below is the milestone plan and a Gant diagram with an overview of when tasks should be done.

Table 1: Milestones

Task	Milestone	Finish by Week
Planned the project and establish relevant methodology	M1	3
Found out what's state of the art for thermal, mechanical and ergonomics	M2	5

Table 1: Milestones continues

Task	Milestone	Finish by Week
Found conceptional solutions for thermal, mechanical and ergonomics	M3	9
Developed new concepts	M4	11
Performed testing on thermal, structural and ergonomics	M5	13
Investigated materials	M6	15
Find a final concept	M7	15
Completed thesis	M8	17
Deliver thesis	M9	19

2.3 Gant diagram

Table 2: Gant diagram

Chapter/FW	1	3	5	7	9	11	13	15	17	19	21	23	25
Mile stones		M1	M2		M3	M4	M5	M6	M7	M8			
Introduction													
Project plan													
Method description													
Technology and theory													
Product specification													
Concept generation													
Concept evaluation													
Materials													
Thermal solutions													
Final concept													
Process evaluation and discussion													
Conclusion													
Report													
Presentation													

2.4 Limitations

Due to the timeframe of this project the following limitations have been set:

- For this thesis it will initially be focused at solutions using the 3D printers available at GE Vingmed Ultrasound
- This thesis will not go deeply into the physics behind the ultrasound imaging
- The probe shell should fit all necessary electronics designed and specified by GE Vingmed Ultrasound
- The boundary conditions for thermal analysis will be done based on previous analysis at GE Healthcare

3. METHOD DESCRIPTION

To get the best result out of the project, different methods have been used.

3.1 Symbols and terminology

Different symbols and abbreviations are used through the project, these needs to be explained.

3.1.1 Abbreviations

Table 3: Abbreviations

Abbreviation	Definition
GE	General Electric
RP	Rapid Prototyping
PCB	Printed circuit board
HSE	Health, safety and environment
IPD	Integrated product development
GDPM	Goal directed project management
NMBU	Norwegian University of Life Sciences
MSDS	Material safety data sheet
UTS	Ultimate tensile strength
CW	Continues wave
PW	Pulsed wave
FEM	Finite Element Method
CAD	Computer Aided Engineering

3.1.2 Axis

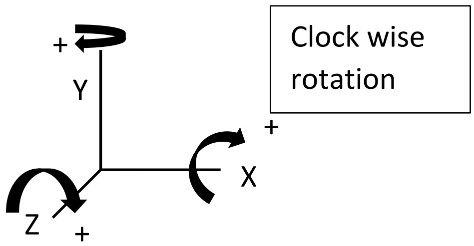


Figure 2: Axis system for six degrees of freedom

3.1.3 Symbols

Table 4: Symbols used in the project report, see table 3.1.5 formulas

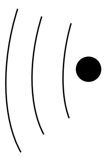
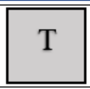
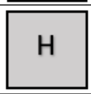
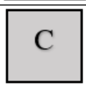
Symbols	Meaning	SI unit
F	Force	N
q	Heat flow through a single medium	W
Rcond	Resistance conduction heat transfer	K/W
qn	Heat flow through multiple mediums	W
T	Temperature	K

Table 4: Symbols used in the project report see table 3.1.5 formulas continues

Symbols	Meaning	SI unit
Rconv	Resistance against convection heat transfer	K/W
l	Length	m
k	Thermal conductivity	W/mK
h	Film coefficient	W/m^2K
A_s	Surface area	m^2
ρ	Density	m^3/kg
v	Velocity	m/s

3.1.4 Graphical symbols

Table 5: Graphical symbols

Graphics	Meaning
	Ultrasound waves
	Blue color indicates cold
	Red color indicates heat
	Transducer
	Handle
	Cable cord

3.1.5 Formulas

Table 6: Formulas

Term	Formula	Index
Heat flow through a medium	$q = \frac{T_2 - T_1}{R}$	3.1
Resistance against heat transfer, conduction	$R = \frac{l}{A * k}$	3.2

Table 6: Formulas continues

Term	Formula	Index
Heat flow through multiple mediums, conduction	$q_n = \frac{T_n - T_1}{\sum_1^n R_n}$	3.3
Heat flow through multiple mediums, convection	$q = \frac{T_s - T_\infty}{R}$	3.4
Resistance against heat transfer, convection	$R = \frac{1}{hA_s}$	3.5

3.2 Method and tools

Through the development process different methods has been used to organize the project and to develop new concepts. IPD, Pugh's, and GDPM method are used for building up the project and make sure all necessary steps of the development process are completed and sufficient, while SCAMPER, Modularity, and reverse engineering are used for brainstorming and concept development. The Oxford method for source reference is used through the project and direct quotes are marked with quotation marks.

3.2.1 IPD

IPD [6] Is a method that focuses on development, production, economy and HSE in development of new products. The IPD method bases itself on data flow and communications between all four focus areas, making sure all important aspects of the product development are highlighted.

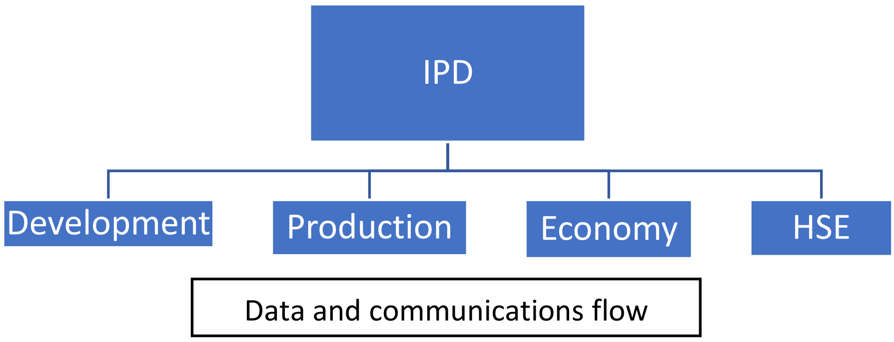


Figure 3: The IPD work flow

The four focus areas play different parts in the process of getting the product from idea to market. The development is usually done by the R&D department of a company. Based on feedback from customers and the market supplied by the management and sales team. The production is synchronized with the R&D department at an early stage, giving feedback on the design and possibilities for optimizing the design for manufacturability. This can either be done inhouse or with external suppliers depending on the company. The economy is often done in cooperation with the sourcing department of the company, helping with financial calculations and agreements with suppliers. The HSE part is a cooperation between the production and the development, finding the right materials that fulfils the requirements set by the standards determined by the marked and the company.

The method is based on early focus on the following points:

- Interdisciplinary and early interaction in the development and design
- Economy and resource use in the different development stages
- Integration of computer aids and data communications in all steps
- Learning and continue improvements through the workflow

3.2.2 Pugh's method

In almost every product design project, input from engineers and non-engineers are necessary. In a man-machine interface ergonomics, shape, form texture and color need to be considered and balanced to make sure the product does not fail in the market. In Pugh's method [7] this balance is called "Total design". Total design uses metri through the project to evaluate concepts and ideas and make decision. The decisions made reasons in quality versus the importance.

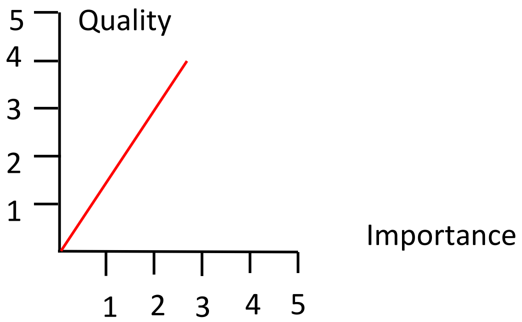


Figure 4: Importance versus quality

In this thesis the quality of the finished product is rated higher than the importance. The total design is built up with different design cores:

- Market's/User's needs and demands
- The product design specification
- Conceptual design
- Detail design
- Manufacture
- Sales

The design cores can be evaluated trough the method using metri to set up different features, technical properties and concepts against each other.

Table 7: Pugh's design cores [7]

Design cores	Definition
Market's/User's needs and demands:	Getting an overview of the marked, finding the customer's needs and demands, investigate patents, trademarks, registered design and copyright, look into research progress in the product area, look into competitive manufactures
The product design specification:	Performance, environment, size, weight, aesthetics, appearance and finish, materials, product life span, ergonomics, standards and specifications, quality and reliability
Conceptual design:	Getting ideas and generating concepts, form and presentation of the concepts, criteria for evaluation, evaluation of the solutions, the evaluation is done using a +/- matrix to sort out the ideas.
Detail design:	Performance, environment, testing, quality, maintenance, weight, manufacturing facility, processes, component cost, ergonomics/safety, standards, aesthetics, quantity, materials

Manufacture:	• Design for assembly
	  ○ Selection of assembly method
	  ○ Design for manual, high-speed automatic or robot assembly
	• Design for piece part producibility

Marketing:	Marked research to establish the user needs, get an overview over product distribution, service and marketing of the final product.

3.2.3 SCAMPER

SCAMPER is a method by which different questions are asked to form new ideas, developed by Alex F. Osborn and later arranged by Bob Eberle creating the acronym SCAMPER [8]. The idea is to use the method to provoke the users to attack to the problem from different angles. The method is divided into seven different aspects [9]:

Table 8: SCAMPER [9]

SCAMPER	Definition
Substitute	- Are there any parts that can be replaced to make the design better? - How can this be done in another way? - Can we use other materials? - Is there another way to approach this?
Combine	- Can parts of the design be combined to reduce the total number of parts? - Can we combine materials? - Are there any functions of the design that can be combined?
Adapt	- Can parts be adjusted to improve the design? - Can the design be changed to reach different costumers? - Are there any designs we can copy to produce this?
Modify	- Can simple modifications be done to a part to improve the design? - Can the design be made smaller or larger? - Can the shape be changed?
Put to another use	- Can parts of the design be used in a different way?
Eliminate	- Are there parts of the design that are unnecessary for the functionality of the design? - Can parts of the design be separated or divided?
Reverse or rearrange	- Can a part be reversed on turned to change to outcome of the design? - Are there parts of the design that are unnecessary?

3.2.4 Modularity

In the idea and concept development of the project modularity [6] is also used. This method breaks down the geometry of the design to see how it can be rearranged. With the Handle(H), Transducer(T) and Cord(C).

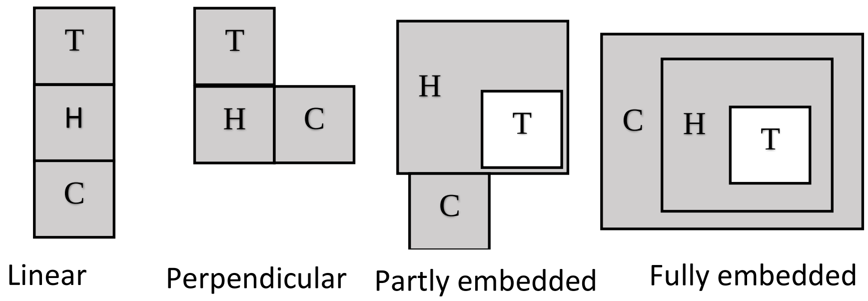


Figure 5: Modularity breakdown

3.2.5 Goal directed project management

The GDPM method is used to organize the project with project planning, milestones and Gant diagram. This has been used in early project planning, see chapter 2. The method of GDPM [10] described this development with three different aspects:

- Personal development
- System development
- Organizational development

These three different aspects are abbreviated as "PSO". Projects can be divided into two different categories: specialist projects and process orientated projects. In a specialist project the project is performed by specialists in the field and finding the best technical solution is the main goal, usually without any involvement or input from the end user. In a process orientated project there is little or no focus on planning the project, but rather focus on the process itself and the cooperation between the people involved. The PSO method is a way of connecting these two categories, finding the best technical solution and the process and increasing the knowledge of the people involved in the project, thereby increasing the competence within the organization.

3.2.6 Reverse engineering

Through the thesis, the product development will be done using reverse engineering. Reverse engineering is a method of design used when there are already existing solutions that should be studied for inspiration and guidance for a new design. In this thesis existing probes and their technical solutions where analyzed. Reverse engineering has also been used since most of the design on the electronics are locked and the probe needs to be designed from inside-out.

3.3 Software

Table: 9 Software used

Software	Used for
Dassault systems SOLIDWORKS 2019	3D modeling and design development
Microsoft Office 2018	Writing of thesis
ANSYS Workbench 19.2	Thermal and strength simulations

3.4 Literature

Table: 10 Literature search and review

Search engine	Used for	Example of search words
Oria	Literature search	SCAMPER
Google	Literature search	Ultrasound
Google Patents	Patent search	Esaote apple probe
Nasjonalbiblioteket	Literature search	Goal directed project management
GE's intranet	Literature search	Material restrictions

3.5 Quality management

- IEC60601 Medical electrical equipment
- ISO 9001 Quality management systems Requirements: Chapter 7 Product realization
- ISO 128 Technical drawings
- ISO 9000 Quality management systems – Fundamentals and vocabulary

3.6 Analysis

The following programs will be used for thermal and mechanical analysis:

- Thermal analysis will be done with ANSYS workbench Steady-State thermal analysis
- Strength analysis will be done with ANSYS workbench Static structural analysis

3.7 Expert Screening

Table 11: Expert screening team

Name	Work place	Competence
Madeleine Eng, Jiun Yi	Ge Vingmed Ultrasound	Ultrasound test engineer
Thea H Ottesen,	Ge Vingmed Ultrasound	Systems Test Engineer
Glenn Reidar Lie	Ge Vingmed Ultrasound	Global Product Manager
Gunnar, Hansen	Ge Vingmed Ultrasound	Global Clinical Research Manager
Jan Yee	Ge Vingmed Ultrasound	Global Clinical trainer/educator

3.8 Processes

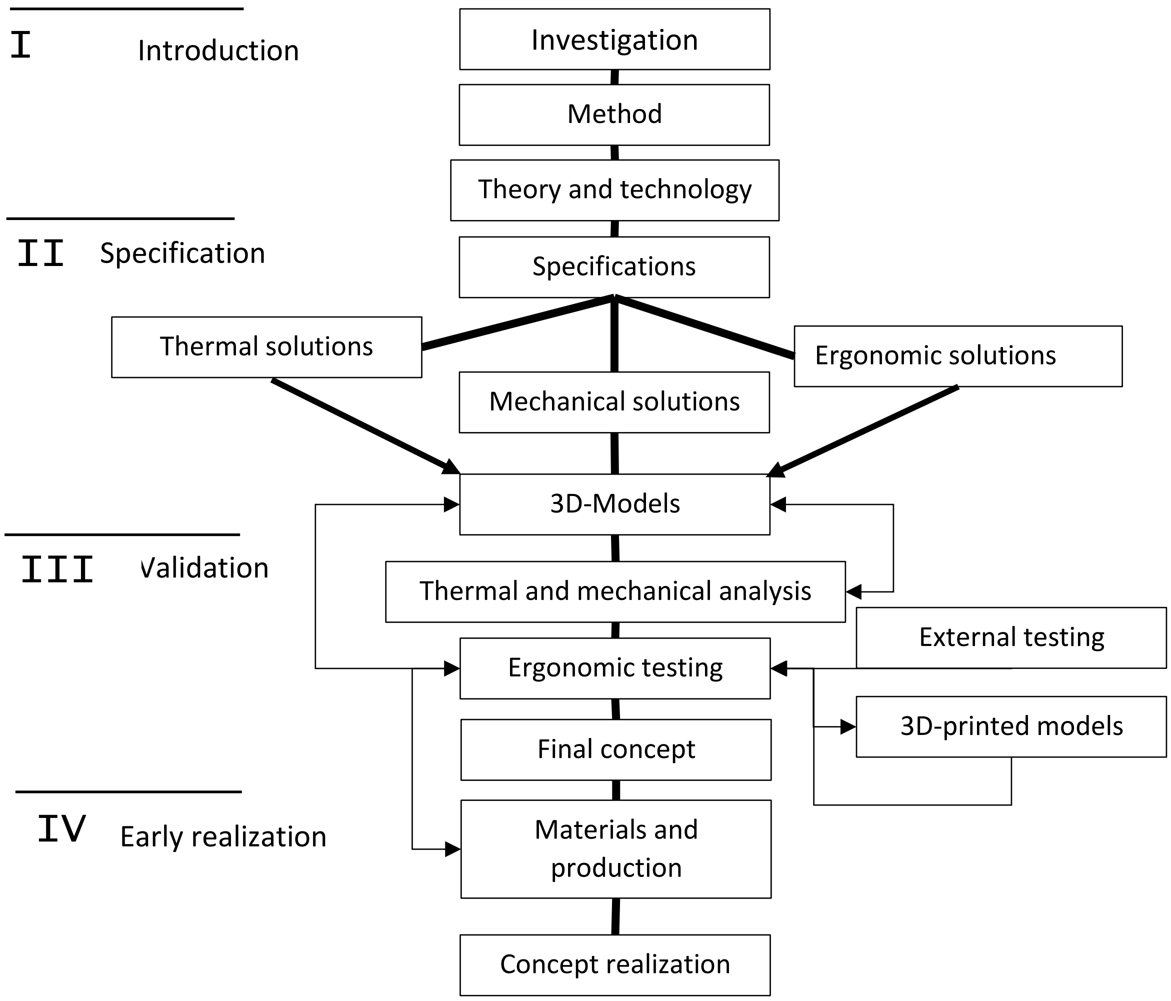


Figure 6: Project processes. The process will be done in iterations, until the best solution for all three focus points are achieved. The arrows indicate the workflow of the project, with backwards and forwards connections for improvements.

When the 3D-models are ready, 3D-printed models will be used for ergonomic testing, while simultaneously the same 3D model is used for thermal and mechanical analysis. With these iterations the final concept will be a combination of the feedback from the external testing and the results of the computer analysis.

4. TECHNOLOGY AND THEORY

To understand the technology of already existing solutions a basic study of principles and technology is necessary.

Ultrasonic imaging is a non-destructive method for diagnosing patients. Since ultrasonic imaging does not cause any harm, it's used for many different applications such as fetal scanning on pregnant women. It is also used for NDT of weldments and as a weapon against riots sending out high pitched sound to disoriented attackers [11]. Ultrasound also exists in nature. Bats use this same technique for navigation. Sending out calls in the range of "14 000 Hz to over 100 000 Hz", the bat uses the echo of the sound to locate its prey and navigate in the dark [12]. The figure below shows the link between the theory, technology, and the patient and user for cardiac scanning.

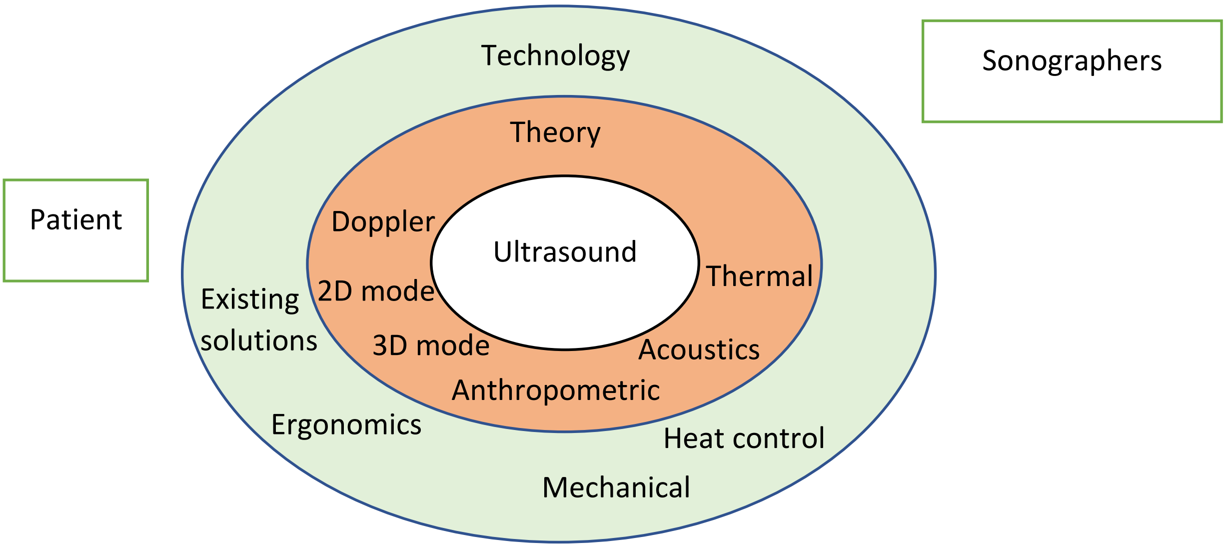


Figure 7: Link between theory and technology of ultrasound

The ultrasound is in the center, followed by the theory of ultrasound and ergonomics. The outer circle is the technology which will affect the user and the patient

4.1 The probe

For surface skin scanning, there are two different types of probes, linear and cardiac. The linear probes are using for scanning veins and muscles while the cardiac probes are used for scanning the heart. The ultrasound probes usually have the same buildup, as seen in figure 8 below.

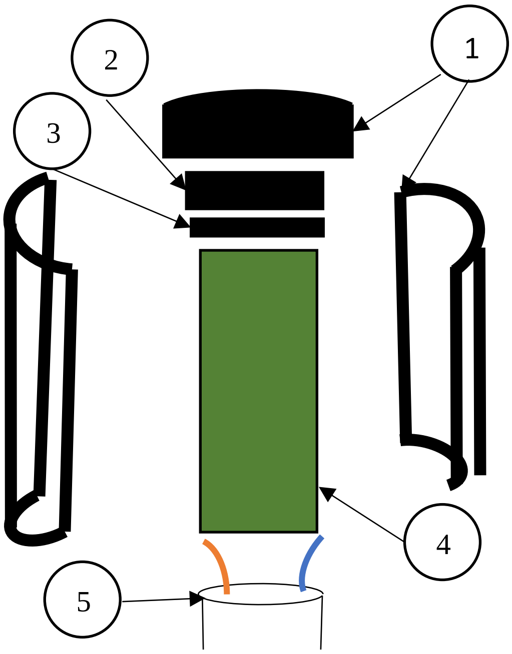


Figure 8: Traditional probe build: Three plastic shells (1), Transducer (2), Heatsink (3), PCBs (4), Cable cord (5)

The cardiac scanning sequence is built up in the following order:

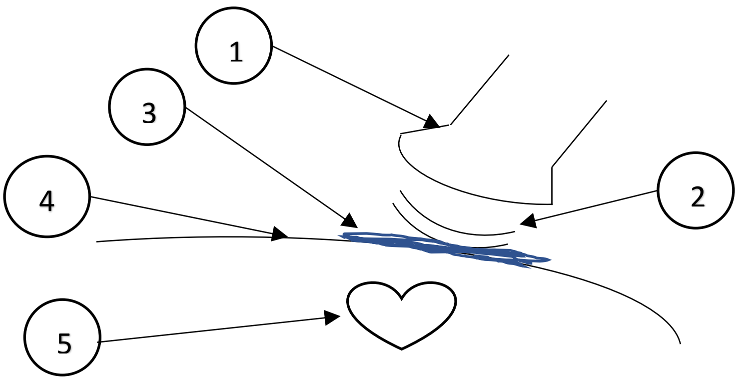


Figure 9: Cardiac scanning sequence. Probe (1), Sound waves (2), Ultrasound gel (3), Skin surface (4), Heart (5).

The ultrasound imaging sequence is built up by different steps. The transducer sending out beams of ultrasound, and receiving the echo, different premade parameters are used to generate the image. The sequence is built up in the following order.

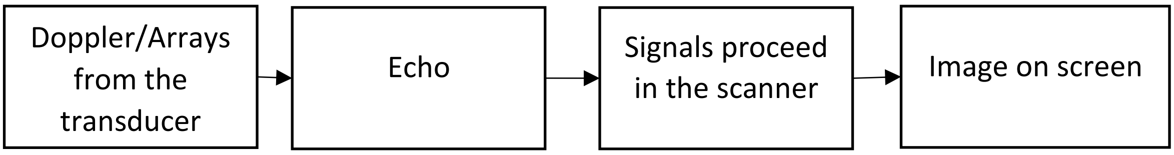


Figure 10: Ultrasound sequence build up Source [13]

4.2 The Doppler effect

When you are out driving in your car and you hear an ambulance in the distance, it is common practice to try to hear if the frequency is increasing or decreasing. If the frequency is increasing, you know that the ambulance is approaching you. This effect of the frequency of the sirens increasing or decreasing is called the Doppler effect. This effect was described by the Austrian physicist Christian Johann Doppler that if a person is moving away from the source of the sound it will decrease, but when you are moving towards it, it will increase. The ultrasound probes are using the same Doppler effect. The probes are sending out acoustic waves normally in the range from 1 to 10 MHz and at this high frequency the sound moves along a straight line like a beam of light [14]. The red blood cells will then echo the ultrasound waves from the blood, and the software will separate red blood cells from the bone, tissue and other disruptions.

The Doppler technique for ultrasonic imaging is divided into two parts, continues wave (CW) and pulsed wave (PW).

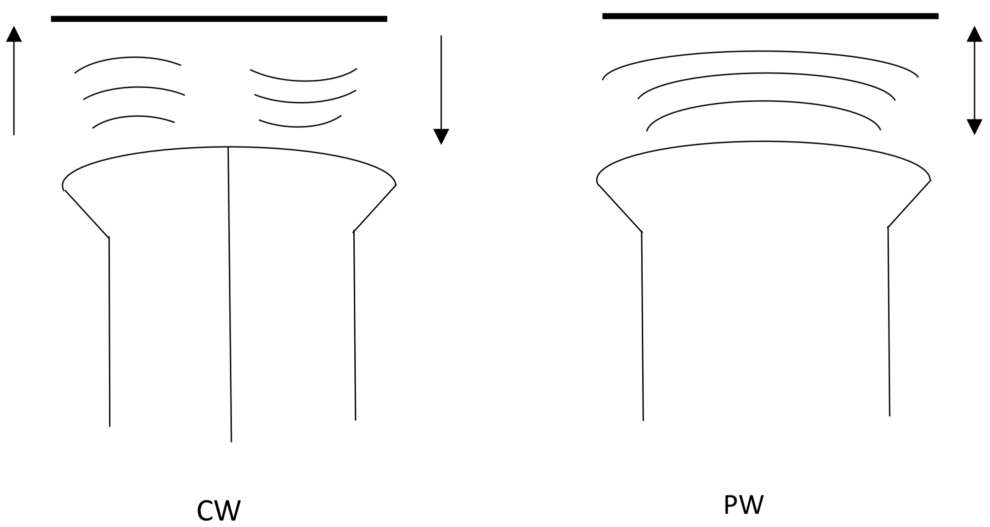


Figure 11: Continues and pulsed waves.

In CW the probe is sending continuous ultrasound waves towards the vessel on one side of the transducer while the other side is receiving the echo. The CW has no range resolution and no maximum measurable velocity. The CW method is calculating the shift in the Doppler frequency with the formula: $f_d = 2f_0 \frac{v cos\theta}{c}$ where v is the velocity of a small element of blood where the velocity constant is essentially constant, Θ is the angle between the ultrasonic beam and the velocity vector, f_0 is the transmitted frequency and c is the velocity of sound in blood (c≈ 1560 m/s).

In PW we can obtain range resolution along the beam. The transducer is sending out a burst of ultrasound in a repetitive frequency, the signal is then received by the same transducer with a time delay allowing to us to select the echoed signal from a selected depth.

The two different techniques have different limitations, example the PW mode is a good method of localizing disturbed flow within the heart region. When we know the Doppler shift we can calculate the velocity of the blood. The disadvantage with the PW method is that there is a limit on the maximum velocity. With CW there is no limit on the velocity, but there is no range resolution. There for the two techniques complement each other [15].

4.3 2D and 3D mode

2D mode or brightness mode, builds up an image using multiple scan lines. The intensity of the echo is then shown on the screen in different gray levels giving a real-time 2D image. This mode can also be combined with the Doppler, merging the velocity information with the 2D image giving an indicator of the blood flow [16]. The 3D image is generated using a set of spatial coordinates, in 3D space with different directions from the same origin by sending short pulses into a selected direction. The beam can be controlled either mechanically or with a two-dimensional array [15]. The 3D image is built up from the sliced 2D images building them together to a 3D image. The resolution of the 2D and 3D image can be linked to the effect of the transducer, the transmitted effect controls the frequency sent out, higher frequency gives better resolution of the images, higher frequency however gives higher dampening.

4.4 Acoustic impedance

The acoustic impedance is an indicator of how sound travels through a medium. The impedance is given by the density of the medium and how fast speed travels through the medium $z = \rho v$ when the sound travels through multiple mediums the intensity of the reflections can we written $a = \frac{(Z_2 - Z_1)^2}{(Z_1 + Z_2)^2}$ this relationship is used in ultrasound to form the image [17].

4.5 Acoustic attenuation

The acoustic attenuation is the loss of sound propagation in a medium, this is measured in Db/mm. The acoustic attenuation can affect the ultrasound quality because the attenuation in the medium will decrease the amplitude of the ultrasound beams. This can be prevented if the attenuation is known and the input signal amplitude can be adjusted to compensate [18], [19].

4.6 Thermal theory

The heat transfer through a medium can be calculated similarly to electrical resistance. By using Ohm's law, we can calculate how much heat that flows through (W) using formula:

$$q = \frac{T_2 - T_1}{R} \quad [3.1]$$

Where T_2 and T_1 Is there temperature at each side of the medium and R is the resistance against heat transfer. The higher R the less heat will flow through the medium(K/W). R is calculated with

$$R_{Cond} = \frac{l}{A*k} \quad [3.2]$$

L is the thickness of the medium(m), A is the area(m^2) and k is the mediums thermal conductivity (W/mK). When the heat travels through multiple mediums, the resistance against heat transfer is summed, the formula for multiple mediums is:

$$q_n = \frac{T_n - T_1}{\sum_1^n R_n} \quad [3.3]$$

Where T_n is the temperature on the outside and T_1 is the inner temperature divided by the summed resistance. This formula is used for calculating the conduction heat, for convection heat transfer the formula is:

$$q = \frac{T_s - T_\infty}{R} \quad [3.4]$$

Where T_s is the surface temperature, T_∞ is the temperature as far away from the surface that it does not make a difference. The resistance is calculated with:

$$R_{Conv} = \frac{1}{hA_s} \quad [3.5]$$

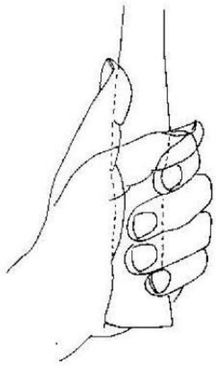
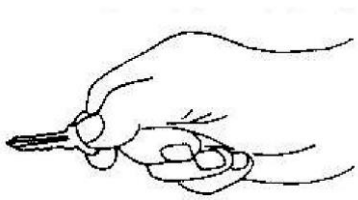
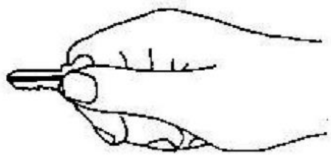
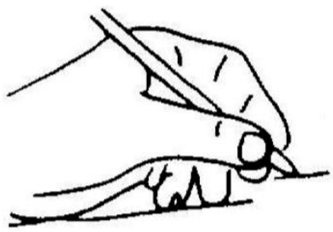
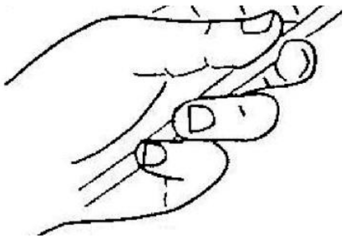
Where A_s is the surface area of the heat source and h is the film coefficient [20]. The formulas above will be used to help calculate the boundary conditions for the thermal analysis.

4.7 Hand anthropometric

Anthropometry is the measure of the human body and is used to understand the physical properties of the human body [21].

There are many ways to grip and hold an item, the most commonly used grips are the power grip for large heavy items and the pinch grip for small light items. The pinch grip can be divided into different sub-grips such as external and internal precision grip [22].

Table 12: Different hand grips [22]

Traditional power grip	
	
Traditional pinch grip	
	
External precision grip	Internal precision grip
	

For use of ultrasound probes, the precision grips are the most common due to the small adjustments for controlling the probe.

To get an overview over the different hand sizes, the book; *The measure of man and woman* [23] was studied. The book divides the legend of hand sizes into three different categories for man and woman:

- Large which covers 99 percentiles of large man or woman
- Mean which covers 50 percentiles of average man or woman
- Small which covers 1 percentile of small man or woman

The percentile is measuring the mean size of a large sampling group and add or subtract a Standard deviation (SD) multiplied by a factor. 99 percentiles of the population are calculated with: $Mean + (2{,}236\ x\ SD)$ this includes 98% of the population [23]. In the following figures different measurements of the hand for man and woman are displayed, showing large, medium and small average hand sizes. This size will be used to justify the geometry of the shell.

Hand data man

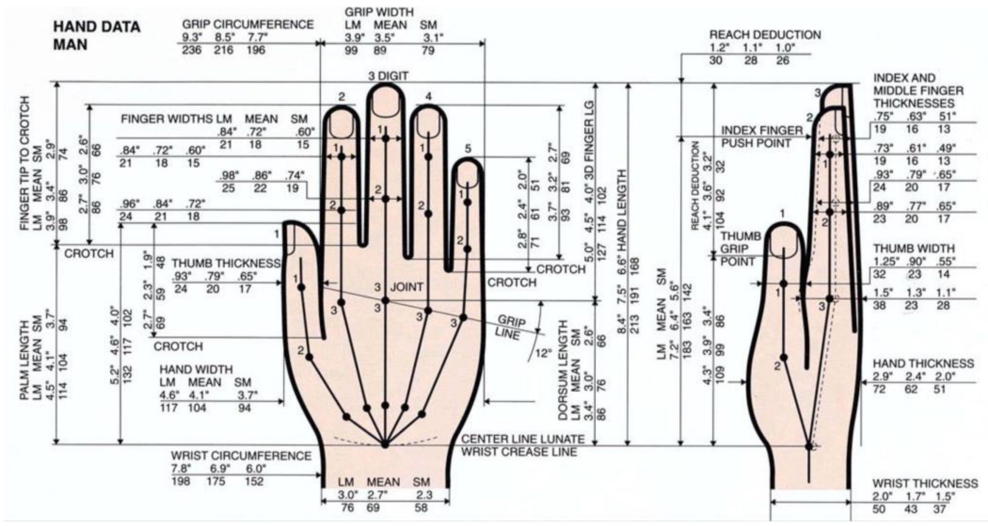


Figure 12: Hand data man (in mm and inches) [23]

Hand data women

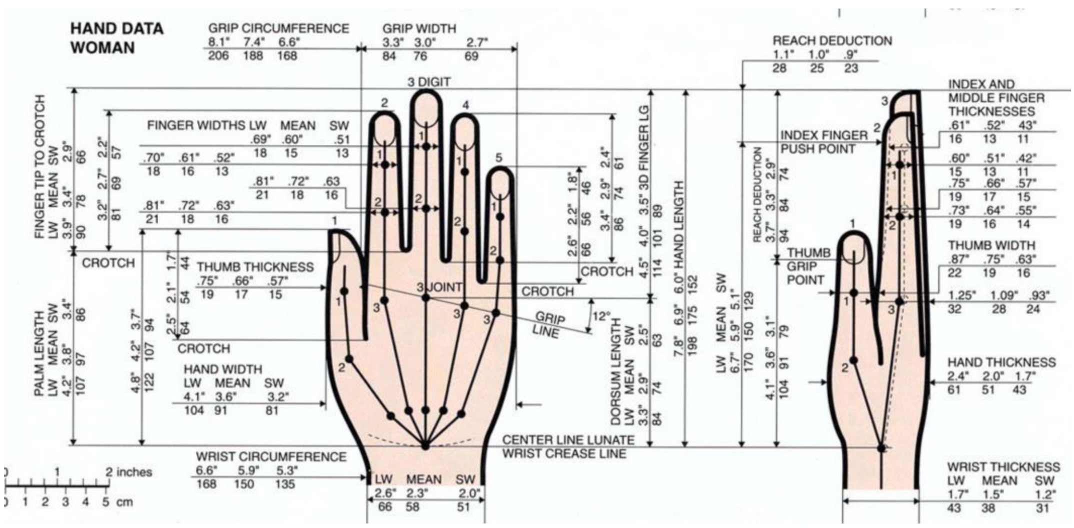
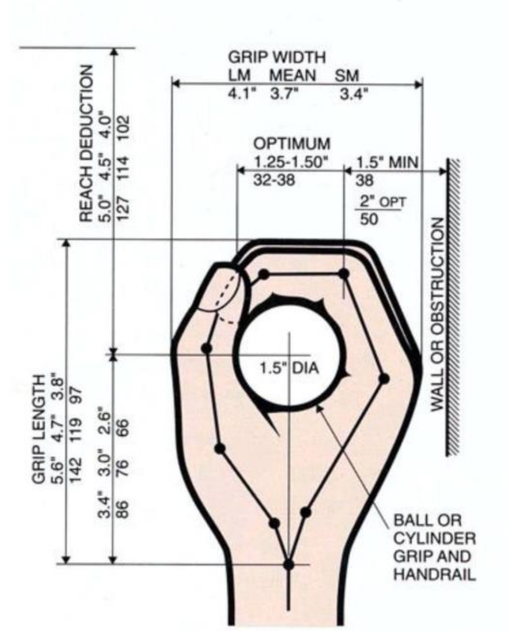


Figure 13: Hand data woman (in mm and inches) [23]

Grip data man	Grip data woman



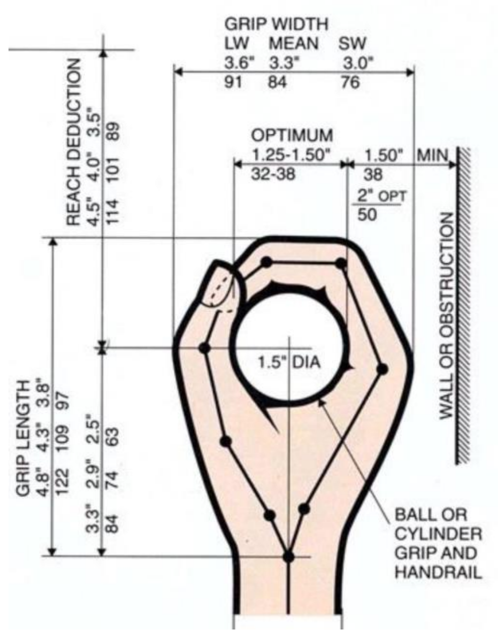


Figure 14: Grip data man and woman (in mm and inches) [23]

The sonographer employment consists of mostly women. During a study among Swedish sonographers only 30 out of 321 where male [24]. Given this aspect, the ergonomics of the new probe shell should if possible be formed after the size of the hand of a large woman. The hand anthropometrics of a large woman is close to the size of the hand of an average man, this means the design would cover 99 percentile of women and 50 percentiles of men.

4.8 Using existing probes

During a normal scanning procedure, the patient is laying in a hospital bed either laying on the back or sideways, there are different grips used by the technician, when holding the probe. Use of the probe also varieties if the operator is right of left handed.

Table 13: Most common scanning grips

Most common right handed	Most common left handed

Table 13: Scanning grips continues

Right handed	Left handed
The operator adjusts the probe with small movements with the index finger and the thumb. The probe can also be tildet up and down using the wrist. The patient is laying on the right side of the operator The three other fingers are resting on the chest of the patient supporting the hand [Own photo]	The operator adjust the probe using the wrist. This is more exhawsting for the operator. The patient is laying on the left side of the operator [Own photo]

A study done in Sweden on the ergonomics of sonographers divides the working positions for the sonographers into three different positions, where method A and C is most commonly used.

Table 14: Different working positions for sonographer

Description	Ilustration
A: Patient facing the examiner, holding the transducer with left hand [24]	
B: The patient facing the sonographer, but the transducer is held with right hand [24]	

Table 14: Different working positions for sonographer continues

C: The patient is facing away from the sonographer and sonographer the leaning over the patient holding the transducer with right hand [24]	

During the interviews the suggestions for improvements by the sonographers were; Lightweight, neutral grip and flexible cables. It was also pointed out during the survey that the use of ultrasound gel makes the probe slippery and difficult to grip, this applies specially transducers made from hard smooth plastics [24].

4.9 Existing solutions

There are different approaches to the design of the probe, the following chapter will look at some already existing solutions.

Table 15: 4Vc cardiac probe

GE 4Vc - Cardiac	
Top view	**Side view**
	
The rails on the top is used for better friction on the thumb [Own photo]	The fillet is for the index finger [Own photo]

Table 16: ClariusC3 linear probe

ClariusC3 - Linear	
Top View	**Side view**
	
Wireless handheld probe Has attachments to be placed on the front to change the use of the probe The black area is rubber to increase the friction when holding the probe [own Photo]	

Figure 15: Dirt spots on Clarius C3 [Own photo]

The area marked in red in figure 15 we can see some white spots, this is old ultrasound gel not cleaned from the last scanning procedure. This makes the probe look “dirtier” and is not desirable.

Table 17: Siemens 4Z1c

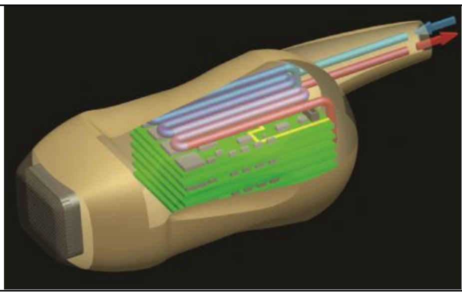
Siemens 4Z1c Real-Time volume Imaging Transducer Cardiac	
Description	**Ilustration**
Siemens 4Z1c is an ergonomic designed transducer, where the operator has a "palm grip" on the probe. Using this grip, the operator uses the larger muscles in the arm and shoulder. The cable is moved to the side of the handle, and the transducer is covered in an elastomeric compound to decrease the slippery of the transducer when covered in ultrasound gel	
The Siemens probe is also featured with active cooling: The active cooling draws the heat out of the transducer and circulates the heat through the transducer connector where the fluid gets cooled before going back to the transducer [25]	

Table 18: Siemens 18L6HD

Siemens 18L6HD Linear	
Description	**Ilustration**
Palm grip for improved stress distribution ElstoGrip coating for non-slip usage Extra-long cable ~ 2.1m [26]	

Table 19: Esaote PA230

Esaote PA230 Cardiac	
Description	**Ilustration**
Electrical razor grip, with a soft area on the tip of the probe instead of hard plastic [27] Small transition between the handle and the nose piece	

Table 20: Philips S4-1 Cardiac

Philips S4-1 Cardiac	
Description	**Ilustration**
Continuous cross-section [28] Electrical razor grip, small transition between the nose piece and the handle	

Table 21: Siemens 8c3 HD Linear

Siemens 8c3 HD Linear	
Description	**Ilustration**
Palm grip Improved access between rips Rubber material to increase the grip friction [29]	

5. PRODUCT SPECIFICATION

Before starting generating concepts, it's necessary to find requirements and specifications for the probe.

5.1 Product goals

The new probe design should, if possible, have state of the art solutions for mechanical, thermal and ergonomic solutions. The new design should also have better or equivalent ergonomic design to the already existing solutions. The following chapters describes in detail focus points and goals for the new shell. However, the part goals for the new design should be:

Table 22: Product goals

Feature	Goal
Thermal	Heat control inside the probe
	Acceptable temperature against the patient
	Acceptable temperature against the user
Ergonomics	Equivalent or better than existing probes
Mechanical	Easy assembly process
	Fitts all necessary electronics
User	Good ergonomic grip
Patient	No changes from other probes

5.2 Functional analysis

The functions of the ultrasound probe can be divided into three different aspects, with patient on one side, user on the other side and the technology in the middle. The patient will only be in contact with the probe for a short time when visiting the hospital for an examination. The sonographer will have contact with the probe every day during normal work procedure.

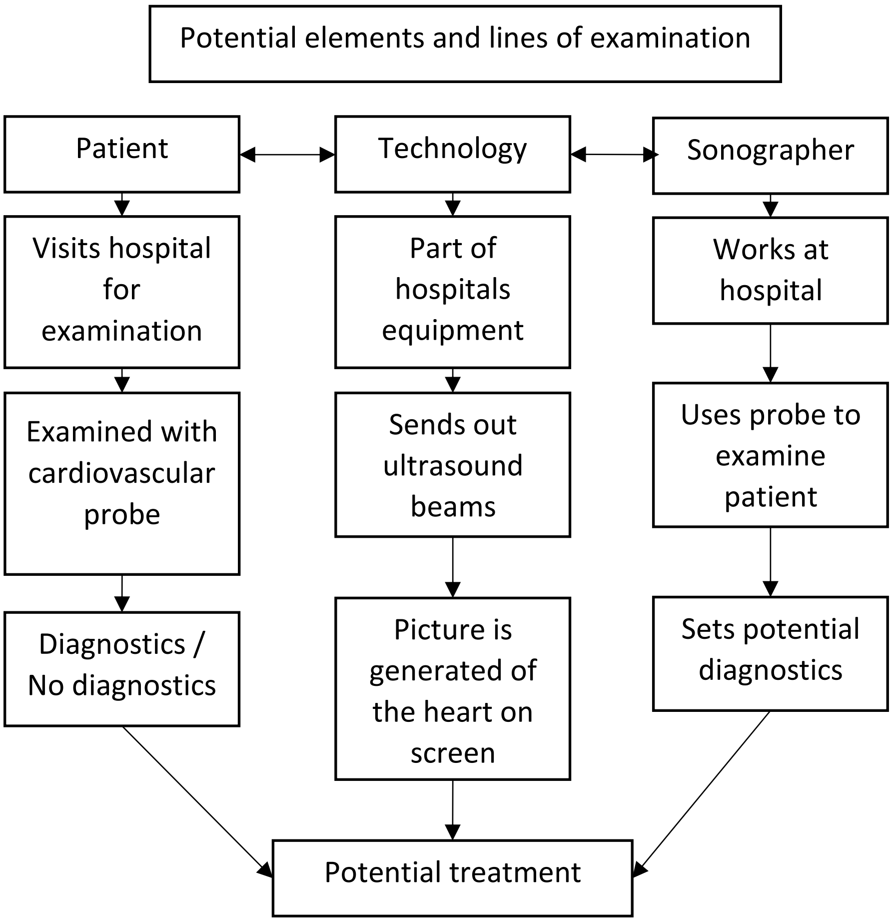


Figure 16: Functional analysis

The focus of this thesis is to find the solution that works best for all three parts. Finding a solution that fits the technology but also is comfortable for the sonographer and the patient.

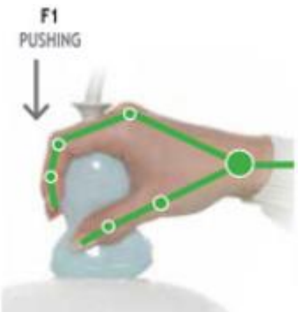
5.3 Ergonomics features

When it comes to the ergonomic aspects the sonographer and the patient needs to be considered. The sonographer will use the probe every day in different positions scanning the patients. The grip of the probe needs to be comfortable for the sonographer, but it also needs to be comfortable for the patient to be scanned, so there should not be any sharp edges around to head of the transducer that can scratch the patient.

Average cardiovascular probes have a spherical grip design, for standard hand design the recommended size of grips a diameter of 22-33 mm is the optimal range [23]. The grip strength for men is an average maximum of 59,3 kg and 35.5 kg for women [23].

Among sonographers there is a known issue of wear and tear, in neck, shoulders, wrists, hands, back, and eyes. "*Almost 80% of sonographers report pain and discomfort within 5* *years of entering the profession."* [30]. Esaote have done studies on the grip of the probe and have introduced an "appleprobe" the new transducer reduces the used muscle strength of between 31% and 79% for the user.

Table 23: Esaote appleprobe grip

<table>
<tr><th colspan="2">Conventional grip [30]</th></tr>
<tr><td colspan="2">
</td></tr>
<tr><td colspan="2">The muscles, tendon and nerves stay in constant tension. The user needs to pinch the probe to hold and maneuvre it [30]</td></tr>
<tr><th>Appleprobe grip [30]</th><th>Relax position apple probe [30]</th></tr>
<tr><td>
</td><td></td></tr>
<tr><td colspan="2">The probe is resting between the fingers and there is no need to squeeze to hold the probe</td></tr>
</table>

Compared to traditional transducers, Esaote's appleprobe gives the user a relaxing position for the palm of the hand. The possibility for placing the cords between the fingers are patented by Esaote. (US20080146936A1)

To get a better understanding of the ergonomics perspective there was a workout with two test engineers at GE Vingmed that has experience with the scanning procedures. During the workout with the test engineers/sonographers gave some feedback on desired changes and specifications for a new probe handle. The feedback was given based on GE's 4Vc probe but can be related generally to all probes and should be taken into consideration when forming the new probe shell.

Table 24: Feedback from sonographers

Comment	Illustration
The cable is too stiff coming out of the handle, making it harder to adjust the probe [Own photo]	
The waist of the probe shall be thin and easy to hold with the fingers. An hourglass design would be nice, as marked with red circle [Own photo]	
The surface friction of the handle plays a big part, if the plastic is to smooth the probe is more tiring to hold because it will get slippery from the ultrasound gel [Own photo]	
The nose piece of the probe should not exceed the foot print too much, as marked with red circle [Own photo]	

The ergonomics of the sonographers are a big part of the development of the ultrasound equipment. *The industry standards for the prevention of work related musculoskeletal disorders in sonography 2016* [31] lists the following points as guidance for transducer design:

- "Transducers and cables should be lightweight and balanced to minimize torque on the wrist"
- "Transducer design that facilitate a palmar grip and a neutral wrist position are recommended"
- "Transducer housing should be slip resistant and sized to fit the 5th to 95th percentile of the hand size of the user population and reduce grip force required to hold and manipulate the transducer."
- "It is recommended that cables be a suitable length for intended applications and not interfere with access to equipment, system interaction, or create safety hazards such as tripping or entanglement."

- "Low profile and easily accessible cable management systems are recommended."
- "Transducer holders should be easily accessible with the ability to secure a variety of probes, including endocavitary probes."
- "Transducer connector should be easily accessible, with minimal reach and permit single-handed use with minimal force or pinch grip; if applicable, customizable controls on the transducers are recommended. "

These guidelines should be taken into consideration when forming the shell of the probe.

5.4 Product ergonomic goals for the shell

The ergonomic goals will be divided into several features. The comfort of the patients is the top priority followed by the grip for the sonographer.

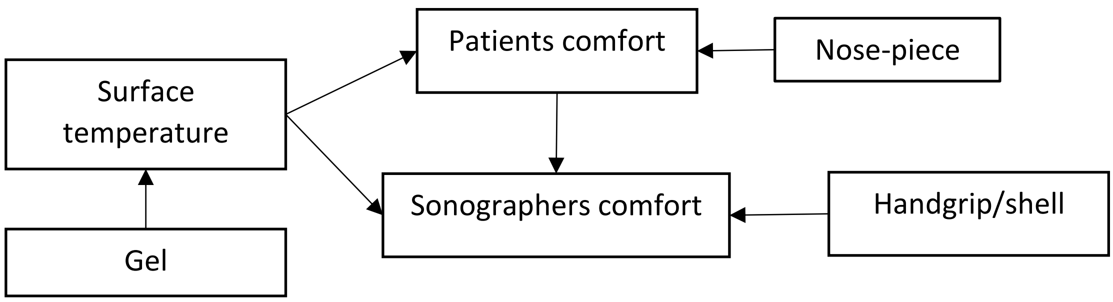


Figure 17: Ergonomic goals and points of influence

The ergonomic goals and investigation can be broken down to demands and points of interest in the development in a new probe shell. These points will later be used for idea screening and evaluation of design.

The following product goals should also be fulfilled:

- Comply with many as possible request from the Workout ref table 24
- Comply with as many as possible points from the guidance for transducer design
- Designed after the hand size of a large woman and a medium man

5.5 Thermodynamics

To get an overview over the scope and existing thermal solutions.

5.5.1 Thermal product goals

It's also necessary to find a solution for controlling the heat in the probe, and the shell needs to isolate and spread the heat, so that shell has a comfortable temperature for the operator. There is higher tolerance of heat against the operator than against the patient

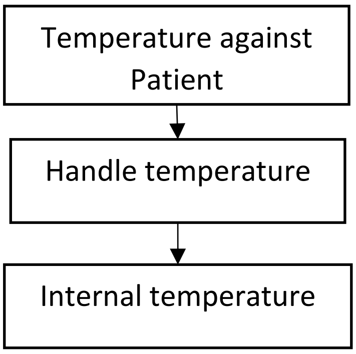


Figure 18: Thermal interaction goals

Product goals:

- The surface temperature on the front of the probe should not exceed 41 °C
- The internal temperature of the probe at an acceptable temperature
- Find a solution for controlling the temperature in the probe
- The surface temperature shall not exceed 43 °C

5.5.2 Existing solutions:

The main goal with the thermal design, is to draw the heat away from the patient. Most of the heat in the conventional ultrasound probe is generated in the transducer. The first challenge that needs to be solved is to draw the heat away from the transducer facing the patient. This is normally done using a heatsink in the front of the probe. The material of the heatsink needs to have high thermal conductivity to lead the heat away. To get a better understanding of how the thermal aspect could be solved three different previous existing solutions have been analyzed:

Existing solution 1:

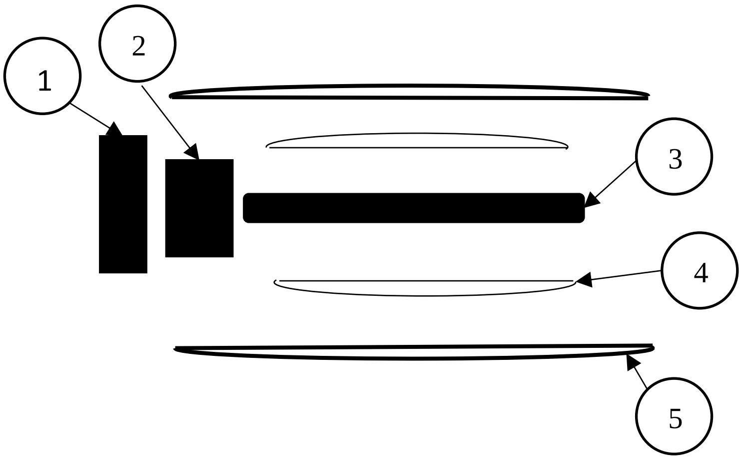


Figure 19: Existing thermal solution one, with heatsink (2), heat pipe (3) and heat spreaders (4)

For this case there was a lot of heat generation in the probe. This was used with multiple steps of leading the heat away. The heatsink (2) first leads the heat away from the transducer (1), a heat pipe (3) leads the heat further out in the probe and two heat spreaders (4) is on the inside of the plastic leading the heat out in the handle (5). The handle is made of a plastic with low thermal conductivity insulating the probe.

Existing solution 2:

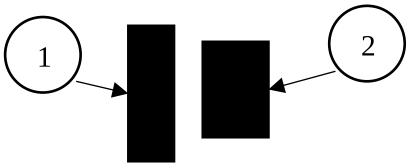


Figure 20: Existing thermal solution two with heatsink (2) and transducer (1)

For this case thermal was not a problem. The heat was led away from the transducer using a heatsink and was released into the probe from there.

Existing solution 3

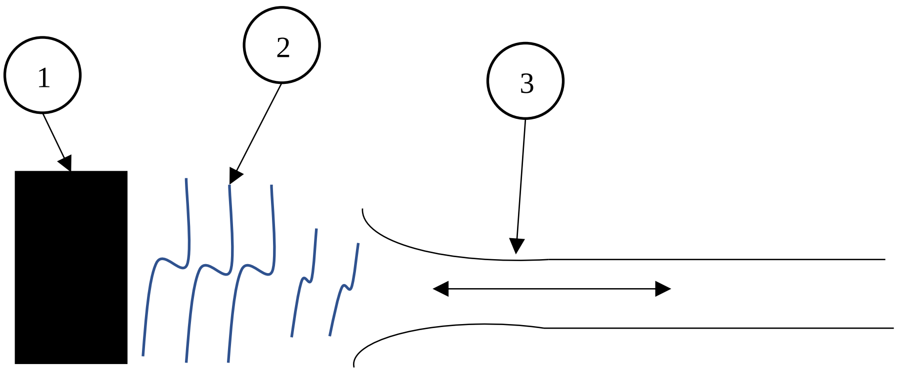


Figure 21: Existing thermal solution three with active cooling, transducer (1), circling fluid (2) cable (3)

In this case due to high temperatures the heat was controlled by using active cooling. The active cooling uses a fluid circling inside the probe in pipes over the electronics between probe trough the cable down to the connector and then back to the probe.

5.6 Mechanical

The new solution should be able to hold six different PCBs and one Flex support. The PCBs will be stacked over two dimensions:

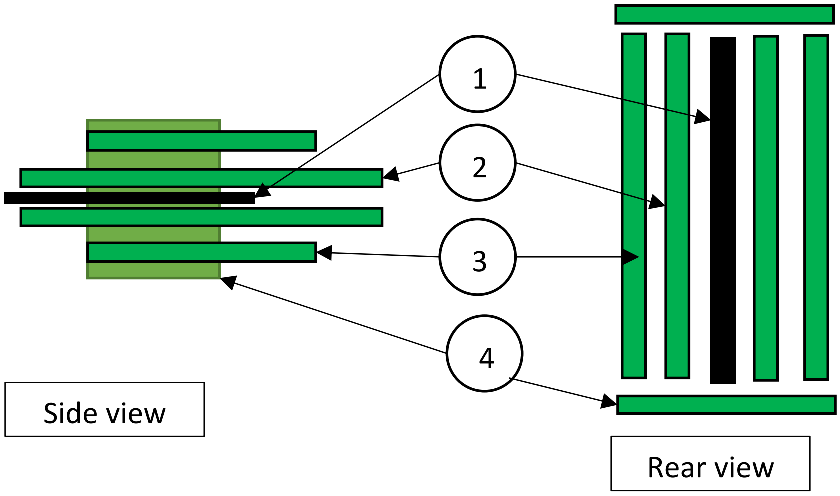


Figure 22: PCB stacking: Flex support (1), two large PCBs (2), two small PCBs (3), two smaller versions of the large PCB (4)

The two large PCBs in center will be fastened to the flex support marked as black in figure 22 above. It's necessary to find solutions for stacking the PCBs, but also a solution for fastening the cable cord and assembling the probe shells. The priority of the mechanical solutions should be built up in the following order:

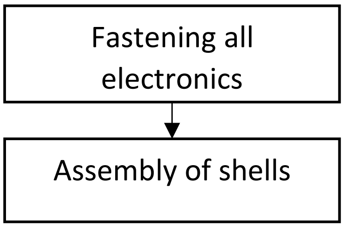


Figure 23: Mechanical goals

5.6.1 Functional goals

The priority can be broken down to product goals.

Product goals:

- Find a solution for assembling the shell
- Fit all electronics
- The shell must be able to withstand applied loads
- Find a suitable material for rapid prototype of shell
- Find a solution for fastening the cord

The connectors needed are approximately 28,57 mm wide, this means that the PCBs will need to be approximately 30 mm wide. These connectors also require a 1,6 mm thick PCB. The height of the connector is 5,78 mm. If the PCBs and flex support is looked on as a box, it will have geometry close to:

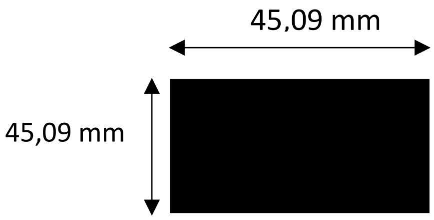


Figure 24: Blackbox geometry of electronics

5.6.2 Decomposition of electronics

As mentioned earlier there will be 6 different PCBs and a flex support. There is a need for finding different mechanical solutions for fasting each of these parts. The larger boards will be fastened to the flexes coming from the transducer. The flexes from the transducer need to be fasted with two screws each, eight in total. A support needs to be made for fastening these flexes:

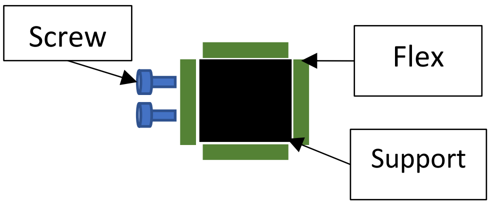


Figure 25: Fasting of flexes

This support can also be used for fastening the flex support. This can be solved by making a trace in the support for inserting the flex support:

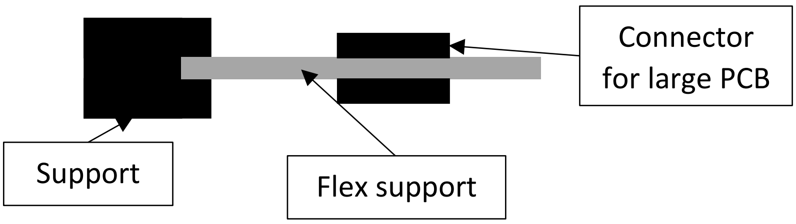


Figure 26: Fasting of flex support

Dimensions of flex support can be changed if necessary. The size of the current flex support:

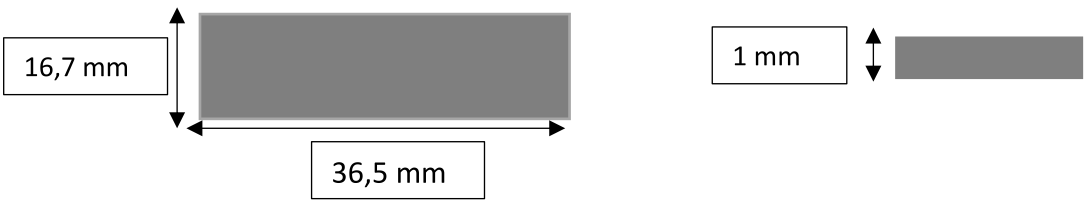


Figure 27: Flex support dimensions

The large PCBs will be placed on top of the flex support, the dimension of the large PCBs is:

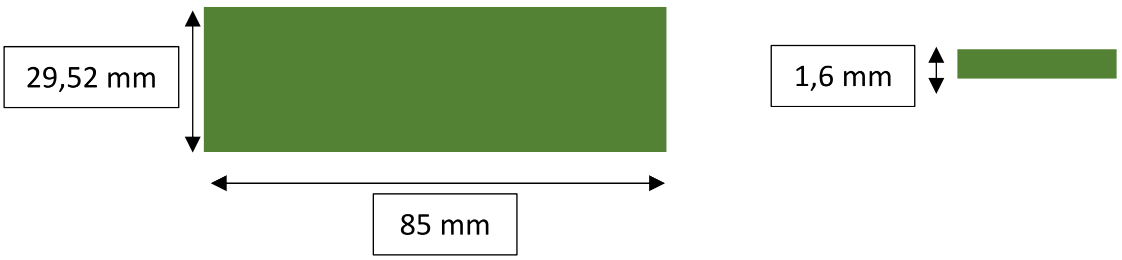


Figure 28: PCB dimensions

On top of the large PCBs there will be placed smaller PCBs, using the same connector as to the flex support. The dimension of the smaller PCBs:

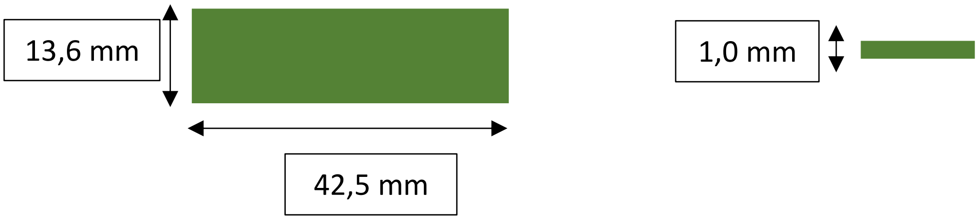


Figure 29: PCB dimensions

There will be two smaller versions of the large PCBs vertically stacked on the outside of the large PCBs. They will be connected to the two remaining flexes.

Figure 30: PCB dimensions

The dimensions of the flex support and the support can be changed as needed, but the PCBs dimensions are locked and cannot be changed.

6. CONCEPT GENERATION

To find the best concept different solutions for thermal, ergonomics, and mechanical will be examined.

6.1 Thermal possible solution

There are different ways to control the heat in the probe. Different solutions will be found for leading the heat of the probe and away from the patient and the operator. During the idea swirling the ideas for thermal solutions will be divided into these three different aspects.

6.1.1 Ideas for reducing the surface temperature of the probe

To find solutions for reducing the surface temperature, the SCAMPER method was used to generate different solutions.

Modify:

Normally the shells are injection-molded. This means the shell is made of solid plastic. By using 3D printing as a production method, the shell of the probe is freed from the restrictions that comes with traditional production, and gives the opportunity to change the topology of the shell.

Table 25: Ideas for heat control in shell isolating with air

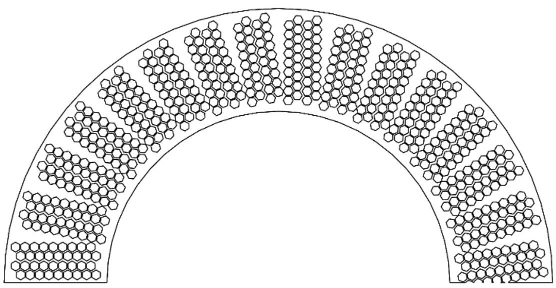
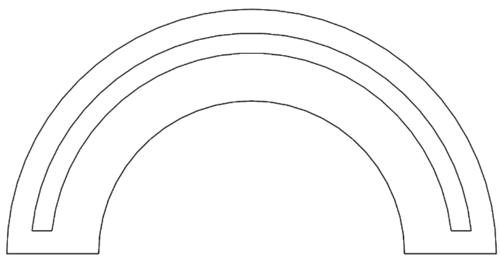
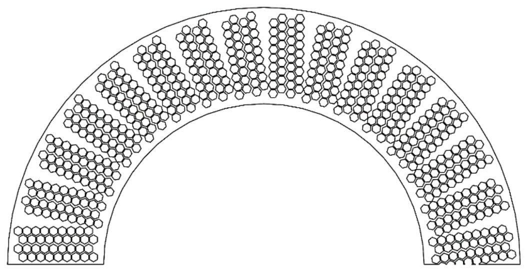
Isolating with Air	
Air has a lower thermal conductivity than plastics. A way to reduce the surface temperature of the probe would be to have air in the probe shell. This can be done in different approaches;	
Honeycomb structure	**Open shell**
	
The honeycomb structure allows to have multiple openings in the plastic, making room for air. This is also a common way for applying layers used by 3D printers	Have an opening in the plastic shell for air. With this concept there might be some structural issues and stiffeners might need to be added to make sure the shell does not break during scanning

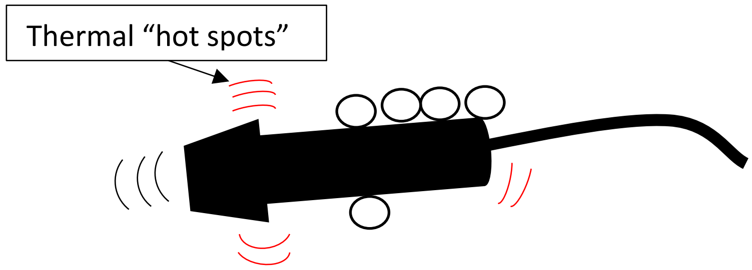
Table 26: Ideas for heat control in shell isolating with fluids

Isolating with fluids
Based on same technique as with air, but instead the shell is filled with fluid with low thermal conductivity isolating the heat inside the probe. This solution can be built up with honeycomb structure or just normal squares


Combine:

The 3D printing also gives the possibility to combine materials in production of the shell.

Table 27: Thermal hotspots on the probe

Mixing materials
Using 3D printing allows to mix materials in the shell. This can be used to give the shell different thermal properties at different areas of the shell

For a large probe the shell can be given high thermal conductivity at spots that’s not held by the operator, so that the griping point feels colder than the rest of the probe

6.1.2 Ideas for controlling the heat in the probe

Adapt:

Table 28: Heat cord on PCBs or flex support

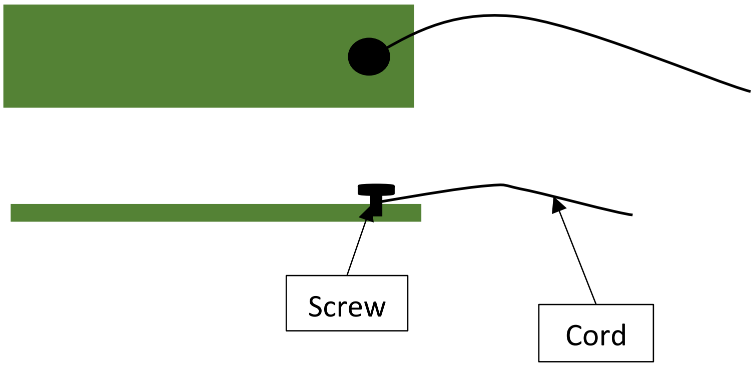
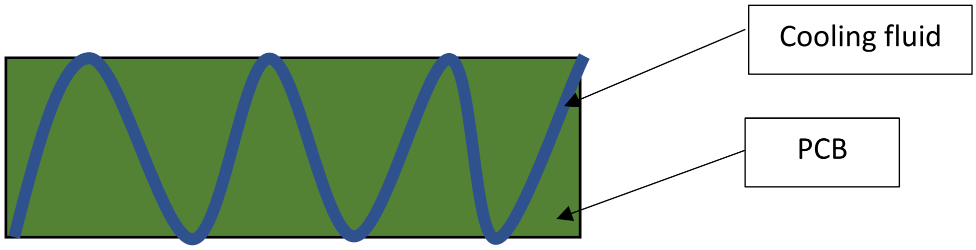
Cord on PCBs or flex support
A solution can be to have a cord on the PCB or the flex support, fastened with a screw close to the components that generates the most heat

The cord can be made from a metal that has high thermal conductivity and leads the heat out of the probe and into the power cord

Table 29: Active cooling over the PCBs

Active cooling
This solution is as mentioned already used on some probes with high heat generation

The blue lines indicate tubes that will go across the PCBs with a fluid with high thermal conductivity, carrying the heat out of the probe and into the cord

6.1.3 Ideas for leading the heat away from the patient

Table 30: Heatsink/backing

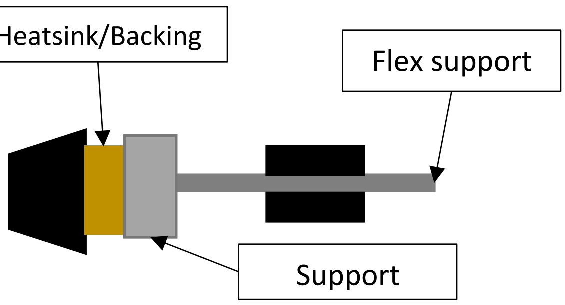
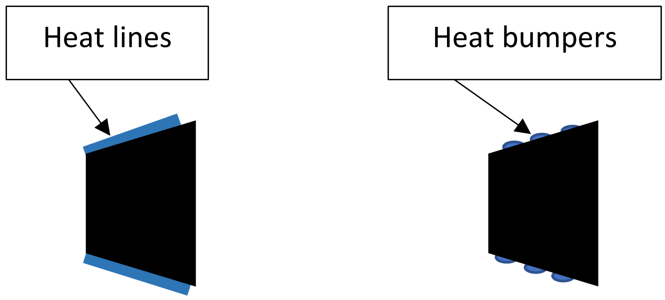
Heatsink/Backing
The traditional way for leading the heat away from the patient is using a heatsink

The heatsink will be fastened to the support, used for fastening the flex support. The heat would go through the heatsink and into the support and flex support

Table 31: Heat spreaders on nose-piece

Heat spreaders on the nose-piece
Adding lines on the nose-piece to increase the area and lead the heat away from the patient

The blue lines and dots indicates how material could be added to increase the surface are of the nose-piece

The heatsink/backing solution, is the easiest solution to go with, based on feedback from the supplier of the transducer, there will be low heat generation, and a backing is necessary for fastening support. Therefore, this solution will be the main solution for controlling the heat in the probe, and possibly combined with a solution for isolating the heat in the probe shell. Multiple solutions should be simulated to see the difference and impact on the heat control.

6.2 Ergonomic solutions

In chapter 5 already existing ergonomic solutions was analyzed. The "apple probe", door knob and electrical razor shape are the most common way to form the probes. But there are many other ways for good ergonomic grips. In this chapter new concepts for probe design based on previous solutions, but also an attempt to think outside the box and see if there could be any other solutions that could be good, breaking away from the traditional design.

Table 32: Pistol grip separating handle from transducer and cord

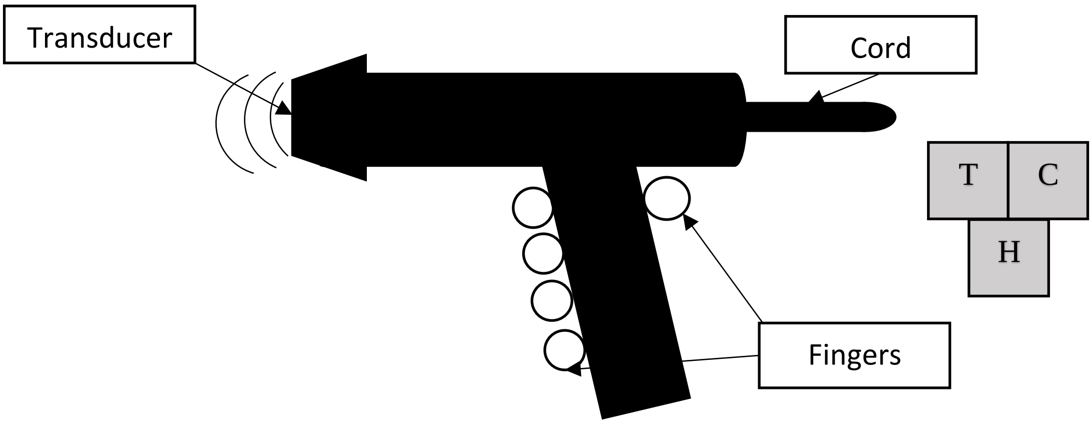
Pistol grip	
	
The operator holds the handle like a pistol while the probe is vertical along the hand, tilting the wrist up and down for adjusting the view	
Pros (+)	**Cons (-)**
The idea as a neutral grip, and traces can be added for increasing the surface friction	Fine adjustments of the transducer might be hard, awkwardly direction for left handed and sideways scanning

Table 33: Knob grip shaped as a cylinder

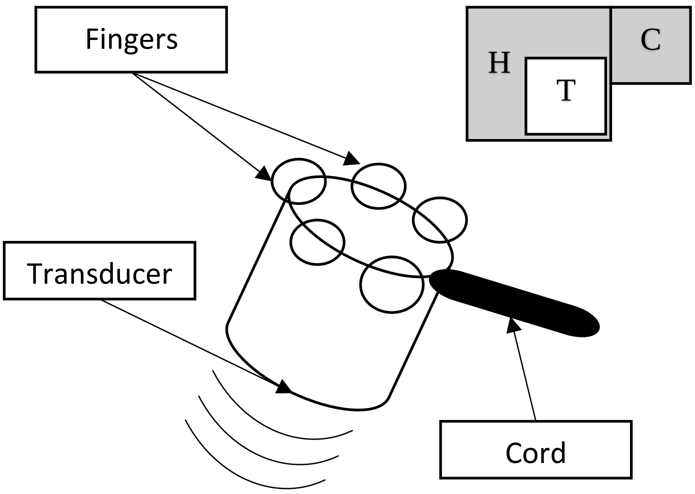
Knob grip


Table 33: Knob grip shaped as a cylinder continues

The operator grips the probe like a knob, adjusting the ultrasound beam using fingers and wrist. A palm support can be added to support the hand	
Pros (+)	**Cons (-)**
Palm grip	The size of the PCBs and electronics might make the probe longer and harder to hold

Table 34: Semicircle kettlebell grip

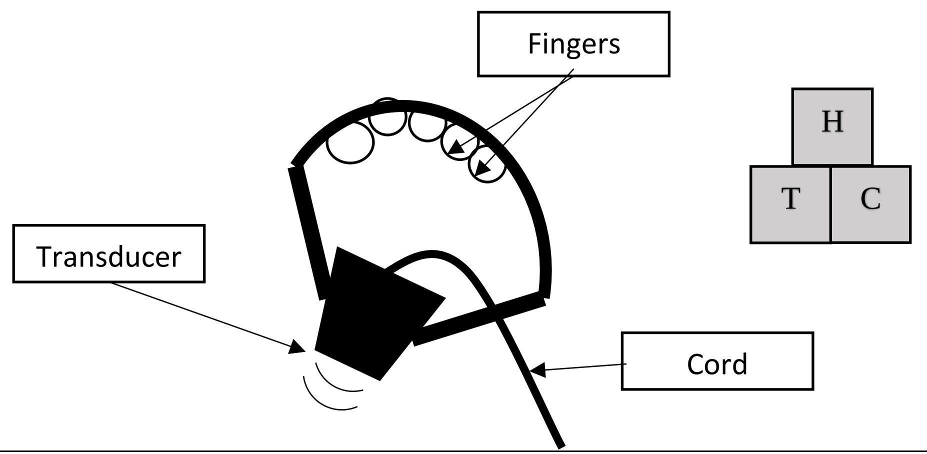
Kettlebell grip	
	
A wrist support can be added to on top of the arc. The transducer is adjusted with moving the wrist up and down	
Pros (+)	**Cons (-)**
Neutral grip	The fitting of the electronics might ruin the design, and the center of gravity might be off making the probe hard to control

Table 35: Syringe grip with palm rest

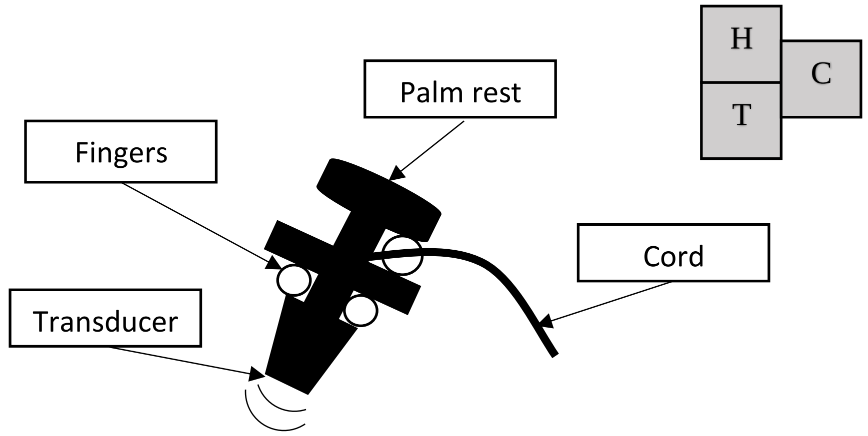
Syringe grip


Table 35: Syringe grip with palm rest continues

Holding the probe with the index, middle finger and thumb, resting surface for palm. Adjusting the probe with fingers and wrist	
Pros (+)	**Cons (-)**
Good finger grip, palm support	Fitting size of the PCBs will decide the diameter of the probe and might make the finger grip too wide

Table 36: Thumb locker on shell

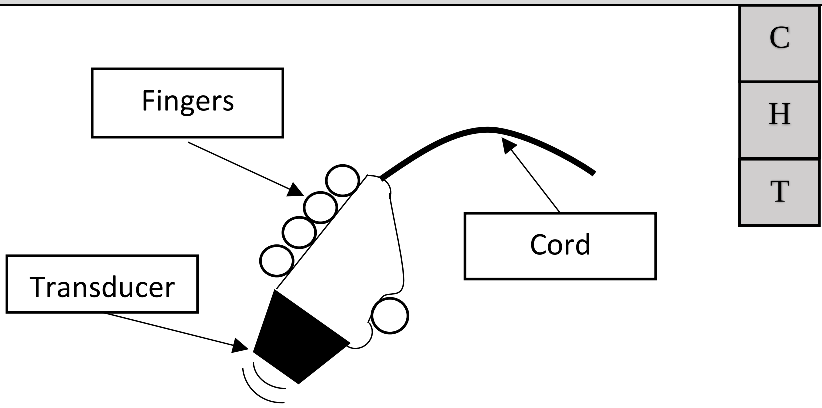
Thumb locker	
	
Holding the probe with all five fingers, locking position for thumb. Adjusting the probe with the wrist	
Pros (+)	**Cons (-)**
Palm grip, the size can adjust to fit the electronics	Fitting the cord might be difficult

Table 37: Wing on probe shell

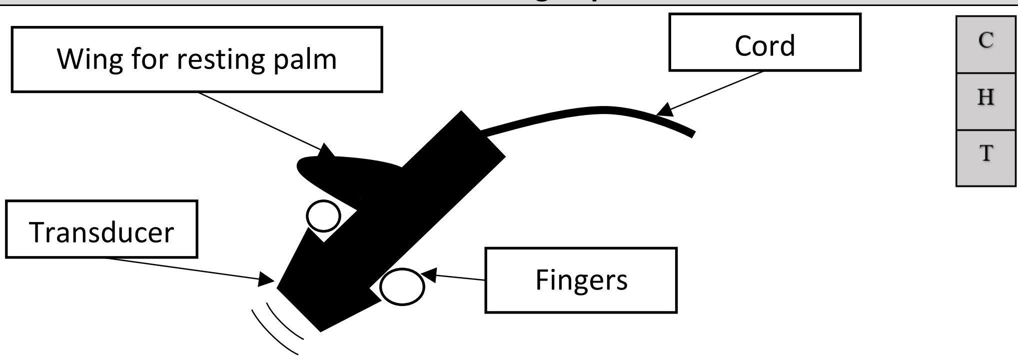
One-winged probe	
	
Build up as a traditional probe, but with a wing on one side for the operator to place the palm of their hand, giving extra support. The probe is adjusted with fingers and wrist	
Pros (+)	**Cons (-)**
Palm support	It might be hard to find a shape for the palm support that fits 95 percent of the population

Table 38: Thumb support on shell

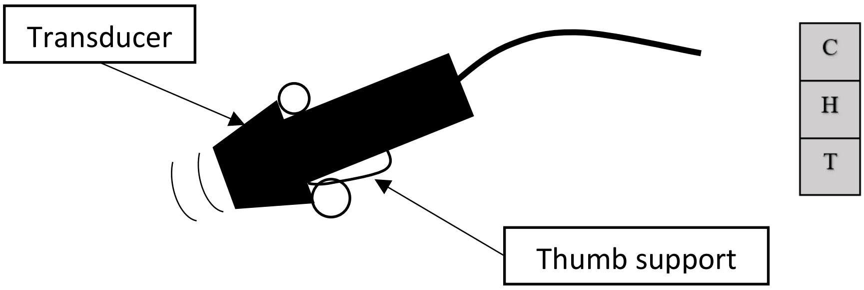
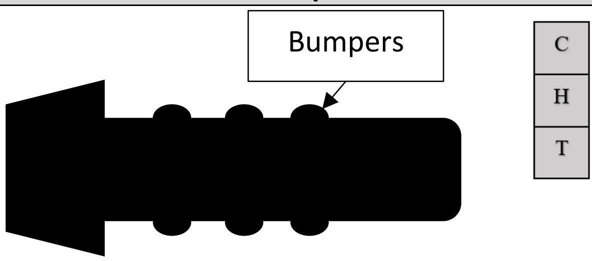
Thumb support	
	
Build up as a traditional but with a trace for supporting the thumb of the user. The support can be formed as groove or as a hole where the operator inserts thumb	
Pros (+)	**Cons (-)**
Support on the thumb might improve the finger grip	No palm grip or palm support

Table 39: Bumpers on the shell

Bumpers	
	
Traditional probe design but with bumpers to increase the friction of the surface	
Pros (+)	**Cons (-)**
Increases the friction on the surface of the probe, making it less slippery	The bumpers might be uncomfortable to hold with a firm grip over a longer period

Combine:

Table 40: Combining of parts

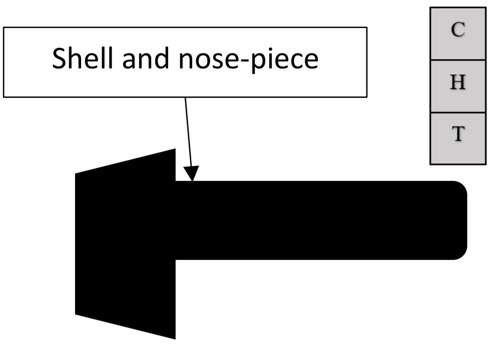
Combining of parts


Table 40: combining of parts continues

Combining one of the two body shells and the nose-piece	
Pros (+)	**Cons (-)**
Fewer parts to produce	Might be more difficult to assembly the shell with the electronics

Having a traditional design of the probe can be both a good and a bad thing. It depends on what the user is familiar with, but at the same time standing out can give a “market advantage” if the design is good. Therefore, in the screening at least one of each idea should be chosen.

6.3 Idea screening Ergonomics:

To find out which ideas to bring forward a simple idea screening has been done. The goal with this screening is to get an early selection of the ideas and find out which one to use for modeling and simulation to find different concepts. The evaluation of the ideas is done according to Pugh’s methodology see chapter 3 for description, using a +/- matrix where a + is positive weighted and – is negative and means potential hiccups in the design.

The following criteria will be used to evaluate the ideas:

- Fitting of electronic: How likely it is to fit all necessary electronics without severe geometry changes.
- Complexity: The complexity of the design, how “outside the box” is the new design.
- Own motivation: How motivated is the student to follow through with the design.
- Palm grip or apple grip: Is the new grip either a palm grip or an apple grip
- Realization of implementation: How realistic is it do implement the new design.

Table 41: Idea screening

Criteria	**Pistol grip**	**Knob grip**	**Kettlebell grip**	**Syringe grip**	**Thumb locker**	**one-winged probe:**
Fitting of electronics	+	-	-	-	+	+
Complexity	-	+	-	=	+	+
Own motivation	-	+	-	=	+	+
Palm or apple grip	=	+	=	+	+	-
Realization of implementation	-	-	-	=	=	+
SUM	-2	1	-4	0	4	3

Table 41: Idea screening continues

Criteria	**Thumb support**	**Bumpers**	**Combining the shells**
Fitting of electronics	+	+	-
Complexity	+	+	=
Own motivation	=	-	-
Palm or apple grip	-	-	-
Realization of implementation	+	+	-
SUM	2	1	-4

The thumb locker and the one-winged probe come best out of the idea screening. The one-winged probe can potentially also be combined with the thumb support. These two ideas differentiate that one is close to the traditional design and one is a new shape.

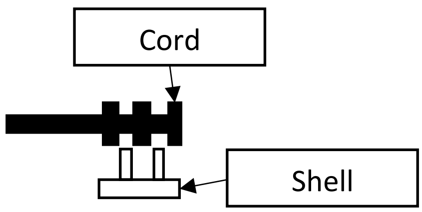
6.4 Mechanical solutions

The flexes will be fastened with eight screws. The large PCBs will be fastened in the flex support and the top two small PCBs with the transducer connectors will be fastened to the large boards. It's necessary to be find a solution for fastening the cable cord and fitting the shells together.

6.4.1 Fastening the cord

The cord of the probe needs to be attached to the shell. This is usually done with ribs as shown below.

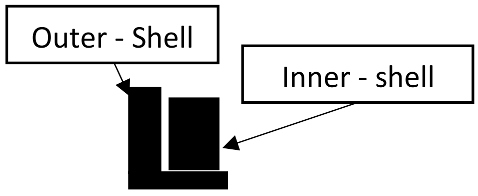
Table 42: Fastening of cord to the shell

Fastening of cord

The cord is normally fastened with ribs on both sides in the end of the plastic shell, and notches in the end of the cord. When locking the shell, the cord is held in place

6.4.2 Assembling shells

If the shell is made of two parts, they need to be fitted together. This is normally solved with using a lip and groove. Using this technique, the two shells overlap locking them together.

Table 43: Lip and grove for combining the shells

Lip and groove

The lip and groove technique can also be used for fastening the shell to the nose piece. This technique can be combined with glue to keep the shell from falling apart

With a direction for the design and solutions for combining the shell and nose-piece. The next step would be to start developing concepts and testing the ergonomics with 3D printing.

7. EARLY CONCEPT GENERATION

To find a desirable shape for the shell, based on the previous ideas. A concept generation will be conducted.

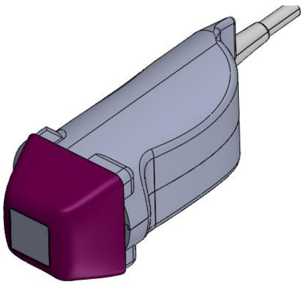
With the ideas for the shape of the probe in place, CAD models were generated. This gives a perspective of the design ideas and how they will fit with the electronics. 3D prints have also been generated to get a feeling of the shape of the probe shell designs. This early concept generation will be used to form the design for build of the final concepts. The concepts will be evaluated with a go/ no go screening to decide if the concept shall be further developed.

The development process will be done in iterations, screening the early concepts and analyze them to find out what to scrap and what to bring forward. In this part of the development the sonographers grip will be in the highest focus.

7.1 Shell concepts

Total of five different shell concepts were generated and tested, one traditional grip and four different palm grips. Detailed description of the concepts can be seen in appendix C. The traditional grip was modeled first to see the necessary outer dimensions of symmetric circular grip, and the potential of a wing on side of probe. This design was not good to maneuver or to hold and was therefore scrapped, and it was decided to design more in the direction of palm grip with thumb support. Different shapes and sizes of palm grip was tested and evaluated before a solution was selected. The selected solution was concept 5, a smaller palm grip with a radius for resting the palm at the end:

Table 44: Concept 5 from early concept generation

Concept 5	
Assembly	**3D Print**
	
Manuvering the probe	
	

Concept 5 still has potential for improvements, but an early user screening should be conducted to get insight from the test engineers/sonographers.

7.2 Early user screening

With the early concept in place, an early screening of the concept was done to get feedback from an inhouse test engineers/sonographers to get a direction for further development of the concept.

Table 45: Early user screening

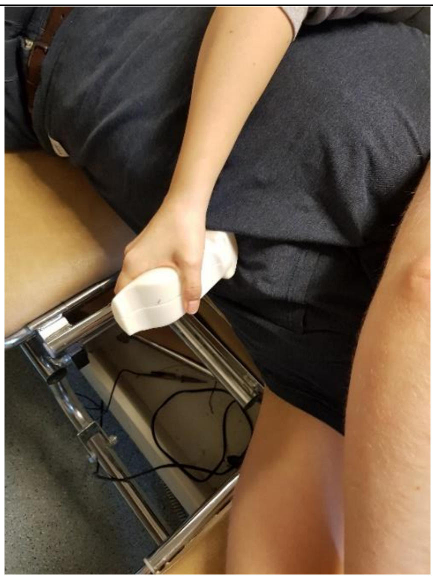
Grip test	
Finger grip	**Palm grip right hand**
	
Test with patient	
	
The palm grip makes it harder to make small adjustments to the probe	The wide diameter makes the probe tiresome to hold

Table 46: Screening table early user screening

Screening table	
Finger grip	The diameter at the transition between the nose piece and the shell is too big. The diameter needs to be reduced
Palm grip right hand	When holding the probe and leaning over the patient, the muscles in the wrist are tightened
Palm grip left hand	For left hand scanning the palm grip works

The feedback from the sonographers was that for left hand scanning the palm grip works, but for the righthand scan where the examiner is leaning over the patient the probe is tiresome to hold and the diameter in the transition between the nose piece and the shell should be reduced so it’s possible to use finger grip. Based on this feedback the design of the shell will be developed to make it better for right hand users, but simultaneous trying to keep the shape making it good for left hand users.

8. FURTHER CONCEPT DEVELOPMENT

To further develop the concept decided in chapter 7, new concepts had to be developed based on the screening and feedback from the sonographers.

Based on the feedback from the Sonographers on the concept, the design was further developed. The palm grip was brought on so that the probe will still be good to use for left-hand users, but the diameter for the finger grip was reduced. Two new concepts were developed, with a smaller nose piece and a “slimmer” design

Table 47: Concept 7

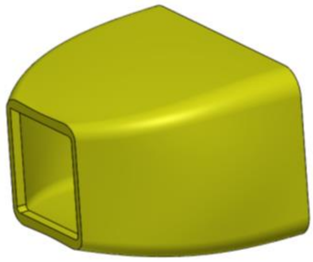
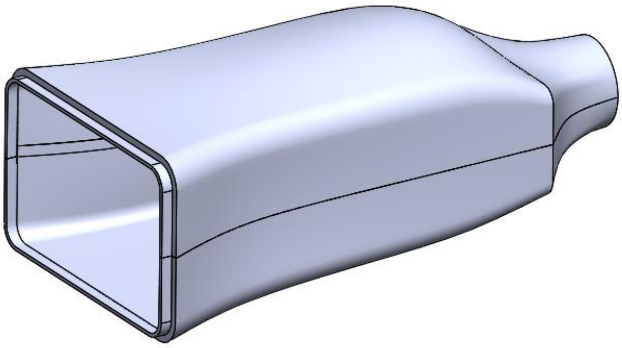
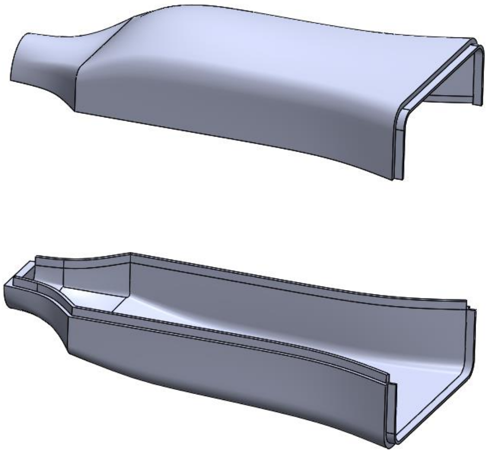
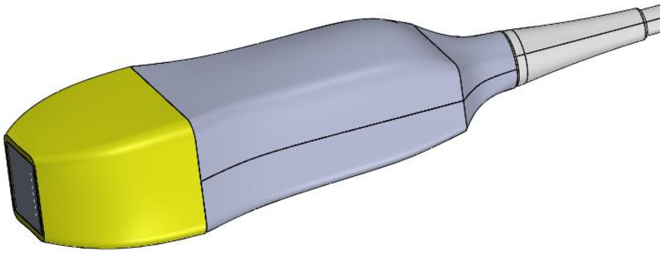
Concept 7	
Description	**Visualization and dimensions**
The nose-piece was made longer to cover move of the electronics and making it possible for a smaller cross-section after the transition between the nose-piece and shell	
Length	42 mm
Cross section at intersection	34x52 mm
The palm support for lefthanded scanning was kept	

Table 47: Concept 7 continues

Description	Visualization and dimensions
A curved of ending with space of placing the cord	
Assembly of the probe	
Shell thickness	2 mm
Shell length	100 mm
Total length	142 mm
Wide at nose piece	52 mm
Diameter at finger grip	34 mm

To get a better feeling of the dimensions and design of the shell. The three parts was 3D printed

Table 48: Concept 7 3D print

3D print	
Top view	**Bottom view**
	

Table 48: Concept 7 3D print continues

Front view


Table 49: Concept 8

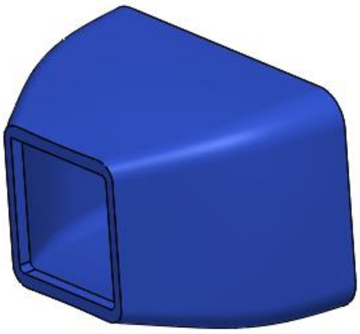
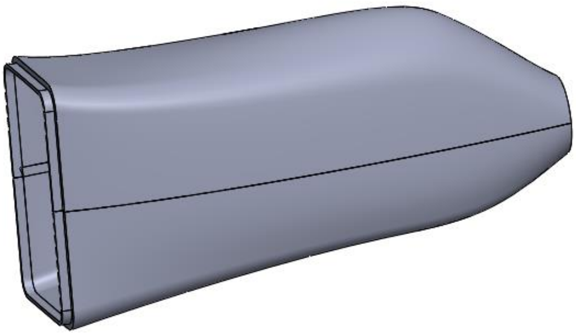
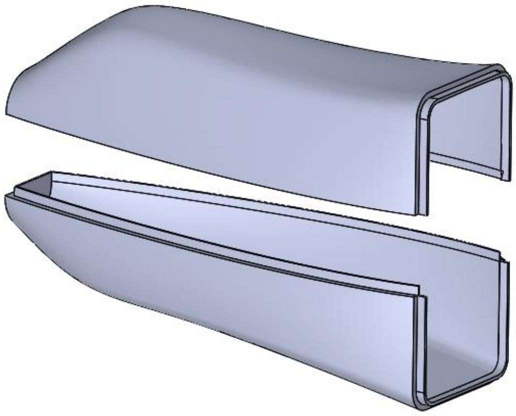
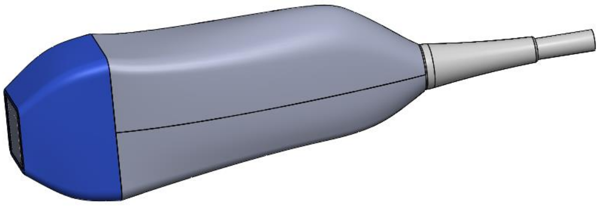
Concept 8	
Description	**Visualization and dimensions**
The nose piece was shortened by 10 mm	
Length	32 mm
Cross section at intersection	34x52 mm
The shell was made longer making the palm support 10 mm further back on the probe	

Table 49: Concept 8 continues

Description	Visualization and dimensions
The palm support was also rotated 90 degrees giving the design another geometry	
Assembly of the probe	
Shell thickness	2 mm
Shell length	110 mm
Total length	142 mm
Wide at nose piece	52 mm
Diameter at finger grip	34 mm

Concept 8 was also 3D printed to be able to test the ergonomics and get a feeling of the shell.

Table 50: Concept 8 3D-print

3D print	
Top view	**Bottom view**
	

Table 50: Concept 8 3D-print continues

Front view


The nose-piece from concept 8 can also be used on concept 7 with some length adjustments. Both Concept 7 and 8 have a lot of potential. It was therefor decided to bring both concepts forward to a user screening with the sonographers to get a final opinion from them for finalizing the ergonomic design.

9. CONCEPT EVALUATION

The two different concepts show earlier have different geometry. To find out which direction to go further with different screening and testing needs to be done.

9.1 Evaluation methods

To decide which concept to go forward with several steps will be done to evaluate the concepts. For evaluating the mechanics and the thermal properties of the shell's simulations in ANSYS Workbench will be done. For evaluating the ergonomics, the shells would be compared against measurements from Dreyfuss's book. The results from the different evaluations will be weighed against each other. The results will also be used for shaping the final concept.

9.2 Thermal comparison

Two different thermal simulation was done on both shells, one with free convection to air on all external surfaces and one with conduction to patient on the lens. Both tests were done with the same boundary conditions and two different heat sources, one on the PCBs inside the probe and one in the transducer. A backing leads the heat away from the patient and towards the support and flex support.

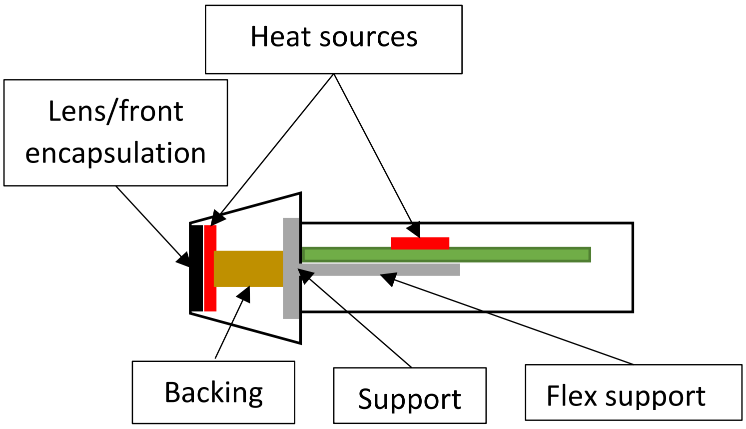


Figure 31: Thermal analysis structure

None of the shells exceeds the maximum temperature against the operator of 43 °C, shell 7 has the lowest temperature against the operator. Both shells have the same temperature against the patient, but the temperature does not overcome 41 °C. The full thermal comparison can be seen in appendix D.

Table 51: results thermal analysis

Concept	Lens temperature free convection to air on all external surfaces (°C)	Lens temperature conduction to patient on the lens (°C)	Shell temperature (°C)
Concept 8	52,2	40,6	34
Concept 7	52,2	40,6	23,1

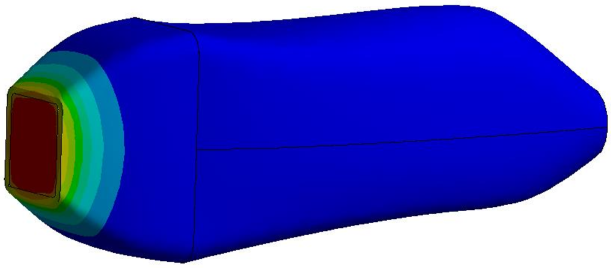


Figure 32: Illustration of thermal analysis

9.3 Mechanical compression

Both the shells were simulated with applied load according to Dreyfuss's book:

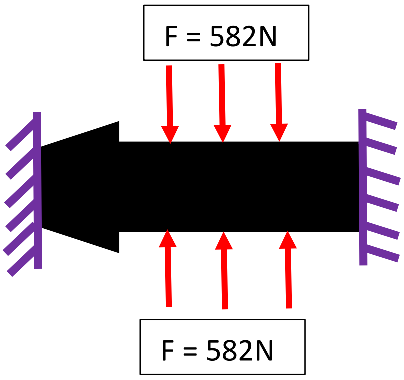


Figure 33: Test setup crush test

Both the probes withstand the applied load. Shell 7 has more deformation and a higher stress, due to the larger area were the load is applied. For the final concept ribs should also be applied, to decrease the deformation and strengthen the shell. But for this test shell 8 would be the best choice. The full mechanical comparison can be seen in appendix E.

Table 52: Results crush test

Concept	Maximum deformation (mm)	Maximum Von mises stress (MPa)
Concept 8	0,331	8,16
Concept 7	0,535	12,7

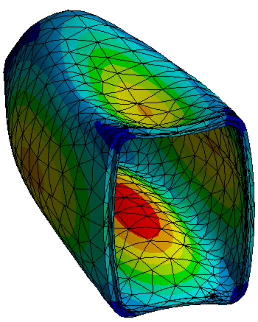


Figure 33: Illustration of deformation in crush test

9.4 Selection matrix

The different aspects will be evaluated, with different weighting. The following criteria's will be considered when evaluating the concepts:

- **Thermal:** The thermal testing will give an indicator of how the heat will spread in probe. Counts 35%
- **Mechanical:** The mechanical simulation will give an indicator of how the geometry of the shells will withstand the applied crush force. Counts 25%
- **Ergonomics:** Ergonomic aspects such as minimum grip diameter and length of the probe and nose-piece. Counts 40%

The concept that has the best result in the criteria would get score 2 while the other will get score 1, this will give an indicator of which shell that would be the best to proceed with

Table 53: Selection matrix

Selection Matrix					
Criteria	**Weighting**	**Shell 8**		**Shell 7**	
Thermal	35%	1	0,35	2	0,7
Mechanical	25%	2	0,5	1	0,25
Ergonomics	40%	1	0,4	2	0,8
Sum	100%	1,25		1,75	

Both concepts have potential, but concept 7 scores higher in the selection Matrix. Ergonomics variates very from person to person. To get more input on the ergonomics of the potential designs a user screening should be conducted. The feedback from the user screening regarding the designs showed will be used to generate a final concept.

10. USER SCREENING

To see if the two concepts will meet the requirements for the ergonomics goals, the requests from the workout, guidance for the transducer design and fits well for different hand sizes.

10.1 Objectives for screening

The main objectives for the user screening are to find out if the shape of the shells and the nose-piece are comfortable for the operator to hold. The two different probes will be used to find out which one is more comfortable and what possible changes can be done to make the probes even more comfortable. The screening will give an indicator on the ergonomic fitting and if the designs are good enough to bring back to the company as recommendations for further development. The following points will be used as a guideline for the screening:

1. Which probe is best for left hand scanning
2. Which probe is best for right hand scanning

10.2 Screening sequence

Hence the technology is moving forward this screening will be emphasizing the ergonomics over the mechanics and thermal solutions. The screening will only be focusing on the grip of the operator. To have a good screening process and get good feedback it's important that the questions asked is good and not leading. Besides which probe is best for right or left hand scanning it's also important with the following points:

- Use: How is the probe to operate?
- Feel good factor: How does the probe fit in the hand of the operator?
- Design: Is the probe good to look at?
- First impression: First impression of the design?
- Finger grip: How does it feel to hold the probe with finger grip?
- Palm grip: How does it feel to hold the probe with palm grip?

The points above will be rated on a scale from 1-6 to get an indication from the screening personnel and to weigh the concepts against each other.

10.3 Test population

For the test the two test engineers/sonographers used earlier from the workout with the 4Vc probe will be used. To get a wider span of test population three other employees at GE Vingmed Ultrasound will also be asked to participate in the test. This is due the wide span of hand sizes and to get feedback from people that are not too familiar with operating an ultrasound probe. The sonographer's feedback will be more weighted on the use of the probe, but the three other employees opinion should be weighted equal on the other factors.

10.4 Screening setup

The probes will be given new names, for the screening and further in the report they will be referred to as A and B

Table 54: View of Probe A and B

Probe A	**Probe B**
	

To be able to separate the test personnel, the outer dimensions of their palm sizes and length of index finger and thumb will be measured. From earlier it's decided that the shell should be designed for a large woman, so that it also should fit for a small man.

Table 55: Hand dimensions of a large woman

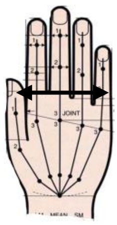
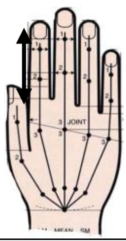
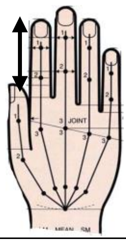
Palm width	**Thumb length**	**Index finger length**
		
84 mm	64 mm	81 mm

Table 56: Screening form

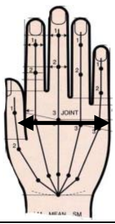
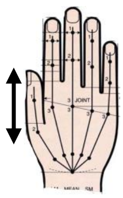
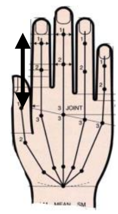
Screening form	
Test personnel	
Palm width	
Thumb length	

Table 56: Screening form continues

Index finger length		
The shells:		
First impression of the design?	Rate 1-6	
	Shell A	
	Shell B	
How does the probe fit in the hand of the operator?	Shell A	
	Shell B	
Is the probe good to look at?	Shell A	
	Shell B	
How is the probe to operate?	Shell A	
	Shell B	
How does it feel to hold the probe with finger grip?	Shell A	
	Shell B	
How does it feel to hold the probe with palm grip?	Shell A	
	Shell B	
Comments on Shell A		
Comments on shell B		

10.5 Screening results

The completed forms can be seen inn appendix F, below is a summary of the results from the screening.

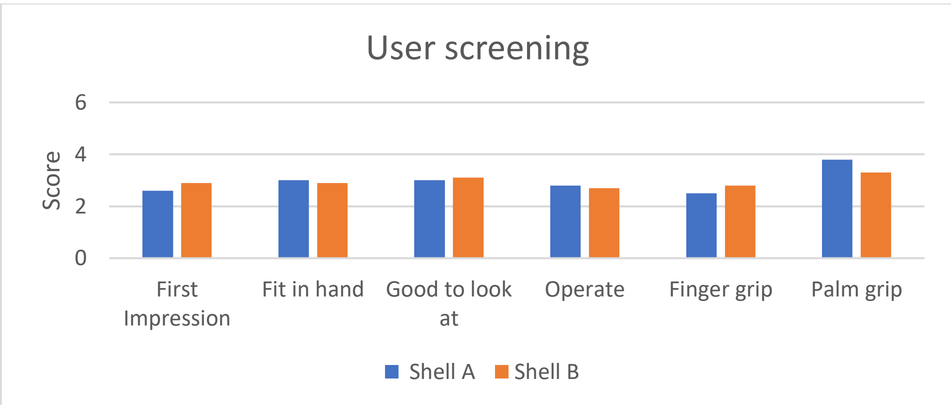


Figure 34: User screening results

Both the shells scores around an average of 3 in the user screening, which means that there is a lot of improvement potential for both concepts. Shell A scores higher on Palm grip, fit in hand and operate, while shell B scores best on first impression, good to look at and finger grip. The table below shows the feedback from the user screening and a estimate of their hand sizes compered to measures from chapter 4.7.

Table 57: Feedback from user screening

Comments	
Test person A: Ultrasound Test engineer (Woman)	
Hand size	Palm width: M Thumb Length: M Index Finger: S
Comments Shell A	A bit edged, would be easier to maneuver a more curved off shell
Comments Shell B	Smaller probe than A, easier to hold with finger grip, the palm grip depends on where the indicator would be placed A bit edged, fits best with the nose-piece used on probe A, should be something to increase the grip on the nose-piece
Preferred Shell	B with nose piece from A
Test person B: System test Engineer (Woman)	
Hand Size	Palm width: M Thumb Length: S Index Finger: M
Comments Shell A	Entire length of the probe is slightly long, especially tail edge, the probe is slightly covering my palm, prefer more waist, to ease the gripping, especially when rotating to get views
Comments Shell B	With the nose-piece from shell A the proportion of more balance, better grip because of the waist and with is slightly reduced, making it more comfortable on smaller palms, would be great if it can couple with good gripping materials outside, reduce the radius of the nose-piece, this should be more a line, more angular
Preferred Shell	B with nose piece from A
Test person C: Global Product Manager (Man)	
Hand Size	Palm width: M Thumb Length: M Index Finger: S
Comments Shell A	The probe is too big
Comments Shell B	Too edgy, too sharp at the end towards the cord
Preferred Shell	A
Test person D: Global Clinical Research Manager (Man)	
Hand Size	Palm width: L Thumb Length: M Index Finger: M

Table 57: Feedback from user screening continues

Comments Shell A	First impression: Too big, missing orientation line, which must be long enough, too sharp edges on foot print
Comments Shell B	First impression: Too big, rounder edges in grip, not a logical grip (twisted), too wide after footprint, too sharp edges on footprint
Preferred Shell	A
Test person E: Global Clinical trainer/educator	
Hand Size	Not available
Comments Shell A	Too big, hard to rotate
Comments Shell B	Too big, too edgy both shells are too large, the size needs to be severely reduced to be usable
Preferred shell	B with nose piece from A

Shell A was preferred by the men in the screening group. This might be due to their hand sizes being bigger and making the shell fit better into their hands. But the feedback from the user screening was quite similar from the test group. The sizes of both designs are too big, and the size needs to be reduced. This would require changes in the electronics which is out of the scope of this thesis. It's therefore decided to proceed with a combination of a rounder shell B with the nose-piece from shell A.

11. THERMAL INVESTEGATION AND SOLUTIONS

Based on the ideas from chapter 6 for potential thermal solutions simulations needs to be done to find a suitable solution for our case. ANSYS workbench will be used to simulate how the heat will move through the probe.

11.1 Thermal investigation testing

Three of the different thermal concepts from chapter 6 was tested to see how it would help reduce the temperature facing the patient and the operator

- Isolating with air
- Heat cord
- Heat spreaders on nose-piece

The heat cord and head spreaders test were set up with the same boundary conditions as the testing done in chapter 9.3 thermal comparison and tested on shell A. For the isolating with air test a simplification was done due to the complexity of the geometry and the time consume it would take to model the shell hollow.

11.2 Thermal investigation results:

The full test can be seen inn appendix G, below is a short summary of the results.

Table 58: Thermal investigation results

Solution	**Impact on Shell temperature (°C)**	**Impact on lens temperature Free convection (°C)**	**Impact on lens temperature conduction to patent (°C)**
Isolating with air	-0,3	-	-
Heat cord	-0,3	-0,6	-0,2
Heat spreaders	+0,4	-3,3	-0,5
SUM	-0,2	-3,9	-0,7

Isolating with air and the heat cord would reduce the temperature of the shell, but the heat spreaders would increase this temperature. This could be because more heat would be forced over the shell. But the heat spreaders would have the largest impact on reducing the temperature against the patient, and the new temperature would still be within the requirements. All three solutions should be kept in mind for the final concept.

12. CONCEPT REALIZATION

With the concept evaluation in mind and the feedback from the user screening a concept realization could be made.

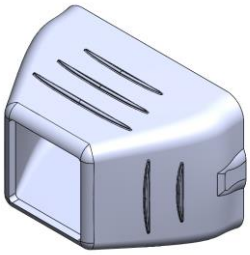
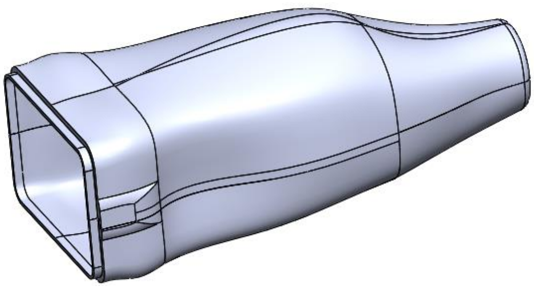
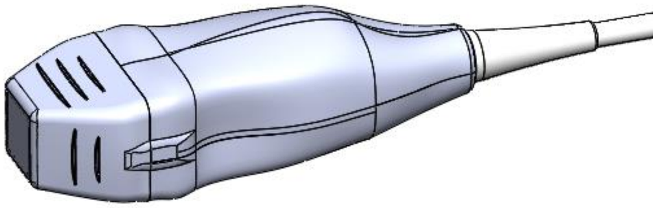
12.1 Change of the model

With concept B coming best out of the user screening and concept evaluation the following points needs to be considered when designing the final concept.

- The edges need to be rounded off
- There should be something to increase the grip on the nose-piece
- An indicator needs to be placed
- The end of the probe is to sharp
- The radius of the nose piece should be reduced
- To sharp edges on the foot print of nose-piece

12.2 New shell

Table 59: New shell concept

Description	Visualization
The edges against the patient has been rounded of, cross lines have been added to increase the grip and to lead the heat away from the patient. An indicator for probe orientation has been added	
The edges have been rounded off, the indicator for probe orientation continues on the shell, the end of the shell towards the cord have been given a smoother transition	
Assembly of the probe	

12.3 Thermal and mechanical testing final concept

Too test the mechanical and thermal properties of the new design, a thermal and a mechanical simulation was performed with the same boundary conditions as previous tests, described inn appendices E and D.

12.3.1 Thermal results final concept

The test was simulated with two different scenarios; free convection on all surfaces and free convection on handle and conduction to patient on lens. From the thermal testing it was proven that the heat spreaders on the nose-piece would give the most effect for reducing the heat against the patient, this solution was brought on to the final concept.

Table 60: Results thermal analysis new shell

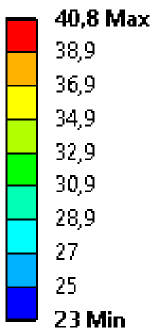
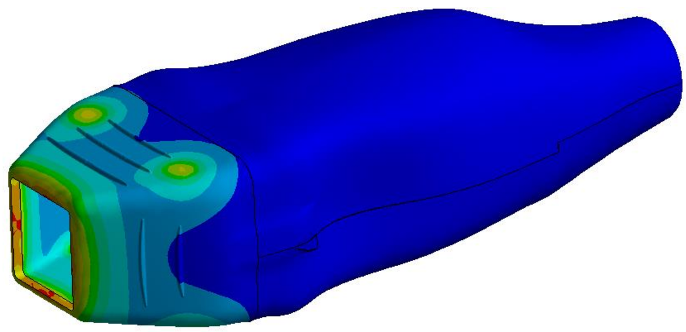
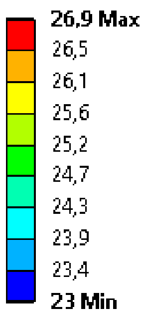
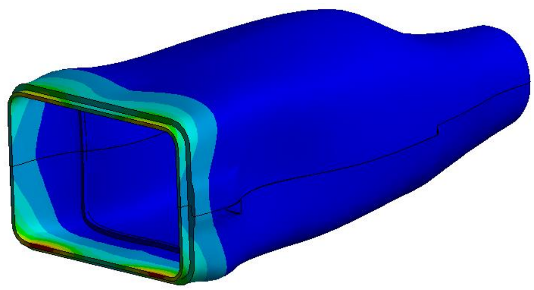
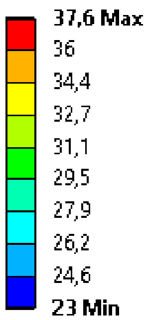
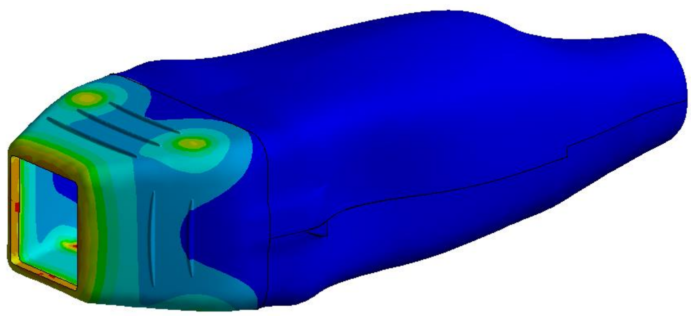
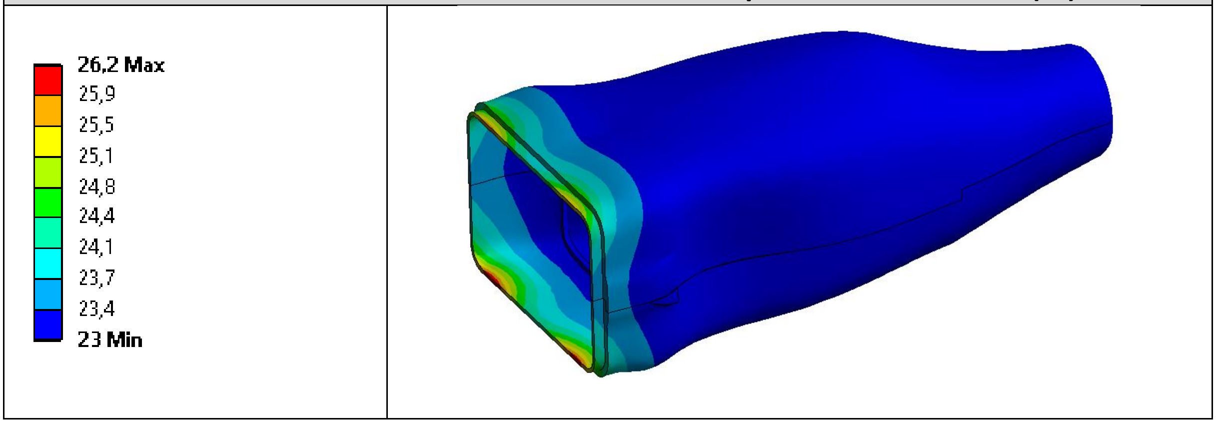
Free convection on all external surfaces: shell and nose-piece (°C)	
	
Free convection on all external surfaces: shell (°C)	
	
Free convection on handle and conduction to patient on lens: shell and nose-piece (°C)	
	

Table 60: Results thermal analysis new shell continues

Free convection on handle and conduction to patient on lens: shell (°C)



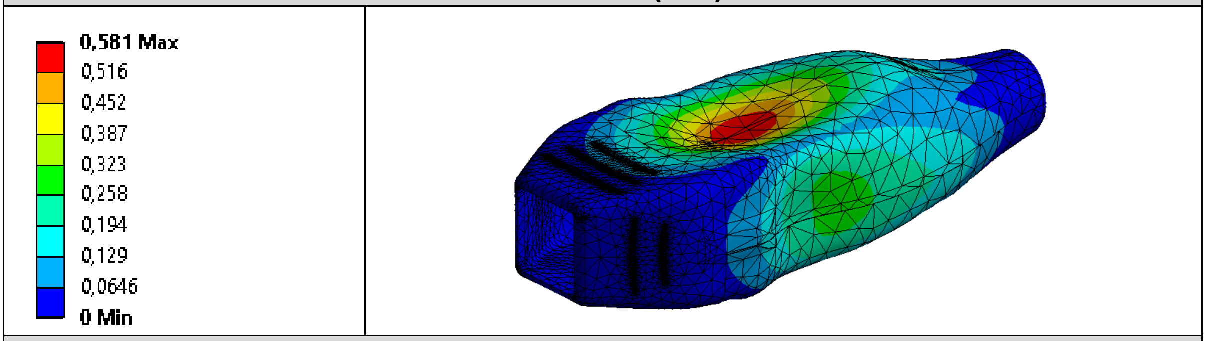
The thermal results for the new shell and nose-piece is better compered too the two original concepts. The maximum temperature is within the limitation of 41 °C against the patient. With the right combination materials for example adding metal filaments too the backing, the temperature might even be reduced more.

12.3.2 Mechanical test result final concept

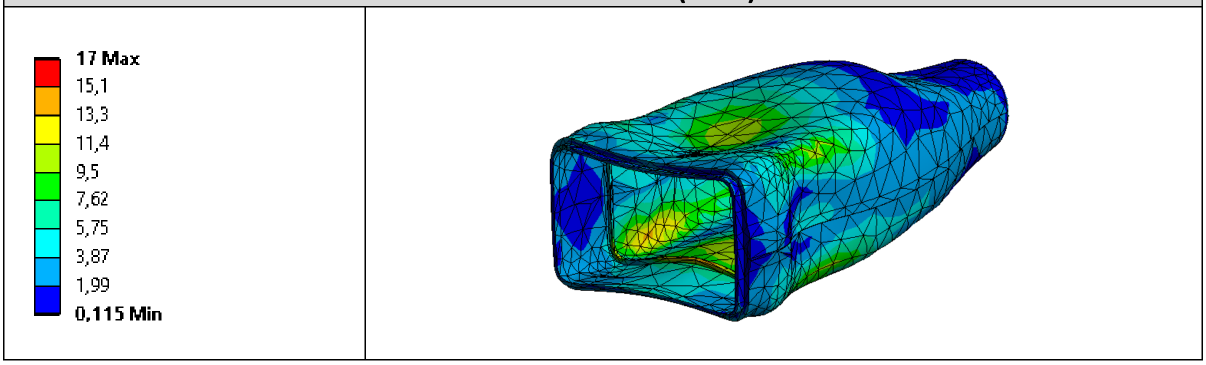
Too see how the new shell would withstand the applied load, a static analysis with the same boundary conditions as for the mechanical compression was set up.

Table 61: Deformation and von mises stress on new shell

Deformation(mm)



Von mises stress (MPa)



The stress on the new shell is higher than on the two original concepts. The highest stress on the shell seems to be a singularity, but overall the stress is higher. The applied stress is still within an acceptable range. The deformation is lower than on concept 7 and should not cause any issues.

13. MATERIALS,PRODUCTION AND COST

To find a suitable material for the prototype and potential materials for production.

13.1 Material restrictions

There are a lot of restrictions when it comes to plastic materials used for medical devices. The probe will be held by operators daily and the material can't be in risk of potentially causes skin irritation or allergic reactions. In GE the risk around materials is set to be as low reasonably achievable (ALARA). Materials used for both patient and operator contact needs the be according to ISO 10993, which is a series of standards covering biocompatibility and safe use of materials in medical devices.

Category 1 material: Intended to be touched by hands (bare or gloved) for more than 1 minute continuously, and cumulatively during the day. Category 1 material are subject to MSDS (Material safety data sheet) data search. The probe shell will be a category 1 material according to GE's standards. Category 1 materials also requires a risk assessment per ISO 14971-1: 2012 Medical devices – Risk management – Part 1: Application of risk analysis.

GE does already have different plastic that they already use that are within the requirements of ISO 10993 with risk analysis according to ISO 14971 that are used for probe shells today. These polymers are different from the ones that are used by the 3D printer and the material suppliers for the polymers for the 3D printer have lesser information about bio combability in their MSDS. Hence this shell is for a prototype probe and will not be used for production initially. There will not be done a thoroughly analysis of the material nor any testing. The choice of material will be based on the given information, but the mechanical properties of the material will be put at a higher focus.

13.2 Choosing production method for prototype shell

At GE Vingmed Ultrasound there are two available printers that can be used for production of the probe, Ultimaker S5 and Formlabs Form 2. Formlabs Form 2 is a stereolithography (SLA) printer, that uses a laser to form solid parts from liquid photopolymer resin. The SLA technology gives high accuracy of the print and can form detailed shapes with small sizes. The Ultimaker S5 uses a technology called fused filament fabrication and is working with laying layers of filament of plastic on a heated glass plate. The printer has two nozzles which allows it to apply to materials at the same time. Due to the potential of detailed shapes it was decided to use the Formlabs 2 printer.

13.3 Potential materials

There are a lot of different components in the probe with different materials and different tasks. Some of the materials are already pre-decided for PCBs and electronics but for the shell the material needs to be decided.

13.3.1 Material Shell and nose piece

It's already been decided to use the Formlabs 2 printer for printing the shell and the nose piece. Formlabs delivers a wide range of different materials that can be used with their printers. The table below shows some of their materials with desired material properties.

Table 62: Material properties

Properties	Black/White [32]	Durable [32]	Tough [32]	Gray [32]
Density	0,993	-	-	-
Ultimate tensile strength (MPa)	65	31,8MPa	55,7	61
Tensile modulus (GPa)	2,8	1,26	2,7	2,6
Heat deflection °temperature*(°C)	58,4	43,3	45,9	62,4
Thermal conductivity**(W/m-k)	0,283	0,283	0,283	0,283
*Tested according to ASTM D 648-07 at 1,8 MPa post cured. **The thermal conductivity from MDS was limited from Formlabs, the data was obtained from contacting Formlabs support central.				

For the prototype for the shell it was decided to use Formlabs Black/white, due to the higher heat deflection temperature and UTS.

13.3.2 Other materials

The probe consists of many other parts besides the shell and the nose-piece. The list below contains material listing for the other components in the probe.

Table 63: Material selection other parts

Component	Material
Flex Support	6061-T6 aluminum alloy
PCBs	FR-4
Support	6061-T6 aluminum alloy
Backing	Filled Epoxy
Lens/front encapsulation	RTV Silicone

The materials above would be used for thermal simulations.

13.4 Injection molding

The finished concept design does not differ too much from traditional probe design. If the concept ends up in series production, injection molding might be the most suitable production method. By using this production method materials that has already been tested and approved according the material restrictions discussed in chapter 13.1 could be used.

13.5 Cost estimate

Table 64: Cost estimate

	Hours/quantity	Price (NOK)	Sum (NOK)
Project planning	70	500	35 000
Market studies	50	500	25 000
Concept development	150	500	75 000
3D modeling	120	500	60 000
Analysis	100	500	50 000
Project report	80	500	40 000
Sum concept development:	570		285 000
Other costs			
Material 3D printing	1	2000	2000
Total sum			287 000

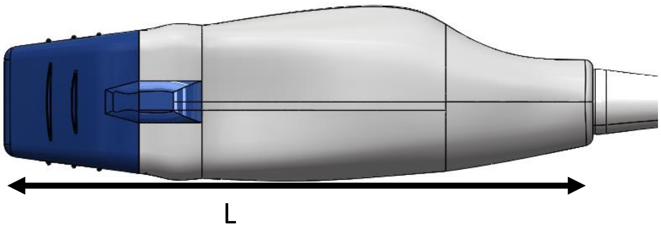
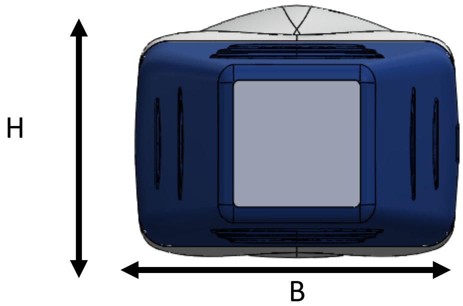
The total development price of the new shell, this is without the price of the 3D printer and potential tooling costs if the shell is put into production is 287, 000 NOK,

14. MARKET PRESENTATION

To show the final presentation of the concept, renderings and a final 3D printed model should be made.

14.1 Final concept dimensions

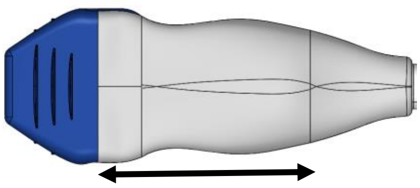
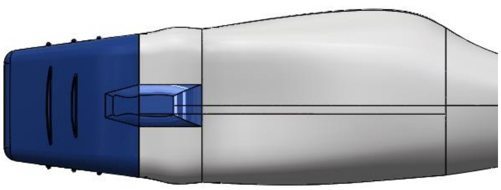
Table 65: Final concept dimensions

Description	Visualization and dimensions
New shell assembly seen from side	
New shell assembly seen from front	
Width	53 mm
Hight	42 mm
length	140 mm

The colors chosen for the shell and nose-piece are blue and white, reusing the colors from the GE logo.

Anthropometrics:

Table 66: Final concept anthropometry

Description	Visualization and dimensions
The length of the side of the probe is made to fit the length of the thumb of a medium to large woman and a medium man	
A palm support is added at the same length to fit into the hand of the user	

14.2 Renderings and model

Table 67: Renderings

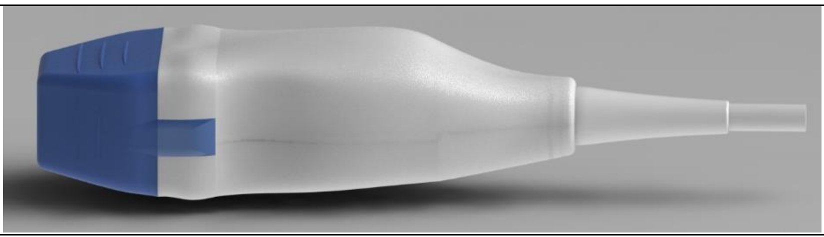
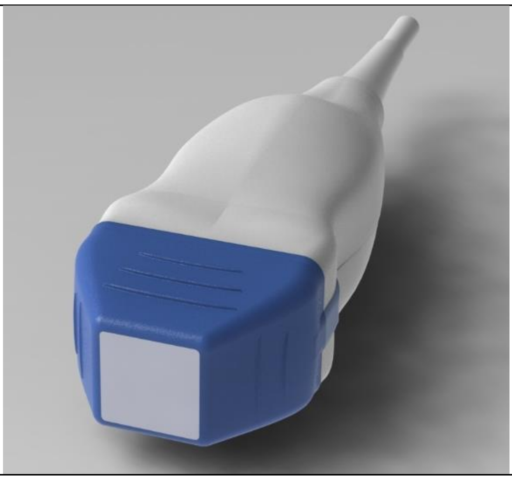
Renderings of CAD model
Probe side view

Probe front view


Table 68: 3D printed model

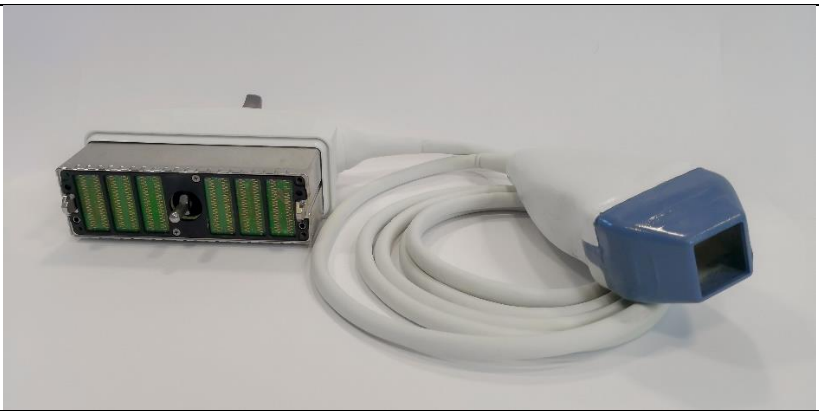
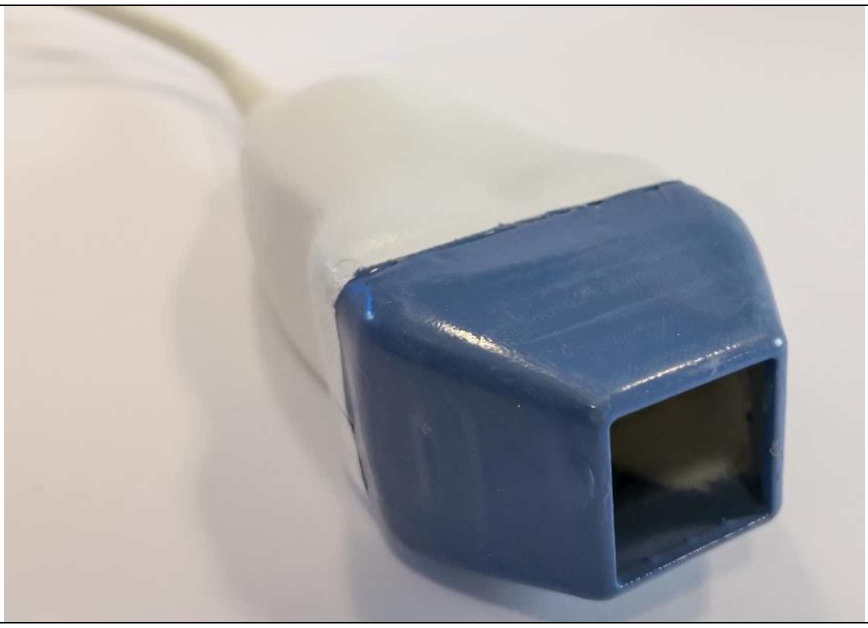
3D printed and painted model
Probe with cord and connector


Table 68: 3D printed model continues

Probe front view

Probe right side view

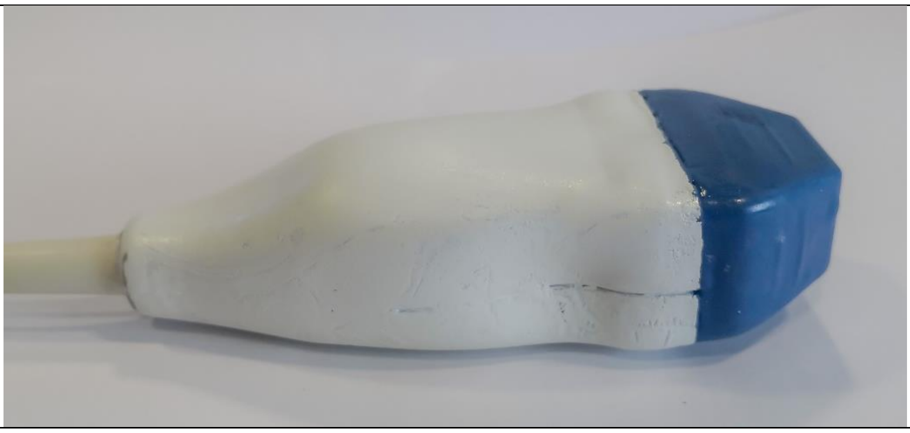
Probe left side view


Table 68: 3D printed model continues

Finger grip	
	
Palm grip	
	

Figure 35: Probe placed on system

Figure 36: Probe placed on system

15. PROCESS EVALUATION AND DISCUSSION

In this chapter the development and learning process will be analyzed and a summary of technological bottlenecks.

15.1 Potential improvements

The project has been a process for learning and competence building, of planning and executing a project, and theory of ultrasound, thermodynamics and ergonomics. Based on these experiences, potentials of improvements are listed pointwise below:

- The feedback on the early concepts from the sonographers could have been on an earlier stage.
- Too much time was spent in the early concept development. This part could have been shorter

The early concept development was too thoroughly and too much time was spent to develop different probe shells. The concept generated was made regards to palm grip for left- and right-hand scan, but after feedback from the first screening the design had to be changed into a smaller finger grip. But the large size of the electronics made it challenging to find a solution with good finger grip.

More time should have been used on finding different thermal and mechanical solutions and testing them with simulations.

- Thermal solution with honeycomb structure
- More data on the electronics and thermal properties

The thermal studies of a probe are a complex future, there are many parts that needs to be considered. The thermal studies done in this thesis are a simplification but gives an indicator of how the heat will spread through the probe. The data for the electronics used in the analysis were the available data at this point.

Through the project it has been focused that 3D printing should be used as a production method for the shell. Hence the materials found for the shell are the once available for the printers at GE Vingmed Ultrasound. With the given geometry of the final concept, injection molding would not be impossible. Hence materials for injection molding should have been looked at and used for simulations.

- Mechanical simulation with honeycomb structure
- A mechanical simulation to simulate drop test

The scope of the project touches many different focus areas, with thermal, mechanical and ergonomics. It has been difficult to pay equal attention to all focus areas, and in hindsight it shows that too much time was spent on ergonomics and grip design instead of focusing on thermal and mechanical solutions. For further work the production method and thermal solution should be taken more into account.

15.2 Design revision, production and cost reduction

The shell is produced to be used on a prototype for next generation ultrasound probes, so cost have not been a large topic in this thesis. If a cost reduction is desirable the following points can be looked at:

- Optimization of the geometry to reduce the material used
- Take a cost breakdown to see if injection molding would be more appropriate
- If 3D print is used as production method various printers should be considered
- See if there are changes that can be done to the electronics to optimize the ergonomic design.

16. CONCLUSION

The concept developed through the project is a new shell for next generation ultrasound probe. The final concept has been reached used different methods, such as SCAMPER, modularity and user screening. Through the project different solutions of ergonomic grips have been tested, analyzed and weighted up against each other.

The new shell is ready to be delivered to GE Vingmed Ultrasound to be paired with the electronics to continue with the development process. The shell is a combination of the best solutions for thermal, ergonomic and mechanical solution based on the given information for the electronics. FEM and thermal analyzes has been used for concept evaluation and confirm that the new shell would meet the requirements set.

The results from the user screening was that the size of the shell was too large. For the probe to be attractive on the market the size needs to be reduce considerably. This is out of scope for this project but should be taken into consideration for further development

16.1 Results and recommendations:

The new shell designed have potential for production and to be used to with the electronics design.

- The new design has the same interface as existing probes
- The shell can fit all necessary electronics
- The maximum temperature towards the patient 37,6 °C
- The maximum temperature towards the operator 26,9 °C
- The new shell will withstand the applied loads of 59,3 kg
- The weight of the new shell is approximately 37 grams
- The shell is designed as good as possible for large woman and small man hand size

Further Recommendations:

- The new design has an ergonomic grip but could be further improved
- The new design fits all specified electronics, but changes could be made
- The temperature of the shell is within the limits specified by standards

16.2 Further work

For further work the following points should be investigated

- Print up a small prototype series for testing of electronics
- Look deeper into thermal solutions and do a more thoroughly thermal analysis
- Look into other materials and if the materials would have an impact on the acoustic attenuation
- Do further mechanical testing and simulations to optimize the structure, and make sure the shell fulfills the requirement from IEC60601
- Look into possible production methods, either large scale 3D printing or injection molding
- Reduce the size of the electronics to reshape the shell, for a more desirable design for the market

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18. APPENDICES

List of appendices

Appendix A: Drawing of the probe

Appendix B: Work schedule

Appendix C: Concept generation

Appendix D: Thermal compression of shells

Appendix E: Crush test

Appendix F: User screening feedback

Appendix G: Thermal investigation

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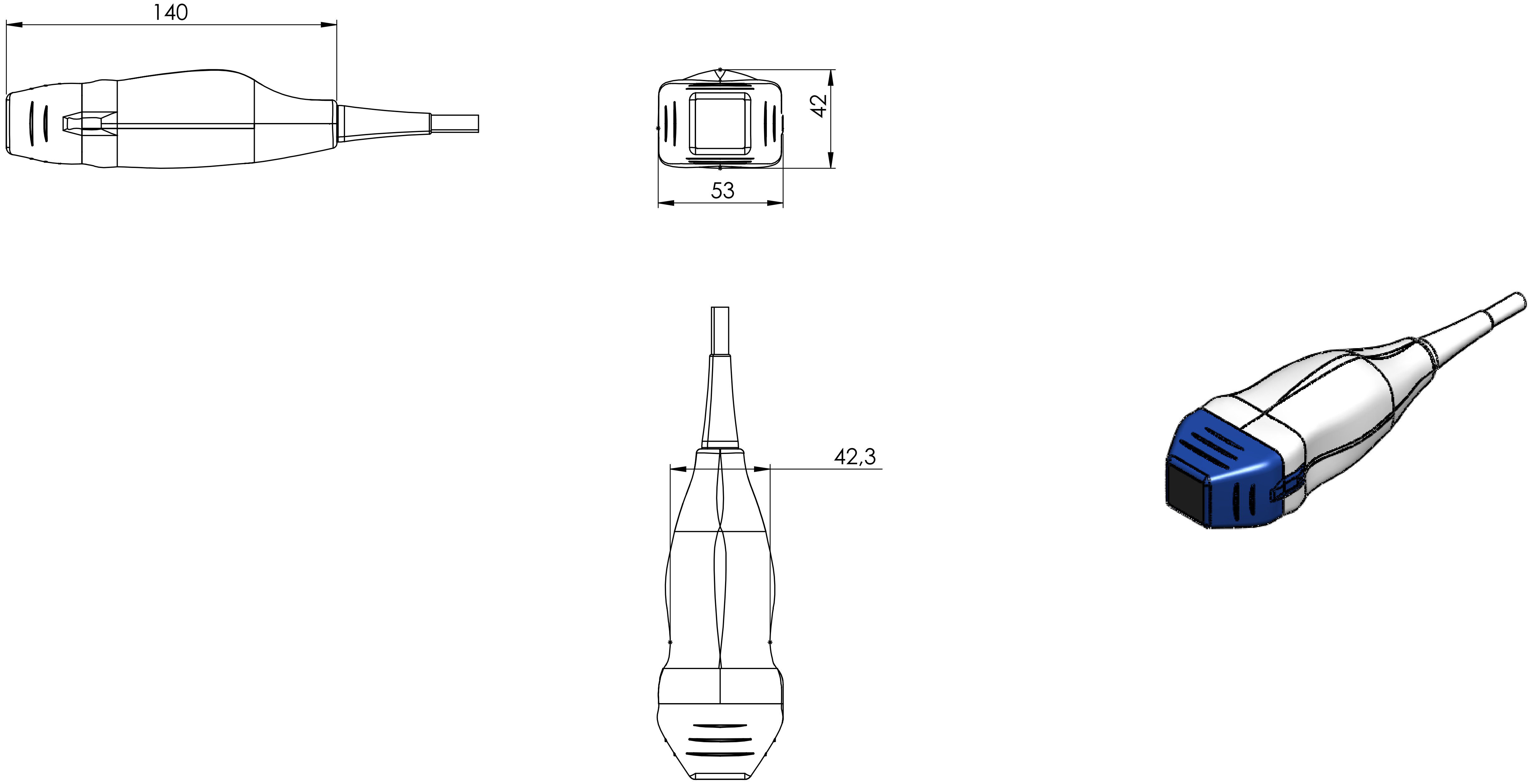
General notes:



UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN MILLIMETERS
SURFACE FINISH:
TOLERANCES: ISO 2768-m
LINEAR:
ANGULAR: +/- 0.2 per bend
FINISH: DEBUR AND BREAK SHARP EDGES

FIRST ANGLE PROJECTION

ESSENTIAL CLASSIFICATION		
N	ESSENTIAL	ECXX
Y	NON-ESSENTIAL	

DO NOT SCALE DRAWING

REVISION 01

Module Name: Master Thesis 2019

GE Healthcare Clinical Systems

Description: New Probe shell Asm

Part to be RoHS Compliant per GEHC 5240305GSP

RoHS 2002/95/EC

PDF EXPORT DATE: 14. mai 2019

MATERIAL: See BOM

WEIGHT: 37 gram +/- 5%

DWG NO. MT216

SHEET 1 OF 2 | SCALE:1:2 | A3

ZONE	REV.	DESCRIPTION	DATE	APPROVED
	01	Initial release	14. mai 2019	FS

REVISIONS
ECR/ECO number on title page. No title page = Not released DOC

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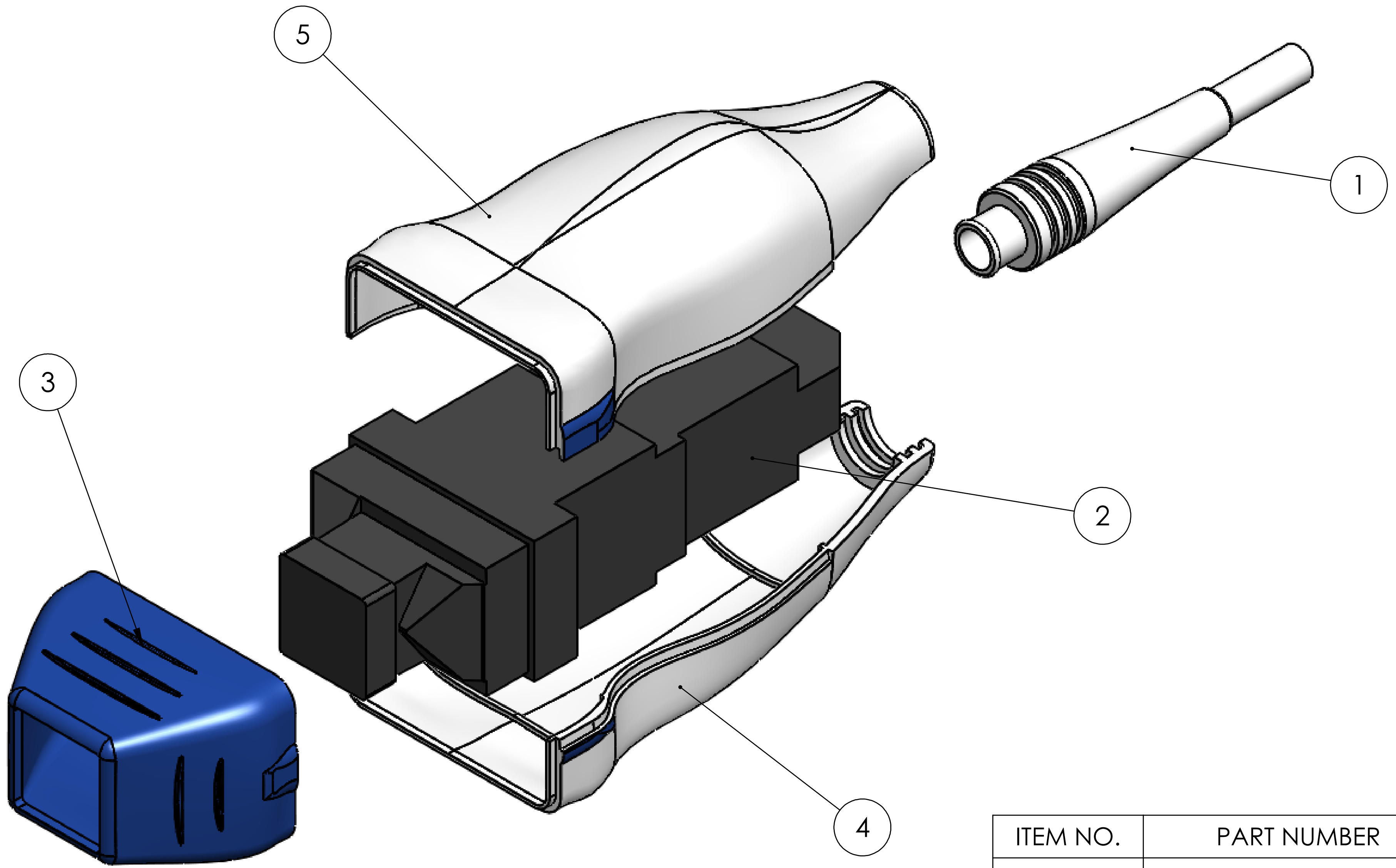

ITEM NO.	PART NUMBER	/MATERIAL	QTY.
1	Cable-Cord	N/A	1
2	Electronics	N/A	1
3	Nose-Piece	Formlabs White	1
4	Shell bottom	Formlabs White	1
5	Shell Top	Formlabs White	1

UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN MILLIMETERS
SURFACE FINISH:
TOLERANCES: ISO 2768-m
LINEAR:
ANGULAR: +/- 0.2 per bend
FINISH: DEBUR AND BREAK SHARP EDGES

FIRST ANGLE PROJECTION

ESSENTIAL CLASSIFICATION

N	ESSENTIAL	ECXX
Y	NON-ESSENTIAL	

DO NOT SCALE DRAWING

REVISION 01

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PDF EXPORT DATE: 14. mai 2019

MATERIAL: See BOM

WEIGHT: 37 gram +/- 5%

DWG NO. MT216

SHEET 2 OF 2

SCALE:1:1

A3

ZONE	REV.	DESCRIPTION	DATE	APPROVED
	01	Initial release	14. mai 2019	FS

REVISIONS
ECR/ECO number on title page. No title page = Not released DOC

Tasks	Week	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
	Dato	1.jan	7.jan	14.jan	21.jan	28.jan	4.feb	11.feb	18.feb	25.feb	4.mar	11.mar	18.mar	25.mar	1.apr	8.apr	15.apr	22.apr	29.apr	6.mai	13.mai
Start the project			x																		
Gather information:																					
Theory ultrasound			x	x	x																
Theory and technology			x	x																	
Look at previous solutions, whats state of the art?			x	x	x																
Thermal			x	x	x																
Ergonomics			x	x	x																
Tecnichal																					
Look up mechanical solutions (scamper)						x	x	x													
Look up thermal solutions(scamper)								x	x												
Find ergonomical solutions (scamper)									x	x											
Develop new consepts											x	x									
Thermal and mechanical analyses											x	x	x	x							
Ergonomic testing											x	x	x	x							
Durability and materials														x	x	x					
Final concept														x	x	x					
Theisis writing																					
Product arcitecture																	x	x			
cost																	x	x			
Marked presentation, rendrings																	x	x			
Prosses evaluation and discusion																	x	x			
Conclusion																			x		
																			x		
Orthography																			x		
Printing																			x	x	
Delivary																			x	x	
Yellow = Easter if posible																					

Appendix C: Concept generation

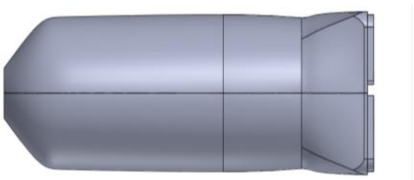
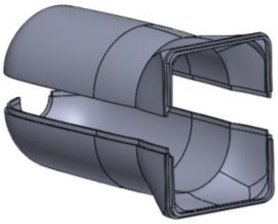
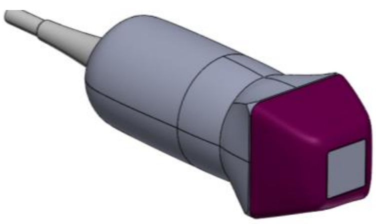
1.CONCEPT GENERATION

Various concepts were generated, to test the potential grip designs. The modeling was done in iterations, bringing forward the best characteristics of each concepts.

1.1 Traditional probe

The first cad model that was generated was with a standard probe design, to see the necessary outer geometry to fit the electronics.

Table 1: Concept 1

Concept 1: Circular shape	
Description	**Visualization and dimensions**
Nose-piece	
Two-part symmetric shell, with a circular shape	
2 mm thick shell with lip and groove	
Assembly of the probe The shell is build up with a circulare form, with a increase in the crosssection at the intersection with the nose piece.	
Lenght	146 mm
Center diameter	50 mm
Wide at nose pice	52 mm
Shell thicknes	2 mm

A 3D printed of the model was made to get a feeling of how the shell would fit in the hand of the operator

Table 2: Concept 1 3D print

3D print		
Side view	**Front view**	
		
Finger grip	**Palm grip**	
		
Good finger grip	No	-
Nose piece exceeding foot print	Yes	-
Palm grip	No	-
Apple grip	No	-
Neutral wrist position	No	-
	Sum	-5
Summary/characteristics to bring forward:		
The design was voluminous and not comfortable to hold. The diameter was to big		
<u>No GO</u>		

The first design shows that the dimensions of the probe will be rather big. According to "The measure of man and women" as mention in earlier chapters, the diameter of a spherical grip should not exceed 22-33mm. With the needed diameter to fit all necessary electronics, a standard probe design with finger grip would not be recommended. This means the one-winged probe design is not doable. The palm grip design would therefore be the best option hence the apple grip is pretended by Esaote and making a similar design can cause problems later in the project.

1.2 Palm grip

Based on the thumb locker idea, the first palm grip design idea was made. The Nose piece is the same as in the previous concept, but the grip of the probe is built up with a different geometry. A 3D-printed model was made for all concepts to test how it would be to operate the probe.

Table 3: Concept 2

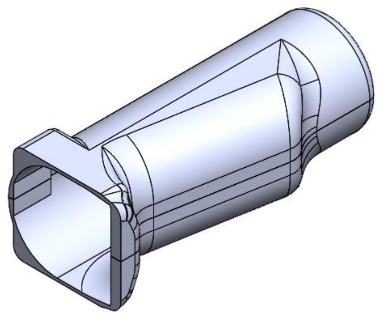
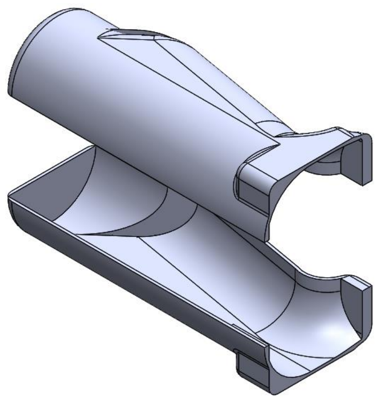
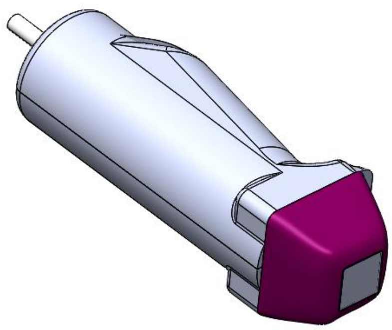
Concept 2: Large palm grip	
Description	**Visualization and dimensions**
The thumb is placed down along the "bulk out" while the four other fingers rest on the rest on the cylindrical surface on the opposite side	
In the transition between the shell and the nose piece the geometry becomes thicker, so the fingers can slip of the probe. The nose piece is attached with a lip and groove	
Assembly of the probe	
Shell thicknes	1,5 mm
Lenght	176 mm
Wide at nose pice	60 mm
Center diameter	60 mm

Table 4: Concept 2 3D-print

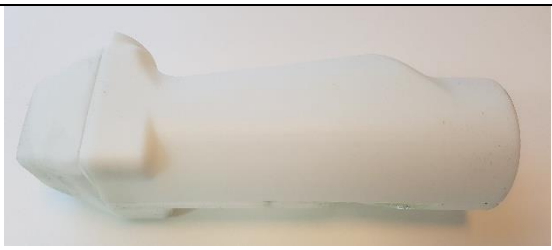
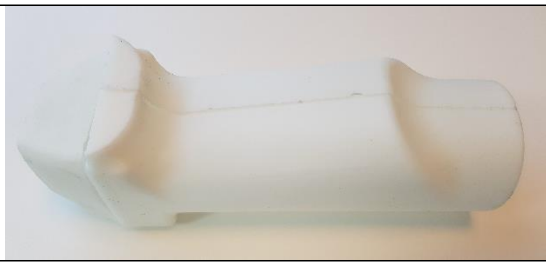
3D print		
Side view	**Bottom view**	
		
Front view		
		
Palm grip	**Palm grip**	
		
		
Good finger grip	No	-
Nose piece exceeding foot print	Yes	-
Palm grip	Yes	+
Apple grip	No	-
Neutral wrist position	No	-
	Sum	-4
Summary/characteristics to bring forward:		
The palm grip works as intended, but the probe is too long and difficult to operate		
<u>No GO</u>		

Table 5: Concept 3

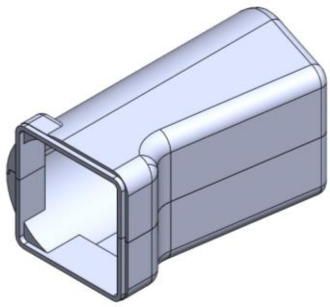
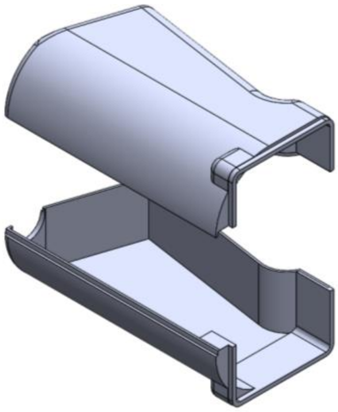
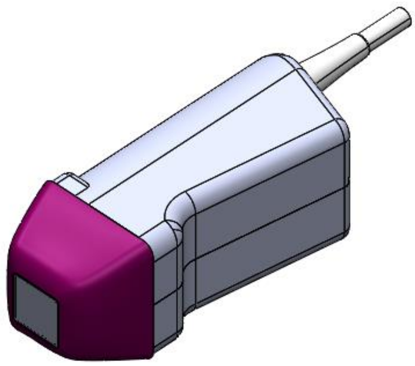
<table>
<tr><th colspan="2">Concept 3: Smaller Palm grip</th></tr>
<tr><th>Description</th><th>Visualization and dimensions</th></tr>
<tr><td>In this design the hand anthropometry was emphasized. The Radius for placing the thumb is at 10mm and the length for placing the thumb is approximately 65mm
This size of the geometry is based on the anthropometrics from earlier chapter and is close to the sizes for a medium sized hand for men and large for woman</td><td></td></tr>
<tr><td>The shell thickness was set to 2mm</td><td></td></tr>
<tr><td>The cable cord was placed on the side of the probe instead of in center</td><td></td></tr>
<tr><td>Shell thicknes</td><td>2 mm</td></tr>
<tr><td>Lenght</td><td>135 mm</td></tr>
<tr><td>Wide at nose pice</td><td>60 mm</td></tr>
<tr><td>Center diameter</td><td>57 mm</td></tr>
</table>

Table 6: Concept 3 3D-print

<table>
<tr><th colspan="3">3D print</th></tr>
<tr><th>Top view</th><th colspan="2">Bottom view</th></tr>
<tr><td></td><td colspan="2"></td></tr>
<tr><th colspan="3">Front view</th></tr>
<tr><td colspan="3"></td></tr>
<tr><th colspan="3">Palm grip</th></tr>
<tr><td></td><td colspan="2"></td></tr>
<tr><td>Good finger grip</td><td>No</td><td>-</td></tr>
<tr><td>Nose piece exceeding foot print</td><td>Yes</td><td>-</td></tr>
<tr><td>Palm grip</td><td>Yes</td><td>+</td></tr>
<tr><td>Apple grip</td><td>No</td><td>-</td></tr>
<tr><td>Neutral wrist position</td><td>No</td><td>+</td></tr>
<tr><td></td><td>Sum</td><td>-3</td></tr>
<tr><td colspan="3">Summary/characteristics to bring forward:</td></tr>
<tr><td colspan="3">The Shell was to short for the palm grip to work properly while scanning straight forward, the sharp ending was unconfertable ageinst the palm. While holding the probe as in the picture to the right the grip was betther.</td></tr>
<tr><td colspan="3"><u>No GO</u></td></tr>
</table>

Table 7: Concept 4

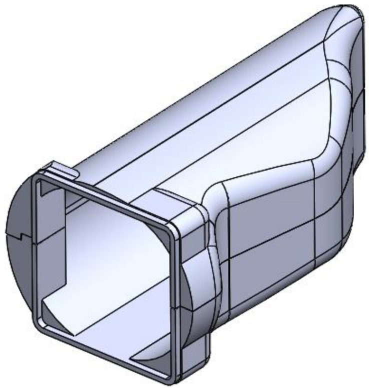
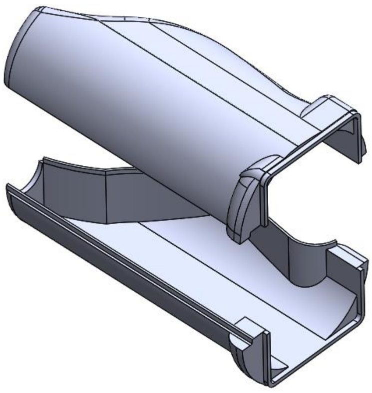
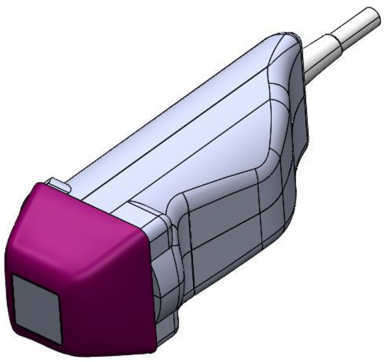
Concept 4: Small palm grip with radius	
Description	**Visualization and dimensions**
In this design the probe was made longer and the transition between the thumb and the palm is smoother	
The shell thickness was set to 2 mm with a lip and groove	
Assembly of the probe	
Shell thickness	2 mm
Length	150 mm
Wide at nose piece	64 mm
Center diameter	52,5 mm

Table 8: Concept 4 3D-print

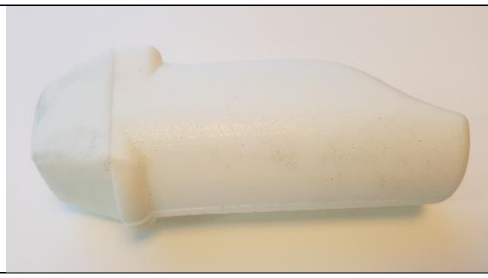
3D print		
Top view	**Bottom view**	
		
Front view		
		
Palm grip		
		
Good finger grip	No	-
Nose piece exceeding foot print	Yes	-
Palm grip	Yes	+
Apple grip	No	-
Neutral wrist position	No	+
	Sum	-3
Summary/characteristics to bring forward:		
The palm grip for scanning from above and from the side works good in this design. But the transaction between the end of the thumb and the palm is to “sharp” making the probe uncomfortable to hold. The end needs to be rounded off.		
<u>No Go</u>		

Table 9: Concept 5

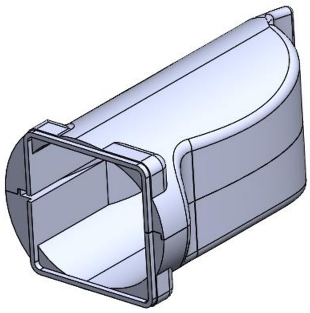
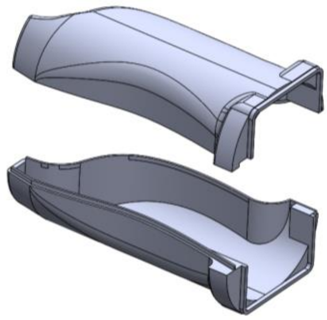
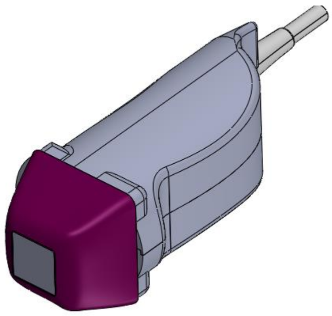
Concept 5: Palm grip with more organic shapes	
Description	**Visualization and dimensions**
In this concept the transitions were made smoother and more organically	
An inverse radius was made on the other side for a smaller grip diameter	
Assembly of the probe	
Shell thickness	2 mm
Length	150 mm
Wide at nose piece	64 mm
Diameter at center	46 mm

Table 10: Concept 5 3D-print

3D print		
Top view	**Bottom view**	
		
Front view		
		
Palm grip		
		
Good finger grip	No	-
Nose piece exceeding foot print	Yes	-
Palm grip	Yes	+
Apple grip	No	-
Neutral wrist position	No	+
	Sum	-3
Summary/characteristics to bring forward:		
The palm grip feels betther in this designe, the transaction between the palm and the thumb feels beter. The radie at the end of the shell as shown In picture to the left above show that the thumb falls in a nuteral postion when scanning from above.		
GO		

Appendix D: Thermal comparison of shells

1. THERMAL ANALYSIS OF THE TWO CONCEPTS

1.1 Thermal analysis whole probe

To get an overview of the thermal properties in the hole probe and locate possible changes

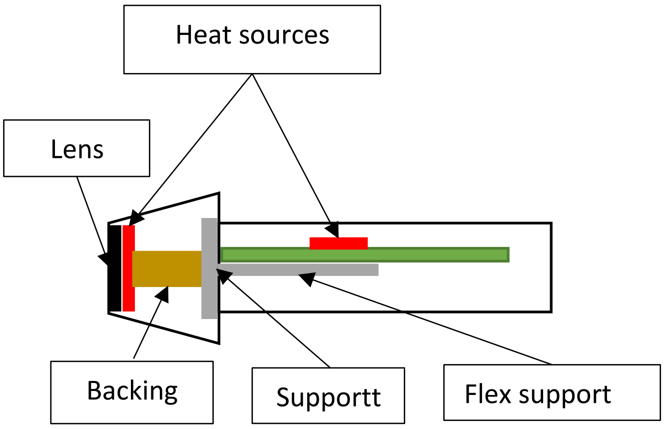
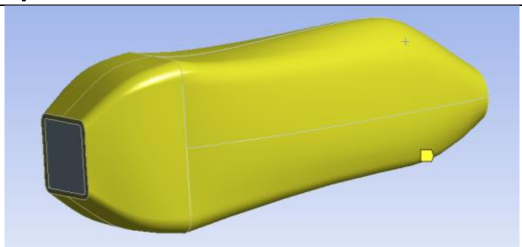
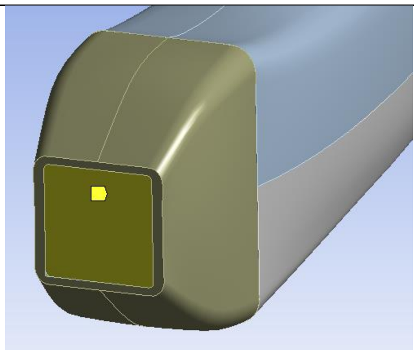


Figure 1: Thermal analysis structure

1.2 Boundary conditions

Two different cases will be tested, free convention to air on all external surfaces and free convection to air on handle and conduction to the patient on the lens.

Table 1: Film coefficient boundary conditions

Film coefficient = 10 W/m^2 °C*, ambient temperature = 23°C	**Film coefficient = 71 W/m^2 °C**, ambient temperature = 33°C**
	
* Film coefficient baset on previus simulations by GE ** Film coefficient baset on previus simulations by GE	

1.3 Heat sources

There will be two main sources of heat in the system, the 12 Max4805 amplifiers and the transducer. The Max4805 connectors will produce a total of 2 Watt, but due to lose in cables and the system this total watt is set to 1,4 with a loss of 30%

Table 2: Heat sources volume loss

Body	Loses(W)	Volume(m^3)	Vol losses (W/m^3)
Max4805(x12)	0,1167	$1{,}9x10^{-8}$	6142105
Transducer	0,32	$6{,}48x10^{-7}$	493827

1.4 Material properties

Table 3: Material properties of components

Part	Material	k (W/mK)
Max4805	-	1,05
transducer/Wire bounding	Filled Epoxy	15
Backing	Filled Epoxy	15
Plastic Shell	Formlabs	0,283
PCBs	FR-4	0,29
Lens/front encapsulation	RTV630	0,31
Flex Support	6061-T6 Alu	167
Support	60601-T6 Alu	167

1.4 Thermal results

Table 4: Results thermal analysis

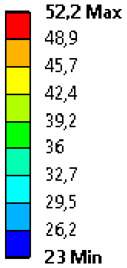
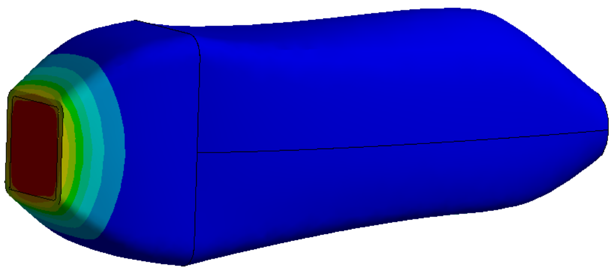
Concept 8 Free convection to air on all external surfaces	
Shell and nose-piece temperature (°C)	
	
The maximum temperature on the shell and nose-piece occurs on the lens facing the patient. With a temperature of 52,2 °C	

Table 4: Results thermal analysis continues

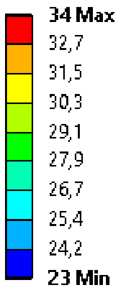
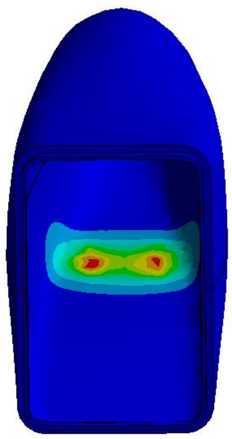
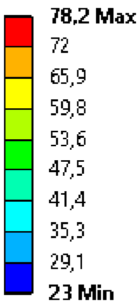
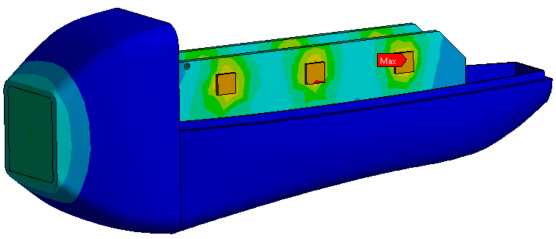
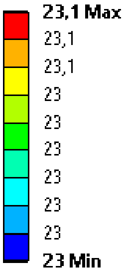
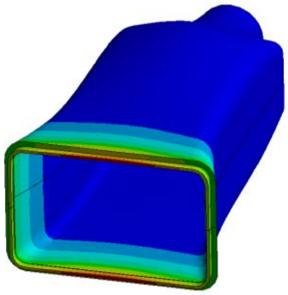
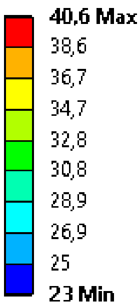
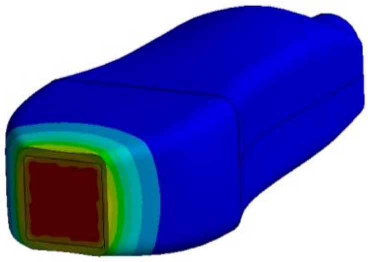
Shell temperature (°C)	
	
The maximum temperature on the shell occours on the bottom part of the shell at 34 °C	
Maximum internal temperature (°C)	
	
The maximum temperature in the probe occurs at the max connectors, theere are surten insecurety to this temperature but the temperature is an indicator of how the heat will spread.	

Table 5: Concept 7 free convection

Concept 7 Free convection to air on all external surfaces	
Shell temperature (°C)	
	
The Heat on shell 7 is lower than on shell 8, this is because the distance from the plastic to the PCBs is lager	

The maximum temperature on the shell is higher on Shell 8, this is because the distance from the PCBs to the shell is smaller on concept 8. The lens temperature with free convection to air is the same for both cases with 47,8 °C. With Conduction to patient the temperature is considerably lower:

Table 6: Concept 7 conduction to patient

Concept 7 Free convection to air on handle, conduction to patent on lens	
Lens temperature (°C)	
	

Both cases are within the range set from thermal goals in chapter 5.5.1 with maximum temperature on shell 41 °C and 43 °C on shell.

1.5 Summary

None of the shells exceeds the maximum temperature against the user of 43 °C, shell 7 has the lowest temperature against the operator. Both shells have the same temperature against the patient, but the temperature does not overcome 41 °C. There are some uncertainties around the maximum temperature at the Max4805 connectors, their operating temperature is specified by the supplier to 70 °C and the temperature in the analysis is approximately 78 °C. Still the temperature of the shells does not over come the goals, so this should not be an issue.

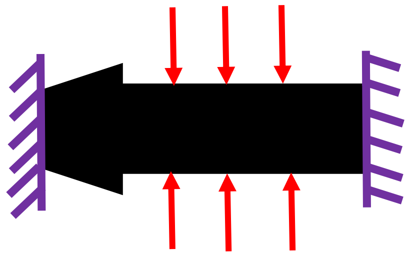
Appendix E Crush test

1. CRUSH TEST

From Dreyfuss book [23] it's estimated that the maximum hand pressure from a man is 59,3 Kg. A static analysis was set up to see if the plastic shells could withstand this force.

1.1 Boundary conditions

The test was set up with 2 forces of 582N and I fixture in front of the probe to see the stress and the deformation on the shell



1.2 Material properties

The first strength test was done with the Formlabs standard material with the following properties:

Table 1: Material properties crush test

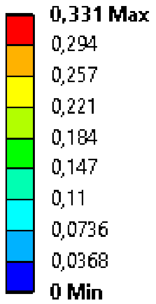
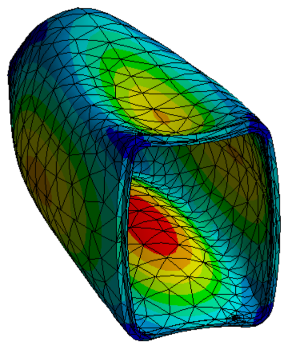
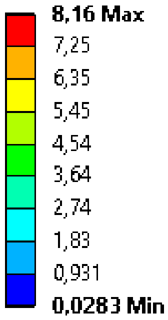
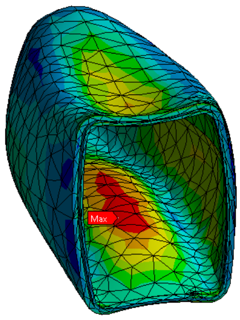
Properties	Value
Density	995Kg/m^3
Young's modulus	2,8GPa
UTS	65MPa

1.3 Temperature deformation

The material properties of plastic changes with temperature, for the selected material used in the testing Formlabs White will deform at 58,4 degrees Celsius at a pressure of 1,82 MPa, tested according to ASTM D 648-07. This is within the temperature range specified by IEC60601 at 43 degrees, which means that there will not be additional deformation due to the temperature

1.4 Crush test results

Table 2: Results crush test concept 8

<table>
<tr><th colspan="2">Concept 8</th></tr>
<tr><th colspan="2">Deformation (mm):</th></tr>
<tr><td></td><td></td></tr>
<tr><th colspan="2">Von mises stress (MPa)</th></tr>
<tr><td></td><td></td></tr>
</table>

The maximum deformation occurs at the bottom shell at 0,3 mm, this deformation is not critical, the deformation that can make a difference is the deformation around the lip and groves that could make the probe fall apart.

The stress at 8MPa at the bottom of the probe will not be inn issue hence it's good within the UTS of 65 MPa

Table 3: Crush test result concept 7

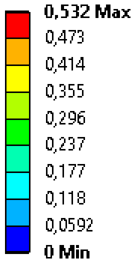
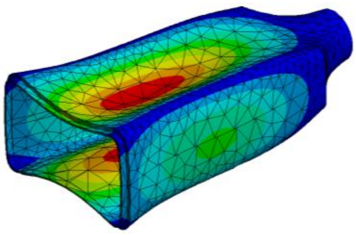
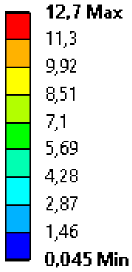
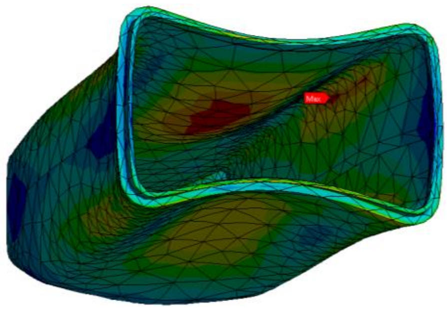
<table>
<tr><th colspan="2">Concept 7</th></tr>
<tr><th colspan="2">Deformation (mm):</th></tr>
<tr><td></td><td></td></tr>
</table>

Table 3: Crush test result concept 7 continues

Von mises stress (MPa)	
	

The maximum deformation on concept 7 is 0,5 mm. The maximum deformation occurs at the center of the shell and should not cause any issues, the deformation that would be critical is the deformation around the lip and grooves where the shells and nose-piece is connected.

For the applied stress at 12,8 MPa this should not be an issue hence the UTS for the material is 65 MPa.

1.5 Summary crush test

Both the probes would withstand the applied load, concept 7 has more deformation and a higher stress, this is due to the larger area were the load is applied. For the final concept ribs should also be applied, which should also decrease the deformation and strengthen the shell. But for this test concept 8 would be the best choice.

Appendix F: User screening feedback:

Table 1: Screening from 1

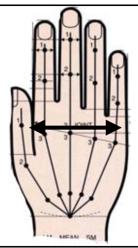
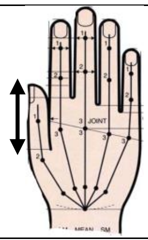
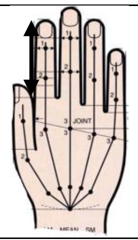
Screening form		
Test personnel	Jann Yee	
Palm width		
	Not available	
Thumb length		
	Not available	
Index finger length		
	Not available	
The shells		
First impression of the design?	Rate 1-6	
	Shell A	1
	Shell B	1
How does the probe fit in the hand of the operator?	Shell A	1
	Shell B	1
Is the probe good too look at	Shell A	1
	Shell B	1
How is the probe to operate?	Shell A	1
	Shell B	1
How does it feel to hold the probe with finger grip?	Shell A	1
	Shell B	1
How does it feel to hold the probe with palm grip?	Shell A	3
	Shell B	3
Comments on Shell A		

Table 1: Screening from 1 continues

- Hard to rotate - To big
Comments on shell B
- To big - Works better with nose piece from shell A - To edgy - Both shells are to large the size needs to be severely reduced to be usable

Table 2: Screening from 2

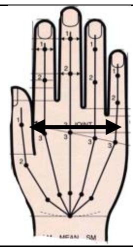
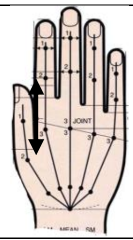
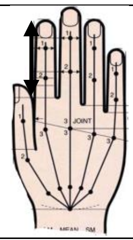
Screening form		
Test personnel	Thea H Ottesen	
Palm width		
	75 mm	
Thumb length		
	50 mm	
Index finger length		
	62 mm	
The shells		
First impression of the design?	Rate 1-6	
	Shell A	3
	Shell B	4
How does the probe fit in the hand of the operator?	Shell A	2
	Shell B	3,5
Is the probe good too look at	Shell A	3
	Shell B	4
How is the probe to operate?	Shell A	2
	Shell B	3
How does it feel to hold the probe with finger grip?	Shell A	1

Table 2: Screening from 2 continues

	Shell B	2
How does it feel to hold the probe with palm grip?	Shell A	3
	Shell B	3
Comments on Shell A		
- A bit edged, would be easier to maneuver a more curved off shell - Looks more like the 4vD probe than the 4Vc-D		
Comments on shell B		
- Smaller probe than A, easier to hold with finger grip - The palm grip depends on where the indicator would be placed - A bit edged - Fits best with the nose-piece used on probe A - Should be something to increase the grip on the nose-piece		

Table 3: Screening from 3

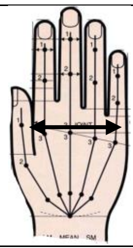
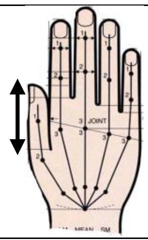
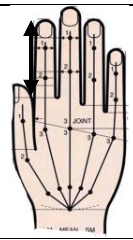
Screening form		
Test personnel	Madeleine Eng Jiun Yi	
Palm width		
	74 mm	
Thumb length		
	48 mm	
Index finger length		
	69 mm	
The shells:		
First impression of the design?	Rate 1-6	
	Shell A	4
	Shell B	4,5
How does the probe fit in the hand of the operator?	Shell A	3
	Shell B	4
Is the probe good too look at	Shell A	4

Table 3: Screening from 3 continues

	Shell B	4,5
How is the probe to operate?	Shell A	3
	Shell B	4,5
How does it feel to hold the probe with finger grip?	Shell A	3
	Shell B	4
How does it feel to hold the probe with palm grip?	Shell A	5
	Shell B	5,5
Comments on Shell A		
- Entire length of the probe is slightly long, especially tail edge - The probe is slightly covering my palm - Prefer more waist, to ease the gripping, especially when rotating to get views		
Comments on shell B		
- With the nose-piece from shell A the proportion of more balance - Better grip because of the waist and with is slightly reduced, making it more comfortable on smaller palms - Would be great if it can couple with good gripping materials outside - Reduce the radius of the nose-piece, this should be more a line, more angular		

Table 4: Screening from 4

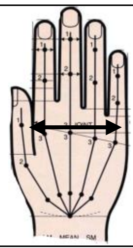
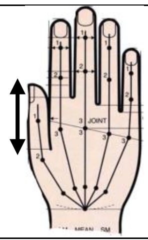
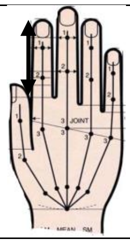
Screening form	
Test personnel	Gunnar Hansen
Palm width	
	96 mm
Thumb length	
	56 mm
Index finger length	
	76 mm
The shells	
First impression of the design?	Rate 1-6

Table 4: Screening from 4 continues

	Shell A	4
	Shell B	4
How does the probe fit in the hand of the operator?	Shell A	6
	Shell B	4
Is the probe good too look at	Shell A	4
	Shell B	4
How is the probe to operate?	Shell A	6
	Shell B	4
How does it feel to hold the probe with finger grip?	Shell A	5
	Shell B	5
How does it feel to hold the probe with palm grip?	Shell A	6
	Shell B	4
Comments on Shell A		
- First impression: Too big - Missing orientation line, which must be long enough - Too sharp edges on foot print		
Comments on shell B		
- Frist impression: Too big - Rounder edges in grip - Not logical grip (twisted) - Too wide after footprint - Too sharp edges on footprint		

Table 5: Screening from 5

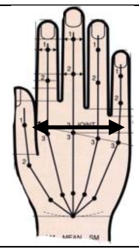
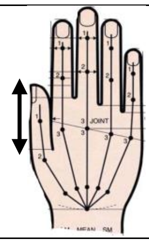
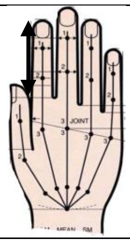
Screening form	
Test personnel	Glenn Reidar Lie
Palm width	
	88 mm
Thumb length	

Table 5: Screening from 5 continues

	55 mm	
Index finger length		
	70 mm	
The shells:		
First impression of the design?	Rate 1-6	
	Shell A	1
	Shell B	1
How does the probe fit in the hand of the operator?	Shell A	3
	Shell B	2
Is the probe good too look at	Shell A	2
	Shell B	2
How is the probe to operate?	Shell A	2
	Shell B	1
How does it feel to hold the probe with finger grip?	Shell A	2
	Shell B	2
How does it feel to hold the probe with palm grip?	Shell A	2
	Shell B	1
Comments on Shell A		
- The probe is to big		
Comments on shell B		
- To edgy - To sharp at the end towards the cord		

Appendix G Thermal investigation

1. ISOLATING WITH AIR

Initially the first simulation will be to test the effect of filling the shell with pockets of air. The first simulation will be a simplification to test the effect.

The large PCBs will generate a total heat of approximately 1.4W divided on 12 different amplifiers 6 on each board. The order of the heat transfer will be:

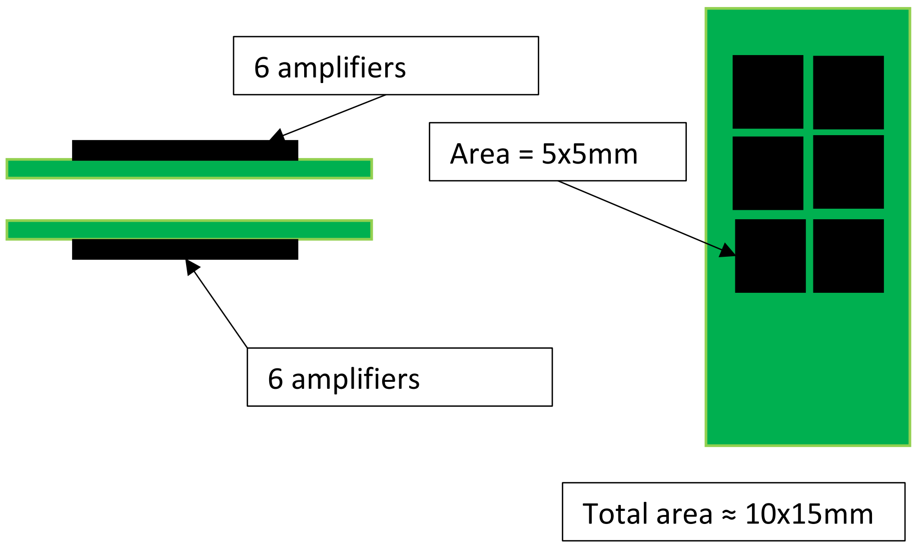


Figure 1: Layout connectors on PCB

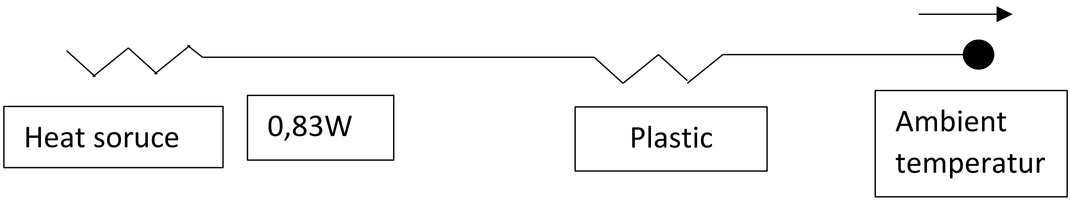


Figure 2: Order of heat transfer

1.1 Boundary conditions

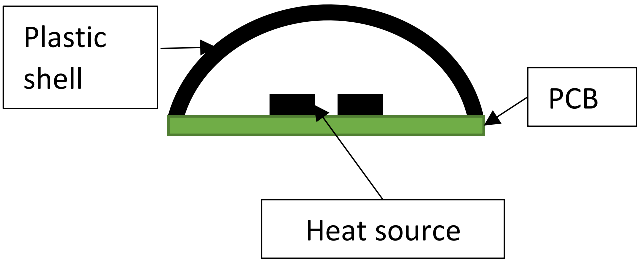


Figure 3: Analysis setup

The two large PCBs on each side will be working in cycles, one reviving and one sending signals. This means that in theory there will only be generated 0,7W per cycle but for the test the watt generated was set to 1,4 to see the how high the temperature could get.

To see the effect of the air in the shell the two simulations was setup with the same settings:

1.2 Heat sources

Table 1: Heat sources in analysis

Body	**Vol Losses(W/m^3)**
Max4805(6x)	6142105

1.3 Material properties

Table 2: Material properties in analysis

Material	**Thermal conductivity**
Air	0,0242 W/m-k
Shell	0.283 W/m-k
FR-4	0,29 W/m-k
Max4805	1,05 W/m-k

1.4 Thermal results

Table 3: Thermal results compression shells

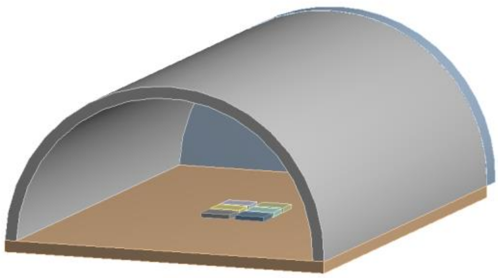
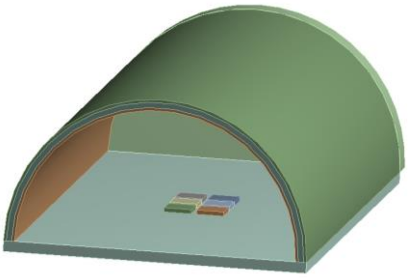
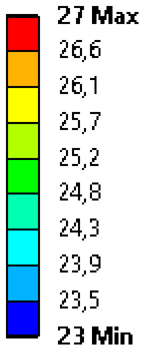
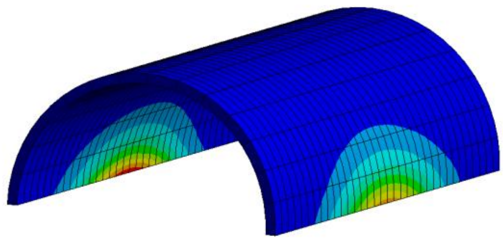
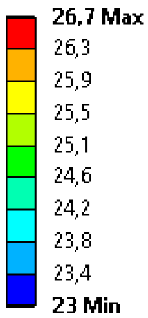
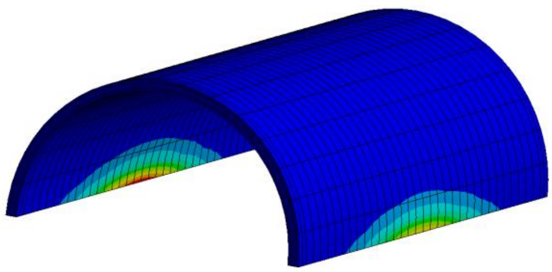
Dense shell	**With air in Shell**
2mm Thick plastic	0,5mm plastic 1mm air 0,5mm plastic
	

Table 3: *Thermal results compression shells* continues

<table>
<tr><th colspan="2">Temprature plot dense shell (°C)</th></tr>
<tr><td>
</td><td></td></tr>
<tr><td colspan="2">For the shell without air the maxiumum temperature on the surface of the shell was 27 °C</td></tr>
<tr><th colspan="2">Temprature plot shell with air (°C)</th></tr>
<tr><td>
</td><td></td></tr>
<tr><td colspan="2">With air in the shell the maximum teperature was decreesed to 26,7 °C</td></tr>
</table>

1.5 Summary

The maximum temperature is very high around the bottom of the shell, this might come from the settup of the test. But the test confirms the that filing the shell with air will reduce the surface temperature of the probe. 1 mm of air reduced the temperatue with aproxemently 0,3 °C. More air would perhaps decrees the temperature more, but this would result in a thicker shell and a larger diameter off the shell.

2 HEAT CORD

To see if a cooper cord attached to the flex support would reduce the temperature, a new test was set up.

2.1 Boundary conditions

The boundary conditions were the same as the previous tests in chapter 9.3, the only difference was a 2mm thick copper cord fastened to the flex support with a M2 screw.

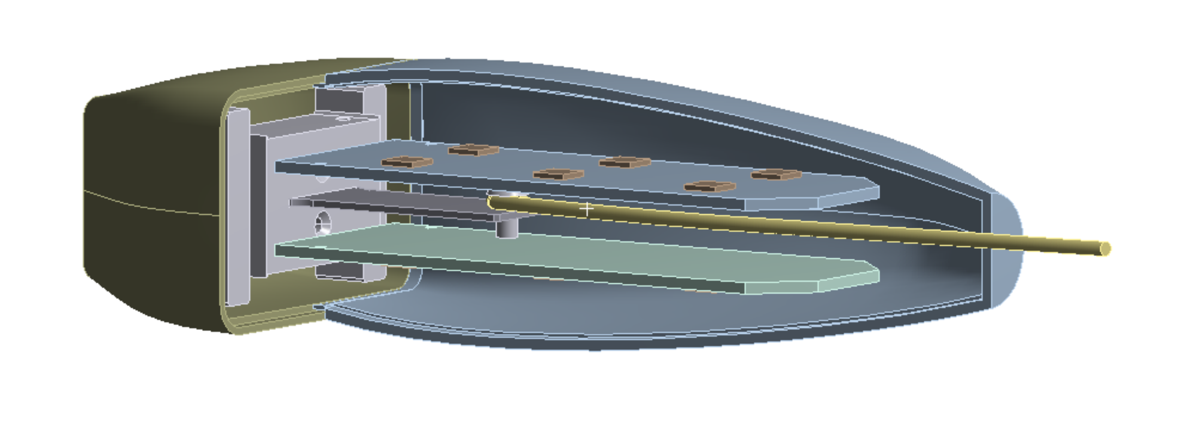


Figure 4: Heat cord in shell

2.2 Results Heat cord

Table 4: Shell A free convection

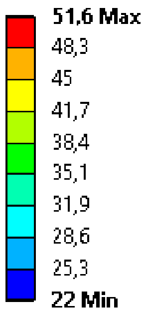
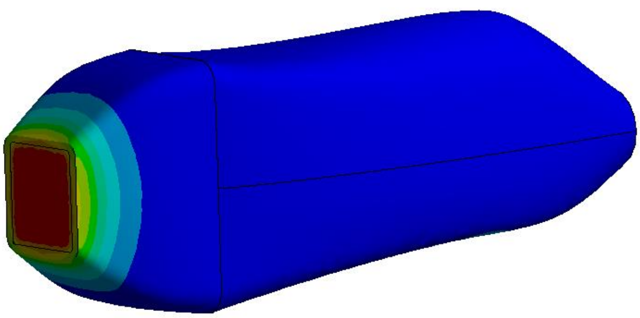
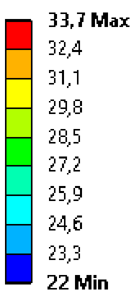
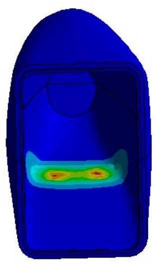
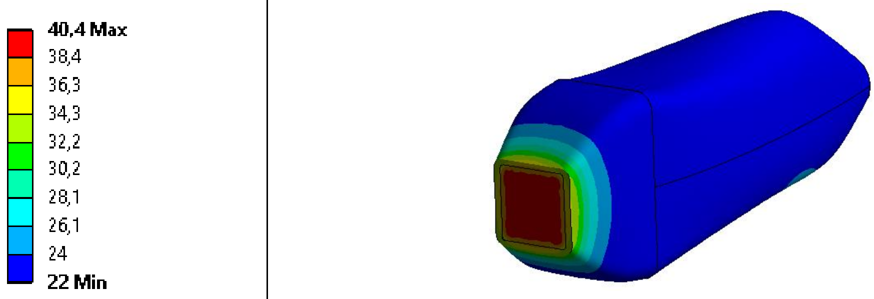
Shell A with cord, Free convection to Air on all external surfaces.	
Shell and nose-piece temperature (°C)	
	
Shell tempterature (°C)	
	

Table 5: Shell A conduction to patient

Free convection to air on handle, conduction to patent on lens
Shell temperature (°C)


2.3 Summary heat cord

The heat cord reduces the temperature of the lens facing the patient with 0,6 degrees for free convection on all faces and 0,2 degrees with conduction to patient on lens. The reduction is not much but it would lead some heat out of the probe

3. HEAT SPREADERS ON NOSE-PIECE

To see if using lines to increase the area of the nose-piece would reduce the temperature against the patient.

3.1 Boundary conditions

The boundary conditions are the same as in previous tests. The only difference was the lines added on the nose piece. The test was done in two iterations one with four lines and one with twelve lines to see how it would differ.

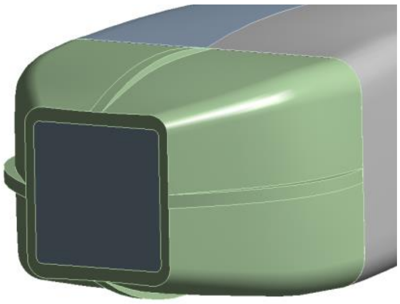


Figure 5: Heat spreaders on nose-piece

3.2 Results heat spreaders

Table 6: Heat spreaders on nose-piece results

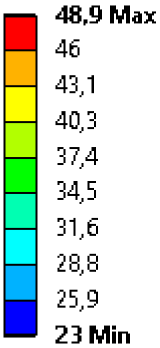
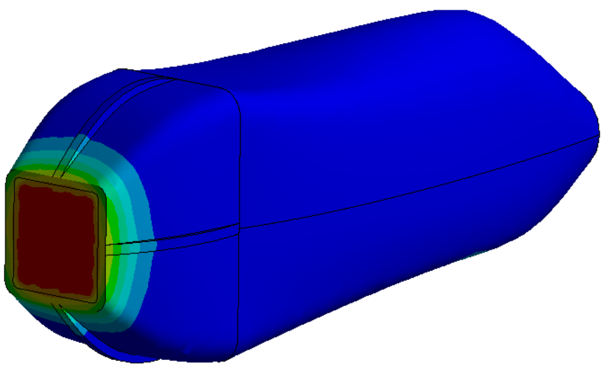
Shell A with cord, free convection to air on all external surfaces	
Lens temperature (°C)	
	

Table 6: continues

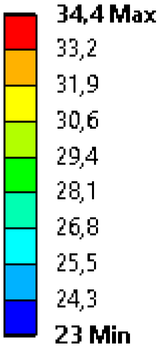
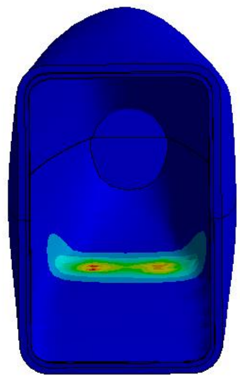
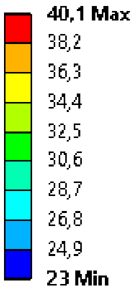
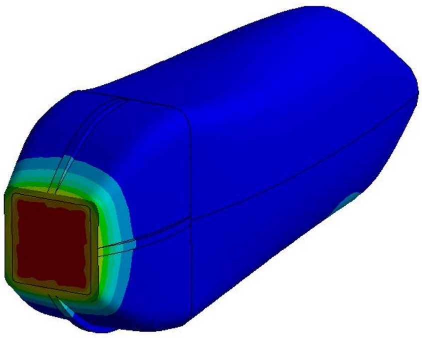
Shell temperature (°C)	
	
Shell A with cord, free convection to air on handle, conduction to patient on lens	
Lens temperature (°C)	
	

Table 7: Multiple lines

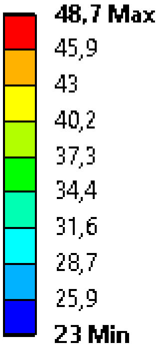
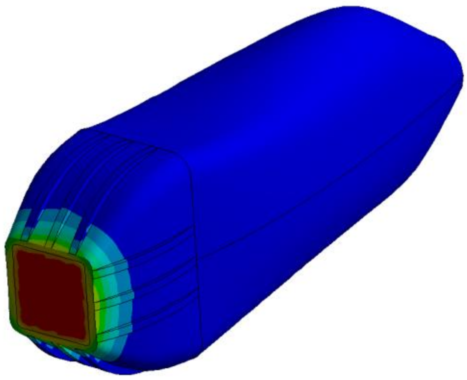
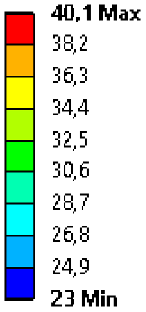
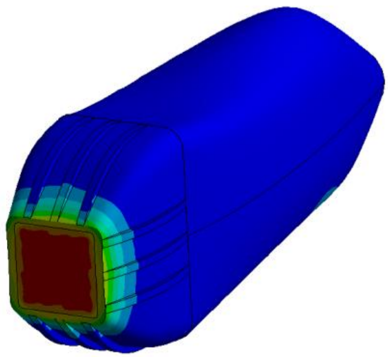
Adding multiple heat spreaders to the nose-piece	
Free convection to all external faces (°C)	
	
Free convection to air on handle, conduction to patent on lens	

Table 7: Multiple lines continues

Lens temperature (°C)	
	

3.2 Summary Heat spreaders

The heat spreaders on the nose-piece reduced to temperature with 3,3 °C for the free convection on all surfaces and 0,5 °C for conduction to patent on lens. Adding more lines will not decreese the temperature severlie.

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