Ultra-Personalized Breast Pumps:

Reducing Discomfort and Improving Breast Pumping Experience

Qing Sheng

Author

Qing Sheng
Q.Sheng-1@student.tudelft.nl

Msc Integrated Product Design
Faculty Industrial Design Engineering
Delft University of Technology

Chair

Dr. Yu Song
Y.Song@tudelft.nl

Sustainable Design Engineering
Faculty Industrial Design Engineering
Delft University of Technology

Mentor

Lyè Goto
L.Goto@tudelft.nl

Human Center Design
Faculty Industrial Design Engineering
Delft University of Technology

Mentor

Farzam Tajdari
F.Tajdari@tudelft.nl

Sustainable Design Engineering
Faculty Industrial Design Engineering
Delft University of Technology

Company Mentor

Dr. Loes Wijnoltz
loes.wijnoltz@philips.com

Philips Research
Royal Philips

Foreword

“I do not think it is ‘discomfort’… maybe I have suffered a lot, so it is nothing to me.”

—- that was a conversation I had with a mother participant while doing the breast discomfort threshold study. She was pressing her breast hard with the force gauge and smiling when she said that. I had to tell her any physical feelings that make her not pleasant, and she does not like —- worse than itching —- can be called “discomfort”. I also implemented the same experiment with a lot of nonparous participants; it is much easier for them to understand “discomfort”.

I cannot help thinking that if the “discomfort criteria” of some mothers is higher than “normal people”, which is, to be more specific, mothers have a greater tolerance to it? If the public implicitly agrees that giving birth and nursing is physically unpleasant to women, so mothers must suffer it? If mothers also accept the “implicit agreement” and they did suffer a lot, so they ignore discomfort that is nonignorable to ordinary people and increases their discomfort threshold, to accept the inevitable fate? If mothers’ strong desire to sacrifice themselves for babies and hormone effect cover up their real feelings? Maybe most mothers, who born with strong physiological functions or high tolerance, are okay with nursing as they just feel nothing; should we ignore the rest of mothers who suffered and think they all could or should bear it by default?

In my thesis, I explored how to reduce discomfort and pain in breastfeeding by ultra-personalizing and ergonomic developing of breast pumps. I hope my findings can contribute a bit to future ultra-personalized breast pump design.

Many thanks to my supervisory teams.

Many thanks to the experts and colleagues who helped me.

Many thanks to the research participants and interviewees.

Many thanks to my friends and family.

And many thanks to myself.

Glossary

Breastfeeding/nursing
Infants receive human milk, either at the breast or from the bottle.

Breast pumping
Mothers express breastmilk by a manually or electric breast pump.

Lower sensory threshold/sensation threshold
The weakest pressure that people can feel, it can also be called tactile threshold.

Content

Foreword 4
Glossary 5
Content 6
1 Project Overview 9
1.1 Summary 9
1.2 Context 10
1.3 Assignment 11
1.4 Approach 11
2 Understanding Breastfeeding 13
2.1 Research Method Overview 13
2.2 Breastfeeding Literature Study 13
2.3 Existing Breast Pump Product 14
2.4 Interviews 16
3 Analysis & Insights 19
3.1 User Journey Map 19
3.1.1 Persona 19
3.1.1.1 Minimal breast pump dependency user 19
3.1.1.2 Partial breast pump dependency user 19
3.1.1.3 Complete breast pump dependency user 19
3.1.2 A Day of Life for Three mothers 20
3.2 Stakeholders in Breastfeeding 21
3.2.1 Breastfeeding families 21
3.2.1.1 Mothers 21
3.2.1.2 Infants 22
3.2.1.3 Other family members 22
3.2.2 Lactating experts 22
3.2.3 Breast pump manufacturers 22
3.3 Breast Pump-Related Discomfort and Injuries 22
3.3.1 Summaries 22
3.3.2 Assumptions 23
4 Envisioning 24
4.1 Comfortable Breast Pumping 24
4.2 Frame Innovation 24
4.2.1 Archaeology of Existing Context & Earlier Attempts 24
4.2.2 Paradox: Why are breast pump-related problems hard to solve? 25
4.2.3 Reframe Breast Pumping Problems 25
4.3 Design Scope and Vision 26
5 LoR & Consolidating Plan 27
5.1 Preliminary Design Requirements 27
5.2 Consolidating LoR 28
6 Key Drivers Exploration 30
6.1 Known and Unknown 30
6.1.1 Ideal Breast Contour 30
6.1.2 Ideal Pressure Distribution 30
6.1.3 Effective Nipple/Areola stimuli 31
6.2 Breast Sensitivity Research 31

6.2.1 Analysis 31
6.2.1.1 Breast Sensitivity 31
6.2.1.2 Breast Anatomy Map 32
6.2.2 Research Objectives & Research Questions 33
6.2.3 Pilot Study 34
6.2.4 Methods 34
6.2.4.1 Participants 34
6.2.4.2 Stimuli & equipment 34
6.2.4.3 Procedure 35
6.2.4.4 Data Analysis 37
6.2.4.4.1 Prelimiary Data Visualization 37
6.2.4.4.2 Statistical Method 40
6.2.5 Results 40
6.2.6 Discussions 45
6.4 Vacuum Sensitivity Study 45
6.4.1 Introduction 45
6.4.2 Protocol 46
6.4.3 Results 46
6.5 Perfect Fit Shield Study 47
6.5.1 Study Plan 47
6.5.2 Act 47
6.5.3 Results 49
7 Concepting and Design Recommendation 51
7.1 Ideation 51
7.2 Concepting 52
7.3 Virtual Exploration 57
7.4 Feedback & Evaluation 57
8 Final Design Recommendation 59
8.1 Consolidated List of Requirements 59
8.2 Final Shield Design 61
8.2.1 Shield Prototyping 62
9 Verification 65
9.1 Phantom Breast 65
9.1.1 Model Casting 65
9.2 Pressure Verification 68
9.2.1 Verification Goals 68
9.2.2 Verification Setup 68
9.2.3 Verification Results & Conclusions 70
10 Evaluation and Reflection 78
10.1 Limitations & Contributions 78
10.2 Evaluation of the Design 79
Reference 80
Appendix 83
Appendix A. Project Brief 83
Appendix B. Interview questions & notes 90
Appendix C. Ethical approval 91
Appendix D. Experiment instructions 92
Appendix E. Pilot research findings 99
Appendix F. Data Analysis 100
Appendix G. Verification 109

1 Project Overview

1.1 Summary

Breast pumps are often used by nursing mothers as breastfeeding support in lactation. However, breast pumping is sometimes not a pleasant journey for mothers. Pump-related discomfort and pain were reported by many women. The goal of this project is to solve pump-related problems and optimise breast pumping ergonomic comfort by reducing discomfort and ultra-personalizing.

Fig. Breastfeeding at the breast and pumping milk (Armstrong & Bjarnadottir, 2021)

I closely studied the principles of breastfeeding/lactating, the problems mothers encountered during breast pumping, and the existing solutions and breast pump products on the market. The insights were gathered from the research, which formed the two pain points for pump-related problems: **mothers lack emotional connections with breast pumps which restricts the hormone release for milk ejection reflex; the mismatch of breast pump shields causes most pain and discomfort.** After analysis of the causal model and the frame innovation, the two main problems were reframed as follows:

There could be more physical stimuli on the nipple and areola to make up for the shortness of psychological stimuli;
The optimized pressure distribution could reduce the pain and discomfort.

To solve the two problems above, the envisioned breast pump design direction was narrowed into three perspectives:

Ideal breast contour achieved by 3D scanning;
Ideal pressure distribution based on perceived discomfort differences in different breast areas;
Effective physical stimuli applied on nipple and areola based on correct mechanisms (compression), intensity and local pressure sensitivity differences.

The preliminary design requirements were concluded according to the previous research. To consolidate the LoR (List of Requirements), **experiments regarding breast sensitivity were implemented on 20 women to find the discomfort thresholds and lower sensory thresholds of women's breasts.** Two breast sensitivity map towards positive pressure was made to present the difference: **the breast discomfort thresholds increase from the nipple top to the outer breast. The breast tactile thresholds decrease from the nipple side to the outer breast, and the sensitivity of nipple top is between the nipple base and the areola.** And there are correlations between breast sensitivity and other parameters such as breast volume. Apart from that, other experiments show that a personalized perfectly-fit breast pump shield has a better force distribution than normal breast pump shields. An artificial breast was also made for further verification.

After that, concept ideas were generated and used for virtual exploration. According to the experiment conclusions and views from users and experts, a consolidated LoR (list of requirements) for a possible ultra-personalized breast pump design was made. **The consolidated LoR was applied for a design proposal, which has a personalized adjustable shield shape with better pressure distribution and bigger contact areas.** The design proposal was prototyped and verified on an artificial breast and compared with traditional breast pump shields. It was proved to be theoretically more comfortable than traditional breast pumps.

1.2 Context

According to the 2018 Breastfeeding Report Card released by the Disease Control and Prevention (CDC), most infants (83.2%) started out breastfeeding, and 62.6% exclusively received human milk after being born within one month. Among those, a significant number of breastfeeding families use breast pumps for milk expression to reach their breastmilk feeding goals. Literature indicates that breastmilk feeding with expressed milk that is usually by pumping has been “normalised”, which means pumping milk is not only done in a specific situation, such as pumping for premature babies who are unable to get enough milk supply (Thorley, 2011). “Breastfeeding benefits both infants and mothers” has been widely acknowledged and proven. However, approximately 60% of families stopped breastfeeding at an earlier time than they desired. At 6 months, the percentage of infants who received any breastmilk decreased to 55.8%, and only 24.9% of them received exclusive breastmilk feeding (Breastfeeding Report Card, 2022). One of the main reasons for earlier than desired cessation of breastmilk feeding is the effort associated with milk pumping problems (Odom et al., 2013). In fact, breast pumping is not always a pleasant experience for many lactating mothers: for instance, faulty breast pump techniques, poor fit, and wrong pump operations and settings are related to sore nipples and breast tissue damage (Morton, 2002; Zoppou et al., 1997). Research that included 1844 mothers shows that about 62% and 15% of samples reported problems and injuries associated with breast pumps, respectively (Qi et al., 2014). The public seems to have a too optimistic attitude toward the devices for pumping human milk, but breast pumps actually hurt mothers more than people perceive.

A comfortable breast pump will significantly support nursing mothers to continue a longer desired breastmilk feeding journey. Evidence from the literature shows that breast pumps that mothers view as comfortable and effective will facilitate babies to receive more human milk and is beneficial for health and well-being (Becker, 2021). However, breast pump-related problems are always neglected or not well studied (Buckley & Charles, 2006). Little research focuses on mothers' comfortable experience of pumping breast milk.

Apart from the overlook of pumping comfort study, the complexity and dynamic of the breastfeeding process especially the individual difference between mothers, is another barrier to addressing pump-related problems. On the existing breast pump market, limited types and designs of breast pumps can not meet mothers’ various needs; one-fits-all or few size selections for pump shields do not fit different mothers’ bodies (Dwyer, 2008).

1.3 Assignment

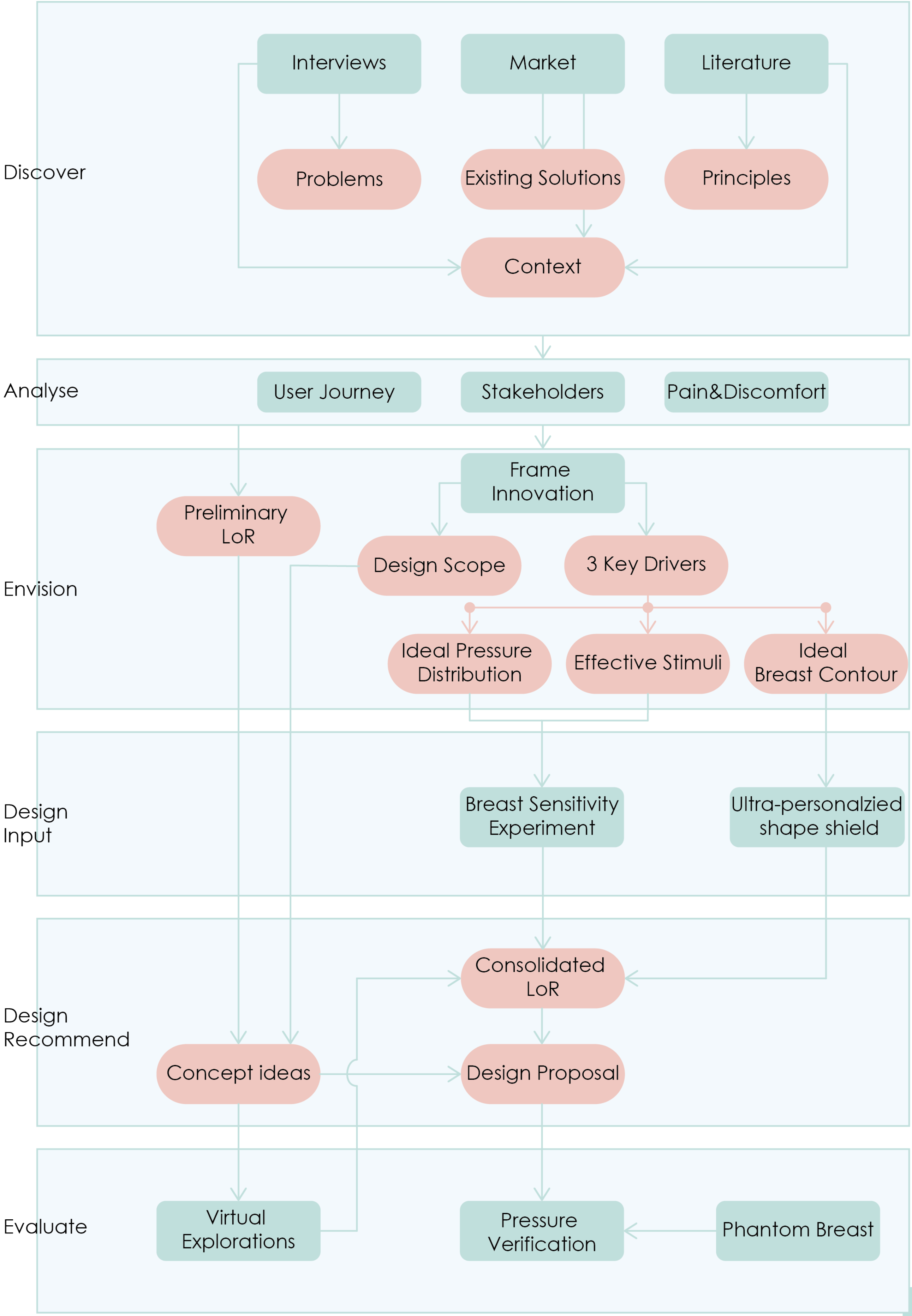
Philips Research cooperating with TU Delft within the Next UPPS project, gave assignments for exploring the comfort, user experience and nipple/areola deformations during breast pumping. These include closely investigating the body-product interactions during breast pumping, studying the cause of the discomfort, pain, tissue injuries and bad lactating performance associated with breast pumps, and exploring the possibilities of 3D/4D scanning technologies for investigating nipple/areola deformation during breast pumping. In this project, the 4D scanning parts of capturing the nipple/areola motions were excluded due to the impossibility within the time limitations. Then the data collected from the research could be used for speculating on existing breast pump products, and ideally, applied as a design approach and give recommendations for comfortable and useful electric breast pump ideas such as ultra personalisation.

1.4 Approach

This project aims to understand problems and injuries concerning breastfeeding and breast pumping, conducting research and field studies which specifically focus on the comfort of mothers. Based on the results and analysis, generating initial ideas for extremely comfortable breast pumps.

A comfortable and useful breast pump is only desirable for breastmilk-feeding mothers when considering ergonomic parameters and product experience as the centre point, which can be achieved by ultra-personalisation based on user context and mothers' physiological parameters. The ultra-personalization is only feasible when the critical parameters that influence comfort have been defined by ergonomic research and applied to design through scientific ways of anthropometric data collection and to support technologies such as additive manufacturing.

Report Structure



2 Understanding Breastfeeding

2.1 Research Method Overview

This section includes design research in the early design stage and a summary of the results. In this section, the problems was discovered with three methods; the different research methods and related research questions are listed below (Fig. Research questions):

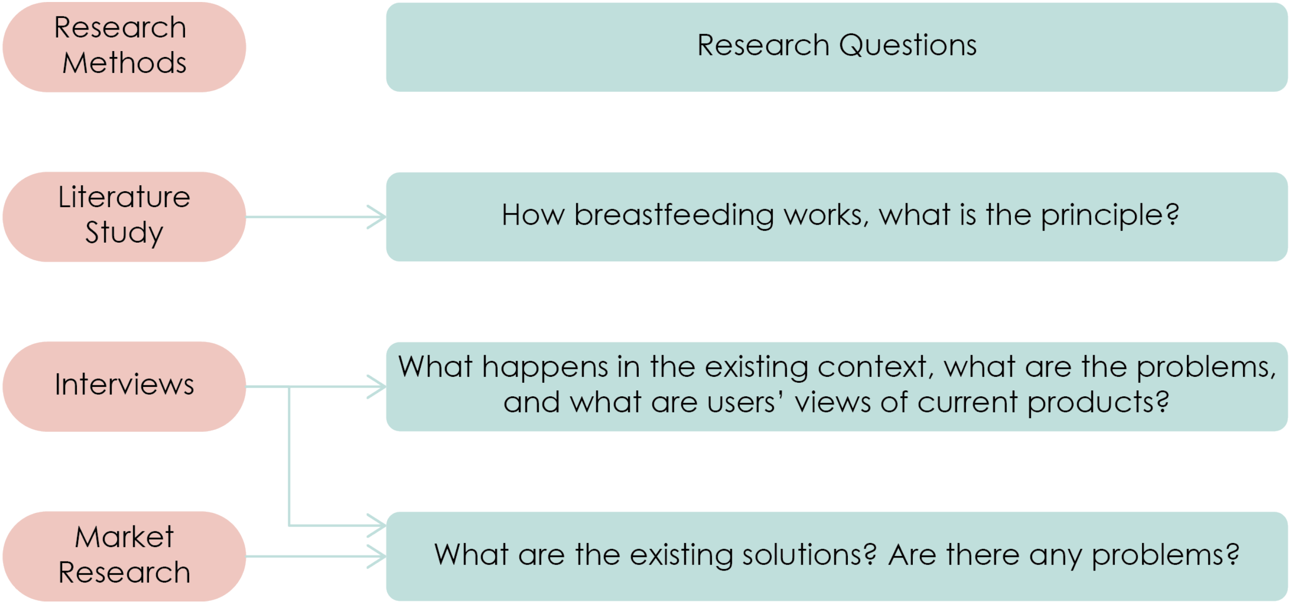


Fig. Research questions

2.2 Breastfeeding Literature Study

Articles, videos and webinars have been studied in order to understand the context and problem in essence and learn about lactation and breastfeeding principles.

Breastfeeding behaviour is a unique behaviour for infants to receive ideal nourishment supplies during the postpartum period and is profoundly influenced by the physiological parameters and behaviours of both mothers and infants (Kent, 2007). Lactation performance could be impacted by mothers' physical characteristics such as breast volume, sensitivity, the proportion of ducts and glands, and psychological perspectives like subjective views and even moods. On the other hand, infants' milk intake and sucking habits influence milk production and mothers' breastfeeding experience as well.

The breastfeeding process is a complex dynamic process with hormone effects and pressure mechanisms, which need both psychological and physical stimulation for mothers (Fig. Breastfeeding process). The let-down reflex is the most crucial mechanism in this process; only quite a small volume of milk will be expressed without the ejection reflex (Kent et al., 2003). The associated hormones are prolactin and oxytocin, which work for making milk and releasing milk, respectively. The stimulation of the nipple initiates nervous impulses transmitted to the hypothalamus, which stimulates the oxytocin release to the blood by the posterior pituitary gland. After the oxytocin has been released, myoepithelial cells start to contract alveoli, forcing milk to go into the ducts. This leads to intraductal pressure change and duct dilation, and as a result, the milk flow comes out (Newton, 1948; Ramsay et al., 2004).

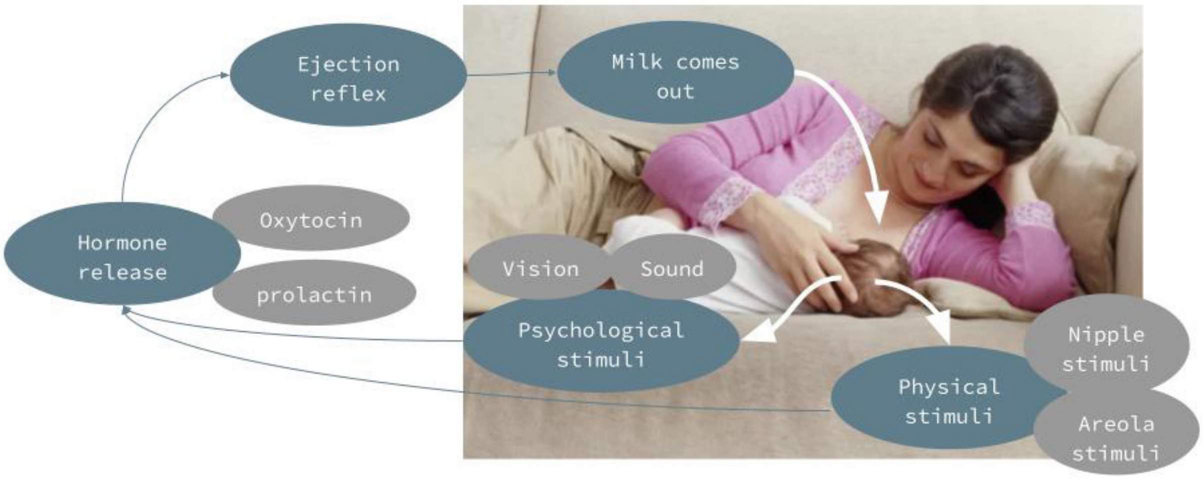


Fig. Breastfeeding process

The breast pumps almost imitate the patterns of natural breastfeeding and infant sucking behaviours. Infants use their jaws, tounges, soft palate and hard palate together to apply pressure to the breast for suckling milk; breast pump shields simplify the shape of infants' mouths to a funnel shape and apply pressure through a pump.

2.3 Existing Breast Pump Product

Existing versions of Philips breast pumps and competitors' products from other brands on the market have been studied via videos, customer reviews and other literature associated with the products, and 7 of them were tried by myself. The findings are summarised below:

1. When I was trying seven breast pump shields of different brands (with different shapes and sizes), I found the local perceived pressure applied to different breast areas changed a lot when the shape and size changed.

2. Most products have one-fits-all shields, and some of them have limited size choices for the tunnel diameters: Medela PersonalFit Flex Breast Shield has four tunnel sizes; The Liquid Shield Kit system from Pumpables has 4 sizes of silicone flange inserts (17mm, 21mm, 25mm and 29mm) to match the hard shields.

3. Many brands try to improve the comfort of breast pumps by making some changes to the shield shape, and some of them get positive feedback from users. Medela alleges their Freestyle Flex™ products with a 105° opening angle for the funnel, which is wider than the traditional 90° shields, are nicely match the breast contour and more comfortable (Medela, n.d.). PumpinPal angled the flanges and put the sucking pressure back to the less sensitive upper part of the breast (Pumpin Pal, n.d.).

4. There is a trend for breast pump designs to imitate infants' sucking behaviours and physical structures of the mouth; for instance, BabyMotion Flange from LacTech mimics babies' tongue movement (LacTech, n.d.).

5. Convenience and portability have become another trend in electric breast pump products such as Elvie Pump, which can be put inside the bra, and mothers can pump and do other things at the same time.

Fig. PumpinPal angled shields (Pumpin Pal, n.d.)

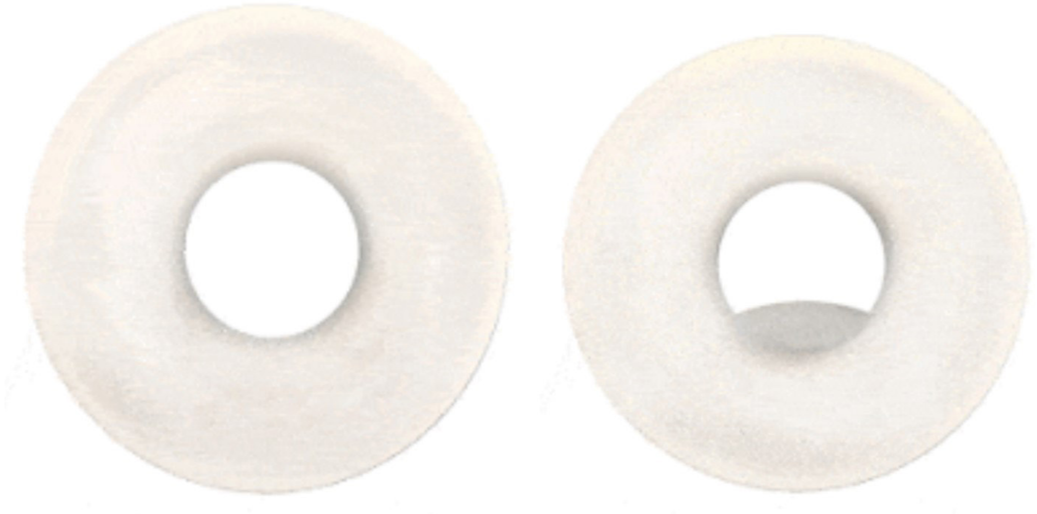


Fig. LacTech silicone flange (LacTech, n.d.)

2.4 Interviews

Eight mothers and one lactating expert were interviewed. The full interview setup and notes can be found in Appendix. Interviews.

The interviewees were in age 27 to 42 from 4 countries. The sample covered mothers with different pump dependencies, numbers of children (and a mother who gave birth to twins), views on breast pumps and multiple backgrounds.

The questions setup are from four perspectives:

1. Questions for breast pumps they used/are using. For example, how often they used/use it; the most comfortable breast pump using experience, and a most terrible one.
2. Pump-related discomfort and injuries. How did they deal with the injuries, and did they know the reasons?
3. Other problems they met associated with breast pumps.
4. Experience of breastfeeding at the breast, and the comparison between feeding milk with bottle and breast.

The interview results are summarised:

1. Most mothers like feeding babies at the breast rather than expressing milk, physically and psychologically. 3 interviewees think babies' suckling is more comfortable than pumping; 4 interviewees think in general the feelings of the two breastfeeding ways are similar, but they prefer babies because it is more relaxed, happy and usually more efficient; one participant thinks pumping is more comfortable than babies' suckling as her baby has latching problems, and sometimes make her painful with teeth, but she still preferred feeding with the breast.

2. Mothers agree that breastfeeding takes much time and effort. The efforts come not only from breastfeeding itself but also from the stuff that comes with it: such as cleaning and disinfecting the bottles.

3. Two of eight mothers gave up breast pumping in the first several weeks of giving birth. The main reasons were that breast pumps caused pain or pumps could not express enough milk.

4. Not hurt, easy to use, perfectly fit, expressing more milk in a short time and portable are several keywords that mothers mentioned most for views on an ideal breast pump; not too expensive and easy to clean were also mentioned a lot.

5. Hardly any mother's breastfeeding journey went well from beginning to end; some think breastfeeding is even more unbearable than childbirth.

6. Mothers with sensitive breasts and high breast pump dependency are easier to suffer pain and discomfort.

After that, the participants were asked to mark the areas they felt uncomfortable or painful during or after pumping milk. 5 of 8 participants marked on the pictures (Fig. Uncomfortable areas of breast pumping), and 2 participants forgot which certain areas were uncomfortable. Only one participant said she has never experienced any problems in breast pumping.

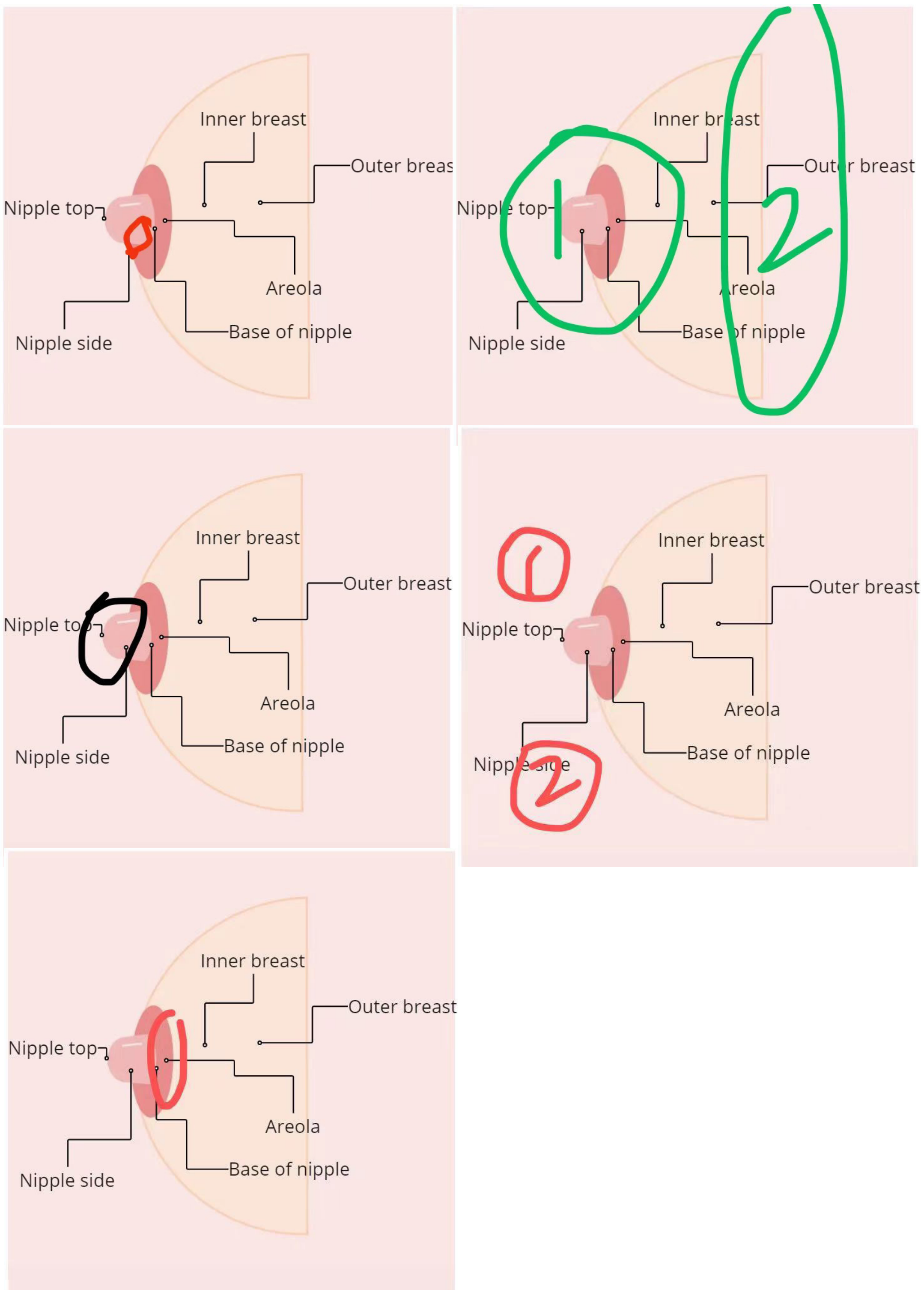


Fig. Uncomfortable areas of breast pumping

3 Analysis & Insights

Introduction

From the previous research, I found pump-related pain and discomfort have individual differences in areas, types and levels, but the similarities were still vague. In order to find what is the crucial influence of pain and discomfort and what is the common issues, this chapter tries to simplify the problems by dividing the users with similarities into groups and analysing contexts around them. The analysis used the user journey map (3.1 User Journey Map) and stakeholders analysis (3.2 Stakeholders in Breastfeeding) methods as the approach. By understanding the context further, exploring what mothers value the most, and finding different reasons for pain and discomfort in different user scenarios, the Breast Pump-Related Pain and Discomfort (3.3) was summarised in the last part of this chapter.

3.1 User Journey Map

3.1.1 Persona

The literature considers that one of the most critical parameters of breast pump selection is to what extent breast pumps replace infants to regulate lactation (Meier, 2016; Felice& Rasmussen, 2015). And it divides the mothers' dependency on breast pumps into minimal, partial and complete dependency. The Interview results also show the importance of breast pump dependency: mothers meet different problems and choose different breast pump products depending on their use frequency. For instance, mothers who have a high breast pump dependency would be easier to feel pain, and they would chose ma. Therefore three lactating mothers' persona regarding three breast pump dependency degrees: minimal, partial and complete dependency, is created for analysis. The characters' personalities, lives, and user journey context is based on the interview results and literature studies.

3.1.1.1 Minimal breast pump dependency user

The first mother's name is Lupita; she is 29 and lives in the Netherlands. She had her first baby 2 months ago. She has enough time to take care of her baby and breastfeed. Lupita does not like pumping milk and bottle feeding because she likes to have intimate interaction with her baby, but the breast pump is just a device. So she occasionally pumps to relieve breast fullness when her baby is not hungry at that moment.

3.1.1.2 Partial breast pump dependency user

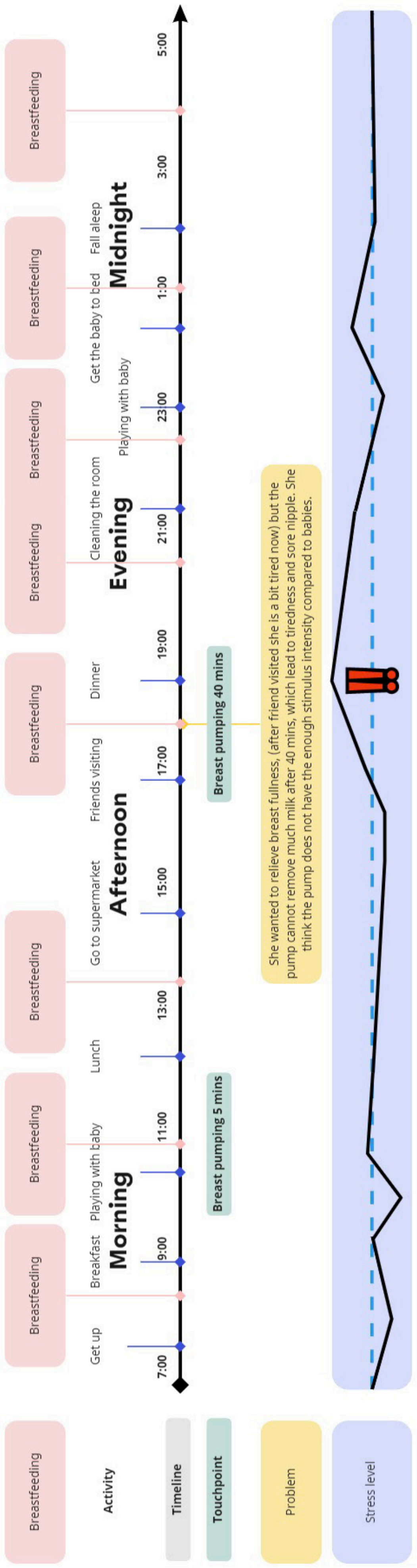
The second mother is Xia, an old mother (42 years old) coming from China. She is a product manager in a big company and gets really busy work. After 3 months of giving birth to the second baby, Xia went back to work. She pumps breastmilk at work and feeds the baby at the breast during the night and on non-working days. However, working overtime is common in the company, so she cherishes the motherent of being together with and feeding her baby by breast.

3.1.1.3 Complete breast pump dependency user

May is 31 and lives in the US. She exclusively pumps milk for her preterm baby who cannot drink properly, so she fully depends on breast pumps. Moreover, this baby is her third baby, so she is quite familiar with using breast pumps, and has a large amount of breast pumps collections.

3.1.2 A Day of Life for Three mothers

A day of life presents a normal breastfeeding day for three mothers. Pink bubbles show how often mothers breastfed (either with bottles or breasts) within the whole day; green bubbles show how often they use breast pumps. The bottom curves indicate their stress level changes within one day; red exclamation marks indicate when the stress increased to a high level, and yellow bubbles mark the problems.



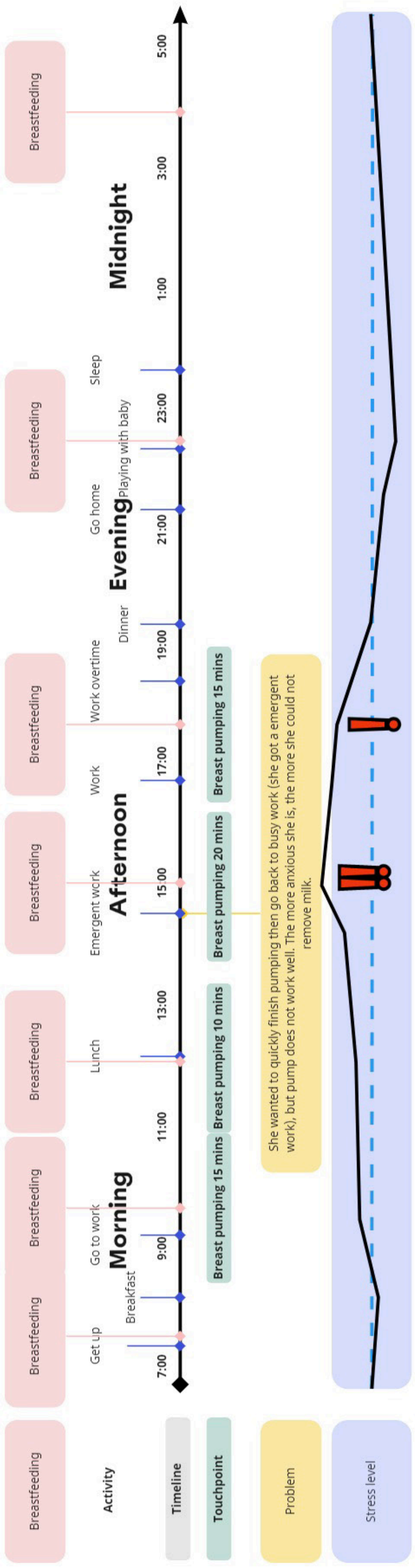
She wanted to relieve breast fullness, (after friend visited she is a bit tired now) but the pump cannot remove much milk after 40 mins, which lead to tiredness and sore nipple. She think the pump does not have the enough stimulus intensity compared to babies.

A breastfeeding day of April

April feeds her baby or expresses milk 8 to 9 times per day. After a friend visited at 17:00, she was a bit tired and wanted to relieve breast fullness, but the pump could not remove much milk after 40 minutes, which led to more tiredness and sore breast. She thinks the pump does not have enough stimulus intensity compared to babies.

A breastfeeding day of May

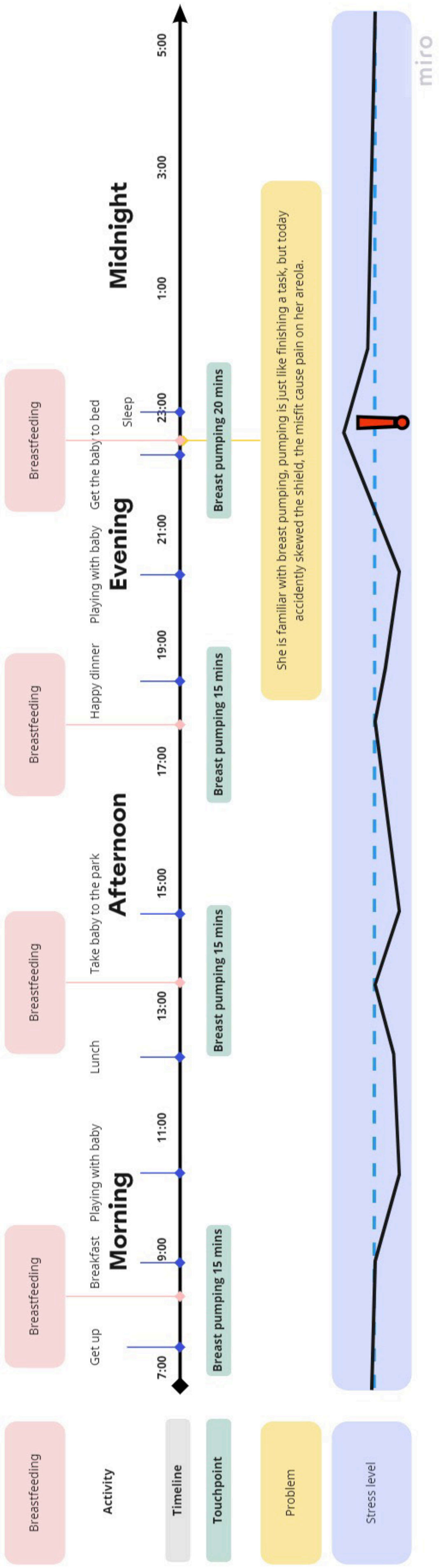
May pumps 3 to 4 times at work during the daytime. She was busy in the morning; after lunch at 14:00, she got an emergent assignment, so she wanted to finish pumping quickly and then go back to process it. However, her breast pump did not work well even though she tried the most intensive vacuum level. The more anxious she was, the more she could not express the milk.



She wanted to quickly finish pumping then go back to busy work (she got a emergent work), but pump does not work well. The more anxious she is, the more she could not remove milk.

A breastfeeding day of June

June is familiar with breast pumping; she does it approximately four times on a almost fixed schedule every day. For her, pumping is just finishing a task. But today, she changed a new shield and accidentally skewed the shield; the misfit caused pain to her areola.



She is familiar with breast pumping, pumping is just like finishing a task, but today accidently skewed the shield, the misfit cause pain on her areola.

3.2 Stakeholders in Breastfeeding

The stakeholders analysis aims to further understanding the scenario. Apart from trying to find what mothers value the most, it is also important to find what other stakeholders' needs would influence mothers' choices. Other minor stakeholders are also possible to be the causes of problems. The other advantages is that by understanding the stakeholders in the contexts, it is possible to find some approach and solve the problems in other ways.

3.2.1 Breastfeeding families

3.2.1.1 Mothers

Mothers are the most important stakeholders in breastfeeding. Nevertheless, most mothers lack knowledge and support for pumping breast milk. They get experience and tips from friends and experts, but not enough to cope with changeable situations and multiple breastfeeding issues. When a problem happens, mothers may blame their bodies instead of breast pumps.

Many mothers think breast pumping is just “finishing a task” and they hardly feel any pleasure while doing this task, but feeding babies at the breast is more than that. Mothers enjoy breastfeeding directly by touching, hugging and having intimate interactions with their babies.

What mothers value the most for breastfeeding is in two aspects: their own well-being and comfort, and their baby’s well-being. When there are contradictions between the benefits of two aspects, mothers tend to sacrifice themselves in order to maintain a sufficient milk supply for babies. In some cases, mothers even compromise on comfort to improve milk expression or removal efficiency; some of them believe that they need to tolerate discomfort or pain to increase speed (Becker, 2021).

3.2.1.2 Infants

The needs of infants mainly show up in milk intake. Babies need sufficient nutrition to grow up, and the milk intake change throughout growing before the baby’s weaned. The suckling behaviour is another parameter, if an infant could not drink properly, a breast pump becomes necessary.

3.2.1.3 Other family members

Fathers usually have a role in breastfeeding by feeding babies with a bottle. What they desire focuses on the well-being and happiness of mothers and babies. As for themselves, they have similar needs for breast pumps as their wife: easy and efficient to use, easy to clean.

3.2.2 Lactating experts

For healthcare professionals, settings, sizes and types of recommendations for breast pumps are often given based on personal experience due to lack of evidence and limited choices (Meier et al., 2016). They said the most useful way for breast pump selection is“have a try”, as they usually lack data and information on both customers and products. Lactating experts can always give useful suggestions for breastfeeding families based on rich experience, but they need more scientific evidence support and more breast pump product options so they can recommend to users the most suitable one.

3.2.3 Breast pump manufacturers

Manufacturers want more feasible and innovative breast pump solutions. There is a large number of breast pumps in the existing market; the innovation needs to make the product stand out from other competitors; on the other hand, lowering the cost of production is an important requirement as well.

3.3 Breast Pump-Related Discomfort and Injuries

3.3.1 Summaries

After the analysis of users, stakeholders and contexts, combing the notes from interviews, I found that the most mentioned typical pump-related problems are:

Sore nipple/areola on account of pumping too long;
Injuries/discomfort caused by shield misfit (For example, nipple sides rub the tunnel side; areola goes into the tunnel and is hurt by the flange; funnel part applies too much pressure on the breast);
Anxiety and depression about unsuccessful pumping or inefficient pumping;
Numbness in which the feeling of themselves as a “milk machine” because of psychological distinctions compared with feeding babies at the breast, and annoyance because of taking up too much personal time.

3.3.2 Assumptions

According to the summaries in 3.3.1, I made some assumptions based on the reasons for pump-related discomfort and injuries.

Firstly, pumping too long typically happens when mothers feel pumps have weaker pressure than babies' mouths or when mothers have a high-stress level; the low efficiency of milk let-down reflex is, in essence, because of poor hormone release (Kent et al., 2003).

Secondly, discomfort is a signal of pain (Ashkenazy & Ganz, 2019) ---- the brain is warning there are risks of tissue damage. Mothers may neglect some discomfort at the beginning of milk expression on account of the urgent context, or the discomfort is covered up by breast swelling pain. Long-time discomfort may lead to pain.

Finally, mismatches cause the contact pressure to be unevenly between the shield and the breast. Gaps between the breast and standard shield lower the contact areas, then improve the pressure (Fig. Discomfort/pain caused by mismatch). And the tissue deformation is different under uneven pressure, which would lead to tissue damage in the areas that are stretched/pressed too much.

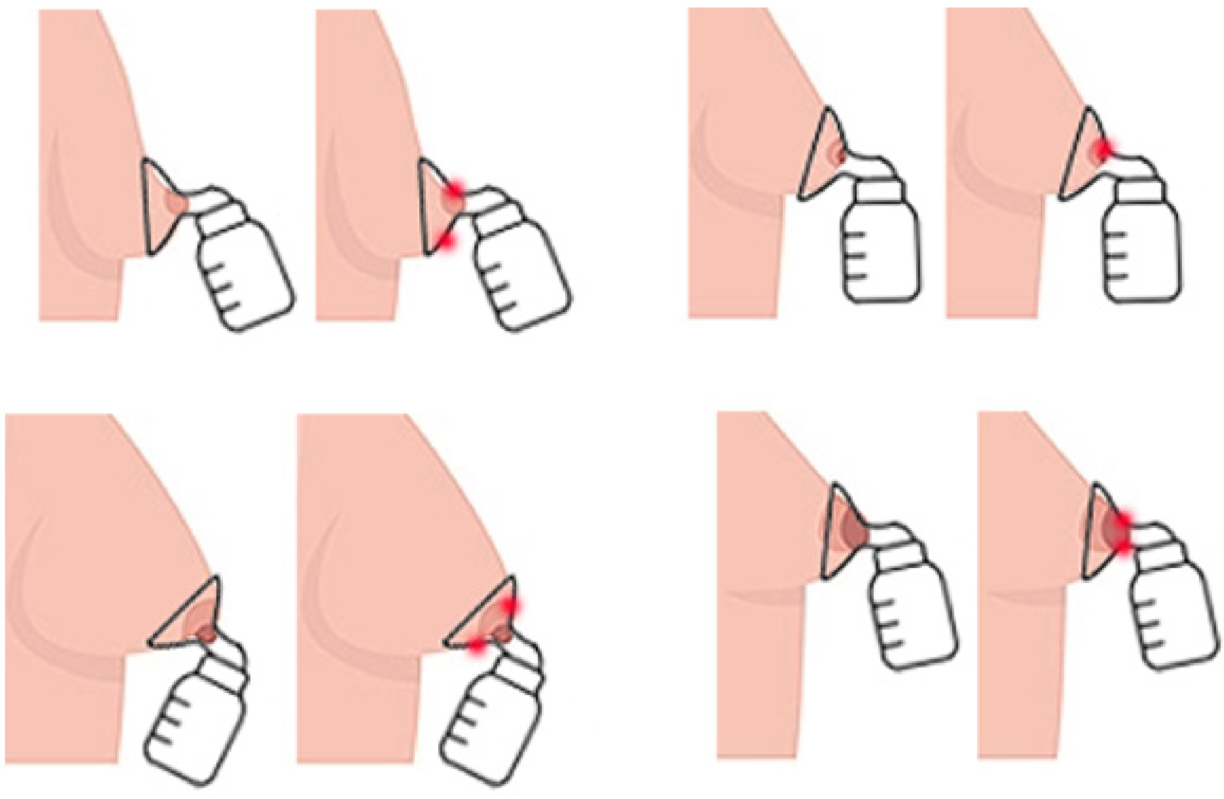


Fig. Discomfort/pain caused by the mismatch. (The red marks mean painful/ discomfort areas)

4 Envisioning

4.1 Comfortable Breast Pumping

According to the Oxford Dictionary, the word “Comfort” is defined as “the state of being physically relaxed and free from pain” and “a feeling of not suffering or worrying so much; a feeling of being less unhappy”, which indicates that “comfort” includes both physical and psychological perspectives. Regarding comfort in breastfeeding, it is challenging to consider physical and psychological comfort separately; mothers sometimes cannot distinguish them. Physical comfort always leads to psychological comfort (it is quite reasonable that mothers feel relaxed when there is no pain or body discomfort, and less worried and less unhappy when they see the milk comes out really well); psychological distinctions influence mothers’ judgment of physical comfort levels (mothers ignore some physical unwellness when they feel happy and relaxed, and more oxytocin tricks the brain that they are in an easy state).

The principles of breastfeeding are presented in the casual model (See the Figure. Casual model). There are some vicious circles in which the more mothers feel stressed, the less milk comes out, so they get more stressed, and easier to suffer pain.

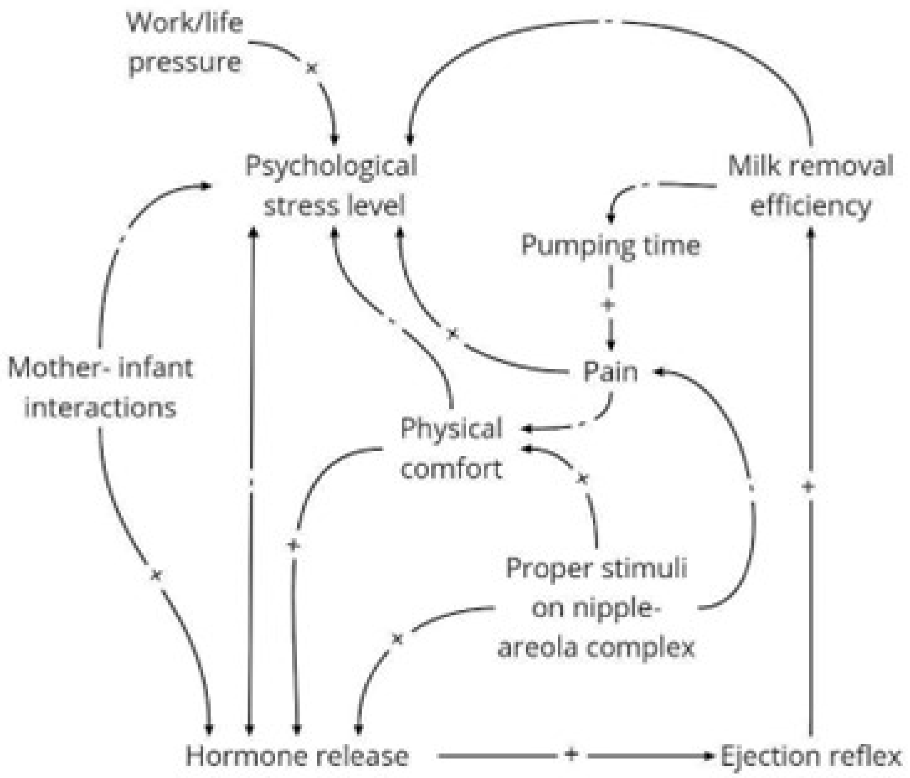


Fig. Casual model. "+" means the parameter is positively related; "-" means the parameter negatively influences the other that the arrow is pointing at.

4.2 Frame Innovation

4.2.1 Archaeology of Existing Context & Earlier Attempts

As mentioned and discussed earlier in the 3 Analysis & Insights, we can see a lot of pumping problems. Lactating experts, breast pump manufacturers and mothers themselves attempt to solve these problems in some smart ways:

For pain and discomfort problems, mothers attempt to try and buy a large number of different brands of breast pumps to find the most suitable one, especially for mothers with "nonnormal" sizes of the nipple and high breast pump dependency. And they use different breast pumps for different situations, such as using portable pumps at work, using comfortable electric pumps at home, and for releasing emergent breast fullness, they chose manual pumps.

As for mothers' breast sizes and sensitivity may change every day, they usually use a silicone insert put into the tunnel part to make the size smaller, or change to different sizes of shield to make breast pumps more fit.

Psychological effects are considered important. mothers are told that they need to keep a good mood during lactation. Sometimes nurses suggested them to watch babies' videos and pictures while pumping milk.

To make breast pumping easier, mothers may warm compress the breast before pumping milk. Moreover, breast massage by prolactinists is quite popular among Chinese mothers.

4.2.2 Paradox: Why are breast pump-related problems hard to solve?

Three paradoxes make breast pump-related discomfort and injuries still happen frequently even though there have been many products on the market:

Firstly, psychological effects are crucial to improve oxytocin release for milk ejection, which is increased by intimate interactions such as seeing, listening and touching babies. Apparently, mothers do not have emotional connections with breast pumps.

Secondly, hormone release is also negatively related to stress levels, but people all have bad days. Fatigue, anxiety and sad moods influence lactating performance; keeping mothers happy all the time is unrealistic.

Finally, shield mismatch is the main reason for pain and discomfort, but perfectly fitting is impossible for existing products as users have unlike breast shapes and sensitivity.

4.2.3 Reframe Breast Pumping Problems

As previously discussed, two primary problems are:

1. Breast pumping lacks emotional stimuli;
2. Mismatches cause pain and discomfort.

For the former problem, according to the diagram (Fig. Casual model) in 3.4, improving proper physical stimuli on the nipple/areola can make up for the psychological deficiency in the breast pumping system. Therefore "Breast pumping lacks emotional stimuli" can be reframed as "Breast pumping could have more effective physical stimuli". External drivers that benefit hormone release are approaches as well (Fig. Design approach).

For the latter problem, as discussed in 3.3, problems associated with "mismatch" reported by mothers are in essence too much compression, friction or vacuum pressure applied in certain areas of the breast, due to mothers with diverse breast shapes and sensitivity pumped with "not diverse enough" shield shapes and vacuum intensity. Even though a breast perfectly fits the shield, existing breast pump designs think less about the appropriate force that can be applied and users' local perceived discomfort. Therefore apart from shields not fitting breast shape, "Mismatch" is actually "poor pressure distribution".

In conclusion, the two main problems mentioned at the beginning of 4.2.2 are framed as:

1. Breast pumping could have more effective physical stimuli;
2. Poor force distribution caused pain and discomfort.

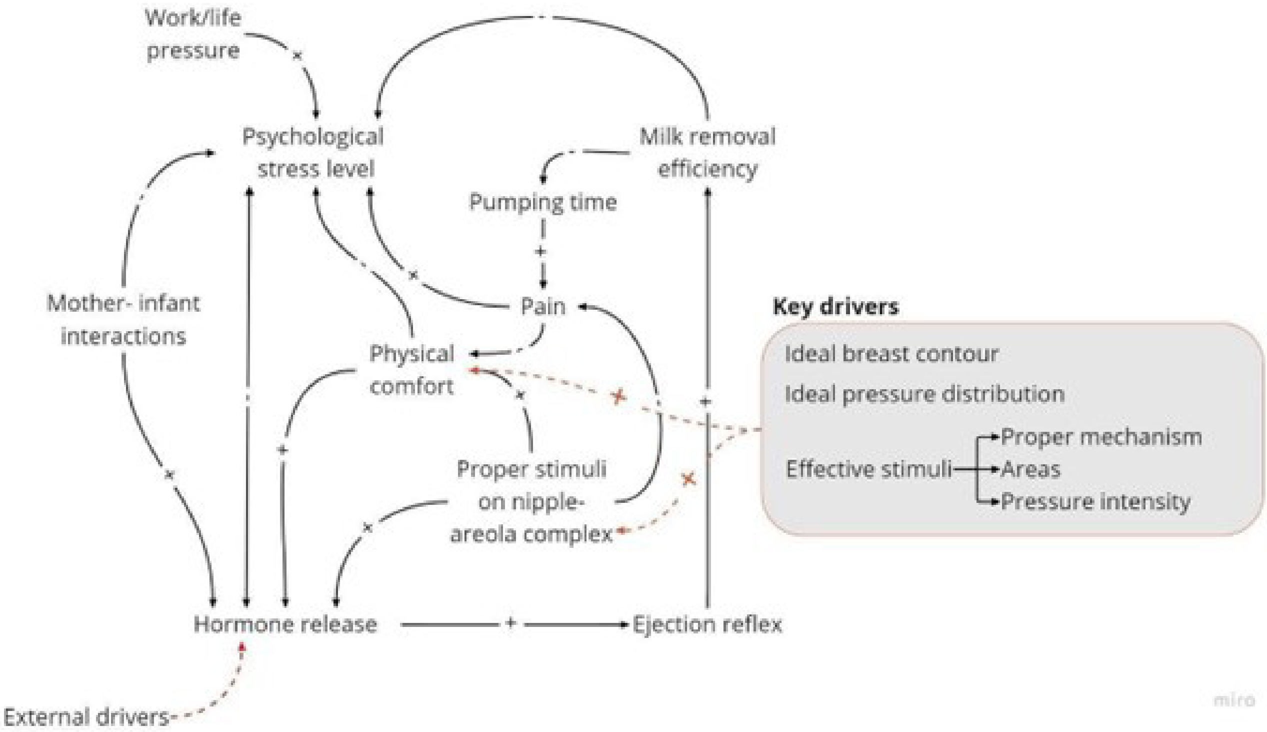


Fig. Design approach.

4.3 Design Scope and Vision

Based on the analysis of research results, the design scope for this project focuses on physical comfort during breast pumping: An ultra-personalized breast pump shield functions with proper vacuum intensity based on ergonomic considerations: ideal breast contour, ideal pressure distribution and effective stimuli on nipple and areola. The research will focus less on psychological aspects, milk production and milk quality of breast pumping. However, as mothers' moods have a critical influence on hormone release, some external drivers to stimulate hormone release will also be considered.

What can be personalised?

The influential parameters below are some directions that are different from mother to mother, therefore can be personalized for breast pumps.
1. Mothers' breast sensitivity (it relates to different biological tissues). When applying the same pressure on the breast, some mothers feel nothing but others feel pain. I get an assumption that women have individual differences in breast sensitivity but have similar sensitivity-distributing principles.

2. Mothers' breast shapes. For one-fits-all shields or 3-sizes shields, the largest pressure may apply to different areas of the breast for different breast shapes. A personalized-fit shield will control the largest pressure to apply on similar breast areas. Even for one user, the shapes of her left and right breast are different.

3. Lactation stages/before and after pumping. The breast sensitivity and shape change a lot in different lactation stages; they even change every day based on mothers' moods and physical conditions; when the breast is full of milk, it is stiffer; after removing the milk, the breast turns softer. The degree of change varies from mother to mother.

4. Babies' needs. Babies need different milk supplies and have a different dependency on bottle-feeding or feeding on the breast; their needs change during the whole lactation period.

What is ultra-personalisation?

The personalized product is designed depending on users' data, preference and behaviors, and give users' desired products or services which are fixed; ultra-personalization is something more: the product becomes dynamic, it changes following the users' interactive behavior and habits changes (Bika, 2021). In addition, personalized products and services are different within multiple user groups, while ultra-personalized products and services are varies from different single users.

5 LoR & Consolidating Plan

5.1 Preliminary Design Requirements

A preliminary list of requirements is generated from previous research and analysis, which includes general design requirements:

1. **The shield design depends on women's breast contour and sensitivity.** From the interview, I found that women's different breast shapes caused mismatch, and their breast sensitivity is different but may follow a general principle.

2. **The shield shape can be adjusted by mothers.** Even though the breast shield shape is the same as women's breast shape, women's breast shapes keep changing during nursing.

3. **The mechanism needs to be adjusted during breast pumping.** It is because both breast softness and sensitivity reduce after milk comes out.

4. **Compression stimuli and vacuum for milk removal should be applied separately.** From the literature, I found that vacuum and compression do not have relationship when they are conducted by babies' suckling. And the simultaneous compression applied together with the vacuum (for milk removal) blocks the milk ducts.

5. **Less friction should be applied to the nipple-areola complex.** Some mothers mentioned they felt uncomfortable when their nipples or areola were rubbed on the shield sides or flange connections, especially in long-time breast pumping and shield mismatching.

6. **External drivers that are beneficial for hormone release should be considered.** According to the causal model analysis, it is possible to think about some ideas to make up for the psychological stimuli loss in breast pumping as a result of infants' absence.

7. **The breast pump should be easy-to-use.** Pumping takes mothers' a lot of time and effort every day, the breast pump should not bother them more. There could be fewer components in the design, and the pumps should be easy to clean.
The efficiency of breast pumps should be improved. Some mothers said babies are "the most efficient breast pumps", the real pumps usually take more time for milk removal than feeding milk on the breast. Someone thinks the pump vacuum is not strong enough so it can not drain the breast milk.

8. **The breast pumps should fit various contexts.** For example, a mother mentioned in the interview that she has different pumps for different situations. When staying at home, she uses handy and comfortable Medela electric breast pumps; when pumping at work, she prefers Horigen wearable breast pumps with convenient milk storage.

9. **The breast pump should provide enough stimuli on the nipple.** The lactating expert said silicone shields do not work for some mothers because the silicone rubber is too soft and cannot give enough stimuli to the nipple-areola complex. (but what is enough stimuli?)

10. **The shield should protect the nipple and areola, especially the nipple areas while applying the vacuum.** A lot of mothers reported sore nipples caused by breast pumping. Most mothers think their nipples and areola are easy to get painful and uncomfortable when pumping milk. It can be assumed that the nipple part is sensitive for many women, and it should be protected while pumping. (So the nipple-areola is more sensitive than other parts, how sensitive they are?)

5.2 Consolidating LoR

The preliminary list of requirements discussed above represents the general needs of mothers and basic theories of the existing context. However, there are still a number of unknown barriers that still need to be explored. Even though some clues could be found from the interviews, no reliable and scientific conclusions were made. In order to make the LoR more detailed and compellent, the action plan method was used to explore further to consolidate the design requirements list. This process started with the key problems: ideal breast contour, ideal pressure distribution and effective stimuli. one experiments and two explorations were conducted to explore the following problems:

1. What is the pressure distributed on "perfectly fit" breast shields? (Ideal breast contour)
2. What is the proper vacuum? What are positive pressure sensitivity differences in different breast areas? (Ideal pressure distribution)
What is the proper pressure to stimulate the nipple-areola complex? (Effective stimuli)
3. After the exploration of the three problems above, the ideation and concepting was done based on the same 3 key drivers and 1 external driver for stimulating hormone release. Then users and experts were asked for their feedback and opinions about those concepts. The feedback was used to develop concepts and

modify the list of requirements.

In the end, a final version list of requirements and a design proposal will be proposed to give guidance and recommendations for personalized breast pump designers with strong evidence.

6 Key Drivers Exploration

6.1 Known and Unknown

As discussed in the previous part, the key drivers to promote physical comfort are ideal pressure distribution of the shield and effective nipple-areola stimuli. In order to solve these two primary problems, this section analyses what existing evidence from the literature is and what is something that needs further exploring; later on, experiments were designed for the unknown parts to get the supporting evidence. Further consolidated LoR and design recommendations will be made based on the findings.

6.1.1 Ideal Breast Contour

The ideal contour is possible to achieve by either direct 3D scanning (Lee, 2015) or parametric modelling, combing key parameters and existing data (Chu, 2017). Multiple non-contact measurement technologies have been developed to get the body geometry. Mothers can personalise the breast pump shield based on their breast shape.

Therefore the ideal breast contour can relatively easily be implemented by existing technology, but would a perfectly-fit shield actually provide a better force distribution? The previous research (see 3.3) shows that the shields which are not fit would cause some pain and even tissue damage, and it could imagine and infer from experience that a breast pump shield with personalized shape would create more uniform pressure. However, what exactly the pressure will differ compared with traditional breast pump shields? The first step to adjust and optimise the pressure distribution would be exploring the pressure patterns of a perfectly-fit shield under an existing vacuum system.

6.1.2 Ideal Pressure Distribution

The ideal pressure distribution involves applying different proper forces to different areas with various perceptions of discomfort, and it is only feasible when the shield is perfectly matched. As breast shape and perceived discomfort vary from person to person, we will discuss the possibilities for personalized breast contour and personalized local pressure system.

The pressure sensation and perceived discomfort in different breast areas are relatively unexplored. Zoppou et al. (1997) simplify the dynamic force of breast pumping to axial suckling and radial compression, which is vacuum pressure and positive pressure applied on the teat. There is positive pressure conducted on the breast by breast pump shields or infants' palates and tongues, which is an indirect result of vacuum pressure. Still, recent research regarding breastfeeding pressure within infants' mouths shows no obvious relationship between vacuum and areola compression (Alatalo, 2020). Therefore, the two forces are applied independently, ideally not simultaneously: compressing the superficial ducts inside the breast may indeed compromise milk flow. Experiments to find the discomfort thresholds by applying separate vacuum and positive pressure on breast sections are possible to explore this problem.

6.1.3 Effective Nipple/Areola stimuli

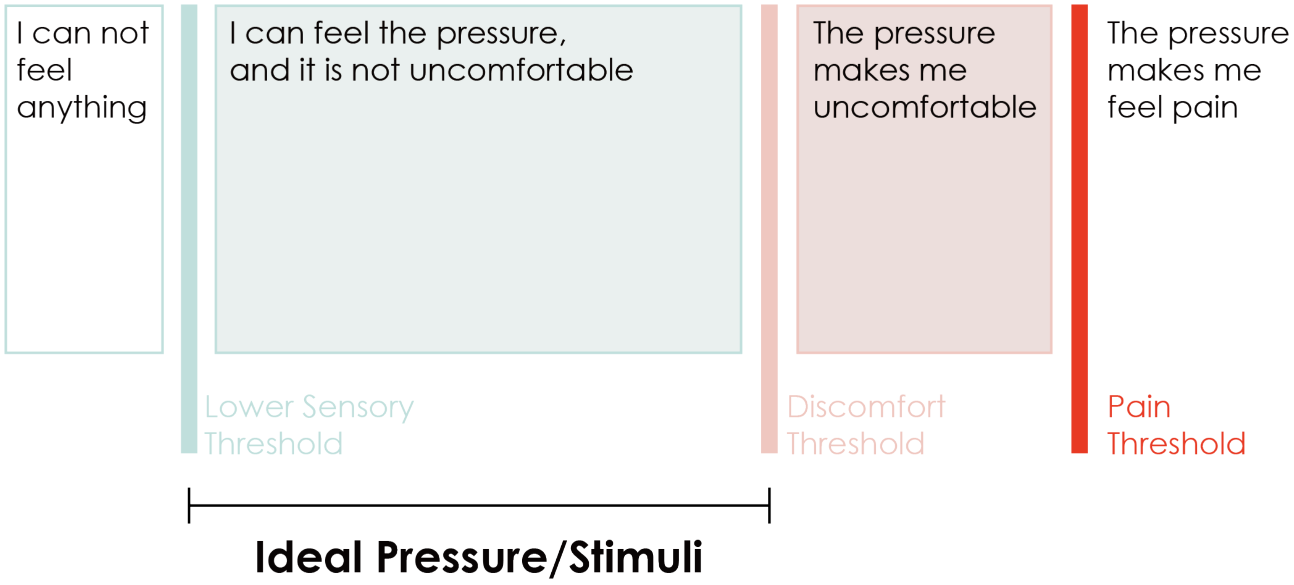


Fig. Lower sensory threshold - discomfort threshold - pain threshold

Effective physical stimuli on the nipple-areola complex include three perspectives: the areas —- where to stimulate; the stimulating mechanisms —- how to stimulate; and pressure intensity —- to what extent we apply the stimuli.

The areas and stimulating mechanisms have been explored in lots of research. Research (Alekseev et al., 2000; Alatalo, 2020) indicate that the rhythmic oscillatory positive pressure continuously stimulates the nerve endings at the nipple-areola complex, leading to milk ejection; The compression stimuli (Alekseev, 1998; Alekseev & Ilyin, 2016) have been proved as a useful mechanism for the let-down reflex compared to others.

The relation between compression intensity and milk ejection is explored in some research (Alekseev et al., 1998), but the relation between compression intensity and mothers' perceived (dis)comfort is unexplored. The resolution of compression consists of several radial vertical forces towards the teat and areola; the force needs to be in the range of tactile thresholds and discomfort thresholds (mothers should feel the pressure but not feel discomfort). Experiments can be designed to find the two thresholds on the nipple and areola sections.

6.2 Breast Sensitivity Research

6.2.1 Analysis

This part includes the literature study towards current breast sensitivity and anatomy research. Some assumptions was made after collecting the findings and the research questions was proposed based on the findings

6.2.1.1 Breast Sensitivity

Pressure sensitivity is related to skin and underlying body tissues; it influences (dis) comfort in particular body areas (Vink & Lips, 2017). Designers usually apply less pressure to sensitive areas by changing the product form and softness. Nevertheless, breast sensitivity has a broader meaning: The pressure sensation at the nipple-areola complex can be identified as a “positive sensation”: the more sensitive the nipple-areola complex is, the more oxytocin will be released by stimulation, then the easier ejection reflex will be caused for milk removal. On the contrary, the pressure sensation for the rest of the breast tissue is considered negative; the more sensitive the areas are, the more discomfort mothers will perceive. As discussed in 6.1, breast sensitivity includes touch and positive pressure, which need to be explored to find the lower sensory thresholds and discomfort thresholds.

6.2.1.2 Breast Anatomy Map

According to the breast anatomy map (Fig. Breast anatomy), small milk ducts are below the nipple, with the end of ducts on the nipple top, and the milk ducts branch from the base of the nipple; The areola contains several glands and tubercles of Montgomery glands opening in the peripheral. Tubuloalveolar glands, lactiferous sinus and milk ducts distribute under the skin, and they are thinner in the outer breast areas and thicker in the inner breast areas. Intraglandar fat is between them. Subcutaneous fat is far from the breast centre, covering the gland tissues deeply below (Jesinger, 2014; Geddes, 2007; Pandya & Moore, 2011). We can see from the figure (Fig. Breast sensory innervation) that different intercostal nerves and anterior nerves support the four quadrants of the breast. Furthermore, there are more nerve branches when close to the centre area of the breast (Prendergast, 2015).

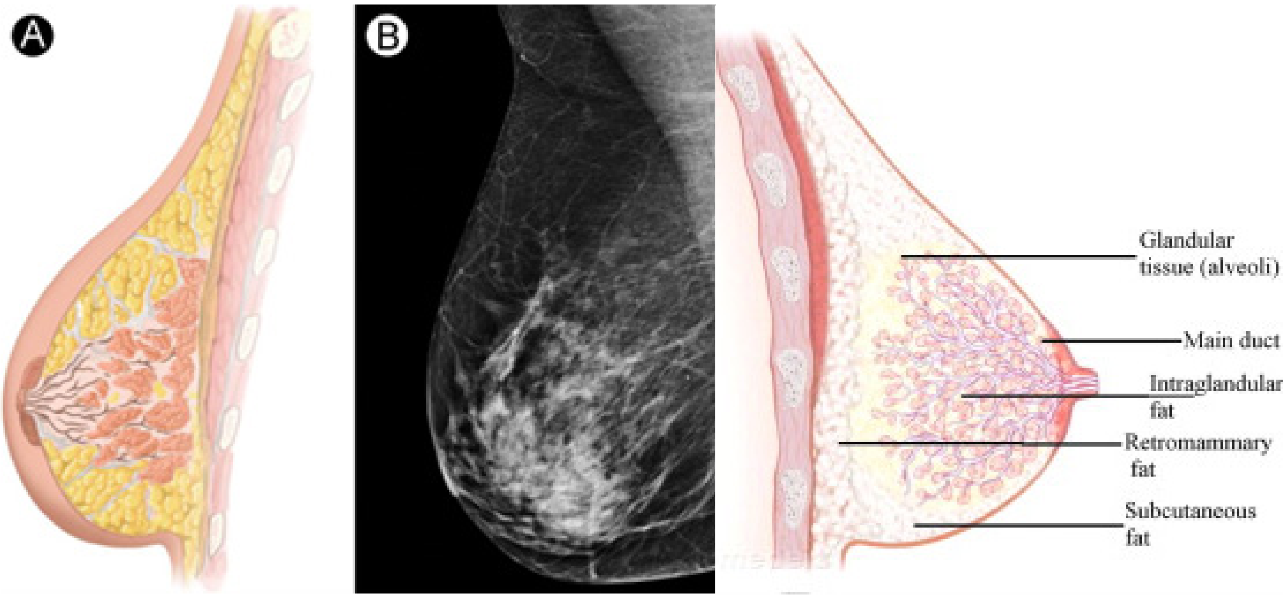


Fig. Breast anatomy (Jesinger, 2014)

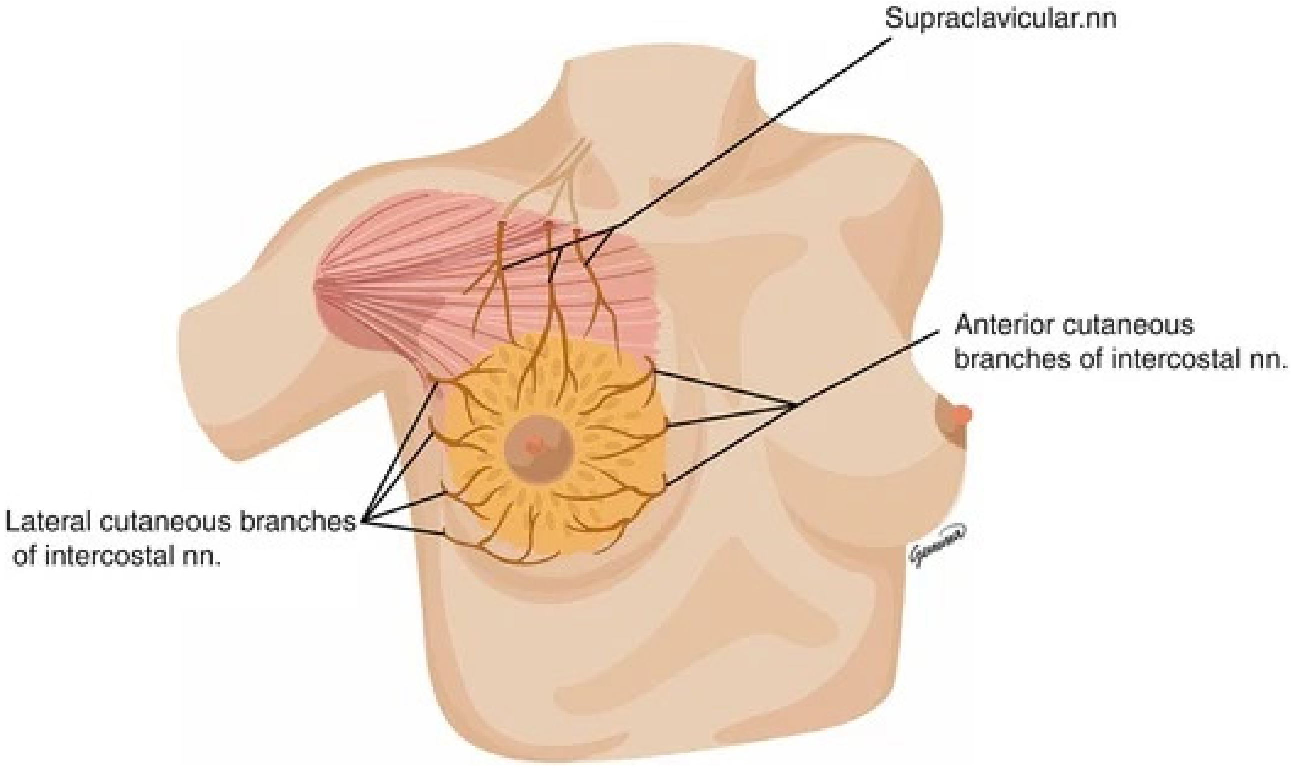


Fig. Breast sensory innervation (Prendergast, 2015)

Tissues and nerve differences cause the touching and pressure sensitivity differences. A breast map with 21 points distributed at four breast quadrants is created for the experiment. The points on the breast map show anticipation for the sensory and discomfort threshold differences (Fig. Breast map).

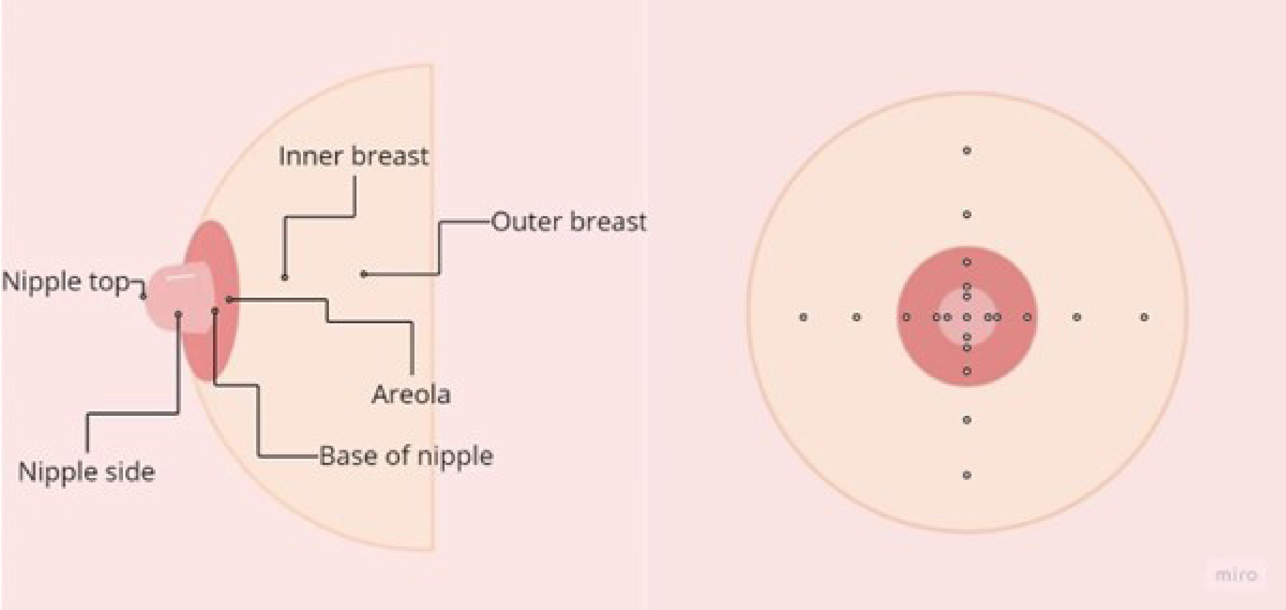


Fig. Breast map

6.2.2 Research Objectives & Research Questions

Based on the previous information, this research aims to explore the correlation between breast comfort and pressure sensation in order to design breast pump shields that apply ideal pressure distribution and effective stimuli. On the one hand, positive pressure exerted on the breast should be able to effectively generate compressive stimulation on the nipple-areola complex, which is found to be more sensitive than other parts of the breast in previous research, and does not cause any discomfort at the same time, as well as on the rest of breast areas. On the other hand, the negative pressure applied to the nipple and areola should not exceed the comfort threshold by stretching the tissues too much. The points in the breast map in 4.2.1.2 represent breast areas that are assumed to have similar sensitivity; we would like to explore which points are more sensitive to pressure and which are less sensitive. Therefore, two research questions are defined below:

1. What is the lower sensation threshold of the nipple-areola complex (how to make mothers feel the pressure (compression stimuli))?
2. What is the perceived discomfort threshold of different breast areas when applying pressure (how to ensure the pressure will not cause any pain/discomfort)?

6.2.3 Pilot Study

Pilot study was done on two non-lactating girls' breasts, I found that:

1. When participants operated the monofilament by themselves, the sensory threshold results were lower compared with participants who kept blind and other people operated the equipment. However, if participants press more times, like five, the result difference would be lower and can be ignored.

2, Participants operated the equipment by themselves according to the Ethical approval, but they may press each time differently as they are not familiar with the equipment, and the equipment does not have a precise lower measurement range (for some participants with sensitive breasts, small pressure applied by the AFG (9i500N) may cause severe discomfort). In addition, the discomfort in different breast areas is different and can be ranked; therefore, a 5-points Likert scale could be used for the discomfort evaluation to make the results more precise.

6.2.4 Methods

6.2.4.1 Participants

As lactating women group is small and hard to approach, the participant's group enlarged to a bigger group —- based on the anatomy and sensation similarities of human breasts. The competent, healthy lactating and non-lactating female adults without breast complaints aged 18 to 45 volunteered to participate in the experiments, to assess their breast sensitivity quantitively. The participants were recruited by posting advertisements on local Facebook/WhatsApp groups and from the researcher's network. Then potential participants contacted the researcher by email or WhatsApp; the researcher selected participants with healthy breasts. Participants who were suffering from any breast complaints, such as breast inflammation, breast abscess, and nipple fissures, were excluded from the study; Participants who refused to, or could not, give informed consent were excluded as well.

6.2.4.2 Stimuli & equipment

Potential participants received an online pre-questionnaire and a digital questionnaire/inquiry before and after the experiment, respectively. The age, gender, breast complaints history, and lactating history data were collected from the pre-questionnaire; Comfort scales, breast anthropometric data, and breast volume were recorded in the digital questionnaire.

An easy-to-follow equipment manual and a breast map were given to participants to guide them to control the equipment by themselves and apply force to certain areas of their breasts.

A twenty-pieces Semmes-Weinstein monofilament set was used for the sensory test. The minimum touching sensory numbers marked on the monofilament were recorded. The Advanced Force Gauge (AFG) connected to a cylinder of 2 millimetres in diameter was used to push participants' breasts until they did not feel comfortable anymore; then, the maximum pushing pressure was recorded. The reason to use 2mm long cylinders is that it is a reasonable diameter to press the narrowest areas, nipple side and nipple base, which are included in a 4mm long nipple in some cases. In addition, the materials of the cylinders are PLA, and it covers the metal adapter of AFG. It is because the temperature is one of the crucial influences for discomfort, and metal is a good heat conductor, it may get the heat from the breast quickly and make participants feel cold. Then the cold feelings will influence their discomfort evaluation. The equipment was washed with antiseptic solutions before use.

A discomfort 5 points Likert scale was used in the discomfort sensitivity experiment (see Fig. Discomfort evaluation). The 0 point means participants' best line as they feel nothing or just a gentle tug; from 0 to 1 point means some extreme slight non-ease, such as boredom and itching; the point greater than 5 means extreme discomfort that can not be bear or pain.

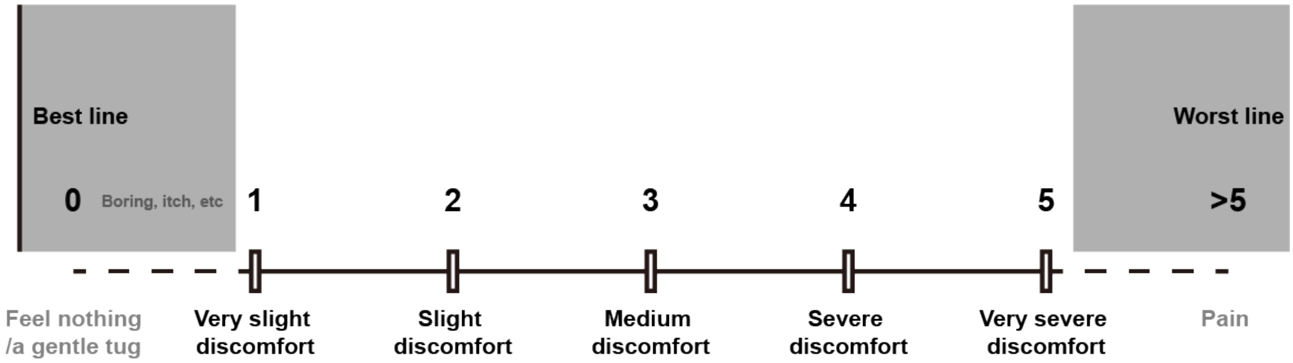


Fig. Discomfort evaluation

6.2.4.3 Procedure

An online pre-questionnaire was sent to participants before the experiment; the researcher reviewed the questionnaire, got the basic information, and identified whether participants fulfilled the selection standard. Pre-questionnaires were destroyed if potential participants did not meet the standards, for example, had a medical history of breast.

Researchers brought or sent a package of experiment equipment to participants' homes; participants followed the instructions with informative pictures for experiment steps and equipment usage, guided by researchers online or face to face, and conducted the experiments by themselves.

The participant sat in a room that was not colder than 20 degree Celsius, had more than 7 hours of sleep last night, and did not feel hungry or unwell. Lactating participants could not conduct the experiment after nursing or expressing milk as the breast would be less sensitive (FIXME). Participants used their hands to make the nipple erect, and it should keep erecting state during the experiment.

The first experiment was the lower touch sensation threshold. Participants applied pressure vertically on the right breast to a single point 5 times with the thinnest Semmes Weinstein nylon monofilament, and each time stopped when the monofilament bent into a C shape for 1.5 seconds (Fig. Touch sensation). If the participant felt 0, 1, 2 or 3 touches in the five times contact, change to the next nylon monofilament with a larger number and continue. Until participants felt 4 or 5 times touches out of 5 times, they stopped changing the next one and wrote down the number of the monofilament that felt 4 or 5 times (FIXME). The contact points were followed with a random sequence of the breast map in 4.2.1.2 (Fig. Breast map). The sliding tactile sensation of the monofilament is not counted.

After that, participants turned on the AFG and applied gradually increasing pressure vertically to push a single point until they felt not comfortable anymore, following the same sequence of points as the first experiment (Fig. Discomfort). According to results from the pilot study, they need to give a grade on the discomfort scale (1-5) based on a five-point scale of discomfort, repeating each point three times (Vink & Lips, 2017). Then recorded the number and the discomfort grade for each press.

Fig. Tactile sensation

Fig. Discomfort

Then participants measured the breast anthropometric data nipple length, nipple diameter, areola diameter and breast cup. The breast volume was assessed by the Breast-V formula (Longo et al., 2013) based on three data: sternal notch–to-nipple distance S-N; fold-to-nipple distance F-N; fold-to-fold projection distance F-FP (Fig. Anatomical distances for breast volume assessment).

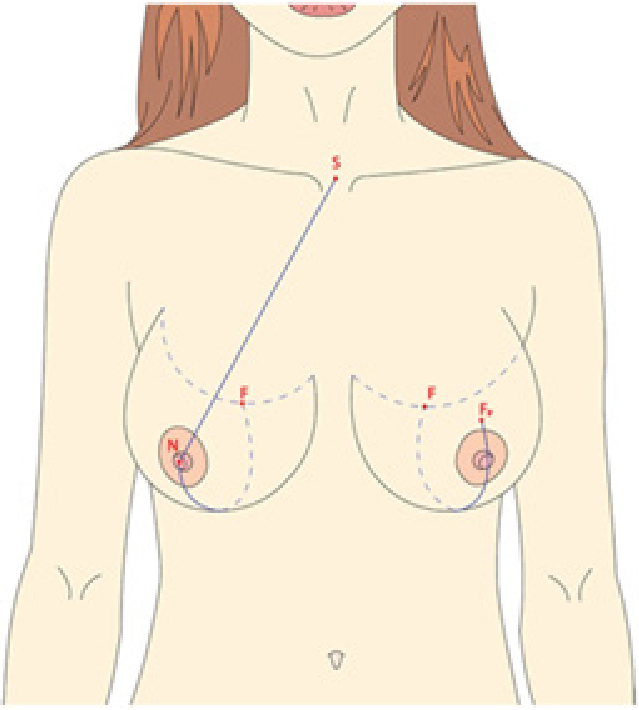


Fig. Anatomical distances for breast volume assessment

6.2.4.4 Data Analysis

6.2.4.4.1 Prelimiary Data Visualization

The data were firstly processed and visualised by Orange—- a nice visual programming software for data processing. From the data visualization, I get a general impression of how the data distribute, and what the possible principles might be. For example, from the visuals (Fig. Orange Data Visualization 1) we can clearly see that the points for nipple top discomfort thresholds are condensed in the bottom, meaning that nipple tops are more sensitive than other areas of the breast; the larger women’s breast is, the lower their tactile sensory threshold will be (Fig. Orange Data Visualization 2). When choosing one single example, from the visual (Fig. Orange Data Visualization 3) it is clear that the nipple-areola complex usually has higher tactile thresholds and lower discomfort thresholds, on the contrary, other breast areas have lower tactile thresholds and higher discomfort thresholds. Besides, by comparing the general differences between different breast areas (Fig. Orange Data Visualization 4), I got a general feeling for which breast areas might be more sensitive, and how is touch sensitivity different from discomfort sensitivity regarding anatomical areas.

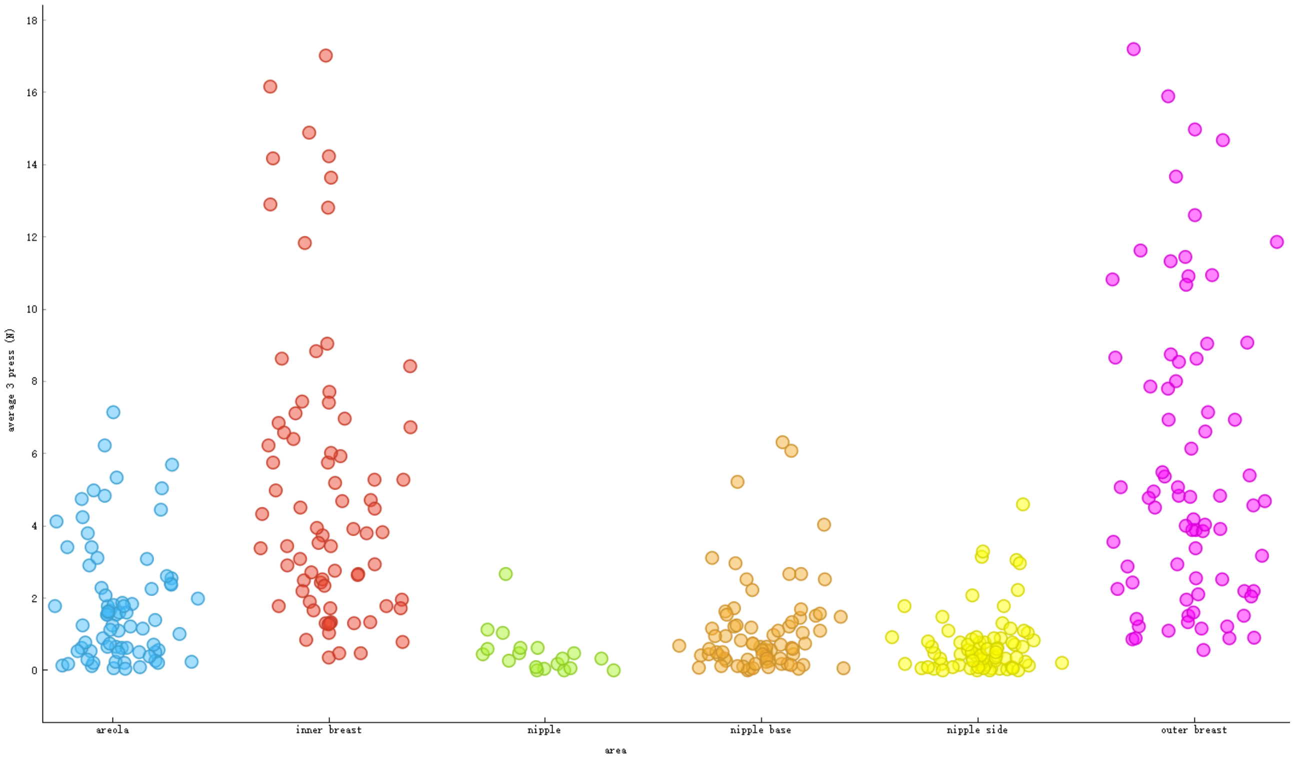


Fig. Orange Data Visualization 1

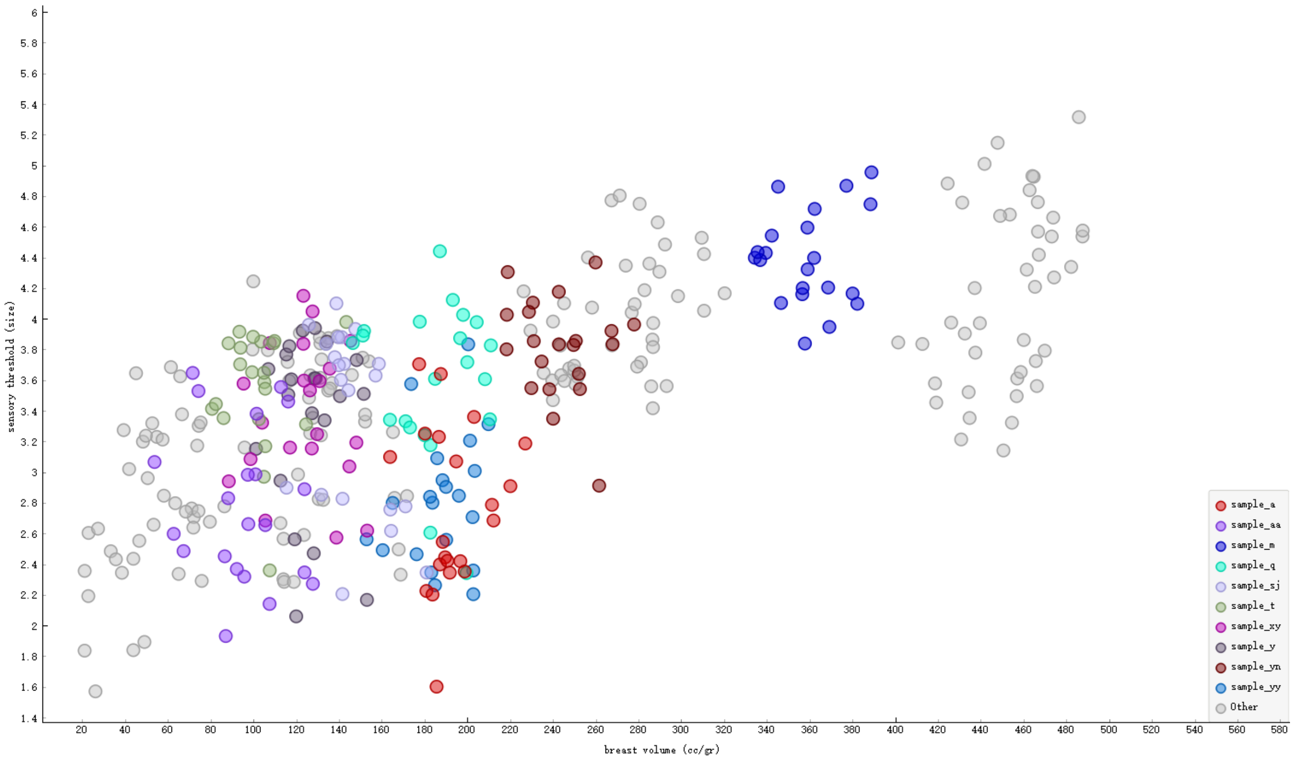


Fig. Orange Data Visualization 2

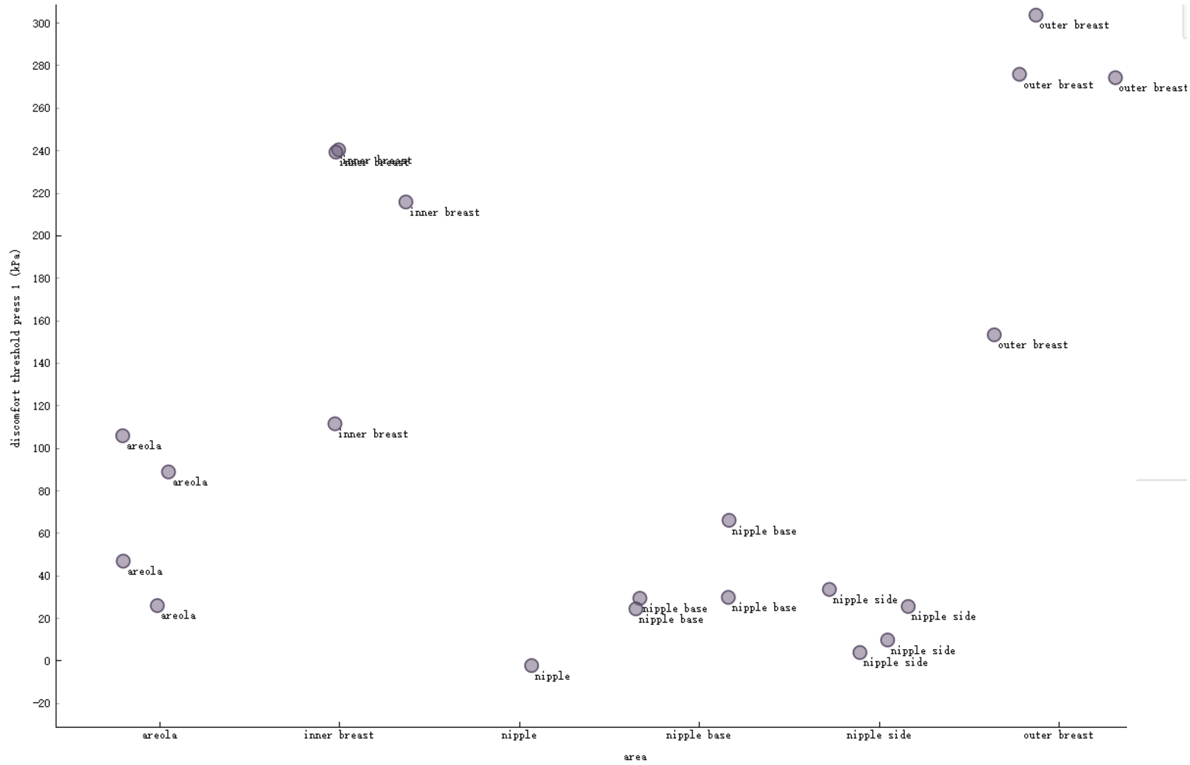


Fig. Orange Data Visualization 3

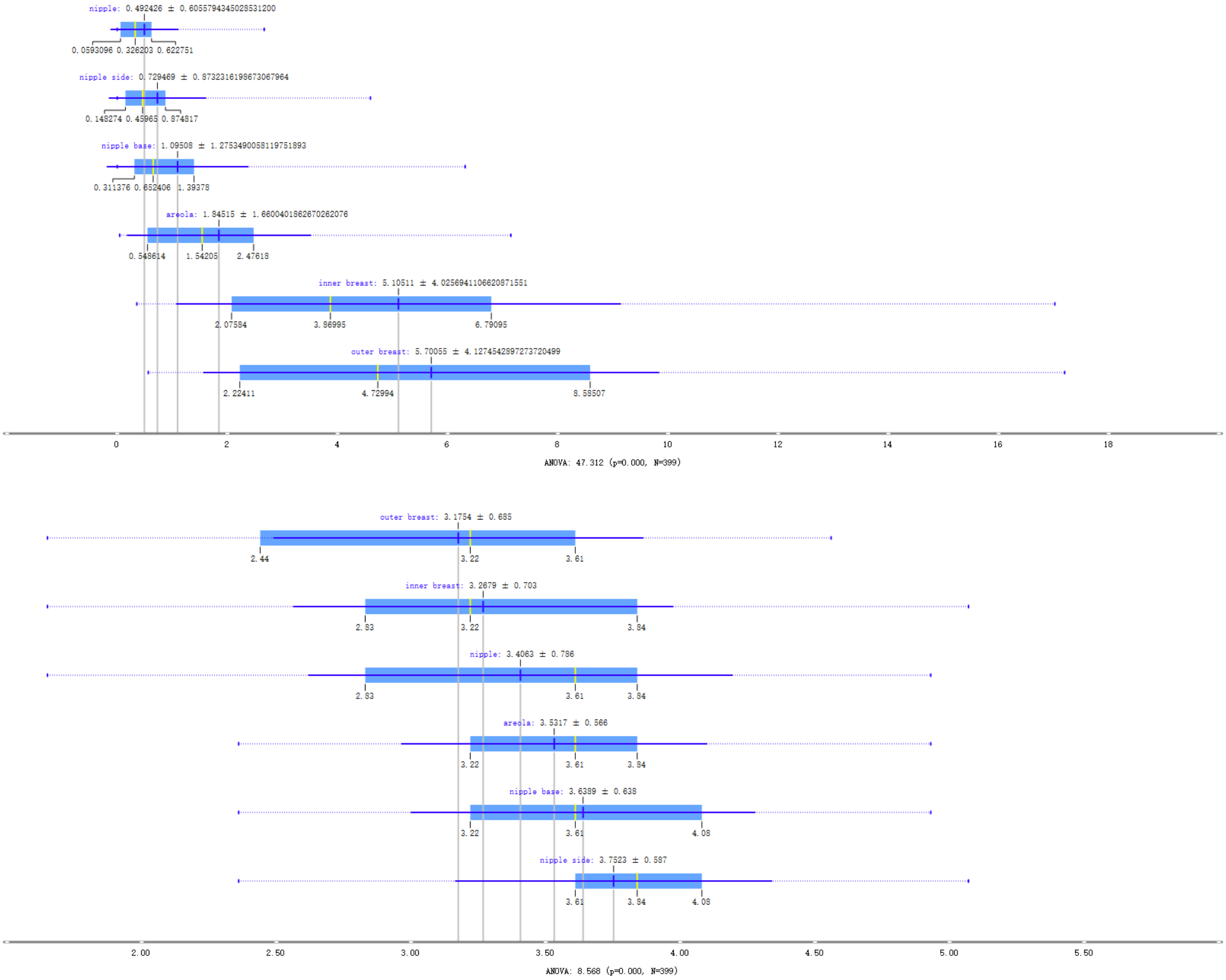


Fig. Orange Data Visualization 4

6.2.4.4.2 Statistical Method

After making data visualisation, the SPSS, which is a more accurate statistical software, was used for further data analysis. The data normality was checked by Shapiro–Wilk test (the results can be found in Appendix G. Data Analysis). The non-parametric test, Mann–Whitney U test was used to explore differences between lactating and non-lactating women groups;
Kruskal–Wallis H test was used to identify the differences for the six breast areas (nipple top, nipple side, nipple base, inner breast and outer breast) and four quadrants (upper, lower, lateral and medial). Finally, the Spearman test was implemented for exploring the non-parametric correlation between critical parameters and tactile threshold or discomfort threshold, and between tactile threshold and discomfort threshold themselves.

6.2.5 Results

There were 20 women, including 3 lactating participants and 17 non-lactating participants, participated in the breast sensitivity study, with 30% A cup, 45% B cup and 25% C cup, aged from 23 to 33 (Fig. Participants).

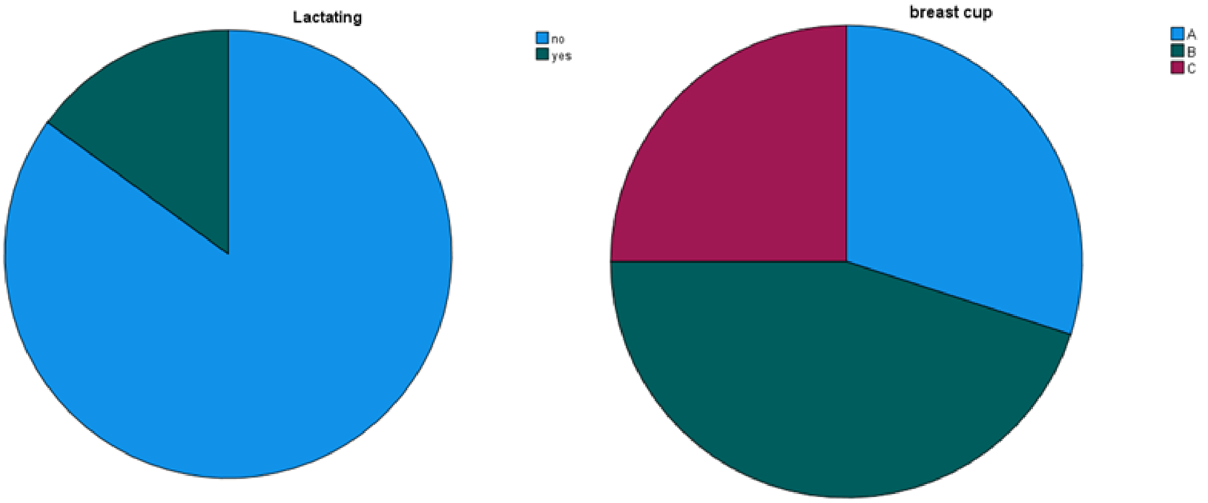


Fig. Participants

The mean and standard deviation values for lower tactile threshold and pressure discomfort threshold in different breast areas were calculated, and the data were used to draw breast sensitivity heat maps (Fig. Breast pressure discomfort threshold map & Fig. Breast tactile threshold map). The breast pressure discomfort threshold and its standard deviation increase from the central breast to the peripheral breast; the tactile threshold and its standard deviation decrease from the central breast to the peripheral breast, except the nipple top: it has a low tactile threshold that is lower than the areola.

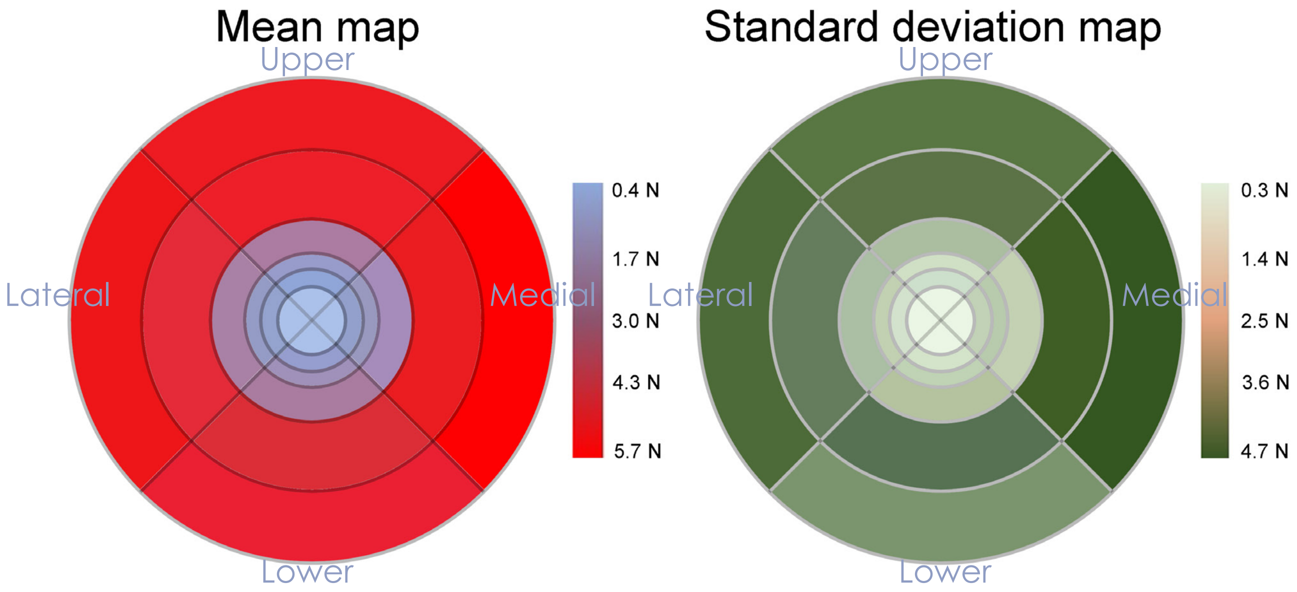


Fig. Breast pressure discomfort threshold map

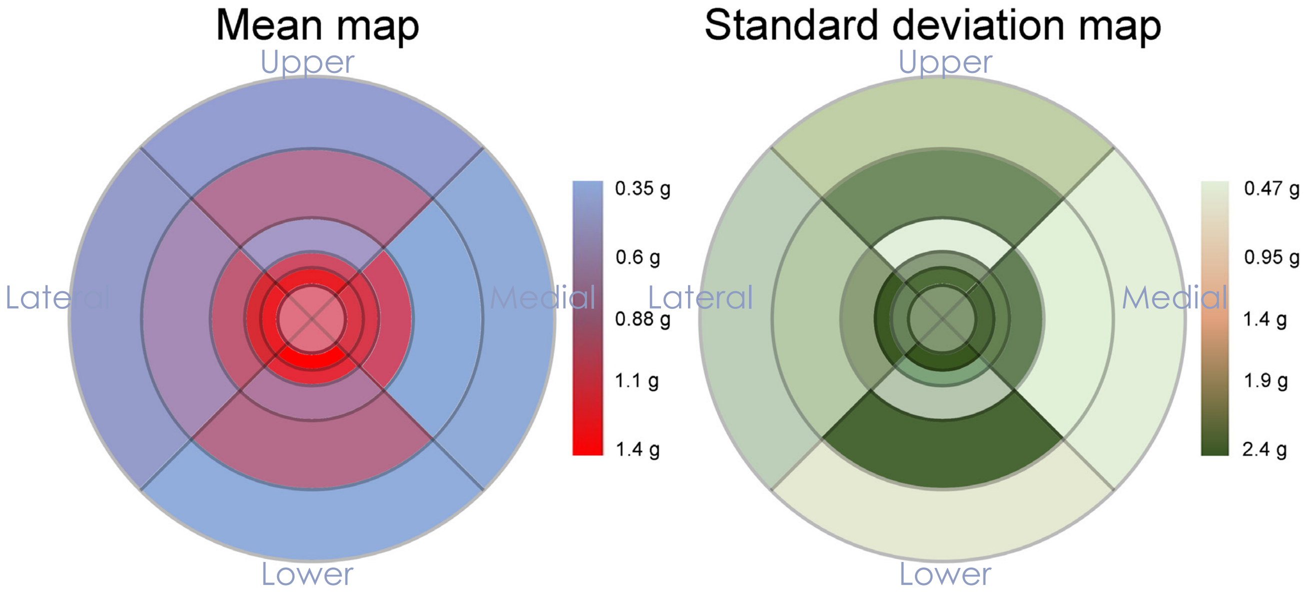
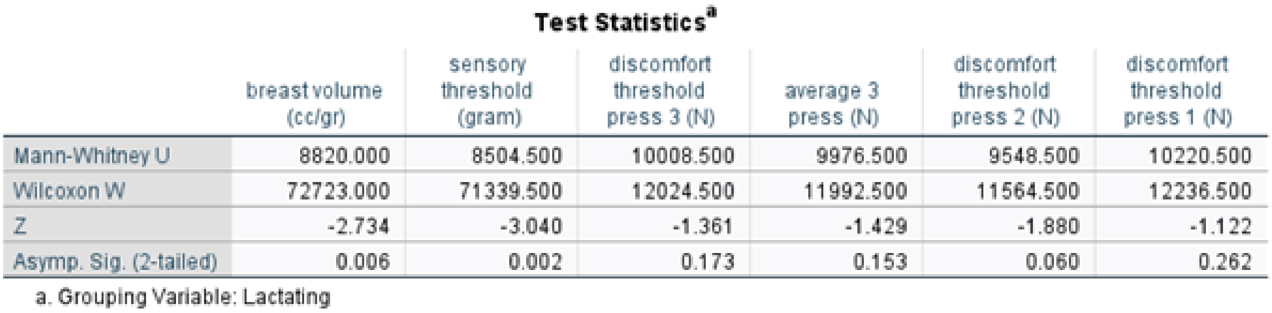


Fig. Breast tactile threshold map

According to the results for the lactating & non-lactating women comparison, it can be found from the result charts (Fig. Comparing lactating & non-lactating) that lactating moms may have a more sensitive tactile feeling ($p<0.05$) than non-lactating women, but for the pressure discomfort thresholds, it is hard to find differences.



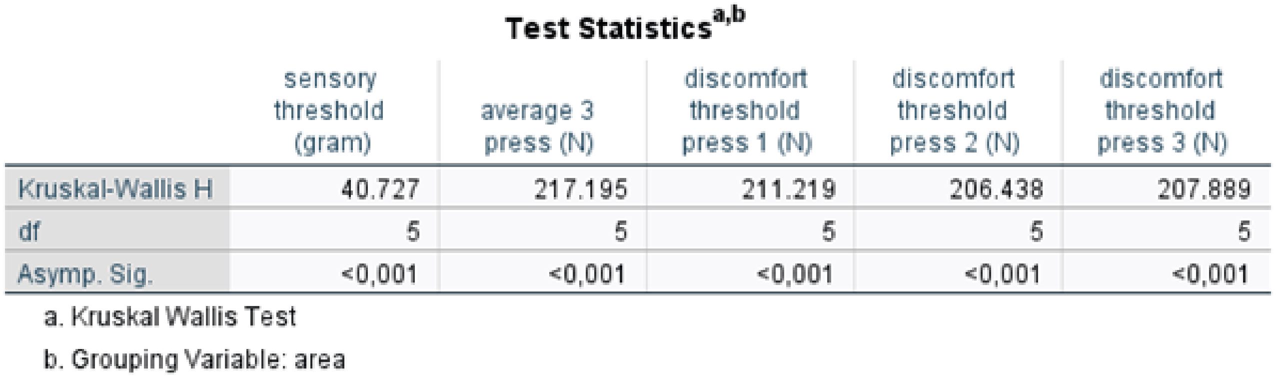
Test Statistics[a]

	breast volume (cc/gr)	sensory threshold (gram)	discomfort threshold press 3 (N)	average 3 press (N)	discomfort threshold press 2 (N)	discomfort threshold press 1 (N)
Mann-Whitney U	8820.000	8504.500	10008.500	9976.500	9548.500	10220.500
Wilcoxon W	72723.000	71339.500	12024.500	11992.500	11564.500	12236.500
Z	-2.734	-3.040	-1.361	-1.429	-1.880	-1.122
Asymp. Sig. (2-tailed)	0.006	0.002	0.173	0.153	0.060	0.262

a. Grouping Variable: Lactating

Fig. Comparing lactating & non-lactating

From the results chart (Fig. Comparing 6 anatomical breast areas) we can conclude that the six breast anatomical areas have significant differences in lower tactile thresholds and pressure discomfort thresholds ($p<0.01$); but when it comes to the differences on four quadrants, there are no significant differences within the lower tactile thresholds and pressure discomfort thresholds (Fig. Comparing 4 quadrants).



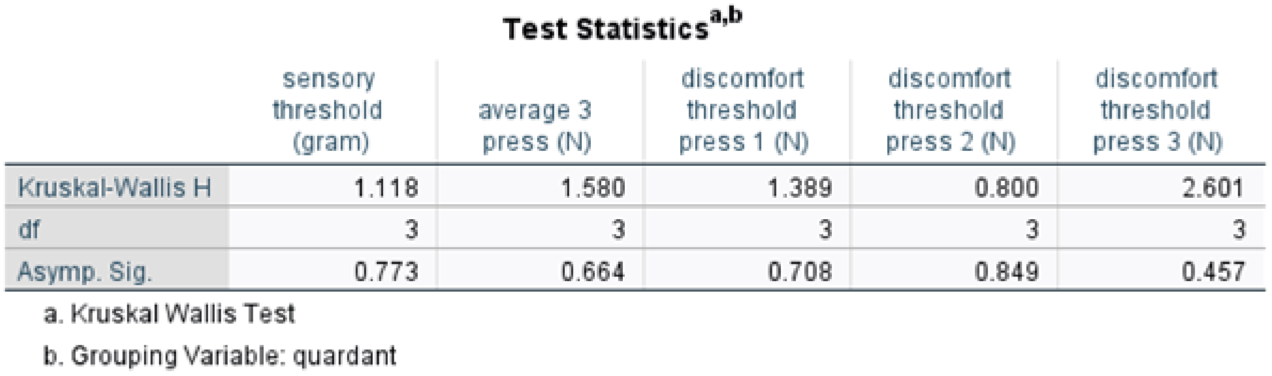
Test Statistics[a,b]

	sensory threshold (gram)	average 3 press (N)	discomfort threshold press 1 (N)	discomfort threshold press 2 (N)	discomfort threshold press 3 (N)
Kruskal-Wallis H	40.727	217.195	211.219	206.438	207.889
df	5	5	5	5	5
Asymp. Sig.	<0,001	<0,001	<0,001	<0,001	<0,001

a. Kruskal Wallis Test

b. Grouping Variable: area

Fig. Comparing 6 anatomical breast areas



Test Statistics[a,b]

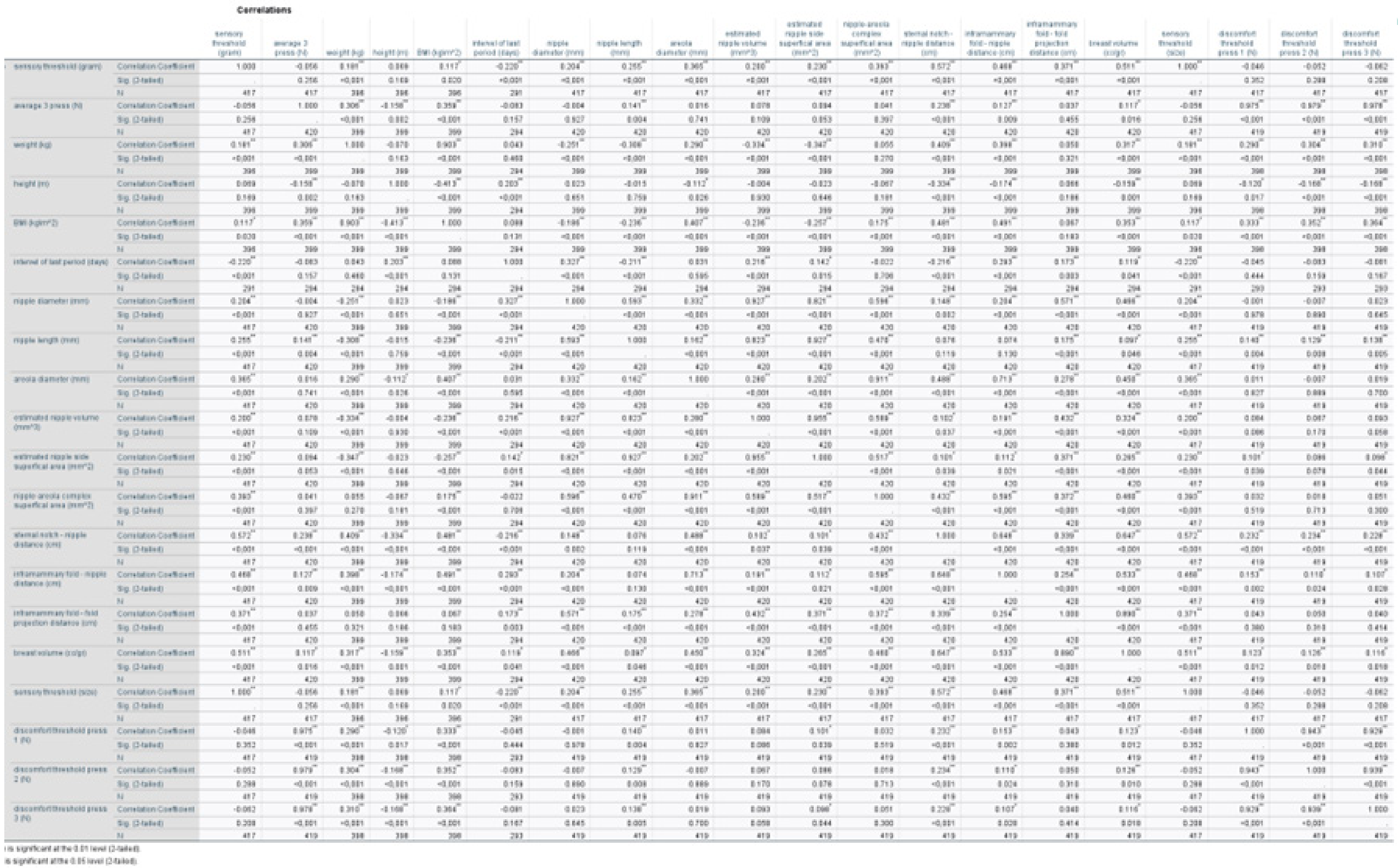
	sensory threshold (gram)	average 3 press (N)	discomfort threshold press 1 (N)	discomfort threshold press 2 (N)	discomfort threshold press 3 (N)
Kruskal-Wallis H	1.118	1.580	1.389	0.800	2.601
df	3	3	3	3	3
Asymp. Sig.	0.773	0.664	0.708	0.849	0.457

a. Kruskal Wallis Test

b. Grouping Variable: quardant

Fig. Comparing 4 quadrants

According to Fig. Correlation, there is no significant correlation between lower sensory threshold and discomfort threshold. The lower sensory threshold has a strong positive correlation ($p<0.001$) with weight, nipple length, nipple diameter, areola diameter and breast volume and a positive correlation ($p<0.05$) with BMI; it also has a strong negative correlation ($p<0.001$) with the interval of the last period. The breast discomfort threshold has a strong positive correlation ($p<0.001$) with weight, BMI, nipple length, sternal notch to nipple distance and inframammary fold to nipple distance and a positive correlation ($p<0.05$) with breast volume; it has a strong negative correlation ($p<0.001$) with height.



Correlations

		sensory threshold (gram)	average 3 press (N)	weight (kg)	height (m)	BMI (kg/m^2)	interval of last period (days)	nipple diameter (mm)	nipple length (mm)	areola diameter (mm)	estimated nipple volume (mm^3)	estimated nipple side superfical area (mm^2)	nipple-areola complex superfical area (mm^2)	sternal notch - nipple distance (cm)	inframammary fold - nipple distance (cm)	inframammary fold - fold projection distance (cm)	breast volume (cc/g)	sensory threshold (size)	discomfort threshold press 1 (N)	discomfort threshold press 2 (N)	discomfort threshold press 3 (N)
sensory threshold (gram)	Correlation Coefficient	1.000	-0.056	0.181**	0.069	0.117*	-0.220**	0.204**	0.255**	0.365**	0.280**	0.230**	0.383**	0.572**	0.468**	0.371**	0.511**	1.000**	-0.046	-0.052	-0.062
	Sig. (2-tailed)	.	0.256	<0.001	0.169	0.020	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	.	0.352	0.288	0.208
	N	417	417	398	398	398	291	417	417	417	417	417	417	417	417	417	417	417	417	417	417
average 3 press (N)	Correlation Coefficient	-0.056	1.000	0.306**	-0.150**	0.359**	-0.083	-0.004	0.141**	0.016	0.078	0.094	0.041	0.238**	0.127**	0.037	0.117*	-0.056	0.975**	0.979**	0.978**
	Sig. (2-tailed)	0.256	.	<0.001	0.002	<0.001	0.157	0.927	0.004	0.741	0.109	0.053	0.397	<0.001	0.009	0.455	0.016	0.256	<0.001	<0.001	<0.001
	N	417	420	399	399	399	294	420	420	420	420	420	420	420	420	420	420	417	419	419	419
weight (kg)	Correlation Coefficient	0.181**	0.306**	1.000	-0.070	0.903**	0.043	-0.251**	-0.308**	0.290**	-0.334**	-0.347**	0.055	0.409**	0.398**	0.050	0.317**	0.181**	0.290**	0.304**	0.310**
	Sig. (2-tailed)	<0.001	<0.001	.	0.163	<0.001	0.460	<0.001	<0.001	<0.001	<0.001	<0.001	0.270	<0.001	<0.001	0.321	<0.001	<0.001	<0.001	<0.001	<0.001
	N	398	399	399	399	399	294	399	399	399	399	399	399	399	399	399	399	398	398	398	398
height (m)	Correlation Coefficient	0.069	-0.150**	-0.070	1.000	-0.413**	0.203**	0.023	-0.015	-0.112*	-0.004	-0.023	-0.067	-0.334**	-0.174**	0.066	-0.159**	0.069	-0.120*	-0.168**	-0.169**
	Sig. (2-tailed)	0.169	0.002	0.163	.	<0.001	<0.001	0.651	0.759	0.026	0.930	0.646	0.181	<0.001	<0.001	0.186	0.001	0.169	0.017	<0.001	<0.001
	N	398	399	399	399	399	294	399	399	399	399	399	399	399	399	399	399	398	398	398	398
BMI (kg/m^2)	Correlation Coefficient	0.117*	0.359**	0.903**	-0.413**	1.000	0.088	-0.196**	-0.236**	0.407**	-0.238**	-0.257**	0.175**	0.481**	0.491**	0.067	0.353**	0.117*	0.333**	0.352**	0.364**
	Sig. (2-tailed)	0.020	<0.001	<0.001	<0.001	.	0.131	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	0.183	<0.001	0.020	<0.001	<0.001	<0.001
	N	398	399	399	399	399	294	399	399	399	399	399	399	399	399	399	399	398	398	398	398
interval of last period (days)	Correlation Coefficient	-0.220**	-0.083	0.043	0.203**	0.088	1.000	0.327**	-0.211**	0.031	0.218**	0.142*	-0.022	-0.216**	0.293**	0.173**	0.119*	-0.220**	-0.045	-0.083	-0.081
	Sig. (2-tailed)	<0.001	0.157	0.460	<0.001	0.131	.	<0.001	<0.001	0.595	<0.001	0.015	0.706	<0.001	<0.001	0.003	0.041	<0.001	0.444	0.159	0.167
	N	291	294	294	294	294	294	294	294	294	294	294	294	294	294	294	294	291	293	293	293
nipple diameter (mm)	Correlation Coefficient	0.204**	-0.004	-0.251**	0.023	-0.196**	0.327**	1.000	0.593**	0.332**	0.927**	0.821**	0.596**	0.148**	0.204**	0.571**	0.466**	0.204**	-0.001	-0.007	0.023
	Sig. (2-tailed)	<0.001	0.927	<0.001	0.651	<0.001	<0.001	.	<0.001	<0.001	<0.001	<0.001	<0.001	0.002	<0.001	<0.001	<0.001	<0.001	0.979	0.890	0.645
	N	417	420	399	399	399	294	420	420	420	420	420	420	420	420	420	420	417	419	419	419
nipple length (mm)	Correlation Coefficient	0.255**	0.141**	-0.308**	-0.015	-0.236**	-0.211**	0.593**	1.000	0.162**	0.823**	0.927**	0.470**	0.076	0.074	0.175**	0.097*	0.255**	0.140**	0.129**	0.138**
	Sig. (2-tailed)	<0.001	0.004	<0.001	0.759	<0.001	<0.001	<0.001	.	<0.001	<0.001	<0.001	<0.001	0.119	0.130	<0.001	0.046	<0.001	0.004	0.008	0.005
	N	417	420	399	399	399	294	420	420	420	420	420	420	420	420	420	420	417	419	419	419
areola diameter (mm)	Correlation Coefficient	0.365**	0.016	0.290**	-0.112*	0.407**	0.031	0.332**	0.162**	1.000	0.280**	0.202**	0.911**	0.488**	0.713**	0.279**	0.450**	0.365**	0.011	-0.007	0.019
	Sig. (2-tailed)	<0.001	0.741	<0.001	0.026	<0.001	0.595	<0.001	<0.001	.	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	0.827	0.889	0.700
	N	417	420	399	399	399	294	420	420	420	420	420	420	420	420	420	420	417	419	419	419
estimated nipple volume (mm^3)	Correlation Coefficient	0.280**	0.078	-0.334**	-0.004	-0.238**	0.218**	0.927**	0.823**	0.280**	1.000	0.955**	0.589**	0.102*	0.181**	0.432**	0.324**	0.280**	0.084	0.067	0.093
	Sig. (2-tailed)	<0.001	0.109	<0.001	0.930	<0.001	<0.001	<0.001	<0.001	<0.001	.	<0.001	<0.001	0.037	<0.001	<0.001	<0.001	<0.001	0.086	0.170	0.058
	N	417	420	399	399	399	294	420	420	420	420	420	420	420	420	420	420	417	419	419	419
estimated nipple side superfical area (mm^2)	Correlation Coefficient	0.230**	0.094	-0.347**	-0.023	-0.257**	0.142*	0.821**	0.927**	0.202**	0.955**	1.000	0.517**	0.101*	0.112*	0.371**	0.265**	0.230**	0.101*	0.086	0.098*
	Sig. (2-tailed)	<0.001	0.053	<0.001	0.646	<0.001	0.015	<0.001	<0.001	<0.001	<0.001	.	<0.001	0.039	0.021	<0.001	<0.001	<0.001	0.039	0.079	0.044
	N	417	420	399	399	399	294	420	420	420	420	420	420	420	420	420	420	417	419	419	419
nipple-areola complex superfical area (mm^2)	Correlation Coefficient	0.383**	0.041	0.055	-0.067	0.175**	-0.022	0.596**	0.470**	0.911**	0.589**	0.517**	1.000	0.432**	0.585**	0.372**	0.468**	0.383**	0.032	0.018	0.051
	Sig. (2-tailed)	<0.001	0.397	0.270	0.181	<0.001	0.706	<0.001	<0.001	<0.001	<0.001	<0.001	.	<0.001	<0.001	<0.001	<0.001	<0.001	0.519	0.713	0.300
	N	417	420	399	399	399	294	420	420	420	420	420	420	420	420	420	420	417	419	419	419
sternal notch - nipple distance (cm)	Correlation Coefficient	0.572**	0.238**	0.409**	-0.334**	0.481**	-0.216**	0.148**	0.076	0.488**	0.102*	0.101*	0.432**	1.000	0.646**	0.339**	0.647**	0.572**	0.232**	0.234**	0.228**
	Sig. (2-tailed)	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	0.002	0.119	<0.001	0.037	0.039	<0.001	.	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	N	417	420	399	399	399	294	420	420	420	420	420	420	420	420	420	420	417	419	419	419
inframammary fold - nipple distance (cm)	Correlation Coefficient	0.468**	0.127**	0.398**	-0.174**	0.491**	0.293**	0.204**	0.074	0.713**	0.181**	0.112*	0.585**	0.646**	1.000	0.254**	0.533**	0.468**	0.153**	0.110*	0.107*
	Sig. (2-tailed)	<0.001	0.009	<0.001	<0.001	<0.001	<0.001	<0.001	0.130	<0.001	<0.001	0.021	<0.001	<0.001	.	<0.001	<0.001	<0.001	0.002	0.024	0.028
	N	417	420	399	399	399	294	420	420	420	420	420	420	420	420	420	420	417	419	419	419
inframammary fold - fold projection distance (cm)	Correlation Coefficient	0.371**	0.037	0.050	0.066	0.067	0.173**	0.571**	0.175**	0.279**	0.432**	0.371**	0.372**	0.339**	0.254**	1.000	0.890**	0.371**	0.043	0.050	0.040
	Sig. (2-tailed)	<0.001	0.455	0.321	0.186	0.183	0.003	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	.	<0.001	<0.001	0.380	0.310	0.414
	N	417	420	399	399	399	294	420	420	420	420	420	420	420	420	420	420	417	419	419	419
breast volume (cc/g)	Correlation Coefficient	0.511**	0.117*	0.317**	-0.159**	0.353**	0.119*	0.466**	0.097*	0.450**	0.324**	0.265**	0.468**	0.647**	0.533**	0.890**	1.000	0.511**	0.123*	0.126**	0.116*
	Sig. (2-tailed)	<0.001	0.016	<0.001	0.001	<0.001	0.041	<0.001	0.046	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	.	<0.001	0.012	0.010	0.018
	N	417	420	399	399	399	294	420	420	420	420	420	420	420	420	420	420	417	419	419	419
sensory threshold (size)	Correlation Coefficient	1.000**	-0.056	0.181**	0.069	0.117*	-0.220**	0.204**	0.255**	0.365**	0.280**	0.230**	0.383**	0.572**	0.468**	0.371**	0.511**	1.000	-0.046	-0.052	-0.062
	Sig. (2-tailed)	.	0.256	<0.001	0.169	0.020	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	.	0.352	0.288	0.208
	N	417	417	398	398	398	291	417	417	417	417	417	417	417	417	417	417	417	417	417	417
discomfort threshold press 1 (N)	Correlation Coefficient	-0.046	0.975**	0.290**	-0.120*	0.333**	-0.045	-0.001	0.140**	0.011	0.084	0.101*	0.032	0.232**	0.153**	0.043	0.123*	-0.046	1.000	0.943**	0.929**
	Sig. (2-tailed)	0.352	<0.001	<0.001	0.017	<0.001	0.444	0.979	0.004	0.827	0.086	0.039	0.519	<0.001	0.002	0.380	0.012	0.352	.	<0.001	<0.001
	N	417	419	398	398	398	293	419	419	419	419	419	419	419	419	419	419	417	419	419	419
discomfort threshold press 2 (N)	Correlation Coefficient	-0.052	0.979**	0.304**	-0.168**	0.352**	-0.083	-0.007	0.129**	-0.007	0.067	0.086	0.018	0.234**	0.110*	0.050	0.126**	-0.052	0.943**	1.000	0.939**
	Sig. (2-tailed)	0.288	<0.001	<0.001	<0.001	<0.001	0.159	0.890	0.008	0.889	0.170	0.079	0.713	<0.001	0.024	0.310	0.010	0.288	<0.001	.	<0.001
	N	417	419	398	398	398	293	419	419	419	419	419	419	419	419	419	419	417	419	419	419
discomfort threshold press 3 (N)	Correlation Coefficient	-0.062	0.978**	0.310**	-0.169**	0.364**	-0.081	0.023	0.138**	0.019	0.093	0.098*	0.051	0.228**	0.107*	0.040	0.116*	-0.062	0.929**	0.939**	1.000
	Sig. (2-tailed)	0.208	<0.001	<0.001	<0.001	<0.001	0.167	0.645	0.005	0.700	0.058	0.044	0.300	<0.001	0.028	0.414	0.018	0.208	<0.001	<0.001	.
	N	417	419	398	398	398	293	419	419	419	419	419	419	419	419	419	419	417	419	419	419

is significant at the 0.01 level (2-tailed).

is significant at the 0.05 level (2-tailed).

Fig. Correlation

6.2.6 Discussions

Breast sensitivity has significant inter-individual variations but general intra-individual patterns. This principle makes ultra-personalization meaningful for breast pump design. According to the heat map in 6.3.5, it is clear that the nipple-areola complex has a higher tactile threshold and a lower discomfort threshold than other parts of the breast, which means that it is difficult for the nipple and areola to feel the stimuli, but they are easy to get painful and uncomfortable. These results verified the findings from the interviews: mothers are easier to feel pain and discomfort at the nipple and areola areas. The reasons might be there are more nerve ends and mechanoreceptors like Merkel disk receptors and Pacini corpuscles which are sensitive to pressure distributing at the nipple and areola, and fewer Ruffini corpuscles which are sensitive to light touch (Longo B et al., 2014). Moreover, there is more fatty tissue in other breast skin areas that cover the nerves and mechanoreceptors to make them less sensitive.

The six areas of separation based on breast anatomy have significant sensitivity differences on both lower sensory and discomfort thresholds, which is a valuable principle in breast pump shield design. The nipple top is the easiest to get uncomfortable, while the peripheral breast is hard to feel uncomfortable. The breast shield design may put more pressure on the peripheral breast areas and less on the nipple areas. The nipple side is the most insensitive to lower pressure but is the second easiest to get uncomfortable. Therefore putting the compression stimuli on the nipple base and areola would be more effective than stimulating the nipple side. The four quadrants do not show any sensitivity differences, so designing breast pump shields to put more pressure on certain areas (for example, discussed in 2.3 PumpinPal angled shields tried to put more pressure on upper area of the breast) is not that meaningful.

When the period comes, the breast has a more sensitive lower sensory, but the discomfort threshold does not significantly change. So for not-exclusively breastfeeding mothers, who have a menstruation recovery after giving birth, it would be easier to get effective stimuli when menstruation is coming. Women with smaller breast volume, shorter nipples, and lower weight/BMI would have lower tactile and discomfort thresholds, so less pressure could be applied on their breasts when personalising their breast pumps.

6.4 Vacuum Sensitivity Study

6.4.1 Introduction

Apart from the breast positive pressure sensitivity discussed in 6.2, on the other hand, the negative pressure (vacuum) during breastfeeding should also be considered. Moreover, some positive pressure is actually indirectly caused by the vacuum because the volume of breast tissues changes under vacuum pressure. Then they touch and are compressed by the breast pump shields. The vacuum applied to the nipple and areola should not exceed the discomfort threshold by

stretching the tissues too much.
Therefore, the research question of the vacuum sensitivity study is: Are there any correlations between discomfort threshold, negative pressure, and nipple-areola complex volume change?

6.4.2 Protocol

An inverted nipple puller (Fig. Nipple Puller) was used to apply the vacuum to participants' nipple-areola complex, and the scale on the nipple puller was recorded as well as the maximum pressure scale on the force gauge when participants perceived discomfort.
A nipple sucker (See Fig. Nipple sucker) (CE certified) connected to the AFG was used by participants to apply a gently increasing vacuum on the nipple and part of the areola. When they feel not comfortable anymore, they stop pulling the injectors. Then the scales on the advanced force gauge and nipple sucker were recorded. Then participants gave discomfort scales according to the same discomfort 5 points Likert scale mentioned in 5.2.4.2 for discomfort evaluation. Before participants applied the vacuum, the initial scales on nipple suckers were recorded, so we got the volume change of the nipple & areola complex.

Fig. Nipple sucker

6.4.3 Results

When holding the nipple puller and pulling it by AFG with constant velocity, the scale on AFG was 1. Therefore the friction of the nipple puller is 1N. The mean value of vacuum is 1.67 N, and the mean value of volume scale change is 1.3. As the diameter of the injector is 1.35cm, the scale change 1.3 equal to 1.3cm, the volume change of nipple and part of areola is approximately 1.86 cm^3. In conclusion, when the vacuum pressure is approximately 0.67 N and the nipple and areola get 1.86 cm^3 deformation, women might feel uncomfortable.

6.5 Perfect Fit Shield Study

6.5.1 Study Plan

The research objective of this study is to explore what is the force distribution for a personalized breast pump shield with ideal breast contour and test the differences between the normal breast pump silicone shield and the personalised perfect fit breast pump silicone shield.

A simple prototype for a perfect-fit silicone shield was made with a breast 3D scanned model that is similar to the fake silicone breast from the breast models dataset. The perfect-fit shield has a larger diameter and covering areas on the breast than a normal shield. The shields were connected to a pump in order to acquire the vacuum. The 5WL pressure film was used for measuring the pressure between the phantom breast and the perfect-fit shield. The pressure films were cut into rectangle shape pieces and stuck on the breast. The pumping spent 2 minutes to let the film record the force.

Fig. Normal silicone shield and perfect fit shield

6.5.2 Act

The perfect-fit silicone shield was connected to a pump in order to apply the vacuum and pressure film was attached to the breast. After 2 minutes of pumping, the pressure was recorded on the pressure film. After that, the normal breast pump silicone shield was connected to the pump and pumped the phantom breast with a new pressure film in between again. Then 2 films were put together to observe the differences in the force intensity and what is the pressure distribution.

Fig. Normal silicone shield on the breast

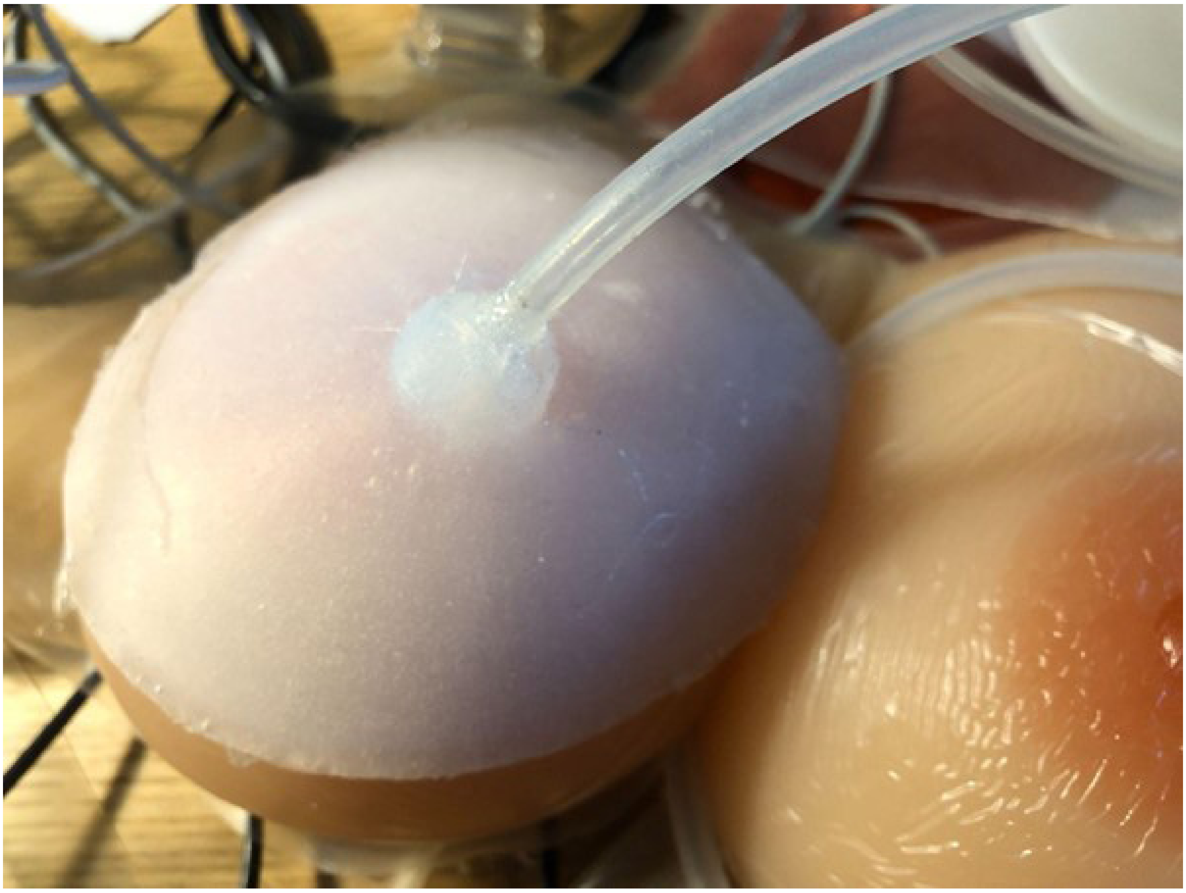


Fig. Perfect fit silicone shield on the breast

6.5.3 Results

The two pressure films are presented below (Fig. Pressure films). The upper one is the pressure applied to the breast with a regular breast pump shield with smaller contact areas on the breast; the lower one is the pressure from a perfect-fit pump shield with larger contact areas. The darkness of the purple color indicates the pressure intensity on these areas, the darker the color is, the more pressure there was. It is clear that the perfect-fit shield has a lower force intensity than the usual shield.

Furthermore, the pressure from the standard shield is concentrated on certain areas, such as the areola and nipple base, but the perfect-fit shield does not have an obvious pressure concentration, and the pressure distribution is more uniform. The results also indicate that if we do not design the personalized shield with different materials or angles, it does not fit the different sensitivity distribution of the breast. And soft materials can not apply enough pressure on the breast.

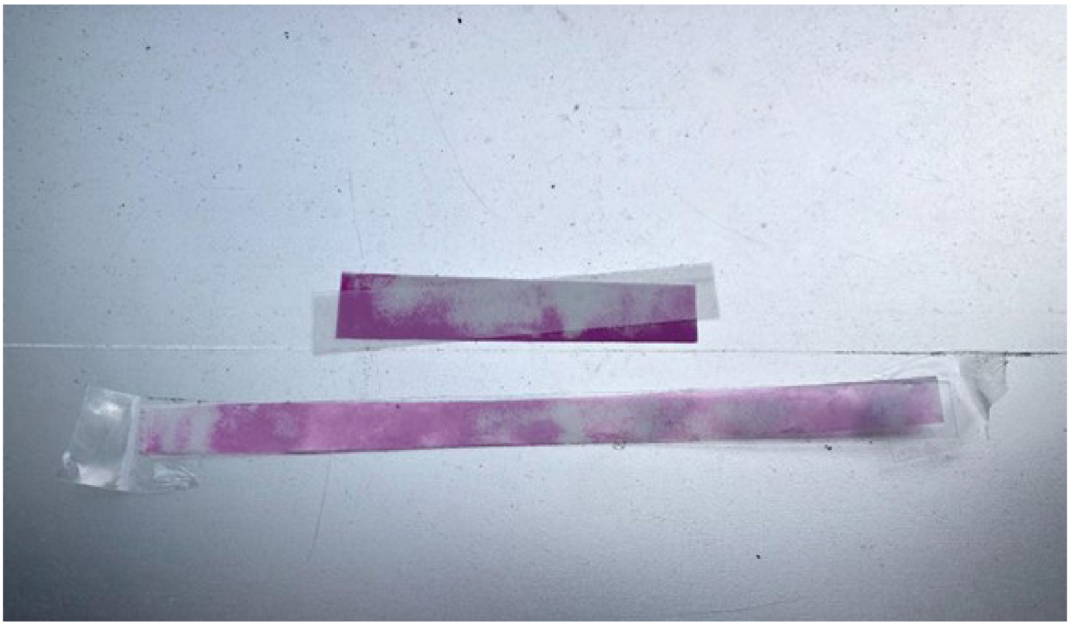


Fig. Pressure films.

7 Concepting and Design Recommendation

This section is about the conceptualization and virtual exploration research with the groups that are interested in this topic. Some concepts were created for the research. The feedback from mothers and experts was used to consolidate the list of requirements. Then a developed design proposal was made based on the consolidated list of requirements as a recommendation for possible design directions.

7.1 Ideation

The ideations went 3 rounds. The first round started in the early design stage, it was brainstorming around the question: “What can be personalized?”. The design directions that could be personalized was listed as a reference that would be used for the further explorations.

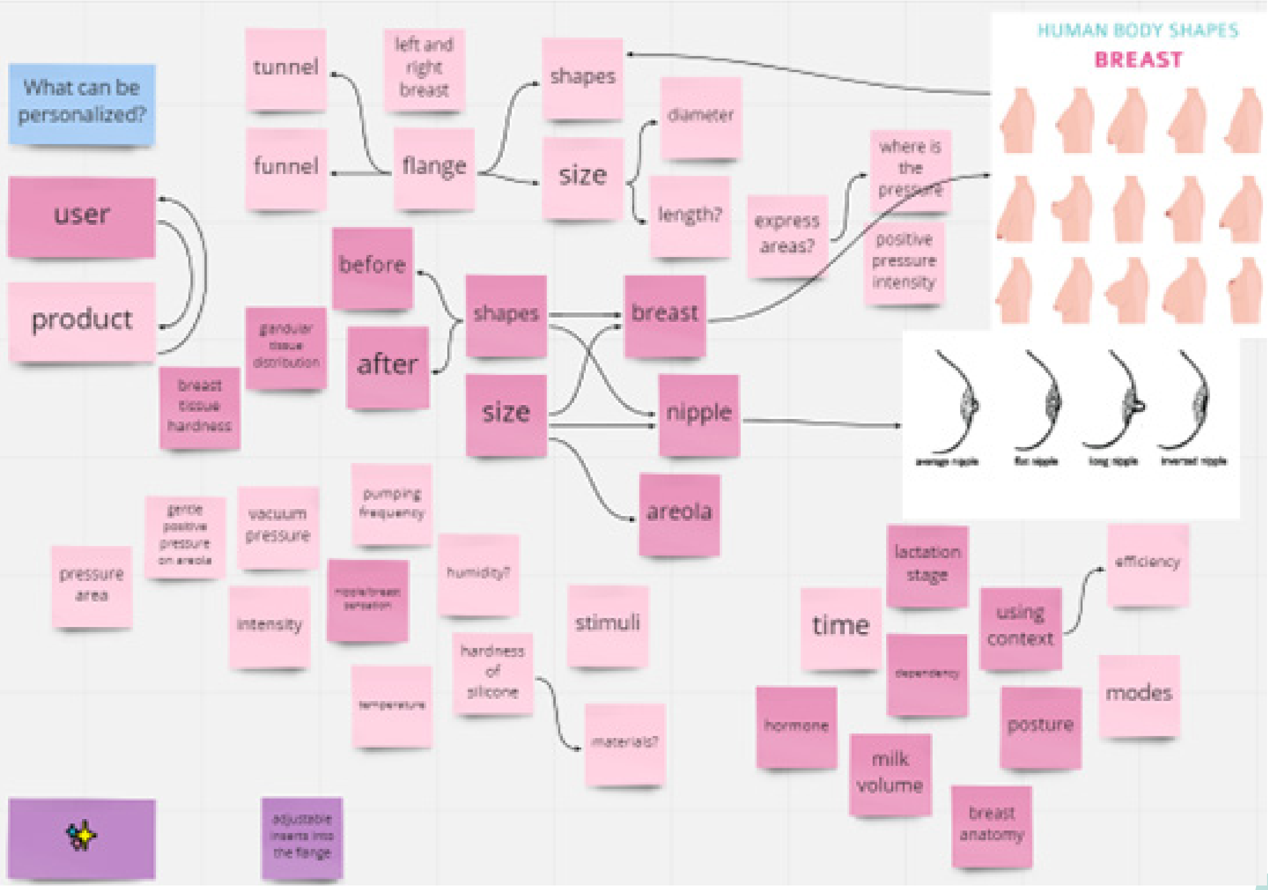


Fig. What can be personalized?

Then I did the second brainstorming according to the four main problems of breastfeeding: pain and discomfort, wasting time and taking too much effort, lack of emotional connections and inconvenience. Basic ideas regarding the four main questions was generated, then they were selected and combined to four concept ideas (see 7.2 Concepting) for the next design stage.

Fig. Brainstorming

The third ideation began based on the general list of design requirements. I used the method "How-Tos" for idea generation according to the problem formulations from design requirements. Final design ideations focused on breast pump shields, which is the main sub-function of the breast pumps. Three ideas were developed to three shield design directions, and were used for virtual exploration in the next chapter.

7.2 Concepting

After the ideation, 4 concept ideas refer to the general list of requirements and 3 concept directions that especially adapt to the breast pump shield design were created.

Concept Idea 1 P-Massage

A lot of mothers, especially Chinese mothers, mentioned the benefits of breast massage. Some mothers chose massage products, and others asked for professional massagists. P-Massage is a product for mothers and they can enjoy massage and pump milk at the same time by using P-Massage. Massage during lactation is very popular in many countries, and a lot of mothers find that it is beneficial to prevent mastitis and other problems regarding breast pumping. The design is some air inflation massage balls distributed on the breast, except the sensitive nipple-areola complex. When applying the vacuum, the massage ball will be inflated at the same time, and then apply pressure and vibration on the breast skins.

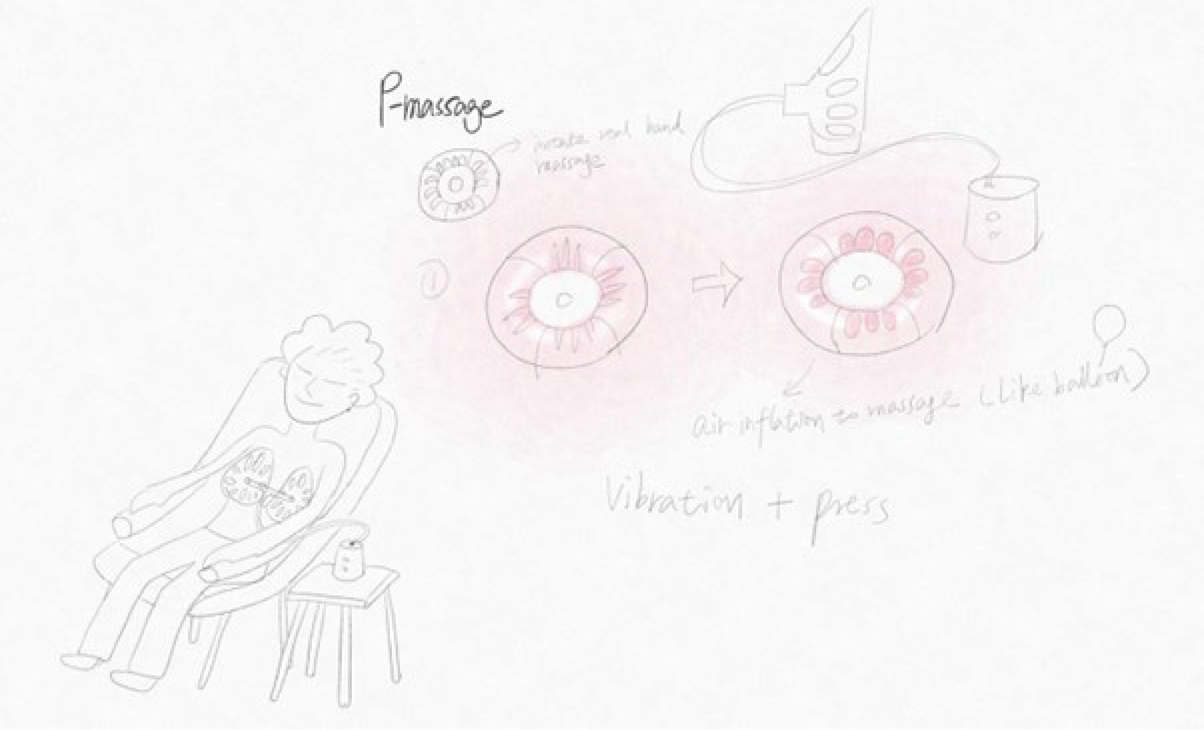


Fig. P-Massage

Concept Idea 2 MyCloth

MyCloth is a product that is very portable and convenient. It is an assembly breast pump attached to clothes. The shield is made of foam instead of silicone, which is softer, mothers may feel like they are not wearing any “breast pumps”, but just wearing comfortable clothes. This breast pump is good to keep privacy. Mothers can wear this breast pump and pump in a public place, and they do not need to worry about exposing their breasts or being embarrassed to pump in a public space.

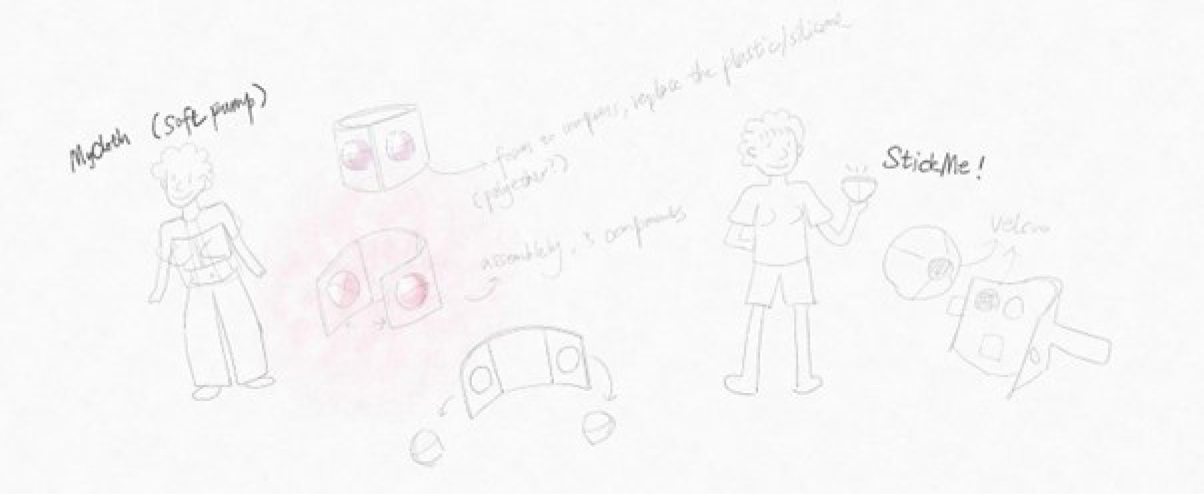


Fig. MyCloth

Concept Idea 3 ToyPump

A lot of mothers meet problems in which it is difficult to interact with babies while pumping. Lactating experts sometimes give advice on how to entertain babies if they need attention during mothers' pumping time. The ToyPump can solve this problem: mothers can entertain babies and pump milk at the same time. The babies' favourite toys or bells can be attached to the pumps, and dance or make music following the vacuum rhythm. Mothers could embrace babies while pumping, and babies can play with and grab the little bear on the pump. Playing with babies also stimulates hormone release, it would be easier and more efficient for mothers to generate and remove milk.

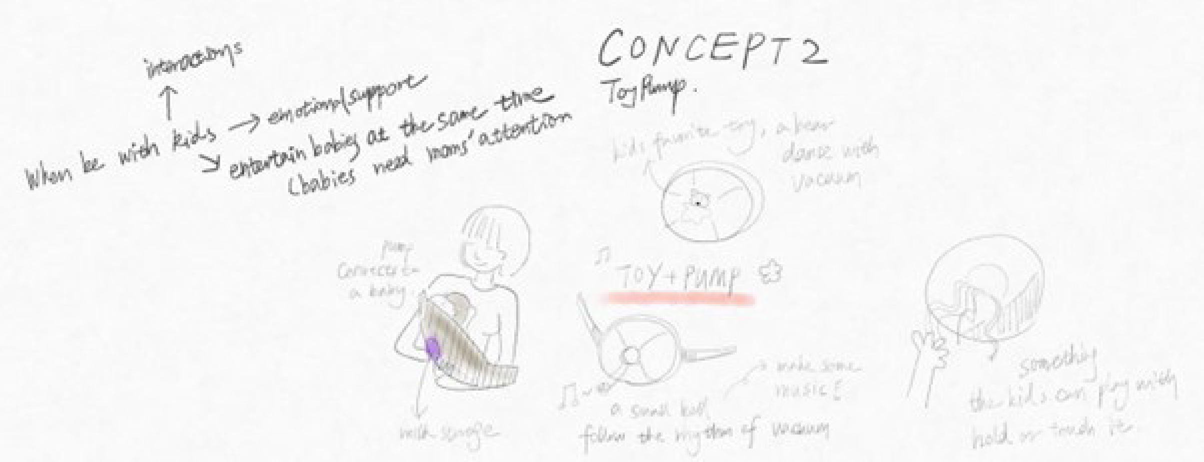


Fig. ToyPump

Concept Idea 4 PumpKit

The PumpKit is a product that includes one personalized breast pump shield and a lot of other accessories. Mothers can choose accessories and use them for different contexts depending on what they need. PumpKit is economical and sustainable, as mothers do not need to buy a lot of different products that are suitable for different scenarios. And after they end nursing, mothers can give them as a gift to other friends and family members, or sell them in the second-hand market. The next users do not need to worry about the mismatch problems, they can build up a breast pump with their personalized shield, and that would be a perfect fit breast pump for them.

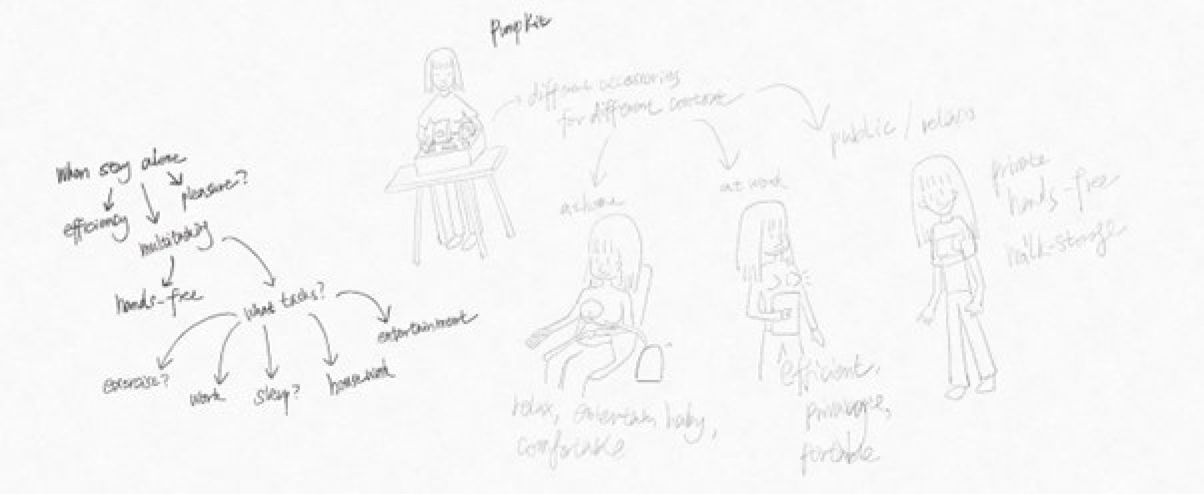


Fig. PumpKit

Shield Concept direction 1

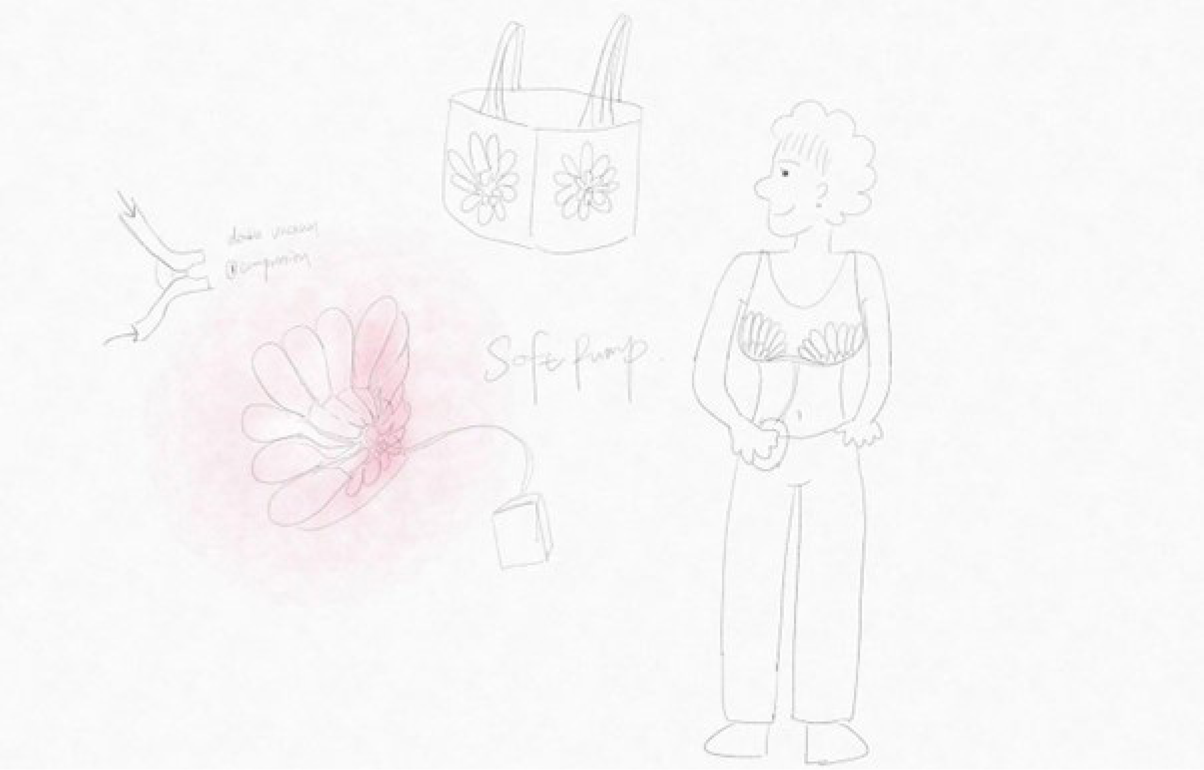


Fig. Shield concept direction 1

The first shield concept direction was inspired by the inflatable bed for bedsores. It can be called “SoftPump”. The flower shape shield is composed of multiple silicone parts. The silicone petals in the nipple-areola complex will compress the nipple and areola, and the petals in other breasts are used for the massage. All the petals are controlled by a pump.

Shield Concept direction 2

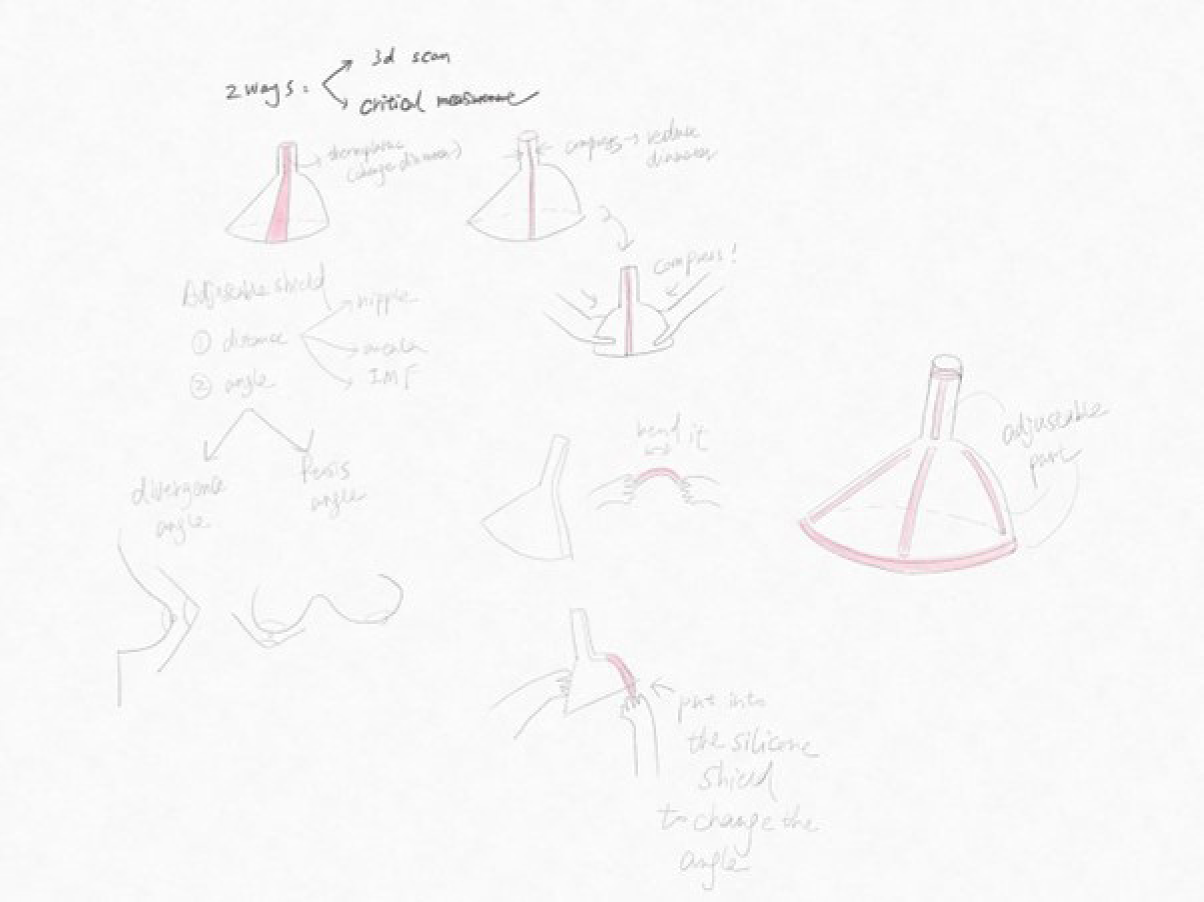


Fig. Shield concept direction 2

The second shield concept is an adjustable breast pump shield, the adjustable parts inside the silicone shields are made of thermo-soft plastic, which is a type of material that is easy to change shapes after putting in hot water. There are several critical parts on the shields that can be adjusted by the thermoplastic parts, such as the angles of breast 2D shapes from the top and the sides, and the diameter and length of the nipple and areola. The breast pump shield perfectly solved the problem that mothers' breasts and nipples may change in shape during nursing and even every day.

Shield Concept direction 3

Fig. Shield concept direction 3

The third concept is an assembly shield with a lot of different components, it is like an interesting “jigsaw puzzle”. Mothers can build up their breast pump shields based on the breast shapes.

7.3 Virtual Exploration

All the concepts were drawn on the iPad, and there are some text instructions next to them. Apart from the text explanation, I also prepared a short oral presentation to well explain the concepts and open up the discussion. Then mothers and experts will give their opinions regarding the concepts. The reviews were collected and reflected on the list of requirements and further product development.

7.4 Feedback & Evaluation

Mothers gave the feedback that they really like the massage ideas. Some of them got a massage from professional breast massagists, and the effects were really well. But the price of an experienced massagist is high, so it is nice to get an electric massage product combing with breast pumps. However, one mother mentioned she has really sensitive breasts, so the normal massage is painful to her; she hopes the force of massage can be adjusted.

From the feedback of experts, I learned that breast pumps should be innovative and have good competitiveness in the big market. For instance, there are many breast massage products on the market; the massage shield may not be that innovative. However, massage is proved useful with existing evidence, and the mechanisms should be well considered. As the breast is different from other parts of the body, the professional breast massagist very much relies on personal experience, and they use different massage patterns for different breasts. It might be difficult to find the right principles.

Mothers gave positive feedback to the “SoftPump”. They think pumping privacy and convenience are essential. In most cases, mothers pump milk separated from their babies. And in those cases, it is always in a public space. Some mothers said they are kind of “shameless” to breastfeed in public places, but there are still many mothers who feel embarrassed to pump in front of strangers. The “SoftPump” can be worn like a cloth, which makes the pumping process more private. And as users are wearing the pumps, it is also quite portable. In addition, mothers also mentioned the temperature of breast pumps is important. They think the SoftPump looks warmer than other products. Warm shields can always give mothers good and comfortable feelings during breast pumping. Users gave the feedback that the warm mouth of infants improves their comfort level, which is one of the reason why they do not like the electric pump, which is a cold machine.

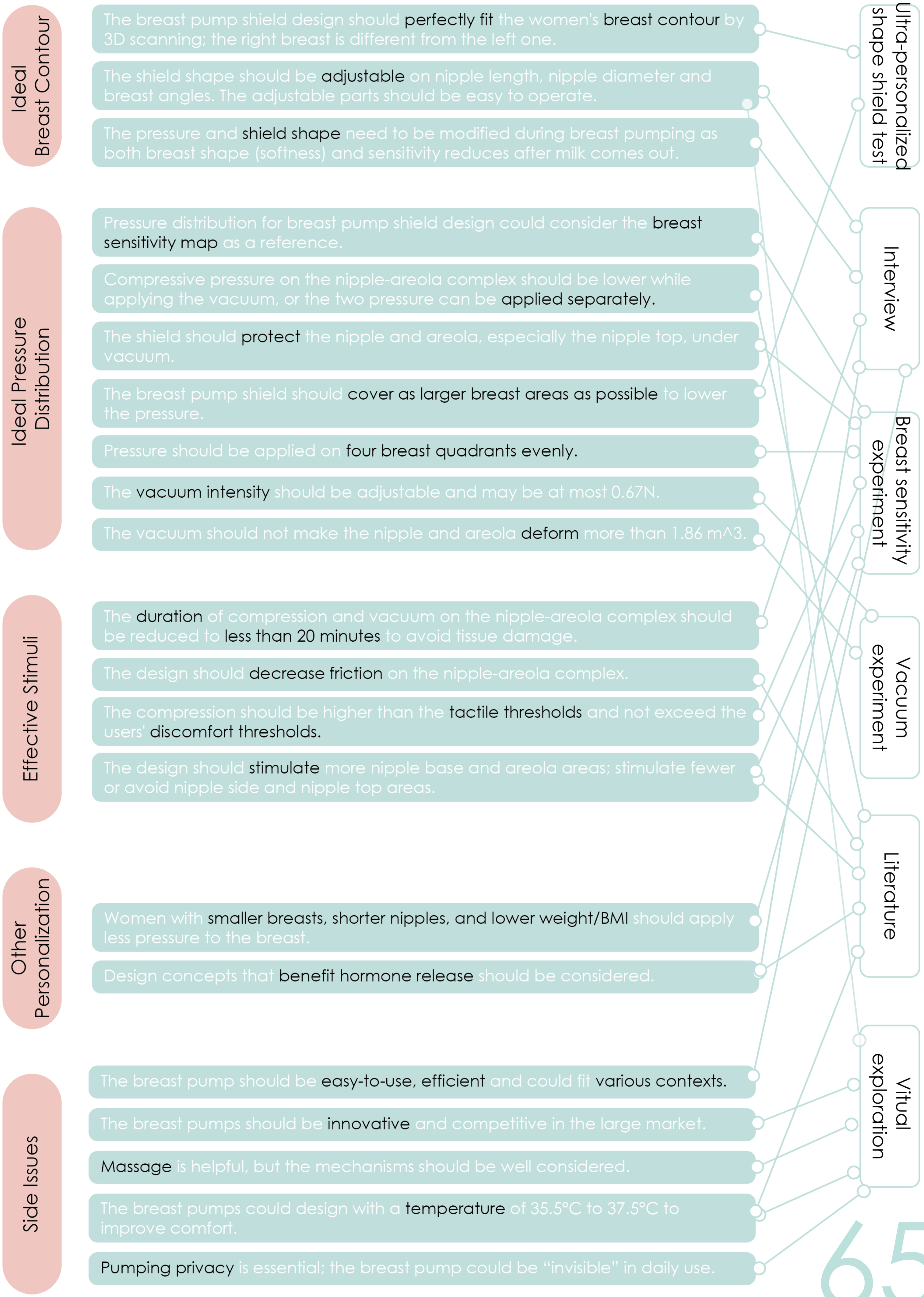
Some mothers especially like the PumpToy concept idea. Some of them have trouble pumping milk and entertaining their baby at the same time. Sometimes babies need attention when they are pumping milk; the PumpToy product can combine these two tasks together and create a happy experience with their babies.

Both mothers and experts gave good comments about the adjustable pumps. And they think the adjustable parts should be easy to operate. Therefore the second shield design direction adjustable shield is better than the third shield design direction assembly shield because the third one causes much trouble. Mothers reflected that the adjustable parts are useful, but their breasts are not changing every day, so sometimes it might be annoying to change the shapes. They may prefer to put a silicone insert instead of spending time changing the breast pump shield.

8 Final Design Recommendation

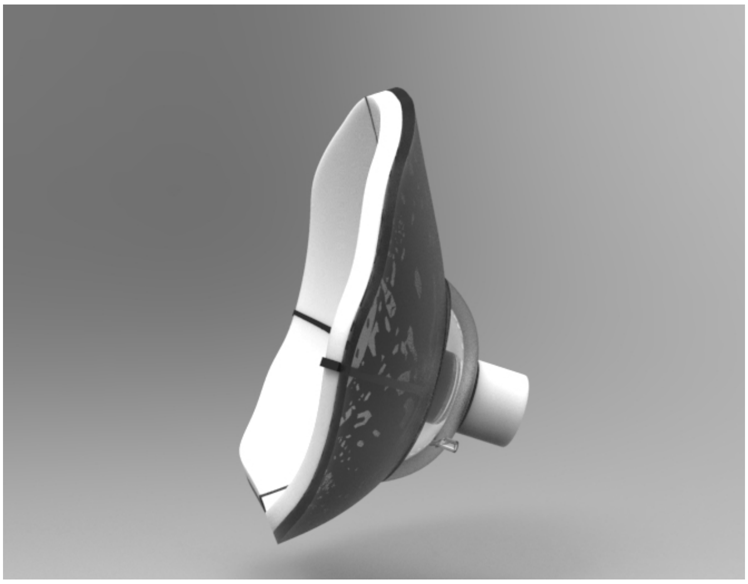
8.1 Consolidated List of Requirements

After finishing experiments and getting feedback from experts and users, some knowledge gaps were filled, and the LoR was developed. The final LoR for the ultra-personalized breast pump design are listed below:



8.2 Final Shield Design

The final design is a possible direction that implements a consolidated list of requirements listed above. I chose the shield design direction 2 in 7.2, the adjustable breast pump shield as the base of the final design direction. The final shield design gets an ultra-personalized shape of a human breast by 3D scanning, and the size can be adjusted on the nipple, areola and other breast areas by transformable thremoplastic. It consists of silicone and plastic components and applies different pressure on the nipple side, nipple base, areola, inner breast and outer breast. The vacuum is applied separately with the compression stimuli at the breast. When applying the vacuum, the silicone part is sucked away by the vacuum and does not contact the nipple and areola; all pressure would be applied to other breast areas, and the vacuum removes the milk; when it is a gap without the vacuum, the silicone stimulates the nipple and areola for milk ejection. The pressure on the nipple base and areola is higher than the pressure on the nipple side; there is no pressure applied on the nipple top. The hardness and thickness of silicone are higher at the areola and nipple base, so it would push the breast and make it deform more, which creates a higher pressure. All pressure applied on the nipple-areola complex is lower than the pressure at other areas of the breast. The new shield can be attached to the pump and other accessories to fit different using contexts, for example pumping at home or pumping at work.



8.2.1 Shield Prototyping

The new ultra-personalzied breast pump shield consists of silicone parts and plastic parts. The silicone parts are made of shore 10 hardness silicone. Four silicone molds (Fig. Silicone Molds) are in the figure. The shield shape was made based on the small size phantom breast in 9.1.

Fig. Silicone Molds 3D models

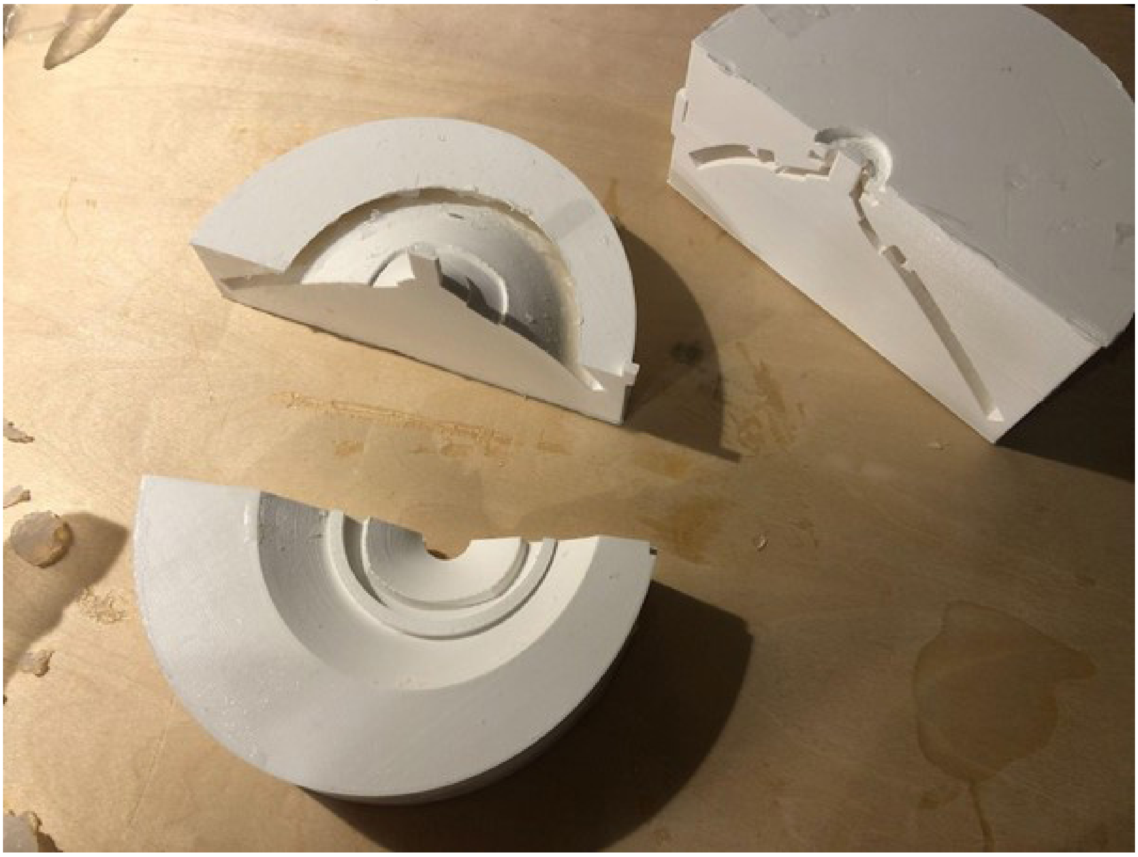


Fig. Silicone Molds

The plastic parts were mainly used for connecting the vacuum and supporting the silicone to make it harder. The components were made in Rhino and 3D printed (Fig. Prototype).

Fig. Prototype

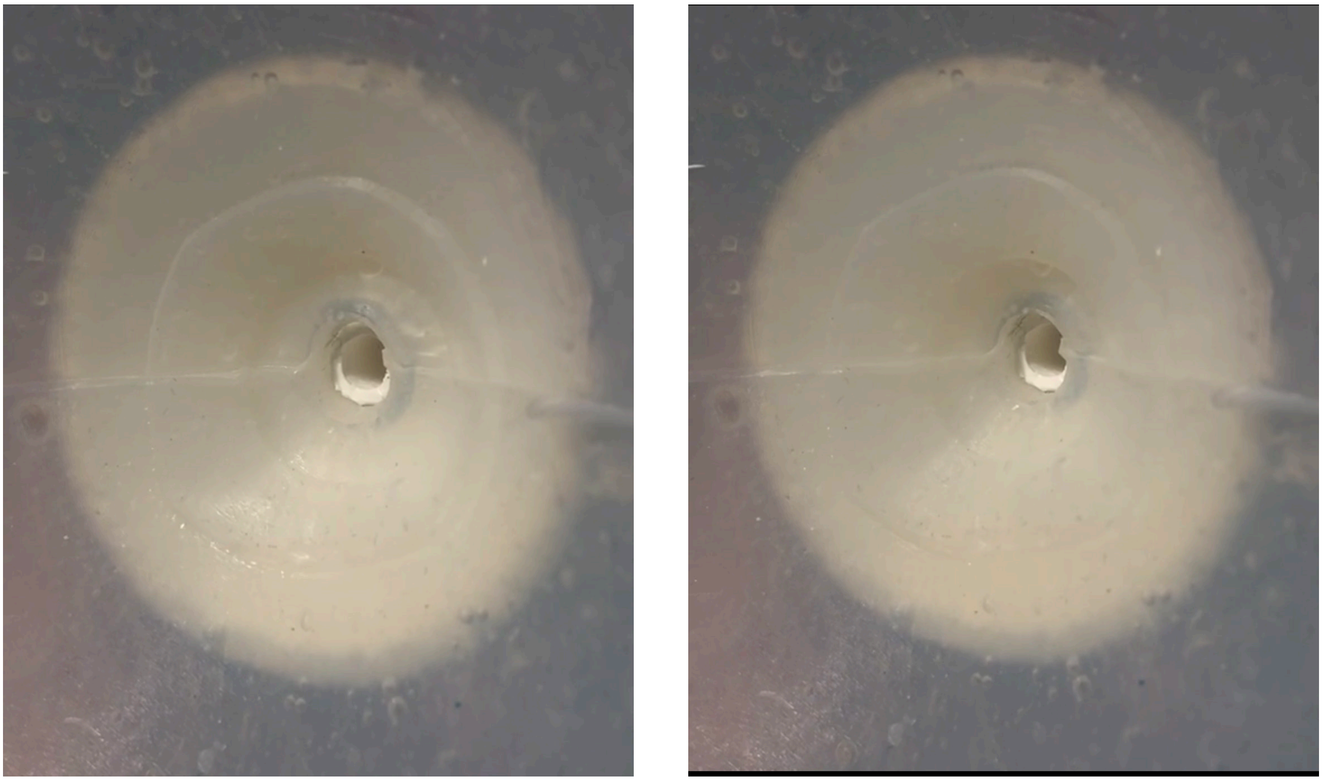


Fig. Shield deformation. (Left: with vacuum, right: without vacuum) When applying vaccum, the silicone shield would not contact the nipple-areola complex

9 Verification

9.1 Phantom Breast

As the time limitation for acquiring the ethical approval to implement experiments with real humans, phantom breasts were made for the design verification. The phantom breasts well presented the women group with small size nipples and areola, and average breast size.

9.1.1 Model Casting

The phantom breast should have a similar deformation performance as real breasts. It can be found from the breast pumping videos and literature (Rajagopal, 2008) that the areola part has a larger elongation than the nipple and other sections of the breast.

The model was made with the different hardness of silicone, with shore 10A hardness silicone as skin, and silicone gel that was softer than shore 00 as inside fatty and gland tissues (Veitch, 2019). The areola skin is 1.5 mm thick, and the rest breast skin is 3 mm thick, so they got different elongation performances when applying the same vacuum.

The breast models were made based on the data on nipple length, nipple diameter and areola diameter from 16 pieces of literature. Furthermore, the breast shape data is a mean model from the Regensburg Breast Shape Model (RBSM) database with 110 breast scans (Weiherer et al., 2022).

After the iteration of material, molds and silicone skin thickness, the final molds and phantom breast can be found below:

Fig. Phantom Breast Molds

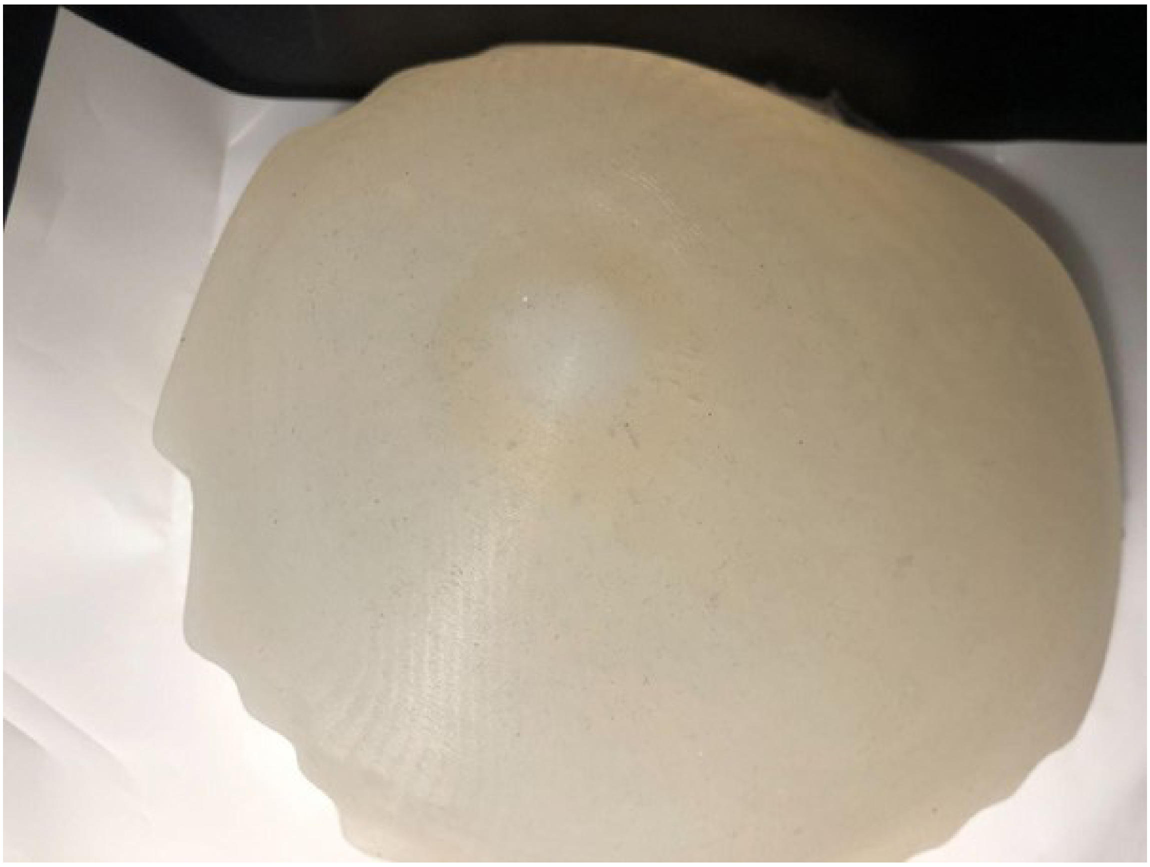


Fig. Phantom Breast

9.2 Pressure Verification

9.2.1 Verification Goals

The pressure verification experiment aims to measure how much force is applied to different areas of the breast by breast pump shields under a certain vacuum. There are six breast pump shields products, and one optimized shield design was tested (Fig. 7 shields). The main verification question is: Can the optimized shield design create a better pressure distribution while applying a vacuum than existing breast pump shields?

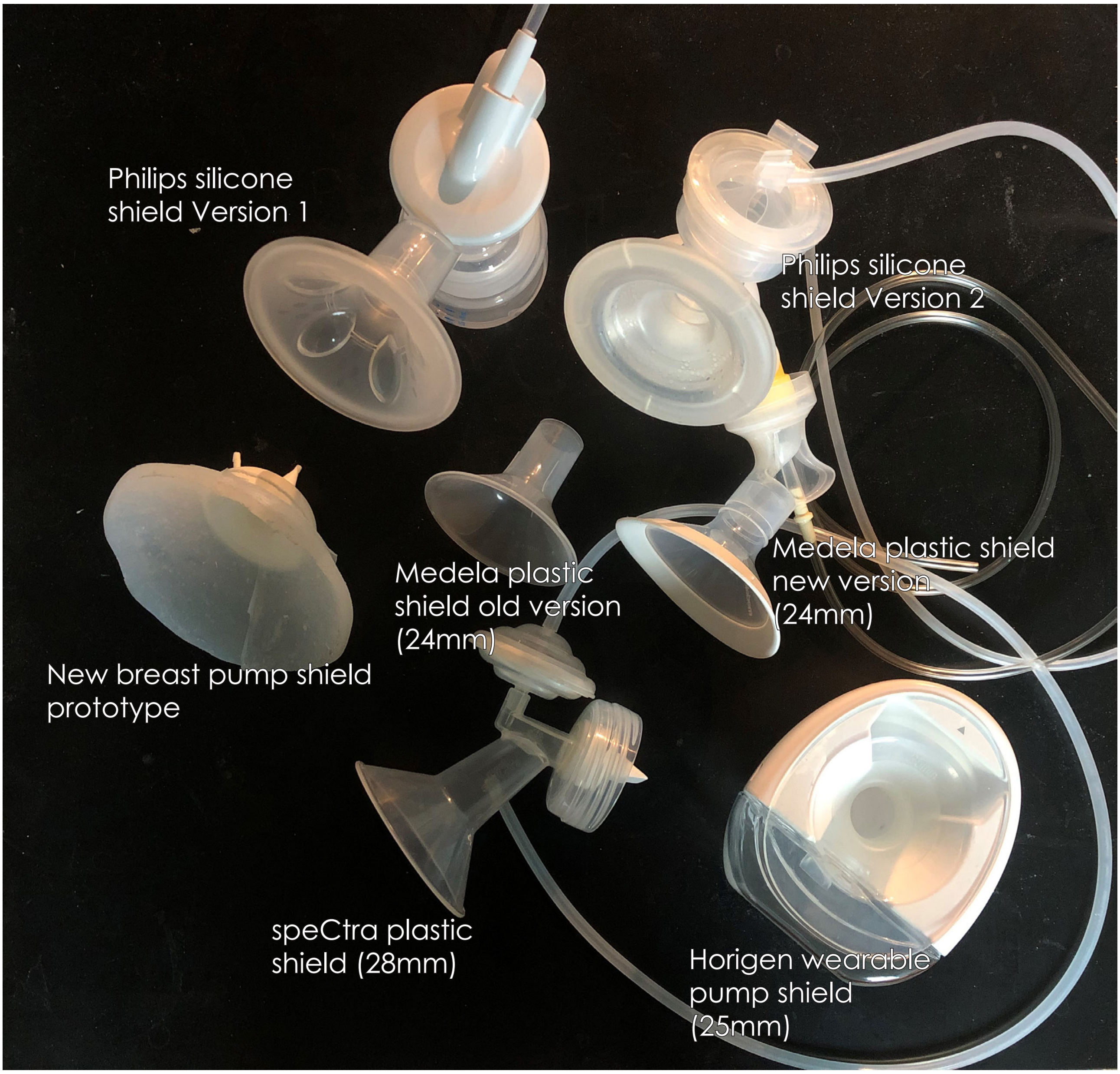
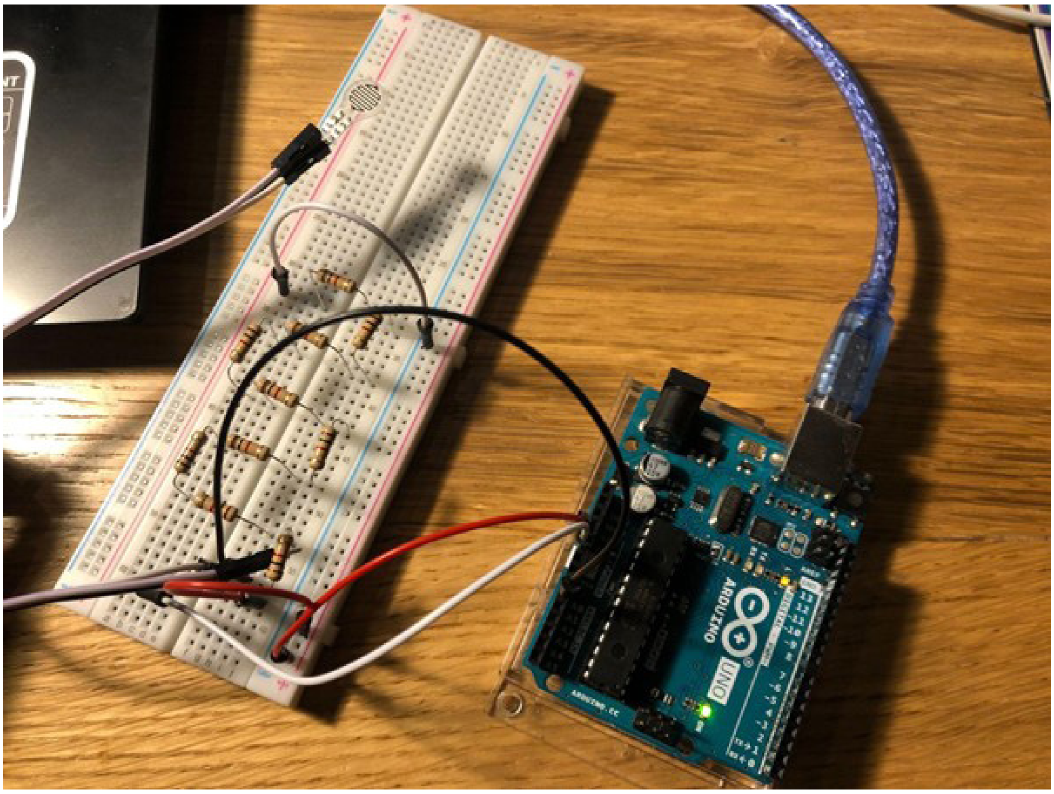
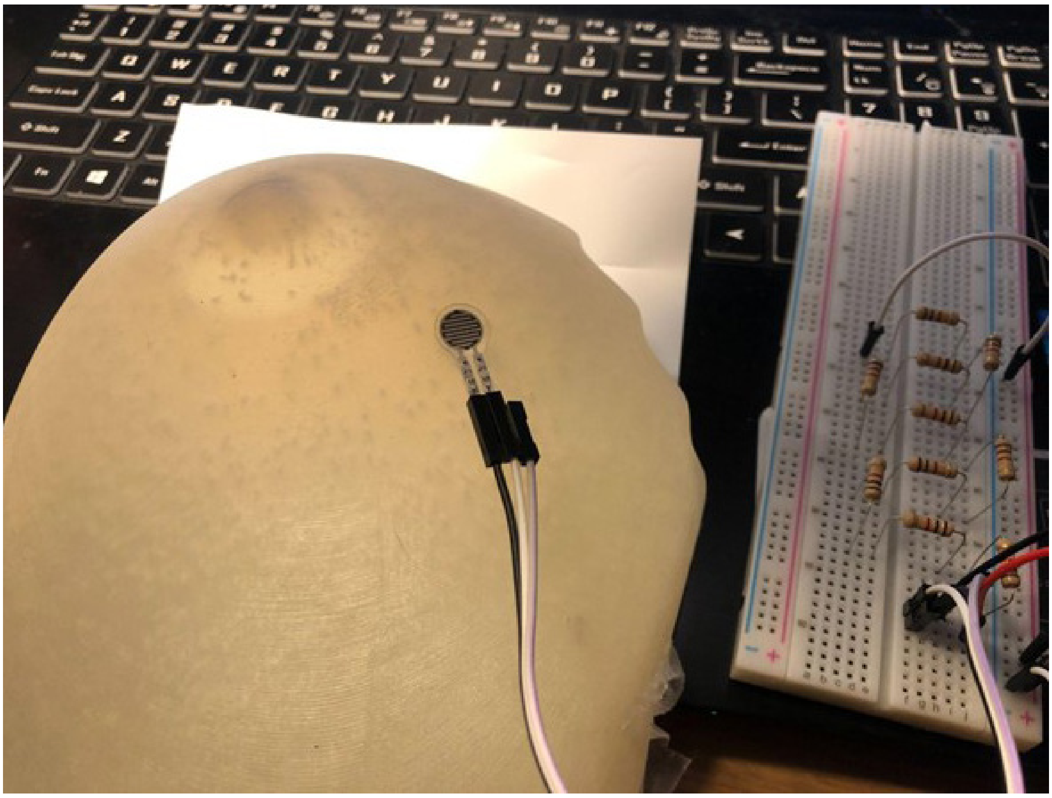


Fig. 7 shields

9.2.2 Verification Setup

The Force sensitive resistor (FSR) was stuck at five points of the breast to measure the dynamic, positive pressure between the phantom breast and the shield (Fig. FSR). As the nipple and areola size of the phantom breast is quite small, it is difficult to distinguish the nipple side and nipple base, therefore the two points were considered as the one point in the verification experiment. The FSR was connected to Arduino and the laptop; the programme generated the pressure data and serial plot captured by the FSR. Then the FSR could capture the voltage change and transmit it to an approximate force value (Fig. Pressure change).





Each breast pump shield was connected to a Philips Avent Pump for applying vacuum, except the Horigen wearable breast pump shield because it can not be connected to other pumps, but can only get vacuum from itself. Every shield was used for one minute, the peak force and voltage was recorded in excel (see Appendix. Verification). A dynamic pressure mapping for the existing and new breast pump shield was created.

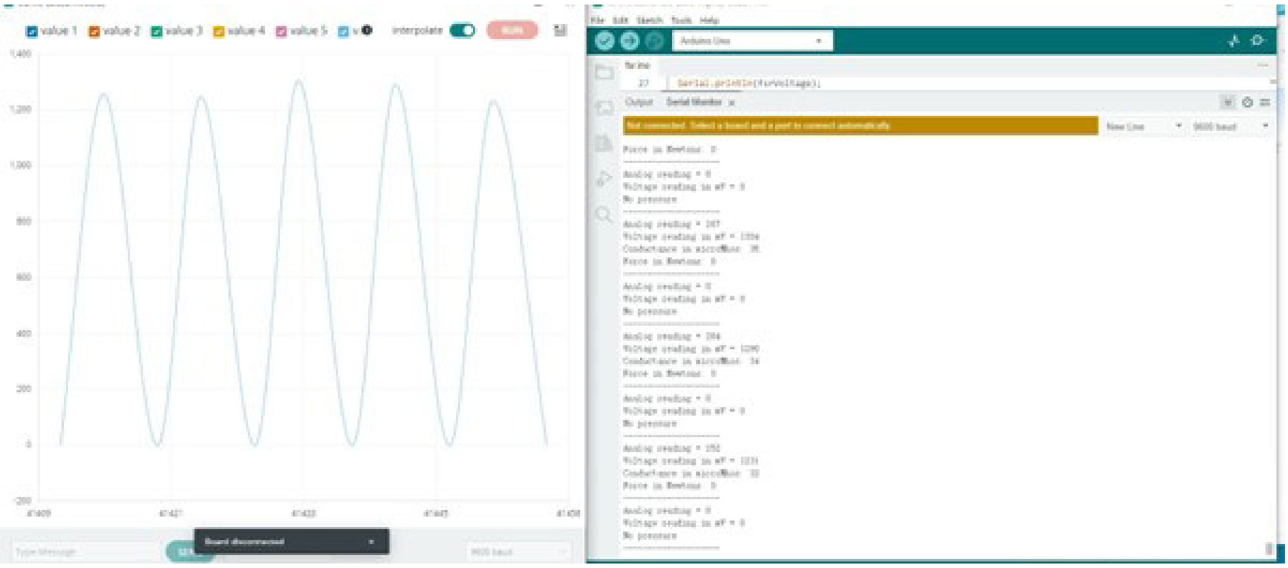


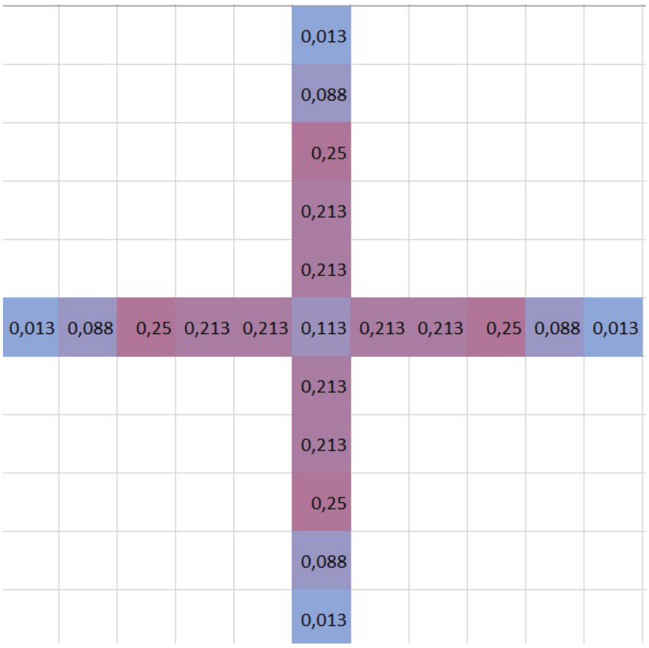
Fig. Pressure change

9.2.3 Verification Results & Conclusions

Seven pressure heat maps based on the results in the Excel were created (Fig. Heat Map). According to the result, it is clear that only the new breast pump shield design has a similar pressure distribution principle that is the same with the breast sensitivity heat map in 6.2.5: the pressure applied to areola is higher than nipple base/side, and higher than nipple top. Moreover, the pressure of the new breast pumzp shield distributed evenly on the whole breast areas, and covered the peripheral breast areas; but between some other breast pump shields and some areas of the breast, the pressure could not be measured. Apart from the new breast pump design, all the other breast pump shields do not have the pressure on the outer breast areas, as their contact areas to breast skin are smaller and do not cover those areas. It can also be seen from the heat map that the 28mm shield created lower pressure on areola areas than 25mm and 24mm size shields. The reason is that the nipple and areola size of the phantom is small, so the breast pump shields which are too large could not reach and touch the areola areas.

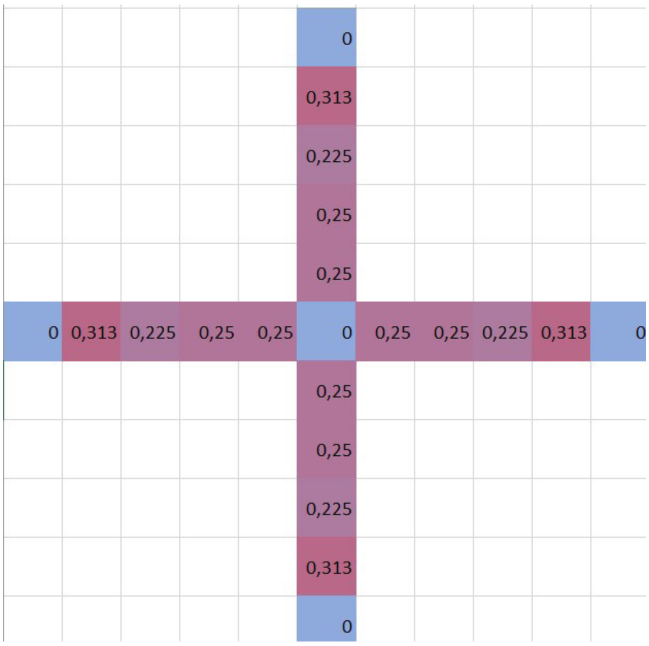
Besides, the new breast pump shield design has separate vacuum and compressive pressure on the nipple-areola complex. The other breast pump shield created the vacuum and positive pressure on the nipple-areola complex at the same time.

In conclusion, the new breast pump design is theoretically more comfortable than other traditional breast pump shields as it creates an optimised pressure distribution which is similar to the breast sensitivity map.



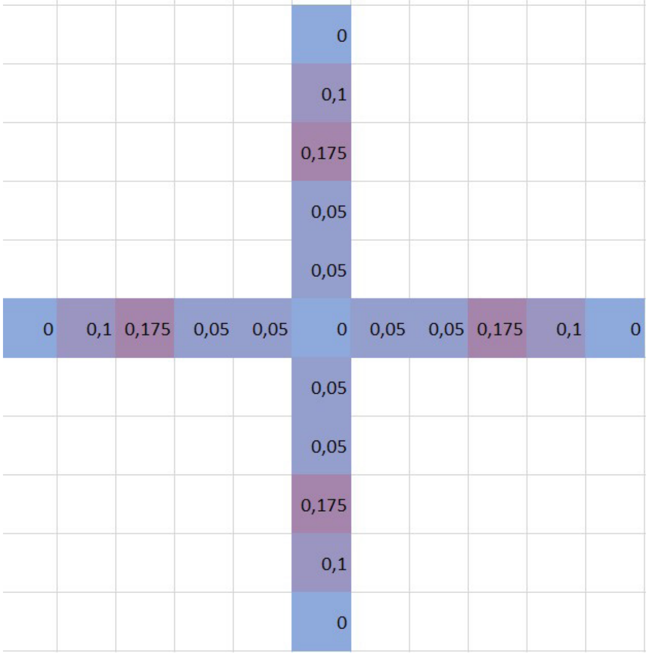
					0,013					
					0,088					
					0,25					
					0,213					
					0,213					
0,013	0,088	0,25	0,213	0,213	0,113	0,213	0,213	0,25	0,088	0,013
					0,213					
					0,213					
					0,25					
					0,088					
					0,013					

New breast pump shield prototype



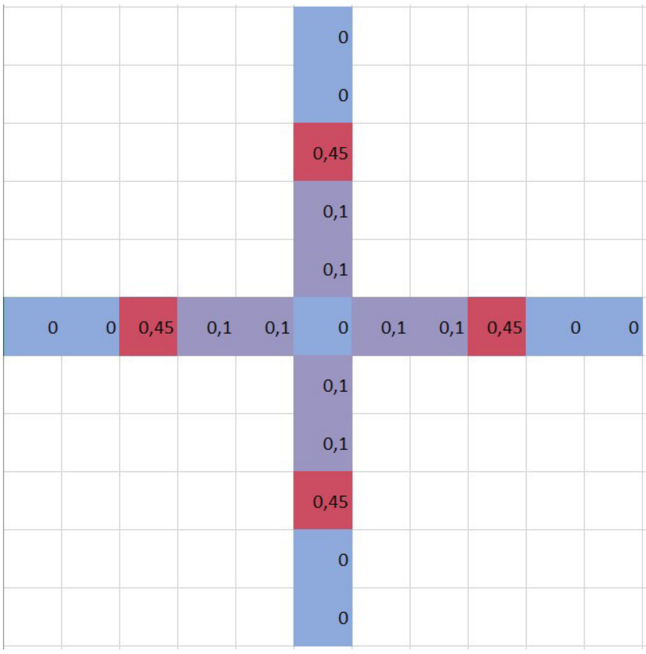
					0					
					0,313					
					0,225					
					0,25					
					0,25					
0	0,313	0,225	0,25	0,25	0	0,25	0,25	0,225	0,313	0
					0,25					
					0,25					
					0,225					
					0,313					
					0					

Philips silicone shield Version 1



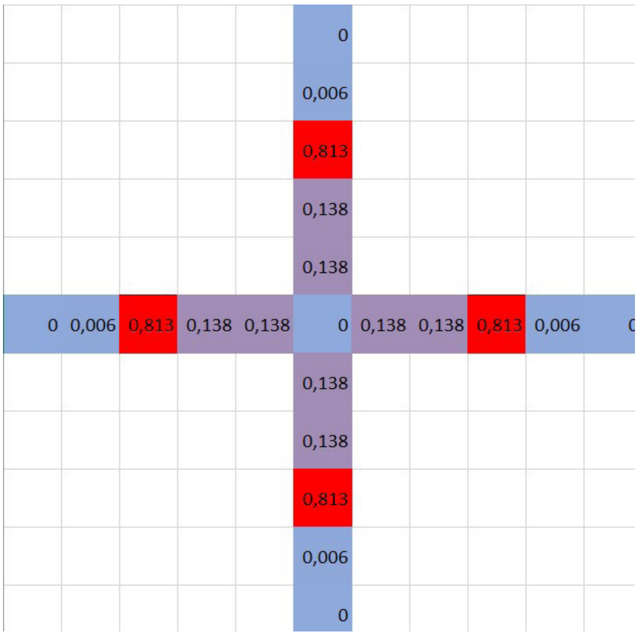
					0					
					0,1					
					0,175					
					0,05					
					0,05					
0	0,1	0,175	0,05	0,05	0	0,05	0,05	0,175	0,1	0
					0,05					
					0,05					
					0,175					
					0,1					
					0					

Philips silicone shield Version 2



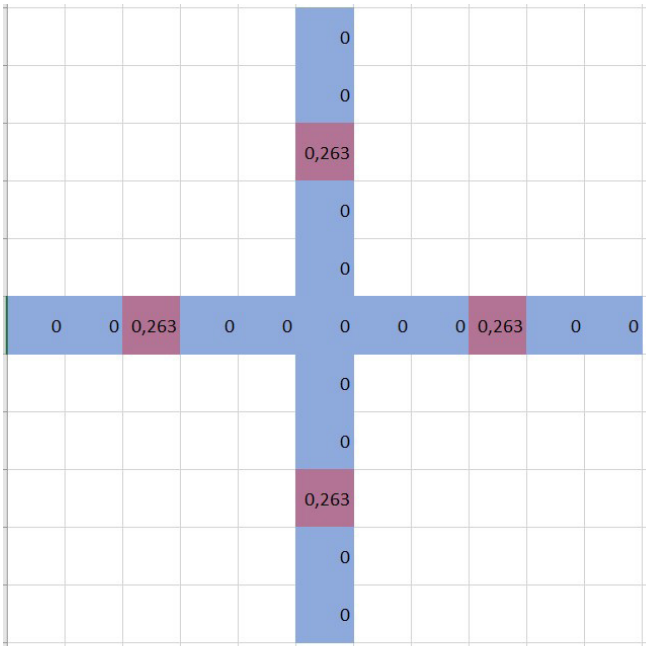
					0					
					0					
					0,45					
					0,1					
					0,1					
0	0	0,45	0,1	0,1	0	0,1	0,1	0,45	0	0
					0,1					
					0,1					
					0,45					
					0					
					0					

Medela plastic shield old version (24mm)



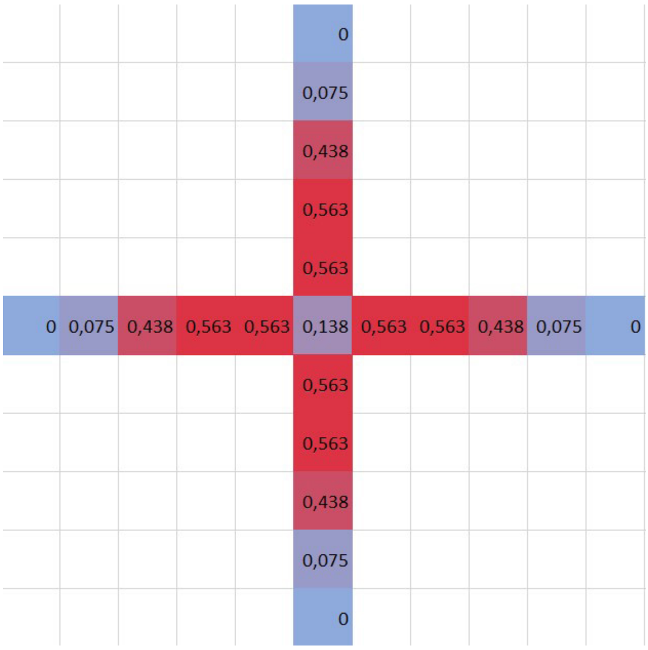
					0					
					0,006					
					0,813					
					0,138					
					0,138					
0	0,006	0,813	0,138	0,138	0	0,138	0,138	0,813	0,006	0
					0,138					
					0,138					
					0,813					
					0,006					
					0					

Medela plastic shield new version (24mm)



					0					
					0					
					0,263					
					0					
					0					
0	0	0,263	0	0	0	0	0	0,263	0	0
					0					
					0					
					0,263					
					0					
					0					

speCtra plastic shield (28mm)



					0					
					0,075					
					0,438					
					0,563					
					0,563					
0	0,075	0,438	0,563	0,563	0,138	0,563	0,563	0,438	0,075	0
					0,563					
					0,563					
					0,438					
					0,075					
					0					

Horigen wearable pump shield
(25mm)

Fig. Heat Map

10 Evaluation and Reflection

10.1 Limitations & Contributions

The most valuable contribution of this project is the breast sensitivity study results, and a consolidated LoR with design recommendation for guiding the ultra-personalized breast pump design. The final design proposal that applied the LoR was verified as it reduces the discomfort during breast pumping and creates a new start of ultra-personalizing breast pump design.

However, the breast sensitivity study has some limitations and can be further developed and improved.

Firstly, the equipment for testing breast sensitivity is a 500N AFG, which cannot capture the lower force that is applied. However, for some women with small breasts, their nipples are quite sensitive to pressure and the pressure making them feel uncomfortable is lower than the AFG scales, therefore cannot be measured. That is the reason there are a lot of zeros in the data collection table.

Secondly, the limitation of the non-experienced operator. Due to the limitation of ethical approval, the participants need to do the experiments by themselves. As they are all novice with AFG and this experiment, there were some errors happening during data collection. It makes the results not that precise.

Thirdly, the breast difference between lactating mothers and non-lactating women. As it is difficult to find lactating women participants, a lot of non-lactating women were recruited. Even though the breast structure between them are similar, after women give birth to a baby, the breast shape and glands would be a bit different than before. Therefore there can be some deviations in the results.

Fourthly, the contact areas may influence the discomfort. When the contact areas are small, the perceived discomfort might be higher. However, when the contact areas are large enough, the perceived discomfort would increase following the contact areas increasing (Goonetilleke,1994). As the experiment used a small contact adapter to measure the breast sensitivity, the actual perceived discomfort would differ when the whole nipple and areola areas were pressed.

After that, limitations of remote experiments. Some experiments were conducted remotely and researchers were giving online guidance. The remote guiding is not convenient compared to face-to-face guiding, which may cause some misunderstanding and decrease the experiment precision.

Finally, the critical discomfort feelings. At the beginning of some discomfort threshold research, some mothers said they did not feel any "discomfort" at all even if they applied large force on the breasts and the breast shape changed a lot, for instance one mother mentioned "I may misunderstand the discomfort evaluation… I have suffered a lot from feeding my baby, I just feel nothing when applying such small pressure on my breast." Therefore the criteria of discomfort might be very subjective and hard to measure in the real context.

Apart from that, the final LoR also can be further developed. First of all, the LoR mainly includes the physical aspects of how to improve breast pumping comfort, but the actual comfort is strongly related to psychological aspects. Combining the psychological and physical aspects together can create a real comfortable breast pumping experience. Besides, some design requirements can be further detailed after the design verification and evaluation. For example the materials and the actual embodiment.

10.2 Evaluation of the Design

Besides the advantages of the final design that was mentioned in 9.2.3, the new breast pump shield also has a lot of drawbacks to be further developed. For instance, the pressure applied on the inner and outer breast could be higher, and the design development could concentrate on how to improve the pressure in the peripheral breast areas. The pressure on the nipple-areola complex did not exceed the mean value of the breast pressure discomfort threshold in 6.2, but it should be designed lower for some mothers with sensitive breasts. Moveover, the method to estimate the individual breast sensitivity levels of mothers is another important parameter that should be considered in the future ultra-personalized breast pump design.

The final design also lacks the consideration of breast deformation. The breast would deform during breast pumping under the vacuum and the deformation would influence the perceived pressure. The vacuum itself would cause the discomfort as well, but the vacuum study in the 6.4 only measured the deformation of the nipple and part of the areola; the deformation of the whole breast should be considered in the further research: what is the individual differences of the breast deformation, what parameters can influence the breast deformation (for instance the breast volume, if the breast is full of milk, etc). The deformation data would be really valuable to be applied in the breast pump design.

Finally, the milk production is another missing part that is important in breast pumping. One of the golden standards to validate if the stimuli on the nipple-areola complex is effective is the sufficient and efficient milk production. This is also an important parameter in many current breast pumps and breastfeeding research. The new breast pump design improves the physical comfort for breast pumping, but if the comfortable shield is also effective in milk production is still unknown. The combination of milk production research and comfort shield design could be a meaningful research direction in the future.

Reference

Kuehn, B. (2022). Breastfeeding report card. JAMA, 320(14), 1426-1426.
Thorley V: The dilemma of breastmilk feeding. Breastfeed Rev. 2011, 19: 5-7.

Odom, E. C., Li, R., Scanlon, K. S., Perrine, C. G., & Grummer-Strawn, L. (2013). Reasons for Earlier Than Desired Cessation of Breastfeeding. Pediatrics, 131(3), e726–e732. https://doi.org/10.1542/peds.2012-1295.

Morton, JA . Strategies to support extended breastfeeding of the premature infant. Adv Neonatal Care. 2002;2(5):267-282.

Zoppou, C, Barry, SI, Mercer, GN. Comparing breastfeeding and breast pumps using a computer model. J Hum Lact. 1997;13(3):195-202.

Qi, Y., Zhang, Y., Fein, S., Wang, C., & Loyo-Berríos, N. (2014). Maternal and breast pump factors associated with breast pump problems and injuries. Journal of Human Lactation, 30(1), 62–72. https://doi.org/10.1177/0890334413507499

Buckley, K. M., & Charles, G. E. (2006). Benefits and challenges of transitioning preterm infants to at-breast feedings. International breastfeeding journal, 1(1), 1-7.
Dwyer, D. (2008). Coping with breast pump problems. Nursing2022, 38(4), 25.

Kent, J. C. (2007). How Breastfeeding Works. Journal of Midwifery & Women’s Health, 52(6), 564–570. https://doi.org/10.1016/j.jmwh.2007.04.007

Kent, J. C., Ramsay, D. T., Doherty, D., Larsson, M., & Hartmann, P. E. (2003). Response of Breasts to Different Stimulation Patterns of an Electric Breast Pump. Journal of Human Lactation, 19(2), 179–186. https://doi.org/10.1177/0890334403252473

Newton, M., & Newton, N. R. (1948). The let-down reflex in human lactation. Journal of Pediatrics, 33, 698-704.

Ramsay, D. T., Kent, J. C., Owens, R. A., & Hartmann, P. E. (2004). Ultrasound Imaging of Milk Ejection in the Breast of Lactating Women. Pediatrics, 113(2), 361–367. https://doi.org/10.1542/peds.113.2.361

Ramsay, D. T., Mitoulas, L. R., Kent, J. C., Cregan, M. D., Doherty, D. A., Larsson, M., & Hartmann, P. E. (2006). Milk Flow Rates Can Be Used to Identify and Investigate Milk Ejection in Women Expressing Breast Milk Using an Electric Breast Pump. Breastfeeding Medicine, 1(1), 14–23. https://doi.org/10.1089/bfm.2006.1.14

Medela. (n.d.). Freestyle Flex™ | Mobile Double Electric Breast Pump. Medela. Retrieved 2022, from https://shop.medela.co.uk/products/breast-pumps/freestyle-flex

Pumpin Pal. (n.d.). Pumpin Pal Breast Pumping Accessories – Innovative breast pumping accessories to make pumping more comfortable and enjoyable.

Retrieved 2022, from https://pumpinpal.com

LacTech. (n.d.). Mimic nursing while pumping. LacTeck. Retrieved 2022, from https://www.lacteck.com/babymotion-flange

Meier, P. P., Patel, A. L., Hoban, R., & Engstrom, J. L. (2016). Which breast pump for which mother: an evidence-based approach to individualizing breast pump technology. Journal of Perinatology, 36(7), 493–499. https://doi.org/10.1038/jp.2016.14

Bika, N. (2021, August 27). What is Hyper-Personalization? Future of Customer Experience. Acquire. Retrieved October 8, 2022, from https://acquire.io/blog/hyper-personalization/

Felice, J. P., & Rasmussen, K. M. (2015). Breasts, pumps and bottles, and unanswered questions. Breastfeeding Medicine, 10(9), 412-415.

Becker, G. E. (2021). Measuring Mothers' Viewpoints of Breast Pump Usage. International Journal of Environmental Research and Public Health, 18(8), 3883.

Ashkenazy, S., & Ganz, F. D. (2019). The differentiation between pain and discomfort: a concept analysis of discomfort. Pain Management Nursing, 20(6), 556-562.

Lee, W., Lee, B., Kim, S., Jung, H., Jeon, E., Choi, T., & You, H. (2015). 3D scan to product design: Methods, techniques, and cases. In Proceedings of the 6th International Conference on 3D Body Scanning Technologies, Lugano, Switzerland. October 27-28, 2015; Authors version. Hometrica Consulting.

Chu, C. H., Wang, I. J., Wang, J. B., & Luh, Y. P. (2017). 3D parametric human face modeling for personalized product design: Eyeglasses frame design case. Advanced Engineering Informatics, 32, 202–223. https://doi.org/10.1016/J.AEI.2017.03.001

Zoppou, C., Barry, S. I., & Mercer, G. N. (1997). Dynamics of human milk extraction: A comparative study of breast feeding and breast pumping. Bulletin of Mathematical Biology, 59(5), 953–973. https://doi.org/10.1007/BF02460001

Alatalo, D., Jiang, L., Geddes, D., & Hassanipour, F. (2020). Nipple deformation and peripheral pressure on the areola during breastfeeding. Journal of Biomechanical Engineering, 142(1). https://doi.org/10.1115/1.4043665

Alekseev, N. P., Omel'ianuk, E. v, & Talalaeva, N. E. (2000). [Dynamics of milk ejection reflex during continuous rhythmic stimulation of areola-nipple complex of the mammary gland]. Rossiiskii Fiziologicheskii Zhurnal Imeni I.M. Sechenova, 86(6), 711–719. http://www.ncbi.nlm.nih.gov/pubmed/10955309

Alekseev, N. P., Ilyin, V. I., Yaroslavski, V. K., Gaidukov, S. N., Tikhonova, T. K., Specivcev, Y. A., Omelyanjuk, E. V., & Tkachenko, N. N. (1998). Compression stimuli increase the efficacy of breast pump function. European Journal of Obstetrics &

Gynecology and Reproductive Biology, 77(2), 131–139. https://doi.org/10.1016/S0301-2115(97)00269-8

Alekseev, N. P., & Ilyin, V. I. (2016). The Mechanics of Breast Pumping: Compression Stimuli Increased Milk Ejection. Breastfeeding Medicine, 11(7), 370–375. https://doi.org/10.1089/bfm.2015.0172

Jesinger, R. A. (2014). Breast Anatomy for the Interventionalist. Techniques in Vascular and Interventional Radiology, 17(1), 3–9. https://doi.org/10.1053/J.TVIR.2013.12.002

Geddes, D. T. (2007). Inside the Lactating Breast: The Latest Anatomy Research. Journal of Midwifery and Women's Health, 52(6), 556–563. https://doi.org/10.1016/j.jmwh.2007.05.004

Pandya, S., & Moore, R. G. (2011). Breast Development and Anatomy. Clinical Obstetrics & Gynecology, 54(1), 91–95. https://doi.org/10.1097/GRF.0b013e318207ffe9

Prendergast, P. M. (2015). Fascia, nerve supply, and lymphatics of the breast. In Aesthetic Surgery of the Breast (pp. 39-42). Springer, Berlin, Heidelberg.

Stevenson, A. (Ed.). (2010). Oxford Dictionary of English. Oxford University Press, USA.
Vink, P., & Lips, D. (2017). Sensitivity of the human back and buttocks: The missing link in comfort seat design. Applied Ergonomics, 58, 287–292. https://doi.org/10.1016/J.APERGO.2016.07.004

Longo, B., Farcomeni, A., Ferri, G., Campanale, A., Sorotos, M., & Santanelli, F. (2013). The BREAST-V. Plastic and Reconstructive Surgery, 132(1), 1e–7e. https://doi.org/10.1097/PRS.0b013e318290f6bd

Rajagopal, V., Lee, A., Chung, J.-H., Warren, R., Highnam, R. P., Nash, M. P., & Nielsen, P. M. F. (2008). Creating Individual-specific Biomechanical Models of the Breast for Medical Image Analysis. Academic Radiology, 15(11), 1425–1436. https://doi.org/10.1016/j.acra.2008.07.017

Veitch, D. (2019). A Tactile Correct (Biofidelic) Teaching Model for Training Medical Staff to Diagnose Breast Cancer Detecting Breast Disease using Palpation. https://doi.org/10.4233/uuid:d4b385c9-6d47-44f6-a959-4125825e7f06

Weiherer, M., Eigenberger, A., Egger, B., Brébant, V., Prantl, L., & Palm, C. (2022). Learning the shape of female breasts: an open-access 3D statistical shape model of the female breast built from 110 breast scans. The Visual Computer. https://doi.org/10.1007/s00371-022-02431-3

Goonetilleke, R. S., & Eng, T. J. (1994). Contact Area Effects on Discomfort. Proceedings of the Human Factors and Ergonomics Society Annual Meeting, 38(10), 688–690. https://doi.org/10.1177/154193129403801032

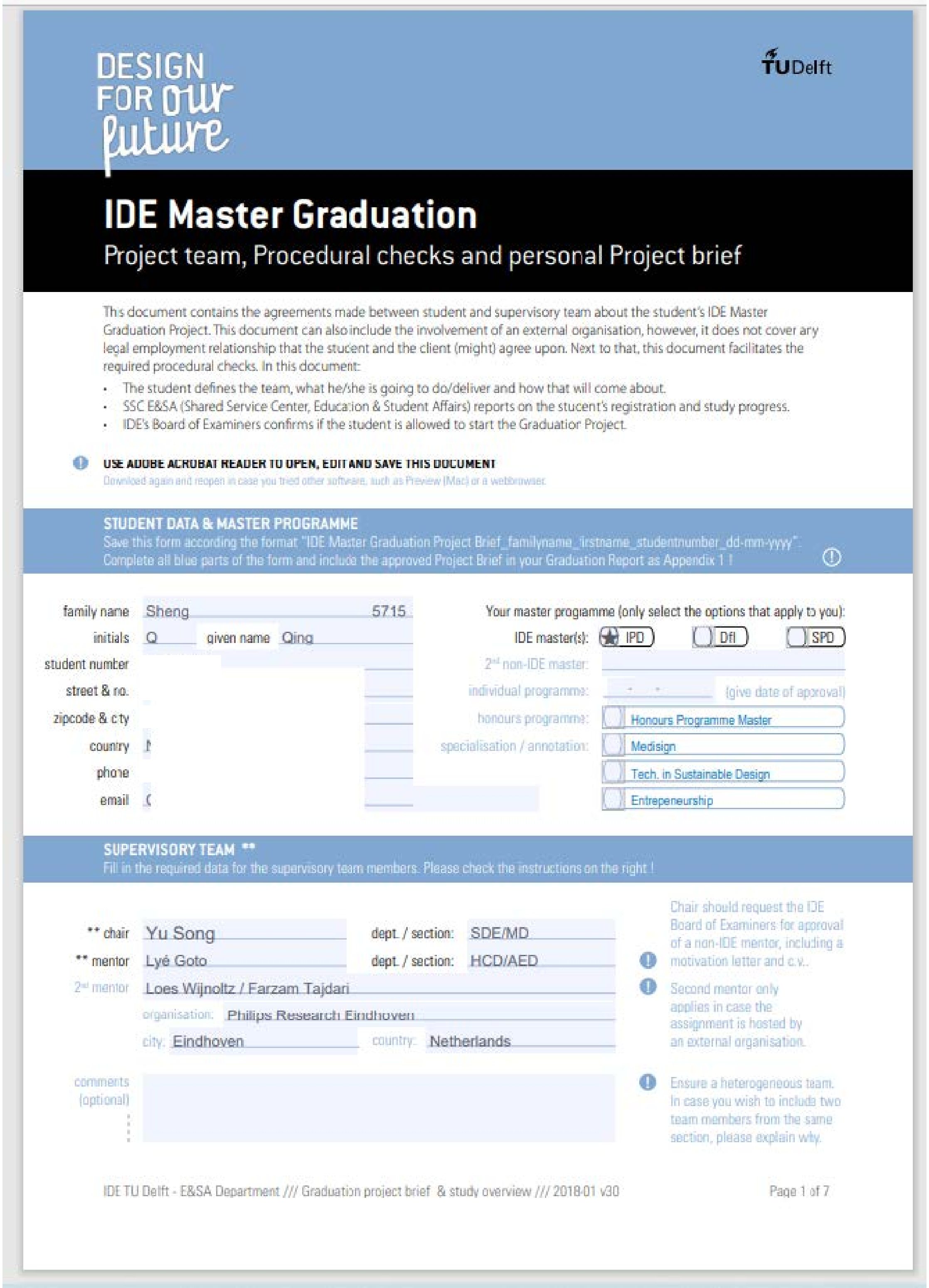
Armstrong, M., & Bjarnadottir, A. (2021, August 24). Combining Breastfeeding and Pumping: Reason, Tips, and More. Healthline. Retrieved 2022, from https://www.healthline.com/health/breastfeeding/how-to-combine-breastfeeding-and-pumping

Jesinger, R.A. (2014). Breast anatomy for the interventionalist. Techniques in vascular and interventional radiology, 17 1, 3-9 .

Prendergast, P. M. (2015). Fascia, nerve supply, and lymphatics of the breast. In Aesthetic Surgery of the Breast (pp. 39-42). Springer, Berlin, Heidelberg.

Appendix

Appendix A. Project Brief



DESIGN
FOR our
future

TUDelft

IDE Master Graduation

Project team, Procedural checks and personal Project brief

This document contains the agreements made between student and supervisory team about the student's IDE Master Graduation Project. This document can also include the involvement of an external organisation, however, it does not cover any legal employment relationship that the student and the client (might) agree upon. Next to that, this document facilitates the required procedural checks. In this document:

- The student defines the team, what he/she is going to do/deliver and how that will come about.
- SSC E&SA (Shared Service Center, Education & Student Affairs) reports on the student's registration and study progress.
- IDE's Board of Examiners confirms if the student is allowed to start the Graduation Project.

USE ADOBE ACROBAT READER TO OPEN, EDIT AND SAVE THIS DOCUMENT
Download again and reopen in case you tried other software, such as Preview (Mac) or a webbrowser.

STUDENT DATA & MASTER PROGRAMME
Save this form according the format "IDE Master Graduation Project Brief_familyname_firstname_studentnumber_dd-mm-yyyy".
Complete all blue parts of the form and include the approved Project Brief in your Graduation Report as Appendix 1 !

family name Sheng 5715
initials Q given name Qing
student number [redacted]
street & no. [redacted]
zipcode & city [redacted]
country [redacted]
phone [redacted]
email [redacted]

Your master programme (only select the options that apply to you):
IDE master(s): ● IPD ○ DfI ○ SPD
2nd non-IDE master:
individual programme: - - (give date of approval)
honours programme: ○ Honours Programme Master
specialisation / annotation: ○ Medisign
○ Tech. in Sustainable Design
○ Entrepeneurship

SUPERVISORY TEAM **
Fill in the required data for the supervisory team members. Please check the instructions on the right !

** chair Yu Song dept. / section: SDE/MD
** mentor Lyé Goto dept. / section: HCD/AED
2nd mentor Loes Wijnoltz / Farzam Tajdari
organisation: Philips Research Eindhoven
city: Eindhoven country: Netherlands

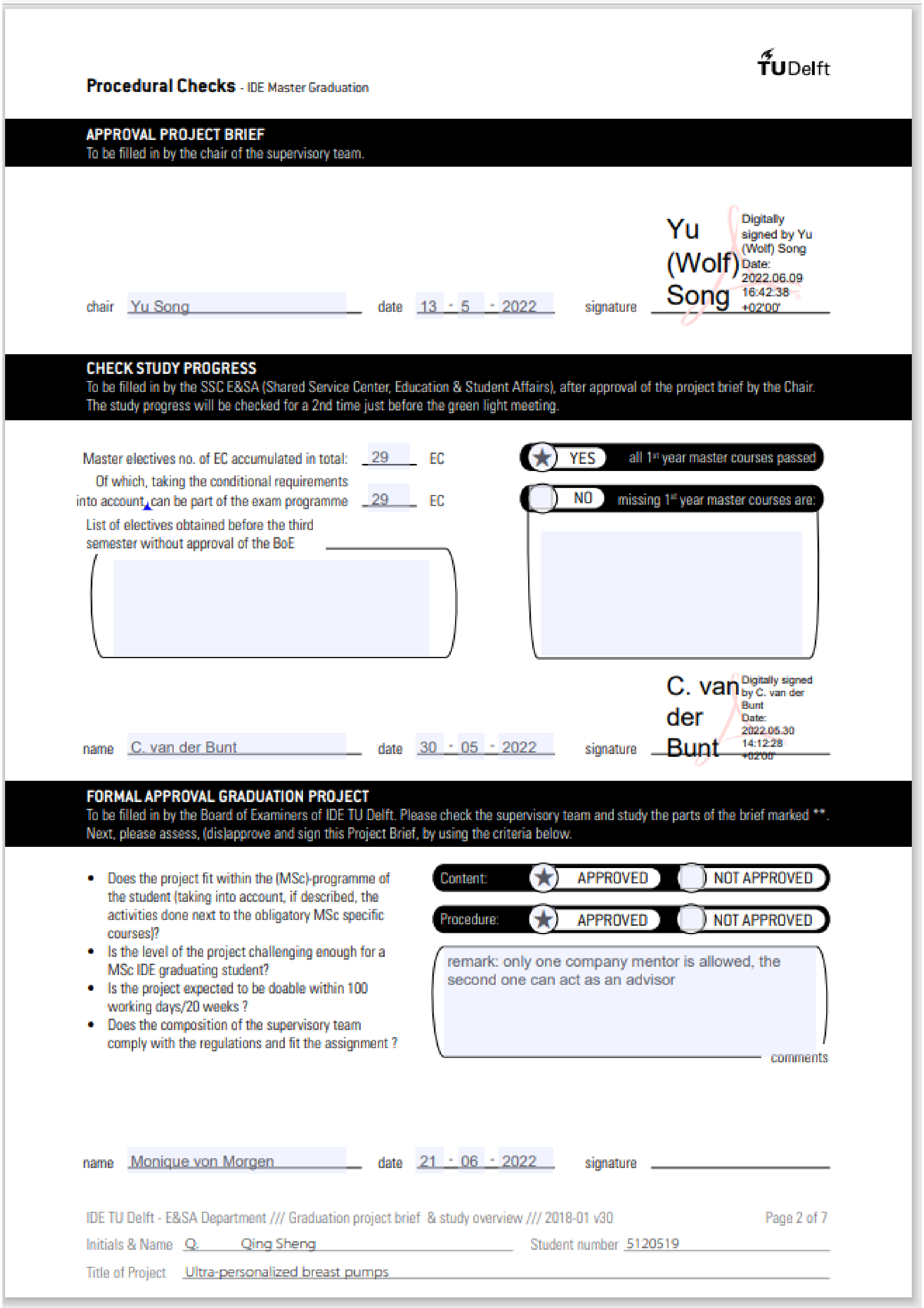
comments (optional)

Chair should request the IDE Board of Examiners for approval of a non-IDE mentor, including a motivation letter and c.v..

Second mentor only applies in case the assignment is hosted by an external organisation.

Ensure a heterogeneous team. In case you wish to include two team members from the same section, please explain why.

IDE TU Delft - E&SA Department /// Graduation project brief & study overview /// 2018-01 v30 Page 1 of 7



Procedural Checks - IDE Master Graduation

TU Delft

APPROVAL PROJECT BRIEF

To be filled in by the chair of the supervisory team.

chair Yu Song date 13 - 5 - 2022 signature Yu (Wolf) Song

Digitally signed by Yu (Wolf) Song
Date: 2022.06.09 16:42:38 +02'00'

CHECK STUDY PROGRESS

To be filled in by the SSC E&SA (Shared Service Center, Education & Student Affairs), after approval of the project brief by the Chair.
The study progress will be checked for a 2nd time just before the green light meeting.

Master electives no. of EC accumulated in total: 29 EC

Of which, taking the conditional requirements into account, can be part of the exam programme 29 EC

List of electives obtained before the third semester without approval of the BoE

● YES all 1st year master courses passed

○ NO missing 1st year master courses are:

name C. van der Bunt date 30 - 05 - 2022 signature C. van der Bunt

Digitally signed by C. van der Bunt
Date: 2022.05.30 14:12:28 +02'00'

FORMAL APPROVAL GRADUATION PROJECT

To be filled in by the Board of Examiners of IDE TU Delft. Please check the supervisory team and study the parts of the brief marked **.
Next, please assess, (dis)approve and sign this Project Brief, by using the criteria below.

- Does the project fit within the (MSc)-programme of the student (taking into account, if described, the activities done next to the obligatory MSc specific courses)?
- Is the level of the project challenging enough for a MSc IDE graduating student?
- Is the project expected to be doable within 100 working days/20 weeks ?
- Does the composition of the supervisory team comply with the regulations and fit the assignment ?

Content: ● APPROVED ○ NOT APPROVED

Procedure: ● APPROVED ○ NOT APPROVED

remark: only one company mentor is allowed, the second one can act as an advisor

comments

name Monique von Morgen date 21 - 06 - 2022 signature

IDE TU Delft - E&SA Department /// Graduation project brief & study overview /// 2018-01 v30 Page 2 of 7

Initials & Name Q. Qing Sheng Student number 5120519

Title of Project Ultra-personalized breast pumps

Personal Project Brief - IDE Master Graduation

TU Delft

Ultra-personalized breast pumps

project title

Please state the title of your graduation project (above) and the start date and end date (below). Keep the title compact and simple. Do not use abbreviations. The remainder of this document allows you to define and clarify your graduation project.

start date 16 - 5 - 2022

21 - 10 - 2022 end date

INTRODUCTION **

Please describe, the context of your project, and address the main stakeholders (interests) within this context in a concise yet complete manner. Who are involved, what do they value and how do they currently operate within the given context? What are the main opportunities and limitations you are currently aware of (cultural- and social norms, resources (time, money,...), technology, ...).

Breastfeeding is beneficial for both mothers and infants. Most breastfeeding mothers use breast pumps for milk expression in order to achieve different personal goals of human milk feeding. However, there are a lot of breast pump-related discomfort and injuries reported by mothers, for instance sore nipples, nipple dryness and pressure bruises. Discomfort and pain may lead to anxiety, fatigue, stress and fear of mothers, affect lactation and reduce mothers' willingness for maintaining milk supply.

Breast pump-related discomfort and injuries could be caused by several reasons such as pump misoperation, wrong flange size or pumping strength, which are in essence the one-fits-all or limited sizes and types of breast pumps do not fit all mothers' bodies and individual situations. For breastfeeding women, breast shapes, nipple sizes, dependency for breast pumps, lactation stages and pumping postures differ from mothers to mothers. For healthcare professionals, settings, sizes and types recommendations for breast pumps are often given based on personal experience due to lack of evidence and limited choices (PP Meier et al, 2016).

Current research with regard to breast pumps mainly focused on milk production, human milk removing speed and efficiency or infants' behaviors imitation, the infants were considered as gold standard for estimating breast pumps. There is unfortunately little research aimed at mothers' comfort experience during breastfeeding. In some cases, mothers even compromise on comfort in order to improve milk removing efficiency, some of them believe that discomfort or pain needed to be tolerated to achieve speed (Becker, G. E., 2021).

Philips Research, cooperating with the Next UPPS team, intends to investigate the body-product interactions during breast pumping and to figure out the cause of discomfort. To solve those problems, studying nipple and areola deformations during breast pumping are a potential approach. The Next UPPS team has been doing some research about 4D scanning and volumetric registration, which works as design automation tools for personalized product design.

With those stakeholders and requirements in mind, main opportunities for this project are research and analysis specifically focusing on mothers' comfort during breast pumping, breast deformations studies can be important independent variables. There is also an opportunity to design ultra-personalized products for each mother, in order to support health-care professionals with practical advice and improve the wellbeing of breastfeeding mothers.

Limitations of this project mostly relate to the topic sensitivity and complexity. Breast pumps and lactation are sometimes sensitive topics for many mothers, people perceive them differently in different cultures, which may lead to difficulties for ergonomics research and comfort tests with mothers. On the other hand, breastfeeding is a dynamic process with complex physical and hormonal control, which means that one parameter change may have influence on others, therefore biological perspectives of breasts need to be considered well.

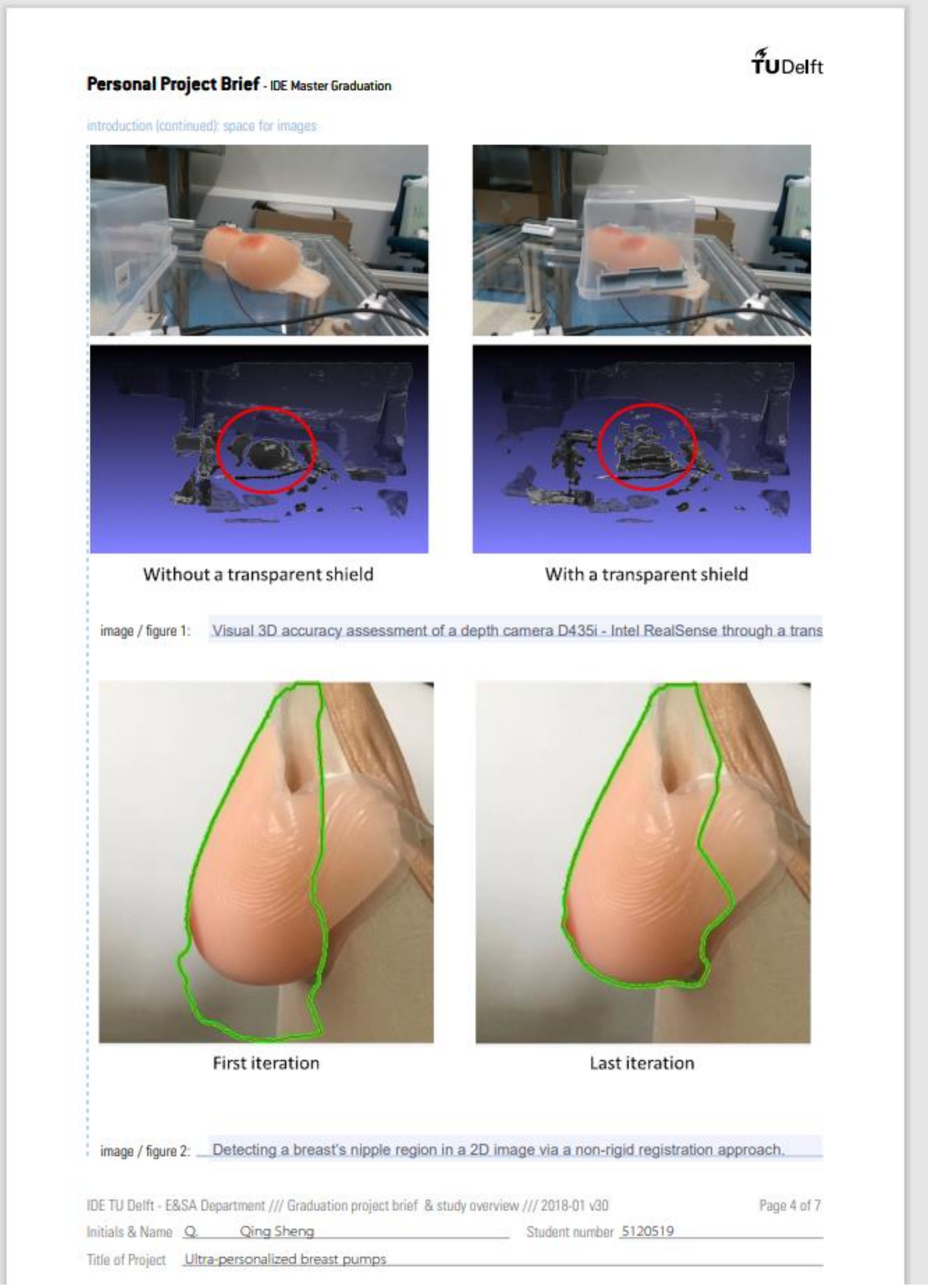
Reference

space available for images / figures on next page

IDE TU Delft - E&SA Department /// Graduation project brief & study overview /// 2018-01 v30 Page 3 of 7

Initials & Name Q. Qing Sheng Student number 5120519

Title of Project Ultra-personalized breast pumps



Personal Project Brief - IDE Master Graduation

introduction (continued): space for images

Without a transparent shield

With a transparent shield

image / figure 1: Visual 3D accuracy assessment of a depth camera D435i - Intel RealSense through a trans

First iteration

Last iteration

image / figure 2: Detecting a breast's nipple region in a 2D image via a non-rigid registration approach.

IDE TU Delft - E&SA Department /// Graduation project brief & study overview /// 2018-01 v30

Page 4 of 7

Initials & Name Q. Qing Sheng

Student number 5120519

Title of Project Ultra-personalized breast pumps

TU Delft

Personal Project Brief - IDE Master Graduation

PROBLEM DEFINITION **

Limit and define the scope and solution space of your project to one that is manageable within one Master Graduation Project of 30 EC (= 20 full time weeks or 100 working days) and clearly indicate what issue(s) should be addressed in this project.

Breastfeeding process is quite complex and there has been a lot of research addressed in this topic mostly in biological perspectives. A design perspective, which focuses on mothers' comfort and using experience, is essential for combining and applying data from multidisciplinary areas, to achieve a mother-centered breast pump design approach. What parameters do mothers value the most? How do mothers feel and what causes their discomfort?

Vacuum pressure is the main power for human milk removing than other pressures and is currently used in many existing breast pumps. In addition to that, this kind of pressure mainly applys to nipples and the areola areas surrounding the nipples. Therefore, the research scope towards that can be formulated as: Analysing nipples and areola deformations and motions under different pumping vacuum pressures and breast pump shields is crucial for evidence-based comfort tests. How do nipples and areola deform when mothers perceive comfort and discomfort with varied negative pressures and shield sizes?

Ultra-personalized solutions for breast pumps are potential applications of this project. How to apply the data collected from research to design and balance mothers' needs with lactation performance are issues that should be addressed, in order to create a not only comfortable but also efficient breast pumping experience.

ASSIGNMENT **

State in 2 or 3 sentences what you are going to research, design, create and / or generate, that will solve (part of) the issue(s) pointed out in "problem definition". Then illustrate this assignment by indicating what kind of solution you expect and / or aim to deliver, for instance: a product, a product-service combination, a strategy illustrated through product or product-service combination ideas, ... In case of a Specialisation and/or Annotation, make sure the assignment reflects this/these.

The primary goal of this project is that through mother-centered comfort experience ergonomics research based on nipple and areola deformations and motions during breast pumping by 4D scanning breasts, to design affordable ultra-personalized breast pumps with smart data applications. The solution will improve mothers' using experience for breast pumps and reduce breast pump-related discomfort and injuries.

The project will include 3 phases: research and analysis, ideation and conceptualization, implementation and iteration.

In the research and analysis stage, literature reviews and interviews will be conducted to get insights from existing research and stakeholders, what do they value, need and concern. The insights will be used as a basis for ergonomics experiment set up and assumptions making, a list of requirements will be created. After that, there will be 4D scanning for participants' breasts with deformations and motions captured during breast pumping, which will use the Philips' breast pump products on the market, to study the relations between nipples and areola deformations and users' local perceived discomfort.

For the ideation and conceptualization stage, the data and insights collected from previous research will be used for speculating on potential approaches for ultra-personalized breast pump design.

The final implementation and iteration stage is about prototyping the concept in the previous stage, trying to make good use of users' digital twin and transfer the data into a meaningful design. The low-cost manufacturing method should also be considered.

IDE TU Delft - E&SA Department /// Graduation project brief & study overview /// 2018-01 v30 Page 5 of 7

Initials & Name Q. Qing Sheng Student number 5120519

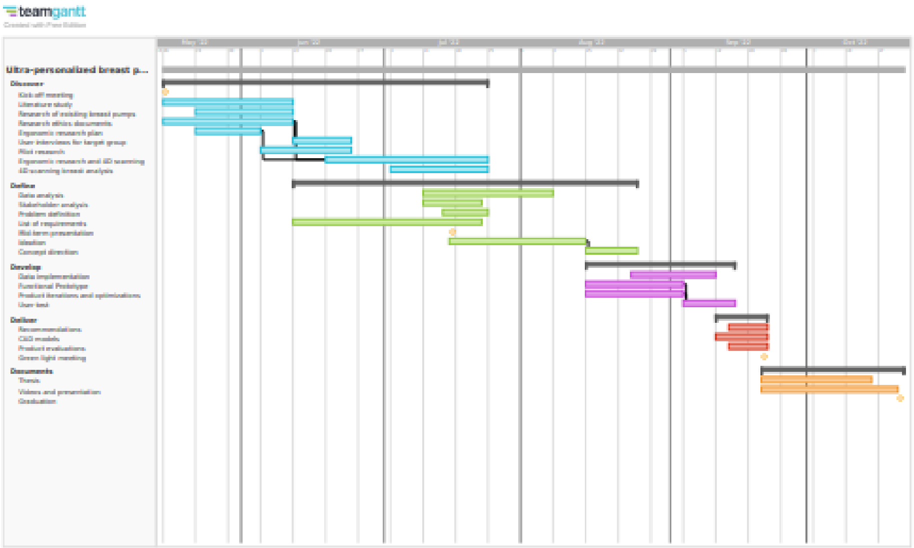
Title of Project Ultra-personalized breast pumps

PLANNING AND APPROACH **

Include a Gantt Chart (replace the example below - more examples can be found in Manual 2) that shows the different phases of your project, deliverables you have in mind, meetings, and how you plan to spend your time. Please note that all activities should fit within the given net time of 30 EC = 20 full time weeks or 100 working days, and your planning should include a kick-off meeting, mid-term meeting, green light meeting and graduation ceremony. Illustrate your Gantt Chart by, for instance, explaining your approach, and please indicate periods of part-time activities and/or periods of not spending time on your graduation project, if any, for instance because of holidays or parallel activities.

start date 16 - 5 - 2022

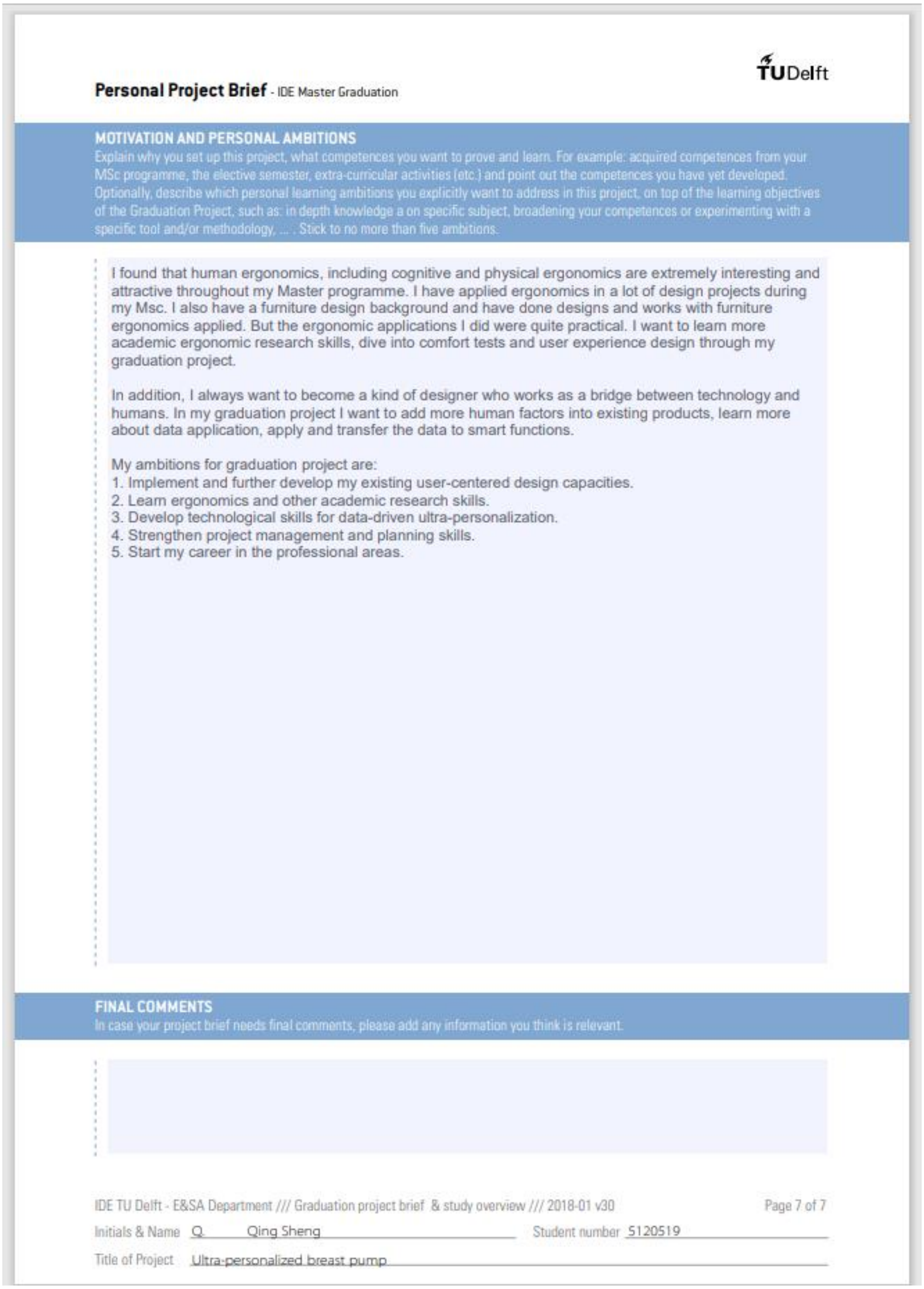
21 - 10 - 2022 end date



The presented graduation planning applied the Double diamond design process model as an approach, dividing the graduation project into four phases: Discover, Define, Develop and Deliver. The project begins with two months' Discover and Define phase that involves studying literatures, technologies, doing ergonomic research and 4D scanning. After that the concept direction will be defined, followed by the Development and Deliver phase, focusing on prototyping, iterations and user tests. Then there will be a time period for the thesis, other deliables and presentation preparation.

The planning consists of 100 working days (23 working weeks), including 3 national holidays (Ascension Day and Whit Monday) and one week break after mid-term meeting. From week 5 to week 8 in Q4, I work four days per week as I have an 3 ECs elective on Tuesday. I will start five days full time working from June 13. The planning might be changed a bit according to the research ethics documents approval time and the implementation of each phase.

4 important project days:
Kick-off meeting: May 16
Mid-term meeting: July 15
Green light meeting: September 23
Graduation ceremony: October 21



Personal Project Brief - IDE Master Graduation

TUDelft

MOTIVATION AND PERSONAL AMBITIONS

Explain why you set up this project, what competences you want to prove and learn. For example: acquired competences from your MSc programme, the elective semester, extra-curricular activities (etc.) and point out the competences you have yet developed. Optionally, describe which personal learning ambitions you explicitly want to address in this project, on top of the learning objectives of the Graduation Project, such as: in depth knowledge a on specific subject, broadening your competences or experimenting with a specific tool and/or methodology, ... Stick to no more than five ambitions.

I found that human ergonomics, including cognitive and physical ergonomics are extremely interesting and attractive throughout my Master programme. I have applied ergonomics in a lot of design projects during my Msc. I also have a furniture design background and have done designs and works with furniture ergonomics applied. But the ergonomic applications I did were quite practical. I want to learn more academic ergonomic research skills, dive into comfort tests and user experience design through my graduation project.

In addition, I always want to become a kind of designer who works as a bridge between technology and humans. In my graduation project I want to add more human factors into existing products, learn more about data application, apply and transfer the data to smart functions.

My ambitions for graduation project are:
1. Implement and further develop my existing user-centered design capacities.
2. Learn ergonomics and other academic research skills.
3. Develop technological skills for data-driven ultra-personalization.
4. Strengthen project management and planning skills.
5. Start my career in the professional areas.

FINAL COMMENTS

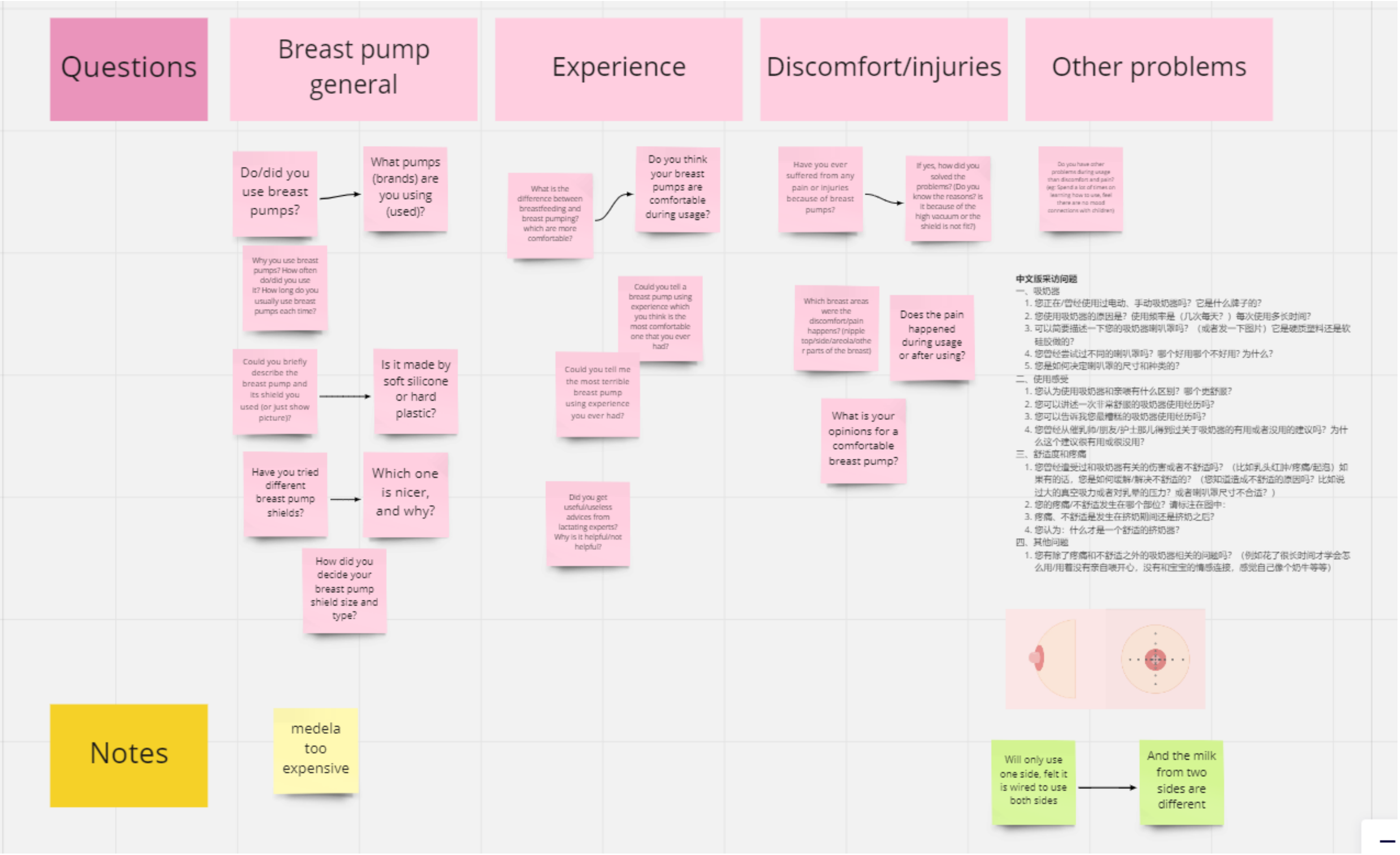
In case your project brief needs final comments, please add any information you think is relevant.

IDE TU Delft - E&SA Department /// Graduation project brief & study overview /// 2018-01 v30 Page 7 of 7

Initials & Name Q. Qing Sheng Student number 5120519

Title of Project Ultra-personalized breast pump

Appendix B. Interview questions & notes



Questions

Breast pump general

- Do/did you use breast pumps? → What pumps (brands) are you using (used)?
- Why you use breast pumps? How often do/did you use it? How long do you usually use breast pumps each time?
- Could you briefly describe the breast pump and its shield you used (or just show picture)? → Is it made by soft silicone or hard plastic?
- Have you tried different breast pump shields? → Which one is nicer, and why?
- How did you decide your breast pump shield size and type?

Experience

- What is the difference between breastfeeding and breast pumping? which are more comfortable? → Do you think your breast pumps are comfortable during usage?
- Could you tell a breast pump using experience which you think is the most comfortable one that you ever had?
- Could you tell me the most terrible breast pump using experience you ever had?
- Did you get useful/useless advices from lactating experts? Why is it helpful/not helpful?

Discomfort/injuries

- Have you ever suffered from any pain or injuries because of breast pumps? → If yes, how did you solved the problems? (Do you know the reasons? Is it because of the high vacuum or the shield is not fit?)
- Which breast areas were the discomfort/pain happens? (nipple top/side/areola/other parts of the breast)
- Does the pain happened during usage or after using?
- What is your opinions for a comfortable breast pump?

Other problems

- Do you have other problems during usage than discomfort and pain? (eg: Spend a lot of times on learning how to use, feel there are no mood connections with children)

中文版采访问题

一、吸奶器

1. 您正在/曾经使用过电动、手动吸奶器吗？它是什么牌子的？
2. 您使用吸奶器的原因是？使用频率是（几次每天？）每次使用多长时间？
3. 可以简要描述一下您的吸奶器喇叭罩吗？（或者发一下图片）它是硬质塑料还是软硅胶做的？
4. 您曾经尝试过不同的喇叭罩吗？哪个好用哪个不好用？为什么？
5. 您是如何决定喇叭罩的尺寸和种类的？

二、使用感受

1. 您认为使用吸奶器和亲喂有什么区别？哪个更舒服？
2. 您可以讲述一次非常舒服的吸奶器使用经历吗？
3. 您可以告诉我您最糟糕的吸奶器使用经历吗？
4. 您曾经从催乳师/朋友/护士那儿得到过关于吸奶器的有用或者没用的建议吗？为什么这个建议很有用或很没用？

三、舒适度和疼痛

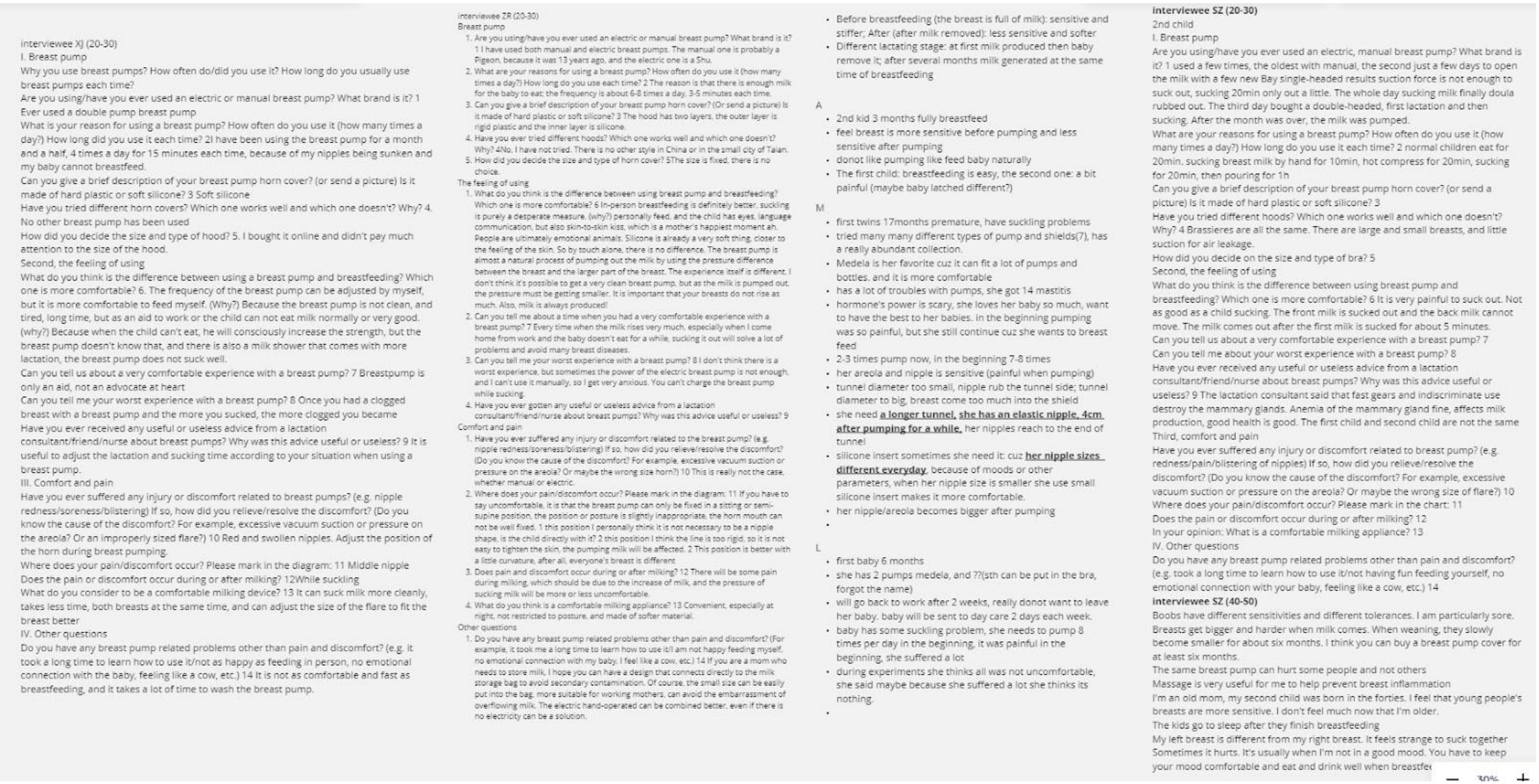
1. 您曾经遭受过和吸奶器有关的伤害或者不舒适吗？（比如乳头红肿/疼痛/起泡）如果有的话，您是如何缓解/解决不舒适的？（您知道造成不舒适的原因吗？比如说过大的真空吸力或者对乳晕的压力？或者喇叭罩尺寸不合适？）
2. 您的疼痛/不舒适发生在哪个部位？请标注在图中：
3. 疼痛、不舒适是发生在挤奶期间还是挤奶之后？
4. 您认为：什么才是一个舒适的挤奶器？

四、其他问题

1. 您有除了疼痛和不舒适之外的吸奶器相关的问题吗？（例如花了很长时间才学会怎么用/用着没有亲自喂开心，没有和宝宝的情感连接，感觉自己像个奶牛等等）

Notes

- medela too expensive
- Will only use one side, felt it is wired to use both sides → And the milk from two sides are different



interviewee XJ (20-30)
I. Breast pump
Why you use breast pumps? How often do/did you use it? How long do you usually use breast pumps each time?
Are you using/have you ever used an electric or manual breast pump? What brand is it? 1 Ever used a double pump breast pump
What is your reason for using a breast pump? How often do you use it (how many times a day?) How long did you use it each time? 2I have been using the breast pump for a month and a half, 4 times a day for 15 minutes each time, because of my nipples being sunken and my baby cannot breastfeed.
Can you give a brief description of your breast pump horn cover? (or send a picture) Is it made of hard plastic or soft silicone? 3 Soft silicone
Have you tried different horn covers? Which one works well and which one doesn't? Why? 4. No other breast pump has been used
How did you decide the size and type of hood? 5. I bought it online and didn't pay much attention to the size of the hood.
Second, the feeling of using
What do you think is the difference between using a breast pump and breastfeeding? Which one is more comfortable? 6. The frequency of the breast pump can be adjusted by myself, but it is more comfortable to feed myself. (Why?) Because the breast pump is not clean, and tired, long time, but as an aid to work or the child can not eat milk normally or very good. (why?) Because when the child can't eat, he will consciously increase the strength, but the breast pump doesn't know that, and there is also a milk shower that comes with more lactation, the breast pump does not suck well.
Can you tell us about a very comfortable experience with a breast pump? 7 Breastpump is only an aid, not an advocate at heart
Can you tell me your worst experience with a breast pump? 8 Once you had a clogged breast with a breast pump and the more you sucked, the more clogged you became
Have you ever received any useful or useless advice from a lactation consultant/friend/nurse about breast pumps? Why was this advice useful or useless? 9 It is useful to adjust the lactation and sucking time according to your situation when using a breast pump.
III. Comfort and pain
Have you ever suffered any injury or discomfort related to breast pumps? (e.g. nipple redness/soreness/blistering) If so, how did you relieve/resolve the discomfort? (Do you know the cause of the discomfort? For example, excessive vacuum suction or pressure on the areola? Or an improperly sized flare?) 10 Red and swollen nipples. Adjust the position of the horn during breast pumping.
Where does your pain/discomfort occur? Please mark in the diagram: 11 Middle nipple
Does the pain or discomfort occur during or after milking? 12While suckling
What do you consider to be a comfortable milking device? 13 It can suck milk more cleanly, takes less time, both breasts at the same time, and can adjust the size of the flare to fit the breast better
IV. Other questions
Do you have any breast pump related problems other than pain and discomfort? (e.g. it took a long time to learn how to use it/not as happy as feeding in person, no emotional connection with the baby, feeling like a cow, etc.) 14 It is not as comfortable and fast as breastfeeding, and it takes a lot of time to wash the breast pump.

interviewee ZR (20-30)
Breast pump
1. Are you using/have you ever used an electric or manual breast pump? What brand is it? 1 I have used both manual and electric breast pumps. The manual one is probably a Pigeon, because it was 13 years ago, and the electric one is a Shu.
2. What are your reasons for using a breast pump? How often do you use it (how many times a day?) How long do you use each time? 2 The reason is that there is enough milk for the baby to eat; the frequency is about 6-8 times a day, 3-5 minutes each time.
3. Can you give a brief description of your breast pump horn cover? (Or send a picture) Is it made of hard plastic or soft silicone? 3 The hood has two layers, the outer layer is rigid plastic and the inner layer is silicone.
4. Have you ever tried different hoods? Which one works well and which one doesn't? Why? 4No, I have not tried. There is no other style in China or in the small city of Taian.
5. How did you decide the size and type of horn cover? 5The size is fixed, there is no choice.

The feeling of using
1. What do you think is the difference between using breast pump and breastfeeding? Which one is more comfortable? 6 In-person breastfeeding is definitely better, suckling is purely a desperate measure. (why?) personally feed, and the child has eyes, language communication, but also skin-to-skin kiss, which is a mother's happiest moment ah. People are ultimately emotional animals. Silicone is already a very soft thing, closer to the feeling of the skin. So by touch alone, there is no difference. The breast pump is almost a natural process of pumping out the milk by using the pressure difference between the breast and the larger part of the breast. The experience itself is different. I don't think it's possible to get a very clean breast pump, but as the milk is pumped out, the pressure must be getting smaller. It is important that your breasts do not rise as much. Also, milk is always produced!
2. Can you tell me about a time when you had a very comfortable experience with a breast pump? 7 Every time when the milk rises very much, especially when I come home from work and the baby doesn't eat for a while, sucking it out will solve a lot of problems and avoid many breast diseases.
3. Can you tell me your worst experience with a breast pump? 8 I don't think there is a worst experience, but sometimes the power of the electric breast pump is not enough, and I can't use it manually, so I get very anxious. You can't charge the breast pump while sucking.
4. Have you ever gotten any useful or useless advice from a lactation consultant/friend/nurse about breast pumps? Why was this advice useful or useless? 9

Comfort and pain
1. Have you ever suffered any injury or discomfort related to the breast pump? (e.g. nipple redness/soreness/blistering) If so, how did you relieve/resolve the discomfort? (Do you know the cause of the discomfort? For example, excessive vacuum suction or pressure on the areola? Or maybe the wrong size horn?) 10 This is really not the case, whether manual or electric.
2. Where does your pain/discomfort occur? Please mark in the diagram: 11 If you have to say uncomfortable, it is that the breast pump can only be fixed in a sitting or semi-supine position, the position or posture is slightly inappropriate, the horn mouth can not be well fixed. 1 this position I personally think it is not necessary to be a nipple shape, is the child directly with it? 2 this position I think the line is too rigid, so it is not easy to tighten the skin, the pumping milk will be affected. 2 This position is better with a little curvature, after all, everyone's breast is different
3. Does pain and discomfort occur during or after milking? 12 There will be some pain during milking, which should be due to the increase of milk, and the pressure of sucking milk will be more or less uncomfortable.
4. What do you think is a comfortable milking appliance? 13 Convenient, especially at night, not restricted to posture, and made of softer material.

Other questions
1. Do you have any breast pump related problems other than pain and discomfort? (For example, it took me a long time to learn how to use it/I am not happy feeding myself, no emotional connection with my baby, I feel like a cow, etc.) 14 If you are a mom who needs to store milk, I hope you can have a design that connects directly to the milk storage bag to avoid secondary contamination. Of course, the small size can be easily put into the bag, more suitable for working mothers, can avoid the embarrassment of overflowing milk. The electric hand-operated can be combined better, even if there is no electricity can be a solution.

- Before breastfeeding (the breast is full of milk): sensitive and stiffer; After (after milk removed): less sensitive and softer
- Different lactating stage: at first milk produced then baby remove it; after several months milk generated at the same time of breastfeeding

A

- 2nd kid 3 months fully breastfeed
- feel breast is more sensitive before pumping and less sensitive after pumping
- donot like pumping like feed baby naturally
- The first child: breastfeeding is easy, the second one: a bit painful (maybe baby latched different?)

M

- first twins 17months premature, have suckling problems
- tried many many different types of pump and shields(7), has a really abundant collection.
- Medela is her favorite cuz it can fit a lot of pumps and bottles. and it is more comfortable
- has a lot of troubles with pumps, she got 14 mastitis
- hormone's power is scary, she loves her baby so much, want to have the best to her babies. in the beginning pumping was so painful, but she still continue cuz she wants to breast feed
- 2-3 times pump now, in the beginning 7-8 times
- her areola and nipple is sensitive (painful when pumping)
- tunnel diameter too small, nipple rub the tunnel side; tunnel diameter to big, breast come too much into the shield
- she need **a longer tunnel, she has an elastic nipple, 4cm after pumping for a while,** her nipples reach to the end of tunnel
- silicone insert sometimes she need it: cuz **her nipple sizes different everyday**, because of moods or other parameters, when her nipple size is smaller she use small silicone insert makes it more comfortable.
- her nipple/areola becomes bigger after pumping

L

- first baby 6 months
- she has 2 pumps medela, and ??(sth can be put in the bra, forgot the name)
- will go back to work after 2 weeks, really donot want to leave her baby. baby will be sent to day care 2 days each week.
- baby has some suckling problem, she needs to pump 8 times per day in the beginning, it was painful in the beginning, she suffered a lot
- during experiments she thinks all was not uncomfortable, she said maybe because she suffered a lot she thinks its nothing.

interviewee SZ (20-30)
2nd child
I. Breast pump
Are you using/have you ever used an electric, manual breast pump? What brand is it? 1 used a few times, the oldest with manual, the second just a few days to open the milk with a few new Bay single-headed results suction force is not enough to suck out, sucking 20min only out a little. The whole day sucking milk finally doula rubbed out. The third day bought a double-headed, first lactation and then sucking. After the month was over, the milk was pumped.
What are your reasons for using a breast pump? How often do you use it (how many times a day?) How long do you use it each time? 2 normal children eat for 20min. sucking breast milk by hand for 10min, hot compress for 20min, sucking for 20min, then pouring for 1h
Can you give a brief description of your breast pump horn cover? (or send a picture) Is it made of hard plastic or soft silicone? 3
Have you tried different hoods? Which one works well and which one doesn't? Why? 4 Brassieres are all the same. There are large and small breasts, and little suction for air leakage.
How did you decide on the size and type of bra? 5
Second, the feeling of using
What do you think is the difference between using breast pump and breastfeeding? Which one is more comfortable? 6 It is very painful to suck out. Not as good as a child sucking. The front milk is sucked out and the back milk cannot move. The milk comes out after the first milk is sucked for about 5 minutes.
Can you tell us about a very comfortable experience with a breast pump? 7
Can you tell me about your worst experience with a breast pump? 8
Have you ever received any useful or useless advice from a lactation consultant/friend/nurse about breast pumps? Why was this advice useful or useless? 9 The lactation consultant said that fast gears and indiscriminate use destroy the mammary glands. Anemia of the mammary gland fine, affects milk production, good health is good. The first child and second child are not the same
Third, comfort and pain
Have you ever suffered any injury or discomfort related to breast pump? (e.g. redness/pain/blistering of nipples) If so, how did you relieve/resolve the discomfort? (Do you know the cause of the discomfort? For example, excessive vacuum suction or pressure on the areola? Or maybe the wrong size of flare?) 10
Where does your pain/discomfort occur? Please mark in the chart: 11
Does the pain or discomfort occur during or after milking? 12
In your opinion: What is a comfortable milking appliance? 13
IV. Other questions
Do you have any breast pump related problems other than pain and discomfort? (e.g. took a long time to learn how to use it/not having fun feeding yourself, no emotional connection with your baby, feeling like a cow, etc.) 14
interviewee SZ (40-50)
Boobs have different sensitivities and different tolerances. I am particularly sore. Breasts get bigger and harder when milk comes. When weaning, they slowly become smaller for about six months. I think you can buy a breast pump cover for at least six months.
The same breast pump can hurt some people and not others
Massage is very useful for me to help prevent breast inflammation
I'm an old mom, my second child was born in the forties. I feel that young people's breasts are more sensitive. I don't feel much now that I'm older.
The kids go to sleep after they finish breastfeeding
My left breast is different from my right breast. It feels strange to suck together
Sometimes it hurts. It's usually when I'm not in a good mood. You have to keep your mood comfortable and eat and drink well when breastfe

Appendix C. Ethical approval

Informed consent

Dear participant,

You are being invited to participate in a research study titled **Breast Comfort Threshold Assessment of Positive and Negative Pressure**. This study is being done by Lyè Goto from the Next UPPS Team of TU Delft, collaborating with Royal Philips Company.

Study Purpose

The purpose of this research study is to explore the correlation between breast comfort and pressure sensation and will take you approximately ***20*** minutes to complete. The data will be used for ultra-personalized breast pump design, which aims to create an extreme comfort breast pumping experience for mothers. And it might also be used for the ergonomic comfort of other breast-related products hence promoting women's wellbeing.

Study Procedures

There are four flexible choices for you to conduct the experiments:

1. The experiments will be conducted by the participant at his or her home.
2. The experiments will be conducted by the researcher at the participant's home.
3. The experiments will be conducted by the participant in a private room at IDE.
4. The experiments will be conducted by the researcher in a private room at IDE.

For choice 1, you will receive a package of experiment equipment.

You will first be given a manual with clear instructions and informative pictures for experiment steps and equipment usage. And for choices 1 and 3, the researcher will provide real-time communication via online chat and face-to-face guide if there are any questions.

There will be three experiments conducted. Firstly, you/the researcher will test the sensation on different areas of the left breast according to a breast map by monofilament (Semmes Weinstein monofilament with CE certified). The force will be recorded.

After that, an advanced force gauge (CE certified) will be controlled by yourself/the researcher to gently push different left breast areas with progressively increased force. When you feel not comfortable anymore, stop it and the scales on the gauge will be recorded.

Finally, a nipple sucker (CE certified) with the advanced force gauge will be used together to gently tug the left nipple and part of the areola with an increased vacuum. The scales on the two pieces of equipment will be recorded when you feel your breast is not comfortable.

You will be asked to fill in a questionnaire at the end of the experiment.

Risks and Benefits

You will choose whether you want to conduct the experiment by yourself or by the researcher. If you choose to let the researchers conduct the experiment, there are no risks. If you decide to conduct the experiment by yourself, there are no risks at all if following the instructions. The equipment is easy to use, clear instructions will be provided, and real-time communication tools such as online chats will be engaged in the experiment process to help you perform experiments correctly if needed.

If you have any breast complaints or are ill at the moment of study, you cannot join the experiment.

There are not any financial rewards for this study. We will be so grateful for your contribution as your participation will promote related product design and improve women's wellbeing worldwide. A little gift will be given for many thanks.

Personal Data Collection and Management

Your address, IP address, and name will be completely anonymous and will never be identified. The data below will be published:

1. Age, gender, BMI, and lactating history.
2. Statistic results of breast volume and anthropometric measurements.
3. Statistic results of force intensity and volume data from scales on the equipment.
4. Comfortable experience comments from the questionnaire.

We will safely store the data in a secure server at TU Delft and safely manage it according to the attached data management plan. Only researchers have access to the server.

Withdraw Participation and Participant's Rights

Your participation in this study is entirely voluntary **and you can withdraw at any time**. You have the right to refuse to answer any questions and rectify or erase personal data. You are free to omit any questions, please contact Q.Sheng-1@student.tudelft.nl.

Explicit Consent Points form

PLEASE TICK THE APPROPRIATE BOXES	Yes	No
A: GENERAL AGREEMENT – RESEARCH GOALS, PARTICPANT TASKS AND VOLUNTARY PARTICIPATION		
1. I have read and understood the study information dated [*DD/MM/YYYY*], or it has been read to me. I have been able to ask questions about the study and my questions have been answered to my satisfaction.	☐	☐
2. I consent voluntarily to be a participant in this study and understand that I can refuse to answer questions and I can withdraw from the study at any time, without having to give a reason.	☐	☐
3. I understand that taking part in the study involves providing my age, gender, lactating history, body weight and height, breast anthropometric measure, scales on the equipment, and subjective comfort experience.	☐	☐
4. I understand that the study will take approximately 20 minutes	☐	☐
B: POTENTIAL RISKS OF PARTICIPATING (INCLUDING DATA PROTECTION)		
5. I understand that taking part in the study involves the following risks: - My breast will be applied slight negative and positive pressure - I will conduct the experiment following instructions (only if you choose to conduct the experiment by yourself) - I need to travel to TU Delft (only If you choose TU Delft as the experiment site) - I need to fill in the questionnaire with the data stated in 3. above after the experiment.	☐	☐
6. I understand that taking part in the study also involves processing specific personally identifiable information (PII) name, address, and IP address by this Informed Consent, and from the communication with researchers, but it will not be shared beyond the study team.	☐	☐
7. I understand that the following steps will be taken to minimise the threat of a data breach, and protect my identity in the event of such a breach: Anonymous data collection.	☐	☐
8. I understand that the (identifiable) personal data I provide will be destroyed at the end of this study.	☐	☒
C: RESEARCH PUBLICATION, DISSEMINATION AND APPLICATION		

PLEASE TICK THE APPROPRIATE BOXES	**Yes**	**No**
9. I understand that after the research study the de-identified information I provide will be used for: - Ultra-personalized breast pump product design - Possibly other breast-related product development - Master thesis, reports, and possibly article publications	☐	☐
10. I agree that my responses, views or other input can be quoted anonymously in research outputs	☐	☐

Signatures

________________________ ________________________ ________

Name of participant [printed] Signature Date

I, as researcher, have accurately read out the information sheet to the potential participant and, to the best of my ability, ensured that the participant understands to what they are freely consenting.

Lyè Goto ________________________ 29 June 2022

Researcher name [printed] Signature Date

Study contact details for further information: *Lyè Goto, L.Goto@tudelft.nl / Qing Sheng, 0612201176, Q.Sheng-1@student.tudelft.nl*

Appendix D. Experiment instructions

Do it on your right breast 😉 *Using equipment to apply pressure on different points. Please follow the sequence of points listed in the data table.*
Before the experiment: Keep warm, eat well and get good sleep

Experiment 1 – Monofilament for touch threshold
💡How to use the equipment?
(See video) Apply pressure vertically to a single point with the monofilament, and stop when it is bent into a C shape, 1.5 seconds for each touch, repeat 5 times.

💡Step by step:
1. Put monofilaments on the table, following the sequence of numbers marked on them.

2. Start from the thinnest monofilament, and apply pressure 5 times. If you feel 0, 1, 2 or 3 touches out of 5 times contact, change to the next monofilament with a larger number and continue. Until you feel 4 or 5 touches out of 5, stop changing the next one.
3. Record the number of the monofilament that you felt 4 or 5 touches out of 5.

ps: The sliding tactile feelings are counted. Nipples should keep erect, you may use your hands to stimulate the nipple to keep it erect.

Experiment 2 – Force gauge for discomfort threshold
💡How to use the equipment?
(See video) Press the power button on the up-left corner to start it, apply pressure vertically to a point, and press the “reset” button to return to zero each time.

💡Step by step:
1. Apply gradually increasing pressure vertically to push a point until you feel not comfortable anymore, stop and record the number on the force gauge. Then give a grade of the discomfort level (1-5) based on the five-point scale of discomfort chart (see below). Each point repeats 3 times, following the same sequence of points as the first experiment

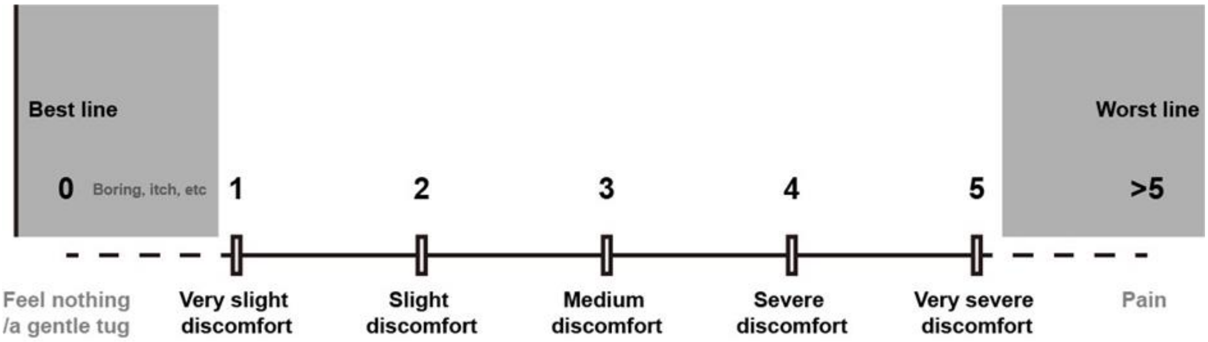
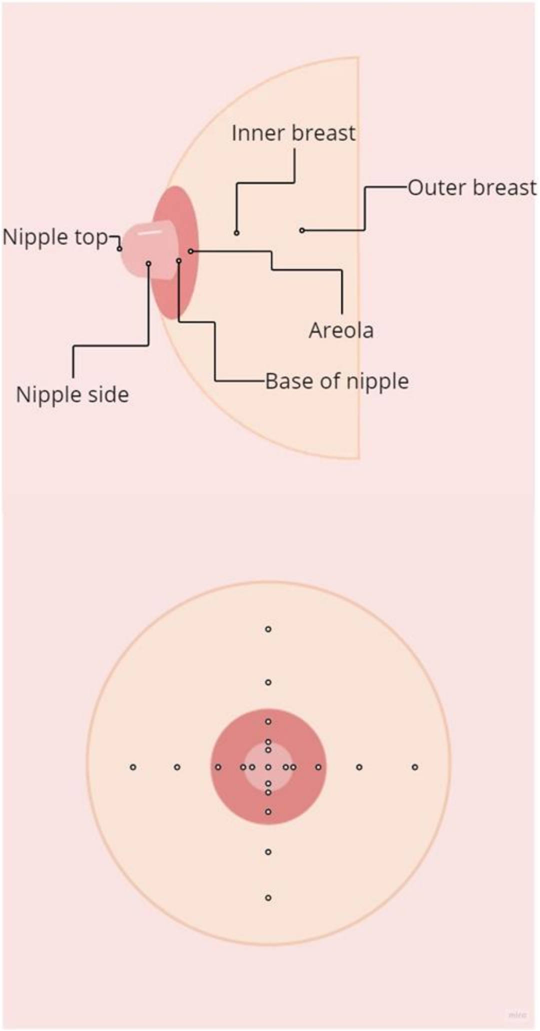


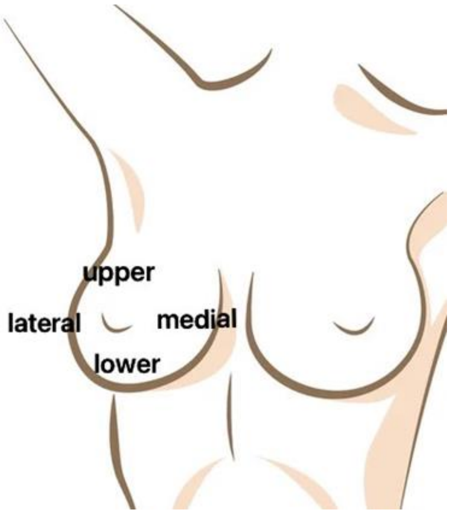
Fig. Five-point scale of discomfort

2. Record the measurement on the force gauge and the discomfort grade each time. There are 6 data for each point (3 measurements of force and 3 discomfort grades).

ps: You may fix the nipple by using your hand to support it, and apply force at the same time, to avoid deformation.

Breast Map





Experiment 1/2 data table

ps：1. Nipple base means the connections between the areola the and nipple

2. Divide the breast into three parts, the inner breast means one-third of the area that is close to the nipple, and the outer breast means two-thirds area.

Name/sequence	Monofilament numbers/the times you feel touch	The first press	The first discomfort grade	The second press	The second discomfort grade	The third press	The third discomfort grade
1 lateral nipple base	eg：1.65/4	eg：0.42	eg：2	eg：0.82	eg：4	eg：0.70	eg：3.5
2 lower outer breast							
3 lower nipple base							
4 upper inner breast							
5 upper nipple base							
6 lateral outer breast							
7 medial nipple base							
8 lateral inner breast							
9 lateral areola							
10 medial nipple side							
11 lower inner br							

Name/sequence	Monofilament numbers/the times you feel touch	The first press	The first discomfort grade	The second press	The second discomfort grade	The third press	The third discomfort grade
east							
12 upper areola							
13 lateral nipple side							
14 upper outer breast							
15 medial areola							
16 lower nipple side							
17 nipple top							
18 medial inner breast							
19 lower areola							
20 medial outer breast							
21 upper nipple side							

Body data measurement
1. Nipple-areola complex anthropometric data + basic information
Nipple diameter:
Nipple length:
Areola diameter:
Breast cup:
Height:
Weight:
The end time of the last period:

2. Breast volume data

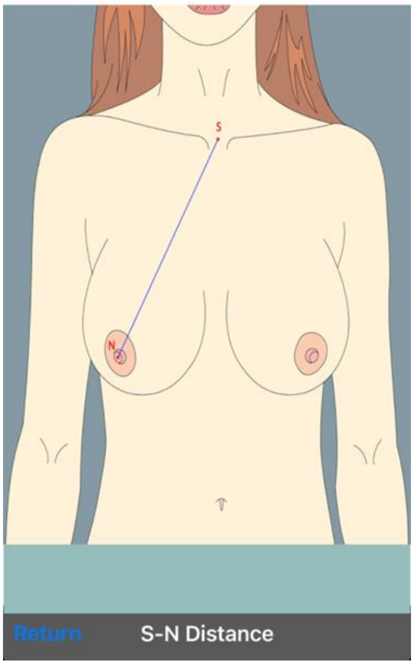
Sternal Notch - Nipple Distance (cm)

Inframammary Fold - Nipple Distance (cm)

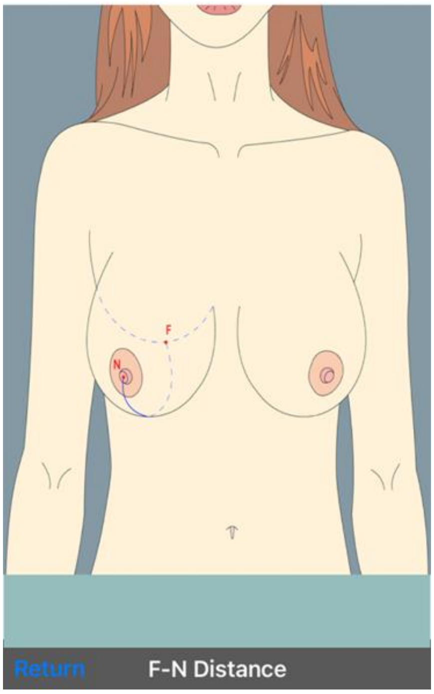
Inframammary Fold - Fold Projection Distance (cm)

3 Data：

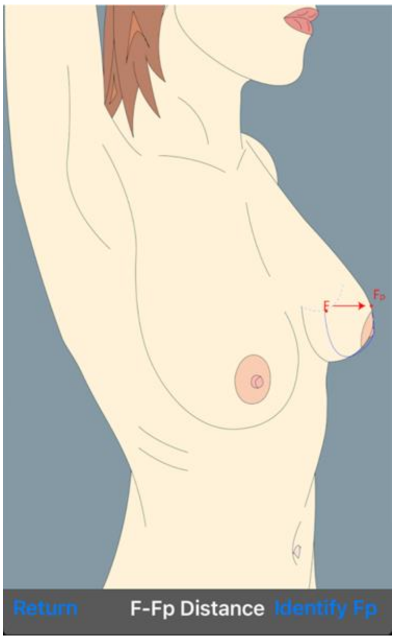
（1）S-N distance, the distance from sternal notch to nipple (see below) :



（2）F-N distance, the distance from inframammary fold to nipple (see below) :

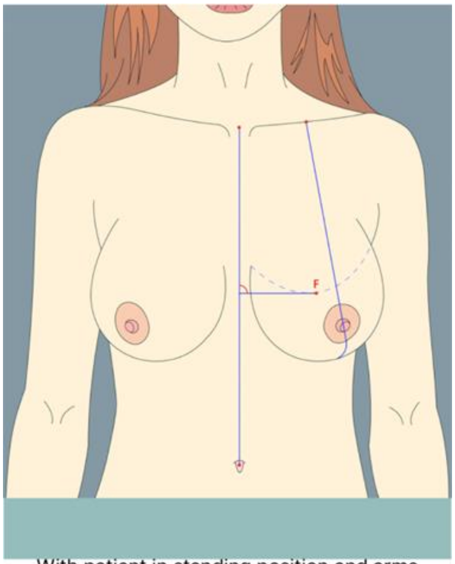


（3）F-Fp distance, the distance between the inframammary fold to fold projection point(the blue line, see below):



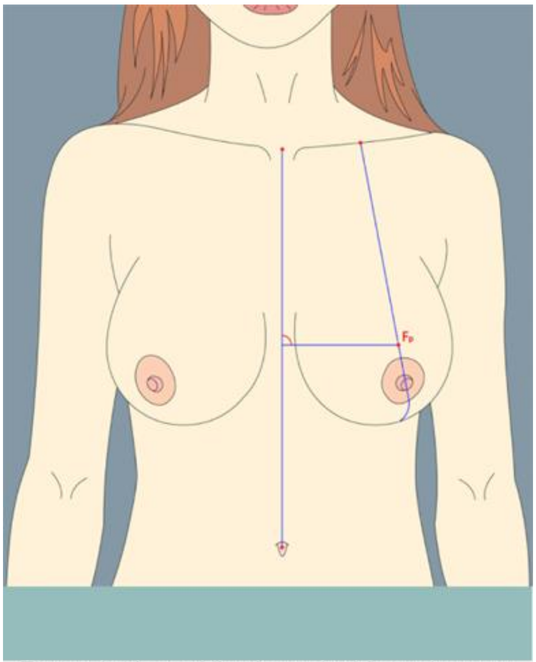
2 steps to define fold projection point (Fp)：

1. With patient in standing position and arms adducted, design standard breast marking including chest midline from the sternal notch to umbilicus, inframammary fold and breast meridian line from the clavicle down through the mound (see below).



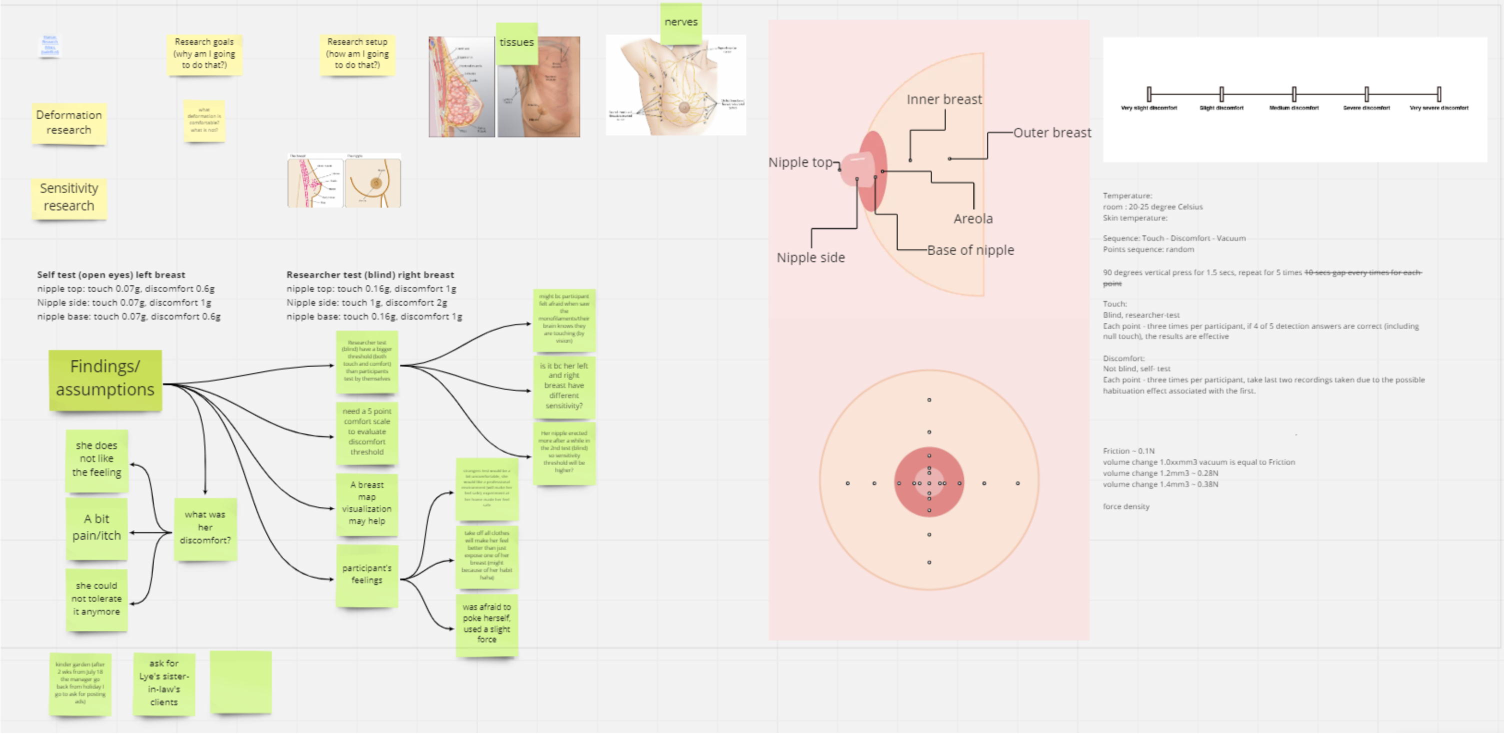
With patient in standing position and arms adducted, design standard breast marking including chest midline from the sternal notch to umbilicus, inframammary fold and breast meridian line from the clavicle down through the mound.

2. Then a horizontal line is marked from the most caudal point of the inframammary fold to the chest midline, and from there is extended to the anterior surface of the breast. Its intersection with the breast meridian line identifies the Fp point (see below).



Then a horizontal line is marked from the most caudal point of the inframammary fold to the chest midline, and from there is extended to the anterior surface of the breast. Its intersection with the breast meridian line identifies the Fp point

Appendix E. Pilot research findings



Self test (open eyes) left breast
nipple top: touch 0.07g, discomfort 0.6g
Nipple side: touch 0.07g, discomfort 1g
nipple base: touch 0.07g, discomfort 0.6g

Researcher test (blind) right breast
nipple top: touch 0.16g, discomfort 1g
Nipple side: touch 1g, discomfort 2g
nipple base: touch 0.16g, discomfort 1g

Temperature:
room : 20-25 degree Celsius
Skin temperature:

Sequence: Touch - Discomfort - Vacuum
Points sequence: random

90 degrees vertical press for 1.5 secs, repeat for 5 times ~~10 secs gap every times for each point~~

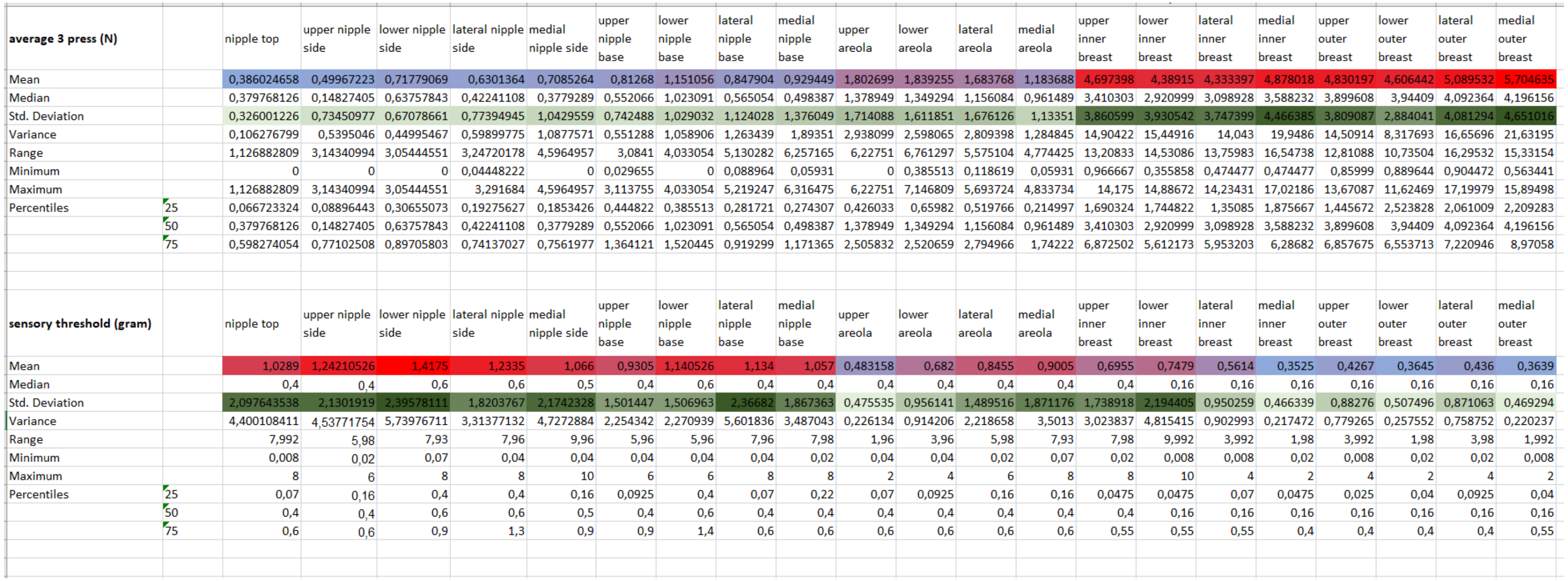
Touch:
Blind, researcher-test
Each point - three times per participant, if 4 of 5 detection answers are correct (including null touch), the results are effective

Discomfort:
Not blind, self- test
Each point - three times per participant, take last two recordings taken due to the possible habituation effect associated with the first.

Friction ~ 0.1N
volume change 1.0xxmm3 vacuum is equal to Friction
volume change 1.2mm3 ~ 0.28N
volume change 1.4mm3 ~ 0.38N

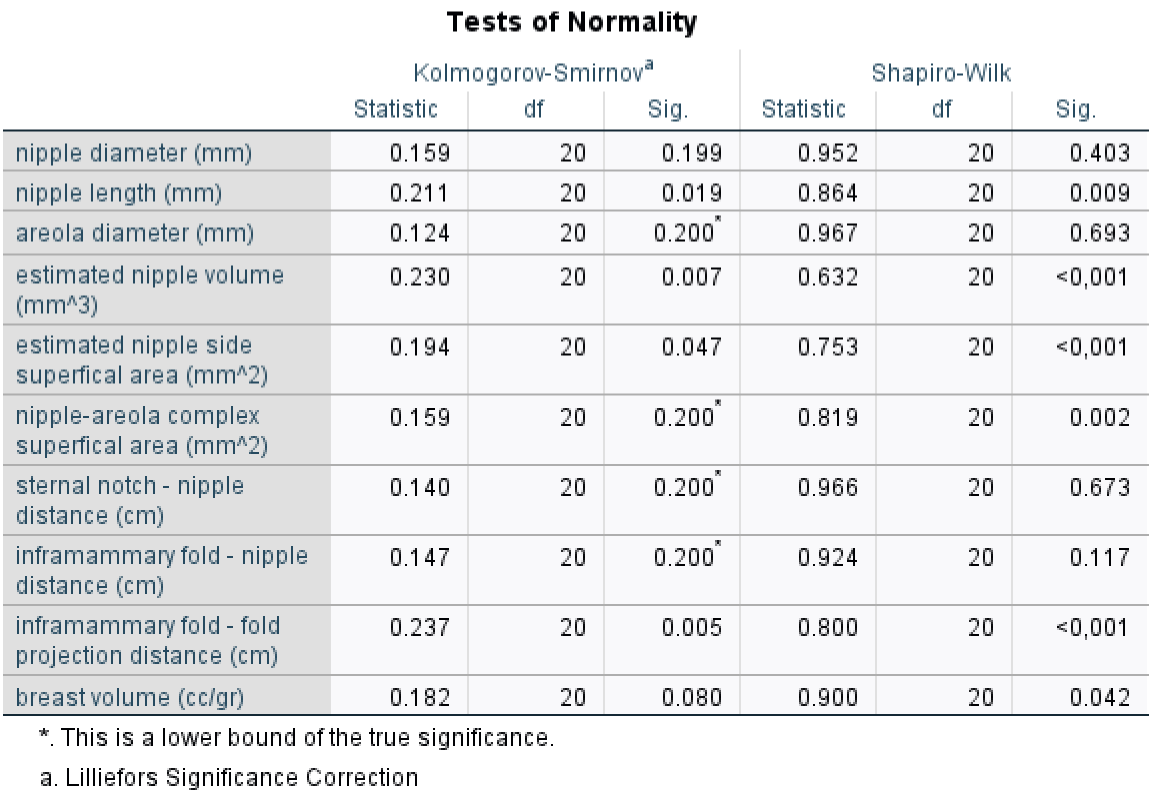
force density

Appendix F. Data Analysis



average 3 press (N)		nipple top	upper nipple side	lower nipple side	lateral nipple side	medial nipple side	upper nipple base	lower nipple base	lateral nipple base	medial nipple base	upper areola	lower areola	lateral areola	medial areola	upper inner breast	lower inner breast	lateral inner breast	medial inner breast	upper outer breast	lower outer breast	lateral outer breast	medial outer breast
Mean		0,386024658	0,49967223	0,71779069	0,6301364	0,7085264	0,81268	1,151056	0,847904	0,929449	1,802699	1,839255	1,683768	1,183688	4,697398	4,38915	4,333397	4,878018	4,830197	4,606442	5,089532	5,704635
Median		0,379768126	0,14827405	0,63757843	0,42241108	0,3779289	0,552066	1,023091	0,565054	0,498387	1,378949	1,349294	1,156084	0,961489	3,410303	2,920999	3,098928	3,588232	3,899608	3,94409	4,092364	4,196156
Std. Deviation		0,326001226	0,73450977	0,67078661	0,77394945	1,0429559	0,742488	1,029032	1,124028	1,376049	1,714088	1,611851	1,676126	1,13351	3,860599	3,930542	3,747399	4,466385	3,809087	2,884041	4,081294	4,651016
Variance		0,106276799	0,5395046	0,44995467	0,59899775	1,0877571	0,551288	1,058906	1,263439	1,89351	2,938099	2,598065	2,809398	1,284845	14,90422	15,44916	14,043	19,9486	14,50914	8,317693	16,65696	21,63195
Range		1,126882809	3,14340994	3,05444551	3,24720178	4,5964957	3,0841	4,033054	5,130282	6,257165	6,22751	6,761297	5,575104	4,774425	13,20833	14,53086	13,75983	16,54738	12,81088	10,73504	16,29532	15,33154
Minimum		0	0	0	0,04448222	0	0,029655	0	0,088964	0,05931	0	0,385513	0,118619	0,05931	0,966667	0,355858	0,474477	0,474477	0,85999	0,889644	0,904472	0,563441
Maximum		1,126882809	3,14340994	3,05444551	3,291684	4,5964957	3,113755	4,033054	5,219247	6,316475	6,22751	7,146809	5,693724	4,833734	14,175	14,88672	14,23431	17,02186	13,67087	11,62469	17,19979	15,89498
Percentiles	25	0,066723324	0,08896443	0,30655073	0,19275627	0,1853426	0,444822	0,385513	0,281721	0,274307	0,426033	0,65982	0,519766	0,214997	1,690324	1,744822	1,35085	1,875667	1,445672	2,523828	2,061009	2,209283
	50	0,379768126	0,14827405	0,63757843	0,42241108	0,3779289	0,552066	1,023091	0,565054	0,498387	1,378949	1,349294	1,156084	0,961489	3,410303	2,920999	3,098928	3,588232	3,899608	3,94409	4,092364	4,196156
	75	0,598274054	0,77102508	0,89705803	0,74137027	0,7561977	1,364121	1,520445	0,919299	1,171365	2,505832	2,520659	2,794966	1,74222	6,872502	5,612173	5,953203	6,28682	6,857675	6,553713	7,220946	8,97058

sensory threshold (gram)		nipple top	upper nipple side	lower nipple side	lateral nipple side	medial nipple side	upper nipple base	lower nipple base	lateral nipple base	medial nipple base	upper areola	lower areola	lateral areola	medial areola	upper inner breast	lower inner breast	lateral inner breast	medial inner breast	upper outer breast	lower outer breast	lateral outer breast	medial outer breast
Mean		1,0289	1,24210526	1,4175	1,2335	1,066	0,9305	1,140526	1,134	1,057	0,483158	0,682	0,8455	0,9005	0,6955	0,7479	0,5614	0,3525	0,4267	0,3645	0,436	0,3639
Median		0,4	0,4	0,6	0,6	0,5	0,4	0,6	0,4	0,4	0,4	0,4	0,4	0,4	0,4	0,16	0,16	0,16	0,16	0,16	0,16	0,16
Std. Deviation		2,097643538	2,1301919	2,39578111	1,8203767	2,1742328	1,501447	1,506963	2,36682	1,867363	0,475535	0,956141	1,489516	1,871176	1,738918	2,194405	0,950259	0,466339	0,88276	0,507496	0,871063	0,469294
Variance		4,400108411	4,53771754	5,73976711	3,31377132	4,7272884	2,254342	2,270939	5,601836	3,487043	0,226134	0,914206	2,218658	3,5013	3,023837	4,815415	0,902993	0,217472	0,779265	0,257552	0,758752	0,220237
Range		7,992	5,98	7,93	7,96	9,96	5,96	5,96	7,96	7,98	1,96	3,96	5,98	7,93	7,98	9,992	3,992	1,98	3,992	1,98	3,98	1,992
Minimum		0,008	0,02	0,07	0,04	0,04	0,04	0,04	0,04	0,02	0,04	0,04	0,02	0,07	0,02	0,008	0,008	0,02	0,008	0,02	0,02	0,008
Maximum		8	6	8	8	10	6	6	8	8	2	4	6	8	8	10	4	2	4	2	4	2
Percentiles	25	0,07	0,16	0,4	0,4	0,16	0,0925	0,4	0,07	0,22	0,07	0,0925	0,16	0,16	0,0475	0,0475	0,07	0,0475	0,025	0,04	0,0925	0,04
	50	0,4	0,4	0,6	0,6	0,5	0,4	0,6	0,4	0,4	0,4	0,4	0,4	0,4	0,4	0,16	0,16	0,16	0,16	0,16	0,16	0,16
	75	0,6	0,6	0,9	1,3	0,9	0,9	1,4	0,6	0,6	0,6	0,6	0,6	0,6	0,55	0,55	0,55	0,4	0,4	0,4	0,4	0,55

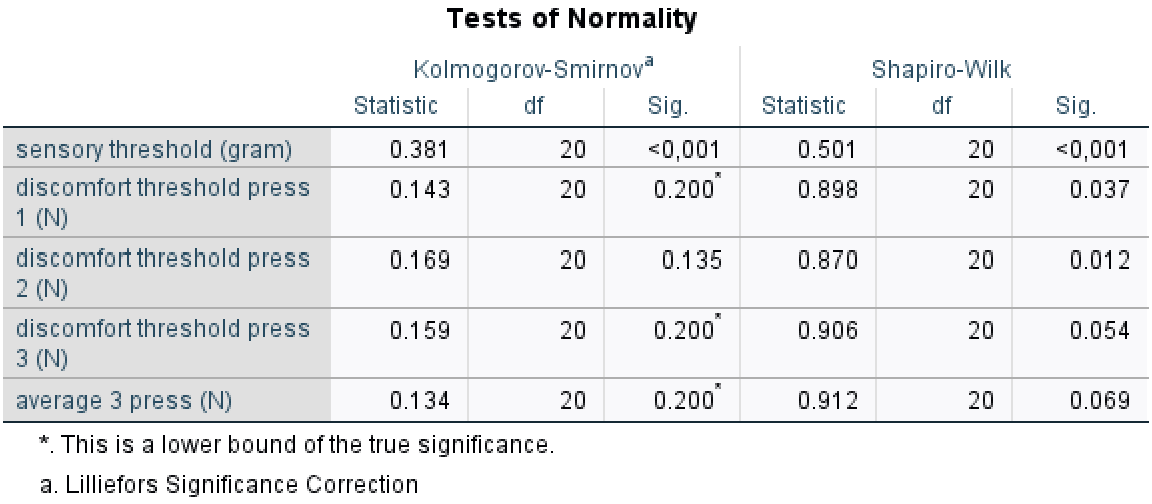


Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
nipple diameter (mm)	0.159	20	0.199	0.952	20	0.403
nipple length (mm)	0.211	20	0.019	0.864	20	0.009
areola diameter (mm)	0.124	20	0.200*	0.967	20	0.693
estimated nipple volume (mm^3)	0.230	20	0.007	0.632	20	<0,001
estimated nipple side superfical area (mm^2)	0.194	20	0.047	0.753	20	<0,001
nipple-areola complex superfical area (mm^2)	0.159	20	0.200*	0.819	20	0.002
sternal notch - nipple distance (cm)	0.140	20	0.200*	0.966	20	0.673
inframammary fold - nipple distance (cm)	0.147	20	0.200*	0.924	20	0.117
inframammary fold - fold projection distance (cm)	0.237	20	0.005	0.800	20	<0,001
breast volume (cc/gr)	0.182	20	0.080	0.900	20	0.042

*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction



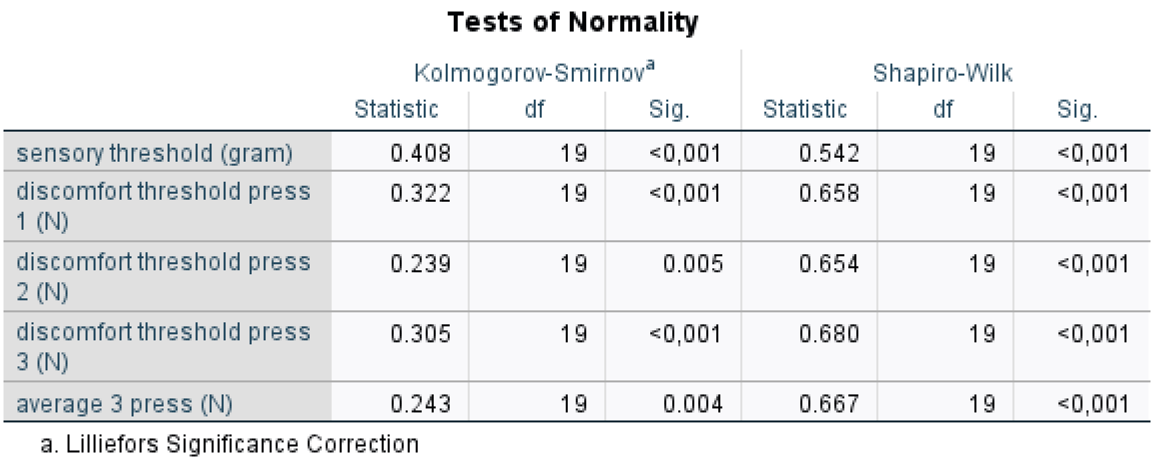
Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
sensory threshold (gram)	0.381	20	<0,001	0.501	20	<0,001
discomfort threshold press 1 (N)	0.143	20	0.200*	0.898	20	0.037
discomfort threshold press 2 (N)	0.169	20	0.135	0.870	20	0.012
discomfort threshold press 3 (N)	0.159	20	0.200*	0.906	20	0.054
average 3 press (N)	0.134	20	0.200*	0.912	20	0.069

*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction

nt

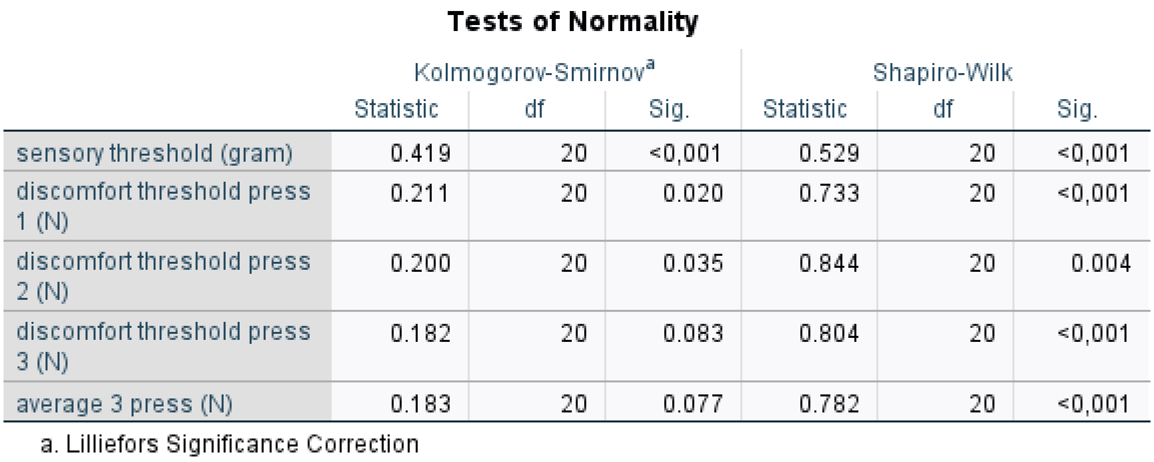


Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
sensory threshold (gram)	0.408	19	<0,001	0.542	19	<0,001
discomfort threshold press 1 (N)	0.322	19	<0,001	0.658	19	<0,001
discomfort threshold press 2 (N)	0.239	19	0.005	0.654	19	<0,001
discomfort threshold press 3 (N)	0.305	19	<0,001	0.680	19	<0,001
average 3 press (N)	0.243	19	0.004	0.667	19	<0,001

a. Lilliefors Significance Correction

1ns

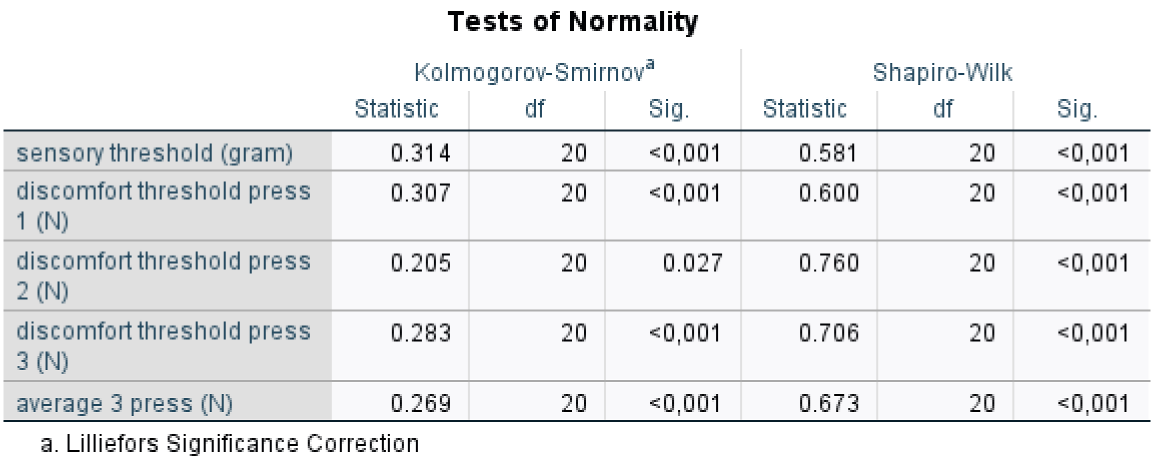


Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
sensory threshold (gram)	0.419	20	<0,001	0.529	20	<0,001
discomfort threshold press 1 (N)	0.211	20	0.020	0.733	20	<0,001
discomfort threshold press 2 (N)	0.200	20	0.035	0.844	20	0.004
discomfort threshold press 3 (N)	0.182	20	0.083	0.804	20	<0,001
average 3 press (N)	0.183	20	0.077	0.782	20	<0,001

a. Lilliefors Significance Correction

2ns

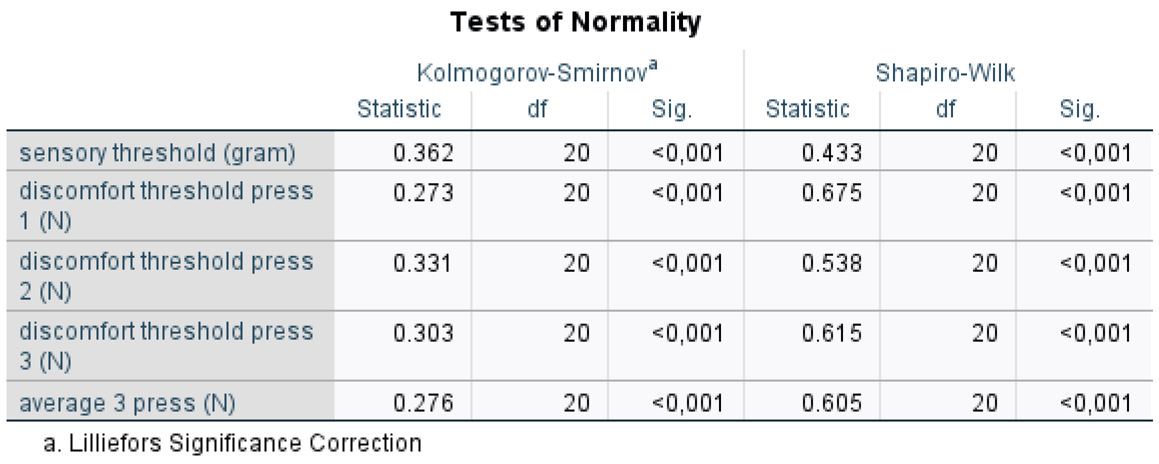


Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
sensory threshold (gram)	0.314	20	<0,001	0.581	20	<0,001
discomfort threshold press 1 (N)	0.307	20	<0,001	0.600	20	<0,001
discomfort threshold press 2 (N)	0.205	20	0.027	0.760	20	<0,001
discomfort threshold press 3 (N)	0.283	20	<0,001	0.706	20	<0,001
average 3 press (N)	0.269	20	<0,001	0.673	20	<0,001

a. Lilliefors Significance Correction

3ns

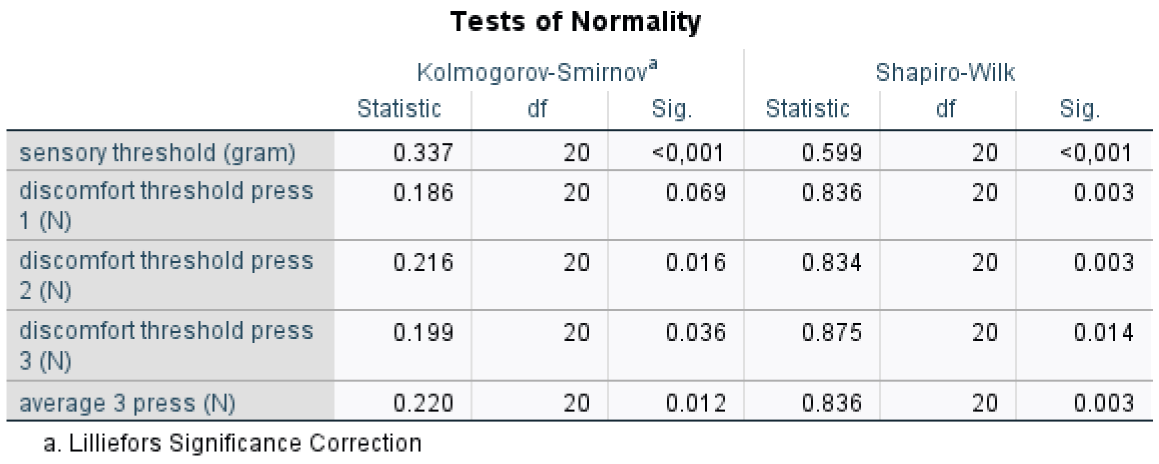


Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
sensory threshold (gram)	0.362	20	<0,001	0.433	20	<0,001
discomfort threshold press 1 (N)	0.273	20	<0,001	0.675	20	<0,001
discomfort threshold press 2 (N)	0.331	20	<0,001	0.538	20	<0,001
discomfort threshold press 3 (N)	0.303	20	<0,001	0.615	20	<0,001
average 3 press (N)	0.276	20	<0,001	0.605	20	<0,001

a. Lilliefors Significance Correction

4ns

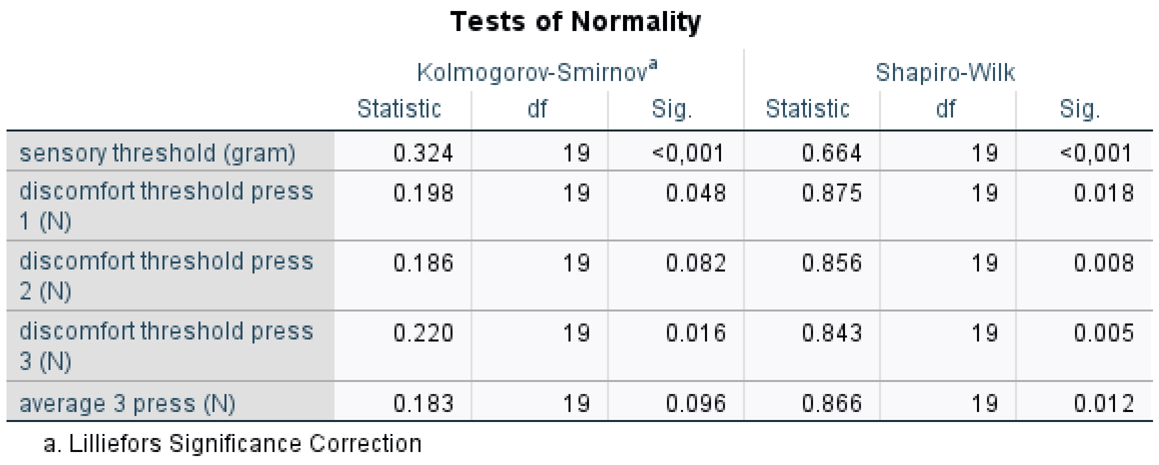


Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
sensory threshold (gram)	0.337	20	<0,001	0.599	20	<0,001
discomfort threshold press 1 (N)	0.186	20	0.069	0.836	20	0.003
discomfort threshold press 2 (N)	0.216	20	0.016	0.834	20	0.003
discomfort threshold press 3 (N)	0.199	20	0.036	0.875	20	0.014
average 3 press (N)	0.220	20	0.012	0.836	20	0.003

a. Lilliefors Significance Correction

1nb

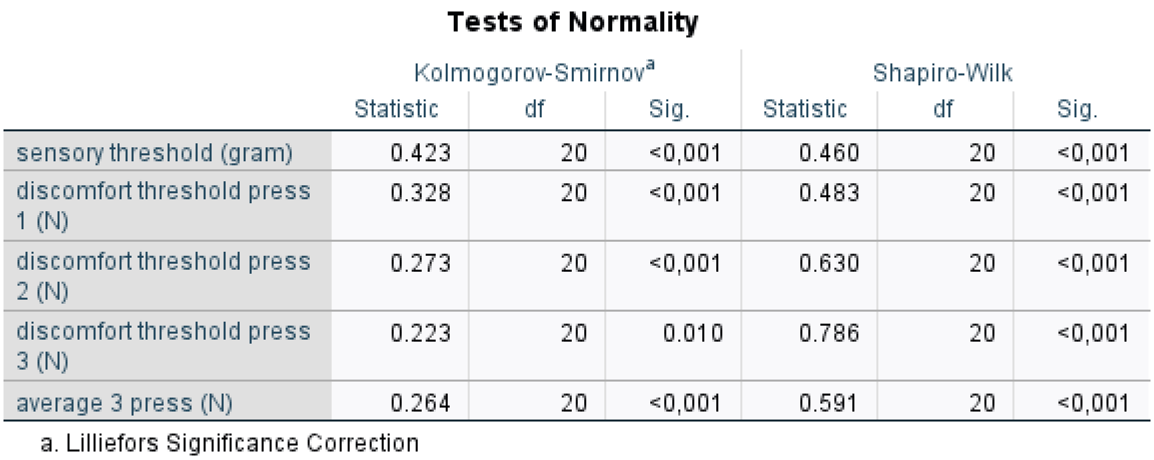


Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
sensory threshold (gram)	0.324	19	<0,001	0.664	19	<0,001
discomfort threshold press 1 (N)	0.198	19	0.048	0.875	19	0.018
discomfort threshold press 2 (N)	0.186	19	0.082	0.856	19	0.008
discomfort threshold press 3 (N)	0.220	19	0.016	0.843	19	0.005
average 3 press (N)	0.183	19	0.096	0.866	19	0.012

a. Lilliefors Significance Correction

2nb

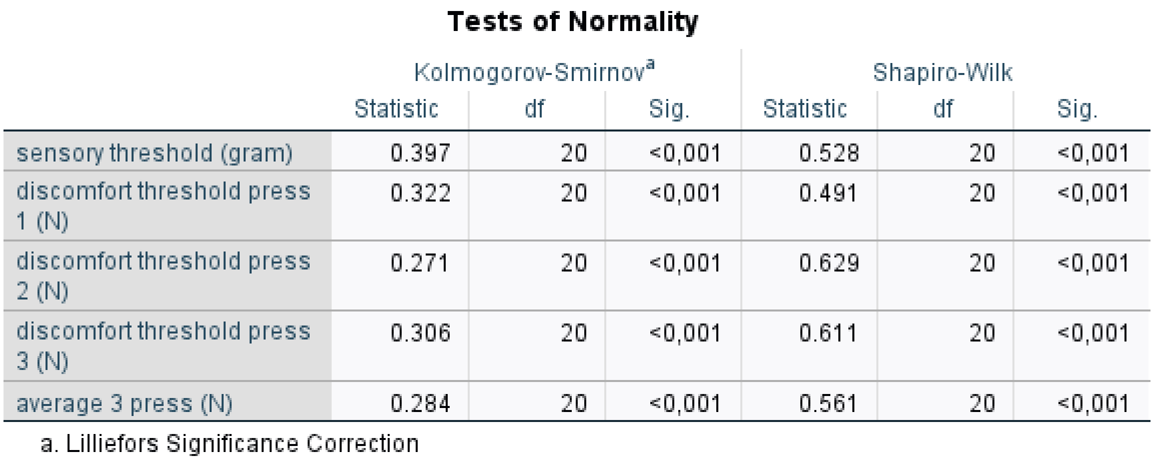


Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
sensory threshold (gram)	0.423	20	<0,001	0.460	20	<0,001
discomfort threshold press 1 (N)	0.328	20	<0,001	0.483	20	<0,001
discomfort threshold press 2 (N)	0.273	20	<0,001	0.630	20	<0,001
discomfort threshold press 3 (N)	0.223	20	0.010	0.786	20	<0,001
average 3 press (N)	0.264	20	<0,001	0.591	20	<0,001

a. Lilliefors Significance Correction

3nb

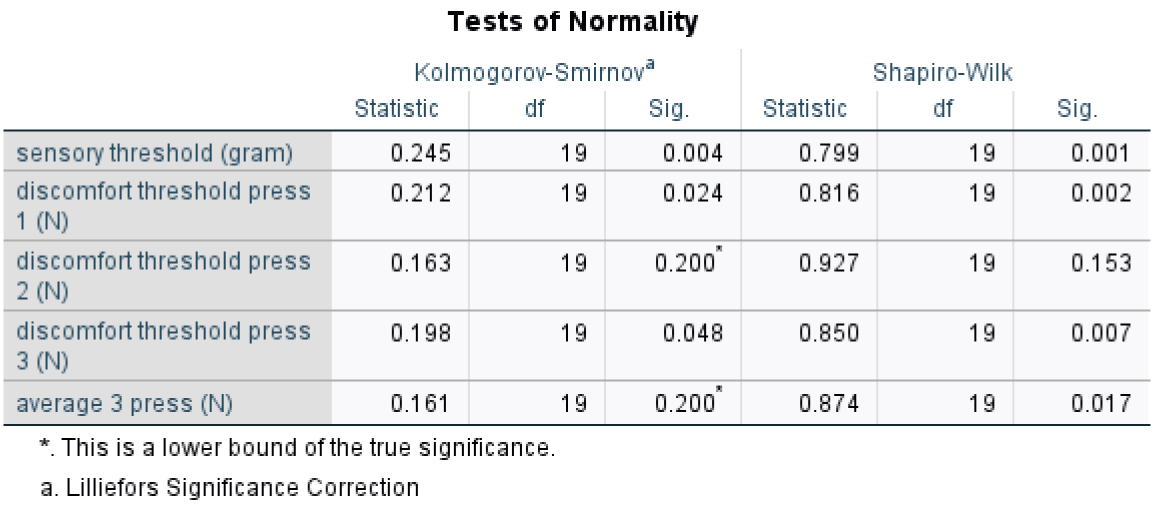


Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
sensory threshold (gram)	0.397	20	<0,001	0.528	20	<0,001
discomfort threshold press 1 (N)	0.322	20	<0,001	0.491	20	<0,001
discomfort threshold press 2 (N)	0.271	20	<0,001	0.629	20	<0,001
discomfort threshold press 3 (N)	0.306	20	<0,001	0.611	20	<0,001
average 3 press (N)	0.284	20	<0,001	0.561	20	<0,001

a. Lilliefors Significance Correction

4nb



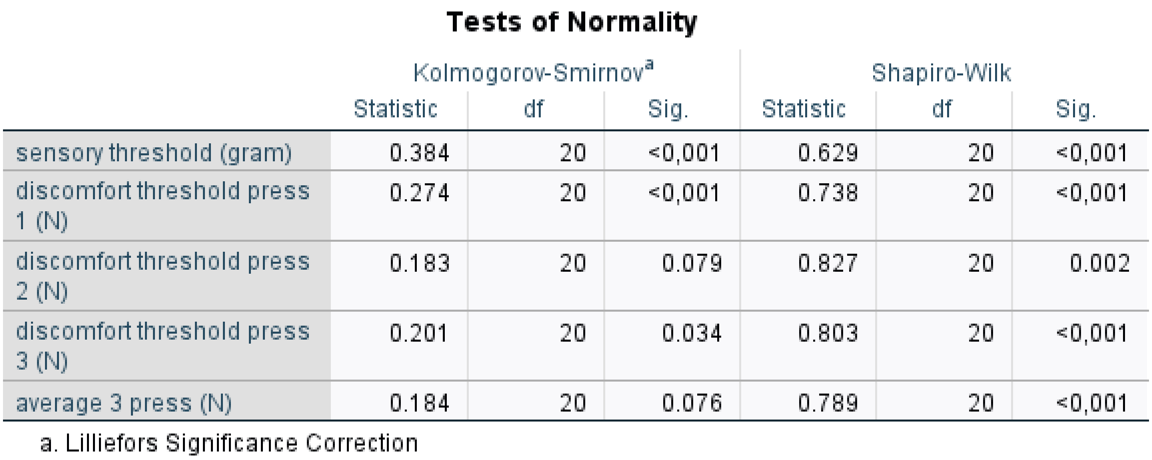
Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
sensory threshold (gram)	0.245	19	0.004	0.799	19	0.001
discomfort threshold press 1 (N)	0.212	19	0.024	0.816	19	0.002
discomfort threshold press 2 (N)	0.163	19	0.200*	0.927	19	0.153
discomfort threshold press 3 (N)	0.198	19	0.048	0.850	19	0.007
average 3 press (N)	0.161	19	0.200*	0.874	19	0.017

*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction

1a

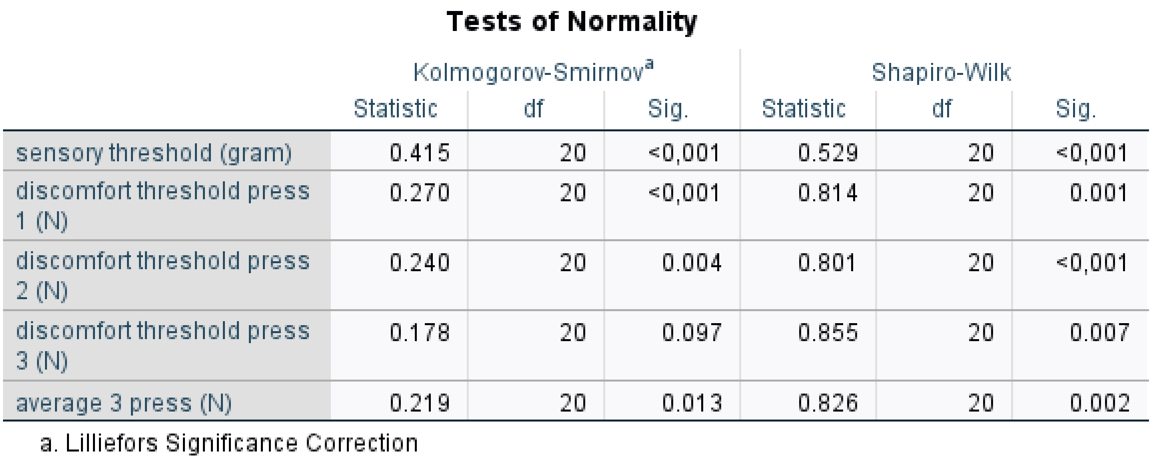


Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
sensory threshold (gram)	0.384	20	<0,001	0.629	20	<0,001
discomfort threshold press 1 (N)	0.274	20	<0,001	0.738	20	<0,001
discomfort threshold press 2 (N)	0.183	20	0.079	0.827	20	0.002
discomfort threshold press 3 (N)	0.201	20	0.034	0.803	20	<0,001
average 3 press (N)	0.184	20	0.076	0.789	20	<0,001

a. Lilliefors Significance Correction

2a

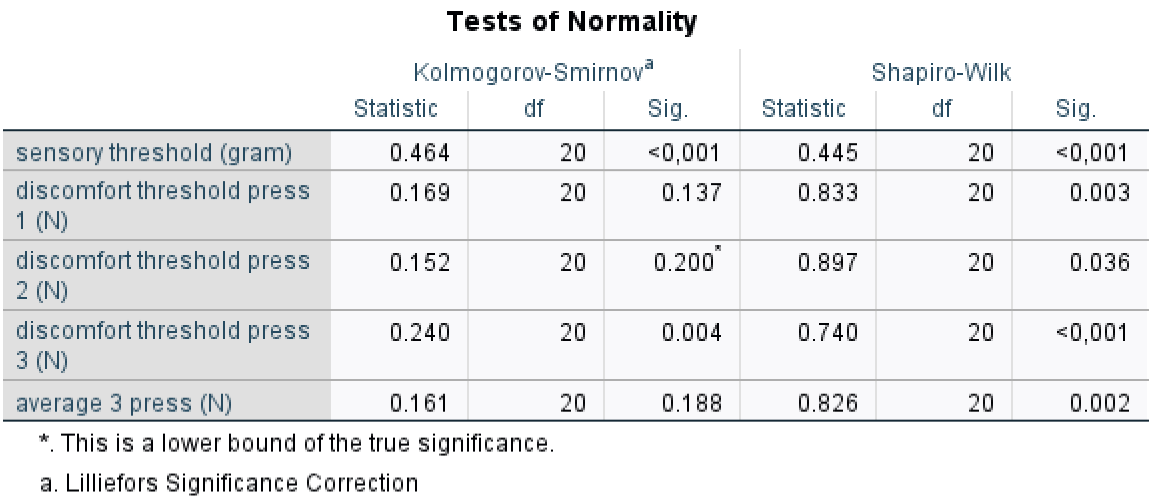


Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
sensory threshold (gram)	0.415	20	<0,001	0.529	20	<0,001
discomfort threshold press 1 (N)	0.270	20	<0,001	0.814	20	0.001
discomfort threshold press 2 (N)	0.240	20	0.004	0.801	20	<0,001
discomfort threshold press 3 (N)	0.178	20	0.097	0.855	20	0.007
average 3 press (N)	0.219	20	0.013	0.826	20	0.002

a. Lilliefors Significance Correction

3a



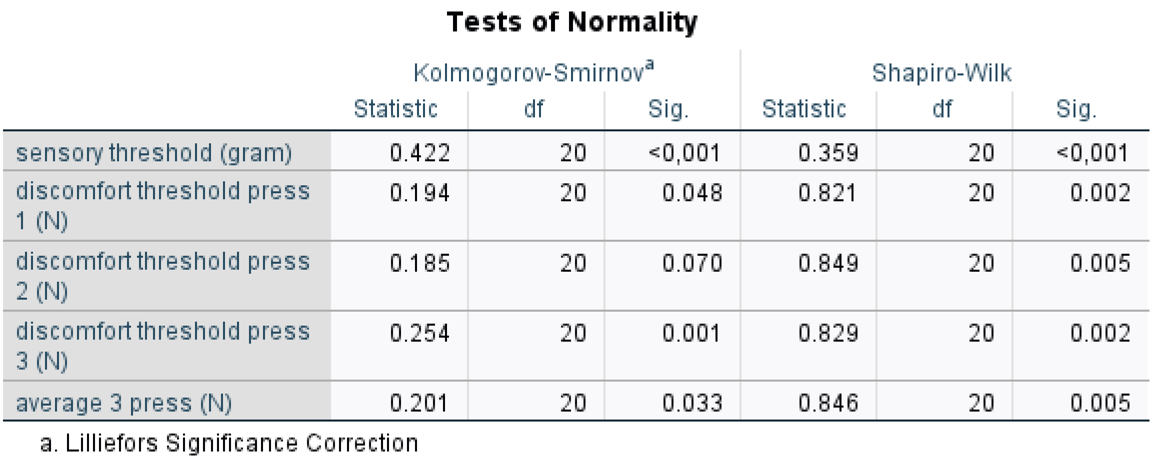
Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
sensory threshold (gram)	0.464	20	<0,001	0.445	20	<0,001
discomfort threshold press 1 (N)	0.169	20	0.137	0.833	20	0.003
discomfort threshold press 2 (N)	0.152	20	0.200*	0.897	20	0.036
discomfort threshold press 3 (N)	0.240	20	0.004	0.740	20	<0,001
average 3 press (N)	0.161	20	0.188	0.826	20	0.002

*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction

4a

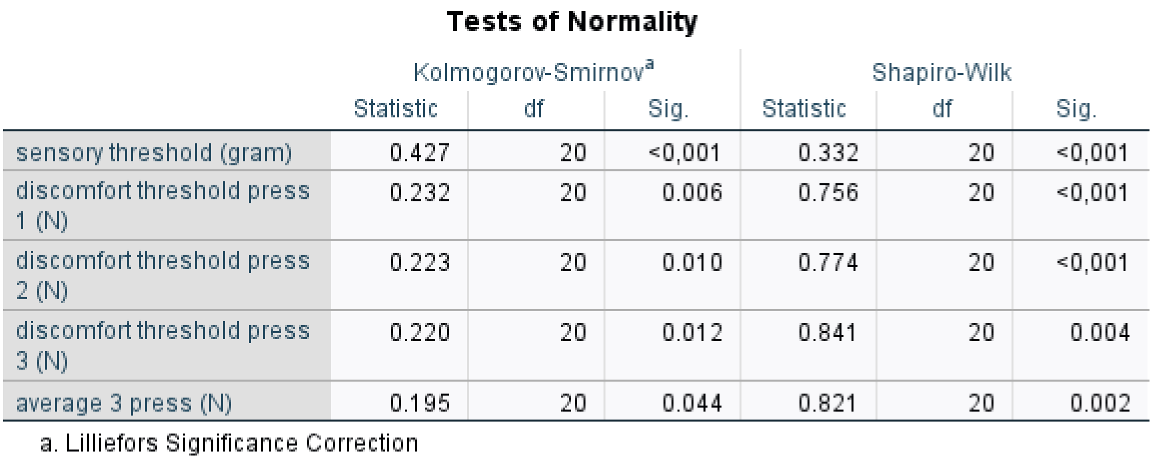


Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
sensory threshold (gram)	0.422	20	<0,001	0.359	20	<0,001
discomfort threshold press 1 (N)	0.194	20	0.048	0.821	20	0.002
discomfort threshold press 2 (N)	0.185	20	0.070	0.849	20	0.005
discomfort threshold press 3 (N)	0.254	20	0.001	0.829	20	0.002
average 3 press (N)	0.201	20	0.033	0.846	20	0.005

a. Lilliefors Significance Correction

1ib

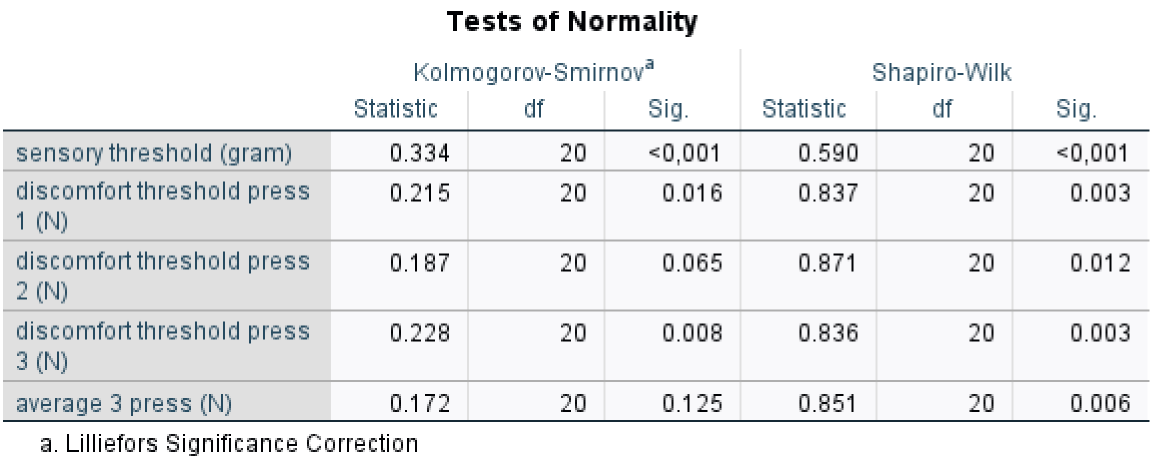


Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
sensory threshold (gram)	0.427	20	<0,001	0.332	20	<0,001
discomfort threshold press 1 (N)	0.232	20	0.006	0.756	20	<0,001
discomfort threshold press 2 (N)	0.223	20	0.010	0.774	20	<0,001
discomfort threshold press 3 (N)	0.220	20	0.012	0.841	20	0.004
average 3 press (N)	0.195	20	0.044	0.821	20	0.002

a. Lilliefors Significance Correction

2ib

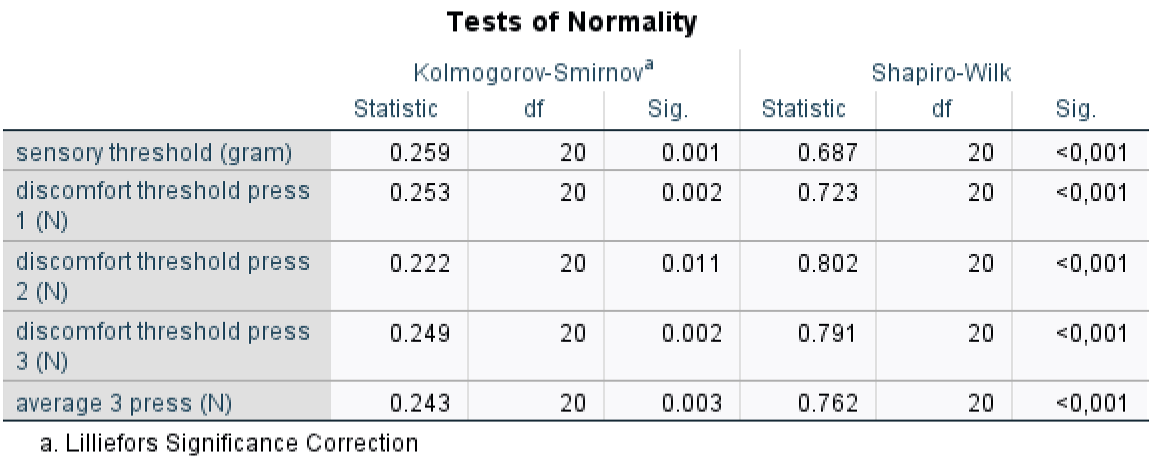


Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
sensory threshold (gram)	0.334	20	<0,001	0.590	20	<0,001
discomfort threshold press 1 (N)	0.215	20	0.016	0.837	20	0.003
discomfort threshold press 2 (N)	0.187	20	0.065	0.871	20	0.012
discomfort threshold press 3 (N)	0.228	20	0.008	0.836	20	0.003
average 3 press (N)	0.172	20	0.125	0.851	20	0.006

a. Lilliefors Significance Correction

3ib

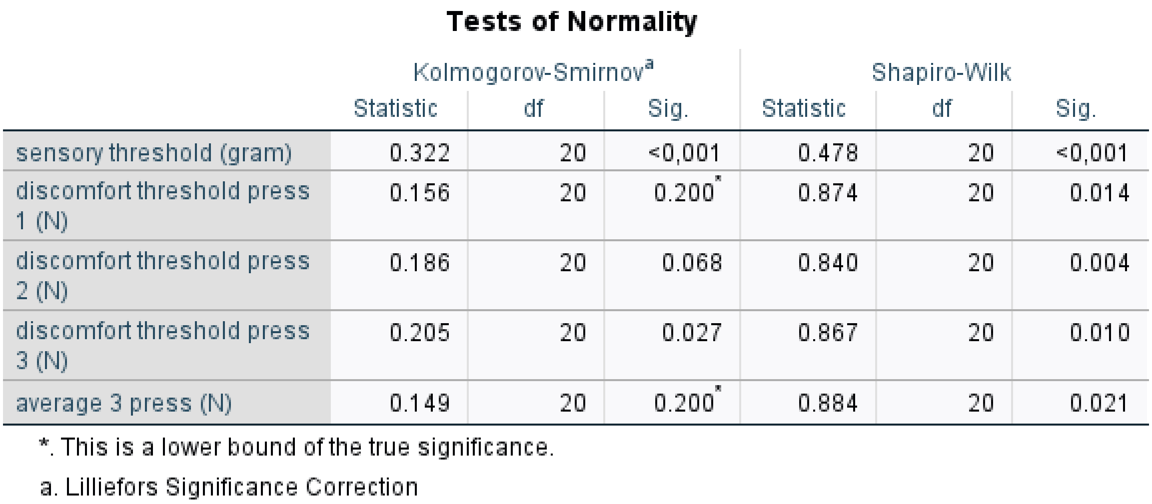


Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
sensory threshold (gram)	0.259	20	0.001	0.687	20	<0,001
discomfort threshold press 1 (N)	0.253	20	0.002	0.723	20	<0,001
discomfort threshold press 2 (N)	0.222	20	0.011	0.802	20	<0,001
discomfort threshold press 3 (N)	0.249	20	0.002	0.791	20	<0,001
average 3 press (N)	0.243	20	0.003	0.762	20	<0,001

a. Lilliefors Significance Correction

4ib



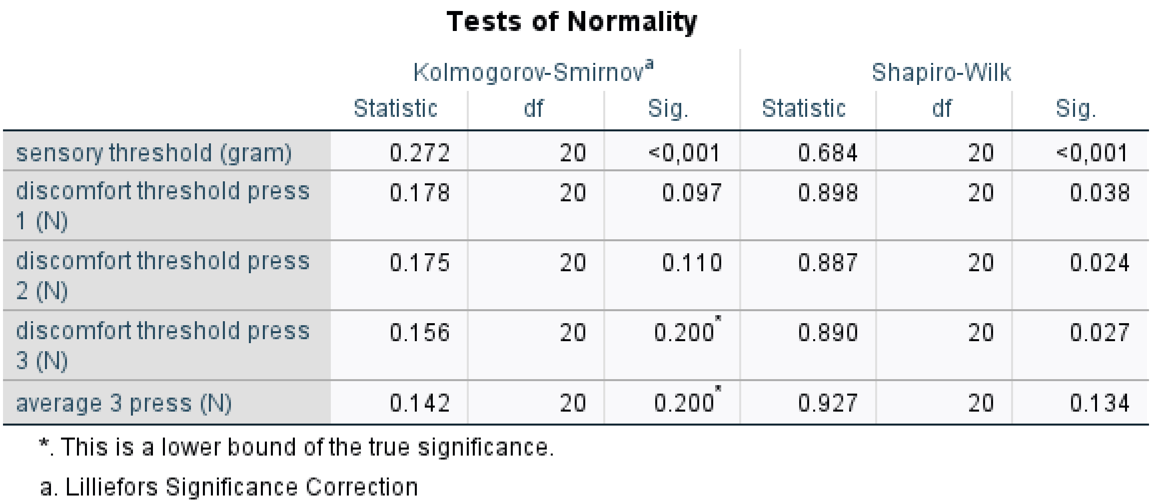
Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
sensory threshold (gram)	0.322	20	<0,001	0.478	20	<0,001
discomfort threshold press 1 (N)	0.156	20	0.200*	0.874	20	0.014
discomfort threshold press 2 (N)	0.186	20	0.068	0.840	20	0.004
discomfort threshold press 3 (N)	0.205	20	0.027	0.867	20	0.010
average 3 press (N)	0.149	20	0.200*	0.884	20	0.021

*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction

1ob



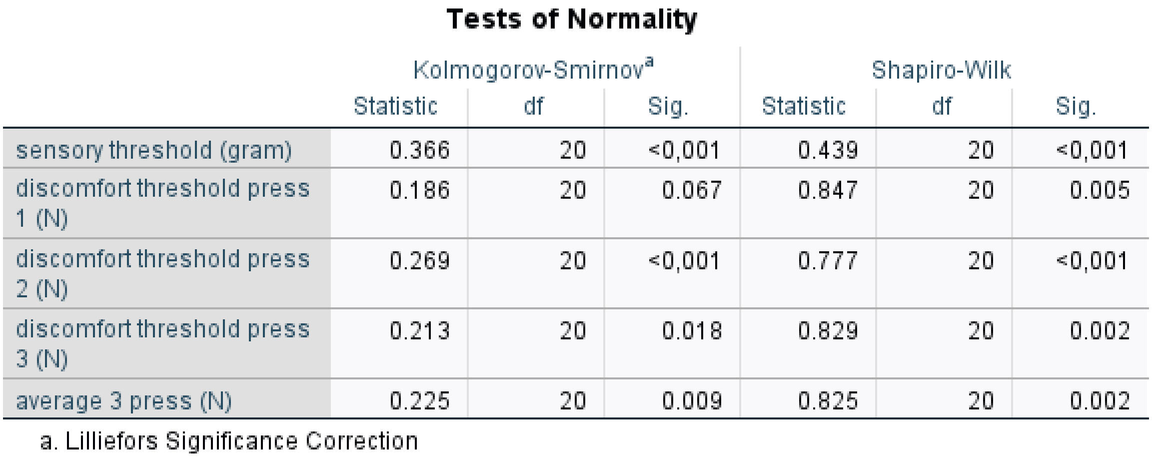
Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
sensory threshold (gram)	0.272	20	<0,001	0.684	20	<0,001
discomfort threshold press 1 (N)	0.178	20	0.097	0.898	20	0.038
discomfort threshold press 2 (N)	0.175	20	0.110	0.887	20	0.024
discomfort threshold press 3 (N)	0.156	20	0.200*	0.890	20	0.027
average 3 press (N)	0.142	20	0.200*	0.927	20	0.134

*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction

2ob

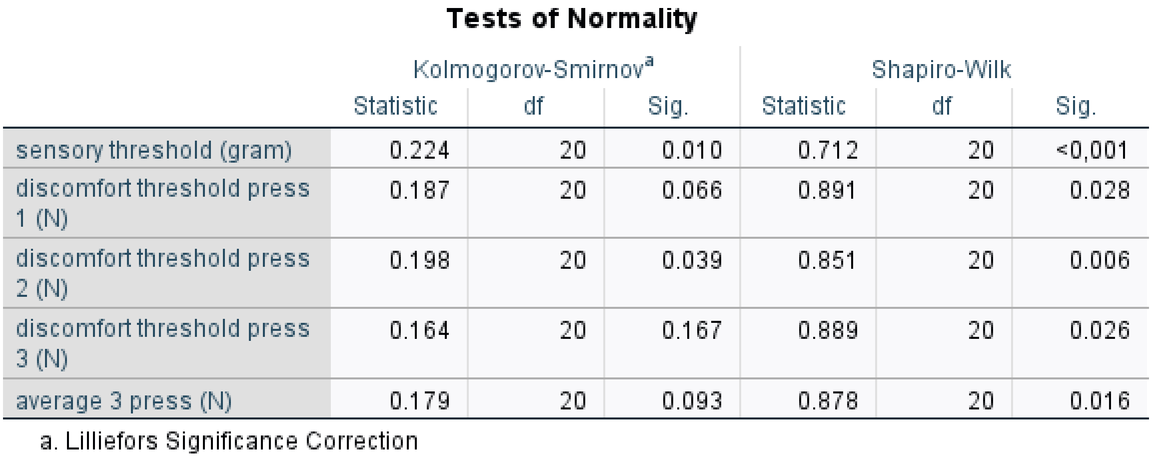


Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
sensory threshold (gram)	0.366	20	<0,001	0.439	20	<0,001
discomfort threshold press 1 (N)	0.186	20	0.067	0.847	20	0.005
discomfort threshold press 2 (N)	0.269	20	<0,001	0.777	20	<0,001
discomfort threshold press 3 (N)	0.213	20	0.018	0.829	20	0.002
average 3 press (N)	0.225	20	0.009	0.825	20	0.002

a. Lilliefors Significance Correction

3ob

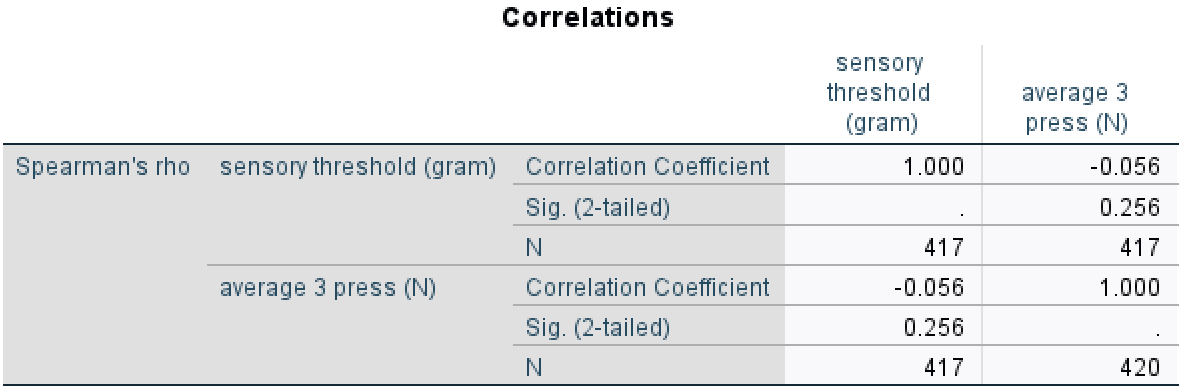


Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
sensory threshold (gram)	0.224	20	0.010	0.712	20	<0,001
discomfort threshold press 1 (N)	0.187	20	0.066	0.891	20	0.028
discomfort threshold press 2 (N)	0.198	20	0.039	0.851	20	0.006
discomfort threshold press 3 (N)	0.164	20	0.167	0.889	20	0.026
average 3 press (N)	0.179	20	0.093	0.878	20	0.016

a. Lilliefors Significance Correction

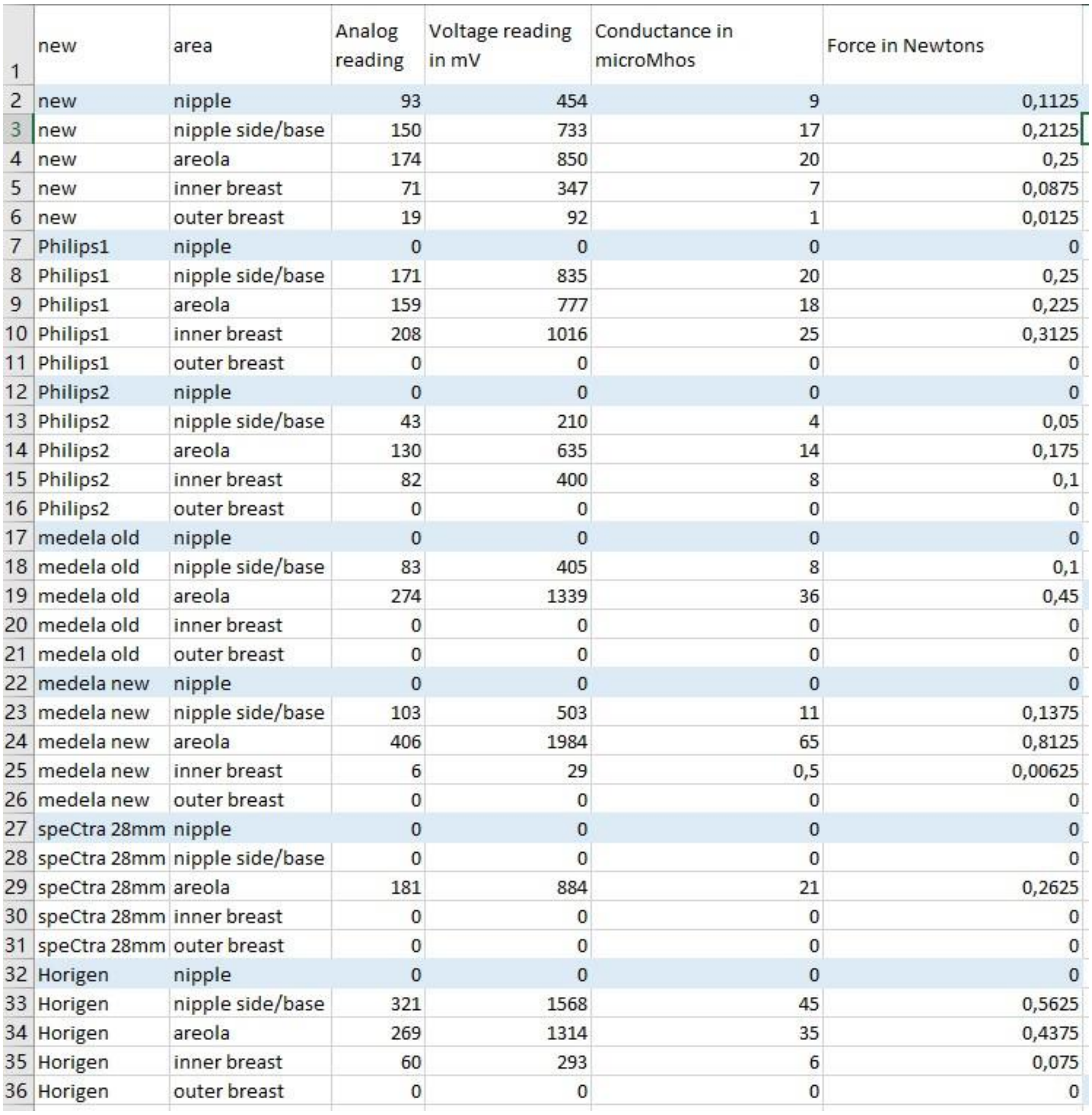
4ob



Correlations

			sensory threshold (gram)	average 3 press (N)
Spearman's rho	sensory threshold (gram)	Correlation Coefficient	1.000	-0.056
		Sig. (2-tailed)	.	0.256
		N	417	417
	average 3 press (N)	Correlation Coefficient	-0.056	1.000
		Sig. (2-tailed)	0.256	.
		N	417	420

Appendix G. Verification



1	new	area	Analog reading	Voltage reading in mV	Conductance in microMhos	Force in Newtons
2	new	nipple	93	454	9	0,1125
3	new	nipple side/base	150	733	17	0,2125
4	new	areola	174	850	20	0,25
5	new	inner breast	71	347	7	0,0875
6	new	outer breast	19	92	1	0,0125
7	Philips1	nipple	0	0	0	0
8	Philips1	nipple side/base	171	835	20	0,25
9	Philips1	areola	159	777	18	0,225
10	Philips1	inner breast	208	1016	25	0,3125
11	Philips1	outer breast	0	0	0	0
12	Philips2	nipple	0	0	0	0
13	Philips2	nipple side/base	43	210	4	0,05
14	Philips2	areola	130	635	14	0,175
15	Philips2	inner breast	82	400	8	0,1
16	Philips2	outer breast	0	0	0	0
17	medela old	nipple	0	0	0	0
18	medela old	nipple side/base	83	405	8	0,1
19	medela old	areola	274	1339	36	0,45
20	medela old	inner breast	0	0	0	0
21	medela old	outer breast	0	0	0	0
22	medela new	nipple	0	0	0	0
23	medela new	nipple side/base	103	503	11	0,1375
24	medela new	areola	406	1984	65	0,8125
25	medela new	inner breast	6	29	0,5	0,00625
26	medela new	outer breast	0	0	0	0
27	speCtra 28mm	nipple	0	0	0	0
28	speCtra 28mm	nipple side/base	0	0	0	0
29	speCtra 28mm	areola	181	884	21	0,2625
30	speCtra 28mm	inner breast	0	0	0	0
31	speCtra 28mm	outer breast	0	0	0	0
32	Horigen	nipple	0	0	0	0
33	Horigen	nipple side/base	321	1568	45	0,5625
34	Horigen	areola	269	1314	35	0,4375
35	Horigen	inner breast	60	293	6	0,075
36	Horigen	outer breast	0	0	0	0