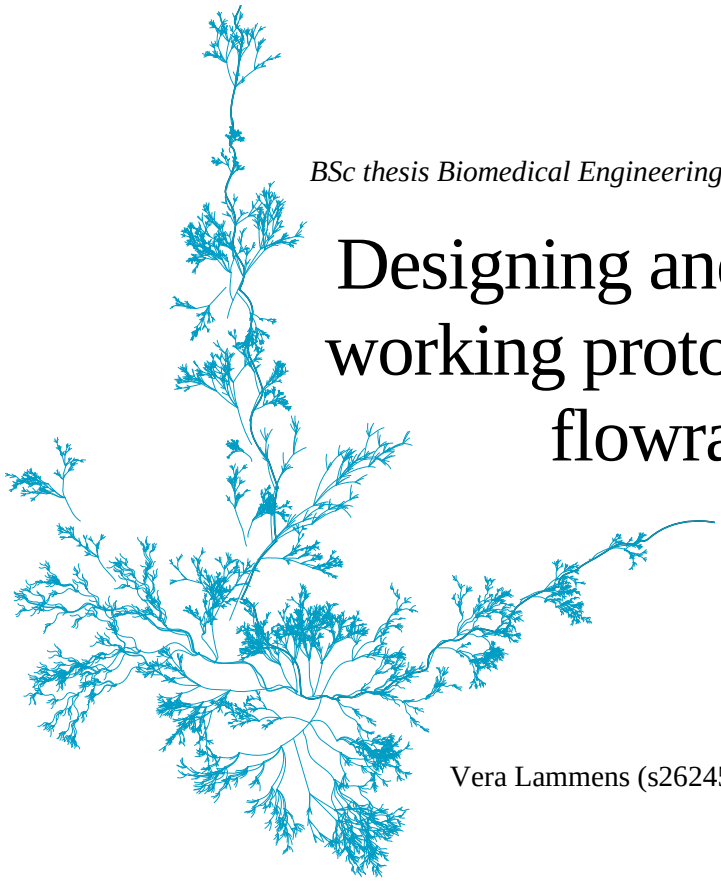

BSc thesis Biomedical Engineering

Designing and developing a working prototype for measuring the flowrate and composition of human breast milk

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Abstract

Human breast milk has a lot of benefits regarding the health of both infant and mother, both in short and long term[1]. Despite all these benefits, a lot of mothers discontinue breastfeeding and start giving formula. In 2023, still fewer than half of infants globally were exclusively breastfed in the first six months of life[2]. The main reason for mothers to discontinue breastfeeding is (perception of) insufficient milk supply[3-5]. At this moment, tools for directly estimating the milk intake are lacking. The aim is to design and develop a working prototype for measuring the volume and composition of human breast milk. This is necessary for getting a better understanding of the lactation process in terms of the milk volume consumed and its time-varying composition during a breastfeed. The research question of this thesis is: what does an optimal design of a prototype look like that is able to measure the flowrate and composition of human breast milk in lab setting? To answer this question, identification of the stakeholders and their interests was needed for creating the list of requirements. These requirements were used for the concept development. This was done by silent brainstorming and using the morphological scheme method for choosing the best concept for further prototype development. By testing the prototype with both semi-skimmed milk from the supermarket and fresh milk sourced from a local farm, a comparison between the two samples could be made for validating the performance of the prototype. Based on identified findings during this project, several recommendations were identified that could be used for the development of this prototype in further research.

Contents

1. Introduction

Human breast milk has a lot of benefits regarding the health of both infant and mother, both in short and long term[1]. Research has shown that it protects the infant against multiple diseases and illnesses, for instance diarrhoea, obesity and several noncommunicable diseases later in life[6]. Also, they have a reduced risk of life-threatening infections[6]. For the mother, it reduces the risk of getting breast cancer, ovarian cancer, obesity, type 2 diabetes and heart diseases[1]. In addition, the skin-to-skin contact establishes an intimate bond between mother and child[7].

Despite all these benefits, a lot of mothers discontinue breastfeeding and start giving formula. In 2023, still fewer than half of infants globally were exclusively breastfed in the first six months of life[2]. The target set by the Global Breastfeeding Collective of the World Health Organisation (WHO) and the United Nations Children's Fund (UNICEF) is to reach 70% by 2030[2]. For reaching this target, better breastfeeding support on both a medical and societal level is essential[6, 8].

The main reason for mothers to discontinue breastfeeding is insufficient milk supply[3, 4]. However, it is not clear if it is really insufficient, perceived as insufficient, or both[5]. When the mother has a low confidence in her parenting abilities resulting in the perception of supplying insufficient milk, this can cause the mother to replace breast milk with formula[5]. Because of the benefits of exclusive breastfeeding for the mother, the child, and public health, this is undesirable[8]. Since it is commonly believed that all women should be biologically capable of breastfeeding, the decision to discontinue breastfeeding is often dismissed as perception only[9]. However, this overlooks the scientific evidence indicating that 10-15% of mothers actually don't manage to produce a sufficient amount of milk[10]. At this moment, tools for directly estimating the milk intake are lacking. Due to this absence, actual insufficient milk supply is often not identified, or identified too late. This will lead to the infant consistently receiving insufficient milk, or to the mother discontinuing breastfeeding which will exclude them both from the benefits of breastfeeding[10]. The underlying causes of lactation insufficiency are not well understood or misdiagnosed, due to the lack of objective methods for investigating and supporting lactation. To solve this problem, fundamental research of lactation physiology and the cause of lactation problems is necessary.

1.1 Objective

The aim is to design and develop a working prototype for measuring the volume and composition of human breast milk, with the focus on fat content since the milk energy content mainly depends on calories from fat[11]. This is necessary for getting a better understanding of the lactation process in terms of the milk volume consumed and its time-varying composition during a breastfeed. This prototype could potentially be used in combination with other measurement equipment for investigating breast physiology simultaneously with milk transfer.

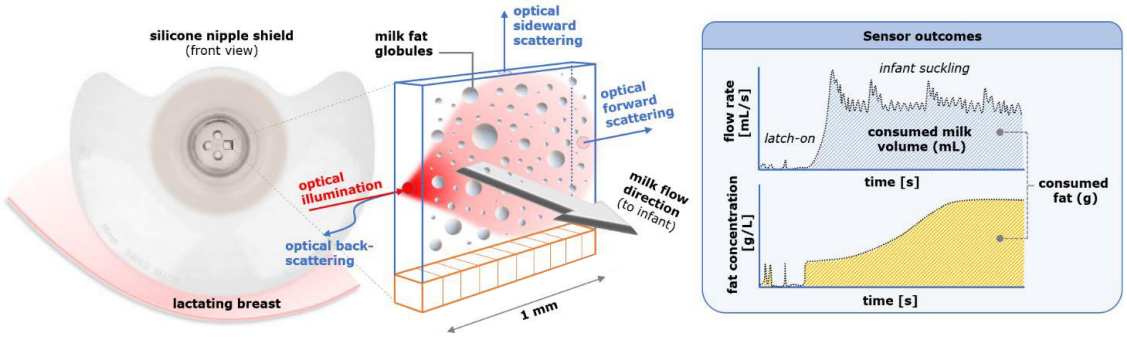


Figure 1: Schematic overview of the proposed sensor prototype and sensor outcomes from the LactIns-and-outs proposal[12].

The desired product would be a sensor that is embedded within an orifice of a nipple shield (Figure 1). A nipple shield (Figure 2) is an already existing aid that mothers use for reducing pain during breastfeeding and to facilitate latching, which is the initiating phase of the lactation process. It was developed to be like a 'second skin', in a way that feeding should be unaffected while using it[13].

Figure 2: Nipple shield[14].

Since it already exists, it is qualified as a safe tool that can be in contact with human milk as well as the skin of both infant and mother. The remaining challenge is the integration of the sensor into an orifice of the nipple shield. Here, techniques are needed for the detection that are compact in size, do not disturb the nursing process, are non-invasive and are still very accurate.

A previous study did this using a miniature Doppler ultrasound flow transducer, which was located inside the tip of a nipple shield[13]. However, only the volume of the milk intake was monitored, lacking the information about the composition of the milk. Therefore, it is necessary to develop new measuring methods that can measure both properties at once.

To tackle the challenge of integration of the sensor into an orifice of a nipple shield strategically, a step by step approach is made. This overview can be seen in Table 1. In the first steps towards development of this nipple shield, the sensor will be embedded into a breast pump. Here, the milk will not be directly consumed by the baby, which gives more freedom regarding regulatory guidelines of the prototype and usage of the prototype. Since newborn babies and mothers are both very vulnerable target groups, these guidelines are necessary when developing new medical techniques or devices[15]. However, the process of meeting these guidelines is very complex and time-consuming. That is why the exclusion of consumption is in some cases necessary to foster the process. In addition, to reduce the amount of wasted breast milk by doing measurements, first bovine milk or milk like samples will be used. Hereafter, measurements with donated breast milk can be done using the same prototype. When the regulatory guidelines for new medical devices are met, the breast milk can be used for consumption and no milk will go to waste.

Table 1: Overview of different prototypes.

Prototype	Sensor embedded into	Suited for	Used for	Consumption milk
1	Breast pump	Bovine milk/milk like samples/donated breast milk	Measurements in lab setting	No
2	Breast pump	Breast milk	Volunteer measurements	Yes
3	Nipple shield (milk extraction by breast pump)	Breast milk	Volunteer measurements	No
4	Nipple shield (milk extraction by baby)	Breast milk	Volunteer measurements	Yes

When all these prototypes are developed, the steps to the final product are getting more obtainable. This final product will allow the baby to drink directly from the mother, while the whole lactation process is monitored.

However, for this project there is limited time and therefore the goal is set to developing a working prototype of a sensor embedded within a breast pump that is suitable for measuring bovine milk, milk like samples or donated human breast milk in lab setting (prototype 1). It will be used the same way as a breast pump and it will be able to measure the volume of the milk as well as detect the composition of the milk. Also, future development will be kept in mind and recommendations for next steps will be given.

1.2 Research Question and Hypothesis

The objective of this thesis leads us to the following research question:

What does an optimal design of a prototype look like that is able to measure the flowrate and composition of human breast milk in lab setting?

Here, the definition of 'optimal' will be specified in the list of requirements (3.4 List of Requirements). The hypothesis is that the prototype measurements will not give quantitative results of the volume and composition measurements. However, the obtained light scattering signals for different situations will be compared and a difference in signal is expected. This could be used for further research.

1.3 Thesis Outline

In the next chapter (Chapter 2) current methods, both subjective and objective, for measuring the volume and composition of human breast milk will be discussed and other techniques that will be applied in the prototype will be explained. Then, in the requirement specification all the stakeholders and their interest will be listed followed by the list of requirements in Chapter 3. Here, the requirements are categorized by functional and non-functional requirements. For the concept development, the methods used will be explained (Chapter 4) followed by the different concepts in Chapter 5. These concepts were tested by giving them a score based on the list of requirements. One concept was chosen and used for prototype development, described in Chapter 6. This prototype was tested in Chapter 7, using the techniques that use light scattering described in Chapter 2. Thereafter comes the conclusion (Chapter 8) and finally the limitations and recommendations for further development will be given in Chapter 9.

2. Background

2.1 Current Objective Methods

There are currently few objective methods used for studying lactation. For detection of milk volume the methods test weighing and isotope dilution are used. For detecting of the composition of milk biochemical techniques and near/mid-infrared spectroscopy are used.

Test weighing is the easiest method for estimating infant milk intake, where the infant is weighted before and right after feeding[16, 17]. The difference in mass can be converted by a calculation to the volume of the consumed milk. It is commonly done during the initial weeks after birth, during the build-up phase of breastfeeding and when the infant is ill, both at home and in hospital setting[18-20]. It is a time-consuming method, which interferes with the feeding habits and maternal lifestyle[16]. This indirect method significantly depends on the accuracy of the instrument as well as evaporative water loss[21]. Different studies concluded that test weighing is therefore too imprecise for usage in clinical practice[16, 19].

A method which does not interfere with feeding habits and maternal life style is the deuterium oxide 'dose-to-mother' technique (Figure 3). Here, heavy water, also deuterium oxide (^2H_2O), is orally given to the mother and after mixing it with body water, it is eliminated from the body in urine, saliva, sweat and human milk[22]. This is followed by the disappearance of the deuterium from the mother and its appearance in the baby. Since this technique requires more analysis and involves a lot of complex mathematical methods, it is less feasible[23]. Also, the milk consumed by the infant can be assessed over a period of 14 days, so it is not suitable for daily use[22].

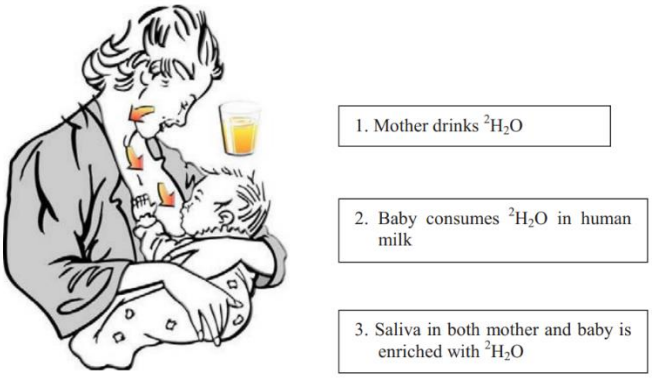


Figure 3:Dose-to-mother technique for assessing human milk intake[22].

Biochemical methods or near/mid-infrared spectroscopy are methods that provide an accurate determination of all the components of the milk[24, 25]. However, these techniques require costly equipment, sample preparation procedures, are labour-intensive and the milk can only be measured offline in extracted milk.

All in all, there is a long felt need for an accurate technique to quantify both the volume and composition of human breast milk consumed by the infant and it would be very desirable if such a method were non-invasive and did not interfere with the nursing process[16, 26].

2.2 Current Subjective Methods

Several subjective methods exist which can be used by mothers to measure their milk supply. Despite that they are not as precise and accurate as objective methods, they can give valuable insight into milk production.

One subjective method is observing the breast: its fullness or changes in size, firmness or leaking can be indicators of milk supply[27]. Usually, breasts feel fuller and heavier when they are producing a sufficient amount of milk. And the other way around, if breasts less full and softer, it may indicate that there is a lower milk supply.

Another method is to observe the baby's behaviour during breastfeeding. When the baby is actively sucking, audibly swallows, shows contentment after feeding and has a good weight gain over time, the milk supply is sufficient. On the other hand, when the baby does not provide these clues and is crying a lot, mothers can feel less confident after feedings which may result in the perception of insufficient milk supply and the discontinuation of breastfeeding[28-30].

Lastly, the baby's diaper output can provide an indirect evidence of sufficient milk intake and milk supply. Sufficient diaper output usually includes frequent wet diapers and regular bowel movements. Here, the baby's age and feeding patterns need to be taken into account[31].

2.3 Possible Techniques Using Light Scattering

For this project, the first technique that will be used is Laser Doppler Flowmetry (LDF) for measuring the flowrate and the breastfeed duration during lactation, from which the volume can be directly derived. For determining the composition of the milk, with the focus on fat content, Multiple Angle Light Scattering (MALS) will be used.

2.3.1 Laser Doppler Flowmetry (LDF)

This non-invasive technique is currently used for continuous real-time measurements of a local microcirculatory blood flow by backscattered light from tissue. A fraction of this backscattered light is scattered by moving red blood cells, resulting in one or multiple Doppler shifts. This backscattered light interferes on the photodetector which causes the detector current to fluctuate depending on the Doppler shifts of the backscattered light[32]. The effectiveness of LDF depends on minimizing movement artifacts since it is very sensitive to movement. This introduces noise which affects the accuracy of measurements[33]. LDF is considered a semi-quantitative technique, since its measurements are relative rather than absolute. This is partly due to the optical properties of biological tissue. For absolute quantification, accounting for the heterogeneous nature of biological tissues and the complex scattering and absorption of light within these tissues is necessary[34].

For measurements during this project, a simplified situation can be described since no effects of biological tissues need to be accounted for. However, the quantification of LDF measurements will remain complex as well as the qualification due to movement artifacts. Also, measurements during this project are done with transmission instead of reflection, so the detector will have to be placed straight across the light source. This way more signal can be detected than when the detector is placed backwards.

2.3.2 Multiple Angle Light Scattering (MALS)

MALS is a non-destructive technique. It provides accurate measurements and offers real-time analysis of samples. By using this technique, the particle size in a solution can be determined. Scattering of light in various directions occurs due to the multiple particles inside a solution. Detectors are positioned at multiple different angles around the sample to measure the intensity of the scattered light at each angle. Rayleigh scattering occurs for small particles, the scattered intensity is symmetrical and related to particle size. For larger particles, Mie scattering occurs and the pattern is more complex since it depends on size, shape and refractive index of the particles. The Mie scattering theory is used when the diameter of the particle is about the same size as the wavelength of the light. It can mathematically be described

by solving Maxwell's equation for the interaction of electromagnetic waves with spherical particles. The solution provides a detailed prediction of the scattered light intensity as a function of angle and particle size. So, the intensity of the scattered light varies with angle and particle size. For Mie scattering the intensity is the highest in forward direction (small angles) compared to backward direction (larger angles)[35]. When assuming the particles are spherical, the size of the fat globules can be determined based on the Mie scattering theory.

2.4 Relationship Between Flow and Pressure of Fluids in Pipes

For designing a prototype of a sensor embedded into a breast pump, it is important to understand the relationship between flow and pressure of fluids in pipes. When designing prototype 1, a comparable flowrate to the flowrate during lactation is desired (NFR 2.1.8). To obtain this flowrate, an understanding of the influences is necessary. The flowrate depends on the dimensions of the input tube, which can be calculated using the Hagen-Poiseuille equation (Equation 1). The equation is only applicable to laminar flows in a pipe[36]. Considering stationary laminar flow in a pipe with flowrate Q, pipe radius r, pressure difference (p1-p2), viscosity , and pipe length L, the Hagen-Poiseuille equation is given as:

$$Q = \frac{\pi * r^4 * (p1 - p2)}{8 * \mu * L}$$

Equation 1: Hagen-Poiseuille equation[36].

Using this equation with a known viscosity of the liquid, a known range of pressure values generated by the pump and a desired range of flowrate values, the optimal dimensions of the length and diameter of the input tube can be determined. This will be described in Chapter 6.1.

3. Requirement Specification

For a successful development and use of the design, a requirement specification is needed. It will provide a clear description of the functionality, quality criteria and performance in terms of requirements. This will help to communicate the different expectations to the different stakeholders that are involved in the whole process. In addition, regulatory requirements are included to ensure safety guidelines and avoid potential risk. For the whole design and development process, this requirement specification will also perform as a guidance. It will outline all the functional, performance and usability aspects that have to be incorporated into the design. Next to that, it provides a documented record of the design inputs and requirements, which facilitates traceability throughout the whole process. It overall serves as a foundation for the development, design and regulatory guidelines to ensure that all the safety, efficiency and quality standards are met while the needs of end-users and stakeholders are addressed[37].

3.1 Product Scope

For this project the goal is set to developing a working prototype of a sensor embedded within a breast pump that is suitable for measuring human breast milk in a lab setting (prototype 1 from Table 1). It will measure photodetector signals under multiple angles around the sample, as a function of time, to determine the composition and flow of the milk. This prototype will support researchers in effectively monitoring and optimizing a lactation process. The list of requirements will be linked to this project and may differ from requirements for further development.

3.2 Product Value

Because of concerns about the nutritional intake of the infant as mentioned in Chapter 1, mothers may give up breastfeeding and switch to formula[28-30]. The need for a measuring device that accurately measures the volume and composition of human breast milk is therefore very high[3]. This development would be valuable for mothers to be certain of their milk being sufficient and this will result in fewer mothers switching to formula. In addition, this design would be valuable for researchers since there is still not much known about the lactation process. Overall, it will help with getting more information about the lactation process.

3.3 Stakeholders and Their Interests

It is important to know who the sensor is intended to serve. Who are the end-users and stakeholders and what are their interests? This information will provide valuable insights during the design process. In addition, considering user feedback and iterative testing will help refine the sensor's performance and overall usability.

3.3.1 Stakeholders

For the final product (sensor embedded into nipple shield), the three end-users and therefore the key stakeholders are healthcare professionals, breastfeeding mothers, researchers, and infants. Healthcare professionals are people who provide guidance and support to mothers regarding breastfeeding and infant nutrition. There are multiple different professionals who provide postpartum care to both the mother and newborn, but with different specialisations. These can be seen below in Table 2. Breastfeeding mothers that may be uncertain about their milk supply can use the final product on a daily basis.

For this project, where the focus lies on the development of prototype 1, the end-users and therefore the key stakeholders are only the researchers. Despite that breastfeeding mothers and healthcare professionals are no key stakeholders in this project, they need to be taken into account.

Next to them, other additional stakeholders have to be considered. For instance, the infant that drinks the milk, the manufacturer, regulatory agencies, insurance providers, and retailers. For all different stakeholders, determination of the volume and composition of human breast milk is important, but with different interests.

3.3.2 Interests

Acknowledging and addressing the different interests of the different stakeholders is essential for decision-making. When there is an understanding of the perspectives of all stakeholders involved, it is possible to achieve an inclusive outcome. The different interest of the different stakeholders will be discussed in Table 2.

Table 2: Overview of the stakeholders and their interest.

Stakeholder	Interests
1) Researchers	Having a better understanding of the lactation process in terms of the composition values for human breast milk and the factors that influences the milk composition. Potential to combine with other measurement equipment for investigating breast physiology simultaneously with milk transfer. In addition, the prototype should be easy to use and easy to clean.
2) Breastfeeding mothers	Knowledge about the quality and quantity of the milk provided to their infants. In addition, the position they have to sit in while using the sensor should be as comfortable as possible. Also, the sensor should be safe, so the milk should be consumable and there should be no loose parts. The prototype should be easy to use and easy to clean.
3) Healthcare professionals:	Applicable to all healthcare professionals: the sensor should be safe, so the milk should be consumable and there should be no loose parts. Also, it should be easy to use and clean.
a) Pediatricians (specialized in care of infants and children)	Monitoring the infant nutrition to ensure that the infant received sufficient nutrition, otherwise supplemental feeding may be necessary. Tracking growth and development of infant.
b) Neonatologists (physicians specialized in the care of newborns, particularly those who are premature, critically ill or have complex medical conditions)	Monitoring milk supply for infants in neonatal intensive care units (NICUs). Premature or critically ill newborns (for example diabetes or dehydration as a result of diarrhoea) may need supplementary feeding to get extra nutrients in addition to breast milk, which is adapted in terms of volume and composition to the amount of milk that has been consumed at the breast (target fortification).
c) Neonatal nurses (nurses specialized in caring for newborn infants, especially those requiring intensive care)	
d) Lactation consultant (provides support and guidance to mothers on breastfeeding and lactation-related issues)	Using data from the sensor to assess the breastfeeding process, observe breastfeeding issues and provide personalized guidance to mothers. In addition, monitoring the breastfeeding process to provide support to mothers during postpartum period and assist with breastfeeding, pumping techniques and addressing any breastfeeding challenges.
e) Midwives (provide prenatal care, assist with childbirth	Monitoring the breastfeeding process to provide support to mothers during postpartum period and assist with

and provide postpartum care to both mother and newborn)	breastfeeding, pumping techniques and addressing any breastfeeding challenges.
f) Postnatal nurse (provides care to mothers and newborn babies during the postnatal period)	
g) General Practitioner (GP)	Monitoring health of both mother and newborn, that includes breastfeeding success and milk supply to provide guidance on breastfeeding and pumping as part of routine postnatal care.
4) Infant	Getting sufficient nutrients in a way that is most similar to the natural lactation process where skin-to-skin contact is possible. They are directly affected by the accuracy and effectiveness of the prototype. The milk should not be affected by the prototype.
5) Manufacturer	Low production and material costs.
6) Regulatory agencies	Application of the correct rules and guidelines. (see 3.5 Regulatory Compliance for Medical Devices)
7) Insurance providers	That it is not too expensive while maintaining high-quality sensor performance.
8) Retailers	Low manufacturing costs and at the same time high quality.

3.4 List of Requirements

The list of requirements consists of preconditions and principles. The preconditions are restrictions imposed from outside and the principles are self-imposed restrictions[38]. A good requirement must be necessary, verifiable and attainable. That means that it should be an essential capability, physical characteristic or quality factor of the prototype. If it is removed or deleted, a deficiency will exist. It should state something that can be verified by examination, analysis, test or demonstration and it should be technically feasible and fit within budget, schedule and other constraints[37].

Every requirement will be coded with a number varying from zero to ten (0-10). Where 0 means that the requirement is not important and 10 means it is very important. This will give an indication of the importance of the requirement for the design during this project. These weighing factors can also indicate whether a specific characteristic can be considered to be a wish instead of a requirement. These characteristics are desirable but non-essential for prototype functionality. So when it is possible they will be met, but when impossible they will be ignored. These are the requirements with a weighting factor below 5. It is important to note that these weighing factors could differ for development of other prototypes and for the final product.

The requirements will be organized in different categories. These categories will give an overview of the different requirements also regarding the different stakeholders. First of all, there is a difference between functional and non-functional requirements.

Functional and non-functional requirements are both essential for the definition of what the product should perform, they have different purposes and relate to different aspects of the product. Functional requirements focus on what the product must do in terms of its capabilities, operations and features. They are directly observable and testable as they involve the system's behaviour and outputs. Non-functional requirements focus on how well the product performs its functions and other aspects such as physical characteristics, operational characteristics, production characteristics, material characteristics. They are more subjective and more difficult to quantify compared to functional requirements. Both types

of requirements are crucial for understanding and specifying the complete set of criteria that the product must meet to satisfy stakeholders and deliver value.

For the ease of finding specific requirements, the non-functional requirements are categorized in different categories. These categories will be:

1. physical requirements;
2. operating requirements, these include:
    - power requirements;
    - noise level requirements;
    - user interface requirements;
    - hygiene and cleaning requirements;
    - compliance and standards requirements;
3. production requirements;
4. material requirements, these include:
    - durability and reliability requirements;
    - biocompatibility requirements;
    - food safety requirements;
5. cost requirements.

The List of Requirements for the prototype of this project can be seen in Table 3.

Table 3: List of Requirements.

		Specification	***Weighting factor***
1.0 Functional Requirements (FR)			
FR 1.1	Shall measure the flowrate by using Laser Doppler Flowmetry (LDF)	Milk flowrate: 0,86 - 37,61 mL/min = 0,014 - 0,627 mL/s[39] Range: 0,01 – 1,0 mL/s with an accuracy of 10%[12] Measurement rate >= 1 fps	10
FR 1.2	Shall measure the flowrate by measuring the mass on a scale during the lactation process	Milk flowrate: 0,86 - 37,61 mL/min = 0,014 - 0,627 mL/s [39] Range: 0,01 – 1,0 mL/s with an accuracy of 10% Framerate >= 1 fps	10
FR 1.3	Shall measure the total volume of the human breast milk based on the measured flowrate	The mean breast milk intake is: 54-234 mL per session[40] Shall have a higher accuracy than current technique: test weighing (±30 mL)[16]	10
FR 1.4	Shall measure the total mass of the human breast milk using the scale during the lactation process	The mean breast milk intake is: 54-234 mL per session[40] Shall have a higher accuracy than current technique: test weighing (±30 mL)[16]	10
FR 1.5	Shall measure the fat concentration of the human breast milk	5-100 g/L with an accuracy of ±0,5 g/L Framerate >= 1 fps	10
FR 1.6	For experimental purpose shall it have a comparable flowrate of the human breast milk during lactation	Milk flowrate: 0,86 - 37,61 mL/min = 0,014 - 0,627 mL/s [39]	10

		Range: 0,01 – 1,0 mL/s with an accuracy of 10%	
FR 1.7	For experimental purpose, the milk shall be collected in a bottle for determining the composition of the milk by chemical/NIR measurements	5-100 g/L with an accuracy of ±0,5 g/L	10
FR 1.8	Shall transfer or read-out data with a cable (as long as the wireless transfer is not available)	This helps users track the milk production and identify patterns over time	10
FR 1.9	Shall store all the data for later analysing	This helps users track their milk production and identify patterns over time	10
FR 1.10	Shall measure enough data points to be able to determine the fat concentration	At least one data point per second, the higher the better but not necessary, framerate >= 1 fps	9
FR 1.11	Shall contain some internal clock so the time-points can be stored together with the flow/composition data		8
FR 1.12	Shall be suitable for measuring human breast milk	The human milk that is detected should stay intact for feeding the infant (relevant for development of prototype 2 and 4)	4
FR 1.13	Shall give visual feedback to the user during the pumping session with current values of fat concentration and cumulative volume	Based on the detected/calculated/analysed quantities	3
FR 1.14	Air bubbles shall be avoided during measurement so that only the milk will be measured	Large air bubbles are detectable so it is not necessary, but nice to have	3
2.0.0 Non-Functional Requirements (NFR)			
2.1.0 Physical requirements			
NFR 2.1.1	The bottle where the milk is collected shall stand firmly on the scale	The bottle stands completely on the scale and no other elements are touching the bottle or the scale	10
NFR 2.1.2	The sampling tube (located at the sensor) shall have a small diameter for the light to propagate from one side of the tube through the scattering liquid to the other side of the tube	Diameter <=1mm	10
NFR 2.1.3	Shall contain at least one laser with a particular wavelength	The optimal wavelength of the laser will follow from research (probably between 550-800 nm)	10
NFR 2.1.4	Shall have one detector straight across from the laser	Different detection options: - Photodiode directly placed against tube, no fibre in order to directly measure the signal - Single mode fibre, less movement artifacts, but detects less light (option to use lens) - Multi-mode fibre, detect more light, but will have	10

		more movement artifacts (shall not move)	
NFR 2.1.5	Shall have enough detectors in different angles regarding the laser that point to the middle of the sampling tube	At least 3 detectors (but ideally five or six or more). The specific angles will follow from (ongoing) research	10
NFR 2.1.6	All the reuseable parts that are in contact with milk, shall be easy to detach and able to directly clean with cold water after lactating	This prevents the proteins to solidify and makes it sanitary	10
NFR 2.1.7	All cables shall be organized in a logical way	An overview of where all the cables are going is desired for a good understanding of the function of each cable Cables that are going to the same output will be connected to each other to provide an organized structure	10
NFR 2.1.8	Shall have a input tube with a diameter and length that gives a comparable flowrate of the human breast milk during lactation (Chapter 2.4)	This is only the case for prototype 1 suitable for measurements in lab setting	10
NFR 2.1.9	Shall contain a small narrow hole at the top to allow air to flow in the system to have a standard atmospheric pressure	It should not be possible for the milk to be spilled through this hole, so it will be placed at the top	9
NFR 2.1.10	Shall have a neutral and simple design	Neutral colours are preferred like white and light blue, this looks clean and calm	8
NFR 2.1.11	Shall have minimal motion artifacts	Possible motion artifacts: - Probe displacement: movement of LDF probe from its original position - Vibration interference: external vibrations from nearby machinery	8
NFR 2.1.12	Shall have minimal other artifacts	Electrical interference: interference from electrical sources	8
NFR 2.1.13	Shall have a maximum amount of cables	Maximum of 10 cables: 1) scale: 1 cable 2) pump: 2 cables 3) optical fibres: 2 cables detectors: 5 cables	7
NFR 2.1.14	Shall have 1 sampling tube through which the milk will be measured. When there are multiple tubes, the sampling tube shall have a representative flow for all tubes	Preferably a maximum of 1 tube, otherwise the milk is possibly not evenly distributed over the multiple tubes	6
NFR 2.1.15	Shall contain two lasers with two different wavelengths in order to increase sensitivity for the fat concentration and particle size	Two lasers in different angles measuring different points would be ideal for better validity and reliability	5

NFR 2.1.16	Shall detect and correct movement artifacts to minimize the impact of movement	Frequence range LDF: 0-100 kHz So frequences outside this range are detectable as artifacts and can be corrected.	5
NFR 2.1.17	Shall have a flexible part/tube between the mother and the device to allow an angle which gives the mother a comfortable position to sit in	The flexible part/tube must go from high to low to regulate good flow This requirement will be relevant in future developments (development of prototype 2)	4
2.2.0 Operating requirements			
NFR 2.2.1	Shall comply with relevant safety and performance standards for medical devices to meet regulatory requirements	(see 3.5 Regulatory Compliance for Medical Devices)	10
NFR 2.2.2	Parts in contact with milk that are not easy to clean, shall be disposable/replaceable	Cost estimation has to be made to decide which parts should be reusable and which replaceable	10
NFR 2.2.3	All parts in contact with milk shall be easy to clean and to sterilize in order to maintain proper hygiene standards	This shall be possible within 2 minutes by an experienced user.	9
NFR 2.2.4	Shall make very little to no noise (generated by the sensor) to enhance the user experience, since breast pumping is preferably done in quiet of private settings	The sensor will not make more noise than the pumping device (normally 45 dB with a max of 60 dB)	7
NFR 2.2.5	Shall consume the minimal amount of power to reduce the need for frequent charging		6
NFR 2.2.6	Shall contain a real-time feedback mechanism or user-friendly indicators that enhance the overall user experience	This includes a display for the obtained sensor's data to ensure it can be easily interpreted by the user and intuitive controls that provide clear information and instructions to the user. Also, an on-and-off button that will not allow to switch off accidentally during measurements This requirement will be relevant in future developments.	5
NFR 2.2.7	Shall be compatible with already existing breast pumps, ensuring ease of use for users	With the large amount of different breast pumps on the market, this will be a tough challenge	2
NFR 2.2.8	Shall incorporate wireless connectivity options to transmit data to a companion app for monitoring and tracking purposes	Maybe somewhere in the future. If so, include data safety	2
2.3.0 Production requirements			
2.3.1	Shall be easy to manufacture	Possible to build within two or three weeks with the use of materials available at the University of Twente	6

2.3.2	Shall be compatible with mass production processes and materials	This helps the transition from prototype development to commercial manufacturing. This requirement will be relevant in future developments.	3
2.4.0 Durability and reliability			
NFR 2.4.1	No parts shall break off or shall come loose		10
NFR 2.4.2	Under any circumstance, the child shall not be exposed to a risk of suffocation if any part breaks off or comes loose		10
NFR 2.4.3	Shall have a lifespan of at least 12 months	The American Academy of Pediatrics (1997) recommends that breastfeeding continue for at least 12 months[5]	5
NFR 2.4.4	Shall be robust and durable to withstand repeated use (keeping in mind the teeth and chewing of the infant)	8 – 12 times a day for 12 months so around 5000 times in total	5
2.5.0 Biocompatibility and materials			
NFR 2.5.1	The material of the sampling tube (located at the sensor) shall be as transparent as possible	Material with low absorption and especially low scattering	10
NFR 2.5.2	Parts that have been in contact with breast milk, shall be made out of a material that can withstand high temperatures	These parts have to be sterilized. Thermal resistance: 0 < Temp. < 100 degrees Celsius	10
NFR 2.5.3	Shall withstand moisture	Because of the milk and cleaning processes	10
NFR 2.5.4	Shall withstand soap, so the material shall be compatible with basic cleaning agents	Because of the cleaning processes	10
NFR 2.5.5	Shall withstand temperature changes	During cleaning processes, the temperature rises to 100 degrees Celsius. Thermal resistance: 0 < Temp. < 100 degrees Celsius	10
NFR 2.5.6	Shall consist of lightweight materials	For the sensor to be lightweight to provide comfort for the user	7
NFR 2.5.7	Shall contain safe and non-toxic materials that will be in contact with breast milk and the breast in order to ensure the health and safety of both the baby and the user	For this, parts of already approved existing breast pumping equipment will be used where possible. Materials used for other purposes must meet certain standards that have to be tested (for instance IV tubing, because it possibly reacts differently to milk than to blood). This requirement will be relevant in future developments (development of prototype 2)	4
2.6.0 Cost requirements			
NFR 2.6.1	Shall be affordable due to reasonable manufacturing costs while maintaining high-quality sensor performance	This requirement will be relevant in future developments.	3

3.5 Regulatory Compliance for Medical Devices

In designing and developing a prototype of a medical device, ensuring regulatory compliance is a crucial component. It verifies that the device meets safety, efficiency, and quality standards required for market approval and user needs. In this section, the approach to achieving regulatory compliance throughout the design and development process is outlined.

To ensure that medical devices are safe and perform as intended, the MDR (Medical Device Regulation) and WMO (Wet medisch-wetenschappelijk onderzoek met mensen) are critical for the development of new medical devices. They both aim to ensure safety and protection, but are used in different development stages[41, 42].

The WMO is a Dutch law that regulates medical and scientific research involving human subjects in the Netherlands [43]. It aims to protect the rights, safety and well-being of research participants and ensures that human research is conducted ethically and scientifically. The WMO is used for conducting medical research[41].

The MDR is concerned with safety and regulatory compliance of medical devices within the EU market. It aim is to ensure that medical devices are safe and perform as intended and sets the requirements for device safety, performance and quality. The MDR is used for putting new medical devices on the market[42].

Since for the development of the prototype during this project, no human subjects are involved and the device will not be put on the market, these regulations do not apply for this project. However, it will apply for future development. Therefore, the approach of both the WMO and MDR will be discussed in the recommendations.

4. Method

In this chapter, the methods used for the ideation of the prototype of a sensor embedded within a breast pump is described. This is a crucial step in the design process since it focusses on generating, developing and refining ideas while taking into account the list of requirements set in Chapter 4. It involves study design, participants, data collection, analysis and results.

4.1 Study Design

Here, an outline of the methodology, approach and materials that are used to conduct the design process will be given. The morphological scheme method was used for generating different concepts.

4.1.1 Morphological Scheme

The morphological scheme method is a structured approach for exploring, developing and evaluating potential solutions to complex problems. It provides a framework for breaking down a problem into its component parts and systematically combining them together in order to generate innovative design concepts.

The first step was identifying the key parameters that define the problem. This was done by looking at the list of requirements. Then, within each parameter, a range of possibilities or solutions was identified. These ideas were gathered by the technique silent brainstorming, which is another form of traditional brainstorming. In chapter 6, all these possibilities or solutions will be organized in a structured table, called the morphological scheme. By making multiple combinations between various solutions of each parameter, different concepts were generated. These combinations were evaluated against predefined criteria stated in the list of requirements. Lastly, the best concept was selected for further development and refinement.

4.1.2 Parameter Identification

Based on the requirements and user needs for this project, the relevant parameters of the problems could be identified. These are listed in Table 4.

Table 4: Relevant parameters of problems that are based on multiple requirements.

Parameter	Problem	Requirements related to problem
1) Flowrate	How to generate a comparable flowrate during measurements in lab setting to the flowrate during breastfeeding?	FR 1.6 NFR 2.1.8 NFR 2.1.9
2) Collection bottle	How to stabilize the bottle collecting the milk after detection and what would be the best design?	FR 1.7 NFR 2.1.1
3) Sensor (location and stabilization)	What are the perfect sensor properties? (sampling tube properties, detector properties, location of sensor, laser properties)	NFR 2.1.2 NFR 2.1.4 NFR 2.1.5 NFR 2.1.11 NFR 2.1.12 NFR 2.1.14 NFR 2.1.15
4) Cleaning process	How to easily attach and detach parts that have to be directly cleaned after measurements?	NFR 2.1.6 NFR 2.2.3
5) Cable management	How to provide cable management for a structured work environment?	NFR 2.1.7 NFR 2.1.13

4.1.3 Traditional Brainstorming

Traditional brainstorming is a method for stimulating creativity in the early design phase[44]. This group technique will help generating a lot of new ideas quickly in response to a specific question or problem. Here, multiple people will be calling out as many ideas as possible within a set timeframe. By disallowing critique and stressing that there are no bad ideas, quantity over quality will be emphasized[45].

4.1.4 Silent brainstorming

Silent brainstorming is a technique used to generate ideas in a group setting without verbal communication. Instead of traditional brainstorming sessions where participants openly share ideas aloud, silent brainstorming allows individuals to generate ideas on their own. This technique allows equal participation where contributing ideas without pressure of speaking up in a group setting is needed. This reduces the influence of dominant personalities to the group and helps combat problems with social loafing and groupthink[46]. Also, more time and space is available for creating and exploring different perspectives without interruptions from others.

The silent brainstorming method was used for generating ideas for the different parameters listed in Table 4. After generating all the ideas, they were shared and discussed in the group to evaluate all the ideas together.

4.1.5 Materials

During the brainstorming session, pen and paper was used as a tool to quickly write down thoughts, sketch ideas, create lists without the need of electronic devices. This made the process feel more immediate and tangible, which encouraged engagement, interactions and communication with other participants. All this led to more productive and effective ideation outcomes.

4.2 Participants

Since researchers are the key stakeholders of this design, the silent brainstorming session was done with four other researchers. All of them having different interests in the design. These interest being: doing flowrate measurements; doing milk composition measurements; and doing breast physiology measurements during lactation. Also, a technician participated.

4.3 Data Collection

Every participant would be writing and drawing all their ideas down on a blank sheet of paper in silence. These drawing can be seen in Appendix A. For every parameter, different ideas were generated.

For this prototype, where no lactation process actually takes place, the milk is pumped through the input tube starting at a reservoir. Simulation of the lactation process during measurements in lab setting is necessary for comparable measurements. This is quite a challenge since the narrow sampling tube inside the sensor part will affect the milk flowrate. A possible solution for this could be having multiple narrow tubes to facilitate a constant flowrate and putting the sensor at one of these tubes. However, the multiple tubes could have different flowrates, which does not provide realistic measurements. In addition, having multiple tubes close to each other would make it difficult to include a sensor really close to only one of these tubes. Next to that, it is important that no milk is left behind in the system. To avoid this some sort of funnel shaped tubes are necessary. This design would be too complex. Another important factor that influences the flowrate is the pressure. For the whole system, except the part where vacuum is needed, it is desirable to have a standard atmospheric pressure. During the concept development this should be taken into account.

The collection bottle collects the milk after detection to verify the composition of the milk detected with the sensor. At the same time it stands on a scale to verify the flowrate of the milk detected with the sensor. Because of the sensitivity of the scale, small movements or other elements could influence the values of the scale. To avoid this, the bottle should stand firmly on the scale. One option for this would be attaching the bottle to the scale using clamps or making sure there are no other elements touching the bottle or the scale. For the design of the bottle, a funnel shape at the neck would be desirable for generating a smooth weight measurement.

There were multiple options for the location of the sensor. It would be most desirable to place the sensor as close to the reservoir as possible, since this would be most identical to the final product, that is the sensor embedded into the nipple shield. However, placing the sensor in this position, the milk flow will be effected by the narrowing because of the sensor. Since it is stated in the list of requirements that the diameter of the sampling tube shall not be bigger than 1 mm (NFR 2.1.2), this could not easily be avoided. Another option for the location would be as close to the vacuum valve as possible. Nevertheless, still the effect on the flowrate should be kept in mind.

By the stabilization of the sensor, it is meant that the fibres that detect the signal should be as still as possible to avoid movement artifacts. An option would be making sure the fibres remain in a really steady position so that no vibrations of the fibres is possible. This could be done by gluing or clamping the fibres in position, considering that gluing is permanent and clamping not.

Regarding the cleaning process, some parts have to be detachable. To connect or disconnect certain parts, different connection techniques are considered. Firstly, non-permanent connection could be possible, for instance a click connection or connection with screws. Another option would be cleaning the system as a whole, so no parts have to be disconnected.

As for cable management, the cables can be colour coded by marking them at their in- and output with the same colour. Also, when multiple cables are going to the same output, they can be clamped or taped together. Tape could also be used for taping the cables to a surface to make sure they are not in the way.

4.4 Analysis

For the analysis of the outcomes of the silent brainstorming session, reviewing, organizing and extracting insights from the generated ideas was done in order to identify potential solutions. The different solutions were put in the morphological scheme. Different combination of the possible solutions were made. These combinations represent the different concepts. Thereafter, each concept was analysed by giving a score. These scores were generated by looking at the requirements and their weighing factor. The concept with the highest score was chosen for further prototype development.

4.5 Results

Looking at the data collection, the following potential directions as solutions of the earlier stated parameters are listed in Table 5.

Table 5: Solutions of parameters.

Parameter	Solutions
Flowrate	Multiple tubes at sensor, where only one sampling tube is detected
	Funnel/cone shape before sensor
	Hole after vacuum valve to generate standard atmospheric pressure
Collection bottle	Physical attached to the scale with clamps
	No elements touching the bottle or scale
	Funnel/cone shape at the top
Sensor location	As close to the reservoir as possible
	As close to the vacuum valve as possible
	Further away from the vacuum valve
Sensor stabilization	Using glue to keep fibres in place and as stable as possible
	Using clamps to keep fibres in place and as stable as possible
Cleaning process	Click connection of parts that have to be cleaned
	Connection with screws of parts that have to be cleaned
	Cleaning only by flushing the whole system, so no disconnection is needed
Cable management	Colour labelling each beginning and ending of each cable
	Clamp cables together
	Tape cables together or to the surface

These ideas led to different concepts which will be discussed in the next chapter.

5. Concept development

Here, all possibilities or solutions are organized in a structured table, called the morphological scheme. By making combinations between various solutions of different parameter, different concepts can be generated. These combinations are then evaluated against predefined criteria stated in the list of requirements. Lastly, the best concept is selected for further development and refinement.

5.1 Morphological scheme

Now that all the possibilities or solutions are identified, these can be organized using the morphological scheme (Table 6). Each row represents a specific parameter, and each column represents a possible solution for each parameter.

Table 6: Morphological scheme.

Parameter	**Solution 1 (S1)**	**Solution 2 (S2)**	**Solution 3 (S3)**
Flowrate	Multiple tubes at sensor, where only one sampling tube is detected	Funnel/cone shape before sensor	Hole after vacuum valve for a standard atmospheric pressure
Collection bottle	Physical attached to scale with clamps	No elements touching the bottle or scale	
Sensor location	As close to the reservoir as possible	As close to the vacuum valve as possible	Further away from the vacuum valve
Sensor stabilization	Using glue to keep fibres in place and as stable as possible	Using clamps to keep fibres in place and as stable as possible	
Cleaning process	Click connection of parts that have to be cleaned	Connection with screws of parts that have to be cleaned	Cleaning only by flushing the whole system, so no disconnection is needed
Cable management	Colour labelling each beginning and ending of each cable	Clamp cables together	Tape cables together or to the surface

This morphological scheme led to different concepts: Concept 1; Concept 2; Concept 3.

5.2 Concepts

5.2.1 Concept 1

In this concept the location of the sensor is as close to the reservoir as possible. Therefore, the collection bottle will be attached to the prototype directly after the vacuum valve just as a usual breast pump. The multiple tubes at the sensor will provide faster flow in order to achieve a flowrate comparable to the flowrate during breastfeeding. Here, it is important to note that the one sampling tube that is measured should have a representative flow for all tubes. Because it consists only of the sensor part, cleaning can be done by flushing the system and no disconnections are needed (Figure 4).

Table 7: Choices concept 1.

Parameter	Concept 1
Flowrate	Multiple tubes at sensor, where only one sampling tube is detected
Collection bottle	No elements touching the bottle or scale (however it is connected to the prototype)
Sensor location	As close to the reservoir as possible
Sensor stabilization	Using clamps to keep fibres in place and as stable as possible
Cleaning process	Cleaning only by flushing the whole system, so no disconnection is needed
Cable management	Clamp cables together
	Colour labelling each beginning and ending of each cable

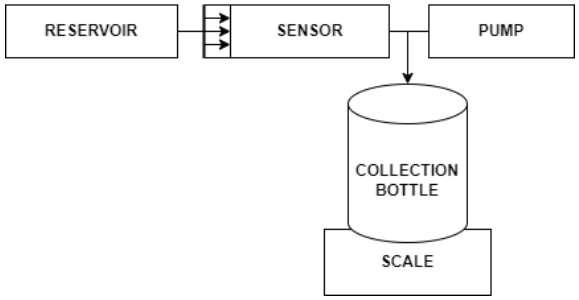


Figure 4: Concept 1.

5.2.2 Concept 2

In this concept, the sensor is placed further away from the vacuum valve. The main reason is that the sensor has one narrow sampling tube which will slow down the flowrate and the milk has to be collected before going through the sensor part. Collecting the milk is done in the funnel/cone shaped part. This way, all the milk will be measured and there is no accumulation inside the prototype (Figure 5).

Table 8: Choices concept 2.

Parameter	Concept 2
Flowrate	Funnel/cone shape before sensor
	Hole after vacuum valve for a standard atmospheric pressure
Collection bottle	No elements touching the bottle or scale
Sensor location	Further away from the vacuum valve
Sensor stabilization	Using glue to keep fibres in place and as stable as possible
Cleaning process	Connection with screws of parts that have to be cleaned
Cable management	Colour labelling each beginning and ending of each cable
	Tape cables together or to the surface

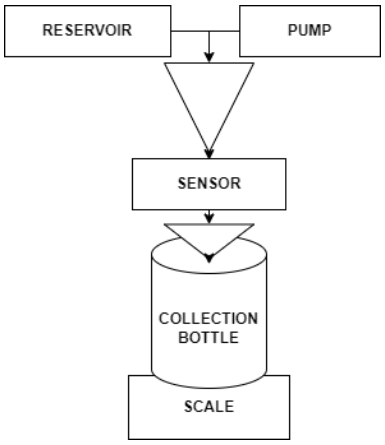


Figure 5: Concept 2

5.2.3 Concept 3

In this concept, the location of the sensor is as close to the vacuum valve as possible. This means that after the pump, the milk will be directly measured. To make this possible, multiple tubes at the sensor are necessary regarding the flowrate. Because it consists only of the sensor part, cleaning can be done by flushing the system and no disconnections are needed (Figure 6).

Table 9: Choices concept 3.

Parameter	**Concept 3**
Flowrate	Multiple tubes at sensor, where only one sampling tube is detected
	Funnel/cone shape before sensor
	Hole after vacuum valve for a standard atmospheric pressure
Collection bottle	No elements touching the bottle or the scale
Sensor location	As close to the vacuum valve as possible
Sensor stabilization	Using glue to keep fibres in place and as stable as possible
Cleaning process	Cleaning only by flushing the whole system, so no disconnection is needed
Cable management	Colour labelling each beginning and ending of each cable
	Tape cables together or to the surface

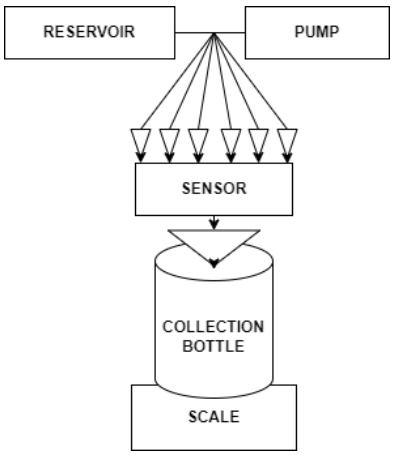


Figure 6: Concept 3.

5.3 Concept Testing

All the corresponding requirements with their weighing factors for each concept are listed in Table 9. These weighing factors are added up to conclude which concept will be used for further development. For some requirements (FR 1.6; NFR 2.1.11; NFR 2.1.12) it cannot be said whether these are met, due to the lack of validation of these statements.

Table 10: Testing of the concepts by analysing the weighing factors of the corresponding requirements.

Requirement	Weighing factor	Concept 1	Concept 2	Concept 3
FR 1.6	10	-	-	-
FR 1.7	10	10	10	10
NFR 2.1.1	10	10	10	10
NFR 2.1.2	10	10	10	10
NFR 2.1.4	10	10	10	10
NFR 2.1.5	10	10	10	10
NFR 2.1.6	10	10	10	10
NFR 2.1.7	10	10	10	10
NFR 2.1.8	9	9	9	9
NFR 2.1.9	9	0	9	9
NFR 2.1.11	8	-	-	-
NFR 2.1.12	8	-	-	-
NFR 2.1.13	7	7	7	7
NFR 2.1.14	6	0	6	0
NFR 2.1.15	5	0	0	0
NFR 2.2.3	9	9	9	9
Total		**95**	**110**	**104**

The concept with the highest score is concept 2. Thus, this concept is chosen and will be used for further development in the next chapter.

6. Detailed Design

First, the optimal dimensions for the input tube were determined by doing a test on a prototype that already existed before starting this project. Then, the chosen concept and therefore the final prototype is discussed in detail.

6.1 Optimal Dimensions for Input Tube

Before starting this project, there was already a first prototype made (Figure 7). It did not meet the requirements and was not suitable for measuring the composition of the milk. Nonetheless, this prototype was suitable for experiments to investigate the optimal dimensions for the input tube, made from flexible PVC, where the milk is pumped through from the reservoir. This way, achieving a comparable flowrate of the flowrate during breastfeeding was possible (FR 1.6).

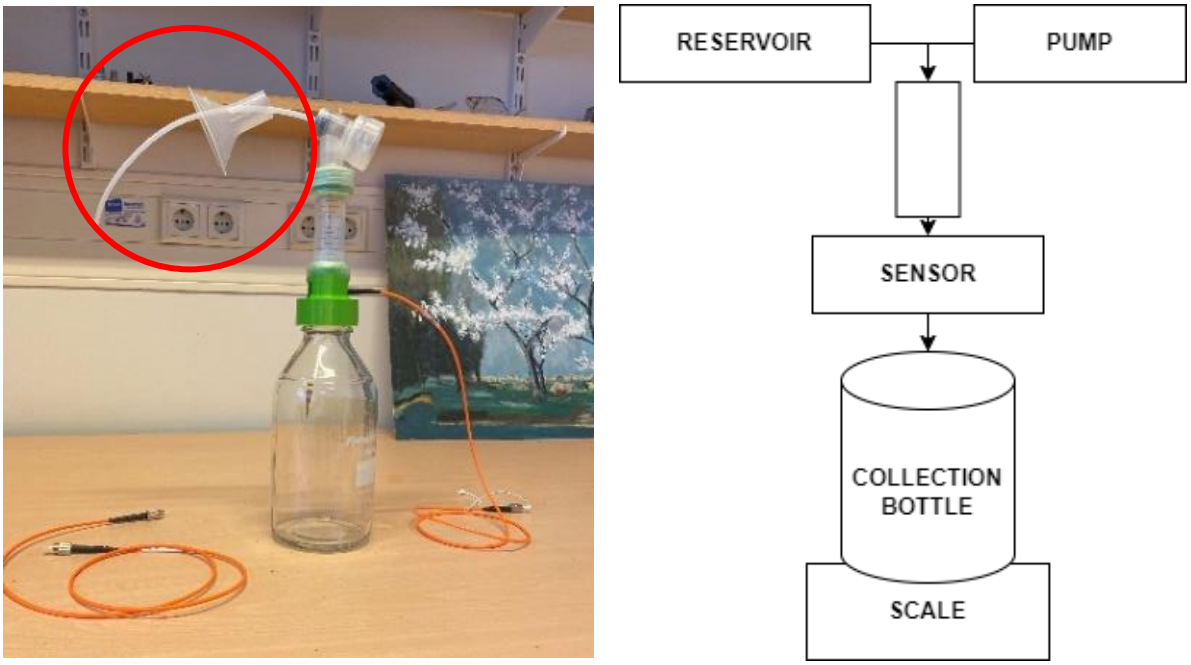


Figure 7: (a) The dimensions of the input tube surrounded by the red circle were investigated. (b) A schematic overview of the design.

In this prototype, the sensor is placed with some distance after the vacuum valve, since accumulation of the milk would occur due to the narrow sampling tube inside the sensor part. The sensor part was not actually used for the detection of the milk. Only the scale data was used during these tests. By collecting the scale data, the mass flowrate could be calculated by taking the difference in mass of two points and divide it by the time difference between these points. These calculations were done using MatLab (Appendix B). Demi water was used as the liquid, since the only result would be the data from the scale and not from measurements using LDF. As explained in Chapter 2.4, the flowrate depends on the diameter of the tube, the length of the tube, pressure, viscosity and density of the liquid (Equation 1). The Medela Symphony breast pump has a pressure range (7-33 kPa)[47]. The viscosity and density of the liquid are set (properties of demi water). As stated in the requirements (FR 1.1), the prototype should provide a flowrate range of 0,1-1,0 mL/min. With both ranges of flowrate and pressure and the diameter of the input tube set (1 mm), a range of lengths of the input tube could be calculated using the Hagen-Poiseuille equation (Equation 1). These parameters can be seen in Figure 8. From here, it was expected that when the input tube has a length of 1 m, the ranges of pressure and flowrate could be achieved. This was tested with the already existing prototype using demi water.

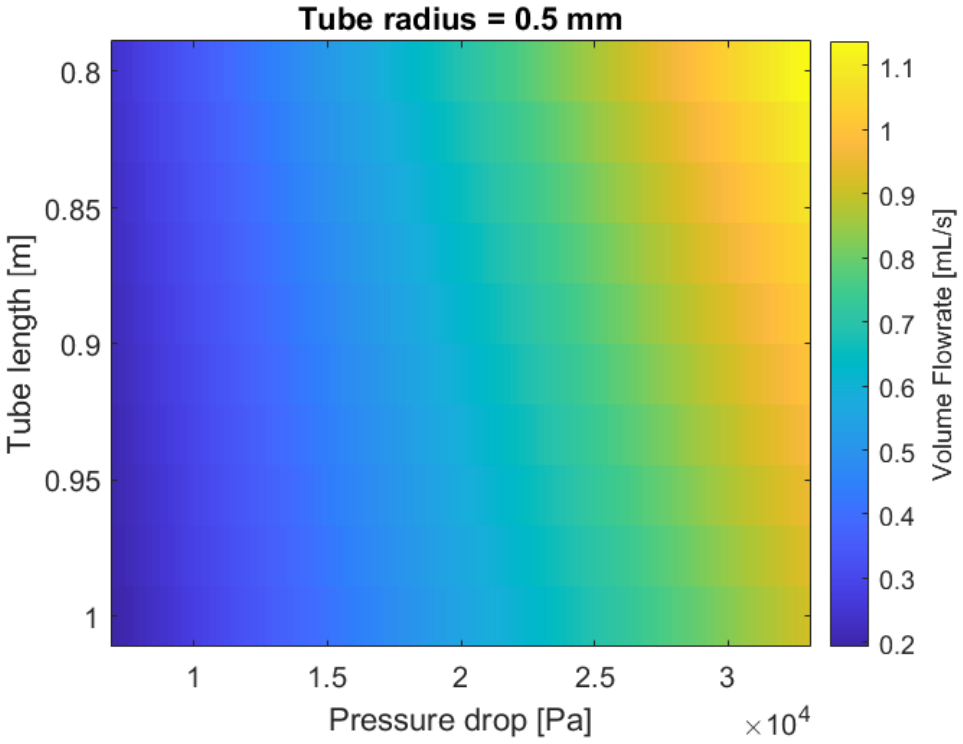


Figure 8: Matrix of (range of lengths)x(range of pressure)x(range of flowrate).

During the first ten seconds of pumping, the pump was generating the lowest vacuum (7kPa). In the second ten seconds, the pump was set at the highest vacuum (33kPa). It can be seen that the flowrate was indeed within the range as calculated (Figure 9). Therefore, these dimensions of the input tube will be used for the design of the prototype.

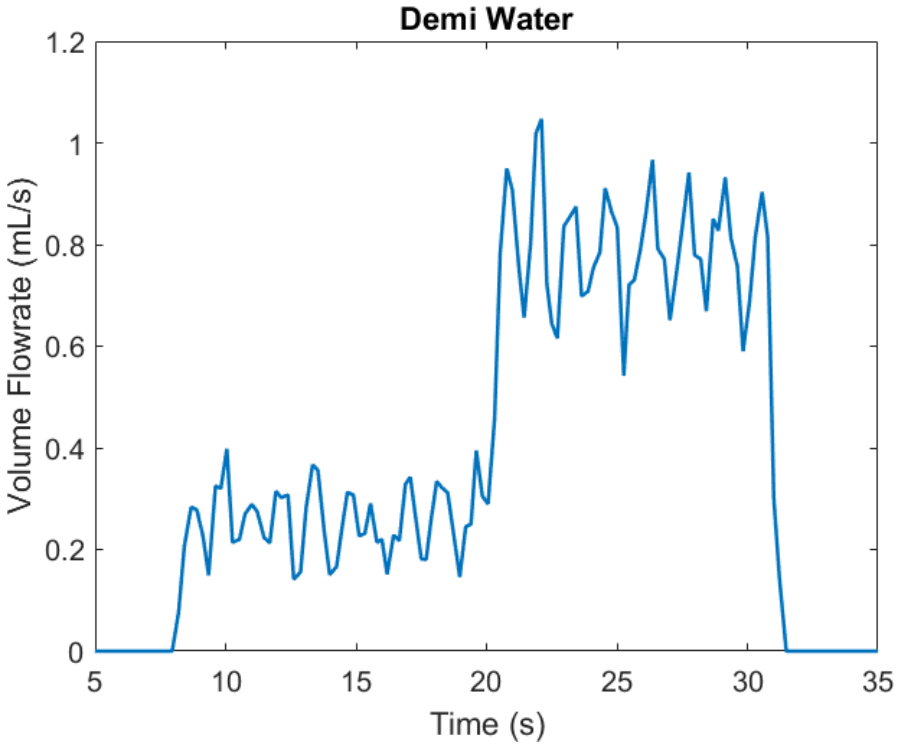


Figure 9: Results of flowrate of test with the input tube having the dimensions of 1 mm in diameter, 1 m in length, a pressure range of 7-33kPa. From 8-20 seconds, the pressure is 7kPa (lowest). From 20-31 seconds, the pressure is 33 kPa (highest).

6.2 Chosen concept

The chosen concept for the detailed design is concept 2. This concept consists of two parts that have to be designed, the other parts already exist and are available. The first part being a funnel shape and the second part being the octagonal sensor. The specifications of the design, drawings and technical data, can be seen in Appendix C.

6.2.2 Part 1 – Funnel

The funnel part was made through fused filament fabrication, also known as 3D printing. First, the part was designed using SolidWorks and then made using the 3D printer (Ultimaker 3 extended) located at the University of Twente at the research group BMPI of the faculty TNW. With use of the software Ultimaker Cura, the designs made in SolidWorks could easily be transferred to the printer.

The dimensions of this design were based on the dimensions of the octagonal part. These were then again based on the dimension of the metal parts, called mating sleeves (Figure 13b), that are used to attach the fibres to the octagon[48]. These have the dimensions of 15x15mm. To align these parts perfectly together, the sides of the octagonal have the exact same dimensions (15x15mm). The height of the funnel was an approximation. To make sure that there was enough volume for collecting the milk, the funnel in height had a dimension of 123 mm. At the top of the funnel shaped part, there are four holes for allowing air inside (Figure 10). This generates a standard atmospheric pressure in the system which is important for the flow of the milk.

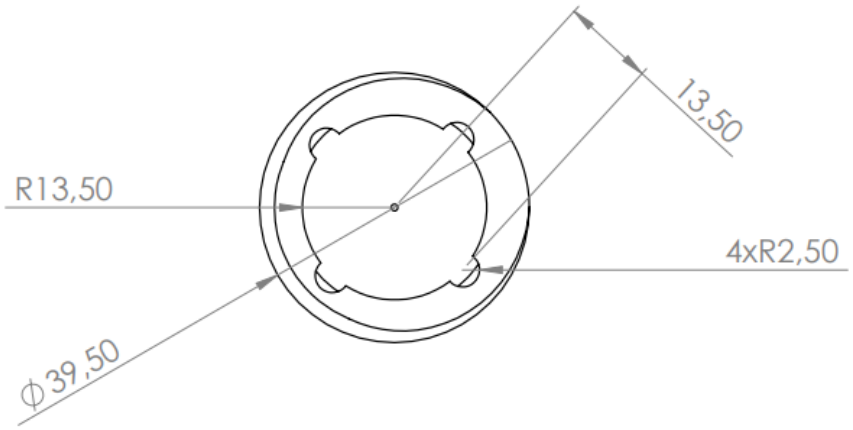


Figure 10: Upper view of the funnel part with dimensions.

The material used for the funnel shape was PLA filament (polylactic acid) which was available in multiple different colours. PLA has a thermal resistance of 59 degrees. It is a biodegradable, biocompatible and renewable thermoplastic polyester and is mainly derived from corn starch[49]. PLA can be printed with high dimensional accuracy and quality surface finish. Since this prototype would only be used during measurements in lab setting, colour choice was not really important. However, keeping in mind further development where neutral colours are preferred (NFR 2.1.10), the chosen colour for the final version of this prototype was white.

Multiple designs were made during the process, because of iterations made step by step (Figure 11). When first designing the funnel, the downside part was squared. According to NFR 2.1.10, the prototype shall have a neutral and simple design to provide a clean and calm look. This was the reason for iterating the shape of the part into a more clean shape, that is round. Since it was still not looking as clean as preferred because of the sharp corners of the octagonal sensor attached, the downside part was also made

in an octagonal shape to make the connection as smooth as possible. This also improved the alignment of the two parts together (Figure 11d).

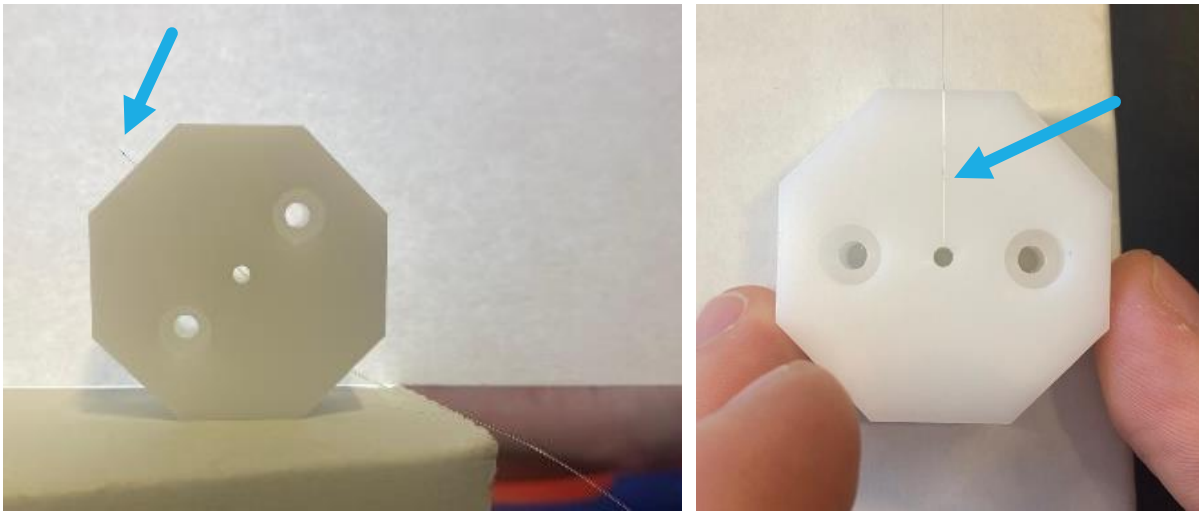
(a) **(b)** **(c)** **(d)** **(e)**

Figure 11: Evaluation of the funnel part.

6.2.3 Part 2 – Octagonal sensor

The octagonal part for the sensor was made out of Delrin (polyoxymethylene), which has excellent mechanical, thermal and chemical properties, and its low friction and wear resistance combined with ease of machining and processing makes this material to be ideal for precision parts[50]. It was made by hand by someone specialized in making instruments at the self-service workshop. As said, the dimension were based on the dimensions of the metal parts, called mating sleeves, that are used to attach the fibres to the octagon (Figure 13b).

The fibres used for the sensor are multimode fibres[51]. These fibres detect a lot of signal of the scattered light, but are very sensitive to movement. The holes made inside the Delrin part are made to perfectly fit one fibre. This way, vibration of the fibres is minimized. How the fibres will fit inside the Delrin part can be seen in Figure 12.



(a) **(b)**

Figure 12: Octagonal part, showing the placement of the fibres. (a)Fibre is placed inside, pointed to with blue arrow. (b)Shows how deep the fibre will be placed inside the octagonal part, blue arrow shows the fibre.

The fibres were placed inside the Delrin part to the centre where they will reach the surface of the sampling tube where the milk will flow through. To keep the fibres in place, they have to be glued to the fibre connectors, which can be screwed together with the mating sleeves connected on the outside of the octagonal part (Figure 13)[52]. The tip of the fibre connectors is called a 'ferrule', where the glue is mainly placed.

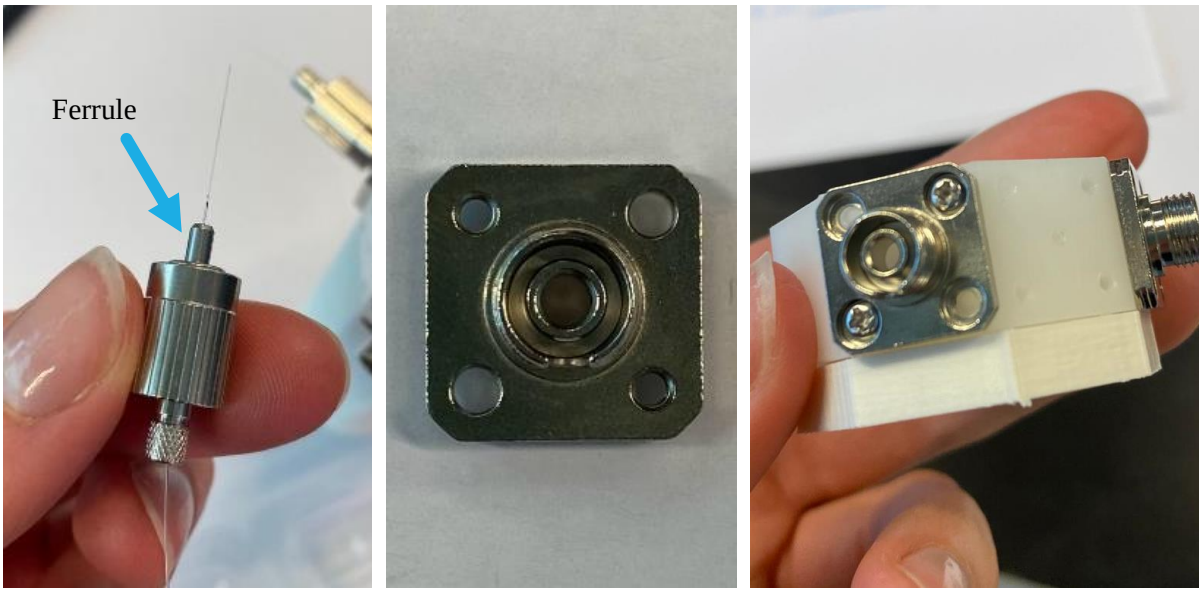


Figure 13: Parts used for attaching the fibre to the Delrin part. (a)Fibre attached to the fibre connector with glue. (b)

Since the Delrin part was made by hand, some alterations had to be made to the funnel part because some dimensions were slightly different (Figure 14). These dimensions being the holes for screwing the two parts together. When this was done, the two parts could be assembled.

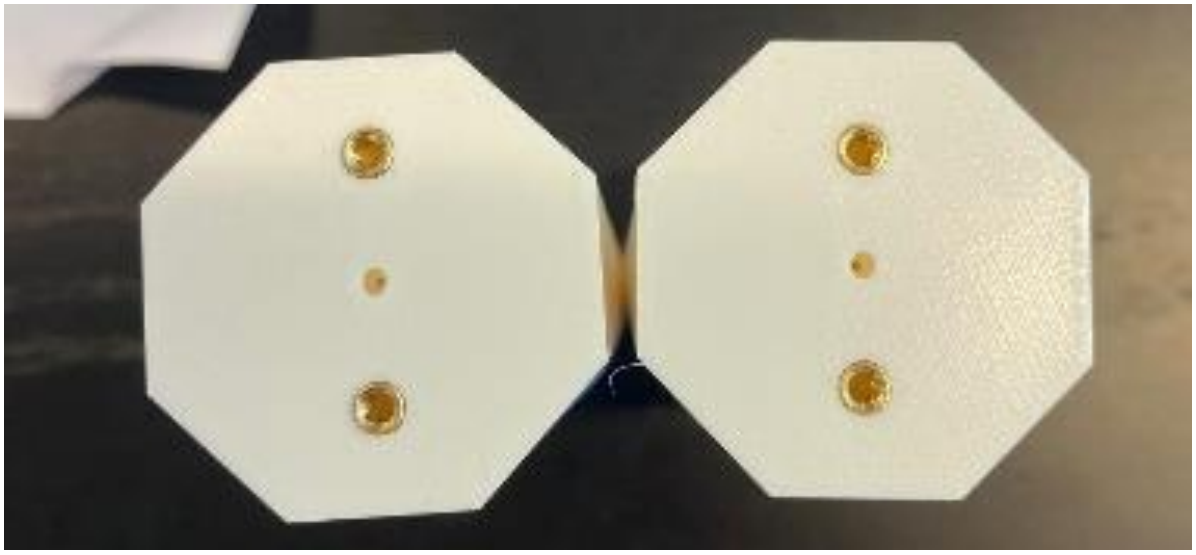
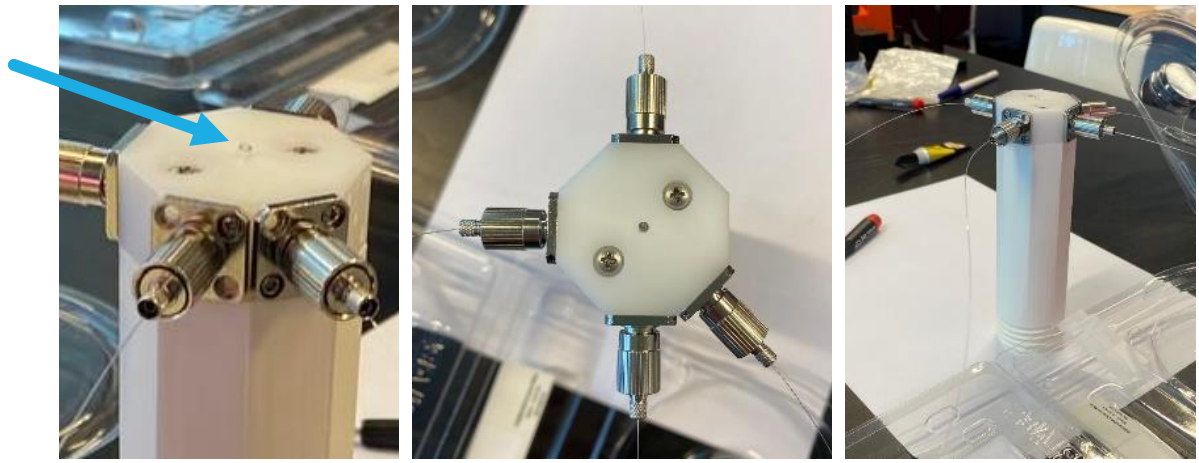


Figure 14: Different versions of the funnel part due to change in dimensions of the Delrin part.

6.4 Assembly

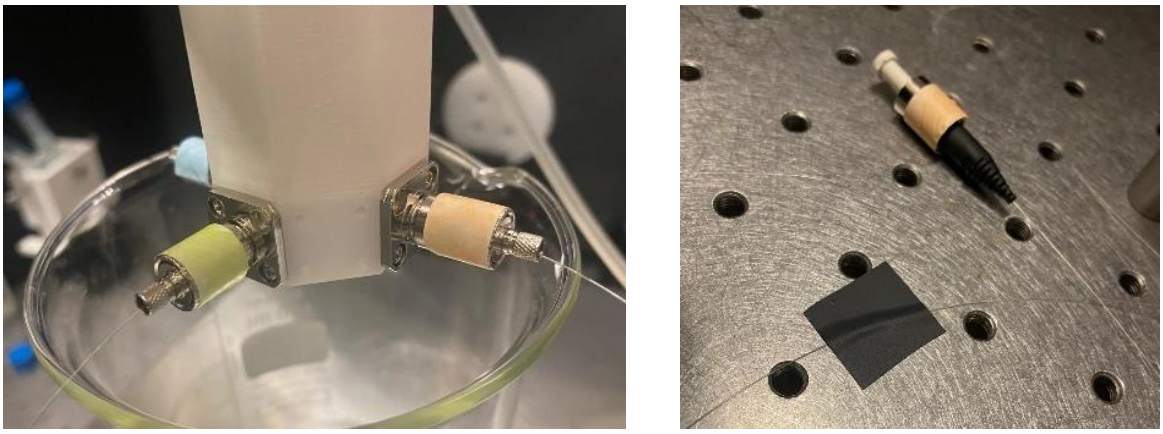
After iterating and making sure the two parts fit perfectly together, the assembly could be made. First, the sampling tube, made from flexible PVC, was placed inside the hole of the funnel part and then permanently attached by glue (Figure 15a). Placing the octagonal part together with the funnel part could easily be done by screwing the two parts together (Figure 15).



(a) **(b)** **(c)**

Figure 15: Assembly. (a)Blue arrow points to the sampling tube placed inside the funnel and octagonal parts. (b)Bottom view of the assembly. (c)Assembly standing upside down.

Since the fibres are very thin and therefore hard to see, colour labelling each fibre was helpful to identify which fibre was measuring which angle (Figure 16). In addition, by taping the fibres to the table, a better overview of the fibres was provided.



(a) **(b)**

Figure 16: Colour labelling and taping of the fibres.

To connect the parts to the pump and the reservoir, an existing coupling piece is used (Figure 17). Since the input tube is much smaller in diameter than the coupling piece, a small part had to be made to connect them together. This was done by designing it in SolidWorks and 3D printing it. The technical drawings of this coupling piece can be seen in Appendix C. It was connected by using tape and parafilm.

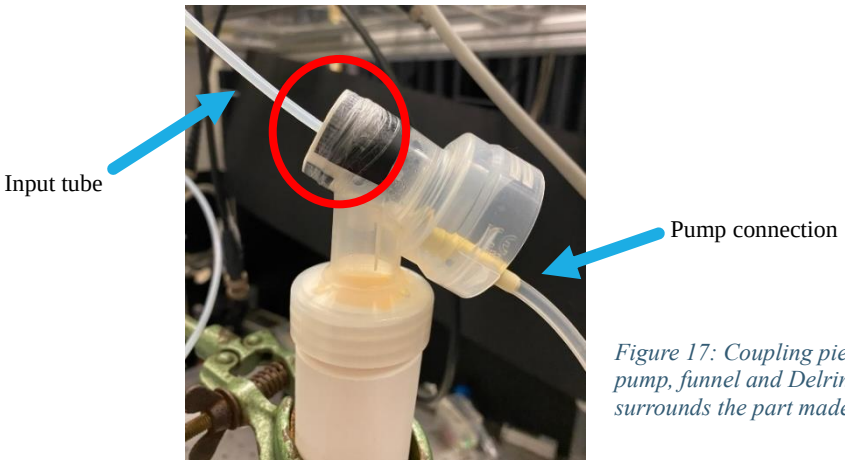


Figure 17: Coupling piece for connecting the reservoir, pump, funnel and Delrin part together. The red circle surrounds the part made that was 3D printed.

7. Prototype Testing

For validation of the performance of the prototype, tests were conducted using bovine milk. Bovine milk was chosen due to its similar properties to human milk, making it suitable for preliminary testing. The tests were performed using two types of bovine milk: commercially available milk from the supermarket and fresh milk directly sourced from a farm (Figure 18). This section details the methodology, results and analysis of these tests.

Figure 18: Fresh milk directly sourced from a farm.

Since semi-skimmed milk has a lower viscosity than fresh milk, it is expected that the signal during the flowrate measurements of semi-skimmed milk will be higher than for fresh milk (Equation 1). The intensity of the signal of the composition of fresh milk is expected to be higher in different angles since the light will be scattered a lot more when measuring the fresh milk, since the fat concentration is higher than for semi-skimmed milk Also, the particle size should be considered since in fresh milk this is larger. This will result in more anisotropic scattering, so the intensity of the signal will probably be larger when detection is done under an angle. It is expected that the intensity of the signal in forward direction will be the highest for low fat concentrations (semi-skimmed milk) and it will decrease when increasing the angle of detection. For high fat concentrations (fresh milk), it is expected that the intensity of the signal may be higher in backward direction compared to semi-skimmed milk, but still the highest signal is expected to be obtained in forward direction.

Next to scattering due to the particles inside the sample, it is expected that the light will also be scattered due to the colour white of the Delrin part. This scattered light may disturb or complicate detection of the signal when conducting measurements. The distinction between the light scattered by particles and by the Delrin part is not yet possible, so it cannot detected what signal has what cause. This should be taken into account when analysing the results. Also, the multimode fibres used are very sensitive to movement. So when the fibre vibrates even a bit, the signal will be influenced. The movement of the fibres should also be taken into account when analysing the results.

7.1 Methodology

Standardized semi-skimmed milk was purchased from a supermarket. This milk is pasteurized and homogenized, providing a consistent sample for testing. The fresh raw milk was obtained directly from a local farm ‘Boer Snuverink’ in Hengelo[53].

Firstly, the semi-skimmed milk was tested. The milk was pumped through the whole system and then measured by the sensor to record the flowrate and composition (fat content) data. This was done step by step, since only one individual fibre could be detected. Figure 19 gives a schematic overview of the input (LASER) and outputs. For each measurement, the data was saved at two different moments in time. For the flowrate measurements, four different measurements with different generated vacuum settings were conducted, but only the MAINTAIN program of the Medela Symphony pump was used[47].

Here, only one fibre straight across the laser fibre was detecting the light. For the composition measurements, only one vacuum setting was generated by the pump (MAINTAIN program 6) and the scattered light was detected at 0, 45, 90, and 135 degrees. Before repeating this exact same process with fresh bovine milk, the whole system was cleaned by flushing it with cleaner (Miris cleaner) and then with demi water[54]. This cleaner is meant to clean the tube of a Miris Human Milk Analyser[55].

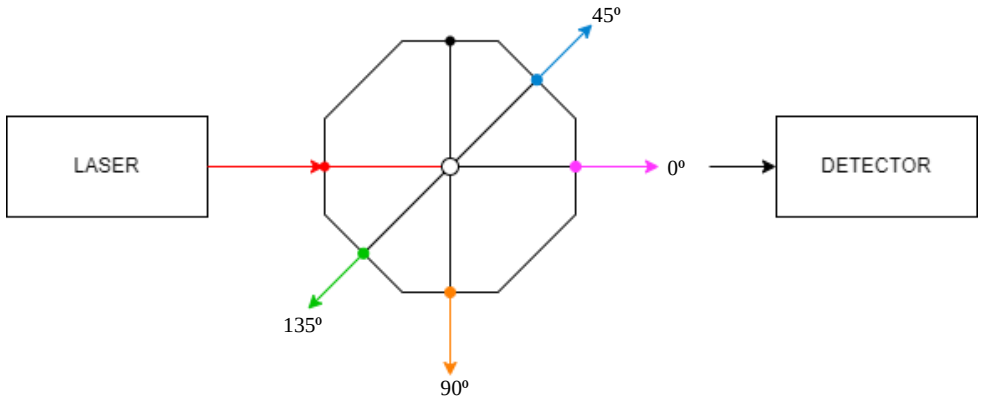


Figure 19: Overview of in- and outputs of the sensor, where one fibre is attached to the laser and one fibre is attached to the detector. To measure the scattered light at multiple angles, the fibres could be easily attached and detached to the detector. Colour labelling the fibres allows identification of which fibre measures which angle.

The approach of measurements conducted can be seen in Table 11. For the flowrate measurements the oscilloscope was set in AC coupling since the change in signal is relevant for LDF. For the composition measurements it was set in DC mode since the average signal is relevant.

Table 11: Measurements of the flowrate and composition of bovine milk.

Measurement	Setting	Detection angle
Flowrate measurement for semi-skimmed milk		
1	Setting 1 (lowest vacuum)	0 degrees
2	Setting 6	0 degrees
3	Setting 10	0 degrees
4	Setting 16 (highest vacuum)	0 degrees
Composition measurements for semi-skimmed milk		
1	Setting 6	0 degrees
2	Setting 6	45 degrees
3	Setting 6	90 degrees
4	Setting 6	135 degrees
Flowrate measurements for fresh milk		
1	Setting 1 (lowest vacuum)	0 degrees
2	Setting 6	0 degrees
3	Setting 10	0 degrees
4	Setting 16 (highest vacuum)	0 degrees
Composition measurements for fresh milk		
1	Setting 6	0 degrees
2	Setting 6	45 degrees
3	Setting 6	90 degrees
4	Setting 6	135 degrees

Next to these measurements, the milk was collected in the collection bottle which was standing on a scale. The data of the scale was used for verification of the sensor data of the flowrate measurements.

7.1.1 Setup

For the setup, the bovine milk is pumped from the reservoir to the funnel. Then the milk flows through the sensor where laser light is generated by a laser (OBIS 633 nm LX SF 50 mW, Coherent Europe BV). The photodetector (DET10A2 Si-detector, 200-1100 nm, Thorlabs) detects the scattered light signal and converts it into an electrical signal. This electrical signal is graphically displayed on the oscilloscope (DPO3014 Digital Phosphor Oscilloscope, Tektronix) and then saved on a flash drive for later analysation. The milk will then be collected in the bottle that stands on the scale (Ranger 3000 Ohaus)[56]. The scale data will be recorded by the laptop using MatLab. A schematic overview of the setup can be seen in Figure 20.

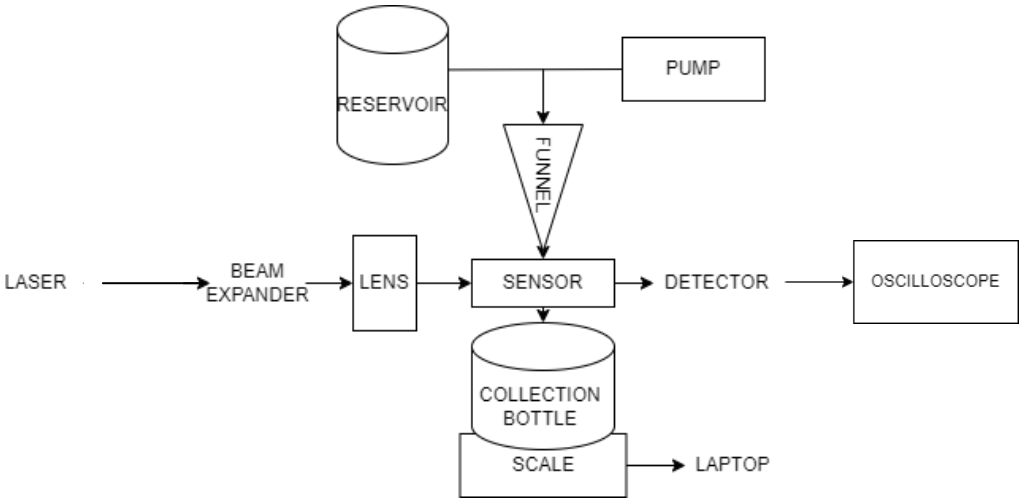


Figure 20: Schematic overview of the setup.

7.2 Results

Figure 21 shows the flowrate measurements of semi-skimmed milk. When comparing the measurement flow and no flow in Figure 21a, a difference in signal can be observed. This means there is indeed a Doppler shift and that the sensor is able to measure it. Different settings of the pump generate different flowrates (Figure 21b, Table 12), however this difference cannot be observed in the measurements using LDF (Figure 21a). That means that the Doppler measurements are barely present.

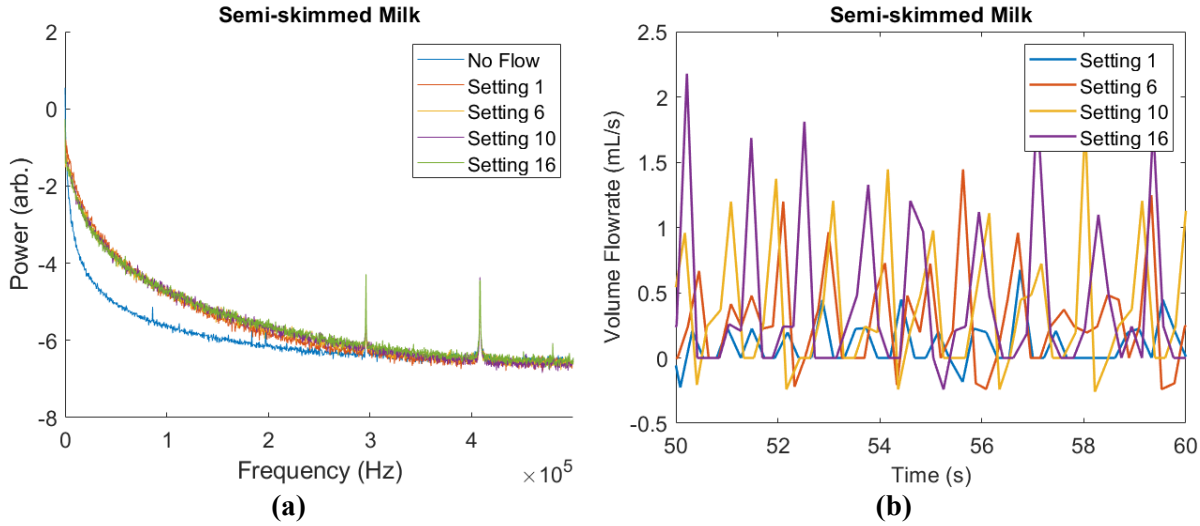


Figure 21: Flowrate measurements of semi-skimmed milk. (a)Results of LDF measurements in the frequency domain. (b)Results of the scale measurements.

The flowrates obtained from the scale data were individually plotted and an average value for every setting was calculated. These average flowrates can be seen in Table 12.

Table 12: Average values of the flowrates obtained from the scale data.

	Average flowrate (mL/s)
Setting 1	0,01
Setting 6	0,30
Setting 10	0,37
Setting 16	0,41

Figure 22 shows the results of the flowrate measurements of fresh milk. Here, the no flow measurement was not conducted. Here, the no flow measurement was not conducted. Again, different settings of the pump generate different flowrates (Figure 22b, Table 13), however this difference cannot be observed in the measurements using LDF (Figure 22a), so Doppler measurements are barely present.

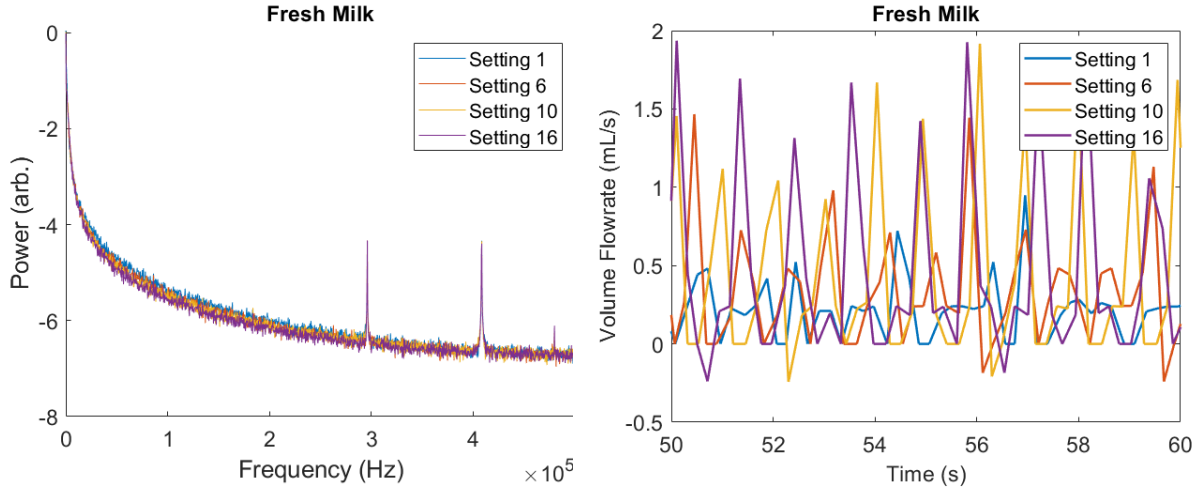


Figure 22: Flowrate measurements of fresh milk. (a) Results of LDF measurements in the frequency domain. (b)Results of the scale measurements.

The flowrates obtained from the scale data were individually plotted and an average value for every setting was calculated. These average flowrates can be seen in Table 13.

Table 13:Average values of the flowrates obtained from the scale data.

	Average flowrate (mL/s)
Setting 1	0,13
Setting 6	0,33
Setting 10	0,42
Setting 16	0,46

When comparing the LDF measurements of semi-skimmed milk with fresh milk (Figure 23), it can be seen that the signal for semi-skimmed milk is higher. This was done for every different setting of the pump generating a different flowrate and the same results can be observed.

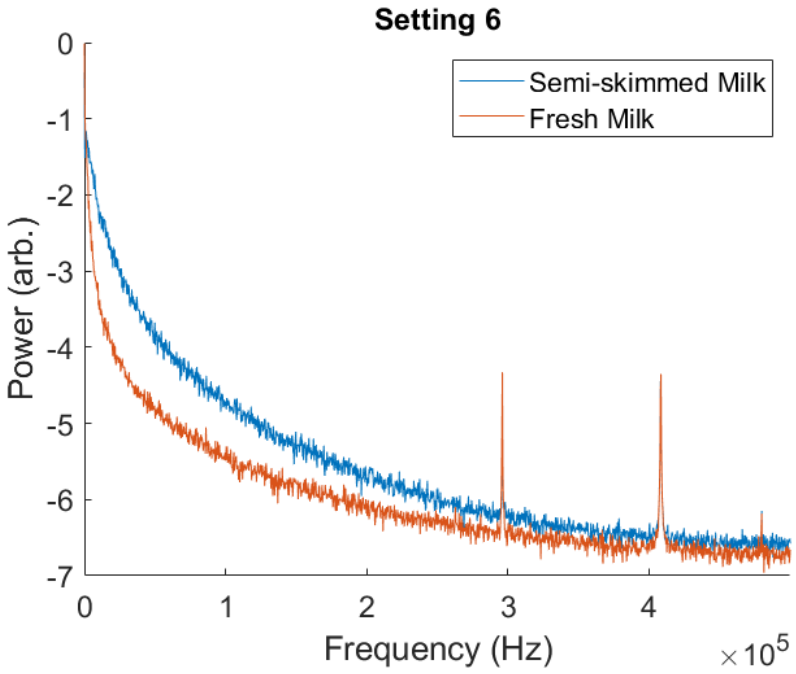


Figure 23: Comparison between flowrate measurements of semi-skimmed milk and fresh milk in Setting 6.

In Figure 24, the composition measurements of semi-skimmed milk can be seen. When measuring at 0 degrees, there is a high signal. This signal decreases when increasing the angle of detection.

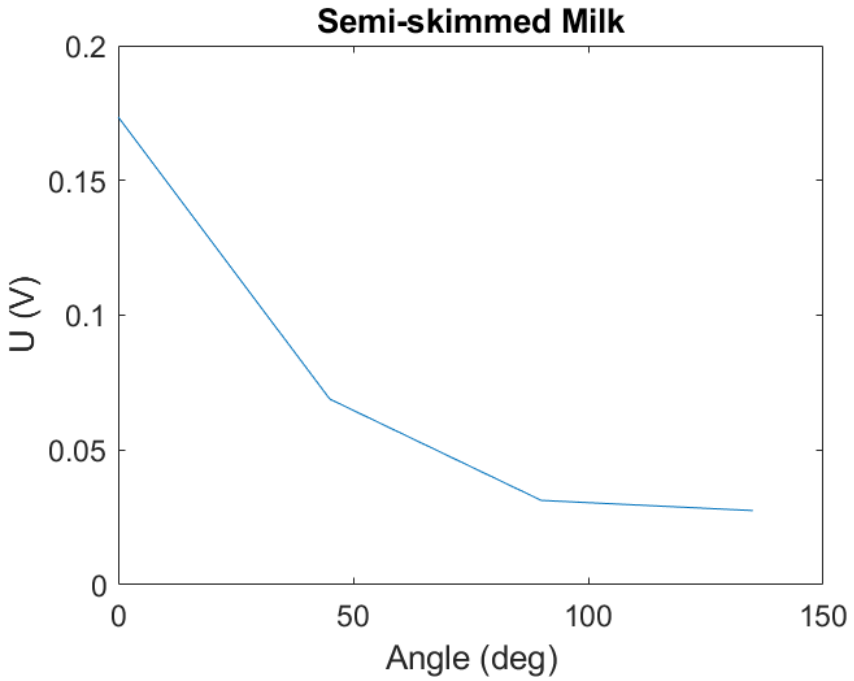


Figure 24: Composition measurements of semi-skimmed milk.

In Figure 25, the composition measurement of fresh milk can be seen. There is a high peak at the detection at 45 degrees, which is different from the expectation. The expectation was obtaining the highest intensity of the signal at 0 degrees. In comparison to semi-skimmed milk, the expectation was obtaining a higher intensity of the signal .

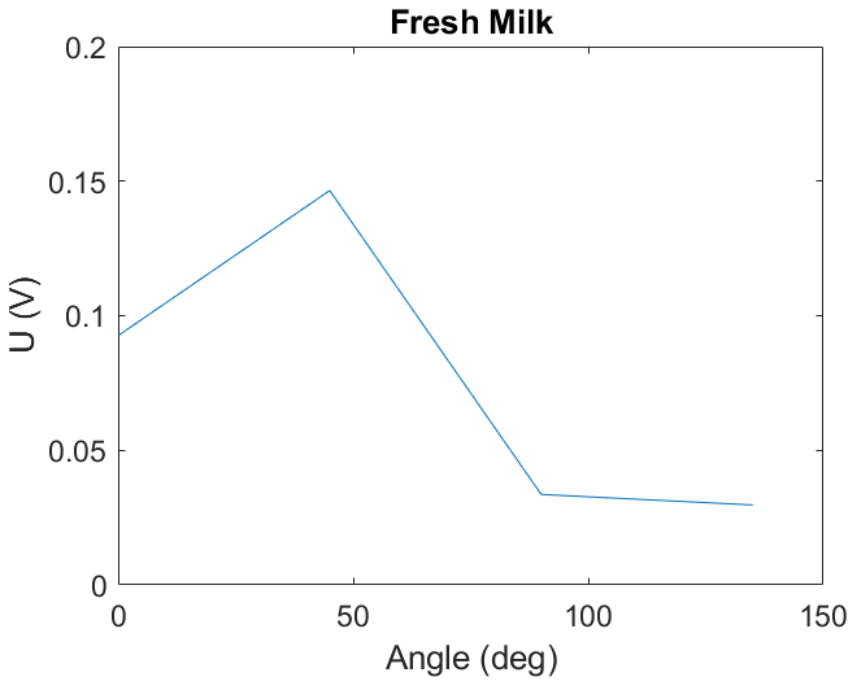


Figure 25: Composition measurements of fresh milk.

When looking at the results of the flowrate measurements using LDF, the Doppler measurements between the different settings are hard to observe. Therefore, some alterations to the design are necessary and the technique must be improved. However, it can be said that there is a Doppler shift since a difference can be observed for flow and no flow measurements. For the composition measurements, the signal was the highest in forward direction for semi-skimmed milk as expected. However, for fresh milk, the signal was the highest at 45 degrees which was not as expected. The exact reason for this is unknown and could be investigated in further research. In conclusion, the prototype is not yet able to quantify the flowrate, but the prototype is able to detect a signal and the two different samples can be distinguished. As for the composition, the prototype is able to measure different signals under different angles regarding the sample, but quantification of the fat concentration is not possible.

8. Conclusion

The research question of this bachelor thesis was:

What does an optimal design of a prototype look like that is able to measure the flowrate and composition of human breast milk in lab setting?

Here, the definition of 'optimal' will be specified in the list of requirements (3.4 List of Requirements). The hypothesis was that the prototype measurements would not give quantitative results of the volume and composition measurements. However, the obtained light scattering signals for different situations would be compared and a difference in signal was expected, which could be used for further research. For the flowrate measurements it was expected that semi-skimmed milk would give a higher signal compared to fresh milk since it has a lower viscosity (Equation 1). For the composition measurements it was expected that the intensity of the signal in forward direction would be the highest and would decrease when the angle increased for semi-skimmed milk. For fresh milk, the fat concentration is higher and particle size is bigger, so the scattering would be more anisotropic and the intensity of the signal would be more distributed over the multiple angles but still the highest in forward direction.

As the specifications of a prototype that measures the flowrate and composition of human breast milk in lab setting are stated in the requirement specification, it can be concluded what an optimal design looks like. However, the realization of this design did not meet all the requirements, therefore improvements of the prototype are necessary. Testing the prototype with both supermarket and fresh bovine milk has provided valuable insights into the performance of the prototype.

For the flowrate measurements, flow and no flow could be distinguished using LDF. This means Doppler shifts could be measured. However, when a flow was generated, the different signals for different flowrates were hard to observe.

For the composition measurement, there was a signal obtained in every angle. The signal for semi-skimmed milk was as expected, however for fresh milk the signal was the highest at 45 degrees which was not expected. Improvement and development of the prototype and techniques is necessary for obtaining better results. Detailed recommendations for improvements and further development of the prototype will be provided in Chapter 9.

9. Recommendations

Based on finding detailed in this thesis, several recommendations have been identified for further development of a sensor for measuring the volume and composition of human breast milk. These recommendations are aimed at addressing the identified issues of current design, improving user experience and assuring compliance with regulations.

9.1 Design Optimalization

For further development of the design, it is desirable to be able to observe the milk volume inside the funnel part. This way the vacuum setting of the pump could be adjusted according to the preferred milk flowrate.

Furthermore, the chosen colour of the Delrin part was white since white gives the design a 'clean' look. However, this colour causes the laser light to scatter. This scattered light by the Delrin part could disturb or complicate detection of the signal when conducting measurements. Changing the colour into black would minimize the scattered light by the Delrin part for possibly obtaining a better signal. Since requirement 2.1.10 states 'the prototype shall have a neutral and simple design', it would also be a possibility to paint the inside of the Delrin part using black coloured ink (Indian ink or ecoline).

For obtaining a better signal during flowrate measurements, the influence of implementing a photodiode at some distance from the sample at 0 degrees could be investigated. This would generate a speckle pattern with bigger speckles, which would possibly improve the Doppler signal. Here, the influence of placing the photodiode at a distance on MALS measurements should be considered, since this is possibly not preferred for this technique. In addition, changing the multimode fibres into single mode fibres could also possibly generate a better signal. Single mode fibres are less sensitive to movement, however they detect less light compared to multimode fibres. By using a lens, this problem could be solved. Since single mode fibres are thinner than multimode fibres, the same Delrin part could be used for further research, but some sort of filling should be added to be certain the fibres cannot move for minimizing movement artifacts.

In addition, the number of photodiodes used in this prototype is in current situation sufficient. However, in future prototypes, when the techniques are more developed, more photodiodes are preferred (NFR 2.1.5). The specific angles will follow from (ongoing) research. This could include a photodiode at 180 degrees, which means a fibre has to be split into two, one part as input (laser) and one part as output (detector). The feasibility for this purpose should be investigated.

For conducting volunteer measurements (prototype 2, 3, 4), it is desired to have an overview of all the cables used for the setup. The cables could also be colour labelled and taped just as the fibres. When a problem occurs, the cables could be easily checked using this overview. This would improve the measuring procedure.

For maintaining hygiene, the prototype was cleaned with demi water and cleaner. An optional possibility for optimizing the cleaning process could be sterilizing all parts that were in contact with the milk. This could be done using an autoclave, a microwave sterilizer or boil the parts in a pan of water. By adding a dash of vinegar to the water when boiling them in a pan, limescale on the parts are prevented to make the parts last longer[57]. Sterilizing the parts should only be done after first cleaning them with water and cleaner. This prevents the proteins to solidify and simplifies cleaning the parts.

As sterilizing happens at 100 degrees, materials should be heat resistant. The material of the funnel part, PLA, does not meet the requirement (NFR 2.5.2 and NFR 2.5.5): 'shall resist temperatures between 0-

100 degrees'. This means, sterilization of this prototype is not possible, so for further development, during material choices, the thermal resistance of the materials should be considered.

For further development of prototypes 2, 3, and 4, the implementation of some requirements (FR 1.12, NFR 2.1.17, NFR 2.2.6, NFR 2.2.8, NFR 2.3.2, NFR 2.5.7, NFR 2.6.1) could be realised.

9.2 User-Centred Design

The end-users of the prototype developed during this project were researcher. For future development of the design, breastfeeding mothers, healthcare professionals and infants will be the end-users as well. Including their preferences and needs will provide valuable insights and will improve satisfaction of the users. Common engagement methods for this are surveys and questionnaires, interviews, focus groups, observational studies, usability testing and co-design.

By conducting one-on-one interviews with lactation consultants and breastfeeding mothers, challenges of breastfeeding, preferences for a breast pump design, and feedback on existing products could be discussed and understood. Preparing open-ended questions about these topics will allow participants to provide additional information including emotions and feelings[58]. Approval from the ethics committee is necessary, as well as consent from the participants being interviewed. Consent forms explain the purpose of the interview, how the data will be used throughout the research, and the way in which privacy and confidentiality of the information is guaranteed.

Collecting all data and looking at the findings from the interviews, will lead to the idea generation phase. When different concepts are developed, these can be suggested to the mothers or lactation consultants to get their feedback and preferences. Iterations to the design can be made and the product can be developed.

9.3 Regulatory Compliance for Medical Devices

As stated in the regulatory compliance for medical devices (Chapter 3.5), the WMO and MDR will be important for further development of the prototype. They both aim to ensure safety and protection, but are used in different development stages[41, 42]. When looking at the possibilities of the technology and doing volunteer measurements, the regulations are applicable to the WMO. When a medical device is realised, the regulations are applicable to the MDR.

The first step is to write a regulatory strategy. This involves outlining the different steps and considerations that are needed for ensuring that the prototype complies with relevant regulations and standards. This should function as a guidance during the development process to ensure regulatory compliance and successful market entry. It starts by identifying the intended use and indications for use, so who are the end-users, what is the device used for, and what are the conditions or reasons for using the device? Based on the intended use, possible claims regarding the performance of the device are stated. Qualification is necessary for determining if the definition of the product satisfies the definition of a medical device stated in the MDR or (EU)2017/745[42]. Classification of the device is needed for knowing the risk class. For this, there are templates and guidance documents available[59]. The next step is identifying harmonised and non-harmonised standards that apply to this device. Harmonised standards are European standards developed through one of the three European Standards Organisations: the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (CENELEC), and the European Telecommunications Standards Institute (ETSI)[60]. They are created following a request from the European Commission to one of these organisations and can be used to demonstrate that products comply with relevant EU legislation[61]. Non-harmonised standards may come under the national rules and could also be used to indicate a device is State of the Art. All

standards can be found online, on the website of ISO (International Organisation for Standardisation) or IEC (International Electrotechnical Commission) and can be downloaded via NEN-connect[62-64]. When standards are harmonised, an EN version of the standards was made by CENELEC[65]. There, a ZA annex can be found which describes for which General Safety and Performance Requirements (GSPRs) a standard 'presumption of conformity' is given. An outdated ISO standard (16142, -1, -2) gives an overview of standards applicable to medical devices. Important standards for this device are the electrical safety (60601-x), biocompatibility (10993-x), and LASER standards. When placing a device on the market, identification of the 13485 standards is needed. This is important for the Quality Management System (QMS) of a manufacturer. All the related standards can be filled in in the GSPR checklist using templates[66].

Writing a risk management should be done to outline the potential risks associated with the design and development of the prototype. These risks should be evaluated based on their likelihood of occurrence and impact on the project. Strategies to avoid or minimize these risk should be proposed. For writing a risk management, a template can be used as well[67].

For the process with regard to setting up or involving a company to place a medical device on the market, a medical device QMS needs to be certified by a Notified Body. The QMS is a structed system of procedures and processes including aspects about quality and objectives of the medical device. The complexity of the QMS varies based on the classification of the device[68]. A Notified Body is an organization, designated by an EU country, that assesses the conformity of medical products before they are put on the market[69].

In a Clinical Evaluation Plan, current clinical practices will be investigated by doing research and the change the medical device will bring is described (Annex XIV part A point 1)[42]. To prove the improvement of performance and patient benefit due to the medical device, measurements should be conducted to compare the results with those of current practices. The same applies for the risks of the medical device. Here, it is important to think about methods to test and compare those results and risks and which clinical studies will be necessary for proving safety and effectiveness of the medical device[70, 71].

Steps to affix a CE marking to the medical device, should be taken by manufacturers. They have to ensure that products places on the market of the European Economic Area (EEA) are safe. It is their responsibility to check whether their products meet EU safety, health and environmental protection requirements[72].

The recommendations outlined above address the identified limitations of current design during prototype development and prototype testing. By focusing on the design optimalization, user-centred design and regulatory compliance for medical devices, research could be continued and the aim of developing a working sensor embedded into a nipple shield that measures the volume and composition of human breast milk could be realised.

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11. Appendix

11.1 Appendix A

The sketches made during the brainstorm session can be seen in Figure 26.

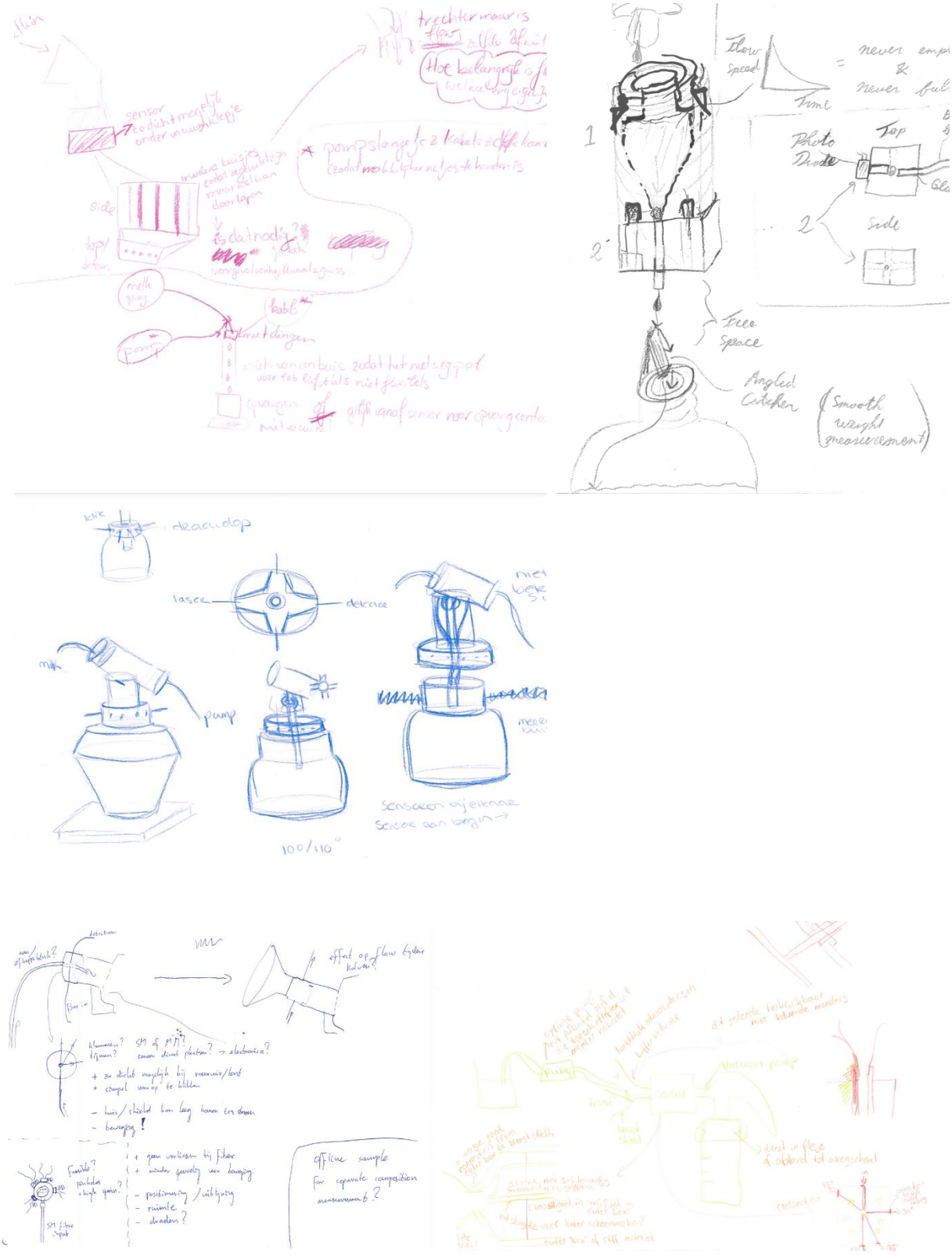

Figure 26: Sketches made during the brainstorm session.

11.2 Appendix B

ParameterScan_TubeFlow.m

```
R = [0.5e-3];                                          %Tube radius [m]
L = linspace(0.8,1,10);                                %Tube length [m]
dP = linspace(7e3,33e3,1e2);                           %Pressure drop [Pa]
dynVisc = 8.9e-4;                                      %Water dynamic viscosity [Pa
s]
volumeFlow = zeros(length(L),length(dP),length(R)); %Volume flow rate [m^3 s^-1]
for n = 1:length(R)
    volumeFlow(:,:,n) = (pi*R(n).^4.*dP)./(8*dynVisc.*L');
    figure;
    imagesc(dP,L,volumeFlow(:,:,n).*1e6)
    fontsize(gcf,12,'points')
    xlabel('Pressure drop [Pa]')
    ylabel('Tube length [m]')
    title(['Tube radius = ' num2str(R(n)*1e3) ' mm'])
    c = colorbar;
    c.Label.String = 'Volume Flowrate [mL/s]';
end
```

flowanalyse_weegschaal.m

```
clf, clear

legendLabels = [{'Setting 1'},{'Setting 6'},{'Setting 10'},{'Setting 16'}];

load(['halfvollemelk_maintain_stand1.mat']);
m_1 = m;
clear('m');
t_1 = t;
clear('t');

load(['halfvollemelk_maintain_stand6.mat']);
m_2 = m;
clear('m');
t_2 = t;
clear('t');

load(['halfvollemelk_maintain_stand10.mat']);
m_3 = m;
clear('m');
t_3 = t;
clear('t');

load(['halfvollemelk_maintain_stand16.mat']);
m_4 = m;
clear('m');
t_4 = t;
clear('t');

figure(1);
plot(t_1,m_1,'LineWidth',1.5);
title('Semi-skimmed Milk')
xlabel('Time (s)')
ylabel('Mass (g)')
fontsize(gcf,14,'points')

hold on
```

```
plot(t_2,m_2,'LineWidth',1.5);
plot(t_3,m_3,'LineWidth',1.5);
plot(t_4,m_4,'LineWidth',1.5);
legend(legendLabels)


[massFlowArray,avgMassFlow] = OhausMassFlow(m_1,t_1);
massFlowArray_1 = massFlowArray;
clear('massFlowArray');
smooth_massFlowArray_1 = smoothdata (massFlowArray_1);

[massFlowArray,avgMassFlow] = OhausMassFlow(m_2,t_2);
massFlowArray_2 = massFlowArray;
clear('massFlowArray');
smooth_massFlowArray_2 = smoothdata (massFlowArray_2);

[massFlowArray,avgMassFlow] = OhausMassFlow(m_3,t_3);
massFlowArray_3 = massFlowArray;
clear('massFlowArray');
smooth_massFlowArray_3 = smoothdata (massFlowArray_3);

[massFlowArray,avgMassFlow] = OhausMassFlow(m_4,t_4);
massFlowArray_4 = massFlowArray;
clear('massFlowArray');
smooth_massFlowArray_4 = smoothdata (massFlowArray_4);

figure(2);
plot(t_1,smooth_massFlowArray_1,'LineWidth',1.5);
title('massFlowRate')
xlabel('Time (s)')
ylabel('Mass Flowrate (g/s)')
fontsize(gcf,14,'points')

hold on

plot(t_2,smooth_massFlowArray_2,'LineWidth',1.5);
plot(t_3,smooth_massFlowArray_3,'LineWidth',1.5);
plot(t_4,smooth_massFlowArray_4,'LineWidth',1.5);
xlim([50 60])
legend(legendLabels)

sampleDensity = 1.028;%[g/mL]
volumeFlowRate_1 = massFlowArray_1./sampleDensity;%[mL/s]
volumeFlowRate_2 = massFlowArray_2./sampleDensity;%[mL/s]
volumeFlowRate_3 = massFlowArray_3./sampleDensity;%[mL/s]
volumeFlowRate_4 = massFlowArray_4./sampleDensity;%[mL/s]

%tubeRadius = 0.5;%[mm]
%meanFlowVelocity = (1e-6.*volumeFlowRate./60)./(pi.*(tubeRadius.*1e-
3).^2);%[m/s]

smooth_volumeFlowRate_1 = smoothdata (volumeFlowRate_1);
smooth_volumeFlowRate_2 = smoothdata (volumeFlowRate_2);
smooth_volumeFlowRate_3 = smoothdata (volumeFlowRate_3);
smooth_volumeFlowRate_4 = smoothdata (volumeFlowRate_4);

figure (3)
plot(t_1,volumeFlowRate_1,'m--','LineWidth',1.5)
```

```
title('Semi-skimmed Milk')
xlabel('Time (s)')
ylabel('Volume Flowrate (mL/s)')
fontsize(gcf,14,'points')

hold on

plot(t_2,volumeFlowRate_2,'b--','LineWidth',1.5)
plot(t_3,volumeFlowRate_3,'r','LineWidth',1.5)
plot(t_4,volumeFlowRate_4,'k','LineWidth',1.5)
legend(legendLabels)
xlim([50 60])
```

LDF_process_prototype.m

```
dataFolder = '\\Ad.utwente.nl\TNW\BMPI\Data\Vera Lammens\Data\Metingen\';
fileNumbers = [{'0003'} {'0020'}];
timeFig = figure;
specFig = figure;
numAverages = 32;
downSamplingStep = 1;
legendLabels = [{'Semi-skimmed Milk'},{'Fresh Milk'}];
for n = 1:length(fileNumbers)
    dataMatrix = readmatrix([dataFolder 'tek' fileNumbers{n}
'.csv'],'NumHeaderLines',21);
    dataMatrix = dataMatrix(1:downSamplingStep:end,:);
    dataMatrix = dataMatrix(1:length(dataMatrix) -
mod(length(dataMatrix),numAverages),:);
    powerSpectrum = zeros(length(dataMatrix)/numAverages,numAverages);
    for m = 1:numAverages
        signalSegment = dataMatrix((m-1)*length(dataMatrix)/numAverages +
1:m*length(dataMatrix)/numAverages,:);
        timeAxis = signalSegment(:,1);
        voltages = signalSegment(:,2);
        numPoints = length(timeAxis);

        sampleFreq = 1/(timeAxis(2) - timeAxis(1));
        freqAxis = linspace(0,sampleFreq,numPoints);
        powerSpectrum(:,m) = abs(fft(voltages)).^2;
    end

    figure(timeFig);hold on
    plot(timeAxis,voltages+(n-1)*2e-3)
    fontsize(gcf,14,'points')
    %title('Fresh Milk')
    figure(specFig);hold on
    plot(freqAxis,log10(mean(powerSpectrum,2)))
    fontsize(gcf,14,'points')
    title('Setting 1')
    sum(mean(powerSpectrum,2).*freqAxis')
```

LDF_process_prototype_samenstelling.m

```
dataFolder = '\\Ad.utwente.nl\TNW\BMPI\Data\David Thompson\Data\Milk Flow
Quantification\Prototype\';
fileNumbers = [{'0010'},{'0012'},{'0014'},{'0016'}];
timeFig = figure;
specFig = figure;
numAverages = 1;
downSamplingStep = 1;
legendLabels = [{'label1'},{'label2'},{'label3'},{'label4'}];
```

```
for n = 1:length(fileNumbers)
    dataMatrix = readmatrix([dataFolder 'tek' fileNumbers{n}
'.csv'],'NumHeaderLines',21);
    dataMatrix = dataMatrix(1:downSamplingStep:end,:);
    dataMatrix = dataMatrix(1:length(dataMatrix) -
mod(length(dataMatrix),numAverages),:);
    powerSpectrum = zeros(length(dataMatrix)/numAverages,numAverages);
    for m = 1:numAverages
        signalSegment = dataMatrix((m-1)*length(dataMatrix)/numAverages +
1:m*length(dataMatrix)/numAverages,:);
        timeAxis = signalSegment(:,1);
        voltages = signalSegment(:,2);
        numPoints = length(timeAxis);

        sampleFreq = 1/(timeAxis(2) - timeAxis(1));
        freqAxis = linspace(0,sampleFreq,numPoints);
        powerSpectrum(:,m) = abs(fft(voltages)).^2;
    end
    signalAmplitude(n) = mean(voltages);
    figure(timeFig);hold on
    plot(timeAxis,voltages)
    figure(specFig);hold on
    plot(freqAxis,log10(mean(powerSpectrum,2)))
    sum(mean(powerSpectrum,2).*freqAxis')
    xlim([0,sampleFreq/2])
end
legend(legendLabels)
xlabel('Frequency (Hz)')
ylabel('Power (arb.)')
figure(timeFig)
legend(legendLabels)
xlabel('time (s)')
ylabel('U (V)')
figure()
plot([0 45 90 135],signalAmplitude);
fontsize(gcf,14,'points')
title('Fresh Milk')
xlabel('Angle (deg)')
ylabel('U (V)')
ylim([0 0.2])
```

11.3 Appendix C

The specifications of the design, drawings and technical data can be seen in Figures 27-32.

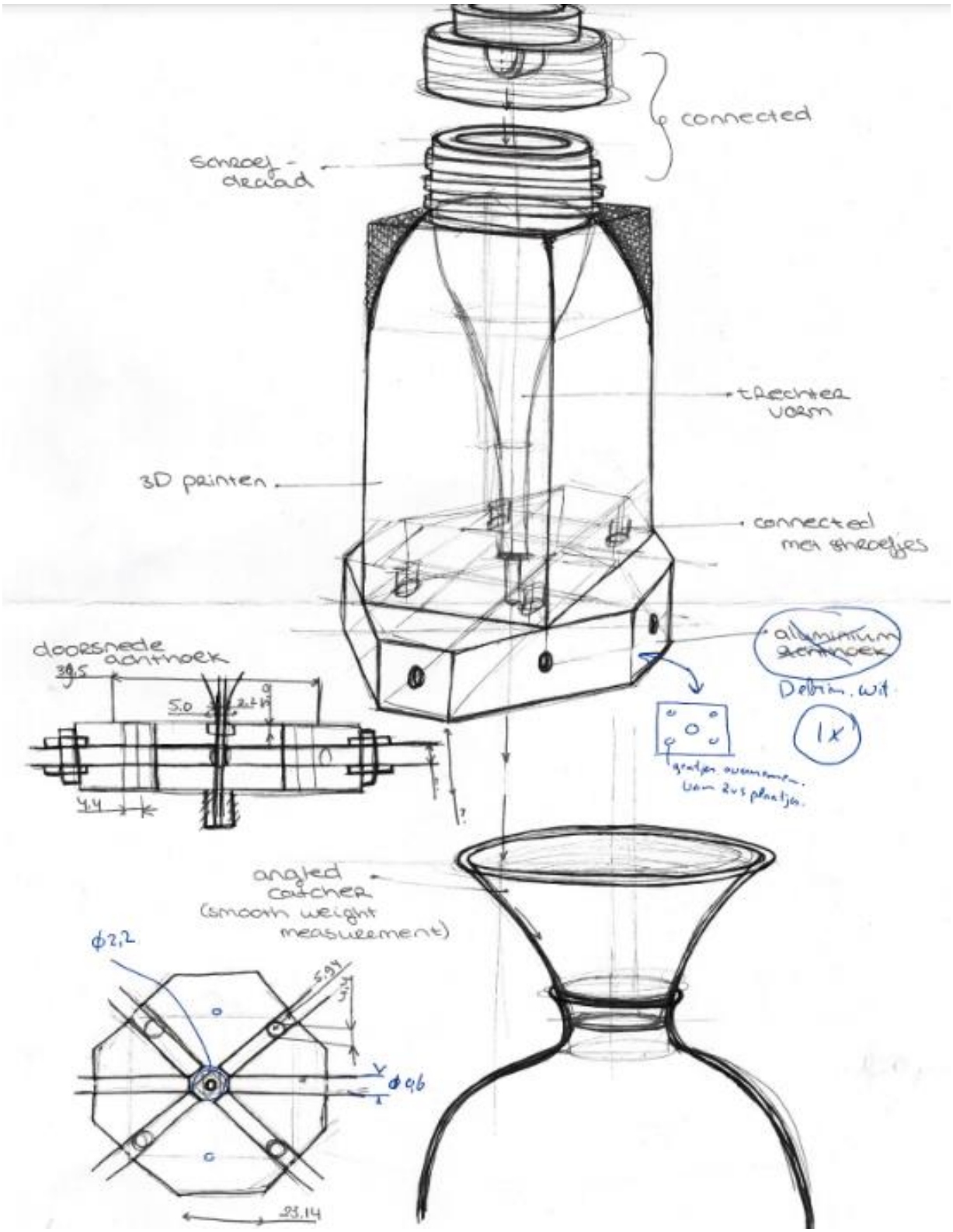

Figure 27: Drawing of the developed concept.

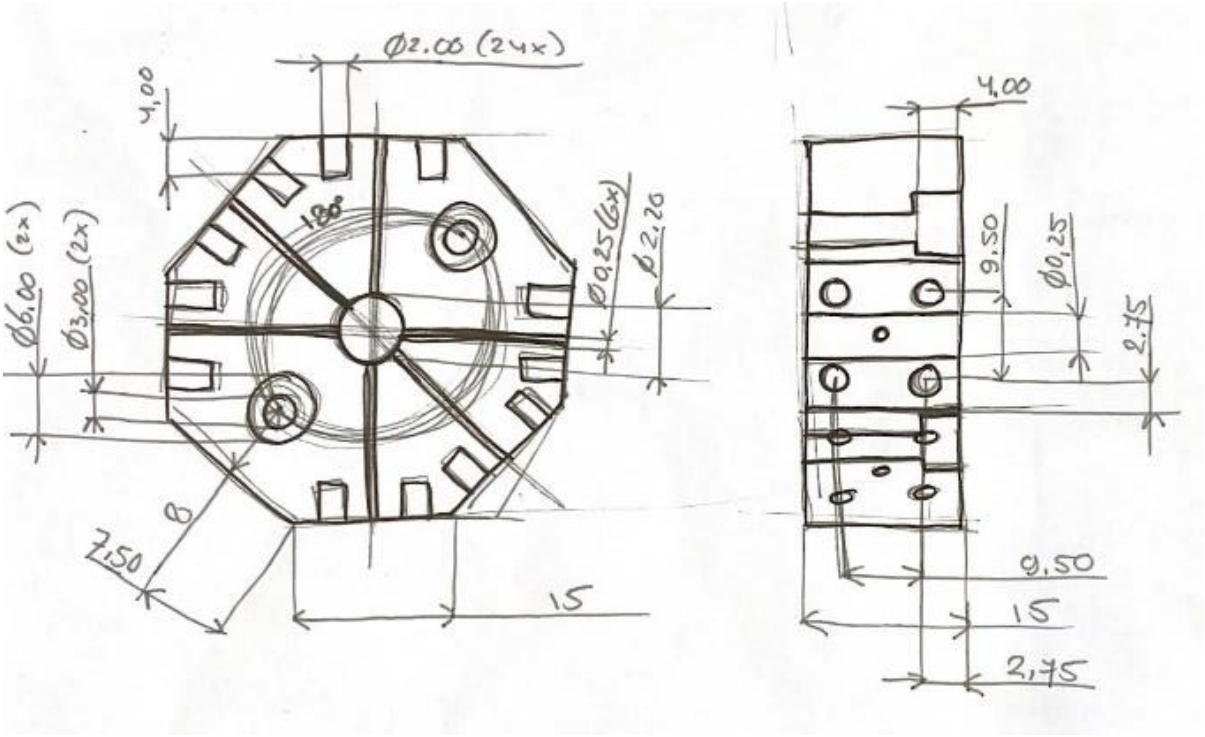

Figure 28: Drawing of the octagonal part.

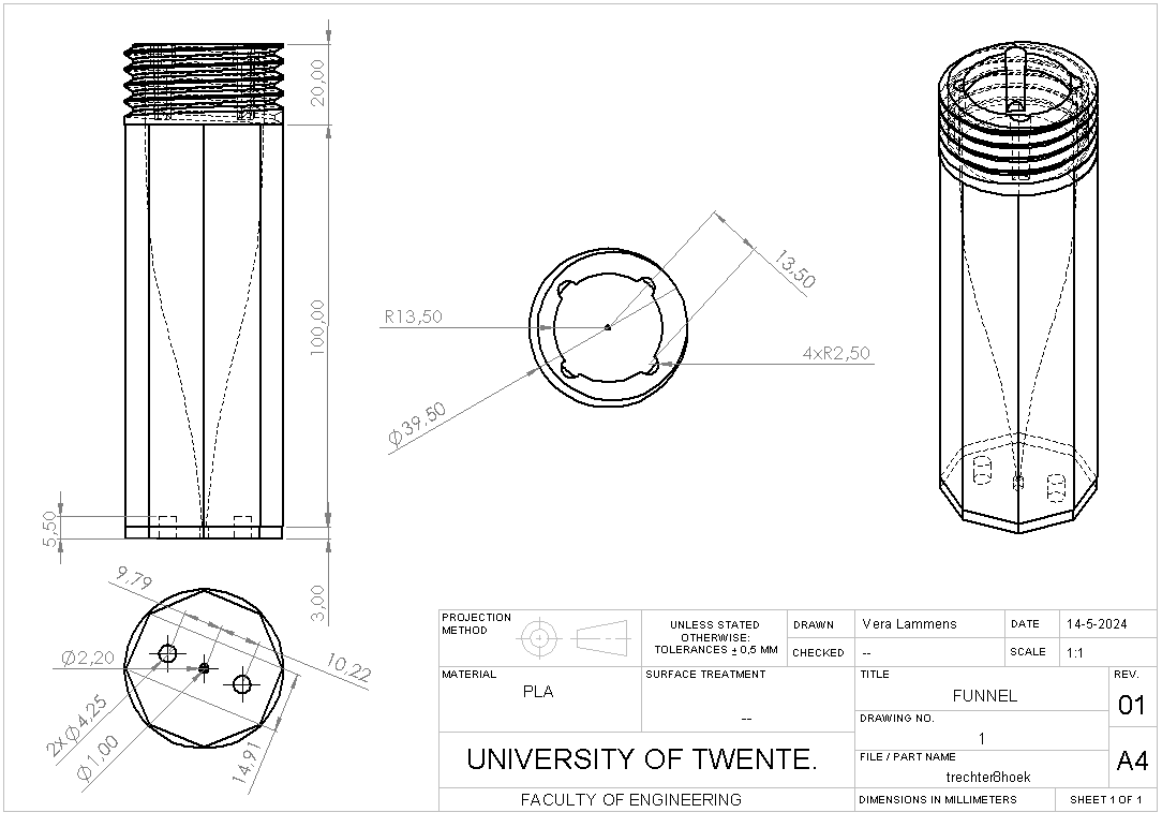

Figure 29: Solidworks drawing of the funnel part.

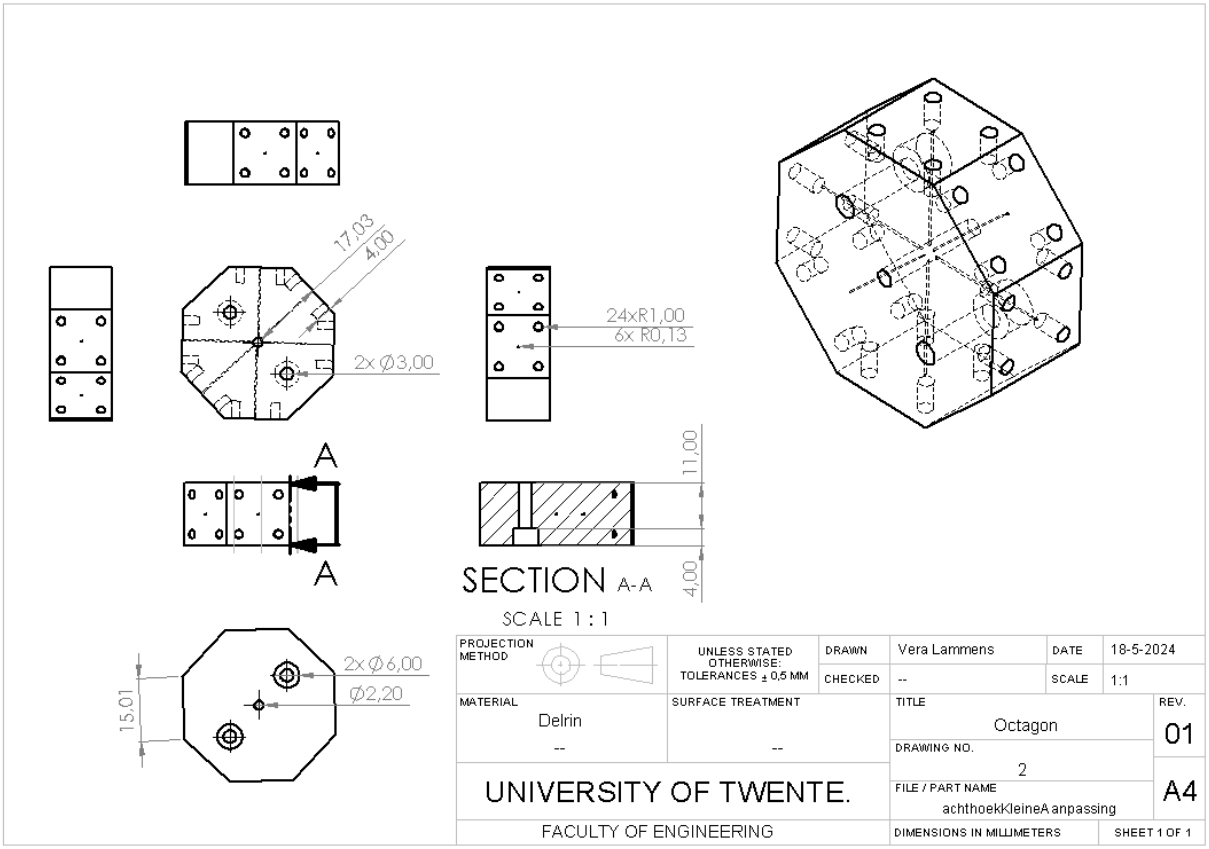

Figure 30: Solidworks drawing of the octagonal part.

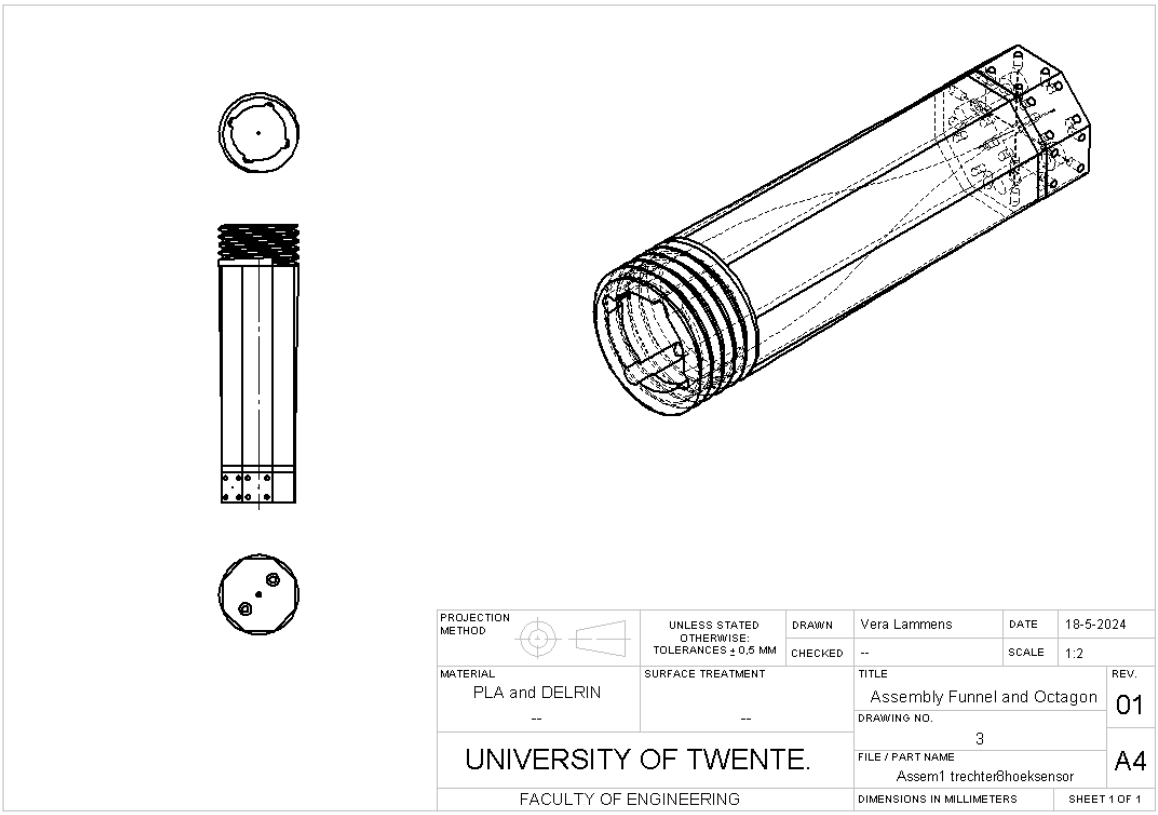

Figure 31: Solidworks drawing of the assembly.

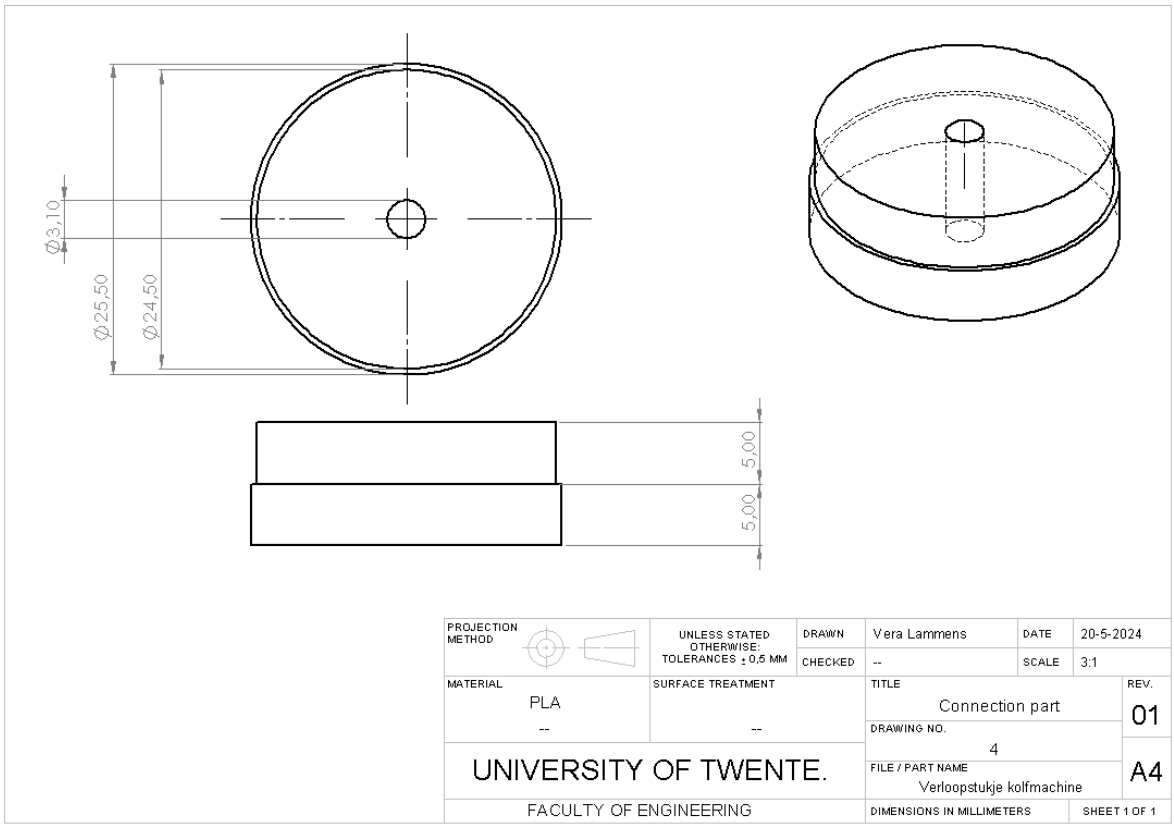

Figure 32: Solidworks drawing of the connecting part for the input tube.