TAILORED NON-INVASIVE VENTILATION MASKS FOR PAEDIATRIC INTENSIVE CARE

MASTER THESIS
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TAILORED NIV MASKS FOR PAEDIATRIC INTENSIVE CARE

MAY 2020

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Preface

This thesis is the final result of half a year of hard work. This project has been a great learning experience; many challenges were faced. I find the intensive care very interesting, and enjoyed being in the tumultuous environment. I am glad contributing to the improvement of care, and hope that the two proposed masks, will be further clinical tested and eventually will be implemented in Paediatric Intensive Care Units. I would like to express my gratitude to all the people that helped me achieve this result.

Marijke Melles, first of all for helping me find this project. Although embodiment projects are normally not your cup and tea, never the less you wanted to be my chair. You have been very enthusiastic and positive about my work to motivate me. But you also provided critical comments to improve my work, often originating from your DFI background, and were always ready to help me.

Lyè Goto, you were very enthusiastic about this project. Even though you told me you were already full with other graduates you could not say no to be my mentor. You have been excited about my work and were always prepared to help. As an expert in the ventilation mask topic, you have given me insights from your chronic home ventilation background. I also could use your database and tool for the development of these masks.

Coen Dijkman & MIO, you gave me the opportunity to work on this project. You were very easy going and flexible as my company mentor. I liked working at MIO, everyone was glad to help me, and I got plenty of opportunity to prototype. While being stuck in my own vision you gave me new ideas by having a broad perspective and put me in contact with others that could give me insights.

Reinout Bem, your enthusiasm and full commitment improving the intensive care inspired me. You found always time to help me and have been very enthusiastic about the masks. You participated in the Amsterdam Science & Innovation Award 2019 with NIV optimization in children, I hope you could use my content to win next year! I wish you all the best in the currently hectic period for the PICU with the COVID-19 virus.

Gerrit Muller, you initiated the need for better NIV masks, your passion to improve ventilation for children explodes out of you, and was very inspiring. When we met you immediately immersed me in the topic during the training day of practitioners. You were always willing to help me in between practice at the PICU. I wish you all the best in this hectic period, and I hope that a better NIV mask will be developed before you retire.

Others from Amsterdam UMC, all other intesivist staff that helped me, the Skills centre for letting me test with reanimation mannequins, Niels Liberton & Sjoerd te Slaa of the 3D Innovation Lab for helping me with 3D scanning, Nicole Stalpers for showing me production techniques at the Radiotherapy department, and Anne Knegt as participant.

Jan Peter Wille of 3D4Makers, you helped me validate the production of the masks. You were always very welcoming and prepared to think along with me in finding suitable production solutions.

My parents, for always supporting me. You were always interested in my projects, keeping me up to date with the latest news, and thinking along with me. Without your effort in my education, especially when I was younger, I would have never achieved a master's degree.

My girlfriend, brother, roommates, friends, and family, for always supporting me also non-graduation related. For this graduation in particular: Iris as a critical reader, Marije & Bas for giving advice, Bram for helping photograph, and Erica for helping me with my graduation approach.

Executive Summary

This project aims to develop tailored non-invasive ventilation (NIV) masks for children in the Paediatric Intensive Care Unit (PICU), to offer suitable masks and to improve the NIV intervention. In the PICU, there is a preference for NIV (see Figure 1) compared to invasive ventilation, because of complications, such as airway injuries. Their biggest challenge is finding a suitable non-vented NIV mask. They often do not fit well, resulting in too much air leakage and patient-ventilator asynchrony. This increases the breathing effort of the patient, and can lead to NIV failure. The air leakage is often too high, therefore the mask has to be repositioned and tightened to reduce the air leakage. This disturbs the patient and influences the patient's comfort.

The core problem of NIV is the excess of unintentional air leakage. Therefore the main focus lies on reducing air leakage by increasing the fit of the new developed NIV mask. The new masks need to fit patients up till the age of seven, because the available masks do often not fit well. There are no non-vented NIV masks available for patients below one year. An oronasal mask is developed, it is most effective and relatively non-intrusive compared to the other types of non-vented NIV mask. NIV at the PICU can be divided into acute NIV, for which an acute NIV mask will be developed, and extended NIV, for which an ideal NIV mask will be developed.

Four concept NIV masks are developed, of which two concepts are selected based on the results of the simulation and most important requirements. The NIV intervention is simulated by ventilating a reanimation mannequin with prototypes of the concepts to determine the effectiveness in terms of air leakage and contact pressure. The two selected concepts shows reduced air leakage compared to commercially available masks.

Figure 1. *NIV, positive pressure ventilation via a mask.*

The final design proposal consists of two masks: the Modular Mask, and the Quick Curable Mask (see Figure 2). The Quick Curable Mask is developed for patients who require acute NIV. The Modular Mask is developed for patients who need NIV for an extended time. Due to overcrowding at the PICU of Amsterdam UMC there was a shortage of NIV tubes and sensors, it was not responsible to test the masks. Therefore a protocol is written to test the air leakage and evaluate the wearing comfort of the two proposed masks with a test participant after the COVID-19 pandemic.

The final design proposal is suitable for NIV at the PICU. A roadmap describes how the two mask can be further developed by the hospital and implemented in the PICU. It consists of the following phases: the optimising phase, the clinical testing phase, the implementing phase, and the redesigning phase.

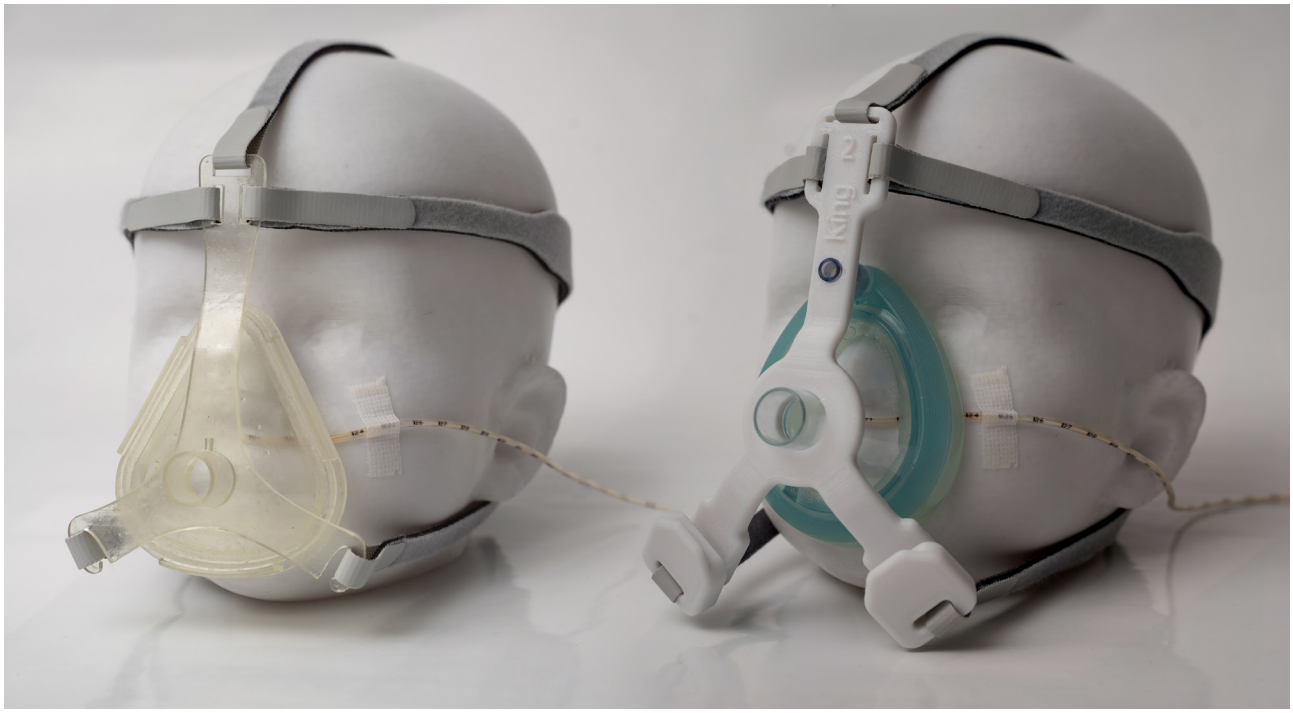

Figure 2. *The Modular Mask (on the left), and the Quick Curable Mask (on the right).*

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Introduction

Invasive ventilation for children involves several risks and can cause complications, such as airway injuries. Therefore the Paediatric Intensive Care Unit (PICU) preferably uses non-invasive ventilation (NIV). NIV is a form of positive pressure ventilation delivered by a mask. The biggest challenge of NIV is choosing a NIV mask that has minimal air leakage and offers maximal comfort for the patient. However, the commercially available NIV masks for the PICU are very limited. The market is small and detailed anthropometric data of children faces is lacking. Therefore the production of NIV mask for children is less interesting for manufacturers because of the profitability. Production of NIV masks for children with the aid of 3D scanning and printing techniques holds a promising solution, since the masks will perfectly fit the individual facial features of the patient. My project focuses on the development of a new NIV mask, which is tailor-made, and aims to reduce air leakage. The project's design brief can be found in Appendix A.

This graduation project is executed in collaboration with Amsterdam University Medical Centres (Amsterdam UMC), a collaboration between the two Amsterdam-based academic hospitals: Academisch Medisch Centrum (AMC) and Vrije Universiteit medisch centrum (VUmc). I have executed this project as an intern at the Medical-Technical Innovation and Development department (MIO) located at AMC, see Figure 3. This department develops prototypes and products for physicians and patients aimed at increasing the quality of care.

The structure of this report is based on five design phases in Figure 4.

Figure 3. *Amsterdam UMC, location AMC.*

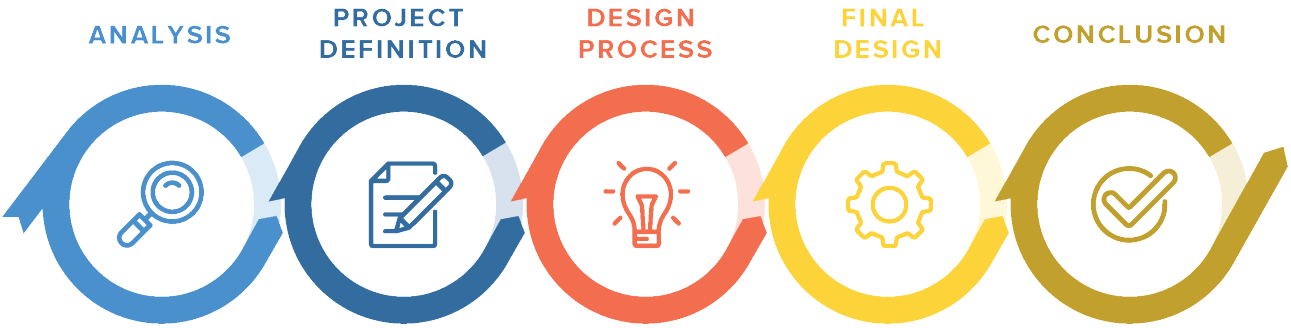


Figure 4. *Five design phases, based on Design Thinking (Gibbons, 2016).*

Chapter 1
The analysis

In the first phase, the analysis, a thorough understanding of NIV and its context is gained by literature and field research. In this phase the problems and needs of the different stakeholders are identified, and possibilities for tailored production are explored.

Chapter 2
The project definition

In the second phase, the project definition, the core problem and focus of the project is captured. What has to be designed and for whom? Target group, type of mask, requirements and wishes, and the envisioned future scenario at the PICU are defined.

Chapter 3
The design process

In the third phase, the design process, ideas are generated. Four ideas are further developed into concepts. The effectiveness of the concepts is tested with prototypes. Two concepts are selected and further developed into the next phase.

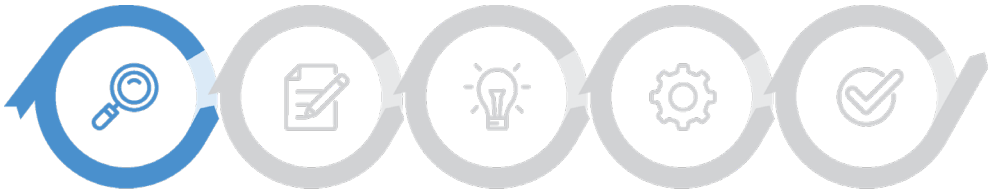
Chapter 4
The final design

In the fourth phase, the final design, two NIV mask proposals are developed. The masks are elaborated in terms of product-use, production, materials, and measurements. Iterations of prototypes have been made to optimise the effectiveness of the NIV masks. A protocol is written to test the effectiveness of the final design.

Chapter 5
The conclusion

In the fifth and last phase, the conclusion, the final design proposal is evaluated, and recommendations are given for further development of the masks. A roadmap describes how to further develop and realise the implementation of the mask proposals in the PICU.

1
Analysis



The aim of the analysis is to gain a deep understanding of non-invasive ventilation (NIV) and its context; the Paediatric Intensive Care Unit. What is the exact problem and which needs have the different stakeholders. After analysing the Paediatric Intensive Care Unit and their stakeholders, ventilation is investigated: the different types of ventilation, ventilators, type of masks, and NIV related problems. Production possibilities for tailored production with 3D printing and scanning are investigated. The anthropometry of children's faces is investigated, including anthropometry sources, dimensions, and skin sensitivity. The custom-made medical devices rules and regulations are analysed. Finally, NIV in practice is analysed by conducting field research, including: the workflow, ventilators, masks, process, and related problems. A conclusion of the analysis is drawn which is used for the next phase, the project definition (chapter 2).

1.1 Paediatric Intensive Care Unit

PICU's offer intensive care for children between 0 and 18 years old who are critically ill (ICK, 2019). The critical situation can be caused by diseases, accidents, or surgery. Treatment is complex because the condition is often unclear, the patients are vulnerable and unstable, and the outcome of the treatment is unsure (Melles, 2011). Therefore medical care of all specialisms is offered (ICK, 2019). Continuously monitoring the vitals (such as the lungs) with medical equipment, to correct and take over the vitals is fundamental (Melles, 2011). The vitals of the patient are monitored with sensors and their status is displayed with parameters (e.g. respiration and saturation). The breathing of the patient can be supported with mechanical ventilation, on which this project is focused.

Figure 5. *The PICU at the Emma children's hospital of Amsterdam UMC.*

In the Netherlands there are seven academic hospitals with a Paediatric Intensive Care Unit (PICU): Amsterdam UMC, Erasmus MC Rotterdam, UMC Leiden, Groningen UMC, Nijmegen UMC, Maastricht UMC, and Utrecht UMC (ICK, 2019). The PICU of Amsterdam UMC can be seen in Figure 5. The PICU of Amsterdam UMC is located in the Emma Children's hospital section of the AMC. The PICU has seventeen rooms (ICK, 2019). The PICU offers transport for the patients with a special ambulance unit, an intensivist practitioner and a paediatrician intensivist (ICK, 2019). The patient's data (general information, healthcare status etc.) is displayed throughout the PICU on several screens for supervision by the medical team. Three months after dismissal from the PICU the patient and parents are invited to the aftercare polyclinic. The goal of this polyclinic is to improve the quality of the lives of children and investigate possible post-traumatic stress in the children (ICK, 2019).

PICU patients can be categorised in two groups: patients with acute problems and patients with chronic problems. Most patients have acute problems, such as respiratory tract infections. These are patients with: bronchiolitis, pneumonia, and

ACS. Bronchiolitis, a common lung infection among infants, is the primary reason for hospitalization of infants younger than twelve months worldwide (Mecklin et al., 2018). The symptoms for adults and older children are mild, but bronchiolitis can be dangerous for young babies. Literature describes that hospitalisation due to bronchiolitis is required for 3% of infants younger than one year old, of which 2 to 6% has to go into the PICU (Mecklin et al., 2018). When a child gets infected there is no medication available. The virus causes daily 700 child deaths worldwide (NOS, 2019). In the Netherlands there is a peak season for these acute infections during autumn and winter, which caused an admission stop in 2019 (NOS, 2019).

The other group of patients at the PICU are chronic patients. These are patients with metabolic or muscle diseases. Patients with metabolic diseases are in general more vulnerable. Patients with muscle diseases are often also increasingly weakened over time. These patients typically require long periods of NIV, and even longer for every time they are hospitalised because they will be more weakened. Therefore this chronic group is defined as Do Not Intubate (ICK protocol, 2019), because when intubated, their muscles will further deteriorate and it will be hard to wean from the intervention.

The stakeholders are analysed to identify their needs and involvement in mechanical ventilation. There are many stakeholders involved in the PICU because medical care of all specialisms is offered (ICK, 2019). Figure 6 illustrates the different stakeholder teams.

Patients

The patients stands central in the stakeholder map; they are critical ill and require intensive medical care. In the Netherlands are yearly 5.000 children admitted in the PICU's (Stichting Kinder Intensive Care, 2019), the hospitalisation time varies from days up to a year. Ventilation can be beneficial for patients in the acute setting that have insufficient gas exchange in the lungs (Mortamet, 2017).

Parents

The parents accompany their child. The parents are allowed to be 24/7 with their child during the stay in the PICU. Parents can even participate in the care of the child led by the practitioners. It is important to convince the parents of the treatment, because this has a big impact on the patient's motivation. The PICU stay of their child is often stressful for the parents, because of the critical situation of their child. Therefore they are guided by physicians at the PICU.

Medical team

The medical team determines the treatment plan of the patient. The paediatric intensivist leads the team of specialists and determines the policy in the PICU. The paediatric intensivist is accompanied by a fellow (paediatric intensivist in training) and paediatric assistants (paediatricians in training). If a certain expertise is needed, the paediatric intensivist consults paediatric specialists.

Medication team

The medication team are experts of medication. The pharmacist is always present at the PICU because of the wide range of medications used in the PICU. The sedation specialist will provide sedation if the patient has to undergo a painful treatment. For example, inserting a central intravenous infusion.

Ventilation team

The ventilation intervention is teamwork between the paediatric intensivists, ventilator practitioners, and intensivist practitioners. The ventilation practitioners are specialised in ventilation. Intensivist practitioners are practitioners specialised in the PICU-setting. There is one intensivist practitioner per one or two patients in the PICU, depending on the critical situation of the patient. Firstly, the paediatric intensivist and ventilator practitioner determine which ventilation type will be used. Secondly, the intensivist practitioner (with the help of the ventilation practitioners) provides the ventilation. The assistants at the PICU take care of all the practicalities, such as filling the stock, bringing and getting materials.

Social team

The parents play an important role in the guidance, they often communicate to their child. The first responsible practitioner is specialised in the patient-journey, and guides the patient and parents through the treatment. Social workers can take care of the

parents during the period when their child is in the PICU. Their tasks involve assisting in furlough from work, financial problems, and other practicalities.

Exercise team

The patients are critical ill and are during their stay at the PICU often lying in bed. The physiotherapist takes care of the rehabilitation by exercising with the patients.

Psychological team

The admission at the PICU is a stressful for the patient, the patients are mentally supported. The parents have a key role, they have a relationship of trust. The psychologist can support patients and the relatives of the patient if necessary. The childcare worker informs the child about the treatments and can entertain the child by playing with him and reading to him.

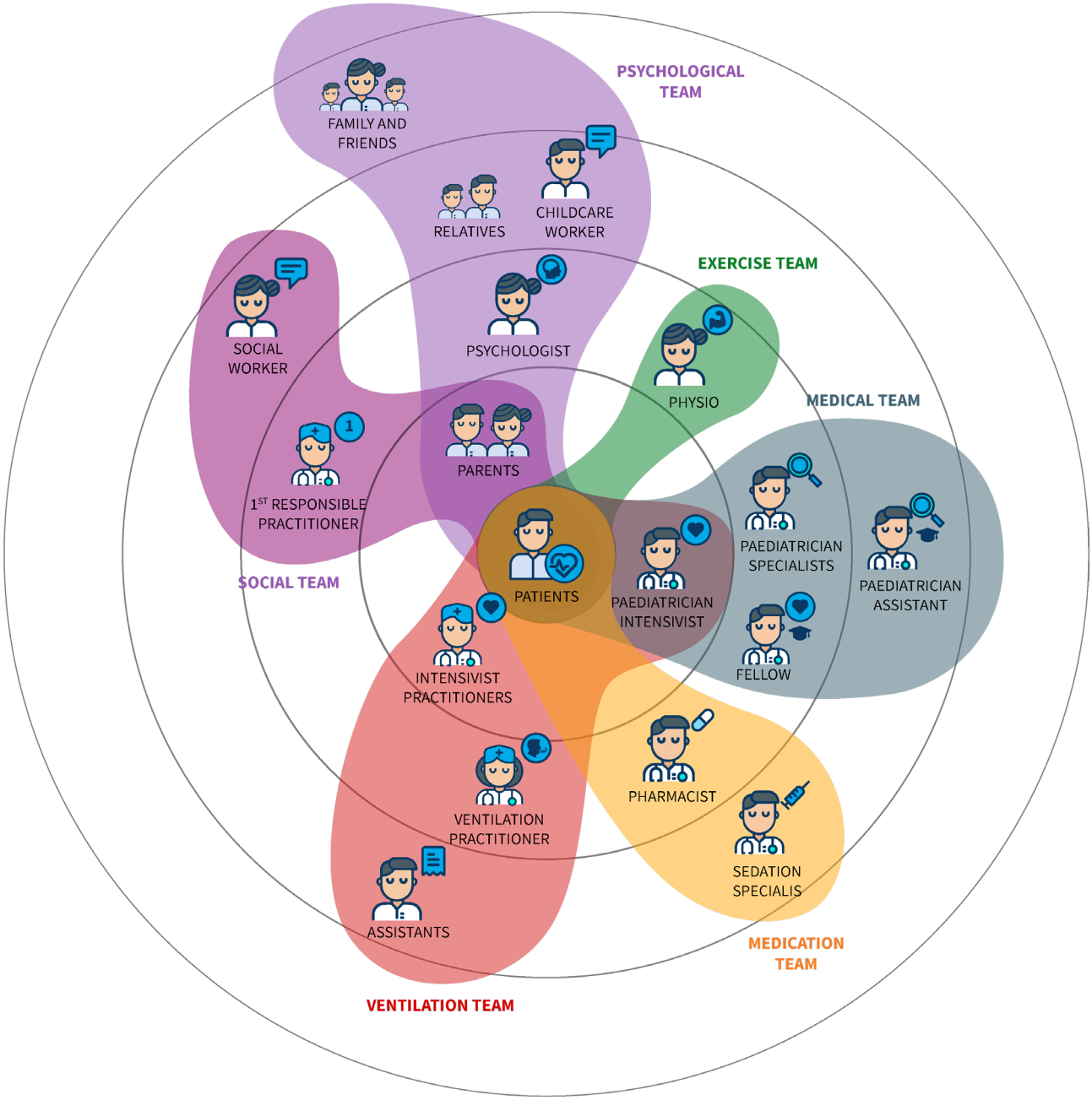


Figure 6. *The stakeholder map of the different stakeholders at the PICU.*

1.2 Ventilation

Ventilation can be delivered through positive- and negative pressure (Guy, 2017). Negative pressure ventilation is delivered through a cuirass over the body creating a vacuum, which makes the chest expand. From the 1980s positive pressure ventilation has been adopted and preferred therapy (Guy, 2017). Negative pressure is not preferred because this makes it hard to treat and take care of the patients. Therefore this project will focus on positive pressure ventilation.

There are two main categories of positive pressure ventilation: invasive ventilation and non-invasive ventilation (NIV) (see Figure 7). Within invasive ventilation there are two types of intubation methods: nasotracheal and orotracheal intubation. Within NIV there are three types based on the way of delivery: High flow nasal cannula oxygen (HFNC), Bi-level Positive Airway Pressure (BiPAP), and Continuous Positive Airway Pressure (CPAP). The different types are further explained in the following two paragraphs.

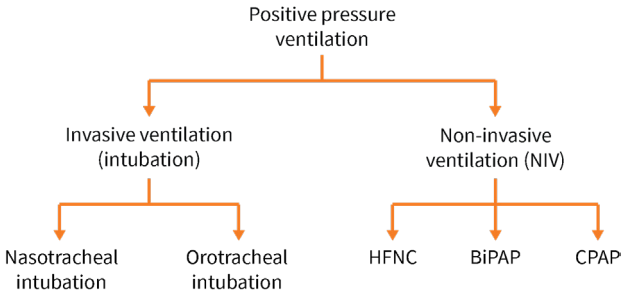


Figure 7. *The different types of ventilation (Morley, 2016).*

Invasive ventilation

Invasive ventilation is a form of positive pressure ventilation delivered through an invasive artificial airway, which is a flexible tube with a small balloon. The tube is placed in the trachea to keep the airways open, and the balloon is inflated to fixate tube. The complications of invasive ventilation can be found in Appendix B. Patients in the PICU are invasively ventilated by endotracheal intubation which can take place via the nose or mouth (NaFix Project, 2018); nasotracheal or orotracheal, see Figure 8.

Invasive ventilation is in some cases inevitable, e.g. if the patient is injured to the face and a mask cannot be worn. Intubation can cause complications, airway injuries, such as pneumonia and sinusitis (Nava et al., 2009), but also because of the excessive need of sedation (Morley, 2016). Although invasive ventilation is in some situations inevitable, should the use be minimised, because of related problems. The focus of this project is to improve NIV intervention which potentially can decrease the use of invasive ventilation. In the next paragraph is non-invasive ventilation further explained.

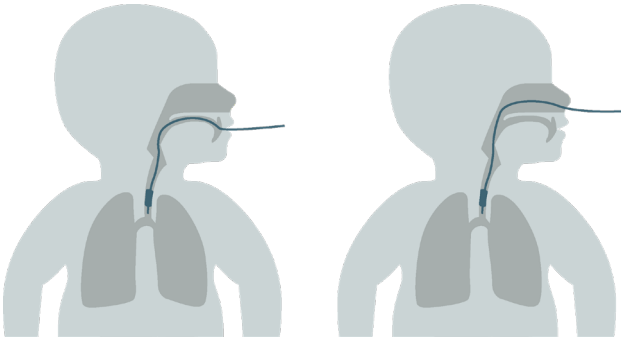


Figure 8. *Nasotracheal intubation (left), and orotracheal intubation (right).*

1.2.1 Non-Invasive Ventilation

NIV is a form of positive pressure ventilation delivered by a face mask, which minimizes the effort of breathing and improves gas exchange (Morley, 2016). NIV is a well-established therapy that originally is used to treat people with chronic respiratory failure, like Chronic Obstructive Pulmonary Disease(COPD) (Shah et al., 2017). NIV has become an increasingly popular treatment in intensive cares (Morley, 2016). NIV can be beneficial in particular for patients in

the acute setting with bronchiolitis, pneumonia, post extubation, respiratory failure, acute chest syndrome (ACS), or status asthmaticus (Mortamet, 2017). Bronchiolitis and pneumonia are viral lung infections. Post extubation is after a patient is invasive ventilated. Respiratory failure is if a patient has insufficient gas exchange in the lungs. ACS is a complication of the sickle cell disease. Status asthmaticus is an acute exacerbation of asthma.

According to Mortamet et al. (2017) the following things are important for NIV use in the critical care setting. First of all, the mask has to be available immediately, and the initiation has to be fast and easy. In addition, NIV masks are often used for extended times. In such cases there is a higher risk of skin injury. This is further explained in ventilation related problems in paragraph 1.2.4.

NIV is associated with a lower mortality rate, shorter ICU stay, a lower risk of nosocomial infection (infection acquired in a hospital), and reduction of the use of antibiotics (Nava et al., 2019; Morley, 2016). However NIV is not for every patient beneficial; there are contraindications, e.g. if the patient is in shock. The full list of contraindications and complications can be seen in Figure 9. The usage of NIV has risks, which are further elaborated in paragraph 1.2.4.

Absolute Contraindications
Apnoea
Shock
Cardiopulmonary arrest or Peri-arrest (except palliation)
Life threatening hypoxaemia (except palliation)
Decreased conscious level GCS <8
Inability to protect airway
Untreated Pneumothorax
Recent facial surgery / significant facial fractures
Inadequate monitoring / trained staffing
Relative Contraindications
Excessive vomiting
Confusion / agitation
Significant chest trauma
Haemodynamic instability
Facial / airway burns
Bullae
Recent upper gastrointestinal surgery
Excessive secretions
Bowel obstruction
Nasal obstruction / atresia
Epistaxis

Figure 9. *List of contraindications for NIV (Morley, 2016).*

There are three types of NIV: High flow nasal cannula oxygen (HFNC), Continuous Positive Airway Pressure (CPAP), and Bi-level Positive Airway Pressure (BiPAP). In Figure 10 the differences are illustrated. The red reference line shows the pressure in the lungs when breathing without ventilation support as a reference. The green line resembles CPAP (and HFNC), and the yellow line shows the pressure in the lungs during BiPAP.

- High Flow Nasal Cannula (HFNC) provides oxygen and humidity via high gas flows via the nasal cannulae (nose) of the patient (Morley, 2016). In literature HFNC is not always seen as NIV; because the nasal cannulae does not seal the face it is not considered as a mask. However, the system makes use of positive pressure, although the amount of pressure is not set. The advantage of HFNC is that sedation is not needed (ICK protocol, 2019). HFNC can be seen as the lightest form of NIV.
- Continuous Positive Airway Pressure (CPAP) provides a constant positive pressure during both the inhalation and exhalation (Morley, 2016). The patient is breathing spontaneously (see Figure 10). CPAP is used with hypoxic respiratory failure; there is a shortage of oxygen in the blood and the carbon dioxide level are near to normal. The advantage of CPAP compared to HFNC is that the pressure can be set (Morley, 2016). Higher pressures can decrease the effort of breathing. Therefore, can CPAP be seen as a mild form of NIV.
- Bi-level Positive Airway Pressure (BiPAP) gives pressure during the exhalation and a set amount of (extra) positive pressure during the inhalation (Morley, 2016). BiPAP is used with hypercarbic respiratory failure; there is too much carbon dioxide in the blood and oxygen levels are near to normal (Morley, 2016). Since BiPAP gives extra pressure during the inhalation and hence reduces the breathing effort further compared to CPAP, BiPAP is seen as the strongest NIV form.

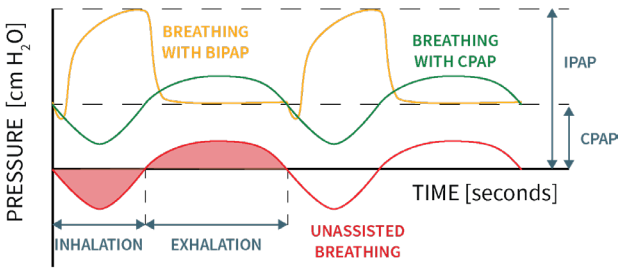


Figure 10. *Pressure diagram of unassisted and ventilated breathing (Strong, 2011).*

This project will focus on the CPAP and BiPAP types of NIV. These types require non-vented masks, this is explained in paragraph 1.2.3.

1.2.2 Ventilators

In general there are two types of ventilators (Bahammam et al., 2018; Figure 11):

- Ventilators with an open single-limb circuit make use of one ventilation tube. For the removal of CO2 are two options: using a ventilated mask, or adding an exhalation valve (Bahammam et al., 2018). Illustrated in Figure 11 with A and B. This type of ventilator is mainly used for chronic use taking place at home.
- Ventilators with a closed dual-limb circuit makes use of two ventilation tubes, one tube for inhalation and another for exhalation. Both are connected with the ventilator. Therefore, a non-vented mask is required to maintain the closed circuit (Bahammam et al., 2018). The CO2 is removed by a built-in exhalation port in the ventilator. This type of ventilator is mainly used for the acute setting at the hospital, such as the PICU, because it gives more control over the breathing of the patient.

The ventilator machine in the PICU is controlled by the intensivist practitioner. Setting the ventilator machine is a specialised skill; there is not one ideal setting for all patients (Bamahammam et al., 2018). The settings will be determined and adjusted, based on the critical situation and preferences of patients. Positive pressure ventilation can be controlled by controlling volume or pressure or controlling both volume and pressure (Morley, 2016):

- Volume controlled means that the volume is the variable and the pressure can be set. The advantage of volume control is that the tidal volume is more stable (Morley, 2016); which is the volume that is normally displaced between an inhalation and exhalation.
- With pressure control, the pressure is the variable and volume can be set. The advantage of pressure control is that the ventilator delivers volume following the patient's natural breathing rhythm (Morley, 2016). Pressure control makes sure in the case of high air leakage that the volume is delivered to the patient.
- All other forms of control are a combination of volume control and pressure control. For example pressure control, with a minimum amount of delivered volume.

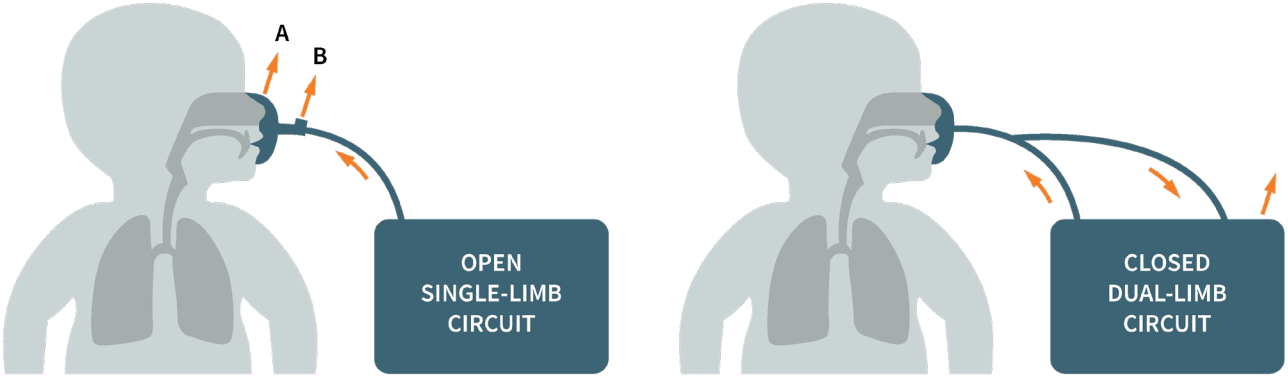


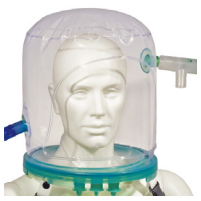
Figure 11. *The two type of ventilators, with (A) a ventilated mask and (B) an exhalation valve.*

1.2.3 Type of masks

Seven different mask types can be distinguished, see Table 1: nasal cannula, nasal mask, nasal pillows, oral mask, oronasal mask, total face mask, and helmet. The masks, are fixated with headgears. The headgear consists of fabric straps and clips for fixation. The seven different masks can be categorised into vented and non-vented masks;

- Vented masks have holes where the air could leak through to remove CO2. This type of masks is used with ventilators with an open single-limb circuit. These types are in general not preferred in the acute setting, because the breathing of the patient cannot accurately be determined (Bahammam et al., 2018). However when patients are stable, they may be shifted to a vented mask, because these are in general more comfortable (Bahammam et al., 2018).
- Non-vented masks do not have exhalation ports. This mask type is used with ventilators with a closed dual-limb circuit. Non-vented masks, such as the oronasal mask, are preferred for the acute setting (Bahammam et al., 2018; Shikama, 2018). Note that masks are considered non-vented if only both the mouth and nose of the patient are covered, because the exhalation otherwise can take place via either the mouth or nose.

Mortamet et al. (2017) conclude that the amount of commercially available vented masks for children is quite big, even for the youngest patients. However, there is a paucity of commercially available non-vented masks for children, especially for younger children. Well-fitting masks are important to increase the patient's tolerance and NIV efficacy (Brill et al., 2014). The masks selection is hard because paediatric patients develop rather quick and therefore have a wide range of facial dimensions (Argent, 2015). The choice of mask depends according to literature on many factors: the patient's age, weight, clinical situation, facial anatomy, the mode of ventilation, the type of circuit, the risk of skin injury, breathing pattern, preferences and experience of the physicians (Bahammam et al., 2018). In Europe the oronasal masks is the most popular mask (Shallom et al., 2015), in 70% of the cases oronasal mask is the first choice (Bishopp, 2019).

INTERFACE	IMAGE	DESCRIPTION
Nasal cannula (Nasal prong)		The nasal cannula are two tubes which are placed in the nostrils. There is air flow through the nose.
Nasal mask		The nasal mask rest on the nasal bridge and the sides of the nose, there is only air flow through the nose.
Nasal pillows		The nasal pillow rest on the inside of the rim of nostrils, there is only air flow through the nose.
Oral mask		The oral mask is placed inside the mouth and sealed with the lips around the mask, there is only air flow through the mouth.
Oronasal mask (Full face mask)		The oronasal mask rest on the nasal bridge, nose, around the mouth, and chin. Air flows through both the nose and mouth.
Total face mask		The total face mask covers the whole face, it seals over the chin and follows the hairline. Air flows through both the nose and mouth.
Helmet		The helmet encases the whole head, air flows through both the nose and mouth.

VENTED OR NON-VENTED	ADVANTAGES	DISADVANTAGES
Vented	• Minimal contact interface • Comfortable	• Not indicated if mouth breathing • Mouth leaks • Not indicated if nasal obstruction
Vented	• Easy fitting and comfortable • Allows communication, coughing, eating, talking, use of a pacifier, secretion management • No risk of aspiration • Less gastric distension • Low risk of asphyxia in case of ventilator malfunction • All sizes available (infants)	• Mouth leaks • Not indicated if mouth breathing or nasal obstruction • Contact at the nose, which has a high risk on skin injury • Risk for nasal dryness, and bleeding • Risk for BiPAP asynchrony
Vented	• Easy fitting and comfortable • Allows communication, coughing, eating, talking, use of a pacifier, secretion management • No risk for aspiration • Less risk for skin injury (no contact with nasal bridge) • Less gastric distension • Low risk of asphyxia in case of ventilator malfunction	• Mouth leaks • Not indicated if mouth breathing or nasal obstruction • Limited use if high nasal resistance • Risk for nasal dryness, bleeding and nostril pain • Risk for BiPAP asynchrony • No infant sizes commercially available
Vented	• Comfortable, free face and head • No risk for nasal symptoms • Low risk for skin injury • No risk of aspiration	• Requires volume-cycle ventilation • No leak compensation (lips sealing required) • Not suited for use during sleep
Non-vented	• Relatively comfortable, does not cover the eyes • Small, and low risk on CO_2 rebreathing • No mouth or nose leaks • Most effective • Low risk for claustrophobia	• Increase risk of aspiration and air swallowing • Limit cough, communication, eating, use of pacifier, and secretion management • High risk for skin injury, contact with the nasal bridge • Risk for upper airway obstruction • Limited commercially available, no infant sizes • Not compatible with glasses
Non-vented	• Low risk pressure ulcers and skin injuries because of big contact area • No mouth or nose leaks	• High risk for claustrophobia • Increase risk of aspiration and air swallowing • Limit cough, communication, eating, use of pacifier, and secretion management • Less effective because of big dead space, higher risk on CO_2 rebreathing • Risk for upper airway obstruction • Limited commercially available, no infant sizes • Not compatible with glasses
Non-vented	• Low risk pressure ulcers and skin injuries • Less resistance to flow, better tolerance to high pressure • Compatible with glasses • No mouth or nose leaks	• Makes face unreachable for practitioners • Intrusive set up, and lot of noise • High risk on claustrophobia • Increase risk of aspiration and air swallowing • Biggest dead space, highest risk on CO_2 rebreathing • Ventilator adaptation • Difficult humidification • Risk for upper airway obstruction

Table 1. *Overview of type of NIV masks (Mortamet et al., 2017; Morley, 2016; Castro-Codesal et al., 2019).*

1.2.4 Ventilation-related problems

The usage of NIV brings several risks and can lead to complications. These NIV related risks involve air leakage, facial skin irritation, nasal symptoms, eye irritation, claustrophobia, gastric distention, and aspiration (Bahammam et al., 2018; Guy, 2017).

Air leakage

There are two types of air leakage with the use of NIV: leakage of the mask and leakage via the patient's nose or mouth (Bahammam et al., 2018). With air leakage is meant the leakage of the mask because this is unintentionally. During the NIV intervention some degree of air leakage is always expected. Ideally there is almost no air leakage; but some air leakage is necessary to prevent CO2 rebreathing, because if there is no leakage there will get CO2 stuck in the dead space of the mask (Mortamet et al., 2017). Air leakage can be reduced by tightening of the headgear. However excessive tightening should be prevented because it increases the risk of skin injury (Castro-Codesal et al., 2019).
Although clinical ventilators have the ability to compensate air leakage out of the mask (Nava et al., 2009), can air leakage cause problems. Too much air leakage, which can happen if the mask does not fit the patient well, can cause patient-ventilator asynchrony and will cost the patient effort to breath (Itagaki et al., 2017). This increases the risk of NIV-failure, dyspnea (shortness of breath), eye injuries and sleep disturbance (Raurell-Torredà et al., 2017; Castro-Codesal et al., 2019).

Skin injury

NIV has the risk for skin injury because the NIV mask is pressed on the patient's face with the headgear. The wearing time varies from days to weeks. Patients at the PICU might have a higher risk because children have a fragile skin, especially infants (Argent, 2015). Pressure ulcers related to NIV for Patients at the PICU is as high as 60% (Raurell-Torredà et al., 2017). Pressure ulcers and can cause pain, loss of function, and infection, resulting in extended hospital stays and increasing costs (Shikama et al., 2018).

The pressure ulcers are categorised in four different stages (Raurell-Torredà et al., 2017), illustrated in Figure 12. In practice the first phase of pressure ulcers has to be prevented. Blanchable erythema, when the skin loses redness with pressure, is the phase before the first stage, and is acceptable.

1. In the first stage, non-blanchable erythema, the skin has turned red.
2. In the second stage, partial-thickness ulcer, is an open ulcer, often red or pink.
3. In the third stage, full-thickness skin loss occurs. Fat may be visible. The depth may change per location.
4. After the fourth stage, there is deep tissue damage, which often includes darker purple and brown colours.

Skin injury of paediatric patients is described by Visscher et al. (2015) for the oronasal mask, illustrated in Figure 13. The injury is most common at the nose bridge (39%), followed by left cheek (30%), right cheek (18%), forehead (10%), and chin (3%). The severity of the wounds was greatest at the nose bridge. Also Brill et al. (2018) concludes that the nose area is most vulnerable. However replacing the commercial masks with tailored mask can reduce skin injury. In the study of Faroux et al. (2015) was skin injury reduced for chronic paediatric patients by replacing commercial nasal mask with a tailored nasal masks.

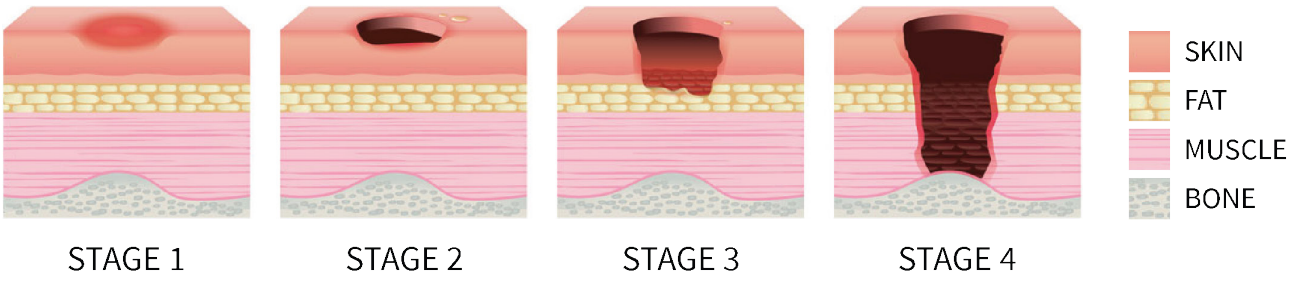


Figure 12. *Four stages of pressure ulcers (MedicalNewsToday, 2017).*

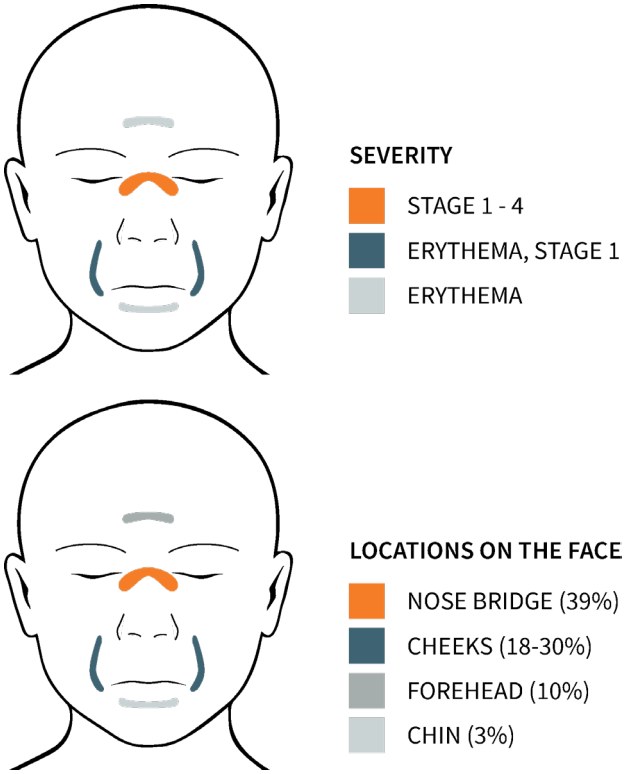


Figure 13. *Overview the severity of wounds (top) and the affected areas (bottom) (Visscher et al., 2015).*

The pressure of the mask on the face has to be below the capillary closing pressure, with this pressure blood vessels get occluded, although not every patient develops pressure ulcers above the capillary closing pressure (Brill et al., 2018). In practice there is not a method to determine pressure performed by the mask on the patient's face (Shikama, 2018). Literature describes strategies to reduce the risk for skin injury, see Appendix C.

Nasal symptoms

Patients undergoing NIV have the risk for nasal or oral dryness and nasal congestion (Bahammam et al., 2018). Nasal symptoms are more frequent with the use of the nasal mask. Nasal and oral dryness is often caused by air leakage through the mouth, the nose is able to heat and humidify the inhaled air (Bahammam et al., 2018). If the nasal mucosa dries, inflammation increases. Adding heated humidification is a strategy to reduce the symptoms (Castro-Codesal et al., 2019).

Eye irritation

Air leakage of the NIV mask can lead to eye irritation (Morley, 2016). The leakage of air around the eyes of the patient can make the eyes dry, which can cause infections, such as a conjunctivitis (Bahammam et al., 2018). Conjunctivitis is an infection of the eye conjunctiva, which makes the eyelids swollen and the eyes red.

Claustrophobia

Some of the NIV mask can feel claustrophobic to a patient (Castro-Codesal et al., 2019), because they can make it hard to communicate because of the positive pressure, or the masks surrounds or block the patient's view. In particular non-vented masks, like the oronasal mask have a higher risk for claustrophobia (Morley, 2016), because these masks are more intrusive.

Gastric distension

The positive pressure of the ventilator causes air swallowing, which can cause abdominal distension or stomach pain. The risk for gastric distension is higher for non-vented masks such as the oronasal and total face mask (Mortamet et al., 2017).

Aspiration

The positive pressure delivered by the mask brings the risk of aspiration (Morley, 2016). If the patient has to vomit during NIV, and the mask is not removed, the vomit will be pumped into the airway, which can cause suffocation (Castro-Codesal et al., 2019). To reduce this risk of suffocation there have to be extra precautions during feeding (Fedor, 2017). This includes paying attention to feeding times, the patient's head and body positioning, and suctioning too keep the airways clear. Masks that do not cover the mouth of the patient, such as a nasal mask also reduce the risk of aspiration (Fedor, 2017).

1.3 Antropometry

For the sizing of the new NIV mask antropometry sources are identified and the key facial dimensions are determined. The antropometry sources include: datasets of facial dimension of children, a tool to develop enriched statistical shape models, and 3D scanning for tailored production.

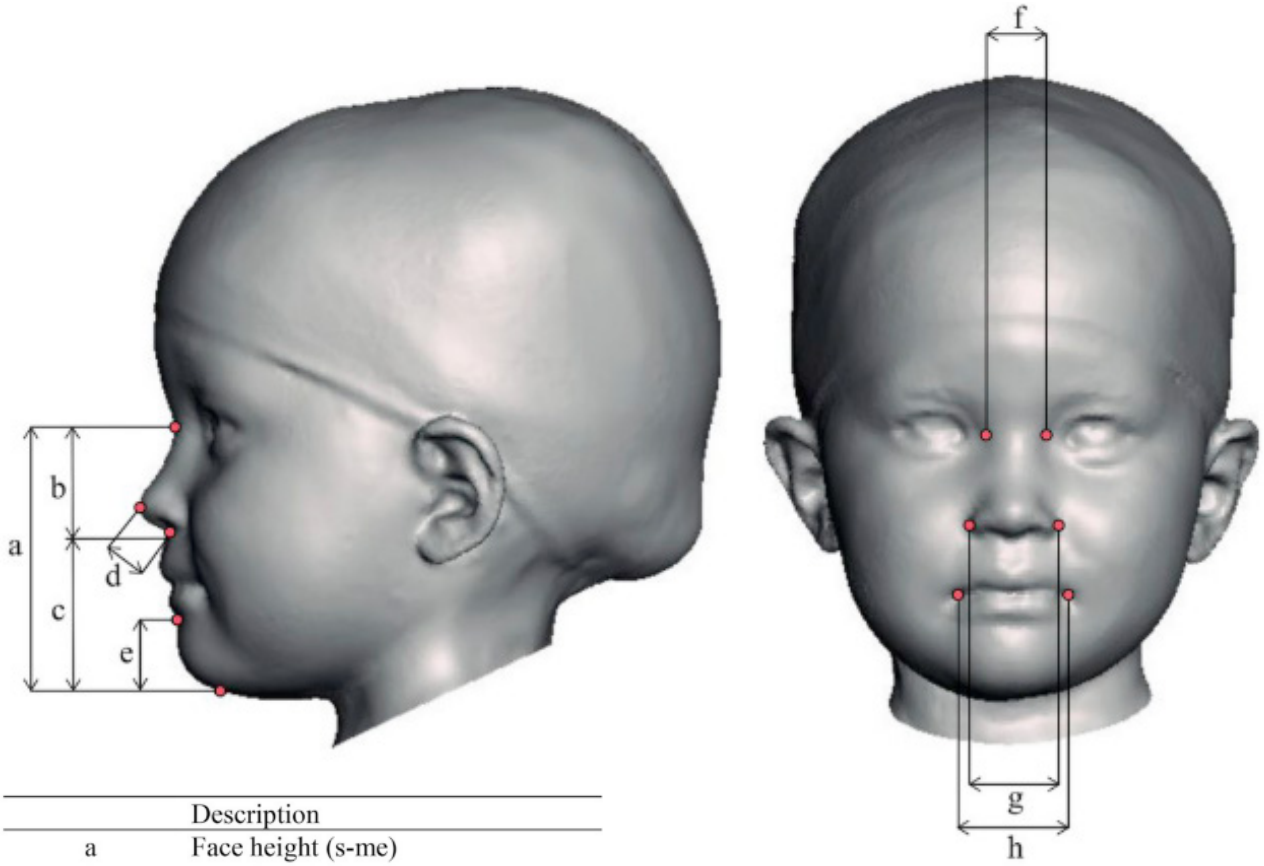
Anthropometry of the face is investigated for the development of the NIV mask. Goto et al. (2019) concluded that there is a lack of detailed anthropometric data of children faces. With the aid of 3D scanning techniques the detailed anthropometric data of children can be captured. For the further development of the mask the following anthropometry sources can be used:

- 3D facial scans of patients can be captured for the development of tailored parts. For the determination of the individual fit landmarks could be used. Landmarks are universal anatomical orientation points. These are used to identify facial features (Goto et al., 2019) and to determine measurements, by measuring the distance between landmarks.
- Databases of facial dimension of children could be used for the development of parts that have a fit within a cluster; which have a sizing system. Such as, the most recent dataset of Goto et al. (2019), containing measurements of the head region of Dutch children between 0.5 to 7 years. Older datasets of Steenbekkers (1993) of 2421 Dutch children aged between 0 to 12 years. From other continents, such as the dataset of Farkas (1994) of North American children, which contains measurements of the heads and faces of around 1590 North American Caucasian children aged between 1 to 18 years.
- Enriched statistical shape models (enriched SSM) can also be used for the sizing of parts. Enriched SSM can be constructed from a database of 3D scans. Enriched SSM's are models that preserve a certain set of anthropometric landmarks (Verwulgen et al., 2018). At TU Delft a tool is developed by Toon Huysmans in DINED, which can create enriched SSM based on the dataset of Goto et al. (2019). These enriched SSM's can be used as a design tool for the development of the NIV masks.

All the relevant face dimensions in the contact area of the oronasal face mask are described by Goto et al. (2019). The dimensions can be seen in Figure 14 and include face height, nose length, lower face height, nasal tip protrusion, chin height, nasal root breadth, nose width, and mouth width. The most important dimensions for oronasal masks are the width of the mouth and the sellion-promentale length (Amirav et al., 2013), because the oronasal mask has to cover both the nose and mouth.

Although the headgear of the mask does not require a tailored fit, it should also fit the patient's head, because the headgear should fix the mask on the patient's face. Relevant headgear dimensions include head length, head width, head breadth, and head circumference.

The dimensions of the developed tailored NIV masks can be found in chapter 4, and is elaborated in Appendix Q. For the determination of the dimensions are the database of Goto et al. (2019) and enriched statistical shape models used.



	Description
a	Face height (s-me)
b	Nose length (s-sn)
c	Lower face height (sn-me)
d	Nasal tip protrusion (sn-prn)
e	Chin height (sl-me)
f	Nasal root breadth(nrp-nrp)
g	Nose width (al-al)
h	Mouth width (ch-ch)

Figure 14. *Relevant face dimensions in the contact area of the oronasal mask (Goto et al., 2019).*

1.4 Production possibilities

Production of tailored NIV masks can be realised with the aid of 3D scanning and printing techniques. In this scenario is the detailed anthropometric data of patient's face captured with a 3D scanner at the PICU. Next are individual NIV masks (tailored to each patients) produced with 3D printing. The 3D scanning analysis for capturing the anthropometric data of patients involves scanning techniques, setup, and scan quality are analysed. The 3D printing analysis for tailored manufacturing involves printing techniques and methods, and printing materials.

1.4.1 3D Scanning Techniques

Techniques

There are many 3D scanners available on the market all based on five 3D scanning techniques: Structured light, Photogrammetry, Laser 3D scanning, Laser triangulation, and Contact-based (EDGE3D, 2019). The techniques are elaborated in Appendix D. An overview is can be seen in Table 2.

Structured light, photogrammetry and Laser 3D scanning are suitable for scanning patient faces at the PICU. Laser triangulation and contact based 3D scanning are not suitable techniques for scanning patients faces at the PICU. Laser triangulation has a low scanning speed, is not portable and is very expensive. Contact based is invasive, time consuming, and has a disability for organic shapes.

Scanners

In Appendix E 3D scanners are analysed. The ideal 3D scanner for the PICU is a portable photogrammetry scanner, mainly because the capture speed is almost instant. Also the patient is not required to sit still, and does not have to move. However the photogrammetry scanners with high accuracy are currently not portable and very expensive. Infrared depth-sensing scanners (Laser 3D scanning) of phones are cheap and have potential for absolute

TECHNIQUE	DESCRIPTION	(DIS)ADVANATAGES
Structured light 3D scanning	Measures the deformation of a projected light pattern	+ Cost effective (affordable) + High resolution - Time consuming
Photogrammetry 3D scanning	Measures distance from the reconstruction of photographs from different angles	+ Fast capture speed + DIY options - Software complexity - Process time
Laser 3D scanning	Measures the time of flight of a laser beam which is reflected on a surface	+ Easy to use + Budget option (Phones) - Scan quality and accuracy
Laser triangulation 3D scanning	Measures the deformation of a laser beam	+ High resolution and accuracy - Expensive - Not portable - Slow scanning speed
Contact-based 3D scanning	Measures sample points on a surface with a probe (echo apparaat)	+ High precision - Scanning speed - Disability for organic shapes

Table 2. *Overview of 3D scanning techniques.*

measurements (Verdaasdonk et al., 2019), but have currently resolutions often larger than 1 mm, see Appendix E. Structured light 3D scanner offers high accuracy and is also affordable and therefore is currently the best option. The Artec EVA by Artec3D is developed for professional use for healthcare applications, it is used at the oral and maxillofacial department of Amsterdam UMC. The handheld device can capture the front of the face in a few seconds. The main disadvantage of this scanner is that the patient has to sit still during 3D scan, this might requires holding the patient's head still for a few seconds.

1.4.2 3D Printing

Techniques

3D printing production techniques are investigated for the development of tailored NIV mask. There are four types of polymer 3D printing techniques: Material Extrusion, Vat Polymerisation, Powder Bed Fusion, and Material Jetting (AMFG, 2019; 3Dinsider, 2019; 3Dhubs). The 3D printing techniques are elaborated in Appendix F, an overview is made in Table 3. For the production different kinds of 3D printing techniques could be used. FDM seems the most promising one because it is most cost effective and there is a wide range of (biocompatible) materials. The available 3D printers at Amsterdam UMC and TU Delft can be found in Appendix G.

Materials

There are many materials available for 3D printing of hard thermoplastics. 3D printing of soft and flexible materials is relatively new (All3dp, 2019). See the material exploration in Appendix H. The hardness of materials is expressed by different shore scales (Smooth-On, 2019), some shores partly overlap. In Figure 15 an overview of the different scales can be found. The 00 scale is used for the soft materials, like gels and rubbers. The A scale is used for flexible to almost not flexible materials, like rubbers. The D scale is used for hard rigid materials, like rubbers and plastics.

Silicones

Many masks contain silicones. Silicones are used a lot in the medical field because of the following material properties: bio-compatibility, elasticity, and transparency (all3dp, 2019). The biocompatibility is important, because the NIV mask makes contact with

TECHNIQUE	DESCRIPTION	METHOD(S)	(DIS)ADVANATAGES
Material extrusion	Filaments are heated and extruded through a nozzle, layer for layer.	Fused Deposition Modelling (FDM) or Fused Filament Fabrication (FFF)	+ Most cost effective + Wide range of materials - Low accuracy - Anisotropic (material properties are not equal in all directions) - Visible layer-lines
Vat Polymerisation	Liquid photopolymers are converted into a solid object, bottom up, layer for layer.	Stereolithography (SLA) and Digital Light Processing (DLP)	+ High accuracy and precision + Good surface quality - Brittle parts - Mechanical properties will degrade over time (because of sunlight) - Need for post processing (to remove the support)
Powder Bed Fusion	The fusion of powder, layer for layer.	Selective Laser Sintering (SLS), Selective Laser Melting (SLM), Multi Jet Fusion (MJF), and Electronic Beam Melting (EBM)	+ High accuracy and precision + Freedom of design, no need for support structure - Only industrial systems available - Grainy surface
Material Jetting	Resins drops solidified under UV light, layer for layer.	Drop On Demand (DOD)	+ Smooth parts + Multi material printing (visual applications) - Poor mechanical properties - Expensive technology

Table 3. *Overview of 3D printing polymer techniques.*

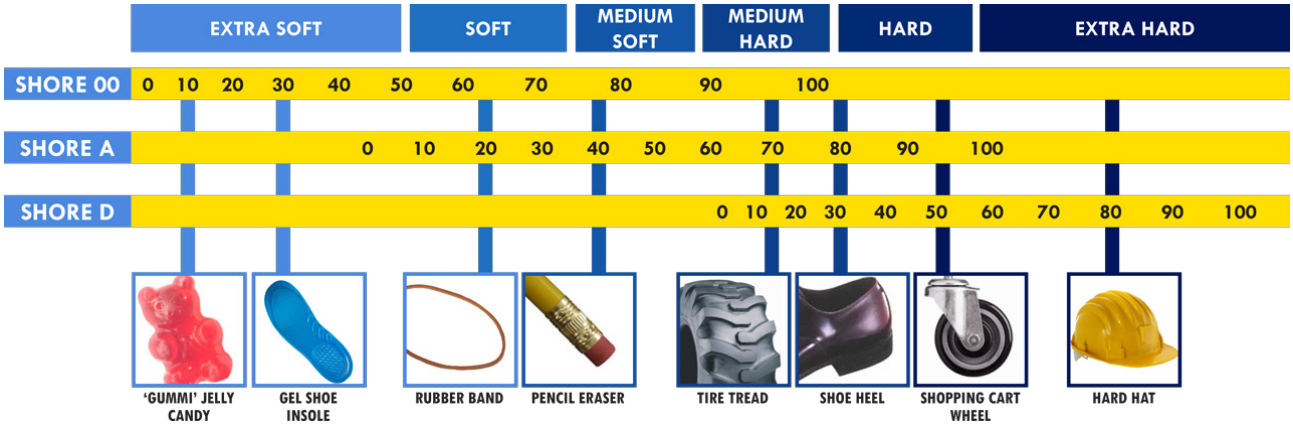


Figure 15. *Three different shore scales: 00, A, and D (Smooth-On, 2019).*

the skin of the patient. Elasticity allows the material to deform, which is necessary to prevent skin injury. Transparency is wanted for optical reasons. In the setting of the PICU is transparency preferred for closely monitoring the patient.

Silicone 3D printing is in its infancy, the market is expected to be growing (All3DP, 2019). Silicones typically required to be formed into moulds via injection or moulding. 3D printing does not require moulds and can be used for the production of customized (tailored) parts. Although it is also possible to use injection or moulding by creating customized moulds. But this requires extra production steps and human labour. The latest developments of 3D printing silicones can be found in Appendix I.

1.5 Rules and regulations

The rules and regulations for the development of a new tailored NIV mask are analysed. The tailored NIV mask is categorised as custom medical device. The rules of medical devices are in a transitional period (European Commission, 2018), after 25 May 2020 new rules apply. The new regulations change the rules of custom medical devices.

1.5.1 Custom medical devices

The NIV mask is a medical device; it is used in a treatment of a disease (RIVM, 2017). This rules of medical devices are currently described by Directive 93/42/EEG (European Commission, 2018). With this directive the tailored NIV mask is considered custom made. However, Regulation (EU) 2017/745 will be the substitute of Directive (93/42/EEG) from 25 May 2020. The tailored NIV mask is not considered custom made but as mass produced (El Azzouzi, 2018), see Figure 16. The tailored NIV mask is seen as standard and slightly adapted to the specific face of the patient and therefore considered as mass-produced.

For mass-produced products, like the new tailored masks, should the producer build a Quality Management System (QMS) and a Technical File for each tailored NIV mask (El Azzouzi, 2018). The tailored NIV mask is classified as Non-Invasive Devices class IIa because it used for the exchanges of gas (El Azzouzi, 2020). The QMS includes computer system validation and process validation.

1.5.2 Biocompatibility of materials

The materials of the new NIV mask should be tested for biocompatibility and toxicity (El Azzouzi, 2020). The rules for the materials are described in the ISO 10993-1 Norm (NAMSA, 2016). The NIV mask is categorised as a surface device and duration of skin contact is categorised as category B or C, therefore the material has to be tested on: cytotoxicity, sensitization, and irritation (NAMSA, 2016). The mask is a surface device because the mask makes contact with the skin. Category B is prolonged contact duration between 24 hours and 30 days, normally the case in the PICU. Category C is permanent use of longer than 30 days, which can be the case if the mask is used by chronic patients.

(3) 'custom-made device' means any device specifically made in accordance with a written prescription of any person authorised by national law by virtue of that person's professional qualifications which gives, under that person's responsibility, specific design characteristics, and is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs.

However, mass-produced devices which need to be adapted to meet the specific requirements of any professional user and devices which are mass-produced by means of industrial manufacturing processes in accordance with the written prescriptions of any authorised person shall not be considered to be custom-made devices;

Figure 16. *Definition of custom-made device in Regulation (EU) 2017/745 (European Parliament, 2017).*

1.6 NIV in practice

In this chapter the practice of NIV is investigated through field research conducted at the PICU of Amsterdam UMC. Ventilation experts (ventilation practitioners) have been consulted and a patient is observed undergoing NIV. The results include the ventilation workflow, ventilators, masks, procedure, and related problems. The observation plan can be found in Appendix J.

1.6.1 Workflow

The ventilation workflow of the PICU at Amsterdam UMC can be seen in Figure 17 (ICK protocol, 2019). A patient undergoing NIV is evaluated every hour, if there is no progression in the critical condition the NIV intervention needs to be aborted and invasive ventilation is inevitable. When patients are in a stable with invasive ventilation, NIV is used to wean from invasive ventilation.

The PICU of Amsterdam UMC is merged of the PICU's of the VUmc and AMC. NIV was introduced fifteen years ago at the AMC. At the VUmc NIV was not introduced before the merger. NIV requires experience and is labour intensive. The staff originating of the VUmc are not experienced with NIV, for them NIV is relatively new because NIV was not used. At the moment most patients are invasively ventilated, because it is a convenient treatment and the staff is well adapted to it.

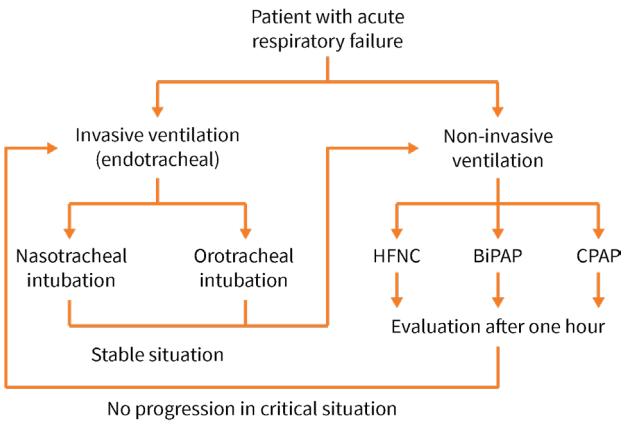


Figure 17. *The ventilation workflow of the PICU.*

1.6.2 Ventilators

In the PICU at Amsterdam UMC four different ventilators are used: the Hammilton T1, G5, C6, and the Respironics Triology 100 (see Figure 18 and Figure 19). The Hammilton T1 has a closed dual-limb circuit. It is a portable ventilator, and used for ventilation of patients during transport in the ambulance. The Hamilton G5 and C6 have a closed dual-limb circuit. These ventilators are used in the rooms of the PICU and are not easily transportable. The Respironics Triology 100 has an open single-limb circuit. This ventilator is easy transportable and used for patients who want to get out of their rooms, and walk through the Emma hospital. The Triology ventilator is also often used for ventilation at home. The new developed NIV masks are compatible with the Hammilton ventilators, also with the Triology ventilator if a vented swivel is used.

The ventilator tubes are available in two sizes, for children below and above 10 kg. For children below 10 kg tubes have a diameter inlet of 15 mm. For children above 10 kg tubes have a diameter inlet of 22 mm.

Figure 18. *The Respironics Triology 100 and Hammiloton T1.*

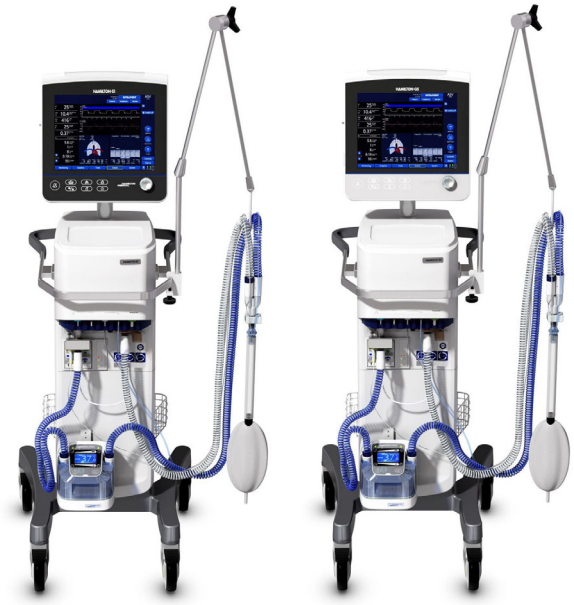


Figure 19. *The Hammilton G5 and Hammilton C6.*

1.6.3 Masks

Four types of masks are used: the total face mask, the oronasal mask, the nose mask, and the nasal prong (see Figure 20). There is a supply of masks stored in the PICU, based on the sizing. The four masks of the PICU are described in Appendix K. An overview is given in Table 4. There are two non-vented masks available. Although the King oronasal mask is not developed for NIV, but for inhaling anaesthetics. The PICU was forced to use these masks because there were no non-vented masks commercially available for the youngest patients (approximately below 2 year old). The ventilation practitioners are responsible for the selection of NIV masks. They investigate the market. The NIV masks have to be transparent and have a quick release system, mainly to reduce the risk of aspiration. Masks might be used in MRI scanners and is therefore it is preferable that NIV masks not contain metal parts.

MASK	TYPE OF MASK	BRAND	COSTS	PAEDIATRIC SIZES	HEADGEAR
Performax	Total face mask	Respironics (distributed by Philips)	60 euro	Three sizes for children above one year old	Four-point straps and bonnets
King mask	Oronasal mask	Ambu	2 euro	Four sizes for all children	Mesh pants is connected to the pins on the mask
Flexitrunk (For nasal mask and prong)	Nasal mask	Fisher & Paykel	20 euro	Four sizes for all children	Bonnets, headgears, and chin straps
	Nasal prong	Fisher & Paykel	20 euro	Eleven sizes for all children	Bonnets, headgears, and chin straps

Table 4. *Overview of NIV masks at the PICU.*

Figure 20. *NIV masks of the PICU: (1) Performax (Philips, 2019), (2) King mask (observation), (3) Flexitrunk with nasal mask (Fisher & Paykel, 2019), and (4) Flexitrunk with nasal prong (Fisher & Paykel, 2019).*

1.6.4 NIV procedure

The selection of the type of NIV mask is based on the required type of ventilation, the patients age, and the experience of the practitioners. The size of the NIV mask is determined with the aid of transparent sizing sheet (see 11:47 in Figure 21), the headgear size is determined by measuring the patient's head circumference. The practitioners introduces NIV to the patient and his parents. It is important to make the patient calm and comfortable, because with NIV the patient's cooperation is mandatory. Also the parents are introduced and convinced of NIV, because they have a huge impact on the patient's motivation. Although babies do not get introduced because it is not possible to communicate with them. In general NIV gets easier if patients are older, because it is easier to communicate with them (NIV can be adjusted to their preferences). During mask placement the patient is placed in a sitting position. Repositioning and tightening of the headgear is also executed when the patient is lying. The patient is closely monitored by the intensivist practitioner to evaluate the progression and treatment changes have to be made.

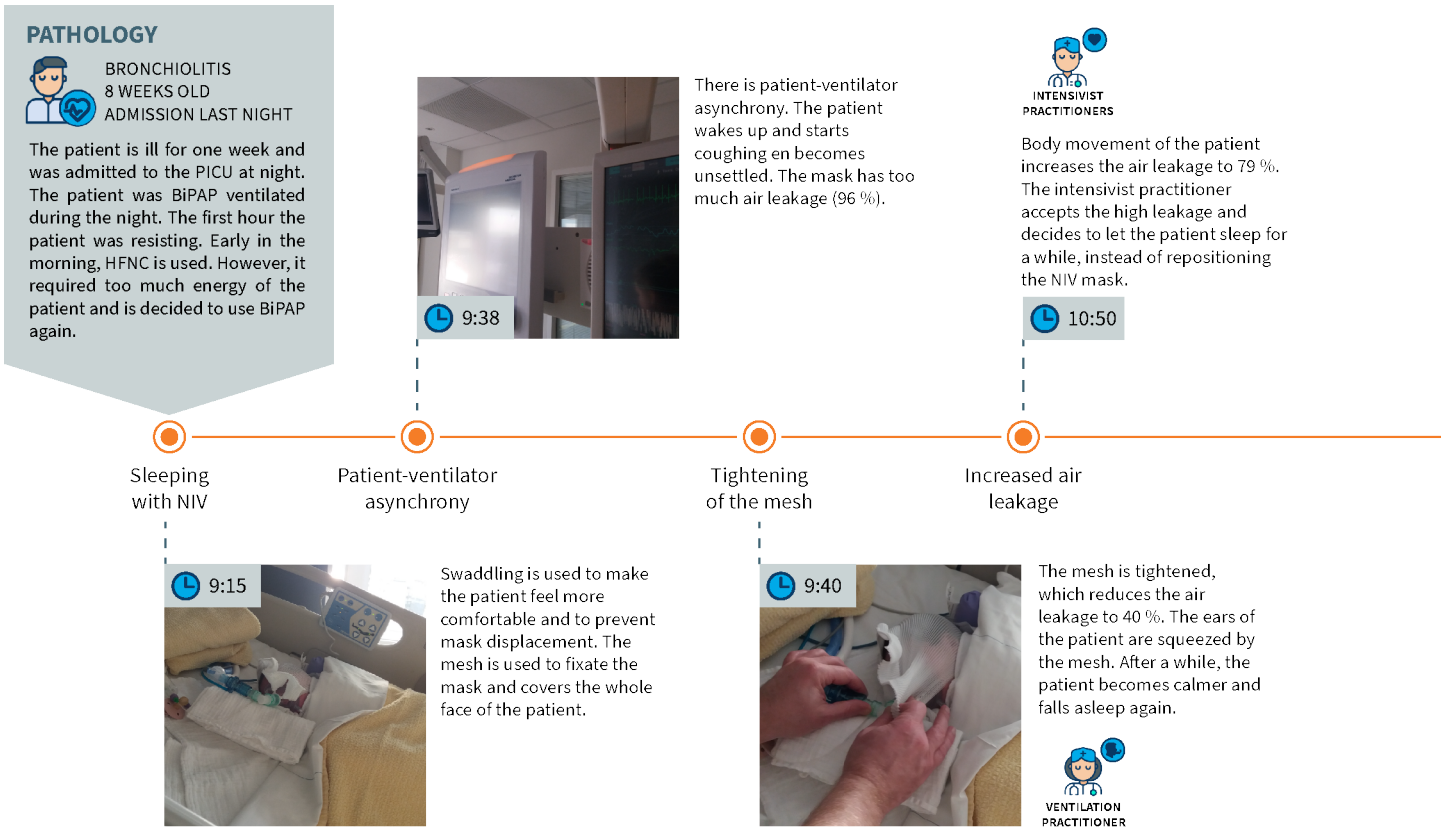


Figure 21. *Overview of the observations (see other side).*

1.6.5 Problems with NIV

The main problem of NIV at the PICU was air leakage. The anaesthesia mask did not fit optimally because the air leakage was often too high, see 9:38 in Figure 21 the mask had a leakage of 96%. Too high air leakage results often in patient-ventilator asynchrony, increasing the breathing efforts of the patient. Air leakage is increased by the use of the nasogastric tube; there is a gap where the tube goes under the mask. The intensivist practitioner often has to reposition the mask to reduce air leakage, after high air leakage at 9:40 in Figure 21 the mesh is tightened. This disturbed the patient who was resting and often sleeping. Also is it time consuming, providing NIV for one patient is a full day tasks for the intensivist practitioner. The air leakage leads also to other problems: skin irritation, and eye irritation. Air leakage made the skin dry, it had to be treated with petroleum jelly, see 11:16 in Figure 21. Air leakage around the nasal bridge lead to eye irritation, eye ointment was used to treat the eyes. Retightening of the headgear was necessary to reduce air leakage, but this increased the risk for skin irritation. The risk of aspiration is reduced by taking gastric retention, stomach fluid is pumped out via the nasogastric tube.

The ventilation practitioner checks the patient's vital values on the display, from outside the room while the patient is sleeping. The displays are positioned towards the glass door.

VENTILATION PRACTITIONER

The intensivist practitioner cleans the patient face and requests the assistant to get the vaseline and eye ointment to take care of the dry areas caused by the NIV intervention.

INTENSIVIST PRACTITIONERS

ASSISTANT

Monitoring vitals

Mask displacement PEEP Alarm

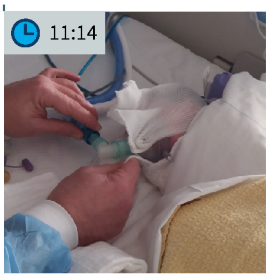
Evaluating skin irritation

Patient-ventilator asynchrony

11:00

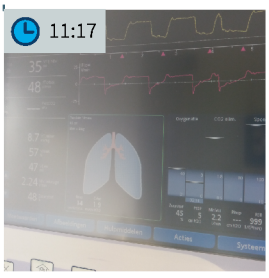
The mother leaves the room to eat something. The room is cleaned and supplies are filled.

MOTHER



PEEP alarms go off because the mask has moved off the patient's face caused by body movement. The mother is watching the repositioning of the mask next to the bed.

INTENSIVIST PRACTITIONERS



The patient is calm, but there is still asynchrony between the patient and ventilator. The air leakage varies between 30 and 70 %.

11:23

The ventilation tubes are repositioned; to reduce air leakage. But the air leakage is still too high, 90 %.

INTENSIVIST PRACTITIONERS

Repositioning ventilation tubes

System updating

11:23

The intensivist practitioner updates the patient's dossier. In the meantime the machine often gives alarms for a short period (frequency, and PEEP).

INTENSIVIST PRACTITIONERS

Evaluating skin irritation

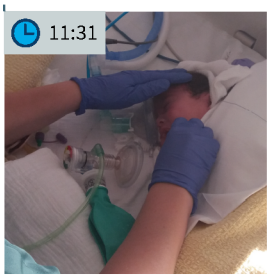
INTENSIVIST PRACTITIONERS

The patient becomes restless and starts moving. The ventilator gives another PEEP alarm. The intensivist practitioner takes the mask off, the face of the patient has red areas.

11:28

Alarms keep going off

11:31



Alarms keep going off, the frequency is too high. The practitioners discuss what to do. The ventilation practitioner searches the paediatrician intensivist to discuss.

INTENSIVIST PRACTITIONERS

VENTILATION PRACTITIONER

Visit physiotherapist

PHYSIO

The physiotherapist comes along, but let the patient rest. The air leakage is between 70 and 80 %.

11:32

11:54

The diaper of the patient is changed. In the meantime, the equipment for the CPAP is gathered. The intensivist practitioner and ventilation practitioner place the nasal mask.

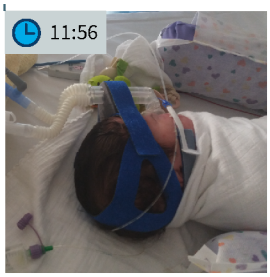
INTENSIVIST PRACTITIONERS

VENTILATION PRACTITIONER

Preparing CPAP

Starting CPAP

11:56



After placing the mask the intensivist practitioner sets the ventilator values. Hereafter the patient is swaddled. The mother is glad that she can make eye contact with her child.

INTENSIVIST PRACTITIONERS

VENTILATION PRACTITIONER

12:00

The bedside is folded down so that the mother can see her child while sitting on the side. The bed is cleaned up by removing all the packaging and equipment.

INTENSIVIST PRACTITIONERS

Cleaning up

12:00 - 13:10

The patient is calm; he has minimal body movement. The alarms go off a few times for a short period (frequency, and SPO2). In the meantime, the mother is alone with her child.

The NIV mask is taken off. The intensivist practitioner takes care of the dry areas by using the vaseline and eye ointment. Eyes are a bit swollen according to the mother.

INTENSIVIST PRACTITIONERS

MOTHER

The nasal mask size is determined by a transparent sizing sheet. The mask has to cover the whole nose of the patient.

INTENSIVIST PRACTITIONERS

Alarms keep going off

Preparing CPAP

Determining mask size

Determining headgear size

The practitioners prepare the nasal mask to provide CPAP. The ventilator is calibrated, and new flow sensors are installed.

INTENSIVIST PRACTITIONERS

VENTILATION PRACTITIONER

Head circumference is measured to determine the right headgear size. The headgear sizes are suitable for a range of head circumferences.

INTENSIVIST PRACTITIONERS

INTENSIVIST PRACTITIONERS

A blood test is taken to determine the O2 and CO2 values in the blood, to evaluate the treatment progression.

13:30

MOTHER & FATHER

PAEDIATRICIAN INTENSIVIST

FELLOW

The RS virus is diagnosed and it is hard to say if the patient has overcome the virus. During the night the patient will be ventilated, and the next day the patient will be weaned from ventilation.

14:01

The intensivist practitioner is looking for a nasal prong to replace the nasal mask. The available nasal prongs are too big, the assistant is asked to call the Neonatal Care Unit.

INTENSIVIST PRACTITIONERS

ASSISTANT

Blood test

Consultation with parents

Determining mask size

Sleeping patient

Preparing nasal prong

END OBSERVATION

14:00

The father and sibling of the patient join the room. The paediatrician intensivist and the fellow evaluate the treatment with the family.

MOTHER & FATHER

PAEDIATRICIAN INTENSIVIST

FELLOW

The physicians leave the room and the caregivers shortly after. The patient is lying calmly in the room.

14:30 - 16:00

The patient is sleeping quietly, sometimes the alarm goes off (frequency too high). The patient is alone in the room.

1.7 Conclusion

The biggest challenge of NIV is choosing a non-vented NIV mask that has minimal air leakage and offers maximal comfort for the patient. The commercially available non-vented NIV masks for the PICU is limited. NIV masks often do not match the exact facial features of the patient. Resulting often in too much air leakage, which can cause patient-ventilator asynchrony and can lead to NIV failure. The patient should feel comfortable, because fighting against the intervention will cause exhaustion.

The patients can be categorised in two groups: patients with acute problems and patients with chronic problems. Based on this patient categorisation NIV can be divided into three different phases;

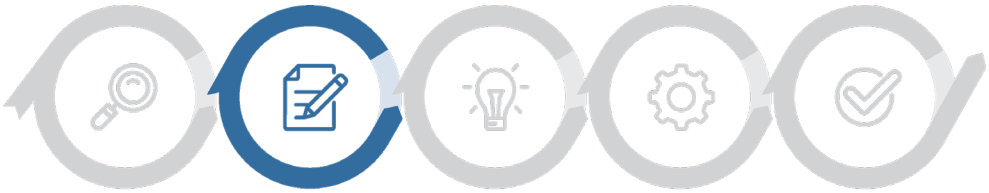
- In the first phase, a NIV mask should be available immediately for patients with acute respiratory failure.
- The second phase is applicable if patients require a longer NIV-period, at least longer than 48 hours. In practice, do patients with respiratory tract infections typically require a longer period of NIV, approximately two weeks.
- The third phase is applicable if patients require more than a few weeks of ventilation. This applies to chronic patients.

The datasets of Goto et al. (2019) and the possibility to construct enriched statistical shape models with DINED offer opportunities to: to determine the dimensions of a new NIV mask, and develop sizing groups.

Production of tailored NIV masks for children with the aid of 3D scanning and printing techniques is promising. The ideal 3D scanner to capture the anthropometric data of patient's face at the PICU is a portable photogrammetry scanner, because the capture speed is almost instant. However based on the current state of technology is a structured light scanner the best option. The tailored NIV masks can be produced with different 3D printing techniques. There are many hard polymer 3D print materials, 3D printing with soft materials like silicone is possible, but relatively new.

The rules for custom medical devices, like a tailored NIV mask, are in a transitional period. After 25 May 2020 the new rules apply; regulation (EU) 2017/745 (European Commission, 2018). According to the new rules the tailored NIV mask is considered mass-produced. Therefore the producer has to build a Quality Management System and a Technical File for each produced tailored NIV mask.

2
Project definition



In this chapter is determined what for NIV mask has to be designed. Firstly, the problem definition is defined, what is the problem that needs to be solved, and what is the focus of this project. Secondly, the target group of the new NIV mask is determined, who are the intended users of the new NIV mask. Thirdly, the type of mask is selected. Fourthly, a design vision is created, which covers the question what the future scenario at the PICU should look like. Fifthly, all the design objectives, the requirement and wishes of the new NIV mask, are captured in the list of requirements. Finally, a conclusion for the development of the new NIV mask is drawn which is used for the next phase, the Design Process (chapter 3).

2.1 Problem definition

The largest challenge of NIV for paediatric care is choosing an well-fitting non-vented NIV mask. Non-vented is required in the acute setting, because it gives full control over both inhalation and exhalation. The standard non-vented NIV masks mostly do not fit well on young patients. At the PICU of Amsterdam UMC are anaesthesia masks used, because the available non-vented NIV masks for children are limited. However these masks are not optimal, and often have too much air leakage, see Figure 22.

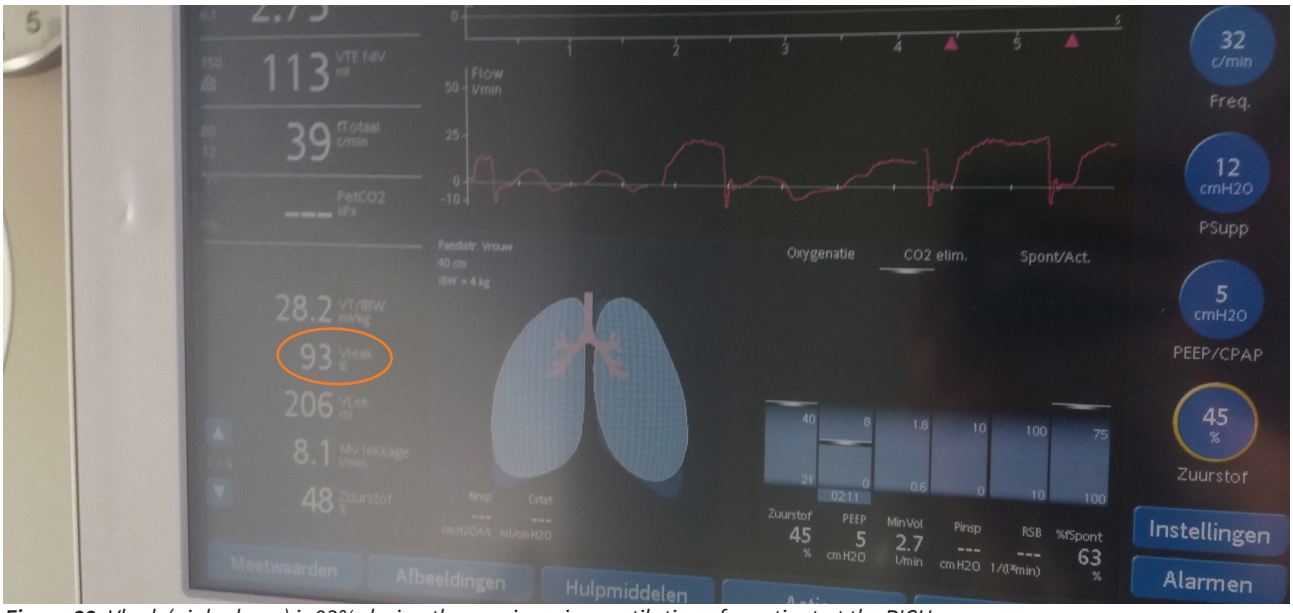


Figure 22. *Vleak (air leakage) is 93% during the non-invasive ventilation of a patient at the PICU.*

The core problem of NIV at the PICU is unintentional air leakage of the NIV mask. This can lead to NIV failure and increase the risk of other complications such as: nasal symptoms, and eye injuries. Tightening of the headgear of the mask can reduce air leakage. However this increases the risk of skin injury, and therefore should overtightening of the headgear be prevented. NIV can be improved if the air leakage of the NIV mask is reduced. Therefore is the focus of this project reducing the air leakage of the NIV mask by increasing the fit. In the next paragraph is defined for which patients the new NIV mask will be developed.

2.2 Target group

The target group for the NIV mask is defined as all admitted patients in the PICU younger than seven years who require NIV for a longer period (more than 48 hours). The target group include patients that: start immediately with NIV, start with invasive ventilation and shift to NIV to early wean of intubation, that are already weaned but require NIV to prevent re-intubation.

Figure 23. *Patient at the PICU non-invasive ventilated with an anaesthesia mask (observation).*

For patients youngest patients at the PICU (below one year old) are no non-vented NIV masks commercially available. At Amsterdam UMC anaesthesia masks are used for this group, see Figure 23. For older patients, below seven year old, are standard NIV masks available, but in practice do these often do not fit well. For patients older than seven years are more non-vented NIV masks commercially available (small adult masks). Although, these patients also could benefit from a tailored NIV mask, they might be included if the new NIV mask is proven to be more effective than standard NIV masks.

2.3 Type of Mask

In the analysis many types of masks were identified. The new tailored NIV mask will be non-vented. The non-vented masks are: the oronasal mask, the total face mask, and the helmet. Based on three criteria are the non-vented masks compared (see Table 5), and is decided to focus on an oronasal mask.

The selection criteria are the most important wishes of the NIV mask:

1. The NIV masks should be as effective as possible;
2. The risk for skin injury of the NIV mask should be as low as possible;
3. The NIV mask should be as non-intrusive as possible.

The oronasal mask is most effective, because it has the smallest dead volume, decreasing the risk for CO2-rebreathing. Also is the mask less intrusive than the other non-vented masks because it only covers the nose and mouth of the patient. The mask has a higher risk for skin injury because it makes contact with the most vulnerable area; the nasal bridge. However the new NIV mask will be tailored, which can reduce skin injury. Fauroux et al. (2005) showed that skin injury can be reduced by tailoring, in this study commercially nasal masks were replaced by tailored ones. Discomfort level of oronasal masks were reduced in the study of Shikama et al. (2018), by placing tailored element in between the mask and the face.

The main advantage of the helmet is a low risk for skin injury because there is no contact with the patient's face. But the helmet is: less effective than the other two non-vented masks, makes the caregiving hard, and is intrusive for the patient. The mask is less effective than the other non-vented mask because it has a large dead volume, which increases the risk of CO2-rebreathing. The caregiving for the practitioners is hard because the helmet makes the patient's face unreachable. For patients is the helmet intrusive and uncomfortable because it covers the whole head of the patient, they experience a lot of noise (Mortamet et al., 2017).

The total face mask also has a lower risk for skin injury than the oronasal face mask because the contact area is larger and there is no contact with the

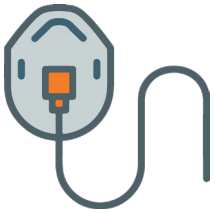
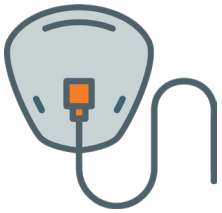
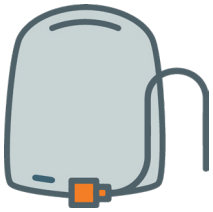
TYPE	ORONASAL MASK	TOTAL FACE MASK	HELMET
			
1 Effectiveness	+ Small dead space	- Big dead space	- Huge dead space
2 Skin injury	- Nasal bridge connection	+ Big surface area	+ No facial contact
3 Intrusiveness	+ Only cover nose and mouth	- Cover the whole face	- Cover the whole head

Table 5. *Comparison between the three different types of non-vented masks.*

nasal bridge. But the total face mask is: less effective, and more intrusive than the oronasal mask. The total face mask has a larger dead volume compared with the oronasal mask. The total face is more intrusive because it covers the whole face, increasing the risk of claustrophobia. The patients view can get blocked in the total face mask fogs up. Also is the total face mask is a more restrictive in body- and sleeping positions.

Although this project focuses on an oronasal mask, this will not be the ideal type of mask for all patients. Bahammam et al (2018) concludes that there is no universally ideal type of NIV mask, the choice of type of mask also depends on the patient's preferences. For the oronasal masks is the ideal mask described by Mortamet et al. (2017), the ideal oronasal mask is: small with a minimal dead volume, causes minimal air leaks, light-weight, easy to fit and remove, nontraumatic, manufactured with non-allergenic materials, inexpensive, comfortable, and have a well-adopted headgear. These characteristics are included in the List of Requirements in paragraph 2.5.

2.4 Design vision

The design vision in Figure 24 is my view of the future of NIV at the PICU. There is a second team besides the medical team, the technical team. They use 3D scanning and printing techniques to improve NIV. With the aid of these techniques ideal NIV masks are produced for patients. Ideal masks have to potential to decrease the amount of intubated patients, decrease the length of intubation, prevent reintubation, improve the effectiveness of NIV, decrease the hospital stay, and increase the patient's comfort.

The medical team of the PICU, provides care to the patients. When the patient is admitted to the PICU, a treatment plan is made for that patient during the multidisciplinary meeting of the medical team. Based on the patient's situation is a decided by the paediatric intensivist and ventilation practitioner if a tailored NIV is needed. Different masks are used based on the treatment plan. An acute mask is used if there is started with NIV directly, phase 1 in Figure 24. An ideal mask is produced if patients situation requires extended NIV (longer than 48 hours), phase 2 in Figure 24. After the production of the ideal the mask, which takes approximately 24 hour, the acute mask is be replaced or in the case of intubation there can be weaned of invasive ventilation. Patients that require chronic NIV, can also use the ideal mask for ventilation at home, phase 3 in Figure 24. The feedback gained from the after care clinic will be used for further optimisation of the NIV.

The technical team is in charge of the production of tailored NIV masks. The technical team is located in the hospital. The team can be quickly in the PICU for 3D scanning the patient, and 3D printing at the hospital reduces transportation time. The technical team will make the PICU less dependent on external parties. For the production, first, the patient's face is 3D scanned at the PICU by a technician of the production team. This 3D scan is uploaded to a software programme that creates an ideal fitting NIV mask. Next the ideal fitting NIV mask is produced. The technician uploads the ideal NIV mask to the 3D printer. After the 3D print is finished, the mask is brought to the PICU.

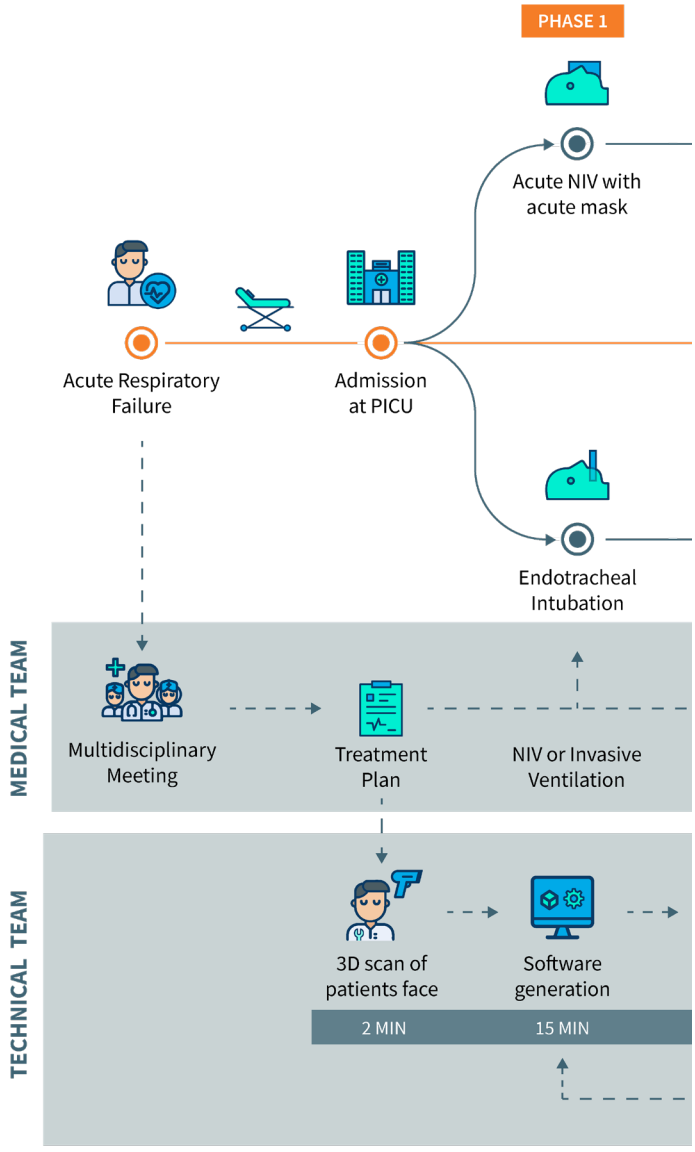
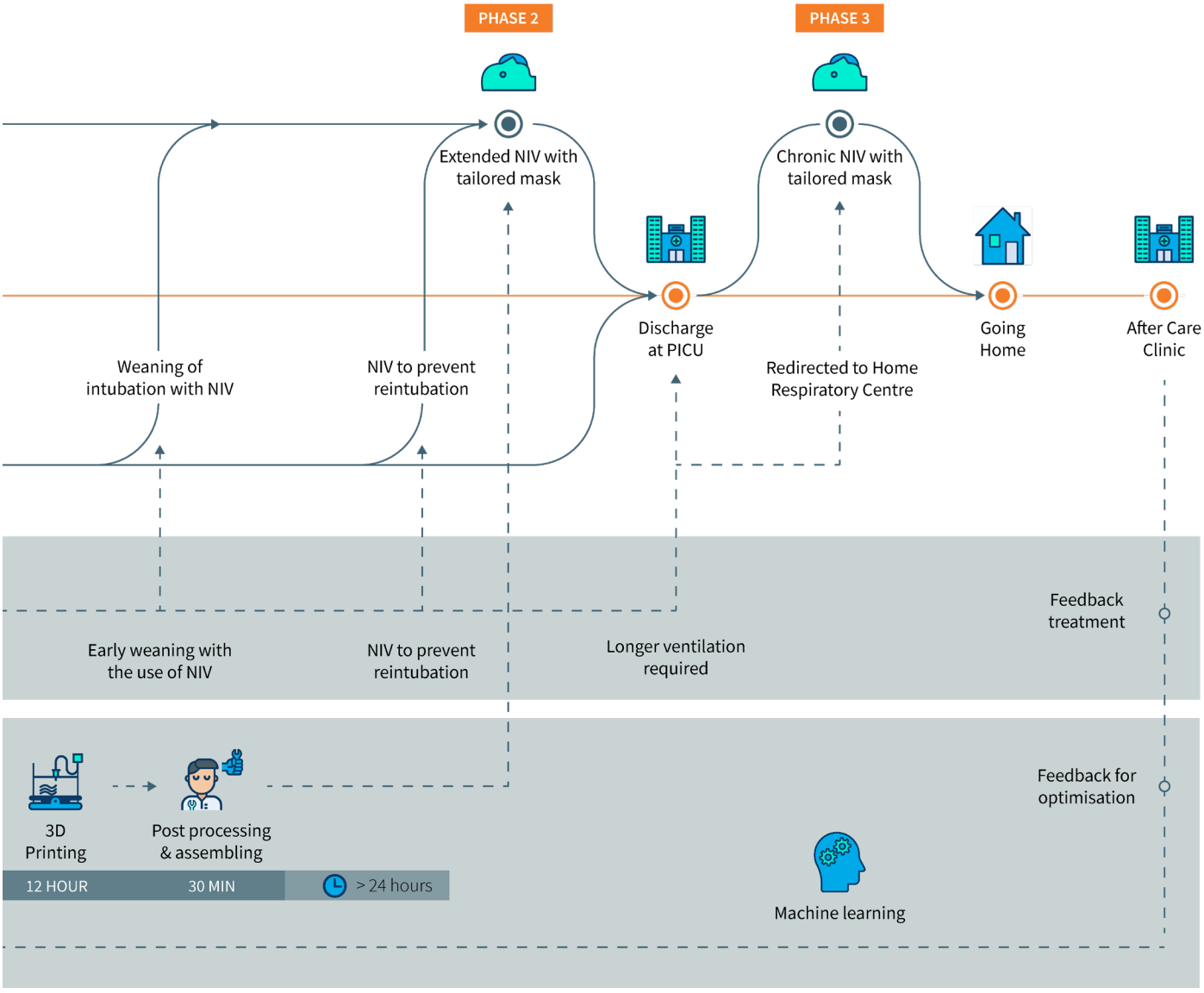


Figure 24. *Design Vision of the patient journey at the PICU.*


PHASE 2
PHASE 3
Extended NIV with tailored mask
Chronic NIV with tailored mask
Weaning of intubation with NIV
NIV to prevent reintubation
Discharge at PICU
Redirected to Home Respiratory Centre
Going Home
After Care Clinic
Feedback treatment
Early weaning with the use of NIV
NIV to prevent reintubation
Longer ventilation required
Feedback for optimisation
3D Printing
Post processing & assembling
12 HOUR
30 MIN
> 24 hours
Machine learning

2.5 List of Requirements

The list of requirements describes all the design objectives of the new NIV mask, and what is beneficial for the new NIV mask. The list is based on the analysis and Pugh's checklist (Pugh, 1991).

Performance

- The tailored mask has to reduce air leakage in comparison with the currently used NIV masks for children below seven year old. This gives the new NIV mask right to exist. (Problem definition)
- The mask has to be non-vented (cover both the mouth and the nose of the patient) to prevent air leakage through the mouth or nose. (Type of masks)
- The mask has to decrease the risk for skin injury, compared to standard NIV masks that are currently used for children below seven year old. This gives the new NIV mask right to exist. (Problem definition)

Production

- The material used in the new NIV mask has to meet ISO 10993-1; the material has to be tested for cytotoxicity, sensitization, and irritation. (Rules and regulations)
- 3D scanning of the patient's countenance has to fit into the workflow of the PICU. (Design vision)
- The headgear has to be available in sizes to fit the target group of 0-7 year old patients. (Target group)
- The new NIV mask has to have an inlet with a diameter of 10 mm for children below 10 kg, to fit the standard ventilation tubes. (NIV in practice)
- The new NIV mask has to have an inlet with a diameter of 22 mm for children above 10 kg, to fit the standard ventilation tubes. (NIV in practice)

Usage

- The intensivist practitioners has to be educated about the new NIV mask. Including how the mask is produced, assembled, and positioned. (Stakeholders)
- The headgear has to be easy to fit and remove, and offer stability. (Type of mask)
- The mask has to have a quick release system, and be removable within two seconds. Mainly to reduce the risk of aspiration. (NIV in practice)
- The NIV mask has to be repositioned by the intensivist practitioner if there is air leakage above 90%, to prevent patient-ventilator asynchrony. (NIV in practice)

Stock

- All the sizes of masks has to be in supply at the PICU, and have an easy sizing system to sort them in storage. So the NIV equipment can be quickly gathered. (Pugh)

Safety

- The mask has to be transparent, mainly for monitoring the patient. (NIV in practice)
- The straps of the headgear should not be overtightened (to prevent air leakage) because this increases the risk for skin injury. (NIV related problems)
- The patient's progression with NIV should be evaluated every hour, if there is no progression in the critical condition NIV has to be aborted and invasive ventilation has to be used. (NIV in practice)
- The mask has to have minimal air leakage around the nose, to prevent conjunctivitis. (NIV related problems)

Regulations

- A Quality Management System has to be made for the new tailored NIV mask. (Rules and regulations)
- Each produced tailored NIV mask has to have a Technical File. (Rules and regulations)

Maintenance

- The mask has to be daily cleaned by the Intensivist Practitioner with cleaning napkins. (NIV in practice)
- The masks has to disinfected with alcohol if the patient throws up in the mask. (Pugh)
- The headgear has to be hand washable, to reduce the amount of disposed headgears. (Pugh)

Wishes

Performance

- The NIV masks should be as effective as possible. The mask should leak a minimum of air, however some leakage is necessary to prevent CO2 rebreathing, so the air leakage should be above 0%. (NIV related problems)
- The mask should be as small as possible with a minimum dead space for the most effective ventilation. (Type of mask)

Production

- The manufacturing of the tailored NIV mask should be as fast as possible, to make the tailored NIV mask as soon as possible ready for use. (Design vision)
- The 3D scanning of the patient's countenance should be as fast and non-disturbing possible. (Production possibilites)

Usage

- The risk for skin injury of the NIV mask should be as low as possible. (Type of mask)
- The NIV mask should be as non-intrusive as possible. (Type of mask)
- The NIV masks are used in combination with the nasogastric tubes and should reduce the air leakage caused by the gap between the NIV mask and the nasogastric tube. (NIV in practice)
- The NIV mask should also be compatible for single limb circuit ventilators, which is used to walk around in the hospital or for home ventilation. The mask should be configurable into a vented mask. (Ventilators)
- The mask should have as much tailoring freedom in shape as possible. So it is possible to tailor fit patients which differ from the norm, which have facial deformations or abnormalities. (Pugh)
- The nasal bridge, which is one of the most vulnerable areas of contact points between the face and NIV face mask should be relieved in pressure. (NIV related problems)
- The new NIV mask should reduce air leakage around the nose, to prevent eye injuries such as conjunctivitis. (NIV related problems)
- The NIV mask should be as small and light as possible. (Type of mask)
- The NIV mask should be compatible with glasses. (Type of masks)
- There should be a variety of different type of masks at the PICU, to alternate masks. (NIV related problems)
- The mask might be used in the MRI scanner, therefore the NIV mask must not contain any metal. (NIV in practice)

Costs

- The NIV mask should be as inexpensive as possible. (Type of mask)

Recycling

- The parts and materials of the NIV mask should be recyclable and easy to separate. (Pugh)

2.6 Conclusion

The main problem of NIV for the PICU is unintentional air leakage, because this increases the risk of NIV failure and other discomfort. Therefore the main focus of this project is reducing unintentionally air leakage by increasing the fit of the new NIV mask.

The target group consists of all admitted patients at the PICU below seven years old who require NIV for a longer period; at least more than 48 hours. For patients older than seven years old there are more masks available.

An oronasal mask will be developed, because: it is most effective and least intrusive. This type of mask has a small dead volume and therefore is it more effective than the other non-vented masks. It is less intrusive, because it only covers the nose and mouth.

In my design vision are 3D scanning and printing techniques used within hospitals. With the aid of these techniques production of ideal NIV masks are realised. The medical team makes an treatment plan. For the acute first phase an acute NIV mask will be used. If patients require NIV for an extended time, the second phase, an ideal NIV mask is developed. The technical team, located in the hospital, will be in charge of the production of the ideal NIV mask. The tasks of the technical team include: 3D scanning the patient's countenance, creating an ideal NIV mask with a software programme based on the 3D scan, and 3D printing of the ideal NIV mask.

Most important requirements:

- The mask has to cover both the mouth and the nose of the patient, to be non-vented.
- The material has to be biocompatible and non-toxic for safety.
- The mask has to have an inlet tube with a diameter of 10 mm for children below 10 kg and 22 mm for children above 10 kg.
- The mask has to have a quick release system, mainly to reduce the risk of aspiration.
- The mask has to be transparent, mainly for monitoring the patient.
- There has to be an easy number system to differentiate the different sizes.

Most important wishes:

- The masks should be as effective as possible, and leak a minimum of air. However some leakage is necessary to prevent CO2 rebreathing, so the air leakage should be above 0%.
- The mask should reduce the air leakage caused by the gap between the mask and the nasogastric tube.
- The risk for skin injury of the NIV mask should be as low as possible.
- The mask should be as small as possible with a minimum dead volume for the most effective ventilation.
- The manufacturing of the tailored mask should be as fast as possible.
- The mask should be as light as possible, to prevent pressure points of the mask on the face.
- The NIV mask should be as inexpensive as possible.

3
Design Process

In this chapter the development of new NIV masks is described. Firstly, ideas are generated by brainstorming with How-tos. How-tos are questions that capture problem statements that support idea generation (Tassoull, 2007). Secondly, combining promising solutions of the How-tos leads to four ideas that have been developed in four concepts: the Flexible Mask, the Modular Mask, the Quick Curable Mask, and the Deformable Mask. Thirdly, the effectiveness of the concept masks, in terms of the amount of air leakage and contact pressure, is tested with prototypes. These prototypes are tested on a reanimation mannequin with a ventilator. Finally, conclusions are drawn and two concepts are selected based on the results of the simulation and wishes of the programme of requirements. The selected concepts are further developed into a proposal, the final design (chapter 4).

3.1 Brainstorm

The following problem statement questions have been generated:

- How-to prevent the gap between the nasogastric tube and the mask?
- How-to connect the face mask to the patient's face?
- How-to make the NIV mask quickly releasable?
- How-to make the skin contact more comfortable for the patient?
- How-to configure the non-vented mask in a vented mask?
- How-to connect the ventilator tube to the mask?
- How-to shape the mask to the patient's face?
- How-to cover both the nose and mouth of the patient?
- How-to connect the inner part with the outer part of the mask?

A example of the How-tos can be seen in Figure 25, see Appendix L for the full brainstorm. Four directions are created by combining promising sub solutions of the brainstorm, see Appendix M. The four ideas are further developed into four concepts. The four developed concepts can be categorised into two categories based on the approach of tailoring: tailor-made production, and manually tailoring. The Flexible Mask and the Modular Mask are tailor-made during production. The Quick Curing Mask and Deformable Mask are manually tailored at the PICU.

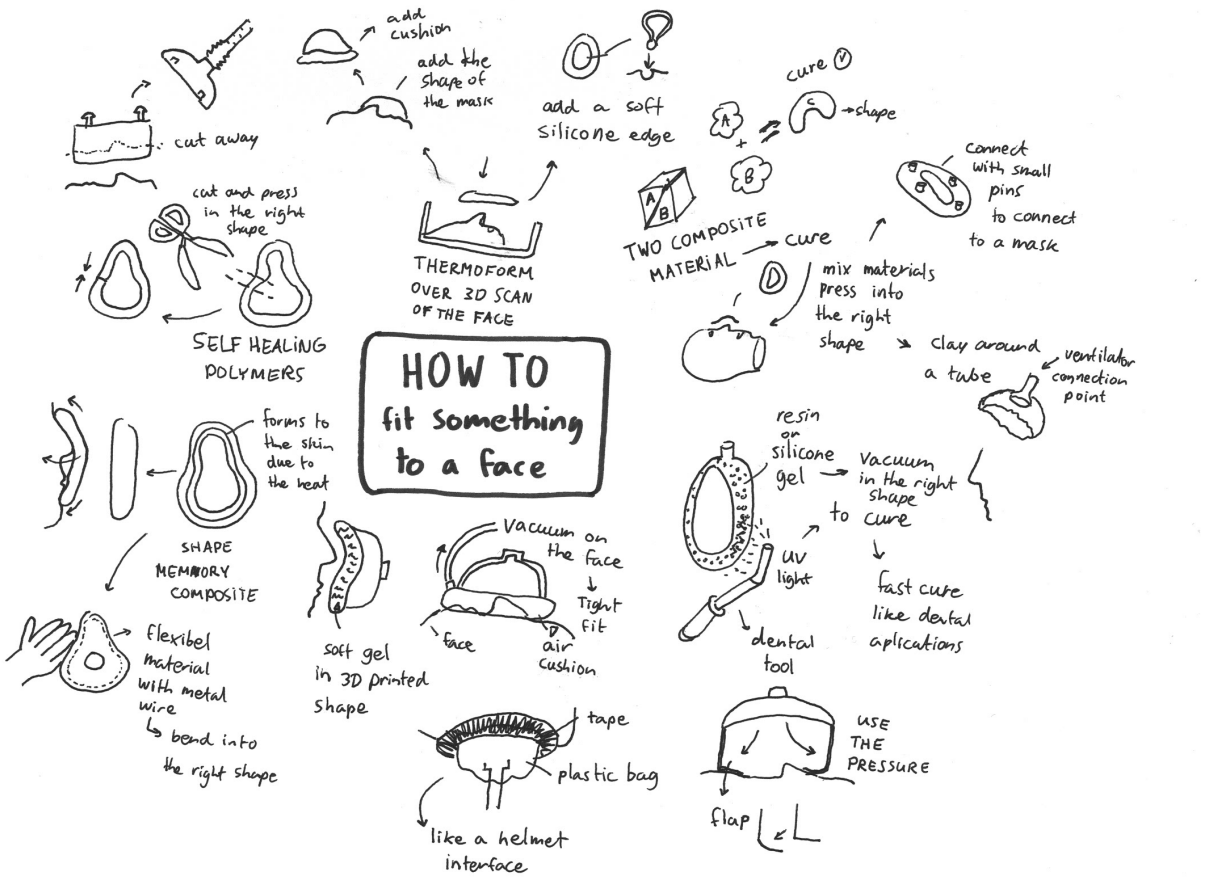


Figure 25. *How to fit something to a face.*

3.2 Concept 1: Flexible Mask

The first concept is called the Flexible Mask. The mask is made out of flexible material, see Figure 26. The Flexible Mask is tailor-made during production. This mask is aimed for extended NIV usage (phase 2), the mask is not suited for acute NIV since the production with 3D printing takes relatively long.

3.2.1 Advantages and disadvantages

The main advantage of this concept is its flexibility. This mask can easily adjust to the movement of the face (e.g. when coughing or speaking) since the mask is very flexible. The disadvantage is that the cushion has to be fully tailored-made, resulting in relatively long production time (large 3D print).

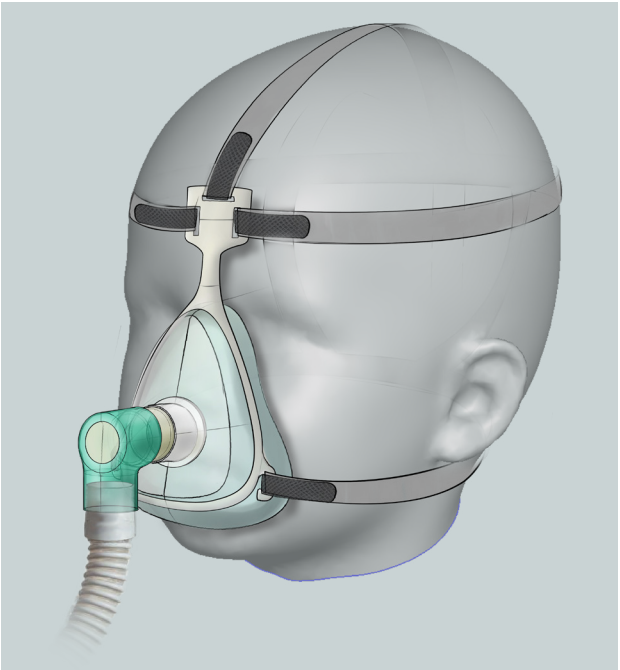


Figure 26. *The Flexible Mask.*

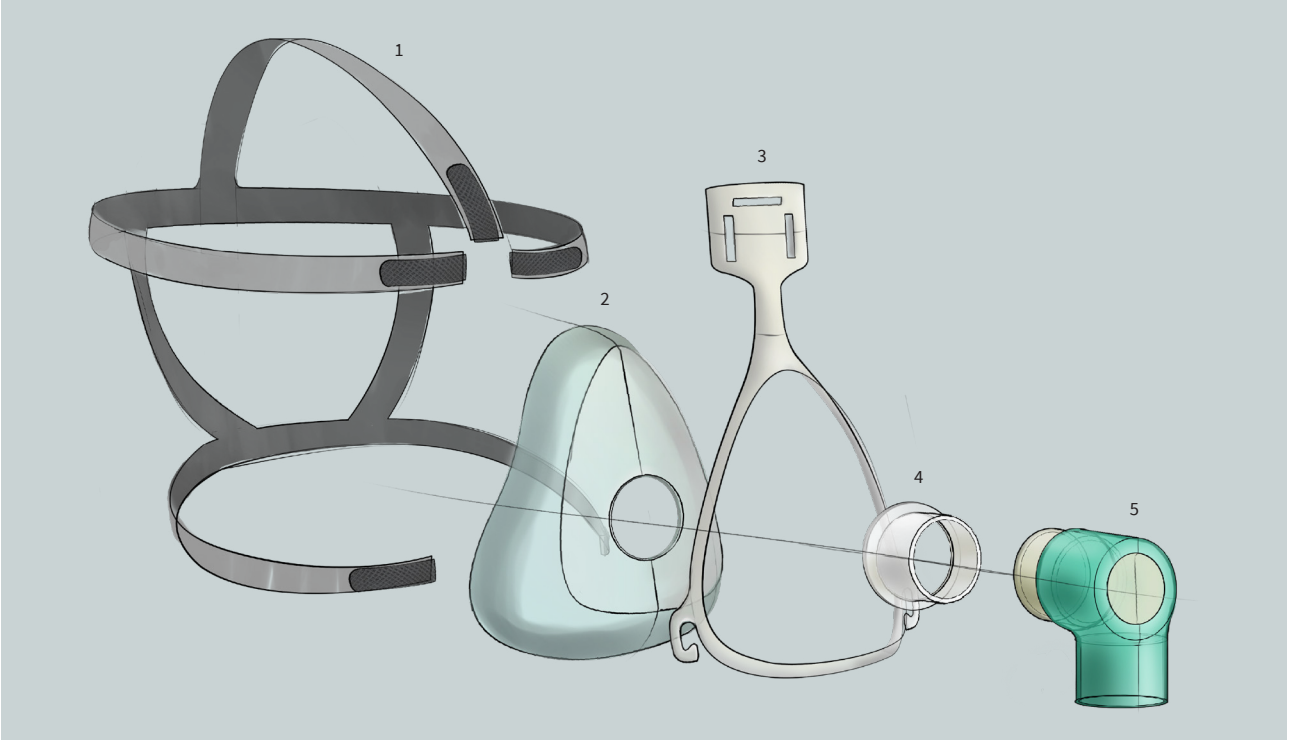


Figure 27. *Parts of the Flexible Mask, (1) headgear, (2) cushion, (3) holder, (4) inlet, and (5) swivel.*

3.2.2 Parts

The concept consists of the following parts: headgear, cushion, holder, inlet, and the swivel (see Figure 27):

1. The headgear is used to fixate the mask on the face and makes it possible to adjust the position and clamping force. The headgear has a fit within clusters, so it is available in multiple sizes.
2. The cushion is a transparent part that seals the mask with the skin. The cushion has an individual fit, so it is tailor-produced. First, the holder and inlet were integrated into the flexible cushion. However during prototyping (see Appendix P) is concluded that flexible material did not function well, the holder and inlet were made into separate stiff parts.
3. The holder is connected between the headgear and mask and holds the mask into the right position. The holder has a fit within clusters, so is available in multiple sizes.
4. The inlet is used to easily connect the swivel. The inlet has a fit within clusters, it is available in two sizes.
5. The swivel makes it possible to rotate the ventilator tube, which decreases the friction of the tube during body moment. The swivel has a collective fit, it is available in one size.

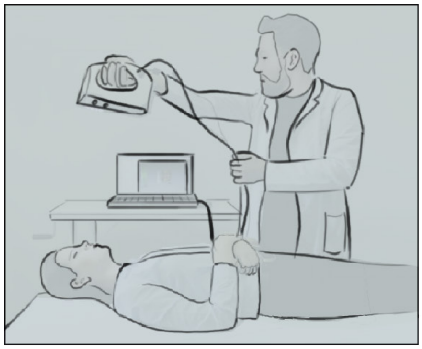
3.2.3 Production

For the production of the cushion, the patient's countenance has firstly to be scanned with a 3D scanner. Hereafter the tailored mask will be produced.

1. The headgear is cut and sewed of Neoprene. This part could be a buy-in part, this mostly depends on the developer of the mask. In the case that Amsterdam UMC would produce this concept, I suggest the headgear to be a buy-in part since the hospital does not have the facilities for the production of the headgear. If a company would produce this concept, I suggest producing the headgear, because the buy-in headgears are expensive.
2. The cushion is 3D printed with silicone. The cushion can also be casted in a 3D printed mould. However, casting requires extra labour steps and is therefore not the first choice. Casting labour steps include 3D printing moulds, mixing the silicone, casting the silicone, and removing the mould after the silicone is cured. However, 3D printing silicone is relatively new and it might not be possible jet to print the cushion directly.
3. The holder is 3D printed of ISO-PC, and is produced with the available 3D printers at Amsterdam UMC.
4. The inlet is also 3D printed of ISO-PC.
5. The swivel is a buy-in part. The rotational part is not integrated in the concept to decrease the complexity of production and assembly and therefore to reduce costs.

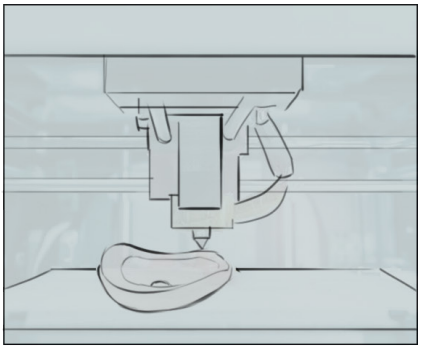
3.2.4 Storyboard

The scenario in Figure 28 describes how the Flexible Mask is used.



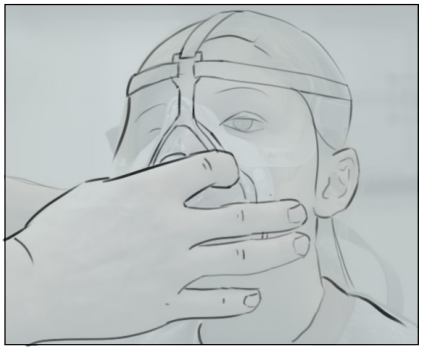
3D scanning the patient's countenance with a handheld scanner

Generating the optimal fit for the cushion with a software programme



Starting the production of the tailored cushion

Assembling of the mask by using the tailored cushion and the other stock parts



(Re)placing the tailored mask on the patients face and start the ventilation

Figure 28. *Scenario of the Flexible Mask at the PICU.*

3.3 Concept 2: Modular Mask

The second concept is called the Modular Mask. The mask consists of separate modules, see Figure 29. The cushion of the Modular Mask is tailor-made during the production. This mask is aimed for extended NIV usage (phase 2), the mask is not suited for acute NIV since the production with 3D printing takes relatively long.

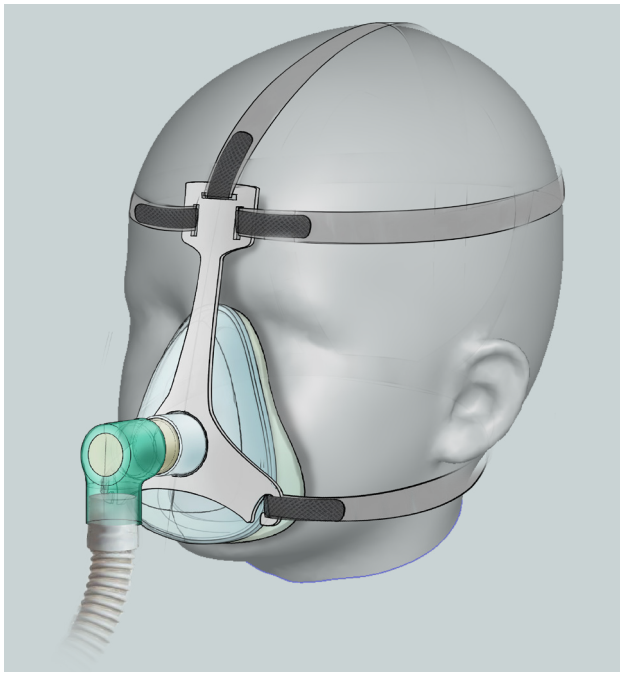


Figure 29. *The Modular Mask.*

3.3.1 Advantages and disadvantages

The main advantage of this concept is relatively fast production. The production of the tailored cushion is faster compared to the Flexible Mask because the tailored cushion is a lot smaller. Also is the frame stiffer which equally distributes the contact pressure (see chapter 3.6). The main disadvantage of this concept is the assemblage of multiple parts.

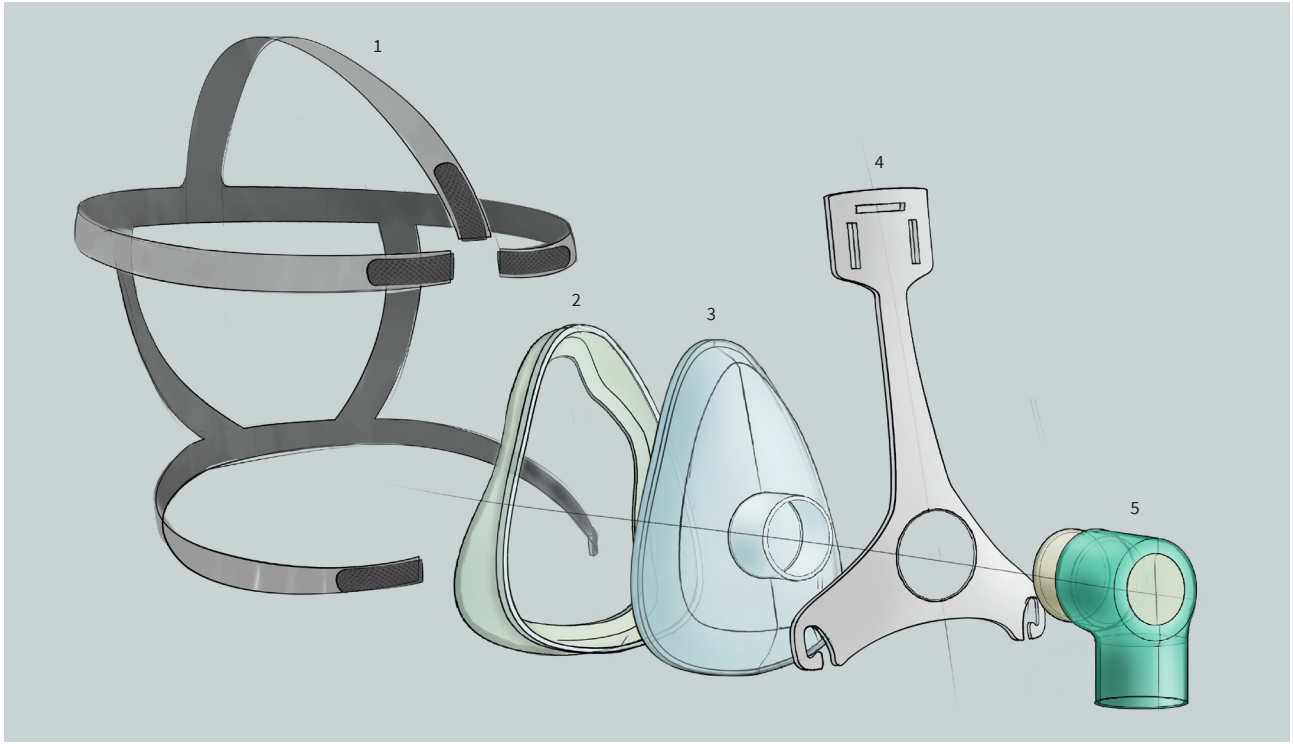


Figure 30. *Parts of the Modular Mask, (1) headgear, (2) cushion, (3) frame, (4) holder, and (5) swivel.*

3.3.2 Parts

The concept consists of the following parts: headgear, cushion, frame, holder, and the swivel (see Figure 30):

1. The headgear is used to fixate the mask on the face and makes it possible to adjust the position of the mask. The headgear has a fit within clusters, so it is available in multiple sizes.
2. The cushion seals the mask with the skin. The cushion has an individual fit, so it is tailor-produced.
3. The frame connects the cushion to the holder and has an inlet. The frame is transparent for safety reasons. The frame has a fit within clusters, so it is available in multiple sizes.
4. The holder connects the headgear and mask and holds the mask into the right position. The holder has a fit within clusters, so it is available in multiple sizes.
5. The swivel makes it possible to rotate the ventilator tube, which decreases the friction of the tube during body moment. The swivel has a collective fit, it is available in one size.

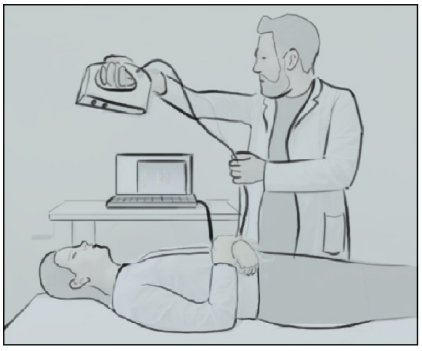
3.3.3 Production

The production of the Modular Mask is comparable to the production of the Flexible mask. First, the patient's countenance has to be scanned with a 3D scanner. Hereafter the tailored mask will be produced:

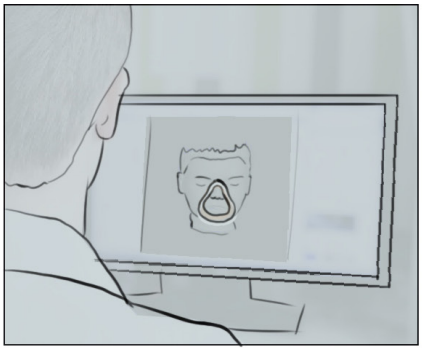
1. The headgear is cut and sewed of Neoprene. This part could be a buy-in part, this mostly depends on the developer of the mask. In the case that Amsterdam UMC would produce this concept, I suggest the headgear to be a buy-in part, since the hospital does not have the facilities for the production of the headgear. If a company would produce this concept, I suggest producing the headgear, because the buy-in headgears are expensive.
2. The cushion is 3D printed with silicone. The cushion can also be casted in a 3D printed mould. However, casting requires extra labour steps and is therefore not the first choice. Casting labour steps include 3D printing moulds, mixing the silicone, casting the silicone, and removing the mould after the silicone is cured. However, 3D printing silicone is relatively new and it might not be possible jet to print the cushion directly.
3. The frame is thermoformed of transparent PVC. Injection moulding requires expensive moulds, this can be beneficial for large batch sizes. Thermoforming, on the other hand, does not require high investment cost, so it could be used for small case testing. The thermoforming process is used at the radiotherapy department of Amsterdam UMC. Here are shells produced for radiation, see Appendix N. After thermoforming the mask, the plate has to be trimmed off.
4. The holder is 3D printed of ISO-PC, and is produced with the available 3D printers at Amsterdam UMC.
5. The swivel is injection moulded and is a buy-in part. The rotational part is not integrated into the concept to decrease the complexity of production and assembly and therefore to reduce the costs.

3.3.4 Storyboard

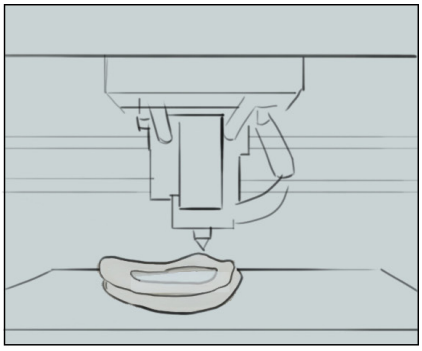
The scenario in Figure 31 describes how the Modular Mask is used.



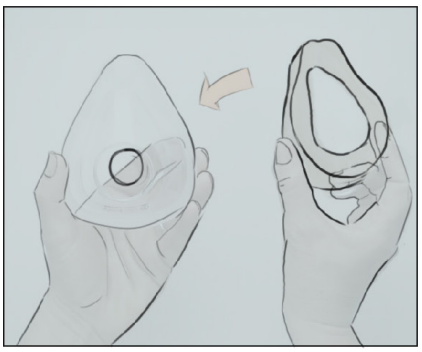
3D scanning the patient's countenance with a handheld scanner



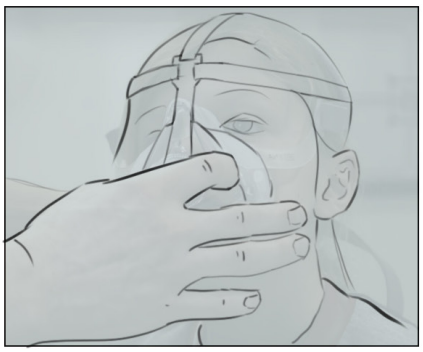
Generating the optimal fit for the cushion with a software programme



Starting the production of the tailored cushion



Assembling of the mask by using the tailored cushion and the other stock parts



(Re)placing the tailored mask on the patients face and start the ventilation

Figure 31. *Scenario of the Modular Mask at the PICU.*

3.4 Concept 3: Quick Curable Mask

The third concept is called the Quick Curable Mask, see Figure 32. The mask can be quickly tailored by letting material in the cushion cure. The mask is manually tailored in the PICU by the intensivist practitioner, that injects the cushion. This mask is aimed for acute NIV (phase 1) because the initiation of the mask is fast.

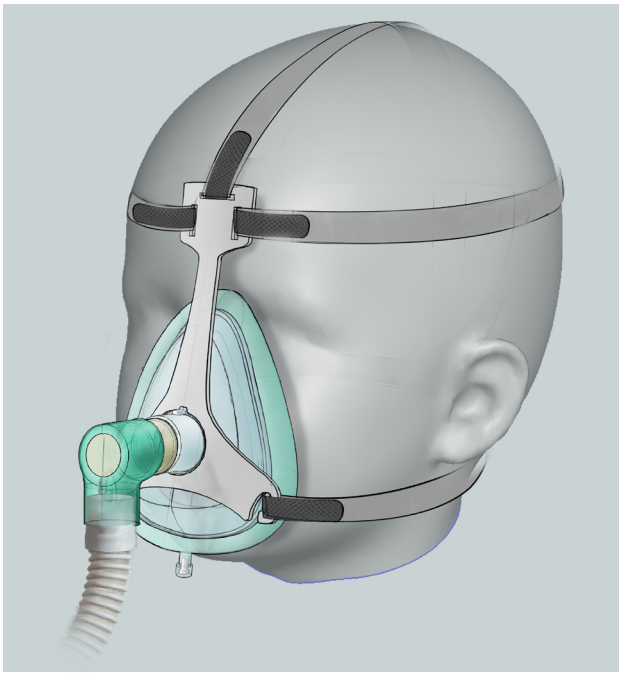


Figure 32. *The Quick Curable Mask.*

3.4.1 Advantages and disadvantages

The main advantage of the Quick Curable Mask is that the mask can be quickly tailor-made for patients who require acute NIV. All the parts of the mask are in the supply of the PICU because they are produced beforehand. Also, this concept is relatively easy to implement since anaesthesia masks are already used at hospitals. The main disadvantage is the extra labour for the practitioners, the tailoring of the mask.

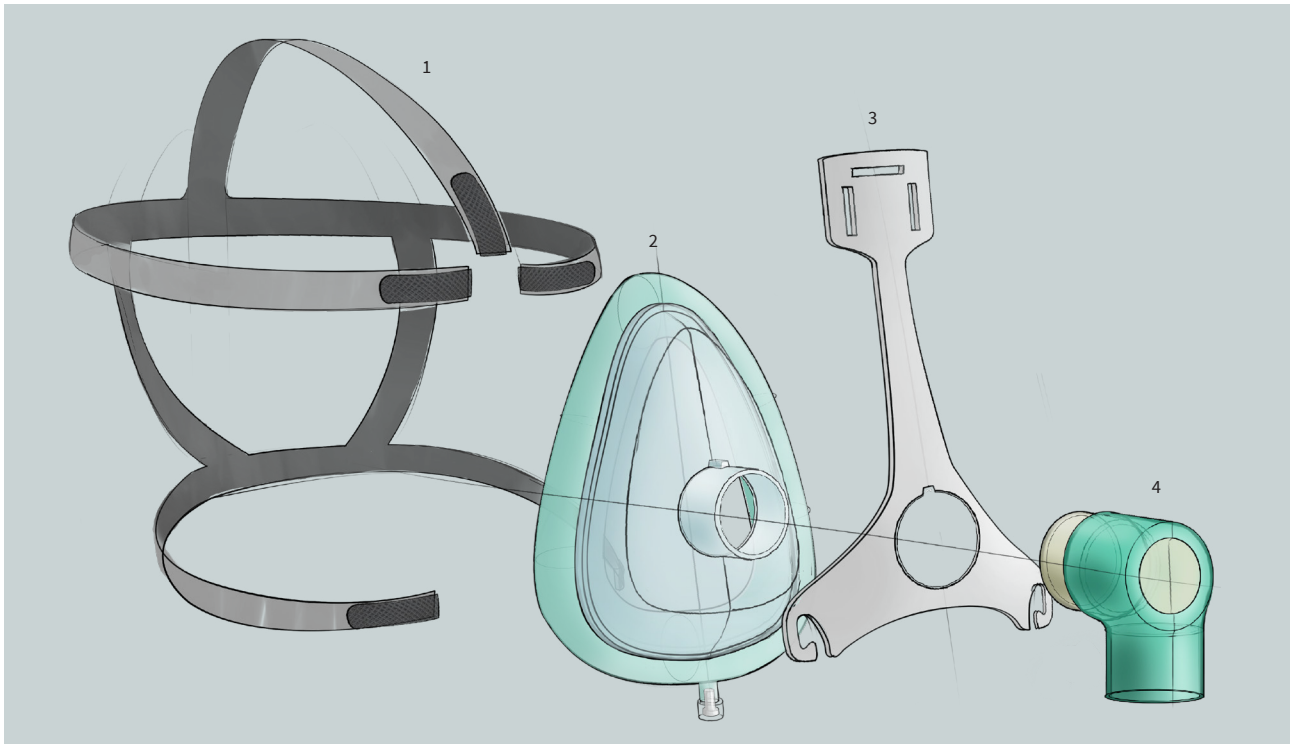


Figure 33. *Parts of the Quick Curable Mask, (1) headgear, (2) anaesthesia mask, (3) holder, and (4) swivel.*

3.4.2 Parts

The concept consists of the following parts: headgear, anaesthesia mask, holder, and swivel (see Figure 33):

1. The headgear is used to fixate the mask on the face and makes it possible to adjust the position and clamping force. The headgear has a fit within clusters, so it is available in multiple sizes.
2. The anaesthesia mask has a ventilator inlet and an inflatable cushion. The inflatable cushion is filled with silicone. The anaesthesia mask has a fit within clusters, so it is available in multiple sizes.
3. The holder is the connection between the headgear and mask and holds the mask into the right position. The holder has a fit within clusters, so it is available in multiple sizes.
4. The swivel makes it possible to rotate the ventilator tube, which decreases the friction of the tube during body moment. The swivel has a collective fit, it is available in one size.

3.4.3 Production

The mask is tailored to the patient by the intensivist practitioner in the PICU. The parts are produced beforehand are in the supply of the PICU.

1. The headgear is cut and sewed of Neoprene. This part could be a buy-in part, this mostly depends on the developer of the mask. In the case that Amsterdam UMC would produce this concept, I suggest the headgear to be a buy-in part, since the hospital does not have the facilities for the production of the headgear. If a company would produce this concept, I suggest producing the headgear, because the buy-in headgears are expensive.
2. The anaesthesia masks are buy in parts. For tailoring the masks at first the two components of the silicone are mixed in a cup. Mixing the two components will activate the curing process of the silicone. Secondly, the two mixed components are sucked into the syringe. Thirdly, the mask is filled with the syringe, see Figure 34. Fourthly, the mask is positioned on the patient's face. Lastly, the mixed components are cured over time; the liquid silicone mix will become solid.
3. The holder is 3D printed of ISO-PC, and is produced with the available 3D printers at Amsterdam UMC. The developed holder for the King mask by the Medical-Technical Innovation and Development department could be used. This mask uses small clips to connect the headgear with the holder.
4. The swivel is injection moulded and is a buy-in part. The rotational part is not integrated into the concept to decrease the complexity of production and assembly and therefore to reduce costs.

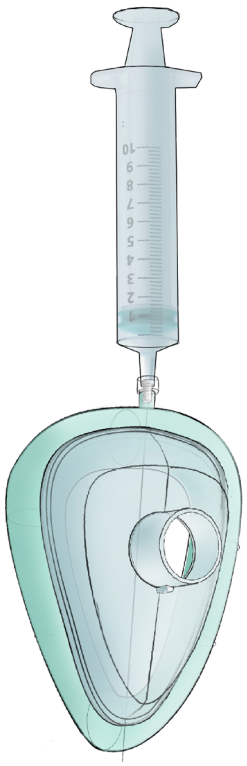
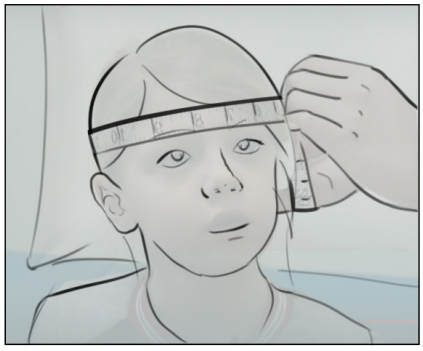


Figure 34. *Injecting the anaethesia mask.*

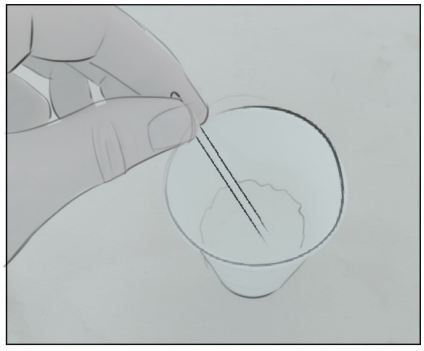
3.4.4 Storyboard

The scenario in Figure 35 describes how the Quick Curable Mask is used.

Determine the right size of the mask with the helping sheet

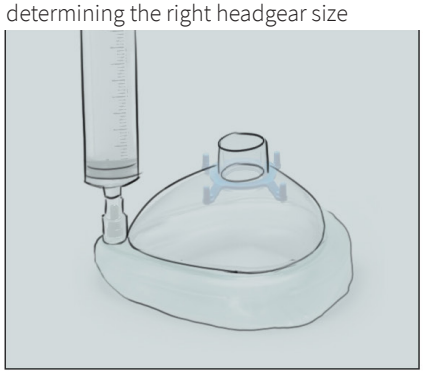


Measure the head circumference for determining the right headgear size

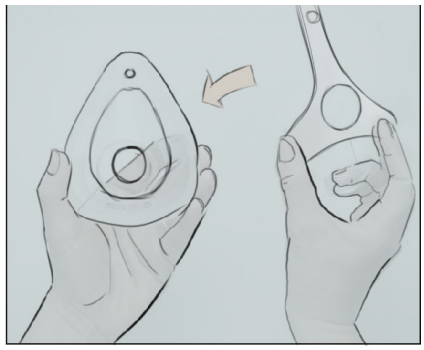


Mix the two silicone components is the ratio 1:1

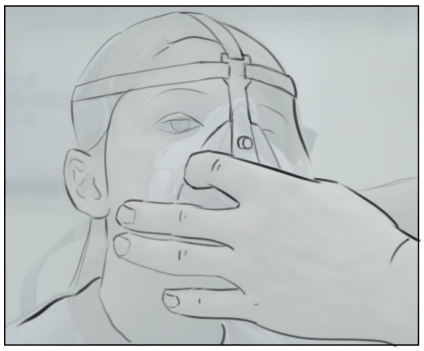
Press the syringe vacuum and pull to suck the silicone



Screw the syringe on the inlet and press the silicone in the cushion



Assembling of the tailored cushion with the other parts which are in stock



Placing the mask and let the silicone cure, hereafter start the ventilation

Figure 35. *Scenario of the Quick Curable Mask at the PICU.*

3.5 Concept 4: Deformable Mask

The fourth concept is called the Deformable Mask, see Figure 36. The material used in a part of this mask is deformable. The Deformable Mask is tailored by the intensivist practitioner that deforms the mask to the patient. This mask is aimed for acute NIV (phase 1) because the initiation is fast.

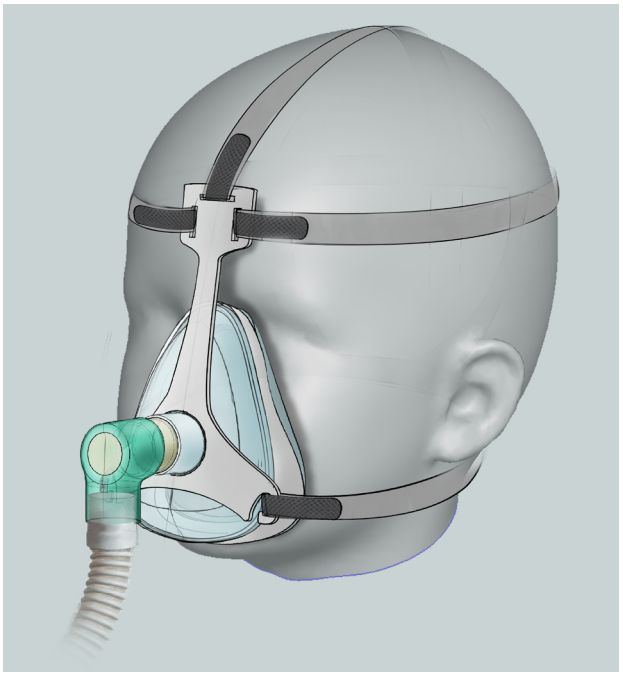


Figure 36. *The Deformable Mask.*

3.5.1 Advantages and disadvantages

The main advantage of the deformable mask is that the mask can be quickly tailor-made for patients that require acute NIV. All the parts of the mask are in the supply of the PICU because they are produced beforehand. Compared to the Quick Curable Mask this concept could be deformed multiple times. The main disadvantage is that the tailoring process of the mask is intrusive for the patients.

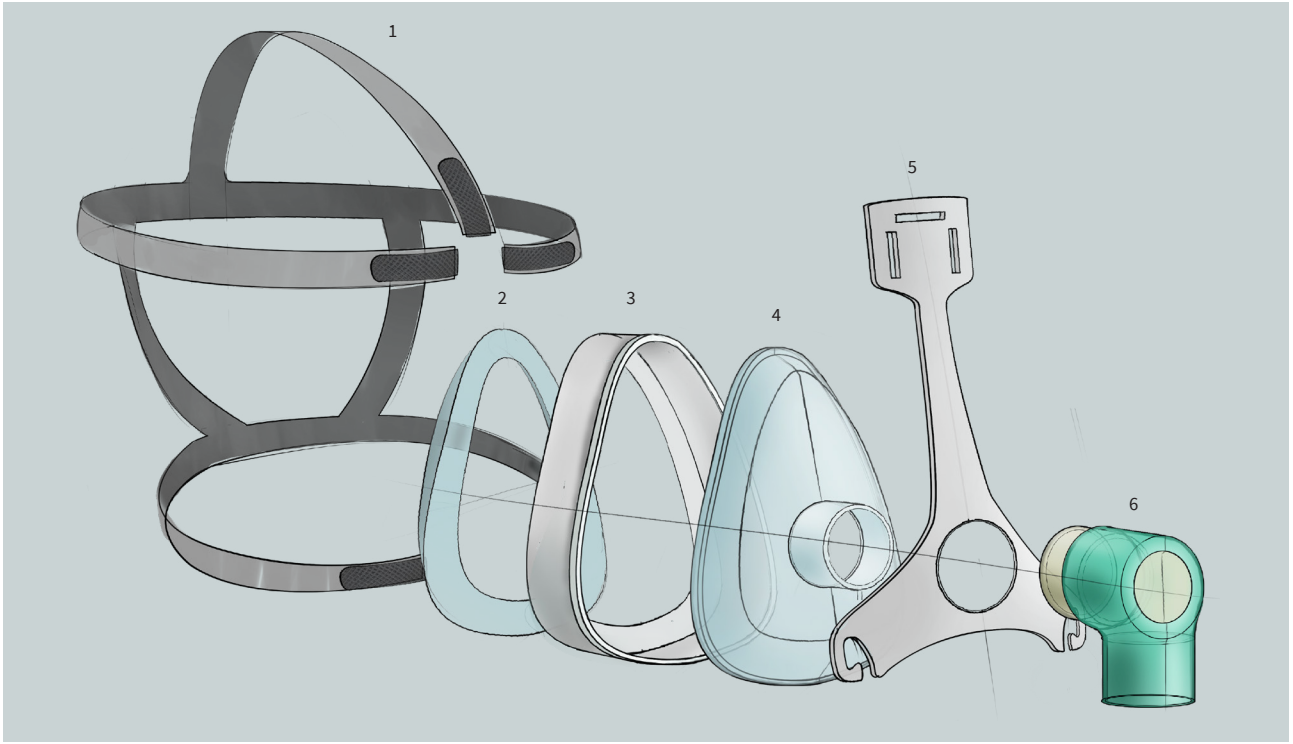


Figure 37. *Parts of the Deformable Mask, (1) headgear, (2) cushion, (3) cushion holder, (4) frame, (5) holder, and (6) swivel.*

3.5.2 Parts

The concept consists of the following parts: headgear, cushion, cushion holder, frame, headgear holder, and the swivel (see Figure 37):

1. The headgear is used to fixate the mask on the face and makes it possible to adjust the position and clamping force. The headgear has a fit within clusters, so it is available in multiple sizes.
2. The cushion seals the mask with the skin. The cushion has a fit within clusters, so it is available in multiple sizes.
3. The cushion holder is formed to the patient's face, see Figure 38. The cushion has a fit within clusters, so it is available in multiple sizes.
4. The frame connects the cushion holder to the headgear holder and is the inlet for air. The frame is transparent for safety reasons. The frame has a fit within clusters, so it is available in multiple sizes.
5. The headgear holder is the connection between the headgear and mask and holds the mask into the right position. The headgear holder has a fit within clusters, so is available in multiple sizes.
6. The swivel makes it possible to rotate the ventilator tube, which decreases the friction of the tube during body moment. The swivel has a collective fit, so there is one size.

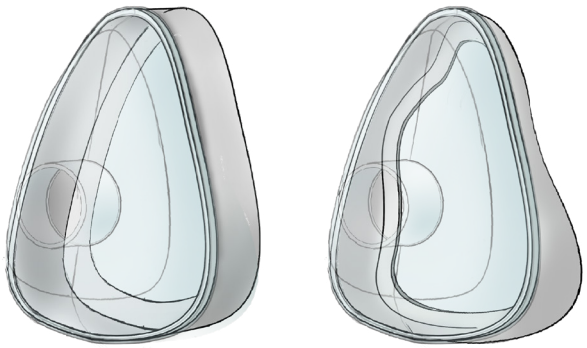


Figure 38. *Deforming of the cushion holder.*

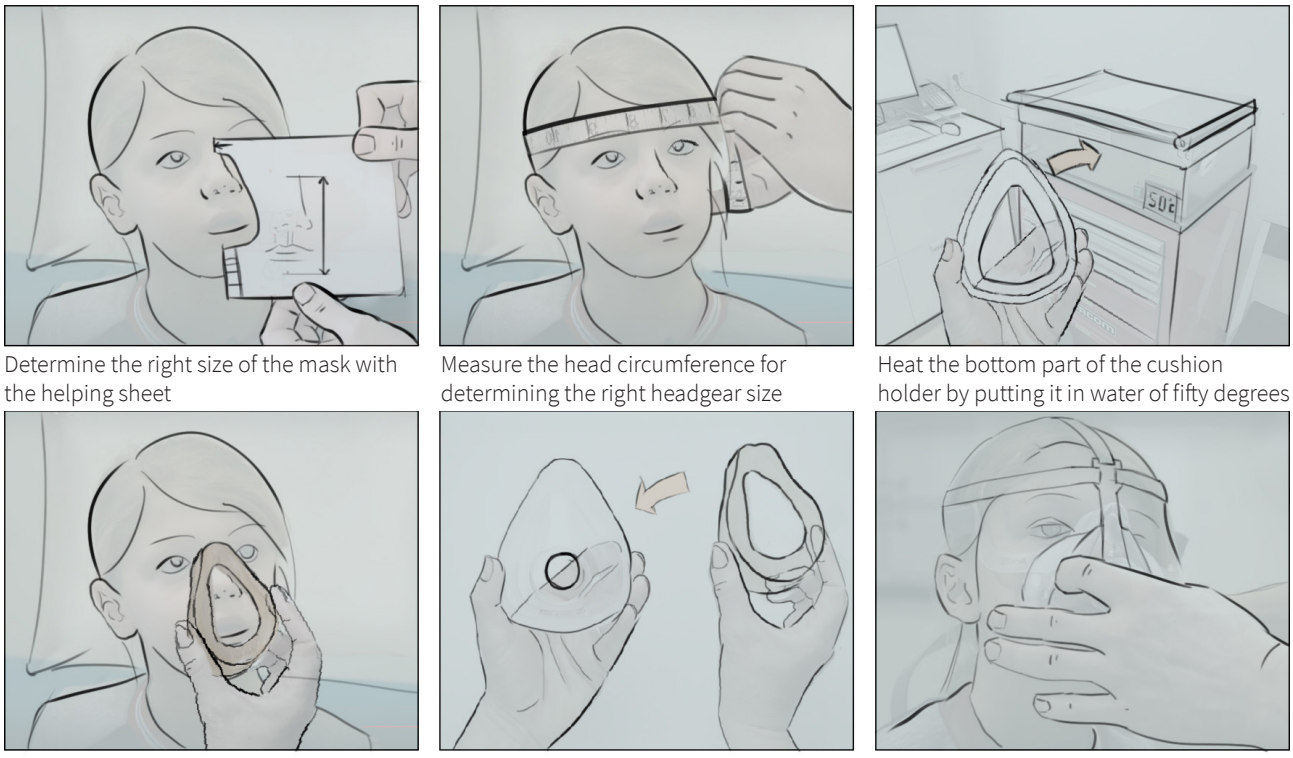
3.5.3 Production

The mask is tailored to the patient by the intensivist practitioner at the PICU. The parts are produced beforehand are in the supply of the PICU.

1. The headgear could be a buy-in part or be cut or sewed, this depends on the developer of the mask. If Amsterdam UMC would produce this concept, I suggest buy-in, since the hospital does not have the facilities for producing the headgear. If a company would produce this concept, I suggest producing the headgear by cutting and sewing, since the buy-in headgears are expensive.
2. The silicone cushion is produced in multiple sizes by casting in moulds. The cushion will be glued together with the cushion holder.
3. The cushion holder is 3D printed in multiple sizes of the material PCL. For the tailoring of the deformable mask, the part is heated in water of fifty degrees. This will make the PCL deformable. The shape is deformed in the right shape by placing the cushion holder on the patient's face. After approximately ten seconds the shape is hardened and the mask will be further assembled.
4. The frame is thermoformed of transparent PVC. Injection moulding requires expensive moulds, this can be beneficial for large batch sizes. Thermoforming, on the other hand, does not require high investment cost, so it could be used for small case testing. The thermoforming process is used at the radiotherapy department of Amsterdam UMC.
5. The holder is 3D printed of ISO-PC, and is produced with the available 3D printers at Amsterdam UMC.
6. The swivel is a buy-in part. The rotational part is not integrated in the concept into decrease the complexity of production and assembly and therefore to reduce costs.

3.5.4 Storyboard

The scenario in Figure 39 describes how the Deformable Mask is used.



Determine the right size of the mask with the helping sheet

Measure the head circumference for determining the right headgear size

Heat the bottom part of the cushion holder by putting it in water of fifty degrees

Deforming the cushion holder by placing it on the patients face and wait 10 seconds to let it harden

Assembling, connecting the silicone cushion to the mask by applying pressure on the glue strip

Placing the tailored mask on the patients face and start the ventilation

Figure 39. *Scenario of the Deformable Mask at the PICU.*

3.6 Concept simulation

In the concept simulation are prototypes of the concepts tested on a ventilation mannequin to simulate the NIV intervention. The prototypes are tailored for the mannequin, and tested with a ventilator of the PICU. Also commercially available non-vented masks are tested as benchmark. The objective of the simulation is to determine the effectiveness, in terms of the amount of air leakage and contact pressure, for the selection of concepts.

3.6.1 Aim

The objective of the concept simulation is to determine the effectiveness of the concepts. The effectiveness is determined by the air leakage and contact pressure. Prototypes of the concepts are compared with two commercially available non-vented masks, the Performax, and King mask.

3.6.2 Method

The patient is simulated with a reanimation training mannequin, the Resusci Junior of Laerdal (see Figure 40). The concept masks are prototyped with 3D printers at the Medical-Technical Innovation and Development department. The materials are not biocompatible and should therefore not be used on humans.

The mannequins are normally used for intubation training, and have a realistic anatomical body with full construction of the airways. The mannequin has a realist anatomical body with fully constructed airways, and the junior variant resembles a five year old child (the target group). The face of the mannequin is made of flexible rubber and is compressible.

The mannequin is ventilated with a ventilator containing a closed dual-limb circuit, because it accurately determines the unintentional air leakage. The air leakage percentage (Vleak) is displayed on the screen of the ventilator. After ten breaths the leakage percentage is written down, to make sure the air leakage is updated and settled. The Hamilton-T1 is used because this ventilator is easy to transport.

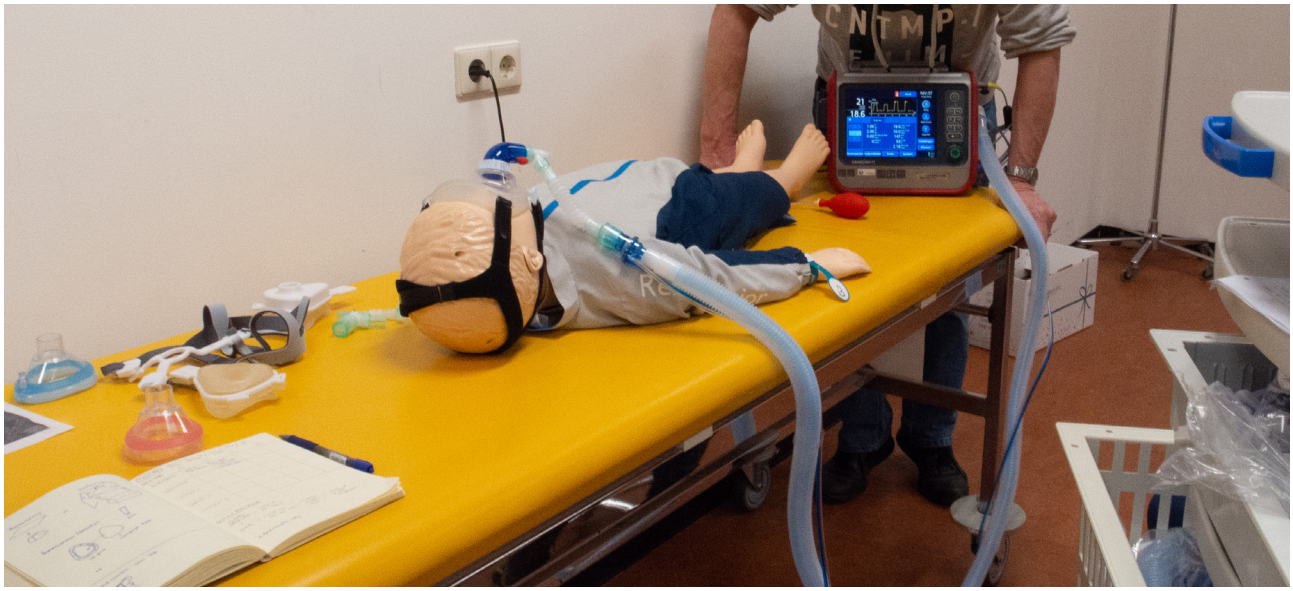


Figure 40. *Test set-up of the concept simulation.*

In consult with the ventilation practitioner pressure modes were selected. The pressure settings include: 5/5, 5/10, 5/15, and 5/25. The first number is the exhalation pressure in cm H2O, and the last number is the inhalation pressure in cm H2O. The lowest three pressure modes are realistic for ventilating a five year old patient. The highest pressure mode is used to identify the air leakage spots, but is normally not used to ventilate a five year old patient.
The contact pressure is determined with carbon paper; a sheet of paper coated with ink. Via pressure the ink is transferred on a paper sheet underneath. The sheets are placed in between the NIV mask and the mannequin's face. The contact pressure of the NIV mask transfers ink onto the blank paper sheet. Although the contact pressure cannot accurately be determined with carbon paper, the relative contact pressures of the different masks is compared. This principle is tested which can be seen in Figure 41.

Figure 41. *Carbon paper sheet test to compare the contact pressures of different masks.*

The prototypes of the concepts are simplified and tailored to the mannequin's face. For the tailoring of the cushions of the masks the mannequin's face is 3D scanned with an Artec Eva, and the manually CAD-modelled (see the result in Figure 43). The headgear of the Respireo Nasal Mask is used to fixate the prototypes on the mannequin's head. The prototypes are described in Appendix P. Note that the deformable mask is not prototyped, because the deformable material could not be 3D printed. An alternative test with the deformable material is conducted and can be found in Appendix P. The needed tools and step by step guideline of the test are described in Appendix P.

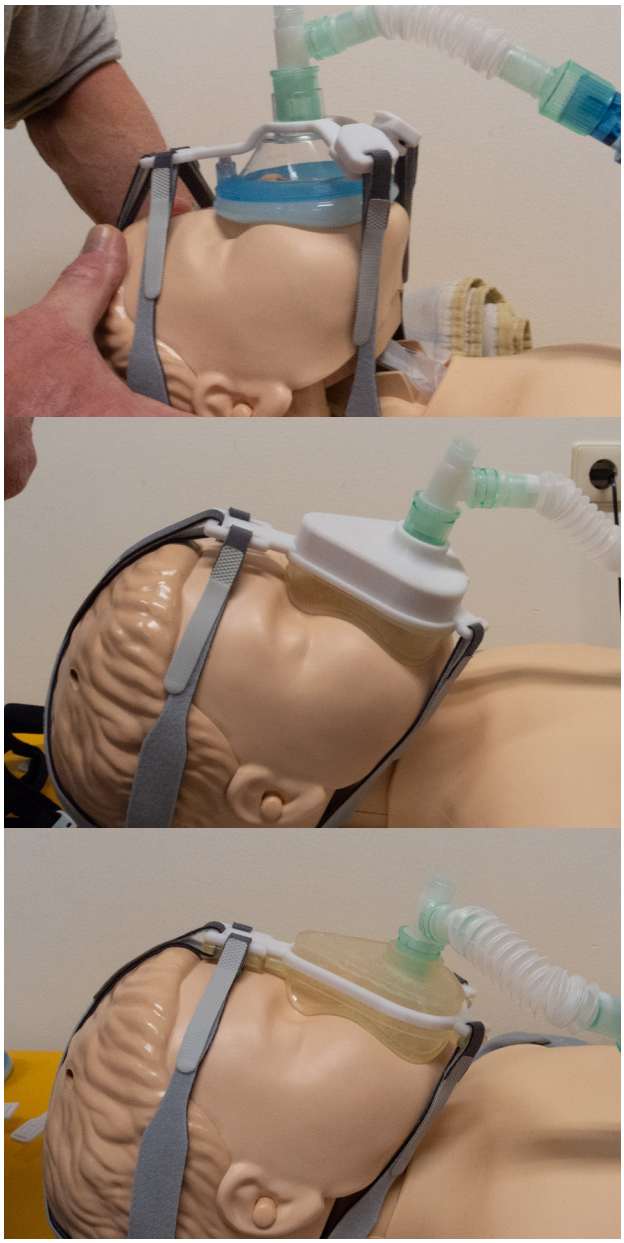


Figure 42. *Prototypes of the concepts: (1) Deformable Mask, (2) Modular Mask, and (3) Quick Curable Mask.*

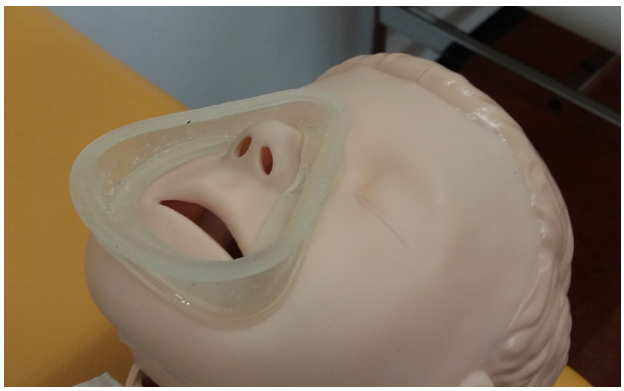


Figure 43. *Cushion of the Modular Mask tailored to mannequin.*

3.6.3 Results

The effectiveness of the masks is determined by comparing the air leakage and the contact pressure.

Air leakage

NIV masks with low air leakage percentages are preferred, because they are more effective. Figure 44 shows the results of the air leakage.

- The Performax had an air leakage between 78-86% with the different pressure modes. The results show that the mask performed better with high pressure settings. The cushion of the mask was pushed outwards by the pressure in the mask, this reduced air leakage. However the mask had leakage spots at the forehead and chin.
- The anaesthesia mask had an air leakage between 79-88%. The leakage spot was around the nasal bridge. Higher pressures seems to lead to more air leakage. The mask required a firmly tightened headgear to press the inflatable cushion into the required shape.
- The Flexible Mask had an air leakage between 80-99%, the leakage spots were located at the nasal bridge and at the left side of the mask.
- The Modular Mask had an air leakage of 76-90%, the leakage spots were located at the nasal bridge and at the left side of the mask.
- The Quick Curable Mask performed best, the mask had an air leakage of 58-87%. With the first three pressure settings the air leakage was below 70%. Only when applying extreme pressure (setting 5/25), the air leakage was larger.

Contact pressure

NIV masks with less contact pressure are preferred, because they reduce the risk for skin injury. The results of the contact pressure is illustrated in Figure 45, the impressions can be found in Appendix P.

- The Performax required a lot of deformation to fit the mannequins face, but the cushion is very flexible. There was a gap at the forehead and chin. The carbon paper showed a lot of pressure, peak pressures are located at the top corners of the cushion.
- The anaesthesia mask performed best in terms of contact pressure. There was almost no carbon impression on the paper sheet, also the pressure was well distributed because it had an equal colour intensity. Peak pressures were not found.
- The Flexible Mask was tailor-made to the mannequin's face, there was not a lot of deformation needed. But the material of the mask was quite stiff. The carbon paper impression of the Flexible Mask showed a lot of pressure. The peak pressure was located at the nasal area.
- The Modular Mask was tailor-made to the mannequin's face, there was not a lot of deformation needed. The mask showed less pressure than the Flexible Mask. The material of the cushion was quite stiff. However, the peak pressure was also located at the nasal area.
- The Quick Curable Mask was tailor-made to the mannequin's face, there was not a lot of deformation needed. It showed well distributed contact pressure. The colour intensity is higher than the anaesthesia mask. The peak pressure was located at the nasal bridge.

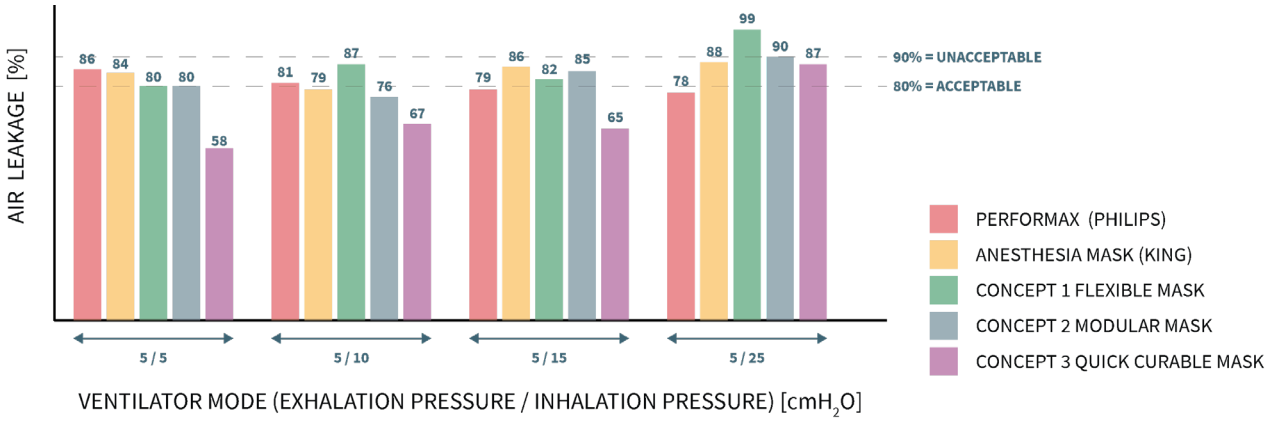


Figure 44. *Results of the air leakage comparison.*

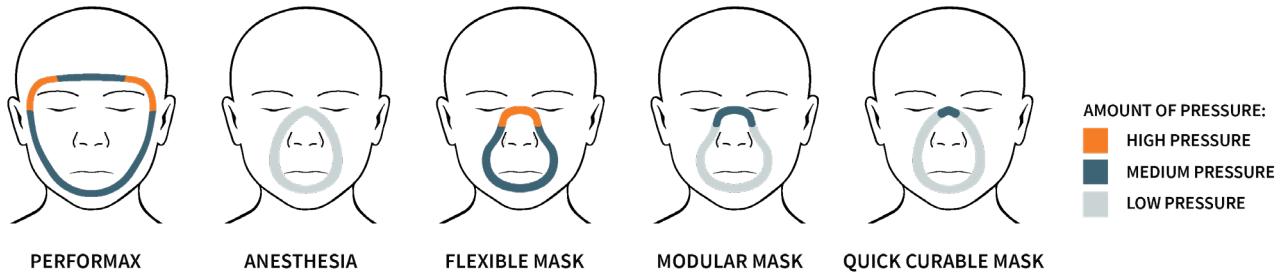


Figure 45. *Results of the face pressure test.*

3.6.4 Discussion

For testing the concepts the real situation was simulated. Below the limitations of the test are elaborated.

- The patient is simulated by a mannequin. Although the mannequin has a realistic anatomical and fully developed airways, the flexible rubber face is not the same as human skin. The skin of patients has underlying tissue layers.
- The masks are tested in a static situation, body and facial movement are not taken into account.
- The tightening of the mask has influenced both the air leakage and contact pressure. The mask is fixated by the ventilation practitioner based on experience. Differences in tightening could have influenced the test results.
- The contact pressure is determined with carbon paper sheets, which is not an accurate method. It only gave an indication for the comparison between the masks. For the contact pressure determination Prescale film is considered. It can accurately determine contact pressure, see Appendix O (Fujifilm, 2019). However it was too expensive for this project.
- The Modular Mask and Flexible Mask are manually tailored. The air leakage spot at the left side of the mask can be caused by CAD-modelling the cushion slightly under an angle.
- The prototyping materials have influenced the effectiveness of the masks. The Flexible Mask and Modular mask were made of flexible material with shore 50A (flexible resin), which was quite stiff comparted to the Quick Curable Mask, that was filled with silicone of shore 5A.
- The King mask size 3 was used for the Quick Curable Mask. This size was on the large side for the mannequin. This could have influenced the performance of the anaesthesia mask and the Quick Curable Mask.

3.6.5 Conclusion

The Flexible Mask was less effective than the other concepts. It had more air leakage and a relatively high contact pressure. The Modular Mask had a better pressure distribution than the Flexible Mask because of the stiff frame. Also was it a struggle to connect the swivel to the flexible inlet of Flexible Mask. The inlet was not properly closed, resulting in air leakage. Therefore the inlet should be made of stiff material.

Although the Modular Mask was more effective than commercially available masks with low pressure settings. It did not outperform the commercially available masks with high pressure settings. The cushion of the Modular Mask was relatively stiff and did not adjust well to the mannequin's face. The Modular Mask can be improved with a thinner and softer cushion, like the Performax, which had less air leakage with higher pressure modes. The cushion flaps were pushed outwards by the pressure in the mask. Improvements of the Modular Mask have been made, see Appendix S.

The Quick Curable Mask was the most effective mask of the simulation. It outperformed the other masks in terms of air leakage and the contact pressure was relatively low. The Quick Curable Mask can be further improved with softer materials, and lower fill percentage of silicone in the cushion. The cushion is still relatively hard compared to commercially available masks and does not adjust well to the face. Filling the cushion fully leads to surface tension and makes the cushion hard. This is tested and several iterations of the Quick Curable Mask have been made, see Appendix T.

3.7 Concept selection

The four concepts (see Figure 46) can be categorised into two design directions: tailored manufacturing, and manually tailoring. Both directions offer advantages relative to each other and are useful for the different kinds of situations at the PICU. Tailored manufacturing is beneficial for patients that require NIV for a longer period. Manually tailoring is beneficial for patients with acute problems.

Tailored manufacturing is beneficial for patients who require NIV for a longer period, for example with pneumonia, because these masks can be fully optimised. The main advantage of the Modular Mask is the design freedom for optimisation (form, thickness, and material of the cushion) based on the 3D scan of the patient. For these patients more preparation time is available for the production, and tailored manufacturing offers the greatest design freedom for optimisation. The Modular Mask is selected, this mask performed better than the Flexible Mask. The stiff frame of the Modular Mask distributes the pressure better in comparison with the Flexible Mask, resulting in less air leakage. Another advantage is that the production of this mask quicker, because the tailored cushion is smaller. Although the Modular Mask did not outperform the other commercially available masks with high pressure settings, using softer material can increase the effectiveness, as is observed with the Performax. The soft cushion flaps of the Performax were pushed outwards by the pressure in the mask, resulting in less air leakage with higher pressure modes. The Modular Mask prototype was made of material with a shore 50A, which was too stiff.

Manually tailoring is beneficial for patients with acute problems, such as respiratory failure, because it requires NIV directly and the mask can be quickly tailor-made. The Quick Curable Mask is selected . The mask was most effective of all masks during the simulation, because it had the lowest air leakage and the contact pressure was relative low. The mask outperformed the standard commercially benchmark masks. Another advantage is that the implementation of the mask is relatively easy compared to the Deformable Mask. The Quick Curable Mask uses an anaesthesia mask which is cheap and already used at hospitals. Besides that the Deformable Mask showed setback of the material, resulting in increased air leakage. The main disadvantage is that the Quick Curable Mask offers less design freedom for further optimisation (only the injected material), e.g. the cushion dimensions of the Quick Curable Mask cannot be varied.

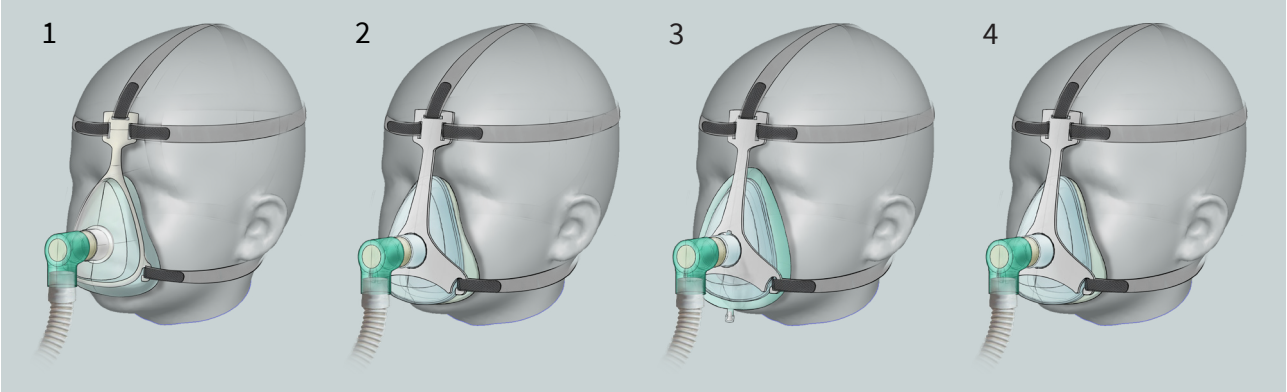
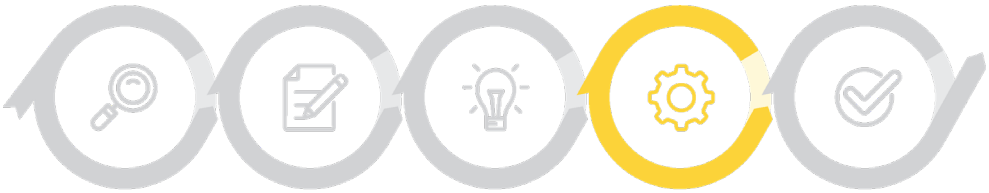


Figure 46. *Four concept masks: (1) Flexible Mask, (2) Modular Mask, (3) Quick Curable Mask, and (4) Deformable mask.*

4
Final Design



The final design consists of two NIV mask proposals: the Quick Curable Mask, and the Modular Mask. The Modular mask is developed for patients who need NIV for an extended time. The Quick Curable Mask is developed for patients who require acute NIV. A protocol is written to test the effectiveness of the two masks after the COVID-19 pandemic. Due to overcrowding at the PICU of Amsterdam UMC there was a shortage of NIV tubes and sensors, therefore it was not permitted to continue this test. However, it is important to test the effectiveness, in terms of the amount of air leakage and wearing comfort, to conclude if the two masks are more effective than the commercially available masks. The two masks will be tested on an adult participant. Firstly, tailored prototypes for the test participant will be made. Secondly, the prototypes and commercially available masks will be tested by ventilating the test participant. The final design is evaluated in the next chapter, conclusion (chapter 5).

4.1 Final design of the Modular Mask

The Modular Mask is aimed for patients that require NIV for a longer period. For the production of the NIV mask at first, the patient´s countenance is 3D scanned, secondly the tailored cushion is produced. All other parts used for making the NIV mask are in the supply of the PICU. So as soon as the tailored part is produced, the mask can be assembled and is ready for use.

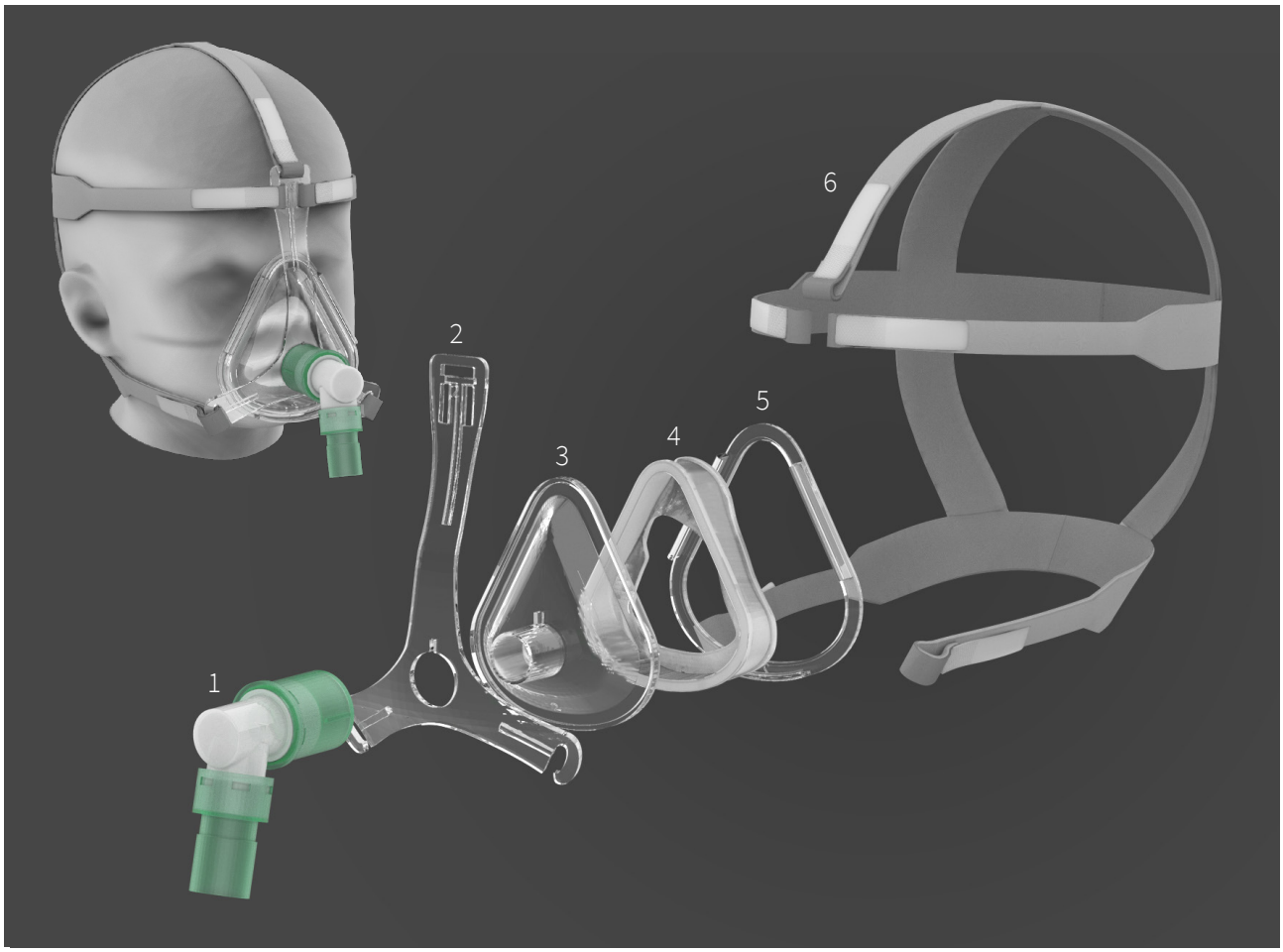


Figure 47. *Parts of the Modular Mask, (1) headgear, (2) frame ring (3) cushion, (4) frame, (5) holder, and (6) swivel.*

4.1.1 Parts

The parts of the Modular Mask can be seen in Figure 47, and further described below.

1 Swivel

The swivel connects the frame with the ventilator tubes. The swivel is rotational into two directions which makes the ventilator tubes easily movable in every direction without friction during body movement of the patient. The inlet of the swivel is compatible with two sizes of frame inlets. For the two smallest frames, numbers one and two, the swivel makes use of the female connection; the swivel slides over the inlet. For the larger frames, above number

two, the swivel makes use of the male connection; the swivel slides into the inlet.

2 Holder

The holder connects the frame with the headgear. The holder is slid over the frame inlet and rests on the frame. An edge is added to the frame inlet to prevent the holder from rotating and assembly faults; the holder fits only in one way. At the back of the holder are ribs added to make the holder stiff. The holder has three gaps at the top, and two at the bottom for the headgear straps. The gaps at the bottom have an opening to be able to release quickly the mask of the patient's face, by pulling the straps down. Each frame size has a corresponding holder, in total there are five holders. The sizing number located at the top of the holder, see Figure 48. The holder height and width are determined with enriched statistical shape models, see Figure 49. The measurements of the holder and explanation can be found in Appendix Q.

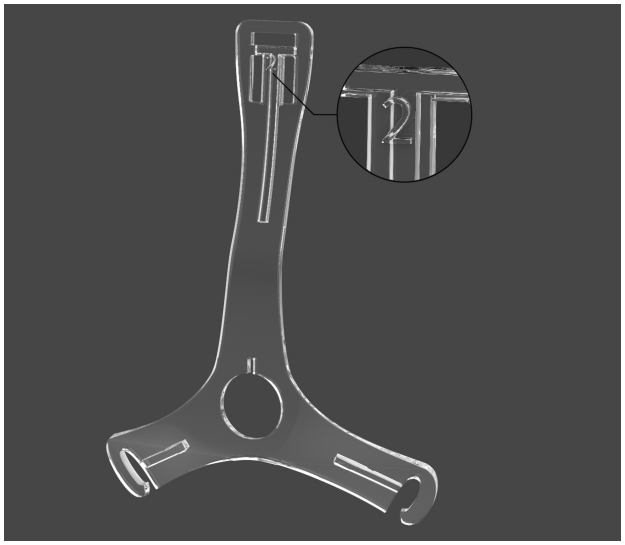


Figure 48. *The holder with a detail of size number.*

3 Cushion

The cushion is tailored to each patient. Manual CAD-modelling of the cushion is labour-intensive and is therefore not desirable because it increases the costs of the mask significantly. The tailoring software is described, but the development of the programme does not belong to the scope of this project. An intern at the PICU of Amsterdam UMC worked on the software programme for this concept; an optimal fit for a 3D scan of a face is developed. Further development of the software is needed for the described production, see the roadmap in chapter 5.2.

For the production first, the most optimal frame size is determined by measuring the sellion-promentale length (see Figure 52). Secondly, a tailored cushion is generated for the selected frame size in the tailoring programme. In this programme the size of the nasogastric tube is selected, for which a cut-out is made, see Figure 50. The height of the cushion is determined with the height of the nose, a margin is added to prevent touching the nose while wearing the Modular Mask.

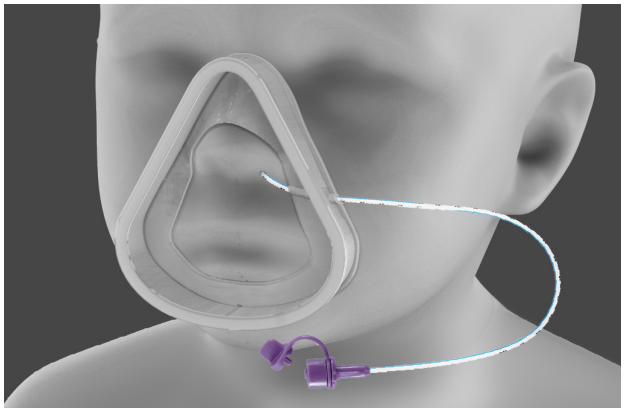


Figure 50. *A tailored cushion for a size 2 frame, with a cut-out for the nasogastric tube, size 6 French.*

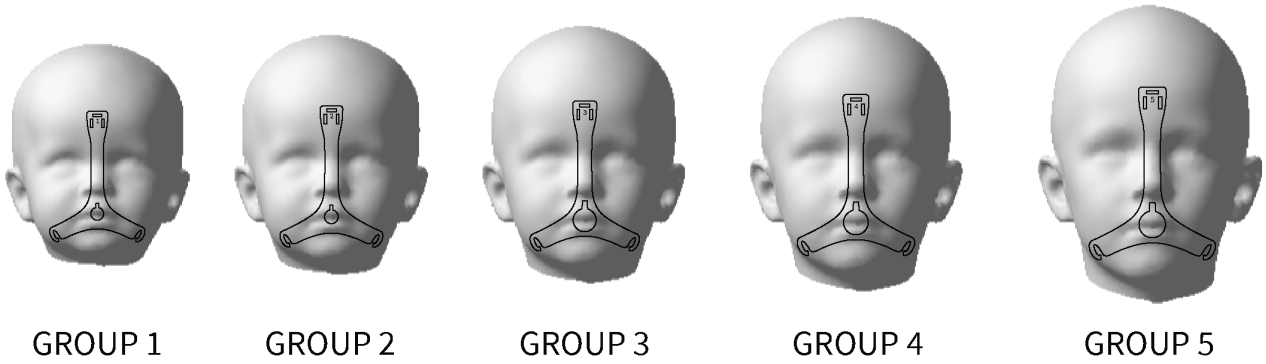


Figure 49. *Enriched SSM based on the avarage sellion-promentale length of the five size groups (DINED, 2019).*

4 Frame

The frame holds the cushion in place and connects to the holder. The frame is transparent to ensure that the patient's face can be monitored by the medical team. At the bottom of the frame is the size number located, see Figure 51.

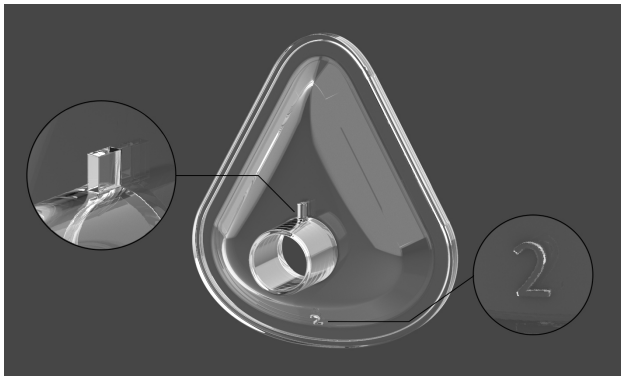


Figure 51. *The frame in size 2 with on the right a detail of size number, and on the left the small edge at the inlet.*

The dimensions of the frame are based on the two most important dimensions for oronasal masks for children; the width of the mouth and sellion-promentale length (Amirav et al., 2014), see Figure 52. The width of the mouth is the length from left to right corner, and the sellion-promentale length is the length from the sellion to promentale. The sellion is the lowest point of the cross-section of the nasal bridge. The promentale is the highest point of the cross-section of the chin.

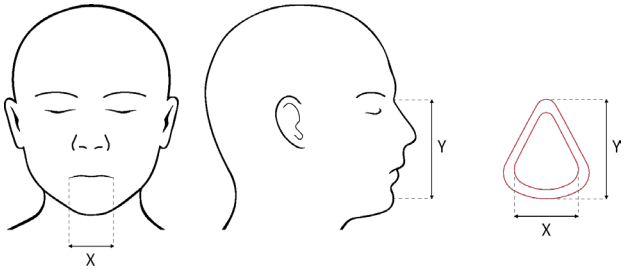


Figure 52. *Width of the mouth on the left, and the sellion-promentale length on the right.*

For the determination of the frame sizes at first, the maximum height is determined. This the maximum size of the sellion-pormentale length, the 99th percentile of the male population between six and seven years old is used. For the sizing system, it is assumed that a decrease of 10% in height is acceptable. This resulted in five sizes (see Figure 53), which are evaluated with the database, see Appendix Q. Note that the two smallest sizes have a small inlet and the larger sizes a large inlet.

Figure 54 gives an overview of the ellipse of the width of the mouth and the sellion-pormentale length of the population of children between based on the database of Dutch children between 0.5-7 years (Goto et al, 2019). The five sizing groups are shown in the ellipse (DINED, 2019). Note that this database covers the target group partially, the anthropometric data of children younger than half a year have not been found.

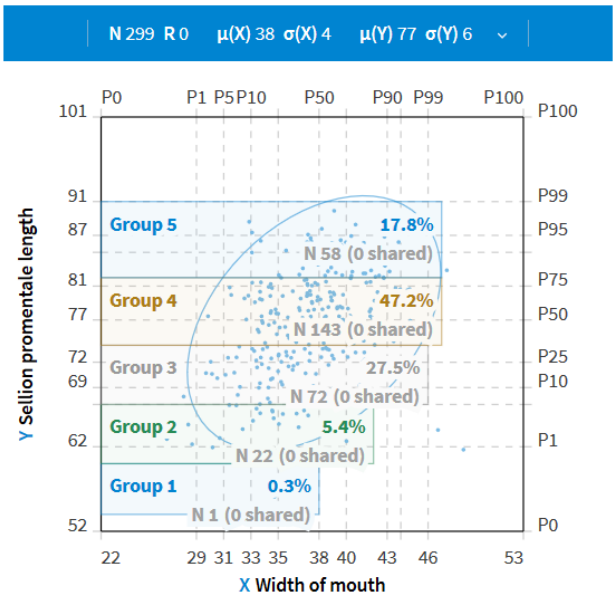


Figure 54. *Ellipse of the the width of mouth and sellion-pormentale length with the five size groups (DINED3D, 2019).*

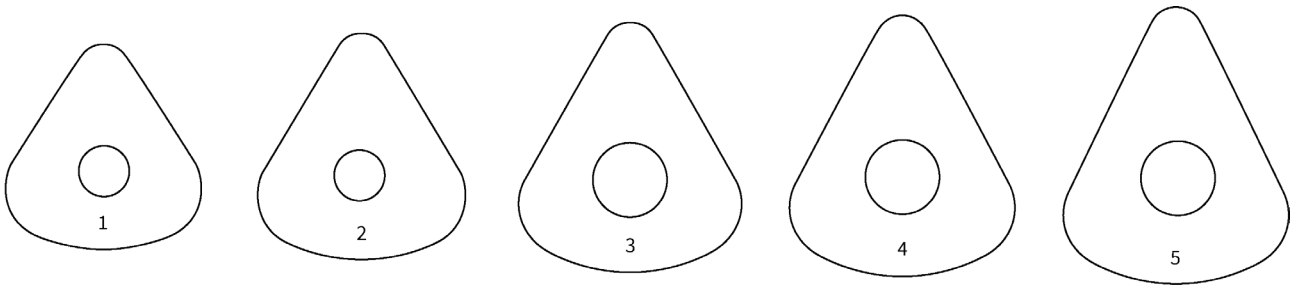


Figure 53. *Frame sizes number one till five.*

5 Frame ring

The frame ring clamps the cushion in the frame. The frame ring is shoved over the cushion and pressed onto the frame. The snap fits of the frame ring locks on the frame, and make sure that the cushion and frame are sealed (see Figure 55). The size of the frame rings is based on the frame sizes. In total there are five sizes, each frame size has a corresponding frame ring. The frame ring has a number on the bottom corresponding with the frame's size number, see Figure 55.

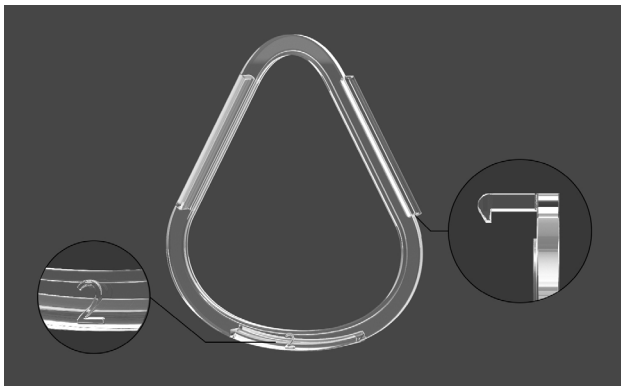


Figure 55. *The frame ring with on the right a detail of the snap fit, and on the left the size number.*

6 Headgear

The headgear has five straps, which gives the intensivist practitioners control over the fit of the mask at the nasal bridge. The headgear is die-cut and sewed together. At the end of the straps, velcro strokes are sewed, for adjusting the length of the straps. The fabric contains a layer of lycra and neoprene. This fabric is stretchable, soft to the touch, and connects well to the velcro. The headgear is available in three sizes. At the back of the headgear is a sizing label sewed.

4.1.2 Production

The cushion of the Modular Mask is produced at the hospital. All other parts are in the supply of the PICU. An overview of all the parts of the Modular Mask including their name, material, fit, production method, price can be seen in Table 6. The cushion ring, frame, and holder are made of polycarbonate because it has: good toughness, unique optical transparency, lightweight, and impact-resistant (CES Edupack, 2019).

The tailored cushion is produced by the technical team at the hospital, this will reduce the transport time. The technical team is in charge of the 3D scanning of the patient's face, generating the optimal fit by using the software programme, and producing the tailored cushion. For the production of the tailored cushion, two techniques have been considered: 3D printing and casting. The main advantage of 3D printing is that no additional casting steps are needed. The main advantage of casting is that there is a broader range of silicones available. 3D printing of the cushion is validated by German RepRap GmbH (a company that 3D prints silicones with a shore between 20A and 50A). Currently, it was not possible to print this model due to shape complexity. However, this might be possible in the near future because the 3D printing field of silicones is developing rapidly. Therefore the cushion is initially casted in a 3D printed mould. The mould is printed with gypsum at the hospital. These gypsum moulds are also used for skin applications at the oral and maxillofacial department, see Figure 56. The advantage of gypsum mould is that it is possible to cast thin-walled parts, and it can simply be broken off the casted silicone.

PART	MATERIAL	FIT	PRODUCTION METHOD	PRODUCTION PRICE (€)
Swivel	Plastic	Collective fit	Purchase part	2,00*
Holder	Polycarbonate	Fit within clusters, 5 sizes	Injection moulding	0,78
Frame	Polycarbonate	Fit within clusters, 5 sizes	Injection moulding	0,79
Cushion	Silicone Dragon Skin	Tailor-made	Casting in 3D printed gypsum mould	84,07
Cushion ring	Polycarbonate	Fit within clusters, 5 sizes	Injection moulding	0,77
Headgear	Lycra & neoprene, velcro	Fit within clusters, 2 sizes	Die-cutting and sewing	4,68

Table 6. *Overview of the Modular Mask parts (*Purchase price).*

The cost price estimation is determined with the help of a cost calculation sheet of Industrial Design Engineering, see Appendix R. Table 6 gives an overview of the different parts. The total manufacturing costs are estimated at 93 euros. The retail price is estimated at 276 euros in the case the product is produced by a company.

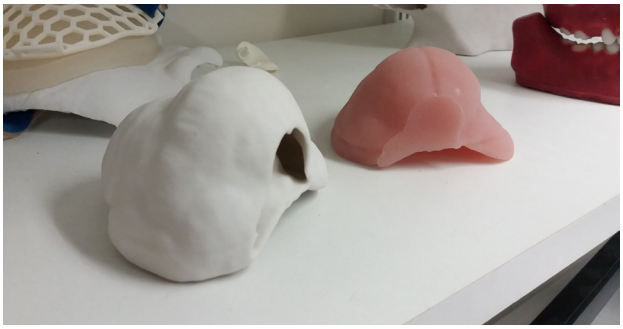
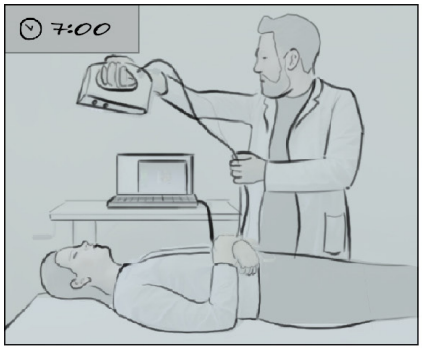


Figure 56. *Gypsum 3D printed mould and cast for skin application at the maxillofacial department.*

4.1.3 Scenario

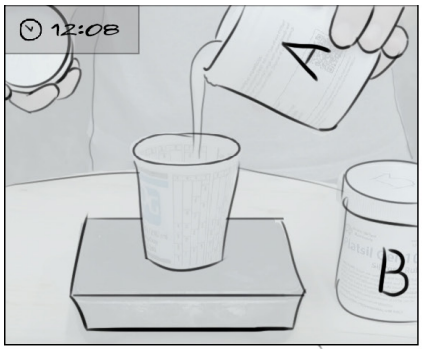
The scenario in Figure 57 describes how the Modular Mask is used at the PICU.



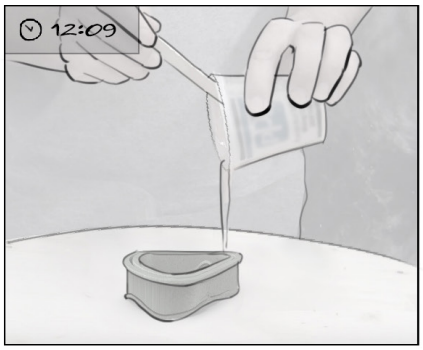
A technician scans the patient's countenance (without the nasogastric tube on contact area of the cushion).

With the 3D scan a software programme calculates an optimal fit and a mould for the cushion is generated.

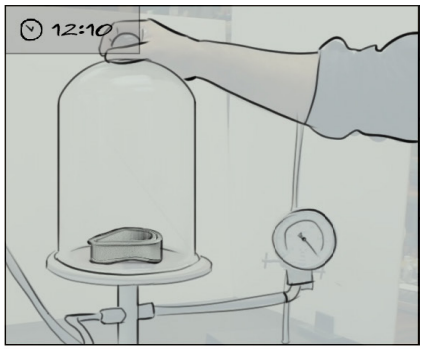
The cushion mould is uploaded and 3D printed with gypsum at Amsterdam UMC.



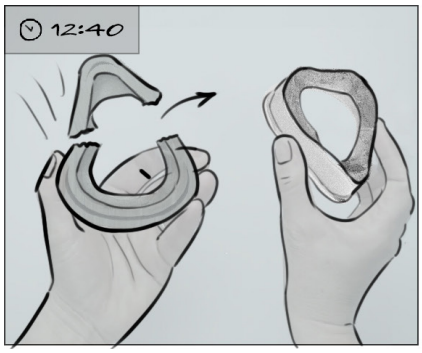
The two silicone components are mixed into a cup in the right ratio A:B.



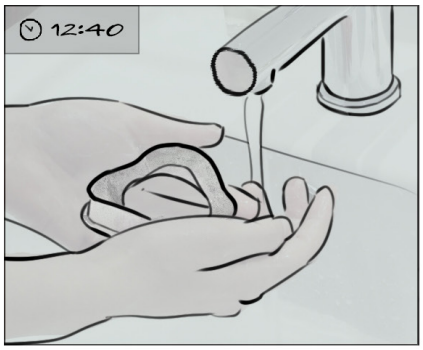
The silicone is casted into the mould.



The mould is placed in an evacuated bell jar to remove air bubbles out of the silicone.

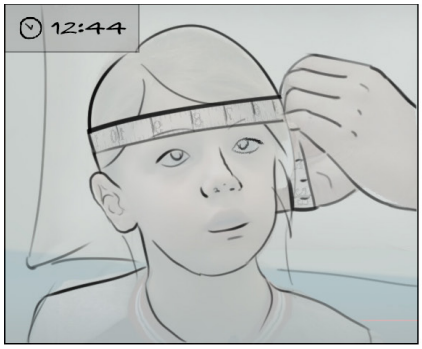


After 30 minutes the silicone is cured, the mould the silicone is cured, the mould is brittle and can easily be broken off.



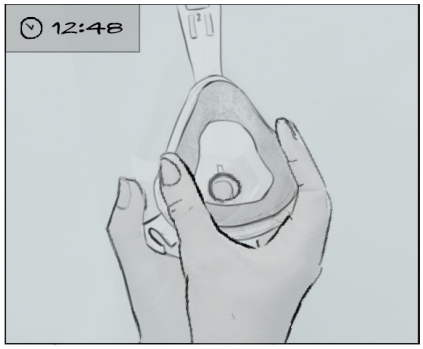
The cushion is washed with water to remove dust.

The cushion is transported to the PICU.

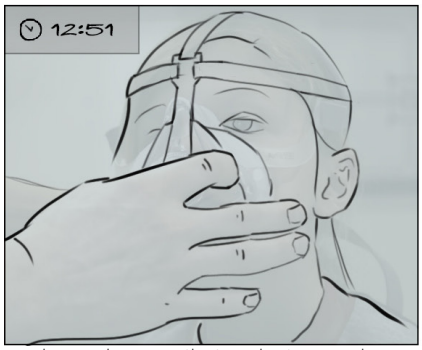


The intensivist practitioner measures the head circumference of the patient to determine the right headgear size.

The frame, holder, frame ring, headgear are collected out the supply.



The NIV mask is assembled by the intensivist practioner with the tailored cushion and supply parts.



Replace other ventilation devices and fixate the mask on the patient's face.

Start the Non-invasive ventilation.

Figure 57. *Scenario of the Modular Mask at the PICU.*

4.2 Final design of the Quick Curable Mask

Quick Curable Mask is aimed for patients that require acute NIV. The mask is immediately available for patients with acute respiratory failure. The Quick Curable Mask is based on the anaesthesia mask that is currently used at the PICU of Amsterdam UMC; the King mask by Ambu. The mesh pants that are used to connect the mask to the patient's face, will shortly be replaced by the 3D printed frame with headgear, developed by the Medical-Technical Innovation and Development department. This is used as the basis of the Quick Curable Mask. Additionally, the mask is tailored to each patient.

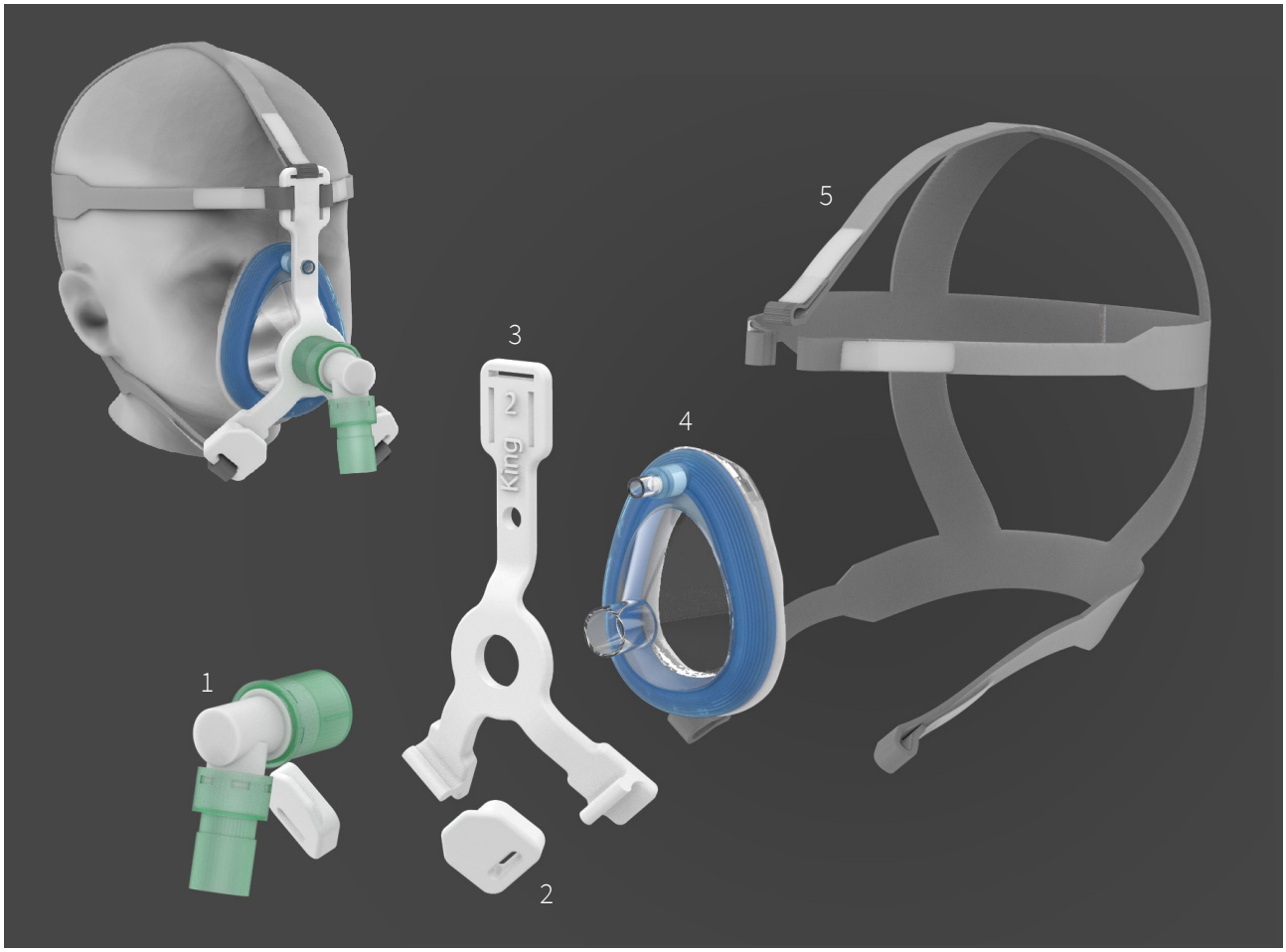


Figure 58. *Parts of the Quick Curable Mask, (1) headgear, (2) anesthesia mask (3) holder, and (4) swivel.*

4.2.1 Parts

The parts of the Quick Curable Masks can be seen in Figure 58, and further described below.

1 Swivel

The swivel connects the frame with the ventilator tubes. The swivel is rotational into two directions which makes the ventilator tubes easily movable in every direction without friction during body

movement of the patient. The inlet of the swivel is compatible with two sizes of frame inlets. For the two smallest frames, numbers one and two, the swivel makes use of the female connection; the swivel slides over the inlet. For the larger frames, above number two, the swivel makes use of the male connection; the swivel slides into the inlet.

2 Clips

The clips connect the two bottom straps of the headgear with the holder. The clips ensure that the straps are firmly connected and also can be quickly removed. The clips come in one size and are 3D printed at the hospital with PC-ISO.

3 Holder

The holder connects the headgear with the anaesthesia mask. The holder is slid over the ventilation and cushion inlet. For the four anaesthesia mask sizes are holders developed by the Medical-Technical Innovation and Development department. The holders are 3D printed at the hospital with PC-ISO. The holder has a number at the top with the corresponding mask size. King is written on the holder because other brands of anaesthesia masks are used at the hospital.

4 Mask

The anaesthesia mask has a hard frame with a ventilator inlet and an inflatable cushion. For paediatrics there are four different sizes: neonatal (#1), small child (#2), child (#3), and large child (#4). The inflatable cushion of the mask is filled via the inlet with silicone.

5 Headgear

The headgear has five straps, which gives the intensivist practitioners control over the fit of the mask at the nasal bridge. The headgear is purchased off the Respireo Child SOFT Nasal Mask. Three different sizes are used: Baby XS, Baby S, Child. The headgear has a size label on the back. This headgear is stretchable and soft to the touch. At the end of the straps, velcro strokes are sewed, for adjusting the length of the straps.

4.2.2 Production

The inflatable cushion of the anaesthesia mask is tailored for each patient. The intensivist practitioner pumps silicone in the mask with a cartridge gun dispenser, see Figure 59. The nozzle is screwed on the cushion inlet. By pumping the silicone through the static mixer nozzle, the two components get mixed by the flow. The cartridge gun dispenser consists of the following parts: a cartridge gun, 2K cartridge with the two components of silicone, and a static mixer nozzle (see Figure 59). For the tailoring of each mask, a new static mixer nozzle is required because it cannot be reused.

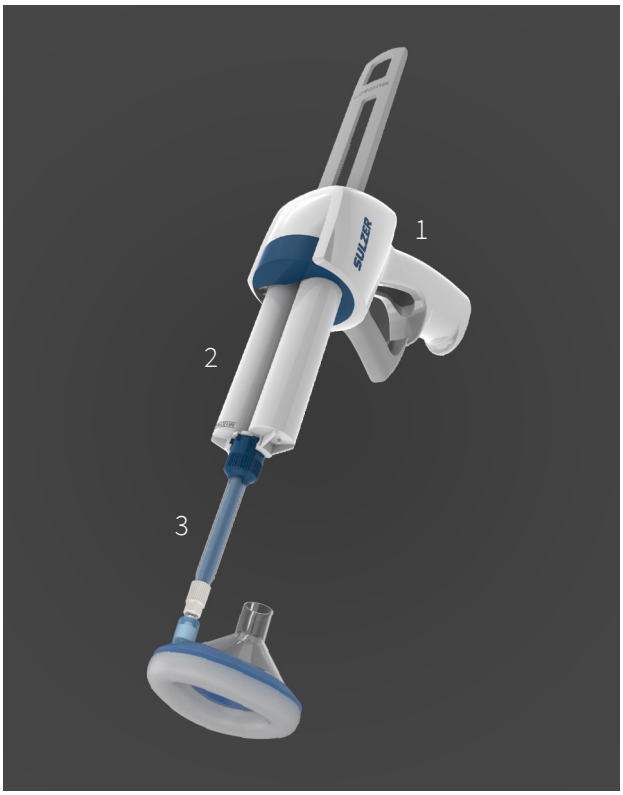


Figure 59. *Parts used for the tailoring of the Quick Curable Mask, (1) cartridge gun, (2) 2K cartridge with the two components of silicone, and (3) static mixer nozzle.*

An overview of all the parts including their name, material, fit, production method, price can be seen in Table 7. The total manufacturing costs are estimated at 125 euros. Note that the purchased headgear is very expensive. However, the 5-point straps are favoured for the control over the nasal bridge. Nevertheless, can the costs significantly reduced if an alternative 5-point headgear manufacturer is found.

PART	MATERIAL	FIT	PRODUCTION METHOD	PRICE (€)
Swivel	Plastic	Collective fit	Purchase part	
Clip	PC-ISO	Collective fit	3D printing	2,00*
Holder	PC-ISO	Fit within clusters, 4 sizes	3D printing	10,00
Anesthesia Mask	Polycarbonate	Fit within clusters, 4 sizes	Purchase part	2,00
Silicone	Ecoflex silicone 00-35	Tailor-made	Purchase material	0,36 ~ 1,80
Headgear	Lycra & neoprene, velcro	Fit within clusters, 3 sizes	Purchase part	105,00
2K Cartridge	Plastic	-	Purchase part	0,93
Static mixer nozzle	Plastic	-	Purchase part	0,76
Cartridge gun dispenser	Metal	-	Purchase part	27,60
Syringe	Plastic	-	Purchase part	0,59

Table 7. *Overview of the Quick Curable Mask parts (*two per mask).*

4.2.3 Material selection

For the injected silicone the following properties are important: the working time, the full curing time, the hardness, and the price.

- The hardness of the silicone in the cushion should be as soft as possible because the cushion is one massive part that is comfortable to wear for the patient.
- The working time is the time that the silicone can be moulded into the cushion, there has to be enough time for the intensivist practitioner to fill the cushion with silicone (approximately 1-2 minutes).
- The curing time is the time needed to let the two silicone components cure fully. The curing time should be as short as possible so that after the curing time has elapsed, the mask is tailored. The practitioner can continue with other care tasks.

A selection of silicones with low durometers, and short curing times have been made, see Table 8. Note that long working time typically requires a longer curing time. During the curing time, the intensivist practitioner has to ensure the mask is not displaced.

Soma Foama is a silicone foam used for cushioning and orthopaedics (Smooth-On, 2019). Although it has the lowest hardness because it is foam is the material not selected. Its original volume expands two to four times and is hydrogen gas released. This makes it hard to predict the right amount of fill. A fully filled cushion leads to surface-tension of the cushion, and makes the cushion hard. Also, the Soma Foama is not certified skin safe. Although the material is injected into the cushion and does not directly touch the skin, skin safe material is preferred because the material could leak during the filling due to human errors.

Ecoflex silicone is selected because it is softer than Dragon Skin, it is available in lower shores (Smooth-On, 2019). Ecoflex is available in six hardnesses, shore 00-35 is selected. This silicone has the required curing properties. The working time of two and a half minutes is enough time for the intensivist practitioner to inject the cushion of the mask. Also, the curing time of five minutes is acceptable. Another advantage of Ecoflex is the material costs.

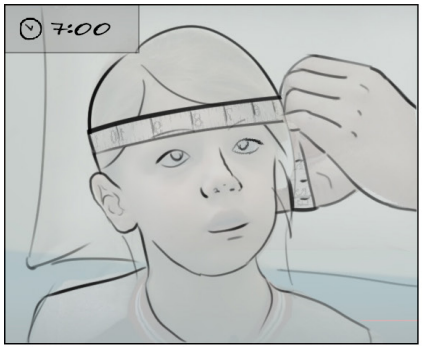
Ecoflex shore 000-35 is used to experiment, see Appendix T. Although this material does not have the preferred curing properties, this material is selected for the hardness properties. With a prototype is explored if this super-soft gel has the ideal hardness.

MATERIALS	HARDNESS	WORKING TIME	FULL CURING TIME	PRICE	NOTES
Ecoflex 5	Shore 5 A	1 min	5 min	50.81 euro/kg	Certified skin safe
Ecoflex 00-35	Shore 00-35	2,5 min	5 min	25,55 euro/kg	Certified skin safe
Ecoflex 000-35	Shore 000-35	15 min	2 hour	25,55 euro/kg	Certified skin safe
Dragon Skin FX-Pro	Shore 2 A	5 min	40 min	25,55 euro/kg	Certified skin safe
Soma Foama 15	Low density foam (240 kg/m^3)	30 seconds	1 hour	28,60 euro/kg	Not skin safe certified, may cause irritation Expands 4 times Small amount of Hydrogen gas is released during the reaction
Soma Foama 25	High density foam (400 kg/m^3)	30 seconds	1 hour	28,60 euro/kg	Not skin safe certified, may cause irritation Expands 2-3 times Small amount of Hydrogen gas is released during the reaction

Table 8. *Selection of injected silicones, that have a low durometers and short working and curing time (Smooth-On, 2019).*

4.2.4 Storyboard

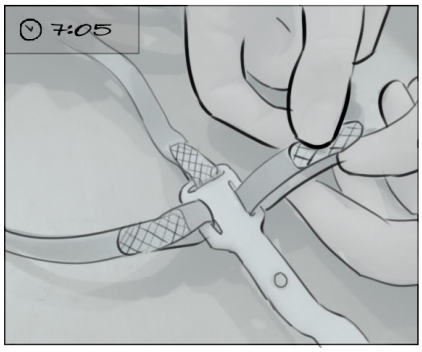
The scenario in Figure 60 describes how the Quick Curable Mask is used at the PICU.



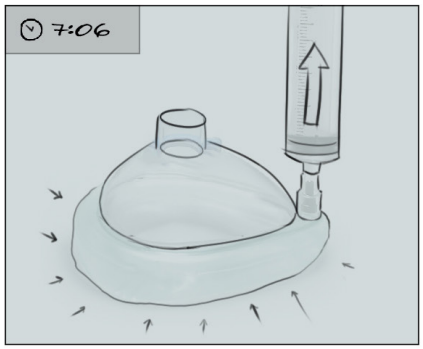
Measure the head circumference of the patient to determine the right headgear size.

Determine the right mask size with a sizing sheet.

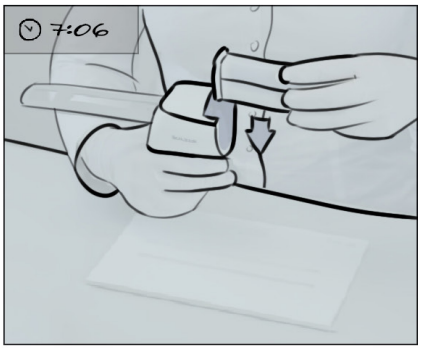
Place the nasogastric tube on the patient, and fixate it with a plaster on the patient's cheek.



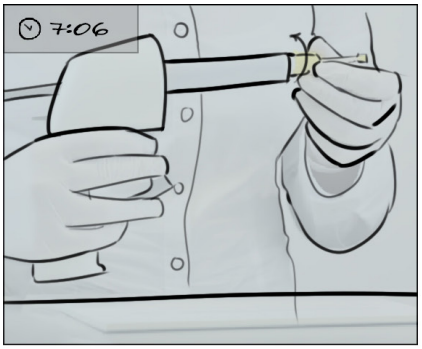
Fixate the three top straps of the headgear to the holder and connect the clips to the two bottom straps.



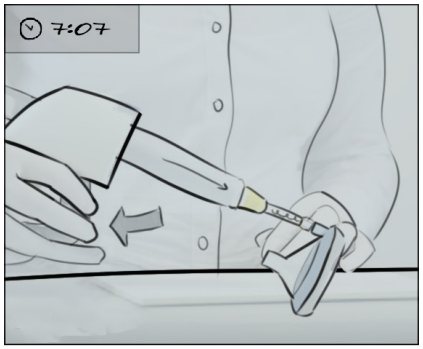
Screw the syringe on the cushion inlet and vacuum the cushion.



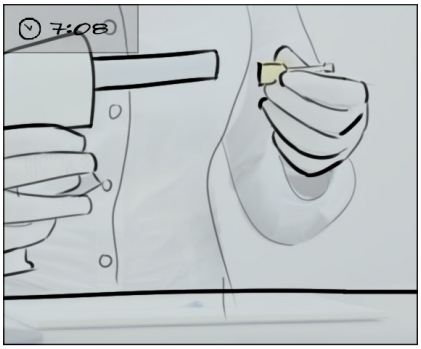
Place the 2K cartridge into the gun dispenser.



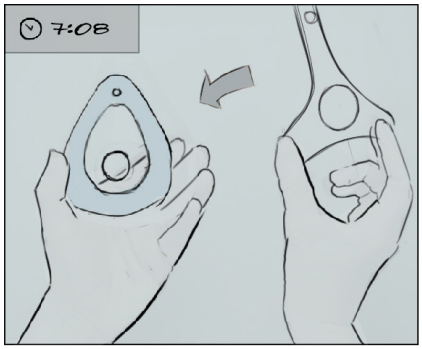
Place the static mixer nozzle on the 2K cartridge.



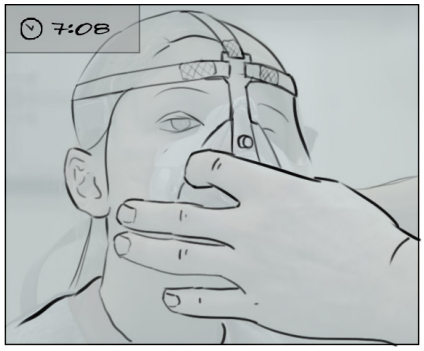
Fill the cushion of the mask with silicone by squeezing the handle of the gun dispensor.



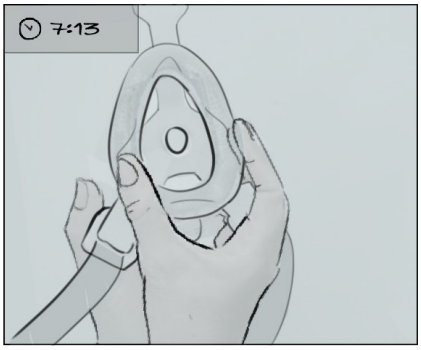
Remove the static mixer nozzle off the cartridge and dispose it.



Slide the mask into the holder.



Fixate the mask on the patient's face and let the silicone cure for five minutes (the mask is placed over the nasogastric tube).



After the silicone is cured the mask is checked by the intensivist practitioner.

Start the Non-invasive ventilation.

Figure 60. *Scenario of the Quick Curable Mask at the PICU.*

4.3 Final design test

The goal of the final test is to prove the working principle of the two final designs, by testing the two masks on a test participant. The main objective is to determine the effectiveness, which is determined by measuring the air leakage. But it also takes the comfortability into account. During the preparation of the tailored prototype the test is postponed due to the COVID-19 pandemic on the 30th of March. However the proof of concept is necessary for further development. Therefore a protocol is written for the moment the test can be conducted.

Aim

The objective of the final design test is to determine the effectiveness, which is determined by measuring the air leakage, and taking the wearing comfortability of the final design into account. The final design prototypes are compared with two commercially available non-vented masks, the Performax, and King mask.

Method

In this stage the test will be conducted with an adult test participant instead of a child, considering the risk management and ethics. The goal of the test is to prove the working principle with a person. Adults can express their experience more nuanced, which is important for feedback to optimise the masks. Furthermore testing with young children have to be approved by the Medical Ethical Committee, young children are considered a vulnerable group, they can find participating stressful and ventilation too uncomfortable.

The test is executed with the Hamilton-T1 ventilator, it has a closed dual-limb circuit and accurately determines the unintentional air leakage. The air leakage percentage (Vleak) is displayed on the screen of the ventilator. Three different pressure modes are tested for both mask: 5/5, 5/10, and 5/15. The maximum pressure mode is 5/15, 5 cm H2O pressure when exhaling, and 15 cm H2O when inhaling. Higher pressure modes are really uncomfortable, and are therefore not tested.

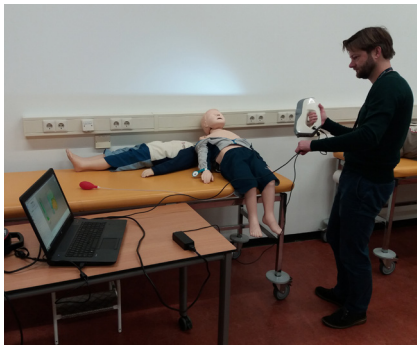
The comfortability of the final design prototypes and commercially masks are evaluated by asking the participant to rate their comfort after they are ventilated for five minutes. A few minutes of ventilation is necessary to let the test participant get used to NIV and to evaluate the wearing comfort. The comfort is rated on the Likert scale, a seven point scale.

Apparatus

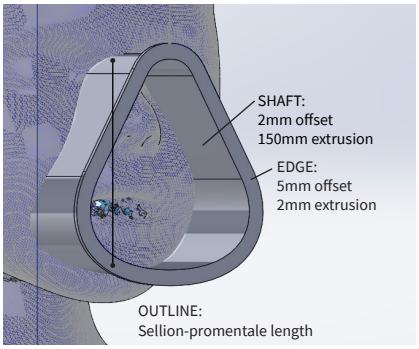
- Artec Eva 3D scanner
- Computer with Artec Studio Software
- Sheet with the result table and pen to write down measurements
- Hamilton T1 ventilator
- Ventilator tubes to connect the mask to the ventilator
- Tailored prototypes: Modular Mask, and Quick Curable Mask
- Anaesthesia mask (size 4, large enough for a small adult)
- Perfomax mask (size S or L)
- Headgear of Respireo (size child, large enough for a small adult)

Procedure

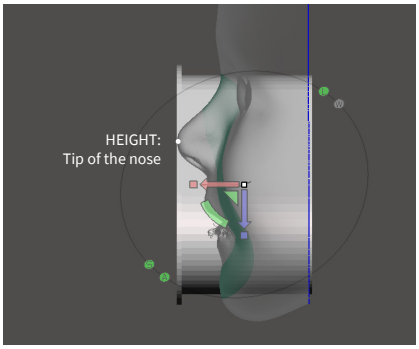
1. First the tailored masks for the test participant are produced. The Modular Mask prototype is produced before the testing moment with the test participant. The production process is explained on the right. The Quick Curable Mask is produced during the testing moment with the test participant. The production process is explained see other side.



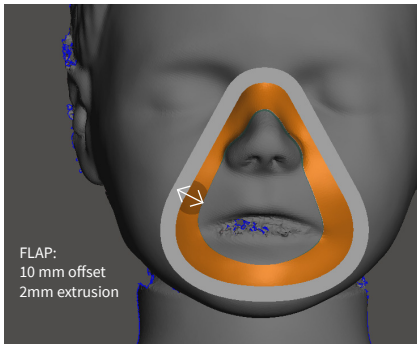
1. 3D scan the test participant's face with the Artec Eva of the 3D Innovation Lab.



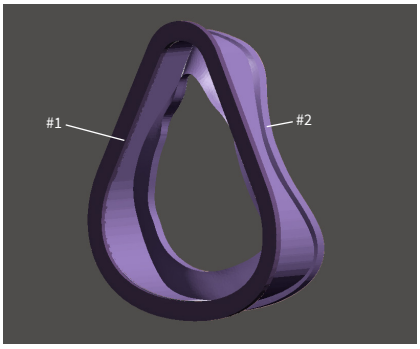
2. CAD-model a tailored cushion with the 3D scan (the shaft is cut later).



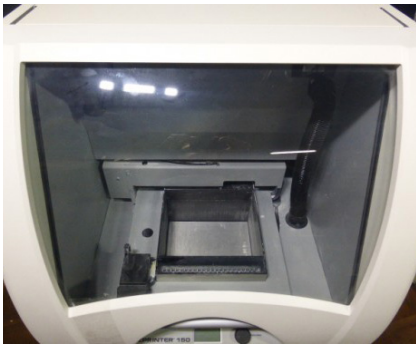
3. Position the cushion on the 3D scan. Cut the shaft with 3D scan plane.



4. CAD-model the flap of the cushion on the 3D scan.



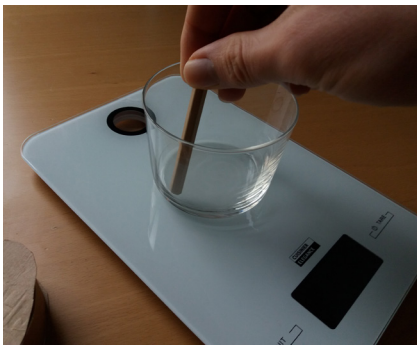
5. Combine the cushion extrusion and flap into one part, and exported as a STL file for 3D printing.



6. 3D print the moulds of the cushion with gypsum, at the Oral and Maxillofacial Department.

7. After the mould is finished, carefully lift it off the build platform and place it on a desk for the casting process.

8. Pour the two silicone components of Dragon skin A20 (ratio 1:1) in a cup.



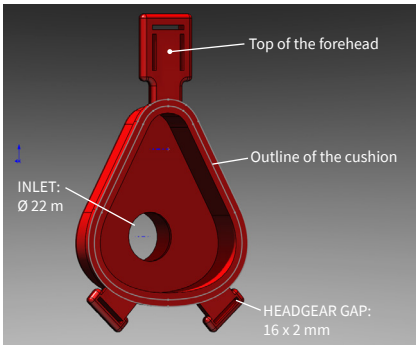
9. Mix the two components for a minute with a stick.

10. Inject the silicone into the casting hole, fully fill the mould.

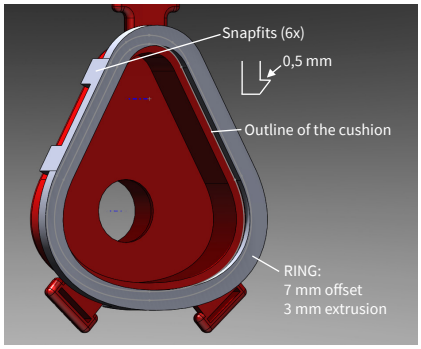
11. Place the mould in a vacuumed bell jar, to remove air via the gas vents.

12. Wait four hours till the silicone if fully cured (full curing time of Dragon skin A20).

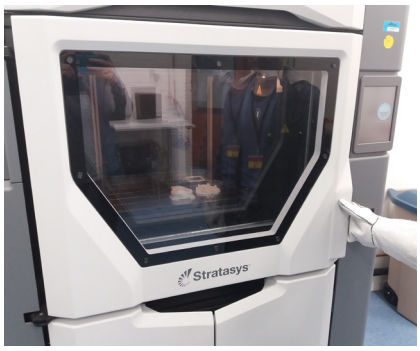
13. Carefully break the gypsum mould off the cast, remove dust by washing the cushion with water.



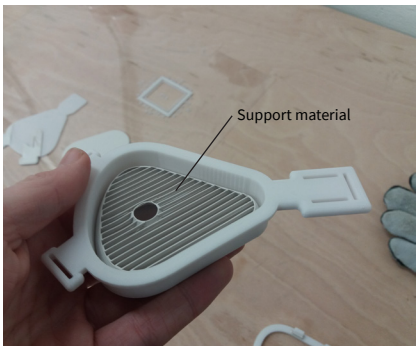
14. CAD-model the frame on the outline of the cushion. Export the frame as a STL file for 3D printing.



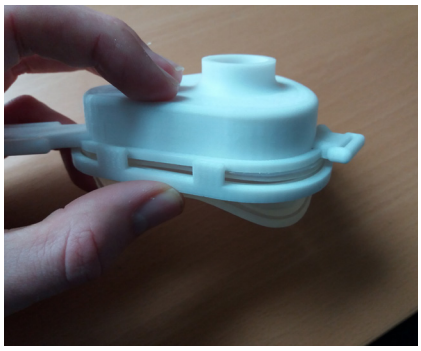
15. CAD-model the fame ring on the frame and cushion. Export the frame ring as a STL file for 3D printing.



16. 3D print the frame and frame ring with PC-ISO, at the MIO department.



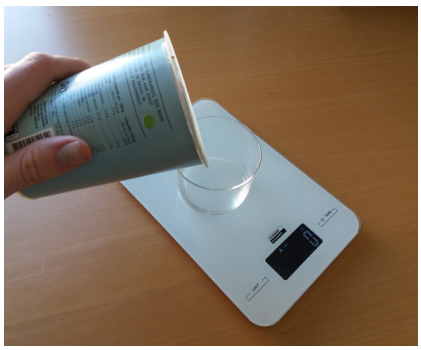
17. Remove the support material with a sharp pin after the 3D print is finished.



18. Assemble the Modular Mask (if there are small gaps fill them with silicone kit).

1. Prepare the holder and headgear by connecting the headgear straps to the holder and clips.

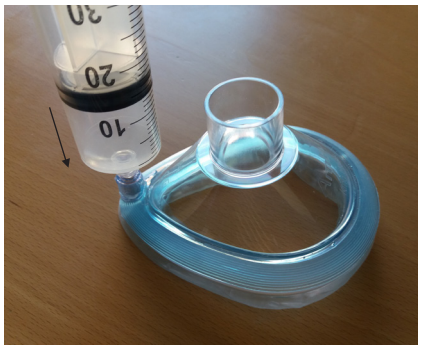
2. Remove all the air in the cushion with a syringe.



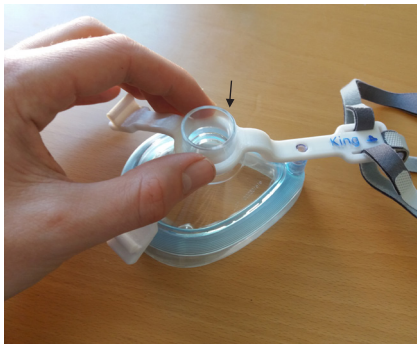
3. Pour the two silicone components of Ecoflex 00-35 in a cup (ratio 1:1) on a scale (at least 80ml in total).

4. Mix the silicone components for 30 seconds with a stick.

5. Suck 50ml into the syringe



6. Screw the syringe on the inlet, and inject the cushion with 50ml of silicone.



7. Slide the mask into the holder.

8. Place the mask onto the test participant's face, and fixate the mask by connecting the clips onto the holder.

9. The curing of the silicone will take four minutes, hereafter the mask is tailored.

2. The Modular Mask is fixated on the test participant by the ventilation practitioner, in a sitting position.
3. The mask is connected to the ventilator, and the test participant lies down and is ventilated for five minutes with the 5/5 pressure mode, the air leakage (Vleak in %) is observed and written down in Table 9.
4.After five minutes of NIV the test participant evaluates his comfort level on a seven point scale, it is written down in the Table 10 (1 feeling not comfortable, and 7 feeling very comfortable). Next the participant is asked to corroborate their rate, to find elements to improve the two masks.
5. Repeated with the other pressure modes (5/10, 5/15), and hereafter with the Quick Curable Mask, , King mask, and Performax.

PRESSURE SETTING	5/5	5/10	5/15
Modular Mask			
Quick Curable Mask			
King mask			
Performax			

Table 9. *Air leakage results of the final design test*

PRESSURE SETTING	5/5	5/10	5/15
Modular Mask	1-2-3-4-5-6-7	1-2-3-4-5-6-7	1-2-3-4-5-6-7
Quick Curable Mask	1-2-3-4-5-6-7	1-2-3-4-5-6-7	1-2-3-4-5-6-7
King mask	1-2-3-4-5-6-7	1-2-3-4-5-6-7	1-2-3-4-5-6-7
Performax	1-2-3-4-5-6-7	1-2-3-4-5-6-7	1-2-3-4-5-6-7

Table 10. *Comfort results of the final design.*

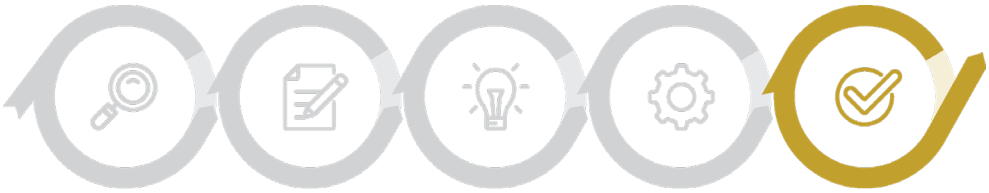
4.3.1 Discussion

- The test is only conducted with one test participant (qualitative research). The test only gives an indication of the wearing comfort, because it is subjective and the test is not conducted with multiple participants. However the goal of the test in this phase is to prove the working principle and not to gather quantitative findings (this will be done in the next testing phase, see chapter 5.2).
- The comfortability rating of the test participant gives an indication of the short term wearing comfort. Long term usage is not taken into account, and has to be further explored.
- An adult is used as a test participant instead of a child, which can have influenced the effectiveness. Young children for example have a rounder head and a smaller nose, adults often have a narrower face. In the next phase, the masks will be clinical tested with patients, see chapter 5.2.
- Variation in the tightening of the headgear of the masks can have influenced the effectiveness and comfort.
- The mask effectiveness and comfort can be influenced by small variation in the tightening of the headgear. The mask is fixated by the ventilation practitioner based on his experience.
- The sizing of the king mask (the mask could be slightly small or large for the test participant).

4.3.2 Conclusion

Conducting the test protocol will show the effectiveness of the mask, which is determined by the air leakage and wearing comfort. The final design test is include in the roadmap, see chapter 5.2. The proof of concept will be succeeded if the masks have reduced air leakage and increased wearing comfort compared to commercially available non-vented masks.

5
Conclusion



In this chapter the final design proposal is evaluated and recommendations are given for the further development. The final design proposal consists of two masks which are used in different situations at PICU: a mask used for acute NIV, and a mask used for an extended period of NIV. The two masks of the final design are evaluated with the design vison, and the list of requirements. Recommendations are given for further development of the final design proposal, and for the two masks separately. A roadmaps is created, which is a future scenario how to further develop and realise the implementation of the mask proposals in the PICU.

5.1 Evaluation

The two proposed masks are evaluated with the List of Requirements to conclude if the masks are suitable for the PICU. Next the final design proposal is compared to the design vision to conclude if it fits my vision. Then conclusions are drawn regarding the usage costs, investment costs, and optimisation possibilities of the two masks.

Both two mask proposals are suitable for NIV at the PICU, because the two masks meet the requirements of the List of Requirements (the assessment can be found in Appendix U). The final design proposal is consistent with my design vision. The Modular Mask functions as an ideal mask for patients who require NIV for an extended time. However, it can only be realised after producing the tailored cushion to the individual patient. The Quick Curable Mask functions as an acute mask; the mask can be quickly tailored in approximately seven minutes. The Modular Mask can replace the Quick Curable Mask after the tailored cushion is produced.

The Modular Mask has a lot of optimisation freedom to improve the fit of the mask, but to make it is laborious, and it is expensive and has high investment costs:

- Expensive tooling equipment (e.g. injection moulds) needs to be purchased to realise the production of the mask.
- Also a technical team of technicians is needed to realise the production of the tailored cushion, because technical knowledge of 3D scanning and printing is required. The technical team needs to coordinate with the medical team to plan the 3D scan of the patient.
- The estimated retail price is five times as high as the Performax, a commercially available mask.

The Quick Curable Mask has low investment costs, decreases the workload of the practitioners, but it is expensive and has limited optimisation freedom to improve the fit of the mask:

- The investment costs are low because: the anaesthesia masks are already available in the hospital, the tailoring equipment only consists of cheap cartridge gun dispensers, and no additional employees are needed. The tailoring of the Quick Curable Mask is executed by the intensivist practitioners, who need to be educated and trained for the tailoring process. The usage of the Quick Curable Mask will increase the time needed to provide NIV. But it will decrease the workload of the practitioners during the NIV intervention, because the masks do not have to be repositioned (as often) compared to commercial masks.
- The manufacturing costs for the hospital are estimated twice as high as the Performax, a commercially available NIV mask. Although the masks can become much less expensive if a cheaper five point strap headgear is found, because the purchased headgear contributes to 84 % of the total costs.
- Optimising the injected cushion can only be done by adjusting the fill percentage and the injected material. Silicones with different shores can be injected, and different amounts of material can be injected. The shape of the cushion cannot be adjusted, as is the case with the Modular Mask.

5.2 Recommendations

Recommendations are given for further development of the final design proposal, summarised in the roadmap in Figure 61. The roadmap describes the future scenario how the masks can be implemented in the PICU. The roadmap is divided into four phases: the optimising phase, the clinical testing phase, the implementing phase, and the redesigning phase. The phases are explained below.

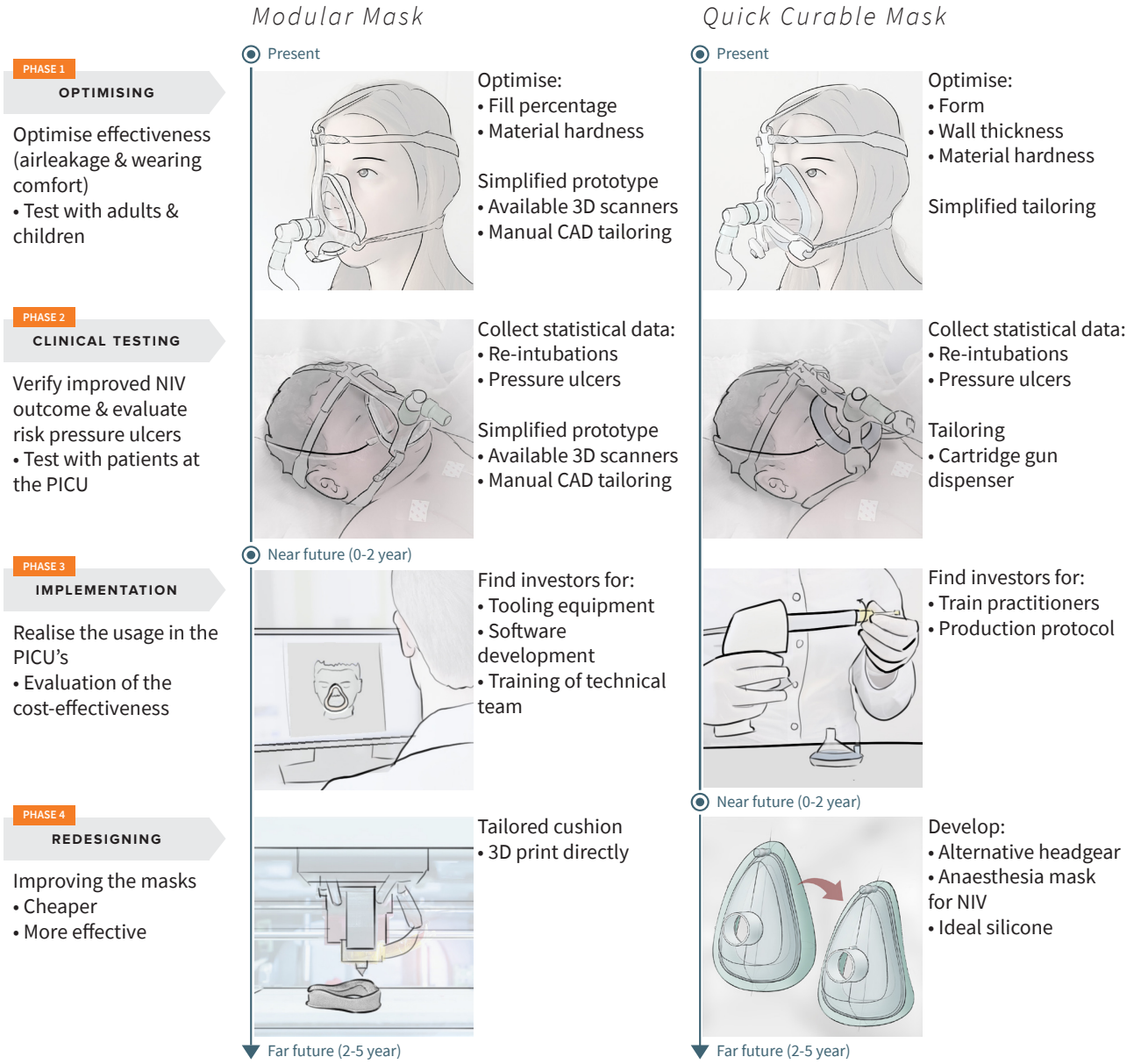


Figure 61. *Roadmap of the final design proposal.*

5.2.1 Optimising phase

In the optimising phase, I recommend to optimise the effectiveness of the two mask proposals. The objective is to reduce air leakage and increase the wearing comfort of the two masks. Firstly, the Final Design test will be conducted, see chapter 4.3. This test will prove the working principles of the masks. The two masks will be optimised based on the results of the air leakage and wearing comfort. Secondly, the masks will be tested on healthy children, to optimise the effectiveness of the two mask proposals for children by adjusting the design parameters:

- The fit of the Modular Mask is determined by the casted tailored cushion, which has three design parameters: form, wall thickness, and material hardness. Furthermore, for reduction of air leakage around the nasogastric tube I suggest starting with a gap in the cushion, because the nasogastric tube remains easy accessible for the practitioners. However, if the nasogastric tube remains the bottle neck of air leakage I suggest using an inlet in the frame.
- The fit of the Quick Curable Mask is determined by the injected cushion, which has two design parameters: the fill percentage, and material hardness.

For the production of the Modular Mask at this phase I recommend producing simplified prototypes, because the high investment costs for injection moulding and software development (the automatic tailoring programme) cannot be verified at this point. For the tailoring I recommend using the already available 3D scanners at the hospitals to reduce investment costs. For the production of the Quick Curable Mask at this phase I recommend manually mixing and injecting the mask with a syringe. In this phase the mask will be tested with healthy children, so there is no actual acute situation and the investing in tailoring gear is not needed.

The result of this phase are two optimised masks for children. If the air leakage with one of the prototypes is not decreased compared to the commercial masks, it is not sensible to continue with that particular mask proposal.

5.2.2 Clinical testing phase

In the clinical testing phase, I recommend to test the two mask proposals in the clinical setting with patients. The objective is to verify if the two masks improve the NIV outcome at the PICU compared to the currently used commercial masks, and to evaluate the risk of skin injury (because skin injury is a contraindication of NIV). Mask alternation, using different types of masks, can be used as strategy to reduce skin irritation. Statistical data of the NIV outcome of the two masks need to be collected and evaluated. Decreased air leakage does not imply an improved NIV outcome, because the air leakage fluctuates during the NIV intervention. Long term excessive air leakage will lead to NIV failure. Therefore I suggest to count the number of patients who need re-intubation while using the two masks, and compare it with the number of patients who need re-intubation using the commercial masks. Also, statistical data of skin irritation caused by the two masks, need to be collected to evaluate the risk for skin irritation and to determine if mask alternation is required. The location, and the severity of skin irritation need to be reported (using the different stages of pressure ulcers, see paragraph 1.2.4) with the two masks. For the collection of data I recommend to collaborate with the other PICU's in the Netherlands. They have the same problems and needs, and therefore the same interests in developing an improved NIV mask. At Amsterdam UMC most patients are currently invasively ventilated, so the collection of statistical data will take a very long period.

For the production of the Modular Mask at this phase I recommend producing manually simplified prototypes, because the high investment costs for injection moulding and software development (the automatic tailoring programme) cannot be verified at this point. For the tailoring I suggest using available 3D scanners at the hospitals to reduce investment costs. For the production of the Quick Curable Mask at this phase I recommend investing cartridge gun dispensers for the clinical testing. It makes the production of the tailored mask easier for the intensivist practitioners, when testing the mask on real patients in an acute situation.

The results of this phase are: two masks that are statistically proven to improve the NIV outcome

of patients at the PICU, and the need of mask alternation with the usage of the masks. If the NIV outcome of the masks are proven, the investment for the implantation in the next phase is legitimate. If mask alternation is required with the usage of the masks, I suggest alternating the masks with a total face mask because it has a different contact area.

5.2.3 Implementation phase

In the implantation phase, I recommend realising the usage of the two mask proposals if they are considered cost-effective. The objective is to find companies and hospitals that want to invest in the development and production of the Modular Mask, the development of a protocol for the tailoring of the Quick Curable Mask, and the training of practitioners in the tailoring of the Quick Curable Mask. The implementation of the Modular Mask requires high investments in tooling equipment (such as injection moulds), software development for the tailoring, and the training of the technical team (for the production of the tailored cushion). Health insurance companies can be interested, because the two masks have the potential to reduce healthcare costs of admitted patients at the PICU, e.g. by reducing the hospital stay. The implementation of the Quick Curable Mask requires skilled practitioners in the tailoring procedure, because they will execute the tailoring. A protocol can be developed to give the practitioners a guideline. Training for the practitioners can be organised to make them competent in tailoring.

For the production of Modular Mask at this phase I recommend to form technical teams with employees of the hospital, and produce tailored cushions at one central place if NIV is increasingly used:

- Using employees will decrease the cost of hiring new people. The tasks of the technical team include: 3D scanning the patient's countenance, creating an ideal NIV mask with a software programme, and producing an tailored cushion. This will not be a full time job. However, multiple employees will be needed, because the team has to be available every day of the week.
- If NIV is increasingly used, I suggest production at one central place to reduce the investment costs of multiple 3D printers. Currently, one 3D printer is sufficient for the PICU, because most patients are invasively ventilated.

The result of this phase are manufactured masks for the PICU. However this requires investment costs, if investors cannot be found or if the investment is not fully covered, the masks cannot be further developed.

5.2.4 Redesigning phase

In the redesigning phase, I recommend redesigning the masks. The objective is to optimise the mask and make them cheaper. The purchased headgear of the Quick Curable Mask is expensive; it contributes to 84 % of the total costs. The anaesthesia mask which is used as basis of the Quick Curable Mask is developed for inhaling anaesthetics, with NIV the anaesthesia mask is worn during a longer period of time. The silicone that is injected into the anaesthesia mask is based on the availability on the market. Possibilities are:

- Collaborating with NIV mask producers to develop an alternative headgear which replaces the purchased headgear, to make the mask cheaper.
- Collaborating with anaesthesia mask manufacturers to improve the anaesthesia mask for NIV. Improvement points are: anatomically shaping the frame (to improve the wearing comfort), reducing the cushion size (to minimise material use), and adding Luer-Lock to the inlet (to improve the injection process).
- Collaborating with silicone producers to develop an ideal silicone for the Quick Curable Mask application. The ideal silicone, has a low shore, and short working and curing time (see paragraph 4.2.3).

For the Modular Mask in the future it might be possible to 3D print the tailored cushion directly, because the 3D printing possibilities with silicones are developing rapidly. In that case costs of the tailored cushion are reduced because it decreases the human labour.

The result of this phase are cheaper masks for the PICU.

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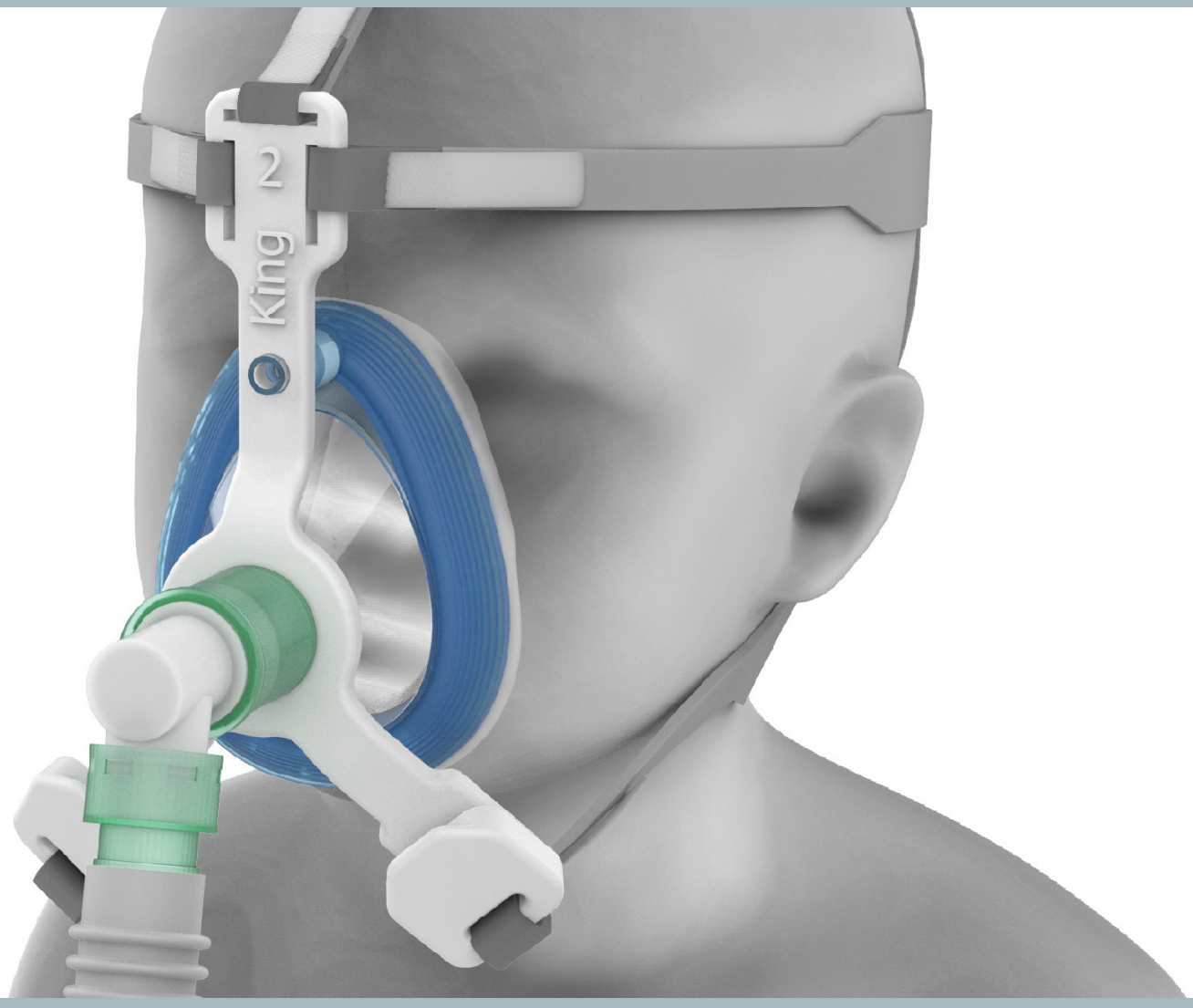

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