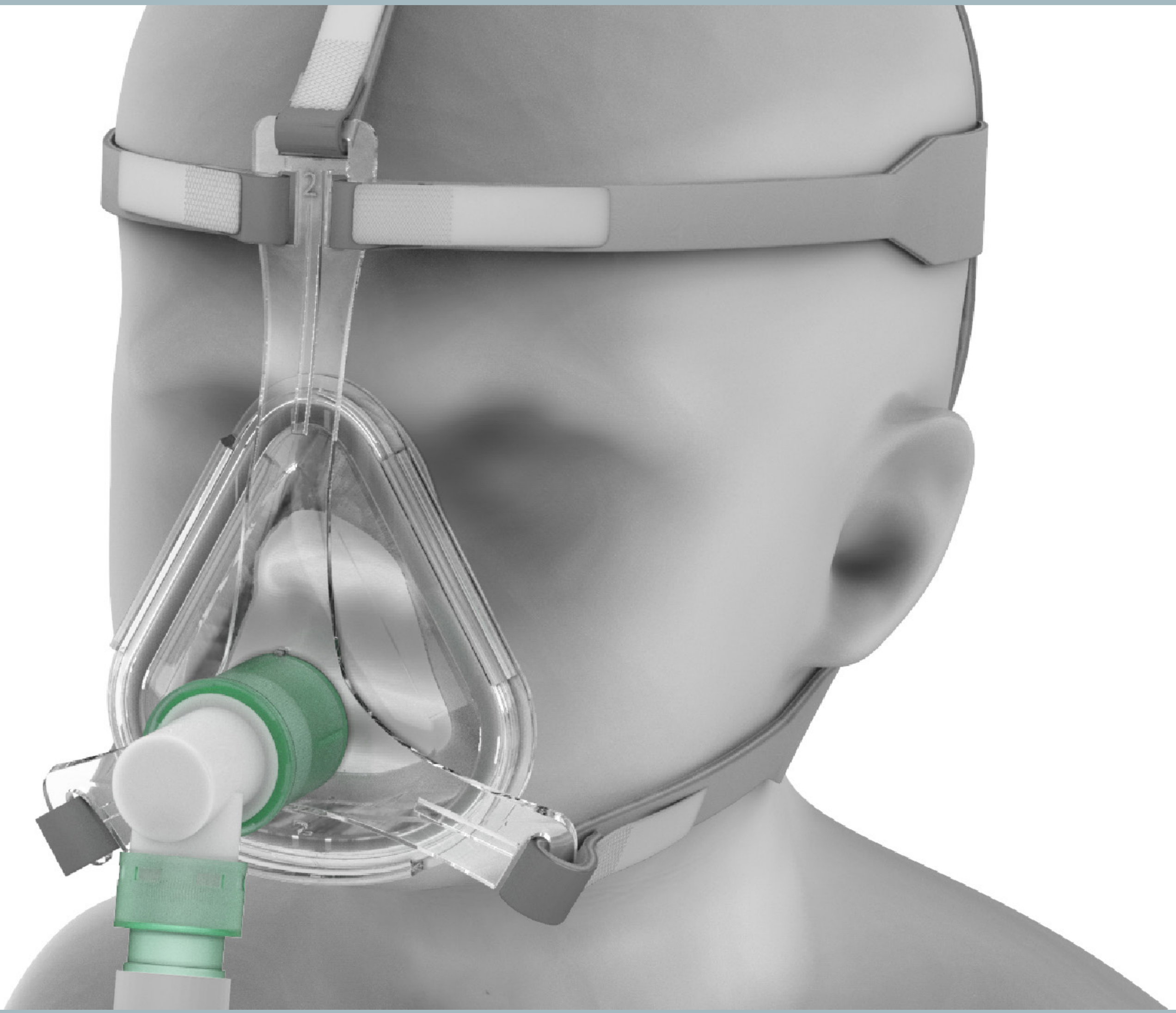
TAILORED NON-INVASIVE VENTILATION MASKS FOR PAEDIATRIC INTENSIVE CARE



APPENDICES

JIP SPIJKER

Appendices

Appendix B: Complications of intubation

One of the main problems of intubation involves the fixation of the tube on the patient (MIO, 2018). The tube used to be fixed by adhesive plasters. However, this fixation does not work long because the tube and plasters can be moved by mucus and other human fluids. Movement of the intubated tube can cause three categories of complications (MIO, 2018), and can be seen in Figure 62:

- The first complication occurs if the tube moves too far out of the body, also known as extubating, with the risk that the patient is not well ventilated anymore. This can be a life threatening situation, because the patient's situation is critical.
- The second one occurs when the tube moves too far into the body. The tube can hit the carina of trachea, which is the division of the two main bronchi. This feels uncomfortable, can cause bradycardia (a slow heart rate), and coughing.
- The third one happens if the tube goes inside one of the two bronchi, which can cause a pneumothorax (collapsed lung).

To prevent these complications the tube is daily tightened, sometimes even up to three times a day. This retightening costs considerable time and it is uncomfortable for the patient. Furthermore, retightening often requires sedation, and causes skin irritation or wounds.

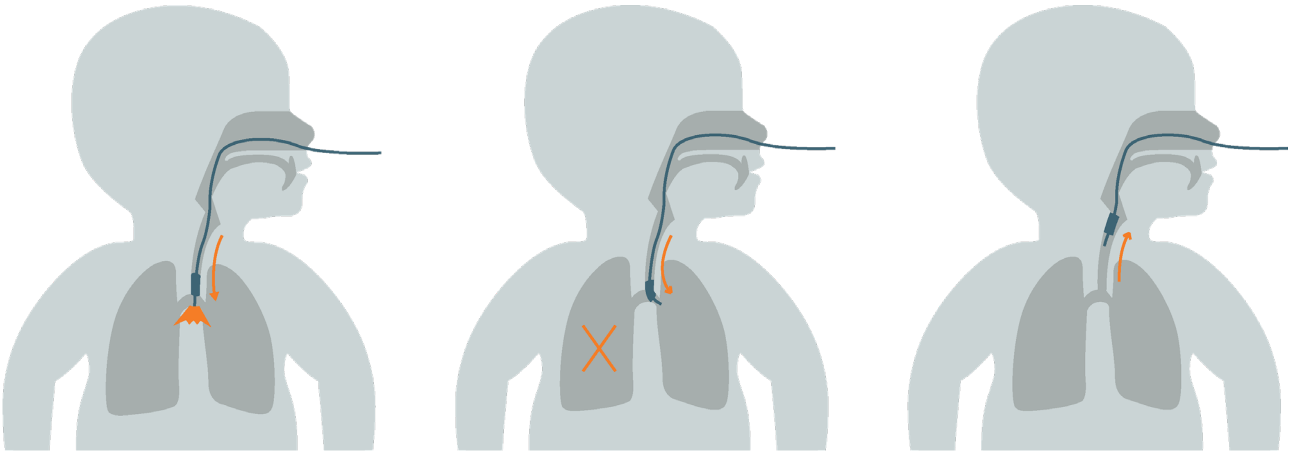


Figure 62. *Three main complications of intubation, (1) tubes hit the carina, (2) tube moves in the bronchi, (3) tube moves too far out.*

Appendix C: Strategies to reduce skin injury

Strategies to decrease the risk of skin injury in literature include:

- Regularly checking the skin under the NIV mask, at least every four hours (Raurell-Torredà et al., 2017).
- Use of light masks (Castro-Codesal et al., 2019).
- Alternating different type of masks, to change the contact area (Castro-Codesal et al., 2019).
- Avoid excessive tightening with the Two-finger rule; allowing one finger on both sides of the mask (Castro-Codesal et al., 2019).
- Taking the gravitational force into account when fixing the mask in seated position and ventilating in the supine position, less tightening is needed (Brill et al., 2018).
- Protecting the skin with dressing (Peña Otero et al., 2017).

Appendix D: 3D scanning techniques

There are five techniques 3D scanning techniques (Edge 3D, 2019):

- Laser triangulation 3D scanning technology, projects a laser beam on a surface and measures the deformation of the laser ray by a sensor. The measured distances of the laser the software can map the surfaces. The advantage of this technique is the high resolution and accuracy. The disadvantages are that the applications are very expensive, not easy to transport, and the scan is relatively slow.
- Structured light 3D scanning technology measures the deformation of a project light in linear pattern on a surface. By analysing the deformations of the pattern the distances can be calculated and the software can map the surfaces. For this technology often white light ray is used in a series pattern. The advantages of this technique are the affordability, and resolution. The disadvantage is that it is time consuming.
- Photogrammetry 3D scanning technology reconstructs a 3D scan from two dimensional photographs from different angles with computer vision and computational geometry algorithms. Photogrammetry is the technology that calculates distances from photographs. The advantage is that this technique is extremely fast, very inexpensive, and portable. The disadvantage is the software complexity and process time.
- Contact-based 3D scanning technology (digitizing) relies on the sampling of several points on a surface. A probe is connected to the measurement device, the deformation of the probe gives data about the surface. These scanners are mainly used for quality control after manufacturing or for maintenance purposes. The advantage is the high precision. The disadvantage is the scanning speed and the inability for organic shapes.
- Laser (Time of flight) 3D scanning technology is based on the time measurement of the flight of a laser beam. The laser beam is projected on a surface and is collected by a sensor. The advantage of this technique is the easy use and the affordability. The disadvantage is that the scan quality and accuracy decline with increased distance.

Appendix E: 3D scanners

Scan setup

There are two kinds of 3D scanner setups: handheld and desktop scanners (Formlabs, 2018). The desktop scanners have a fixed station. Handheld are easy to transport. An handheld 3D scanner is required for the PICU, so patients do not have to move and the 3D scanner can.

Scan quality

The quality of the 3D scan depends on the accuracy and resolution (Formlabs, 2018): accuracy is the distance between the measured points and the actual locations, and resolution is the distance between captured points at a given scan distance. Details lower than the scanners resolution are not captured. The accuracy and resolution are illustrated in Figure 63. The accuracy of the face scan is important, since the tailored NIV mask has to fit precisely on the face. Although the human face is not rigid and can also adjust to the NIV mask. In general high scan quality comes with high costs (Formlabs, 2018).

Structured light 3D scanners have the highest quality around and above 0.1 mm (Formlabs, 2018). A test scan is made with a structer light 3D scanner, see Figure 64. Infrared depth-sensing cameras (Laser 3D scanners), achieve lower accuracy and resolution often larger than 1 mm, are the cheapest option. Smart phones often have infrared depth-sensing cameras. Photogrammetry 3D scanners, consisting of DSLR camera and software, have worse scanning accuracy than Infrared depth-sensing. However, with a fixed reference setup, high accuracy can be realised. But these setups are the most expensive set up. An overview of 3D scanners can be seen in Figure 65.

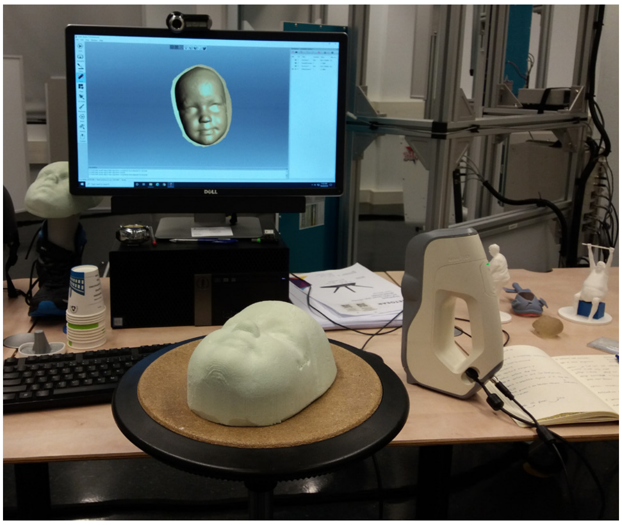


Figure 64. *Test 3D scan with the Artec Eva scanner at TUDelft.*

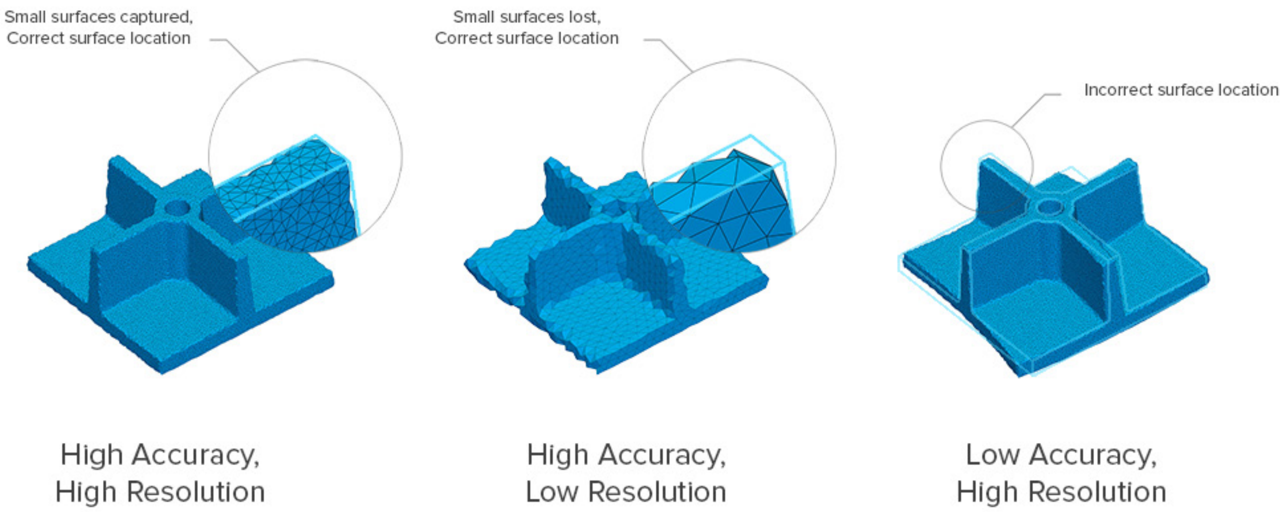


Figure 63. *Difference between accuracy and resolution of a 3D scan (Formlabs, 2018).*

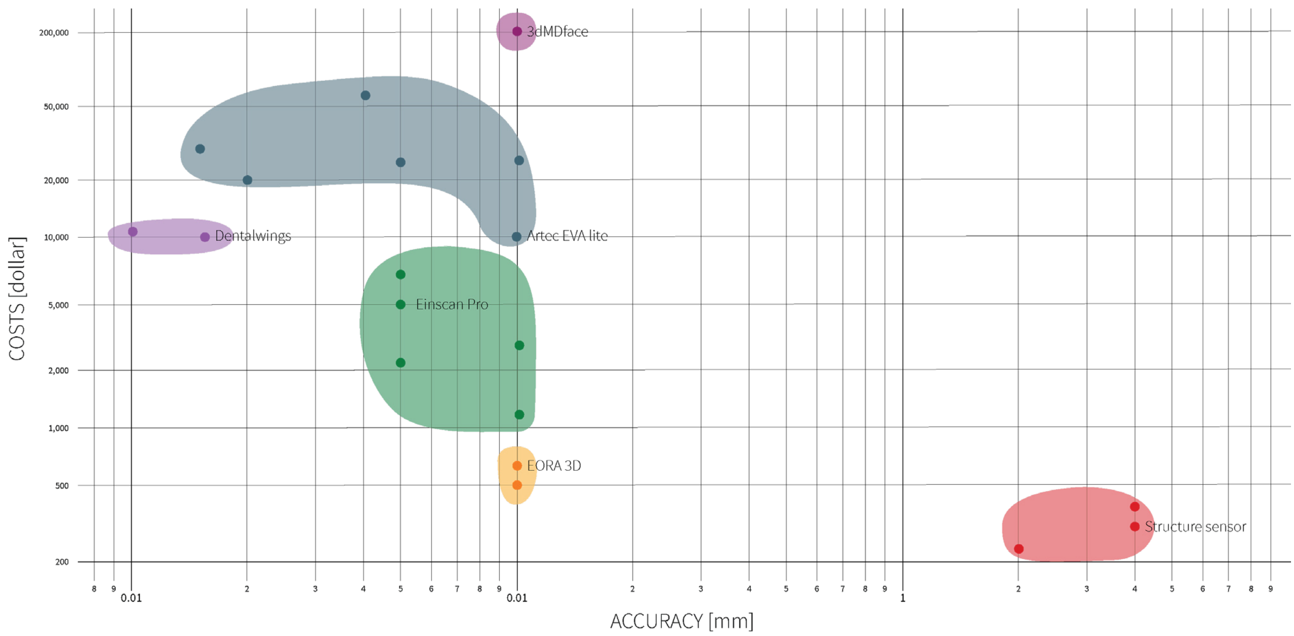


Figure 65. *Overview of 3D scanners plotted in a diagram based on the accuracy and costs (logarithmic scale).*

Appendix F: 3D printing techniques

There are four types of polymer 3D printing techniques (AMFG, 2019; 3D Onsider, 2019):

- Material extrusion uses filaments that are heated and extruded through a nozzle onto the printing platform, layer for layer. This technology is one of the most popular printing methods and is also known as Fused Deposition Modelling (FDM) or Fused Filament Fabrication (FFF). The disadvantage of material extrusion is the relative slow printing speed compared to Vat Polymerisation, the need for pre-processing, because of layer-lines for visual applications, and that the material properties of the print are not equal in all directions. However, FDM is both functional and durable. The filaments are available in a wide range from elastic TPU to durable and reinforced plastics.
- Vat Polymerisation convers liquid photopolymers into a solid object, bottom up, layer for layer. After the print is done, a chemical bath is used to remove resin. Often the 3D print have to be hardened in an ultra violet oven. There are two different technologies: Stereolithography (SLA), and Digital Light Processing (DLP). DLP is quite similar to SLA, DLP uses another light source, usually arc lamps. The main advantage of DLP over SLA is the higher printing speed, because the entire printing layer is exposed at once. The main advantage of Vat Polymerisation is the high accuracy and precision, which result in good surface quality, while remaining low in costs. There are developments in printing biocompatible materials for medical applications.
- Powder bed fusion, is the fusion of powder, layer for layer. There are four types of technologies used: Selective Laser Sintering (SLS), Selective Laser Melting (SLM), Multi Jet Fusion (MJF), and Electronic Beam Melting (EBM). SLS fuses plastic powder material with a laser. The main difference with SLA is the use of powdered material instead of liquid resins. This technique offers high accuracy, speed and lack of support structure. This technique is mostly used for strong reinforced thermoplastics, like Nylons, PEKK, and PEEK. However it is also possible to print flexible TPU. MJF uses dropping fusing agent to fuse every layer. Therefore MJF is faster, but the materials are limited to nylon. SLS is quite similar to SLM in terms of speed and quality. The difference between SLS and SLM is that with SLM power is melted, and therefore every layer has to be added by the printer. In general SLS is stronger than SLM. It is mostly used for precise, durable and light parts in for example the aerospace industry. EBM is a variation of SLM. It uses another power source, an electron beam in vacuum. EBM is mainly used to print 3D metal parts. The advantage over SLM is the freedom of design.
- Material Jetting (MJ), uses resins drops that solidify under UV light. Photoreactive material is deposited on the printing plate, layer for layer. With this technique it is possible to combine two materials optimising material properties. The main difference with SLA is that the ink print material used with MJ is less viscous and more expensive. The main advantage is the possibility to produce full colour parts. The disadvantage is the mechanical properties. Therefore this printing technique is mostly used for visual prototypes.

Appendix G: 3D printers

The Medical-Technical Innovation and Development department at Amsterdam UMC is equipped with two 3D printers: the Fortus 450 mc of Statasys and the Form 2 of Formlabs.

- The Fortus is a FDM printer and prints with PC-ISO (biocompatible polycarbonate). The PC-ISO is only printed in white, so contamination of non-biocompatible materials (printed in dark colours) is noticed.
- The Form 2 is a SLA printer used for prototyping that does not print biocompatible materials. This printer can be used for prototyping; printing elastic and semi-transparent parts with the elastic and clear resin. The elastic resin is transparent, has high elongation, and has a shore of 50A (Formlabs, 2019). Although the material will become harder over time because it hardens under UV light. The clear resin requires preprocessing, such as: sanding, polishing or using a solvent, or coating (Formlabs, 2019).

At TU Delft the Objet Connex and Ultimaters are available which can be used for prototyping.

- The Objet Connex of Stratasys prints in multiple non-biocompatible rubber-like materials, with a water removable support material.
  - Tango has a hardness of 27A and an elongation of 170-220%.
  - Agilus 30 has a hardness of 30A, an elongation 220-270%.

Appendix H: 3D printing materials

Materials for the NIV mask have been explored by consulting 3D4Makers, a company that produces filaments for FDM printing.

- PET-G is a semi-transparent material. Although the transparency decreases with thicker walls. 3D printing of transparent parts is in general very hard.
- PCL is a biocompatible material used for tissue engineering, see Figure 66. The material is deformable when heated above 40 degrees Celsius. The form freedom of the material is limited.
- TPU is a flexible polymer, see Figure 66. The TPU FDM material is stiff but with a minimal wall thickness of 1 mm it is possible to make flexible parts.

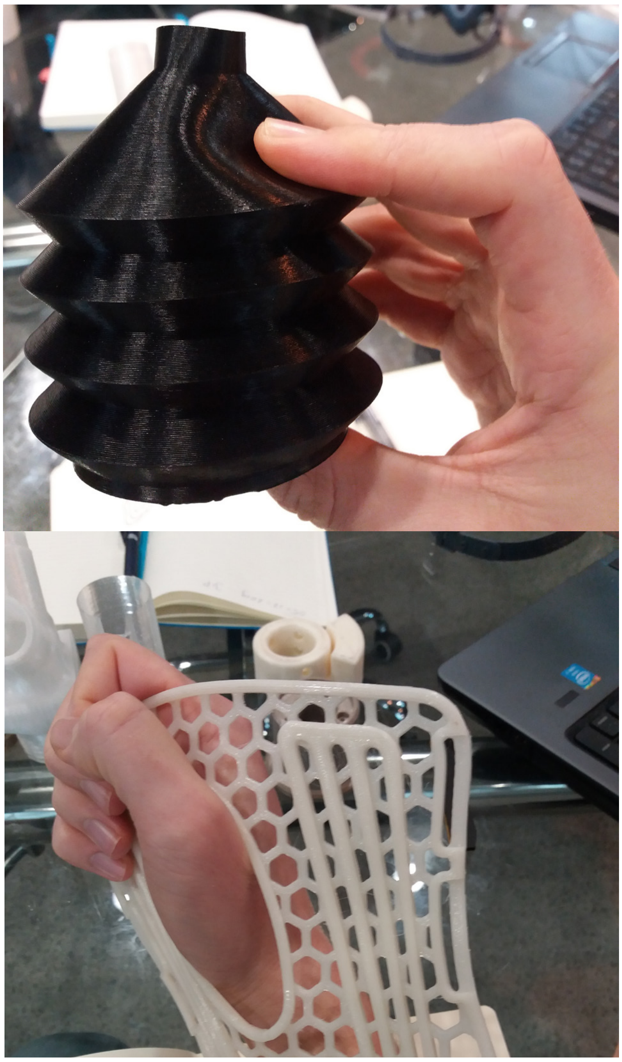


Figure 66. *TPU cone at the top, and at the bottom a PCL brace.*

Appendix I: 3D printing with silicone

The latest developments in the area of 3D printing silicones involve (All3DP, 2019):

- The first 3D printer for liquid silicone rubber (LSR) by ACEO for WACKER (Beamler, 2019). The silicone is dropped out of a nozzle and hardened by UV light, the Drop On Demand method. The 3D printers are able to print with a thickness of 0,6 mm, and a shore of 20A. The silicones are tested for bio-compatibility and are therefore suited for medical applications, see Figure 67. ACEO is not licensing out their technology (Philip Osterloh, Managing Director of ACEO).
- EnvisionTEC developed E-Silicone. This 3d print material used for printing shells for the casting of medical silicones. The shell is produced with the Digital Light Processing method, which has high precision. E-Silicone is aimed for hearing aids and medical devices, see Figure 67. The brittle shell can easily broke off the casted silicone (Envision Tech, 2019).
- Carbon 3D developed SIL 30 Silicone, with a shore of 35A (Carbon3d, 2017). The material is used for skin-contact applications, the material is tested for bio-compatibility (Carbon3d, 2017). The material is printed with Digital Light Processing method, and has a high tear strength and is very flexible and can extend up to 330%.
- Printing service Picsima by Fripp Design. The silicone can be printed as soft as shore 10A, see Figure 67. This material is biocompatible and used in the hearing aid. The parts are printed in a base of silicone oil, and by adding a cross linker material and a catalyst to accelerate the curing process a 3D part is created. This method does not require post processing.

Figure 67. *3D print examples of: (1) ACEO, (2) Envision TEC, (3) Carbon 3D, and (4) Picsima.*

Appendix J: Observation plan

Objective of the study

The two objectives of the observation at the PICU are to clarify the NIV procedure and to identify NIV related problems in practice. The observations of a patient undergoing NIV will be captured in an overview, which will be used to evaluate the NIV related problems described by literature (in paragraph 1.2.4).

Research questions

The main research question is what problems arise in practice of NIV at the PICU? This is important to determine what problem have to be tackled in the development of a NIV mask.

Sub questions:

<u>Procedure</u>

- How is the NIV mask selected?
- How is the size of the NIV mask determined?
- How is the NIV mask introduced to the patient?
- How are the parents of the patient involved?
- How is the mask placed and fixed on the patient's head?
- When is it decided if the NIV intervention should be aborted?

<u>NIV related problems</u>

- What is the severity of the following NIV risks:
- Air leakage
- Facial skin irritation
- Nasal symptoms
- Eye irritation
- Claustrophobia
- Gastric distention
- Aspiration
- Are there other problems in the practice of NIV?

Method

Observation of patients, undergoing NIV, is challenging. Patients do not arrive announced, the developments are unsure, and most patients are invasive ventilated. Therefore the ventilation practitioners are informed to keep an eye out for a patient undergoing NIV.

Before starting the observation, first the permission is asked to the parent of the patient for the observation. Which include making notes and pictures of their child.

Observations are executed by shadowing the patient(s) for a full working day. Capture the proceedings by making pictures and writing notes, and put these afterwards on a timeline to create an overview of the observation. After the observations the findings are discussed with a ventilation practitioner to evaluate the findings and to clarify unclear situations.

Apparatus

- Phone for taking pictures during proceedings (camera is more intrusive) and to determine the time indication (clock).
- Pen and notebook for taking notes.

Results

After several weeks of standing standby for the observation, on the 2nd of December one patient undergoing NIV is observed for seven hours.

Procedure

- The selection of the interface is based on the required type of ventilation (vented or non-vented masks), the age of the patient (the total face mask for example is not available for children below one year old), and the experience of the practitioners (they decided to replace the oronasal mask with the nasal mask).
- The mask sizes are determined with the aid of a transparent sizing sheet. The headgear sizes are determined by measuring the circumferences of the patient's head.
- Babies do not get introduced with the NIV mask, because it is not possible to communicate with them. The mask placed, the headgear fixed and the ventilation has just started. However

older patients, who can communicate, do get introduced verbally first.

- The mother was not involved with care tasks of NIV. For her the comfortability of her child was most important, she realised that if her child was fighting against the NIV it would lead to exhaustion. The mother found it therefore important to be able to see her child's face to see how her child was doing.
- For the positioning of the mask the patient was placed in a sitting position. This made it easy to pull the headgear over the head and place the mask straight (this is important to prevent tilting of the mask. The repositioning of the mask and tightening of the mesh was the patient in a lying position.
- The patient's progression was evaluated by closely monitoring of the intensivist practitioner and ventilation practitioner. Before the starting the observation the team tried if the patient could NIV with HFNC. But the patient was worsening so BiPAP had to be used again.

NIV related problems

- Air leakage was the main problem during the observations at the PICU. The air leakage was often too high, resulting in patient-ventilator asynchrony (increasing the breathing efforts of the patient). Therefore had the intensivist practitioner often reposition the mask because it would have resulted in NIV failure. The anaesthesia mask often had too much air leakage, causing a lot of disturbance. The air leakage caused also other problems: skin irritation and eye irritation. The usage of the nasogastric tube leads to increased air leakage; there is a gap where the tube goes under the mask.
- Consequently of the high air leakage percentages the mesh had to be firmly tightened, increases the risk of skin injury. The skin is evaluated when the mask is removed. During the NIV intervention the mask was disconnected for short periods to unburden the skin. The mask and face are cleaned with cleaning napkins, and dry skin areas were treated with petroleum jelly. The practitioner used the nasal mask for alternating masks.
- Nasal symptoms have not been observed.
- The air leakage around the nasal bridge lead to eye irritation. Eye ointment was used to treat the eyes of the patient. The risk for eye injury can be reduced by closely monitoring the fit of the mask around the nasal bridge.
- Claustrophobia have not been observed. This is hard to identify if the patient cannot speak. The oronasal mask that is used is less intrusive than a total face mask, covering the whole face. Fogging of the total mask can block the patient's view and can be prevented with anti-condense fluid.
- Gastric distension have not been observed. The air in the stomach is released with the nasogastric tube. Nasogastric tubes are used for all patients younger than seven years old to release air. There are single tubes and dual tubes. The single tube is available in five diameter sizes at the PICU: 6 to 10 French. The dual tubes is available in three diameter sizes: 12 to 14 French. (French is 1/3 mm). The use of the nasogastric tube with NIV masks leads to air leakage where the tube goes under the mask.
- The gastric retention (fluid in the stomach) is frequently measured via the nasogastric tube, therefore the risk of aspiration is relatively low.
- The NIV mask was often displaced. The displacement is often caused by body movement if the patient feels uncomfortable. Body movement was minimised by swaddling the patient. Tilting of the NIV mask is also caused by friction of the ventilator tubes. Therefore the connection is supported by a pillow or towel on the bed.

Discussion

- For this observation a consent form (permission for observing) is considered. However because this project is executed as an intern at Amsterdam UMC, it was not required. Before the observation the approval of the patient's parent is asked for making notes and pictures.
- Only one patient has been observed, the overview only gives qualitative data. Finding patients was challenging and time consuming, it took several weeks of standby. Therefore I decided not to observe more patients, because of the considerable amount of time it costs. The qualitative data is discussed with the ventilation practitioner to evaluate the quantitative aspects.

- The pathology of the patient was the RS virus which required acute NIV.
- The patient was a baby of 8 weeks old, which is the target group. The ventilation practitioner noted that NIV is in general easier if patients are older, since it is easier to communicate with them. If communication is possible will the practitioners introduce NIV to the patient. The patient can first get used to how the NIV mask fits. Hereafter the ventilator machine is connected to the NIV mask. Starting with a low pressure setting, to let the patient get used to the pressure. At last is the ventilator set according to the treatment plan and possibly adjusted to the patient's preferences.
- Problems might have not been identified because of the following reasons:
- Long terms effects are not taken into account, the patient is only observed for seven hours.
- The patient was 8 weeks old and not able communicate (this makes it hard to identify claustrophobia).
- During the observations an oronasal mask was used. The total face mask could have caused other problems. Although the ventilation practitioner noted that the total face masks also often leak too much at the chin and forehead.

Appendix K: NIV masks in practice

Total face mask PerforMax by Respironics: PerforMax is a total face mask (see Figure 68) produced by the American company Respironics and distributed by Philips in the Netherlands. The Performax for single-use costs 60 euro and is available in the sizes: XL, L, S, XS, and XXS (Philips, 2019). The three smallest sizes are suitable for paediatrics. The XS and XXS are for patients above one year old and heavier than seven kilogram. The S-version is for patients older than seven years old and heavier than 20 kilograms. The PerforMax mask is compatible with single-limb and dual-limb NIV ventilators using different elbows in the mask. There are three types of elbows in the mask: a standard elbow (blue) and two expiration elbows (amber or transparent). For the headgear the following options are available: normal and paediatric headgear (Philips, 2019). The normal headgear, made of a four-point straps, comes in sizes ranging from M to L. The bonnet headgear with four point straps, comes in two sizes: small and petite.

Figure 68. *The total face mask Performax by Respironics (Philips, 2019).*

Oronasal anaesthesia mask by Ambu: Anaesthesia face masks (see Figure 69) are masks that are designed for inhaling anesthetics before an anesthetic procedure. The mask has an inflatable cushion used to suit the patient's anatomical contours. The anaesthesia mask of Ambu costs 2 euro per mask and is available in the following sizes: large adult #6, adult #5, large child #4, child #3, small child #2, and neonatal #1 (Ambu, 2019). To fixate the mask to the patient, a mesh pants is torn and connected to the pins on the mask. The pants will shortly be replaced by a 3D printed holder to fixate the mask with a headgear. At the moment of writing clinical testing started comparing the pants and 3D printed holder.

Figure 69. *The King mask by Ambu, which is an oronasal mask.*

Flexitrunk nose mask and nasal prong by Fisher & Paykel (see Figure 70): Flexitrunk is a tube that can be used with two types of masks: the nose mask (in four sizes) and the nasal prong (in eleven sizes) (Fisher & Paykel, 2019). Both masks cost 20 euro. A transparent sheet with illustrations of the different sizes is used as a sizing guide. These masks are vented masks. The tube of Flexitrunk is available in two sizes: 70 and 100 mm (Fisher & Paykel, 2019).

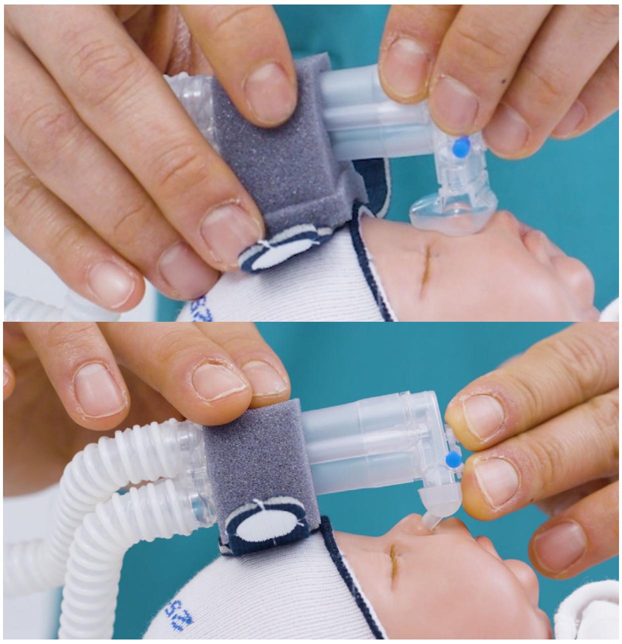
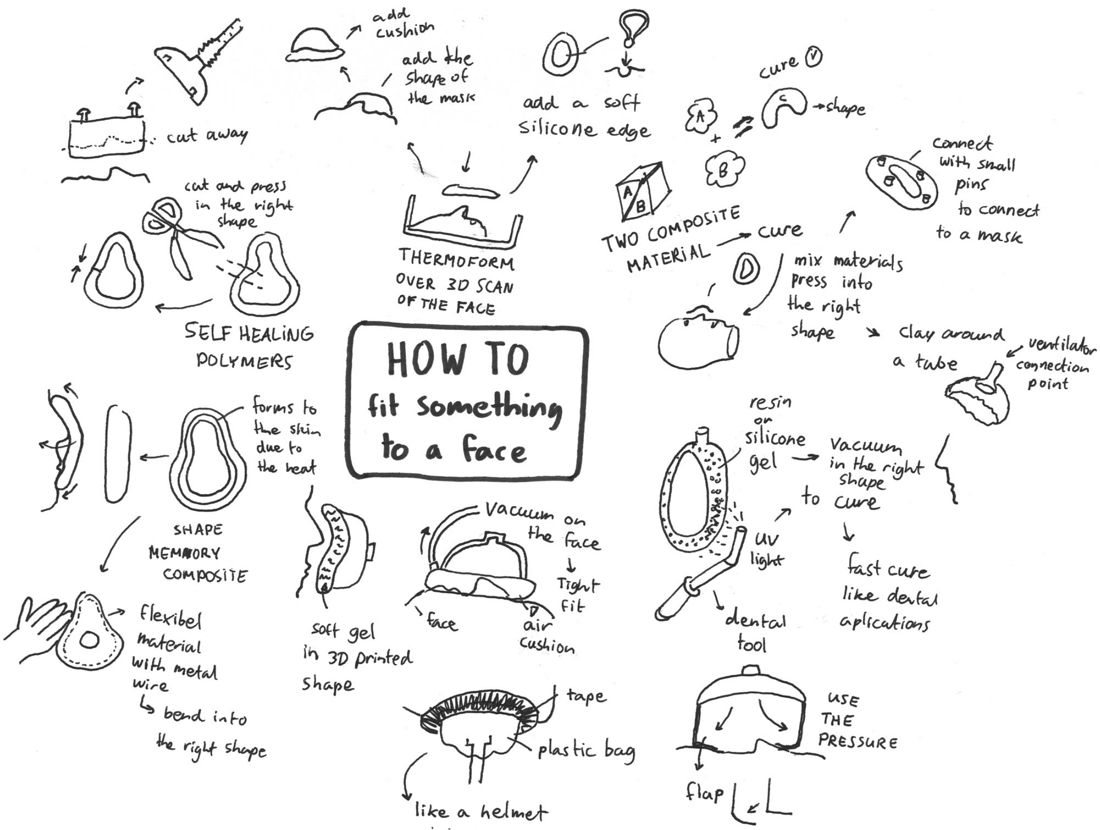


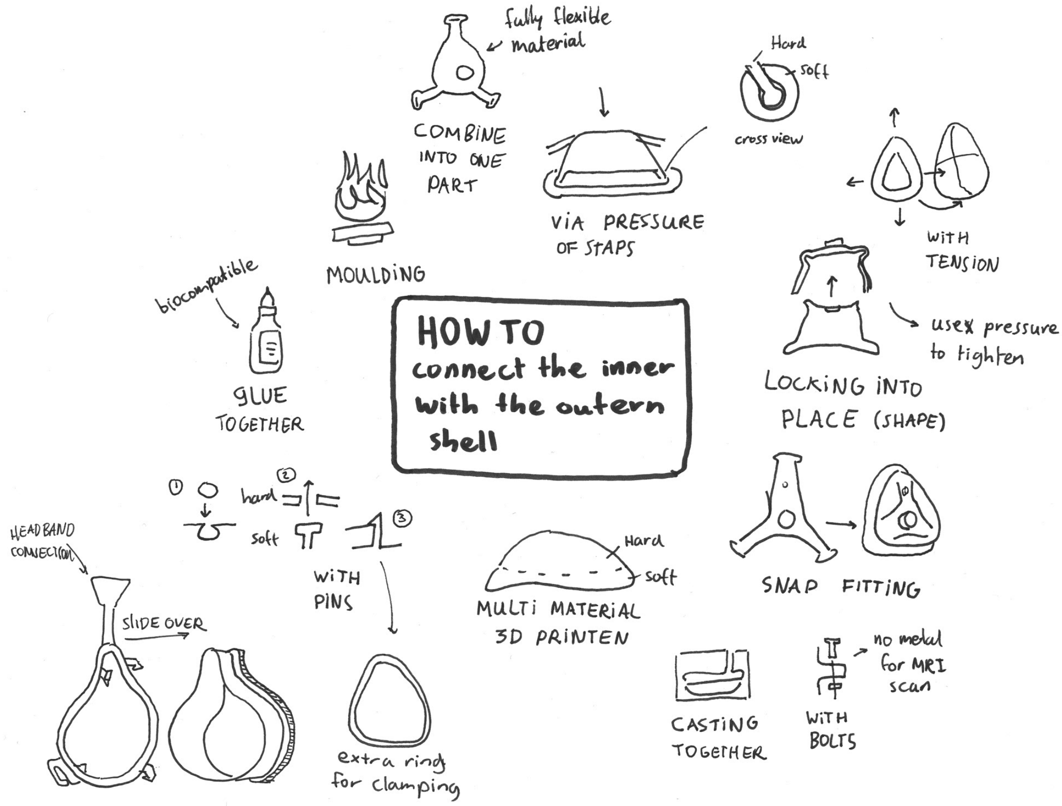
Figure 70. *The nose mask (top) and nasal prong (bottom) for Flexitruk by Fisher & Paykel (Fisher & Paykel, 2019).*

Appendix L: How-tos




HOW TO cover the nose and mouth?
distribute pressure
P = F/A [N/m²]
COVER THE WHOLE NOSE
TOTAL FACE MASK
remove pressure of the chin
COVER THE CHIN
sensitive area
clear view
USE WITH GLASSES
OVER THE MIDDLE PART OF THE NOSE
JUST ABOVE THE CHIN (under lip)
ON THE JAW LINE
air
MOUTH GUARD

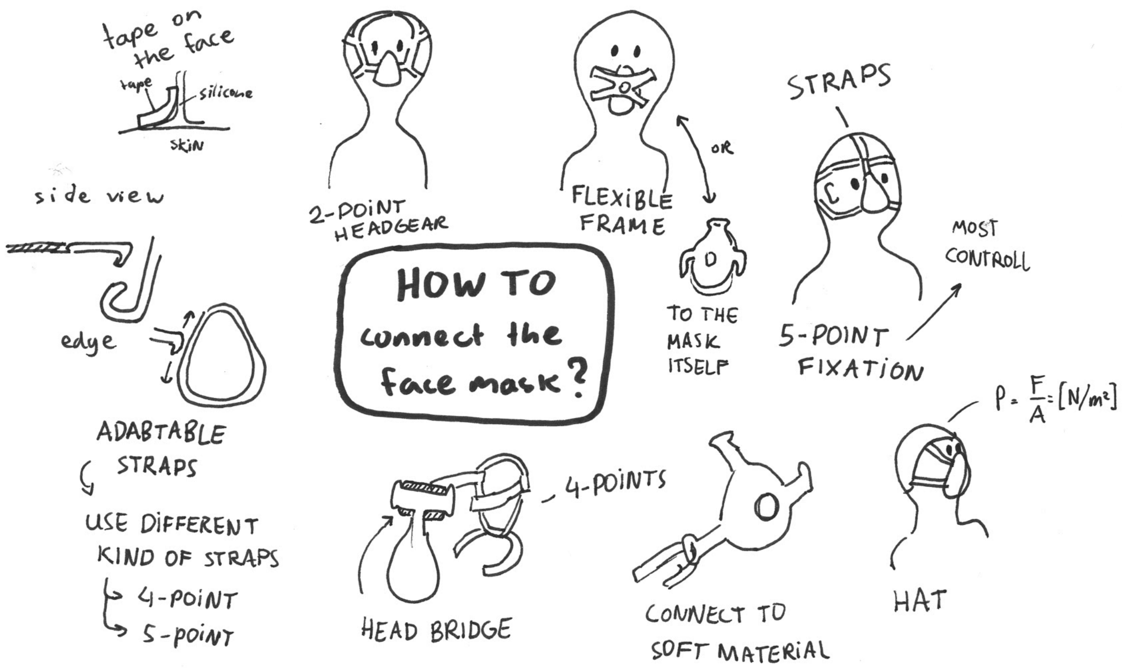

HOW TO make comfortable skin contact?
DRESSING
INCREASE CONTACT AREA
at sensitive areas
use multiple materials
silicone
SOFT/FLEXIBLE MATERIAL
fabric
silicone
FABRIC LINER
FABRIC CUSHION
PILLOW CUSHION
HOFA
HYPER OXYGEN-ATED FATTY ACIDS
THIN
THIN STRUCTURE
AIR CUSHION
↳ AIR CAVITIES IN MATERIAL
soft skin contact area
A
B
C
+ shore
USE MULTIPLE LAYERS
DEFORMABLE STRUCTURE

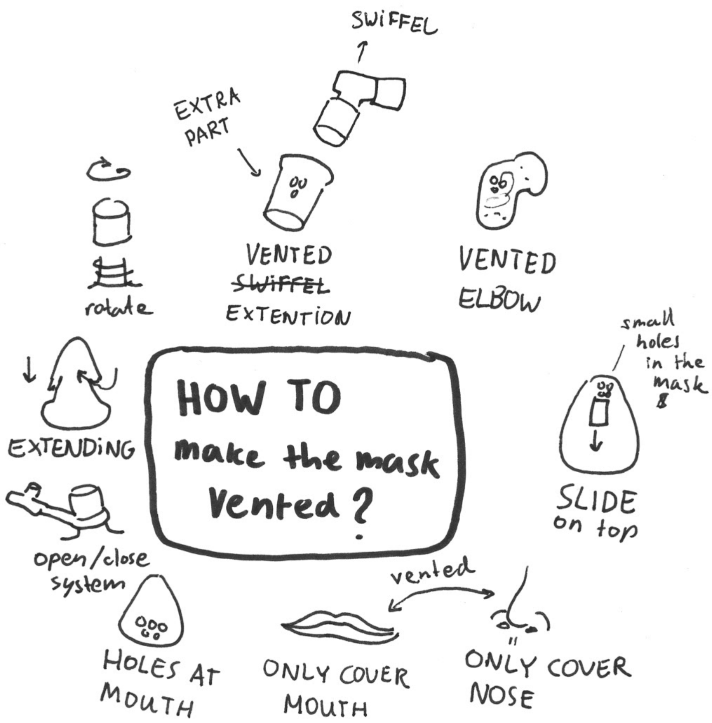

HOW TO connect the inner with the outern shell
fully flexible material
COMBINE INTO ONE PART
VIA PRESSURE OF STAPS
Hard
soft
cross view
WITH TENSION
MOULDING
biocompatible
GLUE TOGETHER
use pressure to tighten
LOCKING INTO PLACE (SHAPE)
hard
soft
WITH PINS
HEADBAND CONNECTION
SLIDE OVER
Hard
soft
MULTI MATERIAL 3D PRINTEN
SNAP FITTING
no metal for MRI scan
CASTING TOGETHER
WITH BOLTS
extra ring for clamping


OR UPWARDS
extrusion
Velcro
SOFT MATERIAL
CLICK/SLIDE HOOK
HOOK & PULL
clip
BALL CLICK
BUCKLE
press both sides to release
HOW TO ? quick release the NIV mask
CLIP
reinforced
MRI
MAGNET
HOLE IN THE FABRIC
PULLING A CORD
SNAP FITTING
CLIP
RELEASE BUTTON
CARABINDER
QUICK RELEASE KNOT
press
PUSH BUTTON

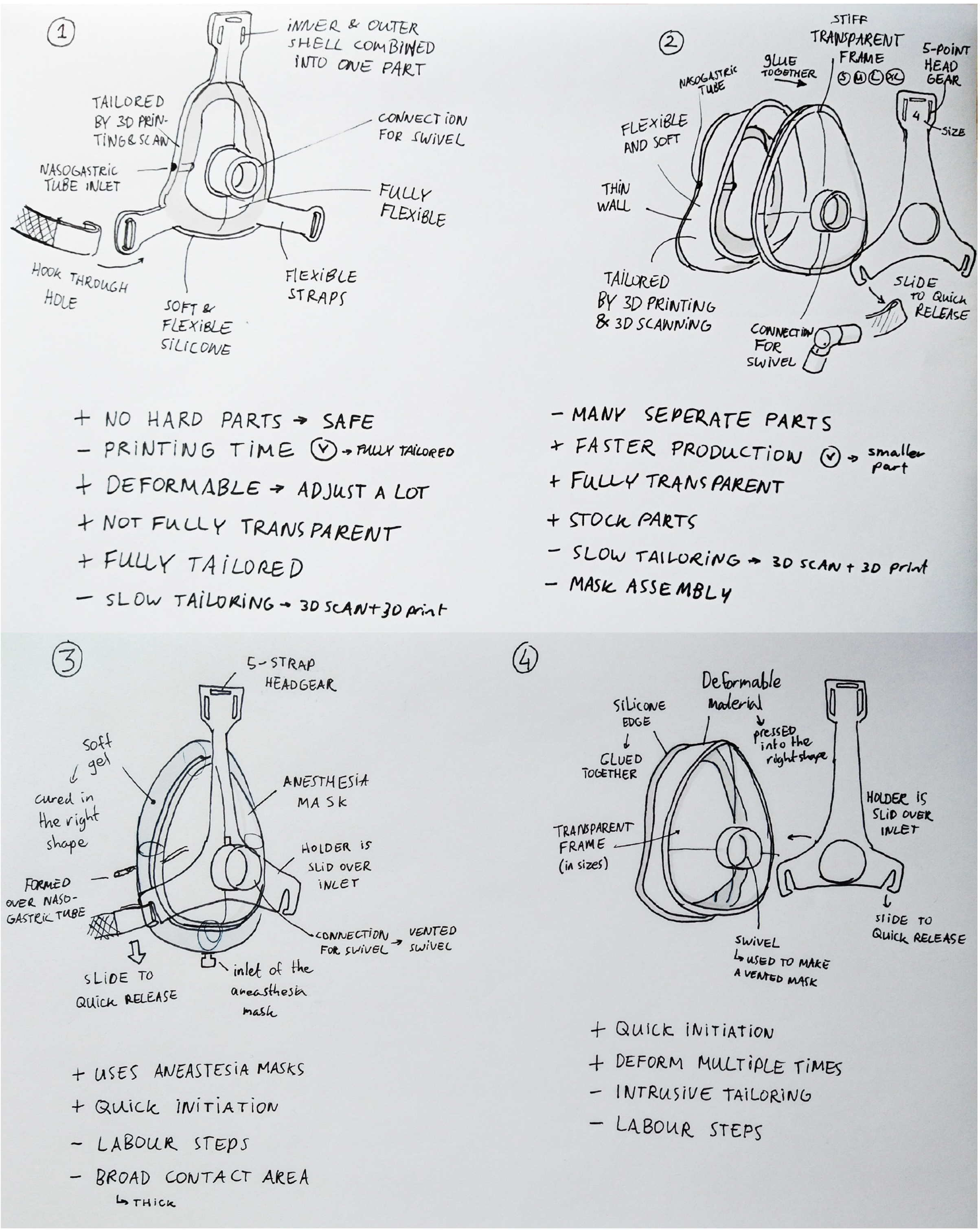

HOW TO prevent the gap at the nasogastric tube?
SOFT / DEFORMABLE MATERIAL
PLASTER
SMALL FLAPS
side view
CUTOUT SIDE
Sliderat side
3D SCAN FIT WITH NASOGASTRIC TUBE
OPENABLE HOLE
USE THE 3D SCAN FOR CAD MODEL


HOW TO connect the tube?
tube
MULTIPLE INLETS
TUBE CLIP
rotating
90°
ELBOW
BALL & SOCKET
SIMPLE TUBE
TOTAL FACE MASK
less annoying
USE AN EXTRA TUBE
connected to the mask
standard
angle
UNDER AN ANGLE
HANGING SYSTEM
comfort during sleep
OVER THE HEAD
CONNECT ON TOP OF THE HEAD
CO_2 rebreathing
TO THE SIDE OF THE MACHINE
USE AN EXTRA PART
HARMONICA
OR
SWIFFEL


HOW TO connect the face mask?
tape on the face
tape
silicone
skin
side view
edge
ADABTABLE STRAPS
USE DIFFERENT KIND OF STRAPS
4-POINT
5-POINT
2-POINT HEADGEAR
FLEXIBLE FRAME
OR
TO THE MASK ITSELF
STRAPS
5-POINT FIXATION
MOST CONTROLL
P = F/A = [N/m²]
HAT
4-POINTS
HEAD BRIDGE
CONNECT TO SOFT MATERIAL


HOW TO make the mask Vented?
SWIFFEL
EXTRA PART
VENTED SWIFFEL EXTENTION
VENTED ELBOW
rotate
small holes in the mask
SLIDE on top
EXTENDING
open/close system
HOLES AT MOUTH
ONLY COVER MOUTH
vented
ONLY COVER NOSE

Appendix M: Four design directions



Appendix N: Radiotherapy

At the Radiotherapy department are shells made, to hold the bodyparts of the patient still during radiation, see Figure 71.

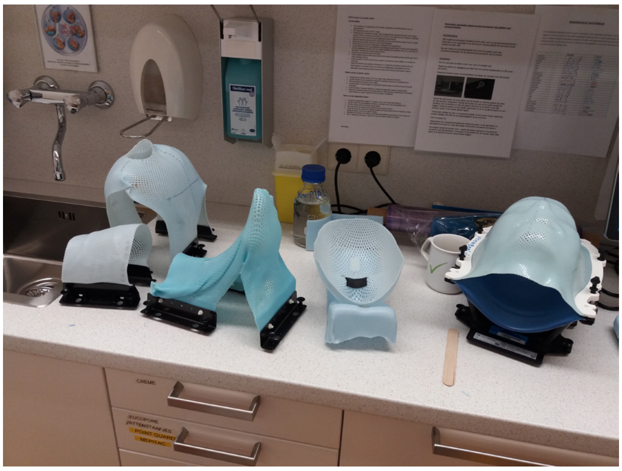


Figure 71. *Examples of bodyparts shells.*

First the plates are heated in water for two minutes at 70 degrees celcius, Figure 72. Next the plate is formed to the patient, see Figure 73.

Figure 72. *Shell water tank.*

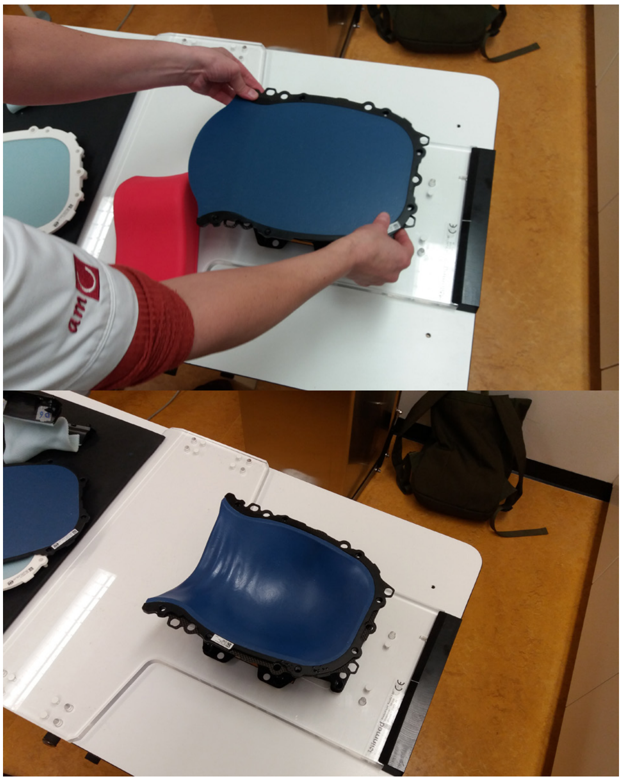


Figure 73. *Shell forming process.*

Appendix O: Prescale film

The contact pressure at the face can be accurately determined by the aid of the Prescale film of Fujifilm. Prescale film is an extremely thin sheet (less than 200 µm) and red areas will appear on the prescale film where pressure is applied (Fujifilm, 2019). Visually the distribution can easily be checked. A test sample of Extreme Low Pressure Prescale (see Figure 74) was ordered to test. However the Prescale was too expensive, 395 euro plus additional software cost to analyse the Prescale (Althen BV, 2019).

Product	Product Code	Pressure range [MPa] 1 MPa≒10.2kgf/cm² (0.05, 0.2, 0.5 0.6, 2.5, 10, 50, 130, 300) / (7.25, 29, 73 87, 363, 1,450, 7,250, 18,850, 43,500) Pressure range [psi] 1 psi≒6895 pa	Product Size W(mm) × L(m)	Type
Super High Pressure (HHS)	PRESCALE HHS R270 10M		270 × 10	Mono-sheet
High Pressure (HS)	PRESCALE HS R270 10M		270 × 10	Mono-sheet
Medium Pressure (MS)	PRESCALE MS R270 10M		270 × 10	Mono-sheet
Medium Pressure (MW)	PRESCALE MW R270 10M		270 × 10	Two-sheet
Low Pressure (LW)	PRESCALE LW R270 10M		270 × 10	Two-sheet
Super Low Pressure (LLW)	PRESCALE LLW R270 6M		270 × 6	Two-sheet
Ultra Super Low Pressure (LLLW)	PRESCALE LLLW R270 5M		270 × 5	Two-sheet
Extreme Low Pressure (4LW)	PRESCALE 4LW R310 3M		310 × 3	Two-sheet

Figure 74. *Prescale films variants, varying pressure range starting from 200 up till 0.05 MPa (Fujifilm, 2019).*

Appendix P: Concept simulation

Prototypes

The masks are tailored for the mannequin's face. Therefore the mannequin's face is 3D scanned, see Figure 75. (with an Artec Eva).

Figure 75. *3D scanning the mannequin's face with the Artec Eva.*

The prototyping included: 3D printing the parts, removing support material (see Figure 76), and assembling the mask. The three prototypes can be seen in Figure 77.

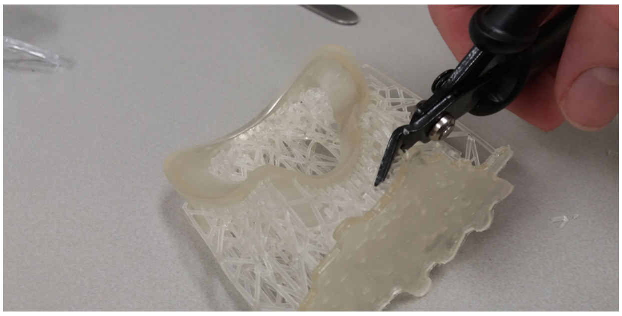


Figure 76. *Removing the support material of the cushion.*

Figure 77. *Removing the support material of the cushion.*

Flexible Mask

The Flexible Mask is tailored CAD-modelled with the 3D scan of the mannequin. The mask is 3D printed with flexible material, flexible resin on the Form 2. However the strap connections of the mask did not function properly, it was not possible to tighten the headgear firmly (see Figure 78). Therefore a holder is CAD-modelled and 3D printed of stiff material, PC-ISO on the Fortus 450 mc (see Figure 77).

Figure 78. *Flexible connection of the Flexible Mask prototype.*

Modular Mask

The Modular Mask is tailored CAD-modelled with the 3D scan of the mannequin, see Figure 79. The cushion is 3D printed with flexible material, flexible resin on the Form 2. The frame with strap holders is printed with PC-ISO. The cushion is fixated into the frame with glue.

Figure 79. *The Modular Mask prototype.*

Quick Curable Mask

The Quick Curable Mask is tailor-made with a 3D print of the mannequin's face. The anaesthesia mask is filled with silicone, and the mask is cured on the 3D print, see Figure 80.

Figure 80. *Making of the Quick Curable Mask prototype*

Deformable mask

The deformable cushion holder could not be 3D printed with available 3D printers. A test is conducted to evaluate how well the deformable material (PCL) is formed to the patient's face. The material is heated to fifty degrees Celsius (in water), and formed into the contour of the mask on the 3D printed face, see Figure 81. The material stayed stiff, therefore it was hard to deform the material to the contour. Also was the shape slightly deformed after removal. Which would result with a mask in gaps, increased air leakage. The deforming of PCL was hard.

Figure 81. *Test with PCL, the deformable material of the Deformable Mask.*

Apparatus

- Artec Eva 3D scanner
- Computer with Artec Studio Software
- Laeradal Resusci Junior
- 3D print of the face of the Laeradal Resusci Junior
- Carbon paper (brand Kangaroo)
- Thin paper (60 gram)
- Scissors
- Tape
- Hamilton T1 ventilator
- Ventilator tubes to connect the mask to the ventilator
- Camera to capture the test setup and carbon pressed onto the paper
- Tailored prototypes: Flexible Mask, Modular Mask, and Quick Curable Mask
- Benchmark masks: Respironics Performax (size XS) and Anaesthesia mask (size 3)
- Notebook and pen to write down measurements

Procedure

Preparation

Cutting the carbon paper for the masks, fully covering the contact area of the different masks. Next putting the carbon paper on top of the plastic sheet and the carbon paper facing down on the paper. A hole is removed for the tip of the nose.

Air leakage test

Step 1 : Placing the Laeradal Resusci Junior next to the ventilator.
Step 2 : Place the Performax on the mannequin, and fixate the mask with the straps of the headgear (executed by ventilation practitioner).
Step 3 : Start the ventilator with the first pressure setting 5/5, and wait ten breaths.
Step 4 : Read the Vleak (%) on the display of the ventilator, and note down the leakage percentage with corresponding pressure setting and mask. Check with feeling around the mask were the air flows out of the mask.
Step 5 : Repeat from step 3, with other ventilator pressure settings (5/10, 5/15, 5/25).
Step 6 : After finishing all the ventilator pressure settings repeat the process from step 2 with other NIV masks (King mask, Flexible Mask, Modular Mask, and Quick Curable Mask).

<u>Contact pressure test</u>

Step 1 : Placing the Laeradal Resusci Junior next to the ventilator.
Step 2 : Place the sheet with carbon paper and paper over the face of the mannequin.
Step 3 : Place the Performax on top of the sheets and fixate the mask by tightening the straps of the headgear.
Step 4 : Start the ventilator (setting: 5/5), and wait 10 breaths.
Step 5 : Remove the mask.
Step 6 : Remove the carbon paper sheet, and photograph the contact pressure of the mask.
Step 7 : Repeat from step 2 with other masks (King mask, Flexible Mask, Modular Mask, and Quick Curable Mask).

Results of the contact pressure

The impressions of the test can be seen in Figure 82.

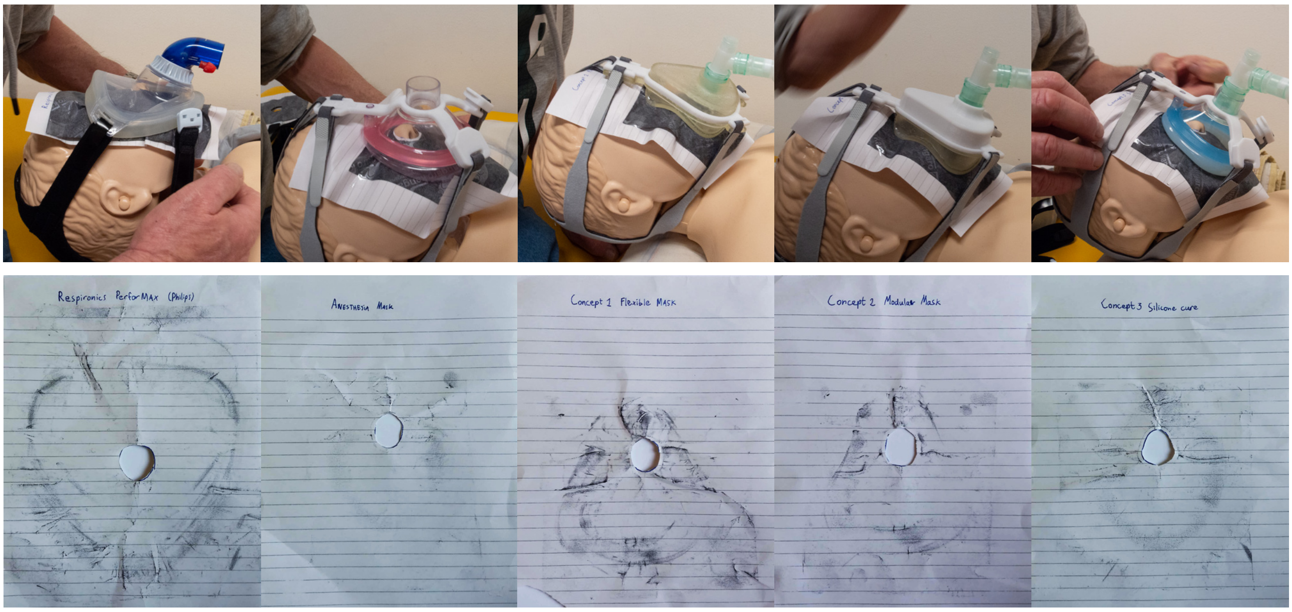


Figure 82. *Results of the face pressure test.*

Appendix Q: Sizing system

For developing a sizing system, firstly the maximum size is determined based on the 99th percentile of the male population between six and seven years old of 91 mm (DINED, 2019). Secondly a sizing range is determined based on the assumption that a decrease of 10% in size is acceptable. The five developed sizes are evaluated. First of all covers size one easily the 1st percentile of female population below one year old of 57mm (DINED, 2019). Since the databases do not cover the children below half a year old. The maximum growth in half a year of the sellion-promentale length is calculated 2,23 mm. So the size one frame is acceptable for the smallest child with a sellion-promentale length of 55 mm.

$$\text{Maximum growth of the sellion. promentale length in half a year} =$$
$$0{,}5\ \text{year}\ \frac{(\text{P99} - \text{P1 sellion. promentale length})}{6{,}5\ \text{year}} = 0{,}5\ \frac{(91-62)}{6{,}5} = 2{,}23$$

The height of the frame is determined based on the maximum sellion-promentale length of that sizing group (99th percentile). The width is determined based on the maximum width of the mouth (99th percentile) of the sizing group(DINED, 2019). Since covering the corners of the mouth is not desirable extra 10mm is added to the width on both sides; the minimal size of the flaps of the cushion. The height and width of the frame can be seen in Table 11.

The height and width of the holder is determined with the use of enriched statistical shape models (DINED, 2019), see Table 12. For each of the five sizes an enriched SSM is created based on the average sellion-promentale length of the five frame sizing groups, see chapter 4.1. With these heads holders have been developed. The holder is developed for the average of the group. Consequently for individuals within the group the holder can fall smaller or larger. However this is not problematic because the straps can still be connected and can control the fit of the mask.

SIZE	HEIGHT (MM)	WIDTH (MM)
One	109	81
Two	118	87
Three	125	93
Four	135	99
Five	145	107

Table 12. *Sizing of the holder.*

The headgear sizes are based on the headgear of the Quick Curable Mask. The headgear comes in three sizes. The headgear does not need to be tailored because the head bands can be stretched and the length of the straps can be adjusted in length.

SIZE	HEIGHT (MM)	WIDTH (MM)	SELLION-PROMENTALE LENGTH (MM)	MAXIMUM MOUTH WIDTH (MM)
One	60	58	54 - 60	38
Two	67	62	60 - 67	42
Three	74	66	67 - 74	46
Four	82	67	74 - 82	47
Five	91	67	82 - 91	47

Table 11. *Sizing of the frame.*

Appendix R: Cost price estimation

Material costs

Price of polycarbonate is 3,03 euro/KG (CES edupack, 2019)

Injection moulds

The cost price of the moulds is estimated with the pricing guide for injection moulding in China, see Table 13 (Sidotek Technology, 2019). Based on the examples in the overview I conclude that the injection moulded parts have med-complexity, for example the snap fits of the frame ring and the inlet of the frame. The mould costs are €2.900 ($3.200), which is able to inject 50.000 pieces.

Batch size estimation

Numbers about the amount of patient's non-invasive ventilated, the amount of PICU's, and total market size are lacking in literature. An estimation have been made to get an indicative order of magnitude of the total market.

Step 1: estimation of the percentage that is NIV

The research of Morris et al. (2017) analysed the data of 21 PICU's in the UK and Ireland over eight years from 2007 till 2014. In total were 147.387 patients under 16 years old admitted to PICU's, of which 39.494 patients were not ventilated via NIV or invasive ventilation on day 0. So approximately 73% of patients is ventilated, of which 32% received NIV first. So of the total admissions is estimated that 23%

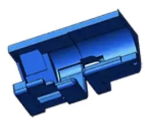
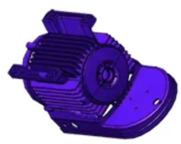
Complexity Level	Low-Complexity Part	Med-Complexity Part	High-Complexity Part	Large Part
Design				
Part Size (mm)	43 x 43 x 15	167 x 64 x 75	150 x 178 x 270	750 x 218 x 158
Part Material	Any plastic material	Any plastic material	Any plastic material	Any plastic material
Lead Time	2 to 4 weeks	2 to 4 weeks	4 to 8 weeks	6 to 10 weeks
Prototype Mold (1,000 parts)	**$850**	**$1,700**	**$15,000**	**$66,000**
Production Mold A (50,000 parts)	**$1,600**	**$3,200**	**$24,000**	**$115,000**
Production Mold B (1,000,000 parts)	**$3,000**	**$6,000**	**$43,000**	**$140,000**

Table 13. *Pricing guide for injection moulding in China (Sidotek Technology, 2019).*

of the patients are NIV. This estimation is validated with Reinout Bem (paediatrician intensivist), who estimates the percentage of NIV at Amsterdam UMC between 15 and 30% of the total amount of admissions.

Step 2: estimation of the total market

In the Netherlands there are approximately 5000 admissions a year at the PICU's (Stichting Kinder Intensive Care, 2019). The Netherlands has a population of 17 million people. For the estimation of the total market is assumed that the amount of admissions of other countries is equal to the admission population ratio of the Netherlands. Although the Netherlands have relatively limited intensive care capacity compared to the rest of Europe (NOS, 2020). The population of the first world countries, which have a high standard of living, is estimated at 1 billion people (First World Countries Population, 2020). The total amount of admissions in the western world are estimated at 307.000 patients per year. Of which 71.000 patients per year are NIV.

Step 3: estimation of the batch size

It is very hard to estimate the batch size, this also depends how effective the mask is. For the youngest patient group at the PICU, below one year old are no masks available, so here is a gap in the market. However for older patients, patients between one and seven years old, these mask have to outperform other available non-vented masks. Given the fact that these masks are tailored to individual patient is higher effectiveness expected. An batch size of 5,000 units is estimated (7%). Note that chronic patients also not included.

Benaming	**Holder**		**Productieserie**	**5.000**	**stuks**	**per onderdeel**
Materiaalkosten		**bruto hoeveelheid/product**	**eenheid**	**prijs/eenheid**	**bedrag**	
halffabrikaat	Polycarbonaat	0,00516	kg	€ 3,03	€ 0,02	
		0	m	€ 0,00	€ 0,00	
				totaal materiaalkosten	**€ 0,02**	**€ 0,02**
Bewerkingskosten	**capaciteit [stuks/u]**	**machineuren**	**machine-uurtarief**	**machine-kosten**		
machine 1	80	62,50	€ 10,00	€ 625,00		
machine 2	1000	0,00	€ 0,00	€ 0,00		
etc.	1000	0,00	€ 0,00	€ 0,00		
nabewerking	1000	0,00	€ 0,00	€ 0,00		
				totaal machinekosten	**€ 625,00**	
machines als bovenstaand	**mens/machine-bezetting**	**arbeidsuren**	**mensuurtarief**	**arbeidskosten**		
machine 1	1	62,50	€ 15,00	€ 937,50		
machine 2	1	0,00	€ 0,00	€ 0,00		
etc.	1	0,00	€ 0,00	€ 0,00		
nabewerking	1	0,00	€ 0,00	€ 0,00		
				totaal arbeidskosten	**€ 937,50**	
				totaal bewerkingskosten	**€ 1.562,50**	**€ 0,31**
Instelkosten serie	**insteltijd [u]**	**uurtarief insteller**	**mach.uurtarief**	**kosten**	**per product**	
machine 1	10	€ 15,00	€ 10,00	€ 250,00	**€ 0,05**	**€ 0,05**
Gereedschapskosten	**aanschafprijs**	**standtijd [stuks]**	**restwaarde**	**prijs/eenheid**		
matrijsen (#1 - #5)	€ 14.500	50.000	€ 0,00	€ 0,29		
		1	€ 0,00	€ 0,00		
subtotalen	€ 14.500		€ 0,00			
gemiddelde waarde	€ 7.250					
kapitaalrente	0,0%	rentekosten	€ 0,00	€ 0,00		
				totaal gereedschapskosten	**€ 0,29**	**€ 0,29**
Algemene toeslagen						
uitval-factor*	1,0%	*afgekeurde producten, zie Kals voor percentages			**subtotaal**	**€ 0,67**
overheadfactor**	15,0%	** algemene toeslag voor productiefaciliteiten				
totaal	**16,0%**					**€ 0,11**
		K_{Fi} voor interne calculatie:			**Productiekostprijs Holder**	**€ 0,78**

Benaming	**Frame**		**Productieserie**	**5.000**	**stuks**	**per onderdeel**
Materiaalkosten		**bruto hoeveelheid/product**	**eenheid**	**prijs/eenheid**	**bedrag**	
halffabrikaat	Polycarbonaat	0,00837	kg	€ 3,03	€ 0,03	
		0	m	€ 0,00	€ 0,00	
				totaal materiaalkosten	**€ 0,03**	**€ 0,03**
			machine-	**machine-**		
Bewerkingskosten	**capaciteit [stuks/u]**	**machineuren**	**uurtarief**	**kosten**		
machine 1	80	62,50	€ 10,00	€ 625,00		
machine 2	1000	5,00	€ 0,00	€ 0,00		
etc.	1000	5,00	€ 0,00	€ 0,00		
nabewerking	1000	5,00	€ 0,00	€ 0,00		
				totaal machinekosten	**€ 625,00**	
machines als bovenstaand	**mens/machine-bezetting**	**arbeidsuren**	**mensuurtarief**	**arbeidskosten**		
machine 1	1	62,50	€ 15,00	€ 937,50		
machine 2	1	5,00	€ 0,00	€ 0,00		
etc.	1	5,00	€ 0,00	€ 0,00		
nabewerking	1	5,00	€ 0,00	€ 0,00		
				totaal arbeidskosten	**€ 937,50**	
				totaal bewerkingskosten	**€ 1.562,50**	**€ 0,31**
Instelkosten serie	**insteltijd [u]**	**uurtarief insteller**	**mach.uurtarief**	**kosten**	**per product**	
machine 1	10	€ 15,00	€ 10,00	€ 250,00	**€ 0,05**	**€ 0,05**
Gereedschapskosten	**aanschafprijs**	**standtijd [stuks]**	**restwaarde**	**prijs/eenheid**		
matrijzen (#1 - #5)	€ 14.500	50.000	€ 0,00	€ 0,29		
		1	€ 0,00	€ 0,00		
subtotalen	€ 14.500		€ 0,00			
gemiddelde waarde	€ 7.250					
kapitaalrente	0,0%	rentekosten	€ 0,00	€ 0,00		
				totaal gereedschapskosten	**€ 0,29**	**€ 0,29**
Algemene toeslagen						
uitval-factor*	1,0%	*afgekeurde producten, zie Kals voor percentages			**subtotaal**	**€ 0,68**
overheadfactor**	15,0%	** algemene toeslag voor productiefaciliteiten				
totaal	**16,0%**					**€ 0,11**
		K_{Fi} voor interne calculatie:			**Productiekostprijs Frame**	**€ 0,79**

Benaming	**Frame ring**		**Productieserie**	**5.000**	**stuks**	**per onderdeel**
Materiaalkosten		**bruto hoeveelheid/product**	**eenheid**	**prijs/eenheid**	**bedrag**	
halffabrikaat	Polycarbonaat	0,00311	kg	€ 3,03	€ 0,01	
		0	m	€ 0,00	€ 0,00	
				totaal materiaalkosten	**€ 0,01**	**€ 0,01**
			machine-	**machine-**		
Bewerkingskosten	**capaciteit [stuks/u]**	**machineuren**	**uurtarief**	**kosten**		
machine 1	80	62,50	€ 10,00	€ 625,00		
machine 2	1000	5,00	€ 0,00	€ 0,00		
etc.	1000	5,00	€ 0,00	€ 0,00		
nabewerking	1000	5,00	€ 0,00	€ 0,00		
				totaal machinekosten	**€ 625,00**	
machines als bovenstaand	**mens/machine-bezetting**	**arbeidsuren**	**mensuurtarief**	**arbeidskosten**		
machine 1	1	62,50	€ 15,00	€ 937,50		
machine 2	1	5,00	€ 0,00	€ 0,00		
etc.	1	5,00	€ 0,00	€ 0,00		
nabewerking	1	5,00	€ 0,00	€ 0,00		
				totaal arbeidskosten	**€ 937,50**	
				totaal bewerkingskosten	**€ 1.562,50**	**€ 0,31**
Instelkosten serie	**insteltijd [u]**	**uurtarief insteller**	**mach.uurtarief**	**kosten**	**per product**	
machine 1	10	€ 15,00	€ 10,00	€ 250,00	**€ 0,05**	**€ 0,05**
Gereedschapskosten	**aanschafprijs**	**standtijd [stuks]**	**restwaarde**	**prijs/eenheid**		
matrijzen (#1 - #5)	€ 14.500	50.000	€ 0,00	€ 0,29		
		1	€ 0,00	€ 0,00		
subtotalen	€ 14.500		€ 0,00			
gemiddelde waarde	€ 7.250					
kapitaalrente	0,0%	rentekosten	€ 0,00	€ 0,00		
				totaal gereedschapskosten	**€ 0,29**	**€ 0,29**
Algemene toeslagen						
uitval-factor*	1,0%	*afgekeurde producten, zie Kals voor percentages			**subtotaal**	**€ 0,66**
overheadfactor**	15,0%	** algemene toeslag voor productiefaciliteiten				
totaal	**16,0%**					**€ 0,11**
		K_{Fi} voor interne calculatie:			**Productiekostprijs Frame ring**	**€ 0,77**

Benaming	**Headgear**		**Productieserie**	**5.000**	**stuks**	**per onderdeel**
Materiaalkosten		**bruto hoeveelheid/product**	**eenheid**	**prijs/eenheid**	**bedrag**	
halffabrikaat	Lycra & Neoprene	1	headgear m2	€ 1,15	€ 1,15	
		0		€ 0,00	€ 0,00	
			totaal materiaalkosten		**€ 1,15**	**€ 1,15**
Bewerkingskosten	**capaciteit [stuks/u]**	**machineuren**	**machine-uurtarief**	**machine-kosten**		
machine 1	30	166,67	€ 10,00	€ 1.666,67		
machine 2	1000	5,00	€ 0,00	€ 0,00		
etc.	1000	5,00	€ 0,00	€ 0,00		
nabewerking	30	166,67	€ 0,00	€ 0,00		
			totaal machinekosten		**€ 1.666,67**	
machines als bovenstaand	**mens/machine-bezetting**	**arbeidsuren**	**mensuurtarief**	**arbeidskosten**		
machine 1	1	166,67	€ 15,00	€ 2.500,00		
machine 2	1	5,00	€ 0,00	€ 0,00		
etc.	1	5,00	€ 0,00	€ 0,00		
nabewerking	1	166,67	€ 15,00	€ 2.500,00		
			totaal arbeidskosten		**€ 5.000,00**	
			totaal bewerkingskosten		**€ 6.666,67**	**€ 1,33**
Instelkosten serie	**insteltijd [u]**	**uurtarief insteller**	**mach.uurtarief**	**kosten**	**per product**	
machine 1	10	€ 15,00	€ 10,00	€ 250,00	**€ 0,05**	**€ 0,05**
Gereedschapskosten	**aanschafprijs**	**standtijd [stuks]**	**restwaarde**	**prijs/eenheid**		
ponsgereedschap (#1 - #3)	€ 15.000	10.000	€ 0,00	€ 1,50		
		1	€ 0,00	€ 0,00		
subtotalen	€ 15.000		€ 0,00			
gemiddelde waarde	€ 7.500					
kapitaalrente	0,0%	rentekosten	€ 0,00	€ 0,00		
			totaal gereedschapskosten		**€ 1,50**	**€ 1,50**
Algemene toeslagen						
uitval-factor*	1,0%	*afgekeurde producten, zie Kals voor percentages			**subtotaal**	**€ 4,03**
overheadfactor**	15,0%	** algemene toeslag voor productiefaciliteiten				
totaal	**16,0%**					**€ 0,65**
		K_{Fi} voor interne calculatie:		**Productiekostprijs Headgear**		**€ 4,68**

Cushion mould (3D Innovation Lab)

Bewerkingstijd (min)	30
Binder (mL)	153,0
Printtime (min)	52
Volume stl (mm3)	9270,00
Oppervlakte stl (mm2)	11457,00
Prijs materiaal model	€ 46,14
Prijs man uren	€ 22,50
Prijs afschrijf-uren	€ 15,08
Totaal prijs verwacht	€ 83,72

Silicone for casting are estimated at 0,35 euro.

- Ecoflex 00-35: 268 euro for 7,2 kg (FormX, 2020)
- Losses of silicone during production are neglected.

Production price

Product	**Modular Mask**					
						prijs per product
In-huis te vervaardigen	**prijs/stuk**	**stuks/product**	**prijs per product**			
Holder	€ 0,78	1	€ 0,78			
Frame	€ 0,79	1	€ 0,79			
Frame ring	€ 0,77	1	€ 0,77			
Headgear	€ 4,68	1	€ 4,68			
Cushion	€ 84,07	1	€ 84,07			
			€ 91,08		**totaal vervaardiging**	**€ 91,08**
Inkopen	**prijs/eenheid**	**eenheid**	**eenheid/product**	**prijs per product**		
Swivel	€ 2,000	st	1	€ 2,00		
			0	€ 0,00		
			0	€ 0,00		
			0	€ 0,00		
			0	€ 0,00		
				€ 2,00	**totaal inkoop**	**€ 2,00**
K_{ft} Productiekostprijs geassembleerd product voor interne calculatie:				**Productiekostprijs Modular Mask**		**€ 93,08**

Retail price

Voorbeeldberekening voor de winkelprijs op basis van de fabricagekostprijs (bron: Erik Thomassen).		
Productiekostprijs geassembleerd product voor interne calculatie:	**Modular Mask**	**€ 93,08**
Overheadfactor voor algemene bedrijfskosten*	15%	
Overheadfactor voor verkoopkosten	5%	
Winstfactor (onvoorziene kosten worden a.h.w. uit de winst betaald)	25%	
Totaalfactor = product van (elk van deze factoren+1) min 1	50,9%	**€ 47,41**
Verkoopprijs af-fabriek (moet je betalen als je product bij de fabriek zelf ophaalt)		**€ 140,49**
Marge tussenhandel (bijvoorbeeld: importeur, groothandel, leverancier, distributeur)	30,0%	**€ 42,15**
Groothandelsverkoopprijs		**€ 182,64**
Marge detailhandel (winkel) is zeer branche- en aanbiedingsafhankelijk, ligt tussen 25% voor een webshop en 300% voor een servicegerichte detaillist in een mooi pand op een A-locatie. Strategie met oog op o.a. concurrentie en voorraad bepaalt de marge.	25,0%	**€ 45,66**
Netto verkoopprijs (exclusief BTW)		**€ 228,30**
BTW (= Belasting op de toegevoegde waarde, = omzetbelasting)**	21,0%	**€ 47,94**
Verkoopadviesprijs, normale winkelprijs		**€ 276,24**
*) Voordat iets geproduceerd wordt, moet er doorgaans van alles gedaan zijn: niet alleen het ontwerpproces, maar ook bijvoorbeeld prototyping in meerder stadia, gebruiksonderzoek, marktontwikkeling, certificering, octrooiaanvragen en dergelijke. Als dit allemaal in de productprijs verdisconteerd moet worden, kan deze aardig oplopen.		
**) hoog tarief = 21%, laag tarief =6% (voeding, boeken), soms ook nog heffingen zoals bijvoorbeeld de wettelijke verwijderingsbijdrage.		

Appendix S: Modular Mask prototypes

Test 1 Simplified mask (Figure 83)

Production

- Step 1: CAD-model tailored cushion with the 3D scan.
- Step 2: CAD-model frame and frame ring.
- Step 3: Determine the printing orientation.
- Step 3: 3D print cushion with Flexible Resin with the Formlab 2.
- Step 4: Let the cushion cure in Form Cure.
- Step 5: Remove support material with a scalpel.
- Step 6: 3D print the frame and frame ring with PC-ISO with the Fortus 450 mc.
- Step 7: Remove the support material with a sharp pin.
- Step 8: Assemble the mask and fixate the cushion with glue in the frame.

Conclusion

- Material is too thick (3mm) and hard (shore 50A).

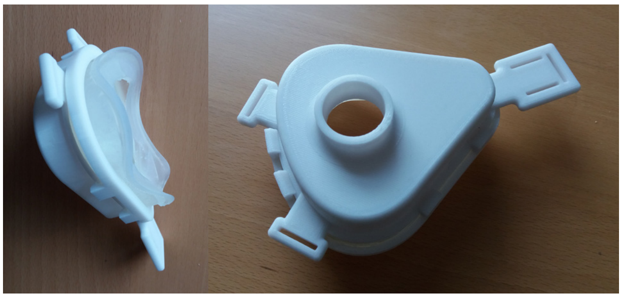


Figure 83. *Simplified Modular Mask.*

Test 2 Prototype (Figure 84)

Production

- Step 1: CAD-model tailored cushion with the 3D scan.
- Step 2: CAD-model frame, holder, and frame ring.
- Step 3: Determine the printing orientation.
- Step 4: 3D print cushion with Flexible Resin with the Formlab 2.
- Step 5: Let the cushion cure in Form Cure.
- Step 6: Remove support material with a scalpel.
- Step 7: 3D print the frame, holder, and frame ring with Clear Resin with the Formlab 2.
- Step 8: Let the Clear Resin cure in Form Cure.
- Step 9: Remove support material with a scalpel.
- Step 10: Assemble the mask.

Conclusion

- Remove support before curing, the material becomes brittle. Removing the cured support can damage the model.
- Decrease the tolerances, the Form 2 has layer thickness of 0.025mm (model might be shrunken).
- Increase the size of the quick release hole, and make the small tip less sharp.
- Make the strap holes at the top of the holder slightly bigger.
- Add more material around the strap holes for strength.
- For transparency rub the part with a brush (remove the ribs and numbers for the visual model so it is easier).

Figure 84. *Transparent Modular Mask.*

Test 3 Improved prototype (Figure 85)

Production

- Step 1: Add a nasogastric tube gap to the cushion just the cushion.
- Step 2: Adjust the CAD-model of the frame, holder, and frame ring.
- Step 3: Determine the printing orientation.
- Step 4: 3D print cushion with Flexible Resin with the Formlab 2.
- Step 5: Let the cushion cure in Form Cure.
- Step 6: Remove support material with a scalpel.

- Step 7: 3D print the frame, holder, and frame ring with Clear Resin with the Formlab 2.
- Step 8: Remove support material with a scalpel.
- Step 9: Let the Clear Resin cure in Form Cure.
- Step 10: Brush Clear Resin on the parts for transparency.
- Step 11: Let the Clear Resin cure in Form Cure (Figure 86).
- Step 12: Assemble the mask.

Conclusion

- Dimensions of the parts are right.
- Prototype material is not stiff enough.
- Gap of the nasogastric tube is reduced (see Figure 87).

Figure 85. *Improved transparent Modular Mask.*

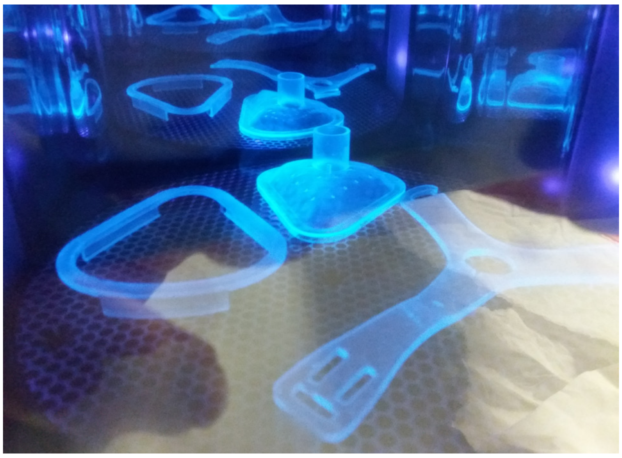


Figure 86. *Transparent Modular Mask.*

Figure 87. *The Modular Mask tailored for an enriched statistical shape model of a one year old child.*

Appendix T: Quick Curable Mask prototypes

Test 1 UV curable silicone (Figure 88)

Production

- Step 1: Vacuum the mask with a syringe.
- Step 2: Fill the mask fully with Elastic Resin (shore 50 A).
- Step 3: UV-cure the mask on 3D printed face in half a hour.

Conclusion

- Mask cusion is too hard.
- UV curing takes too long.
- Mask becomes harder over time (UV in sunlight).

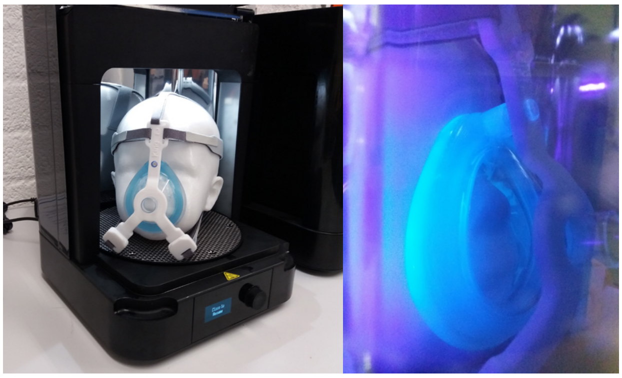


Figure 88. *UV curing of Elastic Resin.*

Test 2 Component curable silicone

Production

- Step 1: Vacuum the mask, see Figure 89.
- Step 2: Mixing the two silicone components of Formsil5T (shore 5A), see Figure 89.
- Step 3: Sucking the silicone in a syringe and fully inject the cushion of the mask, see Figure 89.
- Step 4: Fixate the mask on a 3D printed face in a vice and let the silicone cure, see Figure 90.

Conclusion

- Mask is compressible.
- Mask is hard because of surface tension.

Figure 89. *UV curing of Elastic Resin.*

Figure 90. *Silicone curing on a 3D printed face in a vice.*

Test 3 Lower fill percentage (Figure 91)

Production

- Step 1: Vacuum the mask.
- Step 2: Mixing the two silicone components of Formsil5T (shore 5A).
- Step 3: Sucking the silicone in a syringe and partly inject the cushion of the mask.
- Step 4: Fixate the mask on a 3D printed face in a vice and let the silicone cure.

Conclusion

- Mask is more compressible if the mask is not fully filled, the silicone can expand and move in the sleeve.
- Mask has to be fixated on a head to distibute the injected silicone better.

Figure 91. *Filling the mask with less silicone to evaluate the surface tension.*

Test 4 Foam

Production

- Step 1: Determine the optimal fill percentage for the size 2 King mask, by testing the mask on the 3D printed face. The optimal amount is estimated at 30ml.
- Step 2: Soma Foama 15 expands four times in volume, so 7,5 ml Soma Foama has to be injected.
- Step 3: The mix ratio is 2A:1B, so 5ml of component A and 2,5 ml of component B has to be injected.
- Step 4: Mix the the two components and quickly inject it in the anaesthesia mask.
- Step 5: Press the mask on the face, wait 30 seconds till the mask is cured.

Conclusion

- During the injection the material already started to expand. Therefore the inlet of the mask became stuck, blocking the inlet flow. The working time of 30 secends is too short for manual mixing and injecting with a syringe.
- The material is super soft.

Test 5 Ecoflex 00

Production

- Step 1: Vacuum the cushion of the mask.
- Step 2: Mixing the two silicone components of Ecoflex 00-35 (shore 00-35), see Figure 92.
- Step 3: Sucking the silicone in a syringe and inject 30ml in the cushion of the mask.
- Step 4: Press the mask on a 3D printed face (with nasogastric tube) and let the silicone cure in 4 minutes.

Conclusion

- Cushion is soft and compresseble.
- Working time (2,5 minute) and curing time (5 minute) work great.
- Gap of the nasogastric tube is reduced (see Figure 94).

Figure 92. *Filling of the mask with the two components of Ecoflex 00-35.*

Figure 93. *Pressing the mask on the face and nasogastric tube.*

Figure 94. *The Quick Curable Mask tailored for an enriched statistical shape model of a one year old child.*

Test 6 Ecoflex 000

Production

- Step 1: Vacuum the cushion of the mask.
- Step 2: Mixing the two silicone components of Ecoflex 000-35 (shore 000-35).
- Step 3: Sucking the silicone in a syringe and inject 30ml in the cushion of the mask.
- Step 4: Fixate the mask on a 3D printed face (with nasogastric tube) and let the silicone cure in two hours.

Conclusion

- Cushion feels like soft gel, but still harder than the foam. As Ecoflex 00 turns to out to be too hard in the Final Design Test, shore 000 can be considered. Although this specific silicone has a curing time of 2 hour, which is too long.

Appendix U: Final design evaluation

The requirements and whises in chapter 2.1 have been evaluated.

Performance

- The final design test has to be conducted to determine if air leakage is reduced with both masks compared to standard NIV masks.
- The Modular Mask and Quick curable mask cover both the mouth and nose.
- It is hard to determine the risk for skin injury for both masks, this need to be evaluated with the clinical test, the mask will be worn for a longer period.
- Production
- Both masks are made with materials that are certified skin safe.
- The Modular Mask is tailored with the aid of the 3D scan, this need to be included in the treatment plan and protocol.
- For both masks three sizes of headgears are available for 0-7 year old patients.
- For both masks, size 1 and 2 are for children below 10 kg.
- The Modular Mask size 3 to 5 are for children above 10 kg. The Quick Curable Mask size 3 and 4 are for children above 10 kg.

Usage

- The intensivist practitioners will be trained for the tailoring of the Quick Curable Mask during the implementation phase. Both masks will be implemented in the protocol of the PICU.
- The five strap headgears offer good stability and are easy to adjust and disconnect.
- The Modular Mask can be released by pulling the two bottom straps. The Quick Curable Mask can be released by pulling the two clips off.
- The intensivist can reposition the masks by adjusting the straps of the headgear.
- Stock
- For the Modular mask has the holder, frame, frame ring, headgear, and swivel have to be in stock. For the Quick Curable Mask the swivel, holder, clips, anaesthesia mask, headgear, syringe, a cartridge gun dispenser, 2K cartridge with the two components of silicone, and a static mixer nozzle has to be in stock.

Safety

- The frame of the Modular Mask is made of polycarbonate, which has optical transparency. The anaesthesia mask of the Quick Curable Mask is also transparent.
- When using the masks the skin has to be at least every four hours checked on skin irritation.
- Both masks can quickly be removed if patients need to be invasively ventilated.
- The Modular Mask cover a larger part of the nose to prevent air leakage. Both masks have three straps at the top of the holder that give the intensivist practitioner full control over the fit of the nose area.
- Regulations
- During the implementation the Quality Management System has to be developed.
- The technical team has to make a Technical File for the Modular Mask.
- Maintenance
- Both masks are easily cleanable.
- Both masks are easily cleanable, the Modular Mask can also be disassembled.
- The headgears are made of fabric and hand-washable.

Wishes

Performance

- The cushion of the Modular Mask is tailor-produced for each patient, to decrease the unintentional air leakage. The Quick Curable Mask is formed to the patients face, to decrease the unintentional air leakage.
- Both masks are an oronasal mask and have a small dead volume.

Production

- The production of the Modular Mask takes approximately one day. The Quick Curable Mask can be tailored within approximately 15 minutes.
- The Modular Mask requires a 3D scan. The structured light 3D scanner used for the production of the Modular Mask scans the face in a few seconds. The Quick Curable Mask does not need a 3D scan.

Usage

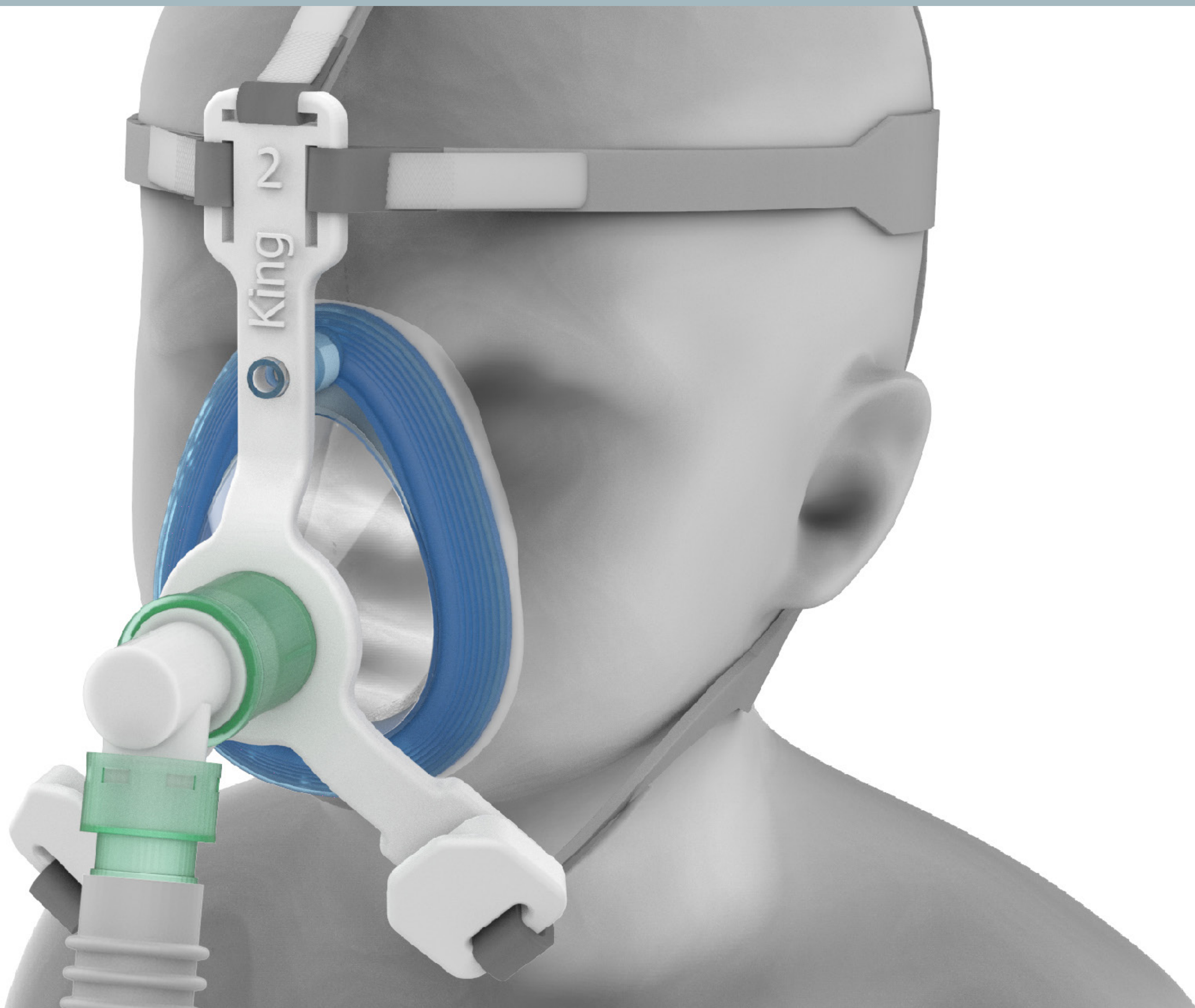
- The Modular Mask has a cushion of soft silicone. The Quick Curable Mask is filled with soft silicone gel.
- Both masks are oronasal masks and relatively non-intrusive comparted to other non-vented masks.
- The Modular Mask has a gap for the nasogastric tube in the cushion to reduce air leakage at this spot. The Quick Curable Mask is cured over the nasogastric tube to reduce the air leakage at this spot.
- For both masks the swivel with a ventilation hole can be used, to make the mask vented.
- The Modular Mask has a lot of form freedom to adjust the cushion for patients. The Quick Curable Mask has a cushion with limited form freedom.
- The cushion of the Modular Mask covers a larger part of the nose to distribute the pressure. The Quick Curable Mask is filled with a soft and deformable material to distribute the pressure.
- The Modular mask covers a larger part of the nose to reduce air leakage at the nose. The Quick Curable Mask is filled with soft deformable silicone.
- Both masks are made of lightweight plastic. Also are oronasal mask relatively small and light compared to other types of non-vented masks. The cushion of the Quick Curable Mask is fully filled with silicone, which increases the weight of the mask.
- Both masks are not compatible with glasses, because the masks makes contact with the nasal bridge.
- Both masks are oronasal masks. However with tailored masks it might not be necessary to alternate masks.
- Both masks do not contain metal.

Costs

- Both masks are more expensive as standard masks. The costs of the Modular Mask is estimated at 275 euros. The costs of the Quick Curable Mask is estimated at 125 euros.

Recycling

- The Modular Mask can be easily disassembled. The Quick Curable Mask is injected and cured, so cannot easily be separated.



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