REDESIGN OF CPAP DEVICE

PRODUCT DESIGN PROJECT (II)

BY

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GUIDE: PROF. PURBA JOSHI

CO-GUIDE: PROF. G. G. RAY

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Approval Sheet

The project titled 'Redesign of CPAP Device' by Deepanwita Ghosh is approved in partial fulfillment of the requirements for the degree of Master of Design in Product Design.

Guide:

Co Guide: 17.06.2014

Chairperson: 17-6-14

Internal examiner:

External examiner:

Date: 17. 06. 2014

Declaration

I declare that this written submission represents my ideas in my own words and where others ideas and words have been included , I have adequately cited and referenced the original sources. I also declare that I have adhered to all the principles of academic honesty and integrity and have not misrepresented or fabricated or falsified any idea/data/fact/source in my submission. I understand that any violation of the above will be cause for disciplinary action by the institute and can evoke penal action from the sources which have thus not been properly cited or from whom proper permission has not been taken when needed.

Signature: Deepanwita Ghosh

Name : Deepanwita Ghosh

Roll No : 126130009

Date: 04 - 06 - 2014

Acknowledgement

I wish to express my sincere gratitude towards my guide , Prof. Purba Joshi and my co guide , Prof G.G.Ray who have been there to support and inspire me during the complete journey of my project..

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Special mention to Avinash Prabhune, my friend and classmate who was always there with me for all the field trips to the various hospitals and to my other friends from whom I have received some very important inputs and insights which have been of great value to me. I would like to thank them all for their support and encouragement which helped me complete this project..

Contents

Abstract

Recent study and medical surveys on neonatal mortality[1] have shown that India accounts for the maximum percentage of demises among newborns, worldwide, which is 28%.[1] These newborn infants pass away majorly due to either of the following causes- infections due to pre-maturity, asphyxia, low-birth weight, pneumonia- complications which hospitals with low-end facilities cannot handle.

Even if the these infants stabilize and get discharged from the hospitals, they are susceptible to frequent chest respiratory infections and have problems with asthma [2] or problems caused due to the environment they go back to. The first 20-25 weeks after birth is a period of viability in which the infants are prone to acquire infections, if proper care is not taken. Three main reasons why despite India's growth, neonatal mortality rates remain high are:

i) socio-economic factors

ii) lack of infrastructure

iii) inadequate specialized staff for maternal and infant care for pre, during and post birth.[3].

The Continuous Positive Airway Pressure **(CPAP)** equipment is a recent break-through innovation in the field of neonatology, that is efficiently life-saving. The CPAP device is used in most developed countries to cure the causes of infant deaths mentioned previously. In spite of being a great boon, this equipment has some issues and problems associated with it which have been identified after studies and discussions with doctors.

The objective of this project is therefore to facilitate the use of CPAP device by making it compact, portable, easy to use and maintain.

Use of the CPAP device in multiple directions were thought of - like during transit (emergency vans), in local clinics - where the accessibility of the people to obstetric care is much more easier, and use in hospitals were made-wherever its use is relevant and such that infant lives could be saved.

The final concept was an outcome of insights gained from considering the direction for local clinic set-up.

[1]The World Health Organization defines neonatal mortality rate as the number of resident newborns in a specified geographic area dying at less than 28 days of age divided by the number of resident live births for the same geographic area for a specified time period, usually a calendar year, and multiplied by 1,000 (WHO, 2012)

Introduction

Developing countries account for deaths of thousands of newborns every year because these newborns are mostly premature and they can't breathe in adequate amounts of air into their lungs, leading to respiratory distress. Premature infants lack surfactant in their lungs, a complex protein compound coating that prevents the interior of the alveoli from collapsing together. Without a CPAP machine, an estimated 30% of the newborns with respiratory distress will suffocate- a condition called hypoxia which increases the carbon dioxide content in the lungs.

The lives of these infants are most critical for the first 28 days since their birth.
The "two-thirds" rule:

- *Almost two-thirds of infant deaths occur in the first month of life*
- *Among those who die in the first month, about two-thirds die in the first week of life*
- *Among those who die in the first week, two thirds die in the first 24 hours of life*

Close to 50% of all newborn deaths occur within 24 hours of delivery and up to 75% in the first week postpartum.
And more than 50% of newborn deaths occur at home [4].

Most of the newborn deaths are unrecorded and remain unseen. There is a major absence of continuity between maternal and child health care. *The survival and health of newborn babies is a critical part of the push towards lower child mortality in Millennium Development Goal 4* [5].

Many of these deaths which are related to care during birth and after birth can be easily prevented. On one side *Terri Bresenham,CEO, GE Healthcare South Asia* mentions that 'Care for infants in India is challenged by rising costs of medical facilities, inequality of access and persistent quality and maintenance issues, while Mosley and Chen have identified five factors that affect child survival : maternal factors, environmental contamination factors, nutrient availability factors, injury factors, and personal illness control factors. The authors asserted that these factors directly influence the risk of morbidity and mortality [6].

In a research paper written by Anu Rammohan, Kazi Iqbal and Niyi Awofeso, data from the unique nationally representative survey of India 2008 *District Level Household Survey* (DLHS-3) was used to analyze '*the links between neonatal mortality at the household level and household's access to health facilities*' and their findings underscore the importance of '*having well-functioning obstetric and neonatal services of District Hospital closer to the rural households*'. The results show that if the '*services of District Hospitals are brought 10 km closer to the village, it can save one more child out of 1000 births in India*'. Another important finding was to have emergency obstetric care at the District Hospital –which is also found to significantly reduce neonatal deaths.[3]

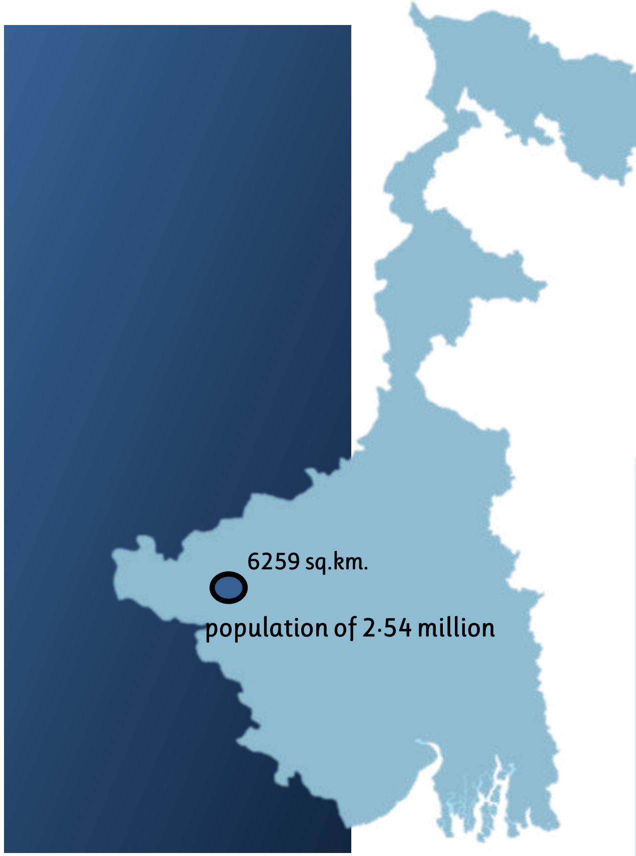
Literature on child mortality has diverged out into three diverse but interrelated directions in social science. The most studied branch is the role of socio-economic factors. These factors play a major role in influencing child mortality in general and particularly in India . Patinson *et al.* (2011) state that lack of access to obstetric care services in low-income countries is a serious constraint in improving pregnancy outcomes[7].

The reference for the Health care Infrastructure in India has been taken from the research article' Reducing Neonatal Mortality in India: Critical Role of Access to Emergency Obstetric Care written by Anu Rammohan,
Kazi Iqbal, Niyi Awofeso
Published: March 27, 2013DOI: 10.1371/journal.pone.0057244

Health Care infrastructure in India

The Public Health System of India has been established over the years - as a 3-tier system of the primary, secondary and tertiary level of health care. A characteristic Indian state is divided into a number of districts which are in turn segmented into Blocks. The District Health System is the central and essential source for employing various health policies and delivery of healthcare, management of health amenities for defined geographic zone. Every district is estimated to have a district hospital(DH) connected with the public hospitals/ health centers which are far below the district such as Sub-district/Sub-divisional hospitals, Community Health Centers (CHCs), Primary Health Centers (PHC) and Sub-centers (SC). According to the Ministry of Health and Child Welfare (2011), the role of DH is to give effective, affordable health care services for a definite number of people. The DH also acts as a secondary level appointment center for the public health institutions such as Sub-divisional Hospitals, Community Health Centers, Primary Health Centers and Sub-centers.

A typical CHC is required to be manned by four medical specialists i.e. Surgeon, Physician, Gynaecologist and Paediatrician supported by 21 paramedical and other staff. According to a study in 'Health infrastructure & immunization coverage in rural India', there was shortfall in CHCs of approximately 50 per cent across the country [8].



The Purulia district of the state of West Bengal, has a birth rate of 24.8, and a neonatal mortality rate (NMR) of 55 per 1000 live births. The government healthcare infrastructure in this district comprises:

1 district hospital,
1 sub-district hospital
5 rural hospitals,
15 community health centers, and
53 primary health centers.

Although an essential newborn care program has been operational in the district for several years, no specialized sick newborn care unit (SNCU), government or private, is available in the district [A].

Study of **44** public hospital facilities for Infant and Maternal Care Infrastructure :

Only 19 had qualified obstetrician/s
Only 13 had qualified anaesthetist/s
while **77%** do not have either/ both of these specialists
(Chartuvedi and Bandime, 2010).

India has a **chronic shortage** of the core staff, with less than **23** doctors, nurses and midwives **per 10,000** populations.

Case Study conducted to determine adequacy of neonatal and maternal care infrastructure in the relatively rich state of Maharashtra.

[A] The Lancet -Correspondence-Volume 366, Issue 9479, 2-8 July 2005,pages 27-28
Development and effects of a neonatal care unit in ruralIndia
Amitava Sen, Dilip Mahalanabisa , Arun K Singh, Tapas K Som, Sudipta Bandyopadhyay

Ref for images are taken from maps of.net

The Design Process

During the project ,user-centered design process was followed to understand the user needs, tasks and their environment before coming up with the final concepts and solution. Following are the steps involved in the process.

1 Data collection

Doctors and intensivists were interviewed to understand the use and administration of the CPAP device. The working of the equipment and its set-up was studied and documented.

2 Observations

After observation and discussion with the doctors, key design problem areas were identified and listed. From research paper findings, possible direction for use of CPAP was identified.

3 Ideations

From the data collected, possible solutions were ideated and discussed with the doctors. The ideations were then clustered according to three directions of use of the CPAP device- use in hospitals, use in-transit(emergency vehicles) and use in local clinics.

4 Final concept and output

Based on need and feasibility, concepts were formed. The final concept was then selected after evaluating the pros and cons of all the 3.

Ref for images taken from http://sentimentswithstyle

Data Collection

General overview is referenced from http://www.pipa.org.au/helping-your-prem-to-breathe on 30/5/2014

General Overview

A baby is completely formed by its 13th week of gestation and spends the forthcoming 27 weeks developing and evolving inside the womb. For a premature baby, the main difficulty is that they are born before their body is developed enough to live outside the sheltered environment of their mother's womb. During such conditions ,generally ,the most fatal problems develop due to immaturity of the lungs.

While in the uterus, the lungs have no function to perform. They are filled with fluids and are deflated. The developing baby gets its supply of oxygen from its mother. Usually during birth, with the baby's first breath, the fluid is expelled and air rushes into the lungs and inflate them- getting them to work. Due to prematurity, the lungs cannot expire and inspire air naturally. The oxygen that they will inspire to their lungs with great difficulty is not sufficient for their needs.

This will cause them to breathe quicker and the lungs to work harder while their body tries to get sufficient oxygen. This problem is called “wet lung” or “transient tachypnea”.

Our lungs are made up of tiny air sacks (alveoli) that take in the oxygen and absorb it into the blood that flows through the lungs. The oxygen rich blood is then circulated back to the heart to be pumped throughout the body. These air sacks in the lungs have a substance called ‘surfactant’. This substance is very important for the process of breathing. The ‘surfactant’ holds the alveoli open and makes breathing easy. Without enough surfactant the alveoli collapse with each breath. Even in a full term pregnancy, the baby's lungs are not mature enough to fully able to function before the 35th or 36 week. In a preterm birth before the 35 week, the majority of baby's will need some sort of help to get enough oxygen into their system for example Ventilator, CPAP device, incubator oxygen etc. depending on the infant's symptoms.

Breathing issues - symptoms in premature babies

Respiratory Distress Syndrome

Respiratory Distress Syndrome (RDS) is a lung ailment occurring in preterm infants most commonly. RDS occurs in babies with imperfect lung development. The more premature the infant, the greater the probability of RDS.

RDS is due to deficit of surfactant in the lungs. Open air sacs are essential for oxygen to enter the blood from the lungs and for the carbon dioxide to be released from the blood into the lung during exhalation. Due to less surfactant the collapsed alveoli cannot go back to the extended form and hence causes distresses .

RDS in premature babies can range from mild,(where the baby only needs a little help to get its breathing accurate), to very severe (where the baby might be put on a ventilator for a long time which eventually causes lung damage). There are a number of equipment that help a baby breathe and these range from a ventilator to nasal cannulas (or prongs).

Most premature babies will recover well from lung problems and before the majority go home they will be totally weaned of any oxygen needs. However, there is a possibility of lung damage and these babies can be more vulnerable to frequent chest respiratory infections and have problems with Asthma or similar breathing problems.

A baby with RDS will have the following symptoms:

-rapid breathing

-pulling in of the ribs and center of the chest
-with each breath, called retractions.

-an "ugh" sound with each breath, called grunting.

-widening of the nostrils with each breath, called flaring.

Apnea

This is the term for episodes when a baby stops breathing. Premature babies often stop breathing, or breathe very shallowly, for 5-10 seconds, before restarting to breathe normally – this is known as periodic breathing. True apnea is defined as episodes that last more than 20 seconds. This often happens because the breathing center of the brain has not yet matured.

Studies suggest that most babies will have overcome apnea by 37 to 40 weeks age. However extremely premature babies may not achieve this until 43 weeks age.

In older infants this condition might occur when the infant has contracted some sort of respiratory infection.

Nasal flaring

If a baby's nostrils open widely or flare out, this could be a sign that it is having a difficult time breathing.

Recession

The center of the chest of a baby is sucked in to breathe if the airways are not completely open. When this happens, there is a visible dip between the ribs.

Bronchopulmonary dysplasia (BPD)

This ailment, formerly known as chronic lung disease of infancy, ensues in babies who need extra oxygen at 36 weeks age. The more premature the baby, the more common BPD is. It may be made worse by artificial ventilation, which may be used in the early weeks of life to improve the baby's chance of survival but can cause scarring or inflammation in the baby's lungs. A baby with BPD may need to continue this therapy for several months, or even years.

CPAP

The **continuous positive airway pressure** (**CPAP**) is used to provide respiratory sustenance for preterm/term infants in the intensive care unit. As mentioned in the Textbook of Neonatal Resuscitation, 6th Edition, page 275, "*CPAP keeps the lungs slightly inflated and is most helpful for preterm babies whose lungs may be surfactant deficient and whose alveoli tend to collapse at the end of each exhalation.*".

Most alveolar surfactant in babies are produced after 30 weeks of gestation. Insufficient surfactant creation causes air sacs to collapse on expiration and greatly increases the energy required for breathing.

Few infants have a pair of partially developed lungs.

Rapid fluid shifts and other changes that occur during the postnatal transition period, might lead to grunting respirations in these infants which eventually may get stabilized naturally with growth advancements and adaptations. However, if the transition is hindered due to stresses during delivery, contact of the fetus to sedating agents, or fetal lung fluid retention, administering CPAP for a short duration may lead to major improvement in such cases.[9]

Grunting is one of the few distress signs (RDS) which might be observed in the new born. The others include - tachypnea, nasal flaring, sternal In drawing , rib retractions etc. Prior to administering CPAP, the above mentioned signs of distress along with respiration rate, effort, breath sounds are observed and documented as a baseline assessment .[10]

CPAP must be used carefully whenever administered. If CPAP is provided, pulse oximetry should be used to confirm appropriate concentration of oxygen. Pulse oximetry is used as a non-invasive tool to observe oxygen saturation, which should be maintained at 85-93%[10],[11].Once CPAP is administered, the baby should be reassessed to determine whether the initial problems have resolved or whether CPAP should be continued as part of post-resuscitation care.[12]

Ambient air contains 21% oxygen and the baby needs higher oxygen(85-95% Spo2) to stay pink. The added oxygen might be delivered by placing a **hood** made of plastic over the baby's head. The infant may need nCPAP (Nasal Continuous Positive Airway Pressure). Through this method, oxygen is delivered under a small amount of pressure typically through little **tubes** that fit into the nostrils of the infant's nose. Delivering oxygen under pressure assists to keep the air sacs open.

Depending on, the condition – whether it is moderate or severe, the infant might have a breathing tube inserted into his/her wind pipe. This is essential if help with breathing is mandatory or if the baby is to receive surfactant as a medication. Inserting the tube is called intubation. Once intubated, the baby may be placed on a breathing machine (respirator or ventilator) to help him/her breathe.

Surfactant is given directly down the breathing tube. A baby needs to be intubated to accept surfactant.

Apart from this, the baby may have an umbilical arterial catheter (UAC) and/or an umbilical venous catheter (UVC) placed into one or two of the blood vessels in the baby's umbilical cord stump.

These catheters are used to:
-give the infant needed fluids intravenously (by vein).
-give the infant medications.
- give the infant nutrients.
- obtain blood samples from your baby without invasive measures.

Frequent blood sampling is necessary to determine if the baby is receiving the right amount of oxygen, sugar water and other things to keep the body in balance.

The need for each interface and its use for which purpose is discussed in page 16.

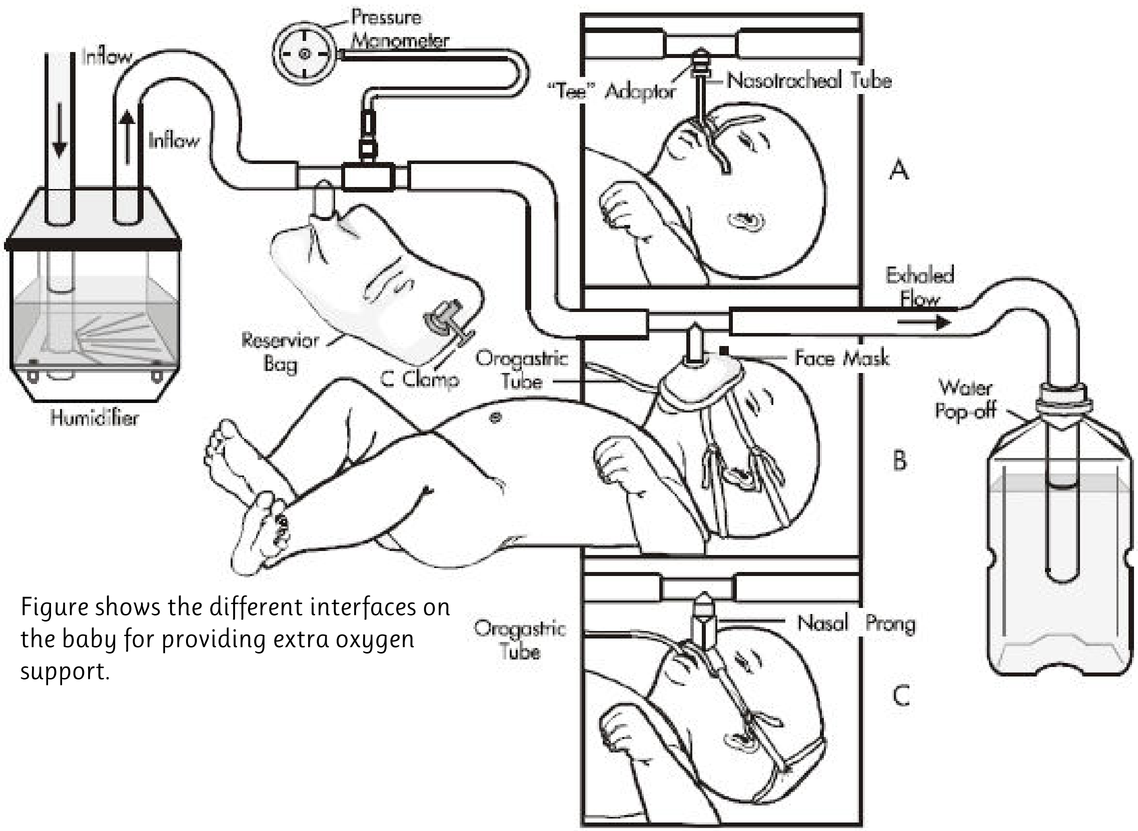
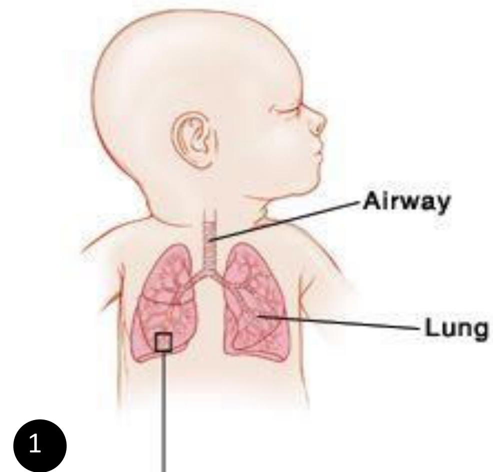
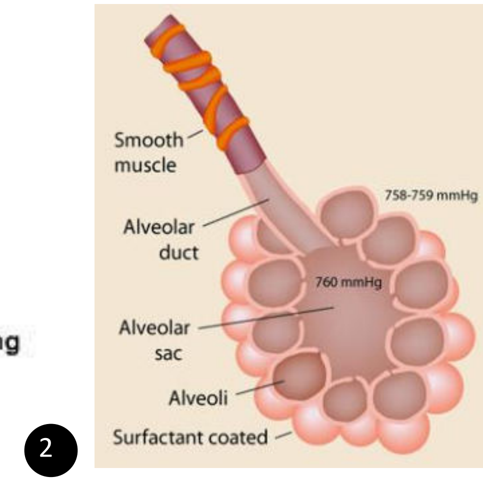


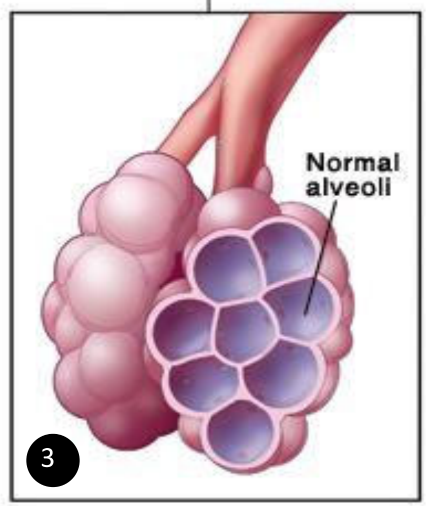
Figure shows the different interfaces on the baby for providing extra oxygen support.

Above shown is a pulse oximeter attached to the infant to monitor the oxygen level in the blood.

Ref for images - viseembryo.com







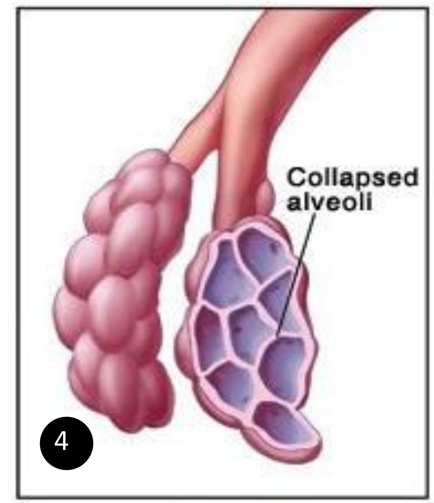


Fig 1 – shows the inside structure of the lungs and the airway

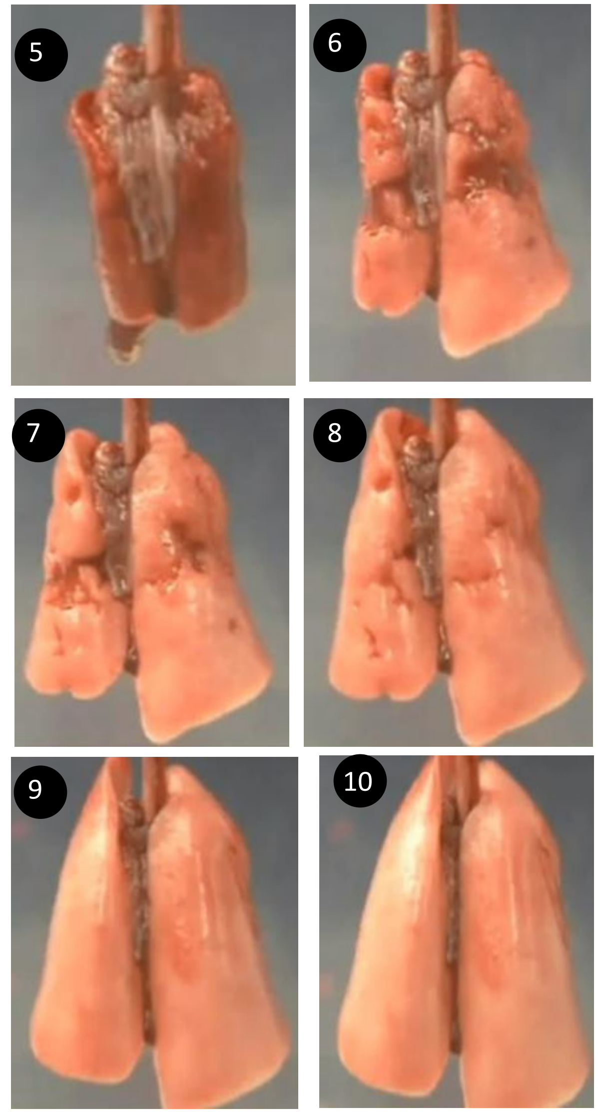
Fig 2 – the details of the alveoli are shown along with the rest of the parts

Fig 3 – shows how the alveoli looks when completely filled with air during the process of inhalation

Fig 4 – the structure of the alveoli during exhalation – collapsed yet there is asmall amount of air inside it

Ref for images taken from wikipedia.org_RDS and http://sentimentswithstyle

Air travels through the airways(tubes in the lungs) to the alveoli(air sacs). Normally, alveoli stay open after each breath. RDS occurs when alveoli collapse and the walls almost stick together after each breath. This means the baby has to work harder to breathe.



Exhale Inhale

Ref for images - http://www.youtube.com/watch?v=oKH7CtsEgH retrieved on 5/2/2014

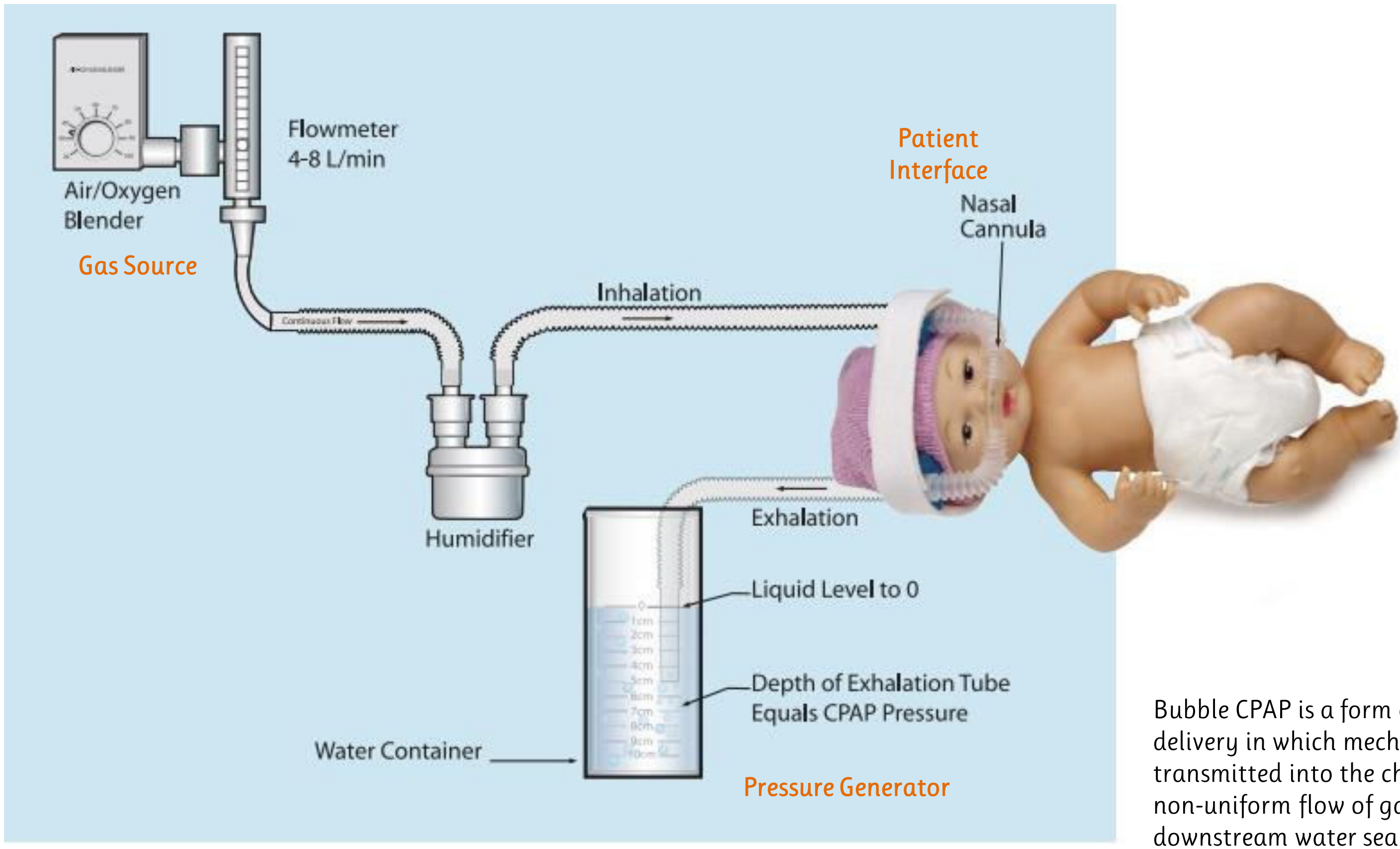
Without CPAP

Fig 5,6 - The condition of the lungs during inhalation and exhalation when CPAP is not administered to the infant and the infant is breathing on its own with great difficulty as air sacs have collapsed due to lack of surfactant.

With CPAP

Fig 7,8 – show the condition of the lungs when CPAP has been initiated and the lung is recovering from the collapse
Fig 9,10 – shows the complete recovery of the lungs and at its full normal capacity.

Subsystems of the CPAP Device- Bubble CPAP



1- **Gas source** - a continuous supply of warm, humidified, blended gases at a flow rate set by the doctor is sent through inspiration tube which connects to the patient interface.

2- **Patient Interface** – wearable device to connect the CPAP equipment to the infant's airway.

3- **Pressure Generator** - Means of creating a positive airway pressure to maintain the pressure inside the system.

Bubble CPAP is a form of oscillatory pressure delivery in which mechanical vibrations are transmitted into the chest secondary to the non-uniform flow of gas bubbles across a downstream water seal. This system results in waveforms similar to those produced by high-frequency ventilation when recorded by a transducer attached to the infant's airway(Early Bubble CPAP and Outcomes in ELBW Preterm Infants)[13].

Ref for images taken from www.i-ma.com

Patient Interface and when to use them






System	Percent oxygen delivered	Indications	Comments
Blow by	Less than 30 percent	Use for spontaneously breathing children who require low doses of oxygen and do not tolerate a mask	Monitor pulse oximetry
Nasal cannula	25 to 40 percent	Use to deliver low dose oxygen to spontaneously breathing patients	Percent oxygen delivered affected by respiratory rate, tidal volume, and extent of mouth breathing. Flow rate 2L/min or less for infants
Simple mask	35 to 50 percent	Use to deliver low dose oxygen to spontaneously breathing patients	Percent oxygen delivered affected by mask fit and respiratory rate
Partial rebreather mask	50 to 60 percent	Use to conserve oxygen	
Nonrebreather mask	Up to 95 percent	Use to deliver high dose oxygen to spontaneously breathing patients	Tight mask fit required to deliver higher concentrations of oxygen
Hood	80 to 90 percent	Infants less than one year of age	Noisy for patient
Tent	Less than 50 percent	Use for children who require 30 percent oxygen or less	Mist may obscure view of patient. Noisy for patient.
Self-inflating ventilation bag	95 to 100 percent, with reservoir	Use to provide assisted ventilation and oxygen	Do not use to provide blow by. Must use with a reservoir to provide higher oxygen concentrations.
Flow-inflating ventilation bag	100 percent	Use to provide assisted ventilation and oxygen	May use to provide blow by. Requires experience to use reliably.

Ref for images taken from google.com

Field Study

Visit to Hinduja Hospital

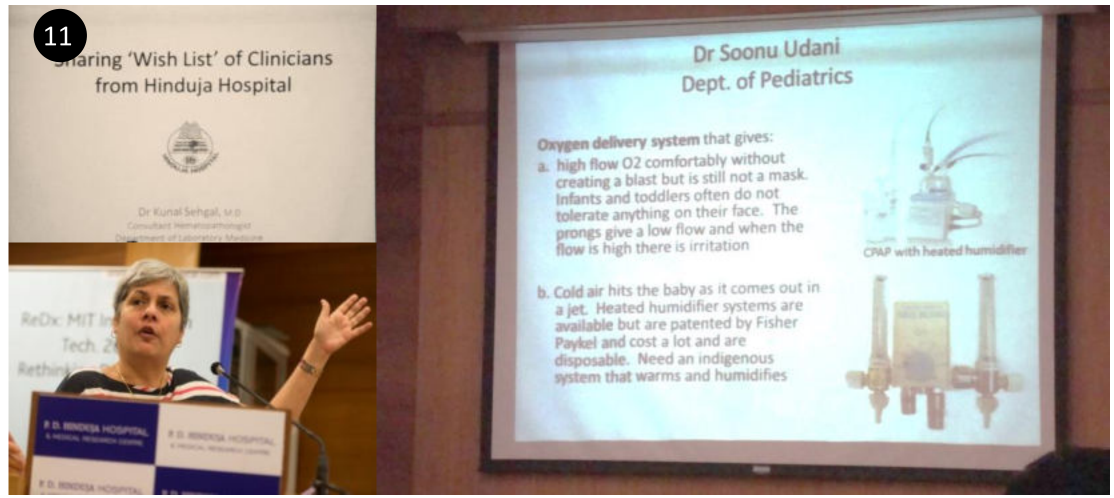


Fig 11 - Dr. Soonu Udani, a leading pediatrist in the Hinduja Hospital-with high end facilities-pointing out the needs of their department and the areas that need improvement for better infant healthcare.

As a part of the MIT-IIT health tech workshop, an opportunity arose to meet the doctors of the Hinduja Hospital in the month of February,2014 and interact with them to understand the problems associated within their field and how engineering and design can help improve the current situation.

Initial interactions with them paved a way to understand the difficulties in the department of pediatrics which was mostly to do with the oxygen delivery systems. The doctors mentioned that the interface and the humidifier were the utmost pain areas.

Visit to IIT Hospital

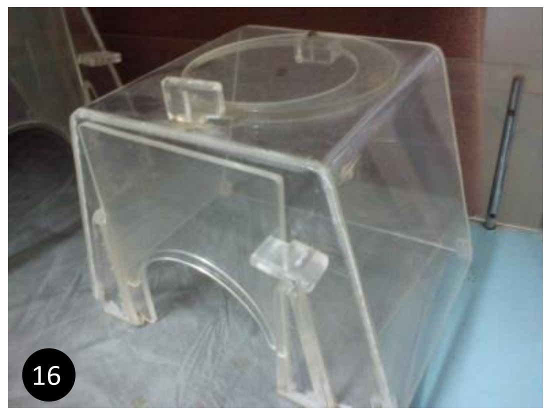


Fig 12 – shows the setup of the warmer and the hood which is now not in use
Fig 13 – shows the Interface of the warmer
Fig 14 – two hood sizes being displayed- one for smaller infants and the other for a larger one
Fig 15 – nurse demonstrating the use of the hood
Fig 16 – the hood with all its features

Insights:

The IIT Hospital had a very basic set-up of a warmer which was not in use as the maternity ward was dysfunctional. But they showed us the way the hood would be used had a baby required oxygen support.

- The unit looked very difficult to handle
- There were two knobs on the side which were used to fix the slider position to prevent oxygen from leaking out and it kept slipping down.
- There was no provision for the oxygen tube attachment which is the inspiration tube and it had to be fixed using a masking tape.
- Major losses in oxygen flow happened through the slide opening

Visit to Lokmanya Tilak Municipal Hospital

Fig 17 – LTM Hospital, Sion
Fig 18 – the CPAP set-up in the NICU
Fig 19 – the humidifier interface showing an error in reading
Fig 20 – space crunch-two infants share the same bed, one being given oxygen support through hood

Insights:

The LTM Hospital had a very different crowd of people coming for treatment it compared to the Hinduja Hospital which is a hospital with high end facilities. Since this is a government hospital, the facilities are not up to date and had a lot of maintenance issues as mentioned by the doctors we interacted with.

- The cpap unit had many handling issues
- The stand was on wheels and locking it for stability was an issue
- There were a lot of tubings coming into and away from the system which gave a disordered look
- The humidifier display gave erroneous output and yet it was being used
- The connections of the tubings were not tight enough and would come off easily

Visit to Lokmanya Tilak Municipal Hospital

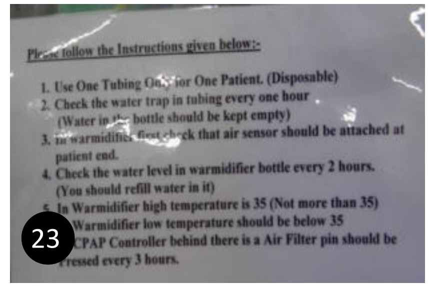


Fig 21 – shows how the interface is attached to the infant using rubberband, safety-pins and masking tape.
Fig 22 – position to see the reading on the humidifier, check the bubbling of the air in the water container.
Fig 23 – the list of do's n don't's
Fig 24 – blender unit's interface
Fig 25 – the chart for air and oxygen blending ratio.

Insights:

- The tiny infant was hooked on to the device using a lot of tapes and pins which showed signs of injury on the skin and nasal trauma
- The blender unit had knobs for rotating it to the flow required and was placed quite away from the water column – confusing alignment
- The chart for the air-oxygen ratio was placed on the side creating visibility issues.
- The entire set-up needed accessibility from 3 sides to work on it, fix tubings and connect it to the power source.
- The stem of the bubble tube is inserted using hand and most of the time it remains at a slant.

Discussion with doctor at Lokmanya Tilak Municipal Hospital

Fig 26,27 – the mask used for a smaller sized neonate and a larger sized neonate- the aluminum clip at the top fixes it on the nose bridge
Fig 28– Dr. Abhishek showing the problems associated with the hood
Fig 29 – Jugad method of connection of the tubings
Fig30 – the nasal cannula attachment

Insights:

- Doctor mentioned that from all the methods of oxygen administration, clinically it is proven that the nasal cannula is the most effective interface
- The attachment of the interfaces are quite problematic
- The infants are subjected to a lot of rough handling in the process of attaching the equipment firmly.

Process of attaching the patient interface

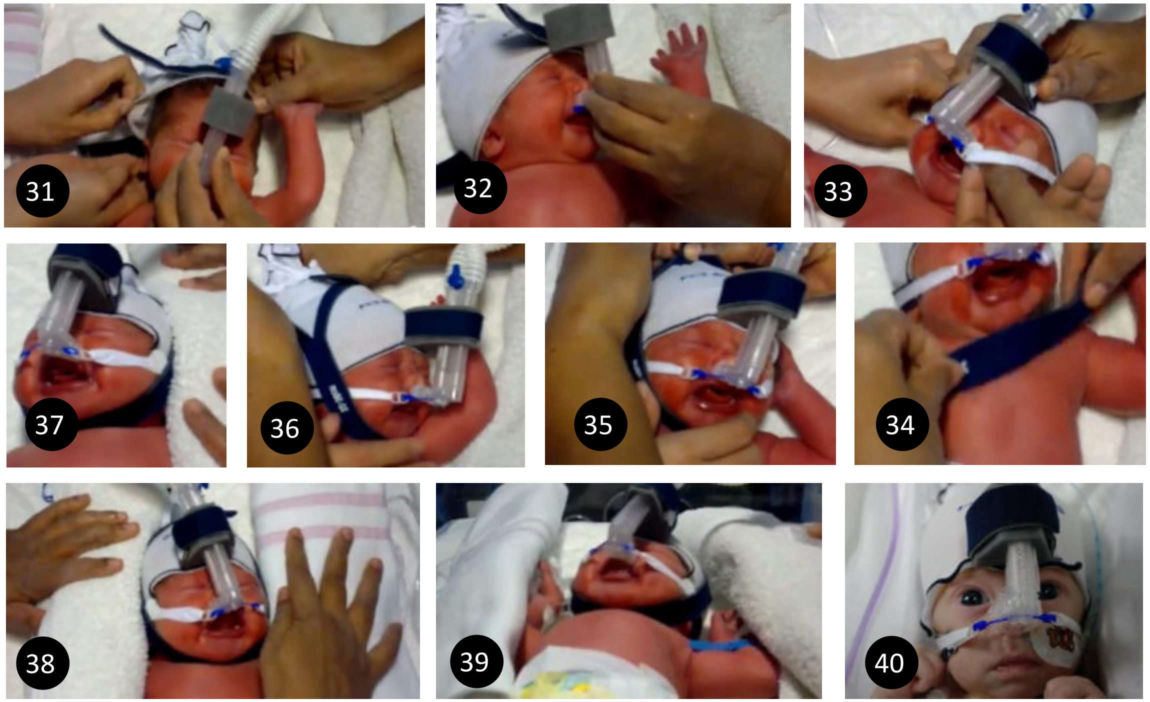


Fig 31 – two staff members are required to hold the baby and fix the socks like cap on the infant's head
Fig 32 – the cannula is inserted into the nasal passage
Fig 33 – the unit is then fixed on the forehead using Velcro and the white straps are hooked on the cannula unit
Fig 34-37 – the chin strap is being fixed so that the baby's mouth remains closed for the entire system to remain closed
Fig 38,39 – side cushioning for warmth and protection
Fig 40 – baby's face after all the attachments are completed.

Ref for images taken from youtube_fixing the cap on a neonate

Insights:

- Difficult to fix inside the infant's nasal airway – as the baby is constantly moving
- If the Cannula used are not curved it can cause trauma to the Nasal Septum
- Preferred if the mouth is closed else end-expiration pressure is variable.
- Fixing the cap and strap on the baby is a cumbersome process

Market Study

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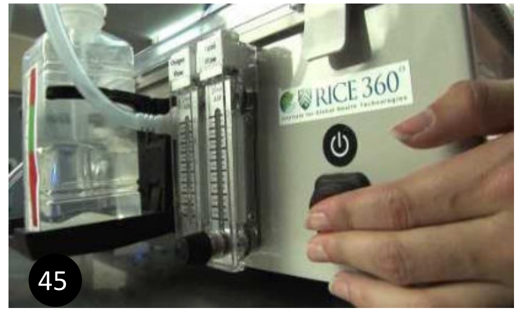
43

44



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46

Fig 41,42,43,46 are the standard vertical CPAP devices available in the market.
Fig 44- the components that get attached to form the unit.
Fig 45- the horizontal cpap unit made by RICE university
Fig 46 – set up by fisher & paykel and the interface attachments that come with it.

Ref for images taken from www.alibaba.com,veronicakatherine.blogspot

- The products are mostly in separate parts and they need to be assembled to make a functional unit.
- The unit as such has a less 'equipment like' feel.
- The network of tubings are distracting

Defining Project Brief

> To redesign the current CPAP system used for delivering oxygen to the infants. The focus would be to make it ***compact and portable*** , ***easy to use***(*intuitive*) *and* ***maintenance free.***

Primary Users

The primary users of the device are the doctors, nurse and specialized staff majorly, who have the required knowledge of the amount of medication and oxygen delivery etc.

Secondary Users

The secondary users would be the infants who are being administered CPAP through this device. The Pre-term infants mostly and infants with respiratory complications. Also certain respiratory infections may occur in infants until 8 months which require cpap administration even after they have crossed the 25 week viability period.

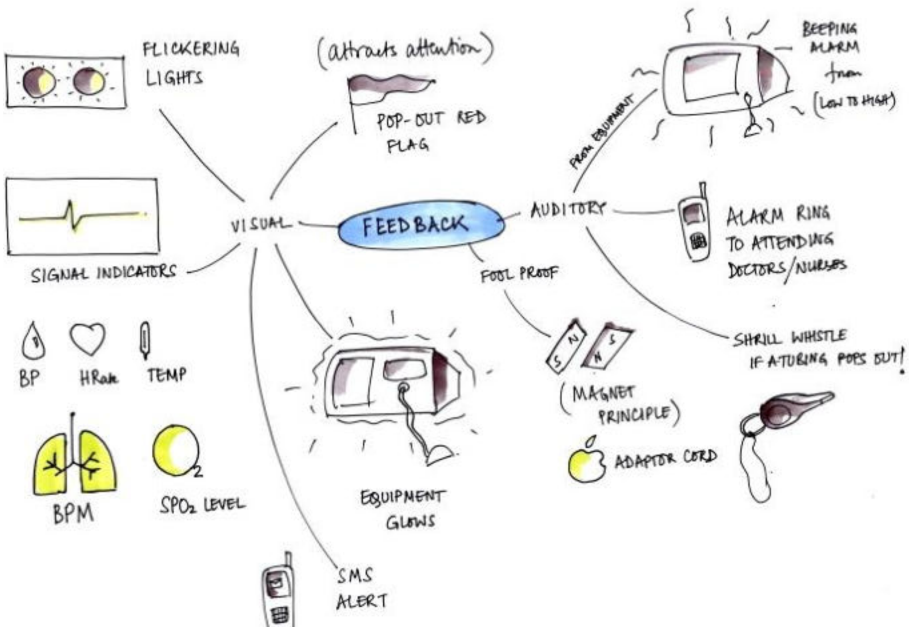
Need

From the inferences listed previously the need is to make the system more robust by solving the issues by design methodology/ process.

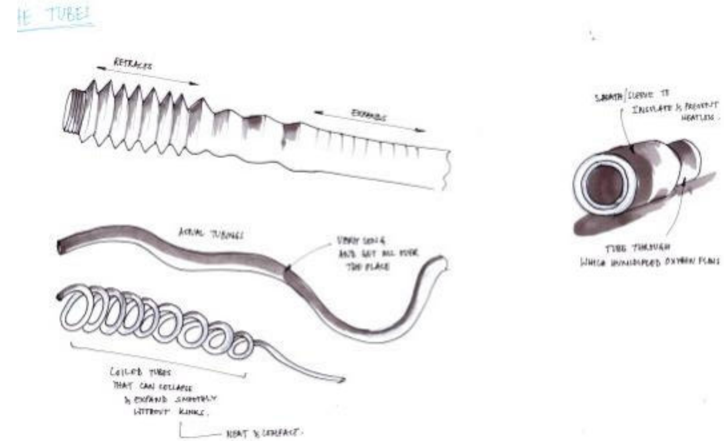
Constraints

It must be noted that this project does not aim to make modifications in the existing internal medical technology in the equipment in any which way. The goal is to work out the solution considering there are no flaws in the internal technology.
If any new concept possibility is suggested, then it would be done considering that it is an industrial standard and the technology has been used/applied/tested previously.

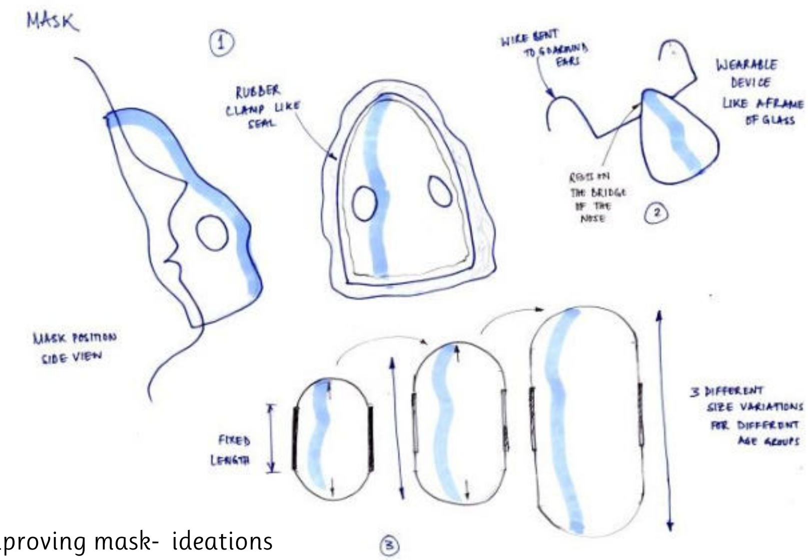
Initial Ideations



47 Mind Map of areas to look into for feedback which was lacking in the existing unit

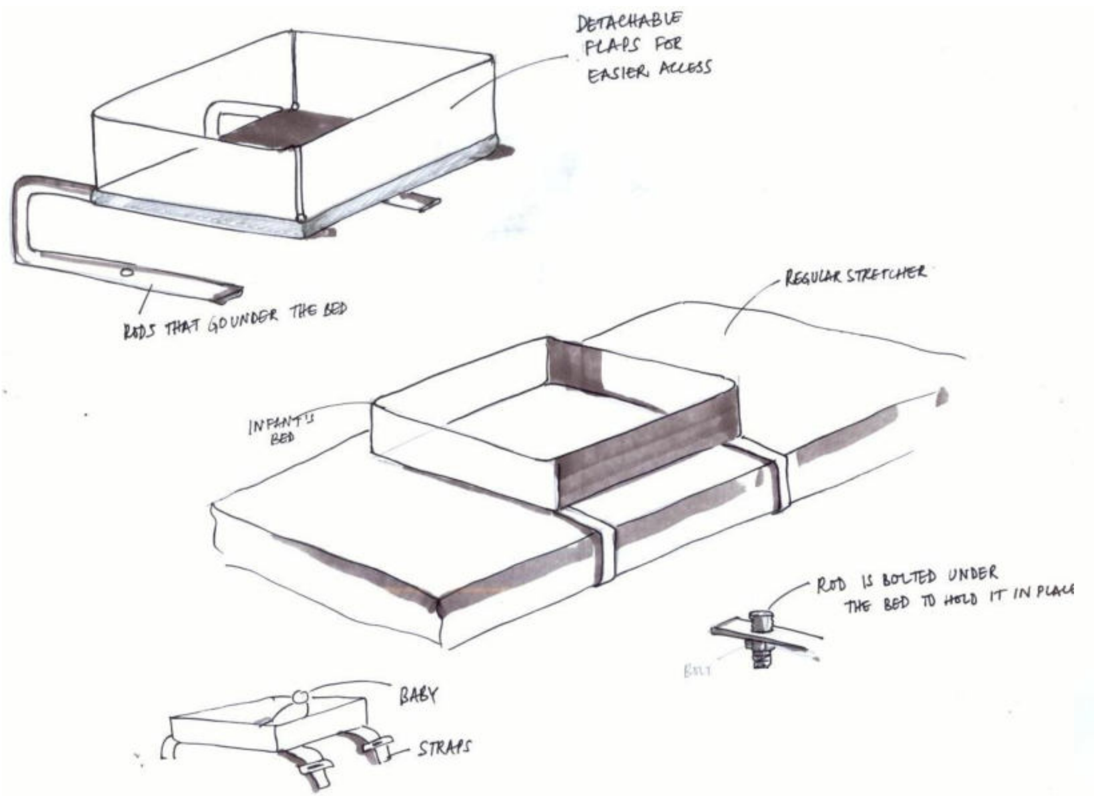


48 Tubing for inspiration and expiration



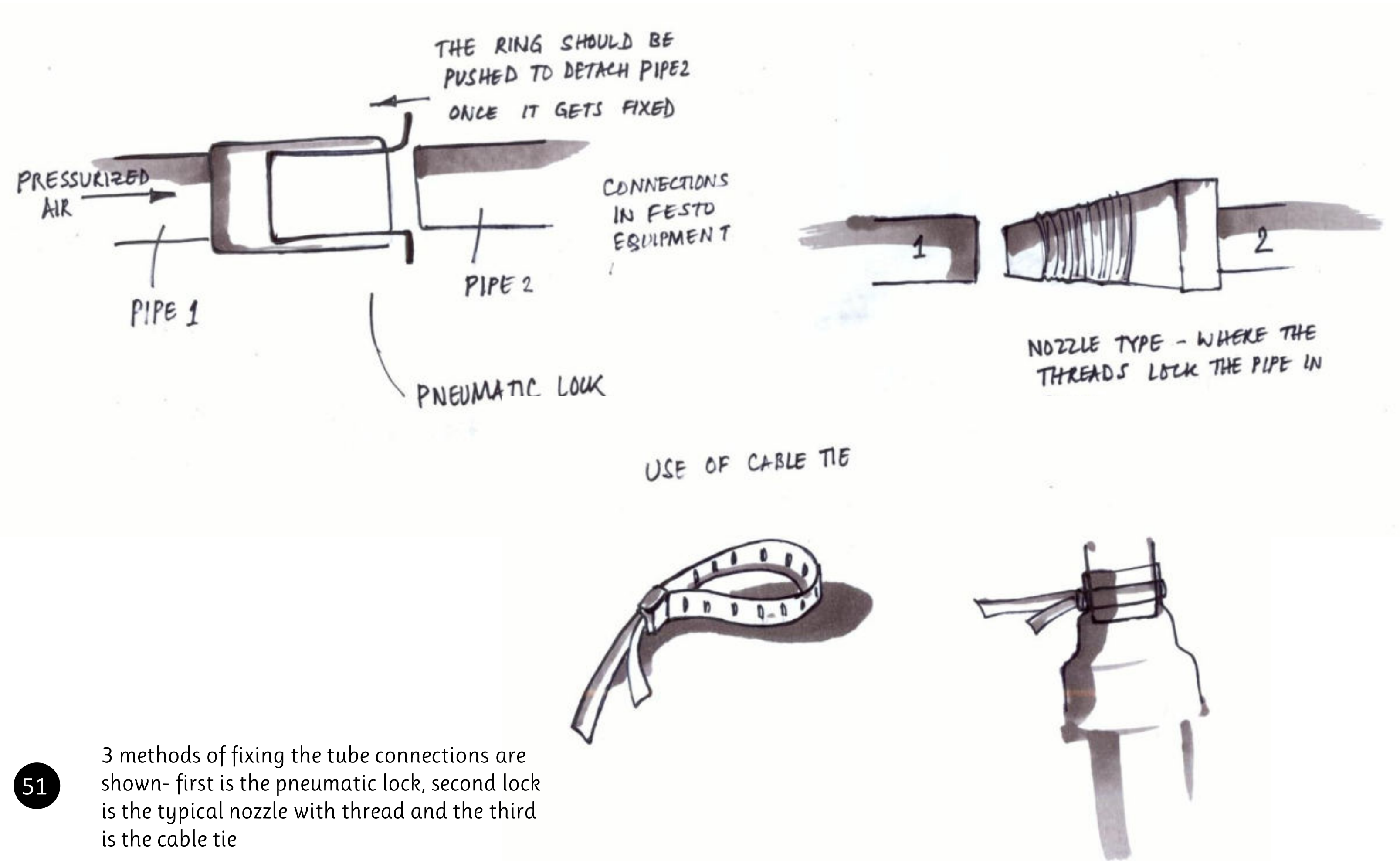
49 Improving mask- ideations

Ideations based on Separate subsystem – Bed/ warmer for in transit situations



50 Picture shows the possibility of fixing a small bed unit on the regular stretcher in which the baby can be placed and the warming ideations are shown on the right side

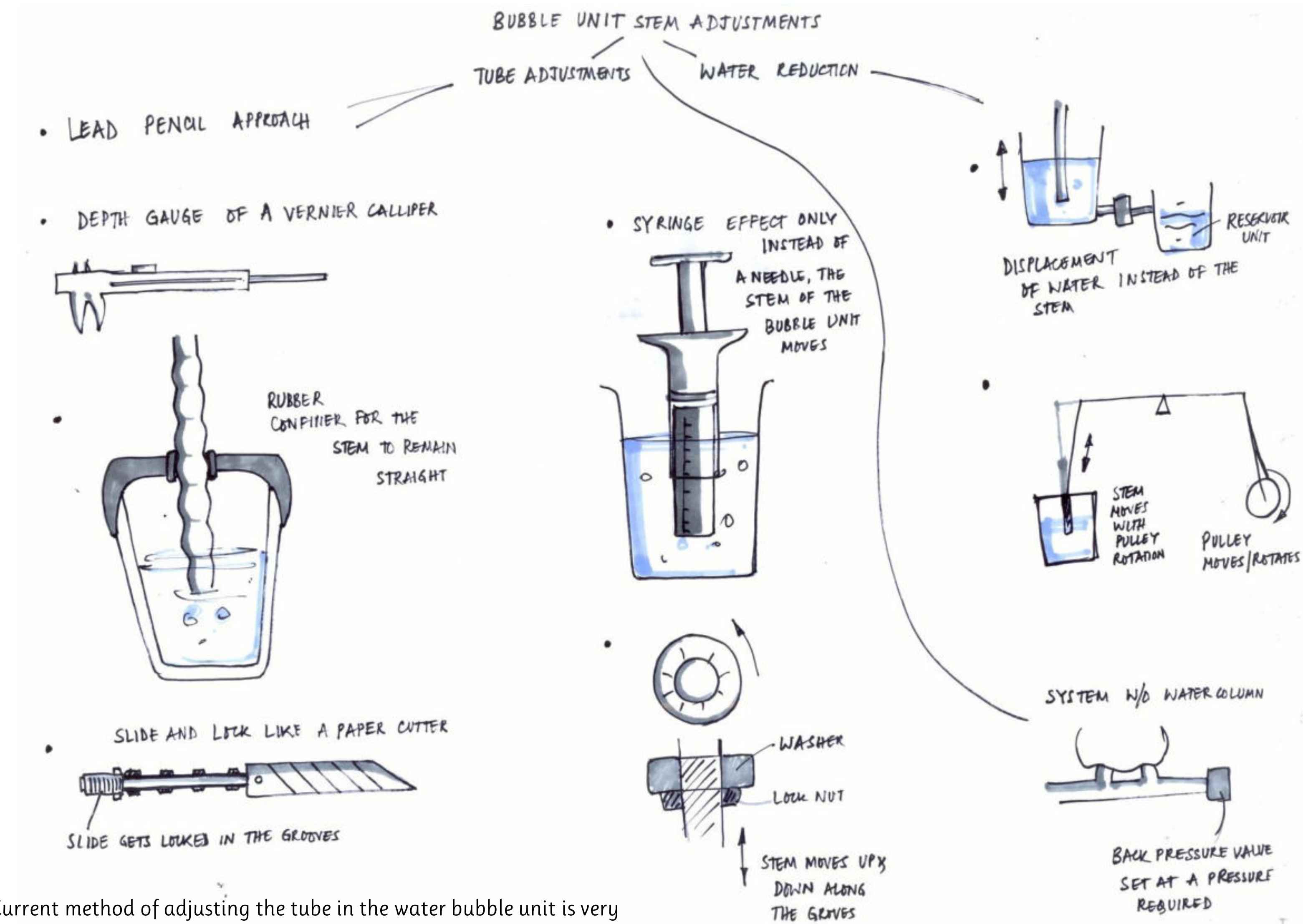
Ideations based on Separate subsystem - Connections



51

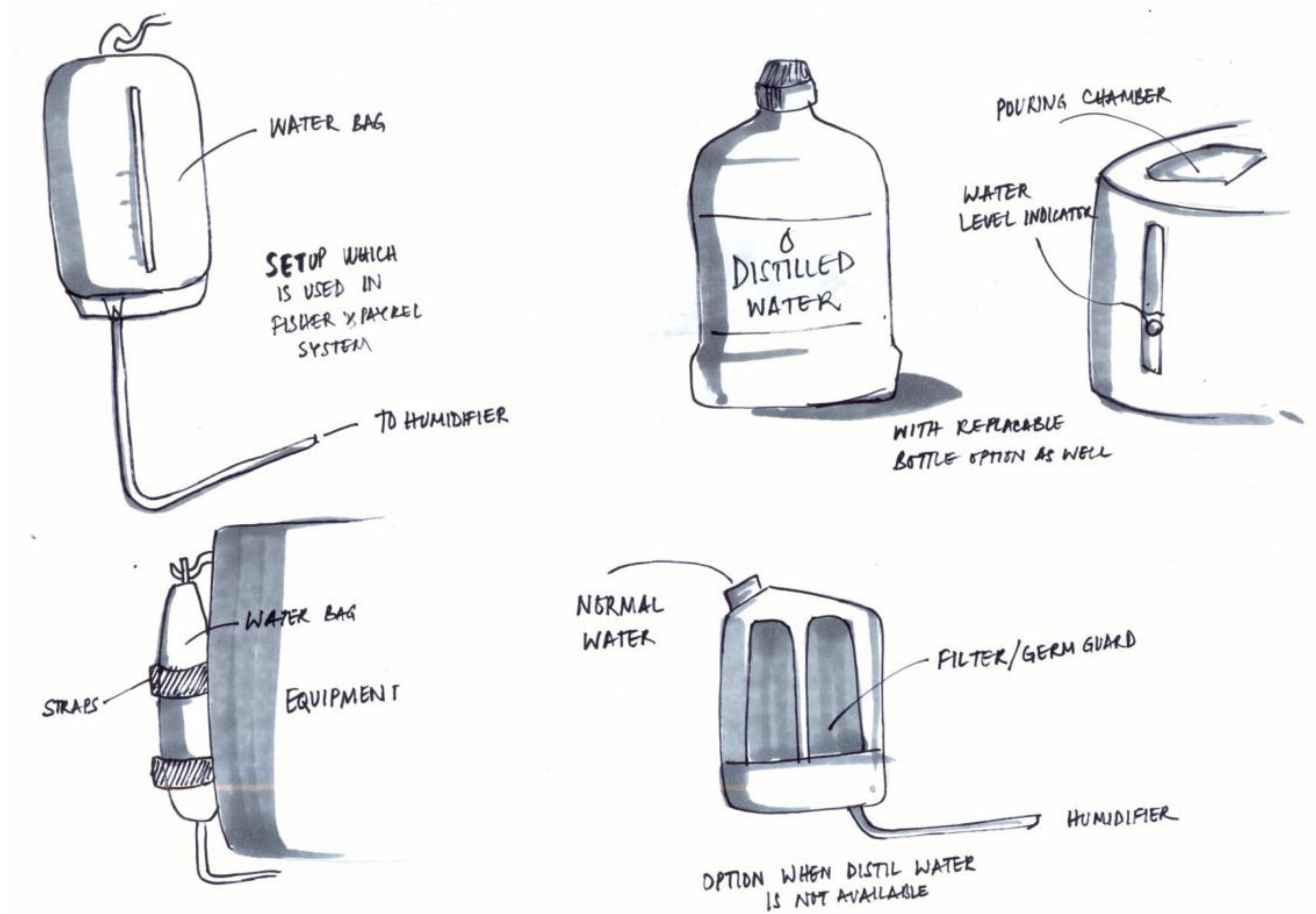
3 methods of fixing the tube connections are shown- first is the pneumatic lock, second lock is the typical nozzle with thread and the third is the cable tie

Ideations based on Separate subsystem – Bubble Unit



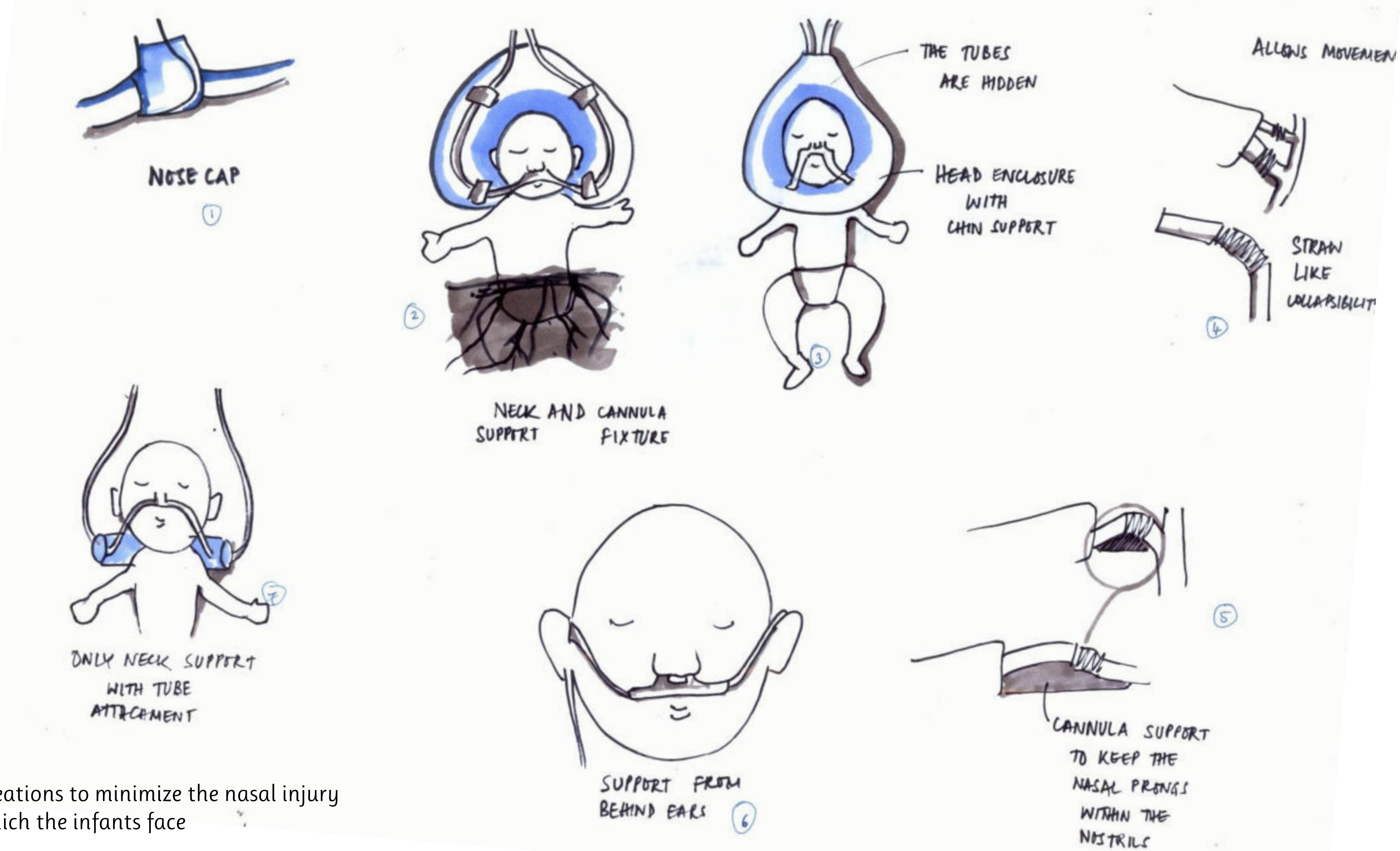
52 Current method of adjusting the tube in the water bubble unit is very crude . The above illustration shows the possiblities explored.

Ideations based on Separate subsystem – water unit for humidifier



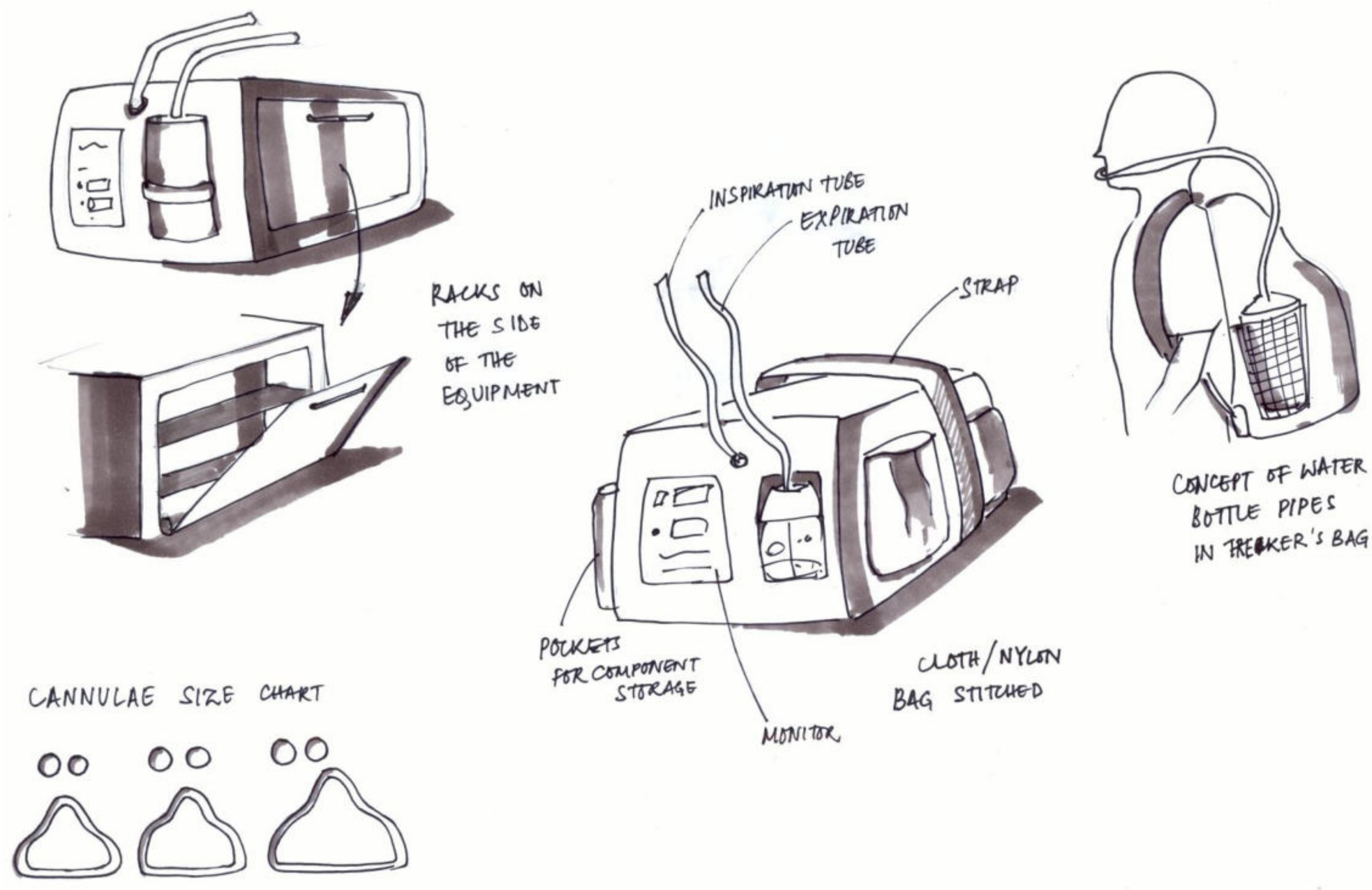
53 In the standard water unit for humidifier the bag was hung from an IV pole. Sketches show other ideations

Ideations based on Separate subsystem – patient interface



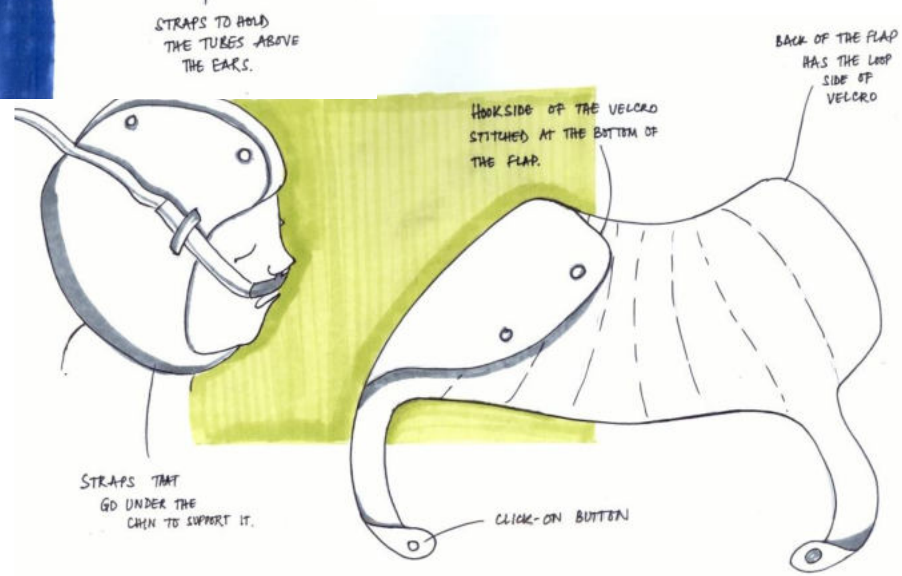
54 Ideations to minimize the nasal injury which the infants face

Ideations based on Separate subsystem - storage unit



55 Ways of storing the other equipment like the user interface, pulse oximeter, tubes for intubation, intubation assiter etc.

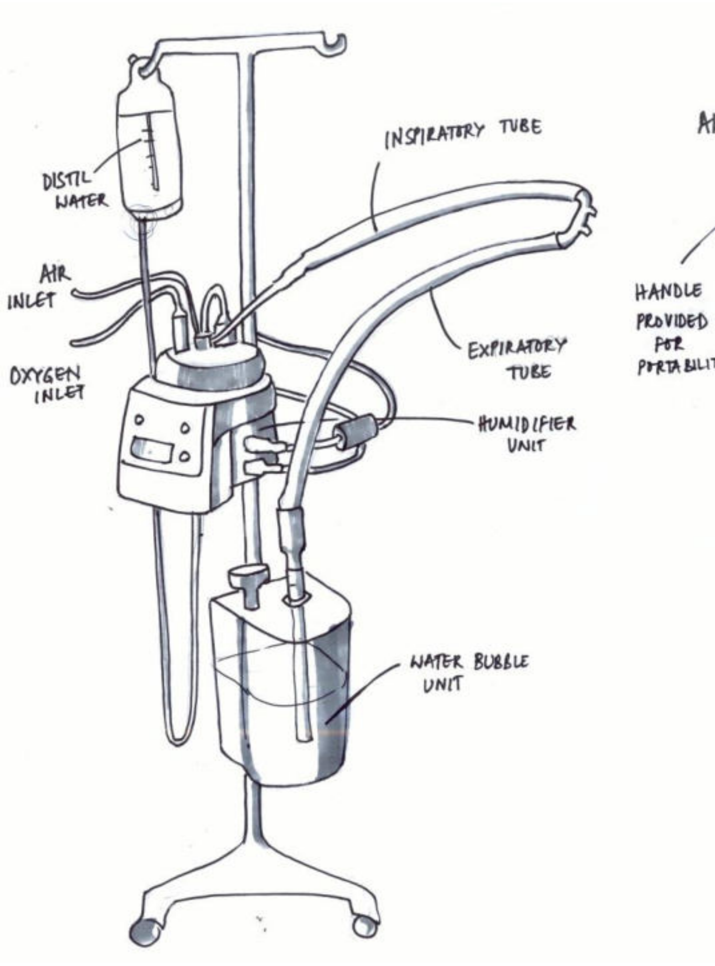
Ideations based on Separate subsystem – cap

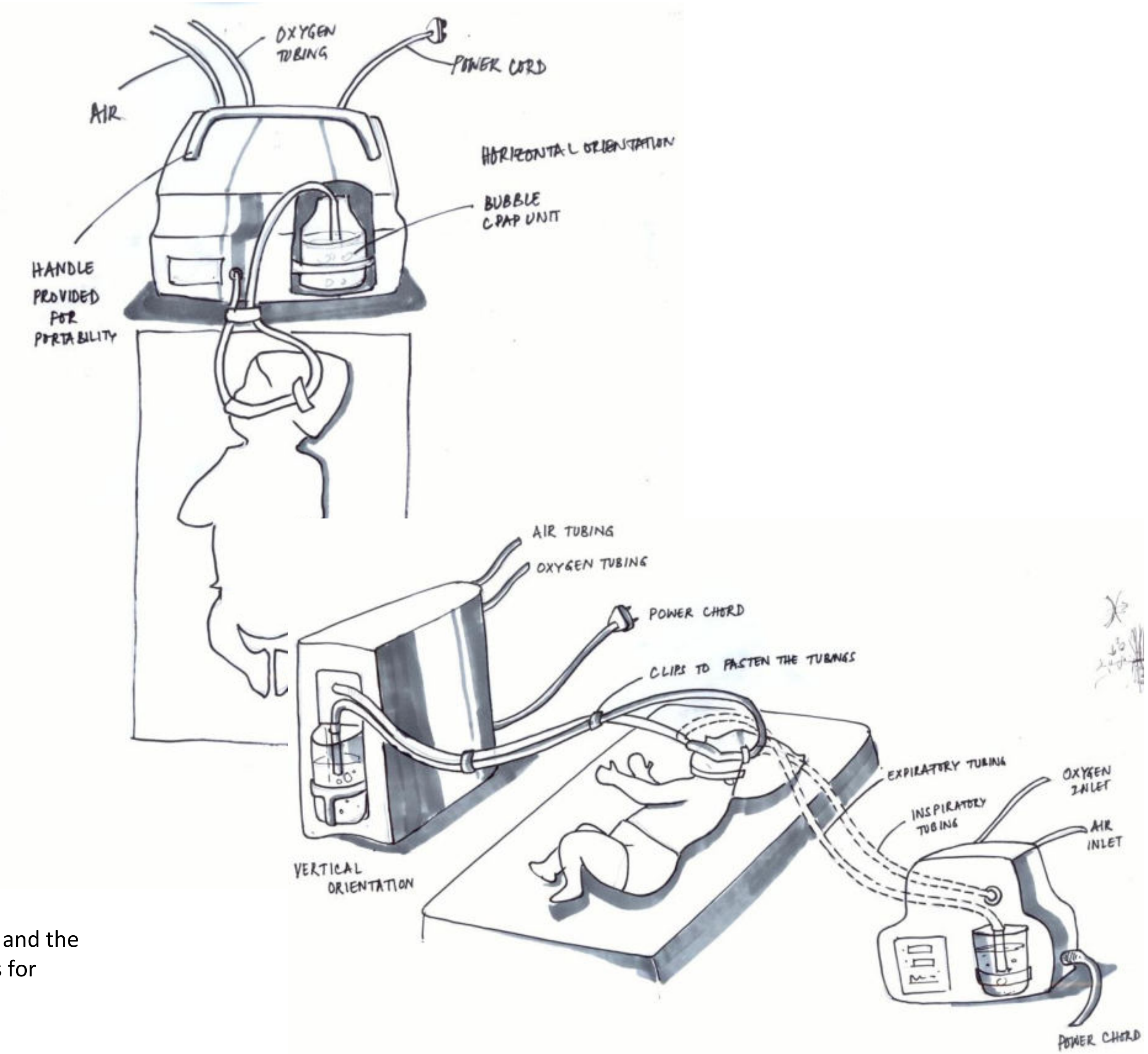


56

Instead of a cap, a band like unit can be easily fixed on the neonate by one person and tightened with velcro instead of tapes and pins.

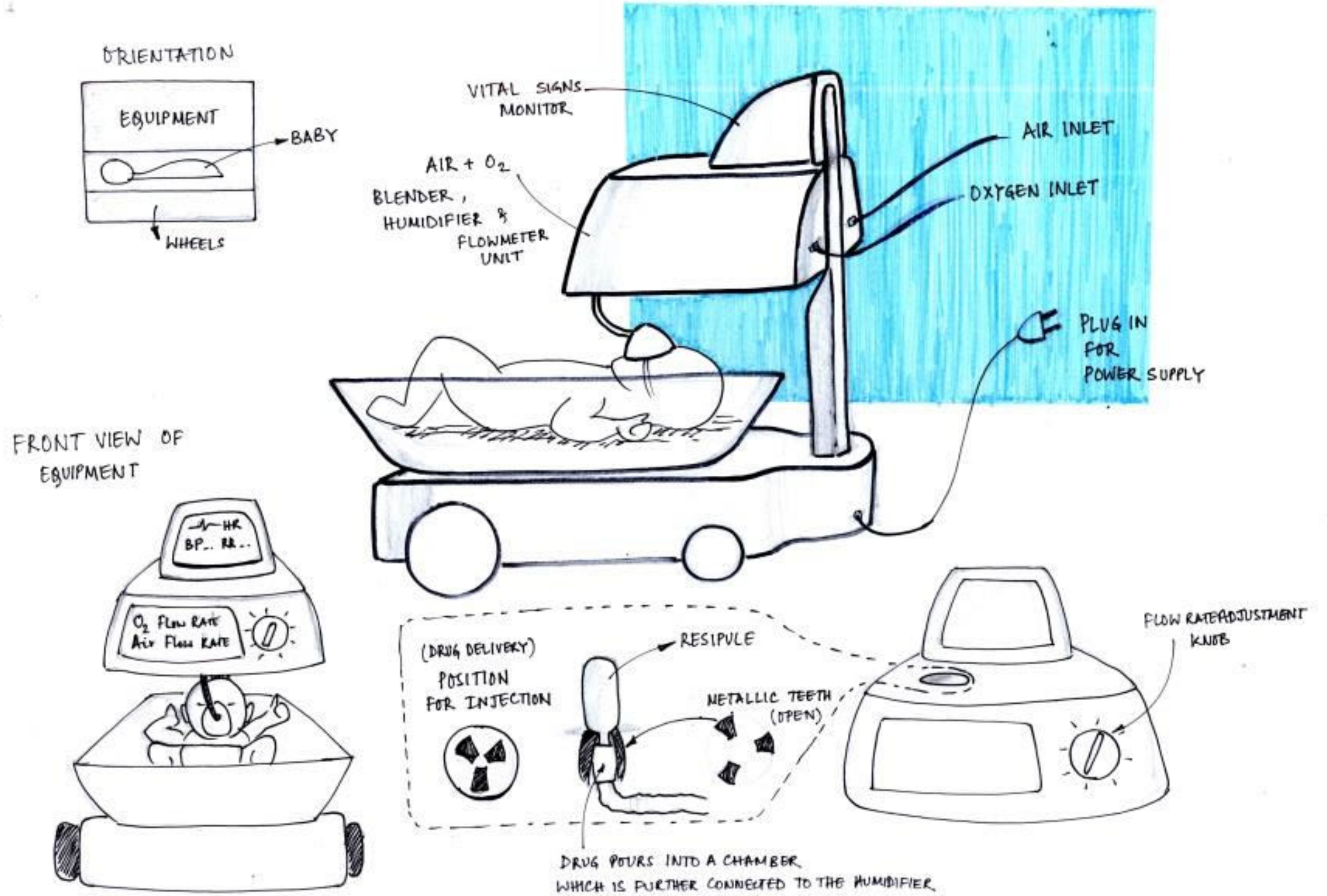
Ideations based on Separate subsystem – compact





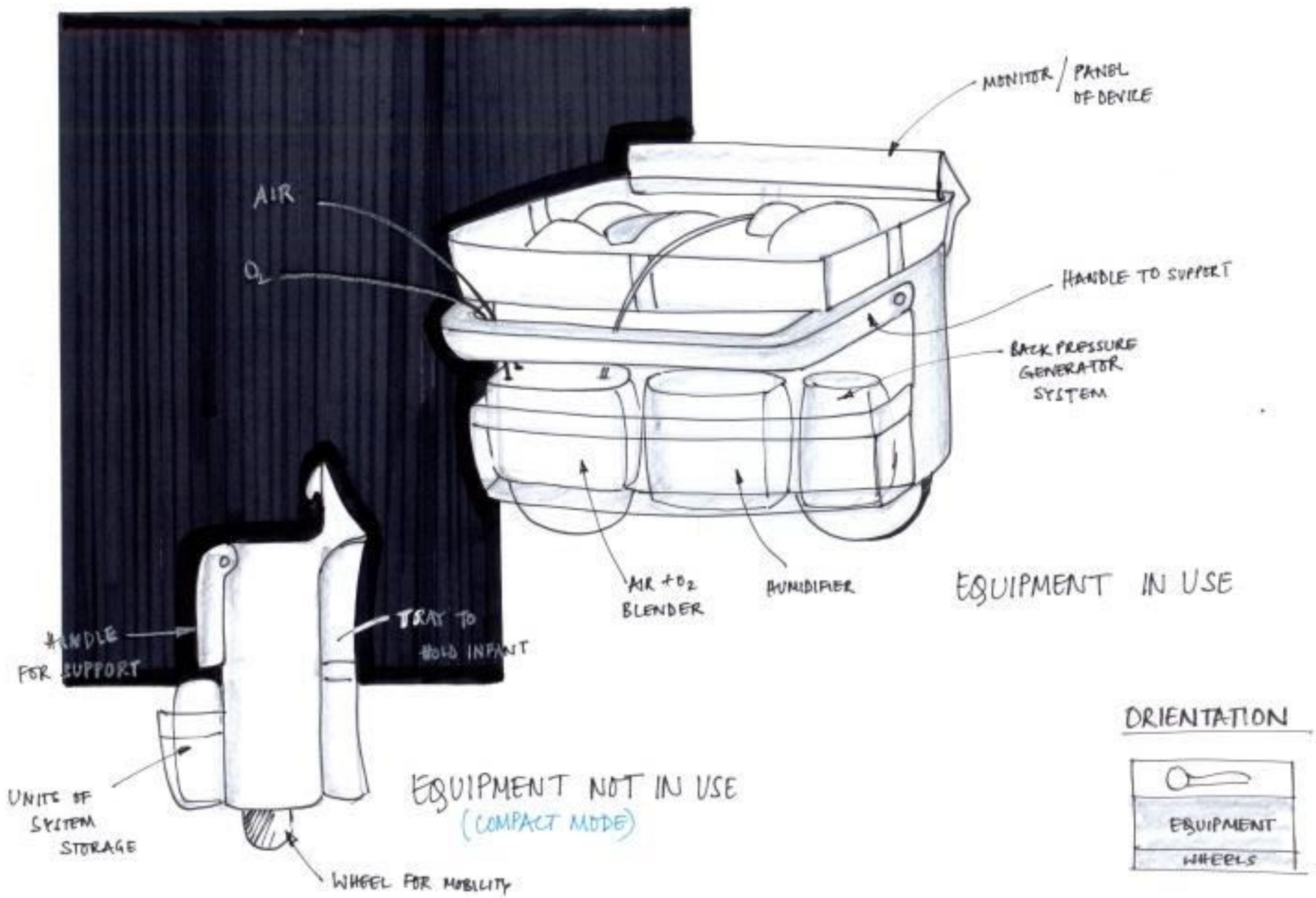
57 Picture on the left is of a standard device and the ideations on the right are the possibilities for compactness.

Ideations based on orientation



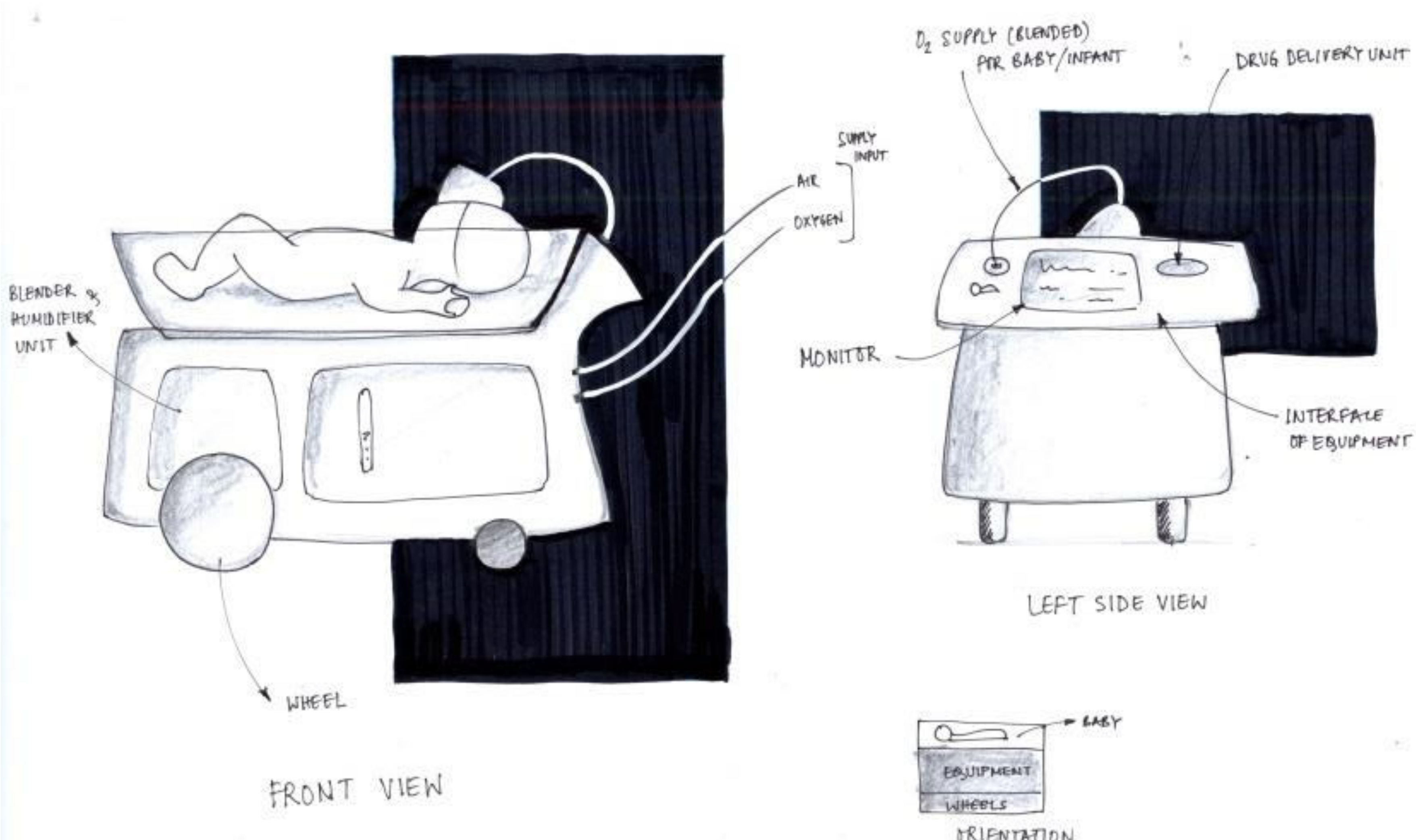
58 Orientation of the system as shown above. Note that the form shown is just for representation

Ideations based on orientation



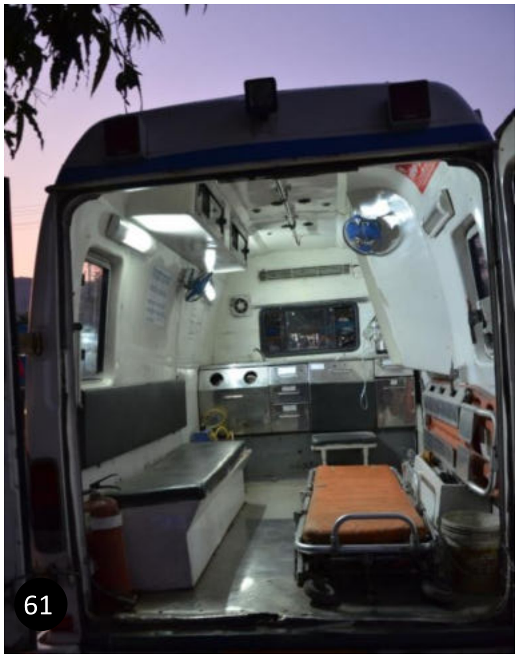
59 Note that the form shown is just for representation. Here the casing approach was being looked into where the equipment subsystems can be separately kept for ease of use/maintenance

Ideations based on orientation



60 Note that the form shown is just for representation. Here the trolley approach was being considered to keep the baby and the equipment in one unit which is easily portable.

Inside ambulance – equipment available and future possibility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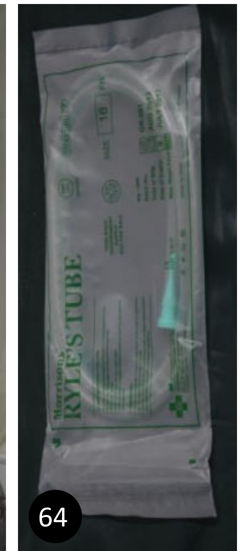

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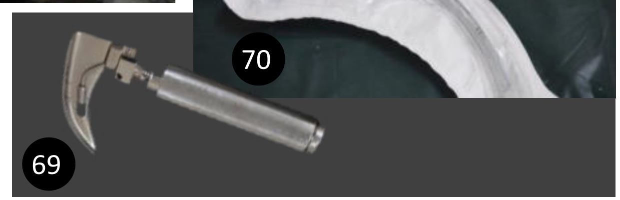

69

The inside of an ambulance was also observed for the use of a CPAP equipment in case of emergency delivery during 'in utero transfer'.

Moving the mother to a specialist neonatal unit may be the safest option if the baby is likely to be born very prematurely. This is known as 'in utero transfer' as the doctors are effectively making sure that the baby is in the best place for its care while it is still in the mother's womb. It is often safer to transfer the baby while it is still protected inside the womb than after it is born. Yet there could be a situation where delivery needs to take place during the transfer. For that situation, the emergency van would be equipped with the CPAP device which would prevent many of the possible respiratory complications.

Fig 61 – shows the inside of an emergency van and the internal set -up

Fig 62 – shows the pipes for air and oxygen

Fig 63 – place for drawer and mask position

Fig 64,65,70 – different types of tubes available

Fig 66,67 – masks for elders and kids

Fig 68 – bag valve mask

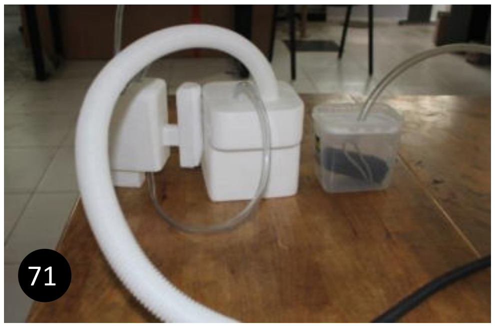
Fig 69 – intubation guide

The set up inside the emergency vehicle had the above mentioned equipment in different locations inside the drawers.

There is a scope of keeping a compact CPAP unit which will be effective when an infant would require oxygen administration instead of looking for all the equipment one by one from the drawers and setting it up.

The time taken for all this activity will also get reduced and efficiency will increase.

Role play with test rigs



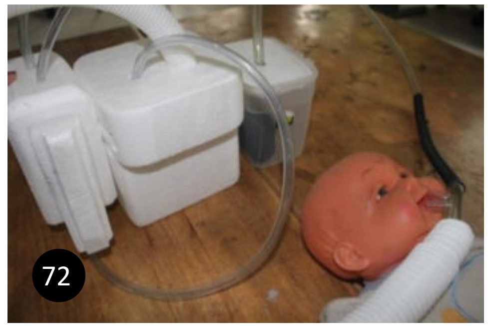


Fig 71-74 show the possibilities of orientation(water container should be at nose level or below) to see how compact can a system get if the subsystems were of standard dimensions.
The inference from the role-play was that the space occupied by the standard equipment would remain within 400mm in length,350 mm in breadth and 200 mm in height. Fig 73 shows that the water container is above the level of the baby's nose hence this orientation should not be considered to prevent back suction of water into the infant's lungs.

Fig 75-77 show how the head dimensions are necessary for a cap like unit. But if a band like interface(fig 76,77) is used the dimensions need not be taken, an adjustment below the chin with a Velcro would fit all head sizes.

Direction from Ideations

After making possible solutions for the problems inferred, ideations were clustered on the basis of 3 directions. The CPAP device can be used in 3 possible areas.

A Inside hospitals

The aim is to reduce the clutter surrounding the equipment which is currently present

B During transit

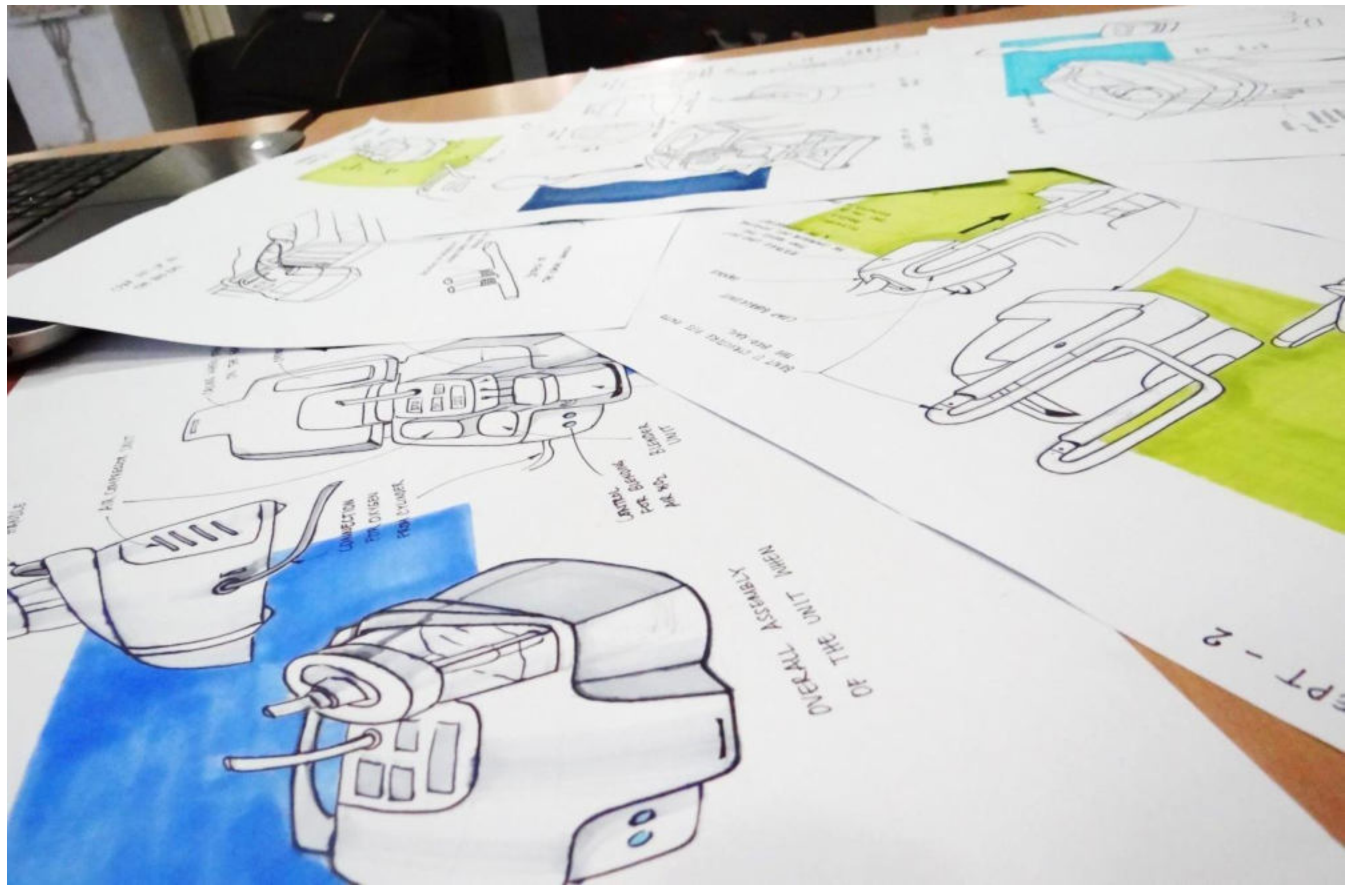
In emergency delivery situation- the aim is to make the device suitable for installing inside a vehicle.

C In local clinics

Local clinics are more accessible to the people in very small towns and villages

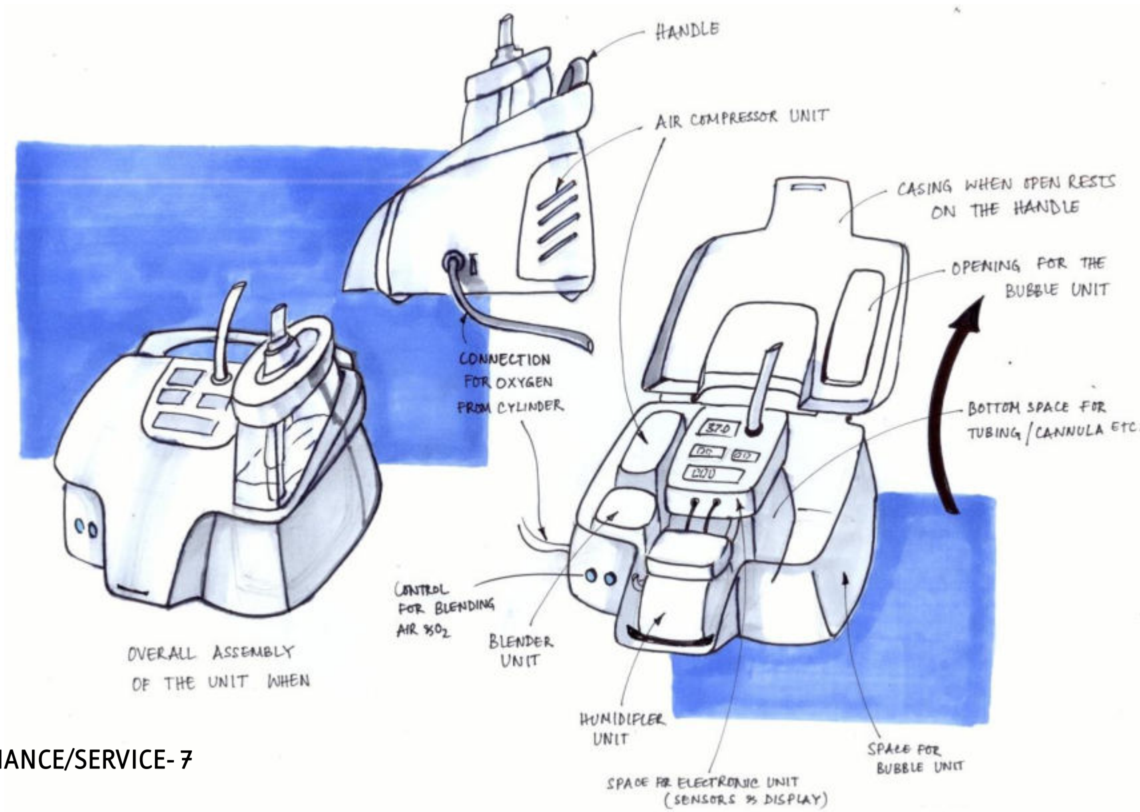
From the research papers and from the visit to the various levels of hospitals, it was decided to go ahead with **option C** which is to modify the CPAP device for a local clinic set up. Albeit, the other two are also challenging areas to work on, the need to have an independent set-up in a local clinic which is the first touch point for the people in case of any emergency situation is much greater than the rest.

Concepts



Concept-1

The first concept is to have the entire set-up as a covered casing which is easily portable. This will house the subsystems like the air compressor unit, blender unit, the humidifier and the water-bubble unit under the front cover as shown. Here the storage space is very small for the connecting tubes but other equipment like the nasal cannula, the head-neck support etc. can be stored.
This set-up would be placed on a flat surface close to the infant's bed inside the clinic.



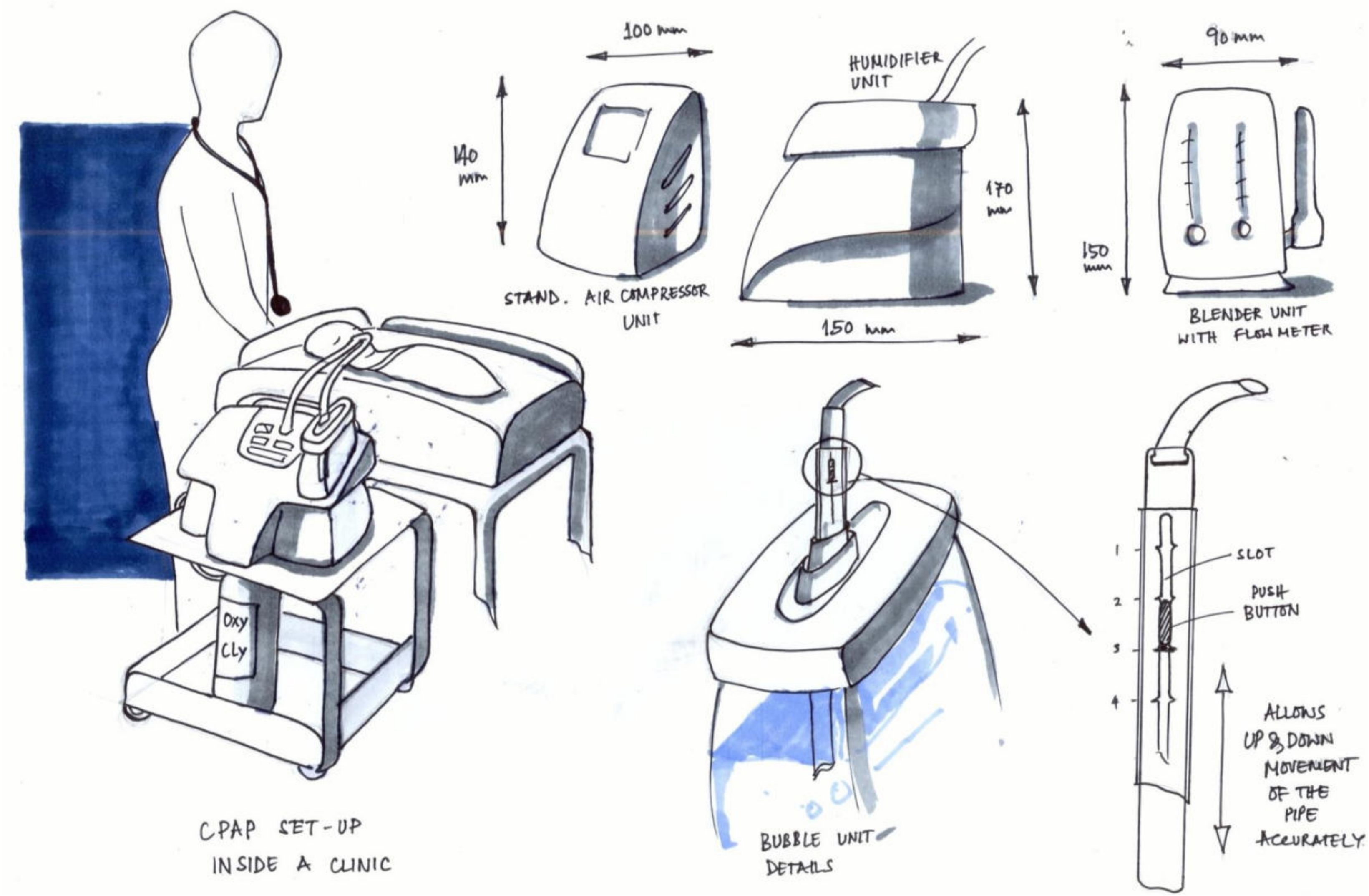
COMPACT- 7 PORTABLE- 7 EASE OF USE- 8 MAINTENANCE/SERVICE- 7

Advantages:

1- Easy to carry and can be placed anywhere
2- Front open cover
3- Accessibility to internal components for maintenance
4- Least visibility and posture issue(for the user)
5- Handles on the side for carrying the unit

Disadvantages:

1- Use of both hands to carry the unit around
2- Cannot be placed at a position above the bed
3- The bottle needs to be removed for opening the front cover
4- Weight of the system needs to be considered for moving around
5- Visibility of the controls should be clear
6- Separate oxygen cylinder source need to be attached
7- The unit needs to be kept near a power source
8- Comparatively less space to store the pipes/cannula/other imp. Equipment

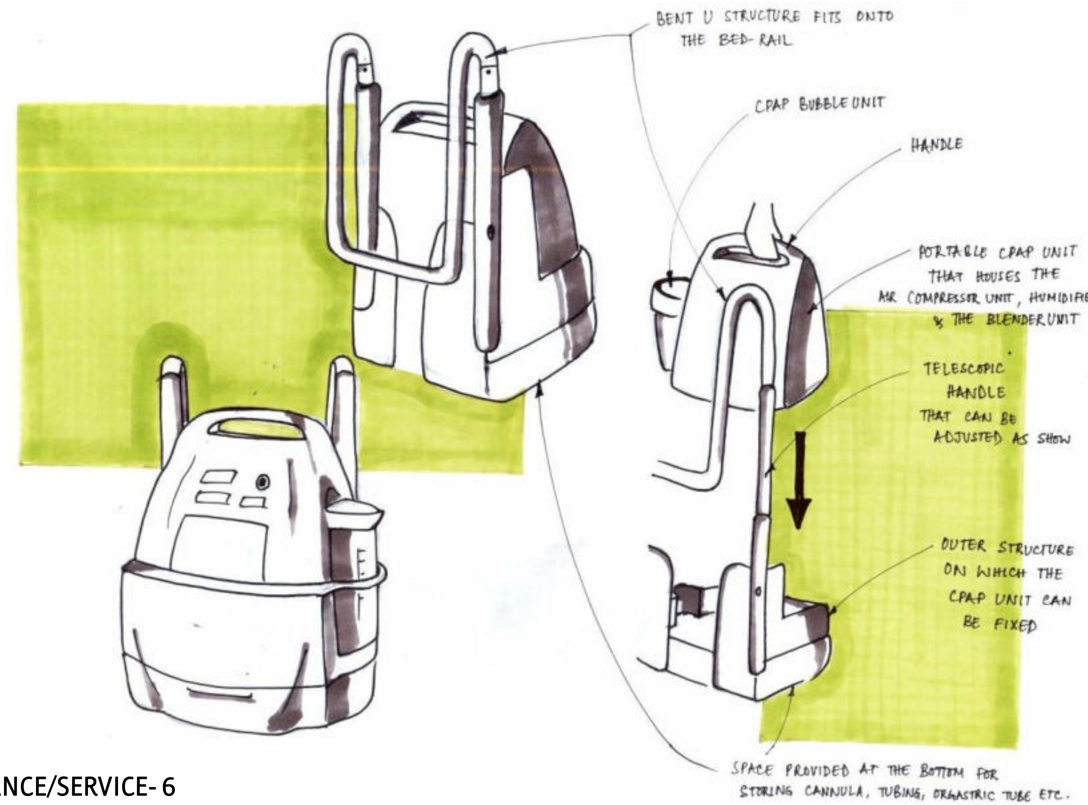


Picture shows how the device would be used in the clinic environment. The dimensions of the standard subsystems are as shown on the top and top left corner.

The bubble unit has a modification in the stem which is tightly fixed onto the cap while the stem is adjusted to the required height by using a push button that fixes into a slot once the height is set.

Concept-2

Most clinics have a bed with railing on the head and foot side. This product's casing is meant to be fixed on one of these rails and used.
The subsystems mentioned earlier would have a bag like outer unit which is detachable from the casing and can be carried to another location.
The casing unit has a storage rack at the bottom which is used to store the tubing and interface components.



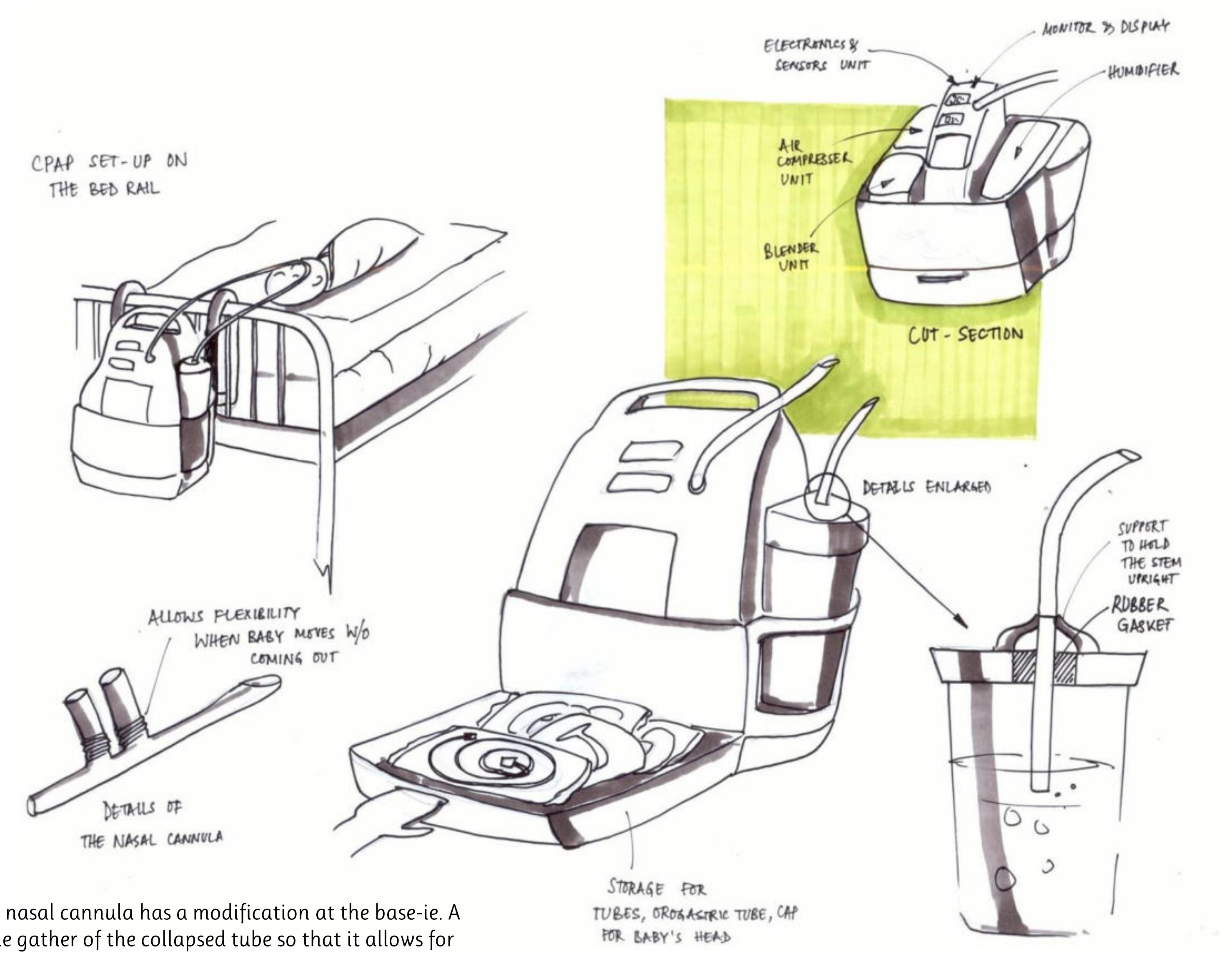
COMPACT- 7   PORTABLE- 6   EASE OF USE- 6   MAINTENANCE/SERVICE- 6

Advantages:

1- Flat surface not required for keeping the unit
2- Telescopic handle for adjustment of the height
3- Larger space for storage of the equipment at the bottom drawer
4- Can be carried with one hand when not placed inside case.

Disadvantages:

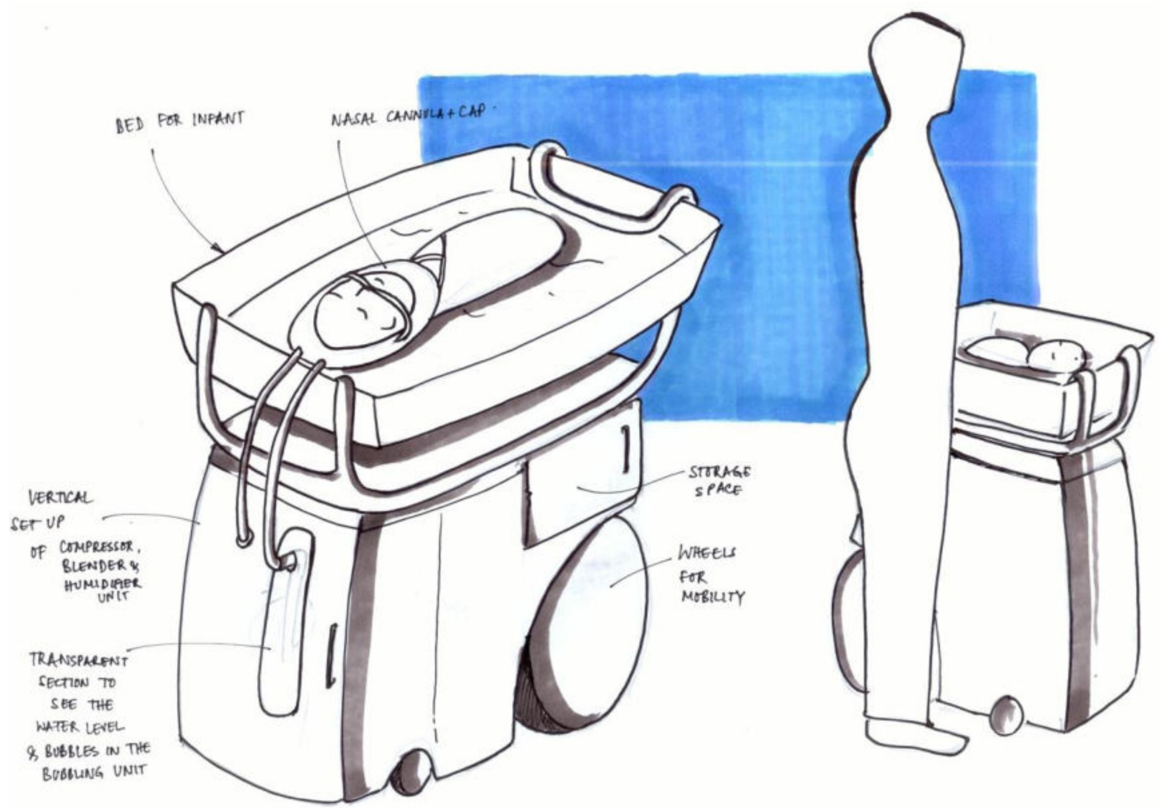
1- Not applicable for beds without rail
2- Extra parts – telescopic handle – chances of failure
3- Visibility and posture issues
4- Weight factor needs to be considered to hang out over the rail



The nasal cannula has a modification at the base-ie. A little gather of the collapsed tube so that it allows for flexibility when the baby moves its head and it does not pop out.

Concept-3

This concept explores the portability aspect more since it has wheels. There is a unit at the base which holds the entire subsystem along with other provisions like the oxygen cylinders, additional components and there could be an addition space managed for power back up.
The unit can be moved easily around by one staff with the baby on cpap.



COMPACT- 8   PORTABLE- 8   EASE OF USE- 7   MAINTENANCE/SERVICE- 7

Advantages:

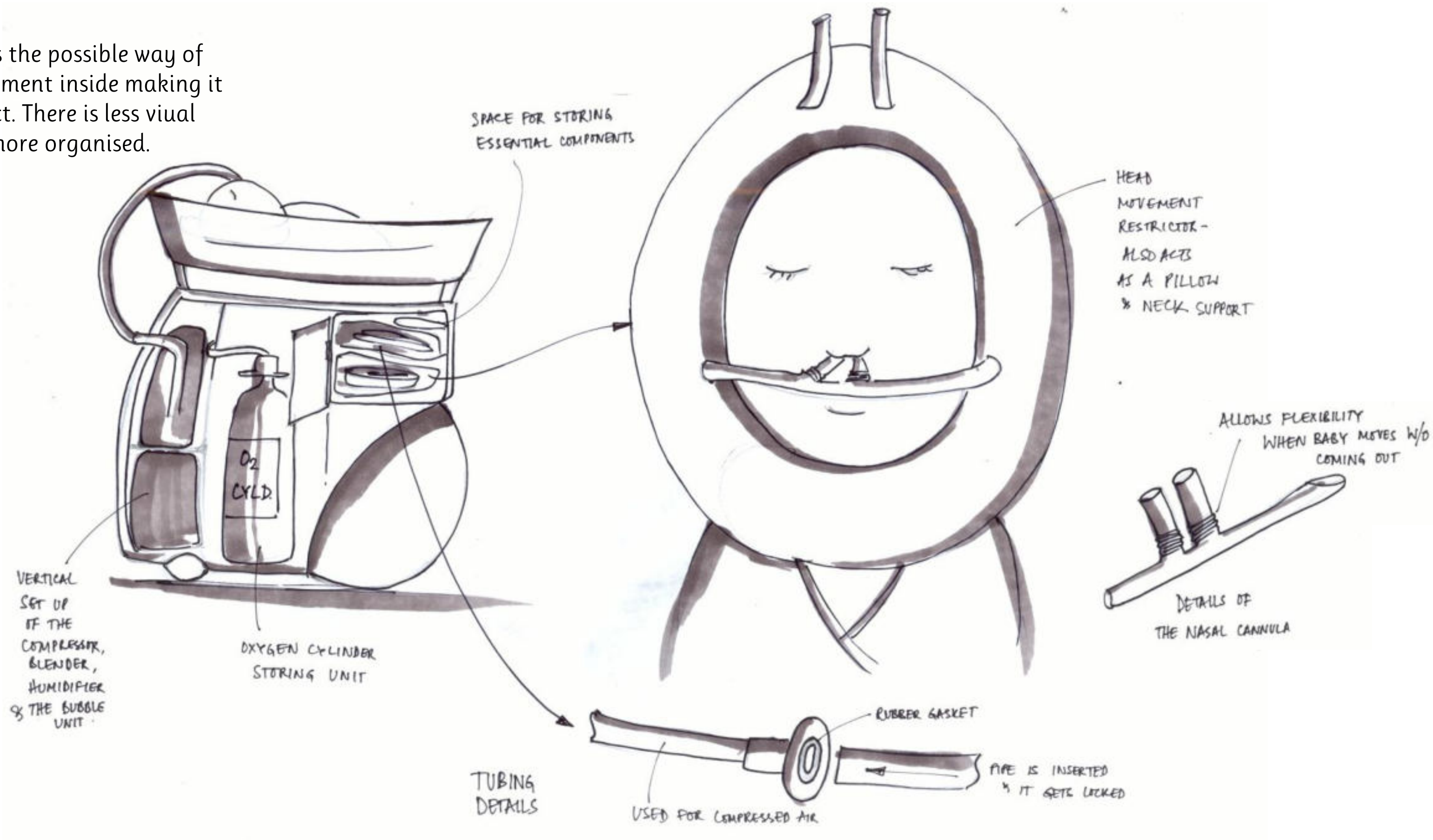
1- One compact unit on wheels
2- Better space allocation for other components within
3- Better mobility- within the room/outside/to the emergency van
4- Power back-up unit may/can be provided(secondary wishlist)

Disadvantages:

1- Need to have controls/monitor units at working height
2- Visibility and Accessibility issues need to be looked into
3- Motion should not affect the units inside

Picture shows the head and neck support for the baby and how the nasal cannula rests inside the casing and takes its support instead of it being attached on the baby's head

Picture on shows the possible way of storing the equipment inside making it neat and compact. There is less viual clutter and it is more organised.



One of the tube connection detail which is easy to lock and remove without chances of it coming off

Concept Evaluation

Defining the words in the brief:

Compact – condensed/packed layout/ concise packaging or closely packed together.

Portable - able to be easily carried or moved about especially because being of a lighter and smaller version than usual. Managable/ handy/ convenient/ cartable/ haulable

Ease of Use – make better to handle/soften the severity of use or complexity

Maintenance free – technologically repairable, diminish system failures due to subsystem failure, standard components are replaceable off -the- shelf .

	Concept 1	Concept 2	Concept 3
Compact	7	7	8
Easy to use	8	6	7
Portable	7	6	8
Maintenance free	7	6	7

The numbers marked on a ten point scale under each concept was based on discussion with the doctors and the insights gained from the field visits.

Since **concept 3** scores the highest rating as an average, it will be considered as the final concept for this project.

Concept Selected

This is a representative model of the final concept. The form and aesthetics will be further explored.

The entire set-up showing the scale of the model.

Section showing the space for CPAP equipment, component storage and cylinders space. There is a possibility of power back-up unit if space is efficiently utilized.

Test rig of the Concept

After the final concept was selected, a quick test rig was made out of bamboo, cardboards and foam boards to test the ergonomic factors like working height, working area etc. Position, Orientation, Usability and visibility testing of the interface was also carried out to understand the various possibilities and the problems associated with each.
The temporary test rig was then measured for various dimensions as follows.
L: 680 mm W: 460 mm H: 1000 mm

The insights obtained were:

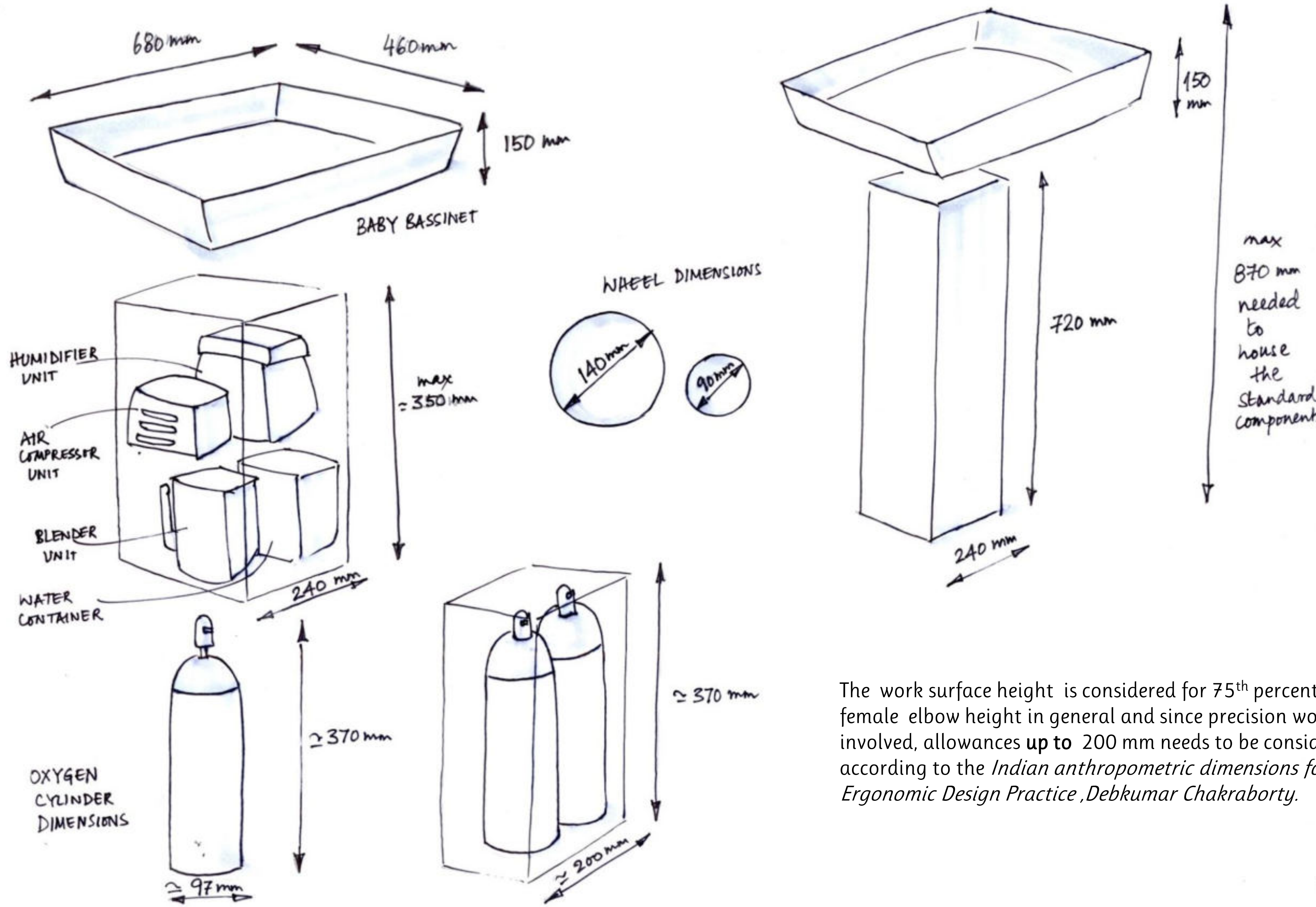
- The baby's orientation was a key issue since the ease of accessibility matters here and from doctor's opinion keeping the head toward the accessible area of the doctor was important. In fact having the whole body accessibility would be much preferred.
- The interface should not restrict access

Fig 78 displays the entire structure of set up
Fig 79 accessibility of the interface from the head side
Fig 80 working height and area testing

Fig 81 – user is working on fixing the baby's interface but his attention is caught by the signals on the interface
Fig 82 – bringing the interface on the side makes the user lift up his toes and work – very difficult posture to work in

Fig 83 – testing one of the interface layouts
Fig 84 – accessibility from the front side - monitor interface may have an affordance of hand rest
Fig 85-86 – testing the oxygen cylinder orientations- horizontal/vertical to understand ease of access, replacing and setting up connection.

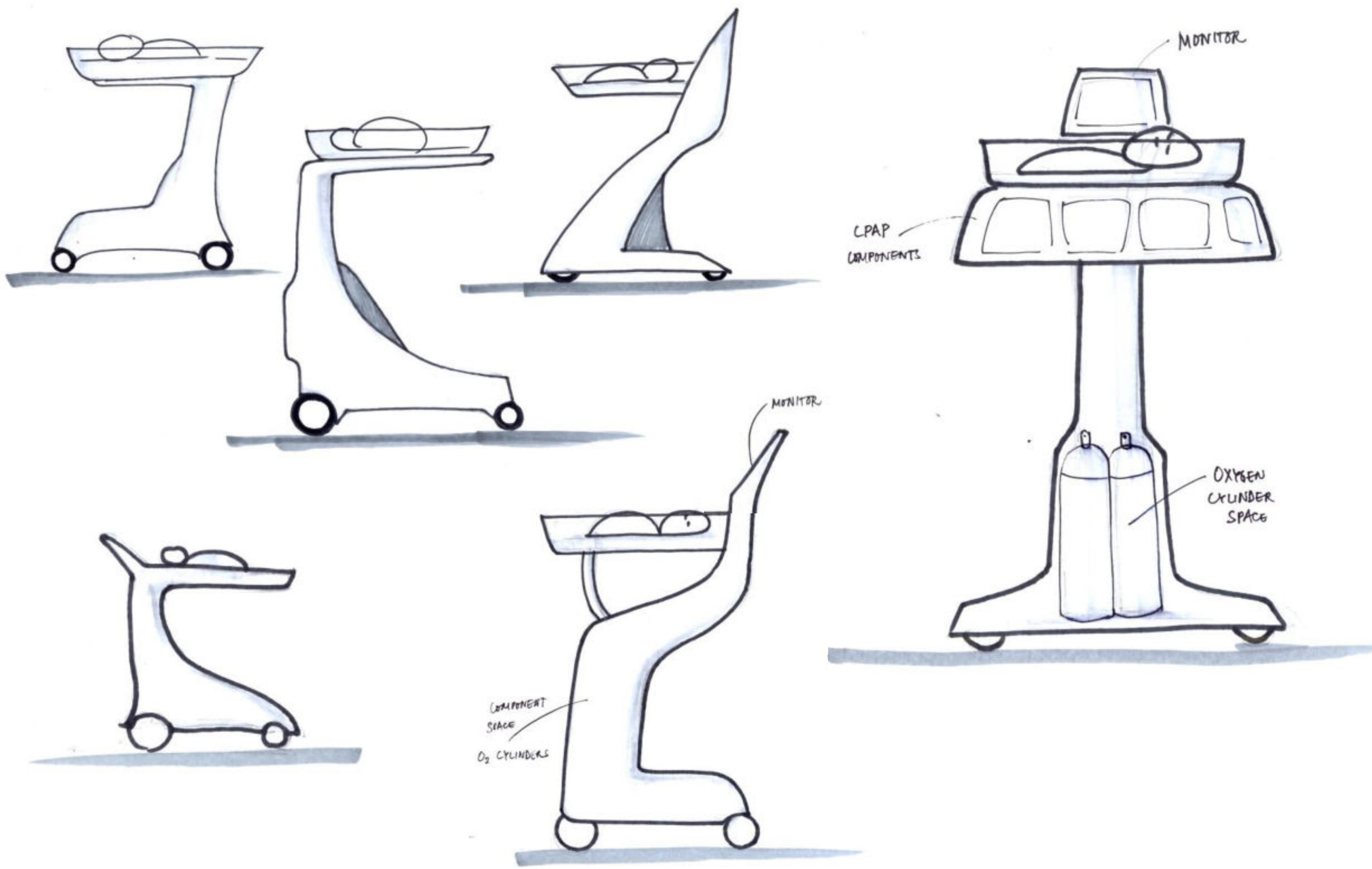
Form Exploration Constraints



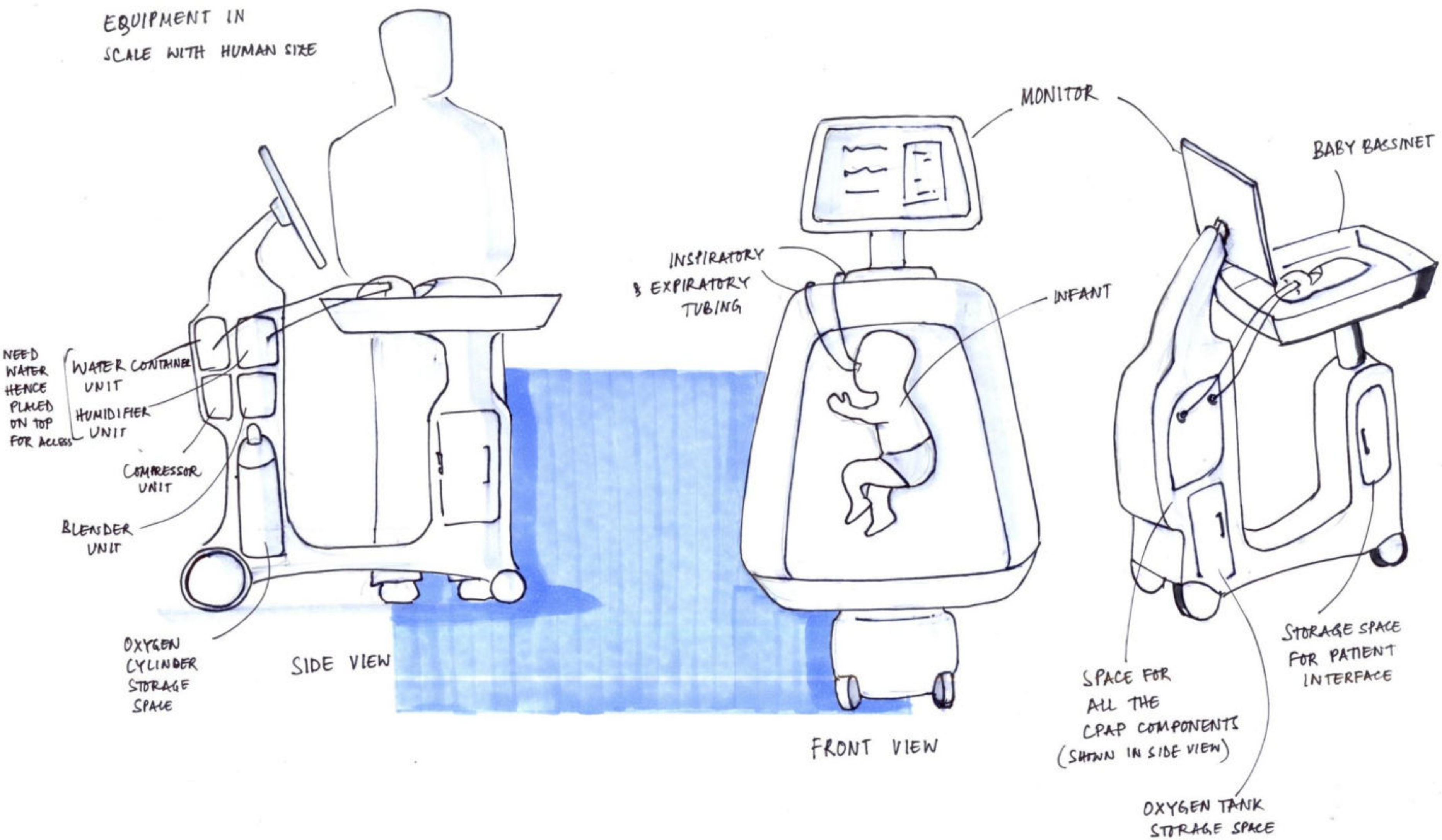
The work surface height is considered for 75th percentile female elbow height in general and since precision work is also involved, allowances **up to** 200 mm needs to be considered according to the *Indian anthropometric dimensions for Ergonomic Design Practice ,Debkumar Chakraborty.*

Initial Form Explorations

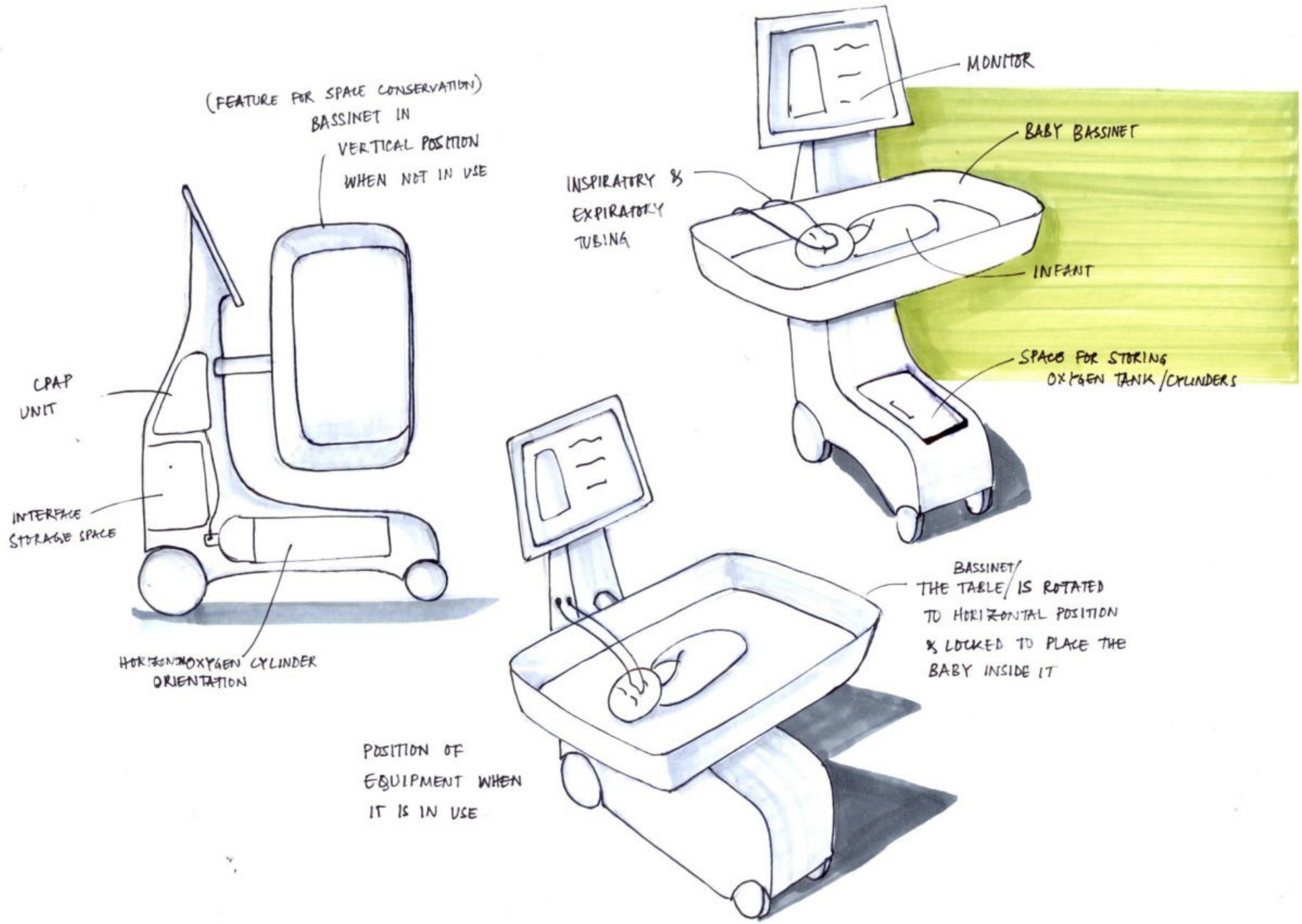
After determining the different component sizes to obtain the inside structural space, external features were added to the structure to get the sketched forms.



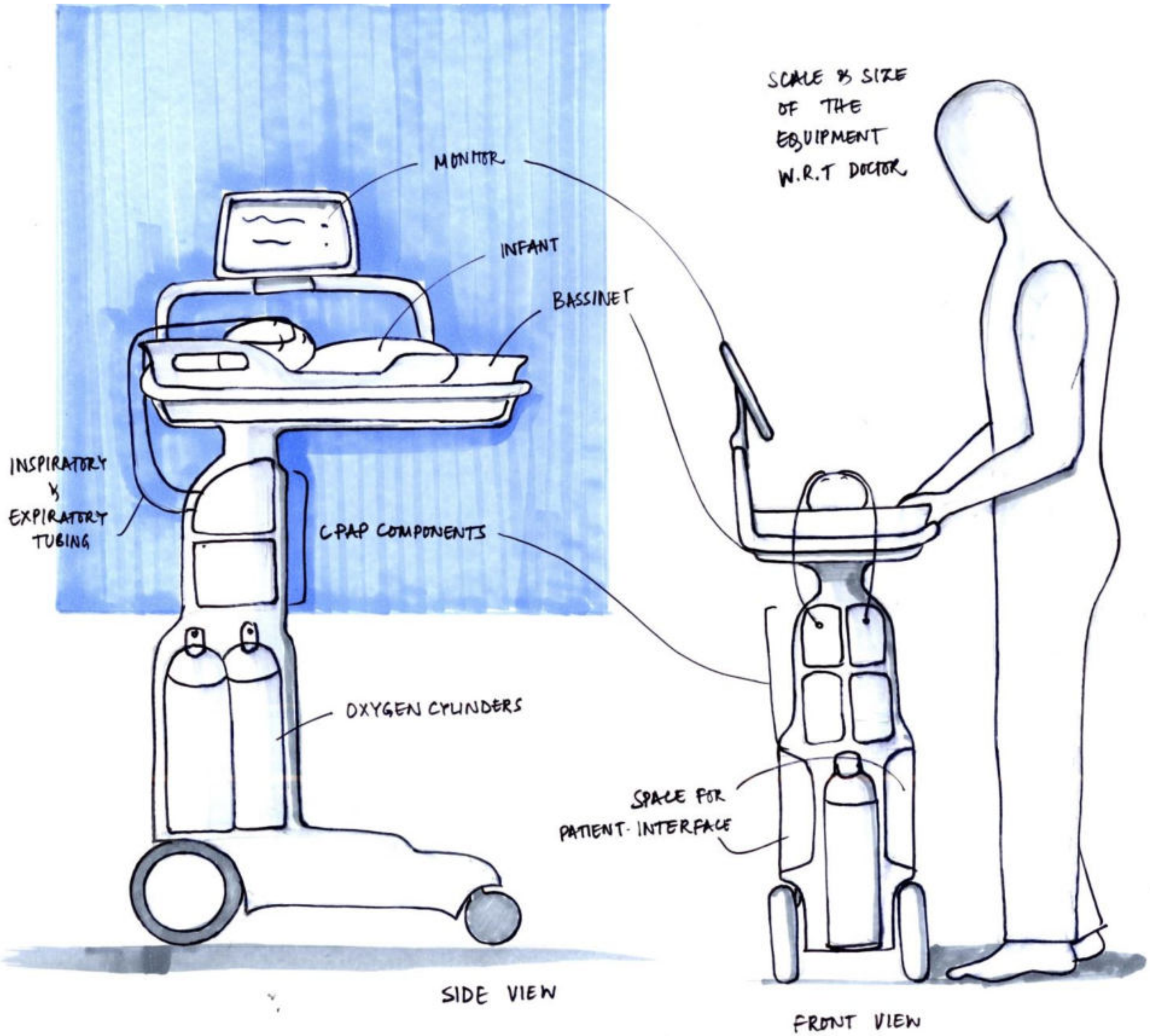
Form Explorations

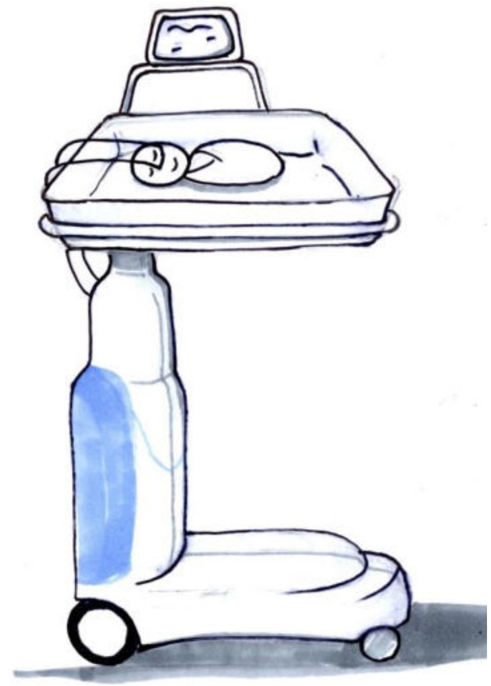


Form Explorations



Form Explorations



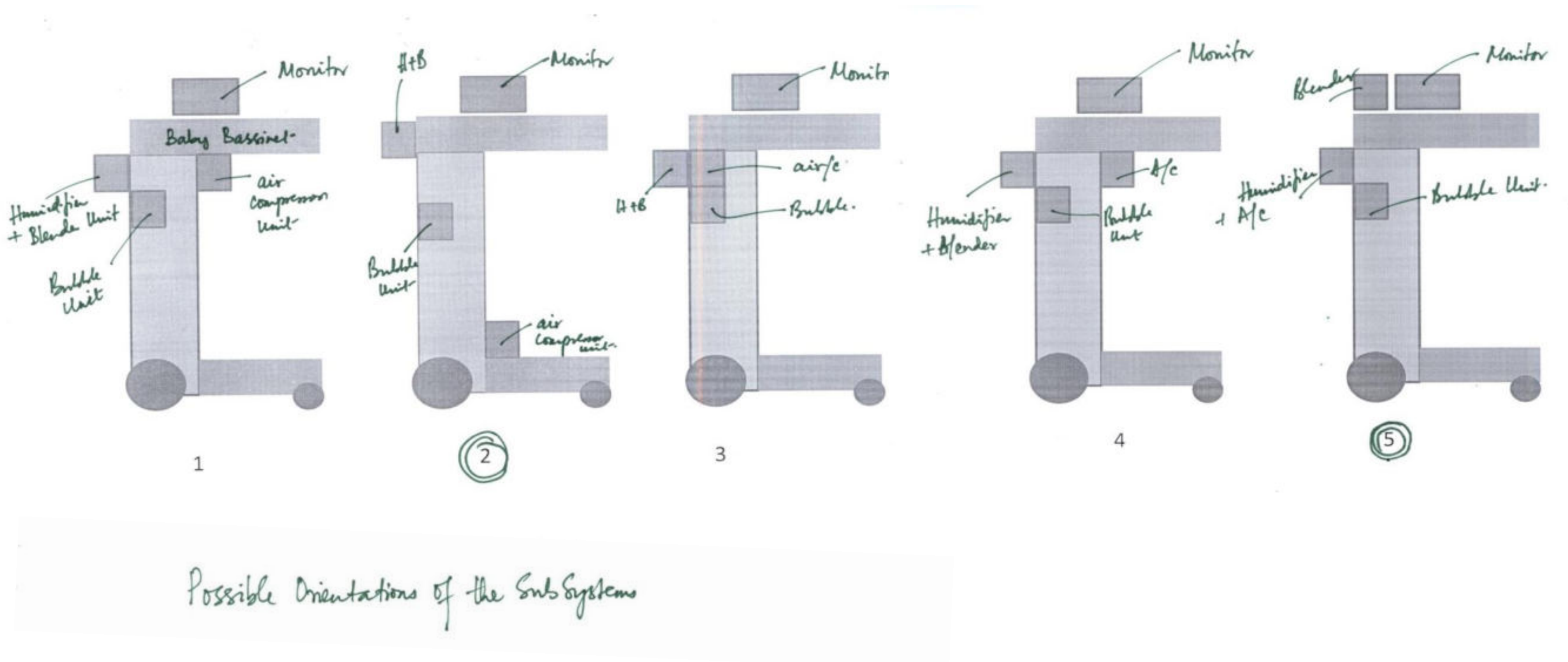


This cantilevered structure was eventually selected as the FINAL FORM TYPE.

Further explorations were done keeping the internal components fixed as shown in the next pages.

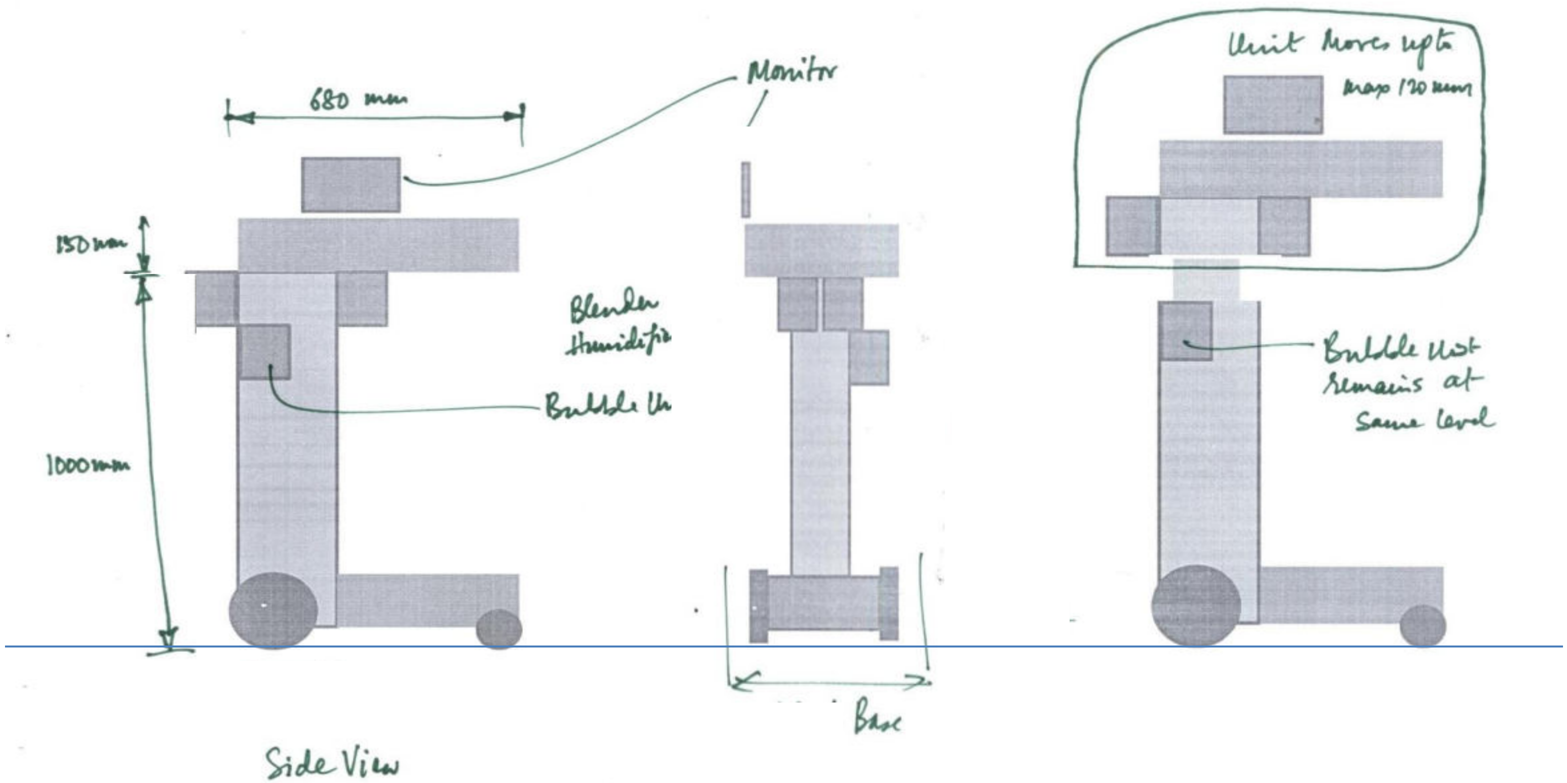
Form Explorations

Orientation possibilities with different subsystems was looked into. The possible places to fix the various subsystems were ideated.

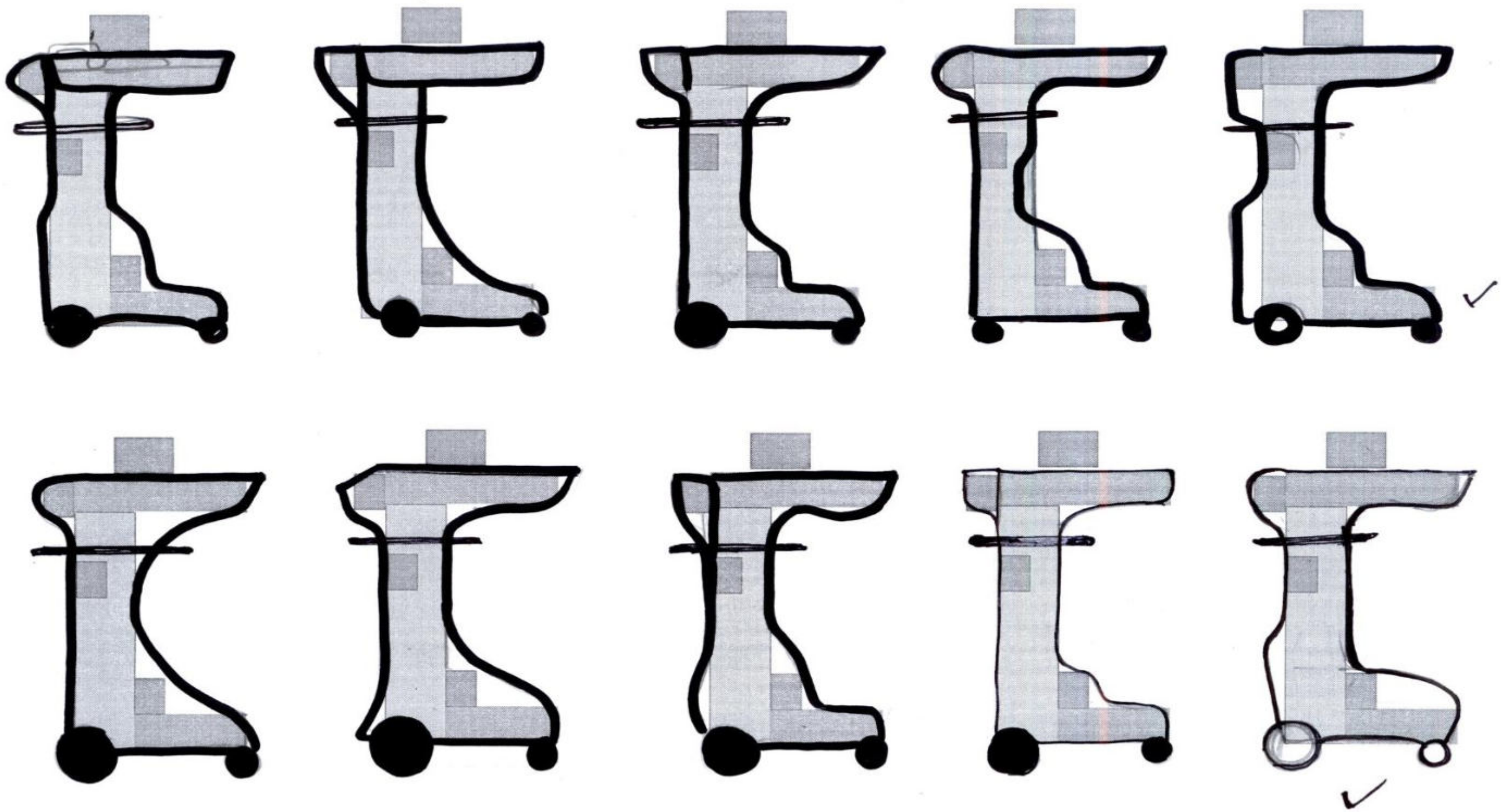


Form Explorations

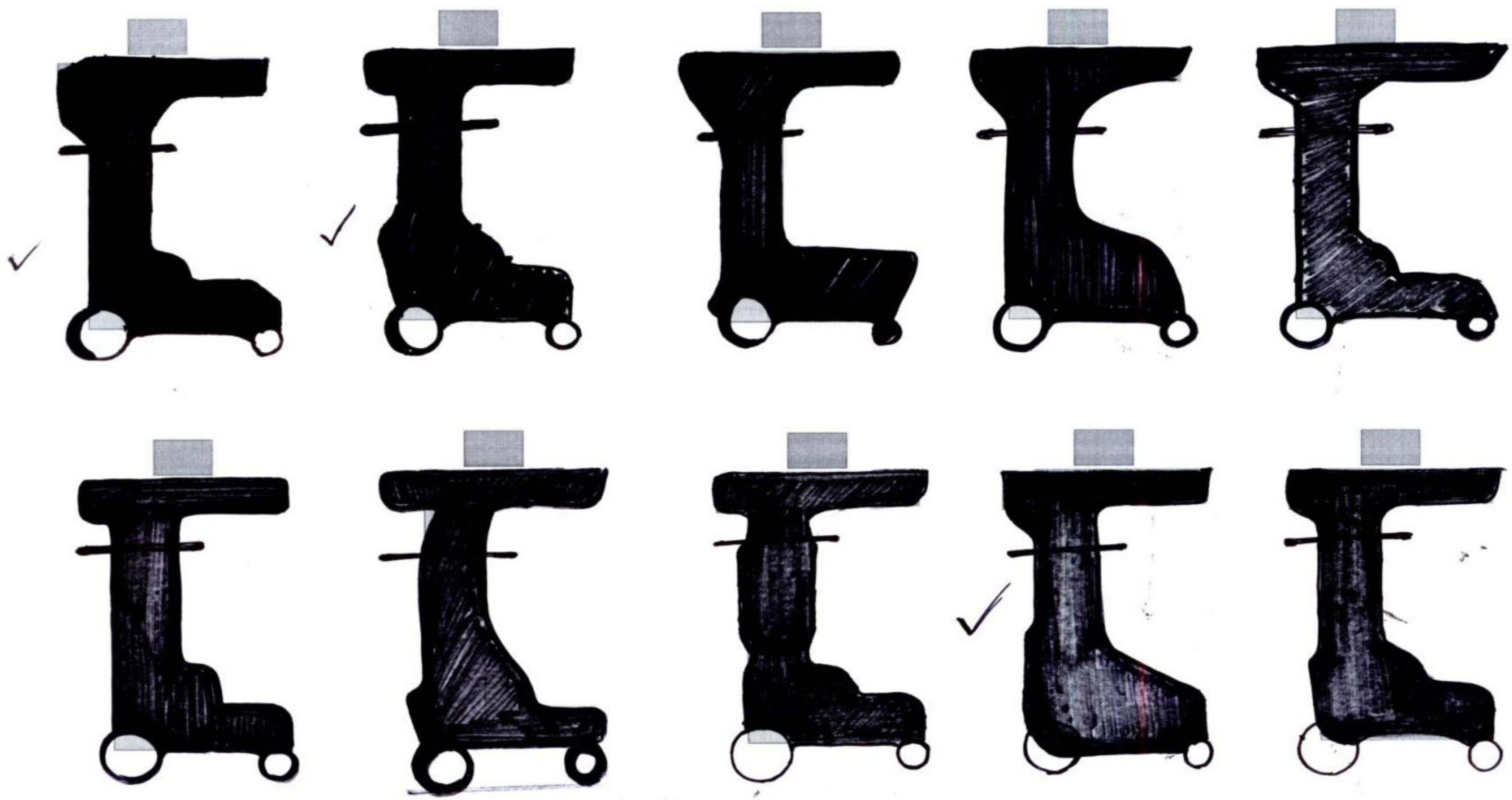
Equipment with adjustable height and dimensions



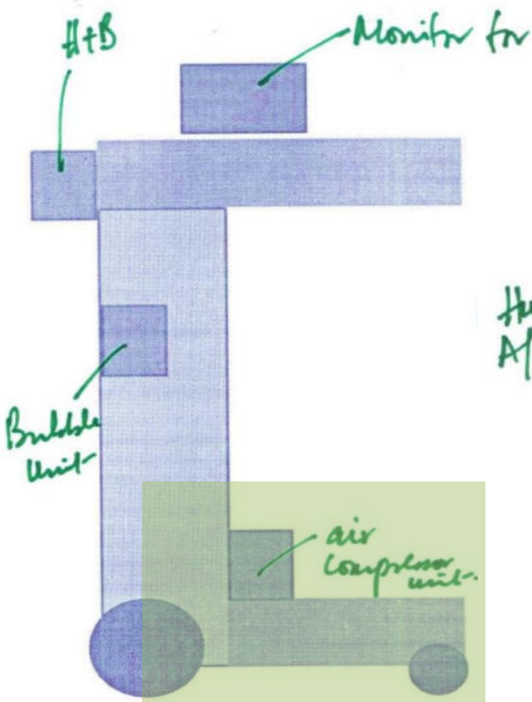
Form Explorations



Form Explorations



Final form derived from different orientations



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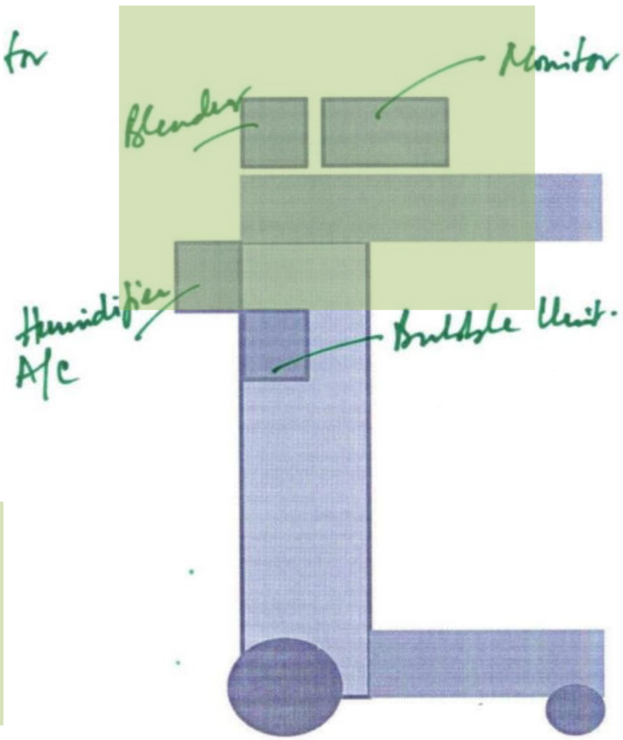

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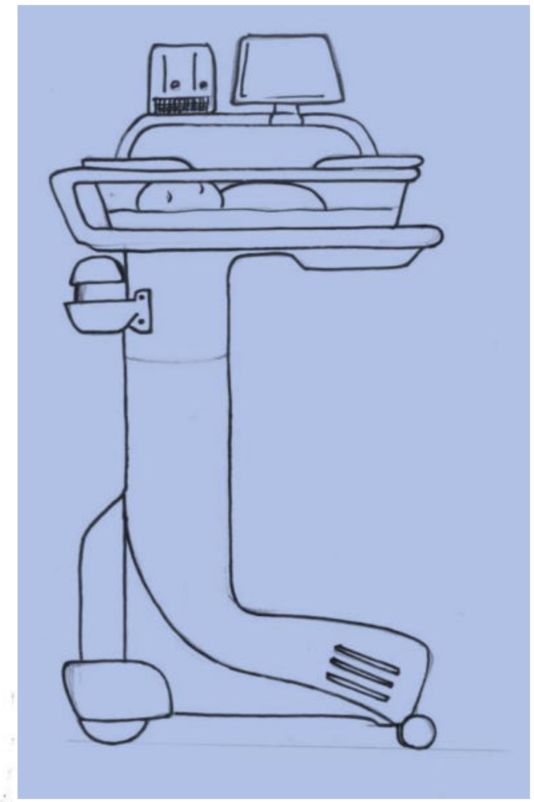
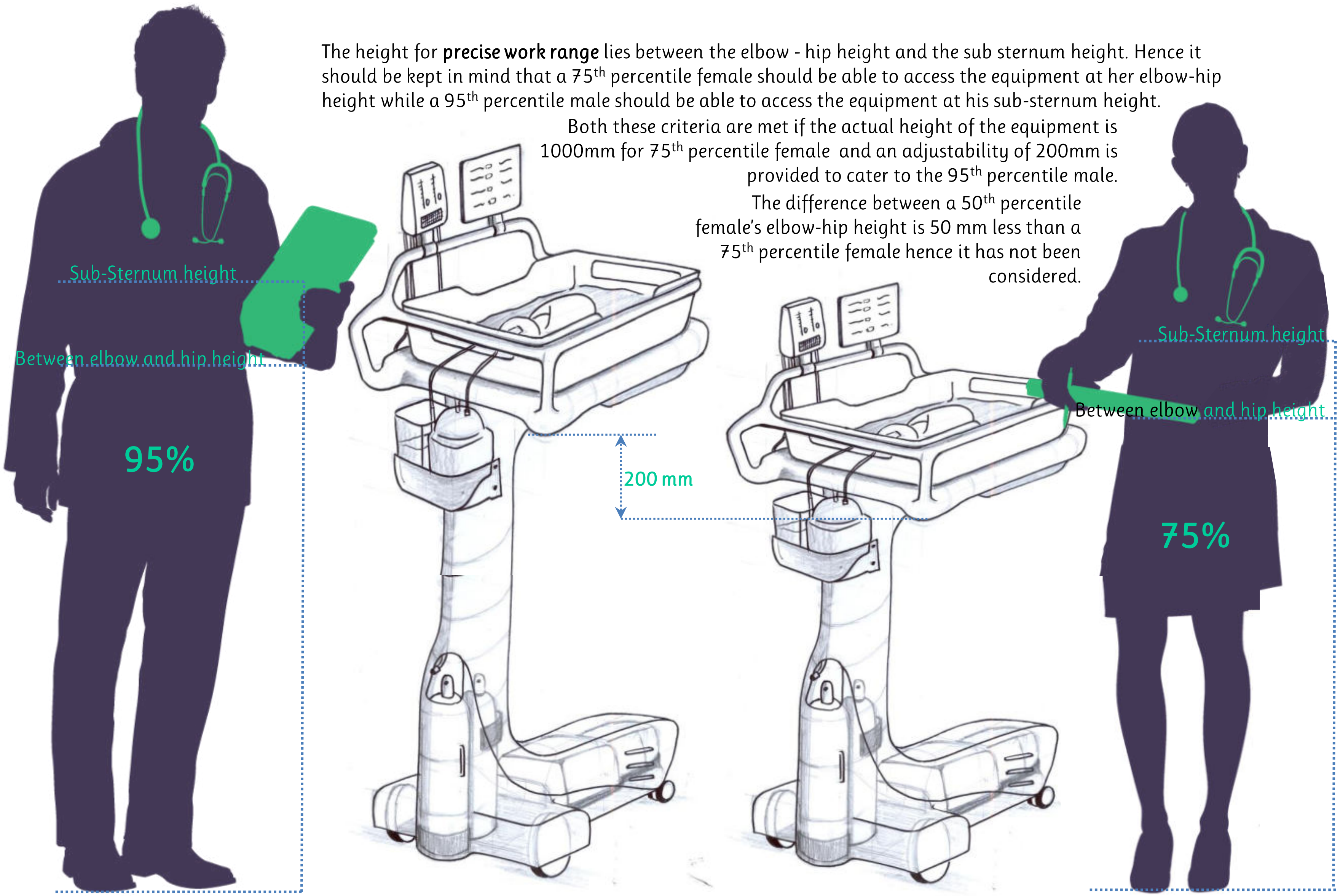


Ergonomic Considerations

The height for **precise work range** lies between the elbow - hip height and the sub sternum height. Hence it should be kept in mind that a 75th percentile female should be able to access the equipment at her elbow-hip height while a 95th percentile male should be able to access the equipment at his sub-sternum height.

Both these criteria are met if the actual height of the equipment is 1000mm for 75th percentile female and an adjustability of 200mm is provided to cater to the 95th percentile male.

The difference between a 50th percentile female's elbow-hip height is 50 mm less than a 75th percentile female hence it has not been considered.



Full Scale Test Rig

A full scale Test rig was developed to check the feasibility of the height and the use of different components.

The current height of the equipment takes into account the 75th percentile women population since most of the staff taking care of the babies in the hospitals and clinics are nurses.

The figure on the side shows how the 95th percentile man would interact with the device.

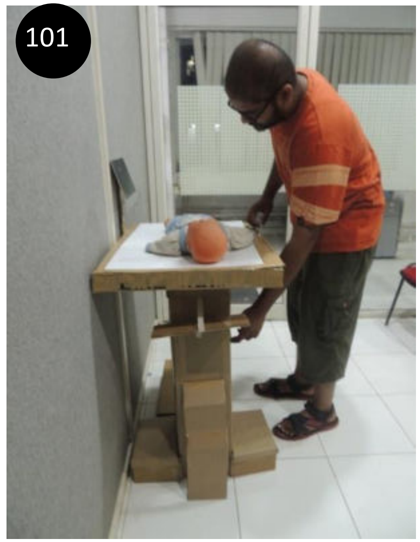
The current scenario of the height of the device is at the 1000mm from the ground. However an adjustment of 200 mm is allowed to fix the appropriate working height as is suited for the Doctor.

Steps of Equipment and Patient Interface Setup- current scenario in hospitals

The sequence of operation as followed in the hospitals are shown from Fig 87 to Fig. 99. The nurse takes out all the components on a table for assembling it into a working unit as shown in Fig.87. The connections of air and oxygen are taken out from the IV poles as shown in Fig. no.88. The appropriate connections to the port are made for the air and oxygen supply to start. The humidifier is then placed as shown in Fig. 90. The water chamber is attached to the base and filled with water upto the mark as in Fig. 92. The inspiratory and expiratory limb connections are made to the humidifier and the water successively as shown in Fig.93. The blender unit is adjusted in Fig.94 for correct ratio of air/oxygen supply.

The cap is then fixed on the baby's head and the device to hold the tubes is velcroed on the forehead of the baby- Fig 95-96.. The cannula is attached to the nose and further secured by means of straps – Fig 97-98. Finally the chin strap is placed to prevent air leaks.- Fig – 99.

Reduced Steps of Setup after developing the Full Scale Test Rig and Role-Play



The sequence of putting the cap and the 6 steps have been reduced to 2. The inspiratory tube and expiratory tube are fixed on the head gear which is currently horizontal as shown in Fig 104.

The same horizontal gear is fixed around the baby's head as shown in Fig 105. The head gear is made of a flexible hinged structure on which a soft cushion covering is attached which comes in contact with the baby's skin after bending the horizontal gear to the shape of the baby's head. This flexibility allows it to be used for different sizes of baby head. The tubings are connected over the surface which takes the weight of the entire structure so that minimum contact is made just at the nose for preventing their tender skin tissue rupture.

The sequence of operation has been reduce to 8 steps from the previous 13 steps. 2 steps have not been shown in photographs, it will be mentioned in the steps of operation.

Previous to fig 100, the entire unit's power supply is turned on.

Fig 100 shows how the monitor is turned on and gives the vital signs reading of the baby. The buttons for the air compressor unit and the blender unit are also present here., which will be used later.

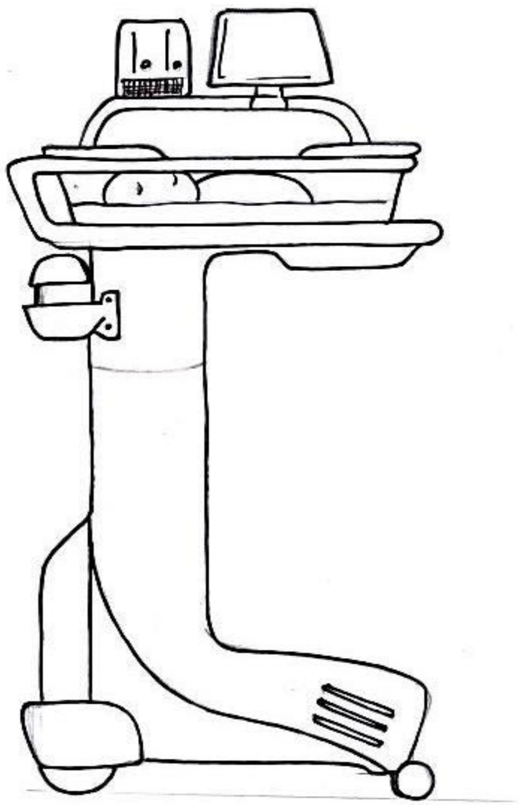
Fig 101 shows that the doctor connects the oxygen cylinder to the flow meter.

The tubings have been taken out of the drawer and it is being connected to the blender and water unit in Fig 102

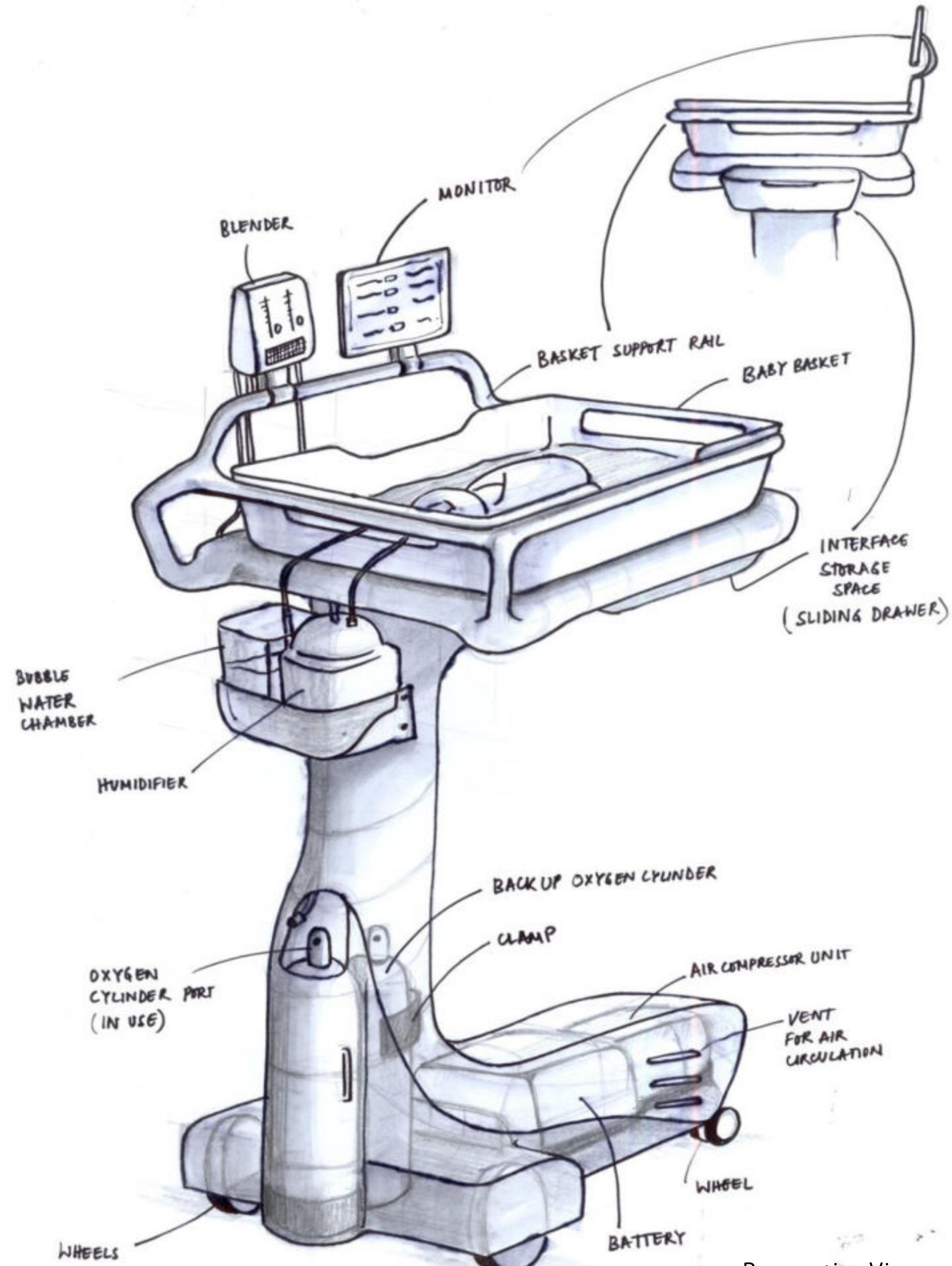
Water is being filled in the humidifier unit in fig 103.

After this the compressor unit and the blender unit's switch is turned on. And the readings of the temperature and flow rate and other sensor readings can be seen on the monitor.

Final Detailed Sketch



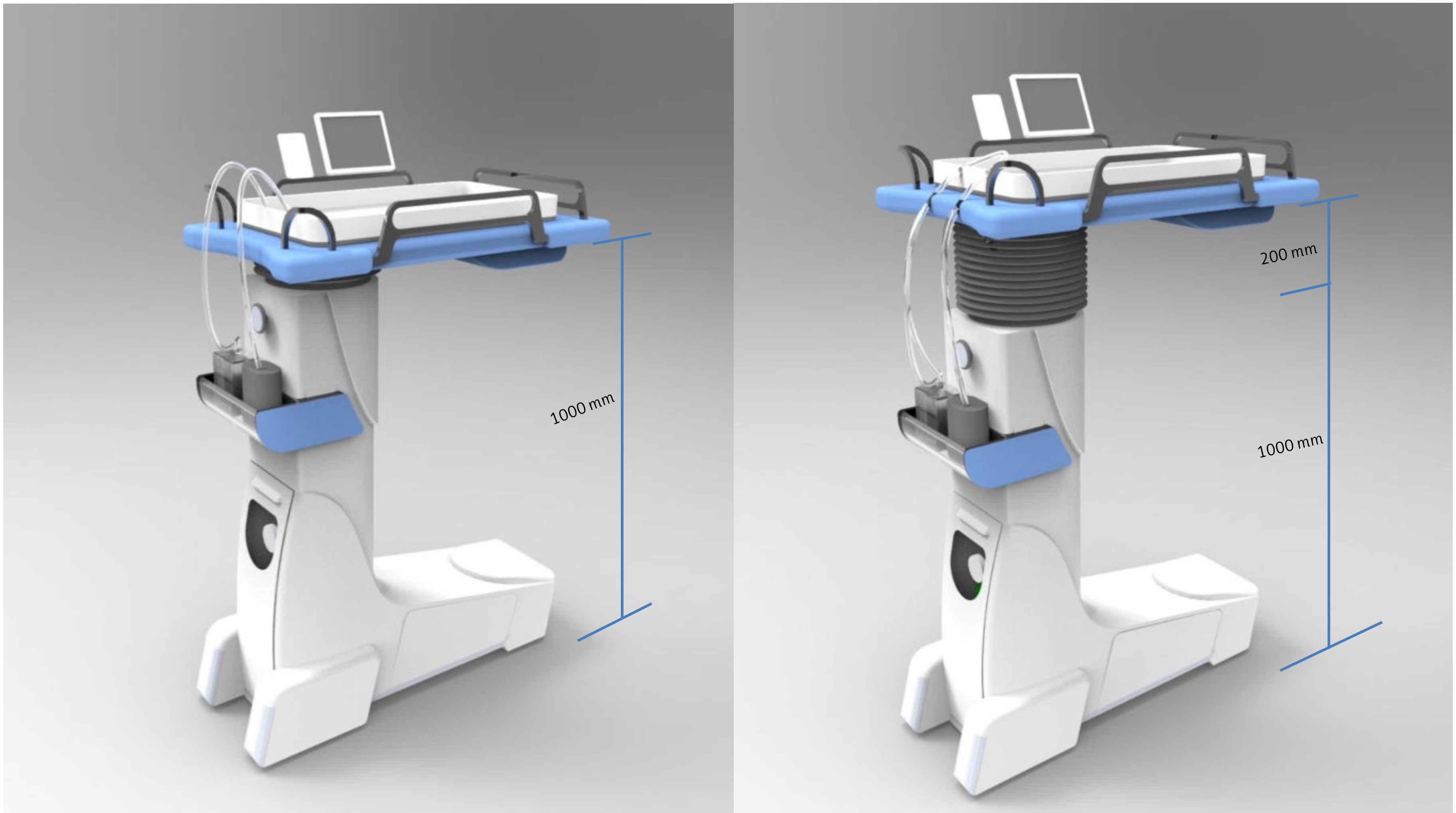
View of the equipment from the Side.



Perspective View

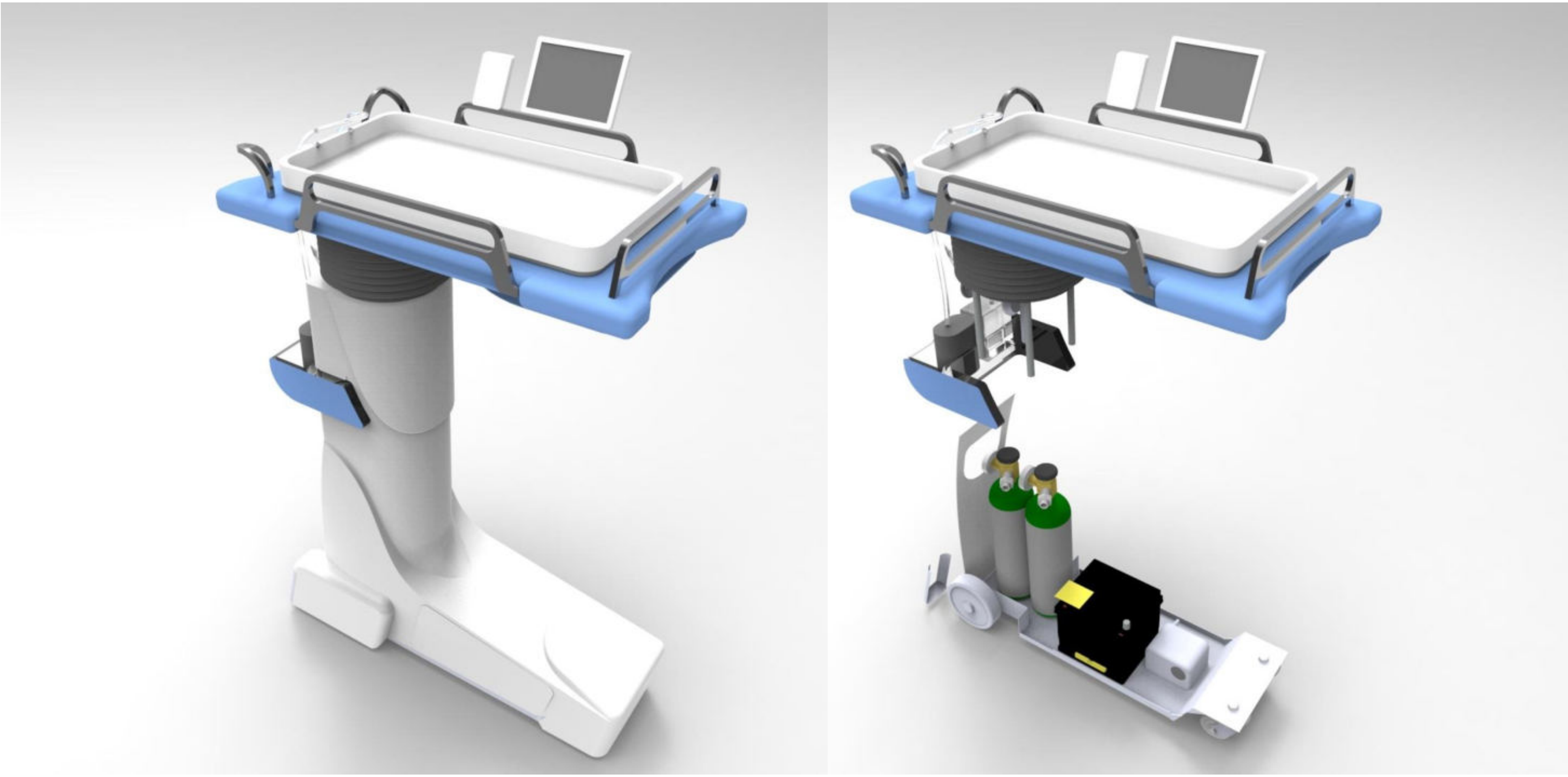
Device Adjustability

Figure on the left shows the minimum height of the bed from the ground which is 1000mm and accessible to the 75th % female. The figure on the right shows that the bed is at a maximum height of 1200 mm from the ground. The adjustable height is 200 mm for the 95th % male.



Internal Configuration

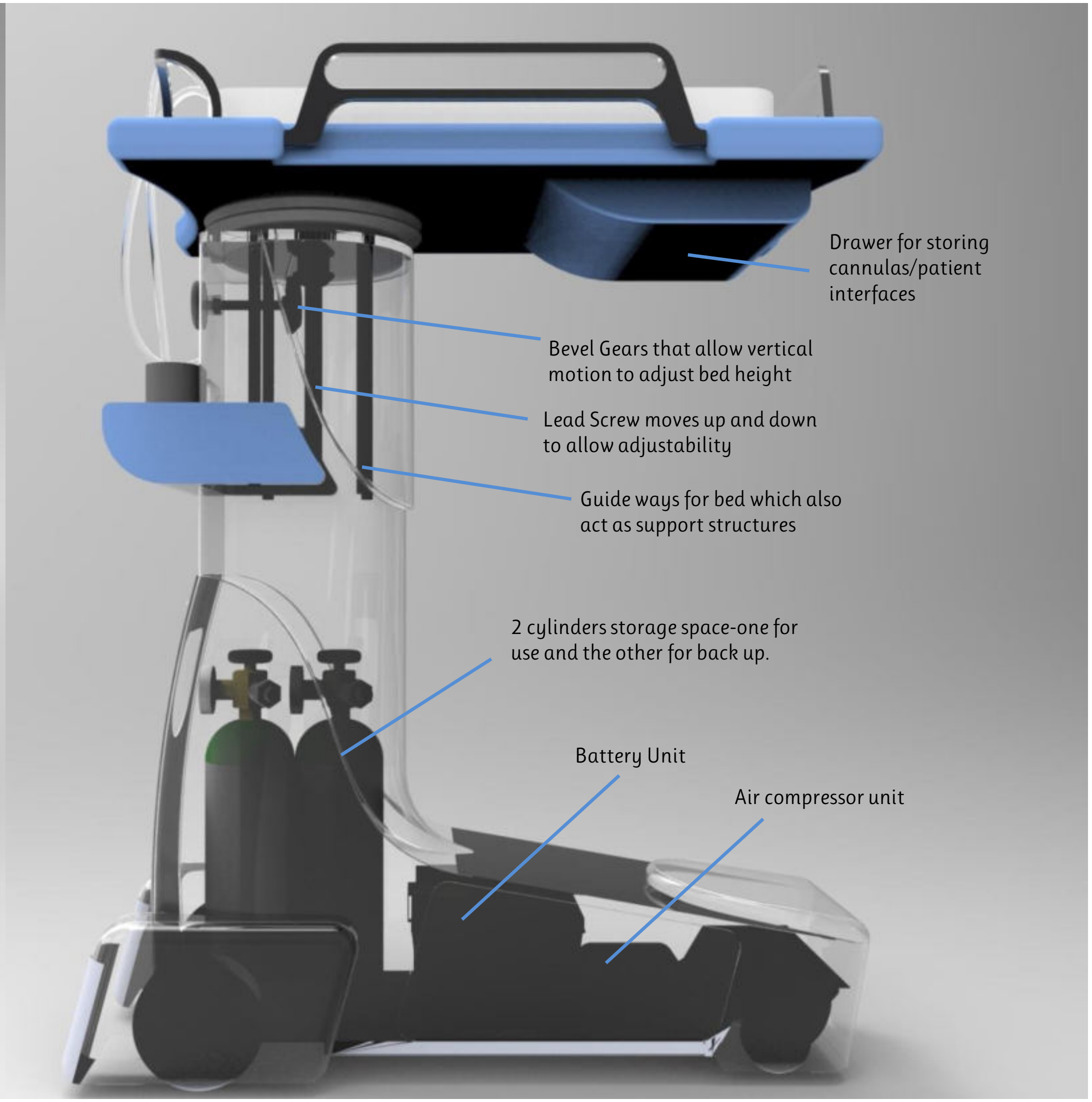
The figure on the left shows the final rendered form of the CPAP device while the figure on the right shows the internal configuration of the components.



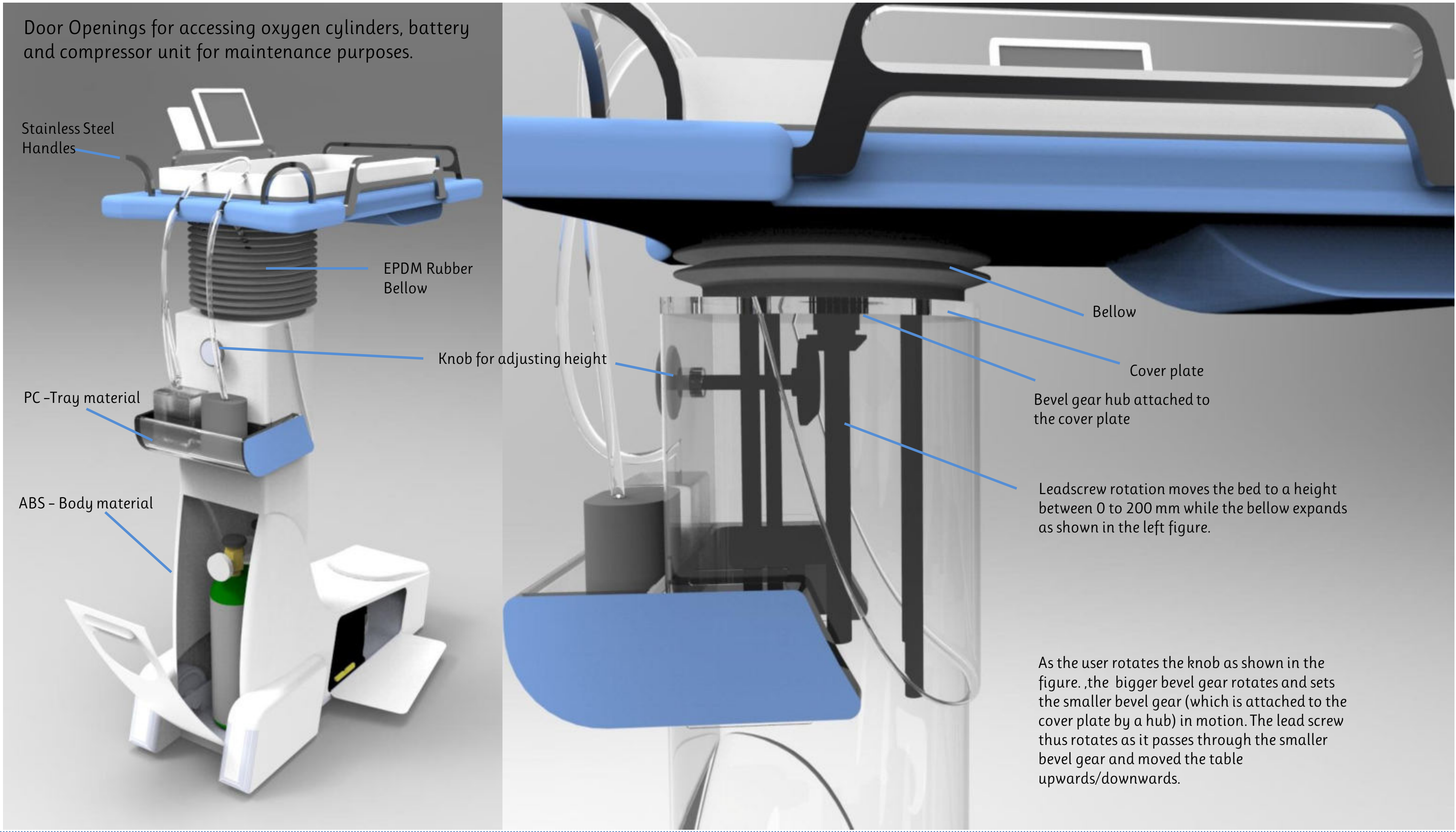
Internal details

Left side view

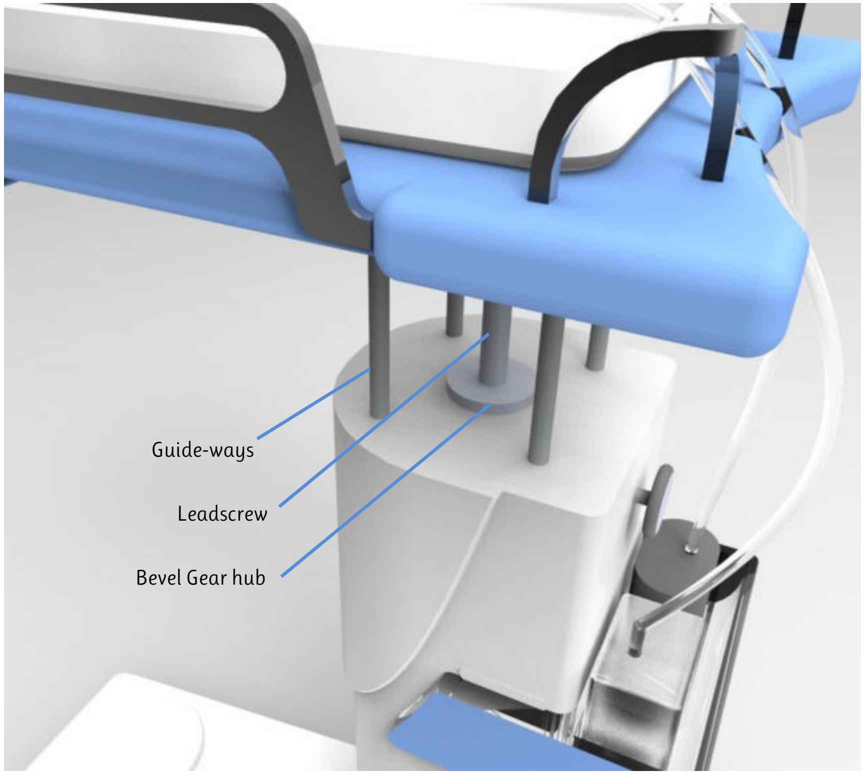
Details shown through a clear body

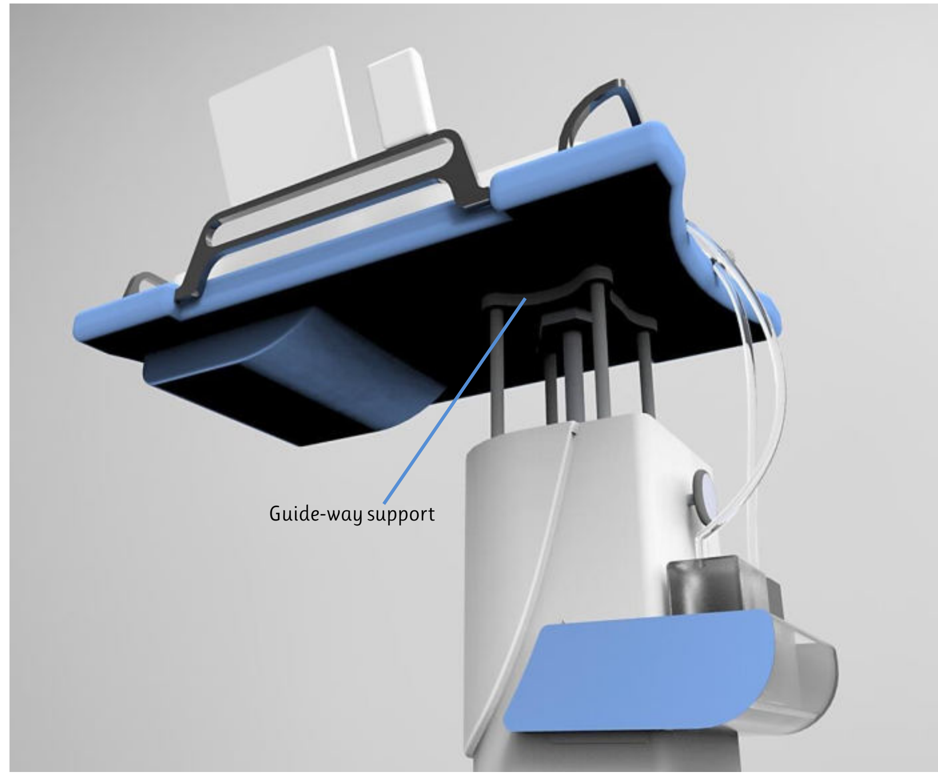


Internal details



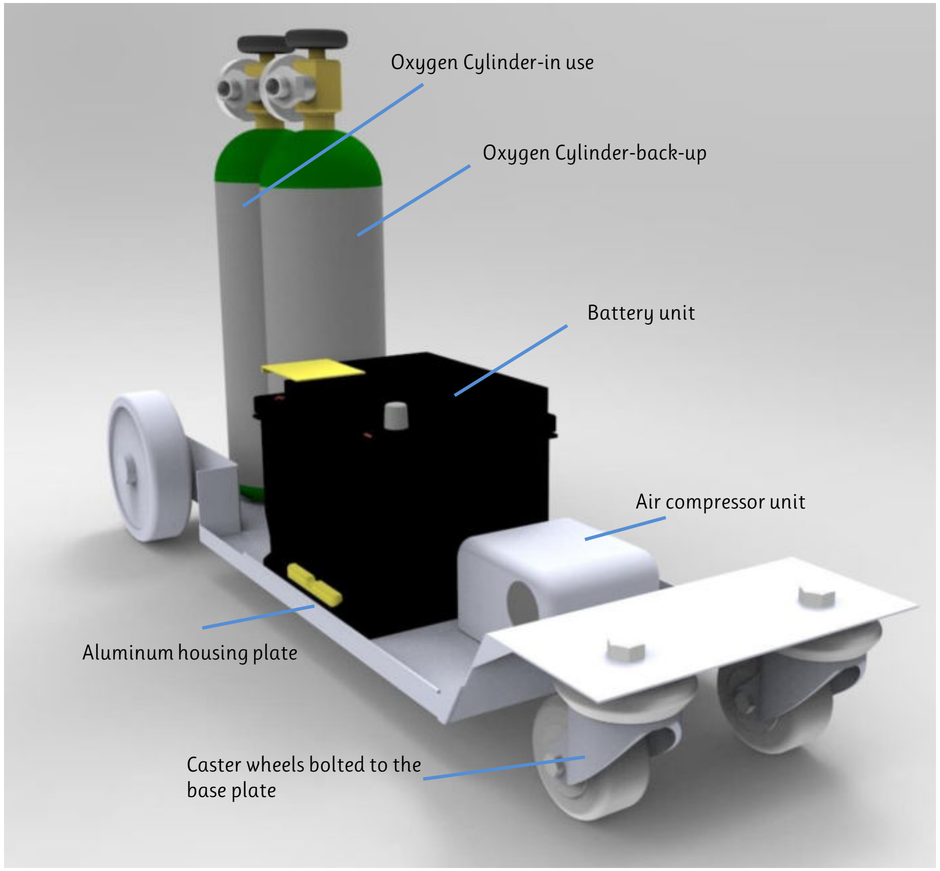
Internal details

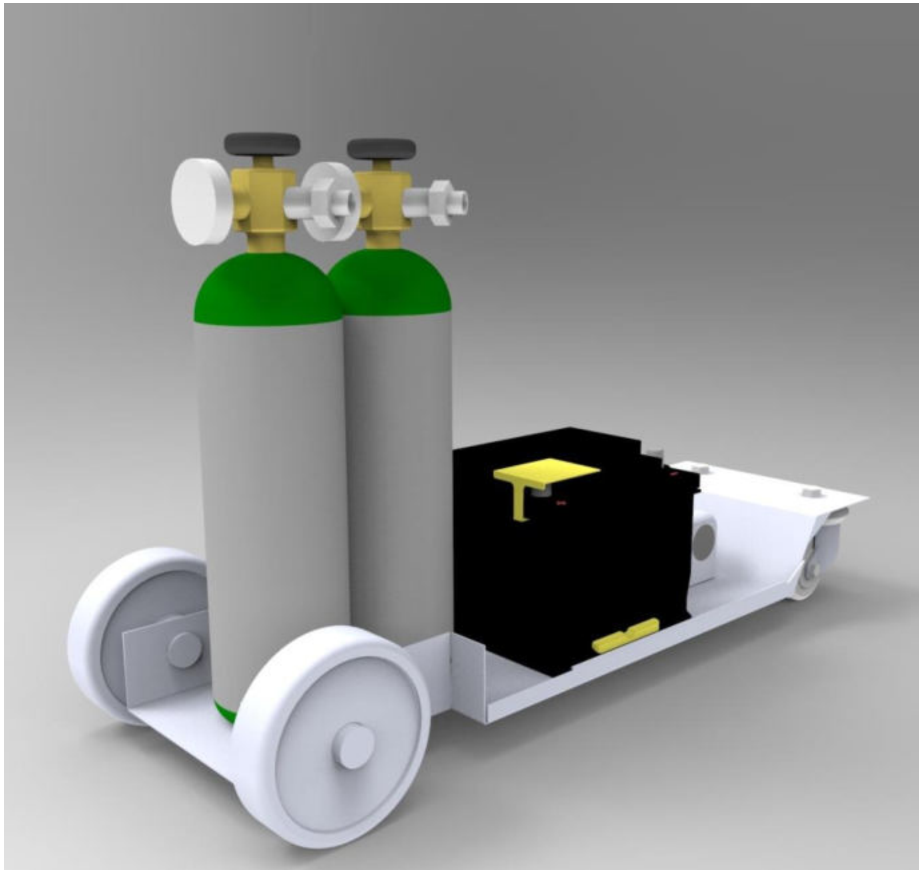




The pictures above show the components which facilitate the upward/downward movement of the bed which are the guide-ways. The guide-way support prevents the guide-ways from buckling and the weight of the bed gets uniformly distributed to the lead screw and the guide-ways. These components are covered with the bellow as shown in the pictures before.

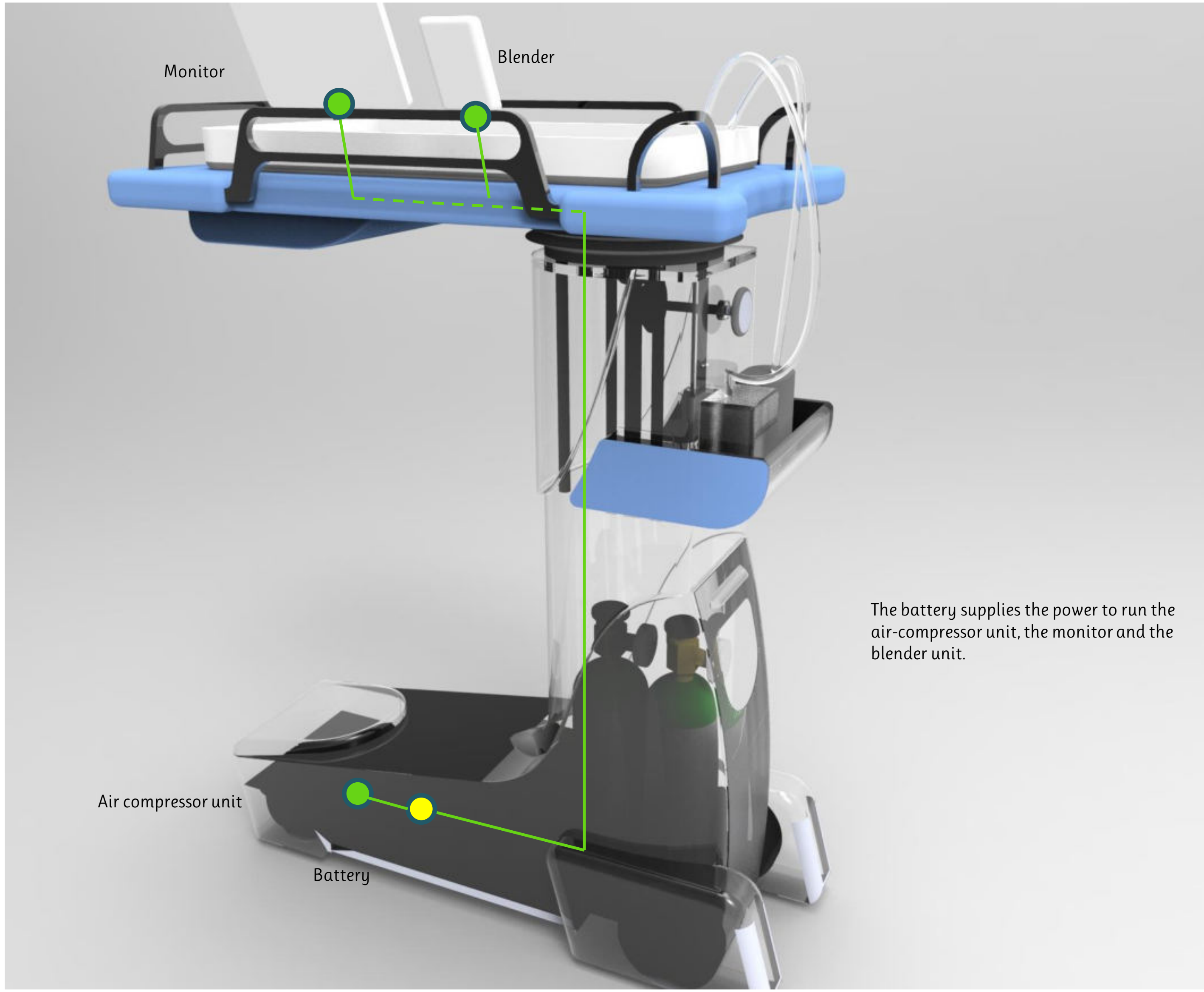
Housing Platform details





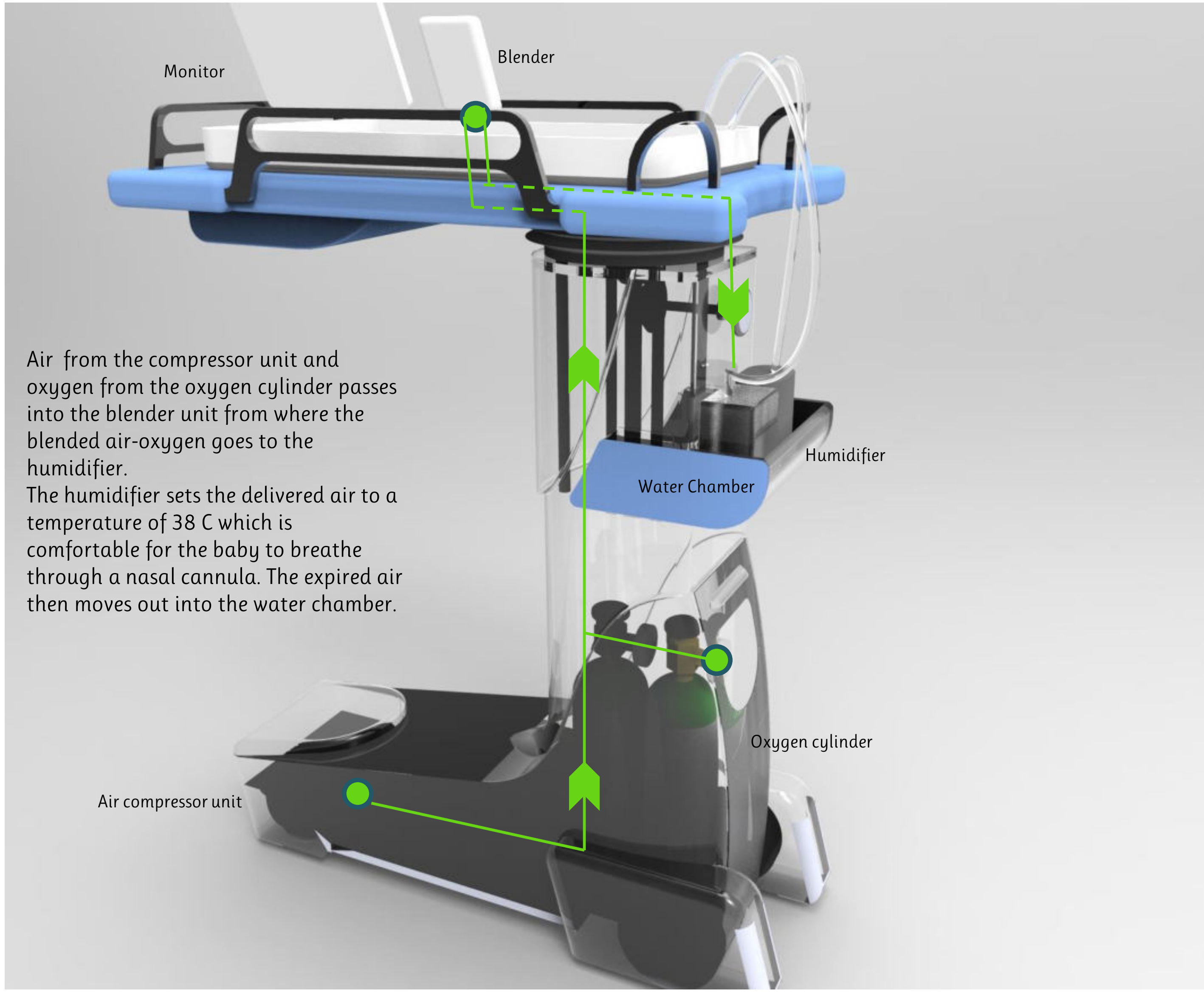
The pictures above show how the components are placed on the aluminum housing platform. The wheels are also bolted to this platform as shown. The oxygen cylinders, the battery unit, the air compressor unit and the wheels are housed on the aluminum housing platform.

Power Supply



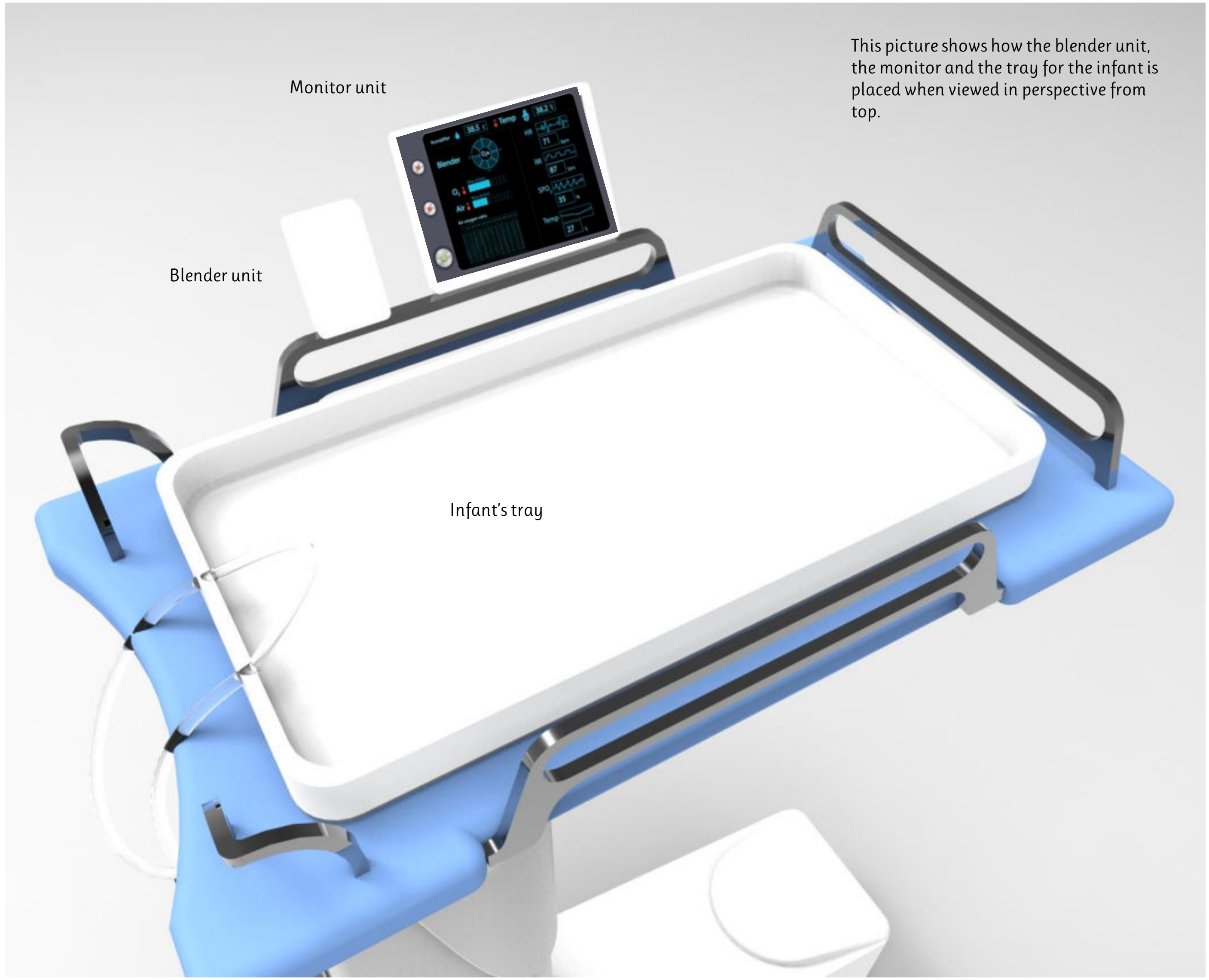
The battery supplies the power to run the air-compressor unit, the monitor and the blender unit.

Air Supply



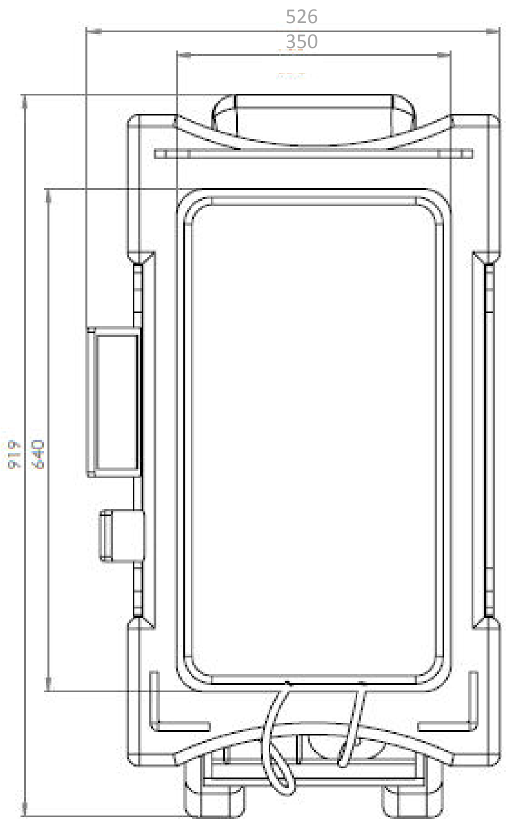
Air from the compressor unit and oxygen from the oxygen cylinder passes into the blender unit from where the blended air-oxygen goes to the humidifier.
The humidifier sets the delivered air to a temperature of 38 C which is comfortable for the baby to breathe through a nasal cannula. The expired air then moves out into the water chamber.

Perspective View of Infant's tray

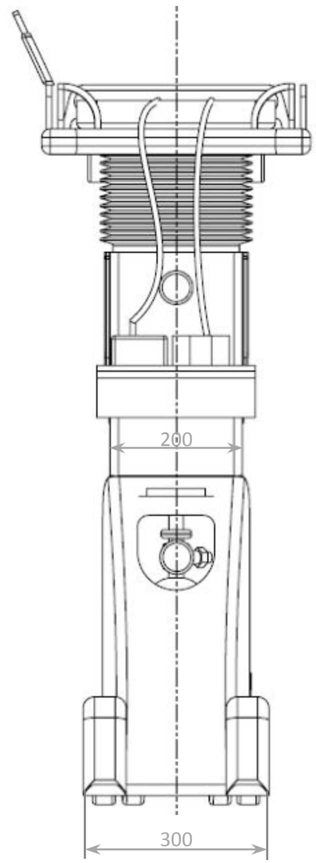


This picture shows how the blender unit, the monitor and the tray for the infant is placed when viewed in perspective from top.

Dimensional Drawings

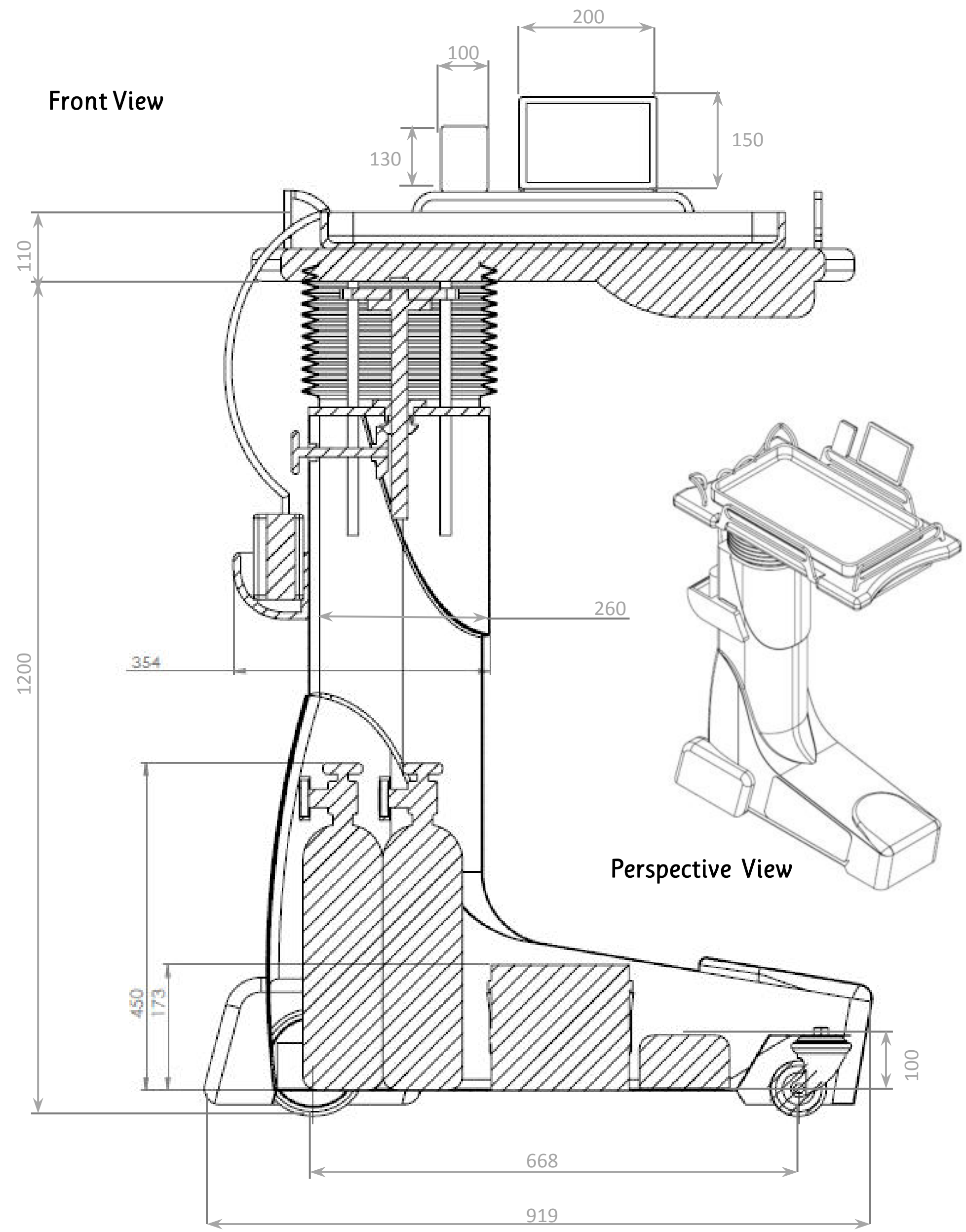


Top View



Side View

Front View



Perspective View

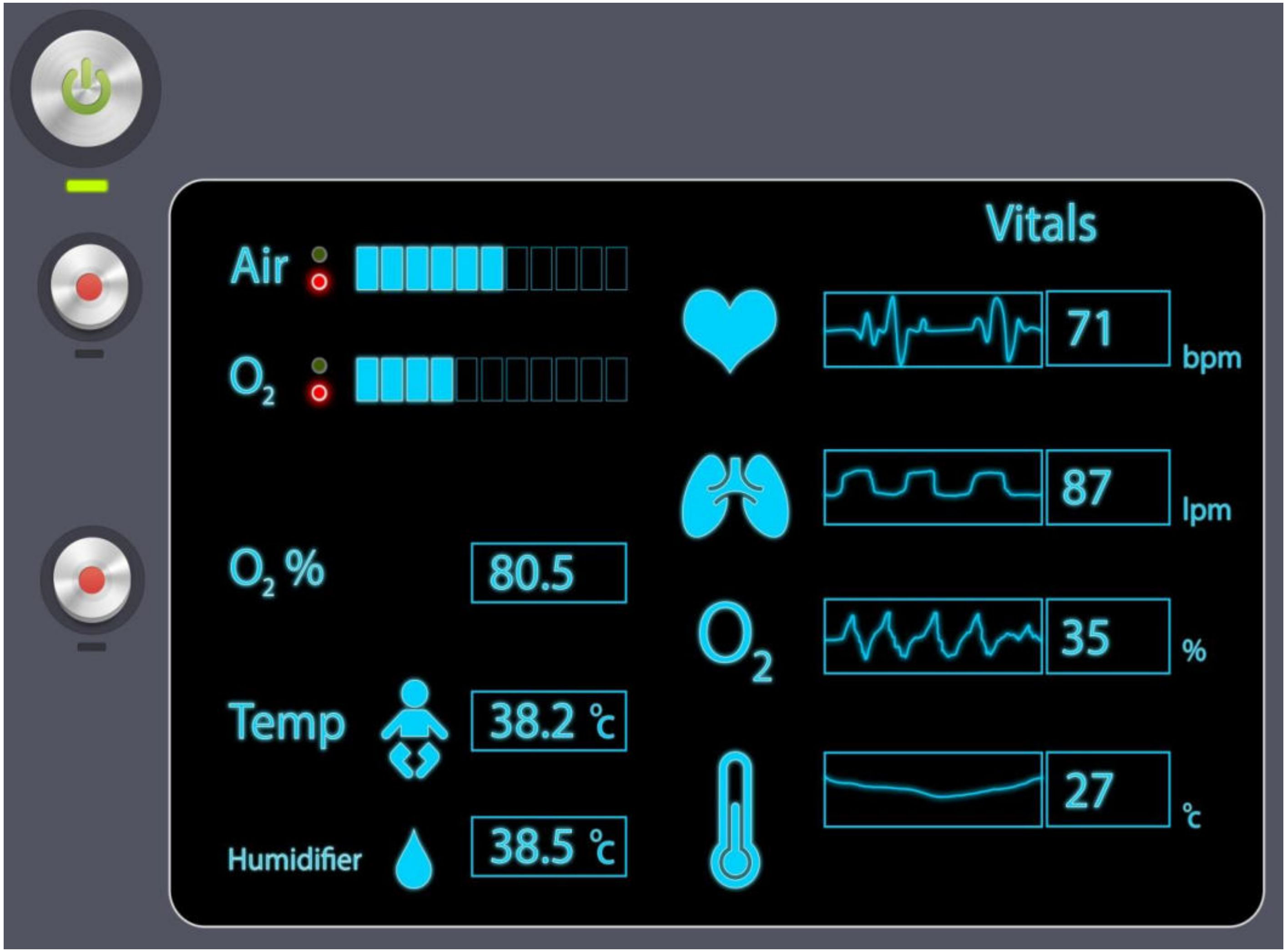
Exploration of the Interface (Basic)

The idea here was to integrate the blender and the monitor unit as one .
The top half is the blender unit with the air and oxygen adjusting knobs. The ratio chart is also given for reference purposes.
The bottom unit is where the sensors and the vital signs are displayed.

The blender and the monitor unit was decided to be kept separate to avoid complications and reduce cost.

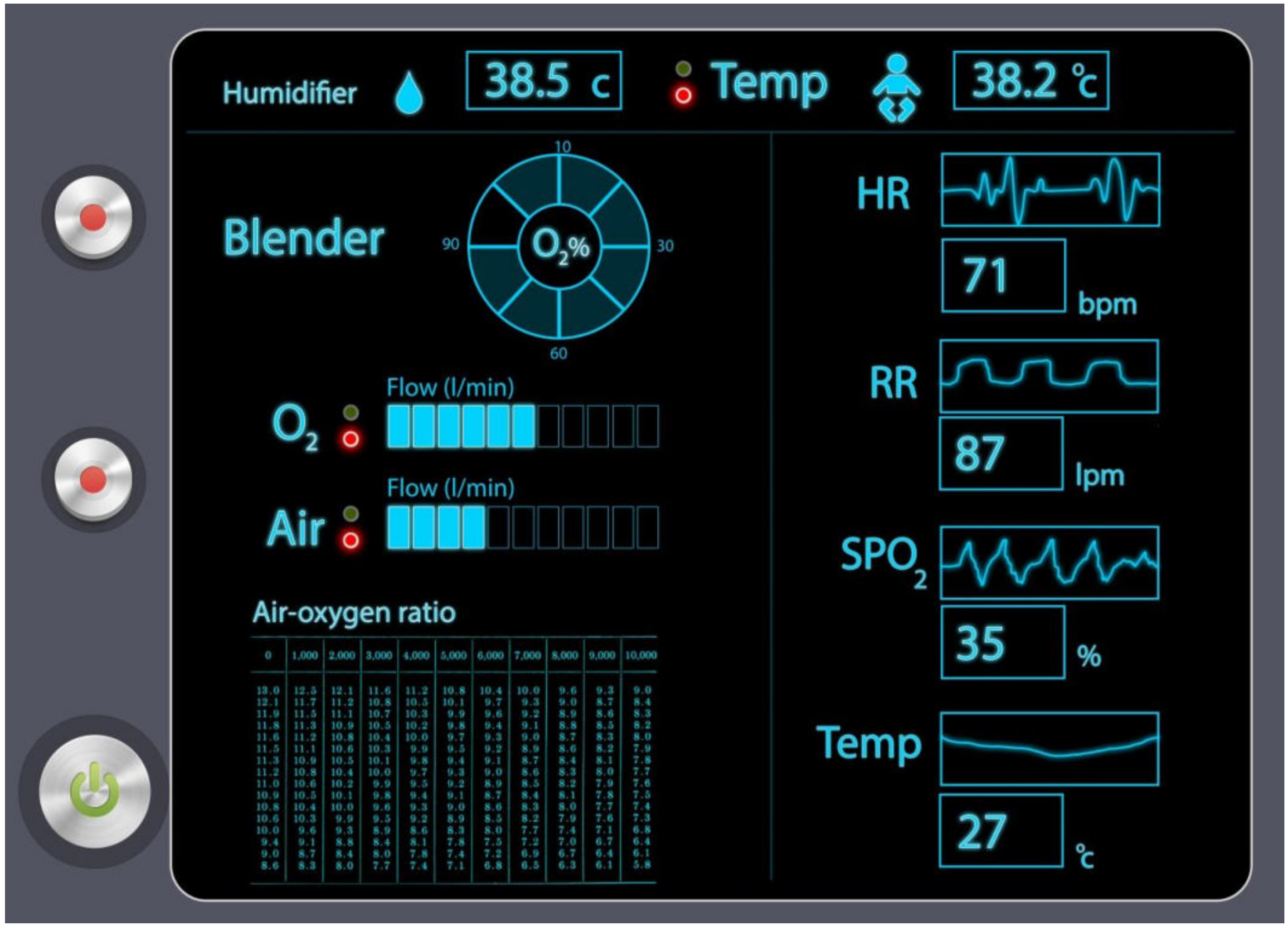
Exploration of the Interface (Basic)

This is the improvised version of the interface where there is control for the compressor unit and the blender unit is provided along with the main power button.
The task traversal starts from the top right with the equipment electronic output displayed on the left and the vital signs on the right.



Exploration of the Interface (Final)

This is another option of the interface where there is control for the compressor unit and the blender unit is provided along with the main power button.
The task traversal starts from the bottom left with the equipment electronic output displayed on the left and the vital signs on the right. Here the blender mix is also displayed for the doctors to get a feedback from the output of the blender.



Final Model

This picture shows the proportion of the 95^{th}% male and the Equipment with maximum height of 1200mm.

Final Model

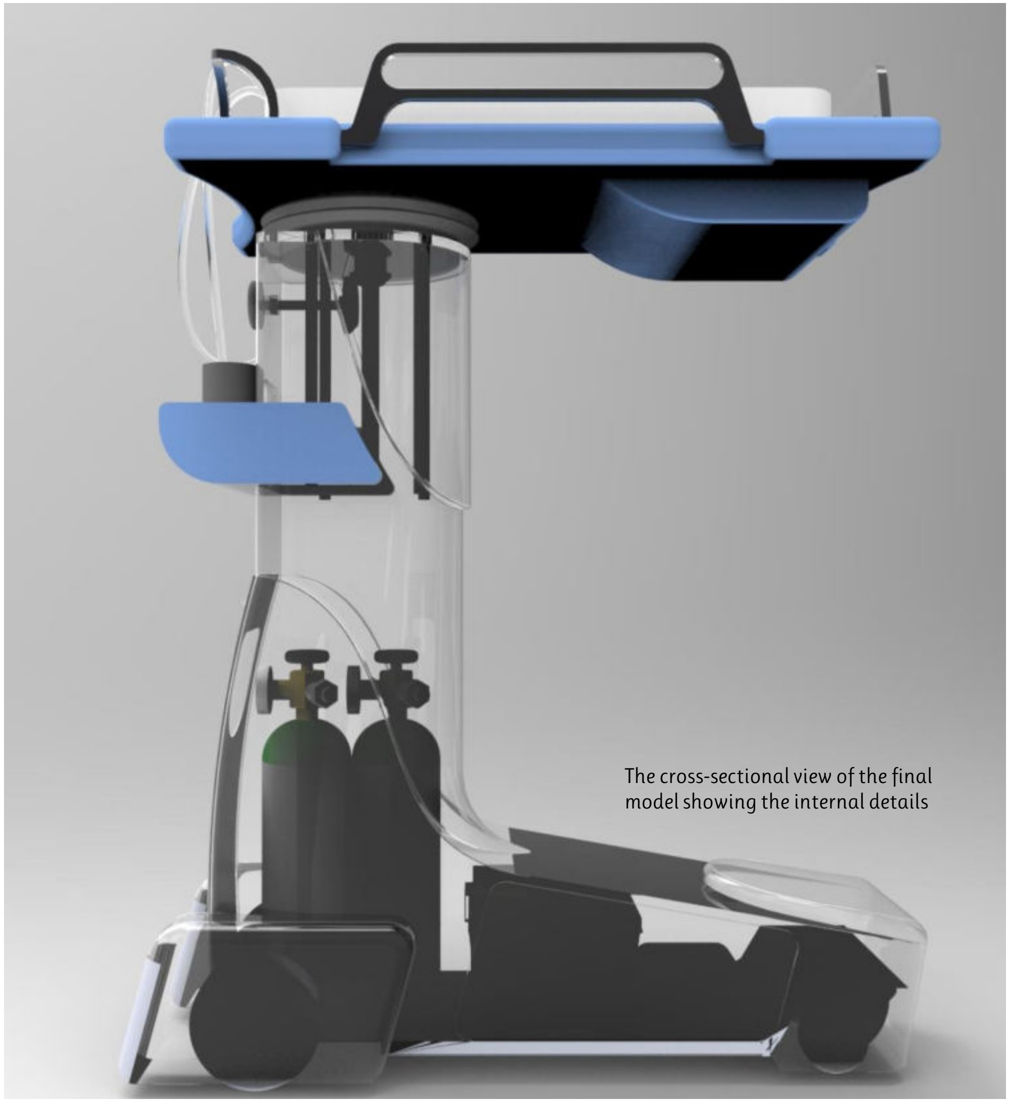
This picture shows the proportion of the 75th% female and the Equipment with minimum height of 1000mm.

Final Form Model

Equipment inside Clinic Environment

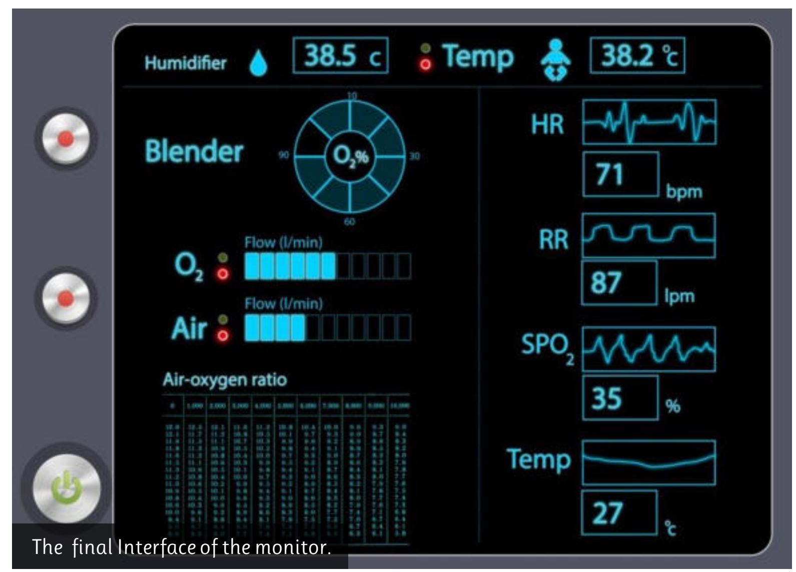
Equipment portable to Ambulance Van

Overall View of the Final Model



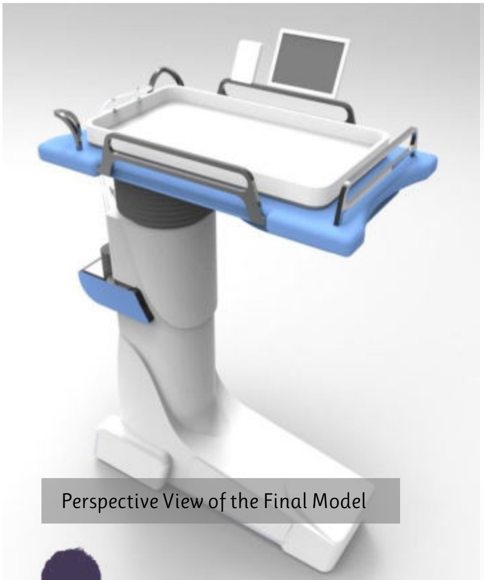
The cross-sectional view of the final model showing the internal details

The Patient Interface which wraps around the baby's head and take the load of the components

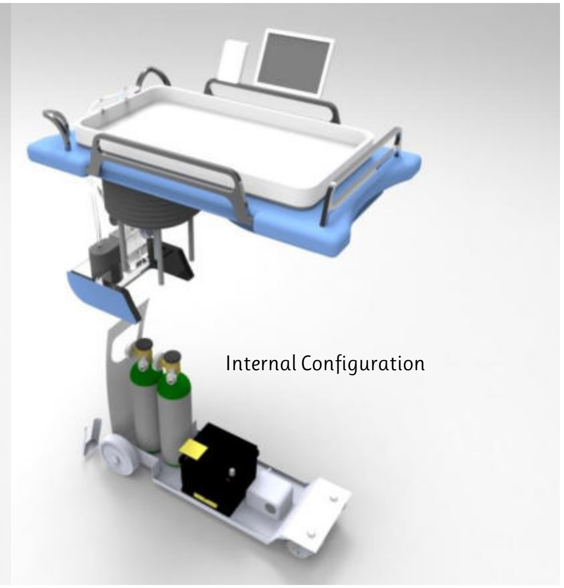


The final Interface of the monitor.

Overall View of the Final Model



Perspective View of the Final Model



Internal Configuration

Proportion of the Equipment with respect to human figure.

Accessing the internal components

Conclusion

The project about the Redesign of CPAP device had certain limitations due to the time and resource constraints.

It was possible to get feedback on the final design modifications from two pediatricians only. Getting useful insights from doctors who do not see a final product to use was difficult.

The testing would have been better with a full scale model in real time situations but time constraints did not permit the full scale manufacturability of the device. Hence the test rig was the only means to validate the usability issues as identified previously. Even through this test rig a lot of insights were obtained. The problems of accessibility, visibility, approachability were major insights for developing the final form and structure for the equipment from the user testing through the test rig. The 13 steps of operation to set up the entire unit of the CPAP device in hospitals have been reduced to 8 steps hence bringing down the set-up time and increasing the chances for saving an infant's life.

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i) www.alibaba.com