

Portable operation room for remote locations

MDP 490

Industrial Design Project-3

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“Health care is a right, not a privilege”

-Edward Moore Kennedy

Fig 1.0

Acknowledgement

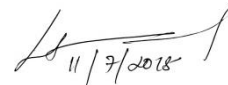
I take this opportunity to thank the entire faculty at IDC school of design for the inputs that helped me to successfully complete this project.

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Last but not the least i am grateful to my classmates for contributing their valuable insights to this project.

A handwritten signature in black ink, followed by the date '11/7/2018' written in a similar style.

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*The photographs clicked by the author and sketches or 3D models made by the author haven't given source by default, the source is mentioned for the photographs by others

Key definitions

- **OR** -Operating room
- **SSI**-surgical site infection
- **ANTISEPTIC**- A chemical that is applied to living tissue, such as mucous membrane or skin to reduce the number of organisms present, through inhibition of their activity or destruction.
- **STERILEFIELD**-
specified area, such as within a tray or on a sterile towel, that is considered free of microorganisms.
- **STERILIZATION**- The process by which an article is made free of all living organisms either in vegetative or in spore state.
- **DISINFECTION**- The destruction or removal of all pathogenic organism / organisms capable of giving rise to infection.
- **ACH**- Air change per hour(measure of the air volume added to or removed from a divided by the volume of the space)

Introduction

As *Edward Moore Kennedy* once said 'health care is a right and not a privilege', there are 5 billion unprivileged people across the world who don't have access to safe surgery and 18 million deaths occur each year due to lack of or inadequate safe surgical care.

If a medical emergency occurs at a remote and inaccessible location and a surgical procedure needs to be done, either it will be done at an unsterile environment with minimum facilities or the patient has to be transported over long distances to the nearest hospital. Both are equally risky and could worsen the situation. Even if portable surgical equipment and auxiliary facilities are available in the market, creating and maintaining a sterile atmosphere for conducting the surgery is still a major challenge.

So, in general, the project focuses on designing a portable Operating room which can provide a sterile environment throughout the surgical procedure, it can also integrate necessary equipment and instruments required for executing various surgical procedures such as caesarean, gastrointestinal surgeries, lacerated wounds, dental surgeries, eye surgery etc. The design of portable OR is much different from a mobile OR's in which an OR is set up inside a vehicle, here the entire OR with its equipment should be portable and should be assembled at the site.

The applications of this project ranges from Medical camps, disaster management, defence, trauma care during accidents etc. Organ extraction surgeries for transplantation could be another wide area of application for the project.

01 Primary Research

Operating room

What's an operating room(OR) ?

An operating room (also known as an Operation theater, Operation suite) is a facility within a hospital where surgical operations are carried out in a sterile environment.

Fig:1.1 represents a modern operating room

Important parameters in OR

- Ventilation (For operating rooms, that is Category 4 which is 10,000 particle/M³ of 0.1 microns or larger (Table ISO 14644-1))
- Temperature
Should be maintained between 24°C-27°C
- Humidity
Should be maintained between 45°C-60°C for adults and 55°C-65°C for infants.

Types of surgeries

- Clean (no *viscus opened)
- Clean-contaminated (viscus opened, minimal spillage)
- Contaminated (open viscus with spillage or inflammatory disease)
- Dirty (pus or perforation, or incision through an abscess)

*The internal organs,e.g. the heart, lungs, stomach and intestines.

- *Bailey And Love's Short Practice of Surgery. 25th Edition*

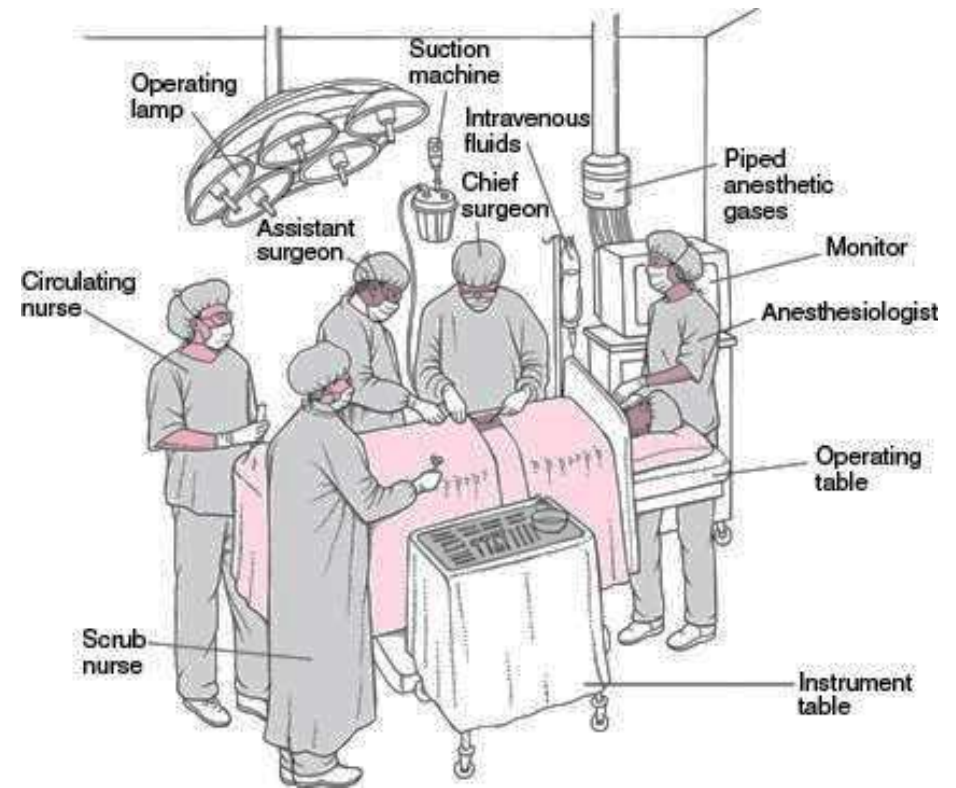
Any operating room designed should have similar features and conditions as per medical directives.



(Fig:1.a) A modern Operating room.

Surgical Team

- **Chief surgeon**, who directs the surgery
- One or more **assistant surgeons**, who help the chief surgeon
- **Anesthesiologist**, who controls the supply of anesthetic and monitors the person closely
- **Scrub nurse**, who passes instruments to the surgeon
- **Circulating nurse**, who provides extra equipment to the operating team



So any surgical room should be able to accommodate the entire surgical team.

(Fig:1.1.a) The positions of surgical team during a surgery,

General surgical instruments.

(Fig:1.3.a)

Cutting and Dissecting

(Fig:1.3b)

Grasping and Holding (used to grasp and hold tissue or blood vessels that may be in the way during a surgical procedure) e.g. Forceps. Allis Tissue Forceps



Fig 1.3.a



Fig 1.3.b

(Fig:1.3.c)

Clamping and Occluding (Are used in many surgical procedures for compressing blood vessels or hollow organs, to prevent their contents from leaking. Occlude means to close or shut.)



Fig 1.3.c

(Fig:1.3.d)

Retracting and Exposing (used to hold back, or retract organs and tissue so the surgeon has access to the operative area)



Fig 1. 3.d

The surgical instruments should be maintained sterile throughout the procedure.

Common surgical instruments,

General surgery equipment's cont..

The listed equipment's are designed for OR in normal hospitals

- Anesthesia machine (fig 1.4.a)
- Suction machine (fig 1.4b)
- Instrument tray (fig 1.4c)
- Electro cautery unit (fig 1.4d)
- OT Table (fig 1.4e)
- Lights and IV stand (fig 1.4f)
- Instrument storage vessels (fig 1.4g)



(Fig: 1.4.a)



(Fig: 1.4.b)



(Fig:1.4.c)



(Fig: 1.4.d)



(Fig: 1.4.e)



(Fig: 1.4.f)



(Fig:1.4.g)

All the equipment listed are the mandatory items so the designed OR should have provision for integrating all of them.

Field surgery equipment's cont..

The items listed are the field equipment's exclusively used for general surgeries.

- Portable defibrillator (fig 1.5a)
- Emergency medicines (fig 1.5b)
- Sevoflurane anesthesia machine (fig 1.5c)
- Digital imaging instruments (fig 1.5d)
- Portable suction (fig 1.5f)
- Ambubag (fig 1.5f)
- Portable ventilator (fig 1.5g)
- Laryngoscope (fig 1.5h)



(Fig:1.5a)



(Fig:1.5b)



(Fig:1.5c)



(Fig:1.5d)



(Fig:1.5e)



(Fig:1.5f)



(Fig:1.5g)



(Fig:1.5h)

The [portable field equipment's could be used for the portable Operating room design.

Market study

Various types of portable operating units are available in the market but most of them are for large medical camps or for large scale disaster relief medical camps. the mobile ambulance operating units effective but the accessibility to remote locations are a major issue.

- Disaster management portable surgical care units (fig1.6a)
- Post operative care ward (fig1.6b)
- Air filtering unit for huge portable OR facility (fig1.6c)
- Diagnosing facility/ OR (fig1.6d)
- Mobile eye surgery unit (fig1.6e)
- Inflatable surgical training unit(fig1.6f)

Similar product available in the market was not found and the existing products wont be suited in the context of the project.



(Fig:1.6a)

Source: <https://blu-med.com>



(Fig:1.6b)

Source: <https://blu-med.com>



(Fig:1.6c)

Source: <https://blu-med.com>



(Fig:1.6d)

Source: <http://suncoast-chc.org>



(Fig:1.6e)

Source: <https://blu-med.com>



(Fig:1.6f)

<https://www.timesunion.com>



Inflatable sterile field

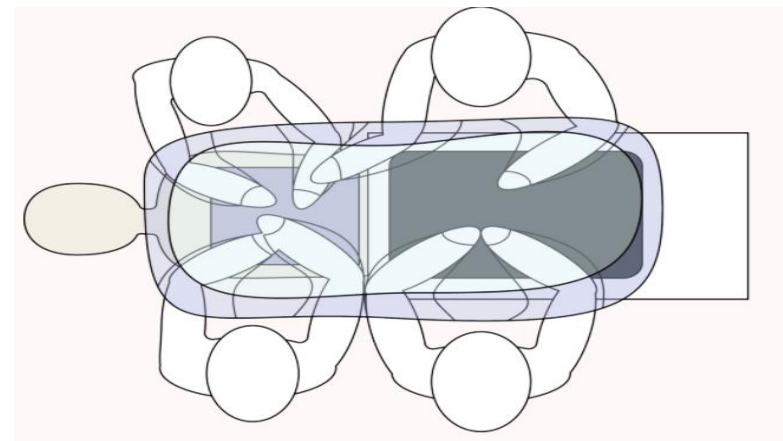
'Surgi box' is the product similar to the context of the project, its an Inflatable covering which can be placed over the patient this acts as the sterile space over the patient were the surgical procedure can be done . The surgeon can aces the space through the holes provided t the sides the product is under development by MIT.

The main drawback of design would be that the surgeons movement is restricted by the setup, also its difficult to face emergency situations with keeping a sterile environment. The placement of surgical instruments and accessing it would be another issue.

The fig 1.7a shows the prototype designed and fig1.7.b shows the schematic top of the prototype.



(Fig:1.7a)

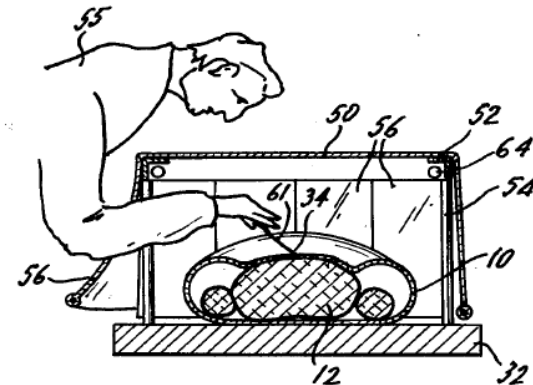


(Fig:1.7b)

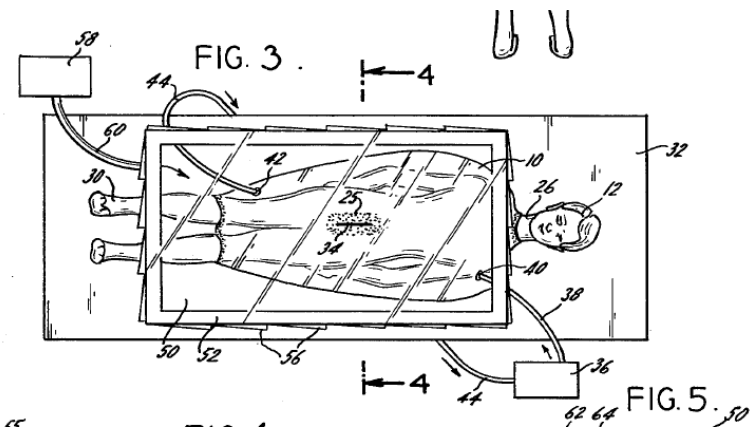
The product still in its research phase , the concept is good but the execution part has to be modified further.

Relevant patents in the field

Patient No:EP2413018 (Filed on June 30,1981)
similar to surgical box invention, it explains about a plastic film which is attached to the patient and the sterile field is kept inside a box with access to the patient. (Fig 1.8a,b) shows the pictures of the design while in use.



(Fig:1.8a) side view of the design

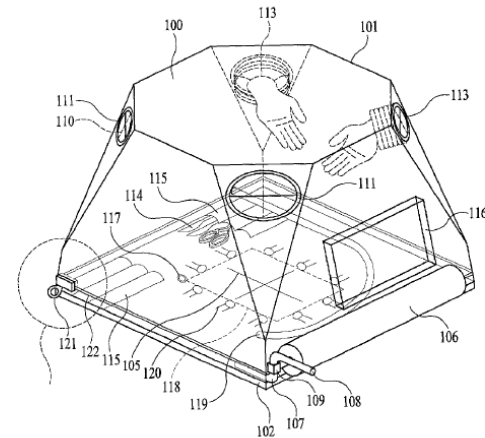


(Fig:1.8b) top view of the design

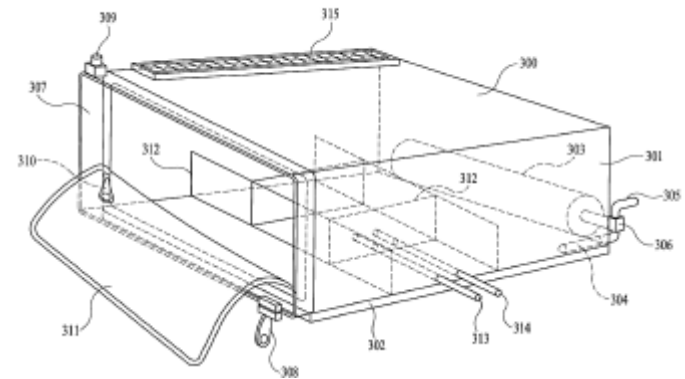
The using of physical enclosure could be a solution for the problem but the enclosure shouldn't obstruct vision and motion of surgeons hands.

Relevant patents in the field cont..

Pub. No.: US 2002/0045796 A1, Pub. Date: Apr. 18, 2002. It's a sterile physical enclosure where it has access to hands in it the instruments has to be either placed in the sterile field or has to be kept outside. The design is mainly for protecting sterile field. . (Fig 19a,b) shows the pictures of the design while in use.



(Fig:1.9a) isometric view of the design

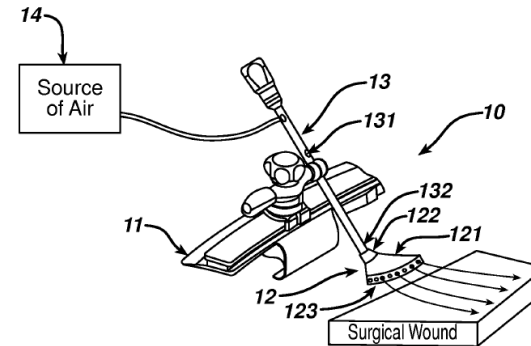


Its also similar to the previous design but the geometry of the sterile field is different.

(Fig:1.9b)the clamping mechanism of the enclosure

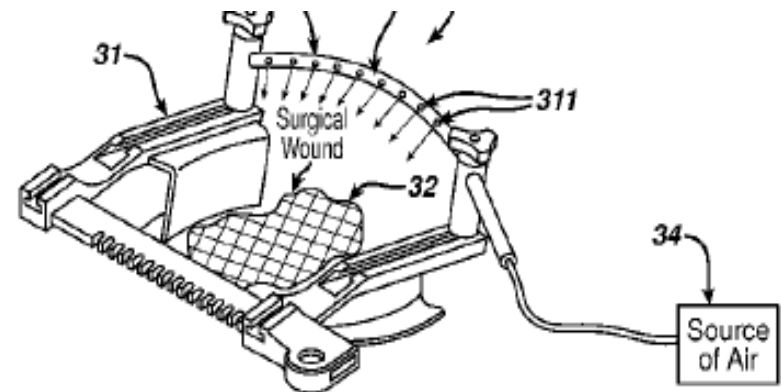
Relevant patents in the field cont..

Pub. No.: WO2010/105005 A1, Pub. Date: Jun. 16, 2010, In this invention a set of nozzles are attached neat the surgical site so the surgical it will be kept clear from contaminated air. The (fig 1.10a) shows the air nozzle which is clamped close to the surgical site in (fig 1.10b) shows the mechanism to mount the nozzle with the air source.



(Fig:1.10a)

Source : WO2010/105005



(Fig:1.10b)

Source : WO2010/105005

This idea is interesting and no physical barrier to obstruct the surgeon is there but in the design air is only pumped to the surgical site and not to the instruments so at a controlled atmosphere this could be an effective to reduce surgical site infection from air borne contaminants.

Relevant patents in the field cont..

Pub. No. WO 2010/126956 A1, Pub. Date: Nov. 04, 2010 In this design a stream of sterile air is bowled to the surgical site to prevent contamination from the contaminated air. This design also just like the previous one only provides a sterile atmosphere near the insertion. (Fig 1.11a) shows the sketch of the device while in operation, (Fig 1.11b) shows the nozzle with sterile air generator.

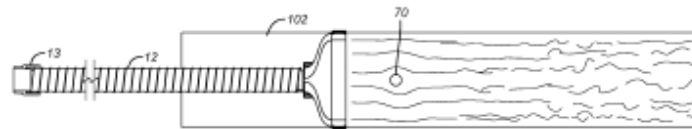
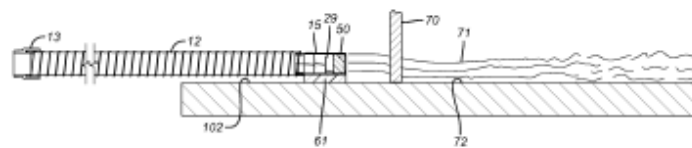
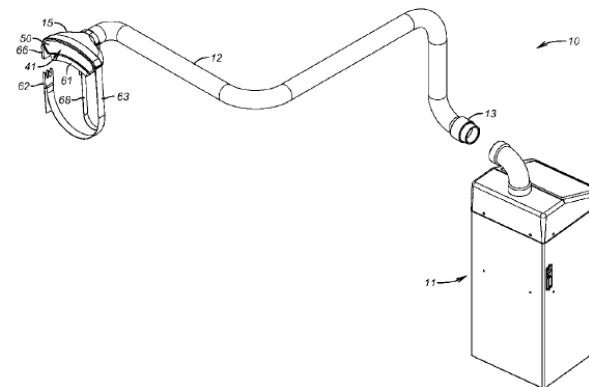


FIG. 5



(Fig:1.11a)

Source : WO 2010/126956



(Fig:1.11b)

Source : WO 2010/126956

This could be mounted near a surgical instrument tray also so a sterile stream of air which protects the surgical site and instrument tray could be an effective solution.

02 Secondary research

Scenario building and user study

12 hospitals all over India operating at villages and remote locations were contacted & witnessed pancreatic cyst removal laparoscopic surgery and appendectomy surgery at hospitals in Mumbai. Among the hospitals contacted two hospitals here identified and field study with user research was conducted. The hospital details are given below.

- Lok Biradari Prakalp, Hemelkasa run by Padma shri Dr Prakash Baba Amte
- Comprehensive Rural Health Project, Jamkhed (CRHP) (Dr Ravi Aole)

As a case study the works of Dr Ruit (ophthalmologist, Nepal) for the Himalayan cataract project was also studied. He does cataract surgeries by hiking 3-4 days to the remotest places of Nepal.



(Fig:2.1a) shri Dr Prakash Baba Amte



(Fig:2.1b) Dr Ravi Aole



(Fig:2.1c) Dr Ruit

Scenario 1

- Lok Biradari Prakaalp(LBP), Hemelkasa run by Padmashri Dr. Prakash Amte, is situated at Hamalkasa, in Gadchroli forest range in the east of Maharashtra, India. Its one of the remotest hospitals that can find in the country itself.
- Patients from an area of around 250Km come to the hospital that's the only good medical facility available for the tribal communities nearby.
- Major emergency cases addressed by the hospital was gynaecological cases where caesarean section surgery is required, lacerated wounds due to animal attacks, accidents and fights etc. at present the patient has to bring to the hospital its risky and difficult because of no proper transportation facilities or road, also the villages are far and scattered around the hospital. During monsoon, most of the villages are isolated from the hospital where its impossible to transfer the patient t the hospital.
- So their requirement was to have a portable Operating room facility which could be carried to the location and deployed easily. The operation room should have the basic features for execution of general gynaecological surgeries.



(Fig:2.2a) Hemalkasa on map



(Fig:2.2a)



(Fig:2.2c)



(Fig:2.2c)

(Fig:2.2b,d) shows the terrain of the place and (fig 2.2c) shows a villager explaining the problems of transporting the patient at a medical emergency.

Scenario 1 cont..

In the Himalayan cataract project almost all the places are very difficult to access and most of the time the surgical team has to walk days to reach the destination. So from the research it was found him explaining about the need for other surgeries and he mentions creating a sterile space was one of their major challenge.

Fig Source : Documentary on Dr Sanduk Ruit 'The gift of sight' by Al Jazeera



(Fig:2.3a) Dr. Ruit conducting cataract surgery years back



(Fig:2.3b) Dr. Ruit conducting cataract surgery years back



(Fig:2.3c)



(Fig:2.3d)

(Fig:2.3c,d) the rocky terrains which they need to travel . The team has to carry everything manually usually in baskets which are attached on their back.

Scenario 2

- The second hospital was Comprehensive rural health project (CRHP)(Fig2.4b), which is situated at a village called Jamkhed at south of Maharashtra, India.
- The hospital was founded by Drs Raj and Mable Arole and presently run by Dr Ravi Arole. The hospital has been working among poor and marginalized people for the past 45 years. The conditions here were much different from LBP hospital, they conduct lots of medical camps within the hospital, in the nearby villages and during disaster relief medical programs. So their main challenge was to have a portable sterile field for execution of various preplanned surgeries.

(Fig:2.4a)Senior head nurse explaining the requirements of anagological surgery. On the table are the maximum instruments and other consumables required for Cesarean surgery.



(Fig:2.4a)



(Fig:2.4b) CRHP Health workers

Scenario 3

- The 3rd context is for trauma care, during an injury resulting in lacerated wounds the patient has to be stabilized before transporting to the nearest hospital. In such cases, the first aid is given at the site itself since there's no effective provision for creating a sterile space risk of infection is increased.
- It can be an add-on feature for emergency response teams for road accidents, disaster relief agencies, fire fighting medical team, for defence medical teams during a compact.

(Fig 2.5a) 1st aid given and victim being transported to the nearest hospital after a bus accident

(Fig 2.5b 1st aid given during a war scenario, theirs no special sterile space to do the 1st aid.)

From the above three scenarios the 1s scenario of Lok Biradari Prakalp(LBP) is mainly focussed in the project and final concept is designed for that. Since the other scenarios are equally important and similar in nature separate ideation and concept generation is done for those scenarios and designs are proposed.



(Fig:2.5a) Source:



(Fig:2.5b)

03 Design objective

‘To design a portable operating room for general surgical procedures’

*The will include design of a portable surgical table, sterile field, provision for integrating necessary surgical instruments and equipment's

04 Design Brief

Primary needs

- Should be portable
- Should be ergonomic and should be able to accommodate a surgical team
- Identified The design should be modular so necessary equipment's or other facilities could be attached.
- Should maintain the cleanliness and sterility were ever required
- Should be reusable and easy to disinfect after a procedure.
- Should also consist of a suitable OR table with provision for adjusting height, tilt and reclining features
- Should have facility to deal with emergency situations

User related issues

- Should be easy to operate with minimum training.
- Should be comfortable for patient and surgical team air conditioning should be provided.
- Should be easy conduct the procedure, the surgical teams body movements should least restricted

Servicing issues

- Should be easy to operate with minimum training.
- Device should conform to class 5 clean room standard and Class 2 according to FDA(Federal Drug Administration) regulations, Should also comply with FDA 510K regulations.

Manufacturing issues

- Materials and design should be easy to manufacture and maintain.
- The material should be easy to clean with minimum accumulation of dust or dirt.
- The components should also be easily available.
- Necessary components should be autoclave able or should be able to sterilize /disinfect by other means of approved sterilization methods.

Operating condition

- Should maintain the quality of sterilization throughout the procedure
- Should work in at dry or humid conditions temperatures varying from 0°C – 60°C dry or humid conditions.

04 Design Brief cont..

Functional requirements

- The components in the device should be easy for the OR staff themselves to clean, decontaminate and sterilize if required.
- Should consume minimum space if not in use.
- Should be aesthetically good and design itself should increase the value of perception of the product.
- Should be suitable to use standard surgical equipment's available in the market
- Should have provision to keep surgical instruments and other necessary items
- Should have inbuilt power and all necessary equipment with it.
- The entire weight of OR with mandatory equipment's should be less than 50KG
- All components should fit inside a box of 150cm*80cm*40cm
- Should be capable of 8 hours of continuous operation
- Should consume electric power less than 150W

Target user

Primary user

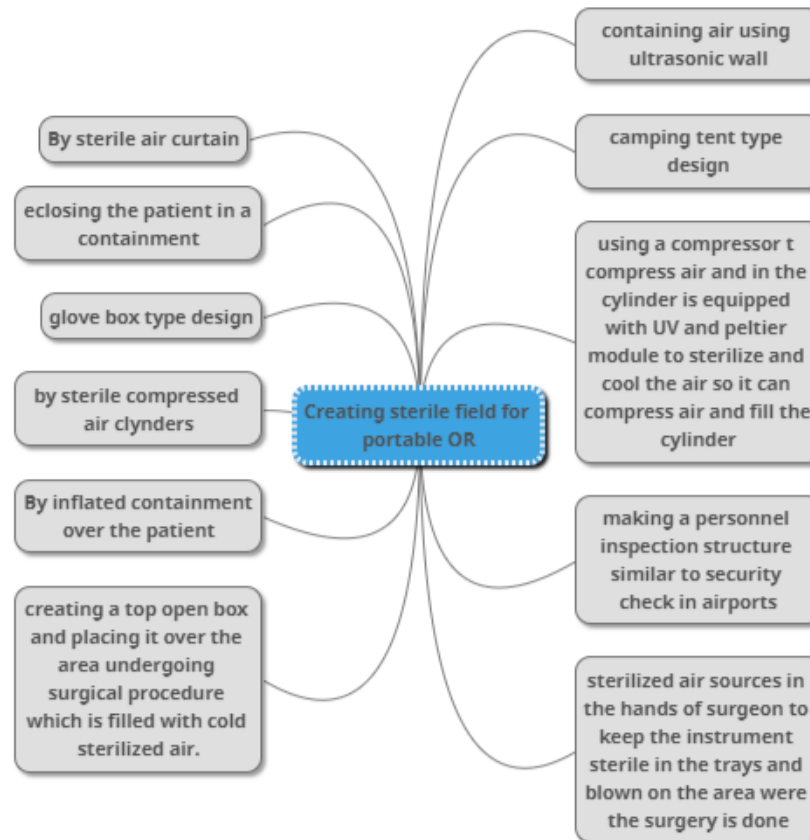
- Surgeon
- Scrub nurse (Nurse who assist the surgeon during the surgery)

Secondary user

- Circulating nurse (The nurse who gives provides the instruments to the scrub nurse during surgery)
- Anesthetist
- Other OT staff (the one who cleans and disinfects the OT)
- Persons who transport and assemble the OT
- Sterilization department personnel

05 Ideations for sterile space

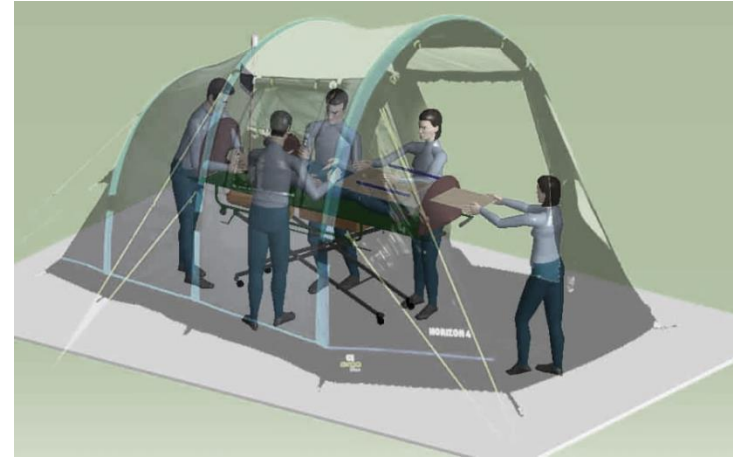
Mind map



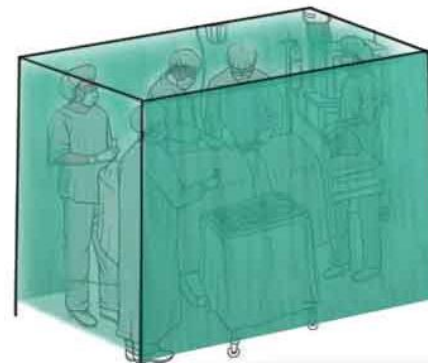
5.1 Camping tent inspired design

The idea is to conduct the surgery in a camping tent kind of enclosure where the atmosphere inside is kept sterile. The main drawback of it would be maintaining the quality of sterilization inside; there is always a risk of contamination while people enter in to it or else it has to be made tent within a tent setup so the inside air quality can be maintained. But then the entire setup becomes bulky.

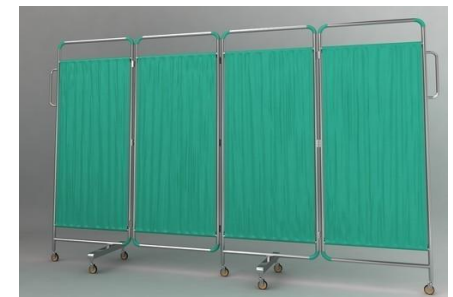
(Fig 5.1a) the enclosure can be as similar to a camping tent or a cloth partition which is similar to a hospital room partition as in (Fig 5.1b)



(Fig:5.1a)



(Fig:5.1b)

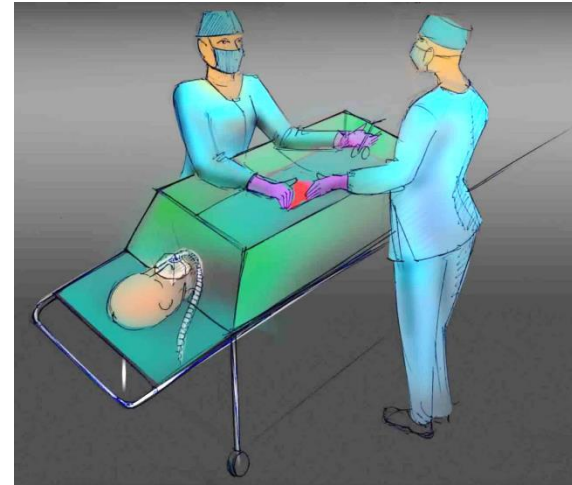


(Fig:5.1c) cloth partition used in hospitals

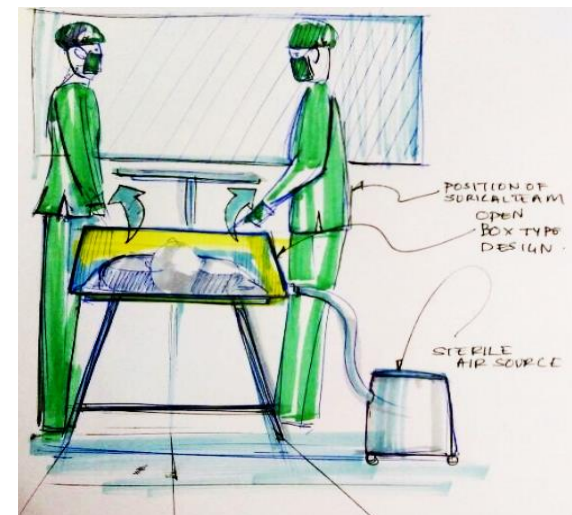
5.2 Open Box type design

In the design a open box type barrier is placed around the patient and sterile cold air is supplied inside since the cold air is denser it could reduce infiltration of contaminated air.

(Fig 5.1a,b) shows the above mentioned idea. The efficiency of the design is less due to possibility of air mixing that could happen due to the movement of surgeons hands. Also the physical barrier will act as a restriction for the surgeon. The surgical instruments have to be taken care separately or it has to be kept in the same enclosure.



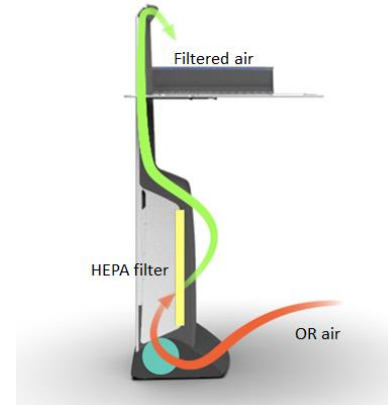
(Fig:5.2a)



(Fig:5.2b)

5.3 Blowing sterilized air

(Fig 5.3b) is a device for maintaining sterility of surgical instruments in an OR, this product was designed as a part of my IDC academic project(P2) so the same device can be used to blow sterilized air to the sterile field thus ensuring no external air comes in to the sterile field. But it doesn't ensure the quality of sterile field and it will be energy intensive to maintain the air flow. The same idea of sterile air blowing has to be used in an effective way.

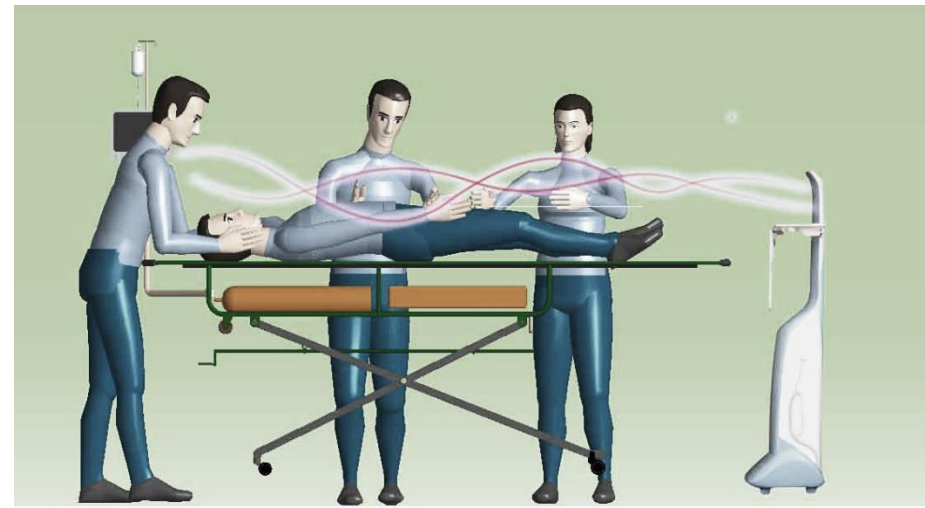


(Fig:5.3a)



(Fig:5.3b)

Fig 5.3a shows the working of the device and Fig 5.3c shows the device position during a surgical procedure.

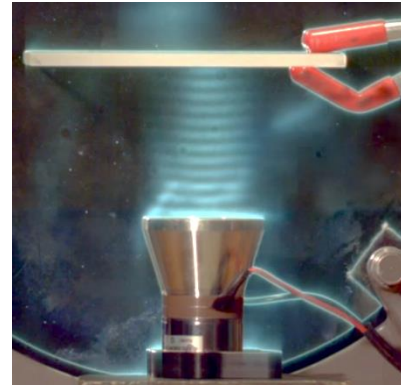


(Fig:5.3c)

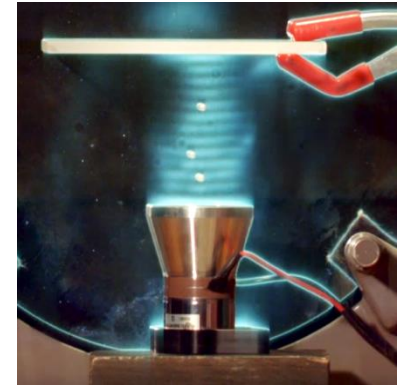
5.4 By the principle of ultrasonic levitation

Standing wave is a vibration of a system in which some particular points remain fixed while others between them vibrate with the maximum amplitude. The standing waves can levitate small Styrofoam balls or such light weight objects. So the idea was which microbes can be levitated, if in the air passage if theirs a device which makes this ultrasonic standing waves and it lets the air to pass but levitates the microbes. This will create a sterile source o air supply. Another idea is if it a standing wave barrier is provided and it creates an obstruction to the air flow then such a system could be made around the area of surgery and a source of sterile air can be provided so the sterile air will be contained inside the area effectively.

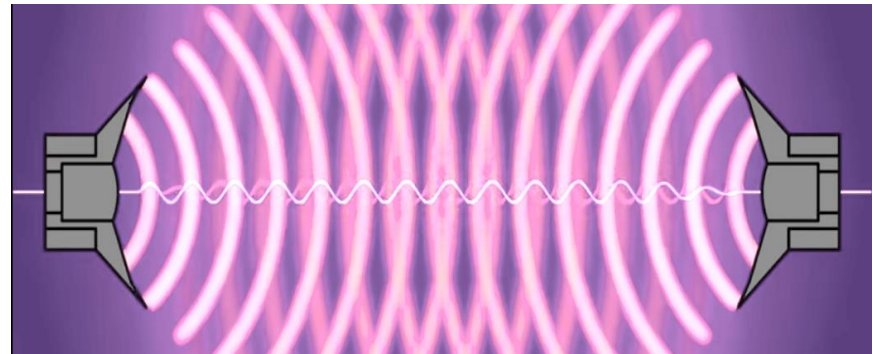
(Fig 5.a,b) The standing pattern can be visible by Schlieren imaging and Styrofoam balls being levitated in on the standing wave column.



(Fig:5.4b)



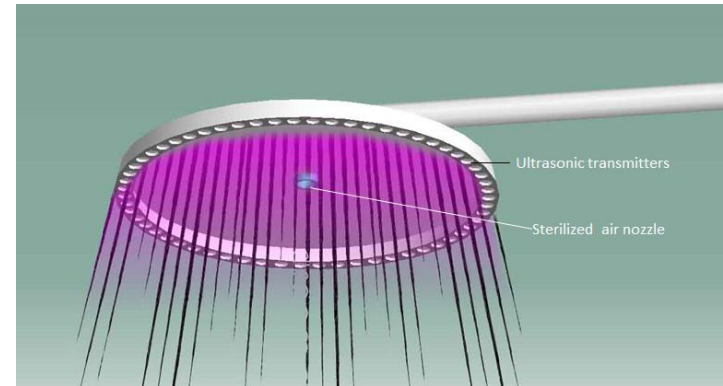
(Fig:5.4c)



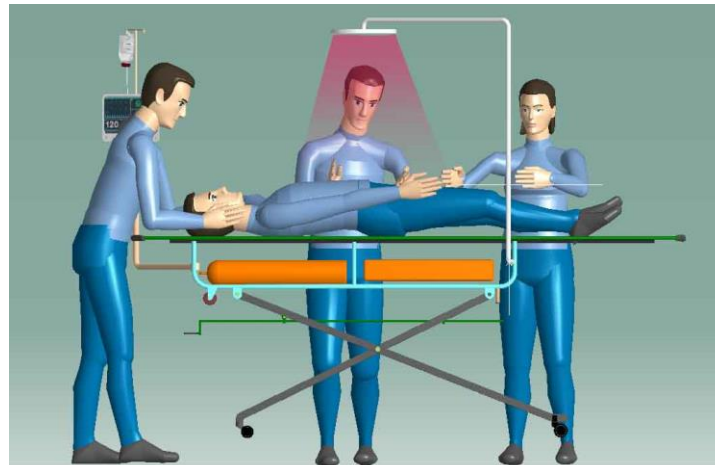
(Fig:5.4a)

Source: (Fig:5.4a,b,c) Harvard Natural Sciences

The (Fig 5.4d) shows ultrasonic transducers laced t a circular array which make a diverging standing wave wall in shape of a cone, sterilized air is vented inside to maintain the sterile atmosphere there will be a surface below to reflect the waves, This will be ideal for dental procedures, cataract surgery , vasectomy etc. But not enough information for proving the concept was not found after research, so this idea is not taken forward since developing technology is not the main intention of this design project



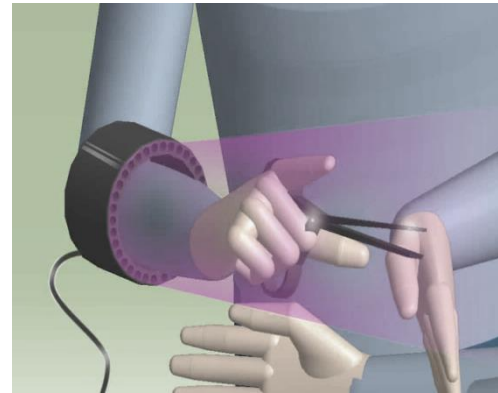
(Fig:5.4d)



(Fig:5.4e) Positioning of the device during a surgery

5.5 By a source of portable sterile air

As explained earlier blowing sterile air on to the surgical site could be an effective way of reducing surgical site infections. So a sterilized air source can be placed on the hand to keep the instruments in contact with contaminated air. Sterilized air source can be placed on the head of the surgeon also but the direction of the air changes when the surgeon moves head. The main drawback of the idea is to the air source if mounted on head or had it doesn't supply sterile air to a place constantly, so there should be another steady sterile air supply on to the surgical site. The idea will be effective for keeping the instruments sterile while transferring them from the tray to the surgical site. Again the solution is complex and less effective.



(Fig:5.5a) sterile air source covering the instrument while instrument transfer.



(Fig:5.5b) Sterile source is mounted on head



(Fig:5.5c) sterile air source mounted on hand

06 OR Table design

6.1 Types of surgical tables and features

General Surgery Tables requirements.

- Accessibility
The table need to have various features like Height should be adjustable from 60cm to 1000cm
Back support angle from 75° -15° from horizontal
Head plate 60° -70° from horizontal
Leg plate 15° to -85°
Flux of 15° should be provided
- Stability – Positioning placement and precision are critical to delivering the right dosage of anaesthesia. So the surgical table should be steady and cannot sway or move if the patient's shift positions.
- Imaging Support feature for placing the x ray film or position imaging devices should be provided.
- Support for larger patients –Quality surgical care shouldn't be limited by the maximum weight allowances of surgical tables. The standard table should support minimum weight of 140 Kg.

Refrence:

<https://www.futurehealthconcepts.com/blog/posts/4-surgical-table-types-and-their-features.html>

Types of surgical tables

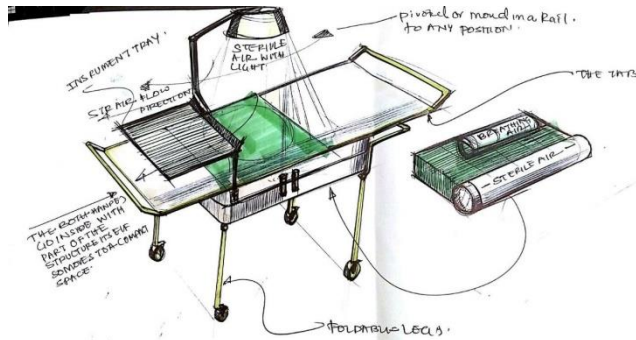
- General Surgery Tables
- Imaging Tables
- Neurology Tables.
- Urology and Cysto Tables



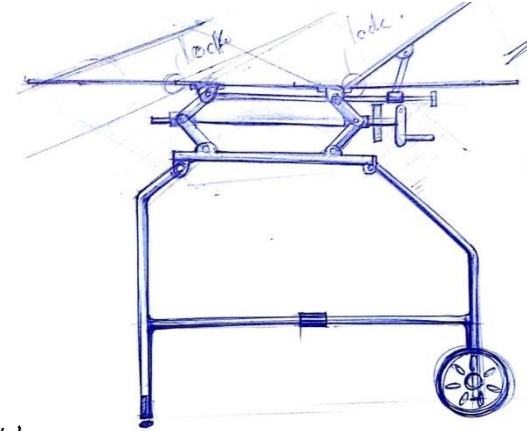
(Fig:6.1a) A general OR table wit the necessary features

07 OR Table concepts

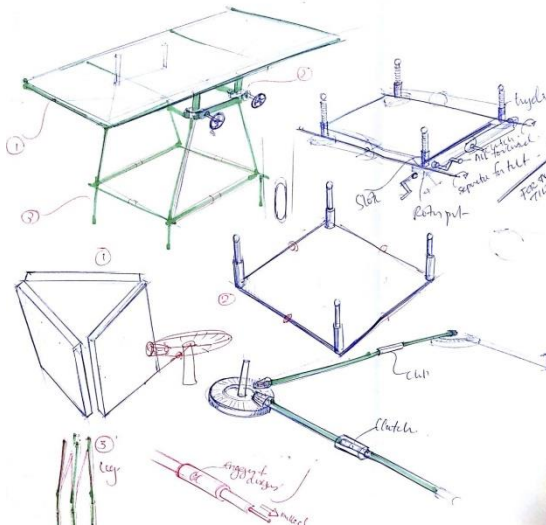
7.1 Ideation sketches



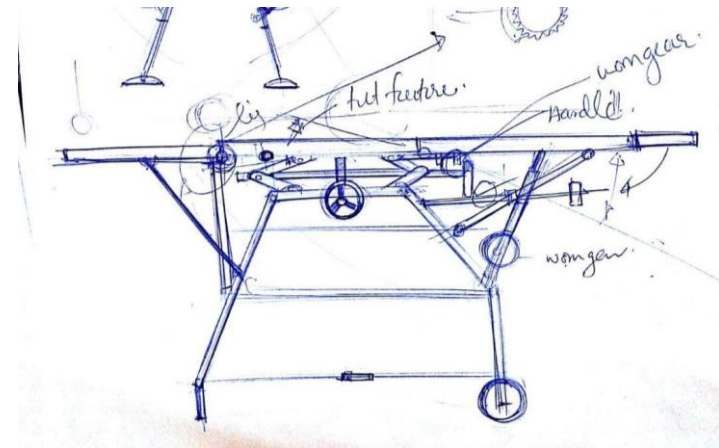
(Fig:7.1a)



(Fig:7.1b)

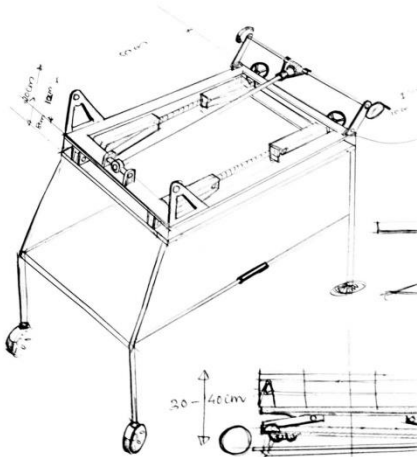


(Fig:7.1c)

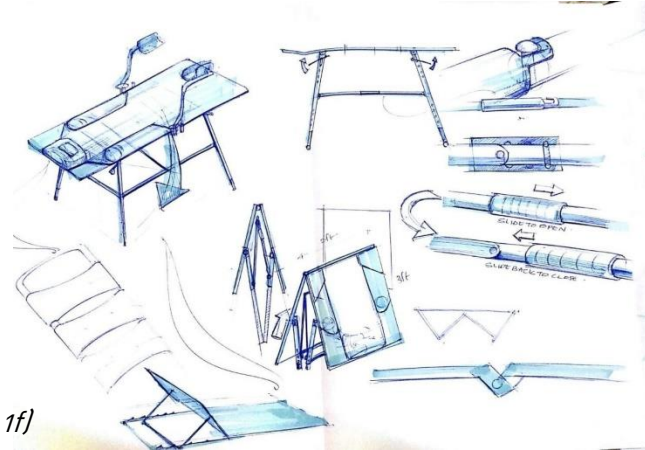


(Fig:7.1d)

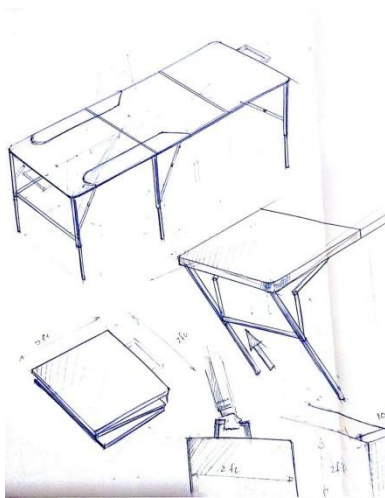
7.2 Ideation sketches cont..



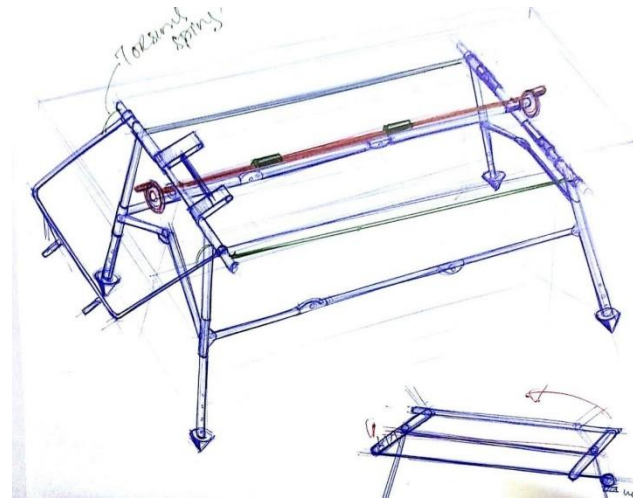
(Fig:7.1e)



(Fig:7.1f)

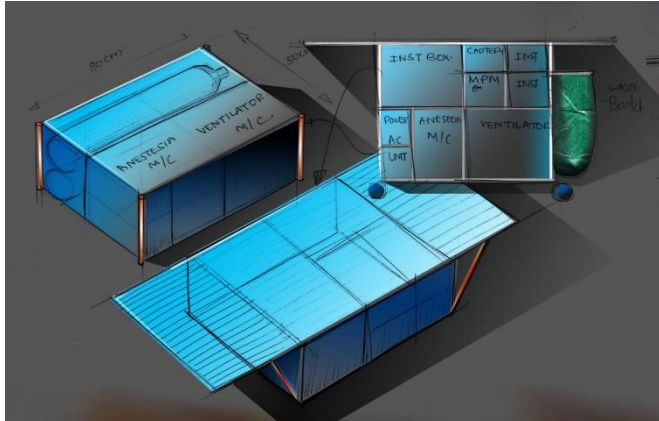


(Fig:7.1g)

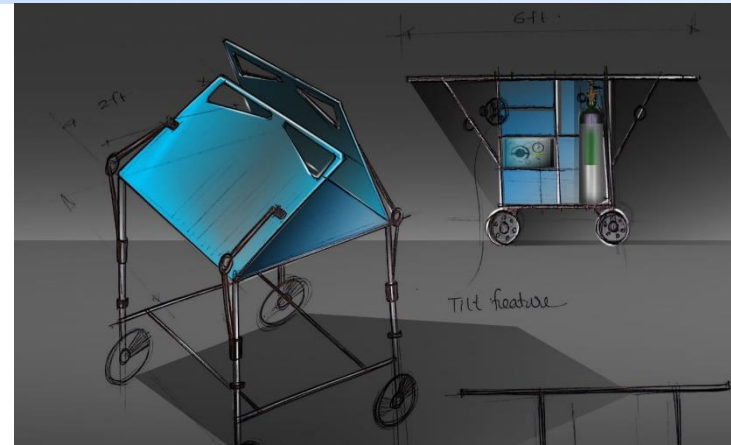


(Fig:7.1h)

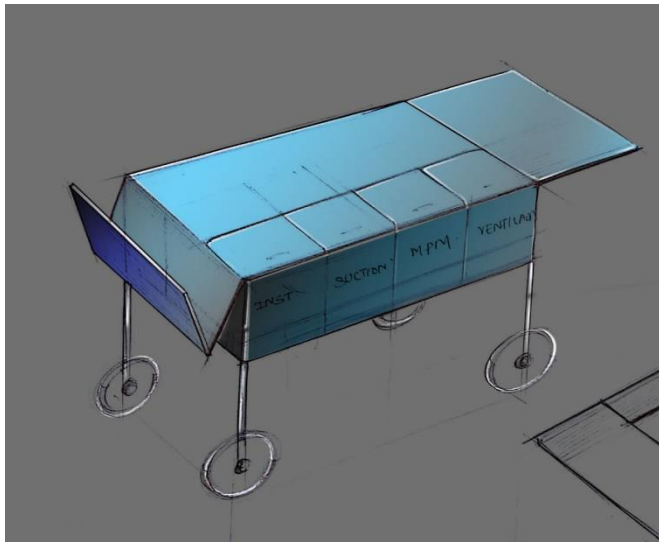
7.2 Ideation sketches cont..



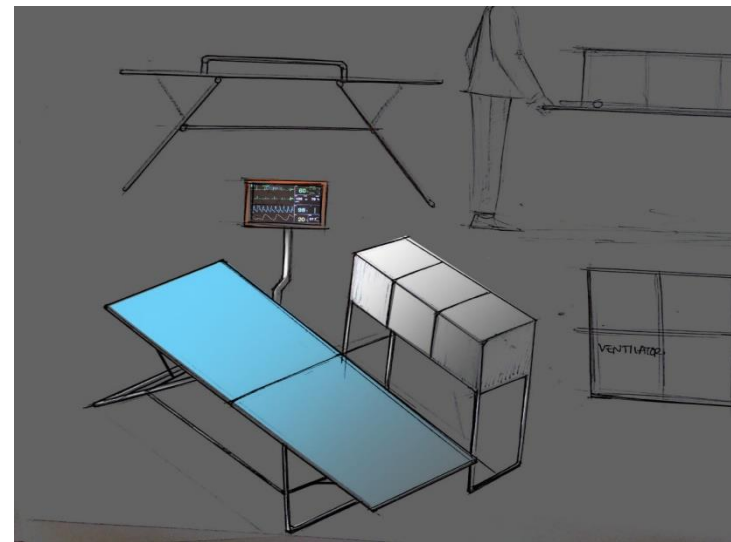
(Fig:7.1i)



(Fig:7.1j)



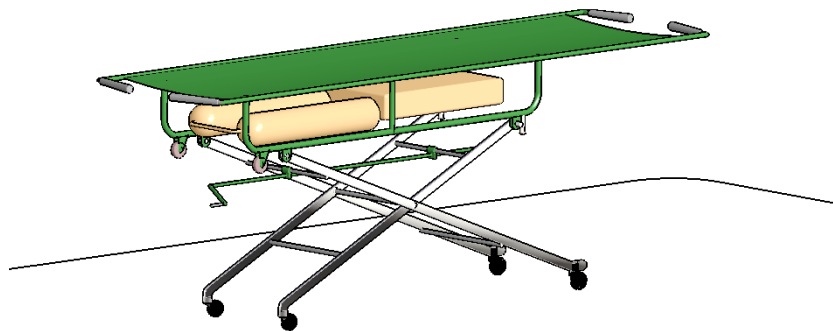
(Fig:7.1k)



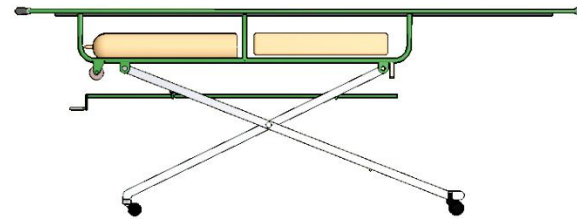
(Fig:7.1l)

7.2 Concept 1

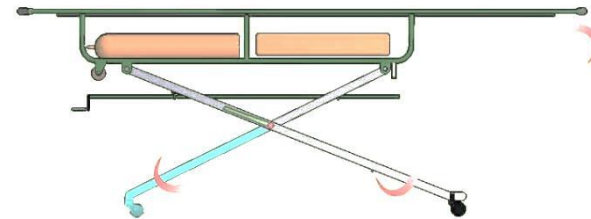
For trauma care In the design the table consists of necessary equipment's mounted below the table. The either sides of the table can be extended to accommodate the patient. So the table can be folded as shown in (fig 7.2b,c,d) and the wheels help in transporting it.



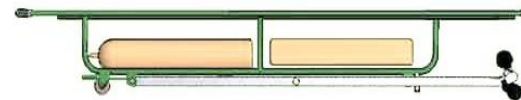
(Fig:7.2a) the equipment's can be placed below the table.



(Fig:7.2b) OR table in normal position



(Fig:7.2c) Direction of folding of the table



(Fig:7.2d) In folded position

7.3 Concept 2

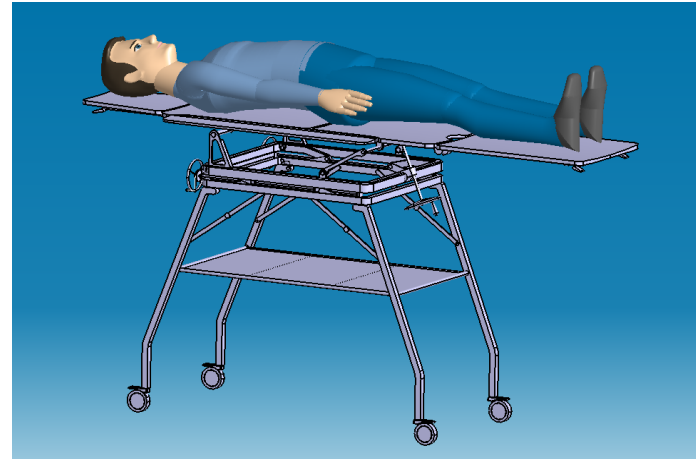
This concept of OR table is for the medical camps were pre planned and wide variety of surgeries will be done so the OR table should also satisfy such needs.

The portable table has the features of Height adjustment, lateral and longitudinal tilt features. Also the head plate and leg plate scan be separately folded at required angles. The hand plate can be rotated 90degree for connecting IV lines easily. At the base of the table a detachable surface is provided to keep any equipment or items as required.

On the surface of table can be attached with cushioning covering . Silicon or traditional rexine with sponge can also be used.

Stainless steel 316,440r or 420 grades can be used for manufacturing.

The entire table can be folded to 30cm*120cm*60cm size its estimated to weight less than 20kg



(Fig:7.3a)Position of patient on the table

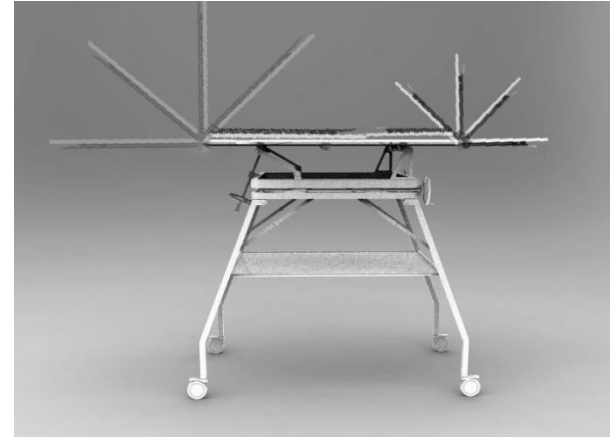


(Fig:7.3a) The adjusting handles are shown

7.4 Different Table positions



(Fig:7.4a) leg plate can be adjusted 90 degrees



(Fig:7.4b) the head plate and leg plate can be folded inward for storage

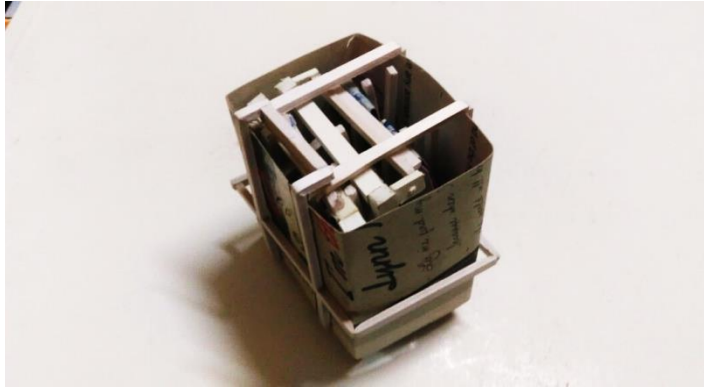


(Fig:7.4c) longitudinal tilt of 35degrees

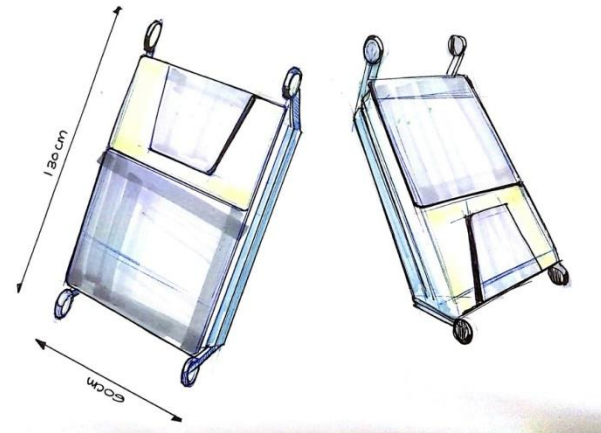


(Fig:7.4d) Lateral tilt of 22degree

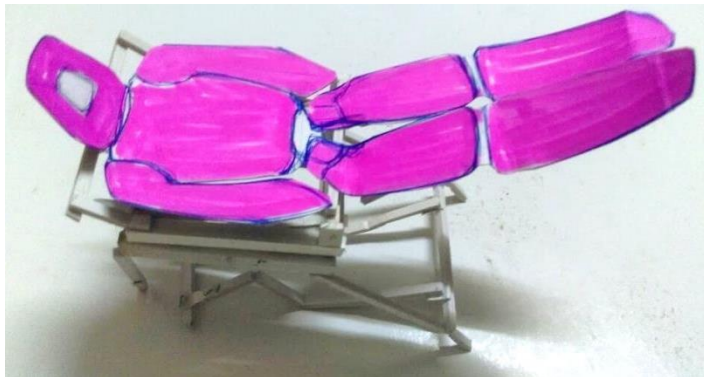
7.5 Folding and storage



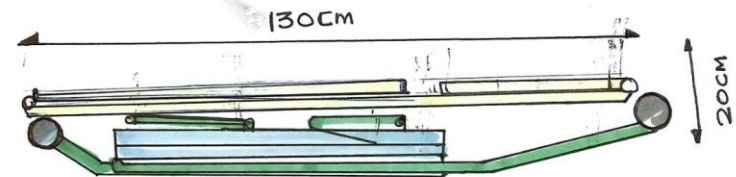
(Fig:7.4a)Mock up model of OR Table in folded and packed position



(Fig:7.4a) folded views of OR Table



(Fig:7.4c)Mock up model of OR Table in open position



(Fig:7.4d) front view of folded OR Table

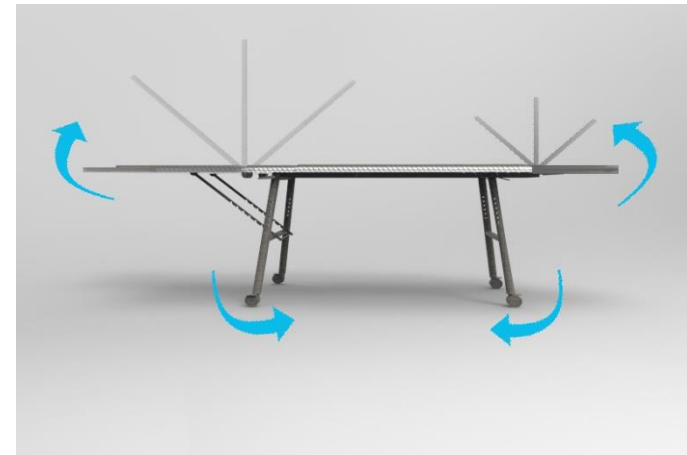
7.6 Concept 3

In the 1st scenario where emergency surgeries will be at remote locations the table needs to be light weight and portable with the minimum adjustability features. In this concept only basic movements like height adjustment lateral tilt with back plate, head plate, leg plate, and hand plate adjustments are provided. It doesn't have lateral tilt feature but the existing features are good enough for most of the general surgical procedures.

The table can be folded to a size of 12cm*120cm*60cm. And expecting to weight be less than 15kg. Stainless steel 316, 440 or 420 grades can be used for manufacturing.

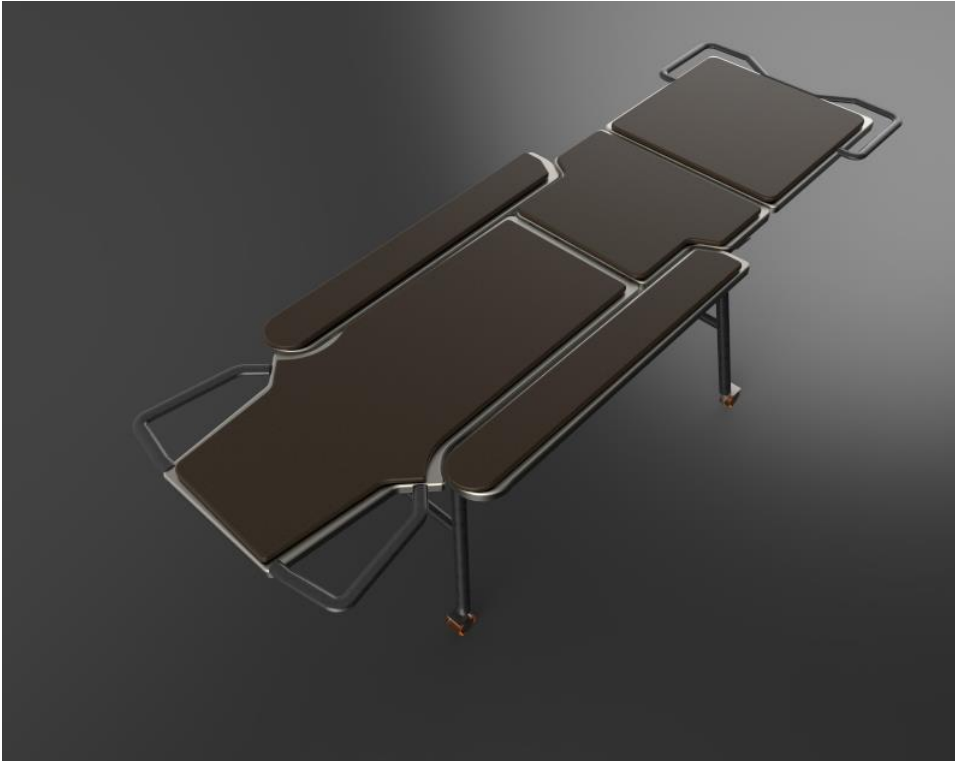


(Fig:7.6a) OR table 3D model



(Fig:7.6b) The leg and head plates also the legs are folded inward, hence becomes very compact

Concept 3 CAD renderings



The table have lateral and longitudinal tilt adjustment with height adjustment feature.
Or other field operation tables could be integrated with the design

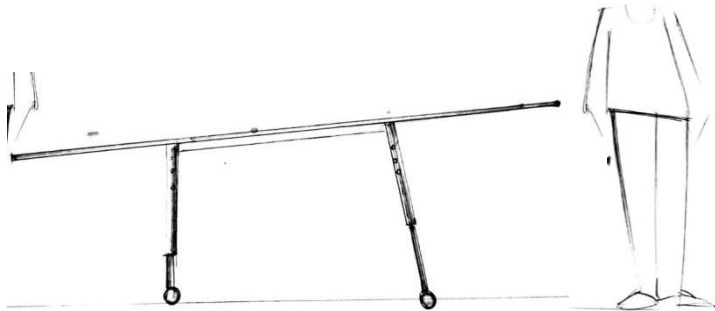
7.7 Different table positions



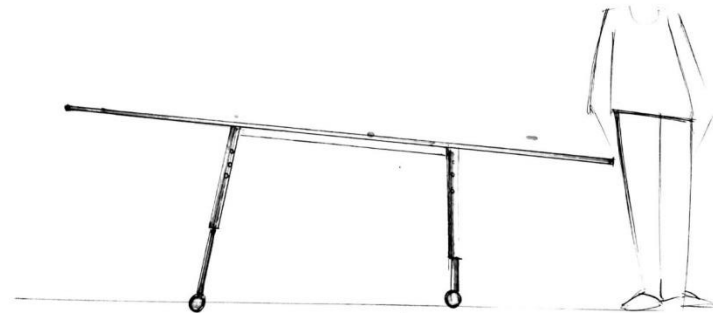
(Fig:7.7a) For adjusting height the telescopic legs are extended



(Fig:7.7b) OR table lowered by retracting the telescopic legs

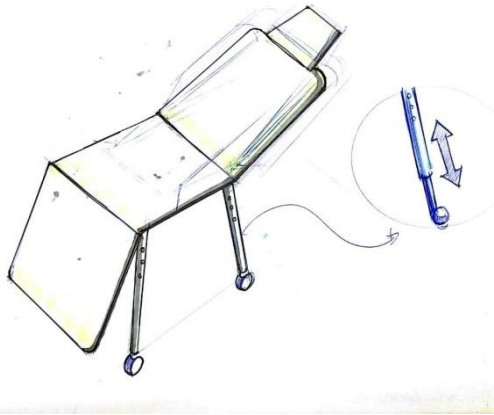


(Fig:7.7c) If legs at one side is only retracted the table tilts laterally

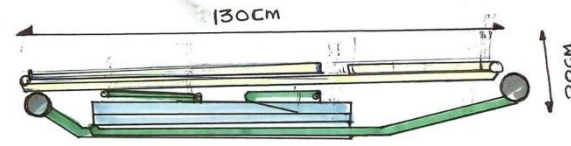


(Fig:7.7d) the table tilts in the other way if the opposite legs are retracted

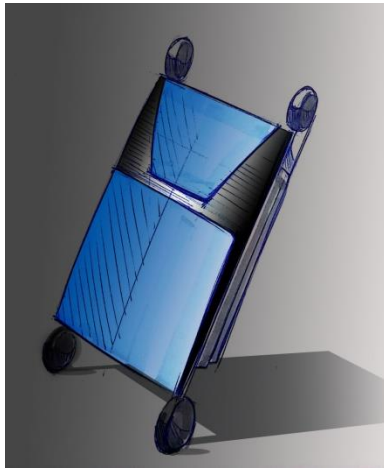
7.8 Folding and storage



(Fig:7.8a) The Table can be folded in form of a dental chair



(Fig:7.8b) Table folded along with the legs



*(Fig:7.8c) The table folds to a size of 12cm*120cm*60cm, since wheels are there it can be pulled like a trolley bag.*



(Fig:7.7d) the arms of the table can be extended out for better accessibility for connecting intravenous tubes during surgery.

7.8 1/10th scale model



(Fig:7.8a) The Table can be folded in form of a dental chair



(Fig:7.8b) Table folded along with the legs



*(Fig:7.8c) The table folds to a size of 12cm*120cm*60cm, since wheels are there it can be pulled like a trolley bag.*



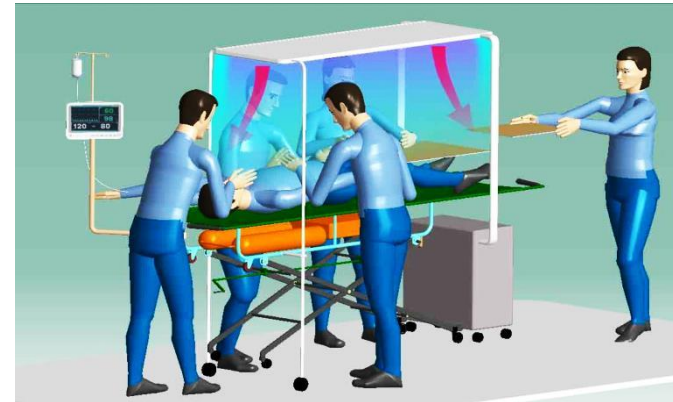
(Fig:7.7d) the arms of the table can be extended out for better accessibility for connecting intravenous tubes during surgery.

08 Sterile space design

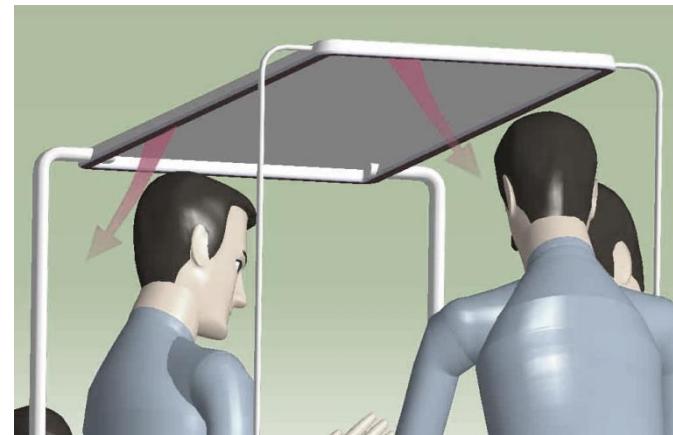
8.1 Concept 1

Creating an air curtain

- Air is filtered and an overhead structure is created to make an air curtain around the sterile field.
- Once the air curtain is formed sterilized air is pumped in to the sterile field This minimizes the quantity of sterilized air and prevent infiltration of contaminated air to the sterile field
- Creation of vortex and mixing of air can takes place due to surgeons hands is a drawback and the possibility of air getting mixed cant be avoided.
- At high flow rate it can be noisy as well.



(Fig:8.1a) The surgical team



(Fig:8.1a) Air curtain is placed above the patient, and flow channels can be seen in the picture

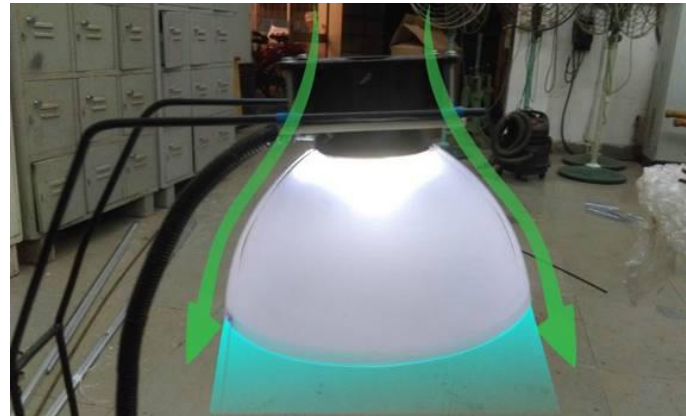
8.2 Air curtain using coanda effect

(Fig 8.2 b) shows the air flow direction by a fan mounted on the hemispherical object and inside of it sterile air is applied so the outside air contains the inner supply of air. Right shows the working prototype used to know the ergonomic constraints

Coanda effect is the phenomena in which a jet flow attaches itself to a nearby surface and remains attached even when the surface curves away from the initial jet direction. In free surroundings, a jet of fluid entrains and mixes with its surroundings as it flows away from a nozzle.

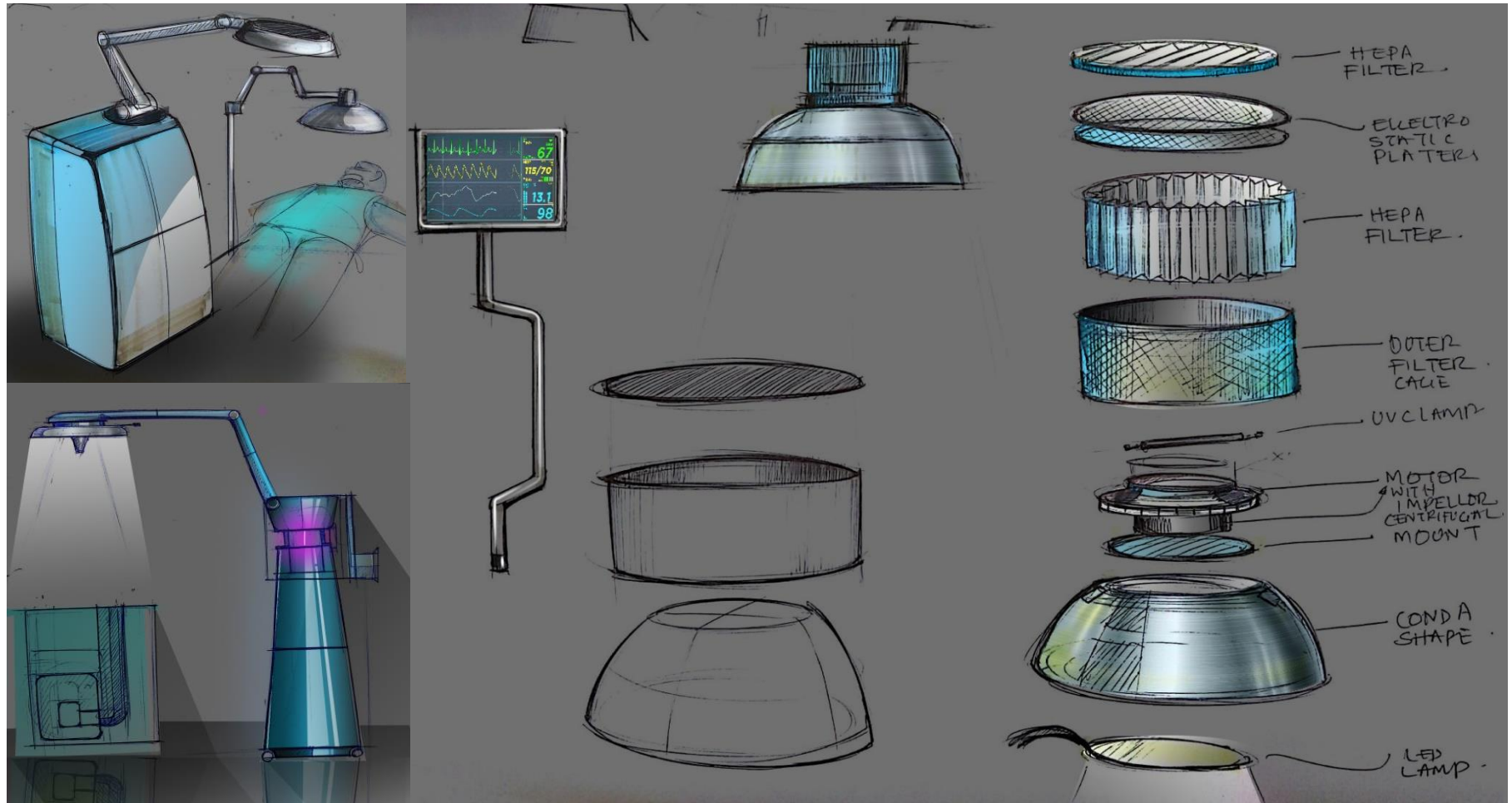


(Fig:8.2a) working prototype positioned over a subject



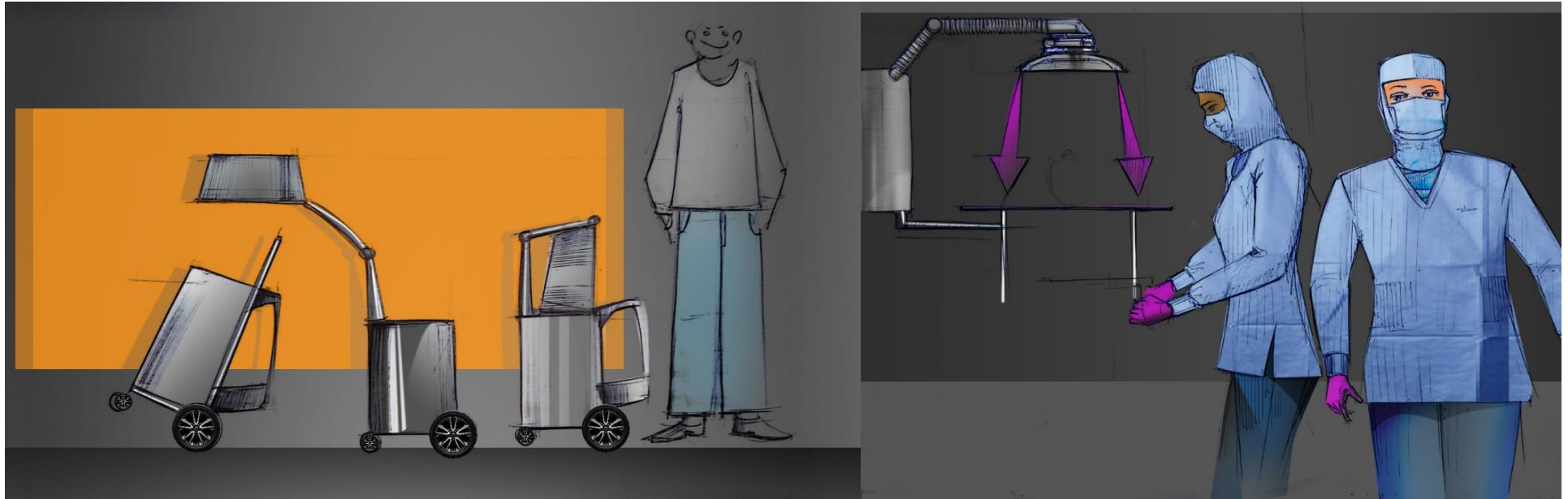
(Fig:8.2b) working prototype positioned over a subject

Ideation sketches



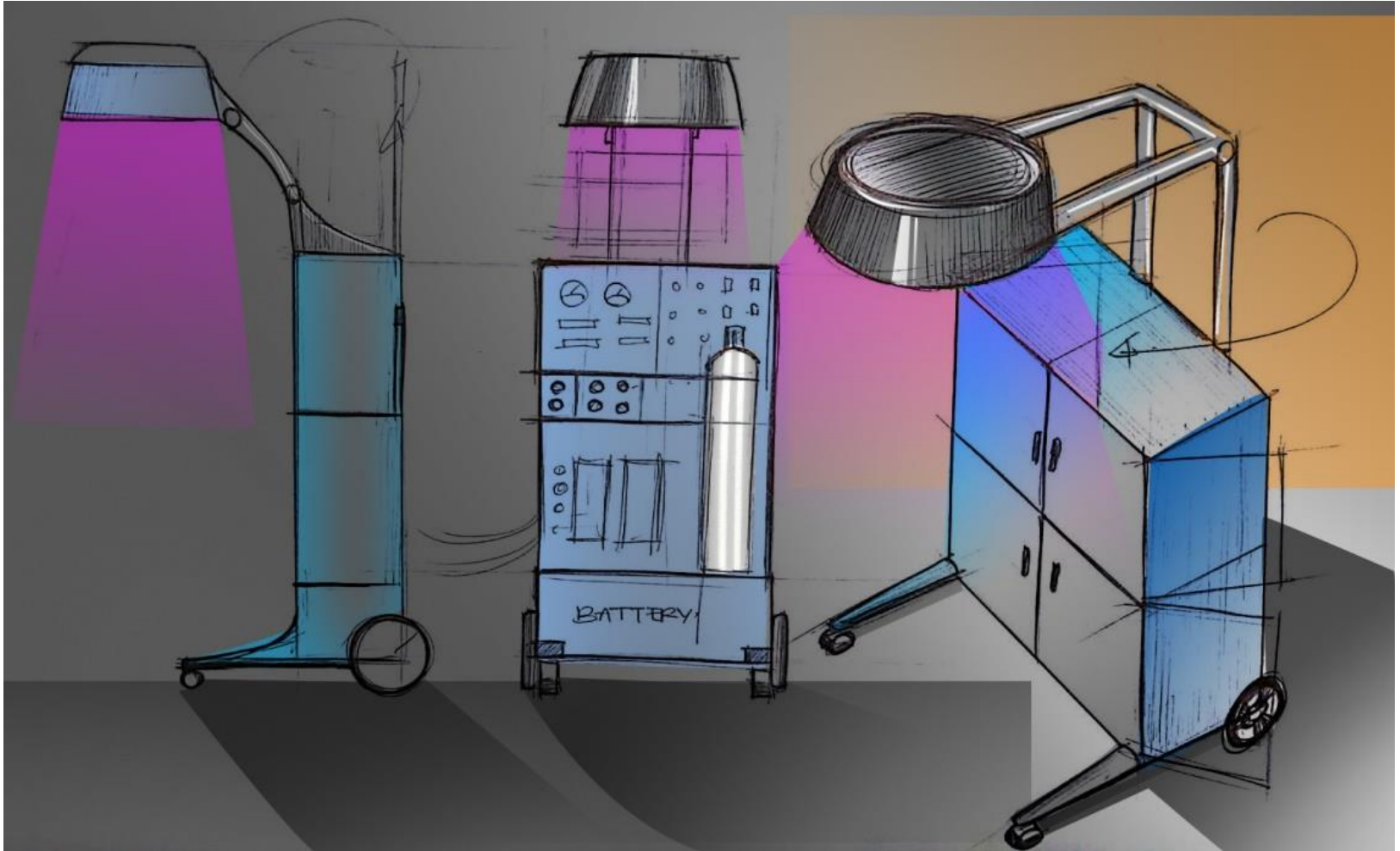
(Fig:8.2.1)

Ideation sketches



[Fig:8].2.2]

Ideation sketches

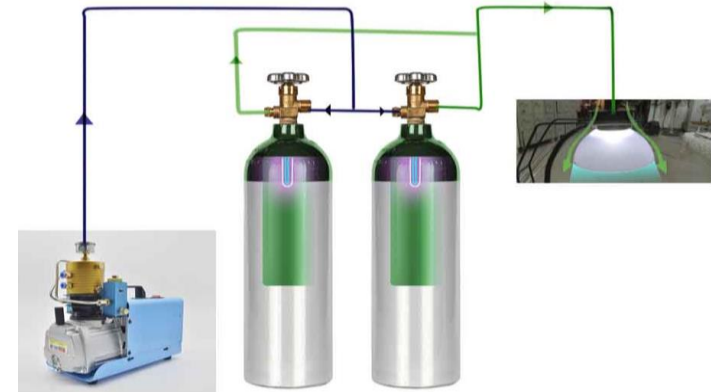


(Fig:8.2.3)

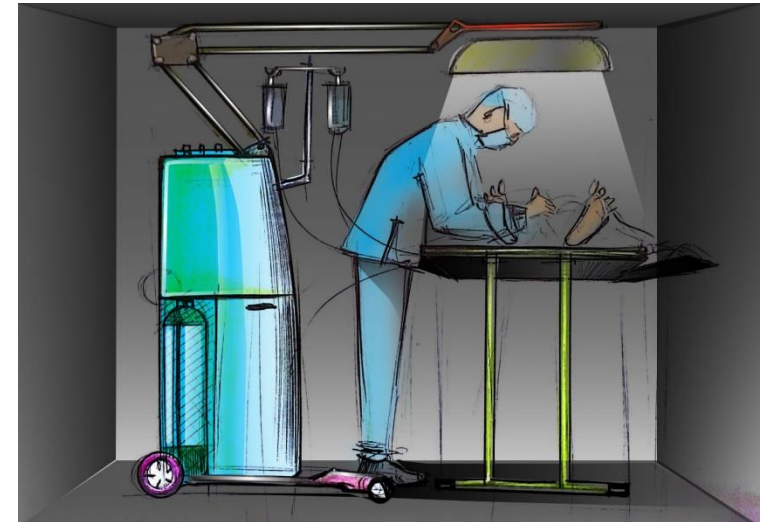
8.3 Air curtain using coanda effect

The sterile air source is the most important part of the design. Standard 0.68m³ medical compressed air cylinders can supply sterile air for around 15minutes. This can be used for short duration emergency medical procedures and also for Enucleation (eye extraction for eye donation) process. If the air cylinder get empties another cylinder can be connected for steady air supply so by the time if theirs a compressor the empty cylinder can be filled.

In (fig 8.3a) shows a easy way for sterling compressed air using UV C lamp mounted in the cylinder itself so a high pressure oil free compressor can be used for filling of air cylinders. The another ways to make sterile air using air filtration and feeding it to the device. This system will require power for its operation.



(Fig:8.3a)



(Fig:8.3b) Air source with light positioned above the patient

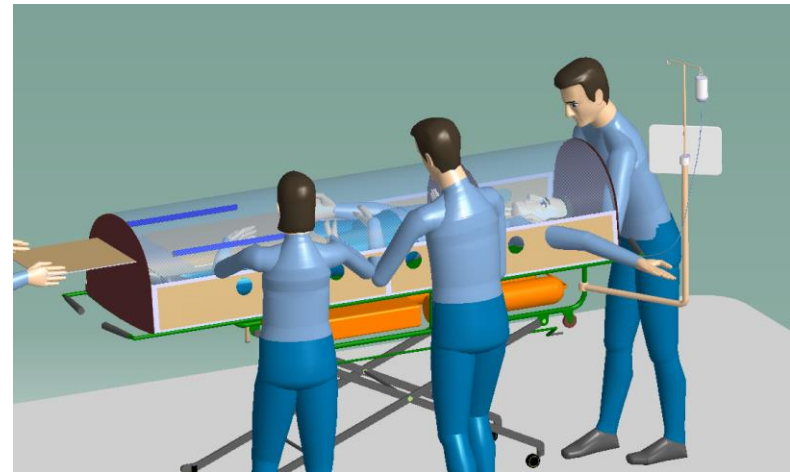
8.4 Concept 2

Glove box inspired design

- The procedure can be done with a setup similar to glove box or similar to the enclosure used for robotic surgeries.
- This ensure cost effective and efficient maintenance of sterile field .
- It could work well for few surgeries but difficult for gynecological surgeries .
- It restricts the doctors movement, that is the major drawback.



(Fig:8.4a)



(Fig:8.4b)

8.4 Real scale mockup model



(Fig:8.4c)

Opening for surgery

Inside the sterile field contains two layers the inner layer contains opening which is sealed. This could be stuck to the patients body after wiping the body of patient by antiseptics.



(Fig:8.4c)

Holes at the side for accessing inside the sterile field

Opening for head

Holes can be attached to the walls of the hood for inserting surgeons hands. Either gloves can be attached to it or positive pressure could be kept inside to avoid outside air entering inside.

8.4 Real scale mockup model



(Fig:8.4e)

The head of the patient is kept outside from the sterile field for easy access by anesthetist



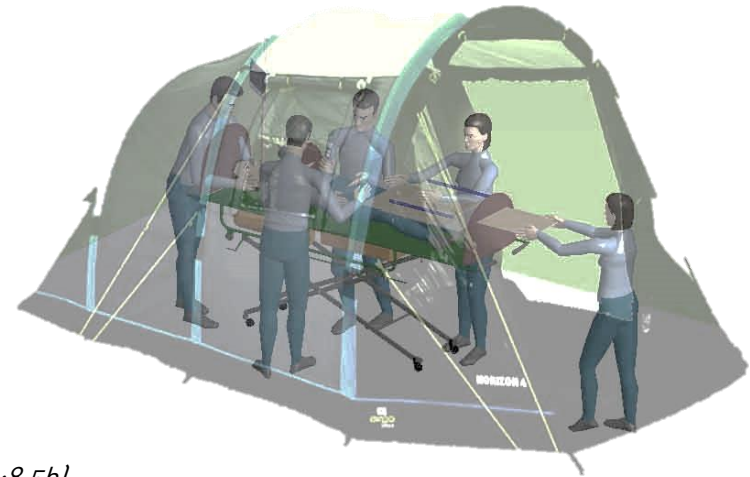
(Fig:8.4f)

The surgical tray and body of the patient excluding hand are kept in the sterile field

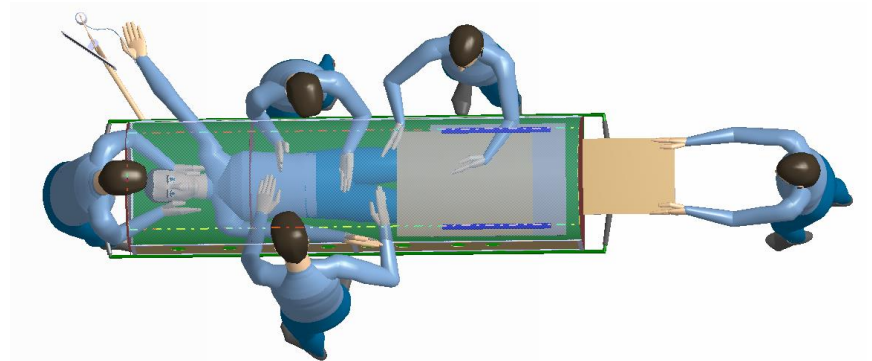
8.5 Concept 3

Glove box& Tent combined design

In the design of the features of tent type design and glove box type design is combined.



(Fig:8.5b)



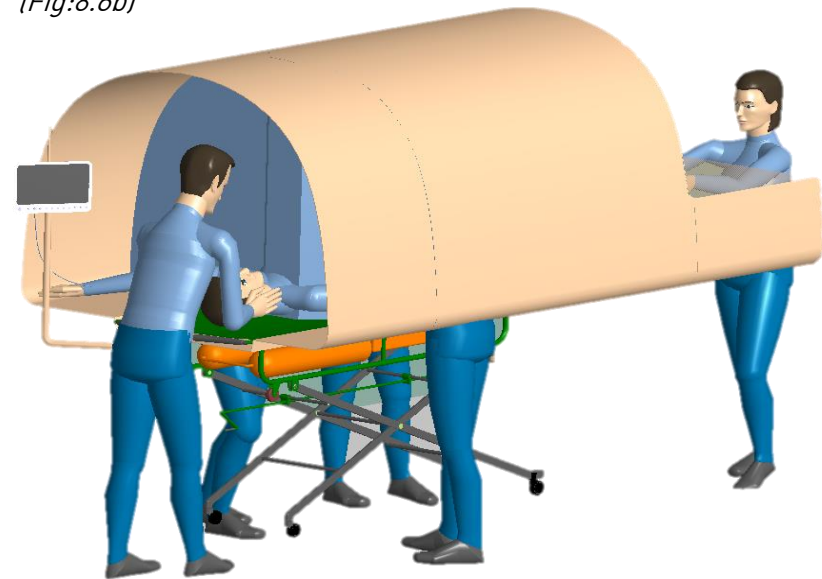
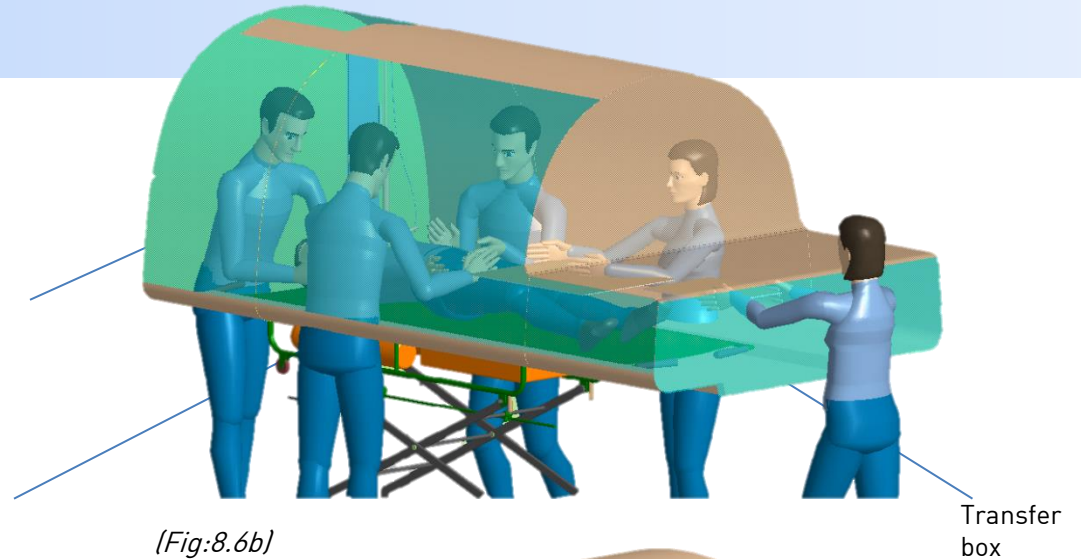
(Fig:8.5b)

8.6 Design features

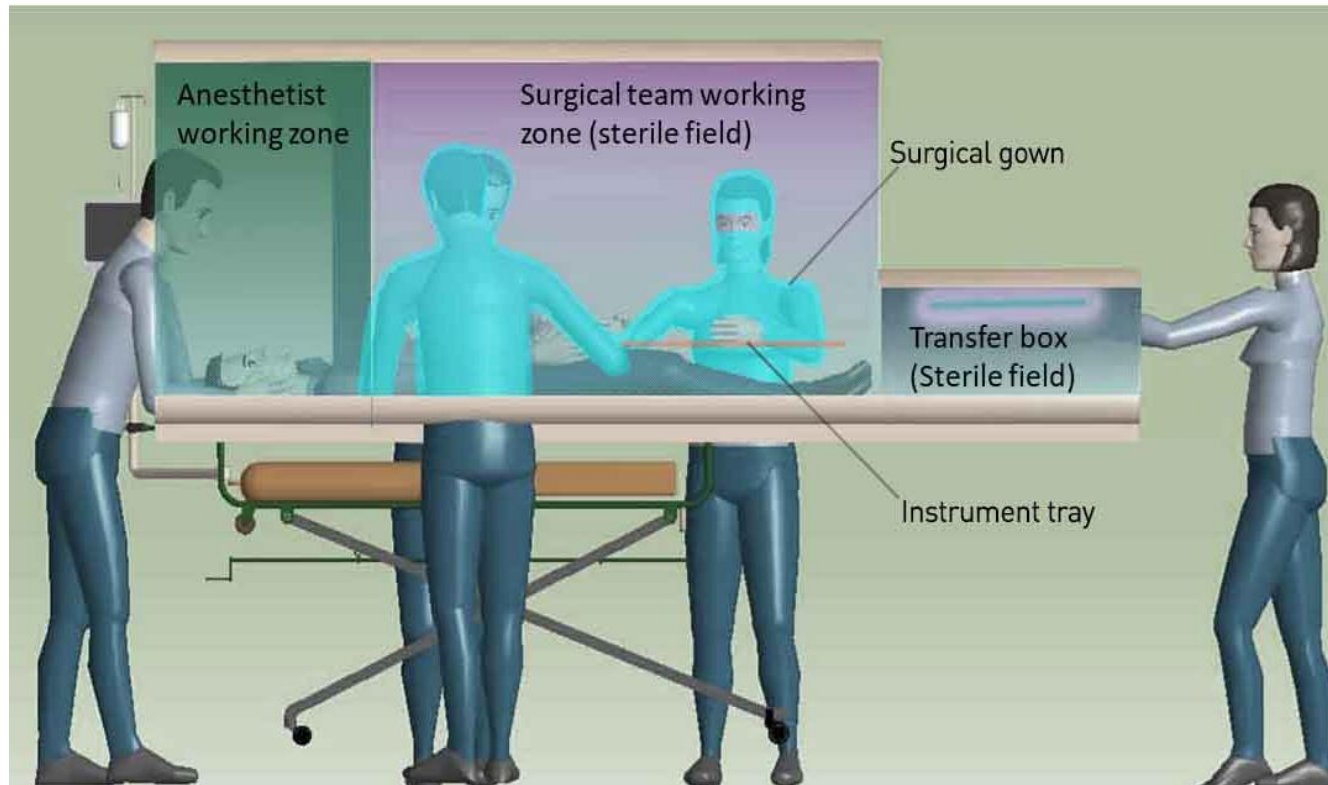
- A contained sterile field is created as shown in the figure.
- Surgical gown is attached inside there are holes entering to the surgical gown along the side of the enclosure
- Transfer box is there at the right end to take in and out materials or equipment's
- Transfer box is equipped with UV C lamps to surface sterilize the materials taken in and also to disinfect the space after procedure.
- The anesthetist space is separated and not coming under the sterile field
- Personnel in sterile field can be reentered the sterile field without spoiling the sterility in case of emergency.

Surgical gown

Holes for entering to the surgical gown fixed to the enclosure

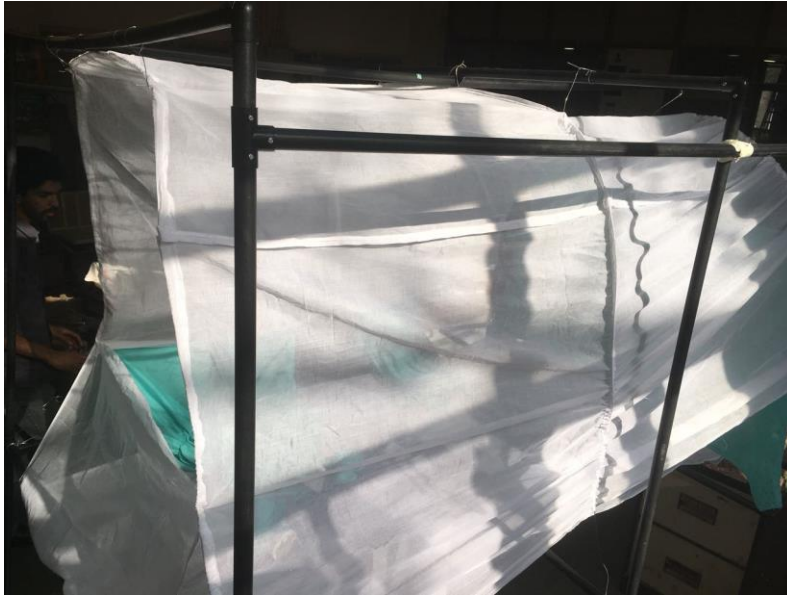


8.7 Zoning of the working space



(Fig:8.6b) The OR is divided to three zones according to kind of work executed and level of sterility

8.8 Test rig made to understand the ergonomic requirements



(Fig:8.8a)

The volume of sterile field was created to understand the ergonomic constraints.



(Fig:8.8b)

Instrument transfer and other common activities during the surgery were conducted.

8.9 Time motion analysis



(Fig:8.9a)



(Fig:8.9b)



(Fig:8.9c)



(Fig:8.9d)

Time motion analysis was done for the mock up model made and it took 36 seconds to get in to the sterile field in the 1st trail. After 3 trails it to approximately 22seconds to get in to the sterile field.

8.10 Concept Evaluation for sterile field

Concept No	Effectiveness of maintaining sterile field	Ease of surgeons to conduct the procedure	Reliability	Compatibility with different surgical procedures	Cost effectiveness	Total marks
1	6	8	4	8	7	33
2	8	5	8	5	6	32
3	8	7	8	8	8	39

Marks are given out of 10 according to the expert feed back

- The third concept which is a combination of tent and glove box is found most effective and reliable while considering reliability cost versatility in conducting different procedures etc.
- But concept 1 could be used of trauma care (the scenario 3 which is explained earlier)

9 Final design

*The final design is based on the 3rd concept for sterile space with the 3rd concept for portable OR Table.

9.1 Inspiration board

Portable



(Fig:9.1a)

Stable



(Fig:9.1b)



Light weight

(Fig:9.1c)



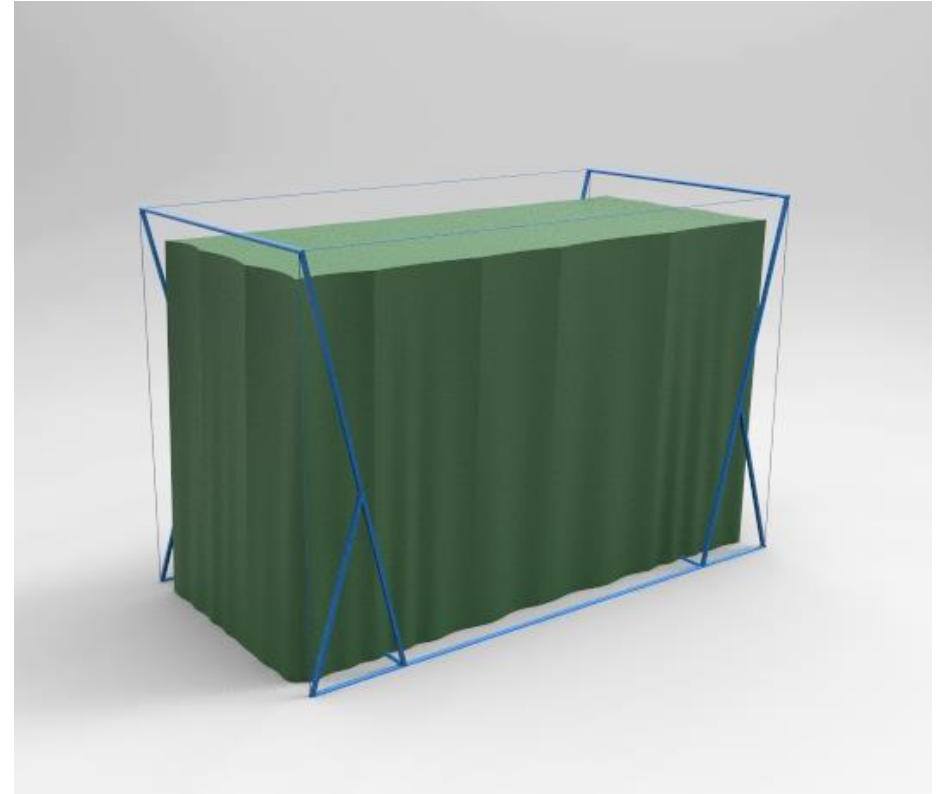
Elegant

(Fig:9.1d)

9.1 Concept 1

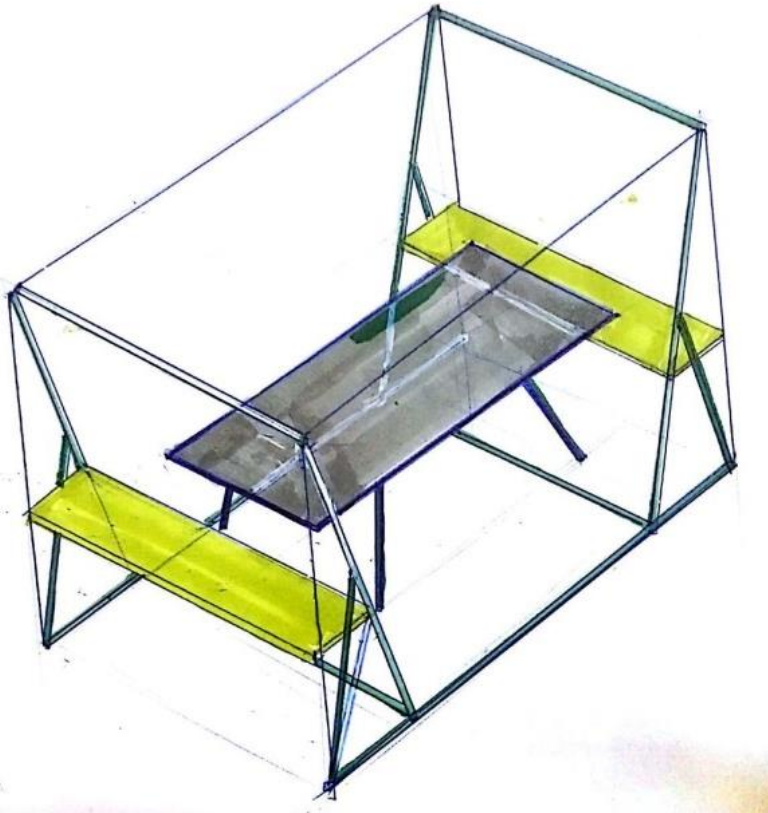
Rigid frame type design

- The enclosure is hung on the frame as shown in the (fig 9.1a) all the equipment's and instruments will be placed inside the enclosure
- The frame can be made with aluminium steel fibreglass rods or natural materials like cane, bamboo, paper tube etc.
- The frame is made simple and easy to be manufactured in local workshops or by craftsman's in the locality where the medical camp or the surgery will be conducted, this will help the team not to carry the tent at least. Such scenarios has been observed in the user study.



(Fig:9.1a)

9.2 Product sketches



(Fig:9.2a) The frame with table and benches for placing equipment's



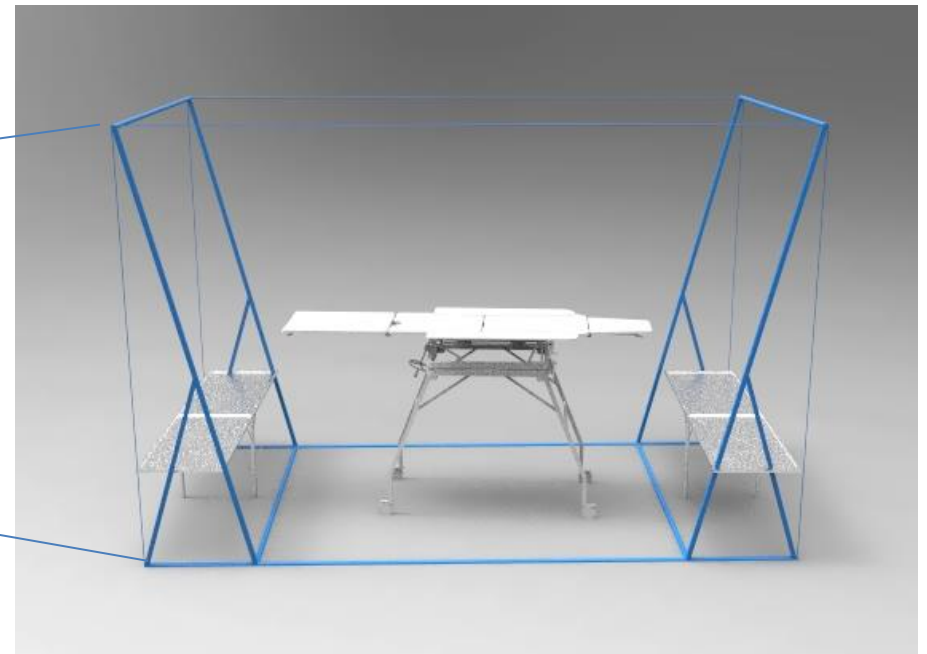
(Fig:9.2b)The inner sterile enclosure can be mounted inside.

9.3 Frame design

A frame is assembled where the OR table will be positioned at the centre of it., the entire frame can be folded in to a 20cm*15cm*15cm size bag. The total weight estimated is less than 10kg

Metal wire is attached to the base and flat surface for placing equipment's, this enhances the stability of entire structure along with facilitating the canopy to be hung.

It serves as a space for keeping the surgical equipment's and if more weight makes it more stable, its also detachable.



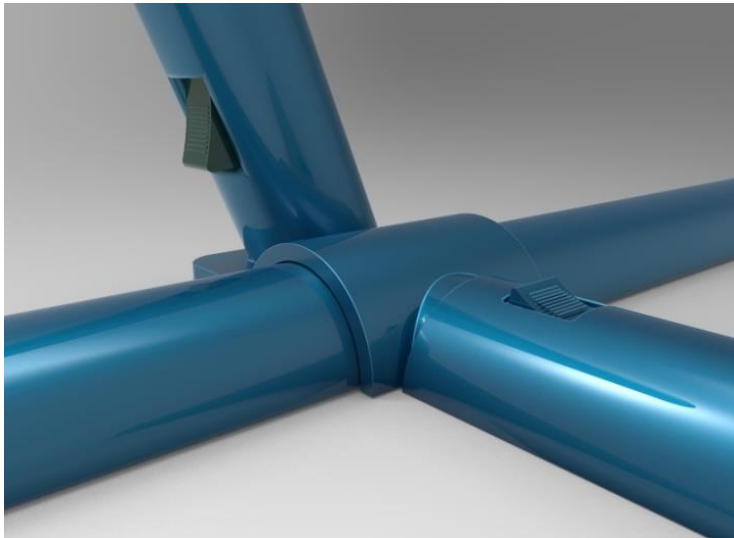
(Fig:9.3a)

9.4 Manufacturing & Assembly



(Fig:9.4ba)

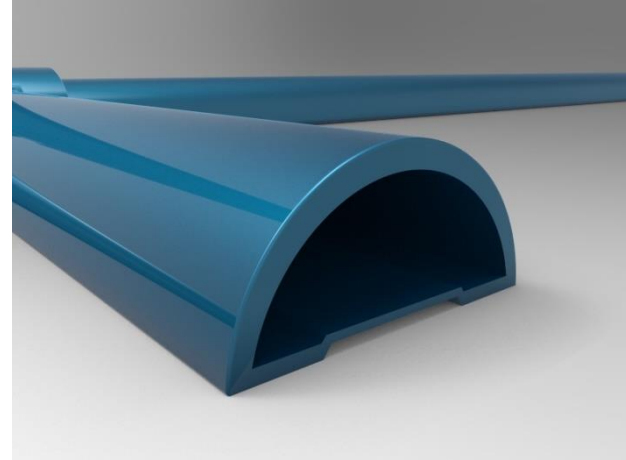
The joints are made by just pressing the in to the respective slots, to release push witches are provided on each joinery. both (fig 9.4 a,b) shows various joinery details.



(Fig:9.4b)

9.5 Manufacturing & Assembly

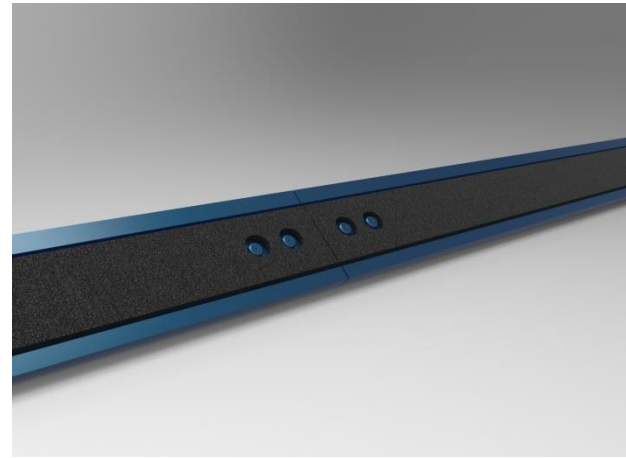
The base tubing's are made hemispherical to have good seating with ground and the OR table can rolled over it easily since due to the shape it will act like a ramp,. The hemispherical sections with the base slightly forming an edge enhances the strength of the section.



(Fig:9.5a)

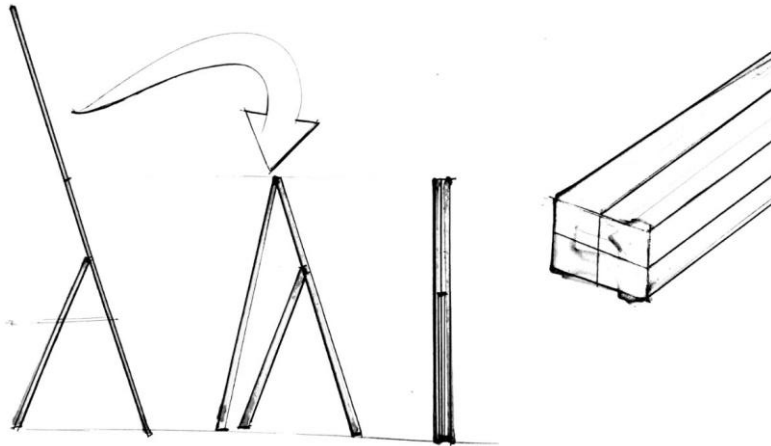
The bottom side of the hemispherical base tubes are designed with rubber lining, this ensure efficient grip and it compensates if the surface is un even.

All the joineries are riveted to connect to the min frame.



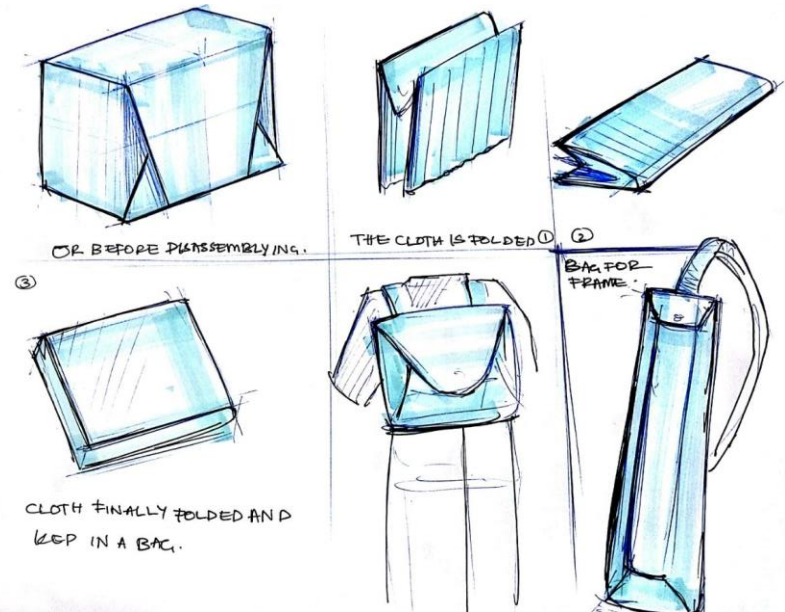
(Fig:9.5b)

9.6 Packaging and storage



(Fig:9.6a)

The frame can be folded and placed inside a bag



(Fig:9.6b)

The fabric can be separately folded and kept inside a backpack.

9.7 Concept 2

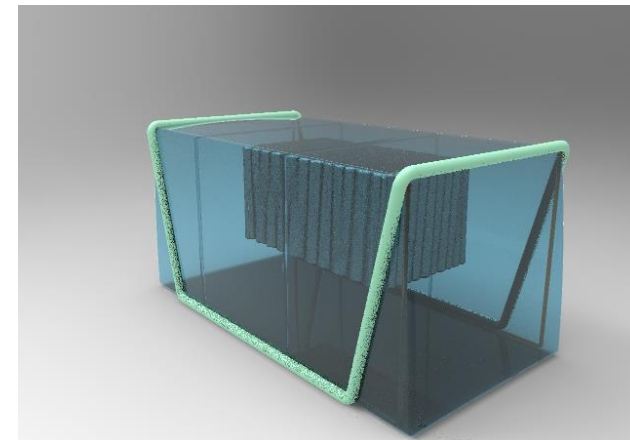
Inflatable tent

The enclosure is hung on the frame as shown in the figure all the equipment's and instruments will be placed inside the enclosure .



(Fig:9.7a)

The outer fabric enclosure is made transparent so the inner sterile field is visible. It will be hung inside and instruments will also be placed inside.



(Fig:9.7b)

9.8 Inflatable structures market study

The inflatable stents are very widely used for camping most of them are having an arch shaped roof that's mainly for resisting wind, also arch shape is structurally more strong. By stitching the airtight fabric in the desired form vertical horizontal or beams at any angle can be obtained. Its robust and easy to use since its not required assembled but inflated. Using a manual or electric pump.

Source: (Fig 9.8a,b,c,d)
<https://in.pinterest.com/>



(Fig:9.8a)



(Fig:9.8b)



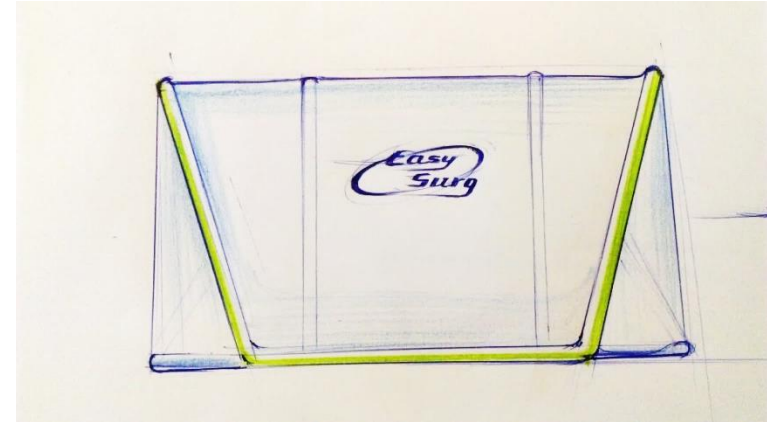
(Fig:9.8c)



(Fig:9.8d)

9.9 Design of inflatable structure material

The tent inflatable beams are made with TPU (Thermoplastic polyurethane) it's a hybrid material(made by a mixture between hard plastic and silicon) its extremely durable. Polyester or nylon fabric could be another choice of material for the tent material.



(fig 9.9e)

The (fig 9.9b) shows an antibacterial nylon fabric such fabrics will help in safe maintenance of the fabric for longer duration and reduce chance of contamination.



(fig 9.9f) source : <https://www.profabrics.co.uk>

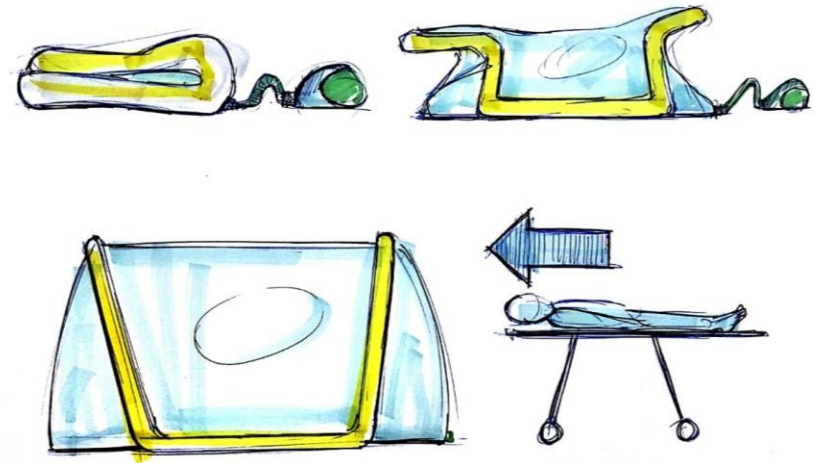
9.10 Manufacturing & Assembly



(fig 9.10a)



(fig 9.10b)

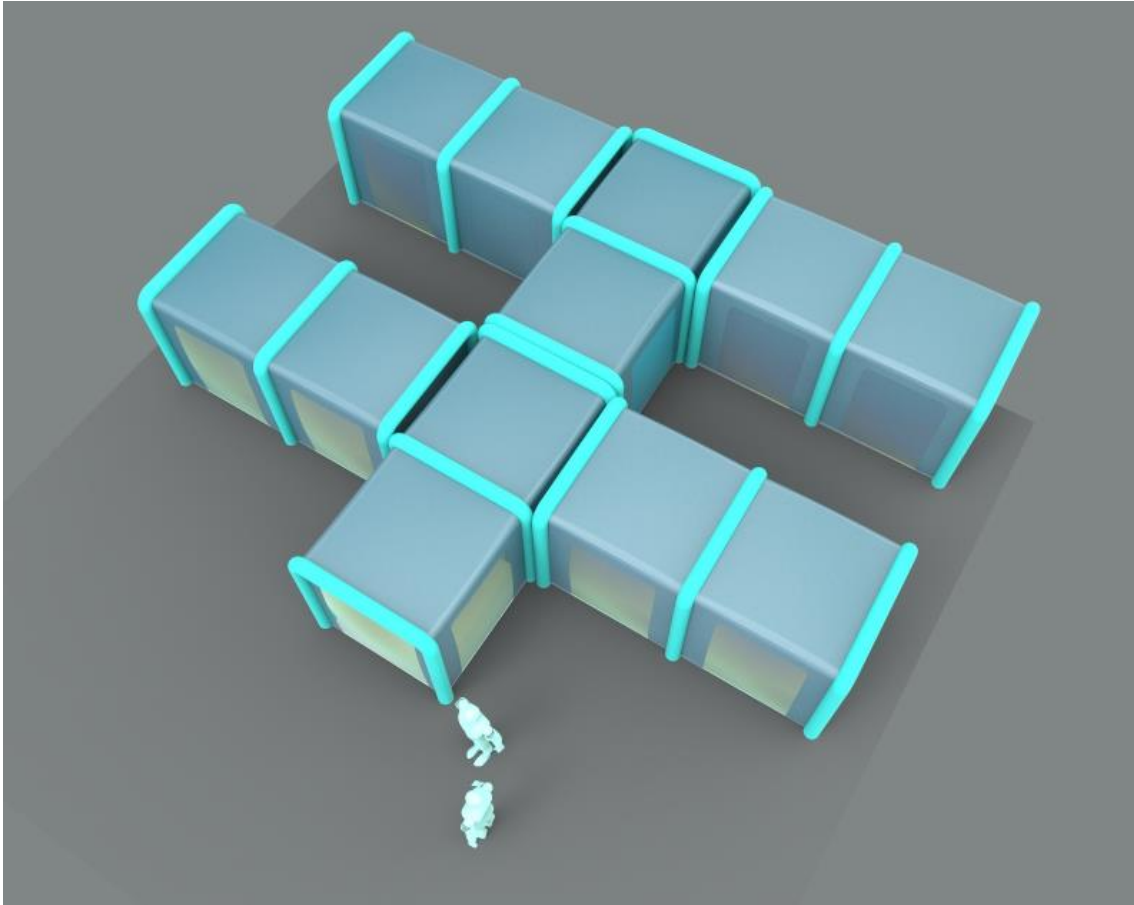


(fig 9.10bc)

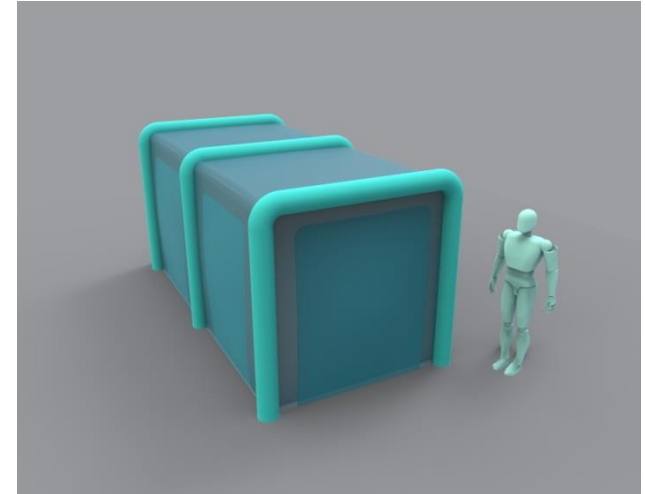
Tent inflation manual hand pump and automatic electric pump

Stages of inflation by electric or manual air pump

9.10 Manufacturing & Assembly



(fig 9.10d)



(fig 9.10e)

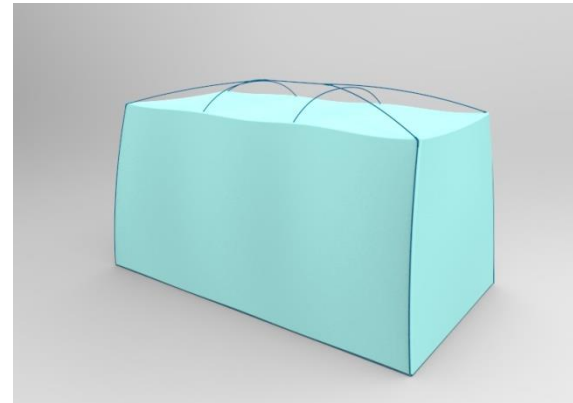
In the concept the outer structure consisting sterile enclosure is made inflatable such that it will be fitted in a backpack when deflated. Electric pump, hand pump etc. could be used for inflating it. Such units could be interconnected (left) thus forming an OR complex if required.

9.11 Concept 3

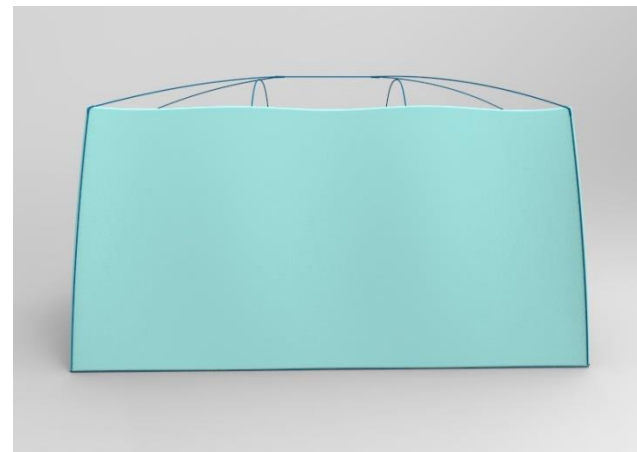
By joining flexible frame

In this design the frame for the enclosure is made similar to blind man support cane where an elastic band supports the members of the frame and when assembled its excellent in taking compressive loads. The inner enclosure is done similar to the previous one.

Nylon or polyester fabric can be used as fabric material. The frame material can be fiberglass rods which can be interconnected. Compared to stainless steel and aluminum fiberglass is far more flexible and equally strong.

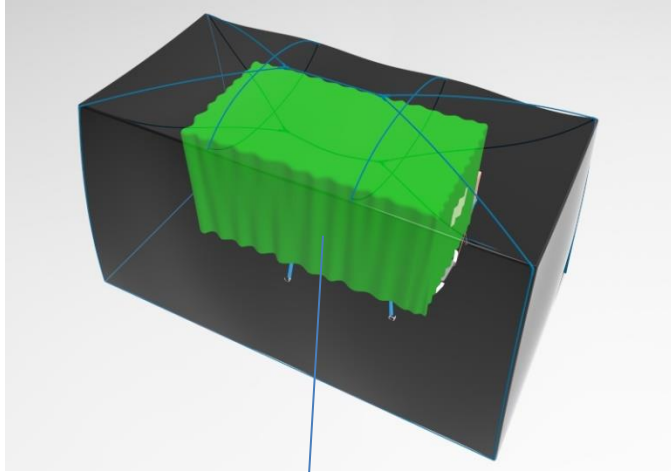


(Fig:9.11a)

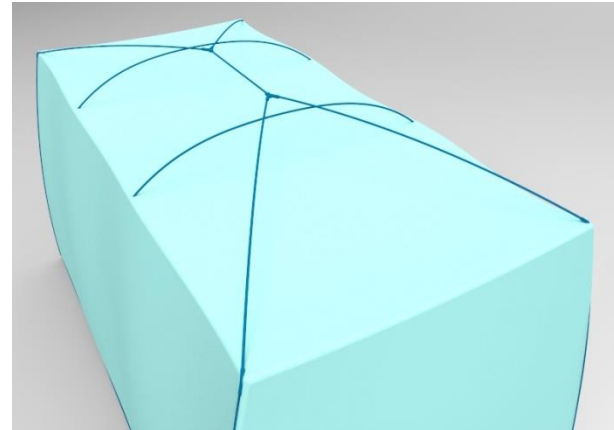


(Fig:9.11b)

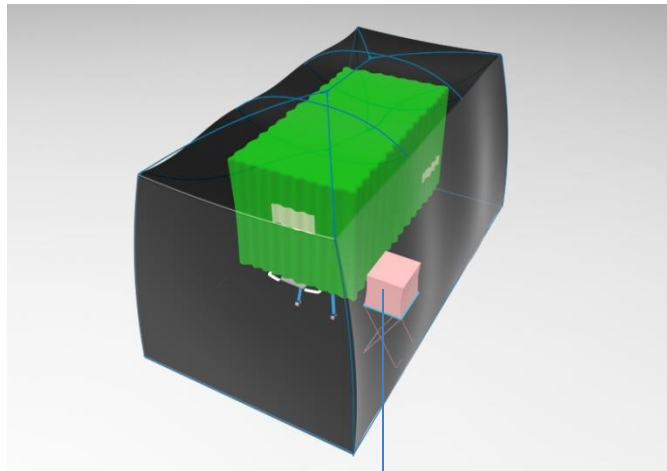
9.12 frame design and internal components



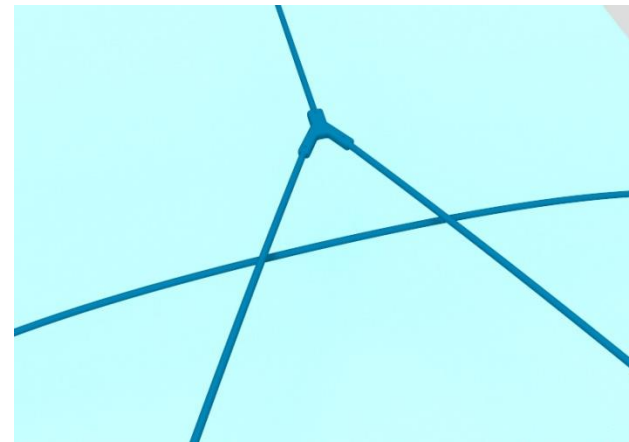
(Fig.:9.12a) the internal sterile enclosure is shown



(Fig:9.12b) frame work over the roof

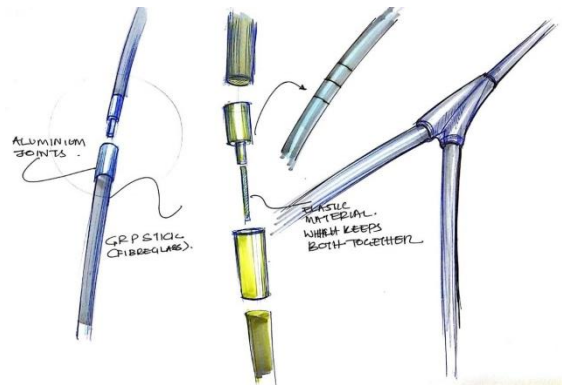


(Fig:9.c) location for keeping transfer box

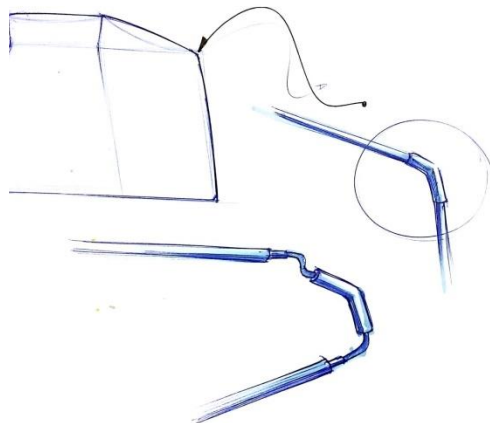


(Fig:9.12d) close-up of joinery

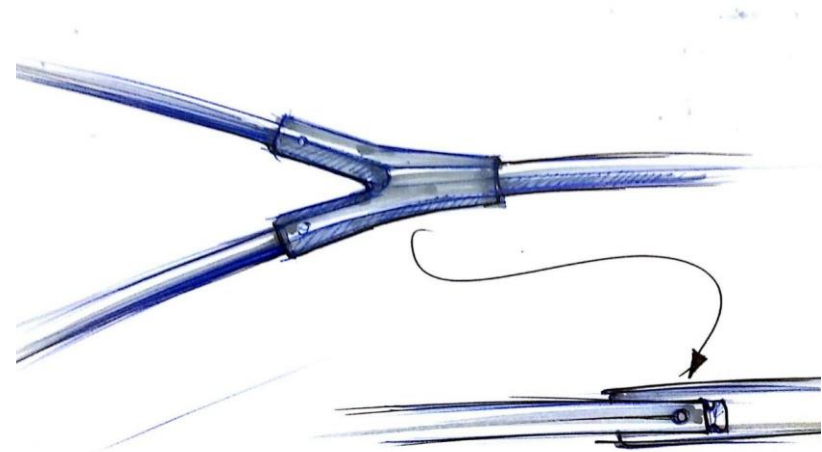
9.12 joineries of the frame



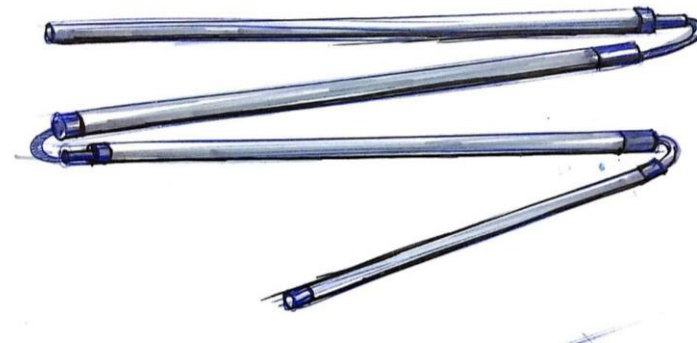
(Fig.: 9.12e) each joint will be like male to female coupling with elastic member inside



(Fig:9.12g) the joints were there's sharp turn an L shape joint is provided

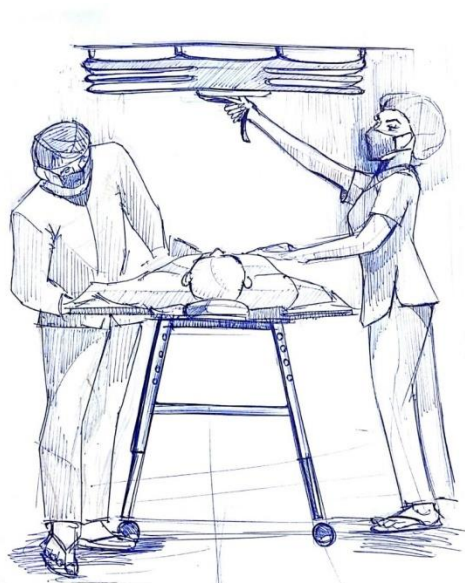


(Fig:9.12f) On the junctions where bars are connected have a push button type latch which locks the while connected

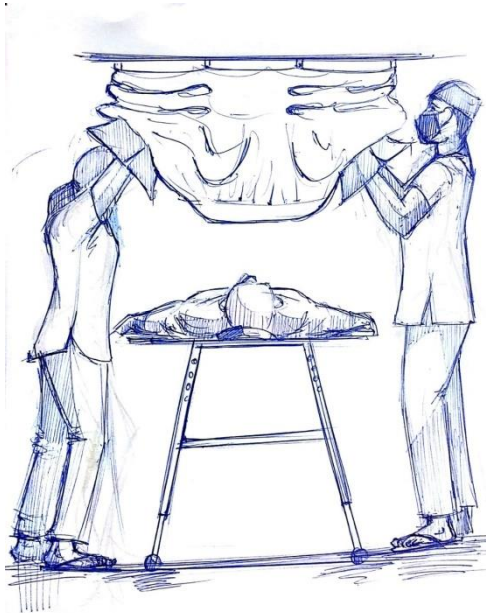


(Fig:9.12h) like the blind mans cane the entire frame can be folded and packed.

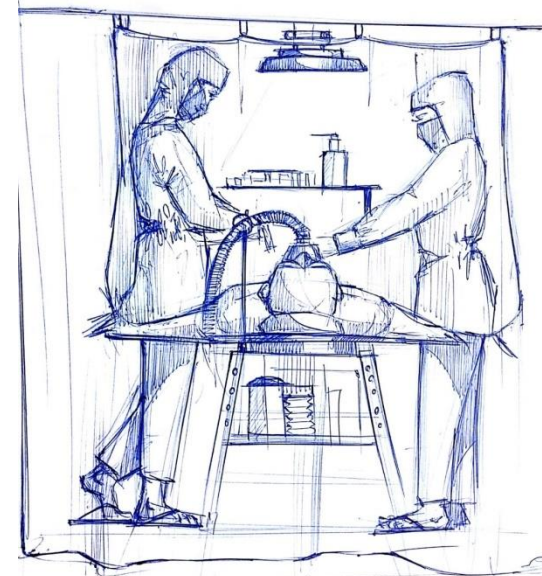
9.13 Installation of sterile space



(Fig:9.13a) Once the tent is inflated the inside sterile unit is connected to the ceiling of tent and the string which bind everything together is pulled down.



(Fig: 9.13b) after pulling the string the surgeon enters in to the sterile field through surgical gown mounted on the sides.



(Fig: 9.13c) The procedure can be started once the team has entered inside the bottom side of sterile enclosure has an opening which can be attached on the surgical side of the patient where surgery has to be done.

9.14 Concept Evaluation for sterile field

Concept No	Ease of installation	Ease of fabrication	Portability	Reliability	Cost effectiveness	Total marks
1	6	7	6	8	8	35
2	10	6	8	7	6	37
3	8	7	7	8	8	38

*Marks are given out of 10 according to the expert feed back

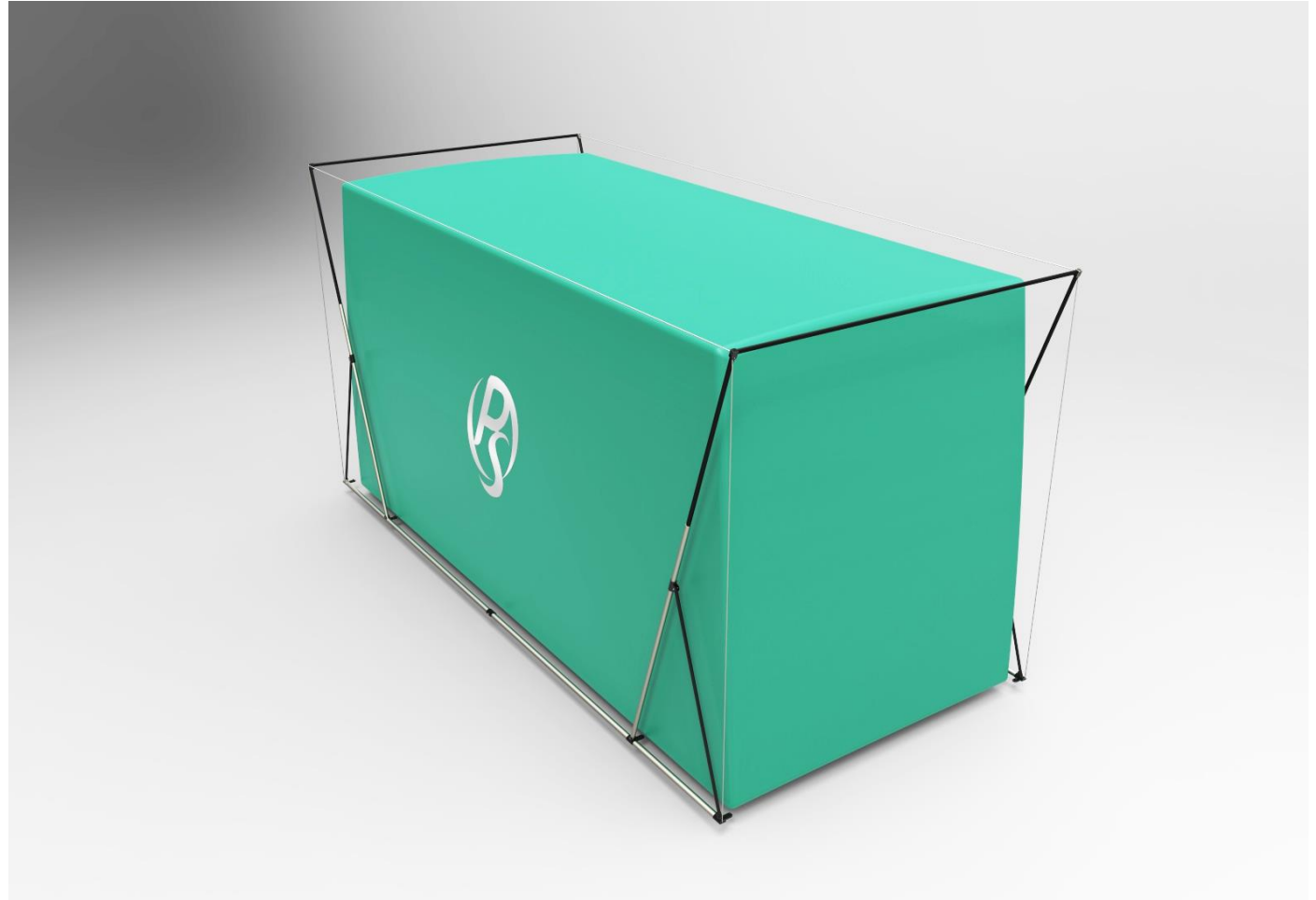
- Even if the second concept of inflatable OR was the most convenient one to use the other factors such as manufacturing and designing was found little difficult so the first concept using mechanical links are finalized, the design is easy to fabricate cost effective and reliable.

9.15 Final design after concept evaluation



Scan QR code to watch the
assembly video of portable OR

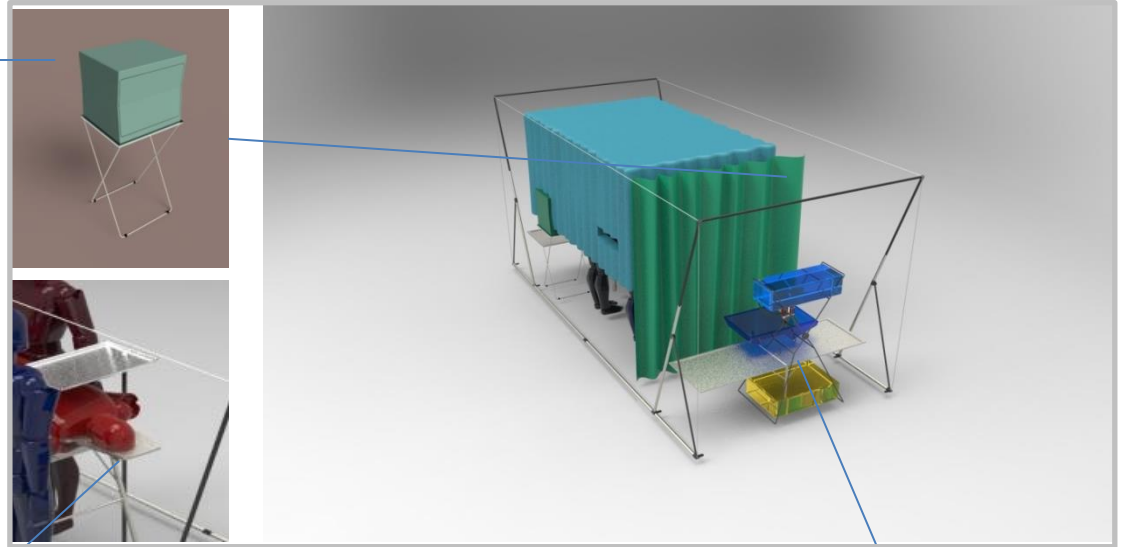
(Fig: 9.14)



9.15 components of final design

Instrument transfer box for storage of surgical instruments, the instruments can be accessed by the surgical team from the sterile enclosure.

Instrument tray is positioned inside the sterile enclosure



(Fig: 9.15a)

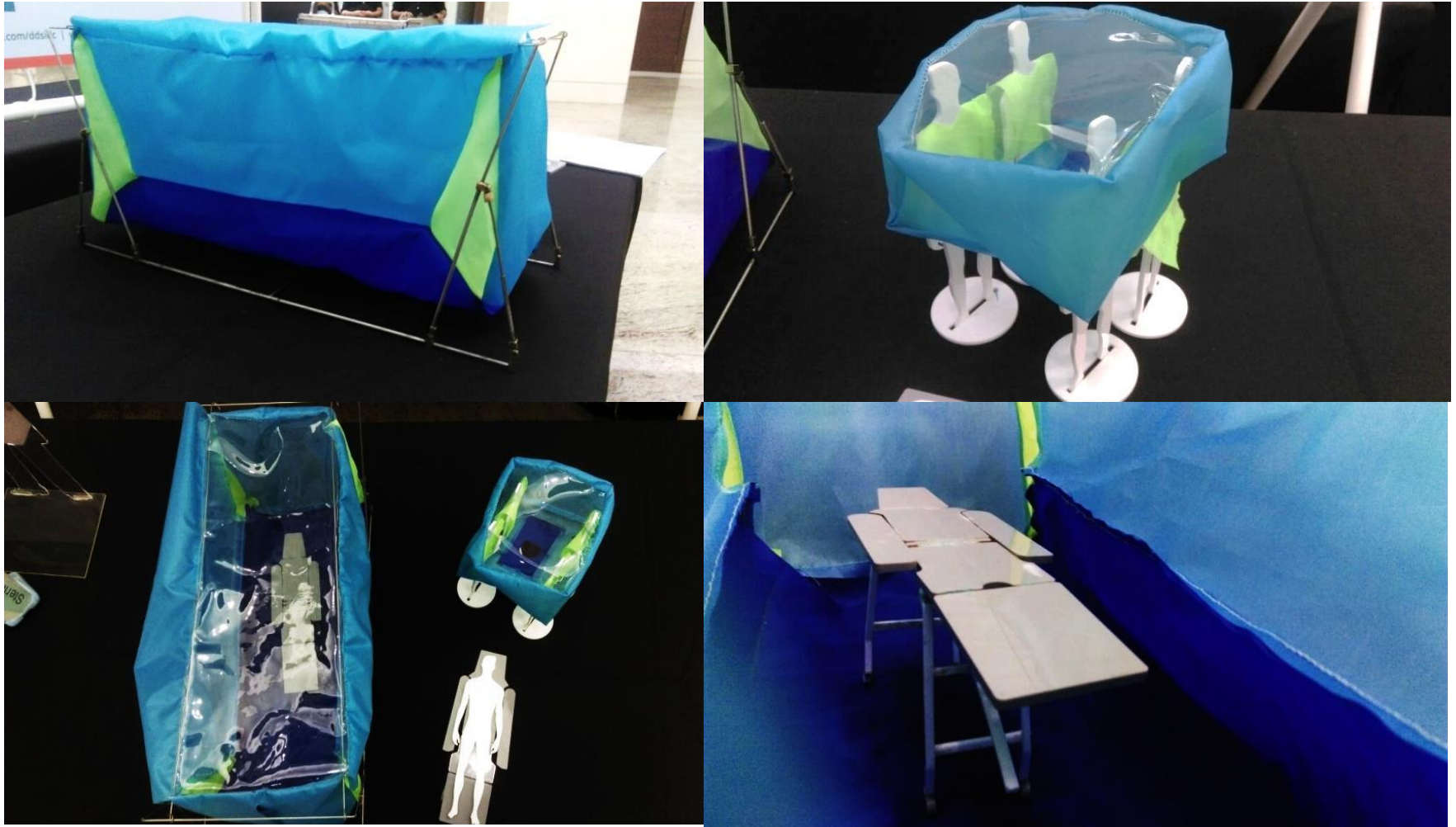


Curtain for separating the scrubbing area

Portable scrubbing unit contains water and chemicals for sanitizing hands of surgical team.



9.16 1/10th scale model developed



(Fig: 9.16a)

9.17 Engineering drawings of Operation table

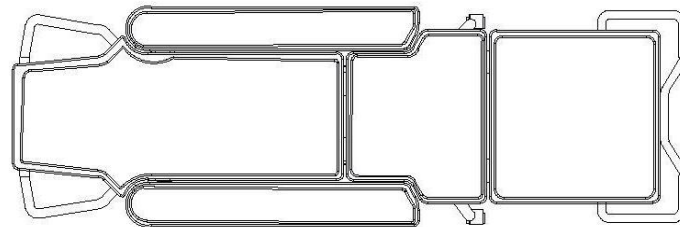
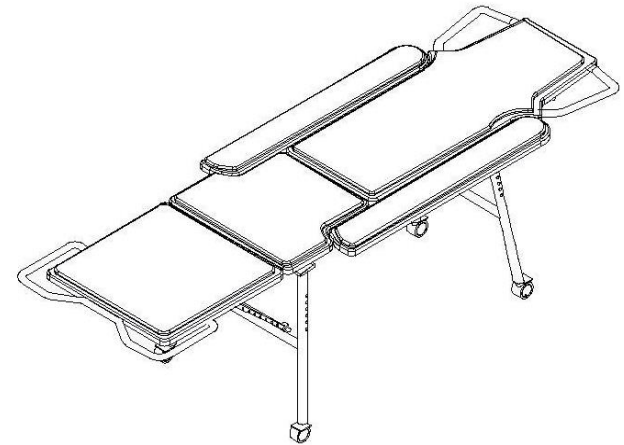
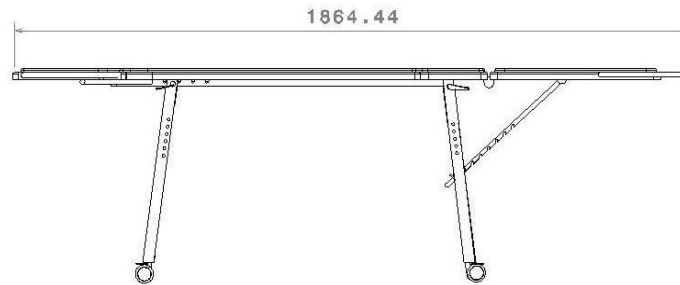
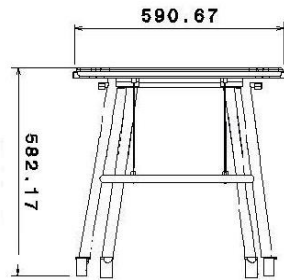
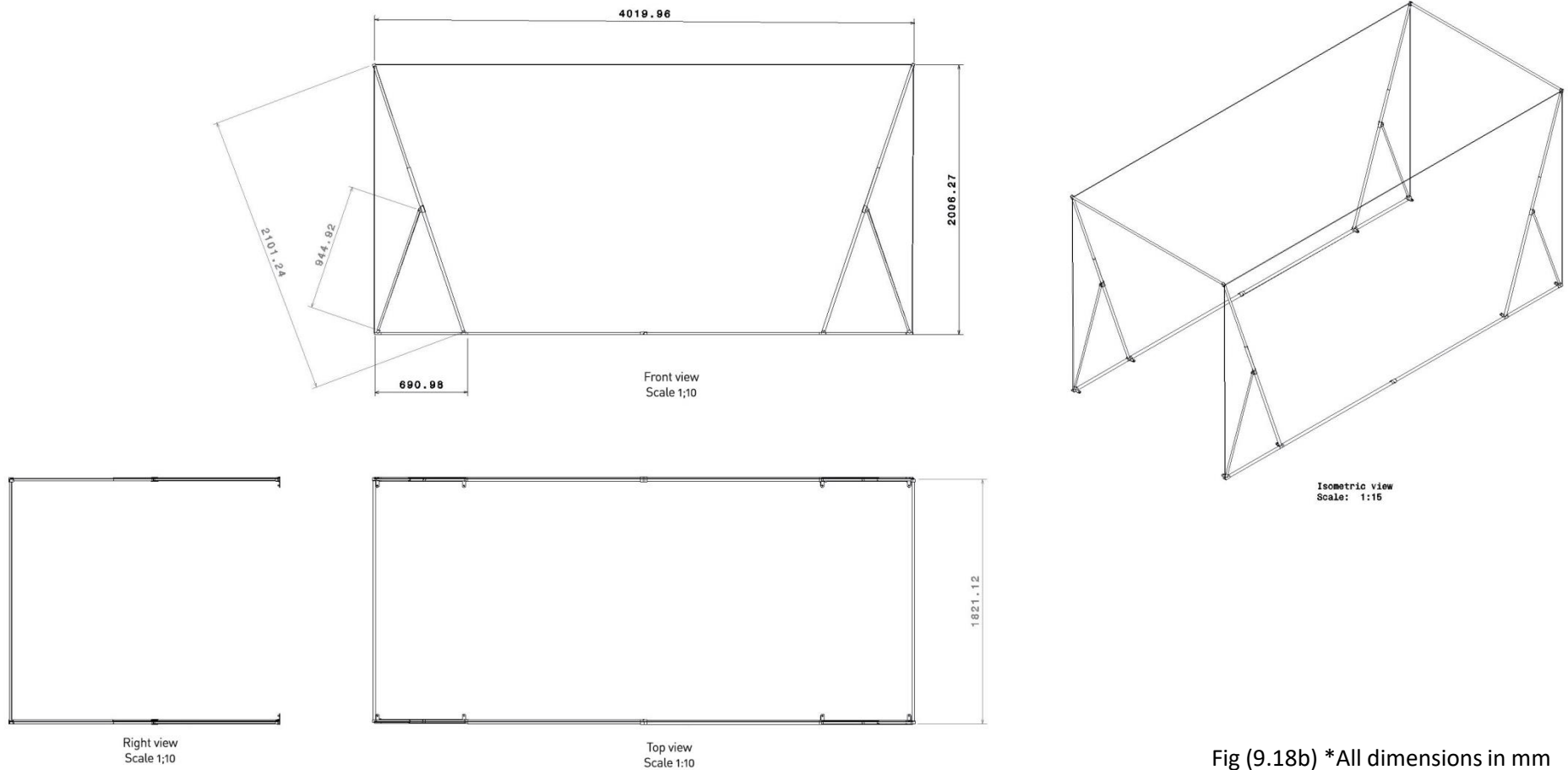


Fig (9.17a) *All dimensions in mm

9.17 Engineering drawings of sterile field frame



10 Conclusion

Overall the project was an eye opener for me to understand about the healthcare needs in the country. It also made me aware of the importance and the scope of design intervention in this domain. The systematic approach towards problem solving through the design process has helped me to collaborate various ideas and to come up with the optimal one. The project also gave me a deep insight on design optimization for manufacturing.

The final design was discussed with the doctors and other medical personnel working in this domain the feedbacks were quite satisfying. Its actual effectiveness and scope for improvement can be more understood after prototyping and testing of the product. If the design proves to be successful as expected it would be a great leap in making healthcare affordable for millions.

Reference

- Fig: (1.a) <http://www.shiranetoku.jp/kangobu/departments/gairaiyoteihyou/>
- Fig: (1.1.a) <https://i.pinimg.com/474x/cf/04/82/cf04824aa640accc6058748a5b402e6a--nurse-scrubs-scrub-nurse.jpg>
- Fig : (1.3.a,b,c,d) <https://immexls.com/the-four-basic-classifications-of-surgical-instruments/>
- Fig: (1.4.d) <http://mib-medlab.com/wp-content/uploads/2018/01/OP-8600.jpg>
- Fig: (1.5a,c,d,e,f,h) <https://blu-med.com>
- Fig : (1.7a,b) <https://www.surgibox.org/>
- Fig : (1.8a,b) Patient No: EP2413018
- Fig : (1.9a,b) Pub. No.: US 2002/0045796
- Fig : (1.10a,b) Pub. No.: WO2010/105005
- Fig : (2.1 a) <http://lokbiradariprakash.org/>
- Fig : (2.1 b) <https://org.elon.edu/>
- Fig : (2.1 c) https://en.wikipedia.org/wiki/Sanduk_Ruit
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- Fig : (2.3 a,b,c,d) <https://www.youtube.com/watch?v=ukuWCeINchw&t=2s>
- Fig : (2.4 b) <http://jamkhed.org>
- Fig : (2.5 a) <http://www.nagajournal.com>
- Fig : (2.5 b) http://www.vfp62.com/odds_and_ends_5.html
- Fig : (5.1 c) <http://www.kainternational.co.in>
- Fig : (6.1 a) <http://www.futurehealthconcepts.com>
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- Fig : (9.1 b) <http://www.videezy.com/free-video/spider-web>
- Fig : (9.1 c) <http://www.pinterest.com/pin/53832158023502626/>
- Fig : (9.1 d) <https://www.pinterest.com.au/pin/325174035587799890/?lp=true>
- Fig : (9.10 a) <https://www.kampa.co.uk/accessory/gale-electric-pump>
- Fig : (9.10 b) <http://www.gooutdoors.co.uk/hi-gear-push-pull-pump-including-pressure-gauge-p287530>