Self sterilizing surgical instrument tray

MRP 470

Industrial Design Project- 2

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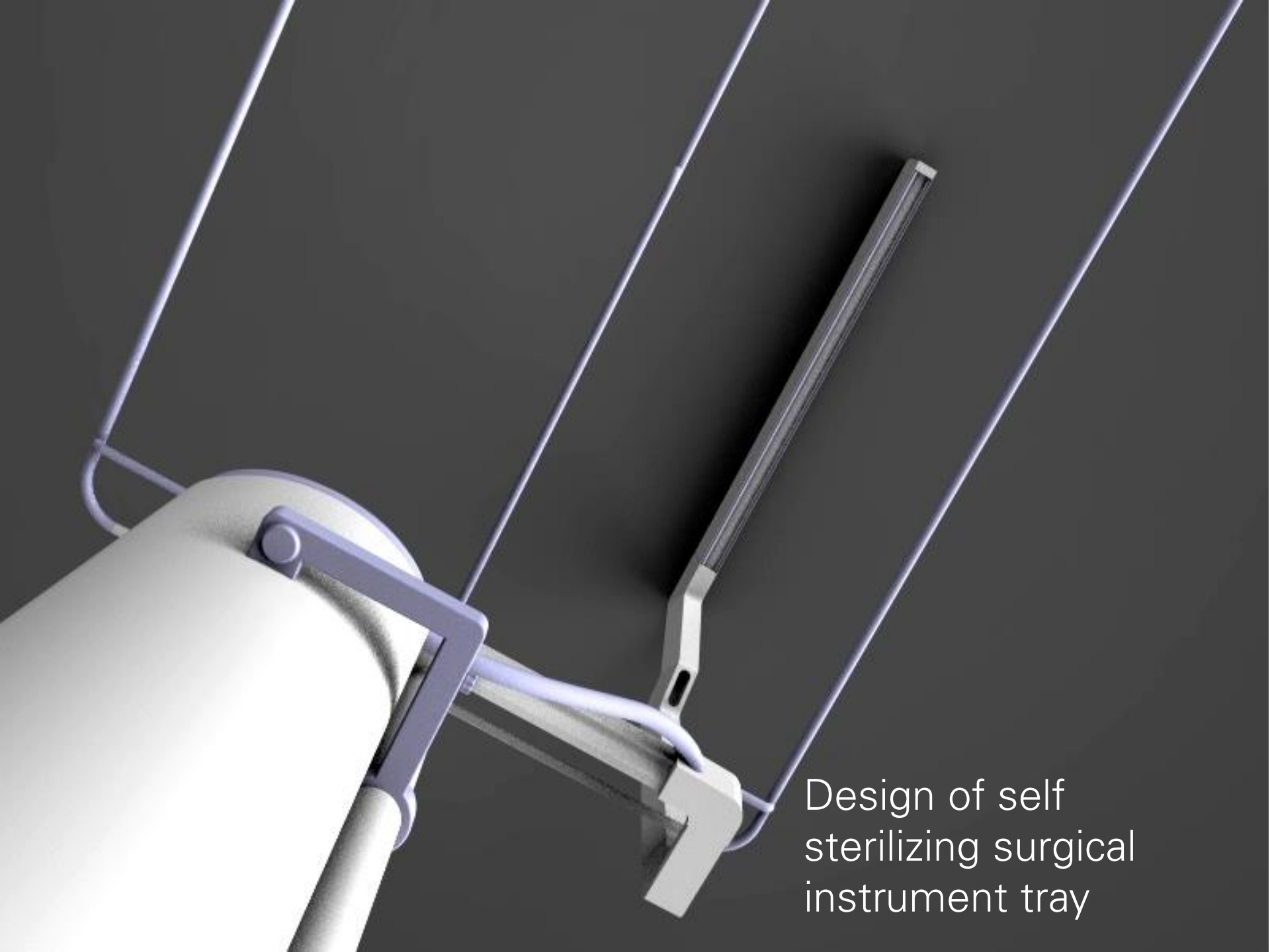

Design of self
sterilizing surgical
instrument tray

Acknowledgment

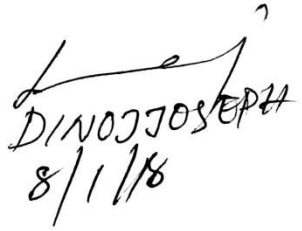
I take this opportunity to thank the entire faculty at IDC school of design for the inputs that helped me successfully complete this project.

I express my gratitude to my guide Prof. Vijay Bapat for his consistent support and guidance in this project.

The Feed backs I received at every stage of the project were immensely helpful and it allowed to look at a wider perspective of the project.

I like to thank BETiC team IITB and Dr Bansali for the immense help in knowing the practical aspects of the project.

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



Contents

*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

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Key definitions

- **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.
- **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.
- **DISINFTECTANTS :** A chemical used on non-vital objects to kill surface vegetative pathogenic organisms but not necessarily spore forms/ viruses.
- **ACH**: Air change per hour(measure of the air volume added to or removed from a divided by the volume of the space)

Introduction

"Can the surgical instruments maintain the quality sterilization throughout the surgery", The whole idea of self sterilizing surgical instrument tray started from these words of laparoscopic surgeon Dr.Bansali.

A study conducted by Normedtec shows almost 70% of bacteria found in the patient's wounds come directly or indirectly from the instruments. In India alone it's estimatedthat10 – 22% of all Hospital acquired infections(HAI) are from Surgical site infections(SSI) this increase the post operative care of patient by 5 - 18 days. This usually adds up 30% extra cost compared to normal treatment and no authentic data is available in India regarding SSI. Most of the India Operation rooms(OR) which doesn't adhere to effective decontamination procedure the SSI rates can even be higher Even if the instruments are sterilized before they are brought to OR once they are kept open for the surgical procedure theirs a high probability of getting the instruments contaminated due to air bone microbes during the procedure.

Surgical site infection(SSI) is a type of healthcare-associated infection in which a wound infection occurs after an invasive (surgical) procedure. On various studies conducted in different OR different bacterial colonies have been found and this was responsible for most of SSI. So a system which maintains sterility of surgical instruments is very essential through out the procedure will bring down the SSI rates and.

Design Process

Design process cant be fruitful with out design insights at each stage, so this thought bubble contains my design insight at each stage

Empathy
Understanding the need of user through research

- **Empathy**
  - Understanding the need of user through research
- **Analyze**
  - Processing research inputs to obtain design directions
- **Imagine**
  - From possible solutions to solid concepts..
- **Evaluate**
  - Mockups for quick user feedback
- **Final Design**
  - Building final prototype

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 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.

(Fig:1.1)A modern Operating room.

Design should be functional and should aesthetically suit to modern OR

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*

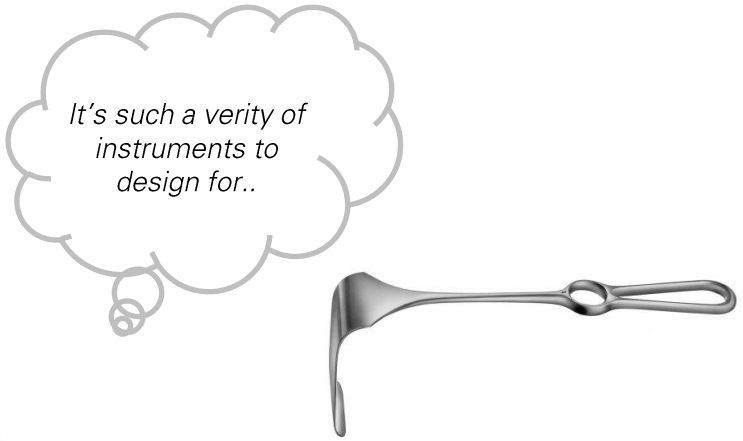
Surgical instrument classification

a) Classification based on function

(Fig:1.2a)
Cutting and Dissecting

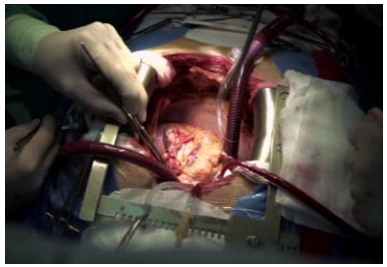
(Fig:1.2b)
Grasping and Holding (used to grasp and hold tissue or blood vessels that may be in the way during a surgical procedure) eg Forceps. Allis Tissue Forceps

(Fig:1.2c)
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:1.2d)
Retracting and Exposing (used to hold back, or retract organs and tissue so the surgeon has access to the operative area)

*Surgical instruments are specially designed tools that assist health care professionals carry out specific actions during an operation. There are precision instruments used in microsurgery, ophthalmology and otology. Figure 1.2a-1.2d shows different type of surgical instruments classified based on function



(Fig:1.2f)
Surgery were retractors being used.

b) Classification by Earle H. Spaulding classification based on level of sterilization required for patient protection.

The main aim of the design is to keep the critical instruments sterile

Critical items(These include any item that enters or touches sterile tissues, the vascular system or bodily fluids like blood. This includes surgical instruments, catheters, implantable sensors and other equipment used inside a patient.)

Critical

(Fig:1.3a)

semi-critical(item comes into contact with mucous membranes but is not used inside sterile tissues, usually a high level of disinfection will be enough) e.g. anesthesia equipment, some scopes (endoscope) and temperature probes.

Semi-critical

(Fig:1.3b)

Non critical items(do not come into contact with mucous membranes but touch intact skin) e.g.: blood pressure cuffs, surgical beds and stereotaxic frames

Non Critical

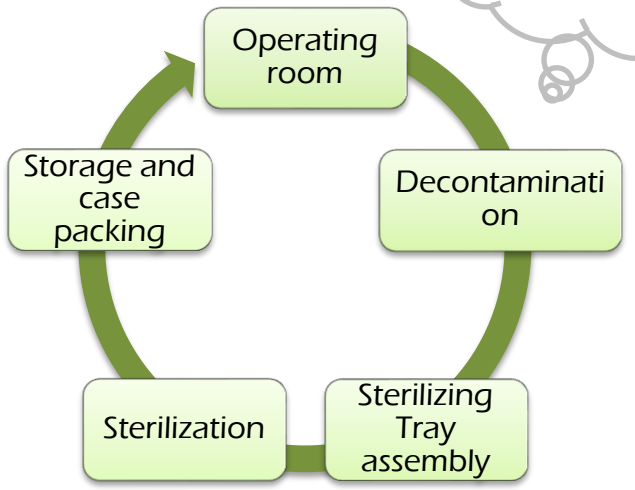
(Fig:1.3c)

Figure 3a-3c are examples of surgical instruments based on level of sterilization required .
Source::condor med

Sterilization cycle of surgical instruments

Its this hard it make it sterile but its very easy to lost its sterility

Each instruments are Instruments after sterilization is stored in OR sterile storage area in sterile supply departments (CSSD), theater sterile supply unit (TSSU) . Usually it is kept in plastic or steel containers in the same autoclave wrappings or sterile boxes. Each instrument used for a certain surgical procedure undergo a life cycle of events which starts from OR its detailed below.



(Fig:1.4a) sterilization cycle of surgical instruments

Operating room : the surgical instruments arrive at operating there with cont. sheets detailing the quantity of instruments, type and exact order of the instruments. After the completion of surgery the OR staff counts the counts send and un used instruments and records in the count sheet then its carried to decontamination area. But in small hospitals surgery's carried out will be similar and less number of surgeries will be performed so the instruments are separated according to ease of autoclaving after decontamination and stored inside OR itself.

Decontamination: In this process the blood and tissue from the instruments or from the trays are removed then its cleaned manually or mechanically soap solution and chemical disinfectants are used in the process. Decontamination process doesn't sterilize the instruments but it makes safe for the satirize processing department (SPD) personnel to handle the instrument and ease the process of sterilization

(Fig:1.4b)

Decontamination process using forming spray which acts similar to dishwashing liquid.

Sterilization cycle of surgical instruments Cont...

.***Sterilizing Tray assembly**: the instruments are assembled in special tray according to each procedure and they are wrapped and autoclaved or in some cases instruments are simply placed in cloth wrappings and sterilized.

Sterilization: After tray assembly the SPD technicians place the instruments in sterilizer in large satirizers they are kept in special racks inside the sterilizer. For sterilizing the instruments correct method duration of sterilization etc. to be followed or else it may affect the patient safety or can damage the instruments .

(Fig:1.5a)

CSSD staff preparing instruments for autoclaving

Storage and case picking: After sterilization, trays are stored in a store room area usually near to OR in small hospitals kept inside OR itself. Surgical sets may sit in storage for a few days or for as long as two years. When instruments are required, the OR indicates what trays and other items are needed for an operation on a pick list. The OT staff pick the trays/ instrument bundle from the store and moves it to OT along with case carts to the OR and the instrument life cycle starts all over again.

(Fig:1.5b)

Instruments stored in sterile storage facility Source: southwest solutions

Surgical instrument tray

The tray contains sterile consumables and surgical instruments, so can they be separated.

It's an instrument in which holds the surgical tools or other instruments that is expected to be required to complete a scheduled surgical procedure, usually those tray stands are placed in surgical instrument tray stand or trays will be fixed pertinently on the stand.
The main three types of trays used in *general surgical procedures are detailed in fig(6)

(Fig:1.6) A typical gastrointestinal laparoscopic surgical instrument tray before surgical procedure. The tray will be usually made of stainless steel or normal steel with paint coated. And only sterile items will be placed on the tray. The instruments are kept at one side(left side in the picture) and other consumables like sterile cotton, gloves, specimen trays, disinfecting solutions etc. are kept at the other side(Right side of the tray)

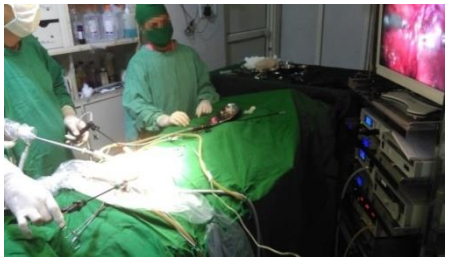
*__General surgery__ is a surgical specialty that focuses on abdominal contents including esophagus, stomach, small bowel, colon, liver, pancreas, gallbladder, appendix and bile ducts, and often the thyroid gland (depending on local referral patterns). They also deal with diseases involving the skin, breast, soft tissue, trauma, peripheral vascular surgery and hernias and perform endoscopic procedures such as gastroscopy and colonoscopy.
(https://en.wikipedia.org/wiki/General_surgery)

Main types of surgical instrument trays

(Fig:1.7c)

Source: *Just dial*

(Fig:7a)



(Fig:1.7b)

Instruments arranged on a fixed type instrument tray were the tray is permanently fixed to the tray stand.Fig:7A and .7b shows the fixed type trolley in use. They are good in loading with heavy sterilization boxes contained with instruments.

Fixed type tray trolley(Fig:1.7c)

Floating types trolleys are ideal for space consumption and it can be kept very close to surgeon as shown in fig:7f

(Fig:1.7d)

Source: *Just dial*

(Fig:7e)

(Fig:1.7f)

Floating type tray were the tray can be removed from the stand usually used for easy accessibility of instruments by doctor and if there are space constrains. Tray. Fig:7e and .7f shows the floating type trolley in use.

Floating type Tray trolley(Fig:1.7d)

Surgical site infections overview

Other than the SSI related issues mentioned in introductory part the current situation is much more worse. Infectious disease journal points out hospitals in India as origin of a new drug resistant super bug. NDM-1(New Delhi metallo-beta-lactamase) the superbug named after the national capital, were a Swedish patient were reportedly infected after undergoing a surgery in 2008.Simillar cases are also arising from other parts of the word even from developed countries.

In 2006 WHO as the year for creating awareness on hospital infections. Antibiotics are the most powerful tool used in medicine to fight against these infections but this gives rise to another set of problems such as, the overuse of antibiotics have caused a class of viruses and bacteria which are resistant to most treatments. In 1974, only 2% of Staphylococcus aureus infections in the USA were MRSA (methicillin-resistant). By 2003, it has reached to 57%, and now is over 60%.

Main issues of SSI

- Delayed recovery.
- Recurring infections or slow wound healing also chance of scars after wound is healed.
- Affecting general health of patient.
- Reduce the immunity of patient due to excessive consumption of antibiotics.


Worried about side effects of antibiotics

Four more infe-

They are likely to have caught the bug locally; more cases may

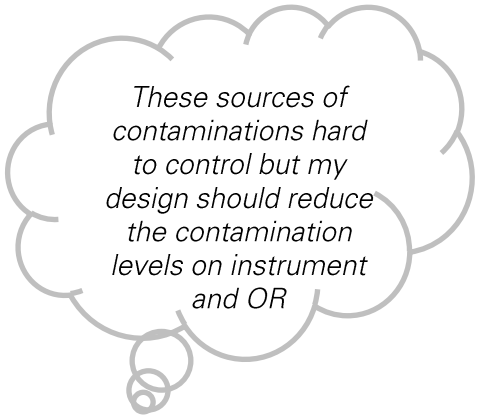
New superbug found in two patients here

Both cases successfully contained as experts urge health officials to track deadly bacteria

(Fig:1.8) News paper reports about NDM-1 and other superbugs

The excess microbial load on the patient due to surgical procedures is taken care by antibiotics and all other issues related to it emerges as explained earlier. In other words if the microbial load on the patient is reduced the dosage of antibiotics cane be reduced. If we consider surgeries of longer duration multiple doses of antibiotics are administered to prevent infection.

Sources of contamination in OR



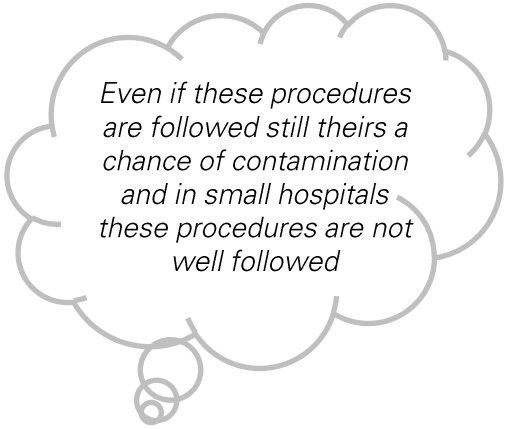
There can be external sources and internal sources of contamination internal sources can be from the body of patient itself epically in case of clean contaminated and dirty surgeries.

- Each person emits 10k CFU/min(colony forming units per minute) at rest and 50k CFU/min with activity normally, **its reduced to 140-830 cfu/min in OT**.
- Smallest particle that can carry bacteria is 4-5 microns.
- Poor scrubbing up, gowning and gloving.
- Movement into and out of OT
- Number of people.
- Contamination from machines inside the OT
- From occupants by talking, nose, shedding of skin.
- Infiltration of air due to leaks, frequent opening or closing of OT door
- Contamination through central air conditioning system.
- Laminar flow or other techniques doesn't reach the instrument table effectively.
- Instrument are set long before the surgery started.
- If instruments are dropped or touched.
- Bacteria culturing in live tissue or blood on the instruments.

Standard procedures for maintaining cleanliness in OR

- Zoning of operating department
- Air filtration: 1 change/hr , 2 change/hr, 10 change/hr : contamination reduced by 60%, 86%, 99%. (If sterilized air is pumped in to OR)
- Daily cleaning should be carried out after the operating sessions are over(which usually doesn't happen in most of the OR's).
- All the surfaces should be cleaned with detergent and water and may be wiped over with a phenol if any spills with blood / body fluid are present.
- All the walls must be wiped down to hand height everyday.
- The floors should be scrubbed with warm water and detergent and dried. No disinfectant is necessary.
- The O.T. table and other non clinical equipment's must be wiped to remove all visible dirt and left to dry.
- Weakly cleaning of all the areas inside the operating theatre complex should be done thoroughly with warm water and detergent and dried.
- The storage shelves must be emptied and wiped over, allowed to dry and restacked.

- Fumigation Is the process of filling the OR with a disinfecting chemical in gaseous state this eliminates the microbes either by killing them or making them unable to replicate. Usually microbes can colonize in areas where its hard for liquid disinfectants to reach especially corners and inside of the fixed equipment's in OR. The ventilation is blocked and OR is sealed during the process.
- Staphylococcus aureus (16%), Coagulase negative staphylococcus aureus (26.7%), Acinobacter species (2.03%), Klebsiella (0.3%) etc are bacterial colonies were majorly isolated from various areas of OR even after thorough cleaning this indicates the need of fumigation after each procedure which is not practical due to practical difficulties (for proper fmigation it takes 12 hrs of fumigation after a routine case and 24hrs of fumigation after an infected one)



Zoning

It helps in ensuring aseptic condition the operating department is divide into 4 zone :

1. Protective zone

Reception, Waiting room, Changing room, Autoclave, Trolley bay, Control area of Electricity

2. Clean zone

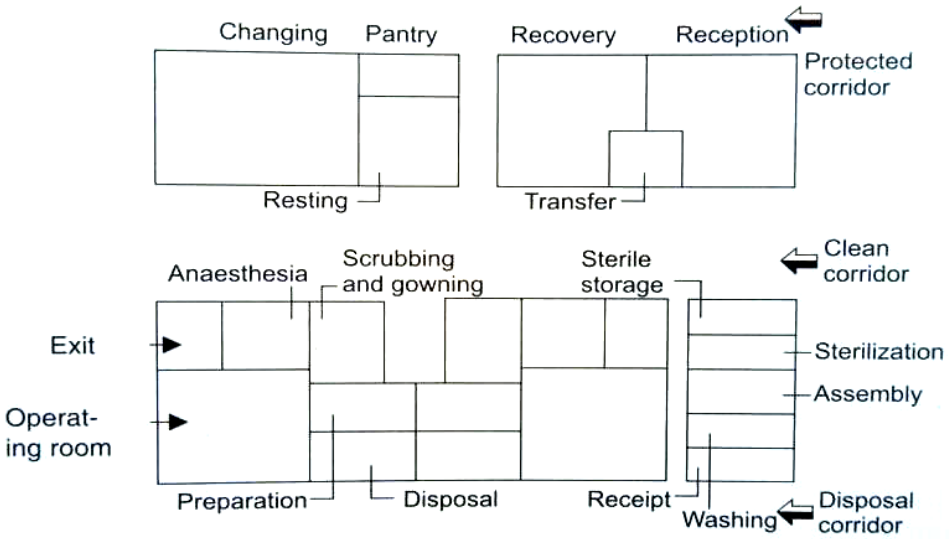
Pre-operating room, Recovery room, Theatre work Room, Plaster room, Blood storage & frozen section
room, Doctor's work room, Aesthesia store

3. Sterile zone

Operating room, Scrub room, Aesthesia room, Instrument sterilization area, Trolley area

4. Disposal zone

Dirty items wash room, Disposal corridor



(Fig:1.9) schematic diagram of zoning in hospitals

The equipment should be designed for working in sterile zone

Advantages of zoning

1. Minimizes risk of hospital infection.
2. Minimizes unproductive movement of staff, supplies & patient.
3. Increases efficacy of operative team members.
4. Ensures smooth workflow.
5. Deceases hazards in operating room.
6. Ensures proper positioning of equipment's.

Existing practices to prevent OT contamination

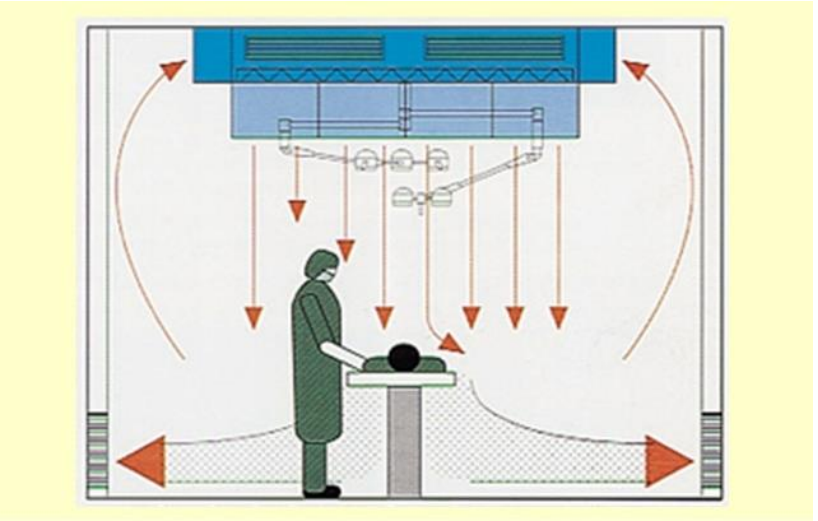
Laminar flow air conditioning system using (High efficiency particulate air)HEPA filter

This there are different configurations of designing laminar flow air conditioning using HEPA the fig(9a) shows a configuration which the HEPA filters are mounted on the air duct inlet above the OR table and air exit ducts are positioned on the sidewalls of the walls which always maintain a negative air pressure. This ensure uniform flow of filtered air throughout the procedure minimizing the airborne contaminants. These HEPA filters of 0.2 microns filter out almost all microbes including viruses. Even there are HEPA filter systems which are UV C radiated which ensure the filtered microbes are destroyed to prevent replication of them in the filter itself.

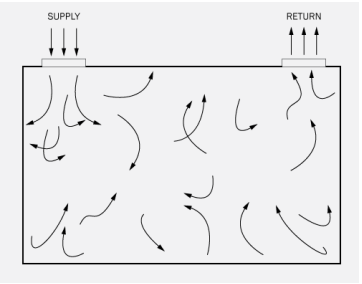
The draw back of this system is its high cost of installation and the filters have to be maintained to ensure the desired air flow. Also the cost of operation is also high. So most of the hospitals cant afford this or else the cost of surgery itself will be high.

In my user study only one of the best hospital in Mumbai only had laminar flow air conditioning system. Other hospitals OR were having normal window A/C and those were meant for personnel comfort rather than decontaminating the air.

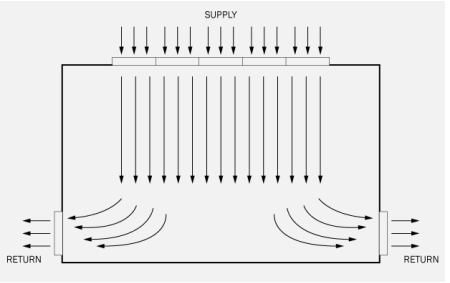
I can bring the effectiveness of laminar flow in my design



(Fig:10.a)



(Fig:1.10b) laminar flow in OR Source: ASHE



(F ig:1.10c) laminar flow in OR air mixing is minimum

Surgical instrument sterilization methods

Physical

- Dry heat(Instruments heated to red hot, Hot oven 160°C for 1-2hrs,used for glass ware)
- Moist heat (Pasteurization(holder method(63d°C 30min) and flash method(72dC 15-20Min), Boiling in water with sodium bicarbonate 20% at 100°C , 30 Min, Autoclaving steam at 120°C for 15-20Min,15Kpa pressure)
- Radiation(Ionizing alpha(specially for glasses plastic items) and non ionizing(UV for OT ,;Labs etc.)
- Filtration (For plasma, vaccine, antibiotic etc. it separates the microbes)
- Hyper steam sterilization using hydrogen peroxide

*Heat causes the metal to expand, which can crack the hinges of locked instruments

Physical sterilization (Fig10a,b,) are the most common method used in hospitals.

(Fig:1.11a)

Vertical Autoclave.

(Fig:1.11b)

Dry heat sterilization unit Source: Wayne

Surgical instrument sterilization methods Cont..

Chemicals that can case sterilization is known as sterilants

- Phenols(2st antibiotic to be used and coal tar derivatives)
- Halogen(oxidizing agents iodinating and chlorinating agents)
- Alcohol(60-70% alcohol + water)
- Aldehyde(damages the protein)

Other methods

- Sterilization using UV –C.
- High energy Pulsed Electric Fields (PEF) The lowest effective voltages for killing microbes was published by Dr. Robert O. Becker, M.D. in his book "Body Electric" at about 1.0 volt and a current of only 100-200 Nano-amperes.

Chemical servants are toxic to occupants even some are carcinogenic

(Fig:1.11a)

Chemical sterilization by dipping the instrument in chemical bath.

(Fig:1.11b)

UV Sterilization Tunnels (*Sterilization using pulsed UV flash lamp) these methods are not common in hospitals*

Secondary research

Use study

- 7 doctors (4surgens,1dermatologist,1dentist & a medical college director),& 3OT staff were interviewed.
- Two ENT OR *(at Trissur district Kerala)* were visited and witnessed two laparoscopic appendectomy *(surgical removal of vermiform appendix).* 1st surgery was in a super specialty hospital in Mumbai witch represent a luxury hospitals and 2nd one was in a nursing home in Mumbai representing the vast majority of hospitals in the country.

Both The surgery lasted for approximately 95minutes and the important stages in the surgery were:

- Preparing patient for the procedure.
- Anesthetizing the patient.
- Preparing instruments *(Arranging the instruments on instrument tray, usually done in parallel with scrubbing)*
- Scrubbing(it's the process were body is wiped with anti microbial solution to create microbe free environment awhile leaving antimicrobial residue to prevent growth of microbes during the procedure).
- Making insertions in the abdomen and positioning trocars *(they act as ports for insertion of laparoscopic instruments and other probes).*
- Insufflation *(blowing the abdomen with carbon dioxide gas to create working space for laparoscopic procedure).*

(Fig:2.1a)

Patient after scrubbing just before insertion of trocars. Body of patient expect the surgical site is covered using sterile cloth

(Fig:2.1b)

Laparoscopic grasping tool holding appendix prior to electro cautering viewed through camera inserted to the abdomen,

The tray or its components shouldn't hinder the view of the display monitor or the patient

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

(Fig 2.2) Instrument tray should be compact same time should accommodate al the instruments

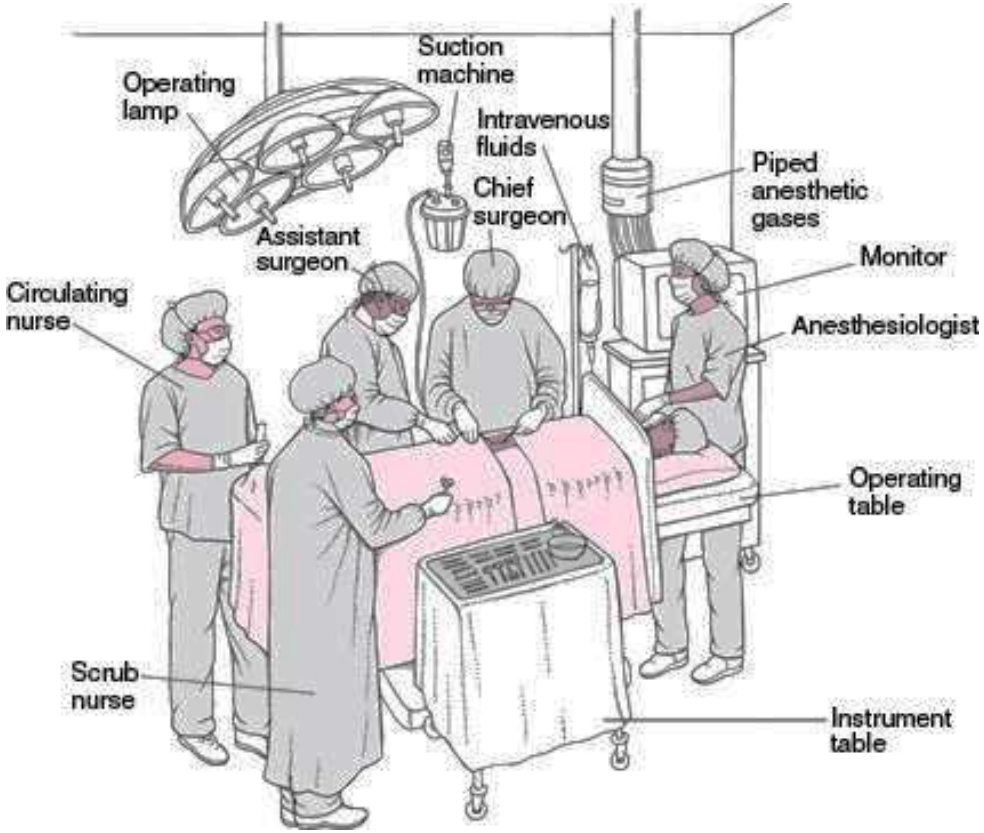


Fig:2.2 The positions of surgical team during a surgery, Source: MERCK

Surgery at 1st OR

There were 12 persons in OR (chef surgeon, 2 assistant surgeon, 1surgeons scrub nurse, 1anesthetist, 2circulating nurse, 1vistior and 2 OR helper,3medical students). Their typical positions with position of equipment's and other facilities are shown in the fig(2.3)
The OR was clean and was equipped a good team of assistants, proper zoning of OR complex was there and the level of adherence to procedures were also good.
It also had laminar flow air conditioning system in place.
**In good hospitals the OR's are generally large but in medical collages the re will be lot students to watch the procedure this enhance the chance of contamination*

Do two trays are really required since in the 2nd hospital there was only a single instrument tray

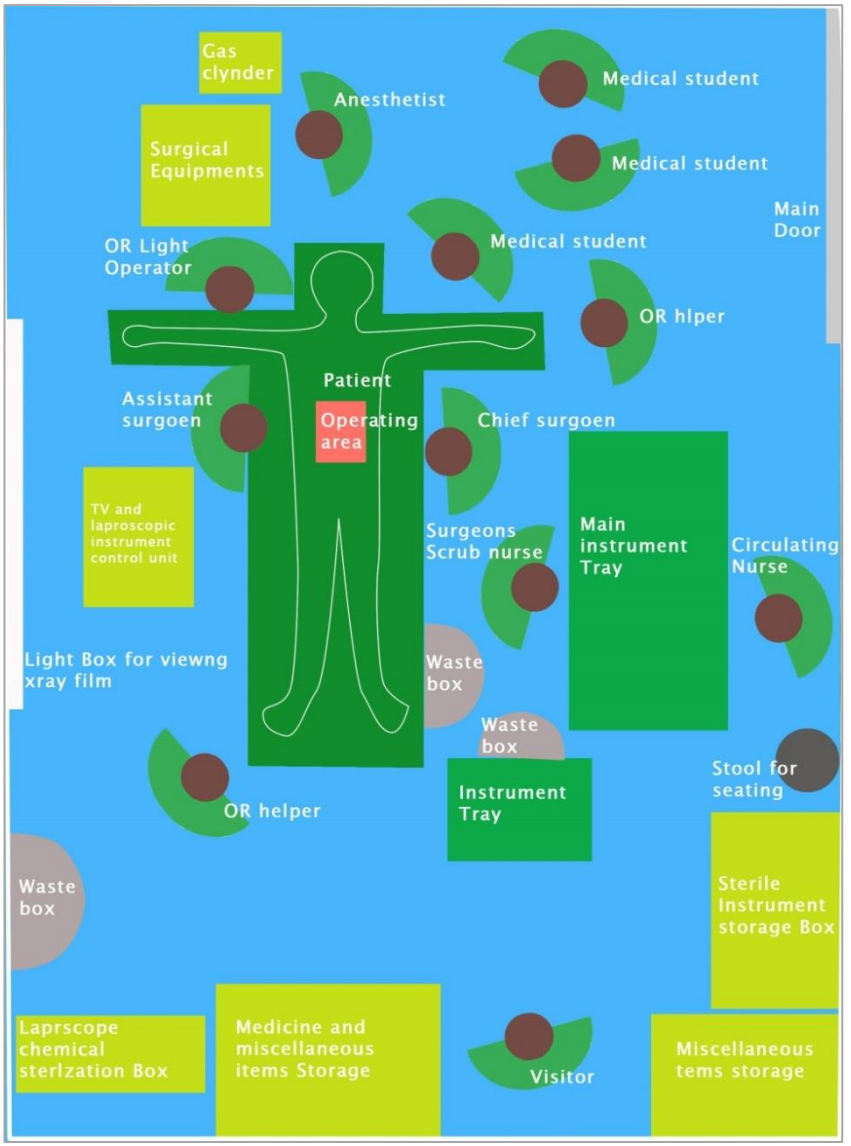


Fig2.3 Schematic representation of 1st OR

Surgery at 2nd OR

There were 7 persons *(chef surgeon, assistant surgeon, surgeons scrub nurse, anesthetist, circulating nurse, 1vistior and 1helper). Their typical positions with position of equipment's and other facilities are shown in the fig(2.4).*
It was just an room converted to OR in Mumbai with out proper zoning. The number of assistant's were less and expect the doctor and scrub nurse no ne was wearing the sterile gown.

*All instruments for appendectomy can be accommodated in a single tray of 50*60 cm size*

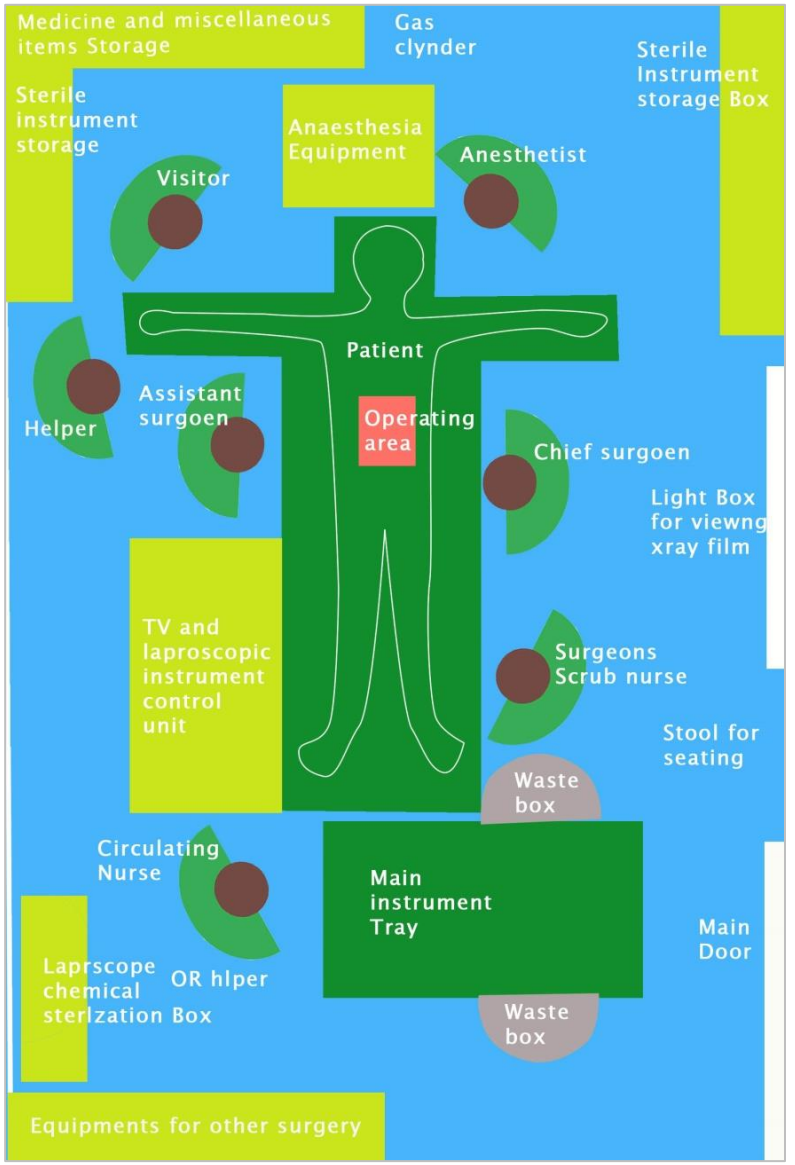


Fig:2.4Schematic representation of 2nd OR

Micro activity analysis of OR tray assembling

Fig:2.5a

Prior to other patient preparation Scrub nurse puts on the surgical gown and sterilized gloves circulating assisted by circulating nurse.
By holding the at the neck strap surgical gown is opened and worn.

Fig:2.5ba

A paper card is attached with the gown tying strip so the assistant handle it without contacting the sterile gown, front side is considered sterile, the waist knot is on front in this case.

Fig:2.5c

A special holder s there for opening the cloth of autoclaved instruments

Fig:2.5.d

The gloves cover is opened after wearing gown, hands will be inside the gown while opening glove inner cover.

Fig:2.5.f

Scalpels blades are mounted using blade holder

Fig:2.5.g

Towel rolled beneath to take the instruments easily and to keep them at place

Micro activity analysis of instrument transfer at OR

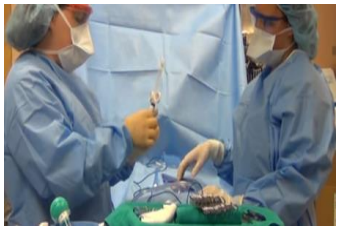


Fig:2.6a

Transferring syringe by holding just below the handle carefully without touching any other part and doctor holds it at handle.

Fig:2.6b

If the instruments are not sharp like scissor tweezers etc are hold on the nose tip rather than holding at middle or near to handle

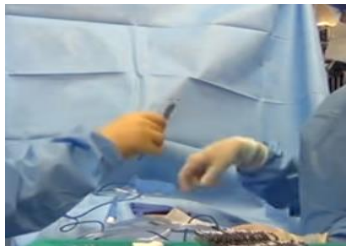


Fig:2.6c

The scalpel knife also hold below the handle or at the middle while giving or returning

Fig:2.6d

Scrub nurse transferring switcher needle the doctor

*During the 1st 15 minutes of the surgery the instruments were very frequently taken from and to the tray, even 5-6times in a minute. After that it was less frequent and it became 4-10 times in 15minutes.

The shouldn't be any hindrance to pick and find the instruments from tray during surgery

General instruments used for laparoscopic surgery and their dimensions

Fig:2.7a

Graspers (40-60cm in length)

Fig:2.7b

***Catering device** (40-60cm in length)*

Fig:2.7f

The laparoscopic instruments arranged in the tray during surgery

Fig:2.7c

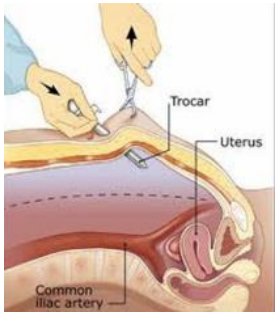


Fig:2.7d

Main laparoscopic instruments and order of use Trocars length 15-25cm, it widens the insertion made by scalpel while inserted and act as widow for inserting other laparoscopic devices.

The tray should accommodate instruments varying from20cm to 60cm

Existing products Market study

Normeditec sterilized air flow units (Fig2.8a-2.8c) uses HEPA filters that remove all bacteria and microorganisms of 0.1 Microns and above: the bacterial load in the operating environment and on the instruments is reduced by 95%

Air Flow Unit: Size: L 70 x W 60 cm; H 156-186 cm
Power Supply:230 VAC, 50 Hz for Europe, 115 VAC, 60 Hz for US
Power consumption: 280 W
Air Flow Data: 0,5-0,7 m/s, 400 m3/h
Working Temperature: +10° to +40°C (+ 50° to +104°F)
Humidity: 5-80% (non condensing)
HEPA filter:Type: CAMFIL, High Efficiency Particles Filter; Filters 99,997% particles >0,3 µm
ISO class 5 equipment (ISO standard for clean room)

This design is bulky and the head part from were the air blows is huge which can obstruct the view of instruments in the tray. But air filtration improves the OR air quality

Fig:2.8a

Fig:2.8b

Fig:2.8c

Sorce:Normedic

UV C applications in sterilizing

Fig:2.9a

UV sterilizer used in beauty parlors and saloons.

Fig:2.9b

UV sterilizer used in water purifiers

Fig:2.9c

Fig:2.9d

UV-C Hospital room sterilizer(IPT 3200).Its used in hospitals to sterilize patient rooms, toilets OR , intensive care units etc., if switched on it sterilizes the surroundings were UVC is irritated. Even operated for 5 minutes could destroy most of the microbes the reflected UV C will also destroy microbes.

Fig:2.9e

Fig:2.9f

UV C tubes used in material transfer boxes in biosafety rooms. These boxes are used to sterilize the objects being transferred from a non sterile environment to a sterile environment E.g. semiconductor fabrication facilities, biotechnology laboratories etc.

Using UV C can be a good idea to disinfect the room in between surgery's and could also be used for the instruments in the tray

Different types of medical trolleys

Fig:2.10a]

Fig:2.10b

Fig:2.10c

Fig:2.10d

General purpose hospital trolleys

Fig:2.10e

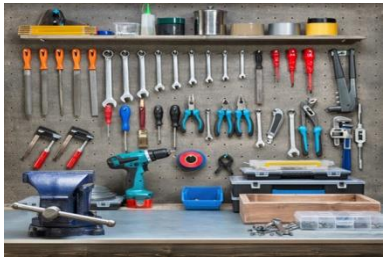


Fig:2.10f

The visibility of instruments and its accessibility cant be compromised in the design

(Fig2.10a,b,c,d,e,f) Represent portable trolleys for hand tools storage these are ideal for compact storage of tools. This arrangement is continent for occasional use not for frequent use but in (Fig 2.10f) tools are arranged for frequent use and the tools can be very easily identified.

Design objective

‘To design a surgical instrument tray which maintain sterility of surgical instruments through out the surgery’

Design Brief

Primary needs

- It should reduce the bio burden on the instrument.
- Should be ergonomic and easy to use.
- Instruments to be easily recognizable.
- If surgeon looks for the optimum tool the tools should be easily identified
- Either it will be a part of trolley or separately mountable

User related issues

- Should be easy to operate with minimum training.
- Should be easy to arrange and find instruments .

Servicing issues

- Should be easy to operate with minimum training.
- Should be easy to arrange and find instruments .
- Device should conform to class 5 clean room standard and Class 1 according to FDA(Federal Drug Administration) regulations.

Manufacturing issues

- Materials and design should be easy to manufacture.
- The material should be easy to clean with minimum accumulation of dust or dirt.
- The components should also be easily available.

Operating condition

- Its used in sterile atmosphere should it shouldn't be a source of contamination. Should take consume minimum space

Design Brief

Functional requirements

- Should cater to Clean, Clean-contaminated & Contaminated Surgeries.
- 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.
- Easy to install in exiting OT.
- Should be aesthetically good and design itself should increase the value of perception of the product.
- The tray should help to arrange the instruments neatly without messing.
- The components in the device should be easy for the OR staff themselves to clean, decontaminate and sterilize if required.
- It can have additional features like provision for hanging IV drip bottles.

Target user

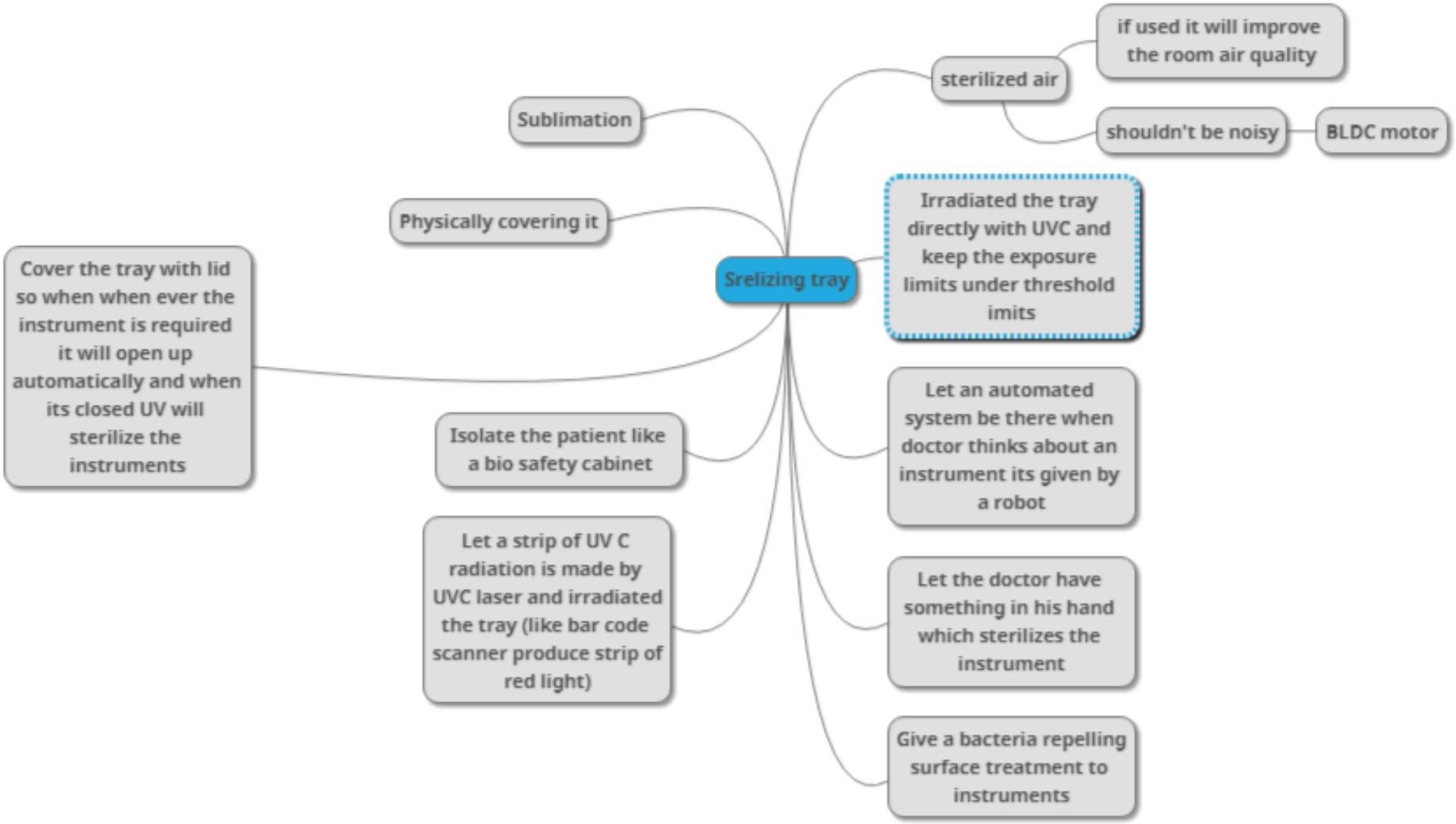
Primary user

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

Secondary user

- Circulating nurse (The nurse who gives provides the instruments to the scrub nurse during surgery)
- Other OT staff(the one who cleans and disinfects the OT)

Mind map


Srelizing tray
Sublimation
Physically covering it
Cover the tray with lid so when when ever the instrument is required it will open up automatically and when its closed UV will sterilize the instruments
Isolate the patient like a bio safety cabinet
Let a strip of UV C radiation is made by UVC laser and irradiated the tray (like bar code scanner produce strip of red light)
sterilized air
if used it will improve the room air quality
shouldn't be noisy
BLDC motor
Irradiated the tray directly with UVC and keep the exposure limits under threshold imits
Let an automated system be there when doctor thinks about an instrument its given by a robot
Let the doctor have something in his hand which sterilizes the instrument
Give a bacteria repelling surface treatment to instruments

Mood Board

The design should have these aesthetic and functional traits

Fig:8.1a

Stability

Fig:8.1b

Authority

Fig:8.1c

Tranquility

Fig:8.1d

Trust

Ideations

1.Keeping the instruments in a stream of sterilized air.

The (fig:9:1a &b) shows the design in which the instruments are kept in a sterilized air curtain. In (Fig:9.1) the air nozzle will be kept just above the tray cantilevering from the tray sides the sterilized air generating unit will be placed under the tray attached to tray stand.

In (Fig:9.1b) the compressed satirized air generated and unit will be kept outside and the air will be ducted to the air delivery nozzle which is hanged from the celling similar to an OR light hanging from the ceiling.

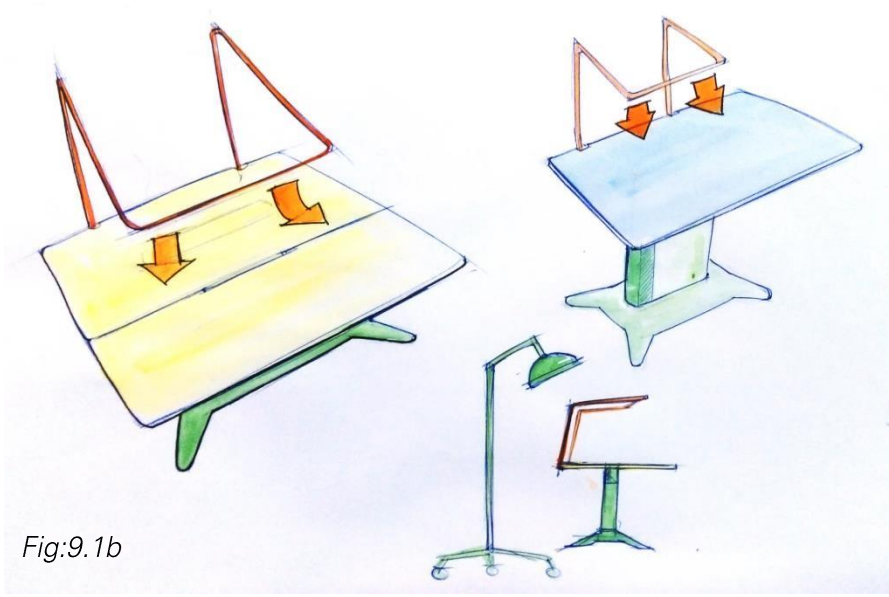


Fig:9.1b

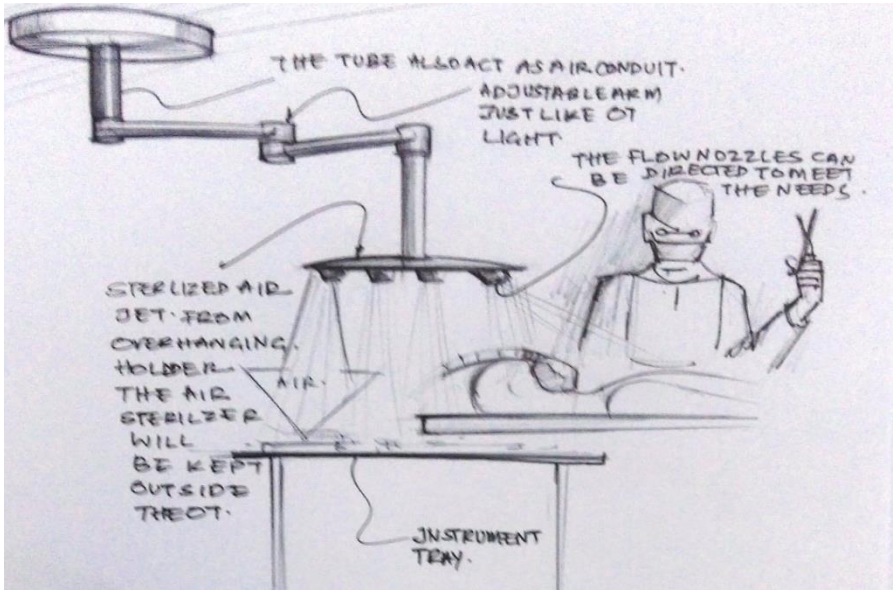


Fig:9.1b

The 1st idea is practical and second one will be expensive . But sterilized air wont destroy the microbes.

2.Instruments kept in a retractable tray and irradiated with UV-C radiation

The (fig:9:2a &b) The instruments are kept in retractable trays and each tray will be equipped with individual UV C lamps. Each tray will be kept with the picture of the instrument in it. When hand is brought near the concerned tray it will be opened automatically and when hand is moved away it closed and sterilization begins

In (Fig:9.2b) it's a normal tray which is having UV C lamp inside with a lid so the lid has to be opened manually to take the instrument in and out.

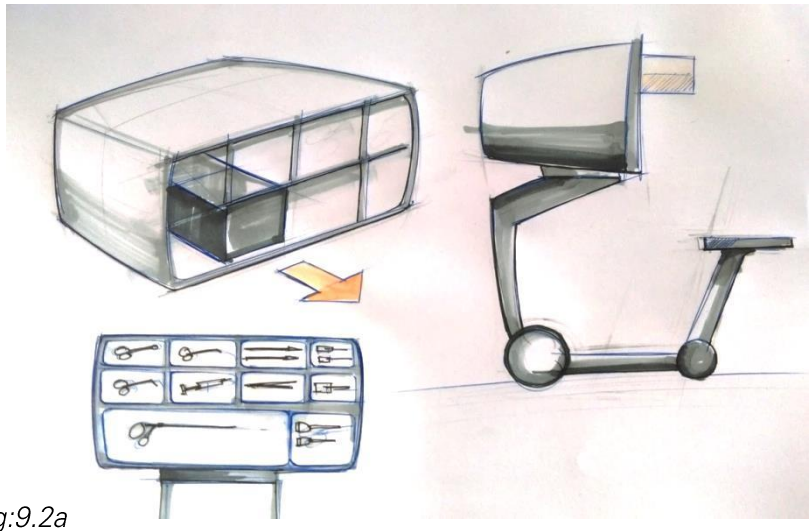


Fig:9.2a

Both ideas are not suitable for very frequent instrument transactions but the idea of UVC sterilization will be useful

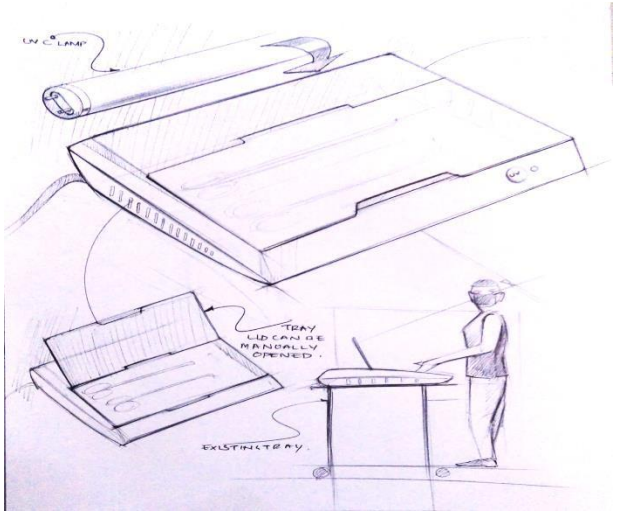


Fig:9.2b

5.Directly irradiating the instrument table by UV-C radiation

In this the idea is to irradiate the instruments directly with UV C radiation just like a normal table lamp this will sterilize the instruments. Fig:3a&b shows how is done, the square markings are laser guide lines to set the irritated area, so apart of the tray can be kept normal for keeping items which are not to be irradiated e.g.: Medicines, packed items such as suturing needle etc.

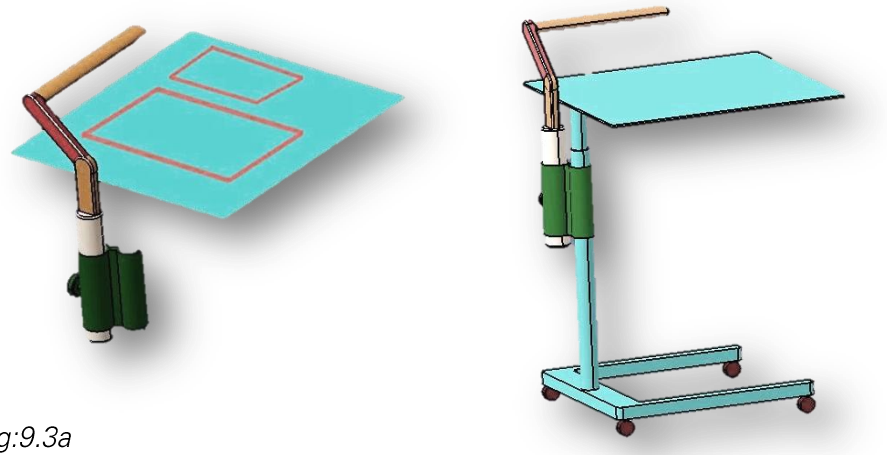


Fig:9.3a

This seems to be the most simple and efficient idea but UVC is cacogenic for humans so will have to study about its feasibility

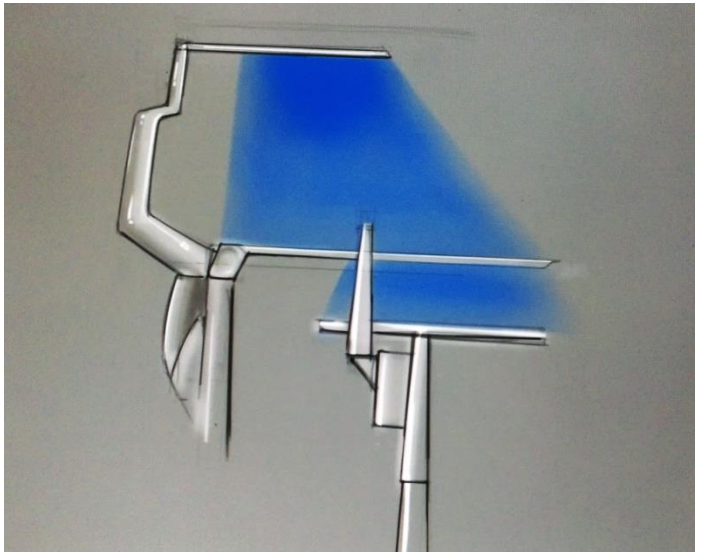


Fig:9.3b

6.Keeping the instruments in sterilized chemical vapor

This tray is specifically designed to create a sterile environment in the tray. The handle of the tray is loaded with sublime chemicals an its ducted to the tray and opens to the tray through small holes its similar o the holes in an air hokey table,. The chemical vapors in the tray which h has to be denser than air so it will make a bath chemical fumes inside the tray.

A tray containing pool of chemical vapors were the instruments will be kept in, but most of the chemicals used for sterilization are also lethal to humans . But the air from A/C or other sources displace the chemical vapors.

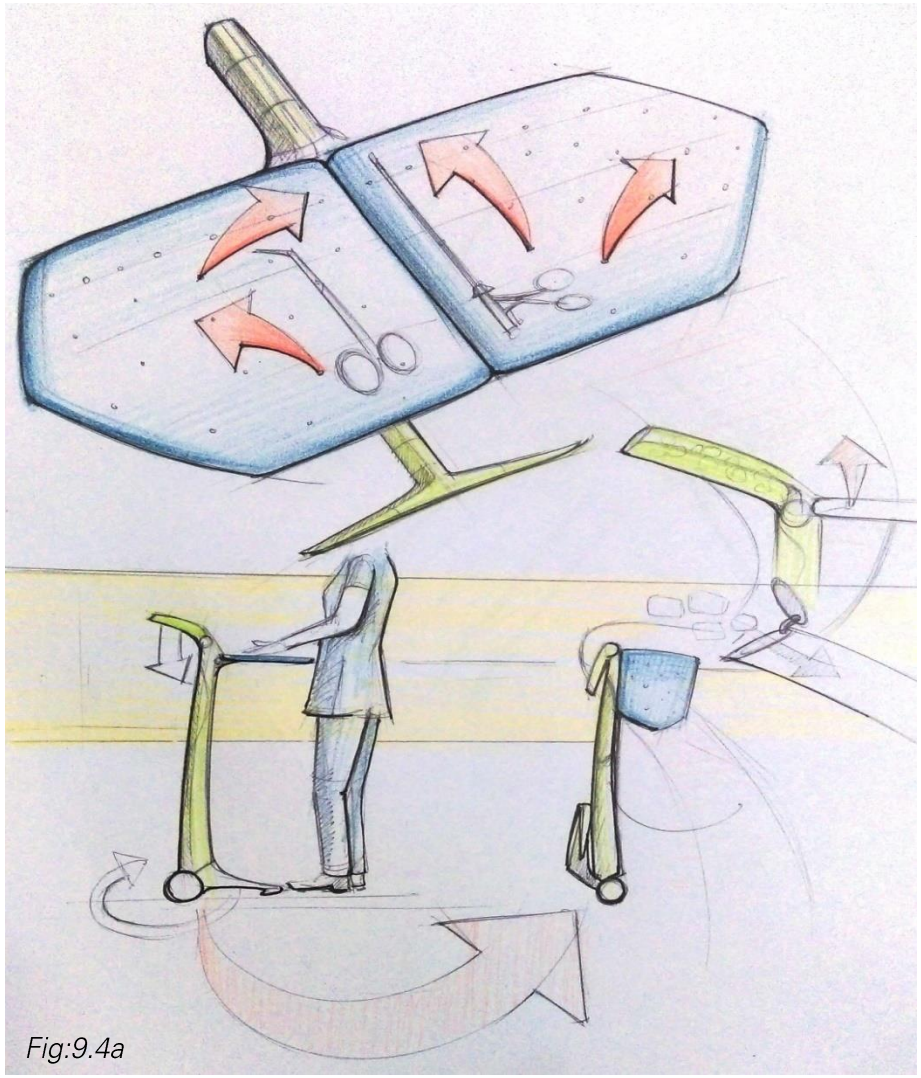


Fig:9.4a

Idea evaluation

1. Keeping the instruments in a stream of sterilized air.
2. Instruments kept in a retractable tray and irradiated with UV-C radiation
3. The instruments are kept vertically in the holders the lid covers it and UV sterilizes it.
4. Automated instrument storage like carousel storage
5. Directly irradiating the instrument table by UV-C radiation
6. Keeping the instruments in sterilized chemical vapor

Among these using UV is the simple and efficient technique it destroys the DNA of microbes and prevents replicating within few seconds . The UVC tubes are easily available and not expensive. Also the size of those tubs are less and can be formed to different shapes. Mot of the microbes usually found in OT will get destroyed by 50mJ/cm2 of radiation. But human threshold of UV exposure is 4mj/cm2 during 8hrs and it shouldn't be exceeded. So the reflected radiation shouldn't be exceeded this limit and UV shouldn't make direct contact with occupants.

Sterilized air is the next efficient technique to solve this issue if the instruments are placed on a sterilized air atmosphere the microbes wont come in contact with it but if while taken the instrument out of that satirized air zone and gets contaminated it wont prevent the ,microbes form colony forming on the instrument.

So a system which combines the both techniques can be the ideal solution.

Concepts

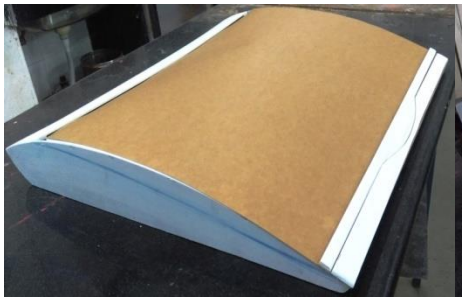
Concept 1

An instrument tray with automatic lid which retracts while in use, when the lid is closed UV C is irritated using inbuilt UVC discharge tubes to sterilize the instruments..

Fig:10 3d render of concept 1

In this design the tray is covered with an automated lid. The inbuilt proximity detectors detects the presence of hand near to it and opens the lid when someone is trying to take an instrument from the tray.

The UV C lamp mounted inside is automatically switched on if the lid is closed. It not necessary that it has to be switched on continuously it depends on factors like the amount of contamination it varies according to the type of surgery air quality of OR, cleanliness of OR etc. even switching for 2miniutes between 10 minutes would drastically reduce the microbial growth.



(Fig:10,.1a) The tray lid when closed

(Fig:10,.1b) when the tray lid opens up

Fig:10,.1c The lid opening mechanism assembly.

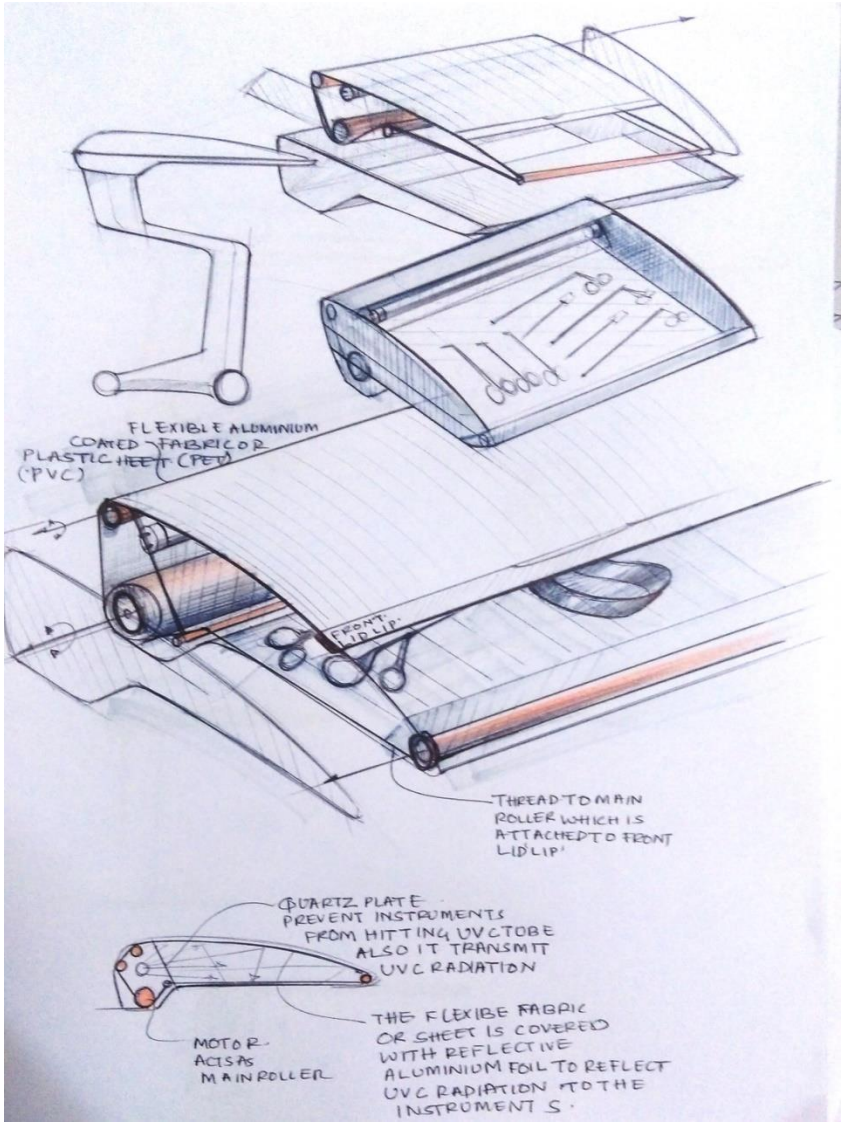


Fig:10,.1d Internal components explained

Ideation sketches

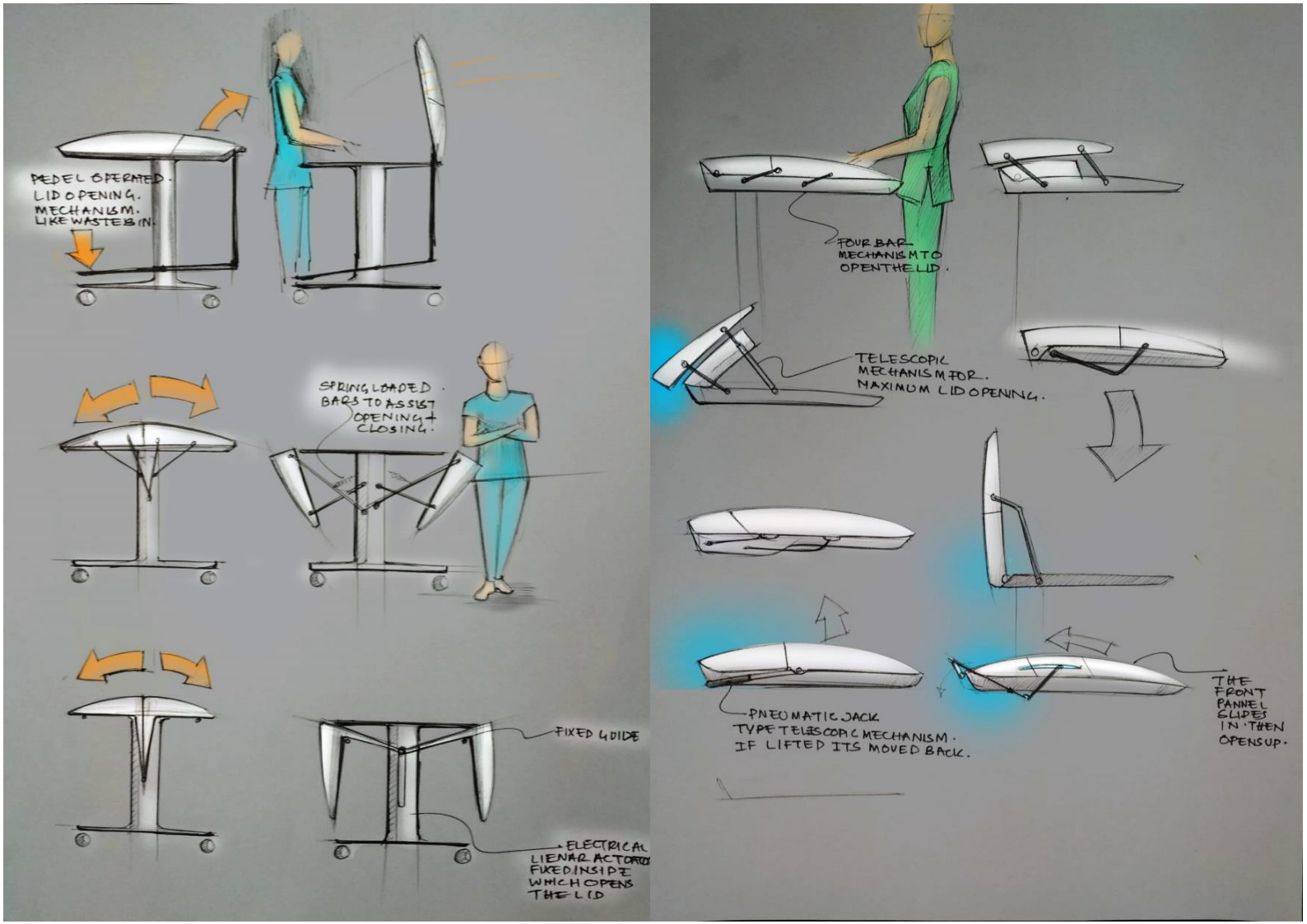


Fig:10 3f

Form exploration..

Fig:10,.1g form explorations for tray with trolley for the current concept

Concept 2

A portable compact UVC led source which can be mounted on trays of any length.

Fig:10,2a 3d render of concept 2

Here the UV C Led strip is stick to a flexible spring steel strip which can retract in to the housing if not in use. The UV C strip automatically comes out from the housing by moving hand on the top side of deice (Fig:10b)

Fig:10,2b

Fig:10,2c

If hand is waved over the device to the pointed face LED strip comes out if done in the opposite direction it retracts in to the housing. The length of opening will depend on time of hand kept above the device.

The main issue is UVC led have an efficiency less than 5% which are available in market so to get sufficient irradiation the length has to be very large and to keep the reflective UV C from the tray under limit it can be operated in intervals only.

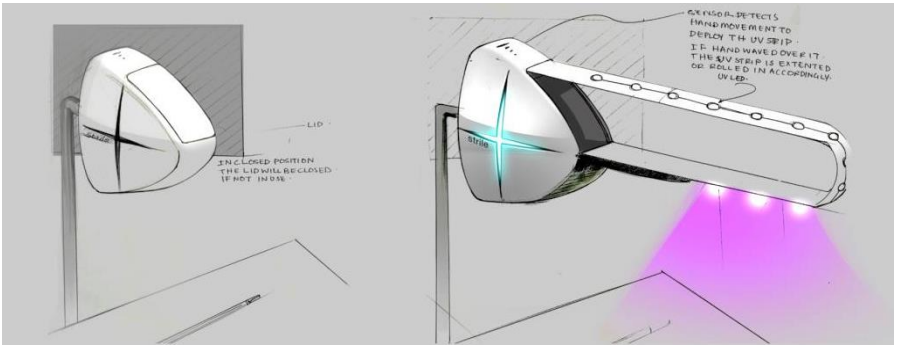


Fig:10,2d when not in use the LED strip is retracted

Fig:10,2f while in use the LED strip comes out

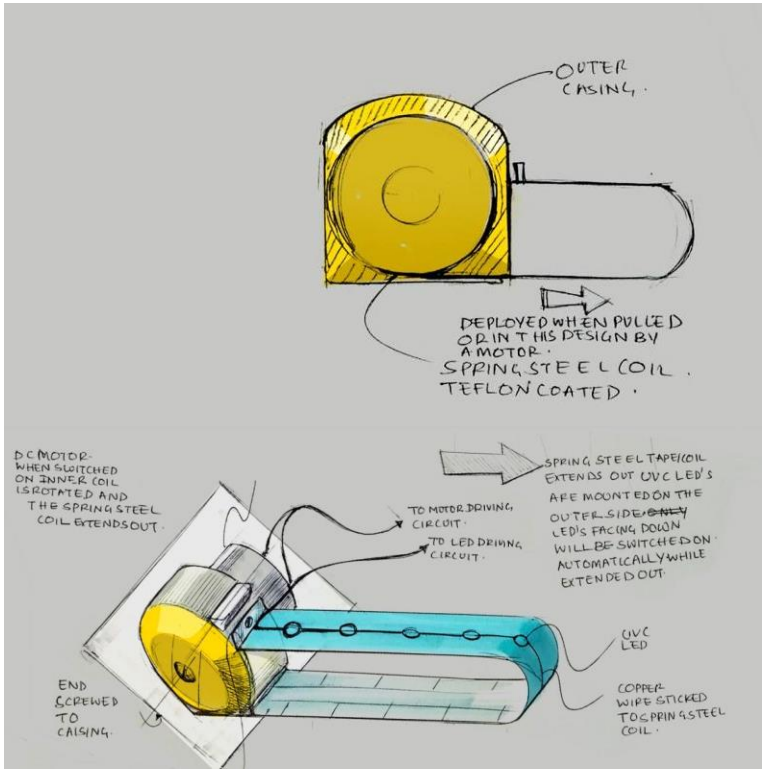


Fig:10,2gMeasuring tape inspired design

Fig:10,2h Mock up made for form study

Fig:10,2iworking mockup model made for studying the mechanism

Concept 3

This concept is a portable design with UV C irritated to the tray using a UVC discharge tube mounted above the tray , it also it creates a sterilized air blanket over the tray to keep the instruments out of contaminated air inside OR

Fig:10,3a 3d render of concept 3

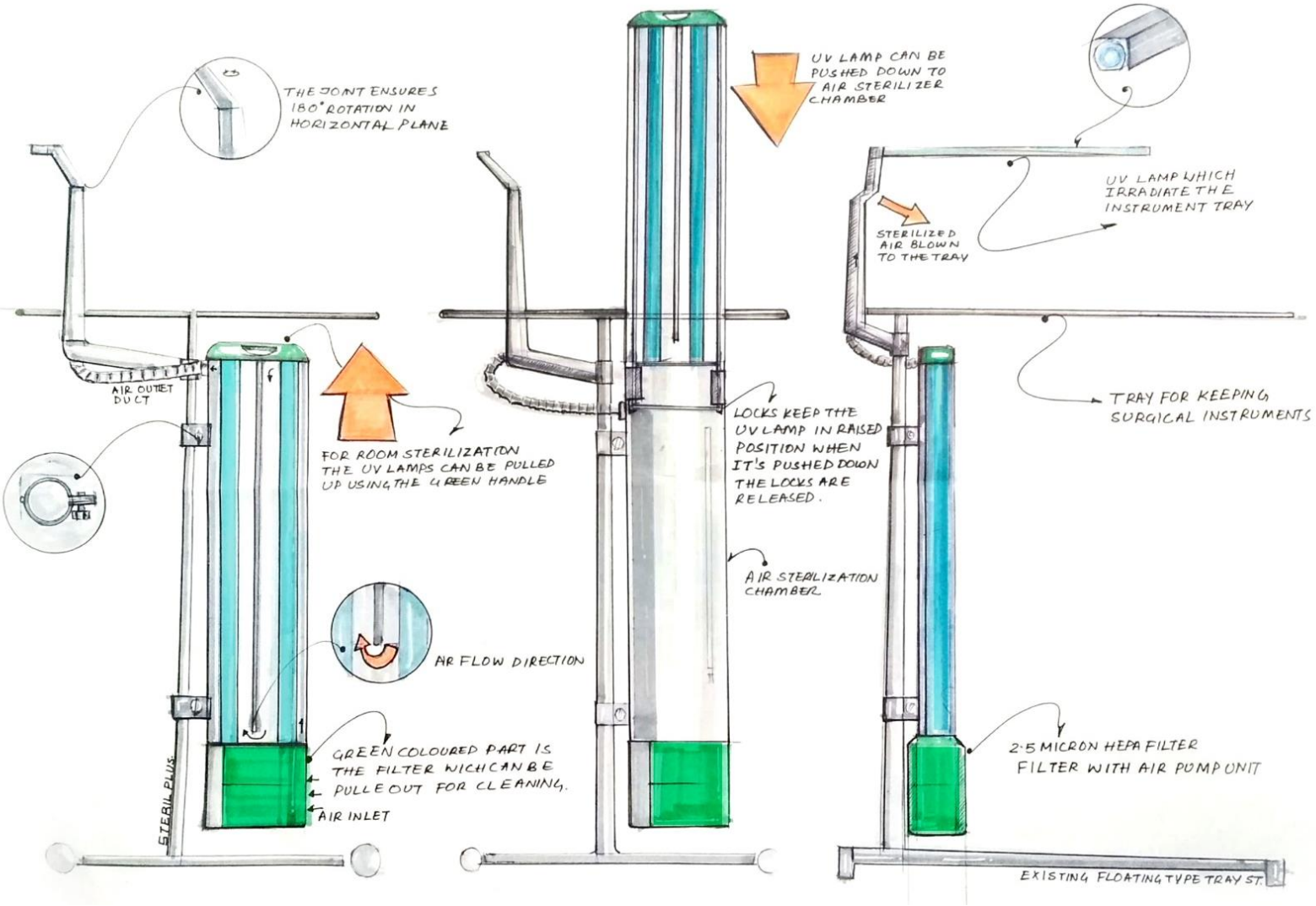


Fig:10,3b Working of concept 3 explained, UV C discharge tubes used for sterilization of air HEPA filters can also be used . The current efficiency of UVC discharge tubes are less and its only 35% in most of the lamps so will have to go for HEPA filters. HEPA filters will be bulky and will be difficult to attach on the current tray stands so tray stand should also be designed.

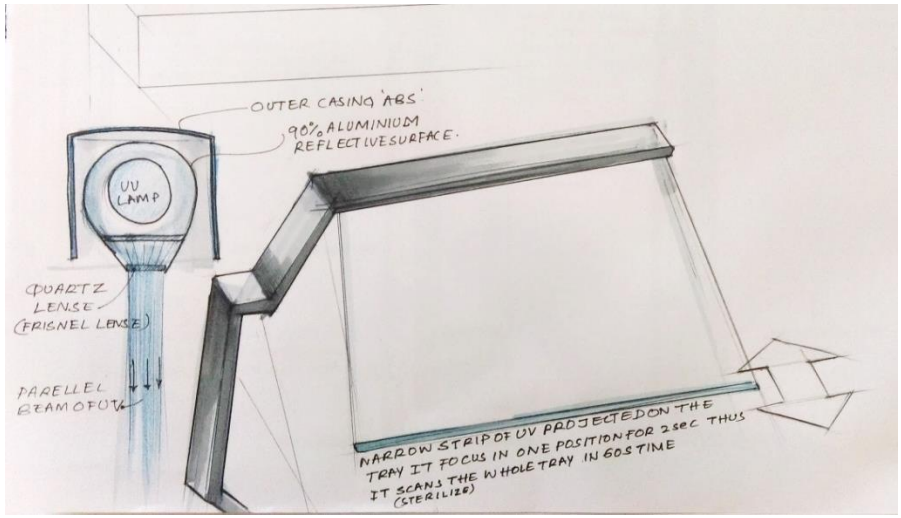


Fig:10,3c UV C light source functioning , here a strip of UVC light will be produced and it will be scanning the tray surface this is to reduce the reflected UV C at any given time because if a person is facing the instrument tray for a given time the radiation received by t he person should be minimum or else the UVC has to be automatically switched off if someone is facing to the tray.

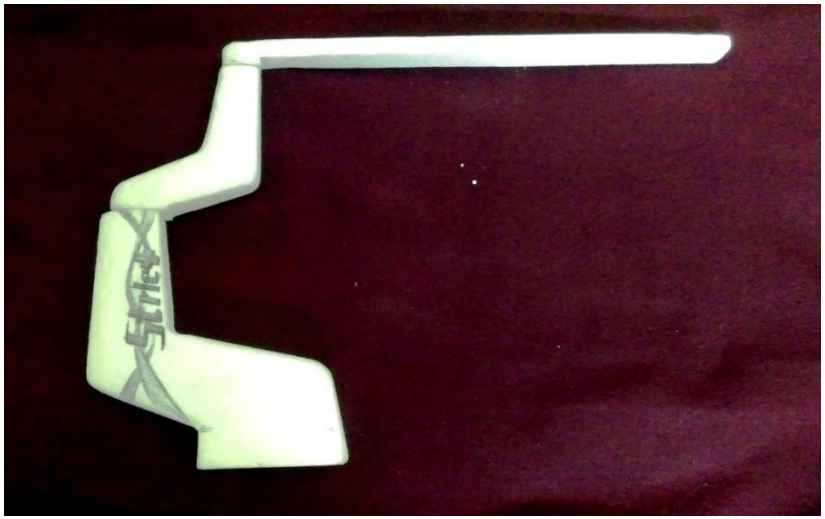


Fig:10,3d Form study of UV C source mounting set up

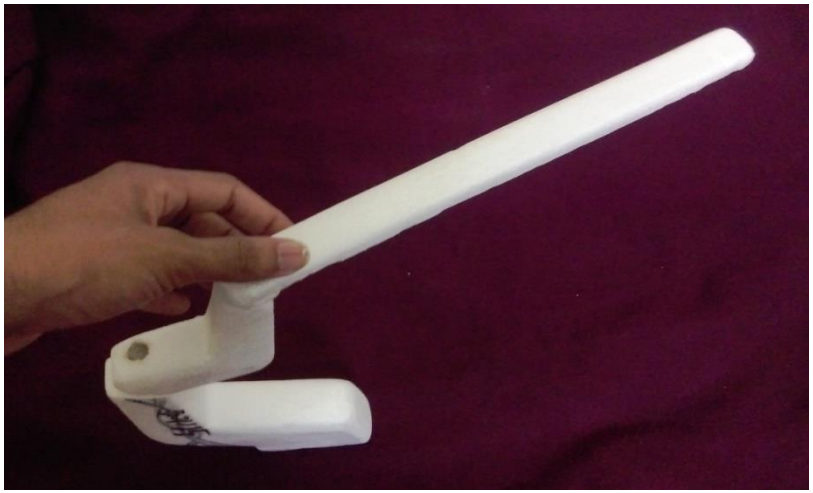


Fig:10,3e The UVC source can be adjusted to focus control the irritated area.

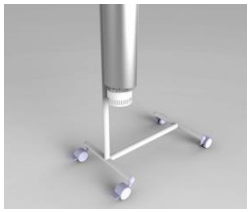


Fig:10,3f The UVC source can be adjusted to focus control the irritated area.

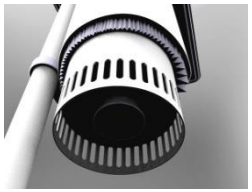


Fig:10,3f The UVC source can be adjusted to focus control the irritated area.

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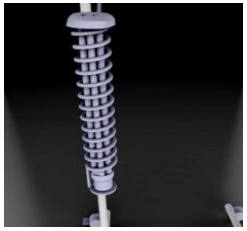


Fig:10,3f The UVC source can be adjusted to focus control the irritated area.

Fig:10,3f The UVC source can be adjusted to focus control the irritated area.

Fig:10,3k 3d rendering of the concept (view shows the bottom of the tray)

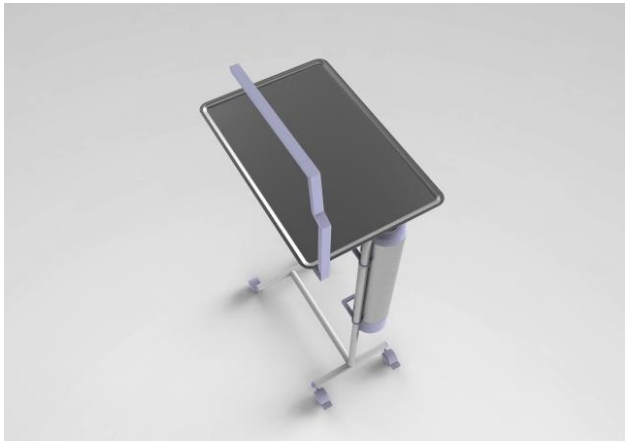


Fig:10,3k 3d rendering of the concept (view from the top of the tray)

Concept Evaluation

Concept No	Effectiveness of sterilization	Safety of occupants while equipment is in operation	Ease of operation	Cost effectiveness	Total marks
1	8	8	3	3	22
2	8	1	8	7	24
3	8	8	7	6	29

Marks are given out of 10 according to the expert feed back
The third concept which uses UV with sterilized air is found most effective in terms of efficiency, usability and occupant safety.

Final Design

Fig:11

Ideation Sketches

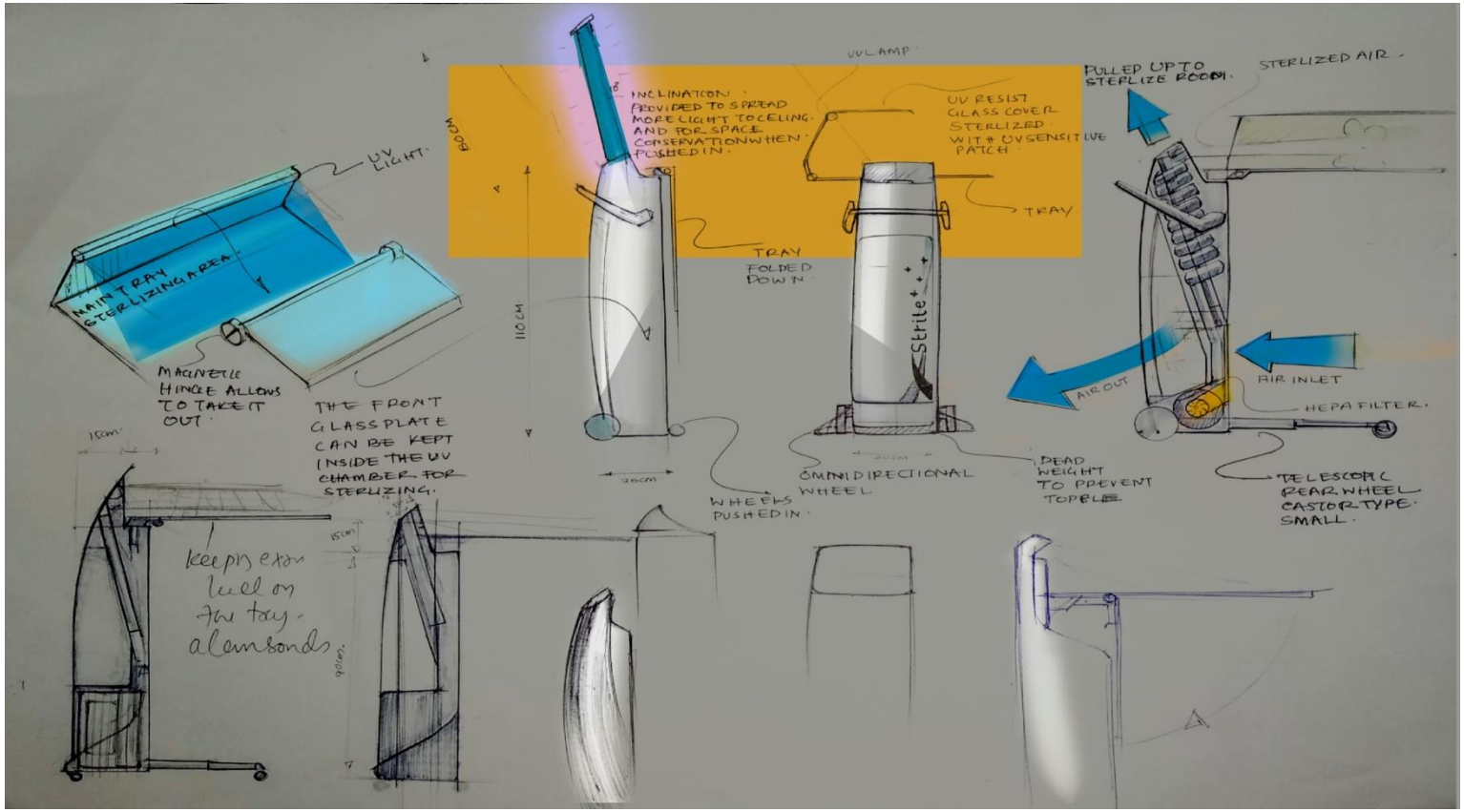


Fig:11,b internal components design, here UV C is used for air sterilization, were air is passed through spiral quartz tube (quarts doesn't absorb UVC)

Ideation Sketches

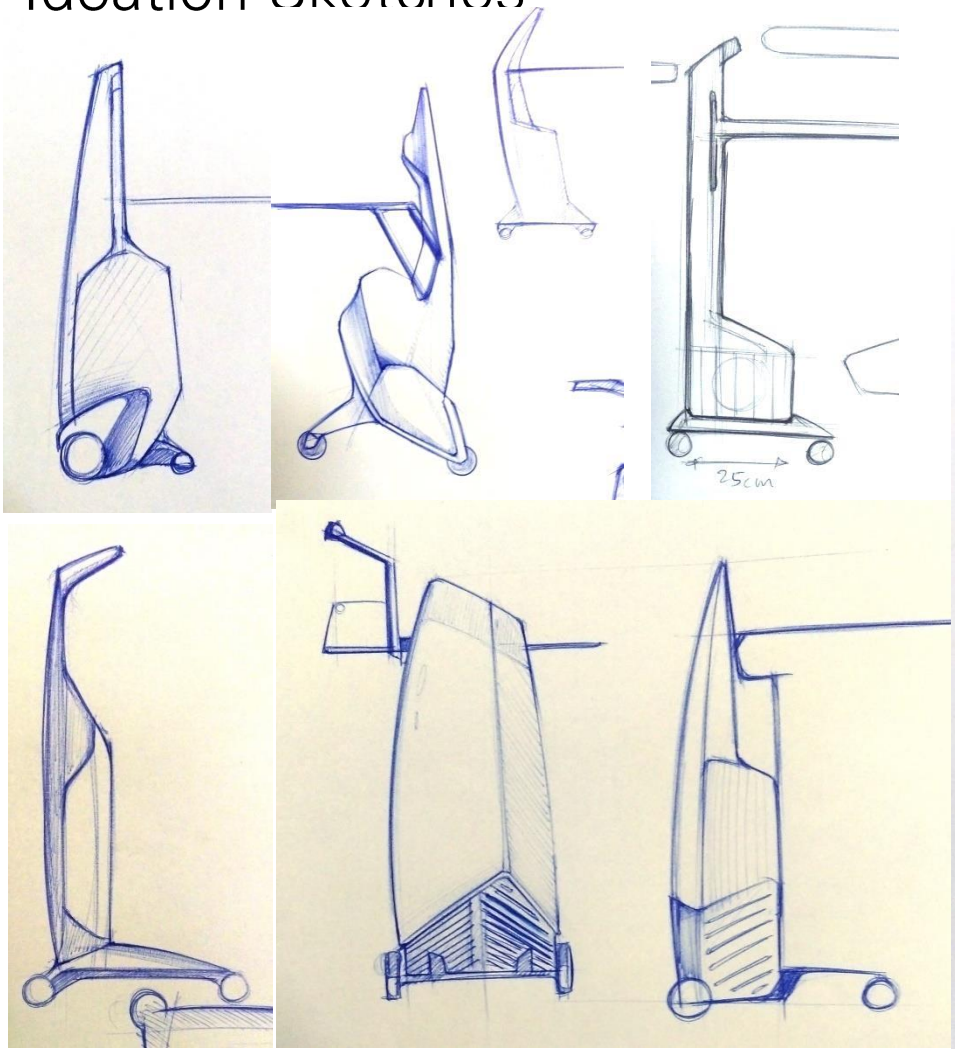


Fig:11,c initial concept sketches ,tried to give a modern look t the device.

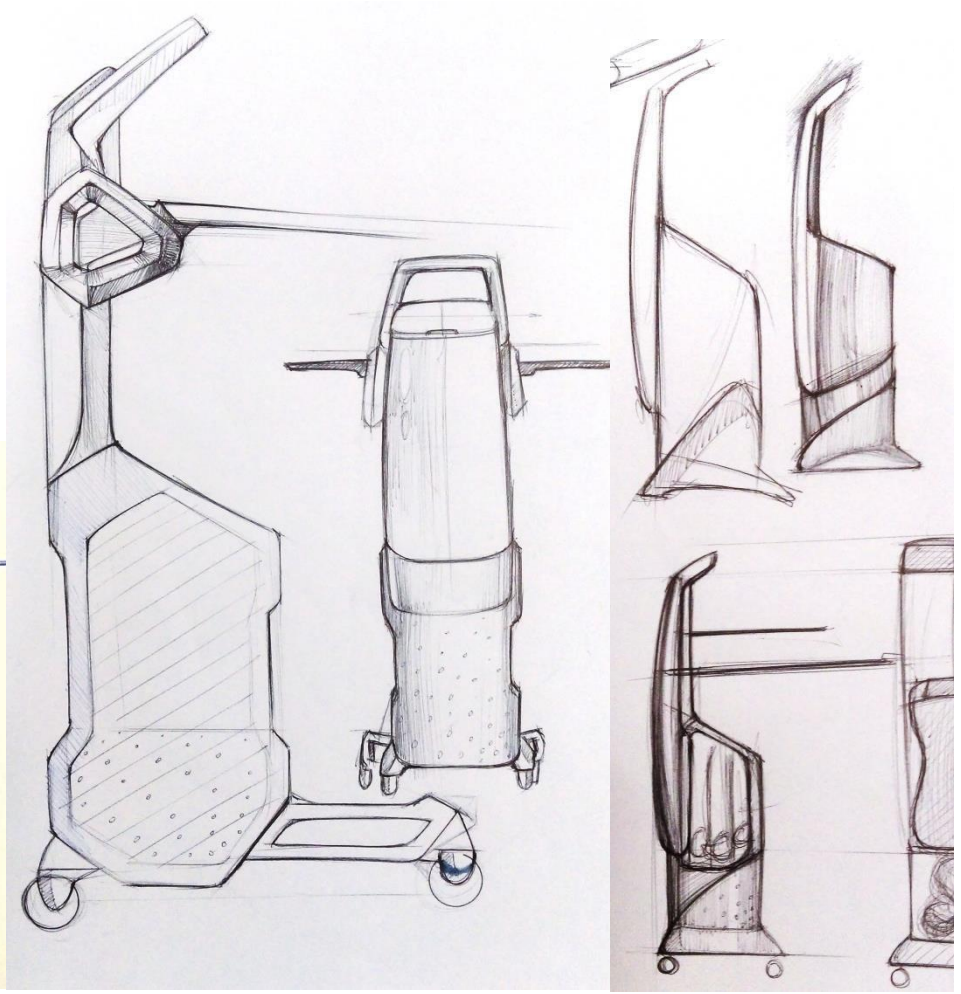
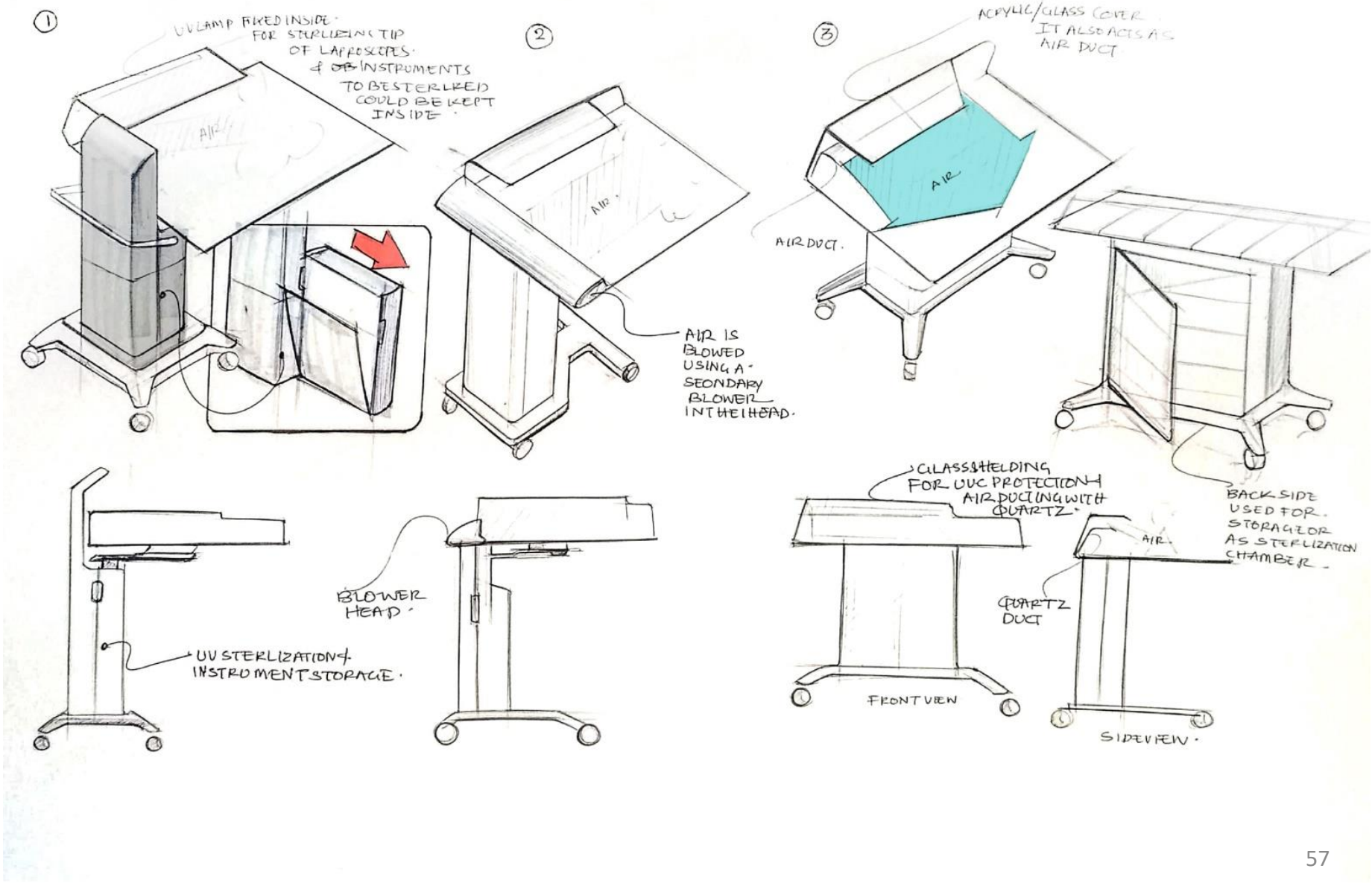


Fig:11,d Initial concept sketches ,tried to give a rugged look to the device

Ideation Sketches



Ideation Sketches

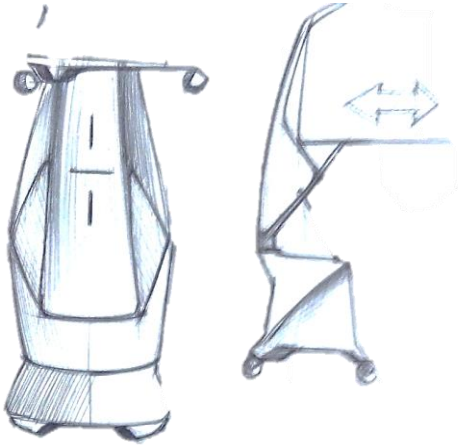
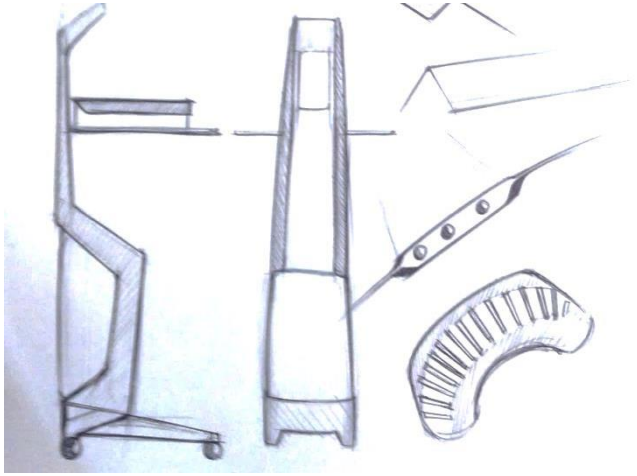


Fig:11,h Initial concept sketches (structural form)



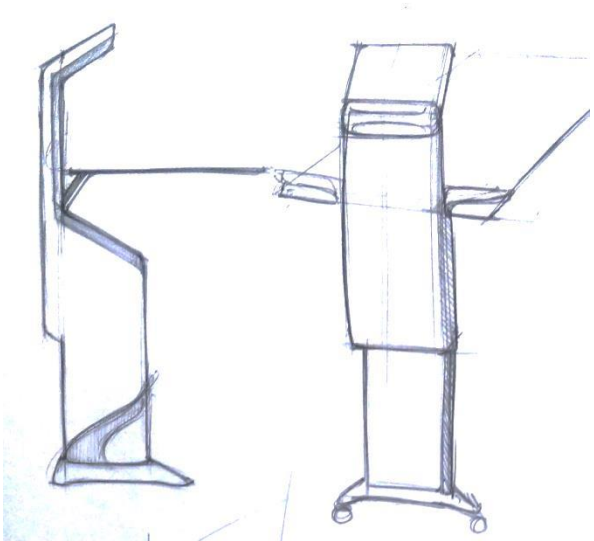


Fig:11,f Initial concept sketches (classic medical product form)

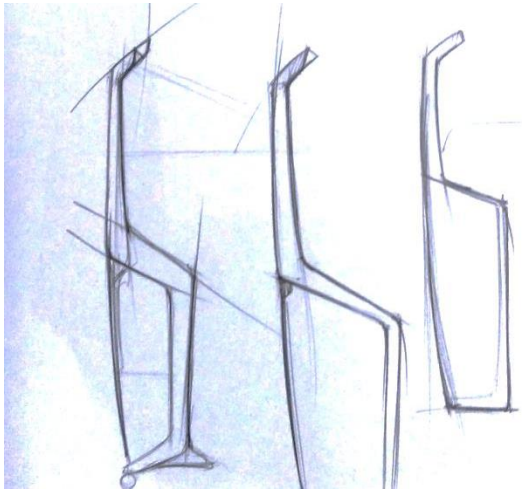
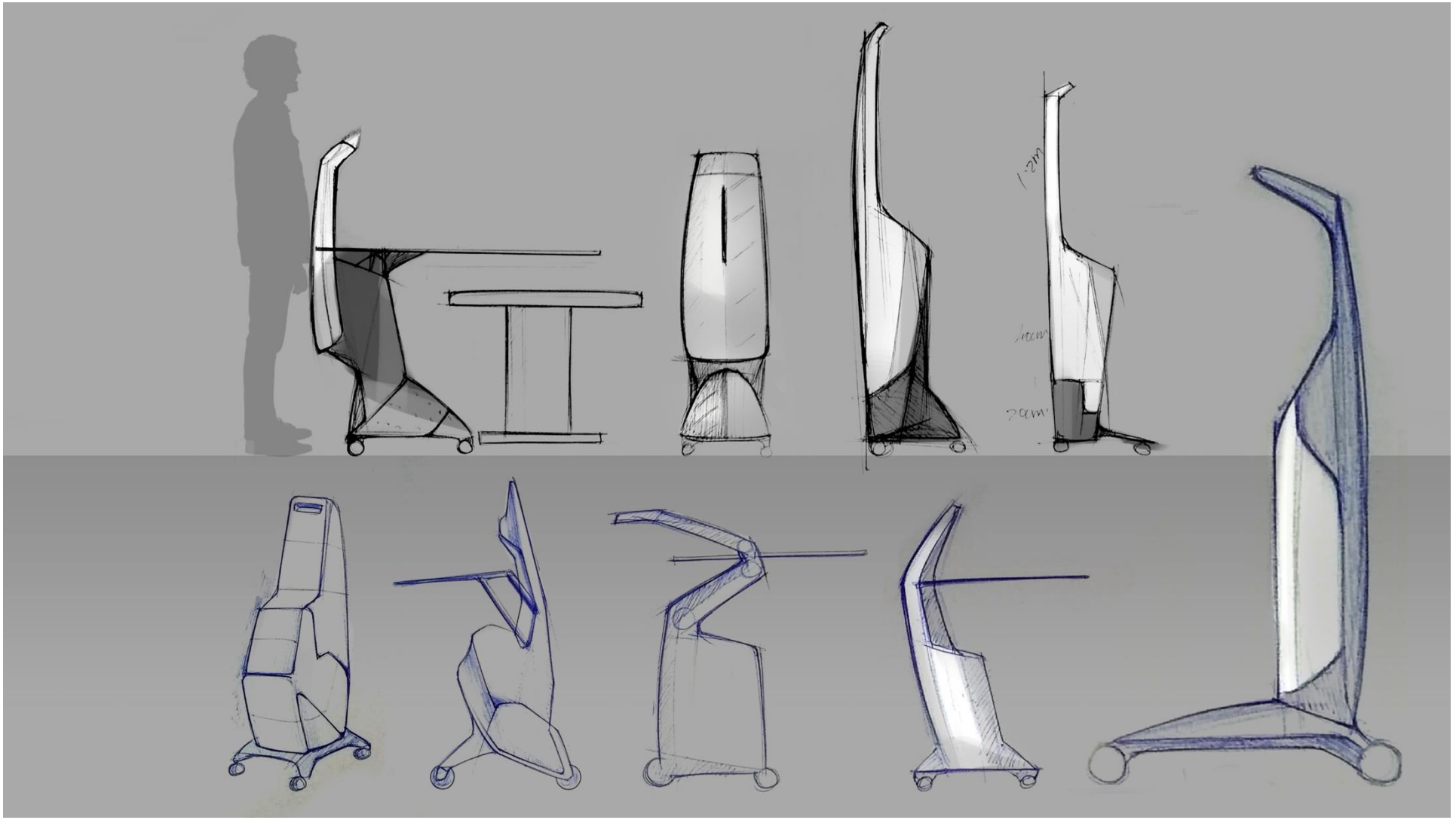


Fig:11,g Initial concept sketches (stable and simple forms)

Ideation Sketches



Ideation Sketches

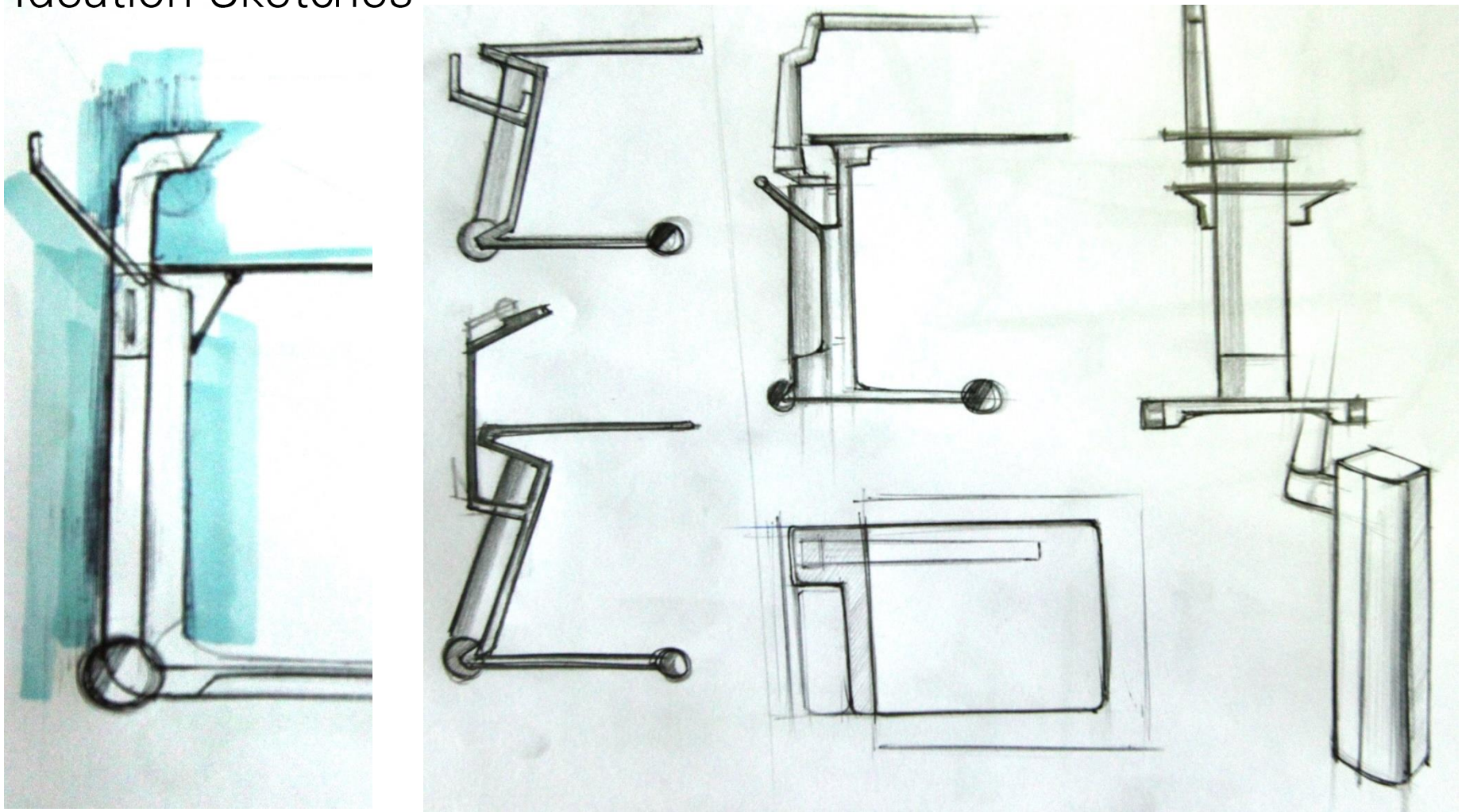
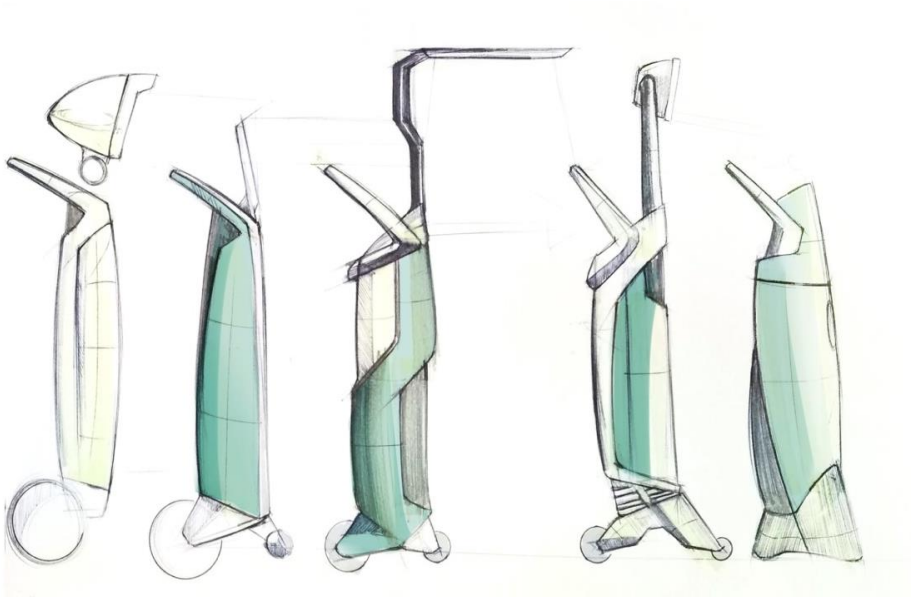
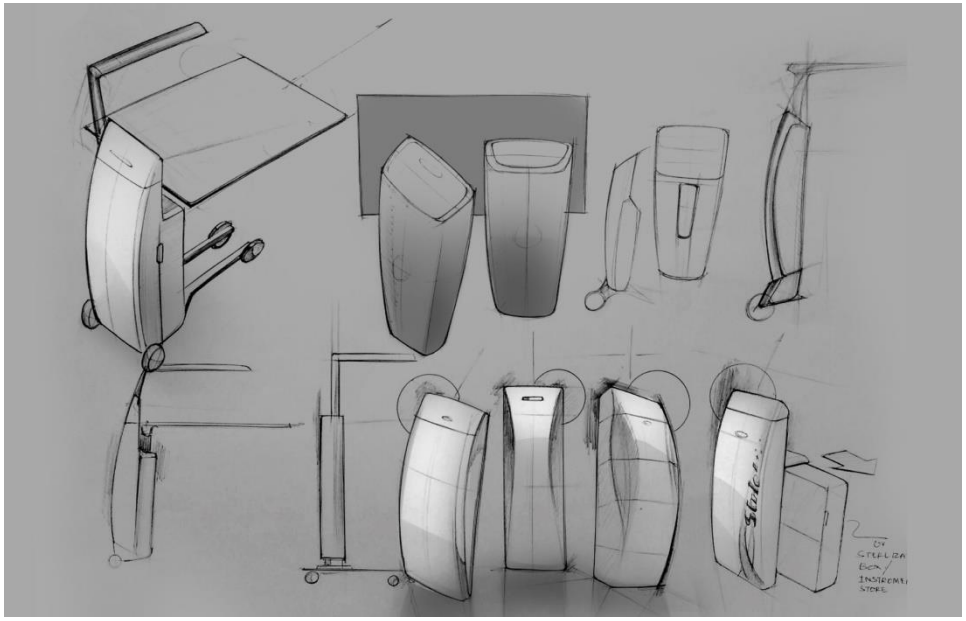


Fig:11,h Initial concept sketches (Simple easy to manufacture forms)

Ideation Sketches





Form study

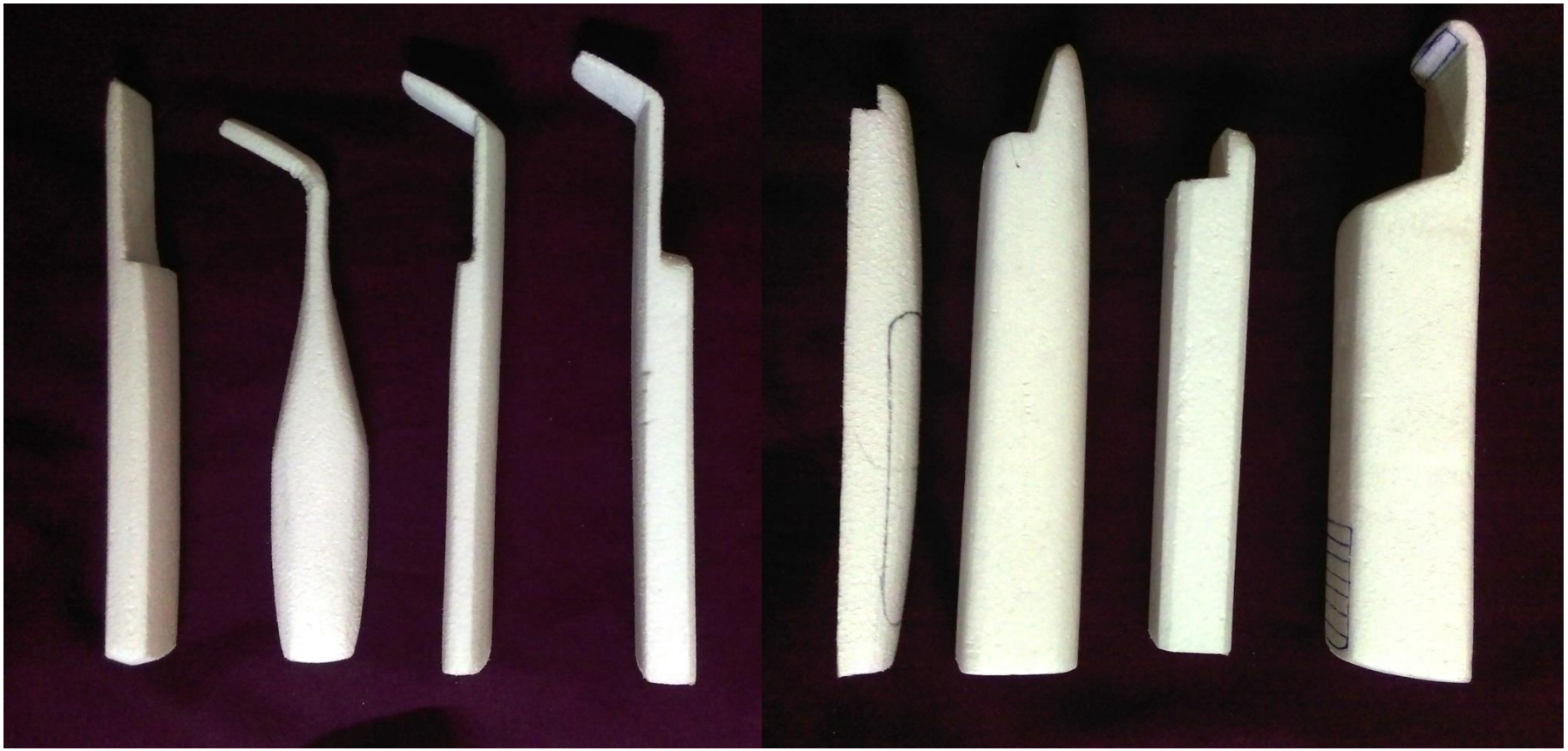


Fig:11,n Initial sketches to physical forms for better understanding

Form study

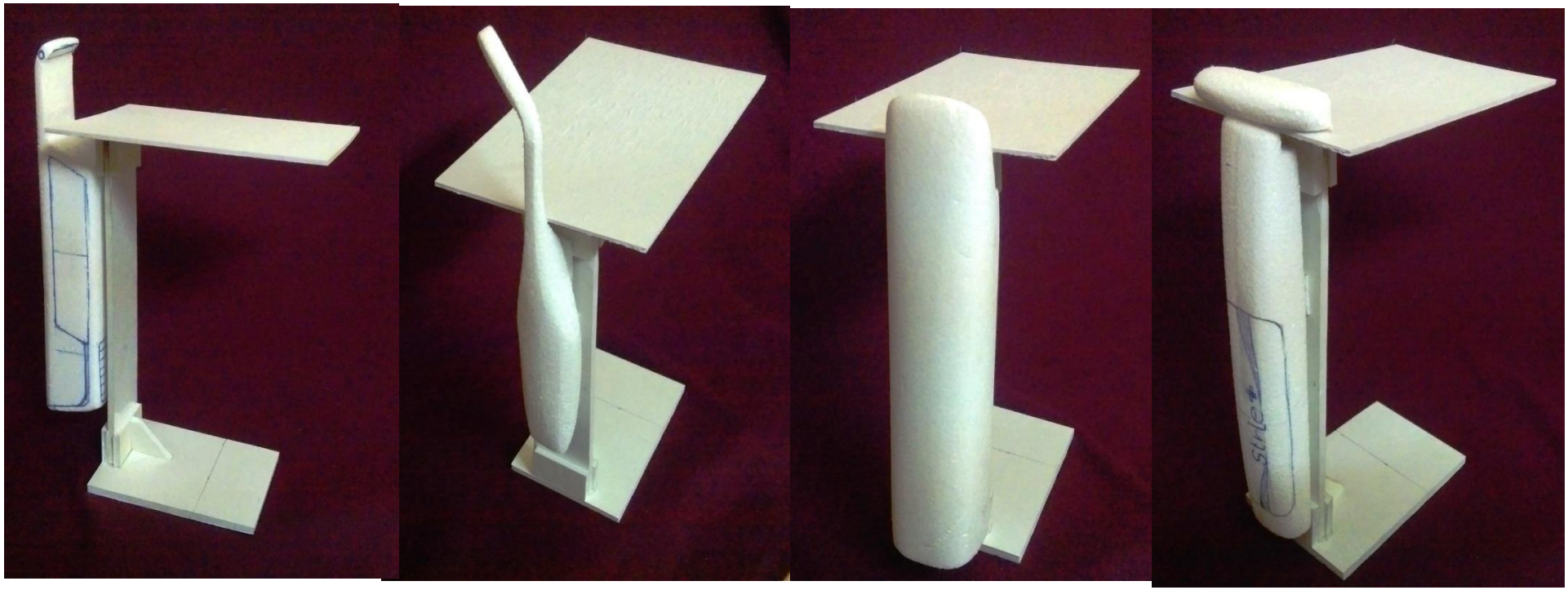


Fig:11,o Initial sketches to physical forms with tray (1:10 scale) for better understanding

Form study

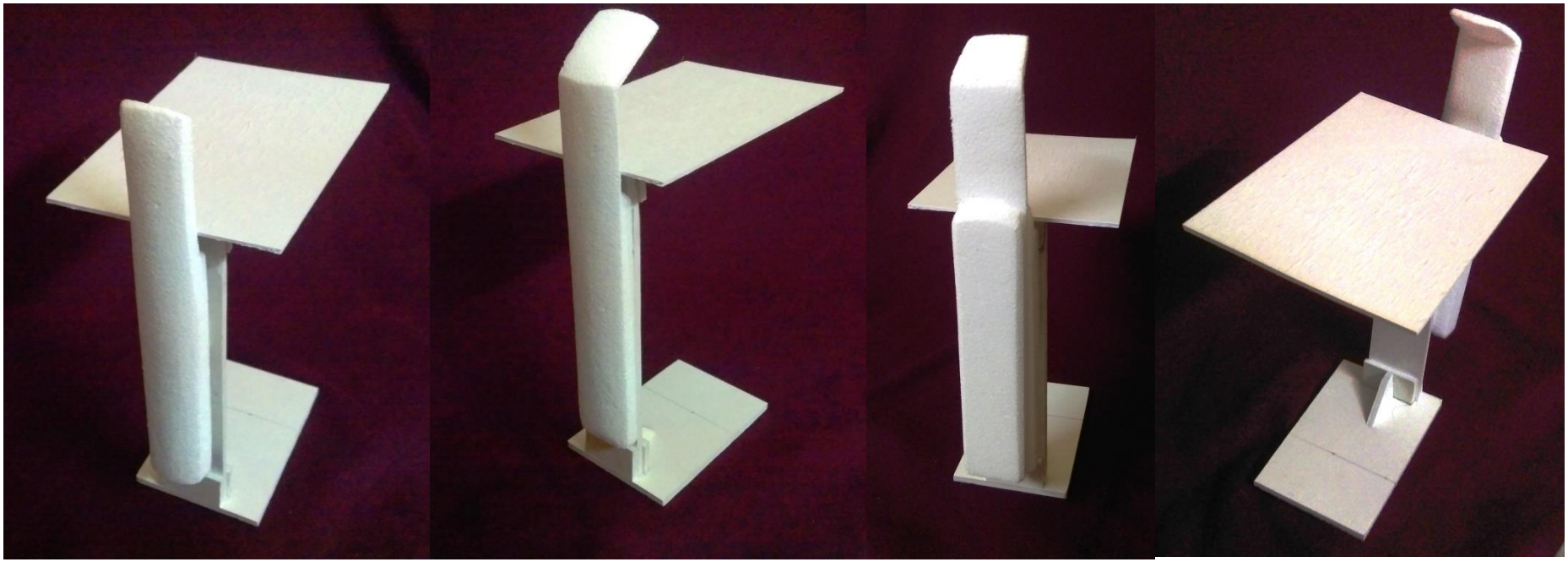


Fig:11,P Initial sketches to physical forms with tray (1:10 scale) for better understanding

Ergonomic study

Fig:11,Q Real scale geometric model to understand the ergonomic constrains.

- *The protruding legs were an issue since there was a change of leg hitting on it.*
- *The side facing the person is protruding out wastes the space.*
- *Cantilever type tray is effective since it require less floor space and can be kept over the patient without making contact to have better accessibility of instruments.*
- *The air delivery head has to be at least 10 cm above the tray to get the air distributed over the tray uniformly.*

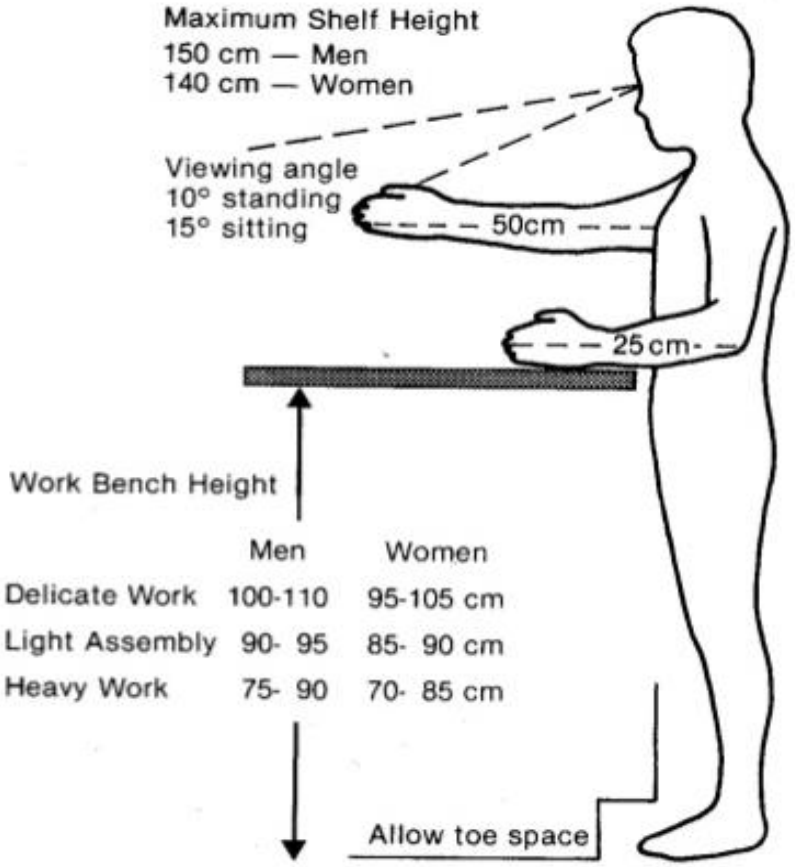


Fig:11,R Source: arido-ergonomics-amp-design-by-opc

Features of model

- In the final concept HEPA filter is used to filter out the microbes and this filtered air is pumped to the tray to keep the instruments to be in contact with contaminated air in OR
- A part of tray is provided with UVC light in an UV absorbing transplant plastic chamber which ensures the visibility of the instruments.
- Mainly tip of the instruments are irritated with UVC.
- The UVC irradiation chamber have depressions for placing the instrument head so the instruments can be arranged effectively.
- The tray divided in to two parts so it can be folded while not in use.
- IT also consists of UVC tubes inside the body which can be used to sterilize the OR in between the surgeries this will help to reduce the microbial load in the OR, 5-10min of operation will be sufficient enough to attain satisfactory limits of disinfection.
- The equipment body also contains space for keeping the instruments and sterilizing them using UV.
- Overall this device Improves the air quality, Continuously sterilize the instrument were it makes direct contact with patient. Maintains the whole instrument away from contaminated air source in the OR, Acts as OR disinfector in between surgeries, provides provision for UV Sterilization in closed UVC chamber and finally it can be used as a source if sterilized air for blowing it on any surface or t the patient operating area if required.

Fig:12.a 'STERIL+' is the proposed name of the Equipment

Final renderings

Fig:12.b, Different views of the final model

Internal components

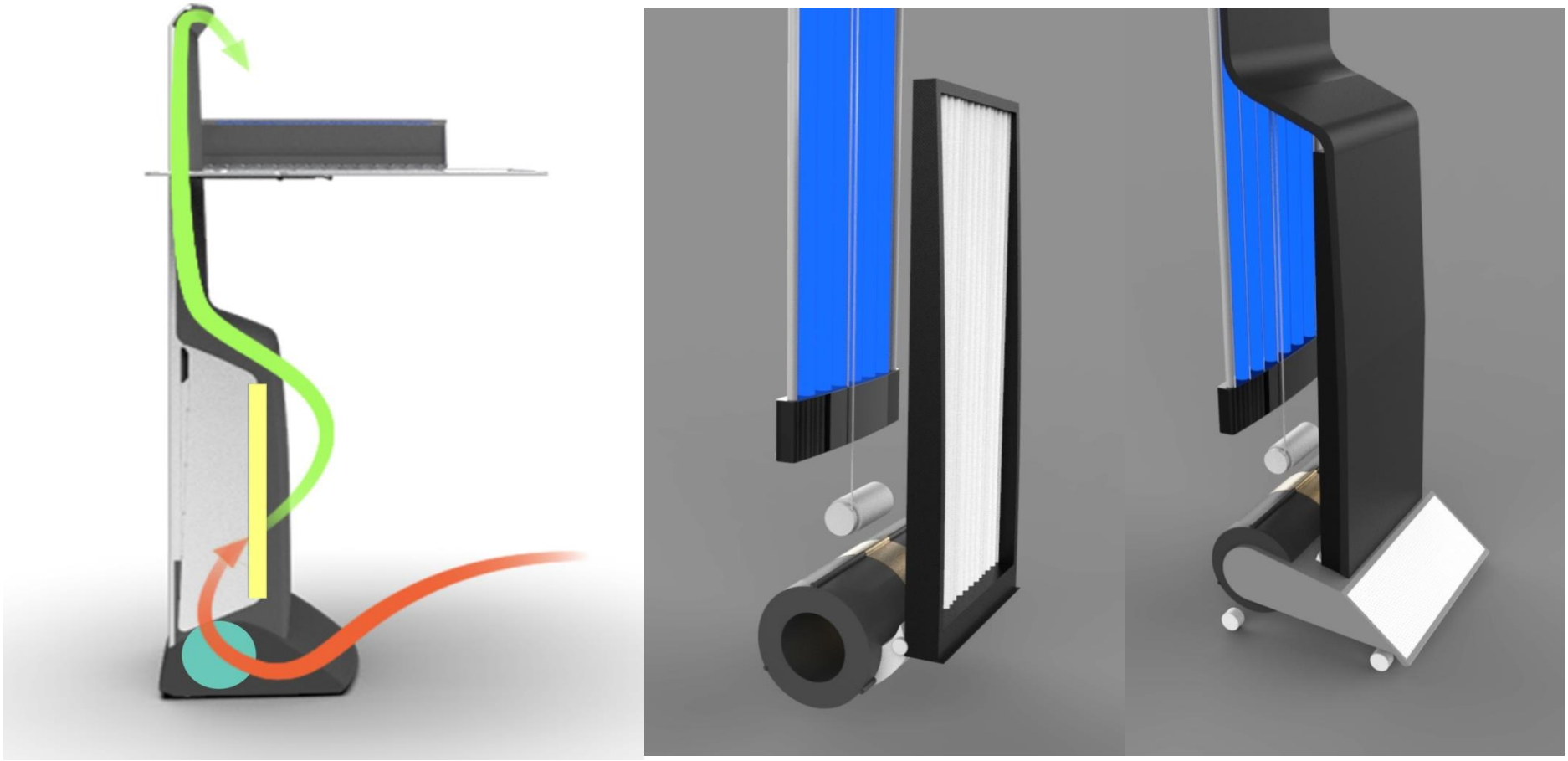


Fig:12.c, Internal components of the design, the HEPA filters and UV units can be seen

Internal UV C discharge tubes and lifting mechanism

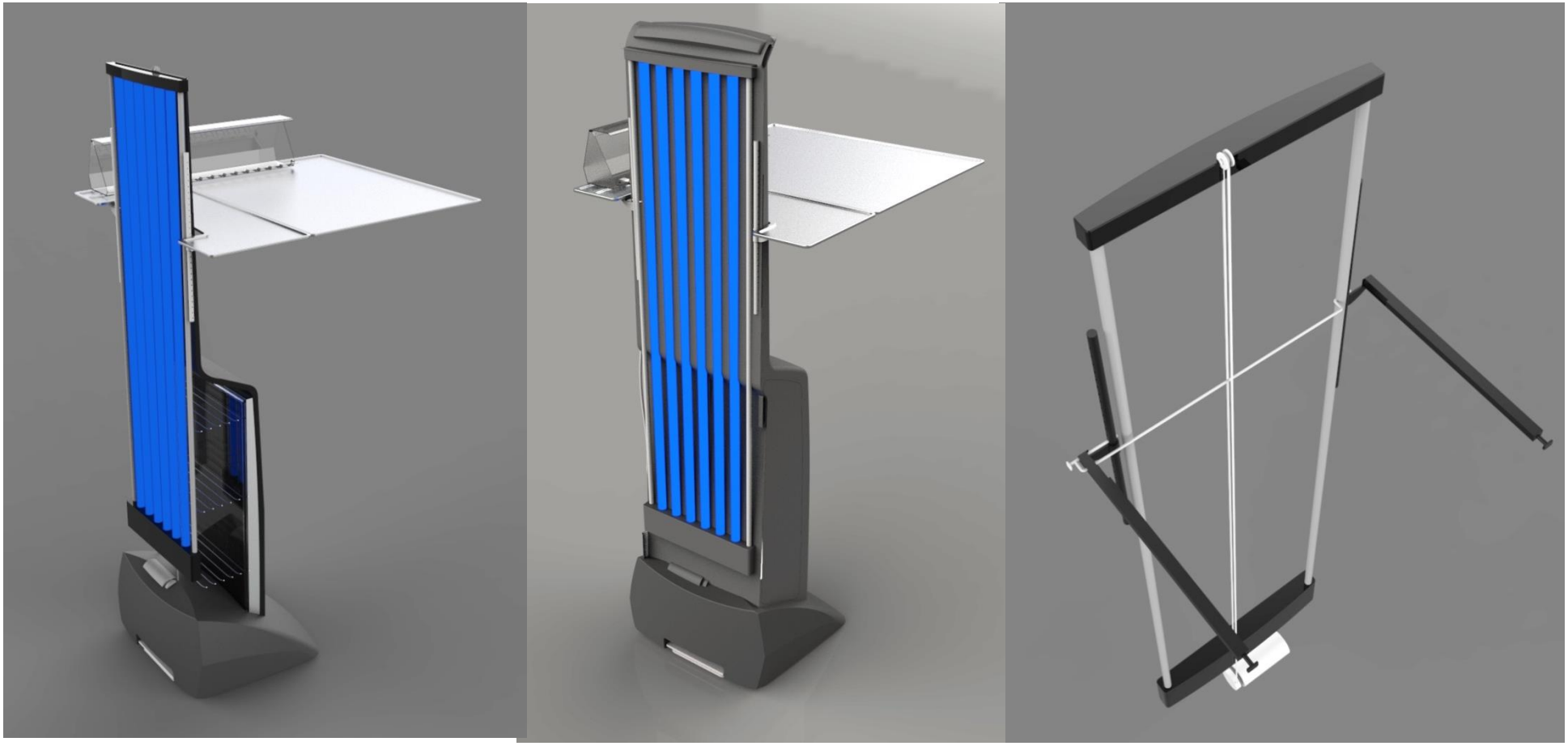


Fig:12.d,The UV discharge tubes inside it can be raised up automatically for room disinfection the inbuilt sensors switch's off automatically when it detects any personnel in its vicinity. The last figure shows the UVC automated tube lifting mechanism for room disinfection.

Instrument sterilization unit on the tray

Instrument sterilization using UVC, Instrument holder with slots to position the instrument are also provided.

Cam lock quick release mechanism to remove UV sterilizer unit

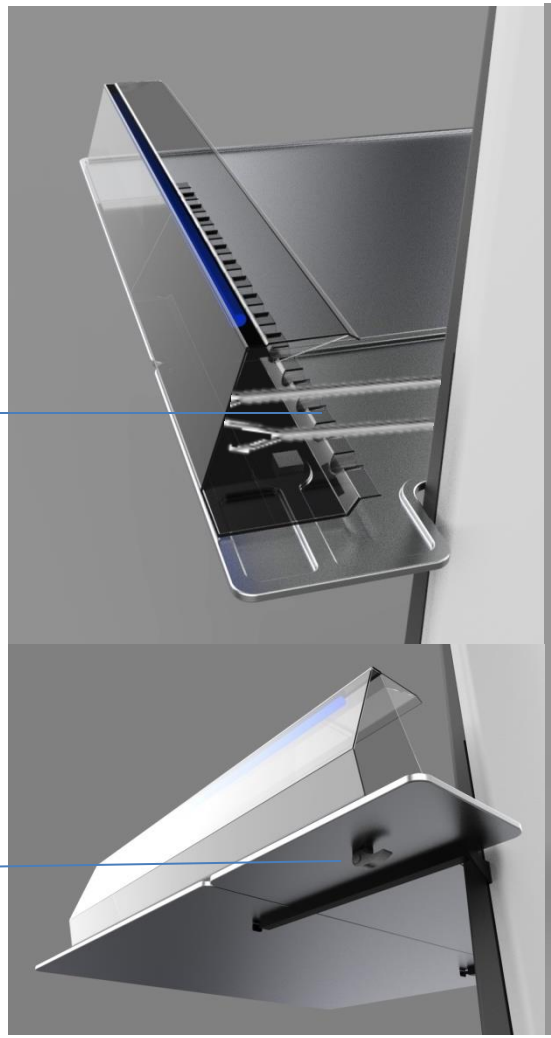


Fig:12.d,

Fig:12.f,

Various modes of operation.

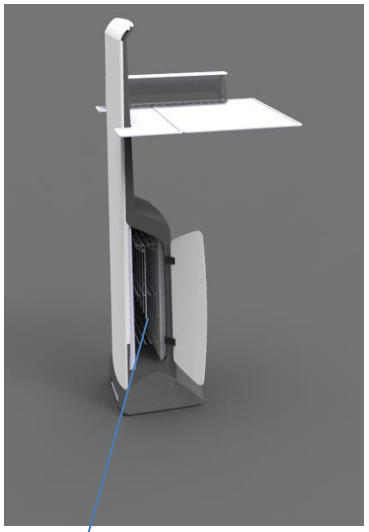


Fig:12.g

UVC sterilization chamber were instruments can be kept for surface sterilization

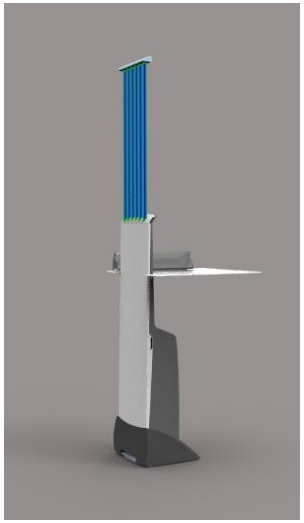


Fig:12.h

While in UV room sterilization mode, the Xenon UV C lamps rise up to sterilize the room in-between the surgery bio sensor detects the presence of personnel in its irritated area and switches it off and the tubes are automatically retracted.

Fig:12.i

The device can be folded for storage

Fig:12.j

The UV sterilization unit on the tray can also be twisted 90degree for compact storage.

Manufacturing and product specification

Equipment Body
For mass manufacturing
Material: ABS/PVC/HDPE
Manufacturing process: Injection moulding/vacuum forming/extrusion blow moulding.

For batch production
Material: HDPE
Manufacturing process: Vacuum forming

Component specification

- UV C lamp specification: TL-D 75W HO(Philips)
- Primary HEPA filter 0.7 micron
- Secondary HEPA filter 0.2 micron
- BLDC Blower
- Working voltage 230v
- Approximate total power consumed during normal opration300W
- Power consumption during OR disinfection using UVC 1500-2000W

Scale model

1/5 scale model developed with various features.
Fig 13.a shows the instrument storage unit partially opened
Fig:13.b equipment in room disinfecting mode

Fig:13.a

Fig:13.b

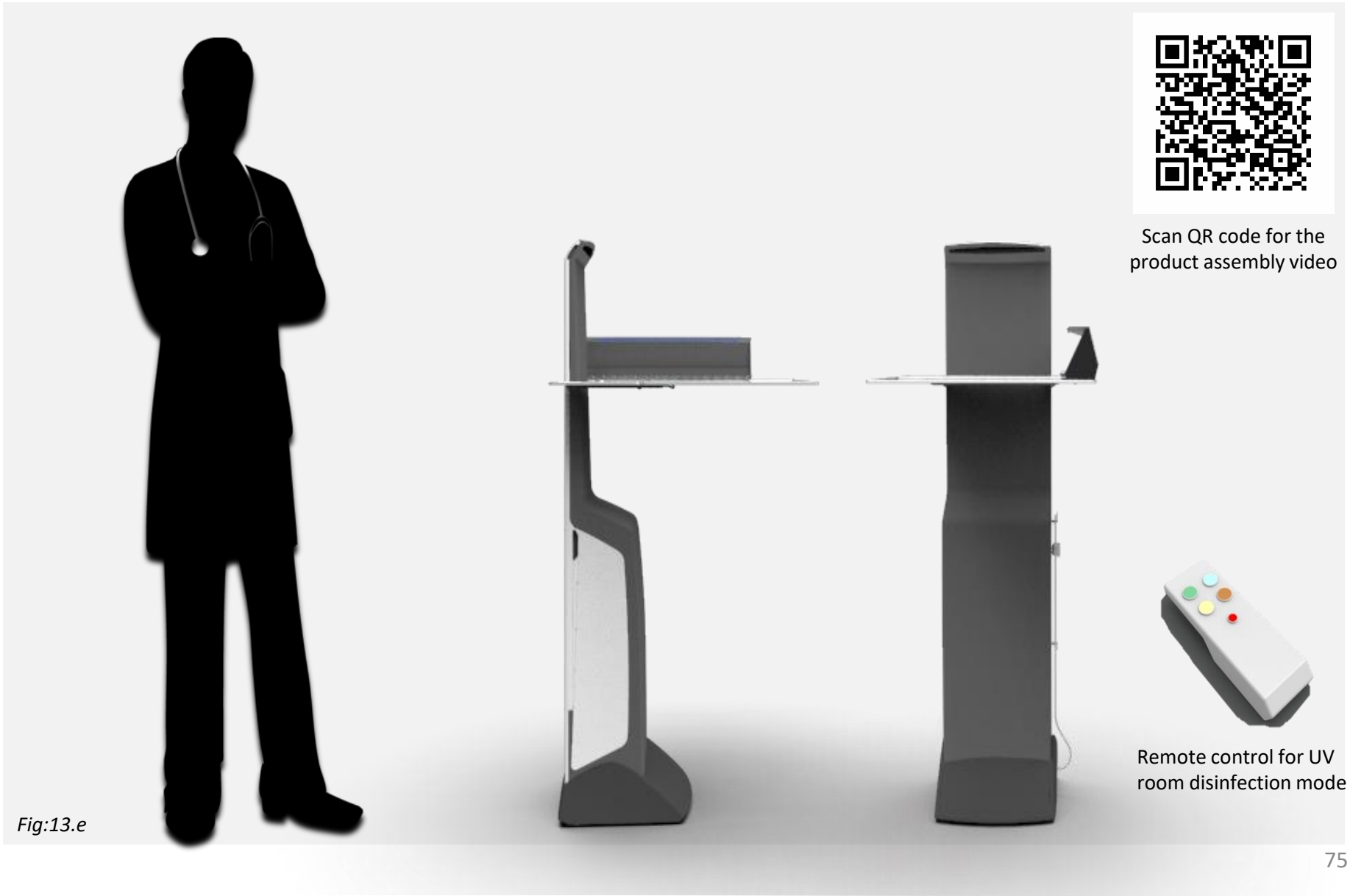
Scale model

Fig:13.c

Fig:13.d

1/5 scale model developed with various features.
Fig 13.c shows the instrument tray detached.
Fig:13.d The instrument tray at folded position.

Product video

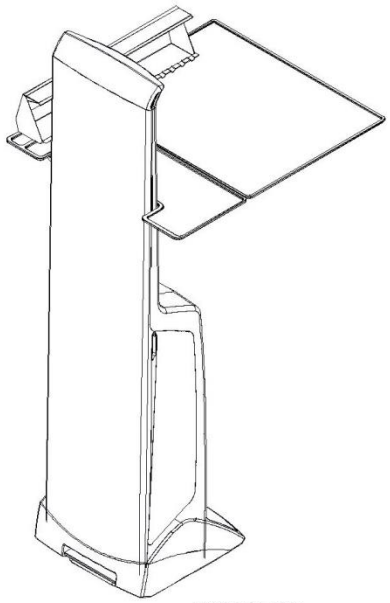


Scan QR code for the product assembly video

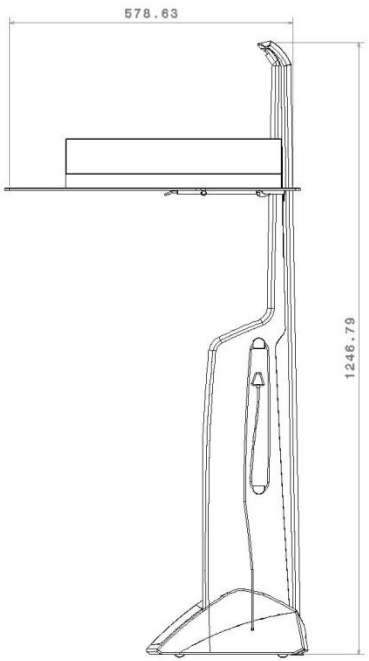
Remote control for UV room disinfection mode

Fig:13.e

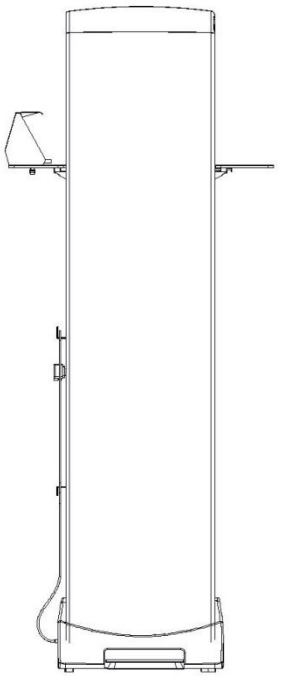
Engineering drawings



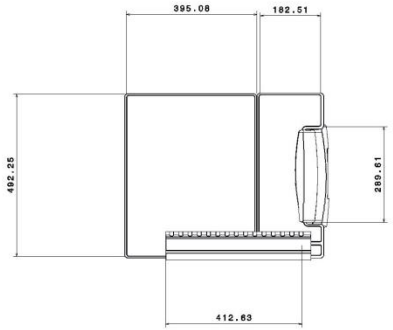
Isometric view
Scale: 1:5



Front view
Scale 1:5



Side view
Scale 1:5



Top view
Scale 1:5

Fig:14.f

Conclusion

The project began with the intention of designing tray which will keep the instruments from contamination but the research and user study indicated that just by keeping the instruments sterile won't alone solve the issue of SSI as expected. In the Indian context, the lack of awareness, professional negligence, a large number of patients, improper infrastructure and lack of expertise and instruments are aggravating to SSI. If constructive measures are not taken to prevent SSI excess use of antibiotics will be inevitable, this will lead to arising of Superbugs and a new stream of incurable diseases. This shows the amount of study and intervention needed in this area.

This device which is designed is supposed to be an optimal solution for the problems like instrument contamination OR air quality improvement and OR sterilization in between surgeries. Its also designed to cater to the needs of small OR's to OR's at good hospitals. Other than its core function the aesthetics and form give more confidence and reliability to the staff and patient. This innovation will be a great leap to fight against the never ending conquest against SSI. As said, "Prevention is better than cure"

Reference

- Fig: (1.1) http://www.shiranetoku.jp/kangobu/departments/gairaiyoteihyou/
- Fig :(1.2.a,b,c,d) https://immexls.com/the-four-basic-classifications-of-surgical-instruments/
- Fig: (1.2 f) https://goo.gl/zLRx5x
- Fig: (1.3.b) https://goo.gl/jxzNf8
- Fig: (1.3.b) https://goo.gl/Fn2Fwh
- Fig: (1.4,b) https://goo.gl/HFVCkb
- Fig:(1.5,a) https://goo.gl/WZE9e5
- Fig:(1.5,b) https://goo.gl/CX3TQG
- Fig:(1.7,c) https://goo.gl/GyWJf5
- Fig:(1.7,d) https://goo.gl/MvNScf
- Fig:(1.10,a) https://goo.gl/EZSKqQ
- Fig:(1.10,b) https://goo.gl/c2fUyM
- Fig:(1.10,c) https://goo.gl/DbA152
- Fig:(1.11,a) https://goo.gl/mNooPp
- Fig:(1.11,b) https://goo.gl/ssnq9L
- Fig:(1.12,a) https://goo.gl/T3htV2
- Fig:(1.12,b) https://goo.gl/mCYDy7
- Fig:(2.2) https://goo.gl/XQnvjs
- Fig:(2.5,a,b,c,d,e,f,g) https://www.youtube.com/watch?v=YTTXRT0fqPY
- Fig:(2.6,a,b,c) https://www.youtube.com/watch?v=YTTXRT0fqPY
- Fig:(1.12,c) https://goo.gl/DTVPa6
- Fig:(1.12,d) http://www.vidyya.com/images/figure_obgyn.jpg
- Fig:(1.8,a,b,c) http://www.normeditec.com/
- Fig(2.9,a,b) https://www.justdial.com
- Fig(2.9,d,e) http://www.infectionpreventiontechnologies.com/best-uv-light-disinfection-robots.html
- Fig2.10a,b,c,d,e,f) https://www.justdial.com
- Fig(8.1,a) https://goo.gl/be5Jgp
- Fig(8.1,b,c,d) https://in.pinterest.com/