

Social Innovation in Industry 4.0
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Lecture 35

Design and Social Innovation in Medical Devices (Part 2 of 2)

Welcome back to the course, we are discussing the design medical devices in this week. This is the second lecture of this week. In the first lecture, I have discussed the general things about the design of medical devices.

Contents



- ✓ Human factor Engg. in Medical Devices Design
- ✓ User Centred Design and User Interface
- ✓ Cognitive and Physical Ergonomics in Medical Device Design
- ✓ Usability Testing and Evaluation
- ✓ Designing for Accessibility and Inclusivity
- ✓ Risk Management and Human Factor
- ✓ Future Trends in Medical Device Design
- ✓ Ethical Considerations and Challenges

Now, here we will also try to put more focus on Human Factor Engineering in Medical Device Design, User-Centered Design and User Interface, Cognitive and Physical Ergonomics in Medical Device Designs, Usability Testing and Evaluation, Design for Accessibility and Inclusivity, Risk-Management in Human Factors will be discussed, Future Trends in Medical Devices, and Some Ethical Consideration and Challenges. And, we will also see some examples of the medical devices which are developed considering all these factor, and which are developed through the ISO 13485 compatibility.

Human Factors Engineering (HFE) in Medical Device Design

- ❖ Human factors engineering (HFE) is the application of knowledge about human capabilities, behaviours, and limitations to the design of products and systems.
- ❖ In the context of medical devices, HFE is used to ensure that devices are
 - Safe
 - Effective
 - Easy to use
- ❖ HFE encompasses a wide range of activities, including:
 - ✓ User-Centered Design
 - ✓ Task Analysis
 - ✓ Usability Testing
 - ✓ Error Analysis

Now, Human Factors Engineering in Medical Device Design, HFE or Human Factor Engineering is the application of knowledge about human capabilities, behaviors, and limitations to the design of products and systems.

In the context of medical devices, HFE is used to ensure that devices are safe, effective, and easy to use, this we have discussed in the previous lectures. Now, HFE encompasses a wide range of activities, which include user centered design. One is a User-Centered Design that means tailoring the medical devices as per our own users need, this is User-Centered Design. Then, comes the task analysis, task analysis means the overall task of the medical device design is broken down into small Work Breakdown Structures (WBS), so these work breakdown structures are then taken care using different kind of small activities, so this is task analysis which is also part of the Human Factor Engineering.

Then, comes usability testing, that is the user friendliness of the device is assessed, and it is refined. Then, comes error analysis as I said it is an iterative process, so recognizing and preventing potential errors is an important factor whenever we try to design a medical device.

Human Factors Engineering (HFE) in Medical Device Design



HFE experts should be involved in the early stages of design, when decisions about the user interface, functionality, and packaging are being made.

By integrating HFE early in the design process, it is possible to:

- Identify and eliminate usability problems before they become costly to fix.
- Improve the safety and effectiveness of medical devices.
- Reduce the risk of medical errors.
- Improve the user experience of medical devices.

HFE experts should be involved in the early stages of design, when decisions about the User Interface, functionality, packaging are being made. By integrating HFE early in the design process, it is possible to identify and eliminate usability problems, even before they have existed or at least before they have become costly to fix. Then, improve the safety and effectiveness of a medical device, reduce the risk of medical device errors, and improve the User Experience of the medical devices, it is important to eliminate the errors prior because some errors could only cost some amount of money, certain other errors could also cost the health of the patients. So, it is important in medical devices to be more strict, in what we are trying to do and try to eliminate the usability problems early.

Human Factors Engineering (HFE) in Medical Device Design



HFE (Human Factors Engineering) addresses:

- ✓ Usability: To design user interfaces that are easy to understand and use.
- ✓ User experience (UX): To create medical devices that are enjoyable and satisfying to use.
- ✓ Safety in medical device design: To identify and mitigate the risks of medical errors.

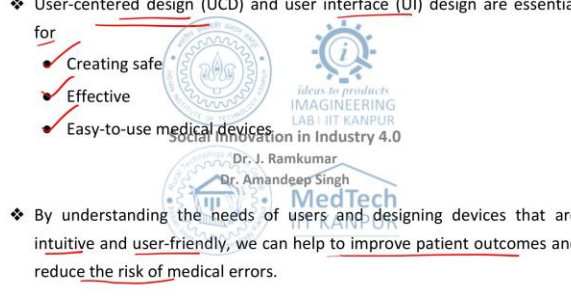
Now, Human Factor Engineering addresses usability, User Experience and safety in Medical Device Design. when I say usability, it means to design User Interfaces that are easy to understand and use. Here for example, HFE experts can help to design clear and concise instructions and to create User Interfaces that are consistent and predictable. For User Experience to create medical devices that are enjoyable and satisfying to use, here

HFE experts can help to design devices that are aesthetically pleasing, because User Experience is there, then this also helps to provide feedback from the users and also encouragement sometimes to use the medical device.

Safety in medical device design that is to identify and mitigate the risks of medical errors. So here, HFE experts can help to design devices that are resistant to misuse, or that provide user with warnings or alerts. So, these safety concerns are taken into consideration always.

User-Centered Design and User Interface (UI) Design in Medical Devices

- ❖ User-centered design (UCD) and user interface (UI) design are essential for
 - Creating safe
 - Effective
 - Easy-to-use medical devices
- ❖ By understanding the needs of users and designing devices that are intuitive and user-friendly, we can help to improve patient outcomes and reduce the risk of medical errors.



Now, UCD (User-Centered Design) and UI (User Interface) both of them are essential for a creative safe, effective and easy to use medical devices. As I said, User interface, User-Centered Design, User Experience all of these are the part of design.

In medical devices, the User interface is important because the user is the one who is already not feeling well sometimes or who is into a situation where the disease is to be cured, maybe it is a doctor, maybe it is a nurse, maybe it is a patient or so. So here, User interface and User-Centered Design becomes more critical. So, by understanding the needs of users and designing devices that are intuitive and user friendly, we can help to improve patient outcomes and reduce risks of medical errors.

User-Centered Design and User Interface (UI) Design in Medical Devices

Some specific examples of how UCD and UI design can be used in medical devices:

- ✓ User Feedback
- ✓ Clear Instructions : *Give in plain language, icons, symbols*
- ✓ Error Prevention : *Warnings, Alerts*
- ✓ Aesthetic UI : *Visually appealing*

Now, some of the specific instances could be taken or examples could be taken on how User-Centered Design and User interface design can be used in medical devices. For example, user feedback, clear instructions, error prevention and aesthetic User Interface are the major points, which are to be taken when we are trying to design something for user and it is centered towards user and User interface has to be made better.

When I say user feedback, user feedback means we try to gather input from potential users to improve usability especially creating to specific user groups like elderly people, like children or so. Then, clear instructions, clear instructions means we ensure that the instructions are concise, then plain-language, it should not be very tough mechanical or maybe medical language, the language of use should be very plain. The plain-language instructions which are consistent with User interface include maybe icons, symbols or so. Then, error prevention which means implementing error proofing techniques such as warnings, alerts, etc. These are there to avoid any mistakes in use of the medical devices.

Then, comes aesthetic in User interface. So, visually appealing design is a part of the User interface because visually appealing if I say, the red color could be given wherever the alert is to be given. The green color means it is clear. So, these color coding could be used and also the device could have some patterns or colors, so that visually it is appealing. So, to create visually appealing interfaces, we need to have the help of the designer, and creating these kind of interfaces for a more enjoyable, or stress reducing User Experience, considering color, font, choices could also be made.

Cognitive and Physical Ergonomics in Medical Device Design

Cognitive ergonomics is concerned with how users mentally process information and make decisions when interacting with medical devices. This includes factors such as:

- ✓ Cognitive workload: *Mental effort required to use a device*
- ✓ Mental models: *User's understanding*
- ✓ Error-prone situations: *Highly prone areas/aspects*

Next comes, Cognitive and Physical Ergonomics in Medical Device Design. Cognitive Ergonomics is concerned with how users mentally process information and make decisions when interacting with medical devices. This includes factors such as cognitive workload, mental models and error prone situations. When I say cognitive workload, this is the amount of mental effort that is required to use a device. Mental effort required to use a device.

The mental model means the users understanding on how to use the device. Then, error-prone situations, error-prone situations mean conditions that make it more likely for users to make mistakes. So, wherever the mistakes are more prone or highly prone areas or aspects in the design where errors could be made those are focused and those are also mitigated in the Cognitive and Physical Ergonomics Design, so this is taken care of.

Cognitive and Physical Ergonomics in Medical Device Design

Physical ergonomics is concerned with the physical demands of using medical devices, such as the size, weight, and portability of the device. This includes factors such as:

- ✓ Reach: Distance to reach
- ✓ Force: Effort to be applied
- ✓ Posture: Position of users body

- ❖ By considering cognitive and physical ergonomics, it is possible to design medical devices that are easy to use, safe, and effective.
- ❖ This can help to improve patient outcomes and reduce the risk of medical errors.

Next comes the Physical Ergonomics. It is something that is concerned with physical demands of using medical devices such as size, weight, portability of the device.

This includes factors such as reach of the device, force required to use the device, and the posture in which the device is to be used. When I say reach of the device, this is the distance at which the device is kept. So, whenever we say distance, there are working areas, this is normal working area, this is maximum working area. Whenever I am standing, anything that lies within my this radius, when I am trying to move my hand around my elbow, this is my normal working area. If I move it around my shoulder, this is my maximum working area.

So, within this range, the medical device are to be used. So, this is the most easy area where very frequently used things are to be kept. This is where less frequently used are to be kept, and if suppose, I have to take a step, and then to pick something, those are the parts or components which are to be used rarely.

So, reach or distance at which the product is kept or the product components, or may be small connected wires, or certain probes are kept, so that has to be taken care of. It is the distance, that the user has to reach to interact with the device. This is known as reach.

Then, comes force. The amount of force that user has to apply to interact with the device, that is easy for an elderly people to pick something, the weight has to be designed accordingly. So, what is the effort or amount of force to be applied to use the product.

Then, comes posture. Users body posture when using the device is also an important point, because we are talking about the ergonomics in medical device designing. When I

say ergonomic design, ergonomic design of medical device that means we are trying to focus on human comfort. Human comfort, because ergonomics itself, ergo is human, nomics is norms. Human norms that is the comfort, that is human experiencing while using something in that posture is very important. If something is designed for Indian population, for example Indian anthropological dimensions are to be taken, because suppose average Indian height is 5 feet 8 inches something, average American height is 5 feet 11 inches something.

So, whenever the medical device is to be designed, it is designed according to the population who is going to use it and the posture and everything is designed accordingly. So, posture is the position of the user body. Only then, the innovation would be called Social Innovation, if the local population who is using the device is happy to use it, and they really feel that it has made a social change and social impact has been positive. So, then only the things would be there. So, these things that is the ergonomics becomes one of the critical factors, when we are trying to design a medical device.

Now, by considering cognitive and physical ergonomics, it is possible to design medical devices that are easy to use, safe and effective. This can help to improve patient outcomes and reduce the risk of medical errors.

Cognitive and Physical Ergonomics in Medical Device Design

Some specific examples of how cognitive and physical ergonomics can be applied to medical device design:

- ✓ Use clear and concise language in the user interface.
- ✓ Provide feedback to the user.
- ✓ Make the user interface consistent.
- ✓ Design the device for the specific needs of the user.
- ✓ Optimize the size, weight, and portability of the device.

Further in Cognitive and Physical Ergonomics in Medical Device Design some specific examples of how these can be applied to medical device design are use clear and concise language in the user interface. Then, provide feedback to the user that whether the product is being used correct or not. For example, if the user is trying to use something correctly, green light could be there otherwise alerts in the red light could also come.

Then, we need to make the User Interface consistent, that is for each or any of the users who so ever come it has to give the similar results. Then, design the device for the

specific needs of the users specific needs which means if it is designed for elderly, it has to be taken care or used by elderly people who would not like to use many buttons on their device. They would also only like to know this is start button, stop button, these are two-three lights which are giving indications and not many part or many textual instructions are there only symbolic instructions are given. So, it is specific needs of the user are to be met here. Then, we need to optimize size, weight, portability of the design. So, these are certain specific tips whenever we are trying to design something for ergonomics and for cognitive design.

Usability Testing and Evaluation

Usability testing is a method of evaluating the usability of a product or system by testing it with users.

Usability testing can be used to identify usability problems, such as:

- Errors
- Confusion
- Frustration

Non-Conformance

It can also be used to gather feedback from users on how to improve the usability of the product or system.

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Then, comes Usability Testing and Evaluation. Usability Testing and Evaluation here usability testing is a method of evaluating the usability of a product or system by testing it with users. It can be used to identify usability problems such as errors, confusions, frustrations. So, this is the level of the error or the non-conformances.

If they are low, they call it errors, further it becomes confusion, it also make frustration if it keeps on giving something time and again incorrect. It can also be used to gather feedback from users on how to improve the usability of the product or a system.

Usability Testing and Evaluation



There are two main types of usability testing:

- Formative usability testing is conducted early in the design process to identify usability problems and make improvements.
- Summative usability testing is conducted later in the design process to assess the overall usability of the product or system.

The following steps should be taken when planning a usability test:

- Identify the goals of the usability test.
- Identify the users who will be participating in the test.
- Develop a test plan.
- Develop a test protocol.

The data collected from a usability test should be analyzed to identify usability problems.

Now, Usability Testing and Evaluation are of two types, formative and summative, as I told in the previous lecture as well. Formative testing is conducted early in the design process to identify usability problems and make improvement. Summative is conducted later and it is done to assess the overall usability of the product or system.

So, overall usability is the key word here. For summative usability testing, for formative. In the early design process, we only work upon usability problems in the beginning. So following steps should be taken when planning is usability test. That is, we need to identify the goals of usability test, what usability has been trying to work upon significant part to be tested upon.

Then, we try to identify the users who will be participating in the test. Then, we develop a test plan, develop a test protocol. Not only the plan, the protocol, this is the test protocol that will be followed. For the specific kind of the problem, this kind of test could be conducted. This is a kind of a plan to have a usability testing evaluation. Now, the data collected from a usability test should be analyzed to identify usability problems.

Designing for Accessibility and Inclusivity in Medical Devices

Accessibility and inclusivity are important considerations in the design of medical devices.

Examples of how accessibility and Inclusivity can be considered in the design of medical devices :

- ✓ Use clear and concise language in the User interface
- ✓ Provide auditory feedback.
- ✓ Design the device for different sizes and shapes of hands
- ✓ Provide text alternatives for images.
Braille tags. (Visually impaired)

Designing for Accessibility and Inclusivity in Medical Devices. Accessibility and inclusivity are important considerations in the design of medical devices. Examples of how accessibility and inclusivity can be considered in the design of medical devices.

Certain example tips are given here. Number one is use clear and concise language in the User Interface. For users with reading and comprehension difficulties clear language, concise language, with may be some visual presentation of symbols, icons that could be given. Then, we provide auditory feedback as well, auditory means for users with visual impairments. For elderly people, for children auditory feedback okay, you did good okay, not correct, something like that. Okay, not okay, this auditory feedback could be given.

Then, design the device for different sizes and shapes of hand. it could be even hands or feet or any body part depending upon the population you are trying to target for design. If it is for kids it has to be smaller, if it is for adults it has to be bigger, for elderly people it has to be software, for different kinds of sizes it could be designed, so that you try to hit the maximum population. Then, we can also provide text alternatives for images that means the text alternatives may be the braille language. This is not I am talking about the general text because that is already covered here, in the point number one. This is for people who are visually impaired.

Risk Management and Human Factors



- Risk management is a critical part of the design process for medical devices,
- By integrating human factors into risk management, we can identify and mitigate risks that are related to the human use of medical devices.

Human factors can be integrated into risk management for medical devices by:

- ✓ Identifying use-related hazards
- ✓ Assessing the likelihood and severity of use-related hazards
- ✓ Mitigating use-related hazards (آی ایستاده)

Risk management and Human Factors, risk management is a critical part of design process for medical devices. By integrating human factors into risk management, we can identify and mitigate risks that are related to the human use of medical devices.

Risk Management and Human Factors



Use-related hazards in medical device design can include:

- ✓ Confusing or misleading labels
- ✓ Difficult-to-use controls
- ✓ Physical hazards
- ✓ Environmental hazards

All these Use hazards can be mitigated by

- Improve clarity and simplicity, enhance visual cues, Simplify user interaction.
- Address physical and environmental hazards.

Human factors can be integrated into risk management for medical devices by identifying user-related hazards, assessing the likelihood and severity of user-related hazards, mitigating user-related hazards. When I say identifying we are only trying to analyze User Interface, we are only trying to observe interactions, we are also we are trying to conduct user interviews or so.

When I say assessing the likelihood or severity here, we are considering factors, such as device complexity the training that is given to the user or the environment. When I say mitigating use-related hazards, use-related hazards means we can also adjust the UI, adjust User Interface, or we can also provide user training or we can also include user

warning or instructions or so. So, these are all risk management when we are trying to consider the human factors as well. Further, use-related hazards in medical device design can include confusing or misleading labels. Also sometimes the controls are difficult to use, physical hazards could also come and environmental hazards could also be an unwanted outputs.

Confusing and misleading labels implies wrong medication could also be given, Settings device to wrong settings could also lead something that is not required or that is mislead could be there. Difficult-to-use controls means the controls are making user frustrated. As I said errors, confusions, frustrations do come and mistakes might also happen. Physical hazards include the sharp edges, the hot surfaces, the electrical shocks, or anything of these kind could be physical hazards. Environmental hazards could be the radiation exposure or maybe the exposure to hazardous chemicals.

All of these use hazards can be mitigated by improving clarity and simplicity, enhance visual cues, simplify user interaction, and also addressing physical and environmental hazards is to be taken care of.

Future Trends in Medical Device Design

The field of medical device design is constantly evolving, with new technologies emerging all the time.

Some of the most promising future trends in medical device design:

- ✓ Emerging technologies in healthcare
- ✓ Impact of artificial intelligence (AI) on medical device design
- ✓ The rise of IoT and connected medical devices

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Impact of artificial intelligence (AI) on medical device design

The rise of IoT and connected medical devices

Next comes Future trends in Medical Device Design. The field of medical device design is constantly evolving with new technologies emerging all the time. Some of the most promising future trends in medical device design include emerging technologies in healthcare, impact of artificial intelligence that is AI on medical device design, the rise of IoT that is the Internet of Things and connected medical devices. So, we learn more about these in the coming slides, and we will try to see what kind of medical devices now are using different kinds of the future trends.

Future Trends in Medical Device Design



1) Emerging Healthcare Technology Trends:

- Artificial Intelligence (AI):
 - AI transforms medical device design, aiding disease diagnosis, patient monitoring, and personalized treatment.
 - AI-powered devices advance cancer treatments for effectiveness and reduced toxicity.
- Internet of Things (IoT):
 - IoT links diverse medical devices, generating valuable data for enhanced patient care.
 - IoT-connected devices improve chronic disease monitoring like diabetes and heart conditions.

Now, emerging healthcare technology trends, healthcare technology trends, in which artificial intelligence which is trying to imitate what human could do, that is, AI transforms medical device design, aiding disease diagnosis, patient monitoring, personalized treatment all in one set. AI-powered devices advance cancer treatment for effectiveness and reduce toxicity. Internet of Things, it is a part of AI, Internet of Things, that is using different sensor, and gadgets to get the data from the patients or from the doctor, the data could be live, the data could be directly monitored or so. So, IoT links diverse medical devices generating valuable data for enhanced patient care. IoT-connected devices improve chronic disease monitoring like diabetes or heart conditions.

Because they are connected to the Internet of Things there are sensors that could be directly connected to heart, your heartbeat monitoring could be done directly, and with small connection to the Wi-Fi the heart could be monitored directly within your home itself. So, that means the chronic disease monitoring such as diabetes, heart conditions can all be connected through IoT.

Diabetes is the number of steps you are taking each day, simply we have smart watches nowadays that can also calculate the number of steps you are taking the overall BMI (Body Mass Index) that you have, that can also be monitored using these small devices. Then, comes VR because we are talking about the emerging healthcare technology trends. VR is Virtual Reality, in which virtual reality shapes medical training and surgical planning offering immersive experiences.

Virtual reality means we are trying to imitate what is happening in reality into the virtual environment. Like, for example, some dissection has to be happened, cockroach direct dissection has to happen. In virtual environment, we can try to do it, how it would actually be done in the reality that is also imitated here. VR aids pain management and

surgery preparation for patients. Surgery preparation means before doing actual surgery we try to do a surgery in a virtual environment.

So, that is simulation of surgery in the virtual environment. Next comes impact of AI on medical device design that is enhanced intelligence, personalized care and cost reduction. When I say enhanced intelligence AI enables autonomous decision-making which boost device safety and efficacy. Personalized care means AI driven data collection tailors treatment enhances effectiveness and efficiency. Cost reduction AI driven automation cuts human task which also lower certain medical device expenses. So, that is why cost reduction also happens.

Future Trends in Medical Device Design

3) The rise of IoT and connected medical devices:

- ✓ Data Richness
- ✓ Continuous & Personalized Care

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Rise of IoT and connected medical devices. The IoT and connected medical devices is on rise because we have data richness in it, and continuous and personalized care is taken. When I say data richness IoT connected medical devices yield patient data for enhanced care, remote monitoring could happen, early issue deduction could be there. So, we get a large amount of data in very less amount of time, and this could also be monitored remotely the data richness is there. Then, continuous and personalized care which means connectivity offers ongoing personalized attention, which fosters improvement in the outcomes and also the cost savings.

Ethical Considerations and Future Challenges



The design of medical devices raises a number of ethical considerations,

including:

- ✓ Privacy and data security
- ✓ Accuracy and reliability
- ✓ Accessibility
- ✓ Cost



The last point is the Ethical Considerations and Future Challenges. The design of medical devices raises a number of ethical considerations, which includes privacy and data security, accuracy and reliability, accessibility and cost. The privacy means the device has to be synthesized in such a way that the data should not be given to the people who are not authorized for it. That is data collected by medical devices can be sensitive and it must be protected from any unauthorized accesses. Then, accuracy and reliability, medical devices must be accurate and reliable in order to provide safe and effective care.

Accessibility, that is medical devices must be accessible to all patients regardless of their age, size, disability or whatever the target population, we are trying to hit all of them should be able to access the medical device. Then, comes the cost, medical devices must be affordable for patients and healthcare providers. So, this also becomes an important consideration in medical devices and future challenges are there.

Examples:
SHUDH
Smartphone Operated UV Disinfection Helper

In order to continue the practices of sanitizing learned through Covid-19, Imagineering Laboratory IIT Kanpur has developed an Ultraviolet (UV) sanitizing product named SHUDH. SHUDH has six UV lights of 15 Watts each that can be individually monitored from a distance. Initial testing has proved that the device at its full operation can disinfect a 10x10 square feet room in about 15 minutes.



There are certain examples of medical devices which are designed at Medtech IIT Kanpur. For example, this is SHUDH, this is S for Smartphone and H is Handheld. Smartphone Handheld Operated UV Disinfection Helper. In order to continue the practices of sanitizing learned through COVID-19, Imagineering Lab IIT Kanpur has developed an ultraviolet sanitizing product named SHUDH. SHUDH has 6 UV lights of 15 watts each, that can be individually monitored from a distance. Initial testing has proved that the device at its full expression can disinfect a 10 into 10 square feet room in about 15 minutes. These were a few devices which were developed during COVID-19 era just to sanitize the rooms using the ultraviolet light.

Examples:
SHUDH
Smartphone Operated UV Disinfection Helper

Features:

1. Bluetooth controlled device allows perfect placement
2. Easily portable UV sanitizer/sterilizer
3. UV-C Disinfection Lamp is disinfecting with dry cloth
4. Built-in motion sensor detects movement and flipping ON - OFF.

Now, certain features for this device which were developed are Bluetooth control device allows perfect placement at any part in the room, easily portable UV sanitizer that is sterilizer is there, UV-C range disinfection lamp is disinfecting with dry cloth, built-in motion sensor detects movements and flipping on and off.

Examples: IV Fluid Warmer

Controlled to a temperature range of 36 to 38 °C (99 to 101 °F), the Floor Mount IV Fluid Warmer delivers a thermal normal IV solution consistently. This helps to reduce the risk of induced or secondary hypothermia while providing greater patient comfort.

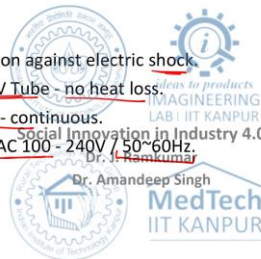


Next comes another device that is IV Fluid Warmer whenever IV fluid is given to the patients. So, the temperature of the fluid is quite low then what is the temperature of the human body. So, fluid warmer is designed so that this IV fluid that is connected to the human body. It is heated up to the human body temperature that is from 36 to 38 degrees. The floor mount IV fluid warmer delivers a thermal normal IV dissolution consistently. This helps reduce the risk of induced or secondary hypothermia while providing greater patient comfort.

Examples: IV Fluid Warmer

Features:

1. Class - I protection against electric shock.
2. Fully wrapped IV Tube - no heat loss.
3. Operating mode - continuous.
4. Power supply - AC 100 - 240V / 50~60Hz.



This device is a class-1 production against electric shock, I will try to talk about the classes in the forthcoming slides, that is, the devices does not have high risk involved with them those are the class-1 devices. It is a fully wrapped IV tube with no heat loss, it is continuous in operating mode only a simple power supply, that is AC power supply from 100 to 240 volts within the frequency of 50 to 60 hertz could be used.

Examples:
IV Fluid Warmer

Controlled to a temperature range of 36 to 38 °C (99 to 101 °F), the Floor Mount IV Fluid Warmer delivers a thermal normal IV solution consistently. This helps to reduce the risk of induced or secondary hypothermia while providing greater patient comfort.



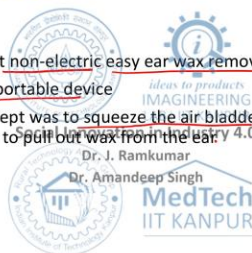
Next comes the Handheld Suction Device Ear Wax. This is a handheld device doctors generally what they use is, an electrically operated or motor operated suction device to suck the wax from the ear. This is a handheld device that does not require any electricity, so this is a handheld ear wax suction device, when used by an ENT specialist that is ear knot throat specialist.

He fixes an ear suction probe to one end of the silicon tube the bottle is used to collect the wax, and disinfectant used by the doctor while handing the patient. The maximum suction pressure generated by the machine is about 600 to 700 millimeter of HG.

Examples:
Handheld Suction Device
Ear Wax Suction Device

Features:

1. Automatic smart non-electric easy ear wax removal
2. An economical portable device
3. The design concept was to squeeze the air bladder which would create a suction pressure to pull out wax from the ear




Here, certain features of this device is that, it is an automatic smart non-electric and easy ear wax removal setup.

It is an economical portable device. The design concept was to squeeze the air bladder, which would create a suction pressure to pollute the wax from the ear, so this is how it works.

**Examples:
Jaw Opening Device
Dental Tool**

- The Jaw Opening Device is a portable device used to open the jaw to treat hypomobility, dysfunction, and trismus.
- The user's jaw, joint, and facial tissues are stretched using the device which work with a passive motion to improve mobility, flexibility, and function.
- When doing oral surgery on patients, a tool known as Gag is used to hold the patient's mouth open or to force it open.
- The mouth opening device is being developed in India to treat trismus, radiation fibrosis in patients with oral cancer, and restricted mouth opening brought on by eating foods like Pan Masala, Gutkha, betel nuts, and spicy foods.



Also Jaw Opening Device, that is a dental tool was also one of the designs which are novel here, and almost all the devices which I am showing you here are patented with IIT Kanpur only. This jaw opening device is a portable device used to open the jaw to treat hypomobility, dysfunction and trismus. The users jaw, joint and facial tissues are stressed using the device, which work with passive motion to improve the mobility and flexibility and function. Sometimes, the jaw is stuck, for example people in the area of Uttar Pradesh and Bihar, they are in a habit of tobacco chewing.

Because of the excessive tobacco chewing, sometimes the jaw is stuck. So, to open the jaw to practice that for the dental procedures as well, and just for practicing this at home itself the jaw design or jaw opening device was designed. So, when doing oral surgery as well on patients, a tool known as GAG is used to hold the patients mouth open to force it open.

The mouth opening device is being developed in India to treat trismus, radiation fibrosis in patients with oral cancer and restricted mouth opening brought on by eating foods like pan masala, gutkha, betel nuts and spicy food or so.

Examples:
Jaw Opening Device
Dental Tool



Features:

1. Made from durable & prescribed material approved by FDA
2. Made of high grade of stainless steel i.e. Rust free
3. Maximizes jaw range-of-motion with fast recovery
4. Easy clean for proper hygiene for a jaw opening device



Features of this product is, it is made from durable and prescribed material approved by FDA. It is made of high grade stainless steel that is dust free. It maximizes jaw range of motion with fast recovery. It is easy to clean for proper hygiene for a jaw opening device.

Examples:
Ezy Ampoule Breaker
Glass Ampoule Breaker



- Ezy ampoule breakers are simple but effective devices allowing the tops of pre-scored ampoules to be broken, quickly and safely.
- Once broken, the glass ampoule top remains in the ampoule breaker for secure disposal.
- The ampoules are aligned on the dispensers in the machines where the contents are poured into the ampoules, and the next step is sealing.
- These single-use polyethylene sleeve ampoule breakers help protect your fingers from glass shards when opening 1 ml to 3 ml glass ampoules.



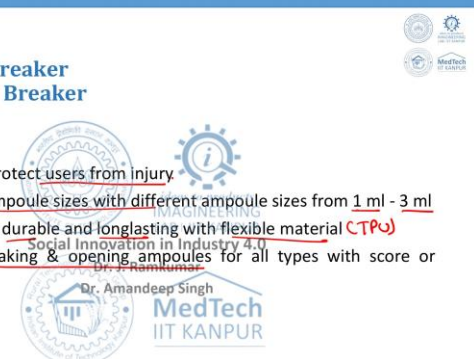
Next device I would like to show you here is the EZY Ampoule Breaker or Glass Ampoule Breaker. EZY ampoule breakers are simple but effective devices allowing the tops of the pre-scored ampoules to be broken quickly and safely. Generally, the ampoule which has the medicine, which is to be sucked by the injection are broken using the impact force of a blade.

This is the ampoule breaker where it would have broken using this cover here. Once broken the glass ampoule top remains in the ampoule breaker for secure disposal. The ampoules are aligned on the dispensers in the machines where the contents are poured into the ampoules and the next step is just sealing. These are single-use polyethylene sleeve ampoule breakers and they help to protect your fingers from glass shards, when opening 1 ml to 3 ml of the glass ampoules.

Examples:
Ezy Ampoule Breaker
Glass Ampoule Breaker

Features:

1. Designed to protect users from injury
2. Compatible ampoule sizes with different ampoule sizes from 1 ml - 3 ml
3. Make product durable and longlasting with flexible material (TPU)
4. Ideal for breaking & opening ampoules for all types with score or without score



The features of the glass ampoule breakers are they are designed to protect users from injury. Users are generally in the nurses or the doctors. They are compatible to the ampoule sizes with different ampoule sizes available that is from 1 ml to 3 ml. This product is made durable and long lasting with flexible material.

Generally, in the beginning TPU is used as a material. I will talk about TPU another polymer materials and metal materials for rapid prototyping in the next week. This is ideal for breaking and opening ampoules for all types with score and without score.

Examples: Sanjeevani O₂ Concentrator

To ensure a sufficient supply of oxygen and prevent future crisis amid the probable third wave of the Covid-19 pandemic, the Indian Institute of Technology, Kanpur (IIT KANPUR) has developed an advanced oxygen concentrator named Sanjeevani. Equipped with the pressure swing adsorption (PSA) technique, the technology has been transferred and licensed to Albot Technologies Private Limited Bangalore.

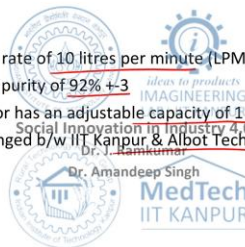


Next comes the Oxygen Concentrator which is one of the pioneer products developed at IIT Kanpur Imaginary Lab. So, during the COVID 19 pandemic the IIT took an effort to develop an in-house oxygen concentrator which was later given as a lessons to Albot Technologies Private Limited to sell it in the market. So, this is designed using the PSA technology that is the pressure swing absorption technique.

Examples: Sanjeevani O₂ Concentrator

Features:

1. Works at a flow rate of 10 litres per minute (LPM)
2. With an oxygen purity of 92% +3
3. The concentrator has an adjustable capacity of 1 to 10 LPM
4. MoU has exchanged b/w IIT Kanpur & Albot Technologies



The features of the oxygen concentrator are that it has a capacity of 10 litres per minute, and the oxygen concentrator has a purity of oxygen of around 92% plus minus 3.

The concentrator has an adjustable capacity of 1 to 10 litres per minute. The MOU has exchange between IIT Kanpur and Albot Technologies, So, this is also used finally by the consumers and it was a Social Innovation, in the beginning when we started during the COVID 19 pandemic, and it has become a business theatre when it is now also being sold for various medical uses.

Examples:
Shoe Warmer Heating Insoles

- The battery powered heating foot warmer shoes provide basic-level settings to allow the user to regulate the degree of warmth according to their preferences.
- A small but accessible switch is provided for activating the shoes.
- The footwear includes robust internal adhesive covers and strips and are waterproof for enhanced durability in the snow and ice.



Next come one of the products or prototypes that is shoe warmer heating insoles. This is a battery powered heating foot warmer shoes that provide basic level settings to allow users to regulate the degree of warmth according to their preferences. A small but accessible switch is provided for activating the shoes. So, in the freezing temperatures the soldiers when they work in the areas of maybe Kargil or maybe wherever in Kashmir the temperatures are even as low as minus 40 degrees.

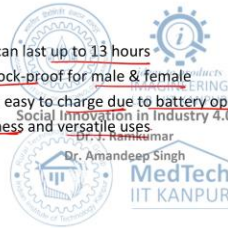
Their duty is just given for 2 hours or 3 hours a day so that they come and rest later for their recovering from the cold that they have suffered in these 2-3 hours. So, this is a shoe warmer that could be used in the freezing temperatures as well to keep the foot warm. So, when the feet are kept warm so the duty times could also be increased. The footwear includes robust internal and adhesive covers and strips and are waterproof for enhanced durability in snow and ice.

Examples: Shoe Warmer Heating Insoles



Features:

1. Shoe warmers can last up to 13 hours
2. Suitable and shock-proof for male & female
3. Convenient and easy to charge due to battery operated
4. Process robustness and versatile uses



The features are the shoe warmers can last up to 13 hours with the existing battery capacity that it was designed for.

These are suitable and shock proof for both male and female. They are convenient to use and easy to charge because these are battery operated. There are certain robust and versatile uses of this because not even in freezing temperature also in hospitals, where the doctors are using or working in the temperatures which are quite low for the long hours there also, the shoe warmers could also be used so that they keep their foot warm.

**Examples:
Universal Smartphone Based Fundoscope
for Retinal Imaging**

- To aid precise alignment and high-quality retinal imaging, the lens holder has three translational degrees of freedom, making the device compatible with all smartphone cameras.
- The simple design makes it possible even for a general practitioner to perform retinal imaging and send the results to a specialist for further diagnosis and treatment.

Next comes the universal smartphone based fundoscope for retinal imaging. So, to aid precise alignment and high quality retinal imaging the lens holder has 3 translational degrees of freedom making the device compatible with all smartphone cameras.

So, this is the fundoscope to give the image of your eye retina here. Generally, the fundoscopes are used by the doctors they have the specific size of the fundoscopes. This is the fundoscope where any smartphone could be put here using a simple smartphone camera and the lens that is used in this fundoscope. We put a lens here and here the smartphone is held so it can give you the image of the retina as required. The simple design makes it possible even for a general practitioner to perform retinal imaging and

send results to the specialist for further diagnosis. This is what we call as a Social Innovation something for which a specialist is required in an eye specialist who would just like to have the image of your retina.

This is something designed for any user who has a smartphone in hand he can just fix the smartphone over it, and try to have its image and send it to the specialist for the prescription later.

Examples:
Universal Smartphone Based Fundoscope for Retinal Imaging

Features:

1. The alignment can be frozen at desired position
2. Can be used with any brand or model of smart phone
3. Easy to align the camera and condenser lenses on one axis
4. Easy to handle with three translational DOF

General smartphone based fundoscope has following features that alignment can be frozen at a desired position. It can be used with any brand or model of smartphones. Generally, the smartphones are of sizes of the screen may be between 4 inches to 6 inches so any of these sizes could be used. It is easy to align the camera and condenser lenses on one axis. It is easy to handle with 3 transnational degrees of freedom.

Summary

- The design of medical devices is a rapidly evolving field.
- New technologies are emerging all the time, which presents both opportunities and challenges for medical device designers.
- It is important to stay up-to-date on the latest trends in medical device design in order to create innovative and effective products.
- The design of medical devices has a significant impact on patient care.
- By carefully considering the needs of patients, clinical evidence, regulatory requirements, and other factors, medical device designers can create products that improve patient outcomes and save lives.

To summarize this lecture, the design of medical devices is a rapidly evolving field. New technologies are emerging all the time which presents both opportunities and challenges for medical device designers. It is important to stay up to date on the latest trends in the medical device design in order to create innovative and effective products.

The design of medical devices has a significant impact on patient care. By carefully considering the needs of patients, clinical evidence, regulatory requirements and other factors medical device designers can create products that can improve patient outcomes, and save lives and hence generate or create a social innovation that helps to improve the standard of the society. With this the second lecture of this week is over. We will try to cover small classification of the medical devices in the coming lectures, and also we will try to talk about the design in agriculture machinery. Thank you.