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MEDICAL DEVICES: AN OVERVIEW

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ABSTRACT

In today's healthcare system, medical devices are essential for improving patient outcomes, increasing the precision of diagnoses, and expediting clinical procedures. Innovative medical gadgets, from implantable sensors to portable diagnostic equipment, have been developed as a result of recent technological breakthroughs. These gadgets use data analytics, IoT connectivity, and artificial intelligence to deliver predictive diagnoses, remote monitoring, and personalized therapy. This abstract discusses the advantages, difficulties, and potential future directions of medical devices as they relate to healthcare. Medical devices have the potential to transform healthcare delivery, enhance patient quality of life, and lower healthcare costs as they develop further. Clinical, regulatory, marketing, and business knowledge are all necessary for the development of a successful medical product in addition to engineering design work. Items pertaining to the medical device design process are reviewed in this study. It talks about how a medical product idea must be developed, verified, validated, approved by regulators, and released onto the market.

KEYWORDS : New medical device rule, Classification , Manufacturing, Robotic surgery , Pacemaker, Insulin Pump, Pulse Oximetry, Ventilators

INTRODUCTION

Healthcare area is one of the promising growing fields in India, this is Because of the multiplied populace, accelerated existence Expectancy, decreased infant mortality, increased Health expenditure of sufferers, and authorities Support. The USA has diverse area of expertise centers, Nicely-certified docs and telemedicine which makes India emerge as a main medical tourism u. s [1] .As of 2020 Indian healthcare enterprise accounts for $a hundred ninety billion and is expected to reach $370 billion By means of 2024-2025, that is feasible due to the Demand for first-rate hospital therapy system [2] **.** An Instrument, gadget, appliance, material, or other item utilised for a health condition's diagnosis, prevention, monitoring, treatment, or alleviation is referred to as a medical device. [3] The Indian medical equipment market is one of the top 20 medical equipment markets in the world. It is growing at a rate of 15% per year and is expected to reach $50 billion by 2025. [4] The largest segment is medical equipment and medical equipment (34%), followed by diagnostic equipment (31%), equipment and facilities (19%), and medical equipment and others (16%). [5]

HISTORY

For the duration of nineteenth and 20th century, various discoveries and technological trends played an crucial role in the evolution of a tremendous range of clinical devices inflicting the transformation to the way, the scientific care Is relinquish nowadays to the entire occupiers globally. Clinical gadgets have been in lifestyles for centuries. There's confirmation that scalpels, slings, splints, crutches and other medical devices have been used as a ways lower back as 7000 BCE by using the Egyptians [6] as proven in [Fig. 1]. The have a look at of archaeology and Roman medical literature additionally specify that there had been many varieties of scientific devices used notably at some point of the time of historical Rome [7]]. In the America it wasn't until the Federal meals, Drug, and beauty Act (FD&C Act) in 1938 that medical gadgets have been regulated. Later in 1976, the medical tool Amendments to the FD&C Act installed medical tool regulation and oversight as we realize it today within the United States of America [8]. Scientific device regulation in Europe came into impact in the 1993 by means of what is collectively regarded as the scientific tool Directive is (MDD) [9]. On May 26, 2017 the scientific device law (MDR) [10] replaced the MDD. Remarkable advances and achievements have remolded the course of the past six many years in many clinical fields. Scientific device producers are business firms accountable to their shareholders to produce earnings. Product-development choices are primarily based upon market length and return-on-funding calculations [11]. For the reason that Fifties there was an enormous boom of technology in laboratory medication. Scientific era is sustained to be researched on and further advanced due to the desires of our health. The landmarks and key developments in extra recent scientific device development are mentioned in gift article.

FIGURE: ANCIENT MEDICAL DEVICES

NEW MEDICAL DEVICES RULE

Medical devices are manufactured in a highly regulated environment and must meet strong regulatory requirements because they are related to patients' health and safety [12] Specifications and directives. While drug rules in India have been well-established for decades, there has long been a lack of a well-defined regulation for medical devices. However, there has been a lot of activity recently in the Indian medical device regulatory framework. [13] The Central Drug Standard Control Organization (CDSCO)'s Medical Devices and Diagnostics Division created the Medical Device Regulations (IMDR), which were published in January 2017 and went into effect in January 2018.[14] In February 2020, the "Medical Devices (Amendment) Rules, 2020" were created to update the IMDR, and they went into effect in April 2020. With the issuance of the 2020 amendment, "registration of certain medical devices" was included [15].The introduction of the IMDR and other supporting recommendations has made it possible for India to take its first step towards improved patient safety with regard to medical devices, even if many of them are still classified as pharmaceuticals under the pharmaceuticals and Cosmetics Act, 1940. Future IMDR revisions should concentrate on closing the gaps that would have brought these laws into line with the EU's MDR and IVDR, the most recent worldwide standards for medical device performance and safety.

MEDICAL DEVICES MARKET IN INDIA

The Indian medical equipment market is valued at US$ 3 billion, making it the fourth largest market in Asia, offering huge opportunities to domestic and international investors (Figure 5). In the early 1990s, the market was dominated by domestic players, but now with the opening up of the Indian market, the situation has changed. The fact that 75% of sales are imported medical devices or devices requiring foreign materials indicates that the current Indian medical device sector is dominated by international organizations. Due to their significant position in the Indian economy, many different companies have entered India; more than 60% of the domestic production is exported. [16]

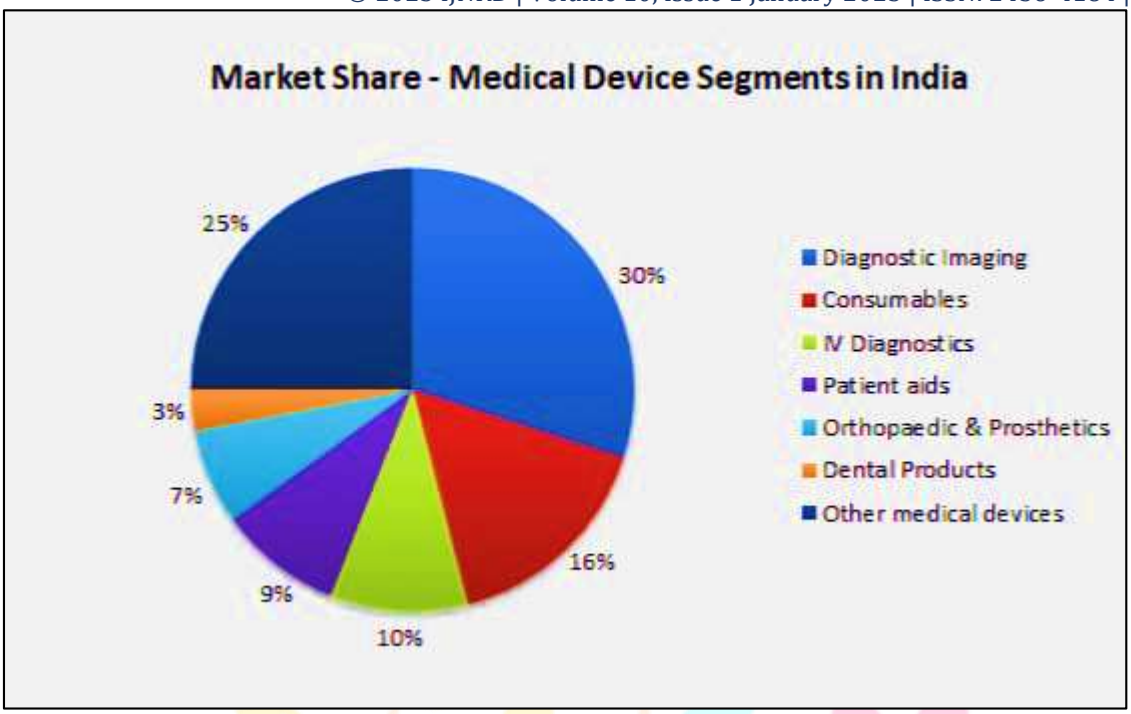


FIGURE : MEDICAL DEVICES IN INDIA

CLASSIFICATION

Medical devices are classified according to their manufacture point, technological model, or intended medical application. However, the regulatory bodies have categorized medical devices based on their effectiveness, safety, and quality requirements that are globally established. The danger, the impacted body system, the effectiveness, and other local and systemic impacts are determined using several criteria. Medical equipment are categorized differently in each nation.

CLASS A: Known as low risk equipment, these medical devices are governed by broad rules. Class 1 is governed by regulations. This category mostly includes prohibited equipment as well as good manufacturing practices, replacement, refund, repair, and notification. Devices classified as class 1 are not intended to prevent any harm to human health. These are primarily spared from pre-market disclosure. Compared to previous articles, these use an essentially simpler approach. Examples include an examining glove, a toothbrush, surgical instruments, and elastic bandages [17, 18].

CLASS B: The general control and the specialized controls are the fundamental components of this class. Compared to class 1, it needs additional regulatory oversight. These are classified as the low medium risk devices. The notified body must certify them. They are carried out as directed without endangering the user or the patient. These include of post-marketing surveillance and unique criteria. As an illustration, consider sterile supplies such as tracheal tubes, stomach tubes, catheters, and surgical gloves. [17 ,18]

CLASS C: Known as the medium-high risk devices, these devices require certification from the authority that is notified in order to be designed and manufactured as medical equipment. They adhere to the system of quality management. As an example ă blood bags, condoms, no absorbable sutures, Anaesthesia machine, contact lens care products.

CLASS D: General controls and specific control with premarket approval. These are referred as the high risk medical devices. These devices required premarket approval to ensure the device effectiveness and safety. These devices usually sustain human life. It is useful in preventing impairment of human health or risk of injury (Figure 1). Examples ă pacemakers, vascular grafts, angioplasty catheters. Heart valves, implantable defibrillator. [17 ,18]

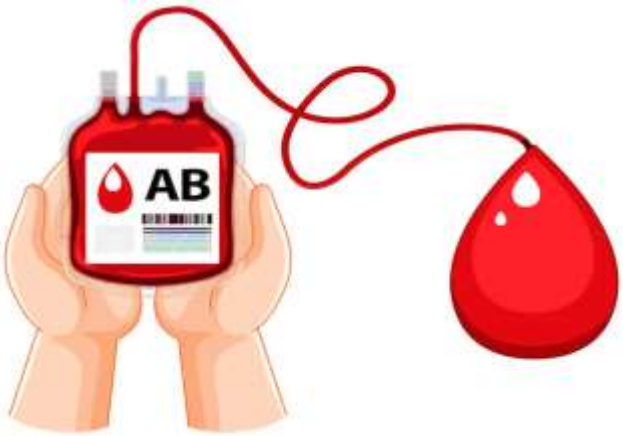
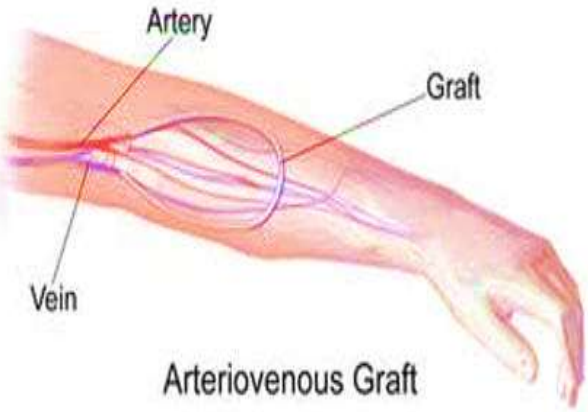
CLASS	RISK LEVEL	EXAMPLE
Class A	Low risk	
Class B	Measured potential risk	
Class C	Significant potential risk	
Class D	High risk	

FIGURE : CLASSIFICATION OF MEDICAL DEVICES

MANUFACTURING OF MEDICAL DEVICES

In India import, manufacture, sale and distribution of Medical devices is regulated under Drugs and Cosmetics Act, 1940; and Rules, 1945 and guidelines is given by CDSCO headed by DCGI of India. DCGI grant permission by reviewing the manufacturing site and document submitted by manufacturer or Indian agent for manufacturing medical device in India. For manufacturing and sale of notified medical device under Central Licenses Approval Authority (CLAA) scheme in India, CDSCO provide form 28 which is

filled by manufacturer with required appropriate document under drug and cosmetic rule. Drug and cosmetic rule 76 describe the data and document required for grant permission of manufacturing license. Applicant fill form 27 for the grant of license for manufacturing of medical device in India. Application is submitted to the concerned State Drugs Licensing Authority, The concerned C"SCO Zonal/Sub-Zonal Office. The Drugs Controller General of India with requisite fee prescribed in the drug and cosmetic rule. Documents required to be submitted in the manner and order given below for grant of license in form-28 for Manufacture of Medical Devices in India: -

1. Covering Letter ă It is the most Important part of the application which specify the intent of application duly signed by authorized signature (name and designation). List of document required under guidelines was provided in the signature (name and designation). List of document required under guidelines was provided in the covering letter.

2. An authorisation letter: The name and designation of the person authorised to sign on the firm's behalf in a legal document, such as form 27, should be included in the authorisation letter issued by the director, company secretary, or partner agent.

3. Completed Form 27: The Indian agent's name and designation are signed and stamped on the form.

4. The necessary payment (as per the Drugs & Cosmetics Act & Rules): A) Rs. 6000 for license fees; B) Rs. 1500 for inspection fees (totalling Rs. 7500 for 10 items per category of device); and C) Additional fees at Rs. 300 for each extra device.

5. Details about the Firm's Constitution: Articles of Association, Memorandum, and Partnership Deed, among other documents pertaining to the Firm's Constitution.

6. Approved Manufacturing Premises: Plan/Layout approved by the License Master File specifies how the Licensing Authority should be presented.

7. Complete information about the skilled and consistent technical personnel for the production and testing of medical devices, including their educational background, experience certificate, etc.

8. Site Master File: a record of precise and factual GMP data regarding the manufacture and management of pharmaceutical manufacturing processes by the producer. It includes: a) general details about the manufacturing facilities; b) information about the persons in charge of the device's manufacturing; and c) details about the facilities' amenities, such as the plan layout, a description of the manufacturing rooms, texturing and fittings, ventilation system, etc. d) a synopsis of the equipment utilised e) manufacturing quality control, sanitation, storage, safety, etc.

9. Particular Environmental Requirements: Moulding, assembly, and packing are done under HVAC (heating, ventilation, and air conditioning) guidelines. Testing facilities for necessary tests that perform Physico-chemical and chemical testing of raw materials utilised on the premises as well as medical equipment.

10. Master File for Devices: The properly signed document includes details about a medical device. It includes an executive summary of the medical device, a description of the product, product specifications, labelling, variations and accessories, biocompatibility, biological safety data, sterilisation, animal testing and model, stability data, and finally a vigilance report. It also includes essential principles that provide conformity about the standard applies on the medical device manufacturing process. The list of medical devices and the undertaking in the provided prescribed pro-form are the additional documents that are included for the manufacturing of medical devices.[19]

COMMON MEDICAL DEVICES

ROBOTIC SURGERY

For more than 20 years, robotic surgery has been a game-changer in the advancement of surgical techniques. Over the past ten years, robots has become widely used in medical treatments. The widespread adoption of robotic surgery is pushing researchers to new heights in their quest for more compact, effective, and affordable technology. Robotic surgery has gained international acceptability and been effectively used in a number of hospitals worldwide. This paper's main goal is to evaluate the most recent advancements in robotic surgery technology. We categorise, contrast, and talk about the future of surgical robotic systems. [20]. Surgical operations have been profoundly altered by technology, requiring the creation of new methods to assess their success, especially in the technical, legal, and bioethical domains. Human-machine interaction has led to a number of ethical issues that require a more thorough analysis. Even though they have been depicted in Isaac Asimov's science fiction novels, they were a part of his conceited and technophilic future vision, which held that robots will greatly benefit humanity in the decades to come. This is due to the fact that in the not-too-distant future, robots will become "companions" of people, carrying out activities and assisting people at work and at home. Take the robot BINA48, which has the ability to comprehend. [21 , 22]

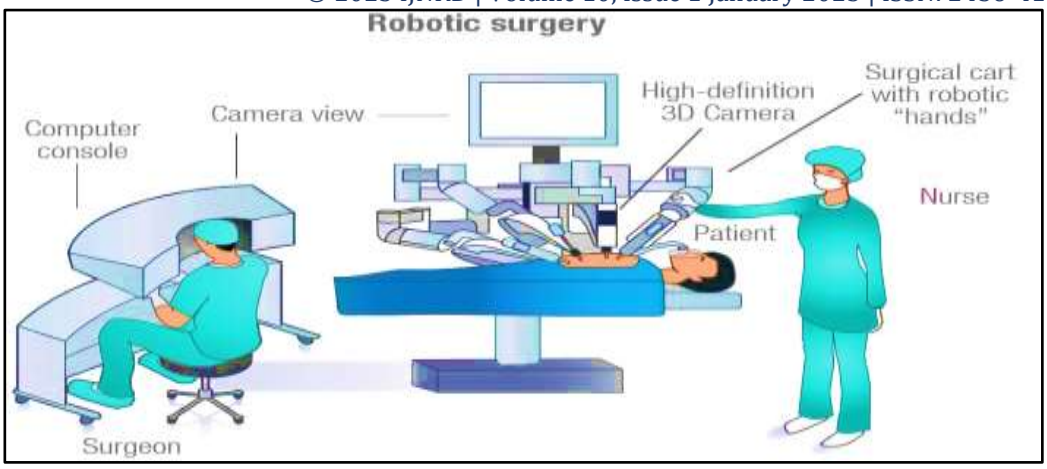


FIGURE : ROBOTIC SURGERY

WORKING

In order to use the robotic system, your surgeon makes small incisions in your body and inserts a high-definition three-dimensional camera and miniature devices. In certain cases, no skin incisions are necessary. Your surgeon then uses those tools to do the procedure from a console close by. Contemplate the robotic system as a supercomputer, enabling the device to convert the surgeon's motions into actual time, enabling more accuracy. While a Using a robotic-assisted technique, your surgeon the surgeon console's master controls to During your procedure, control the instruments. Your surgeon's words are translated by the computer. motions to the moving instruments precisely where the surgeon is moving, within your body. The robot is controlled by your surgeon. continuously ; the surgical system .[23]

ADVANTAGES

1. Improved visualization
2. Increased precision
3. Less pain
4. Reduce blood loss
5. Faster recovery

DISADVANTAGES

1. Cost
2. Malfunction
3. Complication
4. No tactile sensation
5. Nerve damage

PACEMAKER

When the heart's intrinsic electrical mechanism is unable to produce a heartbeat at a rate sufficient to sustain cardiac output, a pacemaker—an electrode device—can be utilised to start the heartbeat. When the heart's natural conduction route is harmed or sick, a pacemaker is an electronic device that speeds up the heart. [24]

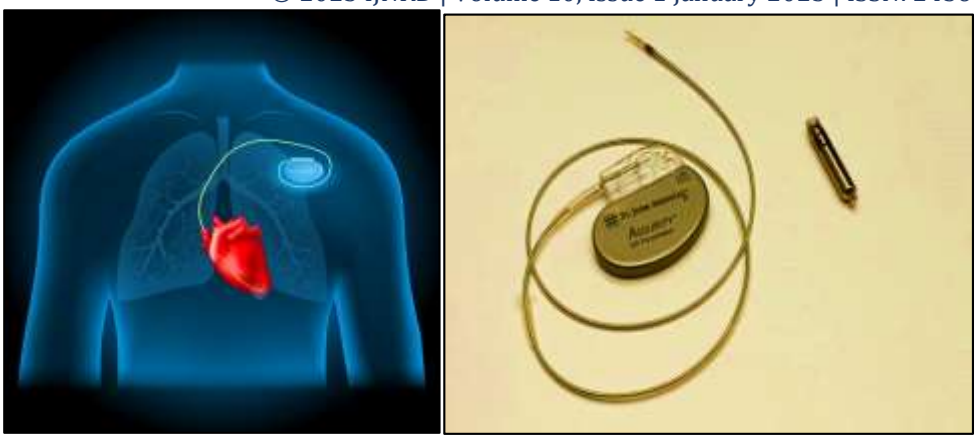


FIGURE : PACEMAKER

WORKING

Pacemaker consists of a battery, a computerized generator and wires with sensors at their tips (called as electrodes). The battery powers the generator and both are surrounded a thin metal box. The wires connect the A generator to the heart. A pacemaker helps monitor and control the heartbeat. The electrodes detect heart's electrical activity and send data through the wires to the computer in the generator. If heart rhythm is abnormal, the computer will direct the generator to send electrical pulses to heart. The pulses travel through the wires to reach the heart. [25]

ADVANTAGES

1. Improved quality of life

2. Increased activity

3. Improved heart function

4. Lifesaving

DISADVANTAGES

1. Infection

2. Blood clots

3. Collapsed lung

4. Pacemaker malfunction

5. Limited battery life

INSULIN PUMP

An insulin pump is a small computerized device. It delivers insulin through a thin tube that goes under your skin.The device releases insulin almost the way your body naturally does: a steady flow throughout the day and night, called basal insulin, and an extra dose at mealtime, called a bolus, to handle rising blood sugar from the food you eat. You program the pump for both basal and bolus doses. If you eat more than normal, you can program a larger bolus to cover the carbs in your food. A bolus can lower high blood sugar at other times, too. [26]

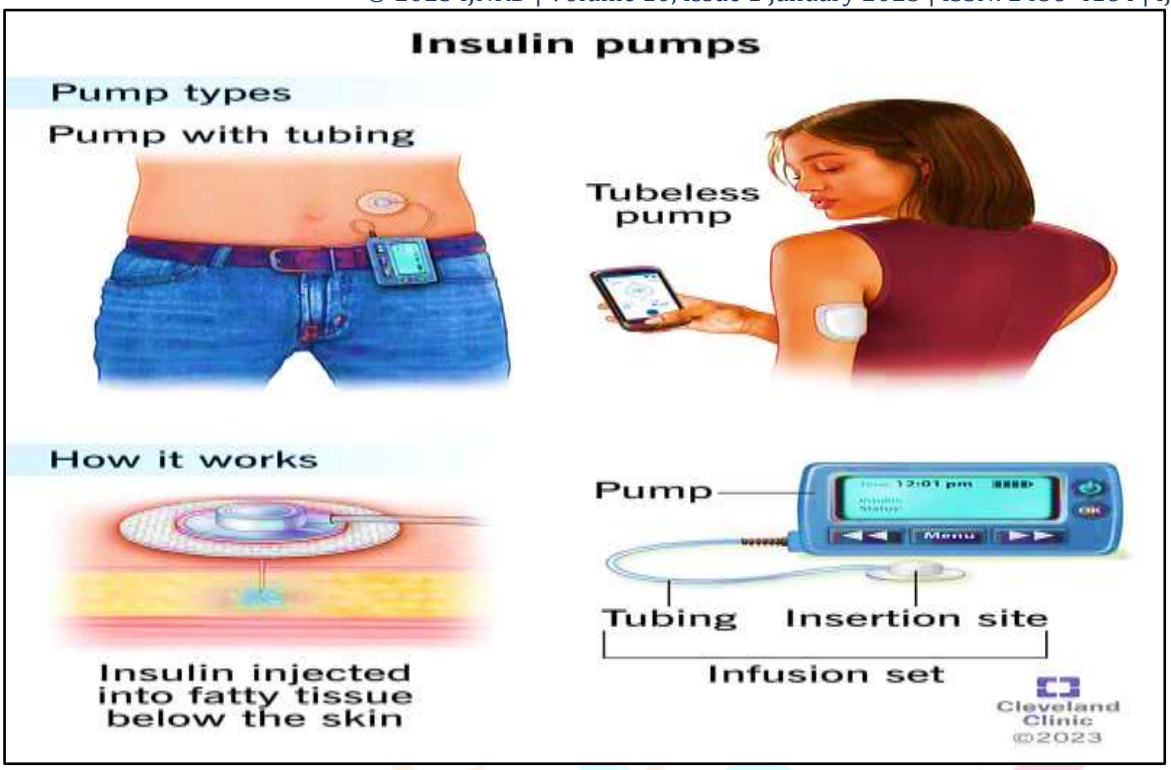


FIGURE : INSULIN PUMPS

WORKING

Insulin pump works on action by binding to a glycoprotein receptor on the surface of the cell. Insulin pump delivers insulin through a thin tube connected to a tiny needle or soft tube (called a cannula) that sits just below your skin, usually on your upper arm, belly, hip, buttock, or thigh. The pump itself has a display screen so you can see your data and change the pump's setting [27]

ADVANTAGES

1. More accurate insulin delivery
2. Fewer injection
3. Improved blood sugar control
4. More flexibility
5. Improved quality of life
6. Download data

DISADVANTAGES

1. Cost
2. Skin irritation
3. Visibility
4. Clothing
5. Time commitment

PULSE OXIMETRY

Pulse oximetry is based on the principle that O2Hb and HHb differentially absorb red and near-infrared (IR) light. It is fortuitous that O2Hb and HHb have significant differences in absorption at red and near-IR light because these two wavelengths penetrate tissues well whereas blue, green, yellow, and far-IR light are significantly absorbed by non-vascular tissues and water.3 O2Hb absorbs greater amounts of IR light and lower amounts of red light than does HHb; this is consistent with experience – well-oxygenated blood with its higher concentrations of O2Hb appears bright red to the eye because it scatters more red light than does HHb. On the other hand, HHb absorb more red light and appears less red. Exploiting this difference in light absorption properties between O2Hb and HHb, pulse oximeters emit two wavelengths of light, red at 660 nm and near-IR at 940 nm from a pair of small light-emitting diodes located in one arm of the finger probe. The light that is transmitted through the finger is

then detected by a photodiode on the opposite arm of the probe; i.e., the relative amount of red and IR light absorbed are used by the pulse oximeter to ultimately determine the proportion of Hb bound to oxygen.[28]

FIGURE : PULSE OXIMETRY

WORKING

By measuring how much light is absorbed by the blood in capillaries beneath the skin, a pulse oximeter can determine how much oxygen is in a patient's blood. Typically, a spring-loaded clip or an adhesive band is used to secure a sensing probe to the patient's finger. The probe has a photodiode on one side and two Light-Emitting Diodes (LEDs) on the other. Infrared light is produced by one of the LEDs, while red light is produced by the other. The optical properties of haemoglobin, the oxygen-carrying blood protein, are essential to pulse oximetry. Haemoglobin absorbs more infrared light and transmits more red light when it is more highly oxygenated. Haemoglobin that has little oxygen content becomes comparatively When it comes to exercise machines, heartbeat tracking is crucial for automatically regulating treadmill speed. One especially practical non invasive measurement tool is a pulse oximeter. A pair of tiny light-emitting diodes (LEDs) are often positioned in front of a photodiode through a translucent area of the patient's body, typically an earlobe or fingertip. Red LEDs have a wavelength of 660 nm, while infrared LEDs have wavelengths of 905, 910, or 940 nm. The ratio of the absorption of red and infrared light can be used to determine the oxy/deoxyhaemoglobin ratio since oxy haemoglobin and its deoxygenated form exhibit markedly different absorption at these wavelengths. For wavelengths of 590 and 805, the absorbance of oxyhaemoglobin and deoxyhaemoglobin is equal (isosbestic point). [29]

ADVANTAGES

1. Non-invasive and painless
2. Quick and easy to use
3. Continuous monitoring
4. Accurate readings (±2% accuracy)
5. Portable and compact
6. Low cost
7. Real-time data
8. Features for critical Alarm

DISADVANTAGES

1. Limited accuracy in hypoperfusion or shock
2. Interference from movement or ambient light
3. Skin pigmentation or thickness affects accuracy
4 .Nail polish or artificial nails. interfere with readings

VENTILATOR

In acute or emergency situations, ventilation is a vital intervention to maintain life, especially for patients with hypoxemic respiratory failure, damaged airways, or hindered ventilation. Positive pressure breathing is used during this process, which depends on the resistance and compliance of the airway system. Critical care unit clinicians must be well-versed in the safe application principles of mechanical ventilation and its effects on patient physiology and responsiveness to different illness conditions. When treating intubated patients, doctors must have a firm grasp of human physiology and the fundamentals of airway mechanics, which serve as the cornerstone of safe and efficient ventilation techniques.[30]

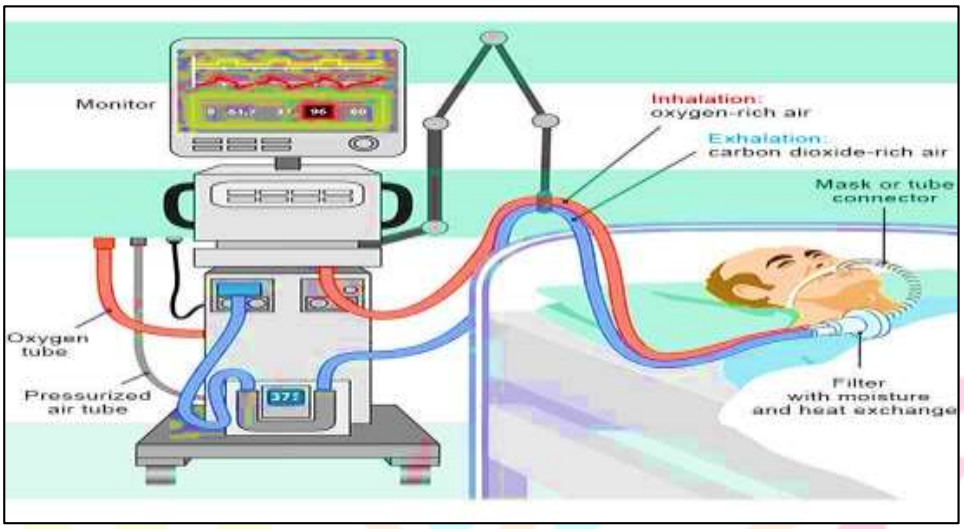


FIGURE : VENTILATOR

WORKING

A ventilator blows air into the lungs using pressure. Positive pressure is the term used to describe this pressure. Although the ventilator occasionally accomplishes it for the patient, the patient typically exhales the air on their own. Through a monitor attached to the ventilator, the patient's oxygen dosage can be managed. The monitor will be configured to alert the caregiver to an increase in air pressure if the patient's health is extremely precarious. The device functions by removing carbon dioxide from the lungs and supplying oxygen to them. This makes it possible for a patient who has respiratory difficulties to get the right amount of oxygen. Because it removes the excess energy from laborious breathing, it also aids in the healing process for the patient. A uses a breathing tube to force air into the airway. The tube is connected to the ventilator at one end and placed into the patient's windpipe at the other. By allowing oxygen and air from the ventilator to enter the lungs, the breathing tube acts as an airway. The patient may be able to utilize a respiratory mask in place of the breathing tubes, depending on their health.[31]

ADVANTAGES

1. Life-saving device for patients with respiratory failure
2. Supports breathing in critically ill patients
3. Helps maintain adequate oxygenation and ventilation
4. Allows for precise control over respiratory rate and depth
5. Facilitates weaning from mechanical ventilation

DISADVANTAGES

1. Risk of ventilator-associated pneumonia (VAP)
2. Potential for barotrauma and lung damage
3. Risk of skin breakdown and pressure ulcers
4. Requires specialized training and expertise
5. High cost and resource-intensive

GUIDELINES MEDICAL DEVICES

1 .ISO 13485

Medical equipment — Quality control systems — Regulatory requirements

2. Medical devices—Applying risk management to medical devices (ISO 14971)

3. IEC 62304: Software life cycle methods for medical devices

4. Part 1 of ISO 62366-1

Medical Devices: Usability Engineering's Application to Medical Devices

5. ISO 11135

Sterilization of Health Care Products — Ethylene Oxide — Requirements for the creation, verification, and regular monitoring of a medical device sterilization procedure

6.ISO 15223-1

Medical Devices — Part 1: General requirements — Symbols to be used with information provided by the company

7.ISO 80369-1

Part 1: General criteria for small-bore connectors for gases and liquids in healthcare applications

8.ISO 11607-1

Packaging for Medical Devices That Have Been Terminally Sterilized — Part 1: Materials, Sterile Barrier Systems, and Packaging Systems Requirements

9. Packaging for ISO 11607-2 for or procedures involving forming, sealing, and assembling

10 .ISO 111371

Sterilization of Health Care Products — Radiation — Part 1: Needs for the creation, verification, and regular monitoring of a medical device sterilization procedure

11. Good clinical practice: ISO 14155 Clinical investigation of medical devices for human subjects

12. Information provided by the manufacturer regarding in vitro diagnostic reagents for biological staining in medical devices that comply with ISO 19001

13 .ISO/TR 24971 Medical Devices: Instructions for Using ISO 14971

14. ISO 11737-2

Healthcare product sterilization — Microbiological techniques — Part 2: Sterile tests carried out throughout the establishment, verification, and upkeep of a sterilized product

15. ISO 16571

Mechanisms for medical device-generated plume evacuation

16. ISO 20916

Clinical performance studies utilizing human specimens for in vitro diagnostic medical devices Effective study techniques

17 .IEC 80001-1

Part 1: Risk management application Safety, efficacy, and security in the implementation and use of connected medical devices or linked health software

18. Medical device software — Part 1: Instructions for applying ISO 14971 to medical device software IEC/TR 80002-1

19. IEC/TR 80002-2Effective study techniques Effective study techniques0.

20. IEC/TR 80002-3 Medical Device Software Part 3: Medical Device Software Life Cycle Process Reference Model (IEC 62304)

21. ISO 10993-1 Part 1: Assessment and testing in a risk management procedure for biological evaluation of medical devices

22.ISO 10993-2 Part 2: Requirements for animal welfare in the biological evaluation of medicinal devices

23. ISO 10993-4

Part 4 of the biological evaluation of medical devices: Choosing tests to check for blood interactions

24 .ISO 10993-5 Part 5: In vitro cytotoxicity tests for biological evaluation of medical devices

25. ISO 27186

Active implantable medical devices — Four-pole cardiac rhythm management device connector system — Test and dimension specifications

26. ISO 15194

Medical instruments for in vitro diagnosis Quantity measurement in biologically derived samples — Certification of reference materials and associated documentation content requirements

27. ISO 15883-1

Washer Disinfectors — Part 1: Overview of Definitions, Terms, and Tests

28 .ISO 15883-2

Washer Disinfectors — Part 2: Tests and requirements for washer-disinfectors that use thermal disinfection for components such as glassware, cutlery, surgical instruments, anaesthetic equipment, bowls, and plates.

29 .ISO 15883-5

Washer Disinfectors — Part 5: Criteria for test methods and performance standards to demonstrating cleaning

30. ISO 9626

Stainless steel needle tubing for the manufacture of medical devices -Requirements and test methods

31. ISO 11117

Gas cylinders – Valve protection caps and guards Design, construction and tests

32. ISO 16142-1

Medical devices – Recognized essential principles of safety and performance of medical devices – Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards.

33. ISO 16142-2

Medical devices – Recognized essential principles of safety and performance of medical devices – Part 2: General essential principles and additional specific essential principles for all IVD medical devices and guidance on the selection of standards.

34. ISO 17664-1

Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices – Part 1: Critical and semi-critical medical devices

35. ISO 17664-2

Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices – Part 2: Non-critical medical devices

36. ISO 12052

Health informatics – Digital imaging and communication in medicine (DICOM) including workflow and data management

37. ISO 14117

Active implantable medical devices Electromagnetic compatibility – EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices

38. ISO 19223

Lung ventilators and related equipment – Vocabulary and semantics

39. ISO/IEEE 11073-10101

Health informatics – Device interoperability – Part 10101: Point-of-care medical device communication Nomenclature

40. ISO 13482

Robots and robotic devices – Safety requirements for personal care robots

41. ISO 18113-1

In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) Part 1: Terms, definitions and general requirements

42. ISO 22610

Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment – Test method to determine the resistance to wet bacterial penetration

43. ISO 23640

In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents

44. ISO 23747

Anaesthetic and respiratory equipment – Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans

45. ISO 28620

Medical devices – Non-electrically driven portable infusion devices

46. ISO 14708-1П

Implants for surgery – Active implantable medical devices – Part 1: General requirements for safety, marking and for information to be provided by the manufacturer

47. ISO 14708-2

Medical devices – Implants for surgery – Active implantable medical devices – Part 2: Cardiac pacemaker

48. ISO 14708-5

Implants for surgery – Active implantable medical devices – Part 5: Circulatory support devices

49. ISO 20417

Medical devices – Information to be supplied by the manufacturer

50. ISO 22442-1

Medical devices utilizing animal tissues and their derivatives – Part 1: Application of risk management.

CONCLUSION

According to the committee, the FDA shouldn't be the arbiter of what innovation is or try to direct device development and premarket review toward agency-determined public-health priorities, even though the regulatory process can encourage innovation that enhances public health by ensuring that consumers have timely access to safe and effective Class II medical devices. According to the committee, the FDA's Establishing a regulatory framework that establishes suitable standards for introducing items to the market should be a key component of premarket review's role in promoting innovation in Class II medical devices. The requirements should be both realistic enough to allow for the timely entrance of new devices that may bring advantages over currently marketed devices and strict enough to meet the agency's goal of guaranteeing that marketed medical devices will be safe and effective throughout their life cycles. The committee feels that the FDA should work to assist innovation rather than be tasked with fostering it, making sure that the premarket evaluation of Class II devices doesn't.

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