Al-Mustaqbal University

Biomedical Engineering Department

Class: 4th

Subject: Clinical issues of Biomedical Engineering

Lecturer: M.SC. ZAINAB SATTAR JABBAR

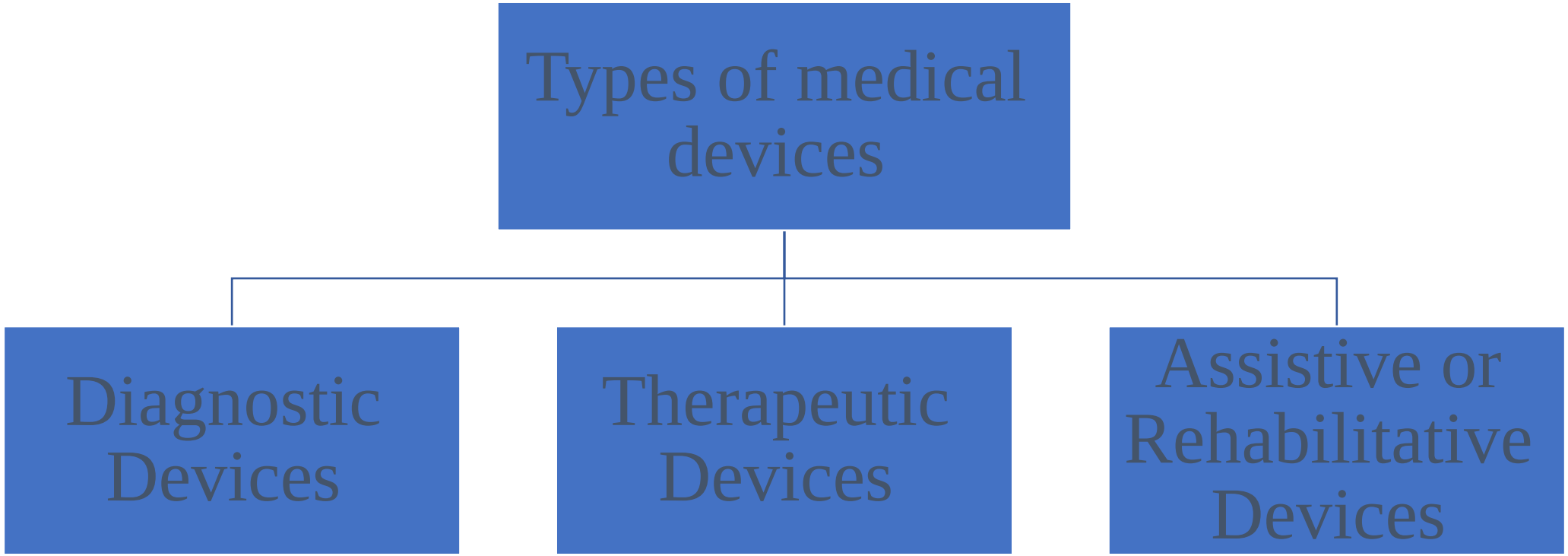
1st term – Lect. 5: Types of medical devices

Email: zainab.sattar.jabbar@uomus.edu.iq

Medical devices

Medical devices are products which are used to diagnose, prevent, relieve or treat a disease, disability, injury, etc. There are more than 500,000 different types of medical devices available, covering anything from wheelchairs and glasses to pacemakers, mobile phone apps and state of the art surgical equipment.

Types of medical devices



Diagnostic Devices

- Diagnostic devices are devices used to identify the nature or cause of a certain phenomenon, usually related to a medical condition. Examples of diagnostic devices are magnetic resonance imaging apparatuses, temperature sensors.
- The diagnostic device acquires information for presentation to the human senses. In essence, the diagnostic or data-acquiring device is an extender of the human senses. It is in this area that transducers and display devices play key roles.
- Example of diagnostic equipment:

✓Stethoscope, which is used to listen to internal body sounds.

✓ Blood pressure monitors.

✓ Pulse oximeters.

✓ Electrocardiographs (ECGs).

✓ Ultrasonography (US).

✓ X-ray machines.

Therapeutic Devices

- Therapeutic equipment serve any of the following purposes, or a purpose in connection with any of the following purposes: preventing, diagnosing, monitoring, alleviating, treating, or compensating for, a disease, ailment, defect, or injury.
- The therapeutic device is used by the physician, or the physician's delegated representative, to arrest or control a physiological process that has gone awry because of disease, trauma, or some other agent.
- Example of therapeutic equipment:

✓Pacemakers (to initiate rhythmic heartbeats)

✓ Defibrillators.

✓Contact and ophthalmic lenses.

✓Dental equipment.

✓Surgical laser systems.

Assistive or Rehabilitative Devices

- Assistive devices are external devices that are designed, made, or adapted to assist a person to perform a particular task. Many people with disabilities depend on assistive devices to enable them to carry out daily activities and participate actively and productively in community life.
- The objective of many rehabilitative devices is to make the subject capable of being self supporting, thereby allowing him or her to do things without reliance on the help of others.
- Example of Assistive equipment:

✓Wheelchairs.

✓Walkers.

✓Canes

✓Prosthetic devices.

✓Orthotic devices.

✓Hearing aids to help people hear or hear more clearly.

Failure Modes, Accidents, and Liability

- Failure Modes : Although well designed, well made, and closely regulated, the three types of medical devices can fail and cause injury, property damage, or death to a patient.
- Medical device failures, like those of any engineered structure, generally fall into one of three categories:

1. Improper design.
2. Manufacturing defect.
3. Misapplication/abuse.

Diagnostic Devices

- Provide inaccurate information leading to inappropriate medical decision and action.
- Malfunction or give erroneous information due to environmental effects.
- Are hazardous or injurious to the patient due to component failure or due to excessive leakage current because the device is not grounded properly.
- Are hazardous due to multiple devices connected to the patient (device interaction).
- Fail when alarm is turned off.
- Can cause an allergic response when it contact with the body.

Therapeutic Devices

- Failure to deliver adequate or delivery of excessive therapeutic agent.
- Lack of indication that therapeutic agent is being delivered.
- Delivery of inappropriate therapy.
- Inadequate training or experience of the operator.
- Failure to heed warnings in instruction manual.
- Allergic response to therapeutic agent or delivery system.
- Interaction between multiple therapeutic agents or multiple devices connected to same patient.

Assistive or Rehabilitative Devices

- Patient inadequately informed or trained.
- Failure to report for check up.
- Device inadequately protected from environmental agents (e.g., noise, vibration, heat, moisture, and ultraviolet rays).

Product Liability

- A product liability case can arise from injuries caused by defective or dangerous medical appliances, equipment, organ transplants, prosthetic devices, surgical implants, surgical equipment, diagnostic equipment, and hearing and visual aids. Any of these products can be the subject of a products liability lawsuit if they cause injury to a patient.

- Example : Hip replacement devices that break apart inside of patients and cause serious health problems

Product defect

- Legally, a product is defective when it fails to meet the provider's own specifications and applicable industrial and/or governmental standards.
- Inspection and maintenance records are very useful in showing that a product was or was not defective. Manufacturer's instruction manuals often specify the type and frequency of these activities. However, if the maintenance is performed by unauthorized personnel, the manufacturer's warranty becomes void, and the manufacturer cannot be held responsible for any harm done by a defective product.

Defect in a medical device

If a medical device is supposed to be safe but isn't because of its form, construction or the materials used to make it, then the device may have a design defect. Manufacturing Defects – Even if a medical device's design is safe, it can become defective due to issues with the manufacturing process.

Types of defects

1. Design Defects.
2. Manufacturing Defect.
3. Warning Defect.

Design defect

- A product does not have a design defect when it is safe for any reasonably foreseeable use. Such a safe product also has met all of the applicable functional specifications.
- Design defects are those problems that occur based on a poor or faulty design of the product.
- A design defect occurs when the design of the medical device is flawed, making it unsafe or prone to malfunction.
- Before a design defect can be alleged, it is necessary to establish that the product has met all applicable manufacturing, industrial, and governmental requirements, and that despite the manufacturer having met these requirements, the harmful incident occurred.

Design defect

➢To establish that a design defect exists involves the following elements:

1. Identification of the design defect

2. Establishing a link between the design defect and the harm done

3. Identification of alternate designs that would have prevented the harmful incident

4. Comparing the product performance with like products offered by other manufacturers

Manufacturing defect

- A manufacturing defect refers to an issue that occurs during the production or manufacturing process, leading to a specific unit or batch of devices being defective. It means that a particular product or group of products within a line is flawed rather than the entire line.
- A manufacturing defect occurs when an individual device or lot of devices are fabricated incorrectly.

Warnings

Failure to warn or provide adequate instructions. A medical device may be rendered defective when the manufacturer fails to provide sufficient warnings or instructions regarding its proper use, risks, side effects, or limitations.

THANK YOU!