



EBreast II

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Overview

Medical Devices

Definition

- Medical devices are products or equipment intended for a medical purpose (1).
- Medical devices include all the health technologies (except for vaccines and medicines) required for prevention, diagnosis, treatment, monitoring, rehabilitation and palliation (2).

Definition

What are medical devices?

- Articles, instruments, apparatuses or machines that are used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose (3).

Definition

What are medical equipment?

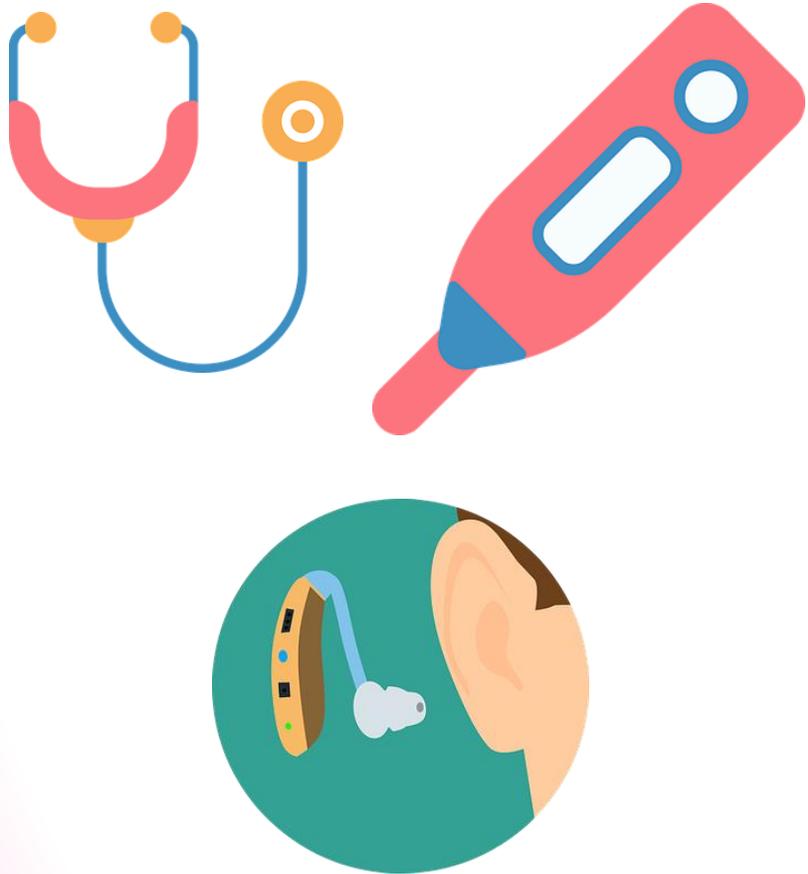
- Medical devices requiring calibration, maintenance, repair, user training and decommissioning. Medical equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury. Medical equipment excludes implantable, disposable or single-use medical devices. (3.)

Definition

What are In Vitro Diagnostic (IVD) devices?

- Medical devices intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes (4.)

Examples of medical devices



- Examples of medical devices:
 - Single use devices (i.e. syringes, catheters)
 - Implantable (i.e. hip prosthesis, pacemakers, breast implants)
 - Imaging (i.e. ultrasound and CT scanners, X-ray machines)
 - Medical equipment (i.e. anesthesia machines, patient monitors, hemodialysis machines)
 - Software (i.e. computer aided diagnostics, apps)
 - In vitro diagnostics are used to perform tests on samples (i.e. glucometer, HIV tests, pregnancy tests)
 - Personal protective equipment (i.e. mask, gowns, gloves)
 - Surgical and laboratory instruments. (2.)

Importance of medical devices

- Medical devices have a key role in health care (5).
- Medical devices are indispensable for:
 - Monitoring wellbeing
 - Addressing outbreaks or emergencies
 - Prevention of disease or illness
 - Diagnosis of disease or illness
 - Treatment of disease or illness
 - Patient rehabilitation
 - Patient palliation (5).

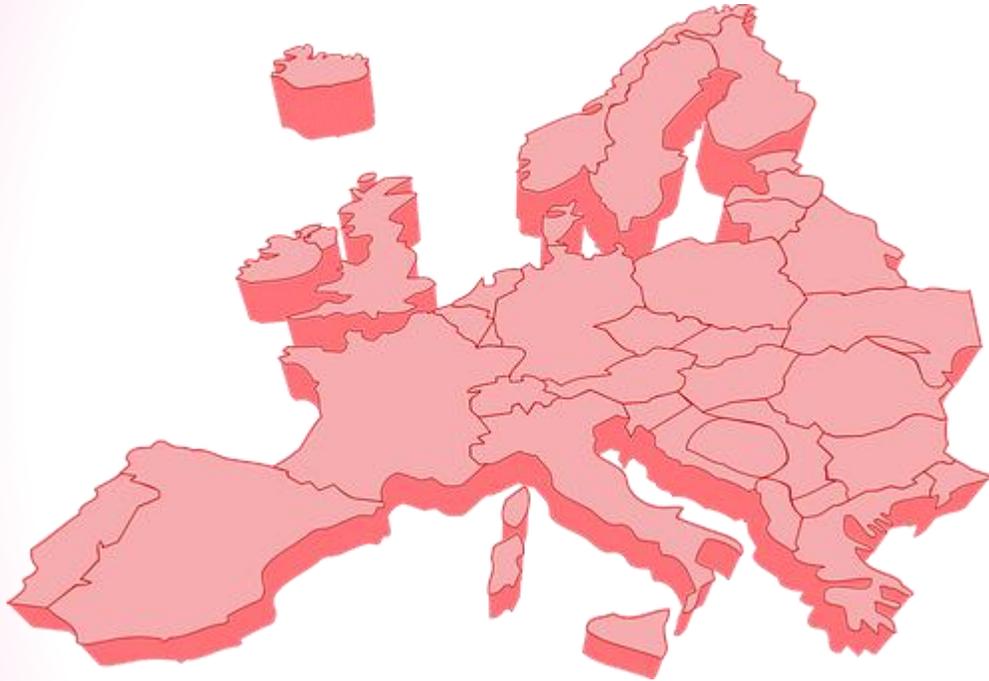


Use of medical devices

- Medical devices are used in many diverse settings, e.g.
 - By laypersons at home
 - By paramedical staff and clinicians in remote clinics
 - By opticians and dentists
 - By health-care professionals in advanced medical facilities (6).



Medical devices in EU



- On the EU market there are over 500 000 types of medical devices (7).
- Medical device sector in EU is supported by a regulatory framework that aims to
 - ensure the smooth functioning of the market, taking as a base a high level of protection of health for patients and user (7).

Policies for medical devices

- Policies, strategies, and action plans for medical devices are required in any national health plan (8).
- WHO works in supporting the formulation and monitoring of comprehensive national policies, norms and standards, and evidence-based policy guidance, to ensure improved access to high-quality medical devices (8).
- Please see section *Mandatory reading*
 - WHO's publication *Development of medical device policies*

Nomenclature for medical devices

- On the world market there are over 2 million different kinds of medical devices, categorized into more than 7000 generic devices groups (6).
- The number and types of devices are increasing exponentially (2).
- The nomenclature of medical devices by WHO is a coding and naming system used to generically classify and identify all medical devices and related health products (2).
- Please see section *Mandatory reading*
 - WHO's publication *Global Atlas of medical devices*

Nomenclature for medical devices

- A standardized classification and nomenclature of medical devices serves as a common language for recording and reporting medical devices across the whole health system, at all levels of health care, and for a whole range of uses (2).
- Standardization of nomenclature is also essential for:
 - Grouping and evaluating innovative technologies
 - Classifying for regulatory approval (registration)
 - Streamlining procurement
 - Supporting device descriptions for universal health coverage benefits packages
 - Ordering and grouping of devices in electronic health records and other health information systems (2).

MeDevIS (Priority Medical Devices Information System)

- MeDevIS is WHO's open access electronic database of medical devices (9).
- Aim of MeDevIS is to promote
 - The selection, planning and safe use of accessible, appropriate and affordable medical devices for prevention, diagnosis, treatment, rehabilitation and palliation (9).
- Please see section *Mandatory reading*
 - MeDevIS Priority Medical Devices Information System

Examples of medical devices in breast cancer treatment, Surgery



Surgery: Instruments



Surgery: Ventilator and monitoring device

Examples of medical devices in breast cancer treatment, Clinical laboratory & pathology

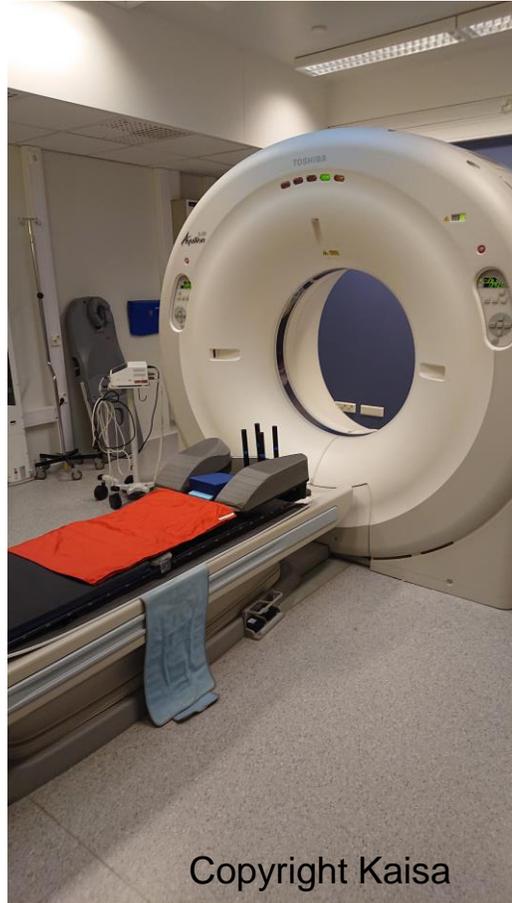


Clinical laboratory & pathology: Centrifuge



Clinical laboratory & pathology: Microscope

Examples of medical devices in breast cancer treatment, Radiotherapy



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Radiotherapy: Planning CT



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Radiotherapy: Linear accelerator

Examples of medical devices in breast cancer treatment, Systemic therapy

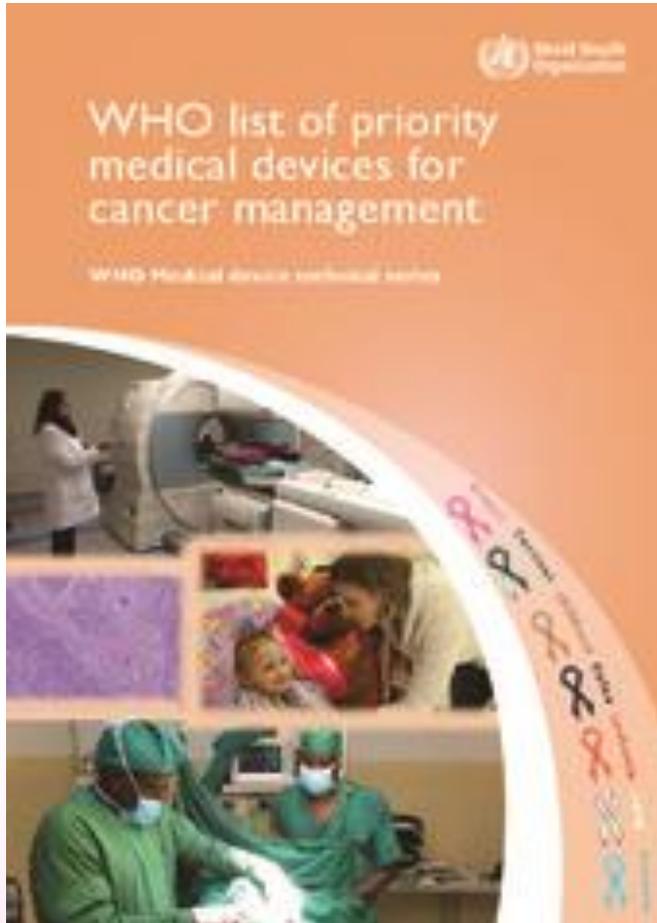


Systemic therapy: Injection set



Systemic therapy: Infusion giving set

More detailed information



[WHO list of priority medical devices for cancer management](#)

- Download WHO's publication to your computer and read the following chapters/tables:
 - Surgery
 - 3.2.2.1 Breast
 - 3.2.3 Surgical instrument sets, catheter and needle sizes
 - Clinical laboratory & pathology
 - 4.2.2.1 Breast
 - 4.3 Priority medical devices for pathology
 - Radiotherapy
 - 5.2.1 General medical devices for external radiotherapy
 - 5.2.2 General medical devices for brachytherapy
 - Systemic therapy
 - 6.2.1 General medical devices for systemic therapy

References

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