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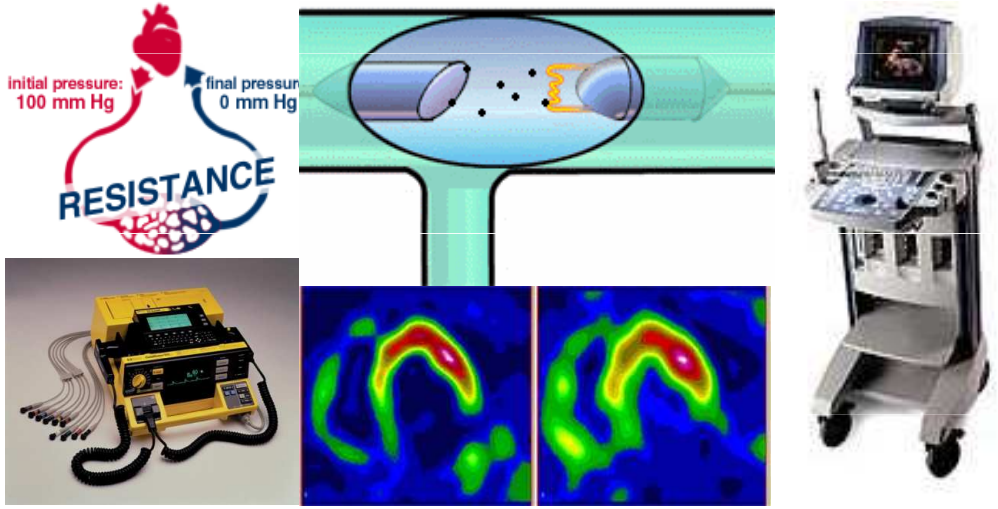
Lectures on Medical Biophysics

Medical Devices: Introduction



1 Department of Biophysics, Medical Faculty, Masaryk University in Brno

Medical Biophysics

- *In Medical biophysics we will be dealing with the physical principles of biomedical methods and devices and their interactions with the human body - which makes them useful in health care, including patient and user safety aspects and healthcare quality issues.*
- The physical processes in living organisms and the effects of physical factors on them are important as background information.

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Links

- Natural sciences (physics, chemistry and biochemistry, biology)
- Morphological disciplines
- Physiology and pathological physiology
- **Clinical disciplines (almost all!)**

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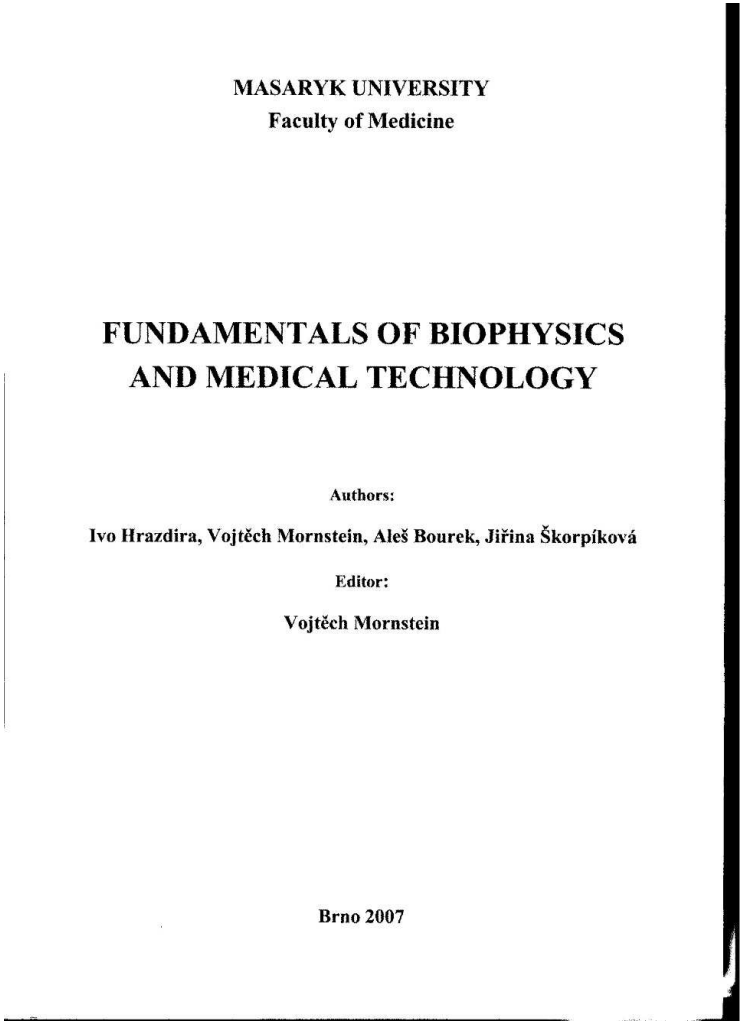
Recommended textbook



MASARYK UNIVERSITY
Faculty of Medicine

FUNDAMENTALS OF BIOPHYSICS
AND MEDICAL TECHNOLOGY

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This textbook and all the presentations shown in the lectures provide the information necessary to be **successful** in the exam!!!

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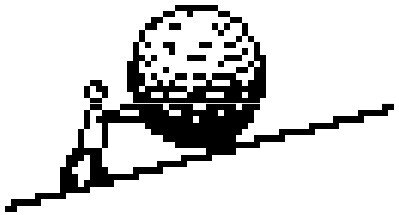
How to study?

Studying medical biophysics, there is no problem with the amount of knowledge which is necessary to master, but with **understanding** the physical principles and their application. Memorisation without understanding will **not** be sufficient to have a success at the exam.



Do not use the unauthorised texts!

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Medical Devices : Introduction

What is a Medical Device?

According to EU directives:

"any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used on human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, or alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means." (MDD Article 1(2a))

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HealthCare Activities

- Prevention
- Diagnosis
- Curative (therapeutic)
- Rehabilitation
- Palliative care (when cure is not possible)

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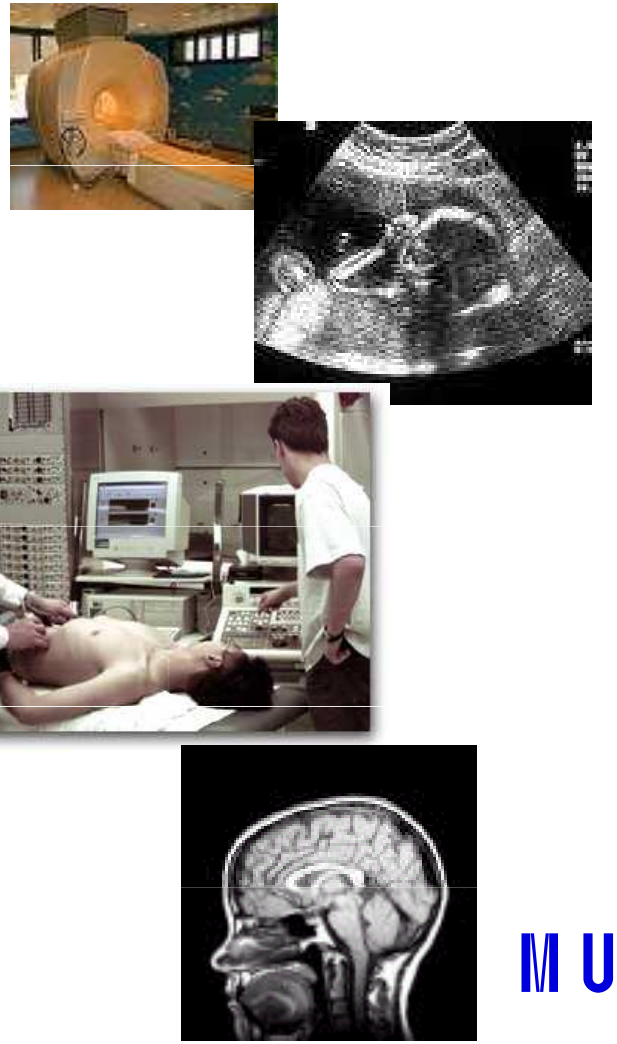
Medical Imaging Devices (*in vivo* diagnosis)

- X-ray projection imaging
- Computerised Tomography (CT)
- Ultrasound (USI), Doppler imaging
- Magnetic resonance imaging (MRI)
- Radionuclide imaging (nuclear medicine)
- Thermography
- Etc.



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Medical Imaging Devices (*in vivo* diagnosis)

Theoretical background:

Ionising radiation (origin, measurement, interactions with matter), properties of atoms and nucleus, radioactivity, basic terms of acoustics, electromagnetic spectrum….

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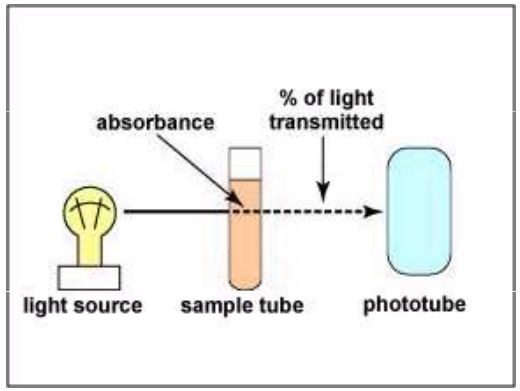
Medical Laboratory Devices (*in vitro* diagnosis)

- sample separation, centrifugation etc
- electrophoresis, capillary electrophoresis
- pH / ISE meters
- particle / cell counters
- spectrophotometers
- flow cytometry
- microscopy
- HPLC (chromatography)
- clinical chemistry
- haematology
- immunology
- scintillation systems
- genetic analysis
- .....



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Medical Laboratory Devices (*in vitro* diagnosis)

Theoretical background:

Structure of biopolymers, properties of water and electrolytes, electric properties of living matter, galvanic cell, sedimentation of particles, dosimetry, light absorption…

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Physiological Measurement Devices (*in vivo* diagnosis)

- Instruments for measuring physical and chemical variables *in vivo*
- Thermometers
- Cardiovascular physiology: blood pressure monitors, flowmeters, pulsed Doppler US systems
- Electrophysiology: ECG, EEG, EMG
- Audiology and ophthalmology
- Respiratory physiology: spirometers, pulse oximetry, impedance pneumograph….
- Endoscopes

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Physiological Measurement Devices (*in vivo* diagnosis)

Theoretical background:

Introduction to thermodynamics, basic laws of hydrodynamics, origin of bioelectric potentials, properties of sound and light, ear and hearing, eye and vision, mechanical properties of living matter…

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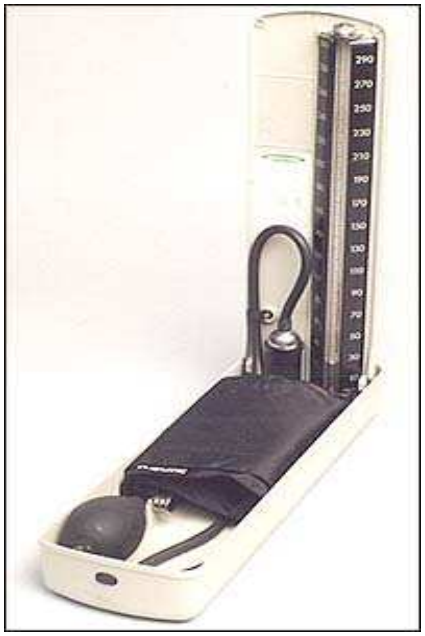
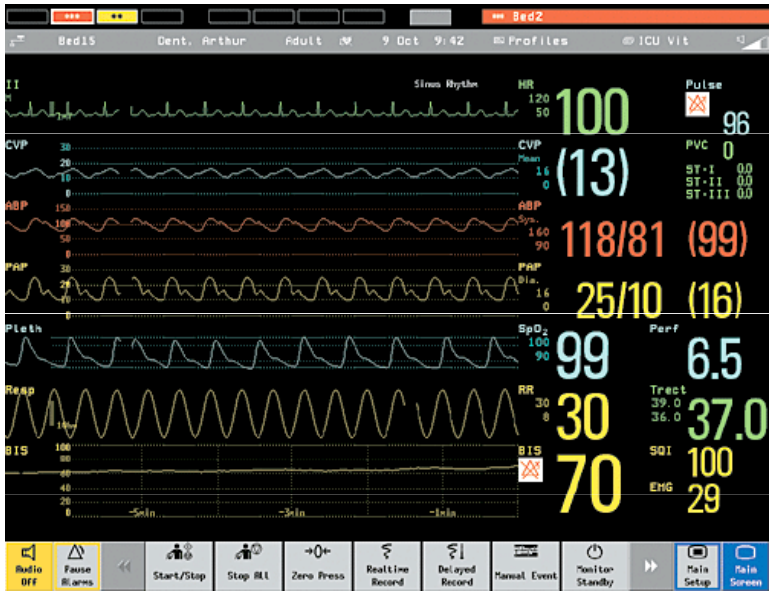
ECG (aka EKG)

Measuring lung capacity using a spirometer.



sphygmomanometer



Screen of a multipurpose clinical monitor

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Paediatric Intensive Care

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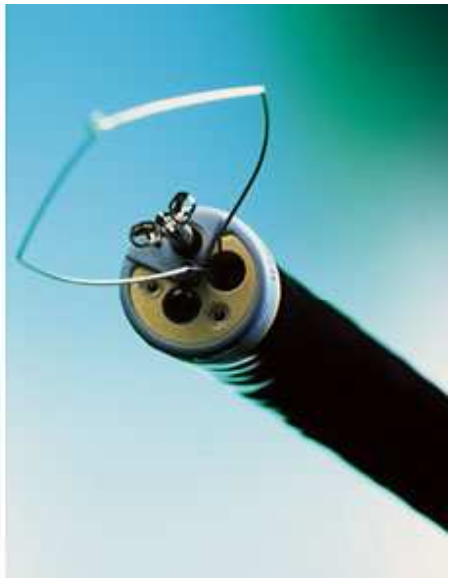
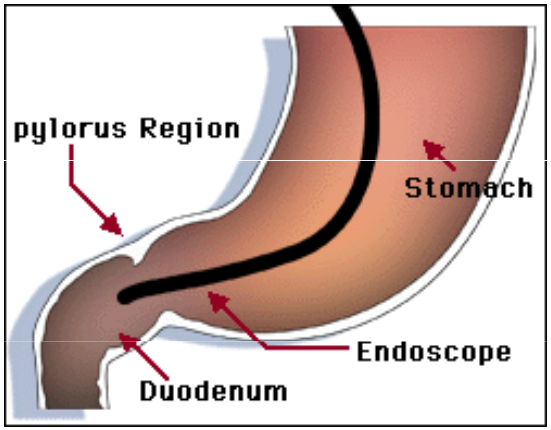
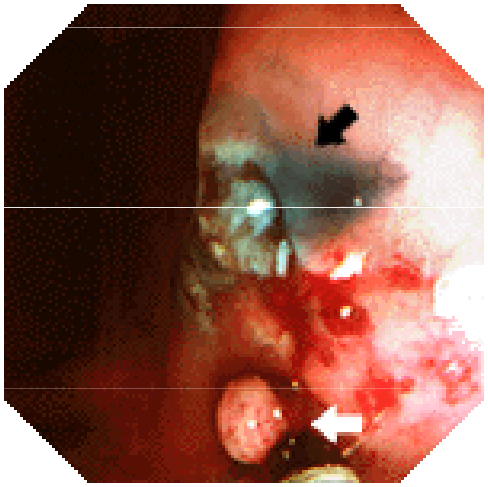
Endoscopy







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Radiotherapy Devices

- X-ray and electron, resp. hadron beams from accelerators (shape, direction, and intensity of beam changed often continuously)
- gamma-ray beams from tele-isotope radioactive sources like Co-60
- treatment planning systems
- simulators
- brachytherapy
- dosimeters

Linear accelerator

Patient prepared for Leksell gamma knife treatment

Radiotherapy Devices

Theoretical background:

Ionising radiation (origin, measurement, interactions with matter), properties of atom nucleus, radioactivity, biological effects of ionising radiation, dosimetry….

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Physical therapy Devices

- Electrotherapy
- UV and IR therapy
- Shortwave diathermy
- Ultrasound therapy
- Laser therapy
- …..

Ultrasound therapy unit

Shortwave diathermy

Muscle stimulator

Laser therapy unit

Physiotherapy Devices

Theoretical background

Biological interactions of ultrasound, electromagnetic fields, electric current, infrared, visible and ultraviolet light, laser principle….

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POC (Point of Care) Devices

- Address clinicians' requirements for rapid access to information to support critical care decisions
- Advances in **microelectronics** and **biosensor tools** have brought technology to the bedside in a miniaturized form.
- Examples:
  - Performing blood tests at the patient's side rather than in a central laboratory
  - portable ultrasound imaging devices

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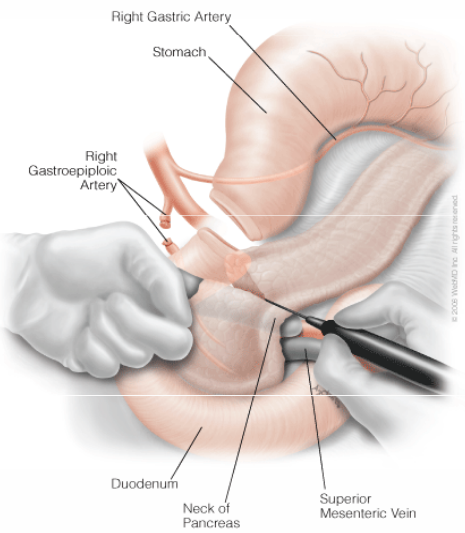
Surgical Theatre Devices, Lithotripsy

cryosurgery

anaesthesia



electrocautery

Surgical Theatre Devices, Lithotripsy

Theoretical background

Biological interactions of ultrasound, electromagnetic fields, electric current, infrared, visible and ultraviolet light, laser principle, low temperatures, acoustic shock waves…

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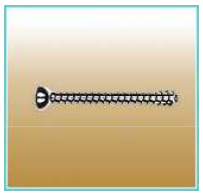
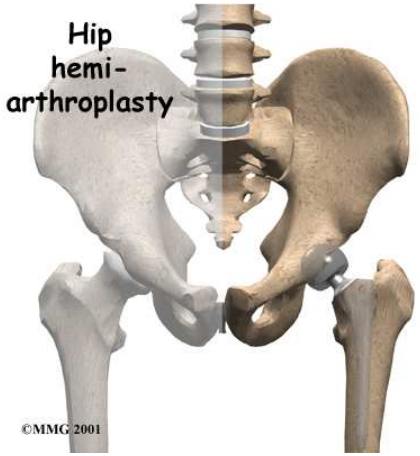
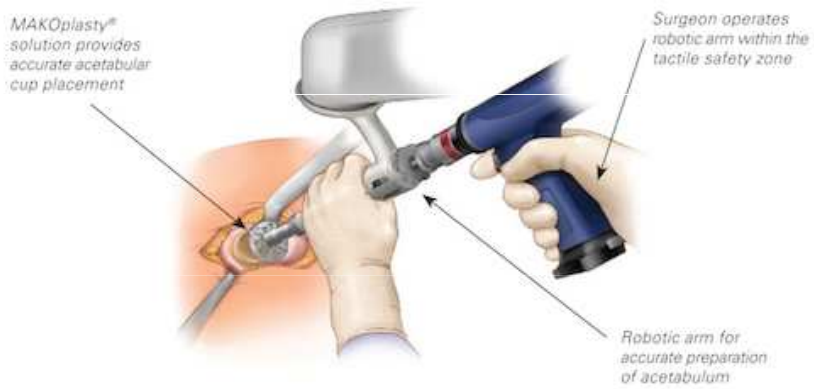
Prosthetic Devices - Implants



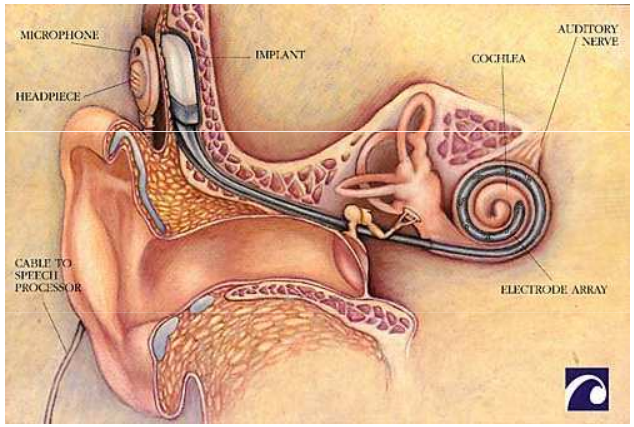




Robotic device for
acetabular cup implantation

Prosthetic Devices – „Artificial Organs“

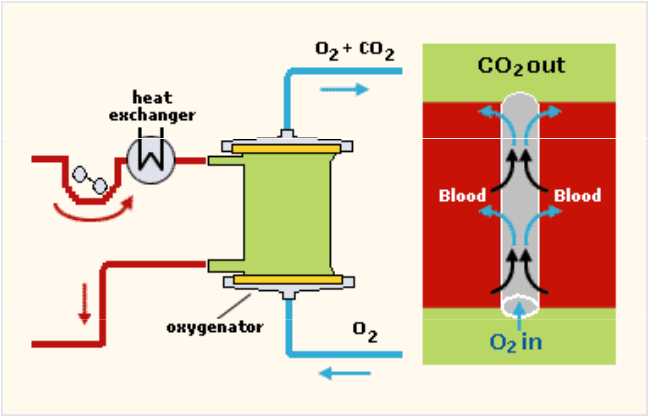
Artificial heart

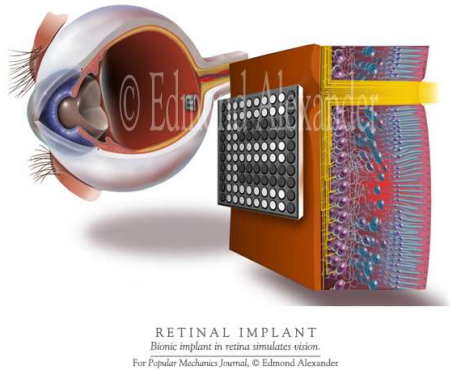


Cochlear implant

Pulmonary Ventilator

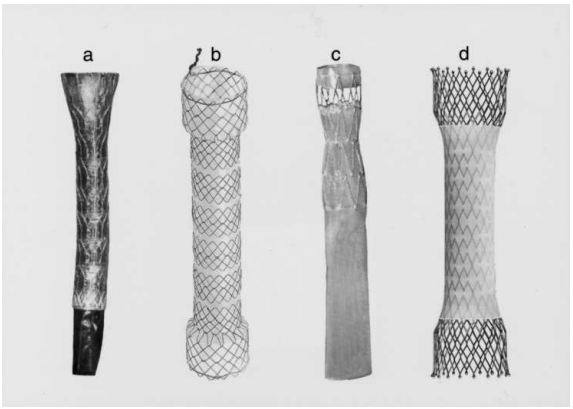
Cardiopul-
monary bypass

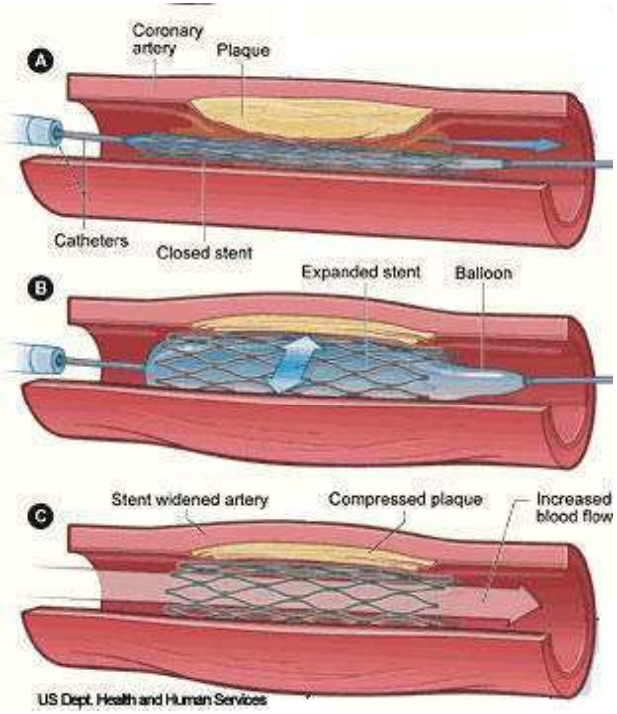




Retinal implant

Prosthetic Devices – „Artificial Organs“

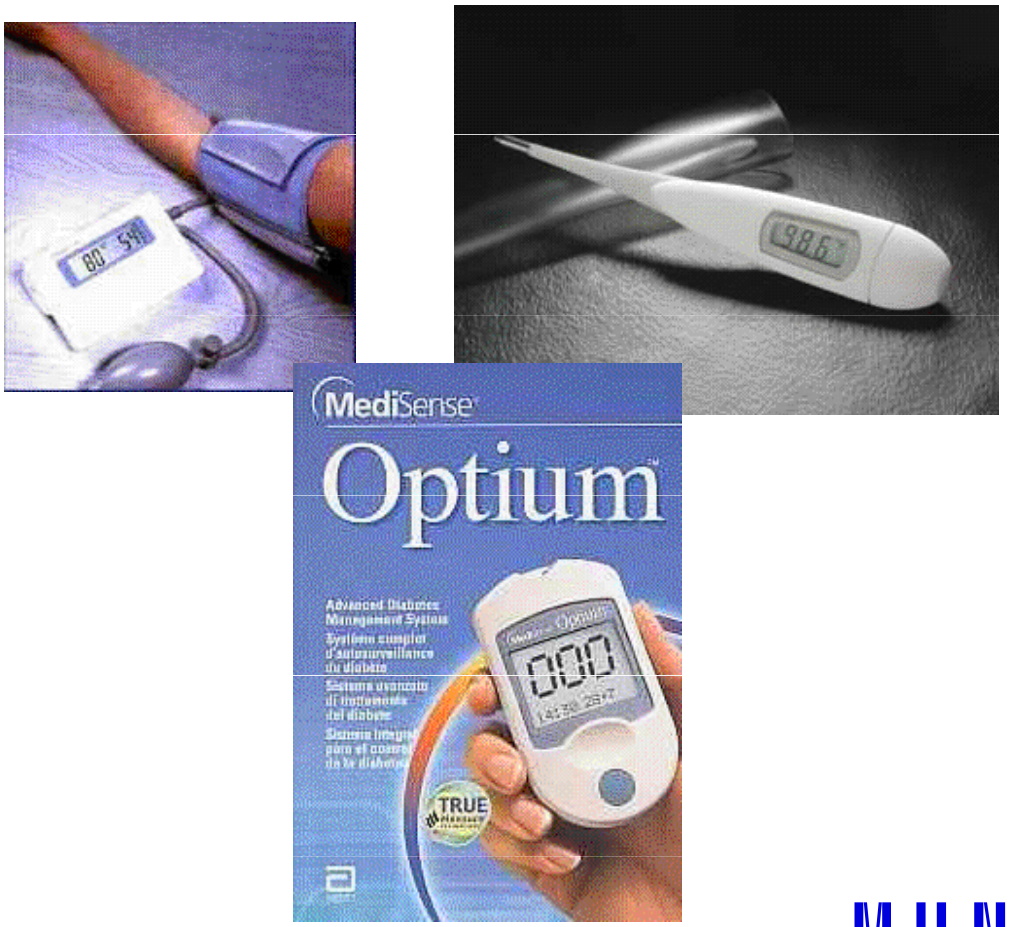




Stents are inserted into the damaged blood vessels, oesophagus etc. They are often made of a metal with a „shape memory“ – nitinol, which adopts the intended shape when heated to body temperature.

Devices for Self-testing (‘home devices’)

- 'device for self-testing`: any device intended by the manufacturer to be able to be used by lay persons in a home environment
- thermometers, pressure measuring instruments etc.
- test kits (pregnancy, glucose levels in blood used by diabetes patients etc)



Blood glucose meter

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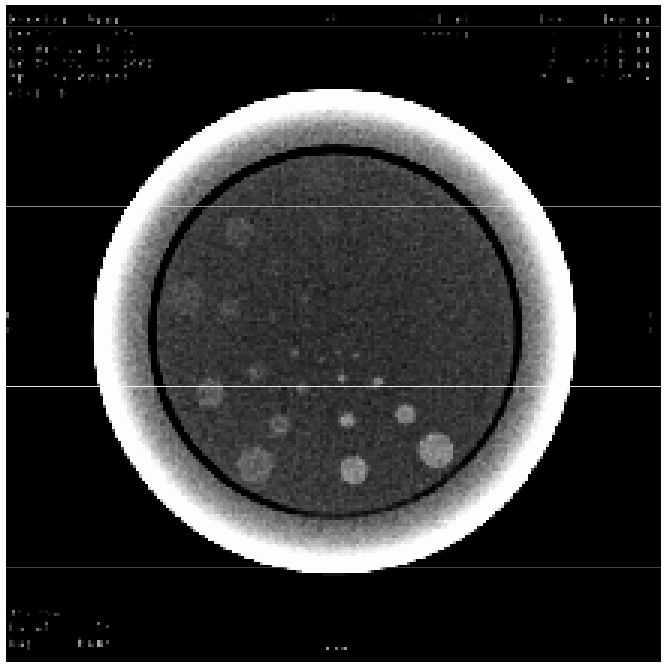
Devices for Performance Evaluation of Devices

'device for performance evaluation`: devices to check the performance of medical devices are also considered as medical devices



Testing contrast resolution in XRI

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What is the Purpose of this Course?

- Create awareness that medical devices should be used effectively and safely (reduce patient, occupational and others' risk to a minimum)
- Use medical devices in a professional and scientific manner
- Appreciate uses of medical devices in the clinical areas and in research
- Have an idea of the devices used in other professions

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Some Competences for Users of Medical Devices

What is expected the doctor does with or knows about the device?

- State the specific diagnostic, therapeutic etc outcomes expected when using the device
- Explain the physics principles underpinning the functioning of the device and the device use protocols
- Describe the structure of commercially available devices including user option settings and controls
- Identify possible health hazards (e.g. mechanical, electrical, radiation etc) to patient, self and colleagues
- Describe measurable objective device performance indicators which are directly related to device effectiveness or safety

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Cont ...

- Demonstrates a level of capability in the use of the device that ensures the required level of effectiveness whilst minimising risk to patient, self and others
- Explains limitations of the device and contraindications for use
- Describes the impact on effectiveness and risk arising from device malfunction or inappropriate user protocol
- Demonstrates timely device malfunction recognition and local procedures for reporting such faults
- Demonstrates skill in preventive maintenance and quality control including calibration of the device appropriate for users
- Demonstrates an awareness that a device should be checked before use and in the case of re-usable devices left in a condition for subsequent use
- Demonstrates adherence to International, European, National and local legislation and/or regulations regarding the use of the device

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