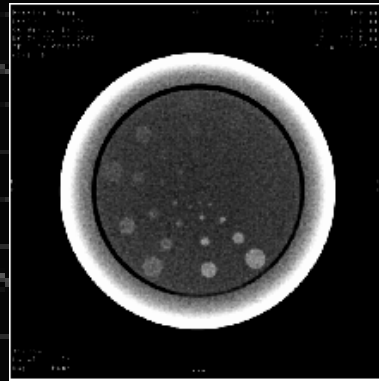


Lectures on Medical Biophysics

Department of Biophysics, Medical Faculty,
Masaryk University in Brno

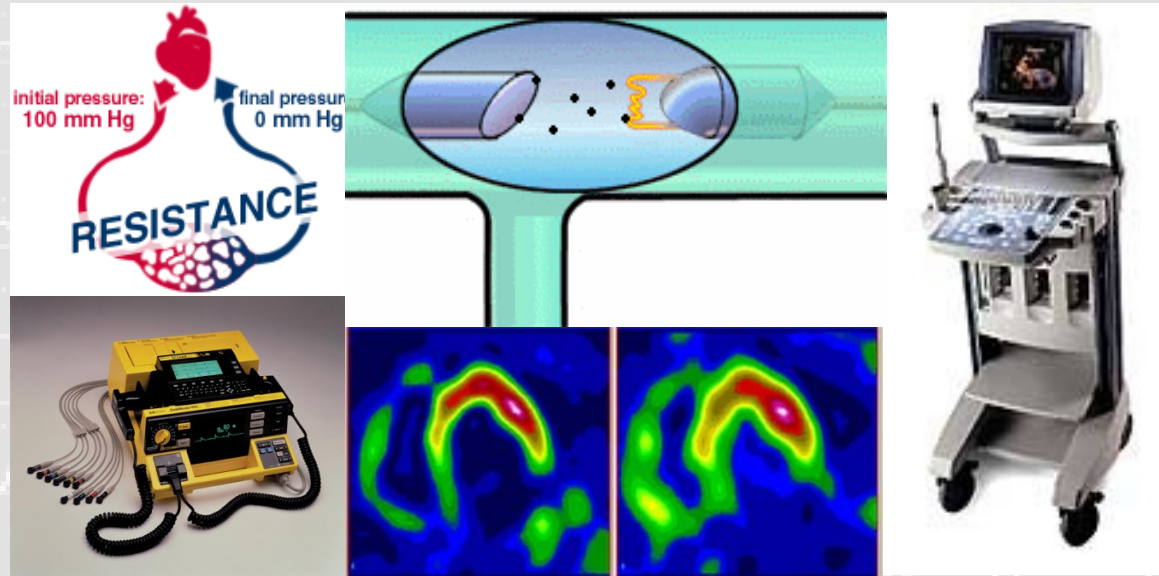


Sinus Rhythm
HR 120
50
CVP Mean 16
0
ABP Sys. 160
Dia. 90
PAP Dia. 16
0
SpO₂ 100
90
RR 30
8
BIS

-5min -3min -1min

Lectures on Medical Biophysics

Department of Biophysics, Medical Faculty,
Masaryk University in Brno



Medical Devices: Introduction

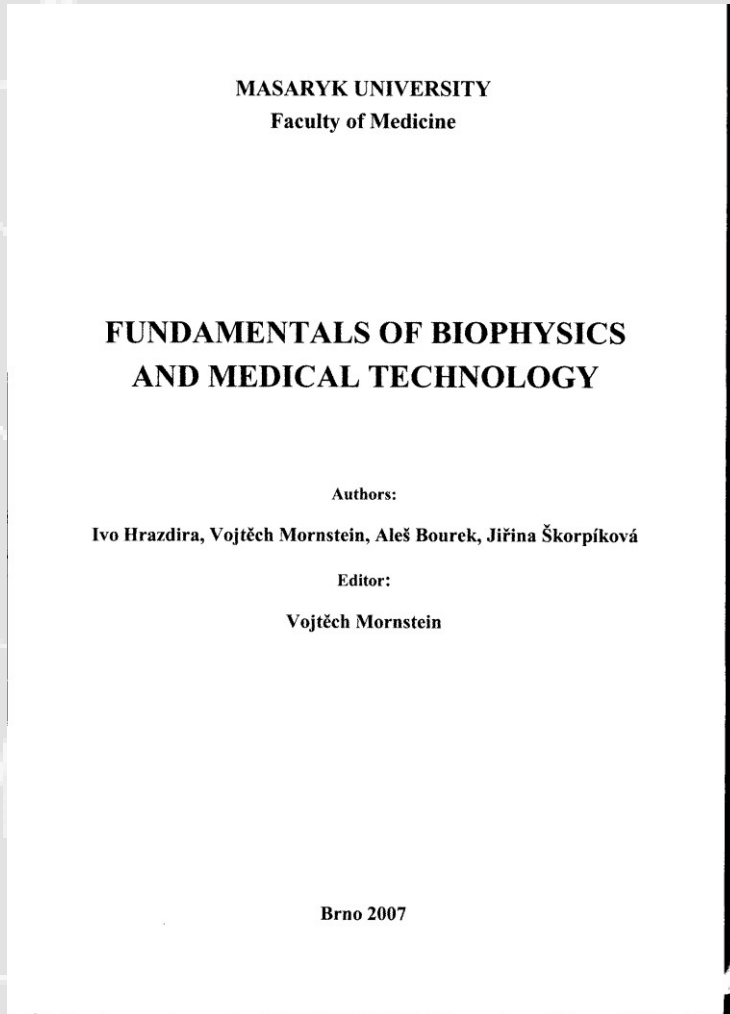
Medical Biophysics

- *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.*

Links

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

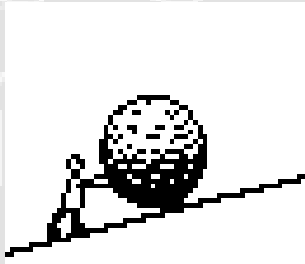
Recommended textbook

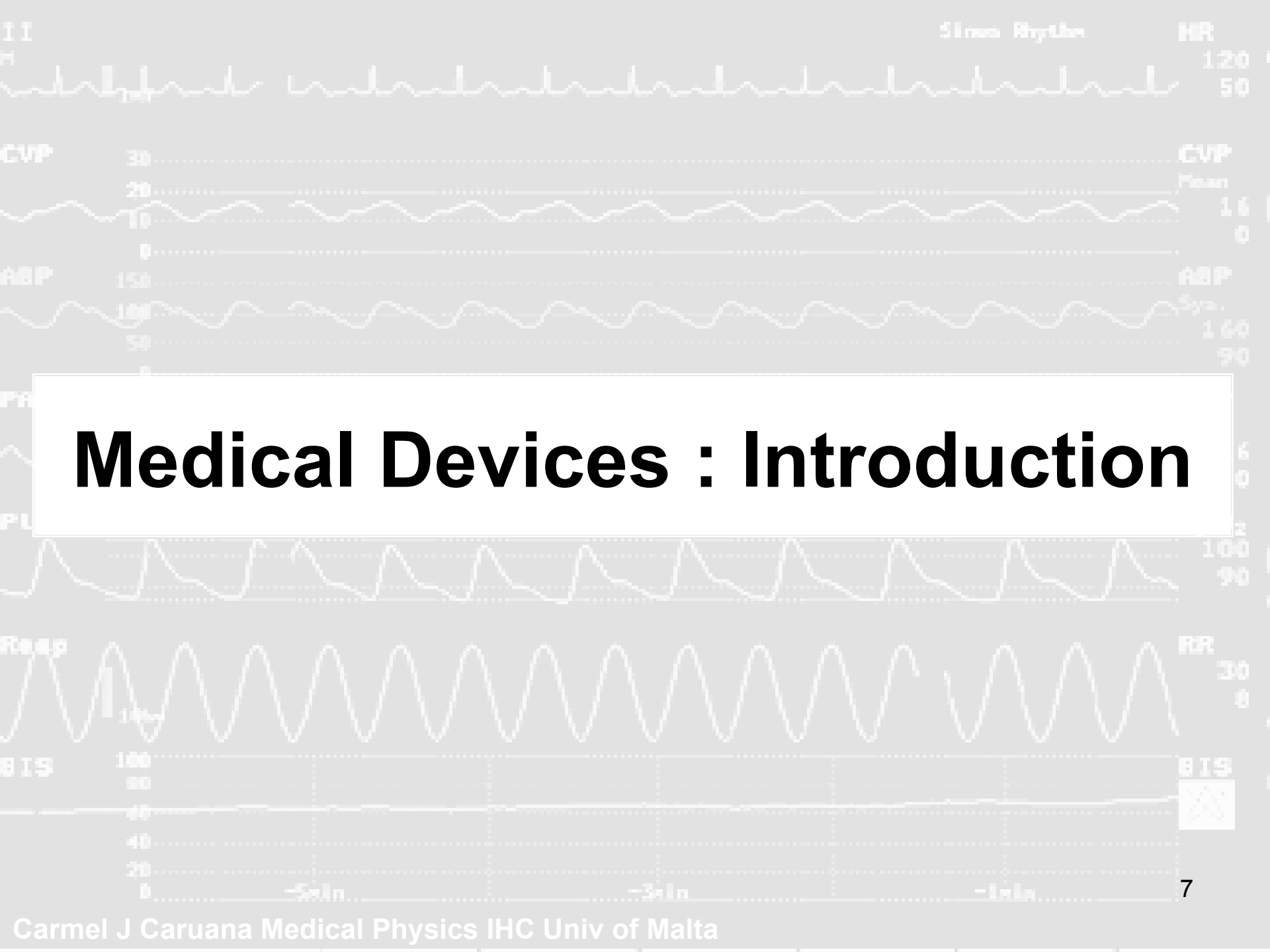


This textbook and all the presentations shown in the lectures provide the information necessary to be successful in the exam!!!

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.





Medical Devices : Introduction

What is a Medical Device?

“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))

The EU Medical Device Directives

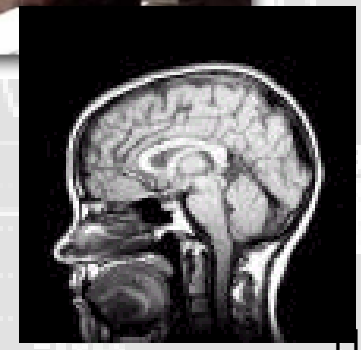
- The Medical Devices Directive (MDD) (93/42/EEC, OJ L169 p0001-0043) : from bandages, tongue depressors, thermometers to contact lenses, stethoscopes, splints, first-aid kits, breathalysers, heart valves and imaging equipment
- The In-Vitro *Diagnostic* Medical Devices Directive (IVDD) (98/79/EC OJ L331 p0001-0037): reagents, control standards, test-kits, equipment ... intended for the *in-vitro* examination of human specimens e.g. blood grouping reagents, pregnancy test kits, Hepatitis B test kits
- The Active Implantable Medical Devices Directive (AIMDD) (90/385/EEC OJ L189 p0017-0036): *active* (i.e. include an energy source) implants or partial implants e.g. heart pacemakers
- Most countries have transposed these directives into a single national legislation (e.g. UK Medical Devices Regulations 2002)

HealthCare Activities

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

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



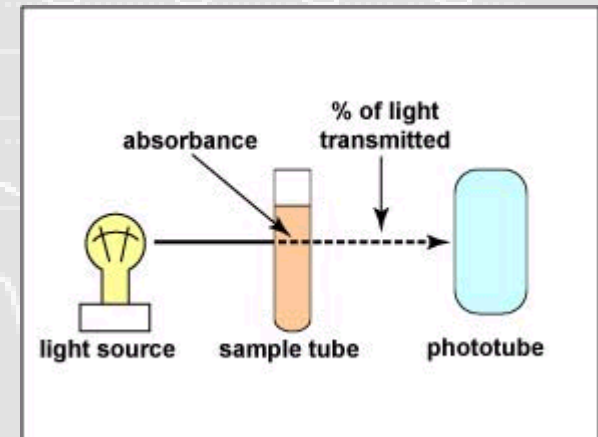
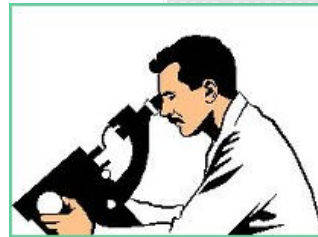
Medical Imaging Devices (*in vivo* diagnosis)

Theoretical background:

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

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



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...

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

Physiological Measurement Devices (*in vivo* diagnosis)

Theoretical background

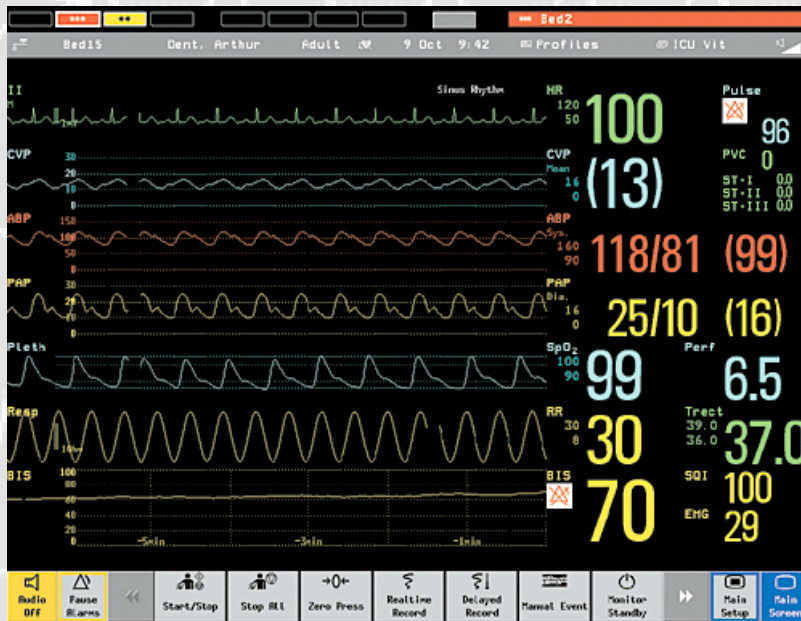
Introduction to thermodynamics, basic laws of hydrodynamics, origin of bioelectric potentials, properties of sound and light, ear and hearing, eye and vision, mechanical properties of living matter...



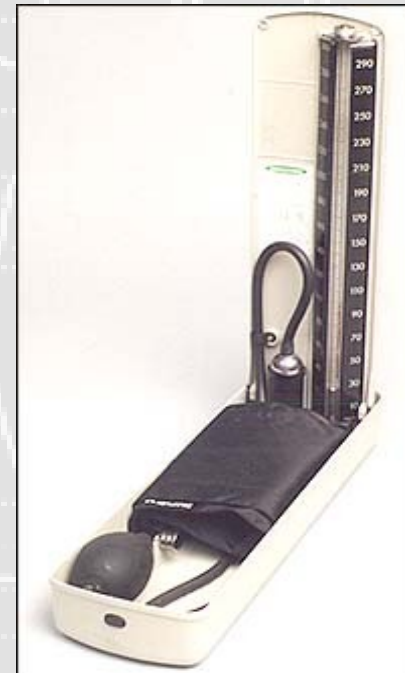
ECG (aka EKG)



Measuring lung capacity using a spirometer.



Screen of a multipurpose clinical monitor



sphygmomanometer

Paediatric Intensive Care



CVP

Mean

16

0

ABP

Sys.

160

90

PPAP

Dis.

16

0

SpO₂

100

90

RR

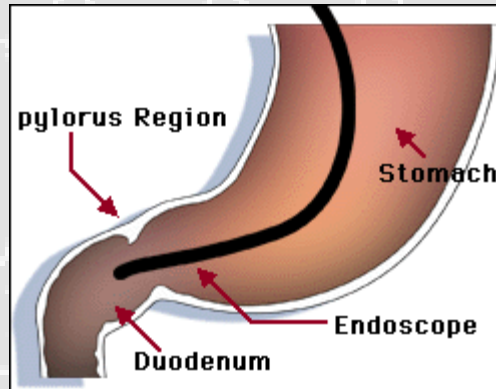
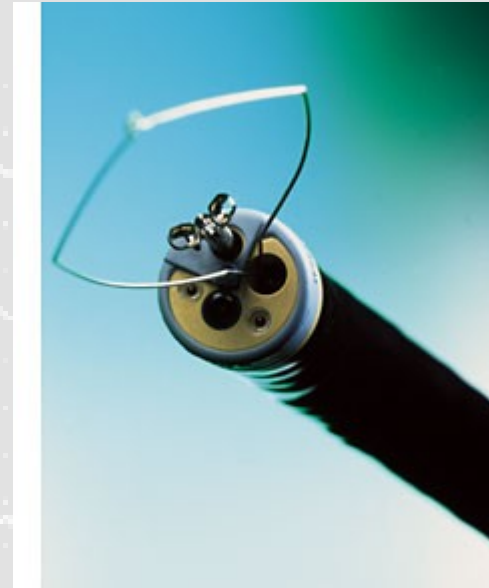
30

8

BIS



Endoscopy



HR	120
50	
CVP	Mean
	16
	0
ABP	Sys.
	160
	90
PRP	Dis.
	16
	0
SpO ₂	100
	90
RR	30
	8
BIS	

Radiotherapy Devices

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



Linear accelerator



Leksell gamma knife

Radiotherapy Devices

Theoretical background:

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

Physical therapy Devices

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



Ultrasound therapy unit



Muscle stimulator



Laser therapy unit



Shortwave diathermy

Sinus Rhythmic

HR

120
50

CVP

Mean
16
0

ABP

Sys.
160
90

30
8

BIS



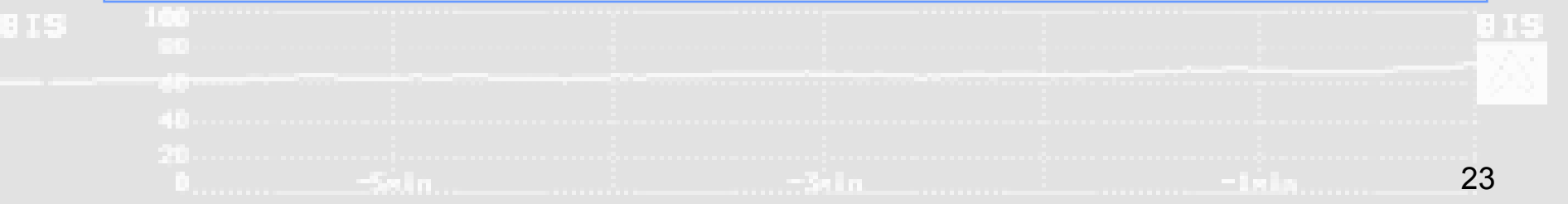
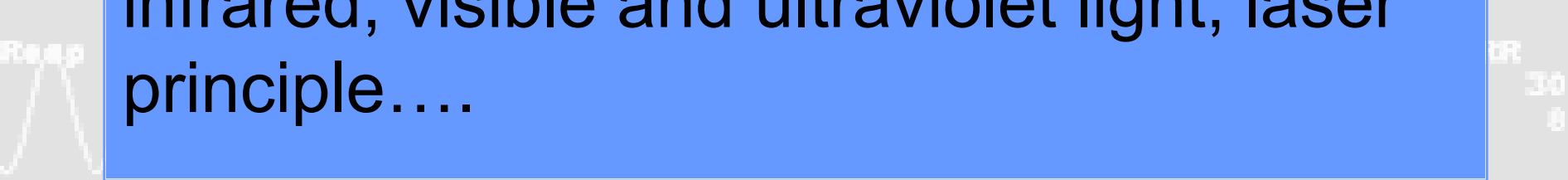
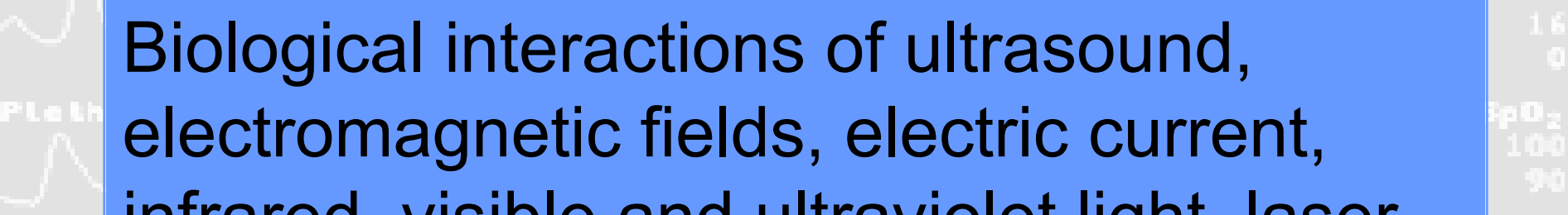
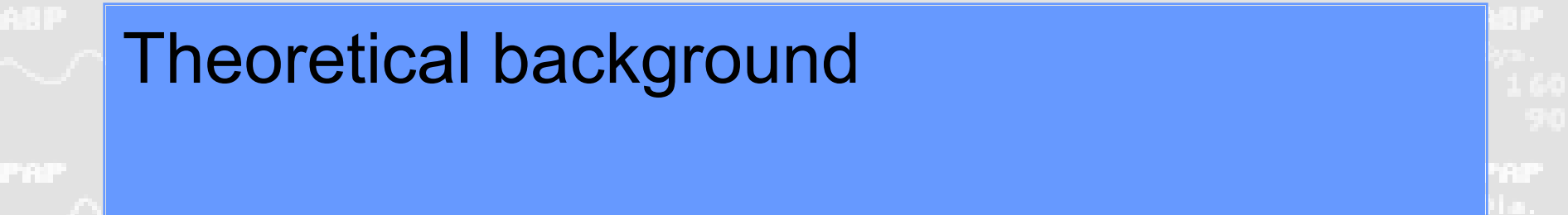
Sinus Rhythm HR 120
50

Physiotherapy Devices



Theoretical background

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



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

Surgical Theatre Devices, Lithotripsy



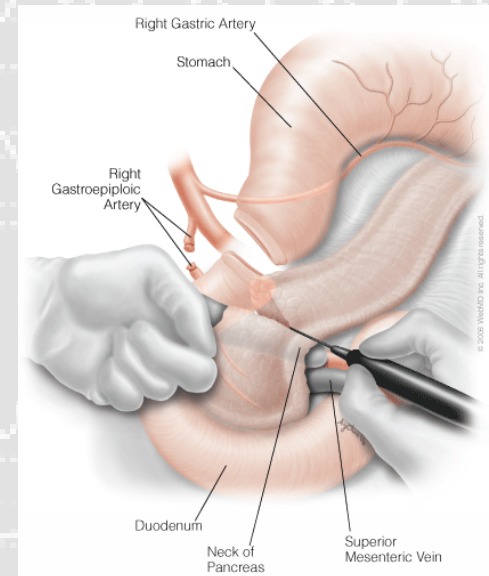
cryosurgery



Operating lamps



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...

Sinus Rhythmic

HR

120

50

Surgical Theatre Devices

CVP

CVP

Mean

16

0

ABP

ABP

Sys.

160

90

PAp

PAp

Dis.

16

0

Pleth

SpO₂

100

90

Resp

RR

30

8

BIS

BIS



20

0

-5cm

-3cm

-1cm

Surgical Theatre Devices

Sinus Rhythmic

HR

120

50

CVP

CVP

Mean

16

0

ABP

ABP

Sys.

160

90

PIP

PIP

Dis.

16

0

Pleth

SpO₂

100

90

Resp

RR

30

8

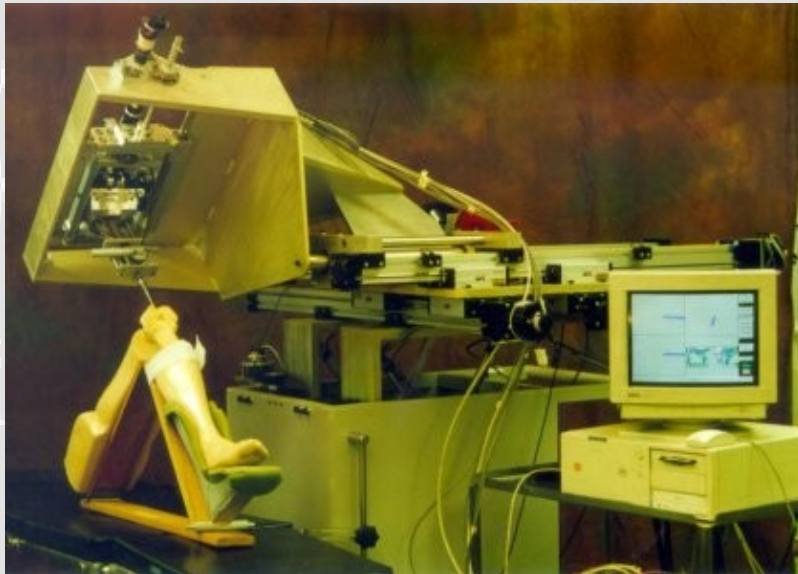
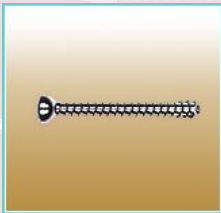
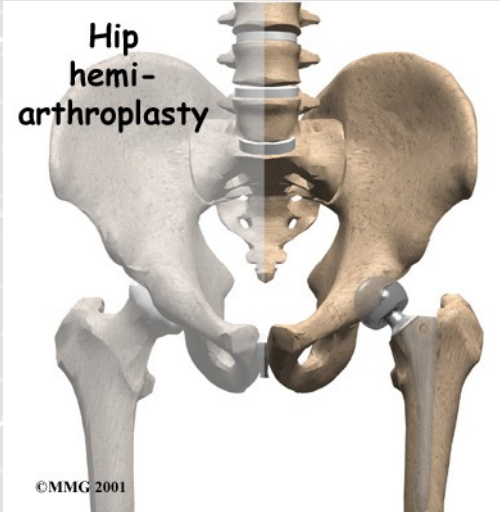
BIS

BIS

28



Prosthetic Devices - Implants

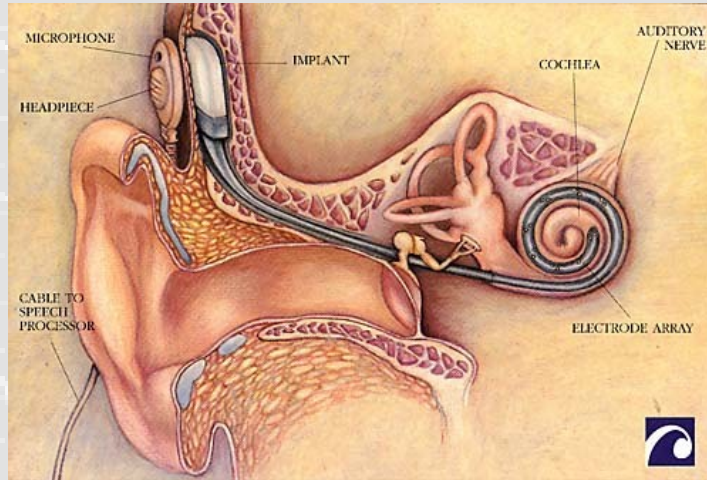


Robotic device for knee prosthesis implantation

Prosthetic Devices – „Artificial Organs“



Artificial heart

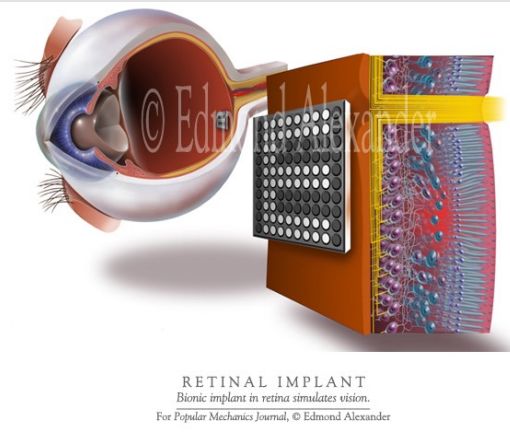
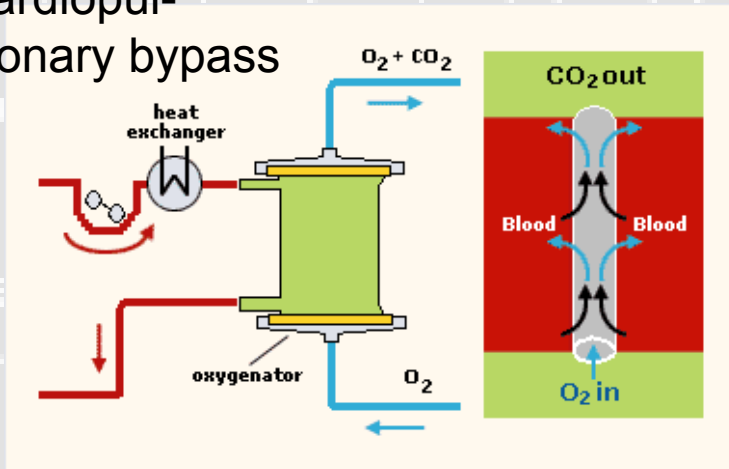


Cochlear implant



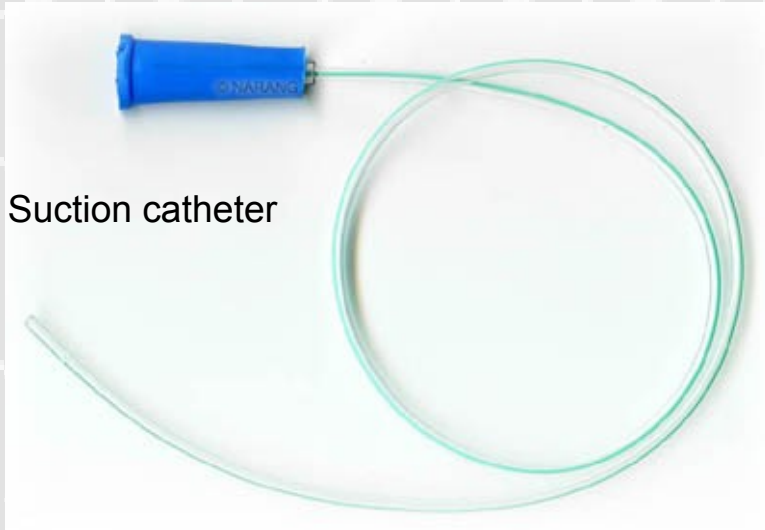
Ventilator

Cardiopulmonary bypass



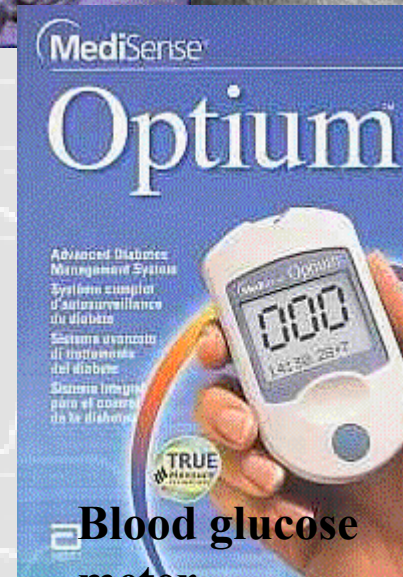
Retinal implant

Disposable Medical Devices



Devices for Self-testing ('home devices')

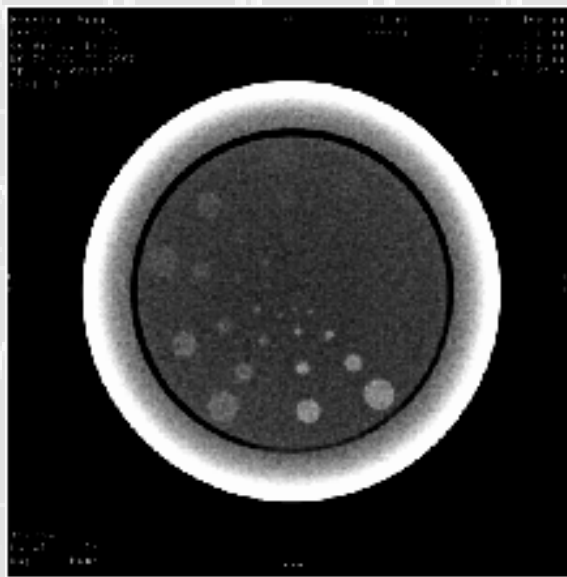
- 'device for self-testing': any device intended by the manufacturer to be able to be used by lay persons in a home environment
- thermometers, pressure measuring instruments etc
- test kits (pregnancy, glucose levels in blood used by diabetes patients etc)



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



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

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

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

Authors:

Carmel J. Caruana, Vojtěch Mornstein

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Carmel J. Caruana

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Lucie Mornsteinová

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