MDI²
Medical devices innovation institute | Institut d'innovation d'appareils médicaux

Carleton UNIVERSITY

uOttawa

Medical Devices

Lecture 1 – Medical Devices

Medical Devices

- Definition of Medical Devices
- Who Needs to Understand Medical Devices?
- What is Life?
- Major Focus
- Examples of Applications of Medical Devices
- Job Opportunities
- Human Physiology and Anatomy

Course Overview

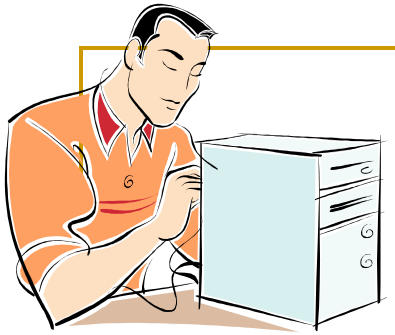
This course describes, in outline form, medical devices fundamentals. These can be grouped into various medical devices essentials:

- Needs for medical devices
- Design of medical devices
- Testing of medical devices
- Regulatory approval of medical devices
- Clinical use of medical devices
- Business of medical devices

The application of each of the above disciplines to the study of biology is a field by itself. This course covers, in an outline form, the application of major engineering fundamentals to medicine, with a special emphasis on mechanical engineering principles.

What are Medical Devices?

- Any instrument, apparatus, appliance, equipment, etc. used in the prevention, diagnosis, treatment, rehabilitation, and/or knowledge generation of disease. Healthcare delivery would not be possible without medical devices.



Who Needs to Understand Medical Devices

Medical devices field is multidisciplinary, requiring the understanding of a broad range of expertise.

Examples of those groups whose knowledge would be of great value include:

- biologists
- physiologists
- biomedical engineers
- clinical engineers
- nurses
- clinical technicians
- doctors (surgeons, cardiologists, pediatrics, orthopedics, radiologists, etc.)
- artificial organs specialists
- healthcare managers
- manufacturers
- regulatory agencies
- medical devices experts
- neurophysiologists
- biochemists
- pharmaceutical companies
- universities
- hospitals
- nursing homes
- sports physiologists & sports medicine specialists
- physiotherapists
- rehabilitation & prevention professionals
- psychiatrists
- biomaterialists
- perfusionists
- others…

What is Life?

Some major identifiers of life as we know it are:

1. The ability to make an effort (energy production)
2. Use of energy to perform work (energy expenditure)
3. Response to external and/or internal stimuli (sensing energy stimulation)
4. Self duplication (replication, energy conversion, hereditary information)

Can life be described in terms of energy?

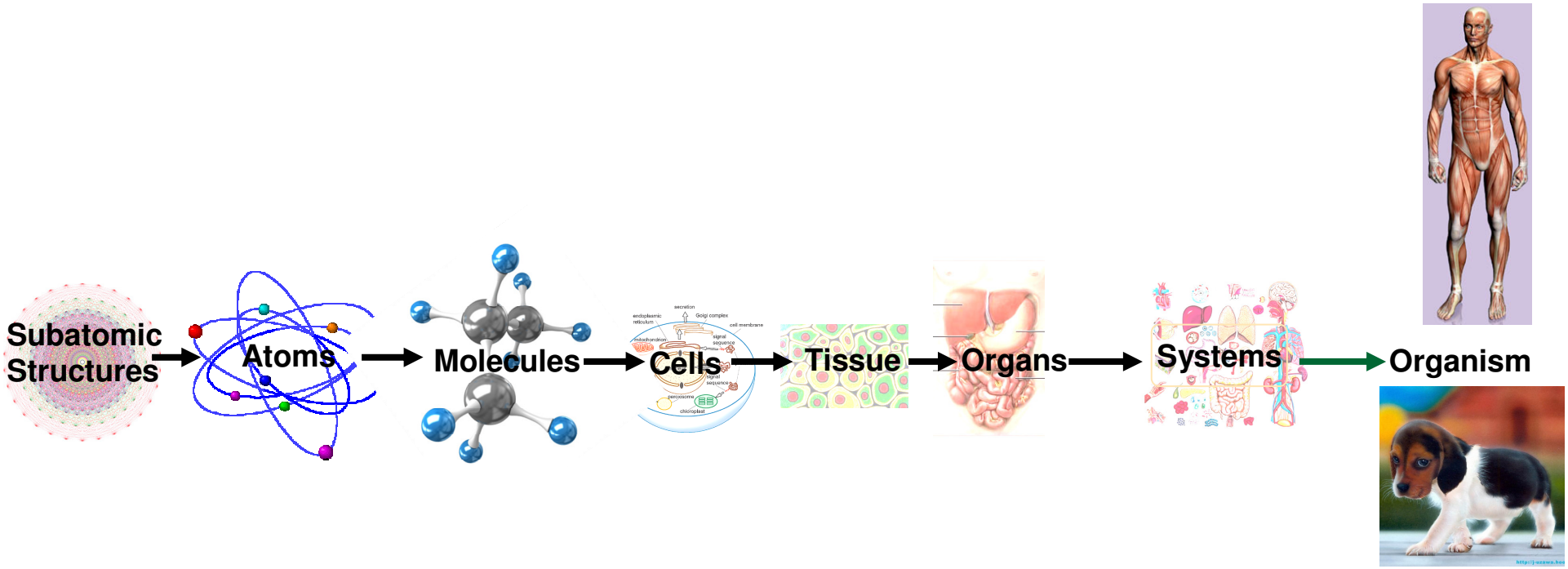
- Life, as we know it on Earth, is a cascaded process to obtain energy from the sun and use it. The solar energy originates from the conversion of hydrogen to helium, creating heat and light (both needed). The light, through photosynthesis, creates food (energy) for life.
- Life depends on energy and its transformation.

What is an Artificial Organ?

Artificial organs are:

- instruments, devices and equipments made by humans for various purposes including structural and functional replacement.

What is an Organ?



Major Focus

- These lectures will concentrate on anatomical, physiological and medical applications of medical devices:
  - Understand living cells
  - Analyze and obtain insight into the normal and abnormal functions of human organs and systems
  - Predict abnormalities
  - Measure changes and properties
  - Perform diagnosis
  - Formulate solutions (including treatment, medications and artificial organs)
  - Provide an outline of applied relevant knowledge and know how

Major Focus

- **What?, Why?, How?, Where?, When?, Who?**
- **Example :**

In order to design, manufacture and apply a suture, it is important to know the type of tissue, the resistance to puncture with the needle, the strength (compression and tensile strength) reliability, risk analysis, etc., procedures and manufacturing of the tools and instruments.

Examples of the Medical Devices Application

- Diagnostic applications such as neuromuscular, sensitivity to impact (Examples: knee jerk test, oscillation tests)
- Puncturing tools such as scalpel, blunt tunnelling, suturing, etc.
- Cavitation studies of the valve, restenosis of grafts, fluid dynamics and platelet activation
- Design of artificial hearts, valves, stents
- Hemodialysis
- Optimization of fluid dynamic forces and reduction of thrombosis
- Physiological membrane transport
- Rheology of blood and other tissues
- Biomaterialists
- Monitoring and control of medical devices
- Manufacturing of medical devices
- Orthopaedics and orthodontics activities
- Neuromuscular stimulation of injured spinal cords
- Bed sore reduction
- Artificial organs
- Biometric pressure
- Diseased heart, kidney, etc.
- Medical and physical sciences
- Business and legal
- Other applications…

Job Opportunities for Medical Devices Trained Personnel

- If you are an trained in medical devices field, there are excellent job opportunities; however, you must be:
  - A knowledgeable person with good, in depth knowledge of medical devices
  - Capable of being creative in joining and converting both scientific areas.
  - Capable of creating innovative and visionary goals.
  - Assertive, capable negotiator, communicator, both with engineers and medical scientists.
  - Able to compete with the best in the world. Just being average, above average or very good is not good enough.
  - Combination of a scientific knowledge with a creative mind.

- Job opportunities can be found in:
  - ✓ Hospitals
  - ✓ Universities
  - ✓ Medical devices companies
  - ✓ Pharmaceutical companies
  - ✓ Computer companies
  - ✓ Reliability and quality control
  - ✓ Environmental protective agencies
  - ✓ Health and safety protection Sales
  - ✓ Regulatory agencies
  - ✓ Scientific publications
  - ✓ Biomaterials
  - ✓ Artificial organs
  - ✓ Government
  - ✓ Education
  - ✓ Other areas…

Applicability of Fundamentals

- **Application of fundamental laws:** The principles of various sciences (i.e., Law of gravity, thermodynamics, fluid dynamics, electrical conductivity, chemical reaction and entropy) apply to human body structure and function as well as all non-living objects. All these principles are applicable to cells, tissue and the living system.

- **Engineering and scientific principles the human body:** Understanding the anatomy and physiology of the human body is simplified through applied principles (Examples: biofluidmechanics, membrane transport, action potential, simulation, information transmission, formation of energy, disease diagnosis, organ replacement, treatment, prevention and rehabilitation).

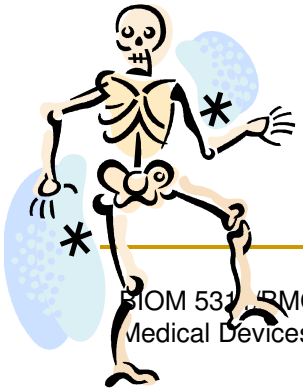
- **Centuries of work by engineers, scientists and others:** Medical devices, implantable material, suturing, diffusion of gases and exchange of gases in the lungs are examples of dynamic mass transfer, biofluid dynamics and other principles which have been looked as part of medical devices.

Applicability of Fundamentals

- **Need to integrate:** Through the combination of biological sciences, engineering principles, business, and law, it is easier and more practical to design and use wheelchairs, artificial valves, artificial hearts, diagnostic tools, safety equipment, control systems, medications, etc.

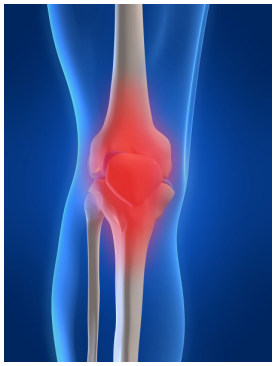
- **Multidisciplinary nature:** The quest for healing crosses all boundaries of science and all disciplines.

Examples: Bone healing, wound healing, bed sore mechanics, orthopaedics, orthodontics, bone fracture, cartilage damage and healing, tissue reaction to stress and strain, growth, reabsorption, lubrication, joint replacement and other examples which, by combining engineering, biological and medical sciences, become more effectively understood.



Bone Healing as an Example

- The exploration of the human body structure requires knowledge of the properties of its components. Bone tissues and their interrelations and mechanics of interaction are examples:
  - The bone material, methods of formation, mechanical properties, (density, porosity, loss of elasticity, compression, tensile, strength, etc.)
  - Tissue variations and their characteristics
  - Skeletal muscle and its relation to muscle, connective tissue and other tissues.
  - Body cavities and fluids, cells and their structures (membrane, nucleus, cytoplasm, etc)
  - Methods of imaging and structure of the body such as:
    - MRI
    - Ultrasound
    - Light microscopy
    - Scanning electron microscopy (SEM)
    - Positron emission tomography (PET) scanning



Physiology

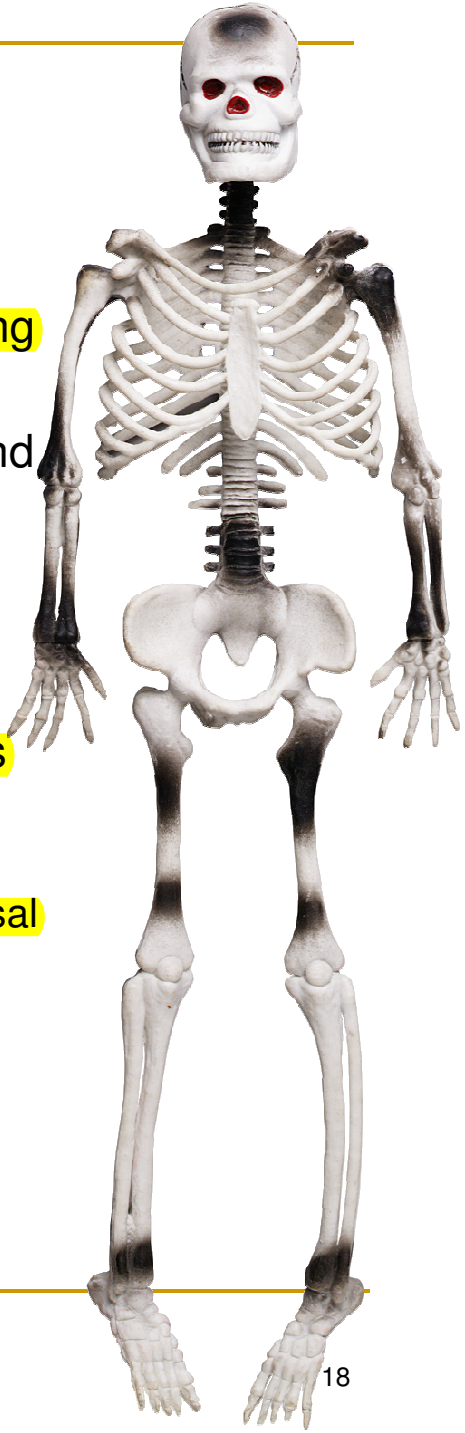
- Physiology is the study of the function of the body and its parts
- The quest for healing goes back to the beginning of man and physiology is the result of this quest.
- The abnormality of function becomes sickness.
- Is it better to prevent abnormal physiology than treat abnormal physiology? Some say prevention is best, but the ability to repair is also necessary because of aging. The answer is not simple, both are required.
- The answer to the above question has preoccupied mankind for thousands of years. Prevention and healing have mushroomed in the following areas:
  - Orthodox medicine (medicine, surgery, etc)
  - Osteopathic - manipulation of bones, nervous system, etc
  - Neuropathic - manipulation of nerves
  - Herbal medicine
  - Holistic medicine
  - Other methods (chiropractors, acupuncture, Energy Based Healing, Schitzu, etc)

Physiology Continued

- The understanding of physiology is one of the basics for effective healing.
- Physiology is based on, and can be described very effectively by, applying the principles of science.
- Physiology by itself is a major field in medicine. Only an overview is presented in this lecture series.
- Without mechanical principles, descriptions and explanations of the physiological function of the human body, it is impractical to describe the function of cells, tissue, organs and the body.
- For example:
  - Cardiovascular function
  - Pulmonary function
  - Transport across the cell membrane
  - Mechanics of muscle contraction
  - Mechanics of gas exchange
  - Implantable devices
  - Quantification of physiology signals
  - Other…

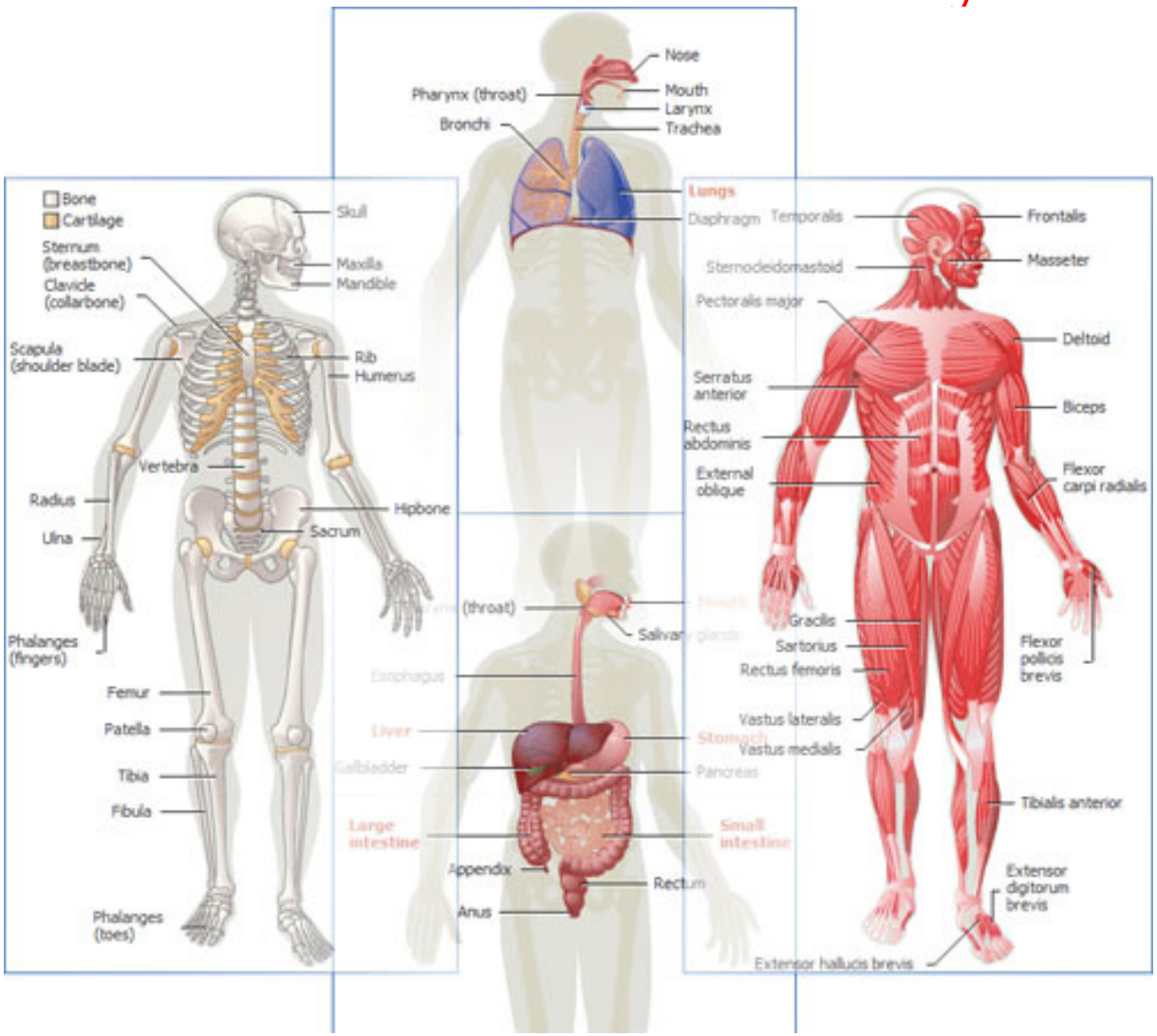
Human Anatomy

- Anatomy is derived from “anatome” meaning “to dissect”.
- Anatomy is the study of the structure and the relationship among various component structures within the body.
- The human body, as a living system, has parts, components and subsystems.
- From a chemical point of view, beginning with subatomic structures such as a vibrating superstring of energy to atoms, molecules, cells, tissue, organs, systems and the whole body.
- Each of these parts, subcomponents, systems and subsystems are responsible for specific functions:
  - Pulmonary systems: deals with respiration.
  - Circulatory system: circulates blood (nutrition, oxygen, waste disposal for the body).
  - Gastrointestinal system: mainly responsible for digestion of food.
  - Nervous system: sensing and response.



Characteristics of the Human Body

- The human body has a backbone (a vertebral column). Humans are part of a large group of organisms called vertebrates.
- The human body is a tube within a tube type structure (double tubing). The outer tube is formed by the body wall and the inner tube is the digestive tract.
- The human body is bilaterally symmetrical. Externally, the left and right sides of the body are mirror images.
- The human body functions as a whole and its organs cannot survive for long on their own.

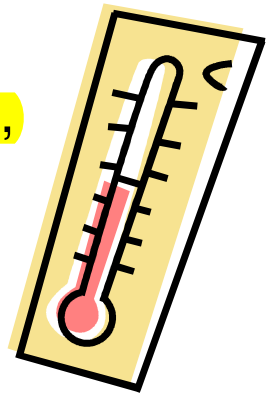


Internal Body Environment

Homeostasis is the ability to maintain a relatively stable internal environment despite changes in the surroundings.

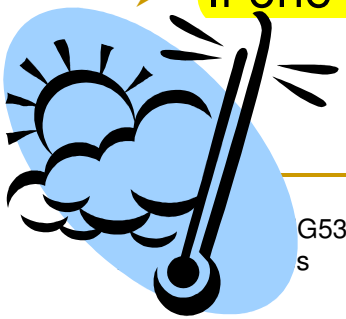
To sustain life, cells and tissue, the body needs to communicate with the environment and react to environmental conditions:

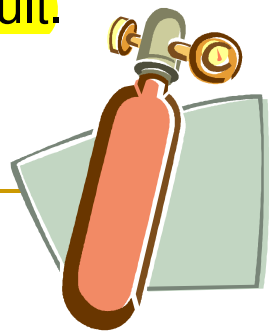
- **Required conditions for survival:** temperature, energy, waste disposal, liquid, pH, ionic concentration, etc.
- **Stress:** A cell is exposed to stress when required conditions to live are not correct (changed out of narrow band of conditions). Example, change in temperature, pH, light, physical stress, mental stress, anxiety, etc. Every stress has a response from cell or organism if it wants to survive.
- **Action:** Reaction to stimulus.



Required Conditions

- The optimum chemical composition for living cells may require such conditions as concentration of:
  - Gases (getting rid of CO_2, obtaining O_2)
  - Nutrients
  - Ions
  - Water
- Optimum temperature.
- Optimum pressure. Example: Astronauts in no gravity where stroke volume is reduced by 15%.
- Means of communication: needs sensors, transmitters, receivers, signal to control centre. Energy is required in order to sense variations in conditions.
- Optimum pH.
- If one or more of the above is not correct, then ill health may result.





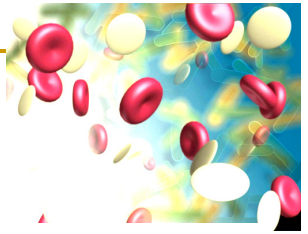
Stress

- Stress is any stimulus that creates an imbalance (change) in the internal or external environment.
- Stress may be in the form of external (heat, cold, noise, lack of oxygen, infection, etc).
- Stress may also arise from within the body in the form of high blood pressure, pain, tumours, unpleasant thoughts, or creation of hormones (as a reaction to physiologic stress).
- Transfer of energy becomes a physical thing (e.g., bad thoughts create an increase in heart rate, good thoughts a decrease in heart rate - so have good thoughts).
- Finally, stress may be from external sources, such as infection, poisoning and surgical operations.

Homeostasis

- Homeostasis is derived from homeo meaning “same” and stasis meaning ”stand still”.
- Homeostasis is the condition in which the body’s internal environment remains relatively constant allowing the body cells to survive.
- It is the regulating function of the internal part of the body and is a condition required for survival.
- There are mechanics that oppose the forces of stress and bring the internal environment back into balance.
  - Adaptation is one of the main features of all organisms. Some people have no problem at 49°C (120°F) temperature and others could work outside in sub-zero temperatures.
  - Everyone’s internal temperature must remain about 37°C (90°F). Permanent damage can occur at greater than 45°C. At high and low temperature or at high elevations (low oxygen) what happens and how does the body cope with such environmental extremes?
- It is the mechanism of maintaining equilibrium and an optimal medium for living tissues that is called homeostasis.
- Every part of the body, from the cellular level to the system level, contributes in some way to keeping the internal environment within normal limits.

Example: the Circulatory System



The homeostatic function of the circulation system of the body is to keep the fluids of all parts of the body constantly moving (blood).

- ✓ Blood moves within the tubes of the body by pressure differences. If there is no differential pressure there is no movement of blood.
- ✓ Blood pressure is exerted by the heart.
- ✓ The pressure is the force exerted by blood as it presses against an attempt to stretch the walls of the blood vessels.
- ✓ The pressure is mainly determined by three factors:
  - ➢ The rate of strength of the heart beat.
  - ➢ The amount of blood.
  - ➢ The resistance offered by the vessels.
- ✓ Stress (internal or external) causes the heartbeat to speed up.
- ✓ Once the heartbeat speeds up, the following sequences occur:
- ✓ The increased heartbeat pushes more blood into the vessels (arteries) per minute. Increasing blood within the arteries creates more pressure. The higher pressure is detected by pressure sensors (nerve cells in the walls of certain blood vessels which send nerve impulses to the brain). The increase in blood pressure is sensed and a message is sent to the brain that the pressure is high. The brain interprets the message and responds by sending impulses to the heart to slow the heart rate. Slowing the heart rate decreases the blood volume and decreasing the blood volume decreases the blood pressure. This continual monitoring of blood pressure by the nervous system is an attempt to maintain a normal blood pressure and is called a feedback system.

Summary

- Medical Devices area is a broad field requiring cross disciplinary knowledge and offering many opportunities.
- Medical devices is any instrument, apparatus, appliance, equipment, etc. used in the prevention, diagnosis, treatment, rehabilitation, and/or knowledge generation of disease. Healthcare delivery would not be possible without medical devices.
- Physiology is the study of the function of the body. Anatomy is the study of its structure.
- Life can be defined as the ability to harness energy, perform work, react to the environment and reproduce.
- Homeostasis is the self-regulating process by which the body tends to maintain stability while adjusting to external conditions.