

INTRODUCTION TO MEDICAL DEVICES

Lecture Notes

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BIOMEDICAL INSTRUMENTATION

Involves the following disciplines;

- Systems Theory
- Circuit Theory
- Control Theory
- Signal Processing
- Statistical Analysis
- Digital and Analog Systems Design
- Systems Programming

CLASSIFICATION of BIOMEDICAL INSTRUMENTS

- 1 - Based on quantity that is measured i.e. pressure, flow, temperature etc.
- 2 - Based on transduction principle i.e. resistive, capacitive, electrochemical, ultrasonic, etc.
- 3 - Based on the organ system i.e. cardiovascular, pulmonary, nervous etc.
- 4 - Based on speciality i.e. pediatrics, obstetrics, cardiology, radiology etc.

Worldwide the medical instrumentation and device industry is worth more than 100 billion US dollars annually.

Market Share	Country
49%	US
13%	Japan
12%	Germany
26%	Others

Regulation of Medical Devices

The medical instrumentation industry are required to be most regulated industries. Adequate measures need to be evolved so that the users of medical equipment are not subject to legal, moral and ethical issues in their practice which could be as vital as the question of life and death.

- **Regulations:** A regulation is an organization's way of specifying that some particular standard must be adhered to. These are rules normally promulgated by the government.
- **Standards:** A standard is a multi-party agreement for establishment of an arbitrary criterion for reference. It is a prescribed set of rules, conditions or requirements concerned with the definition of terms, classification of components, delineation of procedures, specifications of materials, performance, design or operations, measurement of quality and quality in describing materials, products, systems, services or practice.

- **Codes:** A system of principles or regulations or a systematized body of law or an accumulation of a system of regulations and standards. The most familiar code in USA is the National Electric Code issued by National Fire Protection Association (NFPA).
- **Specifications:** Documents used to control the procurement of equipment by laying down the performance and other associated criteria. These documents usually cover design criteria, system performance, materials and technical data.

Types of Standards

- **Voluntary Standards:** Developed through a consensus process where manufacturers, users, consumers and government agencies participate. They carry no inherent power of enforcement but provide a reference point of mutual understanding.
- **Mandatory Standards:** Required to be followed under law. They are incumbent on those to whom the standard is addressed and enforceable by the authority having jurisdiction.
- **Proprietary Standards:** Developed either by a manufacturer for its own internal use or by a trade association for use by its members. They can be adopted as voluntary or mandatory standards with the consensus/approval of the concerned agencies.

Regulatory Requirements

According to FDA, *Medical Device* means “any item promoted for a medical purpose that does not rely on chemical action to achieve its intended effect” .

■ Class I

General Controls: A device for which the controls authorized by law are sufficient to provide reasonable assurance of the safety and effectiveness of the device. Manufacturers are required to perform registration, pre-marketing notification, record keeping, labeling, reporting of adverse experiences and good manufacturing practices.

■ **Class II**

Performance Standards: Apply to devices for which general controls alone do not provide reasonable assurance of safety and efficacy, and for which existing information is sufficient to establish a performance standard that provides this assurance. However, until performance standards are developed by regulation, only general controls apply.

■ **Class III**

Pre-market Approval: Apply to devices which are used to support or sustain human life or to prevent impairment of human health, devices implanted in the body and devices which present a potentially unreasonable risk of illness or injury. These are highly regulated devices and require manufacturers to prove their safety and effectiveness prior to their market release.

Device Classification: Upper Tier

Medical specialty	Regulation citation	Medical specialty	Regulation citation
Anaesthesiology	Part 868	Microbiology	Part 866
Cardiovascular	Part 870	Neurology	Part 882
Chemistry	Part 862	Obstetrical and gynaecological	Part 884
Dental	Part 872	Ophthalmic	Part 886
Ear, nose and throat	Part 874	Orthopaedic	Part 888
Gastroenterology and urology	Part 876	Pathology	Part 864
General and plastic surgery	Part 878	Physical medicine	Part 890
General hospital	Part 880	Radiology	Part 892
Haematology	Part 864	Toxicology	Part 862
Immunology	Part 866		

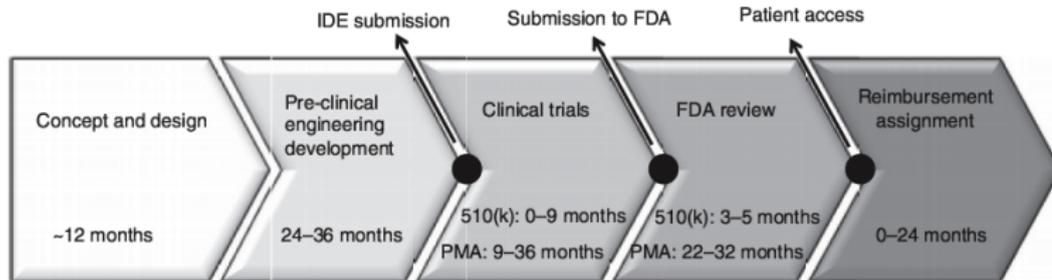
Device Classification: Lower Tier

Device	Section	Device	Section
Arrhythmia detector and alarm (including ST-segment measurement and alarm)	870.1025	Catheter guide wire	870.1330
Blood pressure alarm	870.1100	Catheter introducer	870.1340
Blood pressure computer	870.1110	Catheter balloon repair kit	870.1350
Blood pressure cuff	870.1120	Trace microsphere	870.1360
Non-invasive blood pressure measurement system	870.1130	Catheter tip occluder	870.1370
Venous blood pressure manometer	870.1140	Catheter stylet	870.1380
Diagnostic intravascular catheter	870.1200	Trocar	870.1390
Continuous flush catheter	870.1210	Programmable diagnostic computer	870.1425
Electrode recording catheter or electrode recording probe	870.1220	Single-function, preprogrammed diagnostic computer	870.1435
Fibreoptic oximeter catheter	870.1230	Densitometer	870.1450
Flow-directed catheter	870.1240	Angiographic injector and syringe	870.1650
Percutaneous catheter	870.1250	Indicator injector	870.1660
Intracavitary phonocatheter system	870.1270	Syringe actuator for an injector	870.1670
Steerable catheter	870.1280	External programmable pacemaker pulse generator	870.1750
Steerable catheter control system	870.1290	Withdrawal-infusion pump	870.1800
Catheter cannula	870.1300	Stethoscope	870.1875
Vessel dilator for percutaneous catheterization	870.1310	Thermodilution probe	870.1915

Sec. 870.1130 Non-invasive blood pressure measurement system.

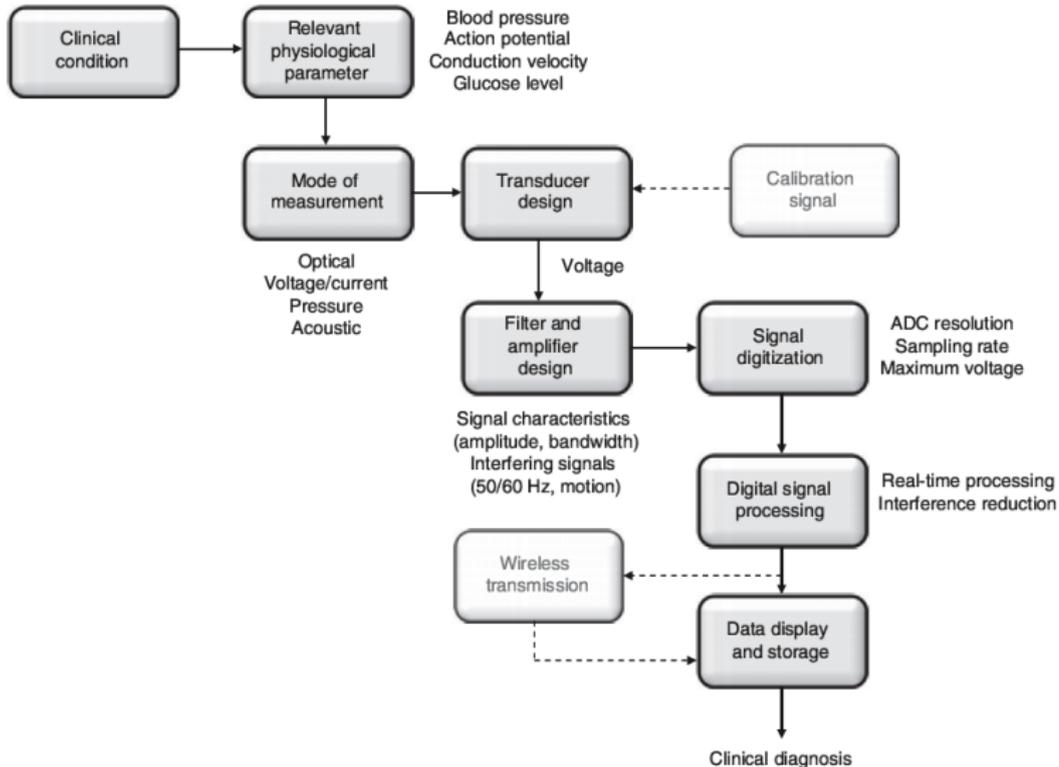
- (a) Identification. A non-invasive blood pressure measurement system is a device that provides a signal from which systolic, diastolic, mean, or any combination of the three pressures can be derived through the use of transducers placed on the surface of the body.
- (b) Classification. Class II (performance standards).

Design process from concept to clinical device



First define the problem and goal and then design the solution in accordance with the anatomy and disease pathophysiology.

A general biomedical instrumentation system.



Design criteria for the electrocardiograph.

Physiological metric	Cardiac action potential (voltage)
Indirect measurement device	Electrode (placed on the skin)
Mode of action	Converts ionic current into a voltage
Size of detected signal	1–10 mV
Frequency of detected signal	1–50 Hz
Interfering signals	Electrode half-cell potential; coupling to power lines; breathing; muscle motion; blood flow
Size of interfering signals	1.5 V (power lines); 300 mV (half-cell potential); ~mV (muscle motion)
Frequency of interfering signals	50/60 Hz (power lines); DC (half-cell potential); ~10–50 Hz (muscle motion); ~0.5 Hz (breathing)
Required time resolution	One measurement every 200 ms
Required accuracy	± 1 mV
Required dynamic range	0–100 mV

US Model

Regulatory bodies as FDA and EC follow international standards as ISO, IEC, ANSI, CEN etc.

- Class I devices do not need to undergo clinical trials or biocompatibility test.
- Class II devices must be shown to be equivalent to an existing design in the market so that they can receive market clearance via a process called *premarket notification* or 510(k). Equivalence can be achieved by bench and animal tests without need for human trials.
- Class III devices require pre-market approval (PMA) since they have the highest potential risk to patients or have a significantly different technology than those already exist in the field.
- Investigational device exemption (IDE) process allows a device to officially start clinical trials before it is clinically approved. IDE does not allow a company to market the device but to carry out the process.



European Model

- EU has 3 directives:
 - 1 implantable devices are regulated under directive 90/385/EC.
 - 2 most other devices are regulated under directive 93/42/EC.
 - 3 in vitro diagnostic devices (i.e. used on substances produced by the body) are regulated under 98/79/EC.

Every marketed medical device must carry a Conformance Européenne (CE).

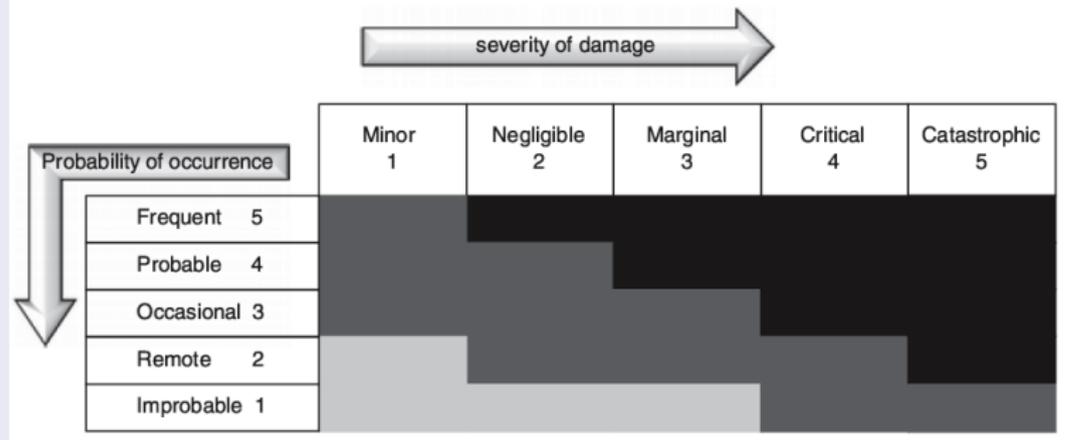
- One fundamental difference between the regulatory systems in the US and EU is that before its approval, a medical device in the US must be shown to be efficacious as well as safe.
- In contrast, in EU, it only needs to demonstrate safety and performance, *i.e.* it is not required to demonstrate clinical efficacy as long as its potential benefits outweigh potential risks and it performs as designed.



Safety of a biomedical instrument or device

- Hardware (2 independent failures should not harm the patient)
- Software (chances of harm arising from inevitable bugs to be kept acceptably low)
- User-interface (a mobile app that controls a glucose monitor, and stores and transmits the data wirelessly is subject to exactly the same regulations as the glucose monitor itself. Mobile technology is classified as I, II or III in the same way as physical medical devices.)

ISO 14971 standard for product risk management.



This International Standard specifies a process through which the manufacturer can identify hazards associated with a medical device, estimate and evaluate the risks associated with these hazards, control these risks, and monitor the effectiveness of that control.

Hardware: Main standard for medical device safety : IEC 60601-1 The Medical Electrical Equipment-Part 1:

One of the fundamental principles of IEC 60601-1 is that a medical device must be safe in the case of a single fault.

- Therefore the starting point for designing the hardware is to have a back-up for every possible *first-line* failure.
- As this safety system has its own possibility of failure, so the next design stage is to perform a risk assessment to determine whether a back-up to the back-up is necessary.

A second fundamental requirement of IEC 60601-1 is that a combination of two independent failures should not be life threatening. If the first failure is obvious to the operator, he/she can stop the equipment immediately.

However, if the first failure is not immediately obvious or cannot be detected, the equipment must be designed so that a combination of the first and second failures cannot cause a hazard.

Software and User Interfaces : IEC 62304

Medical device software-software life cycle processes

IEC 62304 uses the risk management process outlined in ISO 14971, with additions related to hazards such as incorrect information provided by the software resulting in an inappropriate treatment being prescribed.

The primary principle behind software verification is to describe the exact function the software is supposed to perform, and then to devise a very specific test to verify that the software works as designed.

A software risk model defines three different levels of safety.

- Level A software is not harmful if it fails and requires a system test.
- Level B is an intermediate level and requires checks of the individual software modules.
- Level C software can injure or kill someone and requires tests for each subset of software code at the unit level.

Major recommendations are available in IEC 62366 Annex D 1.4 for user interfaces whose standards are simpler than for hardware or software.



FDA Medical Device Categories

Category	Class	Examples
Preamendment (old) Postamendment (new) Substantially equivalent	I,II, or III III same class as their old counterparts	Analog ECG, automated blood-cell separator MRI, ESW lithotripter, YAG-laser Digital ECG, ELISA diagnostic kits
Implanted Custom	III exempt from testing and standards but are subject to controls	Phrenic-nerve stimulator, cardiac pacemaker Dentures, ortopedic shoes
Investigational Transitional	exempt if IDE is granted III	Artificial heart, angioplasty devices Antibiotic susceptibility disks, injectable silicone

New EC Directives

- (EC)2017/745 MDR (Medical Device Regulations)
effective by 26.05.2020
- (EC) 2017/746 IVDR (*in vitro* Medical Device Regulations)
effective by 26.05.2022

Design Criteria and Process

