Minireview Article

FUNDAMENTALS OF BIOMEDICAL INSTRUMENTATION (BMI): PRINCIPLES AND APPLICATION

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ABSTRACT

Biomedical instrumentation is a cornerstone of modern healthcare, combining engineering, medicine and research to enhance diagnosis, monitoring, and treatment. This paper review aims to educate and inspire new researchers and professionals in this interdisciplinary field. It explores the foundational concepts of biomedical devices, with emphasis on measurements, sensors, and signal processing. Key components such as transducers, electrodes, and amplifiers are discussed alongside the classification and application of instruments in clinical settings. Despite their benefits, challenges like electrical safety and rapid technological change remain. We highlight innovations like wearable devices and telemedicine, which promise to advance healthcare delivery. Biomedical instrumentation enhances healthcare through precise diagnoses and therapies, with advancements like wearable technology and telemedicine improving accessibility. Fostering multidisciplinary cooperation and research will lead to customized, efficient treatments.

Keywords: Biomedical instrumentation, Biomedical signal, Instrumentation principles, Biosensor, Medical devices

1. INTRODUCTION

Biomedical instrumentation is an important field that specializes in utilizing principles from engineering, physics and biology in developing devices and instruments for diagnosing, monitoring, and treating medical conditions. With advances in the healthcare industry, the need for more precise and efficient biomedical instruments has increased evidently [1].
The early usage of simple instruments like thermometers and stethoscopes, gave rise for the groundwork for later diagnostic tools. Advanced medical diagnostics and patient care have been transformed by the development of sophisticated technologies like electrocardiograms (ECGs), magnetic resonance imaging (MRI), and ultrasound. These technologies allow healthcare providers to gain comprehensive understanding of the physiological and pathological states of the human body [2].

Improving patient outcomes through precise, real-time data that supports clinical decision-making is one of the main goals of biomedical instrumentation. This calls for the combination of several fields, such as data analysis, electronics, signal processing, and materials science, to create devices that are not only accurate and dependable but also affordable and easy to use [3]. The interdisciplinary nature of this field encourages collaboration between engineers, clinicians, and researchers to address complex medical challenges and improve healthcare delivery [4].

The development of wearable and portable devices has been the focus of recent advances in biomedical equipment. These devices offer the possibility of continuous monitoring of physiological indicators outside of traditional healthcare settings [5]. These innovations are particularly employed in managing chronic conditions such as diabetes and cardiovascular diseases, where continuous monitoring will aid better disease management and improved quality of life for patients [6].

Besides diagnostics, biomedical instruments are crucial for therapeutic uses, including implantable devices like pacemakers and insulin pumps, which offer life-saving solutions for chronic diseases. The use of wireless communication and the Internet of Things (IoT) has enhanced these devices, allowing for remote monitoring and personalized medicine [7].

Despite significant advancements in biomedical instrumentation, challenges persist. These include ensuring device safety and efficacy, addressing ethical issues related to patient privacy and data security, and navigating the regulatory landscape for medical device development and approval [8]. Overcoming these challenges demands continuous research, innovation, and collaboration among healthcare stakeholders.

2. FUNDAMENTAL PRINCIPLES OF BIOMEDICAL INSTRUMENTATION

In this section, we will explore key concepts of Biomedical instrumentation and some of the key elements in the instrumentation. The human body generates various physiological signals that physicians interpret to assess patient health. These signals are typically monitored using an electronic device connected to the patient [9]. Some of the key concepts about Biomedical Instrumentation are explained as follows.

2.1 Concepts of Biomedical Instrumentation

2.1.1 Measurands

This is the physical amount, quality, or condition that the system assesses. The accessibility of the measurand is critical since some of them may be internal (blood pressure) or external (electrocardiogram potential). It can come from the body (infrared radiation) or from a tissue sample (such as blood or a biopsy) that has been taken out of the body. The most important medical measurements include biopotential, pressure, flow, dimensions (imaging), displacement (velocity, acceleration, and force), impedance, temperature, and chemical concentrations. These measures might be exclusive to a single organ or anatomical structure [9].

2.1.2 Sensor

Sensors, often referred to as transducers (the distinction is not crucial here), convert a patient's energy, such as pressure, into a form usable by an instrument [8]. Sensors are grouped into two; the first group are those sensors whose output changes in response to alterations in their surroundings, typically resulting in a change in resistance, capacitance, or inductance [10]. Examples include strain gauge, thermistors, potentiometers. The second group includes sensors that produce voltage or current in response to a change in their surroundings. Examples include thermocouples, piezoelectric crystals and linear variable differential transformers [5].

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2.1.3 Signal

The human body produces a vast range of electrical and other signals, which provide significant information to the medical community. These signals can be categorized into three types: periodic, static, and random [8]. Periodic signals are sometimes called repetitive signals. They are symmetric and repetitive. An example is the signal in an ECG very predictable [6]. Static signals are regular and unchanging, or they change very slowly. An example is Temperature it is often static or changes slowly [9]. Random signals appear to lack a pattern, although some, like EEGs, may share common characteristics. They might have similar frequencies but exhibit unpredictable waveforms.

2.1.4 Wave and Wavelets

A wave is commonly characterized as an oscillating function of time or space, such as a sinusoid. Fourier analysis, which includes converting signals or functions into sinusoids (or complex exponentials), is a valuable tool in mathematics, science, and engineering. It is especially effective when studying periodic, time-invariant, or stationary events [9]. A wavelet is a tiny wave with concentrated energy across time, making it useful for evaluating transitory, nonstationary, or time-varying events. It keeps the oscillatory wave-like features while allowing for simultaneous time and frequency analysis using a flexible mathematical framework [11].

2.1.5 Resonance

Resonance is typically described as a phenomenon where a dynamic system's response is significantly amplified when subjected to an external influence $f = fo\ cos\ cos(wt)$, with the frequency(ω) of the external influence being close to the system's natural frequency(ω0) [10].

2.1.6 Display

This is used to visually depict the measured parameter or amount. Chart recorders and cathode ray oscilloscopes (CRO) are two examples. Alarms can also be used to generate audible signals, such as Doppler Ultrasound Scanners for fetal monitoring [12].

2.1.7 Storage and Transmission of Data

Storage of data is required to keep data for further use, with Electronic Health Records commonly used in hospitals today. Data transmission is utilized in telemetric systems, allowing data to be sent remotely from one location to another [12].

2.2 Generalized Characteristics of Biomedical Instrumentation

To allow buyers to compare commercial instruments and assess new designs, quantitative performance criteria are required. This basis should distinctly define the accuracy of an instrument measuring the intended input and how much its output is affected by changing or tampering with the inputs [8]. Instrument performance attributes are typically divided into two categories depending on the frequency of the incoming signals.

2.2.1 Static Characteristics

Static characteristics describe how instruments perform with direct current or inputs with low frequencies [8]. These characteristics reveal the accuracy of measurement over a wide range of constant inputs, including nonlinear and statistical effects. Some sensors and instruments, like piezoelectric devices, respond only to time-varying inputs, so they are lacking static characteristics. [7]. Some of the quantities used in carrying out static characterization are described below.

2.2.1.1 Accuracy

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A system's accuracy can be defined as the degree to which the measured value is to the true value [13]. A perfectly accurate system is a theoretical ideal, whereas the accuracy of a real system is determined using the measurement error of the system E.

$$E = measuredvalue - truevalue$$
$$E = systemoutput - systeminput$$

2.2.1.2 Precision

The precision of measurement indicates the number of distinct options among which a given result is chosen.

2.2.1.3 Resolution

This refers to the smallest increment in a quantity that can be measured with certainty. When the measured quantity starts from zero, the term threshold can be used interchangeably with resolution. Resolution indicates how well nearly identical values of a quantity can be distinguished.

2.2.1.4 StatisticalControl

An instrument's accuracy is only significant when all factors, including the environment and the usage method, are taken into account. Statistical control helps ensure that random variations in measurements, caused by all factors affecting the measurement process, are kept within acceptable limits [8]. While systematic errors or biases can be corrected through calibration and correction factors, random variations present a greater challenge. The measurand and/or the instrument might introduce variations that make output unreproducible [11].

2.2.1.5 Input Impedance

Due to biomedical sensors and instruments usually turn nonelectric quantities into voltage or current, this has brought about input impedance [8]. This is required so that we can accurately assess the extent to which instruments disturb the quantity being measured. For each needed input Xd1 that we want to measure, there is an inherent input quantity Xd2 such that the product of Xd1 Xd2 has power dimensions. The value represents the instantaneous rate at which energy flows across the tissue-sensor interface. The general input impedance, Zx, is determined by division of the phasor equivalent of a steady-state sinusoidal effort input variable (voltage, force, pressure) by the phasor equivalent of a steady-state sinusoidal flow input variable (current, velocity, flow) [7].

$$Z_x = \frac{Xd1}{X_{d2}} = \frac{effortvariable}{flowvariable}$$

2.2.2 Dynamic Characteristics

Few medical measurements, like body temperature, remain constant or change slowly. Most medical instruments deal with signals that vary over time. This time-varying nature of medical signals necessitates consideration of dynamic instrument characteristics [9]. Differential or integral equations are used in continuous systems to link dynamic inputs and outputs. Fortunately, many engineering instruments can be described using ordinary linear differential equations with constant coefficients. The following equation describes the relationship between the input and output:

$$a_n \frac{d^n y}{dt^n} + \cdots + a_1 \frac{dy}{dt} + a_0 y(t) = b_m \frac{d^m x}{dt^m} + \cdots + b_1 \frac{dx}{dt} + b_0 x(t)$$

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Where the constants $a_i(i = 0,1,\ldots\ldots,n) and b_j(j = 0,1,\ldots.m)$ depends on the physical and electric parameters of the system.

2.2.2.1 Transfer functions

The transfer function of a linear instrument or system mathematically describes the relationship between the input and output signals. If the transfer function is known, the output can be predicted for any given input. The operational transfer function is expressed as the ratio y(D)/x(D) in terms of the differential operator D [9].

$$\frac{y(D)}{x(D)} = \frac{b_m D^m = \cdots . + b_1 D + b_0}{a_n D^n + \cdots . + a_1 D + a_0}$$

This form of the transfer function is particularly useful for transient inputs. For linear systems, the output for transient inputs, which occur only once and do not repeat, is usually expressed directly as a function of time, y(t), which is the solution.

The frequency transfer function for a linear system is gotten by substituting   for D in the above equation. This gives:

$$\frac{y(jw)}{x(jw)} = \frac{b_m (jw)^m = \cdots . + b_1 (jw) + b_0}{a_n (jw)^n + \cdots . + a_1 (jw) + a_0}$$

Where $j = +\sqrt{-1} and w$is the angular frequency in radians per second. The input is usually denoted as $x(t) = Asin\,(wt)$ and all transients are taken to have died out.

The dynamic characteristics of instruments can be defined using the basic order functions. These orders are zero order, first order and the second order. Depending on the order that satisfactorily defines the dynamics of the system the general dynamics equation is reduced.

2.3 Core Elements of Biomedical Instrumentation

Some of the important elements that does the defining work in most biomedical instruments are discussed below;

2.3.1 Transducer

A transducer is an instrument that transforms energy from one form to another. Mechanical, electrical, optical, magnetic, and thermal energy are among the most typical [14]. Transducers are typically divided into two types: sensors, which monitor a system, and actuators, which apply conditions to a system. Sensors and actuators include all transducers, which means that any transducer in use at any given time can function as both a sensor or an actuator. Reversible transducers are those that can switch between acting as sensors and actuators but not both at the same time. A typical example is a loudspeaker (an actuator) that can detect diaphragm movements. Another example is an accelerometer, typically used to sense vibrations, which can also function as a shaker [15].

2.3.2 Electrodes

Electrodes are instruments that convert ionic potentials to electric potentials. The location of the bioelectric event to be measured will determine the type of electrode to be used for that measurement [12]. A transducer is made up of two electrodes which measures the ionic difference between them [10].

2.3.3 Magnetic Sensors

sensors that are magnetic generally work on the same principle: detecting alterations to the magnetic moment of a magnetic material (usually ferromagnetic) as it is exposed to a magnetic field, a temperature change, or, for magnetoelastic materials, mechanical stress

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from the surrounding environment [15]. By measuring these variations, it is possible to analyze the changes occurring around the sensor [13].

2.3.4 Amplifiers

Operational amplifiers, commonly known as op-amps, in biomedical applications, these devices amplify tiny voltages. They are composed of networks of transistors and are considered active devices because they need a voltage comparable to DC to working [12]. Amplifier factor of an op-amp, known as gain, is typically defined by the gain-bandwidth product (GBWP), which is the product of the amplifier's bandwidth and its gain within that bandwidth. For instance, if an op-amp has a GBWP of 1 MHz, it can operate with a unit gain up to 1 MHz without significant signal distortion. However, if the op-amp is used in a circuit with a gain of 10, it will only perform efficiently up to a frequency of 100 kHz [12].

2.3.5 Thermocouple

A thermocouple is a sensor that measures temperature. It is made up of two distinct metal wires coupled at one end and connected to a thermocouple thermometer or similar device that can read thermocouples at the other end [12]. When properly set, thermocouples can monitor temperatures throughout a wide range [16].

2.3.6 X-ray Tube

X-ray tubes are vital parts of any X-ray system, used to generate X-rays for various applications in medicine, technology, science, and engineering. Since its invention in 1895 [14], the technique of X-rays has been widely used for its ability to penetrate materials and reveal internal structures [17]. The X-ray tube operates by accelerating electrons at high speeds and directing them towards a target anode[16]. When these fast-moving electrons collide with the target, they suddenly decelerate and interact with the anode material, resulting in the generation of X-rays. This process requires the X-ray tube to absorb as well as dissipate a significant amount of heat to maintain adequate radiation output, especially for digital radiology [17].

3. CLASSIFICATION OF BIOMEDICAL INSTRUMENTATIONS

Biomedical equipment is classified in numerous ways based on research investigations. Some classify them into two broad categories, which include [18]: Instrumentation for both clinical and research purposes.

Clinical instrumentation is primarily used to diagnose, care for, and treat patients, and includes ECG (electrocardiogram), MRI (magnetic resonance imaging), ultrasound machines, infusion pumps, patient monitors, and so on. In contrast, research instruments such as flow cytometers, spectrophotometers, PCR (polymerase chain reaction) machines, microscopes, autoclaves, and so on are largely used to discover new information about the numerous systems that make up an organism.

However, these instruments are still classed based on their domains of operation [7]. They are:

- A pressure meter, pH meter, a flow meter, and a cell counter are some examples of blood instruments.
- ECG, pacemaker, defibrillator, heart-lung machine, bedside monitor, and other cardiac devices.
- Brain tools include the EEG and tomograph.
- Muscle devices include EMG and muscle stimulators.
- Kidney instruments, including dialysis and lithotripsy machines.
- Ear devices include an audiometer and hearing aids.
- Eye instruments include an oculometer and blindness aides.
- The lung instrument contains a spirometer.

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Some classifications are also dependent on their purposes [20]. They are:

- Analyzers (chemistry and blood gas), electrolyte analyzers, and other medical laboratory equipment.
- Heart-lung devices, hemodialysis devices, and incubators are examples of life support equipment.
- Therapeutic machines include infusion pumps, medical lasers, and surgical machines.
- Long-lasting medical devices, such as insulin pumps and kidney machines.

Some of the instruments mentioned above have been known to be used in a variety of ways rather than for a single function. For example, the magnetic resonance imaging machine (MRI) is used to image the brain, bones, and other body organs.

Other classifications of biomedical instruments include [21]:

i. Based on their sensors (quantity sensed) such as temperature, pressure, and flow.

ii. Based on their transducers such as resistance, induction, and capacitance.

iii. Electrical hazards and dangers classifications include:

- Class I
- Class II
- Class III
- B Type applied part
- BF Type applied part
- CF Type applied part
- Defibrillator proof CF Type applied part

IEC (the International Electrotechnical Commission) classifies appliances into classes I, II, and III according to how they are protected against shock by insulation, with class I being protected earth or earthen [20]. Class II is defined as having at least two insulation wires and one basic layer of insulation, often known as a supplementing layer; examples include cardiac monitors [22]. Class III instruments do not require any protection from input voltage; however, they must be insulated with two layers of protection. Pacemakers and automatic external defibrillators are some examples [23].

The class instruments are defined using IEC rules, whereas the type instruments are classified using IEC 60601 (Safety and vital functionality of medical electrical devices, ensuring devices are safe to use in healthcare environments). It classifies medical devices based on variables such as electrical shock, mechanical risks, and critical performance requirements [24].

The BF type instrument has the same maximum leakage as the B type; however, it is an isolated instrument with conductive contact to the user's skin (blood pressure machines); the CF type instrument has the strictest requirements for instance dialysis equipment have direct contact with the heart and a maximum leakage current of 10 μA [25]. The B type device has a maximum voltage leakage of 100μA and cannot connect directly to the heart.

4. APPLICATIONS OF BIOMEDICAL INSTRUMENTATION

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Biomedical instruments are integral to numerous aspects of healthcare, from clinical diagnostics to patient monitoring and therapeutic interventions.

4.1 Clinical Diagnostics

Diagnostic instruments provide critical data that aid in the early detection and diagnosis of diseases. For example, imaging modalities like MRI and CT scans offer detailed views of internal structures, facilitating the identification of tumors, fractures, and other abnormalities [25].

4.2 Patient Monitoring

Persistent observation of vital indicators such as blood pressure, pulse, and saturation levels of oxygen is required in critical care settings. Devices such as Electrocardiogram monitors and oximeters that give real-time data, allowing doctors to make fast and informed choices [26].

4.3 Therapeutic Interventions

Therapeutic instruments such as defibrillators and insulin pumps play a vital role in managing chronic conditions and acute medical emergencies. Defibrillators can restore normal heart rhythms in cases of cardiac arrest, while insulin pumps provide precise doses of insulin to diabetic patients, improving glycemic control [26].

4.4 Research and Development

Biomedical instrumentation is also pivotal in research settings, where it facilitates the study of physiological processes and the development of new medical technologies. Advanced instruments enable researchers to explore new diagnostic and therapeutic techniques, driving innovation in healthcare [27].

4.5 Technological Advances in Biomedical Instrumentation

Recent advancements in technology have significantly impacted the field of biomedical instrumentation, leading to the development of more sophisticated and user-friendly devices.

4.6 Wearable Instruments

Wearable technology such as health trackers and smartwatches, are growing in popularity. These devices continuously monitor various health parameters, providing users with real-time feedback and enabling remote patient monitoring. Advances in sensor technology and miniaturization have enhanced the accuracy and comfort of wearable devices [26].

4.7 Telemedicine

Telemedicine leverages biomedical instruments and information technology to deliver healthcare services remotely. Devices like digital stethoscopes and portable ultrasound machines facilitate remote consultations and diagnostics, making healthcare more accessible, especially in underserved areas [25].

4.8 Integration with Information Technology

The integration of biomedical instruments with IT systems has led to the development of sophisticated healthcare solutions. Electronic Health Records (EHRs) and Health Information Systems (HIS) enhance the efficiency of healthcare delivery and improve patient outcomes by providing comprehensive and easily accessible patient data [27].

5. Challenges and Limitations of Biomedical Instrumentation

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Some of the major challenges and limitations of biomedical instrumentation will be highlighted here. Just like every other field, biomedical instruments are faced with some challenges, some of these challenges are peculiar to biomedical instrumentation while other affects other fields of new technological advancement. The challenges are discussed as follows:

5.1 Electrical Accident

Electrical shock injuries can happen in any setting, but the risk is higher in hospitals due to the direct contact between patients or caregivers and the equipment. Additionally, a single patient may be associated with numerous devices [6]. The impact of electrical currents on the human body and tissues can vary from a mild tingling sensation to severe tissue burns and heart fibrillation, which can be fatal. The predominant cause of this accident is the leakage of electrical currents unwanted current from electrical devices.

5.2 Biomedical Signal Acquisition and Processing

Biomedical signals typically have very low amplitudes, ranging from a few microvolts to a few millivolts. If not managed properly, these signals can easily be contaminated by noise or artifacts. The presence of noise in biomedical signals can significantly impact them and obscure important information [28].

5.3 Regulations

The Medical Device Amendments, enacted in 1976 and 1990, aimed to ensure the safety and effectiveness of new medical devices before they were marketed.

5.4Cost

The cost of the parts of biomedical instruments for construction is quite expensive, the same goes for the biomedical instruments themselves. However good biomedical instrumentation is not readily available for third world countries and some developing countries.

5.5FastTechnologicalDynamics

Rapid technological advancements present a challenge in the medical device industry, as devices can quickly become outdated, requiring frequent updates and improvements. Companies must find a way to innovate while maintaining stability and reliability in healthcare settings, ensuring that new technologies are implemented without compromising patient safety or care quality.

6. INNOVATIONS AND TRENDS IN BIOMEDICAL INSTRUMENTATIONS

Many instruments have come and gone over time, and many have been upgraded from their bulky, sluggish, or hazardous original forms to newer ones that are more efficient, safer, faster, and produce better results. NASA built some of the earliest biological tools to monitor their astronauts' ECG, respiration, and temperature before introducing blood pressure measuring [29], which allowed physicists to monitor their astronauts' vital signs.

With advancements, for example, from old external pacemakers that limited mobility to the first fully implantable pacemaker in 1958, which could only support the patient's life for three hours [30], it had to be replaced by the next, the Greatbatch Pacemaker, which used mercury-based battery technology in the 1960s and lasted 18 months [31].

Over time, we've developed modern pacemakers that can be installed using minimally invasive techniques, as compared to older ones that required open thoracotomy operations. First-generation pacemakers could only offer asynchronous pacing, however contemporary pacemakers can provide synchronized and/or upon request (VVI/DDD) pacing [29].

Implantable electronic pacemaker technology has matured, and we now have an array of highly sophisticated devices capable of providing reliable pacing to a wide range of patient

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groups [31]. This is true not only for the pacemaker, but also for other medical devices that have profited from innovation. Even looking back a few decades, we can see

that the efficiency of MRI machines in terms of time required has substantially improved, with only 5 to 10 minutes necessary now, as opposed to over an hour in the past.

The most recent advancements in biomedical instrumentation extend beyond the conventional devices we have, such as ECG, MRI, PET scans, and ultrasound machines. We envision them completely embracing bioinstrumentation in terms of robotics and fully functional, lifelike prostheses. For example, there are bionic contact lenses, radiation therapy, nanomaterials, genome editing, transcutaneous electric nerve stimulation, and bionic exoskeletons.

Trends in biomedical equipment are constantly advancing, particularly in the fields of tissue engineering and bioprinting, which enable living tissue to be created from living biologically active cells. Which can be utilized for skin grafting or artificial organ transplantation. Other fields with rapidly changing trends include nanorobots, transdermal patches, medical virtual reality, surgical robotics, wearable medical devices, and many others.

This is a constantly growing field, with discoveries being made daily, revolutionizing the way we conduct research and treatments, and will continue to transform the way things are done, whether in medicine, life sciences, or engineering, as they become more precise and efficient, advancing humanity.

7. CONCLUSION

Biomedical instrumentation is crucial for enhancing healthcare by enabling precise diagnosis and therapies. The sector is evolving with advancements such as wearable technology and telemedicine, which improve capabilities and accessibility while addressing issues like safety, affordability, and education is essential. Biomedical instrumentation can maintain its leadership in medical innovation, patient care, and global health by fostering multidisciplinary cooperation and research. Future innovations will lead to more customized and efficient healthcare treatments and systems.

DISCLAIMER (ARTIFICIAL INTELLIGENCE)

The author(s) hereby certify that no generative artificial intelligence (AI) tools such as Scalable Language Models (ChatGPT, COPILOT, etc.) or text-to-image generators were utilized in the authoring or editing of the paper.

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