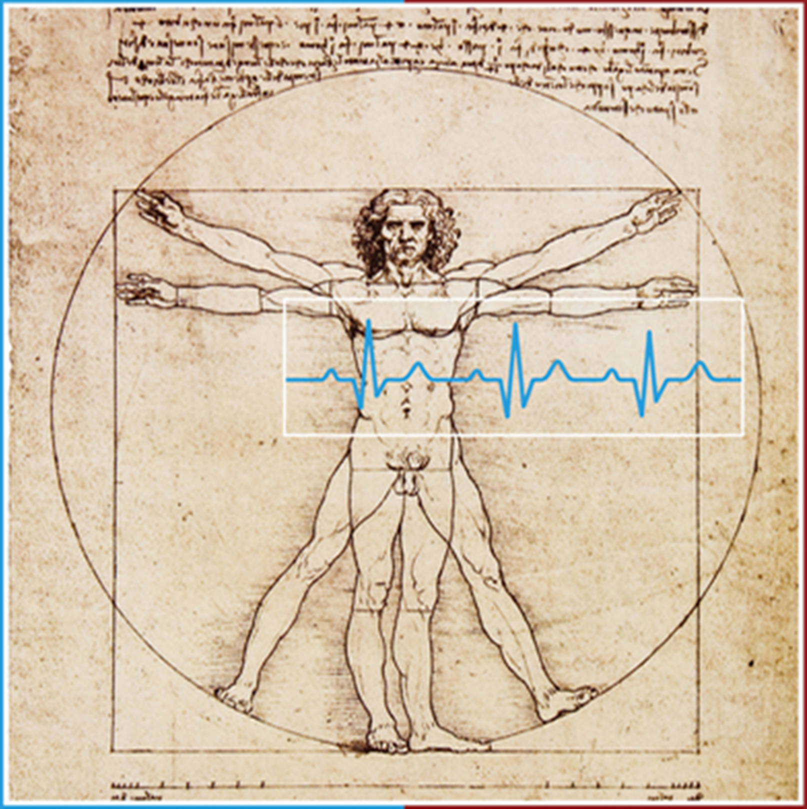
MEDICAL INSTRUMENTATION

APPLICATION AND DESIGN



EDITED BY

JOHN G. WEBSTER

AMIT J. NIMUNKAR

FIFTH EDITION

with website

WILEY

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APPLICATION AND DESIGN

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Edited by
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The authors welcome your suggestions for improvement of subsequent printings and editions.

John G. Webster
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PREFACE

Medical Instrumentation: Application and Design, Fifth Edition, is written for a senior to graduate-level course in biomedical engineering. It describes the principles, applications, and design of the medical instruments most commonly used in hospitals. Because equipment changes with time, we have stressed fundamental principles of operation and general types of equipment, avoiding detailed descriptions and photographs of specific models. Furthermore, because biomedical engineering is an interdisciplinary field, requiring good communication with health-care personnel, we have provided some applications for each type of instrument. However, to keep the book to a reasonable length, we have omitted much of the physiology.

Most of those who use this text have had an introductory course in chemistry, are familiar with mathematics through differential equations, have a strong background in physics, and have taken courses in electric circuits and electronics. However, readers without this background will gain much from the descriptive material and should find this text a valuable reference. In addition, we recommend reading background material from an inexpensive physiology text, such as W. F. Ganong's *Review of Medical Physiology*, 26th edition (New York: McGraw-Hill Education, 2019).

EMPHASIS ON DESIGN

Throughout the book, we emphasize design. A scientist or engineer who has some background in electronics and instrumentation will glean enough information, in many of the areas we address, to be able to design medical instruments. This ability should be especially valuable in those situations—so frequently encountered—where special instruments that are not commercially available are required.

PEDAGOGY

The book provides 282 problems, located at the end of each chapter, plus 127 in-text worked examples. Problems are designed to cover a wide variety of applications ranging from analysis of the waves of the electrocardiogram to circuit design of biopotential amplifiers with microcontroller implementation and identification of electric safety hazards.

REFERENCES

Rather than giving an exhaustive list of references, we have provided a list of review articles and books that can serve as a point of departure for further study on any given topic.

ORGANIZATION

Each chapter has been carefully reviewed and updated for the fifth edition, and many new problems and references are included.

Chapter 1 covers general concepts that are applicable to all instrumentation systems, including the commercial development of medical instruments, on biostatistics, and on the regulation of medical devices, and the design of amplifiers. Chapter 2 describes basic sensors, and Chapter 3 presents microcontroller implementation in medical devices. Chapters 4 through 6 deal with biopotentials, tracing the topic from the origin of biopotentials, through electrodes, to the special amplifier design required.

Chapters 7 and 8 cover the measurement of cardiovascular dynamics–pressure, sound, flow, and volume of blood. Chapter 9 presents the measurement of respiratory dynamics–pressure, flow, and concentration of gases.

Chapter 10 describes the developing field of biosensors: sensors that measure chemical concentrations within the body via catheters or implants. Chapter 11 describes that area in the hospital where the greatest number of measurements are made, the clinical laboratory. Chapter 12 starts with general concepts of medical imaging and shows their applications to x-ray techniques, magnetic resonance imaging, positron emission tomography, and Doppler ultrasonic imaging.

Chapter 13 deals with devices used in therapy, such as the pacemaker, defibrillator, cochlear prosthesis, transcutaneous electrical nerve stimulation, implantable automatic defibrillators, the total artificial heart, lithotripsy, high-frequency ventilators, infant incubators, drug infusion pumps, and anesthesia machines. Chapter 14 presents a guide both to electric safety in the hospital and to minimization of hazards.

We have used the internationally recommended SI units throughout this book. In the case of units of pressure, we have presented both the commonly used millimeters of mercury and the SI unit, the pascal. To help the reader follow the trend toward employing SI units, the Appendix provides the most common conversion factors. The Appendix also provides a number of physical constants used in the book and a list of abbreviations.

A Solutions Manual containing complete solutions to all problems is available for the instructors at www.wiley.com/go/Webster/Medical instrumentation5e

LIST OF SYMBOLS

This list gives single-letter symbols for quantities, without subscripts or modifiers. Symbols for physical constants are given in Appendix A.1, multi-letter symbols in Appendix A.4, and chemical symbols in Appendix A.5.

Symbol	**Quantity**	**Introduced in Section**
a	Absorptivity	10.3
a	Activity	5.2
a	Coefficient	1.10
$\mathbf{a}$	Lead vector	6.2
A	Absorbance	10.3
A	Area	2.2
A	Coefficient	1.10
A	Gain	1.11
A	Magnetic vector potential	4.9
A	Percent	1.9
b	Coefficient	1.10
b	Intercept	1.9
B	Coefficient	1.10
B	Percent	1.9
B	Viscous friction	1.10
$\mathbf{B}$	Magnetic flux density	8.3
c	Coefficient	7.11
c	Specific heat	8.2
c	Velocity of sound	8.4
C	Capacitance	1.10
C	Compliance	1.10
C	Concentration	8.1
C	Contrast	12.1
d	Diameter	5.9
d	Distance	4.1
d	Duration	14.2
D	d/dt	1.10

Symbol	**Quantity**	**Introduced in Section**
D	Detector responsivity	2.19
D	Diameter	5.9
D	Diffusing capacity	9.8
D	Digital signal	3.4
D	Distance	4.4
E	emf	2.10
E	Energy	2.15
E	Irradiance	2.19
E	Modulus of elasticity	1.10
f	Force	2.7
f	Frequency	1.18
F	Faraday constant	4.1
F	Filter transmission	2.19
F	Flow rate	7.3
F	Force	7.14
F	Molar fraction	9.3
g	Conductance/area	4.1
g	Gravity acceleration	7.11
G	Form factor	2.4
G	Gage factor	2.2
G	Gain	1.14
G	Transfer function	1.7
h	Height	7.11
H	Feedback gain	1.7
i	Current	1.12
I	Current	1.9
I	Intensity	12.5
j	$+\sqrt{-1}$	1.10
J	Current density	4.9
J	Number of standard deviations	12.1
k	Constant	6.8
k	Piezoelectric constant	2.7
K	Constant	1.10
K	Number	12.1
K	Sensitivity	1.10
K	Solubility product	5.3
K	Spring constant	1.10
L	Inductance	2.4
L	Inertance	7.3
L	Length	2.2
m	Average number	12.1
m	Mass	7.3
m	Slope	1.9
M	Mass	1.10

(*Continued*)

Symbol	Quantity	Introduced in Section
M	Measured values	12.2
M	Modulation	12.1
$\mathbf{M}$	Cardiac vector	6.2
n	Number	1.8
n	Refractive index	2.16
n	Valence	4.1
N	Noise equivalent bandwidth	12.3
N	Number	5.3
N	Numerical aperture	7.1
N	Turns ratio	1.23
p	Change in pressure	9.1
p	Probability	12.1
P	Permeability	4.1
P	Power	1.9
P	Pressure	7.3
P	Projection	12.7
q	Change in volume flow	9.1
q	Charge	2.7
Q	Heat content	8.2
Q	Volume flow	9.1
r	Correlation coefficient	1.8
r	Radius	7.3
r	Resistance per length	4.1
R	Range	8.4
R	Impedance	1.11
R	Ratio	10.3
R	Resistance	1.10
R	Universal gas constant	4.1
s	d/dt	1.10
s	Standard deviation	1.8
S	Modulation transfer function	12.2
S	Saturation	10.1
S	Slew rate	1.21
S	Source output	2.19
t	Thickness	5.9
t	Time	1.10
T	Temperature	2.10
T	Tensile force	7.14
T	Time	3.4
T	Transmittance	11.1
u	Velocity	4.4
u	Work function	12.5
U	Molar uptake	9.1
v	Voltage	1.11
v	Change in volume	9.1

Symbol	Quantity	Introduced in Section
V	Voltage	1.10
V	Volume	7.3
W	Radiant Power	1.12
W	Power	8.5
W	Weight	10.3
W	Weighting factor	12.7
x	Constant	10.3
x	Distance	2.6
x	Input	1.7
X	Chemical species	9.1
X	Effort variable	1.9
X	Flow variable	1.9
X	Value	1.8
y	Constant	10.3
y	Output	1.7
Y	Admittance	1.9
Y	Flow variable	1.9
Y	Value	1.8
z	Distance	4.1
Z	Atomic number	12.5
Z	Impedance	1.6

Greek Letters

Symbol	Quantity	Introduced in Section
α	Polytropic constant	9.5
α	Temperature coefficient	2.11
α	Thermoelectric sensitivity	2.10
β	Material constant for thermistor	2.11
γ	Gyromagnetic ratio	12.8
Δ	Deviation	10.3
ε	Dielectric constant	2.6
ε	Emissivity	2.12
ξ	Damping ratio	1.10
η	Viscosity	1.10
θ	Angle	2.16
Λ	Logarithmic decrement	1.10
λ	Wavelength	2.12
μ	Absorption coefficient	12.7
μ	Mobility	5.2
μ	Permeability	2.4
μ	Poisson's ratio	2.2

(*Continued*)

Symbol	Quantity	Introduced in Section
υ	Frequency	2.15
ρ	Density	1.10
ρ	Mole density	9.1
ρ	Resistivity	2.2
σ	Electrical conductivity	13.4
σ	Stefan–Boltzmann constant	12.5
τ	Time constant	1.10
ϕ	Divergence	8.4
ϕ	Phase shift	1.10
Φ	Potential	4.6
ω	Frequency	1.10

1

BASIC CONCEPTS OF MEDICAL INSTRUMENTATION

Walter H. Olson and John G. Webster

The invention, prototype design, product development, clinical testing, regulatory approval, manufacturing, marketing, and sale of a new medical instrument add up to a complex, expensive, and lengthy process. Very few new ideas survive the practical requirements, human barriers, and inevitable setbacks of this arduous process. Usually there is one person who is the "champion" of a truly new medical instrument or device. This person—who is not necessarily the inventor—must have a clear vision of the final new product and exactly how it will be used. And most important, this person must have the commitment and persistence to overcome unexpected technical problems, convince the naysayers, and cope with the bureaucratic apparatus that is genuinely needed to protect patients.

Important new ideas rarely flow smoothly to widespread clinical use. There are probably one hundred untold failure stories for each success story! New inventions usually are made by the wrong person with the wrong contacts and experience, in the wrong place at the wrong time. It is important to understand the difference between a crude feasibility prototype and a well-developed, reliable, manufacturable product. Patents are important to protect ideas during the development process and to provide incentives for making the financial investments needed. Many devices have failed because they were too hard to use, reliability and ruggedness were inadequate, marketing was misdirected, user education was lacking, or service was poor and/or slow.

An evolutionary product is a new model of an existing product that adds new features, improves the technology, and reduces the cost of production. A revolutionary new product either solves a totally new problem or uses

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Companion website: www.wiley.com/go/Webster/Medical instrumentation5e

a new principle or concept to solve an old problem in a better way that displaces old methods. A medical instrument that improves screening, diagnosis, or monitoring may not add value by improving patient outcome unless improvements in the application of therapy occur as a result of using the medical instrument.

1.1 TERMINOLOGY OF MEDICINE AND MEDICAL DEVICES

Most biomedical engineers learn the physical sciences first in the context of traditional engineering, physics, or chemistry. When they become interested in medicine, they usually take at least a basic course in physiology, which does not describe disease or pathologic terminology. The book *Medical Terminology: An Illustrated Guide* (Cohen and DePetris, 2013) is recommended. It emphasizes the Latin and Greek roots in a workbook format (with answers) that includes clinical case studies, flash cards, and simple, clear illustrations. An unabridged medical dictionary such as *Dorland's Illustrated Medical Dictionary*, 30th ed. (Dorland, 2003), is often useful. Physicians frequently use abbreviations and acronyms that are difficult to look up, and ambiguity or errors result. Six references on medical abbreviations are given (Cohen and DePetris, 2013; Davis, 2011; Firkin and Whitworth, 2001; Haber, 1988; Hamilton and Guides, 1988; Heister, 1989). Medical eponyms are widely used to describe diseases and syndromes by the name of the person who first identified them. Refer to *Dictionary of Medical Eponyms* (Firkin and Whitworth, 2001).

The name used to describe a medical instrument or device should be informative, consistent, and brief. The annual *Health Devices Sourcebook* (Anonymous, 2013a) is a directory of U.S. and Canadian medical device products, trade names, manufacturers, and related services. This book uses internationally accepted nomenclature and a numerical coding system for over 5000 product categories. The *Product Development Directory* (Anonymous, 1996) lists all specific medical products by the FDA standard product category name since enactment of the Medical Devices Amendments in April 1976. The *Encyclopedia of Medical Devices and Instrumentation*, 2nd edition (Webster, 2006), vols. 1–6 has many detailed descriptions. But beware of borrowing medical terminology to describe technical aspects of devices or instruments. Confounding ambiguities can result.

Recent information on medical instrumentation can be found by searching World Wide Web servers such as www.fda.gov, www.uspto.gov, Library Online Catalogs, and journal electronic databases such as Engineering Village, Science Citation Index, and PubMed.

1.2 GENERALIZED MEDICAL INSTRUMENTATION SYSTEM

Every instrumentation system has at least some of the functional components shown in Figure 1.1. The primary flow of information is from left to right. Elements and relationships depicted by dashed lines are not essential. The major difference between this system of medical instrumentation and conventional instrumentation systems is that the source of the signals is living tissue or energy applied to living tissue.

MEASURAND

The physical quantity, property, or condition that the system measures is called the measurand. The accessibility of the measurand is important because it may be internal (blood pressure), it may be on the body surface (electrocardiogram (ECG) potential), it may emanate from the body (infrared radiation), or it may be derived from a tissue sample (such as blood or a biopsy) that is removed from the body. Most medically important measurands can be grouped in the following categories: biopotential, pressure, flow, dimensions (imaging), displacement (velocity, acceleration, and force),

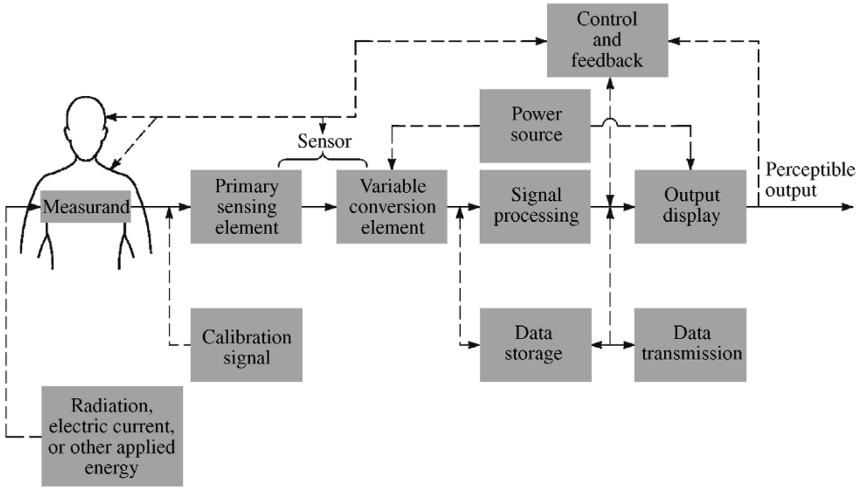

Figure 1.1 Generalized instrumentation system The sensor converts energy or information from the measurand to another form (usually electric). This signal is then processed and displayed so that humans can perceive the information. Elements and connections shown by dashed lines are optional for some applications.

impedance, temperature, and chemical concentrations. The measurand may be localized to a specific organ or anatomical structure.

SENSOR

Generally, the term *transducer* is defined as a device that converts one form of energy to another. A sensor converts a physical measurand to an electric output. The sensor should respond only to the form of energy present in the measurand, to the exclusion of all others. The sensor should interface with the living system in a way that minimizes the energy extracted, while being minimally invasive. Many sensors have a primary sensing element such as a diaphragm, which converts pressure to displacement. A variable-conversion element, such as a strain gage, then converts displacement to an electric voltage. Sometimes the sensitivity of the sensor can be adjusted over a wide range by altering the primary sensing element. Many variable-conversion elements need external electric power to obtain a sensor output.

SIGNAL CONDITIONING

Usually the sensor output cannot be directly coupled to the display device. Simple signal conditioners may only amplify and filter the signal or merely match the impedance of the sensor to the display. Often sensor outputs are converted to digital form and then processed by a microcontroller (Tompkins and Webster, 1981). For example, signal filtering may reduce undesirable sensor signals. It may also average repetitive signals to reduce noise, or it may convert information from the time domain to the frequency domain.

OUTPUT DISPLAY

The results of the measurement process must be displayed in a form that the human operator can perceive. The best form for the display may be numerical or graphical, discrete or continuous, permanent or temporary—depending on the particular measurand and how the operator will use the information. Although most displays rely on our visual sense, some information (Doppler ultrasonic signals, for example) is best perceived by other senses (here, the auditory sense). User controls and the output display should conform to the *Human Factors Engineering Guidelines and Preferred Practices for the Design of Medical Devices* [ANSI/AAMI, 2009/R(2013)] (Anonymous, 2013b).

AUXILIARY ELEMENTS

A calibration signal with the properties of the measurand should be applied to the sensor input or as early in the signal-processing chain as possible. Many forms of control and feedback may be required to elicit the measurand, to adjust the sensor and signal conditioner, and to direct the flow of output for display, storage, or transmission. Control and feedback may be automatic or manual. Data may be stored briefly to meet the requirements of signal conditioning or to enable the operator to examine data that precede alarm conditions. Or data may be stored before signal conditioning, so that different processing schemes can be utilized. The data can be transmitted wirelessly to remote displays at nurses' stations, medical centers, or medical data-processing facilities.

1.3 ALTERNATIVE OPERATIONAL MODES

DIRECT–INDIRECT MODES

Often the desired measurand can be interfaced directly to a sensor because the measurand is readily accessible or because acceptable invasive procedures are available. When the desired measurand is not accessible, we can use either another measurand that bears a known relation to the desired one or some form of energy or material that interacts with the desired measurand to generate a new measurand that is accessible. Examples include cardiac output (volume of blood pumped per minute by the heart), determined from measurements of respiration and blood gas concentration or from dye dilution; morphology of internal organs, determined from x-ray shadows; and pulmonary volumes, determined from variations in thoracic impedance plethysmography.

SAMPLING AND CONTINUOUS MODES

Some measurands such as body temperature and ion concentrations change so slowly that they may be sampled infrequently. Other quantities such as the electrocardiogram and respiratory gas flow may require continuous monitoring. The frequency content of the measurand, the objective of the measurement, the condition of the patient, and the potential liability of the physician all influence how often medical data are acquired. Many data that are collected may go unused.

GENERATING AND MODULATING SENSORS

Generating sensors produce their signal output from energy taken directly from the measurand, whereas modulating sensors use the measurand to alter the flow of energy from an external source in a way that affects the output of the sensor. For example, a photovoltaic cell is a generating sensor because it provides an output voltage related to its irradiation, without any additional external energy source. However, a photoconductive cell is a modulating sensor; to measure its change in resistance with irradiation, we must apply external energy to the sensor.

ANALOG AND DIGITAL MODES

Signals that carry measurement information are either *analog*, meaning continuous and able to take on any value within the dynamic range, or *digital*, meaning discrete and able to take on only a finite number of different values. Most currently available sensors operate in the analog mode, although some inherently digital measuring devices have been developed. Increased use of digital signal processing has required concurrent use of analog-to-digital and digital-to-analog converters to interface computers with analog sensors and analog display devices. Researchers have developed indirect digital sensors that use analog primary sensing elements and digital variable-conversion elements (optical shaft encoders). Also quasi-digital sensors, such as quartz-crystal thermometers, give outputs with variable frequency, pulse rate, or pulse duration that are easily converted to digital signals.

The advantages of the digital mode of operation include greater accuracy, repeatability, reliability, and immunity to noise. Furthermore, periodic calibration is usually not required. Digital numerical displays are replacing most analog meter movements because of their greater accuracy and readability. Most clinicians prefer digital displays when they are determining whether a physiological variable is within certain limits and when they are looking at a parameter that can change quickly, such as beat-to-beat heart rate.

REAL-TIME AND DELAYED-TIME MODES

Of course sensors must acquire signals in real time as the signals actually occur. The output of the measurement system may not display the result immediately, however, because some types of signal processing, such as averaging and transformations, need considerable input before any results can be produced. Often such short delays are acceptable unless urgent