

Medical Devices: Cardiovascular System

Diagnostic Devices

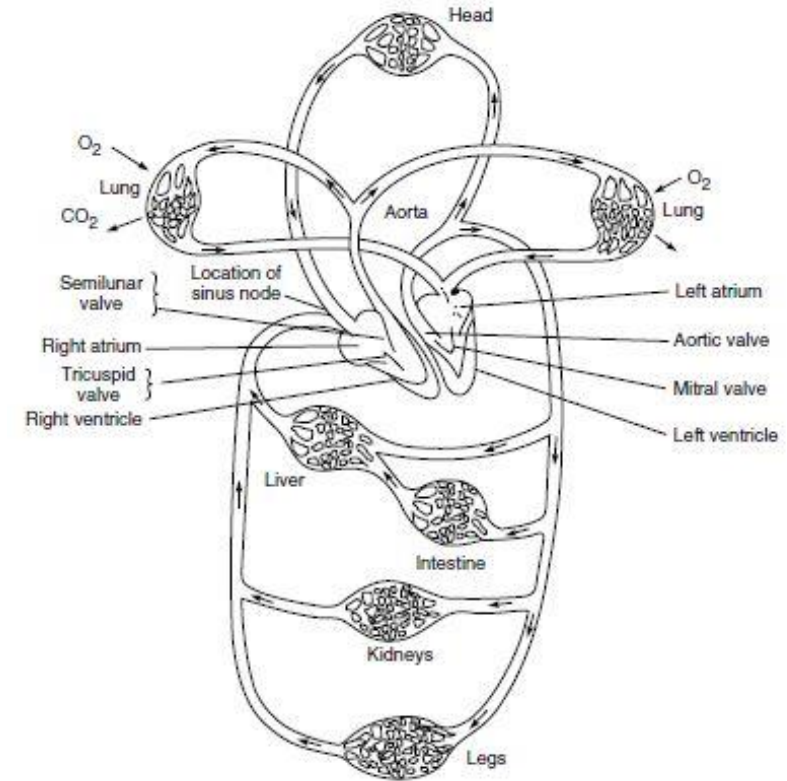
BM4111 - Medical Electronics & Instrumentation

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Cardiovascular System

- The cardiovascular system is a:
 - A complex closed hydraulic system
 - Transportation of
 - Oxygen
 - Carbon dioxide
 - Numerous chemical compounds
 - blood cells



Diagnostic Devices

- Devices used to identify the nature or cause of a certain phenomenon, usually related to a medical condition.[1]



ECG Monitor



Blood Flow Meter



Blood Pressure Monitor



Blood Chemistry Analyzer



Transcutaneous CO2 Analyzers

Therapeutic Devices

- Typically fall into two categories: those that assist a patient in their daily activities, and those that assist medical personal in delivering therapeutic services.[2]



Defibrillator



Pacemaker



Heart – Lung Machine

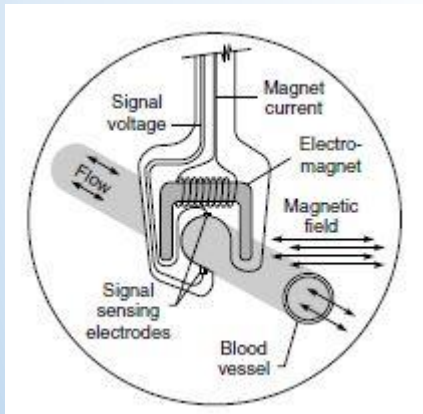
[1] Diagnostic devices – Latest research and news, Nature, <https://www.nature.com/subjects/diagnostic-devices>.

[2] What are Therapeutic devices?, <https://www.thehealthboard.com/what-are-therapeutic-devices.htm>.

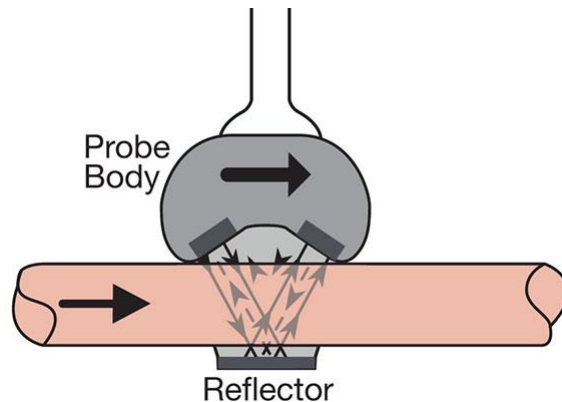
Blood Flow Meters

Medical Background

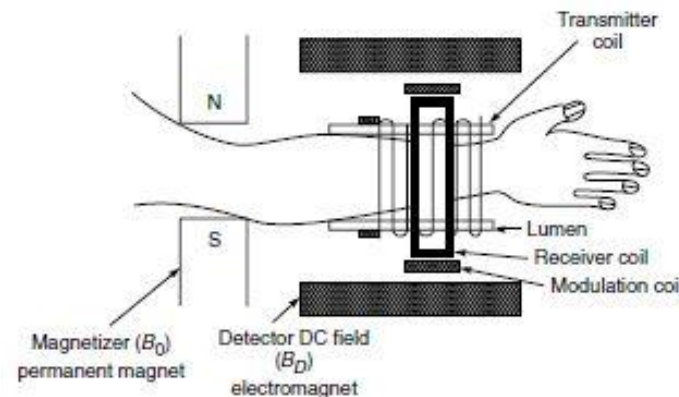
- Tissue health throughout the body depends on adequate blood circulation.
- Circulation can be impaired by various disease conditions or by trauma including surgery.
- Preventive measures can be taken if impaired circulation can be detected before damage occurs.



Electromagnetic
Blood Flow Meters



Ultrasonic Blood
Flow Meters



NMR Blood Flow
Meters



Laser Doppler Blood
Flow Meters

Electromagnetic Blood Flow Meters

Background and Operating Principle

Most commonly used.

Cannulation  Exposed blood vessel 

Faraday's law of electromagnetic induction 

$$e = CHVd$$

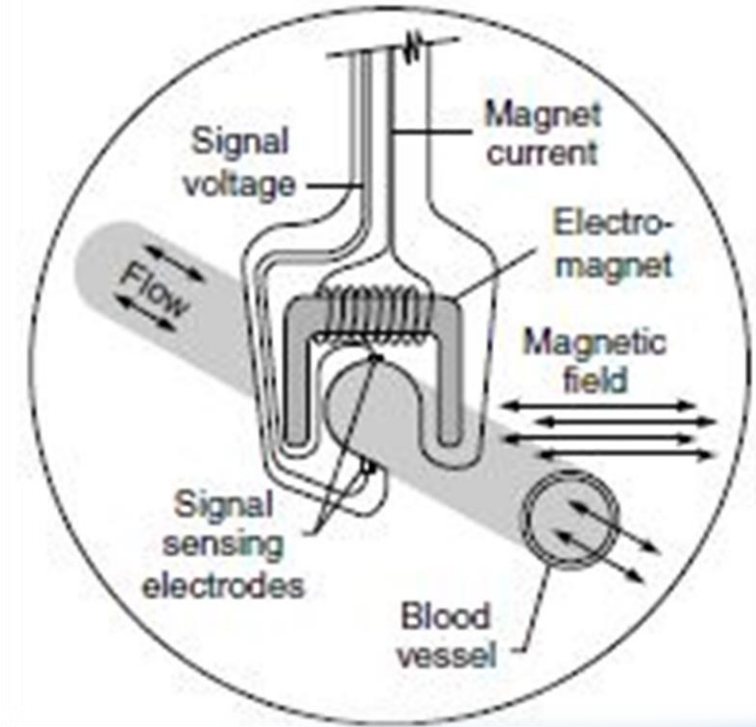
e = Induced Voltage

H = Strength of Magnetic Field

C = Proportionality constant

V = Velocity of blood flow

d = Diameter of Blood Vessel



Background and Operating Principle

$$e = CHVd$$

Flow rate Q through a blood vessel :

$$Q = VA$$

$$e = \frac{CHd}{A} Q$$

e = Induced Voltage

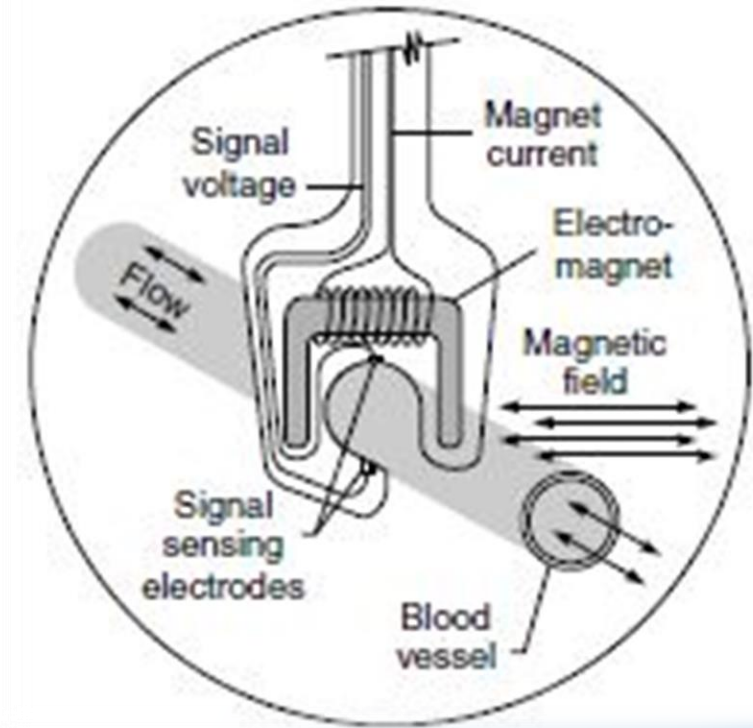
V = Velocity of blood flow

H = Strength of Magnetic Field

d = Diameter of Blood Vessel

C = Proportionality constant

A = Area of cross section of blood vessel



Instrumentation Aspects



Transducer is a tube of non-magnetic materials.



Tube is made of a conducting material and has an insulating lining to prevent short circuiting of induced emf.



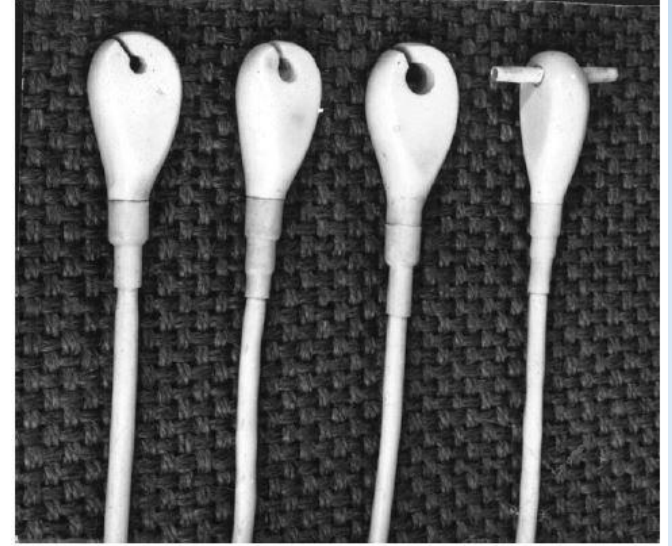
The flow head contains a slot.



Probe must be encapsulated in a biologically inert material having a high electrical and chemical resistance.



Electromagnetic flow meters with magnetic coil supporting different current waveforms (sine, square, trapezium)

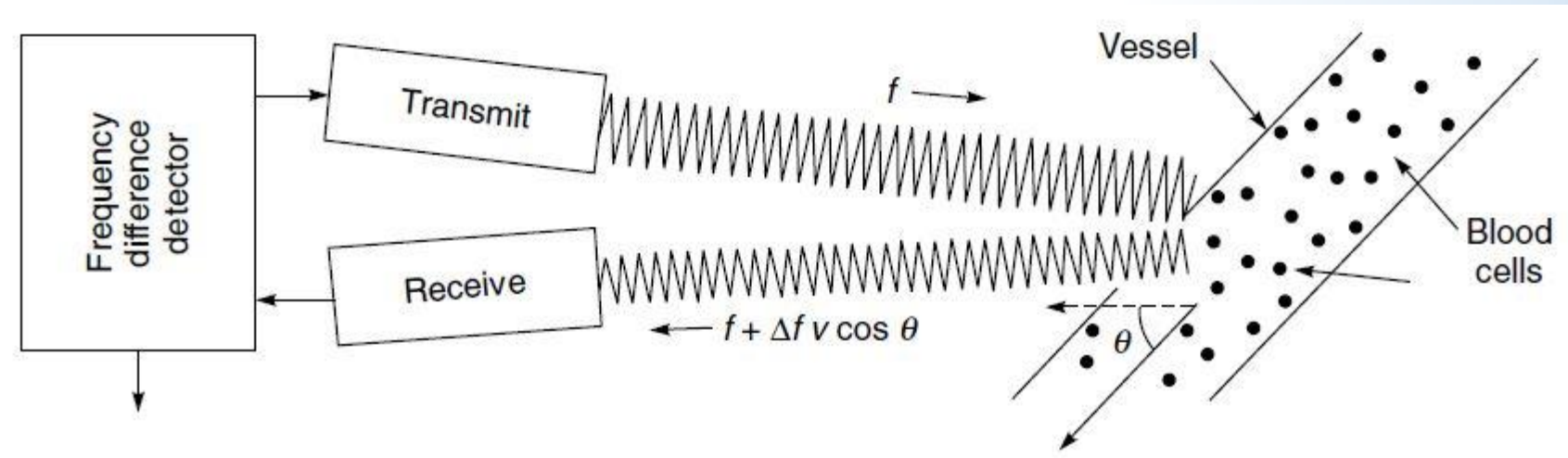


Ultrasonic Blood Flow Meters

Background and Operating Principle

- Two type:
 - Transit-time velocity meter
 - Doppler-shift flow velocity meter
- } Doppler shift superseded transit time
- Non-invasive
 - Based on echo signals from erythrocytes in the vascular structures and Doppler effect.

$$v = \frac{\Delta f C}{2f \cos \theta}$$



Instrumentation Aspects



Ultrasound transducers consist of piezoelectric crystals mounted on a probe.



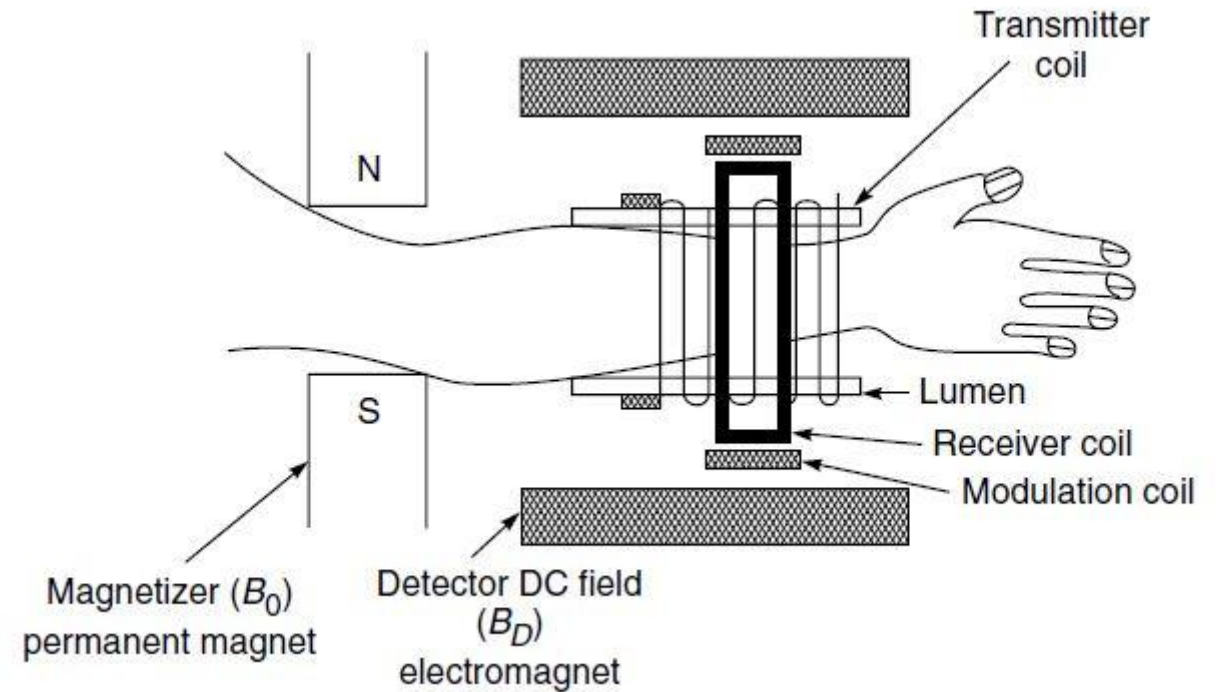
Gel is used to provide better coupling between the probe and the patient



Nuclear Magnetic Resonance Blood Flow Meters

Background and Operating Principle

- Based on magnetic energy levels of the nucleus of some elements and their isotopes.
- Non-invasive
- 83% of blood is water (two hydrogen atoms of water is studied)
- NMR based flowmeters are limited in their applications.



Laser Doppler Blood Flow Meters

Background and Operating Principle

- Based on Doppler-shift of monochromatic laser light.
- A low power (5 mW) He–Ne laser.
- The light is reflected from :
 - non-moving tissues (frequency unshifted reference beam)
 - moving red blood cells (Doppler-shifted beam).
- The laser output is coupled into the fibre using a converging lens.

COOK Doppler Blood Flow Monitor

Operating Principle	Ultrasound
IEC Standards	IEC 61000-4-2: Electrostatic Discharge IEC 61000-4-3: Radiated RF IEC 61000-4-4: Electrical Test Burst IEC 61000-4-5: Surge IEC 61000-4-6: Conducted RF IEC 61000-4-8: Power Frequency IEC 61000-4-11: Voltage Dips and Variations
IEC Device Classification (Protection Against Shock)	Class II Equipment
IEC Device Classification (Protection Against Applied Parts)	Type BF
FDA Classification	Class II (Special Controls)
FDA Approval Process	510(k), Cardiovascular Blood Flow Meter, 870.2100



Doppler Extension Cable



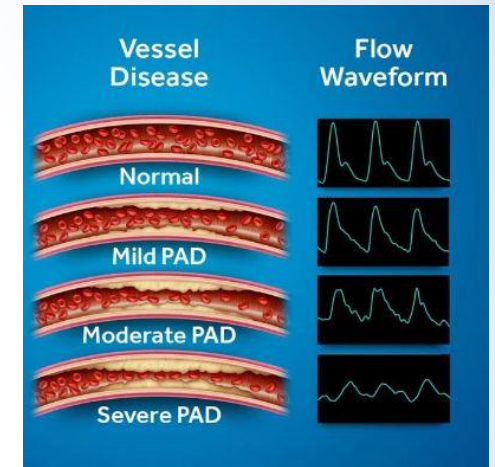
Cook-Swartz Doppler Probe



Doppler Channel/
Cable Verifier

FlowMet - Peripheral Blood Flow Monitoring System

Operating Principle	Laser
IEC Standards	IEC 60825-1:2014: Laser Safety
IEC Device Classification (Protection Against Shock)	Class I
IEC Device Classification (Protection Against Applied Parts)	--
FDA Classification	Class II (Special Controls)
FDA Approval Process	510(k), Cardiovascular Blood Flow Meter, 870.2100



Transcutaneous CO₂ analyzers

Medical Background

In the human body, carbon dioxide is formed intracellularly as a byproduct of metabolism.

CO₂ plays various roles in the human body:

- Regulation of blood pH
- Respiratory Drive
- Affinity of Hemoglobin for oxygen

Hypercapnia
Increased amount of CO₂ in blood



Acidosis, Tachycardia,
Coma leading to death

Operating Principle

Patient's skin is heated when in contact with the electrode



Heat increases perfusion and permeability of skin



Electrode consists of an electrolyte filled cell with a membrane covering



Membrane allows CO₂ to enter electrode cell



Chemical reaction with electrolytes produces voltage potential

TCM5 FLEX Transcutaneous monitor

IEC Standards	IEC60601-1 IEC 60601-1-11 IEC 60601-1-8 IEC 60601-1-6 IEC 60601-2-23
IEC Device Classification (Protection Against Shock)	Class II Equipment
IEC Device Classification (Protection Against Applied Parts)	Type BF
FDA Classification	Class II (Special Controls)
FDA Approval Process	510(k)



Ref: TCM5 Instruction Manual, <https://kvalitet.helse-bergen.no/docs/pub/dok52933.pdf>.

TCM5 FLEX Monitor, Transcutaneous monitor, <https://ifdesign.com/en/winner-ranking/project/tcm5-flex-monitor/204504>

Sentec Digital Monitoring System


IEC Standards	IEC 60601-1 IEC 60601-1-6 IEC 60601-1-8 IEC 60601-2-23 IEC 60601-1-11
IEC Device Classification (Protection Against Shock)	Class II Equipment
IEC Device Classification (Protection Against Applied Parts)	Type BF
FDA Classification	Class II (Special Controls)
FDA Approval Process	510(k), Cutaneous Carbon Dioxide (PcCO ₂) Monitor, 868.2480



Ref: Sentec Digital Monitoring System, Instruction Manual, https://www.sentec.com/fileadmin/2021/06/HB-005771-r-SDMS_InstructionManual_EN_Web.pdf.
FDA, Medical Devices, <https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm?db=pmn&id=K041548>
FDA Summary, https://www.accessdata.fda.gov/cdrh_docs/pdf4/K041548.pdf.

Blood Chemistry Analyzers

Medical Background

- Determining the balance of chemicals in the blood is critical for diagnosis and determining the courses of treatment.
- Imbalances  Life threatening medical conditions.

Blood chemistry analysis in laboratory:

- Requires careful documentation.
- Special sample handling.
- Considerable travel.
- Significant delays

POC blood chemistry analysis:

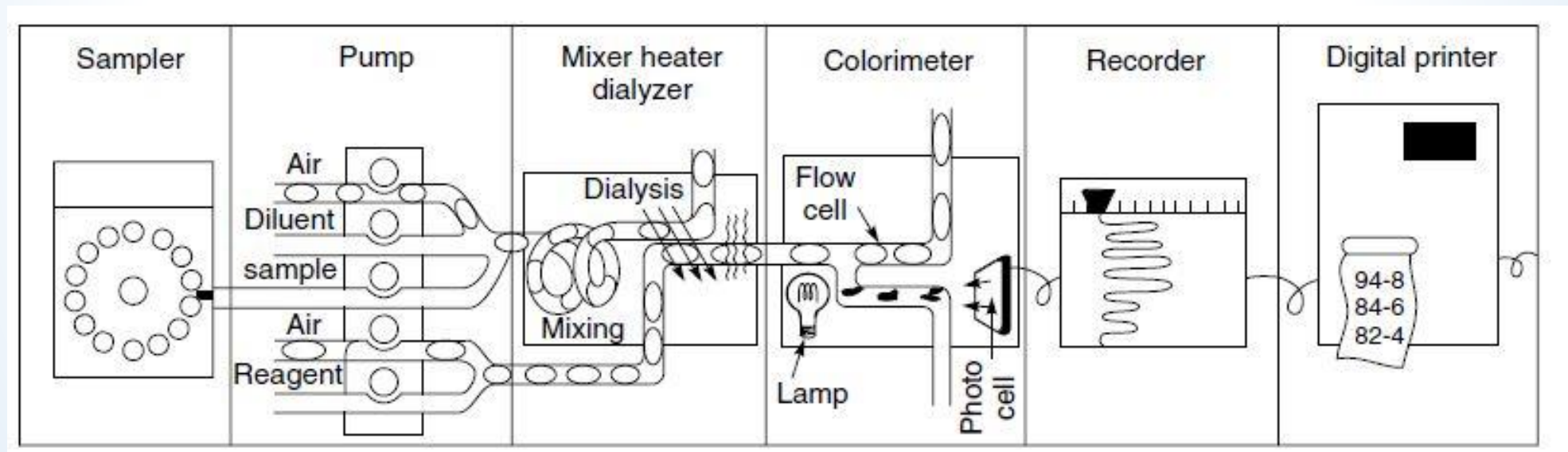
- Requires small samples.
- Analysis done at patient's location.
- Reduced delay in obtaining results.
- Updates values to patient monitoring system.

Medical Background

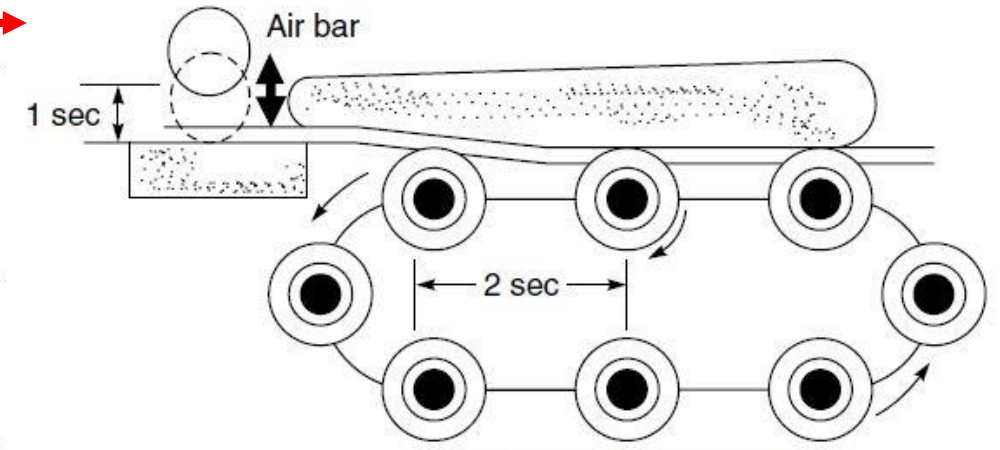
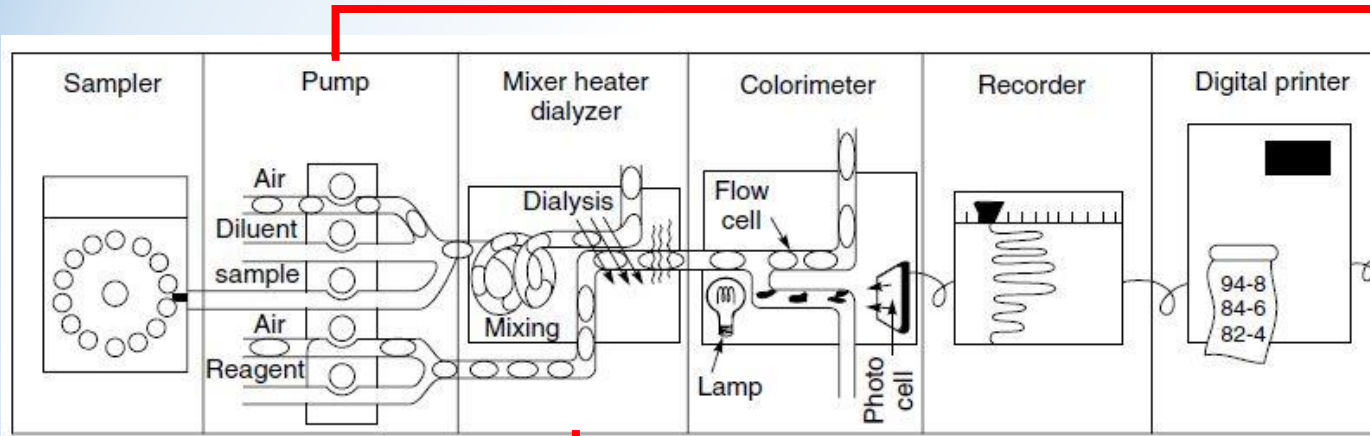
Parameters	Description
BNP	Brain natriuretic peptide, made by heart and blood vessels. BNP levels are higher than normal during heart failure.
Creatine kinase	Type of protein mostly found in skeletal muscles and heart. Often used to diagnose and monitor muscular injuries and diseases.
Blood Urea Nitrogen	Provides information about kidney function. Higher than normal BUN levels suggests that kidney is not functioning properly.
Glucose	Type of sugar. Diagnose and monitor hyperglycemia and hypoglycemia.
Troponin I	Type of protein found in heart muscles. During heart damage greater amounts of troponin can be found in the blood.
Potassium	Type of electrolyte. Monitor diabetes and kidney diseases.
Hemoglobin	Type of protein. Used to check for anemia (low hemoglobin level)

Operating Principles and Design Aspects

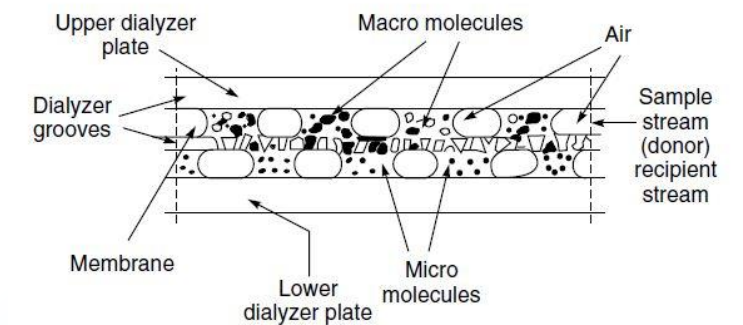
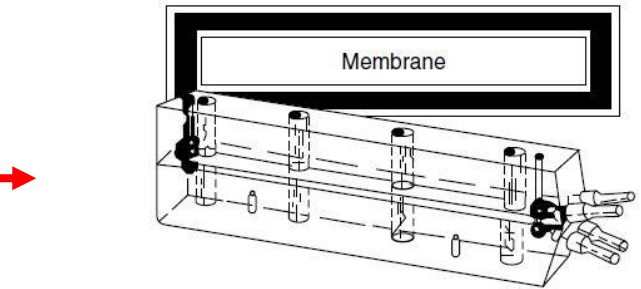
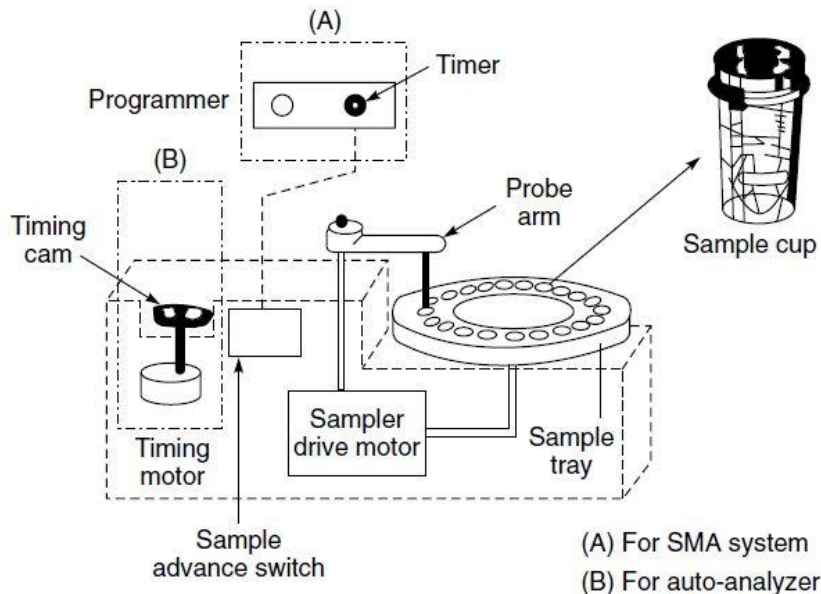
- Continuous flow system.
 - Individual operations performed on flowing stream.
 - End-product goes through colorimeter.
 - Results recorded on a strip-chart recorder along with a calibration curve.



Operating Principles and Design Aspects



Proportioning pump



BS-200 Chemistry Analyzer

IEC Standards	IEC 61326-1: 2005 IEC 61326-2-6: 2005
IEC Device Classification (Protection Against Shock)	Class I Equipment
IEC Device Classification (Protection Against Applied Parts)	Type BF
FDA Classification	Class II (Special Controls)
FDA Approval Process	510(k), Glucose Test System, 862.1345



Ref: BS-200, Chemistry Analyzer, Operator's Manual, <https://medtestdx.com/wp-content/uploads/2019/11/BS-200-Operation-Manual-Complete.pdf>.
FDA, Medical Devices, <https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm?db=pmn&id=K072018>
FDA Summary, https://www.accessdata.fda.gov/cdrh_docs/pdf7/K072018.pdf.

Stat Profile Prime ABG Analyzer System

IEC Standards	IEC 825 Laser Product
IEC Device Classification (Protection Against Shock)	Class II Equipment
IEC Device Classification (Protection Against Applied Parts)	Type BF
FDA Classification	Class II (Special Controls)
FDA Approval Process	510(k), Blood gases (PCO ₂ , PO ₂) and blood pH test system, 862.1120



Ref: Instruction Manual, https://physiology.case.edu/media/eq_manuals/eq_manual_STAT_Profile_Prime_Instructions_for_Use_Manual.pdf.
FDA, Medical Devices, <https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm?db=pmn&id=K151982>
FDA Summary, https://www.accessdata.fda.gov/cdrh_docs/pdf15/K151982.pdf.

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- Street, L. J. (2016). Introduction to biomedical engineering technology. CRC press.
- Diagnostic devices – Latest research and news, Nature, <https://www.nature.com/subjects/diagnostic-devices>.
- What are Therapeutic devices?, <https://www.thehealthboard.com/what-are-therapeutic-devices.htm>.
- Medline Plus, <https://medlineplus.gov/>

Blood Flow Monitors:

- Doppler Blood Flow Monitor, <https://www.cookmedical.com/products/33eecd89-149b-4d3c-955a-213541b21142/>.
- FlowMet™ Peripheral Blood Flow Monitoring System, <https://www.medtronic.com/us-en/healthcare-professionals/products/cardiovascular/intraprocedural-monitoring/flowmet.html>

Transcutaneous CO2 analyzers:

- TCM5 Instruction Manual, <https://kvalitet.helse-bergen.no/docs/pub/dok52933.pdf>.
- TCM5 FLEX Monitor, Transcutaneous monitor, <https://ifdesign.com/en/winner-ranking/project/tcm5-flex-monitor/204504>
- Sentec Digital Monitoring System, Instruction Manual, https://www.sentec.com/fileadmin/2021/06/HB-005771-r-SDMS_InstructionManual_EN_Web.pdf.
- FDA, Medical Devices, <https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm?db=pmn&id=K041548>
- FDA Summary, https://www.accessdata.fda.gov/cdrh_docs/pdf4/K041548.pdf.

References

Blood Chemistry Analyzers:

- BS-200, Chemistry Analyzer, Operator's Manual, <https://medtestdx.com/wp-content/uploads/2019/11/BS-200-Operation-Manual-Complete.pdf>.
- FDA, Medical Devices, <https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm?db=pmn&id=K072018>
- FDA Summary, https://www.accessdata.fda.gov/cdrh_docs/pdf7/K072018.pdf.
- Instruction Manual, https://physiology.case.edu/media/eq_manuals/eq_manual_STAT_Profile_Prime_Instructions_for_Use_Manual.pdf.
- FDA, Medical Devices, <https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm?db=pmn&id=K151982>
- FDA Summary, https://www.accessdata.fda.gov/cdrh_docs/pdf15/K151982.pdf.

Thank you