Equipment Packet: Patient Monitoring

UMDNS #: 12636

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Equipment Packet Contents:

This is a multi-part packet that contains information about the operation, maintenance, and repair of patient monitoring systems. This includes general physiological monitors, blood pressure monitors, oxygen monitors, respiratory monitors, and temperature monitors.

Part I: External From the Packet:

1. **An Introduction to Respiration and Apnea Monitors:** PowerPoint

Part II: Included in this Packet:

SECTION A:
Patient Monitoring (General)

1. Operation and Use of Patient Monitors

Featured in this Section:

Strengthening Specialised Clinical Services in the Pacific. *User Care of Medical Equipment: A first line maintenance guide for end users*. (2015).

WHO. "Monitor, Bedside, Electroencephalography." From the publication: *Core Medical Equipment*. Geneva, Switzerland, 2011.

WHO. "Monitor, Physiologic." From the publication: *Core Medical Equipment*. Geneva, Switzerland, 2011.

Wikipedia. "Monitoring (Medical)." *Wikipedia,* p. 1-6. Retrieved from: https://en.wikipedia.org/wiki/Monitoring_(medicine)

Chapter 4.5 Electronic Diagnostic/Monitoring Equipment

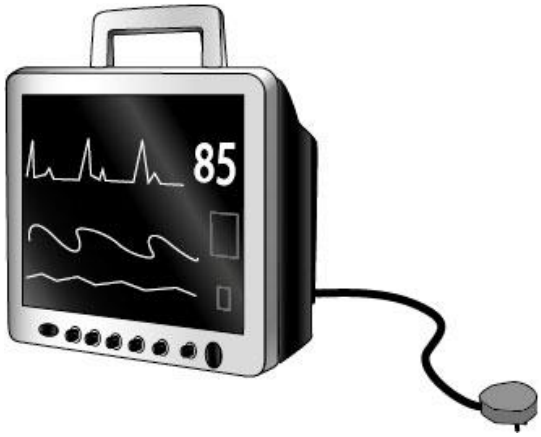
Function

There are many items of equipment in a hospital that use electronics for operation. The maintenance of such equipment is a task for specialised and trained staff. However, regular inspection and cleaning will help such equipment last for a long time and deliver safe function. These are tasks that the equipment user can carry out and should be done regularly, as laid out on the checklists on the next pages.

The types of equipment that might be included in this category are for instance audiometers, blood gas analyzers, cardiac monitors, cardiotocographs (CTGs), cryoprobes, defibrillators, infusion pumps and stimulators. .

How it works

The electrical section of the machine that is most important for safety, and also is the most likely to give problems, is the power supply. See chapter 8 on electrical safety for the background to this. The power supply converts the voltage to a lower, stable value to make the equipment work and also protects the patient from the mains voltage. Any damage to the power supply, or any liquid spilled near it, is very serious indeed. The user care checklist therefore majors on checking the cables, fuses and power connectors. If a device uses low voltage batteries, it is safer to use. In this case, the user should take care that the batteries are removed if the equipment will not be used for longer than one month, as chemical spillage can occur. Rechargeable batteries must be kept topped up with charge.

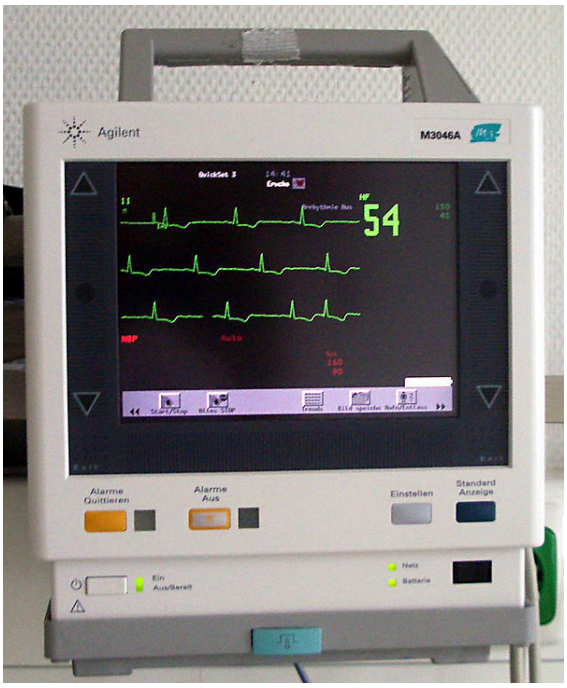


External power supply mounted in cable

Items of electromedical equipment, with internal power supplies.

Overview of Patient Monitoring

Monitoring (medicine)



Display device of a medical monitor as used in anesthesia.

In medicine, **monitoring** is the observation of a disease, condition or one or several medical parameters over time.

It can be performed by continuously measuring certain parameters by using a **medical monitor** (for example, by continuously measuring vital signs by a bedside monitor), and/or by repeatedly performing medical tests (such as blood glucose monitoring with a glucose meter in people with diabetes mellitus).

Transmitting data from a monitor to a distant monitoring station is known as telemetry or biotelemetry.

1 Classification by target parameter

Monitoring can be classified by the target of interest, including:

- **Cardiac monitoring**, which generally refers to continuous electrocardiography with assessment of the patients condition relative to their cardiac rhythm. A small monitor worn by an ambulatory patient for this purpose is known as a Holter monitor. Cardiac monitoring can also involve cardiac output monitoring via an invasive Swan-Ganz catheter.
- **Hemodynamic monitoring**, which monitors the blood pressure and blood flow within the circulatory system. Blood pressure can be measured either invasively through an inserted blood pressure transducer assembly, or noninvasively with an inflatable blood pressure cuff.
- **Respiratory monitoring**, such as:
  - Pulse oximetry which involves measurement of the saturated percentage of oxygen in the blood, referred to as SpO2, and measured by an infrared finger cuff
  - Capnography, which involves CO_2 measurements, referred to as EtCO2 or end-tidal carbon dioxide concentration. The respiratory rate monitored as such is called AWRR or airway respiratory rate)
  - Respiratory rate monitoring through a thoracic transducer belt, an ECG channel or via capnography
- **Neurological monitoring**, such as of intracranial pressure. Also, there are special patient monitors which incorporate the monitoring of brain waves (electroencephalography), gas anesthetic concentrations, bispectral index (BIS), etc. They are usually incorporated into anesthesia machines. In neurosurgery intensive care units, brain EEG monitors have a larger multichannel capability and can monitor other physiological events, as well.
- **Blood glucose monitoring**
- **Childbirth monitoring**
- **Body temperature monitoring** through an adhesive pad containing a thermoelectric transducer.

1.1 Vital parameters

Monitoring of vital parameters can include several of the ones mentioned above, and most commonly include at least blood pressure and heart rate, and preferably also pulse oximetry and respiratory rate. Multimodal monitors that simultaneously measure and display the relevant vital parameters are commonly integrated into the

Wikipedia. “Monitoring (Medical).” Wikipedia, p. 1-6. Retrieved from: https://en.wikipedia.org/wiki/Monitoring_(medicine)

An anesthetic machine with integrated systems for monitoring of several vital parameters, including blood pressure and heart rate.

bedside monitors in critical care units, and the anesthetic machines in operating rooms. These allow for continuous monitoring of a patient, with medical staff being continuously informed of the changes in general condition of a patient. Some monitors can even warn of pending fatal cardiac conditions before visible signs are noticeable to clinical staff, such as atrial fibrillation or premature ventricular contraction (PVC).

2 Medical monitor

A *medical monitor* or *physiological monitor* is a medical device used for monitoring. It can consist of one or more sensors, processing components, display devices (which are sometimes in themselves called "monitors"), as well as communication links for displaying or recording the results elsewhere through a monitoring network.

2.1 Components

2.1.1 Sensor

Sensors of medical monitors include biosensors and mechanical sensors.

2.1.2 Translating component

The translating component of medical monitors is responsible for converting the signals from the sensors to a format that can be shown on the display device or transferred to an external display or recording device.

2.1.3 Display device

Physiological data are displayed continuously on a CRT, LED or LCD screen as data channels along the time axis, They may be accompanied by numerical readouts of computed parameters on the original data, such as maximum, minimum and average values, pulse and respiratory frequencies, and so on.

Besides the tracings of physiological parameters along time (X axis), digital medical displays have automated numeric readouts of the peak and/or average parameters displayed on the screen.

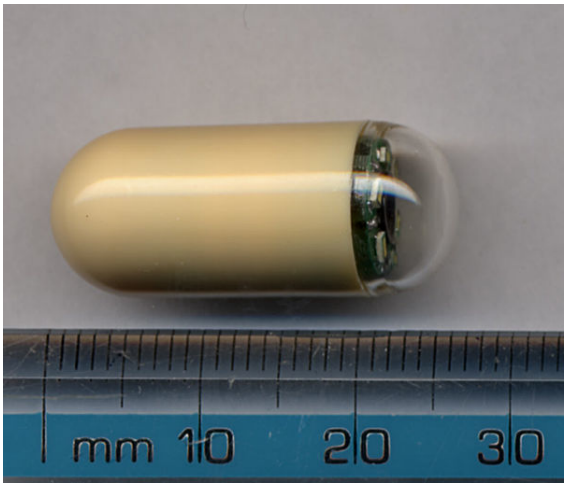
Modern medical display devices commonly use digital signal processing (DSP), which has the advantages of miniaturization, portability, and multi-parameter displays that can track many different vital signs at once.

Old analog patient displays, in contrast, were based on oscilloscopes, and had one channel only, usually reserved for electrocardiographic monitoring (ECG). Therefore, medical monitors tended to be highly specialized. One monitor would track a patient's blood pressure, while another would measure pulse oximetry, another the ECG. Later analog models had a second or third channel displayed in the same screen, usually to monitor respiration movements and blood pressure. These machines were widely used and saved many lives, but they had several restrictions, including sensitivity to electrical interference, base level fluctuations and absence of numeric readouts and alarms.

2.1.4 Communication links

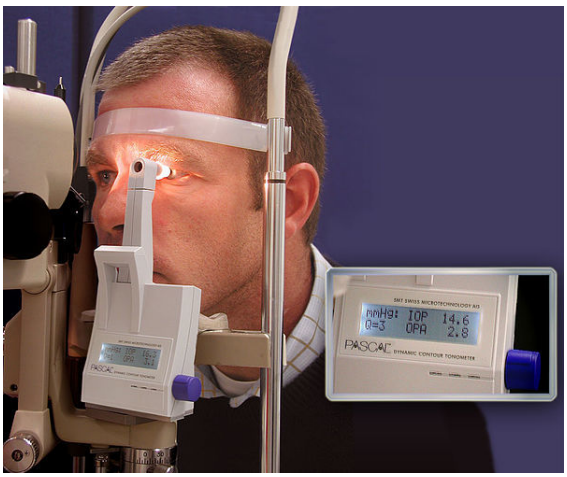
Several models of multi-parameter monitors are networkable, i.e., they can send their output to a central ICU monitoring station, where a single staff member can observe and respond to several bedside monitors simultaneously. Ambulatory telemetry can also be achieved by portable, battery-operated models which are carried by the patient and which transmit their data via a wireless data connection.

Digital monitoring has created the possibility, which is being fully developed, of integrating the physiological data from the patient monitoring networks into the emerging hospital electronic health record and digital charting systems, using appropriate health care standards which have been developed for this purpose by organizations such as IEEE and HL7. This newer method of charting patient data reduces the likelihood of human documentation error and will eventually reduce overall paper consumption. In addition, automated ECG interpretation incorporates diagnostic codes automatically into the charts. Medical monitor's embedded software can take



Given Imaging Capsule endoscopy

of monitoring medicine solutions are not available today in conventional medicine.



The PASCAL Dynamic Contour Tonometer. A monitor for detection of increased intraocular pressure.

Blood glucose monitoring In vivo blood glucose monitoring devices can transmit data to a computer that can assist with daily life suggestions for lifestyle or nutrition and with the physician can make suggestions for further study in people who are at risk and help prevent diabetes mellitus type 2 .[8]

Stress monitoring Bio sensors may provide warnings when stress levels signs are rising before human can notice it and provide alerts and suggestions.[9]

Serotonin biosensor Future serotonin biosensors may assist with mood disorders and depression.[10]

Continuous blood test based nutrition In the field of evidence-based nutrition, a lab-on-a-chip implant that can run 24/7 blood tests may provide a continuous results and a coumputer can provide nutritaion suggestions or alerts.

Psychiatrist-on-a-chip In clinical brain sciences drug delivery and in vivo Bio-MEMS based biosensors may assist with preventing and early treatment of mental disorders

Epilepsy monitoring In epilepsy, next generations of long-term video-EEG monitoring may predict epileptic seizure and prevent them with changes of daily life activity like sleep, stress, nutrition and mood management.[11]

Toxicity monitoring Smart biosensors may detect toxic materials such mercury and lead and provide alerts.[12]

5 See also

- Medical equipment
- Medical test
- Nanoelectromechanical system (NEMS)
- Functional medicine

6 References

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[2] C-reactive protein (serum, plasma) from The Association for Clinical Biochemistry and Laboratory Medicine. Author: Brona Roberts. Copyrighted 2012

[3] "Healthcare 2030: disease-free life with home monitoring nanomedince". Positivefuturist.com.

[4] "Nanosensors for Medical Monitoring.". Technologyreview.com.

[5] "Brain Damage Caused by Neuroleptic Psychiatric Drugs". Mindfreedom.org.

[6] "Medications That Can Cause Nerve Damage". Livestrong.com.

[7] Hyman, Mark (December 2008). *The UltraMind Solution: Fix Your Broken Brain by Healing Your Body First.* Scribner. ISBN 978-1-4165-4971-0.

[8] "Blood glucose testing and primary prevention of diabetes mellitus type 2 - evaluation of the effect of evidence based patient information.". BMC Public health.

[9] ""Stress monitoring using a distributed wireless intelligent sensor system".". IEEE.

[10] "Using biosensors to detect the release of serotonin from taste buds during taste stimulation.". Archives Italiennes de Biologie.

[11] Kamel JT, Christensen B, Odell MS, D'Souza WJ, Cook MJ (December 2010). "Evaluating the use of prolonged video-EEG monitoring to assess future seizure risk and fitness to drive.". *Epilepsy Behav* **19** (4): 608–11. doi:10.1016/j.yebeh.2010.09.026. PMID 21035403.

[12] "Multiarray Biosensors for Toxicity Monitoring and Bacterial Pathogens". CRC.

7 Further reading

- *Monitoring Level of Consciousness During Anesthesia & Sedation* , Scott D. Kelley, M.D., ISBN 978-0-9740696-0-9
- *Healthcare Sensor Networks: Challenges Toward Practical Implementation*, Daniel Tze Huei Lai (Editor), Marimuthu Palaniswami (Editor), Rezaul Begg (Editor), ISBN 978-1-4398-2181-7
- *Blood Pressure Monitoring in Cardiovascular Medicine and Therapeutics (Contemporary Cardiology)*, William B. White, ISBN 978-0-89603-840-0
- *Physiological Monitoring and Instrument Diagnosis in Perinatal and Neonatal Medicine*, Yves W. Brans, William W. Hay Jr, ISBN 978-0-521-41951-2
- *Medical Nanotechnology and Nanomedicine (Perspectives in Nanotechnology)*, Harry F. Tibbals, ISBN 978-1-4398-0874-0

8 External links

- *Monitoring medicine intake in the networked home: The iCabiNET solution*, IEEE Xplore, Issue Date: Jan. 30 2008-Feb. 1 2008, pp. 116 – 117
- *Personal Medical Monitoring Devices*, The University of Maryland

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9.1 Text

- **Monitoring (medicine)** *Source:* https://en.wikipedia.org/wiki/Monitoring_(medicine)?oldid=676379064 *Contributors:* Discospinster, Rjwilmsi, Vegaswikian, Ground Zero, Born2cycle, Bgwhite, Mahahahaneapneap, Cydebot, Shirt58, WhatamIdoing, Mikael Häggström, Squids and Chips, Robert1947, Jdaloner, Sun Creator, Addbot, Wireless friend, AnomieBOT, WikitanvirBot, Bamyers99, יוסי קמחי, Jesanj, Helpful Pixie Bot, Martin Berka, BG19bot, Gurt Posh, Iamthecheese44, CitationCleanerBot, MrBill3, Dexbot, Cbrillaz, Monkbot, Junaid sipra and Anonymous: 4

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Monitor, Bedside, Electroencephalography

Brief Introduction to Bedside Monitors

UMDNS		GMDN	
12602	Monitors, Bedside, Electroencephalography	38736	Electroencephalographic monitoring system, portable

Other common names:
Cerebral function monitors; EEG recorders; electroencephalographs; monitors, bedside, electroencephalography, spectral

Health problem addressed

EEG monitors are used for observing and diagnosing a variety of neurologic conditions, including epilepsy, related convulsive disorders, and brain death. They can also be used to evaluate psychiatric disorders and differentiate among various psychiatric and neurologic conditions. In addition, electroencephalographic studies with EEG monitors can assist in localizing tumors or lesions on or near the surface of the brain.

Product description

EEG monitors use electrodes placed on a patient's scalp to measure, amplify, display in graphic form, and record the weak electrical signals generated by the brain. They continuously display processed EEG signals in graphic form over a period of time so that waveform and pattern changes can be readily detected. EEG monitors use computers to analyze and generate large amounts of electroencephalographic data (as in Fourier analysis), which are processed and displayed in various formats. Many systems can produce and display certain types of EPs or event-related potentials, a specific type of EEG signal that occurs in response to a periodically applied external stimulus.

Principles of operation

Low-amplitude (microvolt range) EPs believed to be generated by large numbers of nerve cells known as pyramidal cells, which are located in the outer layer (cortex) of the brain, polarize and depolarize in response to various stimuli, creating the EEG waveform. These fluctuating electrical potentials are detected by electrodes placed on the scalp and are displayed and/or recorded on the EEG. Each EEG channel amplifies a signal from a pair of electrodes, and these amplified signals can be printed on a chart recorder and/or displayed on a monitor.

Operating steps

Scalp electrodes are usually affixed by a technician with a conductive adhesive or paste. Cup, or disk, electrodes are affixed to the scalp with a special adhesive called collodion or with a conductive paste. Regardless of the electrode-placement procedure used, patients usually lie down, remain awake, and keep their eyes closed during an EEG recording; however, sleep EEG recordings (polysomnography) are also common. The set of electrode pairs that the technician selects for recording is called a montage.

Reported problems

The most common problem is improper electrode application. Avoiding this problem requires use of proper technique during skin preparation and electrode attachment, in addition to positioning the electrodes in the correct system configurations. Poor electrode contact with the scalp can distort the results of EEG recordings. A recurring difficulty with electroencephalography is the failure of EEG monitors to filter out artifacts, which can result in an incorrect signal interpretation or inability to analyze the EEG signal.

Use and maintenance

User(s): Neurologists, neurosurgeons, or other physicians, EEG technicians, sleep lab technicians, nurses, anesthesiologists, OR technicians,

Maintenance: Biomedical or clinical engineer/ technician, medical staff, manufacturer/ servicer

Training: Initial training by manufacturer, operator's manuals, user's guide

Environment of use

Settings of use: ICUs, OR, sleep lab, EEG lab, neurology clinics

Requirements: Uninterruptible power source, battery backup, good lead/cable connections, conductive gel

Product specifications

Approx. dimensions (mm): 350 x 50 x 390

Approx. weight (kg): 8

Consumables: Electrodes, conductive gel

Price range (USD): 1,750 - 113,000

Typical product life time (years): 8-10

Shelf life (consumables): NA

Types and variations

Computer laptop, mobile console, or monitor

WHO. "Monitor, Bedside, Electroencephalography." From the publication: Core Medical Equipment. Geneva, Switzerland, 2011.

World Health Organization http://www.who.int/medical_devices/en/index.html

Monitoring System, Physiologic

Brief Introduction to Physiologic Monitoring Sytems

UMDNS		GMDN	
12636	Monitoring Systems, Physiologic	33586	Physiologic monitoring system, single-patient
		36872	Transportable physiologic monitoring system
		35569	Neonatal physiologic monitoring system

Other common names:
Operating room (OR) monitors, acute care monitoring systems, vital signs monitors, neonatal monitors, physiologic monitors; Single-patient monitoring system and related equipment; Measuring/monitoring system, biophenomena; Monitoring, bedside unit; Single patient monitoring system; Monitor, patient transport; Physiologic monitoring system, acute care, battery-powered; physiologic monitoring system, neonatal

Health problem addressed

Continuous monitoring is a valuable tool that helps provide additional information to the medical and nursing staff about the physiologic condition of the patient. Using this information, the clinical staff can better evaluate a patient's condition and make appropriate treatment decisions.

Product description

These systems usually include a central station monitor that receives, consolidates, and displays the information and a set of monitors that are deployed near the patient (bedside monitors) to provide the required data from each patient (ECG, respiratory rate, noninvasive blood pressure (NIBP) and invasive blood pressure (IBP) (systolic, diastolic, and mean), body temperature, (SpO2), mixed venous oxygenation (SvO2), cardiac output, (ETCO2), intracranial pressure, and airway gas concentrations).

Principles of operation

Physiologic monitors can be configured, modular, or both. Configured monitors have all their capabilities already built-in. Modular systems feature individual modules for each monitoring parameter or group of parameters; these modules can be used in any combination with each bedside monitor or be interchanged from monitor to monitor. Some devices have the capabilities of both modular and configured systems. Many physiologic monitoring systems include a central station capable of displaying ECG waveforms and other information from any bedside within the system, and many are equipped with alarms that are coordinated with those at the bedside monitor.

Operating steps

Once patients are attached to the appropriate monitoring electrodes/pads, the cables are connected to the physiologic monitor. Then the monitor allows patients' physiologic parameters to be continuously monitored so that changes can be identified and, if necessary, treated. The monitored parameters can be seen at the bedside and (if desired) shared with a central station. System suppliers offer different monitoring options to meet a variety of applications (such as critical care, the operating room, or transport).

Reported problems

Poor electrode preparation and attachment are most commonly reported. Cables and lead wires should be periodically inspected for breaks and cracks. Loss of patient alarms, misleading alarms, and parameter errors have been the causes of most monitor recalls. Even monitors that are functioning reliably cannot substitute for frequent direct observation. Many devices produce frequent "false alarms" which can lead to alarm fatigue and missed critical events.

Use and maintenance

User(s): Physicians, nurses, other medical staff

Maintenance: Biomedical or clinical engineer/ technician, medical staff, manufacturer/ servicer

Training: Initial training by manufacturer, operator's manuals, user's guide

Environment of use

Settings of use: Hospital, inter- and intra-hospital transport; mostly in intermediate care/step down units and in general medical and surgical areas

Requirements: Uninterruptible power source, battery backup, good lead/pad/cable connections

Product specifications

Approx. dimensions (mm): 375 x 275 x 238

Approx. weight (kg): 10

Consumables: Batteries, cables, sensors/ electrodes, cuffs

Price range (USD): 3,000 - 50,000

Typical product life time (years): 7-10

Shelf life (consumables): NA

Types and variations

Bedside mounted, pole mounted, wall mounted, transport, handle

WHO. "Monitor, Physiologic." From the publication: Core Medical Equipment. Geneva, Switzerland, 2011.

World Health Organization http://www.who.int/medical_devices/en/index.html

2. Diagrams and Schematics of Patient Monitors

Featured in this Section:

WHO. "Physiological Monitor." From the publication: "WHO Technical Specifications for 61 Medical Devices. *WHO*. Retrieved from: http://www.who.int/medical_devices/management_use/mde_tech_spec/en/

Figure 1: WHO Specification: Physiological Monitor

MEDICAL DEVICE SPECIFICATION *(Including information on the following where relevant/appropriate, but not limited to)*		
i	Version No.	1
ii	Date of initial version	6/13/12
iii	Date of last modification	6/18/14
iv	Date of publication	
v	Completed / submitted by	WHO working group
NAME, CATEGORY AND CODING		
1	*WHO Category / Code*	(under development)
2	Generic name	Physiological monitor
3	Specific type or variation (optional)	single-patient, bedside
4	GMDN name	Single-patient physiologic monitoring system
5	GMDN code	33586
6	GMDN category	02 Anaesthetic and respiratory devices , 04 Electro mechanical medical devices
7	UMDNS name	Monitors, Bedside, Physiologic
8	UMDNS code	20-170
9	UNSPS code (optional)	
10	Alternative name/s (optional)	Single-patient monitoring system and related equipment; Physiologic monitoring system; Monitoring, bedside unit; Physiologic monitoring system, acute care; Single patient monitoring system
11	Alternative code/s (optional)	S 41036; MS 12636; S 36528; S 12647; S 34377
12	Keywords (optional)	Monitors, Bedside, Physiologic
13	GMDN/UMDNS definition (optional)	An assembly of devices designed for continuous assessment of several vital physiologic parameters (e.g., ECG, blood pressure, heart rate, temperature, cardiac output, apnoea, and respiratory/anaesthetic gas concentrations) of one patient. It typically includes a central station monitor that receives, consolidates, and displays the information, and a bedside patient monitor; it often includes portable radio transmitters, receivers, and antennas (telemetry systems) to allow monitoring of an ambulatory patient. The system is used to evaluate and observe trends in a compromised or unstable patient in intensive or general healthcare settings.
PURPOSE OF USE		
14	Clinical or other purpose	
15	Level of use (if relevant)	District hospital, Provincial hospital, Specialized hospital
16	Clinical department/ward(if	Intensive care unit, Inpatiant ward
17	Overview of functional requirements	Continuous display on screen of patient ECG, respiration and heart rates, invasive / non-invasive blood pressure, body temperature and SpO2 Display to be digital of all active parameters and trace display of at least three selectable parameters Unwanted parameters can be deselected from display Allows display of single, 3 lead ECG or simultaneous display of at least 3 waves selected from up to 12 points Operator can set audiovisual alarm levels for low or high levels of each parameter independently Operates from mains voltage or from internal rechargeable battery ECG patient connectors that are sterilisable and reusable are preferred, though reusable cables that attach to disposable connection patches are also acceptable Hard copy printout of traces will not be required
TECHNICAL CHARACTERISTICS		

WHO. "Physiological Monitor." From the publication: "WHO Technical Specifications for 61 Medical Devices. WHO. Retrieved from: http://www.who.int/medical_devices/management_use/mde_tech_spec/en/

18	Detailed requirements	*Multichannel (up to 12 leads) ECG measurement and selectable display; an extra option for simple five lead connection would be preferred. *Heart rate measurement range to be at least 30 to 250 bpm, with accuracy better than ± 5 bpm and minimum gradation 1 bpm *SpO2 measurement range at least 70 to 99 %, with accuracy better than ± 3% and minimum gradation 1% *Blood pressure monitoring range at least 30 to 300 mmHg, minimum gradation 1 mmHg *Internal pump for cuff inflation for non-invasive blood pressure measurement, with over pressure protection *Temperature probe to be reusable, external skin contact type *Temperature range at least 30 to 40 deg C, minimum gradation 0.1 deg C *Respiration rate measurement range at least 0 to 100 bpm, minimum gradation 1 bpm *Alarm override and temporary silence facility to be included * Automatic and programmable memory. * Storage of at least 24 hours of continuous monitoring data. * Trace signal velocity of at least 25mm/sec. * LCD or TFT screen with: a) analog shape signals and numerical values visualization; b) settable limits for the measured variables; c) not less than 14” wide. * At least 5 simultaneous curves visualization. * Protections of all the functions against defibrillator discharges and electrosurgical units. * Pace-maker detection. * All the cables, sensors and connectors needed for full monitor functionality are to be included in the bid.
19	Displayed parameters	Trend display of each parameter over at least previous 24 hours to be selectable
20	User adjustable settings	User operated 1mV ECG test marker function required Alarm override and temporary silence facility to be included Audiovisual alarms required: high and low levels for each parameter (operator variable settings), sensor / wire / probe disconnected, low battery
PHYSICAL/CHEMICAL CHARACTERISTICS		
21	Components(if relevant)	Case is to be hard and splashproof Display must allow easy viewing in all ambient light levels Supplied in protective case for clean storage and safe transport Wired patient cable connections will be preferred above wireless connection Cable connectors to be designed so as fit correct socket only
22	Mobility, portability(if relevant)	
23	Raw Materials(if relevant)	N/A
UTILITY REQUIREMENTS		
24	Electrical, water and/or gas supply (if relevant)	Power input to be ********** fitted with ********** compatible mains plug Battery powered, silenceable alarm for power failure Internal, replaceable, rechargeable battery allows operation for at least one hour in the event of power failure Battery charger to be integral to mains power supply, and to charge battery during mains power operation of unit Voltage corrector / stabilizer / UPS to allow operation at ± 30% of local rated voltage and one hour operation in the event of mains power failure Electrical protection by resettable circuit breakers in both live and neutral supply lines Mains supply cable to be at least 3m in length Rechargeable battery back-up with: a) at least 1 hour of autonomy without electrical source; b) visual alarm in case of low battery; c) automatic shift from battery to line source and vice-versa; d) unit integrated battery charger. Charger electrical source requirements: Amperage: _____; Voltage: _____; Frequency: _____; Phases: _____. Protections against over-voltage and over-current line conditions. Compliance with _____ electrical standards and regulations.

ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
25	Accessories (if relevant)	12 lead ECG cable 5 lead ECG cable (if option offered) 100 sets of ECG connection electrodes (if disposable type) 5 sets of ECG connection electrodes (if reusable type) 5 tubes electrode gel (if required) Two reusable SpO2 probes each for adult and paediatric use Blood pressure – invasive: one sensor for each channel offered; non-invasive: two each paediatric and adult size reusable cuffs Two external skin temperature probes 1 reusable respiratory sensor and connector set.
26	Sterilization process for accessories (if relevant)	
27	Consumables / reagents (if	
28	Spare parts (if relevant)	Two sets of spare fuses (if non-resettable fuses used)
29	Other components (if relevant)	
PACKAGING		
30	Sterility status on delivery (if relevant)	N/A
31	Shelf life (if relevant)	N/A
32	Transportation and storage (if relevant)	N/A
33	Labelling (if relevant)	N/A
ENVIRONMENTAL REQUIREMENTS		
34	Context-dependent requirements	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
TRAINING, INSTALLATION AND UTILISATION		
35	Pre-installation requirements(if relevant)	
36	Requirements for commissioning (if relevant)	Supplier to perform installation, safety and operation checks before handover Local clinical staff to affirm completion of installation
37	Training of user/s (if relevant)	Training of users in operation and basic maintenance shall be provided Advanced maintenance tasks required shall be documented
38	User care(if relevant)	The case is to be cleanable with alcohol or chlorine wipes Unit layout to enable easy cleaning and sterilization of all surfaces
WARRANTY AND MAINTENANCE		
39	Warranty	
40	Maintenance tasks	
41	Type of service contract	
42	Spare parts availability post-warranty	
43	Software / Hardware upgrade availability	
DOCUMENTATION		
44	Documentation requirements	User and maintenance manuals to be supplied in ********** language. Certificate of calibration and inspection to be provided. List to be provided of equipment and procedures required for local calibration and routine maintenance List to be provided of important spares and accessories, with their part numbers and cost. Contact details of manufacturer, supplier and local service agent to be provided
DECOMMISSIONING		
45	Estimated Life Span	7 years
SAFETY AND STANDARDS		
46	Risk Classification	Class B (GHTF Rule 10);Class II (USA); Class I (EU, Japan, Canada and Australia)
47	Regulatory Approval / Certification	Must be FDA, CE or UL approved product.

48	International standards	ISO 13485:2003 Medical devices -- Quality management systems -- Requirements for regulatory purposes (Australia, Canada and EU) ISO 14971:2007 Medical devices -- Application of risk management to medical devices IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-1-1:2000 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-8 :2012 (Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems) IEC 60601-2-49:2011 (Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment) Optional: IEC 60601-2-23:2011 (Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment) IEC 60601-2-26:2012 (Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs) IEC 60601-2-27:2011 (Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment) IEC 60601-2-34:2011 (Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment) IEC 60601-2-40:1998 (Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment) IEC 60601-2-47:2012 (Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems) IEC 80601-2-30:2009 (Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers) ISO 80601-2-55:2011 (Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors) ISO 80601-2-61:2011 (Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment)
49	Reginal / Local Standards	AAMI/ANSI EC38:2007 (Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems) IEEE Std 11073-10406-2011 (Health informatics - Personal health device communication Part 10406: Device specialization - Basic electrocardiograph) EN 12470-4:2000 Clinical thermometersPerformance of electrical thermometers for continuous measurement JIS T 1115:2005 Non-invasive Automated Sphygmomanometers JIS T 3323:2008 Pressure transducers
50	Regulations	**US regulations** 21 CFR part 820 21CFR section 870.2300 monitor,physiological,patient(without arrhythmia detection or alarms) **JP regulations** MHLW Ordinance No.169 33586002 Multiparameter monitor

3. Preventative Maintenance and Safety of Patient Monitors

Featured in this Section:

Engineering World Health. “Preventative Maintenance Schedule for Patient Monitors. *EWH*. 2012.

Strengthening Specialised Clinical Services in the Pacific. *User Care of Medical Equipment: A first line maintenance guide for end users*. (2015).

Preventative Maintenance for Physiological Monitoring Equipment

Monitor, Physiological

1. Inspect exterior of equipment for damage or missing hardware.
2. Inspect the power cord, strain relief and plug/s for any signs of damage.
3. Turn unit off, open user accessible covers and inspect unit for damage.
4. Clean unit interior components and exterior with vacuum or compressed air.
5. Inspect interior for signs of corrosion or missing hardware. Repair as required.
6. Inspect electrical components for signs of excessive heat or deterioration.
7. Push test button and clear error codes.
8. Verify the accuracy of all parameters using simulators.
9. Verify correct operation of the overview and record functions.
10. Clean air filter as necessary.
11. Verify correct operation of all buttons, controls, displays and/or indicators.
12. Verify correct operation of unit in all functional modalities.
13. Clean exterior of unit including all accessories, cables, controls and displays.

Monitor, Physiological, Neonatal

1. Inspect exterior of equipment for damage or missing hardware.
2. Inspect the power cord, strain relief and plug/s for any signs of damage.
3. Turn unit off, open user accessible covers and inspect unit for damage.
4. Clean unit interior components and exterior with vacuum or compressed air.
5. Inspect interior for signs of corrosion or missing hardware. Repair as required.
6. Inspect electrical components for signs of excessive heat or deterioration.
7. Inspect patient cable and connectors for mechanical or electrical damage.
8. Verify correct detenting and lead shorting of lead selector switch.
9. Verify vertical gain and calibration pulse. Inspect monitor/diagnostic switch.
10. Verify correct operation of temperature monitor.
11. Verify common mode rejection and check ECG mode operation.
12. Verify correct brightness and focus of trace.
13. Verify correct operation of displays and correct response times.

Engineering World Health. "Preventative Maintenance Schedule for Patient Monitors. EWH. 2012.

14. Verify correct operation of freeze and cascade controls if applicable.
15. Verify accuracy of heart rate meter at 3 points for ±3% accuracy.
16. Verify operation of high and low alarms for correct trigger and response time.
17. Cycle alarms and verify correct operation of audio and visual indicators.
18. Verify operation of all recorder drive speeds to be within ±3% accuracy.
19. Verify correct dampening and temperature of writing and marker stylus.
20. Use standard pulse to check sensitivity and decay (frequency response).
21. Inspect condition of drive and idler rollers. Clean off wax build-up.
22. Verify correct signal response. Check at lower, mid and upper positions.
23. Verify timing markers. Check data printer and print head.
24. Verify correct operation of apnea alarm delay, alarm reset & re-arming after reset.
25. Verify accuracy of pressure section, displays, alarms, etc.
26. Verify accuracy of temperature section.
27. Inspect recorder drive belts and chains for damage and verify correct adjustment.
28. Verify correct operation of all buttons, controls, displays and/or indicators.
29. Verify correct operation of unit in all functional modalities.
30. Clean exterior of unit including all accessories, cables, controls and displays.

Monitoring Systems Preventative Maintenance Table

User Care of Medical Equipment – First line maintenance for end users

User Care Checklist – Electronic Diagnostic/Monitoring Equipment

Daily	
Cleaning	✓ Wipe dust off exterior ✓ Remove any tape, gel, paper or foreign body from equipment
Visual checks	✓ Check all fittings and accessories are mounted correctly ✓ Check there are no cracks in covers or liquid spillages
Function checks	✓ If in use that day, run a brief function check before clinic ✓ Cover equipment after checks

Weekly	
Cleaning	✓ Unplug, clean outside with damp cloth and dry off ✓ Clean any filters or covers as directed by user manual
Visual checks	✓ Check all screws and parts are fitted tightly ✓ Check mains plug screws are tight ✓ Check mains cable has no bare wire and is not damaged
Function checks	✓ Check any paper, oil, batteries etc. required are sufficient ✓ Check all switches operate correctly

Every six months
Biomedical Technician check required

4. Troubleshooting and Repair of Patient Monitors

Featured in this Section:

Strengthening Specialised Clinical Services in the Pacific. *User Care of Medical Equipment: A first line maintenance guide for end users*. (2015).

Monitoring Systems Troubleshooting Table

User Care of Medical Equipment – First line maintenance for end users

Troubleshooting – Electronic Diagnostic/Monitoring Equipment

	Fault	Possible Cause	Solution
1.	Equipment is not running	No power from mains socket	Check power switch is on. Replace fuse with correct voltage and current rating if blown. Check mains power is present at socket using equipment known to be working. Contact electrician for rewiring if power not present.
		Electrical cable fault	Try cable on another piece of equipment. Contact electrician for repair if required.
2.	Fuse keeps blowing	Power supply or cable fault	Refer to electrician
3.	Equipment not fully operational	Part malfunction	Check controls for correct positioning and operation (refer to user manual) Check all bulbs, heaters and connectors for function. Repair or replace if necessary. Check patient connection, using gel, pads or straps as directed in user manual.
4.	Signals erratic or large	Reference connection loose	Check reference connection for good contact
		Wire broken inside cable (due to bending or crushing)	Replace with spare cable
		Dirt build up on electrodes or contacts	Clean as instructed in the user manual
5.	Electrical shocks	Wiring fault	Refer to electrician

SECTION B:
Blood Pressure Monitors

5. Operation, Use, and Maintenance of Blood Pressure Monitors

Featured in this Section:

Cooper, Justin and Alex Dahinten for EWH. "Blood Pressure Monitor Preventative Maintenance." From the publication: *Medical Equipment Troubleshooting Flowchart Handbook*. Durham, NC: Engineering World Health, 2013.

Cooper, Justin and Alex Dahinten for EWH. "Blood Pressure Monitor Troubleshooting Flowchart." From the publication: *Medical Equipment Troubleshooting Flowchart Handbook*. Durham, NC: Engineering World Health, 2013.

WHO. "Blood Pressure Monitor." From the publication: *Core Medical Equipment*. Geneva, Switzerland, 2011.

Blood pressure monitor

Brief Introduction to Blood Pressure Monitors

UMDNS		GMDN	
18325	Sphygmomanometers, Electronic, Automatic, Auscultatory	16173	Automatic-inflation electronic sphygmomanometer, non-portable
18326	Sphygmomanometers, Electronic, Automatic, Oscillometric		
25209	Monitors, Physiologic, Vital Signs		

Other common names:
Vital signs monitoring units; noninvasive blood pressure (NIBP) monitors; auscultatory sphygmomanometers; oscillometric sphygmomanometers; oscillotonometers, spot check monitors; spot checking; Recorder, sphygmomanometer, automatic

Health problem addressed

NIBP is an essential indicator of physiologic condition. As one of the most frequently used diagnostic tests, it indicates changes in blood volume, the pumping efficiency of the heart, and the resistance of the peripheral vasculature. Vital signs monitors are used to measure basic physiologic parameters so that clinicians can be informed of changes in a patient's condition. Depending on their configuration, these units can measure and display numerical data for NIBP, oxygen saturation, and temperature.

Product description

Automatic electronic sphygmomanometers noninvasively measure and display a patient's arterial blood pressure. The main unit includes controls and a display; it also includes appropriate attached cuffs, probes, and sensors that make possible sequential and/or simultaneous measurements of the parameters. Some of the NIBP monitors can be used as vital sign monitors with the real-time measuring and display of two or more of the vital signs. These monitors typically consist of portable or mobile electronic units. The monitor may be connected to the line and/or powered by internal batteries. Many devices may also perform continuous monitoring during transportation or at the bedside. Vital signs physiologic monitors are intended mainly for periodic automated measuring of the parameters of one or more patients.

Principles of operation

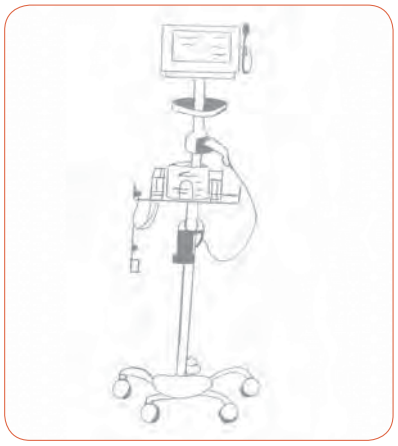
Automatic electronic sphygmomanometers (NIBP monitors) measure by the use of sound and detection of blood sound turbulence (Korotkoff sounds). A microphone positioned against an artery compressed by the device cuff detects the Korotkoff sounds, enabling the unit to directly determine systolic and diastolic values blood pressure values. NIBP is usually measured using cuffs and either auscultatory or oscillometric techniques. The measurement of temperature is typically accomplished using an intraoral sensor, and SpO2 is determined using pulse oximetry sensors. These monitors typically consist of portable or mobile electronic units that facilitate movement from one location to other; the monitor may be connected to the line and/or powered by internal batteries.

Operating steps

The cuffs, probes, and sensors are attached to the patient, and then the monitor will begin taking intermittent or continuous measurements as selected by the clinician. The devices may remain at a patient's bedside or can be transported by a caregiver for vital signs spot checking throughout a care area. Alarms (e.g., for high blood pressure or low oxygen saturation) can typically be set by caregivers and can be manually temporarily silenced.

Reported problems

Problems associated with monitors are often user-related. Poor cuff placement or sensor preparation and attachment are most commonly reported. Cables and lead wires should be periodically inspected for breaks and cracks. Automatic



electronic sphygmomanometry and pulse oximeters may have the inability to effectively monitor patients with certain conditions (e.g., tremors, convulsions, abnormal heart rhythms, low blood pressure)

Use and maintenance

User(s): Physicians, nurses, other medical staff

Maintenance: Biomedical or clinical engineer/ technician, medical staff, manufacturer/ servicer

Training: Initial training by manufacturer, operator's manuals, user's guide

Environment of use

Settings of use: Hospital (all areas), ambulatory surgery centers

Requirements: Battery, uninterruptible power source, appropriate cuffs/sensors

Product specifications

Approx. dimensions (mm): 100 x 150 x 200

Approx. weight (kg): 3

Consumables: Batteries, cables, sensors/ electrodes, cuffs

Price range (USD): 580 - 4,500

Typical product life time (years): 10

Shelf life (consumables): NA

Types and variations

Roll stand, portable, pole or bed mounts

WHO. "Blood Pressure Monitor." From the publication: Core Medical Equipment. Geneva, Switzerland, 2011.

Blood Pressure Monitor Preventative Maintenance

Equipment

Blood Pressure Monitor

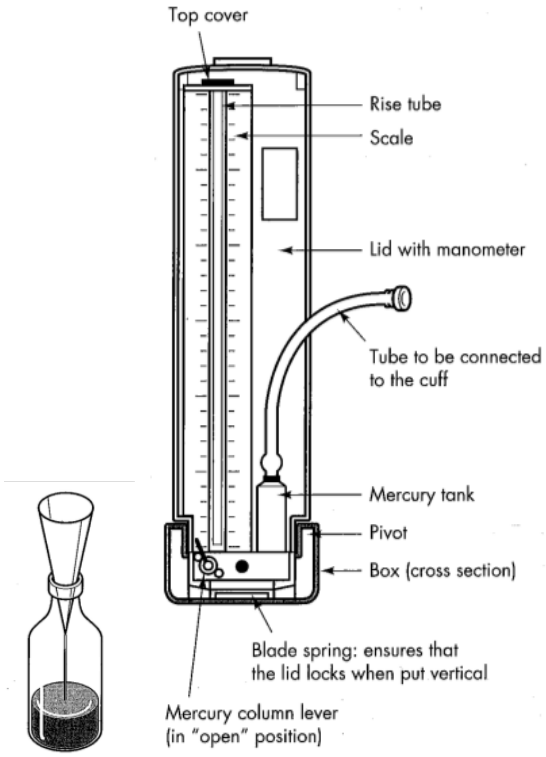
Preventative Maintenance

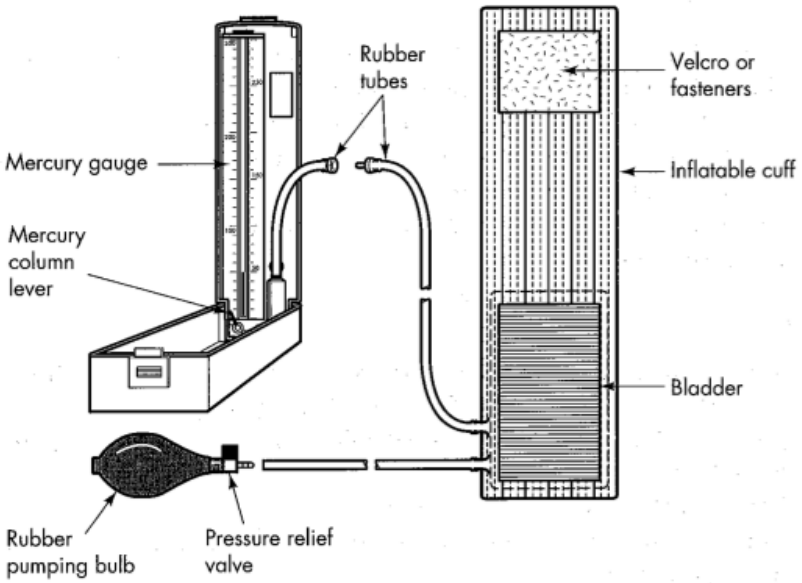
How To: Dissemble a Mercury Manometer

- Remove the cuff and tubing from the mercury apparatus
- Open the mercury column lever, and tilt the apparatus back to allow any mercury in the column to run into the reservoir
- Remove the tank cover (usually using a screwdriver)
- Remove all mercury from the tank using a syringe
- Pour mercury into a clearly labeled container, following proper protocol
- Remove cover over the rise tube (usually using a screwdriver)
- Take out the rise tube

How To: Clean Mercury

- Roll a sheet of paper into a funnel
- The pointed end should have a tiny hole
- Put the funnel in a bottle
- Pour the mercury into the funnel and let pass through





How To: Take Blood Pressure

1. Prepare the patient. ○ Sitting down

○ Arm unobstructed

○ Ask about blood pressure history

2. Wrap the cuff around the upper arm with leads facing the brachial artery.

Should be about level with the heart. Be sure that it is the proper cuff size for the patient's arm.

3. Put on stethoscope. Listen to the brachial artery very close to the cuff.

4. Ensure that the knob is turned completely clockwise.

5. Pump the cuff to a high pressure (for adults: 160-180 mmHg, for children: 140 mmHg)

6. Carefully turn the knob counterclockwise to release the pressure in the cuff at a slow rate.

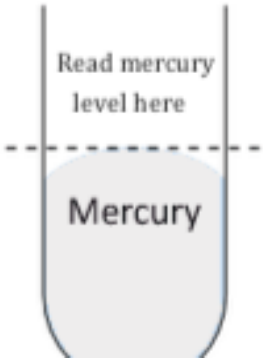
7. Look at the pressure on the dial while listening to the heartbeat through the stethoscope.

8. Obtain and record the blood pressure.

○ Systolic: the pressure at which you start to hear the heart beat ○ Diastolic: the pressure at which you stop hearing the heart beat

Examples of ranges for healthy blood pressures:

Age	**BP (Systolic/ Diastolic)**
Child, <6 months	90-105/70
Child, 6 months to 7 years	105-117/70
Adult	120/80

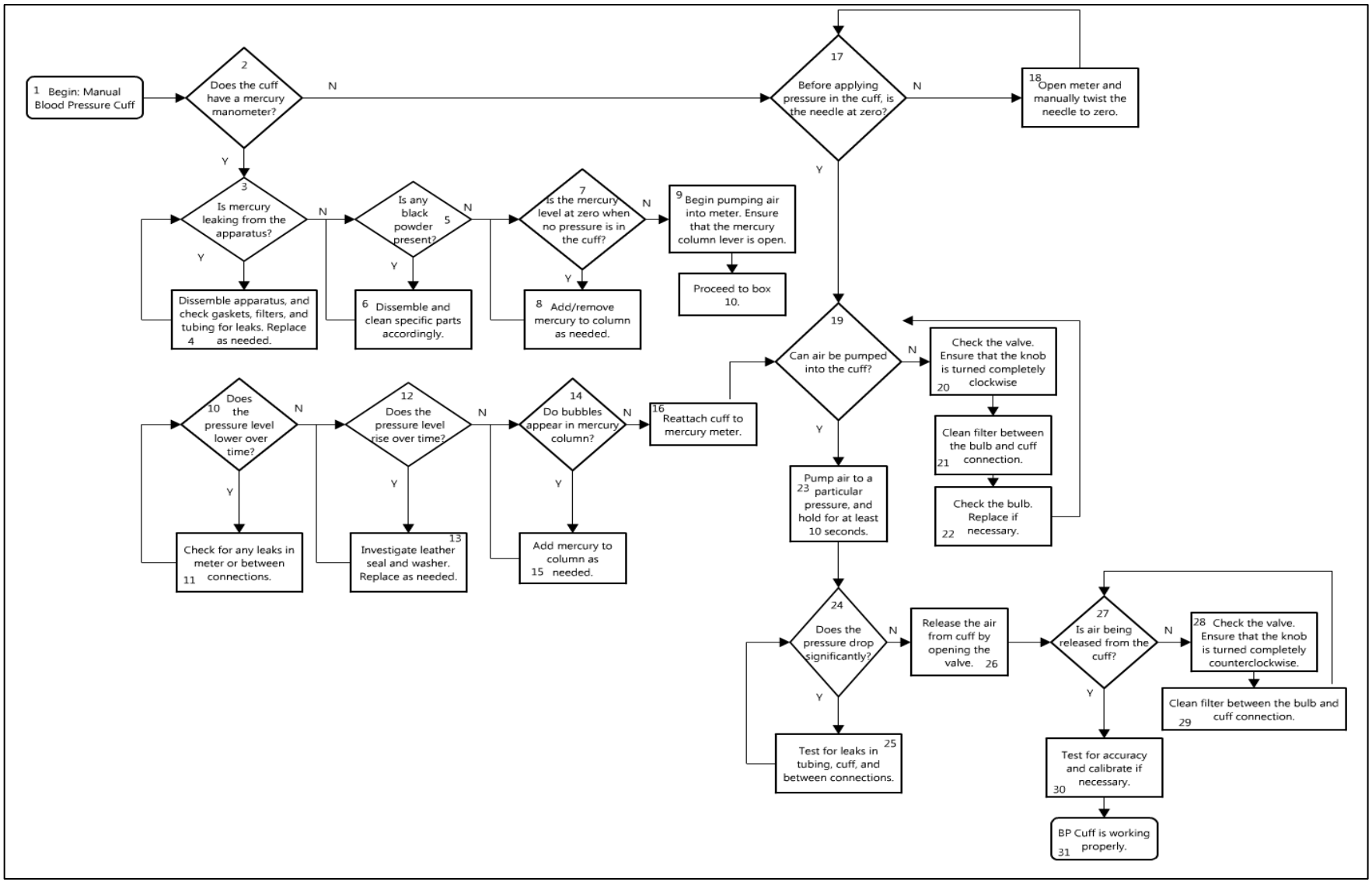


How To: Mercury-Handling Protocol

- When exposed to air, mercury vaporizes and is extremely poisonous
- Always handle mercury while wearing rubber gloves
- Work with mercury outside or in a well-ventilated area
- Recover mercury with a large syringe
- When storing mercury, add some water to prevent evaporation
- Always have an airtight cover on a mercury container
- Wash skin thoroughly if it comes into contact with mercury

Blood Pressure Monitor Troubleshooting and Repair Flowchart

Blood Pressure Monitor (Manual) Flowchart:



Cooper, Justin and Alex Dahinten for EWH. "Blood Pressure Monitor Troubleshooting Flowchart." From the publication: Medical Equipment Troubleshooting Flowchart Handbook. Durham, NC: Engineering World Health, 2013.

Description

#	Text Box	Comments
1	Begin: Manual Blood Pressure Cuff	Testing and maintenance is advised when the manual cuff fails to give out a complete or accurate blood pressure.
2	Does the cuff have a mercury manometer?	There are two types of manual blood pressure cuffs, one with a mercury manometer and an aneroid sphygmomanometer with just a small pressure dial.
3	Is mercury leaking from the apparatus?	If there is any mercury escaping the reservoir, proceed with extreme caution and **follow mercury-handling protocols.** See BTA skills for Leaking and Blockages.
4	Disassemble apparatus and check gaskets, filters, and tubing for leaks. Replace as needed.	Disassemble the apparatus (follow protocol below).Assess each part for any leaks and cracks. Replace or repair faulty parts as necessary. See BTA skills on Plumbing and Mechanical.
5	Is any black powder present?	The black powder is oxidized mercury and needs to be removed.
6	Disassemble and clean specific parts accordingly.	Disassemble the apparatus (follow protocol below) If oxide is in rise tube and mercury tank: -Using a stiff wire, push a small piece of cotton or gauze through the rise tube several times -Gently tap mercury tank (with opening facing downwards) onto tray to make sure all mercury has been removed -Wash tube and tank in a detergent and water solution -Dry thoroughly -Clean mercury using protocol below

Cooper, Justin and Alex Dahinten for EWH. "Blood Pressure Monitor Troubleshooting Flowchart." From the publication: Medical Equipment Troubleshooting Flowchart Handbook. Durham, NC: Engineering World Health, 2013.

7	Is the mercury level at zero when no pressure is in the cuff?	Meter should be at zero when no pressure is applied.
8	Add/remove mercury to column as needed.	**Follow mercury-handling protocol.** Any added mercury can be taken from another existing meter that doesn't work correctly or isn't in use.
9	Begin pumping air into meter. Ensure that the mercury column lever is open.	If possible, disassemble tubing, and attach the bulb and its tubing to the meter so that the cuff is not involved in meter testing. Be sure that the mercury column lever is open, or else no mercury will come up the rise tube.
10	Does the pressure level lower over time?	The mercury level will fall if there are any cracks or leaks.
11	Check for any leaks in meter or between connections.	Use BTA skills on Leaking and Seals to assess for cracks or leaks.
12	Does the pressure level rise over time?	Leather seal and washer may be cracked/broken.
13	Investigate leather seal and washer. Replace as needed.	Use BTA skills to assess for cracks or leaks. Leather seal and washer will usually need to be replaced. See BTA skills on Leaking, Seals and Connections.
14	Do bubbles appear in mercury column?	Small air pockets will form if not enough mercury is in the tank.
15	Add mercury to column as needed.	**Follow mercury-handling protocol.** Any added mercury can be taken from another existing meter that doesn't work correctly or isn't in use.
16	Reattach cuff to mercury meter.	Reassemble cuff to meter if the apparatus was dissembled in step 9.

Cooper, Justin and Alex Dahinten for EWH. "Blood Pressure Monitor Troubleshooting Flowchart." From the publication: Medical Equipment Troubleshooting Flowchart Handbook. Durham, NC: Engineering World Health, 2013.

17	Before applying pressure in the cuff, is the needle at zero?	Needle in the dial should be at zero when no pressure is applied.
18	Open meter and manually twist the needle to zero.	Screw off dial cover and use a screwdriver to loosen or remove needle. Reassemble once needle is back at zero.
19	Can air be pumped into the cuff?	Try putting cuff around your arm or a bottle before pumping air. Is there difficultly in pushing air into the cuff? Does it deflate immediately?
20	Check the valve. Ensure that the knob is turned completely clockwise.	Valve must be turned completely clockwise to inflate the cuff.
21	Clean filter between the bulb, valve, and cuff connection.	Remove the valve from the bulb and cuff tubing. Use a screwdriver to scrape out any dirt in valve connection, or see BTA skills on Blockages Reassemble bulb, valve, and cuff tubing.
22	Check the bulb. Replace if necessary.	Is the bulb able to pump air? Are there any holes or leakage in the bulb? Repair with silicon if possible. Bulbs will typically need to be replaced. See BTA skills on Seals and Leaking.
23	Pump air to a particular pressure and hold for at least 10 seconds.	Pump air to a pressure of approximately 180 mmHg for a human arm.
24	Does the pressure drop significantly?	If the pressure drops more than 5 mmHg in 10 seconds, there is probably a leak.
25	Test for leaks in tubing and between connections.	Use BTA skills for cracks or leaks.
26	Release the air from cuff.	Turn knob completely counterclockwise.
27	Is air being released from the cuff?	You will hear air being released from the valve, and the cuff should deflate with no difficulty.

Cooper, Justin and Alex Dahinten for EWH. "Blood Pressure Monitor Troubleshooting Flowchart." From the publication: Medical Equipment Troubleshooting Flowchart Handbook. Durham, NC: Engineering World Health, 2013.

28	Check the valve. Ensure that the knob is turned completely counterclockwise.	Valve must be turned completely clockwise to deflate the cuff.
29	Clean filter between the bulb and cuff connection.	Remove the valve from the bulb and cuff tubing. Use a screwdriver to scrape out any dirt in valve connection, or see BTA skills on Blockages. Reassemble bulb, valve, and cuff tubing.
30	Test for accuracy and calibrate if necessary.	Use BTA skills on Calibration to calibrate sphygmometer.
31	BP cuff is working properly.	Return apparatus to appropriate clinical staff.

SECTION C:
Oxygen Monitors

6. Operation, Use, and Maintenance of Oxygen Monitors

Featured in this Section:

Developing World Healthcare Technology Laboratory. “Oxygen Monitors.” From the Publication: “Biomedical Technicians Training Program, Session 3 v2, Special Topics: Cardiac Equipment.” *Engineering World Health*, March 1, 2011, p. 1-161.

Engineering World Health. “Preventative Maintenance Schedule for Oxygen Monitors. *EWH*. 2012.

Oxygen Monitors

An oxygen monitor displays oxygen concentrations from zero to 100 percent. It produces audible and visual alarms to indicate:

- That the displayed value is greater than or less than operator selected high O_2 or low O_2 alarm limits.
- that the sensor is disconnected or defective
- that the batteries require replacement

The monitor uses a galvanic sensor that produces a current proportional to the oxygen concentration (partial pressure) at its sensing surface. The sensor does not require special attention and can be replaced without tools.

CAUTION: The oxygen monitor contains electronic components that are susceptible to damage by electrostatic discharge. Always work at a static control workstation. Handle the circuit board by its nonconductive edges and use an anti-static container for transport. Before servicing the monitor, properly ground yourself (and any tool you are using) by wearing a static control wrist strap to discharge accumulated static charges.

Troubleshooting procedures

The best troubleshooting tool is a thorough understanding of what the monitor does and how it does it. Refer to the Operation and Maintenance Manual to learn what the monitor does.

Let the symptoms be your guide. If only a single function is not working, concentrate on the block(s) schematic that controls the function. If several symptoms are present, locate a block that serves multiple functions (such as power supply or hybrid). The following section will guide you in troubleshooting the suspected block.

Functional Description

Refer to the block diagram for an overview of the various systems that make up the oxygen monitor's circuitry. The position of each block, relative to the hybrid, is in the location of the circuitry as it appears on the overall schematic.

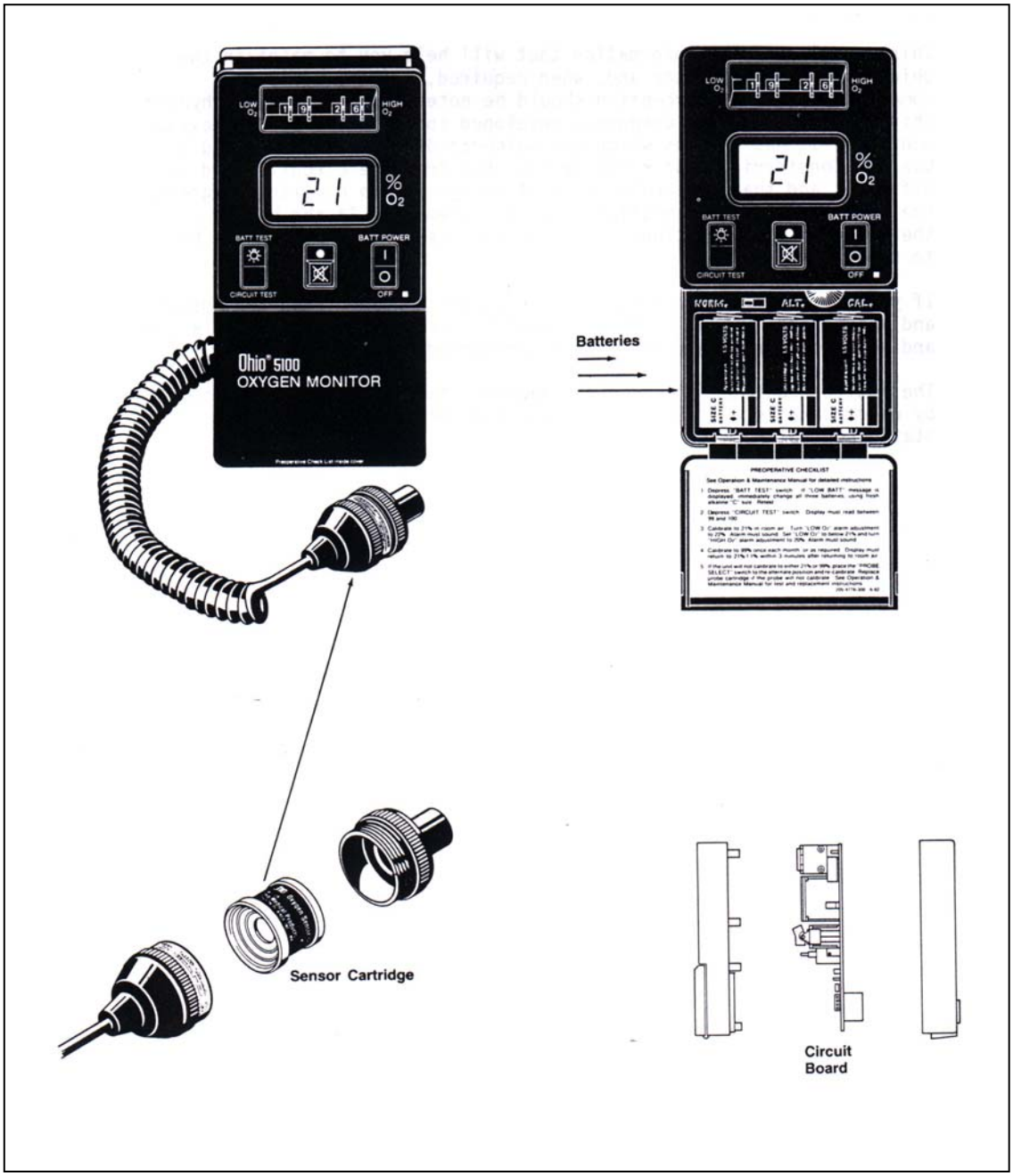
A. The POWER SUPPLY boosts the relatively low voltage produced by three "C" cells (4.5 volts nominal) and regulates it to the 9.5 volts (V+) required by the circuitry throughout the monitor.

B. The BATTERY/POWER SUPPLY TEST circuit continuously monitors the voltage produced by the batteries. When the battery voltage falls to a design-determined threshold the battery check circuitry signals the HYBRID to generate a first level, low battery alarm that is a flashing LOW BATT

Developing World Healthcare Technology Laboratory. "Oxygen Monitors." From the Publication: "Biomedical Technicians Training Program, Session 3 v2, Special Topics: Cardiac Equipment." Engineering World Health, March 1, 2011, p. 1-161.

message on the display. When the battery voltage falls further to a second threshold the HYBRID shuts down the operation of the monitor and generates a high level alarm: the display reading is set to zero, an oscillating two0tone alarm sounds, and the alarm indicator (along with the LOW BATT message) flashes.

C. The CRYSTAL OSCILLATOR produces a clock signal that controls the logic processes within the hybrid.



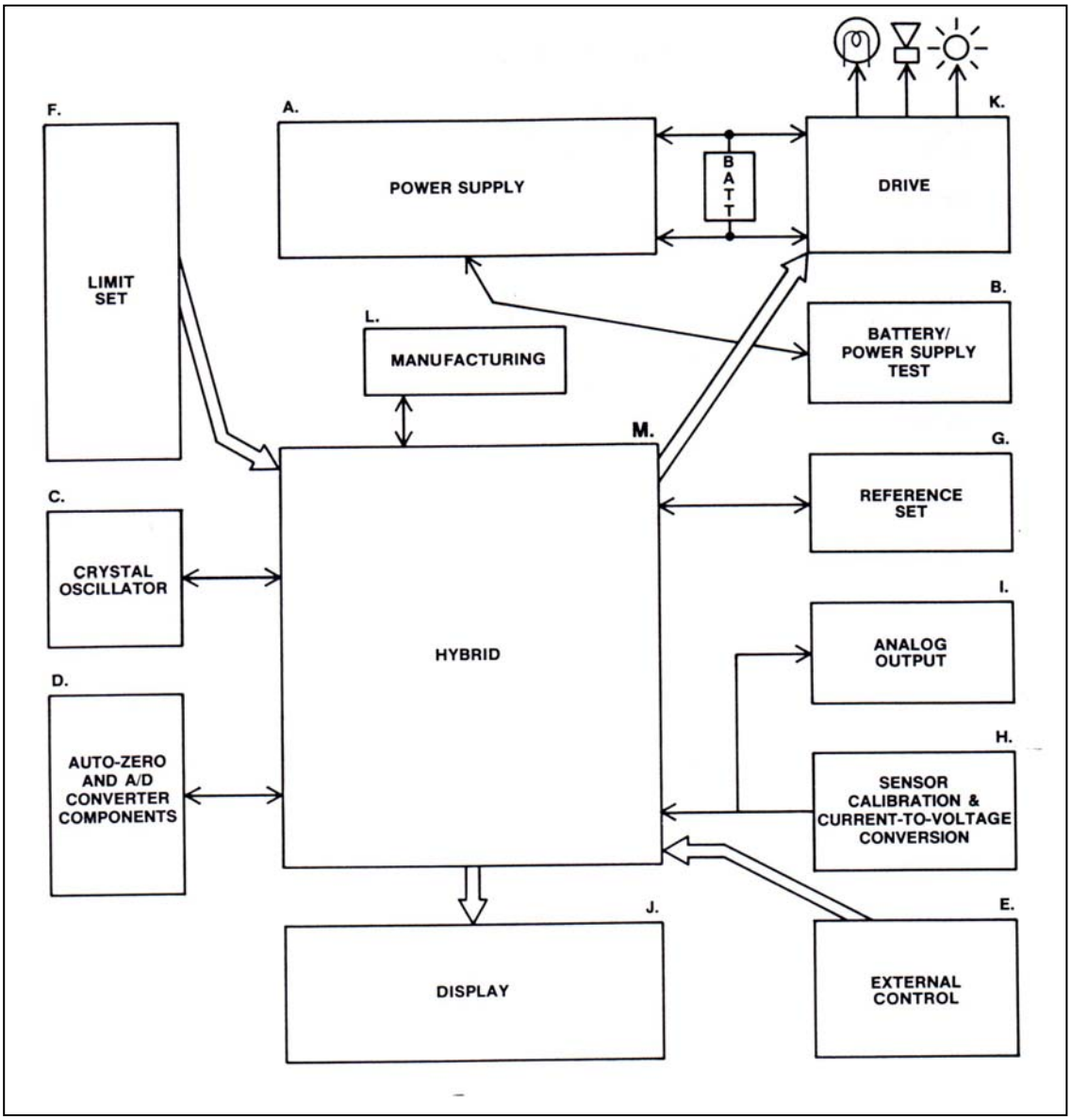
Oxygen monitor

Developing World Healthcare Technology Laboratory. "Oxygen Monitors." From the Publication: "Biomedical Technicians Training Program, Session 3 v2, Special Topics: Cardiac Equipment." Engineering World Health, March 1, 2011, p. 1-161.

D. The hybrid chip contains an analog-to-digital converter (A/D). The AUTO-ZERO AND A/D CONVERTER COMPONENTS, which could not be integrated on the chip, complete the function of the A/D converter.

E. The EXTERNAL CONTROL represents the switches that "tell" the HYBRID what function to implement: Such as BATT TEST (☼), CIRCUIT TEST, and SILENCE.

F. The hybrid chip monitors the LIMIT SET block to determine for which values of % O_2 to generate the HIGH O_2 or LOW O_2 alarms. The HYBRID also monitors these switches for LOW O_2 set to "Less than 18" and High O_2 set to "zero".



Block Diagram – Oxygen monitor

Developing World Healthcare Technology Laboratory. "Oxygen Monitors." From the Publication: "Biomedical Technicians Training Program, Session 3 v2, Special Topics: Cardiac Equipment." Engineering World Health, March 1, 2011, p. 1-161.

G. The REFERENCE SET circuitry generates a calibrated voltage that the HYBRID interprets as 100% O_2.

H. The oxygen sensor produces a current that is proportional to the oxygen concentration at its sensing surface. The SENSOR CALIBRATION AND CURRENT-TO-VOLTAGE CONVERSION circuit converts this current to a calibrated voltage which the HYBRID interprets as a corresponding percent of oxygen.

I. The calibrated sensor voltage is buffered and scaled by the ANALOG OUTPUT circuitry. A 20% O_2 dislay results in a 200 mV output at the rear housing connector for remote monitoring (10 mV per % O_2).

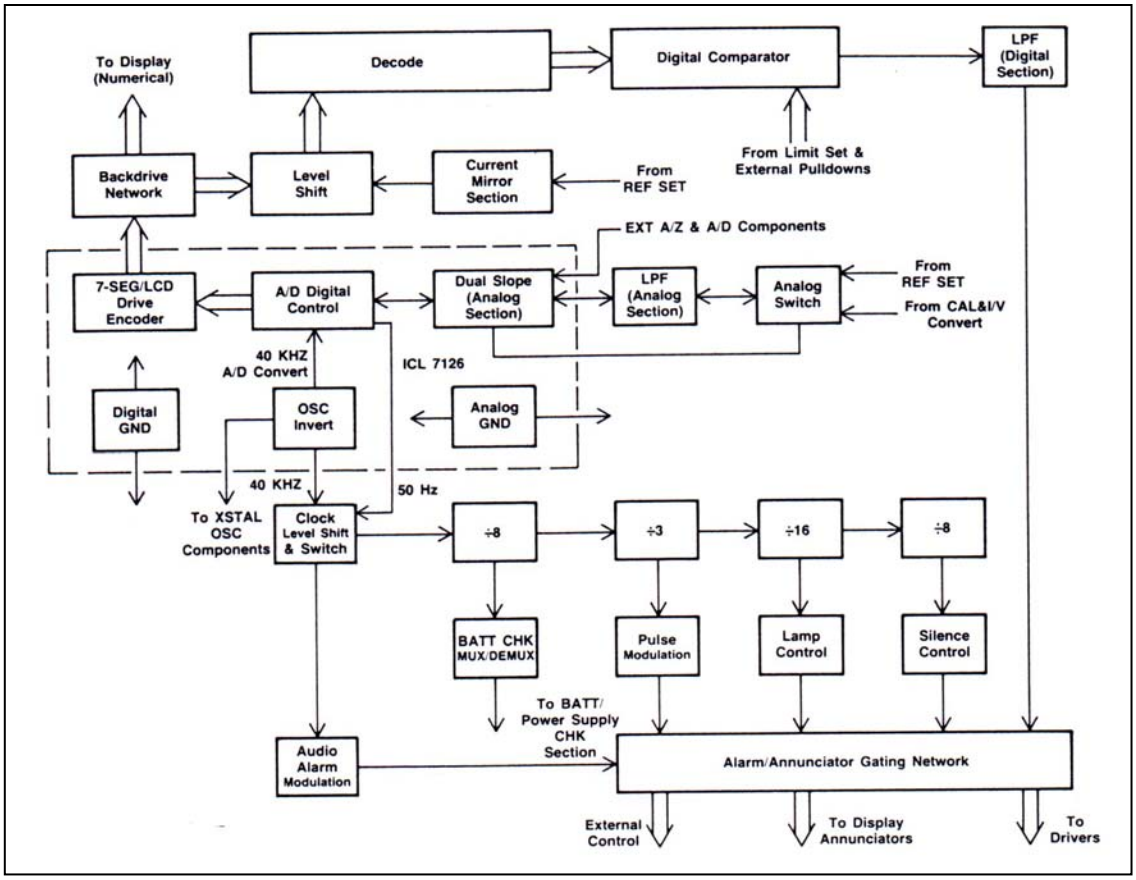
J. The hybrid chip interprets all the inputs from the functional sections discussed so far and sends appropriate signals to the DISPLAY section to generte the displays corresponding to the input conditions. The display is a liquid crystal type (LCD) that includes seven-segment disgits and formed messages.

K. In addition to controlling the display, the HYBRID produces outputs to DRIVE the backlights, the audible alarm, and the alarm indicator (LED).

L. Two input lines to the hybrid chip are used by MANUFACTURING to facilitate production testing.

M. As previously noted, the HYBRID is the central component in the oxygen monitor system. The other functional blocks either input signals to the HYBRID or receive processed signals from it to drive the display, the messages, and the visual and audible alarms.

Developing World Healthcare Technology Laboratory. "Oxygen Monitors." From the Publication: "Biomedical Technicians Training Program, Session 3 v2, Special Topics: Cardiac Equipment." Engineering World Health, March 1, 2011, p. 1-161.



Hybrid section

The Hybrid Section provides A/D conversion of the external sensor signal, display/annunciator drive, and all digital timing and control functions associated with the instrument. The hybrid circuit consists of an ICL 7126 A/D converter chip, a custom gate-array CMOS chip, four ceramic chip capacitors, 20 thick-film resistors, and all associated screened interconnects.

Developing World Healthcare Technology Laboratory. "Oxygen Monitors." From the Publication: "Biomedical Technicians Training Program, Session 3 v2, Special Topics: Cardiac Equipment." Engineering World Health, March 1, 2011, p. 1-161.

Preventative Maintenance for Oxygen, Carbon Dioxide, and Blood Gas Monitors

Monitor, Oxygen

1. Inspect exterior of equipment for damage or missing hardware.
2. Inspect the power cord, strain relief and plug/s for any signs of damage.
3. Turn unit off, open user accessible covers and inspect unit for damage.
4. Clean unit interior components and exterior with vacuum or compressed air.
5. Inspect interior for signs of corrosion or missing hardware. Repair as required.
6. Inspect electrical components for signs of excessive heat or deterioration.
7. Inspect sensor and cable assembly. Inspect alarms and batteries.
8. Verify calibration using 21% and 100% standards.
9. Inspect sensing element (membrane, gel, fuel cell, etc.). Replace per mfr. specs.
10. Verify correct operation of alarms and remote signaling systems if present.
11. Verify correct operation of all buttons, controls, displays and/or indicators.
12. Verify correct operation of unit in all functional modalities.
13. Clean exterior of unit including all accessories, cables, controls and displays.

Monitor, Carbon Dioxide

1. Inspect exterior of equipment for damage or missing hardware.
2. Inspect the power cord, strain relief and plug/s for any signs of damage.
3. Turn unit off, open user accessible covers and inspect unit for damage.
4. Clean unit interior components and exterior with vacuum or compressed air.
5. Inspect interior for signs of corrosion or missing hardware. Repair as required.
6. Inspect electrical components for signs of excessive heat or deterioration.
7. Verify that the unit's power passes on auto test.
8. Using sensor simulator box, check operation and calibration of unit.
9. Verify calibration, referring to service manual as required.
10. Verify correct operation of all buttons, controls, displays and/or indicators.
11. Verify correct operation of unit in all functional modalities.
12. Clean exterior of unit including all accessories, cables, controls and displays.

Monitor, Blood Gas, Carbon-Dioxide

1. Inspect exterior of equipment for damage or missing hardware.
2. Inspect the power cord, strain relief and plug/s for any signs of damage.
3. Turn unit off, open user accessible covers and inspect unit for damage.
4. Clean unit interior components and exterior with vacuum or compressed air.
5. Inspect interior for signs of corrosion or missing hardware. Repair as required.
6. Inspect electrical components for signs of excessive heat or deterioration.
7. Verify calibration using correct controls and standards.
8. Verify correct operation of all buttons, controls, displays and/or indicators.
9. Verify correct operation of unit in all functional modalities.
10. Clean exterior of unit including all accessories, cables, controls and displays.

SECTION D:
Respiratory Monitors

7. Operation, Use, and Maintenance of Respiratory Monitors

Featured in this Section:

Cooper, Justin and Alex Dahinten for EWH. “Respiratory Monitor Preventative Maintenance.” From the publication: *Medical Equipment Troubleshooting Flowchart Handbook*. Durham, NC: Engineering World Health, 2013.

Cooper, Justin and Alex Dahinten for EWH. “Respiratory Monitor Troubleshooting Flowchart.” From the publication: *Medical Equipment Troubleshooting Flowchart Handbook*. Durham, NC: Engineering World Health, 2013.

Malkin, Robert. *Medical Instrumentation in the Developing World*. Engineering World Health, 2006.

WHO, “Apnea Monitor.” *WHO*. From the publication: *Core Medical Equipment*. Geneva, Switzerland, 2011.

Apnea Monitors **Brief Introduction to Apnea Monitors**

UMDNS	GMDN
12575 Monitors, Bedside, Respiration, Apnea	35194 Respiratory apnoea monitoring system

Other common names:
Cardiorespiratory monitors; Monitor, recording, apnoea

Health problem addressed

Apnea monitors detect the cessation of breathing (apnea) in infants and adults who are at risk of respiratory failure and alert the parent or attendant to the condition. Some prolonged respiratory pauses result in low oxygen concentration levels in the body, which can lead to irreversible brain damage and, if prolonged, death.

Product description

The components of apnea monitors depend specifically on the type. However, in general they are composed of a set of sensors which obtain the information of different physiological parameters. This information is passed to a micro computer system, which analyses the sensors' information and determines if apnea is occurring.

Principles of operation

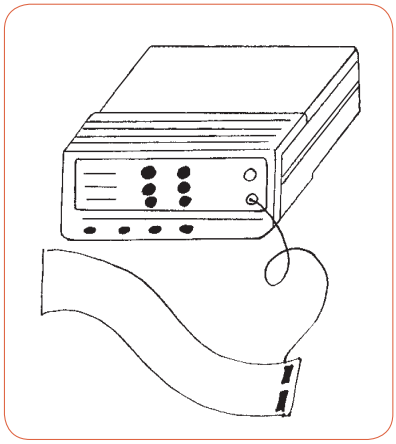
Monitors that use impedance pneumography detect small changes in electrical impedance as air enters and leaves the lungs and as the blood volume changes in the thoracic cavity. Mattress-type motion sensors typically monitor changes in the capacitance or resistance of a mattress transducer. Pneumatic abdominal sensors also detect breaths as changes in pressure. More direct methods of respiration detection monitor the airflow into and out of the lungs; these include thermistors, proximal airway pressure sensors, and carbon dioxide (CO2) sensors.

Operating steps

The apnea monitor is attached to the patient using appropriate sensor for the measurement technique (e.g., mattress motion sensor, pneumatic abdominal sensors, thermistors, proximal airway pressure sensors, carbon dioxide (CO2) sensors, cannula). Once connected, as the patient breathes, the unit monitors different body parameters. If an alarm sounds, the operator must attend the patient immediately.

Reported problems

Apnea monitors may fail to alarm during an episode because they sense artifact (artifacts include vibrations, heart activity, patient movement). Electromagnetic emissions from electronic devices (other electronics or equipment) can also cause interference, possibly leading to false breath and heartbeat detection. Impedance pneumographs are more subject to cardiovascular artifact. Misinterpreting impedance changes because of heartbeats perceived as breaths frequent when instrument sensitivity is not adjusted.



Use and maintenance

User(s): Nurse, medical staff, home care providers

Maintenance: Biomedical or clinical engineer/ technician, medical staff, manufacturer/ servicer

Training: Initial training by manufacturer, operator's manuals, user's guide

Environment of use

Settings of use: Hospital, home, ambulatory care center, nursery

Requirements: Uninterruptible power source, battery backup

Product specifications

Approx. dimensions (mm): 150 x 120 x 120

Approx. weight (kg): 0.75

Consumables: Batteries, cables, electrodes/ sensors

Price range (USD): 200 - 5,000

Typical product life time (years): 8

Shelf life (consumables): NA

Types and variations

Stand-alone, modular

WHO, "Apnea Monitor." WHO. From the publication: Core Medical Equipment. Geneva, Switzerland, 2011.

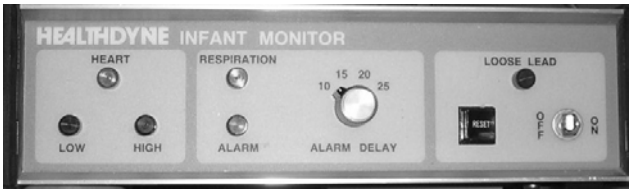
Operation and Use of Respiratory Monitors

2.13 Respiration Rate Meter or Apnea Monitor

2.13.1 Clinical Use and Principles of Operation

Apnea is defined as the cessation of respiratory air flow. The air may have ceased to flow because the patient has stopped trying to breathe (central or diaphragmatic apnea) or because the airway is blocked (obstructive apnea). The two types of apnea are clinically treated quite differently. Obstructive apnea is typically caused by chocking on food or another object. Episodes of central apnea are somewhat common in children and often disappear as the child develops. However, in severe cases, neonates and babies can be kept on apnea monitors for up to one year. When Sudden Infant Death Syndrome (SIDS) is feared, the physician may prescribe continuous apnea monitoring.

An apnea monitor is a device used to monitor a patient's respiration rhythm and often cardiac activity and oxygen saturation. Most monitors will attempt to distinguish between central and obstructive apnea, sounding an alarm if either is prolonged. Most monitors run on both batteries and line power.



This stand-alone apnea monitor would be unusual to find in the developing world. Most apnea monitors are respiration rate meters incorporated into a vital signs monitor.

Transthoracic Electrical Impedance

The most popular type of apnea monitoring is based on transthoracic electrical impedance. To use this device, electrodes are placed in the 5th intercostal space on each side of the neonate. A signal of 55kHz at 2 to 3 mV is injected into the electrodes and the impedance of the chest is measured. As the chest expands during inspiration, the impedance increases. During expiration, the impedance decreases. Simultaneously, the impedance electrodes are used to monitor the ECG.

It is possible for the monitor to read a false positive (presence of breathing when there is none) because it can be fooled by muscle movement. False negatives can occur if the chest motion is slight or in the presence of excessive electrical noise. Despite the popularity of this monitor, it is not effective at distinguishing between obstructive and central apnea.

Pneumatic Abdominal Sensor

Unlike the transthoracic apnea monitor, the abdominal monitor measures the motion of the abdomen. However, the impedance of the abdomen does not tend to change, as the cavity is not filled with air. Therefore, the abdominal sensor operates by detecting the increased circumference of the abdomen, typically with a linear variable displacement transducer (LVDT) or other displacement transducer.

Thermistors and Pressure Sensors

Neither the thoracic nor the abdominal apnea monitor can distinguish between central and obstructive apnea. Currently, only the thermistor and proximal airway pressure sensing apnea monitors can make this distinction. Neither is likely to be found in the developing world. A thermistor monitor measures the temperature of the air entering or exciting the nostrils. A proximal airway pressure sensor measures the change in pressure at the mouth and nose.

2.13.2 Common Problems

The most frequent source of error is caused by false alarms. The worst case is when an apnea monitor fails to alarm during apnea because it senses artifact and interprets it as respiration (false negative). Artifacts include vibration from equipment, interference from the ECG, and patient movement. Electrical impedance monitors are the most prone to this type of error.

A false positive (when the alarm sounds unnecessarily) is often caused by infant movement that loosens an electrode or sensor. Also, a false positive alarm may sound when the child is breathing normally but too shallowly for the monitor to detect.

For any false alarms first consider user error. The alarm limits may be set inappropriately. They can be confusing to program, and may need to be changed as the patient matures. Never change a limit without consulting with the physician.

The next most likely cause of false alarms is the electrodes. The electrodes may not be placed correctly (across the chest). Or, the sensor is in a belt, the belt may be too loose. Ask a nurse to help with tightening the belt, as an excessively tight belt can lead to complications.

If the electrodes are placed correctly, they may be dirty or old. Try rinsing them in isopropyl alcohol, then water. Electrode belts can be gently cleaned with soap and water. Be careful to rinse off all soap residue and hang to dry before applying to the patient's skin. Also, check to see if the skin is dirty. The child may have lotion or powder on the skin under the electrodes. You can clean the child's skin with soap and water. In some cases, electrode paste can be used, and may improve the measurements.

2.13.3 Suggested Minimal Testing

Apnea monitors are easily tested on yourself. Hold your breath to trigger an alarm. If the alarm doesn't sound when you are breathing normally and does sound when you hold your breath, the apnea monitor is ready to release to the floor. If the machine is a respiration rate meter, check to see that the rate matches what you measure when you count breaths with a watch. If the apnea monitor includes ECG, be sure to check your heart rate against the machines rate. The rates should be very close (within 5 beats per minute).

Respiratory Monitor Preventative Maintenance

Preventative Maintenance

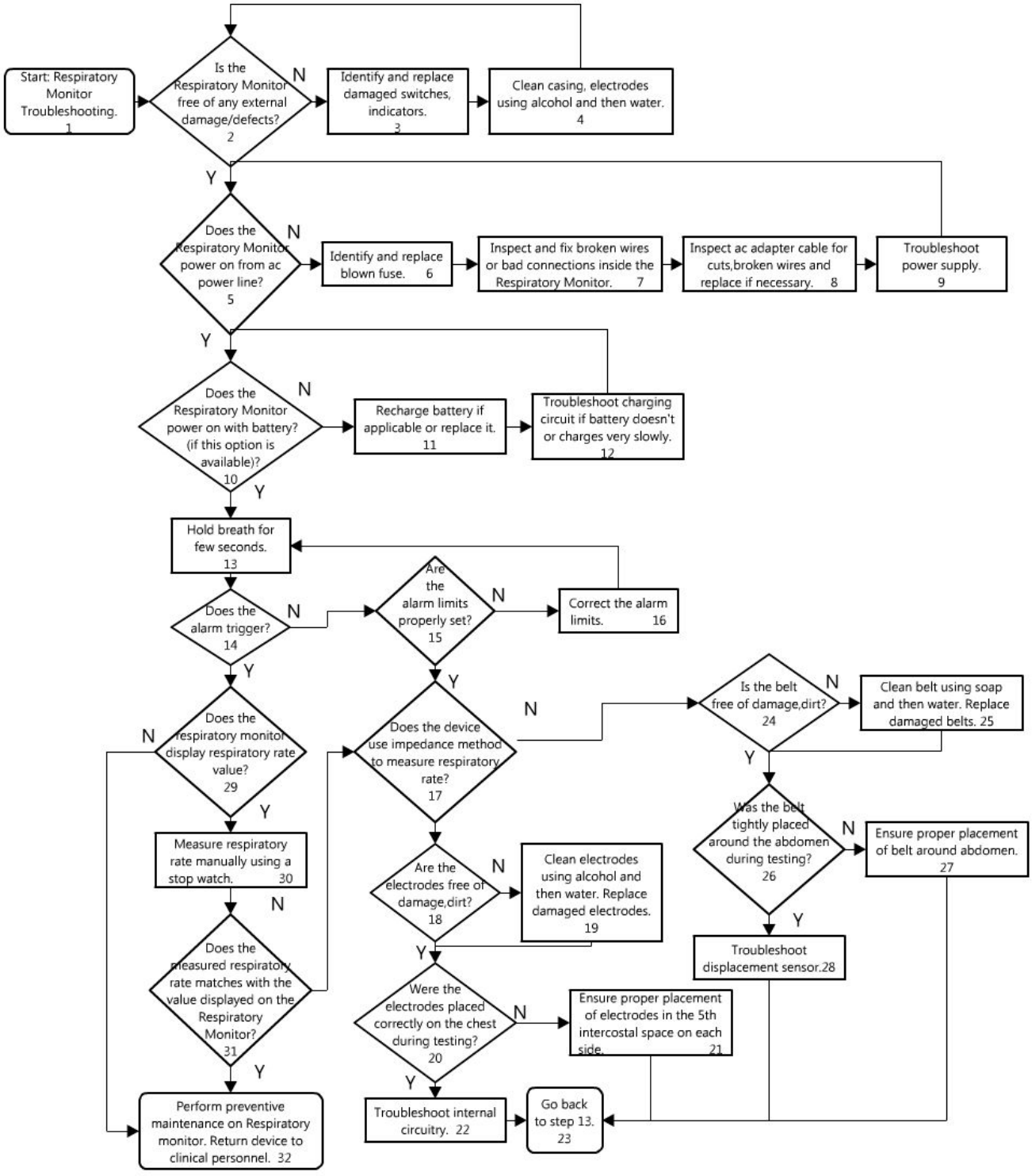
- Keep belt devoid of dirt and debris. Clean regularly with soap and water
- Clean electrodes after each use
- Check all cords for defects and replace as needed

Regularly check device-measured respiratory rate with a manual measurement

Cooper, Justin and Alex Dahinten for EWH. "Respiratory Monitor Preventative Maintenance." From the publication: Medical Equipment Troubleshooting Flowchart Handbook. Durham, NC: Engineering World Health, 2013.

Respiratory Monitor Troubleshooting and Reapir Flowchart

Respiratory Monitor Repair and Troubleshooting



Cooper, Justin and Alex Dahinten for EWH. "Respiratory Monitor Troubleshooting Flowchart." From the publication: Medical Equipment Troubleshooting Flowchart Handbook. Durham, NC: Engineering World Health, 2013.

Description

#	Text Box	Comments
1	Start: Respiratory Monitor troubleshooting	Begin diagnostic process for a work order for Respiratory Monitor.
2	Is the respiratory monitor free of any external damage/defects?	Inspect respiratory monitor for external cracks, broken switch etc.
3	Identify and replace damaged switches, indicators.	Refer BTA skill set on Switches and Lighting/Indicators to identify and replace damaged switches and indicators.
4	Clean casing, electrodes using Alcohol and then water.	Examine casing, electrodes and cables for dirt and contamination. Refer BTA skill set on Cleaning to clean the respiratory monitor.
5	Does the respiratory monitor power on from ac power line?	Power the device from ac line and turn it on.
6	Identify and replace blown fuse.	Refer BTA skill set on Fuse to identify and replace blown fuse.
7	Inspect and fix broken wires or bad connections inside the respiratory monitor.	Inspect wires and connections from power supply circuit board to other boards using multimeter. Refer BTA skill set on Connections for identifying and fixing broken wires and bad connections.
8	Inspect AC adapter cable for cuts, broken wires and replace if necessary.	Refer BTA skill set on Connections and Connectors for identifying and replacing damaged cables.
9	Troubleshoot power supply.	Most respiratory monitors can power on from battery and ac power mains.
10	Does the respiratory monitor power on with battery (if this option is available)?	Disconnect respiratory monitor from ac power line. Turn the device on. If respiratory monitor fails to power on then battery is fully depleted or damaged.
11	Recharge battery if applicable or replace it.	Refer BTA skill set on Batteries to replace and identify damaged batteries.
12	Troubleshoot charging circuit if battery doesn't or charges very slowly.	Refer BTA skill set on Transformer and Regulators to troubleshoot charging circuit.
13	Hold breath for few seconds.	Place electrodes/belt as required and turn the device on. Hold breath for few seconds.

14	Does the alarm trigger?	All respiratory and apnea monitors are designed to detect and trigger an alarm when there is a breathing pause for a period of time.
15	Are the alarm limits properly set?	Alarm limits can be modified by the user.
16	Correct the alarm limits.	Refer device manual for correcting alarm limits.
17	Does the device use impedance method to measure respiratory rate?	There are two types of respiratory monitors commonly found in the developing world. *Transthoracic electrical impedance* makes use of electrodes. *Pneumatic abdominal* type makes use of a belt.
18	Are the electrodes free of damage, dirt?	Electrodes should be clean and dry. Inspect the electrode cables and connectors for cuts and broken wires.
19	Clean electrodes using alcohol and then water. Replace damaged electrodes.	Refer BTA skill set on Connections and Connectors for identifying and replacing damaged cables.
20	Were the electrodes placed correctly on the chest during testing?	User error is one of the main reasons for false alarms.
21	Ensure proper placement of electrodes in the 5th intercostal space on each side.	The 5th intercostal space is between the 5th and 6th ribs.
22	Troubleshoot internal circuitry.	Improper functioning of internal circuitry is a common reason for the failure of transthoracic impedance type respiratory monitor. See BTA skills on Electrical Simple.
23	Go back to step 13.	Restart calibration process.
24	Is the belt free of damage, dirt?	Belts should be clean and dry. Inspect the cables and connectors for cuts and broken wires.
25	Clean belt using soap and then water. Replace damaged belts.	Refer BTA skill set on Connections and Connectors for identifying and replacing damaged cables.
26	Was the belt tightly placed around the abdomen during testing?	User error is one of the main reasons for false alarms.
27	Ensure proper placement of belt around abdomen.	Excessively tight belt can lead to complications.
28	Troubleshoot displacement sensor.	Improper functioning of displacement sensor (LVDT or strain gauge) is a common reason for the failure of pneumatic abdominal sensor type

		respiratory monitor.
29	Does the respiratory monitor display respiratory rate value?	Apnea monitors are provided with only the alarm feature. But respiratory monitors have the alarm feature and can also display the respiratory rate value.
30	Measure respiratory rate manually using a stop watch.	Manually count the number of breaths for a period of 20s using stopwatch. Multiply result by 3.
31	Does the measured respiratory rate matches with the value displayed on the Respiratory Monitor?	Improper functioning of internal circuitry or damaged electrodes/belts if there is a mismatch between the measured respiratory rate and the rate displayed on the Respiratory Monitor.
32	Perform preventive maintenance on Respiratory monitor. Return device to clinical personnel.	Respiratory Monitor is working properly. Perform preventive maintenance before returning the device to clinical personnel.

SECTION E:
Temperature Monitors

7. Operation, Use, and Maintenance of Temperature Monitors

Featured in this Section:

Developing World Healthcare Technology Laboratory. “Temperature Monitors.” From the Publication: “Biomedical Technicians Training Program, Session 3 v2, Special Topics: Cardiac Equipment.” *Engineering World Health*, March 1, 2011, p. 1-161.

Engineering World Health. “Preventative Maintenance Schedule for Temperature Monitors. *EWH*. 2012.

Wikipedia. “Human Body Temperature.” *Wikipedia,* p. 1-6. Retrieved from: https://en.wikipedia.org/wiki/Human_body_temperature

Introduction to Human Body Temperature

Human body temperature

"98.6" redirects here. For other uses, see 98.6 (disambiguation).

Normal human body temperature, also known as **normothermia** or **euthermia**, depends upon the place in the body at which the measurement is made, the time of day, as well as the activity level of the person. Nevertheless, commonly mentioned typical values are:

Oral (under the tongue): 36.8±0.4 °C (98.2±0.72 °F)[7]

Internal (rectal, vaginal): 37.0 °C (98.6 °F)[7]

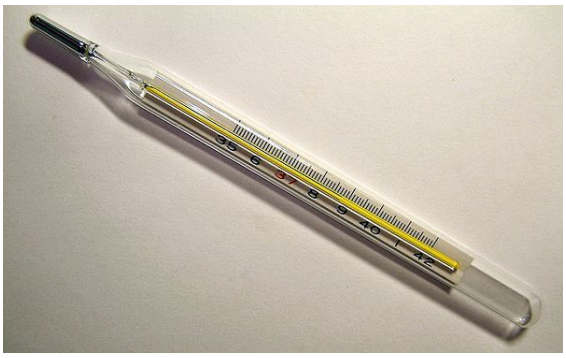
Different parts of the body have different temperatures. Rectal and vaginal measurements taken directly inside the body cavity are typically slightly higher than oral measurements, and oral measurements are somewhat higher than skin measurements. Other places, such as under the arm or in the ear, produce different typical temperatures.[7] Although some people think of these averages as representing the normal or ideal temperature, a wide range of temperatures has been found in healthy people.[4]

The body temperature of a healthy person varies during the day by about 0.5 °C (0.9 °F) with lower temperatures in the morning and higher temperatures in the late afternoon and evening, as the body's needs and activities change.[7] Other circumstances also affect the body's temperature. The core body temperature of an individual tends to have the lowest value in the second half of the sleep cycle; the lowest point, called the nadir, is one of the primary markers for circadian rhythms. The body temperature also changes when a person is hungry, sleepy, sick, or cold.

1 Methods of measurement

Taking a person's temperature is an initial part of a full clinical examination. There are various types of medical thermometers, as well as sites used for measurement, including:

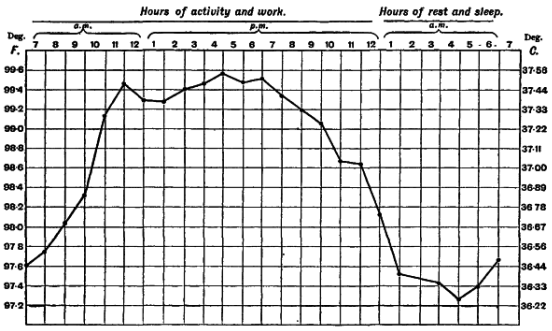
- In the anus (rectal temperature)
- In the mouth (oral temperature)
- Under the arm (axillary temperature)
- In the ear (tympanic temperature)
- In the vagina (vaginal temperature)



A medical thermometer showing a temperature reading of 38.7 °C

- In the bladder
- On the skin of the forehead over the temporal artery

2 Variations



Diurnal variation in body temperature, ranging from about 37.5 °C from 10 a.m. to 6 p.m., and falling to about 36.4 °C from 2 a.m. to 6 a.m.

Temperature control (thermoregulation) is part of a homeostatic mechanism that keeps the organism at optimum operating temperature, as it affects the rate of chemical reactions. In humans, the average internal temperature is 37.0 °C (98.6 °F), though it varies among individuals. However, no person always has exactly the same temperature at every moment of the day. Temperatures cycle regularly up and down through the day, as controlled by the person's circadian rhythm. The lowest temperature occurs about two hours before the person normally wakes up. Additionally, temperatures change according to activities and external factors.[8]

Wikipedia. "Human Body Temperature." Wikipedia, p. 1-6. Retrieved from: https://en.wikipedia.org/wiki/Human_body_temperature

In addition to varying throughout the day, normal body temperature may also differ as much as 0.5 °C (0.9 °F) from one day to the next, so that the highest or lowest temperatures on one day will not always exactly match the highest or lowest temperatures on the next day.

Normal human body temperature varies slightly from person to person and by the time of day. Consequently, each type of measurement has a range of normal temperatures. The range for normal human body temperatures, taken orally, is 36.8±0.5 °C (98.2±0.9 °F).[9] This means that any oral temperature between 36.3 and 37.3 °C (97.3 and 99.1 °F) is likely to be normal.

The normal human body temperature is often stated as 36.5–37.5 °C (97.7–99.5 °F).[10] In adults a review of the literature has found a wider range of 33.2–38.2 °C (91.8–100.8 °F) for normal temperatures, depending on the gender and location measured.[11]

2.1 Natural rhythms

Body temperature normally fluctuates over the day, with the lowest levels around 4 a.m. and the highest in the late afternoon, between 4:00 and 6:00 p.m. (assuming the person sleeps at night and stays awake during the day).[7][9] Therefore, an oral temperature of 37.3 °C (99.1 °F) would, strictly speaking, be a normal, healthy temperature in the afternoon but not in the early morning.[7] An individual's body temperature typically changes by about 0.5 °C (0.9 °F) between its highest and lowest points each day.[7][9]

Body temperature is sensitive to many hormones, so women have a temperature rhythm that varies with the menstrual cycle, called a *circamensal* rhythm.[8] A woman's basal body temperature rises sharply after ovulation, as estrogen production decreases and progesterone increases. Fertility awareness programs use this predictable change to identify when a woman can become pregnant. During the luteal phase of the menstrual cycle, both the lowest and the average temperatures are slightly higher than during other parts of the cycle. However, the amount that the temperature rises during each day is slightly lower than typical, so the highest temperature of the day is not very much higher than usual.[12] Hormonal contraceptives both suppress the circamensal rhythm and raise the typical body temperature by about 0.6 °C (1.1 °F).[8]

Temperature also varies with the change of seasons during each year. This pattern is called a *circannual* rhythm.[12] Studies of seasonal variations have produced inconsistent results. People living in different climates may have different seasonal patterns.

Increased physical fitness increases the amount of daily variation in temperature.[12]

With increased age, both average body temperature and the amount of daily variability in the body temperature tend to decrease.[12] Elderly patients may have a decreased ability to generate body heat during a fever, so even a somewhat elevated temperature can indicate a serious underlying cause in geriatrics.

2.2 Measurement methods

Different methods used for measuring temperature produce different results. The temperature reading depends on which part of the body is being measured. The typical daytime temperatures among healthy adults are as follows:

- Temperature in the anus (rectum/rectal), vagina, or in the ear (otic) is about 37.5 °C (99.5 °F)[14]
- Temperature in the mouth (oral) is about 36.8 °C (98.2 °F)[9]
- Temperature under the arm (axillary) is about 36.5 °C (97.7 °F)[14]

Generally, oral, rectal, gut, and core body temperatures, although slightly different, are well-correlated, with oral temperature being the lowest of the four. Oral temperatures are generally about 0.4 °C (0.7 °F) lower than rectal temperatures.[7]

Oral temperatures are influenced by drinking, chewing, smoking, and breathing with the mouth open. Cold drinks or food reduce oral temperatures; hot drinks, hot food, chewing, and smoking raise oral temperatures.[8]

Axillary (armpit), tympanic (ear), and other skin-based temperatures correlate relatively poorly with core body temperature.[12] Tympanic measurements run higher than rectal and core body measurements, and axillary temperatures run lower.[12] The body uses the skin as a tool to increase or decrease core body temperature, which affects the temperature of the skin. Skin-based temperatures are more variable than other measurement sites.[12] The peak daily temperature for axillary measurements lags about three hours behind the rest of the body.[12] Skin temperatures are also more influenced by outside factors, such as clothing and air temperature.

Each measurement method also has different normal ranges depending on sex.

2.3 Variations due to outside factors

Many outside factors affect the measured temperature as well. "Normal" values are generally given for an otherwise healthy, non-fasting adult, dressed comfortably, indoors, in a room that is kept at a normal room temperature, 22.7 to 24.4 °C (73 to 76 °F), during the morning, but not shortly after arising from sleep. Furthermore, for oral temperatures, the subject must not have eaten, drunk, or smoked anything in at least the previous fifteen

to twenty minutes, as the temperature of the food, drink, or smoke can dramatically affect the reading.

Temperature is increased after eating or drinking anything with calories. Caloric restriction, as for a weight-loss diet, decreases overall body temperature.[8] Drinking alcohol decreases the amount of daily change, slightly lowering daytime temperatures and noticeably raising nighttime temperatures.[8]

Exercise raises body temperatures. In adults, a noticeable increase usually requires strenuous exercise or exercise sustained over a significant time. Children develop higher temperatures with milder activities, like playing.

Psychological factors also influence body temperature: a very excited person often has an elevated temperature.

Wearing more clothing slows daily temperature changes and raises body temperature.[8] Similarly, sleeping with an electric blanket raises the body temperature at night.[8]

Sleep disturbances also affect temperatures. Normally, body temperature drops significantly at a person's normal bedtime and throughout the night. Short-term sleep deprivation produces a higher temperature at night than normal, but long-term sleep deprivation appears to reduce temperatures.[8] Insomnia and poor sleep quality are associated with smaller and later drops in body temperature.[8] Similarly, waking up unusually early, sleeping in, jet lag and changes to shift work schedules may affect body temperature.[8]

3 Specific temperature concepts

3.1 Fever

Main article: Fever

A temperature setpoint is the level at which the body attempts to maintain its temperature. When the setpoint is raised, the result is a fever. Most fevers are caused by infectious disease and can be lowered, if desired, with antipyretic medications.

An early morning temperature higher than 37.2 °C (99.0 °F) or a late afternoon temperature higher than 37.7 °C (99.9 °F) is normally considered a fever, assuming that the temperature is elevated due to a change in the hypothalamus's setpoint.[7] Lower thresholds are sometimes appropriate for elderly people.[7] The normal daily temperature variation is typically 0.5 °C (0.90 °F), but can be greater among people recovering from a fever.[7]

An organism at optimum temperature is considered *afebrile* or *apyrexic*, meaning "without fever". If temperature is raised, but the setpoint is not raised, then the result is hyperthermia.

3.2 Hyperthermia

Main article: Hyperthermia

Hyperthermia occurs when the body produces or absorbs more heat than it can dissipate. It is usually caused by prolonged exposure to high temperatures. The heat-regulating mechanisms of the body eventually become overwhelmed and unable to deal effectively with the heat, causing the body temperature to climb uncontrollably. Hyperthermia at or above about 40 °C (104 °F) is a life-threatening medical emergency that requires immediate treatment. Common symptoms include headache, confusion, and fatigue. If sweating has resulted in dehydration, then the affected person may have dry, red skin.

In a medical setting, mild hyperthermia is commonly called *heat exhaustion* or *heat prostration*; severe hyperthermia is called *heat stroke*. Heat stroke may come on suddenly, but it usually follows the untreated milder stages. Treatment involves cooling and rehydrating the body; fever-reducing drugs are useless for this condition. This may be done through moving out of direct sunlight to a cooler and shaded environment, drinking water, removing clothing that might keep heat close to the body, or sitting in front of a fan. Bathing in tepid or cool water, or even just washing the face and other exposed areas of the skin, can be helpful.

With fever, the body's core temperature rises to a higher temperature through the action of the part of the brain that controls the body temperature; with hyperthermia, the body temperature is raised without the consent of the heat control centers.

3.3 Hypothermia

Main article: Hypothermia

In hypothermia, body temperature drops below that required for normal metabolism and bodily functions. In humans, this is usually due to excessive exposure to cold air or water, but it can be deliberately induced as a medical treatment. Symptoms usually appear when the body's core temperature drops by 1–2 °C (1.8–3.6 °F) below normal temperature.

3.4 Basal body temperature

Main article: Basal body temperature

Basal body temperature is the lowest temperature attained by the body during rest (usually during sleep). It is generally measured immediately after awakening and before any physical activity has been undertaken, although the temperature measured at that time is somewhat higher

than the true basal body temperature. In women, temperature differs at various points in the menstrual cycle, and this can be used in the long-term to track ovulation both for the purpose of aiding conception or avoiding pregnancy. This process is called fertility awareness.

3.5 Core temperature

Core temperature, also called core body temperature, is the operating temperature of an organism, specifically in deep structures of the body such as the liver, in comparison to temperatures of peripheral tissues. Core temperature is normally maintained within a narrow range so that essential enzymatic reactions can occur. Significant core temperature elevation (hyperthermia) or depression (hypothermia) that is prolonged for more than a brief period of time is incompatible with human life.

Temperature examination in the rectum is the traditional gold standard measurement used to estimate core temperature (oral temperature is affected by hot or cold drinks and mouth-breathing). Rectal temperature is expected to be approximately one Fahrenheit degree higher than an oral temperature taken on the same person at the same time. Ear thermometers measure eardrum temperature using infrared sensors. The blood supply to the tympanic membrane is shared with the brain. However, this method of measuring body temperature is not as accurate as rectal measurement and has a low sensitivity for fevers, missing three or four out of every ten fevers in children.[15] Ear temperature measurement may be acceptable for observing trends in body temperature but is less useful in consistently identifying fevers.

Until recently, direct measurement of core body temperature required surgical insertion of a probe, so a variety of indirect methods have commonly been used. The rectal or vaginal temperature is generally considered to give the most accurate assessment of core body temperature, particularly in hypothermia. In the early 2000s, ingestible thermistors in capsule form were produced, allowing the temperature inside the digestive tract to be transmitted to an external receiver; one study found that these were comparable in accuracy to rectal temperature measurement.[16]

4 Human temperature variation effects

4.1 Hot

- 44 °C (111.2 °F) or more – Almost certainly death will occur; however, people have been known to survive up to 46.5 °C (115.7 °F).[17]
- 43 °C (109.4 °F) – Normally death, or there may be serious brain damage, continuous convulsions and shock. Cardio-respiratory collapse will likely occur.
- 42 °C (107.6 °F) – Subject may turn pale or remain flushed and red. They may become comatose, be in severe delirium, vomiting, and convulsions can occur. Blood pressure may be high or low and heart rate will be very fast.
- 41 °C (105.8 °F) – (Medical emergency) – Fainting, vomiting, severe headache, dizziness, confusion, hallucinations, delirium and drowsiness can occur. There may also be palpitations and breathlessness.
- 40 °C (104.0 °F) – Fainting, dehydration, weakness, vomiting, headache and dizziness may occur as well as profuse sweating. Starts to be life-threatening.
- 39 °C (102.2 °F) – Severe sweating, flushed and red. Fast heart rate and breathlessness. There may be exhaustion accompanying this. Children and people with epilepsy may be very likely to get convulsions at this point.
- 38 °C (100.4 °F) – (this is classed as hyperthermia if not caused by a fever) Feeling hot, sweating, feeling thirsty, feeling very uncomfortable, slightly hungry. If this is caused by fever, there may also be chills.

4.2 Normal

- 37 °C (98.6 °F) – Normal internal body temperature (which varies between about 36.12–37.8 °C (97.02–100.04 °F))

4.3 Cold

- 36 °C (97 °F) – Feeling cold, mild to moderate shivering (body temperature may drop this low during sleep). May be a normal body temperature.
- 35 °C (95 °F) – (Hypothermia is less than 35 °C (95 °F)) – Intense shivering, numbness and bluish/grayness of the skin. There is the possibility of heart irritability.
- 34 °C (93 °F) – Severe shivering, loss of movement of fingers, blueness and confusion. Some behavioural changes may take place.
- 33 °C (91 °F) – Moderate to severe confusion, sleepiness, depressed reflexes, progressive loss of shivering, slow heart beat, shallow breathing. Shivering may stop. Subject may be unresponsive to certain stimuli.
- 32 °C (90 °F) – (Medical emergency) Hallucinations, delirium, complete confusion, extreme sleepiness that is progressively becoming comatose. Shivering is absent (subject may even think they are hot). Reflex may be absent or very slight.

- 31 °C (88 °F) – Comatose, very rarely conscious. No or slight reflexes. Very shallow breathing and slow heart rate. Possibility of serious heart rhythm problems.
- 28 °C (82 °F) – Severe heart rhythm disturbances are likely and breathing may stop at any time. Patient may appear to be dead.
- 24–26 °C (75–79 °F) or less – Death usually occurs due to irregular heart beat or respiratory arrest; however, some patients have been known to survive with body temperatures as low as 14.2 °C (57.5 °F).[17]

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6.1 Text

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Temperature Monitor

The example used here is an IVAC TEMP-PLUS vital signs measurement system, Model 2000, consisting of the unit, a battery charger/storage base, and probe assembly. Maintenance sections are written for personnel experienced in the analysis, troubleshooting, and repair of analog and digital electronic equipment.

The TEMP-PLUS is a portable, battery-powered instrument. The PULSE button, °F - °C, and P-M switches on the underside of the instrument control its functions. They are used to activate the pulse mode, convert the displayed temperature reading from Fahrenheit to Celsius (and vice versa), and activate the predictive and monitor modes. The front of the unit contains the probe storage well and the probe connector socket. The power cord supplies 120 VAC or 220 VAC current to the battery charger/storage base.

Inside the unit the major components are a power switch, activated by the probe; a nickel-cadmium battery pack; a coil used to recharge the battery pack; and three printed wiring boards – the display, display driver, and logic boards. The display consists of a seven-segment LED array.

The IVAC probe contains a heat-sensing thermistor in the tip of the stainless steel shaft. The thermistor, a temperature-proportional resistor, is joined electrically and physically to the thermometer through the probe connector and flexible extension cord attached to the base of the probe shaft. Located at the base of the probe is an ejection button for easy disposal of used probe covers. Oral probes are blue; rectal probes are red. The oral and rectal probes are electronically identical.

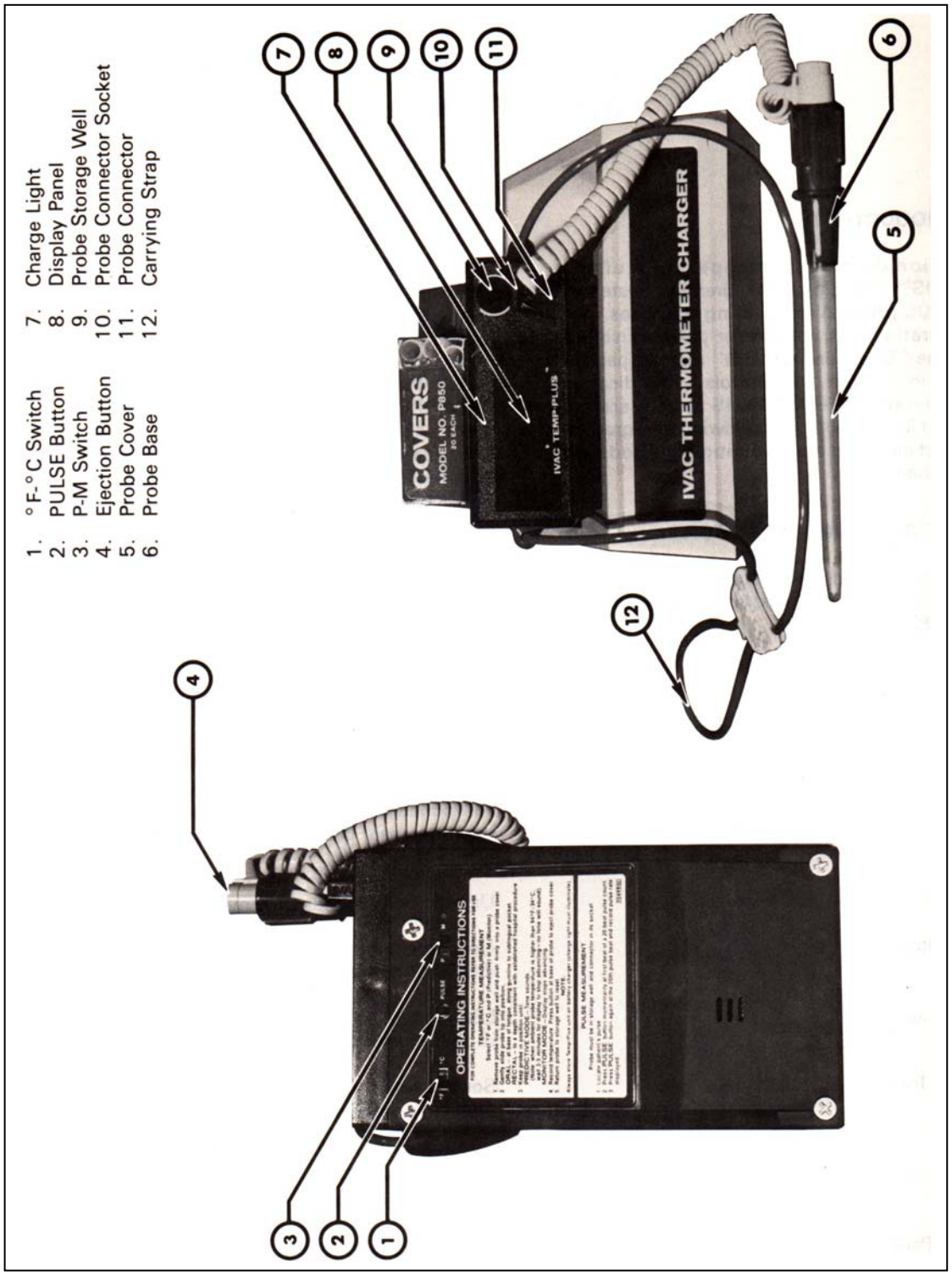
The IVAC probe cover is a thin, plastic sheath with thermal characteristics carefully selected to match the requirements of the unit. It covers the shaft of the thermometer probe during temperature measurement to prevent cross-contamination or infection.

The IVAC battery charger/storage base is an AC operated, solid state device used to recharge the unit battery. A coil positioned inside the unit inductively couples with a coil inside the charger to provide the energy for battery charging without any physical connections.

There are several operating modes for the system. The predictive mode is used under ordinary clinical conditions because it provides the fastest way of taking a temperature with the TEMP-PLUS system. In the monitor mode, the unit continuously measures the patient's temperature as it rises or falls. The pulse mode calculates the patient's pulse rate in beats per minute. The analog-to-digital mode is used for calibration of the TEMP-PLUS unit by service and repair personnel.

Before operating the system, perform the functional checkout to establish that the system is functioning properly (applies only to initial setup).

Developing World Healthcare Technology Laboratory. "Temperature Monitors." From the Publication: "Biomedical Technicians Training Program, Session 3 v2, Special Topics: Cardiac Equipment." Engineering World Health, March 1, 2011, p. 1-161.



Features, controls and indicators of the IVAC TEMP-PLUS system

Developing World Healthcare Technology Laboratory. "Temperature Monitors." From the Publication: "Biomedical Technicians Training Program, Session 3 v2, Special Topics: Cardiac Equipment." Engineering World Health, March 1, 2011, p. 1-161.

Table of Controls and Indicators

Control/ Indicator	Function
°F - °C Switch	Used to convert temperature readout on display to Fahrenheit or Celsius scale. Can convert the temperature scale before, during, or after a temperature is taken.
PULSE button	Used to actuate the pulse mode.
P-M Switch	Used to change mode of TEMP-PLUS unit to Predictive or monitor mode.
Charge Light	LED illuminates on the display panel when battery Is being recharged.
Audible Tone	Sounds when computed temperature is obtained in predictive mode, when pulse is calculated, or when an error occurs.
Tissue Contact Indicator	Short line rotates clockwise on right side Of display panel when probe temperature is Rising,
Display Panel	Indicates temperature reading, pulse rates, battery charging, and error messages on a five-character LED display.

1. Ensure that the correct power connection (120 VAC or 220 VAC) is made to the charger. Unless connected to a receptacle marked “Hospital Use” or “Hospital Grade,” the reliability of the instrument ground cannot be assured. Always use a three-wire grounded receptacle.

2. Properly seat the TEMP-PLUS unit on the battery charger. A small light will appear on the display panel to indicate that the battery is charging. Allow an initial charge of 10 to 14 hours before using the system.

3. Insert the connector from the appropriate probe into the probe connector socket. Insert the probe into the probe storage well in the front of the unit.

NOTE: The performance of the system is affected by the thermal characteristics of the probe cover used.

NOTE” If the room temperature (and probe tip temperature) is higher than 34.4° C (94.0 °F) the unit may not be able to quickly determine the patient’s temperature. Instead, the temperature indicated on the display will slowly rise until, after 3 to 5 minutes, the

patient's temperature has been reached. (No audible toe will sound, and a flashing F or C will appear in the place of the tissue contact indicator. If the instrument is not turned off within approximately 6 minutes, the **Err L** message will appear.

Temperature Error Messages

The following error messages will be displayed during temperature measurement if:

ERR L – In the predictive mode, the TEMP-PLUS unit fails to obtain a temperature within one minute after insertion or the probe tip temperature is still below the displayed temperature (32.2L or 90.0L) 75 seconds after the unit is turned on.

ERR L – In the predictive mode, the TEMP-PLUS unit senses a loss of proper tissue contact within the mouth for more than 35 seconds.

ERR H – The probe temperature exceeds 42.1° C or 107.9°F.

ERR O – There is an electronics error. If the error persists after resetting the TEMP-PLUS unit, refer to the troubleshooting procedures.

If **Lobat** appears on the display, the battery is low and needs recharging.

Cleaning and Sterilizing

CAUTION: Do NOT autoclave or immerse the unit or the battery charger.

It is good practice to periodically clean the instrument surface by wiping it with a soft cloth dampened with isopropyl alcohol (greater than 70% by weight), prepackaged alcohol wipes, warm water, or a general nonstaining chemical disinfectant. Do not use solvents or cleaning agents.

Standard ETO gas sterilization techniques can be used to sterilize the system provided the maximum temperature does not exceed 58 C (135 F) and the relative humidity does not exceed 60%. Aerate the system for 24 hours in free air or 8 hours in an aerator after sterilizing. Test the system for proper operation following aeration.

Troubleshooting

This section describes descriptions of possible malfunctions or troubles that may be encountered in operating the TEMP-PLUS or similar system. These troubles are based on generally known or anticipated conditions that may occur. Referring to this section before attempting to repair, replace, or service any components will save time and may avert unnecessary effort. Refer to the service manual for your particular instrument.

The checkout and troubleshooting procedure may be used periodically as a preventive maintenance measure.

NOTE: Whe4n the unit detects an alarm condition, the appropriate message will flash seven to ten times alternating with an audible tone before the instrument turns off.

Checkout and troubleshooting procedure

The following checkout and troubleshooting procedure should be performed routinely every few months to confirm the proper functioning of the system. The mechanical and electrical inspections locate any parts that may require calibration, repair, or replacement.

BASIC MECHANICAL AND ELECTRICAL INSPECTION

1. Charge the unit for approximately 15 minutes. Verify that the charge indicator light illuminates.
2. Slide the P-M switch to P and the °F-°C switch to ° F. Place the probe tip on warm tissue, such as behind the ear. Verify the display advances, reaching a final temperature reading in about 30 seconds. Make sure the display flashes in alternation with a beeping audible tone when the final temperature is obtained. (Note: Temperature readings taken behind the ear are about 0.3 to 0.6°C [0.5 to 1.0°F] lower than oral temperature readings.)
3. Without moving the probe, slide the °F-°C switch to °C before the instrument turns off. Verify that the unit converts the temperature reading from Fahrenheit to Celsius. Now slide the °F-°C switch back to °F and verify that the display changes to a Fahrenheit reading.
4. Keeping the probe tip in the same location as in step B, slide the P-M switch to M. verify that the temperature reading is now 0.3 – 0.4 °C (0.6-0.8 °F) lower than the final temperature reading obtained in step B.
5. Depress the PULSE button. Verify that 888.888 is displayed, with the decimal point flashing.
6. Release the PULSE button. Verify that inserting the probe into the storage well turns off the unit.
7. Verify that depressing the PULSE button activates the pulse mode.
8. Verify that **ERROR** is displayed if the pulse measure is less than 20 beats per minute or greater than 200 beats per minute.

Technical Troubleshooting Guide

Trouble	Probable cause(s)
Unit is completely inoperative.	Dead or defective battery. Blown fuse. Broken connections or switches, Defective crystal. Defect on logic board.
Pulse mode does not work	Broken connection or defect in flexible circuit.

	Defective pulse switch. Defect on logic board.
Temperature taking modes do not work.	Defective probe. Broken wire or wires. Defective probe switch. Defect on logic board.
Always turns off 2-3 seconds after being turned on.	Broken connection in flexible circuits Defective display driver. Defect on logic board.
One digit missing: instrument may turn off if the center digit is missing.	Broken flexible circuit to driver board Broken flexible circuit to display board Open transistors
Missing segment on one digits	Defective LED
Same segment missing on all five digits; missing decimal point	Broken flexible circuit to display driver or display board Open transistors on display driver board
Same segment of all digits always on; one digit bright and jumbled, or decimal point always on.	Short between traces on a circuit board. Short on display driver board.
Instrument does not turn itself off.	PULSE button is stuck. Short circuit between traces on circuit board. Defect on logic board.
Instrument displays **Lobat** when battery is charged, or does not display **Lobat** when charge is low.	Defective battery. Defect on logic board. Defect on display driver board.
Battery discharges when instrument is turned off.	Defect on logic board. Defective battery.
Charge light does not illuminate.	Defective charger; broken wire to coil or open circuit in coil. Short circuit on logic board. Disconnection in flexible circuits between display, display driver and logic boards. Defective charge light.

Instrument does not read temperature or immediately displays **Err H.**	Defective probe. Break or short circuit in harness. Defective probe connector socket. Defect on logic board
Unit cannot be calibrated.	Defect on logic board.
Err O occurs.	Defect on logic board.
Instrument does not respond to one Or both function switches (°F-°C, P-M)	Defective flexible circuit. Defective switch. Defect on display driver board. Defect on logic board.
Instrument turns on with unusual characters in display, with only decimal point lit, or does not turn off unless probe connector is unplugged.	Defect on logic board.
No audible tone.	Defective speaker Defect on logic board

Preventative Maintenance for Temperature Monitoring Equipment

Monitor, Temperature (With Probe)

1. Inspect exterior of equipment for damage or missing hardware.
2. Inspect the power cord, strain relief and plug/s for any signs of damage.
3. Turn unit off, open user accessible covers and inspect unit for damage.
4. Clean unit interior components and exterior with vacuum or compressed air.
5. Inspect interior for signs of corrosion or missing hardware. Repair as required.
6. Inspect electrical components for signs of excessive heat or deterioration.
7. Verify temperature calibration at 2 points.
8. Verify correct operation of all buttons, controls, displays and/or indicators.
9. Verify correct operation of unit in all functional modalities.

SECTION F:
Resources for More Information

8. Resources for More Information

Featured in this Section:

Developing World Healthcare Technology Laboratory. ""ECG Monitor: How to Use." From the Publication: "Biomedical Technician Assistant (BTA) Skills." *DHT Laboratory, Duke University:* 2011.

Stanco, Cassandra ed. for Engineering World Health. "Blood Pressure Monitor Packet." *Engineering World Health*, 2015.

Stanco, Cassandra ed. for Engineering World Health. "ECG Packet." *Engineering World Health*, 2015.

Stanco, Cassandra ed. for Engineering World Health. "Fetal Doppler and Fetal Monitor Packet." *Engineering World Health*, 2015.

Resources for More Information:

Internal Resources at library.ewh.org: For More Information about patient monitoring, please see these resources in the BMET Library!

1. **Blood Pressure Monitoring:**
    a. Stanco, Cassandra ed. for Engineering World Health. “Blood Pressure Monitor Packet.” *Engineering World Health*, 2015.
2. **ECG (Electrocardiograms):**
    a. Developing World Healthcare Technology Laboratory. “”ECG Monitor: How to Use.” From the Publication: “Biomedical Technician Assistant (BTA) Skills.” *DHT Laboratory, Duke University:* 2011.
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