

## Multiphysiological Parameter Patient Monitoring

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### IDEA IN BRIEF

*Multiphysiological parameter medical devices must leverage ever-improving technology to meet demands for improvements in accuracy, functionality, and size, as well provide advances in data capture, transmission, storage, and compatibility—ultimately empowering improved healthcare and enhanced patient outcomes.*

### MULTIPARAMETER MONITORING

Beyond the basic lead II ECG (electrocardiogram), medical practice demands quick examination of an increasing array of vital signs—both real-time and trending—to better understand a patient's current condition, improvement, or deterioration. A typical multiparameter device simultaneously looks at 12-lead cardiac ECG, oxygen saturation (SpO<sub>2</sub>), CO, hemoglobin, temperature, noninvasive blood pressure, invasive blood pressure, respiration, and implanted pacemaker activity. The multiparameter device used in sleep studies is different: it typically monitors ECG, EEG (electroencephalogram), EOG (electrooculogram), surface EMG (electromyogram), audio, and IR (infrared) temperature. In addition to ECG signals, some Holter monitors are now also recording three-axis acceleration and blood pressure.

Medical device manufacturers are constantly working with clinicians to provide a selectable mix of monitored parameters for specific theaters, from field emergencies through transport to a multidepartment clinical facility, which includes emergency department, intensive care suites, operating suites, post-anesthesia recovery, various labs and treatment suites, and general ward recovery, as well as offsite consulting specialists and freestanding medical providers. Each treatment arena may have differing levels of diagnostic demands, yet need to be compatible and connectable to medical records—including wireless exchanges.

The clinician demands robust, trouble-free operation at competitive costs. The biomedical staff requires rotational interchangeability to reduce model variances, while allowing



Figure 1. Accurate and immediate multiphysiological parameter patient monitoring enables caregivers to enhance patient outcomes.

straightforward use of the basic features without confusion. Recent additional regulatory oversight requirements call for superior detection of patient status deterioration with fully integrated interventions to reduce morbidities and mortalities.

The challenges for the device manufacturer are multiple: The designer of such medical equipment must ensure safety above all other considerations for the patient and the operator under all possible clinical use scenarios, including those of home use by lay patients. The designer must also keep abreast of ever-changing requirements for medical devices from regulatory agencies and must ensure compliance with quality standards for product development and manufacturing. The requirements and recommendations for medical devices vary from country to country; the medical device manufacturer must be aware of these “directives” and “regulations” to ensure compliance.

### PATIENT MONITORING: THE 12-LEAD DIAGNOSTIC ELECTROCARDIOGRAM

Long the gold standard and common denominator of a patient's emerging cardiovascular status, the 12-lead ECG

(sometimes called EKG) continues to be the most used quick analytical tool.

Clinical practitioners demand stable operation and a high level of performance in often less than ideal conditions of field, transport, and critical care settings. They require

- A stable presentation of the heart's electrical activity and anomalies without distortions from RFI (radio frequency interference), medical equipment, or other spurious external environmental conditions.
- The ability to review multiple views of the heart's activity to provide additional information not discernible by looking at a single lead. Multiple views are needed to determine if a patient has had an M.I. (myocardial infarction) and where in the heart it has occurred and to examine various arrhythmias such as A.F. (atrial fibrillation), pacer functions, heart axis deviations, chamber enlargements, and other conduction or impulse data elements.
- Diagnostic quality frequency response (0.05 Hz to 150 Hz) and monitor quality options such as 2 Hz to 30 Hz or 0.5 Hz to 40 Hz. The bandwidth requirements are a function of clinical application. For example, having a 0.05 Hz low end response is critical to detection of ST segment deviations, upon which decisions to activate an entire catheterization procedure might be based. Some standards allow the 0.05 Hz low end response to be raised to 0.67 Hz if a zero phase distortion filter is used. This has significant implications and must be examined carefully as the clinical application and examination of the ECG requires accurate representation over the entire bandwidth.
- An accurate, repeatable view of the electrical activity within the myocardium upon which life-threatening interventions must appropriately be selected and launched.
- Trustworthy capture, storage, preservation, transmission, and reception into another receiving system and down-line computers. The data must always be downloadable for remote or later comparisons. Output must be in a standard format and display for universal understanding by a series of interventional practitioners all along the treatment chain.
- A robust system—including high quality electrodes and cables—that withstands shock, vibration, patient movement and muscle tremor, temperature variations, wandering baseline and electromagnetic interferences, and any other influence that might distort the output and display of actual heart action. These factors can affect sensitivity and specificity for critical diagnoses.

- An effective system at an acceptable investment in terms of acquisition and operation costs, size, and weight. A competitive advantage is gained by reducing the time and labor required to place the system and complete all tasks. An additional expectation is full capability to adjust to changing medical guidelines and practices as they may occur.

### **SINGLE BOX EMS (EMERGENCY MEDICAL SERVICES) DEVICES**

Emergency medical services (EMS)—often the starting point brought on by a frantic call to 9-1-1—may result in an EMT (emergency medical technician) arriving with a simple temperature scanner, electronic blood pressure monitor, and an automated external defibrillator (AED). Should a true life threat condition be confirmed, the basic life support (BLS) personnel will escalate the call to add advanced life support (ALS) by paramedics or a variety of registered nurse specialists. The arrival of the ALS team usually results in enhanced medical equipment such as a multiphysiological monitoring system that includes ECG, capnograph, blood pressure, temperature, SpO<sub>2</sub>, CO detection, and other life supporting devices. Information gleaned on scene can, by protocol, determine the destination hospital for the victim/patient, and data can be transmitted to the receiving facility to direct further field treatments and prepare special teams to meet the patient, reducing the time from door arrival to definitive treatments.

EMS has always looked for combination devices that provide multiple parameter vital signs within a single unit, one power source, and a full palette of patient data. Such a unit is nearly always wrapped around the defibrillator/cardioverter/pacer with ECG display screen and integrated printer. The requirements have grown from a simple ECG presentation to a fully diagnostic and interpretative 12-lead ECG with trending features, along with a growing number of vital sign monitors that constantly update the field medic as to the patient's condition:

- Heart rate monitor and alarm—a basic measure of patient distress, with a descending rate portending a bradycardic emergency, perhaps requiring drugs and temporary pacing, and often permanent implanted pacing. An escalating heart rate may herald runaway rates, often with erratic rhythms decaying into tachycardias, atrial fibrillations, or ventricular fibrillation. The observant clinician, or the trustworthy alarm, can give time to intervene before the trend evolves into a cardiovascular emergency.
- Pulse oximetry—SpO<sub>2</sub> (or SaO<sub>2</sub>) monitor, assessing the oxygen saturation of the hemoglobin within the

bloodstream. This noninvasive monitor uses an infrared light (photoplethysmography) to measure percentage of oxygen. Low readings, or readings that fail to improve with treatment, are indications of a sick patient; and many EMS protocols require upgrade from basic life support personnel (EMTs) to advanced life support personnel (paramedics or other ALS clinicians). Readings can be compromised by reduced blood flow to the sensor site area, caused by a hypothermic finger, a patient in systemic shock, a trauma patient who is hypovolemic (low blood volume), or external factors such as the patient's motion. Readings can be slow to report changes, requiring the clinician to be observant of all monitor indices. Expect the use of SpO<sub>2</sub> monitoring to receive more attention with the changing CPR guidelines where lay public rescuers will perform compression-only/hands-only CPR without accompanying breaths—leading to significant hypoxia. In such situations, high flow oxygen (while avoiding hyperventilation) will be critical.

- End tidal CO<sub>2</sub> monitoring (monitoring a patient's exhaled breath), searching for low values (2 mmHg to 20 mmHg for cardiac arrest, hyperventilation, and other conditions; 1 mmHg to 50 mmHg for general monitoring; and 0 mmHg to 100 mmHg for patients who have advanced chronic obstructive pulmonary disease (COPD).
- Carbon monoxide (SpCO) monitor, assessing the percentage presence of this potentially lethal gas. With CO being odorless and tasteless, victims are often unaware of their crisis and lapse into unconsciousness, even death. Many fire departments require assessments of fire ground personnel to ensure they are not exposed during firefighting and post-event overhaul (cleanup). CO poisoning has been the root cause of many patients who were unaware of exposure, and had no other known reason for their symptoms. The CO monitor measures exhaled patient breath via an inline sensor within a nasal cannula or oxygen face mask.
- Methemoglobin (SpMET), detecting the oxidation of ferrous iron in hemoglobin, which does not transport oxygen. Certain hospital meds can trigger this condition, which affects cardiovascular and central nervous systems.
- Noninvasive blood pressure—an oscillometric (use of a pressure transducer on a restrictive cuff) capture of a patient's BP (blood pressure) at upper arm or thigh, giving diastolic, systolic, and mean readings on demand, or at a variable time setting. Accuracy is important in administering (or withholding) drugs where high or low readings indicate a condition with risky side effects—

such as not administering nitroglycerin for angina, which might cause uncontrolled vascular collapse in the patient who already has low BP. An outlier BP reading, with attendant heart rate compensation to fast or slow rates, indicates a cardiovascular system in trouble—needing rapid interventions.

- Invasive (arterial) blood pressure (IP) monitor—an inline sensor that provides a beat-to-beat confirmation of the patient's BP/waveform. Trending provides an alert to changes that can indicate a deteriorating condition, or a rapid response indicator to administration of some medications. Long range aerial transports and extended surgeries are two situations where monitoring of pressure changes gives the clinician the alert to increase oxygen delivery, change fluid delivery rates, change patient position, or provide medication responses before the situation becomes worse. IP is also useful in monitoring patients with a left ventricular assist device, where a mechanical pump provides constant blood flow—but with no pulse surges!
- 3-lead ECG. Simple or low end devices, including automated external defibrillators (AED), look at a single lead (most often lead II) to determine presence of a pulse, the pulse rate, and the basic shape characteristics of the waveform. Its major limitation is that the display of some electrical activity (pulseless electrical activity or PEA) does not confirm cardiac output. Its main strength is the capability to recognize ventricular fibrillation and provide immediate defibrillation.
- Pacer output—provides display of the pacing spike, superimposed on the ECG rhythm to show response (capture), if any. The monitor should differentiate between pacer spikes and the patient's QRS waveform for the accurate delivery of defibrillation or cardioversion therapies.
- Cardioverter—an integrated (synchronized) delivery of a shock to a patient with particular waveforms to stun accelerated rates in atrial fibrillation and similar conditions. This requires close coordination of the shock precisely at the R wave, not during the refractory period, which could cause cardiac standstill. The feature usually displays until disarmed or automatically disarms, so if the patient lapses into ventricular fibrillation, the machine won't continue searching for an R wave before delivering therapy.
- Temperature—several differing approaches to capturing and reporting temperature information include skin surface temperatures all the way to invasive core temperatures. Continued temperature monitoring has become more prevalent with the American Heart Association and worldwide resuscitation councils now

desiring to control and reduce core temperatures to better preserve brain function after cardiac arrest, stroke, or other brain trauma. Additionally, the hypothermic or hyperthermic patient benefits from close monitoring during treatment to confirm effectiveness and avoid overrunning the target temperature.

- Trending/alarm features for some or all of the above parameters depend on robust software, selectable alarm range limits, and clear display messaging of the trend delta and limit violated.
- Clocks, CPR metronomes, battery consumption, and other data points and messages provide vital documentation, ensuring that the user maintains full awareness and has a record of events and milestones.

The astute advanced cardiac life support clinician is always looking for possible/plausible causes for a patient's out-of-norm stats. The classic lists are the "H's" and "T's" that are the hallmarks of pulseless electrical activity (PEA). The H's include hypovolemia, hypothermia, hypoxia, hydrogen ion (acidosis), and hyper- or hypokalemia. The T's include tablets (accidental overdose or suicide attempts, tamponade (cardiac), tension pneumothorax, and thrombosis (coronary or pulmonary). These are usually considered correctable, if discovered and recognized as they develop, and rapid, definitive responses are instituted according to current practice guidelines.

The technical challenges for the environments described above are multiple. Besides safety issues and compliance to acceptable quality design and manufacturing processes, it is important for the medical device manufacturer to fully appreciate how environmental stimulus, such as other medical equipment that may be attached to the patient, may interact; how motion, RFI, sensor attachment, temperature, and humidity can affect the data that is presented to the practicing clinician; and how this can adversely affect the patient's diagnosis and treatment. For those applications that include aircraft (all types), ships, or trains, additional agency testing is required to ensure compliance with these environments (noninterference with flight, navigation, and communication systems).

## IN-HOSPITAL MULTIPHYSIOLOGICAL MONITORING

There are multiple in-hospital uses for multiphysiological monitors in the OR (operating room), ER (emergency room), CCU (cardiac care unit), ICU (intensive care unit), EP (electrophysiology) lab/catheterization lab, telemetry/Holter unit, sleep disorders center, surgical step-

down unit, general medical floor, and implantable pacer/defibrillator surgical suite—the list is extensive.

- Critical care areas, starting at the triage desk of a busy emergency room, continuing to an exam room, a lab area for a scan or x-ray series, and then to a surgical suite (catheterization lab, open heart) or an intensive care/cardiac care suite—all according to the patient's needs as determined by electronic monitoring devices. Thus, the physician and hospital risk assessment manager, along with the biomed department, may standardize on a single version of any given monitor, where not all features would be used in any given department. This facilitates smooth rotation of units between assignments or between units to equalize their usage. Another facility might opt to purchase a blend of features, some to support intensive care, while others have only the most basic parameters. Hospital use should be considered one of the highest demand settings for quality and ability to communicate. Devices need to alert the clinician of the widest array of vital sign changes when any individual reading violates preset parameters, as the patient will not have 100% moment to moment eye contact as they would with EMS. Here, ease of use in terms of training and case labor, low cost per case use, and recording of events is paramount. Thus, wireless transmission to a central monitoring system has become the gold standard. Any system must reduce confusion factors by reducing the number of individual wires, bundling wires from 12-lead arrays, and using 4-lead and 5-lead arrays for ongoing baseline monitoring during procedures or step-down unit use.
- Freestanding surgery and specialized treatment centers. Here, the expected client is low risk, but the center must be prepared for the unexpected patient crash. To not have full coverage of lifesaving parameters would invite malpractice actions.
- Recovery, convalescent and long-term care centers—a host of specialized care facilities for the patient who doesn't require hospital-level care, but cannot be adequately cared for at home. Here many patients will have do not resuscitate (DNR) orders, but all appropriate care is expected to be provided to the limits of the doctor's orders.
- Specialty centers within a hospital can require multiphysiological monitoring devices that monitor a different mix of parameters. Such is the case with sleep disorders. In sleep disorder screening, the polysomnogram continuously monitors a series of parameters, including EEG brainwaves, rapid eye movement tracking, breath



analysis (volumetric, interruptions, temperature, and carbon dioxide changes), muscle movements, and snoring sounds to capture the duration and quality of sleep, SpO<sub>2</sub>, capnograph, and IR tracking. This type of testing has grown in importance as sleep disorders have been shown to have significant impact on the homeostasis of the human body up to and including cardiac arrest. The challenge is to capture needed data while minimizing patient interference to obtain realistic data representing their typical rest experience. Today's products also seek to measure daytime fatigue and even alarm the patient with motion/attitude sensors that interpret behaviors consistent with nodding off while operating vehicles and machinery or monitoring critical systems such as air traffic control. After the original sleep study in a dedicated sleep lab, monitoring of the selected therapy must continue at home to ensure adequacy and effectiveness of the treatments. Home equipment needs to be comfortable; simple to assemble, operate, and utilize; trustworthy; and capable of providing needed data for clinical interpretations leading to adjustments or changed therapy.

### IN-HOME/OUT-OF-HOSPITAL PORTABLE MEDICAL DEVICES

Typically these multiphysiological units may take multiple forms, from a Holter-type unit that records multiple ECG channels including a blood pressure cuff that periodically records blood pressure, to a home version of a polysomnogram that records multiple physiological parameters as mentioned above but in the home environment.

Details of some of in-home/out-of-hospital portable devices:

- Holter monitors—a fairly simple externally wearable ECG that collects data over time, often 24 hours, and usually with a patient controlled button to time stamp a perceived anomaly event, such as a run of tachycardia or sensation of atrial flutter or atrial fibrillation.
- Vagus nerve stimulators—akin to pacemakers, these stimulators target the vagus nerve to quell major epileptic attacks. Not a cure, but an effective control to reduce number and severity of seizure events.
- Deep brain stimulation—often effective in reducing or suppressing muscle tremors caused by Parkinson's disease.
- Transcranial magnetic stimulators—used for treatment of severe depression
- Glucometers and insulin pumps—used by an increasing number of patients to stabilize their onboard sugar levels and live a more normal life.

The list could go on—monitoring of patient status, changing conditions, and response to treatments is the core of clinical practice and home health care.

### OTHER OUT-OF-HOSPITAL ENVIRONMENTS AND THEIR NEEDS

Residences (home), where a patient may continue recovery at least expense, but with the reassurance that electronic monitoring will alert and launch any necessary help. In many cases, such data was already in use for chronic conditions, which would quickly place the patient in the emergency track if they worsened to an acute stage. Other families become more sophisticated based on a medical condition suffered by a child, a spouse, or extended family and friends. The main challenges for home use are simplicity for the unsophisticated user, with the ability to retrieve data by modem or Wi-Fi to ensure appropriate modification of treatment cycles and dosages. It could be stated as “trust, but verify” when the family reports unexpected changes in a patient's monitors or physical condition.

### WORK, SPORTS, INDUSTRIAL, OR COMMERCIAL ENVIRONMENTS

In work, sports, and other activity centers, an endless variety of stressors can trigger an injury or medical condition. Today's corporate response increasingly includes medical clinics with staff and interventions based on electronic monitoring data gathered in a patient's exam. Other such venues have the barest first aid kit, but quickly seek an AED or other gear based on some recent adverse episode. Yet others gear up as a person with disabilities joins, and the reasonable accommodations clauses of the Americans with Disabilities Act are triggered. Nonmedical business entities face the double standard of proving they were not negligent in preparation or response to a sudden acute medical event. The recording of use/event data for all critical intervention cases provides data driven quality assurance and training to protocols and may squelch attempts to litigate monetary damages for a condition not the fault of the proprietor.

The trend for healthcare is to fully monitor a patient's vital signs from arrival of the EMS team through the hospital stay, with continued monitoring at home if the medical condition warrants it. The type of multiphysiological monitor will depend on the patient's condition.

### SUMMARY

Modern clinical practice is keenly interested in the patient's cardiovascular and pulmonary functions, as well as cerebro-neurological response, and the body's ever-changing homeostasis or faltering condition. The medical device industry demands ever-improving technologies in capturing

immediate condition, change, and rates of change. They call for improvements in accuracy and quality, size reduction, as well as technological advances in data capture, transmission, and storage.

Interventional caregivers of every stripe and level are asking for that next technology in vital sign monitoring—confirming effective overall resuscitation efforts, especially adequate compressions and oxygenated blood flow to the brain.

Additionally, they want improved human factors that reduce labor costs and errors. The ultimate package must respond to the current landscape of oversight agencies and reimbursement regulations, plus significant litigious challenges.