Testing of multi-function medical monitors

White Paper

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Introduction

Durable medical equipment is depended on for support of patient diagnosis and therapy, so it must be safe, effective, and reliable. It is also represents a huge capital investment, and therefore must be supported for maximized life.

The challenge for those responsible for the upkeep of this equipment is both the spectrum and quantity of devices, depending on the size and specialization of your institution.

In the earliest days of medical equipment maintenance, there were no standards or even conventions for verification of equipment safety and function. Clinical Engineering personnel (or their predecessors) were dependent on manufacturers' procedures or recommendations. Without as much as a schematic diagram or block diagram, all that remained was technical intuition. Manufacturer support in this regard varied from complete to non-existent; and the trend today is toward less information from the manufacturers.

Earlier scheduled maintenance was driven primarily by fear of patient injury liabilities. The typical biomedical department met informal industry conventions mainly by documenting completion of preventative maintenance procedures (PMs), with little or no documentation of safety checks or failure rates to justify the depth and frequency of those PM's.

After very public, if distorted, attention was given to the electrical safety of medical equipment in the early 1970's, standards-setting organizations like AAMI and ECRI set standards for electrical safety, and the Joint Commission began to sharpen the focus on medical equipment maintenance. ECRI first used the term "preventive maintenance inspection" in 1972, which included more than electrical safety verification and a superficial examination. In the mid- to late 1980's, several different models were offered as a means to assign medical devices to different inspection frequencies based on risk level, function (therapeutic, diagnostic, or monitoring), and maintenance intensity. By 1996, the American Society for Healthcare Engineering proposed a method to classify a risk level to any clinical device, using a formula of five factors: function, clinical application, preventive maintenance requirement, likelihood of failure, and environment of use. "Likelihood of failure" depended on determining the Mean-Time-Between-Failure (MTBF). In 2006, an improvement on previous models was offered which addresses weaknesses in earlier systems by factoring-in cost-effectiveness and (most importantly) a continuous review of outcomes.

Current conventions and practices

Management of medical equipment should:
– verify the availability of each device,
– assure that each device meets its functional specifications,
– assure that each device is safe for patient and user alike, and
– address the device's eventual replacement

Internationally, there is a wide variety of inspection or credentialing processes for hospitals. Some countries have little or no periodic evaluation of their hospitals, and those in other countries are regulated by a government agency. The majority are inspected by a relatively independent collaborative accreditation agency. There are many such agencies, and there is a trend to harmonize their standards. Many of them are listed in the references below. Two of the more global organizations are the World Health Organization (WHO), and the Joint Commission International (JCI). The WHO has fostered standardized accreditation for some years, and the JCI is part of that effort. In its 2011 "Accreditation Standards for Hospitals", the JCI addresses medical equipment maintenance within its section on "Facility Management and Safety", items FMS.8.1 and FMS.8.2. Almost identical items are also found in the requirements of other accreditation agencies, for example India's National Accreditation Board for Hospitals (NABH) specifies four activities under the heading "The organization has a program for clinical support and service equipment management" in its section FMS.3. The European Hospital and Healthcare Federation deals with clinical equipment in its annual "Hospital Healthcare Europe" reference book.

In the United States, the large majority of healthcare centers subscribe to accreditation by The Joint Commission (TJC) (formerly JCAHO). Medical device management is addressed in their standards manual in the Environment of Care (EC) section. This section subdivides into standards, and each standard includes a number of "elements of performance" (EP) that specify requirements. Those that are relevant for this paper are:

EC.02.02.01 EP 2 – requires that Clinical Engineering maintain a current inventory of all devices

EC.02.02.01 EP 3 – requires a maintenance system is in place that assures reliable equipment function

EC.02.02.01 EP 4 – requires a documented plan for maintenance intervals

EC.02.02.01 EP 6 – requires written procedures for managing equipment failures

EC.02.04.03 EP 1 – requires that all equipment is checked for safety and functionality before initial use

EC.02.04.03 EP 2 – requires that life support equipment is maintained, within schedule, at 100 %

EC.02.04.03 EP 3 – requires maintenance on all non-life support, within the department's own guidelines

EC.04.01.01 EP15 – requires an annual evaluation of the equipment management plan, with revisions In any setting world-wide, the department manager responsible for clinical equipment should know the standards by which his employer is evaluated, and organize a maintenance plan that meets and exceeds those standards.

While there is an established standard for electrical safety in patient care devices, there are no standards for maintenance protocols. There are, however, conventions and recommendations specific to device types. Maintenance in the broadest sense is both **proactive** (i.e. safety and functional checks, replacement of failure-prone components, and manufacturer-driven corrections), and **reactive** (i.e. repair of failures).

"Preventive Maintenance" may be something of a misnomer. What are we preventing? If we find a unit safe and functional today, what assurances are there that it won't fail tomorrow? None, but we know the likelihood of failure based on the device's history, and current trend is toward "evidence-based" or "reliability-centered" programs. A better term for "PM" might be "Management Protocol", and it should include pro-active replacement of failure-prone components, verification of functionality to the manufacturer's specifications, and verification of electrical safety.

The term "inspection" is often interchanged with "maintenance", creating some ambiguity when discussing equipment management. "Inspection" is best used to refer to the most basic evaluation of a device for safety and apparent competence, as when evaluating a device on loan or a demonstrator.

At the end of day, it is important to remember that the patient—the real end-user customer who ultimately pays for the technology and our salaries—trusts that his or her clinical care will include equipment that is safe, fully functional, and cost-effectively managed.

General preparation for management protocols

Assuming your department or company uses a computerized maintenance management system (CMMS), you will have a specific group of devices to check each month. A common tactic is to divide-and-conquer: identify groups of like or identical types of devices and determine when and where you can get access to them. This invariably involves diplomatic interaction with the user clinical staff, and one of the banes of medical equipment maintenance is simply accessing the devices. Depending on the number of devices and their location, set a flexible schedule for the maintenance.

For the majority of equipment, maintenance can (or must) be done on site, i.e. in the user locations. This puts emphasis on good planning: Think ahead about the equipment being maintained, and assemble the appropriate performance analyzers, simulators, electrical safety analyzers, model-specific testing apparatus, and any specific disposables that may be needed. This is in addition to the basics for biomedical work: an adequate tool set, PM labels, a disinfectant cleaning agent, lubricants, canned duster gas, adhesive remover, rags, and a small vacuum cleaner. Have your list of devices to be checked, either as hardcopy, in a laptop, or in a handheld device. And lastly, have the manufacturer's recommended maintenance protocol available as hard copy, if not already incorporated into your CMMS application. Most technicians assemble all this on a compact utility cart.

## Recommended protocol: Adult/infant electrocardiographs

The electrical potentials generated by the heart have been used for diagnostic purposes for over a century, and the electrocardiograph (ECG) remains one of the first parameters used by clinicians to assess the patient. There have been variants, but the nomenclature, placement, and color coding of ECG electrodes are standardized. Testing of the ECG channel in a monitor should include a variety of normal waveforms, with and without added artifacts. The unit under test (UUT) can also be challenged with several non-clinical waveforms intended to check the unit's frequency response, gain, ability to detect specific elements of the typical ECG, and the performance of the ECG printer.

A full function simulator will also offer a variety of arrhythmias useful for training as well as performance verification.

Using the normally supplied ECG cable, the UUT should be connected to the simulator with attention to matching the color coding (the ECG connectors on the simulator should comply with both the AAMI and IEC standards. Ideally, the cable should include all ten connectors in order to fully check all twelve standard ECG leads, including V1 through V6, separately. At a minimum, the cable should have five connectors, to include one for a chest lead. When powered-on, most simulators will provide a pre-set ECG with a normal sinus rhythm (NSR), at a resting heart rate and normal amplitude, with no artifact or deviations from an ideal ECG.

Most simulators will provide a selection of pre-sets that vary from the normal ECG, which enables the technician to test the UUT under a variety of extremes of heart rate, amplitude, S-T segment deviations, and artifact. Verifying that the UUT responds within specifications to these variants will provide reassurance that the UUT meets expectations. The technician can also alter any one of the variables to greater extremes, if the UUT warrants it. Testing the response to very high and very low heart rates, for example, can reveal a decline in the UUT's functions. Applying a "Tall-T Reject" performance wave can verify that the UUT will respond as expected to patients with cardiac anomalies. Adding 50 Hz or 60 Hz artifact to the ECG will confirm the effectiveness of the filter for those power-line frequencies.

Depending on the model being tested, your employer's policies, and time constraints, the technician should formulate a list of those tests of the ECG channel that are appropriate, and apply them consistently to all units.
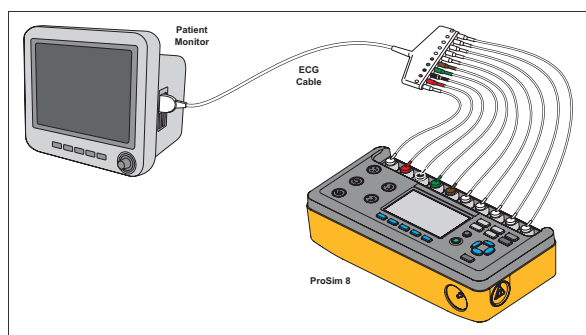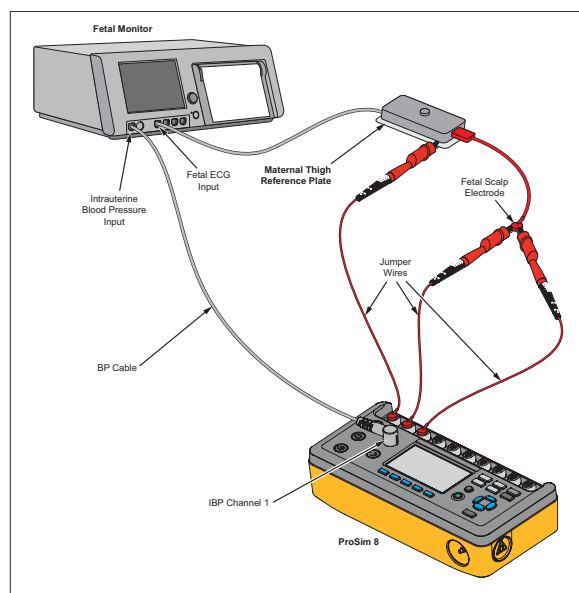
Recommended protocol: Fetal/maternal monitors

Electronic fetal monitors detect, display, and record three parameters specific to the patient in labor: fetal heart rate (FHR), intra-uterine pressure, and uterine contractile force. Fetal heart rate is simulated as an ECG fetal scalp electrode, by connection to the scalp electrode adapter from the UUT. Jumper wires are connected from the ECG posts of the simulator to the adapter provided for the UUT. Simulators capable of testing fetal monitors will enable the technician to vary the fetal heart rate from abnormally low values like 60 b/m, to as high as 240 b/m, with a typical default value of 140.

In the labor setting, intra-uterine pressure is detected by the placement of a catheter in the uterus. This can be simulated by the use of the same pressure channel used for blood pressure simulation, through an adapter cable to the UUT. The simulated contractions are represented by a bell-shaped pressure curve, peaking at 90 mmHg, which can be made to repeat at clinically typical intervals like 2, 3, or 5 minutes. With each elevation of contraction pressure, the simulated fetal heart rate concurrently slows to emulate a normal fetal response to each contraction. The simulator can also be configured for abnormal fetal heart rate responses with each contraction: early deceleration (FHR slows sooner than normal), late deceleration (FHR response is delayed), or a uniform acceleration in which the FHR speeds-up rather than slows.

Besides being a valuable training tool, simulators with this function can test a fetal heart monitor and its recorder through its full range of clinical values.

Figure 1. Configuration for ECG testing, using ten electrode connectors.

Figure 2. Setup for testing fetal heart rate and maternal monitors.

Recommended protocol: Noninvasive blood pressure

The oscillometric technique of determining blood pressure is a variant on the original noninvasive (auscultatory) method created by Riva-Rocci. A cuff surrounding a limb that includes a major artery is pressurized to a point above the presumed systolic blood pressure. The cuff pressure communicates with a transducer in the monitor. As the cuff pressure is slowly decreased (typically at 6 to 8 m Hg per second), the point will be reached where it equals the systolic blood pressure pulses, causing the artery to "snap" open briefly. This causes a pulsation in the pneumatics of the cuff which is detected by the transducer, and noted electronically as the systolic pressure. As the pressure in the cuff is further decreased, it passes a point at which the amplitude of the arterial pulsations reaches its maximum; this point is noted electronically as the Mean Arterial pressure. Finally, as the pressure in the cuff decreases to the point it which there are no more arterial pulses detected, the electronics note that as the diastolic point. The three pressures, systolic, mean, and diastolic, are displayed on the monitor, along with the heart rate derived from the pulsations. The specific manner in which the pneumatics are controlled, and the interpretation of the pressure curve over time, are matters of proprietary software by different manufacturers. A simulator may render a slightly different value for NIBP across a variety of monitors, but the accuracy range for the simulator should be much "tighter" than that specified for the monitor.

The first issue to check in an NIBP monitor is its pneumatic integrity—the NIBP values are meaningless if there is a leak in the system. A cuff or reservoir is configured between the UUT and simulator, and then the UUT is set to close its vents valve by setting it in its "Service" or "Calibrate" mode. The simulator is now asked to pressurize the system to a user-selectable target pressure (we suggest at least 300 mmHg), and an on-screen graphic will indicate the real-time pressure. A leak will be apparent if the graphic shows the pressure decreasing.

To realistically test the NIBP channel, the simulator must pump up a blood pressure cuff as part of the pneumatics of the test array. Failing that, a chamber whose volume is close to that of a cuff could be used. Either way, the test array must include a reservoir that emulates the pneumatics of a typical NIBP scenario. Most simulators include a set of plastic mandrels that can simulate a variety of arm circumferences. In lieu of these, several lengths of PVC tubing of various diameters (3cm to 13cm) will suffice. When the UUT and simulator are arranged, the simulator's NIBP cycle can be started. Any simulator will have pre-set combinations that emulate normal and abnormal situations—for example 120/80 (93), 60/30 (40),

200/150 (167), etc. For neonatal patients, the pre-sets cover a lower range of values from a systolic of 35 to 150 mmHg. The UUT should be assessed at the extremes of these pre-sets, in order to verify that it is within the manufacturer's specifications. Several cycles of the same pre-set should also be run, to confirm the UUT's repeatability. A full function simulator will also provide the option of varying the pulse volume. It can be very useful to challenge a monitor with lower than typical pulse volumes (say 0.2 or 0.3 mL) to emulate a patient with a poor cardiac output or other disease.

Finally, it is a matter of patient safety to verify that the UUT cannot allow an excessively high pressure in the pneumatics, as in a scenario of a stuck relief valve causing the pump to continue pressurizing the system. Here also, the UUT must be its "Service" or "Calibrate" mode. The simulator is set to a target pressure (say 350 mmHg), and asked to start a test. If and when the relief valve in the UUT opens-up, the simulator will stop pumping and display a message indicating that the test has passed. The user will need to consult the UUT specifications to know the relief valve trip point.

Most simulators can also serve as references for verifying the gauge from a sphygmomanometer, or the manometer intrinsic to any clinical monitor.
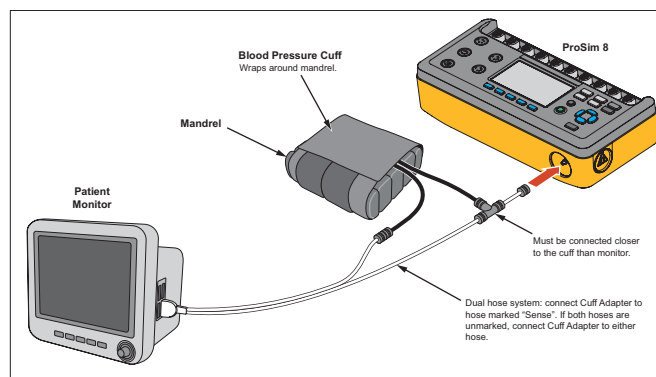

Figure 3. Setup for testing for leaks in an adult NIBP monitor, and for auscultatory blood pressure determinations.
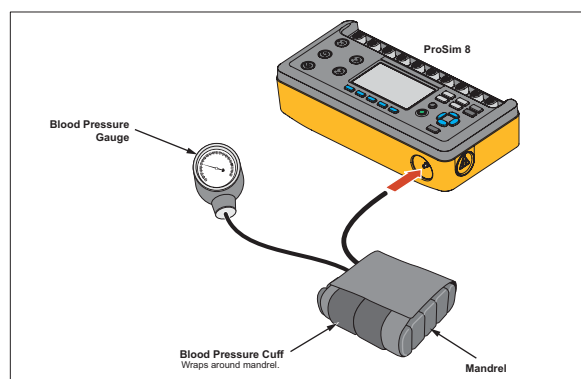

Figure 4. Use of a simulator as a pressure source for testing a sphygmomanometer gauge.

Recommended protocol: Invasive blood pressure

Direct, invasive measurement of blood pressure gives a real-time, beat-to-beat graphic and numeric indication of pressure which is essential for intensive monitoring, commonly for critically ill patients and for patients undergoing extensive surgical procedures. A small in-dwelling catheter is placed in an artery—the radial, just proximal to the wrist, is the location of choice. The catheter is connected to a strain gauge type transducer which is the variable element of a Wheatstone Bridge. Manufacturers have chosen a variety of signals to excite the bridge, which may be as low as 2 V to 16 V, and at frequencies from DC to several thousand Hz. The typical impedance offered by the sensor is 300 Ω. Over the years, two different sensitivities have been used, depending on the make: either 5 µV or 40 µV for each volt of excitation, per mmHg of pressure. 5 µV/Ve/mmHg is the more common, but your simulator should be able to accommodate either sensitivity, as well as the full range of excitation voltages and frequencies.

After connecting the appropriate adapter cable from the UUT to the simulator, it is best to first check the static pressure values. Enter the appropriate screen on the simulator, and then zero the pressure channel on the UUT. Set a low target pressure on the simulator and verify that the UUT displays it within the tolerances of the monitor; then set a clinically high value and repeat the check.

Most simulators have choices of the anatomical location of the catheter, e.g. the radial artery, left ventricle, pulmonary artery, etc, which have differing characteristics. Select the site, and then select a pre-set value for dynamic blood pressure. Choose at least two pre-sets and verify that the UUT responds with graphics and numerics that are within specifications. If respiratory artifact can be added to the simulation, repeat one of the lower pre-sets with that interference, and verify that the monitor meets the challenge.

Pre-defined pressure signals should also be available for simulation of central arterial sites, such as the pulmonary artery pressure or the "wedge" pressure, provided by a Swan-Ganz type catheter. For testing the UUT, as well as for training purposes, some simulators provide a sequence of waveform signals, with typical timings, for clinical procedures such as the placement of a Swan-Ganz catheter, or for cardiac catheterization.

Recommended protocol: Oxygen saturation

Noninvasive, beat-to beat determination of the oxygen saturation of arterial blood has been among the most important additions to clinical monitoring, and has had a great impact on the care of patients in emergent situations or undergoing surgery, as well as in routine outpatient care. Two (or more) wavelengths of infra-red (IR) light are transmitted to well-perfused tissue (usually the distal end of a finger), where the oxygen-carrying hemoglobin absorbs one IR signal and the non-oxygenated hemoglobin absorbs a different IR wavelength. The two IR signals are detected and compared, resulting in a derived percentage of oxygenated hemoglobin, expressed as SpO_2. The ideal saturation is 100 %; saturations down to 90 % are typical, and saturations lower than 90 % are clinically significant, usually requiring some kind of intervention.

Not all pulse oximeter sensors respond to the various saturation levels identically. At any given saturation level, the ratio of IR signals for the oxygenated and for non-oxygenated hemoglobin will differ from one make to another. Each make of sensor thus has its own "R-curve": a graph relating the IR ratios to % saturation. The first determinant in setting-up an SpO_2 test is to know the manufacturer of the SpO_2 sensor used by the UUT (many are licensed to the monitor maker), and select that make in the SpO_2 Functional Tester. The SpO_2 Functional Tester should have the R-curve for the majority of manufacturers in its software. If the make is not selectable, it should be possible to download the R-curve data to the SpO_2 Functional Tester through a port. (See the owner's documentation.)

In addition, the Masimo "Rainbow" technology uses additional IR wavelengths to enable the detection of % methemoglobin, % carboxyhemoglobin, and hemoglobin in g/dL. A fully capable SpO_2 Functional Tester will allow tests of these factors by use of an adapter cable.

Having set the SpO_2 Functional Tester for a specific manufacturer's sensor or R-curve, the primary goal is to verify the response of the UUT by testing several saturation points across spectrum of clinical possibilities: 100 %, 90 %, 85 % and 50 % (patient in asystole) are advisable. A good SpO_2 Functional Tester will emulate saturations as low as 30 %. It should also enable the user to test the UUT with a variety of transmission challenges: a thick, dark finger, as well as a light, thin finger or the greater transmissibility of a neonate's foot. While these are variations in light-absorption, the Perfusion Index—the ratio of the pulsatile signal to the background signal, should also be variable. The Perfusion Index shows the difference between a robust, bounding pulse in the artery of a healthy patient and the weaker, low-volume pulses typical in patients with cardiovascular compromise.

Finally, the SpO_2 channel of the UUT should be tested with several typical interferences. SpO_2 can be influenced by high levels of ambient light (especially light with a high IR component), by power-line frequencies, and by respiratory cycles.

It can be time-consuming to test an SpO_2 monitor with all combinations of these variables, but a SpO_2 Functional Tester minimizes that problem by the use of pre-defined combinations of clinical parameters that emulate a typical "normal" patient and several disease-state scenarios: e.g. Hypertensive, Tachycardia, Heart Attack, etc. These pre-sets can enable the technician to test all the parameters of a monitor simultaneously, at combinations that are realistic, even if they don't go the extremes of each parameter.
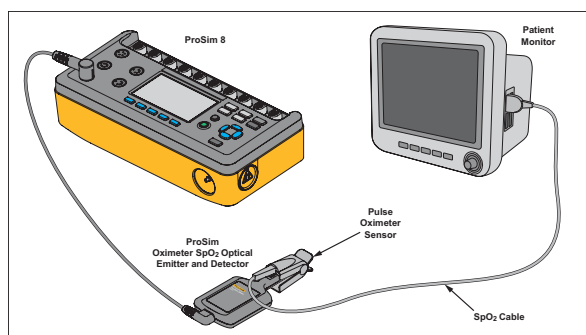
Figure 5. Typical test setup for a pulse oximeter. Placement of the sensor on the digital SpO_2 Functional Tester is critical, and should be verified by a signal indicator on the SpO_2 Functional Tester.
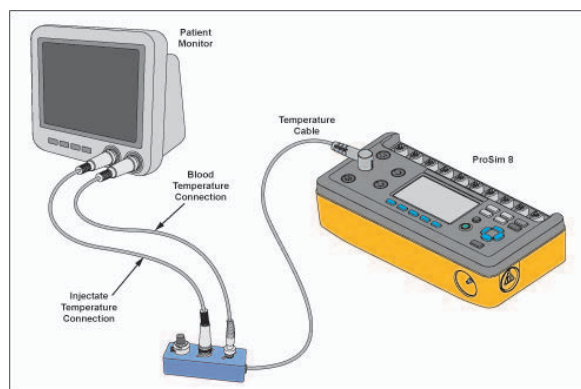
Recommended protocol: Cardiac output (CO)

Although there are alternative methods of determining the output of the heart, the thermal dilution technique is the method of choice in clinical practice, most commonly during cardiac surgery. The technique measures the temperature shift in the blood of a major artery, when an injectate of known volume is injected. The injectate temperature can be at either room temperature (24 °C) or "iced" (zero °C). Given the blood temperature (T_b), the injectate temperature (T_i), the injectate volume (V_i), and a calibration constant specific to the catheter being used, the cardiac output in L/m will be derived from the area under the time-temperature curve. Most monitors display the curve as well as the numeric CO value, as a means of visually verifying that the CO has been derived from an ideal, undistorted waveform. (Injecting in a smooth, rapid motion is essential to an accurate measurement.)

Most simulators of CO will use an adapter to interface to the UUT, specific to the catheter manufacturer. The Baxter (Edwards) catheter series is widely used. The user will need to enter the calibration constant for the catheter, which is specific to the injectate temperature. The user will then enter the injectate temperature as either iced (0 °C) or room temperature (24 °C) injectate. A full function simulator will also give options for blood temperatures slightly above or below the standard 37 °C.

After setting-up the variables on the simulator, begin a CO determination on the UUT, while simultaneously starting an output curve on the simulator. The UUT will complete its CO determination and display the curve and associated CO numerics, which should agree with the pre-set simulator value within the tolerances of the UUT specifications. In addition to accuracy, check for repeatability: at least three determinations should be run, and their values should be almost identical, within ± 0.1 L/m.

A full function simulator will also include the option of a simulated "bad Injectate" i.e. a temperature curve distorted by interrupted injection, or a simulated temperature curve in a patient with a shunt between the left and right ventricles. Both of these are useful to challenge the UUT to detect and display abnormalities.

Figure 6. Setup for simulating cardiac output.

Recommended protocol: Temperature

Most monitors use either of the two thermister-based medical thermometry standards established by Yellow Springs Instruments in the 1950's: The 400-series uses a negative-coefficient thermister with a resistance of 2252 Ω at 25 °C, and the 700-series uses two thermisters for greater linearity: 30 KΩ and 6 KΩ at 25 °C.

Connect the appropriate adapter from the UUT to the simulator, and set the temperature alarm points on the UUT for clinically low and high values, e.g. 36 °C and 40 °C. Set the simulator for two temperatures at the extremes of clinical possibility; we suggest 35 °C and 42 °C. Verify that the UUT displays values within the manufacturer's specified tolerances, and verify also that these temperatures trip the alarm thresholds on the UUT.

Recommended protocol: Respiration

A respiratory waveform and rate is derived by many monitors by taking advantage of those ECG electrodes on the upper body. With each respiratory cycle, the impedance across the electrodes changes slightly, which can be used to detect inspiration and exhalation. In most cases a small signal is impressed on two of the electrodes, and its amplitude is detected, filtered, and amplified for display on the monitor. Rate is derived from the peaks of the wave.

Assuming the simulator is already connected for ECG, there is no adapter needed. The baseline impedance may be settable: typical values are 500 Ω to 2000 Ω. The simulator should be set for at least two extremes of respiratory rate, like 6 brpm and 120 brpm, and the alarm limits on the UUT should be set in order to verify their function.

A full function simulator will also enable the user to vary the ratio of Inspiratory to Expiratory time (I:E) from 1:1 to 1:5, which can be useful to challenge the accuracy of the UUT when used on a mechanically ventilated patient. The simulator may also offer the option of presenting the respiratory waveform of a ventilated patient, in which the waveform varies due to impedance changes with each respiratory cycle.

Finally, if available on the simulator, the apnea alarm of the UUT should be verified by setting the simulator to create a flat-line waveform accompanied by a timer to confirm exactly how long the UUT alarm takes to trip.

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Selected hospital accreditation agencies

International:
The World Health Organization (WHO)
Joint Commission International (JCI)

Europe:
European Hospital and Healthcare Federation (HOPE)
Hauté Autorité de Santé (HAS)

UK, Hong Kong, the Philippines
QHA Trent Accreditation (QHA)

Canada:
Accreditation Canada

Australia:
Australian Council on Healthcare Standards International (ACHSI)

New Zealand:
Quality Health New Zealand (QHNZ)

India:
National Accreditation Board for Hospitals (NABH)

About author

Dennis J McMahon, CBET, is a biomedical equipment technician with over 40 years experience with medical technology, primarily in the surgical setting. After earning a degree in Chemistry in the late '60s, he worked as an anesthesia technician at Harborview Medical Center until 1977, when he moved to Virginia Mason Medical Center. He became certified as a biomedical technician in 1983, and attended service schools for a wide variety of clinical technology over the following two decades.

Dennis has been an instructor at North Seattle Community College since 2002, and is a member of the Washington State Biomedical Association. The WSBA named him Biomed of the Year in 2006. Dennis has written or co-authored ten articles in technical publications, one of which won an AAMI award, and contributed three chapters to a text on anesthesia technology. He retired from full-time employment in 2010, and is now a consultant while continuing to instruct in biomedical technology.

About Fluke Biomedical
Fluke Biomedical is the world's leading manufacturer of quality biomedical test and simulation products. In addition, Fluke Biomedical provides the latest medical imaging and oncology quality-assurance solutions for regulatory compliance. Highly credentialed and equipped with a NVLAP Lab Code 200566-0 accredited laboratory, Fluke Biomedical also offers the best in quality and customer service for all your equipment calibration needs.

Today, biomedical personnel must meet the increasing regulatory pressures, higher quality standards, and rapid technological growth, while performing their work faster and more efficiently than ever. Fluke Biomedical provides a diverse range of software and hardware tools to meet today's challenges.

Fluke Biomedical Regulatory Commitment
As a medical test device manufacturer, we recognize and follow certain quality standards and certifications when developing our products. We are ISO 9001 and ISO 13485 medical device certified and our products are:
• CE Certified, where required
• NIST Traceable and Calibrated
• UL, CSA, ETL Certified, where required
• NRC Compliant, where required