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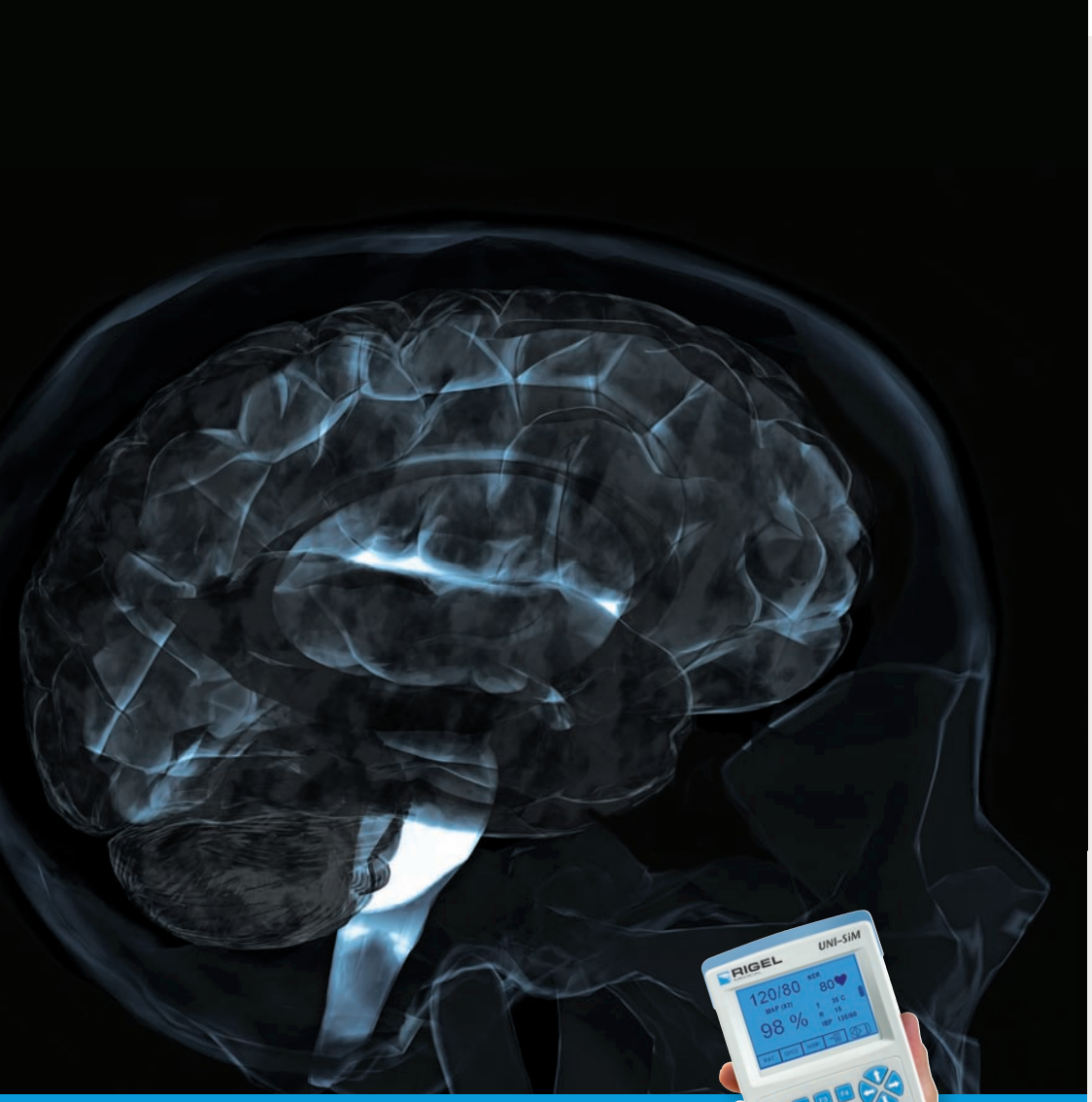
RIGEL MEDICAL

Innovating Together

An introduction to measuring and simulating Vital Signs

Version 1.0

Part of SEAWARD



We've picked your brains to develop the world's most advanced vital signs simulator.

Your ideas have had us thinking. Some of you wondered why the functions of an ECG patient simulator, NIBP and SPO2 simulator couldn't be combined into one compact tester?
So we put our heads together and used our unrivalled expertise to create the hand-held Rigel Uni-Sim. To see the result, or to contribute your own ideas, call us on 813 886 2775, email us at info@rigelmedical.com or visit www.rigelmedical.com

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Contents

Foreword

This booklet is written as a guideline for people involved in testing medical, electrical equipment. All reasonable care has been taken to ensure that the information, reference figures and data are accurate and have been taken from the latest versions of various standards, guidance notes and recognised "best practices" to establish the recommended testing requirements. Rigel Medical, their agents and distributors, accept no responsibility for any error or omissions within this booklet or for any misinterpretations by the user. For clarification on any part of this booklet please contact Rigel Medical before operating any test instrument.

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Rigel Medical assumes that the readers of this booklet are electronically and technically competent and therefore does not accept any liability arising form accidents or fatalities directly or indirectly from the tests described in this booklet.

1 Introduction

For decades, considerable work has been carried out across many industries; to reduce the risk of injury and occupational death to members of the general public. In addition, to aid the process of treating members of the general public, the health sector has evolved, offering an ever increasing portfolio of treatments, monitoring and diagnostic tools.

Risks due to injuries or fatalities during medical treatment or examination are reduced through the introduction of industry practises (i.e. disinfection), guidelines (i.e. best practice), standards (i.e. design criteria, quality processes) and regulations (i.e. mandatory criteria).

To ensure the safety of patients, operators and the members of public, all medical electronic devices must meet the design criteria of the internationally published IEC 60601 standard (or local equivalent where applicable). First published in the 1970's, the IEC 60601 standard (then referred to as IEC 601) describes the design criteria of medical electronic equipment (ME Equipment) in areas such as:

- Electrical safety
- Functional accuracy
- Mechanical safety
- Radiation safety
- Operator safety and errors (labelling, unambiguous instructions)
- Safety of software
- Risk assessment and preventative actions

IEC 60601-1-X (X representing a specific standard number between 1 - 12) is the primary standard and has eleven (sub) standards directly relating to the safety of medical equipment.

IEC 60601-2-X (X representing a specific standard number between 1 - 65). This part of the standard is specific to various types of medical equipment and provides additional information to the four basic standards. Appendix A and B provide an overview of the IEC 60601-1-X and IEC 60601-2-X standards.

This booklet describes the common aspects of vital signs monitoring and performance testing of those vital signs.

The main vital signs described are:

- Blood Pressure (Invasive or Non invasive methods)
- Temperature
- Electro Cardiogram (ECG)
- Respiration
- Blood Oxygen Saturation (SpO2)

To ensure the correct treatment, diagnoses or monitoring of patients, it is of critical importance that the vital signs monitor is able to provide accurate data across all available vital signs. Such accuracy is verified on a regular basis, based on risk assessment, manufacturer recommendations and stages of the monitor's life cycle.

Performances tests (also referred to as quality or functional tests) are typically executed using calibrated simulators across a number of applications and are all part of an acceptance test, preventative maintenance cycle or repair.

A typical test cycle for a vital signs monitor might include:

- Visual inspection
- Self tests (where applicable)
- Electrical Safety Testing (earth bonding, leakage currents)
- Integrity of the device under test (i.e. leak test, over pressure test)
- Parameter accuracy (temperature, pressure, SpO2, time etc.…)
- Check Alarms (pitch, frequency, volume)
- Physiological simulations (Dynamic Patient Simulation)

1.1 Visual inspection

The process of visual inspection is not clearly defined by any standard, however visual inspections form a critical part of the general safety and performance inspections during the functional life of medical equipment.

Visual inspections are a relatively easy procedure to ensure that the medical equipment in use, still conforms to the specifications as released by the manufacturer and has not suffered from any external damage and / or contamination.

These can include the following inspections:

- Housing - Enclosure; look for damage, cracks etc
- Contamination; look for obstruction of moving parts, connector pins, etc.
- Cabling (supply, Applied Parts etc); Look for cuts, wrong connections, etc
- Fuse rating; check correct values after replacement
- Markings and Labelling; check the integrity of safety markings
- Integrity of mechanical parts; check for any obstructions

1.2 Who should verify the correct operation?

The correct function and operation of medical equipment is equally as important as the function it performs. An incorrect reading or missed condition might have considerable consequences for the patient therefore; the

person carrying out the maintenance must be technically competent, appropriately trained and aware of the various parameters being verified.

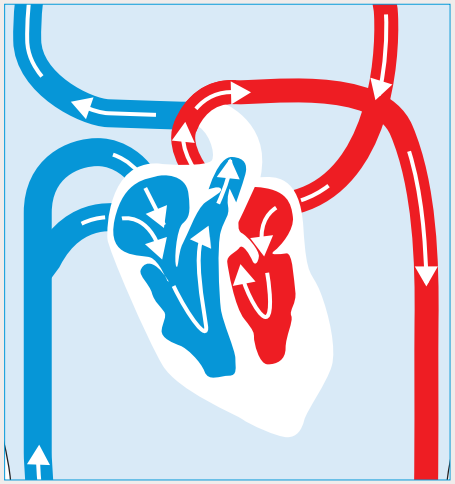
It is the responsibility of the medical equipment manufacturer to provide verification procedures to ensure optimum performance is being achieved. The person or organisation carrying out the maintenance must make themselves aware of the required procedures and operation of the medical equipment. When in doubt, contact the manufacturer.

2 Physiology of the respiratory system

All vital signs are related to the operation and functioning of the respiratory system. Whilst the Electro Cardiogram (see chapter 6) shows the electrical activity of the human heart pumping the oxygenated blood (see chapter 5) around the arteries, blood pressure (see chapter 3 & 4) is generated. Respiration (see chapter 7) rates might show any obstruction (apnoea) in the airways thus affecting the oxygen absorption in the lungs. The core body temperature, together with blood pressure being the most commonly measured vital signs, is maintained through good blood circulation (see chapter 8).

The human heart is central to the respiratory system and can be seen as the main engine within. The heart circulates blood through the body and lungs (the carburettor of the body attaching oxygen to the Haemoglobin protein in the red blood cells) in order to ensure oxygen is able to reach the (brain) tissues and organs in order to sustain life.

Figure 1: A simplified representation of the circulatory system



To establish a single circulation cycle, blood flows through the heart twice, passing through the left and right side of the heart respectively. Acting as two “pumps”, the heart circulates oxygenated blood (red circuit, Systemic circulation) from the lungs through the left side of the heart, whilst de-oxygenated blood from the tissues flows through the right side of the heart to the lungs in order to re-oxygenate the blood cells (blue circuit, Pulmonary Circulation).

The two ventricles (chambers) provide the blood from the heart whilst blood is entering the heart in the two atria (chambers). Valves in and between the different chambers ensure the chambers can fill up with blood during the Diastolic phase (the heart muscle relaxes) and pressures can build-up in the ventricles to provide the required condition to allow circulation from a high pressure (Systolic phase) to the lower pressure areas. A complete cycle of events is referred to as the Cardiac Cycle, a single heart beat and involves;

1. Atrial Systole,
2. Ventricular Systole and
3. Complete Cardiac Diastole.

Cardiac muscles are electrically stimulated and the cardiac cycle is triggered by Sinoatrial Node (S.A. Node), then synchronised through timing (delays) (Atrioventricular A.V. Node and bundle of His) which ensures coordinated contraction and relaxation of the different heart muscles to allow the individual chambers to fill-up and empty. Whilst the heart is self-exciting and able to maintain it’s own pace (S.A. node), the heart rate can be altered due to metabolic demands (e.g. exercise, emotion, anxiety).

During the Cardiac Diastolic phase, the heart relaxes and blood is able to fill the two Atria. As the Atria fill-up to around 70%, the pressure in the Atria releases the valves to the Ventricles (Tricuspid and Mitral Valve). The remaining 30% of blood volume in the Atria is pumped out as the Atria contract (Atrial Systole) at the start of the heart beat. The ventricles contract (ventricle Systole) resulting in the blood flowing out of the heart through the main heart valves (Aortic and Pulmonary valves) into the Pulmonary and Systemic circulation.

The number of circulations per minute (or beats per minute) can vary due to age, as a result of exercise, hormone levels (ie caused by anxiety or stress) and physical condition (related to cardiac output).

The greater the need for oxygen by the body, the greater the need for oxyhaemoglobin. A human heart has a certain capacity to circulate blood (cardiac output) therefore; one way to increase blood supply is to increase heart rate. In general;

- The smaller the cardiac output, the higher the heart rate.
- The greater the cardiac output, the lower the heart rate.

This is evident in infants and children, having a relatively small cardiac output, thus higher heart rate. Their resting heart rate can be between 100-150 bpm. In comparison, a trained athlete has been able to increase their cardiac output through build-up of exercise. The resting heart rate can be as low as 40 bpm or even lower. Cardiac output is not classed as a vital sign and therefore not considered further in this booklet.

3 Blood Pressure

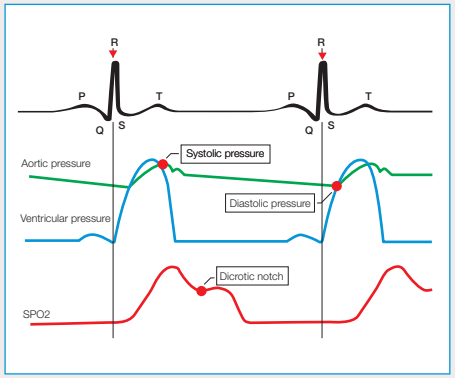
The most common vital sign parameter being monitored or measured is the (arterial) blood pressure. During the cardiac cycle, the ventricles contract (Systole) and the blood pressure is at its highest (Systolic) and during complete cardiac diastole, the blood pressure is at its lowest (Diastolic) which enables the blood to circulate through the body through the Systemic and Pulmonary circulation. The blood flow and pressure change with each stage of the cardiac cycle and are reported in millimetres of Mercury (mmHg).

This is represented in figure 2.

In a healthy patient, the average values for the different pressure variations are:

Systolic pressure	120 mmHg
Diastolic pressure	80 mmHg
Mean Arterial Pressure	90-93 mmHg

Figure 2: ECG waveform vs Aoric pressure and Plethymograph



It is not uncommon to have deviations from these values which can be the result of for example; emotions, anxiety, drug-use, cardiac conditions, life style, fitness, age and diet.

- Hypotension — Blood pressure being abnormally lower than average
- Hypertension — Blood pressure being abnormally higher than average.

3.1 Measuring blood pressure

Blood pressure can be measured both non-invasively (NIBP) and invasively (IBP) and is associated with the pressure in the Arterial blood vessels. Whilst the Invasive method (see 4) is more accurate, the non-invasive method (NIBP) is the most common. Whilst invasive procedures require highly skilled people, the non-invasive method is relatively simple and can be done by both skilled and unskilled people. NIBP monitors range from domestic use to comprehensive multi parameter monitors used in healthcare facilities.

The principles of measuring NIBP can vary from:

- **Palpation method** (feeling) - an indication of the minimum (Systolic) blood pressure obtained through the touch / feel sensation at determined positions (radial, femoral, carotid) of the body. Palpation is often used in emergency and trauma cases where rapid detection of a present blood pressure is required or rapid loss of blood pressure is expected.

- **Auscultatory method** (listening) – as blood flow is interrupted (blocked by external cuff) and released (deflation of the cuff), sounds can be associated with the Systolic and Diastolic pressures. When a cuff is positioned around the upper arm and inflated to the point the artery is blocked (no blood flow), the cuff is then deflated. The pressure at which blood flow regains is the Systolic Pressure and is accompanied by a specific beating sound (referred to as first Korotkoff sound) caused by turbulent blood flow in the artery. The pressure at which the sound stops (fifth Korotkoff sound) is referred to as the Diastolic Pressure. Observation is done by listening through a stethoscope (or can be automated through microphone electronic pick-up), positioned directly on the elbow artery and the use of a calibrated manometer. (The mean arterial pressure is calculated from the systolic and diastolic pressures. There is no agreed standard but the formula below is often referred to:

  - Mean BP = 1/3 (systolic pressure + 2 x diastolic pressure).

- **Oscillometric method** (measuring) – Unlike the Auscultatory method, the Oscillometric method measures the mean arterial pressure and calculates the systolic and diastolic pressures from pressure variations in the cuff when inflated (blocking the blood flow) and then deflated (blood flow regains). Whilst the Auscultatory method often relies on human interpretation (listening), the Oscillometric method is done through automation and the use of electronic pressure sensors. Due to the use of electronic pressure transducers, regular calibrations are required and often advised by the manufacturer.

3.2 Testing your NIBP Monitor

As explained above, Oscillometric NIBP monitors require regular performance verifications to ensure the correct operation. Common issues relating to the accuracy of the NIBP monitor are:

- A leak in the cuff or pressure system, resulting in a lower blood pressure reading.
- Acoustic variance of the cuff due to incorrect cuff volume, variety in materials used and positioning or applying cuff on patient.
- Incorrect operation of the overpressure valve caused by a leak or complete malfunction
- Deviation in accuracy of the electronic pressure transducer caused by wear and tear of electronic components
- Changes in atmospheric pressure including pressure variations caused by closing doors / windows.

A number of tests are provided to determine the correct operation of the NIBP monitors. These are:

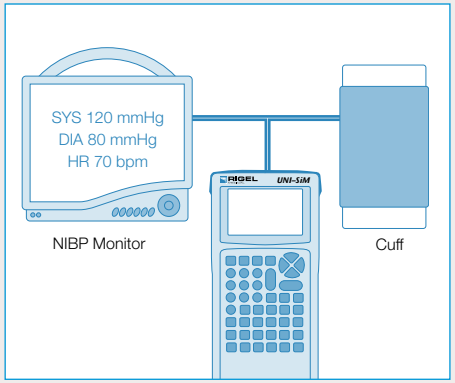
- Pressure Leak Test (see 3.3.1)
- Over pressure valve Test (see 3.3.2)
- Static Pressure & Linearity Test (see 3.3.3)
- Dynamic Pressure (see 3.3.4)

3.3 Test setup

In the example below, the Rigel BP-SiM or UNI-SiM is used to reflect the NIBP simulator. Ensure the correct cuff size and positioning to reduce acoustic errors. An additional 500cc cylinder may also be used to provide a consistent reading.

In order for the NIBP simulator to measure the pressure in the cuff and simulate into the NIBP monitor any pressure variations associated with the Oscillometric method, the simulator must be inserted in (one of) the pressure tubes to the cuff as shown in the figure below.

Figure 3: Test setup: Connecting the NIBP simulator.



3.3.1System pressure leak test:

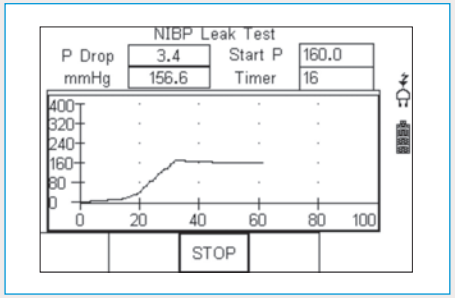
The purpose of the pressure leak test is to verify and ensure the integrity of pressure system including the tubing and cuff. The leak test measures the pressure drop over time and must fall within acceptable values as documented by the supplier or manufacturer of the monitor and or cuffs. Often, the pressure drop is documented as mmHg / min

from a certain start pressure e.g. 200 mmHg. Refer to the service or maintenance instructions provided with the monitor as it may have to be set in service or calibration mode.

For example: a manufacturer could specify a system leak test for a duration of three minutes where the expected total pressure drop must not exceed 15 mmHg. This is equal to 5 mmHg per Minute.

Some NIBP simulators like the Rigel UNI-SiM have a built-in pump to generate the required pressure levels. Inflate the pressure into the system and monitor the pressure drop and time. Figure 4 shows a sample screenshot from the Rigel UNISIM whilst performing the leak test.

Figure 4: NIBP leak test on the Rigel UNISIM.



Once the selected pressure is stabilised, the timer starts and the UNI-SiM will show real-time system pressure over time.

3.3.2 System overpressure valve test

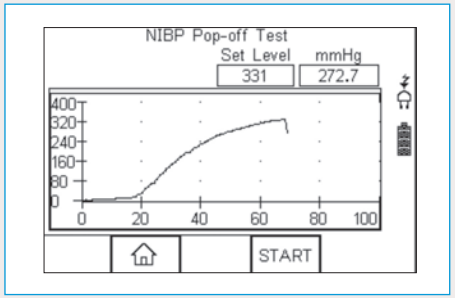
When dealing with pressure systems, it is important to ensure the system is able to vent when pressures reach a value exceeding the safety of the patient or operator and the correct functioning of the monitor itself.

The purpose of the overpressure test is to determine whether the internal safety valve(s) are functioning correctly and release the internal pressure when it reaches the maximum allowable system pressure set by the monitor's manufacturer. Refer to the service or maintenance instructions provided with the monitor as it may have to be set in service or calibration mode.

For example: a manufacturer could specify the set-point of 300 mmHg as the maximum allowable system pressure for an adult setting and 150 mmHg for a paediatric setting (+/-10%).

Some NIBP simulators like the Rigel UNI-SiM have a built-in pump to generate the required pressure levels. Inflate the pressure into the system until the monitor releases the overpressure valve, resulting in an almost instantaneous pressure drop. The inclusion of the original cuff or air reservoir of 500cc during this test is advised to provide consistency with the normal operation of the monitor. Figure 5 shows an example screen shot from the Rigel UNISIM displaying the set-point at which the pressure drop (valve release) occurred.

Figure 5: NIBP pop-off test on the Rigel UNISIM.



In the example above, the test demonstrates that the valve was released at 331 mmHg.

3.3.3 Static pressure or linearity test

The static pressure tests are useful for verifying the performance of the pressure transducer and verifying the integrity of tubing systems internal, external and cuff). In addition, the static pressure test can be used to test the accuracy over a range of pressures. Refer to the service or maintenance instructions provided with the monitor as it may have to be set in service or calibration mode.

Example: A manufacturer could ask to perform a linearity test on the following static pressures: 250mmHg, 200mmHg, 150mmHg, 100mmHg, 50mmHg and 0mmHg. The reading values should be at +/-3mmHg from expected value.

Some NIBP simulators like the Rigel UNI-SiM have a built-in pump to generate the required pressure levels. Inflate the pressure into the system (monitor with or without the cuff) and compare the reading from the monitor with that of the calibrated manometer (UNI-SiM). The inclusion of the original cuff or air reservoir of 500cc during this test is advised to provide consistency with the normal operation of the monitor.

3.3.4 Dynamic pressure

Static testing is useful for verifying the performance of the pressure transducer but it does not prove the accuracy of the monitor under dynamic pressures. The performance of the computing algorithms that enable calculation of systolic, diastolic and mean blood pressures are tested in real conditions.

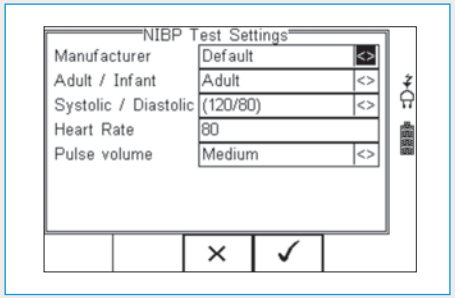
Patient Simulations - It maybe necessary to perform verifications using different patient settings for example; a low (Hypotension), normal and high (Hypertension) blood pressure;

- Patient A : 80/40 Heart rate 80
- Patient B : 120/80 Heart rate 80
- Patient C : 180/140 Heart rate 80

Testing alarms – Most monitors are equipped with both audible and visual alarms. It is important to verify these alarms are working correctly. Refer to the monitor's manual to understand the different alarm conditions.

The simulator can be used to introduce certain conditions and Arrhythmias that will trigger an alarm, subject to monitor and simulator features. Figure 6 shows an example screenshot from the Rigel UNISIM displaying the various dynamic pressure simulation settings available.

Figure 6: Dynamic pressure simulation settings on the Rigel UNISIM.



3.4 Considerations:

There are some physiological variations from one patient to another. Different patients have

different arterial pulse shapes, arterial compliance, flesh rigidity and other factors which simply make the BP cuff respond differently. The Oscillometric signal is complex and changes not only in size but in shape in relation to the cuff pressure.

Manufacturers of automated NIBP monitors are using different methods and aspects to determine the Systolic and Diastolic pressures. These methods and aspects can include:

- Measuring the pulse size
- Measuring the average pulse size
- Determining the peak of the pulse size envelope
- Measuring the average cuff pressure at a set point
- Extracting data during cuff inflation or deflation

All different methods and aspects will result in different readings on the same patient. As such, a single NIBP simulator will read different on a range of different makes of NIBP monitors.

During a dynamic simulation, the NIBP monitor will inflate the cuff to a level above the expected Systolic pressure. The NIBP simulator, such as the Rigel UNI-SiM is connected to the pressure system, and is able to measure the pressure drop in the cuff introduced by the monitor.

When the system (cuff) pressure is above the systolic pressure, blood flow is unable to flow past the cuff. The pressure variations (oscillations) created by the simulator in the cuff are minimal and is the result of simulating the pulsating arterial blood against the cuff.

As the pressure in the cuff drops, the simulator will simulate greater oscillations in the cuff, simulating that blood flow is able to resume further along the artery (along the length of the cuff).

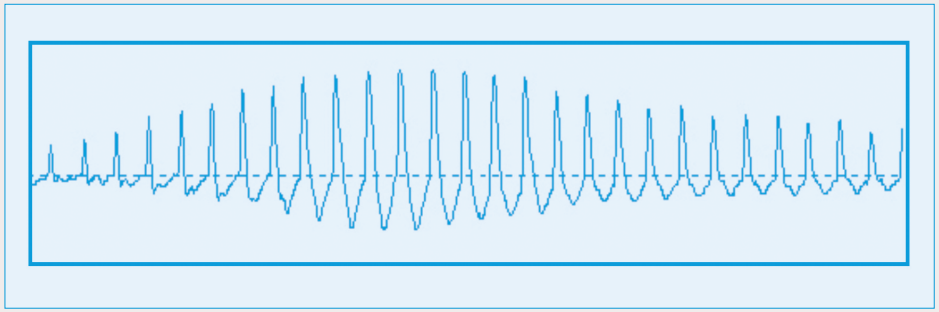
When blood flow in the artery has been established across the full length of the cuff, the systolic pressure has been achieved although the monitor is not able to establish this at this time as the oscillations in the cuff continue to increase until the cuff pressure is equal to the mean arterial pressure.

When the pressure drops below the mean arterial pressure, the oscillations from the simulator decrease again (simulating a reduced pressure on the artery). When the simulated oscillations reach a minimum, the monitor stops the deflation process and determines the Systolic and Diastolic pressures from the measured mean arterial blood pressure and or any of the aspects detailed above depending on the manufacturer.

An example of the shape of the Oscillometric wave form captured by the NIBP monitor is provided in figure 7.

The deviation in NIBP simulation values compared to the values displayed on the monitor, varies between manufacturers of NIBP monitors and of NIBP simulators. Depending on shape of the simulated Oscillometric waveform, each type of monitor might give a different interpretation of the Systolic and Diastolic values. Consistency in deviations is one way of ensuring that the monitor function hasn't deteriorated though accurate simulation of the manufacturer's Oscillometric waveform will allow the verification of whether the correct components are being used (ie compatible or recommended cuffs and tubing), determine the

Figure 7: Oscillometric wave form



accuracy of the calibration and accurately simulate alarm conditions.

To improve the accuracy of simulation, it is essential that the NIBP simulator can simulate manufacturer specific curves so the calculated data is taken from identical parts of the envelop. The Rigel UNI-SiM has the ability to create or upload manufacturer specific envelopes to ensure repeatable and accurate simulations.

4 INVASIVE BLOOD PRESSURE

Arterial pressure can be monitored both invasively (IBP) and non-invasively (NIBP) as discussed in the previous chapter however, it must also be noted that the automated NIBP method can only provide an indirect and non-real time arterial pressure as it calculates pressures based on a typically 30 second cycle.

When a greater accuracy or a real time arterial pressure is required e.g. when a patient's blood pressure is expected to vary greatly during surgical procedures, it's most common to use the invasive method.

During an invasive blood pressure measurement, a liquid filled catheter is placed in the artery (radial, brachial, femoral or axillary). The arterial pressure is directly transferred to the liquid inside the catheter and tubing to the pressure transducer (non-invasive but external from the monitor). The pressure transducer converts the pressure to an electronic signal which is then connected to the monitor for further processing such as determining systolic and diastolic pressures.

4.1 Testing IBP function

A number of tests are provided to determine the correct operation of the IBP monitors. These are:

- Static Pressure & Linearity Test (see 4.2.1)
- Dynamic Pressure (see 4.2.2)

4.2 Test setup

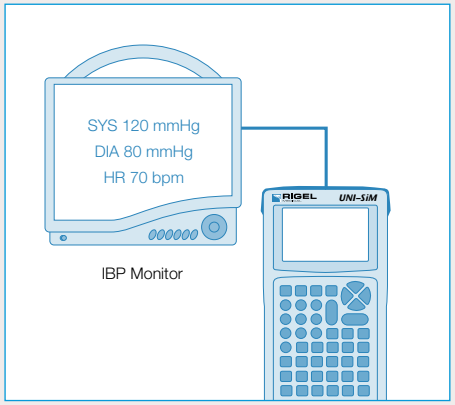
The external pressure transducer produces a milli Volt (mV) signal. The IBP simulator will produce corresponding mV signals on the Signal and Excitation connections to the IBP monitor to

simulate the external pressure transducer.

There are several types of connections depending on the monitor make and the sensitivity of the pressure transducer (mV/mmHg) will also vary by model. It is advised that the correct connections are made and tested prior to the simulations to avoid errors in the simulations.

In this example we connect the Rigel UNI-SiM to the IBP monitor and simulate dynamic pressure values

Figure 8: Test setup: Connecting the IBP simulator



4.2.1 Static pressure or linearity test (verify alarm testing)

The static pressure tests are useful for verifying the performance of the pressure transducer. A linearity test can be done similar to that during the NIBP simulations, in order to verify the accuracy of the IBP monitor over a pressure range.

Start by setting the transducer sensitivity, typically 5µV/V/mmHg. Zero the system by simulating a zero pressure with the simulator and set up the zero value on the monitor. (refer to the service or maintenance manual for instructions)

Once the zero is established, a number of different pressure values can be simulated.

Example: A manufacturer could ask to perform a linearity test on the following static pressures: 250mmHg, 200mmHg, 150mmHg, 100mmHg, 50mmHg and 0mmHg. The reading values should be within +/-3mmHg from expected value.

Record whether the alarm on the monitor occurs at the set value(s) and whether the alarm(s) is at the correct pitch and frequency (refer to the instruction manual).

4.2.2 Dynamic pressure

The accuracy of the pressure transducer can also be verified using a dynamic pressure simulation. The performance of the computing algorithms that enable calculation of systolic, diastolic and mean blood pressures are tested in real conditions.

Patient Simulations - It may be necessary to perform verifications using different patient settings for example; a low (Hypotension), normal and high (Hypertension) blood pressure;

- Patient A : 80/40 Heart rate 80
- Patient B : 120/80 Heart rate 80
- Patient C : 180/140 Heart rate 80

Testing alarms – Most monitors are equipped with both audible and visual alarms. It is important to verify these alarms are working correctly. Refer to the monitor's manual to understand the different alarm conditions.

5 PULSE OXYMETRY

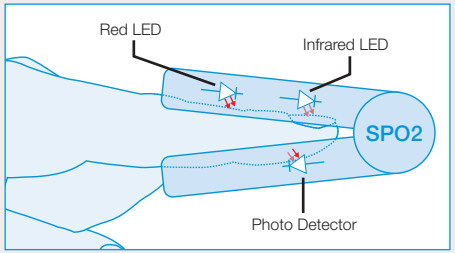
If we consider the heart as the engine of the respiratory system (see chapter 2) and the lungs as the carburettor, oxygenated blood can be considered the fuel whereby the level of oxygen can be directly related to the potential capacity in the blood (or octane level in fuel 95-98% being a typical value).

Oxygen is absorbed by the blood as it passes through the lungs, as oxygen sticks to the haemoglobin protein in the red blood cells. The quantity of oxygen absorbed (oxyhaemoglobin) is a sign of the respiratory system's vitality (performance), hence it is one of the most common monitored vital signs. Displayed in percentage oxyhaemoglobin (SaO2, a direct measurement) in relation to haemoglobin, pulse oximeters can provide a real-time indication of the total oxygen saturation (SpO2) in the blood.

To establish an indication of the oxygen saturation, the pulse oximeter relies on the different light absorption characteristics of oxyhaemoglobin and haemoglobin at different spectrums of light. Using a red (650 - 700 nm) and infrared (850-950 nm) spectrum light source, a pulse oximeter can determine the oxygen concentration by measuring the difference between the red and infrared light being absorbed by the arterial blood.

To do so, a finger probe (or ear probe) is placed on the finger. A red and infrared spectrum LED is driven by the monitor at consecutive intervals of typically 0.2 ms (5kHz). On the opposite side of the finger probe, a broadband receiver converts the unabsorbed red and infrared light signals into electrical signals. Other types of probes (ie foot probes) or techniques are available such as a reflective method used on the forehead. These however, are not part of this booklet although the principles are similar.

Figure 9: The finger probe pulse oximeter



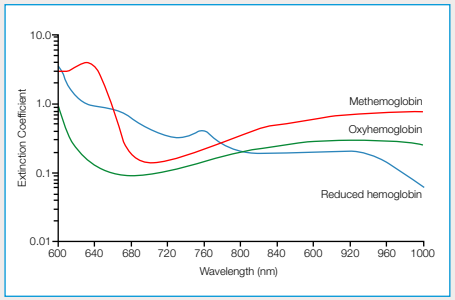
The red light is absorbed more in relation to infrared light when passing through oxyhaemoglobin (oxygenated blood cells) whilst infrared light is absorbed more by haemoglobin (less oxygenated blood cells). The ratio at which the light is being received can therefore provide an indication of the level of oxygen concentration:

In principle, this translates to:

- More infrared than red light being received: higher concentration of oxyhaemoglobin
- More red than infrared light being received: lower concentration of oxyhaemoglobin

A simplified representation of the absorption properties of haemoglobin and oxyhaemoglobin is provided in figure 10. Note that this is not suitable for clinical use.

Figure 10: Absorption properties of haemoglobin and oxyhaemoglobin.



The red line shows the fully oxygenated haemoglobin (HbO2 - 100% SpO2) whilst the blue line shows the fully deoxygenated haemoglobin (Hb - 0% SpO2). At around 800nm wavelength the absorption is equal for both HbO2 and Hb, this is referred to as the isobestic point (803nm)

Typical ratio values are:

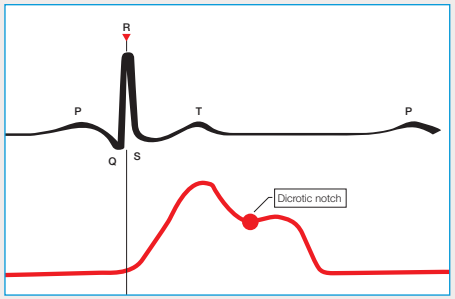
- 100% SpO2 R/IR approximate ratio of 0.5
- 82% SpO2 R/IR approximate ratio of 1.0
- 0% SpO2 R/IR approximate ratio of 2.0

Different manufacturers use different wavelengths (within the described spectrum) and have different absorption look-up tables. This is referred to as the R-curves for each manufacturer.

5.1 Artefacts

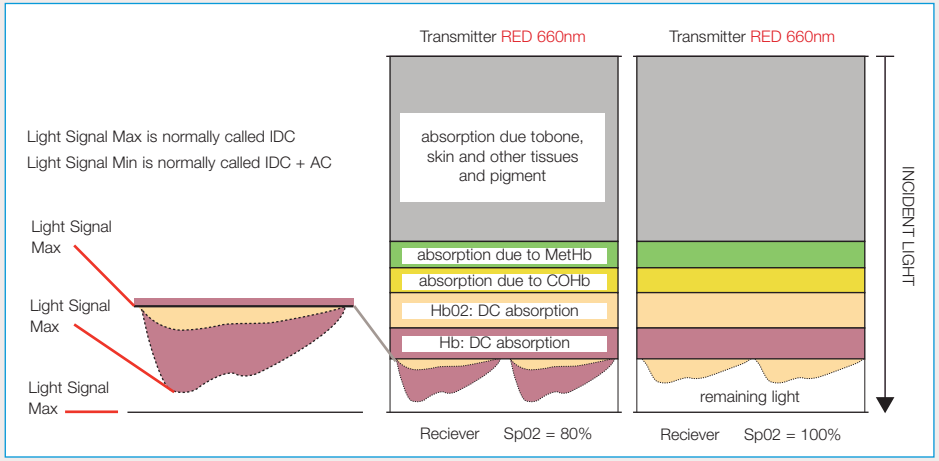
It is important to realise that light is passing through different types of tissue (skin, muscle, bone), cells and vessels (arterial and venous). Therefore, to determine the amount of arterial oxyhaemoglobin, the monitor will look at the "pulsating" light absorption waveform, the so called plethysmograph (see figure 11).

Figure 11: An example plethysmograph vs ECG waveform



As the heart pumps the blood through the lungs, the level of oxyhaemoglobin is "restored" (typically 5% of oxygen in lungs) at every systolic cycle after which it will be absorbed at the capillaries (typically around 40%) until the next systolic cycle. At the peak of the plethysmograph, the monitor measures the total light absorption (Arterial and other cells, tissues, venous vessels) whilst at the troughs, the monitor measures all but the arterial absorption (all remaining cells and tissues). By subtracting peak from the trough, the monitor is able to determine the Arterial oxyhaemoglobin, the value for SpO2. See figure 12.

Figure 12: Light absorption in the red spectrum



The monitor will therefore only respond to peak values in a pulsating plethysmograph.

The measurement process within pulse oximetry can be affected by motion and low perfusion (peak to trough value less than 5%). Motion introduces varying levels of oxyhaemoglobin which might introduce incorrect readings (heart rate and SpO2 %) where as low perfusion can introduce higher inaccuracy due to noise signal ratio.

External light sources may also introduce errors when they contain red and infra red spectrum light. These light sources could introduce a stable amount of light (DC or non pulsating) or a pulsating amount (AC) at frequencies of 50, 60Hz or their harmonics.

Monitors must therefore be able to differentiate between a normal plethysmograph and one with artefacts.

Modern technologies in pulse oximeters are able to differentiate and provide accurate readings during low perfusion, motion and light artefacts however, it is suggested that the performance under such conditions is verified on a regular basis. Recent developments in pulse oximetry see the use of additional light spectrums to obtain more detailed information on the exact content of the arterial blood including methaemoglobin (MetHb) and Carboxyhaemoglobin (COHb).

5.2 Testing your SPO2 monitor – Pulse oximeter

Most pulse oximeters on the market are capable of measuring under extreme conditions (artefacts, low perfusion). In order to establish the correct operation under these conditions, it is important to verify both the performance of the monitor as well as the SpO2 probe and its connection cables.

All parts of the SpO2 probe (LED's, broad band

detector, lens and cabling) are subject to wear and tear and when faulty (or in poor quality) might introduce inconsistent and inaccurate performance with potentially serious implications on the treatment of well-being of patients.

For this reason, we include both the monitor and the SpO2 probe when discussing the testing procedures for pulse oximetry.

Common issues relating to the accuracy of the SpO2 monitor are:

- Faulty (near faulty) LED's (red and infrared)
- Non-OEM probes (white label)
- Contaminated lens / probe window
- Damaged wiring or extension cable.
- Inaccurate calibration of SpO2 monitor
- Testing of audible alarms
- Display of plethysmograph

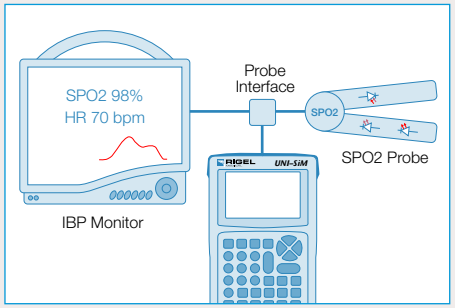
A number of tests are provided to determine the correct operation of the SpO2 monitors. These are:

- Testing monitor accuracy (see 5.3.1)
- Testing alarms and response time (see 5.3.2)
- Testing under low perfusion (see 5.3.3)
- Testing probe quality (see 5.3.4)

5.3 Test setup

In the example below, the Rigel SP-SiM or UNI-SiM is used to represent the SpO2 simulator. Ensure the correct adaptor module is provided during the test as connector shape and pin-out configuration differ between different makes of SpO2 probes and monitors.

Figure 13: Test setup: Connecting the SPO2 simulator (opto-electronic method)



5.3.1 Testing monitor accuracy

The purpose of this test is to verify the performance of the monitor measurement circuits and SpO2 probe characteristics by simply displaying the SpO2% value and heart rate on the monitor.

To simulate the heart rate, the UNI-SIM simulates the (pulsating) plethysmograph at rates of 30 to 300 beats per minute (bpm). Simulated saturation levels can be set between 50 and 100%. In order to verify a range of possible measurements, some simulations can be performed across a number of critical values (see alarm testing) as example: normal, low and critical).

In addition, artefacts (light, motion and arrhythmia's) can be introduced to test the performance of SpO2 monitors either for evaluation, acceptance and as part of preventative maintenance.

Note that the precision of pulse oximeters can vary greatly between brands but typically does not exceed +/-2%

5.3.2 Alarms and Time response test

Use the different values of SpO2 simulation to trigger audible alarms. Alarms of medical devices are specified by the IEC 60601 standard and must be documented by the manufacturer, such as pitch, frequency and strength. Consult the monitor's service or instruction manual for details on the types of alarms available.

In addition, the SpO2 value is updated at set intervals e.g. every 15 seconds. The set response time can be verified using the chronometer function in the UNI-SIM.
The response time and alarm function can be combined in a single test setup i.e. by setting the SpO2 value to 94% with a target of 85%. Wait for the SpO2 monitor to display the 94% SpO2. Activate the chronometer function on the UNI-SIM. This will change the simulation to 85% SpO2 and starts the timer. When the monitor reaches the alarm i.e. when set to 85% SpO2), press the capture button on the UNI-SIM to display the time taken to alarm.

Record whether the alarm on the monitor occurs at the set value(s) and whether the alarm(s) is at the correct pitch and frequency (refer to the instruction manual).

5.3.3 Sensitivity test

To determine whether the SpO2 monitor is able to measure accurately under different pulse volumes, e.g. as a result of different types of patients (normal adult, obese, paediatric, skin colour variation), the UNI-SIM can be used to simulate a variety of pulse volumes and skin colours.

Using the SpO2 simulator, the pulse volume can be reduced until the monitor displays "no SpO2 signal". The value before this point highlights the minimum sensitivity of the monitor. It is important to realise that the quality of the probe can affect the outcome of this test as non-original probes might have poorer quality components and have less sensitivity compared to the original probes (OEM).

Record the sensitivity value over time to monitor the performance of the oximeter.

5.3.4 Testing the SPO2 probe

The SpO2 sensor is often the weakest link in the chain of SpO2 measurement. Probes are considered consumables as they suffer significant wear and tear thus are easily replaceable.
To test the functionality of the probe it is important to realise the different parts that make up the probe and connections:

1. Red LED
2. Infra red LED
3. Broadband detector
4. Lens
5. Cabling
6. Connector
7. Extension cable (where applicable)

The quality or function of the LED's will deteriorate over time. To test the accuracy, the UNI-SIM is able to simulate through the red and infra red circuit individually. This will allow for comparison between the two circuits as the reading on the monitor should be within 1% of each other. When one of the LED's has deteriorated, the readings will differentiate by more than 2% of SpO2 value. Replace the probe and repeat the test again to ensure the new probe is as expected.

Other forms of problems associated with the quality of the SpO2 LED's are a deterioration of the

perfusion sensitivity (see 5.3.3). This could be due to quality of the LED's, broadband detector or the lens (contamination or cuts)

When testing the probe, always ensure that the cable and extension leads are flexed during the tests so that open or short circuits cause an alarm or a "no reading" on the monitor.

Suggestion; Always record the findings on each type of SpO2 probe to build-up an expected performance reference list (perfusion, Delta R / IR reading). This will help in identifying poor or (near) faulty SpO2 probes in the future.

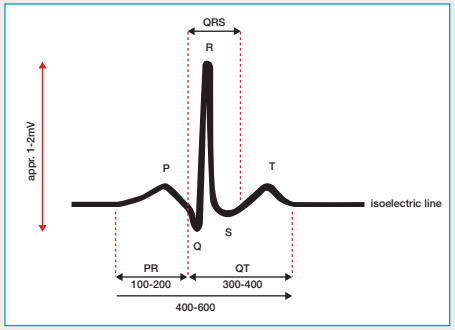
Consideration: Some simulators on the market might make use of an optical finger, capturing the signals from the SpO2 probe and changing the characteristics before converting them back to red and infrared signals. The advantage would be the elimination of probe adaptor boxes however, the disadvantages are significant; Red – Infra Red light / blood absorption characteristics have a strong and direct link with the wave length used (LED spectrum). An optical finger may use different wave length or single LED compared to the manufacturer (OEM). This could result in inaccurate readings. Probe placement will also affect the result and as such can be influenced thus not able to form an accurate reference value.

6 Electrocardiographs (ECG)

The heart, central in the respiratory system, converts bio-electric pulses to a bio- mechanical operation (blood flow). The function of the heart is monitored by measuring the electrical activity (milli-volt signals) generated in the heart and is referred to as Electrocardiography.

The most common ECG tracing of a cardiac cycle (heart beat) is represented below and consists of a P wave, the QRS complex and a T wave. The typical duration of the electrical activity is usually around 400-600 ms. The ECG trace represents the change in voltage across different parts of the body (limbs) because of depolarisation (contracting or Systole) and repolarisation (relaxing or Diastole) in the heart muscles. The baseline voltage of the ECG is referred to as the isoelectric line.

Figure 14: An example of an ECG trace



1. The P wave is generated during the atrial depolarisation.
2. Following this, the right and left ventricals are depolarised, generating the QRS complex.
3. During the T wave, the ventricals repolarise.
4. During the latter part of the T wave, the human heart is most vulnerable against disturbance or fibrillation.

6.1 Einthoven Triangle

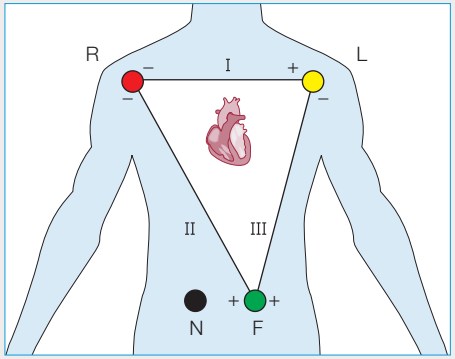
As a result of the body's natural impedance, the electrical activity results in different potentials across the body. One of the most referred to means of measuring the electrical potentials is by positioning electrodes (limb leads) on the patient in a triangular shape, the Einthoven triangle, placed on the left leg (LL), right arm (RA) and left arm (LA).

These limbs can also be referred to as:

Left leg (LL) = Left foot or Foot (F)
Right Arm (RA) = Right (R)
Left Arm (LA) = Left (L)
Right Leg (RL) = Neutral (N)

This is represented in the diagram below:

Figure 15: The Einthoven triangle



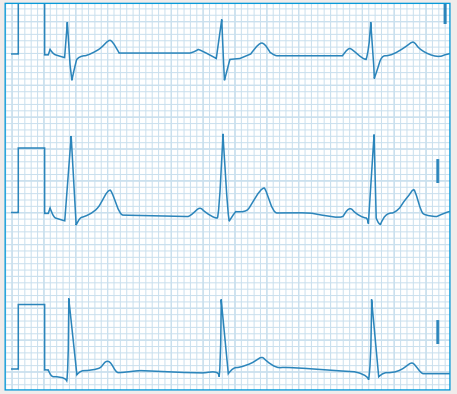
Lead	(+) positive	(-) negative	Potential
I	LA	RA	V1= ΦLA-ΦRA
II	LL	RA	V2= ΦLL-ΦRA
III	LL	LA	V3= ΦLL-ΦLA

Whereby you can calculate that Lead I + Lead III = Lead 2 (Kirchhoff's law[a])

(ΦLA-ΦRA)+(ΦLL-ΦLA)=ΦLL-ΦRA

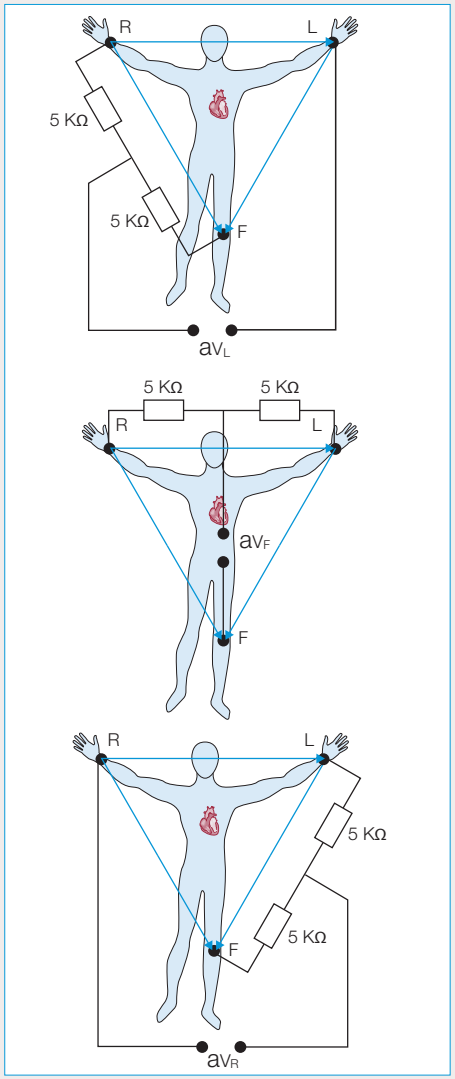
The ECG waveform, (PQRST) can now be determined at various locations of the body, to specifically highlight anomalies in a specific part of the waveform. These can be directly related to the performance of the atrium and ventricle muscles.

Figure 16: A typical waveform (Lead I) and the derived shapes (Lead II and III)



Using vectors, Lead I, II and III can be separated into Augmented limb leads whereby the potential is measured from one (positive) of the three positions on the Einthoven triangle and the combined other two (negative) as shown in figure 17 on the following page

Figure 17: Augmented limb leads



Lead	+	-
aVL	L (LA)	R (RA) + F (LL)
aVF	F(LL)	L(LA) + (RA)
aVR	R(RA)	L(LA) + F(LL)

6.2 Precordial leads

When a more detailed electrocardiogram is required, additional leads, the precordial leads, are placed on the chest. The different lead configurations will allow diagnosis of numerous heart conditions by studying relative amplitudes, heart rates and uniformity across the different leads.

The precordial leads (V1,V2,V3,V4,V5 and V6) are placed in close proximity to the heart to ensure sufficient signal strength and accuracy. Placement of the leads are in accordance with figure 18 below.

Figure 18: Precordial lead placement

For figure 18 use IEC Code 1 for lead identification, not those shown, including the chest leads which should be C1 – C6 not 'Y'.

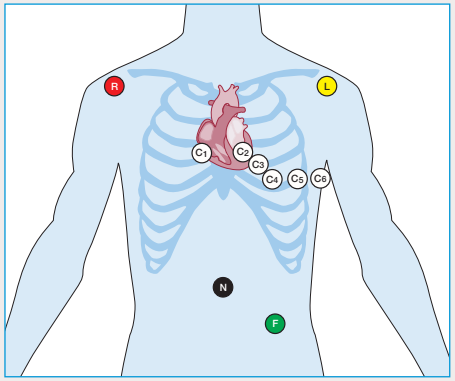
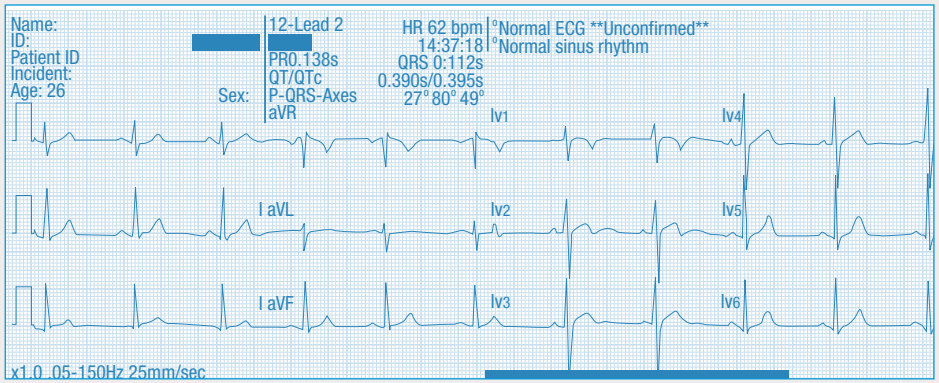


Figure 19: Example of a 12 lead ECG



6.3 Unipolar vs. bipolar leads

ECG leads are split between unipolar and bipolar leads. The limb leads (I, II and III) are bipolar, having both a positive and negative pole. The augmented leads (aVL, aVF and aVR) and precordial leads (V1-6) are considered Unipolar, having only a true positive pole. The negative pole consists of signals from other poles.

6.4 Colour coding

ECG leads are marked with both abbreviations and colour coding according to the corresponding placement on the body. There are 2 common markings available on the market today. These are shown in the table below.

Table 1: ECG Abbreviations and Colour Coding

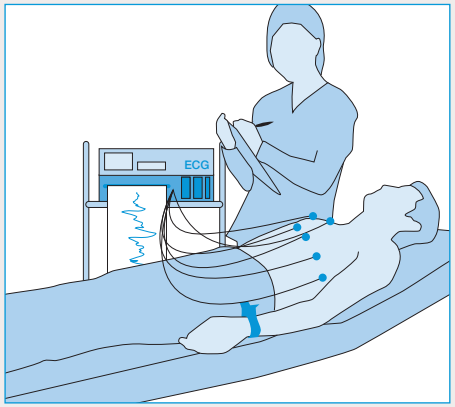
Elecrode	IEC Code 1		IEC Code 2 (American)	
	Abbreviation	Colour	Abbreviation	Colour
Right Arm	R	Red	RA	White
Left Arm	L	Yellow	LA	Black
Right Leg	N	Black	RL	Green
Left Leg	F	Green	LL	Red
Chest 1	C1	White/Red	V1	Brown/Red
Chest 2	C2	White/Yellow	V2	Brown/Yellow
Chest 3	C3	White/Green	V3	Brown/Green
Chest 4	C4	White/Brown	V4	Brown/Blue
Chest 5	C5	White/Black	V5	Brown/Orange
Chest 6	C6	White/Violet	V6	Brown/Violet

6.5 The ECG Machine

To observe an ECG, the difference between two electrical signals at different points on the body must be amplified. Then the electrical potentials can be displayed on the screen.
ECG Machines may typically use 3 lead, 5 lead or 12 lead configurations.

Placement of the ECG leads is standardised so that the interpretation of the ECG is consistent. Cardiac conditions that can be diagnosed using ECG's include abnormally fast heart rate (tachycardia), abnormally slow rate (bradychardia), heart block, acute myocardial infraction (a blood clot in the heart), ischemia (a restriction in the blood supply to a part of the heart) and numerous other conditions. These conditions come under the generic term of Heart Arrhythmias.

Figure 20: Patient on ECG recorder



6.6 Testing ECG Monitor

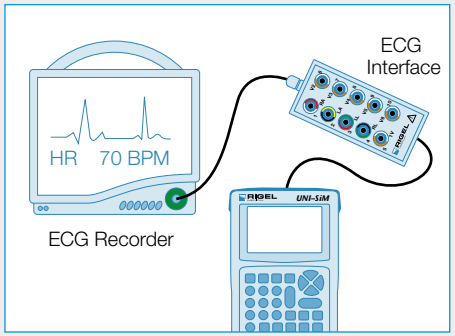
Due to the important analysing role of the ECG monitor, it is crucial to ensure that the input circuits of the ECG monitor are able to measure the small ECG signals accurately. That the software is able to interpret these signals to the corresponding conditions and that alarms are visible and audible according to the manufacturers specifications.

Therefore, the following simulations and performance tests are often part of the regular maintenance:

- Linearity of heart rate measurement
- QRS Beep
- Alarms (high and low)
- Alarms for disconnected electrodes
- Arrhythmias recognition (Asystolic)
- Sensibility Test
- Zero offset
- Frequency response
- Printer calibration (amplitude, timing)

The most common instrument used for the above is a patient or ECG simulator. In the example below, the patient simulator from the UNISIM is used;

Figure 21: Test setup: Connecting the ECG simulator



6.6.1 Linearity of heart rate measurement

The purpose of this test is to verify the capability of the monitor to measure and display Heart Rate accurately. It is recommended to simulate several values in range spanning 30-300 beats per minute (bpm).

Compare the readings with the simulated values and check whether this is within manufacturer specifications (normally +/- 1 bpm or +/- 1% of reading)

6.6.2 QRS Beep

To aid the monitoring process, it is a requirement to fit the ECG monitor with an audible QRS beep. This provides a clear "beep" each time the QRS wave passes. Frequency and pitch variations can provide a clear indication of the heart rate without having to have line of sight to the ECG recorder.

6.6.3 Alarms (high and low)

IEC 60601-1-8 provides the requirements for alarms on medical devices. Alarms can vary in frequency, pitch, volume and melody. In general, the greater the urgency, the higher the pitch, volume and pulse frequency (or melody).

During the performance test of the ECG recorder, alarms can be tested by simulating different heart rates and arrhythmias using a patient simulator. At the end of the test, the final alarm condition can be tested by disconnecting the leads one by one. The monitor should go into alarm condition when this happens.

Record whether the alarm on the monitor occurs at the set value(s) and whether the alarm(s) is at the correct pitch and frequency (refer to the instruction manual).

6.6.4 Arrhythmias recognition (Asystolic)

ECG monitors, which are able to interpret the ECG recording, are required to provide an alarm when they detect a seizure in blood circulation (or lack of pulse). This is the case during Ventricular Fibrillation and Asystole (flat line) when no electrical nor mechanical activity is present in the heart. Ventricular Fibrillation is a condition whereby the ventricals contract erratically with the net result of poor to no blood circulation from the ventricals to the body. During coarse VFIB, the waveform amplitudes are significantly larger than during fine VFIB. The latter is close to an Asystole.

All cases of VFIB lead to rapid loss of consciousness in the patient and must be treated immediately with the use of a defibrillator.

6.6.5 Sensibility Test (Gain)

To ensure the input circuits of the ECG recorder are sensitive enough to measure the ECG mV signals, the input amplifier settings are tested by supplying a Normal sinus Rhythm (NSR) at (e.g.) 60 bpm and with a 1mV amplitude.

When the NSR is displayed on the screen, change the gain of the monitor and check if the changes in amplitude are relative to the gain change i.e. a doubling in gain would result in a doubling of amplitude. The heart rate should not be affected. Some ECG recorders are supplied with a printer and can allow for gain and amplitude settings to be easily crossed referenced.

6.6.6 Zero offset

The zero offset test demonstrates the aligning of the isoelectric line of the ECG wave form with the zero line of the ECG recorder. This is achieved by checking whether the ECG line (flat line on the

recorder) is at zero mV when no leads are connected. When the recorder is fitted with a printer, the printed line shall be at zero mVolt.

6.6.7 Frequency response

To limit the sensitivity of the ECG recorder from external signals i.e. mains frequency and other artefacts, the input circuits are fitted with filters. So called High Pass Filters – HPF's (allowing signals of greater frequency to pass through) and Low Pass Filters – LPF's (allowing frequencies of lower frequencies to pass through) provide a bandwidth of allowable frequencies.

Typical values are 0.5Hz / 1 Hz for HPF's and 40 Hz for LPF's in monitor mode and 0.05 Hz for HPF and 40 / 100 / 150 Hz for LPF's in diagnostic mode.

These filter settings can be selected based upon the application. To test the settings of the filters, performance wave forms such as a sinus of triangular waveform can be simulated to the ECG recorder. By varying the frequency in-and outside the bandwidth, the performance can be verified.

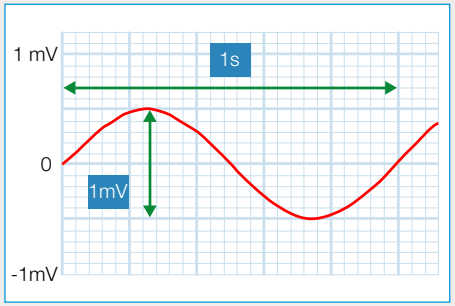
6.6.8 Printer calibration (amplitude, timing)

ECG recorders with build-in printer facility are required to be tested for linearity of the printer speed. Printer rolls typically move at 25 mm / seconds. To test printer speed and linearity, a fixed frequency sinusoidal wave can be simulated. This should result in a consistent wave length width across the print out and must correspond to the print speed.

ECG recording paper consists of a matrix of squares each 1mm x 1mm. At a speed of 25mm/s and a sensitivity of 10mm/mV each square represents 0.04s and 0.1mV respectively.

A signal with an amplitude of 1 mV and frequency of 1 Hz should have an amplitude of 10 mm and wave length of 25 mm

Figure 22: A sinusoidal test signal of 1Hz and 1mV amplitude.



7 Respiration

Unless a human is subject to mechanical ventilation, inspiration of the lungs is controlled by the increase in volume of the thoracic cavity. The thoracic cavity volume is increased as a result of (Involuntary) contraction of the diaphragm (layer between lungs and abdominal cavity). In addition to the diaphragm, the intercostals muscles also aid the breathing process by lifting the lower and upper ribs. Expiration of the lungs is a result of the elasticity of the lungs, forcing air out when the diaphragm and intercostals muscles relax.

When a patient is under general anaesthetic, he/she might no longer be able to sustain the involuntary control of the diaphragm and intercostals muscles. A mechanical ventilator is then required to deliver a set volume per breath and respiratory rate (breaths per minute). Monitoring the respiration rate on patients subject to anaesthesia is vital as it provides immediate warning of changes to the respiration rate including obstruction of the trachea (airpipe). An obstruction in the trachea stops the oxygen supply to the lungs and stops the expiring of carbon dioxide from the blood which can lead to a cardiac arrest and subsequent death if untreated e.g. removing the obstruction via an endotrachea tube).

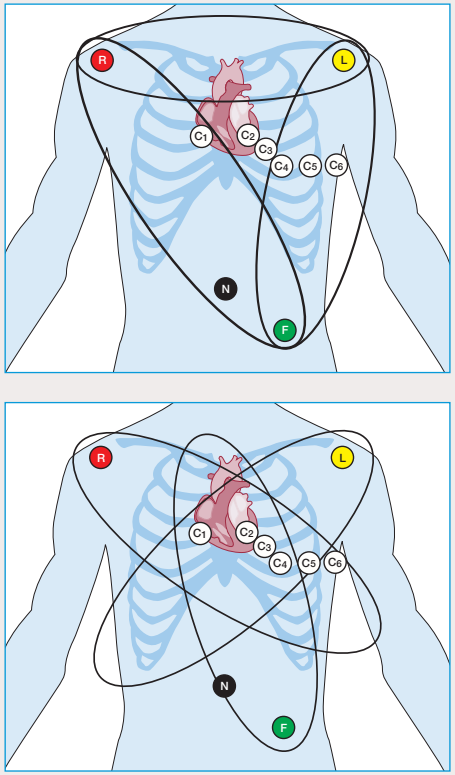
There are several ways of deriving respiration rate from the ECG leads and signals.

1. Most commonly used, is the measurement of the transthoracic impedance between the ECG leads ie Lead I, II or III. As the thoracic cavity expands (inspiration), the impedance of the chest increases. Whilst during expiration, the thoracic cavity reduces in volume thus decreasing its impedance.

2. Another method of determining the respiration is through observing the change in the ECG amplitude (ECG Derived Respiration – EDR) as a result of changes in the position between electrodes and heart as the chest cavity expands and the heart moves as a result of changes in the position of the diaphragm. This method can be visualised on a recorded ECG.

3. A third method to establish the respiration rate is by observing the changes in R-R intervals. (time between the R-peaks of two successive QRS waves).

Figure 23: Respiration through limb and augmented leads



In all instances, the ECG leads are placed on a human chest as shown above. Respiration rates can be monitored through all limb and augmented leads. Most monitors and recorders allow a selection of leads.

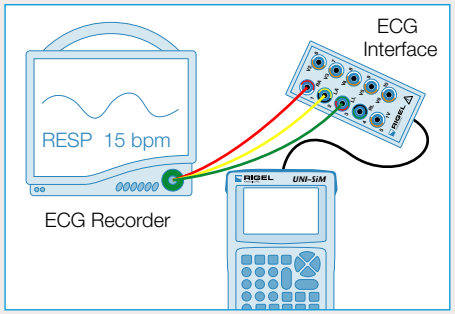
7.1 Testing respiration function

The most common method of monitoring respiration at bedside is through impedance measurement across the ECG leads.

The tests to perform on such monitor are:

- Linearity of Respiration measurement
- Sleep Apnea
- Alarms (high and low)

Figure 24: Test setup: Connecting the respiration / ECG simulator



7.1.1 Linearity of respiration measurement

The purpose of this test is to verify the capability of the monitor to measure and display respiration rate values. It is recommended to simulate several values across a range rates from 100 bpm down to (sleep) apnoea (see 7.1.2)

Check the specification of the monitor to verify the readings are within the required accuracy. Typical accuracies are within +/- 1bpm.

7.1.2 Sleep Apnoea

During our sleep, our airways can become obstructed, preventing oxygen to reach the lungs and stopping the expiring of carbon dioxide from the blood. As a result, the level of carbon dioxide increases in the blood (level of oxyhaemoglobin drops) as it is not able to pass out through the lungs and no new oxyhaemoglobin enter the blood stream. Whilst this is not a direct health risk as the brain will signal a wake-up, when left untreated, it can lead to more serious conditions such as high blood pressure and heart failure.

Whilst sleep apnoea can be monitored in difference ways (CO2 monitoring, SpO2 etc), its most commonly monitored through the respiration rate on bedside monitors via ECG leads. Sleep apnoea will appear as an absence in breath rate (breath rate = 0) and a respiration monitor should sound an alarm when sleep apnoea is detected.

7.1.3 Testing Apnoea alarms

In order to act swiftly to a deteriorating condition of the patient, respiration monitors are supplied with alarms to indicate a unacceptable change in respiration rate (too high, too low or Apnoea). Using a patient simulator, normal (e.g. 15 breath per minute - bpm), low (e.g. 5 bpm), high (e.g. 30 bpm) and apnoea (0 bpm) can be simulated. Depending on the application of the monitor (i.e. adult or paediatric monitoring), the range of values could vary due to natural change in respiration rate in infants (higher) and adults (lower) or when testing monitors used for exercise stress testing (>30 bpm)

Record whether the alarm on the monitor occurs at the set value(s) and whether the alarm(s) is at the correct pitch and frequency (refer to the instruction manual).

8 Temperature

One of the most commonly monitored vital signs is the body temperature. Several devices have been marketed over the years from contact based temperature measurement such as the Mercury filled thermometers (no longer available due to the toxic nature of Mercury) and resistor based sensors to non-contact infrared based temperature sensors.

Our core body temperature (Tc) varies by gender and can vary between different stages of the day. In women, the core body temperature also changes during the menstrual cycle, peaking at the time of ovulation.

The average core body temperature is 37°C ± 0.5°C. Depending on the placement, application and method, different temperature readings are expected in healthy individuals as shown in table 2 on the following page.

The most common temperature sensors used on bedside monitoring are electrical temperature sensors based on a temperature related varying resistor (thermistors). These thermistors are commonly known as NTC's (negative temperature coefficient – meaning that that the resistance decreases when temperature increases) and PTC's (Positive Temperature Coefficient – meaning that the resistance is increasing as temperature increases).

The YSI 400 and YSI 700 have become the standard NTC's used in the medical industry. Whilst the YSI 400 is slightly more accurate over the range of 0-75ºC, the YSI 700, which contains a dual element (Ra = 6kΩ @ 25ºC and Rb = 30kΩ @ 25ºC), is able to provide it's accuracy over a wider range (-25ºC to 100ºC)

Body temperature is simulated by the different resistor values corresponding to the required temperature.

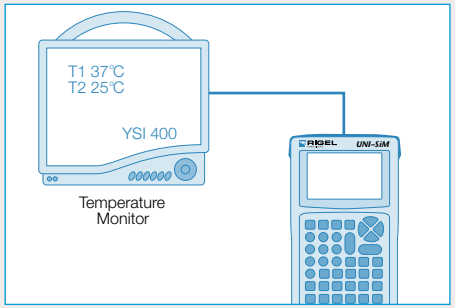
Please see table 3 on the following page.

8.1 Testing Temperature function on Multiparametric Monitors

We have the following performance tests :

- Linearity of Temperature measurement
- Alarms (high and low)
  Ensure the correct temperature sensor (YSI400 or 700) on the patient simulator is selected.

Figure 25: Test setup: Connecting the temperature simulator



8.1.1 Linearity of Temperature measurement

The purpose of this test is to verify the linearity of the monitor over the most typical range of temperatures such as body normal, fever (high), hypothermia (low) and room temperature.

A patient simulator is often able to simulate across this range between 25-41°C.
Check the specification of the monitor to verify the readings are within the required accuracy.

Table 2: Different temperature reading methods

Placement	Application	Method	Accuracy
Ear (Tympanic)	Non-invasive	contact and non-contact	Core temperature (Tc)
Rectally	Invasive	contact	Core temperature (Tc)
Orally	Invasive	contact	0.3 to 0.6˚C < Tc
Armpit (Axillary)	Non-invasive	contact	0.6 to 1.2˚C < Tc
Skin temperature	Non-invasive	contact and non-contact	Depending on direct environment

Table 3: Resistor values on YSI 400 and 700 sensors

(Body) temperature	Resistor Value		
	YSI 400	YSI 700 (a)	YSI 700 (b)
41˚C	1,152 Ω	3,070 Ω	15,520 Ω
37˚C	1,355 Ω	3,610 Ω	18,210 Ω
33˚C	1,599 Ω	4,260 Ω	21,430 Ω
25˚C (room)	2,252 Ω	6,000 Ω	30,000 Ω

A more detailed range of resistor values vs temperature is provided in Appendix C.

8.1.2 Testing temperature alarms

In order to act swiftly to a deteriorating condition of the patient, temperature monitors are supplied with alarms to indicate a unacceptable change in core or skin temperature. (too high or too low). Using a patient simulator, normal (37˚C), low (33˚C), high (41˚C) and room (25˚C) temperature may be simulated.

Record whether the alarm on the monitor occurs at the set value(s) and whether the alarm(s) is at the correct pitch and frequency (refer to the instruction manual).

9 Record Keeping

Overall, the area of risk assessment and the creation of risk management files has become a growing feature of routine safety and performance testing decisions, with different organisations and departments drawing-up individual plans to deal with specific safety hazards. Comparison with previous and expected test results will therefore allow you to monitor deterioration of the Device Under Test and prevent potential failure before a fault occurs.

To ensure proper record keeping is maintained it is important to provide a procedure in which data is collected regarding:

- Inspection Date
- Visual Inspection
- Electrical Safety
- Functional Testing
- Next inspection Date

Rigel Medical have developed Med-eBase, a software package to automate the generation of test reports including visual inspection, electrical safety and performance testing. An example of such test template is provided in Appendix D.

Going forward, determining the appropriate levels of both electrical and functional testing will be central to the introduction of cost effective yet reliable preventative maintenance campaigns.

Conclusion

Planned Preventative Maintenance is an important aspect during the useful life of a medical electronic device. To ensure safety of the patient and operator, procedures are required to cover:

- Visual inspection
- Electrical safety testing (see IEC 62353)
- Performance or functional testing
- Record keeping

This booklet has provided a basic introduction to vital signs monitoring and suggested test procedures for each vital sign. Always ensure that the function and operation of the DUT is understood before commencing on the planned preventative maintenance. Without fully understanding the function and or operation, visual inspections, electrical safety tests and functional tests might be incorrect or incomplete. Prior to any testing, ensure that the manufacturer's recommendations are available as they often supersede any general inspection guidelines.

Considerations and Recommendations:

1. Ensure that the operator of test equipment is properly trained on both the test equipment and DUT to ensure that valid measurements are taken and understood and prevent unneccessary danger during the safety test.

2. Always ensure that the DUT does not pose any danger to the user and / or people within the vicinity to the safety test. (e.g. moving parts, open conductors, Live components, heat etc)

3. Ensure that manufacturer's instructions are followed and any performance is checked against manufacturer's documentation.

4. Ensure high accuracy and repeatability of simulations and measurement readings (some manufacturers might specify full scale accuracy which will effect the accuracy of low value readings or measurements).

5. When determining the correct means of testing a specific Medical Device, ensure that the chosen test procedures are applicable to the DUT and are clearly documented for future use.

Rigel Medical offers a range of test equipment to cover simulation and performance testing as well as a range of electrical safety analysers to meet the IEC 62353 and IEC 60601 requirements. Please visit our website www.rigelmedical.com for a full overview of our product offering or register online for our free newsletter on future product releases and product innovations.

For further questions or comments relating to this booklet or on the Rigel Medical product offering, please contact John Backes via email at johnb@rigelmedical.com

Did you know you can now follow us on:

Appendix A
IEC 60601-1 Collateral Standards (© IEC Geneva, Switzerland)

IEC 60601-1-1	MEDICAL ELECTRICAL EQUIPMENT – PART 1: GENERAL REQUIREMENTS FOR SAFETY 1: COLLATERAL STANDARD: SAFETY REQUIREMENTS FOR MEDICAL ELECTRICAL SYSTEMS
IEC 60601-1-2 (ACDV)	MEDICAL ELECTRICAL EQUIPMENT - PART 1-2: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE - COLLATERAL STANDARD: ELECTROMAGNETIC PHENOMENA - REQUIREMENTS AND TESTS
IEC 60601-1-3	MEDICAL ELECTRICAL EQUIPMENT – PART 1: GENERAL REQUIREMENTS FOR SAFETY – COLLATERAL STANDARD: GENERAL REQUIREMENTS FOR RADIATION PROTECTION IN DIAGNOSTIC X-RAY EQUIPMENT
IEC 60601-1-4	MEDICAL ELECTRICAL EQUIPMENT: PART 1-4: GENERAL REQUIREMENTS FOR COLLATERAL STANDARD: PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS
IEC 60601-1-6	MEDICAL ELECTRICAL EQUIPMENT - PART 1-6: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE - COLLATERAL STANDARD: USABILITY
IEC 60601-1-8 (CCDV)	MEDICAL ELECTRICAL EQUIPMENT - 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 60601-1-9	MEDICAL ELECTRICAL EQUIPMENT - PART 1-9: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE - COLLATERAL STANDARD: REQUIREMENTS FOR ENVIRONMENTALLY CONSCIOUS DESIGN
IEC 60601-1-10	MEDICAL ELECTRICAL EQUIPMENT - PART 1-10: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE - COLLATERAL STANDARD: REQUIREMENTS FOR THE DEVELOPMENT OF PHYSIOLOGIC CLOSED-LOOP CONTROLLERS
IEC 60601-1-11	MEDICAL ELECTRICAL EQUIPMENT - PART 1-11: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE - COLLATERAL STANDARD: REQUIREMENTS FOR MEDICAL ELECTRICAL EQUIPMENT AND MEDICAL ELECTRICAL SYSTEM USED IN HOME CARE APPLICATIONS
IEC 60601-1-12 (CDM)	MEDICAL ELECTRICAL EQUIPMENT - PART 1-12: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE - COLLATERAL STANDARD: REQUIREMENTS FOR MEDICAL ELECTRICAL EQUIPMENT AND MEDICAL ELECTRICAL SYSTEMS USED IN THE EMERGENCY MEDICAL SERVICES ENVIRONMENT

Appendix B
IEC 60601-2 Particular Standards (© IEC Geneva, Switzerland)

IEC 60601-2-1	MEDICAL ELECTRICAL EQUIPMENT - PART 2-1: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ELECTRON ACCELERATORS IN THE RANGE 1 MEV TO 50 MEV
IEC 60601-2-2	MEDICAL ELECTRICAL EQUIPMENT - PART 2-2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF HIGH FREQUENCY SURGICAL EQUIPMENT
IEC 60601-2-3 (ADIS)	MEDICAL ELECTRICAL EQUIPMENT PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF SHORT-WAVE THERAPY EQUIPMENT
IEC 60601-2-4	MEDICAL ELECTRICAL EQUIPMENT PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF CARDIAC DEFIBRILLATORS AND CARDIAC DEFIBRILLATORS MONITORS
IEC 60601-2-5	MEDICAL ELECTRICAL EQUIPMENT - PART 2-5: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ULTRASONIC PHYSIOTHERAPY EQUIPMENT
IEC 60601-2-6 (ADIS)	MEDICAL ELECTRICAL EQUIPMENT - PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF MICROWAVE THERAPY EQUIPMENT
IEC 60601-2-7	MEDICAL ELECTRICAL EQUIPMENT - PART 2-7: PARTICULAR REQUIREMENTS FOR THE SAFETY OF HIGH-VOLTAGE GENERATORS OF DIAGNOSTIC X-RAY GENERATORS
IEC 60601-2-8	MEDICAL ELECTRICAL EQUIPMENT - PART 2-8: PARTICULAR REQUIREMENTS FOR THE SAFETY OF THERAPEUTIC X-RAY EQUIPMENT OPERATING IN THE RANGE 10 KV TO 1 MV
IEC 60601-2-10 (CCDV)	MEDICAL ELECTRICAL EQUIPMENT PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF NERVE AND MUSCLE STIMULATORS
IEC 60601-2-11	MEDICAL ELECTRICAL EQUIPMENT PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF GAMMA BEAM THERAPY EQUIPMENT
IEC 60601-2-13	MEDICAL ELECTRICAL EQUIPMENT - PART 2-13: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ANAESTHETIC WORKSTATIONS
IEC 60601-2-16 (RDIS)	MEDICAL ELECTRICAL EQUIPMENT - PART 2-16: PARTICULAR REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE OF HAEMODIALYSIS, HAEMODIAFILTRATION AND HAEMOFILTRATION EQUIPMENT
IEC 60601-2-17	MEDICAL ELECTRICAL EQUIPMENT - PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF REMOTE-CONTROLLED AUTOMATICALLY DRIVEN GAMMARAY AFTER-LOADING EQUIPMENT
IEC 60601-2-18	MEDICAL ELECTRICAL EQUIPMENT PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ENDOSCOPIC EQUIPMENT
IEC 60601-2-19	MEDICAL ELECTRICAL EQUIPMENT - PART 2: PARTICULAR REQUIREMENTS OF SAFETY OF BABY INCUBATORS
IEC 60601-2-20	MEDICAL ELECTRICAL EQUIPMENT - PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF TRANSPORT INCUBATORS
IEC 60601-2-21	MEDICAL ELECTRICAL EQUIPMENT PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF INFANT RADIANT WARMERS
IEC 60601-2-22	MEDICAL ELECTRICAL EQUIPMENT - PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF DIAGNOSTIC AND THERAPEUTIC LASER EQUIPMENT

IEC 60601-2-23	MEDICAL ELECTRICAL EQUIPMENT - PART 2-23: PARTICULAR REQUIREMENTS FOR THE SAFETY, INCLUDING ESSENTIAL PERFORMANCE, OF TRANSCUTANEOUSPARTIAL PRESSURE MONITORING EQUIPMENT
IEC 60601-2-24 (ADIS)	MEDICAL ELECTRICAL EQUIPMENT - PART 2-24: PARITCULAR REQUIREMENTS FOR THE SAFETY OF INFUSION PUMPS AND CONTROLLERS
IEC 60601-2-25	MEDICAL ELECTRICAL EQUIPMENT - PART 2-25: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ELECTROCARDIOGRAPHS
IEC 60601-2-26 (ADIS)	MEDICAL ELECTRICAL EQUIPMENT PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ELECTROENCEPHALOGRAPHS
IEC 60601-2-27	MEDICAL ELECTRICAL EQUIPMENT - PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ELECTROCARDIOGRAPHIC MONITORING EQUIPMENT
IEC 60601-2-28	MEDICAL ELECTRICAL EQUIPMENT - PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF X-RAY SOURCE ASSEMBLIES AND X-RAY TUBE ASSEMBLIES FOR MEDICAL DIAGNOSIS
IEC 60601-2-29	MEDICAL ELECTRICAL EQUIPMENT - PART 2-29: PARTICULAR REQUIREMENTS FOR THE SAFETY OF RADIOTHERAPY SIMULATORS
IEC 60601-2-31	MEDICAL ELECTRICAL EQUIPMENT - PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF EXTERNAL CARDIAC PACEMAKERS WITH INTERNAL POWER SOURCE
IEC 60601-2-32	MEDICAL ELECTRICAL EQUIPMENT PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ASSOCIATED EQUIPMENT OF X-RAY EQUIPMENT
IEC 60601-2-33	MEDICAL ELECTRICAL EQUIPMENT - PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF MAGNETIC RESONANCE EQUIPMENT FOR MEDICAL DIAGNOSIS
IEC 60601-2-34	MEDICAL ELECTRICAL EQUIPMENT - PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY, INCLUDING ESSENTIAL PERFORMANCE, OF INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT
IEC 60601-2-36 (1CD)	MEDICAL ELECTRICAL EQUIPMENT - PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF EQUIPMENT FOR EXTRACORPOREALLY INDUCED LITHOTRIPSY
IEC 60601-2-37	MEDICAL ELECTRICAL EQUIPMENT - PART 2-37: PARTICULAR REQUIREMENTS FOR THE BASIC SAFETY AND ESSENTIAL PERFORMANCE OF ULTRASONIC MEDICAL DIAGNOSTIC AND MONITORING EQUIPMENT
IEC 60601-2-39	MEDICAL ELECTRICAL EQUIPMENT - PART 2-39: PARTICULAR REQUIREMENTS FOR THE SAFETY OF PERITONEAL DIALYSIS EQUIPMENT
IEC 60601-2-40	MEDICAL ELECTRICAL EQUIPMENT - PART 2-40: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ELETROMYOGRAPHS AND EVOKED RESPONSE EQUIPMENT
IEC 60601-2-41 (CCDV)	MEDICAL ELECTRICAL EQUIPMENT - PART 2-41: PARTICULAR REQUIREMENTS FOR THE SAFETY OF SURGICAL LUMINAIRES AND LUMINAIRES FOR DIAGNOSIS
IEC 60601-2-43	MEDICAL ELECTRICAL EQUIPMENT - PART 2-43: PARTICULAR REQUIREMENTS FOR THE SAFETY OF X-RAY EQUIPMENT FOR INTERVENTIONAL PROCEDURES
IEC 60601-2-44 (CCDV)	MEDICAL ELECTRICAL EQUIPMENT - PART 2-44: PARTICULAR REQUIREMENTS FOR THE SAFETY OF X-RAY EQUIPMENT FOR COMPUTED TOMOGRAPHY

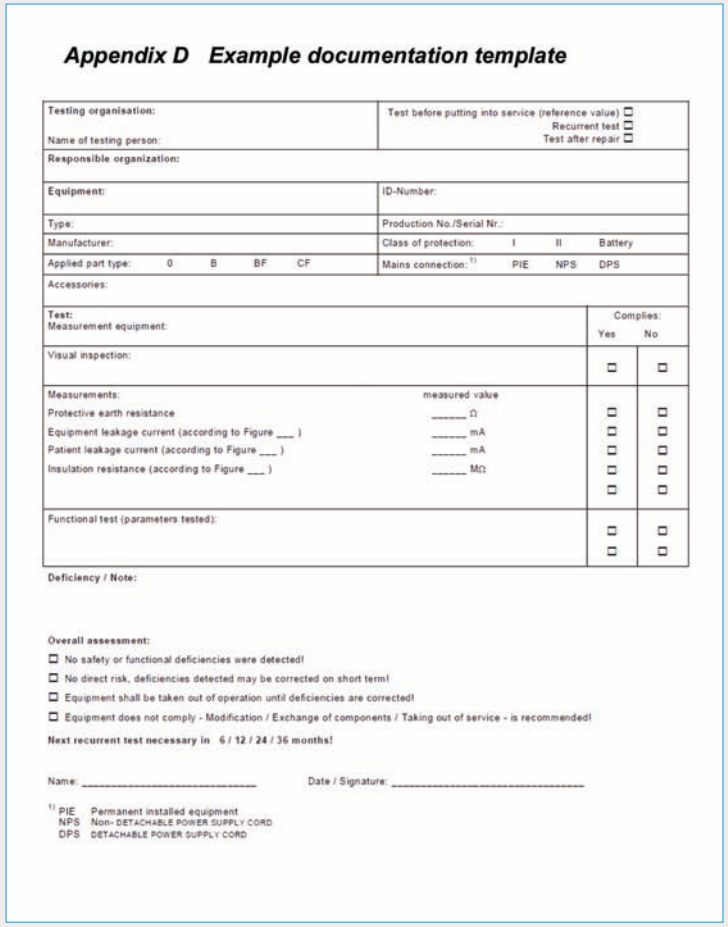
IEC 60601-2-45	MEDICAL ELECTRICAL EQUIPMENT - PART 2-45: PARTICULAR REQUIREMENTS FOR THE SAFETY OF MAMMOGRAPHIC X-RAY EQUIPMENT AND MAMMOGRAPHIC STEREOTACTIC DEVICES
IEC 60601-2-46	MEDICAL ELECTRICAL EQUIPMENT - PART 2-46: PARTICULAR REQUIREMENTS FOR THE SAFETY OF OPERATING TABLES
IEC 60601-2-47 (RDIS)	MEDICAL ELECTRICAL EQUIPMENT - PART 2-47: PARTICULAR REQUIREMENTS FOR THE SAFETY, INCLUDING ESSENTIAL PERFORMANCE, OF AMBULATORY ELECTROCARDIOGRAPHIC SYSTEMS
IEC 60601-2-49	MEDICAL ELECTRICAL EQUIPMENT - PART 2-49: PARTICULAR REQUIREMENTS FOR THE SAFETY OF MULTIFUNCTION PATIENT MONITORING EQUIPMENT
IEC 60601-2-50	MEDICAL ELECTRICAL EQUIPMENT - PART 2-5O: PARTICULAR REQUIREMENTS FOR THE SAFETY OF INFANT PHOTOTHERAPY EQUIPMENT
IEC 60601-2-51	MEDICAL ELECTRICAL EQUIPMENT - PART 2-51: PARTICULAR REQUIREMENTS FOR SAFETY, INCLUDING ESSENTIAL PERFORMANCE, OF RECORDING AND ANALYSING SINGLE CHANNEL AND MULTICHANNEL ELECTROCARDIOGRAPHS
IEC 60601-2-52	MEDICAL ELECTRICAL EQUIPMENT - PART 2-52: PARTICULAR REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE OF MEDICAL BEDS
IEC 60601-2-53	MEDICAL ELECTRICAL EQUIPMENT, PART 2-53: PARTICULAR REQUIREMENTS FOR THE SAFETY AND ESSENTIAL PERFORMANCE OF A STANDARD COMMUNICATIONS PROTOCOL FOR COMPUTER ASSISTED ELECTROCARDIOGRAPHY
IEC 60601-2-54	MEDICAL ELECTRICAL EQUIPMENT - PART 2-54: PARTICULAR REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE OF X-RAY EQUIPMENT FOR RADIOGRAPHY AND RADIOSCOPY
IEC 60601-2-56	MEDICAL ELECTRICAL EQUIPMENT - PART 2-56: PARTICULAR REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE OF SCREENING THERMOGRAPHS FOR HUMAN FEBRILE TEMPERATURE SCREENING
IEC 60601-2-57	PARTICULAR REQUIREMENTS FOR THE SAFETY AND ESSENTIAL PERFORMANCE OF INTENSE LIGHT SOURCES USED ON HUMANS AND ANIMALS FOR MEDICAL AND COSMETIC PURPOSES
IEC 60601-2-62 (ACDV)	MEDICAL ELECTRICAL EQUIPMENT - PART 2-62: PARTICULAR REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE OF HIGH INTENSITY THERAPEUTIC ULTRASOUND (HITU) SYSTEMS
IEC 60601-2-63 (CCDV)	MEDICAL ELECTRICAL EQUIPMENT - PART 2-63: PARTICULAR REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE OF DENTAL EXTRA-ORAL X-RAY EQUIPMENT
IEC 60601-2-65 (CCDV)	MEDICAL ELECTRICAL EQUIPMENT - PART 2-65: PARTICULAR REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE OF DENTAL INTRA-ORAL X-RAY EQUIPMENT

Appendix C
YSI 400 & 700 resistance reference table

Temp 'C	YSI 400 Resistance	YSI 700 Resistance A	YSI 700 Resistance B
-1°C	7741Ω	20620Ω	99800Ω
0°C	7355Ω	19590Ω	94980Ω
1°C	6989Ω	18620Ω	90410Ω
2°C	6644Ω	17700Ω	86090Ω
3°C	6319Ω	16830Ω	81990Ω
4°C	6011Ω	16010Ω	78110Ω
5°C	5719Ω	15240Ω	74440Ω
6°C	5444Ω	14500Ω	70960Ω
7°C	5183Ω	13810Ω	67660Ω
8°C	4937Ω	13150Ω	64530Ω
9°C	4703Ω	12530Ω	61560Ω
10°C	4482Ω	11940Ω	58750Ω
11°C	4273Ω	11380Ω	56070Ω
12°C	4074Ω	10850Ω	53540Ω
13°C	3886Ω	10350Ω	51130Ω
14°C	3708Ω	9878Ω	48840Ω
15°C	3539Ω	9428Ω	46670Ω
16°C	3378Ω	9000Ω	44600Ω
17°C	3226Ω	8594Ω	42640Ω
18°C	3081Ω	8210Ω	40770Ω
19°C	2944Ω	7844Ω	38990Ω
20°C	2814Ω	7496Ω	37300Ω
21°C	2690Ω	7166Ω	35700Ω
22°C	2572Ω	6852Ω	34170Ω
23°C	2460Ω	6554Ω	32710Ω
24°C	2354Ω	6270Ω	31320Ω
25°C	2252Ω	6000Ω	30000Ω

Temp 'C	YSI 400 Resistance	YSI 700 Resistance A	YSI 700 Resistance B
26°C	2156Ω	5744Ω	28740Ω
27°C	2064Ω	5500Ω	27540Ω
28°C	1977Ω	5266Ω	26400Ω
29°C	1894Ω	5046Ω	25310Ω
30°C	1815Ω	4834Ω	24270Ω
31°C	1739Ω	4634Ω	23280Ω
32°C	1667Ω	4442Ω	22330Ω
33°C	1599Ω	4260Ω	21430Ω
34°C	1533Ω	4084Ω	20570Ω
35°C	1471Ω	3918Ω	19740Ω
36°C	1412Ω	3760Ω	18960Ω
37°C	1355Ω	3610Ω	18210Ω
38°C	1301Ω	3466Ω	17490Ω
39°C	1249Ω	3328Ω	16800Ω
40°C	1200Ω	3196Ω	16150Ω
41°C	1152Ω	3070Ω	15520Ω
42°C	1107Ω	2950Ω	14920Ω
43°C	1064Ω	2836Ω	14350Ω
44°C	1023Ω	2726Ω	13800Ω
45°C	983.8Ω	2620Ω	13280Ω
46°C	946.2Ω	2520Ω	12770Ω
47°C	910.2Ω	2424Ω	12290Ω
48°C	875.8Ω	2334Ω	11830Ω
49°C	842.8Ω	2246Ω	11390Ω
50°C	811.3Ω	2162Ω	10970Ω
51°C	781.1Ω	2080Ω	10570Ω

Appendix D
Example documentation template



Appendix D Example documentation template

Testing organisation: Name of testing person:		Test before putting into service (reference value) ☐ Recurrent test ☐ Test after repair ☐	
Responsible organization:			
Equipment:		ID-Number:	
Type:		Production No./Serial Nr.:	
Manufacturer:		Class of protection: I II Battery	
Applied part type: 0 B BF CF		Mains connection: [1] PIE NPS DPS	
Accessories:			
Test: Measurement equipment:		Complies: Yes	No
Visual inspection:		☐	☐
Measurements:	measured value		
Protective earth resistance	_____ Ω	☐	☐
Equipment leakage current (according to Figure ___)	_____ mA	☐	☐
Patient leakage current (according to Figure ___)	_____ mA	☐	☐
Insulation resistance (according to Figure ___)	_____ MΩ	☐	☐
		☐	☐
Functional test (parameters tested):		☐	☐
		☐	☐

Deficiency / Note:

Overall assessment:

☐ No safety or functional deficiencies were detected!
☐ No direct risk, deficiencies detected may be corrected on short term!
☐ Equipment shall be taken out of operation until deficiencies are corrected!
☐ Equipment does not comply - Modification / Exchange of components / Taking out of service - is recommended!

Next recurrent test necessary in 6 / 12 / 24 / 36 months!

Name: _____ Date / Signature: _____

[1] PIE Permanent installed equipment
NPS Non- DETACHABLE POWER SUPPLY CORD
DPS DETACHABLE POWER SUPPLY CORD

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Webster,G.J., (Ed.). (1997). Design of Pulse Oximeters (1st ed.), New York: Medical Science Series
12-Lead ECG System, http://www.bem.fi/book/15/15.htm (Aug 2011)

Vital Signs Simulators

UNI-Sim
Vital Signs Simulator

The world's first combined, fully functional NIBP, SpO2 and Patient Simulator in a single hand-held unit. Extremely accurate and featuring full synchronised functionality. A breakthrough in the way safety testing is implemented, the UNI-Sim saves time and money, as well as simplifying the testing process.

Features include:

- Light, hand-held, battery operation
- Combined NIBP, SpO2 and Patient Simulator in one unit
- User configurable simulations
- Full sychronised functionality
- Memory for up to 10,000 devices

BP-Sim
NIBP Simulator

The first hand-held NIBP simulator to incorporate custom settings, including paediatric and adult NIBP pressure simulations, pulse volume adjustments, heart rate and manufacturer-specific envelopes. Large capacity internal memory for data capture, storage and downloading of test results via Bluetooth.

Features include:

- Light, hand-held, battery operation
- Adult & Paediatric NIBP Simulations
- Manufacturer specific O-curves
- Overpressure and leak test
- Memory for up to 10,000 devices

SP-Sim
SpO2 Simulator

The first hand-held SpO2 simulator featuring pulse volume adjustments, heart rate and manufacturer-specific R-curves. The large capacity internal memory enables test results to be captured, stored and downloaded via Bluetooth.

Features include:

- Light, hand-held, battery operation
- Tests probe and monitor both at the same time
- User configurable simulations
- Manufacturer R-curves
- Memory for up to 10,000 devices

333
Patient Simulator

The 333 is one of the smallest, most powerful and fully comprehensive patient simulators available. Providing a true 12 lead ECG signal with 43 arrhythmias, dual invasive blood pressure, respiration, temperature and industry standard waveforms.

Features include:

- Light, hand-held, battery operation
- Accurate 12-lead simulation of 43 arrhythmias
- Invasive blood pressure
- Temperature & respiration
- Performance wave forms