Testing and Calibration Devices-1

Prepared By:

Dr.Sherif El Gharry

Cairo University

Second Year

2018-2019

Acknowledgments

This two-year curriculum was developed through a participatory and collaborative approach between the Academic faculty staff affiliated to Egyptian Universities as Alexandria University, Ain Shams University, Cairo University , Mansoura University, Al-Azhar University, Tanta University, Beni Souef University , Port Said University, Suez Canal University and MTI University and the Ministry of Health and Population(General Directorate of Technical Health Education (THE). The design of this course draws on rich discussions through workshops. The outcome of the workshop was course specification with Indented learning outcomes and the course contents, which served as a guide to the initial design.

We would like to thank **Prof.Sabah Al- Sharkawi** the General Coordinator of General Directorate of Technical Health Education, **Dr. Azza Dosoky** the Head of Central Administration of HR Development, **Dr. Seada Farghly** the General Director of THE and all share persons working at General Administration of the THE for their time and critical feedback during the development of this course.

Special thanks to the **Minister of Health and Population Dr. Hala Zayed and Former Minister of Health Dr. Ahmed Emad Edin Rady** for their decision to recognize and professionalize health education by issuing a decree to develop and strengthen the technical health education curriculum for pre-service training within the technical health institutes.

Contents

جامعة /أكاديمية : المعاهد الفنية الصحية التابعة لوزارة الصحة و السكان

قسم : صيانة الاجهزة الطبية

توصيف مقرر دراسى

١- بيانات المقرر		
الرمز الكودى :	اسم المقرر: اجهزة القياس -١	الفرقة /المستوى :
التخصص :	عدد الوحدات الدراسية : ٤	نظرى ٢ عملى ٢

٢- هدف المقرر:	**This course is designed to provide basic knowledge and training for students to enter and/or advance in the occupations associated with medical equipment testing and calibration. A biomedical equipment technician must possess the skills necessary to test and troubleshoot problems on medical equipment, perform and record preventative maintenance, and facilitate training sessions on the equipment. This course is intended to be basics for the medical equipment technicians to carry out basic testing calibration tasks. As the majority of equipment problems are either simple or user-related it is the aim that the better care and regular testing enabled by this class will have a significant positive effect on the delivery of healthcare facilities.**
٣- المستهدف من تدريس المقرر :	**Students for Technical Health Institutes**
١. المعلومات والمفاهيم :	Having successfully completed this module, students will be able to: • Recognize principles and concepts of testing medical devices technologies. • Understand the importance of an effective calibration procedures and industry best practices for medical device manufacturers. • Identify and interpret the relationship and differences between the applicable calibration standards and guidance.

• Define key terms relating to calibration and interpret the meaning of each. • Understand traceability requirements and how they are maintained. • Describe characteristics of a good control system technician. • Describe differences between bench calibration and field calibration. List the advantages and disadvantages of each.	
Having successfully completed this module, students will be able to: • Demonstrate competence in the clinical environment through internship or practical experience including performing preventive maintenance and repairs • Bring awareness about common problems, operating conditions, precautions & installation procedures of medical equipment and patient safety • Demonstrate the knowledge about optimum performance tests, operating modes, front & rear panel controls of different medical equipment. • Understand the applicable calibration standards for medical devices	**ب- المهارات الذهنية :**
Having successfully completed this module, students will be able to: • Analysis Technique, testing and assembly of electronic circuit build Confidence for handling instruments, tools analysis circuit. • Apply the applicable calibration standards for medical devices • Develop testing skills by measuring different parameters on medical devices during assigned biomedical lab work. • Utilize skills in using a computerized medical testing software system through successfully completing assigned labs that include inventory, work order generation and completion. • Analyze and integrate the technical equipment requirements with the needs of medical staff and patients. • Prepare technical reports to interpret the medical devices testing acquired from testers.	**ج- المهارات المهنية الخاصة بالمقرر:**

• Analyze different factors on which medical equipment depends on. • Able to perform experiments and measurements, as well as to analyze and interpret data. • Able to use techniques, skills, and modern engineering tools necessary for engineering practice. • Demonstrate ability to organize work done by team members. • Able to use mathematics, science and emerging biomedical engineering tools to solve problems and demonstrate solutions. • Demonstrate skills for life-long learning by locating, evaluating, and applying relevant information using external resources such as the Internet, data books, trade publications ،and library resources. • Demonstrate quality, timeliness, and ability to complete increasingly complex assignments	د- المهارات العامة :
Section 1: Basic Test Equipment Introduction General Test Equipment Digital Multimeters Oscilloscopes Other Test Equipment Specialized Biomedical Test Equipment **Section 2: Monitoring Device Testing** Physiological Simulators ECG Simulators Noninvasive Blood Pressure (NIBP) Analyzers SpO_2 Analyzers **Section 3: Infusion Equipment Testing** Syringe and Infusion Device Analyzers **Section 4: Electrosurgery Devices Testing** Electrosurgery Unit (ESU) Analyzers **Section 5: Electrical Analysis** Electrical safety Analyzer	٤- محتوى المقرر:
• Lectures • Multimedia material (Datashow, instructional videos,	٥- أساليب التعليم والتعلم

webinars…) • Discussions and group work • Problems solving • On-site training in the Ministry of Health calibration devices.	
• Individual guidance • Individual feedback	٦- أساليب التعليم والتعلم للطلاب ذوى القدرات المحدودة
	٧- تقويم الطلاب :
• Assignments • Quizzes • Midterm • Final exam	أ- الأساليب المستخدمة
• Assignments (weekly) • Quizzes (occasionally) • Midterm (week 8) • Final exam (at the end of the semester)	ب- التوقيت
• Lab assignments and practical work (40 pts) • Quizzes and Midterm (20 pts) • Final exam (90 pts)	ج- توزيع الدرجات
	٨- قائمة الكتب الدراسية والمراجع :
	أ- مذكرات
"Testing of Medical Equipment Technologies for Technical Health Institutes"	ب- كتب ملزمة
CBET Exam Secrets Study Guide: CBET Test Review for the Certified Biomedical Equipment Technician Examination by CBET Exam Secrets Test Prep Team	ج- كتب مقترحة

Biomedical Equipment: Use, Maintenance and Management 1st Edition, by Joseph J. Carr (Author)	
• IEEE Transactions on Biomedical Engineering • Journal of Clinical Engineering • Journal of Healthcare Engineering	**د- دوريات علمية أو نشرات ..... الخ**

Course Description

This course is designed to provide basic knowledge and training for students to enter and/or advance in the occupations associated with medical equipment testing and calibration. A biomedical equipment technician must possess the skills necessary to test and troubleshoot problems on medical equipment, perform and record preventative maintenance, and facilitate training sessions on the equipment. This course is intended to be basics for the medical equipment technicians to carry out basic testing calibration tasks. As the majority of equipment problems are either simple or user-related it is the aim that the better care and regular testing enabled by this class will have a significant positive effect on the delivery of healthcare facilities.

Core Knowledge .

By the end of this course, students should be able to:

- Recognize principles and concepts of testing medical devices technologies.
- Understand the importance of an effective calibration procedures and industry best practices for medical device manufacturers.
- Identify and interpret the relationship and differences between the applicable calibration standards and guidance.
- Define key terms relating to calibration and interpret the meaning of each.
- Understand traceability requirements and how they are maintained.
- Describe characteristics of a good control system technician.
- Describe differences between bench calibration and field calibration. List the advantages and disadvantages of each.

Core Skill .

By the end of this course, students should be able to:

- Analysis Technique, testing and assembly of electronic circuit build Confidence for handling instruments, tools analysis circuit.
- Apply the applicable calibration standards for medical devices
- Develop testing skills by measuring different parameters on medical devices during assigned biomedical lab work.
- Utilize skills in using a computerized medical testing software system through successfully completing assigned labs that include inventory, work order generation and completion.
- Analyze and integrate the technical equipment requirements with the needs of medical staff and patients.
- Prepare technical reports to interpret the medical devices testing acquired from testers.

Course Overview

		Methods of Teaching/Training with Number of Total Hours per Topic				
ID	**Topics**	**Interactive Lecture**	**Field Work**	**Class Assignments**	**Research**	**Lab**
1	Basic Test Equipment	6	**3**			**3**
2	Monitoring Device Testing	6	**3**			**3**
3	Infusion Equipment Testing	4	**2**			**2**
4	Electrosurgery Devices Testing	4	**2**			**2**
5	Electrical Analysis	4	**2**			**2**
TOTAL HOURS (48)		**24**	**12**			**12**

Section 1
Basic Test Equipment

Objectives

- Provide an overview of testing and calibrators.
- Define some of electrical and electronic testers in detail.
- Mentioning some biomedical test equipment, their use and benefits.

Introduction to testing and calibrators

Instrument calibration is one of the primary processes used to maintain instrument accuracy. Calibration is the process of configuring an instrument to provide a result for a sample within an acceptable range. Eliminating or minimizing factors that could cause inaccurate measurements is a fundamental aspect of instrumentation design. Although the exact procedure may vary from Product to Product, the calibration process generally involves using the instrument to test samples of one or more known values called "calibrators." The results are used to establish a relationship between the measurement technique used by the instrument and the known values.

Calibration is the process of verifying that a device is within the manufacturer's specifications for certain measurement capabilities. Calibration procedures are based on manufacturer's procedures where available. These processes involve testing the device at specific points, recording and analyzing the results. This is a longer and more detailed process resulting in a calibration report which gives a pass/fail for each specific function. A device which fails to meet the specifications is adjusted. Calibration is not a luxury. Incorrect measurement can result in lost time for trouble shooting and maintenance and could result in undetected hazardous conditions.

Functional testing involves a range of procedures used to determine if an item is functioning correctly. This involves exposing the item to certain stimuli and verifying the equipment responds accordingly. These procedures are designed to test the range or capability of a specific item or group of items. Examples would include voltage detectors (proximity and contact) and various meters. These tests result in a simple pass/fail test report for the unit. A device which fails to pass the test is typically repaired.

General test equipment

General Test Equipment is not industry specific and is typically used for the measurement, analysis or simulation of a broad range of physical properties or component level troubleshooting.

Types of test equipment includes:

1. Mechanical test equipment is used to measure, test, analyze, control, calibrate, display and record data in a wide range of mechanical equipment testing situations.
   Some types of mechanical test equipment run adhesion, compression, fatigue, flexure, ductility, shock, tensile, vibration, and shear tests to make sure that the material being tested will work and behave in the appropriate way.

2. Electrical and Electronic test equipment is used to create signals and capture responses from electronic devices under test (DUTs). In this way, the proper operation of the DUT can be proven or faults in the device can be traced. Use of electronic test equipment is essential to any serious work on electronics systems.

Basic equipment:

The following items are used for basic measurement of voltages, currents, and components in the circuit under test.

- Voltmeter (Measures voltage).
- Ohmmeter (Measures resistance).
- Ammeter, e.g. Galvanometer or Milliameter (Measures current).
- Multi-meter e.g., VOM (Volt-Ohm-Milliammeter) or DMM (Digital Multi-meter) (Measures all of the above).
- LCR meter - inductance (L), capacitance (C) and resistance (R) meter (measure LCR values).

Multi-meters:

A **multi-meter** or a **multitester**, also known as a **VOM** (volt-ohm-milliammeter), is an electronic measuring instrument that combines several measurement functions in one unit. A typical multi-meter can measure voltage, current, and resistance. They can be used to troubleshoot electrical problems in a wide array of industrial and household devices such as electronic equipment, motor controls, domestic appliances, power supplies, and wiring systems **Analog multi-meters** use a microammeter with a moving pointer to display readings. **Digital multi-meters** (DMM, DVOM) have a numeric display, and may also show a graphical bar representing the measured value. Digital multi-meters are now far more common due

to their cost and precision, but analog multi-meters are still preferable in some cases, for example when monitoring a rapidly varying value.

Key terms and concepts:

DUT: is device under test

Digital multi-meters (DMM, DVOM)

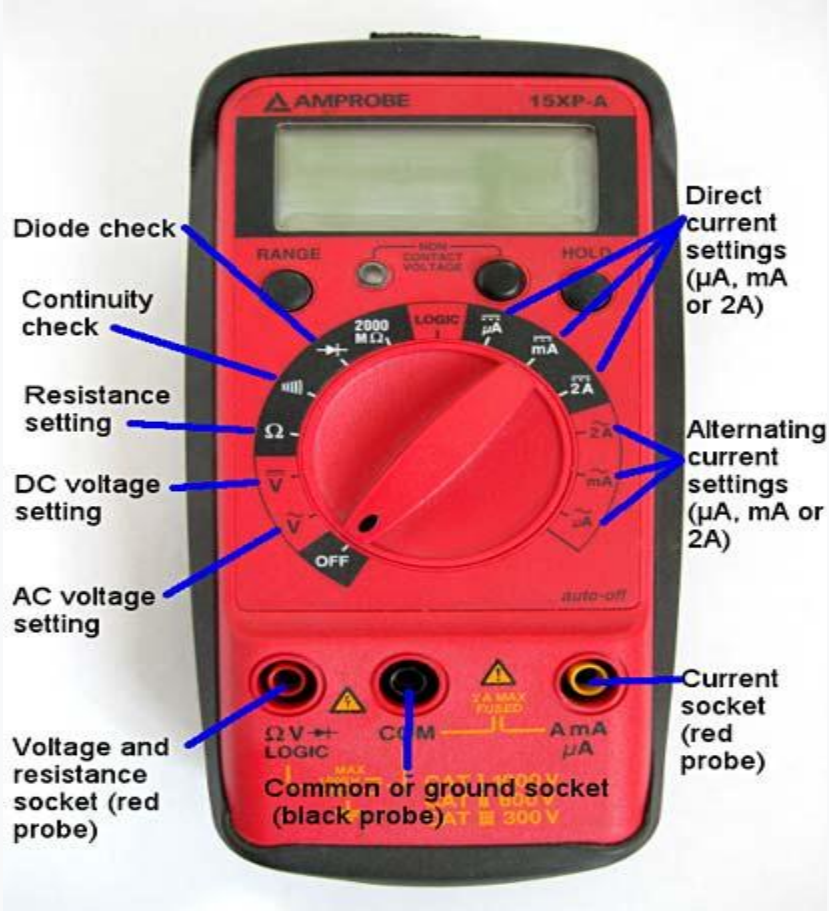


Figure 1.3.1 Digital multi-meters (DMM, DVOM)

Basics of how a DMM works

Modern multi-meters are often digital due to their accuracy, durability and extra features. In a digital multi-meter the signal under test is converted to a voltage and an amplifier with electronically controlled gain preconditions the signal. A digital multi-meter displays the quantity measured as a number, which eliminates parallax errors. There are two types of digital multi-meters (DMM): **scalable digital multi-meter** and **auto-ranging digital multi-meter.** When working with the scalable digital multi-meter you need to have an idea of the value of voltage, current, or resistance that you are attempting to measure. Failure to observe these values will result in inaccurate readings and possible damage to the meter. The auto-ranging digital multi-meter is more widely used due to its ease, high functionality, and quick display readings achieved without the user completing the calculations.
The key process that occurs within a digital multi-meter for any measurement that takes place, is that of voltage measurement.

All other measurements are derived from this basic measurement. Accordingly, the key to understanding how a digital multi-meter works is in understanding this process.

There are many forms of analogue to digital converters, ADCs. However, the one that is most widely used in digital multi-meters, DMMs is known as the successive approximation register or SAR. Some SAR ADCs may only have resolution levels of 12 bits, but those used in test equipment including DMMs generally have 16 bits or possibly more dependent upon the application. Typically for DMMs resolution levels of 16 bits are generally used, with speeds of 100k samples per second. These levels of speed are more than adequate for most DMM applications, where high levels of speed are not normally required.

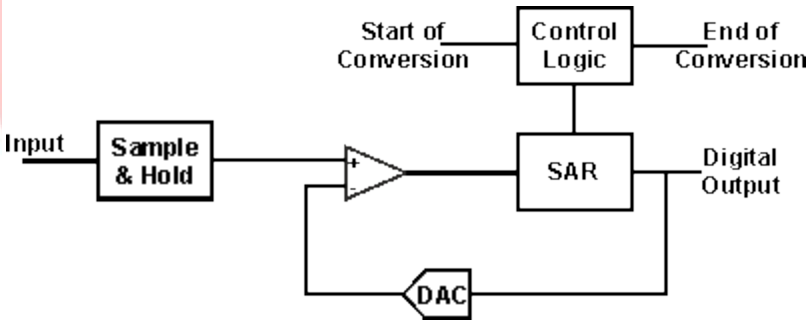


Figure 1.3.2 Successive approximation register ADC used in most DMMs

As the name implies, the successive approximation register ADC operates by successively homing in on the value of the incoming voltage.

The first stage of the process is for the sample and hold circuit to sample the voltage at the input of the DMM, and then to hold it steady.

With a steady input voltage, the register starts at half its full scale value. This would typically require the most significant bit, MSB set to "1" and all the remaining ones set to "0". Assuming that the input voltage could be anywhere in the range, the mid-range means that the ADC is set in the middle of the range and this provides a faster settling time. As it only has to move a maximum of the full scale rather than possibly 100%.

To see how it works take the simple example of a 4-bit SAR. Its output will start at 1000. If the voltage is less than half the maximum capability the comparator output will be low and that will force the register to a level of 0100. If the voltage is above this, the register will move to 0110, and so forth until it homes in on the nearest value.

It can be seen that SAR converters, need one approximating cycle for each output bit, i.e. an n-bit ADC will require n cycles.

DMM operation

Although the analogue to digital converter forms the key element within the instrument, in order to fully understand how a digital multi-meter works, it is necessary to look at some of the other functions around the ADC.

Although the ADC will take many samples, the overall digital multi-meter will not display or return every sample taken. Instead the samples are buffered and averaged to achieve high accuracies and resolutions. This will overcome the effects of small variations such as noise, etc., Noise is created by the analogue in the first stages of the DMM, being an important factor that needs to be overcome to achieve the highest accuracy.

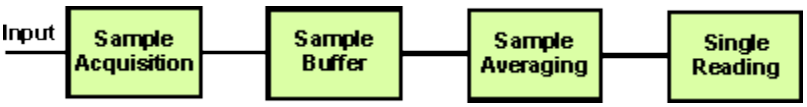


Figure 1.3.3 Operation flow diagram for operation of a DMM

DMM measurements

Digital multi-meters can make a variety of different measurements. Using them is normally very easy, but the right techniques must be adopted to make the measurements correct.

1. DC voltage measurement basics

When measuring voltage using a digital multi-meter, the probes are simply placed across the two points where the voltage is to be measured

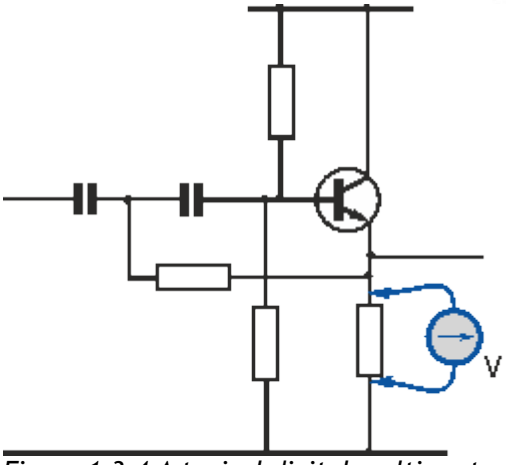


Figure 1.3.4 A typical digital multi-meter voltage measurement

Virtually all digital multi-meters have an auto-polarity function, and therefore there is normally no need to worry about which way round the probes are connected.

However, it is normally best practice to connect the COM or Common connection that is normally the negative connection to the lower voltage or the chassis or zero-volt line.

2. Basics of measuring current with a multi-meter

Voltage measurements are easy to make with a digital multi-meter, but using a digital multi-meter to measure current is slightly more involved.

When measuring current with a multi-meter, it is necessary to place the multi-meter in series with the circuit so that the current actually flows through the digital multi-meter.

The example below shows how a current measurement may be made by breaking the emitter resistor connection and placing the digital multi-meter in series with the circuit to make the current measurement.

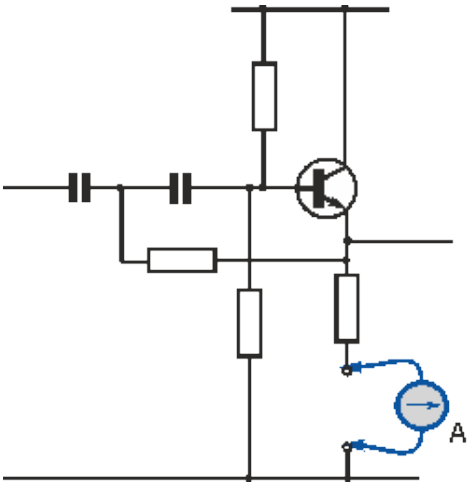


Figure 1.3.5 A typical digital multi-meter current measurement

In this way a direct current measurement using a digital multi-meter can be made.

3. Digital multi-meter resistance tests

When making a resistance measurement, the digital multi-meter supplies current to the item under test and measures the response. The more current the device is able to draw, the lower the resistance

Accordingly, the component should be removed from the circuit to enable accurate testing to be undertaken, free from the effects of other components within the circuit.

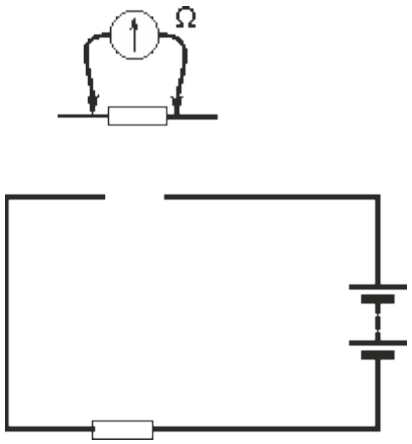


Figure 1.3.6 Measuring the resistance of the component

Similarly, never measure resistance when the circuit is powered, as power from the circuit will not only distort the reading, but could also damage the meter

4. Continuity testing

It is possible to use many digital multi-meters for continuity testing. Often there is a special switch position for this facility. When in this mode, the DMM sounds when there is continuity between two points.

5. Additionally, some multi-meters also measure:

- Capacitance is in farads, but usually the limitations of the range are between a few hundred or thousand micro farads and a few Pico farads. Very few general purpose multi-meters can measure other important aspects of capacitor status such as ESR, dissipation factor, or leakage.
- Conductance is in siemens, which is the inverse of the resistance measured.
- Decibels are in circuitry, rarely in sound.
- Duty cycle is presented as a percentage.
- Frequency is in hertz.
- Inductance is in henry.
- Temperature is in either degrees Celsius or Fahrenheit, with an appropriate temperature test probe, often a thermocouple.
- Diodes (measuring forward drop of diode junctions).
- Transistors (measuring current gain and other parameters in some kinds of transistors).

Various sensors can be attached to (or included in) multi-meters to take measurements such as:

- Light level.
- Sound pressure level.
- Acidity/alkalinity(pH).
- Relative humidity.
- Very small current flow (down to Nano-amps with some adapters).
- Very small resistances (down to micro ohms for some adapters).
- Large currents.
- Very high voltages.

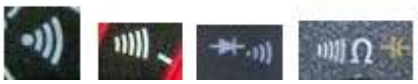
Measurement time

One of the key areas of understanding how a digital multi-meter works, is related to the measurement time. Apart from the basic measurements, there are a number of other functions that are required and these all take time. Accordingly, the measurement time of a digital multi-meter, DMM, may not always appear straightforward.

The overall measurement time for a DMM is made up from several phases where different activities occur:

- ***Switch time:*** The switch time is the time required for the instrument to settle after the input has been switched. This includes the time to settle after a measurement type has been changed, e.g. from voltage to resistance, etc. It also includes time to settle after the range has been changed. If auto-ranging is included the meter will need to settle, if a range change is required.
- ***Settling time:*** Once the value to be measured has been applied to the input, a certain time will be required for it to settle. This will overcome any input capacitance levels when high impedance tests are made, or generally for the circuit and instrument to settle.
- ***Signal measurement time:*** This is the basic time required to make the measurement itself. For AC measurements, the frequency of operation must be taken into account because the minimum signal measurement time is based on the minimum frequency required for the measurement. For example, for a minimum frequency of 50 Hz, an aperture of four time the period is required, i.e. 80 ms for a 50Hz signal, or 67ms for a 60Hz signal, etc.
- ***Auto-zero time:*** When auto-range is selected, or range changes are made, it is necessary to zero the meter to ensure accuracy. Once the correct range is selected, the auto-zero is performance for that range.
- ***ADC calibration time:*** In some DMMs a calibration is periodically performed. This must be accounted for, especially where measurements are taken under automatic or computer control.

Multi-meter Symbol	Samples
~ (squiggly line): You might see a squiggly line next to or above a V or A on the front of your multi-meter, in addition to metric prefixes. This stands for alternating current (AC). Note that the voltage in an AC circuit is usually referred to as "AC voltage" (even though it sounds strange to say "alternating current voltage"). You use these settings when you are measuring a circuit with alternating current (or voltage).	
—, - - - (solid line or dashed line): Like the squiggly line, you might see this next to or above a V or an A. The straight lines stand for direct current. You use these settings when you are measuring a circuit with direct current (e.g., most circuits that are powered by a	

Multi-meter Symbol	Samples
battery).	
DCV, ACV, ACA, DCA, VAC, or VDC: Sometimes, instead of (or in addition to) using squiggly or dashed lines, multi-meters will use the abbreviations AC and DC, which stand for alternating current and direct current, respectively. Note that some multi-meters might have AC and DC after the V and A, instead of before.	
Continuity check (series of parallel arcs): This is a setting used to check if two things are electrically connected. The multi-meter will beep if there is a conductive path between the two probe tips (meaning, if the resistance is very close to zero), and will not make any noise if there aren't any conductive paths. Note that sometimes the continuity check can be combined with other functions on a single setting.	
Diode check (triangle with some lines through it): This function is used to test a diode, which is like a one-way valve for electricity. It only lets current flow in one direction. The exact function of the diode check can be different on different multi-meters. Check your multi-meter's manual to learn about how the diode check function works for your model.	

Oscilloscope

An **oscilloscope** is a type of electronic test instrument that allows the observation of the change of an electrical signal over time, such that voltage and time describe a shape which is continuously graphed against a calibrated scale. Time is displayed from left to right on the horizontal scale. Instantaneous voltage appears on the vertical scale, with positive values going upward and negative values going

downward. The observed waveform can be analyzed for such properties as amplitude, frequency, rise time, time interval, distortion and others. Modern digital instruments may calculate and display these properties directly. Originally, calculation of these values required manually measuring the waveform against the scales built into the screen of the instrument. A typical oscilloscope can display alternating current (AC) or pulsating direct current (DC) waveforms having a frequency as low as approximately 1 hertz (Hz) or as high as several megahertz (MHz). High-end oscilloscopes can display signals having frequencies up to several hundred gigahertz (GHz). The display is broken up into so-called horizontal divisions (hor div) and vertical divisions (vert div). The oscilloscope can be adjusted so that repetitive signals can be observed as a continuous shape on the screen. A storage oscilloscope allows single events to be captured by the instrument and displayed for a relatively long time. These days, typical high-end oscilloscopes are digital devices. They connect to personal computers and use their displays. Software controls the sweep rate, vertical deflection, and a host of other features which can include:

- Storage of waveforms for future reference and comparison.
- Display of several waveforms simultaneously.
- Spectral analysis.
- Portability.
- Battery power option.
- Usability with all popular operating platforms.
- Zoom-in and zoom-out.
- Multi-color displays.

For most modern oscilloscope (Digital Oscilloscope):

- **Brief description**

A digital oscilloscope is a complex electronic device composed of various software and electronic hardware modules that work together to capture, process, display and store data that represents the signals of interest of an operator. Digital oscilloscopes are often referred to as digital storage oscilloscope (DSO) or digital sampling oscilloscopes (DSO). In its simplest form, a digital oscilloscope features six elements — the analog vertical input amplifiers, analog-to-digital converter, a digital waveform memory,

a time base which features a triggering and clock drive, the circuits for waveform display and reconstruction, the LED or LCD display, and the power supply.

- **Working principle**

Digital oscilloscopes periodically sample a time varying analog signal and stores in the waveform memory the signal's values in correlation with time.

Using an internal clock, digital oscilloscopes chop input signals into separate time points. The instantaneous amplitude values are then quantized by the oscilloscope at those points. The resulting digital representations are then stored in a digital memory.

At a predetermined clock rate, the display is regenerated from the device's memory and is consequently viewed as connected dots or a series of dots. Digital Oscilloscopes provide powerful features on how they trigger the digitized data from its memory.

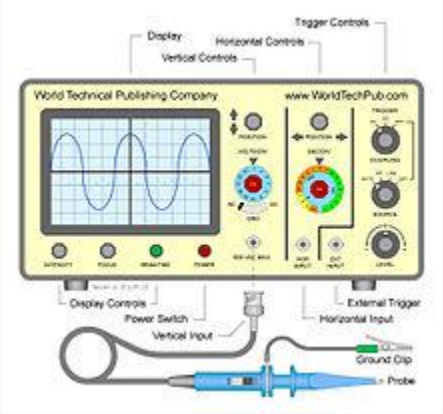


Figure 1.4.1 Basic oscilloscope

Size and portability

Most modern oscilloscopes are lightweight, portable instruments that are compact enough to be easily carried by a single person. In addition to the portable units, the market offers a number of miniature battery-powered instruments for field service applications.

Description

- The basic oscilloscope, as shown in the illustration, is typically divided into four sections: the display, vertical controls, horizontal controls and trigger controls. The display is usually a CRT (historically) or LCD panel which is laid

out with both horizontal and vertical reference lines referred to as the **graticule.**

- **Vertical:** This is the attenuation or amplification of the signal. Use the volts/div control to adjust the amplitude of the signal to the desired measurement range.
- **Horizontal:** This is the time base. Use the sec/div control to set the amount of time per division represented horizontally across the screen.
- **Trigger:** This is the triggering of the oscilloscope. Use the trigger level to stabilize a repeating signal, or to trigger on a single event.

Vertical System and Controls

Vertical controls are used to position and scale the waveform vertically, set the input coupling, and adjust other signal conditioning. Common vertical controls include:

- Position
- Coupling: DC, AC, and GND
- Bandwidth: Limit and Enhancement
- Termination: 1M ohm and 50 ohm
- Offset
- Invert: On/Off
- Scale: Fixed Steps and Variable

Some of these controls are described next.

Figure 1.4.2 control panel of a digital oscilloscope

Position and Volts per Division

The vertical position control allows you to move the waveform up and down so, it's exactly where you want it on the screen.

The volts-per-division setting (usually written as volts/div) is a scaling factor that varies the size of the waveform on the screen. If the volts/div setting is 5 volts, then each of the eight vertical divisions represents 5 volts and the entire screen can display 40 volts from top to bottom, assuming a graticule with eight major divisions. If the setting is 0.5 volts/div, the screen can display 4 volts from top to bottom, and so on.

The maximum voltage that you can display on the screen is the volts/div setting multiplied by the number of vertical divisions. Note that the probe you use, 1X or 10X, also influences the scale factor.

Input Coupling

Coupling refers to the method used to connect an electrical signal from one circuit to another. In this case, the input coupling is the connection from your test circuit to the oscilloscope.

The coupling can be set to DC, AC, or ground. DC coupling shows all of an input's signal. AC coupling blocks the DC component of a signal so that you see the waveform centered around zero volts. Figure 1.4.3 illustrates this difference. The AC coupling setting is useful when the entire signal (alternating current + direct current) is too large for the volts/div setting.

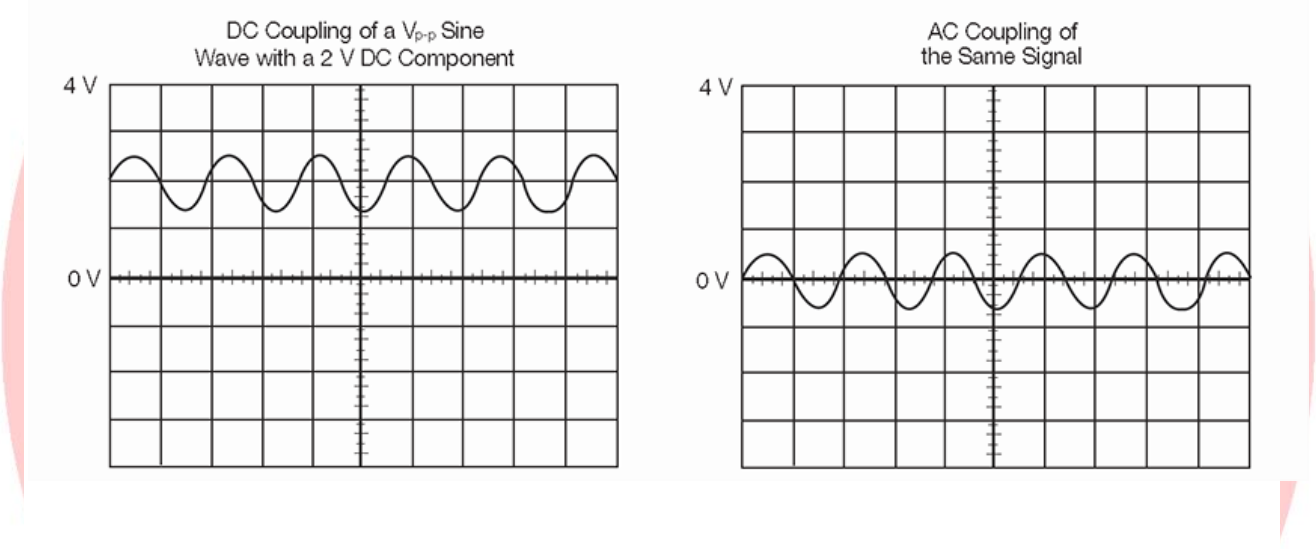


Figure 1.4.3 AC and DC input coupling.

The ground setting disconnects the input signal from the vertical system, which lets you see where the zero volts is located on the screen. With grounded input coupling and auto trigger mode, you see a horizontal line on the screen that represents zero volts. Switching from DC to ground and back again is a handy way of measuring signal voltage levels with respect to ground.

Bandwidth Limit

Most oscilloscopes have a circuit that limits the bandwidth of the oscilloscope. By limiting the bandwidth, you reduce the noise that sometimes appears on the displayed waveform, resulting in a cleaner signal display. Note that while eliminating noise, the bandwidth limit can also reduce or eliminate high frequency signal content.

Bandwidth Enhancement

Some oscilloscopes may provide a DSP arbitrary equalization filter that can be used to improve the oscilloscope channel response. This filter extends the bandwidth, flattens the oscilloscope channel frequency response, improves phase linearity, and provides a better match between channels. It also decreases rise time and improves the time domain step response.

Horizontal System and Controls

An oscilloscope's horizontal system is most closely associated with its acquisition of an input signal. Sample rate and record length are among the considerations here. Horizontal controls are used to position and scale the waveform horizontally. Common horizontal controls include:

- Acquisition
- Sample Rate
- Position and Seconds per Division
- Time Base
- Zoom/Pan
- Search
- XY Mode
- Z Axis
- XYZ Mode
- Trigger Position
- Scale
- Trace Separation
- Record Length
- Resolution

Some of these controls are described next.

1. Acquisition Controls

Digital oscilloscopes have settings that let you control how the acquisition system processes a signal.

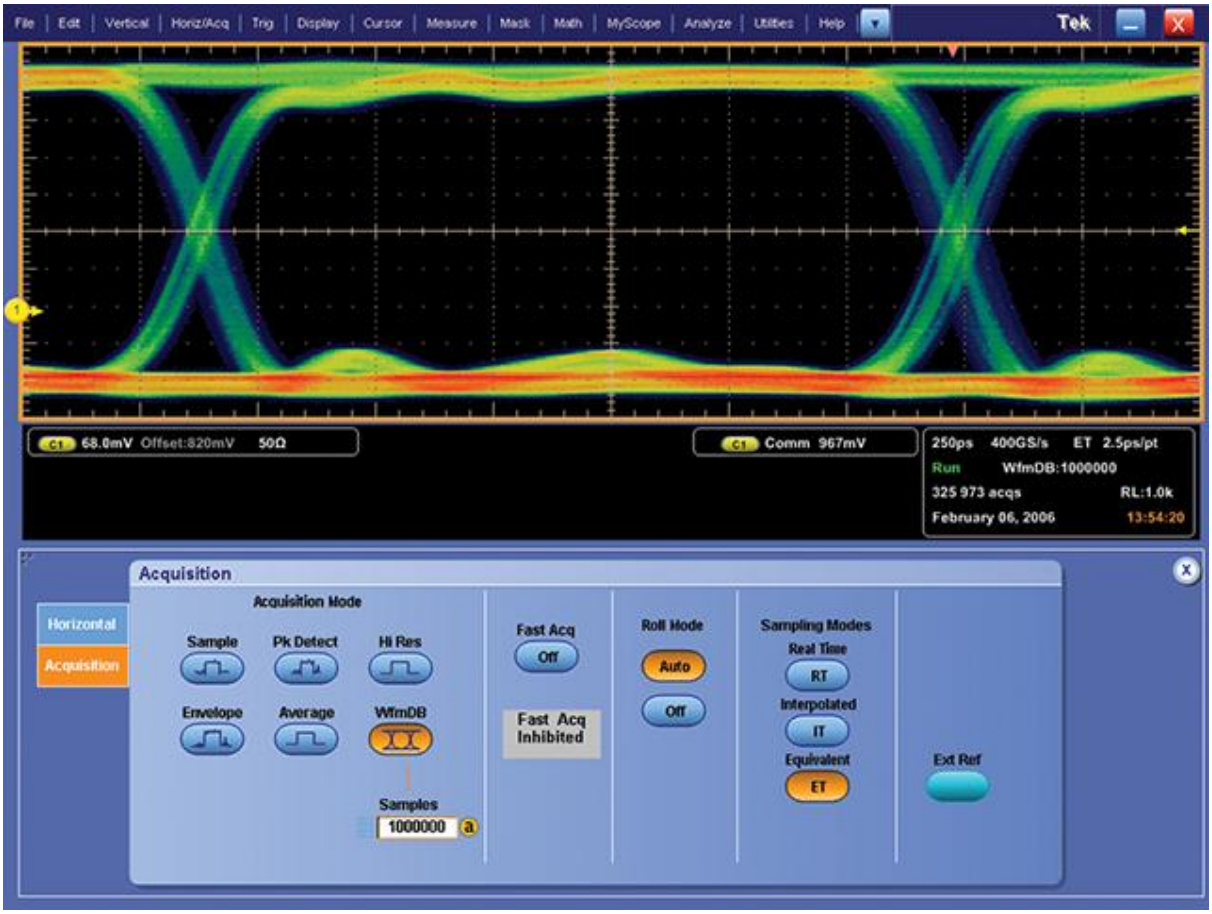


Figure 1.4.4 Acquisition Modes

Acquisition Modes

Acquisition modes control how waveform points are produced from sample points. Sample points are the digital values derived directly from the analog-to-digital converter (ADC). The sample interval refers to the time between these sample points. Waveform points are the digital values that are stored in memory and displayed to construct the waveform. The time-value difference between waveform points is referred to as the waveform interval.

The sample interval and the waveform interval may or may not be the same. This fact leads to the existence of several different acquisition modes in which one waveform point is comprised of several sequentially acquired sample points.

Additionally, waveform points can be created from a composite of sample points taken from multiple acquisitions, which provide another set of acquisition modes. A description of the most commonly used acquisition modes follows.

Sample Mode: This is the simplest acquisition mode. The oscilloscope creates a waveform point by saving one sample point during each waveform interval.

Peak Detect Mode: The oscilloscope saves the minimum and maximum value sample points taken during two waveform intervals and uses these samples as the two corresponding waveform points. Digital oscilloscopes with peak detect mode, run the ADC at a fast sample rate, even at very slow time base settings and are able to capture fast signal changes that would occur between the waveform points, if in sample mode.

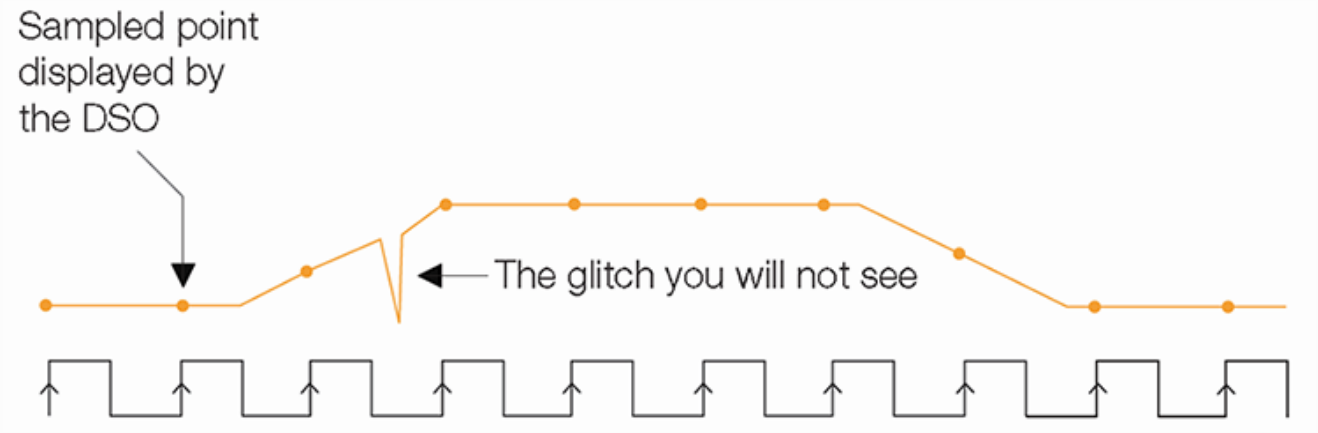


Figure 1.4.5 Sample rate varies with time base settings - the slower the time based setting, the slower the sample rate. Some digital oscilloscopes provide peak detect mode to capture fast transients at slow sweep speeds.

Peak detect mode is particularly useful for seeing narrow pulses spaced far apart in time, as shown in figure 1.4.6.

Figure 1.4.6 Peak detect Mode

Hi-Res Mode: Like peak detect, hi-res mode is a way of getting more information in cases when the ADC can sample faster than the time base setting requires. In this case, multiple samples taken within one waveform interval are averaged together to produce one waveform point. The result is a decrease in noise and an improvement in resolution for low-speed signals. The advantage of Hi-Res Mode over Average is that Hi-Res Mode can be used even on a single shot event.

Envelope Mode: Envelope mode is similar to peak detect mode. However, in envelope mode, the minimum and maximum waveform points from multiple acquisitions are combined to form a waveform that shows min/max accumulation over time. Peak detect mode is usually used to acquire the records that are combined to form the envelope waveform.

Average Mode: In average mode, the oscilloscope saves one sample point during each waveform interval as in sample mode. However, waveform points from consecutive acquisitions are then averaged together to produce the final displayed waveform. Average mode reduces noise without loss of bandwidth, but requires a repeating signal.

Waveform Database Mode: In waveform database mode, the oscilloscope accumulates a waveform database that provides a three-dimensional array of amplitude, time, and counts.

Starting and Stopping the Acquisition System

One of the greatest advantages of digital oscilloscopes is their ability to store waveforms for later viewing. To this end, there are usually one or more buttons on the front panel that allow you to start and stop the acquisition system so you can analyze waveforms at your leisure.

Additionally, you may want the oscilloscope to automatically stop acquiring after one acquisition is complete or after one set of records has been turned into an envelope or average waveform. This feature is commonly called single sweep or single sequence and its controls are usually found either with the other acquisition controls or with the trigger controls.

2. *Sampling*

Sampling is like taking snapshots. Each snapshot corresponds to a specific point in time on the waveform. These snapshots can then be arranged in the appropriate order in time to reconstruct the input signal. The input waveform in figure 1.4.7 appears as a series of dots on the screen. If the dots are widely spaced and difficult to interpret as a waveform, the dots can be connected using a process called interpolation. Interpolation connects the dots with lines or vectors. A number of interpolation methods are available that can be used to produce an accurate representation of a continuous input signal.

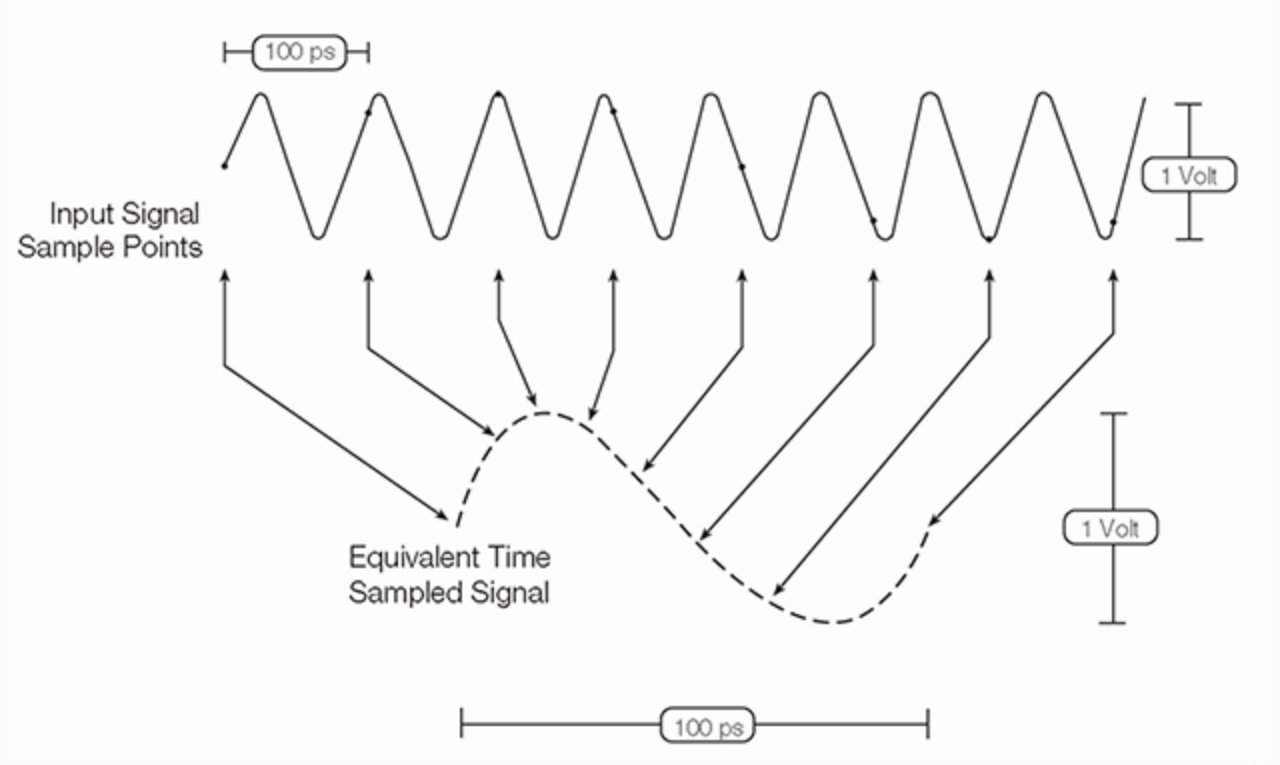


Figure1.4.7 (Basic sampling, showing sample points are connected by interpolation to produce a continuous waveform).

Sampling Controls

Some digital oscilloscopes provide you with a choice in a sampling method, either real-time sampling or equivalent time sampling.

Controls are typically available to give you the choice of three horizontal time based modes of operations. If you are simply doing signal exploration and want to interact with a lively signal, you use the Automatic or Interactive Default mode that provides you with the liveliest display update rate. If you want a precise measurement and the highest real-time sample rate that will give you the most measurement accuracy, then you use the Constant Sample Rate mode. It maintains the highest sample rate and provides the best real-time resolution. The last mode is called the Manual mode because it ensures direct and independent control of the sample rate and record length.

- **Real-time Sampling Method:** Real-time sampling is ideal for signals that have frequency ranges less than half the oscilloscope's maximum sample rate. Here, the oscilloscope can acquire more than enough points in one "sweep" of the waveform to construct an accurate picture, as shown in the following Figure 1.4.8. Real-time sampling is the only way to capture fast, single-shot, transient signals with a digital oscilloscope.

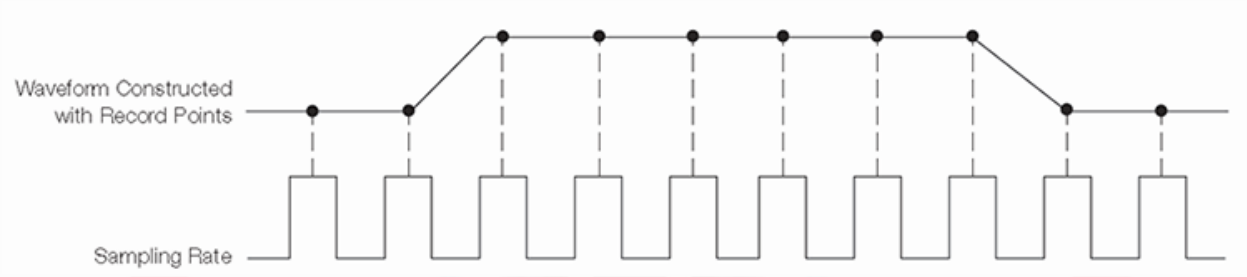


Figure 1.4.8 Real time Sampling method.

For real-time sampling with interpolation, digital oscilloscopes take discrete samples of the signal that can be displayed. However, it can be difficult to visualize the signal represented as dots, especially because there can only be a few dots representing high-frequency portions of the signal. To aid in the visualization of signals, digital oscilloscopes typically have interpolation display modes.

Interpolation display modes:

- Linear interpolation connects sample points with straight lines. This approach is limited to reconstructing straight-edged signals (as in the following Figure 1.4.9), which better lends itself to square waves.
- The more versatile sin x/x interpolation connects sample points with curves (as in the following Figure1.4.9). Sin x/x interpolation is a mathematical process in which points are calculated to fill in the time between the real samples. This form of interpolation lends itself to curved and irregular signal shapes, which are far more common in the real world than pure square waves and pulses. Because of this, sin x/x interpolation is the preferred method for applications where the sample rate is three to five times the system's bandwidth.

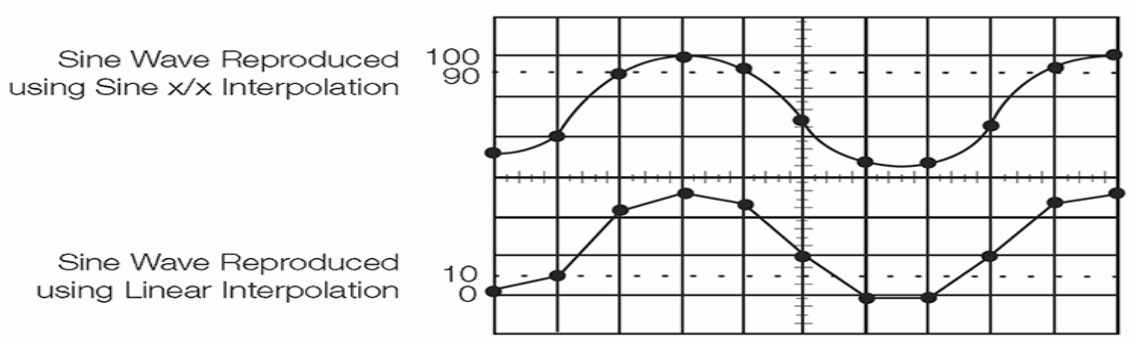


Figure 1.4.9 difference between Sine x/x and linear interpolation.

- **Equivalent-time Sampling Method:**

When measuring high-frequency signals, the oscilloscope may not be able to collect enough samples in one sweep. Equivalent-time sampling can be used to accurately acquire signals whose frequency exceeds half the oscilloscope's sample rate (as in the following Figure 1.4.10).

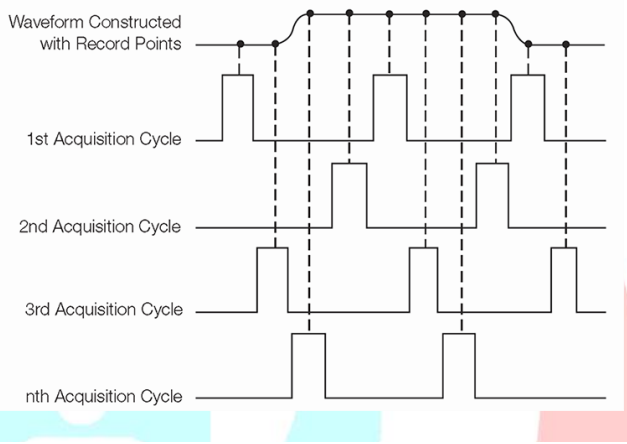


Figure 1.4.10 equivalent time sampling method

Equivalent-time digitizers (samplers) take advantage of the fact that most naturally occurring and man-made events are repetitive. Equivalent-time sampling constructs a picture of a repetitive signal by capturing a little bit of information from each repetition. The waveform slowly builds up like a string of lights, illuminating one-by-one. This allows the oscilloscope to accurately capture signals whose frequency components are much higher than the oscilloscope's sample rate.

Note

As in Figure1.4.10, some oscilloscopes use equivalent-time sampling to capture and display very fast, repetitive signals.

3. *Position and Seconds per Division*

The horizontal position control moves the waveform left and right to exactly where you want it on the screen. The seconds-per-division setting (usually written as sec/div) lets you select the rate at which the waveform is drawn across the screen (also known as the time base setting or sweep speed). This setting is a scale factor. If the setting is 1 ms, each horizontal division represents 1 ms and the total screen width represents 10 ms, or ten divisions. Changing the sec/div setting enables you to look at longer and shorter time intervals of the input signal.

4. *Zoom/Pan*

Your oscilloscope may have special horizontal magnification settings that let you display a magnified section of the waveform on-screen. Some oscilloscopes add pan functions to the zoom capability. Knobs are used to adjust the zoom factor or scale, and the pan of the zoom box across the waveform.

5. *Search*

Some oscilloscopes offer search and mark capabilities, enabling you to quickly navigate through long acquisitions looking for user-defined events.

6. *XY Mode*

Most oscilloscopes have an XY mode that lets you display an input signal, rather than the time base, on the horizontal axis. This mode of operation opens up a whole new area of phase shift measurement techniques.

Trigger System and Controls

An oscilloscope's trigger function synchronizes the horizontal sweep at the correct point of the signal. This is essential for clear signal characterization. Trigger controls allow you to stabilize repetitive waveforms and capture single-shot waveforms. The trigger makes repetitive waveforms appear static on the oscilloscope display by repeatedly displaying the same portion of the input signal. Imagine the jumble on the screen that would result, if each sweep started at a different place on the signal, as illustrated in the following Figure 1.4.11.

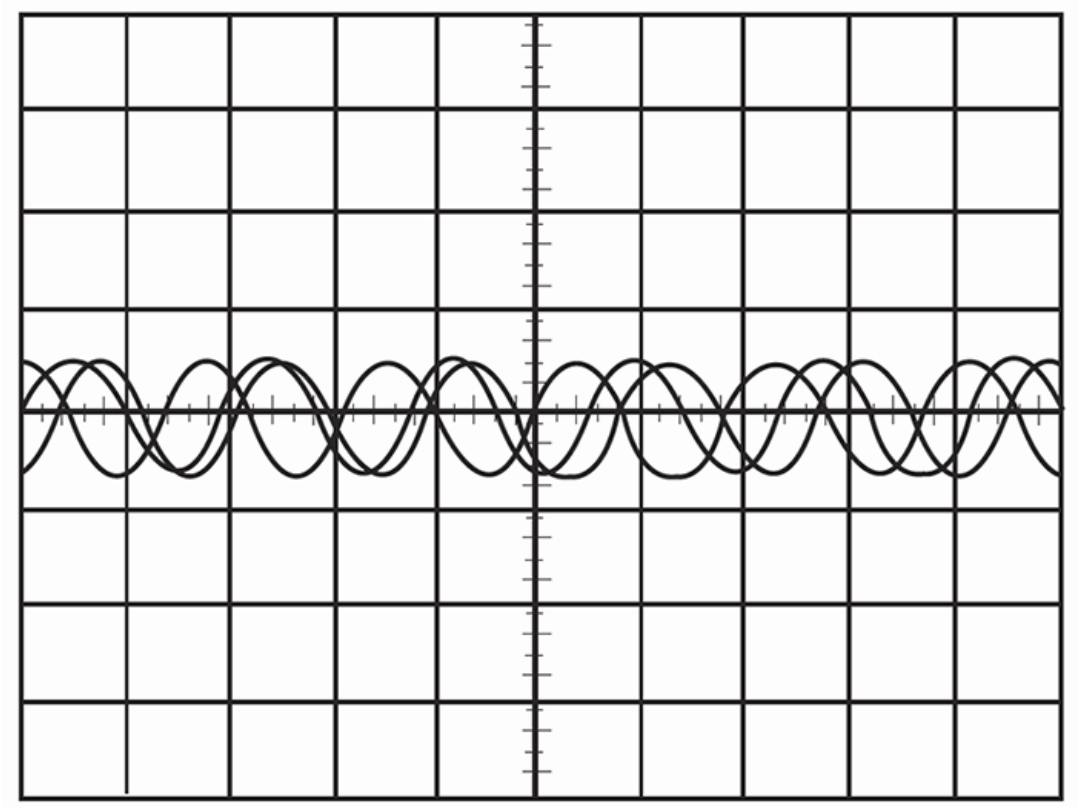


Figure 1.4.11 Untriggered display.

Edge triggering, available in analog and digital oscilloscopes, is the basic and most common type. In addition to threshold triggering offered by both analog and digital oscilloscopes, many digital oscilloscopes offer numerous specialized trigger settings not offered by analog instruments. These triggers respond to specific conditions in the incoming signal, making it easy to detect, for example, a pulse that is narrower than it should be. Such a condition is impossible to detect with a voltage threshold trigger alone.

Advanced trigger controls enable you to isolate specific events of interest to optimize the oscilloscope's sample rate and record length.

Read more about this in https://www.tek.com/document/online/primer/xyzs-scopes/ch4/oscilloscope-systems-and-controls#

1. *Trigger Level and Slope*

The trigger level and slope controls, provide the basic trigger point definition and determine how a waveform is displayed (as in the following Figure 1.4.12).

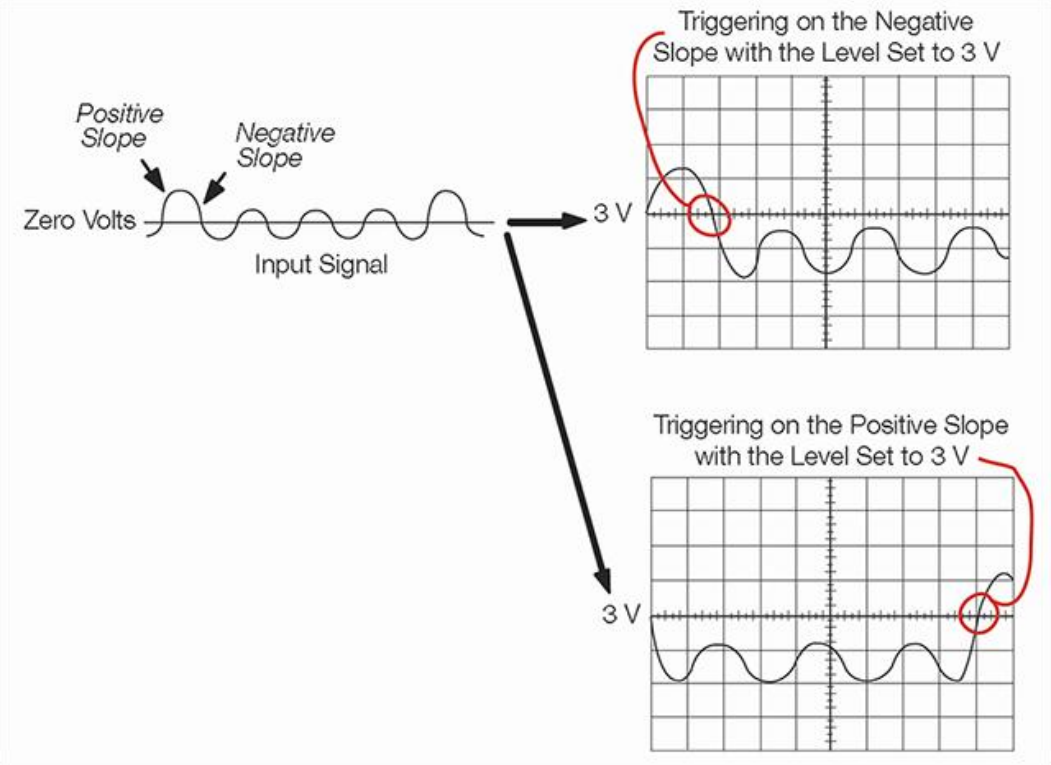


figure 1.4.11 Positive and negative slope triggering.

The trigger circuit acts as a comparator. You select the slope and voltage level on one input of the comparator. When the trigger signal on the other comparator input matches your settings, the oscilloscope generates a trigger. The slope control determines whether the trigger point is on the rising or the falling edge of a signal. A rising edge is a positive slope and a falling edge is a negative slope. The level control determines where on the edge the trigger point occurs.

2. Trigger Modes

The trigger mode determines whether or not the oscilloscope draws a waveform based on a signal condition. Common trigger modes include normal and auto:

- In normal mode the oscilloscope only sweeps, if the input signal reaches the set trigger point. Otherwise, the screen is blank (on an analog oscilloscope) or frozen (on a digital oscilloscope) on the last acquired waveform. Normal mode can be disorienting since you may not see the signal at first if the level control is not adjusted correctly.
- Auto mode causes the oscilloscope to sweep, even without a trigger. If no signal is present, a timer in the oscilloscope triggers the sweep. This ensures that the display will not disappear if the signal does not cause a trigger.

In practice, you will probably use both modes: normal mode because it lets you see just the signal of interest, even when triggers occur at a slow rate, and auto mode because it requires less adjustment. Many oscilloscopes also include special modes for single sweeps, triggering on video signals, or automatically setting the trigger level.

3. Trigger Coupling

Just as you can select either AC or DC coupling for the vertical system, you can choose the kind of coupling for the trigger signal. Besides AC and DC coupling, your oscilloscope may also have high frequency rejection, low frequency rejection, and noise rejection trigger coupling. These special settings are useful for eliminating noise from the trigger signal to prevent false triggering.

Controls for Math and Measurement Operations

Your oscilloscope may also have operations that allow you to add waveforms together, creating a new waveform display. Analog oscilloscopes combine the signals while digital oscilloscopes create new waveforms mathematically. Subtracting waveforms is another math operation. Subtraction with analog oscilloscopes is possible by using the channel invert function on one signal and then using the add operation. Digital oscilloscopes typically have a subtraction operation available.

Using the power of their internal processors, digital oscilloscopes offer many advanced mathematical operations including: multiplication, division, integration, Fast Fourier Transform, and more.

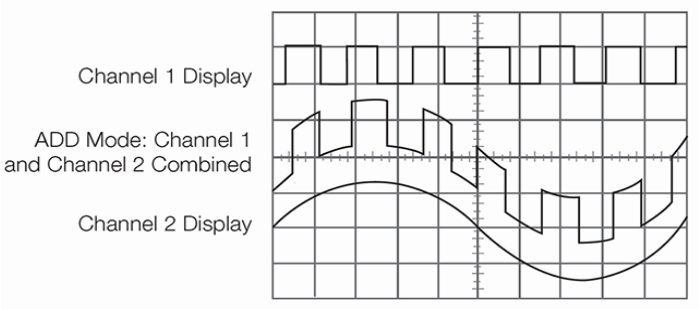


Figure 1.4.13 math adding two waveforms

Other Test Equipment

- **Frequency counter** is an electronic instrument that is used for measuring frequency. Frequency counters usually measure the number of oscillations or pulses per second in a periodic electronic signal.
- **Logic analyzers** are widely used for testing complex digital or logical circuits.

- **Hipot** is an abbreviation for high potential. Traditionally, hipot is a term given to a class of electrical safety testing instruments used to verify electrical insulation in finished appliances, cables or other wired assemblies, printed circuit boards, electric motors, and transformers.
- **Solenoid voltmeter** is a specific type of voltmeter electricians use to test electrical power circuits especially low voltage.
- **Transistor testers** are instruments for testing the electrical behavior of transistors and solid-state diodes.
- **Function generator** is usually a piece of electronic test equipment or software used to generate different types of electrical waveforms over a wide range of frequencies.
- **Cable tester** is a device that is used to **test** the strength and connectivity of a particular type of **cable** or other wired assemblies.
- **Logic probe** is a hand-held test probe used for analyzing and troubleshooting the logical states of a digital circuit.
- **Time-domain reflectometer (TDR)** is an electronic instrument that uses time-domain reflectometry to characterize and locate faults in metallic cables.
- **EMF meter** can measure AC electromagnetic fields, which are usually emitted from man-made sources such as electrical wiring.
- **RF meters** are used to measure Radio Frequency radiation (what some people mean when they say "**RF**" or "Microwaves") from Wi-Fi, cell phones or cell towers, laptops or microwave ovens, they can also be used to locate the source of a field, and to measure the performance of radiofrequency shielding.
- **Tube tester** is an electronic instrument designed to test certain characteristics of vacuum tubes.

Specialized Biomedical Test Equipment

For medical devices:

There's a whole range of businesses who deal with and use medical equipment every day, from dentists to GP's and nursing homes, and there's an even greater amount of people who are subjected to this medical equipment every day, for diagnosis, treatment and assistance.
This is why it is incredibly important from a moral, technological, medical and legal standpoint that all medical equipment is in full working order, safe to use, and calibrated to the highest level of accuracy.

What is Medical Equipment Testing & Calibration?

Medical Equipment Testing & Calibration is the act of ensuring that all medical equipment is in full working order, and is calibrated to a known standard so as to ensure that the reading/result/functionality of the item is accurate at the point of

delivery to a patient. It is your responsibility to ensure that your medical equipment is in full working order and maintained through regular medical device testing.

Why Does Medical Equipment Need Regular Calibration?

Medical equipment like any other equipment is prone to wear and tear over time which directly impacts its performance accuracy. And the only way to retain the equipment's effectiveness and minimize risks or uncertainty is through regular calibration. This is especially important as the accuracy provided by such medical equipment is crucial to the overall output, with respect to both quality and profitability. Apart from this, regular calibration of medical equipment is also required to receive the necessary certifications and licenses from regulatory authorities.

When should you have your equipment calibrated & tested?

You should seek to have your medical equipment tested and calibrated when:

- **You purchase a new or second-hand instrument**, since you cannot be sure that just because it's new, it is properly calibrated.
- **Manufacturer Recommended Frequency**
  In most cases, medical equipment and tools come with manufacturers' recommendations with respect to calibration frequency. However, you must also factor in the nature of its use while doing so. For instance, tools that are used to perform critical measurements may require different intervals.
- **When an instrument has had a shock or vibration.** This is especially important in portable devices, or new devices that might have been shipped over long distances.
- **Whenever observations appear questionable.** Common sense comes into play with this, if it looks damaged or like it's giving off readings, there's a good chance it could be.

Specialized Biomedical Test Equipment

Biomedical Test Equipment is specifically designed to aide healthcare professionals in the validation and maintenance of a wide variety of medical devices, and here are some examples

1. Electrosurgery Unit (ESU) Analyzers
2. Infusion Device Analyzers
3. Physiological Simulators
4. Noninvasive Blood Pressure (NIBP) Analyzers
5. Ventilator Analyzers

6. Incubator Analyzers
7. SpO2 Analyzers
8. Ultrasound Analyzers
9. Defibrillator Analyzers
10. Pacemaker Analyzers
11. Incubator Radiant Warmer Analyzer.
12. Phototherapy Radiometers.

Key terms and concepts:

Graticule: a network of lines representing meridians and parallels, on which a map or plan can be represented, on the screen of an oscilloscope, used as a measuring scale or an aid in locating objects.

Links

- direct365,"A Guide to Medical Equipment Testing & Calibration", Laurence Kellett in Workplace Safety. August 14th, 2015.
- LTL Information system. October 15, 2015.
- ICS Electronics. Extending the GPIB Bus Retrieved December 29, 2009.
- Franklin, Paul and Todd A. Hayes. LXI Connection .Benefits of LXI and Scripting. July 2008. Retrieved January 5, 2010.
- Hardware Mechanical Components VXI Chassis and Case Manufacturers. Retrieved December 30, 2009.
- "Signal Injector Circuit". Retrieved 2018-06-03.
- Cigoy, Dale. R&D Magazine. Smart Instruments Keep Up With Changing RD NeedsRetrieved January 4, 2009.
- ELECTRONICS TEST & MEASUREMENT, Radio-Electronics.com, Ian Poole.
- All About Circuits. (n.d.). Safe Meter Usage. Retrieved February 27, 2013.
- SparkFun. (n.d.). How to Use a Multi-meter. Retrieved February 27, 2013.
- All About Circuits. (n.d.). Voltage and Current. Retrieved February 27, 2013.
- Physics4Kids. (n.d.). Current. Retrieved February 27, 2013.
- SCIENCE BUDDIES, "How to Use a Multi-meter".
- "A New Electronic Rectifier", L.O Grondahl & P.H. Geiger, Transactions, American Institution of Electrical Engineers, February 1927 pp. 358 – 366.
- "Digital Multi-meter Measurement Fundamentals". *National Instruments*. Retrieved 2008-01-26.
- "Model 2002 Multi-meter Specifications". Keithley Instruments.
- Agilent Technologies. "Agilent 3458A Digital Multi-meter Data Sheet" (PDF). Retrieved 2007-01-28.
- Grayen, Michael. "Digital Multi-meter Basics". CARiD.com.
- Goldwasser, Samuel. "Basic Testing of Semiconductor Devices". Retrieved 2007-01-28.

- XYZ of Oscilloscopes, Tektronix.
- Oscilloscope Fundamentals Primer, Rohde & Schwarz.
- WhatIs.com,TechTraget, Oscilloscope, Margaret Rouse. September 2005.

Section 2
Monitoring Device Testing

Objectives

- Provide an overview of Monitoring device testing.
- Define some of analyzers of vital signs measurement devices.

Physiological and ECG simulators

Physiological (patient) simulators is the modeling of the human physiology such as vital signs, clinical signs and symptoms. There are different types of patient simulators the type that is used in the education and training of healthcare professionals and the other that is used in testing some medical devices, such as monitors, this type of patient simulators gives only vital signs.

Figure 2.1.1

Here we are going to talk about patient simulators for testing medical devices (physiological or vital signs simulators).

Now advanced patient simulators are capable of the below simulations:

- ECG
  - ECG wave forms
  - Arrhythmia's
  - Pacemaker Waveforms
  - Performance Waveform
  - Fetal Maternal
- Respiration
- Temperature
- Invasive blood pressure
- Spo2
- Cardiac output
- Non- Invasive blood pressure

Simulation Settings

1. ECG Settings

The Product simulates normal heart signals (ECG) as well as heart signals for a variety of arrhythmias. Heart rate (beats per minute), signal amplitude, and ST segment elevation are all controlled by the Product through the user interface. Artifacts can also be simulated. To measure the ECG performance of a monitor, connect the Product to the monitor as shown in the following Figure 2.1.2.

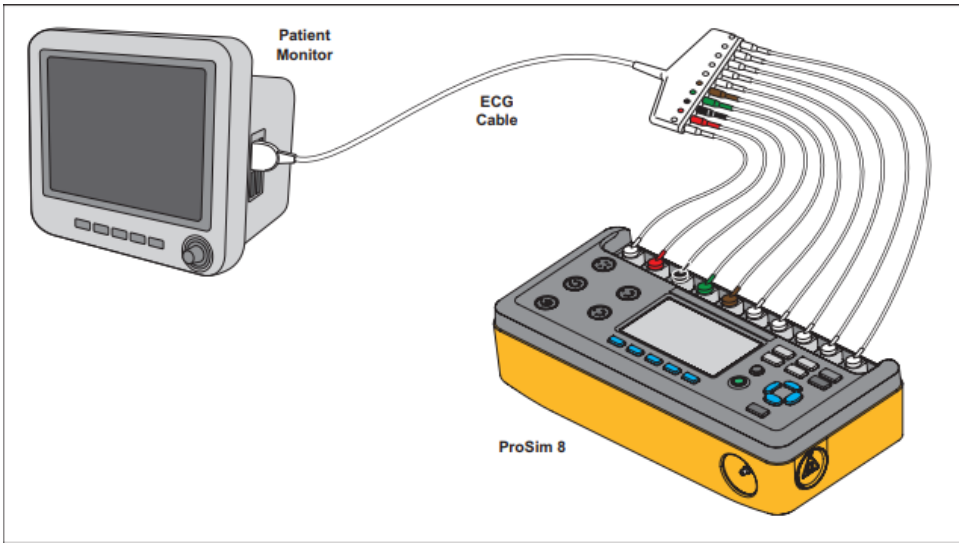


Figure 2.1.2 PATIENT SIMULATOR CONNECTION TO MONITOR SHOWING ECG.

a. **Normal Sinus Rhythm simulation:** Heart rate (beats per minute), signal amplitude, and ST segment can be set.

- Artifacts simulation: some Products simulate a number of different ECG artifacts that can change the accuracy of an ECG indication. You can add several ECG artifact simulations to an ECG wave: line-frequency artifacts of 60 Hz (U.S. lines) and 50 Hz (European lines), as well as artifacts for muscle movement, wandering baseline, and respiration.

b. **Arrhythmias simulation**: All arrhythmia simulations are grouped into related wave groups. These arrhythmias wave groups are Supraventricular, Premature, Ventricular and Conduction.

- Definition of wave groups:
  I. Supraventricular arrhythmia: is an abnormal heart rhythm arising from improper electrical activity in the upper part of the heart.
  II. Premature Arrhythmias: The premature wave group arrhythmias simulate premature contraction of muscle at different nodes of the heart.
  III. Ventricular Arrhythmias are arrhythmias in the lower chambers of the heart, or ventricles.
  IV. Conduction Arrhythmias are caused when the conduction of electrical impulses is stopped or blocked from their usual pathways around the heart.

c. **Pacemaker Waveforms:** Some Products can simulate ECG waveforms with a number of artificial-pacemaker conditions. You can adjust the amplitude of all TV Paced waveforms. You can adjust the amplitude of all TV Paced waveforms.

d. **Advance Cardiac Life Support (ACLS) Waveforms**: Some Simulators can simulate Advanced Cardiac Life Support (ACLS) waveforms.
e. **ECG Performance Tests as well as physiological waveforms:** Some Analyzers can supply signals to measure the performance of an ECG monitor. A set of performance waveforms are used to measure the frequency response (high and low), sensitivity, gain drift, internal calibration, stylus damping, paper speed, linearity, and sweep speed of an ECG monitor. Three more Product functions are used to measure R wave detection, QRS detection, and tall T wave rejection of an ECG monitor.
    - Set a Performance Wave: The waveforms in the performance wave group are sine, square, triangle, and pulse. You can adjust the rate and amplitude of these waveforms to preconfigured values.
    - Set R Wave Detection Values: To sense a heartbeat, a monitor looks for R waves. The sensed R wave is used to calculate the heart rate and other analysis. You adjust the R wave to find the range of values a heart monitor can sense a heartbeat. The R wave is a simple triangular pulse.
    - Set QRS Detection Test Values: The QRS Detection wave group supplies a signal where you can adjust the width of the QT interval.
    - Set Tall T Wave Rejection Test Values: An ECG monitor must sense and reject a large T wave when it calculates the heart rate. Use the Tall T Wave Rejection waveform for this test.

f. **Fetal Simulation** the Simulator simulates a mixed fetal and maternal electrocardiogram (ECG) that occurs during labor, as well as a selection of pressure waveforms made by uterine contractions. You can change the contraction period. There is also a manual contraction.
    - Set Fetal Heart Values: The maternal signal is a P-QRS-T wave at half the set ECG amplitude. The fetal signal is a narrow R wave at full amplitude. Fetal and maternal signals are summed to make a composite signal.
    - Simulate Intrauterine Pressure (IUP) The simulated intrauterine-pressure (IUP) waveform shows a measurement read by an intra-amniotic catheter connected to a pressure transducer. The Product sends waveforms to simulate intrauterine pressure during a contraction of the uterus in childbirth.

    To do an Intrauterine pressure simulation, connect the fetal monitor to the Product as shown in the following Figure 2.1.3

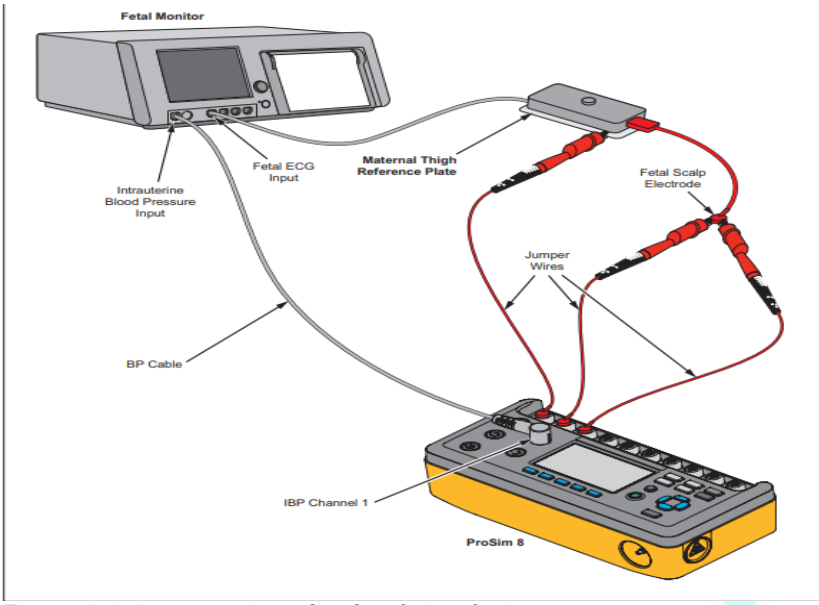


Figure 2.1.3 connections for fetal simulation

- Set the Fetal Heart Rate Response. The Product simulates three types of preconfigured waveforms for a periodic fetal heart rate that is interactive with uterine contractions: early deceleration; late deceleration; or acceleration:
  With early deceleration, the fetal heart rate follows the intrauterine pressure (no lag). The fetal heart rate starts at 140 BPM, slows to 100 BPM at intrauterine pressure peak, and then goes back to 140 BPM as the IUP falls back to zero.

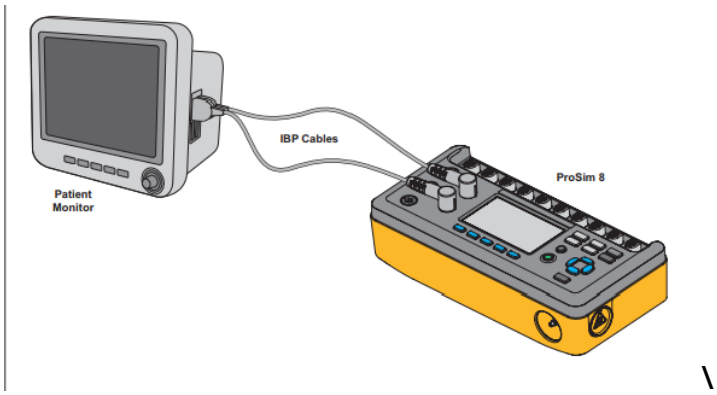
  With late deceleration, the change in fetal heart rate starts when IUP pressure is at its peak and lags the change in intrauterine pressure by 45 seconds. The fetal heart rate starts at 140 BPM, slows to 100 BPM, and then goes back to 140 BPM.

  With acceleration, the change in fetal heart rate lags the change in intrauterine pressure by 30 seconds. The fetal heart rate starts at 140 BPM, increases to 175 BPM, and then goes back 140 BPM.

2. Invasive Blood Pressure Simulation and Tests

The Product simulates blood pressure for Invasive blood pressure monitors.

- Set the Invasive Blood Pressure Variables: The blood pressure variables are set.
  Simulate Invasive Blood Pressure Tests



\

Figure 2.1.4 shows a monitor connected to the two IBP channel jacks on the Patient simulator.

3. Simulate Temperature: Connect the temperature cable to the monitor as in the figure 2.1.5.

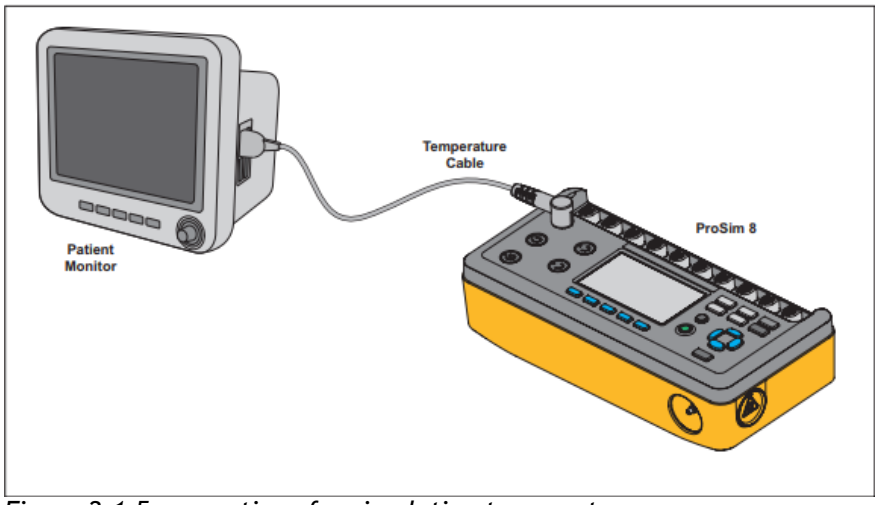


Figure 2.1.5 connections for simulating temperature

4. Simulate Respiration: You can choose between a normal or ventilated respiration waveform and change the respiration rate.
   - Set Apnea Simulation. You can simulate an apnea period manually or for a specified time period.
5. Simulate Cardiac Output: The Cardiac Output function, electronically simulates the dynamic temperature changes in the blood of the patient during a thermal dilution cardiac output measurement.

Thermal dilution cardiac output measurements are given by the heat interchange between the blood of the patient and a known volume of chilled saline put into the heart. Cardiac output is expressed in liters per minute (L/min) and ranges between 3 L/min and 7 L/min in normal adults.

Current cardiac output measurement devices can make sure you get the most accurate measurements. This includes an average of a series of measurements to prevent variations because of artifacts. This rejects measurements because of clinician technique or the underlying cardiovascular disease in a patient.

Note
Cardiac output measurement devices that use different techniques (such as Fick dye injection, Doppler ultrasonography and Bio-impedance) are not addressed or intended for this Product.

To set cardiac output you should set:

- Set the Cardiac Output Waveform
  - Choose a waveform name in the list of waveforms (the following table shows examples of a Product's cardiac output waveform).

Waveform	Description
2.5 L/min	Normal waveform with accuracy of 2.5 L/min
5.0 L/min	Normal waveform with accuracy of 5.0 L/min
10.0 L/min	Normal waveform with accuracy of 10.0 L/min
Interrupted Injectable	Interrupted injection waveform
LR Shunt	Left to right ventricular shunt
Calibrated Pulse	Calibrated square wave pulse

- Set the Baseline Temperature
- Set Injectate Temperature
- Start a Cardiac Output Simulation

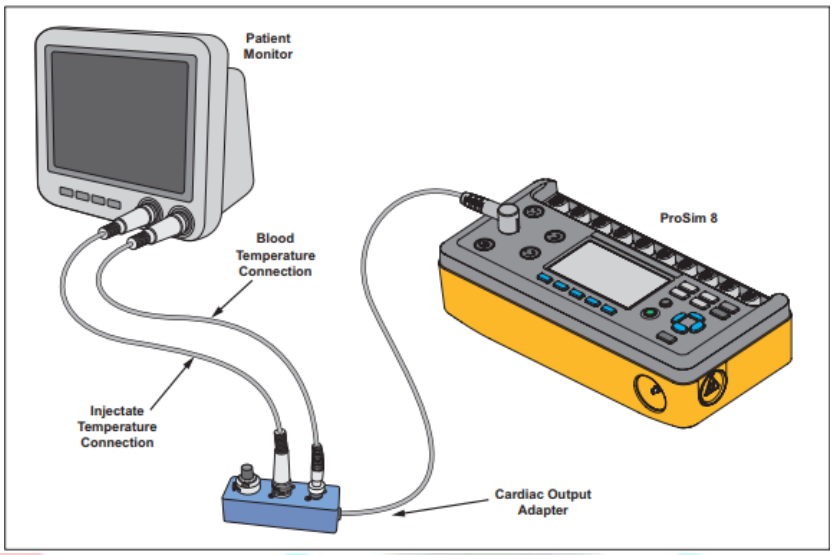


Figure 2.1.6 cardiac output connection

6. Non-Invasive Blood Pressure Simulation and Tests

The Product simulates blood pressure for Non-Invasive blood pressure monitors. They can also do leak, pressure source, and pressure relief tests. The manometer function sets the simulator to measure static pressure and shows the pressure on the display.

- *Set the Non-Invasive Blood Pressure Variables:* Pressure, heart rate, pulse volume, brand, and wave are set. Arrhythmia waveforms can also be simulated in the NIBP simulation.

For non-invasive blood pressure tests, connect the simulator to the BP cuff and monitor as shown in the following figure 2.1.7.

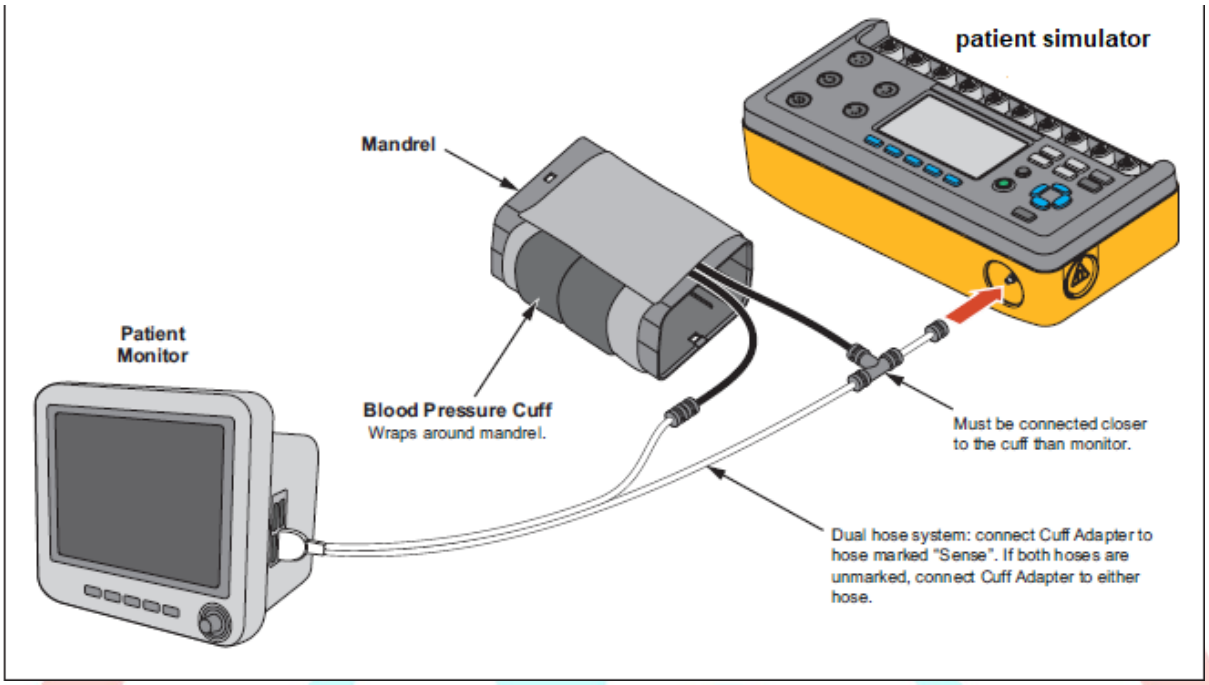


Figure 2.1.7 connections for non-invasive blood pressure tests

❖ *Do an NIBP Monitor Test*

To do an accuracy test on an NIBP monitor:

1. Connect the NIBP monitor to the simulator.
2. Start an NIBP pressure cycle on the monitor. After you start the blood pressure measurement cycle:
   - ➢ The blood pressure cuff inflates around the mandrel.
   - ➢ The Product starts the peripheral pulse simulation and shows the blood pressure measurement graph on the display.
3. Compare the NIBP monitor values with the target values shown in the Product display.

❖ *Do a Pressure Leak Test*

The leak test measures leaks in a non-invasive blood pressure monitor, the hoses connected to the monitor, and the pressure cuff.

Note

Before you do a pressure leak test on a monitor, do the pressure leak test without the monitor to identify the leak rate of the simulator.
Use this leak rate to offset the rate of the full system with the monitor connected.

Note
Put the NIBP monitor in “calibrate” or “service” mode to close the vent valve so, the simulator can inflate the pneumatic system. Refer to the service manual for the NIBP monitor.

Note
If the NIBP device has an internal system leak test or one that vents the cuff inflation pneumatic circuit to the atmosphere when idle, do not use the Leak Test. Rather, do a Manometer check to test for internal system leaks. Refer to the NIBP monitor operator’s manual for the recommended test protocol.

❖ *Do a Pressure Relief Test*

The pressure relief test pressurizes a pneumatic system until the simulator senses a drop in pressure, as occurs when the relief valve opens. Or the test stops if the pressure gets to the target pressure and no relief is sensed.

Note
Put the NIBP monitor in “calibrate” or “service” mode to close the vent valve, so the Product can inflate the pneumatic system. Refer to the service manual for the NIBP monitor.

The simulator pressurizes the pneumatic system to the target pressure with the pressure measurement and a graph of the pressure shown on the display. When the Product senses the pressure valve has opened, the test stops and the results show on the display. It is recommended you do three pressure relief tests in case the relief valve is intermittent. If there is no drop in pressure and the pressure climbs to the target pressure, the pump stops and **Not Tripped** shows on the display.

Note
Some NIPB monitors do not let you access a “Service” mode. If you cannot close the vent valve, the system cannot be pressurized by an external pump. It is possible to start a blood pressure measurement *with the monitor (this closes the valve), then start the Pressure Relief tests, so that two pumps inflate the system. The results can change, but the monitor usually opens a relief valve at some high pressure*.

❖ *Do a Pressure Source Test*

The pressure source test is used to pressurize a pneumatic system while it measures the pressure. You can use the pressure source test for static calibration of non-invasive blood pressure measurement systems, sphygmomanometer checks, and other devices that measure pressure.

To do a pressure source test:

1. Connect the pressure port to the pressure system as shown in the following figure 2.1.8.

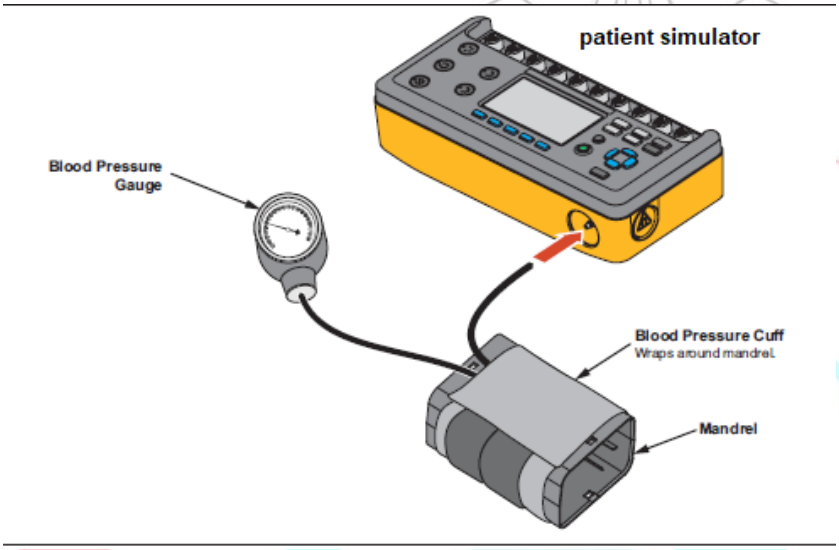


Figure 2.1.8 connections for pressure source test

❖ *Check a Manometer*

The manometer function sets the Product up as a pressure gauge to measure pressure supplied by an external source.

To measure pressure:

- Connect the pressure port to a pneumatic system as shown in following Figure 2.1.9, And then start testing.

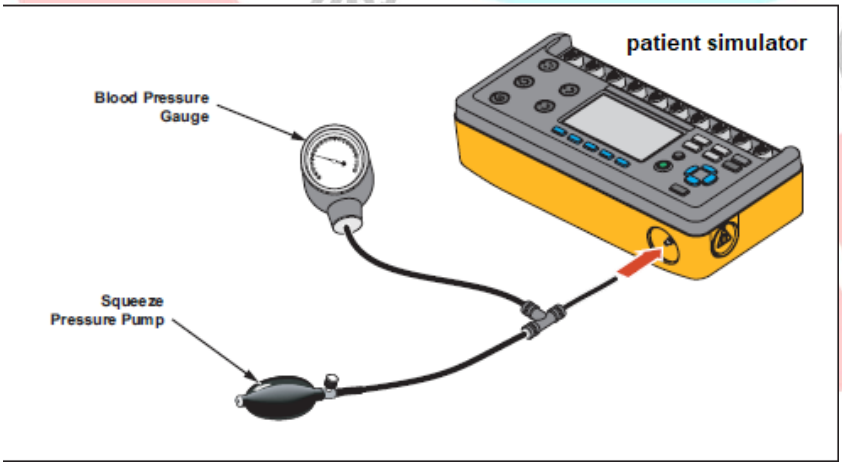


Figure 2.1.9 connections for manual pressure pump

7. Oximeter SpO2 Optical Emitter and Detector

The subject device provides Oximeter SpO2 optical emitter and detector capability, which is solely intended to generate an optical signal to verify that the electronics within the pulse oximeter probe are functional. The subject device presents pulse oximeter equipment with a signal having a predictable value of ratio so that the operator can observe the resulting displayed value of SpO2, and compare it to the expected value derived from the calibration curve for that particular pulse oximeter equipment.

- Set oximeter SpO2 optical emitter and detector parameters: here is an example of patient simulator setting parameters of SpO2.

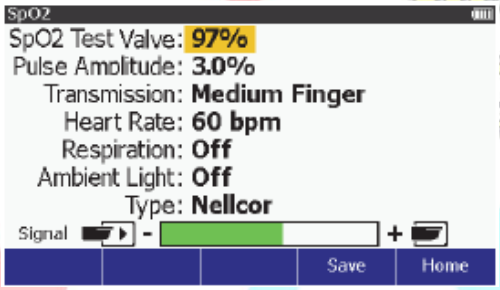


Figure 2.1.10 example of SpO2 test

Connect the SpO2 artificial finger to the SpO2 jack as shown in the following figure 2.1.11.

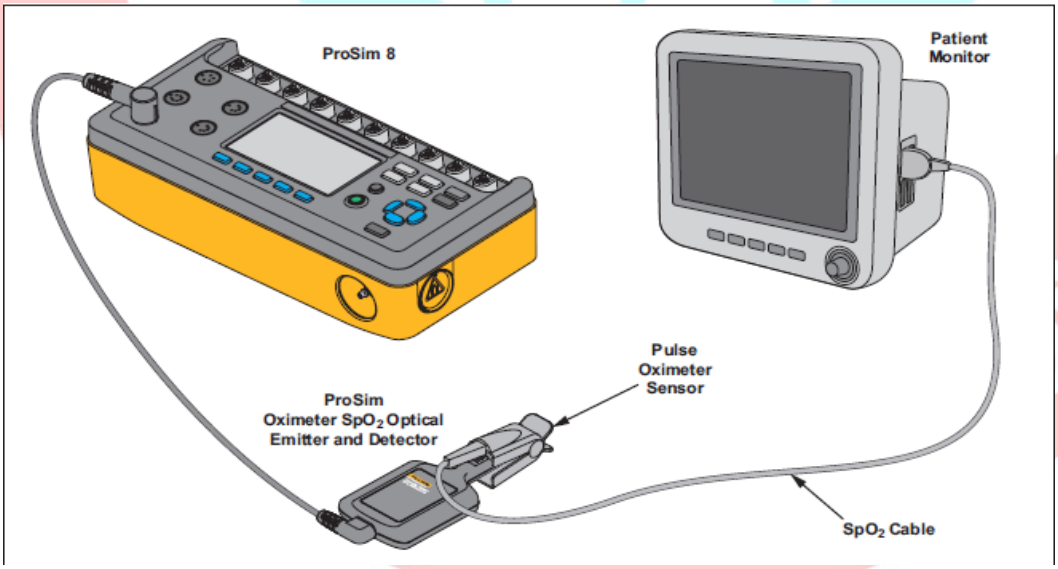


Figure 2.1.11 connections for SpO2 test

Note
When you put the oximeter sensor on the artificial finger, make sure the red LEDs (light emitting diodes) are on the bottom.

Put the SpO2 sensor on the artificial finger as shown in the Figure. Place the sensor with the LEDs on the bottom of the artificial finger. Adjust the sensor on the finger for maximum signal strength.

Set the SpO2 Parameters

- You can raise or lower the degree of oxygen saturation.
- Change the transmission value.
- You can change the simulated heart rate.
- You can test SpO2 under different ambient light conditions.

Note
Some simulators can test Masimo Rainbow SpO2

Test a Masimo Rainbow SpO2

When you set the SpO2 type parameter to Masimo Rainbow, you must connect the simulator to the monitor with the optional SpO2 Masimo Rainbow cable. The SpO2 screen shows three more parameters than what shows for other types of sensors: SpMet, SpCO, and SpHb. SpMet, SpCO, and SpHb cannot be set through the Product. The special Masimo Rainbow cable sets them based on the measured SpO2 percent. At 100 %, SpMet = 0 %, SpCO = 0 %, and SpHb = 25 g/dl. A -1 % change in SpO2 changes SpMet +0.3 %, SpCO by +0.7 %, and SpHb by -0.5 %. SpHb does not change for values of SpO2 above 90 %.

Note
Since a special Masimo testing sensor is required to connect the Product to Masimo Rainbow Oximeter, the Product only validates the performance of the Oximeter, not the Masimo Rainbow sensor (the SpHb, SpCO and SpMet values from the Masimo technology are generated based on the SpO2 value provided to the test sensor and are not able to be changed independently).

Important Note
The manufacturer must be known before you do a pulse oximeter test, optically through an artificial finger. For Masimo, you need to know if the sensor is a 2 wavelength or Rainbow sensor. You can configure the Product for the make of pulse oximeter(s) used for the test. You change variables for each of the pulse oximeters through the type variable.
To test other manufacturer types of oximeters, you must download R-Curve data into the Product through the USB Port.

Perform an Oximeter Limits Test

Most oximeters have alarms that you can set for the parameters it measures. You can use the simulator to trip the alarm as a test. Connect the Oximeter to the Product as shown in the previous Figure.

- *Oxygen Limits Test*

You do a sensitivity test on an oximeter through SpO2 value adjustments.

- *Pulse Rate Test*

  You can simulate different patient conditions while you monitor the effect of different pulse rates on the SpO2 measurement.

- *Pulse Amplitude Test*

You can increase or decrease the peak-to-peak amplitude of the blood pressure wave. You can decrease the amplitude to find where the oximeter fails to sense a pulse.

Autosequences

Autosequences are a series of steps that change the output of the simulator automatically.

For example, to do a temperature test on a monitor, you must change the temperature of the temperature simulation a number of times for a specified time period, so you have to take a look for the Autosequences from the manual of your simulator.

Noninvasive Blood Pressure (NIBP) Analyzers

The NIBP Analyzers provides dynamic blood pressure simulations for testing adult and neonatal noninvasive blood pressure monitors.

Introduction:

Tester provides dynamic blood pressure simulations, static calibration, automated leak testing, and pressure relief valve testing. The Tester allows you to verify the performance claims of different blood pressure monitors. You can quickly recall the fixed onboard simulations or define your own. With its internal pump, the Tester can generate pressures for leak testing, pressure sourcing, and relief valve testing.

In addition, you can define auto sequences that automate the sequencing of tests and NIBP simulations and provide an optional printed report.

Key Features

Key features of the different Tester include:

- Pressure leak testing on cuff, tubing, and connections.
- Relief valve testing on the patient monitor.
- Pressure gauge measurements.
- Pressure source capability.
- NIBP simulations including adult, neonate, arrhythmias, and respiratory artifacts.
- Auto sequences with optional reports.
- Internal Adult and Neonatal Cuff simulation.

Tester capabilities can be extended with optional accessories that allow:

- ECG synchronization with non-invasive output.
- External wrist cuff simulations.

Some Tester pressure accuracy can be improved by upgrading to a high-accuracy pressure transducer.

Cautions and warning

Warnings

To avoid possible electric shock or personal injury, follow these guidelines:

- Read the User's Manual before operating the Tester.
- Use this Tester only in the manner specified by the manufacturer or the protection provided may be impaired.
- Do not connect the Tester to a patient or equipment connected to a patient. The Tester is intended for equipment evaluation only and should never be used in diagnostics, treatment or in any other capacity where the Tester would come in contact with a patient.
- Do not use the Product in wet locations, around explosive gases or dust.
- Never open the Tester case, because dangerous voltages are present. There are no user replaceable parts in the Tester.
- The Tester must be properly earthed. Only use a supply socket that has a protective earth contact. If there is any doubt as to the effectiveness of the supply socket earth, do not connect the Tester.

- Do not use a two-conductor adapter or extension cord, this will break the protective ground connection.
- Ensure that the external power source is properly rated for the system.
- Disconnect the Tester from the power source before changing the supply voltage. The Tester operates at a range of 100 to 240 volts.
- Always connect the system power cord directly to a three-prong receptacle with a functional ground. Never use a two-prong plug adapter to connect primary power to the Tester, thereby disconnecting the utility ground.

Cautions

- To avoid damage to the Tester or adverse effects on its performance, follow these guidelines:
- Allow only qualified technical personnel to service the Tester.
- Do not expose the system to temperature extremes. Ambient temperatures should remain within a specified range written in the manual. System performance may be adversely affected if temperatures fluctuate above or below this range.
- Clean the Tester only by gently wiping down with a clean, lint-free cloth dampened with a mild detergent solution. Do not immerse the unit.
- Do not apply pressures greater than specified ranges, written in the manual, to the pressure port.

Configurations for Devices Under Test (DUT)

Connect the Tester to the NIBPM unit. Here are some different configurations.

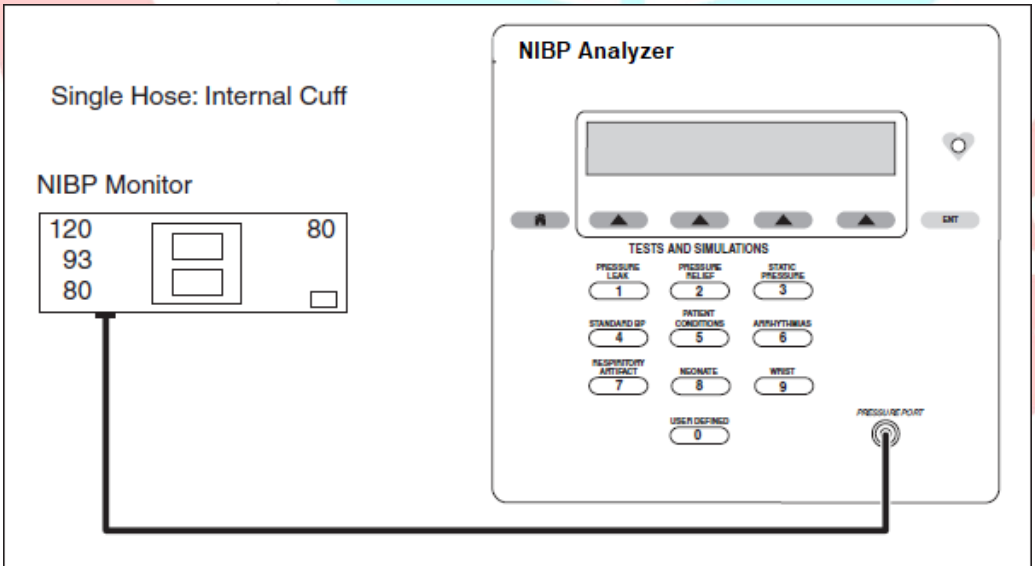


Figure 2.3.1 Connecting Tester to Single-hose NIBP Monitor (Int Cuff)

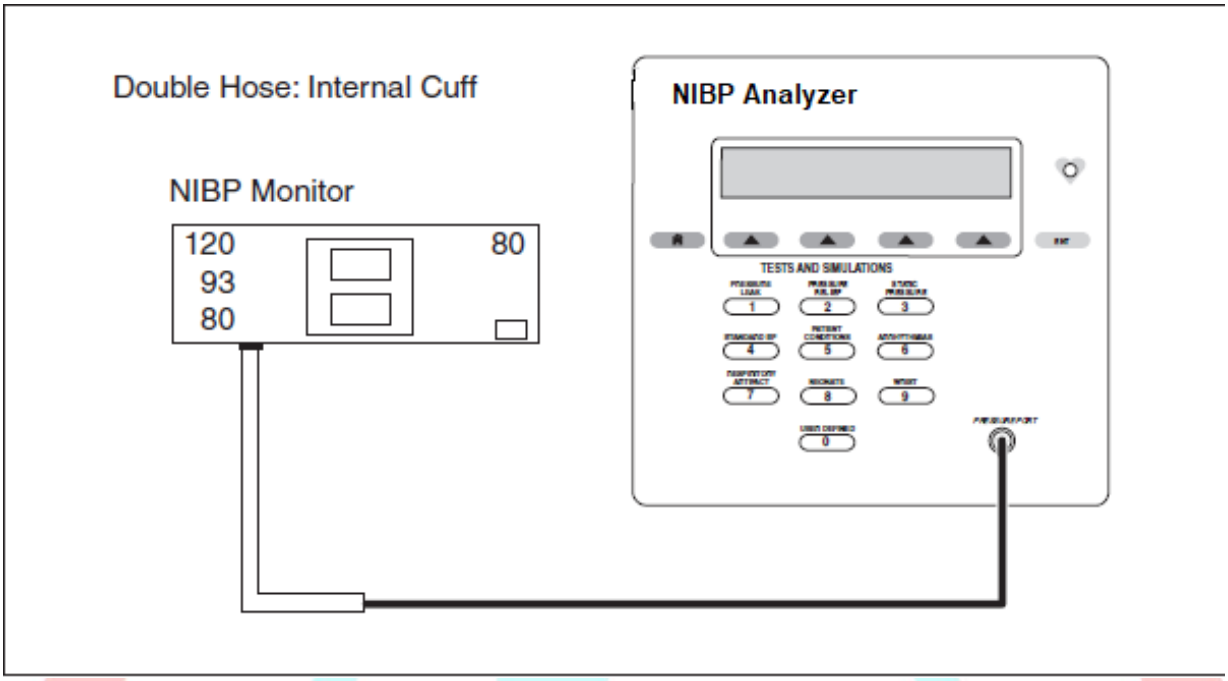


Figure 2.3.2 Connecting Tester to Double-hose NIBP Monitor (Int Cuff)

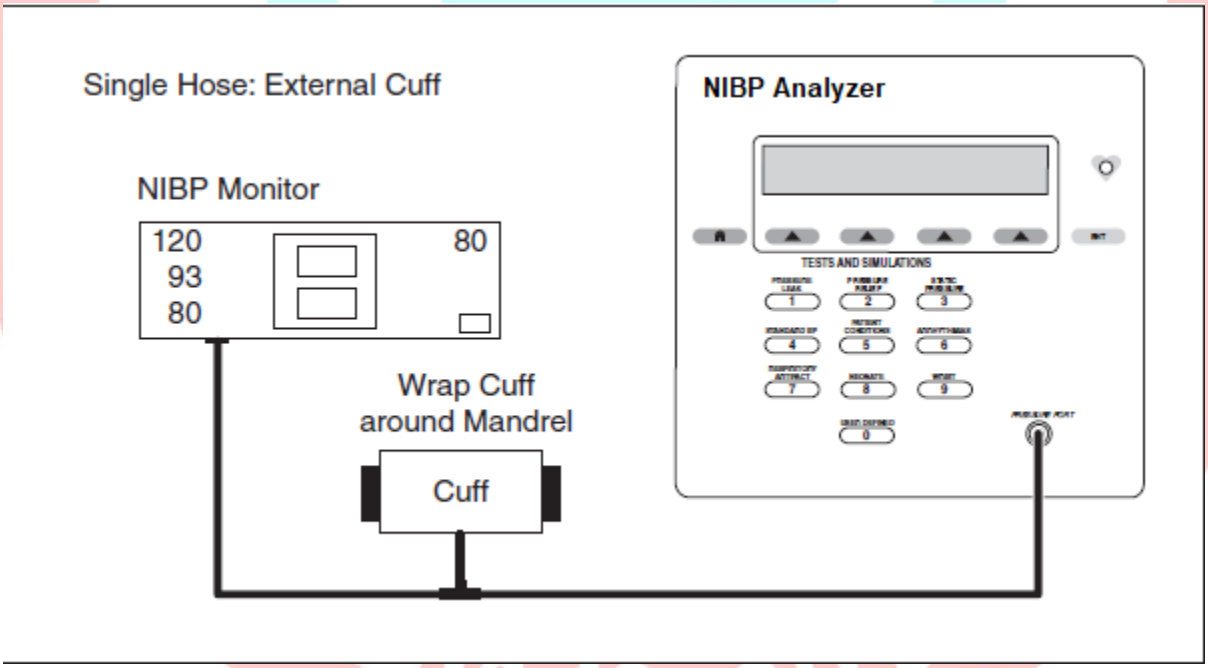


Figure 2.3.3 Connecting Tester to Single-hose NIBP Monitor (Ext Cuff)

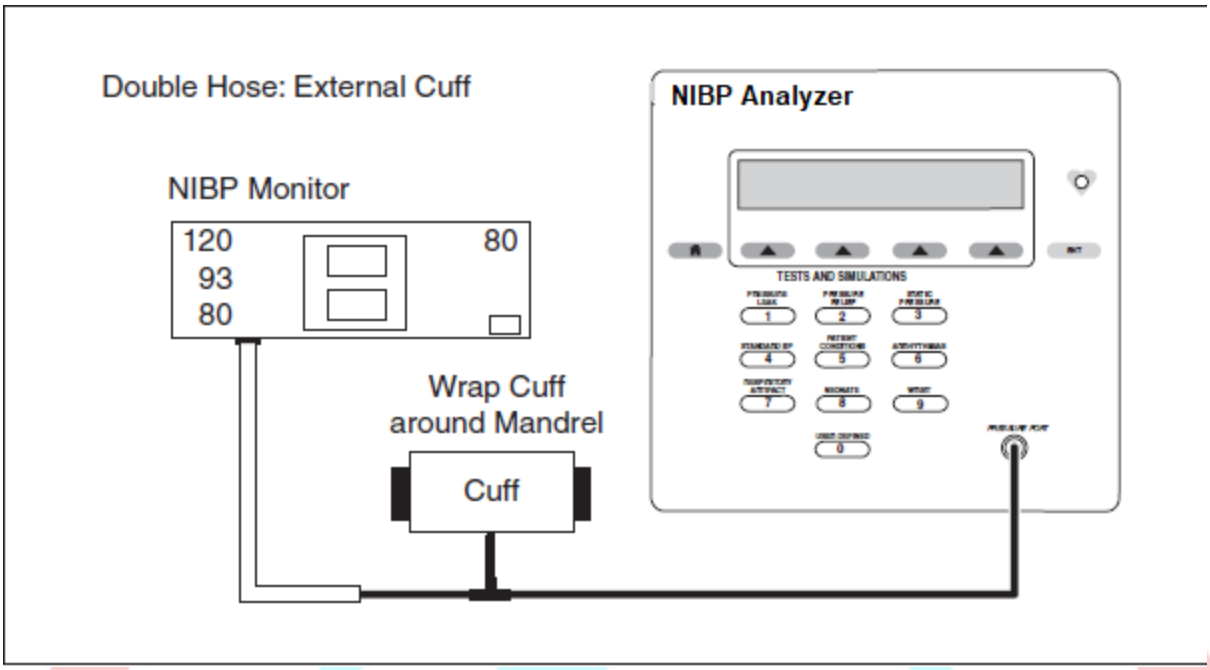


Figure 2.3.4 Connecting Tester to Double-hose NIBP Monitor (Ext Cuff)

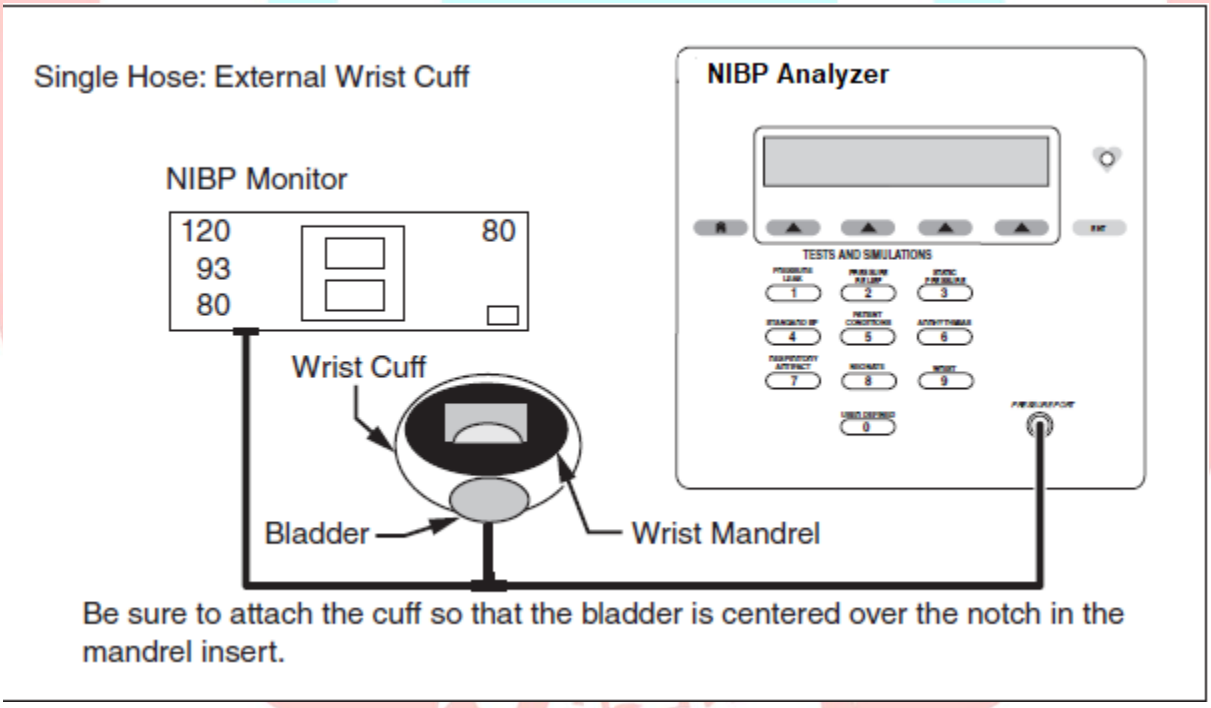


Figure 2.3.5 Connecting Tester to Single-hose NIBP Wrist Monitor (Ext Cuff)

Pressure Tests

The following tests assess the integrity and accuracy of the Tester, as well as the instrument under test.

a) Pressure Leak Test

The Pressure Leak Test pressurizes a pneumatic system to an operator-defined target pressure (labeled Set-point) and then measures the loss of pressure over time. To assess leakage, take the following actions:

1. Define the Set-point

2. Press a key to display the Leak Test.

3. Press a key to release any unwanted pressure in the system before performing the test. This feature vents the system for many seconds and can be repeated as needed to return pressure to zero.

4. Press a key to make the Tester deliver air to the system. Once the system under test reaches the target pressure, the test begins. The pressure leak rate of the system and the current system pressure are shown during the test.

Note

When testing with a NIBP monitor in the system, it is necessary to put the monitor in "Service" mode, because most monitors leave the system open to the atmosphere.

b) Pressure Relief Test

The Pressure Relief Test increases the pressure in the pneumatic system until the relief valve on the NIBP monitor opens, or until the Set-point is reached, whichever occurs first.

To assess the effectiveness of the relief valve, do the following:

1. Define the Set-point.

2. Press a key to display the **Relief Valve Test**.

3. Press a key to release any unwanted pressure in the system before performing the test. This feature vents the system for many seconds and can be repeated as needed to return the pressure to zero.

4. Press a key to make the Tester deliver air to the system. (Measured) and peak pressures are being monitored. If the Set-point is reached and the monitor does not release the pressure, the message **No Relief Detected** appears on the display.

Note
It is recommended that three pressure relief measurements be taken to check for a sticky relief valve.
Some NIPB monitors do not allow access to a "Service" mode, rendering it impossible to close a vent valve so that the system can be pressurized by an outside pump. As a last resort, it is possible to start a blood pressure determination with the monitor (this closes the valve), then start the Pressure Relief tests, so that two pumps inflate the system. The results can vary, but the monitor generally opens a relief valve at some high pressure.

Note
Put the NIBP monitor in "Calibrate" or "Service" mode to close the vent valve, allowing the Tester to inflate the pneumatic system. Refer to the NIBP monitor's service manual to find the method for entering "Service" mode.

Pressure Source Test

The Pressure Source Test enables the Tester to simultaneously generate and measure pressure. The Pressure Source Test can be used for static calibration of Non-Invasive blood pressure monitoring systems, checking sphygmomanometers, and evaluating any medical device that measures pressure within a specified range. Pressures can be generated in 1-mmHg (0.1 kPa) increments.

To perform a Pressure Source test, do the following:

1. Define the Set-point

2. Press a key to display the **Pressure Source screen**.

3. Press a key to release any unwanted pressure in the system before performing the test. This feature vents the system for many seconds, and can be repeated as needed to return the pressure to zero.

4. Press a key to make the Tester deliver air to the system.

Note
Once the Setpoint has been reached, the Tester will not maintain the pressure in the system. Therefore, it is recommended that the system be checked for leaks prior to performing any static pressure tests.

Pressure Gauge Test

The Pressure Gauge Test enables the Tester to measure static pressure generated by an external source

1. Press a key to make **Pressure Gauge** screen appears.
2. Press a key to release any unwanted pressure in the system before performing the test. This feature vents the system for many seconds and can be repeated as needed to return pressure back to zero.

3. Apply pressure to the pressure port and read the displayed pressure in the screen.

Simulations

The following sections describe various simulations that the Tester accomplishes. For all of the following tests, it is important to select the correct cuff.

- *Standard BP*

The Tester provides many variations of NIBP simulations for both arm and wrist cuffs. To perform Standard BP tests, do the following:

1. Access these simulations by pressing the **appropriate** key. The **Standard BP** screen appears.

2. Press to scroll through the simulation choices.

3. Press to select Internal Adult or External cuff.

4. Press to Start the NIBP unit.

5. Compare values on the NIBP unit with those on the Tester.

- *Patient Conditions*

The Patient Condition simulations are intended to provide some basic patient variations.

To perform Patient Conditions simulations, do the following:

1. Access these simulations by pressing a key. The Patient Condition screen appears.

2. Press to scroll through the simulation choices.

3. Press to select Internal Adult or External cuff.

4. Press to Start on the NIBP unit.

5. Compare values on the NIBP unit with those on the Tester.

- *Arrhythmias*

These waveforms cause erratic readings on some NIBPMs. The blood pressure determination strongly depends on exactly what is happening with the subject's blood pressure when the cuff pressure is at a particular level. Some NIBPMs pause until they detect two or more equivalent beats. The pattern of step deflations and the measured blood pressure depend on which beats occur during each step of the cuff pressure.

To perform Arrhythmia Simulations, do the following:

1. Access these simulations by pressing a key. The Arrhythmia screen appears.

2. Press the OPTIONS soft key to scroll through the simulation choices.

3. Press to select Internal Adult or External cuff.

4. Press to Start on the NIBP unit.

5. Compare values on the NIBP unit with those on the Tester.

- *Respiratory Artifacts*

The Respiratory Artifact exhibits a beat-to-beat variation in the blood pressure caused by intra-thoracic pressure. Changes in the intra-thoracic pressure affect filling of the ventricles during diastole. This in turn affects the stroke volume of the heart. A large stroke develops a higher systolic pressure than a small stroke. To perform Respiratory Artifact simulations, do as the previous steps, except that respiratory artifacts screen appears.

- *Neonate*

The Neonate simulations are provided to test the ability of the NIBP monitors to detect blood pressure on neonatal patients. To perform Neonate simulations, do as the previous steps, except that Neonate simulations screen appears, and the cuff used is for neonates

- *Wrist*

The Wrist simulations are provided to test wrist cuff NIBP monitors. To perform Wrist simulations, do as the previous steps, except that Wrist Simulation screen appears.

- *User-Defined*

User-Defined simulations can be done.

- *Auto Sequences*

It is possible to create up to nine customized auto sequences. An auto sequence contains all four pressure tests and five simulations. The operator can disable any of these tests or simulations. A printout of the auto sequence result can also be enabled. The operator must make a cuff selection. This determines what NIBP simulations are displayed for that selection.

- *Editing Auto Sequences*

You can edit the auto sequence.

You are prompted to select, enable, or disable each of the components listed below.

- Print Auto Sequence Result
- Pressure Gauge Test

- Pressure Source Test
- Pressure Leak Test
- Pressure Relief Valve Test
- Cuff Selection
- NIBP Simulations (1-5)

Printing Auto Sequences

You can print an auto sequence definition.

SpO2 Analyzer

Introduction:

Tester is used to measure the performance of SpO2 monitors (pulse oximeters). The tester uses light detection and emission to do tests. The tests examine the electronics of the pulse oximeter and the sensor. It is intended to be used to test and verify the basic operation of patient monitoring devices or systems used to monitor SpO2. Additionally, the Product provides an optical signal to verify the electronics inside the pulse oximeter sensor are functional.

Figure 2.4.1 SpO2 Analyzer

Cautions and warning

Warning

To prevent possible electrical shock, fire, or personal injury, follow these guidelines:

• Do not connect the Product to a patient or equipment connected to a patient. The Analyzer is intended for equipment evaluation only and should never be used in diagnostics, treatment, or any other capacity where the tester would come in contact with a patient.
• Use the Product only as specified, or the protection supplied by the tester can be compromised.
• Replace the batteries when the low battery indicator shows to prevent incorrect measurements.
• Carefully read all instructions.
• Do not use the Product around explosive gas, vapor, or in damp or wet environments.
• Do not use, and disable the Product if it is damaged.
• Do not use the Product if it operates incorrectly.
• Use only current probes, test leads, and adapters supplied with the Product.

Caution

- The pulse oximeter component of the device is not intended to validate the SpO2 accuracy of pulse oximeter equipment.
- This device is not intended to confirm the SpO2 accuracy of the calibration curve of the pulse oximeter monitor or to assess the optical characteristics of representative pulse oximeter sensors to determine their proper calibration.
- Not all functional testers and pulse oximeter equipment are compatible. Functional testers can vary in pulse methods, pulse contours, and amplitude. A functional tester might not accurately reproduce the calibration of the pulse oximeter equipment and can yield different results between pulse oximeter equipment.

How to Use the Tester?

All testers tests are set through the controls on the main screen. As each parameter is set, the test value changes immediately.

SpO2 Sensor Placement

Put the SpO2 sensor on the artificial finger as shown in the following figure 2.4.2.

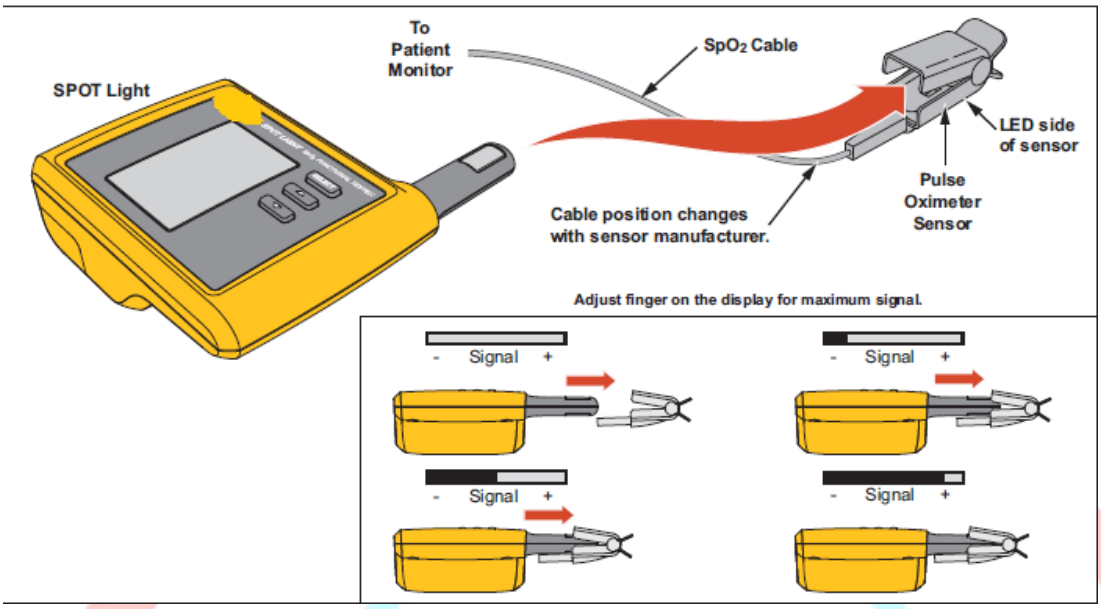


Figure 2.4.2 Oximeter Sensor Placement.

Put the sensor with the LEDs on the bottom of the artificial finger. While you put the sensor on the artifact finger, monitor the signal indicator along the bottom of the tester display. Adjust the sensor on the finger for maximum signal strength.

Note
Cable position changes with sensor Manufacturer.

How to Set Test Parameters?

When you turn on the tester, all parameters are set to their default values, but you can set the parameters as you want.

Note
As each parameter is set, the artificial finger outputs the new parameter value immediately.

Parameter	Values*
SpO2	80%, 85%, 90%, 95%, **97%**, 98%, 99%, 100%
HR (Heart Rate)	30, 60, **80**, 100, 120, 150, 180, and 240 BPM
PA (Pulse Amplitude)	0.2%, **2.0%**, and 10%
Transmission	LG (Large), **Med (Medium)**, and Sm (Small) finger
Artifact	**None**, Respiration: 2.5%, Ambient light: 50 or 60 Hz
Type	Nonin, Masimo, **Nellcor**, Nihon Kohden, Mindray, GE-Ohmeda, Philips/HP, and BCI
Test	**Manual**, Custom 1, Custom 2, and Custom 3

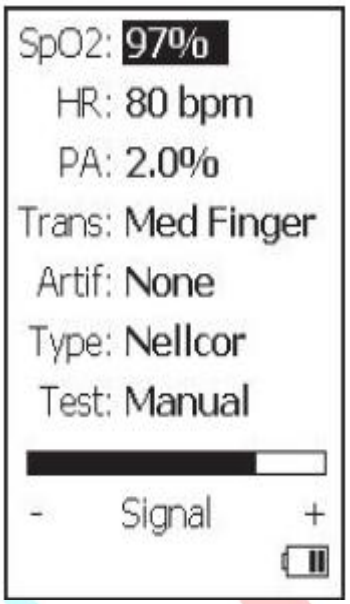


Figure 2.4.3 Here is a Product's Test Parameters setting parameters panel

Example of a Product's

Custom Tests

- When the **Test** parameter is set to **Manual**, no parameter values are stored. A maximum number of customs (three custom tests as an example) can be stored in the tester.
- When the **Test** parameter is set to **Custom 1**, **Custom 2**, or **Custom 3**, each parameter you change becomes a new value for that custom test.

How to Clean the Product?

Caution

- Do not put fluid onto the Product surface. Fluid seepage into the electrical circuitry may cause the tester to fail.
- Do not use spray cleaners on the Product. This action can force the cleaning fluid into the tester and damage electronic components.
- Clean the tester occasionally with a damp cloth and mild detergent. Try to prevent the entrance of liquids.

Battery Maintenance

- For peak battery performance, charge the tester to maximum charge, a minimum of one time each month. If the tester is not to be used for more than a month, keep it connected to the charger.

Note
To get the specified performance, use the specified battery charger that comes with this Product.

- When the battery gets low, a low battery message shows in the display.

Key terms and Concepts:

- **SpHb** provides real-time visibility to changes, or lack of changes, in hemoglobin between invasive blood samples.
- **SpMet** is a breakthrough measurement that allows clinicians to noninvasively and continuously monitor levels of methemoglobin in the blood.
- **SpCO is** Carboxyhemoglobin.
- **Pressure Gauge:** This test monitors system pressure, which must be generated external to the Tester.
- **Leak Test:** This test performs a system leak test at the Setpoint pressure, which was defined when the auto sequence was edited.
- **Relief Valve Test:** This test increases the pressure in the pneumatic system until the relief valve on the NIBP monitor opens or until the Setpoint is reached, whichever occurs first.
- **Pressure Source:** This test causes the system to rise to the Setpoint pressure, which was defined when the auto sequence was edited.

Links

- "RIGEL PatSim200 Patient Simulator", SEAWARD GROUP, RIGEL MEDICAL. 20th December 2016.
- "ProSim8 Vital Signs Simulator", FLUKE Biomedical. January 2011, Rev. 3, 3/16.
- "BP Pump 2 NIBP Simulator and tester", FLUKE Biomedical. June 2007.
- "SPOT LIGHT SpO2 Functional Tester, FLUKE Biomedical. February 2012, Rev. 1.

Section 3

Infusion Equipment Testing

Objectives

- Provide an overview of Infusion Equipment testing.
- Define syringe and infusion analyzer in detail.
- Mentioning how to use syringe and infusion analyzer and tests that is done.

Syringe and Infusion Device Analyzer

Introduction

Infusion Pump Analyzer is an instrument to accurately and swiftly verify the performance of infusion devices. The aim of performing tests is to verify whether the device pumps the required flow rate, volume, and bolus with required rate of accuracy; occlusion alarms are activated during emergency conditions, and the device is safe for patient and operator use? **Some give** the choice of single or multi-channel configurations, the Multi-Flo can test more than one infusion device simultaneously.

Problems Associated with Infusion

There are many dangers when using infusion devices which need to be minimized for patient safety and therefore most infusion devices incorporate detecting warnings and alarm systems including: air in tube, excessive upstream pressure and both up and downstream occlusions, syringe empty / nearly empty and also low battery signals.

Figure 3.1.1 syringe and infusion analyzer

I. Air Embolism

Air in the tubing can be dangerous to the patient if it gets into the blood as approximately 3-8mL of air per kg can cause cardiac arrest, that's about 210-560mL for a 70kg patient. Even if there appears to be no air

In the line, the action of pumping can often draw air out of the solution and this can accumulate into significant sized bubbles or if there is a leak in the upstream

line, air can be drawn into the line. Air entrainment can be prevented by the intrinsic design of the pump or by using an air detector.

II. Free Flow or Siphonage

If the pump is higher than 300mm above the patient's heart, and the roller clamp is fully open on a basic gravity infusion set-up this will allow free-flow or siphonage which allows all the fluid and any air in the infusion bag to infuse into the patient. Siphonage should not occur if the administration set for the appropriate infusion device is loaded correctly.

III. Occlusion

An infusion pump attempts to maintain sufficient pressure on the fluid to cause it to flow at the set rate and detects resistance to flow, allowing the pump to increase the pumping pressure to maintain the set flow rate. Any occlusion or blockage can result in patient harm caused by increased pressure in the line and an interruption to the therapy. This is typically due to a partial or complete block in the delivery tubing e.g. kinks in the tube, clamp or tab closed; or in the cannula e.g. clotted off or a change in position. Occlusion can cause an interruption to the delivery and effectiveness of the therapy. Therefore, occlusion alarms are used to indicate when the pump is unable to sustain the set flow rate or when pressure in the line increases. Any blockage can cause the pressure in the line to increase which causes the tubing to expand and if the pump detects an unacceptably high pressure, known as the occlusion limit, the pump's occlusion alarm will sound. Adult alarm settings should be approximately 150mmHg above working pressure and therefore a default setting of 300mmHg is standard.

IV. Bolus

A syringe that is placed into a pump whilst connected to the patient is highly likely to deliver an infusion bolus. Syringes should always be inserted into pump mechanisms before being attached to patients and the infusion line should be temporarily disconnected. Even if the infusion set is left connected to the syringe driver or volumetric pump during transfers, large alterations in the device height relative to the patient may lead to over or under-infusion because of tubing compliance. Once occlusion is cleared a sudden bolus will infuse into the patient, which is the additional fluid generated in the line during the occlusion. This will cause a momentary raise in the fluid's concentration. The higher the occlusion alarm/pressure limit is set, the longer IV related problems are allowed to develop before the alarm alerts staff of any issue and resulting in a larger bolus. Flow rate also affects alarm response time as higher flow rates result in more rapid alarm response than lower flow rates. To prevent this bolus from occurring, the pressure in the system should be reduced by temporarily opening the system to air or disengaging the clamp on the syringe plunger. Modern syringe drivers have an automatic 'back-off' facility when occlusion is detected which briefly draws back the plunger thus reducing the size of any bolus.

Electronic Devices(Analyzers)

Automated analyzers allow the user to set up a test and the test will run unassisted thus allowing the user to move away from the device during testing. Electronic analyzers provide real-time records of the delivery rate and volume allowing for continuous infusion device testing without constant supervision. Analyzers provide continuous spot readings which can then be graphed to provide quick to read results; where problems and anomalies are easily visible.

Electronic calibrated analyzers provide automation for batch and multi-channel testing with some analyzers having up to 4 independent channels which can run simultaneously, reducing the overall test time while maintaining a good degree of accuracy and minimizing user input and any errors associated.

These devices work by timing how long a small internal volume takes to fill and therefore measures the volumetric accuracy of the infusion device where accuracy is determined by the measuring chamber accuracy and its resolution is determined by the chamber volume. It provides the user with a method to obtain a quick check as to whether a pump is generally working. You can test it over a range of flow-rates and time periods with consistent accuracy.

Note
There is a variety of methods currently used to test infusion devices and determine their performance accuracy. They vary in procedure and equipment but fundamentally, the aim is to measure the accuracy of the delivery volume and *flow rate over a range of time periods, typically between 10 minutes and 1 hour*.

Common flow measuring principles:

1. **Volumetric** - Flow calculated after a certain volume has been delivered. The greater the volume over a certain time, the greater the flow.

2. **Mass** - Flow is calculated based on temperature difference between two points within the sensor, the greater the temperature difference the lower the flow.

3. **Bubble tracking** - Flow calculated based on the displacement of an inserted air bubble into the flow sensor part. The greater the displacement, the greater the flow.

4. **Pressure based** - Flow is regulated within the flow sensor to a set line pressure. The greater the potential pressure built-up in the line, the greater the flow rate.

5. **Displacement of syringe plunger** - Flow rate is calculated based on volume displaced by the syringe plunger over time. The syringe type and volume are required to provide an accurate calculation.

Occlusion and alarm pressures and also bolus delivery, must also be tested to maintain the performance of the infusion device especially in PCA devices where the bolus is self-medicated. A visual inspection and electrical safety test should also be considered to make sure all aspects of patient safety and instrument reliability are covered during the test procedure.

Testing

How does this Analyzer make (hold) the test??

a) Volume & Flow Measurement

Volume and flow measurements are achieved by using a calibrated burette and Opto-sensors (optical sensor) within each measurement transducer accurately monitor the volume and time of the meniscus passing up the burette. This data is processed to provide Average Flow Rates, Bolus and Total Volume Delivered and Timing measurements.

Burette

- What are Burettes?? a graduated glass tube with a tap at one end, for delivering known volumes of a liquid.

- Using burettes in measuring volumes/flow rates.

When using a direct volumetric method, the estimated time is calculated prior to testing by first determining the rate per minute and then the desired volume over the rate per minute, to determine the time to reach the volume. For example: q=V/t When testing a pump with a flow rate of 240mL/hr, the rate per minute = 240/60= 4mL per minute. If the desired measurement volume is 20mL, the desired volume/ rate per minute = 20/4 = 5 minutes. So, it would take 5 minutes to reach 20mL of volume with a flow rate of 240mL/hr. The pump is set to run at the desired flow rate and the amount delivered into the measuring device is measured and the total time recorded, often using a stopwatch. The results are then used to determine the accuracy of the system and the average rate can be calculated as a total volume over total time (mL/hr). Burettes are calibrated, marked in divisions, and are usually more accurate than measuring cylinders. The amount of liquid that is tapped from a burette can simply be read from the burette by checking the level of the meniscus. A burette is particularly suitable for measuring volumes less than 50mL.***And that would have been happening manually if we didn't use the Infusion Pump Analyzers, but now the Analyzers use burette and the optical sensor to do that.***

Optical sensor

What is optical sensor?? An optical sensor converts light rays into an electronic signal.

Detection principle

- The detection of air or liquid in a glass capillary is based on their difference in refractive indexes. An air filled capillary disperses light while a liquid-filled capillary focuses light. The reason is that the refractive indexes of liquid and glass are from 1.3 to 1.5 while that of air is only 1.0.

Optical Sensor Based Liquid Level Indicator. Optical Sensor Based Liquid Level Indicator consist of two main parts an infrared LED coupled with a light transistor, and a transparent prism tip in the front. The LED projects an infrared light outward, when the sensor tip is surrounded by air the light reacts by bouncing back with-in the tip before returning to the transistor. When the sensor is dipped in liquid, the light disperses throughout and less is returned to the transistor. The amount of reflected light to the transistor affects output levels, making point level sensing possible.

b) Occlusion & Back Pressure Measurement

A pressure transducer within each transducer performs pressure measurement. The output of the pressure transducer is fed to a conditioning amplifier then processed and the results displayed on the LCD and, if connected, on the PC screen.

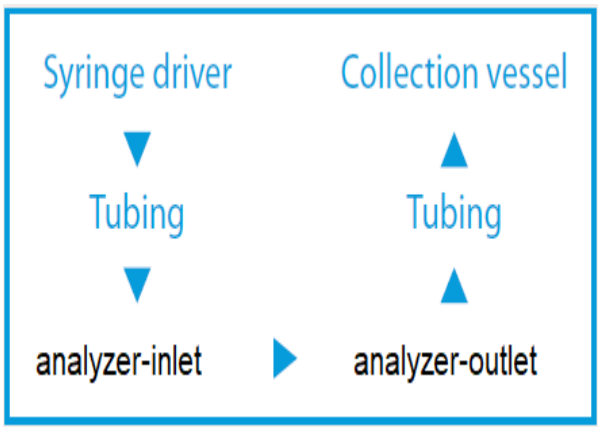
Pressure Gauge

Gauge pressure sensors measure the pressure relative to the atmospheric pressure which surrounds it. The term pressure gauge usually refers to a self-contained indicator that used flexible elements as sensors which converted the detected pressure change into the mechanical motion of the flexible element which then rotated a pointer in front of a dial. In these early mechanical pressure sensors, a Bourdon tube, a diaphragm, or a bellows element detected the process pressure and caused a corresponding movement. ***And that would have been happening manually if we didn't use the Infusion Pump Analyzers***.

Automatic control systems have since evolved and the free end of a Bourdon tube (bellows or diaphragm) no longer has to be connected to a local pointer, but served to convert a process pressure into a transmitted (electrical or pneumatic) signal. At first, the mechanical linkage was connected to a pneumatic pressure transmitter, which usually generated a 3-15psig output signal for transmission over distances of several hundred feet, or even farther with booster repeaters. Later, as solid state electronic matured and transmission distances increased, pressure transmitters became electronic. The early designs generated DC voltage outputs (10- 50mV; 1-5V; 0 100mV), but later were standardized as 4-20mA DC current output signals.

Testing Infusion Devices with the electronic Analyzers

The Analyzer is easily connected to both syringe driver and volumetric pumps as shown in the diagrams below. Ensure the flow direction is as per diagrams. The flow inlet is always the top connection and the flow outlet is positioned below the inlet for each channel.



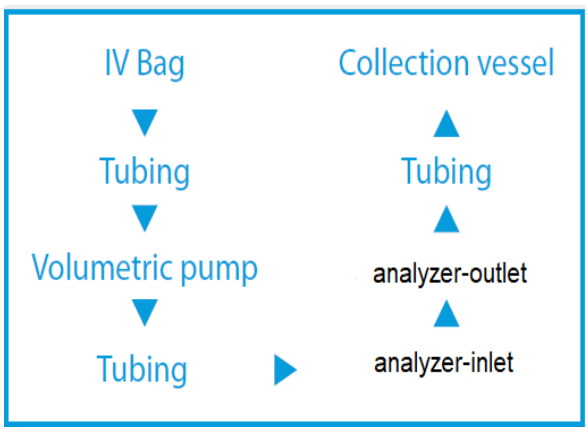


Figure 3.1.2 Syringe Driver Connection *Volumetric Pump Connection*

Test

1. Volume/Flow

The Analyzer is capable of measuring instantaneous flow with different resolutions according to the analyzer in some analyzers it reaches 10µL/hr. Custom tests and sequences can be created on remote control software and user-definable limits help clearly indicate whether the performance is within the manufactures specification.

2. Occlusion

The Analyzer test simulates an obstruction in the infusion process and monitors the variation in pressure due to the blockage. Most infusion devices have the ability to detect this obstruction and provide an occlusion alarm. The occlusion test is able to test this alarm feature in infusion devices. Some infusion devices have an auto rewind function at the occlusion alarm and some Analyzers can detect the maximum occlusion pressure at which auto rewind occurs. In infusion devices that do not have auto rewind (normal stop/alarm pumps) the user must press a button on the Analyzer when the occlusion alarm sounds which will stop the test then record and display the maximum occlusion pressure observed.

3. PCA

The PCA test determines the additional volume delivered on top of the basal flow rate set by the user. The additional volume, sometimes referred to as bolus, is an indication of the correct safety settings of an infusion device. The user needs to enter the basal flow as the basal flow rate setting is used to determine the additional volume being delivered i.e. the bolus.

Accuracy Performance

- Trumpet Curve

Trumpet curves show the accuracy performance of an infusion device at set intervals in the second hour of infusion and during the final hour of infusion as required by IEC 60601-2-24. The trumpet curve indicates the maximum percentage deviation, both positive and negative, from the expected flow rate relative to the time interval, known as the observation window. For example; for one hour the overall deviation may be -2%, whereas over an interval of two minutes the deviations can vary between +7 and -10%. Initially the pump needs a period of time to 'warm up', this is often referred to as the settling in period where the flow rate can vary as the infusion settles. The flow rate of infusion devices is defined as settled after one hour of infusion and the majority of pumps have a stated accuracy of ± 3% of the set flow rate after this one hour settling period. Therefore, trumpet curves are produced during the second and occasionally the final hour of testing to determine whether the manufactures specified performance accuracy is met.

Warning about testing for most of the Analyzers:

1. Patient Circuit

This instrument has been designed for testing infusion devices, but must **NEVER** be used while connected to a patient. Tubing sets utilized to test infusion devices must never be used to administer fluids to patients. Some older style infusion devices may have reusable components that could come in direct contact with the fluids being pumped. When testing these types of devices care must be taken to avoid possible contamination of reusable components due to backflow conditions.

2. Contamination of the Measuring System

For best results use degassed water made up with detergent, as described under 'Test Fluid' on page 3-4. High viscosity fluids cannot be used. Liquid containing oils (solvents, or strong chemicals) may also damage or contaminate the transducer. Do not use "Bleach" type of sterilizing agents, or alcohol's. To extend the life of the transducer and to maintain accuracy, it is recommended that periodically 20 ml of detergent solution be introduced into the fluid inlet port, left for 30 minutes, and then flushed out with 500 ml of clean water. Care should be taken to prevent dirt, dust, metal swarf, or other debris from entering the measuring system since these are likely to damage the transducers.

3. Explosion Risk

This instrument is not to be used in the presence of flammable anesthetic gases or vapors.

4. Switching the Instrument ON or OFF

As is common with most other computing equipment, this instrument may be damaged by repeated interruption of the power supply, either by rapid switching **ON** or **OFF**, or by removing the line cord when the instrument is energized. After switching **OFF** allow at least 3 seconds before switching the unit **ON**. Never disconnect the line cord without first switching the unit **OFF**.

Links

- "A Study on performance and safety test of infusion Pump devices", Tavakoli Golpaygani A, Department of Biomedical Engineering, Standard Research Institute, Iran. July 13, 2016
- "MULTI-FLO Infusion Pump Analyzer", SEAWARD GROUP, RIGEL MEDICAL. 15th October 2013.
- "Rigel Uni Therm" , SEAWARD GROUP, RIGEL MEDICAL.

Section 4

Electrosurgery Devices Testing

Objectives

- Provide an overview of electrosurgery device testing.
- Define ESU analyzer, how it works and tests that are done.

Electrosurgery Unit (ESU) Analyzer

Brief description of ESU

Electrosurgery is the application of a high-frequency electric current to biological tissue as a means to cut, coagulate, desiccate, or fulgurate tissue. Electrosurgical devices are frequently used during surgical procedures because they help to prevent blood loss by sealing the tissue and blood vessels during the cutting of the tissue. Electrosurgery can be used to achieve either the mass destruction of large volumes of tissue as in endometrial ablation, fine incision as required by the reconstructive microsurgeon, or tasks requiring both cutting and coagulation, such as incision of the skin and subcutaneous tissue with hemostasis. Although ESU devices may be used for the cauterization of tissue in some applications, electrosurgery is usually used to refer to a quite different method than electro cautery. Cautery uses heat conduction from a probe heated to a glowing temperature by a direct current (much in the manner of a soldering iron). Electrosurgery, by contrast, uses alternating current to directly heat the tissue itself. This heat causes the destruction of small blood vessels and halting of bleeding correctly called coagulation. To understand electrosurgery, it must be clear that the effects obtained are the result of heat. This heat is derived from the rapid changes in the direction (polarity) that A.C. current flow provides. There is no net transfer of electrons, and likewise, no movement of ions across cell membranes (depolarization). Part of the heat generated is from the tissue's impedance (resistance to current flow), but the majority of heat stems from the rapid vibration of molecules within the tissue under the effect of the changing electromagnetic field.

Electrosurgery Modes Monopolar versus bipolar

The main difference between these two modalities is that in monopolar surgery, the current goes through the patient to a return electrode (patient pad or neutral electrode) to complete the current cycle, while in bipolar surgery, the current only passes through the tissue grasped between the two electrodes of the instrument.

Introduction to ESU Analyzers:

Electrosurgical unit (ESU) analyzers automate the testing and inspection of the output circuits and safety features of ESUs, some of them accurately measure the performance of electrosurgical generators including high frequency leakage, high current, power distribution and patient return plate alarm testing. They perform testing that would otherwise require several other pieces of equipment, as well as considerably more time and greater technician expertise. They are used largely by clinical engineering departments for routine inspection and preventive maintenance (IPM) procedures and, less often, for accident investigations and troubleshooting.

Figure 4.1.1 Electrosurgery Analyzer

Note

The Analyzer can test a wide range of electrosurgical units for basic operation and performance. It is compatible with both isolated and earth-ground referenced outputs, and with both mono-polar and bipolar outputs. If you have any questions about testing an ESU, you can review "Specifications" and the technical service manual for the
ESU that you want to test.

Testing the ESU:

The sections that follow describe the specific ESU tests you can perform using the Analyzer.

Tests:

1. Generator Output Test

The Analyzer provides an effective method of attaching a resistive load to the ESU under test and displays the output directly in either watts or HF current of the applied ESU signal.

Test Procedures

- This test involves:
  - Connecting the ESU you want to test to the Analyzer.
  - Selecting a test load resistance.
  - Measuring the ESU's power output.

- Measuring the ESU's current output.
- Ending the test.

2. Basic Contact Quality Monitor (CQM) Test

This test of the contact quality monitor uses the Analyzer's test load to simulate a patient's skin resistance in contact with the dual element neutral/dispersive electrode pad.

Note

Perform this test on electrosurgical units without energizing the generator output. Do not connect the ESU active electrode to the Analyzer during this test.

The **CQM (REM)** test is intended for the neutral/dispersive electrode of monopolar ESUs equipped with a contact quality monitor. The neutral/dispersive electrode is actually two separate pads attached to the patient's skin. The CQM (REM) circuit issues an alarm only if the patient loses contact with one or both of the two pads.

Test Procedures

- The procedures involved with this test include:
  - Connecting the ESU neutral/dispersive electrode to the Analyzer.
  - Selecting a 50-ohm test load resistance.
  - Increasing load resistance on the Analyzer to observe the ESU's visual or audio alarm.

3. High frequency leakage test

High frequency leakage test of electrosurgical generators is required as specified in the standard.

Why?

- Insure that the ESU circuitry is properly limiting the amount of capacitive leakage of high frequency currents.
- At frequencies exceeding 400kHz, the electrical current has a tendency to stray Leading to decreased functionality and potential patient injury.
- It involves patient safety.

In order to prevent unintended thermal burns, HF LEAKAGE CURRENTS tested from ACTIVE and NEUTRAL ELECTRODES with PATIENT CIRCUITS activated shall, depending on their design, comply with the following requirements.

HIGH FREQUENCY LEAKAGE CURRENTS

1) NEUTRAL ELECTRODE referenced to earth and the PATIENT CIRCUIT is isolated from earth but the NEUTRAL ELECTRODE is referenced to earth at HIGH FREQUENCIES by components (for example a capacitor) satisfying the

requirements of a TYPE BF APPLIED PART. When tested the HF LEAKAGE CURRENT flowing from the NEUTRAL ELECTRODE through a non-inductive 200 Ω resistor to earth shall not exceed 150 mA.

2) NEUTRAL ELECTRODE isolated from earth at HIGH FREQUENCY The PATIENT CIRCUIT is isolated from earth at both high and low frequencies, and the isolation shall be such that the HF LEAKAGE CURRENT flowing from each electrode through a 200 Ω non-inductive resistor to earth does not exceed 150 mA when tested as described below.

Test Procedures

- The procedures involved with this test include:
  - Connecting the ESU electrode you want to test to the Analyzer.
  - Selecting a 200-ohm test load resistance.
  - Measuring the ESU's HF leakage current.
  - Ending the test.

Warnings about testing for most types of ESU Analyzers:

Ventilation

The Analyzer requires proper ventilation so that it does not overheat during operation. Always ensure that the two ventilation ports, located on each side of the Analyzer, are not blocked during use. Maintain at least four inches (10.2 centimeters) of clear space around each of these ports. An internal fan located immediately behind the grille on the left side port supplies forced-air ventilation.

Connecting Test Leads between the ESU and the Analyzer

A complete set of test leads is supplied with the Analyzer. Use these test leads to connect the ESU generator output to the Analyzer and to configure the Analyzer to conduct a specific ESU test. Safe connection to the Analyzer is facilitated by shrouded safety plugs.

Warning

- To avoid possible electric shock, burning of the skin, or personal injury, follow these guidelines: Retractable end of test leads are for use on ESU only.
- To avoid severe electrical shock, disconnect the power source before replacing fuses.

Key terms and concepts:

CQM: Contact Quality Monitor

Links

- "RF303 Electrosurgical Analyzer", FLUKE Biomedical. April 2007

Section 5

Electrical Analysis

Objectives

- Provide an overview of Electrical Analysis.
- Define Electrical Safety Analyzer, its importance and how to use it.

Electrical Safety Analyzer

Introduction

An Electrical safety analyzer is a device dedicated to a various range of electrical safety tests in order to check that the device under test is in compliance with electrical safety requirements.

The Analyzer does the following tests:

- Line (Mains) voltage
- Ground Wire (or Protective Earth) Resistance
- Equipment current
- Ground Wire (Earth) leakage
- Chassis (Enclosure) leakage
- Direct equipment leakage
- Point to point leakage and resistance

Intended Use

The **Electrical safety analyzer** is an electronic signal source and measurement device for verifying the electrical safety of medical devices.

The intended user is a trained biomedical equipment technician who performs periodic preventative maintenance checks on medical equipment in service. Users can be associated with hospitals, clinics, original equipment manufacturers and independent service companies that repair and service medical equipment. The end user is an individual, trained in medical instrumentation technology.

This **Electrical safety analyzer** is intended to be used in the laboratory environment, outside of the patient care area, and is not intended for use on patients, or to test devices while connected to patients.

Figure 5.1.1 Electrical Safety Analyzer

Cautions and Warning

Warning

To prevent possible electrical shock, fire, or personal injury, follow these guidelines:

- Do not connect to live output terminals. The Product can supply voltages that can cause death. Standby mode is not sufficient to prevent electrical shock.
- Do not apply more than the rated voltage, between the terminals or between each terminal and earth ground.
- Limit operation to the specified measurement category, voltage, or amperage ratings.
- Use Product-approved measurement category (CAT), voltage, and amperage rated accessories (probes, test leads, and adapters) for all measurements.
- Measure a known voltage first to make sure that the Product operates correctly.
- Use the correct terminals, function, and range for measurements.
- Do not touch voltages > 30 V ac rms, 42 V ac peak, or 60 V dc.
- Do not use the Product around explosive gas, vapor, or in damp or wet environments.
- Do not use the Product if it is damaged.
- Disable the Product if it is damaged, by removing the power cord and fuses.
- Do not use the Product if it operates incorrectly.
- Examine the case before you use the Product. Look for cracks or missing plastic. Carefully look at the insulation around the terminals.

- Do not use test leads if they are damaged. Examine the test leads for damaged insulation, exposed metal, or if the wear indicator shows. Check test lead continuity.
- Use this Product indoors only.
- Use only the mains power cord and connector approved for the voltage and plug configuration in your country and rated for the Product you are using.
- Make sure the ground conductor in the mains power cord is connected to a protective earth ground. Disruption of the protective earth could put voltage on the chassis that could cause death.
- Replace the mains power cord if the insulation is damaged or if the insulation shows signs of wear.
- Connect the common test lead before the live test lead and remove the live test lead before the common test lead.
- Do not use test leads if they are damaged. Examine the test leads for damaged insulation and measure a known voltage.
- Do not use a current measurement as an indication that a circuit is safe to touch. A voltage measurement is necessary to know if a circuit is hazardous.

Connect the DUT to the Analyzer

A Device Under Test (DUT) can be connected in a number of different ways depending on the device and the number of connections needed for a full electrical safety test. The following Figure 5.1.2 shows a DUT connected to the test receptacle and a separate connection to the DUT's enclosure or protective earth ground.

Cautions and warning

Warning

- To prevent possible electrical shock, fire, or personal injury, follow these guidelines:
- Do not touch exposed metal on banana plugs, they can have voltages that could cause death.
- Remove circuit power before you connect the Product in the circuit.
- When you measure current, connect the Product in series with the circuit.
- Connect an approved three-conductor mains power cord to a grounded power outlet.
- Do not put the Product where access to the mains power cord is blocked.
- Do not put metal objects into connectors.

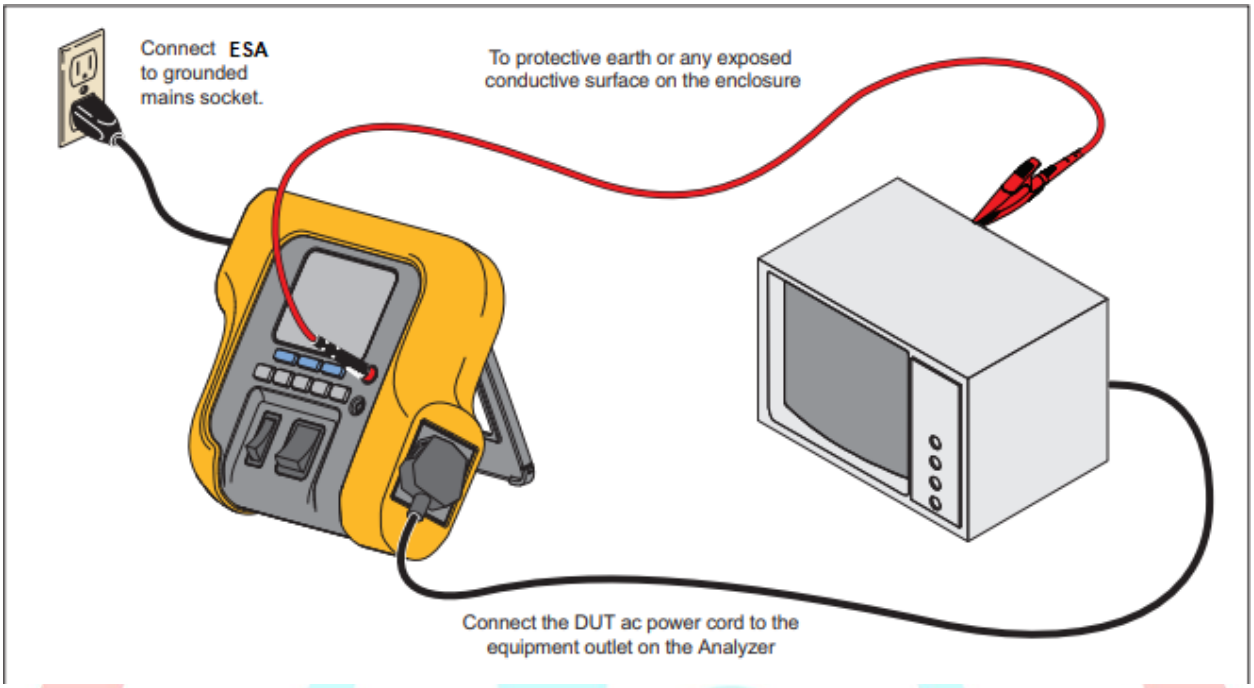


Figure 5.1.2 DUT Connections to the Analyzer

Performing Electrical Safety Tests

The Analyzer performs a number of different electrical and performance tests on biomedical equipment. The following sections describe the various tests and how to perform them using the Analyzer.

Abbreviation	Meaning
MD	Measuring Device (ESA609 Analyzer)
FE	Functional Earth
PE	Protective Earth
Mains	Mains Voltage Supply
L1	Live Conductor
L2	Neutral Conductor
DUT	Device Under Test
DUT_L1	Device Under Test Live conductor
DUT_L2	Device Under Test neutral conductor
DUT_PE	Device Under Test protective earth
REV POL	Reversed mains supply polarity
PE Open	Open protective earth
⏦	Test Voltage

Figure 5.1.3 Schematic Abbreviations

Tests

1. Performing Mains Voltage Testing

The Mains Voltage test measures the voltage on the mains input.

2. Performing a Ground-Wire (Protective-Earth) Resistance Test

The Ground-Wire (Protective-Earth) Resistance test measures the impedance between the Analyzer's test receptacle's PE terminal and the exposed conductive parts of the DUT that are connected to the DUT's Protective Earth. Prior to conducting any leakage tests with the Analyzer, it is best to test the integrity of the ground connection between the Analyzer's test receptacle ground and the DUT's Protective earth ground or enclosure with this test.

To perform a ground-wire resistance test:

1. Press to show the resistance function menu.
2. Connect one end of a test lead to the Ω/A jack as shown in the Figure 5.1.2.
    - If using an accessory probe, connect it to the other end of the test lead and place the probe tip into the Ground Pin of the Analyzer's test receptacle.
    - If using an alligator clip accessory, connect it to the other end of the test lead, place the null post adapter in the Ground Pin of the Analyzer's test receptacle and clamp the alligator clip to the null post adapter.
3. Press a key to make the Analyzer zeroes out the measurement to cancel the test lead resistance.
4. Connect the test lead coming from the red jack to the DUT enclosure or protective earth connection.
5. Plug the power cord from the DUT into the Analyzer's test receptacle. The measured resistance displays after any the DUT connections are made.

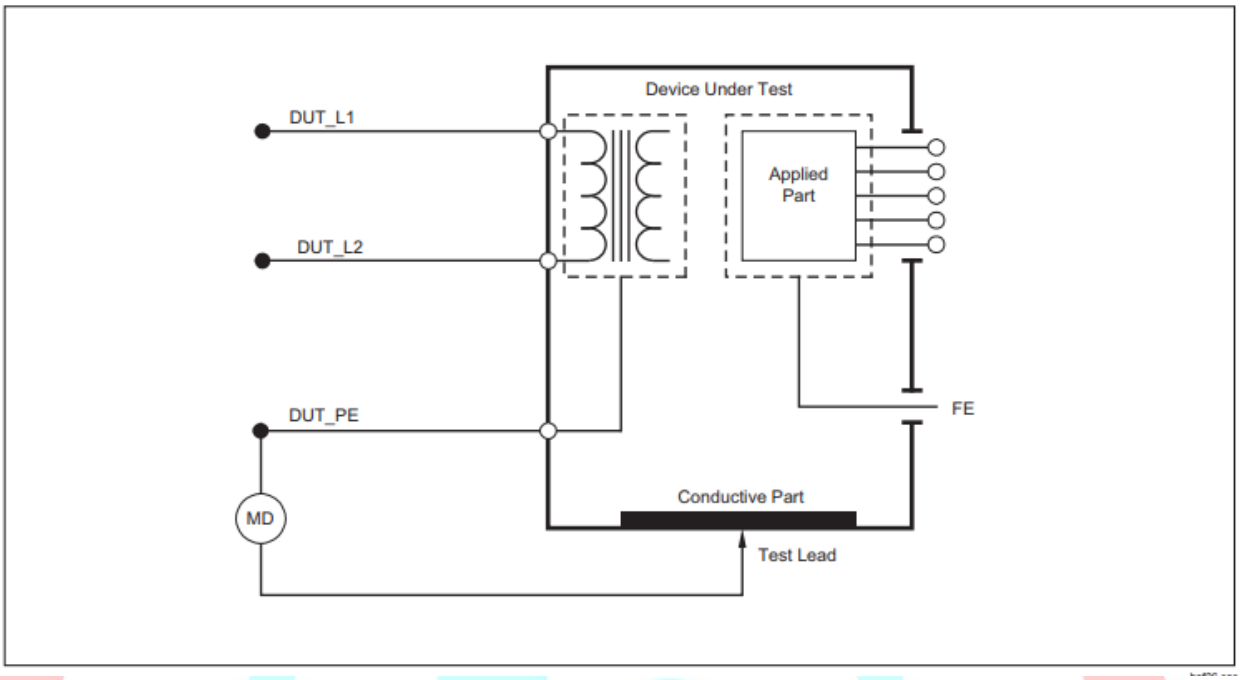


Figure 5.1.4 Ground-Wire (Protective-Earth) Resistance Measurement Schematic

Note

A low resistance reading is required to confirm a good ground connection through the power cord. Refer to the appropriate electrical safety standard for the specific limit value to be followed.

3. Performing a Current Consumption Test

To measure the current consumed by the DUT, there is a key, you could press, on the Analyzer displays the current flowing through the mains connections of the test receptacle.

4. Performing Leakage Current Tests

The Analyzer measures leakage current for a number of different DUT configurations. The leakage tests that are available depend on which standard is selected. The Figure 5.1.6 shows an example of A Product's leakage Current Tests, see the "Selecting the Test Standard" section to change the standard the Analyzer is using. The following figure 5.1.5 lists tests that have different names based on which standard is selected. Press to access the leakage current main test to be measured in microampere.

IEC60601	AAMI/NFPA 99
Protective-Earth Resistance	Ground-Wire Resistance
Earth-Leakage Current	Ground-Wire Leakage Current
Touch- or Enclosure-Leakage Current	Chassis-Leakage Current

Figure 5.1.5 Test Names Based on Selected Standard

Measuring Ground-Wire (Earth) Leakage Current

To measure the current flowing in the DUT's protective earth circuit, press to choose **Ground-Wire (Earth) Leakage Current. The following** Figure shows the electrical connections between the Analyzer and the DUT during a Ground-Wire (Earth) Leakage Current Test. Within the Ground-Wire Leakage Current test, there are a few combination measurements that can be performed.
Press a key to change polarity or to open or close the neutral connection.

Note

When changing polarity, you should perform the action slowly. Allow about 3 seconds to switch from one position to the other. It is possible to damage the analyzer if you switch too quickly. There is no need to open up the test receptacle earth (ground), since this is done internally during the measurement.
The following outlet conditions apply when performing this test:

- Normal Polarity
- Normal Polarity, Open Neutral
- Reversed Polarity
- Reversed Polarity, Open Neutral

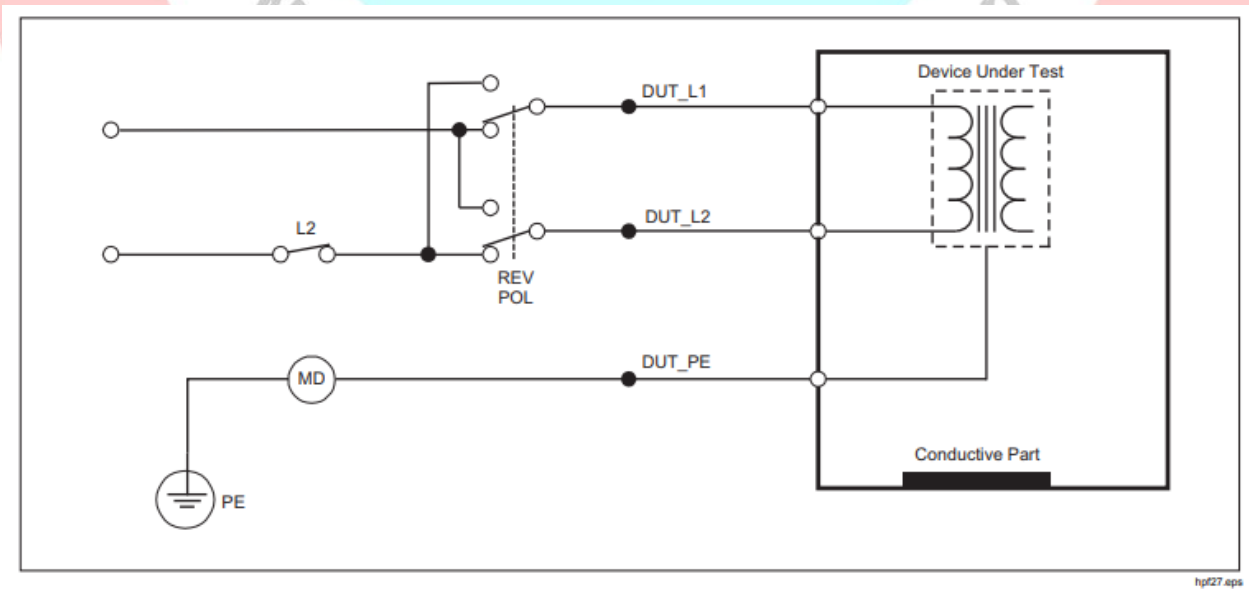


Figure 5.1.6 Earth-Leakage Current Test Schematic

5. Performing a Chassis (Enclosure) Leakage Test

The Chassis (Enclosure) Leakage Test measures the current flowing between the DUT's enclosure and protective earth. The following Figure shows the electrical connections between the Analyzer and the DUT.

To perform a Chassis (Enclosure) Leakage Test:

1. Connect a lead between the Analyzer's Ω/A jack and the DUT's enclosure.
2. Press to choose **a Chassis (Enclosure) Leakage Test**
3. The Analyzer displays the measured current.
4. The Chassis Leakage test can be performed with a number of fault conditions on the test receptacle.
    - Press the polarity rocker switch to change the polarity.
    - Press the neutral rocker switch to open or close the neutral connection.
    - Press a key to open the receptacle's earth connection or press a key to close the earth connection.

The following outlet conditions apply when performing this test:

- Normal Polarity
- Normal Polarity, Open Earth
- Normal Polarity, Open Neutral
- Reversed Polarity
- Reversed Polarity, Open Earth
- Reversed Polarity, Open Neutral

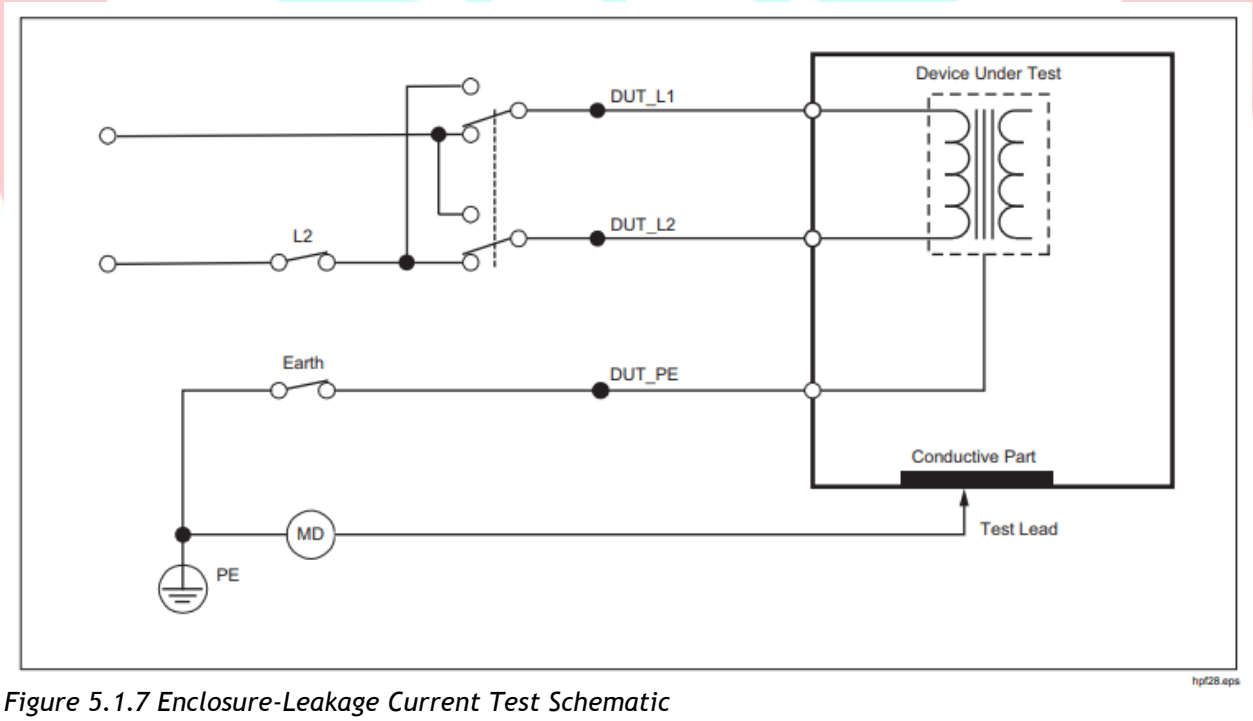


Figure 5.1.7 Enclosure-Leakage Current Test Schematic

6. Performing a Direct-Equipment Leakage Test

The Direct-Equipment Leakage Current test measures the leakage current between the exposed conductive surface on the housing, to mains earth.

To perform a direct-equipment test

press to choose the direct-equipment test. The following Figure 12 shows the electrical connections between the Analyzer and the DUT during a Direct-Equipment Leakage Current Test.

The following outlet conditions apply when performing this test:

- Normal Polarity, Closed Earth
- Normal Polarity, Open Earth
- Reversed Polarity, Closed Earth
- Reversed Polarity, Open Earth

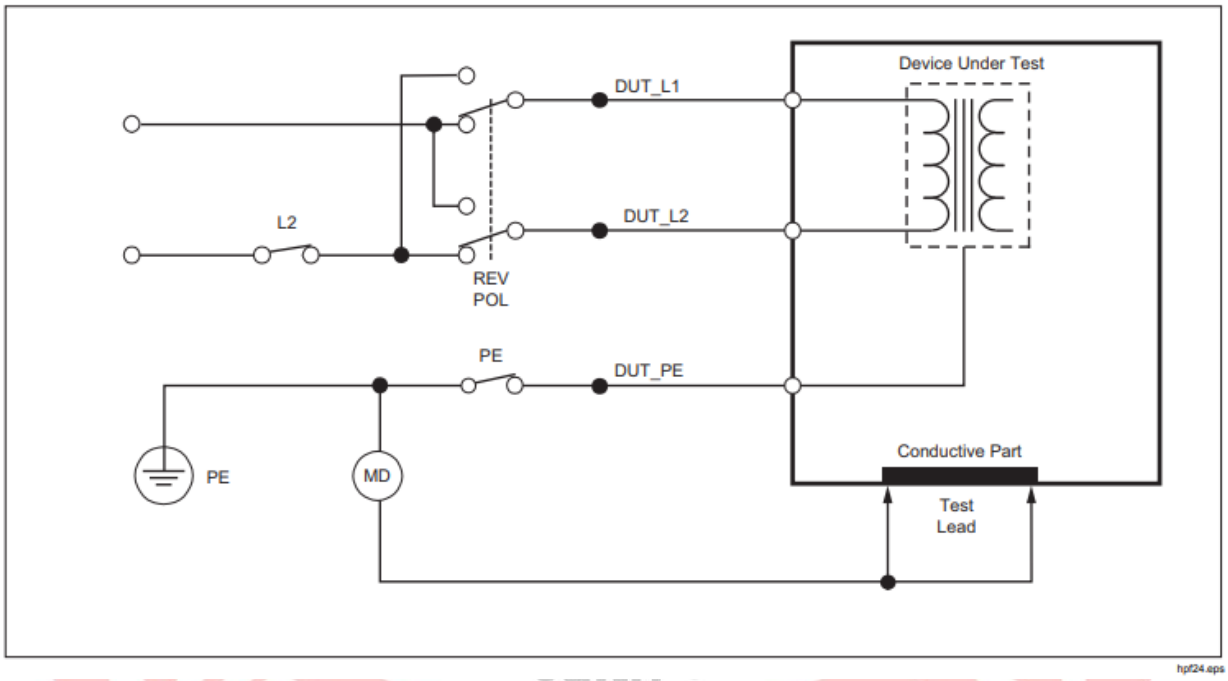


Figure 5.1.8 Direct-Equipment Leakage Test Schematic

7. Making Point-To-Point Measurements

The Analyzer can make resistance and low current measurements through its Point-to-Point function.

A. Measuring Resistance

To make a resistance measurement:

1. Press to choose **Resistance Point-To-Point Measurements test**.
2. Insert test leads in the red (Ω/A) and black jacks.

3. Null lead resistance by shorting the leads together and pressing a key to do that.
4. Place the probes across the unknown resistance and read the measurement in the Analyzer's display.

B. Measuring Leakage Current

The Analyzer can make true rms measurements.
To make a current measurement:

1. Press to choose Leakage Current **Point-To-Point Measurements test**.
2. Insert test leads in the red (Ω/A) and black jacks.
3. Place the leads on the two points the unknown current may flow and read the measurement in the Analyzer's display.

Links

- "ELECTRICAL SAFETY ANALYZER", EATON.
- "ESA906 Electrical Safety Analyzer", FLUKE Biomedical. February 2014, Rev.1

Book Coordinator ; Mostafa Fathallah

General Directorate of Technical Education for Health