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A Practical Guide to NFPA-99

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Foreword

This booklet is written as a guideline for people involved in testing medical electrical (ME) equipment.

This booklet cannot be considered as a replacement for the NFPA health care code (2021), which can be purchased through the official website, www.nfpa.org

All reasonable care has been taken to ensure the accuracy of the information, reference figures and data has been taken from the latest versions of various standards, guidance notes and recognised 'best practices' to establish the recommended testing requirements however, Rigel Medical, their agents and distributors, accept no responsibility for any error or omissions within this booklet, or for any misinterpretations by the user.

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No part of this publication shall be deemed to form or be part of any contract for training or equipment unless specifically referred to as an inclusion within such contract.

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

This guide covers a basic introduction to electrical safety in healthcare facilities, the NFPA-99 Health Care Facilities Code and some of the other common standards found in North America, such as ANSI AAMI/ ES60601-1. Using this format and structure ensures that the widest possible audience can benefit.

Author: Lewis Lennard

Electrical Safety in Health Care Facilities

When any individual encounters faulty electrical equipment, there is always a potential risk for electric shock. The cardiac functions, nervous and muscular systems are all sensitive to the physiological effects of electrical current passing through the body, especially at worldwide commercial frequencies of 50Hz and 60Hz. The results from exposure are dependent on the amount of current delivered and vary from a slight perception to severe burns and ventricular fibrillation.

In healthcare facilities, the risk of electric shock is elevated due to the unique characteristics of the environment. The added protection patients require is highlighted in NFPA-99, but why are patients particularly vulnerable? There are two primary factors.

Firstly, patients are often in poor health, anesthetised and/or unconscious states, so it must be expected that patients may not even be aware of an electric shock occurring. During serious operative procedures or recovery in an ICU, a patient is in an even more vulnerable state and electrocution poses a huge risk to serious injury or death.

Secondly, there are two distinct types of electrocution which need to be considered in healthcare facilities: macroshock and microshock.

Macroshock occurs when current passes through the body via contact with the skin and this aspect applies to all types of electrical safety. However, external dry skin has high resistance, which limits current flow through the body. Many medical procedures involve moistening the skin, which lowers skin resistance significantly, such as ultrasound gel and surgical applicants. Furthermore, patients are often in constant physical contact with medical electrical (ME) equipment, both directly and indirectly e.g., electrical monitoring systems and electrically powered beds. The results from macroshock vary by levels of current at the point of contact. Electrical currents can be perceived by the human body at 1mA, but ventricular fibrillation occurs at approximately 100mA *(See **Figure 1**).*

Microshocks occur when invasive patient connections such as catheters and pacemakers, are placed across or near myocardial tissue, where the biological components have relatively low resistance. Therefore, very small levels of electrical current can induce ventricular fibrillation because tissue impedance below the skin surface is low and current is concentrated at an invasive location. It has been repeatedly estimated that currents of over 20 microamps can lead to death by microshock. Patients in health care facilities are uniquely vulnerable to the risks of micro-electrocution.

Several corresponding studies have recognised the physiological effects of electrical current under macro-shock and micro-shock conditions, and international standards reflect these results in their safety criteria.

The IEC has produced a standard to control all aspects of safety directly or indirectly relating to the handling, use or connection to, of medical equipment. This standard is referenced as IEC 60601.

The first edition of IEC 60601 was published in 1977 to ensure electrical safety of medical equipment for both the patients and operators, and parts of it have survived to this day. Further developments and revisions have led to year-on-year reductions in death from both macro and micro-electrocution.

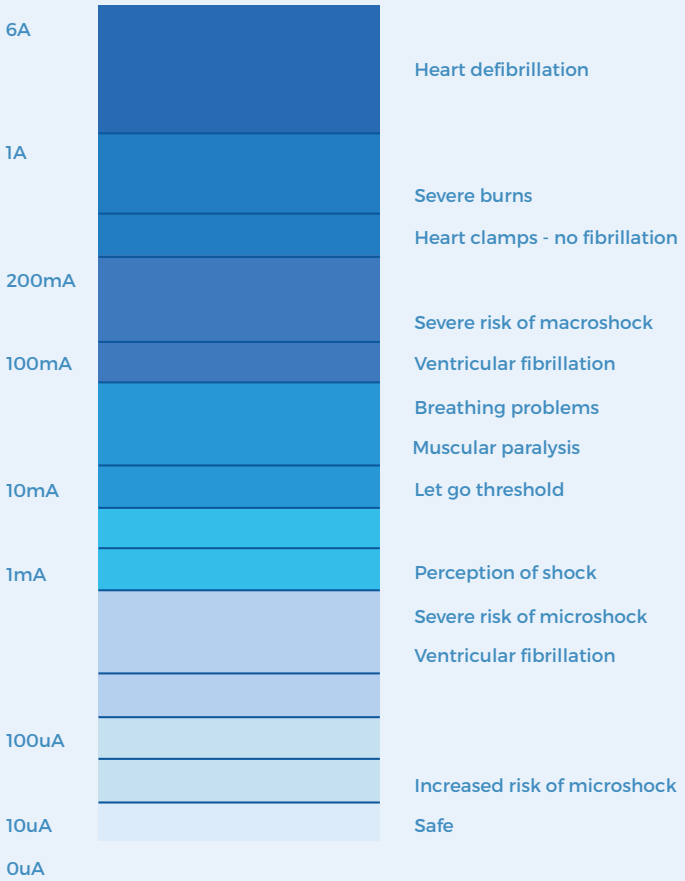


Figure 1 - The physiological effects of macroshock and microshock

Local Adaption of IEC 60601

The IEC 60601 standard is adapted and published locally by AAMI in the United States, and it appears as ANSI/AAMI ES60601-1. This standard sets strict rules on the design of medical equipment. The primary safety process is to prevent any patient or operator being exposed to currents not part of the functional operation of the device. NFPA-99 does align with the electrical safety testing processes in the ANSI/AAMI ES60601 standard, but it also has a broader application within health care facilities.

The primary purpose of NFPA-99 is to establish levels of health care services based on the risk to patients, staff, or visitors in health care facilities, where multiple devices are used in conjunction. Therefore, the broader term “equipment” applies, as it is not only medical electrical equipment in operation.

This booklet, however, has been developed for guidance on testing medical electrical equipment, so the emphasis will be placed on the electrical safety of medical appliances.

Common Terms and Definitions in NFPA-99

Health care facilities – Permanent or temporary locations from a wide range of settings, including hospitals, clinics, dental offices, nursing homes and ambulatory health centers.

Applied part – Part of the medical equipment, which is designed to come into physical contact with the patient, or parts that are likely to be brought into contact with the patient.

Patient leads – (Similar to the term 'patient connections" in IEC 60601). Individual physical connections and/or metal parts intended for connection with the patient e.g., ECG electrodes and catheters. It does not include casual contacts such as bed surfaces.

DUT – Device under test.

Appliance – A subset of the term equipment when designed for a specific purpose.

ME Equipment – Medical electrical equipment.

Ground wire – Dedicated circuit intended to carry the fault and leakage current in Class I equipment to the ground bonded terminal.

Leakage current – Current that is non-functional. It is defined as any current that unintentionally flows from the equipment circuitry to the chassis, ground or patient leads.

Isolated Patient Leads – Patient leads where there is high enough impedance to ground or to a power line to safely limit current in the lead.

Lead Current – Current flowing through a person to earth from the patient leads, or current flowing from a person to earth through the patient leads by applying unintended voltage from an external source.

Ground Wire Current – Current flowing down the ground wire conductor of the mains inlet lead.

Touch Current – Current flowing to earth through a person by touching the medical equipment/system parts or enclosure.

Macroshock – Non-invasive applied current which passes from one side of the body to the other, typically hand to hand or hand to foot, and therefore crossing through the heart.

Microshock – Invasively applied current which passes directly across the heart tissue.

Patient Care Vicinity – An area intended for the examination and treatment of patients, extending 1.8m beyond the location of the device that supports the patient. Referred to as patient environment in IEC 60601-1.

Class I – Equipment protection against electric shock by grounded (protectively earthed) additional protection to basic insulation through means of connecting accessible conductive parts to the protective earth in the fixed wiring of the installation.

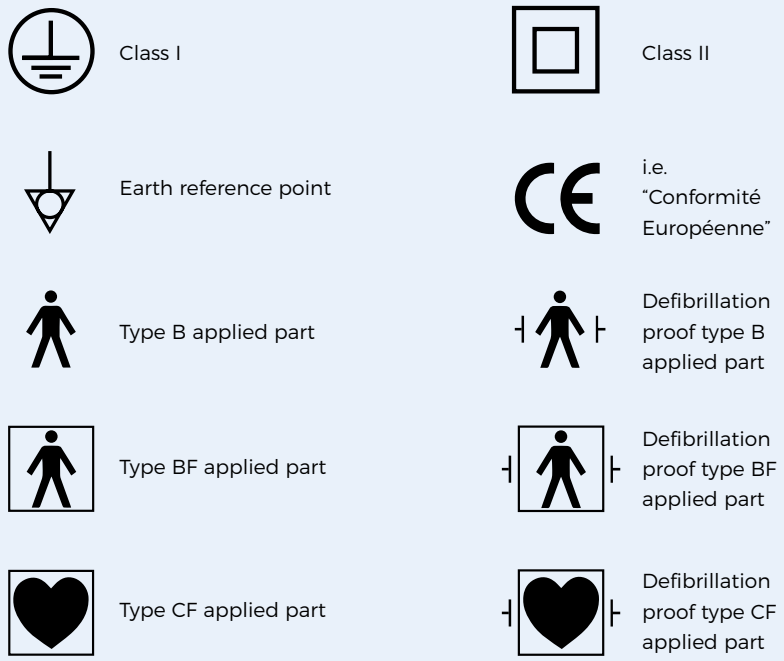


Figure 2 - International symbols from ANSI/AAMI ES60601-1

Class II – Also referred to as double insulated. Equipment protection against electric shock is achieved by additional protection to basic insulation through means of supplementary insulation, there being no provision for the connection of exposed metalwork of the equipment to a protective conductor and no reliance upon precautions to be taken in the fixed wiring of the installation.

Note: One major difference between NFPA-99 and other common standards is there is no mention of routine testing of Class II, or double insulated appliances. It is important to note that these appliances have a primary means of protection against electrical shock that is not through means of grounding. A double insulated appliance is permitted, but not required to have a functional earth conductor. Therefore, there are no ground bond tests, only leakage tests before installation.

Medical Electrical Equipment

Mains powered equipment is developed under ANSI/AAMI ES60601 to ensure safe levels of leakage current are achieved. This sets out all the design criteria for producing equipment that is electrically and mechanically safe, as well as placing the responsibility on the manufacturer to understand reducing the risk of harm when patient and operators are exposed to their medical devices. During development, high levels of isolation from electrical potentials to accessible conductive parts are required. Ground and touch type leakage currents have limits that reflect the values associated with macroshock. This is known as:

Means of operator protection (MOOP) – Means of protection for reducing the risk of electric shock to persons other than the patient.

ME equipment is designed to have even higher degrees of isolation due to the introduction of patient applied parts and the risks associated with micro-electrocution.

Leakage levels of less than 10uA are required in some cases to prevent the risks associated with microshock. The hazards are so evident that many medical equipment manufacturers use optical circuits to prevent electrical currents flowing to the isolated side of the circuitry. ME equipment must have acceptable levels of risk to patient or user during its entire product life cycle. The various single fault conditions ensure no electrical hazard exists should an adverse event happen within the device or from the power supply. This type of patient protection is known as:

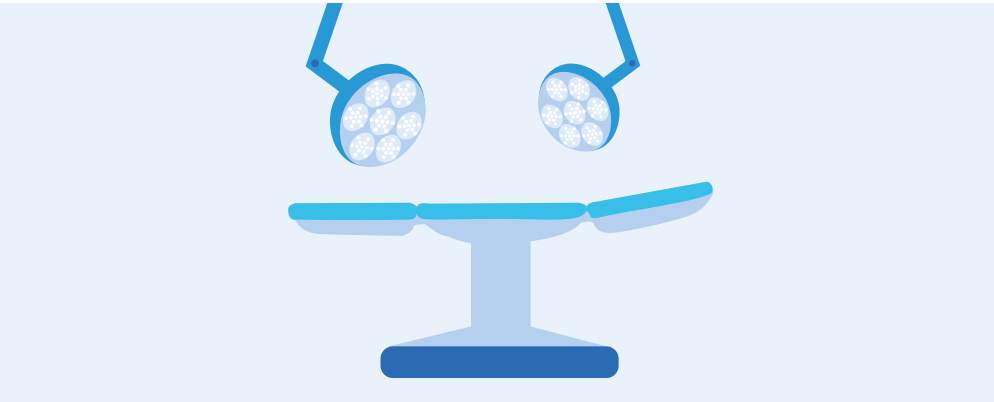
Means of patient protection (MOPP) – Means of protection for reducing the risk of electric shock to the patient.

NFPA-99

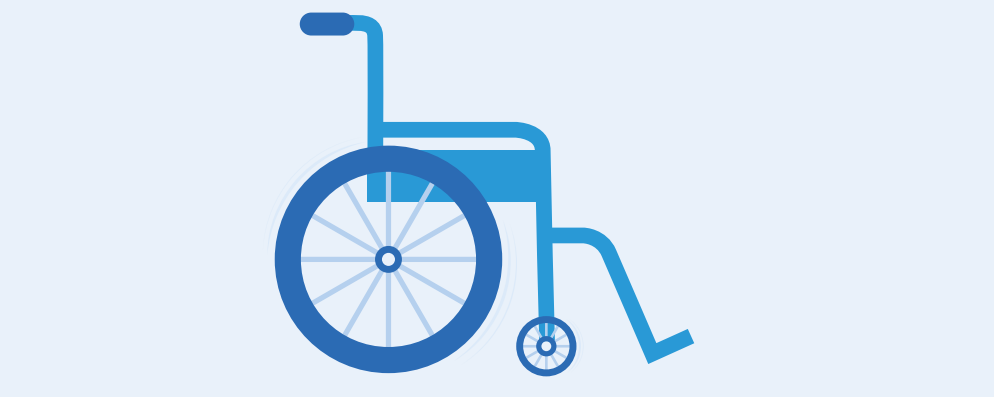
NFPA-99 is revised every three years and the latest version was published in 2021, upon which this booklet is based.

The code defines health care facilities as including hospitals, nursing homes, limited care facilities, clinics, medical and dental offices, and ambulatory health care centers – whether permanent or movable.

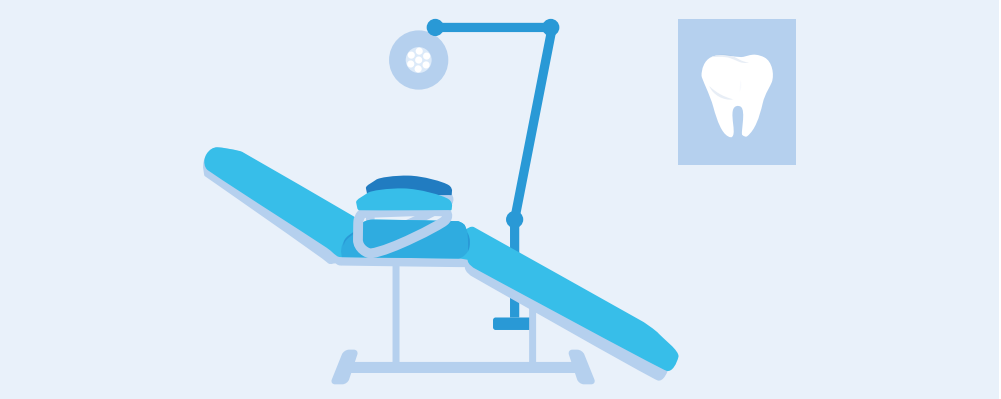
There are four levels of system categories that need to be considered in NFPA-99 and each category is based on the risk to the patients and caregivers in a healthcare facility. It is important to note the examples below may vary depending on impact and risk. As a result, all areas are subject to a risk assessment for categorization.



Category 1: Equipment failure for any duration is likely to cause serious injury or death, e.g. operating rooms.



Category 2: Equipment failure is likely to cause minor injury. Short durations of downtime unlikely to cause problems, e.g. outpatient services.



Category 3: Equipment failure is unlikely to significantly affect patient care, e.g. dental room.

Category 4: Equipment failure will have no impact on patient care, e.g. exam room.

As a health care facilities code, the performance criteria refers to the health care environment in its entirety, and not only the performance and safety of the equipment itself. For example, ground bond and strain relief tests on receptacles, as well as ensuring correct polarity, are part of the procedure. This booklet will focus primarily on the equipment under test, whether fixed and portable. It includes but is not limited to beds, medical imaging equipment, ventilators, infusion pumps and patient monitoring systems.

Each manufacturer typically produces a preventative maintenance (PM) procedure for their equipment and recommends intervals for testing. The NFPA-99 code also provides recommended intervals for the required testing, which is at defined as at least every 12 months.

Regular testing ensures the medical device is free from hazardous current flowing through the patient (MOPP) or operator (MOOP) to ground as they come into normal contact with the device.

Visual Inspections

Visual inspections of the equipment are valuable as they help to identify any hazardous appliances in the healthcare facility. Checking all appliances before use can help identify defects. All staff are expected to be observant of the condition of the equipment they use and if any faults appear, this should prompt repair or removal of the appliance from service. They form a critical part of the general safety inspections during the functional life of medical equipment, as around 70% of all faults are detected during a visual inspection.

Formal or documented visual inspections are not required by the individual carrying out the testing, however, the visual inspection must still be carried out during all scheduled and unscheduled maintenance checks.

Medical equipment inspections are relatively easy procedures to ensure assessment conformance to the specifications from the manufacturer. The physical integrity of the power cord assembly is also a requirement during inspection. A typical inspection includes:

- Cases or chassis – damage or cracks
- Cords and plugs – stress relief, correct amperage, frayed wires, or damaged plugs
- Integrity – check mechanical parts for obstructions
- Multiple outlet connections – ensure receptacles are permanently attached, appliances ampacity does not exceed 75% of the cord rating

Nonpatient care–related electrical equipment must also be visually inspected by staff or other personnel and includes facility or patient-owned appliances which may be used in patient care vicinity and come into contact with a patient.

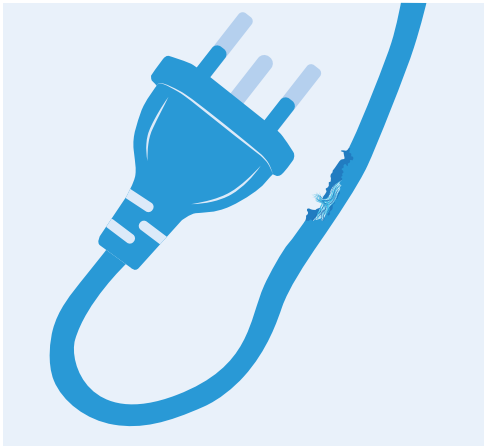


Figure 3 - Example of a frayed wire

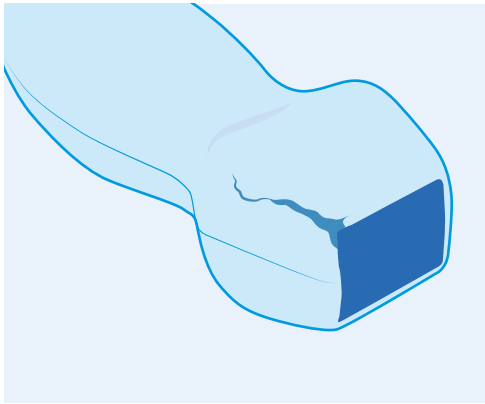


Figure 4 - Example of a probe with cracked housing

Ground Bond Tests

Class I equipment has a ground conductor so leakage current on the chassis or enclosure can flow to ground (or protective earth) without causing harm to any individuals. Grounding is a proven safety measure in preventing electrical shock. In the event of grounding fault an individual touching the appliance chassis or enclosure will complete that circuit, and the touch current will flow through their body.

Ground bond tests ensure low resistance connections between the chassis and grounding conductor are within the limit in testing at the health care facility (Appendix A shows the pass/fail limits for ground bond as per NFPA-99 requirements). When the grounding conductor is below this threshold and a person is in contact with the chassis, almost all the touch current flows through the grounding conductor. This can be explained with a simple divider circuit using the maximum allowable ground resistance value and a typical value of human body resistance. A typical human body resistance is 1kΩ, and if an earth conductor is roughly 0.5Ω, a touch current of 1mA would mean 995µA flowing down the earth conductor, and only 5µA flowing through the patient.

Class I fixed appliances must be grounded with the grounding bus in the distribution panel by an insulated grounding conductor. Class I portable appliances must have a three-wire power cord and a three-pin plug. Resistance is measured between the appliance chassis, or any exposed conductive part of the appliance, and the attachment plug ground pin. There are a few techniques for measuring the resistance of the ground wire mentioned in NFPA-99, but almost all measurements today are done with a two or four-wire resistance technique.

In the two-wire method it is possible to accurately measure resistance values less than 0.1Ω after eliminating the resistance of the lead wires connected to the equipment under test. If custom leads are used, it is always important to zero out the leads before measurement. The Rigel SafeTest range can measure down to **0.001Ω** and has **zap technology** that ensures high accuracy measurement of the ground bond integrity.

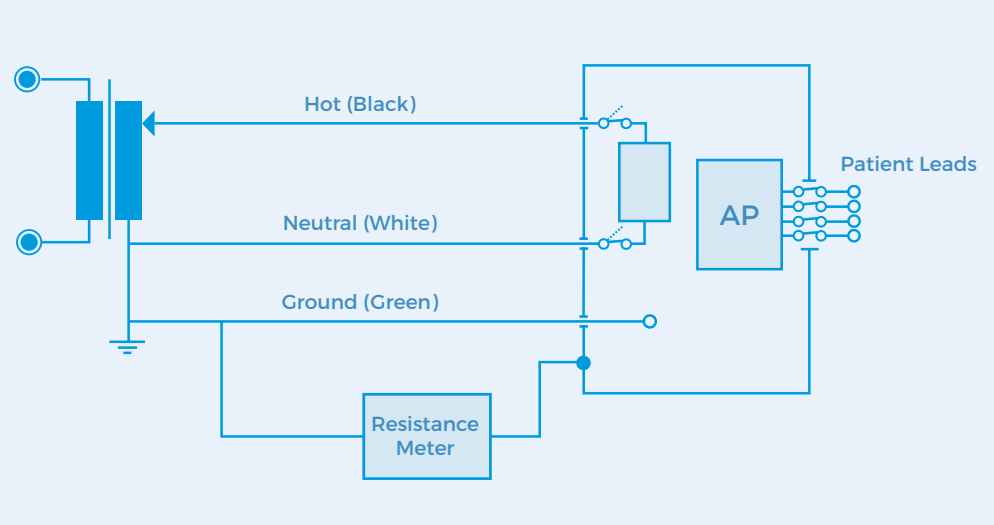


Figure 5 - Simplified diagram for ground bond tests

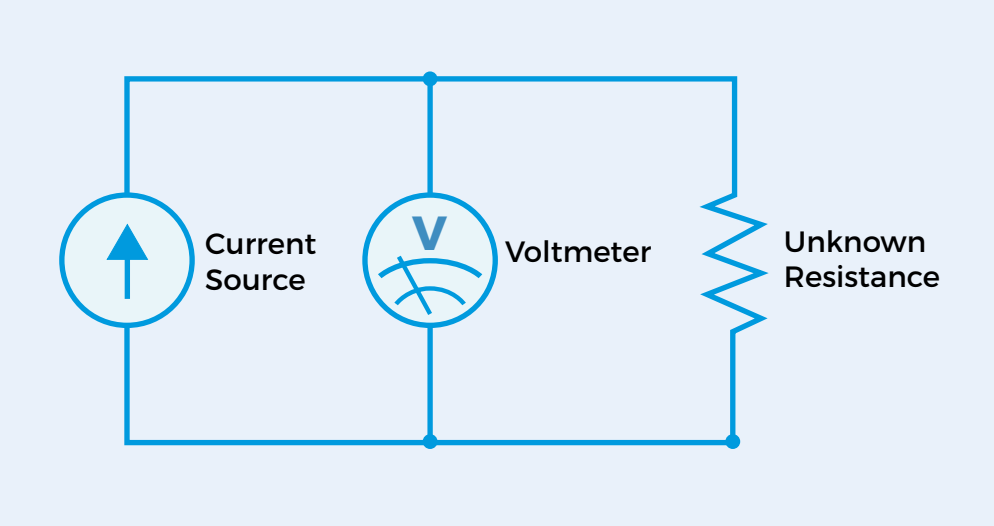


Figure 6 - Simplified diagram of a two-wire resistance measurement method

Leakage Current Tests

In NFPA-99, the leakage measurements can be broken down into ground leakage, touch leakage and patient lead leakage. Leakage currents from the chassis or ground are measured to ensure that the risk from electrical shock is reduced even if the protective ground is open.

Direct bodily contact with patient leads means that measured current values must be significantly less than that of both ground and touch leakage.

Although no body model is mentioned in NFPA-99, section 10.3.3 suggests a leakage reading from a frequency response–shaping network that precedes a flat-response meter, or by a meter whose own frequency response characteristic closely matches the body model found in AAMI/ANSI ES60601 *(See **Figure 7**)*. The suggested circuit to get the desired frequency response is shown in ***Figure 8***.

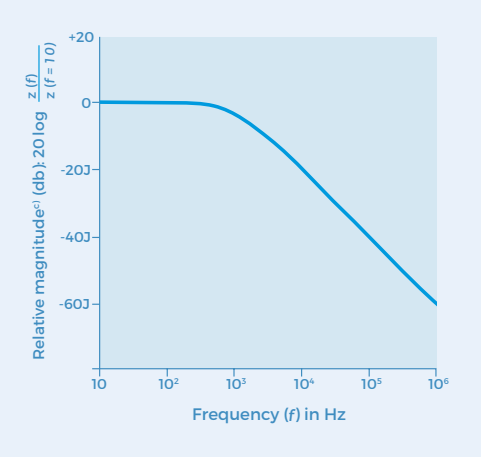


Figure 7 – Frequency response of the body model

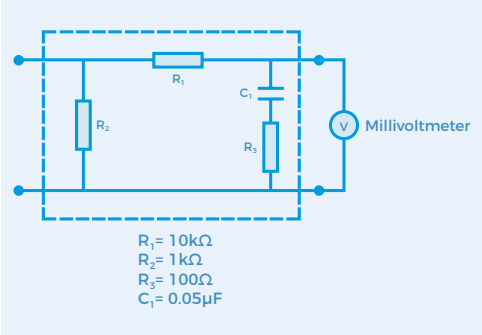


Figure 8 – The suggested measurement circuit according to the NFPA-99 handbook

Using a dedicated safety analyser with a **body model**, such as those found in the Rigel SafeTest range ensures that the frequency response characteristic closely matches the body model found in NFPA-99.

Ground Leakage Tests

Ground leakage tests are relatively rare compared with touch and patient leakage tests. It is only specified for all fixed equipment in Category 1 and 2 spaces before installation.

To ensure all leakage flows to the measurement circuit of the safety analyser, this test is done before any grounds are connected. The leakage current is measured from the ground conductor of the power supply to the ground of the fixed appliance *(See **Figure 9**)*.

The current limit for this test is 10mA (10,000µA) DC or AC. Leakage measurements should be carried out using the suggested circuit and the device under test needs to be tested with the power switch in both the ON and OFF positions.

Appendix A shows the full pass/fail limits for leakage as per NFPA-99 requirements.

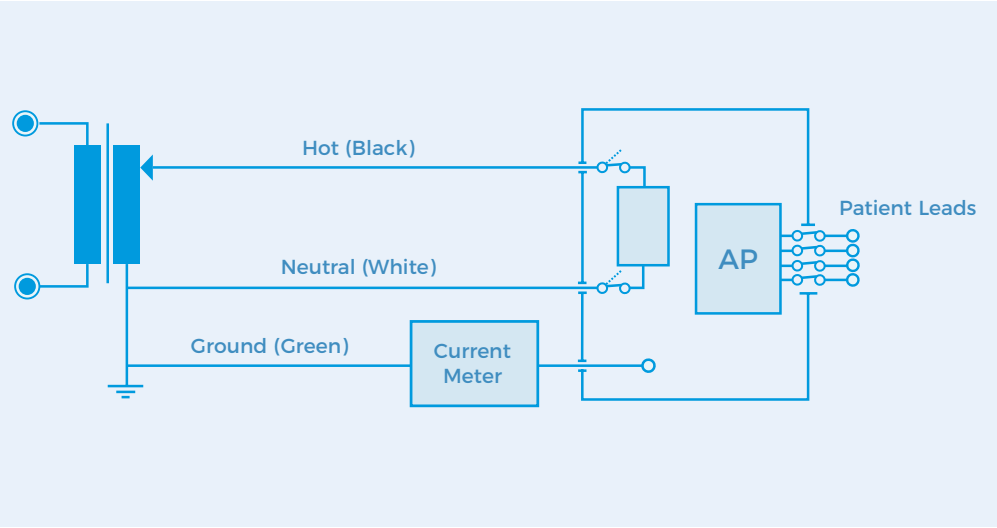


Figure 9 - A simplified diagram for the fixed equipment leakage test

Touch Current Tests

Touch current is any current that would flow to a person from the equipment chassis (or any accessible part not intended for patient treatment or care) during normal operation. It applies to all portable equipment and unlike IEC 60601, there are no single fault conditions (SFC) except that the ground is open.

Touch current tests simulate a human body contacting different parts of the equipment. The measured leakage current values are compared with acceptable limits. As is the case in AAMI/ANSI ES 60601, the current must be measured using power supplied directly from a standard grounded system, not from an isolation system. Measurements under a standard grounded system ensure the hot to ground voltage is equal to the voltage between hot and neutral). This gives the highest possible leakage outcome,

It is possible to test where a grounded service is unavailable by briefly grounding one side of the isolated power system for the leakage measurement. This is undertaken with a suitable adapter, which is plugged into an outlet on the system. The adaptor must ensure the neutral connector is used and not what would be the hot conductor. The adapter must be removed after the measurement is completed.

For the touch leakage test, the ground is switched into the open position. Two measurements are taken, with the appliance power switch in both the ON and OFF positions (only one measurement if a switch is not supplied). ***Figure 10*** shows the set up for this test.

If the appliance is permanently fixed to ground, touch leakage is measured in situ without ground open. There is a statement in 10.3.5.1 of NFPA-99 on touch leakage tests when one power cord supplies the power to multiple devices. If a fault were to occur with the ground connection in the power cord, then the sum of the currents from each individual device would flow to earth via any human contact with the chassis. The touch current must therefore be measured as a group. The limit is 500µA as normal but there are suggested methods of lowering the summed leakage, such as separating the device grouping.

Appendix A shows the full pass/fail limits for leakage as per NFPA-99 requirements.

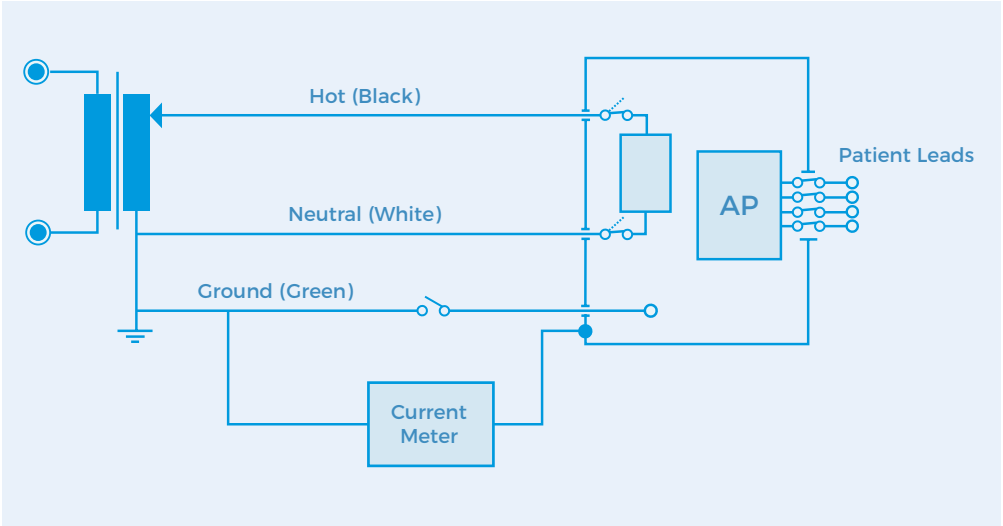


Figure 10 - A simplified diagram for the touch current leakage test

Lead Leakage Current Tests

A patient lead is any lead that has direct conductive contact with the patient and is referred to as an applied part in ANSI/AAMI ES60601-1. This includes non-invasive and invasive connections, such as ECGs and pacemakers. Consequently, non-isolated electrical patient connections have lower leakage limits of 100µA to reflect the associated hazards.

NFPA-99 originally stated that each individual applied part to ground must be measured, however, in the last few editions of NFPA-99, including 2021, patient leads are grouped together for testing.

Testing should be carried out using the suggested circuit in ***Figure 11*** with the device powered on. The leakage current limits are 100µA for ground wire closed and 500µA for ground wire open.

Appendix A shows the full pass/fail limits for leakage as per NFPA-99 requirements.

The electrical safety tester must be capable of measuring values of greater than 100µA due to the lower values found in patient lead leakage. The Rigel SafeTest range has a measuring range from **0.1 - 9999µA**.

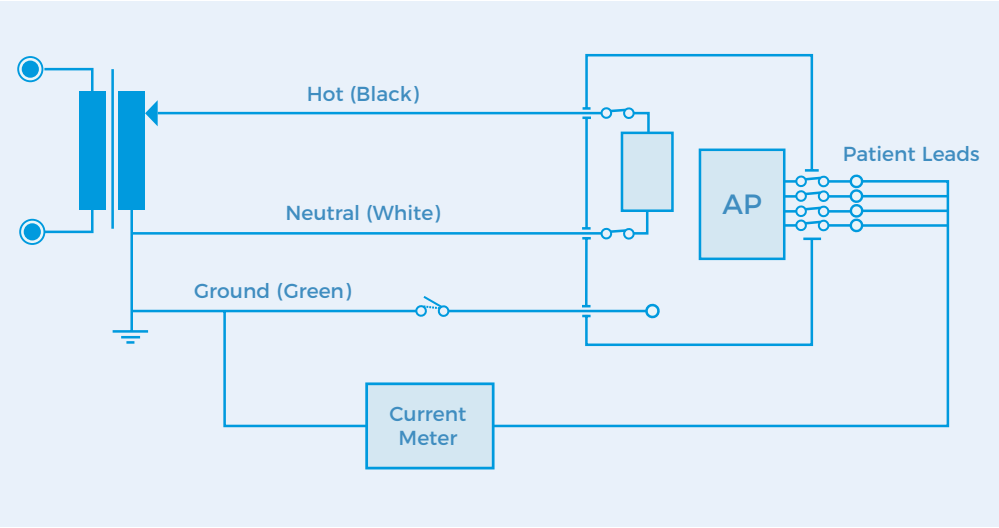


Figure 11 - A simplified diagram for the lead leakage test

Best Practises

NFPA-99 states the minimal standard of documentation required for routine checks of equipment. Each record must define what was tested (The unique identification of the equipment), the date it was tested, and whether it passed or failed. Test protocols should be developed to ensure consistency for each electrical safety check and record.

It is the facilities responsibility to identify which patient care related electrical equipment requires regular checks. Each device must be tested in accordance with 10.3.5.3 or 10.3.6 at acceptance and during any maintenance that may affect the electrical integrity. There are also recommendations on the minimum periods for safety checks whilst in-service - at least every 12 months. The responsibility for the duration of retention for test records falls on the healthcare facilities record policy.

The aim of electrical safety in NFPA-99, and that of all electrical safety standards, is to limit the leakage currents that can cause injury or death to a patient or user. It is always best practise to test where a risk to electrocution may occur regardless of the minimum requirements of each standard. It is always worth looking at the OEM service manuals for their guidance. Service manuals often specify recommended additional safety checks, but the NFPA-99 code is law and must be followed first and foremost regarding electrical safety.

Conclusion

The NFPA-99 handbook clearly states on multiple instances about the use of dedicated electrical safety analyzers. For instance, leakage measurements should be made with a specific body model which would be difficult to replicate using standard test equipment.

When choosing your electrical safety analyser, make sure it can be used to test in accordance with the NFPA-99 requirements and secondly that your analyser will enable you to produce the results you require accurately and repeatedly.

Essential requirements for electrical safety analyzers include:

- User safety – this must never be compromised
- Ground bond tests that can accurately measure down to 0.1Ω
- The measuring device frequency response characteristic closely matches the body model found in AAMI/ANSI ES60601 or has a frequency response–shaping network that precedes a flat-response meter
- High accuracy and repeatability of leakage measurement readings. Some manufacturers may specify accuracy of full-scale reading which will affect the accuracy of low leakage measurements
- Traceability of measurement results
- Test convenience, including test duration, user interface, time efficiency

Considerations and recommendations;

1. Ensure that the operator of the safety analyzer is properly trained on both the safety analyzer and the device under test to ensure that valid measurements are taken and understood, to prevent unnecessary danger during the safety test
2. Always ensure that the device under test does not pose any danger to the user and/or people within the vicinity to the safety test. (e.g. moving parts, open conductors, live components, heat etc.)
3. Appreciate that secondary ground connections will lead to invalid measurements. Understand how to spot secondary ground connections or benefit from the automatic warning feature on the Rigel 288+
4. Ensure accuracy and repeatability of leakage measurement readings. Some manufacturers might specify full scale accuracy which will affect the accuracy of low leakage measurements.
5. Ensure that contact resistance is considered when measuring the earth continuity at low currents (<8A). Contact resistance can influence the readings and cause unnecessary failures of the device under test
6. When determining the correct means of testing a specific piece of medical equipment, ensure that the chosen safety test procedures are applicable to the device under test and are clearly documented for future use

Rigel Medical offers a range of test equipment in line with the NFPA requirements, such as the Rigel SafeTest 99, SafeTest 50 or 288+, which ensure that test protocols are consistently followed correctly. They are synonymous on the market and have a range of electrical safety tests enabling **full compliance to NFPA-99**, with up to **10 lead** patient leakage testing on both the SafeTest 99 and 288+. **Test and fault conditions** that can be selected with a **single key press** make it a common choice among healthcare technicians, ensuring protocols are followed easily and correctly.

Please visit our website **rigelmedical.com** for a full overview of our product offering or register online for our free newsletter on future product releases and product innovations.

If you need any assistance using our electrical safety testers to comply to NFPA-99 please visit **rigelmedical.com/support** and raise a support ticket.

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Appendix A:

A list of the electrical safety tests and the corresponding ground bond and leakage limits found in NFPA-99

Test	Single fault condition	Limit
Ground Bond	None	0.5Ω
Leakage Current (Fixed Equipment)	None	10mA AC/DC
Touch Current	Open Ground	500µA
Lead Leakage	None	100µA
Lead Leakage	Open Ground	500µA

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A cost-effective, easy-to-use patient simulator

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- Simple, fast navigation
- Lightweight, compact unit with rechargeable Li-Ion battery
- Recall most used simulations
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The most complete vital signs simulator

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- Compatible with monophasic, biphasic and pulsed waveforms
- Reliable and non-inductive test load of 50Ω
- Patient simulator with ECG hi output

288+

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- Conforms to IEC 62353 / 60601 / VDE 0751 / NFPA-99 / AS-NZS 3551
- Memory for up to 5,000 devices
- Bluetooth communication
- Full, semi-automatic and manual testing
- Straightforward data transfer with the Rigel 288+ Downloader app

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Accessories and Services from Rigel Medical

Accessories

Having the right accessories can streamline your testing processes and help you get the most from your instrument. Our range of accessories includes scanners, Bluetooth enabled printers, a variety of leads and adaptors, pass/fail labels and verification units.

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Training

Alongside our commitment to quality, we also offer peace of mind to our customers who know that help and advice is always available. Part of that offering includes training to support and help you get the most from your instrument.

Contact us directly to find out more.

Online resources & support

At Rigel Medical we take pride in giving you all of the tools to make your life easier. We have a host of online resources and technical support features on our website including, FAQs, interactive videos, webinars and helpful how-to guides.

Most of our live webinars are CPD certified, meaning you can get 1 hour towards your Continuous Professional Development portfolio. Please look for the CPD mark when signing up to see if that webinar is eligible.

CPD CERTIFIED
The CPD Certification Service

rigelmedical.com/support

Service, calibration & repair

Rigel Medical can also take care of your test and measurement equipment by providing calibration services (including on-site calibration), service, spares and repairs. Extend the life and quality of your instruments by contacting us for a no-obligation quote, wherever you are in the world.

rigelmedical.com/service-centre

RIGEL MEDICAL

TESTED, TRUSTED... WORLDWIDE.

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