

Electrical Safety Testing: What is actually required?

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Today's Speakers



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What We Will Cover Today



1

Is **Electrical Safety Testing** still important to keeping patients and staff safe?

2

What has changed in **NFPA 99**?

3

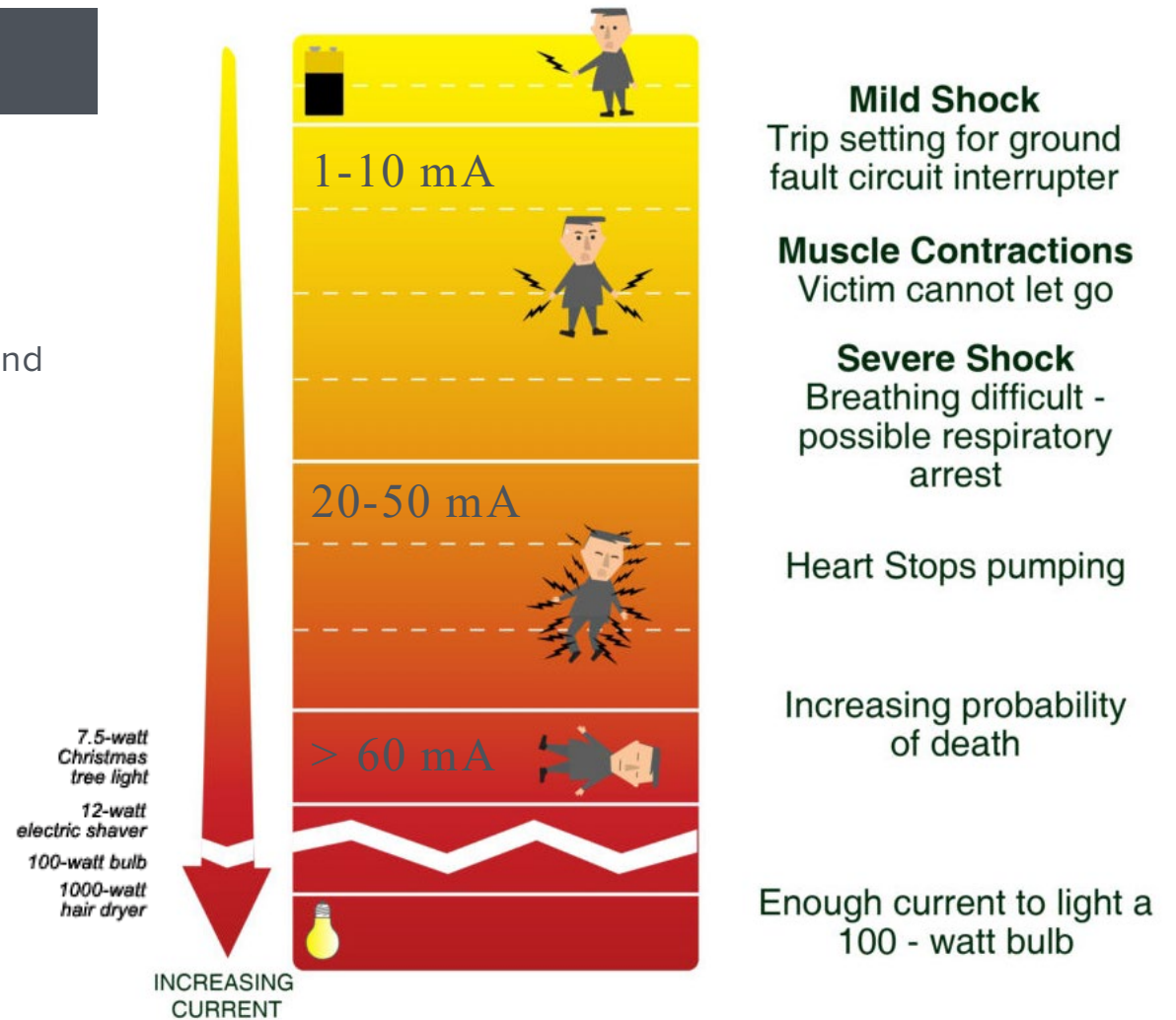
Discussion of **Alternative Maintenance Procedures**

Nature and impact of electric shock

ELECTRIC SHOCK

Factors that determine the effect of electric shock on the human body:

- 1 **How much** current is flowing through the body (measured in amperes and determined by voltage and resistance)
- 2 **The path** of current through the body
- 3 **How long** the body is in the circuit



Safety is key for electrical medical devices

Electric shock hazards in the hospital environment

Safety is important for all sorts of electrical devices, but it becomes **extra critical** when it comes to electrical *medical* devices

- Hospital beds
- Surrounding environment
- ECG leads
- TEE probes
- ... many other

The human body is especially susceptible to electrical shock when the skin is broken or open

Do you perform electrical safety tests annually on all your devices?



We **must** test medical devices for safety

Electrical safety analyzers are used in medical equipment maintenance to verify that electrical medical devices do not pose an electric shock to patients



Electrical medical devices undergo following major testing procedures



- ✓ Design and validation testing **OEM**
- ✓ Type testing **OEM**
- ✓ Acceptance testing **HL**
- ✓ Routine testing (PM) **HL** **OEM**
- ✓ After service and repair testing **HL** **OEM**

Standards **help to define** test procedures

Requirements for safety are prescribed by various **local** and **global** bodies, IEC being the most widely accepted

Which test code/standard is right for you?

IEC 60601-1

- Design **Type Testing** for medical device manufacturers;
- May be used for **acceptance testing** (incoming inspection)

NFPA 99 / IEC 62353

- **Recurring testing**;
- **Post-repair testing**

IEC 61010

- **Design implementation** and **validation testing** of the clinical laboratory device, but not during installation or routine testing of the medical device once installed



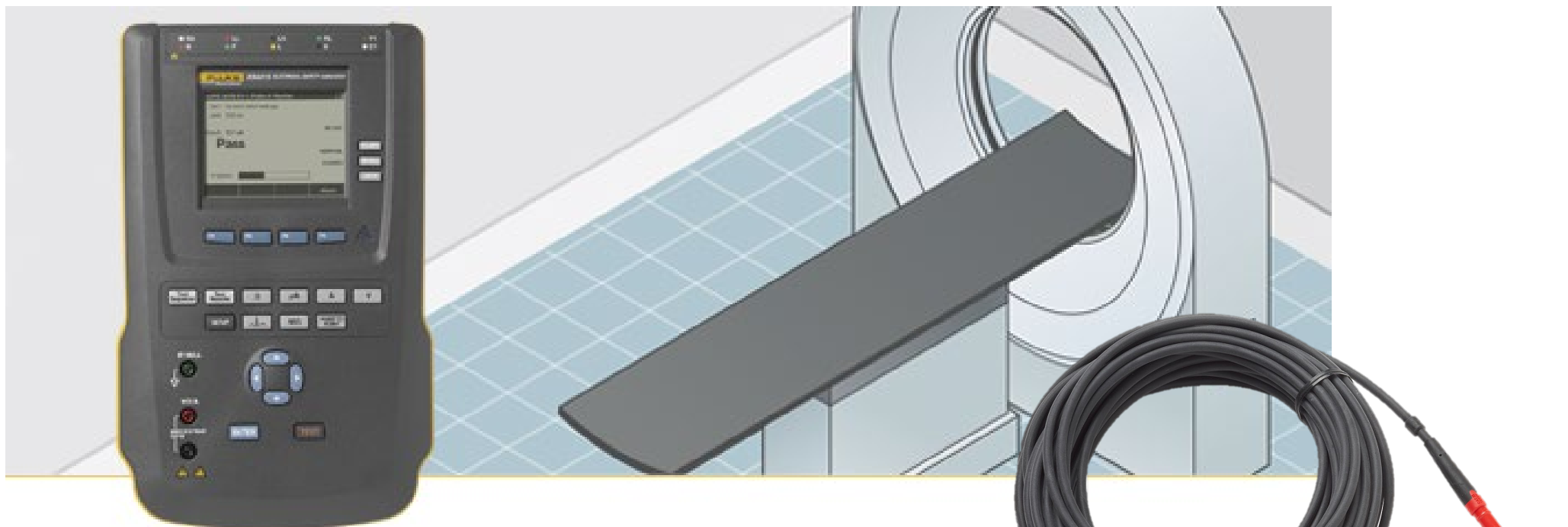
NFPA 99

What it is.
What it is not.

Isolated Power Systems



Point to Point Testing



Use of the 50-foot test lead(s)

- Permanently connected to mains DUTs (Blanket warmers, treadmills, floor centrifuges, clinical laboratory devices; CT, MR, Diagnostic X-ray rooms, etc)



Alternative Maintenance Testing Discussion

Changes to NFPA 99

Patient Care Vicinity & Spaces

The terminology in these definitions has been changed in *two* distinct ways in previous editions.

The first is that the word room was changed to space in all instances. This reflects a change that was made in Chapter 6 to correlate with NFPA 70 and to reflect that, in a large room, there can be many different services being provided in different spaces. The idea of this change is to look at the risk in individual spaces within a room, rather than in the room as a whole.

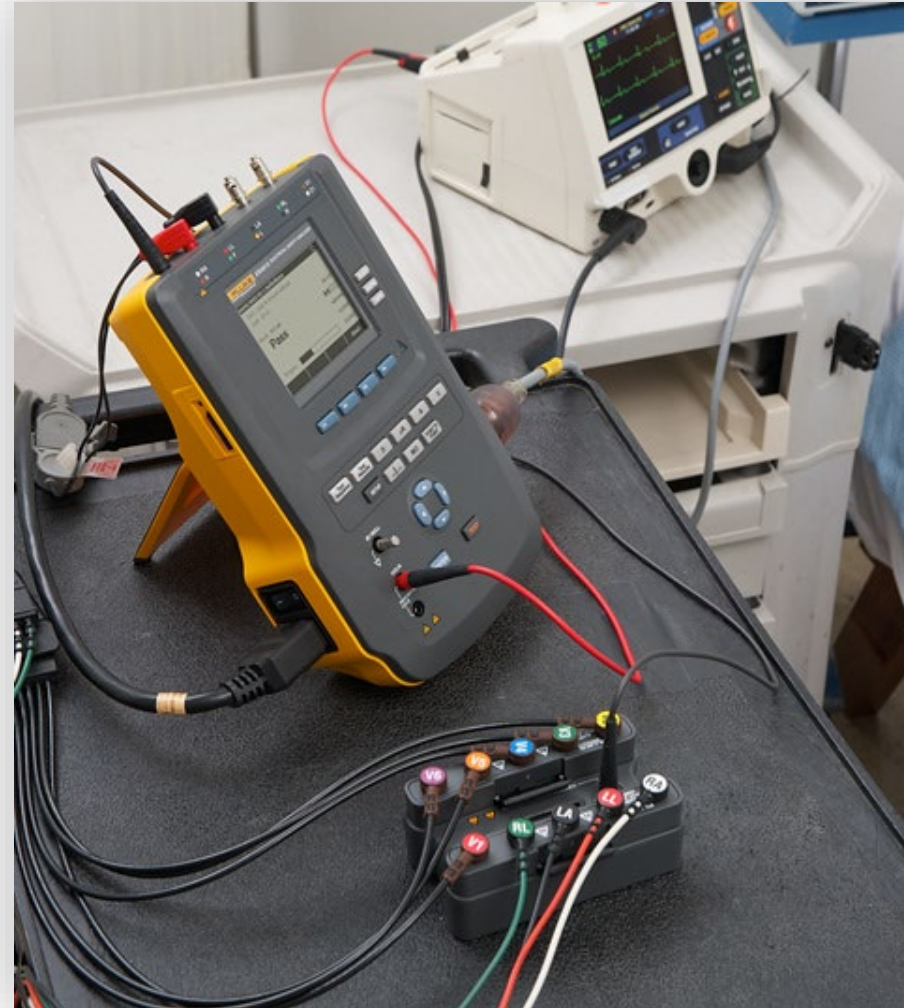
Space is defined as:

A space within the location intended for patient care, extending 1.5 m (~ 6 feet) beyond the normal location of the bed, table, etc that supports the patient during examination or treatment, and extending vertically 2.5 m (~7.5 feet) above the floor.




More than 5 Applied Parts?




Fluke Biomedical 12 10 Adapter




Ultrasound Testing with the ULT800 and ESA612



How to test leakage on an ultrasound probe with the ULT800 and ESA612



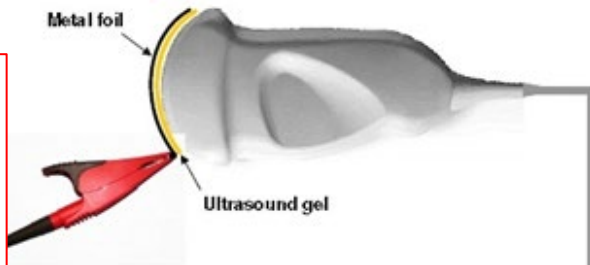
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Testing Ultrasound Transducers

2 Different Testing Scenarios

Testing transducers while they are connected to their diagnostic ultrasound system



Testing transducers while they are being disinfected



How Workflow Automation Could Save You Time and Gain Usable Data!



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Q&A Time