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# **SAFETY IN MEDICAL DEVICES**

THE REQUIRED ACTION FOR SAFETY IN MEDICAL  
DEVICES BASED ON THE TYPE OF HAZARD

**SAFETY  
FIRST**



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# 1. INTRODUCTION

When we talk about the safety of medical devices, the word "safe" implies that we expect a device to keep us safe!

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## WHY DO WE NEED SAFETY IN MEDICAL DEVICES ?

To ensure patient and practitioner safety and lay the foundation for greater regulatory convergence.

## 2. ELECTRICAL SAFETY

To avoid electrical shocks, ensure that medical equipment is electrically safe for use in a healthcare setting by testing for breakdown or damage.

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### 4. THE ELECTRICAL SAFETY TESTS FOR MEDICAL DEVICES:

- AC Hipot /DC Hipot Test.
- Leakage Current Test.
- Ground Bond Test.

## 3. BIOLOGICAL SAFETY



of infections contracted by hospital patients were caused entirely or partially by medical devices.

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PhotoRoom

### HOW TO PREVENT THE INFECTION ASSOCIATED WITH MEDICAL DEVICES?

When a device is no longer needed or a complication is discovered, it should be removed.

## 4. MECHANICAL SAFETY

To avoid physical injury to patients and healthcare staff, as well as physical damage to medical devices that negatively affects performance.

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### MECHANICAL HAZARDS INCLUDE :

- Rough surfaces.
- Sharp corners & device edges that could be dangerous.

## 5. RADIATION SAFETY

To protect patients and healthcare staff from the ionizing radiation.

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### HOW ARE YOU PROTECTING YOURSELF FROM RADIATION?

- Use shielding.
- Minimize time.
- Maximize distance.

