Introduction to MEQA and International Electrical Safety Standards

Things you may not have thought to ask

Medical equipment quality assurance

Ensuring medical equipment is and remains safe and effective for clinical use.

Includes:

Risk-based assessment

- Goals
- Intervals (frequency of inspection)
    - Maintenance strategy worksheet
- Evaluating program effectiveness

Medical equipment quality assurance Goals

- Ensure inclusion in the inventory management
- Ensure proper functionality to standards and equipment specification
- Ensure clinical staff know proper operation
- Determine frequency of inspection, scheduled testing, documentation of results, and tracking failures for long term trends
- Trouble shoot failures to root cause and repair, document actions
- Ensure medical equipment is available for use
- Minimize cost of repair (run to fail is not necessarily least costly)
- Reduce risk of injury to patients who are connected to equipment

Risk Management for MEQA

- Review: Risk Management
- **Device function (intended use)**
  - What function does the equipment perform in a clinical environment? The highest risks are with life-support devices, lower risks with non-invasive, diagnostic devices
- **Risk of misuse or failure**
  - What are the possible consequences to the patient of a device malfunction or misapplication? The range is from "death" to "no significant risk
- **Mission criticality**
  - What is the impact on overall hospital patient care or patient flow? Critical, important, non-critical.

Program development and procedures guide

- University of Vermont and Fluke Biomedical: *Medical Equipment Quality Assurance: Inspection Program Development and Procedures*

Device inclusion – what will be inspected?

Medical Equipment (not every category needs scheduled testing. Minimum of Acceptance/Incoming inspection; and post repair if risk assessment supports this)

*An answer of "**YES**" to any of the three questions below indicates that the device should be included in the medical equipment management program , and be tested with documented measurements, testing limits, and pass/fail results. NOTE: even non electrically powered equipment may need testing.*

Is the powered device used for direct patient treatment or care?	***Yes*** ***No***
Does the powered device provide diagnostic/monitoring information used in treatment?	***Yes*** ***No***
Does this powered device come in contact with the patient?	***Yes*** ***No***

Risk Scoring for Inspection Frequency

- 5 Criteria (light blue rows)
- Select one (1) option from those provided for each
- Transfer the weighting to the Score column
- Sum the data in the Score column to get the Total Risk Score
  - Greater than 13 = 2 x per year
  - Between 9-12 = 1 x per year
  - Less than 9 = Acceptance and Post-repair (okay to run until fail)
- Exception: Certain devices such as life support equipment have more frequent inspections by regulation or manufacturer requirements

Criteria – choose 1 rating from each category	Weight	Score
Clinical function		
No patient contact	1	
Device may make contact with patient but function is non-critical	2	
Device is used for patient diagnosis or direct monitoring	3	3
Device is used to deliver direct treatment to the patient	4	
Device is used for a life support	5	
Physical risk		
Device poses no appreciable risk due to failure	1	
Device failure will result in low risk	2	
Device failure will result in inappropriate therapy, misdiagnosis or loss of monitoring	3	3
Device failure could result in severe injury to death to patient or user	4	
Problem avoidance probability		
Maintenance or inspection would not impact reliability of the device	1	
Common device failure modes are unpredictable or not very predictable	2	2
While common device failure modes are not very predictable, device history indicates TSP testing frequently detects problems	3	
Common device failure is predictable and can be avoided by preventive maintenance	4	
Specific regulatory or manufacturers requirements dictate preventive maintenance or testing	5	
Incident history		
No significant history	1	1
A significant history of incidents exists	2	
Manufacturers/regulatory requirements for specific schedules		
No requirements	1	1
There are requirements for testing independent of a numerical rating system	2	
Total Score:		10
Assignment: 0.0x 0.5x 1x 2x 3x 4x (times per year tested)		1

Summary:

Incoming inspections (acceptance testing)

- Medical equipment new to the facility
- Medical equipment returned after outside repair

Documentation (adding to the inventory, etc.)

Safety

- Electrical, mechanical, infection control, and cleaning equipment

Electrical safety

- Principles
- Standards

Introduction to Medical Equipment Minimum Performance and Safety Standards

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International Electrotechnical Committee (IEC) Standards for Medical Equipment

- How organized
  - IEC 60601 (the overarching umbrella under which all medical device category standards are found)
  - State the minimum performance and safety requirements, testing methods, and testing limits
  - Tried and proven to ensure proper functioning of each category
  - Categories (not a complete listing)
    - Electrical Safety
      - IEC60601-1
      - IEC62353 (choose from 3 testing methods based on medical device design)
    - Patient Monitors
      - Separate standards for each vital sign parameter
    - Defibrillators
    - ESU (Electrosurgery generators; cautery)
    - Infusion devices
    - Ventilators
    - Anesthesia systems
    - Etc.

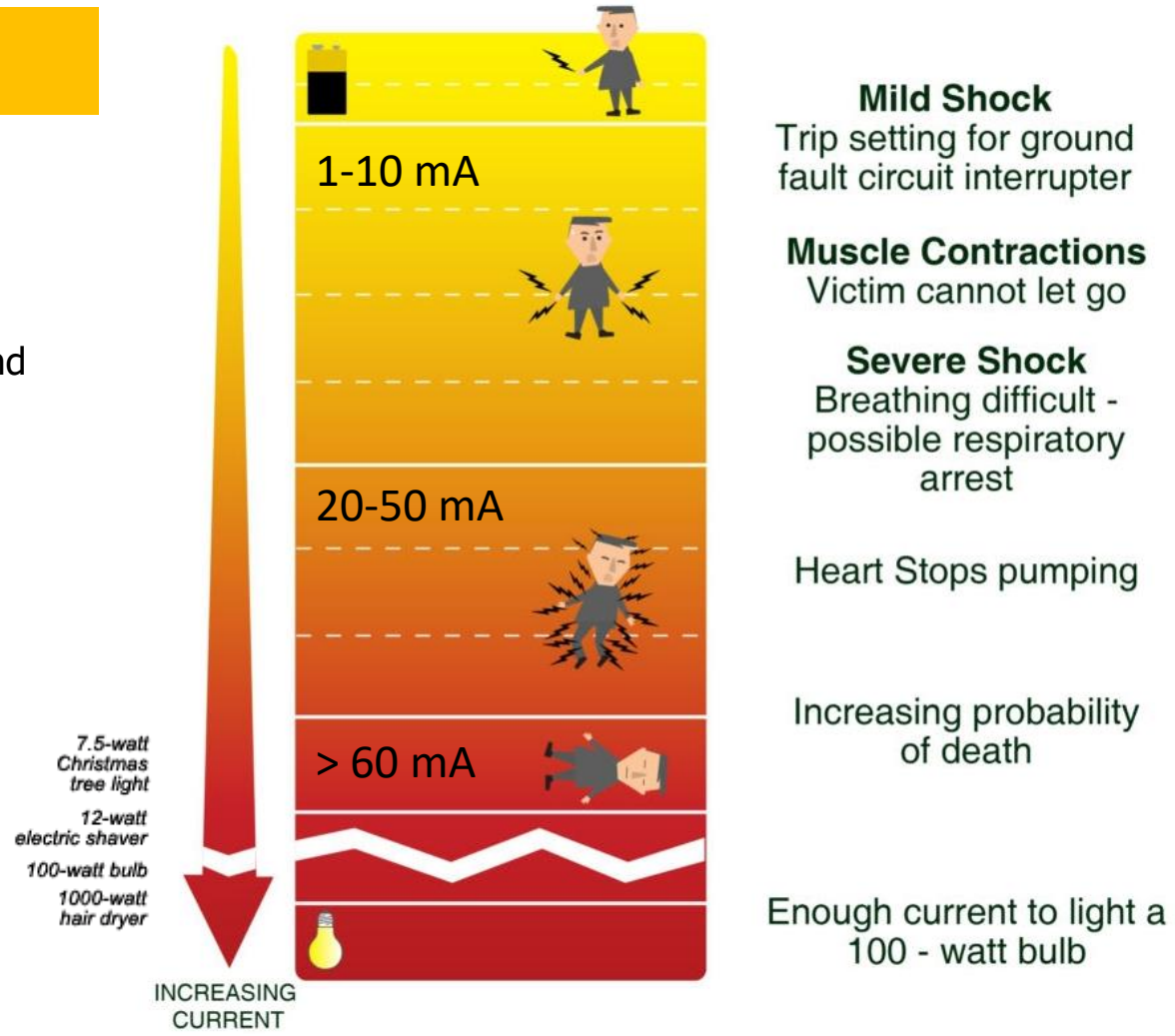
Introduction to Electrical Safety Testing

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

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

Electric shock hazards in the hospital environment

- 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

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

Who should use IEC 60601-1?

- ✓ Medical device design and validation
- ✓ Tests that are not routinely repeated
- ✓ Can shorten the useful life of the medical device

Uses for IEC 60601-1

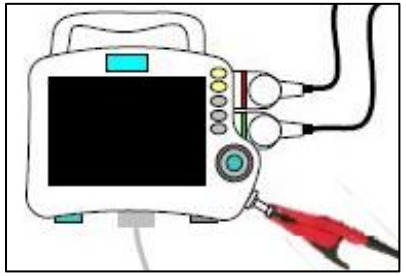
- **R&D:** Design Type Testing
- **R&D:** Design Validation Testing
- **Production:** Final Assembly Testing
- **Hospital:** Incoming Inspection / Acceptance Testing

IEC 60601-1 is focused on the OEM / Medical Device Manufacturer

Current	Description		Type B		Type BF		Type CF	
			NC	SFC	NC	SFC	NC	SFC
Patient Auxiliary		d.c.	10	50	10	50	10	50
		a.c	100	500	100	500	10	50
Patient leakage	AP to Earth	d.c.	10	50	10	50	10	50
		a.c	100	500	100	500	10	50
	Caused by external voltage on a signal input /output part	d.c.	10	50	10	50	10	50
		a.c	100	500	100	500	10	50
Total Patient Leakage	With the same type of AP connected together	d.c.	50	100	50	100	50	100
		a.c.	500	1000	500	1000	50	100
	Caused by external voltage on a signal input /output part	d.c.	50	100	50	100	50	100
		a.c	500	1000	500	1000	50	100
Patient leakage	Caused by external voltage on the Type-F AP		NA		5000		50	
	Caused by external voltage on metal accessible part not protectively earthed		500		500		covered	
Total Patient Leakage	Caused by external voltage on the Type-F AP		NA		5000		100	
	Caused by external voltage on metal accessible part not protectively earthed		1000		1000		covered	

Changes 2nd to 3rd edition (2005)

IEC 60601-1 2nd Edition	IEC 60601-1 3rd Edition	IEC 62353 (Alternative)	IEC 62353 (Direct)	IEC62353 (Differential)
Protective Earth Resistance	Protective Earth Resistance	Protective Earth Resistance	Protective Earth Resistance	Protective Earth Resistance
Insulation Resistance	Insulation Resistance	Insulation Resistance	Insulation Resistance	Insulation Resistance
Protective Earth Leakage	Protective Earth Leakage	NA	NA	NA
Enclosure Leakage	Touch Current	Equipment Leakage Alt	Equipment Leakage Direct	Equipment Leakage Diff
Patient Leakage	Patient Leakage	Applied Part Leakage Alt	Applied Part Leakage Direct	NA
Mains on Applied Part Leakage	Mains on Applied Part Leakage	NA	NA	NA
Patient Aux Leakage	Patient Aux Leakage	NA	NA	NA



Who should use IEC 62353?

IEC 62353 is used in working locations outside of R&D lab environment

- ✓ OEM Field Service
- ✓ Hospital Biomeds

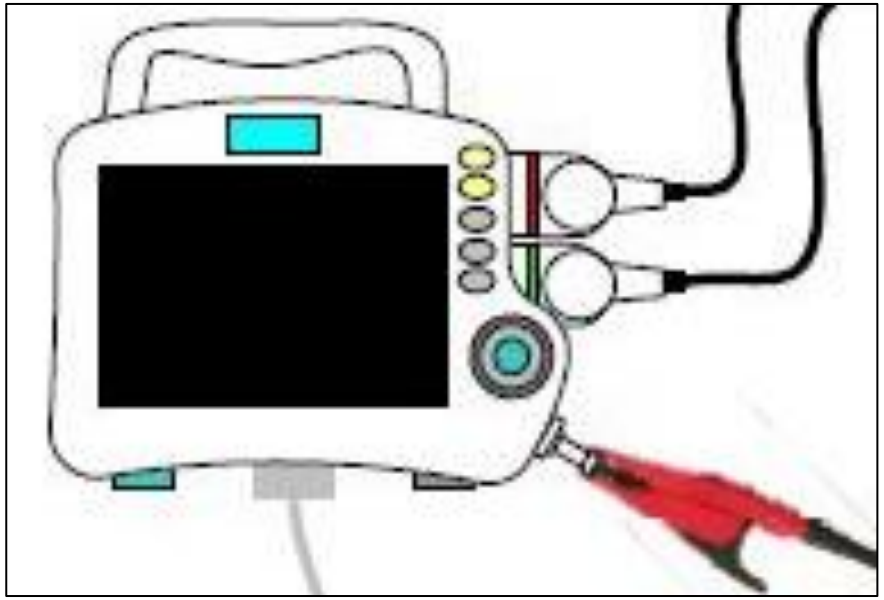
Compared to the baseline IEC 60601-1 standard, **IEC 62353 is less complex** and is meant to be used for in-service and post-repair testing

End users should **rely on the manufacturer's manual** for recommendations on appropriate tests for their equipment

Changes 2nd to 3rd edition (2005)

Touch Current

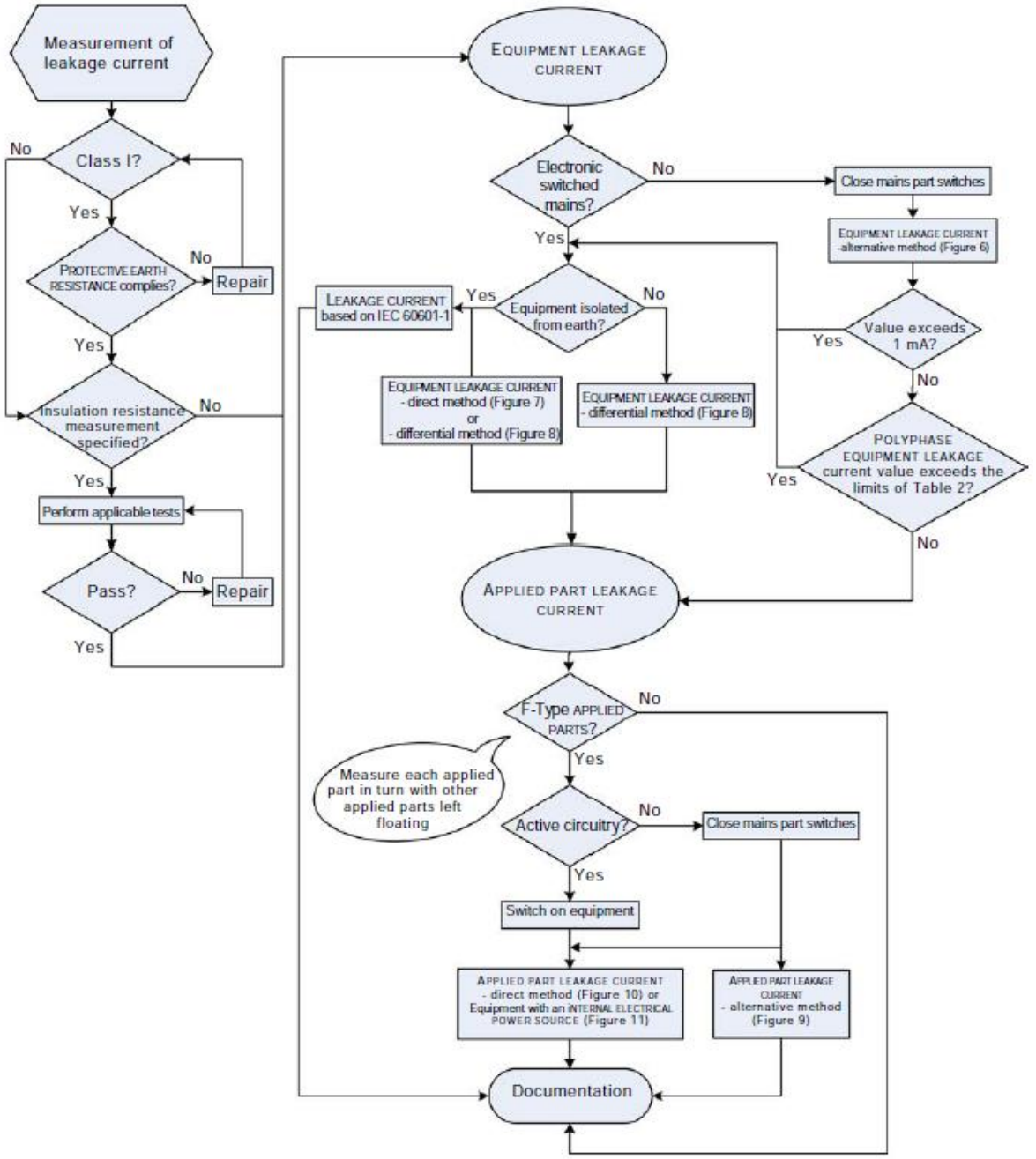
- Previously known as enclosure leakage current
- Requirements are unchanged
  - Must pass at Normal Condition (NC)
  - Must pass at Single Fault Condition (SFC)
- Must be done, even if device is Class I without PE test point (no accessible ground), Class II or Class IP
  - Test point is any conductive, non-earthed point within reach of the patient or clinician



Comparative Tests (reverse polarity and single fault tests not shown)

	IEC 62353 2nd edition	IEC 60601-1 3rd edition
PE (Protective Earth/Ground) test current	200 mA	25 A (Caution: repeated measurements may limit useful life of medical device)
PE (Protective Earth/Ground) limit	300 or 500 mOhm	200 mOhm
Leakage current methods	3 different methods Direct; Differential; Alternative *Proper method defined by the manufacturer or use of decision tree*	1 method
# of leakage current measurements	Reduced	Many
Insulation resistance	If specified by manufacturer / local regulations	Not required
Mains on Applied part voltage	= Mains voltage	= Mains voltage +10% (Caution: repeated measurements may limit useful life of medical device)

How to choose the right method?



Who should use IEC 61010 and When?

Applies to Clinical Laboratory Equipment

- ✓ Clinical Laboratory Equipment Manufacturer
- ✓ Hospital Clinical Laboratory Equipment

After installation, use the appropriate test method from the IEC 62353 standard.

2 Special Tests performed at installation:

Accessible Voltage Test:

- If pass, then no further tests
- If fail, then Accessible Leakage Current Test

Accessible Leakage Current Test:

- If pass then no further tests
- If fail, then fail; perform corrective action

Common Questions

- **Can a digital multimeter be used to determine medical equipment electrical safety?**

Not without the IEC specified test load. Best done with a medical electrical safety analyzer.

- **Must battery powered medical equipment be tested for electrical safety?**

Yes. The safety analyzer company should provide instructions

- **What about 3-phase power supplies?**

Each phase coming from the power supply has its own reference. That reference point is the “ground”/return, but it is NOT protective earth. This subject needs a training all its own.

Questions?

Contact:
Gerald Zion, MS, CBET
Independent Consulting Biomedical Engineer
jerry.zion@comcast.net
http;//www.linkedin.com/in/geraldlzion2013

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