

Justin McCarthy

Changes in standards and guidelines for electrical safety testing



Summary

- Why do we do EST?
- When should we do it?
- What Standards exist?
 - BS EN 60601-1
 - BS EN 62353
- What changes have there been or are coming?
- Guidance documents
 - IPEM Report 97
 - IET Code of Practice
 - HSE Guide HSG 107
 - HSE Guide INDG 236(rev2)

Why do Electrical Safety Testing?

- To ensure patients and staff are not at risk from electric shock – macroshock or microshock
- To meet legal obligations

Legal Context

- Electricity at Work Regulations 1989: Regulation 4(2)
- Provision and Use of Work Equipment Regulations: Regulation 5

Electricity at Work Regs

4(1) All systems shall at all times be of such construction as to prevent, so far as is reasonably practicable, danger.

4(2) As may be necessary to prevent danger, all systems shall be maintained so as to prevent ... such danger.

See also

- Memorandum of Guidance paragraphs 4.7 and 4.8
- Maintaining portable and transportable electrical equipment at
<http://www.hse.gov.uk/pubns/priced/hsg107.pdf>

What EWR does & does not say

- Does NOT say what testing has to be done
- Does NOT say how often

Guidance says

- Regular inspection an essential part of any preventive maintenance programme
- Practical experience may indicate an adjustment to the frequency
- A matter for the judgement of the duty holder

PUWER

Regarding Maintenance, PUWER is stricter than EWR, but is covering all aspects

- 5(1) Every employer shall ensure that work equipment is maintained in an efficient state, in efficient working order and in good repair.*
- 5(2) Every employer shall ensure that where any machinery has a maintenance log, the log is kept up to date.*

When should we do it

- At commissioning of new equipment – reference values
- After repair – assurance of safety
- In service, maybe linked to PPM or PPC – BUT based on experience and risk assessment

Standards – 60601-1

- BS EN 60601-1:2006 Medical Electrical Equipment – Part 1: General requirements for safety and essential performance [Ed. 3.0]
revised to
- IEC 60601-1:2005 + A1:2012 [Ed. 3.1]
- This is a TYPE TEST standard
- We DO NOT test **TO** 60601-1
- but we can derive routine tests from it

Derived tests

- Protective Earthing of Class I equipment
 - 0.1 Ω internal and 0.2 Ω to plug top
- Earth leakage of Class 1 equipment
 - 500 μA for plugged-in equipment but $< 5 \text{ mA}$ if no exposed earthed parts
- Touch current
 - SFC: 500 μA from exposed conductive parts
Class I & II
- Patient leakage current
 - SFC: 500 μA , Types B & BF; 50 μA for Type CF

So what's new (of relevance) in Ed. 3.1

Protective Earth Resistance (PER)

- Now a clear requirement for 0.2 Ω to the plug top earth for fixed **and** detachable mains leads
- Previously, only specified for fixed mains leads

NOTE: 60601-1 does not address Insulation Resistance tests.

So what's new (of relevance) in Ed. 3.1

Earthing of Medical Electrical Systems (MES)

- **Ed 3.0 sub-clause 16.9.2.1c)** allows 0.4 Ω PER if an MES uses a Multi Socket Outlet
- **Ed. 3.1 sub-clause 16.9.2.2** modifies this to 0.2 Ω [same as for an individual equipment]

Standards – 62353

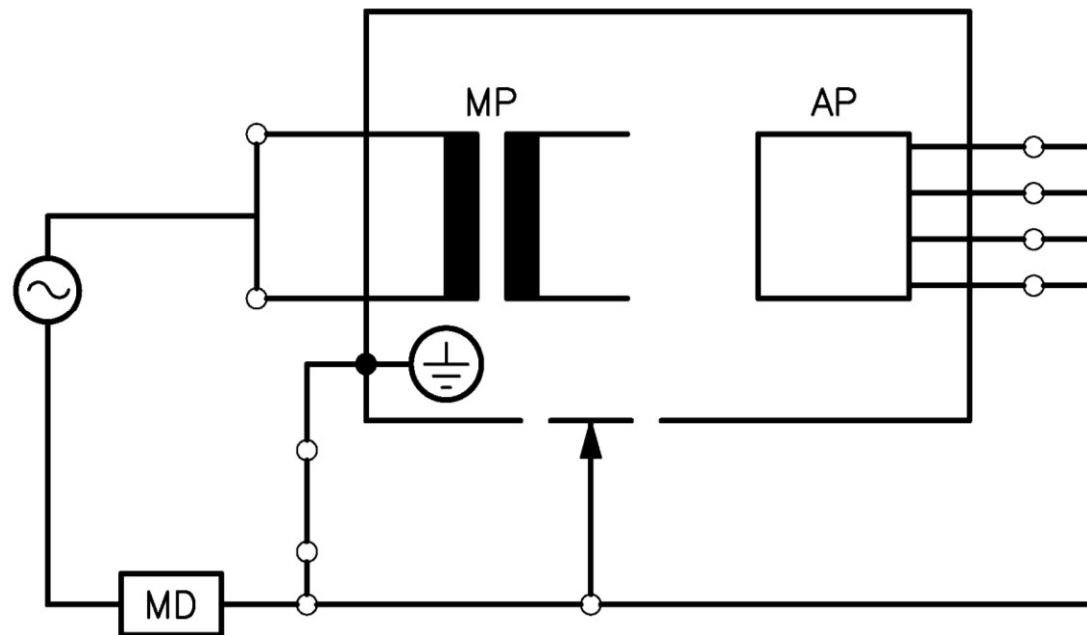
BS EN 62353:2008 Medical electrical equipment – Recurrent test and test after repair of medical electrical equipment

- Based on an Austrian/German standard
- UK did not vote in favour and did not formally contribute to it
- Read the UK National Forward

IEC 62353:2007 Summary

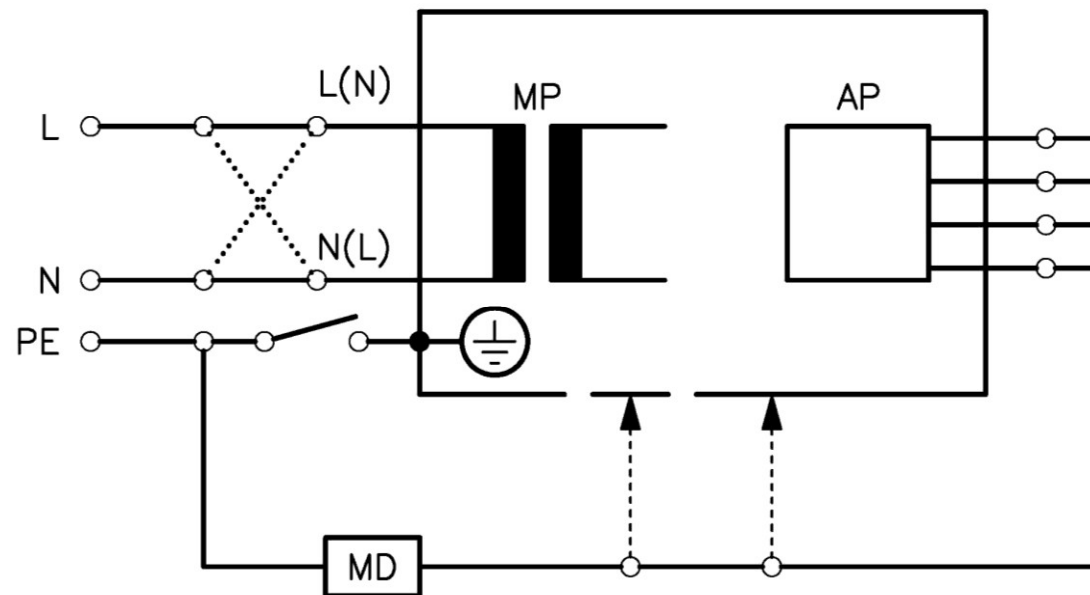
- Recognises three situations for testing
- Adds 0.1 Ω to allowed PER \rightarrow 0.3 Ω
- Allows 0.5 Ω for ME System with MSO
- Introduces three new leakage current test configurations
- Suggests that insulation testing [if required] is done after leakage currents

Alternative method Class I



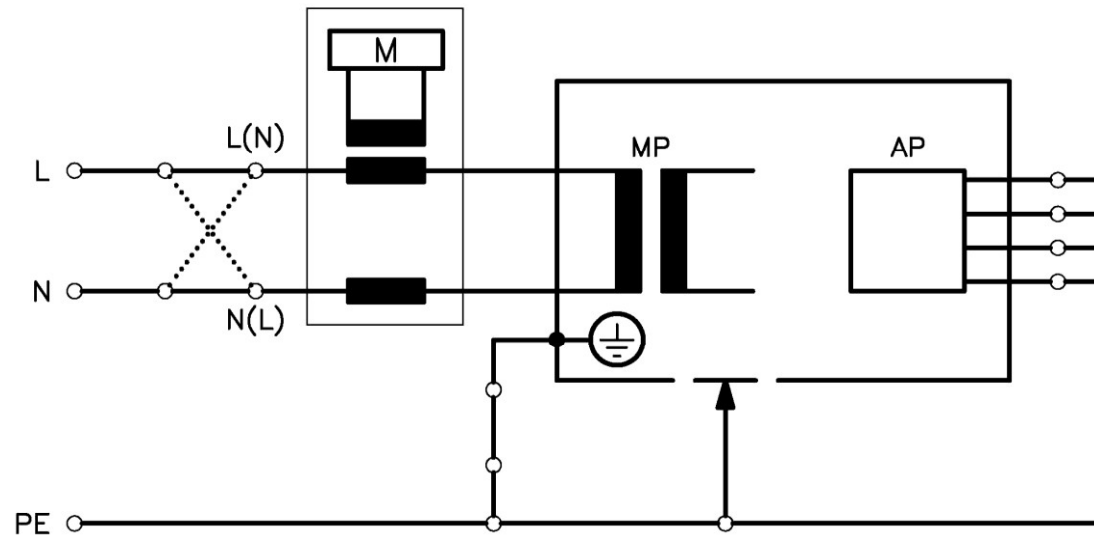
- Similar to leakage current with N open
- Sort of 'insulation test' at 230 V ac

Direct method class I



- Equipment powered up
- All sources of leakage brought together into one measurement – issues!

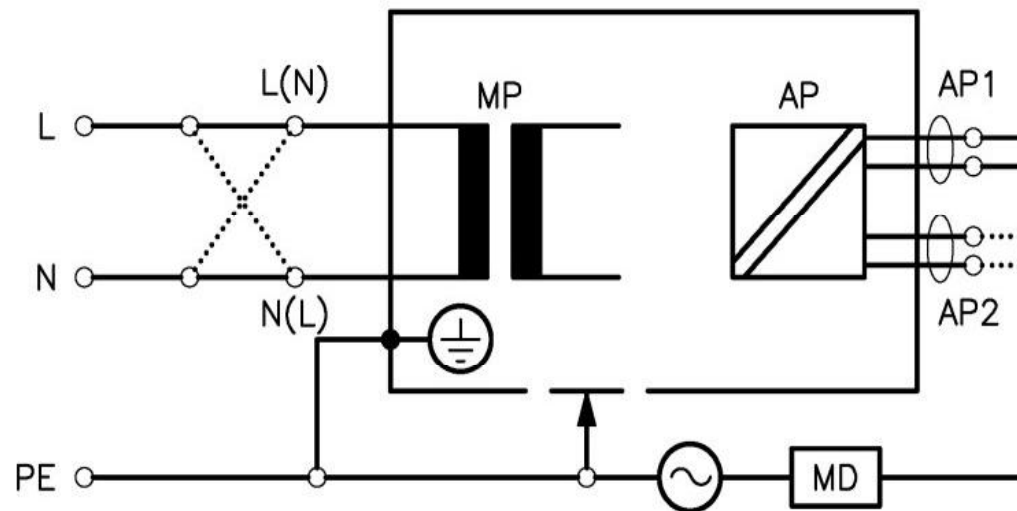
Differential method Class I



- Equipment powered up
- All sources of leakage brought together into one measurement
- Good if multiple earth points

Applied Part leakage current

- Mains on the Applied Part tests
- Again, three alternative methods
- E.g. Direct method shown



IEC 62353 2nd Edition

- Ed. 2 being worked on
- Currently at CDV stage
- CDV should be available as a DPC from BSI in May
- UK has contributed to this revision
- Most of the UK issues addressed

Changes in 62353 2nd Edition

- PER for ME Systems will be 0.3 Ω [0.5 Ω only if RCD powered]
- Insulation testing comes after PER but before leakage current tests
- Allows leakage current tests 'derived from' IEC 60601-1; diagrams provided
- Improved English
- Useful additional notes

Leakage current measurements

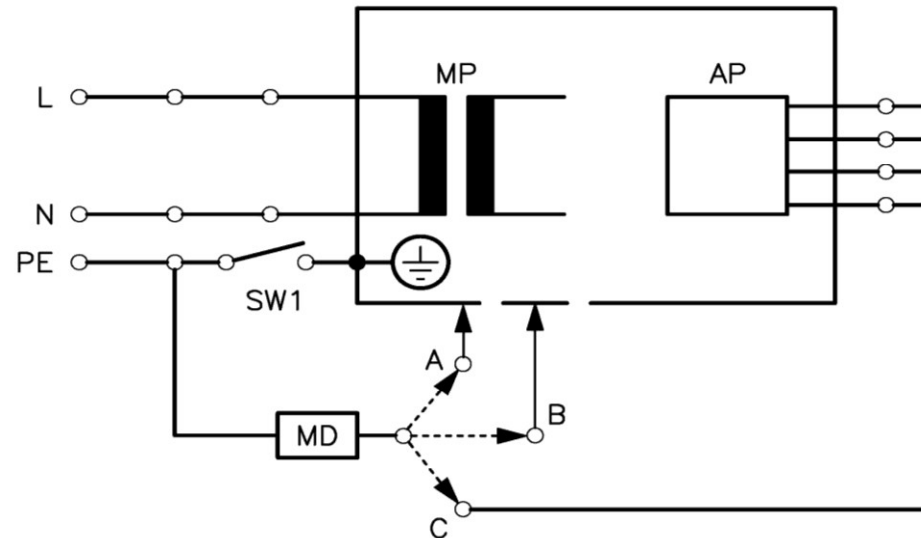
- Compare IEC 62353:2007 (1st Ed.)

“Measurements **according to** IEC 60601-1 (all editions) may be performed, if protection of the personnel and of the environment is guaranteed. ...”

- To 2nd Ed. CDV

“d) * Alternatively, for measurements of earth leakage current, touch current and patient leakage current, test configurations derived from IEC 60601-1 (all editions) may be used. See figures A1, A2 and A3. ...”

Figure A.2



Key

For plugged-in CLASS I ME EQUIPMENT:

A = TOUCH CURRENT (SFC) from earthed ACCESSIBLE CONDUCTIVE PARTS of the enclosure:
500 μ A

(A is equivalent to normal EARTH LEAKAGE CURRENT)

B = TOUCH CURRENT (SFC) from non-earthed ACCESSIBLE CONDUCTIVE PARTS of the enclosure: 500 μ A

C = PATIENT LEAKAGE CURRENT (SFC): TYPE B & BF 500 μ A TYPE CF 50 μ A

NOTE Closing SW1 will give Normal readings for B & C

Other useful guidance

- IPEM Report 97: Guide to electrical safety testing of medical electrical equipment: the why and the how. 2009
- IET Code of practice for in-service inspection and testing of electrical equipment. 4th Ed. 2012
- HSE Guide HSG107: Maintaining portable and transportable electrical equipment. 2004
- HSE Guide INDG236(REV2): Maintaining portable electric equipment in low-risk environments. 2012

Finally

Do enough
But not too much

Thank you