IEC 62353

Medical electrical equipment — Recurrent test and test after repair of medical electrical equipment

Condensed Practical Reference & Field Checklists

Prepared for use by biomedical/clinical engineers performing routine electrical safety testing, acceptance testing, and post-repair testing on medical electrical (ME) equipment already in clinical service.

Important note on scope and use: *This document is an original, independently written condensed overview and practical checklist tool. It summarizes, in the author's own words, the general structure, test types, and typical acceptance-limit concepts covered by IEC 62353 for quick field reference. It is* ***not a reproduction of the official standard text****, is not a substitute for it, and must not be used as the sole basis for formal test-equipment calibration, certification, or regulatory compliance decisions. Numeric limits and intervals shown are illustrative examples only — the current officially licensed IEC 62353 text (and any national deviation, e.g. VDE 0751-1 in Germany, or the destination country's own in-service testing regulation) must be consulted directly for authoritative pass/fail criteria.*

Delara Mohammadi
MedTech Consultant

delaramohammadi.com | info@delaramohammadi.com
+98 938 400 3858

1. About This Standard

IEC 62353 defines methods and typical limits for testing the electrical safety of medical electrical (ME) equipment *after it has entered clinical service* — as distinct from IEC 60601-1, which governs the design, type-testing, and initial certification of new equipment. In practice, the two standards work together: IEC 60601-1 sets the classification and design limits a device was built to meet, while IEC 62353 provides a simplified, practical test method (using lower test voltages and simpler equipment than full type-testing) suited to routine, repeated safety checks throughout a device's working life.

1.1 When it applies

- **Acceptance testing** — before a device (new, used, refurbished, or on loan) is first put into clinical use at a facility.
- **Recurrent/periodic testing** — scheduled electrical safety checks during a device's normal service life, typically as part of the broader preventive maintenance (IPM) programme.
- **Testing after repair or modification** — whenever work has been performed that could affect electrical safety, before the device is returned to clinical use.

1.2 Why it matters for a refurbishment/export business

- Provides a practical, standardized method to demonstrate that a refurbished device remains electrically safe under normal handling and use — a natural companion to the design-level assurances given by IEC 60601-1 compliance at original manufacture.
- Institutional buyers and regulators in destination markets frequently expect documented in-service electrical safety test records as part of acceptance of refurbished equipment.
- Feeds directly into an ISO 13485-aligned QMS (production/service-provision control, Clause 7.5) and into a device's ISO 14971 risk file as ongoing evidence that electrical-shock risk remains controlled after refurbishment and throughout service life.

2. Test Methods Covered

IEC 62353 organizes testing into three broad categories, each with its own applicability depending on device classification and construction:

Test category	What it covers
Visual inspection	A check of the equipment, accessories, and markings for damage, missing parts, legibility of labels, and general condition — performed before any electrical measurement and required regardless of test outcome elsewhere.
Measurement	Quantitative electrical tests: protective earth resistance, insulation resistance, and various leakage currents (see Section 3). Measurements can be taken with the equipment de-energized ("equipment leakage current method") or energized under controlled conditions, depending on the test type and available test equipment.
Functional test	A basic operational check confirming the device performs its intended function after passing the electrical safety measurements — not a full clinical performance verification, but sufficient to confirm the unit powers on and behaves as expected.

3. Core Electrical Measurements

Measurement	What it verifies
Protective earth resistance	Confirms the protective earth conductor (for Class I equipment) provides a low-resistance path — typically expected well under 1 ohm for equipment with a fixed power cord of normal length, though exact limits depend on cord length and connector configuration per the standard's tables.
Insulation resistance	Confirms adequate resistance between live parts and accessible/earthed parts, verifying that basic and supplementary insulation remain intact after time in service.
Earth leakage current	Current that flows to earth via the protective earth conductor under normal conditions — relevant for Class I equipment.
Enclosure (touch) leakage current	Current available at accessible enclosure parts that a patient or operator could touch — relevant for all equipment classes.
Patient leakage current	Current that could flow through a patient via an applied part — measured differently, and against different limits, depending on applied-part type (B, BF, or CF) as classified under IEC 60601-1.
Patient auxiliary current	Current intentionally or incidentally flowing between applied parts through the patient, not intended to produce a physiological effect — measured where the device has multiple applied parts.

Important: *exact numeric limits in IEC 62353 depend on the equipment's protection class (I, II, internally powered) and applied-part type (B, BF, CF) as originally classified under IEC 60601-1 — a technician must know a device's classification before test limits can be correctly applied. See the companion "IEC 60601-1 Condensed Reference" document for a summary of classification concepts.*

4. Typical Test Workflow

- **1. Identify the device and its classification** — protection class, applied-part type, and any manufacturer-specific test requirements from the service manual.
- **2. Visual inspection** — enclosure, cords, connectors, casters, labels; note any damage or contamination before proceeding.
- **3. Protective earth resistance** (Class I equipment) — measured first, since a failure here can affect the safety of subsequent live measurements.
- **4. Insulation resistance** — measured with the device de-energized.
- **5. Leakage current measurements** — earth leakage, enclosure leakage, and patient leakage/auxiliary current as applicable to the device's classification, typically measured under both normal condition and at least one simulated single-fault condition (e.g. reversed polarity, open earth) where the test method calls for it.
- **6. Functional check** — confirm the device operates as expected after electrical testing.
- **7. Documentation** — record all measured values (not just pass/fail), compare to the applicable limit, and file the result in the device's service history / CMMS.
- **8. Labeling** — apply a dated test label/tag indicating pass/fail status and next test due date.

5. Practical Field Checklists

Use one checklist instance per test event (acceptance, periodic, or post-repair). Record measured values, not only pass/fail, so trends can be tracked over successive tests. These checklists are a practical starting template; exact limits must come from the current IEC 62353 text and the equipment manufacturer's service documentation.

A. Visual Inspection Checklist

Check Item / Measurement	Result	Value/Notes
■ Enclosure free of cracks, damage, or missing covers.	P / F / NA	
■ Power cord, plug, and strain relief intact and undamaged.	P / F / NA	
■ Connectors, sockets, and accessory cables free of damage or corrosion.	P / F / NA	
■ Labels and markings (ratings, classification symbols, warnings) legible and intact.	P / F / NA	
■ Casters/mounting hardware secure and functional, if applicable.	P / F / NA	
■ No signs of overheating, discoloration, or contamination near power components or vents.	P / F / NA	

B. Electrical Measurement Checklist

Check Item / Measurement	Result	Value/Notes
■ Protective earth resistance measured (Class I equipment) and within limit.	P / F / NA	
■ Insulation resistance measured and within limit.	P / F / NA	
■ Earth leakage current measured and within limit for the device's class.	P / F / NA	
■ Enclosure (touch) leakage current measured and within limit.	P / F / NA	
■ Patient leakage current measured for each applied part, appropriate to type B/BF/CF classification.	P / F / NA	
■ Patient auxiliary current measured where the device has multiple applied parts.	P / F / NA	
■ At least one relevant single-fault condition simulated where required by the test method (e.g. earth open, polarity reversed) and results recorded.	P / F / NA	

C. Functional Check & Documentation Checklist

Check Item / Measurement	Result	Value/Notes
■ Device powers on and completes self-test/boot sequence without error.	P / F / NA	
■ Core clinical function verified as operating correctly after electrical testing.	P / F / NA	
■ Alarm functions (if applicable) tested and confirmed audible/visible.	P / F / NA	
■ All measured values (not just pass/fail) recorded on the test form or CMMS.	P / F / NA	
■ Result compared against the previous test cycle to check for deteriorating trends.	P / F / NA	
■ Test label/tag applied with date, result, and next-due date.	P / F / NA	
■ Device classification (class/type) confirmed correct in the equipment record for future reference.	P / F / NA	

D. Test-After-Repair Additional Checklist

Check Item / Measurement	Result	Value/Notes
■ Scope of the repair/modification reviewed to identify which safety-relevant parts may be affected.	P / F / NA	
■ Full visual inspection and electrical measurement set repeated (not limited to the repaired component alone), since repair work can affect safety in unexpected ways.	P / F / NA	
■ Any replaced part confirmed to meet original specification (or a documented equivalent).	P / F / NA	
■ Functional check repeated, including alarms and safety interlocks.	P / F / NA	
■ Device tagged "do not use" and the clinical department notified if any test fails, until re-repair and re-test are completed.	P / F / NA	
■ Full result set (not just the final pass) filed in the equipment's service history for traceability.	P / F / NA	

Reminder: *this reference condenses widely-known general practice for orientation and field use. For authoritative pass/fail limits, test-equipment requirements, and single-fault-condition test methods, consult the current licensed IEC 62353 text directly, along with the specific device's manufacturer service manual and any applicable national deviation to the standard.*