

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Electrical safety in low voltage distribution systems up to 1 000 V AC and 1 500 V DC – Equipment for testing, measuring or monitoring of protective measures –

Part 16: Equipment for testing the effectiveness of the protective measures of electrical equipment and/or medical electrical equipment

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Sécurité électrique dans les réseaux de distribution basse tension au plus égale à 1 000 V en courant alternatif et 1 500 V en courant continu – Dispositifs de contrôle, de mesure ou de surveillance de mesures de protection –

Partie 16: Équipement pour les essais de bon fonctionnement des mesures de protection des appareils électriques et/ou des appareils électromédicaux



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CONTENTS

FOREWORD.....	4
INTRODUCTION.....	6
1 Scope.....	7
2 Normative references	7
3 Terms and definitions	8
4 Requirements	9
4.1 General requirements	9
4.2 Measuring functions.....	9
4.2.1 Minimum measuring function requirements	9
4.2.2 Measurement of the resistance of the protective bonding or the protective earth resistance.....	10
4.2.3 Measurement of insulation resistance	10
4.2.4 Measurement of protective conductor current or equipment leakage current with the alternative method	11
4.2.5 Measurement of touch current, patient leakage current and applied part leakage current with the alternative method	11
4.2.6 Measurement of protective conductor current and equipment leakage current with the direct or differential (residual) method	12
4.2.7 Measurement of touch current, patient leakage current and applied part leakage current with the direct or differential (residual) method	13
4.3 Construction requirements	13
4.3.1 Overvoltage capability	13
4.3.2 Terminals	13
4.3.3 Sockets for service purpose	14
4.3.4 Degree of protection	14
4.3.5 Class of protection.....	14
4.3.6 Overvoltage and measurement categories	14
4.3.7 Accessories	14
5 Markings and operating instructions	15
5.1 Markings	15
5.2 Operating instructions	15
6 Tests	15
6.1 General.....	15
6.2 Operating uncertainty.....	15
6.3 Tests of measuring circuits according to measuring functions	18
6.4 Test of construction requirements of test and measurement equipment.....	18
Annex A (normative) Measuring circuit MD	19
A.1 Current measuring circuit MD.....	19
A.2 Frequency characteristic of current measuring circuit MD	20
Bibliography.....	21
Figure A.1 – Current measuring circuit MD.....	19
Figure A.2 – Frequency characteristic of the current measuring circuit MD.....	20

Table 1 – Calculation of operating uncertainty for leakage measurements with direct or differential method	17
Table 2 – Compliance tests of measuring circuits according to measuring function	18
Table 3 – Compliance test of construction requirements of test and measuring equipment.....	18

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

**ELECTRICAL SAFETY IN LOW VOLTAGE DISTRIBUTION SYSTEMS
UP TO 1 000 V AC AND 1 500 V DC – EQUIPMENT FOR TESTING,
MEASURING OR MONITORING OF PROTECTIVE MEASURES –****Part 16: Equipment for testing the effectiveness of the protective
measures of electrical equipment and/or medical electrical equipment**

FOREWORD

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IEC 61557-16 has been prepared by IEC technical committee 85: Measuring equipment for electrical and electromagnetic quantities. It is an International Standard.

This second edition cancels and replaces the first edition published in 2014. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

- a) splitting of uncertainty requirements for medical and non-medical electrical equipment in 4.2.1;
- b) addition of a definition of ranges with defined uncertainty in 4.2.1 to 4.2.7;
- c) addition of an optional measuring device (MD) for non-medical devices in 4.2.1;

- d) addition of a limitation of the maximum intrinsic uncertainty for medical applications at leakage current in 4.2.1;
- e) change of 4.2.3 from test sockets to sockets for service purposes;
- f) addition of a warning in the operating instructions;
- g) integration of former 6.3 into 6.2;
- h) update of Table 1;
- i) alignment of the structure with that of the whole IEC 61557 series.

The text of this International Standard is based on the following documents:

Draft	Report on voting
85/876/FDIS	85/885/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

This International Standard is to be used in conjunction with IEC 61557-1:2019.

A list of all parts in the IEC 61557 series, published under the general title *Electrical safety in low voltage distribution systems up to 1 000 V AC and 1 500 V DC – Equipment for testing, measuring or monitoring of protective measures*, can be found on the IEC website.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

INTRODUCTION

This part of IEC 61557 defines performance requirements of measuring equipment intended for testing the effectiveness of the protective measures of either electrical equipment or medical electrical equipment, or both (in accordance with IEC 62353). It is the intention of this document to achieve comparable measuring results, additional safety for the person carrying out the testing, and non-damaging electrical stress for the unit under test.

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Part 16: Equipment for testing the effectiveness of the protective measures of electrical equipment and/or medical electrical equipment

1 Scope

This part of IEC 61557 specifies the requirements applicable to the performance for test and measurement equipment in order to determine the effectiveness of the protective measures for electrical equipment and/or medical electrical equipment described in IEC 62353.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60529, *Degrees of protection provided by enclosures (IP Code)*

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

IEC 60601-1:2005/AMD1:2012

IEC 60601-1:2005/AMD2:2020

IEC 61010-1:2010, *Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements*

IEC 61010-1:2010/AMD1:2016

IEC 61010-031, *Safety requirements for electrical equipment for measurement, control and laboratory use – Part 031: Safety requirements for hand-held and hand-manipulated probe assemblies for electrical test and measurement*

IEC 61010-2-030, *Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-030: Particular requirements for equipment having testing or measuring circuits*

IEC 61010-2-032, *Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-032: Particular requirements for hand-held and hand-manipulated current sensors for electrical test and measurement*

IEC 61010-2-034, *Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-034: Particular requirements for measurement equipment for insulation resistance and test equipment for electric strength*

IEC 61557-1:2019, *Electrical safety in low voltage distribution systems up to 1 000 V AC and 1 500 V DC – Equipment for testing, measuring or monitoring of protective measures – Part 1: General requirements*

IEC 61557-2, *Electrical safety in low voltage distribution systems up to 1 000 V AC and 1 500 V DC – Equipment for testing, measuring or monitoring of protective measures – Part 2: Insulation resistance*

IEC 61557-4, *Electrical safety in low voltage distribution systems up to 1 000 V AC and 1 500 V DC – Equipment for testing, measuring or monitoring of protective measures – Part 4: Resistance of earth connection and equipotential bonding*

IEC 61557-10, *Electrical safety in low voltage distribution systems up to 1 000 V AC and 1 500 V DC – Equipment for testing, measuring or monitoring of protective measures – Part 10: Combined measuring equipment for testing, measuring or monitoring of protective measures*

IEC 61557-13, *Electrical safety in low voltage distribution systems up to 1 000 V AC and 1 500 V DC – Equipment for testing, measuring or monitoring of protective measures – Part 13: Hand-held and hand-manipulated current clamps and sensors for measurement of leakage currents in electrical distribution systems*

IEC 62353:2014, *Medical electrical equipment – Recurrent test and test after repair of medical electrical equipment*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 61557-1, IEC 61557-2, IEC 61557-4, IEC 61557-10 and IEC 61557-13, and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- IEC Electropedia: available at <https://www.electropedia.org/>
- ISO Online browsing platform: available at <https://www.iso.org/obp>

3.1

test socket outlet

socket outlet on the test equipment that can be switched to either test-condition or supply condition

3.2

service socket

socket outlet on the test equipment to supply mains to further test equipment or additional equipment

3.3

measuring circuit MD

electric circuit with defined components and defined frequency characteristic

3.4

peak factor

ratio of the maximum absolute value of an alternating quantity to its RMS value

[SOURCE: IEC 60050-103:2017, 103-06-15, modified – Note to entry omitted.]

3.5

medical electrical equipment

ME equipment

electrical equipment having an applied part or transferring energy to or from the patient or detecting such energy transfer to or from the patient and which is:

- a) provided with not more than one connection to a particular supply mains, and
- b) intended by its manufacturer to be used:
 - in the diagnosis, treatment, or monitoring of a patient, or
 - for compensation or alleviation of disease, injury or disability

Note 1 to entry: ME equipment includes those accessories as defined by the manufacturer that are necessary to enable the normal use of the ME equipment.

Note 2 to entry: Not all electrical equipment used in medical practice falls within this definition (e.g. some in vitro diagnostic equipment).

Note 3 to entry: The implantable parts of active implantable medical devices can fall within this definition, but they are excluded from the scope of IEC 60601-1 by appropriate wording in IEC 60601-1:2005, Clause 1, IEC 60601-1:2005/AMD1:2012, Clause 1, and IEC 60601-1:2005/AMD2:2020, Clause 1.

[SOURCE: IEC 60601-1:2005, 3.63, modified – Notes 4 and 5 deleted.]

3.6

protective earth resistance

resistance between any accessible conductive part which has to be connected for safety purposes to the protective earth terminal and the

- protective connector of the mains plug, or
- protective connector of the appliance inlet, or
- protective conductor permanently connected to the supply mains;

resistance between protective connectors at each end of a detachable power supply cord

[SOURCE: IEC 62353:2014, 3.34]

4 Requirements

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4.1 General requirements

In addition to the requirements of IEC 61557-1:2019, Clause 4, the following requirements shall apply.

The requirements of IEC 62353:2014, Annex C shall apply for measuring equipment intended for medical electrical equipment testing.

Equipment intended for making measurements on electrical equipment shall be rated for minimum measurement category II in accordance with IEC 61010-2-030.

Insulation measurement equipment shall fulfil the safety requirements of IEC 61010-2-034.

Test leads and test probes used with the measuring equipment shall fulfil the requirements of IEC 61010-031.

4.2 Measuring functions

4.2.1 Minimum measuring function requirements

The measuring equipment shall be capable of measuring the following quantities as a minimum:

- resistance of protective bonding and/or protective earth resistance,
- insulation resistance,
- protective conductor current and/or equipment leakage current,
- touch current,

- applied part leakage current for measuring equipment intended for medical electrical equipment testing (IEC 62353).

The operating uncertainty for all measured parameters within the required ranges at the applicable limits according to IEC 62353 shall be $\pm 15\%$ at the maximum. For measurement of protective conductor current, equipment leakage current, touch current and applied part leakage current the operating uncertainty shall be determined at a frequency of 50/60 Hz. The frequency characteristic for higher frequency ranges is given by the MD circuit according to Figure A.1 and Figure A.2.

Leakage currents for medical electrical equipment shall be measured using a measuring circuit MD with the characteristics defined in Clause A.1 and Clause A.2. Leakage currents for non-medical electrical equipment may be tested using a measuring circuit MD in accordance with IEC 61010-1:2010, Clause A.1.

For medical electrical equipment, the maximum intrinsic uncertainty for leakage current measurements shall be $\pm 5\%$.

NOTE If the measuring equipment evaluates a limit, for example 3,5 mA, the maximum applicable uncertainty can be taken into account, for example $\pm 15\%$. This means that only measurements less than or equal to 2,97 mA can pass the test.

The operating uncertainty shall be determined in accordance with IEC 61557-1 with the influence quantities E_1 , E_2 , E_3 , E_9 modified, E_{11} , E_{12} , and, if applicable, E_{13} , E_{14} , E_{15} in accordance with IEC 61557-13.

4.2.2 Measurement of the resistance of the protective bonding or the protective earth resistance

The measuring equipment shall be in accordance with IEC 61557-4. The withstand capability against extraneous voltages is not required if the test and measurement equipment is not intended to be used on fixed installed or permanently connected equipment.

To prevent damage to the equipment under test it is recommended to select a test current not exceeding 1 A.

The measuring circuit shall be separated from the active parts of mains by double or reinforced insulation in accordance with IEC 61010-1. The protective conductor may be connected to the measuring circuit, but parallel earth connections shall be indicated and/or taken into account by the test and measurement equipment.

When external resistances are included in the calibration as a zero offset, this shall be indicated. The indication shall continue as long as the calibration is valid.

The measuring range shall include the values between 0,05 Ω and 1,99 Ω and the display shall have a minimum resolution of 0,01 Ω . Within the range of 0,1 Ω and 1,99 Ω , the measuring current shall not be less than 0,2 A and the operating uncertainty shall be within the limits of 4.2.1.

Continuous measurements shall be possible for measuring currents below 5 A. For higher test currents, limiting the test duration is allowed.

4.2.3 Measurement of insulation resistance

The measuring equipment shall be in accordance with IEC 61557-2. The withstand capability against extraneous voltages is not required if the test and measurement equipment is not intended to test fixed installed or permanently connected equipment.

The measuring range shall include the values between 100 k Ω and 100 M Ω and the display shall have a minimum resolution of 0,1 M Ω . The operating uncertainty shall be within the limits of 4.2.1. If the test and measurement equipment is not intended to test applied parts type F in accordance with IEC 62353, the measuring range can be limited to 10 M Ω .

The measuring circuit shall be separated from the active parts of mains by double or reinforced insulation in accordance with IEC 61010-1. The protective conductor may be connected to the measuring circuit.

4.2.4 Measurement of protective conductor current or equipment leakage current with the alternative method

The alternative method shows values of the leakage current calculated using the test voltage generated by the measuring equipment.

If the test and measurement equipment include the alternative method, the requirements for the measuring circuit (in the following dashed list) shall apply:

- sinusoidal test voltage at mains frequency, total harmonic distortion (THD) shall not exceed 5 %;
- open circuit test voltage between 25 V and 250 V. If test and measurement equipment is specified in accordance with IEC 62353 the test voltage shall be equal to the nominal mains supply voltage;
- minimum resolution 0,01 mA;
- measuring resistance of up to 1 k Ω (up to 2 k Ω if it is intended for the testing of non-medical electrical equipment only);
- output current limited to 3,5 mA for test voltages above 50 V;
- scaling of the measured results up to the nominal mains voltage;
- minimum current measuring range 0,02 mA and 19,99 mA.

If the test and measurement equipment is intended for tests on non-medical electrical equipment only, the lower limit of the measuring range may be increased to 0,2 mA and the resolution decreased to 0,1 mA.

The operating uncertainty or intrinsic uncertainty for the range of 0,02 mA or 0,2 mA up to 19,99 mA shall fulfil the requirements of 4.2.1.

The measuring circuit shall be separated from the active parts of mains by double or reinforced insulation in accordance with IEC 61010-1. The protective conductor may be connected to the measuring circuit.

4.2.5 Measurement of touch current, patient leakage current and applied part leakage current with the alternative method

If the test and measurement equipment include the alternative method, the requirements for the measuring circuit in the following dashed list shall apply:

- sinusoidal test voltage at mains frequency,
- open circuit test voltage between 25 V and 250 V. If test and measurement equipment is specified in accordance with IEC 62353 the test voltage shall be equal to the nominal mains supply voltage,
- minimum resolution 0,001 mA,
- measuring resistance of up to 1 k Ω (up to 2 k Ω if it is intended for the testing of non-medical electrical equipment only),
- output current limitation to 3,5 mA for test voltages above 50 V,
- scaling of the measured results up to the nominal mains voltage,
- scaled minimum current measuring range between 0,02 mA and 19,99 mA.