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REDLINE VERSION

INTERNATIONAL STANDARD

colour inside

GROUP SAFETY PUBLICATION

Safety of transformers, reactors, power supply units and combinations thereof – Part 2-15: Particular requirements and tests for isolating transformers for medical IT systems for the supply of medical locations

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INTERNATIONAL
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COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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SAFETY OF TRANSFORMERS, REACTORS, POWER SUPPLY UNITS AND COMBINATIONS THEREOF –

Part 2-15: Particular requirements and tests for isolating transformers for medical IT systems for the supply of medical locations

FOREWORD

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This redline version of the official IEC Standard allows the user to identify the changes made to the previous edition IEC 61558-2-15:2011. A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text.

IEC 61558-2-15 has been prepared by IEC technical committee 96: Transformers, reactors, power supply units and combinations thereof. It is an International Standard.

This third edition cancels and replaces the second edition published in 2011. This edition constitutes a technical revision.

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

a) Adjustment of structure and references in accordance with IEC 61558-1:2017;

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

Draft	Report on voting
96/535/FDIS	96/536/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/standardsdev/publications.

It has the status of a group safety publication in accordance with IEC Guide 104.

This International Standard is to be used in conjunction with IEC 61558-1:2017.

NOTE When “Part 1” is mentioned in this standard, it refers to IEC 61558-1:2017.

This document supplements or modifies the corresponding clauses in IEC 61558-1:2017, so as to convert that publication into the IEC standard: *Particular requirements and tests for isolating transformers for medical IT systems for the supply of medical locations.*

A list of all parts in the IEC 61558 series published under the general title *Safety of transformers, reactors, power supply units and combinations thereof,* can be found on the IEC website.

Future standards in this series will carry the new general title as cited above. Titles of existing standards in this series will be updated at the time of the next edition.

Where this document states "*addition*", "*modification*" or "*replacement*", the relevant text of IEC 61558-1:2017 is to be adapted accordingly.

In this document, the following print types are used:

– requirements proper: in roman type;
– *test specifications: in italic type*;
– explanatory matter: in smaller roman type.

In the text of this document, the words in **bold** are defined in Clause 3.

Subclauses, notes, figures and tables additional to those in IEC 61558-1:2017 are numbered starting from 101; supplementary annexes are entitled AA, BB, etc.

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.

IMPORTANT – The "colour inside" logo on the cover page of this document indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

INTRODUCTION

IEC TC 96 has a group safety function in accordance with IEC Guide 104 for transformers other than those intended to supply distribution networks, in particular transformers and power supply units intended to allow the application of protective measures against electric shock as defined by TC 64, but in certain cases including the limitation of voltage and horizontal safety function for SELV, in accordance with IEC 60364-4-41.

The group safety function (GSF) is necessary because of responsibility for safety extra-low voltage (SELV) in accordance with IEC 61140:2016, 5.2.6 and IEC 60364-4-41:2005, 414.3.1 or control circuits in accordance with IEC 60204-1:2016, 7.2.4.

The group safety function is needed for each part of IEC 61558-2 because different standards of the IEC 61558 series can be combined in one construction but in certain cases with no limitation of rated output power.

For example an auto-transformer in accordance with IEC 61558-2-13 can be designed with a separate SELV-circuit in accordance with the particular requirements for IEC 61558-2-6 relating to the general requirements of IEC 61558-1.

SAFETY OF TRANSFORMERS, REACTORS, POWER SUPPLY UNITS AND COMBINATIONS THEREOF –

Part 2-15: Particular requirements and tests for isolating transformers for medical IT systems for the supply of medical locations

1 Scope

Replacement

This part of IEC 61558 deals with safety ~~aspects~~ of **isolating transformers for medical IT systems for the supply of medical locations.**

NOTE 1 Safety includes electrical, thermal and mechanical aspects.

Unless otherwise specified, from here onward, the term **transformer** covers **isolating transformers for medical IT systems for the supply of medical locations.**

This document is applicable to **stationary**, single-phase or three-phase, air-cooled (natural or forced) ~~**independent**~~ **dry-type isolating transformers** for the supply of **medical IT** ~~systems~~ **system** for group 2 medical locations, designed to be permanently connected to the fixed wiring and intended to form the **medical IT** ~~power~~ **system** on the secondary side. The windings ~~may~~ can be encapsulated or non-encapsulated.

NOTE 2 **IT** ~~power~~ **systems** are defined in IEC 60364-1.

~~NOTE 3~~ The installation rules for **medical IT** ~~systems~~ **system** for group 2 medical locations are covered by IEC 60364-7-710.

NOTE 3 National installation rules of some countries have different or additional requirements listed in Annex C of IEC 60364-7-710:2021.

~~NOTE 4~~ **Transformers** covered by this document are intended for **medical IT systems for the supply of medical locations**. All other **transformers** or equipment~~s connected downstream from the **transformer**~~ are not covered by this document.

The **rated supply voltage** does not exceed 1 000 V AC. The **rated supply frequency** and **internal operational frequency** do not exceed 500 Hz.

The **rated output** is not less than 0,5 kVA and does not exceed 10 kVA for single-phase and three-phase **transformers** for **medical IT system** for group 2 medical locations.

This document ~~is~~ can be applicable to **isolating transformers** intended to supply other medical installations that are not group 2 medical locations without limitation of the **rated output** subject to an agreement between the purchaser and the manufacturer.

NOTE ~~5~~4 **Transformers** intended to supply ~~power to~~ distribution networks other than **medical IT systems** are not included in the scope.

The **no-load output voltage** and the **rated output voltage** does not exceed 250 V AC for single-phase or three-phase **transformer** (phase-to-phase voltage).

This document does not cover **power supply units**.

This document is not applicable to external circuits and their components intended to be connected to the input terminals and output terminals of the **transformers**.

Transformers covered by this document are used in applications where **double or reinforced insulation** between circuits is required by the installation rules or by the appliance specification.

~~NOTE 6~~ Attention is drawn to the following, if necessary:

– additional requirements for **transformers** intended to be used in vehicles, on board ships, and aircraft ~~, additional requirements~~ (from other applicable standards, national rules, etc. ~~may be necessary~~);

– measures to protect the **enclosure** and the components inside the **enclosure** against external influences such as fungus, vermin, termites, solar-radiation, and icing ~~should also be considered~~;

– the different conditions for transportation, storage, and operation of the **transformers** ~~should also be considered~~;

– additional requirements in accordance with other appropriate standards and national rules may be applicable to **transformers** intended for use in special environments.

This group safety publication focusing on safety guidance is primarily intended to be used as a product safety standard for the products mentioned in the scope, but is also intended to be used by TCs in the preparation of publications for products similar to those mentioned in the scope of this group safety publication, in accordance with the principles laid down in IEC Guide 104 and ISO/IEC Guide 51.

One of the responsibilities of a TC is, wherever applicable, to make use of BSPs and/or GSPs in the preparation of its publications.

2 Normative references

This clause of Part 1 is applicable except as follows:

Addition

IEC 61558-1:~~2005~~2017, ~~*Safety of power transformers, power supplies, reactors and similar products*~~ *Safety of transformers, reactors, power supply units and combinations thereof – Part 1: General requirements and tests*

3 Terms and definitions

~~This clause of Part 1 is applicable, except as follows:~~

For the purposes of this document, the terms and definitions given in Part 1 apply, except as follows:

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

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

Addition

3.1.101
isolating transformer for medical IT systems for the supply of medical locations
isolating transformer used for the supply of **medical IT** ~~systems~~ **system** for group 2 medical locations, designed to be permanently connected and with **double** or **reinforced insulation** between each part of the transformer (body, screen, circuits, thermal sensitive device) except between the core and the **body**

3.2.101
medical IT system
electric IT system fulfilling all specific additional requirements of group 2 medical locations

[SOURCE: IEC 60364-7-710:2021, 710.3.10, modified – Note 1 to entry has been deleted.]

3.5.101
rated input current
~~unput~~ input current assigned to the transformer by the manufacturer, when the **transformer** is loaded with **rated output**

3.6.101
no-load input current
input current when the **transformer** is connected to the **rated supply voltage**, at the **rated supply frequency**, with no-load on the output

3.6.10~~1~~2
inrush current
maximum instantaneous value of the **no-load input current** of the **transformer** (peak value) when the **transformer** is switched on at **rated supply voltage**

3.~~4~~7.101
functional screening
separation between two windings or between a winding and the core or shielding of a part or of the whole **transformer**, by means of an interposed conductive screen for functional reasons

4 General requirements

This clause of Part 1 is applicable.

5 General notes on tests

This clause of Part 1 is applicable.

6 Ratings

This clause of Part 1 is applicable except as follows:

~~Replacement~~ Addition

6.101 The **rated output voltage** ~~(phase-to-phase voltage)~~ shall not exceed 250 V AC for single-phase or three-phase **transformers** (phase-to-phase voltage).

6.102 The **rated output** shall not be less than 0,5 kVA and shall not exceed 10 kVA for single-phase or three-phase **transformers**.

Transformers intended to supply other medical installations that are not group 2 medical locations without limitation of the **rated output** shall be subject to an agreement between the purchaser and the manufacturer.

6.103 The rated frequency and internal operational frequency shall not exceed 500 Hz.

6.104 The **rated supply voltage** shall not exceed 1 000 V AC.

Compliance with the requirements of 6.101 to 6.104 shall be ~~verified~~ checked by inspection of the marking.

7 Classification

This clause of Part 1 is applicable, except as follows:

Replacement

7.2 ~~*Replacement:*~~

~~According to short-circuit protection or protection against abnormal conditions:~~

~~– **non-short-circuit proof transformer**.~~

Transformers shall be **non-short-circuit proof transformers** in accordance with the short-circuit characteristic or protection against abnormal use.

7.4

Transformers shall be **stationary transformers**.

7.5

Transformers shall be classified for **continuous duty**.

7.8

Transformers shall be classified for **overvoltage category III**.

8 Marking and other information

This clause of Part 1 is applicable except as follows:

8.1 h)

Replacement

~~Replace the first sentence by the following: Relevant graphical symbols shown in 8.11 indicating the type of **transformer;**~~

Replace the content up to the first semi-colon by the following:

relevant graphical symbols shown in Table 101 that indicate the kind of **transformer**

~~t) *Addition:*~~

~~**Transformers** shall be marked with the measured **short-circuit voltage** expressed as a percentage of the **rated supply voltage**.~~

8.1 s)

Replacement

Transformers shall be marked with the measured **short-circuit voltage** expressed as a percentage of the **rated supply voltage**.

Addition

8.1.101 When the **inrush current** exceeds 8 times the peak value of the **rated input current**, the resulting value shall be marked on the transformer.

8.6

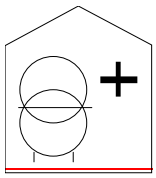
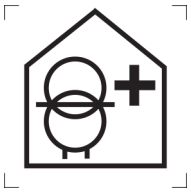
Addition

All terminals shall be clearly marked.

8.11

Addition

Table 101 – Symbols indicating the kind of transformer

Symbol or graphical symbol	Explanation or title	Identification
	~~non-short-circuit proof **isolating transformer** for the supply of medical locations~~	~~IEC 60417-5972 (DB 2010-08)~~
	Non-short-circuit proof **isolating transformers for medical IT systems for the supply of group 2 medical locations** NOTE This symbol is not applicable for **transformers** > 10 kVA	IEC 60417-5972:2003-08

8.14

Addition

The instruction sheet shall state: "Screens whose connection to the earthing is necessary for compliance with the leakage current requirements of Clause 18 shall be connected to the earthing."

~~The instruction sheet shall qualify the type of temperature sensor built in the transformer, if any. The instruction sheet shall give the required value of the circuit of the transformer, when it is allowed by national installation rules.~~

The instruction sheet shall include type and characteristic of sensor to over-temperature monitoring, if any.

The **rated input current** shall be provided as information given either on the transformer marking or made available in the manufacturer's catalogue or similar.

9 Protection against electric shock

This clause of Part 1 is applicable.

10 Change of input voltage setting

This clause of Part 1 is applicable.

11 Output voltage and output current under load

This clause of Part 1 is applicable.

12 No-load output voltage

This clause of Part 1 is applicable except as follows:

Addition

~~The **no-load output voltage** shall be measured when the **transformer** is connected to the **rated supply voltage** at the **rated supply frequency** and at the **rated ambient temperature**.~~

12.101 The **no-load output voltage** (phase-to-phase voltage) shall not exceed 250 V AC for single-phase or three-phase **transformers**.

12.102 The difference between the **no-load output voltage** and the **output voltage** under load shall not be excessive.

~~The difference is expressed as a percentage of the latter voltage calculated according to the following formula:~~

$$\frac{V_{\text{no-load}} - V_{\text{load}}}{V_{\text{load}}} \times 100 \ (\%)$$

~~where $V_{\text{no-load}}$ is the **no-load output voltage** and V_{load} is the output voltage under load.~~

~~*Compliance with the requirements of 12.101 and 12.102 shall be verified by measuring the **no-load output voltage** and output voltage under load, at the **rated ambient temperature** when the **transformer** is connected to the **rated supply voltage** at the **rated supply frequency**.*~~

~~*The difference between the **no-load output voltage** and the output voltage under load shall not exceed 5 %.*~~

*The ratio between the **no-load output voltage** measured in Clause 12 and the **output voltage** under load measured during the test of Clause 11, expressed as a percentage of the latter voltage, shall not exceed 5 %.*

The ratio is determined by Formula (1):

$$\frac{U_{\text{no-load}} - U_{\text{load}}}{U_{\text{load}}} \times 100(\%) \qquad (1)$$

where

$U_{no\text{-}load}$ is the no-load output voltage, expressed in V;

U_{load} is the no-load output voltage, expressed in V.

Compliance with the requirements of 12.101 and 12.102 is checked by measuring the ***no-load output voltage*** *at the* ***ambient temperature*** *when the* ***transformer*** *is connected to* ***the rated supply voltage*** *at the* ***rated supply frequency****.*

13 Short-circuit voltage

This clause of Part 1 is not applicable.

Replacement

13 Short-circuit voltage and inrush currents

13.1 The **short-circuit voltage** shall be measured and marked on the **transformer**.

Compliance shall be ~~verified~~ checked by measurement.

13.2 The **no-load input current** shall not exceed 3 % of the **rated input current** at the **rated supply voltage**.

This requirement shall be fulfilled by construction of the **transformer** without the use of any capacitors in the **transformer** circuits (input/output) or in the installation.

Compliance shall be ~~verified~~ checked by measurements.

13.3 The **inrush current** shall not exceed 8 times the peak value of the **rated input current**. However, it is allowed to increase this value to 12 times the peak value of **rated input current** ~~provided~~**,** if the latter value ~~shall be reflected~~ is marked on the **transformer** ~~marking~~.

This requirement shall be fulfilled by construction of the **transformer** without the use of any electronic devices and additional measures in the **transformer** or in the installation.

Compliance shall be ~~verified~~ checked by the following test:

The ***transformer*** *with no-load operation is connected to the* ***rated supply voltage****. The test supply voltage is then switched on and off 20 times at random intervals of approximately 20 s.*

~~NOTE~~ *The on-off switching ~~on and off~~ may be carried out only twice, if a device is used to switch on at the most unfavourable electrical angle of the supply voltage.*

The voltage drop of the supply source shall ~~be such that the voltage drop does~~ not exceed 2 % as a result of the ***inrush current****.*

The ***inrush current*** *shall not exceed 8 times or 12 times the peak value of the* ***rated input current****~~, respectively,~~ during any of the switching ~~events~~ operations.*

14 Heating

This clause of Part 1 is applicable, except as follows:

Addition

14.101 Immediately after the test ~~of~~ in accordance with 14.1 an additional heating test is required with 150 % of the load for 30 min. After the test the temperature shall not exceed the values of Table ~~1~~ 2 increased by 25 %.

15 Short-circuit and overload protection

This clause of Part 1 is applicable, except as follows:

~~*Addition:*~~

~~**Isolating transformers for the supply of medical locations** are **non-short-circuit proof transformers**. The overload must be monitored by a temperature monitoring system. The test of 15.3 of Part 1 will be carried out. When the circuit breaker is allowed by national installation rules the value for a circuit-breaker shall be mentioned in the instruction sheet.~~

15.1 Short circuit and overload test method

Replacement

Transformers shall be **non-short-circuit proof transformers**.

15.4 Non-short-circuit proof transformers

Addition

The overload shall be monitored by an overload current and over-temperature monitoring warning system.

NOTE 1 For information about monitoring of overload and over-temperature of i**solating transformers for medical IT system** see Annex B of IEC 61557-8:2014.

NOTE 2 In some countries a circuit breaker is allowed by national installation rules.

NOTE 3 In Spain, monitoring of overload and over-temperature is not required.

16 Mechanical strength

This clause of Part 1 is applicable.

17 Protection against harmful ingress of dust, solid objects and moisture

This clause of Part 1 is applicable.

18 Insulation resistance, dielectric strength and leakage current

This clause of Part 1 is applicable, except as follows:

18.2 Insulation resistance

~~Table 7: *Replacement of the 6th and 7th lines by the following:*~~

Replacement:

Replace the 6th and 7th lines of Table 13 by the following three new lines:

Insulation to be tested	Insulation resistance MΩ
Between each **input circuit** and all other **input circuits** connected together	7
Between each **output circuit** and all other **output circuits** connected together	7
Between **input** and **output circuits** (double reinforced insulation)	7

Addition

NOTE In Australia, higher insulation resistance values are required.

18.3 Dielectric strength test

~~Table 8a: *Addition:*~~

Addition

In addition, the dielectric strength tests according to Table 102 shall be performed.

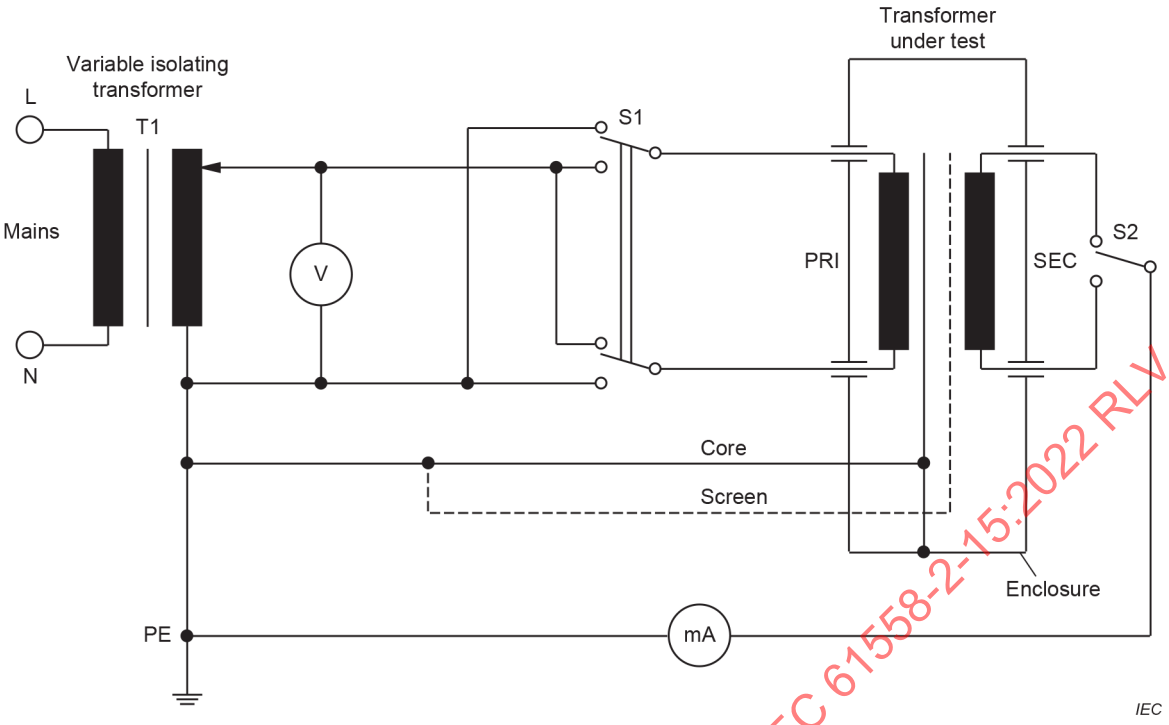
Table 102 – Additional dielectric strength test voltages

Application of dielectric strength test voltage	Working voltage V					
	< 50	**100**	**150**	**300**	**600**	**1 000**
Between **live parts** of adjacent **input circuits** not intended to be connected together	500	1 400	2 800	4 200	5 000	5 500
Between **live parts** of adjacent **output circuits** not intended to be connected together	500	1 400	2 800	4 200	5 000	5 500

Addition

18.101 The leakage current of the **output winding** to the earthing shall not exceed 0,5 mA, when measured under the no-load condition, and at the room temperature with the **transformer** supplied at the **rated voltage** and the **rated frequency**, as shown in Figure 101.

For this test the core and the **functional screen**, if any, shall be connected to the earthing.



The test shall be carried out with all combinations of S1 and S2.

For three-phase **transformers** the switch S1 is used only in closed position. The measurements with switch S2 are repeated connecting it, in turn, to all phases.

The current is measured with an ammeter of negligible impedance.

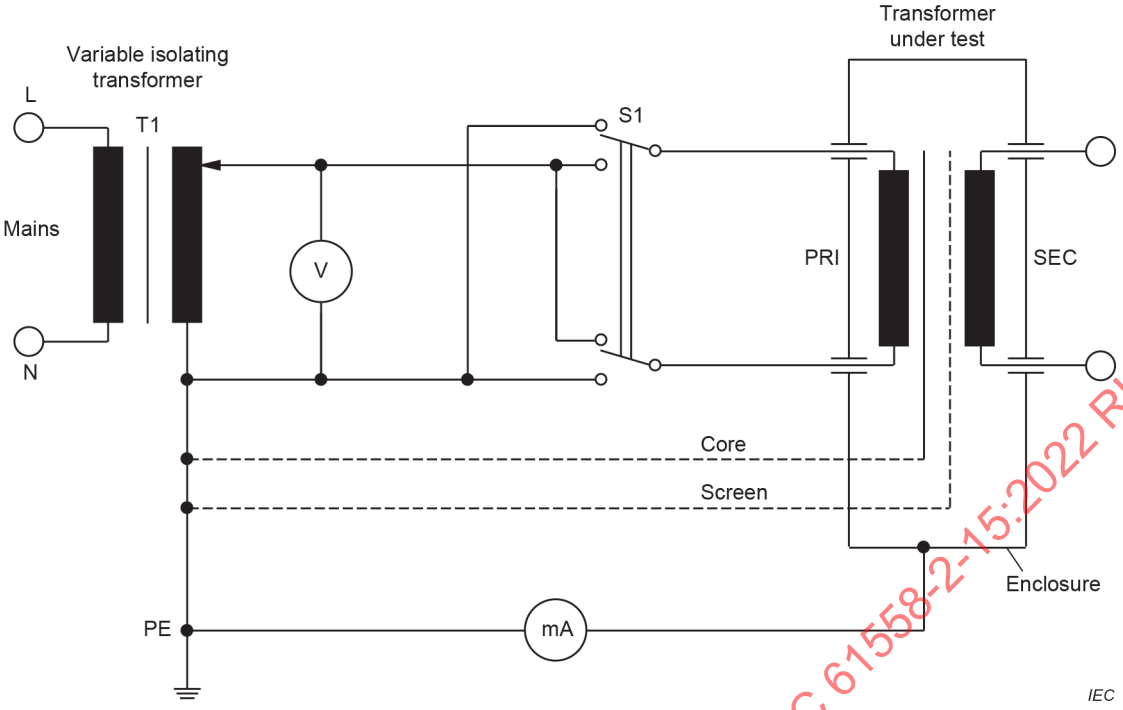
NOTE 1 In Japan, the **leakage current** of the **output winding** is limited to 0,1 mA maximum.

NOTE 2 In Australia, additional leakage current limits apply.

Figure 101 – Required circuit for measuring the leakage current from the output winding to the earthing

Compliance shall be ~~verified~~ checked by measurements.

18.102 The leakage current through the protective earthing conductor from the enclosure to the earthing, shall not exceed 0,5 mA when measured at room temperature under no-load condition with the transformer supplied at the **rated voltage** and the **rated frequency** as shown in Figure 102.



The test shall be carried out with all combinations of S1.

For three-phase **transformers** the switch S1 is used only in closed position.

The current is measured with an ammeter of negligible impedance.

The core, if not connected to the enclosure, and the functional screen, if any, shall be connected to earth.

Figure 102 – Required circuit for measuring the leakage current at the protective earthing conductor

Compliance shall be ~~verified~~ checked by measurements.

19 Construction

This clause of Part 1 is applicable, except as follows:

Replacement of 19.1 (19.1.1 to 19.1.4.10) by the following

19.1 The **input** and **output circuits** shall be electrically separated from each other and the construction shall be such that there is no possibility of any connection between these circuits, either directly or indirectly, via other **conductive parts**, except by deliberate action.

Compliance is checked by inspection and measurements, taking Clauses 18 and 26 into consideration.

19.1.101 The insulation between the **input** and **output winding(s)** shall consist of **double** or **reinforced insulation** (rated for the **working voltage**). The insulation between the **input winding(s)** and the **body**, and between the **output winding(s)** and the **body**, shall consist of **double** or **reinforced insulation** (rated for the **working voltage**).

19.1.101.1 When the **input winding(s)** are not intended to be connected in series or parallel, they shall be separated from ~~one another~~ each other and from other circuits by **double** or **reinforced insulation** (rated for the **working voltage**).

The **input winding(s)**, intended to be connected in series or parallel, may be separated from each other by **basic insulation** (rated for the **working voltage**).

19.1.101.2 The **output winding(s)** shall be separated from each other and from other circuits by **double** or **reinforced insulation** (rated for the **working voltage**).

19.1.101.3 The **functional screening**, if any, shall be separated from the core, the windings and from the **body** by **double** or **reinforced insulation** (rated for the **working voltage**).

19.1.101.4 If the **transformers** are provided with a **functional screening** placed between the **input** and the **output windings**, the **functional screening** shall be constructed of a metal foil so that the adjacent turns overlap without short-circuiting. The lead out of the **functional screening** shall be provided with separate terminals.

For concentric windings, the width of the **functional screening** shall be approximately equal to the axial winding length of the **input winding**. For non-concentric windings, the width of the **functional screening** shall be approximately equal to the radial winding length of the **input winding**. If the **functional screening** is constructed of only one turn it shall be provided with an insulated overlap of not less than 3 mm.

19.1.102 For **transformers** with **intermediate conductive parts** (e.g. the iron core) not connected to the **body** and located between the **input** and **output windings**, the insulation between the **intermediate conductive parts** and the **input windings,** and between the **intermediate conductive parts** and the **output windings** shall consist of at least **basic insulation** (rated for the **working voltage**).

~~NOTE~~ An **intermediate conductive part** not separated from the **input** or **output windings** or the **body** by at least basic insulation is considered to be connected to the relevant part(s).

The insulation between the **input** and **output windings** via the **intermediate conductive part** shall consist of **double** or **reinforced insulation;** the insulation between the **input windings** and the **body**, and between the **output windings** and the **body**, via the **intermediate conductive part** shall consist of **double** or **reinforced insulation** (rated for the **working voltage**).

19.1.103 **Transformers** shall not be provided with capacitors ~~electrically connecting the **input** and the **output circuits**~~ and/or resistors.

Compliance shall be ~~verified~~ checked by inspection.

19.1.104 The input and output terminals for the connection of external wiring shall be so located that the distance measured between the points of introduction of the conductors into these terminals is not less than 25 mm. If a barrier is used to obtain this distance, the measurement shall be made over and around the barrier which shall be of insulating material and permanently fixed to the **transformer**.

*Compliance shall be ~~verified~~ checked by inspection and by measurement, disregarding the **intermediate conductive parts**.*

19.1.105 If the monitoring of the over-temperature in accordance with 15.4 is required, the thermal sensitive device (bimetal, PTC or similar) shall be built-in and shall be connected to separate terminals for external connections.

NOTE The terminals are intended to connect the ~~temperature~~ thermal sensitive device to ~~an acoustical and optical temperature monitoring device~~ visual indicators and/or audible signal located in the medical location and intended to warn the medical staff.

The ~~temperature~~ thermal sensitive device shall be rated to the class of the insulation system minus 10 °C.

19.1.106 If a single-phase **transformer** is provided with a midpoint in the **output winding,** it shall be connected to a separate terminal.

19.1.107 Three-phase **transformers** shall be provided with the vector group star-star or star-delta design.

19.1.108 The star point of the **output winding** in three-phase **transformers** with vector group star-star design shall be connected to a separate terminal.

NOTE The terminal is intended for connection to an external medical insulation monitoring device (MED-IMD) in accordance with IEC 61557-8, if applicable.

19.1.109 The star point of the **input winding** in three-phase **transformers** with vector group star-star or star-delta design shall be connected to a separate terminal.

NOTE The terminal is intended for connection to the neutral point of the supply in order to allow asymmetrical loading.

~~**19.1.110 Isolating transformers for the supply of medical locations** shall be **stationary transformers**.~~

20 Components

This clause of Part 1 is applicable, except as follows:

~~**20.3** *Replacement:*~~

~~Socket-outlets are not allowed to connect the **output circuit** of the **transformer** to the electrical installation of the medical room.~~

20.6

Replacement

Socket-outlets shall not be directly connected to the **output circuit** of the **transformer** without appropriate protection in accordance with the corresponding installation rules.

21 Internal wiring

This clause of Part 1 is applicable.

22 Supply connection and other external flexible cable or cords

This clause of Part 1 is applicable, except as follows:

22.3

Addition

22.3.101 **Transformers** shall be designed for permanent connection.

22.4 to 22.7 ~~This subclause of Part 1 is not applicable.~~

~~**Isolating transformers for the supply of medical locations** shall be designed for permanent connection.~~

Subclauses 22.4 to 22.7 are not applicable.

23 Terminals for external conductors

This clause of Part 1 is applicable.

24 Provisions for protective earthing

This clause of Part 1 is applicable.

25 Screws and connections

This clause of Part 1 is applicable.

26 Creepage distances, clearances and distances through insulation

This clause of Part 1 is applicable.

27 Resistance to heat, fire and tracking

This clause of Part 1 is applicable.

28 Resistance to rusting

This clause of Part 1 is applicable.

Annexes

The Annexes of Part 1 are applicable, except as follows:

Annex H
(normative)

Electronic circuits

This Annex of Part 1 is not applicable.

Annex L
(normative)

Routine tests (production tests)

This Annex of Part 1 is applicable, except as follows:

Addition

L.101 Checking of the **short-circuit voltage**

The **short-circuit voltage** shall not exceed the marked value.

L.102 Checking of the **no-load input current**

The **no-load input current** shall not exceed 3 % of the **rated input current**.

L.103 Checking of the **inrush current**

The inrush current shall not exceed 8 times the peak value of the **rated input current** or the marked value on the label, if any.

Compliance is checked by Subclause 13.103.

Bibliography

The Bibliography of Part 1 is applicable, except as follows:

Addition

IEC 61558 (all parts), *Safety of transformers, reactors, power supply units and combinations thereof*

IEC 60364-1:2005, *Low-voltage electrical installations – Part 1: Fundamental principles, assessment of general characteristics, definitions*

IEC 60364-4-41:2005, *Low-voltage electrical installations – Part 4-41: Protection for safety – Protection against electric shock*

IEC 60364-5-53:2019, *Low-voltage electrical installations ~~of buildings~~ – Part 5-53: Selection and erection of electrical equipment – Devices for protection for safety, isolation, switching, control and monitoring*

IEC 60364-7-710:~~2002~~2021, *Low-voltage electrical installations ~~of buildings~~ – Part 7-710: Requirements for special installations or locations – Medical locations*

IEC 61557-8:~~2007~~2014, *Electrical safety in low voltage distribution systems up to 1 000 V a.c. and 1 500 V d.c. – Equipment for testing, measuring or monitoring of protective measures – Part 8: Insulation monitoring devices for IT systems*

ISO/IEC Guide 51:2014, *Safety aspects – Guidelines for their inclusion in standards*

IEC Guide 104:2019, *The preparation of safety publications and the use of basic safety publications and group safety publications*

~~Index of defined terms~~

~~The index of Part 1 is applicable, except as follows:~~

~~*Addition:*~~

IEC 61558-2-15

Edition 3.0 2022-05

INTERNATIONAL STANDARD

NORME INTERNATIONALE

GROUP SAFETY PUBLICATION
PUBLICATION GROUPÉE DE SÉCURITÉ

Safety of transformers, reactors, power supply units and combinations thereof – Part 2-15: Particular requirements and tests for isolating transformers for medical IT systems for the supply of medical locations

Sécurité des transformateurs, bobines d'inductance, blocs d'alimentation et des combinaisons de ces éléments – Partie 2-15: Exigences particulières et essais pour les transformateurs de séparation de circuits pour schémas IT médicaux pour l'alimentation des locaux à usages médicaux

IEC 61558-2-15:2022-05(en-fr)

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

SAFETY OF TRANSFORMERS, REACTORS, POWER SUPPLY UNITS AND COMBINATIONS THEREOF –

Part 2-15: Particular requirements and tests for isolating transformers for medical IT systems for the supply of medical locations

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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IEC 61558-2-15 has been prepared by IEC technical committee 96: Transformers, reactors, power supply units and combinations thereof. It is an International Standard.

This third edition cancels and replaces the second edition published in 2011. This edition constitutes a technical revision.

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

a) Adjustment of structure and references in accordance with IEC 61558-1:2017;

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

Draft	Report on voting
96/535/FDIS	96/536/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/standardsdev/publications.

It has the status of a group safety publication in accordance with IEC Guide 104.

This International Standard is to be used in conjunction with IEC 61558-1:2017.

NOTE When “Part 1” is mentioned in this standard, it refers to IEC 61558-1:2017.

This document supplements or modifies the corresponding clauses in IEC 61558-1:2017, so as to convert that publication into the IEC standard: *Particular requirements and tests for isolating transformers for medical IT systems for the supply of medical locations.*

A list of all parts in the IEC 61558 series published under the general title *Safety of transformers, reactors, power supply units and combinations thereof,* can be found on the IEC website.

Future standards in this series will carry the new general title as cited above. Titles of existing standards in this series will be updated at the time of the next edition.

Where this document states "*addition*", "*modification*" or "*replacement*", the relevant text of IEC 61558-1:2017 is to be adapted accordingly.

In this document, the following print types are used:

– requirements proper: in roman type;
– *test specifications: in italic type*;
– explanatory matter: in smaller roman type.

In the text of this document, the words in **bold** are defined in Clause 3.

Subclauses, notes, figures and tables additional to those in IEC 61558-1:2017 are numbered starting from 101; supplementary annexes are entitled AA, BB, etc.

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

IEC TC 96 has a group safety function in accordance with IEC Guide 104 for transformers other than those intended to supply distribution networks, in particular transformers and power supply units intended to allow the application of protective measures against electric shock as defined by TC 64, but in certain cases including the limitation of voltage and horizontal safety function for SELV, in accordance with IEC 60364-4-41.

The group safety function (GSF) is necessary because of responsibility for safety extra-low voltage (SELV) in accordance with IEC 61140:2016, 5.2.6 and IEC 60364-4-41:2005, 414.3.1 or control circuits in accordance with IEC 60204-1:2016, 7.2.4.

The group safety function is needed for each part of IEC 61558-2 because different standards of the IEC 61558 series can be combined in one construction but in certain cases with no limitation of rated output power.

For example an auto-transformer in accordance with IEC 61558-2-13 can be designed with a separate SELV-circuit in accordance with the particular requirements for IEC 61558-2-6 relating to the general requirements of IEC 61558-1.

SAFETY OF TRANSFORMERS, REACTORS, POWER SUPPLY UNITS AND COMBINATIONS THEREOF –

Part 2-15: Particular requirements and tests for isolating transformers for medical IT systems for the supply of medical locations

1 Scope

Replacement

This part of IEC 61558 deals with safety of **isolating transformers for medical IT systems for the supply of medical locations.**

NOTE 1 Safety includes electrical, thermal and mechanical aspects.

Unless otherwise specified, from here onward, the term **transformer** covers **isolating transformers for medical IT systems for the supply of medical locations.**

This document is applicable to **stationary**, single-phase or three-phase, air-cooled (natural or forced) **dry-type isolating transformers** for the supply of **medical IT system** for group 2 medical locations, designed to be permanently connected to the fixed wiring and intended to form the **medical IT system** on the secondary side. The windings can be encapsulated or non-encapsulated.

NOTE 2 **IT systems** are defined in IEC 60364-1.

The installation rules for **medical IT system** for group 2 medical locations are covered by IEC 60364-7-710.

NOTE 3 National installation rules of some countries have different or additional requirements listed in Annex C of IEC 60364-7-710:2021.

Transformers covered by this document are intended for **medical IT systems for the supply of medical locations**. All other **transformers** or equipment are not covered by this document.

The **rated supply voltage** does not exceed 1 000 V AC. The **rated supply frequency** and **internal operational frequency** do not exceed 500 Hz.

The **rated output** is not less than 0,5 kVA and does not exceed 10 kVA for single-phase and three-phase **transformers** for **medical IT system** for group 2 medical locations.

This document can be applicable to **isolating transformers** intended to supply other medical installations that are not group 2 medical locations without limitation of the **rated output** subject to an agreement between the purchaser and the manufacturer.

NOTE 4 **Transformers** intended to supply distribution networks other than **medical IT systems** are not included in the scope.

The **no-load output voltage** and the **rated output voltage** does not exceed 250 V AC for single-phase or three-phase **transformer** (phase-to-phase voltage).

This document does not cover **power supply units**.

This document is not applicable to external circuits and their components intended to be connected to the input terminals and output terminals of the **transformers**.

Transformers covered by this document are used in applications where **double or reinforced insulation** between circuits is required by the installation rules or by the appliance specification.

Attention is drawn to the following, if necessary:

– additional requirements for **transformers** intended to be used in vehicles, on board ships, and aircraft (from other applicable standards, national rules, etc.);

– measures to protect the **enclosure** and the components inside the **enclosure** against external influences such as fungus, vermin, termites, solar-radiation, and icing;

– the different conditions for transportation, storage, and operation of the **transformers**;

– additional requirements in accordance with other appropriate standards and national rules may be applicable to **transformers** intended for use in special environments.

This group safety publication focusing on safety guidance is primarily intended to be used as a product safety standard for the products mentioned in the scope, but is also intended to be used by TCs in the preparation of publications for products similar to those mentioned in the scope of this group safety publication, in accordance with the principles laid down in IEC Guide 104 and ISO/IEC Guide 51.

One of the responsibilities of a TC is, wherever applicable, to make use of BSPs and/or GSPs in the preparation of its publications.

2 Normative references

This clause of Part 1 is applicable except as follows:

Addition

IEC 61558-1:2017, *Safety of transformers, reactors, power supply units and combinations thereof – Part 1: General requirements and tests*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in Part 1 apply, except as follows:

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

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

Addition

3.1.101
isolating transformer for medical IT systems for the supply of medical locations
isolating transformer used for the supply of **medical IT system** for group 2 medical locations, designed to be permanently connected and with **double** or **reinforced insulation** between each part of the transformer (body, screen, circuits, thermal sensitive device) except between the core and the **body**

3.2.101
medical IT system
electric IT system fulfilling all specific additional requirements of group 2 medical locations

[SOURCE: IEC 60364-7-710:2021, 710.3.10, modified – Note 1 to entry has been deleted.]

3.5.101
rated input current
input current assigned to the transformer by the manufacturer, when the **transformer** is loaded with **rated output**

3.6.101
no-load input current
input current when the **transformer** is connected to the **rated supply voltage**, at the **rated supply frequency**, with no-load on the output

3.6.102
inrush current
maximum instantaneous value of the **no-load input current** of the **transformer** (peak value) when the **transformer** is switched on at **rated supply voltage**

3.7.101
functional screening
separation between two windings or between a winding and the core or shielding of a part or of the whole **transformer**, by means of an interposed conductive screen for functional reasons

4 General requirements

This clause of Part 1 is applicable.

5 General notes on tests

This clause of Part 1 is applicable.

6 Ratings

This clause of Part 1 is applicable except as follows:

Addition

6.101 The **rated output voltage** shall not exceed 250 V AC for single-phase or three-phase **transformers** (phase-to-phase voltage).

6.102 The **rated output** shall not be less than 0,5 kVA and shall not exceed 10 kVA for single-phase or three-phase **transformers**.

Transformers intended to supply other medical installations that are not group 2 medical locations without limitation of the **rated output** shall be subject to an agreement between the purchaser and the manufacturer.

6.103 The rated frequency and internal operational frequency shall not exceed 500 Hz.

6.104 The **rated supply voltage** shall not exceed 1 000 V AC.

Compliance with the requirements of 6.101 to 6.104 shall be checked by inspection of the marking.

7 Classification

This clause of Part 1 is applicable, except as follows:

Replacement

7.2

Transformers shall be **non-short-circuit proof transformers** in accordance with the short-circuit characteristic or protection against abnormal use.

7.4

Transformers shall be **stationary transformers**.

7.5

Transformers shall be classified for **continuous duty**.

7.8

Transformers shall be classified for **overvoltage category III**.

8 Marking and other information

This clause of Part 1 is applicable except as follows:

8.1 h)

Replacement

Replace the content up to the first semi-colon by the following:

relevant graphical symbols shown in Table 101 that indicate the kind of **transformer**

8.1 s)

Replacement

Transformers shall be marked with the measured **short-circuit voltage** expressed as a percentage of the **rated supply voltage**.

Addition

8.1.101 When the **inrush current** exceeds 8 times the peak value of the **rated input current**, the resulting value shall be marked on the transformer.

8.6

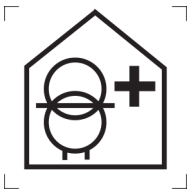
Addition

All terminals shall be clearly marked.

8.11

Addition

Table 101 – Symbols indicating the kind of transformer

Symbol or graphical symbol	Explanation or title	Identification
	Non-short-circuit proof **isolating transformers for medical IT systems for the supply of group 2 medical locations** NOTE This symbol is not applicable for **transformers** > 10 kVA	IEC 60417-5972:2003-08

8.14

Addition

The instruction sheet shall state: "Screens whose connection to the earthing is necessary for compliance with the leakage current requirements of Clause 18 shall be connected to the earthing."

The instruction sheet shall include type and characteristic of sensor to over-temperature monitoring, if any.

The **rated input current** shall be provided as information given either on the transformer marking or made available in the manufacturer's catalogue or similar.

9 Protection against electric shock

This clause of Part 1 is applicable.

10 Change of input voltage setting

This clause of Part 1 is applicable.

11 Output voltage and output current under load

This clause of Part 1 is applicable.

12 No-load output voltage

This clause of Part 1 is applicable except as follows:

Addition

12.101 The **no-load output voltage** (phase-to-phase voltage) shall not exceed 250 V AC for single-phase or three-phase **transformers**.

12.102 The difference between the **no-load output voltage** and the **output voltage** under load shall not be excessive.

*The ratio between the **no-load output voltage** measured in Clause 12 and the **output voltage** under load measured during the test of Clause 11, expressed as a percentage of the latter voltage, shall not exceed 5 %.*

The ratio is determined by Formula (1):

$$\frac{U_{\text{no-load}} - U_{\text{load}}}{U_{\text{load}}} \times 100(\%) \quad (1)$$

where

$U_{\text{no-load}}$ is the no-load output voltage, expressed in V;

U_{load} is the no-load output voltage, expressed in V.

*Compliance with the requirements of 12.101 and 12.102 is checked by measuring the **no-load output voltage** at the **ambient temperature** when the **transformer** is connected to **the rated supply voltage** at the **rated supply frequency**.*

13 Short-circuit voltage

This clause of Part 1 is not applicable.

Replacement

13 Short-circuit voltage and inrush currents

13.1 The **short-circuit voltage** shall be measured and marked on the **transformer**.

Compliance shall be checked by measurement.

13.2 The **no-load input current** shall not exceed 3 % of the **rated input current** at the **rated supply voltage**.

This requirement shall be fulfilled by construction of the **transformer** without the use of any capacitors in the **transformer** circuits (input/output) or in the installation.

Compliance shall be checked by measurements.

13.3 The **inrush current** shall not exceed 8 times the peak value of the **rated input current**. However, it is allowed to increase this value to 12 times the peak value of **rated input current,** if the latter value is marked on the **transformer**.

This requirement shall be fulfilled by construction of the **transformer** without the use of any electronic devices and additional measures in the **transformer** or in the installation.

Compliance shall be checked by the following test:

*The **transformer** with no-load operation is connected to the **rated supply voltage**. The test supply voltage is then switched on and off 20 times at random intervals of approximately 20 s.*

The on-off switching may be carried out only twice, if a device is used to switch on at the most unfavourable electrical angle of the supply voltage.

*The voltage drop of the supply source shall not exceed 2 % as a result of the **inrush current**.*

*The **inrush current** shall not exceed 8 times or 12 times the peak value of the **rated input current** during any of the switching operations.*

14 Heating

This clause of Part 1 is applicable, except as follows:

Addition

14.101 Immediately after the test in accordance with 14.1 an additional heating test is required with 150 % of the load for 30 min. After the test the temperature shall not exceed the values of Table 2 increased by 25 %.

15 Short-circuit and overload protection

This clause of Part 1 is applicable, except as follows:

15.1 Short circuit and overload test method

Replacement

Transformers shall be **non-short-circuit proof transformers**.

15.4 Non-short-circuit proof transformers

Addition

The overload shall be monitored by an overload current and over-temperature monitoring warning system.

NOTE 1 For information about monitoring of overload and over-temperature of i**solating transformers for medical IT system** see Annex B of IEC 61557-8:2014.

NOTE 2 In some countries a circuit breaker is allowed by national installation rules.

NOTE 3 In Spain, monitoring of overload and over-temperature is not required.

16 Mechanical strength

This clause of Part 1 is applicable.

17 Protection against harmful ingress of dust, solid objects and moisture

This clause of Part 1 is applicable.

18 Insulation resistance, dielectric strength and leakage current

This clause of Part 1 is applicable, except as follows:

18.2 Insulation resistance

Replacement:

Replace the 6th and 7th lines of Table 13 by the following three new lines:

Insulation to be tested	Insulation resistance MΩ
Between each **input circuit** and all other **input circuits** connected together	7
Between each **output circuit** and all other **output circuits** connected together	7
Between **input** and **output circuits** (double reinforced insulation)	7

Addition

NOTE In Australia, higher insulation resistance values are required.

18.3 Dielectric strength test

Addition

In addition, the dielectric strength tests according to Table 102 shall be performed.

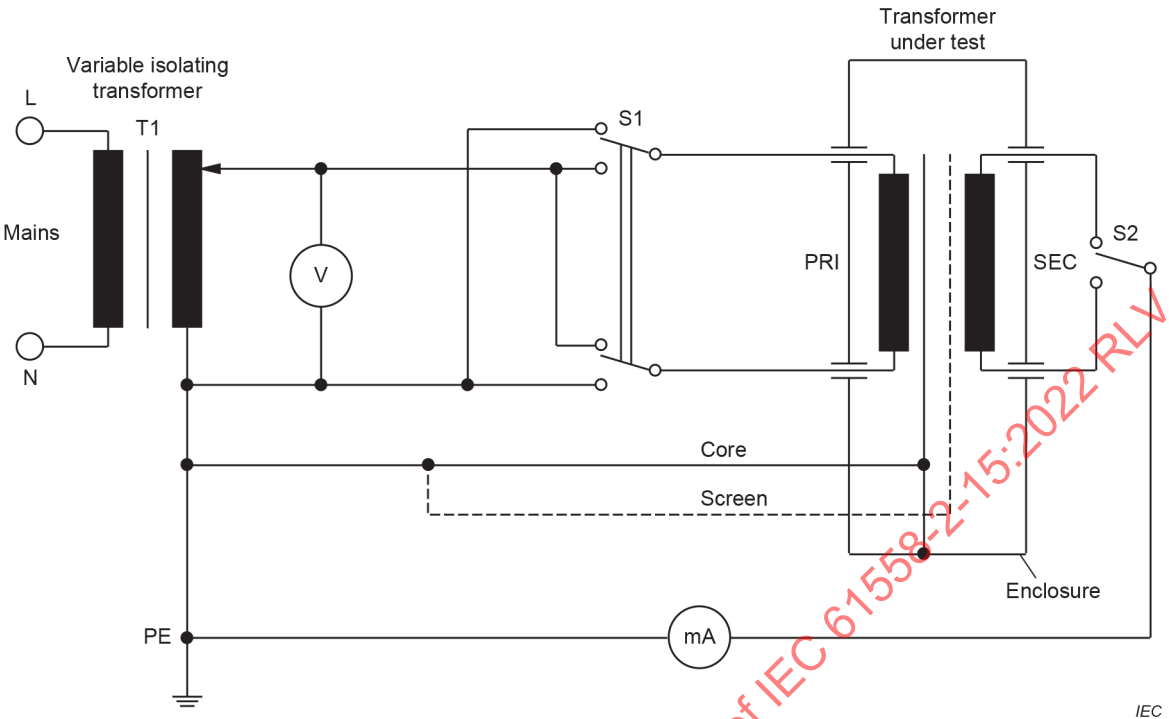
Table 102 – Additional dielectric strength test voltages

Application of dielectric strength test voltage	Working voltage V					
	< 50	**100**	**150**	**300**	**600**	**1 000**
Between **live parts** of adjacent **input circuits** not intended to be connected together	500	1 400	2 800	4 200	5 000	5 500
Between **live parts** of adjacent **output circuits** not intended to be connected together	500	1 400	2 800	4 200	5 000	5 500

Addition

18.101 The leakage current of the **output winding** to the earthing shall not exceed 0,5 mA, when measured under the no-load condition, and at the room temperature with the **transformer** supplied at the **rated voltage** and the **rated frequency**, as shown in Figure 101.

For this test the core and the **functional screen**, if any, shall be connected to the earthing.



The test shall be carried out with all combinations of S1 and S2.

For three-phase **transformers** the switch S1 is used only in closed position. The measurements with switch S2 are repeated connecting it, in turn, to all phases.

The current is measured with an ammeter of negligible impedance.

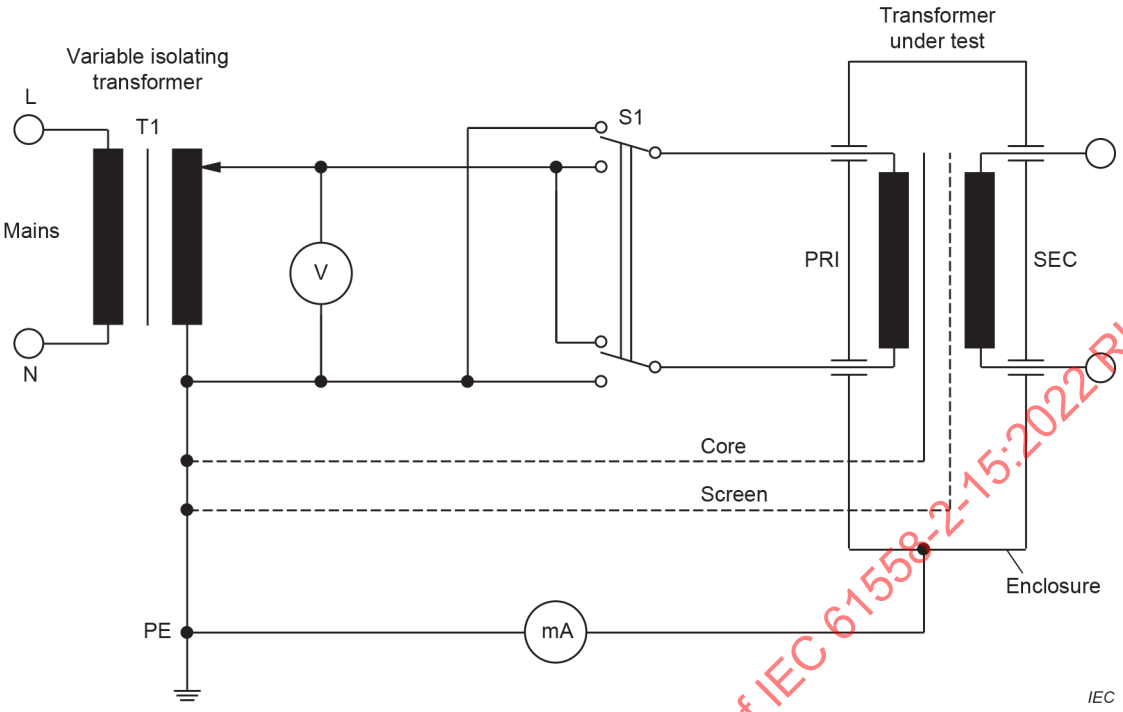
NOTE 1 In Japan, the **leakage current** of the **output winding** is limited to 0,1 mA maximum.

NOTE 2 In Australia, additional leakage current limits apply.

Figure 101 – Required circuit for measuring the leakage current from the output winding to the earthing

Compliance shall be checked by measurements.

18.102 The leakage current through the protective earthing conductor from the enclosure to the earthing shall not exceed 0,5 mA when measured at room temperature under no-load condition with the transformer supplied at the **rated voltage** and the **rated frequency** as shown in Figure 102.



The test shall be carried out with all combinations of S1.

For three-phase **transformers** the switch S1 is used only in closed position.

The current is measured with an ammeter of negligible impedance.

The core, if not connected to the enclosure, and the functional screen, if any, shall be connected to earth.

Figure 102 – Required circuit for measuring the leakage current at the protective earthing conductor

Compliance shall be checked by measurements.

19 Construction

This clause of Part 1 is applicable, except as follows:

Replacement of 19.1 (19.1.1 to 19.1.4.10) by the following

19.1 The **input** and **output circuits** shall be electrically separated from each other and the construction shall be such that there is no possibility of any connection between these circuits, either directly or indirectly, via other **conductive parts**, except by deliberate action.

Compliance is checked by inspection and measurements, taking Clauses 18 and 26 into consideration.

19.1.101 The insulation between the **input** and **output winding(s)** shall consist of **double** or **reinforced insulation** (rated for the **working voltage**). The insulation between the **input winding(s)** and the **body**, and between the **output winding(s)** and the **body**, shall consist of **double** or **reinforced insulation** (rated for the **working voltage**).

19.1.101.1 When the **input winding(s)** are not intended to be connected in series or parallel, they shall be separated from each other and from other circuits by **double** or **reinforced insulation** (rated for the **working voltage**).

The **input winding(s)**, intended to be connected in series or parallel, may be separated from each other by **basic insulation** (rated for the **working voltage**).

19.1.101.2 The **output winding(s)** shall be separated from each other and from other circuits by **double** or **reinforced insulation** (rated for the **working voltage**).

19.1.101.3 The **functional screening**, if any, shall be separated from the core, the windings and from the **body** by **double** or **reinforced insulation** (rated for the **working voltage**).

19.1.101.4 If the **transformers** are provided with a **functional screening** placed between the **input** and the **output windings**, the **functional screening** shall be constructed of a metal foil so that the adjacent turns overlap without short-circuiting. The lead out of the **functional screening** shall be provided with separate terminals.

For concentric windings, the width of the **functional screening** shall be approximately equal to the axial winding length of the **input winding**. For non-concentric windings, the width of the **functional screening** shall be approximately equal to the radial winding length of the **input winding**. If the **functional screening** is constructed of only one turn it shall be provided with an insulated overlap of not less than 3 mm.

19.1.102 For **transformers** with **intermediate conductive parts** (e.g. the iron core) not connected to the **body** and located between the **input** and **output windings**, the insulation between the **intermediate conductive parts** and the **input windings,** and between the **intermediate conductive parts** and the **output windings** shall consist of at least **basic insulation** (rated for the **working voltage**).

An **intermediate conductive part** not separated from the **input** or **output windings** or the **body** by at least basic insulation is considered to be connected to the relevant part(s).

The insulation between the **input** and **output windings** via the **intermediate conductive part** shall consist of **double** or **reinforced insulation;** the insulation between the **input windings** and the **body**, and between the **output windings** and the **body**, via the **intermediate conductive part** shall consist of **double** or **reinforced insulation** (rated for the **working voltage**).

19.1.103 **Transformers** shall not be provided with capacitors and/or resistors.

Compliance shall be checked by inspection.

19.1.104 The input and output terminals for the connection of external wiring shall be so located that the distance measured between the points of introduction of the conductors into these terminals is not less than 25 mm. If a barrier is used to obtain this distance, the measurement shall be made over and around the barrier which shall be of insulating material and permanently fixed to the **transformer**.

*Compliance shall be checked by inspection and by measurement, disregarding the **intermediate conductive parts**.*

19.1.105 If the monitoring of the over-temperature in accordance with 15.4 is required, the thermal sensitive device (bimetal, PTC or similar) shall be built-in and shall be connected to separate terminals for external connections.

NOTE The terminals are intended to connect the thermal sensitive device to visual indicators and/or audible signal located in the medical location and intended to warn the medical staff.

The thermal sensitive device shall be rated to the class of the insulation system minus 10 °C.

19.1.106 If a single-phase **transformer** is provided with a midpoint in the **output winding,** it shall be connected to a separate terminal.

19.1.107 Three-phase **transformers** shall be provided with the vector group star-star or star-delta design.

19.1.108 The star point of the **output winding** in three-phase **transformers** with vector group star-star design shall be connected to a separate terminal.

NOTE The terminal is intended for connection to an external medical insulation monitoring device (MED-IMD) in accordance with IEC 61557-8, if applicable.

19.1.109 The star point of the **input winding** in three-phase **transformers** with vector group star-star or star-delta design shall be connected to a separate terminal.

NOTE The terminal is intended for connection to the neutral point of the supply in order to allow asymmetrical loading.

20 Components

This clause of Part 1 is applicable, except as follows:

20.6

Replacement

Socket-outlets shall not be directly connected to the **output circuit** of the **transformer** without appropriate protection in accordance with the corresponding installation rules.

21 Internal wiring

This clause of Part 1 is applicable.

22 Supply connection and other external flexible cable or cords

This clause of Part 1 is applicable, except as follows:

22.3

Addition

22.3.101 **Transformers** shall be designed for permanent connection.

22.4 to 22.7

Subclauses 22.4 to 22.7 are not applicable.

23 Terminals for external conductors

This clause of Part 1 is applicable.

24 Provisions for protective earthing

This clause of Part 1 is applicable.

25 Screws and connections

This clause of Part 1 is applicable.

26 Creepage distances, clearances and distances through insulation

This clause of Part 1 is applicable.

27 Resistance to heat, fire and tracking

This clause of Part 1 is applicable.

28 Resistance to rusting

This clause of Part 1 is applicable.

Annexes

The Annexes of Part 1 are applicable, except as follows:

Annex H
(normative)

Electronic circuits

This Annex of Part 1 is not applicable.

Annex L
(normative)

Routine tests (production tests)

This Annex of Part 1 is applicable, except as follows:

Addition

L.101 Checking of the **short-circuit voltage**

The **short-circuit voltage** shall not exceed the marked value.

L.102 Checking of the **no-load input current**

The **no-load input current** shall not exceed 3 % of the **rated input current**.

L.103 Checking of the **inrush current**

The inrush current shall not exceed 8 times the peak value of the **rated input current** or the marked value on the label, if any.

Compliance is checked by Subclause 13.103.

Bibliography

The Bibliography of Part 1 is applicable, except as follows:

Addition

IEC 61558 (all parts), *Safety of transformers, reactors, power supply units and combinations thereof*

IEC 60364-1:2005, *Low-voltage electrical installations – Part 1: Fundamental principles, assessment of general characteristics, definitions*

IEC 60364-4-41:2005, *Low-voltage electrical installations – Part 4-41: Protection for safety – Protection against electric shock*

IEC 60364-5-53:2019, *Low-voltage electrical installations – Part 5-53: Selection and erection of electrical equipment – Devices for protection for safety, isolation, switching, control and monitoring*

IEC 60364-7-710:2021, *Low-voltage electrical installations – Part 7-710: Requirements for special installations or locations – Medical locations*

IEC 61557-8:2014, *Electrical safety in low voltage distribution systems up to 1 000 V a.c. and 1 500 V d.c. – Equipment for testing, measuring or monitoring of protective measures – Part 8: Insulation monitoring devices for IT systems*

ISO/IEC Guide 51:2014, *Safety aspects – Guidelines for their inclusion in standards*

IEC Guide 104:2019, *The preparation of safety publications and the use of basic safety publications and group safety publications*

SOMMAIRE

COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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SÉCURITÉ DES TRANSFORMATEURS, BOBINES D'INDUCTANCE, BLOCS D'ALIMENTATION ET DES COMBINAISONS DE CES ÉLÉMENTS –

Partie 2-15: Exigences particulières et essais pour les transformateurs de séparation de circuits pour schémas IT médicaux pour l'alimentation des locaux à usages médicaux

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8) L'attention est attirée sur les références normatives citées dans cette publication. L'utilisation de publications référencées est obligatoire pour une application correcte de la présente publication.
9) L'attention est attirée sur le fait que certains des éléments de la présente Publication de l'IEC peuvent faire l'objet de droits de brevet. L'IEC ne saurait être tenue pour responsable de ne pas avoir identifié de tels droits de brevets et de ne pas avoir signalé leur existence.

L'IEC 61558-2-15 a été établie par le comité d'études 96 de l'IEC: Transformateurs, bobines d'inductance, blocs d'alimentation et combinaisons de ces éléments. Il s'agit d'une Norme internationale.

Cette troisième édition annule et remplace la deuxième édition parue en 2011. Cette édition constitue une révision technique.

Cette édition inclut les modifications techniques majeures suivantes par rapport à l'édition précédente:

a) Ajustement de la structure et des références conformément à l'IEC 61558-1:2017;

Le texte de cette Norme internationale est issu des documents suivants:

Projet	Rapport de vote
96/535/FDIS	96/536/RVD

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à son approbation.

La langue employée pour l'élaboration de cette Norme internationale est l'anglais.

Ce document a été rédigé selon les Directives ISO/IEC, Partie 2, il a été développé selon les Directives ISO/IEC, Partie 1 et les Directives ISO/IEC, supplément IEC, disponibles sous www.iec.ch/members_experts/refdocs. Les principaux types de documents développés par l'IEC sont décrits plus en détail sous www.iec.ch/standardsdev/publications.

Il a le statut de publication groupée de sécurité conformément au Guide IEC 104.

Cette Norme internationale doit être utilisée conjointement avec l'IEC 61558-1:2017.

NOTE Toute référence à la "Partie 1" dans cette norme renvoie à l'IEC 61558-1:2017.

Le présent document complète ou modifie les Articles correspondants de l'IEC 61558-1:2017, de façon à transformer cette publication en norme IEC: *Exigences particulières et essais pour les transformateurs de séparation de circuits pour schémas IT médicaux pour l'alimentation des locaux à usages médicaux.*

Une liste de toutes les parties de la série IEC 61558, publiées sous le titre général *Sécurité des transformateurs, bobines d'inductance, blocs d'alimentation et des combinaisons de ces éléments*, se trouve sur le site web de l'IEC.

Les futures normes de cette série porteront dorénavant le nouveau titre général cité ci-dessus. Le titre des normes existant déjà dans cette série sera mis à jour lors d'une prochaine édition.

Lorsque le présent document indique "*addition*", "*modification*" ou "*remplacement*", le texte correspondant de l'IEC 61558-1:2017 doit être adapté en conséquence.

Dans le présent document, les caractères d'imprimerie suivants sont utilisés:

– exigences proprement dites: caractères romains;
– *modalités d'essais: caractères italiques*;
– commentaires: petits caractères romains.

Dans le texte du présent document, les mots en **gras** sont définis à l'Article 3.

Les paragraphes, notes, figures et tableaux qui s'ajoutent à ceux de l'IEC 61558-1:2017 sont numérotés à partir de 101; les annexes supplémentaires sont désignées AA, BB, etc.

Le comité a décidé que le contenu de ce document ne sera pas modifié avant la date de stabilité indiquée sur le site web de l'IEC sous "http://webstore.iec.ch" dans les données relatives au document recherché. À cette date, le document sera

- reconduit,
- supprimé,
- remplacé par une édition révisée, ou
- amendé.

INTRODUCTION

Le comité d'études 96 de l'IEC dispose d'une fonction groupée de sécurité conformément au Guide IEC 104 pour les transformateurs autres que ceux destinés à alimenter des réseaux de distribution, en particulier les transformateurs et les blocs d'alimentation destinés à permettre l'application de mesures de protection contre les chocs électriques telles que définies par le comité d'études 64, mais dans certains cas incluant la limitation de la tension et la fonction de sécurité horizontale pour les TBTS conformément à l'IEC 60364-4-41.

La fonction groupée de sécurité (FGS) est nécessaire en raison de la responsabilité, par exemple, pour la très basse tension de sécurité (TBTS) conformément à l'IEC 61140:2016, 5.2.6 et l'IEC 60364-4-41:2005, 414.3.1 ou les circuits de commande conformément à l'IEC 60204-1:2016, 7.2.4.

La fonction groupée de sécurité est nécessaire pour chaque partie de l'IEC 61558-2 car différentes normes de la série IEC 61558 peuvent être combinées dans une construction mais dans certains cas sans limitation de la puissance secondaire assignée.

Par exemple, un autotransformateur conforme à l'IEC 61558-2-13 peut être conçu avec un circuit TBTS séparé conformément aux exigences particulières de l'IEC 61558-2-6 concernant les exigences générales de l'IEC 61558-1.

SÉCURITÉ DES TRANSFORMATEURS, BOBINES D'INDUCTANCE, BLOCS D'ALIMENTATION ET COMBINAISONS DE CES ÉLÉMENTS –

Partie 2-15: Exigences particulières et essais pour les transformateurs de séparation de circuits pour schémas IT médicaux pour l'alimentation des locaux à usages médicaux

1 Domaine d'application

Remplacement

La présente partie de l'IEC 61558 traite de la sécurité **des transformateurs de séparation de circuits** pour **schémas IT médicaux** pour l'alimentation des **locaux à usages médicaux**.

NOTE 1 La sécurité comprend des aspects électriques, thermiques et mécaniques.

Sauf spécification contraire, dans la suite du document, le terme **transformateur** couvre les **transformateurs de séparation de circuits pour schémas IT médicaux pour l'alimentation des locaux à usages médicaux**.

Le présent document s'applique aux **transformateurs de séparation de circuits fixes**, monophasés ou triphasés, à refroidissement par air (circulation naturelle ou forcée), **de type sec** destinés à alimenter **le schéma IT médical** pour les locaux à usages médicaux du groupe 2, conçus pour être connectés de façon permanente au câblage fixe et destinés à former **le schéma IT médical** du côté secondaire. Les enroulements peuvent être enrobés ou non enrobés.

NOTE 2 **Les schémas IT** sont définis dans l'IEC 60364-1.

Les règles d'installation **du schéma IT médical** pour les locaux à usages médicaux du groupe 2 sont couvertes par l'IEC 60364-7-710.

NOTE 3 Les règles d'installation nationales de certains pays contiennent des exigences différentes ou supplémentaires qui sont énumérées dans l'Annexe C de l'IEC 60364-7-710:2021.

Les **transformateurs** couverts par le présent document sont destinés aux **schémas IT médicaux** pour **l'alimentation des locaux à usages médicaux**. Tous les autres **transformateurs** ou équipements ne sont pas couverts par le présent document.

La **tension primaire assignée** ne dépasse pas 1 000 V en courant alternatif. **La fréquence d'alimentation assignée** ainsi que **la fréquence de fonctionnement interne** ne dépassent pas 500 Hz.

La **puissance assignée** n'est pas inférieure à 0,5 kVA et ne dépasse pas 10 kVA pour les **transformateurs** monophasés et triphasés destinés au **schéma IT médical** pour les locaux à usages médicaux du groupe 2.

Le présent document peut s'appliquer **aux transformateurs de séparation de circuits** destinés à alimenter d'autres installations à usages médicaux qui ne sont pas des locaux à usages médicaux du groupe 2 sans limitation de la **puissance assignée** sous réserve d'un accord entre l'acheteur et le constructeur.

NOTE 4 Les **transformateurs** destinés à alimenter des réseaux de distribution autres que les **schémas IT médicaux** ne sont pas inclus dans le domaine d'application.

La **tension secondaire à vide** et la **tension secondaire assignée** ne dépassent pas 250 V en courant alternatif pour le **transformateur** monophasé ou triphasé (tension entre phases).

Le présent document ne couvre pas **les blocs d'alimentation**.

Le présent document ne s'applique pas aux circuits externes et à leurs composants destinés à être connectés aux bornes d'entrée et de sortie des **transformateurs**.

Les **transformateurs** couverts par le présent document sont utilisés dans des applications dans lesquelles la **double isolation ou l'isolation renforcée** est exigée entre les circuits par les règles d'installation ou par la spécification de l'appareil d'utilisation.

L'attention est attirée sur le fait que, le cas échéant:

– des exigences complémentaires pour les **transformateurs** destinés à être utilisés dans des véhicules ou à bord de navires ou d'aéronefs, (provenant d'autres normes en vigueur, règlements nationaux, etc.) peuvent être nécessaires;

– des mesures sont prises pour protéger les **enveloppes** et les composants qu'elles contiennent contre les influences du milieu extérieur comme la moisissure, la vermine, les termites, le rayonnement solaire, le givre;

– les différentes conditions de transport, stockage, et de fonctionnement des **transformateurs** sont également prises en compte;

– des exigences supplémentaires conformes à d'autres normes appropriées et règles nationales peuvent être applicables aux **transformateurs** destinés à être utilisés dans des environnements particuliers.

La présente publication groupée de sécurité portant sur les recommandations relatives à la SÉCURITÉ est avant tout destinée à être utilisée en tant que norme en matière de sécurité des produits qui sont cités dans le domaine d'application, mais elle est également destinée à être utilisée par les comités d'études dans le cadre de l'élaboration de publications pour des produits similaires à ceux cités dans le domaine d'application de la présente publication groupée de sécurité, conformément aux principes établis dans le Guide IEC 104 et le Guide ISO/IEC 51.

L'une des responsabilités d'un comité d'études consiste, le cas échéant, à utiliser les publications fondamentales de sécurité et/ou les publications groupées de sécurité dans le cadre de l'élaboration de ses publications.

2 Références normatives

L'Article de la Partie 1 s'applique, à l'exception de ce qui suit:

Addition

IEC 61558-1:2017, *Sécurité des transformateurs, bobines d'inductance, blocs d'alimentation et des combinaisons de ces éléments – Partie 1: Exigences générales et essais*

3 Termes et définitions

Pour les besoins du présent document, les termes et définitions de la Partie 1 s'appliquent, à l'exception de ce qui suit:

L'ISO et l'IEC tiennent à jour des bases de données terminologiques destinées à être utilisées en normalisation, consultables aux adresses suivantes:

- IEC Electropedia: disponible à l'adresse http://www.electropedia.org/
- ISO Online browsing platform: disponible à l'adresse http://www.iso.org/obp

Addition

3.1.101
transformateur de séparation de circuits pour schémas IT médicaux pour l'alimentation des locaux à usages médicaux
transformateur de séparation de circuits utilisé pour l'alimentation de **schéma IT médical** pour les locaux à usages médicaux du groupe 2, conçus pour être connectés de façon permanente, avec une **double isolation** ou **isolation renforcée** entre chaque partie du transformateur (masse, écran, circuits, dispositif sensible à la température) excepté entre le noyau et la **masse**

3.2.101
schéma IT médical
schéma IT électrique remplissant toutes les exigences particulières complémentaires des locaux à usages médicaux de groupe 2

[SOURCE: IEC 60364-7-710:2021, 710.3.10, modifié – La Note 1 à l'article a été supprimée.]

3.5.101
courant primaire assigné
courant primaire attribué au transformateur par le constructeur, lorsque le **transformateur** est chargé avec **la puissance assignée**

3.6.101
courant primaire à vide
courant primaire lorsque le **transformateur** est alimenté à la **tension primaire assignée**, à la **fréquence d'alimentation assignée**, avec la tension secondaire à vide

3.6.102
courant d'appel
valeur maximale instantanée du **courant primaire à vide** du **transformateur** (valeur de crête) quand le **transformateur** est mis sous la **tension primaire assignée**

3.7.101
écran fonctionnel
séparation entre deux enroulements ou entre un enroulement et le noyau ou protection d'une partie ou de l'ensemble du **transformateur**, au moyen d'un écran conducteur interposé pour des raisons fonctionnelles

4 Exigences générales

L'Article de la Partie 1 s'applique.

5 Généralités sur les essais

L'Article de la Partie 1 s'applique.

6 Caractéristiques assignées

L'Article de la Partie 1 s'applique, à l'exception de ce qui suit:

Addition