SLOVENSKI STANDARD
oSIST prEN IEC 61558-2-15:2021

01-julij-2021

Varnost transformatorjev, dušilk, napajalnikov in njihovih kombinacij - 2-15. del: Posebne zahteve in preskusi za ločilne transformatorje za IT sisteme v napajalnikih v medicinskih prostorih

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 locaux à usages médicaux

Ta slovenski standard je istoveten z: **prEN IEC 61558-2-15:2021**

ICS:

29.180	Transformatorji. Dušilke	Transformers. Reactors

oSIST prEN IEC 61558-2-15:2021 **en**

96/508/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER: **IEC 61558-2-15 ED3**	
DATE OF CIRCULATION: **2021-04-30**	CLOSING DATE FOR VOTING: **2021-07-23**
SUPERSEDES DOCUMENTS: **96/503/RR**	

IEC TC 96 : TRANSFORMERS, REACTORS, POWER SUPPLY UNITS, AND COMBINATIONS THEREOF

SECRETARIAT: Germany	SECRETARY: Mr Wolfgang Reichelt
OF INTEREST TO THE FOLLOWING COMMITTEES: SC 3C,TC 14,TC 22,SC 22E,SC 34C,TC 51,TC 55,TC 61,TC 62,SC 62A,TC 64,TC 66,TC 77,TC 97,TC 106,TC 108,TC 109,TC 111,TC 112	PROPOSED HORIZONTAL STANDARD: ☐ Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.

FUNCTIONS CONCERNED:

☐ EMC ☐ ENVIRONMENT ☐ QUALITY ASSURANCE ☒ SAFETY

☒ SUBMITTED FOR CENELEC PARALLEL VOTING ☐ NOT SUBMITTED FOR CENELEC PARALLEL VOTING

Attention IEC-CENELEC parallel voting

The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting.

The CENELEC members are invited to vote through the CENELEC online voting system.

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

TITLE:

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

PROPOSED STABILITY DATE: 2025

NOTE FROM TC/SC OFFICERS:

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

This third edition cancels and replaces the second edition published in 2011. It 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/XXX/FDIS	96/XXX/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 the supply of medical locations – Transformer for medical IT systems.*

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 "http://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 60364-4-41:2017, 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 **isolating transformers**, single-phase or three-phase, air-cooled (natural or forced) **dry-type 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.

Transformers covered by this document are intended for **medical IT systems for the supply of medical locations**. All other **transformers** or equipments 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** does not be 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 may 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 3 **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** and is not intended to be used in conjunction with IEC 61558-2-16 for **switch mode 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 National installation rules of some countries have different or additional requirements listed in Annex C of IEC 60364-7-710:2021.

Attention is drawn to the following:

- for **transformers** intended to be used in vehicles, on board ships, and aircraft, additional requirements (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.

ISO and IEC maintain terminological 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

3.1.2.101
isolating transformers 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]

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
the maximum instantaneous value of the **no-load input current** of the **transformer** (peak value) when 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**

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

The symbol for linear **power supply units** shall be used in conjunction with the symbol indicating the kind of **transformer**.