SLOVENSKI STANDARD
oSIST prHD 60364-7-710:2008

01-september-2008

Električne inštalacije zgradb - 7-710. del: Zahteve za posebne inštalacije ali lokacije - Medicinski prostori (IEC 60364-7-710:2002, spremenjen)

Low-voltage electrical installations - Part 7-710: Requirements for special installations or locations - Medical locations

Errichten von Niederspannungsanlagen - Teil 7-710: Anforderungen für spezielle Installationen oder Standorte - Medizinische Standorte und zugehörige Bereiche

Installations électriques à basse tension - Partie 7-710: Règles pour les installations ou emplacements spéciaux - Locaux à usages médicauxx

Ta slovenski standard je istoveten z: **prHD 60364-7-710:2008**

ICS:

29.020	Elektrotehnika na splošno	Electrical engineering in general
91.140.50	Sistemi za oskrbo z elektriko	Electricity supply systems

oSIST prHD 60364-7-710:2008 **en**

HARMONIZATION DOCUMENT

DOCUMENT D'HARMONISATION

HARMONISIERUNGSDOKUMENT

DRAFT prHD 60364-7-710

June 2008

ICS 29.020; 91.140.50

English version

Low-voltage electrical installations - Part 7-710: Requirements for special installations or locations - Medical locations

(IEC 60364-7-710:2002, modified)

Installations électriques à basse tension - Partie 7-710: Règles pour les installations ou emplacements spéciaux - Locaux à usages médicaux (CEI 60364-7-710:2002, modifiée)

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This draft Harmonization Document is submitted to CENELEC members for CENELEC enquiry. Deadline for CENELEC: 2008-10-17.

The text of this draft consists of the text of IEC 60364-7-710:2002 with common modifications prepared by CLC/SC 64A.

If this draft becomes a Harmonization Document, CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for implementation of this Harmonization Document on a national level.

This draft Harmonization Document was established by CENELEC in three official versions (English, French, German).

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CENELEC

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Project: 2282

Ref. No. prHD 60364-7-710:2008 E

Foreword

The text of the International Standard IEC 60364-7-710:2002, prepared by IEC TC 64, Electrical installations and protection against electric shock, together with the common modifications prepared by WG 710 of SC 64A, Electrical installations and protection against electric shock – Protection against electric shock, of Technical Committee CENELEC TC 64, Electrical installations and protection against electric shock, is submitted to the CENELEC enquiry (4MP) for acceptance as a Harmonization Document.

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9 **Text of prHD 60364-7-710**

10 ## Introduction

11 The requirements of this part of HD 60364 supplement, modify or replace certain of the general
12 requirements as contained in Parts 1 to 6 of HD 60364.

13 The clause numbering following 710 are those of the corresponding parts or clauses from Parts 1 to 6
14 of HD 60364. The absence of reference to a part or a clause means that Parts 1 to 6 of HD 60364 are
15 applicable.

16 Clauses, subclauses, notes, tables and figures which are additional to those in IEC 60364-7-710:2002
17 are prefixed “Z”.

18 In medical locations it is necessary to ensure the safety of patients likely to be subjected to the
19 application of medical electrical equipment. For every activity and function in a medical location,
20 the particular requirements for safety have to be considered. Safety can be achieved by ensuring the
21 safety of the installation and the safe operation and maintenance of medical electrical equipment
22 connected to it. The use of medical electrical equipment on patients undergoing intensive care
23 (of critical importance) has called for enhanced reliability and safety of electrical installations in
24 hospitals so as to improve the safety and continuity of supplies which is met by application of this
25 Harmonization Document. Variations of this document to further enhance safety and reliability are
26 acceptable.

710 Medical locations

710.1 Scope

The particular requirements of this part of HD 60364 apply to electrical installations in medical locations so as to ensure safety of patients and medical staff. These requirements, in the main, refer to hospitals, private clinics, medical and dental practices, health care centres and dedicated medical rooms in the work place.

The requirements of this part do not apply to medical electrical equipment.

This part also applies to electrical installations in locations designed for medical research.

NOTE 1 It may be necessary to modify the existing electrical installation, in accordance with this standard, when a change of utilization of the location occurs. Special care should be taken where intracardiac procedures are performed in existing installations.

NOTE 2 Where applicable, this standard can also be used in veterinary clinics.

NOTE 3 For medical electrical equipment and medical electrical systems, refer to the EN 60601 series.

NOTE Z1 Care should be taken that other installations (e.g. data networks etc.) should not impair the installations. safety level.

NOTE Z2 These requirements concern, for example, electrical installations for medical locations in:

- hospitals and clinics (including container design);
- sanatoriums and health clinics;
- dedicated locations in homes for senior citizens and aged care, where the patients are subjected to medical care;
- medical centres, outpatients' clinics and departments, casualty wards;
- other outpatients' institutions (industrial, sports and others).

NOTE Z3 The application of this Harmonization Document does not exempt to respect the national rules.

710.2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 60439 series, *Low-voltage switchgear and controlgear assemblies* (IEC 60439 series)

EN 60601 series, *Medical electrical equipment* (IEC 60601 series)

EN 60601-1:2006, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance* (IEC 60601-1:2005)

EN 60601-1-1:2001, *Medical electrical equipment – Part 1-1: General requirements for safety; Collateral standard: Safety requirements for medical electrical systems* (IEC 60601-1-1:2000)

EN 61557-8:1997 [1)], *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* (IEC 61557-8:1997)

EN 61557-9, *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 9 : Equipment for insulation fault location in IT systems* (IEC 61557-9)

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1) Will be superseded by EN 61557-8:2007, *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* (based on IEC 61557-8:2007) on 2010-05-01.

EN 61558-2-15:2001, *Safety of power transformers, power supply units and similar – Part 2-15: Particular requirements for isolating transformers for the supply of medical* locations (IEC 61558-2-15:1999, mod.)

HD 384.6.61 S2:2003 [2)], *Electrical installations of buildings – Part 6-61: Verification – Initial verification* (IEC 60364-6-61:1986, mod. + A1:1993, mod. + A2:1997, mod.)

HD 60364 series, *Low-voltage electrical installations* (IEC 60364 series, mod.)

HD 60364-4-41:2007, *Low-voltage electrical installation – Part 4-41: Protection for safety – Protection against electric shock* (IEC 60364-4-41:2005, mod.)

IEC 60364-5-53, *Electrical installations of buildings – Part 5-53: Selection and erection of electrical equipment – Isolation, switching and control*

IEC 60364-5-55:2001, *Electrical installations of buildings – Part 5-55: Selection and erection of electrical equipment - Other equipment*

IEC 60670-24, *Boxes and enclosures for electrical accessories for household and similar fixed electrical installations – Part 24: Particular requirements for enclosures for housing protective devices and similar power consuming devices*

ISO 8528-1:2005, *Reciprocating internal combustion engine driven alternating current generating sets – Part 1: Application, ratings and performance*

710.3 Definitions

For the purposes of this document, the following terms and definitions apply.

710.3.1
medical location
location intended for purposes of diagnosis, treatment (including cosmetic treatment), monitoring and care of patients

710.3.2
patient
living being (person or animal) undergoing a medical, surgical or dental procedure

[EN 60601-1:2006, definition 3.76]

NOTE The person under treatment for cosmetic purposes may be considered, as far as this standard is concerned, as a patient.

710.3.3
medical electrical equipment (ME equipment)
electrical equipment having an applied part or transferring energy to or from the patient or detecting such energy transfer to or from the patient and which is

a) provided with not more than one connection to a particular supply mains, and

b) intended by its manufacturer to be used

- in the diagnosis, treatment, or monitoring of a patient, or
- for compensation or alleviation of disease, injury or disability

NOTE ME equipment includes those accessories as defined by the manufacturer that are necessary to enable the normal use of the ME equipment.

[EN 60601-1:2006]

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2) Will be superseded by HD 60364-6:2006, *Low voltage electrical installations – Part 6: Verification* (based on IEC 60364-6:2006, mod.) on 2009-09-01.

710.3.4
applied part
part of medical electrical equipment that in normal use necessarily comes into physical contact with the patient for ME equipment or an ME system to perform its function

[EN 60601-1:2006, definition 3.8]

710.3.5
group 0
medical location where no applied parts are intended to be used and where discontinuity (failure) of the supply cannot cause danger to life

710.3.6
group 1
medical location where discontinuity of the electrical supply does not represent a threat to the safety of the patient and applied parts are intended to be used as follows:

– externally,

– invasively to any part of the body, except where 710.3.7 applies

710.3.7
group 2
medical location where applied parts are intended to be used in applications such as intracardiac procedures, vital treatments and surgical operations where discontinuity (failure) of the supply can cause danger to life

NOTE An intracardiac procedure is a procedure whereby an electrical conductor is placed within the heart of a patient or is likely to come into contact with the heart, such conductor being accessible outside the patient's body. In this context, an electrical conductor includes insulated wires such as cardiac pacing electrodes or intracardiac ECG electrodes, or insulated tubes filled with conducting fluids.

710.3.8
medical electrical system (ME system)
combination, as specified by its manufacturer, of items of equipment, at least one of which is medical electrical equipment to be inter-connected by functional connection or by use of a multiple socket-outlet

[EN 60601-1:2006, definition 3.64]

NOTE The system includes those accessories which are needed for operating the system and are specified by the manufacturer.

710.3.9
patient environment
any volume in which intentional or unintentional contact can occur between a patient and parts of the medical electrical equipment or medical electrical system or between a patient and other persons touching parts of the medical electrical equipment or medical electrical system

[EN 60601-1:2006, definition 3.79]

NOTE 1 For illustration see Figure 710A.

NOTE 2 This applies when the patients position is pre-determined, if not, all possible patient positions should be considered.

710.3.10
medical IT system
IT electrical system fulfilling specific requirements for medical applications

NOTE These supplies are also known as isolated power supply systems.

710.30 Assessment of general characteristics

Allocation of group numbers and classification of safety services to a medical location shall be made in agreement with the medical staff and the authority responsible for safety. In order to determine the classification of a medical location, it is necessary that the medical staff indicate which medical procedures will take place within the location. Based on the intended use, the appropriate classification for the location shall be determined.

NOTE 1 Classification of a medical location should be related to the type of contact between applied parts and the patient, as well as the purpose for which the location is used (Guidance on the allocation of a group number and classification of safety services for medical locations is shown in Annex B).

NOTE 2 To ensure protection of patients from possible electrical hazards, additional protective measures need to be applied in medical locations. The type and description of these hazards can vary according to the treatment being administered. The purpose for which a location is to be used may justify areas with different classifications (group 0, 1 or 2) for different medical procedures.

NOTE 3 Applied parts are defined by the particular standards for medical electrical equipment.

NOTE 4 The possibility that certain medical locations could be used for different purposes which necessitate a higher group should be addressed by risk management

710.31 Purposes, supplies and structure

710.312.2 Types of system earthing

The TN-C system is not allowed in medical locations and medical buildings downstream of the main distribution board.

NOTE Main distribution board is a board in the building which fulfils all the functions of a main electrical distribution for the supplied building area assigned to it and where the voltage drop is measured for operating the main safety service.

710.313 Power supply

710.313.1 General

In medical locations the distribution system should be designed and installed to facilitate the automatic change-over from the main distribution network to the electrical safety source feeding essential loads (according to IEC 60364-5-55:2001, Clause 556).

710.4 Protection for safety

710.41 Protection against electric shock

710.410.3 General requirements

Add:

Protection by insulation of live parts, according to HD 60364-4-41:2007, Clause A.1, or protection by barriers or enclosures, according to HD 60364-4-41:2007, Clause A.2, are permitted.

NOTE Class II equipment is also permitted.

710.410.3.5

The protective measures "obstacles" and "placing out of reach" as specified in HD 60364-4-41:2007, Annex B, shall not be applied.

710.410.3.6

The protective measures "non-conducting location", "earth-free local equipotential bonding" and "electrical separation for the supply of more than one item of current-using equipment" as specified in HD 60364-4-41:2007, Annex C, shall not be applied.

710.411.3 Requirements for fault protection (protection against indirect contact)

710.411.3.2 Automatic disconnection in case of a fault

710.411.3.2.1

Add:

Care shall be taken to ensure that simultaneous use of many items of equipment connected to the same circuit cannot cause unwanted tripping of the residual current protective device (RCD).

In medical locations of group 1 and group 2, where RCDs are required, only type A or type B shall be selected, depending on the possible fault-current arising.

710.411.3.2.5

Add:

In medical locations of group 1 and group 2, the following shall apply:

– for IT, TN and TT systems, the conventional touch voltage U_L shall not exceed 25 V a.c. ($U_L \leq 25$ V a.c.) or 60 V d.c. ($UL \leq 60$ V d.c.);

– for TN and IT systems, HD 60364-4-41:2007, Table 41.1, shall apply.

NOTE In the TN system 25 V a.c. ($U_L \leq 25$ V a.c.) or 60 V d.c. ($U_L \leq 60$ V d.c.) can be met with an additional equipotential bonding, by complying with the disconnection time in accordance with the general standard.

710.411.3.3

Where medical IT-System is used for protective measure this clause is not applicable.

710.411.4 TN system

In final circuits of group 1 rated up to 63 A residual current protective devices with a rated residual operating current not exceeding 30 mA shall be used (this covers also additional protection).

In medical locations of group 2 protection by automatic disconnection of supply by means of residual current protective devices with a rated residual-operating current not exceeding 30 mA may only be used on the following circuits:

– circuits for the supply of operating tables;

– circuits for X-ray units;

NOTE 1 The requirement is mainly applicable to mobile X-ray units brought into group 2 locations.

– circuits for large equipment with a rated power greater than 5 kVA.

NOTE 2 It is recommended that TN-S systems are monitored to ensure the insulation level of all live conductors and that a decrease should be reported to technical staff.

710.411.5 TT system

Add:

In medical locations of group 1 and group 2 residual current protective devices shall be used as disconnection devices and the requirements of TN system (see 710.411.4) apply.

710.411.6 IT system

710.411.6.3.1

Add:

In group 2 medical locations, the medical IT system shall be used for final circuits supplying medical electrical equipment and systems intended for life support, surgical applications and other electrical equipment located in the "patient environment", excluding equipment listed in 710.411.4.

For each group of rooms serving the same function, at least one separate medical IT system is necessary. The medical IT system shall be equipped with an insulation monitoring device (IMD) in accordance with EN 61557-8 with the following additional specific requirements:

– a.c. internal impedance shall be ≥ 100 kΩ;

– internal resistance shall be ≥ 250 kΩ;

– test voltage shall be ≤ 25 V d.c.;

– injected current, even under fault conditions, shall be ≤ 1 mA peak;

– indication shall take place at the latest when the insulation has decreased to 50 kΩ. If the response value is adjustable, the lowest possible setpoint value shall be ≥ 50 kΩ. A test device shall be provided;

– response and alarm-off time shall be ≤ 5 s.

NOTE 1 An indication is recommended if the protective earth (PE) or wiring connection of the IMD is lost.

NOTE 2 The necessary additional requirements on IMDs given above are at this time not covered in the equipment standard EN 61557-8:1997. They will be removed from this publication as soon as they have been treated in the relevant equipment standard.

NOTE 3 National regulations ensuring equivalent safety may apply.

For each medical IT system, an acoustic and visual alarm system incorporating the following components shall be arranged at a suitable place so that it can be permanently monitored (audible and visual signals) by the medical staff and furthermore is forwarded to the technical staff:

– a green signal lamp to indicate normal operation;

– a yellow signal lamp which lights when the minimum value set for the insulation resistance is reached. It shall not be possible for this light to be cancelled or disconnected;

– an audible alarm which sounds when the minimum value set for the insulation resistance is reached. This audible alarm may be silenced;

– the yellow signal shall go out on removal of the fault and when the normal condition is restored.

Monitoring of overload or high temperature for the medical IT-transformer is required. Monitoring of both is recommended.

Fault location systems which localize insulation faults in any part of the medical IT system may also be installed in addition to an insulation monitoring device.

The insulation fault location system shall be in accordance with EN 61557-9.

710.411.7 Functional extra-low voltage (FELV)

In medical locations functional extra-low voltage (FELV) is not permitted.