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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 médicaux

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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)

Errichten von Niederspannungsanlagen - Teil 7-710: Anforderungen für Betriebsstätten, Räume und Anlagen besonderer Art - Medizinisch genutzte Bereiche (IEC 60364-7-710:2002, modifiziert)

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This Harmonization Document exists in three official versions (English, French, German).

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CENELEC

European Committee for Electrotechnical Standardization
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Foreword

This document (HD 60364-7-710:2012*)* consists of the text of IEC 60364-7-710:2002 prepared by IEC/TC 64 "Electrical installations and protection against electric shock", together with the common modifications prepared by CLC/TC 64, "Electrical installations and protection against electric shock".

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2013-01-09
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2015-01-09

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Endorsement notice

The text of the International Standard IEC 60364-7-710:2002 was approved by CENELEC as a European Standard with common modifications.

Introduction

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

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

In medical locations it is necessary to ensure the safety of patients likely to be subjected to the application of ME (medical electrical) equipment. For every activity and function in a medical location, the particular requirements for safety have to be considered. Safety can be achieved by ensuring the safety of the installation and the safe operation and maintenance of ME equipment connected to it. The use of ME equipment on patients undergoing critical care has called for enhanced reliability and safety of electrical installations in hospitals so as to improve the safety and continuity of supplies which is met by application of this Harmonization Document. Variations of this document to further enhance safety and reliability are 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 ME 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 ME equipment and ME systems, refer to the EN 60601 series.

NOTE 4 Care should be taken that other installations should not impair the installations.

NOTE 5 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 6 The application of this Harmonization Document does not exempt to respect the national regulations.

710.2 Normative references

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

EN 61439 (all parts), *Low-voltage switchgear and controlgear assemblies (IEC 61439 series)*

EN 60601 (all parts), *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 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 (IEC 61557-8:2007 + corr. May 2007)*

EN 61557-9:2009, *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 61557-9:2009)*

EN 61558-2-15:2001 + Corrigendum 2004, *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 60364-4-41:2007, *Low-voltage electrical installations – Part 4-41: Protection for safety – Protection against electric shock (IEC 60364-4-41:2005, mod.)*

HD 60364-6:2007, *Low voltage electrical installations – Part 6: Verification (IEC 60364-6:2006, mod.)*

IEC 60364-5-53: 2001, *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*

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

[SOURCE: EN 60601-1:2006, 3.76]

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

[SOURCE: EN 60601-1:2006, 3.63]

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

[SOURCE: EN 60601-1:2006, 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 where applied parts are intended to be used as follows:

– externally;

– invasively to any part of the body in locations outside of group 2 locations

710.3.7
group 2
medical location where applied parts are intended to be used in applications such as:

– intracardiac procedures; or

– vital treatments or surgical operations where discontinuity (failure) of the supply can cause danger to patients

Note 1 to entry: 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 ME equipment to be inter-connected by functional connection or by use of a multiple socket-outlet

[SOURCE: EN 60601-1:2006, 3.64]

Note 1 to entry: 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 ME equipment or ME system or between a patient and other persons touching parts of the ME equipment or ME system

[SOURCE: EN 60601-1:2006, 3.79]

Note 1 to entry: For illustration see Figure 710A.

Note 2 to entry: 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 1 to entry: These supplies are also known as medical isolated power supply systems.

710.3.11
main distribution board
distribution 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

710.30 Assessment of general characteristics

Add:

Allocation of group numbers and classification of safety services to a medical location shall be made in agreement with the medical staff and the person(s) responsible for the medical 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, the threat to the safety of the patient that represents a discontinuity (failure) of the electrical supply, 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 ME 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

Add:

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

710.313 Power supply

710.313.101 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 HD 60364-5-56:2010).

710.41 Protection for safety – Protection against electric shock

710.410.3 General requirements

710.410.3.5

The protective provisions "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 provisions "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 Protective measure: automatic disconnection of supply

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. ($U_L \leq 60$ V d.c.)

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 a medical IT system is used for protective measure 411.3.3 is not applicable.

710.411.4 TN system

Add:

In final circuits of group 1 rated up to 32 A residual current protective devices with a rated residual operating current not exceeding 30 mA shall be used.

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

– circuits for the supply of movements of fixed operating tables;

NOTE 1 If the power consumption is less than 1 kVA, it could be connected to an ME IT system for touch voltage reasons. Higher power consumption is acceptable, if the maximum touch voltage in the case of a first insulation fault will be less than 10 mV.

– circuits for X-ray units;

NOTE 2 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;

It is recommended that TN-S systems are monitored to ensure the insulation level of all live conductors

NOTE 3 A reduced insulation level of all live conductors 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 systems (see 710.411.4) apply.

710.411.6 IT system

710.411.6.3.101 Medical IT system

Add:

In group 2 medical locations, the medical IT system shall be used for final circuits supplying ME equipment and ME systems intended for life support, surgical applications and other electrical equipment located in the “patient environment” or that may be moved into 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 Annex A and Annex B of EN 61557-8:2007.

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 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.

NOTE 1 A written explanation should be easily readable in the medical location and it should include: the meaning of each type of signalisation, alarm and the procedures to be followed in case of a first fault.

Monitoring of overload and high temperature for transformers for medical IT systems is required.

NOTE 2 When the IMD is designed for monitoring overload and temperature, it should be in accordance with Annex B of EN 61557-8:2007.

The equipment for insulation fault location which localizes 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 equipment 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.

710.414 Protective measures: extra-low-voltage provided by SELV and PELV

710.414.1 General

Add:

When using SELV and/or PELV circuits in medical locations of group 1 and group 2, the nominal voltage applied to current-using equipment shall not exceed 25 V r.m.s. a.c. or 60 V ripple free d.c. Protection by basic insulation of live parts according to HD 60364-4-41:2007, Clause A.1 or by barriers or enclosures according to HD 60364-4-41:2007, Clause A.2 shall be provided.

710.414.4.1

Add:

In medical locations of group 2, where PELV is used, exposed-conductive-parts of equipment (e.g. operating theatre luminaries) shall be connected to the protective bonding conductor.

710.415.2 Additional protection: supplementary protective equipotential bonding

710.415.2.1

Add:

In each medical location of group 1 and group 2, supplementary protective equipotential bonding shall be installed and the supplementary protective bonding conductors shall be connected to the equipotential bonding busbar for the purpose of equalizing potential differences between the following parts, which are located or which may be moved into the “patient environment”:

– protective conductors;

– extraneous-conductive-parts;

– screening against electrical interference fields, if installed;

– connection to conductive floor grids, if installed;

NOTE 1 If, due to floor grid connection to the supplementary equipotential bonding, an earth loop is formed, the connection may be disregarded.

– metal screens of isolating transformers, via the shortest way to protective earthing conductor.

A sufficient number of supplementary equipotential bonding connection points for the connection of ME equipment shall be available in group 2 and are recommended in group 1 (see also 710.30).

NOTE 2 Fixed conductive non-electrical patient supports such as operating theatre tables, physiotherapy couches and dental chairs should be connected to the equipotential bonding conductor unless they are intended to be isolated from earth.

710.415.2.2

Add:

In medical locations of group 1 the resistance of the protective conductors, including the resistance of the connections, between the terminals for the protective conductor of socket-outlets and of fixed equipment or any extraneous-conductive-parts and the equipotential bonding bus bar, shall not exceed 0,7 Ω.

NOTE 1 National regulations ensuring equivalent safety may apply.

In medical locations of group 2, the resistance of the protective conductors, including the resistance of the connections, between the terminals for the protective conductor of socket-outlets and of fixed equipment or any extraneous-conductive-parts and the equipotential bonding bus bar shall not exceed 0,2 Ω.

NOTE 2 National regulations ensuring equivalent safety may apply.

Add:

710.415.2.101

The equipotential bonding shall be located in or near the medical location and it shall be connected to the main protective earth conductor with a conductor having a cross sectional area equivalent to the larger cross sectional area of the conductors connected with the equipotential bonding. Connections shall be so arranged that they are accessible, labelled, clearly visible and that they can easily be disconnected individually.

NOTE 1 It is recommended to use star-shaped or tree-shaped wiring and to avoid “earth-loops”.

NOTE 2 For rooms used for intracardiac procedures special national requirements to isolate the equipotential bonding bus bar may apply.

710.42 Protection for safety – Protection against thermal effects

710.422 Precautions where particular risks of fire exist

Add:

National legislation providing additional requirements may exist.

710.44 Protection for safety – Protection against voltage disturbances and electromagnetic disturbances

710.444 Measures against electromagnetic disturbances

Add:

Special considerations shall be made concerning electromagnetic interference and electromagnetic compatibility. Further information is provided in Annex C.

710.51 Selection and erection of electrical equipment – Common rules

710.510.101 Distribution boards

Distribution boards shall be in accordance with EN 61439 series.

Distribution boards for group 2 shall be installed in close proximity to the group 2 medical locations and shall be clearly identifiable.

NOTE 1 Dedicated distribution boards should be provided for the general power supply and the safety power system.