SLOVENSKI STANDARD

SIST IEC 60364-7-710:2006

september 2006

Električne inštalacije zgradb – 7-710. del: Zahteve za posebne inštalacije ali lokacije – Medicinski prostori

Electrical installations of buildings - Part 7-710: Requirements for special installations or locations - Medical locations

ICS 11.020; 91.140.50

Referenčna številka
SIST IEC 60364-7-710:2006(en)

NORME INTERNATIONALE

INTERNATIONAL STANDARD

CEI
IEC
60364-7-710

Première édition
First edition
2002-11

Installations électriques des bâtiments –

Partie 7-710:
Règles pour les installations ou emplacements spéciaux – Locaux à usages médicaux

Electrical installations of buildings –

Part 7-710:
Requirements for special installations or locations – Medical locations

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Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

CODE PRIX
PRICE CODE R

Pour prix, voir catalogue en vigueur
For price, see current catalogue

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

ELECTRICAL INSTALLATIONS OF BUILDINGS –

Part 7-710: Requirements for special installations or locations – Medical locations

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the 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, the IEC publishes International Standards. 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. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.
3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical specifications, technical reports or guides and they are accepted by the National Committees in that sense.
4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.
5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.
6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 60364-7-710 has been prepared by IEC technical committee 64: Electrical installations and protection against electric shock.

The text of this standard is based on the following documents:

FDIS	Report on voting
64/1268/FDIS	64/1275/RVD

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

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

The committee has decided that the contents of this publication will remain unchanged until 2007. At this date, the publication will be

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

INTRODUCTION

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

The clause numbering following 710 are those of the corresponding parts or clauses from parts 1 to 6 of IEC 60364.

The absence of reference to a part or a clause means that parts 1 to 6 of IEC 60364 are applicable.

In medical locations it is necessary to ensure the safety of patients likely to be subjected to the application of 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 medical electrical equipment connected to it. The use of medical electrical equipment on patients undergoing intensive care (of critical importance) 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 standard. Variations of the standard to further enhance safety and reliability are acceptable.

ELECTRICAL INSTALLATIONS OF BUILDINGS –

Part 7-710: Requirements for special installations or locations – Medical locations

710 Medical locations

710.1 Scope

The particular requirements of this part of IEC 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.

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

NOTE 3 For medical electrical equipment, refer to the IEC 60601 series.

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.

IEC 60364-4-41:2001, *Electrical installations of buildings – Part 4-41: Protection for safety – Protection against electric shock*

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

IEC 60364-6-61:2001, *Electrical installations of buildings – Part 6-61: Verification – Initial verification*

IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*
Amendment 2 (1995)

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

IEC 60617-1:1985, *Graphical symbols for diagrams – Part 1: General information, general index – Cross-reference tables*

IEC 60617-11(DB)[1], *Graphical symbols for diagrams – Part 11: Architectural and topographical installation plans and diagrams*

IEC 61082-1:1991, *Preparation of documents used in electrotechnology – Part 1: General requirements*

1 DB = Data Base.

IEC 61557-8:1997, *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 61558-2-15:1999, *Safety of power transformers, power supply units and similar – Part 2-15: Particular requirements for isolating transformers for the supply of medical locations*

710.3 Definitions

For the purposes of this part of IEC 60364, the following definitions apply.

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

NOTE 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 manner in which a room is to be used necessitates some division into different areas for differing medical procedures.

710.3.2
patient
living being (person or animal) undergoing medical or dental investigation or treatment

(adapted from 2.12.4 of IEC 60601-1)

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

electrical equipment, provided with not more than one connection to a particular supply mains and intended to diagnose, treat or monitor the patient under medical supervision and which

– makes physical or electrical contact with the patient, and/or
– transfers energy to or from the patient, and/or
– detects such energy transfer to or from the patient.

NOTE The equipment includes those accessories defined by the manufacturer as being necessary to enable normal use of the equipment.

710.3.4
applied part
part of the medical electrical equipment which in normal use

– necessarily comes into physical contact with the patient for the equipment to perform its function, or
– can be brought into contact with the patient, or
– needs to be touched by the patient

(adapted from 2.1.5 of amendment 2 to IEC 60601-1)

710.3.5
group 0
medical location where no applied parts are intended to be used

710.3.6
group 1
medical location where 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, operating theatres and vital treatment 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
combination of items of equipment, at least one of which is an item of medical electrical equipment and inter-connected by functional connection or use of a multiple portable socket-outlet

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 patient and parts of the system or between patient and other persons touching parts of the system (for illustration see Figure 710A)

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

710.3.10
main distribution board
board in the building which fulfils all the functions of a main electrical distribution for the supply building area assigned to it and where the voltage drop is measured for operating the safety services

710.3.11
medical IT system
IT electrical system having specific requirements for medical applications

710.30 Assessment of general characteristics

The classification of a medical location shall be made in agreement with the medical staff, health organization concerned or body responsible for the safety of workers in accordance with national regulations. 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 (the possibility that certain medical locations may be used for different purposes which necessitate a higher group should be addressed by risk management).

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 (see Annex B).

NOTE 2 Applied parts are defined by the particular standards for medical electrical equipment.

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.

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, clause 556).

710.4 Protection for safety

710.41 Protection against electric shock

710.411 Protection against both direct and indirect contact

710.411.1 SELV and PELV

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 insulation of live parts according to 412.1 of IEC 60364-4-41 and by barriers or enclosures according to 412.2 of the same standard is essential.

In medical locations of group 2, exposed-conductive-parts of equipment (e.g. operating theatre luminaires), shall be connected to the equipotential bonding conductor.

710.412 Protection against direct contact

710.412.3 Obstacles

Protection by obstacles is not permitted.

710.412.4 Placing out of reach

Protection by placing out of reach is not permitted.

Only protection by insulation of live parts or protection by barriers or enclosures are permitted.

710.413 Protection against indirect contact

710.413.1 Automatic disconnection of supply

710.413.1.1 General

710.413.1.1.1 Disconnection of supply

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 ($U_L \leq 25$ V);

– for TN and IT systems, table 41C of IEC 60364-4-41 shall apply.

NOTE Disconnection of supply when overload or short-circuit conditions occur, can be achieved by different design methods within the procedures of the general rules in order to satisfy the required safety level.

710.413.1.3 TN systems

In final circuits of group 1 rated up to 32 A residual current devices with a maximum residual operating current of 30 mA shall be used (additional protection).

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

– circuits for the supply of operating tables;
– circuits for X-ray units;

NOTE 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;
– circuits for non-critical electrical equipment (non life support).

Care shall be taken to ensure that simultaneous use of many items of such 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 by this subclause, only type A or type B shall be selected, depending on the possible fault-current arising.

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

710.413.1.4 TT systems

In medical locations of group 1 and group 2, the requirements of TN systems (see 710.413.1.3) apply and in all cases residual current protective devices shall be used.

710.413.1.5 Medical IT system

NOTE 1 In the United States such a system is identified as an “Isolated Power System”.

In group 2 medical locations, the medical IT system shall be used for 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 713.413.1.3.

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 in accordance with IEC 61557-8 with the following specific requirements:

– the a.c. internal impedance shall be at least 100 kΩ;
– the test voltage shall not be greater than 25 V d.c.;
– the injected current, even under fault conditions, shall not be greater than 1 mA peak;
– indication shall take place at the latest when the insulation resistance has decreased to 50 kΩ. A test device shall be provided;

NOTE 2 In Germany, an indication is required if the earth or wiring connection is lost.

NOTE 3 The necessary additional requirements on IMDs given above are at this time not covered in the equipment standard IEC 61557-8. They will be removed from this publication as soon as they have been treated in the relevant equipment standard.

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:

– 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;