H+line

Practical guide for group 2 medical locations

Hospitals and medical centers are complex buildings. Operational continuity and energy management are of central importance for the reliable and efficient hospital operation. Power outages are not only a nuisance, they can also be life-threatening. This is why, for many years already, hospitals from all over the world have been relying on ABB technology.

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Introduction

This document is the result of the many years of experience of ABB in the hospital sector and the day-to-day relationship with our customers who operate in this sector, which has made it possible to explore real world issues and applications in depth, while continuously comparing regulatory aspects with technical/installation aspects. We would like to thank all the ABB customers who shared their everyday experience with us for the great sensitivity shown in protecting the safety of the patients.

1.1 Premise and purpose of the document
The aim of this document is to illustrate the requirements provided by IEC 60364-7-710, which are required for the implementation of the electrical systems inside group 2 medical locations: these types of environments involve high risks for patients and, consequently, require the implementation of additional measures compared to traditional domestic and residential electrical systems.

The document is also intended as an aid to anyone approaching this type of system for the first time, which involves specific design criteria and responsibilities for designers and installers.

1.2 ABB serving efficiency in the hospital structures
Implementing a hospital environment involves knowing how to choose and install products with appropriate characteristics. ABB offers a complete range of products in this area for preparing each individual environment, from operating theatres to service rooms, in order to guarantee the best possible organisational conditions in hospitals, clinics, retirement homes, dental or veterinary clinics that will enable healthcare staff to carry out their duties efficiently and to offer patients continuous and high quality assistance in a completely safe environment.

Communication between medical and nursing staff
For example, communication between patients and medical-nursing personnel is guaranteed by the modern Clinos 3000 system, with different versions for only acoustic-luminous calls or also equipped with the possibility for direct voice communication between the individual patients and the staff. QSO switchboards are available for the electrical equipping of operating theatres. Thanks to insulating transformers and ISOLTESTER-DIG and SELVTESTER devices, it is possible to protect the system from indirect contacts, without automatically breaking the circuit at the first fault.

ABB also provides all the products and systems necessary for the implementation of the electrical systems and automation of the various technological systems in the building: from general electrical switchboards to circuit breakers for controlling lights, from buildingautomation systems with EIB/KNX systems to high energetic efficiency drive units and motors for air conditioning and hydrothermal systems, from open and moulded-case circuit breakers to the wall-mounted and flush-mounted consumer units, from plastic and metal ducts to floor foundation systems. The protection, command, control and measurement functions can be implemented, not only by means of general-use devices for electrical distribution, but also using specific devices, such as RCD blocks, RCDs, surge arresters and a huge range of DIN bar products.

Products designed for integration
All ABB products are designed and manufactured to operate in a perfectly integrated manner, allowing the implementation of the best solutions for optimising investments and maximizing results in terms of quality, cost control and operational efficiency.

In all situations, and to meet all requirements, choosing ABB products means entrusting the operation and management of your systems to a leader company in the energy and automation sectors, which has always been in the forefront of the manufacture and supply of components and systems for hospital applications.

1.3 ABB's references in the hospital sector
The experience of ABB in the hospital field is based on and certified by a series of implementations that represent the best from a technological perspective.

The following is a list of the most important hospital structures with which ABB has collaborated recently:

- The Humanitas Clinic in Rozzano, Milan
- The Columbus treatment clinic - Milan
- The Gaetano Pini Orthopaedic Institute - Milan
- The Niguarda Ca'Granda hospitals - Milan
- Spedali Civili in Brescia
- The "Città di Brescia" hospital, Brescia
- The Fondazione Poliambulanza in Brescia
- The Ospedale di Circolo and Fondazione Macchi - Varese
- The Aosta regional hospital
- The Hospital Centre of Castelfranco Veneto, Treviso
- The Hospital Centre of Montebelluna, Treviso.


Azienda Ospedaliera - Polo Universitario

Why it is important to design and implement a system according to the standards

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Left side: The Hospital “Circolo e Fondazione Macchi” - Varese

2.1 Definitions and nomenclature

Before examining the ways in which systems for medical location are implemented, we provide a number of definitions that will make it easier to understand the remaining sections of this document.

2.1.1 Medical location

Location intended for purposes of diagnosis, treatment (including cosmetic treatment), monitoring and care of patients

Medical locations may also consist of a group of rooms, so long as they are connected functionally, even if not directly communicating, and intended for diagnostic, therapeutic, surgical, patient monitoring or rehabilitation purposes (including aesthetic treatments) The operating room, pre-anaesthesia room, and waking-up room are, for example, functionally connected rooms. Medical locations are environments with a greater electrical risk than ordinary premises because patients may find themselves in conditions of increased vulnerability and subject to the application of electromedical devices.

Therefore, particular techniques must be adopted for electrical systems in order to guarantee maximum safety for patients.

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IEC 60364-7-710
Definition 710.3.1

Type of premises	Examples	Max touch voltage (U_L) allowed
Medical locations	Outpatients department	25 V
Ordinary rooms	Waiting room	50 V

- Medical locations
- Greater protection of safety
- Group 2 rooms
- Increased electrical risk

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Figure 2.1: Ordinary room (left) and Medical location (right)

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

The power supply can also be obtained by means of an internal electrical source. Medical electrical equipment can be categorised as class I or class II depending on their degree of insulation. In class I devices, protection against indirect contact is guaranteed by connection to a safety conductor (Fig. 2.2.a), while class II protection is intrinsic in that it is provided by double insulation or reinforced insulation (Fig. 2.2.b).

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IEC 60364-7-710
Definition 710.3.3

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

Medical electrical systems are groups of multiple electromedical devices or of electromedical devices with other non-electromedical devices, connected electrically both for the transfer of data or signals, and through their power supply.
One example could be a device that monitors the physiological parameters of a patient and transfers the corresponding data to another piece of equipment which in turn processes them in order to provide information useful for diagnosis.

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IEC 60364-7-710,
Definition 710.3.8

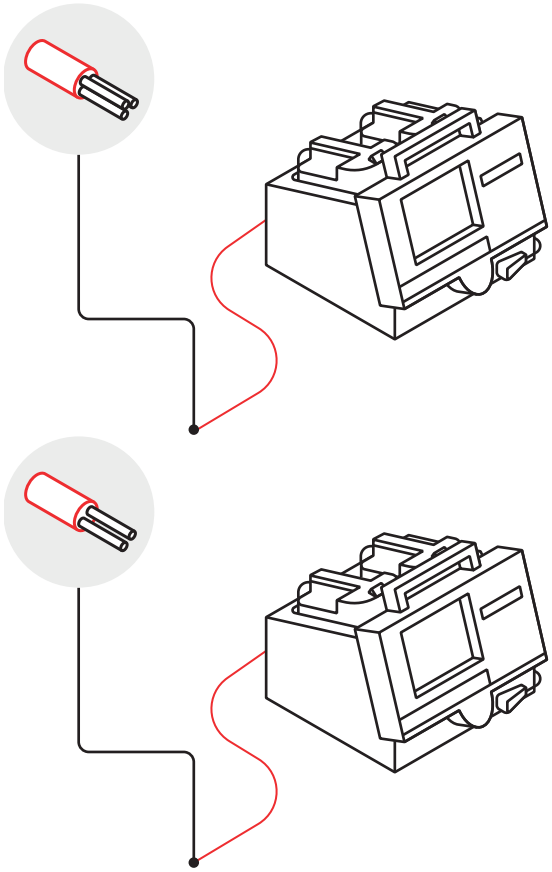

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Figure 2.2:
Medical electrical equipment

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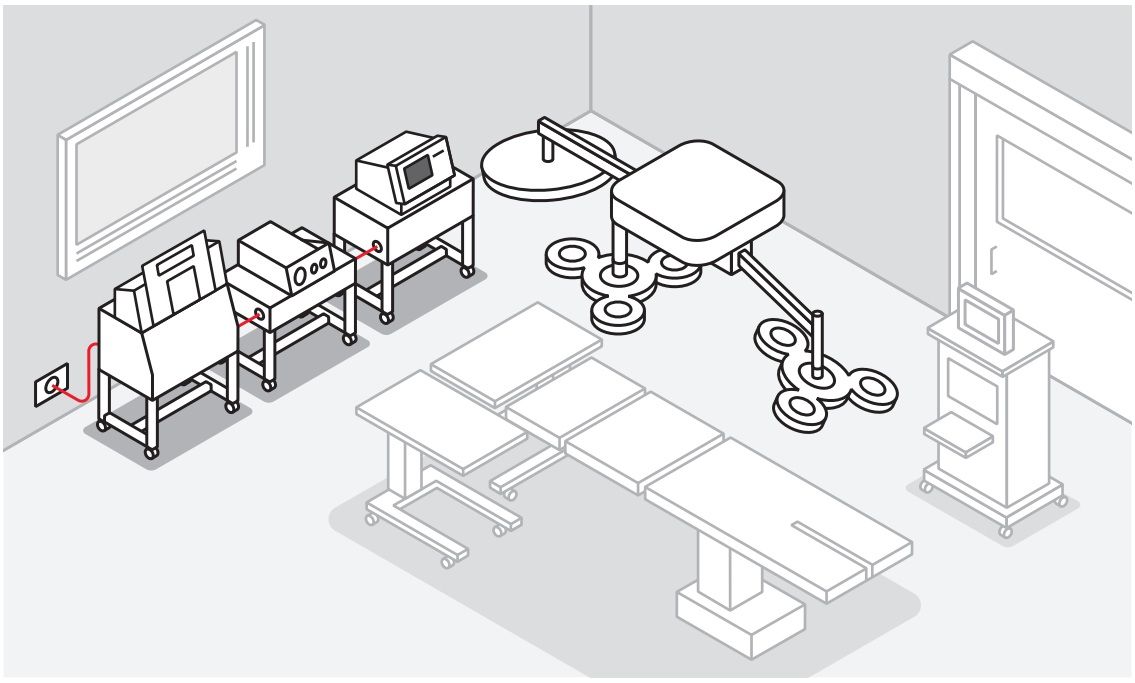
Figure 2.3:
Medical electrical system



2.1.4 Applied part

A 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.

The applied part can be an electrode external or internal to the body or a surface of the device that, for functional reasons, must be brought into contact with the patient. As regards the type of applied part, medical electrical equipment are divided into devices with parts applied of type CF, BF and B, classified in order of decreasing safety.

Part applied	Symbol	Description
CF		Devices whose applied part is earth insulated (F = floating) and can be placed in direct contact with the heart since their applied part is insulated
BF		Devices whose applied part is earth insulated (F = floating), but which provide a lesser degree of protection than CF devices. They are therefore not suitable for direct cardiac application
B		Devices whose applied part is not earth insulated. They are therefore less safe as regards earth leakage

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IEC 60364-7-710, Definition 710.3.4

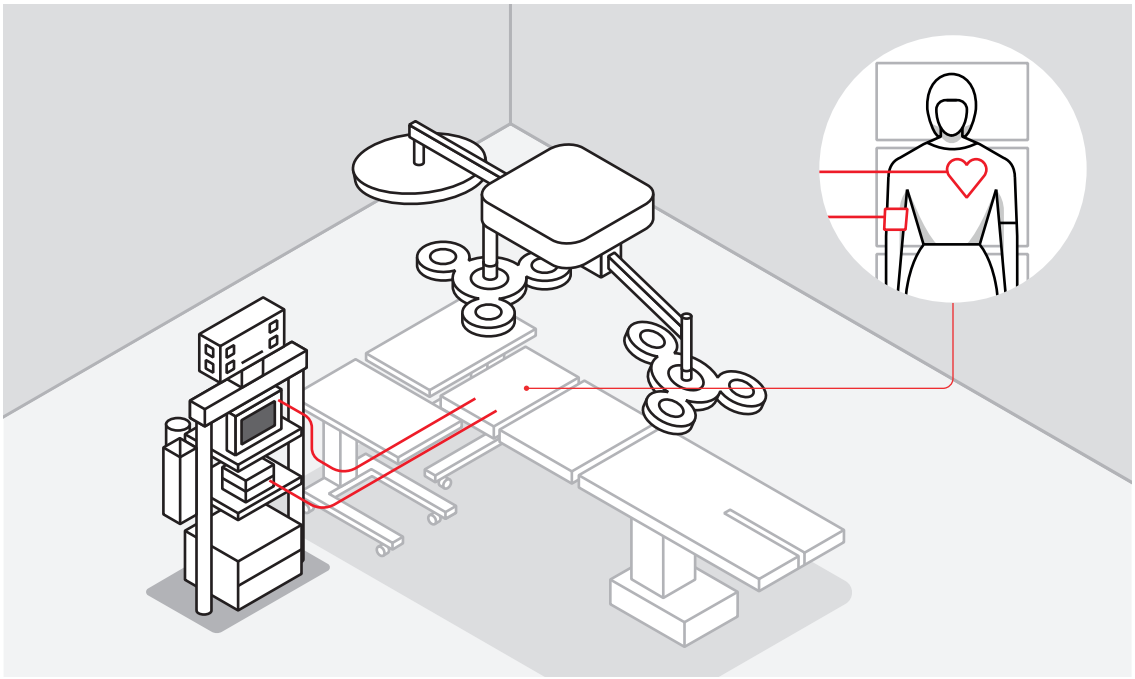

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Figure 2.4:
Example of a medical electrical equipment with applied part

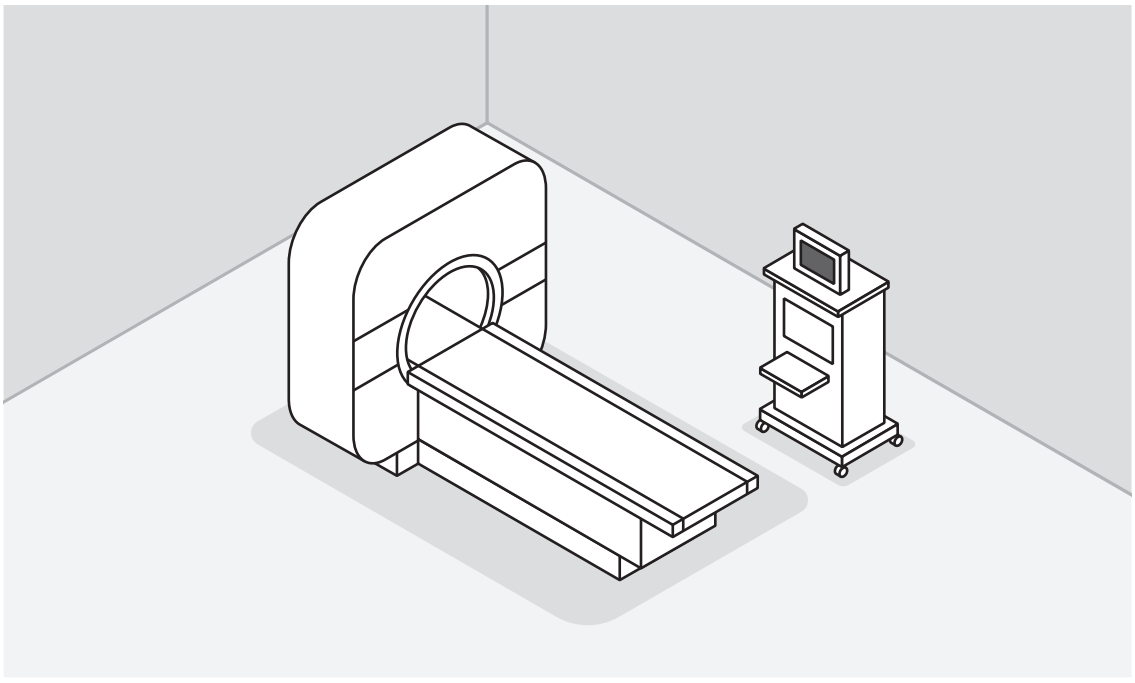

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Figure 2.5:
Example of a medical electrical equipment without applied part

2.1.5 Extraneous conductive part

A conductive part that is not part of the electrical system, which can introduce a potential, generally the earth potential.

Examples of extraneous conductive parts include metal ducts for gas, water, for heating and for medical gases, the operating table, air conditioning ducts and the metal elements of the building, such as metal window frames that extend outside the premises or the structures supporting the plasterboard of the walls. The metal elements present in the premises are to be considered as extraneous conductive parts if they present resistance to earth:

R < 0,5 MΩ	in group 2 medical locations where a microshock hazard exists (for example, surgery rooms in general)
R < 200 Ω	in group 1 and group 2 medical locations where there is not, however,
R < 1000 Ω	in ordinary rooms

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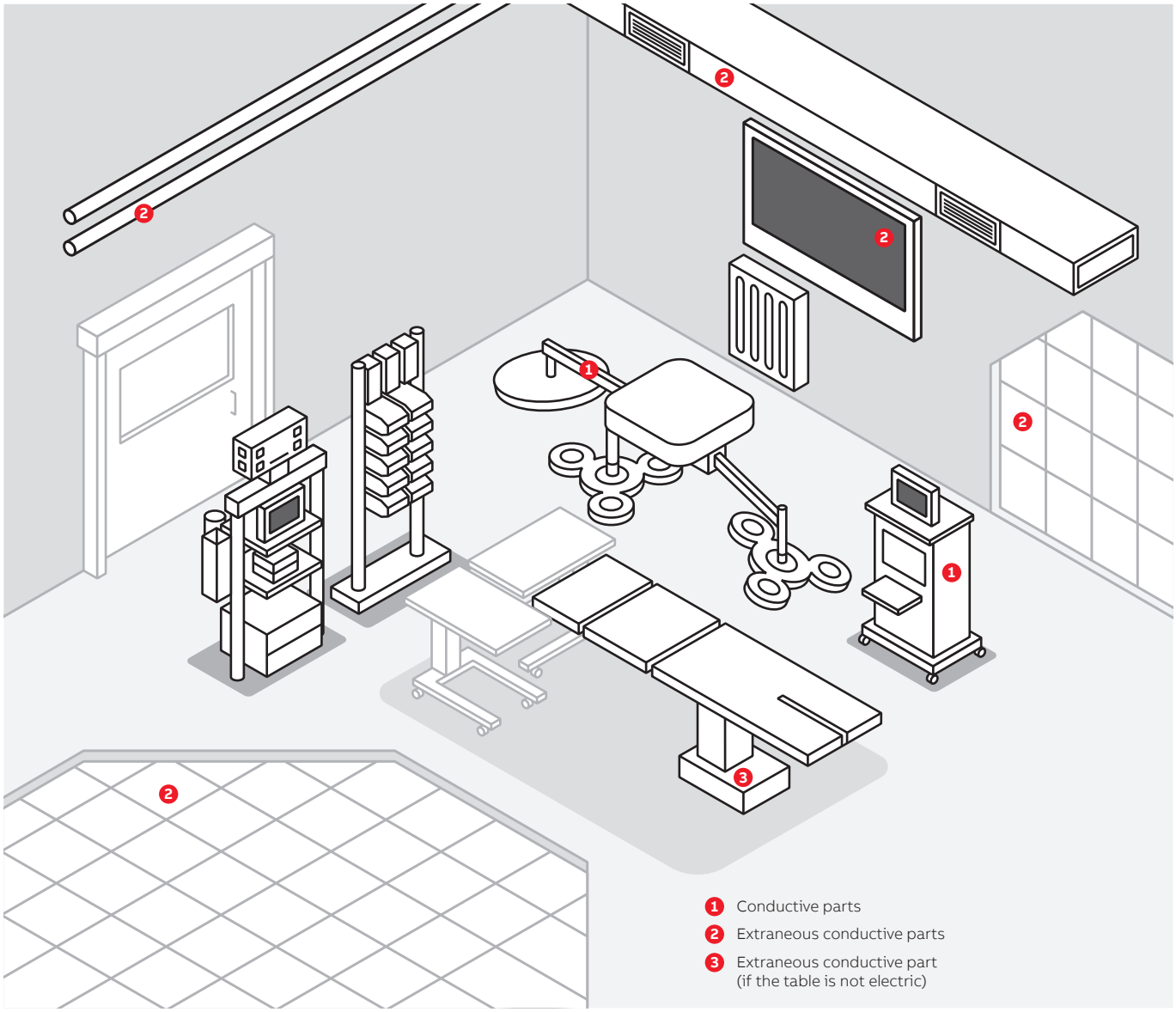
Figure 2.7:
Operating theater



2.1.6 Group 0, 1 and 2 medical locations

The IEC 60346-710 classifies medical locations use as follows:

Group 0 rooms

Medical location where no applied parts are intended to be used. These include outpatients departments and massage rooms where electromedical devices are not used;

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IEC 60364-7-710
Definition 710.3.5

Group 1 rooms

Medical location where applied parts are intended to be used externally or invasively to any part of the body, except for the cardiac zone. These are rooms where electromedical devices with parts applied externally or also internally to the patient's body - except for the cardiac zone - are used;

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IEC 60364-7-710,
Definition 710.3.5

Group 2 rooms

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.

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IEC 60364-7-710,
Definition 710.3.7

These are premises where electromedical devices with catheters, with conductive fluids or electrodes are applied in the cardiac zone or directly to the patient's heart, with a consequent microshock hazard. Group 2 rooms also include those in which patients undergo vital treatments, such that the lack of power supply may involve a risk to life, as well as operation preparation rooms, surgical plaster rooms or post-operative wakingup rooms for patients who have undergone general anaesthesia.

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Figure 2.8:
Group 0 medical locations, outpatients department

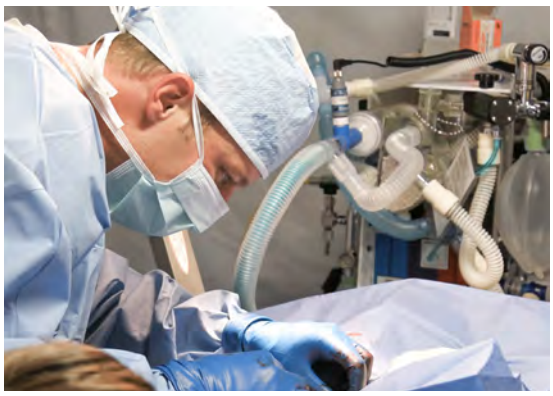

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Figure 2.9:
Group 2 medical locations, operating room

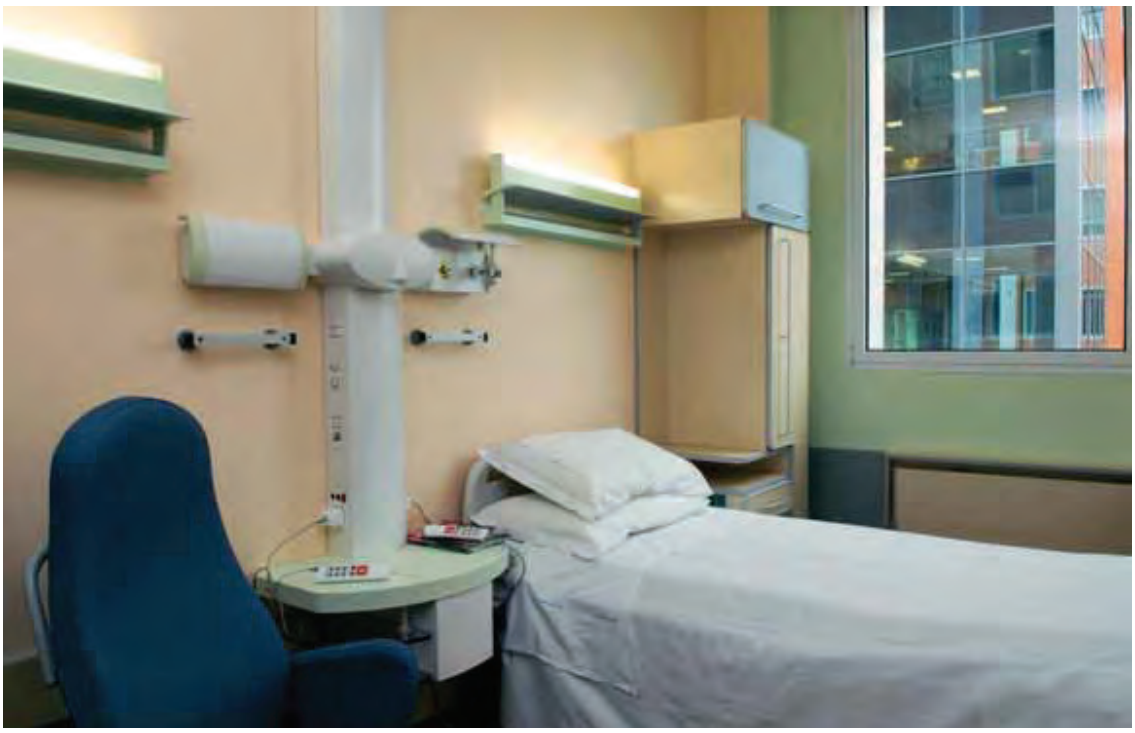

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Figure 2.10:
Group 1 medical locations, hospital accommodation room

Ordinary rooms
These are service rooms for the medical structure, such as offices, rooms for personnel (for example, changing rooms, canteen, etc.), store rooms, corridors for access to accommodation rooms, service rooms, staff hygiene facilities, waiting rooms etc.

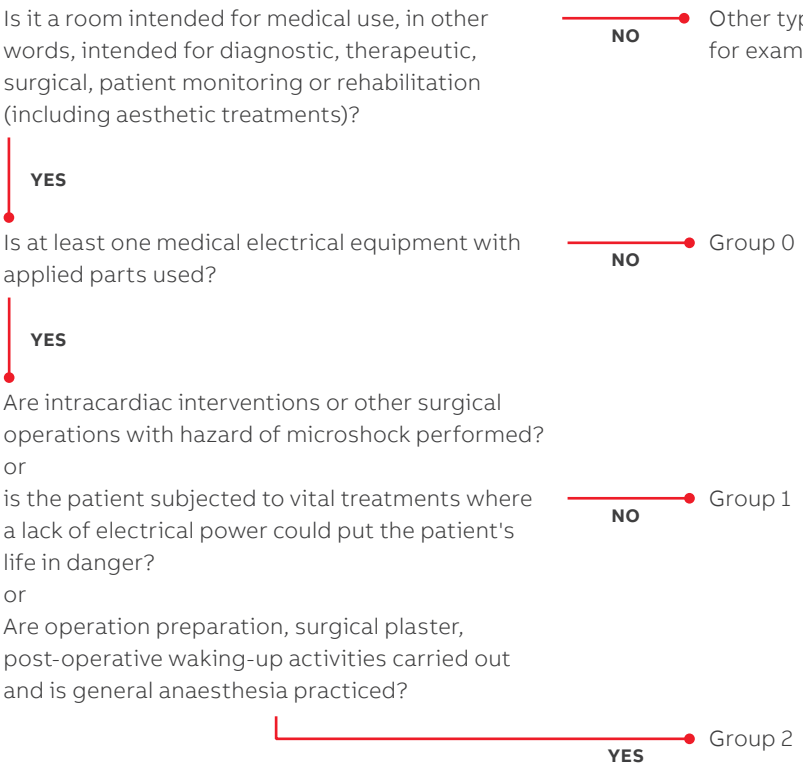

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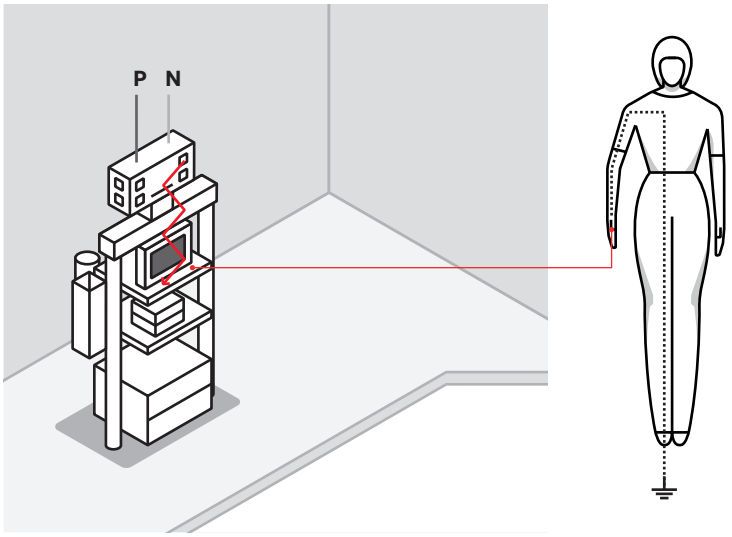
Figure 2.11: Flow diagram for identifying the type of room

The classification of the rooms, which must be carried out according to the normal use of the environment, and the identification of the patient environment must be performed by medical personnel or in agreement with the healthcare organization, which must indicate which medical treatments have to be carried out in the room in question.

In order to identify the group to which the room belongs, risks of macroshock and microshock and situations of general or local anaesthesia must be taken into account .



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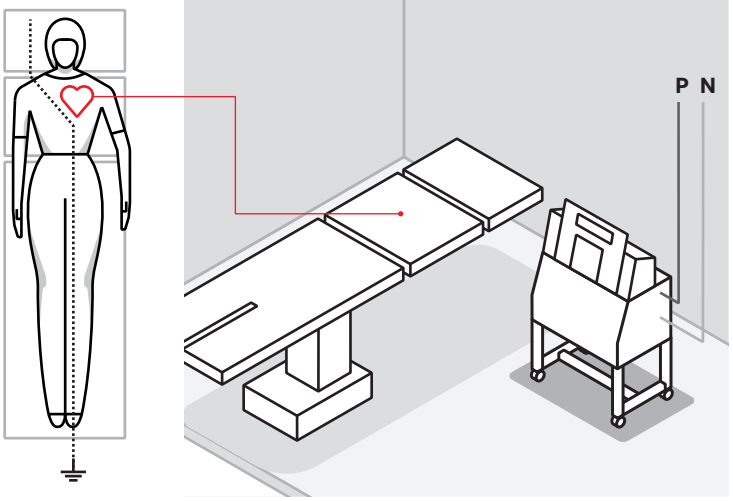
Macroshock is identified with electrocution, in other words the circulation of current through the body that occurs when two portions of skin are subjected to a difference of potential (for example between hand and hand or between one foot and the other). In this case the current is divided over several paths and only one part may involve the thoracic region and touch the cardiac muscle, and therefore it can be hazardous for persons in a normal state of health when it reaches intensities close to 40 ÷ 60 mA



Examples of classification of medical locations

Type of room	Group 0	Group 1	Group 2
Massage room	•	•	
Hospital accommodation rooms		•	
Delivery room		•	
ECG, EEG, EHG, EMG room		•	
Endoscopy room		•(1)	
Outpatient departments	•	•(1)	
Urology room		•(1)	
Radiology and radiotherapy diagnostic rooms		•	
Hydrotherapy room		•	
Physiotherapy room		•	
Anaesthesia room			•
Room for surgery			•
Operation preparation room			•(2)
Surgical plaster room			•(2)
Post-operative waking room			•(3)
Room for applications of cardiac catheters			•
Intensive care room			•
Angiographic and haemodynamic analysis room			•
Haemodialysis room		•	
Magnetic resonance room (MRI)		•	
Nuclear medicine roomx		•	
Premature infant room			•

(1) If not a surgical operating theatre.
(2) If general anaesthesia is practiced.
(3) If it holds patients while they are waking up from general anaesthesia.

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Microshock occurs when a difference of potential, which may even be very small, is applied directly to the cardiac muscle through an intracardiac sensor or a catheter (but also a surgical knife that is a good conductor which is accidentally live). In this case, all the current excites the cardiac mass with greater intensity at the point of application of the probe, causing a high probability of triggering fibrillation. The current becomes hazardous if it exceeds 10 ÷ 60 microampere, values that are several thousand times lower than those of the macroshock

2.1.7 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.

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IEC 60364-7-710,
Definition 710.3.9

The centre of reference in order to determine the patient environment may be, for example, the operating table, the bed in the hospital accommodation room or the dentist's chair. The patient environment does not extend more than 2.5 m above the walking surface and outside the premises. Note that the patient environment can be the container of the patient environments relating to the positions in which the patient may reasonably be located while in contact with applied parts. Similarly, if there are multiple and/or movable electromedical devices, the patient environment is extended to include at most the entire premises. Therefore account is taken of possible movements to which the electromedical devices or the patient may be subjected over time.

Determining the patient environment during the design phase makes it possible to avoid connection of the extraneous conductive parts located outside the patient environment to the equipotential node, reducing the size of the node and simplifying installation, with a consequent reduction of costs. This means therefore that all the possible positions in which the patient may be located while in contact with an electromedical device with applied parts must be established in advance; otherwise, there is a risk that the electrical system will be inadequate when, for medical needs, it becomes necessary to move a medical electrical equipment with parts applied into a position other than those positions originally envisaged.

Sometimes, therefore, it may be opportune to consider the entire room as the patient environment, allowing greater flexibility in the use of the spaces.

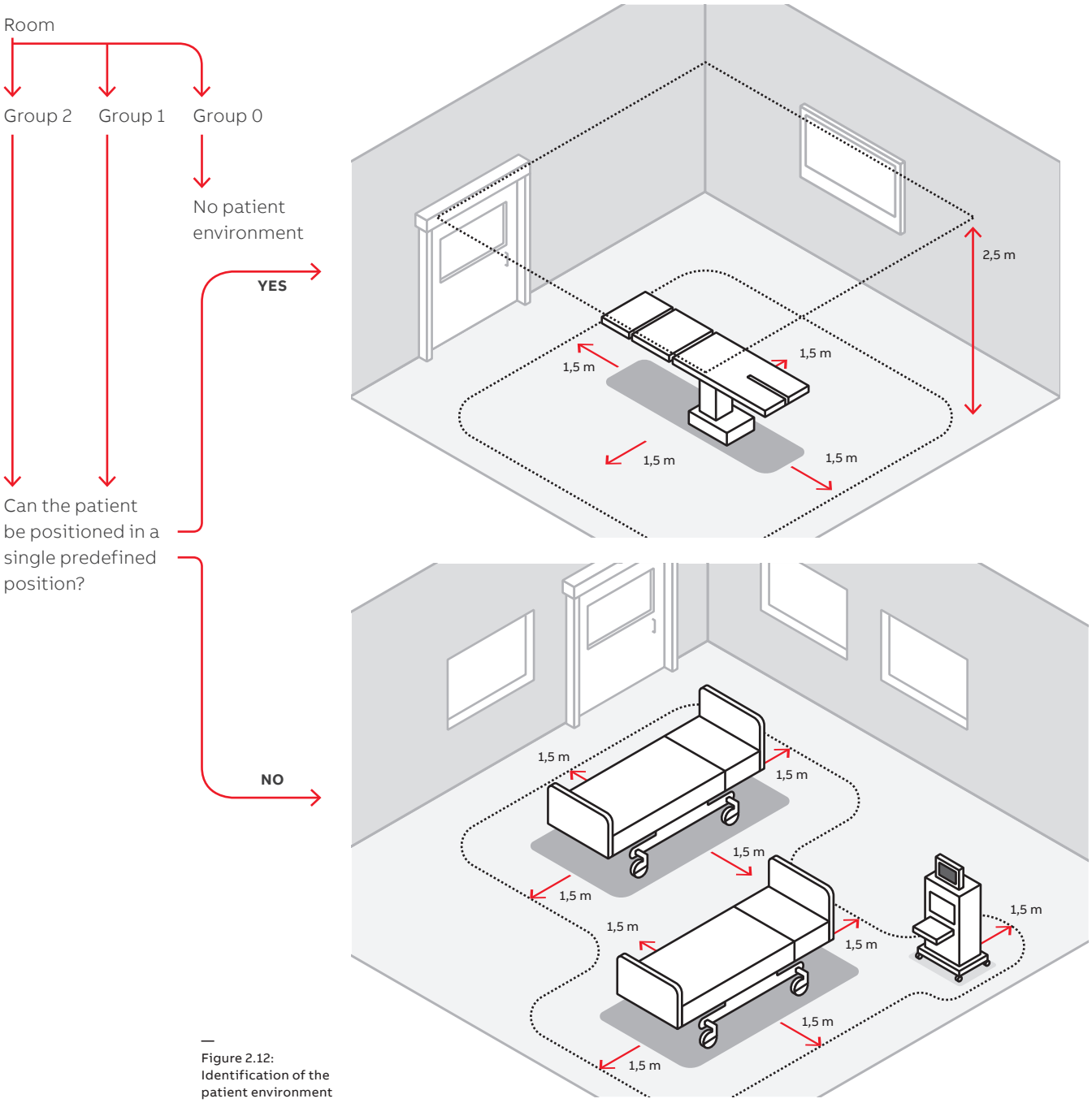

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Figure 2.12:
Identification of the patient environment

2.1.8 Medical IT System

Electrical system having specific requirements for medical applications.

The Medical IT System is intended for supplying power to group 2 medical locations. The Medical IT System consists of an insulating transformer for medical use and a device for permanent earth insulation resistance monitoring.

The insulating transformer provides two essential functions: to guarantee the continuity of operation in the event of an earth fault and to reduce the voltage to which the patient may be subjected so that it is within safety limits (and therefore the current to which the patient could be exposed, protecting him/her from the risk of microshock).

Since a second indirect contact would be equivalent to a short circuit, with the consequent tripping of protection devices and a serious hazard for the patient, a device must be associated to the insulating transformer that can detect any reduction in insulation and signal the first earth fault.

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IEC 60364-7-710
Definition 710.3.11

2.1.9 Main distribution board

A 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.
It is the switchboard powered by the main low voltage switchboard which in turn feeds the zone and department switchboards.

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IEC 60364-7-710,
Definition 710.3.11

It is intended for ordinary and safety distribution (power supply by an electricity-generating unit in the absence of the network). The following are installed in it: protection and cut-off devices, measuring instruments, and possibly an automatic network/generator unit commutator (which could, however, be inserted alternatively on the electricity generator unit switchboard).

The voltage value below which the safety services are activated is measured on this switchboard.

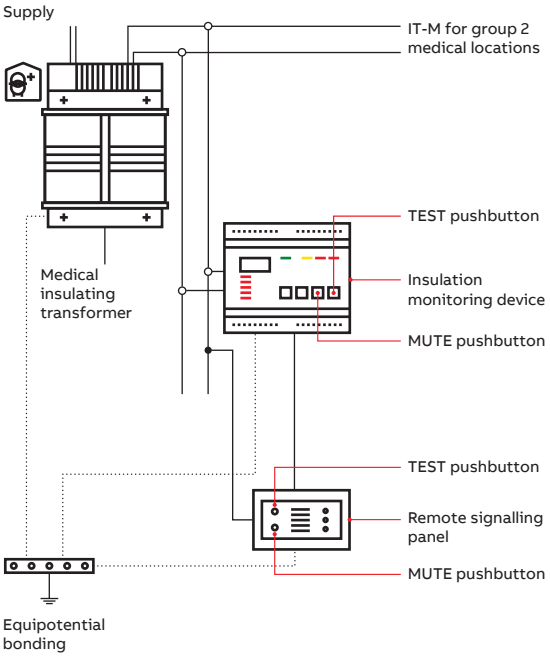

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Figure 2.13:
Medical IT System

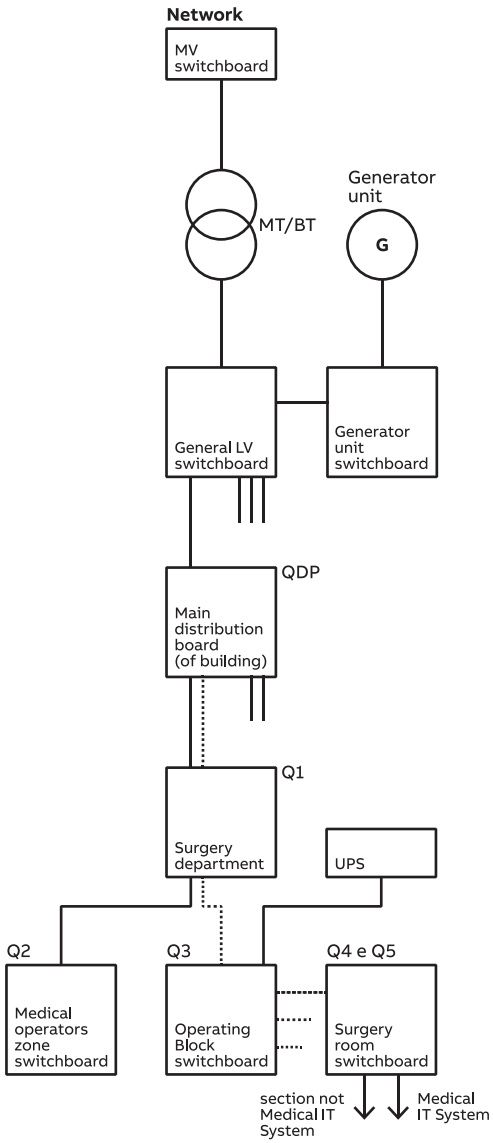

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Figure 2.14: Example of star distribution of electrical energy in a hospital structure

It is advisable:

- that the main distribution board of the building and the department and zone switchboards powered directly by the main distribution switchboard are located in a position protected against fire;
- to position the distribution switchboard for the building in appropriate rooms, not directly communicating with the environments intended for the public and not in proximity to combustible structures or to stores for combustible material.

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Figure 2.15:
Example of a main distribution switchboard

Implementation of systems in medical locations

IEC 60364-7-710 applies to hospitals, clinics, medical and dental surgeries, rooms for massage physiotherapy, beauty centres and veterinary surgeries

3.1 Area of application of the standard

In medical locations it is necessary to guarantee the safety of the medical personnel and in particular of the patients who may come into contact with electromedical devices; therefore specific safety prescriptions must be observed, in additional to the general prescriptions of IEC 60364-7-710, concerning both the devices and the systems. The safety of electrical systems in medical locations is the subject of section 710 of standard IEC 60364 which applies to hospitals, medical clinics, medical and dental studios, rooms for massage physiotherapy, and in all those environments, wherever they may be (for example, medical locations in the workplace or in buildings also intended for residential use), in which electromedical devices with parts applied to the patient are used. The prescriptions also apply to premises for aesthetic use.

3.2 Safety prescriptions for medical locations

The hazard of electrocution may arise from direct contact with a live part of the circuit, or from indirect contact with a metal part, for example the metal body of a steriliser, which is not normally live, but which has become live due to an insulation malfunction.

IEC 60364-7-710 allows the following protection systems against direct and indirect contact in medical locations.

Protection against direct contact

For protection against direct contact with live parts only insulation of the active parts or the segregation thereof through the use of barriers or casings with a protection level no less than IP-XXD (or IP4X) for horizontals surfaces within reach are allowed, and IPXXB (or IP2X) in all the other cases.

Protection against indirect contact.

Protection against indirect contact in medical locations is based on the following provisions:
a) Protection through automatic idisconnection of the power supply;
b) Supplementary equipotential bonding for the conductive parts and the extraneous conductive parts present in the patient environment, or which may enter the zone;
c) Medical IT System;
d) Use of equipment with Class II insulation;
e) Systems with very low safety voltage (SELV and PELV).

Protective measures	Group 1	Group 2
Automatic disconnection of the power supply	•	For all the circuits not powered by the Medical IT System
Medical IT System		•
Supplementary equipotential bonding	•	Resistance of conductors ≤0.2 Ω
Class II devices	•	Connection of conductive parts to the equipotential bonding
Systems with very low safety voltage (SELV and PELV)	•	Connection of conductive parts to the equipotential bonding

Table 3.1:
Overview of protective measures against indirect contact

a) Protection through automatic circuit breaking

This protection must be applied in a way that is compatible with the earth connection method used by the network (TN or TT) and bearing in mind that the value of the limit contact voltage U_L, in the event of a malfunction, is reduced to 25 V (for the section of system in low voltage).

In **TN systems** it is prohibited to use a PEN conductor (TN-C scheme) downstream of the main distribution switchboard because this can cause disturbances and may constitute a fire hazard; therefore only the TN-S system is allowed. In these systems a dead short earth fault must cause the tripping of protection devices (usually automatic miniature circuit breakers) within the times specified in table 3.2.

Voltage U_0 (phase-earth) (V)	Terminal circuits t(s)	Distribution circuits t(s)
120	0.4	5
230	0.2	5
400	0.06	5

Table 3.2:
Maximum interruption times for TN-S systems

The following relationship must be satisfied in **TT systems:** $R_E \cdot I_{dn} \leq 25$

where: R_E is the earth resistance of the earth plate (in ohm);

I_{dn} is the highest nominal operating residual current of the RCDs that for protection of the system (in amperes).

In group 1 medical locations, the standard requires protection only of the terminal circuits that supply sockets outlets with a rated current of up to 32 A, through the use of residual current device with $I_{dn} \leq 30$ mA, although residual current type protection of all the circuits is desirable. In group 2 medical premises it is mandatory for all circuits that are not powered by a medical IT System to be protected by RCDs with $I_{dn} \leq 30$ mA (unless those circuits are supplying power to fixed devices positioned at a height above 2.5 m and which cannot enter the patient environment).

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IEC 60364-7-710.413

Choosing the Residual Current Device (RCD)
Some loads, such as uninterruptable power supplies (UPS), personal computers, printers, electromedical equipment, for example devices for computerized axial tomography or magnetic resonance (RM) etc. incorporate electronic circuits which, in the event of an earth fault, cause currents with continuous components that can compromise the operation of the normal differential devices of the AC type for protecting power supply circuits (the indirect contact currents are not detected by the toroidal transformer).

This is why group 1 and group 2 rooms are obliged, depending on the type of leakage current, to use type A RCDs, which can also intervene with pulsating unidirectional leaking currents or type B RCDs also capable of intervening with unidirectional pulsating and continuous leakage currents.

In the case of power supply via three-phase UPS the product standard requires protection to be achieved by means of RCDs of type B.

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Figure 3.1: Examples of type A and type B RCDs

A unidirectional pulsating current is a current that assumes a value no greater than 6 mA for an interval of at least 150° of each period of the rated frequency (at 50 Hz: 8.33 ms).

Types of RCDs

Symbol	Type	Application	Description
~	AC	Group 1 or 2 rooms with TN distribution system	Only works for earth fault alternating currents, applied instantaneously or increasing slowly
⌇	A	Group 2 rooms: lighting system circuit, radiological sockets, sockets for equipment outside by the patient environment 5	Works only for alternating and unidirectional pulsating earth fault currents, applied instantaneously or increasing slowly
⎓	B		Works for alternating, unidirectional pulsating and direct earth fault currents, applied instantaneously or increasing slowly

b) Supplementary equipotential bonding
IEC 60364-7-710 prescribes the implementation of main equipotential connections, at the base of each building, in order to guarantee the equipotentiality of all the extraneous conductive parts entering the same building, and of supplementary equipotential connections in the environments at greatest electrical risk.
Group 1 and 2 medical locations are expressly covered by this prescription because the differences of potential between conductive parts and extraneous conductive parts and therefore the currents that could affect a patient in contact with such conductive parts are limited to the maximum with the additional equipotential connections.

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Obligation for equipotential connections

Each room for medical use must therefore be equipped with its own equipotential bonding bus bar to which the electrical devices and all the metallic parts that can close an electrical circuit to earth must be connected, so that if an indirect contact of a device (even external to the premises) occurs all the conductive parts and the extraneous conductive parts assume almost the same potential instantaneously (no significant difference of potential between the devices accessible to the patient).
For group 2 medical locations, the equipotential bonding bus bar resistance shall notexceed 0.2 Ω.

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IEC 60364-7-710.413.1.6

c) Medical IT System
It is well known that the RCD does not limit the residual current but the time that it remains (from 30 to 10 ms approximately); in this period of time, although very small, the voltage to the equipotential node can reach high values and the patient can be in serious danger if in contact with the conductive part of the faulty device and another conductive part or extraneous conductive part.

For this reason, in group 2 medical locations with a microshock hazard the ard prescribes the use of a Medical IT System, together with the equipotential bonding bus bar, for all the circuits that supply power to:
- Medical electrical equipments located less than 2.5 m from the walking surface, or which can enter the patient environment;
- Socket outlets (except for those that power devices with a consumption higher than 5 kVA and radiological devices).

In fact the Medical IT System makes it possible to:
- Limit the indirect contact currents by containing the contact voltages;
- Reduce leakage currents;
- Guarantee continuity of service in the event of a first earth fault of a device.

With the Medical IT System, the circuits branched to the secondary must be protected with fuses or thermomagnetic automatic circuit breakers, but not RCDs because the RCD would not be effective in this particular system.

d) Class II components
Medical electric equipments too can be implemented with insulation in class II and carry the “double insulation” symbol.

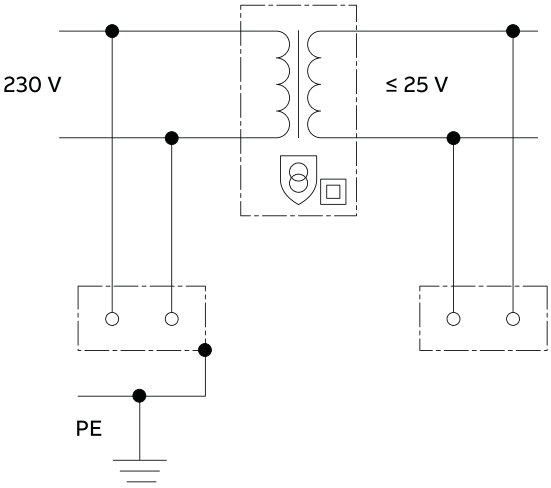
For these devices there is no obligation to connect them to earth if installed in ordinary or group 1 locations; instead they must be connected to the equipotential bonding bus bar (or to a sub-node) if used in group 2 medical locations.

e) Protection against direct and indirect contacts (SELV and PELV systems)
The combined protection against direct and indirect contacts is assured by very low safety voltage which can be implemented with SELV (Safety Extra Low Voltage) and PELV (Protection Extra Low Voltage) systems, provided that their rated voltage is not higher than 25 V in alternating current and 60 V in non inverted direct current.
The power supply must arrive from a safety transformer or from a battery and the SELV and PELV circuits must be installed in the manner prescribed by IEC 60364-4-414.

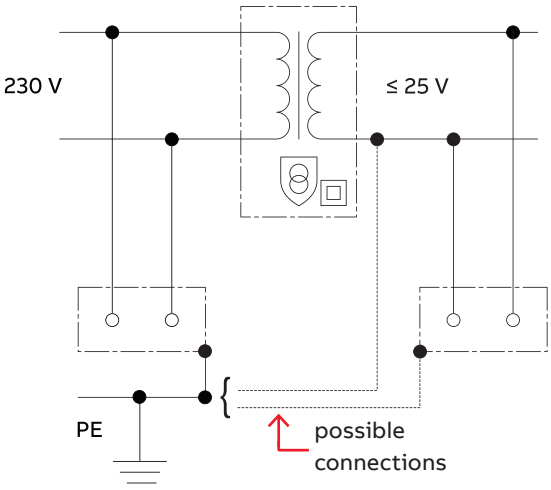
The active parts, if not adequately insulated, must be protected with a protection degree that is at least IP XXB and, for higher horizontal surfaces within reach (for example, beds, tables or other surfaces), at least IP XXD.

The use of these systems in Group 2 rooms requires the following additional provisions:
- The safety transformer must be powered at the primary by the Medical IT System if devices that enter the “patient environment” are connected to SELV or PELV systems (a typical case is the power supply of the scialytic lamp if this is 25 V);
- The devices powered must be connected with the equipotentialisation system of the medical locations (equipotential node). SELV and PELV systems are rarely used, except for supplying power to dedicated devices, such as scialytic lighting devices or infusion pumps.

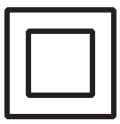
SELV system



PELV system



Conditions that make the use of a Medical IT System mandatory



“Double insulation” symbol

3.2.1 Equipotential node

The function of the equipotential bonding bus bar is to galvanically interconnect all the conductive parts and extraneous conductive parts present or which could enter in the patient environment (fig. 3.2). In this way, if a conductive part malfunction occurs, all the conductive parts will have the same potential and the patient, who may be in contact with two or more conductive parts, is not subject to hazardous currents.

The standards prescribe the installation of an equipotential node bonding bus bar in each group 1 and 2 medical location.

The node can be implemented with a terminal bar or a copper bar with multiple holes (one for each conductor connected) and located on a wall inside or immediately outside the premises.

The general rules apply in group 0 medical locations and therefore there is no equipotential bonding bus bar required, except, of course, for bath and shower rooms.

Elements to be connected to the node
the conductive parts and the extraneous conductive parts(1) that are located in the patient environment, or which may enter it during use, including those installed at a height above 2.5 m, such as the conductive part from the scialytic device (2)
the device protection conductors (3)
the earth contacts of all the sockets of the premises, since they can supply power to devices that could be brought into the patient environment (4)
the iron components of the reinforced concrete of the premises, when possible
any metal screen placed between the windings of the medical insulating transformer (5)
any metal screens intended to reduce electromagnetic fields
any conductive grids located under the floor
Non-electrical and fixed position operating tables unless these are intended to be earth insulated

—
Table 3.3:
Elements to be connected and not to be connected to the node

Elements not to be connected
metal furniture units(6)
metal parts of furnishings

—
The elements that may cause differences on potential must be connected to the equipotential bonding bus bar, each with its own conductor

(1) Piping for hot and cold water, drains, oxygen, medical gases, air conditioning, plasterboard supporting structures, metal fixtures excluding the moving parts such as doors and openable windows
(2) Since in conditions of use it can enter the patient environment
(3) Only for group 2 rooms, also SELV and PELV devices
(4) Apart from the earth contact of the plug sockets positioned above 2.5 m, used exclusively for supplying power to lighting devices, which must however be connected to the earth system
(5) In group 2 rooms
(6) Without electrical components

Patient enviroment

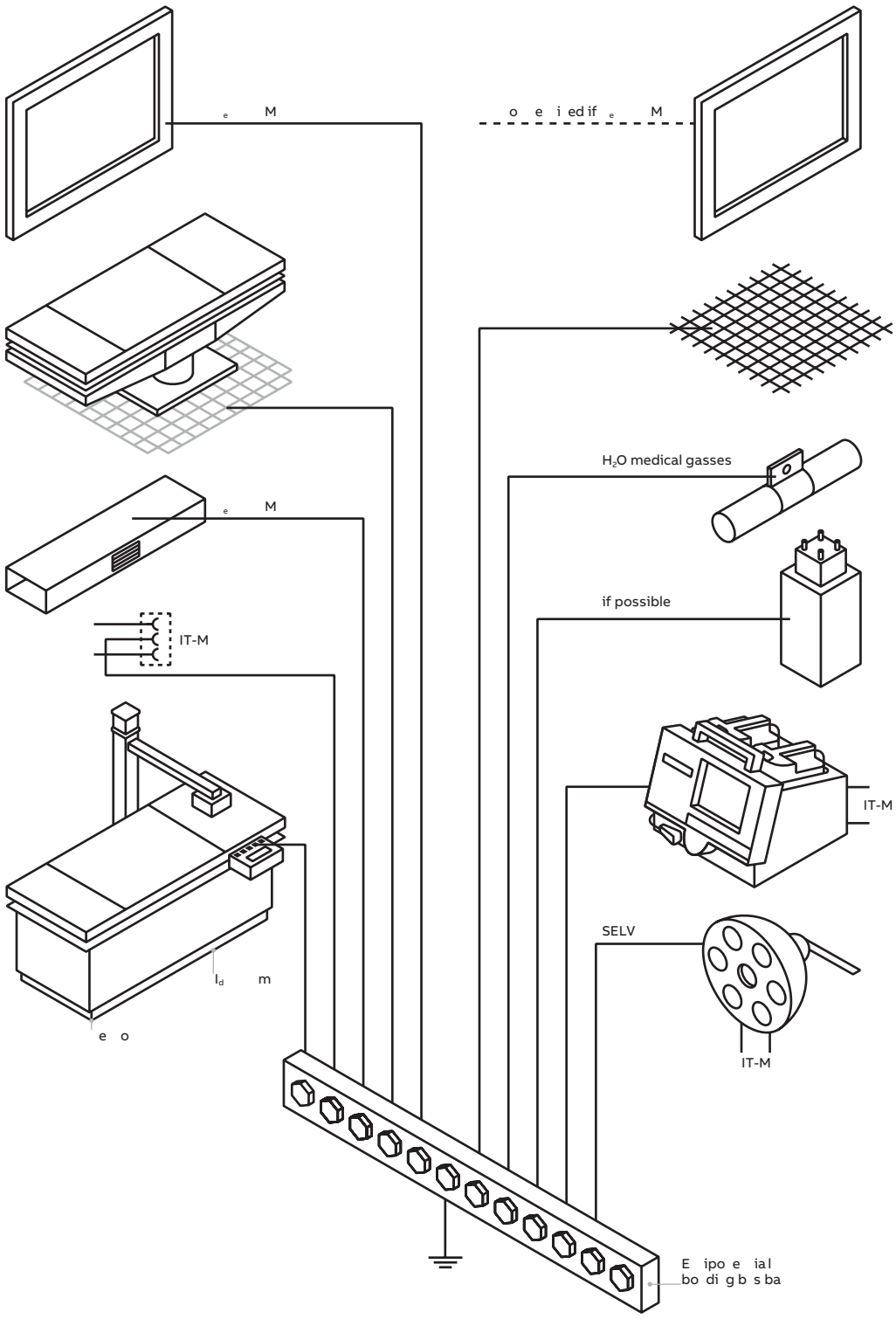


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Figure 3.2:
Example of the elements to be connected to the equipotential bonding bus bar

In the hospital accommodation rooms (group 1 rooms), all the conductive parts and extraneous conductive parts and any screens against electromagnetic interference must be connected to the equipotential bonding bus bar, because the patient environment must be considered as extended to the entire room.

If there are bathrooms or shower rooms functionally connected to the group 1 rooms and ordinarily used by the patient, these too must be equipotentialised through the local node.

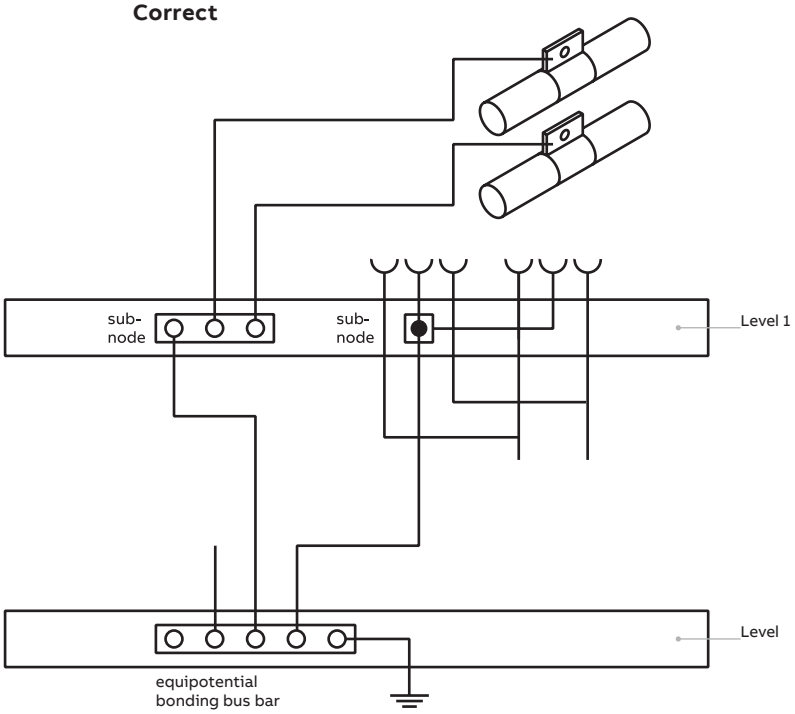
Sub-nodes

In general **cascaded connection is not allowed** (sub-node), with the exception of metal piping and nearby plug sockets.

Only one sub-node may be placed in the equipotential connection between a conductive part or extraneous conductive part and the equipotential node. It is also possible to have several intermediate nodes in the same premises as long as the aforementioned rule is satisfied.

The in-out connection between sockets must be considered as a sub-node, and therefore cannot involve more than two sockets.

Correct



Not allowed

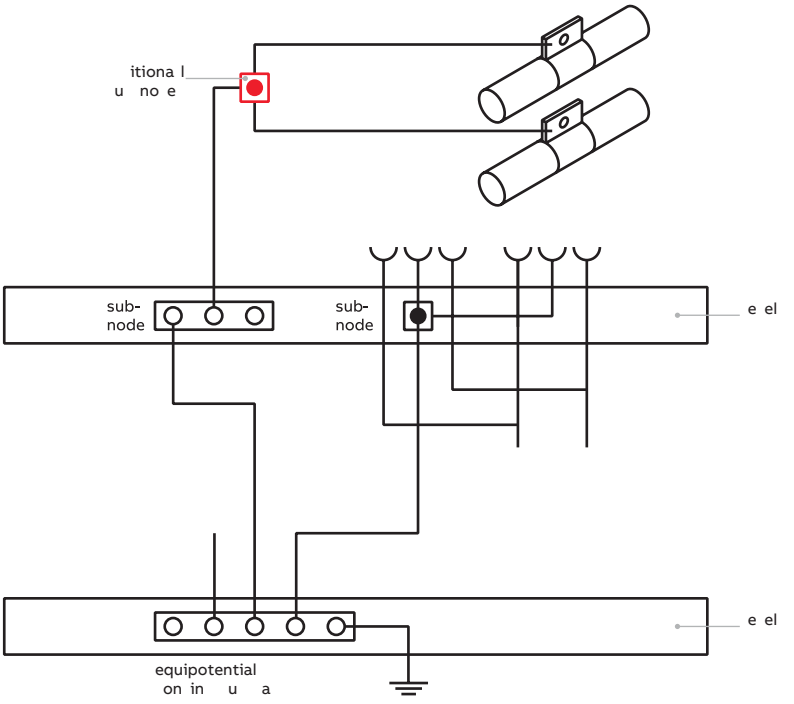


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Figure 3.3:
Correct and not allowed use of sub-nodes

Cross-section of the conductors connected to the equipotential bonding bus bar

The conductors that connect the extraneous conductive parts to the equipotential bonding bus bar are defined as equipotential conductors and must have a cross-section of no less than 6 mm².

The conductors that connect the conductive parts to the equipotential node are protection conductors (PE) and their cross-section must be established using the criteria specified by the general standard; in other words, it must be at least equal to that of the phase conductors.

The cross-section of the conductor that connects a sub-node to the equipotential bonding bus bar must be at least equal to that of the conductor with the largest cross-section connected to the sub-node.

The equipotential bonding bus bar must be connected to the main protection conductor of the earthing system with a conductor that has a cross-section equal at least to the greatest of those of the conductors under the same node. The protection conductor that acts as the building support must also have a cross-section that is not smaller.

For group 2 medical locations, the resistance presented by the conductor and by the connections between an equipotential bonding bus bar and a conductive part or extraneous conductive part must not be greater than 0.2 Ω. In the presence of sub-nodes, the resistance limit of 0.2 Ω refers to the resistance of the total connection, also including the resistance of the sub-node. For group 1 medical locations it is enough to ensure only the electrical continuity of the conductors.

Table 3.4 provides suggestions on the maximum length of protection and equipotential conductors so that their resistance will not exceed the limit indicated.

Cross-section of the conductor (mm²)	1.5	2.5	4	6	10
Maximum length (m)	12	19	31	47	78

—
Table 3.4: Maximum length of the protection and equipotential conductor so that its resistance is no greater than 0.2 Ω

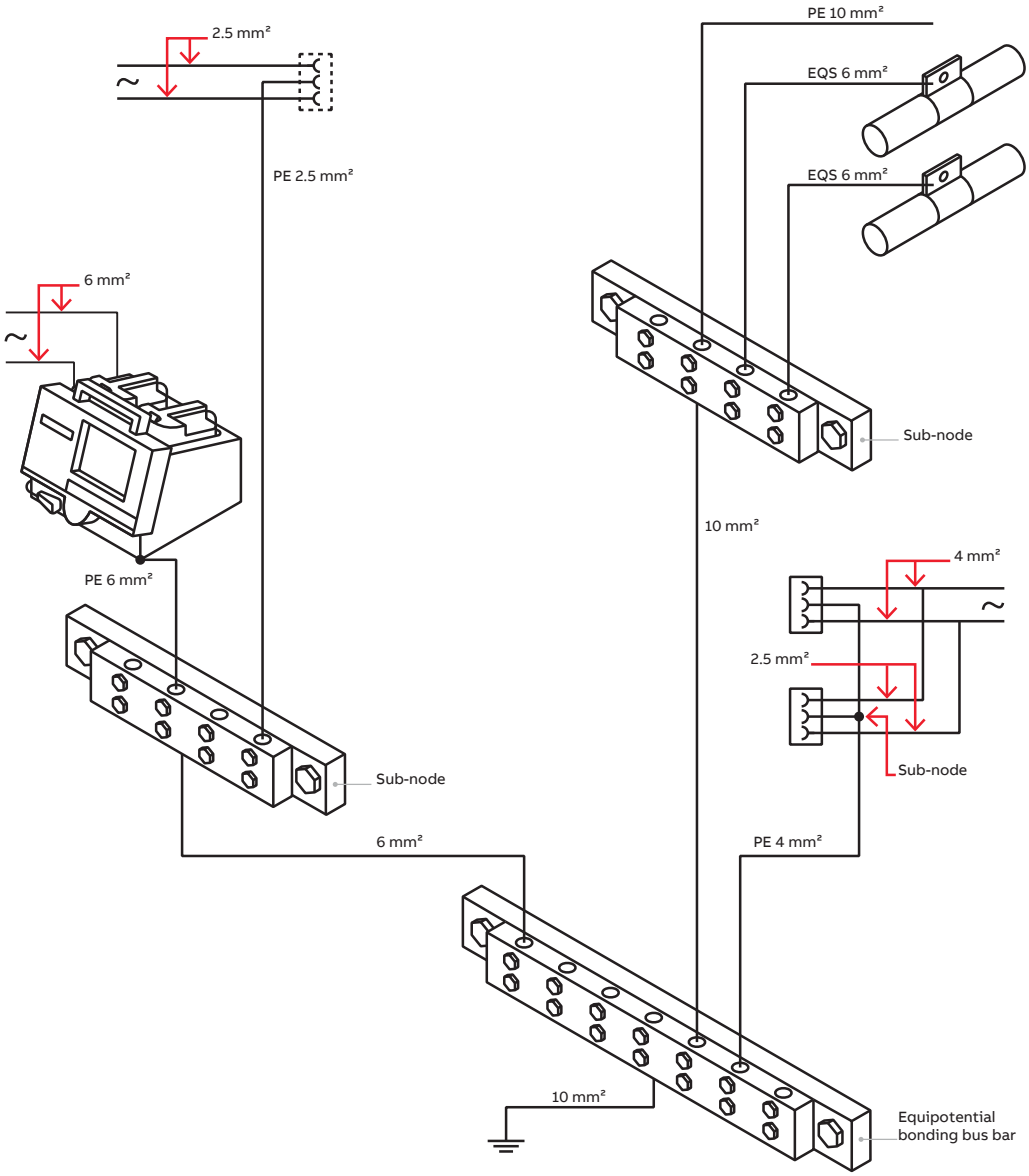

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Figure 3.4:
Minimum cross-sections allowed for equipotential conductors

Identification of the conductors to the equipotential bonding bus bar

The equipotential bonding bus bar must be easy to access and to inspect; for example,it could be installed in a box built in to the wall.

It must be possible to disconnect each of the conductors that meet up in the node individually (it is not allowed to connect two conductors to the same terminal) and they must be clearly identifiable in terms of function and origin (it is therefore advised to identify them at both ends) in order to facilitate testing.

This identification can be implemented with markings that specify the above mentioned information or with numbers whose meaning must be specified in a list that is immediately available (for example, applied to the back of the box covering).

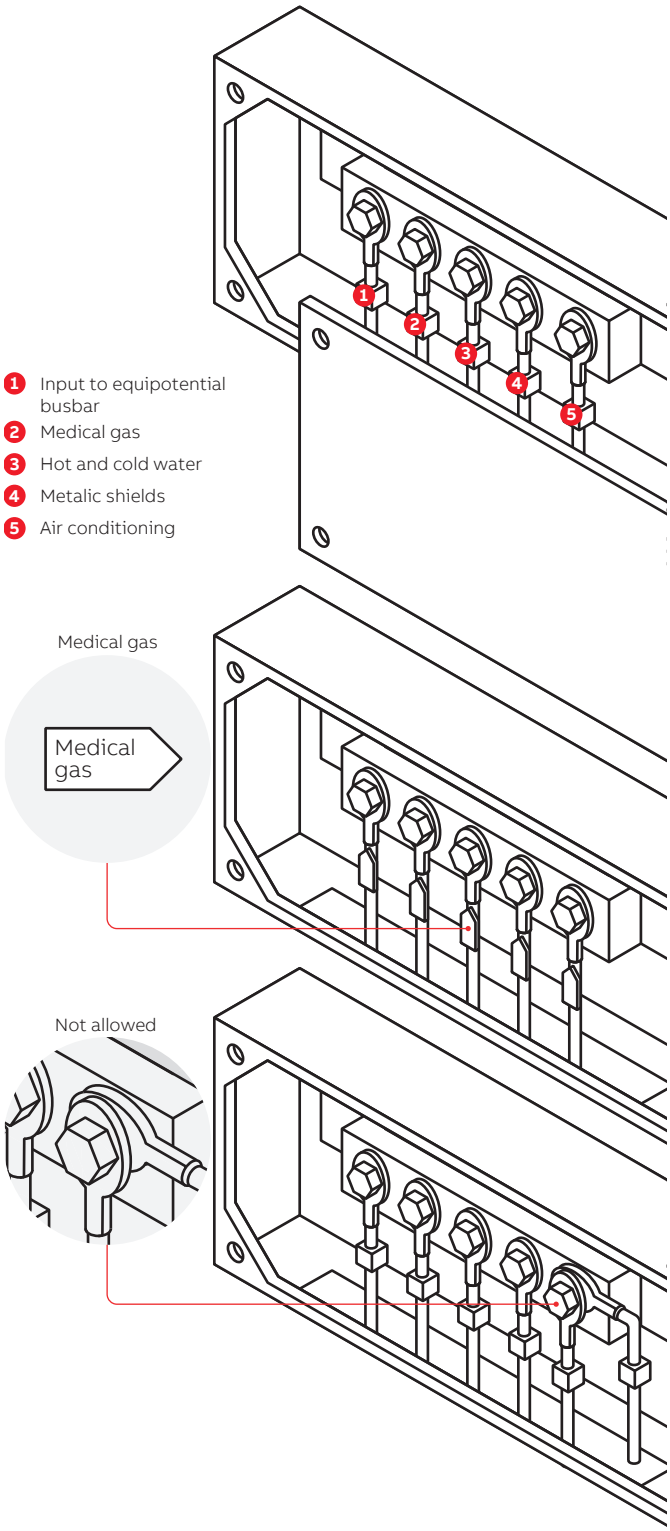

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Figure 3.6:
Identification of the equipotential conductors by means of numbering (top figure) and nameplates (central figure)

3.2.2 Medical IT System

The Medical IT system is prescribed by IEC 60364-7-710, which specifies the necessary characteristics of electrical distribution systems for special uses (Part 7) and for medical locations (710). The Medical IT system is powered with a specific insulating transformer for medical use that has a device for continuous monitoring of insulation as prescribed by EN 61557-8 and EN 61557-1.

—
The Medical IT system guarantees operational continuity in the case of first fault and guarantees the safety of the patient. It is always used in group 2 medical locations

Clause 710.3.11 of IEC 60364-7-710 defines the Medical IT System that meets the requirements specified in article 710.413.1.5 as protection for electrical separation with permanent monitoring of the insulation resistance. The Medical IT System is not mandatory, but recommended, in group 0 and 1 premises, while in group 2 medical locations it is mandatory in the patient environment, for socket outlets and for fixed equipment within reach.

The Medical IT distribution system guarantees operational continuity even in the event of a first earth fault. In a traditional system, as in a domestic scenario, when a malfunction (short circuit, overload or dispersion) occurs, the relevant protection device is tripped. This type of tripping is not suitable for an operating theatre: in the case of a first fault the power supply must be maintained and not interrupted, which could be hazardous since it would involve the interruption of the activities of the doctor and the electrical equipment associated with the patient's health.

Insulation monitoing device

A Medical IT System must be powered with an insulating transformer for medical use and must be equipped with a device for permanent monitoring of the insulation, in accordance with EN 61557-8 and EN 61557-1 standard. The insulation monitoring device must meet a number of basic requirements: – the AC internal impedance shall be at least 100 kΩ;

- The test voltage shall not be greater than 25 V DC;
- 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. It must not be possible to disconnect the insulation monitoring device.

Medical insulating transformers

—
The characteristics of these transformers are specified in clause of IEC 60364-7-710

IEC 60364-7, in clause 710.512.1.6, specifies that:

- The transformers must be installed inside or, in the immediate vicinity, outside the medical locations;
- The secondary U_N rated voltage of the transformers must not exceed 250 V AC;
- The transformers must comply with EN 61558-2-15 and EN 61558-1 in as far as applicable. In addition, they must conform to the following prescriptions:
- The leakage current of the output winding to earth and the leakage current of the enclosure, when measured in no-load condition and the transformer supplied at rated voltage and rated frequency, shall not exceed 0.5 mA;
- Single-phase transformers shall be used to form the medical IT systems for portable and fixed equipment and the rated output shall not be less than 0,5 kVA and shall not exceed 10 kVA;
- If the supply of three-phase loads via an IT system is also required, a separate three-phase transformer shall be provided for this purpose with output line-to-line voltage not exceeding 250 V.

Other prescriptions for transformers:

- They must be air cooled;
- They must have double or reinforced insulation between the windings, and between these and the conductive part of the equipment;
- A metal shield can be placed between the two windings to be connected to earth;
- The short circuit voltage must not exceed 3%;
- The no-load current of the primary must not exceed 3%;
- The peak current must not be greater than 12 times the rated current;
- The marking of the transformer must bear the symbol:

How to implement the Medical IT System and the parameters recommended by the standard

The manufacture of insulating transformers must take account of compliance with standard IEC 61558-1, which specifies the prescriptions relating to the technical requirements specifically for medical insulating transformers. The design must also observe the installation power restrictions established by IEC 60364-7-710, from 0.5 kVA to 10 kVA, with a voltage of 230 V for the primary and 230 V for the secondary. In fact, the use of limited power loads results in:

- Smaller systems;
- Less users;
- Lower probabilities of failure;
- Easier maintenance;
- Greater redundancy of the circuits;
- Greater continuity of service.

In addition, all the prescriptions imposed by IEC 60364-7-710 in this regard must be respected, from the presence of insulation monitoring device, to installation in a permanently monitored location, and the connection of the possible screen of the insulating transformer to the equipotential node in group 1 and group 2 medical locations.

The Medical IT distribution system is shunted, in relation to the upstream power supply line, using an insulating transformer for medical use. This galvanically separates the ordinary circuits from the insulated line and eliminates the continuity of the protection conductor.

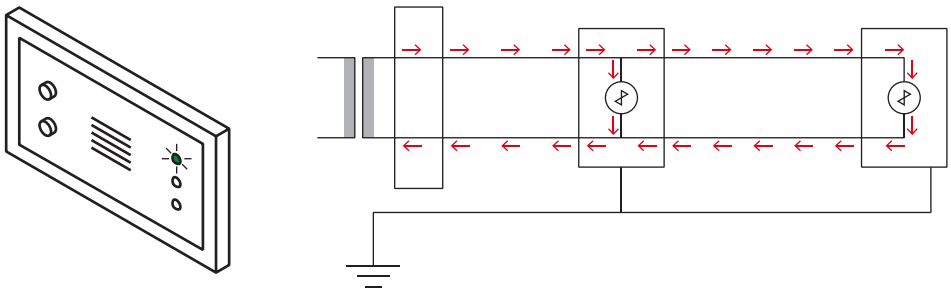
The objective of the structure of these systems is to guarantee the continuity of medical operations after the first fault occurs. Such a situation must, however, be signalled, communicated and monitored in order to repair the first fault condition rapidly, and therefore to avoid a second failure.

—
IEC 60364-710 and insulating transformers for medical use

The operating principle of the Medical IT system is based on the fact that the circuit powered by the secondary of the insulating transformer is galvanically separated, when a conductive part first fault occurs due to a defect of the insulators in a load, the current cannot continue to flow in the phase conductors. In this situation all the electromedical devices are operational.

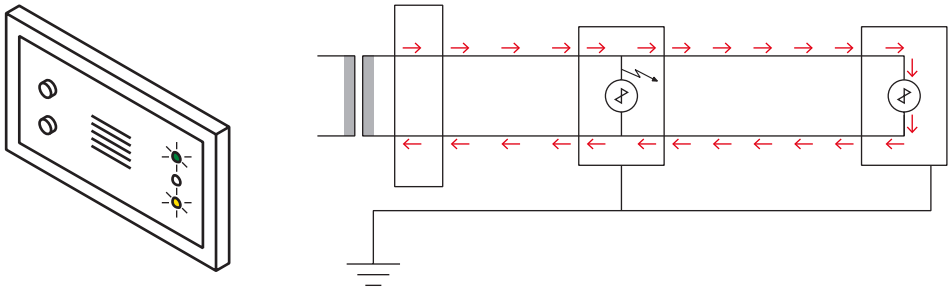
The fault must not however persist for a long time because if a second fault were to taken place, the safety and functioning of the system would be compromised.

—
No fault



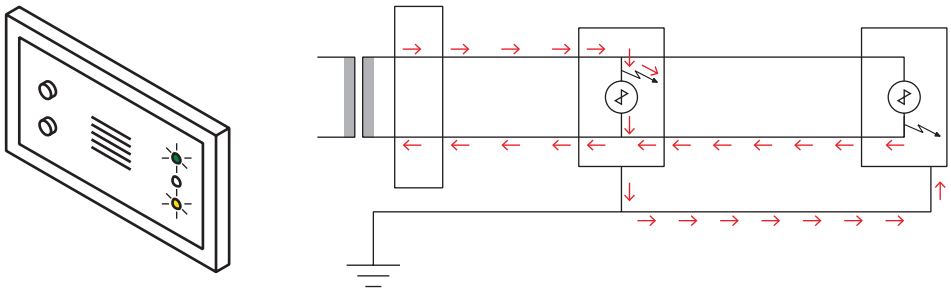
There is no hazardous current circulating on the PE and the user devices are functioning normally.

—
First fault



There are no hazardous currents flowing on the PE, but the first user device remains out of service.

—
Second fault



Because of the current that flows on the PE, it is necessary to disconnect the power supply to the IT network since the obligation of protection cannot be met.

ABB's technological leadership in the hospital sector

With its H+LINE product line, ABB offers its expertise and technical experience in a sector, namely the hospital sector, that requires a very high degree of innovation and research, as well as a constant guarantee of safety and results.

TI medical insulating transformers

The medical insulating transformers from ABB provide the perfect solution to these requirements:

in fact they combine standards compliance with maximum performance and minimum dimensions. These small dimensions make it possible contain the costs for the switchboards in which they are to be located. The range consists of transformers with power consumption of 3, 5, 7.5 and 10 kVA, available with two PT100 temperature probes, on both the primary and the secondary. Its PT100 sensors, unlike the PTC type, are true temperature sensors and not simple thermal alarms that trip when preset limits are overcome.

PT100 sensors allow constant and precise monitoring of the temperature, which can be displayed by the ISOLTESTER-DIG insulation monitor. In addition, these sensors allow compensation of errors deriving from the intrinsic resistance of the temperature sensor cable itself: the error compensation is useful since the sensor connection cables used are very long and the application requires high precision.

An important parameter to be considered when choosing a device of this type is the thermal insulation class, that is, how much the product may "heat up" when loaded, while remaining in conditions of safety. ABB transformers use a particular impregnation system, which allows maximum dissipation of heat, thanks to the exclusive vacuum-pressure technology.

Lastly, the insulating transformer between the two windings has a metal screen that contributes in filtering network interference and the harmonic components generated by the power supply.

Technical characteristics of IT insulating transformers for medical use

Power	kVA	3	5	7.5	10
Primary voltage	V	230	230	230	230
Secondary voltage	V	230	230	230	230
Frequency	Hz	50 - 60	50 - 60	50 - 60	50 - 60
Secondary currents	A	13	21.7	32.6	43.5
Current of the external secondary delayed fuse		T12,5	T20	T32	T40
Thermal insulation class	°C	B 130	B 130	F 155	F 155
Dimensions	mm	205×340×150	240×380×150	240×380×160	277×380×260
Weight	kg	29.5	44	50.5	73
Plug-in current (peak value)		< 12 times the rated current			
Earth leakage current of the secondary winding and current of dispersion of the casing (both without load)	mA	< 0.5			
Maximum ambient temperature	°C	40	40	40	40
Reference standards		EN 61558-1, EN 61558-2-15			
Electrical class		1	1	1	1

TI insulating transformer for medical use ordering codes

Power KVA	PT100 Sensor	Description / Type	ABB Code	BbN 8012542 EAN
3	-	TI 3	2CSM110000R1541	2896005
5	-	TI 5	2CSM120000R1541	2896104
7.5	-	TI 7.5	2CSM130000R1541	2896203
10	-	TI 10	2CSM140000R1541	2521204
3	•	TI 3-S	2CSM210000R15a1	2521402
5	•	TI 5-S	2CSM220000R1541	2521501
7.5	•	TI 7.5-S	2CSM230000R1541	2521600
10	•	TI 10-S	2CSM240000R1541	2521709

—
Figure 3.6:
TI insulating transformer

3.2.3 Insulation monitoring device

A current originating outside the electrical system, for example an earth leakage current circulating in an electrical device, can cause serious damage because of the greater vulnerability of the patient: in surgical conditions, a current of just tens of microamperes is enough to cause ventricular fibrillation, which is not the case under “normal conditions”, where this type of value is more acceptable.

The leakage current can be classified into three different types:

- earth leakage current (of the protection conductor) - Fig. 3.8.A;
- contact current, in other words the current that crosses the person in contact with the
- live casing due to a malfunction of the insulators - Fig. 3.8.B;
- leakage current in the catheterised patient and which flows to earth - Fig. 3.8.C.

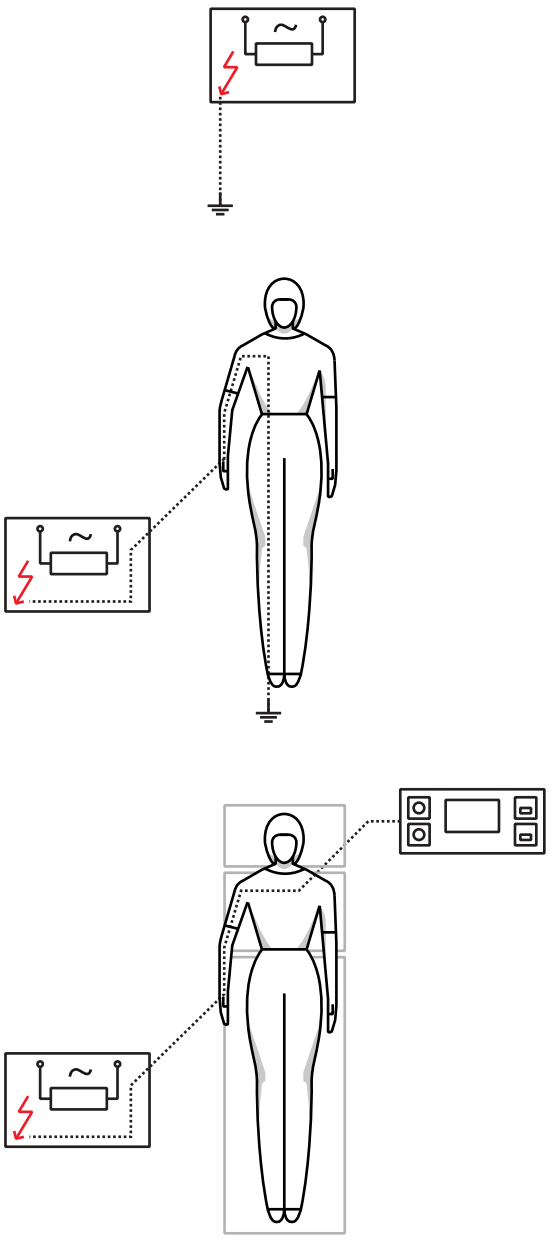


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Figure 3.7: Examples of situations that cause leakage currents

For each of these there are allowable values that in turn depend on the type of electromedical device as established by EN 61010-1 “Medical electrical equipment - General requirements for basic safety and essential performance” which applies to medical electrical equipments intended for use by qualified personnel, or under their supervision, in the environment surrounding the patient, or in relation with the patient, in such a way that they directly influence the safety of persons and animals in that environment. The standard specifies the prescriptions for the transport, storage, commissioning, use and maintenance of such devices in the environmental conditions specified in the standard or by the manufacturer, or prescribed in particular standards. The purpose is to establish a satisfactory level of safety for all the electromedical devices used in an environment surrounding the patient and to serve as a basis for the safety prescriptions of specific standards for the individual types of devices.

Device with parts applied of type B		Less safe
Device with parts applied of type BF		Safer
Device with parts applied of type CF		Even safer

—
Table 3.5: Types of medical electrical equipments with applied parts

Leakage current [mA]	Conditions	Type of part applied		
		B	BF	CF
	Normal	5	5	5
To earth(1)	First fault	10	10	10
	Normal	0.1	0.1	0.1
Contact	First fault	0.5	0.5	0.5
	Normal	0.1	0.1	0.01
In the patient(2)	First fault	0.5	0.5	0.05

—
Table 3.6: Permissible values for leakage currents (EN 61010-1)

(1) Changed in comparison to earlier editions of EN 61010-1.
(2) In the case of direct current the limits for Type B and BF applied parts are one tenth of those specified. In addition, higher values are allowed for particular conditions.

Characteristics of the insulation monitoring device

Permanent monitoring of the first fault to earth must be carried out using an appropriate insulation monitoring device inserted between the secondary of the insulating transformer and the protection conductor. For each insulating transformer for medical use there must be an insulation monitoring device in order to immediately signal a possible first fault and to allow the appropriate maintenance operations necessary to restore the system to optimal conditions. The monitoring device must comply with the provisions of EN 61557- 8 and 61557-1, and must have the following additional characteristics if installed in a medical environment:

- internal impedance: not less than 100 kΩ (measured between system terminals and
- earth);
- test voltage: 25 V DC max (between the measurement terminals);
- test current: 1 mA DC max (between the system and earth, also in the case of a
- malfunction);
- impossibility of deactivation.

When the resistance of earth insulation drops below 50 kΩ the device must signal the malfunction. It must, however, be possible to verify the actual operational capacity of the instrument by means of a test circuit.

—
EN 61557-8

Luminous indications and acoustic signals

The insulation monitoring system must be equipped with acoustic and luminous signals. This function is performed by a remote signalling panel, directly connected to the insulation monitor. This device makes it possible to:

- carry the signal to several parts of the building;
- make the insulation monitor signal immediately visible which may be installed in places inadequately staffed by the appropriate personnel (technical rooms, corridors…);
- identify the type of alarm in progress (low insulation, overload etc).

These are the signals provided:

- green indicator light (normal operation);
- yellow indicator light (insulation has dropped below 50 kΩ);
- an acoustic signal.

It must not be possible to switch off or deactivate the yellow indicator light while the malfunction remains on the system.

This is the sequence of signals in the case of a malfunction:

- the acoustic alarm is put into operation;
- the acoustic buzzer is silenced (continuous yellow indicator light);
- the yellow indicator light switches off as soon as normal conditions are restored (after the malfunction condition has been resolved);
- interruption of the connection between the Medical IT system or earth and the monitoring device is signalled.

Lastly, here are a number of design suggestions: It is not necessary to install an insulation monitoring device if the transformer only supplies power to a single medical electrical equipment; in this case, in fact, the probability of an indirect contact (and, even more so, of a second indirect contact) is remote. In addition, the short circuit deriving from the second indirect contact would not be able to create hazardous voltages on the conductive parts of other devices.

The optical and acoustic alarm system should not be installed in just one location; this allows the alarm to be perceived also by those present in contiguous premises.

—
IEC 60364-7
Clause 710.413.1.5

—
Figure 3.8:
QSD remote signalling panels allow medical personnel to be immediately aware of malfunction situations

3.2.4 Insulation monitoring devices for 230 V lines

ISOLTESTER-DIG is the insulation monitor manufactured by ABB and suitable for insulated neutral Medical IT networks for group 2 medical locations with a Medical IT power supply system. ISOLTESTER-DIG monitors the earth insulation of the electrical power supply grid and the electrical or thermal overloading of the transformer, according to the parameters required and recommended by international standards:

- EN 61557-8
- IEC 60364-7-710
- EN 61557-1

Insulation resistance is monitored by applying a measuring signal in direct current between the insulated line and earth, and measuring the earth leakage generated. A digital filter inserted in the instrument guarantees effective measurement even in the presence of interference and harmonic components.

—
Simple programming with four keys

The four selection keys and LCD display make it easy to program the device, setting the tripping thresholds without any possibility of error (the configurable values are within the range of values specified by the standards).

ISOLTESTER-DIG allows monitoring of the electrical and thermal overload of the medical insulating transformer by managing two distinct temperature thresholds coming from both PT100 and PTC sensors.

Temperature monitoring makes it possible to monitor overloading of the transformer and to avoid the automatic miniature circuit breaker downstream of the secondary.

—
Figure 3.9:
QSO wall-mounted switchboard

All malfunction conditions are remotised thanks to a connection with (up to four) QSD remote signalling panels, thereby guaranteeing adequate and prompt technical supervision. Finally, the Error/Link Fail system executes self-diagnosis of the device by checking that the wiring at the heads of the terminals is present and correct: this excludes the possibility of having the group 2 medical room in operation without the supervision of the insulation monitor.

—
Reliable measurement in all conditions

Thanks to the RS485 serial port, the ISOLTESTER-DIG-RS is able to communicate with the supervision system via ModbusRTU in order to collect all the required information of the monitored IT-M system in a centralized place. It also improves the monitoring activity with the possibility of logging mesaurements (max. and min. values). Logs can then be sent to the centralized control system via the communication protocol.

ISOLTESTER-DIG-PLUS adopts a codified signal which guarantees the reliability of the measurement in any operational condition, even in the presence of serious network interference generated by the electronic equipment in the room. In addition, it is equipped with an RS485 serial port, thanks to which the device can be perfectly integrated with PLC/PC type communication systems by means of the ModbusRTU protocol.

More extensive monitoring is possible because network minimum and maximum values are managed, which help in diagnosis of the system in the case of a failure. Lastly, a programmable relay allows complete control of any alarm condition detected.

—
Keep the keys “-” and “SET” pressed to enter “installation setup” and define the parameters monitored.
Keep the “SET” key pressed to enter “regulation setup” and define the threshold values.

ISOLTESTER-DIG-RZ

Technical characteristics of ISOLTESTER-DIG-RZ	
Supply voltage	110 - 230 V/50-60 Hz
Network voltage to be measured	24÷230 V AC
Maximum voltage measurement	24 V
Maximum current measurement	1 mA
Insulation voltage	2.5 kV/60 sec.
Type of monitoring signal	continuous component with digital filter
Measurements	insulation measurement range 0÷999 kΩ/HIGH resolution 1 kΩ
	temperature measurement by thermal probe type PT100 with 2 or 3 wires -0÷250° C, precision 2% or by PTC probe (DIN 44081)
	current measurement by C.T., external with secondary 5 A, precision 5% (ratio value selectable 1÷40)
	impedance measurement 0÷999 kΩ/HIGH resolution 1 kΩ (test signal 2500 Hz)
Tripping thresholds	low insulation 50÷500 kΩ, hysteresis 10%, configurable delay
	overtemperature 30÷200 °C, precision 2%
	current overload 1÷99.9 A, precision 2%
	low impedance (can be disabled)
	device not connected to the line (Error/Link Fail)
Outputs available	up to maximum of 4 panels QSD-DIG 230/24 for signalling
	auxiliary relay output NO-C-NC, 5 A, 250 V AC
Displays	insulation resistance value with signalling of a value below the scale and dead short earth fault
	temperature value measured 0÷200 °C for trunking 1
	temperature value measured 0÷200 °C for trunking 2
	current value measured 0÷99.9 A
	insulation impedance value
	programming parameters
	absence of device connection to line (Error/Link Fail)
	relay output status
Connections	maximum connectable cross section 2.5 mm²
Operating temperature	-10...60 °C
Storage temperature	-25...70 °C, humidity < 90%
Dimensions	6 DIN modules
Weight	0.4 kg
Casing	self-extinguishing plastic container for mounting on 35 mm DIN rail, with transparent front protection coverwith lead seal
Protection degree	IP50 frontal side, IP20 enclosure
Power consumption	5 VA
Reference standards	IEC 60364-7-710, EN 61557-8, EN 61557-1

ISOLTESTER-DIG-RZ Ordering Codes

Description / Type	**ABB Code**	**BbN 8012542 EAN**
ISOLTESTER-DIG-RZ	2CSM244000R1501	884507

ISOLTESTER-DIG-PLUS/RS

Technical characteristics of ISOLTESTER-DIG-PLUS/RS	
Supply voltage	110 - 230 V/50-60 Hz
Network voltage to be measured	24÷250 V AC
Maximum voltage measurement	24 V
Maximum current measurement	1 mA
Insulation voltage	2.5 kV/60 sec.
Type of monitoring signal	composite codified (only PLUS)
Measurements	insulation measurement range 0÷999 kΩ/HIGH resolution 1 kΩ
	temperature measurement by thermal probe type PT100 with 2 or 3 wires -0÷250° C, precision 2% or by PTC probe (DIN 44081)
	current measurement by C.T., external with secondary 5 A, precision 2% (ratio value selectable 1÷40)
	impedance measurement 0÷999 kΩ/HIGH resolution 1 kΩ (continuos signal for RS while variable one for PLUS)
Tripping thresholds	low insulation 50÷500 kΩ, precision 5%, hysteresis 10%, configurable delay
	overtemperature 30÷200 °C, precision 2%
	current overload 1÷99.9 A, precision 2%
	low impedance (can be disabled)
	device not connected to the line (Error/Link Fail)
Outputs available	up to maximum of 4 panels QSD-DIG 230/24 for remote signalling
	programmable auxiliary relay output NO-C-NC, 5 A, 250 V AC R S 485 serial output, standard Modbus RTU protocol
Displays	insulation resistance value with signalling of a value below the scale and dead short earth fault
	temperature value measured 0÷200 °C for trunking 1
	temperature value measured 0÷200 °C for trunking 2
	current value measured 0÷99.9 A
	insulation impedance value
	value of line earth capacity (only PLUS)
	programming parameters
	absence of device connection to line (Error/Link Fail)
	relay output status
	storage of min. value insulation and max temperature and current
Connections	maximum connectable cross section 2.5 mm²
Operating temperature	-10...60 °C
Storage temperature	-25...70 °C, humidity < 90%
Dimensions	6 DIN modules
Weight	0.5 kg
Casing	self-extinguishing plastic container for mounting on 35 mm DIN rail, with transparent front protection coverwith lead seal
Protection degree	IP50 frontal side, IP20 enclosure
Power consumption	5 VA
Reference standards	IEC 60364-7-710, EN 61557-8, EN 61557-1

ISOLTESTER-DIG-PLUS/RS Ordering Codes

Advanced functions	**Description / Type**	**ABB Code**	**BbN 8012542 EAN**
noise immunization (codified signal) RS485, Min/Max values, programmable relay	ISOLTESTER-DIG-PLUS	2CSM244000R1501	884606
RS485, Min/Max values, programmable relay	ISOLTESTER-DIG-RS	2CSM256833R1521	568339

Operation of the front panel operators

Green LED, SET:

Instrument programming status

Yellow LED, Alarm:

Alarm for a parameter value outside the threshold

Red LED, R:

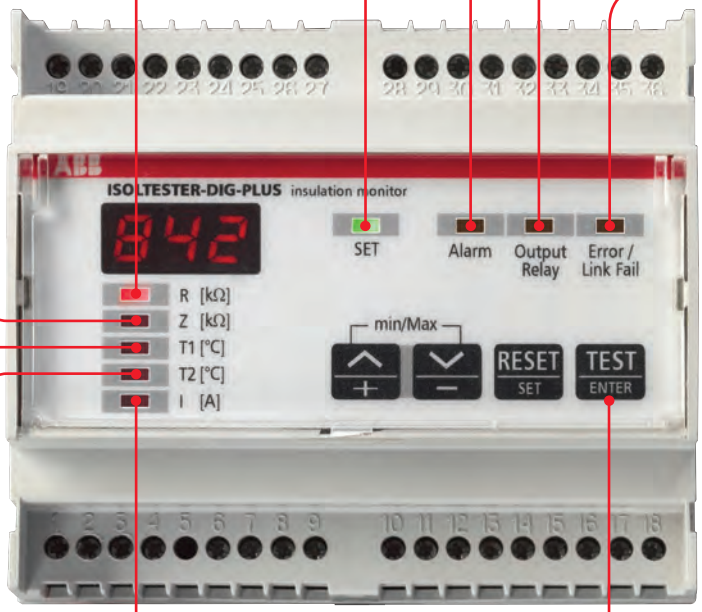
Insulation resistance (kΩ)

Red LED, Output Relay:

Auxiliary relay status

Red LED, Error/Link Fail:

Alarm for internal failure, no connection to the line to be monitored, PT100 temperature probe open or in short-circuit



Red LED, Z:

Insulation impedance (only PLUS/RS while capacity measurement only for PLUS)

Red LED, T1:

Transformer temperature (primary)

Red LED, T2:

transformer temperature (secondary)

TEST | ENTER:

Testing of the instrument and the remote signalling panels

Red LED, I:

Line current

3.2.5 Insulation monitoring devices for 24 V SELV circuits

SELVTESTER-24 is an earth insulation tester for SELV 24 V AC/DC circuits, particularly recommended for installation in medical locations in which 24 V and 230 V lines exist. The systematic and continuous monitoring of the low voltage line in these environments is recommended by IEC 60364-7-710 precisely because a failure or a short circuit could transfer a potential of more than 250 V with consequent damage to persons and things.

Characteristics

SELVTESTER-24 monitors the insulation resistance of dedicated 24 V AC/DC circuits for powering a scialytic lamp.

It is important to monitor the insulation of the scialytic lamp because conductors could become detached and enter into contact with the metal structure while the lamp is being manoeuvred.

SELVTESTER-24 measures the variation of the potential of the two network polarities in relation to the earth, and signals a decrease in resistance below a predefined value, allowing immediate interception of the malfunction. In a direct current situation it is also possible to discern the polarity involved in the failure. The output signal can be carried remotely in rooms with the greatest medical staff presence thanks to remote signalling panels called QSD-DIG 230/24.

The front of the SELVTESTER-24 includes a test pushbutton, status indicator and two LEDs for alarms caused by low insulation. Microswitches allow the activation threshold to be varied (10….50 kΩ). The TEST pushbutton performs the periodic correct operation test.

SELVTESTER

Technical characteristics of SELVTESTER	
Network voltage and auxiliary power supply	24 V 50-60 Hz/DC ± 20%
Max. loss	3 VA
Measurement current	max. 0.5 mA
Internal impedance	50 kΩ
Activation threshold setting	adjustable 10 ÷ 50 kΩ (4 levels by means of microswitches)
Activation delay	approx. 1 s
Signals	ON LED, ALARM + LED, ALARM - LED
Output	For max. 2 QSD-DIG230/24 remote panels Max. 24 V 1 A
Operating temperature	-10 ÷ 60 °C
Storage temperature	-20 ÷ 70 °C
Operating temperature	-10 ÷ 60 °C
Storage temperature	-20 ÷ 70 °C
Relative humidity	≤ 95%
Insulation test	2.5 kV 60 s / 4 kV imp. 1.2/50 µs
Cross section of terminals	4 mm²
Protection degree	IP40 front panel with cover / IP20 container
Dimension	3 DIN modules
Weight	200 g approx.
Reference standards	IEC 60364-7-710, EN 61557-1, EN 61557-8

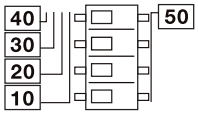
SELVTESTER-24 Ordering Codes

Monitored network	Description / Type	ABB Code	BbN 8012542 EAN
SELV insulated line 24 V AC/DC	SELVTESTER-24	2CSM211000R1511	884705

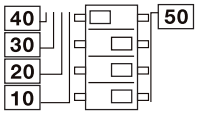
Microbreakers

The front microswitches allow the threshold to be set in the range 10 to 50 kΩ, as shown in the diagram.

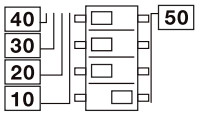
10 kΩ



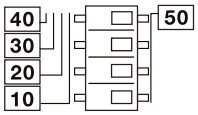
40 kΩ



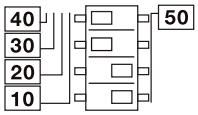
20 kΩ

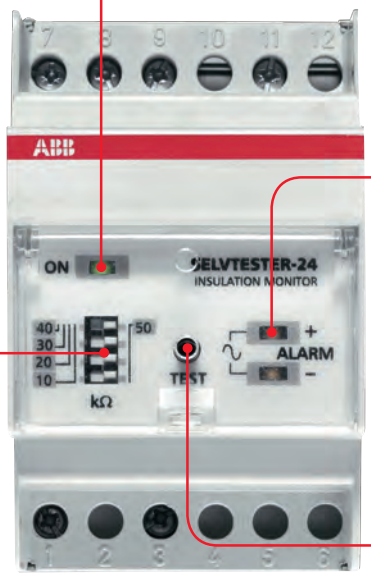


50 kΩ



30 kΩ





Green LED ON

Indication that the instrument is functioning

Yellow LED ALARM

Low insulation alarm signal; in the case of a line to be monitored, with alternating current the two LEDs light up, whereas with direct current only the LED of the polarity below the activation threshold lights up.

TEST pushbutton

Instrument function test

3.2.6 QSD remote signalling panels

It ought to be possible to send an alarm caused by a possible malfunction from a distance, so that it is immediately obvious to medical personnel and specialized technicians.

The QSD remote signalling panels also report alarm signals relating to a low insulation situation or in the case of electrical or thermal overload of the transformer, making it possible to identify the type of fault.

— A single panel for universal remote signalling

Characteristics

QSD-DIG 230/24 control panels can be installed easily in universal flush-mounted boxes with three modules. They have a test pushbutton for periodically checking their operation and a second pushbutton that allows the simultaneous silencing of the acoustic signal of all the panels that may be connected to the same ISOLTESTER insulation monitoring device.

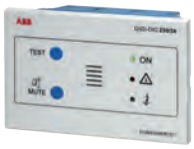
With QSD-DIG 230/24 it is possible to distinguish, even remotely, the type of alarm; in other words whether it is caused, for example, by low resistance, an overload or an overcurrent (identification of the malfunction type). QSD-DIG 230/24 was designed to be fully compatible with all ABB insulation monitors for 230 and 24 V lines, both currently manufactured models and earlier versions:

Type of line monitored	230 V	24 V
Insulation monitoring devices	ISOLTESTER-DIG-RZ ISOLTESTER-DIG-RS ISOLTESTER-DIG-PLUS	SELVTESTER-24

Wiring can be carried out with a common 0.35 mm² cable, which guarantees signal cover up to a distance of 300 m.

— Reference standards for QSD

QSD-DIG 230/24 conforms to the following international reference standards:
- EN 61557/8;
- EN 61557/1;
- IEC 60364-7-710;

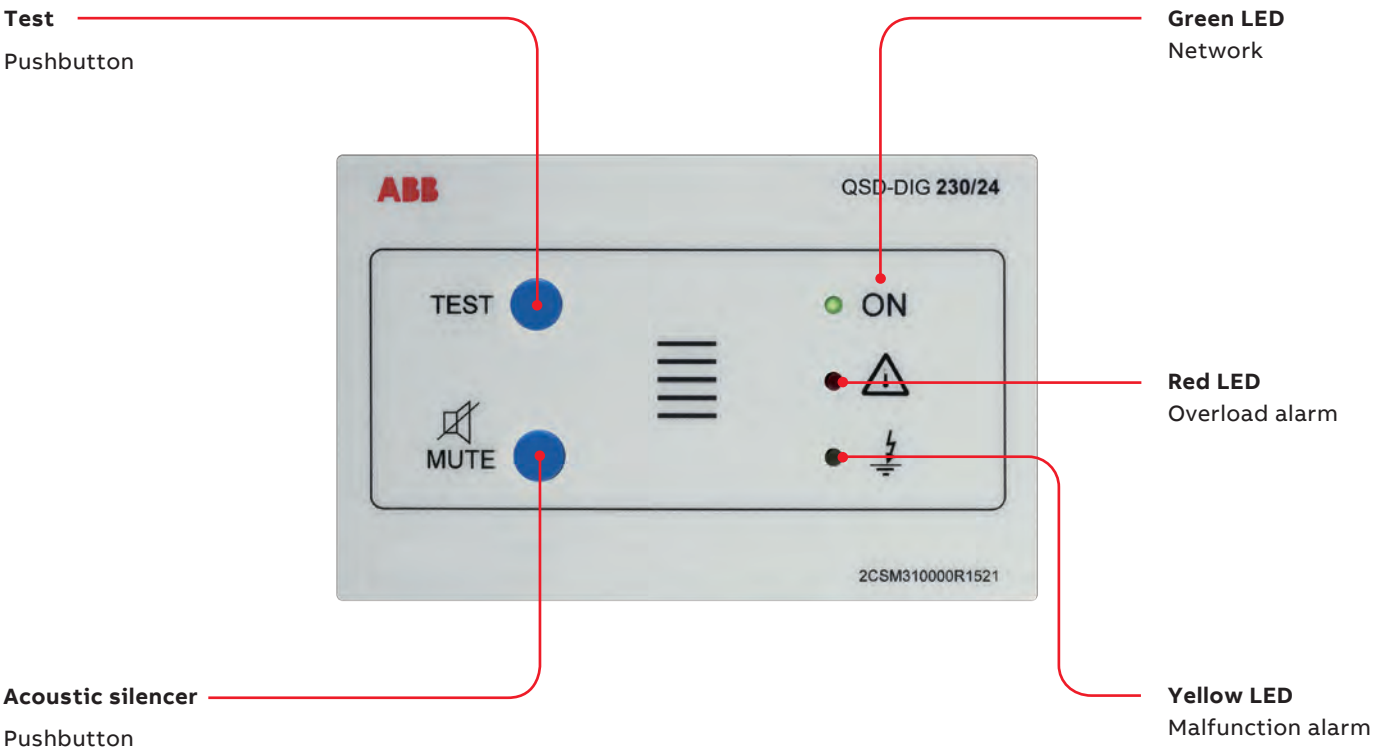


QSD-DIG 230/24

Technical characteristics QSD-DIG 230/24	
Signals	green LED network, red LED overload, yellow LED fault buzzer 2400 Hz intermitting 2 Hz dB
Pushbuttons	test (TEST), acoustic silencing (MUTE)
Cross section of terminals	2.5 mm2
Protection degree	IP30
Installation	universal flush-mounted 3 modules box
Weight	200 g
Operating temperature	-10 ÷ 60 °C, max humidity 95%
Storage temperature	-25 ÷ +80 °C
Insulation	2500 Vrms 50 Hz per 60 s
Minimum cross-section of the cable	0.35 mm2 (300 m max)
Reference standards	EN 61557-1, EN 61557-8 IEC 60364-7-710

QSD-DIG 230/24 Ordering Codes

Compatibility	Description / Type	ABB Code	BbN 8012542 EAN
Universal	QSD-DIG 230/24	2CSM273063R1521	730637


Test
Pushbutton
Green LED
Network
ABB
QSD-DIG **230/24**
TEST
ON
MUTE
2CSM310000R1521
Red LED
Overload alarm
Acoustic silencer
Pushbutton
Yellow LED
Malfunction alarm

3.3 Implementation of the electrical system

To implement the electrical system in medical locations both the general prescriptions of IEC 60364 as well as the specific prescriptions of section 710, included in the seventh part, must be observed.

The main best technique rules are specified below concerning switchboards for the distribution of energy within a hospital structure and the installation of systems in group 2 rooms.

3.3.1 Electrical switchboards

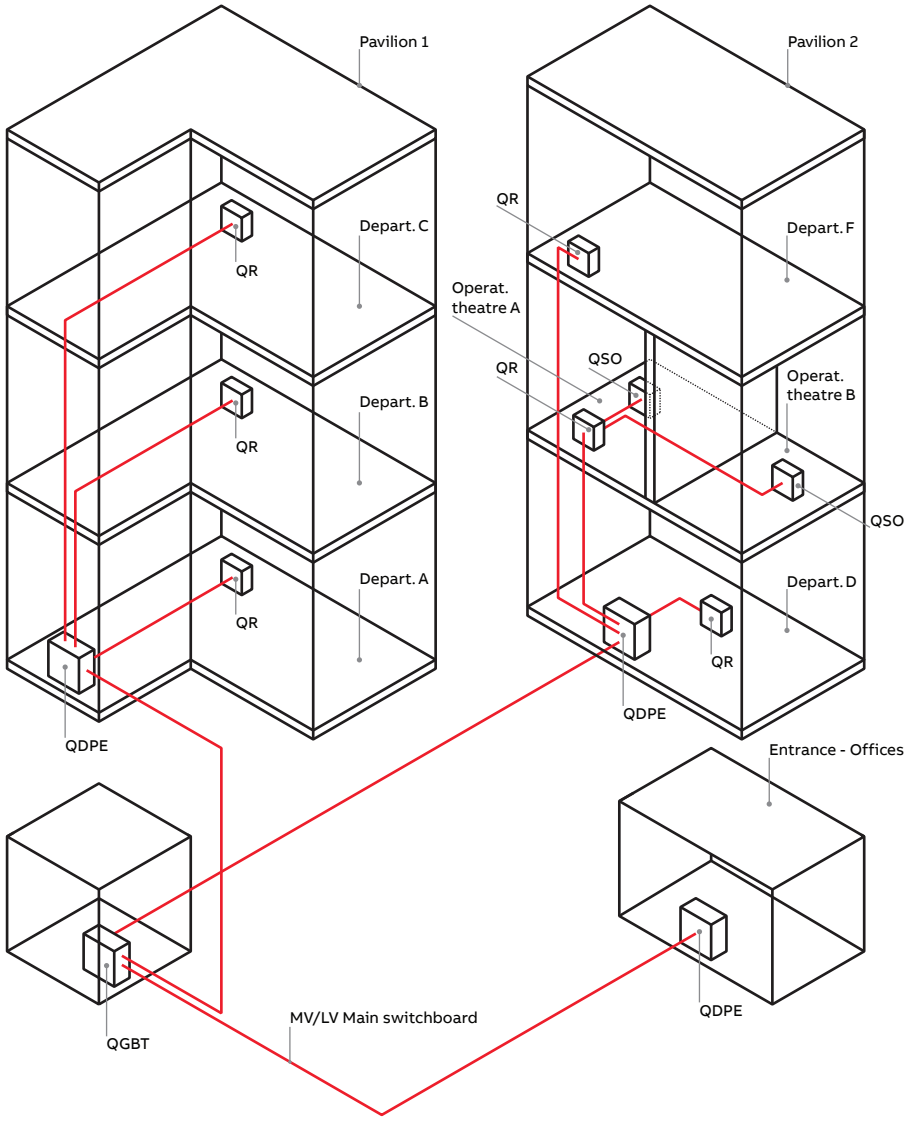
All the electrical switchboards must conform to the safety prescriptions of standards IEC 60439-1 and 3.

In environments for medical use, depending on their size, it may be necessary to use the following types of electrical switchboards (fig. 3.11):

- general low voltage (QGBT);
- for main distribution in the building (QDPE);
- for department (QR);
- for surgery room (QSO).

Types of electrical switchboards

Figure 3.10: Representation of the star distribution system used in healthcare structures



The main switchboard and the distribution switchboard for the building should be located in specific rooms, not directly communicating with the environments intended for the public and not in proximity to combustible structures or stores for combustible material.

	Protection against direct contacts		Protection against external influences
IPXXD (IP4X)	for horizontal surfaces within reach	IPX4	in rooms where fluids are normally spilt
IPXXB (IP2X)	for all the other cases	IPX5	in rooms for the use of jets that must be cleaned with water

General LV switchboard
Switchboard for ordinary energy distribution (from the network) in which the following may, for example, be installed:
- general protection and sectioning devices;
- measuring instruments and remote monitoring devices;
- protection devices for the lines that supply power, for example, to: auxiliary cabinet services;the auxiliary electricity-generator unit services; the main distribution lines to the buildings; the distribution lines of services external to the buildings; the technological stations (air conditioning system, thermal and water station).

Main distribution switchboard of the building
Switchboard for ordinary and safety distribution (through the electricity-generating unit) in which the following are installed:
- general protection and sectioning devices;
- measuring instruments and remote monitoring devices;
- protection devices, preferably suitable for sectioning, for the lines that supply power to
- appliances that require power from an electricity-generating unit (fire-prevention system,
- lifting systems).

Department switchboards
The department switchboards can be the same as the main switchboards of the building. If these switchboards are located inside the pavilion or department, they should preferably be located in a special room. They are recommended to have glass (or transparent plastic material) doors to facilitate checking the state of the devices.

The destinations of the lines leaving the switchboard depend on the functions that the department carries out.

Switchboards for surgery rooms
For group 2 surgery rooms, in addition to the switchboard for the power supply of the ordinary circuits, a switchboard for supplying power to the Medical IT system is also necessary (fig. 3.12). It is also allowed to use a single switchboard that groups the Medical IT system equipment and the power supply equipment for all the other appliances into two distinct sections. In the absence of the ordinary power supply, the switchboard must switch onto the safety power supply provided by an uninterruptible power supply (UPS).

1. Surge arrester

2. Insulating transformer

3. Temperature probe PT100

4. Insulation monitoring device for 230 V circuit

5. Insulation monitoring device for 24 V circuit

6. Transformer 220/24 V - 1 kVA

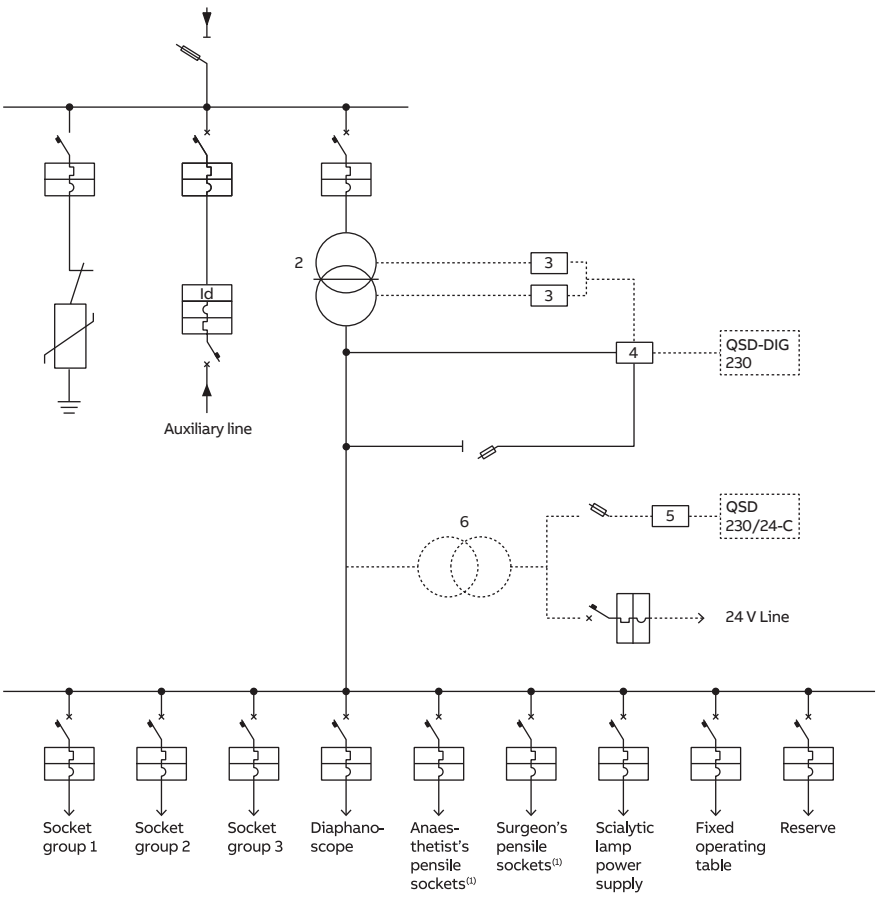


Figure 3.11: Switchboard for the Medical IT system power supply.

(1) The sockets of the anaesthetist and surgeon pensiles are powered by multiple lines

In this way the continuity of service of all the Medical IT powered devices in the premises is improved and high quality power supply for the electromedical devices particularly sensitive to the voltage and frequencies is guaranteed. In the case of a single switchboard, subdivided into two sections, the following components are installed:

- a general sectioning device;
- RCDs on each outbound connection and with Idn ≤ 30 mA, and of type A or B for the ordinary power supply;
- a device for protection against overcurrents upstream of the insulating transformer;
- possibly a circuit-breaker downstream of the insulating transformer for protection against the overloads in the case where there are no temperature sensors on the insulating transformer;
- the Medical IT system devices (insulating transformer, permanent insulation monitoring;
- device with optical and acoustic signalling).
- protection devices against overcurrents of the lines that supply power to the plug sockets;
- and of any other fixed devices of the Medical IT system.

The equipotential node of the switchboard could be used as the equipotential node of the premises if it complies with the prescriptions of the standards.

Choice of power consumption of the medical insulating transformer

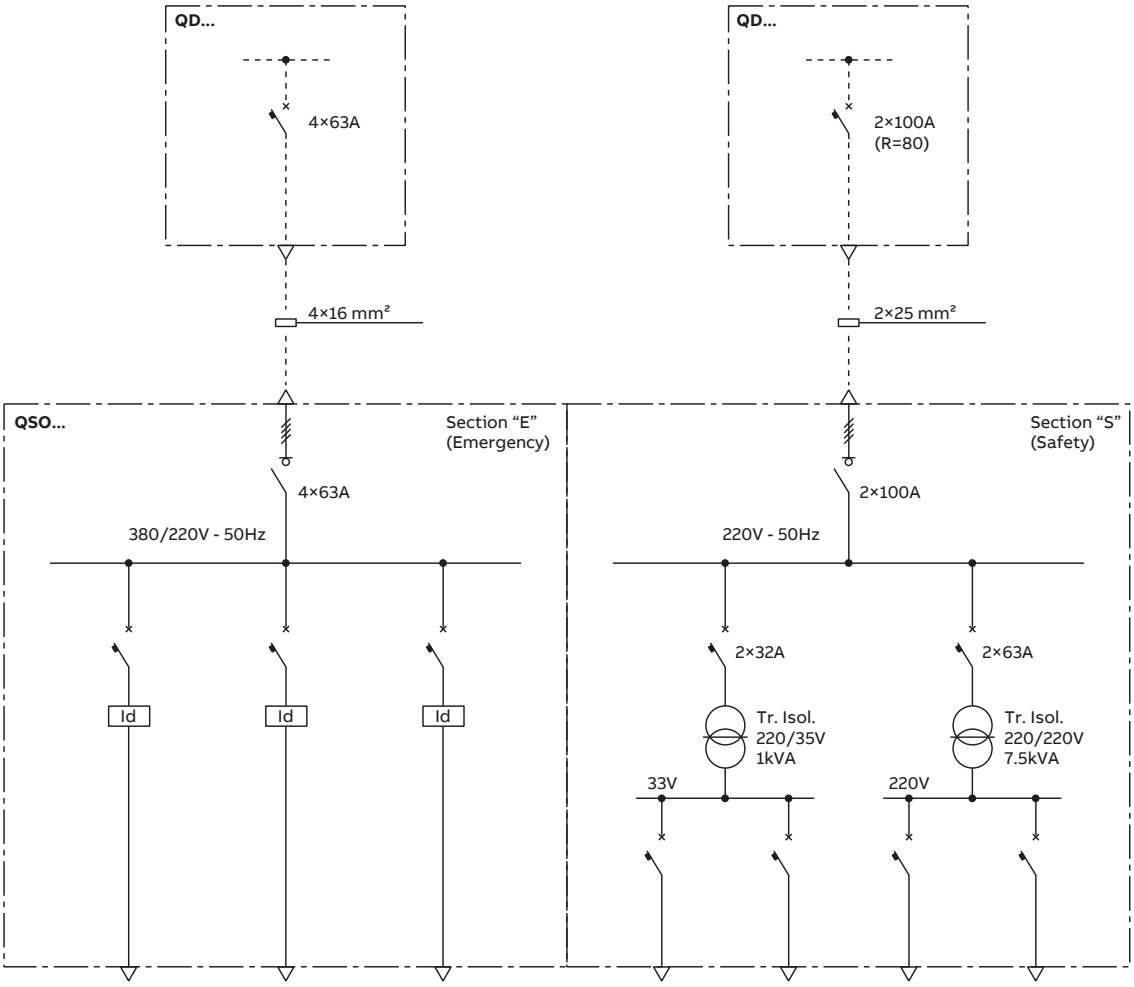
The power consumption of the insulating transformer depends on the type of premises in question, the power consumption of the connected loads and on maintenance and continuity of service requirements.

On average, the Medical IT system supplies power to at least 6 groups of sockets:

- 2 socket groups available to the surgeon
- 2 socket groups available to the anaesthetist
- 2 wall-mounted socket groups.

For very large cardiac surgery rooms power consumption of up to 15 kVA can be envisaged, and therefore two 10 kVA insulating transformers are used so as to have a surplus of power that will allow for future expansion. One transformer can supply power to wall-mounted sockets while the other can power the sockets of the pensiles. In normal operating rooms or outpatient departments the power of the transformer drops to 7.5 - 5 - 3.5 kVA.

In any case, it is always preferable to overestimate power consumption to enable future expansion without having to modify the system.



Electrical switchboard for medical locations
QSO switchboards for operating theatres represent the ideal solution for distribution within group 2 medical locations. Four sizes are available: S, M and L. ABB provides, for its switchboards for operating theatres, the declaration of conformity required to commission the system, ensuring the installer that the system is built in compliance with technical standards.

Power kVA	IT-M line sect. no.	SELV line 24 V	Order details Type code	Order code	Bbn 801254 EAN	Price 1 piece	Price group	Weight 1 piece kg	Pack unit pc.
S series switchboards for medical locations Applications: surgery clinics, post-op recovery rooms, analysis laboratories, dental offices, veterinary clinics									
3	2x10A+5x16A+1x25A	-	QSO 3S Classic	2CSM261122R1551	2611226			73	1
5	2x10A+5x16A+1x25A	-	QSO 5S Classic	2CSM273692R1551	2736929			88	1
3	2x10A+5x16A+1x25A	1x25A	QSO 3S Premium	2CSM273602R1551	2736028			75	1
5	2x10A+5x16A+1x25A	1x25A	QSO 5S Premium	2CSM273682R1551	2736820			90	1
M series switchboards for medical locations Applications: Day hospital rooms, medium sized operating theatres, ICU rooms									
3	3x10A+7x16A	-	QSO 3M Classic	2CSM273592R1551	2735922			126	1
5	3x10A+7x16A	-	QSO 5M Classic	2CSM273672R1551	2736721			141	1
7,5	3x10A+7x16A	-	QSO 7,5M Classic	2CSM273582R1551	2735823			147.5	1
3	6x10A+8x16A+1x25A	1x25A	QSO 3M Premium	2CSM273662R1551	2736622			127	1
5	6x10A+8x16A+1x25A	1x25A	QSO 5M Premium	2CSM273572R1551	2735724			142	1
7,5	6x10A+8x16A+1x25A	1x25A	QSO 7,5M Premium	2CSM273652R1551	2736523			147.5	1
L series switchboards for medical locations Applications: operating theatres, intensive care rooms, cardiac operating rooms									
10	6x10A+9x16A	-	QSO 10L Classic	2CSM273562R1551	2735625			190	1
7,5	6x10A+11x16A+3x 25A+1x32A	2x25A	QSO 7,5L Premium	2CSM273642R1551	2736424			168	1
10	6x10A+11x16A+3x 25A+1x32A	2x25A	QSO 10L Premium	2CSM273552R1551	2735526			193.5	1

Technical features		
	QSO wall type	QSO floor type
Rated operational voltage (Ue)	230 V ~ ± 15%	230 V ~ ± 15%
Rated power frequency	50 - 60 Hz	50 - 60 Hz
Number of phases	1 + N ~/PE	1 + N ~/PE
Rated voltage of auxiliary service circuits	24 - 230 V ~	24 - 230 V ~
Rated insulation voltage (UI)	300 V - *2500 V	300 V - *2500 V
Earthing system	TT / TN-S	TT / TN-S
Maximum prospective short circuit current to the input terminals (Icc)	10 kA RMS Sym ***	10 kA RMS Sym ***
Max. altitude	2000 m a.s.l.	2000 m a.s.l.
Pollution degree	1 **	1 **
Degree of protection against impacts (IK code) EN 50102 I	K 09 (5 kg - 200 mm)	K 09 (5 kg - 200 mm)
Degree of relative humidity at temperature °C	50% with max. temp. +40 °C	50% with max. temp. +40 °C
Ambient air temperature - operation	-5 °C - +55 °C	-5 °C - +55 °C
Ambient air temperature - transport and storage	-25 °C - +40 °C	-25 °C - +40 °C

* Dielectric strength test voltage.

** Corresponds to no pollution or only dry and non-conductive pollution.

*** Value conditioned by upstream coordination with NH 00 100A gL-gG fuses

Degree of protection EN 60529				
	QSO wall type		QSO floor type	
	QSO 3S Classic	IP 40	QSO 3M Classic	IP 54
	QSO 5S Classic	IP 40	QSO 5M Classic	IP 54
	QSO 3S Premium	IP 40	QSO 5M Premium	IP 54
	QSO 5S Premium	IP 40	QSO 7.5M Premium	IP 54
			QSO 10L Classic	IP 54
			QSO 7.5L Premium	IP 54
			QSO 10L Premium	IP 54

3.3.2 SMISSLINE - Pluggable System

Keeps downtime to a minimum SMISSLINE allowes a high maintenance of electrical systems. Wherever availability is necessary in 365 days at 24 hours a day the pluggable system gives a maximum on Flexibility.

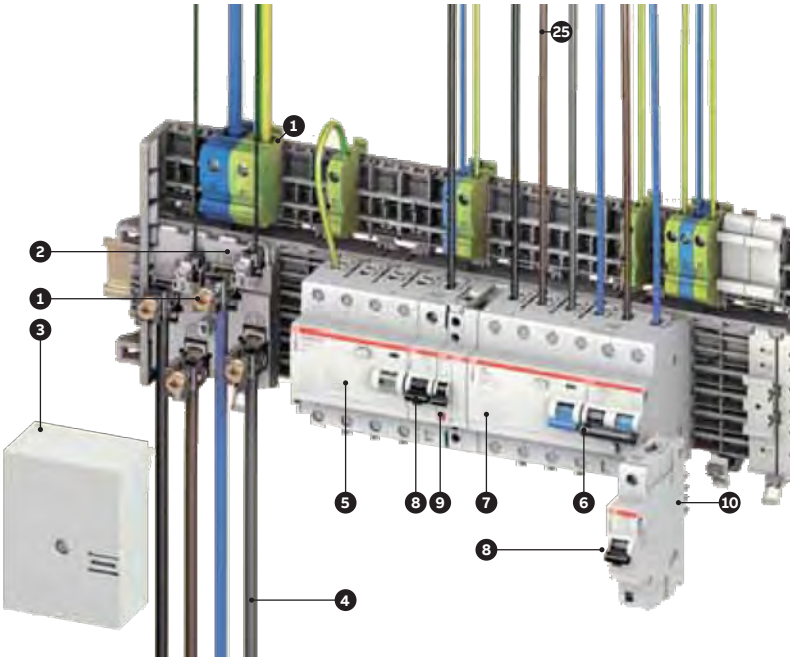
SMISSLINE protection devices are simply snapped into a plug-in socket system. The arduous task of power supply and connection is done. In addition to savings in time and money, another advantage of the system is the quick and easy exchangeability of the devices. If the corresponding spare capacity is planned, subsequent expansion consists merely of plugging in and connecting additional devices.

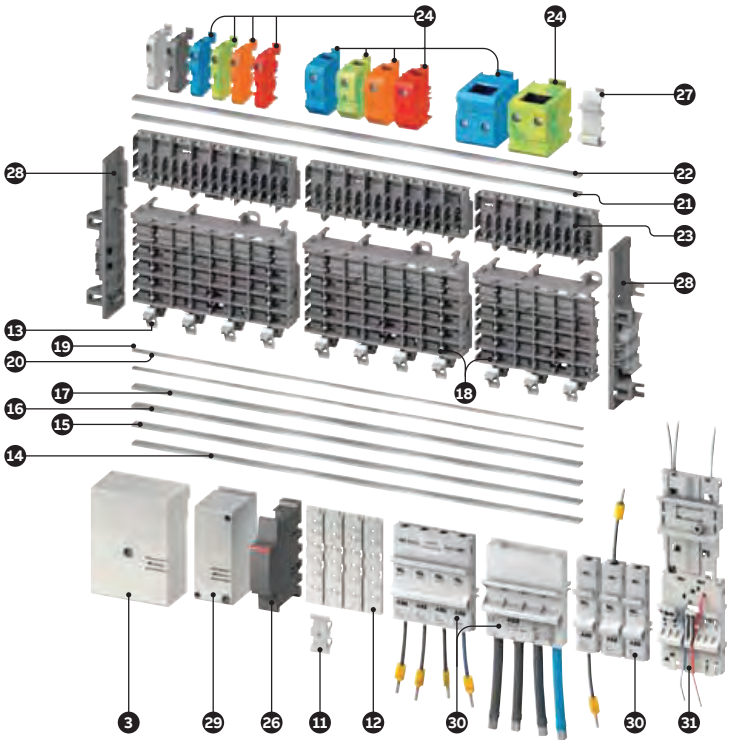
Equipment Availability

Additions, expansions and modifications of panel boards are easily done thanks to the modular structure of this system. Costs and downtime are limited to a minimum.

The SMISSLINE plug-in system really comes into its own when safety, availability and versatility are essential requirements in structures.

System Overview





1. Supply terminal
2. Incoming terminal block with a max. current rating of 160 A 50 mm² (2 x 25 mm²) + 2 x 10 mm² (LA, LB)
3. Cover for incoming terminal block
4. Supply cable
5. Surge arrester OVR404
6. RCBO FS401
7. Residual-current circuit breaker F404
8. Miniature circuit breaker S401 M
9. Signal contact
10. Plug contacts
11. DIN adaptor
12. Spare way cover
13. Device latch
14. Busbar L3 or DC +, –
15. Busbar L2 or DC +, –
16. Busbar L1 or DC +, –
17. Busbar N
18. Sockets, 8-module and 6-module
19. Auxiliary busbar LA
20. Auxiliary busbar LB
21. Busbar N, external
22. Busbar PE, external
23. Additional socket
24. N and PE terminals 32 A 1 mm² to 10 mm², 63 A 16 mm² to 50 mm² and 100 A 16 mm² to 95 mm², red and orange terminals for DC
25. Output circuits
26. Busbar isolator
27. Dummy block and 18 mm cover with DIN top for the additional socket
28. Socket end piece on left and right
29. Incoming terminal component, centre power supply 200 A, maximum 95 mm²
30. Universal adapter with a current rating of 32 A, 63 A or 100 A
31. Combi module with a current rating of 32 A

Pluggable devices on the SMISSLINE System
Miniature circuit breaker S400
1-, 2-, 3- and 4-pole devices with a current rating Between 0.5 A and 63 A

Characteristics B, C, D, K, UC-Z, UC-C

Snap on auxiliary and signal contacts on the left and right

Rated switching capacity Icn: 6 kA (E) and 10 kA (M)

Residual current device F402, F404
2-pole residual-current circuit breaker 25 A to 40

A, 10, 30, 100 mA 4-pole residual-current circuit breaker 25 A to 63 A, 30, 100, 300 mA

Short time delay type FIK (does not react to discharge currents)

Selective residual-current circuit breaker type S (selective to FI or FIK)

Combined RCBO FS401, FS403
Rated breaking capacity kA (E) and 10 kA (M)

Snap-on auxiliary and signal contacts on the left

Short time delayed versions FIK (does not react to discharge currents)

Surge arrester 404 OVR
4-pole protection device, type 2

Potential-free signal contact integrated in the device

Rated discharge surge current Isn 15 kA

Motor protection circuit breaker MS 325
Power motor protection circuit breaker MS325 Un 690 V, In 0.1 to 25 A, breaking capacity 100/50 kA, with phase failure protection, temperature.

Auxiliary and signal contacts
The plug-in socket system gives you the option of signaling via auxiliary busbars. The auxiliary busbars LA and LB can be contacted directly via contacting parts. The contacting parts can be easily changed from LA to LB by replugging them, or they can be removed completely. A collective alarm is possible using the innovative collective alarm signal contact. To do this, contact is made parallel with the auxiliary busbars.

Advantages of vertical construction compared to conventional layouts
Larger assemblies with SMISSLINE can be arranged vertically. The power for the plugin socket system is supplied via an incoming terminal block. Fewer cables are required for the cross connections in the control cabinet. The input wiring is integrated in the plug-in socket system. The N and PE terminals are directly assigned to the devices. The outgoing cables are connected directly to the devices. This results in an overall clear arrangement. Expansion is easy thanks to the plug-in technology.

Customer Benefits with SMISSLINE in Hospitals and Clinics
Reliability and Availability
Fast and easy handling with pluggable devices

Plug-in technology provides 24-hour service, 365 days a year

Freedom in concept and design
Mix of devices, various power supply options

Flexible architecture without risk of damage to life and property

Upgradeability
Easy integration of new devices

Upgrade without changing the existing installation

3.3.3 Ducts

In group 2 medical locations the ducts installed inside the room must be purposed exclusively for the power supply of the electrical devices and their accessories present in the same room; in practice, ducts that supply power to equipment located in other rooms cannot pass through these group 2 medical locations.

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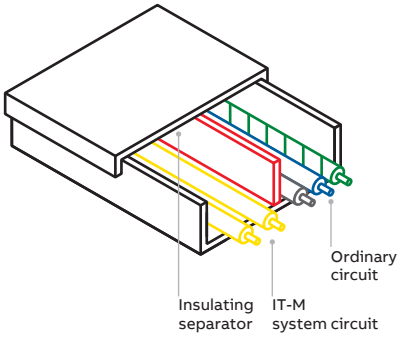
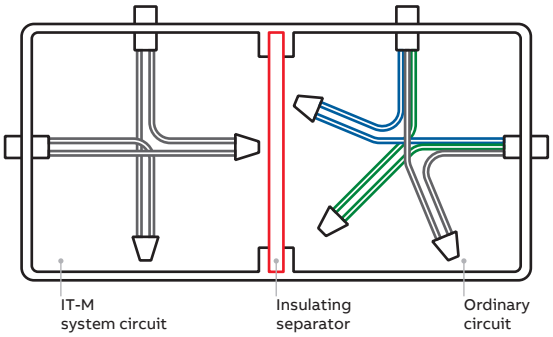
Figure 3.12: Separation of Medical IT circuits from others by means of insulating separators





The circuits branching from a medical IT system must necessarily be separated from the electrical circuits powered by other systems, and must, therefore, be installed in separate piping or ducts and boxes. The use of shared ducts and boxes is also allowed provided that the separation is implemented with an insulating separator (fig. 3.13).

The circuits of the Medical IT system can also be implemented using unipolar cables (cords) of the type N07V-K (with the warning not to use navy, blue or light blue conductors, since a medical IT system never has Neutral).

If it is impossible to implement a physical separation of two electrical systems, and the Medical IT circuit runs through a duct “shared” with the conductors of another system, double insulation cables with a non-metallic sheath must be used. In addition, if the leakage current is due to a capacitive effect, it is recommended that the protection conductor be separated from the phase conductors and then inserted in its own protective tube.

In group 2 medical locations where electromedical devices are used in order to monitor and support vital parameters, such as those of intensive care, resuscitation and similar, the devices should be powered using conductors that are shielded or inserted in metallic piping as a precaution against electrical fields. Both the shieldings of the cables as well as the metal piping must be equipotentialised on the nearest node or sub-node.

For radiology and CAT rooms and rooms with equipment that emits ionising radiation, the power supply conductors should not interrupt the radiation shieldings present.

The protection of the ducts against overcurrents must be implemented using omnipolar automatic miniature circuit breakers. Also in Medical IT systems, the circuits branched to the secondary must be protected with fuses or thermomagnetic automatic miniature circuit breakers, but not with RCDs because the RCD would not be effective in this particular “medical insulation” system.

3.3.4 Power supply ducts for radiological or similar equipment

Radiological devices and those with a power consumption in excess of 5 kVA absorb high value currents from the power supply line. For this reason the sizing of the power supply conductors must be assessed carefully in order to contain voltage drops.

Radiological devices of the fixed type and devices with power consumption greater than 5 kVA, powered directly by the "ordinary" network and in general without the interposition of a socket/plug group, can be protected with RCDs with a differential current of 0.5 A.

If they may enter the patient environment it is mandatory to adopt differential 30 mA thermomagnetic miniature circuit breakers of type "A" (for single phase circuits) or "B" (especially for three-phase circuits).

3.3.5 Selectivity of the protection devices

Particular care must be taken in implementing effective selectivity of the overcurrent protection devices in order to guarantee maximum continuity of service.

As far as possible, horizontal and vertical selectivity must be implemented. With horizontal selectivity, and therefore by subdividing the system into different circuits, downtime in the case of a malfunction is reduced. Subdivision into several circuits also makes it possible to prevent the simultaneous use of numerous devices connected to the same circuit from causing the tripping of the RCD (for example due to the capacitive earth leakages of the devices).

A particular aspect of horizontal selectivity concerns group 2 rooms: the standards require that for every patient treatment position (such as a socket control panel, a wall-mounted power supply unit or the pensile stand) the plug sockets powered by the Medical IT System must be alternatively (fig. 3.14):

- connected to two distinct power supply circuits (each equipped with the respective protection device);
- protected against overcurrents individually or in groups (at least two).

With this provision, if a plug socket downstream fails, with tripping of the related protection device, only one socket or one group of sockets will be out of service, while the others remain in operation.

Together with horizontal selectivity it is also necessary to guarantee vertical selectivity so that, in the event of overcurrent, only the device for protection of the circuit affected by the malfunction will trip, and not the device located upstream (fig. 3.15).

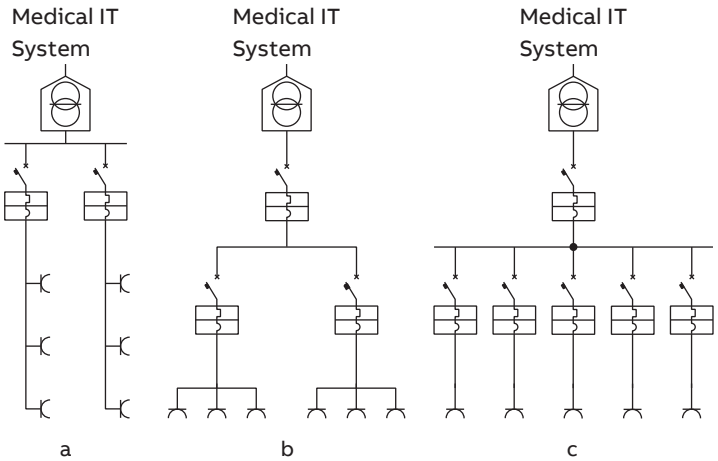


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Figure 3.13:
Protection of sockets powered by the Medical IT System
a) subdivision into two separate circuits protected individually
b) protection in groups
c) single protection

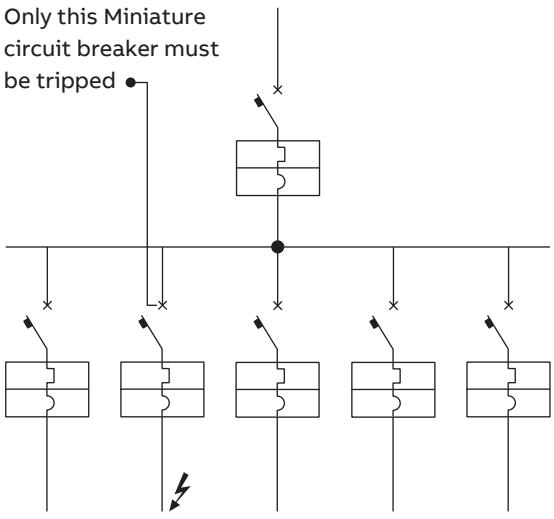

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Figure 3.14:
Vertical selectivity in the presence of Miniature circuit breakers in series.

Selectivity in Medical IT circuits can be implemented with thermomagnetic switches or fuses of adequate size.

When using fuses, their purpose is to protect each socket in the group and, upstream in the room switchboard, to protect the power supply duct for each group of sockets. Total selectivity is implemented by choosing fuses of the appropriate size and the main switch with a very high magnetic trip current.

The advantages are obvious: if one considers that a short circuit in an operating room normally occurs because the plugs have been pulled out by tugging the cable instead of grasping the actual plug, or due to fluids entering into contact with active parts, a shortcircuit on a socket causes tripping of the respective fuses, and therefore it is possible to use another socket (there are always more sockets than necessary) without any serious disservice.

With the use of automatic miniature circuit breakers, selectivity can be obtained by choosing the protection devices so that for all the short circuit values, up to the maximum leakage current provided for the duct protected by the downstream circuit-breaker, the tripping zones of the miniature circuit breakers in series do not overlap (fig. 3.16). In general, however, selectivity between circuit breakers is obtained also by regulating their tripping time delays.

Selectivity must also be implemented for the RCDs assigned to protect equipment powered directly by the network.

For example, in the hospital accommodation rooms (group 1 rooms) there are three circuits (lighting, plug sockets, headboard sockets) each protected with a 30 mA RCD; to protect the power supply circuits for a group of rooms, a 300 mA RCD is installed, while upstream in the cabinet there is a 500 mA RCD. Lastly, total selectivity is obtained by regulating the tripping time delays of the RCDs.

3.3.6 Installation criteria

The switchboard containing the insulating transformer can be installed either wall-mounted or floor-standing outside group 2 rooms, or inside provided that it is outside the patient environment, in order to avoid contact between the patient - including via medical personnel and the cabinet, which contains not just the circuits downstream of the transformer, but also its power supply conductors.

If the requirements demand power higher than that allowed (10 kVA) for the insulating transformer, then multiple insulating transformers must be installed in order to contain the leakage currents. In this way it is possible to benefit from the redundancy of the circuits in order to maximize continuity of service, also in the case of maintenance.

The insulation monitoring and measuring device can be placed in the electrical switchboard of the Medical IT system, but a panel with repetition of acoustic/optical signals and a test pushbutton must be located in the most used premises, where the continuous presence of healthcare operators is assumed.

Both the plug sockets and the miniature circuit breakers must be installed at more than 20 cm (from centre to centre) from any connection for gas for medical use.

The socket outlet powered by a Medical IT system must not be interchangeable with the plug sockets of the same premises that are powered directly by the network.

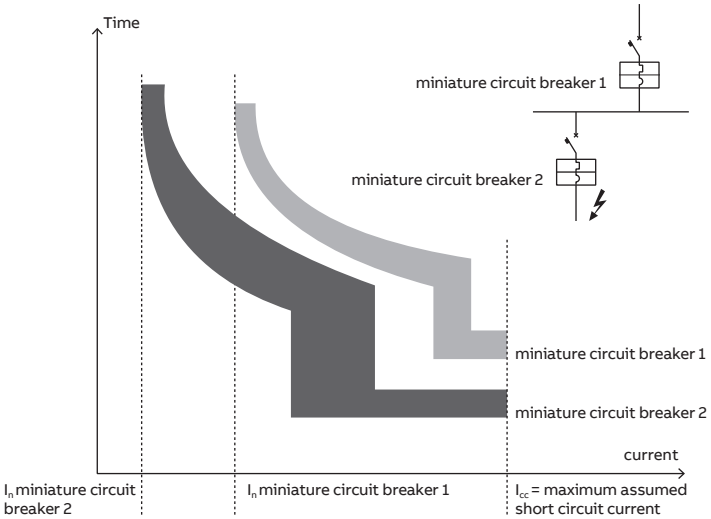

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Figure 3.15:
Total selectivity between two miniature circuit breakers in series

3.3.7 Earthing

In group 1 and 2 premises only the following appliances may be connected directly to the protection conductor (all the others must be connected to the equipotential node):

- fixed appliances, such as ceiling lighting appliances in class 0 and I, as long as they are installed more than 2.5 m above the walking surface or completely outside the patient environment;
- limiters against overvoltages of any origin (it is advisable to install them on the incoming lines that supply power to the medical locations).

3.3.8 Safety services

— Necessity for continuity of operation

In medical locations it is possible to use devices for which total availability of the power supply is required in order to avoid hazards for the patient in the case of malfunctions in the system or the devices, or in the event of a black-out.

To obtain operational continuity following a malfunction, it is recommended to use an insulating transformer even in group 1 medical locations, in outpatient departments and in laboratories, since it guarantees the use of electrical devices even if a "first earth fault" occurs in one of these. In analysis laboratories in particular, continuity is an essential factor because in the case of an interruption in the energy supply a long time is required for reprogramming and recommissioning them.

To deal instead with an interruption of the power supply (black-out) an emergency system must be installed dedicated to the safety power supply for the loads defined as privileged because necessary for the safety of the patient.

The characteristics of the safety power supply must be established by the designer, taking account of the real requirements of the healthcare structure to be served and the standards in force.

In all group 2 (and in some group 1) medical locations, the safety power supply must be automatic with a short interruption (≤ 0.5 s) and must guarantee the power supply of the lighting devices for operating tables, the electromedical devices that require a safety power supply and the monitoring and alarm systems for at least three hours.

For other services and electromedical devices the safety power supply can have a medium interruption time, in other words with an activation time no longer than 15 s (safety lighting for exit routes, electromedical devices etc.), or a long interruption time, greater than 15 s (sterilization devices, refrigerators etc).

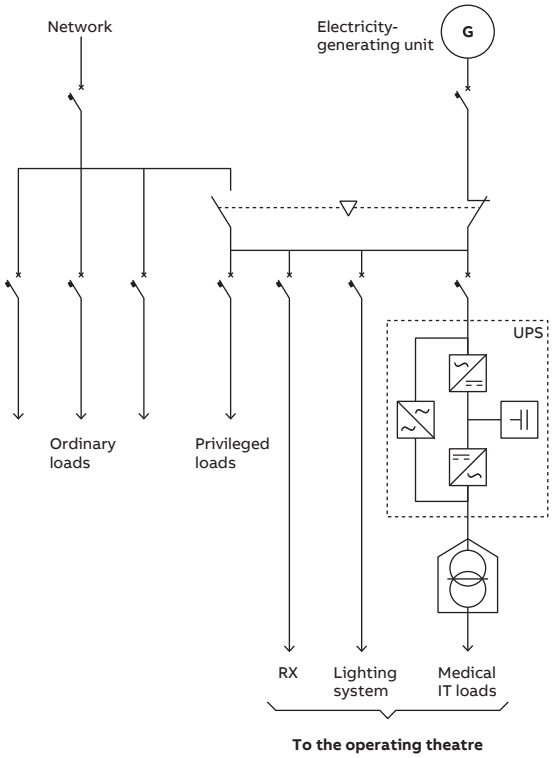
The safety source may consist of batteries, uninterruptable power supplies (UPS) or electricity-generating units.

In each operating room or group of rooms continuity of operation should be implemented with at least two UPS. In this way, each UPS works at 50% of its power, and is not therefore subject to overloads and can stand in for the other in the event of malfunctions.

The use of multiple redundant UPS also benefits maintenance, which can be carried out on one group at a time, thus allowing the operating room to remain active.

A further advantage offered by the UPS is the quality of the energy supplied, with a resulting absence of interference on the circuits downstream.

The UPS are able supply power to the load without any interruption, but they normally have limited autonomy (10 ÷ 30 min) and therefore an electricity-generating unit intervenes afterwards (fig. 3.17).



— Figure 3.17: Safety power supply implemented with a UPS and an electricity-generating unit.

3.3.9 Safety lighting

Safety lighting is required in the following environments:

- group 1 and group 2 medical locations;
- exit routes and safety exits, including the associated safety signs;
- rooms containing cabinets, electrical switchboards, production system sources;
- rooms with essential services, such as elevator machinery, kitchens, air conditioning stations, data processing centres.

Safety lighting must enter into operation within the times specified by the standard (table 3.7).

Safety lighting must be guaranteed via centralized systems (batteries or electricity-generating units) or by means of autonomous devices, individually equipped with a battery with an autonomy of at least 2 hours.

The table specifies the tripping time delays for the safety power supply required by the standard in relation to the type of medical premises.

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Table 3.7:
Tripping time delays of the safety power supply in relation to the type of medical premises

Type of premises	Interruption ≤ 0.5 s	Interruption ≤ 15 s
Massage room		●(1)
Hospital accommodation rooms		●(1)
Delivery room	●(2)	●(1)
ECG, EEG, EHG, EMG room		●(1)
Endoscopy room	●(2)	●(1)
Outpatient departments		●(1)
Urology room		●(1)
Radiology and radiotherapy diagnostic rooms		●(1)
Hydrotherapy room		●(1)
Physiotherapy room		●(1)
Anaesthesia room	●(2)	●(1)
Room for surgery	●(2)	●(1)
Operation preparation room	●(2)	●(1)
Surgical plaster room	●(2)	●(1)
Post-operative waking room	●(2)	●(1)
Room for applications of cardiac catheters	●(2)	●(1)
Intensive care room	●(2)	●(1)
Angiographic and haemodynamic analysis room	●(2)	●(1)
Haemodialysis room	●(2)	●(1)
Magnetic resonance room (MRI)		●(1)
Nuclear medicine roomx		●(1)
Premature infant room	●(2)	●(1)

(1) Only for group 1 medical locations.
(2) Lighting devices and electromedical devices with a life support function that require a power supply within 0.5 s or less.

Other information on systems for medical locations

4.1 Veterinary premises

Area of application of the standards to veterinary premises

The IEC 60364-7-710 specifi es that as far as it is practically applicable, the standard can also be used for veterinary clinics and surgeries".

Veterinary environments can have varying degrees of risk depending on the function that the veterinary medical manager wishes to assign to his studio or to the structure in which he carries on his activity. It is therefore the veterinary medical director who must defi ne the activity carried out in the various premises by means of a written declaration; the designer defi nes the systems to be implemented on the basis of the director's choices.

4.1.1 Electrical risk

Regarding electrocution phenomena (direct and indirect contacts) animals present a higher or lower risk according to the species to which they belong, their size and the treatments or operations to which they are subjected, and in certain conditions (included heart operations on animals for research) they may also be subject to the risk of microshock. The risk of microshock is normally particularly signifi cant in veterinary clinics, hospitals and research centres. In veterinary studios and laboratories, on the other hand:

- intracardiac operations or operations that may involve the cardiac muscle are not performed;
- electromedical devices with applied parts are used with great moderation, while "electrical devices" are used frequently, as well as their accessories such as shearing devices, portable electric drills, as are "electromedical devices" such as fi xed or trolley-supported scialytic lamps that enter the patient environment.

Figure 4.1:
Example of a clinic

We can therefore conclude that veterinary studios and laboratories can always be considered as group 1 even if surgical operations can be carried out in them, while group 2 locations can be present in veterinary clinics, university hospitals with veterinary specialisation and in veterinary or clinico-pharmacological research centres.

4.1.2 Criteria for sizing and protecting the electrical system

The protective methods adopted for the locations, as specified by the IEC 60364-7-710, can also be applied to veterinary rooms, classified as previously mentioned.

4.1.3 The Medical IT system in veterinary rooms

The Medical IT system can be adopted for different requirements depending on the group to which the veterinary room belongs. If the room is declared as group 2 (microshock hazard) the system is mandatory. If the room belongs to group 1 the adoption of the Medical IT system may be advisable in order to guarantee the possibility of using certain electrical devices even if a “first earth fault” occurs in one of these.

The adoption of a device that monitors the insulation of the part of system under the insulating transformer is mandatory for group 2 rooms and recommended for group 1 rooms.

4.1.4 Inspections in veterinary premises

As for premises for huma medical use, in the case of veterinary premises it is also mandatory to perform the initial and periodic inspections according to the provisions of the standards.

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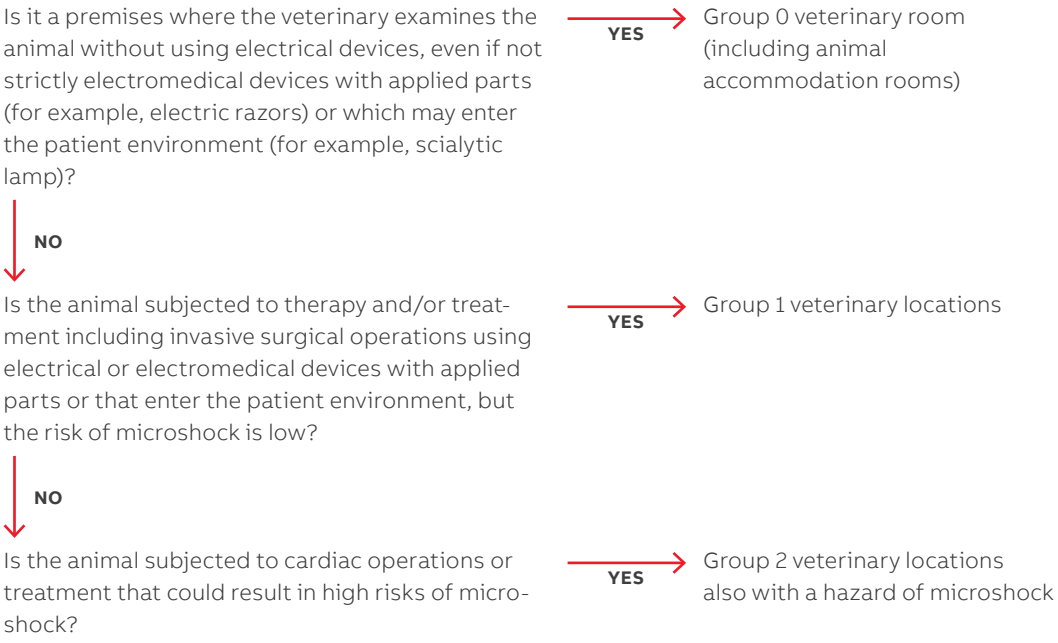
Figure 4.2 shows a flow diagram for choosing the group of the veterinary premises.



4.2 Initial and periodic inspections

The electrical systems in medical locations must be inspected, both before commissioning and also after any modifications or repairs (initial inspections); thereafter, they must be checked at intervals (periodic inspections) pre-established by a technical expert, who may or may not be an employee of the healthcare structure, and the results of each inspection must be recorded.

4.2.1 Initial inspections

The electrical systems of group 0 rooms (ordinary systems) are only subject to the inspections required by IEC 60364. For the systems of the group 1 and group 2 rooms, in addition to the checks required for ordinary systems, the following checks must be performed:

Tests and checks to be carried out	Group 1 premises	Group 2 premises
Functional tests on the insulation monitoring device and the optical and acoustic alarm system of the Medical IT system	-	•
Measurement of the leakage currents of the secondary no-load winding and on the casing of the transformers for medical use; the test is not necessary if it has already been carried out by the manufacturer of the transformer	-	•
Measurement of the resistance of the supplementary equipotential connections	-	•
Check of the continuity of the protection and equipotential conductors	•	-
Visual inspection to ensure that the other regulatory prescriptions specified by Section 710 of standard 60364-7 have been respected	•	•

The checks are carried out on the basis of the design documentation which must include at least:

- floor plans indicating the group to which each medical premises belongs;
- floor plans indicating the position of the equipotential nodes with the related connections;
- the wiring diagrams.

Functional testing of the Medical IT system

The functional test of the insulation monitoring device is carried out through a series of assessments followed by a number of tests.

Initial assessments

- the device must conform to the EN 61557-8, concerning devices for testing, measurement and monitoring protective measures;
- the internal impedance of the device must not be lower than 100 kΩ;
- the supply voltage of the alarm circuit must not be higher than 25 V DC.

Tests

a) measurement of the current circulating in the alarm circuit that, even in the event of a malfunction, must not be higher than 1 mA DC;
b) check that the alarm signal occurs when the insulation resistance drops below 50 kΩ.

—
Instrumentation to carry out the tests and measurements appropriate instrumentation is required, including:

- a Voltmeter;
- a milliammeter grip;
- a milliohm meter with a no-load voltage between 4 and 24 V in DC or AC and test current of 10 A;
- a device for testing the circuit breakers

a) Measurement of the current in the alarm circuit

Purpose of the test: It must be guaranteed that, even in the case of a malfunction, the current in the circuit does not exceed the value of 1 mA DC.

Instrument: Milliammeter.

Procedure: measurement of the current in the alarm circuit can be carried out in conditions of dead short earth fault by inserting the milliammeter in series with the conductor that connects the device to the equipotential node and connecting one of the conductors of the isolated circuit directly to earth (fig. 4.3).

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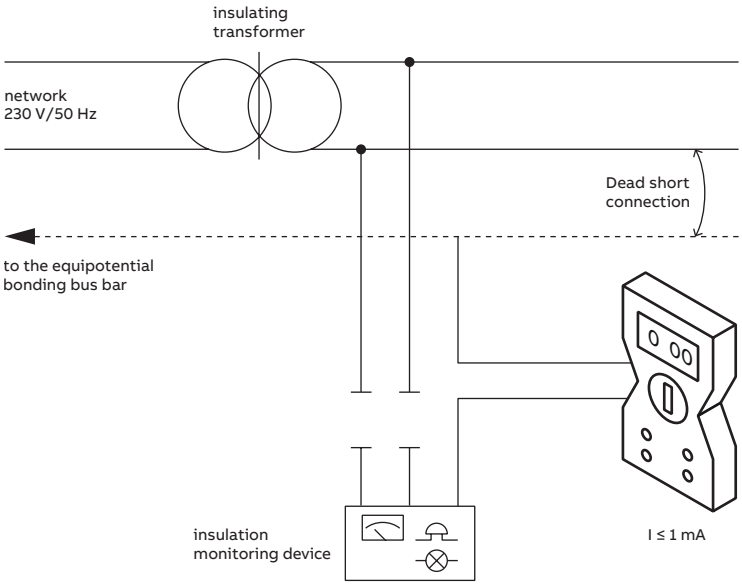
Figure 4.3:
Measurement of the current in the alarm circuit.



b) Trip test

Purpose of the test: to check that the insulation monitoring device is functioning correctly, in other words, that the alarm signal is activated when the insulation resistance value drops below 50 kΩ.

Instrument: Rheostat.

After disconnecting the loads, each conductor of the circuit powered by the secondary of the insulating transformer is connected - one at a time - with the equipotential node using the rheostat (fig. 4.4). Fault simulation is implemented by reducing the resistance of the rheostat to a value R < 50 kΩ.

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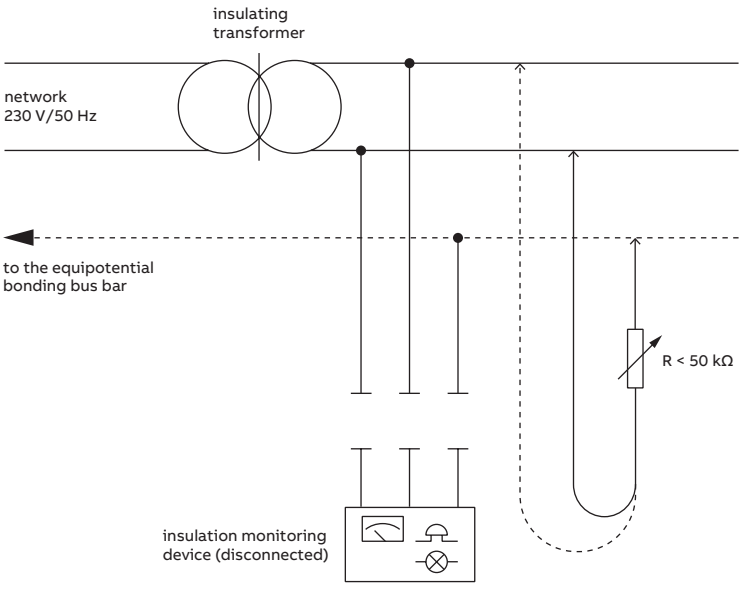
Figure 4.4:
Insulation controller trip test



Functional test of signalling systems
Purpose of the test: to check that the optical and acoustic alarm systems are functioning.

The test is performed by assessing, by means of a visual inspection, that the following prescriptions have been respected:

- presence of the signalling indicator light, lit up green, indicating normal operation;
- presence of the signalling indicator light, lit up yellow, which comes on when the alarm device intervenes (insulation resistance < 50 kΩ);
- impossibility of switching off the yellow indicator light; it must switch off only after the signalled fault has been eliminated;
- presence of an acoustic signal that starts to function when the alarm device is tripped (insulation resistance < 50 kΩ); the signal must be audible in the rooms of the department where medical personnel are expected to be present.

Measurement of the leakage currents of the insulating transformer
Purpose of the test: To check that the earth leakage current of the secondary winding and the casing of the insulation transformer is not higher than 0.5 mA.

Instrument: Milliammeter.

Procedure:
a) earth leakage of the secondary winding is measured with the transformer powered with no load at the rated voltage, with the insulation monitoring device deactivated and by connecting the milliammeter between the equipotential node and each pole of the transformer one at a time (fig. 4.5).
b) the earth leakage on the casing is measured on the accessible metal parts that are not connected to earth (for example, rivets, screws etc.), and on the insulating parts by applying a metal sheet on these.

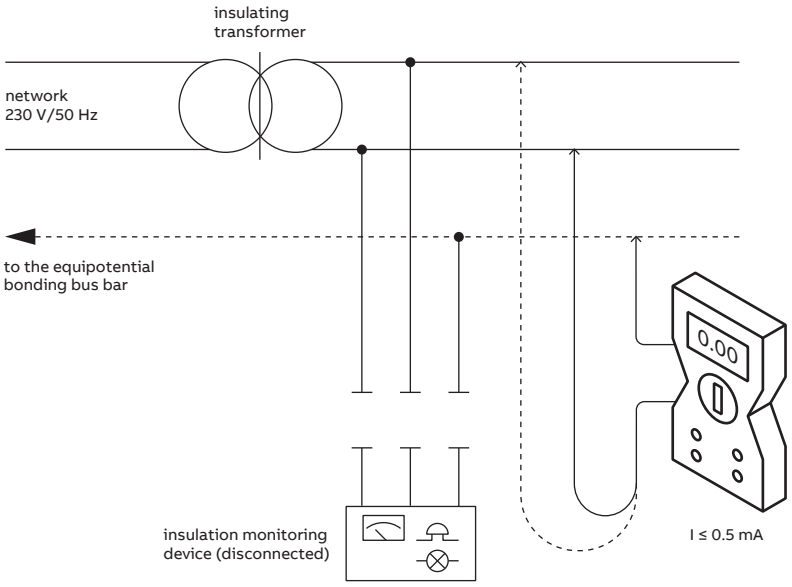


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Figure 4.5:
Measurement of the leakage currents of the insulating transformer

Measurement of the supplementary equipotential connections (group 2 medical locations)
In group 2 medical locations the resistance of each conductor for connection to the equipotential bonding bus bar must be measured.

Purpose of the test: to check that each connection between the equipotential node and the earth of the plug sockets, the earth terminal of fixed user devices and any extraneous conductive part has a resistance no higher than 0.2 Ω.

Instrument: four terminal switchgear, working according to the volt-ammetric principle, with a no-load voltage between 4 and 24 V in AC or DC and capable of providing a current of at least 10 A.

Procedure: the terminals of the instrument are connected on one side to the equipotential bonding bus bar and on the other to the conductive part or extraneous conductive part, as indicated in figure 4.6. The test current is circulated by means of the ammetric circuit (terminals A1 and A2) while voltage is measured by means of the volumetric circuit (terminals V1 and V2). The pins must be located at two different points, both on the equipotential bonding bus bar and on the conductive part. In this way it is possible to measure not just the resistance Rc of the equipotential conductor, but also the contact resistances of the connections of the conductor itself (R1 and R2). In the presence of a subnode, the measurement must be performed between the equipotential bonding bus bar and the conductive part or extraneous conductive part; in other words, it must simultaneously involve both conductors - the one between the equipotential node and the sub-node and the one that connects the sub-node to the conductive part or extraneous conductive part (fig. 4.7).

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Figure 4.6:
Measurement of the resistance of supplementary equipotential conductors.

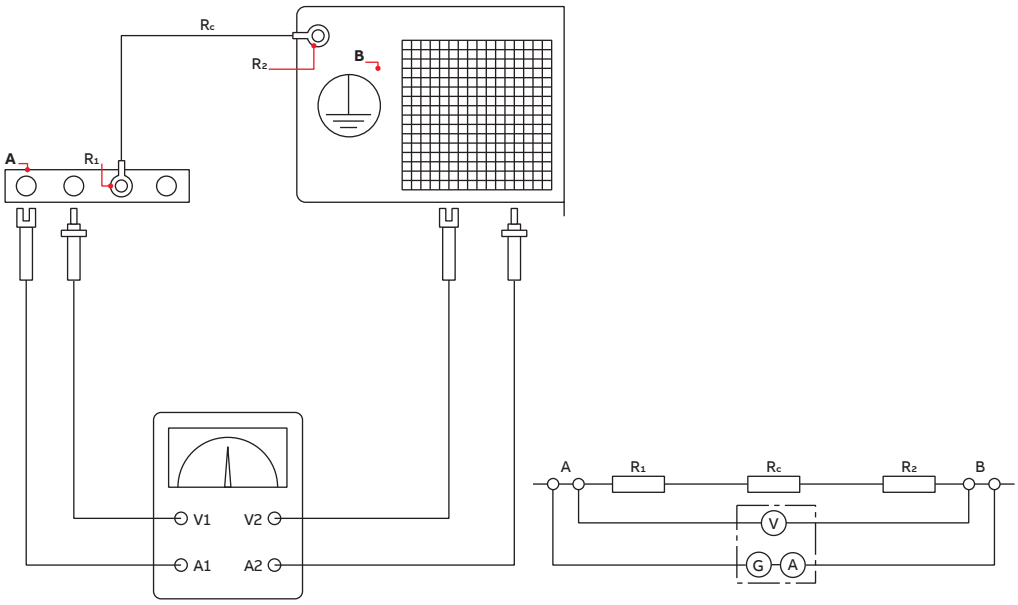

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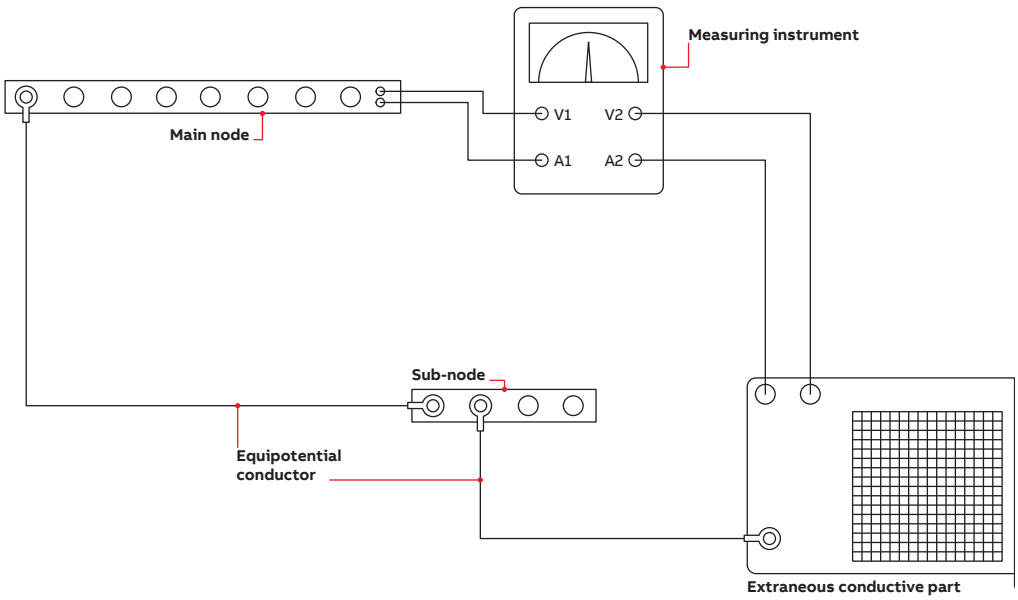
Figure 4.7:
Measurement of the equipotential connection of an extraneous conductive part through a sub-node.



Testing supplementary equipotential connections (group 1 medical locations)
The test is performed by making sure that the connections of the protection and equipotential conductors of the equipotential bonding bus bar are made correctly and that they are intact.

Purpose of the test: to check the electrical continuity of the conductors, in other words that there are no false contacts (without measuring their resistance).

Instrument: ohmmeter with a no-load voltage between 4 and 24 V in AC or DC and that supplies a current of at least 0.2 A.

Procedure: the terminals of the instrument are connected on one side to the equipotential bonding bus bar and on the other to the conductive part or extraneous conductive part, then a check is made to ensure that the current supplied from the instrument does not drop below 0.2 A.

Measurement for the identification of extraneous conductive parts
Purpose of the test: to assess whether a metal part is an extraneous conductive part by measuring resistance to earth. It is considered to be an extraneous conductive part if the resistance value measured is less than 0.5 MΩ in group 2 medical locations and less than 200 Ω in the group 1 medical locations.

Instrument: ohmmeter or appropriate tool equipped with a plug socket to be inserted in a socket of the system and with a sensor to be placed in contact with the possible extraneous conductive part.

Procedure: the measurement is taken by connecting one of the pins of the instrument to the equipotential bonding bus bar and the other on the metallic structure in question (fig. 4.8).

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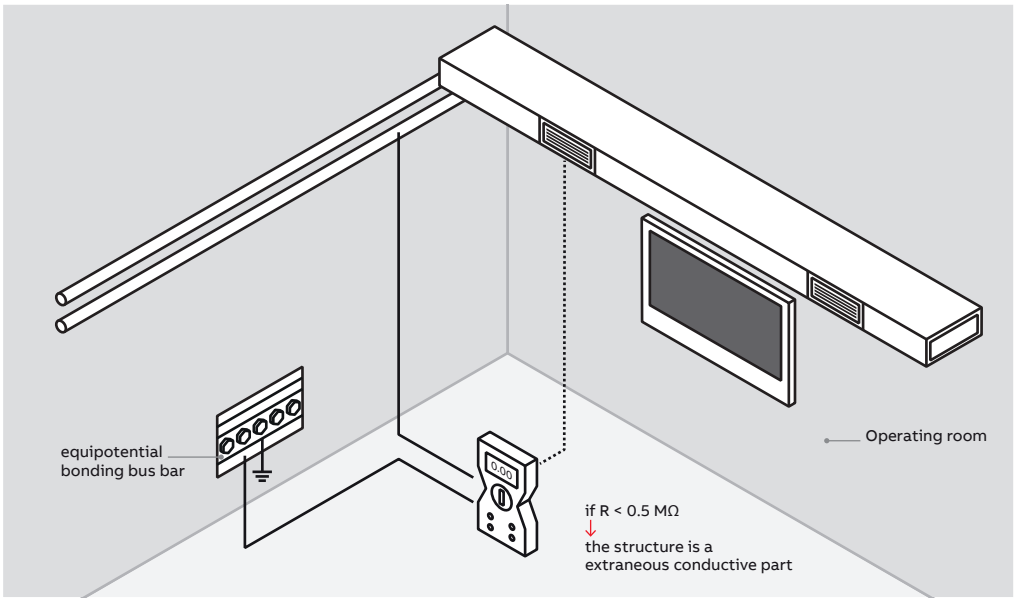
Figure 4.8:
Measurement of the earth resistance of extraneous conductive parts.



Visual inspection
The visual inspection must address the following aspects in particular:
- coordination of protection devices in TN and TT systems;
- calibration of the protection devices;
- characteristics of SELV and PELV systems;
- fire safety devices;
- circuit configurations for supplying power to plug sockets in group 2 medical locations;
- identification of the plug sockets supplied by safety sources;
- performance of the sources and devices for safety power supply and lighting.

4.2.2 Periodic inspections

In addition to detailed and precise prior maintenance, the medical locations also need periodic checks at specific time intervals. The purpose of the periodic checks is to ensure that the conditions of acceptability and standards compliance that were found during the initial checks are maintained, as well as to make sure of the correct operation of the safety devices and systems.

Table 4.1 summarises the checks to be carried out on the electrical systems of medical locations, and the corresponding frequency required by IEC 60364-7-710. It is important to note that these checks are in addition to those required by IEC 60364 for ordinary systems.

—
Table 4.1:
Periodic checks that must be carried out on the electrical systems of group 1 and group 2 medical locations.

Check	Frequency
Functional test of the insulation monitoring devices (on Medical IT systems)	6 months
Check, by means of a visual inspection, of the calibration of adjustable protection devices	1 year
Measurements of the resistance of supplementary equipotential connections	3 years
Test that the RCDs intervene at the value of I_{dn}	1 year
Functional test of the power supply to safety services with combustion engines: • no-load test • test with load (for at least 30 minutes)	 1 month 4 months
Functional test of the power supply of battery-powered safety services, in accordance with the manufacturer's instructions	6 months

4.2.3 Recording of the results

The dates and the results of both initial and periodic tests must be recorded on paper or electronic media and conserved over time, as required by article 710.6 of the IEC 60364-7-710.

Appendix

5.1 Logical path for the design of electrical systems in premises for medical use

Declaration of the healthcare manager on the type of healthcare operations that will be carried out in the medical locations

↓

Definition of the type of medical location

↓

Analysis of the risks deriving from electromagnetic fields, atmospheric discharges, overvoltage on the power supply, fire

↓

Identification of the air conditioning ducts of the premises, and of the piping for medical gases or anything else

↓

Identification of the patient environment

↓

Determination by the healthcare manager of the electromedical devices that will be used in the room and the corresponding power absorption values

↓

Subdivision of the electromedical devices between ordinary devices and devices that must be powered by a Medical IT system

↓

Definition of the size of the insulating transformer according to the power of the equipment envisaged in the room

↓

Identification of the conductive parts and extraneous conductive parts that must be connected to the equipotential node

↓

Identification of the duct paths and the positions where the switchboards and the equipotential node are to be located as well as the spaces required for maintenance

↓

Identification of specific requirements or restrictions and of the possible need for screens against external electromagnetic fields

↓

Sizing of the conductors and the protections

↓

Choice of operating and protection equipment

5.2 Options for design

The design of a hospital electrical system requires a careful appraisal of numerous factors that together guarantee a correct synthesis between two intrinsically antithetic aspects: **protection** and **operational continuity.**

The hospital electrical system for group 2 medical locations has a high degree of complexity and must take account of coordination with the distribution upstream. It is the precise task of the designer to weigh up the possible design choices compatibly with the applicable standards and at the same time with the technical requirements.

As a support, a number of alternative types of installations that the designer may have to evaluate are outlined below, with the intention of illustrating the advantages and disadvantages of the various solutions and, where possible, to offer a qualitative suggestion.

Concentration of loads under a privileged line or separation of the privileged line from the UPS line.

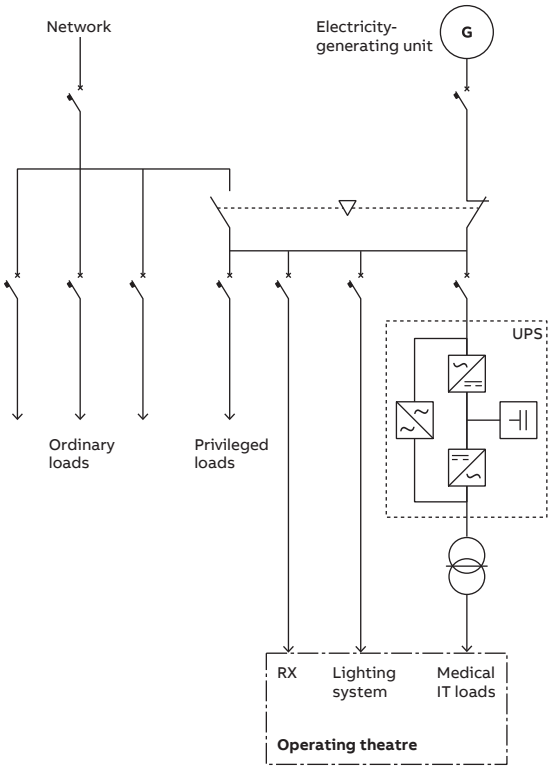
It is advised to divide up the circuits as specified by IEC 60364-7-710 so that there will in any case be a dual power supply on the circuits of the operating room, even when the power absorbed by the non Medical IT loads can be considered as negligible in relation to the installed power.

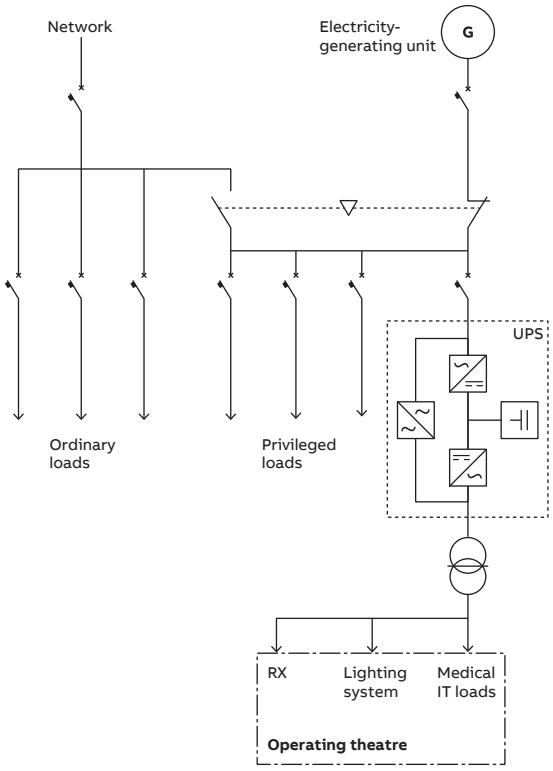
Concentration

- Less complexity of the system
- Lower costs
- No use of the RCD protecting the dedicated lines for the lighting system and machinery with power consumption >5 kVA, such as, for example, radiological devices
- No selectivity on the secondary UPS

Division

- Redundancy of the circuits
- Continuity of service: if the RX does not function, the lines of the emergency section operate normally in any case
- Reduction of the power consumption of the medical insulating transformer
- Reduction of the size of the protection devices inside the Medical IT board





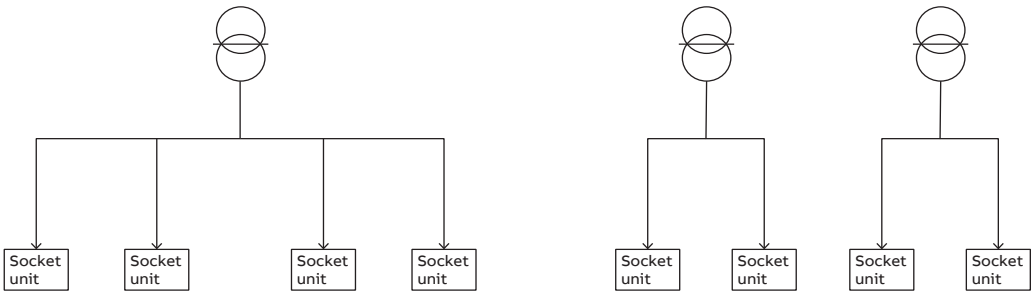
The choice of the most suitable protection device depends on the application context and must be prescribed by the designer. In intensive therapy premises, in which the patients have an extended stay in hospital, it is advisable to service the loads with multiple transformers, both to increase continuity of service and in order to be able to carry out maintenance operations, which must not cause disturbance to the patients.

In the surgical outpatient departments, on the other hand, it may be appropriate to distribute the power supply from a single transformer, because the amounts of power absorbed are generally very limited and it is possible to manage a power reserve also with a 3 or 5 kVA insulating transformer. In these rooms, however, there is very limited space in which to position the switchboard, and therefore it may be preferable to prefer a switchboard with small dimensions.

Concentration or distribution of power in group 2 medical locations

Concentration
- Reduction in the number of switchboards
- Reduction of dimensions
- Power available for future expansions of the system
- Lower costs

Distribution
- Redundancy
- Greater continuity of service
- Ease of maintenance
- Quicker fault finding
- Reduction of the dimensions of the individual switchboard
- Easier to install wall-mounted switchboard

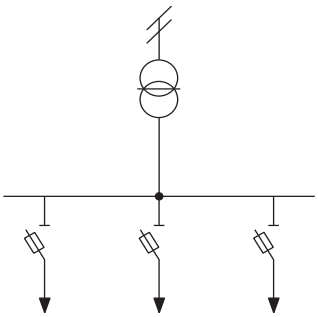


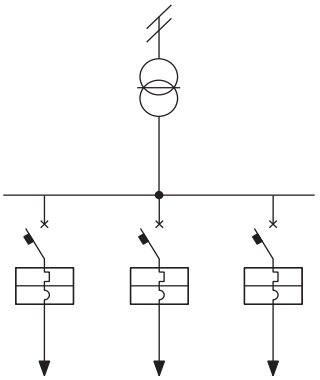
The choice of the most suitable protection device depends on the application context and must be evaluated by the designer taking account of the above considerations.

Protection of Medical IT circuits by means of fuses or miniature circuit breakers

Fuses
- High breaking capacity
- Speed of activation
- Selectivity with the socket units on shelves, headboard and control panels of the room
- Better horizontal and vertical selectivity of
- the circuits
- Replacement of the damaged part only
- The device is not affected by the malfunction since the damaged cartridge has been replaced
- Possibility to section the line with a load by means of a device with an AC-22B usage category

Miniature circuit breakers
- Instantaneous rearming
- Speed of maintenance: no need to replace the active parts
- No special skills required for maintenance
- Calibration of the protection device cannot be altered by the user through replacement of components
- Possibility of installing numerous accessories including signal contacts





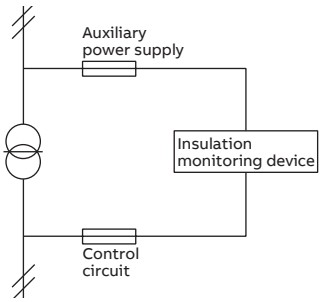
It is strongly recommended to protect the power line of the insulation monitoring device by means of an appropriately coordinated fuse block base.

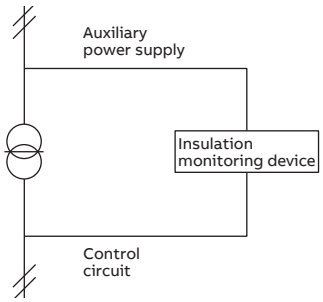
To avoid deactivation of the insulation monitoring device while the IT-M circuit is functioning, it is advisable to install the fuse block in an inaccessible part of the switchboard, typically on the back of switchboard door. For the same reason, it is important that the fuse block base is not subjected to sectioning and is lead-sealed in the closed position: in this way it is guaranteed that the power supply of the insulation monitoring device can only be cut off when the transformer secondary, and therefore the operating room, is not in operation.

Protection of the insulation monitoring device against short circuit and overload

Protect
- Possible overloads and short circuits are avoided
- Breakage of the insulation monitoring device is avoided
- Fire principles are avoided inside the switchboard
- Operational continuity to the Medical IT circuits is guaranteed

Do not protect
- Cost of protection devices
- Internal dimensions of the switchboard
- Risk of making the protection device ineffective if an inappropriate fuse is used
- Risk of breakage of the insulation monitoring device due to overload or contained short circuit



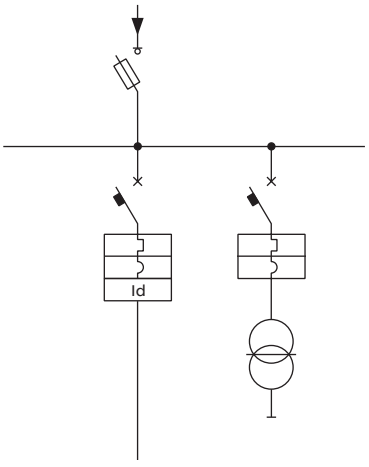


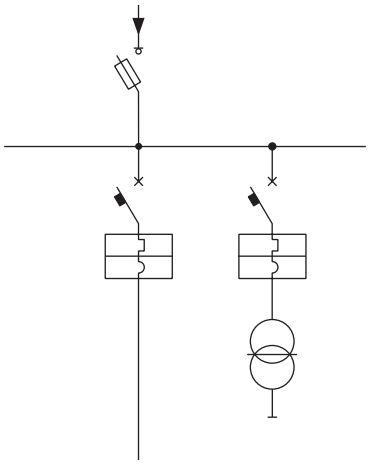
It is always advised to use an RCD on all non Medical IT circuits: RCDs in fact enable protection against fire risks and make it possible to contain a malfunction within the affected circuit, without causing more serious repercussions to the system upstream.

Protection of non Medical IT circuits by means of a Residual Current Device (RCD)

RCD use
- By using an RCD with Idn = 0.03 A additional protection against direct contacts is also guaranteed
- Protection against fire risks with Idn ≤ 0.5 A
- Isolation of the malfunction inside the circuit involved
- Selective coordination between RCDs

No RCD
- No untimely tripping
- Conformance to protection against indirect contacts is guaranteed, in TN systems, by thermomagnetic switches
- Essential configuration of the system
- Reduction of periodic checks
- Selectivity on indirect contacts to be implemented by means of thermomagnetic switches





5.3 Electromedical devices with applied parts

The following table lists the power consumption values of the main electromedical devices installed in operating rooms. As can be seen, the overall power required is close to 13 kW and this involves the use of at least two medical insulating transformers.

Power installed in a heart surgery operating room	
Defibrillator	320 W
Infusion pumps	50 W
Display	100 W
Xenon light source	1500 W
Electroscalpel monitor	1300 W
Local power source (monitoring)	2500 W
Blood heat exchanger	2400 W
Extracorporeal pumps	160 W
Air heating for patient - Thermacare	1400 W
N.3 scialytic lamps	450 W
Negativoscope	200 W
Total installed power	**10380 W**
N.B. Power consumptions to be considered with a simultaneous execution factor of 1, as specified by the standard	

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