

Electrical Safety – Ungrounded Power Supply Systems in Medical Sites

a report by

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Wolfgang Hofheinz serves on the National Committees of the German Commission for Electrical, Electronic & Information Technologies of the Deutsches Institut für Normung (DIN) and Association for Electrical, Electronic & Information Technologies (VDE). He has been with the Bender Company since 1975, becoming the company's Executive Vice-President in 1995. He has been an invited speaker at many national and international conventions and is the author of various publications and books on the subject of electrical safety. These include *Elektrische Sicherheit in Medizinisch Genutzten Räumen* (2001), *Protective Measures with Insulation Monitoring* (2000), *Schutztechnik mit Isolations-Überwachung* (2000) and *Fehlerstromüberwachung in Elektrischen Anlage* (1998). English translations are pending. He is the holder of two patents in the field of insulation monitoring of unearthed direct current systems: Swiss Patent no. 613313 (1979) and German Patent no. DE 2546997 C2 (1984). Mr Hofheinz studied electrical engineering at the University in Giessen, specialising in communications engineering and holds a Dipl.-Ing.

Introduction

Nowhere in daily life is there a more indispensable relationship between safety and life than in the medical profession. The multitude of accidents and subsequent personal and material damage demonstrate that safety cannot always be guaranteed by human intervention. This is especially the case in the hospital environment, where the application of electrical devices in diagnostic and therapy, for example, means exposure to increased electrical hazards, e.g. through faults in the current supply or defective devices.

Hazards in Medical Sites

The safety degree is influenced by many factors that can be categorised essentially into the following three hazard groups:

- hazards through faulty devices;
- hazards through faulty application; and
- hazards through procedural causes.

A risk always remains through unexpected or unavoidable faults but, with consequent safety responsibility, the risk can be reduced significantly.

Legislation has documented its responsibility for care and safety when installing and applying electrical devices and electrical installations through many regulations and standards. This means that the constitutional right of the patient in terms of physical and mental protection in medical locations is safeguarded.

The responsibility of the electronic industry in this area lies in the intricate knowledge of known and as-yet-unknown single fault conditions of the total electrical installation. The foremost aims of all safety measures taken should therefore be:

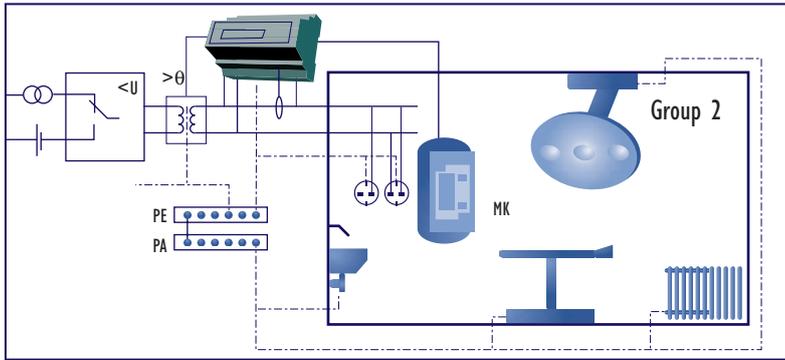
- simple but effective operation – to enable the medical staff, who often are electro-technically inexperienced, to simply and effectively deal with a single fault condition and, henceforth, prevent any additional workload; and
- clear and comprehensive documentation – to supply clearly structured information on the project and application of electrical installation in medical locations to designers, architects and operators, so that the occurrence of a single fault condition is prevented to the best of their technical know-how.
- abnormal or impaired responses of the patient and organs;
- body functions can be temporarily or permanently taken over by machines;
- fire and explosion hazards; and
- electric and magnetic interference.
- patient safety – to protect the patient from being unsettled, damaged or subjected to unreasonable and repeated therapy due to a single fault condition;
- reliability of power supply; and
- reduction of leakage currents.

The reliability of power and reduction of current leakage is also an essential safety aspect, which can be responsible for the following:

International Electrotechnical Commission Regulation 62A

In view of the application of a multitude of electro-technical equipment in use in the medical environment, measures must be taken to prevent electrical accidents. This was the driving idea for the International Electrotechnical Commission (IEC) Regulation 62A (IEC 62A), *Common Aspects of Electrical Equipment used in Medical Practice*, published as a draft in 1976 by IEC Technical Committee (TC) 62A. Besides numerous indications about general installation, this draft contained two essential arguments for the installation of ungrounded power supply systems (information technology (IT) systems) in hospitals:

Figure 1: Structure of an Ungrounded Power Supply System



- The ungrounded power supply has no direct connection between live conductors and earth
- In case of an insulation fault, only a very small capacitive current will flow
- A fuse is not triggered
- Power supply is maintained
- Insulation Monitoring Device (IMD) signals alarms

Both aspects are still valid today; however, the emphasis of the measures taken in this respect vary from country to country. The application and monitoring of ungrounded power supply systems in hospitals are reflected in the different national standards. The following are still valid basic statements according to IEC TC 62A.

- A patient may not be able to respond normally in a hazardous event. This may be due to illness, unconsciousness or anaesthesia or the patient may be connected to electrical apparatus for therapeutic reasons.
- The natural electrical resistance of the skin normally provides important protection against electrical current. With some treatments, this protection may be short-circuited, e.g. through the insertion of a catheter into the patient's body or by treating the skin when an electrode has to be placed on a patient's body. The human heart is more sensitive to electrical current than other parts of the body. Electrical current could inhibit natural heart activity and could lead to heart failure.
- Electro-medical equipment could be used to partly or permanently support or substitute vital bodily functions. A fault in the device or a power failure could be life-threatening.
- A mixture of flammable anaesthetics, disinfectant or cleaning substances with air or with oxygen and nitrous oxide may present fire/explosion hazards.
- Electrical and magnetic interference, e.g. from the power supply, could disturb the reproduction of action potentials, such as electrocardiogram or electroencephalogram equipment.

The use of an ungrounded power supply system may be desirable for the following reasons.

- It improves the reliability of power supply in areas where power failure may cause safety hazards for patient and user.
- It reduces the leakage currents of devices to a low value, thus reducing the touch voltage of the protective conductor through which the leakage current may flow.
- It reduces the leakage currents of devices to a low value, if approximately balanced to earth.

It is necessary to maintain the impedance of the system to earth as high as possible. This is achieved by restricting the following:

- the physical dimensions of the medical isolating transformer;
- the system supplied by this transformer;
- the number of medical electrical devices connected to the system; and
- through high internal impedance to earth of the insulation monitoring device (IMD) connected to such a circuit.

Structure

The operation of the ungrounded power supply system with isolation monitoring and alarm forms the centre of the power supply of Group 2 locations (see Figure 1). The base for the IT system is an insulating power source against ground. An isolating transformer is added, with a nominal power range set to 3.15 kilovolt-amperes (kVA) to 8kVA, e.g. according to the Deutsches Institut für Normung (DIN) standard VDE 0107: 1994-10. More set values are: maximal secondary voltage alternating current (AC) 230V, maximal inrush current under no load conditions $8xI_n$, short-circuit voltage u_o and no-load current $i_o \leq 3\%$.

The ungrounded power supply system also bears the following advantages:

- it has no direct connection between live conductors and earth;
- in the case of an insulation fault, only a small capacitive current will flow;
- a fuse is not triggered;
- the power supply is maintained; and

- IMD signals alarms.

The essential advantage of an IT system is already evident in the event of a single fault condition. Only a small current I_F flows, the value of which is determined through the system leakage capacitance C_E . This does not trigger a fuse, the supply voltage is maintained and the operation of the installation preserved.

Downtime safety is not the only argument for the use of a medical IT system. It also reduces the leakage currents of devices to a low value, if the medical IT system is approximately balanced to ground.

Monitoring

Increasing the availability of supply – a substantial aspect – is guaranteed with the IT system. When operating an IT system at single fault condition, attention has to be given to the fact that the original ungrounded (IT) system has turned into a grounded system. An additional fault could then lead to triggering the short-circuit protection thereby switching off the system. To prevent this occurrence, the insulation resistance is permanently monitored through an IMD. Internationally, the following three measuring principles have proved themselves here:

Figure 2: Monitoring of an Ungrounded Power Supply System with an IMD

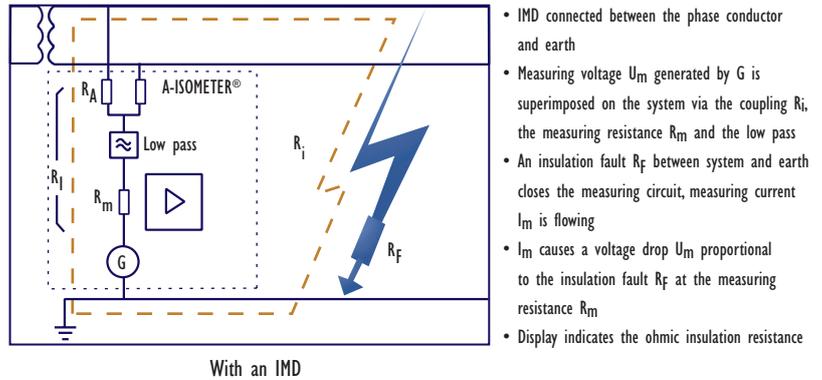
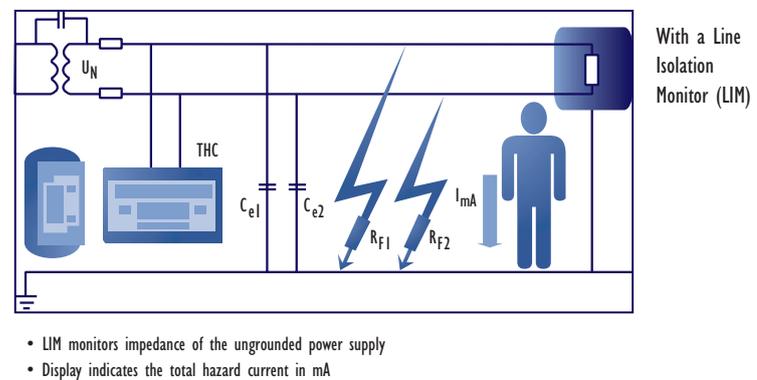


Figure 3: Monitoring of an Ungrounded Power Supply System (IT System)



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- resistance monitoring with an IMD;
- monitoring of impedance through a line isolation monitor (LIM); and
- monitoring of load and temperature.

Resistance Monitoring with an IMD

The task of the IMD is to monitor the insulation resistance between the active phase conductors and earth and to report a certain drop below a set value ($<50\text{k}\Omega$ ($\text{k}\Omega$). The IMD is connected between the active phase conductors and earth and superimposes a measuring voltage to the system. At the occurrence of an insulation fault, the circuit between the system and earth closes over the insulation fault R_F , so that a measuring current I_m occurs that is proportional to the insulation fault. This measuring current causes a voltage drop at the measuring resistor R_m , which is electronically evaluated. If the voltage drop exceeds a set value, which is equal to falling below a set insulation resistance, an alarm is triggered via light-emitting diode (LED) alarms and alarm contacts. The inherent system leakage C_E capacitance is only charged to measuring voltage and, after a short transient reaction, does not affect the measurement (see *Figure 2*).

The remote signalling and testing combination required for the visual and audible alarms in medical locations must be mounted in such a way that the signal can be noticed by the staff on duty.

Monitoring of Impedance Through an LIM

A device known as an LIM (an IMD to measure impedance) should always be included in an ungrounded power supply system. The LIM monitors the impedance of the conductors to earth. It is installed into an isolated power distribution system, as illustrated in *Figure 3*. It is designed in such a way that a green LED alarm, visible conspicuously to the staff in locations for medical use, lights up when the system has reached a sufficient impedance to earth. The red LED alarm lights up and sounds an audible warning signal as soon as the prospective fault current (consisting of resistive and capacitive leakage currents) of an ungrounded power supply system reaches the threshold of 5mA (2mA in Canada). Means are provided for resetting the audible warning signal while leaving the red alarm LED activated. A distinctive visual signal indicates that the audible alarm has been reset. When the fault is eliminated and the green LED alarm lights up again, the audible alarm is automatically reset.

Monitoring of Load and Temperature

To avoid overloading the isolating transformer, a respective installation must be designated in order to protect the transformer and supply conductors between primary and secondary terminals and the distribution bus from overloading or overheating. When the rated current or the temperature is over range, an acoustic or optical alarm is released.

Worldwide Development

The application of ungrounded power supply systems in hospitals began between 1920 and 1930 in the US. Alarming numbers of fires and explosions in operating theatres, in which flammable anaesthetics were used, shocked the experts. In 1939 the National Fire Protection Association (NFPA) began by developing regulations for the safe application of electro-technical equipment in hospitals. In 1944 the first regulation, *Safe Practice in Hospital Operating Rooms*, was published in the US.

Through the increasing application of electrical medical devices, the subject of micro-shock and non-stop operation became increasingly popular and became an integral part of the standards.

Safety Concepts

A safe device is not the decisive factor in guaranteeing sufficient electrical safety for patients, doctors and medical staff. The requirement is foremost for the optimal co-operation of the following:

- safety of devices;
- safety of the location; and
- safety of the application.

In other words, the highest degree of safety for the patient, doctors and their assistants is only achieved when a sufficiently safe constructed and maintained device is applied by a responsible operator in a medical location with installations according to the regulations.

Furthermore, when problems in hospitals in terms of technical safety are considered, the questions of protection from radiation and fire, safety of the environment, hygiene and electromagnetic tolerance can no longer be disregarded.

Safety Measures for Medical Electrical Devices According to IEC 60601-1

Regular testing of medical electrical devices is an essential aspect of the safety concept in hospitals. It is

embodied in European law and the request for testing is stipulated in the European Medical Products Act (MPG), the implementation of Regulation 93/94/EWG in June 1993.

Today, the international standard IEC 60601:1988 (European Standard EN 60601-1:1990) is used for periodic tests. According to this standard the following tests must be conducted:

- resistance of protective conductor;
- earth leakage current;
- enclosure leakage current;
- patient leakage current; and
- patient auxiliary current.

It is requested that all leakage currents are measured under the following 'normal' and 'single fault' conditions:

- Normal conditions:
 - normal and reverse polarity of the supply system;
 - operational earth is or is not connected to protective earth; and
 - applied part of type F is or is not connected to protective earth.

- Single fault conditions:
 - open circuit of the protective conductor (not valid for earth leakage current);
 - break of one of the line conductors; and
 - voltage $\leq 110\%$ of the highest nominal value of the nominal voltage is applied to each applied part of type F against earth.

IEC 60601 is a standard for type tests and production tests that is used also for periodic tests since a dedicated standard for periodic tests is not available in many countries. For this purpose, a draft European and IEC standard is currently being prepared.

Conclusion

The patient is the focus of attention in the hospital. Even the slightest power failure can impair a successful diagnosis and therapy and therefore be life-threatening to the patient. Therefore, the un-grounded power supply system with insulation monitoring is used, because it guarantees the comprehensive protection of patients, doctors and medical staff. ■

A version of this article containing additional information can be found in the Reference Section of the CD-ROM accompanying this business briefing.

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