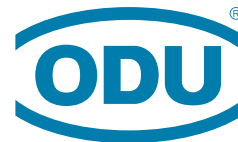


A PERFECT ALLIANCE.



ODU WHITE PAPER 11 | 2018

THE IEC 60601-1

Maximum patient and operator protection



ABSTRACT

The IEC 60601-1 states maximum requirements concerning the protection from electric shock for medical applications in which patients and operators can get into direct contact with electrical equipment and systems. In order to reduce risks to a minimum, manufacturers must integrate two means of protection in their products. For this purpose, they can either implement two separate measures or apply a single measure twice. Overall the specified protection level 2 MOPP (means of patient protection) or 2 MOOP (means of operator protection) must be obtained. In addition, manufacturers must introduce a management process in which they not only investigate all protection-relevant aspects, but also document the results in detail.

Due to these reasons the approval procedures for medical electrical equipment and systems have become recently even more complex than they already were prior to the effective release of the latest version of the IEC 60601-1.

In order to simplify the risk management process and to save time and costs during the implementation of the protective measures from electric shock, manufacturers should involve the suppliers of electronic components in the development process of their products from the start. At best those components would already be fully compliant with the IEC 60601-1. If the implemented components such as connectors fulfill 2 MOPP and 2 MOOP on their own, e.g. by means of mechanical measures, the costs of product development can be reduced to a minimum, and the necessary time for approval procedures can be substantially shortened.

This white paper shows – based on the example of the ODU plastic circular connector series ODU MEDI-SNAP® – how supplier know-how can contribute towards the development of IEC 60601-1-compliant electrical equipment and systems.

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INTRODUCTION

Keeping patients and operators safe is key for medical technology. Particularly this applies for medical electrical equipment and systems which are connected to the regular power supply network and may be in direct contact with patients, operators, etc.. Even minimal leakage currents can be life-threatening for weakened patients. But also the operators, who are generally the medical personnel, may not be put at risk through the unintentional transmission of electrical power.

Therefore, medical electrical equipment and systems used to diagnose, treat or monitor patients, such as electrocardiographs (ECGs), thermal cauteries and monitors, have always had to fulfil extremely high safety requirements. In the third edition of the international IEC 60601-1 standard, which has gradually been enforced since 2006, these requirements

have increased even further. In particular this was the case amongst other things concerning the protection from electric shock, the basic resistance against thermal and mechanical stress as well as the risk management.

The IEC 60601-1 obligates manufacturers of medical electrical equipment and systems to ensure that they are completely fail-safe in their use and work reliably at all times. This can be ensured either by themselves or in collaboration with their suppliers, whereby the latter are named in the new standard as being responsible amongst others for protection from electric shock. Potential suppliers include for example the providers of connectors, whose products represent central elements for the transmission of electrical power, data and signals.

OVERVIEW OF MEDICAL TECHNOLOGY

01 | MEDICAL TECHNOLOGY AND ITS REQUIREMENTS

Continuous performance, maximum reliability and intuitive handling are of essential importance in medical technology. Whether in doctor's practices, in mobile applications at home or in hospitals, reliable and robust components are a basic prerequisite at all times.

The trend to increasingly compact medical devices must also be considered in detail by manufacturers and their suppliers – which is why special attention needs to be paid to reductions in the size of medical equipment and inherent components. Further, interfaces specifically must be reliable for use at all times and may not permit any sources of malfunction. Potential influencing factors such as disinfectants, bacteria or spray water must already be taken into account during the design process and incorporated into the selection process for components and materials.

Ultimately, medical equipment must be self-explanatory and convenient in use for the medical personnel and patients. Another important focus is the topic of the general electric safety in medical devices. Particularly in applications located

in direct proximity to patients and operators, the approval authorities place maximum requirements on the electrical safety of medical products and the well-being of patients. This is regulated in the IEC 60601-1.



02 | AREAS OF APPLICATION IN MEDICAL TECHNOLOGY

Medical applications, more than any other area, require the highest degree of precision, dependability and user protection in each and every component. The health, correct diagnosis and sometimes even lives of patients are dependent on the proper function of medical equipment. Whether in the area of home care, ambulant treatment or diagnostics, each individual field poses specific requirements to be taken into account by medical equipment manufacturers.

One of these is the protection from electric shock as defined in the IEC 60601-1 in point of care application scenarios where medical devices are placed right next to a patient. According to the norm medical electrical equipment and systems must achieve the highest protection level whenever they are in contact or could be in contact by chance with the patient's body. This specific sub-area of medical technology is addressed in more detail below.

THE IEC 60601-1: A SPECIFIC SUB-AREA IN MEDICAL TECHNOLOGY



Today's high-performance medicine is strongly dependent on electrical equipment and systems. Because these are normally connected to the public electricity supply network, these products pose a latent risk for patients and operators. In these networks, power is transmitted at voltages ranging from 230 V to 250 V and a 50-Hz AC, which for example are capable of triggering cardiac irritations. In addition, lightning, for example, if striking into or next to a cable, can lead to dangerous temporary overvoltages of several thousand volts.

Therefore, electrical equipment and systems used in the medical sector must be particularly protected. This primarily

applies if they inevitably come into contact with patients, for example sonic heads on sonography devices, dental drills or electric blankets, but also when used in point of care applications. Point of care applications are characterized by a distance to the patient of less than 1.5 m.

In order to guarantee the highest possible level of protection for patients and operators, the IEC 60601-1 defines both general and technical requirements which have to be fulfilled by the manufacturers of medical electrical equipment and systems.

03 | GENERAL REQUIREMENTS

An important part of the general requirements concerning electrical medical equipment is the **basic safety**. Accordingly equipment must not have sharp edges, excessively thin or insufficiently resilient mechanical insulation, or loosely fastened cables which can easily be pulled out. Further aspects are resistance against chemical substances, high and low temperatures and electromagnetic radiation.

In addition, **equipment respectively application-specific performance characteristics** are defined which guarantee the reliable function of devices, e.g. for pumps from heart-lung machines, cooling devices for blood bags or timers on X-ray apparatus.

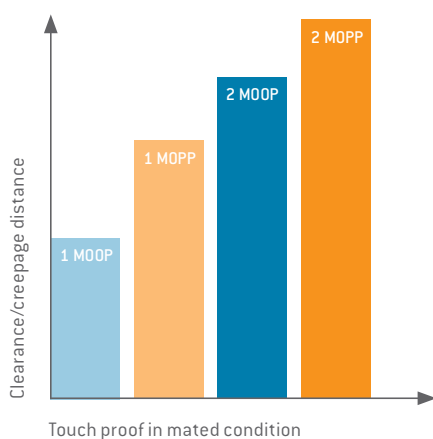
Moreover, manufacturers of electrical equipment and systems must establish a management process for the assessment of potential risks. Even so all safety-relevant aspects had to be investigated prior to this standard, until now the question on how manufacturers reached their results was left open. With the new version of the IEC 60601-1 they are also obligated to keep records every step of the way, resulting in substantially more complex approval procedures.

04 | TECHNICAL REQUIREMENTS

The technical requirements stated in the IEC 60601-1 relate almost exclusively to protection from electric shock. In order to reduce the risk as much as possible, the standard for medical electrical equipment and systems stipulates “Means of Protection” (MOP). These are subdivided into two categories:

- Means of Patient Protection (MOPP)
- Means of Operator Protection (MOOP)

Means of protection designate in general the precautions to be taken to protect people and animals from electric shock as a result of a dangerous voltage when touching a medical device.



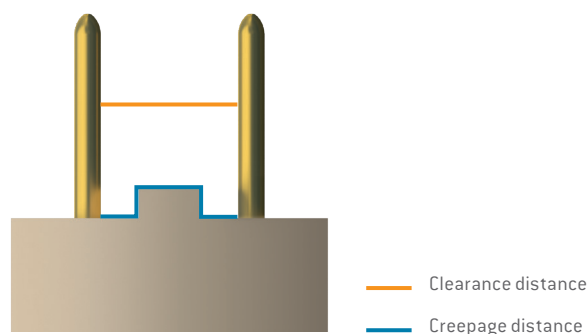
Essentially, the IEC 60601-1 requires that **two means of protection** for both patients and operators from electric shock must be applied in electrical medical equipment and systems (2 MOPP and/or 2 MOOP). In other words: if one means of protection fails, the other takes effect. An effective solution here for example is to double the clearance and creepage distances between conductors.

Because patients frequently have a weaker constitution than medical personnel, and may not be able to react – for example when under anaesthetic – they must be particularly well-protected. Therefore, the requirements placed on measures for patient protection are even more stringent than those placed on measures for operator protection. Accordingly higher clearance and creepage distances, a stronger insulation and reduced leakage currents are required in this case. As soon as electrical equipment or systems are touching the patient or are used in point of care applications, 2 MOPP need to be applied.

In case of applications in which the equipment or systems are not located in the patient’s environment, measures for the protection of medical personnel (2 MOOP) are sufficient. One example of these is operator terminals on X-ray apparatus, which are generally separated from the examination room by a door. In those cases, the operator is the focus for an optimal protection.

To guarantee the means of protection described, the clearance and creepage distances must be increased, as mentioned before. In the following section this topic is explained in detail, based on the example of a medical supplier component (connector). As soon as contacts are installed in the insulation body of a connector, clearance and creepage distances are generated between the conductive components.

- **Clearance distance:** The shortest distance between two contacts outside the solid insulation
- **Creepage distance:** The shortest distance between two contacts along the surface of an insulation body



A clearance distance collapses as soon as the voltage becomes too high for the distance between two contacts. If these clearance distances collapse due to an excessively high field strength, electric flash-arcs occur. Flash-arcs do not only damage individual components such as connectors, but also endanger the well-being of patients and operators and may cause for example burns, muscle paralysis, right up to cardiac arrest.

Creepage distances on the other hand tend to deteriorate gradually. Causes of this can be dirt and dust deposits on the insulation body or moisture which, for example, precipitates onto the insulation body due to significant changes in temperature. This results in the flow of leakage currents on the surface of the insulation body caused by a partial or complete loss of its insulating function. These may cause an electric shock for patients and operators with similar effects mentioned already above.

As clearance and creepage distances cannot be avoided, the aim is to design the distances between the connector contacts in such a way so that they can master the respective voltages. For a Schuko plug, this is unproblematic, as the two contact pins are set approximately 15 mm apart from each other.

In consequence there are hardly any challenges in the transmission of 230 V for this connector. On the other hand, if the same voltage is to be transmitted using a circular connector, on which the pins are set only 1 mm apart, it becomes substantially harder and therefore represents a major challenge for manufacturers of these components.

The following graphic clearly shows the relation of clearance and creepage distances and the resulting means of protection.

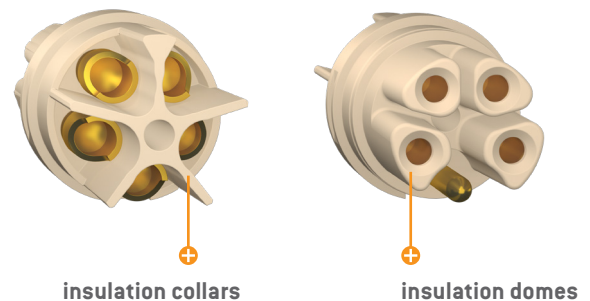
Classification	Insulation	Creepage/ clearance distance	Creepage distance extension
1 MOOP ¹	1,500 V AC	2.5 mm / 2.0 mm	Basic
2 MOOP ¹	3,000 V AC	5.0 mm / 4.0 mm	Double
1 MOPP	1,500 V AC	4.0 mm / 2.5 mm	Basic
2 MOPP	4,000 V AC	8.0 mm / 5.0 mm	Double

Working voltage up to 250 V eff / Mains voltage up to 300 V AC / Overvoltage category II
¹Pollution degree 2

Which possibilities exist to increase clearance and creepage distances and thus to achieve 2 MOPP and 2 MOOP?

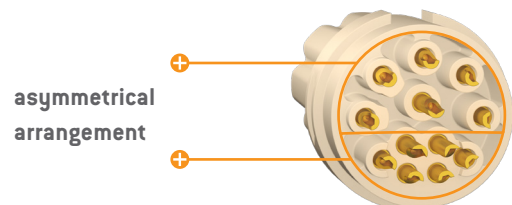
+ Insulating domes & collars

A first option is to extend the distances by integrating labyrinthine geometries into the shape of the insulation body. For this purpose, domes made from plastic are added to the insulating body of the male connector which allows for a partial enclosure of the contact pins. On the other hand side for female connectors insulating collars can be formed around the socket contacts within the insulating body which matching the before mentioned domes. In this way, the contacts are no longer connected in a straight line with each other when mated, and higher clearance and creepage distances are reached in order to achieve maximum patient and operator protection.



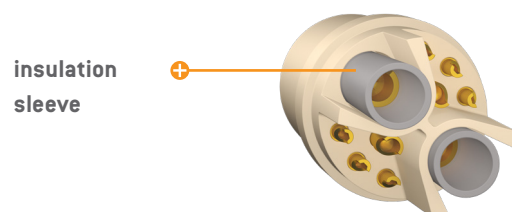
+ Asymmetrical arrangement

In addition to the use of domes and insulating collars, it is possible to arrange the contact pins asymmetrically. In the example shown a multi-position connector enables the transmission of higher voltages with six high-voltage contacts, which are placed further from each other than the other six signal transmission contacts. Accordingly the contacts intended for the high-voltage transmission are separated by a 3 mm distance and have an appropriately higher clearance and creepage distance than the ones used for signal transmission which are set apart only 1 mm.



+ Insulating sleeves

A third option is posed by additional insulating sleeves. These can either be pushed over one or more contacts on the connecting side of a circular connector. Depending on the installers preference this is possible either before or after soldering. In a similar manner to the labyrinthine arrangement, these sleeves extend the distances between the contacts and thus improve the electric insulation.



Apart from the above mentioned measures which enable a 2 MOOP or 2 MOOP level on the connector itself, it is also possible to implement two of the means of protection stated in the IEC 60601-1 into several separate components within the electrical medical equipment. This is the case if it is not possible to reach 2 MOPP or 2 MOOP in just one component. In this way, it is permitted for example to integrate one

means of protection into the power supply whilst the second is implemented within the connector. This has to be verified by manufacturers in the approval procedure. Therefore, it is even more important than before that manufacturers and suppliers collaborate closely during the development of new medical electrical equipment and systems.

05 | IEC 60601-1 COMPLIANT AREAS OF APPLICATION



In the following section, some applications are presented which are subject to maintenance of the IEC 60601-1. This is the case in specific application examples in point of care use and use close to operators of the medical equipment when regular power network voltages are applied.

1. In operating rooms

These applications include, for example, electric blankets which are used during preparation for surgery, so that the patients in their surgery gowns do not get cold or suffer from hypothermia. The required temperature is precisely adjusted on a control device and then constantly monitored via connected sensors. Like the voltage for the electric heating coil on the blankets, the signals from these measuring probes can also be transmitted via plastic circular connectors. It is thus possible for the patient and the operator to get in direct contact with the connector, which is why the medical device must comply with the IEC 60601-1.

Further the connectors can also be employed as an interface to control panels for raising or lowering operating room tables or for charging batteries installed in the operating room tables.

2. In surgery

Circular connectors are used in ultrasonic applications for minimally-invasive surgical procedures, in order to supply the instruments with operating voltages between 100 V and 500 V and to transmit control signals from and to the hand

unit. Sawing with high-frequency micro vibrations facilitates exceptionally accurate cuts and ensures an almost blood-free operation area through the so-called cavitation effect. Broken bones can be “welded” together using special ultrasonic devices and thus heal even without screws. The high voltages applied make it all the more important that the connectors fulfil 2 MOPP and 2 MOOP.

Dental medical devices, used for screwing implant bodies into the jaw, also place special requirements on the technology of interfaces. This is due to the “last twist”. Prior to reaching the final position a particularly great force and therefore a lot of power is required for a brief period. Accordingly connectors have to be designed to withstand the resulting power peaks.

3. In intensive care

For vital applications such as ventilation equipment, reliable connection of interfaces are a must have. Otherwise, the slightest touch of the device could cause malfunctions with life threatening effect. To prevent this from happening, it is an option to employ shortened signal contacts which allow the recognition of the mating status.

Only after these so-called lagging contacts have signaled to the control device that the connection is properly mated the life-supporting functions are initiated. In particular in the field of intensive care, in which medical equipment is frequently used at the point of care and close to operators, maintenance of the two means of protection is particularly vital.

4. In home care

Home care is playing an increasingly important role in the field of medicine. In this way, people having to live with disabilities can be cared for at home as much as possible. For this reason, medical electrical equipment is not only found today in hospitals and doctor's practices, but also at home. There it is even more important that the products can be easily handled excluding any potential misuse without pages of operating instructions first having to be comprehended. Connectors can contribute to this as well, for example when the batteries of an electric wheelchair are connected to the power grid in order to recharge them. It must be possible

to use the connector applied here intuitively and also to offer sufficient protection from electric shock. Especially as during the charging process, currents of several Ampere may well flow at the conventional voltages of 230 to 250 V. Whenever medical applications are directly connected to the power grid 2 MOPP and 2 MOOP must be fulfilled.

This represents only a small selection of applications relevant for the IEC 60601-1 many more are feasible.

CHALLENGES IN THE IMPLEMENTATION OF THE IEC 60601-1

06 | INSTALLATION SPACE VS. CLEARANCE AND CREEPAGE DISTANCES

If we compare the general medical requirements with the specific requirements laid down in the IEC 60601-1, it becomes clear that conflicts can result here.

The challenge is clearly apparent when based on the example of a connector. Manufacturers of medical products are constantly demanding that medical equipment is decreased in size, and as a consequence the related connectors also have to become more compact. The necessary increase in the clearance and creepage distances – due to the requirements stated in the IEC 60601-1 – mean that connectors face the challenge of implementing high power transmission on space-saving products.

In general, the following applies: $P = U \cdot I$

In the case of medical applications which require high power transmission, the following situations may thus occur:

1. $U \uparrow$
2. $I \uparrow$
3. U as well as $I \uparrow$

If the voltage is increased, it influences the touch protection of the medical equipment, which in turn means that specific counter measures have to be put in place by the manufacturers. In specific application cases, the clearance and creepage

distances of the connectors must for example be increased, which in turn has a direct influence on the required construction space. This is the case for example if additional domes have to be added or the clearance distances between electrical conductors have to be extended. This example clearly shows that manufacturers of medical products repeatedly face the challenge of optimal use of the construction space on the one hand side and the fulfilment of the necessary means of protection stated in the IEC 60601-1 on the other hand side.

With regard to the current, the contact diameter of the connector plays an important role. If the current is increased, the diameter of the contacts must also be increased in order for example to counteract the resulting heat development. This in turn means that the construction size of the connector must be adjusted appropriately, at the expense of the existing construction space.

This has no influence on the IEC 60601-1 as long as the voltages are not increased respectively the clearance and creepage distances within the connector do not change.

SOLUTION APPROACHES FOR THE IMPLEMENTATION OF THE IEC 60601-1 BASED ON ODU CIRCULAR CONNECTORS

07 | ODU CIRCULAR CONNECTORS IN GENERAL

The following passages describe how ODU circular connectors contribute to the compliance with the IEC 60601-1 and which technical requirements mentioned in the white paper can be met.

Circular connectors can be used in electrical equipment and systems for the medical sector in order to transmit power, signals and data as well as liquid and gaseous fluids. In contrast to permanent connections, connectors can be disconnected again, whereby they provide a higher level of flexibility, for example if equipment with different application parts has to be used during surgery. Circular connectors with

a plastic, and not a metal housing, are not only lightweight and economically-viable, but also completely insulated. This means that neither patients nor operators can receive an electric shock by getting in contact with the housing – unless a malfunction occurs. In order for patients and operators to be completely protected in case of malfunctions, the requirements stated in the IEC 60601-1 are drawn upon and the plastic connectors designed accordingly. ODU offers a diverse portfolio of solution possibilities with plastic housings in order to fulfil the specific requirements stated in the IEC 60601-1, which are described in more detail below.

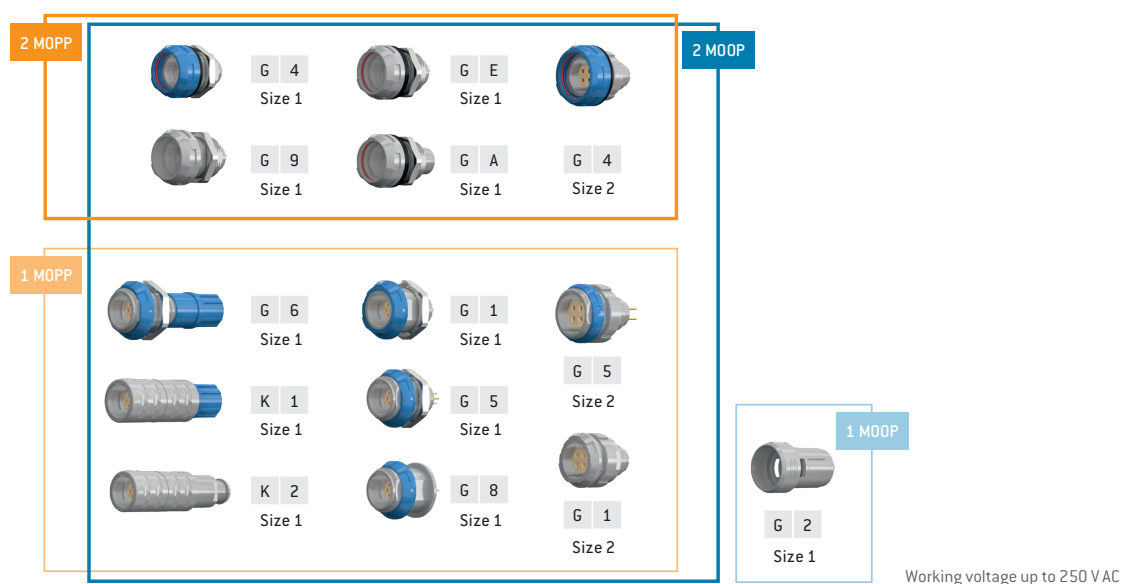
08 | IEC 60601-1 COMPLIANT ODU MEDI-SNAP® RECEPTACLES ACCORDING TO PROTECTION FROM ELECTRICAL SHOCK

The plastic circular connector portfolio of the ODU MEDI-SNAP® series includes over ten different receptacles which can be installed in the medical equipment and systems.

Due to reinforcements in the mating area, five of these receptacles already fulfil the requirements in mated condition for the highest level of patient and operator protection of 2 MOPP and 2 MOOP in accordance with the IEC 60601-1. These receptacles achieve 2 MOOP in ambience with pollution degree 3.

The other eight receptacles and in-line receptacles provide one means of protection for patients (1 MOPP) and further achieve 2 MOOP in ambience with pollution degree 2.

If receptacles and in-line receptacles with only one means of protection are used in equipment and systems, for example together with power supplies which themselves have a means of protection installed in them, the medical end device then achieves as a whole 2 MOPP and 2 MOOP.

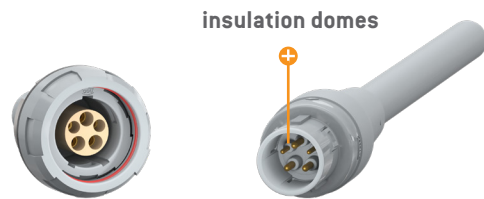


09 | IEC 60601-1 COMPLIANT PIN LAYOUTS ACCORDING TO PROTECTION FROM ELECTRICAL SHOCK

Receptacle interfaces are decisive for the end device manufacturer when developing a new product. For further connections the ODU MEDI-SNAP® series also includes specialized connectors with modified insulation body designs which are capable to achieve 2 MOPP and 2 MOOP as a stand-alone version independent of the receptacle design.

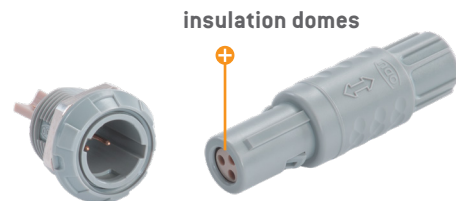
+ 5-pin connector

Applications compliant with IEC 60601-1 can be provided with an overmolded ODU MEDI-SNAP® system solution as a 5-pin Break-Away connector or overmolded cordset, into which two means of protection are already integrated in the pin layout. Through the use of additional domes and insulating collars, the level of protection 2 MOPP and 2 MOOP is achieved independent of the respective receptacle.



+ 3-pin connector

The ODU MEDI-SNAP® portfolio also contains a 3-pin Push-Pull connector in which the insulation body has also been modified in order to fulfil the highest requirements of 2 MOPP and 2 MOOP.



Next to the standard portfolio, customer-specific solutions by ODU always offer the possibility to use additional adaptations such as insulating collars, an asymmetrical layout of the contacts, insulating sleeves and much more. Every piece of medical equipment is individual and therefore requires specific measures in order to guarantee the maximum possible protection for patients and operators from electric shock in accordance with the IEC 60601-1.

How manufacturers and suppliers are able to meet the challenges inherent in this standard has been shown in this white paper based on plastic connectors by the company ODU.



AUTHOR

Alexandra Fuchshuber is Product Manager of the plastic connector series ODU MEDI-SNAP®. In her role she is responsible for the new product development for market-driven and future-oriented solutions. The medical sector is particular focus of her market research next to the areas Industrial and Test & Measurement. While talking to many customers in the medical sector Alexandra has found out that the patient and operator protection from electrical shock is key in all medical applications specifically described in the norm IEC 60601-1.

Alexandra Fuchshuber graduated as Bachelor of Business and Administration Engineering from Landshut University of Applied Sciences and has held various positions in Product Management for the ODU GmbH und Co. KG prior to taking on the role as Product Manager.

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