Medical Electrical Equipment for Home Healthcare

EN 60601-1-11

A Basic Summary
July 2023

drive | DeVilbiss HEALTHCARE

Medical Electrical Equipment for Home Healthcare

Introduction

Use of healthcare equipment in the home presents many more risks compared to a professional environment. Factors such as the presence of children and pets which may interfere with the device, and temperature, ventilation, dust and more must be considered. In a clinical environment these risks are tightly controlled, whereas in the home setting they have the potential to impact patient safety and must be addressed.

The IEC 60601 series of international standards specify requirements for basic safety and essential performance applicable to a specific characteristic of all electrical medical equipment. IEC 60601-1-11 is an international standard that specifies the basic safety and essential performance requirements for electrical medical equipment and systems intended for use in the home environment. The additional requirements address the uncontrolled electrical installations of the home environment, the lack of formal training of the lay operator, and their level of education. In short, the home healthcare environment requires that extra safety, communication and operational precautions are put in place, to prevent harm from occurring to patients, bystanders and property.

The current state-of-the-art standard is EN 60601-1-11:2015/A1:2021. This means if your device is used within the home healthcare environment, your product may use EN 60601-11:2015/A1:2021 to show compliance with the EU Medical Device Regulation (MDR).

What is a Home Healthcare environment?

A home healthcare facility is a place in which the patient(s) lives or is present, and where operators with medical training are not continually available. In Europe this also includes nursing homes as these are considered home healthcare environment. Home healthcare equipment must consider factors like patient activity (indoor or possibly outdoor use), children and pets, electrical installations, frequent transport or storage between uses.

The Essential Performance of the Device

Essential Performance (EP) refers to the performance of a clinical function where loss or degradation beyond the limits specified by the manufacturer results in an unacceptable risk. The IEC 60601 standard also notes, “essential performance is most easily understood by considering whether its absence or degradation would result in an unacceptable risk.” Whilst most of the standard remains technical in nature, it is also risk-based, focusing on what the chances are of failure in a particular situation, and determining the hazard potential of that error. For example, the probability of an oxygen generator being knocked by a visitor may be higher than the chance of its alarm system failing, but the risk formula needs to account for the much greater consequences associated with the failed alarm and resultant decreased oxygen level – i.e., failure probability compared to hazardous consequences. The manufacturer must establish these risk scenarios and assessments and document them in the risk management file. For example, the risk of electrical shock must be applicable to both the patient and the operator.

Testing Category Considerations

Due to the uncertainty of how medical equipment will be operated in a home environment, additional requirements not applicable in a professional healthcare environment need to be considered. Clauses 4, 5 and 6 of EN 60601-1-11 describe how testing parameters vary according to different applications and conditions. **Some of these include testing against specifications for:**

- Minimum transport, storage and operational environmental conditions are specified (rather than left to the manufacturer), to allow the device to be transported in the boot of a car or stored in an outbuilding. Portable devices may be used outside.
- Electrical supply is not as reliable in houses. It is known to have higher fluctuations and unreliable protective earthing.
- Presence of children and pets require the device to be more protected. Another significant requirement is that for connection to a power source, there can be no protective earth connection except for equipment that has been permanently installed by an electrician, and equipment must be Class II (double insulated to further prevent electric shock) or internally powered.

Additional IP Classification Requirements

Ingress Protection (IP) ratings are required for electrical products that are body worn, hand-held, mobile, or portable. The IPXX rating considers both protection from solid foreign objects and water. This takes into consideration that the product can be used outdoors in a rain storm. The products enclosure should provide the minimum ingression protection, but if the carrying case provides protection against ingress of liquids, it should be marked as such. The enclosure is then marked, “Keep Dry,” or carries the umbrella-in-rain icon.

- An IP22 (Transit-operable, Hand-held and Body worn devices) rating means the product is protected from 12.5mm or greater foreign objects and vertical drip with the product tilted 15°.
- An IP21 (all other devices) rating meets the product is protected from 12.5mm or greater foreign objects and vertical drip.

Usability and Instructions for Use (IFU) – Simple and Comprehensive

EN 60601-1-11 is highly focused on the uninitiated user’s ability to understand and operate the equipment properly. The standard stresses that equipment in the home healthcare environment should be designed for simplicity and ease of use. Reference documents should be simplified and readily understood by both lay and professional operators. They should include diagrams, illustrations or photographs that clearly demonstrate the controls and procedures.

Instructions for use should be composed so that a lay operator with eight years’ maximum education can read, comprehend and master the product accordingly. These issues are described in Clause 7. Simplicity of content aside, EN 60601-1-11 also mandates numerous areas that must be included in the instructions, such as setting up, operating, maintaining and contacting the manufacturer for assistance. Instructions must also include any contraindications to the equipment and precautions to take regarding changes in performance, exposure to foreseeable environmental conditions, information on medicinal substances, measuring functional accuracies etc.

drive | DeVilbiss HEALTHCARE

The IFUs are required to contain warnings describing the nature of each possible hazard, its potential consequences, and the precautions for reducing risk (including unsafe practices). Warnings should also address any potential strangulation hazards, allergic reactions and contact injuries. The Clause 7 series of mandates is very specific on each of the above areas. **It also goes into detail on the operation of the equipment and covers areas such as:**

- How quickly the equipment is operable after being turned on
- Effects of lint, dust, light or devices that could cause interference or parts degradation
- The presence of pets and children
- IP ratings and explanations
- Troubleshooting
- Cleaning and storage
- Multiple patient usage
- Equipment service life
- Parts disposal
- Alarm placement
- Protective earth conductor
- Hygienic maintenance for reuse

In short, EN 60601-1-11 places a great emphasis on safe and effective use by professional operators and lay operators alike. Its intention is to protect both the patient and the operator, and to ensure safe, fault-proof operation while providing backup troubleshooting and emergency procedures. The equipment, operational processes and communication must meet these standards both in comprehensiveness and simplicity.

Power Supply, Interruption and Interference

Another aspect of the Essential Performance criteria for EN 60601-1-11 requires measures and capabilities in life-supporting equipment to provide a safety backup should the power supply be interrupted. In a power outage, life-supporting equipment should remain operable for a sufficient time or number of operations to deploy alternate methods. This can be through an automatic activation of an internal electrical power source, or through independent means. The instructions for use must disclose the time allotment and/or provide procedures for life-support during a power outage. A specified alarm system also needs to be in place, audible throughout the facility and with identifiable warning indications. If a shutdown is imminent, an operator should not have to proactively discover the threat and know what action to take. Likewise, internal power sources must warn of possible operation stoppages by indicating the remaining operating time, number of remaining procedures, available fuel, and the like. If wireless communication can impair operations, it must be stated in the instructions for use.

Other Testing and Safety Areas

EN 60601-1-11 prescribes several mechanical tests including drops, vibration, moulding stress relief, shocks and more. These are applied to everything from large stationary systems to small portable mobile devices. Provisions also must be included in the Usability Engineering Process and File for the accuracy of the controls and instruments, and for the protection against hazardous outputs. This needs to account for changes in controls, improper operation, exposure to biological materials and more.

Medical electric enclosures must prevent ingress of water or particulates. Wiring, tubing etc. must provide prevention from the risk of strangulation or asphyxiation by patients and children. Access to critical controls must be limited to authorized personnel through passwords, unique tools, fingerprint recognition and the like.

How to ensure your medical equipment is suitable for homecare use.

The simplest way is to choose equipment which has been tested and verified to the EN 60601-1-11 standards. Suppliers of equipment should be able to provide you with a confirmation certificate from a certified test organisation to verify compliance.

The fact that a medical device carries the CE mark or UKCA mark does not mean that the device has been specifically tested to verify its safety for home healthcare use. The EN 60601-1-11 standard is not required for medical devices designed for professional use in healthcare environments, such as hospitals, and many devices on the market have only been certified for this environment.