

University of Washington Medical Center (UWMC)

Electrical Device Purchasing Specification

Patient Care Equipment

Introduction

These specifications are to insure conformity with established standards for the safety of patients, staff and other persons; and to facilitate installation and use of the device.

It has been determined that the equipment being purchased on this agreement fits the definition of Patient Care Equipment (or Medical Electrical Equipment).

Purpose

The purpose of this specification is to define the expectations that UWMC has for Patient Contact Equipment that we purchase. We base these expectations on the current revisions of "Standard for Health Care Facilities" NFPA 99, the American National Standard "Safe Current Limits for Electromedical Apparatus" ES-1 and Underwriters Laboratories' Standard for Safety, "Medical Electrical Equipment" UL60601-1.

Definition

Patient Care Equipment is defined as powered equipment intended for use in treatment, diagnosis, monitoring, life sustaining or resuscitating functions. Examples of this equipment are defibrillators, patient monitors, infusion devices, patient imaging equipment, diagnostic laboratory equipment, beds, etc. Examples of items that are NOT considered patient care equipment are cart washers, radios, addressographs, etc.

Patient Contact Equipment (Medical Electrical Equipment) is a subset of Patient Care Equipment that requires the most stringent safety requirements. It is defined in Underwriters Laboratories' Standard for Safety UL60601-1 as: "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 as defined by the manufacturer which are necessary to enable the normal use of the equipment.

Agreement

Unless the vendor takes written exception to any of the terms contained herein, vendor will be in agreement with each of these provisions. No modifications to these specifications will be made without the approval of the ordering department and UWMC Clinical Engineering department.

Physical Inspection

The University of Washington Medical Center (UWMC) reserves the right to inspect the equipment for compliance with these specifications and for manufacturing defects prior to approval for payment. If the vendor takes exception to an inspection of the equipment by UWMC, then UWMC shall witness an inspection of the equipment by the vendor.

Registration and Listing

Food and Drug Administration Registration

If the equipment meets the definitions of "medical devices" under Public Law 94-295 "Medical Device Amendments of 1976," it shall be registered with the FDA and meet all applicable standards promulgated by the FDA.

Listing by a Nationally Recognized Testing Laboratory (recognized by OSHA)

All line powered equipment will meet the applicable standards of a nationally recognized testing laboratory (NRTL) and shall be so labeled. Some examples of NRTL's are Underwriters Laboratories (UL), Canadian Standards Association (CSA), and ETL Testing Laboratories (ETL). This requirement

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does not apply to portable patient care equipment when no functionally equivalent and clinically acceptable NRTL listed device is available for purchase.

Fixed equipment that is not listed by a nationally recognized testing laboratory must be field inspected by one of the above testing laboratories for compliance with applicable standards at the vendor's expense. The University of Washington will not accept the equipment for its use or begin the warranty period until this inspection is completed.

Documentation

Operator's Manuals

At least one copy of the operator's manual will be included for each piece of equipment purchased unless otherwise negotiated with the ordering department. Topics covered will include:

- Equipment identification
- Equipment specifications
- Warranty period
- Unpacking and setup
- Controls and connections
- Safety precautions
- Equipment operating procedures
- User maintenance
- Cleaning and Sterilizing
- Operator level troubleshooting

Technical/Service Manuals

At least one copy of the appropriate service manual will be included as part of each purchase, (not one for each item purchased), unless otherwise negotiated with the appropriate maintenance authority within UWMC. Topics covered will include:

- Equipment identification
- Equipment specifications
- Warranty period
- Theory of operation
- Recommended maintenance schedule
- Recommended maintenance procedures
- Recommended test equipment
- Recommended spare parts
- Troubleshooting guide
- Schematic diagrams
- Parts identification

Design Considerations

This equipment is expected to meet the mechanical and electrical safety requirements described in the "Standard for Health Care Facilities", NFPA 99, the American National Standard "Safe Current Limits for Electromedical Apparatus", ES-1 and where applicable, "Standard for Safety, Medical Electrical Equipment" UL60601-1. Some areas that will be inspected are mechanical stability, primary power cord and interface, Over current interrupter, grounding, and risk leakage current.

NOTE: For the purpose of this specification, Underwriters Laboratories' Standard for Safety "Medical Electrical Equipment" UL60601-1 will be considered equivalent to the International Electrotechnical Commission's standard "Medical Electrical Equipment" IEC60601-1