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Medical supply units (ISO/DIS 11197:2002,IDT)

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Normcommissie 301 006 "Anesthesie- en beademingssystemen"

NEN

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Postbus 5059, 2600 GB Delft
Telefoon (015) 2 690 390, Fax (015) 2 690 190

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EUROPEAN STANDARD

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April 2002

ICS

English version

Medical supply units (ISO/DIS 11197:2002)

Gaines techniques à usage médical (ISO/DIS 11197:2002)

This draft European Standard is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 215.

If this draft becomes a European Standard, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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Contents

Foreword

This document (prEN ISO 11197) has been prepared by Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment", the secretariat of which is held by BSI, in collaboration with Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment".

This document is currently submitted to the parallel Enquiry.

This document will supersede EN 793:1997.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative annex ZA, which is an integral part of this document.

For special national conditions for clauses 6.1 bb), 6.2 aa) and 57.1 see annex AA.

For a list of International Standards identical to the European Standards referred to in this European Standard, see informative annex ZB.

Annex AA is a normative part, and annexes BB, ZA and ZB are informative parts, of this standard.

Introduction

This Particular Standard applies in conjunction with EN 60601-1: 1990 "Medical electrical equipment — Part 1: General requirements for safety".

As stated in EN 60601-1:1990 the requirements of this Particular Standard take priority over those of EN 60601-1:1990.

As in EN 60601-1:1990 the requirements are followed by the relevant tests. The structure of this Particular Standard corresponds to that of EN 60601-1:1990 and the sections, clauses and sub-clauses refer to those of EN 60601-1:1990.

Clauses, subclauses, tables and figures additional to those in EN 60601-1:1990 are numbered beginning at "101". Additional annexes are lettered beginning at "AA" except for annexes "ZA" and "ZB".

Additional items in lettered lists are lettered beginning "aa)".

Rationales for some of the requirements of this standard are given in annex BB. Such requirements are indicated by the letter "R" after the clause number.

In any health care facility it is strongly recommended that terminal units of only one type (i.e. with the same set of dimensions for each systems) are used for medical gas systems, anaesthetic gas scavenging systems and liquid systems.

SECTION ONE - GENERAL

1 Scope

Clause 1 of EN 60601-1:1990 applies with the following addition:

This standard applies to medical supply units as defined in 3.4.

This Particular Standard applies in conjunction with EN 60601-1:1990

The requirements of this Particular Standard take priority over those of EN 60601-1:1990.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

Appendix L of EN 60601-1:1990 applies with the following additions:

EN 737-1, Medical gas pipeline systems — Part 1: Terminal units for compressed medical gases and vacuum.

EN 737-2, Medical gas pipeline systems — Part 2: Anaesthetic gas scavenging disposal systems.

EN 737-3, Medical gas pipeline systems — Part 3: Pipelines for compressed medical gases and vacuum.

EN 737-4, Medical gas pipeline systems — Part 4: Terminal units for anaesthetic gas scavenging systems.

EN 739:1998, Low-pressure hose assemblies for use with medical gases.

EN 1441, Medical devices — Risk analysis.

EN ISO 3744, Acoustics — Determination of sound power levels of noise sources using sound pressure - Engineering method in an essential freefield conditions over a reflecting plane (ISO 3744:1994).

IEC 60598-1, Luminaires — Part 1: General requirements and tests.

EN 60601-1:1990, Medical electrical equipment — Part 1: General requirements for safety.

EN 60601-1-2, Medical electrical equipment, Part 1: General requirements for safety — Electromagnetic compatibility — Requirements and tests.

IEC 60669-1, Switches for household and similar fixed electrical installations — Part 1: General requirements.

IEC 60079-4, Electrical apparatus for explosive gas atmospheres — Part 4: Method of test for ignition temperature.

EN 60529, Degrees of protection provided by enclosures.

EN 50086-1, Conduit systems for electrical installations — Part 1: General requirements.

3 Terminology and definitions

Clause 2 of EN 60601-1:1990 applies with the following additions:

3.1
equipment
single self-contained unit or combination of units provided with one or more permanently fixed connections to the building services, e.g. electricity, medical gas(es), liquid(s) or anaesthetic gas scavenging systems

3.2
junction point
connection point between the medical supply unit and the fixed building services

3.3
medical gas
any gas or mixture of gases intended to be administered to patients for therapeutic, diagnostic or prophylactic purposes, or for surgical tool applications

3.4
medical supply unit
permanently installed equipment intended to supply electric power and/or medical gases and/or liquids in medical areas such as general wards and special purpose areas, e.g. operating theatres, induction rooms, recovery wards, intensive care or therapy units and other intermediate care areas

NOTE Medical supply units can include medical electrical equipment or systems or parts of such equipment or systems which might be applied to diagnosis, therapeutics and communications.

Medical supply units can consist of modular sections for electrical supply, lighting for therapy or illumination, communication, supply of medical gases and liquids, anaesthetic gas scavenging systems.

Typical examples of medical supply units are known as bedhead services modules, ceiling pendants, beams, booms, columns and pillars. Examples of configurations are given in Figures 101, 102 and 103.

3.5
compartment
part of an enclosure with openings necessary for interconnection, control or ventilation (IEV 441-13-05)

3.6
enclosure
surrounding case constructed to provide a degree of protection to personnel against accidental contact with live parts and also the equipment enclosed against specified environmental conditions (IEC 61950:1997).

NOTE An enclosure can be subdivided into compartments.

4 General requirements and requirements for tests

4.1 Modifications to clause 3 of EN 60601-1:1990

Clause 3 of EN 60601-1:1990 applies with the following addition:

3.6 Add the following items:

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