

Particular requirements for safety of medical supply units

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British Standard

ICS 11.040.01

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National foreword

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The UK participation in its preparation was entrusted by Technical Committee CH/44, Anaesthetic machines, breathing attachments, medical gas pipeline systems and hose assemblies, to Subcommittee CH/44/2, Medical gas supply systems, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 22, an inside back cover and a back cover.

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English version

Particular requirements for safety of medical supply units

Prescriptions particulières relatives à la sécurité des
gaines techniques à usage médical

Besondere Anforderungen für die Sicherheit von
medizinischen Versorgungseinheiten

This European Standard was approved by CEN on 30 October 1997.

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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Foreword

This European Standard has been prepared by Technical Committee CEN/TC 215, Anaesthetics and respiratory equipment, the secretariat of which is held by BSI.

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

This European Standard 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 Directives, see informative annex ZA which is an integral part of this standard.

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

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 1998, and conflicting national standards shall be withdrawn at the latest by May 1998.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

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Introduction

This Particular Standard amends 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 subclauses 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 annex "ZA".

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

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

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.

1.3 Particular Standards

This Particular Standard amends 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 amendment to or revisions of any of these 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*

prEN 737-2, *Medical gas pipeline systems — Part 2: Anaesthetic gas scavenging disposal systems — Basic requirements*

prEN 737-3, *Medical gas pipeline systems — Part 3: Pipelines for compressed medical gases and vacuum — Basic requirements*

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 essentially freefield condition over a reflecting plane* (ISO 3744:1994)

EN 60598-1, *Luminaires — Part 1: General requirements and tests* (IEC 598-1:1992, modified)

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*

EN 60669-1, *Switches for household and similar fixed electrical installations — Part 1: General requirements* (IEC 669-1:1993, modified)

IEC 79-4, *Electrical apparatus for explosive gas atmospheres — Part 4: Method of test for ignition temperature*

IEC 884-1, *Plugs and socket-outlets for household and similar purposes — General requirements*

3 Terms 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

prefabricated permanently installed equipment of Class I, Type B for application in medical areas such as general wards and special purpose areas, e.g. operating theatres, induction rooms, recovery wards, intensive care of therapy units and other intermediate care areas. It is intended to supply electric power and/or medical gases and/or liquids

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 given in Figures 101, 102 and 103.

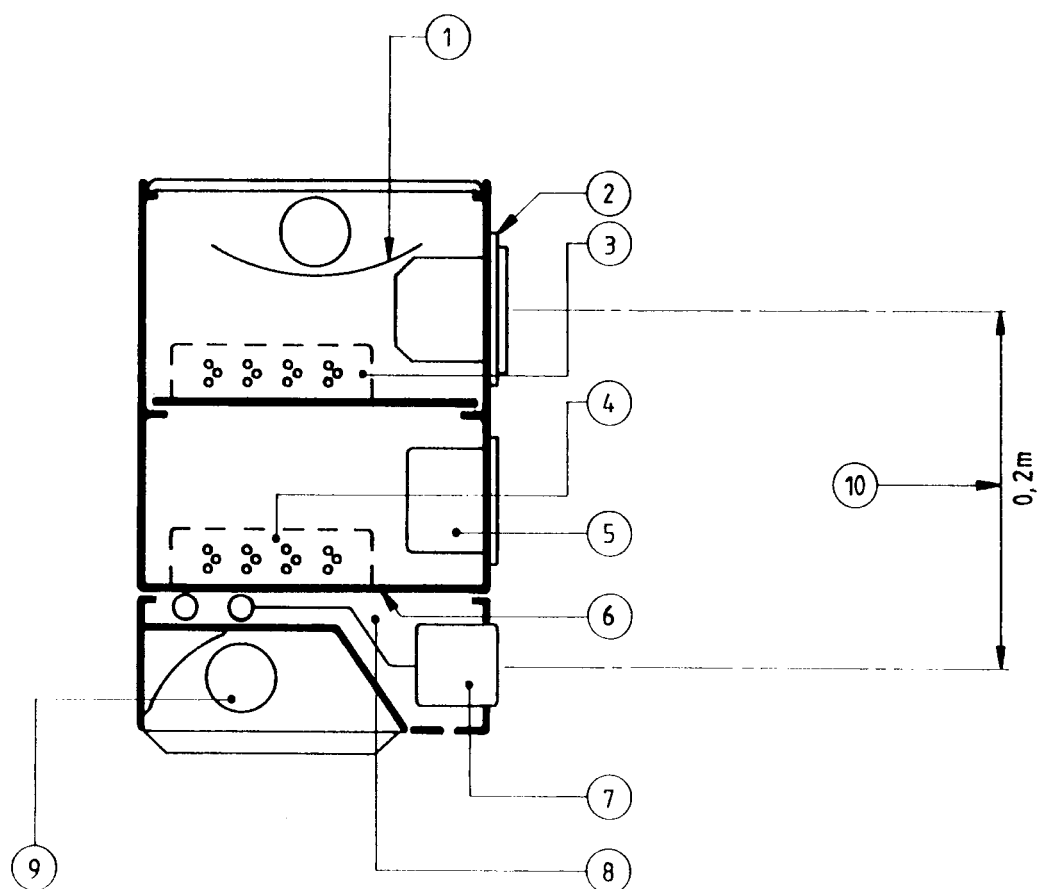
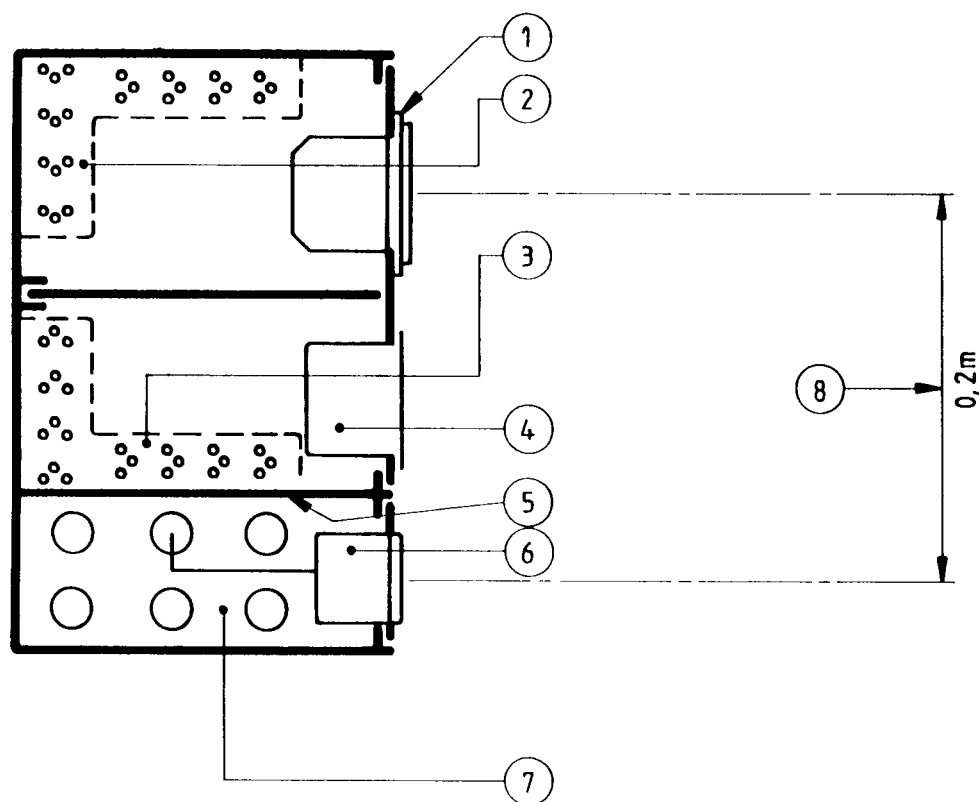


Figure 101 — Sectional drawing of typical medical supply unit for patient care rooms



- | | |
|--|---|
| 1 Electrical socket | 5 Barrier |
| 2 Mains supply | 6 Terminal unit |
| 3 Intercommunication, safety extra-low voltage | 7 Pipeline installation |
| 4 Recessed equipment | 8 Safety distance as distance from centre to centre |

Figure 102 — Sectional drawing of typical medical supply unit for intensive care rooms and operating theatres