

SLOVENSKI
STANDARD

**SIST EN 60601-
1:1995/A13:1998**

prva izdaja
september 1998

Medical electrical equipment - Part 1: General requirements for safety -
Amendment A13

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ICS 11.040.01

Referenčna številka
SIST EN 60601-1:1995/A13:1998(en)

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UDC 615.84:614.8
ICS 11.040.00

Descriptors: Medical electrical equipment, definitions, requirements, testing, construction, safety, symbols

English version

Medical electrical equipment
Part 1: General requirements for safety

Appareils électromédicaux
Partie 1: Règles générales de sécurité

Medizinische elektrische Geräte
Teil 1: Allgemeine Festlegungen
für die Sicherheit

This amendment A13 modifies the European Standard EN 60601-1:1990; it was approved by CENELEC on 1995-07-04. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This amendment exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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CENELEC

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

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Foreword

This amendment was prepared by the Technical Committee CENELEC TC 62, Electrical equipment in medical practice.

The text of the draft was submitted to the formal vote and was approved by CENELEC as amendment A13 to EN 60601-1:1990 on 1995-07-04.

The following dates were fixed:

- latest date by which the amendment has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 1996-07-01
- latest date by which the national standards conflicting with the amendment have to be withdrawn (dow) 1996-07-01

Annex ZD (normative) lists the special national conditions causing a deviation from this amendment for a transitional period ending at the latest at 2006-07-01.

Replace subclause 6.6 by:

The identification of medical gas cylinders shall be in accordance with the future standard series EN 1089.

NOTE: See annex ZD for special national conditions.

In annex ZC, A-deviations, **delete** the A-deviation for Austria concerning subclause 6.6.

Add the following new annex:

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Annex ZD (normative)

Special national conditions

Special national condition: National characteristic or practice that cannot be changed even over a long period, e.g. climatic conditions, electrical earthing conditions. If it affects harmonization, it forms part of the European Standard or Harmonization Document.

For the countries in which the relevant special national conditions apply these provisions are normative, for other countries they are informative.

Clause Special national condition

6.6 **Austria, Germany, Switzerland**

This requirement does not apply for a period ending at the latest on 2006-07-01 subject to review taking into account e.g. the results of a forthcoming European study and the ongoing European standardization activities of the future EN 1089 series.

The national colour coding (informative) in Austria, Germany and Switzerland is as follows:

GAS	GERMANY 1)	AUSTRIA ÖNORM M 7375 ÖNORM M 7377	SWITZERLAND SN 057 600	ISO 32
OXYGEN	BLUE	BLUE	BLUE	WHITE
NITROUS OXIDE	GREY	GREY (colour 1) 2)	GREEN	BLUE
		YELLOW (colour 2) 2)	YELLOW	
AIR	YELLOW	GREY	BROWN	WHITE
				BLACK
OXYGEN/AIR	BLUE	GREY 3)	---	---
	YELLOW			
CO ₂		GREY (colour 1) 2)		
		BLACK (colour 2) 2)		
OXYGEN/CO ₂		GREY (colour 1) 2)		
		BLUE (colour 2) 2)		

1) In Germany, the same colours are used as provided in the colour code scheme for gas-supply hoses of DIN 13252, table A.6.
2) Single and dual colour coding according to prEN 1089-3 figure 1 resp. figure 2.
3) Not specified in ÖNORM M 7375 but according to requirements of ÖNORM M 7377.