SLOVENSKI STANDARD
SIST-TS CEN/TS 14507-1:2003

01-september-2003

Inhalacijski sistemi z dušikovim oksidom – 1. del: Dovodni sistemi

Inhalational nitric oxide systems - Part 1: Delivery systems

Inhalationssysteme für Stickstoffmonoxid - Teil 1: Abgabesysteme

Systemes d'oxyde nitrique inhalé - Partie 1: Systemes d'administration

Ta slovenski standard je istoveten z: **CEN/TS 14507-1:2003**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

SIST-TS CEN/TS 14507-1:2003 **en**

TECHNICAL SPECIFICATION
SPÉCIFICATION TECHNIQUE
TECHNISCHE SPEZIFIKATION

CEN/TS 14507-1

March 2003

ICS 11.040.10

English version

Inhalational nitric oxide systems – Part 1: Delivery systems

Inhalationssysteme für Stickstoffmonoxid - Teil 1: Abgabesysteme

This Technical Specification (CEN/TS) was approved by CEN on 02 November 2002 for provisional application.

The period of validity of this CEN/TS is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

CEN members are required to announce the existence of this CEN/TS in the same way as for an EN and to make the CEN/TS available. It is permissible to keep conflicting national standards in force (in parallel to the CEN/TS) until the final decision about the possible conversion of the CEN/TS into an EN is reached.

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Ref. No. CEN/TS 14507-1:2003 E

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Foreword

This document (CEN/TS 14507-1:2003) has been prepared by Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment”, the secretariat of which is held by BSI.

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).

CEN/TS 14507 consists of the following Parts under the general title "Inhalational nitric oxide systems"

Part 1 - Delivery systems

Part 2 - Supply systems

Attention is drawn to the rationales and guidance on equipment for use with nitric oxide given in CR 13903

Annex AA of this Part of CEN/TS 14507 is given for information and contains rationale statements for this Part of CEN/TS 14507. The clauses which have corresponding rationale statements are marked with R) after their number.

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

Section one — General

1 Scope

This Part of CEN/TS 14507 refers to EN 60601-1:1990 "Medical electrical equipment — Part 1: General requirements for safety", as amended by its amendments 1 (1991) and 2 (1995). For brevity Part 1 is referred to in this Part of CEN/TS 14507 either as the General Standard or as the General requirements.

The scope given in clause 1 of the General Standard applies except that 1.1 is replaced by the following:

1.1 This Part of CEN/TS 14507 specifies particular requirements for inhalational nitric oxide delivery systems and their modules. It covers devices which can be supplied in combined units, integrated into another medical device, for example a lung ventilator, or as individual devices.

This Part of CEN/TS 14507 addresses the monitoring of nitric oxide and oxygen delivery to the patient and minimization of the production of nitrogen dioxide.

This Part of CEN/TS 14507 covers the requirements for inhalational nitric oxide delivery systems intended for medical use, for example, in critical care, anaesthesia, and emergency/transport environments.

NOTE It is recognized that from time to time innovations and designs will appear that offer advantages and yet are not covered by specific safety-related design or performance aspects of this Part of CEN/TS 14507; such innovations are not to be discouraged. As the techniques and technologies in these innovations advance, it is essential that the safety objectives of this Part of CEN/TS 14507 are considered as minimum requirements.

The requirements of clause 1.3 of the General Standard apply with the following additions:

The numbering of clauses and subclauses of this Part of CEN/TS 14507 corresponds to that of the General Standard. The changes to the text of the General Standard are specified by the use of the following words:

´Replacement´ means that the clause or subclause of the General Standard is replaced completely by the text of this Part of CEN/TS 14507.

´Addition´ means that the text of this Part of CEN/TS 14507 is additional to the requirements of the General Standard.

´Amendment´ means that the clause or subclause of the General Standard is amended as indicated by the text of this Part of CEN/TS 14507.

Subclauses or figures which are additional to those of the General Standard are numbered starting from 101. Additional annexes are lettered AA, BB, etc. and additional items aa), bb), etc.

The term ´this Standard´ is used to make reference to the General Standard and this Part of CEN/TS 14507 taken together.

Where there is no corresponding section, clause or subclause in this Part of CEN/TS 14507, the section, clause or subclause of the General Standard applies without modification.

Where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Part of CEN/TS 14507.

2 Normative references

This Technical Specification 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 apply to this Technical Specification only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

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

EN 475, Medical devices — Electrically generated alarm signals.

EN 738-1:1997 + A1: 2001, Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow metering devices.

EN 738-3:1998 + A1: 2001, Pressure regulators for use with medical gases — Part 3: Pressure regulators integrated with cylinder valves.

EN 739:1998 + A1: 2001, Low pressure hose assemblies for use with medical gases.

EN 12598, Oxygen monitors for patient breathing mixtures — Particular requirements.

EN 13221, High pressure flexible connections for use with medical gases.

EN 60068-2-64:1994, Environmental testing — Part 2: Test methods — Test Fh: Vibration, broad-band random (digital control) and guidance (IEC 60068-2-64: 1993 + Corrigendum 1994.

EN 60601-1:1990 + A1:1993 + A2:1995, Medical electrical equipment — Part 1: General requirements for safety (IEC 60601-1:1998 + A1:1991 + A2:1995).

EN 60601-1-2, Medical electrical equipment — Part 1: General Requirements for safety 2.Collateral standard: Electromagnetic compatibility — Requirements and tests (IEC 60601-1-2:1993).

EN 61000-4-2, Electromagnetic compatibility (EMC) — Part 4: Testing and measurement techniques — Section 2: Electrostatic discharge immunity test — Basic EMC publication (IEC 61000-4-2:1995).

CEN/TS 14507-2, Inhalational nitric oxide systems — Part 2: Supply systems.

EN ISO 4135, Anaesthetic and respiratory equipment — Vocabulary .

IEC 60068-2-6:1995, Environmental testing — Part 2: Tests — Test Fc: Vibration (sinusoidal).

IEC 60068-2-29: 1987, Basic environmental testing procedures — Part 2: Tests — Test Eb and guidance: Bump.

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

3 Terms and definitions and terminology

For the purposes of this Technical Specification, clause 2 of the General Standard and EN ISO 4135 apply together with the following additions:

3.1
inhalational nitric oxide delivery device[1)]
device that controls the addition of nitric oxide to the breathing gas

NOTE It can control and indicate flow, concentration or dose.

3.2
inhalational nitric oxide delivery system[2)]
system comprising nitric oxide delivery device(s), monitoring and alarm device(s)

3.3
inhalational nitric oxide delivery system monitoring device[3)]
device that displays or indicates the values of variables pertinent to the delivery of nitric oxide

NOTE Such variables can be related to e.g. oxygen, nitric oxide and nitrogen dioxide.

4 General requirements and requirements for tests

4.1 Modifications to clause 3 of the General Standard

Clause 3 of the General Standard applies with the following additions:

3.6

Additional items

aa) short and open circuits of components or wiring which can increase temperatures (see section seven);

bb) any fault which is not detected by intrinsic means or by periodic inspection (e. g. an oxidant leak) shall be regarded as a normal condition and not a single fault condition;

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1) Called “delivery device” within this Part of EN/TS 14507.

2) Called “delivery system” within this Part of EN/TS 14507.

3) Called “monitoring device” within this Part of EN/TS 14507.

Compliance is checked by simulation of a single fault condition.

4.2 Modification to clause 4 of the General Standard

Clause 4 of the General Standard applies with the following addition:

Additional subclause:

4.101 Type testing of components of the delivery system

For type testing components of the delivery system, the requirements of the appropriate section(s) of this Part of CEN/TS 14507 including the referenced additional standards as stated in the appropriate section apply.

The manufacturer may use type tests different from those detailed within this Part of CEN/TS 14507 if an equivalent degree of safety is obtained.

5 Classification

Clause 5 of the General Standard applies.

6 Identification, marking and documents

Clause 6 of the General Standard applies together with the following additions:

6.1 Marking on the outside of equipment or equipment parts

Additional items:

aa) Device packaging and/or labelling shall distinguish between identical or similar products in both the sterile and non-sterile states by the same manufacturer.

bb) Each gas specific inlet shall be durably marked with either the gas-name or chemical symbol in accordance with EN 739:1997 + A1:2001 for a nitric oxide/nitrogen mixture. This marking shall be legible.

cc) If colour coding is used in addition for nitric oxide/nitrogen mixtures, it shall be bright green and black in accordance with EN 739:1997 + A1:2001 for a nitric oxide/nitrogen mixture.

dd) The delivery device shall be durably marked with the rated supply pressure(s) to which the device can be connected. These markings shall be legible.

ee) The name or chemical symbol in accordance with EN 739:1997 + A1:2001 for the gas shall be legibly marked on or adjacent to the delivery indicator. If colour coding is used, it shall be in conformance with EN 739:1997 + A1:2001.

6.8 Accompanying documents

6.8.2 Instructions for use

Additional items:

aa) The instructions for use shall describe methods of testing the alarm functions specified in this Part of CEN/TS 14507.

bb) Instructions for use shall include testing for correct assembly and connection of each device included in the delivery system.

cc) The instructions for use shall include the operating characteristics of any means of pressure relief provided with the delivery system.

dd) The instructions for use shall describe any medical devices that are recommended for use with the delivery system, together with any restrictions e. g. use with flammable anaesthetic agents.

ee) The instructions for use shall include information about cleaning, disinfection and/or sterilization of reusable parts.

ff) The instructions for use shall include information about the cleanliness and sterility of respiratory gas conducting parts upon delivery.

gg) The instructions for use shall include information about the risk arising from a malfunction in nitric oxide delivery and a recommendation to the effect that an alternative means of nitric oxide delivery be available whenever the delivery system is in use.

hh) If alarm limits are preset by the manufacturer, the limits shall be disclosed in the instructions for use.

ii) The manufacturer shall disclose the operating range(s) of the delivery device.

jj) R The instructions for use shall include a description of the functioning of the delivery system after an unintended interruption of the normal power supply.

kk) The manufacturer shall disclose the procedures recommended to minimize the formation of toxic degradation products of nitric oxide, e.g. by arranging for all gas pathways containing nitric oxide to be kept separate from all oxygen-containing pathways until they reach the breathing system or as close to it as it is practicable and by purging with nitrogen or the nitric oxide/nitrogen mixture .

ll) The instructions for use shall include a warning advising users to ensure that local requirements concerning the occupational safety limits for nitric oxide and nitrogen dioxide should not be exceeded during use.

mm) If an internal power supply is provided, the instructions for use shall contain an estimation of the duration of operation of the device when using its internal power supply and the conditions under which this estimate was determined.

nn) The manufacturer shall disclose the range of inlet pressures over which the delivery device meets the requirements of this Part of CEN/TS 14507.

oo) If 51.101.3, 51.101.4 and 51.101.5 apply and the delivery device is not provided with means to monitor the amount of nitric oxide, oxygen and/or nitrogen dioxide delivered to the patient and to initiate an alarm(s), the instructions for use shall include a statement that the delivery device shall be provided with such means before being put in service

6.8.3 Technical description

Additional items:

aa) Disclosure of accuracies (including bias and precision), display resolutions and range of each calibrated control for each monitored variable that is displayed and the rise time for any monitor provided;

bb) Disclosure of interdependence of controls, if applicable;

cc) Disclosure of all information necessary to check that a delivery system and/or its devices is/are installed correctly and in correct working order, and on the nature and frequency of maintenance operations necessary to ensure continuing correct operation.

dd) Each delivery system shall be provided with a checklist(s) of the procedures recommended by the manufacturer to be performed prior to each use of the system.

NOTE These procedures can be performed automatically, in whole or in part, or by the operator. Attention is drawn to additional checklists established by regional or national medical associations, or government agencies. The use of electronic displays integral to, or provided with, the delivery system is permitted to provide such a checklist.

7 Power Input

Clause 7 of the General Standard applies.

Section two — Environmental conditions

8 Basic safety categories

Not used.

9 Removable protective means

Not used.

10 Environmental conditions

Clause 10 of the General Standard applies.

11 Not used

12 Not used

Section three — Protection against electrical shock hazards

13 General

Clause 13 of the General Standard applies.

14 Requirements related to classification

Clause 14 of the General Standard applies.

15 Limitation of voltage and/or energy

Clause 15 of the General Standard applies.