



SLOVENSKI STANDARD
SIST-TS CEN/TS 14507-2:2003
01-september-2003

Inhalacijski sistemi z dušikovim oksidom – 2. del: Napajalni sistemi

Inhalational nitric oxide systems - Part 2: Supply systems

Inhalationssysteme für Stickstoffmonoxid - Teil 2: Versorgungssysteme

Systemes d'oxyde nitrique inhalé - Partie 2: Systemes d'alimentation

Ta slovenski standard je istoveten z: CEN/TS 14507-2:2003

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ICS:

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| 11.040.10 | Anestezijska, respiratorna in reanimacijska oprema | Anaesthetic, respiratory and reanimation equipment |
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TECHNICAL SPECIFICATION
SPÉCIFICATION TECHNIQUE
TECHNISCHE SPEZIFIKATION

CEN/TS 14507-2

March 2003

ICS 11.040.10

English version

Inhalational nitric oxide systems – Part 2: Supply systems

Inhalationssysteme für Stickstoffmonoxid - Teil 2:
Versorgungssysteme

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.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and United Kingdom.

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Foreword

This document (CEN/TS 14507-2:2003) 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 A of this European Technical Specification is given for information and contains rationale statements for this European Technical Specification. 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 announce 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.

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INTRODUCTION

Supply systems for nitric oxide/nitrogen mixtures are used to provide a continuous flow of gas to delivery and monitoring systems which comply with CEN/TS 14507-2. The components of the system can either be attached to a mobile trolley or fixed to a permanent structure such as a wall. Since nitric oxide reacts spontaneously with ambient oxygen to form toxic products, it is important to prevent the ingress of air into the supply system and also to provide a means of purging the supply system before use. Leakage to atmosphere should also be kept to a minimum. Continuity of supply can be obtained by the provision of two cylinders with an alarm for low cylinder pressure and a means of change-over from one cylinder to another. In order to ensure traceability of the gas supply, only one cylinder should be in use at the same time. It is essential that regular inspection and maintenance are undertaken to ensure that the supply systems continue to meet the requirements of this Part of CEN/TS 14507.

This Part of CEN/TS 14507 pays particular attention to:

- Continuity of supply
- Suitability of materials and components
- Safety (mechanical strength, release of excess pressure, leakage and stability)
- Gas-specificity
- Cleanliness
- Testing
- Identification
- Information supplied (including procedures for purging and replacement of cylinders)

CEN/TS 14507-2:2003 (E)**1 Scope**

1.1 This Part of CEN/TS 14507 applies to systems for the supply of nitric oxide/nitrogen mixtures to a delivery and monitoring system complying with CEN/TS 14507-1 for treatment of one patient at a time, in a healthcare facility.

1.2 This Part of CEN/TS 14507 applies to supply systems with cylinders at a filling pressure up to 20 000 kPa and concentrations up to 1000 µl/l of nitric oxide in nitrogen.

1.3 R This Part of CEN/TS 14507 does not apply to:

- pipeline systems for delivery of nitric oxide/nitrogen mixtures to more than one patient at a time;
- supply systems for nitric oxide/nitrogen mixtures intended for use in home care, emergency and transport.

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 to or revision of any of these publications 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).

EN 738-1:1997 + A1:2001, Pressure regulators for use with medical gases - Part 1: Pressure regulators and pressure regulators with flowmetering devices (including Amendment 1:2001)

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 837-1, Pressure gauges - Part 1: Bourdon tube pressure gauges - Dimensions, metrology, requirements and testing

EN 962, Gas cylinders - Valve protection caps and valve guards for industrial and medical gas cylinders - Design, construction and tests

EN 1441, Medical devices - Risk analysis

EN 12218, Rail systems for supporting medical equipment

EN 13221:2000, High pressure flexible connections for use with medical gases

EN 60601-1:1990, Medical electrical equipment - Part 1: General requirements for safety (IEC 60601-2:1988)

EN 60601-1-2, Medical electrical equipment - Part 1: General requirements for safety – Electromagnetic compatibility (IEC 60601-1-2:2001)

prEN ISO 407:2001, Small medical gas cylinders - Yoke-type valve connections (ISO/DIS 407:2001)

prEN ISO 10297:2002, Transportable gas cylinders - Cylinder valves - Specification and type testing (ISO/DIS 10297:2002)

ISO/DIS 5145:2001, Cylinder valve outlets for gases and mixtures - Selection and dimensioning

3 Terms and definitions

For the purposes of this Technical Specification the following terms and definitions apply:

3.1

low-pressure hose assembly

assembly which consists of a flexible hose with permanent attached gas-specific inlet and outlet connectors which is designed to conduct a medical gas at pressures between 300 kPa and 1400 kPa and for use with vacuum service at pressures above 10 kPa absolute pressure

3.2

quick-connector

pair of non-threaded gas-specific components which can be easily and rapidly joined together by a single action of one or both hands without the use of tools

3.3

single fault condition

condition in which a single means for protection against a safety hazard in equipment is defective or a single external abnormal condition is present

4 Terminology

A typical example of a nitric oxide supply system with examples of terminology is given in Figure 1.

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5 General requirements (standards.iteh.ai)

5.1 R Safety

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Supply systems for nitric oxide/nitrogen mixtures shall, when transported, stored, installed, operated in normal use and maintained according to the instructions of the manufacturer, cause no safety hazard which could be foreseen using risk analysis procedures in accordance with EN 1441 and which is connected with their intended application, in normal condition and in single fault condition.

In particular the risk analysis shall address the possible consequences of a catastrophic release of the entire contents of a cylinder of nitric oxide/nitrogen mixture.

Evidence shall be provided by the manufacturer.

5.2 R Alternative construction

Supply systems for nitric oxide/nitrogen mixtures and components or parts thereof, using materials or having forms of construction different from those detailed in clauses 5 and 6 of this Part of CEN/TS 14507 shall be accepted if it can be demonstrated that an equivalent degree of safety is obtained.

Such evidence shall be provided by the manufacturer.

5.3 Materials

5.3.1 The materials in contact with the gas shall be corrosion-resistant and compatible with nitric oxide/nitrogen mixtures (up to a concentration of 1000 µl/l of nitric oxide in nitrogen) in the temperature range specified in 5.3.2.

NOTE 1 Corrosion resistance includes resistance against moisture and surrounding materials.

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NOTE 2 Although during normal operation no component of the supply systems ought to become contaminated with oxygen and moisture, experience has shown that such contamination is possible. Nitric oxide reacts spontaneously with oxygen (air) forming nitrogen dioxide. In the presence of water, nitrogen dioxide forms nitric acid (HNO_3) and nitrous acid (HNO_2) that can react with materials used for components of the supply system and cause corrosion.

5.3.2 The materials shall permit the supply systems for nitric oxide/nitrogen mixtures and their components to meet the requirements of clause 6 in the temperature range of +10 °C to +40 °C.

5.3.3 The supply systems for nitric oxide/nitrogen mixtures shall be capable, while packed for transport and storage, of being exposed to environmental conditions as stated by the manufacturer.

5.3.4 Springs, highly strained components and parts liable to wear which come in contact with the gas shall not be plated.

NOTE Plating could come off.

5.3.5 R Evidence of conformity with the requirements of clauses 5.3.1 to 5.3.4 shall be provided by the manufacturer.

6 Design requirements

NOTE The criteria to be observed in the design phase are described in Section 4 of CEN Report CR 13903: 2000.

6.1 Components of the supply systems for nitric oxide

Supply systems for nitric oxide/nitrogen mixtures shall comprise the following:

- a) two or more cylinders each fitted with cylinder valve;
- b) two or more pressure regulators;
- c) one high-pressure gauge for each cylinder to indicate the gas contents;
- d) at least one low-pressure gauge to indicate the outlet pressure supplied to the delivery system;
- e) one outlet connector;
- f) one minimum pressure alarm for the cylinder in use;
- g) one back-up power supply (if electrically operated components are fitted);
- h) means for change-over from one cylinder to another;
- i) means for purging of the system.

All components shall be secured to a supporting structure e.g. a mobile trolley or a wall.

NOTE 1 The supply system can be provided with a rail system for supporting medical equipment.

NOTE 2 The supply system can be provided with other means, e.g. a shelf, for supporting accessories of the delivery system such as monitors and flowmeters.

6.2 Cylinders

The cylinders shall comply with the relevant European Standards.

Evidence of conformity shall be provided by the manufacturer.

6.3 R Cylinder valves

Cylinder valves shall comply with prEN ISO 10297:2002.

Evidence of conformity with prEN ISO 10297:2002 shall be provided by the manufacturer.

NOTE The cylinder valve can be provided with a device to limit the ingress of atmospheric air by leaving a minimum positive pressure within the cylinder.

The valve outlet connection shall be one of the following:

- a threaded connection complying with ISO/DIS 5145:2001 (30-RH/15,2-20,8)
- a "pin-index" connection complying with prEN ISO 407:2001 (figure E-F)

If valve protection caps or valve guards are used, they shall comply with EN 962.

Evidence of conformity with EN 962, prEN ISO 407:2001 and ISO/DIS 5145:2001 shall be provided by the manufacturer.

6.4 R Pressure regulators

Pressure regulators shall comply with EN 738-1. The pressure regulators shall be connected to the cylinder valve either directly or by means of a high-pressure flexible connection.

Pressure regulators integrated with cylinder valves, which comply with EN 738-3, can also be used.

The outlet connector of the pressure regulators shall be one of the following:

- a proprietary fitting for permanent connection;
- the female part of a quick-connector complying with 6.9.

Evidence of conformity with EN 738-1 or EN 738-3 shall be provided by the manufacturer.

6.5 Pressure gauges

6.5.1 The indicated value of pressure gauges shall be legible to an operator having visual acuity of 1 (corrected if necessary) seated or standing 1 m from gauges with an illuminance of 215 lux.

6.5.2 The high-pressure and low-pressure gauges shall be class 2,5 or better according to EN 837-1.

NOTE The maximum permissible error for accuracy class 2,5 is $\pm 2,5\%$ of the maximum scale value.

6.5.3 If Bourdon tube pressure gauges are used, they shall conform to EN 837-1.

6.5.4 If Bourdon tube pressure gauges are used, the scale of the high-pressure gauges shall extend to a pressure at least 33% greater than the filling pressure of the cylinder at a temperature of $(23 \pm 2) ^\circ\text{C}$.

6.5.5 R Evidence of conformity with 6.5.2 and 6.5.3 shall be provided by the manufacturer. Compliance with the requirements of 6.5.1 and 6.5.4 shall be verified by visual inspection.

6.6 R High-pressure flexible connections

If high-pressure flexible connections are used between the cylinder valves and the pressure regulators, they