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CEN/TS 14507-2

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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.

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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 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.

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)

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