



SLOVENSKI STANDARD
SIST EN 13014:2000
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Connections for gas sampling tubes to anaesthetic and respiratory equipment

Verbindungen für Gasprobenentnahmeschläuche an Anästhesie- und Beatmungsgeräten

Raccordements pour tubes a prélèvement de gaz du matériel respiratoire et anesthésique

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Ta slovenski standard je istoveten z: **EN 13014:2000**

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ICS:

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

English version

Connections for gas sampling tubes to anaesthetic and respiratory equipment

Raccordements pour tubes à prélèvement de gaz du matériel respiratoire et anesthésique

Verbindungen für Gasprobenentnahmeschläuche an Anästhesie- und Beatmungsgeräten

This European Standard was approved by CEN on 6 June 1999.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard 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 CEN member.

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

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

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

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Foreword

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

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 July 2000, and conflicting national standards shall be withdrawn at the latest by July 2000.

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 Directive(s), see informative Annex ZA, which is an integral part of this standard.

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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1 Scope

This European Standard specifies requirements for construction, dimensions and marking for the connectors in gas sampling tubes which transfer gas from the breathing system of anaesthetic and respiratory equipment to diverting gas monitors and back to the breathing system and/or to the anaesthetic gas scavenging system (AGSS).

This European Standard gives requirements for the following gas sampling tube ports and connectors:

- Gas sampling port on breathing system.
- Gas return port on breathing system and AGSS.
- Gas sampling and return ports on monitors.
- Gas sampling tube inlet and outlet connectors.
- Gas return tube inlet and outlet connectors.

This European Standard does not apply to connection ports intended for connection of sensors in the breathing system.

NOTE 1: It is expected that requirements for the application of this standard will be included in particular standards for specific medical devices and accessories.

NOTE 2: One important consideration is that gas sampling tube connectors are secure but nevertheless can be disconnected by the operator. EN 1707 includes requirements and test methods for separation force, unscrewing torque and air leakage.

According to EN 1707, Luer lock fittings are intended to be used for syringes, needles and certain other medical equipment. In order to minimize the risk of mis-connections, this standard specifies the arrangements of male and female fittings and the marking requirements to identify the different connectors, ports and tubes. Tables 1 to 4 specify the type of Luer lock fitting that is used in actual applications. (standards.iteh.ai)

NOTE 3: Another important consideration is that the ports in the breathing system can be sealed when gas sampling tubes are not connected.

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 amendments to or revision of any of these publications 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.

EN 1041: 1998	Information supplied by the manufacturer with medical devices
EN 1089-3: 1997	Transportable gas cylinders - Cylinder identification - Part 3: Colour coding
EN 1707: 1996	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Lock fittings
EN 60601-1: 1990	Medical electrical equipment - Part 1: General requirements for safety (IEC 60601-1:1988)
ISO 7000: 1989	Graphical symbols for use on equipment - Index and synopsis

3 Definitions

For the purposes of this Standard, the following definitions apply:

3.1 gas sampling port: That port on a breathing system and/or monitor to which a gas sampling tube can be connected and gas can be collected and routed to a diverting monitor.

3.2 gas return port: That port on a breathing system or AGSS to which a gas return tube can be connected and gas is returned.

3.3 diverting monitor: Monitor which transports the gas mixture from the sampling site to the sensing area.

3.4 gas sampling tube inlet connector: That connector on a gas sampling tube which is connected to a breathing system gas sampling port.

3.5 gas sampling tube outlet connector: That connector on a gas sampling tube which is connected to a diverting monitor gas sampling port.

3.6 monitor gas sampling port connector: That connector on a monitor to which a gas sampling tube can be connected.

3.7 monitor gas return port connector: That connector on a monitor to which a gas return tube can be connected.

3.8 gas return tube inlet connector: That connector on a gas return tube which can be connected to a monitor gas sampling port.

3.9 gas return tube outlet connector: That connector on a gas return tube which can be connected to a breathing system or AGSS.

4 Materials and construction

NOTE1: Attention is drawn to the fact that some connectors are used, disinfected, or sterilised at elevated temperatures, and extra care is required when selecting suitable materials.

4.1 Cleaning, disinfection and sterilisation

If connectors are intended for re-use, 44.7 of EN 60601-1 : 1990 shall apply.

4.2 Constructional requirements

Materials used shall be selected with regard to:

- a) Compatibility with substances and gases with which they come into contact during normal use;
- b) Toxicity;
- c) Minimization of health risks due to substances leached from materials.

Compliance shall be checked via manufacturer certification.

NOTE1: Evidence of compliance with the specification(s), either by test or by other methods should be provided by the manufacturer to a Notified Body during CE conformity assessment or to appropriate authorities on request.

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4.3 Alternative constructions

Gas sampling tube connectors using materials, or having forms of construction different from those detailed in this standard shall be accepted if it can be demonstrated that an equivalent degree of safety is obtained.

Evidence shall be provided by the manufacturer.

5 Dimensions and tolerances

5.1 Gas sampling ports on breathing systems

The dimensions of the connector shall be according to EN 1707: 1996 and the connector type shall be as given in table 1.

5.2 Gas return ports on breathing systems or AGSS

Gas return ports on a breathing system or AGSS shall comply with EN 1707: 1996 and the connector type shall be as given in table 1.

5.3 Gas sampling ports on monitors

The dimensions of the connector shall be according to EN 1707: 1996 and the connector type shall be as given in table 2.

5.4 Gas return ports on monitors

The dimensions of the connector shall be according to EN 1707: 1996 and the connector type shall be as given in table 2.

5.5 Gas sampling tube connectors

The dimensions of the connector shall be according to EN 1707: 1996 and the connector type shall be as given in table 3.

5.6 Gas return tube connectors

The dimensions of the connector shall be according to EN 1707: 1996 and the connector type shall be as given in table 4.

6 Requirements

6.1 General

When connected, the probe shall engage with the socket connector and shall meet the requirements of 6.2 to 6.8.

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