
**Anestezijska in dihalna oprema - Priklučki za plinske vzorčne cevke pri
anestezijski in dihalni opremi**

Anaesthetic and respiratory equipment - Connections for gas sampling and gas
return

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English Version

Anaesthetic and respiratory equipment - Connections for gas sampling and gas return

Équipement respiratoire et anesthésique - Raccordements pour prélèvement de gaz et gaz restitué

Anästhesie- und Beatmungsgeräte - Verbindungen für Gasprobenentnahme und Gasrückführung

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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Foreword

This document (prEN 13014:2006) has been prepared by Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment”, the secretariat of which is held by BSI.

This document is currently submitted to the CEN Enquiry.

This document will supersede EN 13014:2000.

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).

For relationship with EU Directive(s), see informative Annex ZA which is an integral part of this document.

The letter 'R' next to a clause number indicates the presence of a rationale for that clause in annex A.

1 Scope R

This European Standard specifies requirements for construction, dimensions and marking of connectors used in gas sampling to 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 ports and connectors:

- gas sampling port on breathing system;
- gas return port on breathing system and AGSS;
- gas sampling and return ports on diverting gas 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.

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 misconnection, 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 fitting that is used in actual applications.

NOTE 1 Manufacturers are encouraged to use the ports specified in this standard on diverting gas monitors, breathing systems and AGS systems even if these are currently not required by the specific device standards. It is expected that requirements for the application of this standard will be included in these particular standards during forthcoming revisions. Attention is drawn to prEN ISO/FDIS 21647 concerning respiratory gas monitors and the work of CEN/BT/TF 123 *Small-bore connectors*.

NOTE 2 During planning and design manufactures will consider the environmental impact from the product during its life cycle. Environmental aspects are addressed in Annex ZB. Additional aspects of environmental impact are addressed in EN ISO 14971.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) 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 20594-1:1993, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements (ISO 594-1:1986)*

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 diverting gas monitor to which a gas sampling tube can be connected and gas can be collected and routed to a sensor in the 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 gas monitor

gas monitor which transports a portion of a gas mixture from a remote sampling site, through a sampling tube, to a sensor in the monitor [EN ISO 4135]

3.4 gas sampling tube inlet connector

that connector on a gas sampling tube which is connected to a gas sampling port on a breathing system

3.5 gas sampling tube outlet connector

that connector on a gas sampling tube which is connected to a gas sampling port on a diverting gas monitor

3.6 gas return tube inlet connector

that connector on a gas return tube which can be connected to a gas sampling port on a diverting gas monitor

3.7 gas return tube outlet connector

that connector on a gas return tube which can be connected to a gas return port on a breathing system or AGSS

4 Materials and construction

4.1 Cleaning, disinfection and sterilisation

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

NOTE 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.

4.2 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.

NOTE 1 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.

NOTE 2 Consideration should be given to the disposal of packaging waste.

4.3 Alternative constructions

Gas sampling / return tube connectors and gas sampling / return ports 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 and tolerances of the port shall be according to EN 1707:1996 and the port type shall be as given in Table 1.

5.2 Gas return ports on breathing systems or AGSS

The dimensions and tolerances of the port shall comply with EN 20594-1:1993 and shall be provided with a sleeve in accordance with Figure 2. The port type shall be as given in Table 1.

5.3 Gas sampling ports on diverting gas monitors

The dimensions and tolerances of the port shall be according to EN 1707:1996 and the port type shall be as given in Table 2.

5.4 Gas return ports on diverting gas monitors

The dimensions and tolerances of the port shall be according to EN 20594-1:1993 and shall be provided with a sleeve in accordance with Figure 2. The port type shall be as given in Table 2.

5.5 Gas sampling tube connectors

The dimensions and tolerances 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 and tolerances of the connector shall be according to EN 20954-1:1993 and in accordance with Figure 3. The connector type shall be as given in Table 4.

6 Requirements

6.1 General

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

6.2 Gauging

When tested, Luer lock type fittings shall comply with EN 1707:1996, 4.1 and Luer type fittings shall comply with EN 20954-1:1993, 4.1.

6.3 Leakage

When tested, Luer lock type fittings shall comply with EN 1707:1996, 4.2 and Luer type fittings shall comply with EN 20954-1:1993, 4.2 and 4.3.

6.4 Separation force

When tested, Luer lock type fittings shall comply with EN 1707:1996, 4.3 and Luer type fittings shall comply with EN 20954-1:1993, 4.4.

6.5 Unscrewing torque

When tested, Luer lock type fittings shall comply with EN 1707:1996, 4.4.

6.6 Ease of assembly

When tested, Luer lock type fittings shall comply with EN 1707:1996, 4.5.

6.7 Resistance to overriding

When tested, Luer lock type fittings shall comply with EN 1707:1996, 4.6.

6.8 Stress cracking

When tested, Luer lock type fittings shall comply with EN 1707:1996, 4.7 and Luer type fittings shall comply with EN 20954-1:1993, 4.5.

7 Marking

7.1 Marking of ports and connectors

7.1.1 General

If colour coding is used, it shall be different from that specified in EN 1089-3:1997.

Marking shall be in accordance with EN 1041:1998, 4.1.6.

7.1.2 Gas ports on breathing systems and AGSS

Gas sampling ports on breathing systems shall be marked with the words "Gas sample" and/or symbol No 0795 of ISO 7000:1989 (see Figure 5).

Gas return ports on breathing systems or AGSS shall be marked with the words "Gas return" and/or symbol No 0794 of ISO 7000:1989 (see Figure 4).

7.1.3 Gas ports on diverting gas monitors

Gas sampling ports shall be marked with the words "Gas sample" and/or symbol No 0794 of ISO 7000:1989 (see Figure 4).

Gas return ports shall be marked with the words "Gas return" and/or symbol No 0795 of ISO 7000:1989 (see Figure 5).

7.1.4 Gas sampling tubes

Gas sampling tubes shall be marked with the words "Gas sample" and/or appropriate symbol in accordance with EN 1041:1998, 4.1.6.

7.1.5 Gas return tubes

Gas return tubes shall be marked with the words "Gas return" and/or appropriate symbol in accordance with EN 1041:1998, 4.1.6.

7.2 Marking on packaging

The packaging of tubes, if supplied separately, shall be marked with the following:

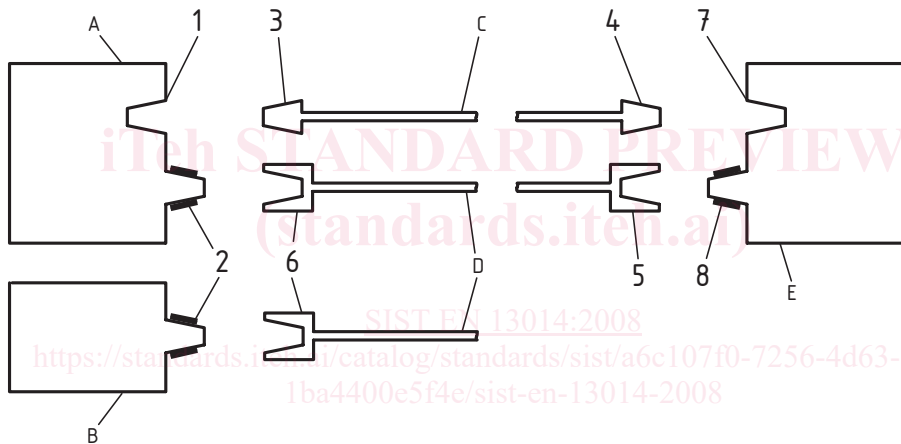
- a) a description of the product;
- b) the name and/or trade mark of the manufacturer and/or supplier and a batch code if appropriate;
- c) cleaning requirements if applicable;
- d) information about requirements for intended use.

The connector for gas sampling and gas return and its parts shall be marked with regard to proper disposal, as appropriate.

8 Information to be supplied by the manufacturer

Information supplied by the manufacturer shall include at least the following:

- a) intended use
- b) any special operating instructions;
- c) recommended methods for cleaning and disinfection or sterilisation, as specified in EN 60601-1:1990, 6.8.2 d);
- d) any special storage and/or handling conditions.
- e) a warning highlighting potential inappropriate connections to other devices that can result in a patient hazard, if applicable e.g. other devices fitted with connectors compatible with Luer connectors.
- f) Information concerning the disposal of the connector for gas sampling and gas return or components thereof.



Device	Connector/port
(A) Breathing system	(1) Gas sampling port, Luer lock, female
(B) AGSS system	(2) Gas return port with sleeve, Luer, male, see Figure 2
(C) Gas sampling tube	(3) Inlet connector, Luer lock, male (4) Outlet connector, Luer lock, male
(D) Gas return tube	(5) Inlet connector, Luer, female, see Figure 3 (6) Outlet connector, Luer, female, see Figure 3
(E) Diverting gas monitor	(7) Gas sampling port, Luer lock, female (8) Gas return port with sleeve, Luer, male, see Figure 2

Figure 1 — Schematic representation of ports and connectors