INTERNATIONAL STANDARD

ISO 9170-1

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Terminal units for medical gas pipeline systems —

Part 1:
Terminal units for use with compressed medical gases and vacuum

Prises murales pour réseaux de distribution de gaz médicaux —

Partie 1: Prises murales pour les gaz médicaux comprimés et le vide

Reference number
ISO 9170-1:1999(E)

Contents

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 9170-1 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 6, *Medical gas systems*.

This first edition, together with ISO 9170-2, cancels and replaces the first edition of ISO 9170 (ISO 9170:1994), which has been technically revised.

ISO 9170 consists of the following parts, under the general title *Terminal units for medical gas pipeline systems*:

— *Part 1: Terminal units for use with compressed medical gases and vacuum*

— *Part 2: Terminal units for anaesthetic gas scavenging systems*

Annex A of this part of ISO 9170 is for information only.

Introduction

Terminal units are the points on a medical gas pipeline system where the operator makes connections and disconnections for the supply of specified medical gases to anaesthetic machines, lung ventilators or other items of medical equipment. A wrong connection can create a hazard to the patient or operator. It is important that terminal units and their components are designed, manufactured, installed and maintained in such a way as to meet the basic requirements specified in this part of ISO 9170.

This part of ISO 9170 pays particular attention to:

— suitability of materials;

— gas-specificity;

— cleanliness;

— testing;

— identification;

— information supplied.

This part of ISO 9170 specifies the provision of information for the installation and subsequent testing of terminal units prior to use. Testing of terminal units prior to use is critical to patient safety, and it is essential that terminal units are not used until full testing in accordance with ISO 7396-1 has been completed.

Terminal units for medical gas pipeline systems —

Part 1:
Terminal units for use with compressed medical gases and vacuum

1 Scope

This part of ISO 9170 specifies requirements for terminal units intended for use in medical gas pipeline systems in accordance with ISO 7396-1, for use with the following services:

— oxygen;

— nitrous oxide;

— air for breathing;

— carbon dioxide;

— oxygen/nitrous oxide mixture [50 %/50 % (by volume)];

— air for driving surgical tools;

— nitrogen for driving surgical tools;

— vacuum.

It is intended especially to ensure the gas-specific assembly of terminal units and to prevent their interchange between different gases.

This part of ISO 9170 specifies requirements for terminal units for supply and disposal of nitrogen or air for driving surgical tools.

This part of ISO 9170 specifies requirements for probes intended to be connected to the gas-specific connection point which is part of the terminal unit.

This part of ISO 9170 does not specify the dimensions of probes and of the gas-specific connection points of the terminal units.

This part of ISO 9170 does not specify the dimensions of NIST connectors, which are defined in ISO 5359.

This part of ISO 9170 does not specify the requirements for terminal units for anaesthetic gas scavenging systems (AGSS), which are defined in ISO 9170-2.

NOTE 1 The requirements of this part of ISO 9170 may be used as guidelines for terminal units for other medical gases. These medical gases will be considered for inclusion in this part of ISO 9170 when they come into general use.

NOTE 2 Throughout this part of ISO 9170, clauses for which a rationale is provided in annex A are indicated by a boldface capital **R.**

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 9170. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 9170 are encouraged to investigate the possibility of applying the most recent edition of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 32:1977, *Gas cylinders for medical use — Marking for identification of content*.

ISO 5359, *Low-pressure hose assemblies for use with medical gases*

ISO 6506-1, *Metallic materials — Brinell hardness test — Part 1: Test method*.

ISO 7396-1, *Medical gas pipeline systems — Part 1: Pipelines for compressed medical gases and vacuum*.

ISO 14971-1, *Medical devices — Risk management — Part 1: Application of risk analysis*.

ISO 15001, *Anaesthetic and respiratory equipment — Compatibility with oxygen*.

3 Terms and definitions

For the purposes of this part of ISO 9170, the following terms and definitions apply.

A diagram of a typical terminal unit and probe, with an example of terminology, is shown in Figure 1.

3.1
diameter-index safety system connector
DISS connector

range of male and female components intended to maintain gas-specificity by allocation of a set of different diameters to the mating connectors for each particular gas

3.2
gas-specific
having characteristics which prevent interchangeability and thereby allow assignment to one gas or vacuum service only

3.3
gas-specific connection point
that part of the socket which is the receptor for a gas-specific probe

3.4
gas-specific connectors
connectors which are either NIST (non-interchangeable screw-threaded) or DISS (diameter-index safety system) or non-interchangeable quick connectors of terminal units

3.5
low-pressure hose assembly
assembly, consisting of a flexible hose with permanently attached gas-specific inlet and outlet connectors, which is designed to conduct a medical gas at pressures less than 1 400 kPa

3.6
medical gas
any gas or mixture of gases intended to be administered to patients for therapeutic, diagnostic or prophylactic purposes, or for surgical tool application(s)

3.7
medical gas pipeline system
central supply system consisting of control equipment, a pipeline distribution system and terminal units at the points where medical gases or vacuum may be required

3.8
medical gas supply system
medical gas pipeline system or any other installation having no permanent pipeline system but employing a medical gas supply source complete with pressure regulators

3.9
nominal distribution pressure
pressure which the pipeline distribution system is designed to deliver at the terminal unit

NOTE Unless otherwise specified, pressures in this part of ISO 9170 are expressed as gauge pressures (i.e. atmospheric pressure is defined as 0).

3.10
non-interchangeable screw-threaded connector
NIST connector
range of male and female components intended to maintain gas-specificity by the allocation of a set of different diameters and a left- or right-hand screw thread to the mating components for each particular gas

3.11
probe
gas-specific male component designed for acceptance by and retention in the socket

3.12
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

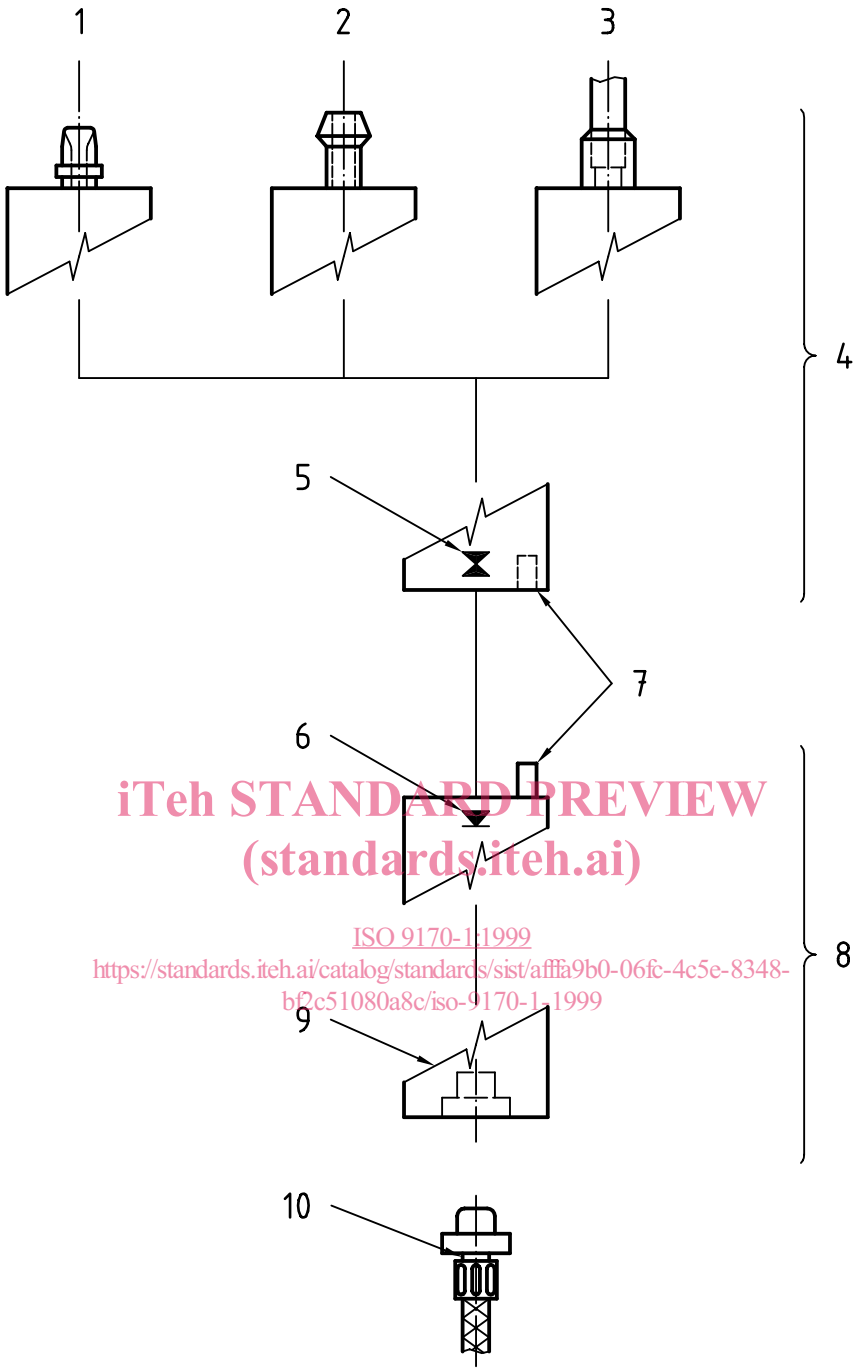
3.13
single-fault condition
condition in which a single means for protection against a safety hazard in equipment is defective or a single external abnormal condition is present

3.14
socket
that female part of a terminal unit which is either integral or attached to the base block by a gas-specific interface and which contains the gas-specific connection point

3.15
terminal unit
outlet assembly (inlet for vacuum) in a medical gas supply system at which the operator makes connections and disconnections

3.16
terminal unit base block
that part of a terminal unit which is attached to the pipeline distribution system

3.17
terminal unit check valve
valve which remains closed until opened by insertion of an appropriate probe and which then permits flow in either direction



Key

1 NIST or DISS body
2 Hose insert
3 Point for brazed connection
4 Base block
5 Maintenance valve
6 Check valve
7 Gas-specific interface
8 Socket
9 Gas-specific connection point
10 Probe

Figure 1 — Diagram showing typical components of a terminal unit and probe

3.18
terminal unit maintenance valve
valve which permits maintenance of the terminal unit without shutting down the pipeline system to other terminal units

3.19
terminal unit for supply and disposal of nitrogen or air for driving surgical tools
combination of an outlet assembly (for supply) and an inlet assembly (for disposal) which are connected to a medical gas supply system and to an anaesthetic gas disposal system respectively and at which the operator makes connections and disconnections by means of a combined probe

4 General requirements

4.1 Safety

Terminal units 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 ISO 14971-1 and which is related to their intended application, in normal condition and in single-fault condition.

4.2 R Alternative construction

Terminal units and components, or parts thereof, which use materials or have forms of construction different from those detailed in clause 4 of this part of ISO 9170 shall be accepted if it can be demonstrated that an equivalent degree of safety is obtained. Such evidence shall be provided by the manufacturer.

4.3 Materials

4.3.1 The materials in contact with the gas shall be corrosion-resistant and compatible with oxygen and the other medical gases and their mixtures in the temperature range specified in 4.3.2.

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

NOTE 2 Compatibility with oxygen involves both combustibility and ease of ignition. Materials which burn in air will burn violently in pure oxygen. Many materials which do not burn in air will do so in pure oxygen, particularly under pressure. Similarly, materials which can be ignited in air have lower ignition energies in oxygen. Many such materials may be ignited by adiabatic compression produced when oxygen at high pressure is rapidly introduced into a system initially at low pressure. For further information, see ISO 15001.

4.3.2 The materials shall permit the terminal units and their components to meet the requirements of 4.4 in the temperature range of −20 °C to + 60 °C.

4.3.3 Terminal units shall be capable of meeting the requirements of 4.4 after being packed, transported and stored as specified by the manufacturer.

4.3.4 R Evidence of conformity with the requirements of 4.3.1, 4.3.2 and 4.3.3 shall be provided by the manufacturer.

4.4 Design requirements

4.4.1 Medical gas supply pressure

4.4.1.1 The terminal units for oxygen, nitrous oxide, air for breathing, carbon dioxide and oxygen/nitrous oxide mixture [50 %/50 % (by volume)] shall operate and meet the requirements of this part of ISO 9170 for a medical gas supply having a pressure range from 320 kPa to 600 kPa.