INTERNATIONAL STANDARD

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Third edition 2017-07

Terminal units for medical gas pipeline systems —

Part 1:

Terminal units for use with compressed medical gases and vacuum

Prises murales pour systèmes de distribution de gaz médicaux — Partie 1: Prises murales pour les gaz médicaux comprimés et le vide





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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC6, *Medical gas systems*.

This third edition cancels and replaces the second edition (ISO 9170-1:2008), which has been technically revised.

This edition includes the following significant changes with respect to the previous edition:

- a) oxygen 93, detailing marking and colour coding, was introduced;
- b) figures for test conditions were clarified.

A list of all parts in the ISO 9170 series can be found on the ISO website.

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. Terminal units are also used for vacuum pipeline systems. A wrong connection can create a hazard to the patient or operator. It is important that terminal units and their components be designed, manufactured, installed and maintained in such a way as to meet the requirements specified in this document.

This document pays particular attention to

- suitability of materials,
- gas-specificity,
- cleanliness.
- testing,
- identification, and
- information supplied.

This document contains information for the installation and 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.

Annex A contains rationale statements for some of the requirements of this document. The clauses and subclauses marked with an asterisk (*) after their number have corresponding rationale contained in Annex A, included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated in this document. It is considered that knowledge of the reasons for the requirements will not only facilitate the proper application of this document, but will also expedite any subsequent revisions.

<u>Annex B</u> contains environmental aspects that should be considered.

Terminal units for medical gas pipeline systems —

Part 1:

Terminal units for use with compressed medical gases and vacuum

1 Scope

This document is intended especially to ensure the gas-specific assembly, mechanical resistance, flow, leakage and pressure drop of terminal units and to prevent their interchange between different gases and services and applies to terminal units:

- a) intended for use in medical gas pipeline systems in accordance with ISO 7396-1;
- b) used as pressure outlets on pressure regulators in accordance with ISO 10524-1;
- c) used as pressure outlets on pressure regulators integrated with cylinder valves (VIPR) in accordance with ISO 10524-3.

This document applies to terminal units for use with the following gases for administration to patients or for medical uses (A):

- oxygen (A);
- nitrous oxide (A):
- medical air (A);
- carbon dioxide (A);
- oxygen/nitrous oxide mixture (A);
- helium/oxygen mixtures (A);
- oxygen 93 (A);
- gases and gas mixtures classified as medical device (A);
- gases delivered to medical devices or intended for medical purposes (A);
- gases and gas mixtures for medicinal use not specified above (A).

This document applies to terminal units for use with the following gases (B):

- air for driving surgical tools (B);
- nitrogen for driving surgical tools (B).

This document applies to terminal units for use with vacuum systems (C).

NOTE The requirements of this document can be used as guidelines for terminal units for other gases. These other gases will be considered for inclusion in this document when they come into general use.

This document specifies requirements for terminal units for supply and disposal of nitrogen and air for driving surgical tools.