Third edition
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Medical gas pipeline systems —

Part 1:
Pipeline systems for compressed medical gases and vacuum

Systèmes de distribution de gaz médicaux —

Partie 1: Systèmes de distribution de gaz médicaux comprimés et de 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 meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 6, *Medical gas systems*.

This third edition cancels and replaces the second edition (ISO 7396-1:2007) and ISO 10083:2006, which have been technically revised. It also incorporates the Amendments ISO 7396-1:2007/Amd1:2010, ISO 7396-1:2007/Amd2:2010, and ISO 7396-1:2007/Amd3:2013.

ISO 7396 consists of the following parts, under the general title *Medical gas pipeline systems*:

– *Part 1: Pipeline systems for compressed medical gases and vacuum*

– *Part 2: Anaesthetic gas scavenging disposal systems*

Introduction

Many healthcare facilities use pipeline systems to deliver medical gases and to provide vacuum to areas where they are used in patient care or to power equipment such as ventilators and surgical tools.

This part of ISO 7396 specifies requirements for pipeline systems for gases for medicinal use, medical device gases, gases for driving surgical tools and vacuum. It is intended for use by those persons involved in the design, construction, inspection and operation of healthcare facilities treating human beings. Those persons involved in the design, manufacture and testing of equipment intended to be connected to these pipeline systems should also be aware of the contents of this part of ISO 7396.

This part of ISO 7396 seeks to ensure that medical gas pipelines contain only the specific gas (or vacuum) intended to be supplied. For this reason, gas-specific components are used for terminal units and for other connectors which are intended to be used by the operator. In addition, each system is tested and certified to contain only the specific gas (or vacuum).

The objectives of this part of ISO 7396 are to ensure the following:

a) non-interchangeability between different pipeline systems by design, installation and testing;

b) continuous supply of gases and vacuum at specified quality, pressures and specified flows by providing appropriate sources;

c) use of suitable materials;

d) cleanliness of components;

e) correct installation;

f) provision of monitoring and alarm systems;

g) correct marking of the pipeline system;

h) testing and commissioning;

i) quality of the gases delivered by the pipeline system;

j) correct operational management;

k) safety features of the sources to ensure the quality of the gases according to specification.

The responsibility for the quality of the medical gas supplied via the medical gas pipeline system should be assigned to a nominated person within the healthcare facility. This role would usually be assigned to the Head Pharmacist, who may in turn nominate other responsible person(s) on site to manage the day-to-day requirements.

Where the medical gas is supplied by a third party (in some jurisdictions under licence from the national, regional or local regulatory body), the supplier is responsible for ensuring that the medical gas as delivered meets the relevant specification requirements. In this case, the healthcare facility is responsible under local regulations for ensuring that the product meets the specifications as ordered, that the product administered to patients is not adulterated and complies with specifications and regulations, and that the product manufacturer is informed immediately of any undesirable effects or defects in the quality of the product.

Where the healthcare facility manufactures the gas on site, e.g. for medical air produced by air compressor systems, medical air produced by proportioning systems or oxygen 93 produced by oxygen concentrator systems, the healthcare facility is responsible for all aspects of the medical gas quality.

NOTE Vacuum is also the responsibility of the healthcare facility.

Annex G provides guidance for the assignment of responsibility for production and quality control of the gases and vacuum.

National, regional or local regulatory bodies may require the manufacture of medical gases on the healthcare facility site to be licenced.

Annexes G and K provide some guidance as to how the quality of the gas should be managed to maintain patient safety at the highest level.

Annex H contains rationale statements for some of the requirements of this part of ISO 7396. It is included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated into this part of ISO 7396. The clauses and subclauses marked with (*) after their number have a corresponding rationale in Annex H.