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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

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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).

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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.

Medical gas pipeline systems —

Part 1:
Pipeline systems for compressed medical gases and vacuum

1 (*) Scope

This part of ISO 7396 specifies requirements for design, installation, function, performance, testing, commissioning and documentation of pipeline systems used in healthcare facilities for the following:

— oxygen;

— nitrous oxide;

— medical air;

— carbon dioxide;

— oxygen/nitrous oxide mixtures (see Note 1);

— helium/oxygen mixtures;

— (*) oxygen 93;

— gases and gas mixtures classified as medical device, gases delivered to medical devices or intended for medical purposes or gases and gas mixtures for medicinal use not specified above;

— air for driving surgical tools;

— nitrogen for driving surgical tools;

— vacuum.

NOTE 1 Regional or national regulations may prohibit the distribution of oxygen/nitrous oxide mixtures in medical gas pipeline systems.

NOTE 2 Anaesthetic gas scavenging disposal systems are covered in ISO 7396-2.

This part of ISO 7396 includes requirements for supply systems, pipeline distribution systems, control systems, monitoring and alarm systems and non-interchangeability between components of different gas/vacuum systems.

This part of ISO 7396 specifies safety requirements for pipeline systems used in healthcare facilities, both public and private. It applies to all facilities providing healthcare services regardless of type, size, location or range of services, including, but not limited to:

a) acute care healthcare facilities;

b) internal patient continuing care healthcare facilities;

c) long-term care facilities;

d) community-based providers;

e) ambulatory and external patient care clinics (e.g. day surgery, endoscopy clinics and doctors' offices).

NOTE 3 This part of ISO 7396 may also be used as reference for pipeline systems for medical gases and vacuum intended to be installed in places other than healthcare facilities.

This part of ISO 7396 applies to the following different types of oxygen supply systems:

— supply systems in which all sources of supply deliver oxygen; in this case the concentration of the oxygen will be greater than 99%;

— supply systems in which all sources of supply deliver oxygen 93; in this case the concentration of the oxygen may vary between 90% and 96%;

NOTE 4 A mixture of oxygen 93 and oxygen may be delivered by a medical gas supply system. In this case the concentration of the gas can vary between 90% and >99%.

This part of ISO 7396 also applies to:

— extensions of existing pipeline distribution systems;

— modifications of existing pipeline distribution systems;

— modifications or replacement of supply systems or sources of supply.

Oxygen concentrators for domiciliary use are excluded from the scope of this part of ISO 7396.

NOTE 5 Requirements for oxygen concentrators for domiciliary use are specified in ISO 80601-2-69.

(*) EN 14931 defines additional requirements for hyperbaric application, in particular for flows and pressures of compressed air required to pressurize the hyperbaric chamber and to drive other connected services. Also included are requirements for oxygen and other treatment gases administered to patients.

This part of ISO 7396 does not apply to vacuum systems intended to be used in dentistry.

This part of ISO 7396 does not apply to filling systems for transportable cylinders and transportable cylinder bundle systems.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE Additional references are listed in the Bibliography.

ISO 3746:2010, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Survey method using an enveloping measurement surface over a reflecting plane*

ISO 5359:2014, *Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases*

ISO 8573-1:2010, *Compressed air — Part 1: Contaminants and purity classes*

ISO 9170-1:2008, *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum*

ISO 10524-2:2005, *Pressure regulators for use with medical gases — Part 2: Manifold and line pressure regulators*

ISO 11197:2004, *Medical supply units*

ISO 14644-1:1999, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness*

ISO 14971:2007, *Medical devices — Application of risk management to medical devices*

ISO 15001:2010, *Anaesthetic and respiratory equipment — Compatibility with oxygen*

ISO 17672:2010, *Brazing — Filler metals*

ISO 18082:2014, *Anaesthetic and respiratory equipment — Dimensions of non-interchangeable screw-threaded (NIST) low-pressure connectors for medical gases*

ISO 21969:2009, *High-pressure flexible connections for use with medical gas systems*

ISO 29463-1:2011, *High-efficiency filters and filter media for removing particles in air — Part 1: Classification, performance testing and marking*

ISO 80601-2-69:2014, *Medical electrical equipment — Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment*

IEC 60601-1-8:2006, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

EN 286-1:1998, *Simple unfired pressure vessels designed to contain air or nitrogen — Part 1: Pressure vessels for general purposes*

EN 1041:2008, *Information supplied by the manufacturer of medical devices*

EN 1254-1:1998, *Copper and copper alloys - Plumbing fittings - Fittings with ends for capillary soldering or capillary brazing to copper tubes*

EN 1254-4:1998, *Copper and copper alloys - Plumbing fittings - Fittings combining other end connections with capillary or compression ends*

EN 13348:2008, *Copper and copper alloys — Seamless, round copper tubes for medical gases or vacuum*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
air compressor system
supply system with compressor(s) designed to provide medical air or air for driving surgical tools or both

3.2
air for driving surgical tools
natural or synthetic mixture of gases, mainly composed of oxygen and nitrogen in specified proportions, with defined limits for the concentration of contaminants, supplied by a medical gas pipeline system and intended for driving surgical tools

Note 1 to entry: Different names or symbols are used for air for driving surgical tools, such as instrument air, surgical air, air motor, air - 700 and air - 800.

3.3
audio paused
state of limited duration in which the alarm system or part of the alarm system does not generate an auditory alarm signal

Note 1 to entry: This is sometimes referred to as silencing.

[SOURCE: IEC 60601-1-8]

3.4
booster compressor
compressor used to raise an elevated pressure to a higher pressure

Note 1 to entry: As used herein, the term applies to compressors used to fill high-pressure reservoir(s).

3.5
branch
portion of the pipeline distribution system which supplies one or more areas on the same floor of the facility

3.6
commissioning
proof of function to verify that the agreed system specification is met and is accepted by the user or the user's representative

3.7
control equipment
items necessary to maintain the medical gas pipeline system within the specified operating parameters

Note 1 to entry: Examples of control equipment are pressure regulators, pressure-relief valves, sensors, manual or automatic valves and non-return valves.

3.8
control system
device or set of devices to manage, command, direct or regulate the behaviour of other device(s) or system(s)

3.9
cryogenic liquid system
supply system containing a gas stored in the liquid state in a vessel at temperatures lower than –150 °C

3.10
cylinder bundle
pack or pallet of cylinders linked together with one or more connectors for filling and emptying

3.11
diversity factor
factor which represents the maximum proportion of terminal units in a defined clinical area which will be used at the same time, at flowrates defined in agreement with the management of the healthcare facility.

3.12
double-stage pipeline distribution system
pipeline distribution system in which gas is initially distributed from the supply system at a pressure higher than the nominal distribution pressure, and is then reduced to the nominal distribution pressure by line pressure regulator(s)

Note 1 to entry: This initial higher pressure is the nominal supply system pressure (see 3.38).

3.13
emergency clinical alarm
alarm to indicate to medical and technical staff that there is a deviation from a monitored parameter which requires an immediate response

3.14
emergency inlet point
inlet point which allows the connection of an emergency supply

3.15
emergency operating alarm
alarm to indicate to technical staff that there is a deviation from a monitored parameter which requires an immediate response

3.16
emergency supply
source of supply intended to be connected to an emergency inlet point

3.17
gas-specific
having characteristics which prevent connections between different gas services or vacuum services

3.18
gas-specific connector
connector with dimensional characteristics which prevent connections between different gas services

Note 1 to entry: Examples of gas-specific connectors are quick connectors, screw-threaded connectors, diameter-indexed safety system (DISS) connectors, non-interchangeable screw-threaded (NIST) connectors and sleeve indexed system (SIS) connectors.

3.19
gas for medicinal use
gas or mixture of gases having properties for treating or preventing disease in human beings which may be used in or administered either with a view to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action, or to make a medical diagnosis

Note 1 to entry: This is also sometimes referred to as medicinal gas.

Note 2 to entry: In Europe this is classified as a medicinal product in accordance with Directive 2001/83/EC.

3.20
medical device gas
gas or mixture of gases intended by the manufacturer to be used for human beings for the purpose of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease;

— investigation, replacement or modification of the anatomy or of a physiological process;

— control of conception;

and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

Note 1 to entry: In Europe these gases are classified as a medical device in accordance with Directive 93/42/EEC.

3.21
healthcare facility
hospital, clinic or similar facility that provides patients with their healthcare needs

3.22
high-dependency patient
patient with a continual need of a medical gas/vacuum supply, who will be adversely affected by a medical gas/vacuum supply failure to such a degree that his/her clinical condition or safety can be compromised

3.23
high pressure
pressures greater than 3 000 kPa

[SOURCE: ISO 15001:2010]

3.24
high-pressure reservoir
permanently installed container(s) with nominal working pressures ranging from 3 000 kPa to 25 000 kPa at 15 °C

3.25
information signal
signal that is not an alarm signal or a reminder signal

3.26
line pressure regulator
pressure regulator used in a double-stage pipeline distribution system to reduce the nominal supply system pressure to the nominal distribution pressure

3.27
low-pressure hose assembly
assembly consisting of a flexible hose with permanently attached gas-specific inlet and outlet connectors and designed to conduct a medical gas at pressures less than 1 400 kPa

3.28
main line
portion of the pipeline distribution system connecting the supply system to risers and/or branches

3.29
maintenance supply assembly
inlet point which allows the connection of a maintenance supply

3.30
maintenance supply
source of supply intended to supply the system during maintenance

3.31
manifold
device for connecting the outlet(s) of one or more cylinders, cylinder bundles or high-pressure reservoir(s) of the same gas to the pipeline system

3.32
manifold pressure regulator
pressure regulator intended to be installed within sources of supply containing cylinders, cylinder bundles, or high-pressure reservoir(s)

3.33
manufacturer
natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party

3.34
maximum distribution pressure
pressure at any terminal unit when the pipeline system is operating at zero flow

3.35
medical air
natural or synthetic mixture of gases, mainly composed of oxygen and nitrogen in specified proportions, with defined limits for the concentration of contaminants, supplied by a medical gas pipeline system and intended for administration to patients

Note 1 to entry: Medical air may be produced by supply systems with air compressors or by supply systems with proportioning units. Medical air produced by air compressor systems is called “medicinal air”, and medical air produced by proportioning systems is called “synthetic medicinal air” by the European Pharmacopoeia.

3.36
medical gas pipeline system
complete system which comprises a supply system, a monitoring and alarm system and a distribution system with terminal units at the points where medical gases or vacuum are required

3.37
minimum distribution pressure
lowest pressure occurring at any terminal unit when the pipeline system is operating at the system design flow

3.38
nominal distribution pressure
pressure which the medical gas pipeline system is intended to deliver at the terminal units

3.39
nominal supply system pressure
pressure which the supply system is intended to deliver at the inlet to the line pressure regulators

3.40
non-cryogenic liquid system
supply system containing a gas stored under pressure in the liquid state in a vessel at temperatures not lower than −50 °C

3.41
non-return valve
valve which permits flow in one direction only

3.42
operating alarm
alarm to indicate to technical staff that it is necessary to replenish the gas supply or to correct a malfunction

3.43
oxygen concentrator supply system
supply system containing one or more oxygen concentrator units

3.44
oxygen concentrator unit
component of source of supply that produces oxygen 93 from ambient air by extraction of nitrogen

3.45
oxygen
gas for medicinal use where the oxygen concentration is at least the minimum specified in the relevant pharmacopoeial monograph

3.46
oxygen 93
gas produced by an oxygen concentrator unit whose concentration is within the limits specified in the relevant pharmacopoeial monograph

3.47
peak demand
maximum foreseeable gas flowrate required by a healthcare facility

Note 1 to entry: This is commonly expressed in litres per minute.

3.48
pipeline distribution system
portion of a medical gas or vacuum pipeline system linking the sources of supply of the supply system to the terminal units

3.49
pressure regulator
device which reduces the inlet pressure and maintains the set outlet pressure within specified limits

3.50
pressure-relief valve
device intended to relieve excess pressure at a preset pressure

3.51
primary source of supply
portion of the supply system which supplies the pipeline distribution system

3.52
proportioning unit
device in which gases are mixed in a specified ratio

3.53
receiver
permanently installed container(s) designed for vacuum application

Note 1 to entry: See also reservoir (3.56).

3.54
reserve source of supply
that portion of the supply system which supplies the complete, or portion(s) of the, pipeline distribution system in the event of failure or exhaustion of both the primary and secondary sources of supply

3.55
riser
portion of the pipeline distribution system traversing one or more floors and connecting the main line with branch lines on various levels

3.56
reservoir
permanently installed container(s) designed for storing gas at pressures up to 3 000 kPa

Note 1 to entry: See also receiver (3.53).

3.57
safety
freedom from unacceptable risk

3.58
secondary source of supply
portion of the supply system which supplies the pipeline distribution system in the event of exhaustion or failure of the primary source of supply

3.59
shut-off valve
valve which prevents flow in both directions when closed

3.60
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

Note 1 to entry: Planned maintenance of equipment is considered a normal condition.

3.61
single-stage pipeline distribution system
pipeline distribution system in which gas is distributed from the supply system at the nominal distribution pressure

3.62
source of supply
portion of the supply system with associated control equipment which supplies the pipeline distribution system

3.63
supply pressure regulator
pressure regulator fitted within a source of supply and intended to regulate the pressure supplied to the line pressure regulator(s)

Note 1 to entry: For a source of supply with cylinders, cylinder bundles or high-pressure reservoir(s), this is referred to as the manifold pressure regulator.

3.64
supply system
assembly which supplies the pipeline distribution system and which includes all sources of supply

3.65
system design flow
flow calculated from the maximum flow requirement of the healthcare facility and corrected by the diversity factor(s)

3.66
terminal unit
outlet assembly (inlet for vacuum) in a medical gas pipeline system at which the operator makes connections and disconnections

3.67
uninterruptible power system
UPS
combination of convertors, switches and energy storage devices (such as batteries), constituting a power system for maintaining continuity of load power in case of input power failure

Note 1 to entry: Healthcare facility emergency electrical power supply may not ensure continuity of supply.

3.68
vacuum supply system
supply system equipped with vacuum pumps designed to provide a flow at negative pressure

4 General requirements

4.1 (*) Safety

Medical gas pipeline systems shall, when installed, extended, modified, commissioned, operated and maintained according to the instructions of the manufacturer, present no risks with an unacceptable level under normal condition and in single fault condition.

NOTE 1 A situation in which a fault is not detected is considered a normal condition. Fault conditions/hazardous situations can remain undetected over a period of time and as a consequence can lead to an unacceptable risk. In that case a fault condition subsequently detected needs to be considered as a single fault condition. Specific risk control measures to deal with such situations need to be determined within the risk management process.

NOTE 2 Typical safety hazards (including discontinuity of supply, incorrect pressure and/or flow, wrong gas supply, wrong gas composition, contamination, leakage, fire) are listed in Annex F.

Supply systems and alarm systems should be designed and manufactured to:

a) minimize the risk arising from emitted electromagnetic fields which could disturb other equipment and medical devices used within the healthcare facility and

b) have the appropriate level of electromagnetic immunity to operate safely within the electromagnetic environment of healthcare facilities

National or regional regulations may exist. IEC 60601-1-2 may apply to equipment classified as medical devices.

NOTE 3 Loss of mains electrical power or water supply is a single fault condition. A fault in control equipment is a single fault condition.

Measures should be taken to minimize electrical and mechanical hazards. National or regional regulations concerning such hazards may exist.

NOTE 4 Planned maintenance of equipment is considered a normal condition.

4.2 (*) Alternative construction

Supply system, monitoring and alarm systems, pipeline distribution systems and components, or parts thereof, using materials or having forms of construction different from those detailed in this part of ISO 7396, shall be presumed to be in compliance with the safety objectives of this part of ISO 7396 if it can be demonstrated that at least an equivalent degree of safety is obtained (i.e. compliance with requirements presumes that risks have been mitigated to acceptable levels) unless objective evidence to the contrary becomes available.

NOTE 1 Objective evidence may be obtained by post-market surveillance.

Evidence of at least an equivalent degree of safety shall be provided by the manufacturer.

NOTE 2 Regional or national regulations may require the provision of evidence to a competent authority or a conformity assessment body, e.g. to a notified body in the European Economic Area (EEA) upon request.

4.3 Materials

4.3.1 (*) The manufacturer shall disclose, upon request, evidence of the corrosion resistance of materials used in components for the actual gas.

NOTE Corrosion resistance includes resistance against the influence of moisture and the surrounding materials.

4.3.2 (*) The manufacturer shall disclose, upon request, evidence that the materials used in components of the medical gas pipeline system which come into contact with the actual gas are compatible with the actual gas and oxygen under normal and single fault conditions. If lubricants are used, except within air compressors and vacuum pumps, they shall be compatible with the actual gas and oxygen during normal and single fault condition of the pipeline system. See 4.3.6.

Evidence shall be provided by the manufacturer.

NOTE 1 Criteria for the selection of metallic and non-metallic materials are given in ISO 15001, ISO 11114-1 and ISO 11114-2.

NOTE 2 Regional or national regulations may require the provision of evidence to a competent authority or a conformity assessment body upon request.

NOTE 3 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 high concentrations of oxygen, particularly under pressure. Similarly, materials which can be ignited in air require less energy to ignite in oxygen. Less energy is required as the pressure increases. Many such materials can be ignited by friction at a valve seat or by adiabatic compression produced when oxygen at high pressure is rapidly introduced into a system initially at low pressure.

4.3.3 The specific hazards of toxic products from abnormal heating, combustion or decomposition of non- metallic materials (including lubricants, if used) and potential contaminants shall be addressed.

Annex E of ISO 15001:2010 gives details of suitable test and quantitative analysis methods for the products of combustion of non-metallic materials. Data from such tests shall be considered in any risk evaluation.

NOTE 1 Some potential products of combustion and/or decomposition for some commonly available non-metallic materials are listed in Table D.7 of ISO 15001:2010.

NOTE 2 See Annex I, Rationale for compressor hazards.

4.3.4 **(*)** Components of systems which can be exposed to cylinder pressure in normal or single fault condition shall function according to their specifications after being exposed to a pressure of 1,5 times the cylinder working pressure for 5 min.

Evidence shall be provided by the manufacturer.

NOTE Regional or national regulations may require the provision of evidence to a notified body or competent authority upon request.

4.3.5 **(*)** Components of systems which can be exposed to pressure greater than 3 000 kPa in normal or single fault condition shall not ignite or show internal scorching damage when submitted to oxygen pressure shocks. The test for resistance to ignition shall be in accordance with ISO 10524-2:2005.

Evidence shall be provided by the manufacturer.

NOTE Regional or national regulations may require the provision of evidence to a notified body or competent authority upon request.

4.3.6 (*) Except for low-pressure hose assemblies and low-pressure flexible connections, metallic materials shall be used for compressed medical gas pipelines. If copper pipes of ≤ 133 mm diameter are used for pipelines, they shall comply with EN 13348. Copper pipes of >133 mm diameter and pipes of materials other than copper which are used for compressed medical gases shall comply with all applicable requirements of EN 13348 (in particular the requirements concerning cleanliness, marking and packaging) or equivalent national standards. If non-metallic materials are used for vacuum pipelines, these materials shall be compatible with the potential contaminants that can be present in the vacuum system.

NOTE 1 Regional or national regulations may require the provision of evidence to a notified body or competent authority upon request.

NOTE 2 Copper is the preferred material for all medical gas pipelines. For vacuum, copper and plastic tubes are in common use.

4.3.7 Components of the system other than pipes, which are liable to come in contact with the actual gas, shall meet the cleanliness requirements of ISO 15001:2010.

NOTE Examples of cleaning procedures are described in ISO 15001:2010.

4.3.8 **(*)** Materials for pipelines and components installed in the vicinity of strong magnetic or electromagnetic fields [e.g. Nuclear Magnetic Resonance (NMR), Magnetic Resonance Imaging (MRI)] shall be selected for compatibility with these applications.

4.4 System design

4.4.1 General

At the time of project design, the management of the healthcare facility, in consultation with the system manufacturer, shall determine essential characteristics for system construction, which should include at least:

— the type of sources of supply:

— the location of the sources of supply;

— the flow and storage capacity of the sources of supply;

— the number of terminal units per bed-space/work-space;

— the location of terminal units in each department or area of the healthcare facility;

— the corresponding flow rate at each terminal unit;

— the diversity factors;

— the location and elevation of area shut-off valves;

— the need of additional local sources of supply in designated departments (e.g. in departments where high-dependency patients are treated, an independent vacuum unit or an independent source(s) of oxygen or oxygen 93, and medical air in case of a catastrophic event).

NOTE 1 Regional or national regulations applying to the number of cylinders or quantity of gas within each department may exist.

NOTE 2 Typical examples of locations of terminal units, flow requirements and diversity factors are given in HTM 02 [33], [34], FD S 90-155 [32], AS 2896-1998 [22] and SIS/HB 370 [38].

The sizing of the pipelines shall take into account the potential hazards arising from high gas velocity.

NOTE 3 Examples of maximum recommended gas velocity are given in FD S 90-155 [32] and SIS/HB 370 [38].

4.4.2 Extensions and modifications of existing pipeline systems

Extensions and modifications of existing pipeline systems (including extensions and modifications of existing sources of supply) shall comply with the relevant requirements of this part of ISO 7396. In addition, the following requirements shall apply:

NOTE Typical examples of locations of terminal units, flow requirements and diversity factors are given in HTM 02-01 [33], [34], FD S 90-155 [32], AS 2896-1998 [22] and SIS/HB 370 [38].

a) the flow capacity of the supply system shall continue to meet the flow requirements of the extended or modified pipeline system. For this purpose, the existing supply system might need to be upgraded;

b) the flow, nominal distribution pressure and pressure drop characteristics of the existing pipeline distribution system shall continue to meet at least the original design specifications;

c) the flow, nominal distribution pressure and pressure drop characteristics of the extension or modification to the existing pipeline distribution system shall meet the requirements of 7.2. For this purpose, modifications of the existing pipeline distribution system might be needed;

d) When extensions or modification are required, the design characteristics of the existing piping systems shall continue to meet at least the original design characteristics.

5 Supply systems

5.1 System components

5.1.1 Except for air or nitrogen for driving surgical tools, each supply system shall comprise at least three independent sources of supply which may be a combination of the following:

a) gas in cylinders, cylinder bundles or high-pressure reservoir(s);

b) non-cryogenic liquid in cylinders;

c) cryogenic or non-cryogenic liquid in mobile vessels;

d) cryogenic or non-cryogenic liquid in stationary vessels;

e) an air compressor unit;

f) a proportioning unit;

g) an oxygen concentrator unit.

5.1.2 A supply system for air or nitrogen for driving surgical tools shall comprise at least two sources of supply.

5.1.3 A supply system for vacuum shall consist of at least three vacuum pumps.

5.1.4 Schematic representations of typical supply systems are given in Annex A (Figures A.1 to A.21).

5.2 General requirements

5.2.1 Capacity and storage

The capacity and storage of any supply system shall be based on the estimated flow profile, usage and frequency of delivery. The location and the capacity of the primary, secondary and reserve sources of supply of all supply systems and the number of full cylinders and cylinder bundles held in storage, as defined by the management of the healthcare facility in consultation with the gas supplier using risk management principles, shall be taken into account by the system manufacturer. Cylinders and cylinder bundles should be maintained in a safe, secured location and clean condition.

Portable equipment, cylinders and cylinder bundles shall be stored under cover and protected from adverse weather conditions, to ensure that they are kept clean until the point of use inside the healthcare facility.

5.2.2 Continuity of supply

5.2.2.1 **(*)** The supply systems for compressed medical gases and vacuum shall be designed to achieve continuity of system design flow at a distribution pressure complying with 7.2 in normal condition and in single fault condition.

NOTE Loss of mains electrical power or water supply is a single fault condition. A fault in control equipment is a single fault condition.

In order to achieve this objective,

a) the supply systems for compressed medical gases and vacuum shall comprise at least three sources of supply (i.e. primary source of supply, secondary source of supply and reserve source of supply), and

b) the layout and the location of the pipelines shall reduce the risk of mechanical damage of the pipeline to an acceptable level.

Damage to the pipeline is considered a catastrophic event and not a single fault condition, and shall be managed in accordance with the emergency procedure (see G.5.3).

5.2.2.2 Control equipment shall be designed to allow maintenance without interrupting the gas/vacuum supply.

5.2.2.3 Where the continuity of supply is not a requirement, application of risk management procedures in accordance with ISO 14971 and in concurrence with the healthcare facility management system shall be performed and documented by the healthcare facility (see Annex G).

The manufacturer shall provide the documentation thereof, validated by the healthcare facility, on request

5.2.3 Primary source of supply

The primary source of supply shall be permanently connected and shall be the main source of supply to the pipeline.

5.2.4 Secondary source of supply

The secondary source of supply shall be permanently connected and shall automatically supply the pipeline in the event that the primary source of supply is unable to supply the pipeline.

5.2.5 Reserve source(s) of supply

The reserve source(s) of supply shall be permanently connected to the pipeline distribution system. The activation of the reserve source(s) of supply, in the event of both the primary and the secondary sources of supply being unavailable, may be automatic or manual but shall ensure continuity of supply to the pipeline.

The activation of the reserve source(s) of supply depends upon the type of component of the sources of supply:

a) if all sources of supply are with gas in cryogenic vessels, cylinders or cylinder bundles, then the activation may be manual or automatic;

b) if the primary and the secondary sources of supply are dependent upon the electrical power supply, then the activation shall be automatic;

c) if all sources of supply are dependent upon the electrical power supply, then the connection of the reserve source(s) of supply to the emergency electrical power supply shall be automatic and the subsequent activation shall be automatic.

The manufacturer together with the healthcare facility management, on the basis of risk management procedures in accordance with ISO 14971 shall determine:

a) whether it is acceptable for the reserve source(s) of supply to be dependent on an electrical supply;

If an air compressor unit, a proportioning unit or an oxygen concentrator unit is used as a reserve source of supply, the design of the supply system and the emergency electrical supply should take into consideration the time required to start the reserve source(s) of supply and obtain the specified quality of the gas supplied to the pipeline distribution system.

b) the size of the reserve source(s) of supply such that the system design flow may be supplied continuously when both the primary and secondary sources of supply are unavailable;

c) the location of the reserve source(s) of supply in order to supply the complete pipeline system and whether to provide for more than a single reserve source of supply;

d) the location of the reserve source(s) of supply which should be such as to allow access to and use of at least the reserve source(s) of supply in case of fire inside the room(s) housing the primary and secondary sources of supply;

NOTE Risk management procedures may consider the need to have separate locations for the reserve source(s) of supply.

e) whether to provide reserve source(s) of supply for air or nitrogen for driving surgical tools.

5.2.6 Means of pressure relief

5.2.6.1 Venting outdoors is not required for air. For all other compressed medical gases the location of the vents of the pressure-relief valves shall be determined in consultation with the healthcare facility management using risk management principles. If the vents are located outside of the building, the vents shall be provided with means to prevent the ingress of, for example, insects, debris and water and be located remote from any air intakes, doors, windows or other openings in buildings. Consideration shall be given to the potential effects of prevailing winds on the location of the vents.

5.2.6.2 All pressure-relief valves shall close automatically when excess pressure has been released.

5.2.6.3 It shall not be possible to isolate a means of pressure relief, for example by a shut-off valve, from the pipeline or the pressure regulator or other components to which it is connected. If a valve or a flow-limiting device is incorporated for maintenance, it shall be fully opened by the insertion of the means of pressure relief.

NOTE Attention is drawn to regional, national and international standards for pressure-relief valves, e.g. ISO 4126-1 [3].

5.2.6.4 Means shall be provided to protect the pressure-relief valve from tampering.

5.2.6.5 Any portion of a pipeline within a supply system where gas in liquid phase can be entrapped between two shut-off valves shall be provided with means to relieve excess pressure resulting from vaporization of the liquid.

5.2.6.6 If a pressure-relief valve is removed, e.g. for maintenance, the pipeline shall be protected from overpressure by another means of pressure relief.

5.2.6.7 Pressure-relief valves shall comply with the supply system manufacturer's design specifications, taking into account that national or regional regulations may exist. Evidence shall be made available by the manufacturer upon request.

5.2.7 Maintenance supply assembly

5.2.7.1 Except for pipelines for vacuum and air or nitrogen for driving surgical tools, one or more maintenance supply assemblies shall be provided downstream of the main shut-off valve(s).

5.2.7.2 The manufacturer together with the healthcare facility management shall determine the location of each maintenance supply assembly.

The location of each maintenance supply assembly should be such as to allow the supply of gas to the pipeline in case of fire inside the room(s) of the sources of supply. Risk management procedures should consider the need for multiple maintenance supply assemblies.

Each maintenance supply assembly should be located outside of the area of the supply system and should allow access by vehicles.

5.2.7.3 The maintenance supply assembly shall have a gas-specific inlet connector, a means of pressure relief, a non-return valve and a shut-off valve. The design of the supply assembly shall take into account the flow which can be required under maintenance conditions. The supply assembly shall be physically protected to prevent tampering and unauthorized access.

5.2.8 Pressure regulators

For single-stage pipeline distribution systems, the pressure regulators within the supply systems shall be capable of controlling pipeline pressure at levels which meet the requirements specified in 7.2.1, Table 2, 7.2.2 and 7.2.3.

5.2.9 (*)Ozone Sterilizers

Ozone sterilizers shall not be connected to the oxygen/oxygen 93 pipeline system in order to prevent backflow into the oxygen/oxygen 93 pipeline system.

5.3 Supply systems with cylinders, cylinder bundles or high-pressure reservoir(s)

5.3.1 A supply system with cylinders, cylinder bundles or high-pressure reservoir(s) shall comprise:

a) a primary source of supply which supplies the pipeline;

b) a secondary source of supply which shall automatically supply the pipeline when the primary source of supply becomes exhausted or fails;

c) a reserve source of supply (except for air or nitrogen for driving surgical tools).

Except for air and nitrogen for driving surgical tools, the supply system with cylinders, cylinder bundles or high-pressure reservoir(s) shall be such that the system design flow can be supplied with any two sources of supply out of service.

5.3.2 The primary and secondary sources of supply which alternately supply the pipeline shall each consist of one bank of cylinders, cylinder bundles or high-pressure reservoir(s). When an exhausted bank of cylinders, cylinder bundles or high-pressure reservoir(s) is replaced, it shall be possible to reset the automatic changeover. Each bank shall have its cylinders, cylinder bundles or high-pressure reservoir(s) connected to a manifold with its own pressure regulator. Except for air, vent valves shall be vented outside of the building.

5.3.3 Except for banks with only one cylinder, cylinder bundle or high-pressure reservoir, a non-return valve shall be installed at the manifold end of each flexible connection between the cylinder, cylinder bundles or high-pressure reservoir(s) and the manifold.

5.3.4 **(*)** The flexible connections between each cylinder or cylinder bundle and the manifold shall comply with ISO 21969. Non-metallic (polymer-lined or rubber-reinforced) flexible hoses shall not be used.

5.3.5 Means shall be provided to individually secure all cylinders located within the supply system to prevent them from falling over. The flexible connections between each cylinder and the manifold shall not be used for this purpose.

5.3.6 All supply systems with cylinders shall comply with 5.2.2.1.

5.3.7 Where the oxygen reserve consists of only one cylinder or cylinder bundle, the manifold shall have at least one additional inlet in order to be able to change the cylinder or cylinder bundle without affecting the continuity of supply.

5.4 Supply systems with cryogenic or non-cryogenic vessels

NOTE Regional or national regulations applying to cryogenic and non-cryogenic vessels may exist.

5.4.1 Except for nitrogen for driving surgical tools, a supply system with cryogenic or non- cryogenic vessels shall consist of one of the following:

a) one cryogenic or non-cryogenic vessel with associated equipment and two banks of cylinders or high-pressure reservoir(s);

b) two cryogenic or non-cryogenic vessels with associated equipment and one bank of cylinders, cylinder bundles or high-pressure reservoir(s);

c) three cryogenic or non-cryogenic vessels with associated equipment.

The sources of supply management procedure (see G.5.8) should take into account the natural vaporization of liquid contained in cryogenic and non-cryogenic vessels.

5.4.2 (*) Where materials subject to cold embrittlement are used downstream of the vaporizer system, means shall be provided to prevent the ingress of cryogenic liquid into the pipeline system and to initiate an alarm when this means is activated.

5.4.3 All supply systems with mobile or stationary cryogenic or non-cryogenic vessels shall comply with 5.2.2.1.

5.4.4 A supply system with mobile or stationary cryogenic or non-cryogenic vessels shall be such that the system design flow can be supplied with any two sources of supply out of service.

5.5 Supply systems for air

5.5.1 General requirements

5.5.1.1 A supply system for medical air or air for driving surgical tools shall be one of the following or a combination thereof:

a) a supply system with cylinders, cylinder bundles or high-pressure reservoir(s) as specified in 5.3;

b) a supply system with air compressor(s) as specified in 5.5.2;

c) a supply system with proportioning unit(s) as specified in 5.5.3.

NOTE Air for driving surgical tools may be supplied from the same sources as medical air.

5.5.1.2 (*) If medical air or air for driving surgical tools is provided for other purposes, such as operation of ceiling columns, anaesthetic gas scavenging systems, breathing air for medical personnel or testing, means shall be provided to prevent backflow into the pipeline. The flow requirements of these applications shall be taken into account by the manufacturer of the system.

5.5.1.3 Medical air and air for driving surgical tools shall not be provided for applications such as general workshop use, motor repair workshop use, spray painting, tyre inflation, reservoirs for pressurization of hydraulic fluids, sterilizing systems and/or pneumatic control of air conditioning. Medical air and air for driving surgical tools shall also not be provided for any other application which can impose unforeseen demands and could compromise the availability and/or quality of air for the intended purposes.

NOTE Such uses could increase service interruptions, reduce service life and introduce contamination.

5.5.1.4 Where the medical air supply system is required to pressurize a hyperbaric chamber, an assessment shall be made to ensure that there is adequate capacity in the source and adequate pipe sizing to meet the total demand.

NOTE EN 14930 provides information about hyperbaric chambers.

5.5.1.5 All supply systems for air shall comply with 5.2.2.1. All compressor units and all proportioning units shall be connected to an emergency electrical power supply.

5.5.2 Supply systems with air compressor(s)

A compressor used in the supply system with air compressors shall not be used in a supply system with oxygen concentrator(s).

5.5.2.1 **(*)** Regional or national regulations applying to medical air produced by a supply system with air compressor(s) may exist. Where such regulations do not exist, medical air produced by a supply system with air compressor(s) shall comply with the following:

a) oxygen concentration ≥ 20,4 % (volume fraction) and ≤ 21,4 % (volume fraction);

b) total oil concentration ≤ 0,1 mg/m^3 measured at ambient pressure;

c) carbon monoxide concentration ≤ 5 ml/m^3;

d) carbon dioxide concentration ≤ 500 ml/m^3;

e) water vapour content ≤ 67 ml/m^3;

f) sulfur dioxide concentration ≤1 ml/m^3;

g) NO + NO2 concentration ≤ 2 ml/m^3.

NOTE 1 Oil can be present as liquid, aerosol and vapour.

NOTE 2 These values are taken from the European Pharmacopoeia monograph for “medicinal air”.

5.5.2.2 (*) Medical air and air for driving surgical tools supplied by compressor systems shall be filtered to maintain the particulate contamination below the following levels:

Maximum number of particles per cubic metre as a function of particle size

From 0,1 µm to 0,5 µm : < 400 000

From 0,5 µm to 1,0 µm : < 6 000

From 1.0 µm to 5.0 µm : < 100

NOTE These values are taken from Table 2, Class 2 of ISO 8573-1:2010.

Evidence of compliance with 5.5.2.2 shall be provided by the manufacturer.

5.5.2.3 If periodic change of the filter element(s) is not scheduled, then means shall be provided to verify the status of filter elements.

Compliance shall be confirmed by inspection.

NOTE Regional or national requirements applying to particulate contamination may exist.

5.5.2.4 **(*)** Regional or national regulations applying to air for driving surgical tools produced by a supply system with air compressor(s) may exist. Where such regulations do not exist, air for driving surgical tools shall comply with the following:

a) total oil concentration ≤ 0,1 mg/m^3 measured at ambient pressure;

b) water vapour content ≤67 ml/m^3.

NOTE 1 Oil can be present as liquid, aerosol and vapour.

NOTE 2 For air for driving surgical tools, a low water vapour content is necessary to prevent the formation of water or ice (from cooling due to adiabatic expansion) which can damage tools.

Consideration should be given to the use of oil-less compressor technologies for producing medical air. See Annex I.

5.5.2.5 A supply system with compressor(s) for medical air shall comprise at least three sources of supply, at least one of which shall be a compressor unit. The supply system shall be such that the system design flow can be supplied continuously with any two sources of supply out of service.

The source of supply shall be one of the following:

a) a compressor unit; or

b) a bank of cylinders, cylinder bundles or high-pressure reservoir(s); or

c) a proportioning unit.

The compressor unit(s) shall be provided with reservoir(s) and conditioning unit(s), as required.

If a supply system includes two or more sources of supply fed from compressor units, at least two conditioning units shall be provided.

Where the medical air supply system consists of three or more compressor units, which can be switched between the different sources of supply to provide adequate capacity, these shall be arranged so that during maintenance on any compressor unit and during a subsequent single fault condition of any component of the system (e.g. the control system), the remaining compressor units and components shall be capable of supplying the system design flow to ensure continuity of supply.

Where the medical air supply system consists of more than two conditioning units which can be switched between the different sources of supply to provide adequate capacity, these shall be arranged so that during maintenance on any conditioning unit and during a subsequent single fault condition of any component of the system (e.g. the control system), the remaining conditioning unit(s) and components shall be capable of supplying the system design flow to ensure continuity of supply of the appropriate product quality.

Each compressor unit shall have an automatic means to prevent backflow through off-cycle units and a shut-off valve to isolate it from the pipeline system and other compressors.

Each compressor unit shall be protected from overheating. Means shall be provided to avoid the release of toxic product into the pipeline in case of overheating (e.g. by shutting off and isolating the affected compressor from the pipeline).

At least one dew-point and one CO alarm sensor shall be fitted to the pipeline system downstream of all conditioning units. Recording capability should be provided.

NOTE 1 Other parameters of the medical air quality may be monitored or recorded. Regional or national regulations may exist.

NOTE 2 A supply system with compressors for medical air typically comprises one of the following:

a) one compressor unit with one reservoir, one conditioning unit and two banks of cylinders, cylinder bundles or high-pressure reservoir(s);

b) two compressor units with at least two reservoirs, two conditioning units and one bank of cylinders, cylinder bundles or high-pressure reservoir(s);

c) three compressor units with two reservoirs and two conditioning units.

NOTE 3 A compressor unit for medical air typically comprises the following:

a) an inlet filter;

b) one or more compressors;

c) an after-cooler with shut-off valve and automatic drain;

d) an oil separator with shut-off valve and automatic drain for oil lubricated compressors;

e) a pressure sensor to ensure that the compressor operates within the range specified by the manufacturer.

NOTE 4 A conditioning unit for medical air typically comprises the following:

a) a dryer with shut-off valves and automatic drain;

b) an adsorber, a catalyst and filter(s) as required to remove contaminants;

c) a dew-point sensor with an alarm and display, fitted to the pipeline system downstream of all conditioning units.

5.5.2.6 If an independent supply system with compressors for air for driving surgical tools is provided, it shall comprise at least two sources of supply, at least one of which shall be a compressor unit.

At least one dew-point alarm sensor shall be fitted to the pipeline system downstream of all conditioning units.

NOTE 1 A supply system with compressors for air for driving surgical tools typically comprises either one compressor unit with one reservoir, one conditioning unit and one bank of cylinders, cylinder bundles or high-pressure reservoir; or two compressor units with one or more reservoirs fitted with a means of bypass and two conditioning units.

NOTE 2 A compressor unit for air for driving surgical tools typically comprises an inlet filter, one or more compressors, an after-cooler with shut-off valve and automatic drain, an oil separator with shut-off valve and automatic drain for oil lubricated compressors, and a pressure sensor to ensure that the compressor operates within the range specified by the manufacturer.

NOTE 3 A conditioning unit for air for driving surgical tools typically comprises a dryer with shut-off valves and automatic drain, filter(s) as required, a dew-point sensor fitted with an alarm and display, connected to the pipeline system downstream of all conditioning units.

5.5.2.7 **(*)** Reservoirs shall

a) comply with EN 286-1 or equivalent national standards, and

b) be fitted with shut-off valve(s), an automatic drain, a pressure gauge and a pressure-relief valve.

5.5.2.8 Each group of reservoirs shall be arranged so as to allow each reservoir in that group to be maintained separately.

NOTE The reservoir(s) may be fitted upstream or downstream of the conditioning unit(s).

5.5.2.9 If two or more conditioning units are fitted, they shall allow the components to be maintained separately.

5.5.2.10 A sample port with a shut-off valve shall be provided immediately downstream of the conditioning system(s).

5.5.2.11 When more than one compressor unit is provided, each compressor shall have a control system arranged so that shutting off, or failure, of one compressor will not affect the operation of other

compressor(s). The control system for multiple compressors shall be arranged so that all the units supply the system in turn or simultaneously. This requirement shall be met in normal condition and in single fault condition.

Each reservoir or group of reservoirs shall be fitted with a means of pressure control, e.g. pressure switch(es) or pressure transducer(s).

Means shall be provided to ensure the continuity of supply following a failure of any control system (if fitted).

5.5.2.12 The inlet of the ambient air for compressors shall be located where there is minimal contamination (e.g. from internal combustion engine exhaust, vehicle parking, access areas, healthcare facility waste and disposal systems, vacuum or plume evacuation system exhausts, vents from medical gas pipeline or anaesthetic gas scavenging systems, ventilation system discharges, chimney outlets).

The inlet shall be provided with means to prevent the ingress of, for example, insects, debris and water. Consideration should be given to the potential effects of prevailing winds on the location of the intake(s) which should be remote from chimney outlets.

Where more than one air supply source is an air compressor, pollution of the intake air is a common mode of failure. This risk should be addressed with risk analysis as required in 5.2.5.

5.5.2.13 A supply system with compressors intended to supply a single-stage pipeline distribution system shall include at least two permanently fitted pressure regulators. The design flow of the pipeline distribution system shall be supplied with at least one pressure regulator isolated for maintenance.

The instructions for use and maintenance shall specify how the permanently fitted pressure regulators are intended to operate.

NOTE The manufacturer may choose between various means of risk control, e.g. automatic switch-over and alarms, manual switch-over and proper emergency procedures, training and local reserve supplies.

5.5.2.14 Means shall be provided to prevent transmission of vibration between each compressor and the pipeline.

5.5.2.15 **(*)** If one of the sources of supply comprises (a) permanently attached high-pressure reservoir(s), it may be replenished using a high-pressure compressor fed from the medical air supply system.

5.5.3 Supply systems with proportioning unit(s)

5.5.3.1 Regional or national regulations applying to medical air produced by proportioning unit(s) may exist. Where such regulations do not exist, medical air produced by proportioning unit(s) shall comply with the following:

a) oxygen content between 95,0 percent to 100 per cent of the nominal value which is between 21,0 percent *V/V* to 22,5 percent *V/V* [≥19,95% (volume fraction) and ≤23,63% (volume fraction)];

b) water vapour content ≤ 67 ml/m^3.

NOTE These values are taken from the European Pharmacopoeia monograph for “synthetic medicinal air”.

5.5.3.2 A supply system with proportioning unit(s) shall comprise of at least three sources of supply, at least one of which shall be a proportioning unit. The supply system shall be such that the system design flow can be supplied with any two sources of supply out of service.

5.5.3.3 A supply system with proportioning units typically consists of one of the following:

a) sources of oxygen and nitrogen, one proportioning unit and two banks of cylinders, cylinder bundles or high-pressure reservoir(s) or air compressor units; or

b) sources of oxygen and nitrogen, two proportioning units and one bank of cylinders, cylinder bundles or high-pressure reservoir(s) or air compressor unit; or

c) sources of oxygen and nitrogen, one proportioning unit, one air compressor unit and one bank of cylinders, cylinder bundles or high-pressure reservoir(s).

The source of oxygen to the proportioning unit shall not be a supply system including an oxygen concentrator.

5.5.3.4 A proportioning unit typically comprises the following:

a) a mixer unit connected to an oxygen and nitrogen source of supply;

b) an automatic shut-off valve controlled by the pressure of the supply gas, a pressure regulator and a non- return valve for each of the supply gases;

c) a process control analyser fitted between the mixer and the reservoir;

d) a medical air reservoir fitted with a pressure-relief valve, a pressure gauge and a means of purging;

e) an automatic shut-off valve fitted to prevent medical air out of specification (see 5.5.3.1) being delivered at the outlet of the supply system.

5.5.3.5 A proportioning source of supply shall consist of at least one proportioning unit. Each proportioning source of supply shall be capable of supplying the design flow.

5.5.3.6 The source(s) of oxygen and nitrogen for proportioning systems shall conform to the requirements of 5.2 and 5.4 and may be the same sources as those supplying the medical gas pipelines separately.

The source of oxygen shall not be an oxygen concentrator.

Means shall be provided to prevent cross-contamination between gases supplying the proportioning unit.

5.5.3.7 A proportioning system shall operate automatically.

The oxygen concentration of the mixture shall be analysed continuously by an oxygen analyser independent from that referred to in 5.5.3.4 c) and fitted on or downstream of the reservoir. Recording capability for oxygen concentration shall be provided. Where the proportioning system consists of more than one proportioning unit, only one independent oxygen analysing system is required.

If the oxygen concentration of the mixture or the pressure supplied to the pipeline distribution system goes out of specification, an emergency operating alarm shall be activated and the proportioning system shall be automatically isolated by closing the shut-off valve fitted to the pipeline. The secondary source of supply shall then automatically supply the pipeline.

The system shall be arranged so that manual intervention is necessary to correct the composition of the mixture before reconnecting the proportioning system to the pipeline system.

Means shall be provided to purge the medical air reservoir.

5.5.3.8 Each oxygen analyser shall ensure an accuracy of ±1% of the measured value. The accuracy shall be specified by the manufacturer

Note 1 National or regional regulations concerning the oxygen analyser may exist.

Note 2 Additional monitoring may be required to show compliance of medical air produced by proportioning unit(s) with national or regional regulations.

5.5.3.9 A proportioning system shall be capable of supplying a mixture of the required composition over the entire range of specified flowrates.

5.5.3.10 A proportioning system shall include means for calibrating the analysing system(s) by reference to mixture(s) of known composition.

5.5.3.11 A sample port with a shut-off valve shall be provided immediately upstream of the main shut-off valve(s).

5.6 Supply systems with oxygen concentrator(s)

5.6.1 General requirements

Compressor units included in supply systems with oxygen concentrators shall be connected to an emergency electrical supply.

Compressor units included in supply systems with oxygen concentrators shall not be used as air compressors for medical air.

NOTE National or regional regulations concerning the use of oxygen 93 may exist.

A supply system with concentrator unit(s) shall comprise of at least three sources of supply, at least one of which shall be a concentrator unit. The supply system shall be such that the system design flow can be supplied with any two sources of supply out of service.

5.6.2 Primary source of supply

The primary source of supply shall include the following:

a) at least an oxygen concentrator unit;

b) at least one oxygen 93 reservoir;

c) a sample port with a shut-off valve immediately downstream of the oxygen 93 reservoir;

d) pressure regulator(s);

e) filter(s) (see 5.6.5.1);

f) means to verify the status of filter element(s) if periodic change of the filter element(s) is not scheduled;

g) oxygen analyser(s).

Compliance of the installation shall be checked by inspection.

5.6.3 Secondary source of supply

If the secondary source of supply consists of an oxygen concentrator, it shall include the same components as the primary source of supply. If the secondary source of supply consists of only cylinders, cylinder bundles or high-pressure oxygen 93 reservoirs, the following requirements apply:

a) the source of supply shall consist of at least one bank of cylinders, cylinder bundles or high-pressure oxygen 93 reservoirs;

b) if there is more than one bank of cylinders, cylinder bundles or high-pressure oxygen 93 reservoirs, gas shall be supplied from one bank of cylinders, cylinder bundles or high-pressure oxygen 93 reservoirs at a time and on depletion of one bank switch automatically to another bank or reservoir.

NOTE This configuration is needed to facilitate replenishment of the secondary source of supply without interruption of supply.

c) the secondary source of supply shall be connected parallel to the primary source of supply.

The determination of how to ensure the continuity of supply shall be made together with the healthcare facility management in accordance with risk management procedures

5.6.4 Reserve source of supply

If the reserve source of supply consists of an oxygen concentrator, it shall include the same components as the secondary source. If the reserve source of supply consists of only cylinders, cylinder bundles or high-pressure oxygen 93 reservoirs, the following requirements apply:

a) the source of supply shall consist of at least one bank of cylinders, cylinder bundles or high-pressure oxygen 93 reservoirs;

b) if there is more than one bank of cylinders, cylinder bundles or high-pressure oxygen 93 reservoirs, gas shall be supplied from one bank of cylinders, cylinder bundles or high-pressure oxygen 93 reservoirs at a time and on depletion of one bank switch automatically to another bank or reservoir.

NOTE This configuration is needed to facilitate replenishment of the reserve source of supply without interruption of supply.

c) the reserve source of supply shall be connected downstream of the oxygen 93 reservoir(s).

5.6.5 Specifications for oxygen 93

5.6.5.1 National or regional regulations which apply to oxygen 93 produced by an oxygen concentrator supply system may exist. Where such regulations do not exist, the oxygen 93 shall comply with the following at system design flow:

a) nominal oxygen concentration 93% +/- 3% V/V;

b) carbon monoxide concentration ≤ 5 ml /m^3;

c) carbon dioxide concentration ≤ 300 ml/m^3;

d) oil concentration ≤ 0,1 mg/m^3 measured at ambient temperature and pressure and corrected to 0°C;

e) water vapour content ≤ 67 ml/m^3;

f) nitrous gases NO/NO_2 concentration ≤2 ml/m^3;

g) sulfur dioxide concentration ≤ 1 ml/m^3.

NOTE 1 These values are taken from the European Pharmacopoeia.

NOTE 2 In accordance with the European and US pharmacopoeias, oxygen 93 is oxygen between 90% and 96%, the balance of the gas being predominantly argon and nitrogen.

NOTE 3 Other terms may be used by national or regional regulations.

5.6.5.2 Oxygen 93 shall be filtered before the supply source shut-off valve to maintain the particulate contamination below the level provided by Table 2, class 2 of ISO 8573-1:2010 (see 5.5.2.2)

5.6.5.3 If periodic change of the filter element(s) is not scheduled, then means shall be provided to verify the status of filter elements.

Evidence shall be provided by the manufacturer.

5.6.5.4 Each concentrator unit included in a supply system shall be capable of supplying a product gas of the required composition over the entire range of specified flow rates.

5.6.6 Oxygen concentrator unit

5.6.6.1 An oxygen concentrator unit consists of:

a) a compressed air supply with at least one air compressor;

b) at least one sieve bed;

c) switching valves as required;

d) at least one CO alarm sensor fitted to the pipeline system downstream of all conditioning units.

NOTE Other parameters of the oxygen 93 quality may be monitored or recorded. Regional or national regulations may exist.

5.6.6.2 An air compressor may be connected to an air reservoir.

5.6.6.3 An air reservoir (if fitted) may be served by more than one compressor.

5.6.6.4 Air reservoirs (if fitted) shall:

a) comply with EN 286-1 or equivalent national standards;

b) be fitted with shut-off valve(s), an automatic drain, a pressure gauge and a pressure-relief valve;

c) be fitted with a means of pressure control, e.g. pressure switch(es) or pressure transducer(s).

Evidence shall be provided by the manufacturer upon request.

5.6.6.5 When waste gases generated during production of oxygen 93 are vented to the outside of the building, the vent(s) shall be provided with means to prevent the ingress of insects, debris and precipitation. The vent(s) shall be located remote from any air intakes, doors, windows or other openings in buildings. Consideration shall be given to the potential effects of prevailing winds on the location of the vents.

Compliance of the installation shall be checked by visual inspection.

5.6.7 Oxygen 93 reservoirs

Each oxygen 93 reservoir or group of oxygen 93 reservoir(s) shall:

a) comply with relevant international, regional or national standards;

b) be fitted with shut-off valve(s), a pressure gauge and a pressure-relief valve;

c) be fitted with a means of pressure control, e.g. pressure switch(es) or pressure transducer(s);

d) be arranged so that each reservoir can be maintained separately.

NOTE An oxygen 93 reservoir may be supplied by more than one oxygen concentrator.

5.6.8 Oxygen analysers

5.6.8.1 An oxygen analyser(s) shall be provided to continuously measure the oxygen concentration from each source of supply incorporating an oxygen concentrator.

Means to display and record oxygen concentration shall be provided.

5.6.8.2 An additional oxygen analyser shall be provided to permit the oxygen concentration of the product gas supplied to the pipeline distribution system to be continuously monitored.

5.6.8.3 Controls shall be provided such that each source of supply incorporating an oxygen concentrator unit shall be automatically isolated from the system if the oxygen concentration of the oxygen 93 produced by that source of supply falls below that specified in 5.6.5 a) taking into account the accuracy of the analysers.

The oxygen analyser and automatic isolating valve on the oxygen 93 reservoir shall be located upstream of the oxygen 93 reservoir.

5.6.8.4 Each oxygen analyser shall be equipped with a low concentration emergency alarm and a high concentration information signal. The setting of the alarm limit(s) shall take into account the accuracy of the analysers. Means shall be provided to prevent unauthorized changes of the alarm setting.

5.6.8.5 Where justified by the specifications of the analyser manufacturer, each oxygen analyser shall include compensation for temperature and barometric pressure variations to ensure an accuracy of within ± 1%. The actual accuracy shall be specified by the manufacturer.

NOTE 1 National or regional regulations concerning the oxygen analyser may exist.

NOTE 2 Additional monitoring may be required to show compliance of oxygen 93 with national or regional regulations.

5.6.8.6 A sample port with a shut-off valve shall be provided immediately upstream of the supply system shut-off valve.

5.6.8.7 A supply system with oxygen concentrators shall include means for calibrating the analysing system(s) by reference to mixture(s) of known composition.

5.6.9 Local filling of permanently attached high-pressure reservoir(s), acting as reserve source of supply

5.6.9.1 Caution shall be taken in filling high-pressure oxygen 93 reservoir(s) as the practice has inherent risks of fire due to the high oxidising capacity of materials, which at ambient pressure are fully compatible with oxygen, but at higher pressures can easily ignite and burn easily in high concentrations of oxygen. These risks may be mitigated by following relevant standards.

5.6.9.2 If oxygen 93 is compressed by a booster compressor into (a) permanently attached high-pressure oxygen 93 reservoir(s), for use as the reserve source of supply the following requirements shall be met:

a) Means shall be provided to ensure that the filling of reserve high-pressure reservoir(s) does not affect delivery of oxygen 93 to the pipeline distribution system.

b) A sample port with a shut-off valve shall be provided adjacent to the filling system.

NOTE Regional or national regulations that apply to the filling system may exist (e.g. Pressure Equipment Directive in Europe).

5.6.9.3 The following safety measures shall be implemented:

a) means (e.g. a non-return valve) to ensure that there is no back flow to the oxygen concentrator supply system;

b) appropriate barrier(s) to protect personnel;

c) in order to ensure safety of patients in the event of temperature build-up, the high-pressure booster compressor shall have a temperature sensor on each compression stage, which may activate an alarm for high temperature thresholds recommended by the manufacturer of the compressor, and may stop the compressor;

d) the following operating alarms shall be provided, set to activate at thresholds as defined by the manufacturer:

—an enclosure temperature sensor;

—an output gas temperature sensor;

—a power sensor;

—a high-pressure sensor.

In the event of actuation of any of these alarms, the compressor unit shall be automatically stopped in order to avoid contamination of the reserve source of supply.

e) a means shall be provided to purge the oxygen 93 high-pressure reservoir.

5.7 Supply systems for vacuum

5.7.1 A supply system for vacuum shall comprise at least three sources of supply, one receiver, two parallel bacterial filters and one drainage trap. A source of supply typically comprises one or more vacuum pumps.

5.7.2 A supply system for vacuum shall be such that the system design flow can be supplied with any two sources of supply out of service.

5.7.3 Where the supply system for vacuum consists of more than three pumps, which can be switched between the different sources of supply to provide adequate capacity, these shall be arranged so that during maintenance on any pump and during a subsequent single fault condition of any component of the system (e.g. the control system), the remaining pumps and components shall be capable of supplying the system design flow to ensure continuity of supply.

NOTE Typical examples of flow requirements are given in HTM 02 [33], [34], FD S 90-155 [32] and AS 2896:1998 [22].

5.7.4 Each pump shall have a control circuit arranged so that shutting off, or failure, of one pump will not affect the operation of other pumps. The controls shall be arranged so that all the pumps supply the system in turn or simultaneously. This requirement shall be met in normal condition and in single fault condition of the control system.

5.7.5 All sources of supply shall be connected to the emergency power supply.

5.7.6 Means shall be provided to ensure correct vacuum to the pipeline system when the mains power is interrupted for a period determined by risk management.

5.7.7 Each receiver shall be fitted with maintenance shut-off valve(s), a drain valve and a vacuum gauge. If only one receiver or one drainage trap is fitted, means of bypass shall be provided. Receivers shall comply with appropriate regional or national standards.

5.7.8 The exhaust(s) from the vacuum pumps shall be piped to the outside and shall be provided with means to prevent the ingress of, for example, insects, debris and water. The exhaust(s) shall be located remote from any air intakes, doors, windows or other openings in buildings. Exhaust locations should be chosen after consideration of the dispersal by prevailing winds of the exhaust plume.

5.7.9 The exhaust line shall be provided with a drain at its lowest point.

5.7.10 If necessary, means shall be provided to prevent the transmission of vibration from the vacuum pumps to the pipeline.

NOTE 1 National or regional regulations regarding noise may exist.

5.7.11 Each bacterial filter shall be rated as HEPA ISO 35H or better under ISO 29463-1 and capable of passing the system design flow under normal operating conditions.

5.7.12 Total filtration capacity shall ensure that the system design flow is sustained at normal operating conditions when at least one bacteria filter is isolated during maintenance, e.g. filter cartridge replacement.

5.7.13 (*) Vacuum supply systems complying with this part of ISO 7396 shall not be used as anaesthetic gas scavenging (AGS) power devices (see ISO 7396-2 [8]).

5.7.14 Vacuum supply systems complying with this part of ISO 7396 shall not be used in dentistry.

5.7.15 Supply systems for vacuum shall comply with 5.2.2.1.

5.8 Location of supply systems

The location of a supply system should be defined by the management of the healthcare facility in consultation with the system supplier, using risk management principles.

5.8.1 Gas and liquefied gas cylinder supply systems shall not be located:

a) in the same room as equipment with electrically driven motors (e.g. air compressors, vacuum pumps, water pumps). An exception may be made for equipment (e.g. fans, blowers) directly ventilating the enclosure and for locations open to the outside without risk of confinement;

b) in the same room as equipment with open flames (e.g. boilers, gas water heaters).

NOTE National or regional regulations may require that air compressors, oxygen concentrators and vacuum supply systems be located in separate technical areas.

5.8.2 (*)The location of supply systems shall take into account potential hazards (e.g. contamination and fires) arising from the location of other equipment or other supply systems within the same room. The location shall be provided with means of fire detection.

Drainage facilities shall be provided for compressor unit(s) and vacuum pump(s).

The ambient temperature in rooms for supply systems shall be maintained in the range of 10°C to 40°C.

Supply systems installed in open air need to be suitable for the environmental conditions to which they will be exposed.

Locations of supply systems which contain gases other than medical air and in which the gas can accumulate shall be provided with an oxygen monitor with an indicator at the entry to warn of oxygen concentrations below 19,5% or above 23,5%. The monitor shall activate an alarm with an auditory and visual signal at the entrance, to warn of oxygen concentrations below 19,5% or above 23,5%.

NOTE 1 National or regional regulations may require monitoring for other gases e.g. CO_2 and N_2O.

NOTE 2 National and regional regulations concerning noise levels may exist. Mechanical equipment (e.g compressors and pumps) may generate noise in excess of 70 dBA.

5.9 Location of cylinder manifolds

The location of cylinder manifolds shall be defined in collaboration with the relevant authorities and in accordance with the relevant national standards. Informative guidelines are given in Annex B.

5.10 Location of stationary cryogenic vessels

The location of stationary cryogenic vessels shall be defined in collaboration with the relevant authorities and the gas supplier and in accordance with the relevant national standards. Informative guidelines are given in Annex B.

6 Monitoring and alarm systems

6.1 General

Monitoring and alarm systems have four different purposes which are fulfilled by operating alarms, emergency operating alarms, emergency clinical alarms and information signals.

a) Operating alarms notify the technical staff that one or more sources of supply within a supply system are no longer available for use and it is essential that action be taken.

b) Emergency operating alarms indicate abnormal pressure within a pipeline or gas quality out of range and could require immediate response by the technical staff.

c) Emergency clinical alarms indicate abnormal pressure within a pipeline and could require immediate response by both the technical and the clinical staff.

d) Information signals indicate any status of the system, with exception of alarms and reminders.

The control panel, the monitoring and the alarm system shall be designed in accordance with IEC 60601-1-8. Except if a single or dual tone is used as an auditory signal, the emergency clinical alarm may be exempt from the auditory requirements of IEC 60601-1-8 (see Table 1).

6.2 Installation requirements

6.2.1 If not specified in this part of ISO 7396, the location of indicator panels shall be determined in consultation with the healthcare facility management using risk management principles.

6.2.2 Monitoring and alarm systems shall comply with the following requirements:

a) the design and location of the indicator panels shall allow continuous observation;

b) an indicator panel displaying all operating alarm signals specified in 6.4 shall be installed in at least one location allowing continual observation or communication;

c) the indicator panel(s) for the emergency clinical alarm signals specified in 6.5 shall be installed in the clinical and critical care areas. An additional panel indicating the area monitored may be installed near the area shut-off valve;

d) an indicator panel displaying all emergency operating alarm signals specified in 6.6 shall be installed at the location of the source(s) of supply;

e) visual indicators shall be provided for each condition monitored and shall be marked according to function;

f) the sensing devices for emergency clinical alarms listed in 6.5 shall be located on the patient side of each area shut-off valve;

g) means shall be provided for testing the activation mechanism and functioning of visual and auditory alarm signals;

h) it shall not be possible to isolate a pressure-sensing device, for example by a manually operated shut-off valve, while it is connected to the pipeline. If a valve is incorporated for maintenance purposes, it shall be opened by the insertion of the sensing device;

i) the operating tolerance on the set point of any pressure-sensing device shall not exceed ± 4 %.

6.2.3 **(*)** Monitoring and alarm systems shall be connected to both the normal and the emergency electrical power supplies and shall be individually electrically protected. Risk assessment shall be performed to determine the advisability of additional batteries or Uninterruptable Power Supplies (UPS).

6.2.4 Alarm systems shall be designed so that an alarm is initiated if there is communication failure between the sensor and the indicator.

6.3 Monitoring and alarm signals

6.3.1 General

The categories and the characteristics of the monitoring and alarm signals shall comply with Table 1.

6.3.2 Auditory signals

6.3.2.1 All other auditory signals shall comprise one or two tones modulated equally, e.g. at a rate of 4 Hz between two tones of 440 Hz and 880 Hz. The A-weighted sound pressure level of the auditory components of these alarm signals at minimum volume shall be at least 2 dB above a white background level of 55 dB when tested in accordance with ISO 3746.

6.3.2.2 If an auditory alarm signal can be audio paused by the operator, the audio pausing shall not prevent the auditory signal from being activated by a new alarm condition.

6.3.2.3 **(*)** If an emergency auditory alarm signal can be audio paused by the operator, the period of audio pausing shall not exceed 15 min.

6.3.2.4 If means to disable the auditory signal are provided, such means shall only be accessible to authorized persons.

6.3.3 Visual signals

6.3.3.1 The indicator colours and the characteristics of visual signals shall comply with Table 1.

6.3.3.2 Visual indications shall be perceived correctly and discriminated between under the following conditions (see IEC 60601-1-8):

a) operator with a visual acuity of 1 (corrected if necessary);

b) viewpoint at a distance of 4 m and at any point within the base of a cone subtended by an angle of 30° to the axis normal to the centre of the plane of display of the visual indication;

c) under an ambient illuminance throughout the range of 100 lx to 1 500 lx.

6.3.4 Emergency and operating alarm characteristics

6.3.4.1 For emergency clinical alarms and emergency operating alarms (see Table 1), there shall be a visual and a simultaneous auditory signal.

6.3.4.2 For operating alarms (see Table 1), there shall be at least a visual signal.

6.3.4.3 When the condition which has caused the alarm has cleared, the auditory signal and the visual signal shall reset automatically or by deliberate operator action.

Table 1 — Alarm categories and signal characteristics

Category	Operator response	Indicator colour	Visual signal	Auditory signal
Emergency clinical alarm	Immediate response to deal with a hazardous situation	Complying with IEC 60601-1-8	Complying with IEC 60601-1-8	Complying with IEC 60601-1-8 [a]
Emergency operating alarm	Immediate response to deal with a hazardous situation	Red	Flashing [b]	Yes
Operating alarm	Prompt response to a hazardous situation	Yellow	Flashing [b]	Optional
Information signal	Awareness of normal status	Not red Not yellow	Constant	No

[a] If a pattern of more than two tones or frequencies is used.

[b] Visual flashing frequencies for operating alarms and emergency operating alarms should be between 0,4 Hz and 2,8 Hz with a duty cycle between 20 % and 60 %.

6.3.5 Information signals

Information signals shall be provided to indicate normal status and shall consist of a visual signal (see Table 1).

6.3.6 Remote alarm extensions

If a remote alarm extension is provided, it shall be arranged so that a failure in the external circuit will not affect the correct functioning of the main alarm.

6.4 Provision of operating alarms

Operating alarm signals shall be provided to indicate the following:

a) change-over from primary to secondary cylinder supplies;

b) any primary, secondary or reserve cylinder supply below minimum pressure or content;

NOTE For nitrous oxide and carbon dioxide cylinders, pressure might not indicate the content.

c) pressure in any cryogenic vessel below the minimum specified by the management of the healthcare facility in consultation with the gas supplier;

d) liquid level in any cryogenic vessel below the minimum specified by the management of the healthcare facility in consultation with the gas supplier;

e) malfunctioning of an air compressor system;

NOTE The compressor overheating alarm threshold is defined by the compressor manufacturer.

f) for air supplied by a compressor system, water vapour content above the level specified in 5.5.2.1 or 5.5.2.4;

g) for medical air supplied from a compressor system and oxygen 93 supplied from a concentrator system, when the CO level exceeds 10 ppm or a lower limit where regional or local regulation specifies a lower value.

5 ppm V/V is the value specified in the European Pharmacopoeia Medicinal Air monograph. 0.001% V/V (10 ppm V/V) is the limit value specified in the USP Medicinal Air monograph. In areas where intermittent high levels of atmospheric CO are present (e.g., near a busy highway), healthcare facilities should consider installing a treatment system to remove CO from the compressed medical air supply.

To reduce transient nuisance alarms the value of 10 ppm V/V was selected based on North American experience with these monitors.

Additional operating alarms may be required by regional or national regulations e.g. for air supplied by a compressor system or oxygen 93 supplied from a concentrator system.

NOTE This could include e.g. monitoring of concentration of O_2, CO, CO_2, NO, NO_2 and oil.

h) malfunctioning of a proportioning system;

i) malfunctioning of a cryogenic system;

j) malfunctioning of a vacuum system;

k) malfunctioning of a supply system for oxygen 93;

l) malfunctioning of a supply system with an oxygen concentrator;

m) reserve source of supply in use;

n) content of reserve source of supply below 50% of capacity for compressed gas(es) in cylinders (e.g. oxygen, air, nitrogen) or less than 40 bar for liquefied gas(es) in cylinders (e.g. nitrous oxide and carbon dioxide);

o) failure of external power supply.

6.5 Provision of emergency clinical alarms

Emergency clinical alarm signals shall be provided to indicate the following:

a) deviation of the pipeline pressure downstream of any area shut-off valve by more than ± 20 % from the nominal distribution pressure;

b) an increase of pipeline pressure for vacuum upstream of any area shut-off valve above 66 kPa absolute.

6.6 (*) Provision of emergency operating alarms

Emergency operating alarm signals shall be provided to indicate the following:

a) for a single-stage distribution system, deviation of the pipeline pressure downstream of the main shut-off valve by more than ± 20 % from the nominal distribution pressure;

b) for a double-stage distribution system, deviation of the pipeline pressure downstream of the main shut-off valve by more than ± 20 % from the nominal supply system pressure;

c) increase of pipeline pressure for vacuum on the patient side of the main shut-off valve above 44 kPa absolute;

NOTE Regional or national regulations/standards may require a different value for the vacuum alarm.

d) temperature of any air compressor exceeding the threshold defined by the manufacturer;

e) medical air supplied from a compressor system, when CO level exceeds 25 ppm or lower if required by regional or national regulation;

NOTE The 25 ppm alarm set point was selected from the American Conference of Governmental Industrial Hygienists (ACGIH) threshold limit value for CO. Other values may be established by local or regional regulations.

f) for systems supplied from oxygen concentrator supply units, an oxygen concentration below 90%;

g) for systems supplied from proportioning units, an oxygen concentration outside the specified limits.

The location of the pressure sensors shall be consistent with the location and the intended use of ring shut-off valves, if fitted.

7 Pipeline distribution systems

7.1 Mechanical resistance

All sections of pipeline distribution systems for compressed medical gases shall withstand a pressure of 1,2 times the maximum pressure which can be applied to that section in single fault condition.

7.2 Distribution pressure

NOTE Unless otherwise specified, pressures in this part of ISO 7396 are expressed as gauge pressure (i.e. atmospheric pressure is defined as 0).

7.2.1 The nominal distribution pressure shall be within the ranges given in Table 2. Different gases may be delivered at different nominal distribution pressures in the same healthcare facility.

Table 2 — Ranges of nominal distribution pressure

Pressure in kilopascals

Compressed medical gases other than air or nitrogen for driving surgical tools	400^{+100}_{0}
Air or nitrogen for driving surgical tools	800^{+200}_{-100} [a]
Vacuum	<60 [b]
[a] Regional or national regulations/standards may require a different range.	
[b] Absolute pressure.	

If gases are delivered at different nominal distribution pressures, nitrous oxide should be delivered at a nominal distribution pressure lower than that for oxygen and medical air in order to prevent flow of nitrous oxide into the oxygen or medical air pipeline when gas mixers or other equipment are used.

If gases are delivered at different nominal distribution pressures, medical air may be delivered at a nominal distribution pressure lower or higher from that for oxygen. A risk analysis should be conducted to determine appropriate pressure settings.

NOTE National or regional regulations may apply.

7.2.2 For compressed medical gases other than air or nitrogen for driving surgical tools, the pressure at any terminal unit shall not be greater than 110 % of the nominal distribution pressure with the system operating at zero flow. The pressure at any terminal unit shall not be less than 90 % of the nominal distribution pressure with the system operating at system design flow.

NOTE 1 System design flow is calculated in accordance with appropriate diversity factors. Examples of diversity factors are given in HTM 02 [33], [34], FD S 90-155 [32] and AS 2896-1998 [22].

NOTE 2 The following factors will contribute to the pressure change: performance of pressure regulators, pressure drop in the pipeline downstream of the pressure regulator and pressure drop across the terminal unit.

7.2.3 For air or nitrogen for driving surgical tools, the pressure at any terminal unit shall not be greater than 115 % of the nominal distribution pressure with the system operating at zero flow. The pressure at any terminal unit shall not be less than 85 % of the nominal distribution pressure with the system operating at system design flow.

NOTE 1 System design flow is calculated in accordance with appropriate diversity factors. Examples of diversity factors are given in HTM 02 [33], [34], FD S 90-155 [32] and AS 2896-1998 [22].

NOTE 2 The following factors will contribute to the pressure change: performance of line pressure regulators, pressure drop in the pipeline downstream of the line pressure regulator and pressure drop across the terminal unit.

7.2.4 For vacuum systems, the pressure at any terminal unit shall not be greater than 60 kPa absolute with the system operating at system design flow.

NOTE System design flow is calculated in accordance with appropriate diversity factors. Examples of diversity factors are given in HTM 02 [33], [34], FD S 90-155 [32] and AS 2896-1998 [22].

7.2.5 **(*)** For compressed medical gases other than air or nitrogen for driving surgical tools, the pressure at any terminal unit shall not exceed 1 000 kPa in a single fault condition of any pressure regulator installed within the system. Means for this purpose (e.g. pressure-relief valves) shall be provided. If fitted, pressure- relief valves shall comply with 5.2.6. Bursting discs shall not be used for this purpose.

Evidence shall be provided by the manufacturer.

NOTE 1 Regional or national regulations may require the provision of evidence to a notified body or competent authority upon request.

NOTE 2 Attention is drawn to regional, national and international standards for pressure-relief valves, e.g. ISO 4126-1 [3].

7.2.6 **(*)** For air or nitrogen for driving surgical tools, the pressure at any terminal unit shall not exceed

2 000 kPa in a single fault condition of any pressure regulator installed within the system. Means for this purpose (e.g. pressure-relief valves) shall be provided. If fitted, pressure-relief valves shall comply with 5.2.6. Bursting discs shall not be used for this purpose.

Evidence shall be provided by the manufacturer.

NOTE 1 Regional or national regulations may require the provision of evidence to a notified body or competent authority upon request.

NOTE 2 Attention is drawn to regional, national and international standards for pressure-relief valves, e.g. ISO 4126-1 [3].

7.3 Low-pressure hose assemblies and low-pressure flexible connections

7.3.1 If a flexible connection is not intended to be replaced during the life of the pipeline system and is part of the pipeline (e.g. when used for isolation of vibration, seismic isolation, building movement and relative movement of the pipelines) the following requirements shall be met:

a) the low pressure flexible connection shall be metallic;

b) the low pressure flexible connection need not be gas-specific;

c) the materials used for the components shall meet the requirements in 4.3;

d) the low pressure flexible connection shall be tested as part of the permanent piping.

7.3.2 If a low-pressure hose assembly is used to connect moving parts of fixed equipment to a pipeline, (e.g. as part of permanently fixed equipment such as booms, pendants, pendant tracks or to electrically isolate terminal units installed close to Magnetic Resonance Imaging (MRI) systems it shall comply with the following:

a) it shall comply with ISO 5359;

b) it shall be tested in accordance with Clause 12;

c) it shall be accessible for inspection and maintenance (see also 8.1.2).

The use of low-pressure hose assemblies and low-pressure flexible connections in the pipeline distribution system should be limited because of the potential hazard arising from their rupture and the subsequent risk of loss of gas supply.

7.4 Double-stage pipeline distribution systems

7.4.1 **(*)** Alternative arrangements for line pressure regulators are shown in Annex A (Figures A.23 and A.24). Each bed space/patient space shall be supplied from at least two permanently fitted line pressure regulators to ensure continuity of supply. The design flow of the area served shall be supplied by each line pressure regulator. The inlet pressure of the line pressure regulator shall not exceed 3 000 kPa (see ISO 10524-2).

NOTE 1 The line pressure regulators may be combined with the area shut-off valve (see 8.3).

The instructions for use and maintenance shall specify how the two permanently fitted line pressure regulators are intended to operate.

NOTE 2 The manufacturer may choose between various means of risk control, e.g. automatic switch-over and alarms, manual switch-over and proper emergency procedures, training and local reserve supplies.

In order to ensure continuity of supply the two line pressure regulators should not be in use at the same time. If in use at the same time they may both fail.

7.4.2 For emergency and maintenance purposes, shut-off valves shall be fitted both upstream and downstream, adjacent to each line pressure regulator.

8 Shut-off valves

8.1 General

8.1.1 Shut-off valves are provided to isolate sections of the pipeline distribution system for maintenance, repair, planned future extensions and to facilitate periodic testing.

The nomenclature for shut-off valves shall be as follows:

a) source shut-off valve;

b) main shut-off valve;

c) riser shut-off valve;

d) branch shut-off valve;

e) area shut-off valve;

f) ring shut-off valve;

g) maintenance shut-off valve;

h) inlet shut-off valve.

NOTE Examples of nomenclature of shut-off valves are given in Annex A.

8.1.2 If not specified, the location of all shut-off valves and the extent of the area served by each area shut-off valve shall be determined by the manufacturer together with the healthcare facility management, using risk analysis procedures in accordance with ISO 14971.

The risk assessment shall also take into account the hazards arising from the possible rupture of low-pressure hose assemblies fitted within any medical supply units.

Consideration should be given to providing a shut-off valve at the point where the pipeline enters a building unless the main, riser or branch shut-off valve is accessible within the building.

8.1.3 All shut-off valves shall be identified by indicating:

a) the gas or vacuum service name or symbol; and

b) the risers, branches or areas controlled.

This identification shall be secured to the valve, valve box or the pipeline and be readily visible at the valve site.

8.1.4 For all shut-off valves in a medical gas pipeline system, it shall be apparent by observation whether the valve is open or closed.

8.1.5 A source shut-off valve shall be provided downstream (upstream for vacuum) of each source of supply.

8.1.6 A main shut-off valve shall be provided on the pipeline immediately upstream of the maintenance supply assembly, if provided.

8.1.7 Either shut-off valves shall be capable of being lockable in the open and closed positions or they shall be protected from operation by unauthorized personnel.

8.2 Service shut-off valves

8.2.1 Typical uses of service shut-off valves are

a) as shut-off riser valves,

b) as shut-off branch valves,

c) as shut-off maintenance valves, or

d) as shut-off ring valves.

8.2.2 Service shut-off valves shall be used only by authorized personnel and should not be accessible to unauthorized persons.

8.2.3 Each riser shall be provided with a shut-off valve adjacent to the connection to the main line.

8.2.4 Each branch shall be provided with a shut-off valve adjacent to the connection to the riser or main line.

8.3 Area shut-off valves

8.3.1 All terminal units in the pipeline system other than those provided only for emergency, system test purposes or maintenance of components (e.g. line pressure regulators) shall be on the patient side of an area shut-off valve (upstream for vacuum). An area shut-off valve shall be provided in each gas and vacuum pipeline serving each operating theatre, general ward area and all other departments, e.g. Intensive Care Unit (ICU), Neonatal Intensive Care Unit (NICU) and emergency treatment area.

8.3.2 Area shut-off valves shall be located on the same floor as the terminal units they serve.

8.3.3 Area shut-off valves shall be used to isolate areas within healthcare facilities for maintenance and emergency purposes. Their operation, in the latter case, should be included as part of the emergency disaster plan.

8.3.4 Area shut-off valves shall be housed in boxes with covers or doors. The boxes shall be labelled with the following or similar wording:

For compressed gases:

CAUTION — Medical Gas Valves for (description of area controlled) Do not close valve(s) except in emergency.

For vacuum:

CAUTION — Vacuum Valves for (description of area controlled) Do not close valve(s) except in emergency

8.3.5 Each box shall contain the following:

a) area shut-off valve(s) for one or more gases;

b) except for vacuum systems, means to allow physical isolation of the service(s). These means shall be clearly visible when deployed. A closed valve shall not be considered an adequate physical isolation when modifications are carried out to existing systems.

8.3.6 Each box shall be vented to the room to prevent accumulation of gas and shall have a cover or door which may be secured in the closed position. The cover or door shall allow quick access in case of emergency.

8.3.7 All boxes shall be visible and accessible at all times.

Consideration shall be given to prevent access by unauthorized personnel, especially in psychiatric or paediatric units.

8.3.8 Except for pipelines for vacuum and for air or nitrogen for driving surgical tools, an emergency and maintenance inlet point shall be provided downstream of each area shut-off valve. The emergency and maintenance inlet point shall be gas-specific (either a NIST, DISS or SIS body or the socket of a terminal unit). The dimensions of the inlet point shall take into account the flow required during emergency and maintenance activities. The emergency and maintenance inlet point may be located within the box containing the area shut-off valve.

8.3.9 No components shall be installed between an area shut-off valve and the terminal unit except for:

— sensors or indicators (e.g. for pressure and flow),

— emergency and maintenance inlet points,

— means to allow physical isolation of the service,

— maintenance shut-off valves (if fitted),

— operator-adjustable low-pressure regulators for air or nitrogen for driving surgical tools (see ISO 10524-4 [19]),

— low pressure hose assemblies complying with ISO 5359 within medical supply units.

8.3.10 No area shut-off valve shall be fitted downstream of the sensor activating the emergency pressure alarm.

9 Terminal units, gas-specific connectors, medical supply units, pressure regulators and pressure gauges

9.1 Terminal units shall be gas specific and comply with ISO 9170-1.

9.2 Gas-specific connectors shall be either the gas-specific connection point of a terminal unit complying with ISO 9170-1 or the body of a NIST, DISS or SIS connector.

9.3 Medical supply units (e.g. ceiling pendants, bedhead units, booms) shall comply with ISO 11197.

9.4 Manifold and line pressure regulators shall comply with ISO 10524-2.

9.5 Pressure gauges shall comply with the requirements given in ISO 10524-2.

10 Marking and colour coding

10.1 Marking

10.1.1 Pipelines shall be marked in accordance with 10.1.2 with the gas name and/or symbol adjacent to shut-off valves, at junctions and changes of direction, before and after walls and partitions, etc., at intervals of no more than 10 m and adjacent to terminal units.

NOTE 1 Typical examples of marking methods are metal tags, stencilling, stamping and adhesive markers.

NOTE 2 For identification of shut-off valves, see 8.1.3.

10.1.2 Marking shall

a) be in accordance with ISO 5359.

b) use letters not less than 6 mm high;

c) be applied with the gas name and/or symbol along the longitudinal axis of the pipeline; and

d) include arrows denoting the direction of flow.

NOTE 1 For piping in a ring, the direction of flow may be in either direction indicated by arrows in both directions.

NOTE 2 Regional or national regulations applying to the marking of pipeline systems and their components may exist.

10.2 Colour coding

If colour coding is used for pipelines, it shall comply with ISO 5359.

NOTE 1 ISO 5359:2014 does not include marking or colour coding for oxygen 93.

NOTE 2 Regional or national regulations applying to the colour coding of pipeline systems and their components may exist.

11 Pipeline installation

11.1 General

11.1.1 All activities in this section shall be carried out by an installer having a current quality management process including training in the installation of medical gas systems according to applicable standards.

NOTE Examples include ISO 13485,[20] ISO 9001,[17] ASSE 6000,[49] CSA Medical Gas Piping and Systems Personnel Certification Program, CSA B-51[50] or equivalent.

11.1.2 Pipeline components which are liable to come in contact with the actual gas shall meet the cleanliness requirements of EN 13348 and ISO 15001 as applicable (see 4.3.6 and 4.3.7) and be supplied protected from contamination prior to, and during, installation.

11.1.3 Terminal units for medical gases and vacuum shall be located only in areas intended for connection of medical devices. No connections shall be made to a pipeline system for other uses. Permitted uses of medical air and air for driving surgical tools related to patient care are given in 5.5.1.2. Non-permitted uses of medical air and air for driving surgical tools are given in 5.5.1.3.

11.1.4 Pipelines and electrical services shall either

a) run in separate compartments, or

b) be separated by more than 50 mm.

NOTE Regional or national regulations which apply to electrical installations in buildings may exist.

11.1.5 The pipeline shall be bonded to an earth terminal as near as possible to the point at which the pipeline enters the building. The pipelines shall not themselves be used for earthing electrical equipment.

NOTE Regional or national regulations which apply to continuity of earthing across all joints within the same building and to electrical isolation of different buildings from each other may exist.

11.1.6 Pipelines shall be protected from physical damage, for example damage which might be caused by the movement of portable equipment such as trolleys, stretchers and trucks, in corridors and in other locations.

11.1.7 Unprotected pipelines shall not be installed in areas of special hazard, e.g. in areas where flammable materials are stored. Where installation of pipelines in such a location is unavoidable, the pipeline shall be installed in an enclosure that will prevent the liberation of medical gas within the area should a leak occur.

NOTE Regional or national regulations which apply to building requirements and fire prevention may exist.

11.1.8 If pipelines are installed underground, they shall be located in tunnels or ducts. The tunnel or duct shall be provided with adequate drainage to prevent the accumulation of water. If pipelines are located in a tunnel or duct alone, with other services or with pipelines for other fluids or gases, the potential hazard arising from this situation shall be assessed using risk analysis procedures in accordance with ISO 14971. The risk assessment shall take into account that a leak which is not detected (e.g. by an alarm or periodic inspection) shall be considered a normal condition and not a single fault condition. The route of pipes located underground shall be indicated at the site by continuous marking tape above the pipeline at approximately one-half the depth of burial.

11.1.9 Pipelines shall not be installed in elevator shafts.

11.1.10 A shut-off valve shall not be installed where a leak is likely to cause an accumulation of gas, for example in a sealed cavity.

11.1.11 Damage due to contact with corrosive materials shall be minimized, e.g. by the use of impermeable non-metallic materials applied to the outer surface of the pipes in the area where the contact can occur.

11.1.12 Means shall be provided to allow expansion and contraction of pipelines.

11.1.13 All pipelines for medical gases shall be routed in such a way that they are not exposed to a temperature less than 5°C above the dew point of the gas at pipeline pressure.

NOTE Attention is drawn to the possibility of restriction of flow due to exposure of vacuum pipeline to low or high temperature.

11.2 Pipeline supports

11.2.1 Pipelines shall be supported at intervals to prevent sagging or distortion. The maximum intervals between supports for metallic and non-metallic pipes should not exceed the values given in Table 3.

NOTE Regional or national regulations specifying intervals between supports may exist.

11.2.2 The supports shall ensure that the pipeline cannot be displaced accidentally from its position.

11.2.3 The supports shall be of corrosion-resistant material, or shall be treated to prevent corrosion. Means shall be provided to prevent electrolytic corrosion between the pipes and the contacting surfaces of the supports.

11.2.4 Where pipelines cross electric cables, the pipelines shall be supported adjacent to the cables.

11.2.5 Pipelines shall not be used as support for, nor shall they be supported by, other pipelines or conduits.

Table 3 — Maximum intervals between supports for pipes

Pipe outside diameter mm	Maximum interval between supports m
≤ 20	1,5
> 20 to 28	2,0
> 28 to 54	2,5
> 54	3,0

11.3 Pipeline joints

11.3.1 Except for mechanical joints used for certain components, all metallic pipeline joints shall be brazed or welded. If a filler metal is used, its liquid temperature shall not be less than 600°C. Filler metal shall be nominally cadmium free. If silver alloys are used, they shall comply with ISO 17672.

NOTE Mechanical joints (e.g. flanged or threaded connections) may be used to connect components such as shut-off valves, terminal units, pressure regulators, controls and monitoring and alarm sensors to the pipeline.

11.3.2 During brazing or welding of pipeline joints, the interior of the pipeline shall be continuously purged with shield gas.

NOTE ISO 13585:2012 [29] specifies requirements for the brazing process, test conditions, assessment and certificate. EN 13134 [51] specifies general rules (test procedures, test pieces) for the specification and approval of brazing procedures for all materials.

11.3.3 If fittings are used to join copper pipes, they shall comply with EN 1254-1 or EN 1254-4.

11.4 Extensions and modifications of existing pipeline systems

11.4.1 The components used in extensions and modification of an existing pipeline system shall comply with the relevant requirements of this part of ISO 7396.

11.4.2 The final connection of extensions shall be undertaken on only one system at a time, in order to minimize the risk of cross-connections. All other systems shall remain at nominal distribution pressure. Careful consideration shall be given to the location of this connection to minimize problems of access during installation and testing.

11.4.3 If an extension to an existing system is to be made upstream (downstream for vacuum) of an area shut-off valve, a shut-off valve shall be added at the connection point if an existing valve cannot be used for this purpose.

11.4.4 When an existing system does not meet the requirement specified in 12.6.10, a duplex filter with isolating valves shall be fitted at the point of connection to fulfil 12.6.10.

11.4.5 All terminal units in an extension shall be temporarily labelled to indicate that they are not to be used.

11.4.6 Connection shall be made to the existing system only after the appropriate tests specified in Clause 12 have been successfully completed on the modification. The shut-off valve specified in 11.4.3 shall then be opened and further relevant tests completed on the modification.

11.4.7 When a connection is made to an existing system which is in use, that connection shall be made at a single brazed connection point which may be tested for leakage at nominal distribution pressure using leak-detection fluid.

11.4.8 When the modification has been completed and tested in accordance with Clause 12, all labels specified in 11.4.5 shall be removed.

11.4.9 The extension of an existing system shall be separated from the existing pipeline system during installation and pressure testing. A single shut-off valve between the two systems is not considered to be a safe separation.

11.4.10 When the shut-off valve specified in 11.4.3 is opened in order to carry out the further relevant tests on the modification, all extended and modified pipeline system shall be at atmospheric pressure. The test gas on the modification shall be purged downstream in order to prevent backflow contamination of the existing pipeline before the valve specified in 11.4.3 is opened.

12 Testing and commissioning

12.1 General

Tests after completion of installation shall be carried out and documented by the manufacturer.

NOTE Regional or national regulations requiring the manufacturer to have an approved quality system may exist.

All tests should be carried out by the manufacturer under supervision of the Authorized Person of the Healthcare facility.

An example of a procedure for testing and commissioning is given in Annex C.

12.2 General requirements for tests

In this part of ISO 7396, requirements for flow rate and volume for the gas delivered are expressed at NTP (Normal Temperature and Pressure).

12.2.1 Except for those tests in which the gas is specified, purging and testing as described in 12.4 shall be carried out with medical air or the specific gas.

NOTE Medical air may be used for oxygen, nitrous oxide, oxygen/nitrous oxide mixture, oxygen 93 and air pipelines.

12.2.2 Before any testing according to 12.4 is carried out, every terminal unit in a system under test shall be labelled to indicate that the system is under test and the terminal unit shall not be used.

12.2.3 The resolution and the accuracy of all measuring devices used for testing shall be appropriate for the values to be measured.

12.2.4 All measuring devices used for testing shall be calibrated at appropriate intervals.

12.2.5 For extensions and modifications of existing pipeline distribution systems, not all the tests listed in 12.3 and 12.4 need to be carried out. The manufacturer shall specify and document which tests shall be carried out.

12.2.6 When the results of a test do not meet the pass criteria, remedial work shall be carried out and previous tests repeated as necessary.

12.3 Inspections and checks before concealment

The following inspections and checks shall be carried out:

a) inspections of marking and pipeline supports (see 12.5.1);

b) check for compliance with design specifications (see 12.5.2).

NOTE Some tests for leakage and mechanical integrity may also be carried out before concealment (see 12.6.1).

12.4 Tests, checks and procedures before use of the system

The following tests and procedures shall be carried out in any order:

a) tests for leakage and mechanical integrity (see 12.6.1);

b) tests of area shut-off valves for leakage and closure and checks for correct zoning and correct identification (see 12.6.2);

c) test for cross-connection (see 12.6.3);

d) test for obstruction and flow (see 12.6.4);

e) checks of terminal units and NIST, DISS or SIS connectors for mechanical function, gas specificity and identification (see 12.6.5);

f) tests or checks of system performance (see 12.6.6);

g) tests of pressure-relief valves (see 12.6.7);

h) tests of all sources of supply (see 12.6.8);

i) tests of monitoring and alarm systems (see 12.6.9);

j) test for particulate contamination of the pipeline distribution systems (see 12.6.10);

k) tests of the quality of medical air produced by supply systems with air compressors (see 12.6.11);

l) test of the quality of air for driving surgical tools produced by air compressor(s) (see 12.6.12);

m) tests of the quality of medical air produced by proportioning unit(s) (see 12.6.13);

n) test of the quality of oxygen 93 produced by oxygen concentrator unit(s) (see 12.6.14);

o) filling with specific gas (see 12.6.15);

p) tests of gas identity (see 12.6.16).

12.5 Requirements for inspections and checks before concealment

12.5.1 Inspection of marking and pipeline supports

Marking shall comply with 10.1. The pipeline supports shall be inspected to verify that they comply with 11.2.

12.5.2 Check for compliance with design specifications

All items shall be shown to comply with the design specifications (e.g. the sizing of the pipelines, location of terminal units, line pressure regulators, if fitted, and shut-off valves).

12.6 Requirements for tests, checks and procedures before use of the system

12.6.1 General

One of the following combinations of leakage and mechanical integrity tests shall be carried out:

a) test for mechanical integrity of vacuum pipeline systems (see 12.6.1.1) + test for leakage into the vacuum pipeline systems (see 12.6.1.2) + combined tests for leakage and mechanical integrity of compressed medical gas pipeline systems (after concealment) (see 12.6.1.6);

b) test for mechanical integrity of vacuum pipeline systems (see 12.6.1.1) + test for leakage into the vacuum pipeline systems (see 12.6.1.2) + test for mechanical integrity for compressed medical gas systems (see 12.6.1.3) + test for leakage from the compressed medical gas pipeline systems (see 12.6.1.4);

c) test for mechanical integrity of vacuum pipeline systems (see 12.6.1.1) + test for leakage into the vacuum pipeline systems (see 12.6.1.2) + combined tests for leakage and mechanical integrity of compressed medical gas pipeline systems (before concealment) (see 12.6.1.5) + test for leakage from the compressed medical gas pipeline systems (see 12.6.1.4);

d) combined test for leakage and mechanical integrity of vacuum pipeline systems (see 12.6.1.7).

NOTE Regional or national regulations which apply to requirements for leakage and mechanical integrity may exist.

12.6.1.1 Test for mechanical integrity of vacuum pipeline systems

This test may be carried out before concealment or after concealment and before use of the system. It may be preferable to test sections of the system individually, provided that no section is omitted.

Apply for 5 min a pressure of 500 kPa.

The source of test gas shall be disconnected after initial pressurization. Check for the integrity of the pipeline distribution system and its components.

12.6.1.2 Test for leakage into the vacuum pipeline system

This test shall be carried out after concealment and before the use of the system.

With the complete system at nominal distribution pressure, with the source of supply isolated and with all other valves open, the pressure increase in the pipeline shall not exceed 20 kPa after 1 h.

12.6.1.3 Test for mechanical integrity for compressed medical gas pipeline systems

This test shall be carried out before concealment.

Apply for 5 min a pressure of not less than 1,2 times the maximum pressure which could occur under single fault condition in each section of the pipeline distribution system.

For double-stage distribution systems, line pressure regulators should not be fitted at this stage of installation and may be replaced by suitable connectors. If so, the test pressure for the complete pipeline should be determined, taking into account the maximum pressure which can be applied to the pipeline downstream of the supply system in single fault condition.

Check for the integrity of the pipeline distribution system and its components.

12.6.1.4 Test for leakage from the compressed medical gas pipeline systems

This test shall be carried out after concealment and before use of the system.

For single-stage pipeline distribution systems, the leakage from the medical gas pipeline system shall be measured from all portion(s) of the system downstream and upstream of each area shut-off valve with the source of test gas disconnected.

For double-stage pipeline distribution systems, the leakage from the medical gas pipeline system shall be measured from all portion(s) of the system downstream and upstream of each line pressure regulator with the source of test gas disconnected.

The means to allow physical isolation of services described in 8.3.5 b) shall be used to isolate the sections upstream and downstream of each area shut-off valve (or each line pressure regulator).

In sections downstream of each area shut-off valve (or each line pressure regulator):

— after a test period of 2 h to 24 h at nominal distribution pressure, the pressure drop shall not exceed 0,4 %/h of the test pressure in portions not including flexible hoses in medical supply units;

— after a test period of 2 h to 24 h at nominal distribution pressure, the pressure drop shall not exceed 0,6 %/h of the test pressure in portions including flexible hoses in medical supply units.

In sections upstream of each area shut-off valve (or each line pressure regulator):

— after a test period of 2 h to 24 h at nominal distribution pressure for single-stage pipeline distribution systems or at nominal supply system pressure for double-stage pipeline distribution systems, the pressure drop shall not exceed 0,025 % of the initial test pressure per hour.

12.6.1.5 Combined tests for leakage and mechanical integrity of compressed medical gas pipeline systems (before concealment)

These tests shall be carried out before concealment.

Apply for 5 min a pressure of not less than 1,2 times the maximum pressure which could occur under single fault condition in each section of the pipeline distribution system.

Check for the integrity of the pipeline distribution system and its components.

For double-stage distribution systems, line pressure regulators should not be fitted at this stage of installation and may be replaced by suitable connectors. If so, the test pressure for the complete pipeline should be determined, taking into account the maximum pressure which can be applied to the pipeline downstream of the supply system in single fault condition.

At the same test pressure, the pressure drop after a test period of 2 h to 24 h shall be less than 0,025 % of the initial test pressure per hour.

12.6.1.6 Combined tests for leakage and mechanical integrity of compressed medical gas pipeline systems (after concealment)

These tests shall be carried out after concealment and before use of the system.

Mechanical integrity shall be tested for 5 min at a pressure of not less than 1,2 times the maximum pressure which could occur under single fault condition of each section of the pipeline distribution system.

Check for the mechanical integrity of the pipeline distribution system and its components.

The leakage shall then be measured from the whole system with the source of test gas disconnected in accordance with 12.6.1.4.

12.6.1.7 Combined test for leakage and mechanical integrity of vacuum pipeline systems

These tests shall be carried out before concealment. It may be preferable to test sections of the system individually, provided that no section is omitted. Apply for 5 min a pressure of 500 kPa. The source of test gas shall be disconnected after initial pressurization. Check for the integrity of the pipeline distribution system and its components. At the same test pressure, the pressure drop after a test period of 2 h to 24 h shall be less than 0,025 % of the initial test pressure per hour.

12.6.1.8 Temperature corrections

If necessary the pressure drop shall be corrected for variations due to pipeline temperature according to the ideal gas laws (see Annex E for information).

12.6.2 (*) Tests of area shut-off valves for leakage and closure and checks for correct zoning and correct identification

12.6.2.1 With the system upstream of each closed area shut-off valve under test at nominal distribution pressure, the downstream line depressurized to 100 kPa and all downstream terminal units closed, the pressure increase downstream of each closed area shut-off valve after 15 min shall not exceed 5 kPa.

This test does not apply to vacuum systems.

12.6.2.2 All area shut-off valves shall be checked for correct operation and identification and to show that they control only those terminal units intended by the design.

12.6.3 Test for cross-connection

It shall be proved that there are no cross-connections between pipelines for different gas services or vacuum services.

12.6.3.1 General

All pipeline systems shall be at atmospheric pressure and all shut-off valves open. A test gas source shall be connected to only one pipeline system at a time.

Only one pipeline shall be pressurized at one time during this test.

That pipeline system shall be kept at nominal distribution pressure throughout the test. In the case of the vacuum pipeline system, the vacuum supply system shall be used.

In the case of a ring pipeline all of the ring valves shall be checked before testing to ensure that they are open. This test shall be applied to all terminal units.

12.6.3.2 Procedure

12.6.3.2.1 Pressurize (or evacuate) the pipeline system to be tested to nominal distribution pressure.

12.6.3.2.2 Check that gas flows through every terminal unit of the pipeline system under test.

12.6.3.2.3 Check that there is no gas flow from any terminal unit of any other pipeline system when opened with a gas-specific probe and that there are, therefore, no cross-connections.

12.6.3.2.4 With all the other pipeline systems at atmospheric pressure, repeat the procedure in 12.6.3.2.1 through 12.6.3.2.3 on each pipeline system in turn, including vacuum, preferably at one session.

12.6.3.2.5 Repeat the test in full if any modifications are made to the pipeline systems during the commissioning procedure.

12.6.3.2.6 Test results shall be documented (e.g. on Form D8). Other methods of checking for cross-connections are shown in C.3.3.

12.6.4 Test for obstruction and flow

The pressure change measured at each terminal unit shall not exceed the values specified in Table 4 when the test flowrate specified in Table 4 is taken from each terminal unit or NIST, DISS or SIS connector in turn. Each pipeline system shall be at its nominal distribution pressure and connected to the test gas supply.

Table 4 — Maximum allowable pressure change

Pipeline system	Pressure change	Test flowrate
Compressed medical gases other than air or nitrogen for driving surgical tools	≤10 %	40 l/min
Air or nitrogen for driving surgical tools	≤15 %	350 l/min
Exhaust pipe for air or nitrogen for driving surgical tools	≤ 40 kPa (backpressure)	350 l/min
Vacuum	< 60 kPa absolute pressure	25 l/min
NOTE During this test, the distribution pressure in the vacuum system is subject to change; therefore, an absolute value for the pressure change is appropriate.		

All exhaust pipes (e.g. from pressure-relief valves, terminal units for supply and disposal of air or nitrogen for driving surgical tools) shall be checked for obstruction.

12.6.5 Checks of terminal units and NIST, DISS or SIS connectors for mechanical function, gas specificity and identification

12.6.5.1 Mechanical function

This test requires that each terminal unit is complete with its fascia plate.

If a NIST, DISS or SIS connector is provided, it shall be demonstrated that the appropriate nipple can be inserted into the body and secured by the nut. If an anti-swivel device is provided, it shall be demonstrated that this retains the probe in the correct orientation.

It shall be demonstrated, for each NIST, DISS or SIS connector, that the appropriate nipple can be inserted into the body and secured by the nut.

NOTE This test may be carried out at the same time as the tests described in 12.6.4, 12.6.5.2, 12.6.5.3 and 12.6.16.

12.6.5.2 Gas specificity

It shall be demonstrated for each terminal unit that gas (or vacuum) is released only when the correct probe is inserted and captured, that no other type of probe used in the same healthcare facility can be captured and that no gas (or vacuum) is released when any other type of probe used in the same healthcare facility is inserted.

If a NIST, DISS or SIS connector is provided, it shall be demonstrated that only the correct nipple can be inserted into the body and secured by the nut and that no nipple for another gas or vacuum can be inserted and secured.

It shall be demonstrated that the inlet connector of each maintenance supply assembly is gas-specific.

NOTE This test may be carried out at the same time as the tests described in 12.6.3, 12.6.4, 12.6.5.1, 12.6.5.3 and 12.6.16.

12.6.5.3 Identification

All terminal units shall be checked for correct identification and labelling.

NOTE This test may be carried out at the same time as the tests described in 12.6.4, 12.6.5.1, 12.6.5.2 and 12.6.16.

12.6.6 Tests or checks of system performance

Each pipeline system shall be shown to deliver the system design flow at the nominal distribution pressure.

It shall be shown using tests or verification of calculation or other suitable methods that whilst the system is delivering the system design flow, the requirements given in 7.2.1, Table 2, 7.2.2, 7.2.3 and 7.2.4 are met at selected terminal units.

12.6.7 (*) Tests of pressure-relief valves

The performance of pressure-relief valves shall be in accordance with 7.2.5 and 7.2.6.

If type-tested and certified pressure-relief valves are fitted, testing after installation is not required. Evidence shall be provided by the manufacturer.

NOTE Regional or national regulations may require the provision of evidence to a notified body or competent authority upon request.

12.6.8 Tests of all sources of supply

Each source of supply shall be verified against its manufacturer's specifications or tested for all specified operating and emergency conditions, including switching from one source of supply to another according to its instructions for use and the requirements of this part of ISO 7396.

12.6.9 Tests of monitoring and alarm systems

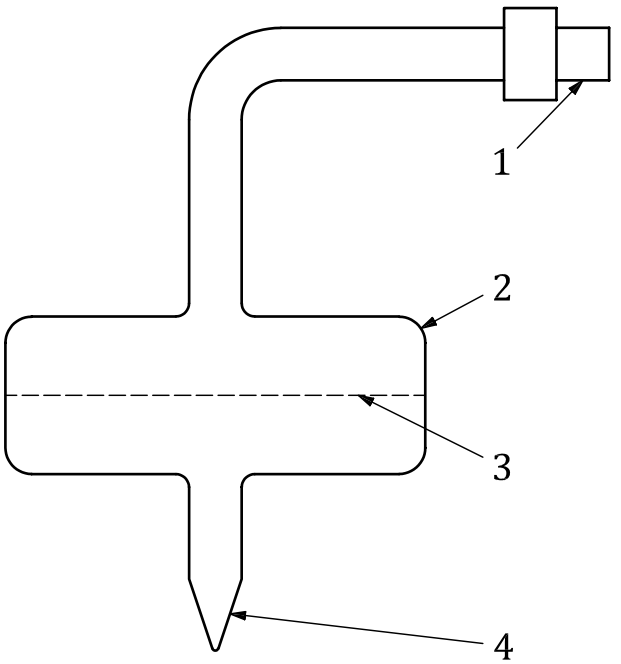
The performance of all monitoring and alarm systems shall be tested in all specified operating and emergency conditions according to their instructions for use and the requirements of this part of ISO 7396.

12.6.10 Test for particulate contamination of pipeline distribution systems

Pipeline distribution systems for compressed medical gases shall be tested for particulate contamination. The test shall be carried out using the device shown in Figure 1 at a flowrate of 150 l/min for at least 15 s.

The filter shall be free from particulate matter when viewed in good light. Purging procedures might be necessary to meet this requirement.

NOTE Alternative methods with similar or superior accuracy may be used for this test.



Key

1 gas-specific probe (interchangeable)
2 filter holder specified to withstand 1 000 kPa
3 filter of diameter (50 ± 5) mm and pore size 10 µm
4 calibrated jet (interchangeable) to provide a flowrate of 150 l/min at nominal distribution pressure

Figure 1 — Test device for qualitative determination of particulate contamination of pipeline distribution systems

12.6.11 Tests of the quality of medical air produced by supply systems with air compressor(s)

Medical air supplied by air compressor systems shall be tested for compliance with 5.5.2.1 before filling the pipelines.

NOTE 1 The test methods are given in the relevant Pharmacopoeia monographs. Alternative equivalent and validated methods of analysis may be used.

NOTE 2 Where water vapour or oxygen concentration is measured downstream of a hose assembly within a medical supply unit, purging may be required before making the measurement because medical gas hose assemblies made of polymers are permeable to water vapour and more permeable to oxygen than nitrogen. Over time the water vapour concentration within the hose can rise above the 67 ml/m^3 limit and the local oxygen concentration can fall.

12.6.12 Tests of the quality of air for driving surgical tools produced by supply systems with air compressor(s)

Air for driving surgical tools supplied by dedicated air compressor systems shall be tested for compliance with 5.5.2.4 before filling the pipelines.

NOTE Where water vapour or oxygen concentration is measured downstream of a hose assembly within a medical supply unit, purging may be required before making the measurement because medical gas hose assemblies made of polymers are permeable to water vapour and more permeable to oxygen than nitrogen. Over time the water vapour concentration within the hose can rise above the 67 ml/m^3 limit and the local oxygen concentration can fall.

12.6.13 Tests of the quality of medical air produced by supply systems with proportioning unit(s)

Medical air supplied by proportioning systems shall be tested for compliance with 5.5.3.1 before filling the pipelines.

NOTE 1 The test methods are given in the relevant Pharmacopoeia monographs. Alternative methods of analysis may be used.

12.6.14 Tests of the quality of oxygen 93 produced by supply systems with oxygen concentrator(s)

oxygen 93 shall be tested for compliance with 5.6.5 before filling the pipelines.

NOTE 1 The test methods are given in the relevant pharmacopoeia monographs. Alternative methods of analysis may be used.

NOTE 2 Regional or national regulations which apply to oxygen 93 produced by supply systems with oxygen concentrator(s) may exist.

12.6.15 Filling with specific gas

Each pipeline distribution system for compressed medical gases shall be filled with, and emptied of, its specific gas for a sufficient number of times to displace the test gas. Each terminal unit shall be opened in turn to allow the specific gas to fill the pipeline system.

12.6.16 Tests of gas identity

A gas identity check shall be carried out on each terminal unit after filling with its specific gas. The outflow from each gas terminal unit shall be tested using an appropriate gas analyser to confirm the presence of the desired gas. The nominal gas concentration shall be measured and recorded.

NOTE 1 This test may be carried out at the same time as the tests described in 12.6.11, 12.6.12, 12.6.13 and 12.6.14.

NOTE 2 National or regional regulations permitting other sampling criteria can exist.

12.6.17 Verification of restart after power supply failure

A supply system connected to the emergency electrical system shall be able to start automatically when essential power is stabilized (from main or emergency power) and restart automatically when normal power is restored.

Compliance shall be checked by appropriate tests.

These tests are to be performed with the cooperation of the healthcare facility.

12.7 Statement of compliance to this part of ISO 7396

12.7.1 *(note that this section is intentionally in BOLD type)* **Before a medical gas pipeline system is used, it shall be documented in writing to the healthcare facility that all the requirements of 12.3 and 12.4 have been met. The results of tests showing details of the services and areas tested should be part of the permanent record of the healthcare facility.**

Typical forms for this purpose are given in Annex D.

NOTE The statement may be issued in two parts:

—Part 1: to cover testing of the requirements of 12.3 and 12.4 [items a) through j)], i.e. up to and including 12.6.10;

—Part 2: to cover testing of the requirements of 12.6.11 to 12.6.16 which are carried out after completion of the installation contract but which need not be done immediately.

12.7.2 The system manufacturer shall ensure that all drawings and manuals, as required in Clause 13, have been supplied to the owner or client.

12.7.3 When all tests have been completed satisfactorily, all construction labels which have been fixed to terminal units shall be removed.

13 Information to be supplied by the manufacturer

13.1 General

The information to be provided by the manufacturer shall be in accordance with EN 1041 or equivalent national standards.

13.2 Instructions for installation

The manufacturer shall provide to the installer suitable instructions for installation of the complete supply system.

13.3 Instructions for use

13.3.1 The manufacturer of the complete system or the manufacturers of each component of the medical gas pipeline system (i.e. supply systems, monitoring and alarm system and pipeline distribution system) shall provide the healthcare facility with instructions for use.

NOTE 1 The supply system, monitoring and alarm system and the pipeline distribution system may be supplied by one or several different manufacturers.

NOTE 2 Regional or national regulations which apply to manufacturers of medical devices can exist.

13.3.2 Where national standards concerning information to be provided by the manufacturer do not exist, the instructions for use shall contain the following:

— the name or trade name and address of the manufacturer or, where the manufacturer does not have an address within the locale, an authorized representative within the locale;

— the year of manufacture and, where appropriate, an indication of the date by which the system and its components should be used, in safety, expressed as the year and month;

— any special storage and/or handling conditions;

— any special operating instructions;

— any warning and/or precaution to be taken;

— the identification number;

— a technical specification including the performances of the system and how to connect and disconnect detachable parts and accessories;

— a description of all alarm signals and information signals;

— the position in normal condition (i.e. open or closed) of all shut-off valves;

— instructions for recommended periodic checks of function of the system. If filters are provided, and periodic change of the filter element(s) is not scheduled, then means shall be provided to verify the status of filter elements;

— adequate information regarding the medicinal product or products which the system is designed to deliver;

— instructions for the disposal of components or consumables (e.g. oil used in compressors and vacuum pumps, bacterial filters, charcoal filters, molecular sieves, desiccants);

— the minimum and maximum oxygen concentrations delivered by the oxygen concentrator unit(s) at the system design flow under the ambient conditions specified by the healthcare facility;

— the starting procedure of the oxygen concentrator unit(s), if applicable;

— the starting time of the oxygen concentrator unit(s), if applicable.

13.3.3 The instructions for use given in 13.3.2 shall be drafted taking into account the possibility that several different parties are involved in operation, use and maintenance.

13.4 Operational management information

13.4.1 The manufacturer(s) of each component of the medical gas pipeline system (i.e. supply systems, monitoring and alarm system and pipeline distribution system) shall provide operational management information to the healthcare facility to enable it to draft its Operational Management Document.

13.4.2 The system manufacturer(s) shall provide instructions to the healthcare facility for recommended maintenance tasks and their frequency, and a list of recommended spare parts, if applicable.

Terminal units should be maintained according to the manufacturer's instruction to prevent leakage.

13.4.3 The system manufacturer shall provide instruction to the healthcare facility for the recommended calibration procedures and their frequency for all analysers and alarm sensors.

13.4.4 The manufacturer(s) of the complete system shall provide information to enable the healthcare facility to prepare a specific emergency procedure to respond to catastrophic failure of one or more pipeline system(s), where the medical gas supplies to all medical devices might cease simultaneously.

NOTE Informative guidelines for the preparation of the Operational Management Document are given in Annex G. Informative guidelines for risk management are given in Annex F.

13.5 "As-installed" drawings

13.5.1 A separate set of "as-installed" mechanical drawings which show the actual locations of the pipelines, the diameters of the pipelines, shut-off valves (including their identification, as appropriate) and all other components shall be maintained during construction, and shall be brought up to date as changes are made. These drawings shall include details which will enable buried or concealed pipelines to be located.

13.5.2 A complete set of "as-installed" drawings of the pipeline system as specified in 13.5.1 shall be presented to the healthcare facility for inclusion as part of the permanent record of the pipeline system.

13.6 Electrical diagrams

Electrical diagrams for the components supplied shall be provided by the system manufacturer to the healthcare facility.

Annex A
(informative)

Schematic representations of typical supply systems and area distribution systems

These schematic representations are intended to give an overview of the essential features of different types of medical gas pipeline systems. The relative position of some components shown may be varied to meet local needs. Many components defined in the requirements of this part of ISO 7396 are not shown (e.g. automatic change-over). Dashed lines indicate additional pipelines. These schematics are for general guidance and are not normative. Figures are not exhaustive and other layouts equally conforming to the standard may be possible.

Table A.1 gives a summary of Figures A.1 to A.26. Tables A.2 and A.3 give the keys to the components and subassemblies, respectively, of the features shown in Figures A.1 to A.26.

Table A.1 — Key to Figures A.1 to A.26

Drawing reference	System description
A.1	Medical gas supply system comprising - Two cylinder / cylinder bundle manifold systems and one manifold changeover system - One cylinder / cylinder bundle manifold system
A.2	Air or nitrogen for driving surgical tools supply system comprising - Two cylinder / cylinder bundle manifold systems and one manifold changeover system
A.3	Medical gas supply system comprising - One cryogenic storage vessel system - Two cylinder / cylinder bundle manifold systems and one manifold changeover system
A.4	Medical gas supply system comprising - Two cryogenic storage vessel systems - One cylinder / cylinder bundle manifold systems
A.5	Medical air supply system comprising - One medical air compressor unit - One medical air conditioning unit / reservoir - Two cylinder / cylinder bundle manifold systems and one manifold changeover system
A.6	Medical air supply system comprising - Two medical air compressor units - Two medical air conditioning units / reservoirs - One cylinder / cylinder bundle manifold system
A.7	Medical air supply system (alternative arrangement) comprising - Two medical air compressor units - Two medical air conditioning units / reservoirs - One cylinder / cylinder bundle manifold system
A.8	Medical air supply system comprising - Three medical air compressor units - Three medical air conditioning units / reservoirs - One optional cylinder / cylinder bundle manifold system

Table A.1 *(continued)*

Drawing reference	System description
A.9	Medical air supply system (alternative arrangement) comprising - Three medical air compressor units - Two medical air conditioning units / reservoirs - One optional cylinder / cylinder bundle manifold system
A.10	Medical air supply system (alternative arrangement) comprising - Three medical air compressor units - Three medical air conditioning units / reservoirs - One optional cylinder / cylinder bundle manifold system
A.11	Air for driving surgical tools supply system comprising - One air compressor unit - One air conditioning unit / reservoir - One cylinder / cylinder bundle manifold system
A.12	Air for driving surgical tools supply system comprising - Two air compressor units - Two air conditioning units / reservoirs
A.13	Air for driving surgical tools supply system (alternative arrangement) comprising - Two air compressor units - Two air conditioning units / reservoirs
A.14	Synthetic medical air supply system comprising - One proportioning unit - Two cylinder / cylinder bundle manifold systems and one manifold changeover system
A.15	Synthetic medical air supply system comprising - One proportioning unit - Two medical air compressor units - Two medical air conditioning units / reservoirs
A.16	Synthetic medical air supply system comprising - Two proportioning units - One cylinder / cylinder bundle manifold system
A.17	Synthetic medical air supply system comprising - Two proportioning units - One medical air compressor unit - One medical air conditioning unit / reservoir
A.18	Oxygen 93 supply system comprising - One oxygen 93 concentrator unit - Two cylinder / cylinder bundle manifold systems and one manifold changeover system
A.19	Oxygen 93 supply system comprising - Two oxygen 93 concentrator units - One cylinder / cylinder bundle manifold system
A.20	Oxygen 93 supply system comprising - Two oxygen 93 concentrator units - One oxygen 93 high-pressure reservoir system
A.21	Oxygen 93 supply system comprising - Three oxygen 93 concentrator units

Table A.1 *(continued)*

Drawing reference	System description
A.22	Vacuum supply system comprising - Three vacuum pump units - One vacuum receiver - Two bacterial filters - One drainage trap
A.23	Single-stage medical gas pipeline distribution system
A.24	Double-stage medical gas pipeline distribution system
A.25	Single-stage medical air pipeline distribution system including distribution system for air for driving surgical tools.
A.26	Medical gas pipeline area distribution system

Table A.2 — Key to item designations used in Figures A.1 to A.26

Key	Item Name
A	Cylinders / cylinder bundles
B	Cylinders manifold system
C	Manifold changeover system
D	Cryogenic storage vessel system
E	Pressure raising air heated vaporiser
F	Supply gas ambient air heated vaporizer
G	Air compressor unit
H	Conditioning unit
I	Medical gas reservoir (medical air / oxygen 93 / air for driving surgical tools)
J	Cryogenic storage supply unit (oxygen or nitrogen)
K	Proportioning unit (mixer / analyser)
L	Synthetic medical air reservoir
M	Synthetic medical air / oxygen 93 analyser
N	Oxygen 93 concentrator
O	Oxygen 93 booster compressor
P	High-pressure oxygen 93 reservoir
Q	Oxygen 93 pressure control system
R	Vacuum pump unit
S	Vacuum receiver
T	Bacterial filter
U	Drainage trap
V	Medical gas area distribution system
W	Area distribution system for air for driving surgical tools
X	Area distribution system for medical air
AA	Connection between medical gas or vacuum supply system and pipeline distribution system
BB	Alternative connection for reserve source of supply and pipeline distribution system
CC	Connection between medical oxygen supply source and medical oxygen pipeline distribution system
DD	Connection between medical nitrogen supply source and medical nitrogen pipeline distribution system
1	Supply source shut-off valve
2	Main shut-off valve
3	By-pass valve
4	Riser shut-off valve

Table A.2 *(continued)*

Key	Item Name
5	Area shut-off valve
6	Maintenance shut-off valve
7	Line pressure regulator
8	Terminal unit
9	Pressure relief valve
10	Non-return valve
11	Maintenance supply assembly
12	Pressure switch
13	Flexible connection

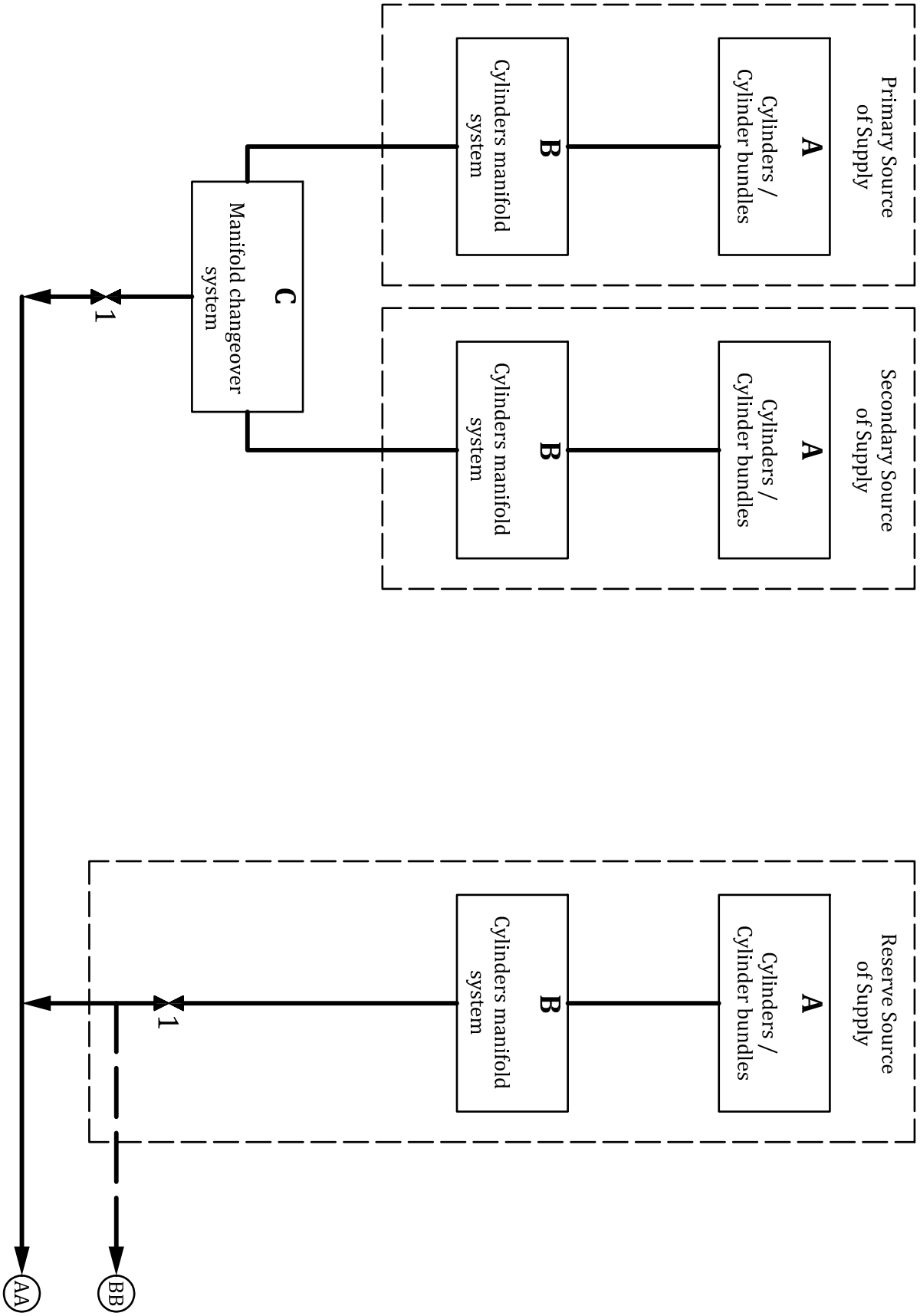


Figure A.1 — Medical gas supply system comprising: Two cylinder/cylinder bundle manifold systems and one manifold changeover system; one cylinder/cylinder bundle manifold system

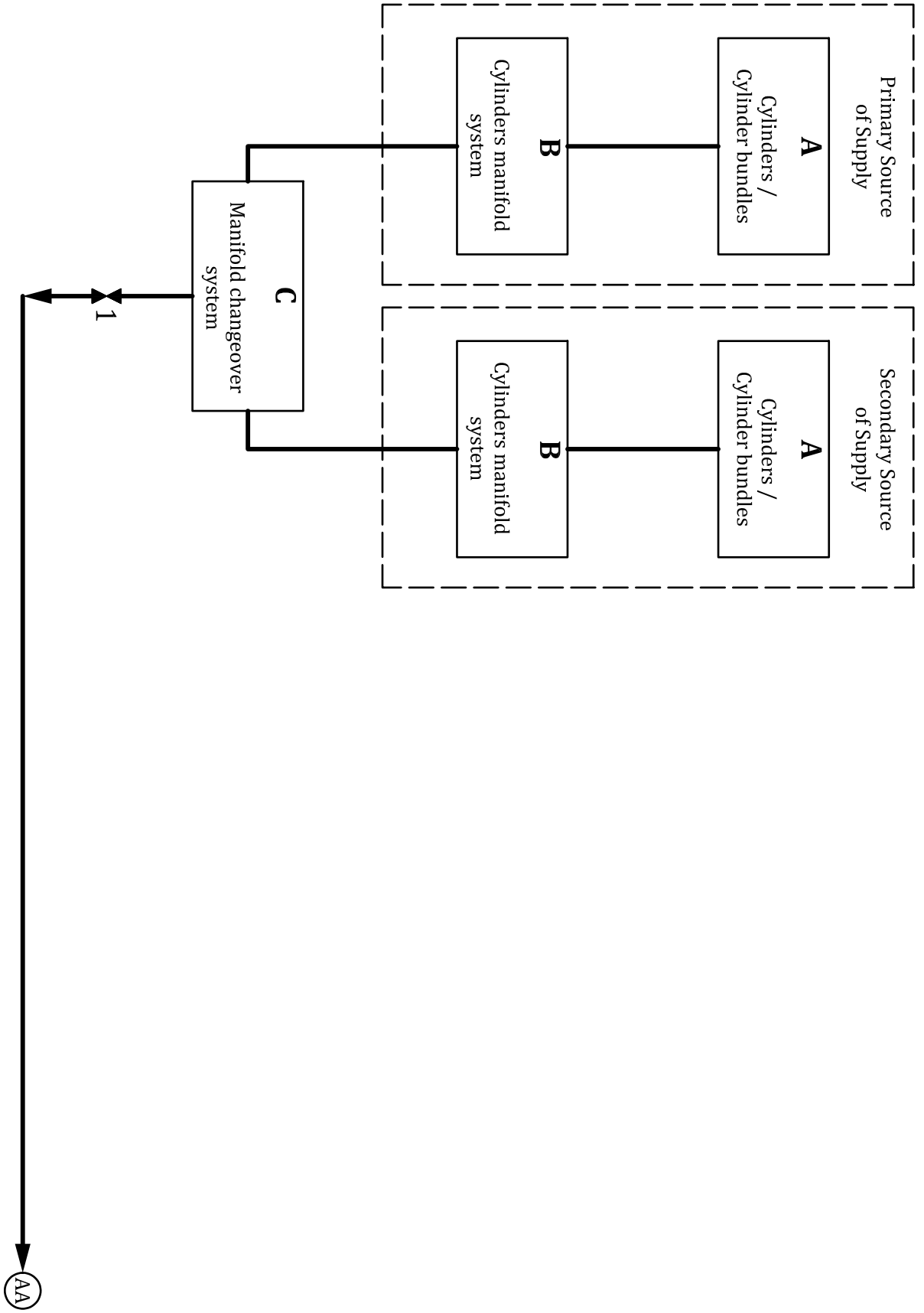


Figure A.2 — Air or nitrogen for driving surgical tools supply system comprising: Two cylinder/cylinder bundle manifold systems and one manifold changeover system

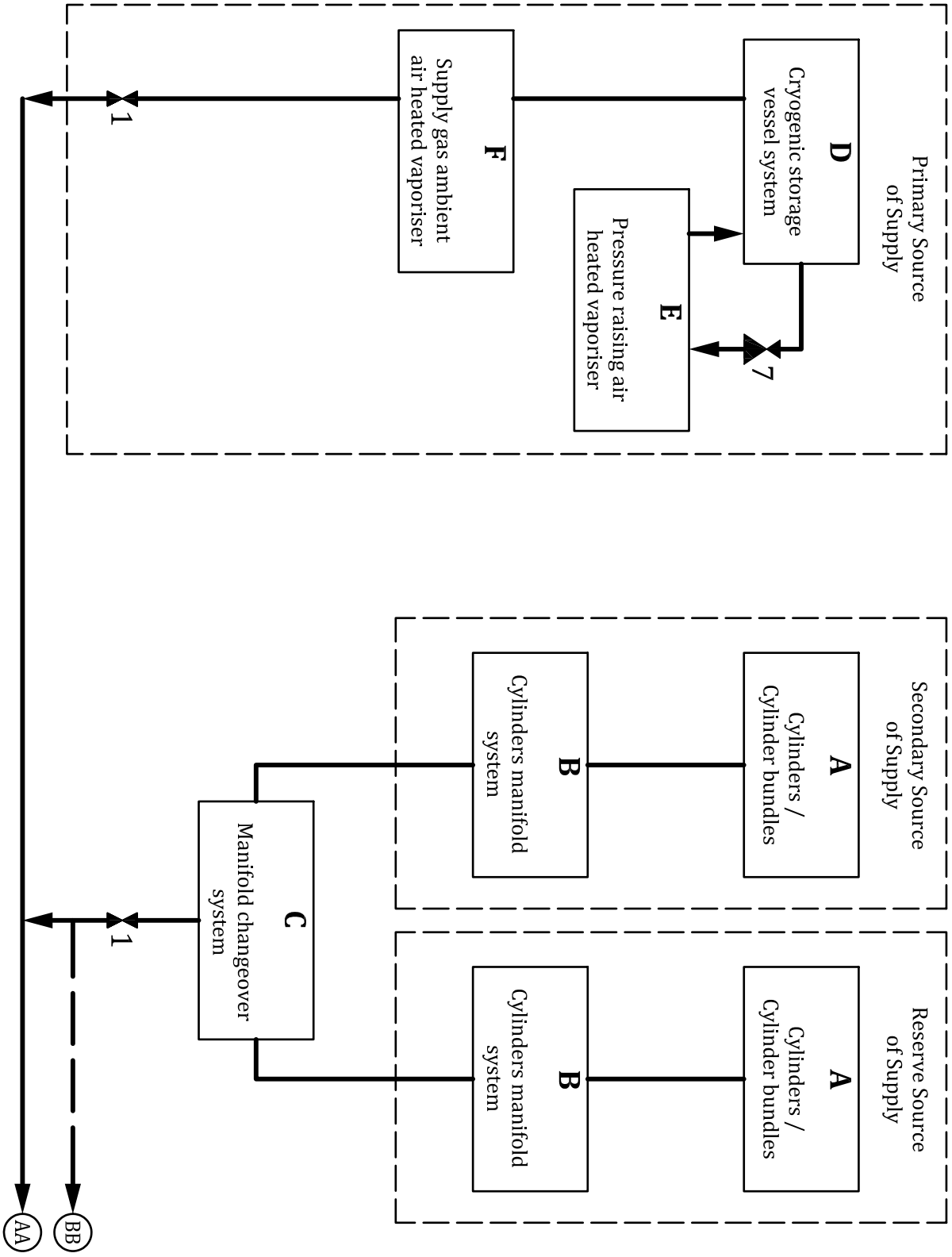


Figure A.3 — Medical gas supply system comprising: One cryogenic storage vessel system; two cylinder/cylinder bundle manifold systems and one manifold changeover system

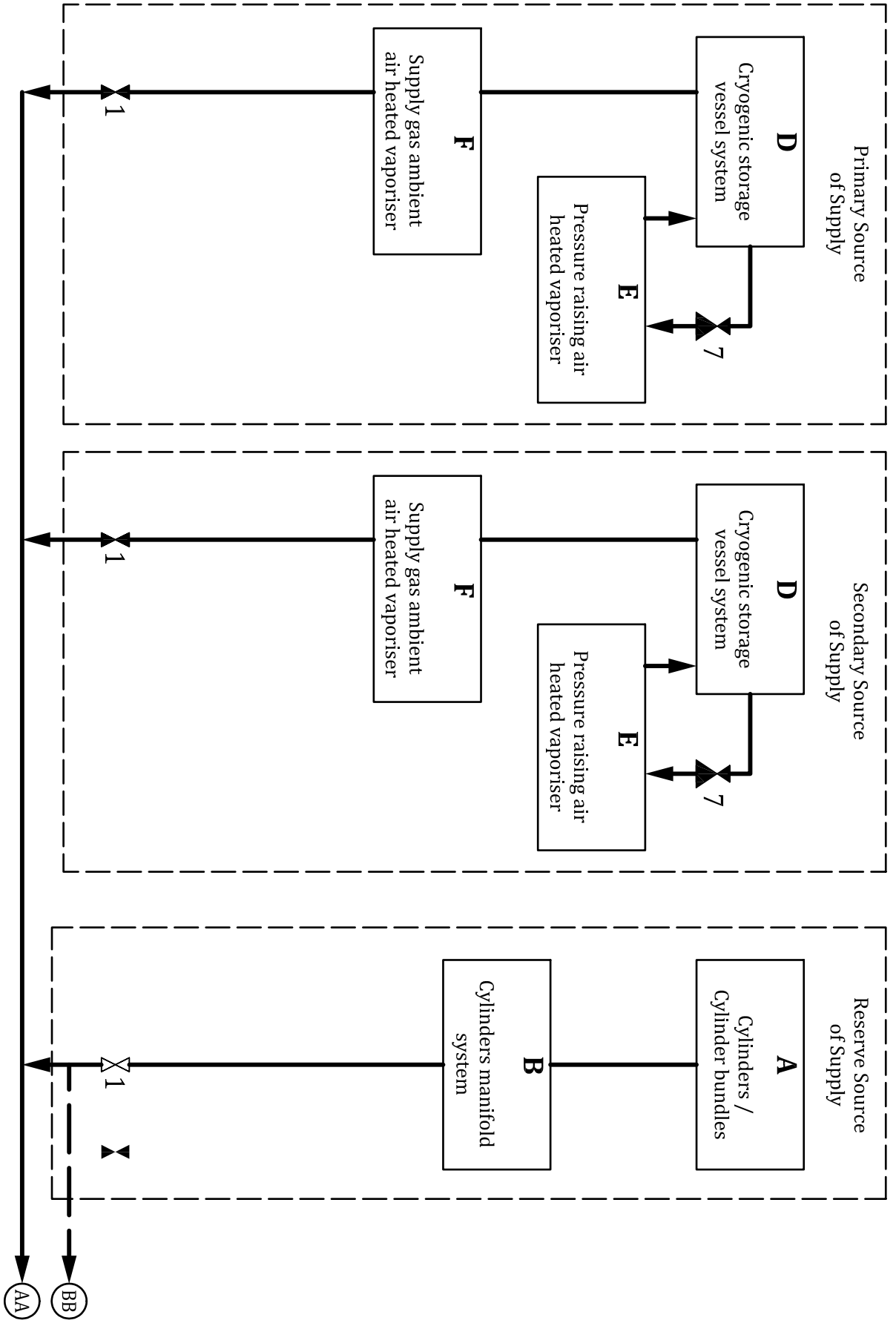


Figure A.4 — Medical gas supply system comprising: Two cryogenic storage vessel systems; one cylinder/cylinder bundle manifold system

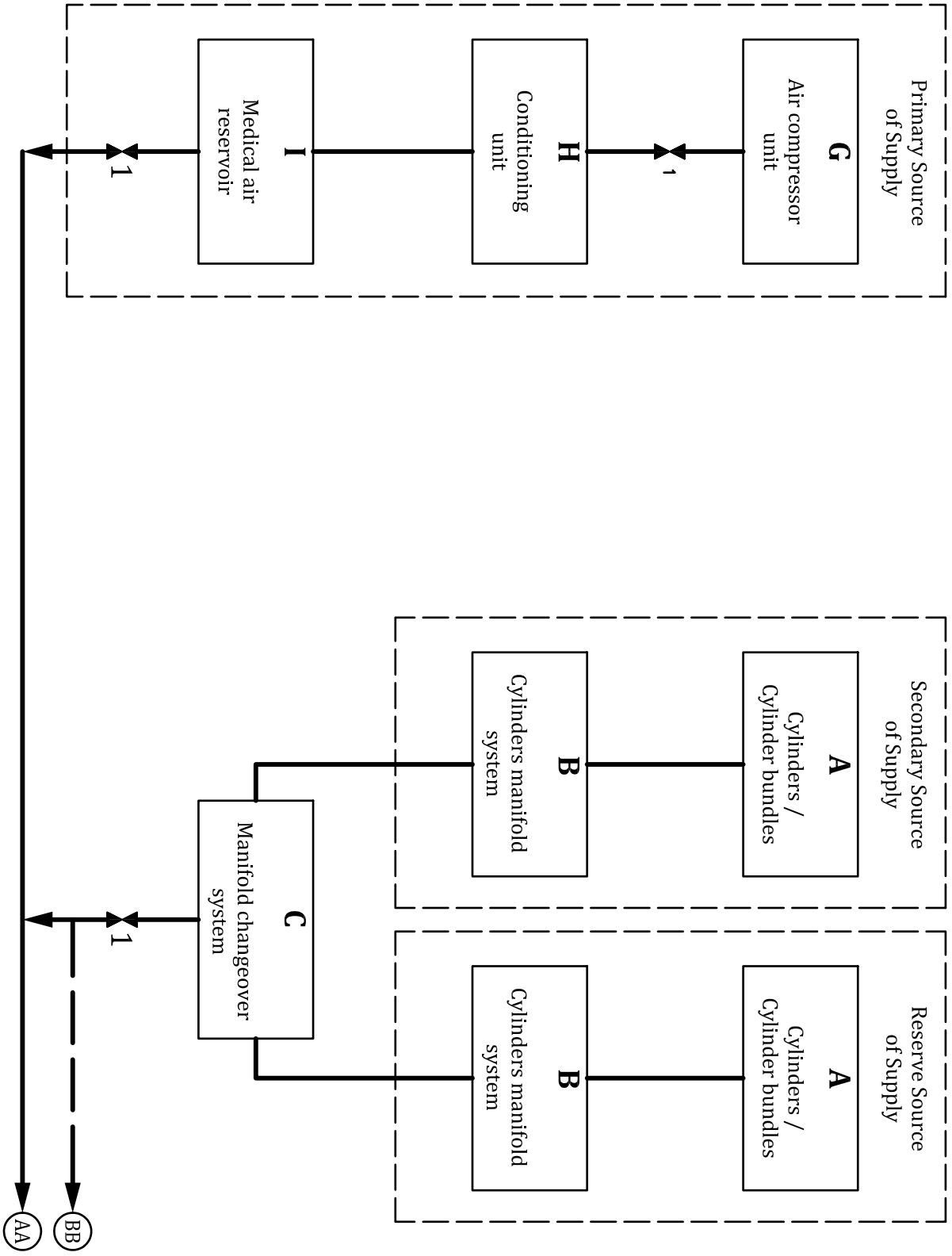


Figure A.5 — Medical air supply system comprising: One medical air compressor unit, one medical air conditioning unit/reservoir, two cylinder/cylinder bundle manifold systems and one manifold changeover system

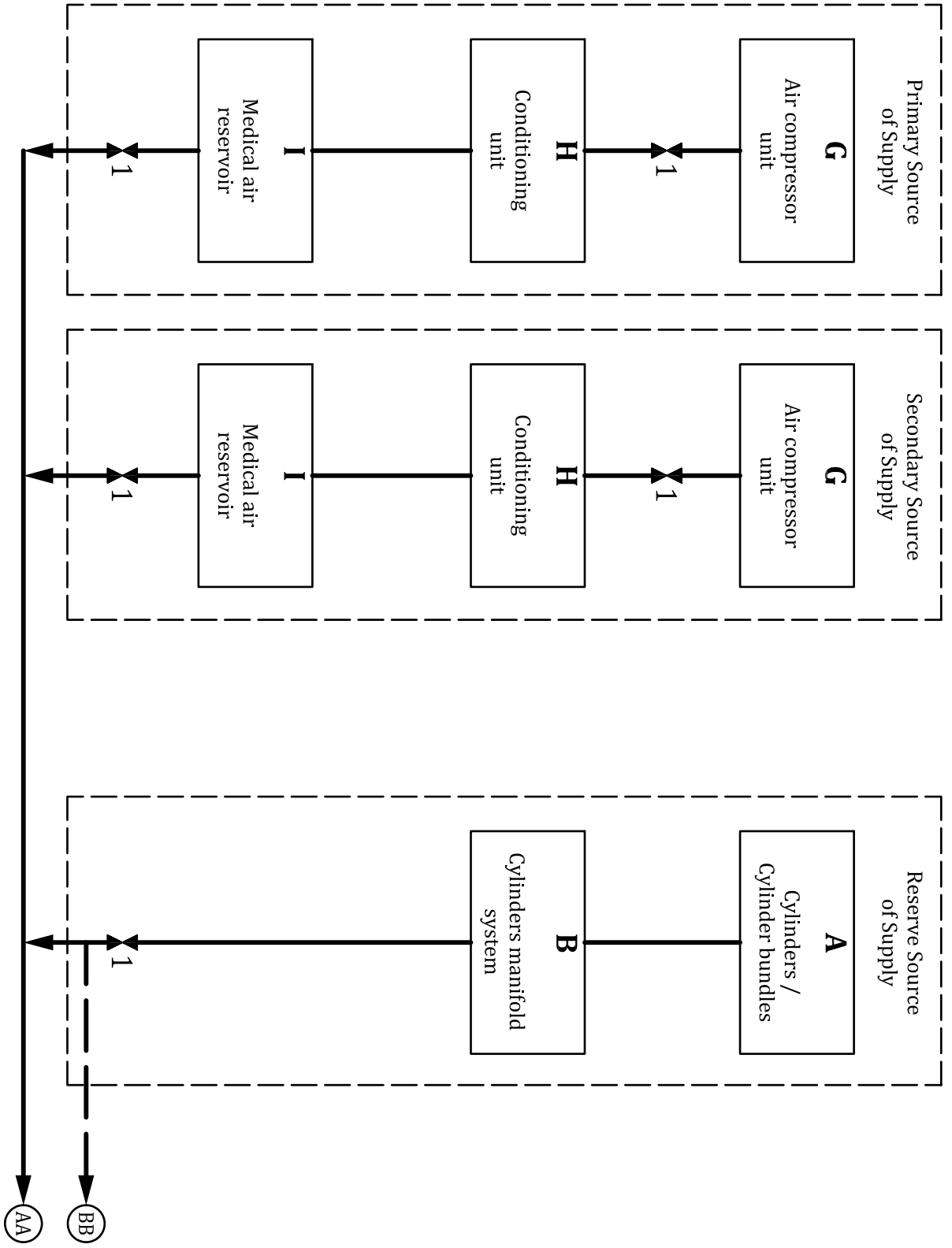


Figure A.6 — Medical air supply system comprising: Two medical air compressor units; two medical air conditioning units / reservoirs; one cylinder/cylinder bundle manifold system

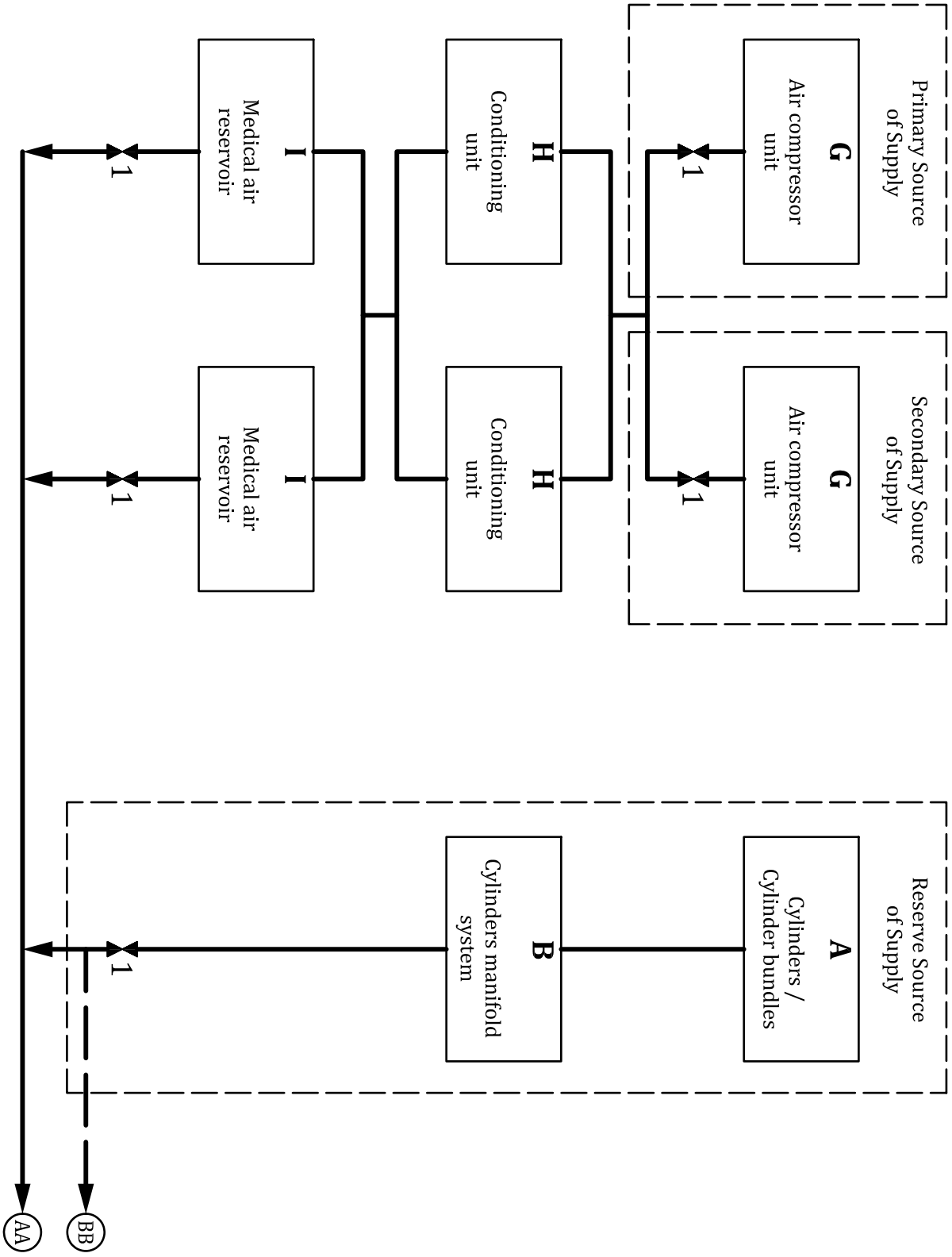


Figure A.7 — Medical air supply system (alternative arrangement) comprising: Two medical air compressor units; two medical air conditioning units/reservoirs; one cylinder/cylinder bundle manifold system

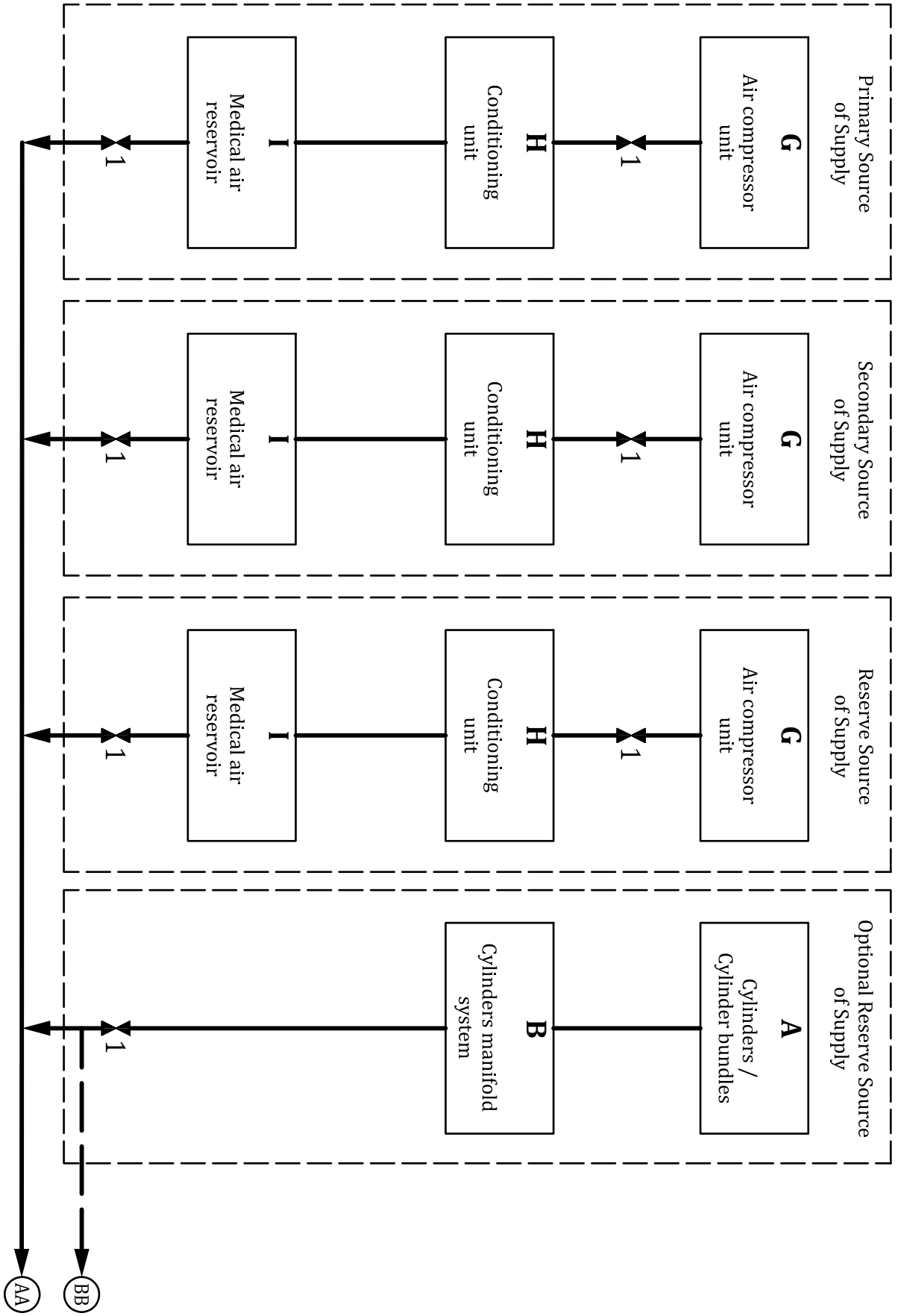


Figure A.8 — Medical air supply system comprising: Three medical air compressor units; three medical air conditioning units/reservoir; one optional cylinder/cylinder bundle manifold system

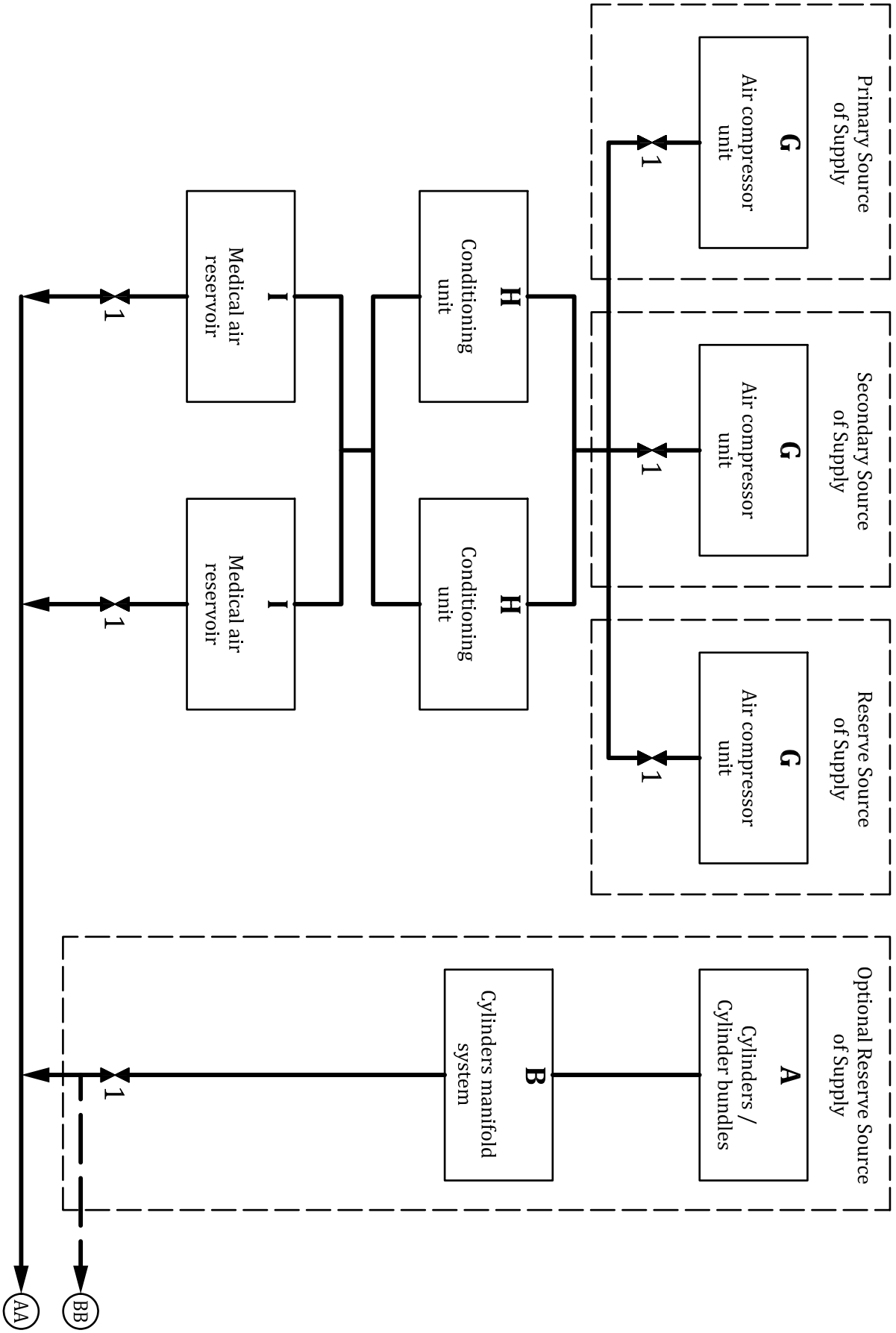


Figure A.9 — Medical air supply system (alternative arrangement) comprising: Three

medical air compressor units; two medical air conditioning units/reservoirs; one optional cylinder/cylinder bundle manifold system

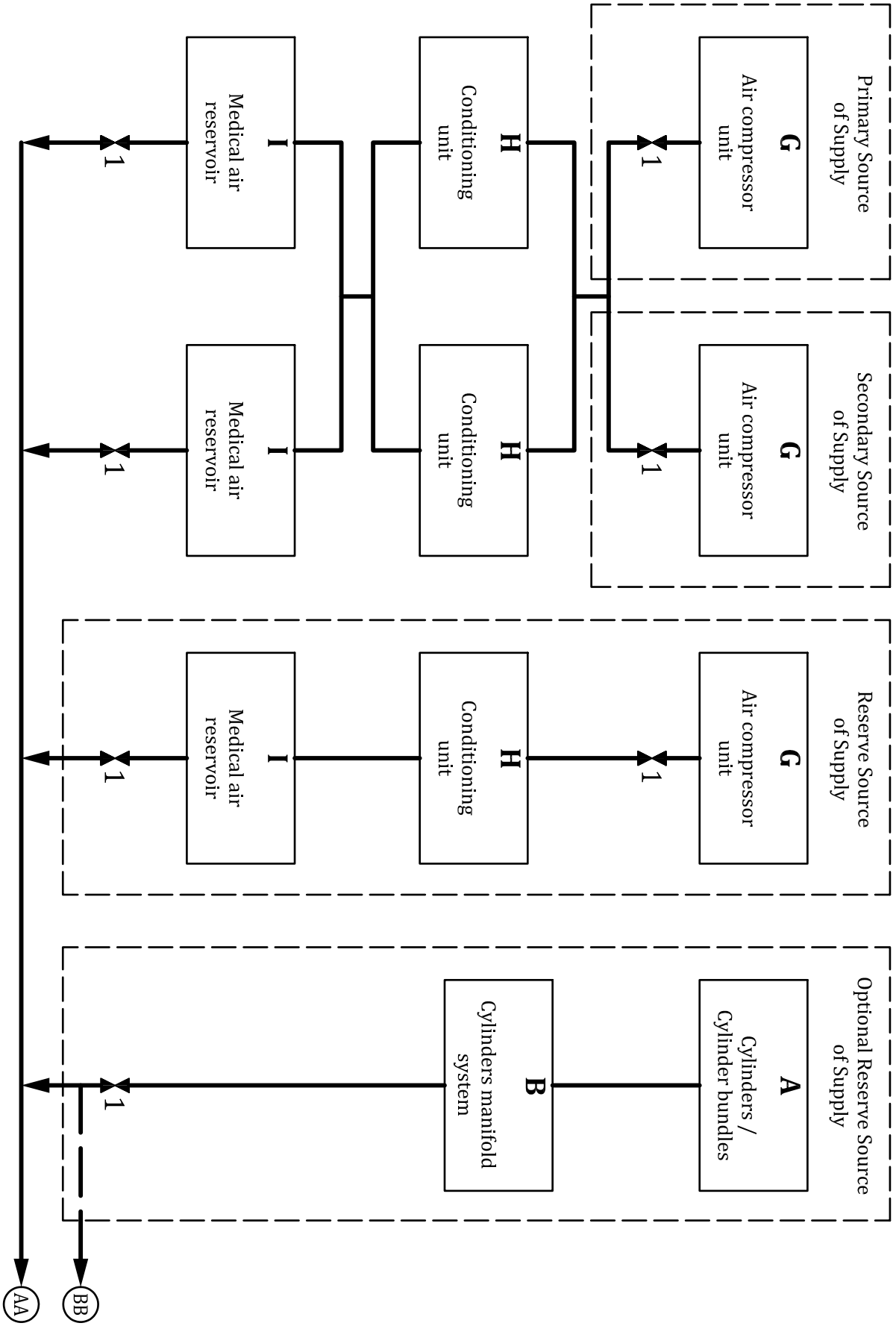


Figure A.10 — Medical air supply system (alternative arrangement) comprising: Three medical air compressor units; three medical air conditioning units/reservoirs; one optional

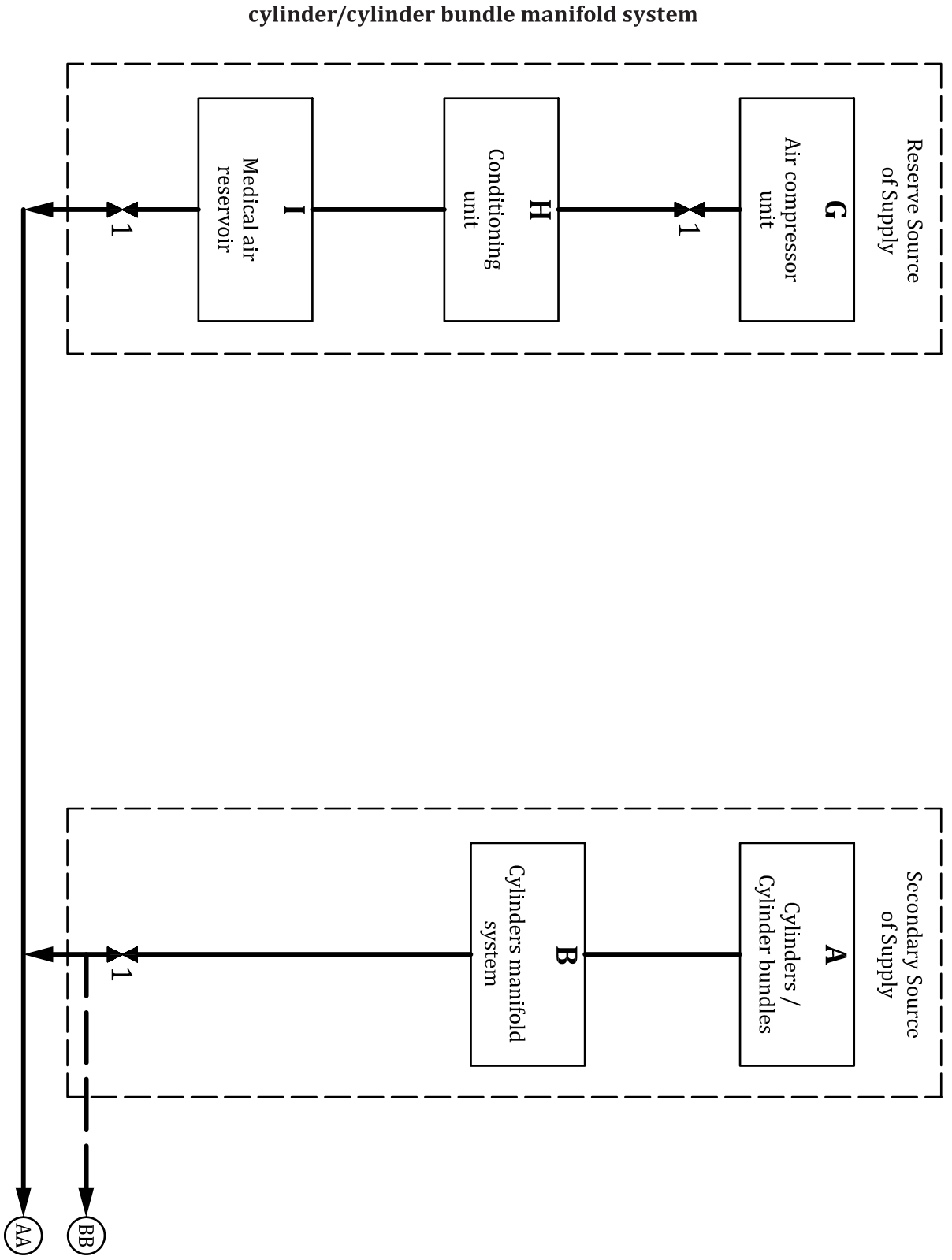


Figure A.11 — Air for driving surgical tools supply system comprising: One air compressor unit; one air conditioning unit (reservoir); one cylinder/cylinder bundle manifold system

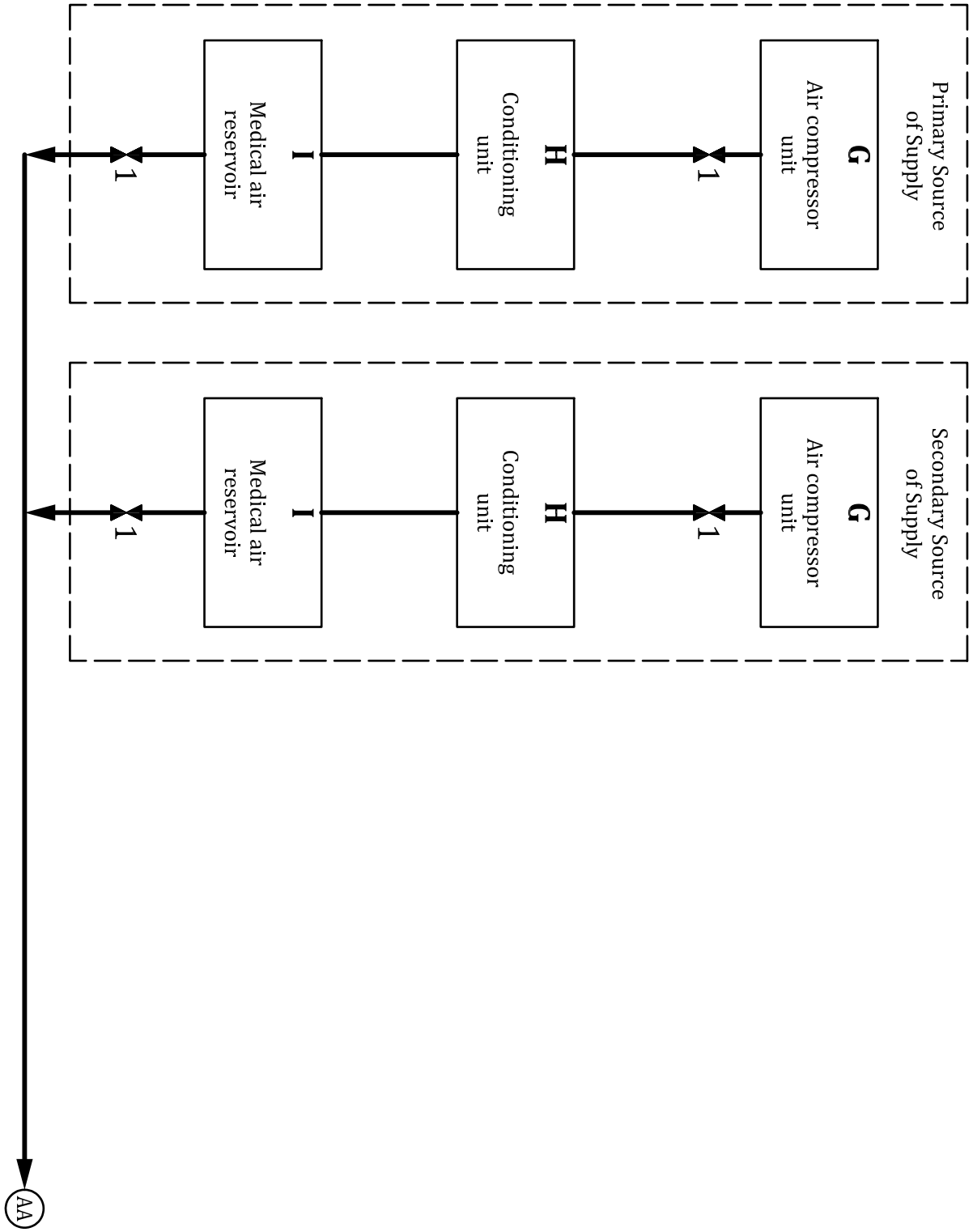


Figure A.12 — Air for driving surgical tools supply system comprising: Two air compressor units; two air conditioning units/reservoirs

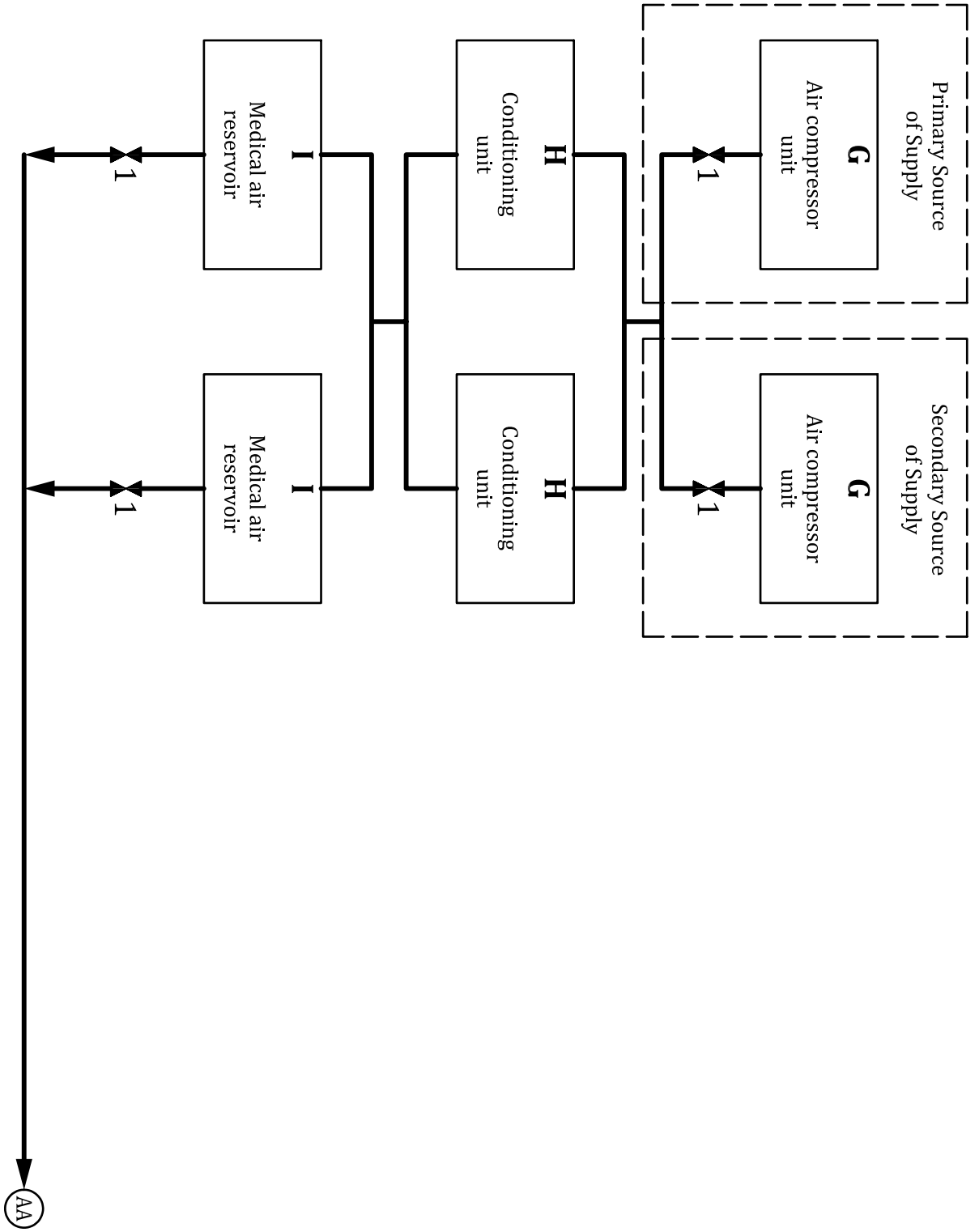


Figure A.13 — Air for driving surgical tools supply system (alternative arrangement) comprising: Two air compressor units; two air conditioning units/reservoirs

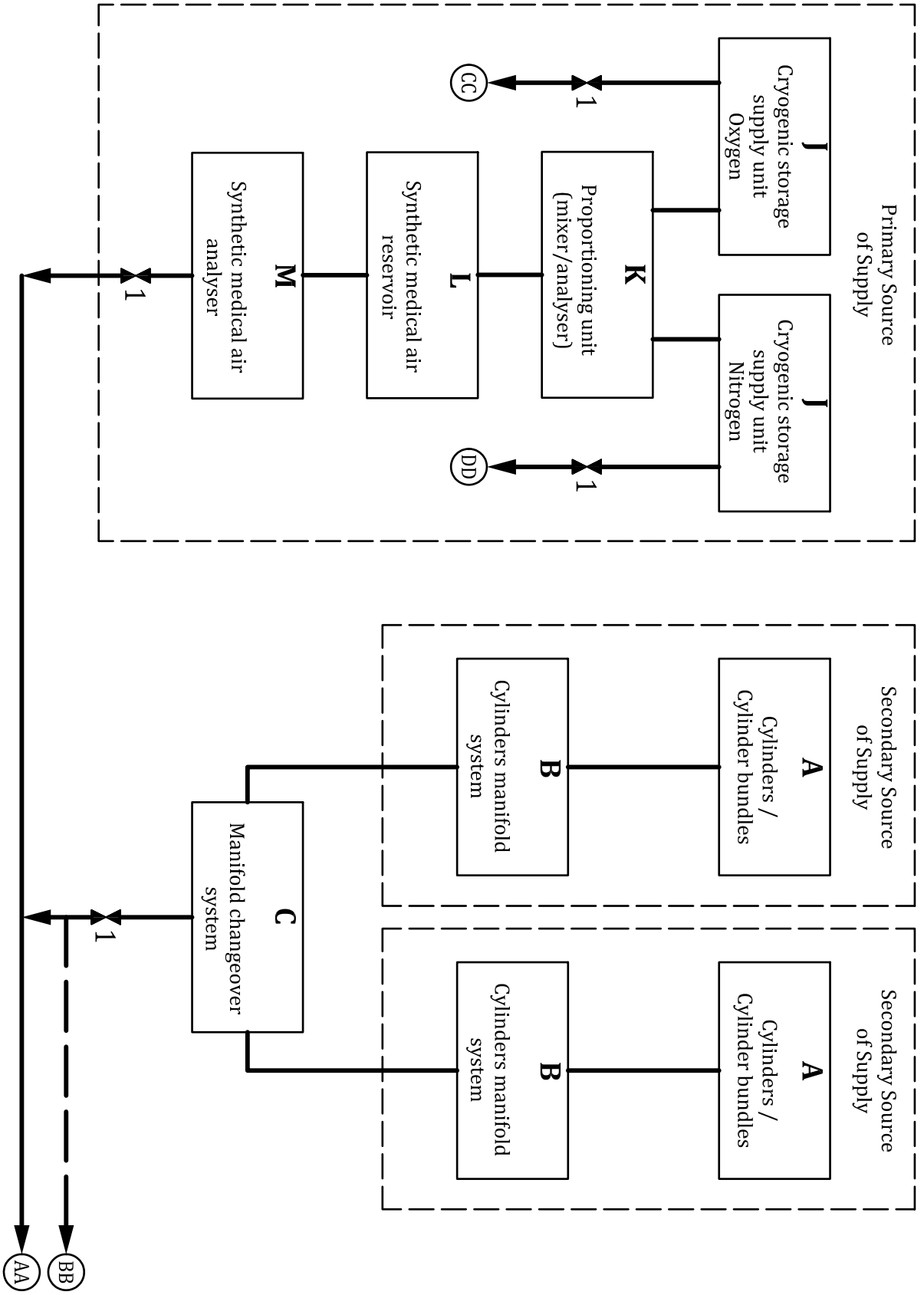


Figure A.14 — Synthetic medical air supply system comprising: One proportioning unit; two cylinder/cylinder bundle manifold systems and one manifold changeover system

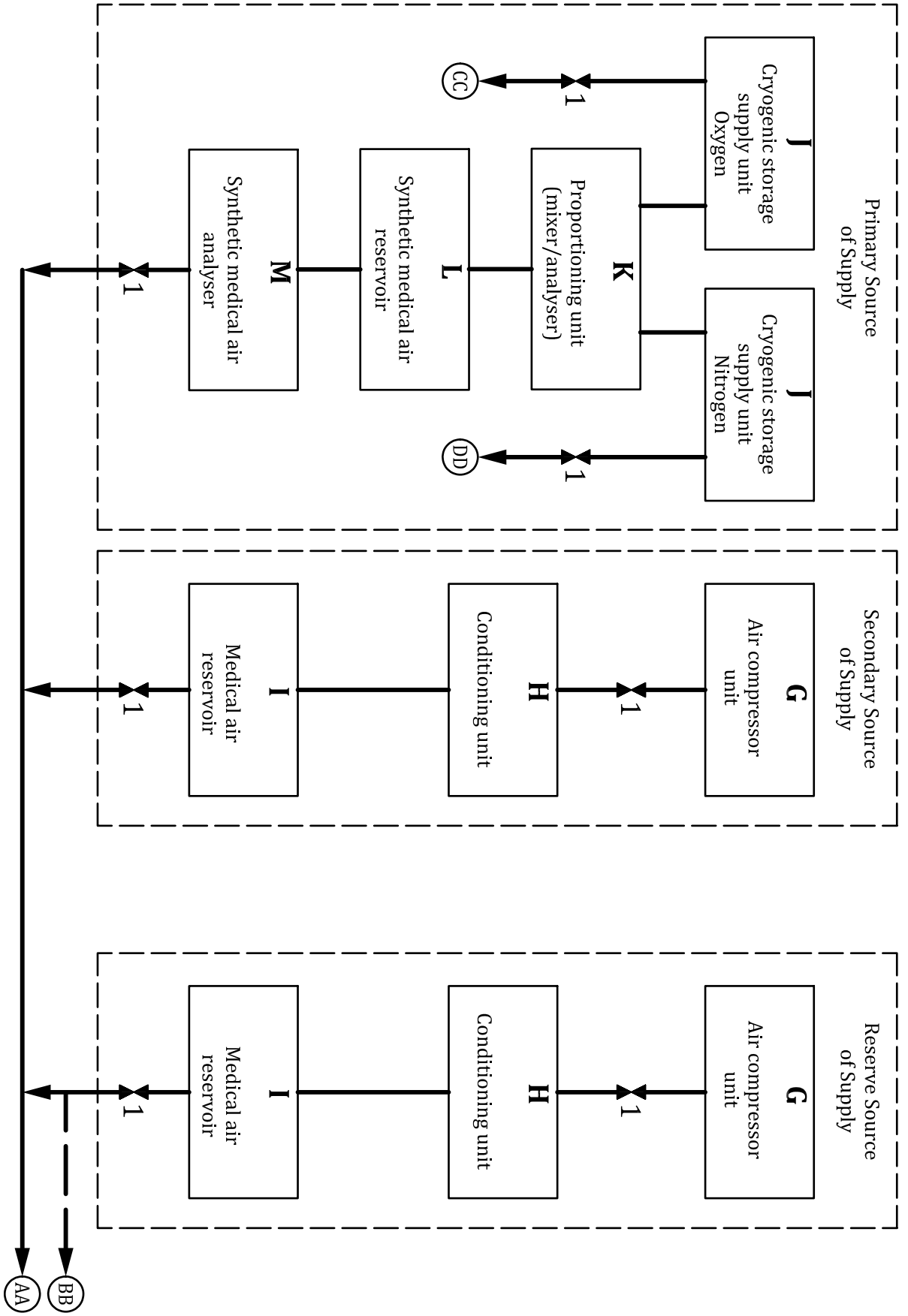


Figure A.15 — Synthetic medical air supply system comprising: One proportioning unit; two medical air compressor units; two medical air conditioning units/reservoirs

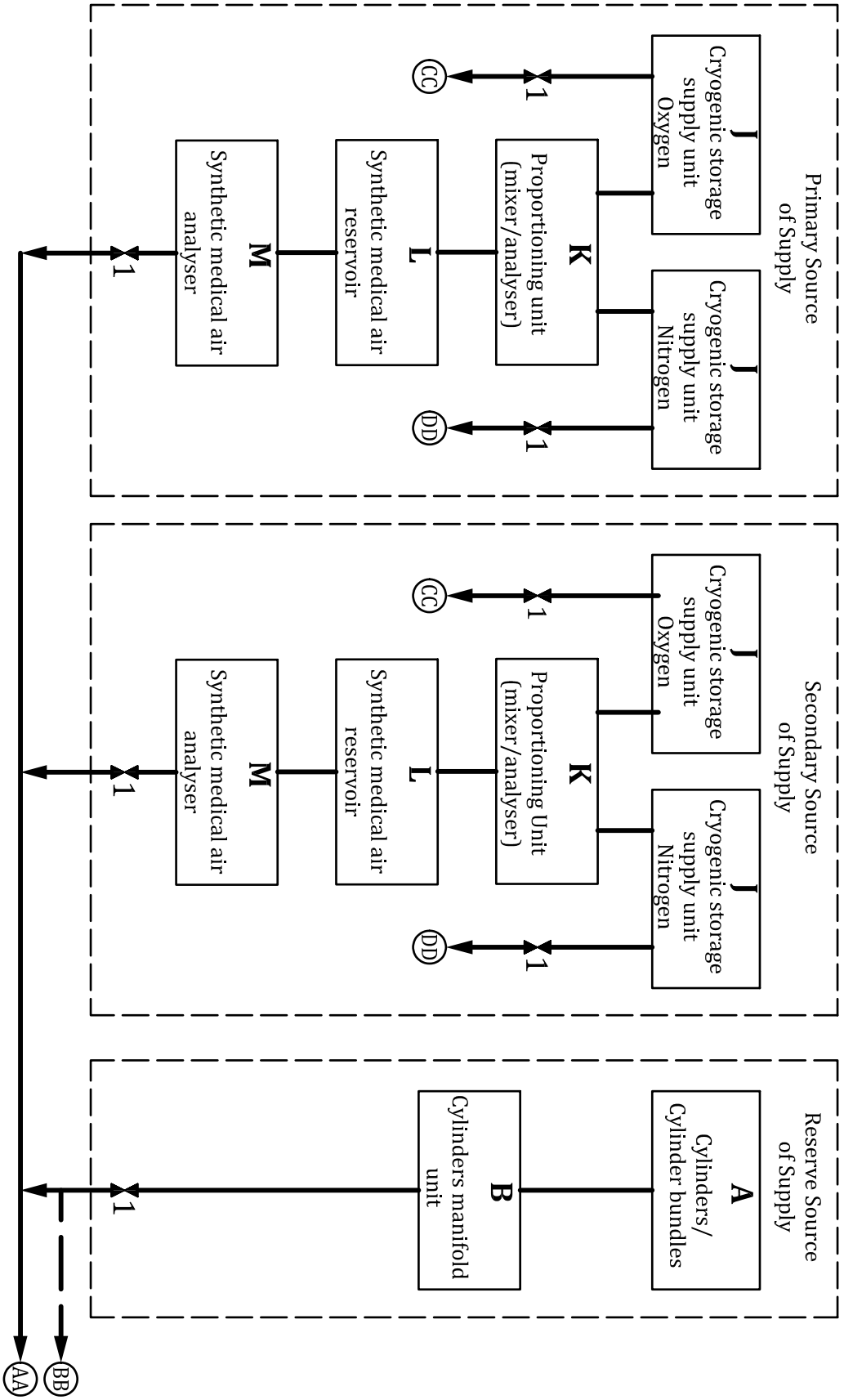


Figure A.16 — Synthetic medical air supply system comprising: Two proportioning units; one cylinder/cylinder bundle manifold system

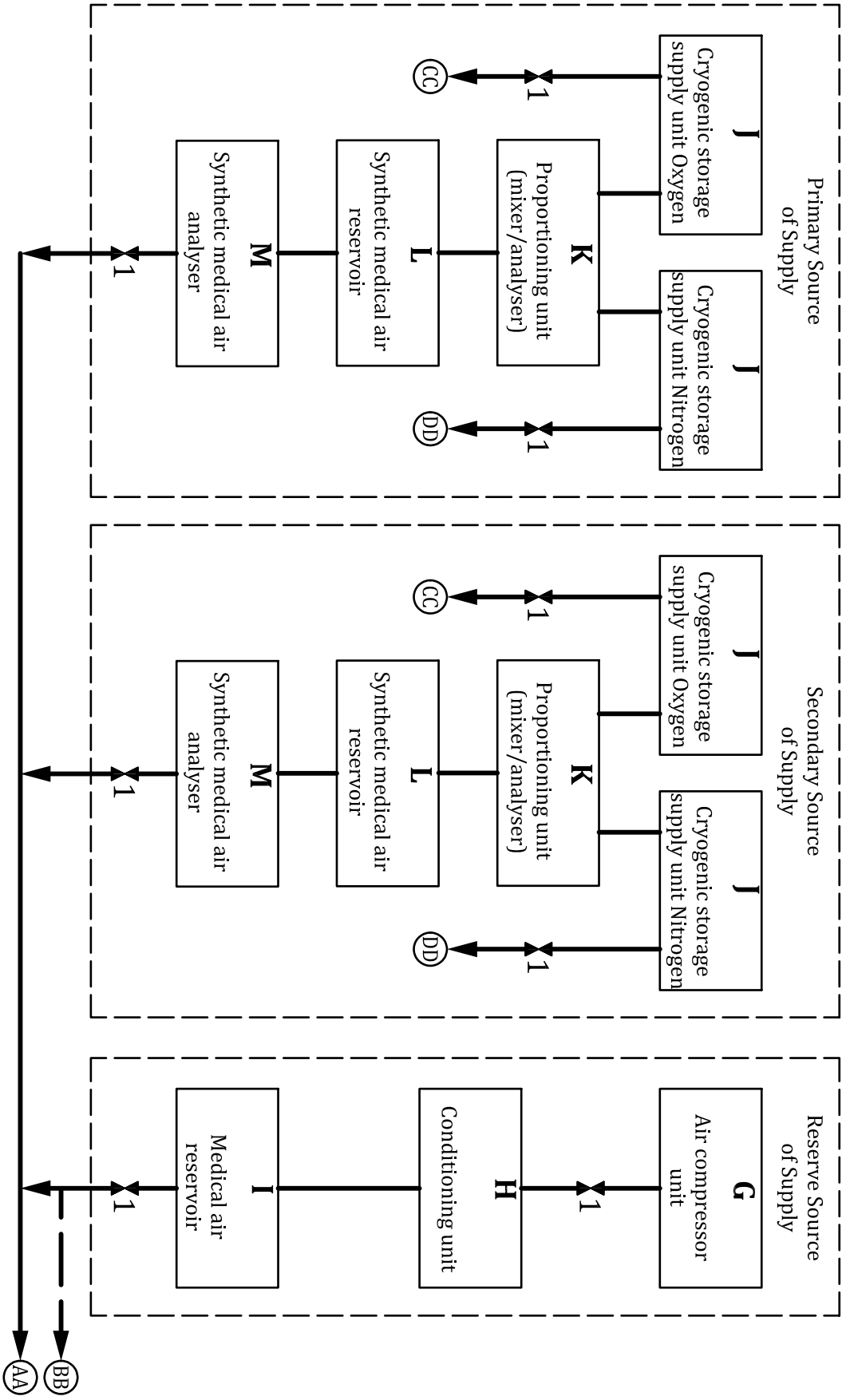


Figure A.17 — Synthetic medical air supply system comprising: Two proportioning units; one medical air compressor unit; one medical air conditioning unit/reservoir

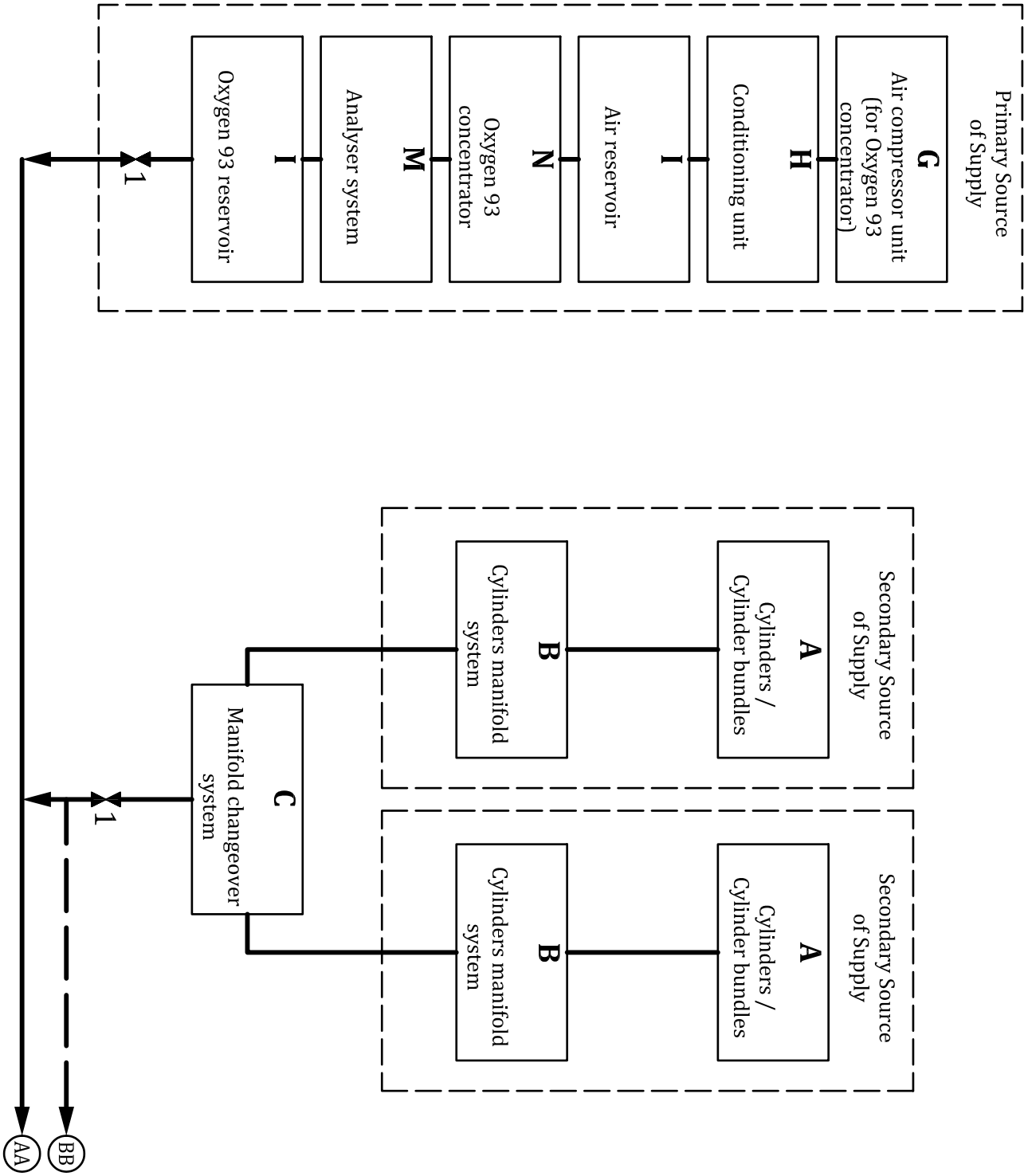


Figure A.18 — Oxygen 93 supply system comprising: One oxygen 93 concentrator unit; two cylinder/cylinder bundle manifold systems and one manifold changeover system

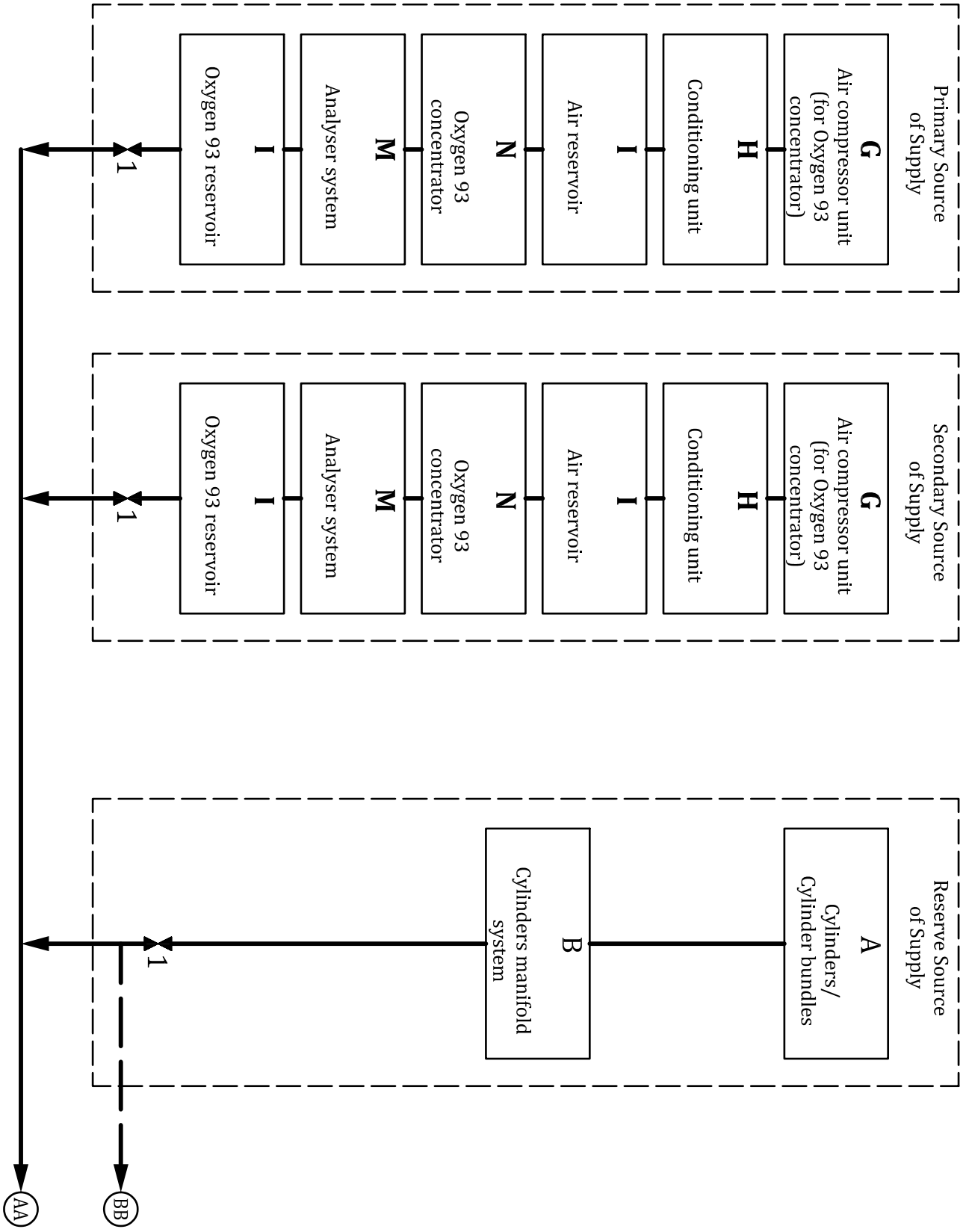


Figure A.19 — Oxygen 93 supply system comprising: Two oxygen 93 concentrator units; one cylinder/cylinder bundle manifold system

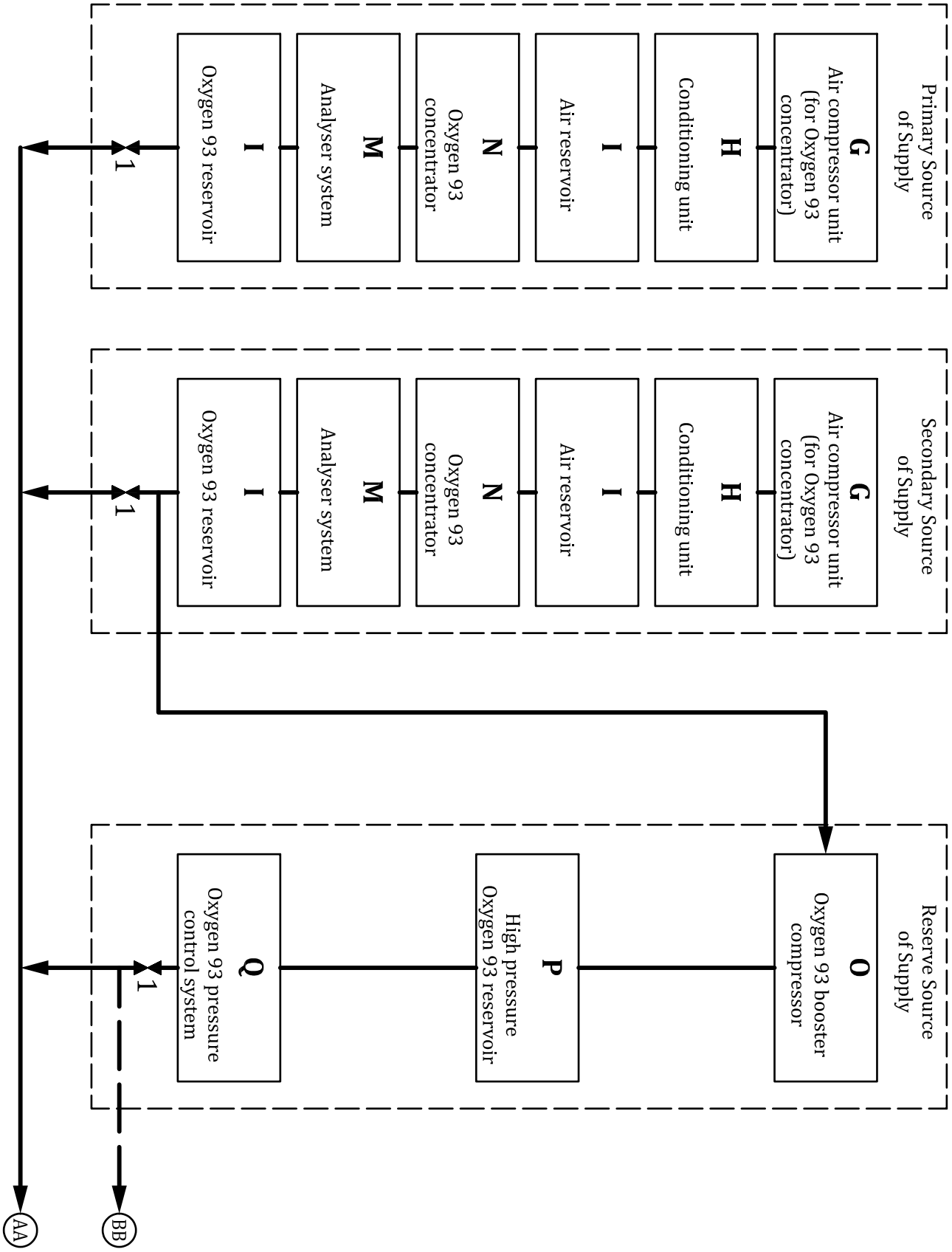


Figure A.20 — Oxygen 93 supply system comprising: Two oxygen 93 concentrator units; one oxygen 93 high-pressure reservoir system

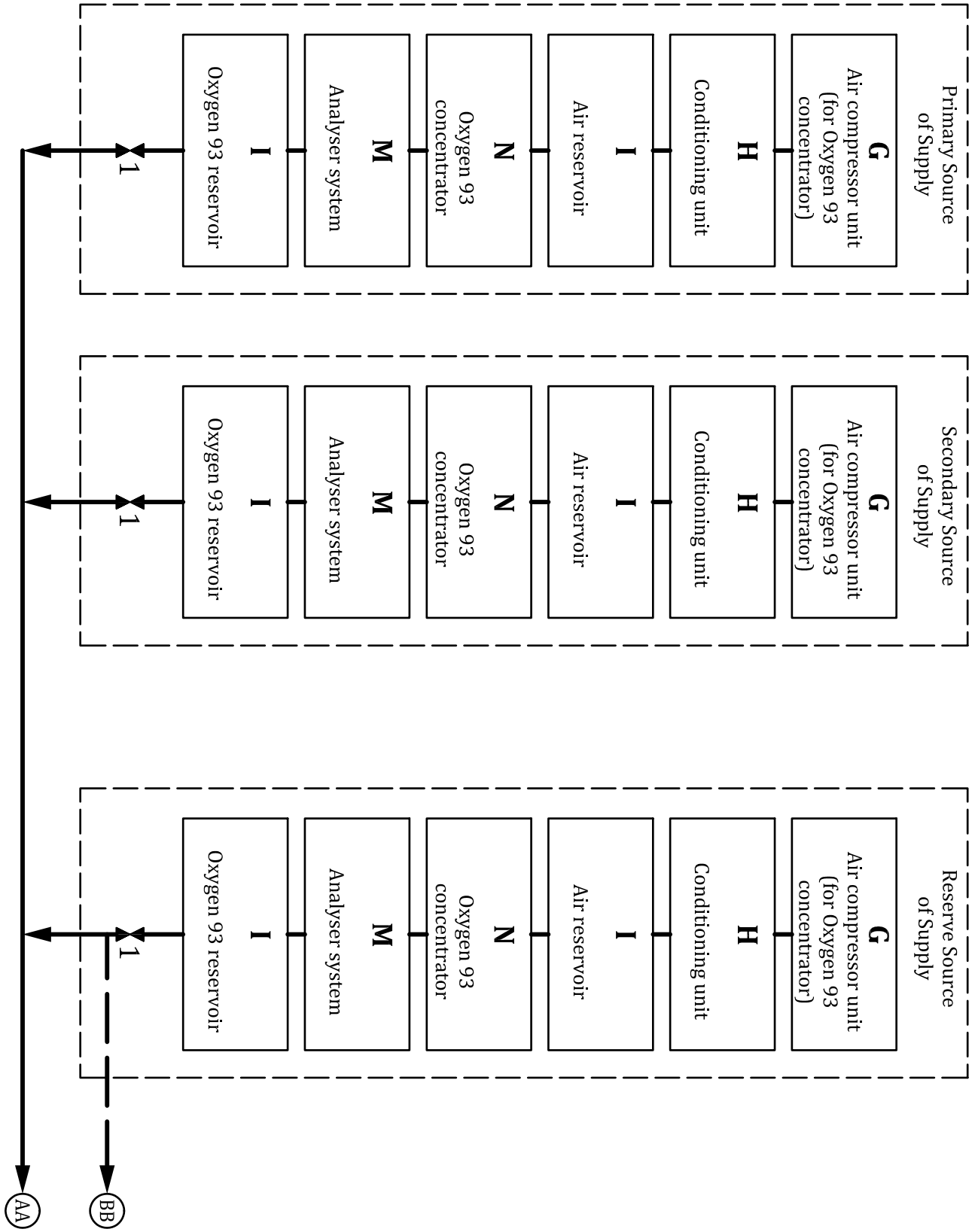


Figure A.21 — Oxygen 93 supply system comprising: Three oxygen 93 concentrator units

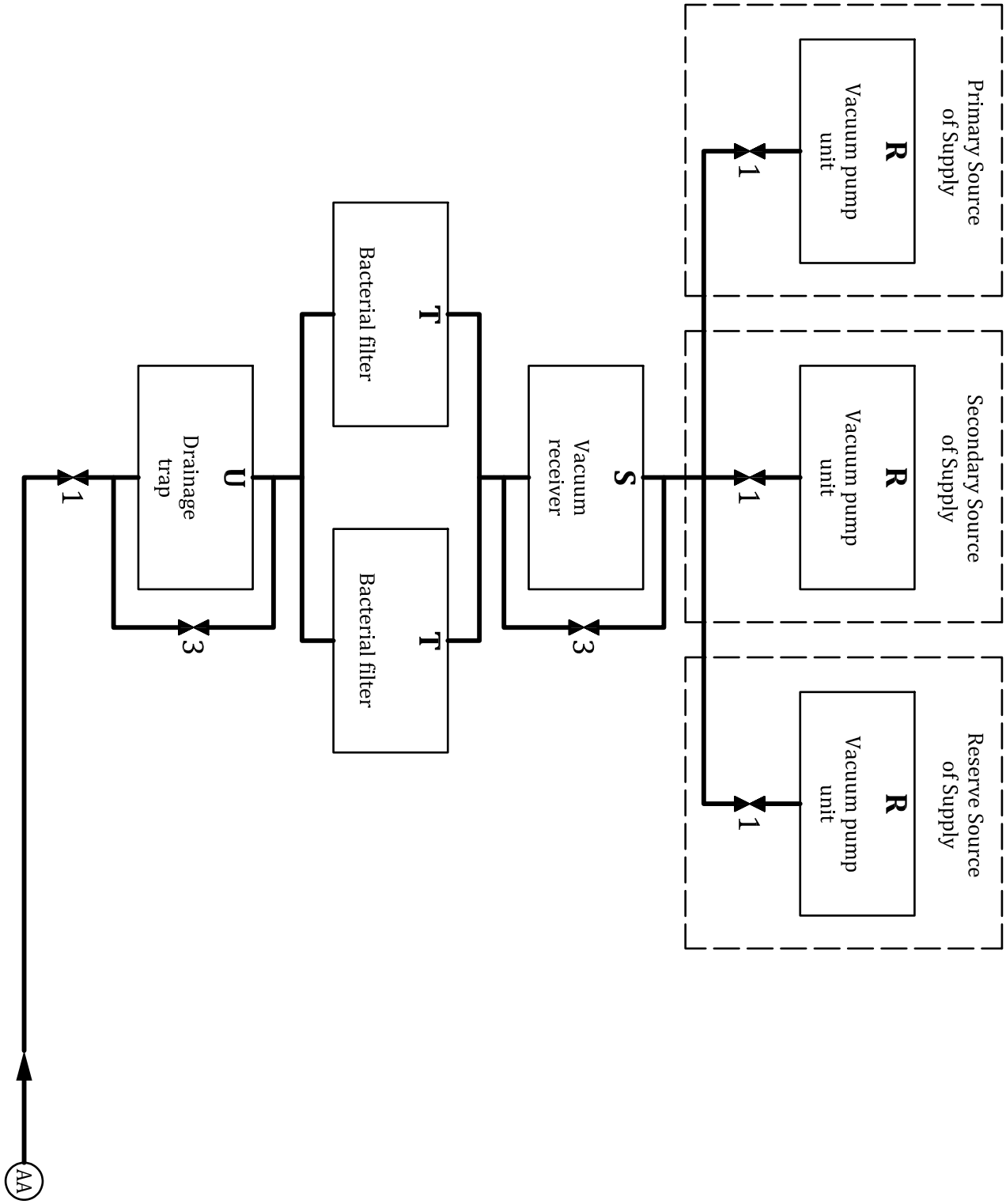


Figure A.22 — Vacuum supply system comprising: Three vacuum pump units; one vacuum receiver; two bacterial filters; one drainage trap

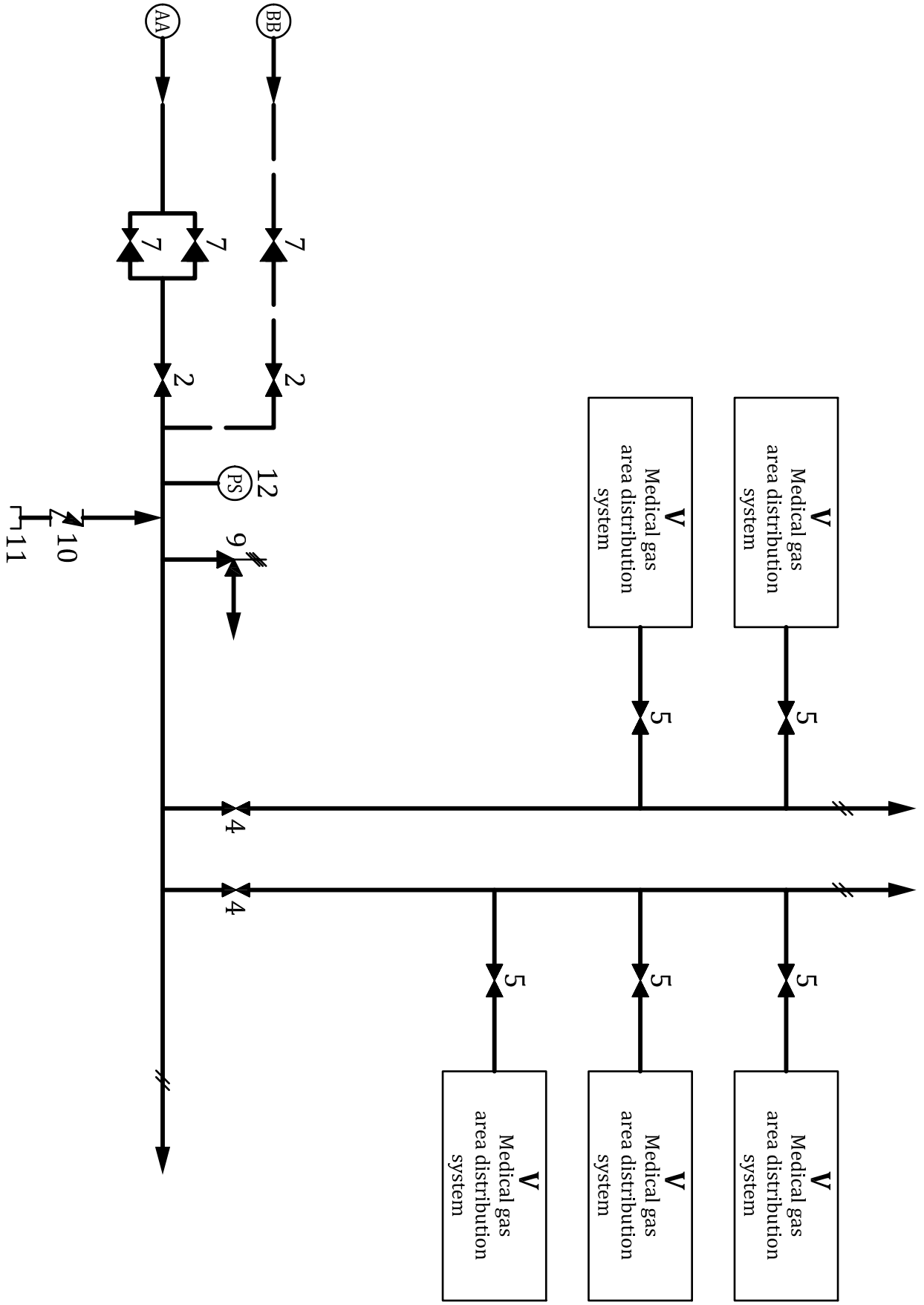


Figure A.23 — Single-stage medical gas pipeline distribution system

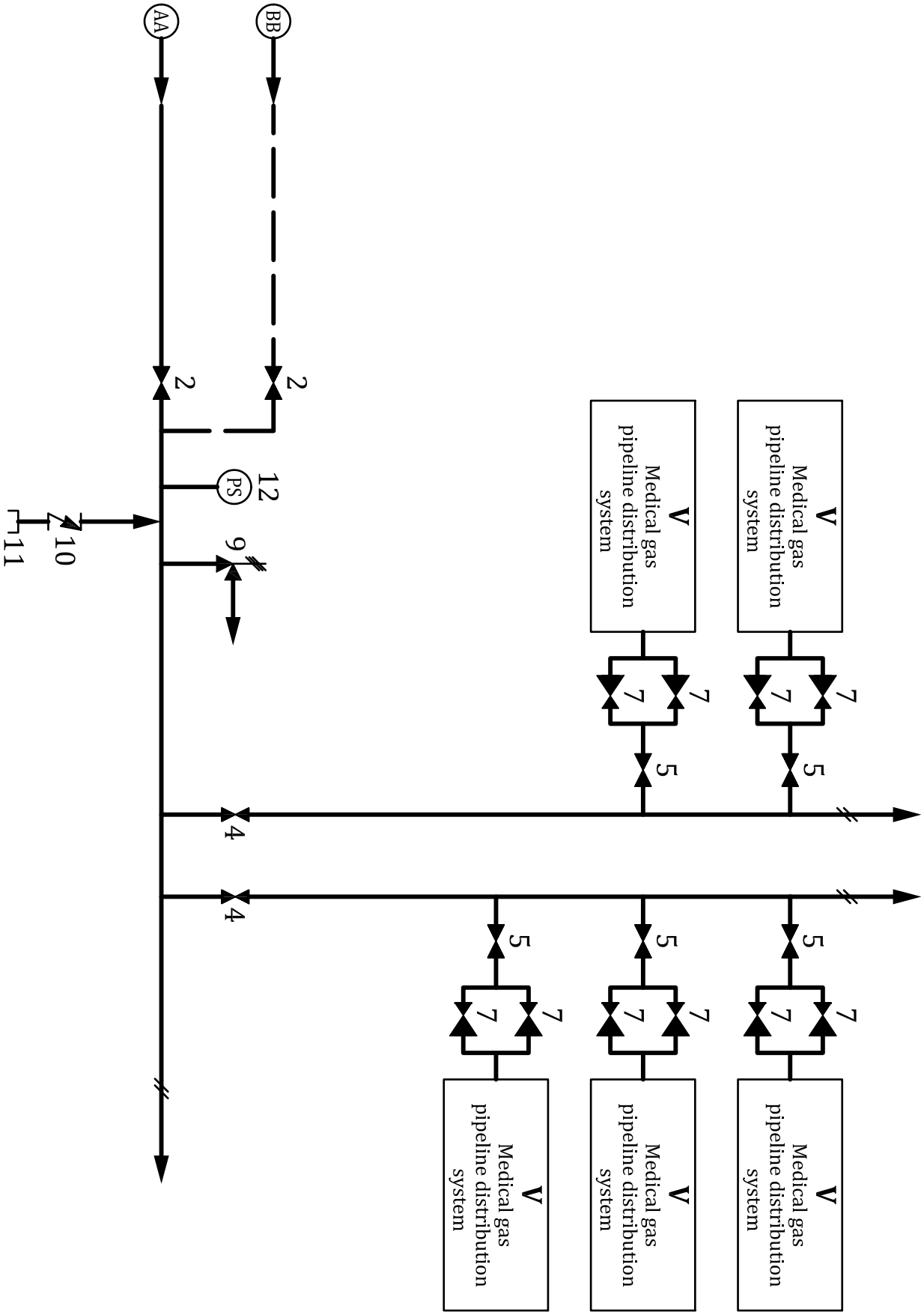


Figure A.24 — Double-stage medical gas pipeline distribution system

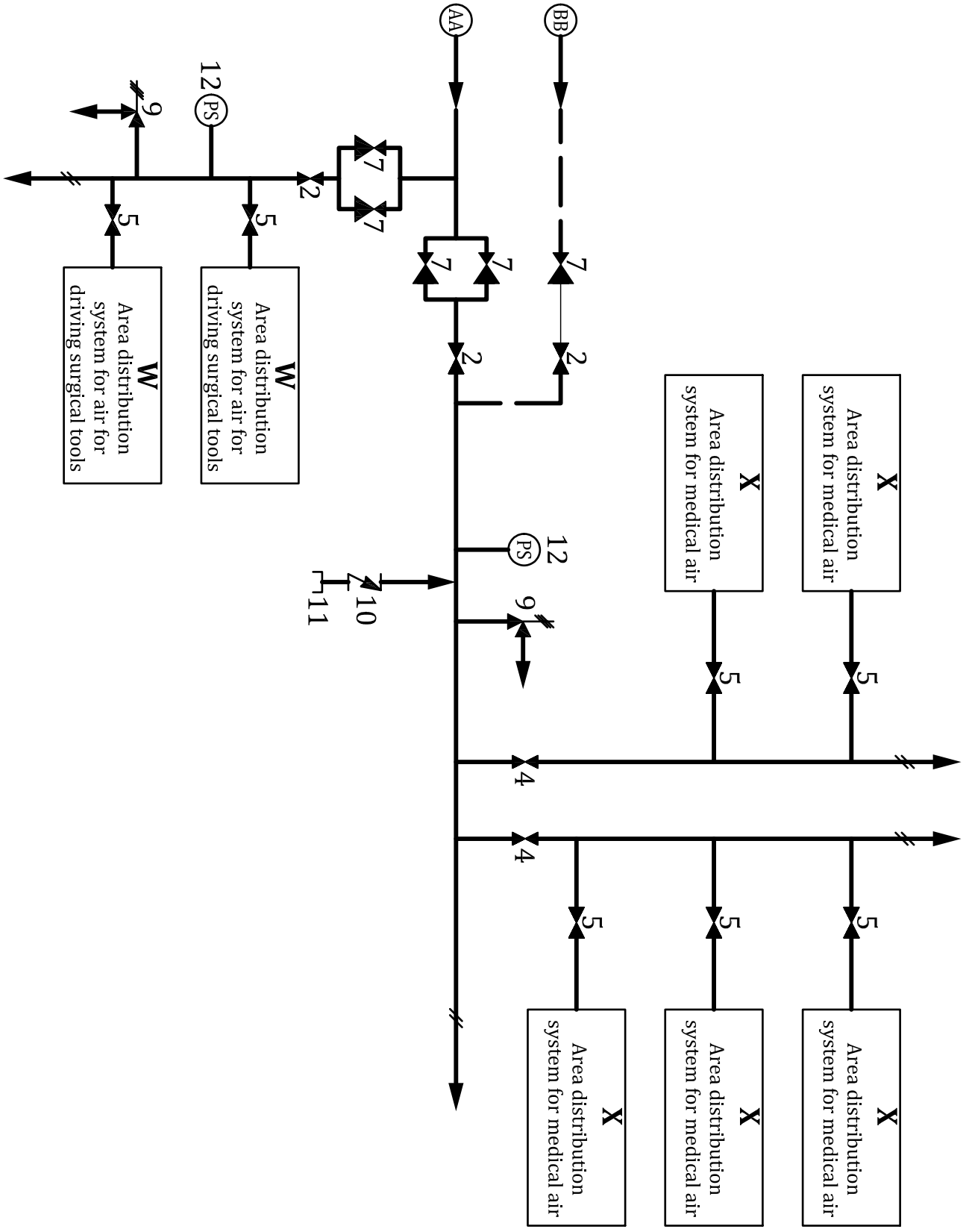


Figure A.25 — Single-stage medical gas pipeline distribution system including distribution system for air for driving surgical tools

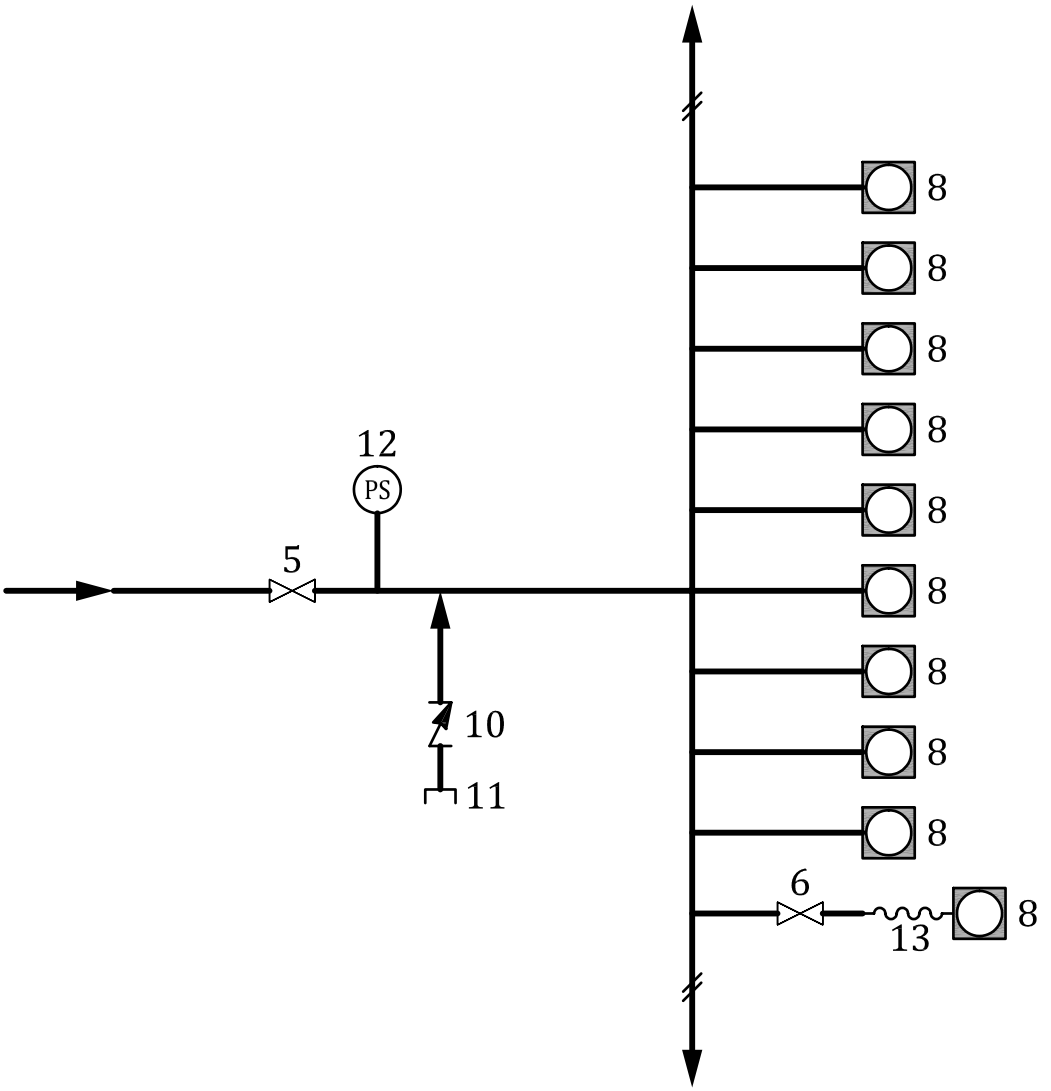


Figure A.26 — Medical gas area distribution system

Annex B
(informative)

Guidelines for location of cylinder manifolds, cylinder storage areas and stationary vessels for cryogenic or non-cryogenic liquids

B.1 Location of cylinder manifolds

A supply system with cylinders should be installed in a well ventilated and fire-resistant room that is specially constructed or suitably modified. Alternatively, it may be installed in the open air under cover, protected from the weather and the area fenced to prevent access by unauthorized persons.

NOTE Regional or national regulations which apply to the location of cylinder manifolds can exist.

B.2 Location of cylinder storage areas

B.2.1 Cylinder storage areas should be well ventilated and fire-resistant. If located in the open air, they should be under cover and protected from the weather. Cylinder storage areas should be fenced to prevent access by unauthorized persons.

B.2.2 Adequate vehicle access for safe unloading and handling of cylinders should be provided.

NOTE Regional or national regulations which apply to cylinder storage areas can exist.

B.3 Location of stationary vessels

B.3.1 Stationary vessels containing cryogenic or non-cryogenic liquids should not be installed over subterranean structures such as underground bunkers, basement rooms, etc., and should be more than 5 m away from openings to trenches, subterranean structures, manholes, gullies or traps, and at least 5 m from public access routes.

NOTE Regional or national regulations which apply to the location of stationary cryogenic or non-cryogenic vessels can exist.

B.3.2 Stationary vessels containing cryogenic or non-cryogenic liquids should be installed in a position which is open to the air and at ground level, not on the roof of a building. The control equipment should be protected from the weather and the area fenced to prevent access by unauthorized persons.

B.3.3 Adequate access for a vehicle should be provided so that a cryogenic or non-cryogenic liquid supply vessel may be filled. The ground in the immediate vicinity of an oxygen or nitrous oxide filling point should be of concrete or other non-combustible material.

B.3.4 Points of possible escape of gas from means of pressure relief should be more than 5 m away from public access areas.

Annex C
(informative)

Example of procedure for testing and commissioning

C.1 General

This test procedure is given as an example of how the specifications of Clause 12 may be verified so that the system can be commissioned and certified. Other procedures which validly test these specifications may be devised. In this procedure, the given sequence of tests and the general requirements of 12.1 and 12.2 are all important and should be followed. When the results of a test do not meet the pass criteria, remedial work should be carried out and previous tests repeated as necessary.

The accuracy of the test equipment should be checked before commencing each test procedure.

Typical forms for documentation of conformity of the system are given in Annex D. Summaries of the typical tests required which list the specification, procedure and form for each test are given in Forms D.1.1 and D.1.2.

C.2 Inspections before concealment (see 12.3)

C.2.1 Inspection of marking and pipeline supports (see 12.5.1)

C.2.1.1 General

Visually inspect that marking has been correctly placed on all pipelines, especially adjacent to T-connections and where pipelines pass through floors or wall partitions. The marking should be in accordance with 10.1. Check that the pipeline supports are in accordance with 11.2.

C.2.1.2 Test results

Record the results on Form D.2.

C.2.2 Check for compliance with the design specifications (see 12.5.2)

C.2.2.1 General conditions

No pipeline should be concealed.

C.2.2.2 Example of procedure

Visually inspect each pipeline to check that the sizing of the pipelines, the location of terminal units, line pressure regulators (if fitted) and shut-off valves are in accordance with the design specification.

C.2.2.3 Test results

Record the results on Form D.3.

C.3 Tests and procedures before use of the systems (see 12.4)

C.3.1 Tests for leakage and mechanical integrity

C.3.1.1 Tests for mechanical integrity of vacuum pipeline systems (see 12.6.1.1)

WARNING — Precautions should be taken to avoid hazards to personnel arising from possible rupture of the pipeline.

C.3.1.1.1 General

This test may be carried out on sections of the pipeline, provided that no part of the system is omitted. The section to be tested should be completely installed and held firmly in place. The base blocks of all terminal units should be fitted and blanked. All connectors for pressure-relief valves, pressure gauges and pressure switches should be blanked. If separate sections are tested, each section under test should be isolated from the remainder of the system.

C.3.1.1.2 Example of procedure

Connect a suitable pressure-measuring device to the section under test. Fill the section(s) to be tested with test gas at 500 kPa. After 5 min, check that the system has not ruptured.

C.3.1.1.3 Test results

Record the results on Form D.4.1.

C.3.1.2 Test for leakage into the vacuum pipeline system (see 12.6.1.2)

C.3.1.2.1 General

All terminal units, valves and other devices such as vacuum gauges and pressure switches should have been installed. The vacuum supply system should be connected to the system under test.

C.3.1.2.2 Example of procedure

Connect a vacuum gauge to the system. Operate the vacuum supply system until the nominal distribution pressure is achieved. With the system at nominal distribution pressure, isolate the vacuum supply system. Check that the pressure increase after 1 h does not exceed 20 kPa with all shut-off valves open.

C.3.1.2.3 Test results

Record the results on Form D.4.2.

C.3.1.3 Test for mechanical integrity for compressed medical gas pipeline systems (see 12.6.1.3)

WARNING — Precautions should be taken to avoid hazards to personnel arising from possible rupture of the pipeline.

C.3.1.3.1 General

This test may be carried out the pipeline in sections, provided that no part of the system is omitted. The section to be tested should be completely installed and held firmly in place. The base blocks of all terminal units should be fitted and blanked. All connectors for pressure-relief valves, pressure gauges and pressure switches should be blanked. If separate sections are tested, each section under test should be isolated from the remainder of the system.

C.3.1.3.2 Example of procedure

Connect a suitable pressure-measuring device to the section under test. Fill the section(s) to be tested with test gas at a pressure 1,2 times the maximum pressure as specified in 12.6.1.3 for that section. After 5 min, check that the system has not ruptured.

C.3.1.3.3 Test results

Record the results on Form D.5.1.

C.3.1.4 Test for leakage from the compressed medical gas pipeline systems (see 12.6.1.4)

C.3.1.4.1 General

These tests may be carried out on sections of each pipeline, provided that no section is omitted and the integrity of the pipeline is maintained. All terminal units, valves, line pressure regulators, gauges and pressure sensors should be fitted. The supply system should be isolated from the pipeline.

C.3.1.4.2 Example of procedure

Connect a suitable pressure-measuring device to each section of the system(s) under test.

For single-stage pipeline distribution systems, pressurize with test gas at the nominal distribution pressure in each section upstream and downstream of each area shut-off valve. The means to allow physical isolation should be used between each section upstream and downstream of each area shut-off valve.

For double-stage pipeline distribution systems, pressurize with the test gas at the nominal supply system pressure for each section upstream of each line pressure regulator and at the nominal distribution pressure for each section downstream of each line pressure regulator. The means to allow physical isolation should be used between sections upstream and downstream of each line pressure regulator.

NOTE For the purposes of this test, the shut-off valves fitted upstream and downstream of each line pressure regulator (see 7.4.2) together with the line pressure regulator set at zero flow may be considered as a means to allow physical isolation.

Disconnect and remove the test gas supply. Record the pressure and room temperature initially and at the end of the test period (2 h to 24 h). Check that in each section upstream of each area shut-off valve (or each line pressure regulator), the pressure drop does not exceed 0,025 % of the initial test pressure per hour.

Check that in each section downstream of each area shut-off valve (or line pressure regulator), the pressure drop does not exceed 0,4 %/h of the initial test pressure in sections not including flexible hoses in medical supply units or 0,6 %/h of the initial test pressure in sections including flexible hoses in medical supply units.

C.3.1.4.3 Test results

Record the results on Forms D.5.2 and D.5.3.

C.3.1.5 Combined tests for leakage and mechanical integrity of compressed medical gas pipeline systems (before concealment) (see 12.6.1.5)

WARNING — Precautions should be taken to avoid hazards to personnel arising from possible rupture of the pipeline.

C.3.1.5.1 General

This test may be carried out on the pipeline in sections, provided that no part of the system is omitted. The supply system should be isolated from the pipeline. The section to be tested should be completely

installed and held firmly in place. The base blocks of all terminal units should be fitted and blanked. All connectors for pressure-relief valves, pressure gauges and pressure switches should be blanked. If separate sections are tested, each section under test should be isolated from the remainder of the system.

C.3.1.5.2 Example of procedure

C.3.1.5.2.1 Connect a suitable pressure-measuring device to the section under test. Pressurize with test gas each section to be tested at a pressure 1,2 times the maximum pressure, as specified in **12.6.1.5**, for that section. After 5 min, check that the system has not ruptured.

C.3.1.5.2.2 At the same test pressure(s), check that the pressure drop during a test period of 2 h to 24 h does not exceed 0,025 % of the initial test pressure per hour, except for pressure changes due to temperature variations.

NOTE The pressure change due to temperature variations is approximately 0,35 %/°C (see Annex E).

C.3.1.5.3 Test results

Record the results on Form D.6.1.

C.3.1.6 Combined tests for leakage and mechanical integrity of compressed medical gas pipeline systems (after concealment) (see 12.6.1.6)

WARNING — Precautions should be taken to avoid hazards to personnel arising from possible rupture of the pipeline.

C.3.1.6.1 General

These tests may be carried out on the pipeline in sections provided that no section is omitted and the integrity of the pipeline is maintained. All terminal units, valves, line pressure regulators, gauges and pressure sensors should be fitted. The supply system should be isolated from the pipeline.

C.3.1.6.2 Example of procedure

C.3.1.6.2.1 Connect a suitable pressure-measuring device to the section under test. Pressurize with test gas each section to be tested at a pressure 1,2 times the maximum pressure, as specified in **12.6.1.6**, for that section. After 5 min, check that the system has not ruptured.

C.3.1.6.2.2 Carry out the test for leakage in accordance with **12.6.1.4**.

C.3.1.6.3 Test results

Record the results on Form D.6.2, Form D.5.2 and/or Form D.5.3.

C.3.2 Test of area shut-off valves for leakage and closure and checks for correct zoning and correct identification (see 12.6.2)

C.3.2.1 General

The tests given in C.3.1 should have been completed satisfactorily and all terminal units should be closed. This test may be carried out on more than one system at a time.

The test for leakage and closure of area shut-off valves does not apply to vacuum systems.

C.3.2.2 Example of procedure

C.3.2.2.1 Pressurize the pipeline system at its nominal distribution pressure with all area shut-off valves open. Connect a pressure-measuring device downstream of each area shut-off valve. Close all area shut-off valves.

C.3.2.2.2 Depressurize the pipeline system downstream of each area shut-off valve to 100 kPa by opening a terminal unit. Close the terminal unit.

C.3.2.2.3 Check that the pressure increase does not exceed 5 kPa after 15 min.

C.3.2.2.4 Note the total number and the location of terminal units controlled by each area shut-off valve and check that these terminal units are correctly labelled.

C.3.2.3 Test results

Record the results on Form D.7.

C.3.3 Test for cross-connection (see 12.6.3)

C.3.3.1 Example 1 of procedure (FD S90-155[32])

To ensure non-inversion and identity of gas, the manufacturer should use the following test method. Begin with an initial test of absence of gas to all terminal units in the sector to be tested, by depressurizing the pipeline system and cutting off the supply to the section. Ensure the absence of gas to all terminal units.

Then pressurize a single gas pipeline, for example oxygen. Verify that the one system has pressure and there is no pressure at other terminal units. Positive identification of the gas with analysis (for example the percentage of oxygen for oxygen terminal units) on the terminal unit nearest and furthest from the pipeline located downstream of the valve area should be confirmed using a gas-specific analyser.

Then, carry out the same test, one at a time, on terminal units for other gases. Start with the more oxidizing gas and progress to the less oxidizing. If two non-oxygenated gases (nitrous oxide, carbon dioxide, nitrogen) are piped into one area, it is imperative to distinguish between the gases using another discriminating test.

NOTE 1 The technical means of identification may be those mentioned above or those of the European Pharmacopoeia, for example by specific analysers or colorimetric tubes.

NOTE 2 Similar test methods may be used provided that they comply with the requirements of 4.2.

In case a cross-connection and/or fault in gas identity is discovered during test, a full test shall be carried out again after identification and correction of the defect.

C.3.3.2 Example 2 of procedure (Taken from CSA Z7396.1-12[52])

On successful completion of the cross-connection tests using Method 1 from B.3.2, Method 2 from B.3.3, or Method 3 from B.3.4, each pipeline distribution system for compressed gases is filled and emptied with its specific gas a sufficient number of times to displace the test gas. Each terminal unit is opened in turn to ensure that no sections of pipeline remain filled with test gas.

For Method 2, the procedure is as follows:

a) When all medical gas piping systems have been tested in accordance with 11.4.3.2, the source of test gas is disconnected and the proper gas source of supply connected to each respective system.

b) Each system is purged a sufficient number of times to remove the test gas.

c) The line pressure regulator controlling each piped gas is adjusted to maintain a clearly recognizable pressure difference of no less than 35 kPa (5 psi) between each gas.

d) The vacuum system is in operation and the cut-in and cut-out settings of the vacuum pump controller are measured and recorded.

e) Following the adjustment and recording of pressures, as specified in Items (c) and (d), every terminal is tested using a pressure gauge. The actual pressure is measured with a gauge attached to the specific adaptor for that terminal unit, locked in place before taking the reading. The test is never made with a so-called "Universal Adaptor". The pressure at the terminal unit is recorded at a flow of 15 to 25 L/min (0.5 to 0.9 ft3/min) and it must be the same as the pressure selected or recorded in accordance with Items (c) and (d).

For Method 3, the procedure is as follows:

a) All medical gas piping systems have been connected to their respective supply systems.

b) Each piping system is back purged a sufficient number of times to remove the test gas and/or nitrogen for non- nitrogen systems.

c) All zone valves for the respective area being tested are closed and the pressure of each gas is adjusted to a level that has a clearly recognizable pressure difference of no less than 35 kPa (5 psi) between each gas.

d) Vacuum and AGSS zone valves are closed and each system is set to a level below nominal system vacuum. Suggest –40 kPa (–12 inHg) for vacuum and –27 kPa (–8 inHg) for AGSS testing.

e) Following the adjustments and recorded pressures as specified in Items (c) and (d), every terminal unit is tested using a pressure gauge. Care must be taken to ensure pressure differentials are maintained. If required, testing is stopped and the pressure is replenished to the initial setting. The actual pressure is measured with a gauge attached to the specific adaptor for that terminal unit.

f) Each terminal unit is identified by name and colour.

g) Once all terminal units have been tested at their adjusted pressure levels, the zone valve for a respective gas with adaptor connected is slowly opened to confirm the respective gas zone valve and respective terminal unit of said gas are the same. All zones are opened individually in this fashion.

h) All the pressure gas terminals are then tested using the appropriate gas analyser.

i) If the pressures cannot be maintained due to a system malfunction (e.g., leak in the system, valve not holding), testing cannot commence until the malfunction is investigated and corrected.

The outflow from each gas terminal unit is tested using an appropriate gas analyser to confirm the presence of the desired gas. The nominal gas concentration is measured and recorded and shown to conform to Table D.4, Part A.

C.3.4 Tests for obstruction and flow (see 12.6.4)

C.3.4.1 General

These tests may be carried out at the same time as the cross-connection test described in C.3.3. In this case, only one pipeline system at a time is under pressure. Alternatively, after completion of the tests given in C.3.3, all pipeline systems may be pressurized at nominal distribution pressure and the tests described in C.3.5 and C.3.6 carried out simultaneously.

C.3.4.2 Example of procedure

C.3.4.3 Insert a gas-specific test probe with pressure gauge(s) and flow-measuring device into each terminal unit in turn.

C.3.4.4 Check that the pressure change between zero flow and the specified test flow at each terminal unit and also the backpressure for air or nitrogen for driving surgical tools with exhaust to atmosphere does not exceed the value given in **Table 4**.

C.3.4.5 Test results

Record the results on Forms D.9 and D.10.

C.3.5 Check of terminal units and NIST, DISS or SIS connectors for mechanical function, gas specificity and identification (see 12.6.5).

C.3.5.1 General

All terminal units should be complete with fascia plate.

These tests may be carried out at the same time as the cross-connection test described in C.3.3. In this case, only one pipeline system at a time is under pressure. Alternatively, after completion of the tests given in C.3.3 all pipeline systems may be pressurized at nominal distribution pressure and the tests described in C.3.5 and C.3.6 carried out simultaneously.

C.3.5.2 Example of procedure

C.3.5.2.1 Check that a gas-specific probe can be easily inserted, captured and released. If an anti-swivel device is provided, check that this retains the probe in the correct orientation.

C.3.5.2.2 Check that no gas is released at any terminal unit by insertion of the probes of any other gases and that no probes for other gases can be captured.

C.3.5.2.3 Check that all NIST, DISS and SIS connectors accept the appropriate nipples and that a mechanical connection is made. Check that the NIST, DISS or SIS nipples for all other gases do not fit the connectors under test.

C.3.5.2.4 Check that all terminal units are identified and labelled correctly and meet the requirements specified in **12.6.5**.

C.3.5.3 Test results

Record the results on Forms D.9 and D.10.

C.3.6 Tests of system performance (see 12.6.6)

C.3.6.1 General

These tests should be carried out on one system at a time. All shut-off valves should be open. Connect a supply of test gas of sufficient capacity to deliver the system design flow for several minutes at the inlet to the pipeline distribution system. The vacuum supply system should be used to test the vacuum pipeline system.

C.3.6.2 Example of procedure

C.3.6.2.1 Pressurize or evacuate the pipeline to a pressure not greater than the maximum distribution pressure or vacuum. Record the pressure.

C.3.6.2.2 Insert probes into selected terminal units throughout the pipeline under test to provide a total flow equal to the system design flow. Each probe shall be equipped with a calibrated orifice.

C.3.6.2.3 Observe and record the gauge pressure at the specified flow at selected terminal units throughout the pipeline system. The selected terminal units should be remote from the supply system (e.g. at the end of each branch).

C.3.6.2.4 Check that the pressure at each of the selected terminal units is within the limits given in 7.2.2, 7.2.3 and 7.2.4.

C.3.6.2.5 Depressurize the system and repeat the test for each service.

C.3.6.3 Test results

Record the results on Form D.11.

C.3.7 Checks of system performance by verification of calculation (see 12.6.6)

C.3.7.1 General

A check of system performance by verification of system design flow calculations is considered an alternative means to show compliance to the requirements given in Table 2, 7.2.2, 7.2.3 and 7.2.4.

C.3.7.2 Check results

Record the check results on Form D.11.

C.3.8 Test of pressure-relief valves (see 12.6.7)

C.3.8.1 General

If type-tested and certified pressure-relief valves are installed, tests of relief valve function are not required, provided that the requirements of 7.2.5 and 7.2.6 are met.

If the pressure-relief valves fitted are not type-tested and certified, their performance should be verified according to the procedure given in C.3.8.2.

C.3.8.2 Example of procedure

C.3.8.2.1 Inspect each pressure-relief valve to check the discharge capacity and the set pressure.

C.3.8.2.2 Inspect the certification supplied with each pressure-relief valve.

C.3.8.2.3 Inspect the installation of the pressure-relief valves to verify that they are correctly vented.

C.3.8.2.4 Isolate a section of pipeline in which the pressure-relief valve to be tested is located.

C.3.8.2.5 Gradually increase the pressure in this section of the pipeline and note the pressure at which the pressure-relief valve opens and the pressure at which it allows maximum discharge.

C.3.8.2.6 Gradually reduce the pressure to that normally present in the section under test and note the value at which the pressure-relief valve reseats and is gas-tight.

C.3.8.2.7 Verify that the pressure at which the pressure-relief valve operates permits the system to meet the requirements of 7.2.5 or 7.2.6 as appropriate.

C.3.8.3 Test results

Record the results on Form D.12.

C.3.9 Tests on sources of supply (see 12.6.8)

C.3.9.1 General

All sources of supply should be installed and connected to normal and emergency electrical power supplies, as required. Specific checklists for each supply system should have been prepared to meet the requirements of Clause 5 and the manufacturer's specifications.

C.3.9.2 Example of procedure

Test all components for leakage. Test air compressor systems for leaks during normal operation. Minor leaks detectable as bubbles are acceptable. Check the function and operating parameters of each supply system from the checklist. Check that the supply system operates on the emergency power supply. Verify that the test results conform to the manufacturer's specifications and the requirements of Clause 5. Verify that the system design flow requirements are met.

C.3.9.3 Test results

Record the results on Form D.13.

C.3.10 Tests of monitoring and alarm systems (see 12.6.9)

C.3.10.1 General

These tests should be carried out for one function at a time, on one system at a time. All alarm systems should be fully installed and in operation.

C.3.10.2 Example of procedure

C.3.10.2.1 Check that all alarms are activated with an appropriate change in the local system condition (for example pressure, moisture content, liquid level and system change-over). Record the settings at which alarm sensors switch on and off.

C.3.10.2.2 Observe all alarm functions, including visual and auditory signals, resetting of the auditory signals and lamp test. Check that the visual and auditory characteristics of all signals are in accordance with **Clause 6**, if applicable.

C.3.10.2.3 Verify that all monitors and alarms operate with the appropriate changes in pipeline system conditions and operate from the normal and emergency electrical power supplies.

C.3.10.2.4 Verify that all monitors and alarms comply with the requirements of **Clause 6**.

C.3.10.3 Test results

Record the results on Form D.14.1 and Form D.14.2.

C.3.11 Test for particulate contamination (see 12.6.10)

C.3.11.1 General

The compressed medical gas pipeline systems should be at nominal distribution pressure and filled with test gas.

C.3.11.2 Example of procedure

Test the terminal unit most distant from the source of supply on each branch line of the pipeline with the device shown in Figure 1 at a flowrate of 150 l/min for 15 s. Verify that the filters are free from particulate matter when viewed in good light.

C.3.11.3 Test results

Record the results on Form D.15.

C.3.12 Tests of quality of medical air and air for driving surgical tools produced by supply systems with air compressor(s) (see.12.6.11 and 12.6.12)

C.3.12.1 General

These tests should be carried out on each air compressor unit in turn, at the sample port immediately downstream of the conditioning systems, before filling the pipeline distribution system with air from the compressor system. The supply system should be isolated from the pipeline distribution system by closing the supply shut-off valve.

NOTE Information regarding test methods can be found in ISO 8573-3,[12] ISO 8573-4,[13] ISO 8573-6 [15] and ISO 8573-8.[16]

C.3.12.2 Example of procedure

C.3.12.2.1 Oxygen concentration

Using an oxygen analyser, verify that the oxygen concentration meets the requirements of 5.5.2.1.

C.3.12.2.2 Oil

Test for oil present as liquid, aerosol and vapour at the sample port using an appropriate test device. Verify that the total oil concentration does not exceed the value given in 5.5.2.1 and 5.5.2.3.

NOTE Information regarding test methods can be found in ISO 8573-2 [11] and ISO 8573-5.[14]

C.3.12.2.3 Water

Test for water vapour content at the sample port using an appropriate test device. Verify that the water vapour content does not exceed the value given in 5.5.2.1 or 5.5.2.3. This test should be repeated after filling the pipeline distribution system with air from a sample of 5 % of terminal units at points remote from the source of supply (see C.3.15.2.5).

C.3.12.2.4 Carbon monoxide and carbon dioxide

Determine the concentrations of carbon monoxide and carbon dioxide at the sample port using appropriate test devices. Verify that the concentrations do not exceed the values given in 5.5.2.1.

NOTE Information regarding test methods may be found in ISO 8573-6.[15]

C.3.12.2.5 Sulfur dioxide, nitrogen monoxide and nitrogen dioxide

Determine the concentrations of sulfur dioxide, nitrogen monoxide and nitrogen dioxide at the sample port using appropriate test devices. Verify that the concentrations do not exceed the values given in 5.5.2.1.

C.3.12.2.6 Particulate contamination

Test for particulate contamination at the sample port using a test device as described in 12.6.10. Verify that the requirements in 12.6.10 are met.

For medical air, record the results on Form D.16. For air for driving surgical tools, record the results on Form D.17.

C.3.13 Test of the quality of medical air produced by supply systems with proportioning unit(s) (see 12.6.13)

C.3.13.1 General

These tests should be carried out before filling the pipeline distribution system with medical air produced by the proportioning system. The supply system should be isolated from the pipeline distribution system by closing the supply shut-off valve.

These tests should be carried out on each proportioning system in turn, if more than one is fitted, at a suitable sample port on each system immediately upstream of the supply shut-off valve.

C.3.13.2 Example of procedure

C.3.13.2.1 Oxygen concentration

Using an oxygen analyser, verify that the oxygen concentration meets the requirements of 5.5.3.1.

C.3.13.2.2 Water vapour content

Using an appropriate test device at the sample port, verify that the water vapour content does not exceed the value given in 5.5.3.1.

C.3.13.3 Test results

Record the results on Form D.18.

C.3.14 Test of the quality of oxygen 93 produced by supply systems with oxygen concentrator(s) (see 12.6.14)

C.3.14.1 General

These tests should be carried out before filling the pipeline distribution system with oxygen 93.The supply system should be isolated from the pipeline distribution system by closing the supply shut-off valve.

These tests should be carried out on each oxygen concentrator unit in turn at a suitable test point immediately upstream of the supply source shut-off valve.

C.3.14.2 Example of procedure

C.3.14.2.1 Oxygen concentration

Using an oxygen analyser, verify that the oxygen concentration meets the requirements of 5.6.5 a).

C.3.14.2.2 Carbon monoxide and carbon dioxide concentration

Using appropriate test devices at the sample port, verify that the concentrations of carbon monoxide and carbon dioxide do not exceed the levels specified in 5.6.5 b) and c).

C.3.14.2.3 Particulate contamination

Using appropriate test devices at the sample port, verify that the particulate contamination does not exceed the level specified in 5.6.5.

C.3.14.2.4 Oil concentration

Using appropriate test devices at the sample port, verify that the concentration of oil does not exceed the level specified in 5.6.5 d)

C.3.14.2.5 Water vapour content

Using appropriate test devices at the sample port, verify that the water vapour content does not exceed the level specified in 5.6.5 e)

C.3.14.3 Test results

Record the results on Form D.19.

C.3.15 Filling with specific gas (see 12.6.15)

C.3.15.1 General

All systems may be filled with their specific gases at the same time. Filling with specific gas may be carried out at the same time as the test for gas identity (see C.3.16). All previous tests should have been satisfactorily completed. Sources of test gas should be disconnected. All pipeline systems should be at atmospheric pressure. Each pipeline system should be connected to its primary source of supply with all shut-off valves except the main supply shut-off valve open. All special connectors should be removed from site.

C.3.15.2 Example of procedure

C.3.15.2.1 Open the main shut-off valve and fill each pipeline system to the nominal distribution pressure or vacuum.

C.3.15.2.2 Except for vacuum pipelines, allow a flow of gas from each terminal unit in turn. Close the main shut-off valve and allow the pressure in each pipeline to fall to atmospheric. All gases except air should be vented outside the building.

C.3.15.2.3 Open the main shut-off valve and refill each pipeline to the nominal distribution pressure. Repeat the procedure given in **C.3.15.2.1** and **C.3.15.2.2** as many times as required to give a gas identity which conforms to the requirements of **12.6.16**.

C.3.15.2.4 Leave each pipeline system at nominal distribution pressure with the supply system connected.

C.3.15.2.5 For medical air or air for driving surgical tools supplied by supply systems with air compressors, at least one terminal unit on each branch (the terminal unit most distant from the source of supply) should be tested for water vapour content.

C.3.15.3 Test results

Record on Form D.20 that all pipeline systems are filled with the specific gas.

C.3.16 Tests for gas identity (see 12.6.16)

C.3.16.1 General

The pipeline systems should be at nominal distribution pressure and filled with the specific gases. All pipeline systems should be tested at the same time. No medical equipment should be connected to the pipeline systems. All other tests in C.3 should have been satisfactorily completed before this test is carried out.

C.3.16.2 Example of procedure

Test all terminal units as follows:

a) for each pipeline system which contains gas with a characteristic oxygen concentration [e.g. oxygen (100 % volume fraction), oxygen 93 (in accordance with specification), oxygen/nitrous oxide mixture (in accordance with specification), medical air (21 % volume fraction) and air for driving surgical tools (21 % volume fraction)], measure the oxygen concentration using an oxygen analyser. For pipeline systems which contain gas with the same characteristic oxygen concentration but at different pressures (e.g. medical air, 400 kPa, and air for driving surgical tools, 800 kPa), measure the pressure using a pressure gauge;

b) for each pipeline system which does not contain oxygen (except as a contaminant), either use a gas-specific analyser or set each system to a different pressure and measure the static pressure. After such a procedure, the pressure should be reset to the nominal distribution pressure for each system;

c) for vacuum systems, measure the pressure using a vacuum gauge.

C.3.16.3 Test results

Record the results on Form D.21.1 and/or Form D.21.2 and/or Form D.21.3.

Annex D
(informative)

Typical forms for documenting compliance of the pipeline systems for compressed medical gas and vacuum

The forms given in this annex are to be completed during testing and commissioning of pipeline systems for compressed medical gases and vacuum in accordance with Annex C.

(Sheet ___ of ___ sheets) D.1.1

(Healthcare facility) _____ in (Area identification) _____

This is to certify that the following tests and procedures have been carried out satisfactorily on the medical gases and vacuum pipeline systems at

Form	Description of tests and procedures	Test req'd (Y/N)	Procedure	Specification	Date of completion
D.2	Marking and supports		C.2.1	12.5.1	
D.3	Design specification		C.2.2	12.5.2	
D.4.1	Mechanical integrity of vacuum pipeline systems		C.3.1.1	12.6.1.1	
D.4.2	Leakage into vacuum pipeline system		C.3.1.2	12.6.1.2	
D.5.1	Test for mechanical integrity of compressed medical gas pipeline systems		C.3.1.3	12.6.1.3	
D.5.2	Leakage from compressed medical gas pipeline systems (upstream sections)		C.3.1.4 or C.3.1.6	12.6.1.4 or 12.6.1.6	
D.5.3	Leakage from compressed medical gas pipeline systems (downstream sections)		C.3.1.4 or C.3.1.6	12.6.1.4 or 12.6.1.6	
D.6.1	Combined leakage and mechanical integrity of compressed medical gas pipeline systems (before concealment)		C.3.1.5	12.6.1.5	
D.6.2	Combined leakage and mechanical integrity of compressed medical gas pipeline systems (after concealment)		C.3.1.6	12.6.1.6	
D.7	Area shut-off valve leakage, closure, zoning and identification		C.3.2	12.6.2	
D.8	Cross-connections		C.3.3	12.6.3	
D.9	Terminal units: obstruction and flow, mechanical function, identification, gas specificity		C.3.4 C.3.5	12.6.4 12.6.5	
D.10	NIST or DISS connectors: obstruction and flow, mechanical function, identification, gas specificity		C.3.4 C.3.5	12.6.4 12.6.5	
D.11	System performance		C.3.6 C.3.7	12.6.6	
D.12	Pressure-relief valves		C.3.8	12.6.7	
D.13	Sources of supply		C.3.9	12.6.8	
D.14.1	Emergency clinical and operating alarms		C.3.10	12.6.9	
D.14.2	Operating alarms		C.3.10	12.6.9	
D.15	Particulate contamination		C.3.11	12.6.10	

Manufacturer's Representative

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Authorized Person

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Form D.1.1 — Summary of tests of requirements of 12.3 and 12.4 [items a) through j)], i.e. up to and including 12.6.10 (see 12.7.1)

(Sheet ___ of ___ sheets) D.1.2

(Healthcare facility) _____ in (Area identification) _____

This is to certify that the following tests and procedures have been carried out satisfactorily on the medical gases and vacuum pipeline systems at

Form	Description of tests and procedures	Test req'd (Y/N)	Procedure	Specification	Date of completion
D.16	Quality of medical air produced by supply systems with air compressor(s)		C.3.12	12.6.11	
D.17	Quality of air for driving surgical tools produced by supply systems with air compressor(s)		C.3.12	12.6.12	
D.18	Quality of medical air produced by supply systems with proportioning unit(s)		C.3.13	12.6.13	
D.19	Quality of oxygen 93 produced by supply systems with oxygen concentrator(s)		C.3.14	12.6.14	
D.20	Filling with specific gas		C.3.15	12.6.15	
D.21.1	Gas identity with oxygen analyser		C.3.16	12.6.16	
D.21.2	Gas identity with different pressures		C.3.16	12.6.16	
D.21.3	Gas identity with gas-specific analyser		C.3.16	12.6.16	
	Construction labels removed				

Manufacturer's Representative

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Authorized Person

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Form D.1.2 — Summary of tests of requirements of 12.6.11 to 12.6.16 (see 12.7.1)

(Sheet ___ of ___ sheets) D.2

(Healthcare facility) _____ in (Area identification) _____

This is to certify that pipeline marking and supports have been inspected before concealment.

Medical gas	Section inspected	Markings	Supports
		Pass/Fail	*Pass/Fail*

Manufacturer's Representative

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Authorized Person

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Form D.2 — Inspection of pipeline markings and supports

(Sheet ___ of ___ sheets) D.3

(Healthcare facility) _____ in (Area identification) _____

This is to certify that the following medical gas pipelines have been checked before concealment for compliance with design specifications.

		Location of		
Medical gas	**Pipeline Sizing**	**Terminal units**	**Line pressure regulators (if fitted)**	**Shut-off valves**

Manufacturer's Representative

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Authorized Person

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Form D.3 — Check for compliance with design specifications

(Sheet ___ of ___ sheets) D.4.1

(Healthcare facility) _____ in (Area identification) _____

This is to certify that a mechanical integrity test was carried out on the vacuum pipeline system(s).

Section tested	Test pressure	Test period	Pass/Fail
	kPa	*min*	

Manufacturer's Representative

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Authorized Person

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Form D.4.1 — Tests For mechanical integrity of the vacuum pipeline system

(Sheet ___ of ___ sheets) D.4.2

This is to certify that a leakage test was carried out on the vacuum pipeline system(s). During the test, the pressures shown below were measured.
(Healthcare facility) _____ in (Area identification) _____

Section tested	Test pressure	Test Period	Pressure increase	Pass/Fail
	kPa	*hr.*	ΔP, *kPa*	$\Delta P \leq 20$ *kPa/hr.*
Measuring instrument(s) used				

Manufacturer's Representative

Position _____ Signature _____

Date ____ / ____ / ____ Name _____

Authorized Person

Position _____ Signature _____

Date ____ / ____ / ____ Name _____

Form D.4.2 — Test for leakage into the vacuum pipeline system

(Sheet ___ of ___ sheets) D.5.1

This is to certify that a mechanical integrity test was carried out before concealment on the medical gas pipeline system(s).
(Healthcare facility) _____ in (Area identification) _____

Medical Gas	Section tested	Test pressure	Test Period	Pass/Fail
		kPa	*min.*	
Measuring instrument(s) used				

Manufacturer's Representative

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Authorized Person

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Form D.5.1 — Tests for mechanical integrity for compressed medical gas pipeline systems

(Sheet ___ of ___ sheets) D.5.2

(Healthcare facility) _____ in (Area identification) _____

This is to certify that a leakage test was carried out on the pipeline system(s). During the test, the pressures shown below were measured:

Medical gas	Portion upstream of area shut-off valve	Test pressure	Test period	Pressure drop	Initial temp.	Final temp.	Pressure change due to temp.	Pass/Fail
		kPa	*hr*	Δp *kPa*	*°C*	*°C*	*kPa*	$\Delta p \leq 0{,}025\%$ */hr*
Measuring instrument(s) used								

Manufacturer's Representative

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Authorized Person

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Form D.5.2 — Tests for leakage from compressed medical gas pipeline systems — Test for leakage on portion(s) upstream of area shut-off valves (or line pressure regulators)

(Sheet ___ of ___ sheets) D.5.3

(Healthcare facility) _____ in (Area identification) _____

This is to certify that a leakage test was carried out on the pipeline system(s). During the test, the pressures shown below were measured:

Medical gas	Portion upstream of area shut-off valve	Test pressure	Test period	Pressure drop	Initial temp.	Final temp.	Pressure change due to temp.	Pass/Fail
		kPa	*hr*	Δp, *kPa*	*°C*	*°C*	*kPa*	$\Delta p \leq 0{,}4\ \%/h$ or $\leq 0{,}6\ \%/h$ [a]

[a] Check that in each section downstream of each area shut-off valve (or line pressure regulator), the pressure drop does not exceed 0,4 %h of the initial test pressure in sections not including flexible hoses in medical supply units or 0,6 %hr of the initial test pressure in sections including flexible hoses in medical supply units.

Measuring instrument(s) used

Manufacturer's Representative

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Authorized Person

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Form D.5.3 — Tests for leakage from compressed medical gas pipeline systems — Test for leakage on portion(s) downstream of area shut-off valves (or line pressure regulators)

(Sheet ___ of ___ sheets) D.6.1

(Healthcare facility) _____ in (Area identification) _____

This is to certify that a mechanical integrity test was carried out before concealment on the medical gas pipeline system(s).

Medical gas	Section tested	Test pressure	Test period	Pass/Fail
		kPa	*min*	

This is to certify that a leakage test was carried out before concealment on the medical gas pipeline system(s).
During the test, the pressures shown below were measured:

Medical gas	Section Tested	Test pressure	Test period	Pressure drop	Initial temp.	Final temp.	Pressure change due to temp.	Pass/Fail
		kPa	*hr*	Δp *kPa*	*°C*	*°C*	*kPa*	$\Delta p \leq 0{,}025\%$ */hr*
Measuring instrument(s) used								

Manufacturer's Representative

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Authorized Person

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Form D.6.1 — Combined tests for leakage and mechanical integrity of compressed medical gas pipeline systems

(Sheet ___ of ___ sheets) D.6.2

(Healthcare facility) _____ in (Area identification) _____

This is to certify that a mechanical integrity test was carried out on the medical gas pipeline system(s) (after concealment).

Medical Gas	Section tested	Test pressure	Test Period	Pass/Fail
		kPa	*min.*	
For the tests for leakage, use Form D.5.2 and Form D.5.3.				
Measuring instrument(s) used				

Manufacturer's Representative

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Authorized Person

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Form D.6.2 — Combined tests for leakage and mechanical integrity of compressed medical gas pipeline systems

(Sheet ___ of ___ sheets) D.7

(Healthcare facility) _____ in (Area identification) _____

This is to certify that leakage, closure, zoning and identification tests of the terminal units controlled by the area shut-off valves were carried out as follows:

Medical Gas	Area shut-off valve identification	Test pressure	Downstream pressure change after 15 min	Identity of terminal units controlled	Correct terminal unit labelling	Pass/Fail
		kPa	*min.*		*yes/no*	
Measuring instrument(s) used						

Manufacturer's Representative

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Authorized Person

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Form D.7 — Tests for leakage, closure, zoning and identification of area shut-off valves

(Sheet ___ of ___ sheets) D.8

(Healthcare facility) _____ in (Area identification) _____

This is to certify that a cross-connection test was successfully completed on the following pipeline systems:

Medical gas	Section inspected
Measuring instrument(s) used	

Manufacturer's Representative

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Authorized Person

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Form D.8 — Tests for cross-connections

(Sheet ___ of ___ sheets) D.9

(Healthcare facility) _____ in (Area identification) _____

This is to certify that the following terminal units were tested on the _____ medical gas pipeline.

Specified flowrate _____ l/min. Specified pressure change _____ kPa.

Room identification	Terminal unit identification	Flowrate	Pressure change	Pressure change backpressure	Mechanical function	Identification	Gas specificity
		Pass/Fail	*Pass/Fail*	*Pass/Fail*	*Pass/Fail*	*Pass/Fail*	*Pass/Fail*
Measuring instrument(s) used							

Manufacturer's Representative

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Authorized Person

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Form D.9 — Tests for obstruction and flow, mechanical function, gas specificity and identification of terminal units

(Sheet ___ of ___ sheets) D.10

(Healthcare facility) _____ in (Area identification) _____

This is to certify that the following NIST or DISS connectors were tested on the _____ medical gas pipeline.

Specified flowrate _____ l/min. Specified pressure change _____ kPa.

Room identification	**NIST, DISS or SIS connector identification**	**Flowrate**	**Pressure change**	**Pressure change backpressure**	**Mechanical function**	**Identification**	**Gas specificity**
		Pass/Fail	*Pass/Fail*	*Pass/Fail*	*Pass/Fail*	*Pass/Fail*	*Pass/Fail*
Measuring instrument(s) used							

Manufacturer's Representative

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Authorized Person

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Form D.10 — Tests for obstruction and flow, mechanical function, gas specificity and identification of NIST, DISS or SIS connectors

(Sheet ___ of ___ sheets) D.11

(Healthcare facility) _____ in (Area identification) _____

This is to certify that the _____ pipeline was tested as follows:

Specified design flowrate _____ l/min. Terminal unit test flowrate _____ l/min.

Nominal distribution pressure _____ kPa. Minimum distribution pressure allowed _____ kPa

Maximum distribution pressure allowed _____ kPa

Room Identification	Terminal unit identification	Specifications met
		Pass/Fail
Measuring instrument(s) used		

Manufacturer's Representative

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Authorized Person

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Form D.11 — Tests or checks of system performance

(Sheet ___ of ___ sheets) D.12

(Healthcare facility) _____ in (Area identification) _____

This is to certify that the pressure-relief valves fitted to the pipeline system have been ____ inspected/ ____ tested as follows:

Medical gas	**Pressure-relief valve identification**	**Location**	**Full discharge capacity**	**Full discharge pressure**	**Correct venting**	**Reseating pressure**
			l/min	*kPa*	*Yes/No*	*kPa*
Measuring instrument(s) used						

Manufacturer's Representative

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Authorized Person

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Form D.12 — Tests of pressure-relief valves

(Sheet ___ of ___ sheets) D.13

(Healthcare facility) _____ in (Area identification) _____

This is to certify that the following sources of supply have been inspected/tested.

Source of supply	Operating condition specification	Pass/Fail	Emergency condition specification	Pass/Fail
Manifold				
Manifold				
Manifold				
Manifold				
Manifold				
Cryogenic oxygen system				
Air compressor system				
Proportioning system				
Oxygen concentrator system				
Vacuum system				

Manufacturer's Representative

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Authorized Person

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Form D.13 — Tests of all sources of supply

(Sheet ___ of ___ sheets) D.14.1

(Healthcare facility) _____ in (Area identification) _____

This is to certify that the monitoring and alarm systems have been tested and comply with the specifications.

Function tested	**O_2**	**N_2O**	**Vacuum**	**Medical Air**	**Air for driving surgical tools**	**CO_2**	**Oxygen 93**	**Nitrogen for driving surgical tools**	**O_2/N_2O Mixtures**
Specified alarm maximum pressure									
Observed alarm maximum pressure									
Return to normal from maximum pressure									
Specified alarm minimum pressure									
Observed alarm minimum pressure									
Return to normal from minimum pressure									
Marking									
Visual characteristics									
Auditory characteristics									
All visual and audible signal functions									
Connection to emergency power supply									

Manufacturer's Representative

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Authorized Person

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Form D.14.1 — Tests of emergency clinical and operating alarms

(Sheet ___ of ___ sheets) D.14.2

(Healthcare facility) _____ in (Area identification) _____

This is to certify that the monitoring and alarm systems have been tested and comply with the specifications.

Function tested	O_2	N_2O	Vacuum	Medical Air	Air for driving surgical tools	CO_2	Oxygen 93	N_2 for driving surgical tools	O_2/N_2O Mixtures
Change-over from primary to secondary cylinder supplies									
Primary cylinder supply below minimum pressure or content									
Secondary cylinder supply below minimum pressure or content									
Reserve cylinder supply below minimum pressure or content									
Pressure in cryogenic vessels below minimum									
Liquid level in any cryogenic or non-cryogenic vessel(s) below minimum									
Liquid level in reserve cryogenic or non-cryogenic vessel below minimum									
Malfunctioning of air compressor systems									
Water vapour content in air supplied by air compressor systems									
Malfunctioning of proportioning system									
Malfunctioning of cryogenic systems									
Malfunctioning of vacuum system									
Malfunctioning of supply system for oxygen 93									

Manufacturer's Representative

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Authorized Person

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Form D.14.2 — Tests of operating alarms

(Sheet ___ of ___ sheets) D.15

(Healthcare facility) _____ in (Area identification) _____

This is to certify that the following medical gas pipelines have been tested for particulate contamination.

Medical gas	Room identification	Terminal unit identification	Visible particles
			Yes/No
Measuring instrument(s) used			

Manufacturer's Representative

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Authorized Person

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Form D.15 — Test for particulate contamination of pipeline distribution systems

(Sheet ___ of ___ sheets) D.16

(Healthcare facility) _____ in (Area identification) _____

This is to certify that the medical air produced by the supply system with air compressor(s) has been tested before filling the pipeline and complies with the requirements of 5.5.2.1 as follows:

Oxygen concentration	Total oil	Water vapour content	Carbon monoxide	Carbon dioxide	Sulfur dioxide	$NO + NO_2$	Particulate contamination
≥ 20,4 % ≤ 21,4 %	≤ 0,1 *mg/m*	≤ 67 ml/m^3	≤ 5 ml/m^3	≤ 500 ml/m^3	≤ 1 ml/m^3	≤ 2 ml/m^3	
Measuring instrument(s) used:							

Manufacturer's Representative

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Authorized Person

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Form D.16 — Tests of the quality of medical air produced by supply systems with air compressor(s)

(Sheet ___ of ___ sheets) D.17

(Healthcare facility) _____ in (Area identification) _____

This is to certify that the air for driving surgical tools produced by the supply system with air compressor(s) has been tested before filling the pipeline and complies with the requirements of 5.5.2.3 as follows:

Total oil	Water vapour content
≤ 0,1 mg/m^3	≤ 67 ml/m^3
Measuring instrument(s) used:	

Manufacturer's Representative

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Authorized Person

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Form D.17 — Tests of the quality of air for driving surgical tools produced by supply systems with air compressor(s)

(Sheet ___ of ___ sheets) D.18

(Healthcare facility) _____ in (Area identification) _____

This is to certify that the medical air produced by the supply system with proportioning unit(s) has been tested before filling the pipeline and complies with the requirements of 5.5.3.1 as follows:

Oxygen concentration	Water vapour content
≥ 19,95 % ≤ 23,63 %	≤ 67 ml/m^3
Measuring instrument(s) used:	

Manufacturer's Representative

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Authorized Person

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Form D.18 — Tests of the quality of medical air produced by supply systems with proportioning unit(s)

(Sheet ___ of ___ sheets) D.19

(Healthcare facility) _____ in (Area identification) _____

This is to certify that the quality of oxygen 93 produced by oxygen concentrator(s) has been tested according to 12.6.14 before filling the pipelines:

Oxygen concentration	Total oil	Water vapour content	Carbon monoxide	Carbon dioxide	Sulfur dioxide	$NO + NO_2$
93 % ± 3 %	≤ 0,1 mg/m^3	≤ 67 ml/m^3	≤ 5 ml/m^3	≤ 500 ml/m^3	≤ 1 ml/m^3	≤ 2 ml/m^3
Measuring instrument(s) used:						

Manufacturer's Representative

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Authorized Person

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Form D.19 — Tests of the quality of oxygen 93 produced by oxygen concentrator(s)

(Sheet ___ of ___ sheets) D.20

(Healthcare facility) _____ in (Area identification) _____

This is to certify that the following medical gas pipelines have been filled with the specific gas as follows:

Medical gas	Filling	Flow from all terminal units observed

Manufacturer's Representative

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Authorized Person

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Form D.20 — Filling with specific gas

(Sheet ___ of ___ sheets) D.21.1

(Healthcare facility) _____ in (Area identification) _____

This is to certify that the identity of the gas at all terminal units has been checked as follows:

Medical gas	**Nominal O_2 concentration**	**Measured O_2 concentration**
	%	%
Medical air	21	
Oxygen	100	
Oxygen-nitrous oxide mixture	(as specified)	
Oxygen 93	≥ 90	
Air for driving surgical tools	21	
Measuring instrument(s) used:		

Manufacturer's Representative

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Authorized Person

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Form D.21.1 — Tests for gas identity using an oxygen analyser

(Sheet ___ of ___ sheets) D.21.2

(Healthcare facility) _____ in (Area identification) _____

This is to certify that the identity of the gas at all terminal units has been checked as follows:

Medical gas	Pressure used	Pressure recorded
	kPa	*kPa*
Nitrous oxide		
Carbon dioxide		
Nitrogen for driving surgical tools		
Medical air		
Air for driving surgical tools		
Vacuum		
Measuring instrument(s) used:		

Manufacturer's Representative

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Authorized Person

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Form D.21.2 — Tests for gas identity using different pressures

(Sheet ___ of ___ sheets) D.21.3

(Healthcare facility) _____ in (Area identification) _____

This is to certify that the identity of the gas at all terminal units has been checked as follows:

Medical gas	**Result**
	Pass/Fail
Nitrous oxide	
Carbon dioxide	
Nitrogen for driving surgical tools	
Measuring instrument(s) used:	

Manufacturer's Representative

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Authorized Person

Position _____ Signature _____

Date ___ / ___ / ___ Name _____

Form D.21.3 — Tests for gas identity using a gas-specific analyser

Annex E
(informative)

Temperature and pressure relationships

E.1 Principle

From the ideal gas law:

$$\frac{p_2}{T_2} = \frac{p_1}{T_1}$$

and

$$p_2 = (p_1)(T_2 / T_1)$$

where

p_1 is the initial pipeline absolute pressure;

p_2 is the final pipeline absolute pressure;

T_1 is the initial pipeline absolute temperature;

T_2 is the final pipeline absolute temperature.

NOTE 1 Absolute pressure = gauge pressure + 100 kPa.

NOTE 2 The relationship between temperature and pressure at typical pipeline pressures is shown in Figure E.1.

E.2 Example

An example of correction using the diagram in Figure E.1 is given below.

The pressure of a system previously at 1 400 kPa will fall to about 1 350 kPa with a 10 °C drop in temperature. This may be confirmed by calculation using the equation in E.1, as follows:

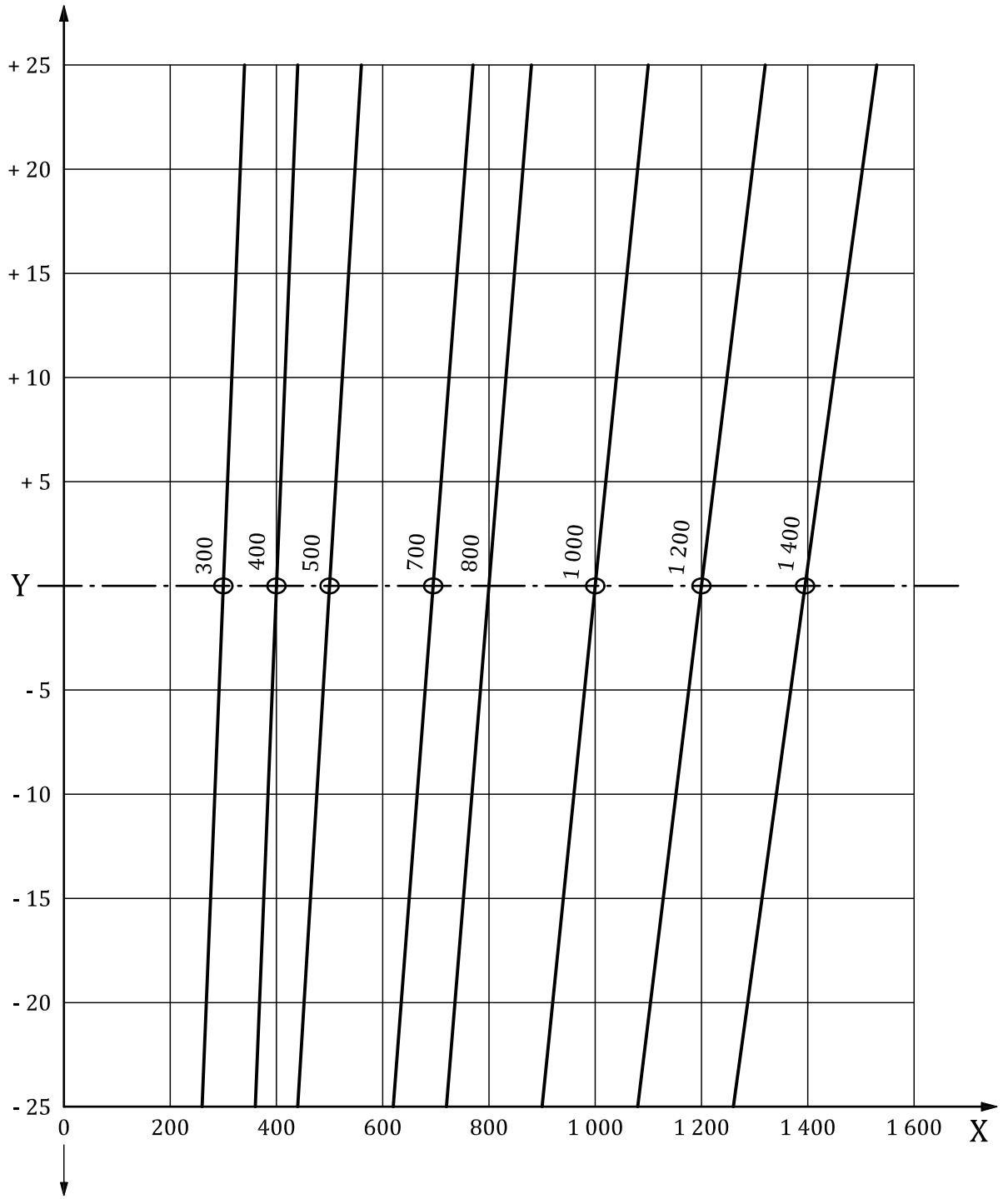
where

p_1 is 1 500 kPa (1 400 kPa gauge pressure);

T_1 is 293 K (20 °C);

T_2 is 283 K (10 °C);

p_2 is 1 449 kPa (1 349 kPa gauge pressure).



Key

X pipeline pressure, in kilopascals (kPa)

Y temperature change, in degrees Celsius (°C)

Figure E.1 — Relationship between temperature and pressure at typical pipeline pressures

Annex F
(informative)

Risk management checklist

F.1 General

Risk management should be carried out in accordance with ISO 14971.

This annex gives the recommended risk management procedure and checklist used to identify the root causes and hazardous situations (i.e. cause of harm) related to defined safety objectives and appropriate risk control measures for medical gas pipeline systems.

The risk management procedure and the risk control checklist should be used by both the manufacturer (M) of the medical gas pipeline system and the healthcare facility (H) representative(s) during:

— design, installation, commissioning and operation of new medical gas pipeline systems;

— ongoing operation and monitoring of existing medical gas pipeline systems.

F.2 Risk management procedure

When managing the risks associated with medical gas pipeline systems, it is first necessary to complete a risk assessment of the overall system.

Having assessed the risks (i.e. the combination of severity and probability of occurrence of the harm), the design should endeavour to mitigate the risks by using procedures in the following order of priority:

a) inherently safe design;

b) protective measures in the medical device itself or in the manufacturing process;

c) information for safety.

F.3 Risk management checklist

Table F.1 gives a list of typical safety objectives, root causes, hazardous situations and appropriate risk control measures to mitigate the risk to acceptable levels. It also identifies the organizations responsible for action.

Safety Objective	Root Cause	Hazardous Situation	Risk Control Measures	Resp. Org.
Continuity of supply	Partial or complete blockage of the pipeline	Loss or reduction of supply to the patient or equipment	Flow and pressure drop tests at every terminal unit before use	M
	Loss of supply from the source of supply in operation	System supplied from the reserve/ emergency source if the primary and secondary source fail. Loss of supply to terminal units if all systems fail	Ensure reserve and emergency sources of supply are included in the design of the supply system	H+M
			Ensure reserve and emergency sources of supply are included in the capacity and location of the supply sources	H
			Stock management system established	H
			Preventive maintenance system set up for each source of supply	H
			Operational procedures established to supply cylinders for emergency situations to ensure continuity of supply	H
			Procedures established to minimize use of gases in emergency situations	H
			Routine testing of the reserve and emergency sources of supply to ensure that they will function when primary and secondary source of supply fail.	H
			Routine testing of the alarm system	H
			Operational Management Document to address failure of supply	H
	Catastrophic failure of the pipeline	Total loss of supply to terminal units Loss of supply to patient and/or equipment	Design pipeline route to limit areas of high risk to the pipeline	H+M
			Design pipeline routing to limit pipeline corrosion	M
			Design supply systems to prevent mechanical damage	H+M
			Support pipelines to provide adequate support/protection and to limit corrosion	M
			Design components in direct contact with the pipelines to minimize electrolytic corrosion	M
			Earthing of pipeline system to limit electrolytic corrosion	M
			Identify location of pipeline routes Use of markers above pipeline to indicate presence of pipeline in underground ducts, etc.	M
			Protect pipes in high risk areas	H
			Permit to work system	H
			Location of the sources of supply relative to the usage areas	H+M
			Emergency plans for areas with high-dependency patients	H
			Use of emergency local sources of supply adjacent to the usage points	H

Table F.1 Page 1 of 16

Table F.1 — page 1 of 16

Safety Objective	Root Cause	Hazardous Situation	Risk Control Measures	Resp. Org.
Continuity of supply	Catastrophic failure of the pipeline	Total loss of supply to terminal units Loss of supply to patient and/or equipment	Use of emergency inlet points near area shut-off valves	H
			Routine testing of the alarm system	H
			Operational Management Document addresses issues of pipeline supply failure	H
	Gas supplier difficulties. *Force Majeure* (e.g. road traffic accident other incident outside the control of the supplier)	Late delivery of liquid or cylinder gases. Supplier unable to deliver product. Supplier with insufficient stocks of cylinders or delivery tank too small.	Selection of gas supplier using risk management principles	H
			Appropriate sizing of the storage tank	H+M
			Use of telemetry on storage tanks	H
			Adequate stock management and reordering systems established	H
			Adequate number of cylinders held on site	H
			Appropriate location of cylinder storage areas	H
			Personnel trained to change cylinders on manifolds	H
			Emergency plan	H
			Routine review of delivery planning	H
			Routine review of the stock of the source of supply	H
			Operational Management Document addresses issues of supply failure	H
	Late ordering of liquid or cylinder gases	Healthcare facility stock level management inadequate	Routine review of the stock of the source of supply	H
	Poor location or housing of sources of supply	Mechanical damage to the sources of supply leading to loss of supply Sources of supply affected by incident involving an adjacent facility Potential damage to other sources of supply Eventual failure of the supply source Access to all sources of supply blocked, leading to loss of supply	Ensure supply source separation distances follow local regulations /guidelines	H+M
			Review risks associated with two sources of supply being located adjacent to each other	H+M
			Ensure that plant rooms and manifold rooms have adequate temperature control and ventilation. Review room temperature control to prevent separation of gas mixtures.	H
			Adequate physical protection from mechanical damage	H+M
			Clear signage to keep delivery areas clear	H
			Site procedures to maintain access to sources of supply	H
			Routine review of location of supply system to ensure system remains safe	H
			Review risks associated with having two sources of supply located at different sites	H

Table F.1 Page 2 of 16

Table F.1 — page 2 of 16

Safety Objective	Root Cause	Hazardous Situation	Risk Control Measures	Resp. Org.
Continuity of supply	Failure of alarms	Alarm condition not detected	Uninterrupted Power Supply (UPS) electrical supply to ensure continuity of electrical supply to alarms	M
			Connect alarms to the emergency electrical supply to ensure continuity of alarm operation	H
			Display of information signals independent from alarm system	M
			Routine testing of the alarm system	H
			Routine review of the alarm system	H
			Operational Management Document addresses issues of alarm failure	H
	Electricity supply failure	Failure of operation of electrical components potentially leading to loss of supply	Uninterrupted Power Supply (UPS) or emergency electrical supply to ensure continuity of electrical system	H
			Check capacity of the emergency electrical supply	H
			Routine testing of the emergency electrical supply	H
			Operational Management Document addresses issues of electrical supply failure	H
			Procedures to ensure that all components are restored to an operational condition following reinstatement of the power supply	H
			Check that reserve sources of supply from compressors or oxygen concentrators are capable of maintaining gas supply during electrical supply failure.	H
	Component failure	Potential for the loss of supply with failure of critical components	Review and identification of critical components	M
			Specific preventive maintenance for critical componenents	H+M
			Specification for the critical componenents to be obtained from approved suppliers	M
			Alarm systems checked to ensure that failure of critical components is detected	H
			Adequate spares/redundancy for critical components	H
			Operational Management Document addresses issues of critical component failure	H
	Failure of the maintenance system	Potential failure of components and subsequent failure of supply system	Operational Management Document addresses issues of critical component failure	H

Table F.1 Page 3 of 16

Table F.1 — page 3 of 16

Safety Objective	Root Cause	Hazardous Situation	Risk Control Measures	Resp. Org.
Continuity of supply	Supply failure to areas of high-dependency patients	High risk to patient with failure of supply	Identification of areas of high risk	H
			Review of emergency supply systems to high risk areas	H
			Design system to provide higher levels of redundancy of critical components	M
			Alarm systems checked to ensure that failure of critical components is detected	H
			Operational Management Document addresses issues of critical component failure	H
			Capability to supply localized areas	H
System performance	Incorrect design/ specification of components and pipeline systems	Inadequate supply to the patient or equipment	Provide usage information	H
			Correct design of components/pipelines based on usage information	M
			Design validation in accordance with Clause 12	M
			Commissioning checks following installation	H+M
			Operational Management Document addresses periodic checks of usage	H
	Inadequate corrosion protection of pipelines/ components	Failure of pipelines/ components. Leakage. Collapse of supports.	Correct design/location/protection of pipelines/components	M
			Operational Management Document addresses periodic inspection and maintenance of the medical gas pipeline system (MGPS)	H
	Failure of pressure control – high pressure	High pressure at the terminal unit	Correct design and location of pressure-relief valves to protect against component failure	M
			Correct design of alarm system to indicate high-pressure condition	M
			Operational Management Document addresses periodic testing and maintenance of pressure-relief valves	H
			Operational Management Document addresses periodic checks of high-pressure alarm	H
			Operational Management Document addresses periodic inspection and maintenance of pressure regulators	H
			Operational Management Document addresses checks of ability of equipment attached to MGPS to cope with failure of pressure control system	H

Table F.1 Page 4 of 16

Table F.1 — page 4 of 16

Safety Objective	Root Cause	Hazardous Situation	Risk Control Measures	Resp. Org.
System performance	Failure of pressure control – low pressure	Low pressure at terminal unit leading to malfunctioning of equipment	Correct design of alarm system to indicate low-pressure condition	M
			Operational Management Document addresses periodic checks of low-pressure alarm	H
			Operational Management Document addresses periodic inspection and maintenance of pressure regulators	H
	Incorrect design/ specification of sources of supply	Failure of supply Inadequate supply to pipeline	Provide usage information	H
			Correct design and sizing of sources of supply based on usage information and supplier's capabilities/contractual arrangements	M
			Design validation in accordance with Clause 12	M
			Commissioning checks following installation	H+M
			Operational Management Document addresses periodic checks of sources of supply installation, layout and access	H
			Operational Management Document addresses periodic checks of usage to review the supply source capability	H
	Leakage from pipework	Potential fire risk. Potential risk of asphyxiation. Potential risk of high concentrations of gases. Potential inadequate/ reduced supply to terminal units.	Commissioning of the system	H+M
			Operational Management Document addresses periodic checks for leakage from MGPS	H
			Operational Management Document addresses periodic maintenance of MGPS	H

Table F.1 Page 5 of 16

Table F.1 — page 5 of 16

Safety Objective	Root Cause	Hazardous Situation	Risk Control Measures	Resp. Org.
Quality of gas supplied to patient	Wrong specification supplied to the supply source	Gas delivered or manufactured on site not complying with specification Gas supplied to the patient not to the correct specification Wrong cylinders/mobile cryogenic tanks supplied/connected to the manifold Gas supplied at the wrong pressure	Certified product supplied by gas supplier	H
			Correct contractual arrangements with the gas supplier	H
			Check for correct connection of flexible connections to the manifold (gas-specific connection where possible)	H+M
			Check that the correct labels are fitted to terminal outlets and area shut-off valves	H+M
			Check that the correct signs are fitted to manifold rooms, cryogenic tanks and medical gas cylinder stores	H+M
			Check that pipelines are marked for the correct gas	H+M
			Operational Management Document to identify the Pharmacist/ QC responsibilities	H
			Correct design of gas mixing/manufacturing processes done on site	M
			Commissioning of gas mixing/manufacturing processes done on site	H+M
			Operational Management Document to identify correct maintenance of gas mixing/manufacturing processes run on site	H
			Operational Management Document to identify correct testing of gas mixed/manufactured on site	H
			Operational Management Document to specify the correct procedures for connecting supply source to manifold	H+M
			Operational Management Document to review quality requirements for gases supplied on site	H
			Operational Management document to specify that adaptors should not be used	H
			Operational Management document to specify that transfilling from a large cylinder into smaller one(s) should not be done and that cryogenic liquid transfilling should be done in accordance with the equipment manufacturer's instructions	H

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Safety Objective	Root Cause	Hazardous Situation	Risk Control Measures	Resp. Org.
Quality of gas supplied to patient	Contamination of gases	Gases contaminated by components not cleaned to an appropriate standard Cleaning agent left in component or pipelines Post-construction purging not complying with specification Contamination from compressors/ vacuum pumps/oxygen concentrators/ Oxygen boosters	Correct procedures to achieve the correct level of cleanliness to ensure proper cleaning and purging	M
			Correct testing procedures identified to demonstrate that conditioning systems are operating correctly	H+M
			Commissioning of the MGPS to ensure the correct cleaning/ purging standard	H+M
			Operational Management Document to identify correct cleaning procedures and testing requirements	H
			Operational Management Document to identify correct maintenance of gas compressors/vacuum pumps/oxygen boosters	H
			Operational Management Document to identify correct testing procedures for possible contaminants in medical air	H
			Correct procedure for validating cleanliness of components used within the MGPS	H+M
			Use components complying with the cleanliness requirements in this part of ISO 7396 Correct location of intake to air compressor(s)	H+M
			Correct functioning of air purification unit/sieve bed	H
	Contamination of gases	Blockage of filters used on components of the system leading to reduced flow Failure of components (pressure regulators, etc.) Leakage of gas through components or connections Wrong functioning of air purification unit/sieve bed	Correct procedures and specification of the cleaning of pipes and components and for checking filters after commissioning	M
			Correct testing procedures identified to demonstrate that filters are not blocked (and that there is not excessive particulate in system)	M
			Operational Management Document to identify correct filter cleaning/replacement procedures and testing requirements for MGPS filters	H
			Operational Management Document to identify correct filter cleaning/replacement procedures and testing requirements for medical device filters connected to the MGPS	H
			Operational Management Document to identify correct maintenace of filters	H
	Ignition/ decomposition of components used in the MGPS	Toxic gases released into the gas stream	Check that all components used are in compliance with ISO 15001	M
			Operational Management Document to ensure that all replacement parts used on the MGPS are in compliance with ISO 15001	H

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Safety Objective	Root Cause	Hazardous Situation	Risk Control Measures	Resp. Org.
Quality of gas supplied to patient	Backfeeding of gases within an MGPS	Potential loss of supply to the patient Potential contamination of the supply source or the gas supplied to the patient	Correct design of the MGPS to prevent backfeeding of gases	M
			Commissioning checks to demonstrate performance of any backflow protection devices or differential pressure settings	H+M
			Operational Management Document to identify correct testing and maintenance of backflow protection devices and differential pressure settings	H
	Supply of the wrong medical gas	Potential risk of asphyxiation	Operational Management Document to forbid the use of adaptors	H
			Ensure that there is no back flow in medical devices connected to the MGPS	H
	Cross-connections between MGPSs	Contamination of the supply source or of the gas supplied to the patient	Correct design of MGPS to prevent cross-connections	M
			Commissioning of MGPS to demonstrate no cross-connections	H+M
			Operational Management Document addresses control of cross-contamination when system is modified/extended	H
System operation	Incorrect operation or maintenance of the MGPS	Wrong quality of gas/ vacuum supplied to the patient. Failure of supply to the patient.	Define the correct procedures in the Operational Management Document for each section/component of the MGPS	H+M
			Define responsabilities for all associated staff/users of the MGPS	H
			Define training requirements for all associated staff/users of the MGPS	H
			Ensure that all area shut-off valves, control panels and alarm panels are located in an appropriate location and correctly labelled	H+M
			Train all associated staff/users of the MGPS	H
			Operational Management Document to specify the need to assess competency of all associated staff/users of the MGPS and specify the retraining requirements; recording of training	H
	Insufficient resources to operate and manage the MGPS	Wrong quality of gas/ vacuum supplied to the patient Failure of supply to patient or equipment	Review the staffing requirements for safely operating the MGPS (in and out of normal working hours)	H
			Operational Management Document to specify the need to review manning requirements on a regular basis	H

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Safety Objective	Root Cause	Hazardous Situation	Risk Control Measures	Resp. Org.
System operation	Inappropriate action taken in the event of an emergency condition with the MGPS	Wrong quality of gas/ vacuum supplied to the patient Failure of supply to the patient	Define the correct procedures for the operation of MGPS in an emergency condition	H+M
			Define emergency training requirements for all associated staff/ users of the MGPS	H
			Provide emergency training for all associated staff/users of the MGPS	H
			Operational Management Document to specify the need to assess competency of all associated staff/users for emergency operation of the MGPS and to specify the retraining requirements; recording of training	H
	Leakage from pipework	Potential fire risk. Potential risk of asphyxiation. Potential risk of high concentrations of gases. Potential inadequate/ reduced supply to terminal units	Need for an ambient oxygen analyser with alarm if situated inside building.	M+H
			Operational Management Document addresses periodic checks for leakage from MGPS.	H
Continuity of supply	Loss of electrical supply to the on site gas production system / booster compressor.	On site gas production system stops running leading to loss of supply to pipeline.	Emergency Power Generator of adequate size to run the on site gas production system required to maintain supply.	H
			Adequate backup oxygen storage / supply source required to allow backup generator to start to prevent supply failure.	M
			Check capacity of the emergency electrical supply.	H
			Routine testing of the emergency electrical supply.	H
	Failure of the on site gas production system / components.	On site gas production system stops running leading to loss of supply to pipeline.	Requirement for the second/third source of supply to maintain the supply to the pipeline system until the on site gas production system / component can be repaired/ replaced (such as air compressor, valves, control panel, analysers).	H
			If second source of supply is a concentrator, there needs to be sufficient storage / third source of supply to allow the second concentrator unit to start and be able to come on stream.	H
	Loss of power to alarm system	Failure to alert health care facility of potential supply failure.	UPS system to maintain electrical supply to alarm system.	H+M
			Routine testing of the alarm system.	H
			Operational Management Document addresses issues of alarm failure.	H
			Procedures to ensure that all components are restored to an operational condition following reinstatement of the power supply.	H

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Safety Objective	Root Cause	Hazardous Situation	Risk Control Measures	Resp. Org.
Continuity of supply	Loss of power to the control panel including analysis panel	Failure of the on site gas production system	UPS system to maintain electrical supply to control panel.	M
			Procedures to ensure that all components are restored to an operational condition following reinstatement of the power supply.	H
	Failure of internal pipework on the outlet of the on site gas production system	Loss of supply to pipeline resulting in high oxygen enrichment levels leading to potential fire	Need for an ambient oxygen analyser with alarm if situated inside building.	H
	Waste gas vented in the Oxygen Concentrator Unit building	High nitrogen enrichment within the building leading to asphyxiation	Need for an ambient oxygen analyser with alarm if situated inside building.	H +M
	Poor location of the on site gas production system	Potential for concentration of atmospheric pollutants to increase that can lead to deteriation of the sieve material. Loss of product quality leading to potential for high levels of toxic pollutants (such as CO) in oxygen supply.	Requirements for monitoring oxygen for pollutants to meet pharmacopoeia requirements / specification detailed in standard.	M
			Ensure that control room has adequate temperature control and ventilation.	M
			Review room temperature control to ensure that the analyser operates correctly.	H
	Poor location or housing of on site gas production system	Mechanical damage to the sources of supply leading to loss of supply. Sources of supply affected by incident involving an adjacent facility. Potential damage to other sources of supply. Eventual failure of the supply source. Access to all sources of supply blocked, leading to loss of supply.	Ensure that plant rooms and manifold rooms have adequate temperature control and ventilation.	H+M
			Review room temperature control to ensure that the analyser operates correctly.	H
			Where part of the plant is located outside plant needs protection from mechanical damage.	H
			Site procedures to maintain access to sources of supply.	H
			Routine review of location of supply system to ensure system remains safe.	H
	Component failure	Potential for the loss of supply with failure of critical components.	Specification for the critical components to be obtained from approved suppliers.	H+M
			Alarm systems checked to ensure that failure of critical components is detected.	H
			Adequate spares/redundancy for critical components.	H
	Failure of the maintenance system	Potential failure of components and subsequent failure of supply system.	Operational Management Document addresses issues of critical components.	H

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Safety Objective	Root Cause	Hazardous Situation	Risk Control Measures	Resp. Org.
Continuity of supply	Booster compressor not available when the primary and secondary source are not available.	No gas available for booster compressor to compress into oxygen 93 reservoir (third source).	Sizing of the third source to cover circumstances when there is no gas to compress (when primary source is unavailable and secondary source is down for maintenance).	M+H
			Sizing of the Oxygen Concentrator Unit to provide sufficent output to allow the pipeline requirements to be met whilst providing sufficient gas to operate the booster compressor.	M
			Sizing of the cylinder backup supply source to take account of product availability when refilling.	M+H
	Changes in the demand for oxygen on site over time.	Lack of oxygen available from any one source of supply.	Sizing of the Oxygen Concentrator Unit to take account of any planned growth in the use of oxygen.	M+H
System performance	Incorrect design/ specification of components and pipeline systems.	Inadequate supply to the pipeline system.	Provide usage information	H
			Correct design of components/pipelines based on usage information.	M
			Sizing and performance validation in accordance with Clause 12.	M+H
			Operational Management Document addresses periodic checks of usage.	H
	Failure of pressure control leading to low pipeline pressure	Low pressure to the pipeline system leading to low pressure in pipeline / frequent switching to second source.	Design of Oxygen Concentrator Unit to ensure plant is of a sufficient capacity to maintain the pipeline minimum pressure.	M+H
			Design of the alarm system to indicate low-pressure condition.	M
			Operational Management Document to address periodic checks on low-pressure alarm.	H
			Operational Management Document addresses periodic inspection and maintenance of Oxygen Concentrator Units.	H
	Leakage from pipework	Potential fire risk. Potential risk of asphyxiation. Potential risk of high concentrations of gases. Potential inadequate/ reduced supply to terminal units	Need for an ambient oxygen analyser with alarm if situated inside building.	H
			Operational Management Document addresses periodic checks for leakage from MGPS.	H

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Safety Objective	Root Cause	Hazardous Situation	Risk Control Measures	Resp. Org.
Quality of gas supplied to patient	Wrong specification supplied from the on site gas production system	Gas manufactured on site not complying with correct specification. Gas supplied at the wrong pressure.	Accountability of the Health care facility Pharmacist (or Executive Manager) established and monitored.	H
			Operational Management Document to identify the Health care facility / QC / Authorised Person responsibilities to ensure that the product quality meets the relevant specification.	H
			Correct design verification of manufacturing processes completed and approved.	H
			Commissioning / validation of manufacturing processes completed on site.	H
			Adequate training of all operatives in the correct operation of the Oxygen Concentrator Unit.	H
			Operational Management Document to identify correct maintenance of Oxygen Concentrator Unit manufacturing processes run on site.	H
			Operational Management Document to identify correct testing of gas manufactured on site.	H
	Contamination of gases	Gases contaminated by components not cleaned to an appropriate standard. Cleaning agent left in component. Post-construction purging not complying with specification. Contamination from oxygen concentrators. Contamination from Booster compressor. Contamination from air supply. Poor operation of air purification in system.	Correct procedures to achieve the correct level of cleanliness to ensure proper cleaning and purging.	M
			Correct testing procedures identified to demonstrate that conditioning systems are operating correctly.	M
			Commissioning of the Oxygen Concentrator Unit(s) to ensure the correct cleaning/purging standard	M
			Operational Management Document to identify correct cleaning procedures and testing requirements	M+H
			Operational Management Document to identify correct maintenance of gas compressors/vacuum pumps	M+H
			Operational Management Document to identify correct testing procedures and frequency of testing, including limits for possible contaminants in the oxygen supply	M+H
			Correct procedure for validating cleanliness of components	M
			Use components complying with the cleanliness requirements in this part of ISO 7396.	M
			Correct location of intake to air compressor(s).	M+H
			Correct functioning of air purification unit/sieve bed.	M+H

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Safety Objective	Root Cause	Hazardous Situation	Risk Control Measures	Resp. Org.
Quality of gas supplied to patient	Excessive particles from the Oxygen Concentrator Units.	Blockage of filters used on components of the system leading to reduce flow. Failure of components (regulators, etc.). Leakage of gas through components or connections. Wrong functioning of sieve bed. Particulate from sieve beds.	Correct maintenance / monitoring of the filter downstream of sieve beds.	H
			Correct procedure and specification of the cleaning pipework and components and for checking filters after commissioning.	M+H
			Correct testing procedures identified to demonstrate that filters are not blocked (and that there are not excessive particulates in system).	M+H
			Operational Management Document to identify correct filter cleaning/replacement procedures and testing requirements for MGPS filters.	H
			Operational Management Document to identify correct filter cleaning/ replacement procedures and testing requirements for medical device filters connected to the MGPS.	H
			Operational Management Document to identify correct maintenance of filters.	H
	Ignition/ decomposition of components used in the on site gas production system	Toxic gases released into the gas stream Risk of ignition of non-metallic components when operating from cylinder supply source filled from the on site gas production system	Check that all components used are in compliance with ISO 15001.	M
			Operational Management Document to ensure that all replacement parts used on the on site gas production system are in compliance with ISO 15001.	H
			Correct design specification of the booster compressor components to ensure that partial ignitions will not lead to toxic gases being delivered to patients.	M
			Correct installation of the booster compressor to ensure that the temperature of the booster compressor is both controlled and monitored to ensure components are maintained low enough to prevent ignitions.	M
	Contamination of the gas filled into high pressure oxygen 93 reservoir from booster compressor	Potential toxic gases transferred	Continual testing of gas supplied to back up high-pressure oxygen 93 reservoir to ensure product is of the correct quality to the pharmacopoeia specification.	H
			Operational Management Document to identify suitable contaminants to monitor to ensure system operating correctly.	H

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Safety Objective	Root Cause	Hazardous Situation	Risk Control Measures	Resp. Org.
Quality of gas supplied to patient	Variability of the oxygen product quality fed to the pipeline system	Lack of trending of the plant performance with respect to product quality and safety	Operational Management Document to identify requirements for documenting key / critical parameters to demonstrate the correct performance of the plant.	H
			Periodic management review of plant data to ensure plant compliance and to ensure no drift on product quality.	H
			Use of trend analysis to monitor the performance of the sieve to ensure sieve material is exchanged prior to the product going out of specification.	H
			Operational Management Document to identify control of non-conformances of the plant.	H
	High pressure oxygen reservoir filled from the booster compressor used within the confines of the healthcare facility	Lack of traceability of the product Need for system to recall product safely and effectively	Batch Management system established to record key data and to label cylinders with the appropriate batch information.	H
			Quality Management System compliant with the requirements of Good Manufacturing Practice Guidelines / Pharmaceutical regulatory to cover the filling and traceability requirements for the products.	H
			Documented procedures to cover the filling of high-pressure reservoirs.	H
			Training of operatives to fill the high-pressure reservoirs.	H
			Competency assessment of operators to ensure compliance with procedures.	H
	Inappropriate action taken in the event of an emergency condition with the on site gas production system.	Wrong quality of gas supplied to the MGPS. Failure of supply to MGPS.	Define the correct procedures for the operation of the on site gas production system in an emergency condition.	M+H
			Define emergency training requirements for all associated staff/ users of the the on site gas production system.	H
			Provide emergency training for all associated staff/users of the the on site gas production system.	H
			Operational Management Document to specify the need to assess competency of all associated staff/users for emergency operation of the on site gas production system and to specify the retraining requirements; recording of training.	H

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Safety Objective	Root Cause	Hazardous Situation	Risk Control Measures	Resp. Org.
System operation	Incorrect operation or maintenance of the on site gas production system.	Failure of supply to the MGPS. Wrong quality of gas supplied to the MGPS.	Operational Management Document to define the correct preventative maintenance system to ensure reliability of plant.	H
			Define responsabilities for all associated staff/users of the on site gas production system.	H
			Define training requirements for all associated staff/users of the on site gas production system.	H
			Ensure that all area shut-off valves, control panels and alarm panels are located in an appropriate location and correctly labelled.	H
			Train all associated staff/users of the on site gas production system.	H
			Operational Management Document to specify the need to assess competency of all associated staff/users of the on site gas production system and specify the retraining requirements; recording of training.	H
	Insufficient resources to operate and manage the on site gas production system	Wrong quality of gas supplied to the MGPS. Failure of supply to MGPS.	Review the staffing requirements for safely operating the on site gas production system (in and out of normal working hours).	H
			Operational Management Document to specify the need to review manning requirements on a regular basis	H
			Availability of external maintenance services to maintain the plant for both preventative and corrective maintenance.	H
Control of oxygen concentration	Use of two different quality of sources of supply (93% versus 99,5%).	Equipment calibrated using the gas supplied in the MGPS as the standard gas.	Operational Management System to define the use of a certified cylinder as the standard for calibrating the analyser on the medical device administering the gas to the patient.	H
			Medical devices not compatible for use with 93% oxygen should be labelled to indicate the specific care needed to enable the device to be used in a safe manner.	H
			In high risk areas within the healthcare facility (such as ICU, operating theatre) there should be a permanent display of the oxygen concentration with alarms on specific limits.	H
			Labelling of the outlet points to indicate the potential quality of the gas being delivered.	H
			Operational Management Document to specify the need to assess competency of all associated staff/users of the MGPS supplied by the on site gas production systemand specify the retraining requirements; recording of training.	H

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Safety Objective	Root Cause	Hazardous Situation	Risk Control Measures	Resp. Org.
Control of oxygen concentration	Use of two different quality of sources of supply (93% versus 99.5%)	Flow sensors used on medical devices may be not suitable for use where there is a relatively high concentration of argon in the gas.	Medical devices not compatible for use with oxygen 93 should be labelled to indicate the specific care needed to enable the device to be used in a safe manner	H
	Use of 93% oxygen.	High levels of argon in gas supplied for patient use at higher pressures	Prevention of the use of oxygen 93 in hyperbaric chambers.	H
			For low fresh gas flow anaesthesia, the possible accumulation of the argon concentration permitted for oxygen 93 shall be taken into account. Appropriate processes shall be defined to keep the argon concentration at an acceptable level.	H
	Use of two different qualities of sources of supply (Oxygen 93 versus Oxygen)	Depending on the condition of the patient, the concentration of the oxygen could have an adverse effect on the patient treatment	The terminal units and the equipment must be labelled.	H
			The health care facility must ensure that the medical equipment used is compatible with the oxygen 93	H
			Low flow oxygen systems (using oxygen 93 can lead to hypoxemia due to the accumulation of argon in the circle system).	H
	Poor management of the on site gas production system	Large variability in the oxygen concentration of the gas produced by the on site gas production system	Operational Document provided by the manufacturer of the on site gas production system to clearly define the operational and maintenance instructions for running the plant correctly. The User Manual should specify the required level of training to ensure patient safety.	H
			Operational Management Document to cover the requirements for operating the on site gas production system on the Healthcare premises, including the requirements for documenting the operational conditions, training and retraining requirements and the approved maintenance frequencies for the key components of the installation.	H

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Annex G
(informative)

Operational management

G.1 Introduction

The guidance given in this annex represents the best operating management practice for the operation of the Medical Gas Pipeline System (MGPS) and should be followed, especially where it impacts on patient or staff safety and where an extension, modification or upgrading of existing installations has occurred.

The primary objective of this annex is to provide guidance for assigning responsibilities to ensure the provision of a safe and reliable MGPS and its efficient operation and use and to maintain patient safety through continuity of supply. This objective will only be achieved if the medical and nursing users and healthcare facilities staff participate in the development of an operational policy designed to minimize the risks resulting from misuse of the system.

This annex looks at issues of operational management including statutory requirements, functional responsibilities, operational procedures, training, communications, management of cylinders and other sources of supply management, preventive maintenance and repair and risk assessment.

It is intended for use by operational managers, engineers, quality controllers, technicians, finance officers and other professionals involved in the day-to-day running of an MGPS. One objective of this annex is to clarify the requirements of the operational management system to the healthcare staff and to any contractors involved, prior to its initial use or after any modifications.

The operational management guidance given in this annex should be followed for all installations, including any extensions, modifications or upgrading of the MGPS.

The operation of existing installations should be assessed for compliance with this part of ISO 7396, including this annex. A plan for upgrading existing systems should be prepared on the basis of risk management, ensuring that patient safety is maintained throughout the process. Managers will need to liaise with medical colleagues and take account of other published guidance in order to assess the system for technical shortcomings.

G.2 Statutory requirements

G.2.1 It is the responsibility of the owners and occupiers of premises, general managers and chief executives to ensure that their premises and the activities carried out within them comply with all national and regional regulations, which should be listed in the Operational Management Document.

NOTE In Europe, medicinal gases are covered by the following relevant directives:

— EU Directive 2001/83 EC (relating to medicinal products for human use);

— Medical Device Directive 93/42/EEC (concerning the design and construction of medical devices);

— EU Directive 2003/94 EC (detailing the principles and guidelines of good manufacturing practice with regard to medicinal products and investigational medicinal products for human use).

G.2.2 Medical gases are classified as medicinal products under the pharmaceutical regulations and are, therefore, subject to the same procurement and quality procedures as all other medicinal products. The quality controller (QC) is responsible for quality control of all medicinal products and this includes medical gases, including the manufacture of any medicinal gases on site.

G.3 Functional responsibilities

G.3.1 General

This annex identifies the distinct functions that need to be exercised and the responsibilities that go with them. The titles given here are generic. They describe the individual's role in connection with the MGPS, but are not intended to be prescriptive job titles for terms of employment. Indeed, some of the personnel referred to might not be resident staff but people employed by outside bodies and working on contract.

The following are the key personnel who have specific responsibilities within the operational policy:

a) executive manager (EM);

b) facilities engineering manager (FEM);

c) authorized person (AP);

d) competent person (CP);

e) quality controller (QC);

f) designated medical officer (DMO);

g) designated nursing officer (DNO);

h) designated person (DP).

Some staff may have other responsibilities unconnected with the MGPS and in some cases the same individual may take on more than one role.

In all cases, however, it is essential to identify an AP who is responsible for the day-to-day management of the MGPS and for seeing that the MGPS is operated safely and efficiently and who can decide whether an MGPS should be taken into or out of service.

The EM, FEM and AP may be responsible for more than one MGPS on more than one site.

In order to avoid confusion with other authorized persons, the key personnel mentioned in this annex are always involved with the MGPS.

G.3.2 Executive Manager (EM)

G.3.2.1 The EM is the person with ultimate management responsibility for the organization in which the MGPS is installed and operated, including the allocation of resources and the appointment of personnel.

G.3.2.2 Formal responsibility for the MGPS rests with the EM, although the AP retains effective responsibility for day-to-day management of the MGPS.

G.3.2.3 The EM is responsible for implementation of the operational policy for the MGPS and to ensure that the Operational Management Document clearly defines the roles and responsibilities of all personnel who can be involved in the use, installation, modification and maintenance of the MGPS. The EM is also responsible for monitoring the implementation of the Operational Management Document.

G.3.2.4 The EM might delegate specific responsibilities for the MGPS to key personnel. The extent of the delegation should be clearly set out in the Operational Management Document, together with the arrangements for liaison monitoring and review.

G.3.3 Facilities Engineering Manager (FEM)

G.3.3.1 The FEM is the person with overall responsibility for the MGPS and who needs to have sufficient technical knowledge and experience in order to understand fully the hazards involved during commissioning, construction, operation, maintenance, modification and upgrading of the MGPS. The FEM usually reports to the EM of the healthcare facility.

G.3.3.2 The FEM of the healthcare facility is responsible for the integrity of the MGPS. The FEM might have one or more authorized persons (APs) with clear line management responsibility for the MGPS reporting to him.

G.3.3.3 The FEM is responsible for implementing and monitoring the Operational Management Document covering the MGPS.

G.3.3.4 The FEM is responsible for ensuring that all APs and CPs employed or contracted by the engineering department are competent and qualified.

G.3.3.5 The FEM is responsible for maintaining a registry of competent APs and CPs employed or contracted on site.

G.3.3.6 The FEM is responsible for taking appropriate corrective actions on reported failure or excessive wear of MGPS equipment and components.

G.3.4 Authorized Person (AP)

G.3.4.1 The AP should be appointed in writing by the EM and have sufficient technical knowledge, training and experience to understand fully the hazards involved with the operation of the MGPS. The AP should be appointed in writing by the executive manager or general manager on the recommendation of a chartered engineer with specialist knowledge of MGPSs.

G.3.4.2 The appointed AP is responsible for the day-to-day management of the designated MGPS(s) or section of the MGPS. For a specific MGPS, there may be one or more APs, with clear line management responsibility.

The Operational Management Document should define the number of APs required to manage the MGPS and the need for an AP to always be available on site or on call.

G.3.4.3 All appointed APs should be listed in the Operational Management Document and be made known to all interested parties on site. The AP should have specific knowledge of the MGPS on site and be independent from the contractor performing the work on the MGPS.

G.3.4.4 The AP is responsible for the following:

a) the issuing of permits and the management and operation of the permit to work procedures related to the MGPS;

b) ensuring that all DNOs in departments likely to be involved are advised of the estimated duration of the work and the interruption to the MGPS;

c) ensuring that all terminal units identified as being faulty or requiring attention are appropriately labelled.

G.3.4.5 The AP should have the responsibility for deciding whether an MGPS should be put into or taken out of service.

G.3.4.6 The AP is responsible for assessing the competency of all CPs and DPs employed directly by the engineering department.

G.3.4.7 The AP is responsible for ensuring that work is carried out only by trained staff or by approved specialist contractors certified to a quality management system as specified in **11.1**. The scope of the testing should be defined as design, installation, commissioning or maintenance of the MGPS, as appropriate. Evidence of current documentation should be demonstrated.

G.3.4.8 The AP is responsible for coordinating the different instruction manuals for each individual section of the MGPS to prepare an instruction manual to cover the complete system.

G.3.4.9 The AP should be consulted prior to the purchase of any medical equipment that will be connected to the MGPS to ensure that the design specifications of the MGPS can still be met with the use of the new equipment.

G.3.5 Competent Person (CP)

G.3.5.1 The CP should have sufficient technical knowledge, training and experience to carry out his/her duties in a competent manner and understand fully the hazards involved with the operation of the MGPS. The CP should be named on the register of competent persons maintained by the FEM.

G.3.5.2 The CP is normally the maintenance person or installer who carries out any work on the MGPS. A list of their responsibilities and duties is set out in **G.5.4**, "Permit to work procedure".

G.3.5.3 The CP might be a member of a specialist contractor's staff or might be a member of the healthcare facility's engineering department. Where the CP is a member of the engineering department, the AP is responsible for assessing the competency of the CP with respect to work on the MGPS. Where the CP is a member of a contractor's staff, the contractor is responsible for assessing his/her competence and maintaining a register of CPs within his/her employment.

G.3.6 Quality Controller (QC)

G.3.6.1 The QC should be appointed in writing by the EM and should be responsible for the quality of the medical gases distributed by the MGPS. The QC might be a pharmacist and should be a suitably qualified person and have specialist knowledge of, training and experience with MGPSs.

Where the QC's duties include carrying out specific quality tests on the medical gases distributed by the MGPS, the tests should be in accordance with the documented procedures to ensure that they comply with the relevant specifications.

G.3.6.2 The person designated as the QC (such as a pharmacist) is responsible for the quality control of the medicinal gases distributed by the MGPS at all terminal units and administered to patients to ensure that they conform to the relevant pharmacopoeia specifications. The AP will need to liaise with the QC before an MGPS can be put into use for the first time or after any maintenance or modification to the MGPS to ensure that the medical gas is of the correct quality.

G.3.6.3 The QC should have received adequate training to enable the verification of the quality of medical gas distributed by the MGPS prior to its being put into service. He/she should also be familiar with the requirements of this annex.

G.3.6.4 The QC should also be responsible for ensuring that the MGPS can continuously deliver medical gas of the correct quality to all patients. This applies especially to medical air supplied by compressor systems or by proportioning systems and oxygen 93 produced by oxygen concentrator systems, where the gases are manufactured on site. It may be appropriate to include a medical product quality warning system within the pharmacy department. Regional or national regulations relating to those gases generated on site may exist.

G.3.7 Designated Medical Officer (DMO)

G.3.7.1 The DMO should act as the focal point for all communications between the engineering department and the specific clinical department related to the MGPS. The DMOs should be defined in the Operational Management Document.

G.3.7.2 The DMO should advise the engineering department of any special requirements for their department relating to the MGPS, such as provision of emergency cylinders.

G.3.7.3 The DMO is the medical person who should be consulted on pipeline extensions and other modifications to the MGPS. The DMO should be responsible for informing the AP of any significant changes in the usage of medical gases or the introduction of new clinical procedures which can affect the medical gas demand.

G.3.8 Designated Nursing Officer (DNO)

G.3.8.1 The DNO should act as the focal point for all communications related to the MGPS between the engineering department and his/her own specified department or departments. There would ideally be a DNO in each department and they should be defined in the Operational Management Document.

G.3.8.2 The DNO is the appointed person in each department with whom the AP liaises on any matters affecting the MGPS and who should be responsible for giving permission for a planned interruption to the supply.

G.3.8.3 When the DNO gives permission for any interruption to the MGPS in a specified department or departments, he should sign the appropriate part of the “Permit to Work”. The Operational Management Document should clearly set out the requirements for such permission.

The AP should describe to the DNO the extent to which the MGPS will be restricted or interrupted while any work is in progress and should indicate the level of hazard involved. The DNO should assist, as necessary, to ensure that service is maintained whilst the MGPS is disrupted.

G.3.8.4 The DNO is responsible for ensuring that the relevant staff in the department are made aware of the interruption to the MGPS and which terminal units cannot be used.

G.3.8.5 The Operational Management Document should list the DNOs for each department and any arrangements for coverage during their absence.

G.3.8.6 The DNO should carry out the appropriate action in the event of an emergency as detailed in the Operational Management Document.

G.3.8.7 All DNOs should be trained in the use of the MGPSs relevant to their departments and on the action to be taken in the event of an emergency.

The Operational Management Document should set out these training requirements.

G.3.9 Designated Person (DP)

G.3.9.1 The DP should be a suitably trained person. He should be given the responsibility of carrying out particular operations on the MGPS (e.g. changing cylinders on the MGPS manifold, testing alarm systems, etc.).

G.4 Operational Management Document

G.4.1 The operational management requirements for operating the MGPS should be detailed in an Operational Management Document.

This annex may be used to develop an Operational Management Document.

G.4.2 The Operational Management Document should include documented procedures for the following:

a) control of documents and records;

b) training and communication;

c) emergency management;

d) change management;

e) permits to work;

f) preventive maintenance;

g) repair;

h) sources of supply management;

i) cylinder storage and handling;

j) medical equipment purchase;

k) contractors management.

NOTE Separate policies or procedures are sometimes prepared to supplement the Operational Management Document.

G.4.3 The EM is responsible for the overall Operational Management Document and its implementation.

G.4.4 The Operational Management Document should state the procedures to be followed and the personnel who need to be consulted before a new item of medical equipment is connected to the MGPS. Special attention should be paid to changes of the supply system.

It is especially important that alarm settings be reviewed prior to using the system.

G.4.5 In some areas of the facility, medical gas equipment may be installed within enclosures or behind decorative panels in order to provide a more domestic environment. In these cases, it is essential that identification is maintained so that staff are aware that equipment is available for patient use.

Where gas blenders (mixers) are used, the manufacturer's instructions should be followed with regard to operation and maintenance to prevent back flow of one gas into the other pipeline in the event of equipment malfunction.

NOTE Some older types of blending equipment can allow the backflow of gas from one pipeline to another, which can lead to oxygen enrichment of medical air systems, or reduction of the oxygen concentration in oxygen pipelines.

G.5 Operational procedures

G.5.1 Procedure for control of documents and records

G.5.1.1 The Operational Management Documents should be controlled by the quality management system to ensure that the relevant and latest versions of applicable documents are available at the point of use.

The procedure should define the controls needed to

— review and approve documents,

— ensure that only the current versions of applicable documents are available at points of use,

— prevent the unintended use of obsolete documents.

G.5.1.2 All records of results of the activities carried out in accordance with the procedures in the Operational Management Document should be retained.

NOTE Subclauses 4.2.3 and 4.2.4 of ISO 13485:2003 [20] give guidelines for control of documents and records.

G.5.1.3 The EM is responsible for monitoring the Operational Management Document to ensure that it is being properly implemented. This should be carried out on a regular basis, and the procedure for such monitoring should be set out in the Operational Management Document.

G.5.1.4 The responsibility for monitoring specific aspects should be delegated to the appropriate key personnel. The details of such delegation should be set out in the Operational Management Document.

G.5.2 Training and communication procedure

G.5.2.1 All personnel involved in the administration and use of medical gases in the healthcare facility should have a sound general knowledge of the operational principles, basic design and functions of the MGPS. They should be trained on those specific systems for which they will be responsible.

G.5.2.2 A training programme should be established for all staff, including nursing staff responsible for the operation and use of the MGPS. All training should be recorded and reviewed regularly.

G.5.2.3 All APs, DPs and CPs should have satisfactorily completed an appropriate training course before they are appointed.

G.5.2.4 All APs, DPs and CPs should have sufficient experience, be familiar with their particular installations and have their competency assessed before they are appointed.

G.5.2.5 It is recommended that all APs have their training reassessed at set intervals and attend a refresher or other training course prior to the reassessment. The recommendation for appointment or re-appointment as an AP should be made by a FEM who has specialist knowledge of the MGPS.

G.5.2.6 The QC should receive specific training covering the responsibilities and duties which he/she will be required to carry out with respect to the MGPS. It may be appropriate for the QC to attend part or all of the training courses for APs.

G.5.2.7 The medical and nursing staff who use the MGPS should be trained in the use of the system. This training should include practical use of the system and emergency and safety procedures. The EM should ensure that all staff have received this training prior to using the MGPS and that refresher courses are arranged.

G.5.2.8 The Operational Management Document should set out the means of communication between the various key personnel. It should define which departments need to be informed of work being carried out on the MGPS, the personnel to be notified and whether such information should be given verbally or in writing.

G.5.2.9 The actions to be taken in the event of a fault with the MGPS should be detailed in the Operational Management Document. There should be a clear means of reporting any faults to the FEM.

G.5.2.10 All staff who are involved in the use, installation or maintenance of the MGPS should be aware of the Operational Management Document and their specific responsibilities within it.

G.5.2.11 The Operational Management Document should detail the need to ensure that

— all users are aware of the capacity and any particular limitations of the MGPS,

— nursing and medical staff are aware of the purpose of alarm systems and the action to be taken in the event of an alarm condition.

G.5.2.12 Staff responsible for the operation of the MGPS should be aware of

— the activities necessary to ensure the continued safe operation of the system,

— the actions to be taken in a single fault condition or in an emergency situation where the MGPS fails to deliver gases to the terminal units.

NOTE Safety objectives and hazardous situations are given in Annex F.

G.5.3 Emergency procedure

G.5.3.1 The Operational Management Document should set out the procedures to be followed in the event of an emergency. These should include:

a) reporting of all incidents;

b) action(s) to be taken, such as shutting off area shut-off valves, use of portable emergency cylinders, etc.;

c) liaison with other staff and departments;

d) calling out contractors.

G.5.3.2 All national or local regulations relating to fire precautions should be complied with.

G.5.3.3 The emergency procedure set out in the Operational Management Document should be followed.

G.5.3.4 Where an incident is likely to cause an interruption to the supply or affect patient and personnel safety, the contractor responsible for dealing with the emergency affecting the MGPS should specify either a maximum time, from the receipt of the initial call to when the contractor is on site, or the need to provide adequate information for immediate action to be taken.

G.5.3.5 The Operational Management Document should include communication procedures to ensure that any emergency involving the MGPS is communicated immediately to all clinical areas likely to be affected and to all staff involved in the maintenance of gas supplies and in remedial actions.

G.5.3.6 Such communication procedures should include:

— the nature of the emergency;

— details of the gas conservation procedures to be applied;

— likely duration of the emergency;

— remedial actions to be taken;

— the need to record the details of any emergency incidents and related communications.

G.5.3.7 Experienced persons in each area to coordinate and communicate actions should be nominated.

G.5.3.8 Regional or national regulations relating to external communications of incidents should be complied with.

G.5.3.9 The DNO should be properly trained in the emergency procedures required to control the medical gases and the MGPS. He/she should be fully familiar with the location of all area shut-off valves in the specific department(s).

G.5.3.10 Emergency procedures should be initiated at least twice a year as an exercise, and any issues or need for retraining noted and followed up.

G.5.3.11 When the normal power supply is reinstated following a power supply failure, the responsible staff should ensure that all sources of supply are in a suitable condition for use.

G.5.3.12 The engineering department should have accurate and up-to-date drawings of the MGPS showing main sections and branches, departments served, pressure regulators, isolation valves, terminal units and alarm systems for each medical gas service. These drawings should be readily available on site and their location known by all AP.

G.5.3.13 The Operational Management Document should specify the requirements for locking valves and medical gas plant rooms and the procedures for keeping the keys in a safe location. The emergency services should be informed of the location of all keys related to the MGPS.

G.5.3.14 In the event of an emergency such as a fire or a major leak, a trained person should isolate the affected section by closing the emergency isolating valves or area shut-off valve. They should notify the AP and the appropriate DNO immediately.

G.5.3.15 On receiving notification of an emergency, the DNO in each clinical area should limit the use of gas from the pipeline system(s) involved to the minimum level required whilst maintaining patient safety.

G.5.3.16 The Operational Management Document should describe the procedures necessary to manage the stocks of gas in the supply system to ensure that there is gas available for use in case of an emergency.

G.5.3.17 The AP should check and ensure that designated trained staff bring into use emergency supplies when required. Sufficient cylinders for use on emergency manifolds or cylinders held in storage for emergency use should be made available, following the appropriate procedures specified in the Operational Management Document.

G.5.3.18 If necessary, additional supplies of gas should be ordered from suppliers or from other healthcare facilities to meet the expected duration of the emergency, following the appropriate procedures specified in the Operational Management Document.

G.5.3.19 Any emergency repairs or actions should be carried out under the control of the AP and controlled by the use of a permit to work.

G.5.3.20 The cause of an emergency failure of supply should be investigated immediately. Time scales for the corrective actions should be specified and, where appropriate, corrective actions to rectify the problem should be initiated immediately.

G.5.3.21 Other areas of the healthcare facility not initially affected might need to be isolated to carry out repairs. In these circumstances, communication and conservation procedures should be instituted in these areas before shutting off the gas supply.

G.5.3.22 Actual emergency situations should be evaluated and appropriate action taken to improve procedures and training to prevent a recurrence.

G.5.4 Permit to work procedure

G.5.4.1 The permit to work procedure should be used to control all planned work on the MGPS. It is used to control the safe withdrawal of the MGPS from service and the manner in which the work is carried out (including the parts of the system affected and the estimated time for completion). It should ensure that the correct procedures and the process for returning the MGPS to service are followed so that the gas supply meets the correct quality specification for patient use.

G.5.4.2 The purpose of the permit issued under the permit to work procedure is to

— safeguard the continuity of supply of gas to the terminal units;

— ensure the safety of the operator working in the vicinity of the MGPS;

— ensure that the MGPS is returned to service in a safe condition, including all examinations where no interruption to the service is anticipated.

Where the work does not involve any planned actions that will affect the supply of medical gases, (such as the inspection of terminal units), the MGPS permit to work need not be used.

G.5.4.3 The permit to work procedure is applicable to all preventive maintenance, repairs, alterations or extensions to the existing MGPS, and any action which can affect the supply of the medical gas to the terminal units.

G.5.4.4 The AP should prepare the permit to work prior to commencing the work. Using risk assessment, the AP should identify, from the MGPS drawings, the work to be done, all necessary documentation and drawings and the means of isolation.

G.5.4.5 The permit should always be issued to the relevant CPs who are to be engaged in work on the MGPS before any work is started.

G.5.4.6 Work should not be allowed to commence on the MGPS without the permission of the DMO or DNO to allow the designated officers adequate time to make appropriate arrangements to supply medical gases to the patients or equipment, except in an emergency.

G.5.4.7 The permit should remain in force until the work is completed and the MGPS is put back into use, in accordance with the approved procedures. The permit should remain in force for the time defined by the AP on the documentation or earlier if it has been signed off by the CP.

G.5.4.8 If the scope of the work covered by the permit changes, the permit should be cancelled and a new one issued.

G.5.4.9 Procedures using permits for the authorization of work require the fullest cooperation of all staff and their acceptance of the responsibilities involved. The AP should take the lead in coordinating the work, explaining fully the extent and duration of any disruption to the service and ensuring that all contractors and nursing staff follow the procedures set out in the permit.

G.5.4.10 The engineering department is responsible for the correct operation of the permit to work procedure. The AP should be responsible for the implementation of the permit to work procedure but might delegate the responsibility of issuing permits to a CP.

G.5.4.11 The AP should use risk management procedures to define the tests to be carried out prior to returning the MGPS back into service. The tests should be detailed on the permit and the test results should be recorded and retained with the permit to work. The AP should authorize the release of the MGPS to allow it to be put back into service.

G.5.4.12 The permit should define the specific test requirements to be carried out prior to returning the MGPS to service and who should be required to witness the tests. The personnel, measuring instruments used, components replaced and the problems arising during the activities should be recorded on the permit.

G.5.4.13 The permit should have a unique reference number and be signed and dated by all relevant personnel. The permit to work should be retained in a register for at least five years.

G.5.4.14 The contractor should maintain a register of approved CPs.

G.5.4.15 The AP should use risk management procedures to assess the hazard level for the work to be carried out on the MGPS at the time of preparing the permit and record it on the permit.

G.5.4.16 The AP is responsible for ensuring that the procedures to be used for isolating the MGPS and making it safe to work on are detailed on the permit. The CP is responsible for witnessing the isolation and for making the plant or system safe to be worked on.

G.5.4.17 Once the CP has accepted a permit, he/she should be responsible for the safe conduct of the work, within the limits of the permit. The work will be subject to the supervision by the AP. The CP should be fully conversant with the terms and requirements of the permit and should give clear instructions to any persons working on the MGPS.

G.5.4.18 Any errors identified in the permits should be corrected and the corrected text initialled by the CP.

G.5.4.19 The CP should sign the permit to certify that work has been completed and request the AP to examine and test the installation.

G.5.4.20 The AP is responsible for ensuring that the work has been satisfactorily completed and should supervise the testing of valve tightness, pressures, flowrates, alarm system, and absence of cross connections in accordance with the recommendations on the permit.

G.5.4.21 On satisfactory completion of all tests, the AP should supervise the reconnection of the isolated system to the main system and purging of the MGPS with the specific gas.

G.5.4.22 The AP should inform the DMO or DNO that the work is completed and that the MGPS is now available for use.

G.5.4.23 The AP should remove any "Do Not Use" or other prohibition notices after completion of the work and closing of the permit to work. The AP should retain the completed original permit.

G.5.4.24 Where isolation of the MGPS is required, the preferred method of physical isolation is by means of a break point at the "supply" end of the section of the pipeline to be worked on. This is not required where the work involves only the terminal units. Where physical isolation is not practicable, a risk assessment should be carried out to ensure that the method of isolation provides adequate protection to the system that remains operational.

G.5.5 Change management procedure

G.5.5.1 The change management procedure is a procedure to manage any change process to the MGPS, including alterations and extensions. It also covers related services to ensure that all identified risks and consequences have been addressed to ensure that patient safety and operator safety are not compromised.

G.5.5.2 Any work involving alterations and/or extensions of the MGPS should be subject to the change management procedure, prior to any work being started. This should include a risk assessment to review the implications of the change and the requirement to record any changes to the MGPS, including modifications to the drawings.

Once the alteration has been approved following the change management procedures, the permit to work procedure should be followed to ensure that the MGPS is safely isolated and returned to service.

G.5.6 Preventive maintenance procedure

G.5.6.1 All maintenance activities should be carried out in accordance with the technical specifications supplied by the manufacturer(s) of the MGPS.

G.5.6.2 A systematic approach to the preventive maintenance of a medical gas pipeline system is essential. This annex provides information that should be used when setting up a preventive maintenance programme, but does not include actual maintenance tasks or frequencies of maintenance.

G.5.6.3 MGPSs should be subjected to planned preventive maintenance and this should be the responsibility of the AP.

G.5.6.4 All preventive maintenance work carried out on the MGPS, whether or not the supply is, or is likely to be, interrupted, should be carried out only under the instructions of the AP. When unplanned maintenance work is necessary, it should be carried out only with the prior permission of the AP.

G.5.6.5 The Operational Management Document should clearly set out the responsibilities and the procedures to be followed for all maintenance work on the MGPS.

G.5.6.6 A permit to work should be issued prior to any planned preventive maintenance work being carried out on an MGPS. This includes all examinations where no interruption to the service is anticipated. Where unplanned emergency work is carried out, where it might not be practicable to raise a permit, the work should be carried out under the direct supervision of the AP.

G.5.6.7 Inspection and maintenance work should be carried out by appropriately trained and qualified personnel.

G.5.6.8 The AP should be responsible for monitoring the maintenance work, including any work carried out by contractors. It may be appropriate to arrange site meetings, when necessary, with the contractor's representatives to discuss progress.

G.5.6.9 All maintenance work on the MGPS carried out by a contractor should be covered by a formal contract.

G.5.6.10 The contractor should be instructed in the healthcare facility's safety procedures and confirm that they will comply with the requirements at all times.

G.5.6.11 All contractor's staff should report to the AP upon arrival on site and prior to leaving the premises. Contractor's staff should not visit the location of the supply plant and distribution equipment without prior permission of the AP.

G.5.6.12 The contractor is responsible for ensuring that the staff working on any part of the MGPS are appropriately trained and qualified to carry out the work. The healthcare facility should not be required to test the competency of the contractor's staff.

G.5.6.13 The preventive maintenance plan should include method statements for each specific task, the recommended frequency of the task, and any records required to be maintained for each identified task. The method statement should be applicable to the actual plant and equipment installed on site and should be in conformance with the manufacturer's instructions. The preventive maintenance plan should also define who is responsible for the work.

G.5.6.14 A maintenance log should be maintained for each plant item. The maintenance log should be updated following each planned maintenance job or following any unplanned work being carried out. It may be appropriate to define the maintenance status on each plant item, providing the date the work was last carried out and the date of the next planned service.

G.5.6.15 In order to ensure that the maintenance service is being carried out in accordance with the contract, the healthcare facility should monitor the work and the performance of the contractor. The AP should be responsible for the satisfactory implementation of the maintenance contract.

G.5.6.16 The AP should prepare an inspection checklist, to be carried out and documented daily, to demonstrate that the MGPS is functioning correctly. The checklist should be based on the inspection routines specified by the manufacturer.

G.5.6.17 The preventive maintenance plan should take into account the manufacturer's recommendations concerning service requirements and maintenance instructions.

Particular attention should be paid to the following:

a) the performance of the system and its components,

b) leakage of gas,

c) excessive wear of any components,

d) the quality of the gas.

A procedure for immediately reporting defective or suspect equipment to the AP should be established to allow its prompt repair or replacement.

G.5.6.18 The healthcare facility should ensure that adequate spare parts recommended by the manufacturer(s) are readily available.

G.5.6.19 The manufacturer(s) of the MGPS should provide the healthcare facility complete as-built drawings of the MGPS, maintenance instructions for all components, associated circuit diagrams and any valve charts.

G.5.6.20 The frequency of maintenance of components in the preventive maintenance plan should be based on information detailed in the manuals for the equipment and components installed. Practical experience with equipment from different manufacturers, and information from plant history logs, might result in the need to vary some frequencies and tasks in particular installations.

G.5.6.21 In addition to the examination, tests and checks set out in the preventive maintenance plan, arrangements should be made for a general overhaul of all MGPSs in conjunction with the manufacturer's recommended frequency.

G.5.6.22 The preventive maintenance plan should include functional testing of the backup supply systems and the alarm systems to ensure that they will operate correctly when required.

The maintenance log should be reviewed regularly by the AP to identify any components or equipment that are requiring excessive attention caused by faulty design or by unsatisfactory conditions of any nature. Maintenance tasks and their frequency should be modified in line with the information detailed in the maintenance log.

G.5.6.23 Equipment checklists should be prepared. Area shut-off valves and line pressure regulators should be referred to in the checklist by a unique number which corresponds with the tag number. It is usually convenient to arrange these checklists in such a manner that a record can be kept for each valve showing whether it has been examined, tested or checked in accordance with the preventive maintenance plan.

G.5.6.24 Following any maintenance activity, the appropriate tests in accordance with **Clause 12** should be carried out.

G.5.6.25 Any instruments used in the maintenance and testing of any equipment associated with the MGPS should be calibrated against an appropriate standard and the results logged.

G.5.6.26 No section of the MGPS should be worked on or pressure tested unless it is adequately isolated from any section in use or available for use.

G.5.6.27 Before any planned preventive or unplanned maintenance work is carried out on any medical equipment, including portable suction units, the equipment should be decontaminated, following approved procedures.

G.5.6.28 The Operational Management Document should define the length of notice which should be given to the DMO and DNOs by the AP before interruption of the MGPS can be made when carrying out planned preventive maintenance. It might not be possible to provide the same notice for any emergency maintenance work carried out on the MGPS.

G.5.7 Repair procedure

G.5.7.1 The repair of any faulty component(s) on the MGPS should be carried out in accordance with the technical specifications supplied by the manufacturer(s) of the MGPS.

G.5.7.2 All repair work on the MGPS should only be carried out under the instructions of the AP, whether or not the supply is, or is likely to be, interrupted.

G.5.7.3 The Operational Management Document should clearly set out the responsibilities and procedures to be followed for all repair work on the MGPS.

G.5.7.4 Repair work should be carried out by appropriately trained and qualified personnel.

G.5.7.5 The AP should be responsible for monitoring the repair work, including any repairs carried out by contractors.

G.5.7.6 All repair work on the MGPS which is carried out by a contractor should be covered by a formal written contract.

G.5.7.7 The contractor is responsible for ensuring that their staff working on any repairs are appropriately trained and qualified to carry out the work. The healthcare facility should not be required to test the competency of the contractor's staff.

G.5.7.8 The results of any action taken to correct faults should be recorded in the maintenance log.

G.5.7.9 Following any repair activity, the appropriate tests in accordance with **Clause 12** should be carried out and the results recorded in the maintenance log.

G.5.7.10 Any instruments used in the repair and testing of any equipment associated with the MGPS should be calibrated against an appropriate standard and the results recorded in the maintenance log.

G.5.7.11 No section of an MGPS should be worked on or pressure tested unless it is adequately isolated from any section in use or available for use. This requirement should be specified in the permit to work.

G.5.7.12 The AP should report to the FEM any recurring equipment failure or evidence of excessive wear of equipment identified by the DP. The FEM should assess these observations and take the appropriate corrective actions.

G.5.7.13 All maintenance operations in which the vacuum is open to air should be carried out with appropriate personal protective equipment.

G.5.8 Supply sources management procedure

G.5.8.1 The capacity of each source of supply used to supply medical gas to the MGPS should be based on the average demand for the healthcare facility, with allowances for any projected growth or reduction in demand over the next five years and any diversity factor, to take into account the variability of demand.

G.5.8.2 The healthcare facility should work together with the medical gas supplier and the system manufacturer to determine the appropriate location of each source of supply, using risk management principles to ensure that the MGPS conforms with the regional or national regulations where required.

G.5.8.3 For medical gases stored on site, the capacity of the source of supply should be reviewed regularly to ensure that sufficient product is stored on site to maintain the supply of medical gas to the MGPS. Where it is determined that there is insufficient product stored on site, either the medical gas supplier should agree with the healthcare facility to revise delivery frequencies to maintain the operational stock levels or the capacity of the storage system on site should be increased.

G.5.8.4 Any anticipated increase in demand due to healthcare facility's site developments, pipeline extensions or changes in clinical practice should be communicated to the medical gas supplier to ensure that the changes do not jeopardize the security of supply.

G.5.8.5 The medical gas demand should be reviewed and documented with the gas supplier at least annually (or after a significant extension to the pipeline causing increases in demand) to reassess the capacity of the installation. As the demand grows, the storage volume requirements will increase. With the increased volume requirements for the reserve stock, the volume available for operational stock will be reduced. Having reviewed the average daily demand with the gas supplier, it may be necessary to either revise delivery frequencies to maintain the operational stock levels or to increase the capacity of the storage systems on site.

G.5.8.6 Where available, historic gas consumption records should be reviewed to assess the current usage and the growth or reduction of the medical gas demand. Growth predictions should be based on any planned extensions to the facility or pipeline systems and changes in clinical practices that could impact the demand for medical gas.

G.5.8.7 For new healthcare facilities, where no historic information is available, the estimated demand should be based on the proposed size and type of the facility and/or, in cases where the new facility is a replacement, the usage figures of the facility being replaced.

G.5.8.8 Where the secondary supply includes compressed gas cylinders, the size of the changeover manifold and the number of cylinders stored on site should be based on the gas supplier's ability to guarantee delivery within a defined period.

G.5.8.9 There should be an adequate number of trained individuals available to ensure that cylinders can be changed on the manifold quickly enough to meet the demand.

G.5.8.10 The delivery period for the primary supply should be based on the gas supplier's normal delivery frequency. The delivery period for the secondary supply should be based on emergency conditions when the primary supply is not available. Under these circumstances, special delivery response times should be agreed upon by the gas supplier and should normally not be less than 24 h.

G.5.8.11 The capacity of the primary and secondary supply source should be determined by the risk management process and be specified as a number of days' stock.

The risk assessment should consider the following issues:

— the estimated average daily demand at the end of the contract period. Any changes to the predicted demand will need to be considered and changes made to the tank capacity or delivery frequency at the appropriate time within the contract period. It may be worthwhile to set a daily demand rate at which point changes to tank size or delivery frequency will be considered;

— the delivery frequency should take into account and review vehicle access to the storage vessels, timing of the deliveries and any restrictions due to local planning requirements;

— the capabilities of the medical gas suppliers to provide a reliable supply;

— the type and dependency of the patients being treated in the healthcare facility;

— the variability of the facility's usage pattern, taking into account seasonal variations or the additional requirements for the facility's major incident plan;

— the use of telemetry to electronically relay stock levels to the gas supplier or the healthcare facility.

G.5.8.12 The use of telemetry systems fitted to the installation permits both the healthcare facility and the gas supplier to monitor the stock levels, permitting more efficient use of the operational stock and allowing for a smaller reserve stock.

G.5.8.13 The reserve stock should be expressed as the number of days of stock. When the daily demand increases, the required volume will grow, reducing the volume of operational stock available.

G.5.8.14 The minimum level of stock for the secondary supply should be based on the exceptional circumstances when the primary supply system is not available for use.

This secondary supply reserve stock level will depend on

— the proximity of the supplier's distribution depot,

— the time that the gas supplier needs to make a delivery under these conditions,

— the delivery frequency that can be sustained when the primary supply is unavailable for use.

G.5.8.15 Under most conditions, compressed gas cylinders are the most appropriate method of providing a reserve source of supply. The preferable solution for the design of reserve systems is to install individual manifolds on each zone of the pipeline system, to provide for the additional protection against the possibility of a pipeline failure within the facility. The positioning of these manifolds is very important to ensure that the critical supply and high-dependency areas defined in the risk management process have adequate stocks of medical gases available in the event of a MGPS failure.

G.5.8.16 In critical care areas with high-dependency patients, the healthcare facility should consider the use of individual cylinders to minimize any delay in maintaining gas supplies in an emergency. Cylinder(s) with pressure regulators integrated with cylinder valves or cylinder(s) with pressure regulators attached to the valve should be used for this purpose. The pressure regulator outlet should be gas-specific and connected to a low-pressure hose assembly.

G.5.8.17 Where medical gases are manufactured or mixed on site, they are subject to the same regulations or standards as for gases supplied by other sources. In particular a Quality Management System (QMS) should be implemented, (based on the principles of Good Manufacturing Practice (GMP)), to manage the production and supply of the gases.

G.5.8.18 Where supply systems with oxygen concentrators are used, medical staff should take into account the range of the oxygen concentration as specified by the manufacturer of the supply system.

G.5.8.19 The functionality of the secondary and reserve sources of supply should be tested using a defined procedure at regular intervals and the results documented in the maintenance log. Following the tests, the condition of the secondary and reserve sources should be reviewed and additional supplies provided where appropriate. The test procedures should take into account the specifications defined by the manufacturer and approved by the AP.

G.5.8.20 The alarm system on the medical gas supply systems should be tested at regular intervals according to a defined procedure and the results documented in the maintenance log. The test procedures for the alarm system should take into account the specifications defined by the manufacturer and approved by the AP.

G.5.9 Cylinder storage and handling procedures

G.5.9.1 The cylinder storage and handling procedures should cover the operational aspects of all medical gas cylinders used within the healthcare facility, including the requirements for storage, handling and general safety.

G.5.9.2 Management of medical gas cylinders within the healthcare facility should be the responsibility of the AP or the QC and defined in the Operational Management Document. Only trained and approved persons should be permitted to handle and/or connect cylinders to the manifold.

G.5.9.3 Medical gas cylinders should be stored in a medical gas cylinder storage area, either in a designated storeroom which is part of the healthcare facility building or in a separate, specially constructed cylinder storage building. The area should be used exclusively for medical gas cylinder storage. These cylinder storage areas should be under cover, provided with adequate ventilation and protected from theft and unauthorized use. They should not be located in close proximity to any installation which can present a fire risk or other hazard. Smoking and naked flames should be prohibited in the vicinity. Plant rooms containing medical gas cylinders should be kept locked, with a prominently displayed notice indicating the location of the key.

G.5.9.4 The use of adapters with medical gas cylinders is strongly discouraged due to the risk of administering the wrong gas to the patient.

G.5.9.5 Due to the hazards related to filling high-pressure cylinders, the need to carry out the transfilling procedures under good manufacturing practice conditions and the requirement to maintain traceability of all medicinal products, transfilling of medical gas cylinders is strongly discouraged.

G.5.9.6 The cylinder storage areas should segregate medical and industrial gas cylinders.

Medical gas cylinders should be stored so that there is segregation of full and empty cylinders and of cylinders of different gases.

NOTE The requirements for separation requirements/distances between different types of gases are defined by local regulations or by industrial guidelines.

G.5.9.7 Medical gas cylinders should be managed so that they are used on a first-in, first-out basis to ensure correct stock rotation. The tamper-evident seal fitted to the valve outlet should remain in place until the cylinder is required for use.

G.5.9.8 The AP should be aware of the hazards related to the storage, transport and use of gas cylinders. The gas cylinder supplier is responsible for supplying the healthcare facility with adequate information on the safe use and handling of all cylinders.

G.5.9.9 The requirements for storing medical gas cylinders apply to both the main cylinder storage areas and any storage of cylinders in wards or in the vicinity of a manifold connected to the MGPS.

G.5.9.10 Safety warning signs and notices should be used where appropriate and posted in prominent positions.

G.5.9.11 Cylinder stores should be located as close as possible to the delivery point. Wherever possible, there should be only one delivery supply point for each site. Vehicle parking, other than for loading and unloading cylinders, should not be permitted within the delivery and storage area.

G.5.9.12 The location of the cylinder storage area should be marked clearly on the site plan for ease of identification in the event of an emergency.

G.5.9.13 Cylinders should only be handled by personnel who have been trained in cylinder handling and who understand the potential hazards. Only specifically designed and approved equipment should be used for handling and transporting medical gas cylinders.

G.5.9.14 Cylinders and valves should be kept free from oil, grease and other debris. The cylinder valve outlet should be inspected for evidence of oil, grease and other debris before being connected to the manifold or to a pressure regulator. Cylinders with evidence of contaminated valve outlets should be labelled as such and returned to the cylinder supplier.

G.5.9.15 Where proprietary leak detection fluids are used to detect leaks between the cylinder valve and the manifold, they should be used sparingly and any excess should be wiped off with a clean damp cloth after use to avoid possible contamination. Proprietary leak detection fluids should not be used for leak testing cylinder valve outlets.

G.5.9.16 Excessive force should not be used when connecting a manifold or a pressure regulator to the cylinder valve, as this can damage the valve outlet. If a leak is detected between the cylinder valve and the manifold or the pressure regulator, the manifold or the pressure regulator should be depressurized and the cylinder removed. The fitted seal should be inspected and replaced if necessary. Sealing or jointing compounds should never be used to cure a leak.

G.5.9.17 The Operational Management Document should cover the control and removal of defective equipment to prevent them from being used with high-pressure cylinders. Faulty cylinders should be labelled and returned to the cylinder supplier.

G.5.9.18 Repairs to cylinder valves should not be carried out under any circumstances. If a fault with the cylinder valve is suspected, the cylinder should be labelled as such and immediately returned to the cylinder supplier.

G.5.9.19 Local regulations applying to general fire precautions related to the storage of high-pressure cylinders may exist.

G.5.9.20 All medical equipment used with high-pressure gas cylinders should be subject to planned preventive maintenance. Only equipment designed for use with the specific gas should be used. When the equipment is connected to a cylinder, the cylinder valve should initially be opened slowly and then opened fully.

G.5.9.21 The number of cylinders in manifold rooms should be restricted to the minimum required for operational and reserve purposes. Only cylinders of the gases required for connection to the manifold should be kept in the manifold room. The manifold room should not be used for any other purpose, although an exception may be made for storage of nitrous oxide/oxygen mixture cylinders on trolleys to permit temperature equilibration before use.

G.5.9.22 The main stocks of oxygen, nitrous oxide, medical air and other medical gas cylinders should be stored in the designated cylinder storage area, protected from adverse weather conditions. No other materials should be kept in the cylinder storage area.

G.5.10 Medical equipment purchase procedure

G.5.10.1 The AP should be consulted prior to the purchase of any medical equipment which will be connected to the MGPS. This is to ensure that the MGPS has sufficient capacity and can deliver the required flows at the specified pressures. It is particularly important that the AP be consulted before any new equipment, such as a ventilator, is connected to the medical air system, to ensure that the system capacity is not exceeded.

G.5.10.2 The Operational Management Document should state the procedures to be followed and the personnel who need to be consulted before a new item of medical equipment is connected to the MGPS.

G.5.10.3 Only medical equipment compatible with the oxygen concentration supplied should be used.

G.5.11 Contractors management procedure

G.5.11.1 The requirements for contractors are different, depending upon the activities to be carried out. Requirements for maintenance and repair activities are lower than those for new pipeline systems, alterations or extensions, which include design, installation and testing.

G.5.11.2 All contractors should comply with the healthcare facility's safety policies. This should be clearly stated in the Operational Management Document.

G.5.11.3 Work on MGPSs should only be carried out by trained staff or by specialist firms certified to **ISO 13485** [20] with the scope of certification defined as design, installation, commissioning and maintenance of the MGPS as appropriate. Evidence of current certification should be demonstrated by currently valid certificates.

G.5.11.4 The Operational Management Document should set out the responsibilities for monitoring the work of contractors. This should be coordinated by the AP. The procedures for calling out a contractor, in the event of a single fault or an emergency, should be set out in the Operational Management Document.

Annex H
(informative)

Rationale

Annex H contains rationale statements for some of the requirements of this International Standard. It is included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated into this International Standard. It is considered that knowledge of the reasons for the requirements will not only facilitate the proper application of this International Standard, but will expedite any subsequent revisions.

The numbering of the following rationale corresponds to the numbering of the clauses and subclauses in this part of ISO 7396. The numbering is, therefore, not consecutive.

H.1 Oxygen concentrators may be used for supplying oxygen 93 to a medical gas pipeline system as a substitute for oxygen. As oxygen 93 is not covered by a Pharmacopoeia monograph in all territories, regional or national regulations might prevent its use as a replacement for oxygen.

H.1.5 Requirements for flow, pressure and storage capacity for compressed air used to pressurize hyperbaric chambers, to maintain the required internal environmental conditions and to drive other connected services (e.g. the fire extinguishing system) are different from those specified in this part of ISO 7396 for medical air and for air for driving surgical tools.

H.1.6 Dental vacuum is not considered in this part of ISO 7396 although there are dental applications which may overlap with medical applications.

Dental vacuum is typically a “wet” system which performs the role of removing liquid and solids from the treatment site. Medical vacuum is a “dry” system, wherein all the waste is captured prior to the system inlet.

In oral surgery, maxillofacial surgery and other procedures, medical vacuum may be used in place of or in conjunction with dental vacuum, which may be an indication for the provision of medical vacuum in specific dental departments.

The systems operate normally at different flow and vacuum levels and should be kept separate.

Vacuum pumps generate high temperatures in the compression process which can lead, in combination with anaesthetic gases and vapours, to fires within the vacuum pumps.

H.4.1 A fault condition can remain undetected for a long period of time and, as a consequence, can lead to a catastrophic event. Such a fault condition cannot be considered as a single fault condition. Specific risk control measures should be determined within the risk management process to deal with such conditions.

H.4.2 Evidence will be provided, for example, to a notified body during conformity assessment and upon request to the competent authority. Attention is drawn to ISO 14971 on risk management and to the standards under development by ISO/TC 210 on risk evaluation and risk control.

H.4.3.2 Components of the pipeline system for different gases are often made with interchangeable parts or subassemblies. The requirement for cleanliness should, therefore, be applied to components for all gases.

H.4.3.1, H.4.3.2, H.4.3.4, H.4.3.5, H.4.3.6, H.4.3.8 Evidence will be provided, for example, to a notified body during conformity assessment and to the competent authority upon request.

H.5.2.2.1 Some activities are carried out on the pipeline systems and their components at regular intervals, in particular on the supply systems; typically the replacement of cylinders or cylinder bundles and the preventive (planned) maintenance. During preventive maintenance on one source of supply (or

during replacement of cylinder or cylinder bundles), that source is unable to supply the pipeline system. If the continuity of supply is an absolute requirement, in case of failure of a second source of supply there is the third which can supply the pipeline system. Where the continuity of supply is not required (e.g. in facilities where the service is not continuous or the service provided is not considered to be life-supporting) and therefore the preventive maintenance or other activities resulting in the interruption of the supply may be carried out when the supply system is not functioning, two sources of supply are sufficient. This situation has already been recognized for the supply systems for air and nitrogen for driving surgical tools: three sources of supply are not necessary; two are sufficient (see 5.5.2.5).

H.5.2.9 A sterilizer that generates ozone should not be allowed to be connected to an oxygen terminal unit. Ozone is very reactive and very hazardous.

People on oxygen therapy and others with impaired respiratory systems are particularly susceptible to the effects of ozone. Even healthy persons, if exposed to low concentrations for a few hours while exercising, may experience health problems.

H.5.3.4 Ignition of polymer-lined high-pressure flexible hoses is known to have occurred in several countries (e.g. as a result of adiabatic compression). Decomposition of certain polymers can occur at temperatures which can be produced by adiabatic compression. The products of decomposition and combustion of some polymers are known to be extremely toxic. ISO 21969 therefore requires that polymer-lined flexible hoses not be used.

H.5.4.2 Liquefied gas will be very cold and can make the material brittle which in turn can cause the material to break. It is therefore important that materials that may be exposed to very low temperatures in single fault condition can withstand this temperature without any risk of breaking.

H.5.5.1.2 The devices and systems listed in 5.5.1.2 are not used to supply medical air to patients and might not be subject to the cleanliness requirements of medical gas pipeline systems. Therefore, it is essential to prevent backflow to avoid contamination of the pipelines for medical air.

H.5.5.2.1, H.5.5.2.2 and **H.5.5.2.4** Experience from several countries over many years has shown that the specifications given in these subclauses are adequate for medical air and for air for driving surgical tools, provided that the supply system is properly maintained. A monograph on “medicinal air” has been published by the European Pharmacopoeia Commission (EPC).[35]

H.5.5.2.7 The reservoir may be fitted upstream or downstream of the conditioning unit. There are persuasive arguments for both locations.

H.5.5.2.15 There are a number of issues (e.g. cleanliness of the inside of the cylinder, risk of high-pressure burst, traceability, corrosion) that have to be considered before filling a cylinder with a medical gas. Therefore filling of transportable cylinders in a healthcare facility is strongly discouraged. Requirements for filling transportable cylinders in the healthcare facility are therefore outside the scope of this part of ISO 7396.

A high-pressure reservoir connected to a permanently installed compressor is normally not subjected to any ingression of impurities and the connectors and tubing are permanently installed and controlled. The risk is thereby reduced and the reservoir may therefore be refilled on site.

Repeated refilling of the high-pressure reservoir may result in accumulation of impurities. Periodic emptying of the high-pressure reservoir should be planned.

H.5.8.2 Low temperatures can result in pressure decrease in cylinders of nitrous oxide and carbon dioxide. Low temperatures can also cause liquefaction of the nitrous oxide in cylinders of oxygen/nitrous oxide mixtures, resulting in the supply of a gas mixture of incorrect composition. High temperatures can result in high pressures and possible loss of gas from cylinders fitted with means of pressure relief. High temperatures can cause malfunctioning of air compressors and vacuum pumps.

H.6.2.3 Electrical power connections for the monitoring and alarm systems require a degree of separation from other electrical circuits.

H.6.3.2.3 The maximum audio pausing period of 15 min is appropriate because equipment in critical areas such as patient monitors, ventilators and anaesthetic workstations are themselves recycling high priority alarms at shorter intervals.

H.6.6 In some countries, the sensors for emergency operating alarms are specified to be upstream of the supply shut-off valve, and in other countries, the sensors are specified to be downstream of the supply shut-off valve. There are persuasive arguments for both locations.

H.7.2.1 These conditions are necessary to maintain patient safety by protecting the medical gas pipeline system from contamination via reverse flow.

The harm of cross-contamination was known to have occurred in connection with medical devices which use multiple gas sources due to reverse gas leakage.

With medical devices having gas input ports for different gases, the hazard is contamination of one gas source by gas from another source. The contamination hazard is particularly likely to occur while the medical device remains connected to the gas supplies but is not drawing flow from the gas supply system.

With a ventilator equipped with more than one different gas input port, even very small leakages from one of the gas systems to the other can cause considerable build-up of contamination in a medical gas pipeline system over extended periods during which little flow is withdrawn.

The contamination of nitrous oxide by air or oxygen is preferred to the reverse situation.

H.7.2.5, H.7.2.6 Evidence will be provided, for example, to a notified body during conformity assessment and to the competent authority upon request.

Bursting discs are not permitted as a means of pressure relief since their operation can lead to complete loss of pressure in a pipeline.

H.7.4.1 Subclause 5.2.2 mandates continuity of supply to the terminal units in normal condition and in single fault condition. Two permanently connected line pressure regulators will allow continuity of supply requirements to be met when one pressure regulator fails.

H.12.6.2 The reason for testing area shut-off valves is that these valves are required to close in an emergency. The equivalent tests of other shut-off valves are impractical.

H.12.6.7 Evidence will be provided, for example, to a notified body during conformity assessment and to the competent authority upon request.

Annex I
(informative)

Rationale for compressor hazards

Different compressor constructions are permitted under 5.5 provided they can achieve the required air quality specified in 5.5.2.1.

The various technologies in common use may be classed into three general groupings: Oil-lubricated (requiring oil for lubrication in normal operation), Oil-free (having oil in the gear end of the machine but designed to prevent oil from reaching the air end), and Oil-less (using sealed bearings and having no loose oil or grease anywhere in the machine).

The shared fundamentals of design within each of these groupings imply specific hazards which the user should consider in their risk assessment for any compressor to be used for medical air. These are summarized in Table I.1. The user is also cautioned that compressor designs vary and different designs are subject to hazards specific to that particular compressor or installation which should also need to be considered.

Table I.1

Hazard category	Oil-lubricated	Oil-free	Oil-less
Chemical	Standard lubricating oil is toxic, flammable when mixed with oxygen and can cause hydrocarbon-induced pneumonias. It is normal to have oil, both as a liquid and a vapour, in the air exiting the compressor.	Standard lubricating oil is toxic, flammable when mixed with oxygen and can cause hydrocarbon-induced pneumonias. Oil-free compressors can expel oil as a liquid or vapour under certain conditions of partial failure (e.g. failure of the rotary seals or rings).	Not applicable.
Thermal	Oil can burn, producing CO, CO_2, hydrocarbons, soot and other combustion products.	Sliding seals and piston skirts are typically made of carbon or polytetrafluoroethylene and can evolve toxic gases if severely overheated.	Sliding seals and piston skirts are typically made of polytetrafluoroethylene and can evolve toxic gases if severely overheated.
Mechanical	Water can condense in the compressor under low use conditions with high intake humidity. This water can form an emulsion with the oil and cause premature compressor failure.	Some of these technologies rely on very exact internal clearances. Operation outside of temperature limits can cause metal-to-metal contact, causing catastrophic failure. Some machines can expel oil if incorrectly stopped and restarted.	Some of these technologies rely on very exact internal clearances. Operation outside of temperature limits can cause metal-to-metal contact, causing catastrophic failure.
Maintenance	Overfilling the oil can increase the quantity of oil expelled in the produced air. Failure to change and refill the oil can result in overheating or premature compressor failure. Failure to change the carbon absorber can result in passing hydrocarbon vapours.	These machines do contain oil and require it be changed periodically. These machines require periodic replacement of seals and bearings. Failure to observe the replacement schedule can result in catastrophic failure.	These machines require periodic replacement of moving seals (which are sacrificial) and bearings. Failure to observe the replacement schedule can result in catastrophic failure.
Environment	Disposal of oil, oil absorber and odour and taste adsorber elements	Disposal of oil and odour and taste absorber elements	Disposal of odour and taste absorber elements.
Usual protections	Oil-air separator Oil level monitor High temperature monitor High-capacity activated carbon absorber Odour and taste absorber	Oil level monitor High temperature monitor Odour and taste absorber	High temperature monitor Odour and taste absorber

Annex J
(informative)

Considerations for implementation and use of oxygen 93

Oxygen concentrators may be used for supplying oxygen 93 to a medical gas pipeline system. Oxygen concentrators supplying pipeline systems have been in use in healthcare facilities internationally for over 30 years and the experience arising from the use of oxygen concentrators to supply oxygen 93 to medical gas pipeline systems is increasing. The purpose of this Annex is to identify the considerations that should be taken before oxygen 93 produced by oxygen concentrators is used as the supply source for a medical gas pipeline system, where their use is permitted by regional or national regulations.

The process allowing the production on site of oxygen 93 is based upon the physical separation of ambient air into oxygen, nitrogen and other components such as argon. This process has been used for many years in small mobile oxygen concentrators which supply flows up to about 5 l/min with oxygen concentrations not lower than 82% (see IEC 80601-2-60). Different systems which allow higher flows and ensure higher oxygen concentrations have been developed for when higher flows are required, such as to supply a pipeline system within a healthcare facility.

Where oxygen concentrators are used, other sources of medical oxygen may be used as the secondary and/or reserve source to supply the pipeline system in the event of failure of the concentrator. This could lead to variation in oxygen concentration of the gas available for administration to the patient. (See NOTE in 1.2).

At least two monographs have been published on the gas produced by oxygen concentrators: by the US Pharmacopoeia and by the European Pharmacopoeia. Both published monographs are named ‘oxygen 93 percent’ and specify the oxygen concentration as 93 ± 3 %.

There are, however, oxygen concentrators that can deliver oxygen with a concentration greater than 96%.

NOTE National, regional or local regulations may stipulate minimum oxygen concentrations and/or ranges of oxygen concentrations different from those specified in this International Standard.

The substitution, within a healthcare facility, of an existing oxygen supply system with a different supply system requires the healthcare facility management to consider all aspects concerning its safe use. The decision to change the oxygen supply system to another one should be based upon a documented risk management process.

Aspects to be considered include, but are not limited to:

— the approval by the healthcare medical management, including the Department of Anaesthesia, and critical care units to use oxygen 93;

— information supplied to and training of the medical staff in the safe use of oxygen 93 as part of the healthcare facility’s quality assurance protocols;

— the concentration of the gas at the terminal units, which can vary, at any time and without notice to the operator, as follows:

  a) from 90% to about 100% when oxygen is used in cylinders, cylinder bundles or high-pressure reservoir(s) or cryogenic vessels within the secondary and the reserve sources of supply.

  b) from 90% to 96% when only oxygen 93% is used (this occurs for example when a filling system associated with the oxygen concentrator is used to fill high-pressure reservoir(s)/ cylinders/cylinder bundles fitted within the secondary and reserve source of supply with oxygen 93%);

— the compatibility with a variable oxygen concentration of medical devices which are intended to be connected to the terminal units, in particular with regard to the calibration. In addition consideration should be given to the calibration of flow-metering devices and gas mixers in order to take account of the range of oxygen concentrations produced by the pipeline system and adjustments made when different oxygen concentrations are used;

— considerations, made by the healthcare management, as to whether this system is suitable for the intended use taking into account the patient safety and the environmental situation within the healthcare facility, according to risk management procedures before procurement of the system. These considerations may include an assessment concerning the delivering of oxygen 93 in an existing pipeline system;

— consideration about potential risk arising if gas-specific connectors for oxygen and oxygen 93 are used. (e.g. incompatibility between portable oxygen cylinders equipped with integrated pressure reducers and transport ventilators or with equipment held for disaster response).

The healthcare facility should have a well-documented emergency plan to indicate the appropriate actions which should be taken when changing the source of supply to ensure that there is no risk to the patient.

The decision to use oxygen 93 and/or a mixture of oxygen and oxygen 93 is outside the scope of this International Standard, and should be made by the healthcare facility in accordance with regional or national regulations, taking into account, in addition, the relevant clinical data and considerations available, in order to treat all patients in that healthcare facility while maintaining patient safety at the highest level.

Annex K
(informative)

Manufacture of medical gases on site, Responsibility for medical gas quality

K.1 Responsibilities for medical gas quality

Medical gases are either supplied as a finished product to the healthcare site or manufactured on site by the healthcare facility.

The responsibility for the quality of the medical gas used on site should be assigned to a nominated person within the healthcare facility, normally the Head Pharmacist (or equivalent role). The responsible person should have a suitable knowledge of the gases being used and should carry out audits of the systems at suitable intervals to ensure that the gases being supplied will not adversely affect patient safety. Where the medical gases are supplied to the healthcare facility, the responsibility for the quality of the gases lies with either the manufacturer or the supplier, depending on the national, regional or local regulations.

Typically the supplier will be required to hold an appropriate Product Licence/Marketing Authorisation, which will be issued by the National Regulatory Authority.

In order to obtain the appropriate licence for the gas, the manufacturer is required to demonstrate that they have an appropriate Quality Management System in place that will demonstrate that the medical gases have been manufactured following Good Manufacturing Practice (GMP), on a site that is registered with the Regulatory Authority.

Where the medical gases are supplied by a third party, the healthcare facility responsibilities are limited to the management of the medical gas pipeline system to ensure that it does not impact on the quality of the medical gas(es). Documented procedures should be established to ensure that the persons operating, maintaining and using the medical gas pipeline system are appropriately informed of the correct operating procedures.

In addition to ensuring that the product complies with the specification, the supplier of the medical gas is responsible for managing any defects reported by the customer and for reporting any adverse events to the national Regulatory Authority as part of a pharmacovigilance system. The healthcare facility has a responsibility to report any adverse events or any product quality defects to the supplier.

Where the medical gases are manufactured on site, the healthcare facility is responsible for the safety, quality and efficacy of the medical gases manufactured.

K.2 On-site manufacture

K.2.1 General

Medical gases that may be manufactured on site include:

— oxygen 93 manufactured using oxygen concentrators;

— medical air manufactured using compressors;

— medical air manufactured using a proportioning system;

— air for driving surgical tools manufactured using compressors.

K.2.2 Equipment

Where medical gases are manufactured on site, the equipment used for the manufacturing should be appropriately certified to demonstrate that it is fit for the purpose.

Within the EU, the appropriate approval of the manufacturing plant is that it should be CE marked by a Notified Body to the Medical Device Directive 93/42/EEC.

K.3 Quality management system

Where the medical gases are manufactured on site, the healthcare facility should establish a Quality Management System (QMS) to ensure that the safety, quality and efficacy of the gas supply is maintained.

The QMS should be established so that it is in line with the principles of Good Manufacturing Practice (GMP).

K.4 Responsibilities

The healthcare facility should assign responsibilities to a number of nominated persons on the site including:

— a person responsible for the manufacture of the medical gases;

— a person responsible for the quality control of the medical gases.

These roles should be carried out by persons who are independent of each other. The responsible persons may formally assign their responsibilities to nominated deputies to ensure that the responsible person is available when required.

K.4.1 Manufacturing responsibility

The person responsible for the manufacture of the medical gases produced on site should:

— ensure that the medical gases are manufactured according to the instructions for use provided by the equipment suppliers and any other appropriate documentation in order to obtain the required safety , quality and efficacy;

— approve any instructions for the manufacture and ensure their implementation through training and audit;

— ensure that the manufacturing records are routinely produced and evaluated;

— ensure that the maintenance of the equipment is carried out according to the maintenance plan;

— approve any contractors employed to maintain / repair any of the manufacturing equipment;

— ensure that the manufacturing plant undergoes an appropriate validation plan.

K.4.2 Quality control responsibility

The person responsible for quality control of the medical gases manufactured on site should:

— approve (or reject) the medical gases manufactured on site;

— review the quality control records produced to ensure that the product being supplied for use on site complies with the specification;

— ensure that all necessary quality testing is carried out;

— approve the test procedures and frequencies, based on risk management;

— check the maintenance of the manufacturing equipment;

— ensure that the manufacturing equipment is subject to an appropriate validation plan;

— ensure that the personnel carrying out any manufacturing or quality control functions are appropriately trained and the training is documented.

K.5 Quality control

K.5.1 On-line testing

As the medical gases manufactured on site are produced using automated equipment, using on-line analysers, an important requirement is to ensure that the analysis equipment is maintained and calibrated to ensure that the quality requirements are met. Any deviations from the defined quality levels should generate an alarm and operate control equipment to prevent out-of-specification product being supplied for medicinal use.

K.5.2 Continuity of supply

The Quality Management System should also address the requirements for ensuring that there is always a supply of medical gas available for use at an appropriate level of quality.

K.5.3 Secondary and reserve supply

Where the plant is used for filling high-pressure reservoir(s) for use as a permanently fitted secondary or reserve source of supply, the process of filling should also be covered by the principles of GMP and the quality management system. It may also be necessary to comply with other pressure system legislation to demonstrate that the high-pressure reservoir(s) are suitable for filling and that they are not subjected to conditions outside their design range.

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