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Medical gas pipeline systems —

Part 1: Pipelines for compressed medical gases and vacuum

Réseaux de distribution de gaz médicaux —

Partie 1: Réseaux de distribution de gaz médicaux comprimés et de vide

Reference number
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Foreword

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

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

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

Attention is drawn to the possibility that some of the elements of this part of ISO 7396 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 7396-1 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 6, *Medical gas systems*.

This first edition of ISO 7396-1 cancels and replaces (with ISO 7396-2) the first edition of ISO 7396 (ISO 7396:1987), which has been technically revised.

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

— *Part 1: Pipelines for compressed medical gases and vaccum*

— *Part 2: Anaesthetic gas scavenging disposal systems*

Annexes A, B, C, D, E, F, G, H, I, J and K of this part of ISO 7396 are for information only.

Introduction

Many health care facilities use pipeline systems to deliver medical gases and 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 compressed medical gases and vacuum. It is intended for use by those persons involved in the design, construction, inspection and operation of health care facilities treating human beings. Those persons involved in the design, manufacture and testing of equipment intended to be connected to pipeline systems should also be aware of the contents of this document.

This part of ISO 7396 seeks to ensure that medical gas pipelines contain only the specific gas 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.

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

a) non-interchangeability between different systems by design;

b) continuous supply of gases and vacuum 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, commissioning and certification;

i) purity of the gases delivered by the system.

Annex K 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 in this part of ISO 7396. The clauses and subclauses marked with **R** after their number have corresponding rationale contained in annex K.

Medical gas pipeline systems —

Part 1:
Pipelines for compressed medical gases and vacuum

1 Scope

This part of ISO 7396 specifies requirements for design, installation, function, performance, documentation, testing and commissioning of compressed medical gas and vacuum pipeline systems in health care facilities to ensure continuous delivery of the correct gas from the pipeline system. It includes requirements for supply systems, pipeline distribution systems, control systems, monitoring and alarm systems and non-interchangeability between components of different gas systems.

This part of ISO 7396 is applicable to pipeline systems for the following medical gases:

— oxygen;

— oxygen-enriched air;

— nitrous oxide;

— air for breathing;

— carbon dioxide;

— oxygen/nitrous oxide mixtures;

— air for driving surgical tools;

— nitrogen for driving surgical tools;

and to vacuum pipeline systems.

R This part of ISO 7396 is also applicable to pipeline distribution systems for oxygen-enriched air connected to supply systems with oxygen concentrators complying with ISO 10083.

This part of ISO 7396 also applies to extensions and modifications of existing pipeline systems.

This part of ISO 7396 is not applicable to provision for gas-specific connectors on mobile or stationary cryogenic vessels or on transport vehicles, or on the inlet/outlet of cylinders for non-cryogenic liquid or gas.

This part of ISO 7396 does not apply to medical gas pipeline systems supplying hyperbaric chambers.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 7396. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 7396 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 407, *Small medical gas cylinders — Pin-index yoke-type valve connections*

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

ISO 4135, *Anaesthesitic and respiratory equipment — Vocabulary*

ISO 5145, *Cylinder valve outlets for gases and gas mixtures — Selection and dimensioning*

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

ISO/TR 7470, *Valve outlets for gas cylinders — List of provisions which are either standardized or in use*

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

ISO 9703-1, *Anaesthesia and respiratory care alarm signals — Part 1: Visual alarm signals*

ISO 9703-2, *Anaesthesia and respiratory care alarm signals — Part 2: Auditory alarm signals*

ISO 10083:1992, *Oxygen concentrators for use with medical gas pipeline systems*

ISO 10524:1995, *Pressure regulators and pressure regulators with flow-metering devices for medical gas systems*

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

ISO 11197, *Medical electrical equipment — Particular requirements for safety of medical supply units*

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

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

EN 143:1990, *Respiratory protective devices — Particle filters — Requirements, testing, marking*

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

EN 13348:2001, *Copper and copper alloys — Seamless round copper tubes for medical gases or vacuum*

3 Terms and definitions

For the purposes of this part of ISO 7396, the following terms and definitions apply.

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

3.2
air for breathing
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 The volume fractions of oxygen and nitrogen in air are approximately 21 % oxygen and 79 % nitrogen.

3.3
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 The volume fractions of oxygen and nitrogen in air are approximately 21 % oxygen and 79 % nitrogen.

3.4
branch
that portion of the pipeline distribution system which supplies one or more areas on the same floor of the facility

3.5
commissioning
proof of function to verify that the agreed system specification is met and is accepted by the user or his representative

3.6
control equipment
those items necessary to maintain the medical gas pipeline system within the specified operating parameters

EXAMPLES Pressure regulators, pressure-relief valves, alarms, sensors and manual or automatic valves.

3.7
cryogenic liquid system
supply system containing liquefied gas stored at a very low temperature

3.8
cylinder bundle
pack or pallet of cylinders linked together with a single connector for filling and emptying

3.9
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 health-care facility

3.10
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 additional line pressure regulators

NOTE This initial higher pressure is the nominal supply system pressure.

3.11
emergency clinical alarm
alarm to indicate to technical and medical staff that there is abnormal pressure within a pipeline

3.12
emergency operating alarm
alarm to indicate to technical staff that there is abnormal pressure within a pipeline

3.13
gas-specific
having characteristics which prevent connection between different gas services

3.14
gas-specific connector
screw-threaded connector of type DISS (diameter-indexed safety system) or NIST (non-interchangeable screw-threaded), or non-interchangeable quick connector

3.15
information signal
visual indication of normal status

3.16
line pressure regulator
pressure regulator designed for a maximum inlet pressure of 3 000 kPa and intended for installation within a medical gas pipeline system

3.17
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

3.18
main line
that portion of the pipeline distribution system connecting the supply system to risers or branches, or both

3.19
manifold
device for connecting the outlet(s) of one or more cylinders or cylinder bundles of the same medical gas to the pipeline system

3.20
manifold pressure regulator
pressure regulator designed for a maximum inlet pressure of 20 000 kPa and intended for installation within sources of supply containing cylinders or cylinder bundles

3.21
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

3.22
maximum distribution pressure
pressure at any terminal unit when the pipeline system is operating at zero flow

3.23
medical gas pipeline system
complete gas pipeline 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 may be required

3.24
minimum distribution pressure
lowest pressure occurring at any terminal unit when the pipeline system is operating at the system design flow

3.25
nominal distribution pressure
pressure of gas which the pipeline system is intended to deliver at the terminal units

3.26
nominal supply system pressure
pressure of gas which the supply system is intended to deliver at the inlet to the line pressure regulators

3.27
non-cryogenic liquid system
supply system containing a gas stored in the liquid state under pressure at ambient temperature

3.28
non-return valve
valve which permits flow in one direction only

3.29
operating alarm
alarm to indicate to technical staff that it is necessary to replenish the gas supply or to correct a malfunction

3.30
oxygen concentrator
device which provides oxygen-enriched gas from ambient air by the extraction of nitrogen

3.31
pipeline distribution system
that part of a medical gas pipeline system linking the supply system to the terminal units

3.32
pressure regulator
device which reduces a variable inlet pressure to keep the set outlet pressure within specified limits

3.33
pressure-relief valve
device activated at a pre-set pressure value and intended to relieve excess pressure

3.34
primary supply
that portion of the supply system which supplies the pipeline distribution system

3.35
proportioning system
supply system in which gases are mixed in a specified ratio

3.36
reserve supply
that portion of the supply system which supplies the pipeline distribution system in the event of exhaustion or failure of the primary and secondary supplies

3.37
riser
that portion of the pipeline distribution system traversing one or more floors and connecting the main line with branch lines on various levels

3.38
secondary supply
that portion of the supply system which automatically supplies the pipeline distribution system in the event of exhaustion or failure of the primary supply

3.39
shut-off valve
valve which prevents flow in both directions when closed

3.40
silencing
temporary stopping of an auditory alarm signal by manual action

3.41
single fault condition
condition in which a single means for protection against a safety hazard in equipment is defective or a single external abnormal condition is present

3.42
single-stage pipeline distribution system
pipeline distribution system in which gas is distributed from the supply system at the nominal distribution pressure

3.43
source of supply
that portion of the supply system with associated control equipment which supplies the pipeline distribution system

3.44
supply system
system which supplies the pipeline distribution system and which includes two or more sources of supply

3.45
system design flow
flow calculated from the maximum flow requirement of the health care facility and corrected by the diversity factor(s)

3.46
terminal unit
outlet assembly (inlet for vacuum) in a medical gas pipeline system at which the operator makes connections and disconnections

3.47
vacuum system
supply system equipped with vacuum pumps designed to provide negative pressure

4 General requirements

4.1 Safety

Medical gas pipeline systems shall, when installed, commissioned, operated in normal use and maintained according to the instructions of the manufacturer, cause no safety hazard which could reasonably be foreseen using risk analysis procedures in accordance with ISO 14971 and which is connected with their intended application, in normal condition and in single fault condition.

4.2 R Alternative construction

Pipeline installations and components, or parts thereof, using materials or having forms of construction different from those detailed in this part of ISO 7396 shall be accepted if it can be demonstrated that an equivalent degree of safety is obtained. Evidence of an equivalent degree of safety shall be provided by the manufacturer.

4.3 Materials

4.3.1 **R** The manufacturer shall disclose, upon request, evidence of the corrosion resistance of the materials used for pipes and fittings.

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

4.3.2 **R** The manufacturer shall disclose, upon request, evidence of the compatibility with oxygen of the materials used for components of the medical gas pipeline system which come into contact with the medical gas under the operating conditions specified by the manufacturer.

NOTE 1 Compatibility with oxygen involves both combustibility and ease of ignition. Materials which burn in air will burn violently in pure oxygen. Many materials which do not burn in air will do so in pure oxygen, particularly under pressure. Similarly, materials which can be ignited in air require less energy to ignite in oxygen. Many such materials may 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.

NOTE 2 Attention is drawn to ISO 15001.

4.3.3 **R** Components of systems which may 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.

4.3.4 **R** Components of systems which may be exposed to cylinder pressure in normal or single fault condition shall not ignite when submitted to a pneumatic impact test with oxygen. The test for ignition shall be in accordance with ISO 10524:1995, 11.8.1. Evidence shall be provided by the manufacturer.

4.3.5 **R** Metallic materials shall be used for compressed medical gas pipelines. If copper pipes of < 54 mm diameter are used for pipelines, they shall comply with EN 13348 or equivalent national standards. Copper pipes of > 54 mm diameter and pipes of materials other than copper which are used for compressed medical gases shall comply with the cleanliness requirements of EN 13348 or equivalent national standards. Evidence shall be provided by the manufacturer.

NOTE 1 Copper pipes of > 54 mm diameter are not covered by EN 13348.

NOTE 2 Copper is the preferred material for all medical gas pipelines, including vacuum.

4.3.6 **R** If lubricants are used, they shall be compatible with oxygen at the operating conditions of the pipeline system. Evidence shall be provided by the manufacturer.

4.3.7 Pipeline components which come in contact with the medical gas shall be protected from contamination prior to installation.

4.3.8 **R** Components of the system, other than pipes, which are liable to come in contact with the medical gas shall meet the cleanliness requirements of ISO 15001.

NOTE Examples of cleaning procedures are described in ISO 15001.

4.4 System design

4.4.1 General

The number of terminal units per bed-space/work-space and their location in each department or area of the health care facility, together with the corresponding flowrate required and the diversity factors, shall be defined by the management of the health care facility in consultation with the system manufacturer. National guidelines, if existing, should be met.

NOTE Typical examples of locations of terminal units, flow requirements and diversity factors are given in HTM 2022, FD S 90-155, CAN/CSA-Z305.1-92 and AS 2896-1998.

4.4.2 Extensions and modifications of existing medical gas pipeline systems

For extensions and modifications of existing pipeline systems, the following requirements apply.

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 may need to be upgraded.

b) The flow and pressure drop characteristics of the pipeline distribution system shall continue to meet the requirements of 7.2. For this purpose, modifications of the existing pipeline distribution system may be needed.

c) A risk analysis in accordance with ISO 14971 shall be carried out on the extended or modified pipeline system.

5 Supply systems

5.1 System components

Each supply system for a compressed medical gas shall consist of one or more of the following:

a) gas in cylinders or cylinder bundles (Figures A.1 and A.2);

b) non-cryogenic liquid in cylinders (Figures A.1 and A.2);

c) cryogenic liquid in mobile vessels (Figures A.3 and A.4);

d) cryogenic liquid in stationary vessels (Figures A.5 to A.8);

e) an air compressor system (Figures A.9 to A.14);

f) a proportioning system (Figures A.15 and A.16);

g) an oxygen concentrator system (see for example ISO 10083).

A supply system for vacuum shall consist of vacuum pumps (Figure A.17).

5.2 General requirements

5.2.1 Capacity

The capacity of any supply system shall be based on the estimated usage and frequency of delivery. The capacity of the primary, secondary and reserve supplies of all supply systems should be defined by the management of the health care facility in consultation with the system manufacturer and the gas supplier. The number of cylinders held in storage should also be defined. Appropriate storage facilities for cylinders should be provided.

5.2.2 Continuity of supply

5.2.2.1 Supply systems shall cause no interruption of supply in normal condition and in single fault condition.

NOTE Loss of mains electrical power or water supply is a single fault condition.

5.2.2.2 Control equipment shall be designed so that components such as pressure regulators can be maintained without interrupting the gas supply to the pipeline distribution system.

5.2.3 Secondary supply

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

5.2.4 Reserve supply

The reserve supply, if required, shall be permanently connected and shall supply the pipeline either manually or automatically in the event of both the primary and the secondary supplies being unable to supply the pipeline or for maintenance.

5.2.5 Pressure regulators

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

5.2.6 Pressure-relief valves

5.2.6.1 For all compressed medical gases except air, pressure-relief valves shall be vented to the outside of the building and the vents shall be provided with means to prevent the ingress of insects, debris and precipitation. The vents shall be located remote from any air intakes, doors, windows or other openings in buildings. All pressure-relief valves shall close automatically when excess pressure has been released. Consideration should be given to the potential effects of prevailing winds on the location of the vents.

5.2.6.2 Means of pressure relief shall not be isolated, for example by a shut-off valve, from the pipeline or the pressure regulator to which they are 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 or national standards for pressure-relief valves, e.g. prEN 1268-1.

5.2.7 Emergency and maintenance supply assembly

5.2.7.1 For oxygen and air for breathing an emergency and maintenance supply assembly shall be provided downstream of the supply shut-off valve.

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

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

5.2.8 Shut-off valves

5.2.8.1 A supply shut-off valve shall be provided between the supply system and the pipeline distribution system.

5.2.8.2 A shut-off valve shall be provided on the pipeline immediately upstream of the emergency and maintenance supply assembly.

5.2.8.3 Shut-off valves should only be used by authorized personnel and should not be accessible to unauthorized persons. Valves which cannot be locked in the open or closed position should be protected from improper operation.

5.3 Supply system with cylinders

NOTE Typical supply systems with gas and non-cryogenic liquid cylinders are shown in Figures A.1 and A.2.

5.3.1 A supply system with cylinders shall comprise

a) a primary supply which supplies the pipeline,

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

c) a reserve supply for oxygen and air for breathing.

NOTE In some countries, national regulations require a reserve supply for other medical gases.

5.3.2 A supply system with cylinders shall have two banks (or groups) of cylinders which alternately supply the pipeline. When an exhausted bank of cylinders is replaced, the automatic changeover may be reset either manually or automatically. Each bank shall have its cylinders connected to a manifold with its own pressure regulator. Vent valves, if fitted on manifolds, should be vented outside of the building, except for air.

5.3.3 A non-return valve shall be installed at the manifold end of each flexible connection between the cylinder and the manifold.

5.3.4 A filter having a pore size no greater than 100 µm shall be provided between the cylinder(s) and the first pressure regulator.

5.3.5 The flexible connections between each cylinder and the manifold, intended to be disconnected during cylinder-changing operations, shall be gas-specific at the cylinder valve connection in accordance with ISO 5145, ISO 407 or relevant national standards (see ISO/TR 7470 for information).

5.3.6 The flexible connections between each cylinder and the manifold shall be gas-specific at the manifold connection.

5.3.7 The flexible connections between each cylinder and the manifold shall be marked with the following:

— the name and/or trademark of the manufacturer and/or supplier;

— the symbol and/or name of the gas or the gas mixture in accordance with ISO 5359.

5.3.8 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.

5.3.9 **R** Polymer-lined flexible hoses shall not be used as flexible connections between each cylinder and the manifold.

NOTE Attention is drawn to ISO 21969.

5.3.10 All supply systems with cylinders shall comply with 5.2.2.1.

5.4 Supply systems with mobile or stationary cryogenic vessels

5.4.1 Typical supply systems with mobile cryogenic vessels are shown in Figures A.3 and A.4. Typical supply systems with stationary cryogenic vessels are shown in Figures A.5 to A.8.

A supply system with mobile or stationary cryogenic vessels shall be provided with a means to relieve excess pressure arising from the evaporation of entrapped cryogenic liquid.

NOTE A typical means of pressure relief is one or more pressure-relief valves and/or bursting discs.

5.4.2 A supply system with stationary cryogenic vessels shall be one of the following:

a) one stationary cryogenic vessel and two banks of cylinders;

b) two stationary cryogenic vessels.

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

5.5 Supply systems for air

5.5.1 General requirements

5.5.1.1 A supply system for air for breathing and/or for driving surgical tools shall be one of the following:

a) a supply system with cylinders as specified in 5.3;

b) a supply system with air compressors as specified in 5.5.2;

c) a proportioning system as specified in 5.5.3.

5.5.1.2 **R** If air for breathing 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 of medical equipment, means shall be provided to prevent backflow into the pipeline. The flow requirements of these applications shall be taken into account.

5.5.1.3 Air for breathing 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, pneumatic control of air conditioning, blowing down or drying equipment or uses which may impose unforeseen demands, which could prejudice the availability and/or quality of air for normal patient care purposes.

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

5.4.1.4 All systems for air supply shall comply with 5.2.2.1. All compressors shall be connected to the emergency electrical power supply.

5.5.2 Supply systems with air compressor(s)

5.5.2.1 **R** Typical supply systems with air compressor(s) are shown in Figures A.9 to A.14. In a supply system with air compressor(s), the dewpoint temperature downstream of the dryer(s) shall not exceed 5 °C at the nominal supply system pressure. If the environmental conditions can affect the operating temperature of the pipeline (e.g. when the pipeline is outside the building), then the dewpoint temperature shall be at least 5 °C below the predicted minimum operating temperature at the nominal supply system pressure.

5.5.2.2 **R** Air for breathing produced by a supply system with compressor(s) shall comply with regional or national regulations.

Where such regulations do not exist, air for breathing shall comply with the following:

a) maximum total oil concentration — 0,5 mg/m^3 measured at ambient pressure

b) maximum carbon monoxide concentration — 5 ml/m^3

c) maximum carbon dioxide concentration — 500 ml/m^3

d) maximum water concentration — 500 mg/m^3 measured at ambient pressure

NOTE Oil may be present as liquid, aerosol and vapour.

5.5.2.3 Air for breathing and air for driving surgical tools supplied by the compressor systems shall be filtered to maintain the particulate contamination below the level provided by Class P3 in EN 143:1990.

Means shall be provided to indicate the status of filter elements, e.g. by measuring the pressure drop across the filter.

NOTE In some countries, national requirements for particulate contamination may apply

5.5.2.4 Air for driving surgical tools produced by a compressor system shall comply with the following:

a) maximum total oil concentration — 0,5 mg/m^3 measured at ambient pressure

b) maximum water concentration — 60 mg/m^3 measured at ambient pressure

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

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

5.5.2.5 A supply system with compressor(s) for air for breathing 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 with any two sources of supply out of service.

The source of supply shall be one of the following:

a) a compressor unit;

b) a bank of cylinders.

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

If a supply system includes two or more compressor units, at least two conditioning systems shall be provided.

Each compressor 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.

NOTE 1 A supply system with compressors for air for breathing typically comprises one of the following:

a) one compressor unit with one receiver, a single conditioning system and two banks of cylinders (Figures A.9 and A.12);

b) two compressor units with one receiver fitted with means of by-pass, a duplex conditioning system and one bank of cylinders (Figures A.10 and A.13);

c) three compressor units with one receiver fitted with means of by-pass and a duplex conditioning system (Figures A.11 and A.14).

NOTE 2 A compressor unit 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.

NOTE 3 A conditioning system typically comprises the following:

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

b) filter(s) as required;

c) a dew-point alarm sensor.

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.

NOTE A supply system with compressors for air for driving surgical tools typically comprises one of the following:

a) one compressor unit with one receiver, a single conditioning system and one bank of cylinders;

b) two compressor units with one receiver fitted with means of by-pass and a duplex conditioning system.

5.5.2.7 Receivers 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.

5.5.2.8 Each receiver or group of receivers shall be fitted with a means of pressure control, e.g. pressure switch(es) or pressure transducer(s). Each group of receivers shall be arranged so as to allow each receiver in that group to be maintained separately.

5.5.2.9 If a duplex conditioning system is fitted, it shall allow the components to be maintained separately.

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

5.5.2.11 When more than one compressor unit is provided, each compressor shall have a control circuit arranged so that shutting off, or failure, of one compressor will not affect the operation of other compressor(s). The automatic controls for multiple compressors shall be arranged so that all the units supply the system in turn or simultaneously.

5.5.2.12 The intake for the air compressors shall be located where there is minimal contamination from internal combustion engine exhaust, vacuum system exhausts, vents from medical gas pipeline systems, anaesthetic gas scavenging systems, ventilation system discharges and other sources of contamination. The intake shall be provided with means to prevent the ingress of insects, debris and water. Consideration should be given to the potential effects of prevailing winds on the location of intake(s).

5.5.2.13 When supplying a single-stage pipeline distribution system, a supply system with compressors for air shall include a pressure regulator. When air for breathing is supplied by compressors only, there shall be duplex pressure regulators.

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

5.5.3 Proportioning systems

5.5.3.1 Typical proportioning systems for blending oxygen and nitrogen to produce synthetic air [a mixture of approximately 21 % oxygen and 79 % nitrogen (volume fraction)] are shown in Figures A.15 and A.16.

A proportioning system shall comprise 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.

NOTE 1 A proportioning system typically consists of a proportioning unit and two banks of cylinders.

NOTE 2 A proportioning unit typically comprises the following:

a) cryogenic vessels for oxygen and nitrogen;

b) a mixer with optional analyser;

c) a pressure-controlled shut-off valve, a pressure regulator and a non-return valve for each of the gases;

d) a receiver fitted with a pressure-relief valve and a pressure gauge;

e) an analyser connected downstream of the receiver;

f) a shut-off valve fitted downstream of the receiver and controlled by both the analyser and a pressure sensor located downstream of the shut-off valve.

5.5.3.2 The sources of supply of medical gases for proportioning systems shall conform to the requirements of 5.2 to 5.4 and may be the same sources as those supplying the medical gas pipelines separately. Means shall be provided to prevent cross-contamination between gases supplying the proportioning unit.

5.5.3.3 A proportioning system shall operate automatically. The mixture shall be analysed continuously and a recording capability shall be provided, e.g. via a data port. This analysing system shall be completely independent of any analyser, if provided, which is used to control the proportioning system. If the mixture goes out of specification, an alarm shall be activated and the proportioning system shall be automatically disconnected. The secondary 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.

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

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

5.6 Supply systems for oxygen-enriched air

5.6.1 Supply systems for oxygen-enriched air shall comply with ISO 10083.

5.6.2 The quality of the product gas shall comply with clause 8 of ISO 10083:1992.

NOTE In some countries national requirements may apply.

5.7 Supply systems for vacuum

5.7.1 A typical supply system for vacuum is shown in Figure A.17. A supply system for vacuum shall comprise at least two vacuum pumps, one reservoir, two bacterial filters, one drainage trap and means to attach an additional pump of equivalent flow capacity. If three or more vacuum pumps are fitted, the means to attach an additional vacuum pump is not required.

For supply systems with two vacuum pumps, means to attach an additional pump is needed to provide two sources of supply during maintenance.

5.7.2 The supply system for vacuum shall be such that the system design flow can be supplied with any one vacuum pump out of service.

5.7.3 Controls shall be provided to activate the additional pump(s) automatically should the operating pump be incapable of maintaining an adequate vacuum.

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 pump(s). The controls shall be arranged so that all the pumps supply the system in turn or simultaneously.

5.7.5 All supply systems for vacuum shall comply with 5.2.2.1. All vacuum pumps shall be connected to the emergency power supply.

5.7.6 Reservoirs shall comply with appropriate regional or national standards.

5.7.7 Each reservoir shall be fitted with shut-off valve(s), a drain valve, a means of by-pass and a vacuum gauge.

5.7.8 The exhaust from the vacuum pumps shall be piped to the outside and shall be provided with means to prevent the ingress of insects, debris and water. The exhaust shall be located remote from any air intakes, doors, windows or other openings in buildings. Consideration should be given to the potential effects of prevailing winds on the location of exhaust(s).

5.7.9 The exhaust line shall be provided with a drain at its lowest point. Means should be provided to prevent environmental contamination from exhaust water from liquid ring vacuum pumps.

NOTE Local authorities may need to be consulted prior to the use of water-sealed vacuum pumps to ensure that appropriate environmental controls are in place.

5.7.10 Means shall be provided to prevent the transmission of vibration from the vacuum pumps to the pipeline.

5.7.11 Means shall be provided to indicate the status of bacterial filter elements.

5.8 Location of cylinder manifolds

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

5.9 Location of stationary cryogenic vessels

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

5.10 Location or vacuum pumps and air compressor systems

Vacuum pumps and air compressor systems shall be located separately from other medical gas supply systems. These locations shall be provided with drainage facilities.

5.11 R General requirements for supply systems

The ambient temperature in rooms for supply systems shall be in the range of 10 °C to 40 °C. Informative guidelines are given in annex C.

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. The purpose of the operating alarms is to 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. Emergency operating alarms indicate abnormal pressure within a pipeline and could require immediate response by the technical staff. Emergency clinical alarms indicate abnormal pressure within a pipeline and could require immediate response by both the technical and the clinical staff. The purpose of Information signals is to indicate normal status.

6.2 Installation requirements

6.2.1 If not specified in this part of ISO 7396, the location of indicator panels shall be determined by the health care facility management using risk analysis procedures in accordance with ISO 14971.

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 6.3 and 6.5 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 6.4 a) and b) shall be installed in the clinical area and an additional panel may be installed near the area shut-off valve and shall indicate the area monitored;

d) pressure gauges or indicators, if provided, shall show deviation from the nominal distribution pressure range and shall be marked to indicate the service and the area monitored;

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

f) the sensing devices for operating alarms listed in 6.3 and for the emergency operating alarms listed in 6.4 a), b) and c) shall be located at appropriate positions within the supply system;

g) the sensing devices for emergency clinical alarms listed in 6.5 a) and b) shall be located downstream of each final area shut-off valve;

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

i) 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;

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

6.2.3 **R** Monitoring and alarm systems shall be connected to both the normal and the emergency electrical power supplies and shall be individually protected.

6.2.4 Alarm systems shall be designed so that an alarm is initiated if there is electrical 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 specified in this part of this International Standard shall comply with Table 1.

6.3.2 Auditory signals

6.3.2.1 If a pattern of more than two tones or frequencies is used as an auditory signal, the auditory signal(s) for emergency clinical alarms shall conform to the requirements of ISO 9703-2.

6.3.2.2 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.

6.3.2.3 If an auditory signal can be silenced by the operator, the silencing shall not prevent the auditory signal from being activated by a new alarm condition.

6.3.2.4 If an emergency auditory signal can be silenced by the operator, the period of silencing shall not exceed 15 min.

6.3.2.5 If means are provided to allow permanent silencing of the auditory signal, such means shall only be accessible to the technical staff.

6.3.3 Visual signals

6.3.3.1 The visual signals for emergency clinical alarms shall conform to the requirements of ISO 9703-1.

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

6.3.3.3 Visual indications should be perceived correctly and discriminated between under the following conditions (see ISO 9703-1):

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

— 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;

— 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 There shall be a visual and a simultaneous auditory signal for emergency clinical alarms and emergency operating alarms (see Table 1).

6.3.4.2 There shall be at least a visual signal for operating alarms (see Table 1).

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 manually.

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 ISO 9703-1	Complying with ISO 9703-1	Complying with ISO 9703-2[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) changeover from primary to secondary cylinder supplies, if different from 6.4 b);

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

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

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

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

e) liquid level in the reserve cryogenic vessel below the minimum specified by the management of the health care facility in consultation with the gas supplier;

f) malfunctioning of air compressors or conditioning systems;

g) for air supplied by a compressor system, water concentration above the level specified in 5.5.2.2 or 5.5.2.4;

h) malfunctioning of the proportioning system;

i) malfunctioning of the cryogenic system;

j) malfunctioning of vacuum pumps;

k) malfunctioning of the oxygen concentrator(s).

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 final area shut-off valve by more than ± 20 % from the nominal distribution pressure;

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

6.6 R 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 adjacent to the supply shut-off valve by more than ± 20 % from the nominal distribution pressure;

b) for a double-stage distribution system, deviation of the pipeline pressure adjacent to the supply shut-off valve by more than + 20 % and − 30 % from the nominal supply system pressure;

c) increase of pipeline pressure for vacuum adjacent to the supply shut-off valve above 44 kPa absolute.

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

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 health care facility. For example, nitrous oxide may be delivered at a nominal distribution pressure lower than that for oxygen in order to prevent flow of nitrous oxide into the oxygen pipeline.

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, b]
Vacuum	$\leqslant 60$ [b]

[a] Regional or national regulations/standards may require a different range.

[b] Absolute pressure.

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 and with a flowrate of 40 l/min at that terminal unit.

NOTE 1 System design flow is calculated in accordance with appropriate diversity factors. Examples of diversity factors are given in HTM 2022, FD S 90-155, CAN/CSA-Z305.1-92, and AS 2896-1998.

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.

7.2.3 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 and with a flowrate of 350 l/min at that terminal unit.

NOTE 1 System design flow is calculated in accordance with appropriate diversity factors. Examples of diversity factors are given in HTM 2022, FD S 90-155, CAN/CSA-Z305.1-92, and AS 2896-1998.

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 and with a flowrate of 25 l/min at that terminal unit.

NOTE System design flow is calculated in accordance with appropriate diversity factors. Examples of diversity factors are given in HTM 2022, FD S 90-155, CAN/CSA -Z305.1-92, and AS 2896-1998.

7.2.5 **R** 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 5.1.6. Bursting discs shall not be used for this purpose. Evidence shall be provided by the manufacturer.

NOTE Attention is drawn to prEN 1268-1.

7.2.6 **R** 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 Attention is drawn to prEN 1268-1.

7.3 Low-pressure hose assemblies and flexible connections

7.3.1 Low-pressure hose assemblies, if provided, shall comply with ISO 5359.

NOTE Low-pressure hose assemblies in pipeline distribution systems are normally used for emergency supply of gas to a pipeline or as part of permanently fixed equipment such as booms, pendants and pendant tracks.

7.3.2 If a flexible connection is part of the pipeline, for example when used for isolation of vibration, building movement and relative movement of the pipelines, and is not normally replaced during its life, the assembly need not be gas-specific.

7.3.3 If a flexible connection is part of a pipeline, it shall be tested in accordance with clause 12.

7.3.4 The use of flexible connections in the pipeline distribution system should be limited as far as possible. Flexible connections in the pipeline distribution system should be accessible for inspection and maintenance.

7.4 Double-stage pipeline distribution system

Typical double-stage pipeline distribution systems are shown in Figures A.2, A.4, A.6, A.8, A.12, A.13, A.14 and A.16. Alternative arrangements for line pressure regulators are shown in Figure A.18.

For emergency and maintenance purposes, shut-off valves shall be fitted both upstream and downstream and close to each line pressure regulator, together with one of the following:

a) a gas-specific connector (either a NIST or DISS body or the socket of a terminal unit) downstream of the downstream shut-off valve;

b) a second line-pressure regulator provided with upstream and downstream shut-off valves;

c) gas-specific connectors (either a NIST or DISS body or the socket of a terminal unit) upstream of the upstream shut-off valve and downstream of the downstream shut-off valve.

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 or planned future extensions and to facilitate periodic testing.

Shut-off valves shall be classified as follows:

a) service shut-off valves;

b) area shut-off valves.

8.1.2 If not specified in this part of ISO 7396, 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 management of the health care facility, using risk analysis procedures in accordance with ISO 14971.

The risk assessment should 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 supply shut-off valve is accessible within the building.

8.1.3 All shut-off valves shall be identified

a) to indicate the gas service name or symbol,

b) to indicate the areas or rooms 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.

8.2 Service shut-off valves

8.2.1 Typical uses of service shut-off valves are

a) riser shut-off valves,

b) branch shut-off valves,

c) equipment shut-off valves.

8.2.2 Service shut-off valves shall be either lockable in the open and closed positions or protected against improper operation.

8.2.3 Service shut-off valves should be used only by the maintenance staff and should not be accessible to unauthorized persons.

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

8.2.5 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 system test purposes shall be downstream of an area shut-off valve. An area shut-off valve shall be provided in each gas pipeline serving each operating theatre, general ward area and all other departments.

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

8.3.3 Area shut-off valves should be used to isolate areas within health care facilities for maintenance and emergency purposes. Their operation, in the latter case, should be included as part of the emergency disaster plan. Guidelines for emergency procedures are given in annex D.

8.3.4 Area shut-off valves in areas such as psychiatric or paediatric units should be located to prevent access by unauthorized personnel.

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

CAUTION — Do not close valve(s) except in emergency.

8.3.6 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 interruption of the service(s). These means shall be clearly visible when deployed. A closed valve shall not be considered an adequate physical interruption when modifications are carried out to existing systems.

8.3.7 All boxes shall be vented to the room to prevent accumulation of gas and shall have covers or doors which can be secured in the closed position. The covers or doors shall allow quick access in case of emergency.

8.3.8 All boxes shall be located within normal hand height and shall be accessible at all times. Boxes should not be located where they can be obscured from view, for example by doors.

8.3.9 Except for pipelines for vacuum, 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 or DISS body or the socket of a terminal unit). The dimensions of the inlet point should take into account the flow required during emergency and maintenance activities. The emergency and maintenance inlet point can be located within the box.

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

9.1 Terminal units shall 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 or DISS connector complying with ISO 5359.

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, if fitted, shall

a) be labelled with the name of the gas on or adjacent to the gauge and the words “USE NO OIL” or the symbol shown in Figure 1,

b) comply with relevant national standards.

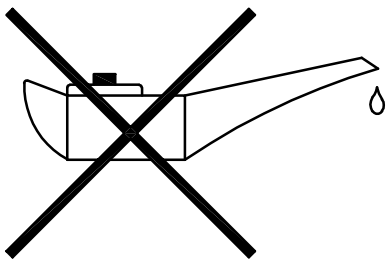


Figure 1 — Symbol for “USE NO OIL”

10 Marking and colour coding

10.1 Marking

10.1.1 Pipelines shall be permanently marked 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 Typical examples of marking methods are metal tags, stencilling, stamping and adhesive markers.

10.1.2 Marking shall

a) be in accordance with ISO 5359 or equivalent national standards,

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,

d) include arrows denoting direction of flow.

10.2 Colour coding

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

NOTE The colours specified in ISO 5359 and national standards are also used for non-medical applications.

11 Pipeline installation

11.1 General

11.1.1 Medical gas pipeline systems shall be used only for patient care. No connections shall be made to a medical gas pipeline system for other uses. Permitted uses of compressed air related to patient care are given in 5.5.1.2.

11.1.2 Pipelines and electrical services shall be

a) run in separate compartments, or

b) separated by more than 50 mm.

11.1.3 The medical gas 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. The relevant parts of national regulations for electrical installations in buildings shall apply. Continuity of earthing across all joints should be ensured.

NOTE National requirements may require different buildings to be electrically insulated from each other.

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

11.1.5 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 which will prevent the liberation of medical gas within the room should leaks occur.

NOTE Attention is drawn to national building requirements and fire regulations.

11.1.6 If pipelines are placed underground they shall be placed in tunnels or ducts. If pipelines for medical gases are placed 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 placed underground should be indicated at the site by appropriate means, e.g. by continuous marking tape above the pipeline at approximately one-half the depth of burial.

11.1.7 Pipelines shall not be installed in elevator shafts.

11.1.8 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.

11.1.9 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 pipework in the area where the contact can occur.

11.1.10 Allowance shall be made for expansion and contraction of pipelines.

11.1.11 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 the distribution pressure.

NOTE It may not be necessary to run pipelines with a fall for drainage purposes.

11.1.12 Pipeline components which come into contact with the medical gas shall be protected from contamination during installation.

11.2 Pipeline supports

11.2.1 Pipelines shall be supported at intervals to prevent sagging or distortion. Maximum intervals between supports for copper pipes should not exceed the values given in Table 3.

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.

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 copper pipes

Pipe outside diameter mm	Maximum interval between supports m
Up to 15	1,5
22 to 28	2,0
35 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. The methods used for brazing or welding shall permit the joints to maintain their mechanical characteristics up to an ambient temperature of 450 °C. Filler metals for brazing shall not contain more than 0,025 % (mass fraction) cadmium (nominally cadmium-free).

NOTE Mechanical joints (e.g. flanged or threaded connections) can be used to connect components such as shut-off valves, terminal units, pressure regulators, control, 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.

11.4 Extensions and modifications of existing medical gas pipeline systems

11.4.1 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 normal distribution pressure. Careful consideration should be given to the location of this connection to minimize problems of access during installation and testing.

11.4.2 When an extension is to be made to an existing system, a shut-off valve(s) shall be added so that the requirements of clause 8 are met.

11.4.3 When an existing system does not fulfil the requirements specified in 12.6.10, a duplex particle filter shall be fitted at the inlet of the extension.

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

11.4.5 Connection may 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 11.4.2 shall then be opened and further relevant tests completed on the modification.

11.4.6 When the modification has been completed and tested in accordance with clause 12, all labels specified in 11.4.4 shall be removed.

11.5 Interconnection of pipelines

At the completion of installation, no two medical gas pipelines designated for different gases shall be interconnected.

12 Testing, commissioning and certification

12.1 General

Tests after completion of installation should be carried out by the system manufacturer, witnessed by a health care facility representative and certified by an authorized person qualified in the testing of medical gas pipeline systems.

An example of a procedure for testing and commissioning is given in annex E.

NOTE 1 The aim of testing and commissioning of medical gas pipeline systems is to verify that all safety aspects and performance requirements of the systems are met.

NOTE 2 Authorized persons may be qualified within a certified quality system or by a national authority or by the health care facility. In some countries such authorization is given only to persons independent of the manufacturer.

12.2 General requirements for tests

12.2.1 Except for those tests in which the gas is specified, purging and testing as described in 12.3 and 12.4 shall be carried out with clean, oil-free, dry air or nitrogen or carbon dioxide. Air should be used for oxygen and air pipelines.

12.2.2 Before any testing according to 12.5 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 certification shall be calibrated at appropriate intervals.

12.3 Tests and inspections after installation of pipeline distribution systems with at least the base blocks of all terminal units fitted but before concealment

The following tests and inspections shall be carried out:

a) test for mechanical integrity;

b) test for leakage;

c) tests for cross-connections and obstructions;

d) inspection of marking and pipeline supports;

e) check for compliance with design specifications.

Intermittent purging of the pipeline to remove particulate matter is recommended at this stage.

12.4 Tests and procedures after complete installation and before use of the system

The following tests and procedures shall be carried out:

a) test for leakage;

b) tests of shut-off valves for leakage and closure and check for correct zoning and correct identification;

c) test for cross-connection;

d) test for obstruction;

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

f) test of system performance;

g) tests of pressure-relief valves;

h) tests of all sources of supply;

i) tests of monitoring and alarm systems;

j) test for particulate contamination;

k) tests for contaminants in air produced by air compressor systems;

l) tests of oxygen concentration and for contaminants in oxygen-enriched air produced by oxygen concentrators;

m) filling with specific gas;

n) tests of gas identities.

12.5 Requirements for tests and inspections after installation of pipeline distribution systems with at least the base blocks of all terminal units fitted but before concealment (see 12.2)

12.5.1 Test for mechanical integrity

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

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

For double-stage distribution systems, line pressure regulators may 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.

12.5.2 Test for leakage

The pressure drop during a test period of 2 h to 24 h shall be less than 0,025 % of the initial test pressure per hour. The pressure drop shall be corrected for variations due to temperature according to the ideal gas laws (see annex F for information).

The test pressure shall be a minimum of 1,5 times the nominal distribution pressure for compressed medical gas pipelines and 500 kPa for vacuum pipelines.

The source of test gas shall be disconnected after initial pressurization.

For double-stage distribution systems, line pressure regulators may be fitted at this stage of installation. If so, the pressure drop should then be measured separately for the pipeline upstream and downstream of the line pressure regulators.

It may be preferable to test sections of the system individually, provided that no section is omitted.

NOTE National regulations for this test may apply.

12.5.3 Tests for cross-connections or obstructions

It shall be proved that there are no cross-connections or obstructions.

12.5.4 Inspection of marking and pipeline supports

Marking shall comply with 10.1. The pipeline supports shall comply with 11.2.

12.5.5 Check for compliance with design specification

Before concealment of the pipelines, all items shall be shown to comply with the design specification (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 and procedures after complete installation and before use of the system (see 12.3)

12.6.1 Tests for leakage

12.6.1.1 Leakage from the compressed medical gas pipelines

The leakage from each completed pipeline distribution system and connected terminal units shall be measured with the supply system and the source of the test gas disconnected.

The leakage from each completed pipeline distribution system and connected terminal units at the nominal distribution pressure shall be less than the sum of the allowable leakage given in 12.5.2 and the total allowable leakage from the terminal units.

This requirement may be met by demonstrating a pressure drop less than that allowed in 12.5.2.

Sections of the system may be tested individually, provided that the integrity of the system is maintained and no section is omitted.

For double-stage pipeline distribution systems, the leakage should be measured separately for the sections upstream and downstream of the line-pressure regulators.

The maximal allowable leakage from a terminal unit is given in ISO 9170-1.

NOTE A method of determining the total leakage from terminal units is given for information in annex G.

12.6.1.2 Leakage into the vacuum pipelines

With the system at nominal distribution pressure and with the source of supply isolated, the pressure increase in the pipeline shall not exceed 2,5 kPa/h.

12.6.2 Tests of shut-off valves for leakage and closure and check for correct zoning and correct identification

12.6.2.1 With the system upstream of the closed 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 the closed valve after 15 min shall not exceed 5 kPa.

This test does not apply to vacuum systems.

12.6.2.2 All shut-off valves shall be checked for correct operation, 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 gases or vacuum.

12.6.4 Test for obstruction

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 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 l/min
Compressed medical gases other than air or nitrogen for driving surgical tools	− 10	40
Air or nitrogen for driving surgical tools	− 30	350
Vacuum	+ 20	25
NOTE During this test, the distribution pressure in the vacuum system is subject to change.		

12.6.5 Checks of terminal units and NIST or DISS 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.

It shall be demonstrated, for each terminal unit, that the appropriate gas-specific probe can be inserted, captured and released.

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 or DISS connector, that the appropriate nipple can be inserted into the body and secured by the nut.

NOTE This test can be carried out at the same time as the tests described in 12.6.4, 12.6.5.2, 12.6.5.3 and 12.6.14.

12.6.5.2 Gas specificity

It shall be demonstrated for each terminal unit that gas is released only when the correct probe is inserted and captured and that no other type of probe used in the same health care facility can be captured and that no gas is released when any other type of probe used in the same health care facility is inserted.

It shall be demonstrated, for each NIST or DISS connector, that only the correct nipple can be inserted into the body and secured by the nut and that no nipple for other gases can be inserted and secured.

NOTE This test can be carried out at the same time as the tests described in 12.6.4, 12.6.5.1, 12.6.5.3 and 12.6.14.

12.6.5.3 Identification

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

NOTE This test can be carried out at the same time as the tests described in 12.6.4, 12.6.5.1, 12.6.5.2 and 12.6.14.

12.6.6 Tests of system performance

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

It shall be shown using tests that whilst the system is delivering the system design flow, the requirements given in Table 2, 7.2.2, 7.2.3 and 7.2.4 are met at the appropriate terminal units.

12.6.7 R 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.

12.6.8 Tests of all sources of supply

Each source of supply shall be tested for all specified operating and emergency conditions according to the manufacturer's manuals and the specifications of this part of ISO 7396.

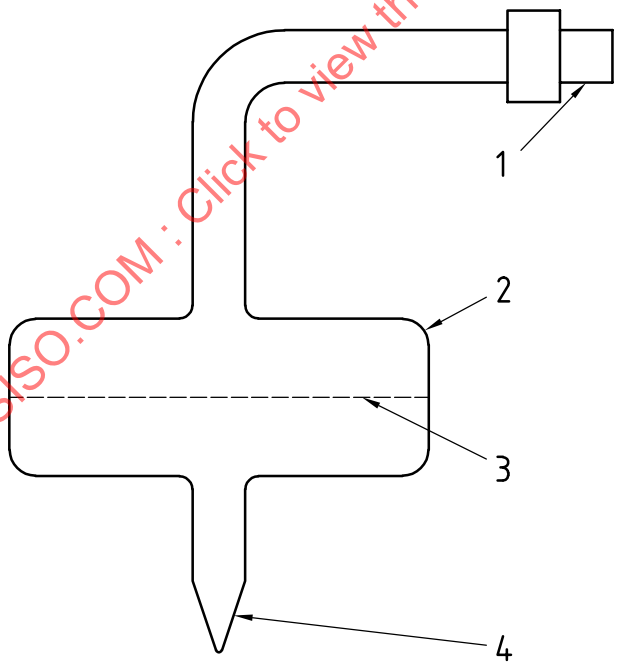
12.6.9 Tests of monitoring and alarm systems

The performance of all monitoring and alarm systems shall be tested in all specified operating and emergency conditions.

12.6.10 Test for particulate contamination

All pipelines for compressed medical gases shall be tested for particulate contamination. The test shall be carried out using the device shown in Figure 2 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 may be necessary to meet this requirement.



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 2 — Test device for qualitative determination of particulate contamination in pipelines

12.6.11 Tests for contaminants in air supplied by air compressor systems

12.6.11.1 Air for breathing supplied by compressor systems shall be tested for compliance with 5.5.2.2 before filling the pipelines.

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

12.6.12 Tests of oxygen concentration and for contaminants in oxygen-enriched air produced by oxygen concentrators

Oxygen-enriched air shall be tested for compliance with clause 8 of ISO 10083:1992 or local or national regulations (e.g. pharmacopoeia monographs).

12.6.13 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.

12.6.14 Tests of gas identities

A gas identity check shall be carried out on each terminal unit after filling with its specific gas, using one or more devices so that positive identification of each medical gas is made.

This test may include a check for absence of odour.

NOTE This test can be carried out at the same time as the tests described in 12.6.4, 12.6.5.1, 12.6.5.2 and 12.6.5.3.

12.7 Certification of the systems

12.7.1 Before a medical gas pipeline system is used, it shall be certified in writing to the health care facility that all the requirements of 12.5 and 12.6 have been met. The results of tests showing details of the services and areas tested should be part of the permanent record of the health care facility.

Typical forms for this purpose are given in annex H.

NOTE The certification can be issued in 2 parts:

— Part 1: to cover testing of the requirements of 12.5 and 12.6 up to and including 12.6.10;

— Part 2: to cover testing of the requirements of 12.6.11 to 12.6.14 which are carried out after completion of the installation contract but may not be done immediately.

12.7.2 The system manufacturer shall certify 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 Instruction manuals

13.1.1 The system manufacturer shall provide to the owner instructions for use of the complete system. Particular attention shall be paid to

— the supply systems,

— the monitoring and alarm systems,

— the danger of fire or explosion due to the use of oil and grease with compressed gas pipeline systems.

13.1.2 The system manufacturer of a vacuum supply system with two vacuum pumps shall disclose in the instructions for use that maintenance of each vacuum pump of the supply system requires temporary connection of a pump of equivalent flow capacity.

13.2 Maintenance schedules

The system manufacturer shall provide to the owner instructions for recommended maintenance tasks and their frequency, and a list of recommended spare parts.

Recommended minimum requirements for the organization of the maintenance are given in annex I.

13.3 “As-installed” drawings

13.3.1 A separate set of “as-installed” mechanical drawings which show the actual locations of the pipelines, the diameters of the pipelines, shut-off valves 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.

13.3.2 A complete set of “as-installed” drawings as specified in 13.3.1 shall be presented to the owner of the pipeline system, for inclusion as part of the permanent record of the pipeline system.

13.4 Electrical diagrams

Electrical diagrams for the complete installation shall be provided by the system manufacturer to the owner.

Annex A
(informative)

Schematic representation of supply systems

A.1 General

This annex gives schematic representations of typical sources of supply for medical gas pipeline systems, as follows:

— Figures A.1, A.2 — Typical supply systems with gas or non-cryogenic liquid in cylinders;

— Figures A.3, A.4 — Typical supply systems with mobile cryogenic vessels;

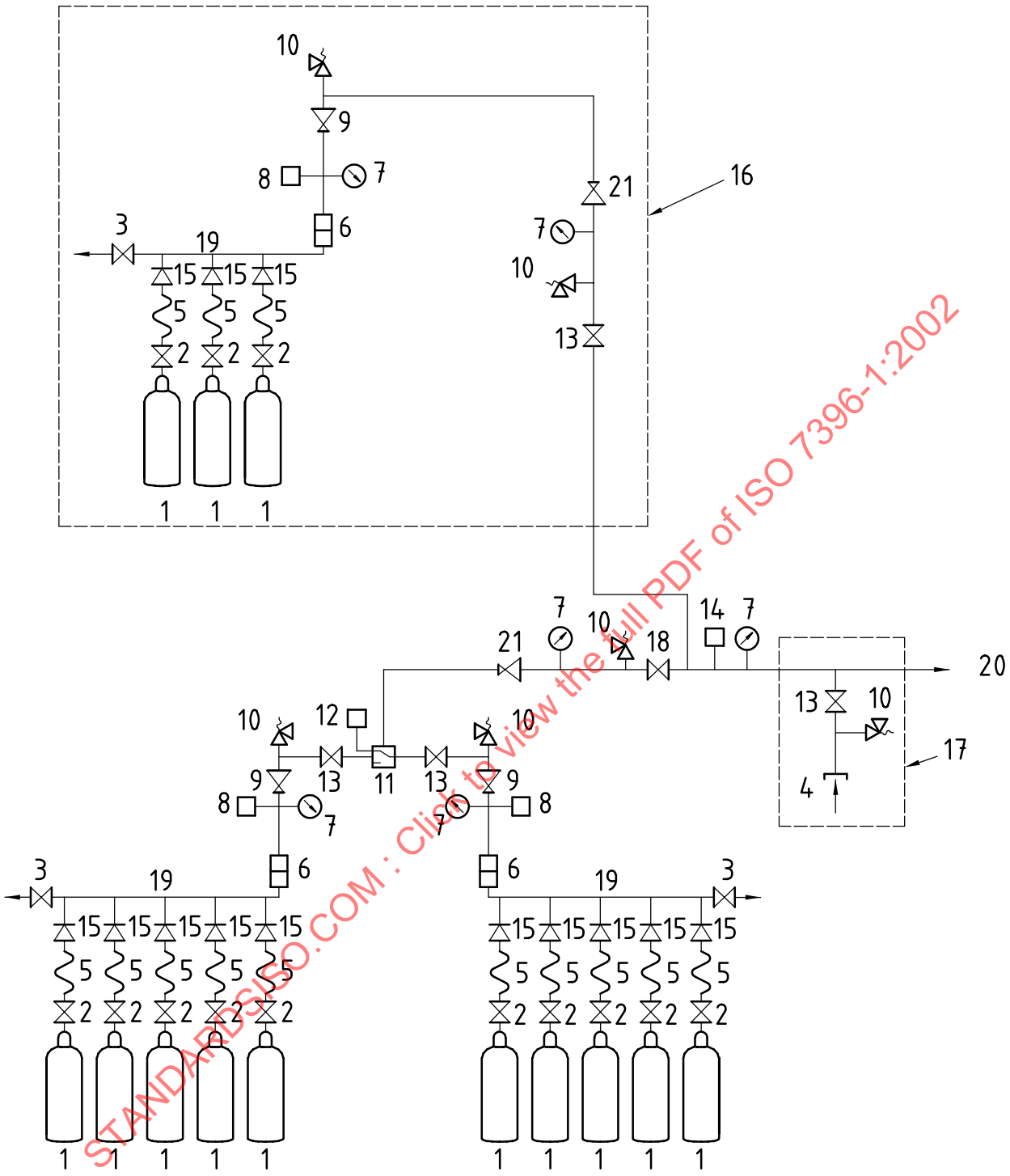
— Figures A.5 to A.8 — Typical supply systems with stationary cryogenic vessels;

— Figures A.9 to A.14 — Typical supply systems with air-compressor units;

— Figures A.15, A.16 — Typical supply systems with proportioning units;

— Figure A.17 — Typical supply system with vacuum pumps;

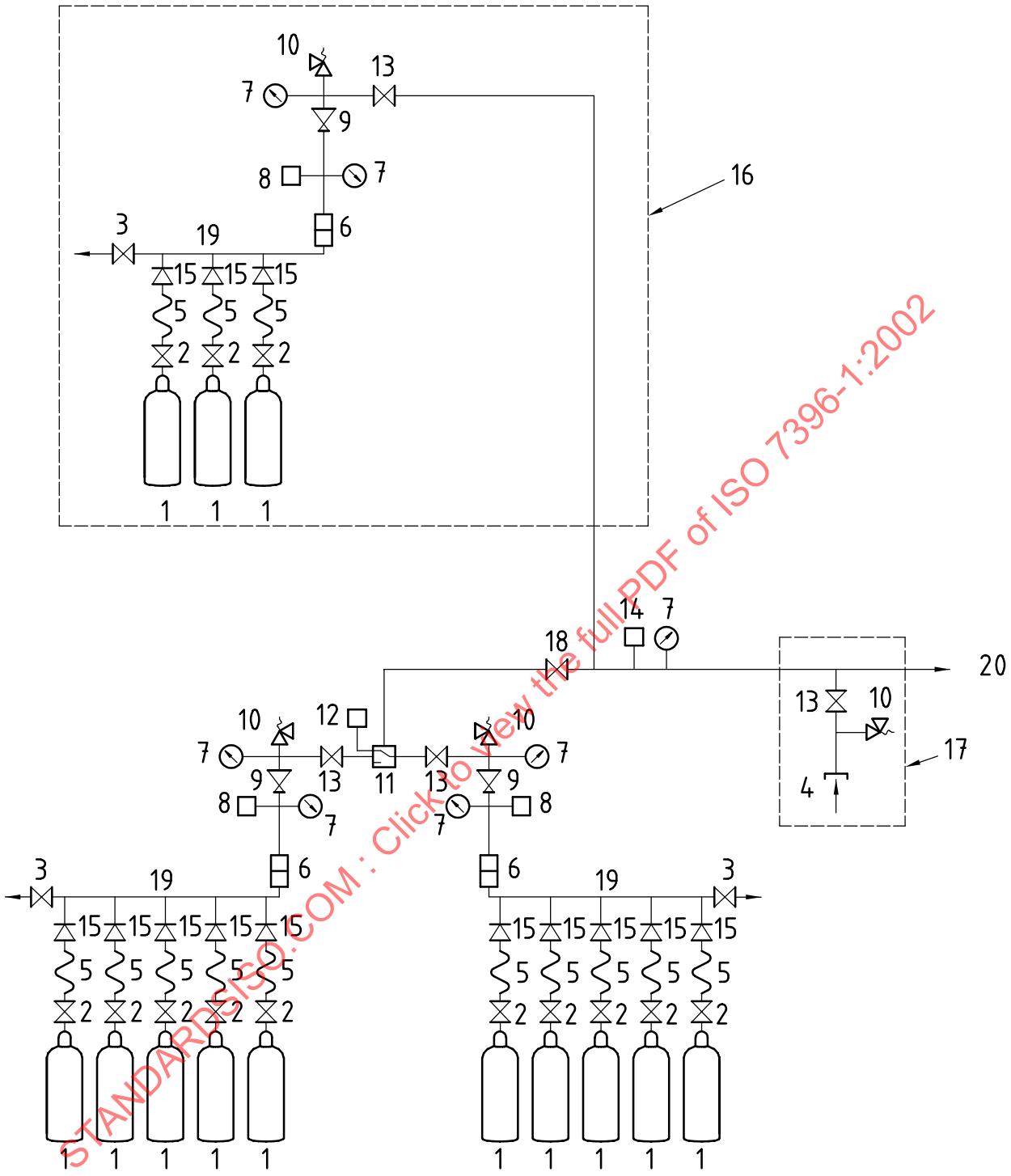
— Figure A.18 — Typical double-stage distribution system with line-pressure regulators within the pipeline system.



Key

1 Cylinder
2 Cylinder valve
3 Vent valve
4 Gas-specific inlet
5 Flexible connection
6 Filter
7 Pressure gauge
8 Pressure switch
9 Manifold pressure regulator
10 Pressure-relief valve
11 Automatic change-over
12 Change-over switch
13 Shut-off valve
14 Low and high pressure switches
15 Non-return valve
16 Reserve supply
17 Emergency and maintenance supply assembly
18 Supply shut-off valve
19 Manifold
20 Supply to pipeline system (at nominal supply system pressure)
21 Line-pressure regulator

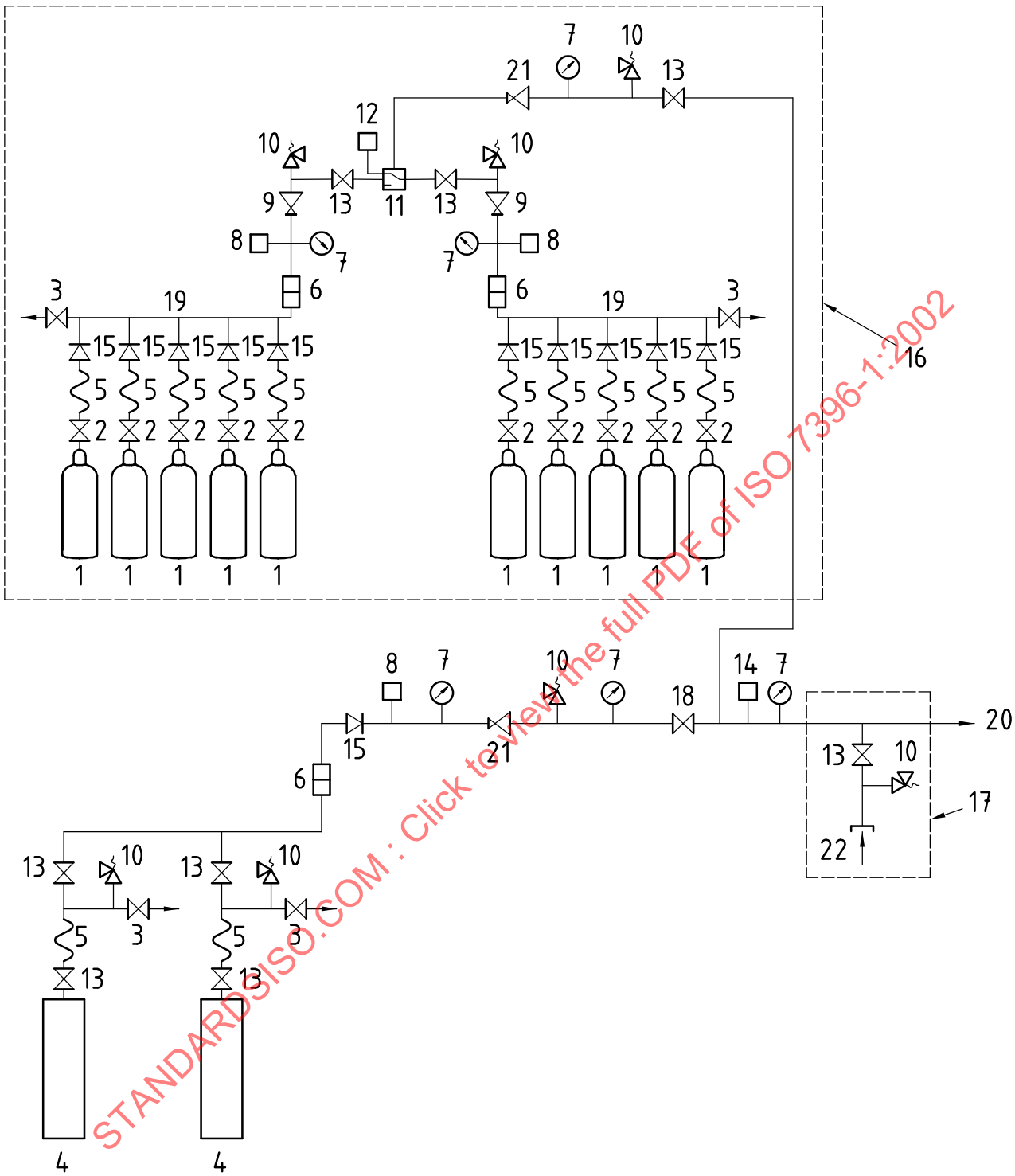
Figure A.1 — Typical supply system with gas or non-cryogenic liquid in cylinders (single-stage distribution system)



Key

1 Cylinder
2 Cylinder valve
3 Vent valve
4 Gas-specific inlet
5 Flexible connection
6 Filter
7 Pressure gauge
8 Pressure switch
9 Manifold pressure regulator
10 Pressure-relief valve
11 Automatic change-over
12 Change-over switch
13 Shut-off valve
14 Low and high pressure switches
15 Non-return valve
16 Reserve supply
17 Emergency and maintenance supply assembly
18 Supply shut-off valve
19 Manifold
20 Supply to pipeline system (at nominal distribution pressure)

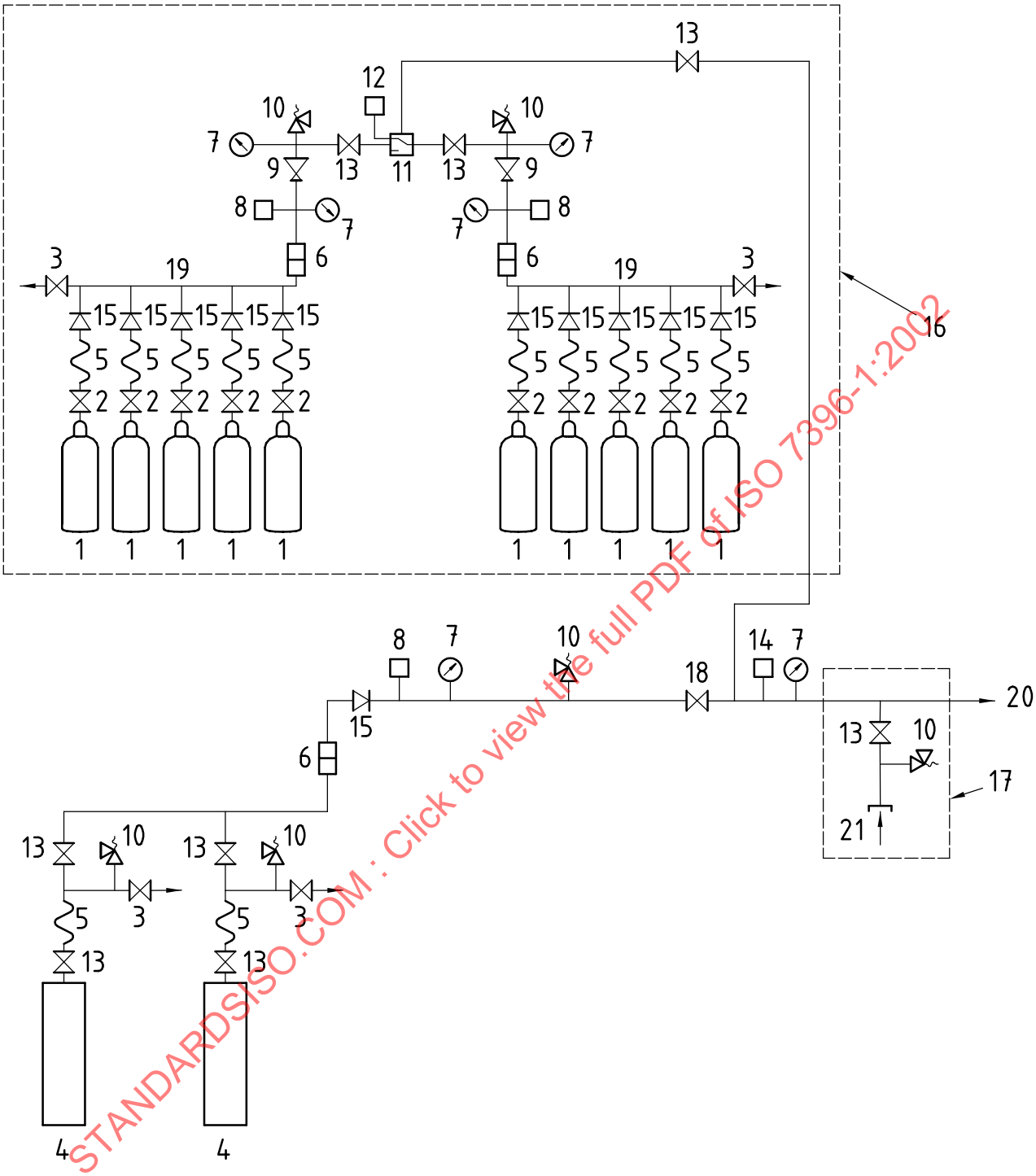
Figure A.2 — Typical supply system with gas or non-cryogenic liquid in cylinders (double-stage distribution system)



Key

1 Cylinder
2 Cylinder valve
3 Vent valve
4 Mobile cryogenic vessel with pressure control and monitoring equipment
5 Flexible connection
6 Filter
7 Pressure gauge
8 Pressure switch
9 Manifold pressure regulator
10 Pressure-relief valve
11 Automatic change-over
12 Change-over switch
13 Shut-off valve
14 Low and high pressure switches
15 Non-return valve
16 Secondary and reserve supplies
17 Emergency and maintenance supply assembly
18 Supply shut-off valve
19 Manifold
20 Supply to pipeline system (at nominal distribution pressure)
21 Line-pressure regulator
22 Gas-specific inlet

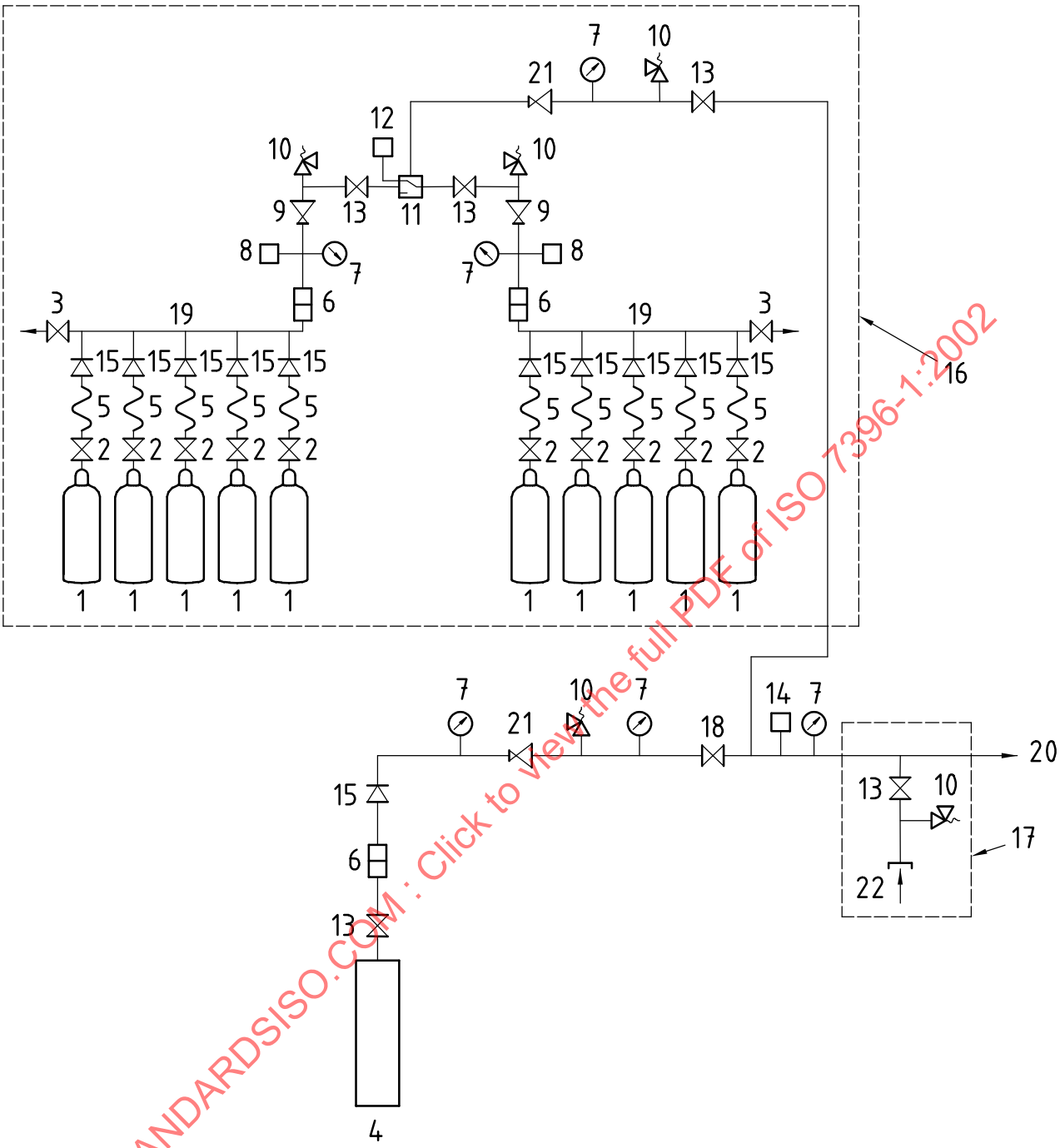
Figure A.3 — Typical supply system with mobile cryogenic vessels (single-stage distribution system)



Key

1 Cylinder
2 Cylinder valve
3 Vent valve
4 Mobile cryogenic vessel with pressure control and monitoring equipment
5 Flexible connection
6 Filter
7 Pressure gauge
8 Pressure switch
9 Manifold pressure regulator
10 Pressure-relief valve
11 Automatic change-over
12 Change-over switch
13 Shut-off valve
14 Low and high pressure switches
15 Non-return valve
16 Secondary and reserve supplies
17 Emergency and maintenance supply assembly
18 Supply shut-off valve
19 Manifold
20 Supply to pipeline system (at nominal supply system pressure)
21 Gas-specific inlet

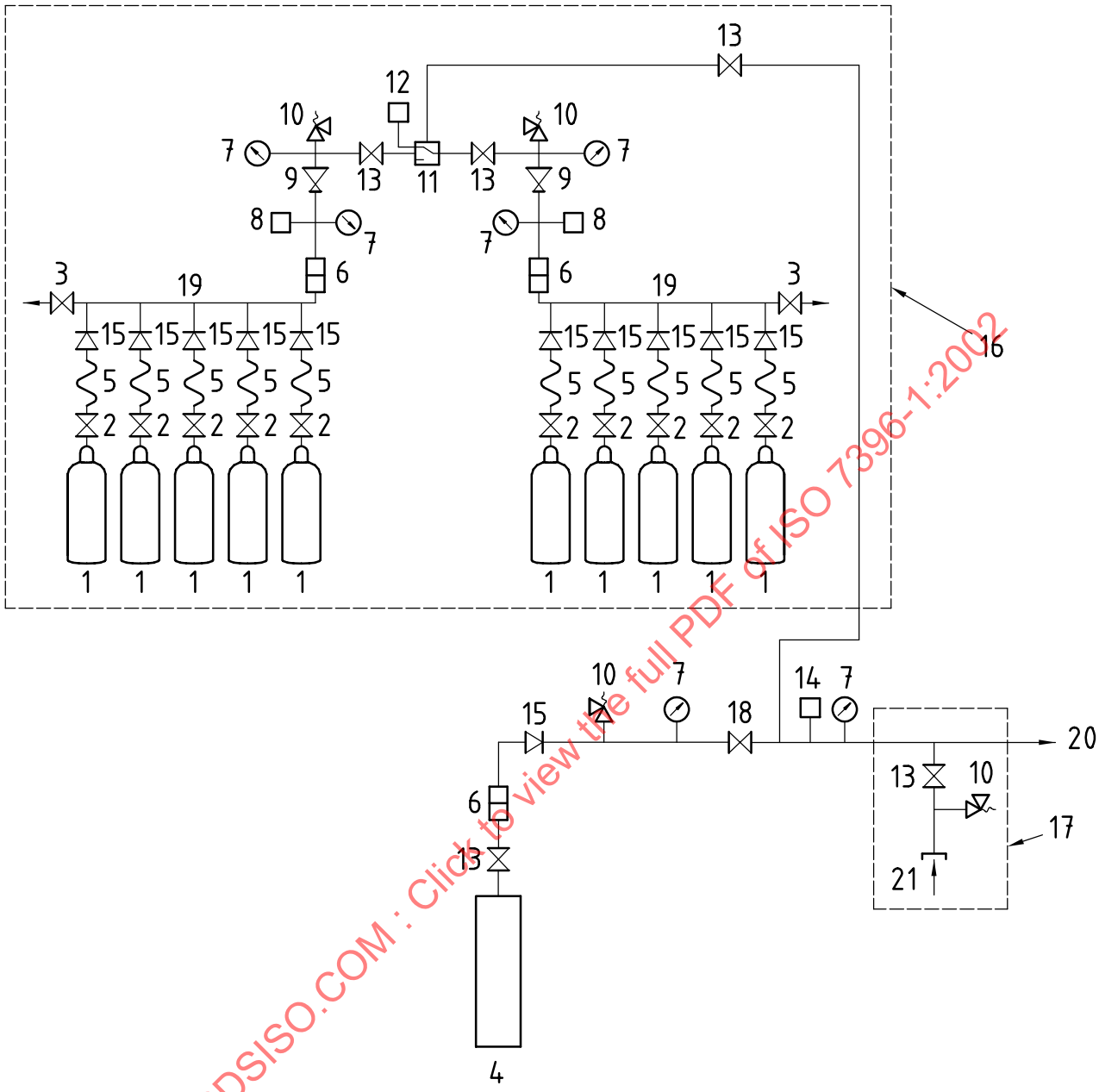
Figure A.4 — Typical supply system with mobile cryogenic vessels (double-stage distribution system)



Key

1 Cylinder
2 Cylinder valve
3 Vent valve
4 Stationary cryogenic vessel with pressure control and monitoring equipment
5 Flexible connection
6 Filter
7 Pressure gauge
8 Pressure switch
9 Manifold pressure regulator
10 Pressure-relief valve
11 Automatic change-over
12 Change-over switch
13 Shut-off valve
14 Low and high pressure switches
15 Non-return valve
16 Secondary and reserve supplies
17 Emergency and maintenance supply assembly
18 Supply shut-off valve
19 Manifold
20 Supply to pipeline system (at nominal distribution pressure)
21 Line-pressure regulator
22 Gas-specific inlet

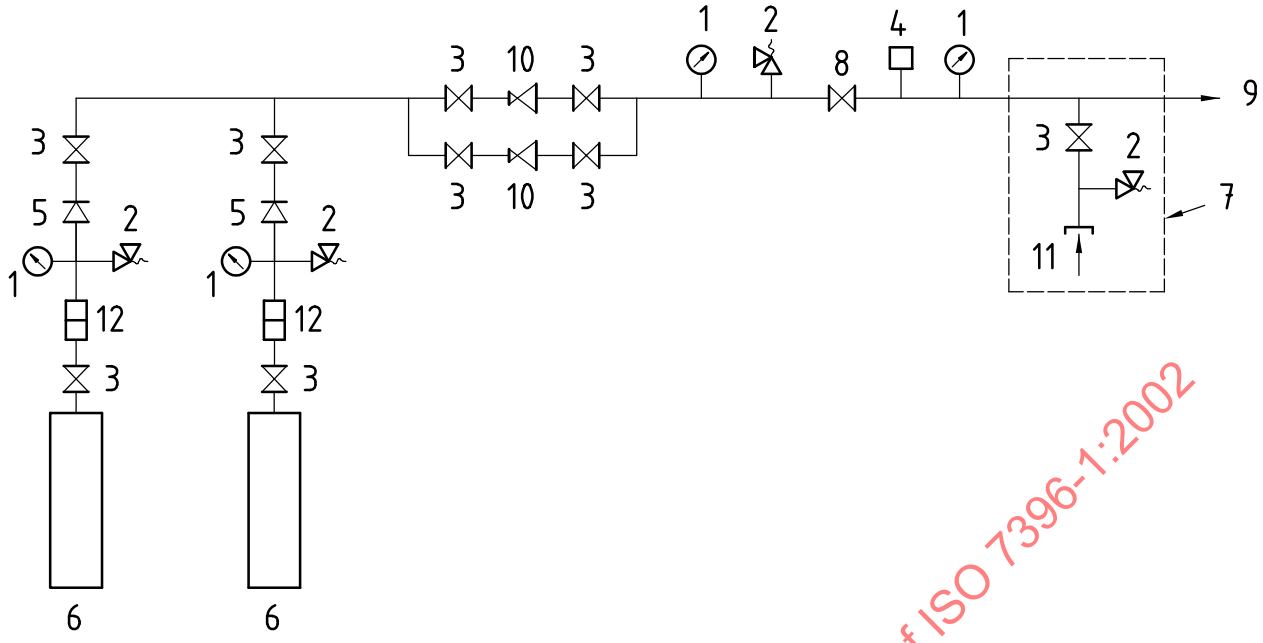
Figure A.5 — Typical supply system with one stationary cryogenic vessel (single-stage distribution system)



Key

1 Cylinder
2 Cylinder valve
3 Vent valve
4 Stationary cryogenic vessel with pressure control and monitoring equipment
5 Flexible connection
6 Filter
7 Pressure gauge
8 Pressure switch
9 Manifold pressure regulator
10 Pressure-relief valve
11 Automatic change-over
12 Change-over switch
13 Shut-off valve
14 Low and high pressure switches
15 Non-return valve
16 Secondary and reserve supplies
17 Emergency and maintenance supply assembly
18 Supply shut-off valve
19 Manifold
20 Supply to pipeline system (at nominal supply system pressure)
21 Gas-specific inlet

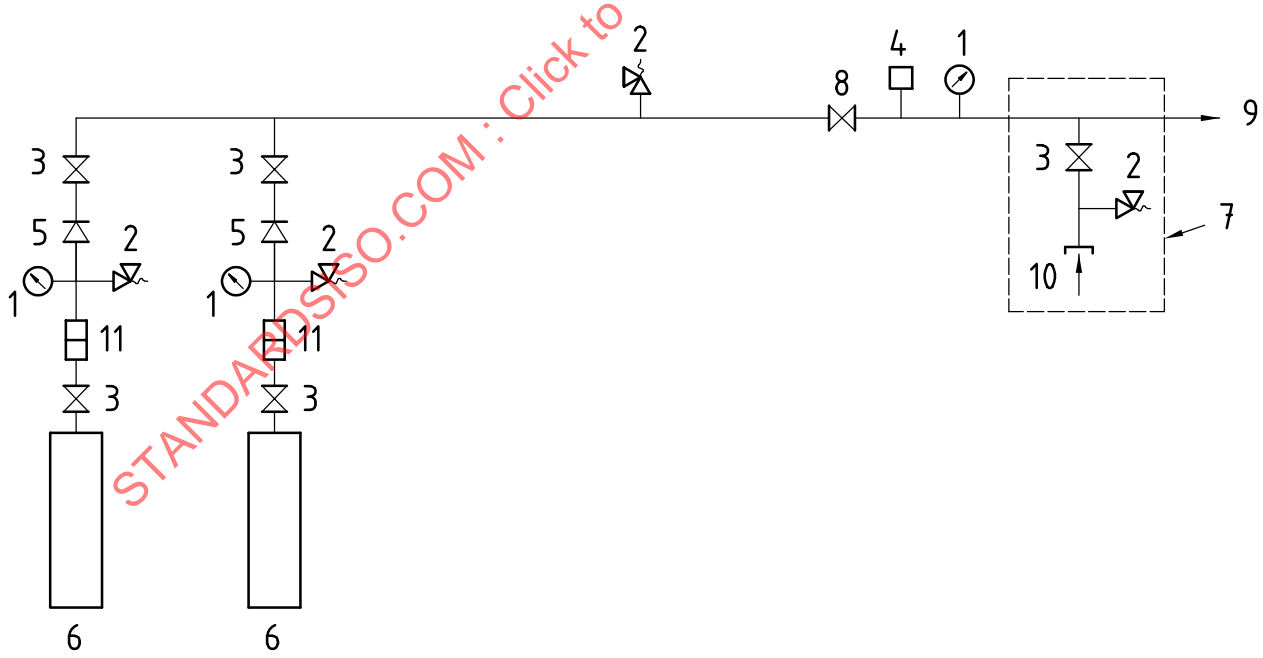
Figure A.6 — Typical supply system with one stationary cryogenic vessel (double-stage distribution system)



Key

1 Pressure gauge
2 Pressure-relief valve
3 Shut-off valve
4 Low and high pressure switches
5 Non-return valve
6 Stationary cryogenic vessel with pressure control and monitoring equipment
7 Emergency and maintenance supply assembly
8 Supply shut-off valve
9 Supply to pipeline system (at nominal distribution pressure)
10 Line-pressure regulator
11 Gas-specific inlet
12 Filter

Figure A.7 — Typical supply system with two stationary cryogenic vessels (single-stage distribution system)



Key

1 Pressure gauge
2 Pressure-relief valve
3 Shut-off valve
4 Low and high pressure switches
5 Non-return valve
6 Stationary cryogenic vessel with pressure control and monitoring equipment
7 Emergency and maintenance supply assembly
8 Supply shut-off valve
9 Supply to pipeline system (at nominal supply system pressure)
10 Gas-specific inlet
11 Filter

Figure A.8 — Typical supply system with two stationary cryogenic vessels (double-stage distribution system)

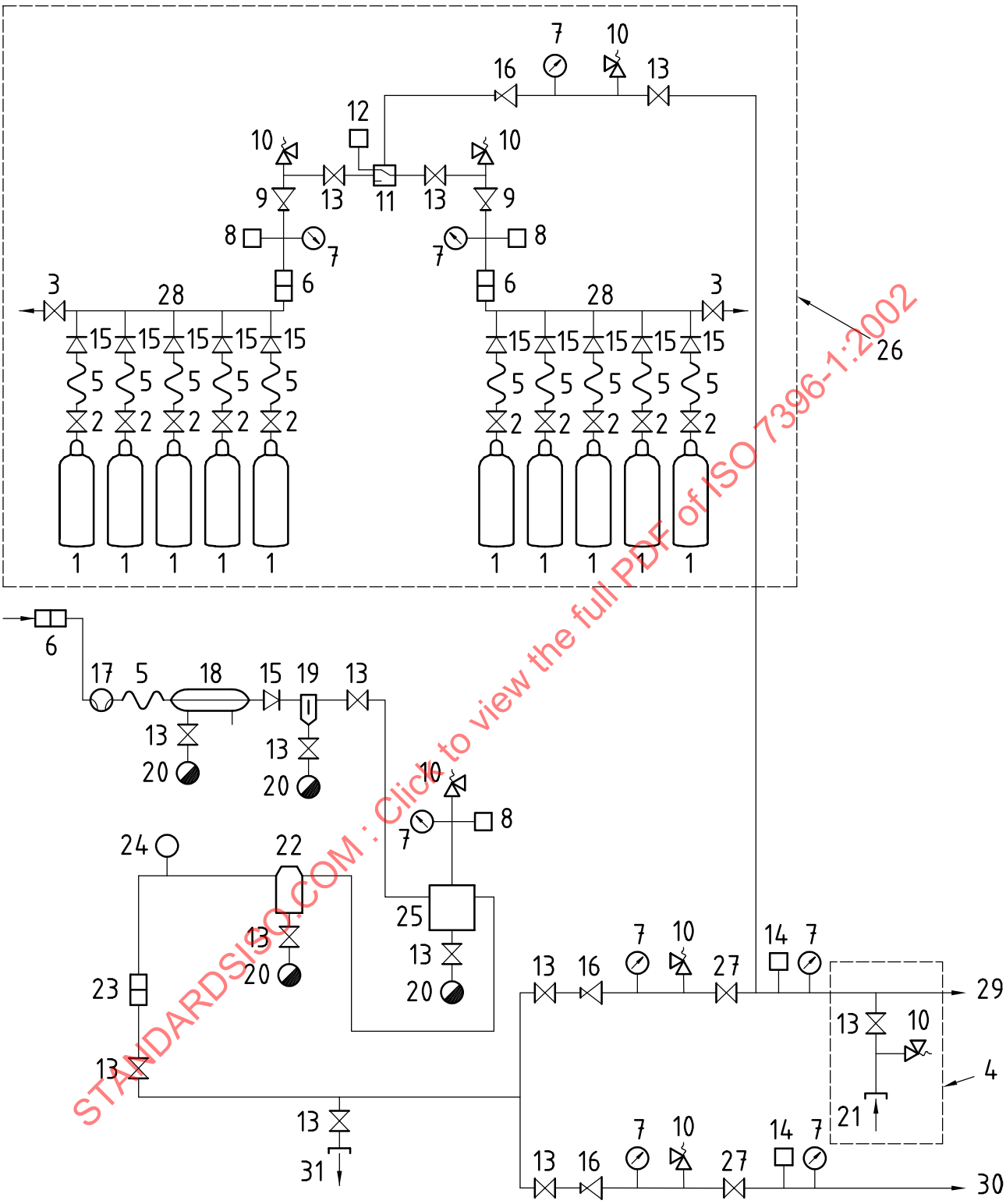


Figure A.9 — Typical supply system with one air compressor unit and two banks of gas cylinders (single-stage distribution system)

Key

1 Cylinder
2 Cylinder valve
3 Vent valve
4 Emergency and maintenance supply assembly
5 Flexible connection
6 Filter
7 Pressure gauge
8 Pressure switch
9 Manifold pressure regulator
10 Pressure-relief valve
11 Automatic change-over
12 Change-over switch
13 Shut-off valve
14 Low and high pressure switches
15 Non-return valve
16 Line-pressure regulator
17 Compressor
18 After-cooler
19 Separator
20 Drain
21 Gas-specific inlet
22 Dryer
23 Filter assembly
24 Dew-point sensor
25 Receiver
26 Secondary and reserve supplies
27 Supply shut-off valve
28 Manifold
29 Supply of air for breathing at nominal distribution pressure
30 Supply of air for driving surgical tools at nominal distribution pressure
31 Sample port

Figure A.9 — Typical supply system with one air compressor unit and two banks of gas cylinders (single-stage distribution system)

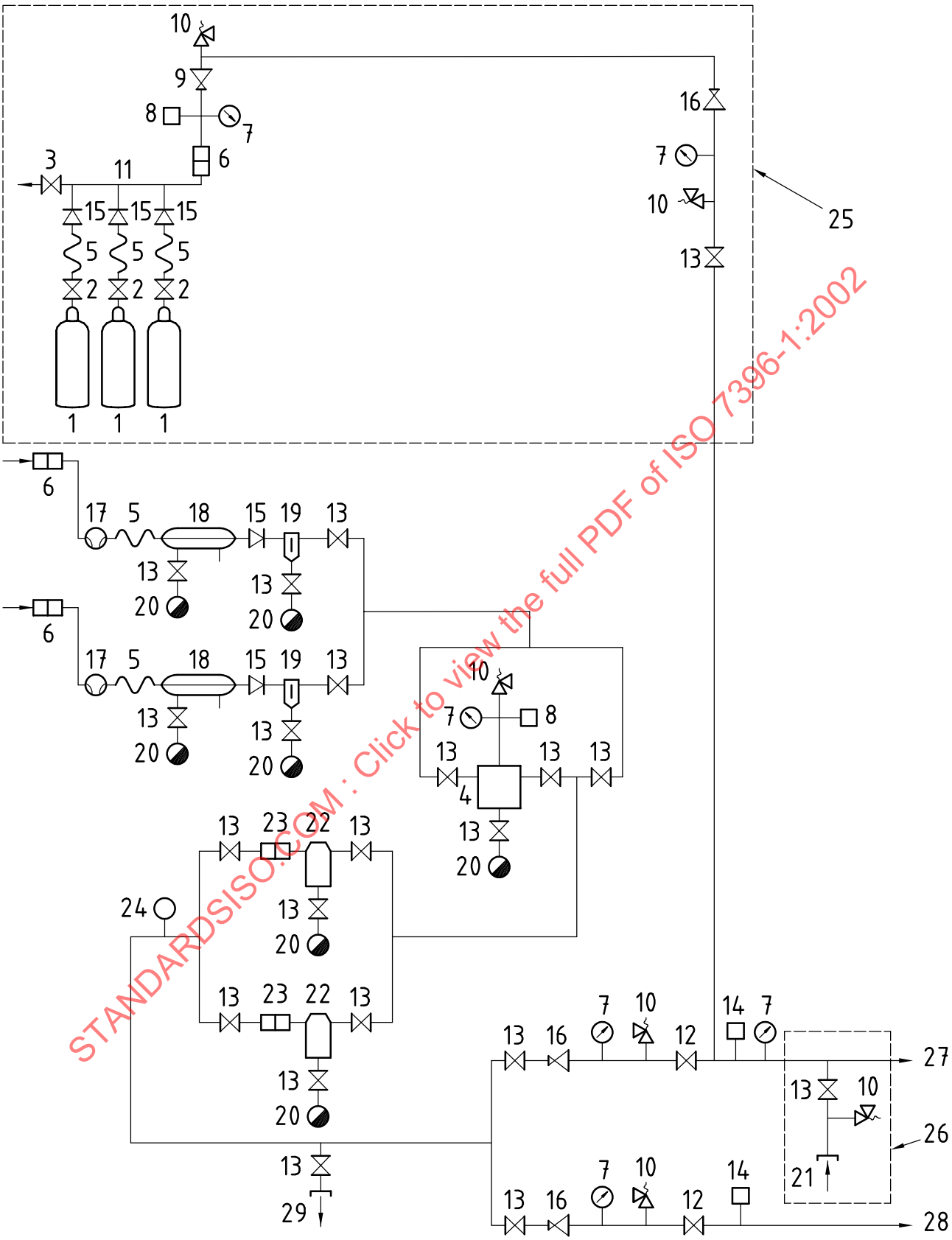


Figure A.10 — Typical supply system with two air compressor units and one bank of gas cylinders (single-stage distribution system)

Key

1 Cylinder
2 Cylinder valve
3 Vent valve
4 Receiver
5 Flexible connection
6 Filter
7 Pressure gauge
8 Pressure switch
9 Manifold pressure regulator
10 Pressure-relief valve
11 Manifold
12 Supply shut-off valve
13 Shut-off valve
14 Low and high pressure switches
15 Non-return valve
16 Line-pressure regulator
17 Compressor
18 After-cooler
19 Separator
20 Drain
21 Gas-specific inlet
22 Dryer
23 Filter assembly
24 Dew-point sensor
25 Reserve supply
26 Emergency and maintenance supply assembly
27 Supply of air for breathing at nominal distribution pressure
28 Supply of air for driving surgical tools at nominal distribution pressure
29 Sample port

Figure A.10 — Typical supply system with two air compressor units and one bank of gas cylinders (single-stage distribution system)

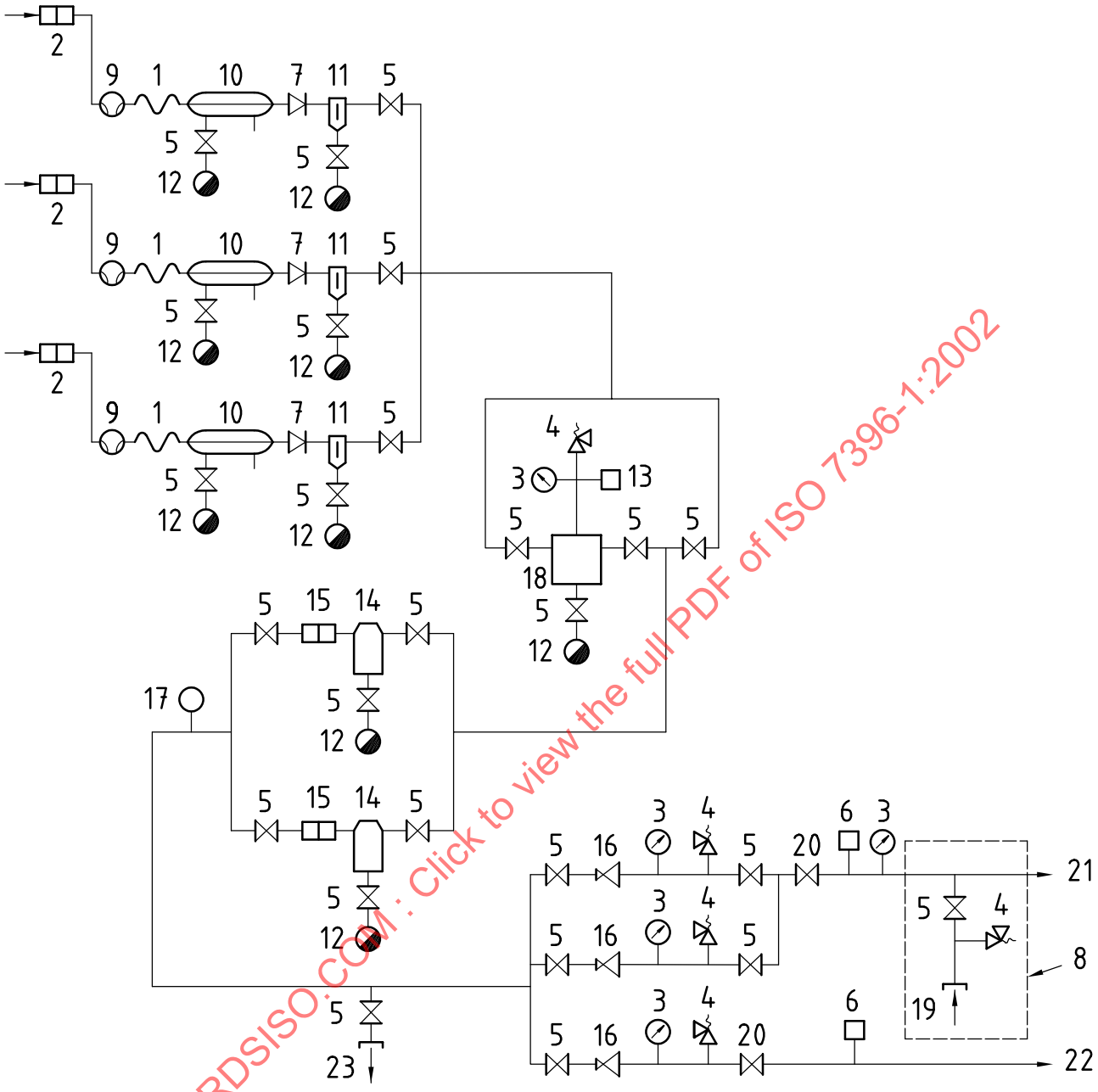


Figure A.11 — Typical supply system with three air compressor units (single-stage distribution system)

Key

1 Flexible connection
2 Filter
3 Pressure gauge
4 Pressure-relief valve
5 Shut-off valve
6 Low and high pressure switches
7 Non-return valve
8 Emergency and maintenance supply assembly
9 Compressor
10 After-cooler
11 Separator
12 Drain
13 Pressure switch
14 Dryer
15 Filter assembly
16 Line-pressure regulator
17 Dew-point sensor
18 Receiver
19 Gas-specific inlet
20 Supply shut-off valve
21 Supply of air for breathing at nominal distribution pressure
22 Supply of air for driving surgical tools at nominal distribution pressure
23 Sample port

Figure A.11 — Typical supply system with three air compressor units (single-stage distribution system)

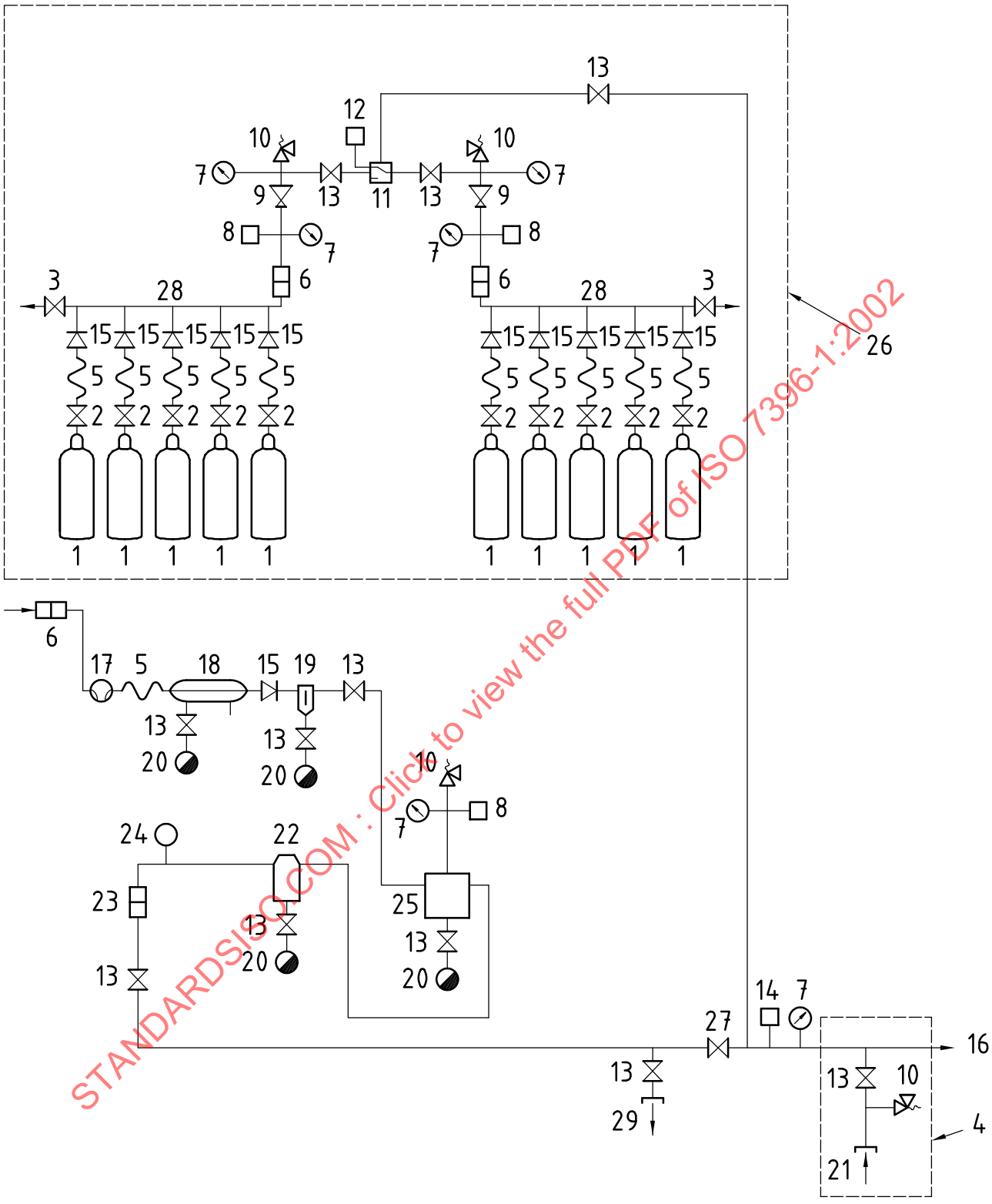


Figure A.12 — Typical supply system with one air compressor unit and two banks of gas cylinders (double-stage distribution system)

Key

1 Cylinder
2 Cylinder valve
3 Vent valve
4 Emergency and maintenance supply assembly
5 Flexible connection
6 Filter
7 Pressure gauge
8 Pressure switch
9 Manifold pressure regulator
10 Pressure-relief valve
11 Automatic change-over
12 Change-over switch
13 Shut-off valve
14 Low and high pressure switches
15 Non-return valve
16 Supply to pipeline system (at nominal supply system pressure)
17 Compressor
18 After-cooler
19 Separator
20 Drain
21 Gas-specific inlet
22 Dryer
23 Filter assembly
24 Dew-point sensor
25 Receiver
26 Secondary and reserve supplies
27 Supply shut-off valve
28 Manifold
29 Sample port

Figure A.12 — Typical supply system with one air compressor unit and two banks of gas cylinders (double-stage distribution system)

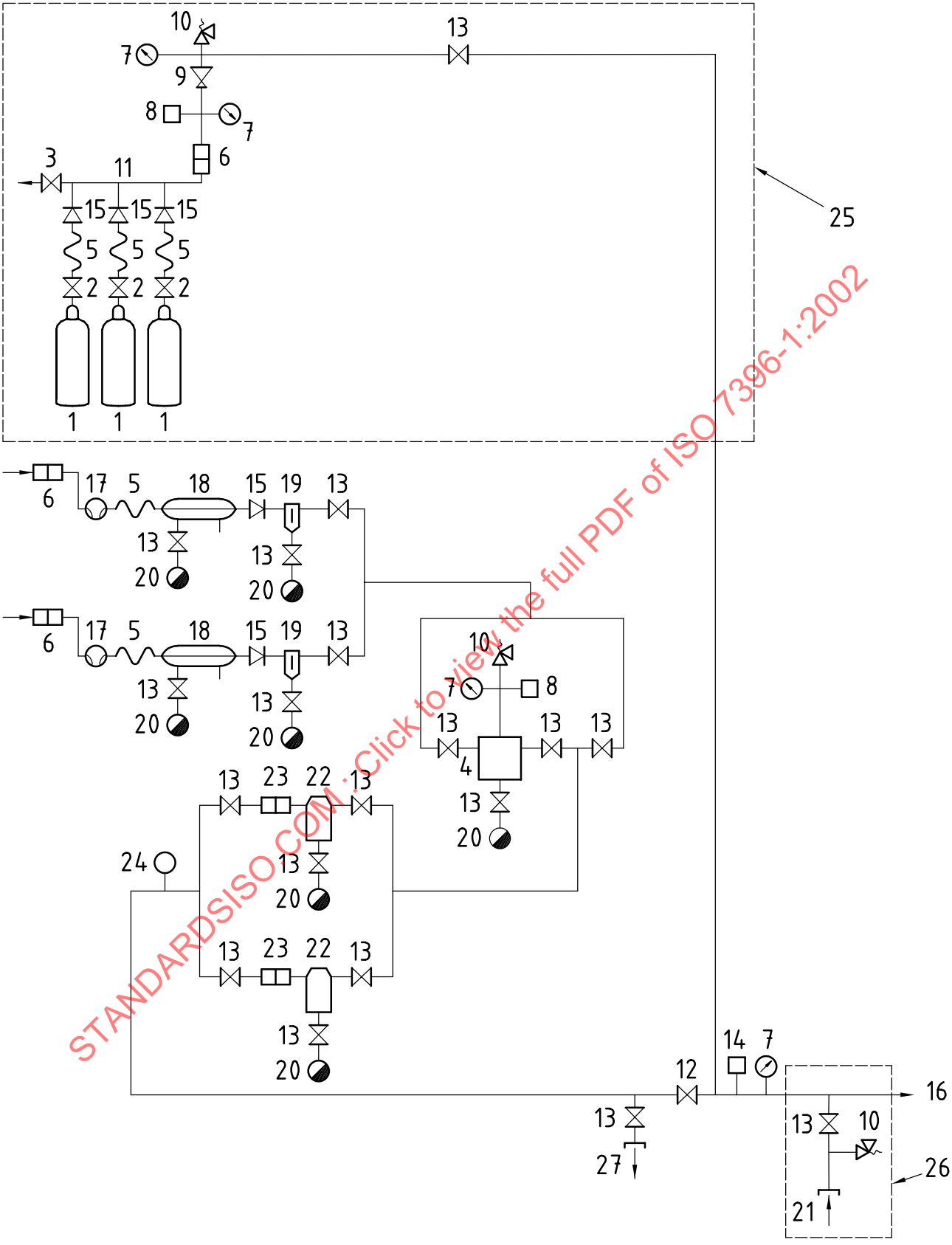


Figure A.13 — Typical supply system with two air compressor units and one bank of gas cylinders (double-stage distribution system)

Key

1 Cylinder
2 Cylinder valve
3 Vent valve
4 Receiver
5 Flexible connection
6 Filter
7 Pressure gauge
8 Pressure switch
9 Manifold pressure regulator
10 Pressure-relief valve
11 Manifold
12 Supply shut-off valve
13 Shut-off valve
14 Low and high pressure switches
15 Non-return valve
16 Supply to pipeline system (at nominal supply system pressure)
17 Compressor
18 After-cooler
19 Separator
20 Drain
21 Gas-specific inlet
22 Dryer
23 Filter assembly
24 Dew-point sensor
25 Reserve supply
26 Emergency and maintenance supply assembly
27 Sample port

Figure A.13 — Typical supply system with two air compressor units and one bank of gas cylinders (double-stage distribution system)

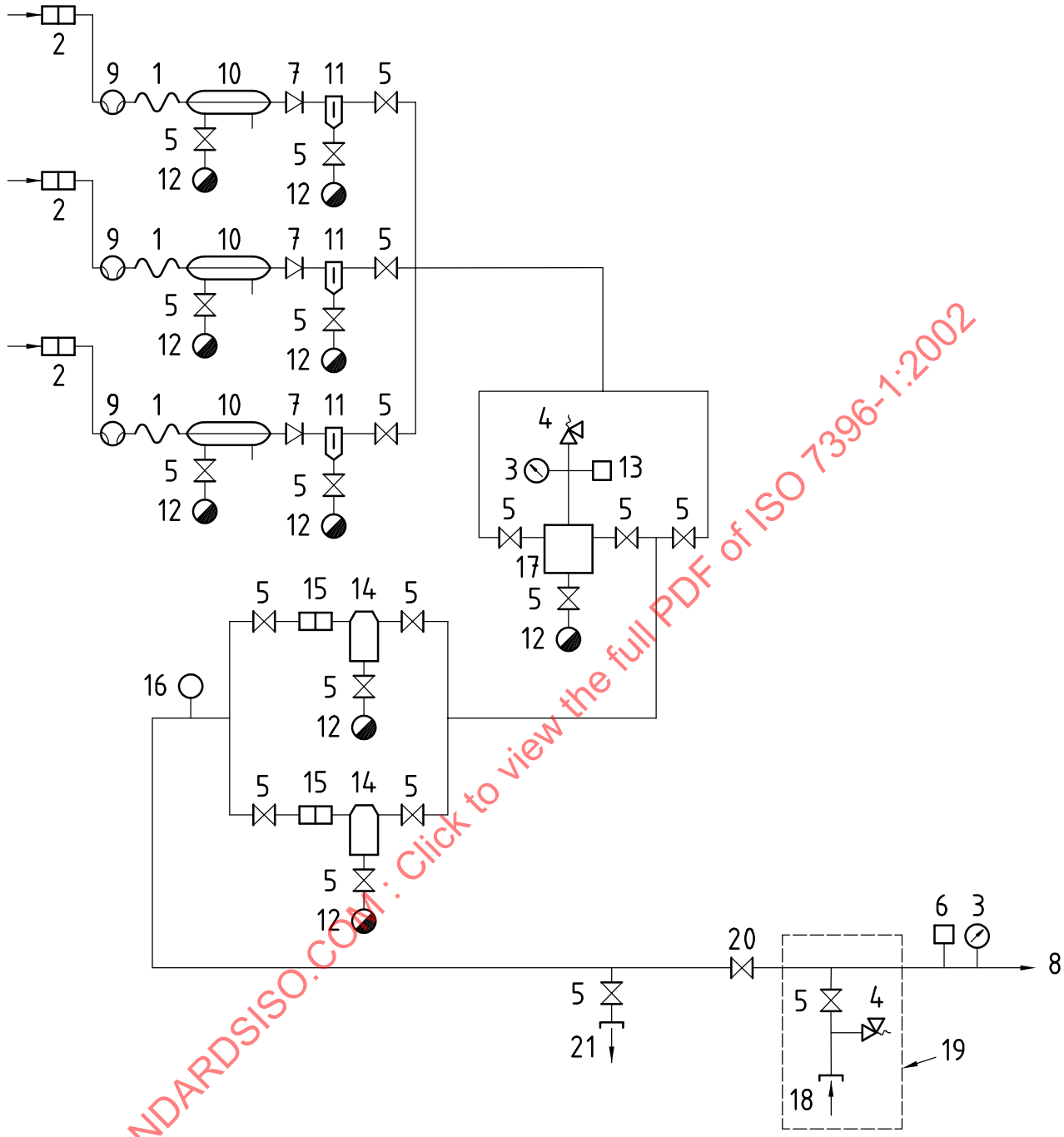


Figure A.14 — Typical supply system with three air compressor units (double-stage distribution system)

Key

1 Flexible connection
2 Filter
3 Pressure gauge
4 Pressure-relief valve
5 Shut-off valve
6 Low and high pressure switches
7 Non-return valve
8 Supply to pipeline system (at nominal supply system pressure)
9 Compressor
10 After-cooler
11 Separator
12 Drain
13 Pressure switch
14 Dryer
15 Filter assembly
16 Dew-point sensor
17 Receiver
18 Gas-specific inlet
19 Emergency and maintenace supply assembly
20 Supply shut-off valve
21 Sample port

Figure A.14 — Typical supply system with three air compressor units (double-stage distribution system)

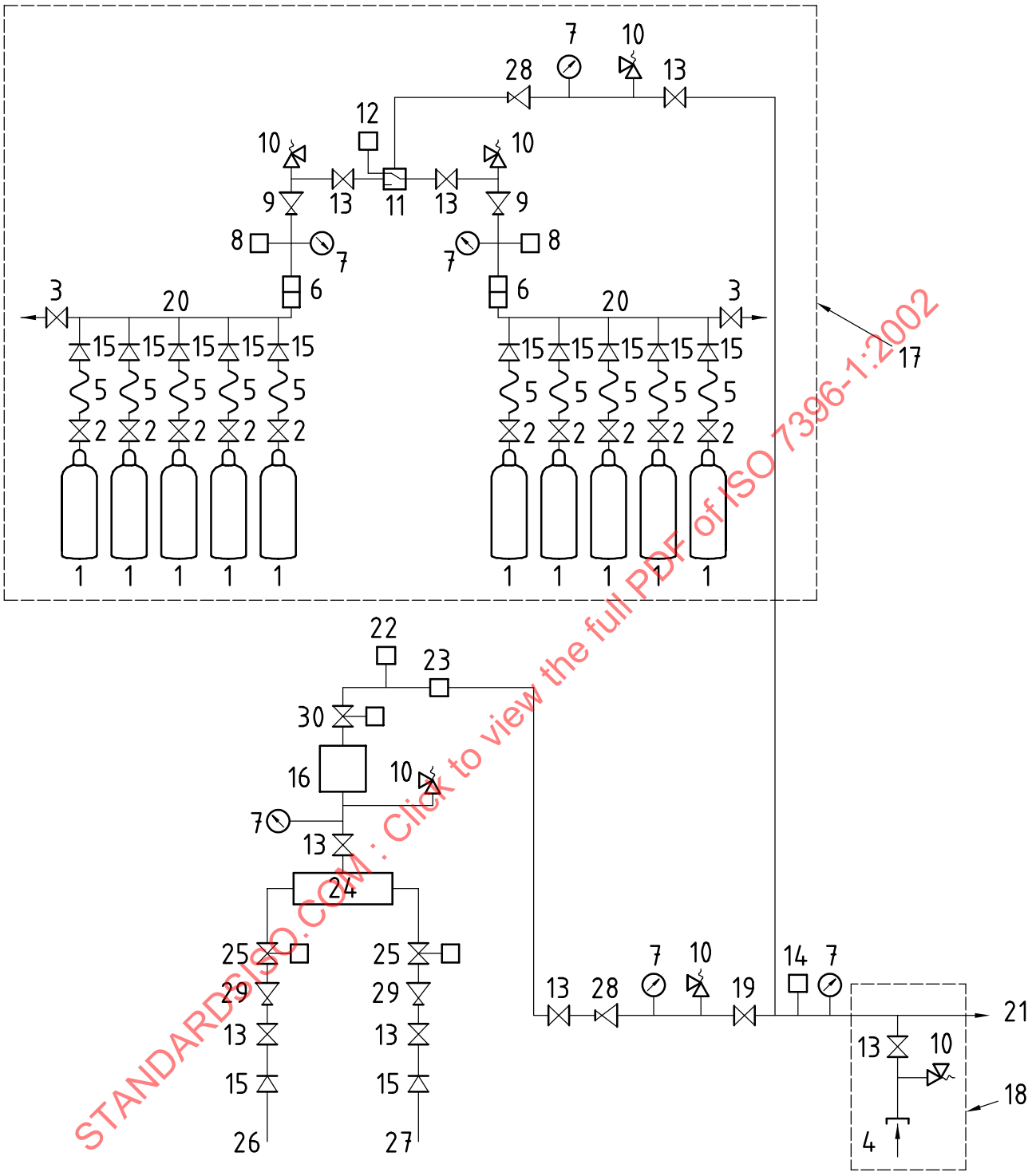


Figure A.15 — Typical supply system with one proportioning unit and two banks of gas cylinders (single-stage distribution system)

Key

1 Cylinder
2 Cylinder valve
3 Vent valve
4 Gas-specific inlet
5 Flexible connection
6 Filter
7 Pressure gauge
8 Pressure switch
9 Manifold pressure regulator
10 Pressure-relief valve
11 Automatic change-over
12 Change-over switch
13 Shut-off valve
14 Low and high pressure switches
15 Non-return valve
16 Receiver
17 Secondary and reserve supplies
18 Emergency and maintenance supply assembly
19 Supply shut-off valve
20 Manifold
21 Supply to pipeline system (at nominal distribution pressure)
22 Pressure sensor
23 Analyser
24 Mixer with analyser independant of 23
25 Valve controlled by pressure
26 From the O_2 source of supply
27 From the N_2 source of supply
28 Line-pressure regulator
29 Pressure regulator
30 Shut-off valve controlled by 22 and 23

Figure A.15 — Typical supply system with one proportioning unit and two banks of gas cylinders (single-stage distribution system)

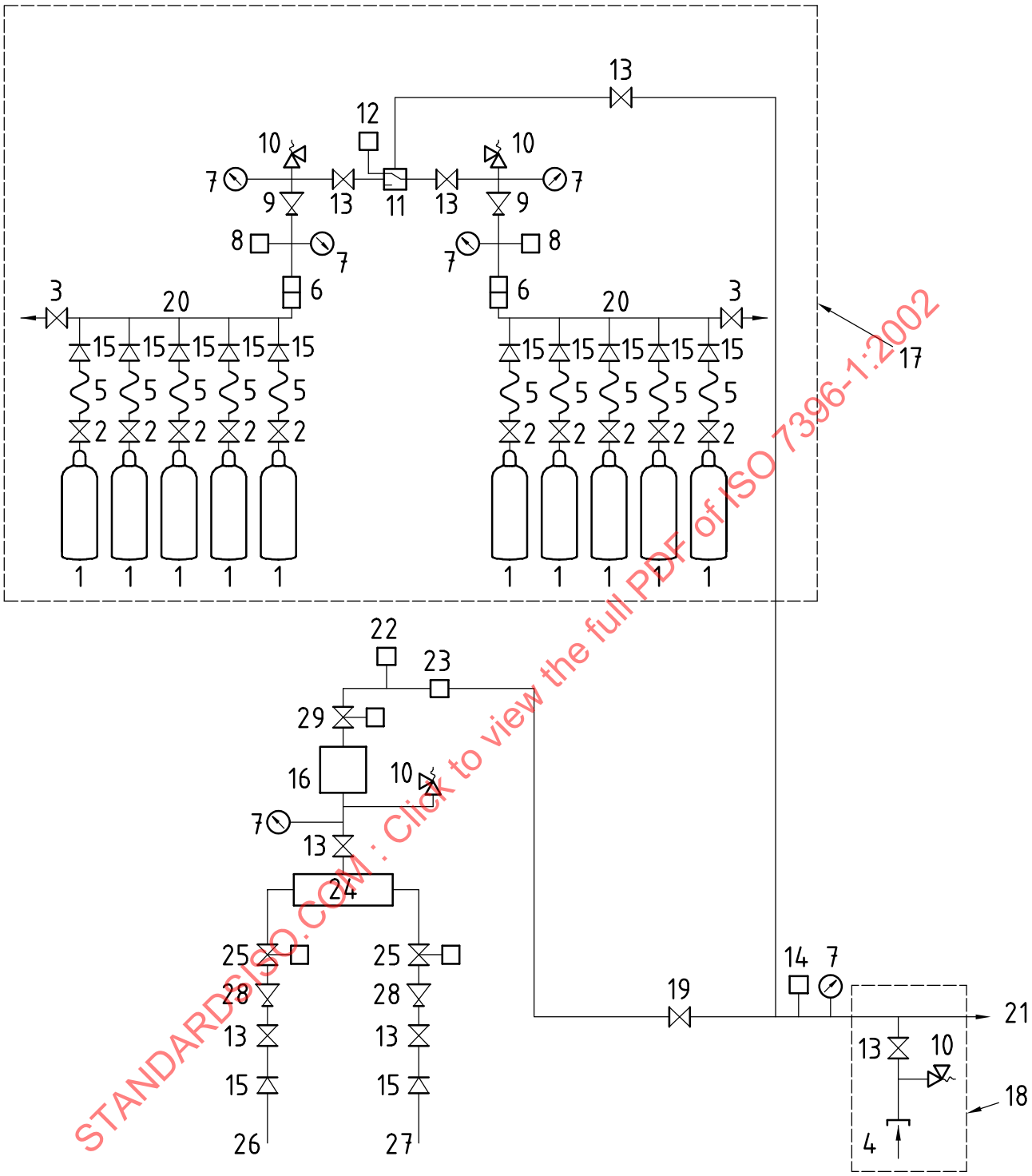
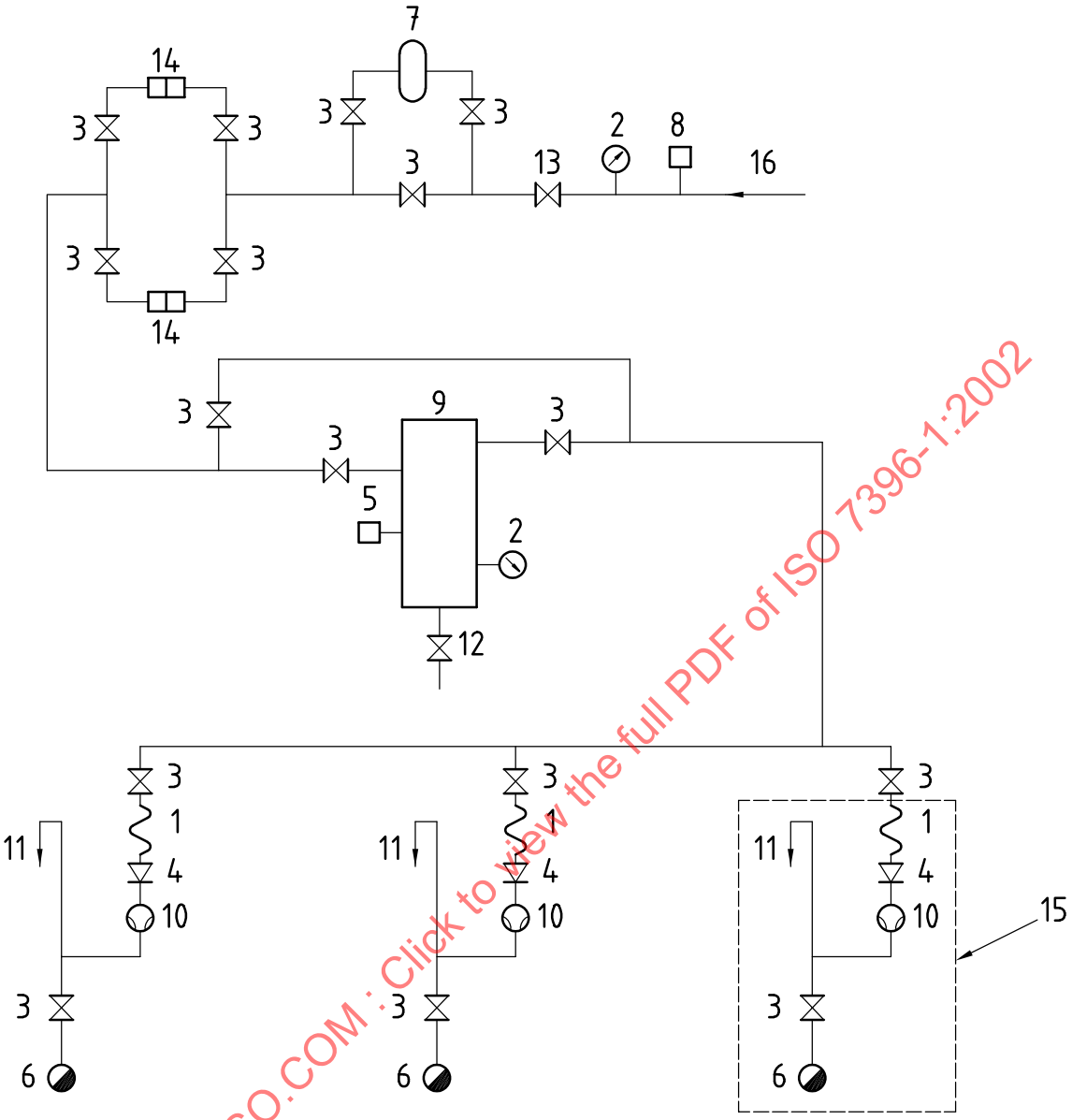


Figure A.16 — Typical supply system with one proportioning unit and two banks of gas cylinders (double-stage distribution system)

Key

1 Cylinder
2 Cylinder valve
3 Vent valve
4 Gas-specific inlet
5 Flexible connection
6 Filter
7 Pressure gauge
8 Pressure switch
9 Manifold pressure regulator
10 Pressure-relief valve
11 Automatic change-over
12 Change-over switch
13 Shut-off valve
14 Low and high pressure switches
15 Non-return valve
16 Receiver
17 Secondary and reserve supplies
18 Emergency and maintenance supply assembly
19 Supply shut-off valve
20 Manifold
21 Supply to pipeline system (at nominal supply system pressure)
22 Pressure sensor
23 Analyser
24 Mixer with analyser independant of 23
25 Valve controlled by pressure
26 From the O_2 source of supply
27 From the N_2 source of supply
28 Pressure regulator
29 Shut-off valve controlled by 22 and 23

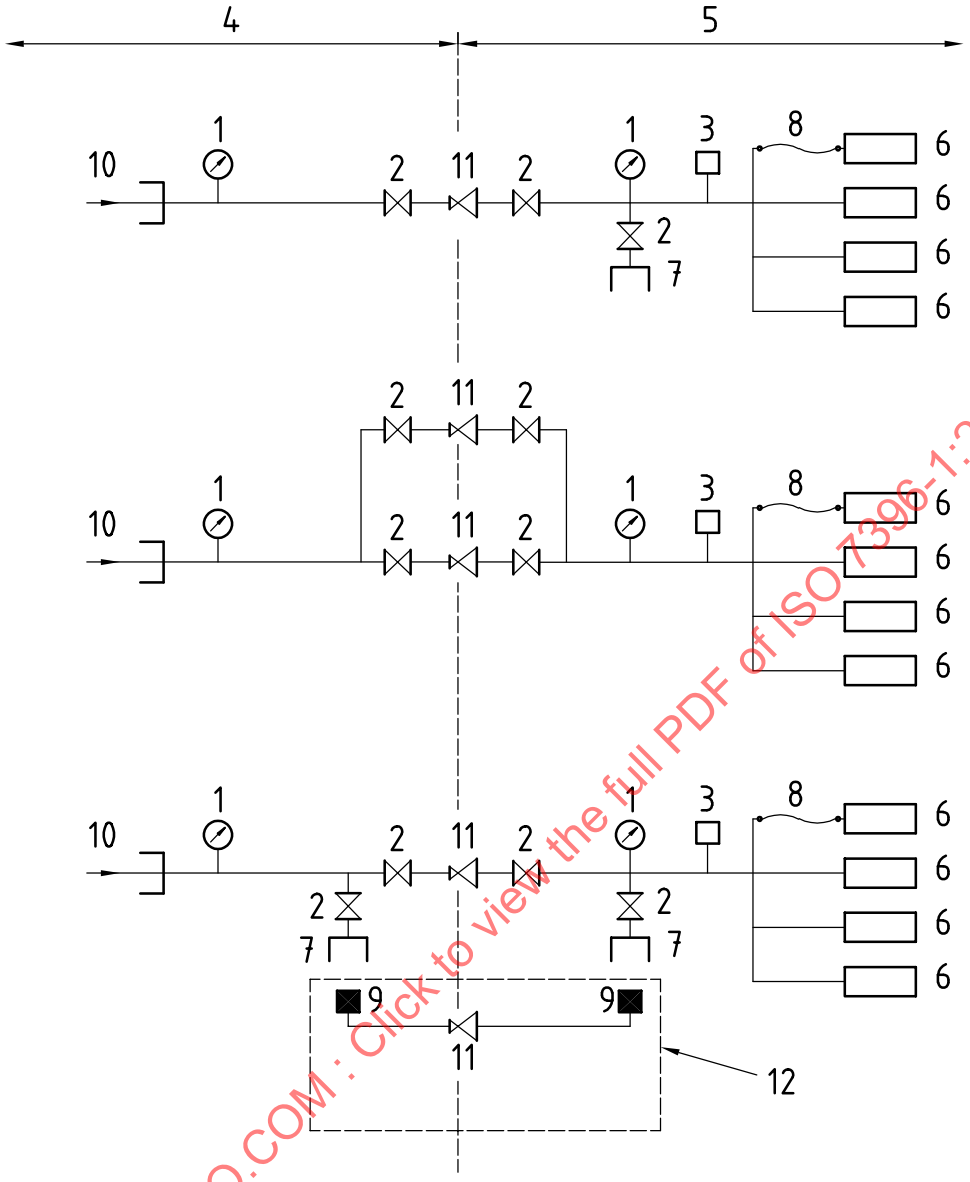
Figure A.16 — Typical supply system with one proportioning unit and two banks of gas cylinders (double-stage distribution system)



Key

1	Flexible connection	7	Drainage trap	13	Supply shut-off valve
2	Vacuum gauge	8	Low-vacuum switch	14	Bacterial filter
3	Shut-off valve	9	Vacuum reservoir	15	Optional assembly
4	Non-return valve	10	Vacuum pump	16	Inlet from pipeline system
5	Vacuum switch	11	Exhaust		
6	Drain	12	Drain valve		

Figure A.17 — Typical supply system with vacuum pumps



Key

1 Pressure gauge
2 Shut-off valve
3 Low and high pressure switches
4 First-stage distribution (at nominal supply system pressure)
5 Second-stage distribution (at nominal distribution pressure
6 Terminal unit
7 Gas-specific connector
8 Low-pressure hose assembly
9 Gas-specific connector
10 Connection to the supply system
11 Line-pressure regulator
12 Emergency and maintenance line-pressure regulator assembly

NOTE Three alternative arrangements in accordance with 7.4 are shown.

Figure A.18 — Typical double-stage distribution system with line pressure regulators within the pipeline system

Annex B
(informative)

Guidelines for location of cylinder manifolds 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, protected from the weather, and the area fenced.

Regional or national regulations may apply.

B.2 Location of stationary vessels

B.2.1 Stationary vessels containing 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.

Regional or national regulations may apply.

B.2.2 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.

B.2.3 Adequate access for a vehicle should be provided so that a cryogenic or non-cryogenic liquid supply vessel can 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.2.4 Points of possible escape of gas from pressure-relief valves or bursting discs should be more than 5 m away from public access areas.

Annex C
(informative)

General guidelines for supply systems

C.1 Rooms or areas for supply systems should not be used for any other purpose. Empty cylinders disconnected from the supply equipment may be stored, pending their removal. One group of filled cylinders sufficient for one side of a manifold may be stored in the same room or area. A separate storage area should be provided for empty cylinders.

C.2 Only nominated persons should be authorized to operate and attend the supply equipment.

C.3 Services or containers of combustible gases or liquids should not be permitted within any manifold room or source of supply area.

C.4 A heating system may be used to heat supply-system enclosures or storage areas, provided that no part of the heating system in contact with the air within the room exceeds a temperature of 225 °C and that cylinders are prevented from coming into contact with the heating system.

C.5 All electrical fittings in supply rooms should be located in fixed positions to minimize the risk of physical damage.

C.6 Fire-fighting equipment should be provided.

C.7 The room or enclosure should be clean, well lit and ventilated to atmosphere.

C.8 The doors or gates for rooms or enclosures containing the source of supply should be capable of being locked. An emergency exit should be provided which should be free from obstructions at all times. All doors should be capable of being opened from the inside, at any time, without a key. All doors should open outwards.

C.9 Enclosures (interior or exterior) for supply systems should conform to the following recommendations:

a) when enclosures are located near sources of heat such as furnaces, incinerators or boiler rooms, construction should prevent cylinder temperature from exceeding 50 °C;

b) enclosures should not be located within 3 m of open electrical conductors and transformers;

c) enclosures should not be located adjacent to oil storage tanks;

d) enclosures should comply with local building codes;

e) enclosures should have concrete floors;

f) a warning notice should be clearly displayed on both sides of each door and for each gas;

EXAMPLE:

WARNING – Oxygen/Nitrous oxide (or chemical symbols, etc., as appropriate)

No smoking

No open flames or sparks

No oil or grease

No combustible material to be placed within 5 m

g) fences and walls should be of a height not less than 1,75 m.

C.10 Enclosures should be easily accessible to vehicles delivering cylinders or cryogenic liquid and be at ground level or vehicle height depending on the method of unloading used.

C.11 No part of the enclosure should be located less than 5 m (for stationary oxygen cryogenic vessels) or 3 m (for other supply systems) from any occupied building or from any roadway or footpath.

Annex D
(informative)

Guidelines for emergency procedures

D.1 General

D.1.1 Emergencies can arise which may result in the sudden cessation or reduction of the gas supply to one or more clinical areas. Should such failures occur, it is vital that procedures be already set up which can ensure immediate action on

— communication of the problem to those persons and areas affected,

— conservation of gas supply,

— remedial action.

D.1.2 National or local regulations relating to fire precautions should be complied with.

D.2 Communication

D.2.1 Communication procedures should be set up to ensure that any emergency arising is notified immediately to all clinical areas likely to be affected and to all staff involved in the maintenance of gas supplies and in remedial actions.

D.2.2 Such communication 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.

D.2.3 Experienced persons should be nominated in each area to coordinate and communicate actions.

D.3 Conservation of supplies

D.3.1 On receiving an emergency notification, the coordinator in each clinical area should reduce the use of gas from the pipeline system(s) involved to the minimum level required (see D.3.2).

D.3.2 The staff responsible should check on, and bring into use as necessary, cylinders on reserve manifolds and cylinders held in storage or other sources at the emergency and maintenance supply assembly or at points of use.

D.3.3 If necessary, additional supplies of gas should be ordered from suppliers or from other health care facilities to meet the expected duration of the emergency.

D.4 Remedial actions

D.4.1 The cause of emergency failure of supply should be investigated immediately and action initiated to remedy the fault or damage.

D.4.2 Such investigations may show that other areas of the health care facility, not initially affected, may need to be isolated to carry out repairs. In this case, communication and conservation procedures should be instituted in these areas before shutting off the gas supply.

D.4.3 Remedial work should be carried out under an effective method of control.

D.5 Training

D.5.1 The staff responsible should be properly trained in the use of medical gases and pipeline systems, and be fully familiar with the medical gas pipeline layout and the location of all area shut-off valves.

D.5.2 Emergency procedures should be initiated at least twice a year as an exercise, and any problem or need for re-training noted and followed up.

D.5.3 Actual emergency situations should be evaluated and appropriate action taken to improve procedures and training.

D.6 Nominated staff

Specific persons should be nominated to attend, operate and maintain the system. They should be appropriately trained and qualified in the handling of cylinders and sources of supply.

D.7 Reserve supplies

D.7.1 It is recommended that gas reserves in cylinders not normally connected to a source of supply be held in addition to reserves connected to a source of supply. The capacity of such supplementary supplies should be calculated to take into account the normal daily usage of the gas, the normal supply arrangements and the emergency procedures which will be taken in the event of failure of a source of supply.

D.7.2 Sufficient cylinders equal to the capacity of one manifold bank may be held in each manifold room. Additional cylinders may be held in an adjacent cylinder storage area.

D.7.3 Critical care areas may require their own cylinder reserves to minimize any delay in maintaining gas supplies in an emergency. If cylinders with attached regulators are used for this purpose, the regulator outlet should be gas-specific and connected to a low-pressure hose assembly.

D.8 Safety

D.8.1 Suitable handling devices (e.g. purpose-designed trolleys) should be provided for the movement of cylinders.

D.8.2 Cylinder storage areas should be well ventilated and the cylinders stored in accordance with the supplier's recommendations. Full cylinders should be segregated from empty ones, and the respective storage areas should be labelled.

D.8.3 Access to cylinder manifold rooms and storage areas should be level and kept clear. In particular, emergency exits from these rooms and areas should be kept free of obstructions at all times. Emergency exits should lead into the open air or other safe locations.

Annex E
(informative)

Example of procedure for testing and commissioning

E.1 General

This test procedure is given as an example of how the specifications of clause 12 can be verified so that the system may be commissioned and certified. Other procedures may be devised which validly test these specifications. In this procedure the given sequence of tests is important and should be followed. The general requirements of 12.1 should be followed.

Typical forms for certification of the system are given in annex H. A summary of typical tests required which lists the specification, procedure and form for each test is given in Tables E.1 and E.2.

E.2 Tests and inspections after installation of pipeline distribution systems with at least the base blocks of all terminal units fitted but before concealment (see 12.3)

E.2.1 Test for mechanical integrity

E.2.1.1 General conditions

This test may be carried out on sections of the pipeline, provided that no part of the system is omitted. More than one pipeline may be tested at the same time and for this purpose the pipelines may be linked.

WARNING — Linking of pipelines for testing purposes is a temporary measure and every precaution should be taken to ensure that the linkages are removed prior to completion of the pipelines.

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.

E.2.1.2 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 a pressure 1,2 times the maximum pressure as specified in 12.5.1 for that section. After 5 min check that the system has not ruptured.

WARNING — Precautions should be taken to avoid hazards to personnel arising from possible rupture of the pipeline.

Record the results on Form H 1.

E.2.2 Test for leakage

E.2.2.1 General conditions

This test may be carried out on sections of the pipeline, provided that no part of the system is omitted. More than one pipeline may be tested at the same time and for this purpose the pipelines may be linked.

WARNING — Linking of pipelines for testing purposes is a temporary measure and every precaution should be taken to ensure that the linkages are removed prior to completion of the pipelines.

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.

E.2.2.2 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 at least 1,5 times the nominal distribution pressure for compressed medical gas pipelines and 500 kPa for vacuum pipelines. Disconnect and remove the test gas supply. Record the pressure and room temperature initially and again at the end of the test period (2 h to 24 h).

Check that the rate of pressure drop during the test is less than 0,025 %/h except for pressure changes due to temperature variations.

NOTE The pressure change due to temperature variations is approximately 0,35 %/°C (see annex F).

Record the results on form H 1.

E.2.3 Test for cross-connection or obstruction

E.2.3.1 General conditions

Any links between the pipeline systems should be removed before this test is carried out. All pipelines should be at atmospheric pressure and all shut-off valves should be open. A single pressure source should be used and connected to only one system at a time which should be kept at nominal distribution pressure throughout the test. At least one base block on each of the other systems should be open to atmosphere.

This test should be carried out on one pipeline at a time and, if possible, on all pipelines within a short period. It is also advisable to check the particulate contamination of the pipeline during these tests.

E.2.3.2 Example of procedure

E.2.3.2.1 Test each terminal unit on the system under test by opening the base block to its maximum and permitting the test gas to flow for approximately 1 min. Check the gas flow and particulate contamination and then re-blank the base block. Remove the pressure source after the last opening has been closed again and leave the connection point open.

E.2.3.2.2 Connect the pressure source to the next pipeline system and repeat the procedures given in E.2.3.2.1. There should be a flow of test gas from every base block on the system under test and no flow from those base blocks left open on other systems. The test gas should be observed to be free from particulate contamination.

E.2.3.2.3 After completion of all tests, re-blank all terminal unit base blocks. It is advantageous to leave the pipeline systems under pressure after these tests are completed. If this is not done and there is a lapse of time, a re-test for leakage should be carried out before final installation of the terminal unit valves.

E.2.3.2.4 If the flow is too low, there is obstruction in the pipeline system which should be remedied.

E.2.3.2.5 If there is no flow from a base block on the system under test, that base block is incorrectly connected or totally obstructed. This situation should be investigated and rectified and the base block re-tested.

E.2.3.2.6 If there is flow from the open base block on a system not under test, that system is cross-connected with the one under test. This should be investigated, rectified and the pipeline system re-tested.

E.2.3.2.7 Record the results on form H 2.

E.2.4 Inspection of marking and pipeline supports

E.2.4.1 Example of procedure

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. Check the pipeline supports.

The marking should be in accordance with 10.1. The pipeline supports should be in accordance with 11.2.

Record the results on form H 1.

E.2.5 Check for compliance with the design specification

E.2.5.1 General conditions

No pipeline should be concealed.

E.2.5.2 Example of procedure

Each pipeline should be visually examined to check that the sizing of the pipelines, the location of terminal units and shut-off valves, the positions of connectors for pressure-relief valves and pressure gauges are in accordance with the design specification.

Record the results on form H 3.

E.3 Tests and procedures after complete installation and before use of the system (see 12.4)

E.3.1 Tests for leakage

E.3.1.1 Test for leakage from compressed medical gas pipelines

NOTE All pipelines may be tested at the same time. 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.

E.3.1.1.1 General conditions

The leakage test described in E.2.2 should have been completed satisfactorily. All terminal units, valves, line pressure regulators, gauges and pressure sensors should be fitted. The supply system should be isolated from the pipeline. There should be no links between the pipeline systems.

E.3.1.1.2 Example of procedure

Connect a suitable pressure-measuring device to the system(s) under test. Fill the system(s) under test with test gas at nominal distribution pressure. This filling procedure may also be used to measure the volume of the pipeline (see annex J). 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).

Record the results on form H 4.

E.3.1.2 Test for leakage into vacuum pipelines

E.3.1.2.1 General conditions

The leakage test described in E.2.2 should have been completed satisfactorily. 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.

E.3.1.2.2 Example of procedure

Connect a vacuum gauge to the system. Operate the vacuum supply system until the nominal distribution pressure (see Table 2) is achieved. With the system at nominal distribution pressure, isolate the vacuum supply system. Record the vacuum shown on the vacuum gauge initially and after 1 h. The pressure increase after 1 h should not exceed 2,5 kPa.

Record the results on Form H 5.

E.3.2 Test of shut-off valves for leakage and closure and check for correct zoning and correct identification

E.3.2.1 General conditions

The tests given in E.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.

E.3.2.2 Example of procedure

E.3.2.2.1 The system should be at its nominal distribution pressure with all shut-off valves closed. Connect a pressure-measuring device to a terminal unit of the system under test at a point remote from the supply system.

E.3.2.2.2 Depressurize the pipeline system downstream of the shut-off valve most remote from the supply system to 100 kPa by opening a terminal unit. Close the terminal unit.

E.3.2.2.3 Check the shut-off valve controlling the area at 100 kPa for identification of area and service controlled.

E.3.2.2.4 Note the total number and location of terminal units downstream of the shut-off valve and check that these terminal units are correctly labelled and that they are all pressurized at 100 kPa or less.

E.3.2.2.5 If necessary, re-adjust the pressure to 100 kPa. Read the pressure in the section under test and then read the pressure again after 15 min.

E.3.2.2.6 On each system open the shut-off valves in sequence toward the supply system, repeating procedures E.3.2.2.2, E.3.2.2.3, E.3.2.2.4 and E.3.2.2.5.

E.3.2.2.7 In compressed medical gas pipeline systems the pressure increase downstream of the shut-off valve under test should not exceed 5 kPa after 15 min. Each shut-off valve should serve only the areas intended by the system design.

E.3.2.2.8 Record the results on Form H 6.

E.3.3 Test for cross-connection

E.3.3.1 General conditions

In no circumstances should this test be carried out by pressurizing more than one pipeline system at a time. All pipeline systems should be at atmospheric pressure and all shut-off valves open. A single test gas source should be used and connected to only one pipeline system at a time which should be kept at nominal distribution pressure throughout the test. In the case of the vacuum pipeline system, the vacuum supply system should be used. This test should be applied to all terminal units.

This test may be carried out in association with the test for obstruction (see E.3.4).

E.3.3.2 Example of procedure

E.3.3.2.1 Pressurize (or evacuate) the pipeline system to be tested to nominal distribution pressure.

E.3.3.2.2 Check that gas flows through every terminal unit of the pipeline system under nominal distribution pressure.

E.3.3.2.3 Check that there is no gas flow from any terminal unit of any other pipeline system when opened with a gas-specific probe.

E.3.3.2.4 There should be no cross-connections.

E.3.3.2.5 With all the other pipeline systems at atmospheric pressure, repeat the procedure in E.3.3.2.1 through E.3.3.2.4 on each pipeline system in turn, including vacuum, preferably at one session.

E.3.3.2.6 Repeat the test in full if any modifications are made to the pipeline systems during the commissioning procedure.

E.3.3.2.7 Record the results on form H 7.

E.3.4 Test for obstruction and check of terminal units, NIST or DISS connectors for mechanical function, gas specificity and identification

E.3.4.1 General conditions

The accuracy of the test equipment should be checked before commencing the test procedure.

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 E.3.3. In this case only one pipeline system at a time is under pressure. Alternatively, after completion of the tests given in E.3.3, all pipeline systems may be pressurized and the tests described in E.3.4 carried out simultaneously.

E.3.4.2 Example of procedure

E.3.4.2.1 Insert a gas-specific test probe with gauge and flow-measuring device into each terminal unit in turn. Check that the pressure change between zero flow and the specified test flow at each terminal unit does not exceed the value given in Table 4.

E.3.4.2.2 Check that the 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.

E.3.4.2.3 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.

E.3.4.2.4 Check that all NIST or DISS connectors accept the appropriate nipples and that a mechanical connection is made. Check that the NIST or DISS nipples for all other gases do not fit the connectors under test.

E.3.4.2.5 All terminal units should be identified and labelled and should meet the requirements specified in 12.6.5.

E.3.4.2.6 Record the results on forms H 8 and H 9.

E.3.5 Test of system performance

E.3.5.1 General conditions

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.

E.3.5.2 Example of procedure

E.3.5.2.1 Pressurize or evacuate the pipeline at a pressure not greater than the maximum distribution pressure or vacuum.

Record the pressure.

E.3.5.2.2 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.

E.3.5.2.3 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).

E.3.5.2.4 The change in pressure at each of the selected terminal units should be within the limits given in 7.2.2, 7.2.3 and 7.2.4.

Remedial work may be needed if these values are not met. The tests should be carried out again following any remedial work.

E.3.5.2.5 Depressurize the system and repeat the test for each service.

E.3.5.2.6 Record the results on Form H 10.

E.3.6 Test of pressure-relief valves

E.3.6.1 General conditions

If type-tested and certified pressure-relief valves are installed, tests of relief valve function are not required; in this case proceed as described in E.3.6.2.1 to E.3.6.2.3.

If the pressure-relief valves fitted are not type-tested or certified, their performance should be verified according to the procedure given in E.3.6.2.3 to E.3.6.2.6.

E.3.6.2.7 applies in all cases.

E.3.6.2 Example of procedure

E.3.6.2.1 Inspect each pressure-relief valve to check the discharge capacity and the set pressure.

E.3.6.2.2 Inspect the certification supplied with each pressure-relief valve.

E.3.6.2.3 Inspect the installation of the pressure-relief valves to verify that they are correctly vented.

E.3.6.2.4 Isolate a section of pipeline in which the pressure-relief valve to be tested is located.

E.3.6.2.5 Gradually increase the pressure in this section of the pipeline and note the pressure at which the pressure-relief valve lifts and the pressure at which it allows maximum discharge.

E.3.6.2.6 Gradually reduce the pressure to that normally present in the section under test and note the value at which the pressure-relief valve re-seats and is gas-tight.

E.3.6.2.7 The pressure at which the pressure-relief valves operate should permit the system to meet the requirements of 7.2.5 and 7.2.6.

E.3.6.2.8 Record the results on Form H 11.

E.3.7 Tests on all sources of supply

E.3.7.1 General conditions

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.

E.3.7.2 Example of procedure

All components should be tested for leakage. Air compressor systems should be tested for leaks during normal operation. Minor leaks detectable as bubbles are acceptable. The function and operating parameters of each supply system should be checked from the checklist. The supply system should be shown to operate on the emergency electrical power supply.

The test results should conform to the manufacturer's specifications and the requirements of clause 5. It should be confirmed that the system design flow requirements are met.

Record the results on Form H 12.

E.3.8 Tests of monitoring and alarm system

E.3.8.1 General conditions

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.

E.3.8.2 Example of procedure

E.3.8.2.1 All alarm sensors should be shown to operate with an appropriate change in the local system condition (for example pressure, moisture content, liquid level, and system changeover). Record the settings at which alarm sensors switch on and off.

E.3.8.2.2 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 the signals are in accordance with clause 6, if applicable.

E.3.8.2.3 All monitors and alarms should operate with the appropriate changes in pipeline system conditions and should operate from the normal and emergency electrical power supplies.

E.3.8.2.4 All monitoring and alarm signals should comply with the requirements of clause 6.

E.3.8.2.5 Record the results on Form H 13.

E.3.9 Test for particulate contamination

E.3.9.1 General conditions

The compressed medical gas pipeline systems should be at nominal distribution pressure and filled with test gas.

E.3.9.2 Example of procedure

The terminal unit most distant from the source of supply on each branch of the pipeline should be tested with the membrane filter device shown in Figure 2 at a flowrate of 150 l/min for 15 s.

The filters should be free from particulate matter when viewed in good light.

Record the results on Form H 14.

E.3.10 Tests for contaminants in air produced by compressor systems

E.3.10.1 General conditions

These tests should be carried out on each air compressor unit in turn at the sample port immediately upstream of the supply shut-off valve (see 5.5.2.10) 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.

Record the results on Form H 15.

E.3.10.2 Oil

The test device should measure oil present as liquid, aerosol and vapour. The total oil level should not exceed the value given in 5.5.2.2 and 5.5.2.4.

E.3.10.3 Water

At the sample port (see 5.5.2.10), test for water-vapour concentration using an appropriate test device. The water concentration should not exceed the value given in either 5.5.2.2 or 5.5.2.4

This test should be repeated after filling the pipeline distribution system with air at a sample of terminal units (5 %) at points remote from the source of supply.

E.3.10.4 Carbon monoxide and carbon dioxide

At a suitable test point downstream of the dryers, determine the concentration of carbon monoxide and carbon dioxide using appropriate test devices. The concentrations of carbon monoxide and carbon dioxide should not exceed the values given in 5.5.2.2.

E.3.11 Test of oxygen concentration and contaminants in oxygen-enriched air produced by oxygen concentrators

E.3.11.1 General conditions

These tests should be carried out before filling with the pipeline distribution system with oxygen-enriched air. 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 in turn at a suitable test point immediately upstream of the supply shut-off valve.

Record the results on Form H 16.

E.3.11.2 Oxygen concentration

An oxygen analyser should be used. The oxygen concentration should meet the requirements of clause 8 of ISO 10083:1992.

E.3.11.3 Carbon monoxide and carbon dioxide

Test the oxygen-enriched air for carbon monoxide and carbon dioxide concentrations using appropriate test devices. The concentrations of carbon monoxide and carbon dioxide should not exceed the levels specified in clause 8 of ISO 10083:1992.

E.3.11.4 Particulate contamination

Test the oxygen-enriched air for particulate contamination using an appropriate test device. The maximum particulate contamination should not exceed the level specified in clause 8 of ISO 10083:1992.

E.3.11.5 Hydrocarbon contamination

Test the oxygen-enriched air for hydrocarbon contamination using an appropriate test device. The maximum hydrocarbon contamination should meet the requirement in clause 8 of ISO 10083:1992.

E.3.11.6 Dewpoint

Test the dewpoint of oxygen-enriched air using an appropriate test device. The dewpoint should not exceed the value in clause 8 of ISO 10083:1992.

E.3.12 Filling with specific gas

E.3.12.1 General conditions

All systems may be filled with their specific gas at the same time.

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 source of supply with all shut-off valves except the supply shut-off valve open. All special connectors should be removed from site.

E.3.12.2 Example of procedure

E.3.12.2.1 Open the supply shut-off valve and fill each pipeline system from its supply system to the nominal distribution pressure or vacuum.

E.3.12.2.2 Except for vacuum pipelines, allow a flow of gas from each terminal unit in turn. Close the supply shut-off valve and allow the pressure in each pipeline to fall to atmospheric.

All gases except air should be vented outside the building.

E.3.12.2.3 Open the supply shut-off valve and refill each pipeline to the nominal distribution pressure. Repeat the procedure given in E.3.12.2.1 and E.3.12.2.2 as many times as required to give a gas concentration which conforms to the requirements of 12.6.14.

E.3.12.2.4 Leave each pipeline system at nominal distribution pressure with the supply system connected.

E.3.12.2.5 A sample of 5 % of terminal units for air for breathing and for driving surgical tools (the terminal units most distant from the source of supply on each branch) should be tested for water-vapour concentration.

E.3.12.2.6 Record on Form H 17 that all pipeline systems are filled with the specific gas and that the water-vapour concentration at selected terminal units is in accordance with 5.5.2.2 or 5.5.2.4.

E.3.13 Tests for gas identity

E.3.13.1 General conditions

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 E.3 should have been satisfactorily completed before this test is begun

E.3.13.2 Example of procedure

All terminal units should be tested as follows:

a) for each pipeline system which contains gas with a characteristic oxygen concentration [e.g. oxygen (100 % volume fraction), oxygen-enriched air (in accordance with specification), oxygen/nitrous oxide mixture (in accordance with specification), air for breathing (21 % volume fraction) and air for driving surgical tools (21 % volume fraction)], measure the oxygen concentration using an oxygen analyser;

b) for pipeline systems which contain gas with the same characteristic oxygen concentration but at different pressures [e.g. air for breathing ($400\,^{+100}_{0}$) kPa and air for driving surgical tools ($800\,^{+200}_{-100}$) kPa], measure the pressure using a pressure gauge;

c) 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;

d) for vacuum systems, measure the pressure using a vacuum gauge.

Record the results on Form H 18.

Table E.1 — Summary of tests required — Pipeline with terminal unit base blocks

Test No.	Description	Specification clause	Procedure clause	Form
1	Mechanical integrity	12.5.1	E.2.1	H 1
2	Leakage	12.5.2	E.2.2	H 1
3	Cross-connection or obstruction	12.5.3	E.2.3	H 2
4	Marking and supports	12.5.4	E.2.4	H 1
5	Design specification	12.5.5	E.2.5	H 3

Table E.2 — Summary of tests required — Complete installation

Test No.	Description	Specification clause	Procedure clause	Form
6	Compressed-gas leakage	12.6.1.1	E.3.1.1	H 4
7	Vacuum leakage	12.6.1.2	E.3.1.2	H 5
8	Shut-off valve leakage	12.6.2.1	E.3.2	H 6
9	Shut-off valve identification	12.6.2.2	E.3.2	H 6
10	Cross-connection	12.6.3	E.3.3	H 7
11	Obstruction	12.6.4	E.3.4	H 8
12	Terminal units	12.6.5	E.3.4	H 8
13	NIST or DISS connectors	12.6.5	E.3.4	H 9
14	System performance	12.6.6	E.3.5	H 10
15	Pressure-relief valves	12.6.7	E.3.6	H 11
16	Sources of supply	12.6.8	E.3.7	H 12
17	Monitoring and alarm systems	12.6.9	E.3.8	H 13
18	Particulate contamination	12.6.10	E.3.9	H 14
19	Contaminants in air	12.6.11	E.3.10	H 15
20	Oxygen concentration and contaminants in oxygen-enriched air	12.6.12	E.3.11	H 16
21	Filling with specific gas	12.6.13	E.3.12	H 17
22	Gas identity	12.6.14	E.3.13	H 18
	Construction labels removed	12.7.3		

Annex F
(informative)

Temperature and pressure relationships

F.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 pressure 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 F.1.

F.2 Example

An example of correction using the diagram in Figure F.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 can be confirmed by calculation using the equation in F.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).

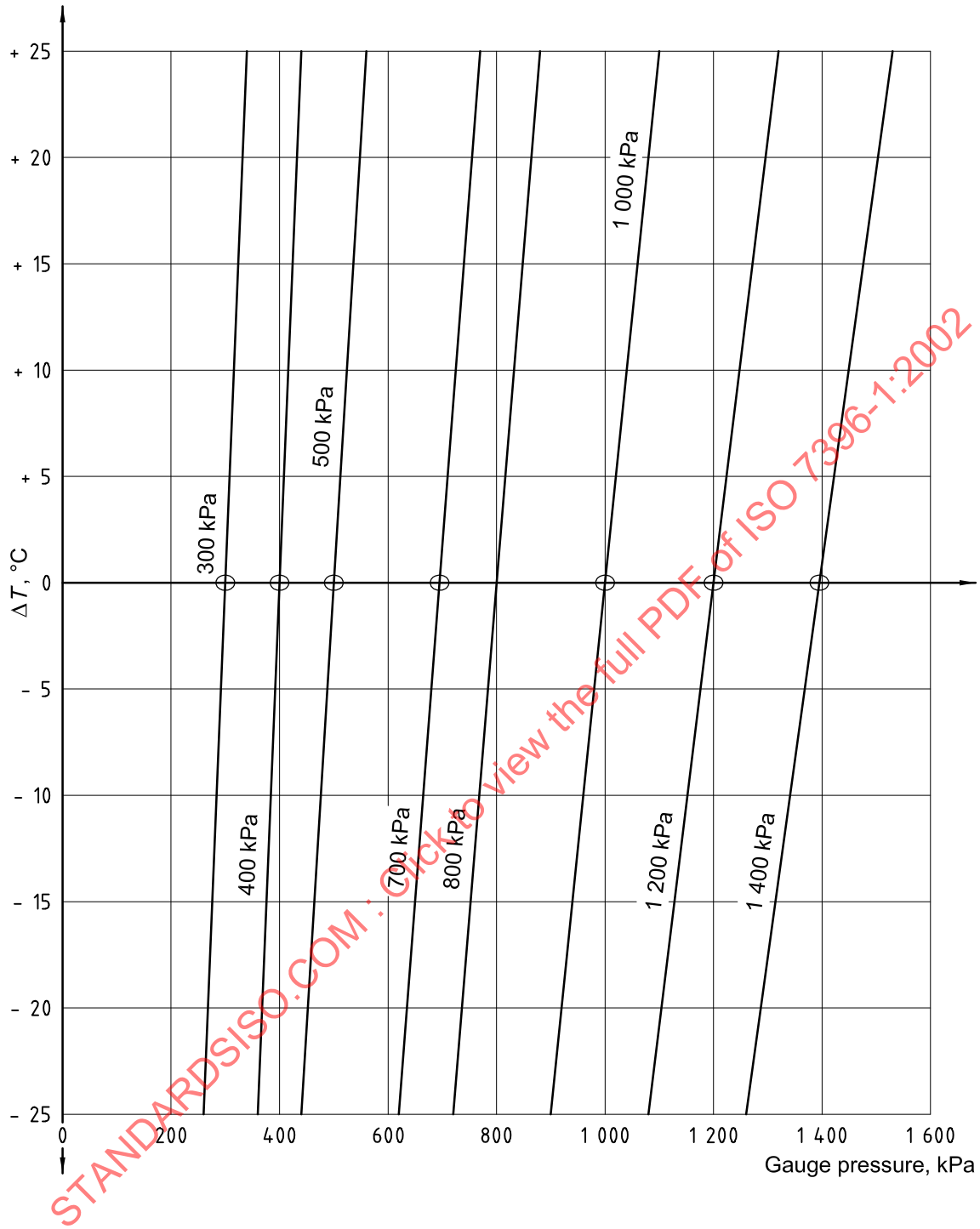


Figure F.1 — Relationship between temperature and pressure at typical pipeline pressures

Annex G
(informative)

Determination of total leakage from terminal units

The maximum permissible leakage per terminal unit specified in ISO 9170-1 is 0,029 6 ml/min (which is equivalent to 0,03 kPa·l/min or 1,8 kPa·l/h). The total leakage will be proportional to both the duration (hours) of the test and the number of terminal units.

The pressure drop in the system due to this leakage will be inversely proportional to the total volume of the system. Therefore the following formula can be used to calculate the maximum pressure drop due to leakage from terminal units.

$$\Delta p = 1{,}8 n \cdot t / V$$

where

Δp is the maximal allowable pressure drop, in kilopascals;

t is the duration of the test (between 2 h and 24 h);

n is the number of terminal units;

V is the volumetric capacity, in litres, of the pipeline system.

NOTE 1 It may be preferable to test small sections of the system individually, in which case the number of terminal units (n) and the volumetric capacity (V) are those of the section under test.

NOTE 2 The volumetric capacity can be calculated from the dimensions of the installed pipe or by the method given in annex J.

NOTE 3 This formula assumes that all terminal units are leaking at the maximum rate permitted by ISO 9170-1. This is unlikely to occur, and the actual leakage due to terminal units installed in a system is normally small.

Annex H
(informative)

Typical forms for certification of the medical gas pipeline system

H.1 General

The forms listed below are to be completed during testing and commissioning pipeline systems for compressed medical gases and vacuum in accordance with annex E.

H.2 Medical gas pipeline system tests — Summary of tests

(Sheet_____of_____sheets)

This is to certify that the following tests have been carried out on the medical gas pipeline system at _____

Test No.	Description	Form	Test and procedures satisfactorily completed on
1	Mechanical integrity	H 1	
2	Leakage	H 1	
3	Cross-connection or obstruction	H 2	
4	Marking and supports	H 1	
5	Design specification	H 3	
6	Compressed-gas leakage	H 4	
7	Vacuum leakage	H 5	
8	Shut-off valve leakage	H 6	
9	Shut-off valve identification	H 6	
10	Cross-connection	H 7	
11	Obstruction	H 8	
12	Terminal units	H 8	
13	NIST or DISS connectors	H 9	
14	System performance	H 10	
15	Pressure-relief valves	H 11	
16	Sources of supply	H 12	
17	Monitoring and alarm systems	H 13	
18	Particulate contamination	H 14	
19	Contaminants in air	H 15	
20	Contaminants in oxygen-enriched air	H 16	
21	Filling with specific gas	H 17	
22	Gas identity	H 18	
	Construction labels removed		

Contractor's Representative

Position _____ Signature _____

Date _____ Name _____

Health Care Facility Representative

Position _____ Signature _____

Date _____ Name _____

Authorized Person

Position _____ Signature _____

Date _____ Name _____

H.3 Medical gas pipeline test — Form H 1

(Sheet_____of_____ sheets)

Health Care Facility _____ Scheme _____

Pipeline with terminal unit base blocks:

Tests for mechanical integrity and leakage, inspection of marking and supports

This is to certify that a **mechanical integrity test** in accordance with E.2.1 and a **leakage test** in accordance with E.2.2 were carried out on the piped _____ system. During the test the pressures shown below were observed. Marking and supports have also been inspected in accordance with E.2.4.

Mechanical integrity test				**Inspection of markings and supports**	
Medical gas	**Section tested**	**Test pressure** kPa	**Hours on test**	**Marking**	**Supports**

Leakage test								
Medical gas	**Section tested**	**Test pressure** kPa	**Hours on test**	**Pressure drop** Δp kPa	**Pass/Fail** ($\Delta p <$ 0,025 %/h)	**Initial temp.** °C	**Final temp.** °C	**Pressure change due to temp.** kPa

For the purpose of this test the following links were made:

Contractor's Representative

Position _____ Signature _____

Date _____ Name _____

Health Care Facility Representative

Position _____ Signature _____

Date _____ Name _____

Authorized Person

Position _____ Signature _____

Date _____ Name _____

H.4 Medical gas pipeline tests — Form H 2

(Sheet_____of_____ sheets)

Health Care Facility _____ Scheme _____

Pipeline with terminal unit base blocks

Cross-connection or obstruction test

This is to certify that a cross-connection or obstruction test in accordance with E.2.3 was carried out as follows:

Medical gas system	Location

No cross-connections were found between these systems. No obstruction was found in any system.

Contractor's Representative

Position _____ Signature _____

Date _____ Name _____

Health Care Facility Representative

Position _____ Signature _____

Date _____ Name _____

Authorized Person

Position _____ Signature _____

Date _____ Name _____

H.5 Medical gas pipeline tests — Form H 3

(Sheet_____of_____sheets)

Health Care Facility _____ Scheme _____

Pipeline with terminal unit base blocks

Check of design specification

This is to certify that the following medical gas pipelines have been checked for compliance with the design specification in accordance with E.2.5.

Medical gas	Pipeline sizing	Location of		Connectors for	
		terminal units	shut-off valves	pressure-relief valves	pressure regulators

Contractor's Representative

Position _____ Signature _____

Date _____ Name _____

Health Care Facility Representative

Position _____ Signature _____

Date _____ Name _____

Authorized Person

Position _____ Signature _____

Date _____ Name _____

H.6 Medical gas pipeline tests — Form H 4

(Sheet_____of_____ sheets)

Health Care Facility _____ Scheme _____

Complete installation

Compressed-gas leakage tests

This is to certify that a leakage test in accordance with E.3.1 was carried out on the following pipeline systems:

Medical gas	**Section tested**	**Number of terminal units** n	**Time on test** t h	**Section volume** V l	$\frac{1{,}8nt}{V}$	$t \times$ **test pressure** $\times$ 0,025 %	**Total pressure drop allowed** kPa	**Observed pressure drop** kPa	**Pass/ Fail**	**Initial temperature** °C	**Final temperature** °C	**Pressure change due to temperature** kPa

Contractor's Representative

Position _____ Signature _____

Date _____ Name _____

Health Care Facility Representative

Position _____ Signature _____

Date _____ Name _____

Authorized Person

Position _____ Signature _____

Date _____ Name _____