

Figure A.23 — Single-stage medical gas pipeline distribution system

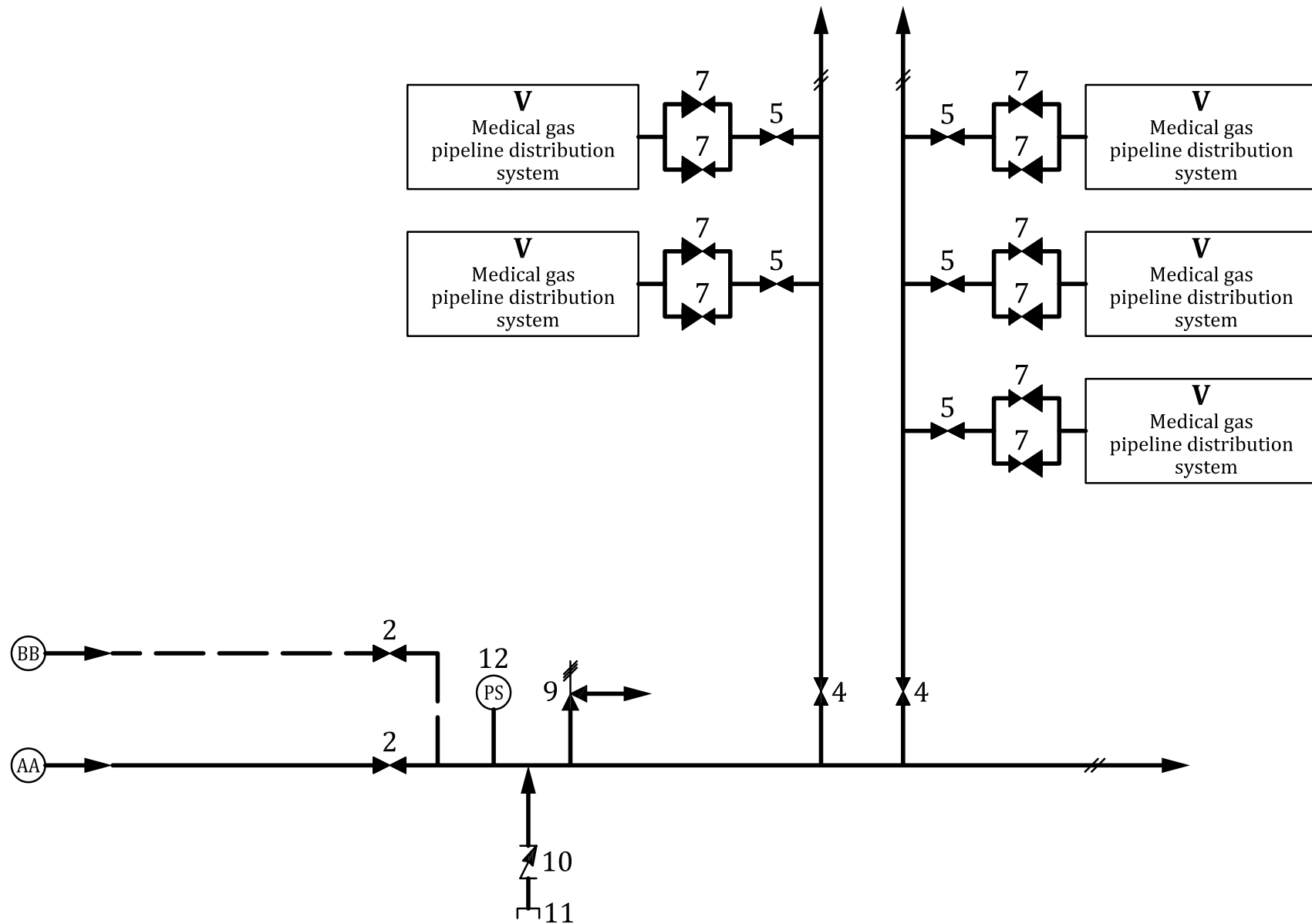


Figure A.24 — Double-stage medical gas pipeline distribution system

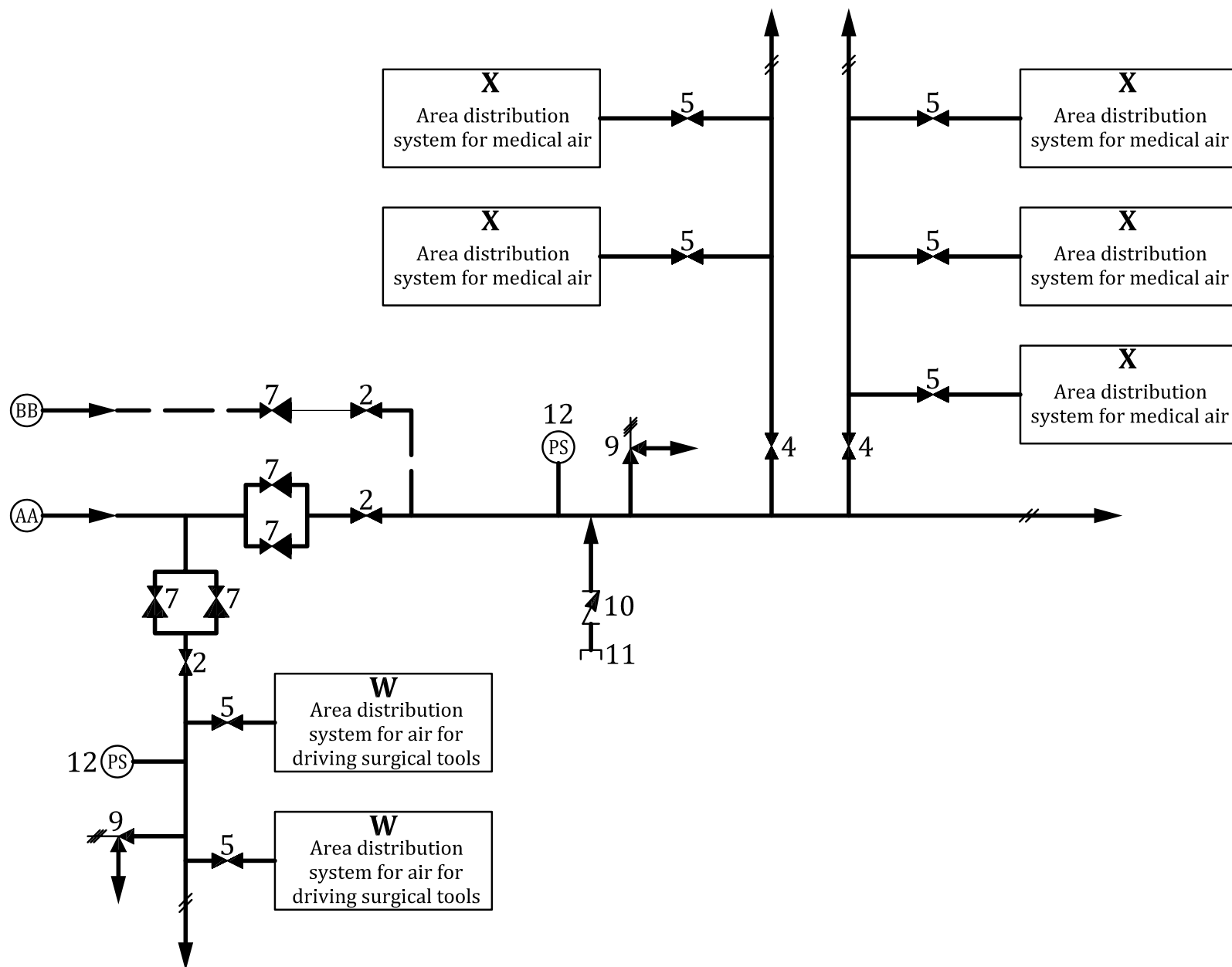


Figure A.25 — Single-stage medical gas pipeline distribution system including distribution system for air for driving surgical tools

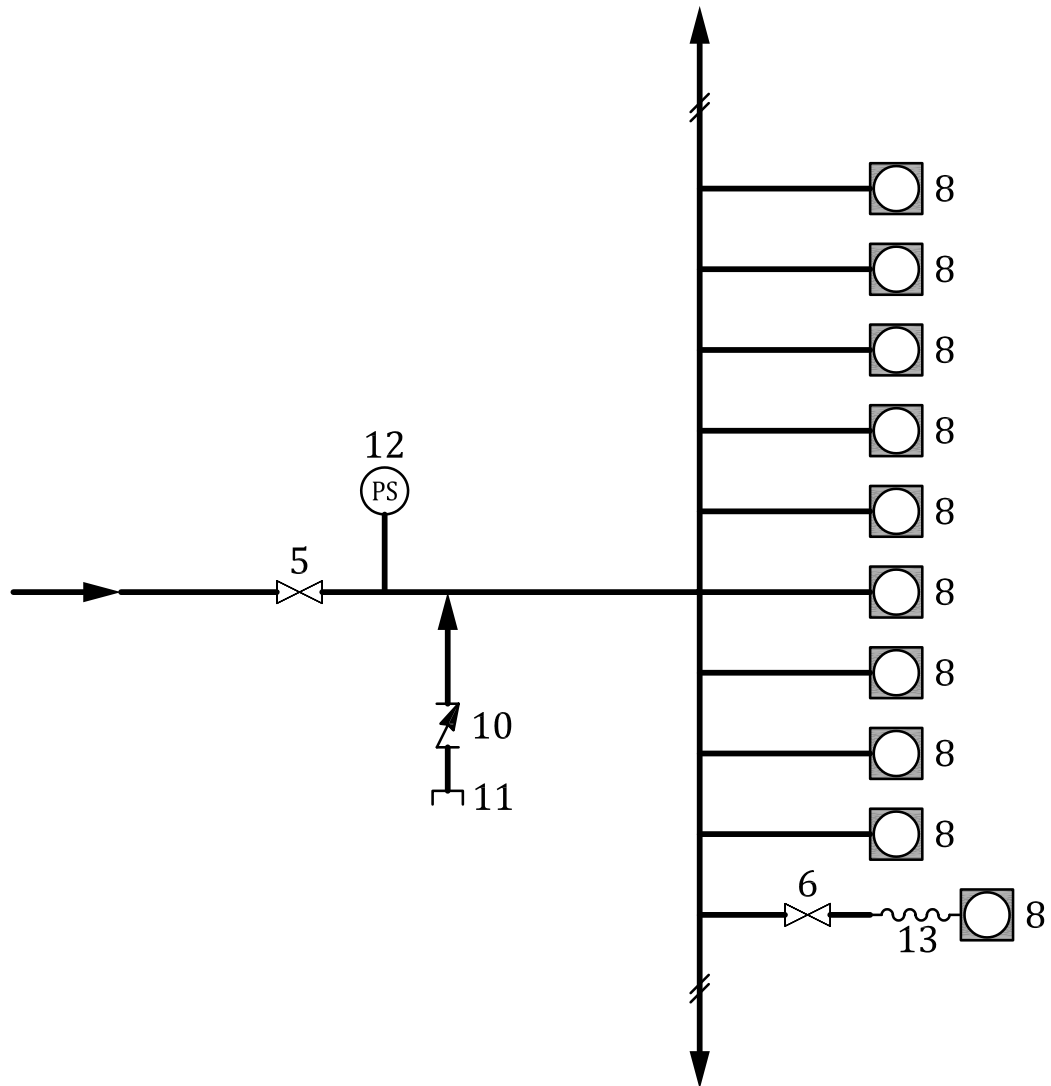


Figure A.26 — Medical gas area distribution system

Annex B

(informative)

Guidelines for location of cylinder manifolds, cylinder storage areas and stationary vessels for cryogenic or non-cryogenic liquids

B.1 Location of cylinder manifolds

A supply system with cylinders should be installed in a well ventilated and fire-resistant room that is specially constructed or suitably modified. Alternatively, it may be installed in the open air under cover, protected from the weather and the area fenced to prevent access by unauthorized persons.

NOTE Regional or national regulations which apply to the location of cylinder manifolds can exist.

B.2 Location of cylinder storage areas

B.2.1 Cylinder storage areas should be well ventilated and fire-resistant. If located in the open air, they should be under cover and protected from the weather. Cylinder storage areas should be fenced to prevent access by unauthorized persons.

B.2.2 Adequate vehicle access for safe unloading and handling of cylinders should be provided.

NOTE Regional or national regulations which apply to cylinder storage areas can exist.

B.3 Location of stationary vessels

B.3.1 Stationary vessels containing cryogenic or non-cryogenic liquids should not be installed over subterranean structures such as underground bunkers, basement rooms, etc., and should be more than 5 m away from openings to trenches, subterranean structures, manholes, gullies or traps, and at least 5 m from public access routes.

NOTE Regional or national regulations which apply to the location of stationary cryogenic or non-cryogenic vessels can exist.

B.3.2 Stationary vessels containing cryogenic or non-cryogenic liquids should be installed in a position which is open to the air and at ground level, not on the roof of a building. The control equipment should be protected from the weather and the area fenced to prevent access by unauthorized persons.

B.3.3 Adequate access for a vehicle should be provided so that a cryogenic or non-cryogenic liquid supply vessel may be filled. The ground in the immediate vicinity of an oxygen or nitrous oxide filling point should be of concrete or other non-combustible material.

B.3.4 Points of possible escape of gas from means of pressure relief should be more than 5 m away from public access areas.

Annex C (informative)

Example of procedure for testing and commissioning

C.1 General

This test procedure is given as an example of how the specifications of Clause 12 may be verified so that the system can be commissioned and certified. Other procedures which validly test these specifications may be devised. In this procedure, the given sequence of tests and the general requirements of 12.1 and 12.2 are all important and should be followed. When the results of a test do not meet the pass criteria, remedial work should be carried out and previous tests repeated as necessary.

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

Typical forms for documentation of conformity of the system are given in Annex D. Summaries of the typical tests required which list the specification, procedure and form for each test are given in Forms D.1.1 and D.1.2.

C.2 Inspections before concealment (see 12.3)

C.2.1 Inspection of marking and pipeline supports (see 12.5.1)

C.2.1.1 General

Visually inspect that marking has been correctly placed on all pipelines, especially adjacent to T-connections and where pipelines pass through floors or wall partitions. The marking should be in accordance with 10.1. Check that the pipeline supports are in accordance with 11.2.

C.2.1.2 Test results

Record the results on Form D.2.

C.2.2 Check for compliance with the design specifications (see 12.5.2)

C.2.2.1 General conditions

No pipeline should be concealed.

C.2.2.2 Example of procedure

Visually inspect each pipeline to check that the sizing of the pipelines, the location of terminal units, line pressure regulators (if fitted) and shut-off valves are in accordance with the design specification.

C.2.2.3 Test results

Record the results on Form D.3.

C.3 Tests and procedures before use of the systems (see 12.4)

C.3.1 Tests for leakage and mechanical integrity

C.3.1.1 Tests for mechanical integrity of vacuum pipeline systems (see 12.6.1.1)

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

C.3.1.1.1 General

This test may be carried out on sections of the pipeline, provided that no part of the system is omitted. The section to be tested should be completely installed and held firmly in place. The base blocks of all terminal units should be fitted and blanked. All connectors for pressure-relief valves, pressure gauges and pressure switches should be blanked. If separate sections are tested, each section under test should be isolated from the remainder of the system.

C.3.1.1.2 Example of procedure

Connect a suitable pressure-measuring device to the section under test. Fill the section(s) to be tested with test gas at 500 kPa. After 5 min, check that the system has not ruptured.

C.3.1.1.3 Test results

Record the results on Form D.4.1.

C.3.1.2 Test for leakage into the vacuum pipeline system (see 12.6.1.2)

C.3.1.2.1 General

All terminal units, valves and other devices such as vacuum gauges and pressure switches should have been installed. The vacuum supply system should be connected to the system under test.

C.3.1.2.2 Example of procedure

Connect a vacuum gauge to the system. Operate the vacuum supply system until the nominal distribution pressure is achieved. With the system at nominal distribution pressure, isolate the vacuum supply system. Check that the pressure increase after 1 h does not exceed 20 kPa with all shut-off valves open.

C.3.1.2.3 Test results

Record the results on Form D.4.2.

C.3.1.3 Test for mechanical integrity for compressed medical gas pipeline systems (see 12.6.1.3)

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

C.3.1.3.1 General

This test may be carried out the pipeline in sections, provided that no part of the system is omitted. The section to be tested should be completely installed and held firmly in place. The base blocks of all terminal units should be fitted and blanked. All connectors for pressure-relief valves, pressure gauges and pressure switches should be blanked. If separate sections are tested, each section under test should be isolated from the remainder of the system.

C.3.1.3.2 Example of procedure

Connect a suitable pressure-measuring device to the section under test. Fill the section(s) to be tested with test gas at a pressure 1,2 times the maximum pressure as specified in 12.6.1.3 for that section. After 5 min, check that the system has not ruptured.

C.3.1.3.3 Test results

Record the results on Form D.5.1.

C.3.1.4 Test for leakage from the compressed medical gas pipeline systems (see 12.6.1.4)

C.3.1.4.1 General

These tests may be carried out on sections of each pipeline, provided that no section is omitted and the integrity of the pipeline is maintained. All terminal units, valves, line pressure regulators, gauges and pressure sensors should be fitted. The supply system should be isolated from the pipeline.

C.3.1.4.2 Example of procedure

Connect a suitable pressure-measuring device to each section of the system(s) under test.

For single-stage pipeline distribution systems, pressurize with test gas at the nominal distribution pressure in each section upstream and downstream of each area shut-off valve. The means to allow physical isolation should be used between each section upstream and downstream of each area shut-off valve.

For double-stage pipeline distribution systems, pressurize with the test gas at the nominal supply system pressure for each section upstream of each line pressure regulator and at the nominal distribution pressure for each section downstream of each line pressure regulator. The means to allow physical isolation should be used between sections upstream and downstream of each line pressure regulator.

NOTE For the purposes of this test, the shut-off valves fitted upstream and downstream of each line pressure regulator (see 7.4.2) together with the line pressure regulator set at zero flow may be considered as a means to allow physical isolation.

Disconnect and remove the test gas supply. Record the pressure and room temperature initially and at the end of the test period (2 h to 24 h). Check that in each section upstream of each area shut-off valve (or each line pressure regulator), the pressure drop does not exceed 0,025 % of the initial test pressure per hour.

Check that in each section downstream of each area shut-off valve (or line pressure regulator), the pressure drop does not exceed 0,4 %/h of the initial test pressure in sections not including flexible hoses in medical supply units or 0,6 %/h of the initial test pressure in sections including flexible hoses in medical supply units.

C.3.1.4.3 Test results

Record the results on Forms D.5.2 and D.5.3.

C.3.1.5 Combined tests for leakage and mechanical integrity of compressed medical gas pipeline systems (before concealment) (see 12.6.1.5)

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

C.3.1.5.1 General

This test may be carried out on the pipeline in sections, provided that no part of the system is omitted. The supply system should be isolated from the pipeline. The section to be tested should be completely

installed and held firmly in place. The base blocks of all terminal units should be fitted and blanked. All connectors for pressure-relief valves, pressure gauges and pressure switches should be blanked. If separate sections are tested, each section under test should be isolated from the remainder of the system.

C.3.1.5.2 Example of procedure

C.3.1.5.2.1 Connect a suitable pressure-measuring device to the section under test. Pressurize with test gas each section to be tested at a pressure 1,2 times the maximum pressure, as specified in **12.6.1.5**, for that section. After 5 min, check that the system has not ruptured.

C.3.1.5.2.2 At the same test pressure(s), check that the pressure drop during a test period of 2 h to 24 h does not exceed 0,025 % of the initial test pressure per hour, except for pressure changes due to temperature variations.

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

C.3.1.5.3 Test results

Record the results on Form D.6.1.

C.3.1.6 Combined tests for leakage and mechanical integrity of compressed medical gas pipeline systems (after concealment) (see 12.6.1.6)

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

C.3.1.6.1 General

These tests may be carried out on the pipeline in sections provided that no section is omitted and the integrity of the pipeline is maintained. All terminal units, valves, line pressure regulators, gauges and pressure sensors should be fitted. The supply system should be isolated from the pipeline.

C.3.1.6.2 Example of procedure

C.3.1.6.2.1 Connect a suitable pressure-measuring device to the section under test. Pressurize with test gas each section to be tested at a pressure 1,2 times the maximum pressure, as specified in **12.6.1.6**, for that section. After 5 min, check that the system has not ruptured.

C.3.1.6.2.2 Carry out the test for leakage in accordance with **12.6.1.4**.

C.3.1.6.3 Test results

Record the results on Form D.6.2, Form D.5.2 and/or Form D.5.3.

C.3.2 Test of area shut-off valves for leakage and closure and checks for correct zoning and correct identification (see 12.6.2)

C.3.2.1 General

The tests given in C.3.1 should have been completed satisfactorily and all terminal units should be closed. This test may be carried out on more than one system at a time.

The test for leakage and closure of area shut-off valves does not apply to vacuum systems.

C.3.2.2 Example of procedure

C.3.2.2.1 Pressurize the pipeline system at its nominal distribution pressure with all area shut-off valves open. Connect a pressure-measuring device downstream of each area shut-off valve. Close all area shut-off valves.

C.3.2.2.2 Depressurize the pipeline system downstream of each area shut-off valve to 100 kPa by opening a terminal unit. Close the terminal unit.

C.3.2.2.3 Check that the pressure increase does not exceed 5 kPa after 15 min.

C.3.2.2.4 Note the total number and the location of terminal units controlled by each area shut-off valve and check that these terminal units are correctly labelled.

C.3.2.3 Test results

Record the results on Form D.7.

C.3.3 Test for cross-connection (see 12.6.3)

C.3.3.1 Example 1 of procedure (FD S90-155^[32])

To ensure non-inversion and identity of gas, the manufacturer should use the following test method. Begin with an initial test of absence of gas to all terminal units in the sector to be tested, by depressurizing the pipeline system and cutting off the supply to the section. Ensure the absence of gas to all terminal units.

Then pressurize a single gas pipeline, for example oxygen. Verify that the one system has pressure and there is no pressure at other terminal units. Positive identification of the gas with analysis (for example the percentage of oxygen for oxygen terminal units) on the terminal unit nearest and furthest from the pipeline located downstream of the valve area should be confirmed using a gas-specific analyser.

Then, carry out the same test, one at a time, on terminal units for other gases. Start with the more oxidizing gas and progress to the less oxidizing. If two non-oxygenated gases (nitrous oxide, carbon dioxide, nitrogen) are piped into one area, it is imperative to distinguish between the gases using another discriminating test.

NOTE 1 The technical means of identification may be those mentioned above or those of the European Pharmacopoeia, for example by specific analysers or colorimetric tubes.

NOTE 2 Similar test methods may be used provided that they comply with the requirements of 4.2.

In case a cross-connection and/or fault in gas identity is discovered during test, a full test shall be carried out again after identification and correction of the defect.

C.3.3.2 Example 2 of procedure (Taken from CSA Z7396.1-12^[52])

On successful completion of the cross-connection tests using Method 1 from B.3.2, Method 2 from B.3.3, or Method 3 from B.3.4, each pipeline distribution system for compressed gases is filled and emptied with its specific gas a sufficient number of times to displace the test gas. Each terminal unit is opened in turn to ensure that no sections of pipeline remain filled with test gas.

For Method 2, the procedure is as follows:

- a) When all medical gas piping systems have been tested in accordance with 11.4.3.2, the source of test gas is disconnected and the proper gas source of supply connected to each respective system.
- b) Each system is purged a sufficient number of times to remove the test gas.

- c) The line pressure regulator controlling each piped gas is adjusted to maintain a clearly recognizable pressure difference of no less than 35 kPa (5 psi) between each gas.
- d) The vacuum system is in operation and the cut-in and cut-out settings of the vacuum pump controller are measured and recorded.
- e) Following the adjustment and recording of pressures, as specified in Items (c) and (d), every terminal is tested using a pressure gauge. The actual pressure is measured with a gauge attached to the specific adaptor for that terminal unit, locked in place before taking the reading. The test is never made with a so-called "Universal Adaptor". The pressure at the terminal unit is recorded at a flow of 15 to 25 L/min (0.5 to 0.9 ft³/min) and it must be the same as the pressure selected or recorded in accordance with Items (c) and (d).

For Method 3, the procedure is as follows:

- a) All medical gas piping systems have been connected to their respective supply systems.
- b) Each piping system is back purged a sufficient number of times to remove the test gas and/or nitrogen for non- nitrogen systems.
- c) All zone valves for the respective area being tested are closed and the pressure of each gas is adjusted to a level that has a clearly recognizable pressure difference of no less than 35 kPa (5 psi) between each gas.
- d) Vacuum and AGSS zone valves are closed and each system is set to a level below nominal system vacuum. Suggest -40 kPa (-12 inHg) for vacuum and -27 kPa (-8 inHg) for AGSS testing.
- e) Following the adjustments and recorded pressures as specified in Items (c) and (d), every terminal unit is tested using a pressure gauge. Care must be taken to ensure pressure differentials are maintained. If required, testing is stopped and the pressure is replenished to the initial setting. The actual pressure is measured with a gauge attached to the specific adaptor for that terminal unit.
- f) Each terminal unit is identified by name and colour.
- g) Once all terminal units have been tested at their adjusted pressure levels, the zone valve for a respective gas with adaptor connected is slowly opened to confirm the respective gas zone valve and respective terminal unit of said gas are the same. All zones are opened individually in this fashion.
- h) All the pressure gas terminals are then tested using the appropriate gas analyser.
- i) If the pressures cannot be maintained due to a system malfunction (e.g., leak in the system, valve not holding), testing cannot commence until the malfunction is investigated and corrected.

The outflow from each gas terminal unit is tested using an appropriate gas analyser to confirm the presence of the desired gas. The nominal gas concentration is measured and recorded and shown to conform to Table D.4, Part A.

C.3.4 Tests for obstruction and flow (see 12.6.4)

C.3.4.1 General

These tests may be carried out at the same time as the cross-connection test described in C.3.3. In this case, only one pipeline system at a time is under pressure. Alternatively, after completion of the tests given in C.3.3, all pipeline systems may be pressurized at nominal distribution pressure and the tests described in C.3.5 and C.3.6 carried out simultaneously.

C.3.4.2 Example of procedure

C.3.4.3 Insert a gas-specific test probe with pressure gauge(s) and flow-measuring device into each terminal unit in turn.