TECHNICAL BULLETIN

Prepared by WG-15 TB 23/25 – January 2025

Checklist of Compliance to New or Modified Requirements of EN ISO 7396-1:2016 Standard

The revision of EN ISO 7396-1, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum* has been published in February 2016. Following publication, there has been requests about what are the significant changes to the standard and how they could be identified to determine whether systems are compliant with the new requirements.

This checklist is not claimed to be exhaustive but will provide an overview of the major changes to the standard to enable an assessment to be made as to whether a medical gas pipeline system will be compliant with the new or modified requirements detailed in the latest revision of EN ISO 7396-1.

When using the checklist, if the answer to any of the following questions is yes, it means that the pipeline system is compliant to the new or modified requirements in EN ISO 7396-1:2016.

It should be noted that compliance to the applicable standards is the responsibility of the medical gas pipeline system owner.

Nr.	DESCRIPTION OF THE REQUIREMENTS	YES	NO	NA
A	**SUPPLY SYSTEMS – GENERAL REQUIREMENTS**			
A.1	If the primary and secondary source of supply are dependent upon an electrical power supply, is the activation of the reserve source(s) of supply automatic? (5.2.5)			
A.2	If all sources of supply are dependent upon an electrical power supply, is the connection of the reserve source(s) of supply to the emergency electrical power supply automatic? (5.2.5)			
A.3	In the case the reserve source(s) of supply are dependent on an electrical supply, has a risk analysis been performed by the manufacturer in accordance to the principle of EN ISO 14971 together with the healthcare facility to determine if this solution is acceptable? (5.2.5)			
A.4	In case of fire inside the room(s) housing the primary and secondary sources of supply, is the reserve source(s) of supply safely accessible and able to be activated? (5.2.5)			
A.5	If a pressure-relief valve is removed, e.g. for maintenance, is the pipeline still protected from overpressure by another means of pressure relief? (5.2.6.6)			
A.6	In case of fire in the room(s) of the sources of supply, is the location of each maintenance supply assembly accessible in order to allow the supply of gas to the pipeline? (5.2.7.2)			
A.7	Is the supply of ozone sterilizers fully independent from the medical oxygen pipeline system? (5.2.9) NOTE The intention is to prevent backflow into the oxygen pipeline system			
B	**SUPPLY SYSTEMS WITH CYLINDERS, CYLINDER BUNDLES OR HIGH-PRESSURE RESERVOIR(S)**	**YES**	**NO**	**NA**
B.1	In the case the oxygen reserve consists of only one cylinder or cylinder bundle, does the manifold have at least one additional inlet point? (5.3.7) NOTE The intention is to be able to change the cylinder or cylinder bundle without affecting the continuity of supply			

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C	SUPPLY SYSTEMS WITH CRYOGENIC OR NON-CRYOGENIC VESSEL(S)	YES	NO	NA
C.1	If materials susceptible to cold embrittlement, such as carbon steel, are used downstream of the vaporizer system, is there means provided to prevent the ingress of cryogenic liquid into the pipeline system and to initiate an alarm when this means is activated? (5.4.2) *Note: copper is not susceptible to cold embrittlement*			
D	**SUPPLY SYSTEMS FOR AIR**	**YES**	**NO**	**NA**
D.1	If periodic change of the filter element(s) of a supply system with air compressor is not scheduled, are any means provided to verify the status of the filter element? .(5.5.2.3) NOTE Such means can be measuring the pressure drop across the filter			
D.2	Are all compressor units protected from overheating and are any means provided to avoid the release of toxic product into the pipeline in case of overheating (e.g. by shutting off and isolating the affected compressor from the pipeline)?.. (5.5.2.5)			
D.3	Is at least one CO alarm sensor fitted to the pipeline system downstream of all conditioning units? (5.5.2.5)			
D.4	Is there a means to ensure the continuity of supply following a failure of any control system? (5.5.2.11)			
D.5	Are any means provided to purge the medical air reservoir? (5.5.3.7)			
D.6	Does each oxygen analyser ensure an accuracy of ±1 % or better of the measured value? (5.5.3.8)			
E	**SUPPLY SYSTEMS FOR VACUUM**	**YES**	**NO**	**NA**
E.1	In case of interruption of the main power, are means provided to ensure correct vacuum to the pipeline system during a specified period of time? (5.7.6) NOTE This period of time should be determined by risk management			
E.2	Is each bacterial filter rated as HEPA ISO 35H or better under ISO 29463-1? (5.7.11)			
E.3	Is the vacuum supply system used for dentistry independent from the healthcare facility general vacuum supply system? (5.7.14)			
F	**LOCATION OF SUPPLY SYSTEMS**			
F.1	Are gas cylinder supply systems located in rooms free from any equipment with open flames (e.g. boilers, gas water heaters)? (5.8.1)			
F.2	Are the rooms used for housing supply systems provided with a means of fire detection? (5.8.2)			
F.3	Are the rooms used for housing supply systems in which the gas can accumulate provided with an oxygen monitor and alarm with an auditory and visual signal at the entrance warning when the oxygen concentration is below 19.5 % or above 23.5 %? (5.8.2) NOTE This requirement doesn't apply to medical air supply systems			
F.4	Are the rooms used for housing CO_2 supply systems in which the gas can accumulate provided with a CO_2 monitor and alarm with an auditory and visual signal at the entrance warning when the CO2 concentration is above a 1,5 %? (5.8.2 in Amendment 1)			
G	**MONITORING AND ALARM SYSTEMS**	**YES**	**NO**	**NA**
G.1	Is the location of the source(s) of supply provided with an indicator panel, displaying all emergency operating alarm signals? (6.2.2) NOTE See paragraph 6.6 of the Standard for the list of the alarms			
G.2	Has a formalized risk assessment been performed to determine the need for additional batteries or uninterruptable power supplies (UPS) for the monitoring and alarm systems? (6.2.3)			
G.3	Is an operating alarm provided for medical air supplied from a compressor system or for oxygen 93 supplied from a concentrator system, when CO level exceeds 10 ppm or lower if required by local regulation? (6.4)			

G.4	Is an operating alarm provided in case of malfunctioning of a supply system with an oxygen concentrator? (6.4)			
G.5	Is an operating alarm provided to indicate that the reserve source of supply is in use? (6.4)			
G.6	Is an operating alarm provided to indicate that the content of the reserve source of supply is below 50% of capacity for compressed gas(es) in cylinder (e.g. oxygen, air, nitrogen) or less than 40 bar for liquefied gas(es) in cylinders (e.g. nitrous oxide and carbon dioxide)? (6.4)			
G.7	Is an operating alarm provided to indicate the failure of the external power supply? (6.4)			
G.8	Are emergency operating alarms provided for the temperature of any compressor exceeding the threshold defined by the manufacturer? (6.6)			
G.9	Are emergency operating alarms provided for medical air supplied from a compressor system, when CO level exceeds 25 ppm or lower if required by local regulation? (6.6)			
G.10	Are emergency operating alarms provided for an oxygen concentration below 90%, for systems supplied from oxygen concentrator? (6.6)			
G.11	Are emergency operating alarms provided for an oxygen concentration outside the specified limits, for systems supplied from proportioning units? (6.6)			
H	**PIPELINE DISTRIBUTION SYSTEMS**	**YES**	**NO**	**NA**
H.1	If gases are delivered at different nominal distribution pressures, is nitrous oxide delivered at a nominal distribution pressure lower than that for oxygen and medical air? (7.2.1)			
H.2	If the pipeline systems incorporate permanent low pressure flexible connections, are they made of metallic material? (7.3.1) NOTE Permanent means are not intended to be replaced during the life of the pipeline system			
H.3	If the pipeline systems incorporate permanent low pressure flexible connections, have they been tested as part of the pipeline system when it was commissioned? (7.3.1)			
H.4	Are the line pressure regulators protected against pressure above 30 bar? (7.4.1) *Note: this can be achieved with a pressure-relief device*			
H.5	Is there a management system controlling the two-line pressure regulators configuration to ensure the continuity of supply in case of failure of one pressure regulator? NOTE: The standard recommends that the two-line pressure regulators are not in use at the same time.			
I	**SHUT-OFF VALVES**	**YES**	**NO**	**NA**
I.1	Are the following the only components installed between area shut-off valves and the terminal units? (8.3.9) — sensors or indicators (e.g. for pressure and flow); — emergency and maintenance inlet points; — means to allow physical isolation of the service; — maintenance shut-off valves (if fitted); — operator-adjustable low-pressure regulators for air or nitrogen for driving surgical tools; and — low pressure hose assemblies complying with ISO 5359. NOTE: Other components could adversely impact with the flow of medical gas.			
I.2	Are all sensors activating emergency pressure alarms downstream of any shut-off valve? (8.3.10)			
J	**PIPELINE INSTALLATION**	**YES**	**NO**	**NA**
J.1	Are terminal units for medical gases and vacuum located only in areas intended for connection of medical devices? (11.1.3)			
K	**REQUIREMENT FOR TESTING AND COMMISSIONING THAT CAN BE USED FOR MAINTENANCE PROCEDURES**	**YES**	**NO**	**NA**
K.1	Are purging and testing carried out with medical air or the specific gas, except for those tests in which the gas is specified? (12.2.1)			

K.2	Is the absolute pressure in the vacuum pipeline systems less than 60 kPa when testing with a test flow rate of 25 L/min is performed? (Table 4)			
K.3	Is each source of supply tested for switching from one source of supply to another according to instructions for use and the requirements of part 1 ISO 7396 Standard? (12.6.8)			
K.4	Can it be proved, in cooperation of the healthcare facility, that a supply system connected to the emergency electrical system is able to start automatically when essential power is stabilized (from main or emergency power) and restart automatically when normal power is restored? (12.6.17)			
L	**INFORMATION TO BE SUPPLIED BY THE MANUFACTURER**	**YES**	**NO**	**NA**
L.1	Did the manufacturer provide instruction to the healthcare facility for the recommended calibration procedures and their frequency for all analysers and alarm sensors? (13.4.3)			

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