

## REFERENCE GUIDE ON MEDICINAL GAS CYLINDER VALVES

AIGA 097/17

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#### 1. Introduction

Many medicinal gases are used in medical facilities such as hospitals, medical clinics, healthcare facilities and homecare. It is of primary importance that medicinal gas cylinders be distinguished from gas cylinders for industrial use because of their impact on the patient's life and safety.

The outlet type of the cylinder valve is the key to connecting the correct medicinal gas to the corresponding equipment such as respiratory apparatus. The correct choice of cylinder valve could reduce the medicinal gas incidents due to gas mix-ups, wrong connections to the gas outlet and so on.

#### 2. Scope & Purpose

The purpose of this document is to provide guidelines for minimum standards in the selection of cylinder valve types for medicinal gas service. The valves for portable liquid containers are excluded. For guidelines on these container types see AIGA 016, Safety Features of Portable Cryogenic Liquid Containers for Industrial and Medical Gases [1]<sup>1</sup> or AIGA 019, Connections for portable liquid cylinders [2].

This document presents the principles for the selection and usage of medicinal gas cylinder valves, with recommendations and industry best practices.

#### 3. Definitions & Terminology

Terminology:

- *Shall* indicates that the procedure is mandatory. It is used wherever the criterion for conformance to specific recommendations allows no deviation.
- Should indicates that a procedure is recommended.
- *May* and *Need not* indicate that the procedure is optional.
- *Will* is used only to indicate the future, not a degree of requirement.
- Can indicates a possibility or ability.

#### 4. Principles of Medicinal Valve Selection and Operation

Valves meant for medical service (for both small and large cylinders) should comply with ISO 10297, Gas Cylinder-Cylinder Valves-Specification & Type Testing [3]. However, specific country regulatory requirements should also be met with regard to the selection and installation of medicinal cylinder valves.

- 4.1 Discriminating
  - Purpose: Discriminating to differentiate medicinal gas from industrial gas as well as to avoid mix-ups of different medicinal gas types.
  - As pin-index connections are unique to the gas type, this is the most effective measure to prevent cylinder mix-up at the cylinder connection including outlets, regulators and so on. Pin index valves are only in use for medicinal gases, hence they distinguish medicinal gas cylinders from gas cylinders for industrial use. The pinindex is defined in ISO 407:2004, Small Medical Gas Cylinder Pin Index Yoke-type Valve Connections [4]. Small cylinders are defined as those with a capacity of less than 10L in ISO 407.

 $<sup>^1</sup>$  References are shown in bracketed numbers and are listed in order of appearance in the reference section

Note: Do not modify the yoke on the pin index valve.

- Chrome-plated valves for all medicinal gases with the exception of those containing carbon monoxide (CO).
- 4.2 Safety and Cleanliness
  - Valve seat material: Non-toxic (non-halogenated polymer)
  - Oxidation prevention: Chrome plated valves
  - No valve adaptors to be used
  - No reuse of gaskets, especially plastic ones for medical oxygen
  - Visual check of the cylinder valves for deformation, damage, foreign objects, etc.
- 4.3 Product Integrity
  - Use of tamper-evident seals (for example, caps, cable ties, shrinkwrap)

#### 5. Recommendations for Selection and Usage of Valves

- 5.1. Valves with parallel threads are recommended for use with aluminium cylinders.
  - This would prevent the scenario where the aluminium cylinder neck thread seizes onto the valve's brass thread when over-tightened.
- 5.2. Residual Pressure Valve (RPV), also known as Minimum Pressure Retaining (MPR) valve.
  - Maintains positive pressure within the cylinder, thus avoiding atmospheric contamination from entering the cylinder in case the cylinder valve is left open.

Note: Cylinders fitted with RPVs shall still be evacuated and/or purged before filling.

- 5.3. Valve Integrated Pressure Regulator (VIPR) or Integrated valve
  - Adjusts the gas flow rate and maintains positive pressure within the cylinder which avoids atmospheric contamination as mentioned above. Note: Use of RPV/MPR or VIPR equipped with a non return device could eliminate the need for inverting small medical oxygen cylinders before filling.

#### 6. Best Practices

- 6.1. Valve Integrity
  - 100% valve leak testing every fill cycle
- 6.2. Valve Refurbishment & Replacement Cycle After hydrostatic testing, medicinal gas cylinders should be installed with new valves or refurbished valves. Do not re-use unserviced valves.
- 6.3. Valve Operation
  - (a) Use spindle key or handwheel type valves
  - (b) If using spindle key, do not over-torque by using lever extension. Follow torque levels as per manufacturer's instructions.
  - (c) Open and close valves slowly.
    - High gas volume and velocity will result in higher wear and tear of valves.
  - (d) One-time connection when gasket or washer is used (i.e. no re-use).
- 6.4. Valve Protection

Valve guards or valve caps shall be used on all cylinders with a neck ring provision to accommodate valve protection. This can:

- protect valves from damage during transportation and handling.
- facilitate ease and safety of cylinder handling

Note: Valve protection should not impede the attachment of regulator or other accessories.

#### 7. References

Unless otherwise specified, the latest edition shall apply.

[1] AIGA 016, Features of Portable Cryogenic Liquid Containers for Industrial and Medical Gases, www.asiaiga.org

[2] AIGA 019, Connections for portable liquid cylinders, www.asiaiga.org

[3] ISO 10297, Gas Cylinder-Cylinder Valves-Specification & Type, www.iso.org

[4] ISO 407:2004, Small Medical Gas Cylinder Pin Index Yoke-type Valve Connections, www.iso.org

[5] AIGA 063, Use of Residual Pressure Valves, www.asiaiga.org

[6] ISO 10297, Gas Cylinder-Cylinder Valves Specification and Type Testing, www.iso.org

#### Appendix 1: Survey of Medicinal Gas Cylinder Valves

A survey of Medicinal Gas Cylinder valves was conducted in the countries in Asia. The results are listed below.

Country	Regulated	Industry Norm
China	Yes	• 15383-2011 :Connection types and
		dimensions for gas cylinder valve outlets
Hong Kong	Yes	ISO 407 for pin index
		• BS EN 850 : 1997
India	Yes	<ul> <li>IS 3224 : 2002 Valve Fittings for Compressed Gas Cylinders Excluding Liquefied Petroleum Gas (LPG) Cylinders – Specification</li> <li>IS 7302 : 1974 Specification for Valve Fittings for Gas Cylinder Valves for Use with Breathing Apparatus</li> <li>IS 3745 : 2006 Specification for Yoke Type Valve Connection for Small Medical Gas Cylinders</li> </ul>
Indonesia	Yes	BS341 Transportable gas container valves,
Japan	Yes	ISO 407 (Pin-index) for less than 10L medical gas cylinders, JIS B 8246
Korea	Yes	• KS B 6214 Valve for High Pressure Cylinder (specifies inlet/outlets and tests required)
Malaysia	Yes	<ul> <li>MS ISO407:2004 Recommend pin-index valves for medical gases.</li> <li>ISO 5145 Cylinder valve outlets for gases and gas mixtures — Selection and dimensioning</li> </ul>
Philippines	No	PNS 296:1990 Standard Valve Outlets for High Pressure Permanent and Liquefiable Gases
Singapore	No	BS341 Transportable gas container valves,
Taiwan	Yes	CGA V-1 and JIS B 8246
Thailand	Yes	<ul> <li>CGA V-1, TIS 1095 and TIS 255</li> </ul>
Vietnam	No	BS 341 Transportable gas container valves

Findings of medicinal gas cylinder valves survey