GUIDANCE NOTE 26

MEDICAL GASES
SELECTION AND MAINTENANCE OF SEALS USED ON HIGH PRESSURE CYLINDERS

REVISION 1: 2019

British Compressed Gases Association

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PREFACE

The British Compressed Gases Association (BCGA) was established in l971, formed out of the British Acetylene Association, which existed since l901. BCGA members include gas producers, suppliers of gas handling equipment and users operating in the compressed gas field.

The main objectives of the Association are to further technology, to enhance safe practice, and to prioritise environmental protection in the supply and use of industrial gases, and we produce a host of publications to this end. BCGA also provides advice and makes representations on behalf of its Members to regulatory bodies, including the UK Government.

Policy is determined by a Council elected from Member Companies, with detailed technical studies being undertaken by a Technical Committee and its specialist Sub-Committees appointed for this purpose.

BCGA makes strenuous efforts to ensure the accuracy and current relevance of its publications, which are intended for use by technically competent persons. However this does not remove the need for technical and managerial judgement in practical situations. Nor do they confer any immunity or exemption from relevant legal requirements, including by-laws.

For the assistance of users, references are given, either in the text or Appendices, to publications such as British, European and International Standards and Codes of Practice, and current legislation that may be applicable but no representation or warranty can be given that these references are complete or current.

BCGA publications are reviewed, and revised if necessary, at five-yearly intervals, or sooner where the need is recognised. Readers are advised to check the Association's website to ensure that the copy in their possession is the current version.

This document has been prepared by BCGA Technical Sub-Committee 7. This document replaces BCGA Guidance Note 26: 2013. It was approved for publication at BCGA Technical Committee 160. This document was first published on 01/05/2019. For comments on this document contact the Association via the website www.bcga.co.uk.

CONTENTS

Section		Page
	TERMINOLOGY AND DEFINITIONS	1
1.	INTRODUCTIONS	2
2.	SCOPE	2
3.	BACKGROUND	2
4.	NON-REGULATED VALVE TYPES	3
5.	EQUIPMENT SELECTION	3
6.	PIN INDEX VALVES	5
7.	FITTING AND MAINTENANCE REQUIREMENTS. PIN INDEX CONNECTIONS	6
8.	VALVE CONNECTIONS USING ‘O’ RINGS	7
9.	FITTING AND MAINTENANCE REQUIREMENTS. VALVE CONNECTIONS USING ‘O’ RINGS	8
10.	MEDICAL GAS CYLINDER VALVE PROCEDURES	9
11.	REFERENCES *	10

APPENDICES:

Appendix 1	MEDICAL GAS CYLINDER VALVE PROCEDURES	11
Appendix 2	BODOK SEAL – NOMINAL DIMENSIONS	12

* Throughout this publication the numbers in [ ] brackets refer to references in Section 11. Documents referenced are the edition current at the time of publication, unless otherwise stated.

TERMINOLOGY AND DEFINITIONS

Adiabatic compression	Occurs when there is no heat transfer during the compression of a gas, either because of perfect insulation or because the change in pressure is so rapid that there is insufficient time for the heat, which is generated, to dissipate. This may happen if a valve in a system is opened too quickly, leading to rapid pressurisation of a system. This results in elevated temperatures and can lead to ignition in some cases, for example in oxygen systems.
Cylinder	A transportable pressure receptacle of a water capacity not exceeding 150 litres.
May	Indicates an option available to the user of this Guidance Note.
Pressure regulator	Fitted to the outlet of the gas cylinder valve, the pressure regulator reduces the pressure of the gas from cylinder pressure to the constant lower pressure required for the operation of the equipment.
Shall	Indicates a mandatory requirement for compliance with this Guidance Note and may also indicate a mandatory requirement within UK law.
Should	Indicates a preferred requirement but is not mandatory for compliance with this Guidance Note.

GUIDANCE NOTE 26

MEDICAL GASES
SELECTION AND MAINTENANCE OF SEALS USED ON HIGH PRESSURE CYLINDERS

1. INTRODUCTION

The objective of this British Compressed Gases Association (BCGA) Guidance Note is to provide information on best practice for users of high pressure medical gas cylinders (up to 300 bar(g)) when they are connecting approved medical equipment to gas cylinders.

Concern has been raised over the lack of knowledge at some medical facilities of the necessary standards needed to ensure gas cylinders, and the associated medical gas systems, are safe to use once they have been connected together. Key to a safe connection is ensuring the serviceability of the seal. The particular properties of medical gases, especially oxygen, necessitate certain precautions are taken and certain rules are followed.

The BCGA is grateful for the active help and co-operation of the Medicines and Healthcare products Regulatory Agency (MHRA) in the preparation of this Guidance Note.

2. SCOPE

This Guidance Note provides advice on the selection of a suitable seal and the correct procedure for the preparation of connections prior to fitting them to a cylinder. It also includes information on the design and types of seals that should be used and the correct operation of the cylinder valve so as to minimise the risks associated with high pressure oxidising gases.

For additional advice on valves and integrated pressure regulators refer to BCGA Technical Information Sheet 36 [8], *Medical gases. The safe handling and use of gas cylinders fitted with valves with integrated pressure regulators*.

3. BACKGROUND

Medical gases are supplied in high pressure cylinders. Fitted to the cylinder is either:

(i) a simple non-pressure regulated cylinder valve. This requires a separate pressure regulator to be fitted to the valve to reduce the internal gas pressure to the operating pressure of 4 bar(g) which is suitable for patient use;

(ii) an integral valve which incorporates a pressure regulator to deliver gas at 4 bar(g).

This Guidance Note deals only with the non-pressure regulated type of cylinder valve (Item 3(i)). It provides information about the checks that should be carried out each time a

regulator is fitted to a medical gas cylinder and details the procedures that should be followed in order to use high pressure cylinders safely.

This Guidance Note provides information and advice about:

- the type of seals that should be selected, fitted and used to obtain a gas tight connection;

- how seals should be maintained for successive use to maintain a gas tight seal and to minimise the risk of an ignition when used on oxidising gases (such as medical oxygen and medical oxygen mixtures where the oxygen content is above 21 %);

- how cylinders should be used safely.

4. NON-REGULATED VALVE TYPES

The non-pressure regulated cylinder valves fitted to UK medical gas cylinders fall into one of three basic categories, dependant on the type of connection. The three types of valves are described in the following standards:

(i) BS EN ISO 407 [3], *Small medical gas cylinders. Pin-index yoke-type valve connections*, which defines the pin index connections and details the pin arrangements for the specified medical gases / medical gas mixtures;

(ii) BS 341, Part 3 [2], *Transportable gas container valves. Valve outlet connections*, which defines the bullnose / flat washer connections and details the type / size of each connection for the specified medical gases / medical gas mixtures;

(iii) ISO 5145 [4], *Gas cylinders. Cylinder valve outlets for gases and gas mixtures. Selection and dimensioning*. This standard provides product specific outlet connections for medicinal gases up to 300 bar(g).

These cylinders are used either by fitting a pressure regulator directly to the cylinder valve or by fitting a manifold tailpipe, which connects a number of cylinders to a pipeline pressure regulator. In either case the connectors on the regulator or the tailpipe are designed to seal against the cylinder valve outlet. The type of seal required for each of the connectors to make a gas tight seal to the cylinder valve outlet are different but require the same level of attention to ensure that they are in a suitable condition prior to use.

5. EQUIPMENT SELECTION

Cylinders fitted with non-regulated type valves can be used either by fitting a regulator or by direct connection to a manifold via a product specific tailpipe.

Pressure regulators for use with a medical gas cylinder should be CE marked to the *Medical Device Directive* (MDD) [1] to ensure that they have been suitably designed and tested for safely administering medical gases to patients. All regulators used for administering gas to patients should comply with BS EN ISO 10524-1 [5], *Pressure regulators for use with*

medical gases - Part 1: Pressure regulators and pressure regulators with flow-metering devices.

When used on a manifold, it is normally the responsibility of the medical gas pipeline installer to ensure that the connections on the cylinder end of the manifold tailpipes are suitable for the intended gas use.

The equipment manufacturer should ensure that any connections are compatible with the relevant cylinder valve outlet standards. The equipment operator should ensure that only cylinders with compatible valve outlets are fitted to the equipment.

NOTE: The use of adaptors to overcome incompatible connections is not good practice, as they may override the safety design features of the valve. The use of adaptors is not recommended by the BCGA or the MHRA.

Care is needed when purchasing equipment fitted with a pin index yoke as there is a comparable USA standard for this type of fitting (CGA V-1 [7], *Standard for compressed gas cylinder valve outlet and inlet connections*, Connection No. 870). Although the dimensions of the valve and the pin index holes are exactly the same, there is a difference to the dimensions of the pin index yoke that may make it difficult to fit the yoke over the pin index valve at the extremes of the tolerances specified in the standards.

The manufacturer of the pressure regulator, or the pipeline system, is responsible for providing the end user with suitable Instructions for Use. These should detail the procedures to be followed to operate the regulator, or the pipeline system, safely and should provide the specification for a replacement seal.

As the majority of medical gases / medical gas mixtures are classed as oxidising gases, it is strongly recommended that all seals used with connectors to high pressure cylinder valves conform to the requirements specified in BS EN ISO 15001 [6], *Anaesthetic and respiratory equipment. Compatibility with oxygen*.

NOTE: BS EN ISO 15001 [6] recommends that materials selected for use with anaesthetic and respiratory systems are compatible with oxygen so that they have the lowest practicable risk of ignition and the lowest risk of producing toxic gases in the event that the component ignites.

For non-metallic components, it is important to avoid using thermoplastic materials that will produce toxic gases when burnt. Hence halogenated hydrocarbons such as Neoprene, polytetrafluoroethylene (PTFE) and polychlorotrifluoroethylene (PCTFE, trade name KEL-F) should be avoided. Materials such as ethylene propylene diene monomer (M-class) rubber (EPDM) and Polyurethane (PUR) should be considered. When selecting seals to be used with high pressure medical gas cylinders it is important to check that the specification for the seals is appropriate for its intended use.

PTFE tape shall not be used to provide, or assist in providing, a seal at the point of connection between the cylinder valve outlet and the medical equipment.

6. PIN INDEX VALVES

The pin index valve system (described in BS EN ISO 407 [3]) has been developed to ensure that the correct pin index yoke (fitted either to a pressure regulator or to a manifold tailpipe) can be used with the selected cylinder valve. Refer to Figure 1.

Figure 1: Pin index yoke

Each medical gas has a unique set of pin positions assigned. The pin index holes are positioned on the face of the valve and the corresponding pins fitted to the face of the pin index yoke.

If an attempt is made to fit the wrong yoke to the gas cylinder, the yoke will not fit and a gas tight seal will not be able to be made. The integrity of this system is dependent on the security of the pins fitted to the yoke. Checks should be made each time the regulator is fitted that the pins are correctly fitted to the yoke and that they have not become dislodged.

When attaching the yoke to the cylinder valve, a special bonded seal (commonly known as a Bodok seal) should be used to make the gas tight seal between the yoke and the valve outlet. Refer to Figure 2. A drawing of a Bodok seal showing its nominal dimensions is displayed at Appendix 2.

Figure 2: Bodok seal

The Bodok seal is manufactured from a medical oxygen-compatible polymer (such as PUR or EDPM) with a peripheral metal reinforcing ring. It is designed to be an interference fit on the yoke spigot to ensure it is retained on the yoke and located correctly. When the seal is clamped between the valve and the yoke, the clamping force is taken on the peripheral metal ring with a controlled compression on the polymer material allowing a safe and

reliable gas tight seal to be made under pressure. The metal ring retains the polymer sealing material, preventing it from splaying.

There are a number of alternative types of bonded seals that are now available and being used with pin index yokes which do not utilise the metal reinforcing ring but have the polymer material bonded to each side of a metal washer, refer to Figure 3. When this type of seal is clamped by the pin index yoke the clamping force is applied to the polymer material and none to the metal part of the seal. This can cause the polymer material to splay and wear rapidly. Dependent on the design of the yoke (and the length of the spigot which retains the bonded seal), this type of seal may not function correctly with all pin index valves and care is needed to ensure that the correct type of seal is used.

Figure 3: Alternative seal

Care is needed to ensure that the Bodok seal is manufactured from suitable and approved materials compliant with BS EN ISO 15001 [6]. As in Section 5, the use of halogenated hydrocarbon polymers shall be avoided.

NOTE: The majority of pin index yokes are designed to be used with a Bodok seal but not all. Some yokes have a built in seal system, for example a retained O-ring face seal. Refer to Section 9 for information on the inspection of O-ring seals.

7. FITTING AND MAINTENANCE REQUIREMENTS - PIN INDEX CONNECTIONS

Prior to fitting the pin index yoke to the cylinder valve, the yoke and the seal should be inspected to ensure they are fit for further use. The inspection should include checks for:

- cleanliness, including signs of contamination (especially of oil and grease) of both the yoke and the seal;
- evidence of wear of the seal, refer to Section 9;
- deterioration or damage to the seal material, where the polymer material becomes hardened, deformed, cracked or blistered, refer to Section 9;
- loose or loss of the pins from the pin index yoke.

If there is any doubt about the suitability of the seal it should be discarded and a new seal fitted. A new Bodok type of seal is fitted by pushing the seal over the spigot fitted to the face of the pin index yoke.

If the yoke is faulty, it should be replaced or returned for reconditioning, normally to the manufacturer.

As the attachment and disconnection of the yoke can lead to wear of the Bodok seal it should be checked regularly under a planned maintenance system to ensure it remains fit for purpose.

Equipment should be serviced in-line with the manufacturer's recommendations. Additional advice can be obtained from the gas supplier. Spare seals, of the correct specification, should be obtained from the manufacturer or the gas supplier.

8. VALVE CONNECTIONS USING 'O' RINGS

The majority of other valves used for medical gases currently are of the 5/8″ BSP female connection type (BS 341-3 [2] No. 3) which require a male nut and bullnose nipple fitted to the connecting equipment. Refer to Figure 4.

Figure 4: BS 341-3 [2] No.3 Bullnose connection

The connecting nipple is fitted with a groove which holds the O-ring in position to prevent it from being displaced when the joint is pressurised. As the O-ring tends to be pushed into its groove each time it is pressurised, it tends to wear in use, causing damage which often leads to cuts in the surface of the material. Under certain conditions, slithers of polymer material can be subjected to adiabatic compression conditions, which could lead to an ignition.

The requirements for cleanliness of the O-rings and the connector are just as important as for the pin index yoke connection. Refer to Section 7. It is important that the O-ring is inspected each time the connector is fitted to the cylinder valve to ensure that it is in a suitable condition for further use. Replace the seal as necessary.

BS ISO 5145 [4] outlet connections also use ‘O’ rings as a means of sealing the valve connection. These require a similar level of care.

9. FITTING AND MAINTENANCE REQUIREMENTS - VALVE CONNECTIONS USING ‘O’ RINGS

For this type of connection, there is a need to both inspect and replace (if necessary) the O-ring seal each time the pressure regulator is fitted to the cylinder valve to ensure that it is in a suitable condition for use.

Typical types of damage to the O-ring are detailed in Figure 5.

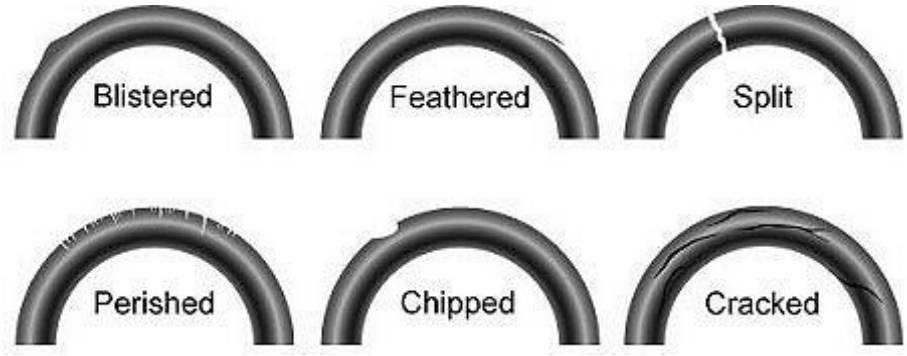


Figure 5: Typical types of seal damage

Seals showing any signs of this type of wear or damage shall be replaced before reconnecting.

Where there is a requirement to replace the seal the old O-ring should first be removed and then the nipple inspected for damage.

There should be no signs of damage to the nipple. The nipple should be checked for cleanliness, including signs of contamination (especially of oil and grease).

A serviceable O-ring shall be fitted. The replacement O-ring should be fully inserted into the O-ring groove to make sure it is sitting securely.

When fitting a bullnose nipple to the valve, only moderate force should be used to prevent over tightening the connection (which can lead to damage to the O-ring seal).

NOTE: The bullnose connection is mainly used on regulator connectors (as all medical gas pipeline systems utilise the pin index valve connection for manifold systems). Regulators should be subjected to routine maintenance, as recommended by the manufacturer, to ensure that the regulator is functioning correctly and that the O-ring seal is in good condition.

As for pin index bonded seals, the material used to manufacture the O-ring is also subject to controls as detailed in BS EN ISO 15001 [6].

When the bullnose connection is not connected, it is vulnerable to:

- damage, for example, if dropped;

- contamination, for example, from handing, if alcohol gels / creams are used prior to connecting the regulator, or from other contaminants which are not compatible with oxygen.

When not connected to a cylinder, the bullnose nut and nipple should be protected by fitting a suitable protective cover over the nipple.

10. MEDICAL GAS CYLINDER VALVE PROCEDURES

Ensure that only trained personnel are allowed to operate a medical gas cylinder. Basic information on the contents of the gas cylinder and instructions for operating the cylinder valve are detailed on the gas cylinder label. Advice on both the gas and the gas cylinder is available from the gas supplier.

To assist with these requirements, the basic procedure detailed in Appendix 1 may be used as a training aide memoir.

NOTE: Appendix 1 is in a format that can be printed to provide personnel who operate medical gas cylinders with a reference document.

Irrespective of the type of valve fitted and the gas service for the medical gas cylinder, the operating procedures shall include the following:

(i) prior to connecting the pin index yoke / bullnose adaptor, the connector seal is inspected to ensure it is clean, shows no signs of wear or damage and remains fit for further use;

(ii) seals are replaced as soon as it has become evident that they are worn, damaged or contaminated, and therefore not fit for further use;

(iii) equipment is serviced in-line with the manufacturer's recommendations, as well as any additional local instructions. Maintenance is carried out by trained personnel;

(iv) spare seals, of the correct specification, are available;

(v) valves are opened slowly.

11. REFERENCES *

	Document	Title
1.	Directive 93/42/EEC	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. Medical Device Directive (as amended).
2.	BS 341 Part 3	Transportable gas container valves. Part 3: Valve outlet connections.
3.	BS EN ISO 407	Small medical gas cylinders. Pin-index yoke-type valve connections.
4.	BS ISO 5145	Gas cylinders. Cylinder valve outlets for gases and gas mixtures. Selection and dimensioning.
5.	BS EN ISO 10524 Part 1	Pressure regulators for use with medical gases. Part 1: Pressure regulators and pressure regulators with flow-metering devices.
6.	BS EN ISO 15001	Anaesthetic and respiratory equipment. Compatibility with oxygen.
7.	USA CGA V-1	Standard for compressed gas cylinder valve outlet and inlet connections.
8.	BCGA Technical Information Sheet 36	Medical gases. The safe handling and use of gas cylinders fitted with valves with integrated pressure regulators.

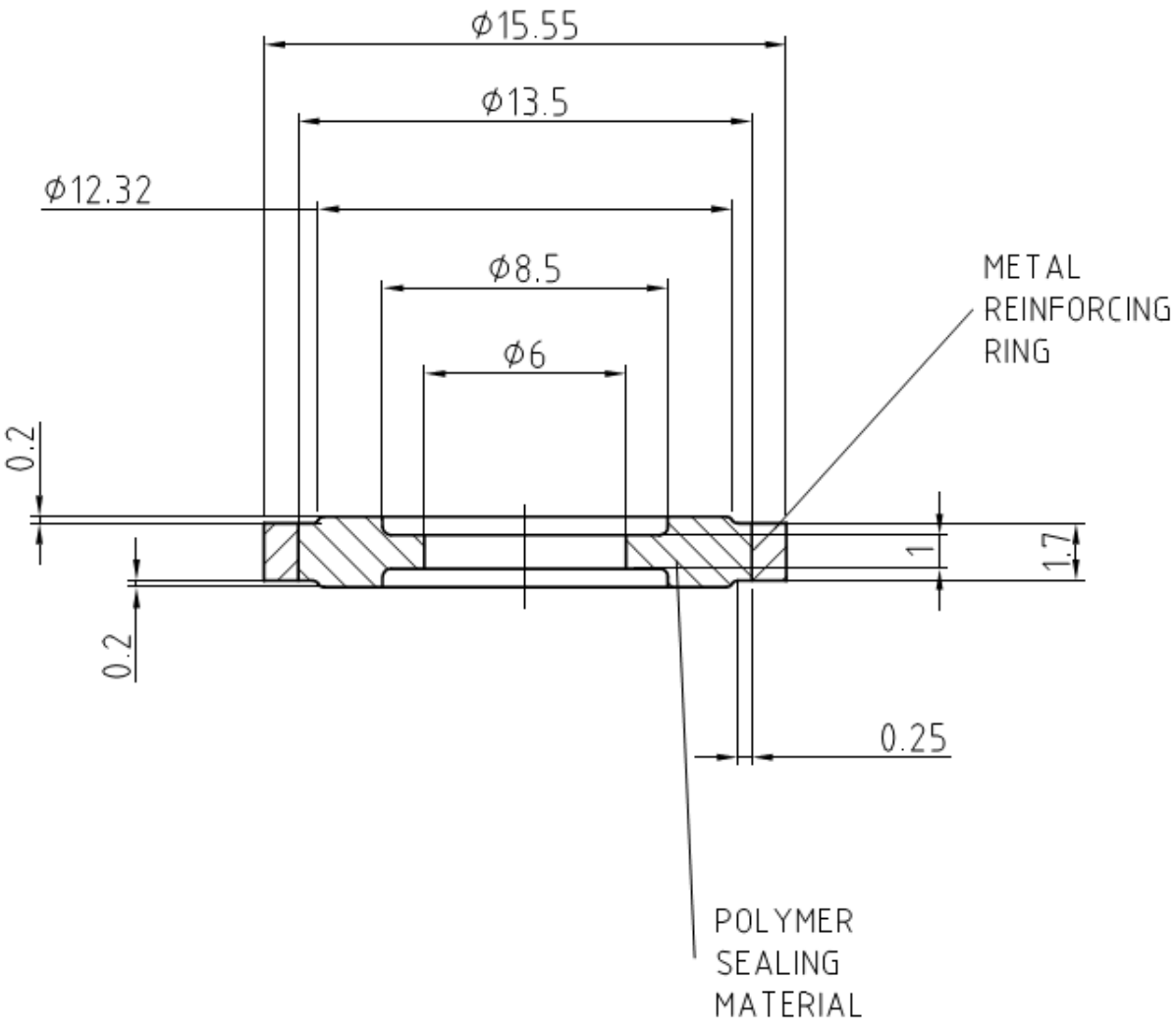
Further information can be obtained from:

UK Legislation	www.legislation.gov.uk
Medicines and Healthcare products Regulatory Agency (MHRA)	www.mhra.gov.uk
British Standards Institute (BSI)	www.bsigroup.co.uk
British Compressed Gases Association (BCGA)	www.bcga.co.uk
USA Compressed Gases Association (CGA)	www.cganet.com

MEDICAL CYLINDER VALVE PROCEDURES

Step	Procedure	Action
Before Use:		
1.	Inspect the cylinder label to ensure that the right product for the patient's prescription has been selected.	Exchange as necessary.
2.	Check the gas pressure in the cylinder is compatible with the equipment it is being connected to.	
3.	Inspect any seal fitted to the connector / yoke for signs of: • Wear (or feathering) of the seal material; • Contamination of the connector / seal; • Oil or grease.	Where the seal shows signs of wear or contamination exchange the seal. Discard any used seals. Do not use creams or alcohol gels prior to handling the valve / connector to ensure it does not become contaminated by handling.
4.	Inspect the connector prior to use for any signs of damage or contamination.	Check pin index yokes for loss of pins. Replace as necessary. Check the connector is within its maintenance service date.
5.	Tighten the connector by hand, using only moderate force to make the connection.	
6.	Ensure any flow device fitted to the regulator is set to zero and then open the main shut off valve slowly.	Ensure that the main shut off valve is fully turned on. Back the spindle off of the stop having opened the valve fully.
7.	Inspect the connection after the valve has been fully turned on for leaks.	Leaks may be evident by a hissing noise or detected by applying an approved leak detector for any signs of leaks
8.	Check the contents gauge on the pressure regulator to check the contents of the cylinder.	Ensure there is sufficient gas in the cylinder by checking the gauge on the pressure regulator / manifold.
9.	Where applicable, set the flow to the desired setting.	Ensure that the gas is being administered correctly to the patient.
After Use:		
10.	Close the cylinder valve when gas no longer required or when the cylinder is empty and requires changing.	Use moderate force only to close the valve.
11.	Allow the regulator to empty before adjusting the flow selector to zero.	The pressure shall be vented from the regulator before it is disconnected.
12.	Remove the regulator from the cylinder valve.	Replace any valve outlet caps fitted to the valve
13.	Check the regulator for any faults. Check if the regulator requires servicing.	As necessary, rectify or report any faults. If serviceable, return the regulator to its storage ready for re-use.

BODOK SEAL – NOMINAL DIMENSIONS



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