

**HIGH PRESSURE MEDICAL
COMBINATION GAS VALVES**

-

BEST PRACTICE ADVICE (BPA)



SECURITY INTEGRITY PRO-ACTIVITY INNOVATION

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Technical Customer Support Team

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DISCLAIMER

This document shares GCE Group's 15+ years of experience on medical combination valve usage and users practices.

This document is for information only, it is provided free of charge. It is not intended to replace the Gas Companies instructions or local regulations but can be used for guidance and improvement.

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This document does not replace the GCE *Instruction For Use* (IFU) provided with the equipment.

Any suggestion, correction or addition is welcome and should be emailed to: med.maintenance@gcegroup.com

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LEGEND



This highlights a Best Practice Advice (BPA) considered to be particularly original.



This highlights a Best Practice Advice (BPA), which is particularly different from standard cylinder valve practices.



This indicates a true live example



This indicates an advice or a note that may vary depending on local regulation or company practice and it has to be reviewed by a competent person.

FOREWORD

Medical combination gas valves as described in EN 10524-3 are replacing conventional gas cylinder valves for the control of gas from high pressure medical gas cylinders. Combination Gas Valves combine the functions of cylinder valve, pressure regulator and flow control device into a single valve which is permanently fitted to the gas cylinder. This eliminates the need for the user to fit a separate pressure / flow regulator to the cylinder.

This has many advantages for the user (security, ergonomics, ease of use and price) and also for the gas company. However it also means that the gas industry has to handle and maintain a more complicated device. This was not fully understood by all the industry when Medical Combination Valves were first introduced.

The purpose of this document is to share Best Practice information regarding the handling, servicing and use of Medical Combination Valves, fitted to refillable high pressure gas cylinders. This is relevant for everyone involved in the use of high pressure Medical Combination Valves.

GENERAL HANDLING

A Medical Combination Valve combines several functions into a single valve, consequently they are more complex than a conventional cylinder valve. Medical Combination Valves are at greater risk to external damage because of the additional external parts fitted, for example the pressure gauge, medical Quick Coupler (QC) pressure outlet, flow outlet, flow control knob. The internal components are also more delicate than a conventional cylinder valve.

Normal handling practices used for conventional cylinder valves may not therefore be suitable for Medical Combination Valves.

MAINTAINING CLEANLINESS BEFORE FITTING TO A CYLINDER

GCE Medical Combination Valves are usually supplied in an individual sealed plastic bag maintaining the internal cleanliness of the valve to oxygen clean standards. When unpacking the valve it is important the valve is not removed from its sealed plastic bag until shortly before it is going to be fitted to a cylinder. This is to minimise risk of contamination entering the valve stem. Once the valve is fitted to the cylinder the valve is less at risk of contamination entering the valve.

BPA - Do not remove a Medical Combination valve from its sealed plastic bag until shortly before it is going to be fitted to the cylinder.

BPA – Do not remove cylinder protection plug or any other means of cylinder protection until the very last moment the valve is fitted.

BPA – Before fitting a valve to a cylinder which has previously been devalved, ensure all old PTFE is removed from the cylinder neck thread, and remove PTFE particles that are likely to have fallen inside the cylinder during devalving.

FITTING A COMBINATION VALVE TO A CYLINDER

When fitting Medical Combination Valves to cylinders, extra care compared to conventional valves has to be taken to ensure the Medical Combination Valve is not damaged. It is important that the tool used to drive the valve into the cylinder is designed to only apply force to the drive flats on the valve and the tool remains clear of any other parts of the valve. Automatic machines which drive an unsupported drive tool from above, via a universal joint are not recommended. This is because this type of tool can apply damaging side loads to the valve and its external components such as pressure gauge.

BPA – The valving spanner must be good fit on the drive flats and not in contact anywhere else on the valve.

Correct valving torques must be used to ensure the neck joint is tight enough to ensure no leaks and the valve will not unscrew in service but not too tight to damage the cylinder neck or valve stem. The maximum allowable torque for the valve and the maximum allowable torque for the cylinder neck may not be the same.

Upper and lower torque limits for both the valve and the cylinder neck should be established before fitting the valve to the cylinder. The torque applied must fall within allowed limits for both the valve and the cylinder neck.

Taper threads generate higher stresses in the cylinder neck than parallel threads. Therefore care has to be taken not to over stress necks of cylinders with taper threads, particularly aluminium cylinders. Parallel threads generate higher stresses in the valve stem than the cylinder neck so extra care has to be taken not to over stress the valve stems with parallel threads.

BPA - Use correct torque levels when fitting the valve to the cylinder. Consult both cylinder manufacturer and valve manufacturer to establish correct torque levels.

If PTFE thread tape is used on tapered threads the thread tape must be suitable for use with oxygen systems. Standard PTFE tape should not be used due to the levels of oil that can be present in standard tape.

Do not use PTFE tape or any other thread sealing compound on parallel stem threads. These threads will use a sealing washer or an O-ring seal. Use only the correct sealing washer or O-ring specified by the valve / cylinder manufacturer. Seals of incorrect dimension or material could result in an ignition and/or valve leakage.

BPA - Use only PTFE tape approved for use on oxygen systems.

BPA – On parallel threads use only the correct sealing washer / O-ring specified by the valve / cylinder manufacturer.

LIFETIME OF A MEDICAL COMBINATION VALVE

The life time of a medical combination valve is specified by the manufacturer and is generally 10 years. This is the same as the retest period for the majority of cylinders.

When either valve life time or cylinder retest date is reached the valve and cylinder must be taken out of the market for appropriate action. It is advisable that the owner of the gas package has an internal policy in place to cover the action required if these two dates are not the same.

BPA – To maximise the life of the valve and the cylinder it is advised to match the valve and the cylinder dates at the time of valving.

BPA – To detect the retest year of the cylinder, a plastic date ring collar with a specific colour and/or shape should be fitted to the neck of the cylinder. This is especially true if there is no automatic system in place (see next chapter on traceability).



Note: there are currently some discussions in Europe to extend the cylinder retest period to more than 10 years (15, 20 ...) and therefore a market push to have the life time of the valve extended as well. For safety reasons, this may not be possible in all cases because cylinder technology is very different than Medical Combination Valves technology which is more complex mechanisms.

VALVE TRACEABILITY

The medical gas package owner should record the valve serial number when fitting the valve to the cylinders and link the serial number to the gas package reference number in a manner which enables the valve to be traced if it is required.

BPA - Maintain a traceability system for the valve.

The serial numbers located on the valves are relatively difficult to read in daily production at the filling centre. It is therefore recommended that an automatic system such as *RFID* or *Bar Code* reader should be installed to identify the gas package. This is particularly important when there is a large fleet of cylinders to control without risk of human error. This then allows the gas company to easily identify cylinders and valves as and when required.



BPA – An automatic traceability system should be used linking the valve, cylinder and gas package numbers enabling efficient management of medical gas packages.

HANDLING AFTER FITTING TO A CYLINDER

Once the valve is fitted to the cylinder the cylinder should be handled in a manner which prevents as far as possible knocks and bangs to the valve. Cylinder size 5 litres and larger should be strapped securely into suitable pallets for transport. Small cylinders, below 5 litres, should be transported in suitable crates or boxes.

During the valve's complete lifetime, including transport and storage the valve should not be exposed to rain, dust, dirt and excessive heat (60°C max is typical).

Standard brass components with nickel coating commonly used in Combination Valves may not be resistant to sea water conditions. Sand and dust additionally adds the problem of mechanical wearing to the mechanisms.

BPA – During transport and storage use suitable dedicated pallets or racks to safely hold cylinders.



BPA - During transport the cylinders and Medical combination Valves should be covered. This is particularly important in winter months when salt and grit are used on the roads.



BPA - Consider with great care applications exposing the Medical Combination Valves to sea, shores and desert conditions. Special controls and/or reduced lifetime are likely to be expected.

BPA - At the filling station cylinders should be stored under cover.



BPA – Insure that any storage area and all transport containers have drainage holes in the bottom to prevent a build-up of water.

FILLING PORT

Medical Combination Valves are different to conventional valves in that they have a filling port which is only accessed by the gas company but not by the end user. Medical Combination Valves have separate outlet ports for the end user. GCE provides a plastic or metal filling port cap on all Medical Combination Valves. This cap is part of the approved CE

marked product. It is a very important component to prevent contamination entering the valve and should not be disposed of.



BPA - The filling port should be covered to maintain cleanliness at all times. Because it is not a user outlet, the cover should only be removed when filling and replaced immediately after filling.



BPA – The metal cap version is more durable and is less likely to be discarded by end users.

Residual Pressure Valve

This mechanism insures positive pressure is always kept inside the cylinder to limit external contamination. Residual pressure valve has to be positioned in the passage supplying gas to the user outlets, stopping the flow just before the cylinder gets completely empty.

In a Medical Combination valve the residual pressure valve is not fitted in the filling port because the filling port is not a user outlet.

For this reason residual pressure valves in most Combination Valve designs can not be accessed via the filling port and are bypassed during the filling process.

Non-Return Valve (NRV)

However for safety reasons the filling port of most Medical Combination valve is fitted with a non-return valve. This is to prevent gas escaping or the filling port being pressurised when

the shut off valve is opened by the patient. The filling port NRV is not a residual pressure valve.



This is different to conventional cylinder valves where the filling port is also the user outlet and therefore the two mechanisms above, when implemented, are located and operates differently

At the start of the filling process of medical cylinders it is normally necessary to allow gas to be vented or purged or vacuumed (or a combination of) through the filling port. This is achieved by the use of a pin on the filling adaptor mechanically holding the NRV open. It is very important the pin length on the filling adaptor is the correct length for the valve. Incorrect pin length can result in damage to the non-return valve, leading to fill port leaks in service and potentially other valve failure modes. Incorrect pin length will also result in the NRV not being held in the optimal position, for optimal filling flow performance. If the pin on the filling adaptor is missing it will still be possible to get gas into the cylinder (less the pressure drop across the NRV), but this is not recommended for safety reasons and it will not be possible to vent, purge or vacuum the cylinder.

Therefore the correct filling adaptor with correct pin size must be used for filling Medical Combination Valves.

Note:

Although EN 10525-3 refers to ISO 5145 for the filling port connection, this standard is not mandatory and there is no



current standardisation for the dimensions of the filling adaptor pin.

Therefore it is very unlikely that combination valves from different manufacturers can use the same filling adapter although it may seem possible to connect.



BPA - Use only filling adaptors approved by the valve manufacturer.

FILLING ADAPTORS

Filling adaptors are specially designed and ignition tested with the corresponding Medical Combination Valve by the manufacturer. They must be kept clean, free from any oil and grease and in good condition. Most oils & greases are hydrocarbons based and are not safe for use with oxygen or patient. Another potential issue is that oil and grease will also travel in the lines contaminating other equipment and valves.

BPA – Never ever grease or oil the filling adaptor

Exposed O-ring seals should be visually checked daily and replaced when showing signs of wear. Replacement o-rings must be the correct size and correct material.

Using o-rings of incorrect material and/or contaminated filling adaptors significantly increases the risk of ignition.

BPA – Check exposed filling adaptor o-rings daily. Replace only with o-rings to correct specification and original manufacturer.



NOT TO DO: An operator put oil on the filling adaptor “to make the mounting and dismounting faster and gain time”!

Condition of the filling adaptor pins should also be checked regularly and replaced when worn or damaged. Shortened or Bent pins can damage the valve filling port and generate leaks or metal particles as they are connected to and disconnected from the filling port. Metal particles in the valve can cause a safety hazard.

BPA – Check filling adaptor pins daily. Replace if bent or worn.

The design of the filling rigs should not allow the filling adaptors to touch the ground when not in use and must prevent the filling adaptors from swinging and contacting other parts of the filling rig which could contaminate or damage the exposed high pressure gas wetted surfaces of the filling adaptor e.g. nipple and pin.

Do not suspend or hang the complete gas package to the filling adaptors if this one is fixed on the installation.

BPA - During filling, mechanically support the cylinder by other means than the filling adaptor.

BPA - If the filling adaptor is at a fixed position & the rack is used to fill different cylinder sizes, a levelling mechanisms or equivalent is required.

Filling adaptors made of Monel can last years if correctly used and not exposed to shocks, as the force to initially open and maintained open the NRV is small.

It is ergonomically easier to manipulate and correctly guide the light filling adaptor towards a fixed heavy gas package than the contrary.

BPA – Avoid all constraints & shocks to the filling adaptors

O-ring joints do not require high torque to seal, even for high pressure hand tight is sufficient. Over tightening will damage the valve and cause faster ware on the filling adaptor.

Impact wrenches must not be used for tightening filling adaptors. Hand tight connectors are preferred. Non-impact torque wrench may be used providing they have controlled torque levels and torques do not exceed 5 Nm.



BPA – Do not allow any unauthorized tool or wrench in the filling area

BPA – Do not over tighten filling adaptors. Do not use impact wrenches to connect filling adaptors to the valve.

Quick release type filling adaptors can be used but care is required to ensure correct positioning on the filling port thread.

If the gas company decides to use quick connectors, they must be adiabatically tested with the valves, in the same manner as the original filling adaptors.

Quick release filling adaptors can cause extra wear on filling port threads and cause potential generation of particles.

Particular attention and care must be taken if they contain aluminium or stainless steel components in order to insure no such particles are created and introduced into the product or the gas (stainless steel is very good from mechanical point of view compared to brass, but its particles are highly flammable in oxygen).

Maintenance programs should take these points into account.

BPA – Have documented maintenance procedures for filling adaptors.

MEDICAL GAS CYLINDER FILLING

Medical gas cylinders can only be filled by a licensed filler; normally this is the owner of the gas package (the Gas Company). The owner requires a licence to place the medical gas package on the market. The production, quality control and packaging of Medical Gases are controlled under Pharmaceutical regulations. Filling must be in accordance with EU GMP (Good Manufacturing Practice) requirements appendix 6.

PRE-FILL VALVE CHECKS

When the gas package is returned from a user for refilling, the valves should be subjected to a pre fill check procedure. Responsibility for the pre fill check procedure is with the gas company. As a minimum the following points should be checked:

The Medical Combination Valve is within its life time date and the cylinder is within its retest date. See valving, traceability and Valve End of Life sections.

Visual - check valve and cylinder external surfaces for visual contamination from dirt or other forms of contamination

Visual - check for mechanical damage, particularly to the control knobs, user outlets, pressure gauge and guard.

Visual - check that the filling port cap is in place. If not the filling port should be carefully examined for contamination. Any Medical Combination Valve found with contamination in the filling port should be withdrawn from service for full clean servicing.

Check for residual pressure inside the cylinder. Before filling it must be established that the cylinder contains a positive gas pressure. If positive gas pressure is not detected, the cylinder should not be filled and the valve and cylinder should be withdrawn from service and corrective actions taken.



BPA – Have documented pre-fill cylinder check procedures in place.

BPA – Do not pass cylinder on for filling if no residual pressure is detected inside the cylinder.

BPA – All valves should be fitted with a filling port cap.

VALVE EXTERNAL CLEANING

Any contamination found should be cleaned off using warm water and cleaning cloths. Do not use any proprietary cleaning fluids which could contain active chemicals which could attack plastic and brass components or leave hydrocarbon based deposits. Cleaning should be by hand wiping only with cloth soaked in warm water. The Medical Combination Valve must not be sprayed with high pressure fluid jets or submerged in water.

During cleaning the filling port must be covered to prevent cleaning fluids and dirt entering the filling port. Valve outlets should also be protected during cleaning to prevent dirt and water entering the valve. Medical Combination Valves shall not be subjected to temperature above 60° C during any cleaning and drying process.

If the user is aware that the cylinder package may have been contaminated by non-visible contamination e.g. biological contamination, they must advise the gas package supplier when returning the cylinder. The cylinder should be labelled with the details of the contamination.

BPA – Use only hand cloth and clean warm water to clean the valve and guard if required.



BPA – User should advise the supplier if the cylinder or valve has been biologically contaminated.

CYLINDER FILLING AND EQUIPMENT

After any extension or modification has been performed on the filling equipment and pipes it is critical that any contamination (particles from cut tubes, welding deposits, flux etc) is removed from inside the pipework and the pipework is purged. Depending on the location of the modification and the equipment, it may be required to clean not only the downstream pipework but the upstream pipework also.

Filters on pipework should only be fitted where the flow of gas is in one direction. All foreseeable reverse flow situations should be taken into account when deciding filter location and equipment design. For example reverse flow direction can be created by temporary pressure differentials resulting from intermediate stages during vacuuming, emptying or disconnecting, or filling different sizes of cylinders or two racks at the same time.

BPA – Modification to the equipment can lead to safety risks if not carried out correctly and submitted to effective post cleaning procedures.

BPA – Design and installation of filling lines, should take into account the location of the vent outlet to atmosphere, to insure it does not contaminate others products or equipment.



BPA – Look for rare or abnormal cases where filters could be subjected to a reverse flow direction.



BPA – Gas companies should have a very clear policy on what the operator should do if, during filling he discovers that he forgot to open a valve. Depending on the installation, the valve could be on the line, on the rack, on the filling adaptors or on the cylinder. Opening the valve during or after filling can be dangerous, causing adiabatic shock and unusual flows (backwards, transfer between cylinders ...).

Not all Medical Combination Valves have a main shut off valve or location within the valve may be different. The following filling procedures and equipment may be different for filling these types of valves.

Procedures for filling Medical Combination Valves which have a main shut off valve in the filling passage are similar to conventional valves. The main shut off valve needs to be open during filling and closed at the end of the filling process. The filling port should be visually checked again for cleanliness before connecting the filling hose. After connecting the filling hose, check the flow control (if fitted) is set to zero. A typical filling cycle includes initial venting, purging, vacuuming and filling. During filling the cylinder temperature will increase. The amount the temperature increases and the final temperature depends on the gas, the design of the filling plant and ambient conditions. Care has to be taken not to exceed the maximum temperature and pressure the cylinder and the valve are designed for.



The process of filling can have more impact on the rise of the temperature inside the cylinder than the filling rate.

If the Medical Combination Valve has high pressure gas locked inside, depending on the design, it may be difficult to connect the filling adapter. The pressure inside the valve should be released through the flow head (if fitted) or the QC before connecting the filling adaptor. If the cylinder contains more than 50 bar, the pressure in the cylinder should be reduced by venting gas through one of the user outlets before connecting the filling adaptor. If the valve has a flow head the gas should be vented through the flow head set to max flow. If the valve only has a

QC outlet and no flow head, the gas should be vented through a QC probe fitted with a flow restrictor.

Venting residual cylinder gas through the flow head and not through the filling port has the additional advantage of purging potential contamination or water ingress which may have taken place during transport or usage and will protect the valves and the filling process line.

BPA – Do not connect under pressure, ie if filling port area has not being purged prior and Combination Valve SOV closed.

BPA – If cylinders contain more than 50 bar pressure vent down to below 50 bar before connecting the filling adaptor.



BPA – Vent residual gas, if present, through the flow outlet. This operation is essential if there is any suspicion of water or contamination ingress inside the valve

BPA – As for all high pressure equipment, whether the cylinder is already connected to the filling lines or not, opening the main shut-off valve must be done slowly and, while doing so, do not stand directly in front of any outlet or gauge.



Operator's vigilance is particularly required when opening cylinders racks after cylinders racks in daily operation with heavy workload.

Vacuum or purge cycles during the first stages of the filling process may cause migration of pollution and/or lubricants in the high pressure area.



BPA – Insure that the flow selector, if fitted, is “off” or at the “zero” position before the start of filling cycle.

POST FILL VALVE TESTS

As it is usually stated in the IFU of the valve, Post Fills checks are critical for security and is part of the procedure that is under the responsibility of the gas company. Medical Combination Valves must be tested after each fill to ensure the valve is fit for purpose. At the first fill, the post fill test should be more thorough than subsequent post fill testing.

At first fill the valve should be subjected to a thorough leak test. Particular attention should be paid to the cylinder neck / valve stem joint. This is best done by monitoring cylinder pressure for a 24 hour period. If this is not possible leak testing by use of suitable leak detection fluid can be used but depending on the design of the guard it may be necessary to remove the guard to gain access to the joints.

After each fill the valve should be checked for correct delivery pressure and correct flows (if fitted with a flow head). If the valve is not delivering correct pressures or flows the valve and cylinder should be taken out of service for repair.

With the shut off valve open, where fitted and flow head control closed, the valve outlets and filling ports should be leak tested after every fill. If leaks are found the valve and cylinder should be taken out of service for repair.

BPA – Check for cylinder neck leaks at first fill.



BPA – Check the valve is delivering the correct pressure and flows after each fill.

BPA – Check the outlet ports and the filling port is not leaking after each fill.

WARNING:

Leak detection fluids must be ammonia free and oxygen compatible. Ammonia /ammonium radicals can cause cracking of brass and plastic materials. Consult EIGA and ASTM documents for more details.

VALVE REPAIR GENERAL

Depending on the product and manufacturer, most repair work can be carried out with the Medical Combination Valve on the cylinder. It is not recommended to remove the valve from the cylinder for repair unless it's essential. This is to minimise the risk of contamination entering the valve via the stem. The only time it is necessary to remove the valve from the cylinder should be when internal examination of the cylinder is required or full clean service of the valve is required.

BPA – Do not remove the valve from the cylinder for repair.

If the valve is removed from the cylinder and it is intended to refit the valve to a cylinder it is essential any loose PTFE tape is immediately removed from the valve stem and the valve is placed inside a sealed plastic bag. This is to prevent contamination entering the valve while it is off the cylinder. Do not place the valve in a cardboard or wooden container without the valve first being placed in a sealed plastic bag.

BPA – Once the valve is removed from a cylinder, immediately remove PTFE tape from the valve stem and place the valve in a sealed plastic bag.

If internal contamination of the Medical Combination Valve is thought to have taken place the valve must not be put back on a cylinder. The valve must have a full clean service or be disposed of.

Under EU regulations Medical Combination Valve servicing or repair can only be carried out by personnel who have been authorised by the original manufacturer and must be according to their instructions. The service or repair must use components supplied by the original manufacturer to ensure compliance of product and warranty.

BPA – Repairs to Medical Combination Valves can only be carried out by personnel authorised by the valve manufacturer.

Experience shows that the parts most frequently serviced are:



- *Damaged manometer/gauges which are by nature, sensitive mechanisms. The gauges have to be mounted externally to be visible and therefore are exposed to external shock.*
- *Damaged fir tree outlet because they have to be designed thin and long and are exposed to direct external shock during transport and handling.*
- *Damaged plastic flow knobs and guards*
- *Damaged Quick Connectors due to transport and handling issues.*

FULL CLEAN SERVICE

A full clean service is required if the Medical Combination Valve is suspected of being contaminated internally. This involves a full disassembly of the valve and a cleaning of all components. The valve is then rebuilt with new components as required.

VALVE END OF LIFE

The valve should not be supplied to the customer once it has passed its End of Life Date as defined by the valve manufacture. These valves should be removed from service by the gas company.

Note:

Depending on the local medical regulation or gas company policy, the valve can normally remain in service after its End of Life date providing the valve was in date when supplied to the customer.

The gas cylinder package owner should operate a system which readily identifies at pre-fill inspection valves which are at or close to end of Life. Ideally this is by a computer read bar code or RF tag system.

Valves should be disposed of according to EU regulations. Refer to the valve manufacturer for valve recycling information.

From experience, due to the high price of quality brass and the ease of reuse, the residual price of the valve is higher than the recycle costs.



BPA – Insure that your storage area of non conforming products (damaged, contaminated or valves passed their ‘End of Life Date...’) is locked and periodically emptied to avoid parts coming back into your fleet, due to for example, operator needing spare parts or other tempting situation

BPA – Medical Combination Valves should be withdrawn from service at ‘End of Life’ specified by the valve manufacturer.



BPA – The valve manufacturer should be able to assist you in valve recycling solutions.



BPA – For security, insure that the recycle company makes the valve and its main components non reusable in the market. This is usually achieved by voluntary damaging or cutting the main body and critical parts.

PATIENT USE

Users of Medical Combination Valves should provide suitable storage for the cylinders when not in use. The cylinders should be stored in a ventilated area, undercover and away for any heat source.

BPA – Store cylinders in suitable locations, under cover, in a ventilated area, and away from any heat source.

An oxygen enriched atmosphere will dramatically increase the risk of fire. Materials that would not ignite in air will burn easily in oxygen. Oils, greases and many creams contain elements that will ignite in oxygen and these must be avoided by anyone handling oxygen equipment.

These conditions can occur close to any oxygen equipment and in particular around the area of the patient when using a mask/nasal tube.

The oxygen not consumed by the patient enriches the patient's clothes and potentially surrounding soft furniture materials e.g. bedding, chair upholstery, carpets, and this will result in an increased fire risk for the patient.

NOT TO DO – It is critical for the safety of the patient and for anybody in the same room as the patient not to smoke or to have any source of heat that could result in a fire close to the patient.

BPA- When oxygen is being used in a confined space, additional ventilation may be required.

NOT TO DO - People on oxygen therapy should not undertake any cooking activities or any other activity which bring them in close contact with a naked flame.

NOT TO DO – Do not apply any kind of cream, oil or grease on the equipment.

NOT TO DO - Do not have any kind of cream, oil or grease on your hands or face when handling oxygen equipment.

NOT TO DO – Do not put down and leave an oxygen mask or nasal cannula while the oxygen is flowing. Always turn the oxygen flow off when the mask or nasal cannula is not in use.

NOT TO DO : Do not put the gas package on or close to flammable materials during use i.e. do not put the cylinder on a patient's bed or on any soft furniture close to the patient as this can make access to the valve controls difficult and it could fuel any potential fire.

BPA - Where possible cylinders should be held upright in a cylinder stand and away from flammable materials.

A Medical Combination valve is a CE marked and third party validated product. It was designed, tested and validated under specific circumstances and for specific usages. Therefore it must not be tampered with in any way for your own safety and for the safety of the next user. It must always be returned to the gas supplier when no longer required by the patient.

BPA – Do not modify any medical equipment provided to you; discuss with the provider if it does not suit your needs or ask for explanations if its usage is unclear to you.



NOT TO DO: Patient drilled a hole in the plastic mask to smoke a cigarette while breathing oxygen!

BPA – The provider of gas packages fitted with Medical Combination Valves must provide suitable instructions to the users of the equipment taking into consideration their experience and ability, for example disabled patients or children.



Some national regulation may oblige the provider to train & keep a record of all end users of a medical device, which includes combination gas valves.

USER OUTLETS

Medical Combination Valves can have two user outlets, a flow outlet (Fir Tree) and or a pressure outlet (QC). The flow at the Fir Tree outlet is

controlled by the Combination Valve. If multiple flows are available a flow control knob is provided which normally includes a ZERO setting.

The QC outlet delivers a constant pressure (set between 3.5 to 5.0 bar depending on market local requirements). The flow at the QC outlet is controlled by the equipment it is supplying not by the valve, for example a demand valve or an anaesthesia machine.

The flow outlet (Fir Tree) connection is a simple hose nipple that the hose from the mask / nasal cannula connects to. The hose used on this connection is normally a clear plastic low pressure hose. The connection is made by simply pushing the hose onto the Fir Tree.



This connection is not gas specific, so care must be taken that the correct gas is being used.

A typical use for a flow outlet (Fir Tree) is in the supply of oxygen gas to an open flow face mask or nasal cannula.

If the flow outlet is being used to supply oxygen conservers or other devices which can stop the gas flow, a special connector may be required to avoid disconnection due to a build-up of pressure in the hose when the gas flow is stopped.

The pressure outlet is normally fitted with a medical quick coupler (QC) outlet conforming to local market requirements. The QC outlets are gas specific preventing miss connection between different medical gases. The hose used to connect to the QC outlet has a higher pressure duty than the hose connected to the flow outlet. It is thicker, heavier and normally not clear.

BPA – Connect user equipment to the correct outlet, with the correct hose and fitting. If unsure consult the Gas Package supplier.

TURNING THE VALVE ON AND CONNECTING TO USER OUTLETS

When turning the Medical Combination Valve on, it is important the shut off valve is opened slowly to minimise pressure shocks inside the valve. Before turning on, check the flow selector is set to zero.

When using the flow outlet (Fir Tree), select the desired flow setting after turning on the main shut off valve.

There are two different procedures for connecting the pressure outlet (QC). Both have advantages and disadvantages as follows.



- *Connecting the hose before opening the shut-off valve: less manual effort to connect with no risk of a temporary external leak (with certain types of QC and if done slowly) but this can be more demanding on the equipment and there is a possible ejection of the hose if the connection was not properly done.*



- *Connecting the hose after opening the shut-off valve: risk of a temporary external leak whilst making a connection (with certain types of QC and if done slowly). Comparatively this method requires more force to make connection and needs*

to be made in a positive and firm manner. There is a smaller pressure shock for the equipment; ejection is less likely (the hose is still in the hand of the operator if wrongly connected).

Gas leaks of N₂O and N₂O/O₂ gas mixtures can produce ‘cold burns’ to the skin. Extra care is required making connections and disconnections to these gases.

BPA – As for all high pressure equipment, open main shut-off valve slowly and, while doing so, do not stand directly in front of any outlet or gauge

BPA – Select flow after turning on the main shut off valve

TURNING THE VALVE OFF AND DISCONNECTING

When the Medical Combination Valve is not in use the main shut-off valve should be closed.

When disconnecting equipment from the flow outlet “ZERO” flow should be selected first.

When disconnecting equipment from the QC pressure outlet the main shut off valve should be closed before performing the disconnection. It is preferable that the pressure should be vented from the hose before

disconnection. If this is not possible the user should be aware that gas will come out of the hose when it is disconnected and a firm grip is required on the hose as this happens.

BPA – Turn off the main shut off valve and if possible vent pressure from inside the Medical Combination Valve and hose before disconnecting equipment from either of the user outlets.

BPA – Turn off the main shut off valve when the combination valve is not in use.

PRESSURE GAUGES

Types of Gauge

There are two types of pressure gauges which can be fitted to Medical Combination Valves. Conventional Bourdon tube type and direct drive type.

How to distinguish them

- Bourdon's tube type: about 3 cm thick; the housing can be made of metal or plastic
- Direct drive type: about 1 cm thick, usually with a metal housing crimping the outer edge of a transparent plastic lens and with vent holes in the middle of the front lens

The Bourdon tube type of gauge offer greater accuracy and larger pointer movement but are less robust due to the delicate mechanism connecting the bourdon tube to the pointer. The direct drive gauges

have a smaller pointer movement but are much more robust as the pointer is fixed directly to the end of the tube without any gears. The direct drive gauges are also more water resistant making them more suitable for Medical Combination Valves which at times may be exposed to outdoor conditions, compared to conventional pressure regulators which are removed from the cylinder when the cylinder is transported and stored.



BPA - GCE recommends the fitting of direct drive type of pressure gauges to medical combination valves.

Active and non-active gauge

The operation of the pressure gauges on Combination Valves can be either 'active' or 'non-active'.

With active systems the pressure gauges show cylinder pressure at all times, irrespective of the main shut-off valve being open or closed. This is a useful feature for medical emergency equipment allowing quick assessment of cylinder content.

With non-active systems the pressure gauges show the correct cylinder pressure only when the main valve is open. Non-active pressure gauges are also subjected to extra strain on the bourdon tube due to more frequent flexing of the tube each time the valve is turned on and off. In order to carry out a quick assessment of the cylinder content, the user is also unfortunately more likely to open the shut off valve quickly.



BPA - GCE recommends active pressure gauge systems are used on Medical Combination Valves.

CYLINDER CONTENTS

The cylinder contains gas under pressure. For oxygen and most other compressed medical gases the level of gas content in the cylinder is proportional to the pressure in the cylinder.

Before using the cylinder check the cylinder contents by looking at the pressure gauge. For an active pressure gauge this can be done without opening the shut off valve. For a non-active pressure gauge it will be necessary to open the shut off valve for true cylinder pressure to register on the pressure gauge. This take more time, as the shut off valve must be opened slowly.

BPA - Before use, ensure the cylinder has sufficient gas content for your requirements.

BPA - Make plans for cylinder change over and backups as required, depending on the criticality of oxygen supply to the patient

CYLINDER CHANGE

When the pointer on the pressure gauge enters the red zone the cylinder should be replaced with a new cylinder. Turn off the cylinder at the shut-off valve and disconnect equipment from the outlet of the valve as described in the relevant section above. Empty cylinders should be stored in a suitable area ready for collection by your gas supplier.

Refit the equipment to a new cylinder and turn on slowly as described in the relevant section above.

BPA – Change cylinder when the pointer on the pressure gauge enters the red zone.



BPA – If there are several Gas Companies operating on your site, sort and organise according to cylinder size and Gas Company.



BPA –It is as important to protection cylinders and valves against rain and dust on the way back to the Gas Company as it is from the Gas Company to the customer.

VALVE & CYLINDER CLEANLINESS

When using Medical Combination Valves avoid any contact with oils and creams. Do not use the equipment if you have recently applied hand cream to your hands or face.

BPA – Keep all oils and creams away from oxygen equipment.

Clean only with cloth and warm water. Do not immerse the Medical Combination Valve or cylinder into water and do not subject to a high pressure water spray (“Kärcher®” or similar). Do not expose the cylinder or valve to temperatures above 60°C.

BPA – Clean Medical Combination Valve with cloth and warm water only. Refer to manufacturer Instructions For Use for usage of cleaning agents.



Not to do: A user turned the cylinder upside down and immersed it into a bucket of water in order to clean it!

USER REPAIRS

The user must not attempt any repair of the cylinder or valve. Repair can only be carried out by authorised personnel according to instructions from Manufacturer.

All faulty valves must be returned to the gas supplier for repair.



BPA – Put aside and label any suspect valve and indicate as precisely as possible the fault(s) observed before returning it to the gas company.

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