BRITISH COMPRESSED GASES ASSOCIATION
Registered office: 4a Mallard Way, Pride Park, Derby, UK, DE24 8GX
Company Number: 71798, England

Technical Information Sheet 21

Revision 1: 2013

Medical Gas Cylinders

BCGA Policy Statement on Valve Outlets

Background

Within the UK and Ireland, the valve outlets used for medical gas cylinders have traditionally used common outlets for a number of products. In addition, the National Health Service (NHS) has been reluctant to change their equipment to utilise higher pressure cylinders.

There is significant anecdotal evidence from the NHS to indicate that patient equipment has been connected to the wrong medical gas cylinder with the potential of either administering the wrong gas to the patient or subjecting the equipment to pressures above the equipment design pressure. These issues have been discussed between the British Compressed Gases Association (BCGA) and the Medicines & Healthcare products Regulatory Agency (MHRA).

This Technical Information Sheet provides guidance on the different standards that can be used within the UK and Ireland to ensure that the cylinder valve outlets used for medical gas cylinders provide a safe environment for patients and healthcare users.

Valve Outlet Standards

There are three main standards that can be used to specify the cylinder valve outlets used with medical gas cylinder packages:

BS EN ISO 407 (2) is typically used to define the valve outlets for cylinders up to 5 litre water capacity. This standard details the pin index valve outlet configurations used specifically for medical gas service, providing up to 16 different outlets for a range of medical gases and medical gas mixtures. This standard has also been adopted for the valve outlets of larger medical gas cylinders to provide a gas specific outlet. There are no proposals to change the specifications of these valve outlets.

BCGA TIS 21 - Revision 1
Published: 09/05/2013
Produced by: BCGA TSC7

BS ISO 5145 (3) includes a number of medical gas connections for the major medical gases and gas mixtures. In medical gas service, this standard is primarily used for the filling connection for valves with integral pressure regulators to provide a product specific connection. This outlet is also used on medical gas cylinders which have non-pressure regulated outlets, where the supplier wants to provide a different valve connection for higher pressure cylinders. This provides some protection against the inadvertent connection of a high pressure cylinder to equipment that is not designed for the pressure. Again there are no proposals to change these connections.

BS 341 Part 3 (1) is used to specify all other medical gas cylinder valve outlets. This standard provides unique product specific valve outlets for nitrous oxide and carbon dioxide but specifies the 5/8" BSP bullnose valve outlet (No.3) for use in medical oxygen, medical air, medical carbon dioxide mixtures, medical helium, medical helium/oxygen mixtures and medical oxygen/carbon dioxide mixtures. This standard is also used to specify the same 5/8" BSP bullnose valve outlet for a number of industrial gas cylinders, including industrial oxygen, nitrogen, argon and helium. Thus there is potential for confusion not only between specific medical gas cylinders but also with other industrial gas cylinders.

Actions

For safety reasons, an agreement was reached to implement a programme of change to convert all non-oxygen cylinders to gas specific outlets, such as pin index valve outlets, to minimise the risk of using the wrong cylinder package.

To achieve this, cylinders currently fitted with bullnose valves:

- Retain the medical oxygen cylinders fitted with bullnose valves (BS 341 Part 3 (1) No.3) as the only medical gas cylinders fitted with this valve outlet.

- Convert all other medical gas cylinders fitted with bullnose valves (BS 341 Part 3 (1) No.3) to use product specific valves (such as BS EN ISO 407 (2) or BS ISO 5145 (3)).

- As an alternative, the suppliers may choose to replace the bullnose valves with valves with integrated pressure regulators, thus eliminating the need for customers to replace their regulators.

The benefits of taking this approach to valve outlets are:

- The valve fitted to medical oxygen cylinders will become product specific in medical gas service.

- In the case of cylinders supplied for use in healthcare facilities, the majority of those fitted with bullnose valves are in medical oxygen service. Changing only the other cylinders will minimise any potential disruption that could be caused during the conversion programme and reduce the number of replacement regulators required to be purchased by the healthcare facilities.

- The bullnose valved cylinders in medical oxygen service are progressively being replaced with cylinders fitted with valves with integral pressure regulators. These cylinders have product specific filling connections and provide the customer with either a BS 5682 (4) pressure outlet or fir tree connection. As this conversion progresses, the number of bullnose valves in medical oxygen service will reduce further.

Although there is still a residual risk that a non-medical cylinder could be used to administer the wrong gas to a patient, the current programme to change the body colour code to white will help to mitigate this risk.

Where the supplier wishes to use a higher pressure cylinder package the supplier will:

- Provide cylinders fitted with an integral pressure regulator so that the gas is supplied either at 4 bar(g) or at a reduced pressure (where it is used for manifold service).

- Use a BS ISO 5145 (3) connection to cylinders fitted with non-regulated valves. The BS ISO 5145 (3) standard provides the same level of gas specific connections but also provides a different outlet to the standard one used for 137 bar(g) cylinders. This will require the equipment manufacturers to confirm that the regulator or manifold and tailpipes are suitable for the higher pressure service before modifying existing equipment.

Where high pressure cylinders are supplied with a BS EN ISO 407 (2) / BS 341 Part 3 (1) valve outlet, it will be the responsibility of the healthcare facility to ensure that the equipment is suitably designed to accept the higher pressure.

Conversion Programme

Each medical gas supplier has in place a plan for the conversions detailed above.

In the case where the supplier decides to replace the BS 341 Part 3 (1) No.3 valves with BS EN ISO 407 (2) or BS ISO 5145 (3) valves, the customers must be closely involved so that they are in possession of the correct regulator when the cylinders are changed over. After the change no further supplies of the ‘old’ BS 341 Part 3 (1) No.3 valves will be provided.

Where the supplier decides to replace the BS 341 Part 3 (1) No.3 valves with valves with integrated pressure regulators there is not the same need for the customers to obtain replacement regulators and the change over can therefore be carried out progressively. There may be a period when either type of valve may be supplied.

If the supplier decides to supply cylinders filled to a higher pressure (greater than 137 bar(g)) with the existing valve outlets, the supplier will advise the customer to

carry out a survey of all existing equipment at their facility. The customer shall then be advised to carry out a Risk Assessment to ensure that the changeover process will not add any additional risks to the safety of the patient or the healthcare user.

In all cases, it is a vital requirement that the supplier communicates the details of the programme to all affected customers, explaining the purpose of the change and how they need to prepare for it.

References:

1. BS 341 Part 3. Transportable gas container valves. Valve outlet connections.

2. BS EN ISO 407. Small medical gas cylinders. Pin-index yoke-type valve connections.

3. BS ISO 5145. Cylinder valve outlets for gases and gas mixtures. Selection and dimensioning.

4. BS 5682. Specification for probes (quick connectors) for use with medical gas pipeline systems.

For more information:

British Compressed Gases Association (BCGA) www.bcga.co.uk
Medicines & Healthcare products Regulatory Agency (MHRA). www.mhra.gov.uk

ISSN 0260 - 4809