MEDICAL GAS CONTROL

Analgesic Demand Valve

Instructions for Use

CE 1639

UKCA 0120

702-0038.26
February 2023

Contents

1. Symbols

Warning!	Indicates a potentially hazardous situation which, if not avoided, could result in personal injury to the user or others
Caution!	Indicates a potentially hazardous situation which, if not avoided, could result in damage to the equipment or property
Note	Highlights points that might allow more convenient or efficient operation of the equipment
	Use no oil
	Service due date

2. Warnings and Cautions

2.1. Warnings!

- Read through this entire instruction manual before using or showing others how to use this demand valve. As with all medical equipment, attempting to use this device without a thorough understanding of its operation may result in patient or user injury.
- N_2O/O_2 50%/50% V/V, hereinafter referred to as analgesic gas, is or should be considered a drug and should only be used for medical purposes as prescribed by a physician or authorised clinician and in accordance with the medicinal product labelling.
- Continuous exposure to elevated levels of nitrous oxide can be harmful. National standards for exposure levels (Time Weighted Average (TWA)), if available, should be applied. Risk controls measures such as adequate room ventilation, gas scavenging and/or environmental monitoring may be necessary.
- Ensure that the analgesic gas supply is sufficient for the proposed therapy and is supplied within the pressure range given in the Device Specification. If the supply is a gas cylinder, check the cylinder contents gauge regularly.
- This demand valve is only for use with medical grade analgesic gas. Check the cylinder or supply is medical grade analgesic gas before use.
- Use a new exhalation valve for each new patient or after 30 days of use for the same patient.
- Gas specific connectors are fitted to the demand valve. Do not attempt to modify the fittings to suit other gases or fitting systems.
- Oxygen and nitrous oxide analgesic gas mixture is not flammable; however the presence of it will drastically increase the rate and severity of combustion. Oil and/or grease in the presence of an oxygen enriched atmosphere will become highly combustible. Analgesic gas must never be allowed to come into contact with oil, grease or other petroleum-based substances. Do not use oil or grease on this demand valve.
- Many hand creams and moisturisers contain paraffin and petroleum bases which are highly flammable and must never be allowed to contact the Demand Valve. Ensure hands are clean and dry before operating the equipment.
- Do not use or store analgesic gas near excessive heat (>50°C/125°F) or below 10°C (50°F). Always refer to the medical gas suppliers recommendations.

- Do not smoke around analgesic gas equipment.
- Only appropriately trained personnel working in controlled conditions may disassemble or assemble this demand valve.
- Do not submerge an assembled demand valve in any fluid.
- If using a cylinder and regulator, ensure that the device is connected to the regulator and the cylinder valve is properly opened before beginning therapy.
- When therapy is complete, disconnect the demand valve from the gas supply. When the source of analgesic gas is from a gas cylinder, always close the gas cylinder valve when the demand valve is not in use and disconnect the demand valve from the pressure regulator.
- Arrange the gas hose carefully to avoid damage to the hose and the potential for causing a trip hazard. Never pull or apply excessive force to the gas hose. A leaking hose may result in high local oxygen and nitrous oxide concentrations and an increased risk of fire.

2.2. Cautions!

- The performance of the demand valve may be affected if it is stored or transported in temperatures outside of the range -20°C to 60°C (-4°F to 140°F).
- The demand valve is not suitable for autoclaving. The handset is protected from contamination in normal use by a single patient use exhalation valve.
- The single patient use exhalation valve is not suitable for cleaning. If the exhalation valve becomes visually soiled or discoloured it should be replaced.

2.3. Notes

- Peak flow through the demand valve might be restricted resulting in increased work of breathing for the patient in the following circumstances:
  - If the analgesic gas regulator or analgesic gas supply used does not meet the specification.
  - If an extension hose other than those listed in this manual for use with the demand valve is used.

3. Functional Description

3.1. Intended Use

The Ultraflow™ Analgesic Demand Valve is intended to be used for self-administration of N_2O/O_2 50%/50% V/V, hereinafter referred to as analgesic gas, in response to the patient's inspiratory effort.

Analgesic gas is or should be considered a drug and should only be used for medical purposes on the authority of a physician and then strictly in accordance with their instructions.

The demand valve is designed for use in all types of clinical environment. Always refer to the medical gas product labelling.

3.2. Technical Description

The demand valve comprises of two main components; a demand valve handset and a single patient use exhalation valve (supplied separately).

The exhalation valve is single patient use to prevent cross contamination between patients. It may be used by a single patient for up to 30 days.

The demand valve handset is designed to be reused and can be cleaned and disinfected, although routine disinfection is not necessary as it is protected from contamination by the single patient use exhalation valve.

The demand valve handset contains a specially designed tilt valve mechanism that opens when the diaphragm in the back of the demand valve handset moves forward as a result of the patient inhaling. When the tilt valve opens, the gas, which is under pressure behind the tilt valve, passes through the handset and is inhaled by the patient. The deeper the patient breathes, the greater the volume of gas delivered. When the patient exhales the diaphragm moves back, the tilt valve closes and no further gas is delivered.

The demand valve offers a very low resistance to flow during both patient inhalation and exhalation, which means less effort for the patient. This is achieved by the unique, patented exhalation valve design that diverts exhaled gas out through a special valve, thus eliminating the need for the patient to exhale through a highly resistant patient filter as is the case with other demand valve systems.

The demand valve can be driven directly from the terminal unit of a medical gas pipeline system or from a medical gas cylinder via a suitable pressure regulator. A gas hose complying with BS EN ISO 5359 carries the gas from the gas supply source to the demand valve.

The demand valve should be used with either a mouthpiece or a facemask. The exhalation valve has a viral filter that allows the flow of inhaled gas to the patient and prevents contamination of the demand valve handset from the patient's expired breath.

4. Operating Instructions

4.1. Fitting the Exhalation Valve

Use a new exhalation valve for each new patient or after 30 days of use for the same patient. The exhalation valve should be replaced if it becomes soiled or discoloured.

4.2. Removing the Lanyard

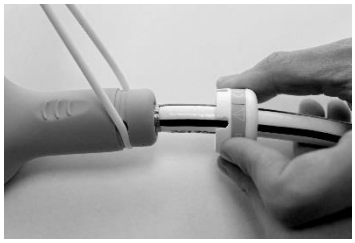
The lanyard helps to prevent the patient dropping the demand valve when they are not actively using it. Should a patient not want the lanyard then it can be removed.

To remove the lanyard, simply pull the lanyard retainer downwards until it is free of the moulded cover and lift the lanyard away. Then refit the lanyard retainer.

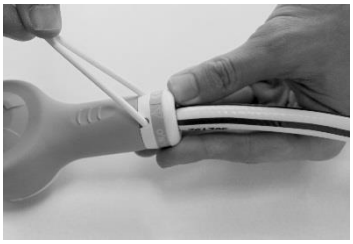
4.3. Refitting the Lanyard

1. To refit the lanyard, simply pull away the lanyard retainer.

2. Fit the lanyard into the groove in the handset cover.



3. Refit the lanyard retainer taking care to line up the slots in the lanyard retainer with the lanyard.



4.4. Connecting to the Analgesic Gas Supply

Before use, visually check both the hose and demand valve for any damage or contamination. Do not connect or use the device if there are any doubts about its condition.

The demand valve is supplied with a gas specific connector that is designed to connect to a mating gas outlet. Gas outlets might be part of a terminal unit in a medical gas pipeline system or part of a pressure regulator outlet on a gas cylinder.

If you are using a cylinder supply, ensure that the cylinder contents are adequate for planned therapy.

Connect the gas specific inlet connector to the appropriate gas outlet.

Warning! Where the gas specific connector is dependent on a threaded fastener (e.g. DISS CGA V-5 1240), make sure that the connection is tight before turning on the supply pressure.

For quick connector probes (e.g. BS 5682, SIS, AFNOR), ensure that the connection is correctly made by gently pulling the gas hose before turning on the supply pressure.

4.5. Testing Prior to Use

Confirm the correct operation of the demand valve before beginning therapy by pressing the Test Button. Gas should flow freely when the Test Button is pressed and should stop when the Test Button is released.

If the demand valve does not operate correctly, remove it from use and refer to the trouble shooting guide in Section 8 of this booklet.

4.6. Fitting an Exhalation Valve

Use a new exhalation valve for each new patient or after 30 days of use. The exhalation valve should be replaced if it becomes soiled or discoloured.

1. Place the exhalation valve on the demand valve handset as shown. Do not apply any force at this stage this stage.

2. Rotate the exhalation valve until it ‘clicks’ into place then press down.

3. Press down the securing clip on each side to lock into place.

4. Fit a face mask or mouthpiece.

4.7. Fitting an Exhalation Valve (AGSS)

1. Place the AGSS* adaptor over the exhalation valve as shown. Do not apply any force at this stage.

2. Press down until it 'clicks' into place.

3. Fit face mask or mouthpiece.

**AGSS = Anaesthetic Gas Scavenging System*

4.8. Operation

The patient should place the mouthpiece into their mouth or the face mask over their nose and mouth and inhale. Where an AGSS adaptor is used to capture the gas, the patient should breathe out through the mouthpiece or into the mask. The deeper the patient breathes, the greater the volume of gas delivered.

The demand valve is designed for self-administration of analgesic gas and should not be used for periods beyond those prescribed. Do not attach the face mask with a head strap or harness.

Continue to monitor the gas cylinder contents (if applicable) during use of the demand valve and be aware that the hose may be a trip hazard.

If a serious incident should occur in relation to the device, it should be reported to BPR Medical (or via or our distributor) and the relevant national regulatory authority of the country where the device was is use.

4.9. After Use

When therapy is complete, disconnect the demand valve from the gas supply. Where the analgesic gas is being supplied from a cylinder, turn the cylinder off and depressurise the handset before disconnection by pressing the Test Button until the gas is fully exhausted.

Store the demand valve in a clean dry environment between uses.

5. Cleaning and Disinfection

Ensure the demand valve handset is disconnected from the gas supply before attempting to clean it.

Caution! The demand valve is not suitable for autoclaving. The handset is protected against contamination during normal use by a single patient use exhalation valve.

5.1. After Every Use

Wipe over the outside of the demand valve handset and the gas supply hose with an alcohol or disinfecting wipe.

5.2. Suspected Contamination

If the demand valve handset becomes contaminated internally it cannot be reprocessed effectively and should be disposed of.

Never immerse the demand valve handset in any fluid or attempt to clean internal parts.

6. Maintenance

6.1. Servicing

The demand valve handset has an intended life of 10 years and must be serviced after 5 years to ensure that it continues to perform in accordance with its specification. Full details of the recommended servicing requirements can be found in the Service Manual or on SupportWeb. Contact your local distributor for information about SupportWeb online service training.

When serviced by BPR Medical Ltd. and where the time to end of life is less than the normal service interval, the Service Due date will be replaced by the End of Life date and preceded by a symbol (⌛). In these cases, the date now indicates when the device reaches end of life.

As an alternative to servicing the demand valve, a service exchange option is available to replace a used handset with a new one.

The Service Manual and access to SupportWeb can be obtained from your local BPR Medical distributor, details of which can be found at www.bprmedical.com.

6.2. End of Life

The materials used to make the demand valve handset can recycled. To assist with recycling, an illustrated list of materials used to manufacture the demand valve handset is available. Please contact BPR Medical at cs@bprmedical.com or your local distributor.

7. Specification

Specification	Value
Inspiratory Resistance	<1.5 kPa (0.22 psi) at 200 l/min <0.25 kPa (0.036 psi) at 10 l/min
Supply Pressure[1]	Maximum 600 kPa (87 psi) Minimum 310 kPa (45 psi)
Supply Flow Capacity[1]	>120 l/min
Demand Valve Peak Flow	>200 l/min
Intended Life	10 years
Environmental	Transport and Storage Temperature: -20°C to 60°C (-4°F to 140°F) Operating Temperature: 5°C to 40°C (41°F to 104°F) Humidity: 0-100% RH non-condensing
Regulatory	CE: Medical Device Directive 93/42/EEC – Active Medical Device – class IIa UKCA: UK Medical Device Regulations 2002 – class IIa medical device
Applied Standards	
BS 4272-2	Anaesthetic and analgesic machines. Specification for intermittent (demand) flow analgesic machines for use with 50/50% (V/V) nitrous oxide and oxygen
BS 5682	Probes (quick connectors) for use with medical gas pipeline systems
BS EN ISO 5356-1	Anaesthetic and respiratory equipment. Conical connectors. Cones and sockets
BS EN ISO 5359	Low pressure hose assemblies for use with medical gases
BS EN ISO 15001	Anaesthetic and respiratory equipment. Compatibility with oxygen
BS EN ISO 15223-1	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements
NF S 90 116	Medico-surgical equipment. Terminal units and related probes for medical fluids
DIN 13260-2	Supply systems for medical gases. Part 2: Dimensions and allocation of probes and gas specific connection points for terminal units for compressed medical gases and vacuum
SS 875 24 30	Medical gas pipeline systems. Connectors for medical gases
CGA V-5	DISS Diameter Index Safety System
SANS 1409	Outlet sockets and probes for medical (gas and vacuum) service used in hospitals
AS 2902	Medical gas systems. Low pressure flexible hose assemblies

[1] Indicates minimum supply pressure at stated value of gas flow. Based upon an adult breathing at 30 bpm with a tidal volume of 1 litre and I:E ratio of 1:2

8. Troubleshooting

Fault	Possible Cause	Solution
No gas flow	Demand valve handset is not connected properly.	Check gas supply. Check that the gas specific probe is correctly connected.
	Gas cylinder empty.	Replace gas cylinder.
	Medical gas terminal unit on a pipeline system is isolated.	Seek advice from someone authorised to operate the medical gas pipeline system isolation valves.
	Demand valve probe blocked.	Repair or service required.
	Hole in demand valve diaphragm. In this instance, the demand valve will work with the Test Button but not when used conventionally by inhaling through the mouthpiece or face mask.	Repair or service required.
Audible gas leak	Valve or diaphragm has become dislodged.	Remove the exhalation valve and check that the diaphragm is laying flat and that it moves forwards and backwards when the Test Button is pressed
	Tilt valve worn, bent or broken.	Repair or service required.
Constant gas flow	Tilt valve damaged or blocked.	Repair or service required.
Insufficient gas flow	Tilt valve damaged.	Repair or service required.
	Diaphragm perforated.	Repair or service required.
	Supply pressure too low and/or gas cylinder nearly empty.	Check gas supply and/or replace gas cylinder.
Exhalation valve will not fit to or be retained on the demand valve body	Single patient use exhalation valve has damaged location lugs.	Check the underside of the single use exhalation valve to see if the locating lugs have been bent over or otherwise damaged. It is important to rotate the single use exhalation valve until it locates in the demand valve housing before pressing it down and engaging the locating ears. Trying to force the single patient use exhalation valve down before correctly locating it will damage the exhalation valve beyond repair. Fit a new single patient use exhalation valve.

9. Parts and Spares

Part Number	Description
828-0013	Analgesic Demand Valve - 2m Hose - BS 5682 connector
828-0001	Analgesic Demand Valve - 3m Hose - BS 5682 connector
828-0014	Analgesic Demand Valve - 4m Hose - BS 5682 connector
828-0015	Analgesic Demand Valve - 5m Hose - BS 5682 connector
828-0016	Analgesic Demand Valve - 6m Hose - BS 5682 connector
828-1002	Analgesic Demand Valve - 2m Hose - AFNOR connector (NF S 90 116)
828-1003	Analgesic Demand Valve - 3m Hose - AFNOR connector (NF S 90 116)
828-1004	Analgesic Demand Valve - 4m Hose - AFNOR connector (NF S 90 116)
828-1005	Analgesic Demand Valve - 5m Hose - AFNOR connector (NF S 90 116)
828-1006	Analgesic Demand Valve - 6m Hose - AFNOR connector (NF S 90 116)
828-3002	Analgesic Demand Valve - 2m Hose - Nordica AGA connector (SS 875 24 30)
828-3003	Analgesic Demand Valve - 3m Hose - Nordica AGA connector (SS 875 24 30)
828-3004	Analgesic Demand Valve - 4m Hose - Nordica AGA connector (SS 875 24 30)
828-3005	Analgesic Demand Valve - 5m Hose - Nordica AGA connector (SS 875 24 30)
828-3006	Analgesic Demand Valve - 6m Hose - Nordica AGA connector (SS 875 24 30)
828-5002	Analgesic Demand Valve - 2m Hose - DISS connector (CGA V-5 2020)
828-5003	Analgesic Demand Valve - 3m Hose - DISS connector (CGA V-5 2020)
828-5004	Analgesic Demand Valve - 4m Hose - DISS connector (CGA V-5 2020)
828-6002	Analgesic Demand Valve - 2m Hose - SANS connector (SANS 1409)
828-6003	Analgesic Demand Valve - 3m Hose - SANS connector (SANS 1409)
828-6004	Analgesic Demand Valve - 4m Hose - SANS connector (SANS 1409)
828-6005	Analgesic Demand Valve - 5m Hose - SANS connector (SANS 1409)
828-6006	Analgesic Demand Valve - 6m Hose - SANS connector (SANS 1409)
828-7002	Analgesic Demand Valve - 2m Hose - SIS connector (AS 2896)
828-7003	Analgesic Demand Valve - 3m Hose - SIS connector (AS 2896)
828-7004	Analgesic Demand Valve - 4m Hose - SIS connector (AS 2896)
828-7005	Analgesic Demand Valve - 5m Hose - SIS connector (AS 2896)
828-7006	Analgesic Demand Valve - 6m Hose - SIS connector (AS 2896)
828-9002	Analgesic Demand Valve - 2m Hose - ¼ BSP connector
828-9003	Analgesic Demand Valve - 3m Hose - ¼ BSP connector
828-9004	Analgesic Demand Valve - 4m Hose - ¼ BSP connector
828-9005	Analgesic Demand Valve - 5m Hose - ¼ BSP connector
828-9006	Analgesic Demand Valve - 6m Hose - ¼ BSP connector
Consumables	
828-0040	Single Patient Use Exhalation Valve with Mouthpiece (25) EN 1281-1 (22mm)
828-0002	Single Patient Use Exhalation Valve with Mouthpiece (100) EN 1281-1 (22mm)

828-0039	Single Patient Use Exhalation Valve for use with Face Mask (25) EN 1281-1 (22mm)
828-0042	Single Patient Use Exhalation Valve for use with Face Mask (100) EN 1281-1 (22mm)
828-0049	Single Patient Use Exhalation Valve (AGSS) for use with Face Mask (50) EN 1281-1 (22mm)
828-0019	Single Patient Use Exhalation Valve (AGSS) with Mouthpiece (50) EN 1281-1 (22mm)
828-0046	Single Patient Use Face Mask (Box 40) EN 1281-1 (22mm)

Spare Parts and Servicing

609-0034	Analgesic Demand Valve Cover - Blue
610-0084	Demand Valve Lanyard (10)
999-1000	Demand Valve Factory Service
999-1102	Analgesic Demand Valve Service Kit - 2m Hose - AFNOR
999-1103	Analgesic Demand Valve Service Kit - 3m Hose - AFNOR
999-1104	Analgesic Demand Valve Service Kit - 4m Hose - AFNOR
999-1105	Analgesic Demand Valve Service Kit - 5m Hose - AFNOR
999-1106	Analgesic Demand Valve Service Kit - 6m Hose - AFNOR
999-3302	Analgesic Demand Valve Service Kit - 2m Hose - Nordica AGA
999-3303	Analgesic Demand Valve Service Kit - 3m Hose - Nordica AGA
999-3304	Analgesic Demand Valve Service Kit - 4m Hose - Nordica AGA
999-3305	Analgesic Demand Valve Service Kit - 5m Hose - Nordica AGA
999-3306	Analgesic Demand Valve Service Kit - 6m Hose - Nordica AGA
999-4402	Analgesic Demand Valve Service Kit - 2m Hose - BS 5682
999-4403	Analgesic Demand Valve Service Kit - 3m Hose - BS 5682
999-4404	Analgesic Demand Valve Service Kit - 4m Hose - BS 5682
999-4405	Analgesic Demand Valve Service Kit - 5m Hose - BS 5682
999-4406	Analgesic Demand Valve Service Kit - 6m Hose - BS 5682
999-5502	Analgesic Demand Valve Service Kit - 2m Hose - DISS
999-5503	Analgesic Demand Valve Service Kit - 3m Hose - DISS
999-5504	Analgesic Demand Valve Service Kit - 4m Hose - DISS
999-6602	Analgesic Demand Valve Service Kit - 2m Hose - SANS
999-6603	Analgesic Demand Valve Service Kit - 3m Hose - SANS
999-6604	Analgesic Demand Valve Service Kit - 4m Hose - SANS
999-6605	Analgesic Demand Valve Service Kit - 5m Hose - SANS
999-6606	Analgesic Demand Valve Service Kit - 6m Hose - SANS
999-7702	Analgesic Demand Valve Service Kit - 2m Hose - SIS
999-7703	Analgesic Demand Valve Service Kit - 3m Hose - SIS
999-7704	Analgesic Demand Valve Service Kit - 4m Hose - SIS
999-7705	Analgesic Demand Valve Service Kit - 5m Hose - SIS
999-7706	Analgesic Demand Valve Service Kit - 6m Hose - SIS
999-9902	Analgesic Demand Valve Service Kit - 2m Hose - ¼ BSP
999-9903	Analgesic Demand Valve Service Kit - 3m Hose - ¼ BSP

999-9904	Analgesic Demand Valve Service Kit - 4m Hose - ¼ BSP
999-9905	Analgesic Demand Valve Service Kit - 5m Hose - ¼ BSP
999-9906	Analgesic Demand Valve Service Kit - 6m Hose - ¼ BSP

10. Distributor Details

Australia

BOC Healthcare
Customer Service Centre
10 Julius Avenue
North Ryde
Sydney
NSW, 2113
T: +61 (0)2 8874 4400
F: +61 (0)2 9886 9000
www.boc.com.au

New Zealand

BOC Healthcare
Customer Service Centre
970-992 Great South Road
Penrose 1061
Auckland
New Zealand
T: +64 (0)9 525 5600
www.boc.co.nz

Canada

BOMImed Inc.
96 Terracon Place
Winnipeg
MB R2J 4G&
Canada
T: +1 204.633.2664
F: +1 204.632.1064
www.bomimed.com

BPR Medical Ltd License No: 86841

South Africa

AFROX Hospital Care
PO Box 5404
Johannesburg
2000
T: +27 (0)11-490-0400
F: +27 (0)11-490-0451
www.afrox.co.za

ENDV25/11/09/V2

AFROX
A Member of The Linde Group

EC REP

Qarad EC-REP BV
BE-AR-000000040
Pas 257, 2440 Geel
Belgium

MedEnvoy
NL-IM-000000248
Prinses Margrietplantsoen 33
Suite 123, 2595 AM, The Hague
The Netherlands

CH REP

Qarad Suisse S.A.
CHRN-20002058
World Trade Center
Avenue Gratta-Paille 2
1018 Lausanne, Switzerland

bpr MEDICAL GAS CONTROL

BPR Medical Limited
22 Hamilton Way, Mansfield, Notts.
NG18 5BU, United Kingdom

☎ +44 (0)1623 628 281
info@bprmedical.com
www.bprmedical.com