Analgesic Demand Valve

Instructions for Use

the trusted brand
carnét®
suction & oxygen therapy products

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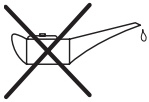
Contents

1. Description of 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.

Attention, consult accompanying documents



Use No Oil

No Smoking

Single Use or Single Patient Use

Service Due date

CE Marked to Medical Device Directive 93/42/EEC modified by directive 2007/47/CE

2. Warnings, Cautions and Notes

2.1 Warnings!

2.1.1 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.

2.1.2 O_2/N_2O 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.

2.1.3 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.

2.1.4 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.

2.1.5 This demand valve is only for use with medical grade analgesic gas. Check the cylinder or supply is medical grade analgesic gas before use.

2.1.6 Use a new exhalation valve for each new patient or after 30 days of use for the same patient.

2.1.7 Gas specific connectors are fitted to the demand valve. Do not attempt to modify the fittings to suit other gases or fitting systems.

2.1.8 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 contact oil, grease or other petroleum-based substances. Do not use oil or grease on this demand valve.

2.1.9 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.

2.1.10 Do not smoke around analgesic gas equipment.

2.1.11 Only appropriately trained personnel working in controlled conditions may disassemble or assemble this demand valve.

2.1.12 Disassemble the device before cleaning. Do not submerge an assembled demand valve in any fluid.

2.1.13 Do not use analgesic gas as a pressure medium to purge obstructed pipelines or equipment, to operate pneumatic tools, or to build up any pressure in tanks.

2.1.14 Secure cylinders to a wall, stand or cart in accordance with local safety regulations.

2.1.15 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.

2.1.16 Never permit compressed medical gases to enter a pressure regulator suddenly. Always open the cylinder valve slowly.

2.1.17 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.

2.1.18 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!

2.2.1 The performance of the demand valve may be affected if it is stored or transported in temperature outside of the range -20°C to +60°C (-4°F to +140°F).

2.2.2 The demand valve is not suitable for autoclaving. The handset is protected from contamination in normal use by a single patient use exhalation valve.

2.2.3 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

2.3.1 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 Carnét Analgesic Demand Valve is intended to be used for self-administration of O_2/N_2O 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 type of clinical environment. Always refer to the medical gas product labelling.

3.2 Technical Description

The demand valve comprises two main components; a demand valve handset and a single patient use exhalation valve.

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 5359:2008 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. Device 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	Maximum 600 kPa (87psi)[1]
	Minimum 310 kPa (45psi)[1]
Supply Flow Capacity	> 120 l/min[1]
Demand Valve Peak Flow	> 200 l/min
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 lla
Applied Standards	BS 5682 - Probes (quick connectors) for use with medical gas pipeline systems
	EN 1281-1 - Anaesthetic and respiratory equipment – conical connectors – Part 1: Cones and sockets
	BS EN ISO 5359:2008 - Low pressure hose assemblies for use with medical gases
	EN ISO 15001 - Anaesthetic and respiratory equipment - Compatibility with Oxygen
	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
	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 EN 980:2008 - Symbols for use in the labelling of medical devices
	AS 2896-1998 Medical gas systems - installation and testing of non-flammable medical gas pipeline systems

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

5. Operating Instructions

5.1 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.

5.2 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.

5.3 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.

5.4 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 – V5 1240), make sure that the connection is tight before turning on the supply pressure.

For quick connector probes (e.g. BS5682, SIS, AFNOR), ensure that the connection is correctly made by gently pulling the gas hose before turning on the supply pressure.

5.5 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 towards the back of this booklet.

5.6 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.

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.

5.7 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*

5.8 Operation

The patient should place the mouthpiece into their mouth or the face mask over their nose and mouth and inhale. 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.

5.9 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 handset before disconnection by pressing the test button until the gas is fully exhausted.

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

6. Cleaning & 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.

6.1 After Every Use

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

6.2 Suspected Contamination

If you suspect that the demand valve handset is contaminated remove it from use and refer to Analgesic Demand Valve Service Manual.

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

7. Maintenance

User Maintenance and Inspection

All Demand Valves should be inspected and tested on an annual basis to ensure correct performance.

The demand valve handset must be serviced every 4 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.

Servicing must be carried out by a suitably qualified person working in a controlled environment.

If there is reason to believe that the demand valve handset is contaminated it can be disinfected using a cold disinfection process but will need to be disassembled first. Full details of how to disassemble, clean and disinfect the device can be found in the Service Manual.

The Service Manual can be obtained from your local Carnét distributor, details of which can be found at www.carnetmedical.com.

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 List

Part No.	Description	Connection
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
828-7002	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
828-3002	Analgesic Demand Valve-2m Hose-Nordica connector	SS 875 24 30
828-3003	Analgesic Demand Valve-3m Hose-Nordica connector	SS 875 24 30
828-3004	Analgesic Demand Valve-4m Hose-Nordica connector	SS 875 24 30
828-3005	Analgesic Demand Valve-5m Hose-Nordica connector	SS 875 24 30
828-3006	Analgesic Demand Valve-6m Hose-Nordica connector	SS 875 24 30
828-0013	Analgesic Demand Valve-2m Hose-BS5682 connector	BS 5682
828-0001	Analgesic Demand Valve-3m Hose-BS5682 connector	BS 5682
828-0014	Analgesic Demand Valve-4m Hose-BS5682 connector	BS 5682
828-0015	Analgesic Demand Valve-5m Hose-BS5682 connector	BS 5682
828-0016	Analgesic Demand Valve-6m Hose-BS5682 connector	BS 5682
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

Consumables		
828-0045	Single Patient Use Exhalation Valve with Mouthpiece (10)	EN 1281-1 (22mm)
828-0002	Single Patient Use Exhalation Valve with Mouthpiece (100)	EN 1281-1 (22mm)
828-0044	Single Patient Use Exhalation Valve for use with Face Mask (10)	EN 1281-1 (22mm)
828-0042	Single Patient Use Exhalation Valve for use with Face Mask (100)	EN 1281-1 (22mm)
828-0048	Single Patient Use Exhalation Valve (AGSS) for use with Face Mask (10)	EN 1281-1 (22mm)
828-0049	Single Patient Use Exhalation Valve (AGSS) for use with Face Mask (50)	EN 1281-1 (22mm)
828-0050	Single Patient Use Exhalation Valve (AGSS) with Mouthpiece (10)	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)
Spares		
609-0034	Analgesic Demand Valve Cover–Blue	Universal
212-0067	Demand Valve Lanyard	Universal

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