THERAPY EQUIPMENT COMFORT RANGE
(O2/N2O DEMAND VALVE)

INSPECTION

Remove the Demand Valve from the packaging and inspect for damage. If there is any damage, DO NOT USE, and contact Therapy Equipment Ltd.

FUNCTION/INTENDED USE

⚠️ The Demand Valve should only be used by Hospital personnel authorised to administer analgesic gas to a patient.

⚠️ Read all instructions before using – DO NOT USE the Demand Valve if you do not understand the instructions given in these User Instructions.

The function of the O2/N2O (“Entonox”) Demand Valve is to provide a patient operated device capable of supplying over 200 Litres of O2/N2O 50%/50% V/V “Entonox” analgesic gas.

Mainly used in the Maternity Department, the Valve can be used wherever Analgesic gas is required i.e. Accident & Emergency, Fracture Clinic, Burns Unit etc.

The Valve fully complies with the requirements of British Standard BS 4272:Part 2: 1996 (Anaesthetic and Analgesic Machines, Part 2: Specification for intermittent (demand) flow analgesic machines for use with 50/50 % (V/V) nitrous oxide and oxygen).

The unit should be stored in an unpressurised, dry and clean environment within the temperature range of -10°C to +40°C.
The Therapy Equipment Comfort Range consists of the following variations:

Complete Comfort Range Kit with PVC Hose (Part No. 6000):
- Single Stage Medireg & Schrader – Pin Index – O2/N2O
- O2/N2O Demand Valve with 2 Metres of PVC Hose/Probe
- Facemask
- Mouthpiece x 5

Complete Comfort Range Kit with Silicone Hose (Part No. 6002):
- Single Stage Medireg & Schrader – Pin Index – O2/N2O
- O2/N2O Demand Valve with 2 Metres of Silicone Hose/Probe
- Facemask
- Mouthpiece x 5

O2/N2O PVC Demand Valve Only (Part No. 6005):
- O2/N2O Demand Valve with 2 Metres of PVC Hose/Probe
- Facemask
- Mouthpiece

O2/N2O Silicone Demand Valve Only (Part No. 6007):
- O2/N2O Demand Valve with 2 Metres of Silicone Hose/Probe
- Facemask
- Mouthpiece

**Technical Specification**

**Demand Valve:**
- **Inlet pressure**
  - Up to 90psi (6Bar) (Cylinder)
  - 60psi (4Bar) (Gas Pipeline)
- **Maximum Flow**
  - Over 200LPM at –1.5kPa Negative pressure
- **Regulatory**
  - CE Marked as Class IIA Device
  - (Medical Device Directive 93/42/EEC)

**Instructions for Use**
- The device is intended for use with 50%O2/50%N2O Only
- The device is only to be used by persons trained in the use of Analgesic Gas.

**General Information**

The device is a demand valve, which will dispense Analgesic Gas, when a small negative pressure (breathing in) is applied by the patient to the Facemask, or Mouthpiece.

The Demand Valve will dispense sufficient gas for any patient demand. The Valve will open at a negative pressure of –2.5cmH2O, and is capable of providing in excess of 200 LPM of gas to the patient.

When the patient exhales, the gas supply is automatically switched off, and the patient exhalation is exhausted through the handle. The Handle has a 30mm Male fitting for connection to a Standard AGSS (Anti-Gas Scavenging System). 30mm is required in accordance with British Standard.
The unit is offered with either a Polymer Hose (to BS EN ISO 5359:2008) or Silicone Hose, which is more flexible and entirely suitable for use, but does not meet the pull and occlusion test of BS EN ISO 5359:2008.

The device is designed to be re-used and should be cleaned after each patient use in accordance with the Comfort Range Demand Valve Cleaning/Sterilising Instructions.

**User Instructions**

1. Unpack the Demand Valve Assembly from the packaging.
2. Ensure the unit is clean, and in a good condition before connecting to a gas pressure source.
3. Connect the Hose/Probe attached to the Demand Valve to either a Hospital Pipeline, or the Schrader Valve on an O2/N2O Pin Index Regulator.
4. If the Demand Valve is connected to a Regulator, ensure that the cylinder contains gas, and is turned on.
5. If an AGSS (Anti Gas Scavenging System) is in use, push the 30mm AGSS connector over the bottom of the Demand Valve Handle.
6. Press the Flush Button twice briefly, to ensure availability of gas. This action should not be carried out in the vicinity of the patient. Also ensure that there is no audible signs of residual gas flow after the Flush Button has been pressed.
7. Fit a mouthpiece or facemask to the 22mm Male Connector on the Demand Valve Head.
8. Secure the wrist strap so that when the Demand Valve is taken away from the mouth for patient comfort, the Demand Valve will stay connected to the patient's hand.
9. Breathe in. The action of breathing in with the Facemask on the face, or the Mouthpiece in the mouth, will cause a negative pressure on the patient outlet of the Demand Valve, and activate the supply of Analgesic Gas. In excess of 200LPM (dependent on amount of negative pressure applied) will be made available to the patient.
11. The action of breathing out will cause the Demand Valve to cease supply of gas. The expired gas will be exhausted through the Demand Valve Handle, by means of an Exhaust Valve.
12. Continue the process, under supervision, until sufficient Analgesic Gas has been dispensed.
13. Once the session has been completed, remove the Demand Valve from the pressurised supply, and reprocess using the undernoted instructions (see cleaning instructions).

**Sterilisation/Cleaning**

Disconnect the Demand Valve from the gas supply before attempting to clean the unit.

The Demand Valve should be cleaned in accordance with the Comfort Range Demand Valve Cleaning/Sterilising Instructions (available as separate sheet or via website www.therapyequipment.co.uk) after each patient use.

The Microbiological filter (if used) and Facemask/Mouthpiece should be considered single patient use, and discarded of after use.

The Demand Valve should be always be purged with gas prior to each patient use.
**General Notes for usage**

1. The unit should not be used if damaged in any way.
2. After use, the unit should be disconnected from the Pipeline or Regulator. The unit should not be left attached to a Pipeline or Regulator in a pressurised condition.
3. Before use the Unit should be checked for function, by pressing the Flush Button at least two times to ensure the unit is supplying gas and is shutting off successfully.
4. The Demand Valve should not be used if the Entonox Cylinder is showing any signs that freezing is taking place. Any sub-zero temperature could cause the gas mixture to separate.
5. There is a risk of fire from ignition sources such as smoking when the machine is used.
6. The Demand Valve requires to be function checked annually and reconditioned every three years. The attached Hose Assembly should also be replaced every three years.

**The clinical user is responsible for the administering and monitoring of patients using “Entonox” gas, and should be have received appropriate training in the use of the Analgesic Valve. Therapy Equipment accepts no responsibility for any incorrect administration of the gas.**

Your attention is drawn to the requirements given in clause 9.1 and 9.2 of BS 1319:1976 for the labelling of cylinders containing a mixture of oxygen and nitrous oxide, and to the recommendations for the storage of these cylinders given in A.3 of BS 1319:1976.

**Hose Assembly**

The Demand Valve is supplied with a Hose Assembly option.

**PVC Hose**

The PVC Hose conforms fully to the British Standard BS EN ISO 5359:2008 (Low Pressure hose assemblies for use with medical gases).

PVC Hose Assemblies may be supplied up to a maximum length of 4 Metres, however cannot be autoclaved.

It is recommended that the Hose Assembly be replaced when the unit is being reconditioned (every three years).

**Silicone Hose**

The Silicone Hose consists of a special gas colour coded braided Silicone Hose, and is fully autoclavable up to 137°C.

The Hose does not however conform to the pull and occlusion test as outlined in the British Standard BS EN ISO 5359:2008 (Low Pressure hose assemblies for use with medical gases), however is CE Marked and entirely suitable for use.

Due to the special crimping arrangements, and the fact that the Hose may only be used in conjunction with the Therapy Equipment Demand Valve, we are only able to supply the Hose complete with the unit distinct end fittings. The Silicone Hose Assembly may be supplied up to a maximum length of 4 Metres.

It is recommended that the Hose Assembly be replaced when the unit is being reconditioned (every three years).
WARNINGS/PRECAUTIONS

⚠️ **DO NOT** use near sources of ignition.

⚠️ **ANALGESIC GAS** must never be allowed to contact oil, grease or other petroleum-based substances. Do not use Oil or Grease on this product.

⚠️ **DO NOT** smoke in an area where this product is being used

⚠️ **DO NOT** use if the product is leaking or malfunctioning

⚠️ **DO NOT** allow the Hose Assembly to rest or be scraped across the floor

⚠️ **DO NOT** use the Demand Valve if apparently contaminated. The Demand Valve should be cleaned/sterilised after each patient use

“Entonox” should be considered a drug and should only be used for medical purposes. Continued exposure to high levels of Nitrous Oxide can be harmful. Consideration should be given to adequate room ventilation, gas scavenging etc.

⚠️ **CLEAN** the product in accordance with the Comfort Range Demand Valve Cleaning/Sterilising Instructions after each patient use.

TROUBLESHOOTING

<table>
<thead>
<tr>
<th>PROBLEM</th>
<th>ANALYSIS</th>
<th>ACTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item is damaged</td>
<td>Gas could escape, and the valve would not function properly</td>
<td>Remove from pressure source, and send for Service/Repair</td>
</tr>
<tr>
<td>Internal Mechanism has been interfered with, and re-assembled incorrectly</td>
<td>Unit will not function (or leaks)</td>
<td>Remove from pressure source, and send for Service/Repair</td>
</tr>
<tr>
<td>Diaphragm Ruptures</td>
<td>Unit will not function</td>
<td>Remove from pressure source, and send for Service/Repair</td>
</tr>
<tr>
<td>Significant Input Pressure Variation</td>
<td>Unit will under perform on High Volume Flow requirement</td>
<td>Remove from pressure source, and check output pressure of either Regulator or Pipeline</td>
</tr>
<tr>
<td>Probe will not fit Regulator Valve or Pipeline Outlet</td>
<td>Unit cannot access pressure source to function</td>
<td>Check to ensure that Probe is the correct type. If the correct type has been fitted check for damage. Return to workshop for Repair</td>
</tr>
<tr>
<td>Entonox Cylinder Freezes</td>
<td>Gas Mixture may separate</td>
<td>Stop using the Demand Valve. Cylinder will return to normal temperature. Before re-use, check supply hose for damage</td>
</tr>
</tbody>
</table>
Smoking within the environment of the exhausted gas
Atmosphere becomes gas enriched causing the possibility of ignition
Ensure that smoking does not take place in the vicinity of the Demand Valve, when in use.

Hose assembly over-stretched against end fittings
Hose Assembly could become damaged and blister/rupture
Ensure that the Hose Assembly is long enough for the application

Recommended Accessories

<table>
<thead>
<tr>
<th>Accessory</th>
<th>Part No.</th>
<th>Each</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Facemask (Large)</td>
<td>6815</td>
<td></td>
</tr>
<tr>
<td>Patient Facemask (Medium)</td>
<td>6816</td>
<td></td>
</tr>
<tr>
<td>Patient Mouthpiece</td>
<td>6061</td>
<td></td>
</tr>
<tr>
<td>2 Metre PVC Hose Assembly</td>
<td>6005-60</td>
<td></td>
</tr>
<tr>
<td>2 Metre Silicone Hose Assembly</td>
<td>6005-50</td>
<td></td>
</tr>
<tr>
<td>AGSS 30mm Male Connector</td>
<td>6020-01</td>
<td></td>
</tr>
<tr>
<td>AGSS 30mm Female Connector</td>
<td>6020-02</td>
<td></td>
</tr>
<tr>
<td>AGSS 30mm Tubing</td>
<td>6020-03</td>
<td>1.5M Lengths</td>
</tr>
</tbody>
</table>

USE OF ANIMAL TISSUES/PHTHALATES/ANTIMICROBIAL PROPERTY

The Comfort Range has not been manufactured using any Animal Tissue or Phthalates. PVC Hose Assemblies, when fitted, do have an Anti-Microbial Biocidal Property – full details are available on request.

Preventative Maintenance

The Demand Valve is supplied with a three-year function warranty. Despite this we do however recommend that the Demand Valve is included in an annual service inspection.

- The unit should be maintained in a clean working condition.
- A check should be made annually to ensure that the unit is damage free and is leak tight. Please note that the unit may show signs of minor leakage if left under continuous pressure for extended periods of time.
- The unit should be connected to a gas pressure source (either Regulator or Gas Pipeline) and the Flush Button be pressed at least twice for one-two seconds (not in vicinity of patient).
- Ensure that the unit is delivering gas, and that there is no audible escape of gas after the valve has closed.
- Check the Hose Assembly for any wear, and perform a leak test on the Hose Assembly by applying leak detection fluid to the end connectors.

Every three years the unit should be returned to the manufacturer, or authorised workshop for an overhaul, which would involve the full strip down, inspection, and renewal of all appropriate parts.