b. If a PRU is not connected to the Regulator and the Regulator is still connected to the Cylinder, connect the PRU to the Regulator by pushing the Probe on the end of the Hose into the Regulator's Schrader/S.S.V. Valve and carry out procedure in 8a. Disconnect the Regulator and replace the "Bodok Seal" (Pin Index Regulators) or "O" Ring (Bull Nose Regulators) on the Regulator Inlet Connector. Inspect the Regulator for damage and if no damage is found connect the Regulator to the Cylinder securely as procedure stated in 8a to c. Turn off the Cylinder Valve and observe the Contents Gauges for 2 minutes. If the indicator-needle drops, this will indicate a leak on the PRU unit. If a leak is detected, please contact our Sales Department for Service Information.

PRU Maintenance and Leakage Test

c. By using the Regulator that has passed the test for leakage in 8 a. and b., turn on the supply to the Regulator by turning the Cylinder anti-clockwise. Connect the Probe on the end of the PRU Hose into the Regulator Schrader/S.S.V. Valve. Momentarily press and release the "Flush" Button at the rear if the PRU and then turn off the Cylinder by turning the Valve Clockwise until it stops. Observe the Regulators Contents Gauge for 2 minutes. If the indicator-needle drops, this will indicate a leak. If a leak is detected, please contact our Sales department. Always fit a new Inspiratory/Expiratory Filter for the next patient. The Inspiratory/Expiratory Filter is to be fitted in between the PRU Demand Valve and the Mask/Mouthpiece.

Cleaning the PRU

d. The PRU can be cleaned by using a solution of luke-warm water and "Dettol" or similar Disinfectant Fluid (use Dettol solution Instructions on "Dettol" Container). Remove the Mask/Mouthpiece and Filter from the PRU. Hold the PRU firmly in one hand and unscrew (anti-clockwise) the White Rear Cap from the PRU. Remove the Main Diaphragm. Unscrew and remove the Dump Valve Cap from the top of the PRU. Hold the PRU upside down so that the Hose is at the top preventing the cleaning solution running down into the Hose. By using a small and smooth Brush/Pipe cleaner or cloth, thoroughly clean out the PRU, Diaphragm and Caps using the cleaning fluid solution. Rinse thoroughly and leave to drip dry or dry with a clean dry cloth. Gently reassemble then function test and leak test as stated in 6.3 and 8c.respectively. A full inspection should be carried out at least annually by qualified personnel only. For Servicing/Maintenance Information please contact the Oxylitre Service Department.

9. Technical Data and Performance (PRU Only)

a.	Input Pressure:	400 kPa. (Operates: from 280 to 600 kPa's).
b.	Inspiratory Cracking Pressure:	up to 0.25 kPa at 10 LPM and up to 1.5 kPa at 200 LPM.
c.	Expiratory Resistance:	up to 0.1 kPa at 12 LPM.

10. Additional/Replacement Parts (Description/Part No.)

a. Filter: PRU010 (Box of 50)
b. Scavenging Outlet Connector: PRU0-20
c. Case: PRU050*
d. Wall Mounting Bracket: PRU003/W
e. Adult Mask: 011-4 (Single patient use)
f. Adult Mask: 012-4 (Re-usable, Autoclaveable)
g. Child Mask: 011-2 (Single patient use)
h. Child Mask: 012-2 (Re-usable, Autoclaveable)
i. Mouthpiece (Pack of 5): 332555
j. Filter & Mouthpiece: PRU01035 (Box of 50)
k. BN "O" Ring: BS110 (Regulator)
l. PI Bodok Seal: OX010: (Regulator)

PHT
PHTHALATE-FREE

Note: The hose material is phthalate free PVC which is antimicrobial or is Silicone which complies with USP Class VI.

*The carry case is protected with an anti-microbial coating (ÆGIS Microbe Shield)

PROTECTED BY THE ægis MICROBE SHIELD® CONTROLS ODOR, STAINING, DETERIORATION

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GMDN 17169 (Demand Valve)

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Oxylitre

PRU Series Demand Valve Unit

For use with N_2O 50%/O_2 50% (Entonox®)
Pain Relief Medical Gas

Operating & Safety Instructions



Made in the UK

1. Introduction

The Oxylitre PRU *(Pain Relief Unit)* Series Demand Valve is a lightweight, hand-held, self-administrating emergency analgesic unit. The product has been designed for use with the pain relieving Gas mixture of 50% Nitrous Oxide and 50% Oxygen, this Gas mixture is formally known as either "Entonox®" or "Gas and Air". The Expiratory Valve at the top of the PRU can be connected to a standard Waste Gas Scavenging System with the aid of a PRU Outlet Scavenging Connector. Please see "Additional/Replacement Parts", section 10. The inspiratory and expiratory action of the PRU is so sensitive that it will automatically follow the patient's breathing pattern (whether stable or unstable) without any strain or discomfort. The PRU has been designed for emergency and non-emergency case scenarios and for use in most Medical environments such as Ambulances/other Emergency Services, Hospitals/Maternity and Dental.

2. Quality at Oxylitre

Oxylitre Ltd has been registered and certified as a Quality Assured organisation complying with BS EN ISO 9001/13485 Standards and the Council Directive 93/42/EEC. The PRU unit's design and performance complies fully with the requirements specified in BS 4272-2, including the Silicone Hose option.

3.Specifications

Inspiratory Connection

The PRU Demand Valve incorporates a standard 22mm Conical Outlet fitting for the connection of an Oxylitre or other brand named standard Child to Adult Mask or Mouthpiece fittings.

Inlet Connection

The Probe connection fittings comply with BS 5682. The Hose is clearly identified by appropriate marking and Gas colour codes for safe and easy connection to the correct supply.

Inspiratory/Expiratory Filtration Cartridge

Each unit is supplied with a disposable in-line Bacterial Inspiratory/Expiratory Filter and it is a requirement (AAGBI Guidelines) that a new Filter is used for each Patient. The Filter Cartridge is easily fitted between the Demand Valve and Mask/Mouthpieces. The Filter helps keep the PRU unit clean by preventing any contamination passed over from the Patient (I.e. Saliva, Vomit). Patients occasionally vomit when using the Pain Relieving Gas mixture Nitrous Oxide/Oxygen (Entonox®).

Waste Gas/Scavenging Outlet

Based at the top of the PRU Demand Unit is the Expiratory Dump Valve that releases Waste Gas in to the atmosphere when in use. To prevent Waste Gas from being dispersed into the environment a Scavenging Outlet connector can be fitted to the PRU Dump Valve for connection to the main Scavenging Exhaust system. (Please see Parts List).

4. Transport & Storage

a. During transportation (especially through postage/carrier), ensure that the equipment is well packed and protected. **Oxylitre will not be liable for any damage to the equipment.**
b. Always handle this equipment with care. This is a vital piece of medical equipment.
c. Always transport & store the equipment within a dry environment. Keep away from excessive heat or dampness.
d. Weight/Dimensions:
   - PRU complete with Case, Regulator, Key and Mask: 2.04 kg approx.
   - PRU complete as above with a D Size Cylinder: 5.40 kg approx.

Carry Case dimensions: Length/Width/Depth: 580 x 250 x 125

5. Safety Precautions for the prevention of Fire & Explosion

The regulator or patient **MUST NOT** be allowed near any source of ignition i.e. Lit Cigarette/Cigar, Sparks, Naked flames, Open electrical appliances. This precaution applies during and after patient use. **Warning:** This Regulator (if used) and the PRU Demand Valve MUST NOT come into contact with any Oil or Grease, a reaction may cause an Explosion/Fire. **Do not use if cylinder is at sub-zero temperatures.**

6. Operating Instructions

6.1 Fitting the Regulator to a Cylinder

Before connecting the Regulator to a Cylinder, momentarily open and close the Cylinder Valve to blow out any accumulated dust or moisture. Also inspect the Inlet Connector Seal for signs of damage. Replacement Seals = *Part No: OX010 (Pin Index) or Part No: BS110 (Bull Nose).*

- Connect the Regulator securely to the Cylinder.
- Open the Valve very slowly (approximately one full turn) to reduce the danger of explosion or fire arising from pressure shock.

6.2 Removing the Regulator from the Cylinder

- Turn OFF the Cylinder Valve and bleed the remaining pressure out of the Regulator by pressing the "Flush" Button at the rear of the PRU.

When the indicator on the Contents Gauge has fully dropped, disconnect from the Cylinder.

6.3 Preparation for use

Please Note: Upon receipt of your PRU (and Regulator if supplied), check for any damage/breakage to the equipment that may cause the unit to fail when operated.

a. If a Regulator is supplied, connect it to the Cylinder as stated in section 6.1.
b. Unravel the tubing on the PRU unit and fit an Inspiratory/Expiratory Filter onto 22mm Tapered Connector at the front of the PRU. Select an appropriate Mask or Mouthpiece and fit onto the 22mm Tapered Connector securely onto the filter.
c. Inspiratory/Expiratory Filter, please see Section 3.
d. Push the Probe on the end of the Hose into the Medical Gas Outlet Schrader/S.S. Valve on the Regulator or a Terminal Wall Outlet and ensure that it is locked into position. If a Pressure Regulator is used ensure that the Cylinder Gas Valve has been turned on as stated in section 6.1.
e. When connected, hold the PRU unit with the Inspiratory/Expiratory Outlet facing away. Gently press the "Flush" Button at the rear of the PRU until gas flushes out, hold for approximately 2 seconds then release. When released ensure the gas flow stops. This will indicate that the PRU is functioning and ready for use. Also see Maintenance, Servicing and Cleaning.

6.4 Gas Administration

Please Note: The PRU must only be used in the presence of qualified medical personnel when a patient administers the Pain Relief Gas of Nitrous Oxide /Oxygen (Entonox®).

a. Qualified Medical Personnel should advise the patient to hold the PRU and Facemask over their Mouth and Nose, then to breathe normally. The PRU will automatically follow the breathing pattern of the patient. The patient does not have to remove the Mask on exhalation.
b. If a Mouthpiece is used, the Qualified Medical Personnel should advice the patient to place the Mouthpiece into their mouth and to grip with their teeth. Their lips should be placed around the Mouthpiece to produce a seal. The patient should then breathe normally as described in 6.4a above.
c. As the patient relaxes the PRU and Facemask may be dropped or if a Mouthpiece is used, the patient may release their lips from around the Mouthpiece. The patient should continue to use the PRU if the pain persists. The Qualified Medical Personnel must monitor the Patient at all times when in use and must NOT hold the Facemask to the patient if the Patient is drowsy.

ALWAYS – use a Filter in line with a Mouthpiece or Mask to protect the PRU from contamination.
DO NOT - use a Mask Harness to hold the Mask to the Patient.
DO NOT - hold the Mask to the Patient to administer the Gas unless the Patient is unable or has difficulty holding the PRU unit for self-administering. The patient must be fully conscious. Gas administering must STOP when the patient becomes drowsy.
DO NOT - press the "FLUSH" Button at the rear of the PRU Unit when the Patient has the Mask or Mouthpiece in place for administering.

7. Overdose (Systems, emergency procedures, antidotes)

An inappropriate, unwitting or deliberate inhalation of the Nitrous Oxide/Oxygen mixture will ultimately result in unconsciousness, passing through stages of increasing light-headedness and intoxication. The treatment is to remove the Demand Valve so that the patient can inhale fresh air, mouth-to-mouth resuscitation and if necessary the use of an Oxygen Resuscitator.

8. Maintenance, Servicing & Cleaning

It is recommended that the Regulator and PRU should be maintained and inspected for leakage at least every 3 months. It is also recommended that a full inspection be conducted annually (and any faulty parts replaced) and that a Major Service be conducted after 5 years from purchase. The Major Service constitutes replacement parts in the Service Kit (SKP3 for the PRU) and the re-hosing of the unit as per Medical Device Alert MDA/2003/007. This Major Service can be conducted by an Oxylitre Service Engineer or a technician/engineer trained in the appropriate procedures. Each unit comes complete with a full Manufacturers 7 Year Warranty.

Regulator: Maintenance and Leakage Test

a. If a PRU is connected to the Regulator, turn the main Cylinder Valve clockwise to turn off the supply. Gently press the "FLUSH" Button at the rear of the PRU to release the excess Gas from the Regulator. Disconnect The PRU by twisting the Schrader/S.S.V. Valve clockwise.