

Nitric Oxide Pressure Regulator

Instructions for Use



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THE QUEEN'S AWARDS
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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



Attention, consult accompanying documents



Use no oil



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



Service due date



Date of manufacture identification

2. Warnings and Cautions

2.1. Warnings!

- ▶ Before using the regulator (whole system) read through the entire instruction manual. As with all medical equipment, attempting to use this device without a thorough understanding of its operation may result in patient or user injury.
- ▶ Nitric oxide is not flammable however; the presence of nitric oxide in high concentrations is a health risk.
- ▶ Nitric oxide therapy may be considered a critical treatment. A nitric oxide system should be used in strict accordance with the prescription and instructions of a physician. No special physiological monitoring is required, since patients undergoing therapy will already have full hemodynamic and other monitoring in place.
- ▶ Never permit compressed medical gases to enter a regulator suddenly always open the cylinder valve slowly.
- ▶ Never use medical gases from a cylinder without reducing the pressure through a suitable regulator intended for that gas.
- ▶ Always close the cylinder valve when the regulator is not in use.
- ▶ Never use nitric oxide as a pressure medium to purge obstructed pipelines or in equipment to operate pneumatic tools or to build up any pressure in tanks.
- ▶ Check condition and routing of connection hose before opening Pressure Regulator.
- ▶ Check for presence of and condition of face seal before connecting Pressure Regulator to cylinder.

- ▶ Check input filter is present and not contaminated or blocked before connecting Pressure Regulator.
- ▶ Check cylinder neck for contamination before connecting Pressure Regulator.
- ▶ Check condition of cylinder and regulator thread before connecting Pressure Regulator.
- ▶ Check function of gauge once connected.
- ▶ Ensure that you have the correct regulator for the type of cylinder you are intending to use. Never attempt to fit a regulator to an incompatible cylinder.
- ▶ Do not stand in front of a regulator outlet when opening the cylinder valve.
- ▶ Before removing a regulator from a cylinder, fully close the cylinder valve and release all gas from the regulator.
- ▶ Secure cylinders to a wall, stand or cart.
- ▶ Only appropriately trained personnel working in controlled conditions must perform disassembly, assembly and testing of regulators.
- ▶ Only BPR Medical approved spare parts should be used to maintain the safe and accurate performance of the regulator.
- ▶ Do not submerge the Pressure Regulator in any fluid. Ensure that no fluid is allowed to enter the inlet valve or the vent holes.
- ▶ The performance of the Pressure Regulator may be affected if it is stored or transported in temperature outside of the range -20 °C to +60 °C.
- ▶ The holes in the side of the body of the Pressure Regulator are for venting gas in the event that the relief valve is activated. Do not obstruct these holes or interfere with the relief valve in any way.
- ▶ BPR Medical Pressure Regulator regulators are designed for use at cylinder pressures up to 20 000 kPa (3 000 psi/ 200 bar); do not attempt to connect BPR Medical regulators to cylinders having fill pressures in excess of this value.

3. Functional Description

3.1. Intended Use

The Nitric Oxide Pressure Regulator is intended to be used as a component part in a wider medical system for the controlled delivery of Nitric Oxide gas in dilute form for patients with respiratory disease.

The purpose of a gas pressure regulator is to provide a safe, stable, relatively low outlet gas pressure from the relatively high and varying gas pressure in a gas cylinder.

The Nitric Oxide Pressure Regulator is not intended to be used alone to deliver dilute Nitric Oxide to patients and must always be used in conjunction with other compatible medical devices. Care should be taken to match the performance of the gas pressure regulator with the dilute Nitric Oxide delivery system for which it is intended to be used.

The Nitric Oxide Pressure Regulator is intended to be used only with dilute Nitric Oxide with Nitrogen as the balancing gas, with maximum concentration not exceeding 1000 ppm.

3.2. Technical Description

A gas pressure regulator reduces the high cylinder pressure of up to 20 000 kPa to a safe working level of typically 400 kPa. The regulator provides a relatively stable output supply even though the cylinder pressure depletes as the gas in the cylinder is used.

It achieves output pressure stability by closing or opening a control valve that limits the flow of gas from the cylinder. The control valve opens to allow more gas flow through when the output pressure is falling and reduces the flow when the output pressure is increasing. At any given output flow (load) the control valve will find equilibrium such that the mass of gas entering the regulator will be equal to that leaving it.

The moving element of the control valve is mechanically connected to a piston head that senses the output pressure. The force applied to the piston head is balanced against a spring of known force. The specific characteristics of the valve seat, piston and spring combine to determine the outlet pressure.

In the unlikely event of single fault failure, an over pressure valve (OPV) protects the user from excessive gas pressure in the output stage by venting excess gas to ambient. The OPV is a spring loaded valve with a pre-set operating pressure.

The regulator is connected to the gas cylinder via one of a number of different inlet connectors as required by the market in which it will be used. It is normal for different countries to have different cylinder connection standards.

Maximum output flow has been limited on this regulator for safety reasons. A particulate filter in the inlet port prevents the ingress of debris.

Nitric Oxide is a particularly reactive gas; the materials used in the Nitric Oxide Regulator have been carefully selected for their compatibility.

4. Operating Instructions

Check that the cylinder type and regulator inlet connector are compatible.

Check the presence and condition of the input connector seal.

Fit the regulator to the cylinder ensuring that it is properly mated and the connectors are hand tighten.

Check the Nitric Oxide Delivery System is correctly connected to the output of the Pressure Regulator. Open the cylinder valve with a suitable cylinder key or by the handwheel.

Check the regulator cylinder contents gauge to verify that there is sufficient gas available.

Use the device as directed by the clinician or Nitric Oxide Delivery Systems software. Continue to check the regulator content gauge.

Upon completion of the therapy, close the cylinder valve.

To remove the Pressure Regulator from the cylinder, first ensure the cylinder valve is closed and the hose disconnected.

Store loose Pressure Regulators with care during transit.

4.1. Routine Care

Before each use

Wipe down the outside of the device with an alcohol wipe.

Do not allow the ingress of water or other solution into the device. Check the exterior condition of the device.

Notes:

- Pay particular attention to the input connector seal and the cylinder contents gauge.
- Check that the vent holes in the side of the regulator body are not obstructed or have otherwise been tampered with in case of the event of relief valve activation.

5. Maintenance

Nitric Oxide Pressure Regulators must be serviced on or before the Service Due Date stated on the device rating label.

This device has a 1 year service interval and intended life of 6 years.

The lack of servicing or incorrect servicing are the main causes of incidents with medical gas regulators and it is strongly advised that devices are serviced according to the manufacturers' guidelines.

Servicing may be undertaken by suitably qualified engineers working in appropriate conditions who have undergone formal training with BPR Medical.

5.1. Factory Maintenance and Inspection

This device should be returned to BPR Medical Ltd for factory service and testing on an annual basis to ensure correct performance.

6. Specification

Environmental Conditions

Transport, Storage and Operating Limits

Temperature	-20 °C to +60 °C
Relative Humidity	0 to 100% RH non condensing

Parameters of Use

Media

Gas Compatibility	Nitric Oxide \leq 1000 ppm balanced with Nitrogen
Maximum Rated Inlet Pressure (P ¹)	20 000 kPa (200 bar)
Minimum Rated Inlet Pressure (P ³)	2 000 kPa (20 bar)

Performance

Nominal Output Pressure (P2)	403 kPa [calibrated at 40 l/min, inlet pressure 5 000 kPa (50 bar)]
Outlet Pressure Range	Min 360 kPa (3.6 bar) Max 550 kPa (5.5 bar)
Operating Flow Range	Min 10 ml/min Max 1 l/min
Pressure Relief Valve Activation Pressure	Nominal Factory Set 700 kPa (7 bar) Min 600 kPa (6 bar) Max 1 000 kPa (10 bar)
Outlet Flow Restriction (safety feature)	Maximum outlet flow in normal use 12 l/min
Maximum External Leak	<0.2 ml/min

Design

Physical Characteristics

Inlet Filtration	40 micron, sintered
Pressure Gauge	Stainless steel, 38mm diameter, Class 2.5
Pressure Adjustment	Fixed. Not user adjustable
Inlet Connection	Model specific
Outlet Connection	Model specific
Weight	Model specific; 0.75 kg typical
Labelling to Show:	Gas Type Rating Information CE Mark Manufacturer's Mark
Packaging	Sealed non-sterile polythene bag inside a cardboard box
Reuse	Device is reusable The device is not designed to be for single patient use

Applied Standards

BS EN ISO 10524-1	Pressure regulators for use with medical gases
BS EN ISO 15233-1	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements
BS EN 837-1	Pressure gauges. Bourdon tube pressure gauges
BS EN 1041	Information supplied by the manufacturer with medical devices
BS EN 14971	Medical devices. Application of risk management
BS 341-1	Transportable gas container valves. Specification for industrial valves for working pressures up to and including 300 bar
CGA V-1	Standard for compressed gas cylinder valve outlet and inlet connection

DIN 477-1	Gas cylinder valves rated for test pressures up to 300 bar
ISO/DIS 5145	Cylinder valve outlets for gases and gas mixtures – selection and dimensioning
UNI 11144	Transportable gas cylinders

7. Parts and Spares List

Part Number	Description	Cylinder Connection
814-0001	Nitric Oxide Pressure Regulator	BS-341 14
814-0002	Nitric Oxide Pressure Regulator	DIN-477 14
814-0003	Nitric Oxide Pressure Regulator	DIN-477 10
814-0004	Nitric Oxide Pressure Regulator	CGA 626
814-0005	Nitric Oxide Pressure Regulator	CGA 660
814-0007	Nitric Oxide Pressure Regulator	UNI 11144
814-0008	Nitric Oxide Pressure Regulator	ISO-5145
814-0009	Nitric Oxide Pressure Regulator	DIN-477 1
814-0010	Nitric Oxide Pressure Regulator	BS-341 3
814-0011	Nitric Oxide Pressure Regulator	BS-341 4

Spare Parts and Servicing

610-0078	O-Ring, NO Regulator, BS14/ ISO 5145 (Pk 10)
610-0079	O-Ring, NO Regulator, BS 341- 3, BS 341- 4 (Pk 10)
610-0080	O-Ring, NO Regulator, DIN 477 No.14/ UNI 11144 (Pk 10)
610-0081	O-Ring, NO Regulator, DIN 477 No.10/ DIN 477-1 (Pk 10)
610-0082	O-Ring, NO Regulator, CGA 626 (Pk 10)
610-0082	O-Ring, NO Regulator, CGA 660 (Pk 10)



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