



NOxBOX_i[®] Nitric Oxide Delivery System Indication

NOxBOX_i[®] Nitric Oxide Delivery System

The NOxBOX_i[®] Nitric Oxide Delivery System is intended for use by healthcare professionals for the delivery and monitoring of a constant (user set) concentration of nitric oxide (NO) and the monitoring of NO₂ and O₂ in the inspiratory ventilator lines of a patient undergoing inhaled nitric oxide therapy (iNO).

The NOxBOX_i Nitric Oxide Delivery System includes:

- The NOxBOX_i, head unit, which delivers NO gas while in the intelligent delivery mode.
- Continuous monitoring and alarms for NO, O₂, and NO₂.
- The integrated NOxMixer, which provides a backup NO delivery capability that is intended to deliver a continuous flow of NO, mixed with O₂, for iNO therapy and provides a continuous treatment option during transit and transfer conditions within hospitals.

The NOxBOX_i Nitric Oxide Delivery System must only be used in accordance with the indications, contraindications, warnings, precautions, and other information and conditions of use described in the nitric oxide drug prescribing information and labeling (currently neonates). Refer to this material prior to use.

Important Delivery Device Considerations

Prior to use, health professionals at neonatal units that administer NOXIVENT[®] (nitric oxide) gas, for inhalation should be properly trained and familiar with the instructions for use of the NOxBOX_i nitric oxide delivery system. This product must be checked and calibrated in-line with the service schedule recommendations. A product found to be faulty must not be used. Any parts or accessories that are broken, damaged, missing, obviously worn, distorted, or contaminated should be replaced immediately. In the event of the product required repair or replacement, contact Linde customer service at (833) 669-8368 (NOX-VENT).

Only validated ventilator systems should be used in conjunction with NOXIVENT (nitric oxide) gas and the NOxBOX_i delivery device. Refer to the Technical Guide for a full list of currently validated ventilators. Ensure that the NOxBOX_i delivery device is kept plugged in at all time and keep available a backup battery power supply and an independent reserve nitric oxide delivery system to address power and system failures.

The NOxBOX_i system is MR unsafe and should not be used in the MRI suite. The NOxBOX_i system is not intended for use in the vicinity of electrosurgical or diathermy devices.

To avoid serious injury, pay attention to all precautionary labels that are attached to the equipment, cylinders, containers, and boxes before startup. Do not remove or obscure any label.

The product user bears sole responsibility for any malfunction that results from improper use, faulty maintenance, improper repair, damage, or unauthorized alteration by any source not authorized to do so by Linde or NOxBOX Ltd.

Distributed by Linde Gas & Equipment Inc.
10 Riverview Dr, Danbury, CT 06810, USA
Phone 800.225.8247, www.linedirect.com

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