

Nitronox Plus

Prescriptive Information

Refer to the device directions for use for complete instructions on the device.

Indication

The Nitronox Plus is intended to provide a mixture of N₂O/O₂, on demand, to a conscious, spontaneously breathing patient. The Nitronox Plus is designed for use with adult and pediatric patients and is not intended to be used with infants or neonates.

Warnings/Precautions

- This product can expose you to chemicals, including lead and formaldehyde, which are known to the State of California to cause cancer, birth defects, or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.
- Federal law restricts this device to sale by or on the order of a physician or dentist.
- Do not use this device for the administration of general anesthesia or as part of, or in conjunction with, a general anesthesia administration system.
- If a serious incident (death or any intervention) has occurred while the device was in use, it should be reported to the manufacturer immediately and the Competent Authority of the member state in which the serious incident occurred.
- For centrally piped facilities, properly connected gas pipelines are essential to patient safety. The ultimate responsibility of assuring that lines are not crossed rests with the user. Per NFPA 99, the certified medical gas plumber, and verifier, should provide written documentation that all gas pipelines are connected properly and that all use points of the system have been tested prior to use. It is important that the user verify by their own test that all gas pipelines are connected properly prior to using the system.
- The Nitronox Plus used with the delivery of Oxygen (O₂). Therefore, when this device is used in conjunction with energy producing devices (such as lasers, radio frequency sources, or other heat sources), the user must adhere to the instructions for use of those devices to avoid ignition of combustible materials.
- The Nitronox Plus is not intended or expected to be used during an MR exam and has not been evaluated for safety and compatibility in the MR environment. The safety of the Nitronox Plus in the MR environment is unknown, but due to the presence of materials in the device that may be ferromagnetic, the Nitronox Plus should be considered “MR Unsafe” and should be kept outside of any MRI scanner rooms.
- Always use clean, dry, medical grade gases, and do not introduce moisture or other contaminants into the system. Never oil or grease any part of the system.

- Always ensure cylinder valves are clear of dust and dirt prior to connection. One method to clear dust and dirt is to briefly “crack” the cylinder valve open to blow out any debris in the line before installing the cylinder. Do not discharge the gas at any person or flammable material.
- Do not use the Nitronox Plus if the O₂ and N₂O supply pressures are out of the green band (45-60psi), or the mixture pressure is out of the green band (30-40 psi).
- If the alarm whistle sounds, check the gas supply pressures to ensure there is an adequate supply of gas. If 100% O₂ delivery is desired without any N₂O supply pressure, turn the Key Lock to OFF to deactivate the N₂O alarm.
- Never use a mask strap to hold the mask to a patient's face. Self-administration is a safety feature of the Nitronox Plus; if for any reason the patient were to become over sedated, the patient will be unable to adequately hold the mask in a tight sealing position against the face. The lack of a tight seal results in the demand valve being unable to trigger, and therefore the supply of mixed gas will cease, allowing the patient to breathe room air through the mouth or nose. If the patient is unable to fully self-administer, a medical professional may aid in placing the mask in a sealing position against the patient's face. Patient observation must be maintained to prevent over sedation; immediately remove the mask upon any observation of over sedation.
- It is best practice upon completion of the procedure to close the cylinders (if portable gas supply) or disconnect from wall outlets (if central gas supply). Failure to do so may result in gas depletion should there be a leak.
- Proper inspection and maintenance of the Nitronox Plus system and accessories is essential to prevent nitrous oxide leaks. All hoses, fittings, and connections should be inspected regularly, and all leaks should be repaired immediately. The healthcare professional is responsible for employing proper techniques, such as scavenging, room ventilation, system maintenance, and patient compliance to reduce exposure (ACGIH recommends a Threshold Limit Value of 50 parts per million over an 8-hour time-weighted average), as nitrous oxide may cause harmful effect when over exposed.
- Do not attempt to change the inlet fittings or the diameters/fittings on the supply hoses. Diameter indexed fittings are designed to prevent misconnection of oxygen and nitrous oxide supply lines.
- Do not modify this equipment without authorization of the manufacturer.
- Do not use or replace any components or accessories, except those specified in these instructions for use and installation guide.
- Do not wipe the inside of the inlet fittings, gas supply hoses, or connection port as this may deposit cleaning agents into the breathing pathway of the device. Do not immerse the device or any of the device's components or accessories in water, cleaning solution, or any other liquid. Always ensure the device and the device's components and accessories are completely dry before use. The effectiveness of other cleaning agents has not been proven. Use of other cleaning agents may damage the labels or exterior housing of the device. The use of an unvalidated cleaning agent is not recommended.

CAUTION: US Federal law restricts this device to sale by or on the order of a physician. Rx Only. The Nitronox Plus system is to be used by a medical professional trained in the use and administration of nitrous oxide and oxygen gases. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device or visit <https://www.porterinstrument.com/medical-support>.

The use of nitrous oxide may result in occupational exposure. For information on nitrous oxide exposure in occupational settings, including guidelines, refer to recommendations from the National Institute for Occupational Safety and Health (NIOSH), the American Conference of Governmental Industrial Hygienists (ACGIH), and the Occupational Safety and Health Administration (OSHA).

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