

Parker Hannifin Corporation Porter Instrument 245 Township Line Road Hatfield, PA 19440



June 3, 2020

Porter Instrument Nitrous Oxide and Oxygen Guidance Update

Since mid-March, medical facilities have had to make difficult decisions regarding procedures and treatments while factoring in the new potential risks associated with Covid-19. Unfortunately, in the rush to identify new potential risks, there was unsubstantiated information provided by some organizations regarding the use of nitrous oxide and oxygen (for pain management and anxiety relief).

This information apparently originated with a "Covid-19 Toolkit" issued by The Society for Obstetric Anesthesia and Perinatology (SOAP™), which included guidance specific to nitrous oxide use. This guidance recommended that facilities consider ceasing the use of nitrous oxide over concerns of safety, infection control, aerosolization and filtering. This resulted in many facilities immediately ceasing their nitrous programs within their Labor and Delivery Departments — without asking questions.

Porter consulted with many nitrous educators, key opinion leaders, industry experts from around the world and our own internal team of nitrous experts. We were not able to find anyone that we spoke with that agreed with the SOAP™ guidance - nor any supporting data or literature that would validate their concerns.

Effective May 22, 2020, SOAP™ has removed the guidance specific to nitrous oxide use within their Covid-19 Toolkit.

Nitrous oxide and oxygen have been a predictable, and reliable option for pain management and anxiety relief for a wide variety of applications and specialties, with a long record of patient safety. We recommend that facilities conduct their own internal risk assessments as well as consult with nitrous system experts (such as Porter) to discuss concerns and questions that may arise under current

conditions. I'm optimistic that all facilities will resume their nitrous oxide programs and allow for their patients to benefit from this pain management option once again.

In addition, Porter has also put together its own Guidance document (see below) with answers to frequently asked questions for your review. Most of the questions that are addressed in the Porter Guidance document are responsive to the unsubstantiated information that was being presented by some outside organizations. If you or your facility have additional questions about nitrous oxide use, please feel free to reach out to me at any time. We are happy to help you – and look forward to you helping your patients once again!

Sincerely,

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Parker Hannifin Corporation Precision Fluidics Division Porter Instrument 245 Township Line Road Hatfield, PA 19440



June 8, 2020

<u>Infection Control Guidance and Frequently Asked Questions For Use of Nitronox</u> During Covid-19:

1. <u>Is nitrous oxide an aerosol?</u>

Nitrous oxide itself is not an aerosol. Use of nitrous oxide and oxygen is not an aerosol producing event or procedure. Patients are inhaling and exhaling as they normally would.

- Aerosol producing procedures with medical gas typically involve pressurized or high flow gas to a patient such as intubation, positive pressure, nebulizers, and high flow oxygen therapy. The Nitronox system is a demand flow system – there is no gas being forced to or blowing on the patient.

2. <u>Do I need a filter on my Nitronox system?</u>

No filters are needed with use of Nitronox. Filters are typically required for devices that allow for the patient exhalation to re-circulate back to the device and potential risk of cross contamination. With Nitronox (and utilization of the manufacturer approved breathing circuit – DMC-5301-6) the patient cannot exhale back to the device. They system is designed as a one-way directional flow. They cannot exhale back "upstream" and cross contaminate the device.

3. <u>Do I need to be concerned about patient exhalation going back to the Nitronox device?</u>

No – the system is designed so that the patient inhalation and exhalation are one-way directional flow. The breathing circuit is a coaxial tubing (hose

within a hose) that only allows for the inhalation to travel through one tube (pulled by the patient) – and the exhalation can only go out through the other tube. On the exhalation side of the tubing there is a one-way valve that prevents the patient from re-breathing their exhalation.

4. <u>Do I need to be concerned with the patient exhalation back into the room when using Nitronox (with Covid)?</u>

Patients using nitrous oxide and oxygen are no different versus patients not using nitrous oxide and oxygen. There is no additional risk or concern with a patient exhaling nitrous oxide and oxygen (aside from concern and management of occupational exposure to nitrous oxide).

5. <u>Do I need to do anything different regarding infection control and disinfection when using Nitronox?</u>

No – you should continue to follow normal use recommendations. The breathing circuit with mask or mouthpiece are single patient use and should be disposed of after one use.

- For disinfection of the Nitronox follow the User Manual instructions.
- Use surface disinfectants and wipes that are approved for use within the facility patient environment.
- Avoid excess liquid and never spray anything directly on any of the parts.
- Do not attempt to clean gas inlets, cylinder connections or regulators.

Sincerely,

Porter Instrument

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