

### **Porter Instrument response to SOAP “Interim Guidelines” regarding use of nitrous oxide:**

Porter instrument does not agree with SOAP’s statement regarding the specific categorization of nitrous oxide as a specific risk in the patient care environment (when using a Porter Instrument system). We have asked many healthcare professionals and nitrous “experts” from around the world – and have not been able to find anyone that agrees with their statements. Nitrous oxide and oxygen have been used globally for decades for a wide variety of applications (in and out of hospitals) – millions of procedures - and there is no data to support the guidance by SOAP and suggesting that a facility “should consider suspending use” .

SOAP should revise their guidelines to be more specific and general. You should be concerned about infection control and cross contamination in the patient care environment. You should be concerned about aerosolization in the patient care environment. This has nothing to do with the use of nitrous oxide and oxygen – unless specific data, studies or literature can be provided to otherwise support it. Healthcare professionals should ask SOAP to provide any data that they have to support their guidelines.

Below, please find responses to each of the concerns that SOAP has published. Ultimately the healthcare facility is responsible and should determine and evaluate “all” potential risks in the patient care environment and make decisions based on the risks as well as factoring each manufacturers recommendations of all of the different products that may be used.

#### **Concerns of Cleaning:**

The Porter device itself is cleaned and disinfected just like any other device that is in the patient room – (that does not come into contact with a patient). The patient is not in direct contact with this device – by physical contact or their exhalation. Hospitals should treat the device like any device or hard surface in the patient environment and clean and disinfect like they clean and disinfect similar items that the *healthcare professional* (not the patient) comes into contact with.

#### **Concerns of Filtering:**

There is no need for filtering with the Porter devices that are equipped with the manufacturer approved single use disposable breathing circuit. The patient exhalation cannot travel back to the device. Their exhalation cannot physically go back to the device nor does it come into contact with the device. Filtering is commonly required for ventilators, anesthesia systems (that recirculate) and vital signs monitors that pull CO2 for sampling, along with other similar products that physically pull back exhalation to the device. This is not possible with our devices. Our system is a one-way directional flow of mixed gas to the patient and one-way directional flow of the patient’s exhalation. The breathing circuit utilized is a coaxial tubing (hose within a hose) and includes a one-way valve. In addition, where the breathing circuit attaches to the device – this is a “dead end” stop that you cannot push back upon with exhalation. When the patient inhales – they can only pull the inhalation through the inner hose of the breathing circuit. When they exhale – the exhalation can only travel through the outer hose and then out the scavenger hose assembly (which includes a one-way flapper). When the patient inhales – the scavenger hose one-way flapper re-seats. The breathing circuit is single use.

#### **Concerns of Aerosolization:**

There is no data or literature to support that the use of nitrous oxide and oxygen in a Labor and delivery (patient room), dental, or other similar application would be any more likely to be considered an aerosol producing event as compared to a patient that was not using nitrous oxide and oxygen and simply breathing on their own. The administration of the gas mixture would not be considered an aerosol

producing activity and neither would the exhalation. The patient is breathing naturally as they would do so normally. There is nothing being forced into the patient and the patient is not forcing anything out on exhalation – they are breathing on their own. If there is concern over aerosolization with this application, then there should be concern with all patients that are simply breathing – regardless of what they are doing. Examples of aerosol producing procedures include (but not limited to): intubation, ventilation, drilling, positive pressure applications, sawing, etc. Use of nitrous oxide and oxygen by a patient in this setting is not similar in any way to what the medical community defines as an aerosol producing procedure. SOAP should revise this guideline to specifically be concerned about aerosol producing procedures in general – not pointing to using nitrous oxide and oxygen.

**Recommendation for Considering Suspension of Use by SOAP:**

SOAP should either remove their guidance pertaining to the use of nitrous oxide and oxygen or supply specific data or literature that would support such a recommendation. Indicating that there is insufficient evidence is vague and misleading. In reality, nitrous oxide and oxygen have been used for many decades in the US and around the world. The suggestions made by SOAP have never been identified as a risk or hazard – through millions of procedures completed every year. Cleaning and infection control are certainly concerns – but should not be any additional concern than in general terms when speaking about the patient environment. Providing this guidance is perceived that SOAP is recommending suspension of using nitrous oxide – and that the organization also has the data to support the recommendation. Healthcare professionals should ask SOAP for this data.

Additional questions and concerns can be sent to: [porternitrous@parker.com](mailto:porternitrous@parker.com)