

INOvent Marketing Application Update #16

INOvent delivery system and helium/oxygen (heliox) mixtures

The purpose of this application update is to provide information about safety issues that arise when the INOvent delivery system is used in conjunction with delivery of helium/oxygen mixtures.

GE Healthcare does not recommend that the INOvent delivery system be utilized with helium/oxygen mixtures in any situation. The INOvent delivery system is intended to delivery nitric oxide therapy gas only in conjunction with the delivery of air and oxygen.

As stated in the Operation and Maintenance manual:

“The INOvent delivery system is intended for use to deliver nitric oxide therapy gas into the inspiratory limb of the patient breathing circuit in a way that delivers a constant concentration of NO, as set by the user, to the patient throughout the inspired breath.”

“The INOvent delivery system provides continuous on-line integrated monitoring of delivered O₂, NO₂ and NO, and a comprehensive alarm system.” Additionally, Appendix A in the Operation and Maintenance Manual specifically identifies NO delivery and gas monitoring parameters which do not include heliox mixtures.

The INOvent delivery system utilizes an injector module, which uses hot film anemometer technology to measure flow. The injector module is specifically calibrated for use with O₂ and air. The thermal conductivity of helium and helium/oxygen mixtures is significantly higher than that of O₂ and air, which renders the calibration of the injector module to be unpredictable. When helium/oxygen mixtures flow through the injector module, it will not function properly causing potentially dramatic over or under delivery of nitric oxide therapy gas. The NO delivery when used with helium/oxygen mixtures can be in error by a factor of 2.5 to 20, is not linear over the flow range and is further exacerbated by the device set-up.

Additionally, the electrochemical cells that monitor O₂, NO₂ and NO within the patient breathing circuit are specifically calibrated for the gases they are monitoring. If an alternative gas is sampled, such as a helium/oxygen mixture (in any concentration), and is drawn past these cells, inaccuracies in the monitoring system may occur. These inaccuracies of gas monitoring could cause the comprehensive alarm system within the INOvent delivery system to no longer function as is specified.



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