

INOvent[®] delivery system

FOR NITRIC OXIDE THERAPY

INOvent application update #5

Infrasonics infant star compatibility

Datex-Ohmeda records indicate that one or more INOvent delivery systems are located at your healthcare facility and were purchased to be used with Infrasonics Infant Star neonatal ventilators. They are intended for investigational purposes under FDA Investigational Device Exemption (IDE) number G960215, by qualified holders of Investigator Investigational New Drug (IND) applications, as filed with FDA for the investigation and use of inhaled nitric oxide.

Datex-Ohmeda has become aware that there is some confusion regarding the use of the INOvent delivery system with the Infrasonics Infant Star neonatal ventilator. This ventilator is available with a conventional ventilation mode as well as a high frequency ventilation (HFV) mode. The INOvent delivery system was deemed compatible with the conventional ventilation mode of the Infant Star ventilator following significant testing.

Additionally, use of the INOvent with the Infant Star in the conventional ventilation mode was covered in IDE G960215 approved by FDA on November 27, 1996.

Although limited testing was performed in the HFV mode, compatibility with this mode was not confirmed through similar, significant testing and is not covered in the IDE.

Use of the INOvent delivery system with the HFV mode of the Infant Star ventilator has resulted in a very limited number of reports of a higher delivered value of nitric

oxide than set for certain ventilator settings (at the higher amplitudes and frequencies ranges). In these reports, the INOvent performed as designed, providing an audio and visual alarm alerting the user of this condition.

It has been determined that the confusion was attributable to information provided to a few customers indicating that the Infant Star ventilator in the HFV mode could be used with the INOvent delivery system. This information was based on an incorrect interpretation of the limited testing performed.

As a result, Datex-Ohmeda has performed additional testing of the INOvent delivery system with the Infant Star ventilator in the HFV mode and has confirmed that higher delivered nitric oxide does occur at certain settings. Accordingly, at this time, the INOvent delivery system should not be used with the Infant Star ventilator in the HFV mode.

Datex-Ohmeda representatives have since received additional training regarding the use of the INOvent delivery system with the Infant Star ventilator. The Operation and Maintenance manual for the INOvent delivery system has also been revised to clarify that the INOvent should not be used with the Infant Star ventilator in the HFV mode. This manual will be provided to your facility as part of the planned 400 ppm to 800 ppm conversion.

We apologize for the confusion and any inconveniences, and thank you for your cooperation.

If there are any questions regarding this information, please contact Datex-Ohmeda Technical Support at 1-800-345-2700.



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