



Technical Bulletin

Ref: **TB-20003-ENG**

Issue date: February 2022

Products: INOmax DS_{IR}® Plus,

Investigational Blinded NO Delivery System,

Investigational NO Delivery System for Human Use Only and

Investigational NO Delivery System for Animal Use Only

Affected parts: Gas Delivery Systems Compatibility

Priority: Low

Classification: Information for General Distribution

Subject: Validated Ventilators - Special Instructions

This technical bulletin is written to advise clinicians that the Airvo 2 and Optiflow Jr have been validated for use with the device (see Products above) using the circuit configurations shown below:

Proper use of these products depends on careful reading and understanding of labeling and instructions. Please refer to the appropriate device operation manual for guidance. Also refer to the gas delivery system (see below) operation manual or instructions for use.

WARNING: The INOmax DS_{IR} must only be used in accordance with the indications, usage, contraindications, warnings and precautions described in the INOMAX (nitric oxide for inhalation) drug package inserts and labeling.

WARNING: Do not use the Integrated Pneumatic Backup with breathing circuit gas flows less than 5 L/min, as the delivered INOMAX dose will be greater than 40 ppm.

Fisher & Paykel Airvo 2

The Airvo 2 has a flow generator internal to the device. The flow generator creates high flow rates which will enter through the filter on the back of the device before passing through the enclosed humidifier. Adding oxygen through the oxygen inlet port (see Figure 1 below) allows for supplementing the FiO₂ being delivered to the patient, but may not account for all of the gas flow going to the patient.

To combat room air from entering through the filter cover and diluting the nitric oxide level coming from the injector module, an air/oxygen blender must be used to drive the flow through the injector module and into the oxygen inlet port (see #11 in Figure 1).

By matching the flow rate on the air/oxygen blender with the flow setting on the Airvo 2, the monitored dose will equal the set dose.

WARNING: Set the INOmax DS_{IR} alarm thresholds for the current patient conditions to monitor any inadvertent changes in treatment.

Caution: Failure to match the air/oxygen blender flow rate with the Airvo 2 flow setting, will result in INOMAX levels delivered to the patient that are lower than the set dose.

Ref: TB-20003-ENG Updated 02-2022
PN 21782, rev. 03

Page 1 of 4

Fisher & Paykel Airvo 2

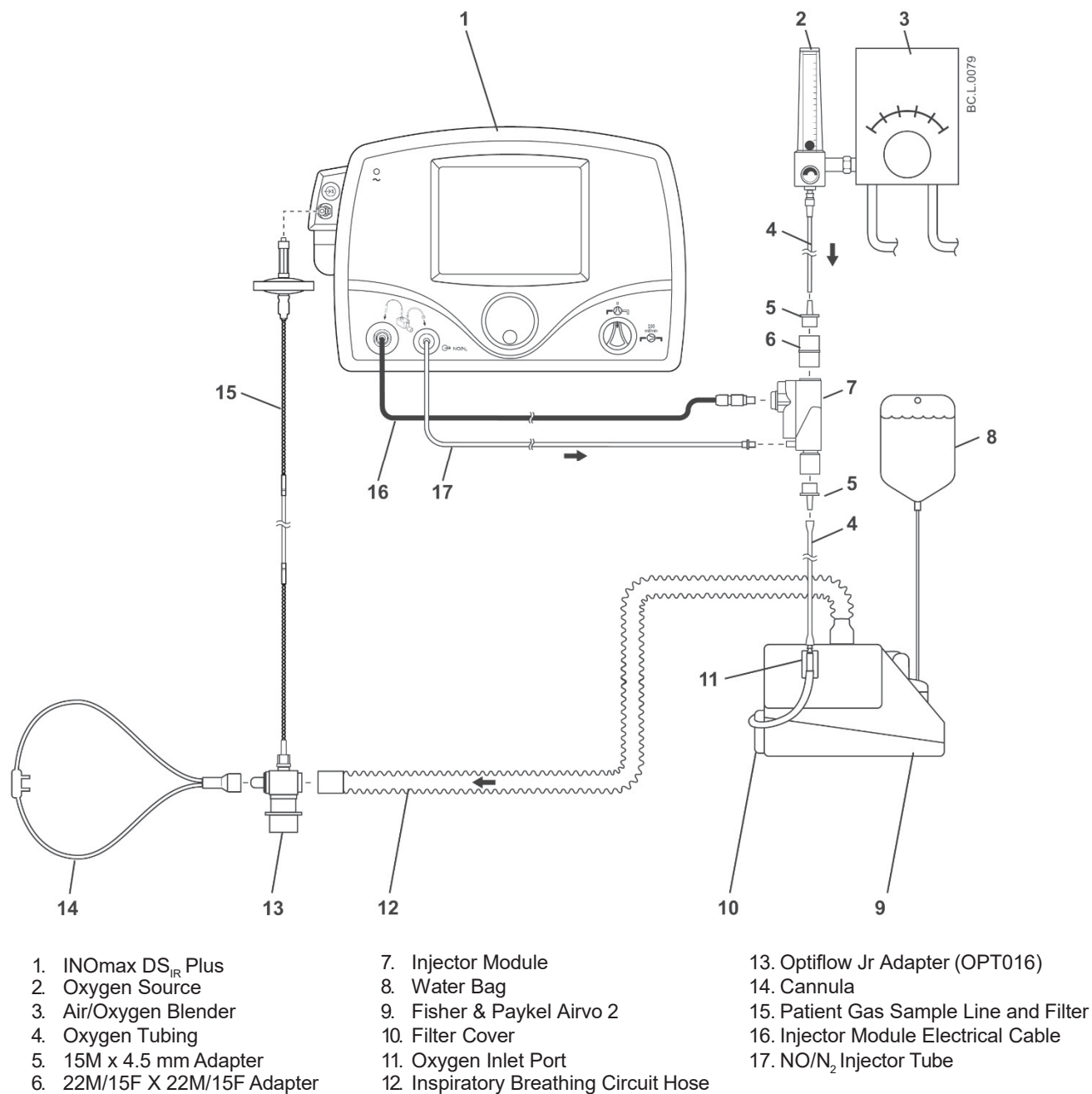


Figure 1: Airvo 2 Infant/Pediatric Setup

Fisher & Paykel Optiflow Jr

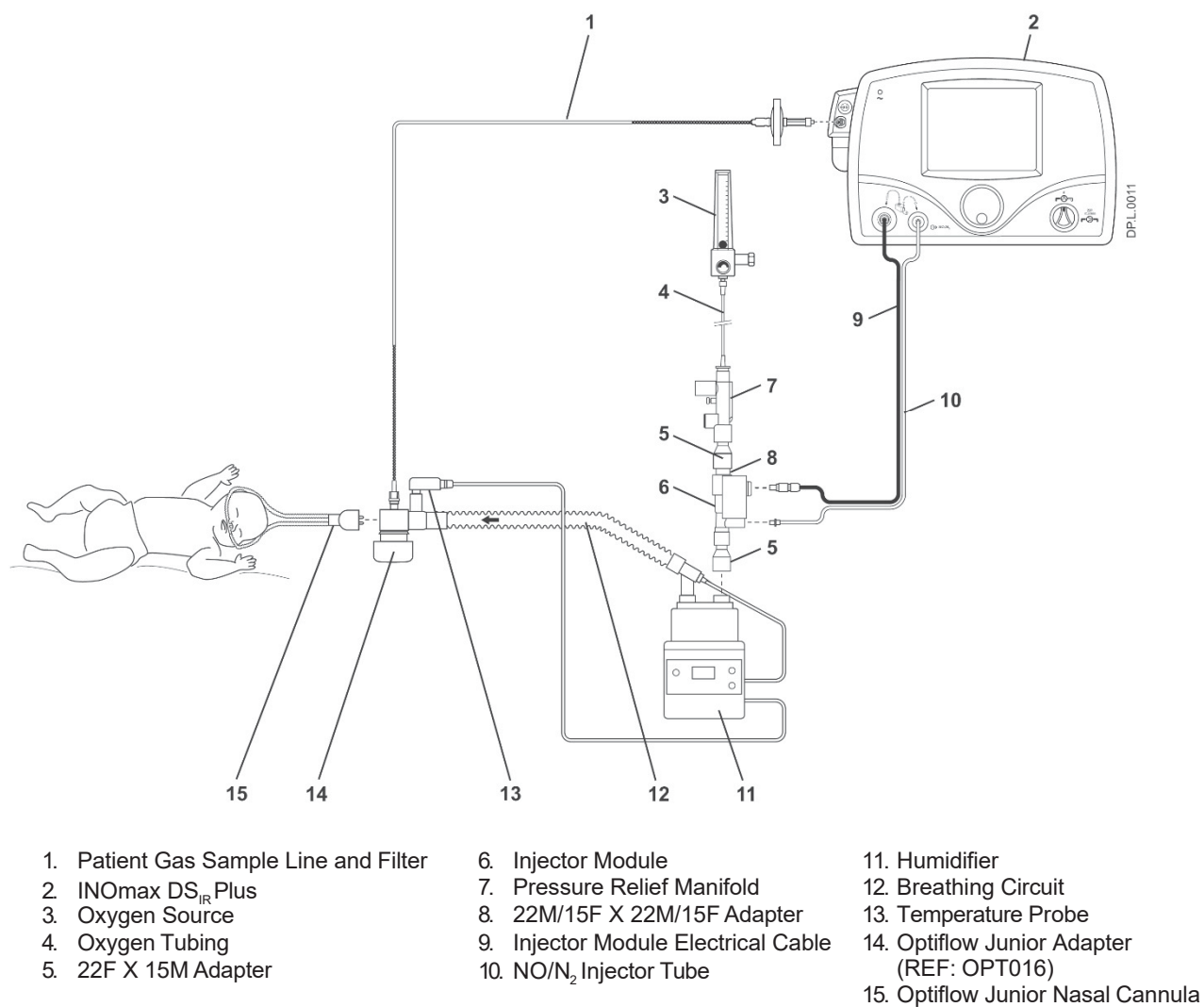


Figure 2: Optiflow Jr Infant/Pediatric Setup

For technical assistance regarding any of the above devices, please contact Product Support at 1-877-566-9466 (North America) or your specific country manager.

Mallinckrodt Manufacturing LLC
6603 Femrite Drive,
Madison, WI 53718-6801 USA

Mallinckrodt, the “M” brand mark and the Mallinckrodt Pharmaceuticals logo are trademark of a Mallinckrodt company. Other brands are trademarks of a Mallinckrodt company or their respective owner. ©2022 Mallinckrodt.



Europe
European Authorized Representative
MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany



Ref: TB-20003-ENG Updated 02-2022
PN 21782, rev. 03