

INFORMATION FOR LIMITED DISTRIBUTION



MallinckrodtTM
Pharmaceuticals

Technical Bulletin

Ref: **TB-16005-ENG**

Issue date: **February 2022**

Product: INOmax DS_{IR}® / INOmax DS_{IR}® Plus and INOvent®

Priority: Low

Subject: **Acutronic Medical Systems AG
Fabian Ventilator Validation Testing**

Classification: Information for
Limited Distribution

This technical bulletin is written to advise clinicians that the following Acutronic Fabian ventilators have been validated for use with the INOmax DS_{IR}/ INOmax DS_{IR} Plus and INOvent using the configurations shown below.

- Fabian HFO circuit diagram for conventional modes ONLY (page 2)
- Fabian HFO circuit diagram for high frequency mode ONLY (page 3)
- Fabian+ nCPAP Evolution circuit diagram (page 4)
- Fabian HFOi circuit diagram for conventional modes ONLY (page 5)
- Fabian HFOi circuit diagram for high frequency mode ONLY (page 6)
- Fabian Therapy circuit diagram (page 7)

Proper use of these products depends on careful reading and understanding of labeling and instructions. Please refer to the appropriate operation manual for guidance. Also refer to the specific ventilator or breathing device operation manual or instructions for use.

Warnings:

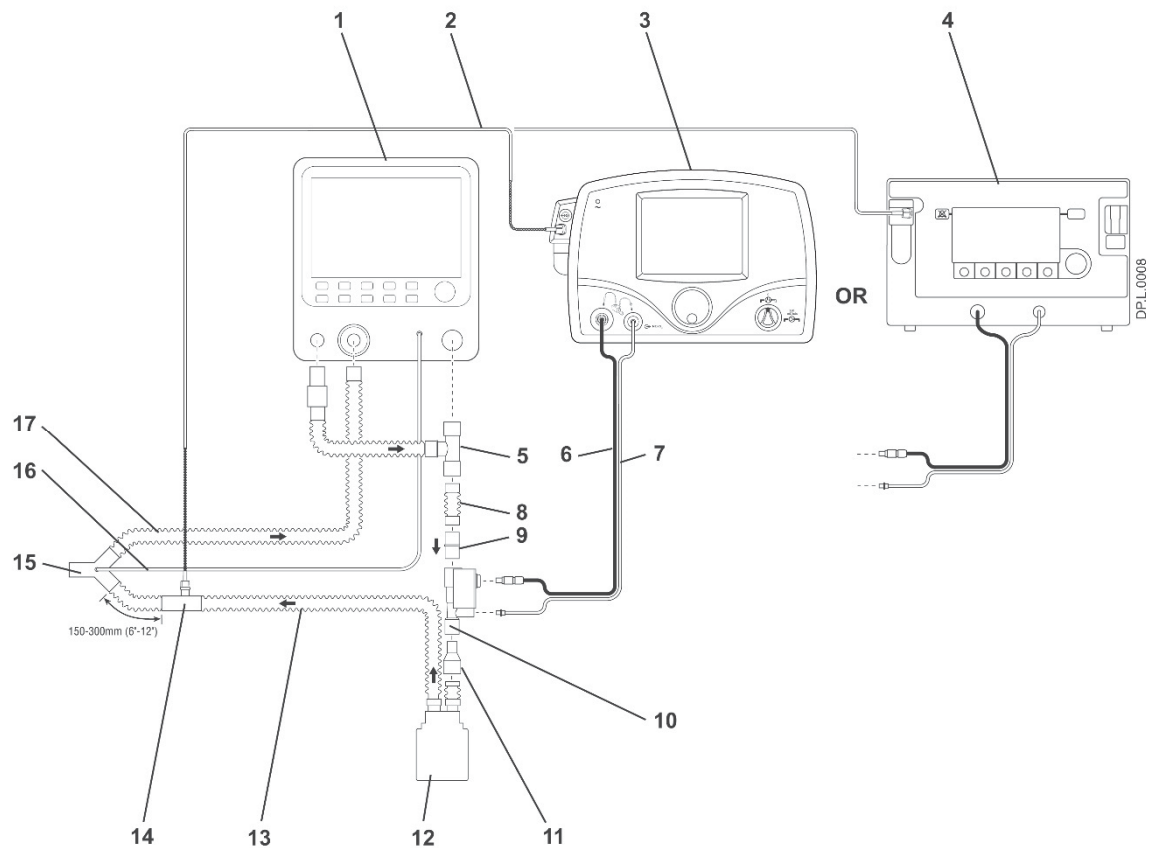
- **The INOmax DS_{IR}/INOmax DS_{IR} Plus and INOvent subtracts gas from the breathing circuit via the gas sampling system at 230 mL per minute; this can affect the sensitivity of a flow triggered synchronized breath mode of some ventilators. The trigger sensitivity of the ventilator should be checked after connecting the INOmax DS_{IR}/INOmax DS_{IR} Plus and INOvent to the breathing circuit.**

Cautions:

- Insert the Injector Module on the dry side of the breathing circuit prior to the humidifier (this will ensure correct flow measurement).
- Avoid medications interfering with the gas monitoring system; administer any aerosolized medications distal to the sampling tee.

Note: Connections to various ventilators as well as their corresponding disposable circuits, are unique to each manufacturer. Please refer to the specific ventilator or breathing device operation manual or instructions for use for guidance.

Example: Fabian HFO circuit diagram for conventional modes ONLY



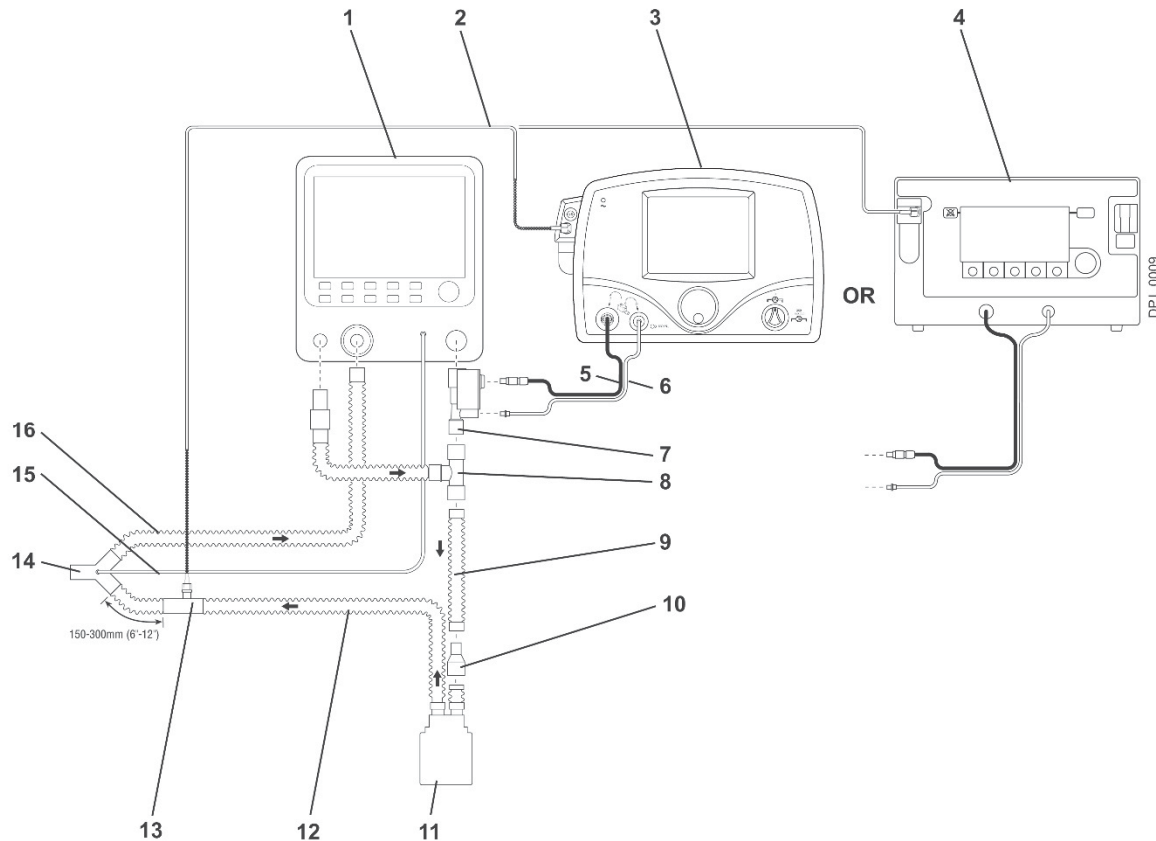
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|---|--|
| 1. Fabian HFO Ventilator | 9. 22M/15F X 22M/15F Adapter |
| 2. Patient Gas Sample Line with Nafion (DSIR/DSIR Plus), without Nafion (INOvent) | 10. Injector Module |
| 3. INOmax DSIR/INOmax DSIR Plus | 11. 22F X 15M Adapter |
| 4. INOvent | 12. Humidifier |
| 5. T-Connector Assembly, #7209.e | 13. Inspiratory Breathing Circuit Hose |
| 6. Injector Module Electrical Cable | 14. Gas Sample Tee |
| 7. NO/N ₂ Injector Tube | 15. Patient Wye |
| 8. Connecting Tube (approx. 24 in.) | 16. Proximal Pressure Tube |
| | 17. Expiratory Breathing Circuit Hose |

Example: Fabian HFO circuit diagram for high frequency mode ONLY

Warning: Do not use dose settings above 40 ppm. Bidirectional flow through the Injector Module may cause over-delivery which can lead to measured NO values greater than 100 ppm

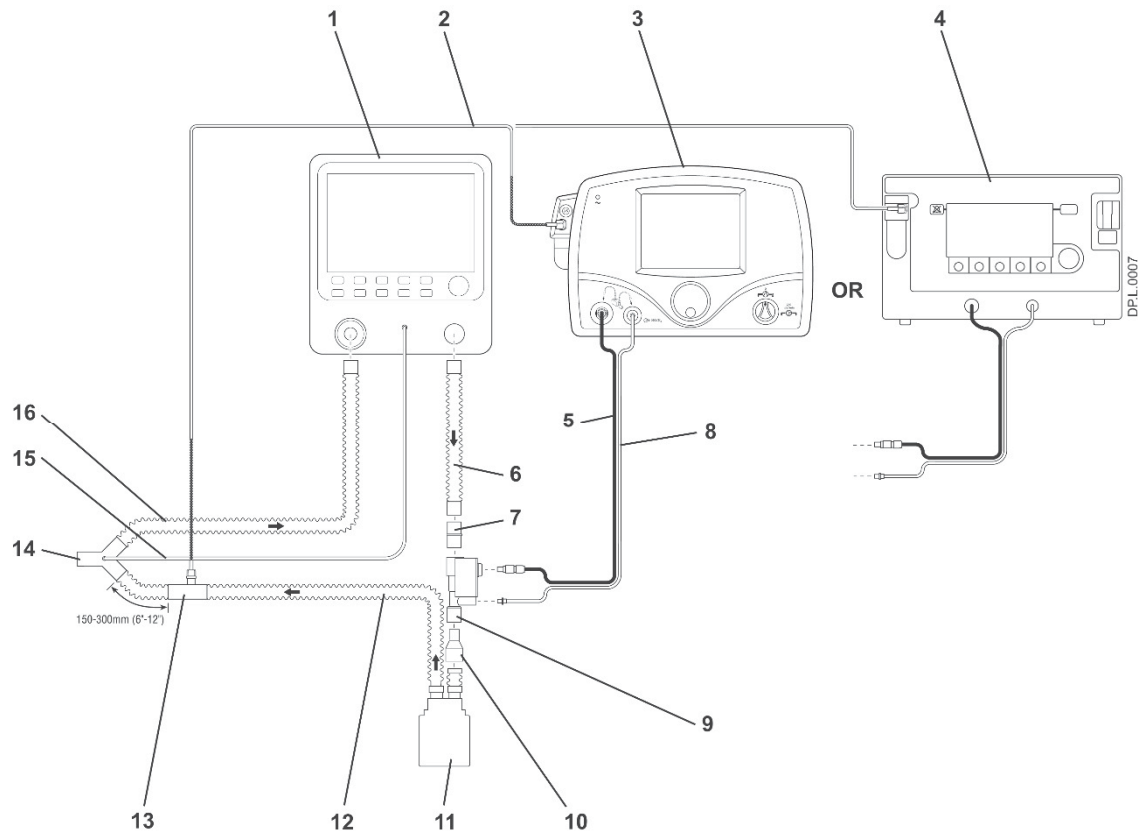
Note:

- Only use the circuit configuration below
- Connect the Injector Module directly to the inspiratory outflow port on the front of the ventilator to prevent over-delivery from bidirectional flow during HFOV (gas flow from connection #7)
- Use of a one-way valve distal to the Injector Module IS NOT necessary



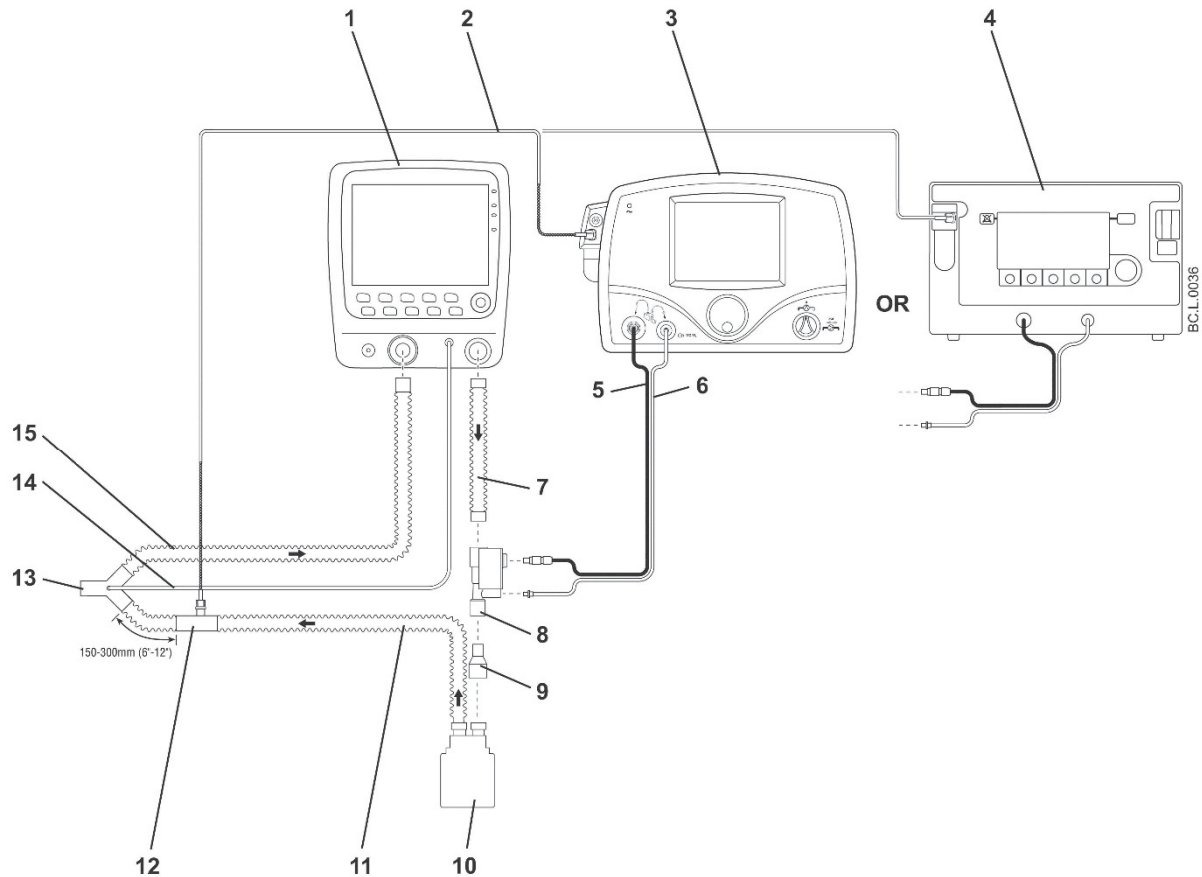
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| 1. Fabian HFO Ventilator | 8. T-Connector Assembly, #7209.e |
| 2. Patient Gas Sample Line with Nafion (DS _{IR} /DS _{IR} Plus), without Nafion (INOvent) | 9. Connecting Tube (approx. 24 in.) |
| 3. INOmax DS _{IR} /INOmax DS _{IR} Plus | 10. 22F X 15M Adapter |
| 4. INOvent | 11. Humidifier |
| 5. Injector Module Electrical Cable | 12. Inspiratory Breathing Circuit Hose |
| 6. NO/N ₂ Injector Tube | 13. Gas Sample Tee |
| 7. Injector Module | 14. Patient Wye |
| | 15. Proximal Pressure Tube |
| | 16. Expiratory Breathing Circuit Hose |

Example: Fabian+ nCPAP Evolution circuit diagram



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| 1. Fabian+ nCPAP Evolution | 8. NO/N ₂ Injector Tube |
| 2. Patient Gas Sample Line with Nafion (DS _{IR} /DS _{IR} Plus), without Nafion (INOvent) | 9. Injector Module |
| 3. INOmax DS _{IR} /INOmax DS _{IR} Plus | 10. 22F X 15M Adapter |
| 4. INOvent | 11. Humidifier |
| 5. Injector Module Electrical Cable | 12. Inspiratory Breathing Circuit Hose |
| 6. Connecting Tube (approx. 24 in.) | 13. Gas Sample Tee |
| 7. 22M/15F X 22M/15F Adapter | 14. Patient Wye |
| | 15. Proximal Pressure Tube |
| | 16. Expiratory Breathing Circuit Hose |

Example: Fabian HFOi circuit diagram for conventional modes ONLY

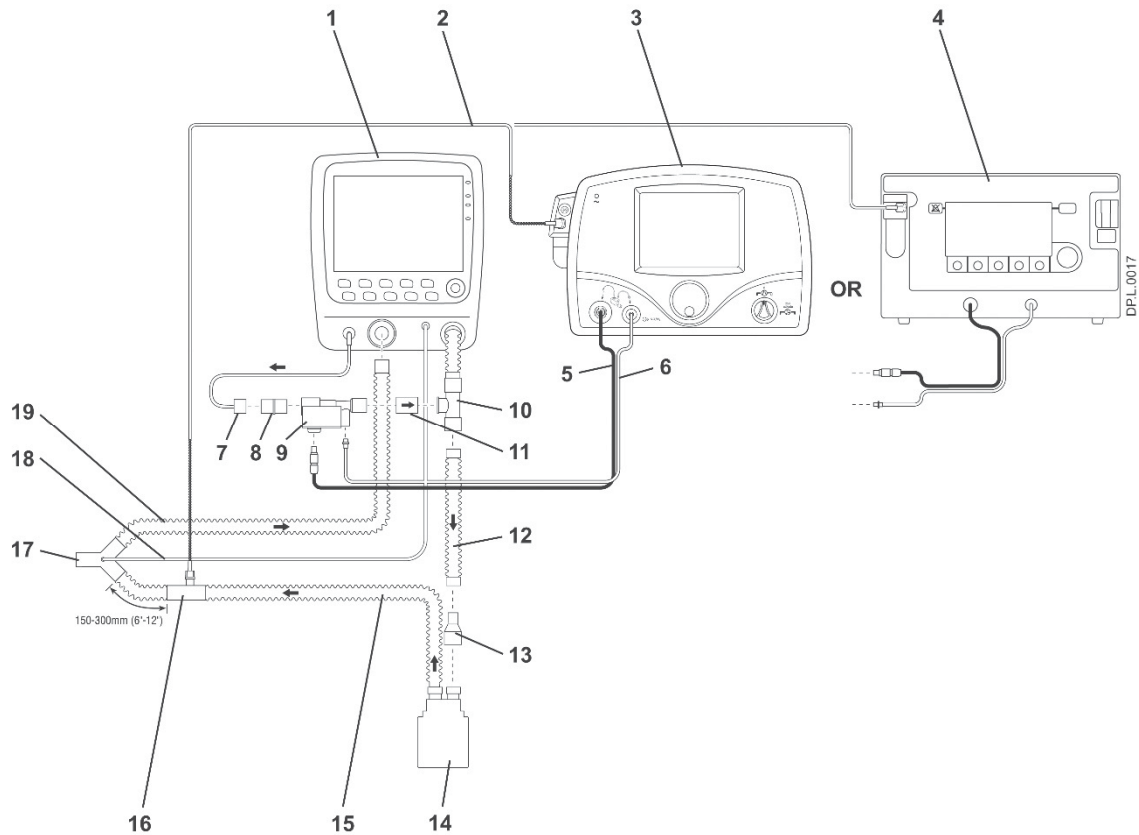


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| 1. Fabian HFOi | 8. Injector Module |
| 2. Patient Gas Sample Line with Nafion (DS _{IR} /DS _{IR} Plus), without Nafion (INOvent) | 9. 22F X 15M Adapter |
| 3. INOmax DS _{IR} /INOmax DS _{IR} Plus | 10. Humidifier |
| 4. INOvent | 11. Inspiratory Breathing Circuit Hose |
| 5. Injector Module Electrical Cable | 12. Gas Sample Tee |
| 6. NO/N ₂ Injector Tube | 13. Patient Wye |
| 7. Connecting Tube (approx. 24 in.) | 14. Proximal Pressure Tube |
| | 15. Expiratory Breathing Circuit Hose |

Example: Fabian HFOi circuit diagram for high frequency mode ONLY

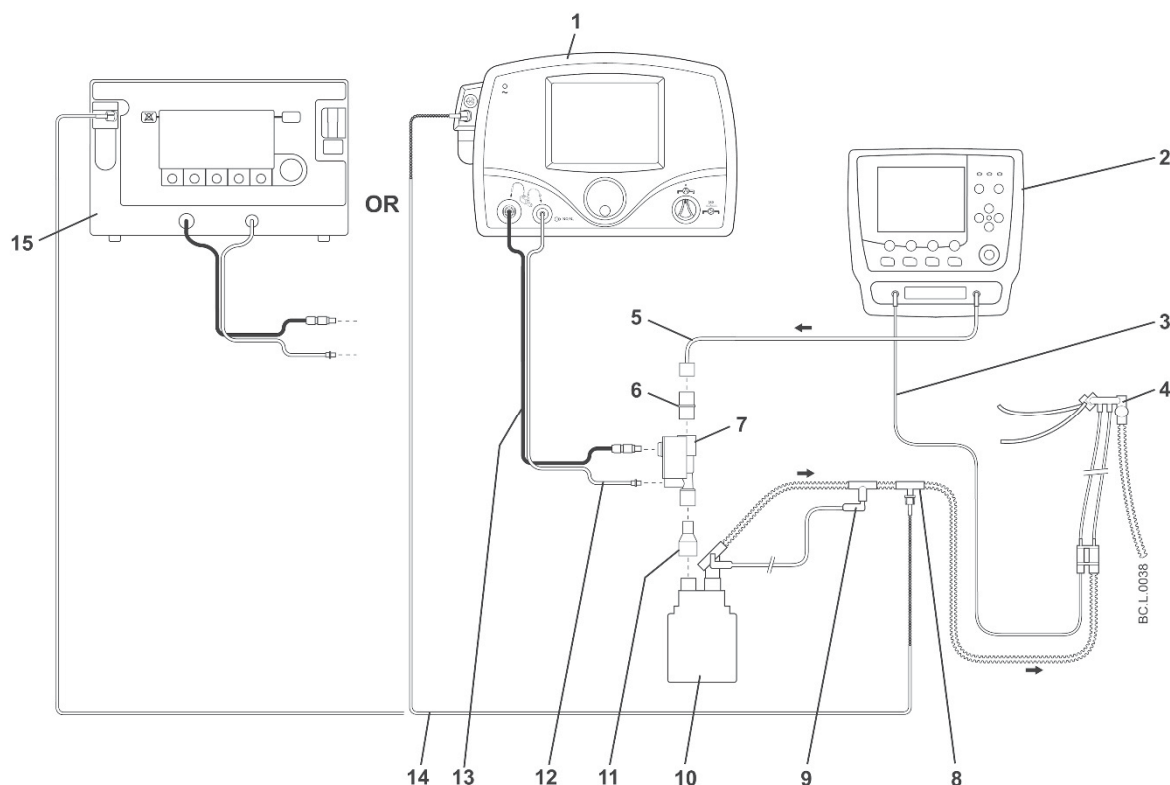
WARNING: A one-way valve (#11 below) is required between the injector module and the tee into the inspiratory limb of the breathing circuit to prevent over-delivery.

Note: The “bias flow external” must be activated to direct gas flow through the injector module.



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| 1. Fabian HFOi | 10. Tee Adapter |
| 2. Patient Gas Sample Line with Nafion (DSIR/DSIR Plus), without Nafion (INOvent) | 11. One-Way Valve |
| 3. INOmax DSIR/INOmax DSIR Plus | 12. Connecting Tube |
| 4. INOvent | 13. 22F X 15M Adapter |
| 5. Injector Module Electrical Cable | 14. Humidifier |
| 6. NO/N ₂ Injector Tube | 15. Inspiratory Breathing Circuit Hose |
| 7. nCPAP Adapter (REF 7067) | 16. Gas Sample Tee |
| 8. 22M/15F X 22M/15F Adapter | 17. Patient Wye |
| 9. Injector Module | 18. Proximal Pressure Tube |
| | 19. Expiratory Breathing Circuit Hose |

Example: Fabian Therapy circuit diagram



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| 1. INOmax DS _{IR} /INOmax DS _{IR} Plus | 9. Temperature Probe |
| 2. Fabian Therapy | 10. Humidifier |
| 3. Pressure Monitoring Tube | 11. 22F X 15M Adapter |
| 4. Infant CPAP Generator | 12. NO/N ₂ Injector Tube |
| 5. Infant Flow Connection Tube (REF 7067) | 13. Injector Module Electrical Cable |
| 6. 22M/15F X 22M/15F Adapter | 14. Patient Gas Sample Line with Nafion (DS _{IR} /DS _{IR} Plus), without Nafion (INOvent) |
| 7. Injector Module | 15. INOvent |
| 8. Sample Tee | |

For technical assistance regarding the INOmax DS_{IR}/INOmax DS_{IR} Plus/INOvent, please contact technical support at 1-877-566-9466 (North America) or your specific country manager.

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

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

