Warning
Carefully read the instructions for use before using the ventilator to familiarise yourself with the function of the equipment.
DISCLAIMER

ACUTRONIC Medical Systems assumes no responsibility for the use or reliability of its software on equipment that is not furnished by ACUTRONIC Medical Systems.

ACUTRONIC Medical Systems makes no warranty of any kind with regard to software applications that are created by the user.

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For any additional parts and accessories, contact your local distributor for available items and price list.
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1 Introduction

1.1 Working with the instructions

These instructions for use describe equipment components and their operation. These instructions are structured so that you can step your way through the procedures and become familiar with the operation of the ventilator.

⚠️ WARNING
Carefully read the instructions for use before using the ventilator.

After you are familiar with the basic construction and operation of the ventilator you can use this manual as a reference.

1.2 Notices and warnings

This document features three categories of notices and warnings.

⚠️ WARNING:
Warnings identify conditions or practices that could result in serious adverse reactions or potential safety hazards.

⚠️ CAUTION:
Cautions identify conditions or practices that could result in damage to the ventilator or other equipment.

NOTE:
Notes provide additional information to clarify an explanation or instruction.

1.3 Applicable product versions

This Instruction for Use is applicable for fabian HFO devices running software version 5.1.x, where (x) can be any number.
## 1.4 Symbols

The symbols defined in this section may appear in this document and on the equipment label or labels.

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>REF</td>
<td>Article No.</td>
</tr>
<tr>
<td>LOT</td>
<td>Batch code</td>
</tr>
<tr>
<td>!</td>
<td><strong>CAUTION</strong>, refer to operator’s manual for important safety information and precautions.</td>
</tr>
<tr>
<td>!</td>
<td>Chemical burn warning</td>
</tr>
<tr>
<td>!</td>
<td>Dangerous voltage warning</td>
</tr>
<tr>
<td>![RS232]</td>
<td>Data input / output RS-232</td>
</tr>
<tr>
<td>![RS232]</td>
<td>Data input / output RS-232</td>
</tr>
<tr>
<td>![Disposal]</td>
<td>Disposal information</td>
</tr>
<tr>
<td>![DO NOT]</td>
<td>DO NOT cover</td>
</tr>
<tr>
<td>![DO NOT]</td>
<td>DO NOT stack no more than 2 on top</td>
</tr>
<tr>
<td>![DO NOT]</td>
<td>DO NOT use hooks</td>
</tr>
<tr>
<td>![Potential]</td>
<td>Potential equalisation connection</td>
</tr>
<tr>
<td>![Flammability]</td>
<td>Flammability/Fire hazard warning</td>
</tr>
<tr>
<td>![Sensor]</td>
<td>Flow sensor connection</td>
</tr>
<tr>
<td>![Flow]</td>
<td>Flow sensor connection</td>
</tr>
<tr>
<td>![External]</td>
<td>External power supply input</td>
</tr>
<tr>
<td>![Fragile]</td>
<td>Fragile, Handle with care</td>
</tr>
<tr>
<td>![High Frequency]</td>
<td>High Frequency interference warning</td>
</tr>
<tr>
<td>![Keep away]</td>
<td>Keep away from heat</td>
</tr>
<tr>
<td>![Keep dry]</td>
<td>Keep dry</td>
</tr>
<tr>
<td>Symbol</td>
<td>Description</td>
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</tr>
<tr>
<td><img src="image" alt="Manufactured without the use of natural latex or derivatives" /></td>
<td>Manufactured without the use of natural latex or derivatives</td>
</tr>
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<td><img src="image" alt="Manufacturer" /></td>
<td>Manufacturer</td>
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<tr>
<td><img src="image" alt="Marking per Medical Devices Directive 93/42/EEC" /></td>
<td>Marking per Medical Devices Directive 93/42/EEC</td>
</tr>
<tr>
<td><img src="image" alt="Nebulizer (obsolete)" /></td>
<td>Nebulizer (obsolete)</td>
</tr>
<tr>
<td><img src="image" alt="Network Ethernet connection (disabled)" /></td>
<td>Network Ethernet connection (disabled)</td>
</tr>
<tr>
<td><img src="image" alt="Non-Sterile" /></td>
<td>Non-Sterile</td>
</tr>
<tr>
<td><img src="image" alt="NOTE symbol" /></td>
<td>NOTE symbol</td>
</tr>
<tr>
<td><img src="image" alt="Nurse Call signal output" /></td>
<td>Nurse Call signal output</td>
</tr>
<tr>
<td><img src="image" alt="Nurse Call signal output" /></td>
<td>Nurse Call signal output</td>
</tr>
<tr>
<td><img src="image" alt="Protective Earth ground" /></td>
<td>Protective Earth ground</td>
</tr>
<tr>
<td><img src="image" alt="Single use" /></td>
<td>Single use</td>
</tr>
<tr>
<td><img src="image" alt="This way UP" /></td>
<td>This way UP</td>
</tr>
<tr>
<td><img src="image" alt="Type BF applied part" /></td>
<td>Type BF applied part</td>
</tr>
<tr>
<td><img src="image" alt="Type B applied part" /></td>
<td>Type B applied part</td>
</tr>
<tr>
<td><img src="image" alt="Unplug power before opening housing" /></td>
<td>Unplug power before opening housing</td>
</tr>
<tr>
<td><img src="image" alt="Video output" /></td>
<td>Video output</td>
</tr>
<tr>
<td><img src="image" alt="USB connection" /></td>
<td>USB connection</td>
</tr>
<tr>
<td><img src="image" alt="Warning regarding operation in explosive areas" /></td>
<td>Warning regarding operation in explosive areas</td>
</tr>
<tr>
<td><img src="image" alt="Do not use if package is damaged" /></td>
<td>Do not use if package is damaged</td>
</tr>
<tr>
<td><img src="image" alt="Expiration date" /></td>
<td>Expiration date</td>
</tr>
<tr>
<td><img src="image" alt="Storage temperature" /></td>
<td>Storage temperature</td>
</tr>
<tr>
<td>Symbol</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>-------------</td>
</tr>
<tr>
<td><img src="image1" alt="Humidity symbol" /></td>
<td>Humidity limitation</td>
</tr>
<tr>
<td><img src="image2" alt="Medical device symbol" /></td>
<td>Medical device</td>
</tr>
<tr>
<td><img src="image3" alt="No symbol" /></td>
<td>Do not use when patient is connected. For training purpose only</td>
</tr>
</tbody>
</table>
# Warnings cautions and notices

## 2.1 Always observe

<table>
<thead>
<tr>
<th>#</th>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>![Note Symbol]</td>
<td><strong>NOTE:</strong> The use of the ventilator requires detailed knowledge and the understanding of this operator’s manual. This device is only intended for the described use.</td>
</tr>
<tr>
<td>2</td>
<td>![Warning Symbol]</td>
<td><strong>WARNING:</strong> Only use this ventilator in combination with an external monitoring device <em>(for example: SpO₂)</em>.</td>
</tr>
<tr>
<td>3</td>
<td>![Warning Symbol]</td>
<td><strong>WARNING:</strong> Only operate the ventilator with accessories recommended by ACUTRONIC Medical Systems AG.</td>
</tr>
<tr>
<td>4</td>
<td>![Warning Symbol]</td>
<td><strong>WARNING:</strong> The ventilator must be operated by qualified clinical staff to ensure immediate remedial action in the event of malfunction.</td>
</tr>
<tr>
<td>5</td>
<td>![Warning Symbol]</td>
<td><strong>WARNING:</strong> The fabian system and associated auxiliary systems must NEVER be used in MRI scanning facilities.</td>
</tr>
<tr>
<td>6</td>
<td>![Warning Symbol]</td>
<td><strong>WARNING:</strong> An alternate ventilation method <em>(for example manual resuscitation)</em> must always be available when using the ventilator.</td>
</tr>
<tr>
<td>7</td>
<td>![Warning Symbol]</td>
<td><strong>WARNING:</strong> DO NOT use the ventilator in combination with flammable gases or narcotic agents or in an oxygen-rich environment to prevent the risk of fire or explosion.</td>
</tr>
<tr>
<td>8</td>
<td>![Warning Symbol]</td>
<td><strong>WARNING:</strong> NEVER use the ventilator in explosive environments.</td>
</tr>
<tr>
<td>9</td>
<td>![Warning Symbol]</td>
<td><strong>WARNING:</strong> An audible signal indicates a system or patient alarm and always requires action by a trained medical professional.</td>
</tr>
<tr>
<td>10</td>
<td>![Warning Symbol]</td>
<td><strong>WARNING:</strong> If an alarm condition <em>(other than the exceptions listed within this manual)</em> occurs while the audible alarm Silence function is engaged, only the visual alarm indications are displayed.</td>
</tr>
<tr>
<td>11</td>
<td>![Warning Symbol]</td>
<td><strong>WARNING:</strong> DO NOT silence an audible alarm, engage the audible Alarm Silence function, or decrease the audible alarm volume if patient safety could be compromised.</td>
</tr>
<tr>
<td>12</td>
<td>![Warning Symbol]</td>
<td><strong>WARNING:</strong> DO NOT obstruct the speaker. Blocking the speaker can result in an inaudible alarm tone.</td>
</tr>
<tr>
<td>13</td>
<td>![Warning Symbol]</td>
<td><strong>WARNING:</strong> Carefully route patient cabling to reduce the risk of patient entanglement or strangulation.</td>
</tr>
<tr>
<td>14</td>
<td>![Warning Symbol]</td>
<td><strong>WARNING:</strong> NEVER connect the ventilator to a patient if an error or malfunction is detected during equipment check.</td>
</tr>
<tr>
<td>15</td>
<td>![Warning Symbol]</td>
<td><strong>WARNING:</strong> NEVER connect to electrical devices not mentioned in this operator’s manual without first consulting the manufacturer.</td>
</tr>
<tr>
<td>16</td>
<td>![Warning Symbol]</td>
<td><strong>WARNING:</strong> Connect only electrical devices which are IEC60601-1 approved.</td>
</tr>
<tr>
<td>17</td>
<td>![No Symbol]</td>
<td><strong>WARNING:</strong> NEVER operate the ventilator while covered or set up in a way to negatively impact the operation or function.</td>
</tr>
<tr>
<td>#</td>
<td>Symbol</td>
<td>Description</td>
</tr>
<tr>
<td>----</td>
<td>--------</td>
<td>-------------</td>
</tr>
<tr>
<td>18</td>
<td></td>
<td><strong>WARNING</strong>: Always unplug the ventilator from the power source before opening the housing.</td>
</tr>
<tr>
<td>19</td>
<td></td>
<td><strong>WARNING</strong>: NEVER use anti-static or electrically conductive tubing.</td>
</tr>
<tr>
<td>20</td>
<td></td>
<td><strong>NOTE</strong>: To support patient and operator safety, the fabian HFO does not contain VOCs, CO, CO₂, O₃, and particulates emitted above hazardous thresholds. Acute, subacute/subchronic, and chronic toxicity from the exposure to these compounds from the intended use of this device are not expected.</td>
</tr>
<tr>
<td>21</td>
<td></td>
<td><strong>WARNING</strong>: The device can only be isolated from the main power supply by removing the power cord completely. Ensure the power socket is always accessible for disconnection. DO NOT disconnect the power cable unless for Service purposes or transport.</td>
</tr>
<tr>
<td>22</td>
<td></td>
<td><strong>WARNING</strong>: DO NOT modify the equipment.</td>
</tr>
<tr>
<td>23</td>
<td></td>
<td><strong>WARNING</strong>: Before applying non-original accessories, ensure that they are biocompatible. All accessories supplied by ACUTRONIC Medical Systems for use on fabian ventilators are biocompatible.</td>
</tr>
<tr>
<td>24</td>
<td></td>
<td><strong>WARNING</strong>: When connected to a patient DO NOT simultaneously touch the external power supply cord and the flow sensor connector cable.</td>
</tr>
<tr>
<td>25</td>
<td></td>
<td><strong>WARNING</strong>: if the volume of the auditory alarms is set less than the ambient noise level this might impede an operator to recognize alarm conditions.</td>
</tr>
<tr>
<td>26</td>
<td></td>
<td><strong>WARNING</strong>: NEVER cover the ventilator while in use.</td>
</tr>
<tr>
<td>27</td>
<td></td>
<td><strong>WARNING</strong>: DO NOT position the ventilator in such a way that this adversely affects its performance or makes it difficult to disconnect the ventilator from the mains supply. In case of emergency, removal of the mains plug from the wall outlet disconnects the ventilator from mains power.</td>
</tr>
<tr>
<td>28</td>
<td></td>
<td><strong>WARNING</strong>: in case of ventilator failure, the lack of immediate access to appropriate alternative means of ventilation can result in patient death.</td>
</tr>
<tr>
<td>29</td>
<td></td>
<td><strong>WARNING</strong>: Ensure that alarms are appropriately set before use of ventilator on a patient.</td>
</tr>
<tr>
<td>30</td>
<td></td>
<td><strong>WARNING</strong>: In case portions of the gas pathways through the VENTILATOR become contaminated with body fluids or expired gases immediately contact ACUTRONIC Medical Systems.</td>
</tr>
</tbody>
</table>
| 31 |       | **WARNING**:  
  - When selecting the neonatal patient size, a Neonatal Flow sensor should be used.  
  - When selecting the pediatric patient size, a Pediatric Flow sensor should be used. |
| 32 |       | **NOTE**: In general, it should be noted that ventilation of children should only be carried out by clinically trained specialists who have sufficient knowledge of ventilation of patients of the specified age. |
| 33 |       | **WARNING**: DO NOT use the eCO₂ module in the presence of flammable anesthetics or other flammable substances in combination with air, oxygen-enriched environments, or nitrous oxide. |
## Warnings, cautions and notices

<table>
<thead>
<tr>
<th>#</th>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>34.</td>
<td>![Warning]</td>
<td><strong>WARNING</strong>: Check alarm limit settings each time the etCO₂ module is used.</td>
</tr>
<tr>
<td>35.</td>
<td>![Warning]</td>
<td><strong>WARNING</strong>: The etCO₂ module is intended only as an adjunct in patient assessment. It must be used in conjunction with assessment of clinical signs and symptoms.</td>
</tr>
<tr>
<td>36.</td>
<td>![Warning]</td>
<td>Before use, carefully read the Oximetry Sensor Directions for Use and PC-Series Patient Cable Directions for Use.</td>
</tr>
<tr>
<td>37.</td>
<td>![Warning]</td>
<td>EXPLOSION HAZARD: Do not use the pulse oximeter in the presence of flammable anesthetics or other flammable substances in combination with air, oxygen-enriched environments, or nitrous oxide.</td>
</tr>
<tr>
<td>38.</td>
<td>![Warning]</td>
<td>Check alarm limit settings each time the pulse oximeter is used.</td>
</tr>
<tr>
<td>39.</td>
<td>![Warning]</td>
<td>A pulse oximeter should NOT be used as an apnea monitor.</td>
</tr>
<tr>
<td>40.</td>
<td>![Warning]</td>
<td>A pulse oximeter should be considered an early warning device. As a trend towards patient deoxygenation is indicated, blood samples should be analyzed by a laboratory co-oximeter to completely understand the patient's condition.</td>
</tr>
<tr>
<td>41.</td>
<td>![Warning]</td>
<td>Always remove the sensor from the patient and completely disconnect the patient from the pulse oximeter before bathing the patient.</td>
</tr>
<tr>
<td>42.</td>
<td>![Warning]</td>
<td>Do not use malfunctioning equipment. Have the pulse oximeter unit repaired by Masimo or a qualified service person.</td>
</tr>
<tr>
<td>43.</td>
<td>![Warning]</td>
<td>ELECTRIC SHOCK HAZARD: Do not remove the pulse oximeter cover. There are no user-serviceable items inside the oximeter. An operator may only perform maintenance procedures specifically described in this manual. ONLY connect IEC 60601-1 or IEC 60950-1 compliant devices to Ethernet, Nurse call, and RS232 ports.</td>
</tr>
<tr>
<td>44.</td>
<td>![Warning]</td>
<td>If the accuracy of any measurement by the pulse oximeter does not seem reasonable, first check the patient's vital signs by alternate means, and then check the oximeter for proper functioning.</td>
</tr>
<tr>
<td>45.</td>
<td>![Warning]</td>
<td><strong>WARNING</strong>: Do not use the ventilator in association with HF (High Frequency) electrosurgical equipment.</td>
</tr>
<tr>
<td>46.</td>
<td>![Warning]</td>
<td><strong>WARNING</strong>: Connect SpO₂ and etCO₂ sensor cables to the machine before the patient is connected.</td>
</tr>
</tbody>
</table>

### 2.2 Maintenance

The device is a ventilator classified as Class Iib according to the European Directive, as such:

- Inspection according to manufacturer specifications is required every 12 months.
- Maintenance must be performed by ACUTRONIC Medical Systems trained personnel with access to appropriate test and measuring equipment.

We strongly recommend ACUTRONIC Medical Systems AG exclusive representatives for service agreements and repairs.

Only use original ACUTRONIC Medical Systems parts for repairs.

Note chapter "Service and maintenance intervals".
2.3 Liability for functionality / damages

In the event of improper equipment maintenance or repair by any person not associated with ACUTRONIC Medical Systems AG Service or improper use, any and all liability for the functionality is transferred to the owner or operator.

ACUTRONIC Medical Systems AG assumes no liability for damages caused by the non-observance of preceding notices. The preceding notices do not extend the warranty and liability terms of the ACUTRONIC Medical Systems AG sales terms and delivery conditions.

2.4 Intended use

The fabian HFO is intended for premature infants, new-borns as well as children weighing up to 30 kg.
The fabian HFO evolution is intended for “in-patient use” in professional healthcare environment including intra-hospital patient transport.
The fabian HFO is an electronically microprocessor controlled ventilator.
The fabian HFO ventilates with positive pressure based on the continuous-flow principle.
(Time cycled, pressure / volume limited or volume guaranteed)
Oxygen is metered by the integrated Air/O2 blender.
The oxygen concentration is measured internally with a galvanic oxygen sensor.

The ventilator is intended for the following ventilation methods:

- HFO (HFO/Sigh) - High Frequency Oscillation (membrane principle)
- IPPV - Intermittent Positive Pressure Ventilation (CMV Controlled Mandatory Ventilation)
- SIMV - Synchronized Intermittent Mandatory Ventilation
- SIPPV - Synchronized Intermittent Positive Pressure Ventilation (A/C, Assist Controlled)
- CPAP (Spn-CPAP/PS) - Continuous Positive Airway Pressure
- PSV - Pressure Support Ventilation
- SIMV + PSV - Synchronised Intermittent Mandatory Ventilation combined with PSV
- Non-Invasive Ventilation (NIV) - nCPAP/duoPAP with variable flow generators (Infant Flow®, Infant Flow LP®, Inspire™, Medijet®)
- HFNC O2 Therapy - High and Low flow oxygen therapy

The equipment is operated by a physician or at their orders by a professional with technical training in this task, whereupon any user must be trained on this equipment and familiar with the operator's manual and the use of the equipment.

fabian HFO is not approved for use in a homecare environment.
3 System overview

3.1 Scope of delivery

The fabian HFO product includes the following items:

- One fabian HFO Ventilator
- One accessory kit:
  - One Flow Sensor (reusable)
  - One Flow Sensor Cable
  - One Test Lung
  - Two single limb connecting tubes
- One power cable \((\text{country specific})\)
- One Instructions for use \((\text{country specific})\)

3.2 Contraindications

Severe airflow obstruction, and intracranial hypertension, would contraindicate the use of the fabian HFO neonatal and infant ventilator.

fabian HFO should not be used in association with HF electrosurgical equipment.

In the event of ventilation for several hours or more, care must be taken for optimal conditioning of the respiratory gases (warmth, humidification) to optimize secretion mobilization and prevent damage to mucous membranes.

3.3 fabian HFO front connections

3.3.1 Devices with serial number prefix AI / AL

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>External Bias Flow (FG - Fresh Gas) port and port for nCPAP system based on flow generators (single limb systems)</td>
</tr>
<tr>
<td>2.</td>
<td>Expiratory limb port</td>
</tr>
<tr>
<td>3.</td>
<td>Proximal Pressure port</td>
</tr>
<tr>
<td>4.</td>
<td>Inspiratory limb port/ HFO port</td>
</tr>
</tbody>
</table>
3.3.2 Devices with serial number prefix 20 / AK / AH

1. Inspiratory limb port/ center port for connecting nCPAP system based on flow generators (single limb systems)
2. Expiratory limb port
3. Proximal Pressure port
4. HFO Port (optional)

3.3.3 Rear panel of device from SN AI-01500 and AL-00400
<table>
<thead>
<tr>
<th>#</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>HDMI connector</td>
</tr>
<tr>
<td>2</td>
<td>USB connection for connection of a USB powered nebulizer. Also available when not in clinical use for data output and software update.</td>
</tr>
<tr>
<td>3</td>
<td>Network connection for data management (disabled)</td>
</tr>
<tr>
<td>4</td>
<td>RS232 interface, service, PDMS</td>
</tr>
<tr>
<td>5</td>
<td>Flow sensor connector</td>
</tr>
<tr>
<td>6</td>
<td>Nurse Call Connector, max switching voltage 30V DC</td>
</tr>
<tr>
<td>7</td>
<td>Loudspeaker (Audio)</td>
</tr>
<tr>
<td>8</td>
<td>Fan</td>
</tr>
<tr>
<td>9</td>
<td>Connector for etCO₂ module (optional)</td>
</tr>
<tr>
<td>10</td>
<td>Connector for SpO₂ module</td>
</tr>
<tr>
<td>11</td>
<td>Mains connection with fuse holder</td>
</tr>
<tr>
<td>12</td>
<td>Terminal stud for potential equalization</td>
</tr>
<tr>
<td>13</td>
<td>Connection for compressed air supply 2.0 – 6.0 bar / max 40 l/min</td>
</tr>
<tr>
<td>14</td>
<td>Connection for oxygen “O₂” supply 2.0 – 6.0 bar / max 40 l/min</td>
</tr>
</tbody>
</table>

3.3.4 Hardware with video input
<table>
<thead>
<tr>
<th></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Connector for 24V DC external power supply (No charging!)</td>
</tr>
<tr>
<td>2</td>
<td>Network jack for data management, PDMS (For connection to network with minimum 3 kV galvanic isolation) (disabled)</td>
</tr>
<tr>
<td>3</td>
<td>USB port for data output, Software update and connection for Masimo SpO₂ module.</td>
</tr>
<tr>
<td>4</td>
<td>DB9 RS-232 port for PDMS</td>
</tr>
<tr>
<td>5</td>
<td>Flow Sensor 7-pin Connector</td>
</tr>
<tr>
<td>6</td>
<td>Nurse Call Connector</td>
</tr>
<tr>
<td>7</td>
<td>Video In, VGA (not used)</td>
</tr>
<tr>
<td>8</td>
<td>Loudspeaker (Audio)</td>
</tr>
<tr>
<td>9</td>
<td>Fan</td>
</tr>
<tr>
<td>10</td>
<td>etCO₂ sensor (optional)</td>
</tr>
<tr>
<td>11</td>
<td>Nebulizer (not used)</td>
</tr>
<tr>
<td>12</td>
<td>O₂ supply connector 2.0 – 6.5 bar / 40 l/min</td>
</tr>
<tr>
<td>13</td>
<td>Pressurised air connector 2.0 – 6.5 bar / 40 l/min</td>
</tr>
<tr>
<td>14</td>
<td>Power Connector (fuse 1.25 AT)</td>
</tr>
<tr>
<td>15</td>
<td>Equipotential connection</td>
</tr>
</tbody>
</table>

### 3.3.5 Initial hardware model
## System overview

<table>
<thead>
<tr>
<th>#</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Connector for 24V DC external power supply (does not charge internal battery!)</td>
</tr>
<tr>
<td>2.</td>
<td>Network jack for data management, PDMS (for connection to network with minimum 3KV galvanic isolation) (disabled)</td>
</tr>
<tr>
<td>3.</td>
<td>USB port for data output, software update and connection for Masimo SpO₂ module</td>
</tr>
<tr>
<td>4.</td>
<td>DB9 RS-232 port for etCO₂ option and PDMS</td>
</tr>
<tr>
<td>5.</td>
<td>Flow Sensor 7-pin Connector</td>
</tr>
<tr>
<td>6.</td>
<td>Nurse Call Connector</td>
</tr>
<tr>
<td>7.</td>
<td>Loudspeaker (Audio)</td>
</tr>
<tr>
<td>8.</td>
<td>Fan</td>
</tr>
<tr>
<td>9.</td>
<td>Optional ports</td>
</tr>
<tr>
<td>10.</td>
<td>Power connector (Fuse 1 AT)</td>
</tr>
<tr>
<td>11.</td>
<td>Equipotential connection</td>
</tr>
<tr>
<td>12.</td>
<td>O₂ Supply Connector 2.0 to 6.5 bar / max 40 l/min</td>
</tr>
<tr>
<td>13.</td>
<td>Pressurized Air Connector 2.0 to 6.5 bar / max 40 l/min</td>
</tr>
</tbody>
</table>

### 3.3.6 General hardware characteristics

**WARNING**

- DO NOT connect Ethernet, Nurse call, USB, RS-232 (etCO₂), SpO₂, Flow Sensor port to anything other than specified devices.
- DO NOT connect anything to ethernet, Nurse call, and RS232, while operating on battery power.
- ONLY connect IEC 60601-1 or IEC 60950-1 compliant devices to Ethernet, Nurse call, and RS232 ports.

For Adapter to DISS see Accessories.

The pin for the Potential Equalization provide additional safety and can be connected to an equipotential zone. Please adhere to local guidelines when using this pin. The guidelines may vary between countries, localities and power companies. Always keep the pin for equipotential connection accessible

**Maximum Connected Loads:**

- **Nurse call:** Isolated relay output
  - Max contact load: 30 VDC @ 1A
- **USB:** 5V @ 150 mA max
- **RS-232:** Signal Levels: EIA/TIA-232 Standard
  - Pin 9 Power: 5V @ 500 mA max (models without DC input)
  - Isolated
<table>
<thead>
<tr>
<th>Device</th>
<th>Maximum Load</th>
<th>Voltage</th>
<th>Operating Current</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethernet</td>
<td>N/A (disabled)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flow Sensor</td>
<td>Maximum load is one Flow sensor</td>
<td>Max. Voltage: 5 V</td>
<td>Max. operating current: 300 mA per hotwire -&gt; 600 mA total.</td>
</tr>
<tr>
<td>SpO2</td>
<td>Max. Voltage: 3.3 V</td>
<td>Max. operating current: 200 mA</td>
<td></td>
</tr>
<tr>
<td>etCO₂</td>
<td>Max. Voltage: 5V</td>
<td>Max. operating current: 700mA</td>
<td></td>
</tr>
</tbody>
</table>
4 System functions and displays

4.1 Control panel options

The Control Panel features three key elements:

The Display (Touch screen)

The Touch screen (1) allows the direct control of the ventilator parameters by pressing defined buttons on the Graphic User Interface (GUI).

Access to Quick Launch settings is on the left side of the touch screen.

The Key / Control Panel (2) with rotary push knob (combined with a push button and selection dial)

4.1.1 Function buttons

The keypad features two rows of buttons with various functions.

Home
Displays the Main Screen for selecting the Respiration mode.

Graphics
Switches to Curve / loop display.

Manual Breath
Used to apply a manual breath. Available in all the Ventilation modes. In HFO mode, it can be disabled in the Ventilation menu.

Alarm limits
Switches to the Alarm Limits Configuration.

Alarm Silence
For acknowledging and audibly silencing alarms for a maximum duration of 120 seconds. Subsequent alarms with higher priority are visually displayed during periods of alarm silence.
The keypad features two rows of buttons with various functions.

**menu / Calibration**
Used to access the Configuration and Calibration menus.
Press once to open the Configuration menu;
Press again to open the Calibration menu.

**Nebulizer**
Obsolete function.

**O₂ Flush**
Used to start O₂ Flush. Flush concentration and time can be preset from the configuration menu.

**Start / Stop**
Used to temporarily stop or commence respiration. During mechanical ventilation this provides a two minute pause in ventilation. In nCPAP, DUOPAP and O₂ Therapy modes this acts as a Standby mode (therapy is disabled until re-enabled by the operator).

**ON / OFF**
Used to switch the device ON or OFF.

4.1.2  Rotary push knob

The Rotary Push knob combines a push button with a rotary knob for executing various settings, selections and confirmation options.

4.2  Display concept structure

4.2.1  Display areas

The information system features two key display areas

1. The Touch screen
2. LED indicators
4.2.2 Display screen

The display screen shows various information, setting and display areas depending on the display settings or menu.

1. Information bar indicating:
   - Battery status,
   - Time/date,
   - Status information,
   - System and alarm information,
   - Patient size symbol
3. Function field (controls of ventilation)
4. Parameter settings and controls fields.
5. Operating modes selection.

Depending on the display mode selected, individual fields can be shown / hidden. Display field options will be described later.

4.2.3 Information bar

The Information bar displays from general information to displaying alarms. It is divided into three sections.

1. The Information bar indicates the following among other things:
   - Neonatal or Pediatric mode
   - Patient Data available
   - Manual Breath in HFO mode ON/OFF
   - Nurse Call Active / Inactive
   - Battery Charge Status
2. Ventilation mode, information and alarm message display
3. Alarm mute (time remaining until audible alarm reactivates) Time / Date.
### Pediatric mode
For patients above 10 kilograms body weight, use of Pediatric mode is recommended. Extended range for flow and volume is available.

### Neonatal mode
Used for patients up to 10 kilograms body weight.

The Patient symbol indicates patient data associated with the current ventilator operation is saved to the device.

The Nurse indicates Nurse Call is activated.

Ventilation mode / Information / and Alarm display. Displays Ventilation mode and, if applicable, additional current information and notices.

A **red** blinking **information bar** also provides alerts to active high priority alarms.

If Screen Lock is in use, the symbol for **Locked Screen** is displayed.

#### 4.2.4 Numeric field / alarm limits

In the Numeric area, all measured values are displayed together with the set limits relevant in the selected Ventilation mode.

There can be multiple pages of Numeric areas.

To go to the next page, press the **button** (1) below the Numeric area.

Depending on the Ventilation mode the data is updated as average / minute or by breath.
The upper and lower limits can be manually or automatically adjusted in the alarm limits menu.

To adjust the alarm limit manually:
1. Press the Alarm Limits button.
2. Touch the Parameter you wish to change.
3. The button turns from dark Blue to Green.
4. With the rotary push knob, change the value.
5. To confirm the setting, either touch the Parameter button again or push the rotary push knob again.

To automatically set the alarm limits, select parameter and touch the AUTOSET button.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Upper limit</th>
<th>Lower limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minute Volume [liter] (in CPAP, IPPV, SIPPV, SIMV, SIMV+PSV, PSV modes)</td>
<td>Neo. 0.01 to 7.0 Ped. 0.01 to 10.0</td>
<td>Neo. OFF, 0.01 to 6.9 Ped. OFF, 0.01 to 9.9</td>
</tr>
<tr>
<td>Minute Volume [liter] (in HFO mode)</td>
<td>0.02 to 20.0</td>
<td>OFF, 0.01 to 19.9</td>
</tr>
<tr>
<td>Leak [%] (in CPAP, IPPV, SIPPV, SIMV, SIMV+PSV, PSV, HFO modes)</td>
<td>OFF, 10 to 50</td>
<td></td>
</tr>
<tr>
<td>Frequency [bpm] (in CPAP, IPPV, SIPPV, SIMV, SIMV+PSV, PSV, NCPAP, DUOPAP modes)</td>
<td>10 to 220, OFF</td>
<td></td>
</tr>
<tr>
<td>Apnea [sec] (in CPAP, NCPAP, DUOPAP, SIMV, SIMV+PSV, PSV modes)</td>
<td>2 to 20, OFF</td>
<td></td>
</tr>
<tr>
<td>PIP [mbar] (in IPPV, SIPPV, SIMV, SIMV+PSV, PSV modes)</td>
<td>1 to 90</td>
<td>OFF, –5 to 29</td>
</tr>
<tr>
<td>PEEP [mbar] (in IPPV, SIPPV, SIMV, SIMV+PSV, PSV modes)</td>
<td>–10 to 89</td>
<td></td>
</tr>
<tr>
<td>P_mean [mbar]</td>
<td>1 to 55</td>
<td></td>
</tr>
</tbody>
</table>
### The alarms can be set between the following ranges:

<table>
<thead>
<tr>
<th></th>
<th>Lower limit</th>
<th>Upper limit</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>(in HFO mode)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>PIP [mbar]</strong></td>
<td></td>
<td>–4 to 30</td>
</tr>
<tr>
<td><strong>PEEP [mbar]</strong></td>
<td>–5 to 19</td>
<td></td>
</tr>
<tr>
<td><strong>CPAP [mbar]</strong></td>
<td>–5 to 19</td>
<td>–9 to 40</td>
</tr>
<tr>
<td><strong>DCO₂ [mL² / sec]</strong></td>
<td>OFF, 1 to 9900</td>
<td>2 to 10000, OFF</td>
</tr>
</tbody>
</table>

**WARNING:** The respiratory rate and minute volume monitors are calculated as averages using an update period of 6 seconds. In the event that the monitored breath rate falls below 11 bpm, these values are not reported.

### 4.2.5 Graphics display

Displays the current Pressure-, Volume- or Flow measurements as a diagram.

Use the **Graphics** key to access the Graphics menu.

Three waveforms are simultaneously displayed.

You can also switch to Loop Display view.

In this view two loops and one of three waves are displayed.

**LOOP Display:**

- Pressure / Volume
- Volume / Flow
## 4.2.6 LED indicators

### The LED Indicators

<table>
<thead>
<tr>
<th>LED Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Warning LED</strong></td>
<td>This LED illuminates or blinks <strong>Red</strong> when a system alarm is triggered.</td>
</tr>
<tr>
<td><strong>Battery LED</strong></td>
<td>This LED illuminates <strong>Yellow</strong> in Battery operation and <strong>Green</strong> when the battery is fully charged. The LED blinks <strong>Green</strong> when the Battery is charging.</td>
</tr>
<tr>
<td><strong>Mains LED</strong></td>
<td>This LED illuminates <strong>Green</strong> in Mains operation and switches OFF in Battery operation.</td>
</tr>
</tbody>
</table>

When powered by the external 24V DC connector, the Mains and Battery LED will NOT illuminate.

If the device shuts down with warning LED blinking simultaneously with battery LED, this represents a device fault. Then follow these steps:

1. Immediately take the device out of service and provide an alternative means of ventilation to the patient;
2. Report the incident to your local distributor

Do not use the device until it has been checked by suitably trained and qualified personnel.
4.3 Ventilation menu

4.3.1 Operation – general

Push the buttons and their statuses are indicated by various colors:

1. Light Blue: Push button.
2. Dark Blue: focused push button.
3. Yellow: (in Functions field): parameter value set automatically
4. Green: selected push button if the push button features a parameter for setting a value, it can now be changed.
5. Orange: parameter is automatically adjusted by the device.

The value that you set indicates the maximum value and will NOT be exceeded.

Depending on the Ventilation mode, the ventilation menu indicates the configuration parameters (4) and measurements (2) relevant in the mode.

Using the push button, you can also switch between the Pressure-, Volume- and Flow curve (3).

The Information bar (1) indicates current information.

The ventilation mode can be changed in the menu (5).
4.3.2 Operation – settings

The Ventilation parameters can be set before starting / activating Ventilation mode:

1. For the desired Ventilation mode, tap the key once: the key will turn Yellow.

2. The Configuration parameters for the preselected Ventilation mode can now be adjusted.

3. Tap Ventilation mode again: the key turns Green, ventilation starts with the parameter settings. The selected parameter can also be confirmed by pressing the rotary push knob.

If the setting is active (Yellow button) and no action is taken within 15 seconds, or the preselected mode is NOT confirmed by tapping again, the device continues in the previous mode, any settings are deleted.

After confirming a parameter, the audible alarm is automatically suppressed for 15 seconds. The audible alarm can be immediately activated by pressing the Alarm Silence button.

Press any blank area or another parameter to NOT accept the parameter and keep the previous value.

Alternating alarms active at the time the mode is switched will automatically be reset.
4.3.3 Ventilation parameter dependency

If parameters are mutually regulating, an arrow will appear on the parameter requiring modification indicating the required direction.

In this example, P_{insp} is being reduced but is NOT able to be reduced further as it is limited by the PEEP setting. The limiting value is indicated by the arrow.

List of Dependencies:
- O_2 Flush min. 2 Vol.% above O_2 setting, max. 100 Vol.%
- Only Volume limit or Volume guarantee possible
- P_{insp} min. 2 mbar above PEEP
- P_{psv} min. 2 mbar above PEEP
- P_{max} min. 2 mbar above PEEP
- P_{manual} min. 2 mbar above CPAP
- P_{psv} ≤ P_{insp}
- P_{manual} min. 1 mbar above P_{mean}
- P_{mean} rec min. 2 mbar above P_{mean}
- Rise-Time ≤ T

4.3.4 Locking ventilator parameters

Some Ventilator parameters are “Locked” to prevent unusual high values.

When this value is reached, a key symbol appears and a “Notice Signal” will sound.

The high value must be confirmed by pressing the rotary push knob again.

(see the following table)
## List of Locked Values

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Neonatal</th>
<th>Pediatrics</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPAP</td>
<td>&gt;10</td>
<td>&gt;10</td>
</tr>
<tr>
<td>E-flow</td>
<td>&gt;20</td>
<td>Not locked</td>
</tr>
<tr>
<td>Flow</td>
<td>&gt;5</td>
<td>&gt;5</td>
</tr>
<tr>
<td>Flow (CPAP mode)</td>
<td>&gt;4</td>
<td>&gt;4</td>
</tr>
<tr>
<td>HFO P&lt;sub&gt;manual&lt;/sub&gt;</td>
<td>&gt;25</td>
<td>&gt;25</td>
</tr>
<tr>
<td>HFO P&lt;sub&gt;manual&lt;/sub&gt;</td>
<td>&gt;20</td>
<td>&gt;20</td>
</tr>
<tr>
<td>HFO P&lt;sub&gt;manual&lt;/sub&gt;</td>
<td>&gt;0</td>
<td>&gt;20</td>
</tr>
<tr>
<td>HFO V&lt;sub&gt;guarantee&lt;/sub&gt;</td>
<td>&gt;30</td>
<td>&gt;30</td>
</tr>
<tr>
<td>I-flow</td>
<td>&gt;20</td>
<td>Not locked</td>
</tr>
<tr>
<td>P&lt;sub&gt;backup&lt;/sub&gt;</td>
<td>&gt;25</td>
<td>&gt;25</td>
</tr>
<tr>
<td>P&lt;sub&gt;PSV&lt;/sub&gt;</td>
<td>&gt;25</td>
<td>&gt;25</td>
</tr>
<tr>
<td>PEEP</td>
<td>&lt;2</td>
<td>&lt;2</td>
</tr>
<tr>
<td>PEEP</td>
<td>&gt;10</td>
<td>&gt;10</td>
</tr>
<tr>
<td>P&lt;sub&gt;insp&lt;/sub&gt;</td>
<td>&gt;25</td>
<td>&gt;25</td>
</tr>
<tr>
<td>V&lt;sub&gt;guarantee&lt;/sub&gt;</td>
<td>&gt;30</td>
<td>&gt;30</td>
</tr>
<tr>
<td>V&lt;sub&gt;limit&lt;/sub&gt;</td>
<td>&gt;30</td>
<td>&gt;30</td>
</tr>
</tbody>
</table>
## 4.4 Graphics menu

The Graphics menu can be accessed from the Graphics button on the Keypad.

<table>
<thead>
<tr>
<th>The Graphics menu</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>The following graphics are available in the Graphics menu:</td>
<td></td>
</tr>
<tr>
<td>1. Curves</td>
<td><img src="image1" alt="Curves" /></td>
</tr>
<tr>
<td>2. Loops</td>
<td><img src="image2" alt="Loops" /></td>
</tr>
<tr>
<td>3. Trends</td>
<td><img src="image3" alt="Trends" /></td>
</tr>
</tbody>
</table>

Curves will be loaded when pressing the Trends button.
4.4.1 Curves

The Graphics menu shows the following curves:

- Pressure
- Flow
- Volume

When auto-scaling of graphics is switched OFF, the graph can be adjusted manually:

1. Select desired graph.
2. Press the graph.
3. The selected graph is marked with the “Cursor” symbol and the Scaling cursor is displayed.
4. Use the cursor to scale the graph in the X and Y direction.

The cursor disappears if not used within five seconds, or by tapping the selected graph again.

The Graphs can be scaled between the following ranges:

<table>
<thead>
<tr>
<th></th>
<th>O₂ therapy, DUOPAP</th>
<th>NCPAP *NIV-trigger Option</th>
<th>IPPV, SIPPV, SIMV, SIMV+PSV, PSV, CPAP</th>
<th>HFO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume [ml]</td>
<td>2 to 60*</td>
<td>2 to 60 (NEO), 2 to 300 (PED)</td>
<td>2 to 80</td>
<td></td>
</tr>
<tr>
<td>Flow [l/min]</td>
<td>2 to 80*</td>
<td>2 to 80</td>
<td>2 to 80</td>
<td></td>
</tr>
<tr>
<td>Pressure [mbar]</td>
<td>10 to 20</td>
<td>10 to 100</td>
<td>0 to 200</td>
<td></td>
</tr>
</tbody>
</table>

Manual scaling mode. Use the Up and Down Keys for scaling Graphics.
The **Freeze** key stops the curve from being updated.

The Configuration parameters and measurements in the Display area continue being updated.

The **key** will turn **Green**.

Press the **Freeze key** again to continue updating the Curve data.

Depending on the Ventilation mode selected, the numeric block will display the parameters that are relevant in this mode.
4.4.2 Loops

The Loops menu features the following loops:

- Pressure / Volume (P/V Loop)
- Volume / Flow (V/F Loop)

The following parameters for the respective Curve can be selected in the upper area of the display:

- Pressure
- Volume
- Flow

The **Freeze** key is used to pause Loop updating.

The Settings parameters and measurements in the display area will only be shown after a Loop has been saved.

The key will turn **Green**.

Press the key again to continue updating the Loop Data.

After freezing the loop, it can be saved as a reference loop to later compare against the current data.

Save Loop:
1. Freeze Loop.
2. Push **Freeze** Key.
3. The Loop will be saved until a new Loop is saved.

Comparing loops:
1. Switch to Loops Display:
2. Freeze current Loop.
3. Current Loop is shown in **Blue**,
   the Saved Loop is shown in **Black**.
4.4.3 Trend menu

The device trending function automatically saves an average of measurements every 30 seconds. Measurements of up to five days can be recorded.

Trend Data is automatically deleted in the following cases:

- Date and / or Time is modified
- New Patient data is entered
- Software Update

A confirmation message will always be displayed before Trend Data is deleted.

1. Parameter / Selection
2. Graphics
3. Parameter values
4. Timeline
5. Adjust Timeline (minimum 30 minutes to a maximum of five days)
6. Shift Timeline
7. Update Data (refresh)
Trend menu
1. Press Graphics (1) key
2. Press Trends key

Loading Trend data
The Trend menu features three simultaneous parameters as curves.

The Parameters displayed can be modified by activating the Select List on left side. Available parameters are:

- % MVmand
- Compliance
- DCO₂
- etCO₂
- FiO₂
- Freq
- HF Amplitude
- Leak
- MV
- P<sub>insp</sub>
- P<sub>mean</sub>
- Resistance
- RSBI
- SpO₂
- SpO₂ PI
- SpO₂ PR
- Vte

Shifting the Timeline.

The Timeline can be shifted for all three parameters simultaneously.

1. Change timeline from the Rotary Pulse encoder or soft keys.
The Trend graphs can be scaled between the following ranges:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>%MV Mand</td>
<td>10 to 120</td>
</tr>
<tr>
<td>Compliance</td>
<td>1 to 12 [mL / mbar]</td>
</tr>
<tr>
<td>DCO₂</td>
<td>10 to 5000 [mL² / sec]</td>
</tr>
<tr>
<td>etCO₂</td>
<td>10 to 160 [mmHg]</td>
</tr>
<tr>
<td>FiO₂</td>
<td>20 to 120 [%]</td>
</tr>
<tr>
<td>Freq</td>
<td>20 to 300 [bpm]</td>
</tr>
<tr>
<td>HF Ampl</td>
<td>10 to 100 [mbar]</td>
</tr>
<tr>
<td>Leak</td>
<td>10 to 100 [%]</td>
</tr>
<tr>
<td>MV</td>
<td>0.1 to 10 [liter]</td>
</tr>
<tr>
<td>Pinsp</td>
<td>10 to 100 [mbar]</td>
</tr>
<tr>
<td>Pmean</td>
<td>10 to 100 [mbar]</td>
</tr>
<tr>
<td>Resistance</td>
<td>10 to 1000 [mbar / Lps]</td>
</tr>
<tr>
<td>RSBI</td>
<td>5 to 250 [l/m]</td>
</tr>
<tr>
<td>SpO₂</td>
<td>10 to 120 [%]</td>
</tr>
<tr>
<td>SpO₂ PI</td>
<td>5 to 20</td>
</tr>
<tr>
<td>SpO₂ PR</td>
<td>10 to 250 [bpm]</td>
</tr>
<tr>
<td>Vₑ</td>
<td>10 to 600 [mL]</td>
</tr>
</tbody>
</table>
5 System operation

5.1 Preparing for operation

Do not use any accessory if individual package is damaged.
If the packaging of the ventilator is damaged use the device only if the startup device check is performed successfully.

For initial installation and when lifting the fabian HFO, disconnect all cables and circuits from the ventilator, grab the ventilator with both hands from each lateral side, see arrows indicating on the left side in the figure below, and lift the ventilator carefully.

Always secure the fabian HFO using the dedicated screw at the bottom of the device.

5.1.1 Connect the power supply

Connect the fabian with power cable to a suitable power outlet.

**WARNING:**
DO NOT connect the device to a power outlet strip.
Power fluctuations from the system may trip the circuit breaker in the power outlet strip causing loss of power to the device.

**Exception:** An approved medical grade power outlet strip with valid amperes rating by the manufacturer for connection to a ventilator.

The device can be operated with 100 to 240 VAC and 50 or 60 Hz and automatically adjusts to voltage and frequency without manual switch-over being necessary.

**WARNING:**
The use of fuses must correspond with the value and type approved for the fabian.
- The fuse type and value is printed on the back of the fabian.
- Replacement of the fuses can only be carried out by trained staff. Replace fuses with identical type and values. Failing to do so, can cause fire hazards.
**WARNING:**
To avoid risk of electric shock, this equipment must only be connected to a Supply Main with protective earth ground.

### 5.1.2 Connect the gas supply

Connect the compressed air and oxygen supply tubes to the back of the device and to the central gas supply. Use water trap (see Accessory list) in case humidity can be present in the compressed air pipeline.

If there is no central gas supply, gas supply from cylinders is also possible. Use cylinder with approved regulator per CGA/ISO standards, including fill indicators.

The inputs are coded to prevent wrong connection.

Input pressure (2.0 to 6.0 bar) for medical grade oxygen and medical grade AIR (dust-free, oil-free and dry).
### 5.1.3 Connect the tubing set

- **WARNING: ELECTRICAL HAZARD**
  NEVER use anti-static or electrically conductive tubes.

- **WARNING:**
  The pressure gradient of the fabian ventilator system measured at the patient connection port can increase when accessories or other components are attached to the system.
  Change in pressure gradient can adversely affect the performance of the fabian system.

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Inspiratory <strong>Insp.</strong> port.</td>
</tr>
<tr>
<td>2.</td>
<td>Expiratory <strong>Exp.</strong> port.</td>
</tr>
<tr>
<td>3.</td>
<td>Proximal Pressure <strong>Prox.</strong> port.</td>
</tr>
<tr>
<td>4.</td>
<td>Use <strong>FG</strong> Connection when connecting to an INOvent Flow sensor.</td>
</tr>
</tbody>
</table>

1. Connect inspiratory tube to **Insp.** port.
2. Connect expiratory tube to **Exp.** port.
3. Connect pressure measuring tube to **Prox.** port.
4. Connect HFO tube to HFO adapter. Only required when operating in HFO mode.

**NOTE:** Always hold tubes by the collar when connecting and disconnecting to prevent damage.

The Expiration membrane can be easily removed by turning the membrane holder counter-clockwise.

**Pay attention to the correct installation position of the Expiration Membrane.**

The label, a 6-digit serial number (SN), must be legible upon installation. *(See illustration).*
5.1.3.1  HFO Tube Set connection with serial number prefix 20 / AH

Connection to HFO Module:

The HFO outlet connector must be connected to the inspiratory limb. Connection to expiratory limb, will result in incorrect ventilation!

5.1.3.2  Connect the Nitric Oxide (NO) tubing set and flow sensor to devices with serial number prefix AI / AL

**WARNING:**
With this setting, flow will only come from the **FG** port, and no flow from the **Insp** port.

1. Connect tube “REF: 153001.01” with the NO Flow Sensor.
2. Place the NO flow sensor on top of the water chamber of the humidifier with a T-piece connector in between.
3. Select in Quick Launch; External Bias Flow. The button will turn Green when selected.

<table>
<thead>
<tr>
<th>Bias Flow intern:</th>
<th>Use when there is no External NO Flow sensor.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bias Flow extern:</td>
<td>Usage of a NO device needs to measure the Bias Flow with an External Flow sensor.</td>
</tr>
</tbody>
</table>
1. Select the **Bias Flow extern**. The button will turn **green** when selected.

2. A **WARNING** message appears. Select the **Confirm Box** to switch to External Bias Flow.

   ![Warning Icon]  
   **Attention:** Select this option if your NO application device has no flow sensor or if no NO is used!  
   **Please read user manual!**

**NOTE:**  
When switching between HFO to a Conventional Ventilation mode, the External NO Flow sensor can be left in this position.

![Warning Icon]  
**WARNING:** When the flow sensor is deactivated, it must be removed from the patient circuit.

## 5.2 Patient circuit assembly

We recommend the use of “Single Use Patient Circuits” to be used on the device. Best performance is achieved with dual limb heated systems.

**Refer to following diagram for setup:**

1. Connect the machine end of the Inspiratory limb to the inspiration port (**Insp**) on the ventilator.  
   1.1. Connect proximal end of the Inspiratory limb to the humidifier chamber inlet.
2. Connect the machine end of the heated Inspiratory limb to the humidifier chamber outlet.  
   2.1. Connect the proximal end of the heated Inspiratory limb to the patient connection wye.
3. Connect the distal end of the Expiratory limb to the air filter and then connect them to the expiration port (**Exp**) on the ventilator.  
   3.1. Connect the proximal end of the Expiratory limb to the patient connection wye.
4. Connect the proximal end of the Proximal Pressure tubing to the patient connection wye monitoring port.  
   4.1. Connect the machine end of the Proximal Pressure tubing to the Proximal Pressure port (**Prox**) on the ventilator.
5. Connect the Inspiratory and Expiratory limb heater connectors with the corresponding connectors on the humidifier chamber heater base.
5.2.1 **Recommended positioning of temperature probe for humidifier**

One of the major sources of problems in neonatal ventilation is, that excessive rainout affects accuracy of flow measurement and therefore compromises its use in various modes of ventilation. We recommend carefully following the manufacturer's instructions for use of the Humidifier to minimize the risk of rainout in the Patient Circuit.
If baby is positioned in incubator, the following setup is recommended:

Place temperature probe outside the incubator and use Incubator extension line.

If the baby is in the open warmer unit, the following setup must be used:

5.2.2 Use of dual limb patient circuit

If Reusable patient circuits are used, they should be used with inspiratory and expiratory limb heater wire or alternatively, a water trap in the expiratory limb:
Assemble the tubing as required:
• Connect Inspiratory / Expiratory line and Pressure limb to Y-piece.
• Connect Flow-sensor to Y-piece.
• Connect Flow-sensor cable to Flow-sensor.

1. Ventilation Circuit
2. Y-piece
3. Flow sensor
4. Flow sensor connection cable
5. Proximal pressure measurement line

Prepare Humidifier according to manufacturer specifications and connect to tubing.

If the humidifier does not have an inspiratory line heater, water traps must be installed in the inspiratory and expiratory limbs.

When using an inspiratory heater, a water trap must be installed at the expiratory end.
Ensure that the Flow-sensor IS NOT exposed to excessive Humidification.

⚠️

We strongly suggest using an Inspiratory and Expiratory Heated Circuit System in HFO mode.
5.2.3 Connect nCPAP tubing

Preventing the nCPAP tubing system:

- Connect nCPAP adapter to the fabian nCPAP port. (REF: 153001).
- Connect the 22 mm adapter connector to the humidifier chamber inlet.
- Connect the nCPAP system pressure measuring limb to the fabian port marked (Prox).
- Connect the nCPAP system to humidifier chamber.
- Apply the nCPAP system to the patient according to its manufacturer instructions.

For details of using nCPAP systems, refer to the manufacturer operator’s manual for consumables.

5.2.4 Triggering in DUOPAP mode with flow sensor *optional*

Preparing the nCPAP InfantFlow/InfantFlowLP/Inspire Tubing System

- Connect Flow sensor to exhalation tube as shown in the picture.

Recommendation:

- Make the Exhalation tube as short as possible.
5.3 System start-up

Switching ON the ventilator

1. Use the ON / OFF button (1) on the device to power ON the equipment.

2. When the device is powered ON, the Start-up screen will appear, and the equipment will perform a “Self-test”.

3. The SOFTWARE REVISION, the CHECK SUMS and the status of the interfaces will be checked.

(ok = no error)

Loudspeaker (audio) check

4. After a successful power ON, the device will prompt the user to perform the acoustic audio alarm test.

5. In order to proceed, you must acknowledge that the alarm is audible, continue using the ventilator without audio alarm or shut down the ventilator.
After the system test is complete, the Calibration menu will appear.

Perform Flow sensor calibration.
6. Select the appropriate Flow sensor (neonatal or pediatric) and set the patient's body weight to see the $V_{te}$ BW [mL/kg] measurement.

7. The $O_2$ will automatically be calibrated after leaving the Calibration menu and calibration will be repeated once every 24 hours.

8. etCO$_2$ and SpO$_2$ modules can be switched ON here as well.

For more information on both modules, refer to the following:
EtCO$_2$: section "12.2: etCO$_2$ monitoring".
SpO$_2$: section "12.3: SpO$_2$ module".

All audible alarms are silenced for 2 minutes.

5.4 Device check

Always perform a device check before each ventilator use or after changing the patient circuit.

The fabian ventilator does not automatically compensate gas fraction measurements for changes in barometric pressure during use. The oxygen sensor is calibrated in the hospital prior to use and this calibration remains in effect. This calibration process is part of the normal pre-use checks for the ventilator. The pre-use calibration should not be skipped if the ventilator has been moved to a location with significant change in altitude.

<table>
<thead>
<tr>
<th>What</th>
<th>How</th>
<th>Target</th>
</tr>
</thead>
</table>
| Gas Supply            | 1. Attach high pressure Air and Oxygen supply hoses to the inlets on the rear panel of the ventilator.  
                        | 2. Connect hoses with the corresponding wall outlets.              | Air and Oxygen supply hoses are correctly connected |
| Breathing System      | Connect the following:  
                        | • Expiration membrane holder and expiration membrane  
                        | • Patient breathing circuit tubes  
                        | • Water traps (if needed)  
                        | • Respiratory humidifier and tube heating  
                        | • Flow sensor                                                              | Expiration membrane holder and membrane correctly installed.  
                        | Patient circuit assembled correctly according to manufacturer's instructions |
| What            | How                                                                 | Target                                              |
|-----------------|----------------------------------------------------------------------|**************************************************|
| **Switch ON test** | 1. Switch ON the fabian ventilator.                                  | Alarm tone is audible and alarm lamp flashes Red during switch-ON test. |
|                 | 2. Perform the acoustic audible alarm test.                         |                                                      |
|                 | 3. Confirm that the audible tone can be heard                        |                                                      |
| **Calibration**  | Calibrate Flow sensor.                                              | Calibration successful                              |
|                 | Calibrate O<sub>2</sub> sensor *(occurs automatically after leaving Calibration menu)* |                                                      |
| **Leakage Test** | Start ventilation mode: CPAP                                         | Pressure of 80 ±4 mbar is achieved on the pressure graph |
|                 | 1. Enter the following settings:                                     |                                                      |
|                 | • CPAP: 5 mbar                                                       |                                                      |
|                 | • P<sub>manual</sub>: 80 mbar                                       |                                                      |
|                 | 2. Press and hold the *Manual Breath* button                         |                                                      |
| **Function Test** | Start Ventilation mode: IPPV                                         | Monitor ventilation parameters to ensure the values are within the following ranges. |
|                 | Enter the following settings:                                       | • P<sub>insp</sub>: 20 ±2 mbar                      |
|                 | • I‒flow: 10 Lpm                                                     | • PEEP: 5 ±1 mbar                                   |
|                 | • E‒flow: 8 Lpm                                                     | • O<sub>2</sub>: 30 ±2 vol.%                       |
|                 | • P<sub>insp</sub>: 20 mbar                                        |                                                      |
|                 | • Freq. (Rate): 30 1 / min                                          |                                                      |
|                 | • I‒time: 1 second                                                   |                                                      |
|                 | • Oxygen: 30 vol.%                                                   |                                                      |
| **Alarms**       | Disconnect the inspiration tube and block the inspiratory port on the ventilator. | Alarm: Tube Occlusion                             |
| **Humidifier**   | Fill level                                                          | Water fill level sufficient.                       |
|                 | Function                                                             | Function OK                                         |

⚠️ **CAUTION:**
Ensure that P<sub>manual</sub> and other pressures are reduced to safe levels prior to connecting to patient.
5.5 System standby / pause

Standby – stopping / pausing mechanical ventilation

<table>
<thead>
<tr>
<th>Standby – stopping / pausing mechanical ventilation</th>
</tr>
</thead>
<tbody>
<tr>
<td>The <strong>Start / Stop</strong> button can be used to interrupt Mechanical ventilation for two minutes.</td>
</tr>
<tr>
<td>• In nCPAP, DUOPAP and O\textsubscript{2} Therapy mode ventilation could be interrupted indefinitely.</td>
</tr>
<tr>
<td>• In both cases the built-in gas mixer delivers a minimal flow to prevent heat build-up inside the Ventilatory Gas Humidifier.</td>
</tr>
<tr>
<td>• Ventilation resumes following the two-minute pause, or when the button is pressed again.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Risk of Oxygen undersupply</th>
</tr>
</thead>
<tbody>
<tr>
<td>• The Standby function is NOT intended for suctioning.</td>
</tr>
<tr>
<td>• A disconnection or reconnection is NOT recognized.</td>
</tr>
</tbody>
</table>

The Standby – stopping / pausing ventilation must **NOT** be used while ventilator is connected to the patient.

Any FOT measurements taken during standby are NOT valid

For device pause or standby:
1. Remove patient from ventilator.
2. Press and hold the Start / Stop button. A menu will appear on the screen stating: “Do you want to pause ventilation for two minutes?”
3. Press YES to pause the ventilator for 2 minutes.

The **Information bar** will display the pause in-progress message “Stop Ventilation”.

When the ventilation has stopped, the **Information bar** will display the following message: “Ventilation stopped”.

**NOTE:** The pause time will count down the two minutes and then the ventilator will resume ventilation

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fabian HFO | SW 5.1.x
Ref: 113003.EN / Date 2020-02-10
5.6 System shutdown

Switching OFF the fabian

1. Remove patient from the ventilator.
2. Power OFF and disconnect any SpO₂ or CO₂ devices connected to the ventilator.
3. Press and hold the ON / OFF button (1) for 6 seconds.
4. After 6 seconds, a menu will appear on the screen stating, “Do you want to shut down the device?”
5. Press YES to power OFF the device.
6. The Information bar displays “Switch off Ventilator” in the shut down process.
7. After the device has powered OFF, a notice tone will sound.
8. Press the Alarm Silence button to confirm system switch OFF.
9. Hold the button for at least three seconds until the WARNING LED stops.
5.7 Emergency shutdown

**WARNING**

In the event of a fault resulting in loss of normal control the emergency shutdown procedure may be used. This procedure disconnects all power to the ventilator and any other devices connected to the ventilator.

Before performing this procedure, ensure that the alternate ventilation method *(for example: manual resuscitation)* is present, ready and standing by.

1. Remove patient from the ventilator.
2. Press and hold the **ON / OFF** button (1) for one to two seconds. Then release it.
3. After one to five seconds, press and hold the **ON / OFF** button (1) again for at least five seconds.
4. After the device has powered OFF, a notice tone will sound.
5. Press the **Alarm Silence** button to confirm system switch OFF.
6. Hold the button for at least three seconds until the **WARNING** LED stops.
The Configuration menu can be accessed by pressing the **Menu / Calibration** button on the keypad and selecting the **Menu** push button.

1. Calibration  
2. Display  
3. Ventilation  
4. Patient data  
5. Language  
6. Date / Time  
7. Tools  
8. Information  
9. PDMS (optional)  
10. Service mode  
11. Close menu (return to previous menu)
6.1 Calibration

The Calibration screen is the first screen that comes up when the Calibration key is pressed. Then you can proceed through the menu options to select the Calibration menu again.

The Calibration menu can be accessed through the Menu / Calibration button on the keypad.

Upon ventilator startup, you will be automatically directed to the Calibration menu. The Calibration menu is displayed as follows.

From the Calibration screen, you can calibrate the following Sensors:

- Flow sensors: Neonatal and Pediatric
- O₂ sensor
- etCO₂ module
- SpO₂ module
6.1.1 Flow sensor

Flow sensors can be calibrated in the upper half of the Calibration menu.

To calibrate a Neonatal Flow sensor, select the **Neonatal** button.

To calibrate a Pediatric Flow sensor, select the **Pediatric** button.

The Calibration procedure is identical for both types of flow sensors and described below.

Ensure that gas will NOT flow through the Flow sensor during Calibration.

The sensor can be held occluding either one or both ends with a sterile glove to ensure zero gas flow.

1. Press the **Flow Cal** button.
If the ventilator is in a Trigger Function mode, the function is deactivated during calibration and respiration will continue in IPPV mode.

2. First “Checking” will appear, then “Calibration running”.

3. The **Red** lines in the diagram (see illustration on the right) move from left to right, until they are centered in this diagram. When centered, these lines will turn **Green**.

4. Following successful Calibration, the Date of the last calibration will be displayed in the corresponding area.
The Flow Sensor Calibration needs to be performed each time:
- A new sensor is put in place.
- After device startup
- After enabling the flow sensor (manual and automatic)
- After patient range change (Note: the sensor type must match the patient range selected)
- After reconnection of a flow sensor resolving a disconnection alarm

We recommend cleaning the Flow Sensor once daily.

If zero flow and tidal volume measurements are detected in numeric and graphs after:
- Disconnection
- High Leaks
- Low-level Rain-out
- Over-breathing

Flow measurement will be automatically re-started after 6 seconds.

If flow and tidal volume measurements are not regained, consider the following:
- Checking ET tube position (high leaks at the patient) and blockage (during or after in-line suction, or after surfactant therapy)
- Flow Sensor Leakage (loose flow insert or leak)
- Flow Sensor Contamination (single-use sensor recommended)
- Rain-out (contact ACUTRONIC Medical Systems sales for recommended Patient Circuits and Humidifier to prevent Rain-out)

6.1.2 O₂ Sensor

The O₂ sensor calibration can be accessed in the Configurations menu, by pushing the O₂ button.

The O₂ sensor is automatically calibrated when the machine starts up and every 24 hours when in use.

During Calibration procedure, the FiO₂ concentration of the fresh gas to the patient is NOT altered.
- In case of a “supply Gas failure”, the oxygen sensor calibration is automatically disabled to avoid false sensor calibration.
## Manual Calibration:

- Press the **21%** button to perform One Point Calibration at 21% $O_2$.

- Press the **21 + 100%** button to perform a Two Point Calibration at 21% and 100% $O_2$.

After one of these buttons has been pressed, the Calibration procedure starts. If the procedure has been successful, a **Green** check mark will appear.

The $O_2$ sensor can be turned OFF in the event that the $O_2$ sensor reaches end of life during use. You must then use a secondary respiratory gas monitor until the ventilator can safely be taken out of service to replace the $O_2$ sensor.

After a successful calibration, the date of the last calibration is displayed in the corresponding area.

### 6.1.3 etCO₂ module

Please refer to chapter “etCO₂ monitoring”

### 6.1.4 SpO₂ module

Please refer to chapter “SpO₂ module”
6.2 Body weight setting

You can set the patient's body weight in the calibration menu. This setting is used to calculate and display the VTe BW [mL/kg] numeric measurement in IPPV and SIPPV modes.

6.3 Display

1. Adjust screen brightness, four levels.
2. Lock Touch screen. The screen will automatically be unlocked if an alarm is triggered or the rotary push knob is pressed.
   The Touch screen automatically locks after a set time.
3. Display Graphs as filled or regular lines.
   Auto scale ON / OFF
4. Display Trends as filled or regular lines.
   Auto scale ON / OFF

### 6.3.1 Touch screen settings

Lock Touch screen:

1. In the touch area of the Display screen, press “lock” and the screen is locked.
   
   **NOTE:** To deactivate the lock, press the Rotary push knob.

2. Program automatic lock, slide bar to the right and the Time will be displayed.

3. Select Time and you can choose the appropriate time from the auto screen lock list.

   **NOTE:** Exit the time menu with the Return button and the chosen time will be displayed.

The touch screen can also be locked by holding the Rotary push knob for 3 seconds

Lock is automatically cancelled in the event of an alarm or by pressing the Rotary push knob.

## 6.3.2 Trend / graph display

<table>
<thead>
<tr>
<th>Auto-scaling graphs:</th>
<th>Curve plotting in Graphics is automatically adjusted.</th>
</tr>
</thead>
<tbody>
<tr>
<td>• ON</td>
<td></td>
</tr>
<tr>
<td>• OFF</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Graphs display:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• filled</td>
<td></td>
</tr>
<tr>
<td>• not filled</td>
<td></td>
</tr>
</tbody>
</table>

Filled
### Auto-scaling trends:
- **ON**
- **OFF**

Trend patterns are automatically scaled.

### Trends display:
- **filled**
- **not filled**

### 6.4 Ventilation parameter settings
<table>
<thead>
<tr>
<th>#</th>
<th>Parameter</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Automatic O₂ Calibration</td>
<td>21 Vol% / 21 and 100 Vol%. In cases where oxygen supply source does NOT provide 100% oxygen, this should be set to 21% only to avoid calibration at false value.</td>
</tr>
<tr>
<td>2</td>
<td>NIV Leak Compensation</td>
<td>Set either Off, Low, Middle or High level of leak compensation (0; up to 10, 20, 30%) in nCPAP and DuoPAP modes.</td>
</tr>
<tr>
<td>3</td>
<td>Unit for Pressure</td>
<td>Selection of Pressure unit (mbar / cmH₂O).</td>
</tr>
<tr>
<td>4</td>
<td>NIV Tube Set</td>
<td>Selection of the nCPAP system used (Infant Flow [Infant Flow or Inspire], Infant Flow LP, Medijet®).</td>
</tr>
<tr>
<td>5</td>
<td>Maximum time for Manual breath</td>
<td>Maximum Inspiration time for Manual breath (2 to 30 seconds).</td>
</tr>
<tr>
<td>6</td>
<td>Alarm Delay</td>
<td>After visual reset of alarm, the reactivation of alarm is delayed for the set time period. This avoids an immediate re-alarm in case Operational parameters have not yet stabilized.</td>
</tr>
<tr>
<td>7</td>
<td>Manual Breath HFO</td>
<td>ON / OFF. The Manual Breath in HFO mode can be used to perform Lung Recruitment Maneuver (sustained lung inflation) if clinically accepted by internal guideline. Length and Pressure level are adjustable.</td>
</tr>
<tr>
<td>8</td>
<td>Trigger (conventional)</td>
<td>Flow Trigger / Volume Trigger / Pressure Trigger. Trigger mode Configuration for assisted breathing</td>
</tr>
<tr>
<td>9</td>
<td>E-flow</td>
<td>E-flow parameter setting</td>
</tr>
<tr>
<td>#</td>
<td>Parameter</td>
<td>Description</td>
</tr>
<tr>
<td>----</td>
<td>----------------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>10</td>
<td>Ratio of I-time</td>
<td>I-time Display Configuration. Setting I time or frequency (Frequency - I-time / I-time / E-time).</td>
</tr>
<tr>
<td>11</td>
<td>Ppsv Parameter</td>
<td>Select Ppsv parameter to be absolute value or above PEEP Parameter.</td>
</tr>
<tr>
<td>12</td>
<td>Use BTB for Vt</td>
<td>Select if Tidal Volume measurement should be updated for every breath.</td>
</tr>
<tr>
<td>13</td>
<td>Hospital Settings</td>
<td>optional: The &quot;Hospital Settings&quot; button is only active if it is enabled in service mode. Resets the device to the hospital defaults.</td>
</tr>
<tr>
<td>14</td>
<td>Factory Defaults</td>
<td>optional: The “factory defaults” button is only active if it is enabled in service mode. Resets the device to the factory defaults.</td>
</tr>
</tbody>
</table>

**WARNING:**

Only reset to hospital and factory settings when the device is NOT connected to patients.
6.5 Patient data

Note:
Entering new patient data will delete all data from the previous patient.
1. Reset, clearing the actual patient data
2. Apply, will store patient data from now
3. Change data is used to add new patient data. Deleting all stored data from the "old" patient

For data input just touch the Change data and choose the field for input
For capital letters touch
Accepting data with "Apply"
6.6 Language

1. Selecting the operator Language.

Available language option (see below).

Choose the required language by selecting the language name. Use the up and down arrows to scroll to see the rest of the list.

2. Restart the device after selecting a new language.

- American
- Chinese
- Czech
- Danish
- Dutch
- English
- French
- Finnish
- German
- Hungarian
- Italian
- Japanese
- Norwegian
- Polish
- Portuguese
- Russian
- Slovak
- Spanish
- Swedish
- Turkish

Only select a new language when the device is NOT connected to patient.

6.7 Date / Time

**NOTE:**
Changing the date or time will delete all trend data.

**Changing the Date and Time:**
1. Use the Up and Down arrows to set the date and time.

2. After the time or date has been changed, the confirmation check mark changes colors.

3. The new information is applied after confirmation.
6.8 Tools

Only available with USB stick connected.

Export of:

Trends
Trend Data will be output in CSV format.

Log files
Alarm and System log.

Device Information
SW and HW Configuration with licenses.

Only allowed when patient is NOT connected.

6.9 Information

Displays the Information screen (System Information) containing Equipment data.
6.10 Service mode

The Service mode is “password” protected.

Service mode provides access to Nurse Call activation / deactivation, etc.

This section is described in the Service Manual and is only for trained Service technicians.

After using service mode and before connecting fabian to a patient, restart the device.

Only allowed when patient is NOT connected.
7 Alarms

7.1 Alarm limits menu

1. Automatically sets individual alarm limits.
2. Alarm volume (three levels).
3. Open Log file.
4. Display measurements with alarm limits.
Access the Alarm Limits menu by pressing the **Alarm Limits** (1) button.

The Alarm Limits menu allows all alarm limits to be manually or automatically adjusted.

In the event of an alarm, a notice appears in the **Information bar** and a **Red Bell** symbol indicates the alarm cause.

In addition, an audible alarm sounds, which can be silenced for two minutes by pressing the **Alarm Silence** button.

The Alarm Limit can be adjusted manually (1).

The Alarm Limits menu automatically focuses on the corresponding parameter.

The limit can also be automatically adjusted by pressing the **Autoset** button (2).

There is a slight delay before the Autoset alarm appears.

After the Alarm Limit has been adjusted or there are no more active alarms, the bell symbol will turn **Grey**.

The Visual Alarm message must be reset by pressing the **Alarm Silence** button.

---

Once the alarm limit has been adjusted or there are no more active alarms, the bell symbol will turn grey.

The visual alarm message must be reset by pressing the “Alarm silence” button.
7.1.1 Automatic alarm limits

7.1.1.1 Alarm conditions

Each numerical parameter value is checked for violations of the current alarm limits. Additionally, the measured pressure will be checked against the limit every 20 milliseconds with the following conditions:

**Upper Alarm Limit of Pressure:**
- CPAP: with a delay of 300 milliseconds in case of a manual or mechanic breath -> pressure will be checked against upper limit, if the pressure is still above the limit after 5 seconds the alarm will be signaled, otherwise it is cleared.
- nCPAP: with a delay of 3 seconds in case of a manual or mechanic breath -> pressure will be checked against upper limit, if the pressure is still above the limit after 5 seconds the alarm will be signaled, otherwise it is cleared.
- All other ventilation modes: pressure will be checked against the upper limit, if the limit is exceeded the alarm will be signaled.
- A breath with peak pressure below the upper limit will reset the delay of 5 seconds.

**Lower Alarm Limit of Pressure:**
- A breath with peak pressure above the lower limit will reset the delay set in the ventilation menu.
- nCPAP: with a delay of 3 seconds in case of a manual or mechanic breath -> pressure will be checked against lower limit, if the pressure is still below the limit after the alarm delay set by the operator in the Ventilation menu, the alarm will be signaled, otherwise it is cleared.
- DUOPAP: pressure will be checked against lower limit, if the pressure is still below the limit after the Alarm delay set by the operator in the Ventilation menu, the alarm will be signaled, otherwise it is cleared.
- If an Alarm Condition has been detected, a dedicated Alarm Array is written, otherwise it is cleared.

7.1.1.2 Automatic alarm presets

The following alarm limit autosets are used as defaults:
- Minute volume upper limit: 180% of measured minute volume
- Minute volume lower limit: 50% of measured minute volume
- Leak upper limit: 150% of measured tube leak up to maximum of 50% tube leak
- Breaths per Minute (BPM) upper limit: 150% of measured breath rate
- APNEA: 10 seconds
- Proximal Pressure upper limit: 5 mbar above set Inspiratory Pressure
- Proximal Peak Pressure lower limit: 2 mbar above PEEP lower limit
- HFO: mean airway pressure upper limit: 5 mbar above set mean Airway Pressure
- HFO: mean airway pressure lower limit: 5 mbar above set mean Airway Pressure
- PEEP lower limit: 3 mbar below set Exhalatory Pressure
- DCO₂ upper limit: 150% of measured DCO₂ value
- DCO₂ lower limit: 50% of measured DCO₂ value
- CPAP [CPAP-mode] upper limit: 5 mbar above set CPAP value
- CPAP [CPAP-mode] lower limit: 5 mbar below set CPAP value
- CPAP [NCPAP-mode] upper limit: 5 mbar above set CPAP value
- CPAP [NCPAP-mode] lower limit: 2 mbar below set CPAP value
- Pduo [DUOPAP-mode] upper limit: 5 mbar above set Pduo value
- CPAP [DUOPAP-mode] lower limit: 2 mbar below set CPAP value

### 7.1.2 Configurable alarms

Following alarm limits are displayed and can be configured in the Alarm Limits menu.
- High SpO₂ alarm: 2 to 99%, off
- Low SpO₂ alarm: off, 1 to 98%
- High Pulse Rate alarm: 35 to 235 bpm, off
- Low Pulse Rate alarm: off, 30 to 230 bpm
- Low Perfusion Index alarm: off, 0.03 to 19%
- Low SIQ Alarm: off, 5 to 100%

### 7.2 Alarm log

Switch to Alarm Limit menu.

Press the button underneath **Show Log** to access the alarm overview.
The alarm list is sorted in chronological order.

The parameters shown are:
- Time
- Message
- Priority
  (highlighted. See: section "7.4.1: Alarms table")

Press the button underneath Hide Log key to return to the alarm limits menu.

Switching OFF the device will erase the Alarm Log displayed in clinical use. The Alarm Log files capable of export from the submenu (Tools) will not be deleted.

In case alarm list or alarm log files reach their limit (100 / ca. 70000 entries respectively), the oldest entries are deleted first.

### 7.3 Nurse call relay

The delay from the nurse call relay is < 1 second.

### 7.4 Alarm causes and solutions

Alarms are categorized by three main priority levels; High, Medium and Low. They differ visually and acoustically according to priority.

- **I=HIGH**
  - Blinking message highlighted **Red**
  - Tone: ♪♪♪-♪♪♪
  - 4 second pause

- **II=MEDIUM**
  - Blinking message highlighted **Yellow**
  - Tone: ♪♪
  - 5 second pause

- **III=LOW**
  - Message highlighted **Yellow**
  - Tone: ♪
  - 15 second pause

Only one alarm can be signalled at a time. In case there is more than one alarm condition at the same time, only the highest priority alarm condition is active and displayed. In the event there are two alarm conditions with the same priority at the same time, the first alarm condition triggered is active and displayed.
# 7.4.1 Alarms table

This table is intended to help you determine and resolve the cause of an alarm message.

<table>
<thead>
<tr>
<th>#</th>
<th>Alarm Text</th>
<th>Alarm Type</th>
<th>Cause</th>
<th>Solution</th>
<th>Main Priority</th>
<th>Sub Priority</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Acoustic audio alarm test failed</td>
<td>System failure</td>
<td>Acoustic audio test has failed</td>
<td>Disconnect the device from AC power and contact your local Acutronic Medical Systems Distributor</td>
<td>I</td>
<td>1</td>
</tr>
<tr>
<td>2.</td>
<td>Cooling fan defect</td>
<td>System failure</td>
<td>Fan not moving</td>
<td>Disconnect the device from AC power and contact your local Acutronic Medical Systems Distributor</td>
<td>I</td>
<td>1</td>
</tr>
<tr>
<td>3.</td>
<td>COM interface</td>
<td>System failure</td>
<td>System error</td>
<td>Disconnect the device from AC power and contact your local Acutronic Medical Systems Distributor</td>
<td>I</td>
<td>1</td>
</tr>
<tr>
<td>4.</td>
<td>DIO interface</td>
<td>System failure</td>
<td>System error</td>
<td>Disconnect the device from AC power and contact your local Acutronic Medical Systems Distributor</td>
<td>I</td>
<td>1</td>
</tr>
<tr>
<td>5.</td>
<td>I2C interface</td>
<td>System failure</td>
<td>System error</td>
<td>Disconnect the device from AC power and contact your local Acutronic Medical Systems Distributor</td>
<td>I</td>
<td>1</td>
</tr>
<tr>
<td>6.</td>
<td>parallel interface</td>
<td>System failure</td>
<td>System error</td>
<td>Disconnect the device from AC power and contact your local Acutronic Medical Systems Distributor</td>
<td>I</td>
<td>1</td>
</tr>
<tr>
<td>7.</td>
<td>SPI interface</td>
<td>System failure</td>
<td>System error</td>
<td>Disconnect the device from AC power and contact your local Acutronic Medical Systems Distributor</td>
<td>I</td>
<td>1</td>
</tr>
<tr>
<td>8.</td>
<td>checksum conductor PIC</td>
<td>System failure</td>
<td>System error</td>
<td>Disconnect the device from AC power and contact your local Acutronic Medical Systems Distributor</td>
<td>I</td>
<td>2</td>
</tr>
<tr>
<td>9.</td>
<td>checksum monitor PIC</td>
<td>System failure</td>
<td>System error</td>
<td>Disconnect the device from AC power and contact your local Acutronic Medical Systems Distributor</td>
<td>I</td>
<td>2</td>
</tr>
<tr>
<td>#</td>
<td>Alarm Text</td>
<td>Alarm Type</td>
<td>Cause</td>
<td>Solution</td>
<td>Main Priority</td>
<td>Sub Priority</td>
</tr>
<tr>
<td>----</td>
<td>-----------------------------------------</td>
<td>------------------</td>
<td>------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
<td>---------------</td>
<td>--------------</td>
</tr>
<tr>
<td>10.</td>
<td>Low physical memory - please reboot!</td>
<td>System failure</td>
<td>System error</td>
<td>Disconnect the device from AC power and contact your local Acutronic Medical Systems Distributor</td>
<td>I</td>
<td>2</td>
</tr>
<tr>
<td>11.</td>
<td>Air supply pressure</td>
<td>System alarms</td>
<td>Air supply pressure too low.</td>
<td>Ensure pressure above 2 bar.</td>
<td>I</td>
<td>2</td>
</tr>
<tr>
<td>12.</td>
<td>Oxygen supply pressure</td>
<td>System alarms</td>
<td>Oxygen supply pressure too low.</td>
<td>Ensure pressure above 2 bar.</td>
<td>I</td>
<td>2</td>
</tr>
<tr>
<td>13.</td>
<td>Safety relay defect</td>
<td>System failure</td>
<td>Safety relay defective.</td>
<td>Disconnect the device from AC power and contact your local Acutronic Medical Systems Distributor</td>
<td>I</td>
<td>2</td>
</tr>
<tr>
<td>14.</td>
<td>Tube Occlusion</td>
<td>System alarms</td>
<td></td>
<td>• Expiration tube blocked/kinked&lt;br&gt;• Inspiration tube blocked/kinked&lt;br&gt;• Excessive deviation between inspiration and expiration pressure sensor.</td>
<td>I</td>
<td>2</td>
</tr>
<tr>
<td>15.</td>
<td>Voltage monitoring</td>
<td>System failure</td>
<td>System error</td>
<td>Disconnect the device from AC power and contact your local Acutronic Medical Systems Distributor</td>
<td>I</td>
<td>2</td>
</tr>
</tbody>
</table>
| 16.| Battery defect                          | Electrical power | No power or too little power from battery. | • Change battery.  
• Check fuse. | I             | 2            |
| 17.| Charge battery (<15min)                 | Electrical power |                                    | • Ventilator is not connected to mains supply.  
• Remaining battery time < 15 min. | I             | 2            |
<p>| 18.| Flat battery!                           | Electrical power | Remaining battery time &lt; 1 min. Ventilation can no longer continue on battery power | Immediately switch to Mains supply or access alternative ventilation | I             | 2            |
| 19.| Exhalation calibration                  | System alarms    | Exhalation calibration failed      | Change exhalation membrane holder or membrane.                           | I             | 2            |</p>
<table>
<thead>
<tr>
<th>#</th>
<th>Alarm Text</th>
<th>Alarm Type</th>
<th>Cause</th>
<th>Solution</th>
<th>Main Priority</th>
<th>Sub Priority</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td>check Blender</td>
<td>System alarms</td>
<td>Proportional mixer or control defective</td>
<td>Disconnect the device from AC power and contact your local Acutronic Medical Systems Distributor</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>21</td>
<td>Patient disconnected</td>
<td>Disconnection / Tubes blocked</td>
<td>Leak or disconnection.</td>
<td>• Check tubing system for leaks. • Check setting of Pinsp.</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>22</td>
<td>check ET tube</td>
<td>Disconnection / Tubes blocked</td>
<td>Tube pinched or clogged.</td>
<td>Check Tube/Clear passage.</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>23</td>
<td>flow sensor calibration required</td>
<td>Sensor alarms</td>
<td>Flow sensor is not calibrated</td>
<td>Calibrate flow sensor</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>24</td>
<td>$O_2$ value out of range</td>
<td>Sensor alarms</td>
<td>$O_2$ level is out of range</td>
<td>Calibrate $O_2$ sensor and / or disconnect the device from AC power and contact your local Acutronic Medical Systems Distributor</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>25</td>
<td>Clean flow sensor</td>
<td>Sensor alarms</td>
<td>Water or secretion in flow sensor</td>
<td>Clean / replace flow sensor.</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>26</td>
<td>Flow sensor defect</td>
<td>Sensor alarms</td>
<td>Damaged heating wires inside flow sensor.</td>
<td>Replace flow sensor</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>27</td>
<td>Flow sensor not connected</td>
<td>Sensor alarms</td>
<td>• Flow sensor not connected. • Defective sensor cable</td>
<td>Check flow sensor and sensor cable connection.</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>28</td>
<td>$O_2$ sensor calibration failed</td>
<td>Sensor alarms</td>
<td>Error occurred during calibration.</td>
<td>Repeat calibration</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>29</td>
<td>Oxygen sensor defect</td>
<td>Sensor alarms</td>
<td>$O_2$ sensor defective.</td>
<td>Replace $O_2$ sensor</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>30</td>
<td>Oxygen sensor used up</td>
<td>Sensor alarms</td>
<td>$O_2$ sensor worn.</td>
<td>Replace $O_2$ sensor as quickly as possible. Calibration still available.</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>31</td>
<td>$O_2$ value out of range</td>
<td>Sensor alarms</td>
<td>$O_2$ sensor or mixer defective.</td>
<td>• Repeat Calibration and/or Replace $O_2$ sensor. • Disconnect the device from AC power and contact your local Acutronic Medical Systems Distributor</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>#</td>
<td>Alarm Text</td>
<td>Alarm Type</td>
<td>Cause</td>
<td>Solution</td>
<td>Main Priority</td>
<td>Sub Priority</td>
</tr>
<tr>
<td>---</td>
<td>---------------------------------</td>
<td>--------------</td>
<td>------------------------------</td>
<td>----------------------------------------------------</td>
<td>---------------</td>
<td>--------------</td>
</tr>
<tr>
<td>32</td>
<td>etCO₂ module disconnected</td>
<td>Sensor alarms</td>
<td>CO₂ module is not connected</td>
<td>Connect etCO₂ module</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>33</td>
<td>etCO₂ FilterLine disconnected</td>
<td>Sensor alarms</td>
<td>CO₂ filter line is not connected</td>
<td>Connect filter line</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>34</td>
<td>check etCO₂ sampling line</td>
<td>Sensor alarms</td>
<td>Malfunctioning CO₂ sampling line</td>
<td>Clean / replace sampling line.</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>35</td>
<td>check etCO₂ airway adapter</td>
<td>Sensor alarms</td>
<td>Malfunctioning CO₂ airway adapter</td>
<td>Clean / replace airway adapter</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>36</td>
<td>etCO₂ sensor faulty</td>
<td>Sensor alarms</td>
<td>CO₂ sensor is faulty</td>
<td>Replace sensor or Contact your local ACUTRONIC Medical Systems Distributor.</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>37</td>
<td>SpO₂ module disconnected</td>
<td>Sensor alarms</td>
<td>SpO₂ module is not connected</td>
<td>Connect SpO₂ module</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>38</td>
<td>SpO₂ sensor failure (XY)</td>
<td>Sensor alarms</td>
<td>XY internal reference:</td>
<td>Replace sensor or disconnect the device from AC power and contact your local Acutronic Medical Systems Distributor.</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>39</td>
<td>check SpO₂ sensor</td>
<td>Sensor alarms</td>
<td>SPO₂ sensor is off patient or malfunctioning</td>
<td>Connect SpO₂ sensor to patient</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>40</td>
<td>Apnea alarm</td>
<td>Patient alarms</td>
<td>No spontaneous patient breathing detected.</td>
<td>• Check patient, • Switch to controlled ventilation.</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>41</td>
<td>low SIQ</td>
<td>Patient alarms</td>
<td>SpO₂ sensor has low SIQe (Signal Quality)</td>
<td>Check SpO₂ sensor for correct contact with patient or replace sensor</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>42</td>
<td>FiO₂ at max</td>
<td>Patient alarms</td>
<td>FiO₂ has reached maximum setting</td>
<td>Adjust settings</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>43</td>
<td>Lower minimum FiO₂</td>
<td>Patient alarms</td>
<td>Lower minimum FiO₂ than set for PRICO</td>
<td>Adjust settings</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>44</td>
<td>Low Pmean</td>
<td>Patient alarms</td>
<td>Leak or disconnection.</td>
<td>• Check patient connection. • Check tubing system for leaks. • Check setting of Pmean.</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>#</td>
<td>Alarm Text</td>
<td>Alarm Type</td>
<td>Cause</td>
<td>Solution</td>
<td>Main Priority</td>
<td>Sub Priority</td>
</tr>
<tr>
<td>----</td>
<td>--------------</td>
<td>------------------</td>
<td>----------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
<td>---------------</td>
<td>--------------</td>
</tr>
<tr>
<td>45</td>
<td>High Pmean</td>
<td>Patient alarms</td>
<td>Pressure rise in tubing system.</td>
<td>• Check patient,</td>
<td>I</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Check tubing system,</td>
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<td></td>
<td>• Check exhalation valve,</td>
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<td></td>
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<td></td>
<td></td>
<td>• Replace patient system,</td>
<td></td>
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</tr>
<tr>
<td>46</td>
<td>High PIP</td>
<td>Patient alarms</td>
<td>Pressure rise in tubing system; mechanical inspiration was reduced to relieve the system.</td>
<td>• Check patient,</td>
<td>I</td>
<td>7</td>
</tr>
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<td></td>
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<td></td>
<td>• Check tubing system,</td>
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<td></td>
<td></td>
<td></td>
<td>• Replace patient system,</td>
<td></td>
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</tr>
<tr>
<td>47</td>
<td>High PEEP</td>
<td>Patient alarms</td>
<td>PEEP 6 mbar above set value for at least 15 seconds.</td>
<td>• Check patient,</td>
<td>I</td>
<td>7</td>
</tr>
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<td></td>
<td>• Check patient connection,</td>
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<td></td>
<td>• Check tubing.</td>
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<td></td>
<td></td>
<td></td>
<td>• Adjust settings</td>
<td></td>
<td></td>
</tr>
<tr>
<td>48</td>
<td>High etCO₂</td>
<td>Patient alarms</td>
<td>End tidal CO₂ above limit</td>
<td>• Check patient,</td>
<td>II</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Adjust settings</td>
<td></td>
<td></td>
</tr>
<tr>
<td>49</td>
<td>Low etCO₂</td>
<td>Patient alarms</td>
<td>End tidal CO₂ below limit</td>
<td>• Check patient,</td>
<td>II</td>
<td>8</td>
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<td></td>
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<td></td>
<td>• Adjust settings</td>
<td></td>
<td></td>
</tr>
<tr>
<td>50</td>
<td>High FiCO₂</td>
<td>Patient alarms</td>
<td>Inspired CO₂ above limit</td>
<td>• Check patient,</td>
<td>II</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Check patient dead space,</td>
<td></td>
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<td></td>
<td></td>
<td>• Adjust settings</td>
<td></td>
<td></td>
</tr>
<tr>
<td>51</td>
<td>Low FiCO₂</td>
<td>Patient alarms</td>
<td>Inspired CO₂ below limit</td>
<td>Adjust settings</td>
<td>II</td>
<td>8</td>
</tr>
<tr>
<td>52</td>
<td>High SpO₂</td>
<td>Patient alarms</td>
<td>SpO₂ measured above set limit</td>
<td>• Check patient,</td>
<td>II</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Check SpO₂ sensor for correct contact with patient</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>• Adjust settings</td>
<td></td>
<td></td>
</tr>
<tr>
<td>53</td>
<td>Low SpO₂</td>
<td>Patient alarms</td>
<td>SpO₂ measured below set limit</td>
<td>• Check patient,</td>
<td>II</td>
<td>8</td>
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<td>• Check SpO₂ sensor for correct contact with patient</td>
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<td></td>
<td></td>
<td></td>
<td>• Adjust settings</td>
<td></td>
<td></td>
</tr>
<tr>
<td>54</td>
<td>High Pulse Rate</td>
<td>Patient alarms</td>
<td>Pulse rate measured above set limit</td>
<td>• Check patient,</td>
<td>II</td>
<td>8</td>
</tr>
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<td></td>
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<td></td>
<td>• Check SpO₂ sensor for correct contact with patient</td>
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<td></td>
<td>• Adjust settings</td>
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<tr>
<td>55</td>
<td>Low Pulse Rate</td>
<td>Patient alarms</td>
<td>Pulse rate measured below set limit</td>
<td>• Check patient,</td>
<td>II</td>
<td>8</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Adjust settings</td>
<td></td>
<td></td>
</tr>
<tr>
<td>#</td>
<td>Alarm Text</td>
<td>Alarm Type</td>
<td>Cause</td>
<td>Solution</td>
<td>Main Priority</td>
<td>Sub Priority</td>
</tr>
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<td>-------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>56</td>
<td>Low Perfusion Index</td>
<td>Patient alarms</td>
<td>Low SpO₂ perfusion index</td>
<td>• Check patient,</td>
<td>II</td>
<td>8</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td>• Check SpO₂ sensor for correct contact with patient</td>
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<td></td>
<td></td>
<td></td>
<td>• Adjust settings</td>
<td></td>
<td></td>
</tr>
<tr>
<td>57</td>
<td>Low PIP</td>
<td>Patient alarms</td>
<td>Leak or disconnection.</td>
<td>• Check patient,</td>
<td>II</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Check patient connection.</td>
<td></td>
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<td></td>
<td></td>
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<td></td>
<td>• Check tubing system for leaks.</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>• Check setting of Pinsp.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>58</td>
<td>Charge battery (&lt;60min)</td>
<td>Electrical power</td>
<td>Ventilator is not connected to mains supply. Power failure. Internal battery remaining time less than 60 minutes.</td>
<td>• Switch to mains supply. Alarm can be silenced with Alarm Silence button to continue in the battery mode.</td>
<td>II</td>
<td>8</td>
</tr>
<tr>
<td>59</td>
<td>Charge battery (&lt;30min)</td>
<td>Electrical power</td>
<td>Ventilator is not connected to mains supply. Remaining battery time &lt; 30 min.</td>
<td>• Switch to mains supply. Alarm can be silenced with Alarm Silence button to continue in the battery mode.</td>
<td>II</td>
<td>8</td>
</tr>
<tr>
<td>60</td>
<td>High breath rate</td>
<td>Patient alarms</td>
<td>Hyperventilation self-trigger</td>
<td>• Check patient,</td>
<td>II</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Adjust frequency</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>• Increase trigger threshold</td>
<td></td>
<td></td>
</tr>
<tr>
<td>61</td>
<td>High DCO₂</td>
<td>Patient alarms</td>
<td>Exceeded upper alarm limit</td>
<td>• Check patient,</td>
<td>II</td>
<td>8</td>
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<td></td>
<td></td>
<td></td>
<td>• Adjust limit value</td>
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<td></td>
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<td></td>
<td>• Check tubing system</td>
<td></td>
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</tr>
<tr>
<td>62</td>
<td>Low DCO₂</td>
<td>Patient alarms</td>
<td>Value below lower alarm limit</td>
<td>• Check patient,</td>
<td>II</td>
<td>8</td>
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<td></td>
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<td></td>
<td>• Adjust limit value</td>
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<td></td>
<td></td>
<td></td>
<td>• Check tubing system</td>
<td></td>
<td></td>
</tr>
<tr>
<td>63</td>
<td>High tube leak</td>
<td>Patient alarms</td>
<td>Upper alarm limit exceeded</td>
<td>• Check patient,</td>
<td>II</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Check tubing system for leaks</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>• Adjust limit value</td>
<td></td>
<td></td>
</tr>
<tr>
<td>#</td>
<td>Alarm Text</td>
<td>Alarm Type</td>
<td>Cause</td>
<td>Solution</td>
<td>Main Priority</td>
<td>Sub Priority</td>
</tr>
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<td>----</td>
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<td>----------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>64.</td>
<td>High minute volume</td>
<td>Patient alarms</td>
<td>• Lung compliance has increased.</td>
<td>• Check patient,</td>
<td>II</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Resistance has decreased.</td>
<td>• Check ventilation settings.</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>• Hyperventilation.</td>
<td>• Adjust settings</td>
<td></td>
<td></td>
</tr>
<tr>
<td>65.</td>
<td>Low minute volume</td>
<td>Patient alarms</td>
<td>• Lung compliance has decreased.</td>
<td>• Check patient,</td>
<td>II</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Resistance has increased.</td>
<td>• Check tubing system for obstructions,</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>• Spontaneous breathing has stopped or is declining</td>
<td>• Check ventilation settings</td>
<td></td>
<td></td>
</tr>
<tr>
<td>66.</td>
<td>Low PEEP</td>
<td>Patient alarms</td>
<td>• Leak or disconnection.</td>
<td>• Check patient,</td>
<td>II</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Insp. flow or exp. flow set too low.</td>
<td>• Check tubing system for tight connection,</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Increase flow.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>67.</td>
<td>VTe not reached / check settings</td>
<td>System limits</td>
<td>Inspiratory pressure default is reached prematurely. Patient compliance has worsened</td>
<td>• Check patient,</td>
<td>II</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Adjust inspiratory pressure setting.</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>• Increase inspiratory period.</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>• Adjust volume setting</td>
<td></td>
<td></td>
</tr>
<tr>
<td>68.</td>
<td>Inspiratory pressure not reached</td>
<td>System limits</td>
<td>• Leak.</td>
<td>• Check patient,</td>
<td>III</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Flow too low.</td>
<td>• Check tubing system for tight connection.</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>• Increase flow.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>69.</td>
<td>Power failure</td>
<td>Electrical power</td>
<td>Power failure/ Ventilator was unplugged from mains power supply and is operating on battery power.</td>
<td>• Switch to mains supply.</td>
<td>III</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Check power cord for loose connection.</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Alarm can be silenced with <strong>Alarm Silence</strong> button.</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• The device continues in battery mode without interruption.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>70.</td>
<td>Tidal Volume limited</td>
<td>System limits</td>
<td>Upper alarm limit exceeded</td>
<td>Adjust settings.</td>
<td>III</td>
<td>9</td>
</tr>
</tbody>
</table>

### 7.4.2 Pressure release behaviour

- **Alarm Text**
- **Alarm Type**
- **Cause**
- **Solution**
- **Main Priority**
- **Sub Priority**
In case of detected obstruction of the breathing tubes, the ventilator alarms and also ceases gas flow to the outlet, and opens the exhalation valve to reduce the pressure in the breathing circuit to ambient pressure (ZEEP). The tube obstruction alarm is terminated once the airway pressure measured by the proximal pressure sensor has fallen below set PEEP and the time of the next breath trigger is reached.

This pressure relief occurs:

- 12 mbar above the set PIP in IPPV, SIPPV, SIMV, SIMV+PSV, PSV and CPAP modes.
- 10 mbar above the set PIP in NCPAP and DUOPAP modes.

In case of detected high inspiratory pressure, the ventilator alarms and switches to the expiratory phase – the exhalation valve pressure control is reduced to PEEP, and the outlet gas flow is switched from I-Flow to E-Flow. Only if this subsequently transitions to a tube obstruction alarm, the outlet flow is switched off and exhalation valve opened as above.

### 7.4.3 Application error

If the device software encounters an unexpected ERROR, a window appears in the middle of the screen with the following text in English: “Application fabianHFO.exe encountered a serious error and must shut down.”

If there is an audible alarm, follow these steps:

1. Immediately start ventilation of patient with an Alternative Ventilation method
2. Shut down the device.
3. Report the incident to your local distributor
4. Use the device only if it is unavoidable

If there is no accompanying audible alarm, follow these steps:
1. Stop interacting with the device
2. Prepare an alternative treatment for the patient while the device is kept under supervision
3. Start ventilation of patient with an Alternative Ventilation Method
4. Shut down the device.
5. Report the incident to your local distributor

Use the device only if it is unavoidable

7.4.4 Watchdog alarms

There is a watchdog circuit, which monitors for failures of the following components:
• NetDCU (responsible for the graphical user interface WDST#4 error)
• Control PIC (responsible for control of ventilation WDST WDST#16 error)
• Monitor PIC (responsible for monitoring functions WDST#32 error)
• Alarm PIC (responsible for alarm audible indication and lamps WDST#64 error)

In case of a failure, the watchdog opens the pressure relief valves and stops power to the blender module to prevent and/or relieve pressure in the patient circuit while alarming.

In case of occurrence, follow these steps:
1. Immediately start ventilation of patient with an Alternative Ventilation method
2. Shut down the device.
3. Report the incident to your local distributor
4. Use the device only if it is unavoidable

In case a WDST 4/16/32/64 error is resolved (only a temporary error) WDST#8 will be triggered and displayed and the device can continue to be used.
8 Battery operation

The device features an Internal Battery.

Battery Run Time in HFO mode on full charge: approx. 1 hour
Battery Run Time in conventional mode on full charge: approx. 2.5 hours

These values may vary depending on the parameter settings. The Battery charge is continuously monitored. The device continuously calculates the remaining Run Time and displays it in the Information bar.

| WARNING: A reduction in battery remaining run time when changing the Operating mode can cause an Automatic shutdown of ventilator! |
| Changing the operating mode can greatly shorten the battery run time. |
| • Monitor the remaining Battery run time when changing the settings. |
| • NEVER leave the device and patient unattended during battery operation. |
| • Establish mains power supply in good time! |

In the event of Power Failure, the pneumatic system will automatically open the safety valve to atmospheric pressure so that pressure can’t build in the breathing system, allowing spontaneous patient breathing.

When operating the device on the Internal Battery, the HFO amplitude is limited to 60 mbar.

WARNING: If you are using HFO mode with higher amplitudes, disconnecting from the main power supply will automatically decrease the amplitude to 60 mbar. When the main power supply is reconnected, the amplitude remains at 60 mbar.

When storing the ventilator for long term storage, please remove the battery pack.
8.1 Power failure

In the event of a Power Failure, the device automatically switches to Battery Power without interruption.

A visual and audible message is triggered. “Power Failure”

This message can be confirmed with the Silence Alarm button.

The device will continuously monitor the battery run time.

Additional messages will be triggered at a remaining Run Time of:

- 15 minutes
- 30 minutes
- 60 minutes, only if the remaining run time is less than 60 minutes during a Power Failure

If the remaining Run Time is less than one minute, a warning will appear prompting to immediately switch to a Primary Power Source.

After 60 seconds, the Battery is drained, and fabian will power OFF.

Depleted Battery
– Connect to Main –
– Charge battery for approx. 5 hours –

After reconnecting the fabian HFO to the mains power, the fabian HFO is running on mains power and the internal battery is charged.
9 Operating on External Power Source (devices with SN till AI-01500 and AL-00400)

The device can also be operated from an external power source.

In this case connect the external 24 Volt power source at the back of the equipment.

<table>
<thead>
<tr>
<th>Mode</th>
<th>Power Source</th>
<th>Current (A)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conventional</td>
<td>24 Volt DC</td>
<td>1</td>
</tr>
<tr>
<td>HFO</td>
<td>24 Volt DC</td>
<td>1.5</td>
</tr>
</tbody>
</table>

External power connection on the back panel.

![External power connection on the back panel](image)

- NO charging when connected to 24V DC external power supply
- NO monitoring of remaining time on external power supply
## 10 Ventilation parameters

<table>
<thead>
<tr>
<th>Ventilation Parameters</th>
<th>Mode</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pressure Rise Control</td>
<td>• IPPV</td>
<td>I-Flow or Rise Time Will allow for use of either I-flow or Rise time based pressure rise control during inspiration</td>
</tr>
<tr>
<td></td>
<td>• SIPPV</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• SIMV</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• SIMV + PSV</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• PSV</td>
<td></td>
</tr>
<tr>
<td>Rise Time</td>
<td>• IPPV</td>
<td>Rise Time</td>
</tr>
<tr>
<td></td>
<td>• SIPPV</td>
<td>Adjustable rise time during inspiration</td>
</tr>
<tr>
<td></td>
<td>• SIMV</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• SIMV + PSV</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• PSV</td>
<td></td>
</tr>
<tr>
<td>I-Flow</td>
<td>• IPPV</td>
<td>Inspiratory flow</td>
</tr>
<tr>
<td></td>
<td>• SIPPV</td>
<td>Adjustable flow during inspiration</td>
</tr>
<tr>
<td></td>
<td>• SIMV</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• SIMV + PSV</td>
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</tr>
<tr>
<td></td>
<td>• PSV</td>
<td></td>
</tr>
<tr>
<td>E-Flow</td>
<td>• IPPV</td>
<td>Expiratory flow (base flow)</td>
</tr>
<tr>
<td></td>
<td>• SIPPV</td>
<td>The continuous expiratory flow is variable separate from the inspiratory flow.</td>
</tr>
<tr>
<td></td>
<td>• SIMV</td>
<td>Flushing dead space in the Y-piece</td>
</tr>
<tr>
<td></td>
<td>• SIMV + PSV</td>
<td>Maintaining the PEEP</td>
</tr>
<tr>
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<td>• PSV</td>
<td></td>
</tr>
<tr>
<td>PEEP</td>
<td>• IPPV</td>
<td>Positive end-expiratory pressure</td>
</tr>
<tr>
<td></td>
<td>• SIPPV</td>
<td>Pressure at the airway connection port at the end of expiration.</td>
</tr>
<tr>
<td></td>
<td>• SIMV</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• SIMV + PSV</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• PSV</td>
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</tr>
<tr>
<td>Trigger</td>
<td>• SIPPV</td>
<td>Trigger</td>
</tr>
<tr>
<td></td>
<td>• SIMV</td>
<td>The trigger sensitivity can be adjusted from level 1 – 10.</td>
</tr>
<tr>
<td></td>
<td>• SIMV + PSV</td>
<td>This corresponds to 10% - 25% of the exhaled tidal volume( Vte ) with volume trigger and 0.12–1.2 l/min in 10 steps (neonatal mode) / 0.6-6.0 l/min in 10 steps (pediatric mode) with flow trigger.</td>
</tr>
<tr>
<td></td>
<td>• PSV</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• duoPAP</td>
<td></td>
</tr>
</tbody>
</table>
### Ventilation Parameters

<table>
<thead>
<tr>
<th></th>
<th>Trigger Functions</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Volume trigger</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Flow trigger</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pressure trigger</td>
<td></td>
</tr>
</tbody>
</table>

Which may be selected in the configurations menu → Ventilation

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>Inspiratory Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>I-time</td>
<td>IPPV</td>
<td>SIPPV</td>
</tr>
<tr>
<td></td>
<td>SIMV</td>
<td>SIMV + PSV</td>
</tr>
<tr>
<td></td>
<td>PSV</td>
<td>duoPAP</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>Frequency (Rate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freq</td>
<td>IPPV</td>
<td>SIPPV</td>
</tr>
<tr>
<td></td>
<td>SIMV</td>
<td>SIMV + PSV</td>
</tr>
<tr>
<td></td>
<td>PSV</td>
<td>duoPAP</td>
</tr>
</tbody>
</table>

Frequency of mandatory breaths. In SIPPV mode the delivered breath rate may be higher depending on the patient’s spontaneous breathing.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>Backup Rate in PSV and S-duoPAP modes</th>
</tr>
</thead>
<tbody>
<tr>
<td>BackupRate</td>
<td>PSV</td>
<td>duoPAP</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>Inspiratory pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>P insp.</td>
<td>IPPV</td>
<td>SIPPV</td>
</tr>
<tr>
<td></td>
<td>SIMV</td>
<td>SIMV + PSV</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>Inspiratory pressure PSV</th>
</tr>
</thead>
<tbody>
<tr>
<td>P PSV</td>
<td>SIMV + PSV</td>
<td>PSV</td>
</tr>
</tbody>
</table>

Inspiratory pressure during inspiration in PSV mode.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>Inspiratory pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>P Backup</td>
<td>PSV</td>
<td>duoPAP</td>
</tr>
</tbody>
</table>

Inspiratory pressure during mandatory inspiration in PSV mode.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>Upper inspiratory pressure in duoPAP mode.</th>
</tr>
</thead>
<tbody>
<tr>
<td>P DUO</td>
<td>duoPAP</td>
<td></td>
</tr>
</tbody>
</table>

The ventilator provides continuous flow for producing airway pressure at the set CPAP level.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>Continuous Positive Airway Pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPAP</td>
<td>duoPAP</td>
<td>CPAP</td>
</tr>
<tr>
<td></td>
<td>nCPAP</td>
<td>HFO</td>
</tr>
</tbody>
</table>

Continuous flow for producing airway pressure at the CPAP level

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>Manual Inspiratory pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>P manual</td>
<td>CPAP</td>
<td>nCPAP</td>
</tr>
<tr>
<td></td>
<td>nCPAP</td>
<td>HFO</td>
</tr>
</tbody>
</table>

Applying a manual breath
Next breath is possible after a block period of 200 ms.
| **Ventilation Parameters** | **O₂** | **All modes** | **Oxygen concentration**  
Inspiratory oxygen concentration setting |
|---------------------------|--------|--------------|----------------------------------------------------------------|
| **O₂ Flush**              | **All modes** | **Oxygen flush**  
Perform O₂ flush / oxygen boost  
(Preoxygenation for max. 2 minutes) |
| **Backup**                | **CPAP** | **Backup Frequency**  
In the event of apnea spontaneous breathing is stimulated after the apnea duration with a default number of mechanical breaths. Backup trigger depends on apnea period setting. |
| **Volume Guarantee/Volume Limit** | **IPPV**  
**SIPPV**  
**SIMV**  
**SIMV + PSV**  
**HFO**  
**PSV** | **Volume Guarantee/Volume Limit**  
Will allow either volume guarantee or volume limit to be enabled in the user interface. |
| **Volume limit** | **IPPV**  
**SIPPV**  
**SIMV**  
**SIMV + PSV**  
**PSV** | **Volume limit**  
Maximum ventilator volume setting.  
When the volume limit is reached, inspiration is stopped. |
| **P_max** | **IPPV**  
**SIPPV**  
**SIMV**  
**SIMV + PSV**  
**PSV** | **Max Pressure**  
Maximum inspiratory pressure during volume guarantee. |
| **V_guarant** | **IPPV**  
**SIPPV**  
**SIMV**  
**SIMV + PSV**  
**PSV**  
**HFO** | **Volume guarantee**  
This additional function controls breaths by volume.  
Changes in the Ventilation system are compensated.  
This ensures the patient receives a guaranteed volume with each breath.  
In SIMV + PSV, the VG is only applied for SIMV breath but not for the PSV breath. |
| **Max. time manual breath** | **All modes** | **Maximum time manual breath**  
Maximum duration allowed for manual breaths.  
Adjustable from 2 – 30s.  
*In Settings menu |
### Ventilation Parameters

| **Flush Time** | **Duration of O₂ Flush**<sup>*</sup>  
Adjustable from OFF; 20 – 120s.  
*In Settings menu |  
| —— | —— | 
| All modes |  
| **Termination Criteria PSV** | **Termination Criteria PSV**  
Flow setting (relative to peak flow) for termination of a PSV breath. Adjustable between 1 – 85 %.  
*In Settings menu |  
| SIMV+PSV |  
| PSV |  

### Parameters in HFO mode

| **Parameter** | **Description** |
|———|———|
| AMP max | Maximal Amplitude in Volume Guarantee. |
| Flow | Constant Flow / Bias  
Adjustable from 5 to 20 Lpm  
Default value: 8 Lpm |
| Freq<sub>rec</sub> | Frequency Lung Recruitment<sup>*</sup>  
Adjustable 5 to 20 Hz.  
*Optional. |
| HF amp | High-frequency Amplitude  
Maximum Pressure Amplitude. Peak-to-Peak. |
| HF Freq | High-frequency – frequency  
Adjustable 5 to 20 Hz. |
| I:E | Inspiration to Expiration Ratio  
Adjustable 1:3 / 1:2 / 1:1. |
| I-time<sub>rec</sub> | Inspiratory Time Lung Recruitment<sup>*</sup>  
Adjustable 2 to 13 seconds  
*Optional. |
| P<sub>mean</sub> | Mean Pressure  
Continuous positive Airway Pressure. |
| P<sub>meanrec</sub> | Pmean Lung Recruitment<sup>*</sup>  
*Optional. |
11 Ventilation modes

The ventilator is intended for the following Ventilation modes:

- **IPPV**
  Intermittent Positive Pressure Ventilation

- **SIPPV**
  Synchronised Intermittent Positive Pressure Ventilation

- **SIMV**
  Synchronised Intermittent Mandatory Ventilation

- **SIMV + PSV**
  Synchronised Intermittent Mandatory Ventilation with PSV support

- **PSV**
  Pressure Support Ventilation

- **CPAP**
  Continuous positive airway pressure

- **NCPAP**
  NIV ventilation (Optional)

- **duoPAP**
  NIV ventilation (Optional)

- **HFO**
  High-frequency oscillation (Optional)

- **O₂ Therapy**
  High and Low Flow Oxygen Therapy HFNC (Optional)
11.1 IPPV

In Intermittent Positive Pressure Ventilation (IPPV) mode ventilation is performed at the specified patterns set on the equipment without consideration to possible spontaneous patient respiration. The Set Rate is the Delivered Rate.

Set following parameters:
- E-flow
- Frequency (Rate)
- I-flow
- I-time
- PEEP
- Pinsp
- Positive pressure is created here during inspiration with Passive Expiration.
- This mode should only be used if no spontaneous breathing from patient is expected.

IPPV can be applied also in Non-Invasive mode (Nasal IPPV or NIPPV), for example: with oro- nasopharynx tube or RAM Cannula; in this case you must turn OFF and remove the flow sensor from the Y-piece of the dual limbed breathing circuit and connect the proper interface.

A higher I-flow can be requested during NIPPV mode, because of potential higher leakages.

Function areas and ventilation parameters.
Ventilation additives.
11.2 SIPPV

Synchronized Intermittent Positive Pressure Ventilation (SIPPV) each spontaneous patient inspiratory effort triggers a mechanical breath of the ventilator according to the ventilator parameters set for Inspiratory Period and Pressure.

The number of breaths per minute supported by the ventilator is controlled by the patient. In this mode the patient breathing frequency must be closely monitored to prevent hyperventilation.

Set the Alarm for high Frequency according with clinical guidelines.

Set following parameters:
- E-flow.
- Frequency (Rate)
- I-flow
- I-Time
- PEEP
- Pinsp
- Trigger Sensitivity

To prevent Auto-Triggering, another breath cannot be triggered for 180 ms following the end of the preceding breath.
11.3 SIMV

Breaths triggered by the patient will be displayed in green (default settings).

Ventilation with specified pattern and frequency synchronous to the patient’s independent breathing. The patient can spontaneously breathe in between breaths but receives no pressure support.

For weaning from ventilation.

If Apnea is detected, ventilation will commence with the specified TI and TE frequency.

The synchronization window for the next mechanical breath is maximum $\frac{1}{2}T_e$. 
11.4 **SIMV + PSV**

In Synchronized Intermittent Mandatory Ventilation + Pressure Support Ventilation (SIMV + PSV) mode, the patient can initiate a PSV breath in between the mandatory SIMV breaths.

The machine breaths (SIMV) are synchronized with the patient’s breathing pattern. The number of mechanical breaths per minute is the same as the preset frequency.

To prevent Auto-Triggering, another breath cannot be triggered for 180 ms following end of each breath.

If the patient stops spontaneous breathing the ventilator will deliver the mechanical breath set with the frequency (rate) button.

Every spontaneous inspiratory effort of the patient is supported with the Preset Ppsv Pressure Level. It ends when flow termination criteria are met.

Each SIMV breath can be triggered by the patient.

Between SIMV breaths, the patient can trigger a supportive PSV breath.

- Minimum pressure for the $P_{psv}$ is 2 mbar (cmH2O) (trigger breath) / 5 mbar (cmH2O) (untriggered breath) above PEEP.
- Maximum PSV Level $P_{psv} = P_{insp}$

**NOTE:** The PSV support is shown as “Absolute Pressure”.

A triggered breath is colored **Green**.

The non-triggered breaths are **Grey**.

The Inspiratory Pressure for the PSV breath is set using the $P_{psv}$ button.

The PSV breath is terminated at one of the following criteria:

- Airway Pressure exceeds a pressure Setting $P_{PSV}$
- Inspiratory Flow has dropped to 1 to 85 % of the maximum value of Inspiratory Flow.

PSV breath is only available with active flow sensor measurement. As a result, in case flow sensor is deactivated in SIMV+PSV, the ventilation mode is automatically changed to SIMV and can be switched back only manually after the activation of the flow sensor.
11.5 **PSV**

The Pressure Support Ventilation (PSV) option is used to support spontaneous breathing. The ventilator provides pressure during the spontaneous inspiration to offset part of the patient work of breathing. The breathing frequency is determined by the spontaneously breathing patient, whereas the ventilator assumes an adjustable portion of the breathing effort.

To prevent Auto-Triggering, another breath cannot be triggered for 180 ms following the end of each breath.

Thus, inspiration is controlled by the patient. However, the ventilator will now control expiration. This will occur when one of the following criteria is met:

- Airway Pressure exceeds a $P_{PSV}$ pressure Setting
- Inspiratory flow has dropped to the preset fraction 1 to 85% of the maximum inspiratory flow setting (as preset by the Termination Criteria PSV control) (indicating a virtually filled lung)

If the patient stops breathing spontaneously the ventilator will assume alternate breathing with the Ventilation parameter settings.

Apnea Backup Ventilation will start after preset Apnea Time. If this is set to OFF, Backup starts after E-time.

PSV is only available with active flow sensor measurement. As a result, in case the flow sensor is deactivated in PSV, the ventilation mode is automatically changed to SIPPV and can be switched back only manually after the activation of the flow sensor.

The Inspiratory Pressure for the PSV breath is set using the $P_{insp}$ button.

11.6 **CPAP**

In CPAP Ventilation the patient breathes spontaneously, the ventilator does NOT provide mandatory breaths. This mode provides a continuous distending positive pressure during inspiration and expiration in order to splint open the airways and lungs, noticeably reducing the patient's breathing effort. The maximum automatic leak compensation is 100% of the Inspiratory Flow.

In the event of an interruption in the patient’s breathing following the default Apnea Period, the ventilator performs a default number of mechanical breaths to stimulate spontaneous breathing. After breathing commences, stimulation stops and only commences with the next Apnea event.

CPAP can also be applied in Non-Invasive mode to the patient (Nasal CPAP), using a device with a 15-millimeter adaptor *for example*: oro- nasopharynx tubes or RAM Cannula; in this case you must turn OFF the ventilator and remove the flow sensor from the Y-piece of the dual limbed breathing circuit and connect the proper interface with a 15-millimeter adaptor.

11.7 **nCPAP / DUOPAP**

In nCPAP / DUOPAP mode the patient breathes spontaneously from a mask or nasal prongs. A NIV Trigger option can be enabled to provide these modes with breath detection (Apnea...
monitoring with Alarms) and triggered supported breaths (or synchronized transition from low to high CPAP levels) in DUOPAP.

Depending on the nasel generator being used, fabian will automatically select the proper NIV Trigger Sensor:

- Flow Sensor (Neonatal) with Infant Flow (Infant Flow or Inspire) and Infant FlowLP generators
- Pressure Sensor with Medijet (by Medin) generator

Additionally, monitoring SpO₂ and PtCO₂ is always recommended.

**nCPAP:** Supplies a positive Airway Pressure with automatic Leak Compensation. The maximum flow compensation is selectable by menu.

**DUOPAP:** Same as nCPAP but with the option of Positive Pressure Ventilation with adjustable frequency and Inspiratory Period.

---

![Warning]

This mode requires a special nCPAP Patient Set with nCPAP generator. Before using the nCPAP / DUOPAP mode the correct system must be specified in the specifications menu.

The following systems currently can be used:

- Infant Flow (Infant Flow or Inspire™)
- Infant Flow LP
- MediJet

![Warning]

When ventilating a patient using a nasal interface in nCPAP or DuoPAP modes, the clinician must make a compromise between providing additional flow to compensate for a leak at the nose, or providing an alarm to warn of a leak, particularly when the appropriate size prongs are small. For a patient who is capable of spontaneous breathing without support, leak compensation may be set to a high setting, in order to provide additional flow to compensate for a leak at the interface between the prongs and the nose. This will provide a more stable pressure support in the presence of variable leak (for example, with patient movement). However in this scenario, the ventilator may fail to provide an alarm is the event of decannulation.

For a patient who requires an alarm in the event of decannulation, leak compensation should be set to a low setting. This will provide less stable pressure support in the presence of variable leak at the nose, but a reliable alarm for decannulation.

![Information]

If Inspiratory Time is set lower than 1 second; the maximum pressure may NOT be reached. Depending on the tubing set, nCPAP generator and humidifier.
11.8 **O₂ Therapy mode (high and low flow oxygen therapy) HFNC**

O₂ Therapy is an option which allows use of a Continuous Flow of blended gas, between 0 to 15 LPM in NEO and 0 to 30 LPM in PED mode. Nasal Cannulas of various makes like F&P, Atom or similar can be used. There are no Alarm functions active in this mode, except for the set FiO₂.

**NOTE:**
This mode can also be used to put the Ventilator in Standby mode. By setting a Flow of 4 LPM, the Humidifier dual servo temperature controls remain active, so there is no need to switch it OFF in case of short-term Standby mode.

There are no patient alarms active in this mode.

11.9 **HFO**

Ventilation with High-frequency Pressure Oscillations allows a gas exchange inside the lung despite the very small tidal volumes (*often on the scale of the anatomical dead space volume*).

While pressure amplitudes inside the breathing tube system can be quite significant, only minor fluctuations around the mean airway pressure occur inside the lung.

The mechanical strain due to periodic lung expansion and relaxation is minimal.

In high-frequency oscillatory ventilation PEEP / CPAP is comparable to the level as mean airway Pressure. The high frequency pulses superimpose the mean airway pressure at the set frequency.

HFOV can be applied also in Non-Invasive mode (Nasal-HFO) with Nasal prongs, Mask or Cannula; in this case you must turn OFF and remove the Flow Sensor from the Y-piece of the dual limbed breathing circuit.

11.9.1 **HFO lung recruitment**

- Lung recruitment is an optional setting in HFO.
- The Pₘₑᵃⁿ is thereby increased cyclically to an adjustable value "Pₘₑᵃⁿ rec."
- The repetition frequency is selectable from one cycle / hour to four cycles / minute.
- The Inspiratory Time can be set from 2 to 60 seconds if the Expiratory Time is ≥2 seconds.
11.9.2 Special HFO mode information

- When operating the device using the internal battery, HFO amplitude is limited to 60 mbar.
- During HFO Ventilation the distinct recognition of disconnection and measurement of the Minute Volume is limited.
- Use of a heated Inspiratory and Expiratory Tubing system is strongly recommended in HFO mode.

11.10 Ventilation Additives

To optimize ventilation, the following additives can be combined with the selected mode.

11.10.1 Volume limit

The Volume limit function automatically switches to expiration when the default Tidal Volume is reached.

When changing the ventilation pattern or adjusting the volume limit, the Tidal Volume is automatically limited.

The display will show the message: “Volume Limited”.

In the event of Flow Measurement Outage (for example: changing the sensor) “V-limit” will automatically be deactivated.

After Flow Measurement is available again “V-limit” is automatically reactivated.

11.10.2 Volume guarantee

Volume guarantee is an additional pressure limiting function with controlled or targeted Tidal Volume application.

Select the volume to be applied in the “V-guarant” area.

The device automatically adjusts the required Pressure $P_{\text{insp}}$ up to the Maximum Pressure “Pmax”. “Pmax” can be set before switching on VG. When the presets are ready, please switch ON by pushing the Volume guarant ON button.

$P_{\text{insp}}$ will be gradually increased breath-by-breath to achieve preset $V_{\text{te}}$. The Maximum Pressure increase breath-by-breath is limited to one-third of the previous breath.

If the $P_{\text{max}}$ setting is insufficient for applying the targeted volume, the following message is displayed: “Tidal Volume NOT reached”. An upward arrow in $P_{\text{insp}}$ area guides you to achieve preset $V_{\text{te}}$, the $P_{\text{max}}$ must be increased.

In the event of Flow Measurement Outage (for example: changing the sensor) “V Guarant” will automatically be deactivated.

After Flow Measurement is available again “V-guarant” will automatically be reactivated.
11.11 Special functions

11.11.1 Manual inspiration (manual Breath)

In virtually all ventilation modes (except in O₂ Therapy, a manual breath can be triggered (with the ventilation parameters set in the current ventilation mode) by pressing the **Manual Inspiration** button.

The manual breath will continue while the manual breath key remains depressed. The maximum the duration of the manual breath can be set under the Configurations menu → Ventilation.

This could last from 2 to 30 seconds, then a termination of the manual breath will be forced.

The next manual breath is only allowed after a Block Period of 200 milliseconds.

**NOTE:** Manual Breath is NOT available in O₂ Therapy mode.

In HFO mode, Manual Inspiration can be deactivated.

If activated, some clinicians use this to re-recruit the lung after suctioning.

A manual breath however can lead to lung overdistension.

11.11.2 Nebulizing medications (*optional*)

**WARNING:** Flow Sensor wires are HOT.

- If the Flow Sensor remains in the breathing system for extended periods during Nebulizing without being cleaned, deposits can form from the medication aerosols and impair Flow Measurement.
- In worst case scenarios these deposits could ignite.
- Disconnecting the plug from the Flow Sensor does NOT deposits and risk of ignition Always remove the Flow Sensor before Nebulizing Medication.

11.11.3 O₂ Flush / preoxygenation

1. Press the **O₂ Flush** button to trigger an O₂ Flush.
2. Short-term Oxygen Flush with an increased O₂ concentration is permissible in all Ventilation modes. This will automatically end after a maximum of 2 minutes.
   (*also see defaults in menu: Configuration → Ventilation → Flush Duration*)
3. Press the **O₂ Flush** button in a Ventilation mode to initiate the O₂ Flush.
4. The Flush Concentration can now be set with the rotary push knob..
5. Pressing the **O₂ Flush** button again will end the Flush immediately.
12 Accessories and options

12.1 Accessories List

<table>
<thead>
<tr>
<th>Description</th>
<th>Picture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Membrane holder, 22mm OD / 15mm ID</td>
<td></td>
</tr>
<tr>
<td>Membrane, expiration</td>
<td></td>
</tr>
<tr>
<td>Oxygen sensor</td>
<td></td>
</tr>
<tr>
<td>Flow sensor connector cable</td>
<td></td>
</tr>
<tr>
<td>Flow sensor, single use, Neonatal</td>
<td></td>
</tr>
<tr>
<td>Flow sensor, reusable, Neonatal</td>
<td></td>
</tr>
<tr>
<td>Flow sensor, reusable, Pediatric</td>
<td></td>
</tr>
<tr>
<td>Adapter NIST – DISS O₂</td>
<td></td>
</tr>
</tbody>
</table>

**WARNING:**
The items shown in this list have been approved for use with fabian HFO ventilator. Use of non-approved items is NOT recommended and will NOT be recognized or supported by the manufacturer. If a system malfunctions with non-approved parts and / or accessories, the user is responsible and liable for any and all issues associated with the system malfunction.
<table>
<thead>
<tr>
<th>Description</th>
<th>Picture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adapter NIST– DISS Air</td>
<td><img src="" alt="Image" /></td>
</tr>
<tr>
<td>Water trap / Filterset</td>
<td><img src="" alt="Image" /></td>
</tr>
<tr>
<td>Masimo SpO\textsubscript{2} module</td>
<td><img src="" alt="Image" /></td>
</tr>
<tr>
<td>Microstream MicroPod etCO\textsubscript{2} Sensor</td>
<td><img src="" alt="Image" /></td>
</tr>
<tr>
<td>Capnostat\textsuperscript{®} 5 Mainstream etCO\textsubscript{2} Sensor</td>
<td><img src="" alt="Image" /></td>
</tr>
<tr>
<td>LoFlo Sidestream etCO\textsubscript{2} Sensor</td>
<td><img src="" alt="Image" /></td>
</tr>
<tr>
<td>Description</td>
<td>Picture</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>---------</td>
</tr>
<tr>
<td>Trolley</td>
<td>![Trolley Image]</td>
</tr>
<tr>
<td>Breathing circuit set – Altera¹</td>
<td>![Breathing Circuit Set Image]</td>
</tr>
<tr>
<td>NIV generator – Vyaire InfantFlow LP¹</td>
<td>![NIV Generator Image]</td>
</tr>
<tr>
<td>NIV generator – Inspire InfantFlow¹</td>
<td>![NIV Generator Image]</td>
</tr>
<tr>
<td>NIV generator – Medin Medijet¹</td>
<td>![NIV Generator Image]</td>
</tr>
</tbody>
</table>

¹ Altera breathing circuits (REF 154308), InfantFlow, Medijet and InfantFlow LP generators are validated, all other circuits can be used but need to be validated by the user itself.
12.2 etCO₂ monitoring

12.2.1 etCO₂ Sensor module types and selection

The fabian HFO supports three different etCO₂ module types to provide etCO₂ monitoring:

1. Microstream, MicroPod™ External etCO₂ Module from Oridion® (Covidien/Medtronic)
2. Capnostat® 5 Mainstream etCO₂ Sensor from Respironics® (Philips).
3. LoFlo Sidestream etCO₂ Sensor from Respironics (Philips).

**NOTE:**
Only one module at a time can be connected and used with the ventilator.

The module can be activated in the etCO₂ submenu of Calibration view of fabian HFO (Figure 1 / Figure 2).

![Figure 1 - fabian HFO Calibration menu](image1)

![Figure 2 - etCO₂ Sensor submenu](image2)
To access the etCO₂ Monitoring view:

1. Press the Graphics button (Figure 3) and
2. Press the etCO₂ button on the touch screen in the Graphics view (Figure 4).

The etCO₂ subview is dependent on the selected module type and discussed in section “12.2.3.5: etCO₂ Module settings and information”.

After a module is selected, the following measurement related alarm limits can be set under the Alarm Limit view (Figure 6), which can be reached by pressing the Alarm Limits button (Figure 5).

- etCO₂ high
- etCO₂ low
- FiCO₂ high
- FiCO₂ low
12.2.2 Connect the etCO₂ module to fabian HFO

12.2.2.1 Connect to fabian HFO with main board version 3.x or 4.x

To connect any of the compatible etCO₂ module to the fabian HFO with main board 3.x or higher (Figure 7),

1. Attach the 7-pin Male Binder Connector from the CO₂ module (Figure 8) to the respective Female Binder Connector at the back of the fabian HFO labelled CO₂ (Figure 9).
2. Please make sure the extrusion on the Male Binder Connector slots in at the bottom of the female connector.
3. Fasten the connection by turning the Binder connector ring clockwise.

Figure 7 - Rear View of fabian HFO (main board 3.x and higher). Arrow points towards CO₂ port.

Figure 8 - Male connector

Figure 9 - Female connector
12.2.2.2 Connect to fabian HFO with Main Board 2.x

To connect any of the compatible CO₂ module to the fabian HFO with Main Board 2.x (Figure 10),

1. Attach the 9-pin RS-232 Connector from the CO₂ module (Figure 11) to the Receptacle RS-232 Connector at the back of the fabian HFO labelled with Data input / output symbol (Figure 12).
2. Fasten the connection by turning the screws on either side of the pinned connector clockwise.

![Figure 10 - Rear View of fabian HFO (Main Board 2.x). Arrow points towards CO₂ port.](image)

![Figure 11 – 9-Pin Connector](image)

![Figure 12 - Receptacle Connector](image)
12.2.3 MicroPod® sensor module

The module is designed to be incorporated into a host monitoring system. The module allows for measurement of inspired/expired carbon dioxide and respiration rate on patients in the Operating Room, ICU, NICU, Sedation procedures, GI, General Floor, Transport and Emergency treatment. The method for measuring etCO₂ is based on non-dispersive IR absorption of the etCO₂ in the breath sample using the Oridion IR source.

**The major components of the module are as follows:**

- etCO₂ sensor assembly, including the Oridion long-life source
- Flow System, including pump
- FRS to identify the correct usage of a Microstream® FilterLine
- Input gas connector with the FRS interface
- Power supply
- Serial interface
- μController + peripherals

The capnography module is intended to provide professionally trained health care providers with continuous, non-invasive measurement and monitoring of carbon dioxide concentration of the expired and inspired breath and respiration rate. The capnography module is intended for use with neonatal, pediatric, and adult patients in hospitals, hospital-type facilities, transport, intra-hospital transport and home environments.

The MicroPod contains the Oridion microMediCO₂ module and uses Microstream capnography. The MicroPod external CO₂ module attaches to the host monitor with an external communication cable, and data from the module appears on the host monitor screen.

Figure 13 - MicroPod inside cradle  
Figure 14 - MicroPod Front View

Microstream capnography modules use Microstream non-dispersive infrared (NDIR) spectroscopy to continuously measure the concentration of CO₂ during every breath, the concentration of CO₂ present at the end of exhalation (EtCO₂) and the respiratory rate. The respiration rate is referred on the fabian HFO as Freq etCO₂. Infrared spectroscopy is used to measure the concentration of molecules that absorb infrared light. Because the absorption is proportional to the concentration of the absorbing molecule, the concentration can be determined by comparing its absorption to that of a known standard.
The Microstream EtCO₂ sampling lines deliver a sample of the inhaled and exhaled gases from the ventilator circuit or directly from the patient (through an oral/nasal cannula) into the monitor for CO₂ measurement. Moisture and patient secretions are extracted from the sample, while maintaining the shape of the CO₂ waveform.

The 50 mL/min. sampling flow rate reduces liquid and secretion accumulation, decreasing the risk of obstruction in the sample pathway in humid ICU environments. This low sampling rate is ideally suited to measure a neonate's low tidal volume.

Once inside the Microstream CO₂ sensor, the gas sample goes through a micro-sample cell (15 microliters). This extremely small volume is quickly flushed, allowing for fast rise time and accurate CO₂ readings, even at high respiration rates.

The Micro Beam IR source illuminates the micro-sample cell and the reference cell. This proprietary IR light source generates only the specific wavelengths characteristic of the CO₂ absorption spectrum. Therefore, no compensations are required when different concentrations of N₂O, O₂, anesthetic agents and water vapor are present in the inhaled and exhaled breath. The IR that passes through the micro-sample cell and the IR that passes through the reference cell are measured by the IR detectors.

The microprocessor in the board calculates the CO₂ concentration by comparing the signals from both detectors.

### 12.2.3.1 MicroPod messages

**The MicroPod supports following messages and alarms**

- "check calibration"
- "check flow"
- "CO₂ value over-range"
- "initialization"
- "invalid CO₂ value"
- "pump off"
- "purging in progress"
- "Sensor off"
- "Sensor state: ok"
- "SFM in progress"
- "standby"
- "Temperature out of range"

The messages are displayed on the information line of the CO₂ Monitoring screen or in the CO₂ Settings menu.
12.2.3.2 MicroPod calibration

Oridion supplies a Calibration kit (including a Calibration software CD and Calibration accessories) that enables calibration of the module on a PC. The fabian HFO displays a Calibration message that indicates on the host monitor CO₂ screen that calibration is required at the designated interval (Figure 15).

![Image of Calibration message](image)

Figure 15 - Calibration required

12.2.3.3 MicroPod calibration interval

The monitor should be calibrated by qualified service personnel after the first 1,200 operating hours of use or 12 months, whichever comes first.

After 1,200 operating hours of use or 12 months, calibration should be performed every 12 months or after 4,000 operating hours, whichever comes first.

12.2.3.4 Basic principles for choosing Microstream® etCO₂ Sampling lines

When choosing Microstream CO₂ sampling lines, the following should be considered:

- The condition of the patient (ventilated or not ventilated)
- If the patient is ventilated, whether ventilation is humidified or non-humidified
- Patient's size and weight
- The probability that the patient will switch between oral and nasal breathing
- Duration of use
For best results, for short term monitoring, use Microstream CO₂ sampling lines with **Orange** connectors. For long term monitoring, use Microstream CO₂ sampling lines with **Yellow** connectors. Products that include an “H” in the name are intended for long term use.

### 12.2.3.5 etCO₂ Module settings and information

In the etCO₂ module menu (Figure 16) you can:

- Disable or switch etCO₂ module
- Specify the time until the pump automatically restarts (5, 10, 15 or 30 minutes or OFF) after it has been manually turned OFF
- Choose the displayed unit for measurement values (mmHg, kPa, Vol%)

![Figure 16 - Settings and Information](image)

In addition, the following information on the module is displayed:

- Calibration state
- Serial number
- Service state
- Software release
- The Sensor state

The fabian HFO CO₂ Monitoring View (Figure 17) displays real time CO₂ data. The displayed data includes:

- Real time “etCO₂” values along with selected unit “mmHg”, “kPa” or “Vol%”.
- Respiration rate (RR) named “Freq” in breaths-per-minute (bpm).
- etCO₂ Waveform.
1. To start the Pump OFF Mode, slide the blue button under the Pump [ON / OFF] text. The Pump OFF timer will begin. If the auto-restart of the CO$_2$ pump is enabled, the state is displayed in the information line of the CO$_2$ Monitoring screen (Figure 18).

2. To restart the timer, press the **Restart Timer** button.

3. On the top of the main screen a message (“! EtCO2 pump will be restarted in 1min!”) appears one minute before the pump turns ON automatically.

**12.2.3.6 Connecting a filter line**

Before monitoring a patient with capnography, the appropriate filter line must be connected to the monitor and to the patient.

**To make the connections:**

1. Slide open the filter line input connector shutter and connect the appropriate filter line.
2. Screw the filter line connector into the monitor clockwise until it can no longer be turned.
3. Connect the filter line to the patient as described in the Instructions for Use supplied with the filter line.

When the FilterLine is connected, the monitor will immediately begin to search for breaths, but it will **NOT** indicate a No Breath condition before any valid breaths have occurred.

**12.2.3.7 MicroPod® Functional testing**

We recommend performing a functional test each time the MicroPod is used. After connection of the MicroPod, verify that the CO$_2$ data is displayed on the monitor in accordance to what is defined in Section “12.2.3.5: etCO2 Module settings and information”.

**12.2.3.8 MicroPod Start-up**

The time before CO$_2$ measurements are available includes power-up time and initialization time. The initialization time includes module initialization and self-tests.

- Power-up time: Maximum 10 seconds
- Initialization time: Typically, 30 seconds, maximum 180 seconds
12.2.3.9 System response time

The system response time of the microMediCO₂ and fabian HFO together is typically 3.1 seconds. This includes the following timing sequences:

- 2.7 seconds delay time
- 0.2 seconds rise time from the microMediCO₂ and
- 0.2 seconds response time from the fabian HFO.

12.2.3.10 MicroPod® Self-maintenance (SFM) interval

Self-Maintenance (SFM) is performed only during measurement mode. The module performs one or more of the following:

- Ambient pressure measurement
- Auto zero (AZ)
- Flow test

SFM is triggered:

- During the first hour after entering measurement mode, periodically for durations of 10 seconds at a rate which limits the total time consumed by SFMs to less than 2% of the time in which active measurements are taken. Following the first hour after entering measurement mode, periodically for durations of 10 seconds at a rate of once per hour.
- A significant temperature change measured by the module (not less than 8°C from the temperature at the time that the last AZ was detected).
- A significant ambient pressure change (not less than 18 mmHg relative to the last ambient pressure measurement) for a period of 30 seconds.

The module prevents the triggering of an SFM in the following situations:

- In case of purging until the end of this state.
- During a breath absence period which follows a valid breath.
- While waiting a minimum of 20 seconds for host SFM enable command. (After the 20-second opportunity given to the host to schedule the SFM passes, the module schedules the SFM according to a priority determined by current conditions).

Periodic service

Periodic maintenance is recommended according to operating hours:

- The CO₂ pump should be replaced every 30,000 operating hours.
- A calibration should be performed as described in section “12.2.3.3: MicroPod calibration interval”.

Limited Operating life

The following parts of a MicroPod with a microMediCO₂ capnography board will require replacement after a set period:

- The CO₂ Pump should be replaced every 30,000 operating hours.
- The I.R. Source should be replaced every 30,000 operating hours.
12.2.4 Respironics® etCO₂ sensors

When using either of the following sensors from Respironics (Philips) you need to select the Respironics option in the etCO₂ menu (Figure 16).

- Capnostat 5 Mainstream (Figure 19) or
- LoFlo Sidestream (Figure 20) EtCO₂

12.2.4.1 Respironics messages

- "Check Airway Adapter"
- "Check Sampling Line"
- "CO₂ out of Range"
- "No Message"
- "Sensor Faulty"
- "Sensor off"
- "Sensor Over Temperature"
- "Sensor state: ok"
- "Sensor Warm Up"
- "Standby"
- "Zero in Progress"
- "Zero Required"
**12.2.4.2  Resprironics module settings and information**

In addition, the following information on the module is displayed:

- The sensor state
- Last service date
- Sensor type

**Figure 21 – Resprironics CO₂ module**
The fabian HFO CO₂ Monitoring View (Figure 22) displays real time CO₂ data. The displayed data includes:

- Real time “etCO₂” values along with selected unit “mmHg”, “kPa” or “Vol%”.
- Respiration rate (RR) named “Freq” in breaths-per-minute (bpm).
- EtCO₂ Waveform.

![Figure 22 - Monitoring CO₂](image)

12.2.4.3 Respironics CO₂ sensor zeroing

The Respironics CO₂ sensor is compatible with a variety of different airway adapters.

- Zeroing allows for the sensor to accommodate the optical characteristics of each of the different adapter types.
- A zero should be performed whenever the type of adapter being used with the Respironics CO₂ sensor is changed.
- For optimal accuracy, a zero should also be performed whenever the sensor is connected to the host system.

Before performing a zero calibration (Figure 23), the Respironics CO₂ sensor should be removed from the patient circuit, and the airway adapter type to be used in the circuit should be inserted into the sensor.

- Care should be taken to ensure that the airway adapter is clear of any residual CO₂ gas.
- The maximum elapsed time for a zero is 30 seconds. The typical time for a zero is 15 to 20 seconds.
Several conditions are required to start the zero calibration procedure:

- These requirements stem from changes in the airway adapter that could indicate that the sensor is not in optimal measuring condition. When this occurs, the airway adapter should be checked to ensure optical occlusions such as mucus have NOT obscured the adapter window.
- If occlusions are found, the airway adapter must be cleaned or replaced.

**Figure 23 - Respironics CO₂ Sensor Zeroing**

### 12.2.4.4 Respironics sensors Start-up

The Capnostat 5 Mainstream CO₂ sensor requires approximately five seconds from power up for internal initialization.

- After the CO₂ sensor has completed the start-up, the sensor is ready to respond to all commands from the serial interface.
- For optimal CO₂ accuracy, the host initializes several settings on start up or whenever the Capnostat 5 Mainstream CO₂ sensor is initially connected to the host.
- The data rate for the continuous waveform modes is 100 Hz, therefore the host can expect a new waveform packet approximately every 10 milliseconds
12.3 SpO₂ module

12.3.1 Setting up the Masimo sensor

To enable the SpO₂ measurement, the module must be enabled. This can be done in the menu of the SpO₂ module.

You can choose from the SpO₂ menu, different module settings described in the following sections.
Here is also displayed information on the sensor state and software release of the connected module. You can select the sensitivity mode, enable or disable Fast SAT mode, Alarm Delay and the SpO2 Averaging Time.

The information on the sensor state is displayed in the configuration menu, in the information bar at the bottom.

In addition, the following general messages for the sensor state can appear in the information bar in the Configurations menu:
- "checking"
- "processing active"
- "pulse search"

### 12.3.2 Sensitivity mode

The Sensitivity mode can be Maximum, Normal or APOD (Adaptive Probe Off Detection).

**Maximum:** This mode should be used for the most critical patients, where obtaining a reading is most difficult. Maximum Sensitivity is designed to interpret and display data for even the weakest of signals. This mode is recommended during procedures and when clinician and patient contact is continuous. However, this mode is less sensitive to detect probe-off conditions.

**Normal:** This mode provides the best combination of sensitivity and probe-off detection performance. This mode is recommended for most patients.

**Adaptive Probe Off Detection (APOD):** This mode is the least sensitive in picking up a reading on patients with low perfusion but has the best detection for probe-off conditions. This mode is useful for patients that are at risk of the sensor becoming detached (pediatric, agitated, etc.).

![Figure 26 Sensitivity mode](image)

### 12.3.3 Fast SAT mode

The Fast SAT mode can also be selected. The Fast Sat mode can either be ON or OFF.

Fast SAT enables rapid tracking of arterial oxygen saturation changes by minimizing the averaging. This mode is clinically applicable during procedures when detecting rapid changes in oxygen saturation is paramount such as induction, intubation, and sleep studies.

![Figure 27 Fast SAT](image)
12.3.4 Alarm delay

You can configure the alarm delay so that transient desaturations do not give an immediate audible alarm or visual display. You can also select alarm delay settings of 0, 5, 10, and 15 seconds.

Figure 28 Alarm delay

12.3.5 SpO₂ averaging time

Selectable averaging time enables clinicians to optimize SpO₂ monitoring for various patient application areas such as the PACU, NICU, ICU, Telemetry, and Sleep. This reduces the number of alarms due to real, yet non-clinically actionable rapid desaturations. There are different averaging times that can be selected (2 to 4, 4 to 6, 8, 10, 12, 14, 16).

Figure 29 SpO₂ averaging time
12.4 PRICO

12.4.1 General information on PRICO

Pulse oximetry is a continuous and non-invasive method of measuring the level of arterial oxygen saturation in blood. The measurement is taken by placing a sensor on a patient, usually on the fingertip for pediatric, adult patients, and the hand or foot for neonates. The sensor is connected to the fabian with a patient cable. The sensor collects signal data from the patient and sends it to the ventilator. The fabian displays the calculated data additional to the ventilation data in four ways:

1. As a Percent value (%) for arterial oxygen saturation (SpO₂),
2. As a Pulse Rate (b/min),
3. The Perfusion Index (PI) and
4. As a plethysmographic waveform

The following figure shows the general monitoring view.

12.4.1.1 USB HPLPM (for devices with SN till AI-01500 and AL-00400)

The USB HPLPM is a patient cable with an integral Masimo MSLP-1 Board contained in an enclosure that connects to Masimo Pulse Oximetry sensors and provides functional oxygen saturation (SpO₂), pulse rate (PR), perfusion index (PI), Plethysmograph Waveforms, and other information through a serial digital interface.

The USB HPLPM contains a 9-pin (DB9) LNCS-compatible sensor connector with latch at the sensor end, and a standard USB Type A connector at the opposite end so that it is compatible with the USB device port on the rear panel of the fabian ventilator. The total length of the USB HPLPM, patient cable, and sensor cannot exceed 5 meters.
12.4.1.1 LEMO HPLPM (for devices with SN from AI-01500 and AL-00400)

The LEMO HPLPM is a patient cable with an integral Masimo MSLP-1 Board contained in an enclosure that connects to Masimo Pulse Oximetry sensors and provides functional oxygen saturation (SpO₂), pulse rate (PR), perfusion index (PI), Plethysmograph Waveforms, and other information through a serial digital interface.
The LEMO HPLPM contains a 9-pin (DB9) LNCS-compatible sensor connector with latch at the sensor end, and a 7-pin LEMO connector at the opposite end so that it is compatible with the 7-pin LEMO device port on the rear panel of the fabian ventilator. The total length of the LEMO HPLPM, patient cable, and sensor cannot exceed 5 meters.

12.4.2 Setting up PRICO

PRICO can be activated in the SpO₂ section of the Graphics menu. PRICO will adjust the FiO₂ to try to keep the SpO₂ within the selected range.

PRICO has the following parameters:

<table>
<thead>
<tr>
<th>PRICO Parameters</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Min FiO₂</td>
<td>Minimum allowed FiO₂. Range: 21 to 99%</td>
</tr>
<tr>
<td>2. Max FiO₂</td>
<td>Maximum allowed FiO₂. Range: 22 to 100%.</td>
</tr>
<tr>
<td>3. SpO₂ low target</td>
<td>The lower target for SpO₂. Range: 0 to 99%.</td>
</tr>
<tr>
<td>4. SpO₂ high target</td>
<td>The higher target for SpO₂. Range: 1 to 100%.</td>
</tr>
<tr>
<td>5. PRICO ON / OFF</td>
<td>ON / OFF switch for PRICO</td>
</tr>
</tbody>
</table>

Dependencies on Alarm Limits:
- “SpO₂ low target” must be greater than or equal to the low SpO₂ alarm limit.
- “SpO₂ high target” must be less than or equal to the high SpO₂ alarm limit.
- PRICO can only be “ON” when the measured SIQ (Signal Quality) is higher than the SIQ alarm limit.
Due to the dependencies of the PRICO alarm limits it is critical that you first select the appropriate alarm limits for the patient, before switching on PRICO.

Dependencies on each other:

- “Min FiO₂” must be less than “Max FiO₂”.
- “SpO₂ low target” must be less than the “SpO₂ high target”.

1. Press the **PRICO parameter** on the touch screen to select. Adjust the parameter with the **rotary push knob**. The value will be shown in the button.
   1.1. The **Green** bars depicting the range of the FiO₂ and the SpO₂ will be adjusted accordingly.
   1.2. The current SpO₂ and FiO₂ values are indicated with vertical **Blue** lines.

2. Press the **rotary push knob** again to confirm the value as a PRICO parameter.
   2.1. SIQ (Signal quality) is depicted as the red to green vertical scale.
   2.2. The **Red** line on the SIQ scale indicates the SIQ alarm limit.

The “FiO₂” parameter in the main screen will be used as the Back-up “O₂” in case the PRICO is turned OFF (either in response to a fault condition, or by the operator). The value can be adjusted also when PRICO is ON.

When all PRICO parameters are set appropriately for the patient, PRICO can be switched ON.

The PRICO algorithm works as outlined in the diagram above. After every 30 seconds, an FiO₂ adjustment is made based on the current SpO₂ and its position in one of the four regions.

- Outside the SpO₂ target range: the FiO₂ step size (1 to 10%) is determined by current SpO₂, trend of SpO₂ data and an extrapolation of SpO₂ data.
- Inside the SpO₂ target range: FiO₂ step of +1%, if FiO₂ is in lower half. If FiO₂ is in upper half decrease FiO₂ by 1%.
- FiO₂ adjustments are made up to the pre-set FiO₂ limits (min FiO₂ to max FiO₂).
12.4.3 PRICO Ventilation modes

PRICO is available on the fabian ventilators in the following modes:

- Continuous Positive Airway Pressure (CPAP)
- High and Low Flow Oxygen Therapy HFNC (O₂ Therapy)
- High-Frequency Oscillation ventilation (HFO)
- Intermittent Positive Pressure Ventilation (IPPV)
- NIV Bi-levels positive airway pressure (DUOPAP)
- NIV Continuous Positive Airway Pressure NCPAP)
- Pressure Support Ventilation (PSV)
- Synchronized Intermittent Mandatory Ventilation (SIMV)
- Synchronized Intermittent Mandatory Ventilation with PSV support (SIMV+PSV)
- Synchronized Intermittent Positive Pressure Ventilation ((SIPPV)

The “O₂ Flush” can be activated during PRICO, this will deactivate PRICO.
- To re-enable PRICO after an O₂ Flush, push the PRICO “ON” button in the PRICO menu.
- To disable the O₂ Flush function, set the Flush Time to 0s

The “Start / Stop” button could be used to interrupt mechanical ventilation for 2 minutes.
In nCPAP, DUOPAP and O₂ Therapy mode ventilation can be interrupted indefinitely.
In both cases PRICO will be switched OFF.

When PRICO is ON, this is indicated by the PRICO icon in the Status bar and the green field with the current FiO₂ labelled PRICO above the O₂ parameter.

Figure 34 PRICO “ON”
12.4.4 PRICO disabling alarms

PRICO is turned OFF and cannot be re-enabled while any of the following alarms are active:

- Air supply pressure
- Check ET tube
- Clean flow sensor
- Check SpO2 sensor
- Flow sensor defect
- Flow sensor not connected
- Input pressure blender
- Low SIQ
- O2 sensor calibration error
- O2 value out of range
- Oxygen sensor defect
- Oxygen sensor used up
- Oxygen supply pressure
- Patient disconnected
- SpO2 module disconnected
- SpO2 sensor failure
- Tube Occlusion

12.4.5 PRICO re-enabling cases

PRICO automatically turns back on in case the following alarms are not active anymore:

- Check ET tube
- Check SpO2 sensor
- Clean flow sensor
- Flow sensor defect
- Flow sensor not connected
- Low SIQ
- O2 value out of range
- Patient disconnected
- Tube Occlusion

12.4.6 PRICO errors

Inaccurate measurements can be caused by:

- Excessive patient movement
- Exposure to excessive illumination, such as surgical lamps (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight (correct exposure to excessive illumination by covering the sensor with a dark or opaque material)
- Incorrect sensor application or use
- Intravascular dyes such as indocyanine green or methylene blue
- Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.
- Significant levels of dysfunctional hemoglobins (for example: carboxyhemoglobin or methemoglobin)
- Venous pulsation

Loss of pulse signal can occur in any of the following situations:

- The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia
- The patient is in cardiac arrest or shock
- The sensor is too tight
- There is arterial occlusion proximal to the sensor
- There is excessive illumination from light sources such as a surgical lamp, a bilirubin lamp, or direct sunlight

An alarm condition due to reached alarm limit is displayed with a **red** alarm icon at the corresponding alarm limit and as a flashing text with **yellow** background in the Information bar.

![High SpO2 Alarm](image)

Figure 35 High SpO2 Alarm

The actual alarm limits and state (OFF) are also displayed in the graphical view next to the numeric values with the high/low alarm limit symbol.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>SpO2 [%]</td>
<td>83</td>
</tr>
<tr>
<td>PI</td>
<td>7.5</td>
</tr>
<tr>
<td>Pulse Rate [bpm]</td>
<td>62</td>
</tr>
</tbody>
</table>

Figure 36 Alarm limits
12.5 **External communication, PDMS**

fabian devices can be connected to various Patient Data Management Systems (PDMS). fabian’s own PDMS interface is called acuLink. A license is needed to activate this feature, which can be ordered through your local distributor.

fabian supports acuLink with three different protocols:
1. Acutronic proprietary RS232 protocol without wave data
2. Acutronic proprietary RS232 protocol with wave data
3. IVOI protocol from Philips for Intellibridge/Vuelink via RS232

There are two major version of our acuLink protocol available: version 3 and version 4. Each one is supported by various drivers on the market. Please contact the manufacturer of your PDMS for further info.

Data from our ventilators can be received by the CIS system of the following brands – meaning that there are drivers from these PDMS manufacturer compatible with the specific acuLink version):

- Qualcomm Life (CapsuleTech)
- Philips:
  - protocol IVOI (modules: IntelliVue / IntelliBridge EC5-EC10 / VueLink)
  - protocol IHE HL7: Intellibridge EC40/80 modules
  - protocol HL7: Intellispace Critical Care and Anesthesia (ICCA) system
- GE Healthcare
- Cerner
- Dräger
- AGFA
- Mindray
- METAVISION iMDSoft

12.6 **FOT**

12.6.1 **Forced Oscillation Technique (FOT) at fabian HFO**

FOT is available as a submenu under Waves / loops in fabian HFO ventilators in the following modes:

- **CPAP** - Continuous Positive Airway Pressure
- **HFO** - High-Frequency Oscillation ventilation
- **IPPV** - Intermittent Positive Pressure Ventilation
- **PSV** - Pressure Support Ventilation
- **SIMV** - Synchronized Intermittent Mandatory Ventilation
- **SIMV + PSV** - Synchronized Intermittent Mandatory Ventilation with PSV support
- **SIPPV** - Synchronized Intermittent Positive Pressure Ventilation

**FOT is only available if:**

- There is an FOT license installed on the device
- Flow sensor is connected and turned ON
- Any of the previously mentioned ventilation modes are active
There are two types of FOT distinguished in fabian HFO:

- **FOT-HFO**: The forced oscillation is created by the HFO module. The measurement does not change the ventilation mode as it is available only in HFOV.
- **FOT-conventional**: The forced oscillation is created by the exhalation membrane. During the measurement, ventilation mode is changed to CPAP.

<table>
<thead>
<tr>
<th>Ventilation Mode</th>
<th>FOT Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>HFO</td>
<td>FOT-HFO</td>
</tr>
<tr>
<td>CPAP</td>
<td>FOT-Conventional</td>
</tr>
<tr>
<td>IPPV</td>
<td></td>
</tr>
<tr>
<td>PSV</td>
<td></td>
</tr>
<tr>
<td>SIMV</td>
<td></td>
</tr>
<tr>
<td>SIMV+PSV</td>
<td></td>
</tr>
<tr>
<td>SIAPPV</td>
<td></td>
</tr>
</tbody>
</table>

FOT-HFO and FOT-conventional shares:

- The same layout
- The same operation steps

FOT-HFO and FOT-conventional differ in:

- Parameter names
- Parameter ranges
- Forced signal creation

The following sensors and ventilation additives can be used together with FOT:

- Volume Guarantee (VG)
- Volume Limit (VL)
- SpO₂ sensor
- Predictive Intelligent Control of Oxygenation (PRICO)

The following option is disabled during the FOT recruitment / derecruitment maneuver:

- Lung recruitment at HFOV
12.6.2  FOT general layout

1. FOT graph: displays and connects the calculated $X_r$ values (always auto scaled).
2. FOT steps setting: used to set the number of reactance measurements between the pressure range defined by low and high-pressure settings.
3. $P_{mean \ low}$ / PEEP$_{low}$ setting: used to set the lower (starting and ending) point of recruitment /derecruitment procedure.
4. $P_{mean \ high}$ / PEEP$_{high}$ setting: used to set the upper (turnaround) point of recruitment /derecruitment maneuver procedure.
5. Step size information field: The pressure difference between two consecutive FOT measurements. It is automatically calculated as the difference between the low and high-pressure settings and FOT.
6. Information field: Depending on the status of FOT it displays if it is OFF; the remaining time of the stabilization period; the remaining time of forced oscillation; the number of next step.
7. PIP$_{max}$ information field: The maximally reached peak pressure during the whole recruitment procedure. It is automatically calculated as the high pressure setting and the ventilation’s actual $\Delta P$.
8. Control buttons: Reverse; ON / OFF; Repeat; Next step / Start measurement.
9. Information field: Depending on the status of FOT it displays the current and next PEEP/ $P_{mean}$ and PIP values; the date and time of last recruitment / derecruitment maneuver; feedback information of unsuccessful measurements.
12.6.3 Erasing the FOT graph

The FOT Graph is cleared if any of the following actions are performed:

- a new FOT sequence is started,
- the device is restarted,
- the patient range is changed,
- device date / time is changed

12.6.4 FOT disabling conditions

FOT is turned OFF and cannot be re-enabled while any of the following actions occurs or alarms are active:

**Any system alarm:**
- Air supply pressure
- Check Blender
- Exhalation calibration
- Oxygen supply pressure
- Tube Occlusion

**Any flow sensor alarm:**
- Clean flow sensor
- Flow sensor defect
- Flow sensor not connected

**Disconnection / Tube blocked alarm:**
- Check ET tube
- Patient disconnected

**Any system failure:**
- Checksum conductor PIC
- Checksum monitor PIC
- COM interface
- Cooling fan defect
- DIO interface
- I2C interface
- Input pressure blender
- Low physical memory
- parallel interface
- Safety relay defect
- SPI interface
- Voltage monitoring

**Alarm actions:**
- Applying Manual breath
- Applying or preset another ventilation mode
- Changing Date / time
- Changing Patient range
- Changing the Bias Flow setting
- Changing the value of any Ventilation parameters, except O₂, O₂ Flush and Trigger sensitivity
- Changing Trigger type
- Changing VL or VG state
- Turning OFF Flow sensor
- Turning ON lung recruitment

The “Manual Breath” can be activated during FOT, but this will deactivate FOT. To re-enable FOT after a Manual Breath / Sustained Inflation, you must restart FOT from the beginning.

The Start / Stop button can be used to interrupt mechanical ventilation for two minutes, but this will deactivate FOT.

Any FOT measurements taken during Standby are NOT valid.

Inaccurate measurements may be caused by:
- Flow sensor not calibrated or defective;
- Incorrect pressure measurement line application or use;
- Excessive patient spontaneous breathing (strong active respiratory drive);
- Excessive leakage at the patient interface.

12.6.5 FOT procedure

Perform the following steps to complete an FOT procedure.

1. Terminate any ongoing EtCO₂ measurements during FOT procedure as it can affect the results.
2. Ventilate in one of the compatible ventilation modes with an active flow sensor.
   2.1. Verify that the flow sensor in the selected mode is calibrated.
   2.2. If Flow sensor is NOT calibrated, calibrate the Flow sensor and continue with the procedure.
3. Go to the Curves / Loops menu by pressing the Graphics button on the front panel and select FOT submenu.
4. Set the three adjustable parameters (FOT steps, low and high-pressure settings) according to the needs (FOT contains a recruitment and a derecruitment phase starting at the set low pressure level and turning back at the high-pressure level).
   4.1. Adjust the pressure related alarms to avoid unnecessary patient alarms during the maneuver.
5. When all FOT parameters are set appropriately for the patient’s respiratory system, FOT is ready to be initiated by pressing the ON / OFF button, which will turn Green and a confirmation message will appear on the display.
6. After confirmation (clicking on Yes) the status bar is updated to “active mode + FOT” and the ventilation remains stable to the set low pressure level and a timer starts to count back from 180 seconds (stabilization period).

7. At the end of the 180 seconds or by pushing the Next button, FOT period is started by either changing to CPAP mode and applying forced oscillation with the FOT parameters (in FOT-conventional) or changing HFOV to the FOT parameters (in FOT-HFO).

8. If the conditions are acceptable (pressure is reached, and leak is low) the three seconds measurement takes place.

8.1. If the measurement passes the Quality check, the calculated reactance measurement is displayed as a squared dot on FOT graph and the Ventilation mode is changed back to the recent Ventilation mode.

8.2. If the measurement does NOT pass the Quality check, or other problems were identified during FOT period, the measurement must be repeated. This can be performed by using the Repeat button.

9. After a successful measurement you can proceed to the next step by using the Next step button. The next PEEP/ Pmean values are displayed in the information field (PEEPnext / Pmean next and PIPnext).

10. If the patient shows signs of discomfort or decreased cardiac output during the recruitment phase because of the higher pressures, the upcoming higher-pressure level measurements can be skipped by pressing the Reverse button and the whole process can be continued at the previous step as a first step of the derecruitment.

NOTE:
If this situation occurs, the FOT procedure can be completed but with having fewer measurements than planned.

11. After completing all the desired steps in the FOT procedure, normal ventilation resumes at FOT low PEEP and the FOT graph displays the reactance behavior during the complete recruitment-derecruitment maneuver.

11.1. The last calculation date and time is also updated with the last measurement’s time.

12. You can then assess PEEP (CPAP) or MAP (CDP) accordingly if there is a need for readjustment and optimization.

NOTE:
In case FOT is terminated, ventilation continues the last / current pressure levels and the whole FOT procedure must be restarted from the first measurement (step 4).

Use only recommended HFO breathing circuit.

The following graphs illustrate a complete FOT maneuver in real time showing pressure levels in FOT Conventional mode with the following settings and how the results are displayed:

<table>
<thead>
<tr>
<th>IPPV settings</th>
<th>FOT settings</th>
</tr>
</thead>
<tbody>
<tr>
<td>PEEP</td>
<td>Pinsp</td>
</tr>
<tr>
<td>6 mbar</td>
<td>14 mbar</td>
</tr>
</tbody>
</table>
The following graph illustrates how a complete FOT maneuver looks in real time regarding pressure levels in HFO mode with the following settings:

<table>
<thead>
<tr>
<th>HFO settings</th>
<th>FOT settings</th>
</tr>
</thead>
<tbody>
<tr>
<td>PEEP</td>
<td>PEEPlow</td>
</tr>
<tr>
<td>10 mbar</td>
<td>15 mbar</td>
</tr>
</tbody>
</table>

- Ventilation before starting recruitment
- Stabilisation period
- FOT period
- Ventilation after FOT
- Ventilation after derecruitment
- Click on next
12.6.6  FOT post data analysis

The exported system log files can be used for post data analysis. The log files contain the FOT settings and the measurement results (Xrs and Resistance) at each pressure level.

12.6.7  FOT specifications

<table>
<thead>
<tr>
<th>Fixed parameters</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Amplitude ((\Delta P)) of forced oscillation</td>
<td>5 mbar</td>
</tr>
<tr>
<td>FOT period</td>
<td>maximum 18 seconds (if the conditions are good, it is shorter)</td>
</tr>
<tr>
<td></td>
<td>3 seconds out of it is the FOT measurement/data collection time</td>
</tr>
<tr>
<td>Frequency of forced oscillation</td>
<td>10 Hz</td>
</tr>
<tr>
<td>I:E ratio of forced oscillation</td>
<td>1:1</td>
</tr>
<tr>
<td>Stabilization time</td>
<td>maximum 180 seconds (can be skipped)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Adjustable parameters</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>FOT steps</td>
<td>1 to 21 (only odd numbers) *</td>
</tr>
<tr>
<td>(P_{\text{mean low}})</td>
<td>5 to 49 mbar</td>
</tr>
<tr>
<td>(P_{\text{mean high}})</td>
<td>6 to 50 mbar **</td>
</tr>
<tr>
<td>PEEP(_{\text{low}})</td>
<td>3 to 29 mbar</td>
</tr>
</tbody>
</table>
## Accessories and options

**PEEP**high | 4 to 30 mbar **
---|---

### FOT operator buttons

<table>
<thead>
<tr>
<th>Button</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Next step</td>
<td>It activates the next step and can be used to skip the remaining time of the stabilization period.</td>
</tr>
<tr>
<td>ON /OFF</td>
<td>It starts the whole FOT procedure and can be used to terminate it anytime.</td>
</tr>
<tr>
<td>Repeat</td>
<td>It can be used to repeat the reactance measurement.</td>
</tr>
<tr>
<td>Reverse</td>
<td>It can be used to skip the upcoming higher-pressure level measurements and continue at the previous step.</td>
</tr>
</tbody>
</table>

### Feedback information fields – automatically calculated values

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PIP&lt;sub&gt;max&lt;/sub&gt;</td>
<td>maximum 100 mbar in HFOV and 80 mbar in Conventional mode</td>
</tr>
<tr>
<td>Step</td>
<td>minimum 1 mbar</td>
</tr>
<tr>
<td>X&lt;sub&gt;rs&lt;/sub&gt;</td>
<td>≈500 to 100 mbar / Lps</td>
</tr>
</tbody>
</table>

* If FOTsteps is set to 1 then high-pressure setting is hidden and Pmean low and PEEPlow text is changed to Pmean and PEEP respectively.

** The difference between the high and low-pressure parameters can be minimum 1 mbar) or more if the setting of the number of FOT measurements (FOTsteps) is bigger than 3 because of the step size cannot be lower than 1 mbar.
13 Ventilator service and maintenance intervals

Always clean and disinfect equipment or equipment components before any maintenance – including when returning the equipment for repair.

The expected service life of fabian is 8 years, assuming the servicing operations are performed as specified by the manufacturer.

<table>
<thead>
<tr>
<th>Every 12 months:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintenance and Safety Inspections</td>
</tr>
<tr>
<td>Perform the following work:</td>
</tr>
<tr>
<td>• Check alarm and limit value functions</td>
</tr>
<tr>
<td>• Check Electrical connections</td>
</tr>
<tr>
<td>• Check Pressure connections</td>
</tr>
<tr>
<td>• Check Safety Shutdown Calibration</td>
</tr>
<tr>
<td>• Device check as specified by manufacturer</td>
</tr>
<tr>
<td>Replace the following components:</td>
</tr>
<tr>
<td>• Air and Oxygen Input Filters</td>
</tr>
<tr>
<td>• Cooling Air Filter (casing bottom)</td>
</tr>
<tr>
<td>• Exhalation membrane</td>
</tr>
<tr>
<td>• Flow sensor</td>
</tr>
<tr>
<td>• O₂ sensor</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Every 4 years:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Replace the following components:</td>
</tr>
<tr>
<td>• Air and Oxygen Input Filter</td>
</tr>
<tr>
<td>• Battery Pack</td>
</tr>
<tr>
<td>• Calibration Valves</td>
</tr>
<tr>
<td>• Cooling Air Filter (casing bottom)</td>
</tr>
<tr>
<td>• Exhalation membrane</td>
</tr>
<tr>
<td>• Flow sensor</td>
</tr>
<tr>
<td>• Input pressure regulator pressurized Air / Oxygen</td>
</tr>
<tr>
<td>• Proportional Valves pressurized Air / Oxygen mixer</td>
</tr>
<tr>
<td>• Lithium Battery (real time clock battery)</td>
</tr>
<tr>
<td>• Membrane HFO module</td>
</tr>
<tr>
<td>• O₂ sensor</td>
</tr>
</tbody>
</table>

Maintenance and safety inspections must be performed by ACUTRONIC Medical Systems trained personnel with access to suitable testing and measuring equipment.

Maintenance Interval Indicator. The symbol will appear in the Information bar 30 days before the next maintenance has to be performed.

13.1 Disposal

Disposal

fabian must not be disposed of with household waste but must be handed in for disposal as electrical and electronic equipment, including battery / batteries according to applicable national, regional and local rules, laws and regulations. Accessories and consumables must be disposed of in accordance with the relevant instructions for use. For information, contact your local environmental or regulatory agency, or an appropriate waste disposal company.
14 Sterilization / cleaning / disinfection

14.1 fabian HFO

The device must be prepared after each patient treatment.

WARNING: The device must NOT be sterilized under any circumstances.

14.1.1 Preparation for disinfection

1. Switch off fabian before cleaning and unplug at the mains in order to prevent damage due to penetration by liquid.

2. Remove any visible soiling on the fabian enclosure with the cleaning agent based on the option selected at the next chapter below.

14.1.2 Manual disinfection options

Option A: CaviWipes Surface Disinfectant Wipes (EPA REG. NO.: 46781-14)

1. Unfold the CaviWipe and wipe the surface of the enclosure completely.
   Note: The surface treated must remain visibly moist for three minutes.
   Use more wipes if necessary to keep the surface moist for three minutes.

2. Wipe the enclosure with a clean lint-free cloth dampened with purified water for one minute.

3. Allow to dry in the air.

Option B: 10% bleach (Clorox EPA REG. NO.: 5813-1)

1. Prepare a 10% bleach solution using purified water.
   Use a clean lint-free cloth dampened with the bleach solution.

2. Wipe the enclosure completely.
   Remove any heavy soiling with additional dampened cloths if necessary.
   Note: The surface treated must remain visibly moist for five minutes.
   Use more dampened cloths if necessary to keep the surface moist for five minutes.

3. Wipe the enclosure with a clean lint-free cloth dampened with purified water for one minute.

4. Allow to dry in the air.

Option C: 5% H2O2, Hydrogen Peroxide (EPA REG. NO.: 335-1)

1. Prepare a 5% H2O2 solution using purified water.
   Use a clean lint-free cloth dampened with the H2O2 solution

2. Wipe the enclosure completely.
   Remove any heavy soiling with additional dampened cloths if necessary.
   Note: The surface treated must remain visibly moist for five minutes.
   Use more dampened cloths if necessary to keep the surface moist for five minutes.
3. Wipe the enclosure with a clean lint-free cloth dampened with purified water for one minute.
4. Allow to dry in the air.

14.2 Accessories

14.2.1 Flow sensor cable

The flow sensor cable must be prepared after each patient treatment.

**WARNING:**
The flow sensor cable must NOT be sterilized under any circumstances.

14.2.1.1 Preparation for disinfection

1. Switch off fabian before cleaning and unplug at the mains in order to prevent damage due to penetration by liquid.

2. Remove the flow sensor from the flow sensor cable.

3. Remove any visible soiling on the flow sensor cable with the cleaning agent using a manual disinfection option listed in section 14.2.1.2.

14.2.1.2 Manual disinfection options

**Option A:** CaviWipes Surface Disinfectant Wipes (EPA REG. NO.: 46781-14)

1. Unfold the CaviWipe and wipe the surface of the enclosure completely.
   - Note: The surface treated must remain visibly moist for three minutes.
   - Use more wipes if necessary to keep the surface moist for three minutes.

2. Wipe the cable with a clean lint-free cloth dampened with purified water for one minute.

3. Allow to dry in the air.

**Option B:** 10% bleach (Clorox EPA REG. NO.: 5813-1)

1. Prepare a 10% bleach solution using purified water.
   - Use a clean lint-free cloth dampened with the bleach solution.

2. Wipe the cable completely.
   - Remove any heavy soiling with additional dampened cloths if necessary.
   - Note: The surface treated must remain visibly moist for five minutes.
   - Use more dampened cloths if necessary to keep the surface moist for five minutes.

3. Wipe the cable with a clean lint-free cloth dampened with purified water for one minute.
4. Allow to dry in the air.

**Option C**: 5% H2O2, Hydrogen Peroxide (EPA REG. NO.: 335-1)

1. Prepare a 5% H2O2 solution using purified water.
   Use a clean lint-free cloth dampened with the H2O2 solution
2. Wipe the cable completely.
   Remove any heavy soiling with additional dampened cloths if necessary.
   Note: The surface treated must remain visibly moist for five minutes.
   Use more dampened cloths if necessary to keep the surface moist for five minutes.
3. Wipe the cable with a clean lint-free cloth dampened with purified water for one minute.
4. Allow to dry in the air.

14.2.2 Flow sensor

![Warning]

**WARNING:**
Conduct hygienic preparation of flow sensor prior to each use.

14.2.2.1 Disassembly

Remove the flow sensor from the flow sensor cable.

14.2.2.2 Preparation for sterilization by automated cleaning

Please follow the steps below:

1. Rinse under running cold tap water (<35°C / 95°F) to remove excess soil.
2. Prepare a detergent bath using Neodisher Mediclean Forte solution at the manufacturer’s recommendation of 10 mL per Liter using utility (tap) water 20°C / 68°F - 30°C / 86°F.
3. Transfer the flow sensor on to the 4-Level manifold rack accessory (or other appropriate rack system) contained inside the washer for processing.
4. Select the appropriate cycle as listed below:

<table>
<thead>
<tr>
<th>Phase</th>
<th>Recirculation Time (Minutes)</th>
<th>Temperature</th>
<th>Detergent Type and Concentration (If applicable)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-wash 1</td>
<td>02:00</td>
<td>Cold tap water</td>
<td>N/A</td>
</tr>
<tr>
<td>Wash 1</td>
<td>02:00</td>
<td>45°C / 113°F Tap water (Set Point)</td>
<td>Neodisher Mediclean Forte 10 ml per Liter</td>
</tr>
<tr>
<td>Neutralization Wash</td>
<td>02:00</td>
<td>Warm tap water</td>
<td>Neodisher Z 1.0 ml per Liter</td>
</tr>
<tr>
<td>Rinse 1</td>
<td>01:00</td>
<td>Warm tap water</td>
<td>N/A</td>
</tr>
<tr>
<td>Dry Time</td>
<td>7:00</td>
<td>90°C / 194°F (Set Point)</td>
<td>N/A</td>
</tr>
</tbody>
</table>
5. After the drying process package immediately for sterilization in packaging suitable for vapor sterilization. Ensure that packaging stays dry before autoclaving. Note: Articles must be individually single pouched in a qualified pouch (e.g. Cardinal Health self-sealing pouch CAT# 92713). Each of the non-critical devices in-scope are thermostable and have been validated for steam sterilization.

14.2.2.3 Sterilization options

The recommended sterilization method is steam sterilization by autoclave. The following validated cycles are suitable for sterilization:

**Option A:**
1. Set the autoclave with the following parameters
   - 4 preconditioning pulses
   - Steam cycle at 134°C / 273°F for 3 minutes
   - Dry cycle for 30 minutes
2. Individually single pouch the cassette articles
3. Autoclave the cassette articles using the cycle parameters in Step 1

**Option B:**
1. Set the autoclave with the following parameters
   - 4 preconditioning pulses
   - Steam cycle at 134°C / 273°F for 4 minutes
   - Dry cycle for 30 minutes
2. Individually single pouch the cassette articles
3. Autoclave the cassette articles using the cycle parameters in Step 1

**Option C:**
1. Set the autoclave with the following parameters:
   - 4 preconditioning pulses
   - Steam cycle at 134°C / 273°F for 5 minutes
   - Dry cycle for 30 minutes
2. Individually single pouch the cassette articles
3. Autoclave the cassette articles using the cycle parameters in Step 1

14.2.2.4 Duration of use

The flow sensor must be replaced after 30 sterilization cycles and also in case that any detected defect is affecting the accessory performance.

14.2.3 Exhalation membrane and membrane holder

**WARNING:**
Conduct hygienic preparation of exhalation membrane and exhalation membrane holder prior to each use.
14.2.4 Disassembly

1. Remove the exhalation membrane holder and membrane from the ventilator:
   - Disassemble the membrane holder from the expiratory limb port by rotating the holder a quarter of turn in counter-clockwise direction and then pull it out from the port.

Containers are recommended to transport used accessories between the NICU and the cleaning/sterilization area.

2. Remove the exhalation membrane from the exhalation membrane holder:
   - Before cleaning the membrane holder and the membrane, disassemble the exhalation membrane from the membrane holder by pulling out from the second circumference of the exhalation valve membrane.

14.2.4.1 Preparation for sterilization by automated cleaning

Please follow the steps below:

1. Rinse under running cold tap water (<35°C / 95°F) to remove excess soil.
2. Prepare a detergent bath using Neodisher Mediclean Forte solution at the manufacturer’s recommendation of 10 mL per Liter using utility (tap) water 20°C / 68°F - 30°C / 86°F.
3. Transfer the cassette items on to the 4-Level manifold rack accessory (or other appropriate rack system) contained inside the washer for processing.
4. Select the appropriate cycle as listed below:

<table>
<thead>
<tr>
<th>Phase</th>
<th>Recirculation Time (Minutes)</th>
<th>Temperature</th>
<th>Detergent Type and Concentration (If applicable)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-wash 1</td>
<td>02:00</td>
<td>Cold tap water</td>
<td>N/A</td>
</tr>
<tr>
<td>Wash 1</td>
<td>02:00</td>
<td>45°C / 113°F Tap water (Set Point)</td>
<td>Neodisher Mediclean Forte 10 ml per Liter</td>
</tr>
</tbody>
</table>
Neutralization Wash | 02:00 | Warm tap water | Neodisher Z 1.0 ml per Liter
Rinse 1 | 01:00 | Warm tap water | N/A
Dry Time | 7:00 | 90°C / 194°F (Set Point) | N/A

5. After the drying process package immediately for sterilization in packaging suitable for vapor sterilization. Ensure that packaging stays dry before autoclaving.
Note: Articles must be individually single pouched in a qualified pouch (e.g. Cardinal Health self-sealing pouch CAT# 92713). Each of the non-critical devices in-scope are thermostable and have been validated for steam sterilization.

14.2.4.2 Sterilization options
The recommended sterilization method is steam sterilization by autoclave. The following validated cycles are suitable for sterilization:

**Option A:**
1. Set the autoclave with the following parameters
   - 4 preconditioning pulses
   - Steam cycle at 134°C / 273°F for 3 minutes
   - Dry cycle for 30 minutes
2. Individually single pouch the exhalation membrane and membrane holder separately.
3. Autoclave the exhalation membrane and membrane holder using the cycle parameters in Step 1 above.

**Option B:**
1. Set the autoclave with the following parameters
   - 4 preconditioning pulses
   - Steam cycle at 134°C / 273°F for 4 minutes
   - Dry cycle for 30 minutes
2. Individually single pouch the exhalation membrane and membrane holder separately.
3. Autoclave the exhalation membrane and membrane holder using the cycle parameters in Step 1 above.

**Option C:**
1. Set the autoclave with the following parameters:
   - 4 preconditioning pulses
   - Steam cycle at 134°C / 273°F for 5 minutes
   - Dry cycle for 30 minutes
2. Individually single pouch the exhalation membrane and membrane holder separately.
3. Autoclave the exhalation membrane and membrane holder using the cycle parameters in Step 1 above.

14.2.4.3 Duration of use
The exhalation membrane and membrane holder must be replaced after 30 sterilization cycles and also in case of any detected defect that is affecting the accessory performance.
## 15 Setting ranges and parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Mode</th>
<th>IPPV</th>
<th>SIPPV</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Neonatal</td>
<td>Pediatric</td>
<td>Neonatal</td>
</tr>
<tr>
<td></td>
<td>min</td>
<td>max</td>
<td>min</td>
</tr>
<tr>
<td>I–flow [Lpm]</td>
<td>1</td>
<td>32</td>
<td>1</td>
</tr>
<tr>
<td>E–flow [Lpm]</td>
<td>1</td>
<td>32</td>
<td>1</td>
</tr>
<tr>
<td>Rise Time [sec]</td>
<td>0.1</td>
<td>2</td>
<td>0.3</td>
</tr>
<tr>
<td>I–time [sec]</td>
<td>0.1</td>
<td>2</td>
<td>0.3</td>
</tr>
<tr>
<td>E–time [sec]</td>
<td>0.2</td>
<td>30</td>
<td>0.2</td>
</tr>
<tr>
<td>Frequency (Rate) [1 / min]</td>
<td>2</td>
<td>200</td>
<td>2</td>
</tr>
<tr>
<td>PEEP [mbar]</td>
<td>0</td>
<td>30</td>
<td>0</td>
</tr>
<tr>
<td>P_{insp} [mbar]</td>
<td>4</td>
<td>80</td>
<td>4</td>
</tr>
<tr>
<td>Trigger</td>
<td>1</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td>V_{limit} [mL]</td>
<td>1</td>
<td>150</td>
<td>10</td>
</tr>
<tr>
<td>V_{guarant} [mL]</td>
<td>0.8</td>
<td>60</td>
<td>10</td>
</tr>
<tr>
<td>P_{max} [mbar]</td>
<td>4</td>
<td>80</td>
<td>4</td>
</tr>
<tr>
<td>O₂ [%]</td>
<td>21</td>
<td>100</td>
<td>21</td>
</tr>
<tr>
<td>O₂ Flush [%]</td>
<td>23</td>
<td>100</td>
<td>23</td>
</tr>
<tr>
<td>Flush Time [sec]</td>
<td>0</td>
<td>120</td>
<td>0</td>
</tr>
<tr>
<td>Man. Breath Time [sec]</td>
<td>2</td>
<td>30</td>
<td>2</td>
</tr>
</tbody>
</table>
## Setting ranges and parameters

### Mode

<table>
<thead>
<tr>
<th>Parameter</th>
<th>SIMV</th>
<th>SIMV+PSV</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Neonatal</td>
<td>Pediatric</td>
</tr>
<tr>
<td>I-flow [Lpm]</td>
<td>1 32</td>
<td>1 32</td>
</tr>
<tr>
<td>E-flow [Lpm]</td>
<td>1 32</td>
<td>1 32</td>
</tr>
<tr>
<td>Rise Time [sec]</td>
<td>0.1 2 0.3 2</td>
<td>0.1 2 0.3 2</td>
</tr>
<tr>
<td>I-time [sec]</td>
<td>0.1 2 0.3 2</td>
<td>0.1 2 0.3 2</td>
</tr>
<tr>
<td>E-time [sec]</td>
<td>0.5 30 0.5 30</td>
<td>0.5 30 0.5 30</td>
</tr>
<tr>
<td>Frequency (Rate) [1 / min]</td>
<td>2 100</td>
<td>2 100</td>
</tr>
<tr>
<td>PEEP [mbar]</td>
<td>0 30</td>
<td>0 30</td>
</tr>
<tr>
<td>P&lt;sub&gt;insp&lt;/sub&gt; (backup)[mbar]</td>
<td>4 80</td>
<td>4 80</td>
</tr>
<tr>
<td>P&lt;sub&gt;psv&lt;/sub&gt; [mbar]</td>
<td>2 80</td>
<td>2 80</td>
</tr>
<tr>
<td>Trigger</td>
<td>1 10</td>
<td>1 10</td>
</tr>
<tr>
<td>V&lt;sub&gt;limit&lt;/sub&gt; [mL]</td>
<td>1 150</td>
<td>10 500</td>
</tr>
</tbody>
</table>
| V<sub>guarant</sub> [mL] | 0.8 60 | 0.8 60 | 10 300
| P<sub>max</sub> [mbar] | 4 80 | 4 80 | 4 80 | 4 80 |
| O<sub>2</sub> [%] | 21 100 | 21 100 | 21 100 | 21 100 |
| O<sub>2</sub> Flush [%] | 23 100 | 23 100 | 23 100 | 23 100 |
| Flush Time [sec] | 0 120 | 0 120 | 0 120 | 0 120 |
| Man. Breath Time [sec] | 2 30 | 2 30 | 2 30 | 2 30 |
| Termination criteria PSV [%] | 1 85 | 1 85 |

---

**fabian HFO | SW 5.1.x**
**Ref: 113003.EN / Date 2020-02-10**
### Setting ranges and parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Mode</th>
<th>PSV</th>
<th>CPAP</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Neonatal</td>
<td>Pediatric</td>
<td>Neonatal</td>
</tr>
<tr>
<td>I–flow [Lpm]</td>
<td>min</td>
<td>max</td>
<td>min</td>
</tr>
<tr>
<td>E–flow [Lpm]</td>
<td>min</td>
<td>max</td>
<td>min</td>
</tr>
<tr>
<td>Rise Time [sec]</td>
<td>min</td>
<td>max</td>
<td>min</td>
</tr>
<tr>
<td>I–time [sec]</td>
<td>min</td>
<td>max</td>
<td>min</td>
</tr>
<tr>
<td>E–time [sec]</td>
<td>min</td>
<td>max</td>
<td>min</td>
</tr>
<tr>
<td>Frequency (Rate) [1 / min]</td>
<td>min</td>
<td>max</td>
<td>min</td>
</tr>
<tr>
<td>Backup Rate [mbar]</td>
<td>min</td>
<td>max</td>
<td>min</td>
</tr>
<tr>
<td>Pbackup [mbar]</td>
<td>min</td>
<td>max</td>
<td>min</td>
</tr>
<tr>
<td>PPSV [mbar]</td>
<td>min</td>
<td>max</td>
<td>min</td>
</tr>
<tr>
<td>Trigger</td>
<td>min</td>
<td>max</td>
<td>min</td>
</tr>
<tr>
<td>Vlimit [mL]</td>
<td>min</td>
<td>max</td>
<td>min</td>
</tr>
<tr>
<td>Vguarant [mL]</td>
<td>min</td>
<td>max</td>
<td>min</td>
</tr>
<tr>
<td>O₂ [%]</td>
<td>min</td>
<td>max</td>
<td>min</td>
</tr>
<tr>
<td>O₂ Flush [%]</td>
<td>min</td>
<td>max</td>
<td>min</td>
</tr>
<tr>
<td>Flush Time [sec]</td>
<td>min</td>
<td>max</td>
<td>min</td>
</tr>
<tr>
<td>Man, Breath Time [sec]</td>
<td>min</td>
<td>max</td>
<td>min</td>
</tr>
<tr>
<td>Termination criteria PSV [%]</td>
<td>min</td>
<td>max</td>
<td>min</td>
</tr>
<tr>
<td>Flowmin [Lpm]</td>
<td>min</td>
<td>max</td>
<td>min</td>
</tr>
<tr>
<td>CPAP [mbar]</td>
<td>min</td>
<td>max</td>
<td>min</td>
</tr>
<tr>
<td>Pmanual [mbar]</td>
<td>min</td>
<td>max</td>
<td>min</td>
</tr>
<tr>
<td>Backup</td>
<td>min</td>
<td>max</td>
<td>min</td>
</tr>
</tbody>
</table>
Setting ranges and parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>HFO</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Neonatal</td>
<td>Pediatric</td>
<td></td>
</tr>
<tr>
<td></td>
<td>min</td>
<td>max</td>
<td>min</td>
</tr>
<tr>
<td>$V_{\text{guarant}}$ [mL]</td>
<td>0.3</td>
<td>30</td>
<td>10</td>
</tr>
<tr>
<td>$\text{AMP}_{\text{max}}$ [mbar]</td>
<td>5</td>
<td>100</td>
<td>5</td>
</tr>
<tr>
<td>$O_2$ [%]</td>
<td>21</td>
<td>100</td>
<td>21</td>
</tr>
<tr>
<td>$O_2$ Flush [%]</td>
<td>23</td>
<td>100</td>
<td>23</td>
</tr>
<tr>
<td>$P_{\text{manual}}$ [mbar]</td>
<td>4</td>
<td>80</td>
<td>4</td>
</tr>
<tr>
<td>$H_{\text{famp}}$ [mbar]</td>
<td>5</td>
<td>100</td>
<td>5</td>
</tr>
<tr>
<td>$H_{\text{Freq}}$ [Hz]</td>
<td>5</td>
<td>20</td>
<td>5</td>
</tr>
<tr>
<td>$P_{\text{mean}}$</td>
<td>5</td>
<td>50</td>
<td>5</td>
</tr>
<tr>
<td>$I:E$</td>
<td>1:3</td>
<td>1:1</td>
<td>1:3</td>
</tr>
<tr>
<td>Flow [Lpm] (constant / bias)</td>
<td>5</td>
<td>20</td>
<td>5</td>
</tr>
<tr>
<td>$\text{Freq}_{\text{rec}}$ [1 / h]</td>
<td>1</td>
<td>240</td>
<td>1</td>
</tr>
<tr>
<td>$P_{\text{mean rec}}$ [mbar]</td>
<td>7</td>
<td>50</td>
<td>7</td>
</tr>
<tr>
<td>$I-\text{time}_{\text{rec}}$ [sec]</td>
<td>2</td>
<td>60</td>
<td>2</td>
</tr>
</tbody>
</table>

When powering the device by internal battery HFO amplitude is limited to 60 mbar.
16 Guide to volume guarantee

Mechanical Ventilation is required to manage neonates with severe respiratory failure. Pressure-limited ventilation (PLV), delivering a fixed peak inspiratory pressure (PIP), has traditionally been used to control the arterial carbon dioxide (PaCO₂). During PLV the tidal volume (VT) fluctuates widely due to the baby's breathing effort, changes in lung mechanics and variable endotracheal tube (ETT) leak.

For some patients, a strategy of targeting a required exhaled tidal volume while maintaining pressure within a prescribed range can improve gas exchange without the risk of lung injury associated with volume control ventilation in preterm infants.

The fabian™ series of neonatal/pediatric microprocessor-controlled ventilators allow volume-targeted ventilation (VTV) even in very preterm infants. Measurements are done with the Flow Sensor placed at the Y-piece. The Flow Sensor measures inspired and expired VT, and ETT Leak is calculated and displayed. The advantage of targeting inspired volume (VTi) is that the ventilator controls the VTi as it is delivered. The major disadvantage is that variable ETT Leak alters volume entering the lungs. The advantage of using the expired volume (VTe) is that this most accurately reflects the VT that entered the infant's lung and is less influenced by ETT Leaks unless they are very large.

Volume Guarantee (VG) Ventilation is a VTV-mode controlling the VTe.

16.1 fabian volume guarantee (VG) operation

The operator sets a target expired volume VTe (set VTe). The ventilator measures the expired VTe for each inflation and automatically adjusts the PIP(Ppeak) for the next inflation of the same type, triggered or untriggered, aiming to deliver the VTe around the Set Level. The detailed guide how to start VG function on the fabian™ Ventilators is described in detail on the following pages.

The maximum difference in Pressure from breath to breath is limited to one-third of the previous breath to avoid any overdistension due to excessive pressure compensation.

The main issue is to choose an appropriate VTe at the start and to give enough pressure to get it in. The following procedure describes the use of VG in (A / C) - SIPPV mode, however, the same procedure can be followed in the other modes where VG function is available. IPPV, SIPPV, SIMV+PSV and PSV.

Look at what VTe the baby is currently getting with the current ventilation settings. You can get this value from the Measured Parameters displayed on the right side of the display.

The usual VTe to aim for is 4 to 6mL/kg per breath. Starting with 5mL/kg is usually a safe point but could be slightly high for some babies.

Look at the pressure settings. The pressure settings are alarm settings. If the ventilator cannot deliver the VTe at the maximum pressure prescribed, it will alarm "Tidal Volume not reached". You may need to increase the Pmax to stop it from alarming.

The Rate Setting is a “back-up” rate if the baby is not breathing. However, it should be set 10 to 15 breaths below the baby’s apparent rate so that the baby has an opportunity to Trigger.

If VG is added to the SIPPV, each breath is maintained at same Exhaled Tidal Volume. In case of an improvement of lung compliance, the Pinsp is automatically reduced.

Every single Inspiratory effort of the patient is supported with a mechanical breath with fixed Inspiratory time and pressure. If the breath was triggered by patient, it is colored Green on the waveform graphics, if none triggered, Grey. The baby controls the rate of ventilation.
16.2 Initial settings

I-flow 8 L/min  
E-flow 6 L/min  
Rate between 35 to 40 B/min  
Inspiratory Time between 0.3 to 0.4 seconds  
Pinsp between 16 to 18 mbar  
PEEP 4 to 6 mbar

16.3 How to start the VG function

Step 1  
Setup Ventilator in SIPPV and start ventilation.

Step 2  
Select the appropriate VT to be Guaranteed.

IMPORTANT: To ensure the VG function works appropriately, a small plateau in the Tidal Volume wave needs to be present. Do not set the inspiratory time to a value too short to allow the plateau pressure to be reached.
Step 3
Set in the Pmax area, the maximal pressure value to which the VG function can regulate.

Triggered and non-triggered breaths are independently supported based on lung compliance. Normally, a triggered breath has a lower Pinsp than a non-triggered one due to the effort provided by the patient.
Step 4
VG can now be activated by selecting the **ON / OFF** button. When VG function is ON, this button will turn **Green**. A **Red** line will appear in the Pressure Wave diagram to mark the Pmax.
NOTE:
If the Targeted Volume cannot be reached with the set $P_{\text{max}}$, a warning saying: "Vte not reached / check settings" will be displayed. An upward pointing arrow will appear in the "Pmax" area to indicate the maximum pressure has been reached.

In case the flow sensor is deactivated, the VG will be shut off and the pre-set $P_{\text{insp}}$ will be used to ventilate.
16.4 Setting up the ventilator PSV+VG

If Volume Guarantee is added to PSV, the Ventilator automatically is adjusting the PPSV level necessary to maintain the preset Target Volume. In case of an Apnea, the Ventilator will start cycling at a preset rate and PBackup. As soon as spontaneous activity restarts, the backup stops.

Settings to start with:

- I-Flow: 8 L/min
- E-Flow: 8 L/min
- Frequency (Rate): between 30 to 40 BPM – Safety backup rate in case of apnea
- Inspiratory time: between 0.3s to 0.4s – Used for backup and as max I-Time
- PBackup: between 16 to 18 cmH₂O used during apnea backup ventilation
- PBackup: PPSV 16 to 18 cmH₂O
- PEEP: 4 to 6 cmH₂O

The minimum pressure difference between PEEP and PPSV is always 2 cmH₂O and P_PSV is limited not to exceed the set P_{insp}.

PSV breaths and Apnea backup breaths are Volume Targeted Breaths in this mode. The delay to start backup Ventilation is set with the Apnea time in Alarm Limit screen.

If Apnea is set to OFF → backup starts after E-time.

In PSV+VG mode, the patient controls the onset of Inspiration as well as the end of Inspiration, offering a total synchrony with patients breathing pattern.

If patient lung compliance is improving, the Ventilator automatically is using the Lowest Pressure, necessary to maintain the Preset Target Volume.

In case of a respiratory fatigue and a ceasing Inspiratory effort, the ventilator automatically provides an Apnea Backup Ventilation with the preset parameters for I-time, Frequency and Pbackup. The delay for the onset of the Apnea Backup Ventilation is set in the Alarm screen, by setting the Apnea Delay Time. If Apnea Backup Ventilation is set to OFF, the ventilator starts Apnea Backup Ventilation immediately after E-time, otherwise after Preset Apnea Time.

We recommend using a delay time to prevent the ventilator from starting unnecessarily and interfering with patient’s breathing pattern.

The apnea backup breaths are volume guaranteed breaths.
17 Special procedures

17.1 Use of NO (Nitric Oxide)

IMPORTANT:
If Nitric Oxide Systems like the InoMax or InoVent are used to deliver NO, make sure the setup of the circuit is done as per below graphic. It is important to place the flow sensor of the NO delivery system directly at the fresh gas outlet of the fabian HFO.

The measuring line must be placed close to patient in Inspiratory Limb.

1. fabian Ventilator
2. Patient Gas Sample Line with Nafion
3. Injector Module Electrical Cable
4. INOmax DSIR
5. NO/N2 Injector Tube
6. Connecting Tube (15 inches)
7. 15M x 15M Adapter
8. Injector module
9. 22F x 15M Adapter
10. Humidifier
11. Inspiratory Breathing Circuit Hose
12. Gas Sample Tee
13. Patient Wye
14. Proximal Pressure Tube
15. Expiratory Breathing Circuit Hose
18 Technical specifications

18.1 Ambient conditions

| During operation:          | 10 to 40°C (50 to 104 °F)       |
|                           | 70 to 106 kPa                   |
|                           | 10 to 90%, non-condensing       |
| During transportation:    | -20 to 60°C (-4 to 140 °F)      |
|                           | 50 to 106 kPa                   |
|                           | 10 to 90%, non-condensing       |
| During storage:           | 0 to 40°C (+32°F to 104 °F)     |
|                           | 70 to 106 kPa                   |
|                           | 20 to 80%, non-condensing       |

The Minimum and Maximum Ambient temperatures in the clinical area will not affect the accuracy of the Flow, Pressure or Oxygen measurement.

18.2 Monitoring

Acoustic Pressure of Alarm tones. Alarm tone sequence according to IEC 60601-1-8:

- **High Priority:** 52.5 to 68.6 dB(A)
- **Medium Priority:** 52.4 to 67.9 dB(A)
- **Low Priority:** 50.4 to 66.9 dB(A)

A weighted sound pressure level in 1m distance: 46 dB

**Expiratory Minute Volume**

- Alarm Lower threshold Value: If Lower Alarm Limit not reached
- Alarm Upper threshold Value: If Upper Alarm Limit exceeded

**Airway Pressure**

- Alarm Lower threshold Value: If Lower Alarm Limit not reached
- Alarm Upper threshold Value: If Upper Alarm Limit exceeded
- maximum airway pressure: <125 mbar

**Inspiratory O₂ concentration**

- Alarm: Set Value ±5 Vol% for >1 minute at setting of 21 Vol% below threshold Value 18 Vol%

**Breath Frequency**

- Alarm: If Alarm Limit exceeded

**Volume Monitoring**

- Alarm Lower Threshold Value: If the breath volume set was not supplied

**Apnea Alarm**

- Alarm: If no breathing activity is recognized
18.3 Measuring

Airway measurement Range: 
-10 to 125 mbar
Accuracy\(^2\): ±4%
Resolution: 0.1 to 1 mbar

Breath volume measurement Range: 0 to 999 mL (BTPS) (inspiratory and expiratory)
Accuracy\(^2\): ±8%
Resolution: 0.1 to 100 mL

Volume Controlled Breaths:
Max. Bias Error: 0.5 mL
Max. Linearity Error: (±0.5 mL + 10% of the set volume)
Max. Error delivered vs. Set Volume: 0.5 mL at 1mL, 1 mL at 10 mL, 8 mL at 100 mL
Max. Error in delivered vs Set PEEP: 0.5 mbar <10 mbar, 1 mbar >10 mbar

Pressure Controlled Breaths:
Max. Bias Error: 0.5 mbar
Max. Linearity Error: 3%
Max. Error of Airway Pressure (Paw): (±0.5 mbar + 3% of the set pressure)
Max. Error in delivered vs. Set PEEP: 0.5 mbar <10 mbart, 1 mbar >10 mbar

Inspiratory Oxygen Concentration:
Inspiratory O\(_2\) Concentration Range: 18 to 100 Vol%
Max. Error delivered vs. Set FiO\(_2\) with oxygen monitoring\(^2\): 3% FiO\(_2\).
Max. Error delivered vs. Set FiO\(_2\) without oxygen monitoring\(^2\): 5% FiO\(_2\).
Response Time to change in FiO\(_2\): Conventional Ventilation: blender delay is 1 breath. HFO mode: blender delay is 500ms.
Total Delay = Blender Delay + Pneumatic Delay
Drift: <1 Vol% per month. <15% rel. over entire service life
Pressure Influence: Proportional to change in Partial Pressure
Warm-Up Time: max. 3 minutes (<30 minutes with New O\(_2\) Sensor)

Tube Leak Range: 10 to 50%
Accuracy\(^2\): ±10%
Resolution: 1% mL
Dynamic Compliance Range: 0 to 500 mL / mbar
Accuracy\(^2\): ±8%
Resolution: 0.1 to 1 mL / mbar

\(^2\) Measurement uncertainty during performance verification

For pressure measurements: ± 1.75% of reading or 0.1 mbar (whichever is greater)
For volume measurements: ± 1.75% of reading or 0.1 mL (whichever is greater)
For oxygen level measurements: ± 1% absolute
18.4 Resistance values

System Resistance at 30 Lpm  
Inspiratory Resistance  
Expiratory Resistance

18.5 Ventilation menu settings

<table>
<thead>
<tr>
<th>Alarm delay</th>
<th>0 to 30 seconds</th>
</tr>
</thead>
<tbody>
<tr>
<td>Automatic O₂ calibration</td>
<td>21% Vol.</td>
</tr>
<tr>
<td>E-flow</td>
<td>1 to 32 Lpm</td>
</tr>
<tr>
<td>Manual breath in HFO</td>
<td>Enabled</td>
</tr>
<tr>
<td>Max. time Manual breath</td>
<td>2 to 30 seconds</td>
</tr>
<tr>
<td>NIV Leak compensation</td>
<td>Off / Low / Middle / High</td>
</tr>
<tr>
<td>NIV Tube set</td>
<td>MediJet</td>
</tr>
<tr>
<td>Pₚₚₛᵥ parameter</td>
<td>Set as absolute value</td>
</tr>
<tr>
<td>Ratio of I-time</td>
<td>Set as frequency / I-time</td>
</tr>
<tr>
<td>Termination criteria PSV</td>
<td>1 to 85%</td>
</tr>
<tr>
<td>Trigger (Conventional)</td>
<td>Volume trigger</td>
</tr>
<tr>
<td>Unit for Pressure</td>
<td>mbar</td>
</tr>
<tr>
<td>Use BTB for Vt</td>
<td>Enabled</td>
</tr>
<tr>
<td>Vₗⁱᵐⁱᵗ / Vₙᵣ₉ₐʳᵃⁿᵗ</td>
<td>Vₗⁱᵐⁱᵗ</td>
</tr>
</tbody>
</table>
## 18.6 Dimensions / weight

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>W x H x D</td>
<td>30 cm x 37 cm x 42 cm</td>
</tr>
<tr>
<td>Weight</td>
<td>≈ 20 kg with HFO module&lt;br&gt;≈ 14 kg without HFO module</td>
</tr>
</tbody>
</table>

## 18.7 Ratings

<table>
<thead>
<tr>
<th>Device Fuse</th>
<th>T 1.25A L 250V</th>
</tr>
</thead>
<tbody>
<tr>
<td>Internal Battery</td>
<td>16.8 V&lt;br&gt;4500 mAh&lt;br&gt;max. charging time: 5 hours&lt;br&gt;Battery charge is continuously monitored&lt;br&gt;Battery life in HFO mode: 1 hour&lt;br&gt;Battery life in Conventional mode (IPPV): 2.5 hours&lt;br&gt;Battery type: NiMH</td>
</tr>
<tr>
<td>IP Protection</td>
<td>From SN AI-01500 and AL-00400: IP 22&lt;br&gt;Till SN AI 01500 and AL00400: IPX1</td>
</tr>
<tr>
<td>Oxygen supply</td>
<td>From SN AI-01500 and AL-00400:&lt;br&gt;2.0 to 6.0 bar / max. 40 L/min&lt;br&gt;Till SN AI-01500 and AL-00400:&lt;br&gt;2.0 to 6.5 bar / max. 40 L/min&lt;br&gt;Connection thread: NIST&lt;br&gt;Note: Medical grade oxygen</td>
</tr>
<tr>
<td>Power rating</td>
<td>IPPV mode: max. 70 W&lt;br&gt;HFO mode: max. 100 W&lt;br&gt;Standby, fabian connected to Mains: 35 W (Battery charging)</td>
</tr>
<tr>
<td>Power supply</td>
<td>100 to 240 VAC&lt;br&gt;0.5 to 0.9 A&lt;br&gt;50 / 60 Hz</td>
</tr>
<tr>
<td>Pressurized air supply</td>
<td>From SN AI-01500 and AL-00400:&lt;br&gt;2.0 to 6.0 bar / max. 40 L/min&lt;br&gt;Till SN AI-01500 and AL-00400:&lt;br&gt;2.0 to 6.5 bar / max. 40 L/min&lt;br&gt;Connection thread: NIST&lt;br&gt;Note: Medical grade air</td>
</tr>
<tr>
<td>Safety Classification (Applied Parts)</td>
<td>From SN AI-01500 and AL-00400: Type BF&lt;br&gt;Till SN AI-01500 and AL-00400: Type B</td>
</tr>
<tr>
<td>Electrical Safety Classification</td>
<td>Class I (mains power)&lt;br&gt;Internally powered (battery power)</td>
</tr>
<tr>
<td>Sound Pressure</td>
<td>Max. 52 dB (A)</td>
</tr>
</tbody>
</table>
18.8 Data storage

<table>
<thead>
<tr>
<th></th>
<th>Maximum: 1.000 messages.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alarms</td>
<td></td>
</tr>
<tr>
<td>Log</td>
<td>Maximum: 10 Log Files.</td>
</tr>
<tr>
<td></td>
<td>Log is stored during power failure.</td>
</tr>
<tr>
<td></td>
<td>When Log capacity is reached index, is shifted and oldest log file deleted.</td>
</tr>
<tr>
<td>Trend</td>
<td>Maximum: 5 days.</td>
</tr>
<tr>
<td></td>
<td>Storage: every 30 seconds.</td>
</tr>
</tbody>
</table>

18.9 Applied parts

Applied parts for the device are Nebulizer, Flow Sensor, SpO2 module (type BF) and tube set (type B).

18.10 Internal device checks

The following internal device checks are performed on Startup:

- COM: Communication between GUI and Conductor PIC.
- DIO: Communication between GUI and Digital I/O.
- I²C: Communication between GUI to Accu PIC, NVRAM and Multiplexer.
- PIF: Communication between GUI and Parallel Interface
- Relay: Check from the SPI
- SPI: Communication between GUI and Monitor PIC.
- SPI/Cks: SPI Checksum
- Voltage: Voltage Error Check from the SPI

18.11 Gas blender function

The Air / Oxygen Blender provides a Gas blend with adjustable proportions of Oxygen and Air. Gas from the central gas supply enters the device through the gas input connections.

Blending of the gases occurs through two proportional valves. The proportional valves, which also act as return valves, prevent the return flow of a gas into the supply line of the other gas. An Oxygen sensor measures the Inspiratory Oxygen Concentration.
Internal Gas Blending function of the fabian HFO

1. Oxygen 2.0 to 6.0 bar
2. Air 2.0 to 6.0 bar
3. Filters
4. Pressure regulators
5. Pressure Sensors
6. Proportional valves
7. To manifold

The fraction of oxygen concentration, measured at the patients mouth, does not change immediately when changing the O\textsubscript{2} concentration on the ventilator. The response time depends on the delivered volume, the set base flow, the used the circuits and the change in fraction of oxygen. When using the Altera circuits and the below listed ventilator settings, the new O\textsubscript{2} levels are reached after 45 sec respectively 75 sec.

<table>
<thead>
<tr>
<th>Change in O\textsubscript{2}</th>
<th>Set base flow</th>
<th>Set tidal volume</th>
<th>Time to reach O\textsubscript{2} level</th>
</tr>
</thead>
<tbody>
<tr>
<td>21% to 90%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>21% to 90%</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

For more information, refer to the Technical Service Manual.
## 18.12 Essential Performance

<table>
<thead>
<tr>
<th>#</th>
<th>Essential Performance Function</th>
<th>Standard</th>
<th>Clause</th>
</tr>
</thead>
</table>
| 1 | Delivery of ventilation at the patient-connection port within the alarm limits set by the operator; ¹ or the following alarm conditions shall occur as appropriate:  
• Low battery as internal electrical power source nears depletion;  
• Low and High Minute Volume;  
• Low and High PEEP;  
• Obstruction/Occlusion;  
• Low and High Air/Oxygen Inlet Pressure;  
• Air/Oxygen Gas Supply Failure; or a technical alarm condition shall occur. | ISO 80601-2-12: 2011 | 201.101.1 |
| 2 | Measurement accuracy of the oxygen respiratory gas monitor (RGM) is maintained within the IFU specification, ± (3% absolute); or Low and High Oxygen Level alarm conditions shall occur, as appropriate; or a technical alarm condition shall occur. | ISO 80601-2-12: 2011 | 201.12.4.101 |
| 3 | Measurement accuracy of the etCO₂ RGM is maintained within the IFU specification:  
0 to 38 mmHg  
± 2 mmHg  
39 to 150 mmHg  
± (5% of reading + 8% of (reading – 39 mmHg)); or Low and High CO₂ Level alarm conditions shall occur, as appropriate; or a technical alarm condition shall occur. | ISO 80601-2-55: 2018 | 201.11.8.101.1 |
| 4 | Measurement accuracy of the SpO₂ monitor is maintained within the IFU specification only within the range 70 to 100%:  
± 2% pediatric patients, no motion conditions;  
± 3% pediatric patients, motion conditions, and all neonatal patients; or Low and High SpO₂ Level alarm conditions shall occur, as appropriate; or a technical alarm condition shall occur. | ISO 80601-2-61: 2017 | 201.13.101/.102 |
<p>| 5 | Measurement accuracy of the pulse rate from the SpO₂ monitor is maintained within | ISO 80601-2-61: 2017 | 201.12.1.104 |</p>
<table>
<thead>
<tr>
<th>#</th>
<th>Essential Performance Function</th>
<th>Standard</th>
<th>Clause</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>the IFU specification within the range 25 to 240 bpm: ± 3 bpm (no motion conditions); or ± 5 bpm (motion conditions); <em>or</em> Low and High Pulse Rate alarm conditions shall occur, as appropriate; <em>or</em> a technical alarm condition shall occur.</td>
<td></td>
<td>208.6.1.2.101</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>201.11.8.101.1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>201.12.4</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>201.13.101</td>
</tr>
</tbody>
</table>
19 Electromagnetic compatibility statement

**NOTE:**
fabian HFO is a MEDICAL APPLIANCE subject to specific precautionary measures regarding EMC and must be installed and started up according to the notices and the instructions in this manual.

**WARNING:**
Portable medical HF communication devices could impact fabian HFO.

**WARNING:**
NEVER use fabian HFO directly adjacent to, or stack with other equipments. If unavoidable, be sure to monitor the equipment for proper operation with this setup.

**WARNING:**
Using other accessories, cables or converters with fabian HFO could result in increased electromagnetic interference and reduce the immunity of fabian HFO.

**NOTE:**
The key performance characteristics of the fabian HFO ventilator are:

- fabian HFO must operate within the defined specifications and the medical purpose. Failure to meet these specifications will result in respiration being stopped.
- For this reason, a second stand-alone ventilation unit must always be available, *(for example: Resuscitation Bag)*.

19.1 Devices from SN Al-01500 and AL-00400

**Guideline and Manufacturer Declaration – Electromagnetic Emissions**

The device fabian HFO is intended for operation in the environment described below. The customer or operator of the fabian HFO apparatus should ensure it is operated in this type of environment.

<table>
<thead>
<tr>
<th>EMI Measurement</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment – Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF Emission CISPR 11</td>
<td>Group 1</td>
<td>The device fabian HFO uses RF Energy solely for internal operation. Its RF emission is thus very low and interference with adjacent apparatuses is unlikely.</td>
</tr>
<tr>
<td>RF Emission CISPR 11</td>
<td>Class A</td>
<td>The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.&quot;</td>
</tr>
<tr>
<td>harmonic Distortion</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Voltage Fluctuations & Flickers
IEC 61000-3-3

<table>
<thead>
<tr>
<th>Immunity Testing</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment – Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic Discharge (ESD)</td>
<td>Air: ±2kV, ±4kV, ±6kV, ±8kV, ±15kV</td>
<td>Floors should be wooden or concrete or tiled with ceramic tiles. For flooring made from synthetic materials, the Relative Air Humidity must be no less than 30%.</td>
</tr>
<tr>
<td>IEC 61000-4-2</td>
<td>Contact: ±2kV, ±4kV, ±6kV, ±8kV</td>
<td></td>
</tr>
<tr>
<td>Electric Fast Transients &amp; Burst</td>
<td>AC Power Leads: ±2kV</td>
<td>The Mains quality should correspond to typical business or hospital environments.</td>
</tr>
<tr>
<td>IEC 610004-4</td>
<td>SIP / SOP &amp; Control ports: ±1kV</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(All cable lengths tested)</td>
<td></td>
</tr>
<tr>
<td>Surges</td>
<td>Differential Mode (Lead-to-Lead) ±0.5kV, ±1kV</td>
<td>The Mains quality should correspond to typical business or hospital environments.</td>
</tr>
<tr>
<td>IEC 61000-4-5</td>
<td>Common Mode (Lead-to-Ground) ±0.5kV, ±1kV, ±2kV</td>
<td></td>
</tr>
<tr>
<td>Power Frequency Magnetic Fields</td>
<td>30 A/m rms</td>
<td>Magnetic areas at the Mains frequency should correspond to typical values in business and hospital environments.</td>
</tr>
<tr>
<td>IEC 61000-4-8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage Dips, Interruptions &amp;</td>
<td>0% $U_T$ (100% dip of $U_T$) for 0.5 cycles at various phase angles: 0, 45, 90,</td>
<td>The Mains quality should correspond to typical business or hospital environments. If the operator of the fabian HFO requires continued use in the event of a power failure we recommend connecting the fabian HFO to an uninterruptible Mains supply or a Battery.</td>
</tr>
<tr>
<td>Voltage Variations</td>
<td>135, 180, 225, 270, 315</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-4-11</td>
<td>0% $U_T$ (100% dip of $U_T$) for 1 cycle at a phase angle of 0.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>40% $U_T$ (60% dip of $U_T$) for 5 cycles at a phase angle of 0.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>70% $U_T$ (30% dip of $U_T$) for 25 /30 cycles at a phase angle of 0.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0% $U_T$ (100% dip of $U_T$) for 250 /300 cycles at a phase angle of 0.</td>
<td></td>
</tr>
</tbody>
</table>

Remark: $U_T$ is the Mains alternating voltage before applying the Test Level.
**Guideline and Manufacturer Declaration – Electromagnetic Immunity**

The device fabian HFO is intended for operation in the environment described below. The customer or operator of the fabian HFO apparatus should ensure it is operated in this type of environment.

<table>
<thead>
<tr>
<th>Immunity Testing</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment – Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted Disturbances Induced RF Fields</td>
<td>3 Vrms 150 kHz to 80 MHz (a)</td>
<td>Recommended Safety Distance (d)</td>
</tr>
<tr>
<td>IEC 61000-4-6</td>
<td>10 Vrms (ISM bands) 150 kHz to 80 MHz (b)</td>
<td>d = 0.35√P</td>
</tr>
<tr>
<td>Radiated RF Electromagnetic Fields</td>
<td>10 V / m Sweep from 80 MHz to 2.7 GHz</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-4-3</td>
<td>27 V / m 385 MHz</td>
<td>d = 1.2√P 80 MHz to 800 MHz</td>
</tr>
<tr>
<td></td>
<td>28 V / m 450, 810, 870, 930, 1720, 1845, 1970, 2450 MHz</td>
<td>d = 2.3√P 800 MHz to 2.7 GHz</td>
</tr>
<tr>
<td></td>
<td>9 V / m 710, 745, 780, 5240, 5500, 5785 MHz</td>
<td></td>
</tr>
</tbody>
</table>

(P) being the transmitter’s nominal rating in Watts (W) per manufacturer specifications and (d) being the recommended safety distance in meters (m).

The area strength of stationary radio transmitters should be below the compliance level on all frequencies as tested on site c.

Interference could occur in proximity of apparatuses bearing the following symbol: (speaker).

**REMARK 1** 
At 80 MHz and 800 MHz the higher frequency range applies.

**REMARK 2** 
These guidelines may not apply to all cases. The propagation of electromagnetic quantities is influenced by absorption and reflection of buildings, objects and people.

**a** The ISM bands (industrial, scientific and medical) between 150 kHz and 80 MHz are:
- 6.765 to 6.795 MHz;
- 13.553 to 13.567 MHz;
- 26.957 to 27.283 MHz;
- 40.66 to 40.7 MHz

**b** The compliance levels in ISM frequency bands between 150 kHz and 80 MHz and between 80 MHz and 2.5 GHz are defined as such to decrease the probability of mobile/portable transmitters causing interference in the event they are accidentally brought into the vicinity of the patient. For this reason, an additional factor of 10/3 is used when calculating the recommended safety distance of transmitters in this frequency range.
Guideline and Manufacturer Declaration – Electromagnetic Immunity

1. In theory the area intensity of stationary transmitters, as for example: base units of radio telephones (mobile/cordless) and mobile land radio devices, amateur radio stations, AM and FM radio stations and television stations cannot be predefined precisely. A study of the location should be conducted to determine the electromagnetic environment regarding stationary transmitters. If the area intensity at the location where the fabian HFO is used exceeds the above compliance levels, fabian HFO should be monitored for proper function. If unusual performance characteristics are observed, additional measures could be required, as for example: changing the direction or location of the fabian HFO.

2. Above a Frequency Range of 150kHz to 80MHz the area intensity should be below 10 V / m.

Recommended Safety Distances between Portable and Mobile HF communication devices and the device fabian HFO.

fabian HFO is intended to be operated in an electromagnetic environment with controlled HF interferences. The operator of the fabian HFO can help avoid electromagnetic interference by maintaining the minimum distance between portable and mobile HF telecommunication devices (transmitters) and the device fabian HFO – depending on the output rating of the communication device, as listed below.

<table>
<thead>
<tr>
<th>Maximum Transmitter Power Output (W)</th>
<th>Safety Distance depending on transmission Frequency in meter</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150 kHz to 80 MHz outside ISM bands</td>
</tr>
<tr>
<td></td>
<td>( d = 0.35\sqrt{P} )</td>
</tr>
<tr>
<td>0.01</td>
<td>0.04</td>
</tr>
<tr>
<td>0.1</td>
<td>0.13</td>
</tr>
<tr>
<td>1</td>
<td>0.40</td>
</tr>
<tr>
<td>10</td>
<td>1.3</td>
</tr>
<tr>
<td>100</td>
<td>4.0</td>
</tr>
</tbody>
</table>

For transmitters with a maximum power output not listed in the above table the recommended Safety Distance (\( d \)) in meters (m) can be determined using the equation from the corresponding column, with \( P \) being the transmitter’s maximum power output in Watts (W) per the transmitter’s manufacturer specifications.

REMARK 1  At 80 MHz and 800 MHz the Safety Distance of the Higher frequency applies.

REMARK 2  The ISM bands (industrial, scientific and medical) between 150 kHz and 80 MHz are:
- 6.765 to 6.795 MHz
- 13.553 to 13.567 MHz
- 26.957 to 27.283 MHz
- 40.66 to 40.7 MHz

REMARK 3  An additional factor of \( 10/3 \) is used when calculating the recommended Safety Distance for transmitters within the ISM frequency between 150 kHz and 80 MHz and between 80 MHz and 2.5 GHz to reduce the probability of mobile/portable transmitters causing interference if accidentally brought into the vicinity of the patient.

REMARK 4  These guidelines may not apply to all case. The propagation of electromagnetic quantities is influenced by Absorption and Reflection of Buildings, Objects and People.
# Electromagnetic compatibility statement

## 19.2 Devices till SN AI-01500 and AL-00400

### Guideline and manufacturer declaration – electromagnetic emission

The device “fabian HFO” is intended for operation in the environment described below. The customer or user of the “fabian HFO” apparatus should ensure it is operated in this type of environment.

<table>
<thead>
<tr>
<th>EMI measurement</th>
<th>Compliance</th>
<th>Electromagnetic environment – guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>HF emission CISPR 11</td>
<td>Group 1</td>
<td>The device &quot;fabian HFO&quot; uses HF energy solely for internal operation. Its HF emission is thus very low and interference with adjacent apparatuses is unlikely.</td>
</tr>
<tr>
<td>HF emission CISPR 11</td>
<td>Class A</td>
<td>The device &quot;fabian HFO&quot; is suitable for use in all other areas except residential areas and areas directly connected to a public mains supply which also supplies buildings used for residential purposes.</td>
</tr>
<tr>
<td>Emission of harmonics IEC 61000-3-2</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>Emission of voltage fluctuations / flickers IEC 61000-3-3</td>
<td>Not applicable</td>
<td></td>
</tr>
</tbody>
</table>
Guideline and manufacturer declaration – electromagnetic immunity

The device "fabian HFO" is intended for operation in the environment described below. The customer or user of the "fabian HFO" apparatus should ensure it is operated in this type of environment.

<table>
<thead>
<tr>
<th>Immunity testing</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment – guideline</th>
</tr>
</thead>
</table>
| Electrostatic discharge (ESD) | ± 6 kV contact ± 8 kV air | ± 6 kV contact ± 8 kV air | Floors should be wooden or concrete or tiled with ceramic tiles. For flooring made from synthetic materials the relative air humidity must be no less than 30%.
| Quick electric transients/burst | ± 2kV for power cords ± 1kV for in-/output cables | ± 2kV for power cords ± 1kV for in-/output cables | The mains quality should correspond to typical business or hospital environments.
| Surges | ± 1 kV lead to lead ± 2 kV lead to ground | ± 1 kV lead to lead ± 2 kV lead to ground | The mains quality should correspond to typical business or hospital environments.

<table>
<thead>
<tr>
<th>Voltage drops, temporary power failures and fluctuations</th>
<th>IEC 61000-4-11</th>
<th>&lt;5% $U_T$ (&gt;95% drop of $U_T$) for ½ period</th>
<th>&lt;5% $U_T$ (&gt;95% drop of $U_T$) for ½ period</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>40% $U_T$ (60% drop of $U_T$) for 5 periods</td>
<td>40% $U_T$ (60% drop of $U_T$) for 5 periods</td>
</tr>
<tr>
<td></td>
<td></td>
<td>70% $U_T$ (30% drop of $U_T$) for 25 periods</td>
<td>70% $U_T$ (30% drop of $U_T$) for 25 periods</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&lt;5% $U_T$ (&gt;95% drop of $U_T$) for 5 seconds</td>
<td>&lt;5% $U_T$ (&gt;95% drop of $U_T$) for 5 seconds</td>
</tr>
</tbody>
</table>
|                                                          |                | The mains quality should correspond to typical business or hospital environments. If the operator of the "fabian HFO" requires continued use in the event of a power failure we recommend connecting the "fabian HFO" to an uninterruptible mains supply or a battery.

<table>
<thead>
<tr>
<th>Magnetic field at supply frequency (50/60 Hz)</th>
<th>IEC 61000-4-8</th>
<th>3 A/m</th>
<th>3 A/m</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Magnetic fields at the mains frequency should correspond to typical values in business and hospital environments.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Remark $U_T$ is the mains alternating voltage prior to applying the test level.
**Guideline and manufacturer declaration – electromagnetic immunity**

The device "fabian HFO" is intended for operation in the environment described below. The customer or user of the "fabian HFO" apparatus should ensure it is operated in this type of environment.

<table>
<thead>
<tr>
<th>Immunity testing</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment – guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>HF interference currents IEC 61000-4-6</td>
<td>3 V_{eff} 150 kHz to 80 MHz beyond ISM bands a</td>
<td>10 V</td>
<td>Never use portable or mobile radio devices closer to the &quot;fabian HFO&quot;, including cables, than the recommended safety distance calculated using the equation applicable to the transmission frequency.</td>
</tr>
<tr>
<td></td>
<td>10 V_{eff} 150 kHz to 80 MHz within ISM bands b</td>
<td>10 V</td>
<td>Recommended safety distance</td>
</tr>
<tr>
<td></td>
<td>10 V/m 80 MHz to 2.5 GHz</td>
<td>10 V/m</td>
<td>d = 0.35 \sqrt{P}</td>
</tr>
</tbody>
</table>

**REMARK 1** At 80 MHz and 800 MHz the higher frequency range applies.

**REMARK 2** These guidelines may not apply to all case. The propagation of electromagnetic quantities is influenced by absorption and reflexion of buildings, objects and people.

a The ISM bands (industrial, scientific and medical) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.7 MHz.

b The compliance levels in ISM frequency bands between 150 kHz and 80 MHz and between 80 MHz and 2.5 GHz are defined as such so as to decrease the probability of mobile/portable transmitters causing interference in the event they are accidentally brought in to the vicinity of the patient. For this reason an additional factor of 10/3 is used when calculating the recommended safety distance of transmitters in this frequency range.

c In theory the field intensity of stationary transmitters, as e.g. base units of radio telephones (mobile/cordless) and mobile land radio devices, amateur radio stations, AM and FM radio stations and television stations cannot be predefined precisely. A study of the location should be conducted to determine the electromagnetic environment with regard to stationary transmitters. If the field intensity at the location where the "fabian HFO" is used exceeds the above compliance levels, “fabian HFO” should be monitored for proper function. If unusual performance characteristics are observed, additional measures may be required, as e.g. changing the direction or location of the "fabian HFO".

d Above a frequency range of 150kHz to 80MHz the field intensity should be below 10 V/m.
Recommended safety distances between portable and mobile HF communication devices and the device "fabian HFO"

"fabian HFO" is intended to be operated in an electromagnetic environment with controlled HF interferences. The operator of the "fabian HFO" can help avoid electromagnetic interference by maintaining the minimum distance between portable and mobile HF telecommunication devices (transmitters) and the device "fabian HFO" – depending on the output rating of the communication device, as listed below.

<table>
<thead>
<tr>
<th>Maximum transmitter power output W</th>
<th>Safety distance depending on transmission frequency m</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150 kHz to 80 MHz outside ISM bands</td>
</tr>
<tr>
<td>0.01 W</td>
<td>d = 0.35√P</td>
</tr>
<tr>
<td>0.1 W</td>
<td>0.04</td>
</tr>
<tr>
<td>1 W</td>
<td>0.13</td>
</tr>
<tr>
<td>10 W</td>
<td>1.3</td>
</tr>
<tr>
<td>100 W</td>
<td>4.0</td>
</tr>
</tbody>
</table>

For transmitters with a maximum power output not listed in the above table the recommended safety distance d in metres (m) can be determined using the equation from the corresponding column, with P being the transmitter’s maximum power output Watts (W) per the transmitter’s manufacturer specifications.

REMARK 1  At 80 MHz and 800 MHz the safety distance of the higher frequency applies.

REMARK 2  The ISM bands (industrial, scientific and medical) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.7 MHz.

REMARK 3  An additional factor of 10/3 is used when calculating the recommended safety distance for transmitters within the ISM frequency between 150kHz and 80 MHz and between 80MHz and 2.5GHz to reduce the probability of mobile/portable transmitters causing interference if accidentally brought into the vicinity of the patient.

REMARK 4  These guidelines may not apply to all case. The propagation of electromagnetic quantities is influenced by absorption and reflexion of buildings, objects and people.
### Appendix A Glossary

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apnea</td>
<td>Temporary inability to breathe.</td>
</tr>
<tr>
<td>Atelectasis</td>
<td>The collapse or closure of a lung resulting in reduced or absent gas exchange.</td>
</tr>
<tr>
<td>Audible</td>
<td>Able to be heard.</td>
</tr>
<tr>
<td>Bias Flow</td>
<td>The continuous flow of gas responsible for replenishing oxygen and removing carbon dioxide (CO₂) from the patient circuit.</td>
</tr>
<tr>
<td>DUOPAP</td>
<td>Time triggered, time cycled pressure SIPPVs at two separate pressure levels.</td>
</tr>
<tr>
<td>B/min</td>
<td>Breaths-per-minute (applies to each spontaneous, triggered and mandatory).</td>
</tr>
<tr>
<td>Checksum</td>
<td>A digit representing the sum of the correct digits in a piece of stored or transmitted digital data, against which later comparisons can be made to detect errors in the data.</td>
</tr>
<tr>
<td>COM</td>
<td>Communication interface with system.</td>
</tr>
<tr>
<td>CSV</td>
<td>Comma Separated Values.</td>
</tr>
<tr>
<td>DCO₂</td>
<td>A value determined by capnography which corresponds to the difference between the arterial and alveolar end-tidal CO₂, which is normally 2 to 3 mmHg.</td>
</tr>
<tr>
<td>Derecruitment</td>
<td>Can occur due to the following respiratory episodes:</td>
</tr>
<tr>
<td></td>
<td>• Low tidal volume ventilation</td>
</tr>
<tr>
<td></td>
<td>• Inadequate positive end-expiratory pressure (PEEP)</td>
</tr>
<tr>
<td></td>
<td>• Use of high FiO₂ (absorption atelectasis)</td>
</tr>
<tr>
<td>DIO</td>
<td>Digital Input / Output interface. Relay digital signals from sensors, transducers, and mechanical equipment to other electrical circuits and devices.</td>
</tr>
<tr>
<td>EtCO₂</td>
<td>Waveform capnography represents the amount of carbon dioxide (CO₂) in exhaled air, which assesses ventilation. It consists of a number and a graph. The number is capnometry, which is the partial pressure of CO₂ detected at the end of exhalation. This is end-tidal CO₂ (EtCO₂) which is normally 35 to 45 mm.</td>
</tr>
<tr>
<td>FiO₂</td>
<td>Fraction of Inspired Oxygen. A fraction of oxygen in the volume being measured.</td>
</tr>
<tr>
<td>Generator</td>
<td>Patient attachment for delivering CPAP, used with nasal prongs and mask.</td>
</tr>
<tr>
<td>IP</td>
<td>Ingress protection rating.</td>
</tr>
<tr>
<td>IR</td>
<td>Infrared radiation [wavelength around 700 nanometers (nm)].</td>
</tr>
<tr>
<td>Leaks</td>
<td>Leakage from patient or system tubings /connections.</td>
</tr>
<tr>
<td>LED</td>
<td>Light Emitting Diode.</td>
</tr>
<tr>
<td>LNCS</td>
<td>Low Noise Cable Sensors (Masimo trade mark).</td>
</tr>
<tr>
<td>MRI</td>
<td>Magnetic Resonance Imaging.</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
</tr>
<tr>
<td>--------------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>MRT</td>
<td>Magnetic Resonance Therapy.</td>
</tr>
<tr>
<td>MV</td>
<td>Mechanical Ventilation.</td>
</tr>
<tr>
<td>NIV</td>
<td>Non-invasive Ventilation</td>
</tr>
<tr>
<td>NO</td>
<td>Nitric oxide.</td>
</tr>
<tr>
<td>NVRAM</td>
<td>Non-Volatile Random-Access Memory.</td>
</tr>
<tr>
<td>O₂ Flush</td>
<td>Delivers oxygen directly into the common gas outlet without passing through a flowmeter or vaporizer.</td>
</tr>
<tr>
<td>PACU</td>
<td>Post-anesthesia care Unit sometimes referred to as Post-Anesthesia Recovery (PAR).</td>
</tr>
<tr>
<td>PDMS</td>
<td>Patient Data Management System.</td>
</tr>
<tr>
<td>PIC</td>
<td>Peripheral Interface Controller.</td>
</tr>
<tr>
<td>Plethysmograph</td>
<td>An instrument for measuring changes in volume within an organ or whole body (usually resulting from fluctuations in the amount of blood or air it contains).</td>
</tr>
<tr>
<td>RAM Cannula</td>
<td>An oxygen delivery device that can be used as an alternative approach to deliver positive pressure.</td>
</tr>
<tr>
<td>Recruitment maneuver</td>
<td>Transient increases in transpulmonary pressure designed to open collapsed parts of the lung. Primarily used in Acute Respiratory Distress Syndrome (ARDS).</td>
</tr>
<tr>
<td>Resistance</td>
<td>The opposition to flow caused by the forces of friction. It is defined as the ratio of driving pressure to the rate of air flow. Resistance to flow in the airways depends on whether the flow is laminar or turbulent, on the dimensions of the airway, and on the viscosity and density of the gas.</td>
</tr>
<tr>
<td>RSBI</td>
<td>Rapid Shallow Breathing Index. The ratio of respiratory frequency to tidal volume (f/VT).</td>
</tr>
<tr>
<td>SPI</td>
<td>Serial Peripheral Interface. A synchronous serial communication interface specification used for short distance communication, primarily in embedded systems.</td>
</tr>
<tr>
<td>SpO₂</td>
<td>Peripheral capillary oxygen saturation.</td>
</tr>
<tr>
<td>Surfactant</td>
<td>A surface-active lipoprotein complex (phospholipidprotein) formed by type II alveolar cells. The proteins and lipids that make up the surfactant have both hydrophilic and hydrophobic regions.</td>
</tr>
<tr>
<td>Test Lung</td>
<td>Used for testing Ventilator equipment.</td>
</tr>
<tr>
<td>Trend</td>
<td>A general direction in which something is developing or changing.</td>
</tr>
<tr>
<td>USB</td>
<td>Universal Serial Bus, communication cables and connections.</td>
</tr>
<tr>
<td>USB HPLPM</td>
<td>Link Power Management.</td>
</tr>
<tr>
<td>VGA</td>
<td>Video Graphics Array.</td>
</tr>
<tr>
<td>Vte</td>
<td>Tidal Volume is the lung volume representing the normal volume of air displaced between normal inhalation and exhalation when extra effort is not applied.</td>
</tr>
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