IMPORTANT

Note
The Gradian Prima is manufactured for Gradian Health Systems by Penlon Limited.

Servicing and Repairs
In order to ensure the full operational life of this device, servicing by an engineer trained by the manufacturer should be undertaken periodically.

The machine must be serviced to the schedule detailed in section 7.1.

Details of these operations are in the Prima service manual, which contains servicing procedures etc. Servicing should be carried out by engineers trained by Gradian Health Systems.

For any enquiry regarding the servicing or repair of this device, contact the nearest accredited Gradian agent:

or communicate directly with:
Technical Support
Gradian Health Systems
Tel: +254 794 764 415
E-mail: info@gradianhealth.org

Always give as much of the following information as possible:
1. Type of equipment
2. Product name
3. Serial number
4. Approximate date of purchase
5. Apparent fault

NOTE
The serial number can be found on the device ID label
This manual has been produced to provide authorised personnel with information on the function, routine, performance and maintenance checks applicable to the Prima anaesthetic machine.

Information contained in this manual is correct at the date of publication. The policy of the manufacturer is one of continued improvement to their products. Because of this policy the manufacturer reserves the right to make any changes which may affect instructions in this manual, without giving prior notice.

Personnel must make themselves familiar with the contents of this manual and the machine function before using the apparatus.

**IMPORTANT OF PATIENT MONITORING**

**WARNING**

Anaesthesia systems have the capability to deliver mixtures of gases and vapours to the patient which could cause injury or death unless controlled by a qualified anaesthetist.

There can be considerable variation in the effect of anaesthetic drugs on individual patients so that the setting and observation of control levels on the anaesthesia system does not in itself ensure total patient safety.

Anaesthesia system monitors and patient monitors are very desirable aids for the anaesthetist but are not true clinical monitors as the condition of the patient is also dependent on his respiration and the functioning of his cardio-vascular system.

**IT IS ESSENTIAL THAT THESE ELEMENTS ARE MONITORED FREQUENTLY AND REGULARLY AND THAT ANY OBSERVATIONS ARE GIVEN PRECEDENCE OVER MACHINE CONTROL PARAMETERS IN JUDGING THE STATE OF A CLINICAL PROCEDURE.**

Before using any monitoring system or device, the user must check that it conforms to the relevant standards.
# Contents

1. **Warnings and Cautions** ................................................................. 2
2. **Purpose** .................................................................................. 4
3. **Description** ........................................................................... 5
   3.1 General Construction .............................................................. 5
   3.2 Gas Circuit ........................................................................... 5
   3.3 Front View ........................................................................... 7
   3.4 Rear View ........................................................................... 7
   3.5 Communications Port .......................................................... 7
   3.6 Control Panel ....................................................................... 8
   3.7 Electrical Power Supply ....................................................... 9
   3.8 Vaporizers .......................................................................... 11
   3.9 Absorber ............................................................................ 12
   3.10 Auxiliary Common Gas Outlet (ACGO) and O₂ Flush control ........................................ 14
   3.11 Anaesthetic Gas Scavenging System (AGSS) ........................................... 14
   3.12 Ventilator .......................................................................... 15
   3.13 Patient monitoring - Parameters ............................................ 16
   3.14 Alarm system ..................................................................... 17
4. **Specification** .......................................................................... 18
   4.1 Physical ................................................................................ 18
   4.2 Gas Supplies ........................................................................ 18
   4.3 Gas Supply Pressure ............................................................. 19
   4.4 Flowmeter Tubes ................................................................ 19
   4.5 Auxiliary Oxygen Supply ...................................................... 19
   4.6 Auxiliary Common Gas Outlet (ACGO) .................................. 19
   4.7 Oxygen Flush ...................................................................... 19
   4.8 Fresh Gas Mixture ................................................................ 19
   4.9 Environmental ...................................................................... 19
   4.10 Electrical Supply .................................................................. 20
   4.11 Absorber and Breathing System .......................................... 20
   4.12 Ventilator .......................................................................... 21
   4.13 Monitored Parameters ......................................................... 21
   4.14 Alarm Settings ................................................................... 22
   4.15 Device Classification and Labelling ....................................... 23
5. **Installation and Pre-Use Checks** .............................................. 24
   5.1 Installation and commissioning before first clinical use ...................... 24
   5.2 Absorber Assembly ................................................................. 25
   5.3 Connecting Gas Monitoring Modules .................................... 27
   5.4 Installing the Vaporizer .......................................................... 28
   5.5 Gas cylinder installation ........................................................ 28
   5.6 Medical Gas Pipeline Connection .......................................... 29
   5.7 Auxiliary Power Outlets ......................................................... 29
   5.8 Anaesthetic Gas Scavenging System (AGSS) ......................... 29
   5.9 Pre-use Test Before a Clinical Procedure ............................... 30
   5.10 Vaporizer Tests .................................................................... 34
   5.11 Alarm System Tests .............................................................. 35
   5.12 Breathing System Test .......................................................... 38
## Contents

5.13 Oxygen Flush Test ................................................................. 39
5.14 Pre-use Procedure ................................................................. 39

6. Operating the Anaesthesia System .............................................. 41
6.1 Basic Operations and Settings ................................................ 41
6.2 Display Controls ....................................................................... 44
6.3 Fresh Gas Settings ..................................................................... 50
6.4 Ventilation Mode ......................................................................... 50
6.5 Monitoring Parameters ........................................................... 62
6.6 Pulmonary Function ................................................................. 62
6.7 Alarm Setup ............................................................................... 63
6.8 Trends ....................................................................................... 63
6.9 Replace Absorbent ..................................................................... 64
6.10 Auxiliary Common Gas Outlet [ACGO] .................................... 65
6.11 Alarms .................................................................................... 65

7. Maintenance ................................................................................ 71
7.1 User Maintenance ....................................................................... 71
7.2 Cleaning and Disinfection .......................................................... 72
7.3 Absorber and Breathing System Components ............................. 74
7.4 Cleaning and Disinfection Methods ............................................. 79
7.5 Absorber and breathing system .................................................. 81
7.6 Pressure Sensor Zeroing ............................................................... 82
7.7 Flow Sensor Zeroing .................................................................. 82
7.8 Oxygen Concentration Calibration ............................................ 83
7.9 Touchscreen Calibration .............................................................. 84
7.10 Prevention of Water Build-up .................................................... 84
7.11 Battery Replacement ................................................................. 85
7.12 Fault Diagnosis and Troubleshooting ........................................ 85

8. Appendix ..................................................................................... 86
Appendix 1 References .................................................................... 86
Appendix 2 Disposal at end of useful life: Risk assessment ............... 86
Appendix 3 Optional extras and approved accessories ........................ 86
Appendix 4 Labelling ........................................................................ 88
Appendix 5 Sidestream CO2 module (optional) ................................ 91
Appendix 6 Masimo IRMA AX+ module (optional) ............................ 103
Appendix 7 Electromagnetic compatibility (EMC) .............................. 111
User Responsibility

This anaesthetic machine has been built to conform with the specification and operating procedures stated in this manual and/or accompanying labels and notices when checked, assembled, operated, maintained and serviced in accordance with these instructions.

To ensure the safety of this device it must be checked and serviced to at least the minimum standards laid out in this manual. A defective, or suspected defective, product must not under any circumstances be used.

The user must accept responsibility for any malfunction which results from non-compliance with the servicing requirements detailed in this manual.

Additionally, the user must accept responsibility for any malfunction which may result from misuse of any kind, or non-compliance with other requirements detailed in this manual.

Worn, broken, distorted, contaminated or missing components must be replaced immediately. Should such a repair become necessary it is recommended that a request for service advice be made to Gradian Health Systems or the nearest Gradian accredited agent.

This device and any of its constituent parts must be repaired only in accordance with written instructions issued by Gradian Health Systems and must not be altered or modified in any way without the written approval of Gradian. The user of this equipment shall have the sole responsibility for any malfunction which results from improper use, maintenance, repair, damage or alteration by anyone other than Gradian or its appointed agents.

 Territory information

USA and Canada

USA and Canadian Federal Law restricts the sale and use of this device to, or on the order of, a licensed practitioner.

Saudi Arabia

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the Saudi Food And Drug Authority.

Statements in this manual preceded by the following words are of special significance:-

**WARNING**
means there is a possibility of injury to yourself or others.

**CAUTION**
means there is a possibility of damage to the apparatus or other property.

**NOTE**
indicates points of particular interest for more efficient and convenient operation.

The reader must take particular notice of the warnings, cautions and notes provided throughout this manual.
1. Warnings and Cautions

The following WARNINGS and CAUTIONS must be read and understood before using this machine.

WARNINGS

1. This anaesthetic machine system is designed for use only with non-flammable anaesthetic agents. It must not be used with or in close proximity to flammable anaesthetic agents, due to a possible fire or explosion hazard.

2. Exterior panels must not be removed by unauthorised personnel and the machine must not be operated with such panels missing. Unauthorised personnel must not attempt to access fuses or other electrical components. There is a possible electric shock hazard.

3. To isolate the machine from the mains power supply, disconnect the mains cable from the hospital power outlet.

4. Always use a mains power outlet socket that can be easily accessed.

5. No oil, grease or other flammable lubricant or sealant must be used on any part of the machine in close proximity to medical gas distribution components. There is a risk of fire or explosion.

6. When you attach or remove a medical gas cylinder:
   a) Follow appropriate manual handling guidelines when lifting.
   b) Ensure that the machine yoke and cylinder faces are dust free and clean and that the sealing washer provided is in position between the cylinder valve and the yoke.
   c) Tighten the yoke securely before opening the cylinder valve. Dust and dirt presents a fire hazard in the presence of high pressure gas. Leakage of high pressure gas can cause serious injury.

7. The machine must be connected to an anaesthetic gas scavenging system (AGSS) to dispose of waste gas and prevent possible health hazards to operating room staff. This requirement must be observed during test procedures as well as during use with a patient.

8. This device must only be used with Selectatec-compatible vaporizers installed on the Selectatec-type backbar system. Free-standing vaporizers may be accidentally tipped, resulting in excessive and uncalibrated volumes of anaesthetic drug entering the breathing system.

9. Do not install or connect any vaporizers of any description between the auxiliary common gas outlet (ACGO) and the breathing system unless they are specifically designed for such use. (If this is done, the oxygen flush flow will pass through the vaporizer and may result in gross overdosage when the flush valve is operated.)

10. Ventilating Neonatal and Paediatric patients:
   a) IMPORTANT
      Use ONLY Volume Control or Pressure Control ventilation for mandatory ventilation of neonates.
   b) IMPORTANT
      Switching ventilation modes during a clinical procedure:
      i. The ventilator will automatically revert to the settings that were last used in the mode that you are about to use.
      ii. To protect the neonatal/paediatric patient from adult ventilation settings, always switch to Standby before switching ventilation modes. Set appropriate neonatal/paediatric parameter values for the mode that you are about to use, before recommencing ventilation.
   c) Always set a low target pressure first and then increase to the required level.
   d) Use breathing circuits and filters specifically designed for neonatal/paediatric use.
   e) Do not ventilate pre-term babies with a birth weight below 2.4 kg.

11. Only vaporizers with the Selectatec-compatible interlock function will interlock if installed on a two station or three station manifold. The installation of non-interlock vaporizers allows the possible operation of more than one vaporizer at the same time.

12. The breathing system which conveys gases from the anaesthesia system to the patient and disposes of expired gases is a vital part of the anaesthetic delivery system. Because breathing systems require frequent cleaning and disinfection they are not a permanent part of the anaesthesia system and therefore cannot be directly under the control of the anaesthetic machine manufacturer. When mechanical ventilation is employed the patient breathing system must be connected directly to an over-pressure relief valve to prevent the possibility of barotrauma.

13. Always perform a pre-use check of the system, including vaporizers, ventilator, absorber and monitors before clinical use. Follow the pre-use checklists (see sections 5.9 to 5.14) before each clinical procedure as a minimum requirement. Many clinical incidents occur because of a failure to check for correct function.

14. The anaesthesia system must not be used if any of the alarm, monitoring or protection system devices are not functioning correctly.

15. The gas supply failure systems within the anaesthesia system will not necessarily operate as indicated in this manual during any procedures that are outside the scope of the indications for use of the machine.
Do not use the system solely to provide large flows of oxygen, via the auxiliary gas outlets, to external devices which may not be equipped with a supply failure alarm.

16. The system must not be fitted with more than three operator accessible mains socket outlets. There is a risk of an excessive leakage current. This can result in a reduced level of safety.

17. Be aware that when equipment is connected to an auxiliary outlet, a medical electrical system is created as defined in IEC 60601-1-1. (Refer to Caution 8)

18. On machines with pipeline connections, be aware that a malfunction of the central gas supply within your facility may cause immediate cessation of gas delivery and total anaesthesia system failure.

19. The use of antistatic or electrically conductive breathing hoses is not recommended when using high frequency electrical surgery equipment (e.g. Diathermy). Burns may be caused.
To avoid the risk of electric shock, this system must only be connected to a mains supply with a protective earth.
Before any electrically powered machine is used clinically for the first time, check that the hospital engineering department has carried out an earth continuity test.

20. Before using any additional electrical equipment powered by the auxiliary outlets on the machine, a trained engineer must check that the additional equipment is correctly wired and is earthed through its plug.
In the event of malfunction of any device powered by the auxiliary outlets, a trained engineer must check the device and machine fuses.

21. A missing or defective protective earth conductor may increase earth leakage currents to the patient to values exceeding the allowable limits, resulting in ventricular fibrillation, or interference with the pumping action of the heart.

22. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of this device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

23. Additional equipment placed on the top shelf must be securely attached.
Take care when moving a fully loaded machine, particularly when negotiating ramps.
Check that hoses or power leads are not trailing on the floor.

24. Accessories must be removed before the machine is transported.

25. MRI compatibility - The Prima is not MRI compatible.

26. To prevent patient injury in the event of total anaesthesia system failure, an alternative means of ventilation must be available whenever the device is in use.

27. The Apnea alarm is a visual, onscreen alarm [no audio function], and is active only in SPONT/PSV mode.

28. User maintenance:
User Maintenance is restricted to cleaning the external surfaces of the machine (see Section 7.2). All other maintenance and servicing and the replacement of components, including fuses and the mains electrical cable, must be carried out only by Gradian-trained engineers.

CAUTIONS
1. Flowmeter needle valves are designed to seal with light torque and may be damaged if tightened excessively. Do not force the control knob past either the fully open or fully closed positions.

2. Open cylinder valves slowly to avoid damage to pressure reducing valves.
Ensure that cylinder valves are at least one full turn open when in use.

3. Do not use anaesthetic agents for cleaning purposes.

4. After use, always disconnect the machine from the piped gas supply and/or close the gas cylinder valves.

5. Anti-hypoxic device (AHD) system - The oxygen flow control is restricted to prevent the needle valve from fully closing. This ensures a minimum basal flow of oxygen. Do NOT attempt to close the flow to zero.
Do not overtighten.

6. Compressed gas supplies must be clean and dry.

7. When the auxiliary gas outlets are in use on a machine using cylinder supply only (i.e. If the pipeline supply is not in use), check flow rate requirements, and ensure that adequate back-up cylinders are available.

8. The requirements of IEC 60601-1-1 apply to any device connected to the auxiliary electrical sockets. Users must be aware of the risks of increased leakage currents when equipment is connected to the auxiliary power sockets.

9. Do not apply excessive pressure to the display screens.

10. Connect the external COMMS outlet only to approved devices using protocol provided by Gradian. Contact Technical Support Department for details.

11. Vaporizers: Read the instruction manual supplied with the vaporizer before clinical use.

NOTE
1. Refer to Appendix 3 for labelling and symbols.
2. Purpose

Purpose
The Prima anaesthetic machine is for use by a professional operator in a professional hospital or clinical environment, and must be continually attended when in use. The device is intended to provide controlled concentrations and flows of anaesthesia gases into a patient breathing system, from where the anaesthesia ventilator and breathing circuit will then deliver this fresh gas mixture to the patient.

Use the device in conjunction with anaesthetic vaporizers, breathing hoses and patient connection fittings which comply with the relevant ISO standard or equivalent.

Depending upon the patient circuit selected, the machine can be used in open, semi-open, semi-closed or closed circuit configurations.

Intended patient population
This product is intended for a patient population from neonatal (infants) to adult.

Gas supplies
Three gases - oxygen, nitrous oxide, and air.

Pin-index cylinder yokes, and provision for up to three pipeline supply inlets.

Backbar manifold for Selectatec-compatible type vaporizers.

Anti-Hypoxic Device (AHD)
The AHD system is designed to minimise the risk of a hypoxic mixture reaching the patient.
3. Description

3.1 General Construction

Frame
The machine has an aluminium base, extruded aluminium uprights, and aluminium and plastic mouldings.

Mobility
Four castors with a brake on each front castor. A footrest is built into the front of the machine.

Mounting Brackets
A mounting system is built into each pair of side uprights, to allow the use of mounting brackets for accessories.

Work Surface and Lighting
The work surface has raised edges to retain instruments, vials etc.

An LED lighting unit, provides work-area lighting. The switch is located under the top shelf, above the display screen.

Extractor Fan Outlet

CAUTION
Do not obstruct the extractor fan outlet (1).

3.2 Gas Circuit

The machine has pipeline (2) and cylinder (3) gas inlets. The user sets the required flows and mixed gas is then supplied to the vaporizer backbar.

The ventilator is a pneumatically driven, microprocessor-controlled anaesthesia delivery system. The drive gas is supplied by the O₂ or Air gas supply, see section 3.12.

A gas circuit schematic is shown on the next page.
Description

Gas Circuit Schematic

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>O₂ pipeline inlet</td>
<td>23</td>
</tr>
<tr>
<td>2</td>
<td>O₂ cylinder inlet</td>
<td>24</td>
</tr>
<tr>
<td>3</td>
<td>Air pipeline inlet</td>
<td>25</td>
</tr>
<tr>
<td>4</td>
<td>N₂O pipeline inlet</td>
<td>26</td>
</tr>
<tr>
<td>5</td>
<td>N₂O cylinder inlet</td>
<td>27</td>
</tr>
<tr>
<td>6</td>
<td>Pipeline supply filter</td>
<td>28</td>
</tr>
<tr>
<td>7</td>
<td>Cylinder supply filter</td>
<td>29</td>
</tr>
<tr>
<td>8</td>
<td>Pressure gauge - pipeline</td>
<td>30</td>
</tr>
<tr>
<td>9</td>
<td>Pressure gauge - cylinder</td>
<td>31</td>
</tr>
<tr>
<td>10</td>
<td>Regulator [350 – 400 kPa]</td>
<td>32</td>
</tr>
<tr>
<td>11</td>
<td>Non-return valve</td>
<td>33</td>
</tr>
<tr>
<td>12</td>
<td>Non-return valve - cylinder supply</td>
<td>34</td>
</tr>
<tr>
<td>13</td>
<td>Regulator [250 kPa]</td>
<td>35</td>
</tr>
<tr>
<td>14</td>
<td>Cut-off valve</td>
<td>36</td>
</tr>
<tr>
<td>15</td>
<td>O₂ flush button</td>
<td>37</td>
</tr>
<tr>
<td>16</td>
<td>Flowmeter assembly</td>
<td>38</td>
</tr>
<tr>
<td>17</td>
<td>Bypass valve on backbar</td>
<td>39</td>
</tr>
<tr>
<td>18</td>
<td>Vaporizer</td>
<td>40</td>
</tr>
<tr>
<td>19</td>
<td>Vaporizer</td>
<td>41</td>
</tr>
<tr>
<td>20</td>
<td>Regulator [250 kPa] - ventilator</td>
<td>42</td>
</tr>
<tr>
<td>21</td>
<td>Inspiratory flow control valve - ventilator</td>
<td>43</td>
</tr>
<tr>
<td>22</td>
<td>Over-pressure valve [100 kPa] - ventilator</td>
<td></td>
</tr>
</tbody>
</table>
Description

3.3  Front View
1. Castors (with brakes)
2. Anaesthesia system switch
3. Pressure gauges
4. Display screen
5. Vaporizer
6. Common Gas Outlet (ACGO) and O₂ flush button
7. Multifunction control
8. Auxiliary oxygen supply outlet
   Refer to Appendix 3 for details of an available O₂ therapy flowmeter kit
9. Absorber assembly

3.4  Rear View
1. Cylinder yoke
2. Multiple socket outlets
3. Mains inlet
4. Communication port (see section 3.5)
5. Battery box cover
6. Medical gas pipeline supply inlets
7. Extractor fan outlet

3.5  Communications Port
1. Calibration and software upgrade port - designed for use by trained Gradian engineers only.
2. RS232 Interface
   Connect the interface only to approved devices using protocol provided by Gradian.
   Contact Technical Support Department for details.
3. VGA port
3.6 Control Panel

1. Multifunction control knob
   Push the control knob to select a menu option or confirm your setting.
   Turn the control knob clockwise or counterclockwise to scroll through the menu options, or to change a setting.

2. Mains electrical supply indicator

3. Power status fields
   Orange: The anaesthesia machine is connected to an AC power source, and the battery is being charged.
   Green: The system is operating on battery power.

4. Start/Standby
   Press the key to enter standby mode, or to exit standby mode and start ventilating the patient.

5. System
6. Alarms
7. Trends
8. Monitoring
9. Modes
   Alarm silence key:
   Press the key to set a 120-second alarm silence period.
   The alarm silence symbol and a 120-second countdown sequence appear to the left of the Date/time display.

Note
The O₂ Supply Failure alarm is not silenceable.

10. Date/time display
11. On/off switch - work surface lighting
3.7 Electrical Power Supply

3.7.1 Mains power supply

WARNING
Always use a mains power outlet socket that can be easily accessed.
To isolate the machine from the mains power supply, disconnect the mains cable from the power outlet socket.

Power is supplied to the machine via the mains cable (1) at the rear upper panel.

3.7.2 Auxiliary mains power supply sockets

Current leakage

CAUTION
The requirements of IEC 60601-1 apply to any device connected to the auxiliary sockets (2). Users must be aware of the risks of increased leakage currents when equipment is connected to the auxiliary mains power sockets.

NOTE
It is the user’s responsibility to ensure that the total sum of leakage currents from additional equipment plugged into the auxiliary sockets plus the leakage current from the machine does not exceed the values specified in any relevant national standards that may apply in the country where the machine is in use.

3.7.3 Battery

A back-up battery automatically provides power to the machine in the event of an AC mains power failure.

CAUTION
1. Use the battery at least once every month.
2. Battery life depends on how often and how long the battery is used. A properly maintained and stored battery has a life expectancy of approximately 2 years. Replace the battery every 2 years.
3. In case of battery failure, a replacement battery must be fitted by a trained engineer. The user must not fit the replacement battery.
4. When the anaesthetic machine is connected to the AC power source, the battery is charged regardless of whether or not the system switch is on.
5. If a battery has been discharged and/or has been stored for a long time, charging may take longer than 4 hours.
Description

**Backup Time**
A fully charged battery will power the anaesthesia machine for up to 2 hours, depending on configuration and operation. For example, frequent use of monitoring modules will shorten the backup time available.

**Battery Recharge**
The battery is charged automatically when the machine is connected to an AC power source.
Recharge time: Approximately 4 hours from total discharge

**CAUTION**
Check every month and fully charge the battery if necessary.

**Battery Life**
Battery life depends on frequency and period of use.
We recommend that the battery is replaced every 2 years.

### 3.7.4 On-screen power status and battery indicators

#### On-screen power status indicator

<table>
<thead>
<tr>
<th>Icon</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="AC power on" /></td>
<td>AC power is being used. Battery icon flashing: Battery is charging</td>
</tr>
<tr>
<td><img src="image" alt="Battery off" /></td>
<td>AC power is off, battery power is being used</td>
</tr>
</tbody>
</table>

#### On-screen battery status indicator

<table>
<thead>
<tr>
<th>Icon</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Battery full" /></td>
<td>Battery is fully charged</td>
</tr>
<tr>
<td><img src="image" alt="Battery charge" /></td>
<td>Battery power is being used</td>
</tr>
<tr>
<td><img src="image" alt="Battery low" /></td>
<td>Battery power is being used - low capacity</td>
</tr>
<tr>
<td><img src="image" alt="Battery critical" /></td>
<td>Battery approaching total discharge</td>
</tr>
</tbody>
</table>

A high level alarm [BATTERY LOW] will be triggered. Ventilation will still be possible when a low battery alarm is triggered.

When the icon shows empty display sectors, and the battery total discharge alarm is triggered, automatic shutdown will occur unless mains power is restored. See section 6.11.6. Connect the AC power immediately or use an alternative ventilation method.

### 3.7.5 Installing and replacing the battery

**WARNING**
Battery installation must be undertaken by a trained engineer, see section 7.11.
3.8  Vaporizers

CAUTION
Read the instruction manual supplied with the vaporizer before clinical use.

3.8.1  Vaporizer mounting system
Two Selectatec-compatible vaporizers for the administration of volatile anaesthetic agents can be fitted to the backbar manifold as follows:

WARNING
1. All vaporizers must always be securely mounted, and never used free-standing. Unmounted vaporizers may be accidentally tipped resulting in uncalibrated and excessive volumes of liquid anaesthetic drug entering the breathing system.

2. Do not install or connect any vaporizer of any description between the auxiliary common gas outlet (ACGO) and the breathing system, unless it is specifically designed for such use. (If this is done, the oxygen flush flow will pass through the vaporizer, and severe overdosage may result).

3.8.2  Selectatec-compatible vaporizer
A maximum of two Selectatec-compatible vaporizers [1] may be installed.

Each backbar station is fitted with two valve capsule assemblies [2] for vaporizer connector block attachment. When a vaporizer is installed on a station the valves on that station open automatically to allow gas flow into and out of the vaporizer.

Removal of the vaporizer from the station closes the valves on that station.

Installation: refer to Section 5.4.

Vaporizer Interlock System
Selectatec-compatible vaporizer interlock systems are described in the literature supplied with the vaporizer.
Description

3.9 Absorber
1. Bag support arm
2. Bag / ventilator switch
3. APL (adjustable pressure-limiting) valve
4. Absorber canister
5. Inspiratory port
6. Inspiratory non-return valve
7. Expiratory port
8. Expiratory non-return valve
9. Leak test plug
10. Airway pressure gauge
11. Bellows housing

3.9.1 Bag/Ventilator switch
The Bag/Ventilator switch (2) facilitates switching between ventilator mode and manual bag mode.

Ventilator mode: move the switch to the right.

Bag mode: move the switch to the left.

Automatic ventilator mode switching
With the system operating in mechanical ventilation mode, moving the switch from Ventilator to Bag position will trigger an automatic ventilator mode change to Manual ventilation.

Moving the switch from Bag to Ventilator position triggers a return to the previous mode.

3.9.2 Adjustable pressure limiting valve
The APL valve (3) provides breathing system pressure control, and excess pressure relief.

Turn the dial clockwise to increase the pressure limit up to a maximum of approximately 70 cmH₂O.

3.9.3 Absorber canister
The absorber canister (4) contains 1.5 litres of carbon dioxide absorbent. Do not overfill. Do not exceed the ‘MAX’ line marked on the canister, refer to section 6.9.2.

WARNING
A gradual colour change of the soda lime absorbent indicates approximately the level of absorption of carbon dioxide. Check the instructions supplied with the absorbent.

Canister ‘not fitted’ alarm
A sensor (12) triggers an alarm when the canister is removed.

CAUTION
Do not obstruct the sensor - do not route any hoses or cables in front of the sensor.
3.9.4  Inspiratory and expiratory ports

A differential pressure flow sensor is located within each port. The sensors measure flow and volume within the patient circuit.

3.9.5  Inspiratory and expiratory non-return valves
The inspiratory [6] and expiratory [8] valves control the direction of the gas flow through the system. Each valve consists of a disc located over a valve seat.

**WARNING**
The discs operate by gravity. The absorber must be securely mounted in an upright position.

The valve discs are visible, and the operation of each valve can be visually checked as the patient breathes in and out.

3.9.6  Airway pressure gauge
The pressure gauge [10] displays airway pressure in the inspiratory circuit.

Pressure is displayed in cmH₂O and kPa.

3.9.7  Bellows housing
The bellows housing [11] provides an airtight compartment for the breathing system bellows.

3.9.8  Breathing bag support arm
The bag arm [1] can be rotated to position the bag for ease of use when manual ventilation is applied.

3.9.9  Oxygen monitor sensor
The oxygen sensor [12] measures the O₂ content of the circle system. The sensor cable connects to an input socket [13] on the side of the machine.

**CAUTIONS**
1. Check the sensor calibration during the start-up tests whenever the system is switched on.
2. Do not route the cable in front of the canister sensor [14].

**NOTE**
If a sidestream gas monitoring module is installed (with optional oxygen monitoring) the oxygen sensor shown [6] is not required and the sensor port is blanked off.
3.10 Auxiliary Common Gas Outlet (ACGO) and \( \text{O}_2 \) Flush control

The ACGO port (1) and ACGO control switch (2) are mounted on the front of the machine.

**ACGO control**

The ACGO control switch (2) has two positions:

1. Upper position (3) - fresh gas is directed to the patient through the breathing circuit to the expiratory port (4).
2. Lower position (5) - fresh gas is directed to the patient through the ACGO port (1).

**\( \text{O}_2 \) Flush control**

The \( \text{O}_2 + \) button (6) directs an oxygen flow of 25-75 L/min to:

(a) the ACGO port [control switch in the lower position (5)]

or;

(b) into the breathing system.

3.11 Anaesthetic Gas Scavenge System (AGSS)

The AGSS receiver (1) is mounted on the side of the machine (2), see section 5.8.

All sources of expired anaesthetic gases [e.g. directed from the absorber APL valve, and the ventilator bellows patient gas exhaust], are directed internally to the outlet (3) at the right-hand-side of the rear of the machine. A hose (4) connects the outlet to the receiver unit inlet port.

The output hose (5) connects to the hospital disposal system.

**WARNING**

1. Do not connect any vacuum system directly to the outlet (3).
2. The receiving system (1), with a positive and negative pressure control function, must be used.
3.12 Ventilator

WARNING
Use ONLY Volume Control or Pressure Control ventilation for mandatory ventilation of neonates - see section 6.4.

The ventilator is a pneumatically driven, microprocessor-controlled device, with manual and mechanical modes.

Drive gas: oxygen or air
The drive gas icon (1) is displayed on screen, below the Alarm message field. 'X' will be shown as the drive gas in use.
If the supply of drive gas in use fails, the system automatically switches to the other gas.

Automatic ventilator mode switching
With the system operating in mechanical ventilation mode, moving the Bag/Ventilator switch (2) on the absorber from Ventilator to Bag position will trigger an automatic ventilator mode change to Manual ventilation.
Moving the switch from Bag to Ventilator position triggers a return to the previous mode.

NOTE
The ventilator will automatically revert to the settings that were last used in the mode that you are about to use.

3.12.1 Volume control ventilation (VCV)
The ventilator delivers a mandatory set volume of gas at preset, fixed breath intervals. Sigh function is available.

The patient is making no respiratory effort

3.12.2 Pressure control ventilation (PCV)
The ventilator delivers a variable flow of gas to achieve a set pressure at fixed breath intervals. The patient is making no respiratory effort

3.12.3 Pressure-regulated volume controlled ventilation (PRVC)
In PRVC a tidal volume is set and the ventilator delivers that volume at a constant pressure. The ventilator will adjust the inspiratory pressure breath-by-breath, so that the lowest pressure is used to deliver the set tidal volume.

3.12.4 Synchronised intermittent mandatory ventilation - Volume control (SIMV-V)
The ventilator delivers volume controlled breaths which are synchronised with the patient’s inspiratory efforts. The ventilator also allows spontaneous breaths with pressure support.
3.12.5 **Synchronised intermittent mandatory ventilation - Pressure control (SIMV-P)**

The ventilator delivers pressure controlled breaths which are synchronised with the patient’s inspiratory efforts. The ventilator also allows spontaneous breaths with pressure support.

3.12.6 **Synchronised intermittent mandatory ventilation - Pressure-regulated volume controlled (SIMV-PRVC)**

The ventilator delivers synchronised pressure controlled breaths at the lowest possible pressure in order to deliver the set tidal volume. The ventilator also allows spontaneous pressure support breaths.

3.12.7 **Spontaneous / Pressure support ventilation (SPONT/PSV)**

The ventilator allows spontaneous breaths and delivers pressure support at a preset trigger level. In the event of an apnea condition, the ventilator enters backup mode - either VCV or PCV, whichever the user has preselected.

3.13 **Patient monitoring - Parameters**

Measured parameters are grouped on-screen into two displays - Values 1 and Values 2.

**Values 1**
- Inspiratory tidal volume (VTI)
- Expiratory tidal volume (VTE)
- Minute ventilation (MV)
- Spontaneous minute ventilation (MVspn)
- Respiratory rate (ftotal)
- Spontaneous breathing frequency (fspn)
- Peak airway pressure (Ppeak)
- Mean airway pressure (Pmean)
- Inspiratory plateau pressure (Pplat)
- Positive end expiratory pressure (PEEP)
- Minimum airway pressure (Pmin)
- Respiratory ratio (I:E)
- Airway resistance (Rst)
- Compliance (Cdyn)
- Fraction of inspired oxygen - FiO₂
- Peripheral oxygen saturation - SpO₂ (optional)
- Pulse rate (bpm)
- Perfusion index (PI) - (optional)

**Values 2**
- Fraction of inspired carbon dioxide - FiCO₂ (optional)
- End tidal carbon dioxide - FiCO₂ - (optional)
3.14 Alarm system

WARNING
1. If the system self-test at start-up indicates an alarm system failure do not use the machine. Contact a service engineer.
2. When the machine is in use, the alarm message field (1) must visible to the user at all times.

3.14.1 Alarm and message types
Alarms are triggered by a vital sign that appears abnormal, or by a technical condition within the anaesthetic machine. Alarms are indicated by visual and audible indicators.

Physiological alarms
Physiological alarms, also called patient status alarms, are triggered by
1. A monitored parameter value that violates set alarm limits
2. An abnormal patient condition

Technical alarms
Technical alarms, also called system status alarms, are triggered by
1. A device malfunction
2. Patient data.

Prompt messages
Prompt messages are not alarm messages. Physiological, technical alarm messages, and system status messages are also displayed. Messages are usually displayed in the prompt message area.

3.14.2 Alarm levels
Values for all technical alarms and some physiological alarms are preset at the factory and are not adjustable.

High level alarm
Indicates a life threatening situation requiring immediate action.

Medium level alarm
Indicates that the patient’s vital signs appear abnormal and immediate action is required.

Low level alarm
Indicates that the patient’s vital signs appear abnormal and action may be required.

3.14.3 Alarm silence
Press the alarm silence key (2) to silence the audio alarm. 'Alarm silenced’ status will be set.

The alarm silence symbol (3) and a 120-seconds countdown period will be displayed.

NOTE
The O₂ Supply Failure alarm is not silenceable.
4. Specification

CAUTION
All technical specifications and ratings are subject to change without notice.

4.1 Physical

Machine
Size 1410 × 950 × 650 mm (H × W × D)
Weight 110 kg (approximately)
Maximum load - top shelf 30 kg

Display
Type Colour TFT LCD (touchscreen)
Size 10.4 inches
Resolution 800 × 480 pixels

Audio sounder
Alarm tones to IEC 60601-1-8, with adjustable volume

Function controls
Multifunction knob Clockwise/counterclockwise rotation and press to operate
Screen button Alarm pause, alarm reset, standby, return to main screen

Interface
Electrical power supply AC power inlet, three auxiliary output outlets
Monitor VGA monitor connector, 15-pin D-sub socket
Equipotential Equipotential ground terminal
USB One standard USB connector
RS232 Connector One standard RS232 connector

Mobility
Castors Diameter: 125 mm
Brake Brake on each castor, plus central brake control option.

Storage and side mounting system
Drawers 200 × 392 × 398 mm (H × W × D)
Mounting system for accessories GCX-type mounting system built into the machine side uprights. Loading: 20 kg maximum (each section)

4.2 Gas Supplies

Cylinders Two (oxygen and nitrous oxide), with pin-indexed cylinder yokes
Pipeline Three pipeline inlets (oxygen, air, nitrous oxide).
Standard: NIST

N₂O cut-off N₂O supply is cut-off when the internal O₂ supply pressure is less than 90 kPa.
4.3 Gas Supply Pressure

Pipeline 280-600 kPa [40.6-87.0 psig]
Cylinder (reduced pressure from regulator) 400 kPa max

4.4 Flowmeter Tubes

Flow range
- Air 0-15 L/min
- Oxygen 0-10 L/min
- Nitrous oxide 0-12 L/min
Accuracy ± 10% of full scale reading or ± 200 ml/min (whichever is greater)

4.5 Auxiliary Oxygen Supply

Supply pressure 250 kPa
Flow rate 100 L/min
Refer to Appendix 3 for details of an available O₂ therapy flowmeter kit

4.6 Auxiliary Common Gas Outlet (ACGO)

Connector 22 mm male conical connector incorporating a coaxial female 15 mm conical connector.

4.7 Oxygen Flush

Flow rate 25-75 L/min

4.8 Fresh Gas Mixture

Anti-hypoxic fresh gas mixture Minimum oxygen concentration : 25% +5%/-4% [of total O₂ + N₂O flow] - a minimum of 21% oxygen

4.9 Environmental

Operating conditions
- Temperature 10 - 40°C
- Atmospheric pressure 70 - 106 kPa
- Humidity 5 - 95% non-condensing

Transport and storage
- Temperature -20 to +55°C
- Atmospheric pressure 50 - 106 kPa
- Humidity 10 - 95% non-condensing

Cleaning and disinfection Refer to section 7.4
4.10 Electrical Supply

Power input:
- Mains supply: 100-240 VAC, 50/60 Hz, 150 VA maximum
- Fuse: T10 A /250 V
- Power cable: 3 m

Power outlets
- Auxiliary power outlets: Three outlets: 2 A (200-240 VAC) or 1 A (100-120 VAC) per outlet, maximum
- Fuses: T215ALH 250 V (on live and neutral on each outlet)

Battery
- Battery specification: NiMH, 12 V, 4.28.4 Ah.
- Back-up time: Up to 2 hours (fully charged battery)
  - Back-up time depends on the configuration of the machine, and operational requirements (see sections 3.7.3 and 3.7.4)
- Recharge time: 4 hours from total discharge (approximately)
  - Note: The battery is charged automatically when the machine is connected to an AC power source.

4.11 Absorber and Breathing System

Bellows volume: 1500 mL (approximately)
Absorber canister volume: 1500 mL (approximately)
Connectors (ACGO, inspiratory and expiratory ports, manual bag port and AGSS)
  - Standard OD: 22 mm, ID: 15 mm, tapered connector
  - Note: AGSS connector has an adaptor.
System leak limit: Not greater than 140 mL/min leakage (in any mode)
System compliance: Loss due to the system's internal compliance:<3 mL/cmH2O
Respiratory system resistance
  - Inspiratory resistance: less than 0.6 kPa.
  - Expiratory resistance: less than 0.5 kPa
APL valve range: 0 to 70 cmH2O (approximately)
Airway pressure gauge: -20 to +100 cmH2O
Water collection container: 12 mL (approximately)
  - Can be emptied during use.

Pressure and flow data (APL valve fully open)

<table>
<thead>
<tr>
<th>Flow rate [L/min]</th>
<th>APL pressure [cmH2O, dry]</th>
<th>APL pressure [cmH2O], moist</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>0.95</td>
<td>1.03</td>
</tr>
<tr>
<td>30</td>
<td>1.86</td>
<td>2.10</td>
</tr>
<tr>
<td>40</td>
<td>2.08</td>
<td>2.45</td>
</tr>
<tr>
<td>50</td>
<td>2.29</td>
<td>2.72</td>
</tr>
<tr>
<td>60</td>
<td>2.57</td>
<td>3.14</td>
</tr>
<tr>
<td>70</td>
<td>3.02</td>
<td>3.41</td>
</tr>
</tbody>
</table>
4.12 Ventilator

Display
10.4” TFT, with touchscreen

Waveforms
Pressure, flow rate, volume, p-v loop, f-v loop,

Drive gas
O2 or Air, user selectable

Inlet pressure
280-600 kPa

Max flow
≤ 120 L/min

Ventilator modes
Volume control ventilation (VCV),
Pressure control ventilation (PCV)
Pressure-regulated volume controlled ventilation (PRVC)
Synchronised intermittent mandatory ventilation - Volume control (SIMV-V)
Synchronised intermittent mandatory ventilation - Pressure control (SIMV-P)
Synchronised intermittent mandatory ventilation - Pressure-regulated volume controlled (SIMV-PRVC)
Spontaneous / Pressure support ventilation (SPONT/PSV),
Manual

Safety pressure
System pressure does not exceed 12.5 kPa

Parameters

Tidal volume
10 - 1500 mL
0 - 1600 ml measured in PCV
Increment: 10 - 100 mL: 5 mL
100 - 1500 mL: 10 mL

Respiratory rate
1 ~ 100 bpm; increment: 1 bpm

Tinsp (inspiratory time)
0.1 ~ 10.0 s; increment: 0.1 s

I:E ratio
4:1 to 1:10; increment: 0.5

Percentage of inspiratory pause
0 to 60%; increment: 5%

PEEP
OFF, 3 ~ 30 cmH2O; increment: 1 cmH2O

Pressure support
0 ~ 70 cmH2O; increment: 1 cmH2O

Pressure control
5 ~ 70 cmH2O; increment: 1 cmH2O

Flow trigger
0.5 ~ 20 L/min; increment: 0.1 L/min

Pressure trigger
0 ~ 20 cmH2O; increment: 0.1 cmH2O

SIMV-P inspiration termination level
5 ~ 80%; increment: 5%

4.13 Monitored Parameters

Inspiratory tidal volume
0 ~ 2500 mL; Resolution: 1 mL

Expiratory tidal volume
0 ~ 2500 mL; Resolution: 1 mL

Minute ventilation (Mv)
0 ~ 60 L / min; Resolution: 0.1 L/min

Spontaneous minute ventilation (Mvspont)
0 ~ 60 L/min; Resolution: 0.1 L/min

Respiratory rate
0 ~ 100 bpm; Resolution: 1 bpm

Spontaneous respiratory rate
0 ~ 100 bpm; Resolution: 1 bpm

I:E
30:1 to 1:150; resolution: 0.1
Specification

Peak airway pressure 0 ~ 100 cmH2O; Resolution: 1 cmH2O
Mean airway pressure 0 ~ 100 cmH2O; Resolution: 1 cmH2O
PEEP 0 ~ 100 cmH2O; Resolution: 1 cmH2O
Inspiratory plateau pressure 0 ~ 100 cmH2O; Resolution: 1 cmH2O
FiO2 15 to 100%; Resolution: 1%
Compliance 0 ~ 300 mL/cmH2O; resolution: 1 mL/cmH2O
Airway resistance 0 ~ 600 cmH2O / (L / S); Resolution: 1 cmH2O / (L / S)
EtCO2 (optional) 0-15% (0 ~ 150 mmHg); Resolution: 1 mmHg
FiCO2 (optional) 0 to 15%; Resolution: 0.1%
Waveforms CO2 (optional)
FiAA Halothane, Isoflurane, Enflurane: 0 to 8%
Sevoflurane: 0 to 10%
Desflurane: 0 to 22%
Resolution: 0.1%
EtAA Halothane, Isoflurane, Enflurane: 0 to 8%
Sevoflurane: 0 to 10%
Desflurane: 0 to 22%
Resolution: 0.1%
FiN2O
EtN2O
MAC values

4.14 Alarm Settings

<table>
<thead>
<tr>
<th>Alarm type</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tidal volume</td>
<td>High: 30 ~ 2000 mL, OFF</td>
</tr>
<tr>
<td></td>
<td>Low: 20 ~ 1500 mL</td>
</tr>
<tr>
<td>Minute ventilation</td>
<td>High: 1 ~ 99 L</td>
</tr>
<tr>
<td></td>
<td>Low: 0 ~ 98 L</td>
</tr>
<tr>
<td>Respiratory rate</td>
<td>High: 1 ~ 100 bpm</td>
</tr>
<tr>
<td></td>
<td>Low: 0 ~ 99 bpm</td>
</tr>
<tr>
<td>FiO2</td>
<td>High: 19 ~ 100%, OFF</td>
</tr>
<tr>
<td></td>
<td>Low: 18 ~ 99%</td>
</tr>
<tr>
<td>Airway pressure</td>
<td>High: 10 ~ 99 cmH2O</td>
</tr>
<tr>
<td></td>
<td>Low: 1~ 98 cmH2O</td>
</tr>
<tr>
<td>ETCO2 (optional)</td>
<td>High: 0 - 15%;</td>
</tr>
<tr>
<td></td>
<td>Low: 0 - 14.9%</td>
</tr>
<tr>
<td>FiCO2 (optional)</td>
<td>High: 0.1 - 15%</td>
</tr>
<tr>
<td>Pulse (optional)</td>
<td>Upper limit: 31 ~ 250 bpm</td>
</tr>
<tr>
<td></td>
<td>Lower limit: 30 ~ 249 bpm</td>
</tr>
</tbody>
</table>
## Specification

<table>
<thead>
<tr>
<th>Alarm type</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuous pressure - High</td>
<td>Airway pressure greater than PEEP + 15 cmH₂O. When an alarm is triggered, 15 is sustained.</td>
</tr>
<tr>
<td>Negative pressure</td>
<td>Airway pressure less than -10 cmH₂O</td>
</tr>
<tr>
<td>Apnea</td>
<td>Setting time: 10 ~ 60 s; increment: 1 s</td>
</tr>
<tr>
<td>Oxygen low pressure</td>
<td>Oxygen pressure less than 280 kPa</td>
</tr>
<tr>
<td>AC power failure</td>
<td>Mains supply failure or power cord disconnection</td>
</tr>
<tr>
<td>Low battery</td>
<td>More than 10 minutes remaining</td>
</tr>
<tr>
<td>Battery is exhausted</td>
<td>More than 5 minutes remaining</td>
</tr>
<tr>
<td>Alarm silence</td>
<td>( \leq 120 \text{ s} )</td>
</tr>
<tr>
<td>FiN₂O (optional)</td>
<td>High: 0 ~ 100%</td>
</tr>
<tr>
<td></td>
<td>Low: 0 ~ 100%</td>
</tr>
<tr>
<td>FiAA (optional)</td>
<td>High</td>
</tr>
<tr>
<td></td>
<td>Halothane, Isoflurane, Enflurane: 0.1 to 7.9%, OFF</td>
</tr>
<tr>
<td></td>
<td>Sevoflurane: 0.1 to 9.9%, OFF</td>
</tr>
<tr>
<td></td>
<td>Desflurane: 0.1 to 19.9%, OFF</td>
</tr>
<tr>
<td></td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Halothane, Isoflurane, Enflurane: 0 to 7.8%</td>
</tr>
<tr>
<td></td>
<td>Sevoflurane: 0 to 9.8%</td>
</tr>
<tr>
<td></td>
<td>Desflurane: 0 to 19.8%</td>
</tr>
<tr>
<td>EtAA (optional)</td>
<td>High</td>
</tr>
<tr>
<td></td>
<td>Halothane, Isoflurane, Enflurane: 0.1 to 7.9%, OFF</td>
</tr>
<tr>
<td></td>
<td>Sevoflurane: 0.1 to 9.9%, OFF</td>
</tr>
<tr>
<td></td>
<td>Desflurane: 0.1 to 19.9%, OFF</td>
</tr>
<tr>
<td></td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Halothane, Isoflurane, Enflurane: 0 to 7.8%</td>
</tr>
<tr>
<td></td>
<td>Sevoflurane: 0 to 9.8%</td>
</tr>
<tr>
<td></td>
<td>Desflurane: 0 to 19.8%</td>
</tr>
</tbody>
</table>
4.15 Device Classification and Labelling

The device is classified as Medical Electrical (ME) equipment as defined in BS EN 60601-1.

Labelling
Refer to Appendix 4

Equipment classification
- Protection against electric shock: Class 1, with internal power supply
- Ingress protection: IP21
- Oxygen compatibility: Not suitable for use in an Oxygen rich environment
- Anaesthetic agent:
  1. Use only non-flammable anaesthetic agents.
  2. Do not use in close proximity to flammable anaesthetic agents.

Mode of operation
Continuous

Patient type
All patient types

Applied parts (if fitted)
- Patient hoses/masks, SpO₂ sensor (optional), sidestream multigas sensor, sidestream CO₂ sensor
- Masimo IRMA module
- Type B
- Defibrillator-proof BF

Accessories
Refer to Appendix 3
5. Installation and Pre-Use Checks

5.1 Installation and commissioning before first clinical use

5.1.1 Warnings and cautions

WARNING
1. Check that pipeline gas supply hoses and breathing circuit components are not toxic, and will not cause allergic reactions in patients or react with anaesthetic vapour and gases.

2. Check that the soda lime in the absorber canister is not desiccated. Continuous use of desiccated soda lime may endanger patient safety. Always turn off all gases after each clinical procedure.

3. When using electrical surgical equipment, keep cables away from the breathing circuit, oxygen sensors, and flow sensors.

4. Manual ventilation devices, and monitoring and life support equipment must be available.

5. Do not use antistatic or conductive face masks. They can cause burns if used near high frequency electrosurgical equipment.

6. This equipment must be installed by a Gradian-trained engineer.

7. The machine has waste gas exhaust ports. Check that residual breathing gas is scavenged.

8. Total mains power usage must be within the specifications listed in section 4.

9. Remove all packing materials before installation and use.

CAUTION
5.2 Absorber Assembly

5.2.1 Absorber assembly Installation

**WARNING**

When the absorber is lifted or carried by hand, always support the weight of the unit under the base. Do not lift the absorber by gripping any of the components attached to the manifold block.

1. Remove all packing materials before installation.
2. Make sure that the eight silicon inserts (1) on the breathing circuit adapter plate (2) are in place and are not damaged.
3. Use BG87 or Fomblin grease to lightly lubricate the eight silicon inserts (1).
4. Lift and turn the locking catch (3) to the unlocked position.
5. Align the two connector pins (4) on the absorber with the matching holes (5) on the circuit adapter plate.
6. Push the absorber assembly into the circuit adapter plate with moderate force.
7. Reset the locking catch (3) to the locked position.

**WARNING**

Always set the locking catch to the locked position after the absorber assembly is installed. Before use, to prevent a serious fresh gas leak and inaccurate tidal volume measurement, always check that the assembly is locked in position.

5.2.2 Absorbent canister filling and installation

**WARNING**

To prevent dust and particles from entering the breathing circuit, the filter (1) must be fitted in the correct position as illustrated.

Before installation, clean the rim of the canister perimeter, the canister support, and the seal to prevent breathing system leakage.

1. Fill with new soda lime to the MAX line (2). Remove any soda lime that has collected on the filter (1).
2. Wipe the dust from the absorber canister support.
3. Position the canister, ensuring that the threads are engaged. Make sure that the triangular marks (3) are aligned.
4. Tighten counterclockwise until the ‘locked’ symbol (4) and the triangular mark on the canister are aligned.
Installation and Pre-Use Checks

5.2.3 Bag arm and bag installation
1. Fit the bag support arm (1) to the port (2) on the top face of the absorber.
2. Turn the locking nut clockwise to secure.
3. Check that the bag arm can be rotated.
4. Fit the bag (3) to the bag arm outlet (4).

5.2.4 Oxygen sensor installation
CAUTION
1. Before installing the oxygen sensor (1), check that the O-ring (2) is in good condition. Fit a new sensor if the O-ring is missing or damaged.
2. Tighten the sensor manually, do not use a wrench or other tool.
   1. Align the oxygen sensor (1) with the port on the side of the absorber.
   2. Fit the sensor and turn clockwise to tighten.
   3. Fit the cable (3) to the sensor.

WARNING
Make sure that the absorber canister position sensor (4) is unobstructed by cables or tubing etc, at all times. Do not route the oxygen sensor cable in front of the canister sensor.
4. Connect the cable (3) to the socket (5) on the side of the anaesthetic machine.

5.2.5 Install the breathing hose and Y-piece connector
CAUTION
1. When installing the breathing hoses, hold the tube connector at both ends of the tube to prevent damage to the tube.
   1. The two breathing hoses are connected to the expiratory and inspiratory connectors.
   2. Connect the breathing hoses to the Y-piece.

Gradian Prima
User Manual
Installation and Pre-Use Checks

5.3 Connecting Gas Monitoring Modules

5.3.1 Connecting a NMed sidestream CO₂ module

1. Connect the elbow (1) to the Y-piece (2).

2. Connect the sampling tube (3) to the water trap (4).

3. Connect the other end of the sampling tube to the elbow.

4. Connect the other end of the elbow to the breathing bag, or to the patient breathing circuit.

5.3.2 Connecting a NMed SpO₂ sensor cable

Insert the sensor cable into the connector socket labelled ‘SpO₂’ on the machine frame rear panel.
5.4 Installing the Vaporizer

NOTE
1. Read the vaporizer instruction manual before clinical use.
2. Up to two Selectatec-compatible vaporizers may be fitted.

Install the vaporizer
1. Carefully offer the vaporizer up to the manifold [1].
2. Check that the gas connection ports [2] on the vaporizer are aligned with the valves [3] on the manifold [1].
3. Carefully lower the vaporizer onto the manifold
4. Turn the locking lever [4] clockwise through and lock the vaporizer into position by clockwise rotation of the locking lever [3] through 90°.

NOTE
Do not use excessive force to lock the vaporizer onto the manifold. Damage to the locking fastener will result.

CAUTION
To prevent damage to the locking shaft (5), check that the gas connection ports are aligned with the valves on the manifold (1), and are correctly engaged, before tightening the locking lever.

5.5 Gas cylinder installation

CAUTION
Open the cylinder valves slowly to avoid damage to the pressure reducing valve and pressure gauges. Ensure that valves are at least one full turn open when in use.
1. Fit the gas cylinders to their respective yokes (1):
2. Follow appropriate manual handling guidelines when lifting.
3. Check that the machine yoke and cylinder faces are dust free and clean.
   The sealing washer (2) must be in position between the cylinder valve and the yoke.
4. Tighten the yoke securely before opening the cylinder valve. Dust and dirt presents a fire hazard in the presence of high pressure gas. Leakage of high pressure gas can cause serious injury.
5. Open the cylinder valves one at a time and check the pressure on each gauge.

WARNING
Do not leave a gas cylinder valve open if the pipeline supply is in use. Cylinder supplies could be depleted, leaving an insufficient reserve supply in case of pipeline failure.
Gas cylinders must conform with the requirements of IEC 60601-1.
5.6 Medical Gas Pipeline Connection

Connect the medical gas hose between the central gas supply terminal and the inlet (1) on the rear panel.

**WARNING**

1. Gas connections are not interchangeable, check the label, symbol, and colour code before connecting.
2. Use medical grade gas supplies only. Other types of gas supplies may contain water, oil, or other contaminants.
3. Check that cylinders are available as a backup in case of a central gas supply failure.

5.7 Auxiliary Power Outlets

**WARNING**

Powering additional devices through the auxiliary power outlets (2) can increase the total leakage current. Test for leakage current at regular intervals. To reduce the total leakage current, use devices with an isolation transformer.

5.8 Anaesthetic Gas Scavenging System (AGSS)

The gas scavenging outlet port (1) is located at the right rear of the machine, as shown:

**WARNING**

1. On new machines, remove the blanking plug from the port before connection to the receiver unit.
3. Do not connect any vacuum system directly to the outlet port. An AGSS receiving system with a positive and negative pressure control function must be interposed.
4. Read the AGSS receiver instruction manual before clinical use.

The AGSS receiver (2) is mounted on the side of the machine (3).

All sources of expired anaesthetic gases [e.g. directed from the absorber APL valve, and the ventilator bellows patient gas exhaust], are directed internally to the outlet (1) at the right-hand-side of the rear of the machine. A hose (4) connects the outlet to the receiver unit inlet port.

The output hose (5) connects to the hospital disposal system.
Installation and Pre-Use Checks

5.9 Pre-use Test Before a Clinical Procedure

WARNING
1. Additional equipment placed on the top shelf must be securely attached. Do not install additional equipment on the top shelf heavier than 30 kg or above 450 mm in height.

2. Obstruction of the breathing system can restrict or stop gas flow to the patient, and can cause injury or death. Make sure that there are no obstructions in the breathing system.
   Keep very small items/components/plugs away from the breathing system.

5.9.1 Recommended test schedule:

<table>
<thead>
<tr>
<th>Test</th>
<th>Daily, before the first patient</th>
<th>Each patient, before use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visual Inspection</td>
<td>Section 5.9.2</td>
<td>--</td>
</tr>
<tr>
<td>System check</td>
<td>Section 5.9.3</td>
<td>--</td>
</tr>
<tr>
<td>Power failure alarm</td>
<td>Section 5.9.4</td>
<td>--</td>
</tr>
<tr>
<td>Pipeline gas supplies</td>
<td>Section 5.9.5</td>
<td>--</td>
</tr>
<tr>
<td>Cylinders gas supplies</td>
<td>Section 5.9.6</td>
<td>--</td>
</tr>
<tr>
<td>Vaporizer</td>
<td>Section 5.10</td>
<td>--</td>
</tr>
<tr>
<td>Alarms</td>
<td>Section 5.11</td>
<td>--</td>
</tr>
<tr>
<td>Breathing circuit</td>
<td>--</td>
<td>Section 5.12</td>
</tr>
<tr>
<td>O₂ flush</td>
<td>--</td>
<td>Section 5.13</td>
</tr>
<tr>
<td>Preparing for system operation</td>
<td>--</td>
<td>Section 5.14</td>
</tr>
</tbody>
</table>

CAUTION
Before using this equipment, read this user manual, and to understand the function and operation of each component.

If the system fails a test, do not use the device. Contact a Gradian-trained engineer.

5.9.2 Visual inspection

CAUTION
Check that the absorber and breathing system are not damaged and are correctly connected.

Checks
1. Make sure that the machine is not damaged.
2. Make sure that all components are correctly attached.
3. Make sure that the breathing system is correctly connected, and that the breathing tubes are not damaged.
4. Make sure that the vaporizers are locked in position and contain sufficient agent.
5. Make sure that the gas supplies are connected and the pressures are correct.
Installation and Pre-Use Checks

6. Check that the cylinder valves are closed.
7. Make sure that the necessary emergency equipment is available and in good condition.
8. Make sure that equipment for airway maintenance and tracheal intubation is available and in good condition.
9. Make sure that the applicable anaesthetic and emergency drugs are available.
10. Make sure that the castors are not damaged or loose and the brakes are set and function correctly.
11. Make sure that the absorber unit is locked in position.
12. Make sure that the AC mains indicator and the battery indicator come on when the power cord is connected to an AC mains power source.

NOTE
If the AC mains indicator and the battery indicator are not illuminated, the system does not have electrical power.

13. Make sure that the machine can be switched on or off normally.

5.9.3 System check
1. Set the anaesthesia system switch (1) to the ON position.
2. Make sure that the yellow and red alarm lamps illuminate.
3. Make sure that an audible beep sound is heard.
4. Make sure that the start-up screen is displayed.
5. Wait for the countdown on the Pre-use Test screen to complete.
6. Make sure that the standby screen is shown after the Pre-use Test screen.
7. Press the blue SYSTEM TEST button to start the pre-use test.
8. Select the Manual Leak Test button from the pre-use test screen.
9. Follow the on-screen instructions before you press the Start button.
10. When the manual and automatic tests are complete press the FINISH button.
11. Press the QUIT button.
12. Set the APL valve to MIN.
13. Make sure that all gas flowmeter controls are turned fully clockwise.

5.9.4 Power failure alarm test
1. Disconnect the machine from the mains power supply.
   a) Make sure that the mains indicator is extinguished.
   b) Make sure that the battery indicator light illuminates.
Installation and Pre-Use Checks

c) Make sure that the message MAINS FAILURE is displayed.

2. Connect the machine to the mains electrical supply.
   a) Make sure that mains indicator is illuminated

NOTE
The battery indicator will not be illuminated if the battery is charged.

5.9.5 Gas pipeline supplies

CAUTION
Close the gas cylinder valves when the pipeline supply is in use to ensure a reserve supply in case of pipeline failure.

O₂ pipeline supply test
1. Make sure that all cylinder valves are closed.
2. Disconnect the air and N₂O pipeline supplies from the machine
3. Use the O₂ flowmeter control knob to set a flow of 2 L/min.
4. Check that the O₂ pipeline pressure gauges shows 300 to 600 kPa.
5. Disconnect the O₂ supply.
6. Make sure that the O₂ SUPPLY DOWN!!! alarm is triggered.
7. Make sure that the O₂ gauge shows zero kPa.
8. Turn the O₂ flowmeter control knob fully clockwise.
9. Connect an O₂ supply to the machine
10. Press the Alarm Reset button.
11. Make sure that no alarms are shown on the screen.

N₂O pipeline supply test
12. Check that the O₂ pipeline pressure gauges shows 300 to 600 kPa
13. Connect an N₂O supply to the machine
14. Check that the N₂O pipeline pressure gauges shows 300 to 600 kPa
15. Use the O₂ flowmeter control knob to set a flow of 2 L/min
16. Use the N₂O flowmeter control knob to set a flow of 2 L/min
17. Disconnect the N₂O pipeline.
18. Check that no O₂ warnings are displayed when the N₂O supply pressure decreases.
19. Connect the Air pipeline.
20. Press the Alarm Reset button.
21. Make sure that no alarms are shown on the screen.
Installation and Pre-Use Checks

Air pipeline test
22. Use the O₂ flowmeter control to set a flow of 0.4 L/min.
23. Check that the Air pipeline pressure gauges shows 300 to 600 kPa
24. Disconnect the Air pipeline supply.

5.9.6 Gas cylinder supplies

CAUTION
Open the cylinder valves slowly to avoid damage to the pressure reducing valve and pressure gauges. Ensure that valves are at least one full turn open when in use.

1. Fit the gas cylinders to their respective yokes, open the cylinder valves one at a time and check the pressure on each gauge.
2. Make sure that the flowmeter controls are turned fully clockwise until gas supplies are required.

5.9.6.1 Cylinder test - cylinder pressure
1. Disconnect all gas pipeline supplies.
2. Open each cylinder valve and check each cylinder pressure.
3. Replace the cylinder if necessary, refer to section 5.5.
4. Close the cylinder valve.

O₂ cylinder high pressure leak test
5. Set the anaesthesia system switch to the OFF position
6. Open the O₂ cylinder valve.
7. Make a record of the current cylinder pressure.
8. Close the O₂ cylinder valve.
9. Make a record of the cylinder pressure after two minute.
10. If the cylinder pressure decreases more than 700 kPa (100 psi), install a new cylinder seal.
11. Repeat steps Section 5.5 through Section 5.9. If the leak continues, contact a Gradian-trained engineer. Do not use the O₂ cylinder supply.
12. Reconnect the Oxygen pipeline.

N₂O cylinder High pressure leak test
13. Open the N₂O cylinder valve, and repeat the leak test sequence given above (O₂ cylinder high pressure leak test, operations 7 to 12).
14. Reconnect the N₂O gas pipeline.

O₂ verification
15. Set the anaesthesia system switch to the ON position.
16. Connect the Y-piece to the test lung
17. Press the Standby button.
18. Make sure that the system is in operational mode.
19. Use the O₂ Flow control to set an O₂ flow of 5 L/min.
Installation and Pre-Use Checks

20. Use the N\textsubscript{2}O Flow control to set an N\textsubscript{2}O flow of 5 L/min.

21. Check the FiO\textsubscript{2} reading, make sure that the FiO\textsubscript{2} level reduces to approximately 50%.

5.10 Vaporizer Tests

5.10.1 Vaporizer back pressure test

WARNING
1. Use only Selectatec series vaporizers
   Check that each vaporizer is securely mounted - refer to section 5.4.
2. The machine must be connected to an anaesthetic gas scavenging system (AGSS).

   1. Turn the O\textsubscript{2} flowmeter control to 6 L/min.
   2. Set a vaporizer concentration of 1%.

CAUTION
Do not test the vaporizer when the concentration control is between “0” (1) and the first graduation above “0” (2).

   3. Adjust the vaporizer control over the full range of movement above the first graduation.
   4. Check that the O\textsubscript{2} flow does not decrease more than 1 L/min through the full range.
   5. If the vaporizer fails this test, install a different vaporizer and repeat operation 4.
      If the problem persists, the malfunction is in the anaesthesia system. Do not use the system, contact trained technical personnel.
   6. Test each vaporizer as above.

5.10.2 Vaporizer interlock system test

1. Make sure that two vaporizers are fitted.

2. Make sure that the interlock mechanism of each vaporizer is working correctly as follows:
   a) Make sure that only one vaporizer at a time can be turned on.
   b) Refer to the vaporizer user manual for additional pre-use checks.
5.11 Alarm System Tests

5.11.1 Alarm system self-test at start-up
Check that the system carries out an automatic self-test at start-up.
1. The alarm lamp flashes yellow and red once in turn and an audible beep sounds.
2. The start-up screen is displayed, followed by the standby screen after approximately 15 seconds.
3. Audio and visual alarm indicators are triggered.

5.11.2 Alarm test preparation
1. Connect a test lung or manual bag to the Y-piece patient connector.
2. Set the bag/vent switch to vent.
3. Set the system switch to ON.
4. Set the system to standby mode.
5. Set the ventilator control setting to the follows:
   - Ventilation Mode: Select ventilation mode [VCV].
   - Tidal volume [VT]: 500 mL.
   - Respiratory rate [FREQ]: 15 BPM.
   - Breathing ratio [I:E]: 1:2
   - PEEP: OFF
6. Push the O2 flush button to fill the bellows.
7. Set the flowmeter to 0.5-1 L/min.
8. Press the standby key to exit to standby mode.
9. Check that the ventilator displays the correct data, and that the bellows inflates and deflates normally during mechanical ventilation.

5.11.3 Minute volume (MV) low alarm test
1. Set the MV low alarm limit to 10.0 L.
2. Check that a MV low alarm is triggered.
3. Set the MV low alarm limit to 2.0 L/min and check that the alarm is cancelled.

5.11.4 High pressure alarm test
1. Set the pressure high alarm limit to 30 cmH₂O.
2. Check the Ppeak reading. Adjust the tidal volume until the reading is higher than the pressure high alarm limit.
3. Check that a high pressure alarm triggered.
Installation and Pre-Use Checks

5.11.5 Continuous high pressure alarm test
1. Connect the manual bag.
2. Set the flowmeter to minimum.
3. Set the APL valve to 30 cmH₂O position.
4. Set the bag/Vent switch to bag.
5. Press and hold the O₂ flush button to fill bag until the reading on the airway pressure gauge is approximately 30 cmH₂O.
6. After 15 seconds, check that a continuous high pressure alarm is triggered.

5.11.6 Low pressure alarm test
1. Set the bag/Vent switch to vent.
2. Set the Paw low alarm limit to 5 cmH₂O.
3. Disconnect the test lung from the Y-piece patient connection.
4. Check that a low pressure alarm triggered.
5. Connect the test lung to the Y-piece port.
6. Make sure the low Paw alarm is cancelled.

5.11.7 Oxygen concentration monitoring and alarm test

**CAUTION**
This test is required if the O₂ sensor (1) is fitted to the absorber.
1. Use the standby key to enter standby mode.
2. Calibrate the O₂ cell as follows:
   a) Press the SYSTEM button
   b) Press the CALIBRATION tab
   c) Press the O₂ CELL CALIBRATION button
   d) Press the 100% button
   e) Follow the on-screen instructions.
3. Set the FiO₂ low alarm limit to 45%.
4. Use the standby key to enter operational mode.
5. Set O₂ Flowmeter control to 2.0 L/min.
6. Set N₂O flowmeter control to 5 L/Min
7. Make sure that after a short period of time, a FiO₂ LOW alarm is triggered.
8. Set the FiO₂ low alarm limit 18%. Check that the alarm is cancelled.
9. Set the FiO₂ high alarm limit to 25%.
10. Check that a FiO₂ HIGH alarm is triggered.
11. Set the FiO₂ high alarm limit to OFF and check that the alarm is cancelled.
Installation and Pre-Use Checks

5.11.8 Minute volume (MV) low alarm test
1. Set the MV low alarm limit to a minimum of 11 L/min.
2. Press the HOME key [2].
3. Make sure that after a short time the MV LOW!!! alarm is triggered.
4. Set the MV low alarm limit to 2.0 L/min.
5. Make sure that after a short time the MV LOW!!! alarm is cancelled.
6. Press the Alarm reset key [1].

5.11.9 High airway pressure (Paw) alarm test
1. Set the pressure high alarm limit to 25 cmH2O.
2. Press the HOME key [2]
3. Adjust the tidal volume (VT) until the Ppeak reading is higher than the pressure high alarm limit.
4. Make sure that an Airway Pressure High!!! alarm is triggered.
5. Set the pressure high alarm limit to 40 cmH2O.
6. Set VT to 500.

5.11.10 Apnea alarm test
1. Use the standby button to start standby mode.
2. Set the ventilation mode to SPONT/PSV.
3. Press the CONFIRM button.
4. Use the standby button to start operational mode.
5. Make sure that a visual APNEA warning is shown.
6. Make sure that ventilation begins.
7. Set the ventilation mode to VCV.
8. Press the confirm button.
9. Press the alarm reset button.

5.11.11 Continuous high positive airway pressure alarm test
1. Use the O2 flowmeter to set a minimum flow.
2. Set the APL valve to 30 cmH2O.
3. Set the Bag/Vent switch to Bag.
4. Press the O2 flush button until the reading on the airway pressure gauge is approximately 30 cmH2O.
5. After 15 seconds, check that a continuous pressure high alarm is triggered.
6. Set the APL valve to Min.

5.11.12 Airway pressure low alarm test
1. Set the bag/vent switch to the vent position.
2. Set the Pressure low alarm limit to 5 cmH2O.
3. Disconnect the test lung from the Y-piece patient connection.
Installation and Pre-Use Checks

4. Check that a low pressure alarm is triggered.
5. Connect the Y-piece to the test lung.
6. Check that the low pressure alarm is cancelled.

5.12 Breathing System Test

1. Check that the non-return valves in the breathing system work correctly:
   a) The inspiratory non-return valve opens during inspiration and closes at the start of expiration.
   b) The expiratory non-return opens during expiration and closes at the start of inspiration.

Bellows test

2. Set the system to standby mode.
3. Disconnect the Y-piece.
4. Set all gas flowmeter controls fully clockwise
5. Deflate the bellows.
6. Connect the Y-piece to the absorber test block.
7. Press and hold the O₂ flush button to fill the bellows.
8. The airway pressure gauge must indicate less than 15 cmH₂O.
9. Release the O₂ flush button.
10. If the bellows deflates within one minute,
   a) Remove the bellows and reinstall, refer to Section 7.3.7.
   b) Repeat the bellows test.

Breathing system leak test

11. Set the Bag/Vent switch to the bag position.
12. Turn the APL valve to 50 cmH₂O
13. Press the O₂ flush button until the airway pressure gauge reads 25 cmH₂O.
14. Release the O₂ flush button.
15. Make sure that the airway pressure gauge reading does not reduce.

**CAUTION**

If a leak is suspected, check the bellows, breathing tube, absorber, and connectors for correct function and security.

Retest the system. Do not use the machine if the circuit continues to leak. Contact a Gradian-trained engineer.

APL valve test

16. Turn the APL valve to 70 cmH₂O position.
17. Connect the Y-piece to the test plug.
18. Push the O₂ flush button until the airway pressure gauge rises to approximately 35 cmH₂O.
Installation and Pre-Use Checks

19. Release the O₂ flush button.
20. Set the APL valve to 30 cmH₂O.
21. Check that the reading on the airway pressure gauge is within the range 25 to 35 cmH₂O.
22. Set the APL valve to 20 cmH₂O.
23. Check that the reading on the airway pressure gauge is within the range 15 to 25 cmH₂O.
24. Set the APL valve to the MIN position.
25. Set the anaesthesia system switch to the OFF position.
26. Check that the reading on the airway pressure gauge is less than 5 cmH₂O.

5.13 Oxygen Flush Test

1. Set the anaesthesia system switch to the ON position.
2. Wait until the system enters standby mode.
3. Set the bag/vent switch to the vent position.
4. Disconnect the Y-piece.
5. Make sure that the bellows are deflated.
6. Connect the Y-piece to the absorber test block.
7. Turn the ACGO control to the closed circuit position.
8. Press the O₂+ button, and hold in position.
9. Check that the bellows fully inflate within 4 seconds.
10. Release the O₂+ button.

Auxiliary common gas outlet (ACGO) test

11. Turn the auxiliary common gas outlet (ACGO) control (1) to the open circuit position (2).
12. Make sure that AGCO is shown at the top of the screen.
13. Press the O₂+ flush button (3), and hold in position.
14. Check that there is a flow of fresh gas from the ACGO (4).
15. Turn the ACGO control to the closed circuit position (5).
16. Check that the flow of O₂ from the ACGO stops.
17. Release the O₂+ flush button.

5.14 Pre-use Procedure

1. Set the anaesthesia system switch to the ON position.
2. Check that the ventilator parameters and alarm limits are set to applicable clinical levels. If necessary, refer to Section 6.
3. Make sure that the system is in Standby.
4. Make sure that equipment for airway maintenance, manual ventilation, tracheal intubation, and applicable anaesthetic and emergency drugs are available.
5. Set the Bag/Vent switch to Bag.

6. Make sure that the manual bag is connected to the bag port.

7. Turn off all vaporizers.

8. Turn the APL valve control counterclockwise to the MIN position.

9. Set all gas flows to a minimum.

10. Make sure that the breathing system is not damaged and correctly connected.

11. Before connecting a patient, flush the machine with 5 L/min of O₂ for at least one minute. This removes unwanted gas mixtures from the system.

12. Set the anaesthesia system switch to the OFF position.
6. Operating the Anaesthesia System

6.1 Basic Operations and Settings

6.1.1 Turn on the system
1. Plug the power cord into an AC mains power outlet. The mains indicator is lit when the AC power is connected. The battery will be charged (if it is not already fully charged).
2. Check that the breathing system is properly connected.
3. Turn the system switch (1) to the ON position.
4. The self-test will start and the indicator lights will be illuminated. The self-test screen will be displayed.
5. The self-test will continue for about 10 seconds. The device will prompt the user to perform a pre-use test.
6. This test must be carried out before the first clinical procedure of the day.

WARNING
If the power-up self-test fails, do not use the device. Contact a Gradian-trained engineer.

6.1.2 Standby mode and operating mode
1. Set the system switch (1) to ON.
2. After the power-up self test, the system enters standby mode automatically.
3. To enter operating mode, press the standby key.

6.1.3 Turn the system off
1. When a clinical procedure is completed:
   a) Check that the vaporizer is in the OFF position.
   b) Check that all gas flow controls are set to the OFF position.
   c) Turn the system switch (1) to the OFF position.

6.1.4 Using the touchscreen
This system uses touchscreen technology and a multifunction control knob (2) to access system functions, menus, and settings.
Touch only one touch point at a time to ensure the correct selection is made.

CAUTION
Do not apply excessive pressure to the display screen.

6.1.5 System settings
1. Alarm volume
   b) Select Alarm volume:
      20%, 40%, 60%, 80%, 100%
Operating the Anaesthesia System

2. System Time
   a) Select [System] -> [Date & Time].
   b) Set [Time] and [Date].
   c) Select [Apply].

3. Sigh breath internal
   a) Select [System] -> [Settings] -> [Sigh Breath Every].
   b) In the [Sigh Breath Every] menu, set 50-150 breaths.

4. Language
   a) Select [System] -> [Settings] -> [Language].
   b) In the [Language] menu, select the required language

5. Oxygen monitoring: On or Off - systems configured with an oxygen sensor in the absorber
   If the O2 sensor is depleted, or not fitted in the absorber, the oxygen monitor can be set to OFF to prevent the occurrence of an O2 sensor alarm.
   a) Select [System] -> [Settings] -> [O2].
   b) Set the oxygen monitor to [ON] or [OFF].

6. CO2 / AA monitoring
   If a CO2 / AG module is fitted, set the on/off switch.
   b) Set [ON] or [OFF].

7. SpO2 monitoring
   If a SpO2 module is fitted, set the ON/OFF switch.
   a) Select [System] -> [Settings] -> [SpO2].
   b) Set [ON] or [OFF]

8. Set patient trigger type
   In [SIMV-V], [SIMV-P] and [PSV] mode, a patient trigger is permitted. Trigger sensitivity can be set in flow triggering [Fsens] or pressure triggering [Psens]. Normally, flow triggering is preferable as this enables the patient to breathe with less effort.
   a) Select [System] -> [Settings] -> [Trigger Type].
   b) Select the desired trigger type.

9. Set driver gas type (O2 or Air)
   a) Select standby mode.
   b) Select [System] -> [Settings] -> [Driver].
   c) Select the desired driver gas type: O2 or Air.
   d) The drive gas icon (1) is displayed on screen, below the Alarm message field. ‘X’ will be shown as the drive gas in use.
Operating the Anaesthesia System

10. Set the Air alarm switch (optional)
   a) Select [System] -> [Settings] -> [Air].
   b) Set [ON]/[OFF].

   **CAUTION**
   When the Air alarm switch is set to OFF, the Air supply pressure alarm is off.
   Note that air supply pressure monitoring is active.

11. Set CO₂ unit
   a) Select [System] -> [Settings] -> [EtCO₂ Unit].
   b) Select: % / mmHg / kPa.
6.2 Display Controls

6.2.1 Standby screen
If the system is not in use, select standby to save power. The system enters standby status automatically after start-up.

Standby mode features:
1. Displayed monitored parameters and waveforms are disabled, and ventilation stops.
2. Parameters can be set and the system will operate based on those settings when standby is exited.
3. Physiological alarms are cleared automatically.
4. Technical alarms function normally.
5. The monitor module enters standby status.
6. Service modes are activated.

6.2.2 Working screen
1. Ventilator setting fields:
   Parameters related to the selected ventilation mode.
2. Waveforms fields:
   Measured value waveforms are displayed. Waveform content can be set by the user.
3. Ventilation mode display:
   For manual ventilation, ‘Manual’ is displayed. If ‘Ventilator’ is selected by using the bag/vent switch, the currently selected ventilator mode is displayed.
4. Alarm message field: Active alarms are displayed.
5. Alarm silence icon:
   The icon is displayed if the alarm silence key is pressed. A 120-seconds countdown is triggered.
   NOTE
   The O2 Supply Failure alarm is not silenceable.
6. Measured values fields:
   Values of standard parameters are displayed.
7. System time fields.
8. Function keys fields:
   Modes, Alarm, System, and Monitoring.
9. Power status display fields:
   Displays power supply in use. If the battery is in use, battery charge level is displayed.
10. Trigger Icons fields:
    The trigger icon is displayed when the patient’s spontaneous inspiration reaches the preset Trigger Level.
11. Multiple Alarm Icon:
    The icon is displayed if two or more alarms are active. The highest priority alarm is displayed in the alarm message field. The number of active alarms is shown.
Operating the Anaesthesia System

6.2.3  Manual ventilation
Set the bag/vent switch to the bag position.
The mode display shows the icon for manual ventilation.

6.2.4  Mechanical ventilation mode selection
1. Touch the Modes button to view the mode selection screen.
2. Touch the hotkey for the required mode.
The parameters for each mode are shown below:

6.2.4.1  Volume control ventilation (VCV) mode
VT  Tidal volume
I:E  Respiratory ratio
FREQ  Respiratory rate
Pause  Inspiratory pause
PEEP  Positive end-expiratory pressure

6.2.4.2  Pressure control ventilation (PCV) mode
Pinsp  Pressure control level
I:E  Respiratory ratio
FREQ  Respiratory rate
Tslope  Pressure rise time
PEEP  Positive end-expiratory pressure

6.2.4.3  Synchronized Intermittent mandatory ventilation –
Volume control (SIMV-V) mode
VT:  Tidal volume
TI:  Inspiratory time
FREQ:  Respiratory rate
Psupp:  Pressure support level
Tslope:  Pressure rise time
Psens/Fsens:  Pressure/Flow trigger sensitivity
PEEP  Positive end-expiratory pressure

6.2.4.4  Synchronized Intermittent mandatory ventilation –
Pressure control (SIMV-P) mode
Pinsp  Pressure control level
TI  Inspiratory time
FREQ  Respiratory rate
Psupp  Pressure support level
Tslope  Pressure rise time
Psens/Fsens  Pressure/Flow trigger sensitivity
PEEP  Positive end-expiratory pressure

6.2.4.5  Spontaneous/ Pressure support ventilation [SPONT /
PSV] mode
In SPONT/PSV mode, the backup mode (VCV or PVC mode)
must be preselected. The parameters for the selected backup
mode must also be preset.
Backup Modes:
1. Select the [Modes] shortcut key-> [Backup].
2. Touch [Volume] or [Pressure].
Operating the Anaesthesia System

Volume mode parameters:

- VT: Tidal volume
- I:E: Respiratory ratio
- FREQ: Respiratory rate

Pressure mode parameters:

- Pinsp: Pressure control
- I:E: Respiratory ratio
- FREQ: Respiratory rate

6.2.4.6 Pressure-regulated volume control (PRVC)

- VT: Tidal volume
- I:E: Respiratory ratio
- FREQ: Respiratory rate
- PEEP: Positive end expiratory pressure
- Tslope: Pressure rise time

6.2.4.7 Synchronised intermittent mandatory ventilation - Pressure-regulated volume controlled (SIMV-PRVC)

- VT: Tidal volume
- TI: Inspiratory time
- FREQ: Respiratory rate
- PEEP: Positive end expiratory pressure
- Psupp: Pressure support level
- Tslope: Pressure rise time
- Psens/Fsens: Pressure/Flow trigger sensitivity

6.2.5 Waveform

To display a waveform configuration screen, touch anywhere within the field for that waveform.
Select the required waveform.

Note that if a hotkey is not available, that function has not been configured.

- Paw: Airway pressure
- Flow: Flow rate
- Volume: Tidal Volume
- Pleth: Plethysmograph
- EtCO₂: End-tidal carbon dioxide

Note that the measured range corresponding to the waveform scales can be adjusted automatically. The sweep time is fixed.

6.2.5.1 Airway pressure waveform

The airway pressure waveform field can be changed.
6.2.5.2 Flow waveform

6.2.5.3 Volume waveform

6.2.5.4 Pleth waveform
On machines with an SpO₂ module, a Pleth waveform is displayed as shown.

6.2.5.5 EtCO₂ waveform
On machines with CO₂, a CO₂ waveform is displayed as shown.

6.2.5.6 Pressure-Volume loop
Select [Monitoring] -> [Graphics]
A Pressure-Volume Loop and Volume-Flow loop will displayed as shown.

6.2.5.7 Volume-Flow loop
6.2.6 Rapid measurement values fields
Important measured values fields are displayed. The position of these parameters cannot be changed.

- **Ppeak**: Peak airway pressure
- **Pmean**: Average pressure
- **PEEP**: Positive end expiratory pressure
- **MV**: Minute ventilation
- **VTE**: Expiratory tidal volume
- **FiO₂**: Fraction of inspired oxygen
- **EtCO₂**: End-tidal carbon dioxide

6.2.7 Parameter monitoring
To monitor more measured values, push the required monitoring hotkey in the function keys fields.

6.2.8 Alarms
Alarms, triggered by a vital sign that appears abnormal or by technical problems within the machine. To prevent patient injury, set upper and lower limits for the following parameters.

When setting alarm limits, push the hotkey, turn the knob to the required, then push to confirm.

6.2.8.1 Limits 1 display
In Limits 1, alarms are related to mechanical ventilation.

- **Pressure**
- **MV**: Minute ventilation
- **FREQ**: Respiratory rate
- **FiO₂**: Fraction of inspired oxygen
- **VTE**: Expiratory tidal volume
- **Apnea time**

6.2.8.2 Limits 2 display
In Limits 2, alarms are related to optional SpO₂ and CO₂ monitoring.

- **ETCO₂**: End-tidal carbon dioxide
- **FiCO₂**: Fraction of inspired carbon dioxide
- **Pulse**: Pulse rate
- **SpO₂**: Pulse oximeter oxygen saturation

6.2.8.3 Alarm log
The alarm log, the system displays up to 100 events, stored in chronological order. When a new event occurs after 100 events are already stored, the new event overwrites the current earliest event.
6.2.9 System settings
This function is used to change the settings for:

- Language
- ETCO₂ unit
- Trigger type
- Masimo IRMA AX+ Module - O₂ Compensation
- System time
- Loudness
- Calibration procedures.

Some hotkeys may not be available. This indicates that these functions have not been configured. Note that if the related switch is set to OFF, the function cannot be used.

6.2.10 System time settings
These settings will be saved and effective until an update is applied.

6.2.11 System information
In this screen, the device displays software versions, running time, and maintenance information.

6.2.12 Calibration
The Gas Module Zero Calibration button refers to the zero calibration of Masimo IRMA AX+ module.

Calibration options are shown.
6.3 Fresh Gas Settings

**WARNING**
Before clinical use, check that all connections are secure and that the pre-operation tests are completed. If any tests failed, do not use the system. Refer the machine to a Gradian-trained service engineer for repair.

6.3.1 N₂O, O₂, and air supply settings
1. Check each gas supply connection and pressure.
2. Gas flow values are shown on the respective flowmeter.
3. The O₂ and N₂O flow controls are linked:
   a) Increase the N₂O flow.
      The O₂ control will increase the O₂ flow, to maintain an O₂ concentration greater than 21% in the mixed gas.
   b) Decrease the O₂ flow.
      The N₂O flow will decrease, to maintain an O₂ concentration greater than 21% in the mixed gas.

6.4 Ventilation Mode

**WARNING**
Ventilating Neonatal and Paediatric patients:
1. Use ONLY Volume Control or Pressure Control ventilation for mandatory ventilation of neonates.
2. Switching ventilation modes during a clinical procedure:
   a) The ventilator will automatically revert to the settings that were last used in the mode that you are about to use.
   b) To protect the neonatal/paediatric patient from adult ventilation settings, always switch to Standby before switching ventilation modes. Set appropriate neonatal/paediatric parameter values for the mode that you are about to use, before recommencing ventilation.
3. Always set a low target pressure first and then increase to the required level.
4. Use breathing circuits and filters specifically designed for neonatal/paediatric use.
5. Do not ventilate pre-term babies with a birth weight below 2.4 kg.
Operating the Anaesthesia System

6.4.1 Manual ventilation mode
1. Turn the APL valve control to adjust the pressure in the breathing system within the appropriate range.
2. Set the bag/vent switch to the bag position. The ventilation mode prompt area displays the icon for manual ventilation mode.
3. Press the O₂ flush button to inflate the bag if necessary. In manual ventilation mode, you can use the APL valve to adjust the breathing system pressure limit and gas volume in the manual bag. When the pressure in the breathing system reaches the pressure limit set for the APL valve, the valve opens to release excess gas. The APL valve is generally set at between 20-30 cmH₂O.

### Key
<table>
<thead>
<tr>
<th>A: Airway pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>B: Flow</td>
</tr>
<tr>
<td>C: Time: inspiration</td>
</tr>
<tr>
<td>D: Time: Expiration</td>
</tr>
</tbody>
</table>

6.4.2 Mechanical ventilation mode
Select settings before starting Mechanical Ventilation
1. Check that the system is in Standby mode.
2. Set the appropriate pressure high alarm value in the parameter setup.
3. Set the bag/vent switch to the vent position.
4. If necessary, push the O₂ flush button to inflate the bellows.

Select mechanical ventilation mode
1. Mode selection
   a) Select the [Mode] hotkey to open the [mode] screen.
   b) Click the hotkey for the required ventilation mode, and then click [confirm].
   c) The ventilation mode selected will be displayed in the mode display field.

NOTE
If SP0NT/PSV mode is selected, PCV or VCV backup mode must be preselected - see section 6.4.9.
6.4.3 VCV mode

Principles of volume control ventilation
In Volume control ventilation (VCV) gas is delivered to the patient at a constant flow, to deliver the preset VT within the gas delivery time.
To achieve the preset VT, the resulting airway pressure (Paw) changes based on patient pulmonary compliance and airway resistance.
As long as Paw is less than the pressure high limit and the gas delivery flow is kept constant, expiration starts immediately after the high pressure limit is reached.
In VCV mode, you must set the Pressure high limit to prevent patient injury caused by high airway pressure.
Select [Pause] to improve patient pulmonary gas distribution and [PEEP] to improve expiration of end-tidal carbon dioxide and to increase oxygenation.

VCV mode waveforms
Paw waveform and flow waveform in VCV mode are shown. In VCV mode, the flow waveform is at a constant flow during inspiration and the Paw waveform rises in the same period.

<table>
<thead>
<tr>
<th>Key</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Airway pressure</td>
</tr>
<tr>
<td>B</td>
<td>Inspiratory pressure</td>
</tr>
<tr>
<td>C</td>
<td>Flow</td>
</tr>
<tr>
<td>D</td>
<td>Time: inspiration</td>
</tr>
<tr>
<td>E</td>
<td>Time: expiration</td>
</tr>
</tbody>
</table>

Setting the parameters in VCV mode

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Range</th>
<th>Step</th>
</tr>
</thead>
<tbody>
<tr>
<td>VT</td>
<td>10-1500 mL</td>
<td>10 - 100 mL: 5 mL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>100 - 1500 mL: 10 mL</td>
</tr>
<tr>
<td>I:E</td>
<td>4:1 - 10:1</td>
<td>0.5</td>
</tr>
<tr>
<td>FREQ</td>
<td>4 - 100 bpm</td>
<td>1 bpm</td>
</tr>
<tr>
<td>PEEP</td>
<td>Off, 3 - 30 cmH₂O</td>
<td>1 cmH₂O</td>
</tr>
<tr>
<td>Pause</td>
<td>0% - 60%</td>
<td>5%</td>
</tr>
<tr>
<td>Sigh</td>
<td>Off, 50 - 150</td>
<td>25</td>
</tr>
</tbody>
</table>
### 6.4.4 PCV mode

**Principles of pressure control ventilation**

In PCV mode, Paw rises rapidly to the preset pressure control value. Then gas flow slows down through the feedback system to keep Paw constant until expiration starts at the end of inspiration.

The tidal volume delivered in PCV mode changes, based on patient pulmonary compliance and airway resistance. Actual tidal volume is measured.

In PCV mode, select PEEP to improve expiration of end-tidal carbon dioxide and to increase oxygenation.

**PCV mode waveforms**

PCV mode waveforms for Paw and flow are shown.

Generally, in PCV mode, the Paw waveform rises sharply during inspiration and stays at the plateau for a relatively long time without peak. The flow waveform declines in the same period.

Tidal volume is measured, instead of preset by the user.

<table>
<thead>
<tr>
<th>Key</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>A: Airway pressure</td>
<td></td>
</tr>
<tr>
<td>B: Pmax</td>
<td></td>
</tr>
<tr>
<td>C: SIMV breath</td>
<td></td>
</tr>
<tr>
<td>D: PEEP</td>
<td></td>
</tr>
<tr>
<td>E: Flow</td>
<td></td>
</tr>
</tbody>
</table>

#### Setting the parameters in PCV mode

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Range</th>
<th>Step</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pinsp</td>
<td>5 - 70 cmH₂O</td>
<td>1 cmH₂O</td>
</tr>
<tr>
<td>I:E</td>
<td>4:1 - 10:1</td>
<td>0.5</td>
</tr>
<tr>
<td>FREQ</td>
<td>4 - 100 bpm</td>
<td>1 bpm</td>
</tr>
<tr>
<td>PEEP</td>
<td>Off, 3 - 30 cmH₂O</td>
<td>1 cmH₂O</td>
</tr>
<tr>
<td>Tslope</td>
<td>0 - 1 s</td>
<td>0.1 s</td>
</tr>
</tbody>
</table>
6.4.5 Pressure-regulated volume control (PRVC)

In PRVC a tidal volume is set and the ventilator adjusts the inspiratory pressure needed to deliver the set tidal volume so that the lowest pressure is used.

The pressure range is between the PEEP +2 cmH₂O level and 5 cmH₂O below pressure high limit.

The inspiratory pressure change between breaths is a maximum of +/- 3 cmH₂O.

This mode delivers breaths with the efficiency of pressure controlled ventilation, yet still compensates for changes in the patient’s lung characteristics.

PRVC mode initially delivers a VCV breath. Patient compliance is determined from this volume breath.

The inspiratory pressure level is then set for the next breath.

### PRVC Waveforms

**Key**
- A: Airway pressure
- B: Peak pressure
- C: PEEP
- D: First ventilation
- E: PRVC cycle
- F: Time [s]
- G: Flow
- H: Inspiratory volume
- J: Expiratory volume

### Setting the parameters in PRVC mode

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Range</th>
<th>Step</th>
<th>Default</th>
</tr>
</thead>
<tbody>
<tr>
<td>VT</td>
<td>Infant: 10 to 100 ml Paediatric: 50 to 360 ml Adult: 100 to 1600 ml</td>
<td>10 - 100 ml: 5 ml 100 - 1500 ml: 10 ml</td>
<td>35 ml 120 ml 510 ml</td>
</tr>
<tr>
<td>I:E</td>
<td>4:1 to 1:10</td>
<td>0.5</td>
<td>1:2</td>
</tr>
<tr>
<td>FREQ</td>
<td>1 to 100 bpm</td>
<td>1 bpm</td>
<td>15 bpm</td>
</tr>
<tr>
<td>PEEP</td>
<td>OFF, 3 to 30 cmH₂O</td>
<td>1 cmH₂O</td>
<td>OFF</td>
</tr>
<tr>
<td>Tslope</td>
<td>0 to 1 s</td>
<td>0.1 s</td>
<td>0.2 s</td>
</tr>
</tbody>
</table>
6.4.6 Synchronized intermittent mandatory ventilation - Volume control (SIMV-V)

SIMV-V
SIMV-V delivers volume controlled breathing to the patient by phase at the preset intermission.
In SIMV-V mode, the ventilator waits for the patient’s next inspiration based on the specified time interval.
Sensitivity is dependent on Trigger level (Fsens = Flow trigger sensitivity; Psens = Pressure trigger sensitivity; Esens = Expiratory trigger sensitivity).

If the Trigger Level is reached within the trigger waiting time (synchronous Trigger Window), the ventilator delivers volume controlled breathing synchronously with the preset tidal volume and inspiratory time.
If the patient does not inspire within the Trigger Window, the ventilator delivers volume controlled breathing to the patient at the end of Trigger Window.
Spontaneous breathing outside of the Trigger Window can acquire pressure support.

SIMV-V Waveforms
Paw waveform and flow waveform in SIMV-V mode.

<table>
<thead>
<tr>
<th>Key</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Within the trigger window</td>
</tr>
<tr>
<td>B</td>
<td>Outside the trigger window</td>
</tr>
<tr>
<td>C</td>
<td>SIMV cycle</td>
</tr>
<tr>
<td>D</td>
<td>Flow</td>
</tr>
<tr>
<td>E</td>
<td>VCV applied (no ventilation within the trigger window)</td>
</tr>
<tr>
<td>F</td>
<td>Airway pressure</td>
</tr>
<tr>
<td>G</td>
<td>Inspiratory time</td>
</tr>
</tbody>
</table>

Parameter range and default values in SIMV-V mode

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Range</th>
<th>Step</th>
<th>Default</th>
</tr>
</thead>
<tbody>
<tr>
<td>VT</td>
<td>Infant: 10 to 100 ml&lt;br&gt;Pediatric: 50 to 360 ml&lt;br&gt;Adult: 100 to 1600 ml</td>
<td>20 to 100 ml: 5 ml&lt;br&gt;100 to 1500 ml: 10 ml</td>
<td>35 ml&lt;br&gt;120 ml&lt;br&gt;510 ml</td>
</tr>
<tr>
<td>Tinsp</td>
<td>0.1 to 10.0 s</td>
<td>0.1 s</td>
<td>1.2</td>
</tr>
<tr>
<td>FREQ</td>
<td>1 to 100 bpm</td>
<td>1 bpm</td>
<td>15 bpm</td>
</tr>
<tr>
<td>PEEP</td>
<td>OFF, 3 to 30 cmH₂O</td>
<td>1 cmH₂O</td>
<td>OFF</td>
</tr>
<tr>
<td>Psupp</td>
<td>0 to 70 cmH₂O</td>
<td>1 cmH₂O</td>
<td>15 cmH₂O</td>
</tr>
<tr>
<td>Tslope</td>
<td>0 to 1 s</td>
<td>0.1 s</td>
<td>0.2 s</td>
</tr>
<tr>
<td>Fsens</td>
<td>1 to 20.0 L/min</td>
<td>0.1 L/min</td>
<td>3 L/min</td>
</tr>
<tr>
<td>Psens</td>
<td>1 to 20 cmH₂O</td>
<td>1 cmH₂O</td>
<td>2 cmH₂O</td>
</tr>
<tr>
<td>Esens</td>
<td>5% to 80%</td>
<td>5%</td>
<td>25%</td>
</tr>
</tbody>
</table>
6.4.7 Synchronized intermittent mandatory ventilation - Pressure control (SIMV-P)

SIMV-P delivers pressure controlled breathing to the patient by phase at the preset intermission. In SIMV-P mode, the ventilator waits for the patient’s next inspiration, based on the specified time interval.

Sensitivity depends on the Trigger Level (Fsens = Flow trigger sensitivity; Psens = Pressure trigger sensitivity; Esens = Expiratory trigger sensitivity). If the Trigger Level is reached within the trigger waiting time (called synchronous Trigger Window), the ventilator delivers pressure controlled breathing synchronously with the preset tidal volume and inspiratory time.

If the patient does not inspire within the Trigger Window, the ventilator delivers pressure controlled breathing to the patient at the end of the Trigger Window. Spontaneous breathing outside of the Trigger Window can acquire pressure support.

If the Trigger Level is reached outside of the Trigger Window, the ventilator delivers pressure-supported ventilation based on the preset [Psupp].

### Paw and flow waveforms in SIMV-P mode.

<table>
<thead>
<tr>
<th>Key</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A: Paw</td>
<td>F: Outside trigger window</td>
</tr>
<tr>
<td>B: Pressure</td>
<td>G: If no ventilation occurs within the trigger window</td>
</tr>
<tr>
<td>C: Pressure control level</td>
<td>H: Time</td>
</tr>
<tr>
<td>D: Pressure</td>
<td>J: Flow</td>
</tr>
<tr>
<td>E: Within trigger window</td>
<td>K: Flow trigger</td>
</tr>
</tbody>
</table>

### Parameter range and default values in SIMV-P mode

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Range</th>
<th>Step</th>
<th>Default</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pinsp</td>
<td>5 to 70 cmH₂O</td>
<td>1 cmH₂O</td>
<td>15 cmH₂O</td>
</tr>
<tr>
<td>Tinsp</td>
<td>0.1 to 10.0 s</td>
<td>0.1 s</td>
<td>1.2</td>
</tr>
<tr>
<td>FREQ</td>
<td>1 to 100 bpm</td>
<td>1 bpm</td>
<td>15 bpm</td>
</tr>
<tr>
<td>PEEP</td>
<td>OFF, 3 to 30 cmH₂O</td>
<td>1 cmH₂O</td>
<td>OFF</td>
</tr>
<tr>
<td>Psupp</td>
<td>0 to 70 cmH₂O</td>
<td>1 cmH₂O</td>
<td>15 cmH₂O</td>
</tr>
<tr>
<td>Tslope</td>
<td>0 to 1 s</td>
<td>0.1 s</td>
<td>0.2 s</td>
</tr>
<tr>
<td>Fsens</td>
<td>1.0 to 20.0 L/min</td>
<td>0.1 L/min</td>
<td>3 L/min</td>
</tr>
<tr>
<td>Psens</td>
<td>1.0 to 20 cmH₂O</td>
<td>1 cmH₂O</td>
<td>2 cmH₂O</td>
</tr>
<tr>
<td>Esens</td>
<td>5% to 80%</td>
<td>5%</td>
<td>25%</td>
</tr>
</tbody>
</table>
6.4.8 Synchronised intermittent mandatory ventilation - Pressure-regulated volume controlled (SIMV-PRVC)

SIMV-PRVC delivers pressure controlled breathing to the patient and the ventilator waits for patient’s next inspiration based on the specified time interval.

Sensitivity depends on trigger level (F = Flow trigger sensitivity; Psens = Pressure trigger sensitivity; Esens = Expiratory trigger sensitivity).

If the trigger level is reached within the trigger waiting time (called synchronous trigger window), the ventilator delivers pressure guaranteed ventilation - volume control breathing synchronously with the preset tidal volume and inspiratory time.

If the patient does not inspire within the trigger window the ventilator delivers pressure controlled breathing to the patient at the end of trigger window.

Spontaneous breathing outside of the trigger window can acquire pressure support.

If trigger level is reached outside of the trigger window, the ventilator delivers pressure-supported ventilation based on the preset \([P_{supp}]\).

**SIMV-PRVC waveforms (Paw and flow)**

<table>
<thead>
<tr>
<th>Key</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A: Paw</td>
<td>F: If no ventilation occurs within the trigger window</td>
</tr>
<tr>
<td>B: Trigger window</td>
<td>G: Time [s]</td>
</tr>
<tr>
<td>C: Pressure support level</td>
<td>H: SIMV cycle</td>
</tr>
<tr>
<td>D: Within the trigger window</td>
<td>J: Flow</td>
</tr>
<tr>
<td>E: Outside the trigger window</td>
<td>K: Flow trigger</td>
</tr>
<tr>
<td>L: PRVC ventilation</td>
<td></td>
</tr>
</tbody>
</table>

**Parameter range and default values in SIMV-PRVC mode**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Range</th>
<th>Step</th>
<th>Default</th>
</tr>
</thead>
<tbody>
<tr>
<td>VT</td>
<td>Infant: 10 to 100 ml Paediatric: 50 to 360 ml Adult: 100 to 1600 ml</td>
<td>20 to 100 ml: 5 ml 100 to 1500 ml: 10 ml</td>
<td>35 ml 120 ml 510 ml</td>
</tr>
<tr>
<td>Tinsp</td>
<td>0.1 to 10.0 s</td>
<td>0.1 s</td>
<td>1:2</td>
</tr>
<tr>
<td>FREQ</td>
<td>1 to 100 bpm</td>
<td>1 bpm</td>
<td>15 bpm</td>
</tr>
<tr>
<td>PEEP</td>
<td>OFF, 3 to 30 cmH(_2)O</td>
<td>1 cmH(_2)O</td>
<td>OFF</td>
</tr>
<tr>
<td>Psupp</td>
<td>0 to 70 cmH(_2)O</td>
<td>1 cmH(_2)O</td>
<td>15 cmH(_2)O</td>
</tr>
<tr>
<td>Tslope</td>
<td>0 to 1 s</td>
<td>0.1 s</td>
<td>0.2 s</td>
</tr>
<tr>
<td>Fsens</td>
<td>1.0 to 20.0 L/min</td>
<td>0.1 L/min</td>
<td>3 L/min</td>
</tr>
<tr>
<td>Psens</td>
<td>1.0 to 20 cmH(_2)O</td>
<td>1 cmH(_2)O</td>
<td>2 cmH(_2)O</td>
</tr>
<tr>
<td>Esens</td>
<td>5% to 80%</td>
<td>5%</td>
<td>25%</td>
</tr>
</tbody>
</table>
6.4.9 SPONT/PSV mode

Spontaneous/pressure support ventilation mode (SPONT/PSV) is an auxiliary breathing mode.

When the patient’s spontaneous inspiration reaches the preset trigger level, the ventilator begins to deliver gas and Paw rises to the preset Psupp rapidly. Flow is reduced to keep Paw constant.

When the inspiration flow drops to the preset level, the ventilator stops delivering gas and the patient is allowed to expire, and the ventilator waits for the next inspiration trigger.

If inspiration is not triggered within the set time (Backup Mode Active), the system automatically switches to the pre-selected backup ventilation mode (Volume or Pressure).

**CAUTION**

The backup mode must be selected in advance. Parameter values for the backup mode must be appropriate.

In SPONT/PSV mode, VT does not need to be set. VT depends on [a] the patient’s inspiratory force and pressure support level, and [b] compliance and resistance of the patient and breathing system.

PSV mode is used only when the patient is breathing spontaneously.

When PSV mode is applied alone, PCV and VCV backup modes are available.

If within the preset time [Backup Mode Active], no spontaneous breathing occurs or is not strong enough to reach the Trigger Level, backup mode ventilation is triggered automatically when the time period for Backup Mode Active ends.

**Apnea**

If there is [1] no spontaneous breathing or [2] spontaneous breathing and an inspiratory trigger condition is not reached, the system automatically enters the preselected backup ventilation mode, in accordance with the preset ‘Apnea time’ see 6.4.10.

**PSV mode waveforms**

Airway pressure (Paw) and flow waveforms in PSV mode.

### Key

<table>
<thead>
<tr>
<th>A</th>
<th>Airway pressure (Paw)</th>
</tr>
</thead>
<tbody>
<tr>
<td>B</td>
<td>Pressure trigger</td>
</tr>
<tr>
<td>C</td>
<td>Pressure support level</td>
</tr>
<tr>
<td>D</td>
<td>Pressure control level</td>
</tr>
<tr>
<td>E</td>
<td>Flow</td>
</tr>
<tr>
<td>F</td>
<td>Expiratory trigger</td>
</tr>
<tr>
<td>G</td>
<td>Flow trigger</td>
</tr>
<tr>
<td>H</td>
<td>Backup mode: active period</td>
</tr>
<tr>
<td>J</td>
<td>Backup mode: applied period</td>
</tr>
<tr>
<td>K</td>
<td>Time (s)</td>
</tr>
</tbody>
</table>

### Parameter range and default values in SPONT/PSV mode

SPONT/PSV mode can be used jointly with SIMV-V or SIMV-P.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Range</th>
<th>Step</th>
<th>Default</th>
</tr>
</thead>
<tbody>
<tr>
<td>PEEP</td>
<td>OFF, 3 to 30 cmH2O</td>
<td>1 cmH2O</td>
<td>OFF</td>
</tr>
<tr>
<td>Psupp</td>
<td>0 to 70 cmH2O</td>
<td>1 cmH2O</td>
<td>15 cmH2O</td>
</tr>
<tr>
<td>Tslope</td>
<td>0 to 1 s</td>
<td>0.1 s</td>
<td>0.2 s</td>
</tr>
<tr>
<td>Fsens</td>
<td>1.0 to 20.0 L/min</td>
<td>0.1 L/min</td>
<td>3 L/min</td>
</tr>
<tr>
<td>Psens</td>
<td>1.0 to 20 cmH2O</td>
<td>1 cmH2O</td>
<td>2 cmH2O</td>
</tr>
<tr>
<td>Esens</td>
<td>5% to 80%</td>
<td>5%</td>
<td>25%</td>
</tr>
</tbody>
</table>
6.4.10 Ventilator settings

**CAUTION**
Confirm each new setting before adjusting another parameter. If confirmation is not given, the ventilator reverts to the preset value.

**Set tidal volume**
2. Press the control knob, and turn to set the required value.
3. Press the control knob to confirm and activate.

**Set respiratory rate**
1. Set Select the [FREQ] hotkey.
2. Press the control knob, and turn to set the required value.
3. Press the control knob to confirm and activate.

**Set inspiratory time**
1. Select the [Ti] hotkey.
2. Press the control knob; turn the knob to set the required value.
3. Press the control knob to confirm and activate.

**Set inspiratory and expiratory ratio**
2. Press the control knob, and turn to set the required value.
3. Press the control knob to confirm and activate.

**Set pressure limit alarm levels**
1. Select [Alarms] -> [Limit 1].
2. Press the control knob, and turn the knob to set the upper and lower limits [pressure] to the required values.
3. Press the control knob to confirm and activate.

**Set PEEP**
1. Select the [PEEP] hotkey.
2. Press the control knob, turn the knob to set the required value.
3. Press the control knob to activate and confirm the change.

**Set pressure control level**
1. Select the [Pinsp] hotkey.
2. Press the control knob; and turn to set the required value.
3. Press the control knob to confirm and activate the change.
Operating the Anaesthesia System

Set pressure support level
2. Press the control knob and turn to set the required value.
3. Press the control knob to confirm and activate.

Set inspiratory trigger
In SIMV-V, SIMV-P, and PSV modes, patient-initiated triggering is permitted. Trigger sensitivity can be set in flow triggering (Fsens) or pressure (Psens) triggering.

Normally, flow triggering is preferable as this enables the patient to breathe with less effort.

To set trigger type, see sections 6.4.6 to 6.4.9.
2. Set Psens or Fsens to the required value.
3. Push the control knob or touch button to confirm and activate the change.

Sensitivity is set as high as possible without self-triggering. This ensures that triggering is patient-initiated and avoids auto-cycling by the ventilator.

Set Apnea time
If SPONT / PSV mode is used, a backup ventilation mode can be selected.

If an Apnea situation occurs, and there is no spontaneous breathing, or spontaneous breathing and an inspiratory trigger condition is not reached, the system in accordance with the set 'Apnea time', automatically enters the pre-selected backup ventilation mode.

1. Select [Alarm] -> [Apnea time].
2. Turn the control knob to set the required value.
3. Press the button to confirm and activate the change.
   To cancel the setting, close the window or return to the main screen.

Set inspiratory pause
In VC mode, select the [Pause] hotkey.

2. Set the pause at the required value: 0 to 60% in 5% increments.
3. Press the control knob to confirm and activate the change.

Set rise time
In pressure mode, rise time is available.
2. Set the [Tslope] at the desired value, namely 0-1 s, (0.1 s increments).
3. Press the control knob again to activate the change.
6.4.11 Starting mechanical ventilation

**CAUTION**
Check the parameters are set to appropriate values before starting ventilation.

To exit Standby mode and start mechanical ventilation, press the Start/Standby key [1].
6.5 Monitoring Parameters

6.5.1 FiO₂ monitoring
If the system is configured with an O₂ module or an oxygen sensor, FiO₂ values are displayed.

**CAUTION**
If an O₂ sensor is used, calibrate the sensor when the measured value of O₂ concentration is outside specification range, or when a new sensor is fitted. Refer to section 7.8.

6.5.2 CO₂ monitoring
If the system is fitted with a CO₂ module, you can monitor FiCO₂ and EtCO₂ by setting the CO₂ module for open state.

6.5.3 Pressure monitoring
Pressure related parameters are listed below.
- PEEP
- Ppeak
- Pplat
- Pmean

6.5.4 Tidal volume monitoring

**CAUTION**
The tidal volume values on the bellows housing give an approximate indication, and may be inconsistent with the actual measured volumes. This is a normal phenomenon.

International standards require that the user must monitor tidal volume during a clinical procedure.

Volume related parameters are measured as shown below.
- VTI
- VTE
- MV
- MVspn

6.5.5 Breath rate monitoring

Breath rate related parameters are measured as shown below.
- ftotal (total respiratory rate)
- fspn (spontaneous respiratory rate)

6.6 Pulmonary Function

The system displays dynamic compliance monitoring, static resistance, and spirometry loops to reflect the patient’s pulmonary function.

The system provides two spirometry loops: Paw-V (Paw-volume) loop and V-Flow (volume-flow) loop.

The scales of volume flow and Paw are adjusted automatically.

Paw-V loop and V-Flow loop are shown in section 6.2.5.
6.7 Alarm Setup

Use the Alarm setup menu to set and adjust alarm limits and to view alarm history. See section 6.11.6 for alarm messages.

6.7.1 Set Ventilator alarm limits
1. Select the [Alarms] hotkey and select the Limits 1 screen.
2. Set upper and lower limits respectively for each parameter, and exit the menu.

6.7.2 Set CO₂ alarm limits
If a CO₂ module (optional) is fitted, select System: >Settings.
1. Set ‘CO₂ alarms’ to On.
2. Select the [Alarms] hotkey and select the Limits 2 display.
3. Set upper and lower limits respectively, and exit the menu.

6.7.3 Set SpO₂ alarm limits
If a SpO₂ module (optional) is fitted, select System: >Settings
1. Select SpO₂ alarm to On.
2. Select the [Alarms] hotkey and select the Limits 2 display.
3. Set upper and lower limits respectively, and exit the menu.

6.8 Trends

A trend graph is used to review parameter values within a specific time period. The trend is reflected through a curve.

Every point on the curve corresponds to the parameter value at a specific time point. You can review parameter data within a maximum of a 24-hour operating period.

Select the [Trends] menu (1) to access the display
- Time Scale button
- Parameter selection button
- Trend graph
- Cursor
- Parameter value
- Cursor position time

Setting
1. Use the Time Scale button (a) to select the desired time scale (1, 4, 12 or 24 hours).
2. Use the Parameter selection button (b) to select the desired parameter.
3. Use the multifunction control to reposition the cursor (d), to view the parameter values at the required time point.

CAUTION
1. If system time is set, the trend graph is recorded again.
2. If 'Patient type' is reset, select save or record again.
6.9 Replace Absorbent

CAUTION
A gradual colour change of the soda lime in the canister indicates approximately the level of absorption of carbon dioxide. Use carbon dioxide monitoring to determine when to change the soda lime.

Follow local regulations regarding disposal of hospital waste when the soda lime is replaced. If left standing for several hours, it may regain its original colour and give a misleading indication of usability.

6.9.1 Using canister bypass mode
Use the canister bypass mode for continued ventilation of the patient while changing the absorber canister.

NOTE
Bypass mode seals the breathing circuit when the canister is removed.
While the absorber canister is out of the breathing circuit, the patient re-breathes exhaled gases. Use carbon dioxide monitoring.
For safety, an infrared sensor monitors if bypass mode is activated. A technical alarm is triggered to warn the user.

6.9.2 Absorbent change procedure

WARNING
To prevent dust and particles from entering the breathing circuit, the filter (1) must be fitted securely, as illustrated. Before installation, clean all the canister components, including the seal (2).

1. Rotate the absorber canister clockwise until the triangular marks (3) are aligned.
2. Detach the canister from the absorber. Canister bypass mode is activated. ‘No absorber!?‘ is shown in the alarm message area.
3. Empty the canister
4. Fill with new soda lime to the MAX line (4). Remove any soda lime that has collected on the filter (1).
5. Wipe the dust from the absorber canister support (5).
6. Position the canister, ensuring that the threads are engaged. Make sure that the triangular marks (3) are aligned.
7. Tighten counter-clockwise until the ‘locked’ symbol (6) and the triangular mark (7) on the canister are aligned.
8. Check that the alarm message is cancelled.
Operating the Anaesthesia System

6.10 Auxiliary Common Gas Outlet (ACGO)

ACGO control (1)
1. Upper position (2) - fresh gas is directed to the patient through the breathing circuit to the expiratory port (3).
2. Lower position (4) - fresh gas is directed to the patient through the ACGO port (5).

O₂ Flush control
The O₂+ button (6) directs an oxygen flow of 25-75 L/min to:
(a) the ACGO port (switch in the lower position 4).
or:
(b) the breathing circuit (switch in the upper position 2).

6.11 Alarms

6.11.1 WARNING
1. If the system self-test at start-up indicates an alarm system failure, do not use the machine. Contact a service engineer.
2. When the machine is in use, the alarm message field (1) must visible to the user at all times.

Visual and/or audible alarms are triggered by (a) A vital sign that appears abnormal, or (b) A technical condition within the anaesthesia machine

NOTE
1. On start-up, the system self-test checks if the alarm lamp and audible alarm tones function normally.
2. Normal function triggers an audible beep, and the alarm lamp flashes yellow and red once in turn.
3. If a failure is detected, do not use the equipment. Contact a Gradian-trained engineer.

6.11.2 Alarm levels
Values for all technical alarms and some physiological alarms are preset at the factory and are not adjustable.

Alarms fall into three categories: high level alarms, medium level alarms and low level alarms.

When multiple alarms of different levels occur simultaneously, the system will select the highest priority alarm and give visual and audible alarm indications accordingly.

High level alarm
Indicates a life threatening situation requiring immediate action.

Medium level alarm
Indicates that the patient’s vital signs appear abnormal and immediate action is required.

Low level alarm
Indicates that the patient’s vital signs appear abnormal; action may be required.
6.11.3 Alarm indicators
Alarms trigger visual or audible indicators:
- Alarm lamp
- Alarm message
- Flashing numeric
- Audible alarm tones

6.11.3.1 Visual indicator - Alarm Lamp
If an alarm occurs, the alarm lamp will flash.
Colour and frequency match the alarm level as follows:

<table>
<thead>
<tr>
<th>Alarm Level</th>
<th>Colour and Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>The red lamp flashes quickly</td>
</tr>
<tr>
<td>Medium</td>
<td>The yellow lamp flashes slowly</td>
</tr>
<tr>
<td>Low</td>
<td>The yellow lamp is lit, without flashing</td>
</tr>
</tbody>
</table>

6.11.3.2 Audible indicator
Alarm tone patterns are varied, to match the alarm level:

<table>
<thead>
<tr>
<th>Priority</th>
<th>Tone Pattern</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>10-note sequence, repeated every 10 seconds</td>
</tr>
<tr>
<td>Medium</td>
<td>3-note sequence, repeated every 2 seconds</td>
</tr>
<tr>
<td>Low</td>
<td>2-note sequence, does not repeat</td>
</tr>
</tbody>
</table>

6.11.3.3 Alarm message
When an alarm occurs, a message appears in the alarm area.
The alarm area background colour matches the alarm level:

<table>
<thead>
<tr>
<th>Alarm Level</th>
<th>Background Colour</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Red</td>
</tr>
<tr>
<td>Medium</td>
<td>Yellow</td>
</tr>
<tr>
<td>Low</td>
<td>Yellow</td>
</tr>
</tbody>
</table>

For physiological alarms, the exclamation symbol (!) identifies the alarm level as follows:

<table>
<thead>
<tr>
<th>Alarm Level</th>
<th>Symbol</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>!!!</td>
</tr>
<tr>
<td>Medium</td>
<td>!!</td>
</tr>
<tr>
<td>Low</td>
<td>!</td>
</tr>
</tbody>
</table>

6.11.3.4 Alarm status symbols
The alarm status icon appears on the screen to show different alarm status conditions, including Alarm Silence.

NOTE
The O₂ Supply Failure alarm is not silenceable.
6.11.4 Set alarm volume
Select [System] hotkeys -> [Settings] -> [Loudness] volume
Loudness range: 20% minimum to 100% maximum.
The settings will be saved and will not be cancelled when the machine is turned off.

WARNINGS
1. Do not rely exclusively on the audible alarm system.
2. Decreasing the alarm volume to a low level may result in a hazard to the patient.

6.11.5 Alarm limits
CAUTION
An alarm is triggered when the parameter value is higher than the High Limit or lower than the Low Limit.
Check that the alarm limits of a specific parameter are set to appropriate values.

6.11.6 Alarm messages

Physiological alarms message

<table>
<thead>
<tr>
<th>Message</th>
<th>Priority</th>
<th>Cause</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>APNEA!!!</td>
<td>High</td>
<td>Breathing or ventilation has stopped.</td>
<td>Check patient’s spontaneous breathing ability. Check for blockages in the breathing circuit</td>
</tr>
<tr>
<td>Continuous Pressure High!!!</td>
<td>High</td>
<td>Airway pressure greater than (PEEP +15) cmH2O for 15 seconds.</td>
<td>Check for blockages in the breathing circuit.</td>
</tr>
<tr>
<td>PRESSURE HIGH!!!</td>
<td>High</td>
<td>Ppeak is higher than the Paw high alarm limit setting.</td>
<td>Decrease tidal volume setting or increase Paw high alarm limit setting. Check for blockages in the patient circuit.</td>
</tr>
<tr>
<td>FiHAL HIGH!!!</td>
<td>High</td>
<td>FiAA is greater than alarm limit.</td>
<td>Set the alarm limits appropriately. Check agent setting.</td>
</tr>
<tr>
<td>FiENF HIGH!!!</td>
<td>High</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FiISO HIGH!!!</td>
<td>High</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FiSEV HIGH!!!</td>
<td>High</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FiDES HIGH!!!</td>
<td>High</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EthAL HIGH!!!</td>
<td>High</td>
<td>EthAA is greater than alarm limit.</td>
<td>Set the alarm limits appropriately. Check agent setting.</td>
</tr>
<tr>
<td>EthENF HIGH!!!</td>
<td>High</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EthISO HIGH!!!</td>
<td>High</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EthSEV HIGH!!!</td>
<td>High</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EthDES HIGH!!!</td>
<td>High</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MV LOW!!!</td>
<td>High</td>
<td>MV is lower than the low alarm limit setting.</td>
<td>Increase settings for tidal volume or breath rate, or decrease low alarm limit.</td>
</tr>
<tr>
<td>MV HIGH!!!</td>
<td>High</td>
<td>MV is higher than the high alarm limit setting.</td>
<td>Decrease settings for tidal volume or breath rate, or increase high alarm limit.</td>
</tr>
<tr>
<td>PRESSURE &lt; -10cmH2O!!!</td>
<td>High</td>
<td>Paw is less than -10 cmH2O.</td>
<td>Check for blockages in the breathing circuit. Increase fresh gas flow. Check if there is high flow gas flowing through the AGSS. If yes, check the negative pressure relief valve on the receiver.</td>
</tr>
</tbody>
</table>
## Operating the Anaesthesia System

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Setting</th>
<th>Description</th>
<th>Recommended Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>RATE LOW!!</td>
<td>High</td>
<td>Rate is less than low alarm limit.</td>
<td>Set the alarm limits appropriately or adjust the Rate setting.</td>
</tr>
<tr>
<td>FiO₂ HIGH!!</td>
<td>High</td>
<td>FiO₂ is greater than high alarm limit.</td>
<td>Set the alarm limits appropriately. Check the O₂ setting. Recalibrate the O₂ cell.</td>
</tr>
<tr>
<td>FiO₂ LOW!!</td>
<td>High</td>
<td>FiO₂ is less than low alarm limit.</td>
<td>Set the alarm limits appropriately. Check the O₂ setting. Check for leaks or blockages in the patient circuit. Recalibrate the O₂ cell.</td>
</tr>
<tr>
<td>EtCO₂ HIGH!!</td>
<td>High</td>
<td>EtCO₂ is greater than high alarm limit.</td>
<td>Check the patient settings. Set the alarm limits appropriately. Check if absorbent needs to be changed.</td>
</tr>
<tr>
<td>FiCO₂ HIGH!!</td>
<td>High</td>
<td>FiCO₂ is greater than alarm limit.</td>
<td>Set the alarm limits appropriately. Check the N₂O setting.</td>
</tr>
<tr>
<td>FiN₂O HIGH!!</td>
<td>High</td>
<td>FiN₂O is greater than alarm limit.</td>
<td>Set the alarm limits appropriately. Check the N₂O setting.</td>
</tr>
<tr>
<td>PRESSURE LOW!!</td>
<td>High</td>
<td>Ppeak is lower than the Paw low alarm limit setting.</td>
<td>Increase tidal volume setting or decrease Paw low alarm limit setting.</td>
</tr>
<tr>
<td>SpO₂ LOW!!</td>
<td>High</td>
<td>SpO₂ is lower than the low alarm limit setting.</td>
<td>Check patient’s condition! Set the alarm limits appropriately.</td>
</tr>
<tr>
<td>PULSE RATE LOW!!</td>
<td>High</td>
<td>Pulse rate is lower than the low alarm limit setting.</td>
<td>Check patient’s condition! Set the alarm limits appropriately.</td>
</tr>
<tr>
<td>VTE HIGH!!</td>
<td>High</td>
<td>VTE is higher than the high alarm limit setting.</td>
<td>Decrease tidal volume setting or increase high alarm limit.</td>
</tr>
<tr>
<td>VTE LOW!!</td>
<td>Medium</td>
<td>VTE is lower than the low alarm limit setting.</td>
<td>Increase tidal volume setting or decrease low alarm limit.</td>
</tr>
<tr>
<td>RATE HIGH!!</td>
<td>Medium</td>
<td>Rate is greater than high alarm limit.</td>
<td>Set the alarm limits appropriately or adjust the Rate setting.</td>
</tr>
<tr>
<td>PULSE RATE HIGH!!</td>
<td>Medium</td>
<td>Pulse rate is greater than high alarm limit.</td>
<td>Check patient’s condition! Set the alarm limits appropriately.</td>
</tr>
<tr>
<td>SpO₂ HIGH!!</td>
<td>Medium</td>
<td>SpO₂ is greater than high alarm limit.</td>
<td>Check patient’s condition! Set the alarm limits appropriately.</td>
</tr>
<tr>
<td>EtCO₂ LOW!!</td>
<td>Medium</td>
<td>EtCO₂ is less than alarm limit.</td>
<td>Ensure that patient is properly intubated. Check for leaks or blockages in the patient circuit. Set alarm limit appropriately.</td>
</tr>
<tr>
<td>FiHAL LOW!!</td>
<td>Medium</td>
<td>FiAA is less than alarm limit.</td>
<td>Check the fill level of the vaporizers. Set alarm limit appropriately. Check agent setting.</td>
</tr>
<tr>
<td>FiENF LOW!!</td>
<td>Medium</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FiISO LOW!!</td>
<td>Medium</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FiSEV LOW!!</td>
<td>Medium</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FiDES LOW!!</td>
<td>Medium</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EtHAL LOW!!</td>
<td>Medium</td>
<td>EtAA is less than alarm limit.</td>
<td>Check the fill level of the vaporizers. Set alarm limit appropriately. Check agent setting.</td>
</tr>
<tr>
<td>EtENF LOW!!</td>
<td>Medium</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EtISO LOW!!</td>
<td>Medium</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EtSEV LOW!!</td>
<td>Medium</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EtDES LOW!!</td>
<td>Medium</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FiN₂O LOW!!</td>
<td>Medium</td>
<td>FiN₂O is less than alarm limit.</td>
<td>Set the alarm limits appropriately. Check the N₂O setting.</td>
</tr>
</tbody>
</table>
### Operating the Anaesthesia System

#### Technical alarms message

<table>
<thead>
<tr>
<th>Message</th>
<th>Priority</th>
<th>Cause</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>O₂ SUPPLY DOWN!!!</strong></td>
<td>High</td>
<td>O₂ pipeline pressure is less than 280kPa.</td>
<td>Ensure the O₂ pipeline and cylinder are properly connected.</td>
</tr>
<tr>
<td><strong>BATTERY DISCHARGED!!!</strong></td>
<td>High</td>
<td>Remaining battery power is between five and fifteen minutes.</td>
<td>Plug in the power cable. Check that the system circuit breaker is on.</td>
</tr>
<tr>
<td><strong>STANDBY ACTIVED!!!</strong></td>
<td>High</td>
<td>Switching from manual ventilation to mechanical ventilation</td>
<td>Press the “Alarm Reset” Elimination of this alarm.</td>
</tr>
<tr>
<td><strong>BATTERY LOW!!!</strong></td>
<td>High</td>
<td>Remaining battery power is between ten and thirty minutes.</td>
<td>Plug in the power cable. Check that the system circuit breaker is on.</td>
</tr>
<tr>
<td><strong>O₂ SENSOR FAILURE!!!</strong></td>
<td>High</td>
<td>Oxygen sensor not connected or oxygen sensor failure.</td>
<td>Check oxygen sensor cable. Recalibrate the O₂ cell. Change O₂ cell.</td>
</tr>
<tr>
<td><strong>Gas Module Software Error!!</strong></td>
<td>Medium</td>
<td>Gas Module Software Error!!</td>
<td>Contact your service personnel.</td>
</tr>
<tr>
<td><strong>Gas Module Hardware Error!!</strong></td>
<td>Medium</td>
<td>Gas Module Hardware Error!!</td>
<td>Contact your service personnel.</td>
</tr>
<tr>
<td><strong>Gas Module Motor Overspeed!!</strong></td>
<td>Medium</td>
<td>Gas Module Motor Overspeed!!</td>
<td>Contact your service personnel.</td>
</tr>
<tr>
<td>**Gas Module Factory calib lost!!</td>
<td>Medium</td>
<td>Gas Module Factory calib lost!!</td>
<td>Contact your service personnel.</td>
</tr>
<tr>
<td><strong>Gas Module Replace Adapter!!</strong></td>
<td>Medium</td>
<td>Gas Module Replace Adapter!!</td>
<td>Contact your service personnel.</td>
</tr>
<tr>
<td><strong>Gas Module No Adapter!!</strong></td>
<td>Medium</td>
<td>Gas Module No Adapter!!</td>
<td>Contact your service personnel.</td>
</tr>
<tr>
<td><strong>CO₂ Unspecified Accuracy!!</strong></td>
<td>Medium</td>
<td>CO₂ Unspecified Accuracy!!</td>
<td>Contact your service personnel.</td>
</tr>
<tr>
<td><strong>N₂O Unspecified Accuracy!!</strong></td>
<td>Medium</td>
<td>N₂O Unspecified Accuracy!!</td>
<td>Contact your service personnel.</td>
</tr>
<tr>
<td><strong>AA Unspecified Accuracy!!</strong></td>
<td>Medium</td>
<td>AA Unspecified Accuracy!!</td>
<td>Contact your service personnel.</td>
</tr>
<tr>
<td>**Gas Module Temp Out Of Range!!</td>
<td>Medium</td>
<td>Gas Module Temp Out Of Range!!</td>
<td>Contact your service personnel.</td>
</tr>
<tr>
<td><strong>Pressure Out Of Range!!</strong></td>
<td>Medium</td>
<td>Pressure Out Of Range!!</td>
<td>Contact your service personnel.</td>
</tr>
<tr>
<td><strong>AA ID Unreliable!!</strong></td>
<td>Medium</td>
<td>AA ID Unreliable!!</td>
<td>Contact your service personnel.</td>
</tr>
<tr>
<td>**Gas Module Sampler Line clog!!</td>
<td>Medium</td>
<td>Gas Module Sampler Line clog!!</td>
<td>Check sampling line</td>
</tr>
<tr>
<td><strong>Gas Module NO Sampler Line!!</strong></td>
<td>Medium</td>
<td>Gas Module NO Sampler Line!!</td>
<td>Check sampling line</td>
</tr>
<tr>
<td><strong>NO ABSORBER ? !!</strong></td>
<td>Medium</td>
<td>No connected Absorber canister</td>
<td>Install Absorber canister</td>
</tr>
<tr>
<td><strong>ETCO₂ LINE OCCLUSION!!</strong></td>
<td>Medium</td>
<td>An error or occlusion occurred to the sampling line.</td>
<td>Check the CO₂ sampling line.</td>
</tr>
<tr>
<td><strong>Mixed anesthetic MAC &gt;3!!</strong></td>
<td>Medium</td>
<td>Two different agents are detected and the MAC calculation is greater than or equal to 3.</td>
<td>Make sure only one agent is on. Wait approximately two minutes for the first agent to wash out of the system.</td>
</tr>
<tr>
<td><strong>Gas Module Inaccurate Gas Zeroing!!</strong></td>
<td>Medium</td>
<td>Gas Module Inaccurate Gas Zeroing!!</td>
<td>Calibrate the Gas Module Zero. Contact your service personnel.</td>
</tr>
<tr>
<td><strong>Mixed anesthetic MAC &lt;3!!</strong></td>
<td>Low</td>
<td>Two different agents are detected and the MAC calculation is less than 3.</td>
<td>Make sure only one agent is on. Wait approximately two minutes for the first agent to wash out of the system.</td>
</tr>
<tr>
<td><strong>MAINS FAILURE!!</strong></td>
<td>Low</td>
<td>AC power disconnected or failure</td>
<td>Plug in the power cable. Check that the system circuit breaker is on.</td>
</tr>
<tr>
<td><strong>SPO₂ SENSOR DISCONNECT?!</strong></td>
<td>Low</td>
<td>SPO₂ sensor is not connected</td>
<td>Connect the SpO₂ sensor.</td>
</tr>
</tbody>
</table>
## Operating the Anaesthesia System

<table>
<thead>
<tr>
<th>Gas</th>
<th>Low</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>EtCO₂ OFF!</td>
<td>CO₂ switch is turned off</td>
<td>Press the “Alarm Reset” Elimination of this alarm. If you need to monitor CO₂ concentration, open the CO₂ switch.</td>
</tr>
<tr>
<td>AA OFF!</td>
<td>AA switch is turned off</td>
<td>Press the “Alarm Reset” Elimination of this alarm. If you need to monitor anaesthetic agent concentration, open the AA switch.</td>
</tr>
<tr>
<td>SpO₂ OFF!</td>
<td>SpO₂ switch is turned off</td>
<td>Press the “Alarm Reset” Elimination of this alarm. If you need to monitor SpO₂, open the SpO₂ switch.</td>
</tr>
<tr>
<td>O₂ OFF!</td>
<td>O₂ switch is turned off</td>
<td>Press the “Alarm Reset” Elimination of this alarm. If you need to monitor O₂ concentration, open the O₂ switch.</td>
</tr>
</tbody>
</table>
7. Maintenance

7.1 User Maintenance

IMPORTANT

User Maintenance is restricted to cleaning the external surfaces of the machine (see Section 7.2).

All other maintenance and servicing and the replacement of components, must be carried out only by Gradian-trained engineers.

Servicing and Repair

The Prima must be only be serviced or repaired by Gradian-trained engineers, according to the schedule and procedures given in the Service Manual, which contains circuit diagrams, service kits and component lists.

WARNINGS

Exterior panels must not be removed by unauthorised personnel and the apparatus must not be operated with such panels missing.

Check that all panels are secure after any work by authorised personnel.

Electrical power supply

Unauthorised personnel must not attempt to access fuses or other electrical components. There is a possible electric shock hazard.

If a replacement fuse mains lead or battery is required, this work must be carried out only by trained engineers.

If a replacement mains lead is required, this work must be carried out only by Gradian-trained engineers.

Ancillary Equipment

Follow the instructions given in the relevant user manual for detailed information on user maintenance and service requirements for the ancillary equipment used with the anaesthetic machine (vaporizers, anaesthetic gas scavenging system, patient monitoring).

Service Schedule

The anaesthetic machine must be serviced to the following service schedule:

6 months
- Inspection and functional check

12 months
- Inspection and function check.
- Calibrate the CO₂ module (if installed)
- Clean the fan filter
- Replace seals etc., as required

2 years
- Fit components supplied in the preventive maintenance kit.
- Inspection and function check.

Further information is given in the Prima service manual, available only to engineers trained by the manufacturer.
7.2 Cleaning and Disinfection

**WARNING**

1. Disconnect the system from the mains power supply before maintenance, repairs, cleaning, disinfection and sterilization.

2. Read the safety information for each cleaning agent, and the user manual for the disinfection equipment.

3. Wear gloves and safety glasses. Take care when removing the \( O_2 \) sensor (1). A damaged sensor can leak and cause burns (the sensor contains potassium hydroxide).

4. Reuse of a non-disinfected breathing system or reusable accessories may cause cross-contamination. Follow infection control and safety procedures to prevent cross-infection from components contaminated with blood and body fluids.

5. To prevent breathing system leaks, avoid damaging the components when disassembling and reassembling. Ensure correct installation, especially seals. Always follow the correct cleaning and disinfection methods and reassembly procedures, as described in this manual.

6. Pre-use tests (see sections 5.9 to 5.14) must be performed before patient use if the anaesthetic machine has been disassembled for cleaning and disinfection, or servicing.

**CAUTION**

1. Clean and disinfect the equipment as required before it is put into use for the first time.

2. Do not use organic, halogenated, or petroleum based solvents, anaesthetic agents, glass cleaners, acetone, or other harsh cleaning agents.

3. Do not use abrasive cleaning agents (such as steel wool, silver polish or cleaner).

4. Keep all liquids away from electronic parts.

5. Do not allow liquid to enter the equipment housings.

6. Limit the soak time for the synthetic rubber cover for the pressure relief valve in the base of the bellows to 15 minutes. This applies to all synthetic rubber components. Swelling or faster aging can occur. This warning applies to the silicon rubber case for the pressure relief valve in the base of the bellows (see section 7.3.1).

7. Cleaning solutions must have a pH of 7.0 to 10.5.
7.2.1 Cleaning

**WARNING**

1. Check that the unit is disconnected from the electrical supply before cleaning.
2. Care must be taken not to allow liquids to run into enclosed areas; serious damage may result.

7.2.1.1 External surfaces

Disconnect the machine from the mains electrical supply.

All the surfaces of the anaesthetic machine and monitors should be cleaned on a daily basis with an appropriate disinfectant, or immediately if visibly contaminated.

The surfaces of the anaesthetic machine, especially those areas which are likely to have been touched by the gloved hand that has been in contact with blood or secretions, should be regarded as contaminated and should be cleaned at the earliest opportunity, between patients.

Appropriate disinfectants suitable for use with the anaesthetic machine are isopropyl alcohol, or alcohol wipes (e.g. azowipes)

7.2.1.2 Flowmeter / display screen surface

**CAUTION**

Do not apply excessive pressure to the display screens.

Cleaning of flowmeter screen surfaces is restricted to soap based sanitising wipes, or Milton sterilising solutions 1.8 % v/v.

7.2.1.3 After cleaning

Make sure that all cleaning agent residues are fully removed after cleaning.

Always allow the machine to dry off thoroughly before clinical use.

**Sterilisation**

Breathing system hoses and other components must be sterilised to the manufacturer’s recommended methods.
7.3 Absorber and Breathing System Components

7.3.1 Disassembly
Disassemble each part of the system that can be cleaned and sterilised:
1. Bellows housing
2. Bellows
3. Bellows base
4. Pressure relief valve silicon rubber cover
5. Pressure relief valve
6. Absorber body
7. Expiration connector assembly
8. Bag support arm
9. Non-return valve cover
10. Airway pressure gauge
11. Non-return valve guide
12. Non-return valve disc
13. Oxygen sensor
14. Inspiration connector assembly
15. Canister support
16. Absorber canister

7.3.2 Remove the breathing hoses
CAUTION
1. When separating the Y-piece, hold both hose connectors to prevent damage.
2. If a filter is fitted, do not reuse the filter. Follow local regulations regarding disposal of hospital waste when the filter is discarded.

1. Remove the inspiratory and expiratory hoses from the absorber outlets.
2. Separate the Y-piece from the two breathing hoses.
7.3.3 Remove the flow sensors
1. Unscrew the inspiratory and expiratory connectors [1], and disconnect the breathing hoses.

7.3.4 Remove the oxygen sensor
1. Unplug the oxygen sensor cable [1] from the sensor [2].
2. Remove the other end of the cable from the machine.
3. Turn the oxygen sensor counterclockwise to remove.

7.3.5 Remove the airway pressure gauge
1. Pull out the pressure gauge from the breathing system.

7.3.6 Remove the bag support arm
1. Loosen the locking nut counterclockwise.
2. Remove the bag arm from the breathing system.
7.3.7  Remove the bellows assembly components

1. Turn the bellows housing counterclockwise, and lift from the base

2. Remove the bellows from the base

3. Remove the bellows base.

4. Remove the pressure relief valve assembly from absorber.

5. Remove the locking tabs and ring from the bellows base.
7.3.8 Remove a check valve assembly
1. Turn the check valve cover counterclockwise to remove.

2. Remove the check valve assembly.

7.3.9 Remove the absorber canister
1. Hold the canister handle, rotate the canister clockwise and remove.

WARNING
Soda lime is a caustic substance and is a strong irritant to eyes, skin and respiratory system. Affected parts should be flushed with water. If irritation continues after flushing with water, seek medical assistance immediately.

Drain the condensation from the canister

WARNING
If the water is drained during a clinical procedure, reinstall the drain plug immediately to prevent gas leakage

The drain plug allows condensation drainage without the need to remove the soda lime.

1. Wear protective gloves
2. Hold the canister over a drain or collection bowl.
3. Carefully pull out the water drain plug.
4. Dilute the drained condensate before disposal.
5. Refit the plug.
6. Empty the canister.
   Dispose of the absorbent in line with local regulations.
7.3.10 Remove the water container
1. Grip the water collection container and turn clockwise to remove.

CAUTION
Removing the water collection container will not cause gas leakage, but always reinstall as soon as possible.

7.3.11 Remove the absorber assembly
1. Pull the locking catch on the adaptor plate up, rotate 90 degrees and pull off.
2. Remove the absorber assembly from the circuit adapter with both hands.
## 7.4 Cleaning and Disinfection Methods

**WARNING**

1. **Before cleaning this device,** disconnect the mains power supply.  
   While cleaning, do not let cleaning fluids flow into the machine.  
   After cleaning, ensure all components are completely dry before use.

2. **O₂ sensor:** Do not autoclave, or immerse in cleaning liquid.

3. **Reusable consumables (breathing system hoses, Y-piece, bag):** check the manufacturer’s instructions.

**CAUTION**

1. Water quality will affect the cleaning process.  
   Water quality should not be lower than the quality of drinking water.  
   Deionized water is recommended.

2. Clean the components thoroughly in water (<35°C).  
   Remove organic matter, such as blood and other residues.  
   Cleaning in water at temperatures above 35°C may cause solidification of organic matter.

3. Recommended cleaning and disinfection methods for the various components are detailed in the table below.

### Cleaning and disinfection methods

A. Use disinfection equipment.

B. Use a mild detergent with a pH of less than 10. For example: soak for a minimum of 45 minutes with 2% glutaraldehyde solution. Rinse with water.

C. Autoclave [maximum temperature: 134°C, see 7.4.3]]

D. Wipe with a damp cloth soaked in a soft detergent solution (70% ethylene glycol or isopropyl alcohol).

<table>
<thead>
<tr>
<th>Component</th>
<th>Cleaning and disinfection method</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A</td>
</tr>
<tr>
<td>Anaesthetic machine interface</td>
<td></td>
</tr>
<tr>
<td>Breathing tubes and Y-piece</td>
<td>✓</td>
</tr>
<tr>
<td>Bag</td>
<td>✓</td>
</tr>
<tr>
<td>Flow sensors</td>
<td></td>
</tr>
<tr>
<td>Check valve cover and base</td>
<td>✓</td>
</tr>
<tr>
<td>Check valve discs</td>
<td>✓</td>
</tr>
<tr>
<td>Oxygen sensor</td>
<td></td>
</tr>
<tr>
<td>Airway pressure gauge</td>
<td></td>
</tr>
<tr>
<td>Bag support arm</td>
<td>✓</td>
</tr>
<tr>
<td>Bellows assembly</td>
<td>✓</td>
</tr>
<tr>
<td>Absorber canister</td>
<td>✓</td>
</tr>
<tr>
<td>Water container</td>
<td>✓</td>
</tr>
<tr>
<td>Absorber body</td>
<td>✓</td>
</tr>
</tbody>
</table>
Maintenance

7.4.1 Using disinfection equipment

**CAUTION**

1. To minimize the impact on the environment, use only water when disinfecting. The maximum temperature during disinfection is within the range 90°C to 95°C.

2. Clean or rinse with clean water.

3. Use disinfected equipment for disinfection. If detergent is used with cleaning and sterilizing, use a detergent with a pH of <10.

4. Dry the components, assemble and/or store.

7.4.2 Using detergent

**CAUTION**

1. Use a detergent with a pH of <10.

2. Limit the soak time for the synthetic rubber cover (1) for the pressure relief valve in the base of the bellows to 15 minutes.

3. Clean or rinse with clean water.

4. Use a mild detergent with a pH of less than 10, for 2% glutaraldehyde solution.

5. Use clean water to rinse off the residual disinfectant.

6. Dry the components, assemble and/or store.

7.4.3 Autoclave

**CAUTION**

1. Steam autoclave will shorten the service life of the component.

2. Use a certified process, typically at temperatures of:
   a) 121°C (250°F) for 15 minutes, or
   b) 134°C (275°F) for 4 minutes.

3. Components can also be autoclaved at a temperature of 134°C (275°F) for 18 minutes.

4. Procedure
   a) Clean or rinse with clean water.
   b) Dry the components.
   c) Use steam autoclave.
   d) Dry the components, assemble and/or store.

7.4.4 Display screen

**CAUTION**

The display screen must not be cleaned with liquid.

1. Wipe with a cotton cloth soaked in soft detergent solution.

2. Wipe off the residual detergent solution with a dry, soft, lint-free cloth.
Maintenance

7.5 Absorber and breathing system

CAUTION
1. Before assembly, check that all components are dry.
2. When installing, make sure that the components and seals are in good condition.
3. Only use lubricants approved for anaesthesia or O₂ equipment. Do not use lubricants containing oil or grease that may burn or explode in high O₂ concentrations.

7.5.1 Reassemble the absorber and breathing system
1. All components must be fully dried before assembly and installation.
2. Replace any parts that are visibly damaged or worn.
3. Reverse the dismantling procedures given in sections 7.3.1 to 7.3.10.
   Pressure flow sensors – see section 7.5.2.

7.5.2 Refit the pressure flow sensors
2. Push the tube into the sensor until the lugs engage the slots.
3. Turn the tubing clockwise until the lugs are fully engaged in the slots [2].
4. Align the flow sensor and tube assembly with the absorber.

CAUTION
a) Make sure that the arrow [3] and the word ‘UP’ [4] are aligned uppermost as shown in the top illustration.

b) The direction of the arrow [3] indicates expiratory sensor (lower illustration) and inspiratory sensor (top illustration) on the sensor.

5. Push the flow sensor and tube assembly into the absorber assembly [5].

7.5.3 Reinstall the absorber and breathing system
1. All components must be fully dried before assembly and installation.
2. Check that the eight silicon inserts [1] on the breathing circuit adapter plate [2] are in place and are not damaged.
3. Use BG87 or Fomblin grease to lightly lubricate the eight silicon inserts [1].
4. Lift and turn the locking catch [3] to the unlocked position.
6. Carefully push the absorber assembly into the circuit adapter plate with moderate force.

7. Reset the locking catch (3) to the locked position.

**WARNING**
Set the locking catch to the locked position after the absorber assembly is installed. Always check that the assembly is locked in position.

### 7.5.4 System test

**CAUTION**
Perform a complete system test, refer to sections 5.9 to 5.14.

### 7.6 Pressure Sensor Zeroing

**CAUTION**
1. Do not calibrate while the unit is connected to a patient.
2. During calibration, do not operate the pneumatic system. Do not move or compress the breathing tubes.
3. If zeroing fails, contact a Gradian-trained engineer.

**Procedure**
1. Stop manual or mechanical ventilation. If a breathing tube is connected, open the breathing tube patient connection to air.
2. Check that the bellows falls to the bottom.
3. Turn the flowmeter to minimum.
4. In standby mode, touch the [System] hotkey -> [Calibration] hotkey -> [Pressure Sensor Cal].

Pressure sensor zero calibration will start automatically. Do not touch the breathing system tubing during calibration.

### 7.7 Flow Sensor Zeroing

1. Stop manual or mechanical ventilation. If a breathing tube is connected to the breathing system, open the breathing tube patient connection to air. Check that the bellows falls to the bottom.
2. Turn off the flowmeter.
3. In standby mode, touch the [System] hotkeys -> [Calibration] hotkey -> [Flow Sensor Cal].

Flow sensor zero calibration will start automatically. Do not touch the breathing tubes during calibration.
Maintenance

7.8 Oxygen Concentration Calibration

CAUTION
1. Calibrate the O₂ sensor (1) at the same ambient pressure in which it will be used.

2. Follow your hospital biohazard disposal procedure for the discarded O₂ sensor. Do not incinerate.
   1. Remove the O₂ sensor.
      Check that there is no water build-up on the O₂ sensor or within the port (2) on the side of the absorber.
   2. Reinstall the O₂ sensor and check that the cable (3) is connected correctly.

7.8.1 O₂ calibration at 21%

CAUTION
1. Calibrate when the measured value of O₂ concentration is outside specification range, or when a new sensor is fitted.

2. If calibration fails:
   a) Check for a technical alarm and then check the troubleshoot section. Repeat the calibration.
   b) In case of repeated calibration failures, fit a new sensor and repeat the calibration. If it still fails, contact a Gradian-trained service engineer.

Calibration procedure at 21% O₂
1. Select standby mode.
2. Press the hotkeys -> [Calibration] -> [Oxygen Cell Cal]
3. Select [21%] and press confirm to start calibration.
4. Follow the on-screen instructions.
5. After a successful calibration, the screen shows [Calibration success!]
6. If the message [Calibration Failure!] is displayed, repeat the calibration.

7.8.2 100% O₂ calibration

CAUTION
1. If the calibration fails, check for a technical alarm. Repeat the calibration.

2. In case of repeated calibration failures, replace the O₂ sensor and repeat the 21% O₂ calibration.

3. Calibrate at 100% O₂ after a 21% O₂ calibration is completed. If it still fails, contact a Gradian-trained engineer.

Calibration at 100% O₂:
1. Check that the 21% O₂ calibration is completed successfully and that the O₂ Supply Failure alarm is not triggered.
2. Select standby mode.
3. Touch the [System] hotkeys -> [Calibration] -> [Oxygen Cell Cal]
4. Select [100%] and press confirm to start calibration.
5. Follow the on-screen instructions.
6. After a successful calibration, the screen shows [Calibration success!]. Repeat the procedure if [Calibration Failure!] is displayed.

7.9 Touchscreen Calibration

CAUTION
Calibrate the touchscreen if the display is out of focus.

Procedure
1. Select Standby mode.
2. Press the System key.
3. Select the Calibration tab [1].
5. Follow the on-screen instructions.

NOTE
1. Touch the centre of the crosshair when it appears on screen – take care to carry this out accurately.
2. The crosshairs appear in a total of nine positions (four calibration points and five verification tests).

7.10 Prevention of Water Build-up

1. Water is formed by the condensation of exhaled gas and a chemical reaction between CO₂ and the soda lime in the absorber canister.
2. Lower fresh gas flows produce more condensation due to higher levels of CO₂ in the canister. In addition, moist, exhaled gas remains in the breathing system and the absorber canister.
3. Check the flow sensors when abnormal flow waveforms or unstable tidal volume fluctuation occurs. Check for moisture and dry, before use.

To prevent water build-up
4. Use a filter between the flow sensor and the patient.
5. Check the water container and absorber canister before use. Dispose of any water build-up.
7.11 Battery Replacement

**WARNING**
Battery installation must be undertaken by a competent, trained engineer.

1. Disconnect the machine mains power cable.
2. Remove the battery cover (illustrated in section 3.4), detach the battery (1) and disconnect the wiring.
3. Install a new battery and reconnect the wiring.
4. Refit the cover and tighten the four screws.

7.12 Fault Diagnosis and Troubleshooting

<table>
<thead>
<tr>
<th>Fault</th>
<th>Cause</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ventilation system leak</td>
<td>APL is not closed during manual mode</td>
<td>Turn the APL valve to the appropriate position</td>
</tr>
<tr>
<td></td>
<td>Absorber canister is not installed correctly</td>
<td>Reinstall</td>
</tr>
<tr>
<td></td>
<td>Damaged or loose breathing tube connector</td>
<td>Reinstall or renew the breathing tube</td>
</tr>
<tr>
<td></td>
<td>Check valve is not installed correctly</td>
<td>Reinstall</td>
</tr>
<tr>
<td></td>
<td>Manual / mechanical ventilation switch failure</td>
<td>Contact a Gradian-trained engineer</td>
</tr>
<tr>
<td>Bellows does not inflate completely</td>
<td>The respiratory rate is set too fast and expiratory time is too short.</td>
<td>Set respiratory rate to a reasonable value</td>
</tr>
<tr>
<td></td>
<td>The breathing system leaks</td>
<td>Carry out a system leak test</td>
</tr>
<tr>
<td></td>
<td>Flowmeter is closed</td>
<td>Reset the flowmeter</td>
</tr>
<tr>
<td>During the inspiratory phase, the bellows is not compressed</td>
<td>Manual / mechanical ventilation switch is still in the manual position.</td>
<td>Turn the switch to mechanical ventilation</td>
</tr>
<tr>
<td></td>
<td>Flow control valve has failed; no drive gas is delivered.</td>
<td>Contact a Gradian-trained engineer</td>
</tr>
<tr>
<td></td>
<td>Bellows housing is damaged</td>
<td>Replace the bellows housing</td>
</tr>
<tr>
<td></td>
<td>During inhalation, the PEEP valve cannot be closed</td>
<td>Contact a Gradian-trained engineer</td>
</tr>
<tr>
<td>Manual breathing airway pressure is too high</td>
<td>APL valve is set too high</td>
<td>Reset the APL valve</td>
</tr>
<tr>
<td>Power indicator is not lit</td>
<td>Power cord is not connected</td>
<td>Connect the power cord</td>
</tr>
<tr>
<td></td>
<td>System and ventilator switch is not turned on</td>
<td>Turn the switch to On</td>
</tr>
<tr>
<td></td>
<td>Power cord is damaged</td>
<td>Replace the power cord. Contact a trained engineer</td>
</tr>
<tr>
<td></td>
<td>Mains power outlet is faulty</td>
<td>Swap to another power outlet. Contact a trained engineer</td>
</tr>
<tr>
<td></td>
<td>Fuse has blown</td>
<td>Contact a trained engineer. Diagnose the fault and fit a new fuse.</td>
</tr>
<tr>
<td>No power at auxiliary outlet</td>
<td>Fuse has blown</td>
<td>Contact a trained engineer. Diagnose the fault and fit a new fuse.</td>
</tr>
<tr>
<td>No airway pressure waveform</td>
<td>There is a disconnect between the pressure sensor and the sample tube, or:</td>
<td>Reconnect. Check the gas supply.</td>
</tr>
<tr>
<td></td>
<td>Gas source is exhausted</td>
<td></td>
</tr>
</tbody>
</table>
Appendix 1 References

The Prima and its anaesthetic breathing system complies with the requirements of ISO 80601-2-13.

Appendix 2 Disposal at end of useful life: Risk assessment

Do not dispose of in landfill, refer to an approved recycling facility. Follow your hospital, local, state and federal regulations.

EC territories: follow the requirements of Directive 2002/96/EC

Disposal of used batteries

Do not dispose of in landfill, refer to an approved recycling facility. Follow your hospital, local, state and federal regulations.

NOTE

Removal/replacement of the battery must only be undertaken by a trained engineer.
## Appendix 3. Optional extras and approved accessories

**WARNING**  
Only use accessories approved by Gradian.

Please contact Gradian, or your local Gradian Distributor.

Tel: +254 794 764 415  
E-mail: info@gradianhealth.org

<table>
<thead>
<tr>
<th>Accessories</th>
<th>Contact Sales Department</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hose - Air / O₂ / N₂O</td>
<td></td>
</tr>
<tr>
<td>Exhalation diaphragm valve</td>
<td>5008688</td>
</tr>
<tr>
<td>Bellows - Latex free</td>
<td>5006441</td>
</tr>
<tr>
<td>O₂ sensor [MOX-4]</td>
<td>5008390</td>
</tr>
<tr>
<td>a) Adult adapter</td>
<td>5008685</td>
</tr>
<tr>
<td>b) Infant adapter</td>
<td>5008686</td>
</tr>
<tr>
<td>a) Sample tube [single use]</td>
<td>5008679</td>
</tr>
<tr>
<td>b) Water trap</td>
<td>5008678</td>
</tr>
<tr>
<td>Back-up battery</td>
<td></td>
</tr>
<tr>
<td>SpO₂ monitor [optional]</td>
<td></td>
</tr>
<tr>
<td>SpO₂ probe</td>
<td>5008690</td>
</tr>
<tr>
<td>CO₂ monitor [optional]</td>
<td></td>
</tr>
<tr>
<td>Adult face mask</td>
<td>50244</td>
</tr>
<tr>
<td>Paediatric face mask</td>
<td>50240</td>
</tr>
<tr>
<td>Manual bag 3 L</td>
<td>2830000</td>
</tr>
<tr>
<td>Bacterial filter</td>
<td>1541197</td>
</tr>
<tr>
<td>Breathing circuit - silicon</td>
<td>2000000</td>
</tr>
<tr>
<td>Breathing circuit - paediatric - silicon</td>
<td>2142000</td>
</tr>
<tr>
<td>O₂ therapy flowmeter and tubing nipple with right angle, direct probe</td>
<td>5009161</td>
</tr>
<tr>
<td>Suction controller kit: High suction, with remote connector and V-plate, plus vacuum hose (4 m) and BS probe</td>
<td>5008959</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Masimo IRMA AX+ mainstream module</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>IRMA AX+ probes</td>
<td>107000086</td>
</tr>
<tr>
<td>IRMA airway adapter: Adult/ Pediatric</td>
<td>107000002</td>
</tr>
<tr>
<td>IRMA airway adapter: Infant</td>
<td>107000004</td>
</tr>
</tbody>
</table>
### Appendix 4. Labelling

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>~</td>
<td>Alternating current</td>
</tr>
<tr>
<td>!</td>
<td>Dangerous Voltage</td>
</tr>
<tr>
<td>⚠️</td>
<td>Type BF equipment</td>
</tr>
<tr>
<td>🔋</td>
<td>Battery</td>
</tr>
<tr>
<td>💡</td>
<td>AC power supply (indicates a connection to mains)</td>
</tr>
<tr>
<td>⚡</td>
<td>Power On</td>
</tr>
<tr>
<td>⚡</td>
<td>Lighting</td>
</tr>
<tr>
<td>⚡</td>
<td>Inspiratory flow</td>
</tr>
<tr>
<td>⚡</td>
<td>Bag/manual ventilation</td>
</tr>
<tr>
<td>⚡</td>
<td>Lock</td>
</tr>
<tr>
<td>⚡</td>
<td>Flow control</td>
</tr>
<tr>
<td>⚡</td>
<td>Oxygen sensor connector</td>
</tr>
<tr>
<td>⚡</td>
<td>Cylinder</td>
</tr>
<tr>
<td>⚡</td>
<td>N₂O supply connector</td>
</tr>
<tr>
<td>⚡</td>
<td>N₂O supply connector</td>
</tr>
<tr>
<td>⚡</td>
<td>N₂O supply connector</td>
</tr>
<tr>
<td>⚡</td>
<td>N₂O supply connector</td>
</tr>
<tr>
<td>⚡</td>
<td>N₂O supply connector</td>
</tr>
<tr>
<td>⚡</td>
<td>Bi-directional rotation</td>
</tr>
<tr>
<td>⚡</td>
<td>Fuse</td>
</tr>
<tr>
<td>⚡</td>
<td>General warning</td>
</tr>
<tr>
<td>⚡</td>
<td>Type B equipment</td>
</tr>
<tr>
<td>⚡</td>
<td>Defibrillator proof type BF equipment</td>
</tr>
<tr>
<td>⚡</td>
<td>Gas Outlet</td>
</tr>
<tr>
<td>⚡</td>
<td>Gas Inlet</td>
</tr>
<tr>
<td>⚡</td>
<td>Equipotential</td>
</tr>
<tr>
<td>⚡</td>
<td>Power Off</td>
</tr>
<tr>
<td>⚡</td>
<td>USB Interface</td>
</tr>
<tr>
<td>⚡</td>
<td>Expiratory flow</td>
</tr>
<tr>
<td>⚡</td>
<td>Mechanical ventilation</td>
</tr>
<tr>
<td>⚡</td>
<td>Unlock</td>
</tr>
<tr>
<td>⚡</td>
<td>O₂ Flush button</td>
</tr>
</tbody>
</table>
### Appendix

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>O₂</td>
<td>O₂ supply connector</td>
</tr>
<tr>
<td>Air</td>
<td>Air supply connector</td>
</tr>
<tr>
<td>AGSS</td>
<td>AGSS connector</td>
</tr>
<tr>
<td>☑️</td>
<td>Multiple activated alarms (&quot;x&quot; indicates the number of active alarms)</td>
</tr>
<tr>
<td>🔊</td>
<td>Audio pause</td>
</tr>
<tr>
<td>👽</td>
<td>Adjust the lower limit alarm parameters</td>
</tr>
<tr>
<td>🚨</td>
<td>Caution</td>
</tr>
<tr>
<td>⚠️</td>
<td>Do not reuse</td>
</tr>
<tr>
<td>🔗</td>
<td>Refer to instruction manual</td>
</tr>
<tr>
<td>🍀</td>
<td>Handle with care</td>
</tr>
<tr>
<td>🧰</td>
<td>Serial number</td>
</tr>
<tr>
<td>🔥</td>
<td>Batch code</td>
</tr>
<tr>
<td>🟢</td>
<td>CE marking and notified body number (XXX)</td>
</tr>
<tr>
<td>🟦</td>
<td>Contains, or presence of, natural rubber Latex</td>
</tr>
<tr>
<td>🌡️</td>
<td>Temperature range limits</td>
</tr>
<tr>
<td>🔥</td>
<td>Standby button</td>
</tr>
<tr>
<td>🔧</td>
<td>Drive gas identification (&quot;x&quot; will be marked as O₂ or Air)</td>
</tr>
<tr>
<td>🟢</td>
<td>Apnea alarm label - Spont mode only</td>
</tr>
<tr>
<td>🔧</td>
<td>Alarm parameter adjustment cap</td>
</tr>
<tr>
<td>⚠️</td>
<td>Do not touch</td>
</tr>
<tr>
<td>📚</td>
<td>Identifies that the user needs to perform the operation</td>
</tr>
<tr>
<td>📚</td>
<td>Operating instructions</td>
</tr>
<tr>
<td>🥫</td>
<td>Manufacturer and date of manufacture</td>
</tr>
<tr>
<td>🍀</td>
<td>Recycle</td>
</tr>
<tr>
<td>🧰</td>
<td>Part number</td>
</tr>
<tr>
<td>🏗️</td>
<td>Protected against solid foreign objects of Ø12.5 mm and greater. 1: Protection against vertically falling water drops</td>
</tr>
<tr>
<td>🌡️</td>
<td>Keep dry</td>
</tr>
<tr>
<td>🚑</td>
<td>Do not roll</td>
</tr>
<tr>
<td>🟳</td>
<td>Upward direction</td>
</tr>
<tr>
<td>⚠️</td>
<td>Do not dispose of in landfill, refer to an approved recycling facility. Follow your hospital, local, state and federal regulations.</td>
</tr>
</tbody>
</table>
## Appendix

<table>
<thead>
<tr>
<th>Icon</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Hazardous waste (infectious)" /></td>
<td>Components that must be disposed of as hazardous waste</td>
</tr>
<tr>
<td><img src="image" alt="SpO2" /></td>
<td>SpO2 inlet connector</td>
</tr>
<tr>
<td><img src="image" alt="Disconnect mains plug" /></td>
<td>Disconnect mains plug</td>
</tr>
<tr>
<td><img src="image" alt="Disconnect gas" /></td>
<td>Disconnect gas</td>
</tr>
<tr>
<td><img src="image" alt="Startup screen" /></td>
<td>Startup screen</td>
</tr>
<tr>
<td><img src="image" alt="Alarm reset" /></td>
<td>Alarm reset</td>
</tr>
<tr>
<td><img src="image" alt="Standby" /></td>
<td>Standby</td>
</tr>
<tr>
<td><img src="image" alt="Calibration port adjustment" /></td>
<td>Calibration port adjustment</td>
</tr>
<tr>
<td><img src="image" alt="Do not obstruct" /></td>
<td>Do not obstruct</td>
</tr>
<tr>
<td><img src="image" alt="Serial interface" /></td>
<td>Serial interface</td>
</tr>
</tbody>
</table>
Appendix 5. Sidestream CO₂ Module (optional)

Appendix 5.1 NMed CO₂ Module

WARNINGS
1. The CO₂ module, components and packaging must be handled in accordance with local regulations concerning disposal.
2. Read the instructions supplied by the manufacturer before using the module in a clinical procedure.

1. Description
The end-tidal CO₂ module can monitor exhaled concentration of CO₂, end-tidal CO₂ concentration, inhaled CO₂ concentration and respiratory rate, inspiratory time and expiratory time. The module can be used for intubated patients (via a three-way sampling system), and bedside patients (via a nasal sampling tube).

The CO₂ module can be used for newborns, children, and adults.

The module can detect and report pipeline blockages and other state data to the host. Do not reverse the airflow in the sampling tube.

The module is factory calibrated and has an automatic zero calibration function. If the user finds a significant deviation from standard performance, return the unit for factory recalibration.

2. Specification

<table>
<thead>
<tr>
<th>Power requirements</th>
<th>5.0 V ± 0.2 V DC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power</td>
<td>80 mA in general use; 300 mA in extreme circumstances</td>
</tr>
<tr>
<td>Operating temperature</td>
<td>5 ~ 50°C</td>
</tr>
<tr>
<td>Storage temperature</td>
<td>-20 ~ +70°C</td>
</tr>
<tr>
<td>Relative humidity</td>
<td>0-85% (non-condensing)</td>
</tr>
<tr>
<td>Size</td>
<td>77 × 50 × 30 mm</td>
</tr>
<tr>
<td>CO₂ measurement range</td>
<td>0 - 20% by volume [0 - 150 mmHg @ BTPS]</td>
</tr>
<tr>
<td>CO₂ measurement accuracy</td>
<td>&lt;5.0% CO₂ (ATPS) time: ± 2 mmHg</td>
</tr>
<tr>
<td></td>
<td>&gt;5.0% CO₂ (ATPS) time: &lt;5% of reading</td>
</tr>
<tr>
<td>Respiratory rate</td>
<td>2 ~ 150 BPM</td>
</tr>
<tr>
<td>Respiratory rate measurement accuracy</td>
<td>1% @ ± 1 BPM</td>
</tr>
<tr>
<td>Warm-up time</td>
<td>10 s</td>
</tr>
<tr>
<td>Response time</td>
<td>Detector 28 ms, system response time depends on the implementation, flow settings and dehydration technology</td>
</tr>
<tr>
<td>Automatic offset calibration</td>
<td>Automatically, according to the time and temperature, or under instruction</td>
</tr>
</tbody>
</table>

Interfering gases and agents: effect on CO₂ measurement accuracy

<table>
<thead>
<tr>
<th>Gases or anaesthetic agents</th>
<th>Gas concentration (volume percentage)</th>
<th>CO₂</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nitrous oxide</td>
<td>60%</td>
<td>1%</td>
</tr>
<tr>
<td>Halothane</td>
<td>4%</td>
<td>1%</td>
</tr>
<tr>
<td>Enflurane</td>
<td>5%</td>
<td>+10% of reading</td>
</tr>
<tr>
<td>Isoflurane</td>
<td>5%</td>
<td>+10% of reading</td>
</tr>
<tr>
<td>Sevoflurane</td>
<td>5%</td>
<td>+10% of reading</td>
</tr>
<tr>
<td>Desflurane</td>
<td>15%</td>
<td>+14% of reading</td>
</tr>
</tbody>
</table>

1) The module allows normal operating conditions, the interference can be ignored.
3. Safety guide

WARNING
1. This module provides data for exhaled CO2 and respiration rate only. The data should only play a supporting role in a diagnosis. Clinical signs and symptoms must be checked before final diagnosis.

2. Do not reuse disposable sampling pipes.

CAUTION
1. This module is to be used by trained professionals. Read the manual before using the module.

2. A single-use water trap must not be reused, to maintain accuracy and prevent damage to the module. The unit must not be shared between patients to prevent cross-infection.

3. Dispose of components in accordance with hospital regulations and in an environmentally safe manner.

4. To prevent damage and maintain accuracy always empty the water trap when it is nearly full. Check the level once a week at least.

5. The sampling tubes must not be bent. This will prevent pump overload and maintain accuracy of measurement.

6. Repairs must be made only by Gradian-trained engineers, or by the manufacturer.

7. The manufacturer will not be held responsible if the operator uses the unit incorrectly. The module must only be used as stated in the manufacturer’s instructions.

8. Do not use the module for the measurement of exhaled gases. Exhaled moisture may cause measurement errors, and moisture accumulation may reduce module life.


10. Any obstruction to the flow of the sample gas (e.g. tubing severely bent, contaminants blocking the sampling tube, filters blocked) may cause inaccurate measurements and damage. An obstruction lasting more than 20 seconds will trigger a pump shut down.


12. A pipeline leak will seriously affect the accuracy of measurement data and waveform shape.

13. Excess humidity can affect measurement accuracy.

4. Connection

Follow the instructions supplied by the manufacturer.

Installation – water trap
Note that the CO2 module is installed inside the machine.
The water trap mounting is on the side of the machine.

Attach the water trap to the mounting and then connect the CO2 sampling components as illustrated.
Connect the sample tube to the water trap sample port.
Appendix

Appendix 5.2  Masimo Nomoline ISA Sidestream CO\textsubscript{2} / AX+ / OR Module (optional)

CAUTION

The Nomoline ISA CO2/AX+/OR+ module is to be operated by, or under the supervision of, qualified personnel only. Read this Appendix, the directions for use supplied with accessories, all precautionary information and specifications before use. Refer to the other sections in this manual for additional safety information, warnings, and cautions.

1. Safety Warnings and Cautions

WARNINGS

1. Do not use this module if it appears or is suspected to be damaged. Damage to the device can result in exposed electrical circuits that may cause patient harm.

2. Do not adjust, repair, open, disassemble, or modify this module. Damage to the device may result in degraded performance and/or patient injury.

3. Do not start or operate this module unless the setup was verified to be correct. Improper set-up of this device may result in degraded performance and/or patient injury.

4. Do not place this module, or accessories in any position that might cause it to fall on the patient.

5. Only use Masimo authorized devices with this module. Using unauthorized devices with this module may result in damage to the device and/or patient injury.

6. Carefully route the sampling line to reduce the risk of patient entanglement or strangulation.

7. Do not lift the module by the Nomoline capnography sampling line. It might disconnect from the module, causing the module to fall on the patient.

8. Do not use the device during magnetic resonance imaging (MRI) or in an MRI environment.

9. Only use sample lines intended for anesthetic agents if N\textsubscript{2}O and/or anesthetic agents are being used.

10. Do not re-use disposable single-patient-use Nomoline Family sampling lines, due to the risk of cross contamination.

11. Do not use the Nomoline Infant/Neonatal Airway Adapter Sets for adults/pediatrics as they may cause excessive flow resistance (0,7 ml dead space).

12. Do not use the Nomoline Adult/Pediatric Airway Adapter Sets for infants/neonates as the airway adapter adds 6 ml dead space.

13. Do not apply negative pressure to remove condensed water from the Nomoline Family sampling line.

14. Successful zeroing requires the presence of ambient air (21% O\textsubscript{2} and 0% CO\textsubscript{2}). Therefore, ensure that the Nomoline ISA CO\textsubscript{2}/AX+/OR+ is placed in a well ventilated place. Avoid breathing near the module before or during the zeroing procedure.

15. Exhaust gases should be returned to the patient circuit or to a scavenging system.

16. Due to the risk of patient cross-infection, always use a bacteria filter on the exhaust port side if sampled gas is intended to be re-breathed.
NOTE
1. Disconnect the device from AC mains by removing the device cable connection from the host device.
2. Use and store the NomoLine ISA CO₂/AX+/OR+ in accordance with specifications. See the Specifications section in this manual.

2. Performance Warnings and Cautions

WARNINGS
1. NomoLine ISA CO₂/AX+/OR+ should not be used as the sole basis for medical decisions. It must be used in conjunction with clinical signs and symptoms.
2. Use of high-frequency electrosurgical equipment in the vicinity of NomoLine ISA CO₂/AX+/OR+ may produce interference and cause incorrect measurements.
3. Do not use the NomoLine ISA CO₂/AX+/OR+ with metered-dose inhalers or nebulized medications as this may clog the bacteria filter.
4. Properly apply sampling lines according to the sampling lines directions for use. Misapplied sampling lines that become partially dislodged may cause no or incorrect readings.
5. Replace the sampling line if the sampling line input connector starts flashing red, or host device displays a check sampling line type of message.
6. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating properly.
7. Portable and mobile RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the NomoLine ISA CO₂/AX+/OR+ including the cable. Otherwise, degradation of performance could result.
8. Excessive positive or negative pressure in the patient circuit might affect the sample flow.
9. Strong scavenging suction pressure might affect the sample flow.

CAUTIONS
1. Do not operate NomoLine ISA AX+ outside of the specified operating environment.
2. To avoid damage, the module should be mounted securely.

3. Cleaning and Service Warnings and Cautions

WARNINGS
1. To avoid electric shock, always physically disconnect the module and all patient connections before cleaning.
2. Do not attempt to remanufacture, recondition or recycle the module as these processes may damage the electrical components, potentially leading to patient harm.

CAUTIONS
1. Do not sterilize or immerse NomoLine Family sampling lines in liquid.
2. To avoid permanent damage to the module, do not use undiluted bleach (5% - 5.25% sodium hypochlorite) or any other cleaning solution not recommended by the manufacturer.

3. Do not use petroleum-based or acetone solutions, or other harsh solvents, to clean the module. These substances affect the device’s materials and device failure can result.

4. Do not submerge the module in any cleaning solution, or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the device.

5. To prevent damage, do not soak or immerse the module in any liquid solution.

4. Compliance Warnings and Cautions

WARNINGS

1. Any changes or modifications not expressly approved by Masimo shall void the warranty for this equipment and could void the user’s authority to operate the equipment.

2. Use of accessories and cables other than those specified or provided could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

3. Make sure that the NomoLine ISA AX+ is used in the electromagnetic environment specified in this manual.

4. Dispose NomoLine Family sampling lines in accordance with local regulations for biohazardous waste.

CAUTIONS

1. Disposal of Product: Comply with local laws in the disposal of the device and/or its accessories.

2. For FCC compliance information, refer to this Operator’s Manual.

NOTE

1. Use the NomoLine ISA CO₂/AX+/OR+ in accordance with the Environmental Specifications section in this Operator’s Manual.

5. Intended Use

This sidestream gas analyzer and accessories (including NomoLine sampling lines) is intended to be connected to other medical backboard devices for monitoring of breath rate and the following breathing gases:

1. NomoLine ISA CO₂: CO₂
2. NomoLine ISA AX+: CO₂/N₂O/ Halothane/ Isoflurane/ Enflurane/ Sevoflurane/ Desflurane
3. NomoLine ISA OR+: CO₂/N₂O/ Halothane/ Isoflurane/ Enflurane/ Sevoflurane/ Desflurane/O₂
4. NomoLine ISA CO₂/AX+/OR+ is intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care. The intended environment is the operating suite, intensive care unit and patient room. The intended patient population is adult, pediatric, infant and neonatal patients.
## 6. Specifications

<table>
<thead>
<tr>
<th>General specifications</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating temperature</td>
<td>NomoLine ISA CO2: 0 to 50 °C (32 to 122 °F)</td>
</tr>
<tr>
<td></td>
<td>NomoLine ISA OR+/AX+: 5 to 50 °C (41 to 122 °F)</td>
</tr>
<tr>
<td>Storage temperature</td>
<td>NomoLine ISA OR+: −30 to 70 °C (−22 to 158 °F)</td>
</tr>
<tr>
<td></td>
<td>All other NomoLine ISA: −40 to 70 °C (−40 to 158 °F)</td>
</tr>
<tr>
<td>Operating humidity</td>
<td>10% to 95% RH (non-condensing) (Not requiring partial pressure greater than 50 hPa.)</td>
</tr>
<tr>
<td>Storage humidity</td>
<td>10% to 95% RH (non-condensing at ambient temperature) (Not requiring partial pressure greater than 50 hPa.)</td>
</tr>
<tr>
<td>Operating atmospheric pressure</td>
<td>525 mbar to 1,200 mbar [52.5 kPa to 120 kPa]</td>
</tr>
<tr>
<td>Storage atmospheric pressure</td>
<td>200 mbar to 1,200 mbar [20 kPa to 120 kPa]</td>
</tr>
<tr>
<td>Ambient CO2</td>
<td>≤800 ppm [0.08 vol%]</td>
</tr>
<tr>
<td>Power supply</td>
<td>4.5 to 5.5 VDC,</td>
</tr>
<tr>
<td></td>
<td><strong>NomoLine ISA CO2:</strong> ≤ 0.9 W (normal operation @ 5V) &lt; 4.0 W (power surge @ 5V can last up to 500 ms when entering measurement mode from sleep mode or during start-up)</td>
</tr>
<tr>
<td></td>
<td><strong>NomoLine ISA AX+:</strong> ≤ 1.6 W (normal operation @ 5V) &lt; 2.0 W (power surge @ 5V can last up to 500 ms when entering measurement mode from sleep mode or during start-up)</td>
</tr>
<tr>
<td></td>
<td><strong>NomoLine ISA OR+:</strong> ≤ 2.0 W (normal operation @ 5V) &lt; 2.4 W (power surge @ 5V can last up to 500 ms when entering measurement mode from sleep mode or during start-up)</td>
</tr>
<tr>
<td>Recovery time after defibrillator test</td>
<td>Unaffected</td>
</tr>
<tr>
<td>Drift of measurement accuracy</td>
<td>No drift</td>
</tr>
<tr>
<td>Water handling</td>
<td>NomoLine Family sampling lines with proprietary water removal tubing.</td>
</tr>
<tr>
<td>Sampling flow rate</td>
<td>50 ± 10 sml/min</td>
</tr>
<tr>
<td>Data output</td>
<td></td>
</tr>
<tr>
<td>Breath detection</td>
<td>Adaptive threshold, minimum 1 vol% change in CO2 concentration.</td>
</tr>
<tr>
<td>Respiration rate</td>
<td>Measured at I/E ratio 1:1, using a breath simulator according to EN ISO 80601-2-55 fig.201.101.</td>
</tr>
<tr>
<td></td>
<td>0 to 150 ± 1 breaths/min</td>
</tr>
<tr>
<td>Fi and ET</td>
<td>Measured according to EN ISO 80601-2-55</td>
</tr>
<tr>
<td>------------</td>
<td>--------------------------------------</td>
</tr>
<tr>
<td></td>
<td>Fi and ET are displayed after one breath and have a continuously updated breath average.</td>
</tr>
<tr>
<td></td>
<td>The following methods are used to calculate end-tidal (ET) values:</td>
</tr>
<tr>
<td></td>
<td>CO2: The highest concentration of CO2 during one breathing cycle with a weight function applied to favor values closer to the end of the cycle.</td>
</tr>
<tr>
<td></td>
<td>O2: The highest/lowest concentration of O2 during the expiratory phase (depending on whether EtO2 is higher or lower than FiO2)</td>
</tr>
<tr>
<td></td>
<td>N2O and anesthetic agents: The momentary gas concentration at the time point where EtCO2 is detected.</td>
</tr>
<tr>
<td></td>
<td>ET will typically decrease below nominal value (ETnom) when respiration rate (RR) exceeds the RR threshold (RRth) according to the following formulas:</td>
</tr>
<tr>
<td></td>
<td><strong>Nomoline ISA CO2:</strong></td>
</tr>
<tr>
<td></td>
<td>CO2: ( ET = ET_{nom} \times \sqrt{\frac{95}{RR}} ) for ( RR_{th} &gt; 95 )</td>
</tr>
<tr>
<td></td>
<td><strong>Nomoline ISA OR+/AX+</strong></td>
</tr>
<tr>
<td></td>
<td>CO2: ( ET = ET_{nom} \times \sqrt{\frac{70}{RR}} ) for ( RR_{th} &gt; 70 )</td>
</tr>
<tr>
<td></td>
<td>N2O, O2, DES, ENF, ISO, SEV: ( ET = ET_{nom} \times \sqrt{\frac{50}{RR}} ) for ( RR_{th} &gt; 50 )</td>
</tr>
<tr>
<td></td>
<td>HAL: ( ET = ET_{nom} \times \sqrt{\frac{35}{RR}} ) for ( RR_{th} &gt; 35 )</td>
</tr>
</tbody>
</table>

| Automatic agent identification | ISA OR+/AX+: Primary and secondary agent. |

<table>
<thead>
<tr>
<th>Flags</th>
<th>Breath detected</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No breaths detected</td>
</tr>
<tr>
<td></td>
<td>Replace O2 sensor</td>
</tr>
<tr>
<td></td>
<td>Check sampling line</td>
</tr>
<tr>
<td></td>
<td>Unspecified accuracy</td>
</tr>
<tr>
<td></td>
<td>Sensor error</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Gas Analyser</th>
<th></th>
</tr>
</thead>
</table>

| Sensor head | **Nomoline ISA AX+/OR+**: Nine channel NDIR type gas analyzer measuring at 4 to 10 μm. |
|-------------|Nine channel NDIR type gas analyzer measuring at 3.5 to 4.5 μm. |
|             | **Nomoline ISA CO2**: Nine channel NDIR type gas analyzer measuring at 3.5 to 4.5 μm. |
|             | Data acquisition rate 10 kHz (sample rate 20 Hz / channel). |

| Compensations | **Nomoline ISA CO2**: Automatic compensation for pressure and temperature. Manual compensation for broadening effects on CO2 |
|---------------|**Nomoline ISA OR+/AX+**: Automatic compensation for pressure, temperature and broadening effects on CO2 |

| Calibration | No span calibration is required. An automatic zeroing is performed 1 to 3 times per day |
### Warm-up time
- **NomoLine ISA CO2:** < 10 seconds (concentrations reported and full accuracy)
- **NomoLine ISA OR+/AX+:** < 20 seconds (concentrations reported, automatic agent identification enabled and full accuracy)

### Rise time at 50 ml/min sample flow
- **NomoLine ISA CO2:** CO2 ≤ 200 ms
- **NomoLine ISA OR+/AX+:**
  - CO2 < 300 ms
  - N2O, O2, ENF, ISO, SEV, DES ≤ 400 ms
  - HAL ≤ 500 ms

### Primary agent threshold (ISA OR+/AX+)
- 0.15 vol%.
  - When an agent is identified, concentrations will be reported even below 0.15 vol%.

### Secondary agent threshold (ISA OR+/AX+)
- 0.2 vol% + 10% of total agent concentration

### Agent identification time (ISA OR+/AX+)
- < 20 seconds (typically < 10 seconds)

### Analyzer system response time
- **ISA CO2:** < 3 seconds
- **ISA OR+/AX+:** < 4 seconds (with 2m NomoLine HH Adult/Pediatric Airway Adapter Set)

### Accuracy - standard conditions
The following accuracy specifications are valid for dry single gases at 22 ± 5 °C and 1013 ± 40 hPa:

<table>
<thead>
<tr>
<th>Gas</th>
<th>Range 1</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>CO2</td>
<td>0 to 15 vol%</td>
<td>±(0.2 vol% + 2% of reading)</td>
</tr>
<tr>
<td></td>
<td>15 to 25 vol%</td>
<td>Unspecified</td>
</tr>
<tr>
<td>N2O</td>
<td>0 to 100 vol%</td>
<td>±(2 vol% + 2% of reading)</td>
</tr>
<tr>
<td>HAL, ENF, ISO</td>
<td>0 to 8 vol%</td>
<td>±(0.15 vol% + 5% of reading)</td>
</tr>
<tr>
<td></td>
<td>8 to 25 vol%</td>
<td>Unspecified</td>
</tr>
<tr>
<td>SEV</td>
<td>0 to 10 vol%</td>
<td>±(0.15 vol% + 5% of reading)</td>
</tr>
<tr>
<td></td>
<td>10 to 25 vol%</td>
<td>Unspecified</td>
</tr>
<tr>
<td>DES</td>
<td>0 to 22 vol%</td>
<td>±(0.15 vol% + 5% of reading)</td>
</tr>
<tr>
<td></td>
<td>22 to 25 vol%</td>
<td>Unspecified</td>
</tr>
<tr>
<td>O2</td>
<td>0 to 100 vol%</td>
<td>±(1 vol% + 2% of reading)</td>
</tr>
</tbody>
</table>

Note: 1All gas concentrations are reported in units of volume percent and may be translated into mmHg or kPa by using the reported atmospheric pressure.

### Accuracy - all conditions
The following accuracy specifications are valid for all specified environmental conditions except for interference specified in section 2.6 (effects from water vapor partial pressure on gas readings) and section 2.7 (interfering gas effects)

<table>
<thead>
<tr>
<th>Gas</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gas</td>
<td>Accuracy</td>
</tr>
<tr>
<td>CO2</td>
<td>±(0.3 kPa + 4% of reading)</td>
</tr>
</tbody>
</table>


**Appendix**

<table>
<thead>
<tr>
<th>Gas or Vapor</th>
<th>Gas Level</th>
<th>CO2</th>
<th>Agents</th>
<th>N2O</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>ISA CO2</td>
<td>ISA AX+/OR+</td>
<td></td>
</tr>
<tr>
<td>N2O</td>
<td>±(2 kPa + 5% of reading)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Agents2</td>
<td>±(0.2 kPa + 10% of reading)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>O2</td>
<td>±(2 kPa + 2% of reading)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Effects from water vapor partial pressure on gas readings

When the breathing gas flows through the sampling line, the gas temperature will adapt to the ambient temperature before reaching the gas analyzer. The measurement of all gases will always show the actual partial pressure at the current humidity level in the gas sample.

As the NOMO section removes all condensed water, no water will reach the NomoLine Capnography gas analyzer. However at an ambient temperature of 37°C and a breathing gas with a relative humidity of 95% the gas reading will typically be 6% lower than corresponding partial pressure after removal of all water.

### Interfering Gas and Vapor Effect

<table>
<thead>
<tr>
<th>Gas or Vapor</th>
<th>Gas Level</th>
<th>CO2</th>
<th>Agents</th>
<th>N2O</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>ISA CO2</td>
<td>ISA AX+/OR+</td>
<td></td>
</tr>
<tr>
<td>N2O⁴</td>
<td>60 vol%</td>
<td>-2</td>
<td>-1</td>
<td>-1</td>
</tr>
<tr>
<td>HAL⁴</td>
<td>4 vol%</td>
<td>-1</td>
<td>-1</td>
<td>-1</td>
</tr>
<tr>
<td>ENF, ISO, SEV⁵</td>
<td>5 vol%</td>
<td>+8% of reading</td>
<td>-1</td>
<td>-1</td>
</tr>
<tr>
<td>DES⁴</td>
<td>15 vol%</td>
<td>+12% of reading</td>
<td>-1</td>
<td>-1</td>
</tr>
<tr>
<td>Xe [Xenon]⁶</td>
<td>80 vol%</td>
<td>-10% of reading</td>
<td>-1</td>
<td>-1</td>
</tr>
<tr>
<td>He [Helium]⁶</td>
<td>50 vol%</td>
<td>+6% of reading</td>
<td>-1</td>
<td>-1</td>
</tr>
<tr>
<td>C2H5OH [Ethanol]⁴</td>
<td>0.3 vol%</td>
<td>-1</td>
<td>-1</td>
<td>-1</td>
</tr>
<tr>
<td>C3H7OH [Isopropanol]⁴</td>
<td>0.5 vol%</td>
<td>-1</td>
<td>-1</td>
<td>-1</td>
</tr>
<tr>
<td>CH3COCH3 [Acetone]⁴</td>
<td>1 vol%</td>
<td>-1</td>
<td>-1</td>
<td>-1</td>
</tr>
<tr>
<td>CH4 [Methane]⁴</td>
<td>3 vol%</td>
<td>-1</td>
<td>-1</td>
<td>-1</td>
</tr>
<tr>
<td>CO [Carbon monoxide]⁵</td>
<td>1 vol%</td>
<td>-1</td>
<td>-1</td>
<td>-1</td>
</tr>
<tr>
<td>NO [Nitrogen monoxide]⁵</td>
<td>0.02 vol%</td>
<td>-1</td>
<td>-1</td>
<td>-1</td>
</tr>
<tr>
<td>O2 ⁵</td>
<td>100 vol%</td>
<td>-2</td>
<td>-2</td>
<td>-1</td>
</tr>
</tbody>
</table>

**Note 1:** Negligible interference, effect included in the specification “Accuracy, all conditions” above.

**Note 2:** Negligible interference with N2O / O2 concentrations correctly set, effect included in the specification “Accuracy, all conditions” above.

**Note 3:** Interference at indicated gas level. For example, 50 vol% Helium typically decreases the CO2 readings by 6%. This means that if measuring on a mixture containing 5.0 vol% CO2 and 50 vol% Helium, the actual measured CO2 concentration will typically be (1-0.06) * 5.0 vol% = 4.7 vol% CO2.

**Note 4:** According to the EN ISO 80601-2-55:2011 standard.

**Note 5:** In addition to the EN ISO 80601-2-55:2011 standard.
## Troubleshooting Nomoline ISA AX+/OR+/CO2

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Possible Cause</th>
<th>Correction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nomoline ISA AX+/OR+/CO2 values are not displayed on host</td>
<td>• Nomoline ISA AX+/OR+/CO2 requires a power cycle</td>
<td>• Disconnect and reconnect the Nomoline ISA AX+/OR+/CO2 connector at the host device.</td>
</tr>
<tr>
<td></td>
<td>• Host device is not configured correctly or is incompatible with Nomoline ISA AX+/OR+/CO2</td>
<td>• Verify that the host device is correctly configured and compatible</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LEGI indicator is dark (indicator is off)</td>
<td>• Nomoline ISA AX+/OR+/CO2 is not plugged in to the host device connector</td>
<td>• Verify Nomoline ISA AX+/OR+/CO2 connection to the host device.</td>
</tr>
<tr>
<td></td>
<td>• Sampling line not plugged in to Nomoline ISA AX+/OR+/CO2 completely</td>
<td>• Disconnect and reconnect the sampling line to Nomoline ISA AX+/OR+/CO2.</td>
</tr>
<tr>
<td></td>
<td>• Internal error</td>
<td>• The Nomoline ISA AX+/OR+/CO2 requires service.</td>
</tr>
<tr>
<td>LEGI indicator blinking red</td>
<td>• Sampling line obstructed (occlusion)</td>
<td>• Inspect sampling line for occlusion (blockage, kink in line).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Replace sampling line. See Sampling Line Replacement on 5.2.</td>
</tr>
<tr>
<td>LEGI indicator steady red</td>
<td>• Nomoline ISA AX+/OR+/CO2 requires a power cycle</td>
<td>• Disconnect and reconnect the Nomoline ISA AX+/OR+/CO2 connector at the host device.</td>
</tr>
<tr>
<td></td>
<td>• Internal error</td>
<td>• If persistent, the Nomoline ISA AX+/OR+/CO2 requires service.</td>
</tr>
<tr>
<td>Gas readings are questionable</td>
<td>• Incorrect sampling line used</td>
<td>• Use the correct sampling line with Nomoline ISA AX+/OR+/CO2.</td>
</tr>
<tr>
<td></td>
<td>• Sampling line attached incorrectly</td>
<td>• Disconnect and reconnect the sampling line to Nomoline ISA AX+/OR+/CO2.</td>
</tr>
<tr>
<td></td>
<td>• Sampling line leaking</td>
<td>• Follow the Directions for Use to properly connect the sampling line.</td>
</tr>
<tr>
<td></td>
<td>• Internal error</td>
<td>• Inspect sampling line for leaks.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Replace sampling line. See Sampling Line Replacement on 5.2.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Perform an Operational Check.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• If persistent, the Nomoline ISA AX+/OR+/CO2 requires service.</td>
</tr>
</tbody>
</table>
Appendix

Operation

LEGI Indicator

The Light Emitting Gas Inlet (LEGI) Indicator provides visual indications of measurement status. The LEGI Indicator (1) is located around the input connector on the front of the device.

The LEGI indicator illuminates in different colors depending on the state of the device as described in the table:

<table>
<thead>
<tr>
<th>LEGI Indicator</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steady green light</td>
<td>Capnography monitoring in operation and OK</td>
</tr>
<tr>
<td>Blinking green light</td>
<td>Zeroing in progress. See Zeroing on page 34.</td>
</tr>
<tr>
<td>Steady blue light</td>
<td>Anesthetic agent present</td>
</tr>
<tr>
<td>Steady red light</td>
<td>Sensor error</td>
</tr>
<tr>
<td>Blinking red light</td>
<td>Check the sampling line (possible occlusion)</td>
</tr>
</tbody>
</table>

Description

Nomoline Sampling Lines

Nomoline ISA AX+/OR+/CO2 samples gas from the respiratory circuit through the Nomoline Family sampling line at a rate of 50 sml/min, making measurements of CO2, O2, N2O, and anesthetic agents possible for adult, pediatric, infant and neonatal patients. The Nomoline Family of sampling lines are designed for optimal performance and measurement fidelity when used with the Nomoline ISA AX+/OR+/CO2 gas analyzers.

Nomoline sampling lines include nasal and nasal/oral cannulas for non-intubated patients with and without supplementary oxygen delivery and airway adapter sets for intubated patients.

As long as no sampling line is connected, the Nomoline ISA AX+/OR+/CO2 gas analyzer remains in a low-power sleep mode. Once the sampling line is connected, the Nomoline ISA AX+/OR+/CO2 gas analyzer switches to measuring mode and starts delivering measurement data.

Sampling Line Replacement

Nomoline sampling lines should be replaced between each patient or when the sampling line becomes occluded.

Occlusion occurs when water, secretions etc. are aspirated from the respiratory circuit to such an extent that Nomoline ISA AX+/OR+/CO2 cannot maintain the normal 50 ml/min sample flow.

This is indicated by a red flashing LEGI indicator and an alarm message; replace the sampling line and wait until the LEGI indicator switches to green, indicating that the Nomoline ISA AX+/OR+/CO2 gas analyzer is again ready for use.
Appendix

Set O\textsubscript{2} range compensation
Range:
0 - 30 vol\% Low
30 - 70 vol\% Medium
70 - 100 vol\% High

Set N\textsubscript{2}O compensation range compensation
Range:
0 - 30 vol\% Off
30 - 70 vol\% On
70 - 100 vol\% High

Ti set compensation for O\textsubscript{2} and N\textsubscript{2}O
Refer to section 6.2.9
Appendix 6Masimo IRMA AX+ Mainstream module
(optional)

WARNING
1. The IRMA probe is intended for use by qualified medical personnel only.
2. The IRMA probe is intended only as an adjunct in patient assessment. It must be used in conjunction with other assessments of clinical signs and symptoms.
3. Disposable IRMA airway adapters shall not be reused. Reuse of the single use adapter can cause cross infection.
4. Used airway adapters shall be disposed of in accordance with local regulations for biohazardous waste.
5. Do not use the IRMA Adult/Pediatric airway adapter with infants as the adapter adds 6 ml dead space to the patient circuit.
6. Do not use the IRMA Infant airway adapter with adults as this may cause excessive flow resistance.
7. Measurements can be affected by mobile and RF communications equipment. It should be assured that the IRMA probe is used in the electromagnetic environment specified in this manual.
8. Use of high frequency electrosurgical equipment in the vicinity of IRMA may produce interference and cause incorrect measurements.
9. The IRMA probe is not designed for MRI-environments.
10. Do not place the IRMA airway adapter between the endotracheal tube and an elbow as this may allow patient secretions to block the adapter windows and result in incorrect operation.
11. To keep secretions and moisture from pooling on the windows, always position the IRMA probe in a vertical position with the LED pointing upwards.
12. Do not use the IRMA airway adapter with metered dose inhalers or nebulized medications as this may affect the light transmission of the airway adapter windows.
13. Incorrect probe zeroing will result in false gas readings.
14. Replace the airway adapter if rainout/condensation occurs inside the airway adapter.
15. Use only Masimo manufactured IRMA airway adapters.
16. The IRMA probe is not intended to be in patient contact.
17. If, for whatever the reason, the IRMA probe is in direct contact with any parts of the infant’s body an insulation material shall be placed between the IRMA probe and the body.
18. No modification of this equipment is allowed.

CAUTION
1. Never sterilize or immerse the IRMA probe in liquid.
2. The IRMA airway adapters are non-sterile devices. Do not autoclave - this will damage them.
Appendix

3. Do not apply tension to the probe cable.

4. Do not operate the IRMA probe outside the specified operating temperature environment.

5. (U.S. only) Caution: Federal law restricts this device to sale by or on the order of a physician. For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

Intended use

The IRMA mainstream gas analyzer is intended to be connected to other medical devices for monitoring of breath rate and the breathing gases CO₂, N₂O and the anesthetic agents Halothane, Enflurane, Isoflurane, Sevoflurane and Desflurane.

It is intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit and patient room for adult, pediatric and infant patients. IRMA CO₂ may also be used in the emergency medical services environment and road ambulances.

NOTE:
The IRMA mainstream gas analyzer shall only be connected to medical backboard devices approved by Masimo Sweden AB.

**Technical Specifications**

**General specifications**

<table>
<thead>
<tr>
<th>Description</th>
<th>Extremely compact infrared mainstream multigas probe available in two parameter configurations.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensions (WxDxH)</td>
<td>38 x 37 x 34 mm (1.49” x 1.45” x 1.34”)</td>
</tr>
<tr>
<td>Cable length</td>
<td>2.5 m ±0.1 m</td>
</tr>
<tr>
<td>Weight</td>
<td>&lt; 25 g (cable excluded)</td>
</tr>
<tr>
<td>Operating temperature IRMA AX+:</td>
<td>10–40°C, 50–104°F</td>
</tr>
<tr>
<td>Storage temperature</td>
<td>-40–70°C, -40–158°F</td>
</tr>
<tr>
<td>Operating humidity</td>
<td>&lt; 50 hPa H₂O (non-condensing) (68 %RH at 40 °C)</td>
</tr>
<tr>
<td>Storage humidity</td>
<td>10–95% RH (95 %RH at 40 °C)</td>
</tr>
<tr>
<td>Operating atmospheric pressure</td>
<td>525–1200 hPa</td>
</tr>
<tr>
<td></td>
<td>(525 hPa corresponding to an altitude of 5211 m / 17 100 feet)</td>
</tr>
<tr>
<td>Storage atmospheric pressure</td>
<td>500 to 1200 hPa</td>
</tr>
<tr>
<td></td>
<td>(500 hPa corresponding to an altitude of 5572 m / 18 280 feet)</td>
</tr>
<tr>
<td>Mechanical strength</td>
<td>Withstands repeated 1.8 m drops on a hard surface.</td>
</tr>
<tr>
<td></td>
<td>Complies with requirements for (a) shock and vibration for professional transportation according to EN ISO 80601-2-55:2011, and (b) for road ambulances according to to EN ISO 80601-2-55:2018 and EN 60601-1-12:2015.</td>
</tr>
<tr>
<td>Power supply IRMA AX+:</td>
<td>4.5-5.5 VDC, max 1.4 W (power on surge @ 5 V less than 350 mA during 200 ms)</td>
</tr>
<tr>
<td>Recovery time after defibrillator test</td>
<td>Unaffected</td>
</tr>
<tr>
<td>Drift of measurement accuracy</td>
<td>No drift</td>
</tr>
<tr>
<td>Surface temperature (at ambient temp: 23°C)</td>
<td>IRMA AX+: Max 46°C / 115°F</td>
</tr>
<tr>
<td>Interface</td>
<td>Modified RS-232 serial interface operating at 9600 bps.</td>
</tr>
</tbody>
</table>
## Appendix

| Airway adapters | Disposable adult/pediatric:  
| - Adds less than 6 ml deadspace.  
| - Pressure drop less than 0.3 cm H₂O @ 30 LPM.  
| Disposable infant:  
| - Adds less than 1 ml deadspace.  
| - Pressure drop less than 1.3 cm H₂O @ 10 LPM.  
| Note: Infant airway adapter is recommended for tracheal tube ID size ≤ 4 mm. |

### Data output

| Breath detection | Adaptive threshold, minimum 1 vol % change in CO₂ concentration. |
| Respiration rate | 0–150 ±1 bpm. The respiration rate is displayed after three breaths and the average value is updated every breath. |

#### Fi and ET

- Fi and ET are displayed after one breath and have a continually updated breath average.  
- The following methods are used to calculate end-tidal (ET) values:  
  - CO₂: The highest concentration of CO₂ during one breathing cycle with a weight function applied to favor values closer to the end of the cycle.  
  - N₂O and anaesthetic agents: The momentary gas concentration at the time point where ETCO₂ is detected.  
  - ET-values for anaesthetic agents and N₂O (IRMA AX+) will typically decrease below nominal value when respiration rate exceeds 80 bpm. The maximum decrease is described by the formula ET = 80*ETnom/RR. ETCO₂ will be within specification for all respiration rates up to 150 bpm. |

### Automatic agent identification

- IRMA AX+: Primary and secondary agent. |

### Gas analyzer

| Probe | 2-9 channel ND IR type gas analyzer measuring at 4–10µm.  
| Data acquisition rate 10 kHz (sample rate 20 Hz/channel).  
| Pressure, temperature and full spectral interference correction. |
| Calibration | Zeroing recommended when changing Airway adapter (IRMA AX+). No span calibration required for the IR bench. |
| Warm-up time | IRMA AX+: <20 s. (agent identification enabled and full accuracy) |
| Rise time (@ 10 l/min) | CO₂ ≤ 90ms  
| 20 ≤ 300ms  
| HAL, ISO, ENF, SEV, DES ≤ 300ms |
| Primary agent threshold | 0.15 vol %. When an agent is identified, concentrations will be reported even below 0.15 vol % as long as apnea is not detected. |
| Secondary agent threshold | 0.2 vol % + 10% of total agent concentration |
| Agent identification time | < 20 seconds. [Typically < 10 seconds] |
| Total system response time | < 1 second |

---

Gradian Prima  
106  
User Manual
**Appendix**

**Accuracy-standard conditions**
The following accuracy specifications are valid for dry single gases at 22 ± 5 °C and 1013 ± 40 hPa.

<table>
<thead>
<tr>
<th>Gas</th>
<th>Range</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>CO₂</td>
<td>0 to 15 vol%</td>
<td>±(0.2 vol% + 2% of reading)</td>
</tr>
<tr>
<td>N₂O</td>
<td>0 to 100 vol%</td>
<td>±(2 vol% + 2% of reading)</td>
</tr>
<tr>
<td>HAL, ISO, ENF</td>
<td>0 to 8 vol%</td>
<td>±(0.15 vol% + 5% of reading)</td>
</tr>
<tr>
<td>SEV</td>
<td>0 to 10 vol%</td>
<td>±(0.15 vol% + 5% of reading)</td>
</tr>
<tr>
<td>DES</td>
<td>0 to 22 vol%</td>
<td>±(0.15 vol% + 5% of reading)</td>
</tr>
</tbody>
</table>

**Accuracy-all conditions**
The following accuracy specifications are valid for all specified environmental conditions - except for interference specified in “Effects from water vapor partial pressure on gas readings” and “Interfering gas effects” (see below).

<table>
<thead>
<tr>
<th>Gas</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>CO₂</td>
<td>±(0.3 kPa + 4% of reading)</td>
</tr>
<tr>
<td>N₂O</td>
<td>±(2 kPa + 5% of reading)</td>
</tr>
<tr>
<td>Agents</td>
<td>±(0.2 kPa + 10% of reading)</td>
</tr>
</tbody>
</table>

**Effects from water vapor partial pressure on gas readings**
The effects of water vapor are illustrated by the examples in the following table. The two columns to the right show the relative error in displayed concentrations when adding or removing water vapor from the gas mixture, and referencing the measurement to dry gas conditions at actual temperature and pressure (ATPD) or saturated conditions at body temperature (BTPS).

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>20</td>
<td>1013</td>
<td>2</td>
<td>0</td>
<td>-0.2</td>
<td>+6.0</td>
</tr>
<tr>
<td>20</td>
<td>20</td>
<td>1013</td>
<td>5</td>
<td>0</td>
<td>-0.5</td>
<td>+5.7</td>
</tr>
<tr>
<td>25</td>
<td>0</td>
<td>1013</td>
<td>0 (ATPD)</td>
<td>0</td>
<td>0</td>
<td>+6.2</td>
</tr>
<tr>
<td>25</td>
<td>23</td>
<td>1013</td>
<td>7.3</td>
<td>0</td>
<td>-0.7</td>
<td>+5.5</td>
</tr>
<tr>
<td>25</td>
<td>50</td>
<td>1013</td>
<td>16</td>
<td>0</td>
<td>-1.6</td>
<td>+4.6</td>
</tr>
<tr>
<td>30</td>
<td>80</td>
<td>1013</td>
<td>42</td>
<td>0</td>
<td>-4.1</td>
<td>+2.0</td>
</tr>
<tr>
<td>37</td>
<td>100</td>
<td>1013</td>
<td>63 (BTPS)</td>
<td>0</td>
<td>-6.2</td>
<td>0</td>
</tr>
<tr>
<td>37</td>
<td>100</td>
<td>700</td>
<td>63</td>
<td>0</td>
<td>-9.0</td>
<td>-2.8</td>
</tr>
</tbody>
</table>

The table illustrates that the gas concentrations in the alveoli, where the breathing gas is saturated with water vapor at body temperature (BTPS), are 6.2% lower than the corresponding concentrations in the same gas mixture after removal of all water vapor (ATPD).

**Interfering gas effects**

<table>
<thead>
<tr>
<th>Gas or vapor</th>
<th>Gas level</th>
<th>CO₂</th>
<th>Agents</th>
<th>N₂O</th>
</tr>
</thead>
<tbody>
<tr>
<td>N₂O ¹</td>
<td>60 vol%</td>
<td>ISA CO₂</td>
<td>ISA AX+ ISA DR+</td>
<td></td>
</tr>
<tr>
<td>HAL²</td>
<td>4 vol%</td>
<td>-¹</td>
<td>-¹</td>
<td>-¹</td>
</tr>
<tr>
<td>ENF, ISO, SEV³</td>
<td>5 vol%</td>
<td>+8% of reading⁴</td>
<td>-¹</td>
<td>-¹</td>
</tr>
<tr>
<td>DES⁴</td>
<td>15 vol%</td>
<td>+12% of reading⁵</td>
<td>-¹</td>
<td>-¹</td>
</tr>
</tbody>
</table>
### Appendix

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Title</th>
<th>Notes</th>
</tr>
</thead>
</table>
| ![REF](image) | Catalog number | 200601 = IRMA AX+ (CO₂, N₂O, 5 AA, AA ID)  
200604 = IRMA AX+ (CO₂, N₂O, 5 AA, AA ID)  
200607 = IRMA AX+ LEMO (CO₂, N₂O, 5 AA, AA ID) |
| ![Pressure limitation](image) | Pressure limitation | |
| ![Humidity limitation](image) | Humidity limitation | |
| ![Waste Electrical and Electronic Equipment (WEEE)](image) | Waste Electrical and Electronic Equipment (WEEE) | Electrical and electric equipment shall be collected and recycled in accordance with (Directive 2002/96/EC) |
| ![IP classification indicating degree of protection against ingress of solid foreign objects and water](image) | IP classification indicating degree of protection against ingress of solid foreign objects and water | IPX4 = “splash-proof” |
| ![Rx only](image) | Rx only | Caution (U.S.): Federal law restricts this device to sale by or on the order of a physician |
| ![Zero-point adjustment](image) | Zero-point adjustment | IRMA Airway Adapter box indicating recommendation to perform zeroing of IRMA AX+ when changing airway adapter. |
| ![Time delay before adjustment of zero-point](image) | Time delay before adjustment of zero-point | IRMA Airway Adapter indicating time delay before zeroing the of IRMA AX+ when changing airway adapter. |

<table>
<thead>
<tr>
<th>Metered dose inhaler propellants</th>
<th>Not for use with metered dose inhaler propellants</th>
</tr>
</thead>
<tbody>
<tr>
<td>C₂H₅OH (Ethanol)</td>
<td>0.3 vol%</td>
</tr>
<tr>
<td>C₃H₇OH (Isopropanol)</td>
<td>0.5 vol%</td>
</tr>
<tr>
<td>CH₃COCH₃ (Acetone)</td>
<td>1 vol%</td>
</tr>
<tr>
<td>CH₄ (Methane)</td>
<td>3 vol%</td>
</tr>
<tr>
<td>CO (Carbon monoxide)</td>
<td>1 vol%</td>
</tr>
<tr>
<td>NO (Nitrogen monoxide)</td>
<td>0.02 vol%</td>
</tr>
<tr>
<td>O₂</td>
<td>100 vol%</td>
</tr>
</tbody>
</table>

1: Negligible interference, effect included in the specification “Accuracy, all conditions” above.
2: Negligible interference with N₂O / O₂ concentrations correctly set, effect included in the specification “Accuracy, all conditions” above.
3: Interference at indicated gas level. For example, 50 vol% Helium typically decreases the CO₂ readings by 6%. This means that if measuring on a mixture containing 5.0 vol% CO₂ and 50 vol% Helium, the actual measured CO₂ concentration will typically be \((1-0.06) \times 5.0\) vol% = 4.7 vol% CO₂.
Appendix

System set-up
1. Plug the AG module connector into the input of the Anaesthetic machine and switch the power on.
2. Snap the AG module probe on top of the airway adapter. It will click into place when properly seated.
3. Depending on IRMA model, perform the following
   - IRMA AX+
     - Wait minimum 30 seconds
     - Perform zeroing
4. A green LED indicates that the IRMA probe is ready for use.
5. Connect airway adapter 15 mm male connector to the breathing circuit Y-piece.
6. Connect airway adapter 15 mm female connector to the patient’s endotracheal tube.
Alternatively, connect a HME (Heat Moisture Exchanger) between the patient’s endotracheal tube and the IRMA probe. Placing a HME in front of the IRMA probe protects the airway adapter from secretions and effects of water vapor and eliminates the need of changing the adapter. It allows free positioning of the IRMA probe as well.

7. Unless the IRMA probe is protected with a HME always position the IRMA probe with the status LED pointing upwards.

**Placement of IRMA Probe**
When connecting the IRMA probe to an infant patient circuit it is important to avoid a direct contact between the IRMA probe and the infant’s body due to the elevated surface temperature of the IRMA Probe.

**WARNING**
If, for whatever the reason, the IRMA probe is indirect contact with any parts of the infant’s body an insulation material shall be placed between the IRMA probe and the body.

**CAUTION**
The IRMA probe is not intended to be in patient contact.

**Pre-use check**
Always verify gas readings and waveforms on the medical backboard device before connecting the IRMA airway adapter to the patient circuit.

Perform the tightness check of the patient circuit according to the User Manual for the medical backboard device with the IRMA probe snapped on the IRMA airway adapter.

**Zeroing**

**WARNING**
Incorrect probe Zeroing will result in false gas readings.

In order to secure high precision of the IRMA probe measurements the following zeroing recommendations should be followed.

Zeroing is performed by snapping a new IRMA airway adapter onto the IRMA probe, without connecting the airway adapter to the patient circuit, and then using the medical backboard device to transmit a Zero reference command to the IRMA probe.

Special care should be taken to avoid breathing near the airway adapter before or during the Zeroing procedure. The presence of ambient air in the IRMA airway adapter is of crucial importance for a successful Zeroing. If a “AA ID Unreliable!!” alarm should appear directly after a Zeroing procedure, the procedure must be repeated.

Always perform a pre-use check after Zeroing the probe.

For the IRMA AX+ module zero calibration button “Gas Module Zero Calibration” please refer to the chapter “6.2.12 Calibration”

**IRMA AX+ probes:**
Zeroing should be performed every time the IRMA airway adapter is replaced, or whenever an offset in gas values or an unspecified gas accuracy message is displayed.

Allow 30 seconds for warm up of the IRMA AX+ probes after power on and after changing the IRMA airway adapter before proceeding with the Zeroing Procedure. The green LED on the probe will be blinking for approximately 5 seconds while zeroing is in progress.
Appendix

Alarms
See Section 6.11.6 for a complete description of the alarm handling related to the IRMA mainstream gas analyzer.

Status LED on the IRMA probe:

<table>
<thead>
<tr>
<th>Indication</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steady green light</td>
<td>System OK</td>
</tr>
<tr>
<td>Blinking green light</td>
<td>Zeroing in progress</td>
</tr>
<tr>
<td>Steady blue light</td>
<td>Anaesthetic agent present</td>
</tr>
<tr>
<td>Steady red light</td>
<td>Sensor error</td>
</tr>
<tr>
<td>Blinking red light</td>
<td>Check adapter</td>
</tr>
</tbody>
</table>

Cleaning
The IRMA probe can be cleaned using a cloth moistened with ethanol or isopropyl alcohol (< 70%).

CAUTION
1. The IRMA airway adapters are non-sterile devices. Do not autoclave the devices as this will damage them.
2. Never sterilize or immerse the IRMA probe in liquid.

Gas span check
Gas readings should be verified at regular intervals with a reference instrument or with calibration gas. The suggested interval for gas span check is once every year.

MAC (Minimum Alveolar Concentration) calculation
Minimum alveolar concentration (MAC) is a standard for comparing the potency of inhalation anesthetics. 1 MAC represents the end-tidal concentration of an agent [at sea level] that, in 50 percent of a tested population, prevents gross muscular movement in response to a painful, standardized stimulus.

If a mechanism to determine MAC values is implemented in the host device, the algorithms used for this calculation must be adequately documented.

The MAC value may be calculated and displayed by using end-tidal (Et) gas concentrations according to the following formula:

\[
MAC = \frac{\%Et(AA1)}{X(AA1)} + \frac{\%Et(AA2)}{X(AA2)} + \frac{\%Et(N2O)}{100}
\]

Note: Altitude, patient age and other individual factors are not considered in the formula above.

Spectral broadening
The presence of oxygen and nitrous oxide can cause some interference in the CO₂ measurement. This is known as spectral broadening, and must be compensated.

To ensure that the carbon dioxide measurement is accurate enough, the oxygen concentration is divided into three ranges: "high", "medium" and "low" compensation buttons. By using the above compensation button and the corresponding O₂ range value in the table below to set the relevant compensation, the maximum relative error of carbon dioxide will be limited to 1.2%.

Set O₂ range - compensation

Range:

<table>
<thead>
<tr>
<th>Range</th>
<th>Compensation</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - 30 vol%</td>
<td>Low</td>
</tr>
<tr>
<td>30 - 70 vol%</td>
<td>Medium</td>
</tr>
<tr>
<td>70 - 100 vol%</td>
<td>High</td>
</tr>
</tbody>
</table>
Appendix 7. Electromagnetic compatibility (EMC)

Electromagnetic environment
The Prima is suitable for use in the specified electromagnetic environment. The user should assure that it is used in an electromagnetic environment as described below.
Changes or modifications to this device, not expressly approved by Gradian, could result in EMC issues with this device. Contact Gradian Health Systems for more information.
The use of phones or RF emitting equipment near this anaesthetic machine may cause interference.
Always monitor anaesthetic machine operation before and during use on a patient.

The essential performance of this device is to provide controlled concentrations and flows of anaesthesia gases into a patient breathing system.

WARNING
The device should not be used adjacent to or stacked with other manufacturer’s equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

Cables, transducers, and accessories

WARNING
The device is EMC-compliant with all cables, transducers and accessories supplied by Gradian.
The use of cables, transducers and accessories other than those specified may result in increased emissions or decreased immunity of this device.
The use of cables, transducers and accessories supplied by Gradian on non-Gradian equipment may also result in increased emissions or decreased immunity of that equipment.

Cables supplied by Gradian

<table>
<thead>
<tr>
<th>Category</th>
<th>Function</th>
<th>Length (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AC mains supply input/output ports</td>
<td>Hospital mains supply to the input port (cable is fixed to the Prima)</td>
<td>≤3.9</td>
</tr>
<tr>
<td>Oxygen sensor cable (Prima with an oxygen sensor on the absorber)</td>
<td>Connects the oxygen sensor on the absorber to the Prima</td>
<td>0.6</td>
</tr>
</tbody>
</table>

Guidance and manufacturer’s declaration – electromagnetic emissions

This device is intended for use in the electromagnetic environment specified below. The customer or user should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Required test</th>
<th>Compliance</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions</td>
<td>Group 1 Class A</td>
<td>Class A equipment is suitable for use in all locations other than those allocated in residential environments and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes provided the following warning is heeded</td>
</tr>
<tr>
<td>Harmonic emissions IEC 61000-3-2</td>
<td>Complies</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations/ flicker emissions IEC 61000-3-3</td>
<td>Complies</td>
<td></td>
</tr>
</tbody>
</table>

NOTE: 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.
## Guidance and manufacturer's declaration - electromagnetic immunity

This device is intended for use in the electromagnetic environment specified below. The customer or user of the device should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Required test</th>
<th>60601 test levels for equipment used in a professional healthcare facility environment only</th>
<th>Compliance level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD) IEC 61000-4-2</td>
<td>± 8 kV contact&lt;br&gt;± 2, 4, 8, 15 kV air</td>
<td>± 8 kV contact&lt;br&gt;± 2, 4, 8, 15 kV air</td>
</tr>
<tr>
<td>Radiated RF EM Fields IEC 61000-4-3</td>
<td>3 V/m&lt;br&gt;80 MHz to 2.7 GHz</td>
<td>10 V/m&lt;br&gt;80 MHz to 2.7 GHz</td>
</tr>
<tr>
<td>Proximity fields from RF wireless communications IEC 61000-4-3</td>
<td>Frequency - Test level&lt;br&gt;385 MHz - 27 V/m&lt;br&gt;450 MHz - 28 V/m&lt;br&gt;710 MHz - 9 V/m&lt;br&gt;745 MHz - 9 V/m&lt;br&gt;780 MHz - 9 V/m&lt;br&gt;810 MHz - 28 V/m&lt;br&gt;870 MHz - 28 V/m&lt;br&gt;930 MHz - 28 V/m&lt;br&gt;1.72 GHz - 28 V/m&lt;br&gt;1.845 GHz - 28 V/m&lt;br&gt;1.97 GHz - 28 V/m&lt;br&gt;2.45 GHz - 28 V/m&lt;br&gt;5.24 GHz - 9 V/m&lt;br&gt;5.50 GHz - 9 V/m&lt;br&gt;5.875 GHz - 9 V/m</td>
<td>Frequency - Test level&lt;br&gt;385 MHz - 27 V/m&lt;br&gt;450 MHz - 28 V/m&lt;br&gt;710 MHz - 9 V/m&lt;br&gt;745 MHz - 9 V/m&lt;br&gt;780 MHz - 9 V/m&lt;br&gt;810 MHz - 28 V/m&lt;br&gt;870 MHz - 28 V/m&lt;br&gt;930 MHz - 28 V/m&lt;br&gt;1.72 GHz - 28 V/m&lt;br&gt;1.845 GHz - 28 V/m&lt;br&gt;1.97 GHz - 28 V/m&lt;br&gt;2.45 GHz - 28 V/m&lt;br&gt;5.24 GHz - 9 V/m&lt;br&gt;5.50 GHz - 9 V/m&lt;br&gt;5.875 GHz - 9 V/m</td>
</tr>
<tr>
<td>Electrical fast transient / burst IEC 61000-4-4</td>
<td>± 2 kV for power supply lines&lt;br&gt;± 1 kV for input / output lines</td>
<td>± 2 kV for power supply lines</td>
</tr>
<tr>
<td>Surge IEC 61000-4-5</td>
<td>± 0.5, 1, 2 kV line(s) to earth,&lt;br&gt;± 0.5, 1 kV line(s) to line(s) for power supply lines&lt;br&gt;± 2 kV line(s) to earth for input / output lines</td>
<td>± 0.5, 1, 2 kV line(s) to earth,&lt;br&gt;± 0.5, 1 kV line(s) to line(s) for power supply lines</td>
</tr>
<tr>
<td>Conducted RF IEC 61000-4-6</td>
<td>3 V - 150 kHz to 80 MHz&lt;br&gt;6 V - ISM bands between 150 kHz to 80 MHz</td>
<td>3 V - 150 kHz to 80 MHz&lt;br&gt;6 V - ISM bands between 150 kHz to 80 MHz</td>
</tr>
<tr>
<td>Voltage dips and interruptions IEC 61000-4-11</td>
<td>0% UT [100% dip in UT] for 0.5 cycle&lt;br&gt;0% UT [100% dip in UT] for 1 cycle&lt;br&gt;70% UT [30% dip in UT] for 25/30 cycles&lt;br&gt;0% UT [100% dip in UT] for 250/300 cycles</td>
<td>0% UT [100% dip in UT] for 0.5 cycle&lt;br&gt;0% UT [100% dip in UT] for 1 cycle&lt;br&gt;70% UT [30% dip in UT] for 25/30 cycles&lt;br&gt;0% UT [100% dip in UT] for 250/300 cycles</td>
</tr>
<tr>
<td>Power frequency [50 Hz] Magnetic field IEC 61000-4-8</td>
<td>30 A/m</td>
<td>30 A/m</td>
</tr>
</tbody>
</table>