



Vivo 3, User's

ENGLISH (EU)

Breas Vivo 3 User Manual

007231 F-1b en-EU

Vivo 3 User Manual



Breas Medical AB, Företagsvägen 1, SE-435 33 Mölnlycke, Sweden
Phone +46 31 86 88 00
Order +46 31 86 88 20, Technical Support +46 31 86 88 60
Fax +46 31 86 88 10, www.breas.com, Date: 2023-04-20 | 22891

CE 2797 UK RA 0086



Table of Contents

| | | |
|-------|--|----|
| 1 | Introduction | 5 |
| 1.1 | Manufacturer Information | 5 |
| 1.2 | What is the Vivo 3? | 6 |
| 1.2.1 | Non Invasive Interfaces | 6 |
| 1.2.2 | Mobility and Usage Environment | 7 |
| 1.2.3 | Continuous Operation | 7 |
| 1.2.4 | Multiple Use | 7 |
| 1.2.5 | Service Life | 7 |
| 1.3 | Intended Use | 7 |
| 1.4 | Intended Users | 7 |
| 1.4.1 | Respiratory Health Care Specialists | 7 |
| 1.4.2 | Lay Operators | 7 |
| 1.4.3 | Service Personnel | 8 |
| 1.5 | Contraindications | 8 |
| 1.6 | About this Manual | 9 |
| 1.6.1 | Audience | 9 |
| 1.6.2 | Icons in this Manual | 9 |
| 2 | Safety Information | 11 |
| 2.1 | General Use — Warnings and Precautions | 11 |
| 2.2 | Electricity — Warnings and Precautions | 13 |
| 2.2.1 | Electromagnetic Compatibility and Electrostatic Discharge (EMC and ESD) | 14 |
| 2.3 | Environment — Warnings and Precautions | 14 |
| 2.4 | Patient Circuit — Warnings and Precautions | 15 |
| 2.5 | Filter Usage — Warnings and Precautions | 17 |
| 2.6 | Invasive Use — Warnings and Precautions | 18 |
| 2.7 | Humidification and Heating — Warnings and Precautions | 19 |
| 2.8 | Cleaning and Maintenance — Warning and Precautions | 20 |
| 2.9 | Oxygen Usage — Warning and Precautions | 20 |
| 2.10 | Mobile Use — Warning and Precautions | 22 |
| 3 | Product Description | 23 |
| 3.1 | Main Components | 23 |
| 3.2 | Ventilator Front | 24 |
| 3.3 | Ventilator Back | 25 |
| 3.4 | Power Management | 26 |
| 3.5 | Menus | 27 |
| 3.5.1 | Use the Menu | 27 |
| 3.5.2 | The Monitor Page | 30 |
| 3.5.3 | The Setup Pages | 32 |
| 3.5.4 | The Alarm Pages | 33 |
| 3.5.5 | The Others Pages | 33 |

| | | |
|--------|---|----|
| 3.6 | Symbols on the Vivo 3 | 36 |
| 3.7 | Symbols on the Display | 39 |
| 4 | Treatment Functions and Settings | 40 |
| 4.1 | Treatment Modes | 42 |
| 4.1.1 | PCV+A — Pressure Controlled Ventilation (Assisted) | 42 |
| 4.1.2 | PSV — Pressure Support Ventilation | 42 |
| 4.1.3 | S — Spontaneous | 42 |
| 4.1.4 | S/T — Spontaneous/Timed | 43 |
| 4.1.5 | T — Timed | 43 |
| 4.1.6 | CPAP — Continuous Positive Airway Pressure | 43 |
| 4.1.7 | High Flow Nasal Therapy | 43 |
| 4.2 | Treatment Settings | 43 |
| 4.2.1 | Auto-EPAP | 44 |
| 4.2.2 | Ramp Up | 46 |
| 4.2.3 | Ramp Down | 46 |
| 4.2.4 | Ramp Pressure | 47 |
| 4.2.5 | Humidifier | 47 |
| 4.2.6 | Humidifier Level | 47 |
| 4.2.7 | Heated Circuit | 47 |
| 4.2.8 | Heated Circuit Level | 48 |
| 4.2.9 | Patient Circuit | 48 |
| 4.2.10 | Flow | 48 |
| 5 | Prepare the Vivo 3 for Use | 49 |
| 5.1 | Checking the Vivo 3 before First Use | 49 |
| 5.2 | Placing the Vivo 3 | 49 |
| 5.3 | Connecting the Vivo 3 to Power Supply | 49 |
| 5.4 | Connecting the Patient Circuit | 52 |
| 5.4.1 | Connect the Heated Patient Circuit | 52 |
| 5.4.2 | Disconnect the Heated Patient Circuit from the Ventilator | 52 |
| 5.5 | Performing Start-up Checks | 52 |
| 5.6 | Performing a Pre-Use Test | 53 |
| 5.6.1 | Actions At Pre-Use Test Failure | 53 |
| 6 | How to Use the Vivo 3 | 55 |
| 6.1 | Switch On the Vivo 3 | 55 |
| 6.2 | Start the Treatment | 55 |
| 6.3 | Stop the Treatment | 56 |
| 6.4 | Switch Off the Vivo 3 | 56 |
| 6.5 | Monitor Treatment | 57 |
| 6.5.1 | Treatment Values Monitored by the Vivo 3 | 58 |
| 6.5.2 | Treatment Values Monitored by External Equipment | 59 |
| 6.6 | Using Accessories | 59 |

| | | | |
|---|--------------|--|----|
| | 6.6.1 | Using the Attachable Humidifier | 60 |
| | 6.6.2 | Using the Heated Circuit | 64 |
| | 6.6.3 | Using the SpO ₂ Sensor | 65 |
| | 6.6.4 | Using the Oxygen Supply Adapter | 67 |
| | 6.6.5 | Using the Remote Alarm Unit | 68 |
| | 6.6.6 | Using the Protective Cover | 69 |
| | 6.6.7 | Using the Lightweight Mobility Bag | 69 |
| | 6.6.8 | Using the Y-Cable | 69 |
| | 6.6.9 | Using the Vivo 3 with the Trolley | 69 |
| | 6.7 | Basic Troubleshooting | 71 |
| 7 | Alarms | | 72 |
| | 7.1 | Operator's Position | 72 |
| | 7.1.1 | Checking the Operator's Position | 72 |
| | 7.2 | Handle Alarms | 72 |
| | 7.2.1 | Identify an Alarm Condition | 72 |
| | 7.2.2 | Pause the Alarm Sound | 74 |
| | 7.2.3 | Reset an Alarm | 74 |
| | 7.2.4 | View Historical Alarms | 74 |
| | 7.2.5 | Adjust the Alarm Sound Level | 74 |
| | 7.3 | Physiological Alarms | 76 |
| | 7.3.1 | High Pressure Alarm | 76 |
| | 7.3.2 | Low Pressure Alarm | 77 |
| | 7.3.3 | High Breath Rate Alarm | 78 |
| | 7.3.4 | Low Breath Rate Alarm | 78 |
| | 7.3.5 | High Minute Volume Alarm | 79 |
| | 7.3.6 | Low Minute Volume Alarm | 79 |
| | 7.3.7 | Rebreathing Alarm | 80 |
| | 7.3.8 | Apnea Alarm | 80 |
| | 7.3.9 | Disconnection Alarm | 81 |
| | 7.3.10 | High EPAP Alarm | 82 |
| | 7.3.11 | Low EPAP Alarm | 82 |
| | 7.3.12 | High SpO ₂ Alarm | 83 |
| | 7.3.13 | Low SpO ₂ Alarm | 83 |
| | 7.3.14 | High Pulse Rate Alarm | 84 |
| | 7.3.15 | Low Pulse Rate Alarm | 84 |
| | 7.3.16 | Circuit Disconnection Alarm | 85 |
| | 7.3.17 | Blocked Circuit Alarm | 85 |
| | 7.4 | Technical Alarms | 86 |
| | 7.4.1 | High Pressure Limitation Alarm | 86 |
| | 7.4.2 | Power Fail Alarm | 86 |
| | 7.4.3 | SpO ₂ Sensor Failure / Disconnected Alarm | 86 |

| | | | |
|----|--------|---|-----|
| | 7.4.4 | SpO ₂ Artifact | 87 |
| | 7.4.5 | Ambient Pressure Compensation Lost Alarm | 88 |
| | 7.4.6 | Low Battery Alarm | 88 |
| | 7.4.7 | Critically Low Battery Alarm | 88 |
| | 7.4.8 | High Patient Air Temp. (High Patient Air Temperature) | 89 |
| | 7.4.9 | Flow Sensor Failure | 89 |
| | 7.4.10 | Internal Function Failure | 90 |
| 8 | | Cleaning and Maintenance | 91 |
| | 8.1 | Cleaning the Vivo 3 | 91 |
| | | 8.1.1 Clean the Main Unit Externally | 91 |
| | | 8.1.2 Air Pathway Disinfection | 91 |
| | | 8.1.3 Clean the Patient Circuit | 92 |
| | 8.2 | Clean and Replace Patient Air Inlet Filters | 92 |
| | 8.3 | Disposal | 93 |
| 9 | | Technical Specifications | 94 |
| | 9.1 | Ventilator Size and Weight | 94 |
| | 9.2 | Power Supply | 94 |
| | 9.3 | Environmental Conditions | 95 |
| | 9.4 | Pneumatic Diagram | 97 |
| | 9.5 | Technical Data | 99 |
| 10 | | Accessories | 103 |
| | 10.1 | Patient Circuits and Air Delivery Accessories | 103 |
| | 10.2 | Power Accessories | 105 |
| | 10.3 | Ventilator Filters and Detachable Parts | 105 |
| | 10.4 | Monitoring Accessories | 106 |
| | 10.5 | Other Accessories | 108 |
| | | Appendices | 111 |
| A | | Patient Settings Record | 112 |
| B | | FAA Compliance | 114 |
| | | Index | 115 |

1

Introduction

WARNING!

Risk of Personal Injury

The Vivo 3 must only be used:

- For the intended treatment in accordance with this manual and with the instructions given by the responsible clinical personnel.
- In accordance with the operating conditions specified in this manual.
- In original and unmodified shape and only with accessories specified or approved by Breas Medical AB.

Every other use may lead to risk of personal injury!



CAUTION!

Read this manual thoroughly so that you completely understand how the Vivo 3 is operated and maintained before taking it into use, to ensure correct usage, maximum performance and serviceability.

Non-professional caregivers (e.g. family members) should consult the medical equipment provider's respiratory therapist if they have any questions about the function, proper use, operation, service or maintenance of the Vivo 3.



WARNING!

The Vivo 3 is not designed for life support treatment:

- The Vivo 3 should not be used for life support treatment.
- The Vivo 3 shall only be used by patients with spontaneous breathing.
- The Vivo 3 should not be used for ventilator dependent patients.



1.1

Manufacturer Information

Legal Manufacturer



Postal Address

Breas Medical AB
Företagsvägen 1
SE-435 33 Mölnlycke Sweden

Web Address

www.breas.com

Email address

breas@breas.com

Phone

+46 31 868800, Order: +46 31 868820, Technical support: +46 31 868860

Fax

+46 31 868810

UK Sales and Support Information

UK Responsible Person: Breas Medical Ltd

Phone UK Head Office

+44 (0)1789293460

Fax UK Head Office

+44 (0)1789262470

General Enquiries and Ordering

orders@nippyventilator.com

Tech Support

techsupport@nippyventilator.com

Local Representatives Information

www.breas.com/contact-us/

1.2 What is the Vivo 3?

The Vivo 3 is an internally powered pressure ventilator capable of delivering invasive or non-invasive ventilatory support for the care of individuals who require long-term support from mechanical ventilation for respiratory insufficiency or respiratory failure, with or without obstructive sleep apnea.

The Vivo 3 can be operated in the following modes:

- PCV+A (Assisted Pressure Controlled Ventilation). See page 42.
- PSV (Pressure Support Ventilation). See page 42.
- S (Spontaneous). See page 42.
- S/T (Spontaneous/Timed). See page 43.
- T (Timed). See page 43.
- CPAP (Continuous Positive Airway Pressure). See page 43.

The following modes can be combined with the Target Volume setting:

- PCV+A
- PSV
- S
- S/T
- T

The following modes can be combined with the Auto-EPAP setting:

- PCV+A
- PSV
- S
- S/T
- T

1.2.1 Non Invasive Interfaces

The ventilator system can be used non-invasively with nasal mask, full/total face mask, and nasal pillow interfaces.

1.2.2 Mobility and Usage Environment

The ventilator system is classified as transit-operable and is intended to be used in homes, public spaces, institutions and hospitals.

The ventilator system is intended to be used together with portable applications such as wheelchairs, personal family vehicles, ground ambulances and civil aircraft (not helicopter). It is not intended for use during emergency transports.

1.2.3 Continuous Operation

The ventilator can be used for continuous operation up to 24 hours/day at least for 90 days without restarting.

1.2.4 Multiple Use

This is a multiple patient multiple use device. If it should be used by multiple patients, see the cleaning instructions in before assigning it to a new patient.

1.2.5 Service Life

The expected service life of the Vivo 3 is 5 years or 20,000 hours.

1.3 Intended Use

Vivo 3 is intended to provide non-invasive or invasive ventilation for patients weighing over 10 kg (22 lbs) who require long-term support or mechanical ventilation for respiratory insufficiency or respiratory failure, with or without obstructive sleep apnea.

Vivo 3 is intended for spontaneously breathing patients.

1.4 Intended Users

This section describes the intended users of the Vivo 3, their qualifications and their related documents.

1.4.1 Respiratory Health Care Specialists

Health care professionals such as physicians and respiratory therapists, assigned to form the clinical authority when it comes to operating mechanical ventilators.

They have a good understanding of the human respiratory system and a general understanding of mechanical ventilators.

They are allowed to change the clinical settings of a ventilator and prescribe new settings.

They may also operate software applications for follow-up on patient's ventilator treatment.

Training

The respiratory health care specialists shall be trained to a good knowledge of the Vivo 3, its capabilities and the settings that can be made. This training consists of reading the Clinician's manual in full and it shall be conducted before operating the Vivo 3.

Related Documents

The Clinician's manual is intended for the respiratory health care specialists. It shall be available for training of new personnel and as reference when operating the Vivo 3. When using a Clinician's manual, make sure that it is of the same version as the User's manual.

1.4.2 Lay Operators

Day-to-day caregivers, patients, relatives and other non-professional users that operate the Vivo 3 within the prescribed settings.

They are allowed to operate the Vivo 3 with the Home mode activated. The lay operator may also perform basic maintenance that doesn't require special equipment or a service environment.

In Home mode, the device is locked in order to limit settings accessibility and hide features/controls.

The User Manual contains the information intended for patients and lay operators.

Training

The lay operator shall be trained to basic knowledge of the Vivo 3 and in the specific operations they are assigned to perform. The training shall be based on the user manual and the responsible clinical personnel shall assess the level of training required for each lay operator.

Related Documents

The User manual is intended for lay operator. It shall be available for the training and as reference when operating the Vivo 3.

1.4.3 Service Personnel

Certified service personnel with responsibility to maintain the equipment in proper working order. They have a technical education and/or relevant experience of technical work on electrical equipment. If local or national regulations requests additional authorization or competence, these shall be complied to.

Certified service personnel may perform any repairs, upgrades or service operations that they have been certified to perform, as long as they have the required equipment and the operation is performed in an appropriate environment. They may also operate software applications for follow-up on ventilators usage and for troubleshooting.

Training and Certification

Service personnel shall be trained on the Vivo 3 and certified by Breas for being allowed to perform any service, repairs or other operations on the Vivo 3. The training consists of reading the services manual in full.

Related Documents

- The Service Manual.
- The Clinician's Manual.
- Service bulletins, available for certified service personnel on the Breas extranet.

1.5 Contraindications

The Vivo 3 is not a life-support ventilator and is contraindicated in patients who are unable to tolerate more than brief interruptions in ventilation.

If a patient has any of the following conditions, therapy with positive airway pressure may be contraindicated and the prescribing clinician shall decide if the benefit of ventilatory assistance outweighs the risks:

- Untreated pneumothorax
- Pneumomediastinum
- Inability to maintain a patent airway or adequately clear excessive respiratory secretions
- Severe acute systemic complications (shock, unstable arrhythmias, myocardial ischemia)
- Severe bullous lung disease

- Risk of vomiting
- Pathologically low blood pressure, especially if associated with intravascular volume depletion
- Cerebrospinal fluid leak, recent cranial surgery or trauma

The use of the Vivo 3 is contraindicated in an MRI environment.

Adverse Effects

If the patient experiences chest discomfort, pain, severe headache or shortness of breath while using the Vivo 3, a physician or responsible clinician should be contacted immediately.

The following side effects may occur during the course of therapy with the Vivo 3, patients are advised to report any new or changing adverse effects to their physician:

- Nasal, mouth or throat dryness
- Nosebleeds
- Abdominal bloating
- Ear or sinus discomfort
- Eye irritation
- Skin rashes

1.6 About this Manual

1.6.1 Audience

This manual is intended for patients and other lay users operating the Vivo 3.






- Care providers, clinical personnel, physicians and others who require a working knowledge of the Vivo 3 will find additional information on settings and functions in the Clinician's Manual. The Clinician's manual should be of the same revision as the User's Manual.
- Service personnel may order the Service Manual that contains detailed technical information for maintenance, service, repair and disposal procedure. The Service manual's revision is independent of the User's Manual revision.



1.6.2 Icons in this Manual

In this manual, icons are used to highlight specific information. The meaning of each icon is explained in the table below.

| Icon | Explanation |
|------|--|
| | Warning! Risk of death or personal injury. |
| | Warning! Risk of Cross-contamination. |
| | Warning! Risk of electric shock. |
| | Warning! Hot surface, risk of burns. |

| Icon | Explanation |
|---|---|
|  | <p>Warning! Flammable material, risk of fire.</p> |
|  | <p>Caution! Risk of equipment damage, loss of data, extra work, or unexpected results.</p> |
|  | <p>MR Unsafe. The device should not enter a magnetic resonance (MR) environment, such as an MRI scanner room.</p> |
|  | <p>Note Information that may be valuable but is not of critical importance, tips.</p> |
|  | <p>Reference Reference to other manuals with additional information on a specific topic.</p> |

2 Safety Information

2.1 General Use — Warnings and Precautions

WARNING!

Risk of Personal Injury

The Vivo 3 is not designed for life support treatment:

- The Vivo 3 shall only be used by patients with spontaneous breathing.
- The Vivo 3 should not be used for ventilator dependent patients.

Risk of Faulty Treatment

If the patient is admitted to a hospital or is prescribed any other form of medical treatment, always inform the medical staff that the patient is on mechanical ventilation treatment.

The Vivo 3 shall not be used with nebulizers.

Risk of Insufficient Ventilation

Usage outside the specified operating conditions may cause reduced performance.

The Vivo 3 must only be used in accordance with the operating conditions specified in this manual.

Risk of Faulty Treatment

Do not use the Vivo 3 in the event of:

- Suspected damage to the device, including the occurrence of Internal Functional Failure alarms.
- Unexpected patient symptoms during treatment.
- Unexplainable or sudden changes of pressure, performance or sound during operation.
- Delivered air being abnormally hot or emitting an odor.

Contact your responsible care provider for an inspection.

Risk of Suffocation

Do not remove the protection for the heated patient circuit connector, the connector can be fitted with the protection in place.

If removed, children can choke or suffocate if swallowing it.

Risk of Asphyxia or Personal Injury

Using incorrect settings may cause personal injury or severe medical conditions, such as hypercarbia, producing arterial acidemia.

The therapy settings shall be based on a physician's description. Changes to settings must be made by authorized clinical personnel only.

Risk of Faulty Treatment

The responsible organization should periodically reassess the settings of the therapy for effectiveness.

Risk of Faulty Treatment

Always prepare the Vivo 3 as described in this manual before use.

Risk of Unnoticed Critical Conditions

- The alarm sound level should be set to a clearly audible level. Setting the alarm sound level below that of the ambient sound level can impede recognition of alarm conditions.



Risk of Unnoticed Critical Conditions

When using the Vivo 3 invasively, physiological alarms, such as the low volume alarm and the low breath rate alarm, must be carefully set, to ensure safe use.

Risk of Reduced Safety and Performance

Accessories that have not been tested with the Vivo 3 might affect safety features and performance negatively. Only use the Vivo 3 with accessories approved by Breas Medical AB.



Incompatible parts can result in degraded performance and change of pressure gradient. If unapproved accessories are used, Breas Medical AB has no responsibility for the safe and effective use of the Vivo 3.

The responsible organization is responsible for ensuring the compatibility of the ventilator and all parts used to connect to the patient before use.

WARNING!

Risk of Electric Shock

Modifying or using the ventilator with accessories that are not specified or approved by Breas may cause cardiac arrhythmia.

The Vivo 3 must only be used in original and unmodified shape and only with accessories specified or approved by Breas Medical AB.

Inadequate use of device or accessories may cause loss of treatment or decreased performance.



WARNING!

Risk of Burns

Covering breathing tubes with a blanket or heating them with an overhead heater can affect the quality of the therapy or injure the patient.



WARNING!

Risk of Fire and Burns

Do not lubricate fittings, connections, tubing, or other accessories of the equipment as the lubrication might be flammable in combination with the oxygen rich gas flow.



CAUTION!



Read this manual thoroughly and understand the operation of the Vivo 3 before operating or using the machine.



Always use the therapeutic pressure setting, as individually determined with the configuration of the equipment and accessories.



Proper placement and positioning of the patient interface is critical to the consistent operation of this equipment.



Handle the Vivo 3 with care.



Make sure to place and pack the device in a way that prevents unintentional start of the machine.



Due to the internal battery, the Vivo 3 may start if the Start/Stop button is pressed even without the mains being connected.



Do not use the Vivo 3 with nitric oxide, helium or helium mixtures. This may affect patient air flow and volume measurements.



If you suspect that the device has been mistreated, perform a functional check before taking it to use. A basic functional check can be performed as described in 5.5 *Performing Start-up Checks*, page 52. A complete functional check can be performed by an authorized service technician.



NOTE

Any serious incident that has occurred in relation to this device should be reported to the competent authority and the manufacturer.

2.2 Electricity — Warnings and Precautions

WARNING!

Risk of Electric Shock

High voltage contact may cause cardiac arrhythmia.

- Do not operate the Vivo 3 if it has a damaged power cord, power supply or casing.
- To avoid electrical shock, only clean the Vivo 3 according to instructions in this manual. Do not soak or immerse the Vivo 3 into any fluids.
- Use the approved power supply units only.

Use of unapproved power supply units may compromise the electrical isolation and lead to risk of electric shock.

- Do not use more than one multiple portable socket-outlet or extension cord. If a multiple portable socket-outlet is used, it must not be placed on the floor.
- The operator must not touch accessible contacts of connectors and the patient simultaneously.
- Nurse Call must only be connected to a safety extra low voltage system with an isolation from AC power (Mains) voltage which complies with the requirements of IEC 60601-1.



WARNING!

Risk of Faulty Treatment

Electromagnetic Interference may cause electrical equipment to malfunction.

- The aspects of electromagnetic compatibility must be considered.
 - The Vivo 3 should not be used adjacent to or stacked with other equipment; if adjacent or stacked use is necessary, the Vivo 3 should be observed to verify normal operation in that configuration.
 - Mobile or transportable radio transmitters may interfere with the Vivo 3.
 - Further guidance for safe installation of the ventilator can be found in the chapter about emission and immunity declaration.
- If a portable AC power supply is used, make sure that the voltage variations are within the operating limits of the Vivo 3.
- 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 the Vivo 3, including cables specified. Otherwise, degradation of the performance of this equipment could result.



2.2.1 Electromagnetic Compatibility and Electrostatic Discharge (EMC and ESD)

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

Electromagnetic disturbance may impair the safety and performance of the Vivo 3. The electromagnetic field levels at the Vivo 3 should not exceed 20 V/m.

Unsteady indicated values for delivered volumes or pressures and the occurrence of alarm conditions without apparent cause may be an indication of loss of performance due to electromagnetic disturbances.

Measures for keeping electromagnetic field levels low should include but are not be limited to:

- Normal precautions with regard to relative humidity and conductive characteristics of clothing in order to minimize the build-up of electrostatic charges.
- Avoiding the use of radio emitting devices (e.g. cellular or cordless telephones, microwave ovens and high-frequency surgery apparatus) closer than 1 meter to the Vivo 3.
- Avoiding the use of known sources of Electromagnetic Interference, (e.g. RFID, diathermy equipment), in the presence of the Vivo 3.

Please note some of these RF emitters may not be visible and the Vivo 3 can potentially be exposed to fields from these RF emitters without the user's awareness. If abnormal performance of the Vivo 3 is observed, and the RF emitters cannot be identified and removed, the Vivo 3 may need to be reoriented or relocated.



See the section *Emission and Immunity Declaration* for detailed information and further guidance for mitigating electromagnetic disturbance.

2.3 Environment — Warnings and Precautions



WARNING!

Risk of Intoxication

Do not use the Vivo 3 in a toxic environment.



Risk of Faulty Treatment

If a room humidifier is used, place it at least 2 meters away from the Vivo 3.



Risk of Faulty Treatment



Do not use or store the Vivo 3 in a magnetic resonance (MR) environment. Use of the Vivo 3 in an MR environment may result in malfunction of the Vivo 3 and pose unacceptable risk to the patient, medical staff or other persons.

Risk of faulty Treatment

The performance of the Vivo 3 may deteriorate at altitudes or ambient temperatures outside the operation conditions specified in the chapter *Technical Specifications*.

- Do not use the ventilator while positioned in a warm place, such as direct sunlight or close to a radiator as this might lead to temperature outside the specifications.
- Do not use the ventilator in an hyperbaric chamber, as this would cause an ambient pressure outside the specifications.
- Do not use the ventilator immediately after storage or transport outside the recommended operating conditions.



WARNING!

Risk of Fire

Do not use the Vivo 3 in environments where explosive gases or flammable anesthetic agents present.



WARNING!

Risk of Electric Shock

Water on and in the device may cause an electric conductive path. Do not expose the Vivo 3 to rain or snowfall.



CAUTION!

The ventilator, any accessories and all replaced parts, must be disposed of in accordance with the local environmental regulations regarding the disposal of used equipment and waste.



2.4 Patient Circuit — Warnings and Precautions

WARNING!

Risk of Insufficient Ventilation

Insufficient ventilation may cause transient hypoxia.

The Vivo 3 ventilator is intended to be used with patient circuits with intentional leakage and compliant to ISO 17510. Recommended leak rate: 20 to 50 liters per minute at 10 cmH₂O.

Failure to use a mask or accessory that minimizes rebreathing of carbon dioxide or permits spontaneous breathing can cause asphyxiation.



Risk of Abnormal Exhalation Volume Measurement

Non-invasive ventilation: The exhaled volume of the patient can differ from the measured exhaled volume due to unintentional leaks around the mask.

Invasive ventilation: The exhaled volume of the patient can differ from the measured exhaled volume due to unintentional leaks around the cannula.

For correct measurements, minimize unintentional leaks.



Risk of Reduced Safety and Performance

Accessories that have not been tested with the Vivo 3 might affect safety features and performance negatively. Only use the Vivo 3 with accessories approved by Breas Medical AB.



Incompatible parts can result in degraded performance and change of pressure gradient. If unapproved accessories are used, Breas Medical AB has no responsibility for the safe and effective use of the Vivo 3.

The responsible organization is responsible for ensuring the compatibility of the ventilator and all parts used to connect to the patient before use.

Risk of Reduced Performance



Filters and patient connected parts must be replaced regularly to ensure correct function of the Vivo 3.

Risk of Insufficient Ventilation

Insufficient ventilation may cause transient hypoxia.

Before use:

- Make sure that the patient circuit and joined parts are undamaged and correctly connected, in order to avoid unwanted leakage.
- Make sure that the leakage port of the circuit or mask is not blocked or obstructed. This port prevents rebreathing by flushing the exhaled air.
- The Vivo 3 should be turned on and the function of the leakage port should be checked before use: The pressurized air from the Vivo 3 causes a continuous flow of air through the leakage port, enabling flushing of exhaled air.



Risk of Insufficient Ventilation

Unapproved patient circuits may come loose.



To prevent disconnection of the patient circuit or patient circuit system during use, especially during ambulatory use, only patient circuits in compliance with ISO 5367 or ISO 80601-2-74.

Risk of Suffocation

Periodically check for moisture in the patient circuit.



When present, remove the moisture. Before attempting to dry the circuit, disconnect it from the Vivo 3 to ensure no water flows back into the Vivo 3.

The frequency at which these checks must be performed will depend on the patient's condition and the device used. The responsible caregiver should assess this on an individual basis in accordance with the patient's needs.

Risk of Suffocation



If the patient needs assistance to remove the patient interface, the patient shall not be left alone. This is to avoid the risk of re-breathing of CO₂ in case of accidental ventilator failure.

Do not breathe through the connected patient circuit unless the ventilator is turned on and operating properly.

Risk of Suffocation



If the patient is using a full face mask (covering mouth and nose), the mask must be equipped with a safety entrainment valve.

Risk of Suffocation or Barotrauma



In HFNT mode, do not use a sealed patient interface.

**Risk of Constriction**

Entanglement with cables or tubing constricting airways may cause asphyxiation. Do not leave long lengths of air tubing or cables around the top of the bed. They could twist around the patient's head or neck while sleeping.

**Risk of Insufficient Ventilation**

Insufficient ventilation may cause transient hypoxia. The use of equipment such as endotracheal tubes, oral/nasal tubes, adaptors etc. with small inner diameters or high resistance filters, humidifiers etc. increase the resistance in the patient circuit which may interfere with the operation of the patient disconnect function. It may also interfere with the device trigger function.

**Risk of Excessive Carbon Dioxide**

Insufficient carbon dioxide removal may cause arterial acidemia. For reducing the risk of rebreathing CO₂, make sure that the leakage port is located as near the patient interface as possible. This is even more important for treatments with low pressure, as this reduces the flow through the leakage port.

**WARNING!****Risk of Electric Shock**

Do not use antistatic or electrically conductive hoses or tubing with the ventilator breathing system. This could result in electrical shock.

**WARNING!****Risk of Cross-Contamination**

Patient circuits might get contaminated by exhaled gases. To avoid cross-contamination, always use a properly cleaned or a new patient circuit when the Vivo 3 is to be used by a new patient.

**NOTE**

For masks and accessories, always follow the manufacturer's instructions.

2.5 Filter Usage — Warnings and Precautions

**WARNING!****Risk of Insufficient Ventilation**

Insufficient ventilation may cause transient hypoxia. Replace or clean the inlet filters as specified in the *Maintenance* chapter. Using old or clogged filters may cause the Vivo 3 to operate at higher temperatures than intended. When operating the Vivo 3, make sure that the air inlet and filters are not obstructed or occluded.

**Risk of Insufficient Ventilation**

Insufficient ventilation may cause transient hypoxia. Do not use high resistance bacteria filter at the air outlet of the Vivo 3. High resistance bacteria filters placed between the air outlet and the patient interface may interfere with the operation of the patient disconnect function. It may also interfere with the device trigger function.



Risk of Insufficient Ventilation

Humidification can increase the resistance of breathing system filters and the operator must monitor the breathing system filter frequently for increased resistance and blockage to ensure the delivery of the therapeutic pressure. Increased resistance may interfere with the operation of the patient disconnected function.

WARNING!

Risk of Cross-Contamination

Deep tissue or mucosal contact with infectious agents may cause infections:

- If assigning the Vivo 3 to a new patient, always replace the filters.
- Always use the Vivo 3 with patient air inlet filters installed.

Risk of Cross-Contamination

Deep tissue or mucosal contact with infectious agents may cause infections.

If the Vivo 3 is used by several patients, a low resistance bacteria filter shall be used between the air outlet and the patient circuit, for preventing patient cross-contamination. Reuse of bacteria filter, patient circuit or mask may expose patients to contagious agents.



2.6 Invasive Use — Warnings and Precautions



WARNING!

Risk of Therapeutic System Performance or Failure

Invasive use of the attachable humidifier may cause reduced performance. The attachable humidifier is not intended for invasive use.

Risk of Faulty Treatment

If using the Vivo 3 for invasive ventilation, humidification is recommended. Make sure to use an external heated humidifier that complies to invasive use according to ISO 80601-2-74.

Risk of Unnoticed Critical Conditions

When using the Vivo 3 invasively, physiological alarms, such as the low volume alarm and the low breath rate alarm, must be carefully set, to ensure safe use.

Risk of Rebreathing

Be aware of risks for rebreathing exhaled gases:

- A blocked, clogged or in other ways occluded leakage port causes exhaled gases to be rebreathed.
- With low pressures the risk of rebreathing increases.
- I:E (inspiration time : expiration time) ratios close to 1:1 increase the risk of rebreathing as the expiratory time allowing exhaled gases to be cleared from the circuit before the next breath is decreased.

The Vivo 3 is equipped with a low leakage alarm. However, the alarm is not a substitute for operator vigilance for ensuring that the leakage ports remains clear at all times. Periodically check the leakage ports during therapy. See the section 2.4 *Patient Circuit — Warnings and Precautions*, page 15 for mitigating the risks of rebreathing.



WARNING!**Risk of Insufficient Ventilation**

The attachable humidifier is not intended for invasive use.

**Risk of Personal Injury**

The attachable humidifier shall not be used with nitric oxide. Such use might cause the humidifier to not function correctly, causing serious deterioration of health.

**Risk of Suffocation**

When the attachable humidifier is installed, the Vivo 3 must be located below the patient and on a flat surface. This is to prevent personal injury from accidental spillage or from excess water or condensation flowing down the patient tube and into the patient's mask. Extra cautions should be taken for patients who are unable to guard their airways or cannot pull off the mask.

**Risk of Suffocation or Loss of Ventilation**

Incorrect placing of the ventilator may cause transient hypoxia.

If using an external humidifier, it shall be placed below both the patient and the Vivo 3. This is to prevent personal injury from accidental spillage or from excess water or condensation flowing down to the ventilator or down the patient tube and into the patient's mask. Extra cautions should be taken for patients who are unable to guard their airways or cannot pull off the mask.

**Risk of Inflammation**

Incorrect connection of the ventilator may cause inflammation.

The attachable humidifier is only enabled when the Vivo 3 is connected to the AC Power supply.

**Risk of Suffocation**

Installation of a water trap may be required if the condensation is extensive in the patient circuit when using a heated humidifier.

The water trap prevents condensed water in the patient circuit from reaching the patient airways and causing personal injury.

**Risk of Suffocation**

Do not use the attachable humidifier during mobile use.

Due to movements, water spillage from the humidifier or condensed water may flow to the patient and cause suffocation.

WARNING!**Risk of Electric Shock**

Do not use the attachable humidifier during mobile use.

Internal water spillage may cause electric shocks and may damage the device.

**Risk of electric shock**

If using the protective cover or the carry bag, first remove the attachable water chamber. Water spillage may cause electric shocks.

**Risk of Electric Shock**

Electrostatic discharge or contact with leakage current may cause an electric shock.

The attachable humidifier must be detached before filling. Do not fill above the *Maximum Water Level* indication on the water chamber.



WARNING!

Risk of Burns

After using the ventilator, wait one minute before you open the water chamber since it can get hot under certain conditions (for example if the humidifier runs out of water).



CAUTION!

The use of external humidifier may require readjustment of the low-pressure alarm.

2.8 Cleaning and Maintenance — Warning and Precautions

This manual contains instructions for cleaning and maintenance that can be carried out by the care provider or users with physical ability and working knowledge of the system.



WARNING!

Risk of Faulty Treatment

Service and Maintenance of the Vivo 3 shall not be performed when the Vivo 3 is in use.



WARNING!

Risk of Electric Shock

Cleaning with excessive water or opening the device's casing without certified training may cause electric shocks.

The Vivo 3 should be regularly cleaned and maintained in accordance with this operating manual.

Risk of Electric Shock

High voltage contact may cause cardiac arrhythmia.

Repairs and modifications must be carried out by authorized technicians only and in accordance with instructions from Breas Medical AB



- The Vivo 3 must not be opened, repaired or modified by unauthorized personnel. If subjected to unauthorized operations, Breas Medical AB is no longer responsible for the device's performance and safety and all warranties will become invalid.
- The Vivo 3 must not be modified or interconnected to unapproved equipment.



CAUTION!

Do not attempt to autoclave or sterilize the Vivo 3.

2.9 Oxygen Usage — Warning and Precautions

When using the Vivo 3 with oxygen, always follow the oxygen provider's instructions and use only medical grade oxygen complying with local regulations.



WARNING!

As this medical device uses an alternative small-bore connector design different from those specified in the ISO80369 series, there is a possibility that a misconnection can occur between this medical device and a medical device using a different alternative small-bore connector, which can result in a hazardous situation causing harm to the patient. Special measures need to be taken by the user to mitigate these reasonable foreseeable risks.



Do not use a humidifier between the oxygen source and the ventilator, in order to humidify the oxygen flow.

If humidification is required, use the attachable humidifier or an external humidifier after the patient air outlet.

Risk of faulty Treatment

At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure or flow delivered, the patient interface and leak rate.

To monitor the oxygen concentration, use an external patient air oxygen saturation monitoring unit which complies with ISO 80601-2-55 and is equipped with a high oxygen level alarm.



Risk of faulty Treatment

The responsible organization shall ensure that the oxygen source is compatible with the rated range of pressure, flowrate and oxygen concentration for this device.

Failure to use a compatible oxygen source may result in serious deterioration of health.



WARNING!

Risk of Fire

The presence of oxygen can speed up combustion of inflammable materials.

- When the equipment is not in use, turn it off. When the equipment turned on, never leave the patient interface on textiles like bed coverings or chair cushions . The oxygen enrichment will make the materials more flammable.
- Use only water-based lotions or salves that are oxygen-compatible before and during oxygen therapy. Never use petroleum-based or oil-based lotions or salves, to avoid the risk of fire and burns.
- Ventilate the room adequately.
- Do not smoke in a room where oxygen is being used, it may result in facial burns or death. If the patient intends to smoke: turn the equipment off, remove the patient interface and leave the room where the equipment is located before smoking. If unable to leave the room, wait 10 minutes after you have turned the equipment off.
- Naked light bulbs, open flames and other sources of ignition must be kept a minimum of 2 meters (6 feet) away from the oxygen cylinder or any oxygen carrying parts and accessories.
- Do not use aerosols or solvents close to the oxygen supply, even when the oxygen supply is shut off.



Risk of Fire

When oxygen is used with the Vivo 3, the oxygen flow must be turned off when the Vivo 3 is not operating. Oxygen delivered into the patient tubing may accumulate within the machine enclosure. Oxygen accumulated in the machine enclosure increases the risk of fire.



CAUTION!

Supplemental oxygen flow must not exceed 30 l/min or 100 kPa.





CAUTION!

Supplemental oxygen is added before the volume measurement sensor and thereby included in the measurements. However, the oxygen concentration still has influence on the volume measurement of the delivered air.

This measurement is based on a normal oxygen concentration of 21%. If the oxygen concentration is higher, the actual inspired volume will deviate from the monitored volume as follows:

- 40% oxygen concentration: -2.5% deviation
- 60% oxygen concentration: -5% deviation
- 80% oxygen concentration: -7.5% deviation

2.10 Mobile Use — Warning and Precautions

This section applies if using the Vivo 3 during transit, for example on a wheel chair or in a car.



WARNING!

Risk of Suffocation

Do not use the attachable humidifier during mobile use.

Due to movements, water spillage from the humidifier or condensed water may flow to the patient and cause suffocation.



WARNING!

Risk of Electric Shock

Do not use the attachable humidifier during mobile use.

Internal water spillage may cause electric shocks and may damage the device.



Risk of Electric Shock

If connecting the Vivo 3 to an external DC power source, always use the DC DC Power Supply accessory. Connecting directly to an external DC power source may compromise the electrical isolation and cause an electric shock.

If connecting the Vivo 3 to a portable AC power generator, make sure its voltage variations are within the operating limits of the Vivo 3.



CAUTION!

During mobile use, protect the device with either of the Protective Cover accessory or the Lightweight Mobility Bag accessory.

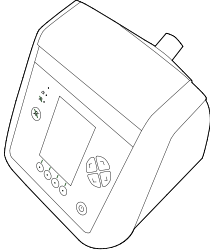
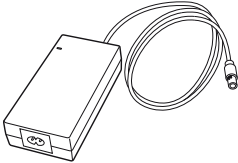
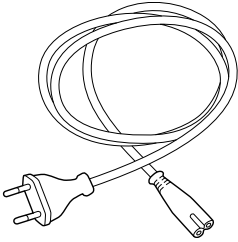
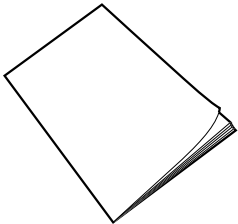
Do not use the Vivo 3 while in a carry bag.

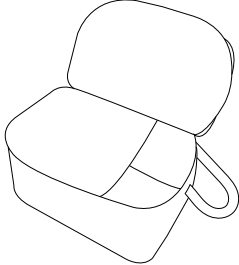
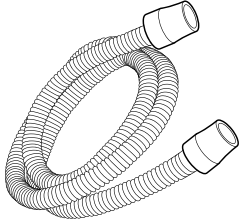
3 Product Description

This section describes the main Vivo 3 medical electric equipment.

For information about accessories and user replaceable spare parts., see .10 *Accessories*, page 103.

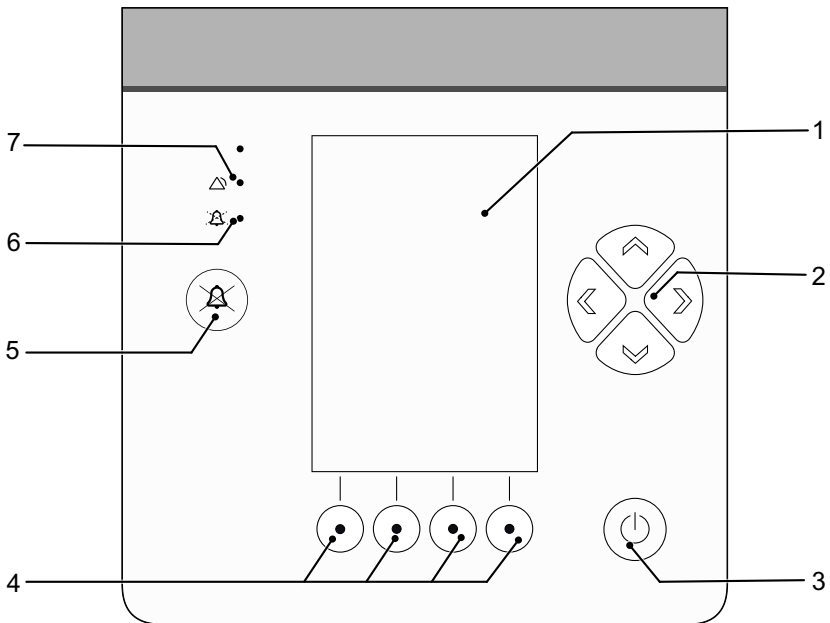
3.1 Main Components

| Part | Function | Breas Part no. |
|--|---|---|
| Ventilator unit  | Main unit. | 229000 |
| RRC PS90M AC/DC Power supply  | Power supply adapter for the Vivo 3. | 006994 |
| Mains power cord  | Power cord between the mains socket and the power supply adapter. | 003520 |
| User Manual  | Instructions for use | User's manual: 007231 Clinician's manual: 007232 |

| Part | Function | Breas Part no. |
|---|--------------------------------------|----------------|
| Carry bag | For transportation, when not in use. | 007013 |
|  | | |
| Patient circuit, 15 mm | Delivers air to the patient | 006712 |
|  | | |

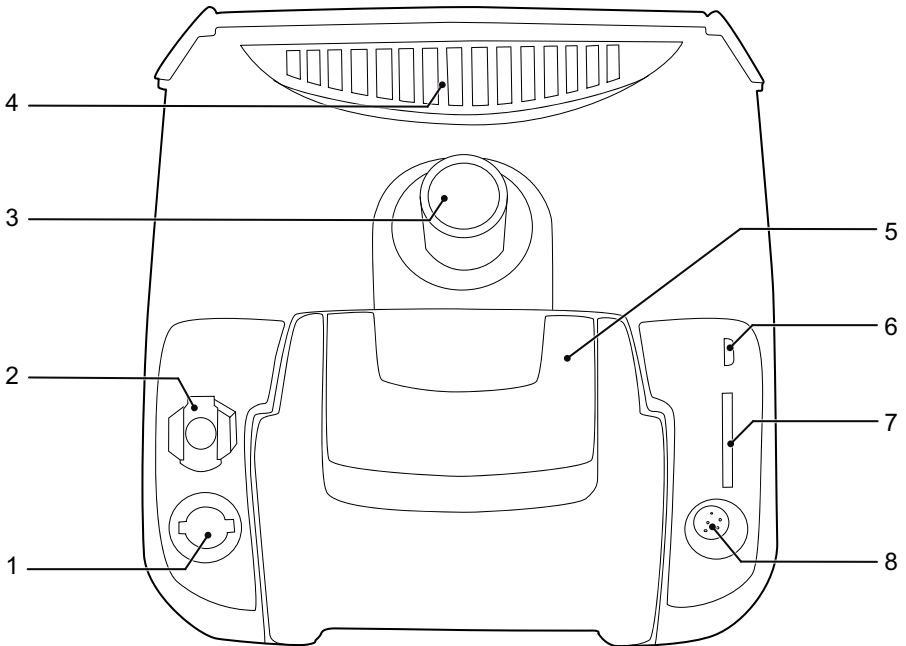
3.2 Ventilator Front

This section describes the front panel.



| No. | Item | Description |
|-----|---------------------|---|
| 1 | Screen | Displays pages with information, settings and commands. |
| 2 | Directional buttons | Moves between and selects objects on the current page. |
| 3 | On/Off button | Starts /stops treatment. Turn the ventilator On/Off. |
| 4 | Navigation buttons | Select pages according to the corresponding label on the display. The navigation buttons can temporarily be designated functions for replying to questions or requests from event windows. |
| 5 | Audio pause button | Pauses the alarm sound. |
| 6 | Audio Pause LED | Lights yellow when the alarm sound is paused. |
| 7 | Alarm LED | Flashes during active alarms. |

3.3 Ventilator Back



| No. | Item | Description |
|-----|--------------------|---|
| 1 | Power port | Port for connecting the power supply. See 5.3 <i>Connecting the Vivo 3 to Power Supply</i> , page 49 |
| 2 | Oxygen port | Connection for low pressure/bleed-in oxygen |
| 3 | Patient air outlet | Connection for patient circuit |
| 4 | Patient air inlet | Patient air inlet, with filter holder |
| 5 | Air bypass module | Directs the patient air flow. Removed if the attachable humidifier is used. |
| 6 | USB port | For data transfer to a PC. |
| 7 | SD Card port | For copying records and logs to a PC. |
| 8 | Communication port | For connection to SpO ₂ sensor or Accessory box (for connection of nurse call or remote alarm) |

The ventilator can be carried by hand using the handle.

3.4 Power Management



WARNING!




Do not connect the ventilator directly to the battery of a wheelchair or any similar external power source, as this can compromise the ventilator performance and result in degradation of the health of the patient.

For external DC power other than the Breas XPAC, always use the DC/DC power supply adapter (accessory).

The Vivo 3 has a power management system that automatically selects the best available power source, according to the priority list below:

1. Mains power via Breas Mains power supply
2. External DC via the Breas XPAC, or the Breas DC/DC power supply adapter
3. Internal battery

The power source is indicated by a symbol at the top of the display.



| Power Source | Icon |
|------------------|---|
| Mains |  |
| External DC |  |
| Internal battery |  |

For connecting the Vivo 3 to both mains and external DC at the same time, the accessory *Power supply Y-cable* is required.

If a power source fails, the Vivo 3 will switch to the next source in priority and show a message on the display. If all available sources fail, the *Power Failure* alarm is given and the Vivo 3 shuts down.

Charging the Internal Battery

The internal battery is automatically charged when the Vivo 3 is connected to external power. The state of charge is indicated by a symbol on the display. The green part of the battery shows the state of charge.

| Battery State of Charge | Icon |
|-------------------------|--|
| High |  |
| Charging |  |

Preparing the Battery for Storage

If storing the Vivo 3, longer than 1 month, make sure that the internal battery is about half charged before storing, in order to maintain maximum battery capacity. Optimal storage temperature is 5 to 30°C (41 to 86°F).

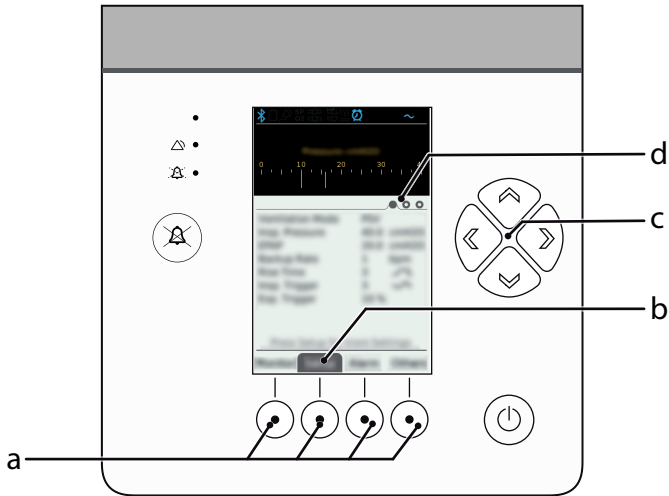
3.5 Menus

3.5.1 Use the Menu

The menu consists of four function sections:

- Monitor
- Setup
- Alarm

- Others

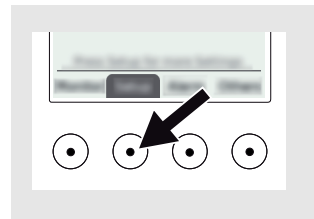


- a. Navigation buttons
- b. Active page indicator
- c. Directional buttons
- d. Page number indicator (for functions with several pages)

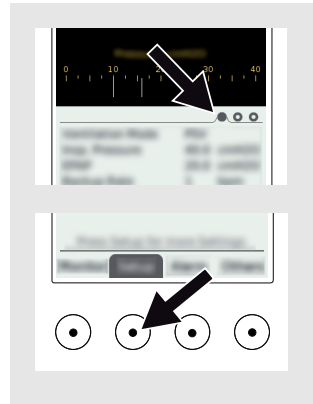
Selecting the Section to Display

1 Press the navigation button for the requested function page.

⇒The page is now displayed.



2 For functions with several pages grouped together, press the navigation button again to browse the pages.



3 For pages with menus, settings or additional information, press the Up and Down arrow buttons to select an item on the page.

Select an Item on a Page

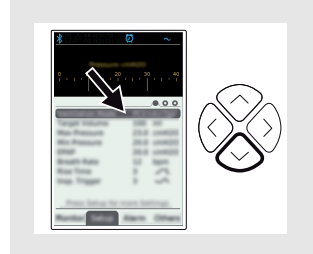
This procedure describes how to navigate between selectable items. Read-only information cannot be selected.

Selectable Items

- Sub pages (indicated by an arrow to the right of the item text)
- Settings
- Commands

1 Press the Up or Down arrow button to select the first selectable item on the page.

⇒ The selected item is highlighted.



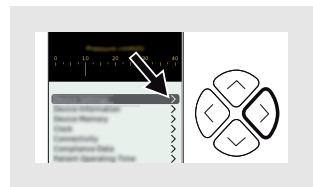
2 To select another item on the list, press the Up or Down arrow until it is highlighted. Note that items with read only information cannot be selected.

Enter a Sub Page

1 Select the sub page (indicated by an arrow to the right of the item text) using the Up or Down arrow button.

2 Enter the sub page by pressing the right arrow button.

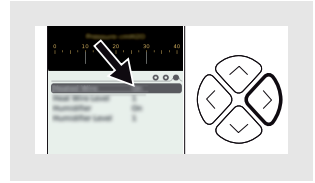
⇒ The sub page is now displayed.



- 3 Leave the sub page using the left arrow button

Change a Setting

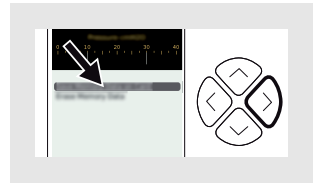
- 1 Select the setting (indicated by an arrow to the right of the item text) using the Up or Down arrow button.
- 2 Change the setting using the right or left arrow buttons to select between the predefined values.
⇒ The currently displayed value will remain selected when leaving the page.



- 3 Leave the sub page using the navigation buttons.

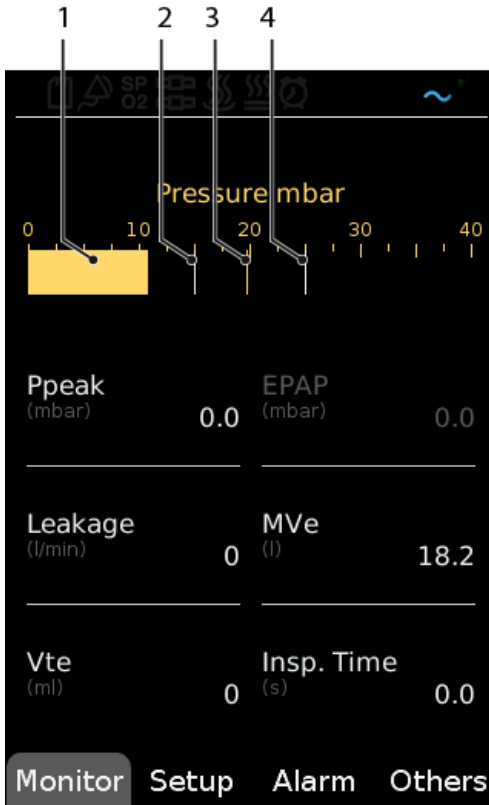
Execute a Command

- 1 To execute a command, select it and press the right arrow button.
⇒ The command execution is started. Additional actions related to the command might be requested in event windows.



3.5.2 The Monitor Page

The monitor page displays the treatment data. It consists of a bar graph illustrating the current pressure and text area displaying current monitored values in text.



Bar graph legend

1. Current pressure
2. Low pressure alarm level
3. Set inspiration pressure level
4. High pressure alarm level

Monitor page with HFNT

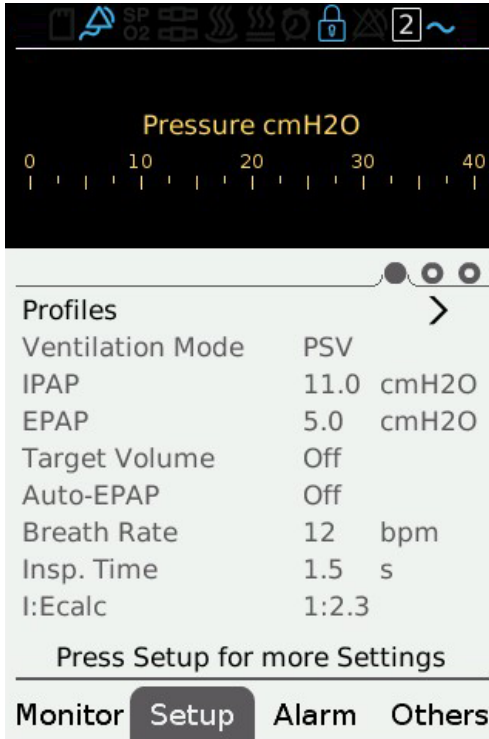
When HFNT is active, flow is displayed instead of pressure.



For information about monitored values, see 6.5.1 *Treatment Values Monitored by the Vivo 3*, page 58.

3.5.3 The Setup Pages

The setup pages contain settings related to the treatment.



WARNING!



Risk of Asphyxia or Personal Injury

Using incorrect settings may cause personal injury or severe medical conditions, such as hypercarbia, producing arterial acidemia. The therapy settings shall be based on a physician's description. Changes to settings must be made by authorized clinical personnel only.

Selecting a profile

If profiles with preset treatment settings have been created, the profiles are selected from the Setup section.

- 1 Select Profiles and press the Down or Up arrow button to select one of the profiles.
- 2 Press Left arrow button to select a profile. The currently active profile is indicated by a checkmark.



For detailed information about each setting, see 4 *Treatment Functions and Settings*, page 40.

3.5.4 The Alarm Pages

The alarm pages contain alarm settings and an alarm history list.

For information about the alarms and their possible settings, see 7 *Alarms*, page 72.

3.5.5 The Others Pages

The Others pages contain non-clinical settings and information.

3.5.5.1 Device Settings

This section describes device settings that don't affect the ventilating function of the Vivo 3.

| Setting | Description |
|--------------------|---|
| Language | Value range: The available languages are listed with their native names accompanied by a flag representing a country where the language is spoken. Default value: English (The language selection menu is displayed when the Vivo 3 is started for the first time.) |
| Confirm Start/Stop | If set to On, the user need to confirm that the treatment is to be stopped. If set to Off, treatment is started and stopped directly when pushing the start/stop button on the machine. Default value: On |
| Pressure Unit | Value range: <ul style="list-style-type: none">• cmH₂O• mbar• hPa Default value: cmH ₂ O |
| Display Light | Value range: <ul style="list-style-type: none">• On — Always lit at the selected intensity• Auto — Always lit, with automatic adjustment of the intensity with regards to the ambient light.• Delayed — The display is dimmed after about 30 seconds (time depends on usage mode and power source). If any button is pressed or any alarm occurs, the display is lit again. Default value: On |
| Light Intensity | Value range: 1 to 5 Default value: 5 |

3.5.5.2 Pre-use Test

The pre-use test is to verify that the machine and the patient circuit work as expected, the default circuit setting is for a 15 mm circuit diameter. Go to Setup > Patient circuit to change the default setting.

If Custom is selected, a pre-use test must be performed. The resistance value is saved to configure the custom circuit.

The pre-use test is performed using a guide in the graphical user interface.

3.5.5.3 Device Information

| Information | Description |
|--|--|
| Product name | |
| Operating time | The total number of hours the ventilator has been running in operating mode. |
| Battery Percentage | Battery charge level |
| Battery Time Left | Estimated remaining usage time on battery power |
| Firmware version Bootloader version GUI Res. Version Board Revision Interface Board Rev Serial number A-Box FW A-Box Board Rev Rem. Alarm FW | Technical information for service personnel |

3.5.5.4 Device Memory

| Command | Description |
|--------------------------|--|
| Save Memory Data on Card | Copies the memory data from the internal memory to the memory card. |
| Erase Memory Data | Erases memory data from the internal memory |
| Remove SD-card | Remove the SD-card from the ventilator. (It must be ejected manually, though.) |

The following data is stored and logged:

- Running hours
- Technical alarms
- Settings
- Asset data
- Treatment hours
- Treatment settings
- Device serial number
- Physiological alarms
- Detailed log (containing at least 24 h data of clinical parameters)
- Breath log (containing at least 30 day data of clinical parameters)
- Usage log (containing at least 1 year data of non-clinical events, alarms and settings)

3.5.5.5 Clock

| Setting | Description |
|--------------------|---|
| Time | Sets the time for the Vivo 3. The time is used for logs and reports. |
| Date | Sets the date for the Vivo 3. The date is used for logs and reports. |
| Time Format | Select whether to use 12 hr clock or 24 hr clock. |
| Date Format | Select the date format to use. |
| Alarm Clock | Activates an alarm clock on the Vivo 3. One short signal every 5 seconds. |
| Alarm Clock Time | Sets the alarm time for the alarm clock. |
| Alarm Clock Volume | Sets the volume for the alarm clock. |



NOTE











The alarm clock works only when the ventilator is running on mains.


3.5.5.6 Compliance Data


| Setting / information | Description |
|-----------------------|--|
| Min daily use | The minimum daily use, in hours, to reach compliance per day. |
| Reset Compliance Data | Reset of data. |
| Start Date | Start date for treatment. |
| Total Usage Hours | The total number of hours the ventilator has been running in operating mode during the download period. |
| Total Days | The total number of days in the download period. |
| Days with Usage | The number of days in the download period where the ventilator has been running in operating mode (all day, or part of the day). |
| Average Usage Hours | The average number of hours per day the ventilator has been running in operating mode. Only days where the ventilator has been running in operating mode are part of the value (days without treatment are excluded in the calculation). |
| Days Compliant | Number and percentage of days when minimum daily use has been reached. |
| AHI | Apnea Hypopnea Index |

3.6 Symbols on the Vivo 3


Symbols on the Product Information Label


| Symbol | Description |
|---|--|
|  | Manufacturer information |
|  | Nemko certification mark (NRTL/SCC accredited) |
| IP22 | Degree of protection provided by enclosure. See 9.3 <i>Environmental Conditions</i> , page 95 for explanation. |
| Rx Only | (Symbol only applicable in U.S.) Caution: U.S. Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner. |
|  | Read user instructions |
|  | RTCA/DO-160 G categorization. Category M This category is defined for equipment and interconnected wiring located in areas where apertures are electro-magnetically significant and not directly in view of radio receiver's antenna. This category may be suitable for equipment and associated interconnecting wiring located in the passenger cabin or in the cockpit of a transport aircraft. |
|  | Meets all requirements for CE marking according to relevant European health, safety and environmental protection legislation. |
|  | Meets all requirements for UKCA marking according to applicable United Kingdom health, safety and environmental protection legislation. |
|  | Internal Battery Information |
|  | Read the "Disposal" section for information about recycling and disposal, see 93. |
|  | Product number |
|  | Serial number |

| Symbol | Description |
|---|-----------------------------------|
|  | This product is a Medical Device. |


| | |
|---|---------------------|
|  | Date of manufacture |
|---|---------------------|


Symbols on the Vivo 3 Back

| Symbol | Description |
|---|--|
|  | Oxygen connection port. Max 30 l/min and 100 kPa. |

| | |
|---|---|
|  | Power connection port. Use approved power supplies only. |
|---|---|














| | |
|---|----------|
|  | USB port |
|---|----------|

| | |
|---|---------------------|
|  | SD memory card port |
|---|---------------------|

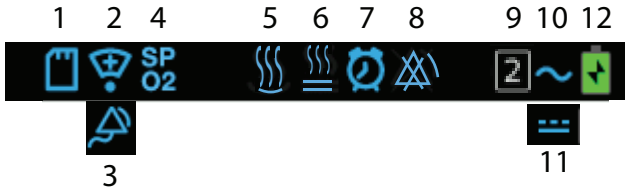
| | |
|---|---|
|  | I/O port for accessory box/SpO ₂ |
|---|---|

Additional Symbols on Parts and Accessories

This section describes additional symbols for Vivo 3 detachable parts and accessories from Breas Medical AB. Each item, or its package, have the symbols that applies for the specific accessory.

| Symbol | Description |
|---|---|
|  | Caution, hot surface |
|  | Caution symbol, read the Accessory's instructions for more information. |
|  | Keep away from rain. |
|  | Single patient multiple use. |
|  | Meets all requirements for CE marking according to relevant European health, safety and environmental protection legislation. |
|  | Meets all requirements for UKCA marking according to applicable United Kingdom health, safety and environmental protection legislation. |
|  | Applied part, type BF Electrically connected to the patient but not directly to the heart. |
|  | IEC protection Class II: Double insulated equipment. |
|  | Remote alarm port |
|  | Alarm nurse call port |
|  | Effort belt port (not used) |
|  | AC power port |
|  | DC power port |
| SP O2 | SPO ₂ port |

3.7 Symbols on the Display



1. SD card inserted and working
2. Nurse call connected
3. Remote alarm connected
4. SpO2 connected
5. Humidifier activated
6. Heated circuit activated
7. “Clock radio wake up” activated
8. All alarms shut off
9. Active profile
10. Powered by mains.
11. Powered by external battery (no icon = powered by internal battery)
12. Battery status (red — yellow — green). A flash indicates charging.

4 Treatment Functions and Settings

This chapter describes the modes, settings and parameters that controls the ventilation of the Vivo 3.

All stated tolerances includes measurement uncertainty. The accuracies have been tested with all allowed configurations. Stated tolerances only disclose the maximum tolerance. If a parameter's tolerance is described with both absolute and relative measures, the greater one applies.

Lay operators must only use the User Manual, not the Clinician's Manual.

Parameters and Modes

The table below shows the parameters that are available for each mode.

| | PSV | PCV+A | S | S/T | T | CPAP |
|---|-------------------------------------|-------|---|-----|---|------|
| IPAP | X | X | X | X | X | |
| EPAP | X | X | X | X | X | |
| CPAP | | | | | | X |
| Breath Rate | X | X | | X | X | |
| Inspiration Time | X | X | X | X | X | |
| Min insp. Time | X | | X | X | | |
| Max Insp Time | X | | X | X | | |
| Inspiratory Trigger | X | X | X | X | | |
| Expiratory Trigger | X | | X | X | | |
| Rise Time | X | X | X | X | X | |
| Target Volume Max IPAP Min IPAP | X | X | X | X | X | |
| Auto-EPAP Min EPAP Max EPAP Auto-EPAP Step Pressure Limit PS ⁽¹⁾ Min PS ⁽²⁾ Max PS ⁽²⁾ | X | X | X | X | X | |
| Ramp Up⁽¹⁾ | X | X | X | X | X | X |
| Ramp Down⁽¹⁾ | X | X | X | X | X | X |
| Ramp Pressure⁽¹⁾ | X | X | X | X | X | X |
| Humidifier | X | X | X | X | X | X |
| Heated Circuit | X | X | X | X | X | X |
| HFNT | Only Flow is available. | | | | | |
| Flow | Only available when HFNT is active. | | | | | |
| (1) Without Target Volume (2) With Target Volume | | | | | | |

4.1 Treatment Modes

This section describes the ventilating modes of the Vivo 3.

4.1.1 PCV+A — Pressure Controlled Ventilation (Assisted)

In PCV+A mode, the ventilation is controlled by set values for pressure, inspiratory time, and rise time.

The inspiration is started by either of the following triggers:

- The patient actively takes a breath.
- The interval set by the breath rate, if the patient does not actively trigger a breath.

The inspiration stops and the expiration starts by either of the following triggers:

- The inspiration time expires.
- The High Pressure Alarm limit is reached.

4.1.2 PSV — Pressure Support Ventilation

In the PSV mode, the patient's spontaneous breathing is assisted by the ventilator. The patient controls the start of inspiration through the inspiratory trigger and the start of exhalation by the expiratory trigger.

The set pressure is used as a target pressure, if the flow is decreased to the expiratory trigger level before the set pressure is reached, the expiration starts.

When an inspiration is started either when the patient triggers a breath, or when the breath rate setting initiates an inspiration in case of a prolonged apnea, the ventilator delivers a flow up to a certain preset pressure limit. In case of a patient-initiated breath, the patient continues the breath for as long as they wish and cycles off when a percentage of drop in peak inspiratory flow (expiratory trigger) has been reached.

Spontaneous breaths stop and an exhalation starts in three cases:

- The inspiration flow has dropped to the value set for expiratory trigger.
- The inspiration time is longer than the limit for maximal inspiration time or when inspiration time reaches 3 seconds.
- The limit for the high-pressure alarm is reached.

4.1.3 S — Spontaneous

In the S mode, the patient's spontaneous breathing is assisted by the ventilator. The patient controls the start of inspiration through the inspiratory trigger and the start of exhalation by the expiratory trigger.

The set pressure is used as a target pressure, if the flow is decreased to the expiratory trigger level before the set pressure is reached, the expiration starts.

When an inspiration is started by the patient triggering a breath, the ventilator delivers a flow up to a certain preset pressure limit. The patient continues the breath for as long as he/she wishes and cycles off when a percentage of drop in peak inspiratory flow (expiratory trigger) has been reached.

Spontaneous breaths stop and an exhalation starts in three cases:

- The inspiration flow has dropped to the value set for expiratory trigger.
- The inspiration time is longer than the limit for maximal inspiration time or when inspiration time reaches 3 seconds.
- The High Pressure Alarm limit is reached.

4.1.4 S/T — Spontaneous/Timed

In the S/T mode, the patient's spontaneous breathing is assisted by the ventilator. The patient controls the start of inspiration through the inspiratory trigger and the start of exhalation by the expiratory trigger.

The set pressure is used as a target pressure, if the flow is decreased to the expiratory trigger level before the set pressure is reached, the expiration starts.

When an inspiration is started either when the patient triggers a breath, or when the breath rate setting initiates an inspiration in case of a prolonged apnea, the ventilator delivers a flow up to a certain preset pressure limit. In case of a patient initiated breath, the patient continues the breath for as long as they wish and cycles off when a percentage of drop in peak inspiratory flow (expiratory trigger) has been reached.

Spontaneous breaths stop and an exhalation starts in three cases:

- The inspiration flow has dropped to the value set for expiratory trigger.
- The inspiration time is longer than the limit for maximal inspiration time or when inspiration time reaches 3 seconds.
- The limit for the high-pressure alarm is reached.

4.1.5 T — Timed

In the T mode the ventilation is controlled by set values for pressure, breath rate, inspiratory time, and rise time.

The inspiration starts by the interval set by the breath rate.

The inspiration stops and the expiration starts by either of the following triggers:

- The inspiration time expires.
- The High Pressure Alarm limit is reached.

4.1.6 CPAP — Continuous Positive Airway Pressure

In CPAP mode the Vivo 3 is applying a continuous positive pressure to the airways. The flow will automatically be adjusted to maintain the set CPAP level.

4.1.7 High Flow Nasal Therapy

In High Flow Nasal Therapy (HFNT), a constant flow is maintained regardless the nature of the connected nasal cannula and patient.

Supported nasal cannulas

Always check manufacturers rated flow rates of cannula before use

- Small Adult
- Medium Adult
- Large Adult

NOTE

The High Flow Nasal Therapy (HFNT) mode requires use of an external humidifier that conforms with ISO 80601-2-74:2021, class 3.

The Vivo 3 HFNT mode has been tested with a *Fisher and Paykel MR850* humidifier and *Intersurgical i-flo* cannulas.



4.2 Treatment Settings

This section describes settings and parameters that affects the ventilating function of the Vivo 3. On the machine, these settings are in the **Settings** menu.

4.2.1 Auto-EPAP

Auto-EPAP's main purpose is to maintain upper-airway patency (within prescribed EPAP limits). All other EPAP functions remain the responsibility of the clinician. When Auto-EPAP is active it remains the responsibility of the clinician to ensure that the minimum and maximum EPAP limits are configured so that any other EPAP objectives are satisfied.

Auto-EPAP is paused during ramp up/down if activated.

Function

With Auto-EPAP, the ventilator will adjust the EPAP within preset limits in response to detection of obstructive Apnea and obstructive Hypopnea events to prevent further occurrence of such events.

- If an Apnea event is detected, the ventilator will raise the EPAP after the event.
- If an Hypopnea event is detected, the ventilator will raise the EPAP immediately.

Auto-EPAP parameters

When Auto-EPAP is on, the following parameters are enabled:

| Min EPAP | | | | | |
|--|---------------|---|--------------------|----------------------|---------------------------------|
| The lowest possible EPAP value during the treatment. This is the EPAP value that the treatment is started with and that will be aimed for at periods of continuous normal breathing. | | | | | |
| Unit | Min | Max | Default | Resolution | Tolerance |
| cmH ₂ O | 2 | 20 or <i>Max EPAP</i> | <i>EPAP</i> value | 0.5 < 10 1.0 ≥ 10 | ± (0.5 cmH ₂ O + 5%) |
| Max EPAP | | | | | |
| The highest allowed EPAP value during the treatment | | | | | |
| Unit | Min | Max | Default | Resolution | Tolerance |
| cmH ₂ O | 2 or Min EPAP | 20 | <i>EPAP</i> | 0.5 < 10 1.0 ≥ 10 | ± (0.5 cmH ₂ O + 5%) |
| PS | | | | | |
| PS (Pressure Support) is the pressure added to the EPAP during the inspiratory phase. When Auto-EPAP is used without T _g V (Target volume), a constant pressure support is used to maintain the inspiratory pressure during EPAP changes. | | | | | |
| Unit | Min | Max | Default | Resolution | Tolerance |
| cmH ₂ O | 2 | <i>Pressure Limit - Min EPAP</i> | <i>IPAP - EPAP</i> | 0.5 < 10 1.0 ≥ 10 | ± (0.5 cmH ₂ O + 5%) |
| Min PS | | | | | |
| When Auto-EPAP is used together with T _g V (Target volume), the pressure support may vary between the set values for Min PS and Max PS for reaching the target volume. If setting high values for both Max PS and Max EPAP, the total pressure (EPAP and PS) is also limited by the Pressure Limit parameter. | | | | | |
| Unit | Min | Max | Default | Resolution | Tolerance |
| cmH ₂ O | 2 | <i>Pressure Limit - Min EPAP</i> or <i>Max PS</i> | <i>IPAP - EPAP</i> | 0.5 < 10 1.0 ≥ 10 | ± (0.5 cmH ₂ O + 5%) |

| Max PS | | | | | |
|---|---------------------------------|----------------------------------|--------------------|----------------------|---------------------------------|
| When Auto-EPAP is used together with TgV (Target volume), the pressure support may vary between the set values for Min PS and Max PS for reaching the target volume. If setting high values for both Max PS and Max EPAP, the total pressure (EPAP and PS) is also limited by the Pressure Limit parameter. | | | | | |
| Unit | Min | Max | Default | Resolution | Tolerance |
| cmH ₂ O | <i>Min PS</i> | <i>Pressure Limit - Min EPAP</i> | <i>IPAP - EPAP</i> | 0.5 < 10 1.0 ≥ 10 | ± (0.5 cmH ₂ O + 5%) |
| Pressure Limit | | | | | |
| Pressure Limit prevents the combination of Max EPAP and Max PS to reach a too high value. | | | | | |
| Unit | Min | Max | Default | Resolution | Tolerance |
| cmH ₂ O | <i>PS + EPAP</i> ⁽¹⁾ | 40 | <i>IPAP</i> | 0.5 < 10 1.0 ≥ 10 | ± (0.5 cmH ₂ O + 5%) |
| (1) With TgV: <i>Max PS + Min EPAP</i> , Without TgV: <i>PS + Min EPAP</i> | | | | | |
| EPAP Step | | | | | |
| The size of each incremental adjustment of the EPAP. | | | | | |
| Unit | Min | Max | Default | Resolution | Tolerance |
| cmH ₂ O | 0.5 | 2 | 1 | 0.5 | ± (0.5 cmH ₂ O + 5%) |
| Relax Time | | | | | |
| The time a status of normal breathing shall be maintained before the algorithm is allowed to decrease the actual applied EPAP. | | | | | |
| Unit | Min | Max | Default | Resolution | Tolerance |
| Minute | 2 | 12 Off | 5 | 1 min | 5 % |

4.2.2 Ramp Up

The ramp up setting defines a ramp time for increasing the airway pressures.

At the beginning of Ramp Up time, IPAP will start at 2 cmH₂O above the configured Ramp Pressure. If the Ramp Pressure was set below EPAP, the EPAP pressure will start at the configured Ramp Pressure.

| Unit | Min | Max | Default | Resolution | Tolerance |
|---------|-----------|-----|---------|------------|-----------|
| Minutes | 10 Off | 60 | Off | 10 | 5 % |

4.2.3 Ramp Down

The ramp Down setting defines a ramp time for decreasing the airway pressures.

At the end of Ramp Down time, IPAP will end at 2 cmH₂O above the configured Ramp Pressure. If the Ramp Pressure was set below EPAP, the EPAP pressure will end at the configured Ramp Pressure.

| Unit | Min | Max | Default | Resolution | Tolerance |
|---------|-----------|-----|---------|------------|-----------|
| Minutes | 10 Off | 60 | Off | 10 | 5 % |

4.2.4 Ramp Pressure

The ramp pressure setting is used for defining the start and end pressure when Ramp Up and/or Ramp Down is configured.

IPAP shall start at 2 cmH₂O above the configured Ramp Pressure. If the Ramp Pressure is set below EPAP, the EPAP pressure will start at the configured Ramp Pressure.

CPAP mode:

| Unit | Min | Max | Default | Resolution | Tolerance |
|--------------------|-----|-----------------|---------|----------------------|---------------------------------|
| cmH ₂ O | 2 | EPAP or CPAP | 2 | 0.5 < 10 1.0 ≥ 10 | ± (0.5 cmH ₂ O + 5%) |

4.2.5 Humidifier

This setting defines whether the attachable humidifier shall be used. If using an external humidifier, this setting shall be *Off*.

The attachable humidifier cannot be used in HFNT mode.

WARNING!



Read the section 2.7 *Humidification and Heating — Warnings and Precautions*, page 19 before activating the humidifier, to make sure all conditions are met and considered.

| Min | Max | Default |
|-----|-----|---------|
| Off | On | Off |

4.2.6 Humidifier Level

This setting defines the level of humidification, if *Humidifier* is set to *On*.

| Min | Max | Default |
|-----|-----|---------|
| 1 | 5 | 1 |

4.2.7 Heated Circuit

This setting defines whether a heated patient circuit shall be used as patient circuit.

The Heated circuit for Vivo 123 cannot be used in HFNT mode. Always check with the manufacturer for the external humidifier that is used.

WARNING!



Read the section 2.7 *Humidification and Heating — Warnings and Precautions*, page 19 before activating the heated circuit, to make sure all conditions are met and considered.

| Min | Max | Default |
|-----|-----|---------|
| Off | On | Off |

4.2.8 Heated Circuit Level

This setting defines the heating level, if *Heated Circuit* is set to *On*.

| Min | Max | Default |
|-----|-----|---------|
| 1 | 5 | 1 |

4.2.9 Patient Circuit

This setting defines which patient circuit is used.

| Selection of | Default |
|--|---------|
| 15 mm 22 mm Custom | 15 mm |
| For 15 mm and 22 mm, predefined values for circuit resistance and compliance will be applied. When you select Custom, a pre-use test must be performed to calibrate the circuit if it is the first time the treatment is started. The values for circuit resistance and compliance values are saved for the current profile. | |

4.2.10 Flow

This setting defines the constant flow for HFNT.



NOTE

Make sure that the O₂ flow is lower than the flow that is set for HFNT.

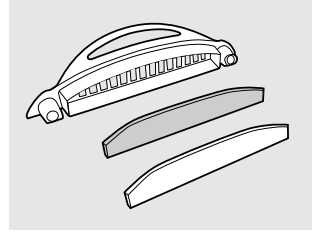
| Unit | Min | Max | Default | Resolution | Tolerance |
|-------|-----|-----|---------|----------------------|------------------|
| l/min | 4 | 60 | 10 | 0.5 < 10 1.0 ≥ 10 | ± (10ml/s + 10%) |

5 Prepare the Vivo 3 for Use

5.1 Checking the Vivo 3 before First Use

Before using the Vivo 3, perform the following checks.

- 1 Ensure that you have the equipment mentioned in 3.1 *Main Components*, page 23
- 2 Ensure that the equipment is in good condition.
- 3 If stored more than 1 month, connect the Vivo 3 to the power supply to recharge the internal battery.
- 4 Check that the air inlet filters are installed.



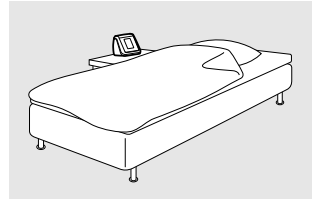
5.2 Placing the Vivo 3



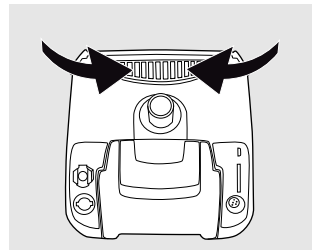
WARNING!

Read the chapter 2.3 *Environment — Warnings and Precautions*, page 14 carefully to make sure all conditions are met and considered.

- 1 Place the Vivo 3 on a solid, flat surface. The Vivo 3 should be placed lower than the patient in order to prevent the device from falling on the patient, as well as preventing condensed water from reaching the patient.



- 2 Make sure that nothing can block the patient air inlet at the back of the Vivo 3, such as a curtain etc.



- 3 Make sure that the controls are accessible for the operator.

5.3 Connecting the Vivo 3 to Power Supply

This chapter describes how to connect a Breas power supply.



WARNING!

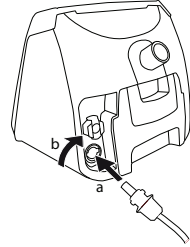
Read the chapter 2.2 *Electricity — Warnings and Precautions*, page 13 carefully to make sure all conditions are considered and met.



CAUTION!

Isolation from external power sources is provided by the approved AC/DC and DC/DC adapters. The ventilator must only be powered by the approved accessories, see 10.2 *Power Accessories*, page 105.

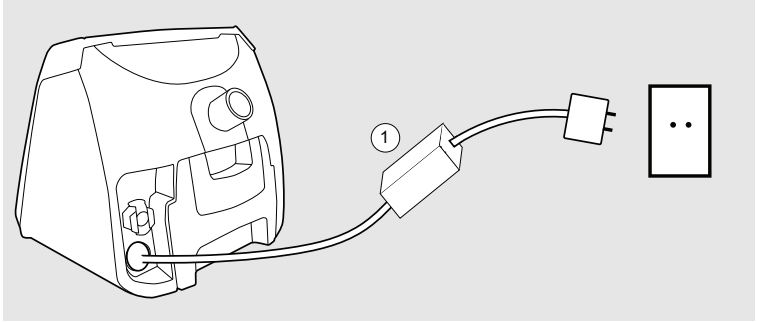
- 1 Plug the power supply's connector into the power port at the back of the Vivo 3 (a).



- 2 Turn the connector clockwise 90 degrees (b).

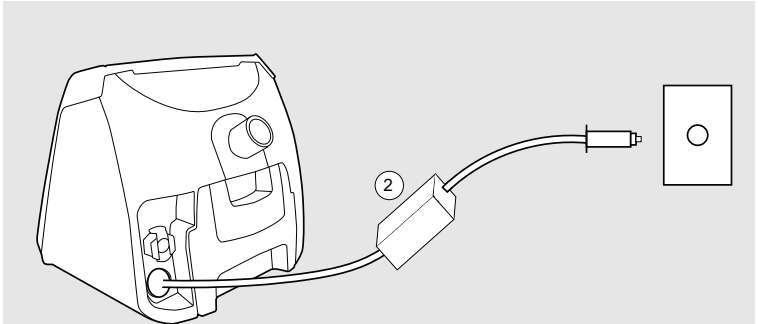
3

- If using the AC/DC power supply, connect the AC plug to the mains supply outlet:



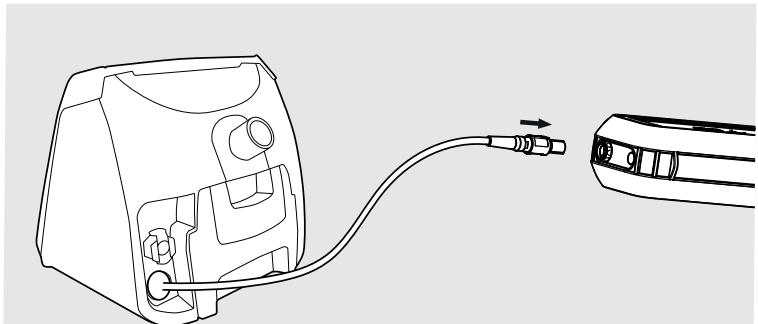
Item 1 in the figure: AC/DC power supply

- If using DC/DC adapter, connect the DC plug to the external DC source:



Item 2 in the figure: DC/DC power supply

- If using the XPAC, connect the battery cable to the XPAC main unit:



- 4 Make sure that the power outlet is not blocked, so that the cord can be unplugged without difficulties.

5.4 Connecting the Patient Circuit



WARNING!

Read the chapter 2.4 *Patient Circuit — Warnings and Precautions*, page 15 Carefully to make sure all conditions are considered and met.

The Vivo 3 is intended to be used with leakage circuits only. Recommended leak rate: 20 to 50 liters per minute at 10 cmH₂O.

- 1 Check that the circuit is clean and undamaged.
- 2 Connect the tube to the air outlet.

If having a heated circuit, make sure to connect the end with the heating plug to the to the air outlet. Refer to 5.4.1 *Connect the Heated Patient Circuit*, page 52 and 5.4.2 *Disconnect the Heated Patient Circuit from the Ventilator*, page 52.

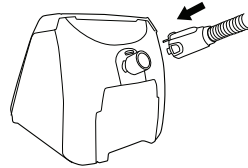
- 3 Check whether the patient interface has an integrated leakage port.
 - If yes, connect the patient circuit to the patient interface.
 - If no, first connect a leakage valve to the patient circuit, then connect it to the patient interface.

A bacterial filter can be attached on the ventilator outlet connector.



5.4.1 Connect the Heated Patient Circuit

- 1 Check the patient circuit for damages.
- 2 Go to Setup to define which circuit is being used. See 4.2.9 *Patient Circuit*, page 48.
- 3 Connect the ventilator cuff to the air outlet of the ventilator. A clicking sound is heard when the latches are fitted correctly.



- 4 If applicable, perform a pre-use test on the ventilator. See 3.5.5.2 *Pre-use Test*, page 33.
- 5 Connect the patient interface cuff to the patient interface.
- 6 On the ventilator, activate the circuit heating.

5.4.2 Disconnect the Heated Patient Circuit from the Ventilator

- 1 Disconnect from the ventilator:
Press the latches and pull the circuit off from the ventilator. Do not pull by the tube.
- 2 Disconnect from the patient interface:
Hold by the cuff and pull the circuit off from the patient interface. Do not pull by the tube.

5.5 Performing Start-up Checks

This procedure may be performed as a functional pre-use check at start-up.

Procedure

Prerequisites

- The Vivo 3 shall be connected to the power supply.

1

Start the treatment.

- If *Confirm Start/Stop* is *Off*, press **On/Off** button shortly.
- If *Confirm Start/Stop* is *On*, press and hold the **On/Off** button until the *Starting Treatment* progress bar is filled.

For information about setting the *Confirm Start/Stop* options, see 3.5.5.1 *Device Settings*, page 33 and 6.2 *Start the Treatment*, page 55.

2 When starting treatment, an automatic alarm signal test is performed. Check that the test is performed successfully, this is indicated by:

- A short beep indicating functional audio signaling.
- The alarm LED first lights yellow, then red, indicating functional visual signaling.
- The audio pause LED lights yellow.
- In about a second, both LEDs are turned off.

If the test fails, do not use the Vivo 3. Contact your supplier of the Vivo 3 for a technical check.

3 Disconnect the power cord for more than 5 seconds.

Check that the device switches to the internal battery and that the information message *Switched to Internal Battery* is shown on the screen.

If not, contact your supplier of the Vivo 3.

4 Reconnect the power cord.

Check that the Vivo 3 switches to the mains supply.

If not, contact your supplier of the Vivo 3.

5.6 Performing a Pre-Use Test

The pre-use test is used for detecting the characteristics of the patient circuit that is connected to the ventilator. The resistance and compliance of the patient circuit are measured and calculated. This will be used to compensate for pressure drop in the patient circuit and the compliance of the patient circuit.

The patient shall not be connected during the pre-use test.

- The ventilator shall be in stand by mode.
- The patient circuit to use for the treatment shall be at hand.

1 On the **Others** menu, select **Pre-use Test** and then press **OK** to confirm the start of the pre-use test.

2 Follow the instructions on the display and review the results at the end of the test.

5.6.1 Actions At Pre-Use Test Failure

At the end of the pre-use test the individual results for leakage, resistance and compliance are shown.

Failure Due To Incorrect Leakage

Indication: **Leakage: Fail**

- 1 Check the ventilator set-up (circuit, filters, humidifier, etc.) for leakage.
- 2 Ensure that all connectors are tightly fitting.
- 3 Run the pre-use test again.

- 4 Replace the circuit if the test is failed repeatedly.

Failure Due To Incorrect Resistance or Compliance

Indication: **Resistance: Fail** or **Compliance: Fail**

- 1 Check the ventilator set-up (circuit, filters, humidifier, etc.) for blockage or pinched tubing.
- 2 Run the pre-use test again.

If the pre-use test is continually failed due to resistance or compliance, it is permitted to use the ventilator but be aware that the pressure (resistance) or volume (compliance) delivered to the patient may not meet with the specified accuracy.

The ventilator will apply the default values to compensate for circuit resistance and compliance. These values will deviate from the values for the circuit in use.

Ensure that the delivered ventilation is closely monitored.

6 How to Use the Vivo 3

For a summary description of the means of initiating and terminating the inspiratory phase in each mode of the ventilator, please refer to 4.1 *Treatment Modes*.

6.1 Switch On the Vivo 3

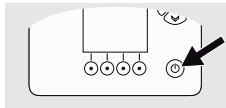
- **Switching on an unpowered ventilator**

Connect the power supply.

⇒The ventilator starts up and enters standby mode.

If the power supply is connected during the *Power Failure* alarm, the ventilator will start the treatment directly instead of entering standby mode.

- **Switch on a powered ventilator**



Press the **On/Off** button.

⇒The ventilator starts up and enters standby mode.

6.2 Start the Treatment

WARNING!

Risk of Asphyxia or Personal Injury

Using incorrect settings may cause personal injury or severe medical conditions, such as hypercarbia, producing arterial acidemia.

The therapy settings shall be based on a physician's description. Changes to settings must be made by authorized clinical personnel only.



It is possible to choose how the machine will start and stop. If you want to confirm the starting and stopping or not, see 3.5.5.1 *Device Settings*, page 33

Confirm Start/Stop is set to On

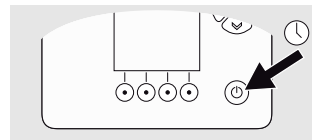
Make sure that the Vivo 3 is in *Standby* mode.

1 Press and hold the **On/Off** button until the *Starting Treatment* progress bar is filled.

⇒The Vivo 3 now performs a function test indicated by a short beep and then starts the treatment. Check that the self test is performed successfully, this is indicated by:

- A short beep indicating successful alarm signalling
- The alarm LED first lights yellow, then red
- The audio pause LED lights yellow
- In about a second, both LEDs are turned off

If the function test beep absents, take the Vivo 3 out of use and contact your supplier of the Vivo 3 .



Confirm Start/Stop is set to Off

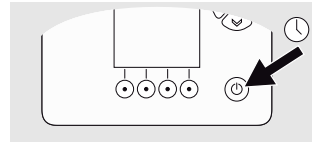
- 1 Make sure that the Vivo 3 is in *Standby* mode.
- 2 Press the **On/Off** button.
- 3 The machine performs a function test as described above.

6.3 Stop the Treatment

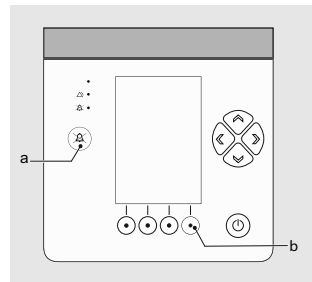
It is possible to choose how the machine will start and stop. If you want to confirm the starting and stopping or not, see 3.5.5.1 *Device Settings*, page 33

Confirm Start/Stop is set to On

- 1 Press and hold the **On/Off** button until the *Stopping Treatment* progress bar is filled.
⇒ A request for a complementary action is now displayed for stopping the treatment. If no complementary action is taken within 6 seconds, the Vivo 3 reverts to normal operation.



- 2 Do one of the following:
 - Press the **Mute Alarm** button (a). (Always available.)
 - Press **Ramp** (b) for a ramped stop. (Available if a *Ramp Down* time has been specified.)



Confirm Start/Stop is set to Off

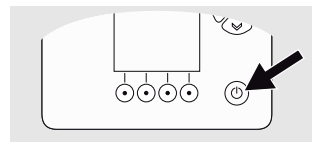
- 1 Press the **On/Off** button.
- 2 Press **Ramp** (b) for a ramped stop. (Available if a *Ramp Down* time has been specified.)

6.4 Switch Off the Vivo 3

Confirm Start/Stop is set to On

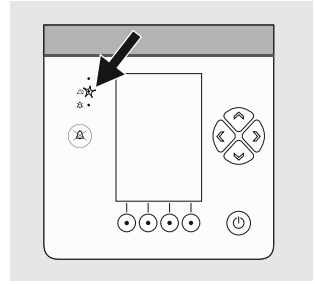
- 1 Make sure that the treatment is stopped and the Vivo 3 is in *Standby* mode.
- 2 Press the **On/Off** button.

⇒ When the message “Do you want to turn off the ventilator?” is displayed, confirm by pressing the **Mute Alarm** button within 6 seconds. Otherwise, the Vivo 3 will revert to standby mode.



3 Press the **Mute Alarm** button.

⇒ The Vivo 3 is now turned off.



Confirm Start/Stop is set to Off

1 Make sure that the Vivo 3 is in *Standby* mode.

2 Press and hold the **On/Off** button.

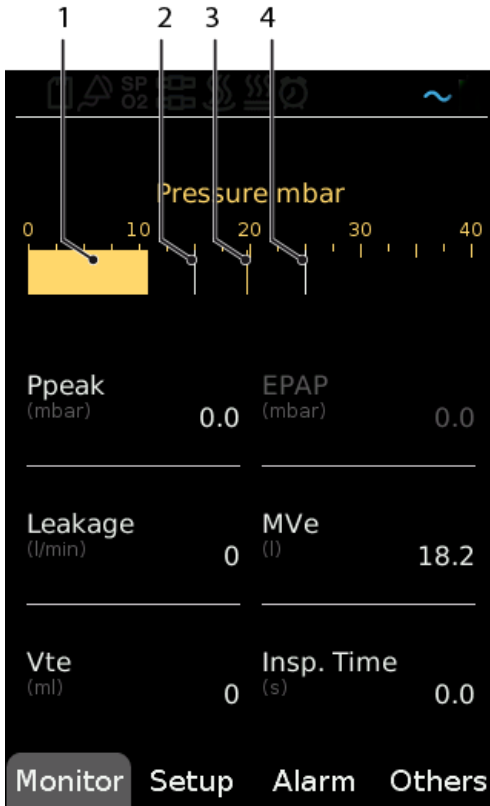
⇒ The Vivo 3 is now turned off.

6.5 Monitor Treatment

1 Press the **Monitor** navigation button.

⇒ The Monitor page is now displayed.

The monitor page displays treatment data monitored by the Vivo 3. It consists of a bar graph illustrating the current pressure and text area displaying monitored values in text.



Bar graph legend

1. Current pressure
2. Low pressure alarm level
3. Set inspiration pressure level
4. High pressure alarm level

Monitor page with HFNT

When HFNT is active, flow is displayed instead of pressure.



6.5.1 Treatment Values Monitored by the Vivo 3

- **Flow**

Flow is the constant flow for HFNT. It is the only monitored value when HFNT is active.

- **Ppeak**
P_{peak} (*Peak pressure*) is the highest pressure that is recorded during the latest inspiratory phase.
- **EPAP**
EPAP (*Expiratory Positive Airway Pressure*) is the lowest pressure that is recorded during the latest expiratory phase.
- **Leakage**
Leakage is the average calculated leak (l/min) over the last breath, with a breath by breath update.
- **MVe**
Mve (*Minute Volume, expiratory*) is calculated as the Tidal Volume multiplied with the Total Breath Rate.
- **Vte**
Vte (*Tidal volume, expiratory*) is the expired tidal volume for each breath.
- **% in TgV**
Percentage of breaths within the target volume window.
- **Rise Time**
Rise Time displays the duration of the pressure increase during the inspiration phase.
- **SpO2**
SpO₂ (*Saturation of Peripheral Oxygen*) displays the patient's oxygen saturation. as measured by the SpO₂ module.
This value is only displayed if the SpO₂ module is connected.
Displayed ranges: According to the manufacturer's specifications.
- **Pulse Rate**
Pulse Rate displays the patients pulse rate as measured by the SpO₂ module.
This value is only displayed if the SpO₂ module is connected.
Displayed ranges: According to the manufacturer's specifications.

6.5.2 Treatment Values Monitored by External Equipment

Monitoring of Expiratory CO₂

For monitoring expiratory CO₂, an external monitoring device shall be connected to the patient circuit.

The device shall comply with ISO 80601-2-55.

Monitoring of Oxygen Saturation

For monitoring the patient air oxygen saturation, an external monitoring device shall be connected to the patient circuit.

The device shall comply with ISO 80601-2-55 and have a high oxygen level alarm.

6.6 Using Accessories

This section describes how to use accessories provided by Breas Medical AB.

6.6.1 Using the Attachable Humidifier



WARNING!

Read the section 2.7 *Humidification and Heating* — *Warnings and Precautions*, page 19 before using the Vivo 3 with the attachable humidifier.



WARNING!

Risk of Burns

If you remove and open the humidifier just after using the ventilator, ensure that you don't touch the heater inside the humidifier since it can be very hot.



WARNING!

The humidifier is for single patient use only.



NOTE

The ventilator can also be used with active stand-alone and passive humidifiers

The humidifier is intended to humidify the patient air. It is intended for non-invasive use only.

About the Attachable Humidifier

The attachable humidifier is intended for non-invasive use only.

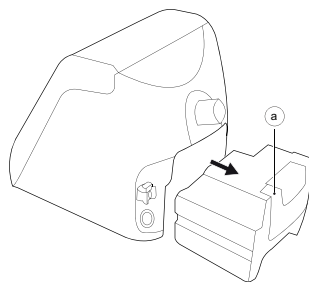
The humidifier is intended for stationary use and requires a connection to the Mains power supply to work. During mobile use of the Vivo 3, remove the humidifier water chamber and insert the air bypass unit.

The information in the below table is applicable to the recommended breathing system configuration, which is the Attachable humidifier and the Heated circuit.

| Property | Value |
|---------------------------|---|
| Humidifier classification | ISO 80601-2-74:2021, Class 2 |
| Rated Flow | 20-50 l/min |
| Operating Conditions | +15°C to +35°C. Humidity: RH from 15% to 95%. |
| Gas leakage | < 0.2 l/min at 50 cmH ₂ O |
| Max humidification output | > 10 mg/l |

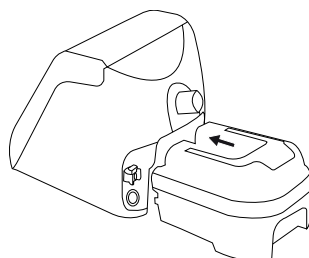
Using the Attachable Humidifier for the First Time — Overview

1 Take out the air bypass unit by pressing the locking latch (a) and then pulling it out.



2 Fill the humidifier with water.

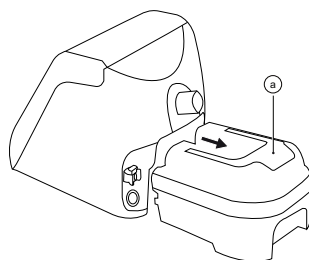
3 Insert the humidifier.



Detach the Humidifier from the Vivo 3

1 If any treatment is running, stop it.

2 Push down the locking latch (a) and then pull the humidifier out.



3 If you will use the Vivo 3 without the humidifier, install the air bypass unit in place of the humidifier.

Fill the Humidifier

Duration of operation between humidifier refills

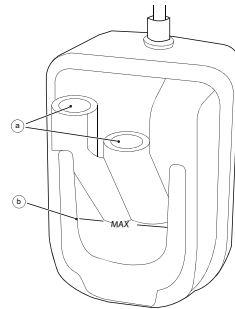
Humidifier level (5): 12 hours. At lower settings, the duration will be longer.



CAUTION!

- The water chamber must be detached from the Vivo 3 when filling water into the water chamber.
- Use only distilled or sterilized water or boiled, chilled tap water in the humidifier water chamber. This is to reduce bacteria and mineral deposits. Do not add any substances to the water, as this can have adverse effect.
- Do not fill the water chamber with hot water.
- Do not overfill the water chamber. The water chamber has a capacity of 350 ml and the maximum filling level is indicated on the chamber.
- After using the ventilator, wait one minute before you open the water chamber since it can get hot under certain conditions (for example if the humidifier runs out of water).

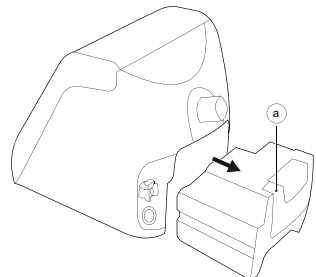
- 1 Detach the water chamber, see above.
- 2 Inspect the water chamber for damages, dirt or deposits. Clean if required, see *Cleaning the Humidifier*, page 63. If the water chamber is damaged, replace it before use.
- 3 Make sure the water meets the quality requirements. It shall be either:
 - Distilled
 - Sterilized
 - Boiled and chilled tap water.
- 4 Hold the humidifier with the air path openings (a) up and fill water into either of the air path openings. Make sure not to overfill (b).



- 5 If the outside of the humidifier is wet, dry it with a lint free cloth before attaching it to the Vivo 3.

Attach the Humidifier to the Vivo 3

- 1 If any treatment is running, stop it.
- 2 If the air path bypass unit is installed to the Vivo 3, remove it by pressing the locking latch (a) and then pulling it out.



3 Make sure the humidifier is correctly filled and push it into the Vivo 3 so the locking latch is engaged.

⇒A click indicates that the humidifier is correctly installed.

Activate the Humidifier

1 Press the **Setup** button twice.

⇒The second setup page is now displayed, with humidifier settings.

2 Press the **Up arrow** button until the setting **Humidifier** is selected.

3 Press the **Right arrow** button to turn the humidifier on.

⇒The value is shifted to On and the humidifier symbol is lit on the display.

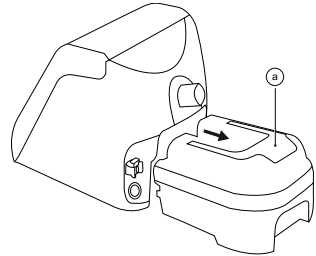
⇒The setting for Humidifier Level is displayed.

4 Press the **Down arrow** to select the **Humidifier Level** setting.

5 Press the **Left arrow** button to decrease the humidification or the **Right arrow** button to increase the humidification.

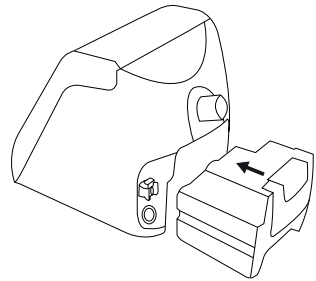
When not Using the Humidifier

1 Take out the humidifier by pushing down the locking latch (a) and then pull the humidifier out.



2 Empty the humidifier of water.

3 Insert the air path bypass unit.



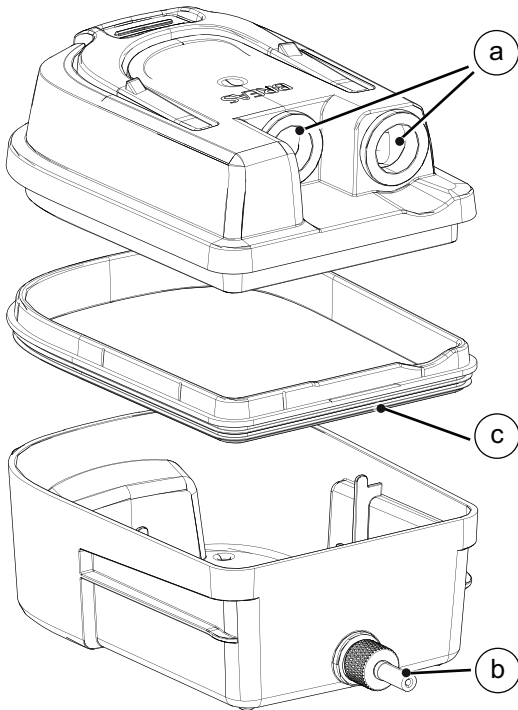
Cleaning the Humidifier

WARNING!

Risk of Burns

If you remove and open the humidifier just after using the ventilator, ensure that you don't touch the heater inside the humidifier since it can be very hot.





- 1 Open the humidifier by pulling the lid up. Don't detach the silicone airpaths (a). Also, don't dismount the cartridge heater (b).
- 2 Wash the humidifier by hand or in a dishwasher (without dishwashing detergent).
- 3 After cleaning, ensure that the silicone gasket (c) is positioned correctly: When closing the humidifier; the grooved edge must be positioned downwards.

6.6.2 Using the Heated Circuit



WARNING!

Read section 2.7 *Humidification and Heating — Warnings and Precautions*, page 19 before using the Vivo 3 with the heated circuit.



NOTE

The heated circuit requires connection to the Mains power supply to work.



Information about safety, warnings, product description, installation, usage, cleaning, maintenance and technical specifications can be found in the user instruction for the heated circuit.



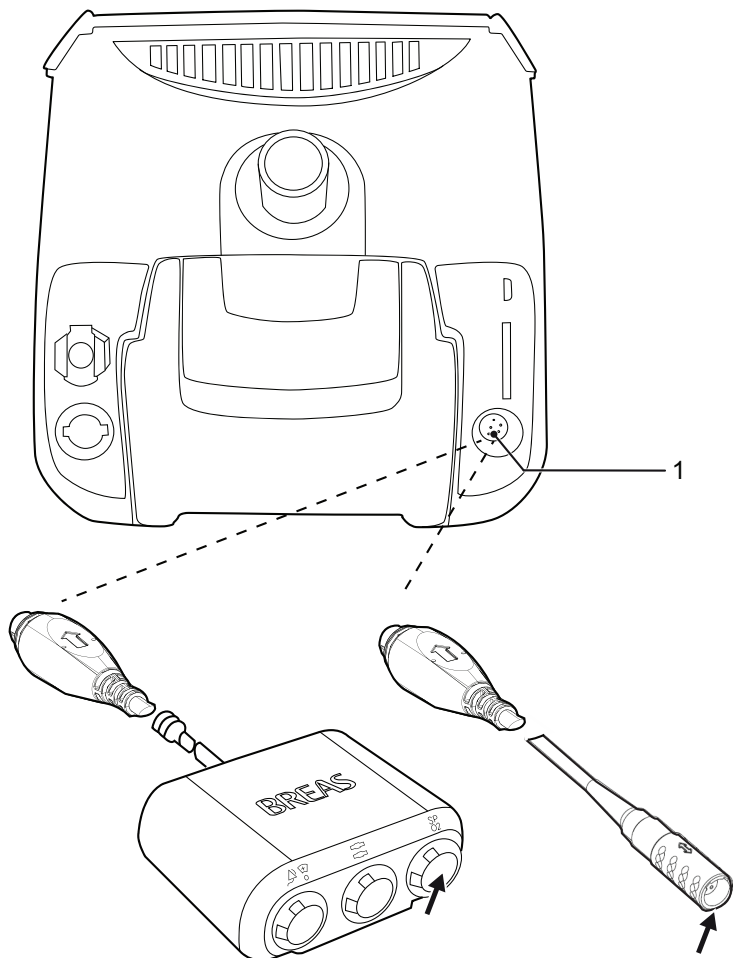
For information about connecting a patient circuit with heated circuit, see 5.4 *Connecting the Patient Circuit*, page 52.

Activate the heated circuit

- 1 Press the **Setup** button twice.
⇒The second setup page is now displayed, with heated circuit settings.
- 2 Press the **Up arrow** button until the setting **Heated Circuit** is selected.
- 3 Press the **Right arrow** button to turn the heated circuit on.
⇒The value is shifted to On and the heated circuit symbol is lit on the display.
⇒The setting for Heated Circuit Level is displayed.
- 4 Press the **Down arrow** to select the **Heated Circuit Level** setting.
- 5 Press the **Left arrow** button to decrease the heating or the **Right arrow** button to increase the heating.

6.6.3 Using the SpO₂ Sensor

The SpO₂ module (consisting of a SpO₂ sensor, an electronic unit) is intended to measure functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate.



The SpO₂ module can be connected to the Vivo 3 (item 1 above) using the SpO₂ adapter cable (007079) or to the accessory box (007000) in order to monitor and store SpO₂ measurements. The SpO₂ measurements will be stored in the data memory which can be downloaded to a PC and viewed in the PC software.



Information about safety, warnings, product description, installation, usage, cleaning, maintenance and technical specifications can be found in the user instruction for SpO₂ module.

CAUTION!



- When using the Vivo 3 with the SpO2 sensor, the Vivo 3 displays functional oxygen saturation measured by the sensor.
- The following information concerns the light emitted by the SpO2
 - Peak Wavelength (red): 660 nm
 - Peak Wavelength (infrared): 905 nm
 - Maximum Optical Output Power: ≤ 15 mW
 - For more information regarding the oxygen probe's range of peak wavelengths, max optical power and usage, please refer to the respective probe manual.
- Environmental factors may influence the function or accuracy of the pulse oximeter, such as ambient light, physical movement, diagnostic testing, low perfusion, electromagnetic interference, dysfunctional haemoglobin, presence of certain dyes and inappropriate positioning of the pulse oximeter probe.
- A functional test cannot be used to assess the accuracy of a pulse oximeter probe or a pulse oximeter.

6.6.4 Using the Oxygen Supply Adapter



WARNING!

Read the section 2.9 *Oxygen Usage — Warning and Precautions*, page 20 before using the Vivo 3 with oxygen.

Supplemental oxygen with a flow up to 30 l/min can be added by an oxygen source with rotameter such as oxygen cylinder, central oxygen supply system or an oxygen concentrator.

Supplemental Oxygen Supply Requirements

| Property | Requirement |
|------------------|---|
| Maximum flow | 30 l/min. |
| Maximum pressure | 100 kPa |
| Supply source | Source equipped with rotameter. Examples of supply sources: <ul style="list-style-type: none">• Oxygen cylinder• Central oxygen supply• Oxygen concentrator |
| Connector | The oxygen source shall be equipped with the Breas Low Pressure Oxygen Adapter, art. no. 005032 |

Connect the Oxygen supply

- 1 Connect the oxygen adapter (article no. 005032) to the oxygen supply's tube.

- 2 Connect the oxygen adapter to the oxygen port at the back of the Vivo 3. See 3.3 *Ventilator Back*, page 25 for detailed information.
- 3 If using a device for monitoring the oxygen saturation, connect it according to the supplier instructions.



CAUTION!

Do not add Oxygen before therapy has been started.

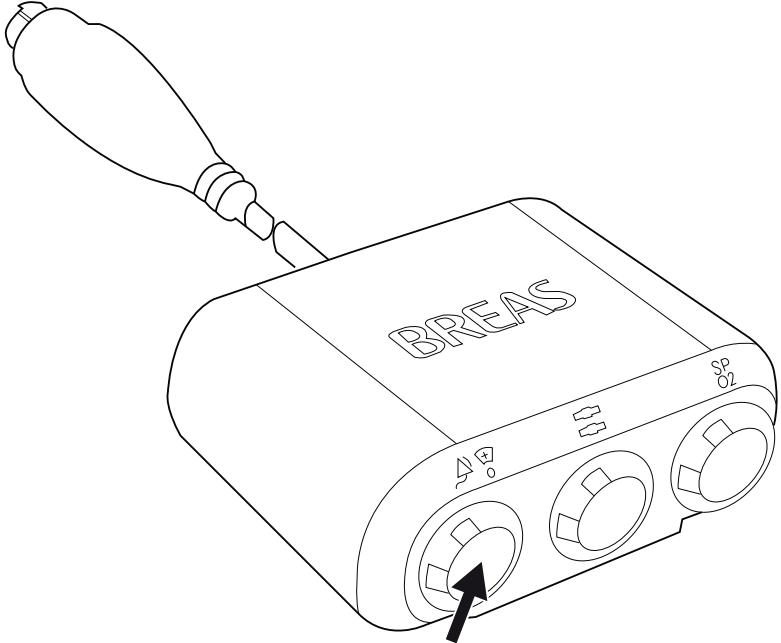
6.6.5 Using the Remote Alarm Unit



Information about safety, warnings, product description, installation, usage, cleaning, maintenance and technical specifications can be found in the user instruction for Remote Alarm.

The Remote Alarm enables care providers and clinical personnel to monitor the Vivo 3 alarms remotely. The Remote Alarm forwards alarms from the Vivo 3.

- 1 Connect the Accessory box to the Communication port at the back of the Vivo 3.
- 2 Connect the remote alarm cable to the Nurse call/ Remote alarm port on the accessory box.



- 3 Start the remote alarm unit.
- 4 Trigger an alarm on the Vivo 3 and check that it activates the remote alarm system.

6.6.6 Using the Protective Cover

The protective cover is intended for mobile use of the Vivo 3 in hospitals, institutions and home care environments. It can be used while the Vivo 3 is operating, for example mounted on a wheelchair, in a personal vehicle, or carried by hand.

The protective cover protects the Vivo 3 from environmental impact such as shock, water spill, sunlight, dust and dirt, under normal handling.

The protective cover does not protect the Vivo 3 from rain or snowfall.

- The protective cover can be used together with external power supply units.
- The protective cover cannot be used together with the attachable humidifier. When using the protective cover, the air path bypass unit shall be installed in place of the attachable humidifier.

6.6.7 Using the Lightweight Mobility Bag

The lightweight Mobility Bag is intended for mobile use of the Vivo 3 in hospitals, institutions and home care environments. It can be used while the ventilator is operating, for example mounted on a wheelchair, in a personal vehicle, or carried by hand.

The lightweight Mobility Bag protects the ventilator from, water spill, sunlight, dust and dirt, under normal handling.

The lightweight mobility bag cannot be used together with the attachable humidifier. When using the lightweight mobility bag, the air path bypass unit shall be installed in place of the attachable humidifier.

It does not protect against environmental impact such as shock, from rain or snowfall.

6.6.8 Using the Y-Cable

The Y-cable is used for connecting the Vivo 3 to both mains and external DC at the same time. see 5.3 *Connecting the Vivo 3 to Power Supply*, page 49. When both power sources are available, the mains will be used.

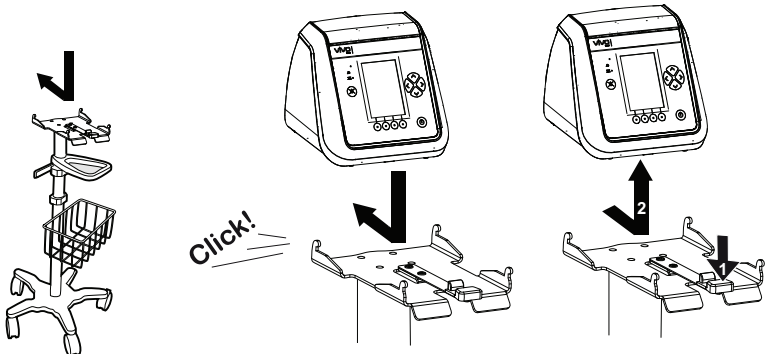
6.6.9 Using the Vivo 3 with the Trolley

Intended Use

The intended use of the trolley system is to allow patient mobility while receiving ventilator treatment. The trolley shall only be used in indoor, hospital environment. The trolley system consists of a trolley base and a mounting bracket.

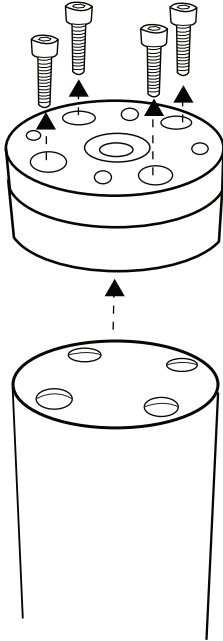
This section describes how to use the Vivo 3 and a trolley with mounting bracket.

Mount and dismount the Vivo 3 as shown in the picture:



The bottom plate is mounted to the trolley using four screws.

Before mounting the bottom plate, the attachment must be dismantled:



Be careful when handling the trolley with the ventilator mounted, in order to avoid any risk of the trolley falling. The trolley can be tipped 10° and return to vertical position, when loaded in accordance with the weight specifications below.

WARNING!

The maximum total weight of the trolley and added accessories is 37 kg (82 lbs). (Trolley base weight = 12 kg (26 lbs), maximum externally added load = 25 kg (55 lbs).)

- The maximum load of the trolley basket is 0.9 kg (2 lbs).
- The maximum load of the trolley rail is 9 kg (20 lbs).

No maintenance is required.



6.7 Basic Troubleshooting

| Problem | Action |
|---|---|
| The ventilator doesn't start. | Check the connection of the power cord between the ventilator and the power outlet. |
| The ventilator starts, but the patient circuit doesn't deliver any air. | Ensure that both ends of the patient circuit are correctly connected. Straighten the patient circuit or replace it. |
| The humidifier doesn't work properly. | If the humidifier is incorrectly assembled, disassemble it and then assemble it correctly. If the air is dry despite using the humidifier, increase the level of humidification. If the humidifier doesn't deliver any heat, check that the Vivo 3 is powered from the AC power supply; the humidifier doesn't work on battery. |

Alarms

WARNING!



Risk of Unnoticed Critical Conditions

- The alarm sound level should be set to a clearly audible level. Setting the alarm sound level below that of the ambient sound level can impede recognition of alarm conditions.

Distributed Alarm System

Distributed alarm system for the ventilator:

- The cable connected remote alarm unit provided by Breas Medical AB

Alarm Function During Power Failure

At power failure, the following will happen:

1. When the mains power is broken, the internal battery takes over the power supply and the following message is displayed: Switched to Internal Battery.
2. When 20 minutes (± 5 minutes) of the battery charge remains, the following alarm (Medium) is displayed: Last Power Source Low Capacity. An audio signal is heard.
3. When 5 – 7 minutes of the battery charge remains, the following alarm (High) is displayed: Critical Low Last Power Source. An audio signal is heard.
4. When 0 minutes of the battery charge remains, the following message is displayed: The internal battery is completely discharged. Connect mains or DC to charge.
5. An alarm is triggered, and the Vivo 3 is powered off.
The alarm settings are maintained during power failure.

7.1 Operator's Position

The alarm priority indications are designed to be recognized from a distance of 4 meters and by an angle of 50 ° from the normal of the Vivo 3 display.

7.1.1 Checking the Operator's Position

1. Activate an alarm. For detailed instructions, see .
2. From the operator's position, make sure that the audible alarm signal is heard and that it is possible to recognize the alarm priority level by either of the visual signals (flashing LED lights and display message on the screen). The sound pressure level range is 55-80 dBA for high and medium priority alarm signals.

For detailed information, see 7.2.1 *Identify an Alarm Condition*, page 72.

3. If the test fails, consider the following actions:
 - Find a better position for the operator.
 - Adjust the alarm sound level, see 7.2.5 *Adjust the Alarm Sound Level*, page 74.
 - Add a remote alarm unit to the system, see 10 *Accessories*, page 103.

7.2 Handle Alarms

7.2.1 Identify an Alarm Condition

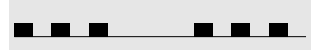
If an alarm condition is detected, the Vivo 3 main unit and the remote alarm unit (if connected) will alarm without delay. The alarms will remain active until the alarm condition is resolved.

Active alarms are indicated by:

- Audible signal, see page 73.
- Alarm message on the screen, see page 73.
- The alarm LED, see page 73.

Alarm Audio signal

- **High priority alarms**
3 short signals followed by 2 more after 0.5 s.
The signal sequence repeats every 3rd second.
- **Medium priority alarms**
3 signals. The signal sequence repeats every 6th second.



For information about adjusting the alarm sound level, see 7.2.5 *Adjust the Alarm Sound Level*, page 74.

Information Message Audio Signal

Short signal every 5 seconds



Alarm Sound Pressure Level

The alarm sound pressure level is adjustable within 55–80 dBA.

Alarm Message on the Screen

The name of the active alarm is displayed on the screen.

- **High priority alarms**
Red highlight color.
- **Medium priority alarms**
Yellow highlight color.



For detailed information about specific alarms, see 7.3 *Physiological Alarms*, page 76 and 7.4 *Technical Alarms*, page 86.

Display of Multiple Alarms

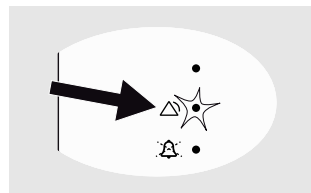
If several alarms are active, active high priority alarms have precedence over medium priority alarms: All high priority alarm conditions must be resolved before any medium alarms are displayed.

If several alarms of the same priority are active at the same time, the alarm descriptions are looped in the display.

A “>>” symbol indicates that more alarms are to be displayed in the loop.

Alarm LED signal

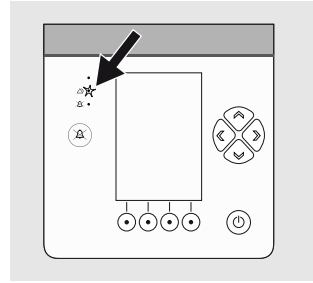
- **High priority alarms**
Red light, flashing quickly (0.5 s. interval).
- **Medium priority alarms**
Yellow light, flashing slowly (2 s. interval).



7.2.2 Pause the Alarm Sound

The audible signal can be paused for 60 seconds by pressing the Audio Pause button. Pressing the button again reactivates the sound.

If a new alarm condition occurs during the audio pause period, the audible signal will be reactivated.



7.2.3 Reset an Alarm

To reset an alarm, correct the cause of the alarm condition.

⇒Once the cause is corrected, the alarm disappears from the display.

WARNING!

If an alarm condition cannot be corrected, take the Vivo 3 out of use and contact your supplier of the Vivo 3 e.



7.2.4 View Historical Alarms

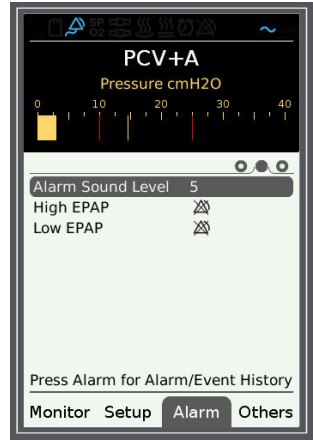
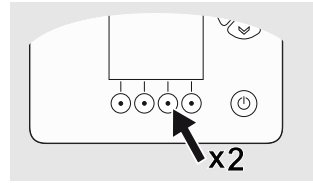
To view historical alarms, press the Alarm button until Alarm/Event history is shown.



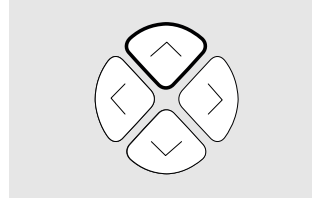
7.2.5 Adjust the Alarm Sound Level

Alarm Sound Level is found in the Alarm Settings.

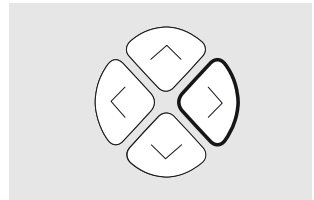
1 Press the Alarm navigation button until the Alarm settings page with Alarm Sound Level is shown.



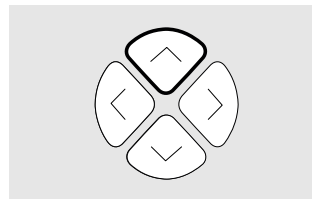
2 Press the Down or Up arrow button to select the Alarm Sound Level setting.



3 Press the Left or Right arrow buttons to adjust the sound level.




4 Press the Up arrow button to finish the adjustment by deselecting the setting.



5 When finished with the sound level adjustment, check that the alarm can be received at the operator's position, see 7.1 *Operator's Position*, page 72.


7.3 Physiological Alarms

7.3.1 High Pressure Alarm

| Property | Description |
|--------------------|---|
| Alarm text | High Pressure |
| Priority | High |
| Alarm condition | A High Pressure alarm will be given when the patient pressure reaches the set High Pressure alarm limit for three consecutive breaths. |
| Possible cause | <ul style="list-style-type: none">• Mismatch between pressure setting and alarm setting.• Coughing during inspiration.• Changes in airway resistance and or compliance. |
| Reset criteria | A full breath is performed with maximum pressure below the alarm limit. |
| Ventilator action | The Vivo 3 will continue treatment according to the current settings. The actual breath is however terminated if the High Pressure alarm limit is reached. |
| Setting range | <ul style="list-style-type: none">• 5 cmH₂O to 45 cmH₂O• Off <p>Note that the High pressure alarm cannot be set lower than the value set for the Low pressure alarm.</p> |
| Setting resolution | Below 10 cmH ₂ O: 0.5 cmH ₂ O Above 10 cmH ₂ O: 1.0 cmH ₂ O |
| Setting Display | The High Pressure alarm setting is displayed by a red line in the pressure bar graph.  |

7.3.2

Low Pressure Alarm

| Property | Description |
|--------------------|--|
| Alarm text | Low Pressure |
| Priority | High |
| Alarm condition | A Low Pressure alarm will be given when the Vivo 3 pressure fails to reach the low pressure alarm limit for 15 seconds. |
| Possible cause | <ul style="list-style-type: none"> • Disconnection of patient circuit. • Mismatch between pressure setting and alarm setting. • Leakage from the mask or other components of the patient circuit. |
| Reset criteria | The pressure rises above the alarm limit. |
| Ventilator action | The Vivo 3 will continue treatment according to the current settings. |
| Setting range | <ul style="list-style-type: none"> • 1 cmH₂O to 40 cmH₂O <p>Note that the Low pressure alarm cannot be set higher than the value set for the High pressure alarm.</p> |
| Setting resolution | <p>Below 10 cmH₂O: 0.5 cmH₂O</p> <p>Above 10 cmH₂O: 1.0 cmH₂O</p> |
| Setting display | <p>The Low Pressure alarm setting is displayed by a red line in the pressure bar graph.</p>  |

7.3.3 High Breath Rate Alarm

| Property | Description |
|--------------------|--|
| Alarm text | High Breath Rate |
| Priority | Medium |
| Alarm condition | A High Breath Rate alarm will be given when the alarm limit has been exceeded for 15 seconds. |
| Possible cause | <ul style="list-style-type: none">• Mismatch between the Breath Rate setting and the alarm setting.• Increased Breath Rate.• Too sensitive setting of the inspiratory trigger setting. |
| Reset criteria | The breath rate goes below the alarm limit. |
| Ventilator action | The Vivo 3 will continue treatment according to the current settings. |
| Setting range | <ul style="list-style-type: none">• 10 bpm to 50 bpm• Off |
| Setting resolution | 1 bpm. |

7.3.4 Low Breath Rate Alarm

| Property | Description |
|--------------------|---|
| Alarm text | Low Breath Rate |
| Priority | High |
| Alarm condition | A Low Breath Rate alarm will be given when the delivered total breath rate is below the alarm limit for 15 seconds. |
| Possible cause | <ul style="list-style-type: none">• Mismatch between the Breath Rate setting and the alarm setting.• The patient cannot trigger breaths because the inspiratory trigger setting is too high.• Decrease in the patient's spontaneous breathing.• Circuit disconnection. |
| Reset criteria | The breath rate goes above the alarm limit. |
| Ventilator action | The Vivo 3 will continue treatment according to the current settings. |
| Setting range | <ul style="list-style-type: none">• 4 bpm to 30 bpm.• Off |
| Setting resolution | 1 bpm. |

7.3.5 High Minute Volume Alarm

| Property | Description |
|--------------------|---|
| Alarm text | High MV |
| Priority | Medium |
| Alarm condition | A High Minute Volume alarm will be given when the minute volume is above the set alarm limit for 15 seconds. |
| Possible cause | <ul style="list-style-type: none">• Disconnection of patient circuit.• Mismatch between pressure setting and alarm setting.• Leakage from the mask or other components of the patient circuit.• Increased breath rate. |
| Reset criteria | The minute volume goes below the alarm limit. |
| Ventilator action | The Vivo 3 will continue treatment according to the current settings. |
| Setting range | <ul style="list-style-type: none">• 1 l. to 40 l.• Off |
| Setting resolution | 0.5 l. |

7.3.6 Low Minute Volume Alarm

| Property | Description |
|--------------------|---|
| Alarm text | Low MV |
| Priority | High |
| Alarm condition | A Low Minute Volume alarm will be given when the minute volume is below the set alarm limit for 15 1 seconds. |
| Possible cause | <ul style="list-style-type: none">• Disconnection of patient circuit.• Mismatch between pressure setting and alarm setting.• Leakage from the mask or other components of the patient circuit.• Decreased breath rate. |
| Reset criteria | The minute volume goes above the alarm limit. |
| Ventilator action | The Vivo 3 will continue treatment according to the current settings. |
| Setting range | <ul style="list-style-type: none">• 1 l. to 30 l.• Off |
| Setting resolution | 0.5 l. |

7.3.7

Rebreathing Alarm

| Property | Description |
|-------------------|--|
| Alarm text | Rebreathing |
| Priority | High |
| Alarm condition | A Rebreathing alarm will be given if the intentional leakage is too low for more than 15 seconds. |
| Possible cause | <ul style="list-style-type: none">• Obstructed or occluded patient circuit.• Incorrect patient circuit.• Obstructed or removed CO₂ port from leakage circuit. |
| Reset criteria | The leakage is back within limits. |
| Ventilator action | The Vivo 3 will continue treatment according to the current settings. |
| Setting range | <ul style="list-style-type: none">• On• Off |

7.3.8

Apnea Alarm

| Property | Description |
|--------------------|---|
| Alarm text | Apnea |
| Priority | High |
| Alarm condition | An Apnea alarm will be given when no patient-triggered breath is detected for the set period of time. |
| Possible cause | <ul style="list-style-type: none">• Patient stopped breathing.• Patient decreases spontaneous breathing.• Circuit disconnection.• Inspiratory Trigger is set too high. |
| Reset criteria | Inspiratory effort detected by the Vivo 3. |
| Ventilator action | The Vivo 3 will continue treatment according to the current settings. |
| Setting range | <ul style="list-style-type: none">• 5 to 60 s.• Off |
| Setting resolution | 5 s below 15 s. 15 s above 15 s. |

7.3.9

Disconnection Alarm



CAUTION!

No single alarm can reliably detect all disconnections due to the number of possible combinations of therapy settings, circuit configurations and patient interfaces. To verify that patient disconnection can be detected, including if the patient interface becomes accidentally detached from the patient, it is advised to test the functionality of the Disconnection Alarm upfront with the complete set-up as used during treatment, including items such as filters, circuit, connectors, interface (mask, cannula etc.)

| Property | Description |
|-------------------|---|
| Alarm text | Disconnection |
| Priority | High |
| Alarm condition | A Disconnection alarm will be given when the measured flow exceeds the expected leakage flow at the set Pressure for 15 seconds. |
| Possible cause | <ul style="list-style-type: none">• Too high leakage in the patient circuit.• The patient has removed the mask.• Circuit disconnection. |
| Reset criteria | The leakage is back within limits. |
| Ventilator action | The Vivo 3 will continue treatment according to the current settings |
| Setting range | <ul style="list-style-type: none">• On• Off |

7.3.10 High EPAP Alarm

| Property | Description |
|-------------------|--|
| Alarm text | High EPAP |
| Priority | Medium |
| Alarm condition | A High EPAP alarm will be given when EPAP has gone 30% above the set value for 3 breaths. |
| Possible cause | <ul style="list-style-type: none">Blocked leakage port.Too short expiratory time.Changes in airway resistance and or compliance. |
| Reset criteria | EPAP has gone below the alarm limit (lower than 30% above the set value). |
| Ventilator action | The Vivo 3 will continue treatment according to the current settings. |
| Setting range | <ul style="list-style-type: none">OnOff |

7.3.11 Low EPAP Alarm

| Property | Description |
|-------------------|--|
| Alarm text | Low EPAP |
| Priority | Medium |
| Alarm condition | A Low EPAP alarm will be given when EPAP has gone 30% below the set value for 3 breaths. |
| Possible cause | <ul style="list-style-type: none">Excessive leakage. |
| Reset criteria | EPAP has gone above the alarm limit (higher than 30% below the set value). |
| Ventilator action | The Vivo 3 will continue treatment according to the current settings. |
| Setting range | <ul style="list-style-type: none">OnOff |

7.3.12 High SpO₂ Alarm

| Property | Description |
|--------------------|--|
| Alarm text | High SpO2 |
| Priority | Medium |
| Alarm condition | A High SpO ₂ alarm will be given when the measured SpO ₂ exceeds the alarm limit for 30 seconds. |
| Possible cause | Too high flow of bleed-in oxygen. |
| Reset criteria | The SpO ₂ value goes back below the alarm limit. |
| Ventilator action | The Vivo 3 will continue treatment according to the current settings. |
| Setting range | <ul style="list-style-type: none">• 80 % to 100 %• Off |
| Setting resolution | 1 % |

This alarm requires a connected SpO₂ sensor.

7.3.13 Low SpO₂ Alarm

| Property | Description |
|--------------------|---|
| Alarm text | Low SpO2 |
| Priority | High |
| Definition | A Low SpO ₂ alarm will be given when the measured SpO ₂ is below the alarm limit for 30 seconds. |
| Possible cause | <ul style="list-style-type: none">• Too low flow of bleed-in oxygen.• Oxygen inlet is disconnected.• Delivered tidal volumes are too small. |
| Setting range | 70% to 100% |
| Setting resolution | 1% |
| Ventilator action | The ventilator will continue treatment with the same settings. |

This alarm requires a connected SpO₂ sensor.

7.3.14 High Pulse Rate Alarm

| Property | Description |
|--------------------|---|
| Alarm text | High Pulse Rate |
| Priority | Medium |
| Alarm condition | A High Pulse Rate alarm will be given when the measured pulse rate exceeds the alarm limit for 15 seconds. |
| Possible cause | <ul style="list-style-type: none">• Insufficient ventilatory support.• Too low flow of bleed-in oxygen.• The EPAP value is set too high.• Bad positioning of the finger probe. |
| Reset criteria | The pulse rate goes back below the alarm limit. |
| Ventilator action | The Vivo 3 will continue treatment according to the current settings. |
| Setting range | 30 to 230 bpm (beats per minute) Off |
| Setting resolution | 5 bpm (beats per minute) |

This alarm requires a connected SpO₂ sensor.

7.3.15 Low Pulse Rate Alarm

| Property | Description |
|--------------------|---|
| Alarm text | Low Pulse Rate |
| Priority | High |
| Alarm condition | A low pulse rate alarm will be given when the measured pulse rate goes below the alarm limit for 15 seconds. |
| Possible cause | <ul style="list-style-type: none">• Bad positioning of the finger probe.• Too low flow of bleed-in oxygen.• Insufficient ventilatory support. |
| Reset criteria | The pulse rate goes back above the alarm limit. |
| Ventilator action | The Vivo 3 will continue treatment according to the current settings. |
| Setting range | 30 to 230 bpm (beats per minute) Off |
| Setting resolution | 5 bpm (beats per minute) |

This alarm requires a connected SpO₂ sensor.

7.3.16 Circuit Disconnection Alarm

| Property | Description |
|-------------------|--|
| Alarm text | Circuit Disconnection |
| Priority | High |
| Alarm condition | Only available when HFNT is active. The alarm will be given if the device detects that the patient circuit is disconnected from the device. It will not detect if the patient is connected or not, only if the cannula and/or tube is connected to the device. |
| Possible cause | The circuit is disconnected. |
| Reset criteria | The device detects that the tube and/or cannula is connected again. |
| Ventilator action | The Vivo 3 will continue treatment according to the current settings. |
| Setting range | On Off |

7.3.17 Blocked Circuit Alarm

| Property | Description |
|-------------------|--|
| Alarm text | Blocked Circuit |
| Priority | High |
| Alarm condition | Only available when HFNT is active. The alarm will be given if the device detects that the patient circuit is blocked and no air can be delivered. |
| Possible cause | The circuit is blocked. |
| Reset criteria | The device detects that the circuit is not blocked anymore. |
| Ventilator action | The Vivo 3 will continue treatment according to the current settings. |
| Setting range | On Off |

7.4 Technical Alarms

7.4.1 High Pressure Limitation Alarm

| Property | Description |
|-------------------|---|
| Alarm text | High Pressure Limitation |
| Priority | High |
| Alarm condition | The High Pressure Limitation alarm is given if the high pressure alarm limitation limit (60 cmH ₂ O) is reached. |
| Possible cause | <ul style="list-style-type: none">• Mismatch between pressure setting and alarm setting.• Coughing during inspiration.• Changes in airway resistance and or compliance. |
| Reset criteria | A full breath with pressure below the set alarm limit. |
| Ventilator action | The current breath is terminated and then the Vivo 3 will continue treatment according to the current settings. |

7.4.2 Power Fail Alarm

| Property | Description |
|-------------------|---|
| Alarm text | The display is turned off. The Power Fail alarm is indicated by the alarm LED and the audible signal only. |
| Priority | High The display is turned off. The Power Fail alarm is indicated by the alarm LED and the audible signal only. |
| Alarm condition | The Power Fail alarm is given if the last power source fails to provide enough power for running the ventilator. |
| Possible cause | The last available power source cannot deliver power to the ventilator. Battery discharged or battery failure. |
| Reset criteria | External power supply connected to ventilator. |
| Ventilator action | The Vivo 3 stops the treatment, turns off the display and gives the Power Fail alarm for at least 2 minutes. If power is restored within the alarm time, the ventilator will automatically resume treatment with current settings. When powered up again, the power failure will be logged. |

7.4.3 SpO₂ Sensor Failure / Disconnected Alarm

This alarm requires a connected SpO₂ sensor.

| Property | Description |
|-------------------|--|
| Alarm text | SpO2 Disconnected |
| Priority | Medium |
| Alarm condition | An SpO ₂ Sensor Failure/Disconnection alarm will be given if one of the conditions below appears: <ul style="list-style-type: none"> • An error signal is received from the sensor • No signal at all from the sensor is received within 2 seconds. |
| Possible cause | Faulty or disconnected sensor. |
| Reset criteria | Normal communication with the sensor is re-established. An information message remains until acknowledged by the user. |
| Ventilator action | The Vivo 3 will continue treatment according to the current settings. |

7.4.4 SpO₂ Artifact

This alarm requires a connected SpO₂ sensor.

| Property | Description |
|-------------------|--|
| Alarm text | Poor SpO2 Signal |
| Priority | Medium |
| Alarm condition | A poor SpO ₂ Signal alarm will be given if perfusion is too low or artifacts are detected by the sensor. |
| Possible cause | Check the sensor and its placement on the patient. |
| Reset criteria | An OK signal is received from the sensor or the sensor is disconnected. An information message remains until acknowledged by the user. |
| Ventilator action | The Vivo 3 will continue treatment according to the current settings. |

7.4.5 Ambient Pressure Compensation Lost Alarm

| Property | Description |
|-------------------|---|
| Alarm text | Pressure Comp Lost |
| Priority | Medium |
| Alarm condition | An Ambient Pressure Compensation Lost alarm will be given when the automatic ambient pressure compensation functionality is out of order. |
| Ventilator action | The Vivo 3 will continue treatment according to the current settings. Normal atmospheric pressure at sea level will be used as approximation for the temporary ambient pressure compensation. If used at other altitude, delivered and measured pressures may deviate. |
| Reset | Reset of ventilator. |

7.4.6 Low Battery Alarm

| Property | Description |
|-------------------|---|
| Alarm text | Low Battery. Connect to Mains. |
| Priority | Medium |
| Alarm condition | This alarm will be given when the last battery source (internal battery) has 15 minutes of operating time left with current settings. |
| Ventilator action | The Vivo 3 will continue treatment according to the current settings. |
| Reset Criteria | Connection of another power source within 15 minutes or the treatment will shut down. |

7.4.7 Critically Low Battery Alarm

| Property | Description |
|-------------------|--|
| Alarm text | Critically Low Battery. Connect to Mains |
| Priority | High |
| Alarm condition | This alarm will be given when the last battery source (internal battery) has 5 minutes of operating time left with current settings. |
| Ventilator action | The Vivo 3 will continue treatment according to the current settings. |
| Reset Criteria | Connection of another power source within 5 minutes or the treatment will shut down. |

7.4.8 High Patient Air Temp. (High Patient Air Temperature)

| Property | Description |
|-------------------|---|
| Alarm text | High Patient Air Temp |
| Priority | High |
| Alarm condition | A High Patient Air Temperature alarm will be given when the patient air temperature exceeds 43°C (109.4°F). If having a patient circuit with an active heated circuit, the patient air temperature is measured by the circuit's temperature sensor. Otherwise, the temperature is measured by the flow measurement sensor inside the Vivo 3. |
| Possible cause | <ul style="list-style-type: none">Blocked air inlets.Too high ambient temperature. |
| Ventilator action | The Vivo 3 will continue treatment. If a heated circuit or attachable humidifier is used, these will be turned off. |
| Reset criteria | The temperature goes below the limit again. |

7.4.9 Flow Sensor Failure

| Property | Description |
|-------------------|---|
| Alarm text | Flow Sensor Failure |
| Priority | Medium |
| Alarm condition | No data or erroneous data from the flow sensor |
| Possible cause | |
| Reset criteria | Correct data from the sensor is received again. An information message remains until acknowledged by the user. |
| Ventilator action | The Vivo 3 will continue treatment but with the following limitations: <ul style="list-style-type: none">Monitoring of leakage is disabled.Volume measurements are disabled.The patient cannot trigger breaths (applies to assisted modes) An information message about the limitations is displayed on the screen. |

7.4.10

Internal Function Failure

| Property | Description |
|-------------------|---|
| Alarm text | Int. Function Failure |
| Priority | High |
| Alarm condition | Failure of internal function that prevents treatment or normal operation of the ventilator. The error code that follows the alarm text indicates the kind of function failure. |
| Reset criteria | Correct function is restored. |
| Ventilator action | The ventilator will stop the treatment. |
| Action to take | Restart the Vivo 3. If the alarm persists or reoccurs: Take a note of the error code and contact your supplier of the Vivo 3 . |

8 Cleaning and Maintenance

This chapter contains instructions for cleaning and maintenance actions that can be carried out by the care provider or by users with physical ability and working knowledge of the system.

WARNING!

Risk of Personal Injury



- Repairs, upgrades and modifications must be carried out by technicians authorized by Breas Medical AB only and in accordance with instructions from Breas Medical AB
- The Vivo 3 must not be opened, repaired or modified by unauthorized personnel. If subjected to unauthorized operations, Breas Medical AB is no longer responsible for the performance and safety of the device and all warranties will become invalid.

The patient-connected parts and the filters must be cleaned and replaced regularly to ensure correct function of the Vivo 3. All replaced parts must be disposed of in accordance with local environmental regulations regarding the disposal of used equipment and waste.

8.1 Cleaning the Vivo 3

WARNING!



Risk of Electric Shock

Disconnect the power supply before cleaning the Vivo 3 according to the instructions in this manual.

Do not soak the Vivo 3 or immerse it into any fluids.

8.1.1 Clean the Main Unit Externally

Equipment

- A lint free cloth.
- A mild soap solution or Ethanol 70%.

- 1 Turn off the Vivo 3 and disconnect the power supply.
- 2 Remove the patient circuit.
- 3 If any cable connected accessories (like the SpO₂ sensor or the accessory box) are used, disconnect them.
- 4 Clean the outside of the Vivo 3 using a lint free cloth moistened with a mild soap solution and / or ethanol 70%.
- 5 When the equipment is clean and dry, reconnect the patient circuit and any accessories that was disconnected during the cleaning.

8.1.2 Air Pathway Disinfection

The table below lists the parts that might get contaminated by exhaled gases or bodily fluids during normal use or single fault condition.

| Condition | Parts |
|-------------------------|---|
| With bacteria filter | <ul style="list-style-type: none"> • Patient circuit • Bacteria filter |
| Without bacteria filter | <ul style="list-style-type: none"> • Patient circuit • Patient air outlet • Air bypass unit/humidifier • Blower unit • Air inlet filters and filter holder |

In case of contamination, the internal air pathways of the Vivo 3 may be disinfected up to 5 times by a maximum 60 minute long validated ozone gas process.

Low resistance bacteria filter, if used, should be replaced every 24 hours.

8.1.3 Clean the Patient Circuit



CAUTION!

The cleaning and replacement intervals should be established by the care provider, based on the care provider's infection control procedures and the instructions from the patient circuit's manufacturer.

Check the patient circuit regularly for damage. In case of damage, replace the circuit.



The patient circuit should be cleaned and replaced in accordance with the manufacturer's instructions, or by the care provider's instructions if additional cleaning or other replacement intervals are prescribed.

8.2 Clean and Replace Patient Air Inlet Filters

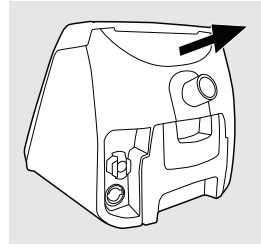
The Vivo 3 patient air inlet filters are located inside a magnetic filter holder at the back of the ventilator. The table below describes the filters and their minimum maintenance intervals.

| Filter | Maintenance Intervals (minimum)* |
|---------------------------------|---|
| Air inlet filter, grey (coarse) | <ul style="list-style-type: none"> • Wash: every week. • Replace: every year or when assigning the Vivo 3 to a new patient. |
| Air inlet filter, white (fine) | <ul style="list-style-type: none"> • Replace: every 4th week or when assigning the Vivo 3 to a new patient. |

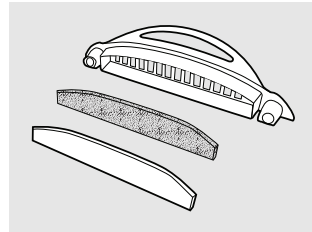
* If the Vivo 3 is used in an environment with high grades of pollen or pollutions, shorter intervals might be required.

- 1 Turn off the Vivo 3 and place it on a clean dust free surface.

- 2 Pull out the filter holder and remove the filters.



- 3 If required by the interval or if visibly dirty, wash the grey coarse filter:
 1. Wash the filter using warm water and a mild soap.
 2. Rinse thoroughly.
 3. Dry the filter by first squeezing it in a towel and then letting it dry in the air. Do not wring the filter.
 4. Check that the filter is undamaged and completely dry before reinstalling it.
- 4 When reinstalling the air inlet filters in the filter holder: first install the grey coarse filter, then the white fine filter.

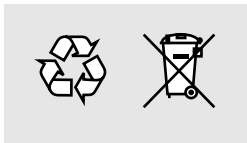


- 5 Reinstall the filter holder on the Vivo 3.

8.3 Disposal

The ventilator, any accessories and all replaced parts must be disposed of and recycled in accordance with the local environmental regulations regarding the disposal of used equipment and waste. Contact your service provider for information regarding the disposal procedure.

NOTE



Batteries used with the ventilator shall be recycled in accordance with the local environmental regulations.

9 Technical Specifications

9.1 Ventilator Size and Weight

| Property | Value |
|--------------------|--------------------|
| Dimensions (WxHxD) | 166 x 185 x 200 mm |
| Weight | 1,8 kg |

9.2 Power Supply

Mains Power Supply

| Property | Value |
|-----------------------------------|--|
| Mains Power Supply | 100–240 V AC tolerance: +10%/-20%, 50 to 60 Hz, max 1.2 A. The approved AC/DC supply listed in 10 <i>Accessories</i> , page 103 must be used. |
| Protection against electric shock | Class II ME Equipment |

External DC Power Supply

| Property | Value |
|--------------------|---|
| External DC Supply | 12–24 V isolated DC The approved DC/DC supply listed in 10 <i>Accessories</i> , page 103 must be used. |

Internal Battery

| Property | Value |
|------------------|-----------------------|
| Battery type | 4 cell Li-Ion battery |
| Nominal Voltage | 14.4 V |
| Capacity | 1.5 Ah |
| Operational time | 3 hours |
| Expected life: | 300 charging cycles |



NOTE

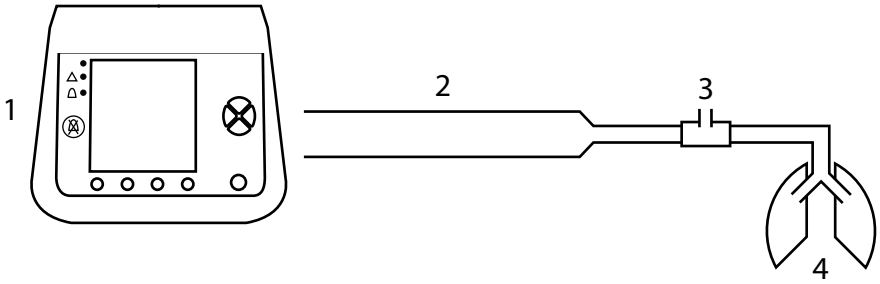
When 300 cycles have been exceeded, a notification message is displayed.

9.3 Environmental Conditions

| Environmental Condition | Specification |
|---------------------------------------|---|
| Normal Operation Temperature | +5°C to +40°C |
| | Precautions |
| | <ul style="list-style-type: none">• Be careful not to position the Vivo 3 in an extra warm place, such as in direct sunlight or above a radiator.• Caution should be exercised if the room temperature is higher than 36°C (97°F). The air flow for breathing produced by the Vivo 3 can be as much as 4°C (7°F) higher than the ambient room temperature. |
| Extended Operation Temperature | -20°C to +5°C |
| | The Vivo 3 is operational during the extended operation temperature for 4 hours, if: |
| | <ul style="list-style-type: none">• The Vivo 3 is first started within the normal operation temperature span.• The Vivo 3 is placed in its protective cover.• This condition happens maximum once a day.• The ambient air is dry and still. |

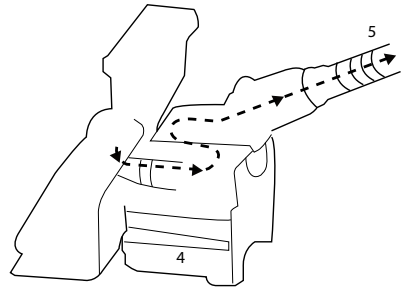
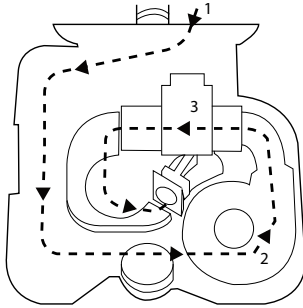
| Environmental Condition | Specification |
|--|---|
| Transport and Storage Temperature | <ul style="list-style-type: none"> +5°C to +45°C (Maximum 90 days) -25°C to +70°C (Maximum 30 days) <p>Precautions</p> <ul style="list-style-type: none"> When the ventilator is brought from minimum/maximum allowed storage temperature, ensure that it is warmed up/cooled down for one hour before starting it. The Vivo 3 must not be stored in a warm place, such as direct sunlight or close to a radiator. If stored in temperatures outside normal operation conditions, let the Vivo 3 acclimate before taking it to use. |
| Humidity | RH from 15% to 95%, non-condensing. |
| Ambient Pressure Range | 70 to 106 kPa This corresponds to ~ 315 m below sea level to ~3000 m above sea level |
| Ventilator ingress protection | <p>IP 22</p> <p>Mechanical ingress protection: protected from touch by fingers and objects greater than 12.5 mm</p> <p>Liquid ingress protection: The device withstands dripping water (equivalent to 3 mm rainfall /minute) when not tilted more than 15 degrees from vertical. The protection has been tested for 10 minutes (2.5 minutes in every tilt direction).</p> <p>Precautions</p> <ul style="list-style-type: none"> There is a silicone lid to protect the USB, SD card, and communication ports. The IP22 classification is applicable only when this lid is in place. However, the accessory box can be connected with retained IP22 classification, but then only the lower part of the silicone lid can be opened. Ensure that the silicone lid on the back of the ventilator is closed when no accessories are connected. |

9.4 Pneumatic Diagram



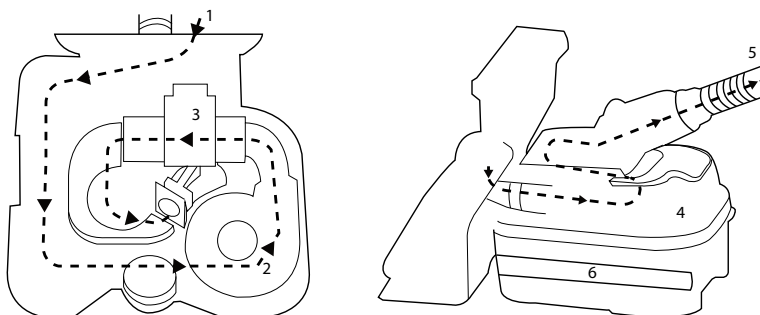
| Number | Description |
|--------|---|
| 1 | Vivo 3 |
| 2 | Patient circuit |
| 3 | Leakage port / Patient interface connection |
| 4 | Patient |

With Bypass Unit



| Number | Description |
|--------|---|
| 1 | Air inlet (Ambient room air intake) |
| 2 | Blower |
| 3 | Sensors |
| 4 | Air bypass unit |
| 5 | Air outlet (Breathing air to the patient) |

With Humidifier



| Number | Description |
|--------|---|
| 1 | Air inlet (Ambient room air intake) |
| 2 | Blower |
| 3 | Sensors |
| 4 | Humidifier |
| 5 | Air outlet (Breathing air to the patient) |
| 6 | Cartridge heater |

The humidification output is controlled by the ventilator by regulating the power to the cartridge heater in the humidifier.

9.5 Technical Data

Noise Levels

| Property | Value |
|--|---|
| Static sound pressure level | < 27.8 dB(A) @ 10 cmH ₂ O, 4 mm leak. Measured at a distance of 1 meter, according to standard. |
| Static sound pressure level, stand by mode | < 22 dB(A) SPL. Measured at a distance of 1 meter, according to standard. |

| Property | Value |
|------------------------------|--|
| Maximum sound pressure level | 40 dB(A) SPL according to applicable standards. Measured at a distance of 1 meter, according to standard. |
| Maximum sound power level | 48 dB (A) according to applicable standards. Measured at a distance of 1 meter, according to standard. |

Maximum Flow

250 l/min

Maximum Flow Rate at Continuous Pressure

| Pressure (hPa) | Flow Rate (l/min) |
|----------------|-------------------|
| 4 | 76 |
| 8 | 105 |
| 12 | 158 |
| 16 | 157 |
| 20 | 149 |

Maximum Pressure

| Property | Value |
|--|-----------------------|
| Maximum pressure limit in the event of fault condition | 60 cmH ₂ O |

CPAP Maximum Dynamic Pressure Variations

Device with standard tube / Device with worst case VBS (external humidifier with 22 mm tube and bacterial filter)

| Pressure [cmH ₂ O] | 10 bpm | 15 bpm | 20 bpm |
|-------------------------------|---------|---------|---------|
| 4 | 0.4/1.0 | 0.5/1.2 | 0.5/1.5 |
| 8 | 0.4/1.0 | 0.5/1.2 | 0.5/1.5 |
| 12 | 0.4/1.0 | 0.5/1.2 | 0.5/1.5 |
| 16 | 0.4/1.0 | 0.5/1.2 | 0.5/1.5 |
| 20 | 0.4/1.0 | 0.5/1.2 | 0.5/1.5 |

Inlet Air Filter Specification

Specification for Air inlet filter, white (part no 007202):

| Performance Characteristic | Value | Tested in Accordance with |
|--|--|---|
| NaCl Penetration | <7.35 % | BS EN 13274-7 NaCl at 16 cm/sec |
| Air flow resistance (pressure drop) flow | 12.5 Pa typical 20 Pa max 0.3 Pa max | at 82.5 l/min (100 cm ²) at 0.2 cm/sec |

Ventilatory Breathing System Characteristics

The ventilator is verified to maintain specified accuracies over these ranges.

| Property | Value |
|------------|---|
| Resistance | 0.4 to 2.7 cmH ₂ O at 40 l/min |
| Compliance | Max 2.5 ml/cmH ₂ O |

Static Temperature Stability

The static temperature stability have been measured at the patient port, when using the attachable humidifier. The measurement conforms to ISO 80601-2-74:2021 and discloses the value for the worst case breathing gas pathway configuration.

| Property | Value |
|------------------------------|--------|
| Static temperature stability | ±2°C |
| Measurement uncertainty | ±0.5°C |

Temperature on applied part

- Ventilator enclosure: 52°C NC, 53°C SFC, touch time < 1 min (NC=normal condition, SFC=single fault condition)
- Accessory box enclosure: 42°C NC
- Y-cable box: 42°C NC
- Humidifier enclosure: 46°C NC, 55°C SFC
- Heated circuit: 42°C NC, 59°C SFC

10

Accessories

The accessories described in this section, together with the *medical electric equipment* defined in chapter 3.1 *Main Components*, page 23, constitute the *Vivo 3 medical electric system*.

CAUTION!

Responsibility for System

Accessory equipment connected to the analogue and digital interfaces must be certified according to the respective IEC standards (e.g. IEC 60950 or IEC 62368 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore all configurations must comply with the valid version of the system standard IEC 60601-1. Anybody who connects additional equipment to the signal input part or signal output part is configuring a medical system, and is therefore responsible for ensuring that the system complies with the requirements of the valid version of the system standard IEC 60601-1. If in doubt, consult the technical service department or your local representative.

A PC, when connected to the ventilator, shall comply with IEC 62368-1, IEC 60950-1 or IEC 60601-1.

Not all accessories are available in all markets.



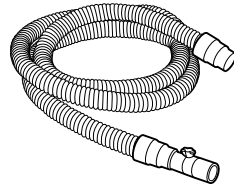
10.1

Patient Circuits and Air Delivery Accessories

Circuit: 22 mm smoothbore with leak port

Function: Delivers air to the patient, applied part

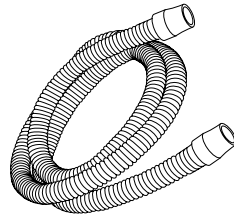
Part No: 005060



Circuit: 1.8m x 22mm Smoothbore disposable

Function: Delivers air to the patient, applied part

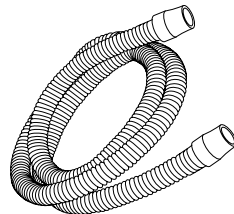
Part No: 009118



Circuit: Single limb 22 mm. Single patient multiple use.

Function: Delivers air to the patient, applied part

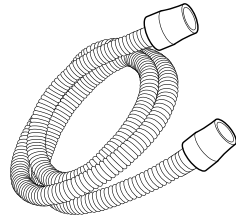
Part No: 008426 (30-pack of 004465)



Circuit: 1.8m x 15mm Smoothbore Disposable

Function: Deliver air to the patient

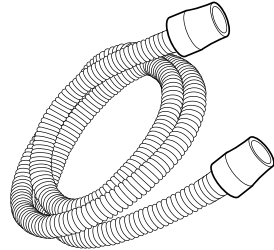
Part No: 009119



Circuit: Single limb 15 mm. Single patient multiple use.

Function: Delivers air to the patient, applied part

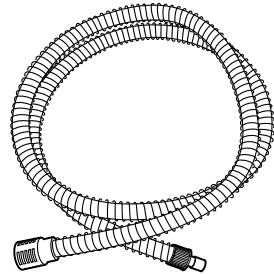
Part No: 008427 (30-pack of 006712)



Heated Circuit

Function: Delivers air to the patient, applied part.
Prevents rain-out.

Part No: 006990



Leakage Port

Function: Providing a leakage for clearing exhaled gases.

Part No: 007243 (10 pieces)

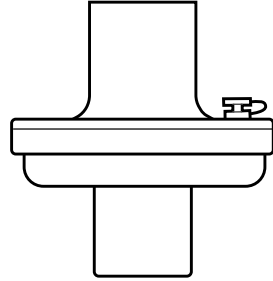
Low resistance bacterial filter, with CO₂ connector

Function: Filter air at ventilator outlet

Characteristics

- Resistance:
0.5 cmH₂O @ 30 l/m
1.4 cmH₂O @ 60 l/m
2.76 cmH₂O @ 90 l/m
- Deadspace: 33 ml
- BFE (Bacterial Filtration Efficiency): 99.9999%
- VFE (Viral Filtration Efficiency): 99.999 %

Part No: 007963



Oxygen Adapter, Low Pressure

Function: Connection of oxygen supply.

Part No: 005032

10.2 Power Accessories

DC/DC Power Supply (RRC CAR 70M)

Function: Power supply adapter for the ventilator. Shall be used when connecting to an external DC source.

Part No: 006995

Y Cable

Function: Power supply cable, for connecting to both AC and DC power supply.

Part No: 007006

XPAC - External battery with charger

Function: Extends usage time of supported Breas products.

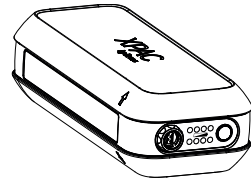
Part No Cable for connection to device: 007803

Part No Charger with cable:

Single: Charger with one battery

Dual: Charger with two batteries

Single: 007995, Dual: 007999

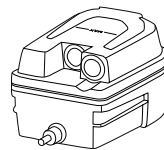


10.3 Ventilator Filters and Detachable Parts

Attachable humidifier

Function: Humidifies the patient air. For non-invasive use only.

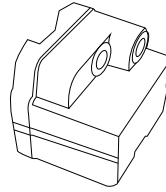
Part No: 006977



Air Bypass Unit

Function: Directs the patient air flow, if the attachable humidifier is not used.

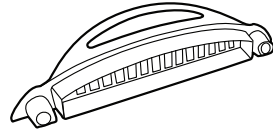
Part No: 006983



Filter Holder

Function: Holder for air inlet filters

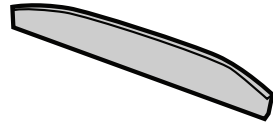
Part No: 007598



Air Inlet Filter, Grey

Function: Coarse air inlet filter, user replaceable part. Long life (washable).

Part No: 007203 (5 pieces)



Air Inlet Filter, White

Function: Fine air inlet filter, user replaceable part. Disposable.

Part No: 007202 (5 pieces)



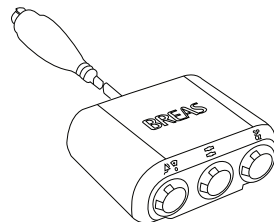
10.4 Monitoring Accessories

Accessory Box

Function: For connecting measurement and communication accessories:

- Nurse call cable or Remote alarm
- SpO₂ sensor (Might also be connected directly to the Vivo 3, if no other measurement or communication accessories are used.)

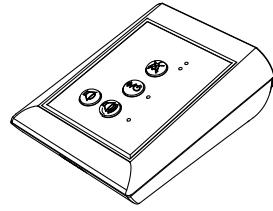
Part No: 007000



Remote alarm with cable

Function: Monitor Vivo 3 alarms remotely

Part No: 10 m: 006348, 25 m: 006349



Nurse call cable

Function: Connect the ventilator to a hospital nurse call system

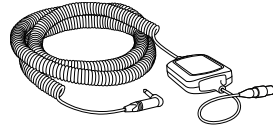
Part No:

NO: 006365

NC: 006364

10 k Ω , NO: 006363

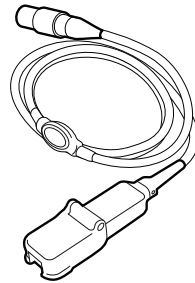
10 k Ω , NC: 006362



SpO₂ module

Function: Connection interface

Part No: 006369



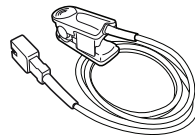
SpO₂ sensor

Function: Finger Clip SpO₂ sensor

Part No:

Adult: 006589

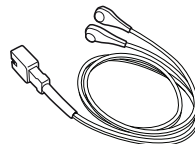
Paediatric: 006590



SpO₂ sensor

Function: Multisite SpO₂ sensor

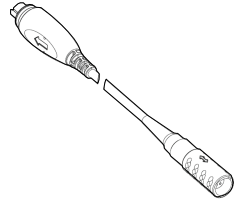
Part No: 006591



SpO₂ Adapter Cable

Function: Connection cable. For use of SpO₂ without accessory box.

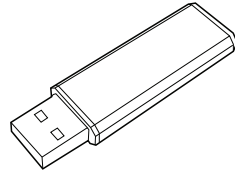
Part No: 007079



PC Software USB

Function: Support software for follow-up on patient treatment.

Part No: 007067



USB Cable

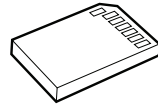
Function: USB cable for transferring data between a PC and the Vivo 3.

Part No: 005757

Memory card

Function: Storage and transfer of settings, patient data and usage data

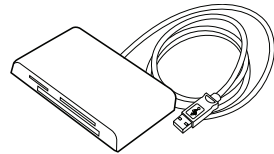
Part No: 006705



Memory card reader/writer

Function: Read/write memory card

Part No: 002185



10.5 Other Accessories

Protective Cover

Function: Shock protection

Part No: 007014

Lightweight Mobility Bag

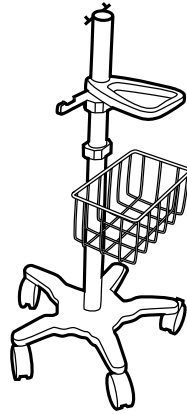
Function: For mobile use of the Vivo 3 in hospital, institutions and home care environments.

Part No: 007380

Trolley

Function: Mobile use, transportation

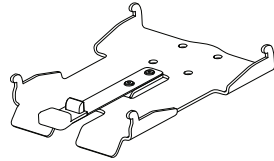
Part No: 007384



Mounting Bracket

Function: Bracket to mount the Vivo 3 to the trolley

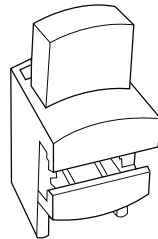
Part No: 006998



Universal rail clamp

Function: Attach a humidifier to a trolley.

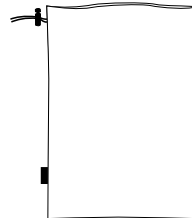
Part No: 007858



Accessory Bag

Function: Storage of accessories

Part No: 007989



Appendices

A Patient Settings Record

This page can be copied and used for noting the patient's settings.

Patient: _____

Clinic: _____

Vivo SN: _____

Set by: _____

Date: _____

Treatment Settings

Ventilation
Mode: _____

IPAP: _____

EPAP: _____

CPAP: _____

_____ Breath Rate: _____

Patient
Circuit: _____

Insp. Time: _____

Min Insp.
Time: _____

Max Insp.
Time: _____

Insp. Trigger: _____

Exp. Trigger: _____

Rise Time: _____

Max Pressure: _____

Min Pressure: _____

Target
Volume: _____

Ramp Up: _____

Ramp Down: _____

Humidifier: _____

Humidifier
Level: _____

Heated
Circuit: _____

Heated Circuit
Level: _____

HFNT: _____

Flow: _____

Notes

Treatment Settings – Auto EPAP

Min EPAP _____ Pressure Limit _____

Max EPAP _____ EPAP Step _____

PS _____ Relax Time _____

Min PS _____

Max PS _____

Notes

B FAA Compliance

To whom it may concern:

In line with the FAA Advisory Circular AC 91.21-1D October 27, 2017, this kind of respiratory assistive device may be used onboard an aircraft, without further testing by the carrier, provided they have been tested for Electromagnetic Compatibility (EMC) in accordance with the current version of RTCA/DO-160, Section 21, Category M.

Breas Medical has successfully completed testing for the ventilator System. The ventilator System complies with RTCA/DO-160, Section 21, Category M and can be considered FAA compliant.

Some airlines may require advance notification before travel, and devices may need to be operated by battery. Breas Medical recommends that customers check with their airline.

FAA Compliance (English text)

To whom it may concern:

In line with the FAA Advisory Circular AC 91.21-1D October 27, 2017, this kind of respiratory assistive device may be used onboard an aircraft, without further testing by the carrier, provided they have been tested for Electromagnetic Compatibility (EMC) in accordance with the current version of RTCA/DO-160, Section 21, Category M.

Breas Medical has successfully completed testing for the ventilator System. The ventilator System complies with RTCA/DO-160, Section 21, Category M and can be considered FAA compliant.

Some airlines may require advance notification before travel, and devices may need to be operated by battery. Breas Medical recommends that customers check with their airline.

Index

A

| | |
|--|--------|
| AC Voltage | |
| supply | 94 |
| Accessories | 103 |
| using | 59 |
| AHI | 35 |
| Air bypass unit | 23 |
| Air outlet | 25 |
| Air pathway | |
| disinfection | 91 |
| Alarm | 35 |
| Ambient Pressure Compensation Lost | 88 |
| Apnea | 80 |
| Circuit | 85 |
| Critically Low Battery. Connect to Mains | 88 |
| Disconnection | 81, 85 |
| Flow sensor failure | 89 |
| High breath rate | 78 |
| High EPAP | 82 |
| High minute volume | 79 |
| High Patient Air Temp (High Patient Air Temperature) | 89 |
| High pressure | 76 |
| High pressure limitation | 86 |
| High pulse rate | 84 |
| High SpO ₂ | 83 |
| Internal Function Failure | 90 |
| Low Battery | 88 |
| Low breath rate | 78 |
| Low EPAP | 82 |
| Low minute volume | 79 |
| Low pressure | 77 |
| Low pulse rate | 84 |
| Low SpO ₂ | 83 |
| Power Failure Alarm | 86 |
| Rebreathing | 80 |
| resetting | 74 |
| SpO ₂ artifact | 87 |
| SpO ₂ sensor failure / disconnected | 86 |
| Alarm condition | |
| identifying | 72 |
| Alarm message | 73 |
| Alarm signal | |
| Check | 52 |

| | |
|--|----|
| LED | 73 |
| Alarm sound | |
| pausing | 74 |
| Alarm time | 35 |
| Alarm volume | 35 |
| Alarms | 72 |
| physiological | 76 |
| Ambient Pressure Compensation Lost alarm | 88 |
| Apnea | |
| Auto-EPAP | 44 |
| Apnea alarm | 80 |
| Auto-EPAP | 44 |
| Average usage hours | 35 |

B

| | |
|--------------------|----|
| Battery | 26 |
| Battery percentage | 34 |
| Battery time left | 34 |
| Battery,(internal) | |
| specifications | 94 |
| Blocked Circuit | 85 |
| Board revision | 34 |
| Bootloader version | 34 |
| Buttons | 24 |

C

| | |
|--|--------|
| Carry bag | 23 |
| Caution | |
| Icon | 9 |
| Check | |
| Compliance and resistance | 53 |
| Start-up | 52 |
| Circuit Disconnection | 85 |
| Cleaning | 20, 91 |
| Clock | 35 |
| Command | |
| execute | 30 |
| Communication port | 25 |
| Compliance | |
| Check | 53 |
| Continuous Positive Airway Pressure, CPAP | 43 |
| Contraindications | 8 |
| Critically Low Battery. Connect to Mains alarm | 88 |

D

| | |
|-----------------------------------|----|
| Date | 35 |
| Date format | 35 |
| Days with usage | 35 |
| DC Voltage supply | 94 |
| Device information | 34 |
| Device memory | 34 |
| Device settings | 33 |
| Disconnection alarm | 81 |
| Disinfection air pathway | 91 |
| Display | 24 |
| Display light | 33 |

E

| | |
|-------------------------------------|----|
| Electromagnetic compatibility | 14 |
| Electrostatic discharge | 14 |
| Environmental conditions | 95 |
| EPAP auto | 44 |
| Erase memory data | 34 |

F

| | |
|---------------------------------|----|
| Filter usage | 17 |
| Filters clean, replace | 92 |
| Firmware version | 34 |
| Front panel | 24 |

H

| | |
|--|----|
| Heated circuit setting | 47 |
| using | 64 |
| Heating | 19 |
| High breath rate alarm | 78 |
| High EPAP alarm | 82 |
| High Patient Air Temperature Alarm (High Patient Air Temp) alarm | 89 |
| High pressure alarm | 76 |
| High pulse rate alarm | 84 |
| High SpO ₂ alarm | 83 |
| Humidification | 19 |
| Humidifier setting | 47 |

| | |
|---------------------------------------|----|
| Humidifier, attachable using | 60 |
| Hypoventilation | 78 |

I

| | |
|---------------------------------------|----|
| Icon Caution | 9 |
| Note | 9 |
| Reference | 9 |
| Warning | 9 |
| Inspiratory time | 42 |
| Interface board revision | 34 |
| Internal Function Failure alarm | 90 |
| Invasive use | 18 |

L

| | |
|----------------------------------|----|
| Languages | 33 |
| Leakage Check | 53 |
| Light intensity | 33 |
| Low Battery alarm | 88 |
| Low breath rate alarm | 78 |
| Low EPAP alarm | 82 |
| Low pressure alarm | 77 |
| Low pulse rate | 84 |
| Low SpO ₂ alarm | 83 |

M

| | |
|----------------------------|--------|
| Mains power cord | 23 |
| Mains power supply | 23 |
| Maintenance | 20, 91 |
| Memory card port | 25 |
| Memory data | 34 |
| Menus | 27 |
| Min daily use | 35 |
| Mobile use safety | 22 |
| Monitor treatment | 57 |

N

| | |
|--------------------|---|
| Note Icon | 9 |
|--------------------|---|

O

| | |
|--------------|----|
| Oxygen | 67 |
| usage | 20 |

| | | | |
|---------------------------------------|----|--------------------------------|--------|
| Oxygen concentration | 22 | Settings | 40, 43 |
| Oxygen port | 25 | change | 30 |
| Oxygen saturation | | Setup pages | 32 |
| monitoring | 59 | Sound level, alarm | 74 |
| P | | SpO ₂ sensor | |
| Pathway | | using | 65 |
| internal disinfection | 91 | Start date | 35 |
| Patient air inlet filter | 23 | Stop the treatment | 56 |
| Patient air outlet | 25 | Switch off | 56 |
| Patient circuit | 23 | Switch on | 55 |
| connect | 52 | Symbols | 36 |
| Placing | 49 | T | |
| Power Failure Alarm alarm | 86 | Technical specifications | 94 |
| Power handling | | Time | 35 |
| Check | 52 | Time format | 35 |
| Power management | 26 | Total days | 35 |
| Power port | 25 | Total usage hours | 35 |
| Power supply | | Transit operation | |
| connect | 50 | safety | 22 |
| Pre-use test | 53 | Treatment | |
| Pre-Use Test | | start | 55 |
| Failure | 53 | Treatment data | 30 |
| Pressure Controlled Ventilation | | Treatment modes | 42 |
| (Assisted), PCV+A | 42 | U | |
| Pressure Support Ventilation, PSV ... | 42 | Undesirable side effects | 8 |
| Pressure unit | 33 | Usage time | |
| Product name | 34 | Internal battery | 94 |
| Protective cover | 69 | USB port | 25 |
| R | | Using instructions | 55 |
| Ramp down | 46 | V | |
| Ramp up | 46 | Voltage | |
| Rebreathing alarm | 80 | supply | 94 |
| Reference | | W | |
| Icon | 9 | Warning | |
| Remote alarm unit | | Icon | 9 |
| using | 68 | Wheel chair | |
| Reset compliance data | 35 | safety | 22 |
| Resistance | | Y | |
| Check | 53 | Y-cable | 69 |
| Rise time | 42 | | |
| S | | | |
| S/T | 43 | | |
| Save memory data on card | 34 | | |
| SD card port | 25 | | |