Vivo 55, User's

ENGLISH (EU)

BREAS

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Vivo 55 User manual

BREAS

USER MANUAL

006625 M-1 EN-EU

vivo55 by Breas

Table of Contents

1 Introduction

WARNING!

Risk of Personal Injury

The Vivo 55 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.

Every other use may lead to risk of personal injury!

CAUTION!

Read this manual thoroughly so that you completely understand how the Vivo 55 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 55.

Breas Medical reserves the right to make changes to this product without any prior notification.

1.1 What is the Vivo 55?

The Vivo 55 is a pressure and volume ventilator capable of delivering continuous or intermittent ventilatory support for patients who require invasive or non-invasive mechanical ventilation.

The Vivo 55 can be operated in 13 different combinations of ventilation and breath modes:

- PSV – Pressure Support Ventilation
- PSV(TgV) – Pressure Support Ventilation with Target Volume
- PCV – Pressure Controlled Ventilation
- PCV(TgV) – Pressure Controlled Ventilation with Target Volume
- PCV(A) – Assisted Pressure Controlled Ventilation
- PCV(A+TgV) – Assisted Pressure Controlled Ventilation with Target Volume
- PCV-SIMV – Pressure Controlled Ventilation with Synchronized Intermittent Mandatory Ventilation
- PCV-MPV – Pressure Controlled Ventilation with MouthPiece Ventilation
- VCV – Volume Controlled Ventilation
- VCV(A) – Assisted Volume Controlled Ventilation
- VCV-SIMV – Volume Controlled Ventilation with Synchronized Intermittent Mandatory Ventilation
- VCV-MPV – Volume Controlled Ventilation with MouthPiece Ventilation
- CPAP – Continuous Positive Airway Pressure

The Vivo 55 can be used with a leakage circuit, a circuit with active exhalation valve or a circuit with mouthpiece interface.

1.1.1 Multiple Use

This is a multiple patient multiple use device. If it should be used by multiple patients, see the cleaning instructions in 7.3 *Change of Patients*, page 116 before assigning it to a new patient.

1.2 Intended Use

The Vivo 55 (with or without the SpO2 and CO2 sensor) is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Specifically, the ventilator is applicable for paediatric through adult patients weighing more than 10 kg.

The Vivo 55 with the SpO2 sensor is intended to measure functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate.

The Vivo 55 with the CO2 sensor is intended to measure CO2 in the inspiratory and expiratory gas.

The device is intended to be used in home, institution, hospitals and portable applications such as wheelchairs and gurneys. It may be used for both invasive and non-invasive ventilation.

1.3 Contraindications

- The use of the Vivo 55 is contraindicated for patients who need to be ventilated with oxygen concentrations (FiO_2) higher than achievable when combining inlet from a low pressure oxygen source at 15 l/min with actual ventilator settings.
- Generally, after surgery, the surgeon should be consulted to avoid organ damage and help determine ventilator parameters that do not adversely affect hemodynamics or have a negative impact on the patient's health status.
- In case of facial surgery, make sure to choose a suitable patient interface, in order to avoid discomfort and injury.

1.3.1 Undesirable Side Effects

WARNING!

The Vivo 55 is not intended to be used as an emergency transport ventilator or critical care ventilator.

If the patient experiences chest discomfort, pain, severe headache or shortness of breath while using the Vivo 55, a physician or responsible clinician shall be contacted immediately.

1.4 About this Manual

CAUTION!

Always read this manual before setting up and using the Vivo 55 or performing maintenance on the machine, to ensure correct usage, maximum performance and serviceability.

Breas Medical reserves the right to make changes to this product without any prior notification.

1.4.1 Audience

This manual is intended for patients and other lay users operating the Vivo 55.

- Care providers, clinical personnel, physicians and others who require a working knowledge of the Vivo 55 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.

1.4.2 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.
	**Warning!** Flammable material, risk of fire.
	**Caution!** Risk of equipment damage, loss of data, extra work, or unexpected results.
	MR Unsafe. The device should not enter a magnetic resonance (MR) environment, such as an MRI scanner room.
	**Note** Information that may be valuable but is not of critical importance, tips.
	**Reference** Reference to other manuals with additional information on a specific topic.

1.5 Manufacturer Information

Legal Manufacturer

CE 2797

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2 Safety Information

2.1 General User Precautions

WARNING!

When a patient is treated, there must be a supervising person present during the treatment in order to take care of alarms and conditions that the patient cannot solve on their own.

Always have immediate access to an alternative means of ventilation, which is ready for use, to avoid patient death or serious injury. Failure to have an alternate means of ventilation can result in serious injury or patient death if ventilator fails.

Failure to have an alternative means of ventilation can result in serious injury or patient death if ventilator fails.

The Vivo 55 must be turned off and on at least every 90 days. This is necessary in order for the Vivo 55 to perform a complete self-test. The self-test automatically tests the alarm sound and certain components.

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

The Vivo 55 must only be used:

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

Do not use the Vivo 55 in the event of suspected damage to the device, unexplainable or sudden pressure, performance or sound changes during operation, or if the delivered air from the Vivo 55 is abnormally hot or emits an odour. In these cases, contact the patient's responsible care provider for an inspection.

The Vivo 55 may not work properly if any part has been dropped, damaged or submerged in water.

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

The Vivo 55 therapy settings must always be based on medical advice and must be carried out by authorised clinical personnel only. Blood gas measurement shall be performed when changing treatment settings or changing to another device.

Always perform the procedure in4.5 *Inspecting the Vivo 55 before Use*, page 34 before use.

The Vivo 55 can be used for life-supporting treatment provided an emergency equipment (e.g. resuscitation bag) is available, and that one of the following means of surveillance of ventilator-dependent patient breathing is used:

- Leakage circuit: The Vivo 55's monitoring of exhaled volume must be supervised.
- Exhalation valve circuit: The CO_2 sensor or an external $EtCO_2$ monitor (capnometer) must be used. The CO_2 sensor must be connected between the patient and the exhalation valve or leakage port to be able to measure exhaled gases. The CO_2 monitor shall fulfil the ISO 80601-2-55 standard (Medical electrical equipment - Particular requirements for the basic safety and essential performance of respiratory gas monitors).

Make sure that accessories are compatible with the Vivo 55 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.

CAUTION!

- Handle the ventilator with care.
- Do not use the ventilator while in the carry bag.
- Do not use the ventilator with nitric oxide, helium or helium mixtures.

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 4.5 *Inspecting the Vivo 55 before Use*, page 34. 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 manufacturer and the competent authority.

2.2 Electrical Safety

WARNING!

Risk of Electric Shock
High voltage contact may cause cardiac arrhythmia.

- Do not operate the Vivo 55 if it has a damaged power cord, power supply or casing.
- To avoid electrical shock, only clean the Vivo 55 according to instructions in this manual. Do not soak or immerse the Vivo 55 into any fluids.
- 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 55 should not be used adjacent to or stacked with other equipment; if adjacent or stacked use is necessary, the Vivo 55 should be observed to verify normal operation in that configuration.
  - Mobile or transportable radio transmitters may interfere with the Vivo 55.
  - 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 55.
- 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 55, including cables specified. Otherwise, degradation of the performance of this equipment could result.

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.

2.3 Environmental Conditions

WARNING!

Risk of Intoxication
Do not use the Vivo 55 in a toxic environment.

WARNING!

Risk of Fire
Do not use the Vivo 55 in environments where explosive gases or flammable anesthetic agents present.

WARNING!

The delivered patient air can be as much as 4°C (7°F) higher than ambient temperature. Caution should be exercised if the room temperature is greater that 36°C (97°F).

Risk of Faulty Treatment
If a room humidifier is used, place it at least 2 meters away from the Vivo 55.

The performance of the Vivo 55 may deteriorate at ambient temperatures below -20°C (-4°F) and above 40°C (104°F). However, the treatment shall always be started in an ambient temperature warmer than 5°C (41°F).

Risk of Faulty Treatment

Do not use or store the Vivo 55 in a magnetic resonance (MR) environment.
Use of the Vivo 55 in an MR environment may result in malfunction of the Vivo 55 and pose unacceptable risk to the patient, medical staff or other persons.

Do not expose the Vivo 55 to rain or snowfall.

Do not use the Vivo 55 while positioned in a warm place, such as direct sunlight or close to a radiator .

CAUTION!

The device complies with the EMC requirements of standards. Measures should include but 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 closer than 1 meter to the Vivo 55. Radio emitting devices include cellular or cordless telephones, microwave ovens and high-frequency surgery apparatus.

Avoid using RFID devices closer than 1 meter to the Vivo 55.

Avoid using the Vivo 55 within 1 meter of electronic article surveillance (EAS) system antennae.

WARNING!

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. Follow the instructions above and the guidance provided in 8.3 *Emission and Immunity Declaration*, page 127 to mitigate the effects of electromagnetic disturbances.

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.

The performance of the Vivo 55 and treatment of the patient may deteriorate if the operation conditions in 8.2.4.2 *Environmental Conditions*, page 124 are not fulfilled. Do not use the Vivo 55 immediately after storage or transport outside the recommended operating conditions.

2.4 Usage of Patient Circuit

WARNING!

For the ventilator to deliver treatment according to settings, it is important that the selection of the patient circuit type (see 5.2.2 *Symbols Used in the Menu*, page 40)is correctly set.

Only use the Vivo 55 with accessories recommended by Breas Medical.

The pressurized air from the ventilator causes a continuous flow of air to exhaust from the leakage ports or exhalation valve, flushing exhaled gas from the circuit. If having a patient circuit with leakage port, the ventilator should be turned on and the function of the leakage port should be checked before use. The ventilator should be turned on and the function of the leakage port or exhalation valve should be checked before use.

Do not breathe in the connected patient circuit unless the Vivo 55 is turned on and operating properly.

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!

Always make sure that the patient circuit and joined parts are undamaged and correctly connected, in order to avoid unwanted leakage.

Always perform a pre-use test when the patient circuit is replaced or modified.

Patient connected parts and all filters must be replaced regularly to ensure correct function of the ventilator. All replaced parts must be disposed of according to local environmental regulations regarding the disposal of used equipment and parts.

Patient circuits used with the Vivo 55 shall have the following characteristics:

- Length: Max 6 feet (2 meters).
- Connector: 22 mm.
- Resistance: Max 2 mbar at 40 l/min.

If an active exhalation valve is used:

- Minimum inner diameter of the exhalation valve control pressure tube: 3 mm.
- The exhalation valve must be of the type that is open (letting the exhaled patient air out) when unpressurized by the control pressure.

By conducting a pre-use test (see 4.6 *Perform the Pre-Use Test*, page 35), the compatibility of the complete patient circuit configuration with the Vivo 55 can be verified. If a pre-use test is successfully performed the circuit configuration meets the required characteristics.

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 55 to ensure no water flows back into the Vivo 55.
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.

When using the Vivo 55 invasively, the low volume alarm and the low breath rate alarm must be carefully set, to ensure safe use.

The use of equipment such as endotracheal tubes, oral/nasal tubes, adaptors, etc. with small inner diameters or high resistance filters (such as humidifiers) increases 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. The impact can be reduced by conducting a pre-use test properly. (See 4.6 *Perform the Pre-Use Test*, page 35.)

In case of invasive application, the use of an appropriate external heated humidifier or HME (Heat and Moisture Exchanger, artificial nose)/HCH (Hygroscopic Condenser Humidifier) is recommended.

Make sure that the exhalation valve or the leakage port never is blocked or obstructed.

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.

Always follow the instructions of the mask manufacturer.

The Vivo 55 is equipped with a rebreathing alarm. The alarm is not a substitute for operator vigilance in ensuring that the leakage port or exhalation valve remains clear at all times. Periodically check the patient circuit during therapy.

In general, as pressure decreases, the potential of rebreathing increases. Lower pressures produce less flow through the leakage port which may not clear all CO_2 from the circuit to prevent rebreathing.

To reduce the risk of rebreathing CO_2:

- Single limb circuit use: make sure that the leakage port or active exhalation valve is present as close as possible to the patient connection.
- Dual limb circuit use: make sure that the Y-piece is present as close as possible to the patient connection.

To reduce the risk of rebreathing CO_2, make sure that the leakage port or active exhalation valve is present as close as possible to the patient connection.

CAUTION!

Contact Injuries: Skin irritation may occur due to prolonged exposure to either a mask (if used) or the SpO_2 module.

WARNING!

Always use a new patient circuit when the Vivo 55 is to be used by a new patient.

NOTE

The Vivo 55 and its packaging do not contain any natural rubber latex.

2.5 Usage of Filters

WARNING!

Always use the ventilator with patient air inlet filters installed. Only use the ventilator with accessories recommended by Breas Medical.

Replace or clean the filters regularly to ensure correct function of the Vivo 55.
Failure to replace or clean a dirty filter may cause the Vivo 55 to operate at higher temperatures than intended. A dirty filter may be caused by dust or animal hair in the home environment.

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 55 to operate at higher temperatures than intended.
When operating the Vivo 55, make sure that the air inlet and filters are not obstructed or occluded.

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.
This impact can be reduced by conducting a pre-use test.

When adding or removing any kind of filter, always perform a pre-use test.

2.6 Humidification

WARNING!

Humidification must only be used if this has been prescribed by your physician. The Vivo 55 therapy settings must always be prescribed by a physician or other licensed health care professional, and be carried out by authorized clinical personnel.

When using an external heated humidifier, it should be located below the Vivo 55 and the patient to prevent injury from accidental spillage.

When using a humidifier or a nebuliser any patient air filter will need more frequent replacement to prevent increased resistance or blockage.

During transportation of the Vivo 55, the humidifier must be disconnected.

If the condensation in the patient circuit is excessive, the use of a heated humidifier may require the installation of a water trap in the circuit. The water trap prevents any condensed water in the patient circuit from running into the patient airways and causing personal injury.

When adding or removing an HME (Heat and Moisture Exchanger, artificial nose) or HCH (Hygroscopic Condenser Humidifier), always reassess the settings, including alarm settings, and perform a pre-use test.

Any humidifier connected to the Vivo 55 must comply with ISO 8185 or 80601-2-74.

Any HME connected to the ventilator must comply with ISO 9360.

The use of an HME or an external humidifier may require readjustment of the ventilator low-pressure alarm.

CAUTION!

Certain HMEs and HCHs are sufficient to provide humidification when the ventilator is used invasively. Check specific suppliers' recommended use.

NOTE

The ventilator has been tested and validated with the Fisher & Paykel MR850 heated humidifier

2.7 Cleaning and Maintenance

WARNING!

The Vivo 55 should be cleaned and maintained in accordance with this operating manual. (See 7 *Cleaning and Maintenance*, page 114.)

CAUTION!

Do not attempt to autoclave or sterilize the Vivo 55.

WARNING!

The Vivo 55 should undergo maintenance, service and control procedures, as well as any applicable upgrades, in accordance with Breas service instructions.

The Vivo 55 shall only be repaired or modified in accordance with Breas service manuals, technical bulletins, and any special service instructions, by service technicians that have been authorised after Breas Vivo 55 service training.

Do not under any circumstances attempt to open, service or repair the Vivo 55 yourself. If you do so, the manufacturer will no longer be responsible for the performance and safety of the Vivo 55. Furthermore, no guarantees will be valid.

2.8 Usage of Oxygen

WARNING!

Always follow the oxygen provider's instructions.

As this medical device uses an alternative small-bore connector design different from those specified in the ISO 80369 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.

WARNING!

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

WARNING!

Risk of faulty Treatment
At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure delivered, the patient's breathing pattern, the patient interface and the leak rate.
To monitor the oxygen concentration, use the FiO_2 sensor accessory.

WARNING!

Risk of Fire
When oxygen is used with the Vivo 55, the oxygen flow must be turned off when the Vivo 55 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.

WARNING!

Do not use a humidifier between the oxygen source and the ventilator, in order to humidify the oxygen flow.
If humidification is required, use a humidifier after the patient air outlet.

WARNING!

Risk of Fire
Ventilate the room adequately. Do not smoke in a room where oxygen is being used.

Risk of Fire
Naked light bulbs and other sources of ignition must be kept a minimum of 2 meters (6 feet) away from the oxygen cylinder or any part of the patient circuit.

WARNING!

Supplemental oxygen with a flow up to 15 l/min can be added by an oxygen source with rotameter such as oxygen cylinder, central oxygen supply system or an oxygen concentrator.

WARNING!

Risk of Fire
Do not use aerosols or solvents close to the oxygen supply, even when the oxygen supply is shut off.

WARNING!

Supplemental oxygen flow and pressure must not exceed 15 l/min and 100 kPa.

CAUTION!

The oxygen concentration in the delivered air has influence on the volume measurement of the Vivo 55. This measurement is based on a normal oxygen concentration of 21%. If the oxygen concentration is higher, the monitored inspired volume will deviate from the actual volume as follows:

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

3 Product Description

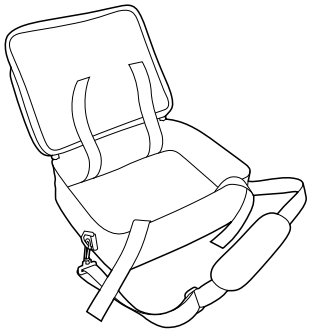
3.1 Main Components

The Vivo 55 system contains the following components (* = optional):

Carry bag

Function: Storage for transportation

Part No: 006343



Manual

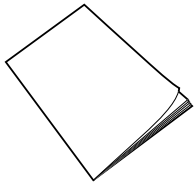
Function: Product and usage information

Part No User manual:

006625

Part No Clinician's manual:

006626

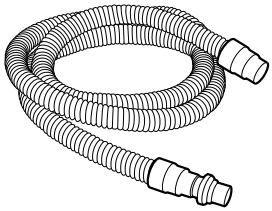


Circuit: Single limb with leakage port

Function: Deliver air to the patient (disposable)

Part No:

005060

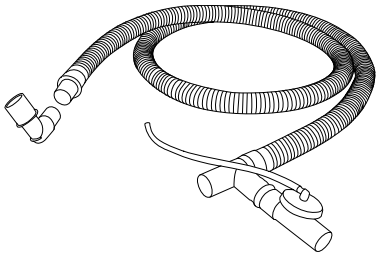


Circuit: Dual Limb with Exhalation Valve

Function: Deliver air to the patient.

Part No:

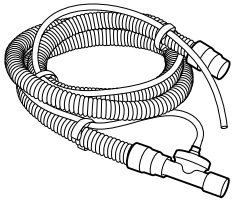
007616 (disposable)



Circuit: Single limb with active exhalation valve

Function: Deliver air to the patient (disposable)

Part No005050



Power cord

Function: Deliver power to the ventilator

Part No:

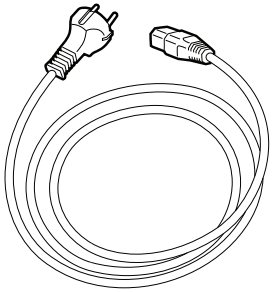
EU: 005336

UK: 005337

AU/NZ: 005049\

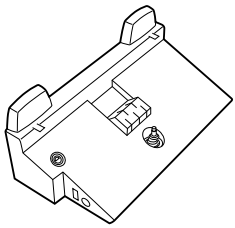
JP: 1,8 m:\005338\3,6 m:\007220

US: 1.8 m:\005432\3.6 m:\007219\



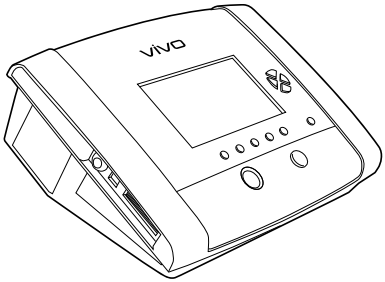
Click-on battery*

Part No: 004559

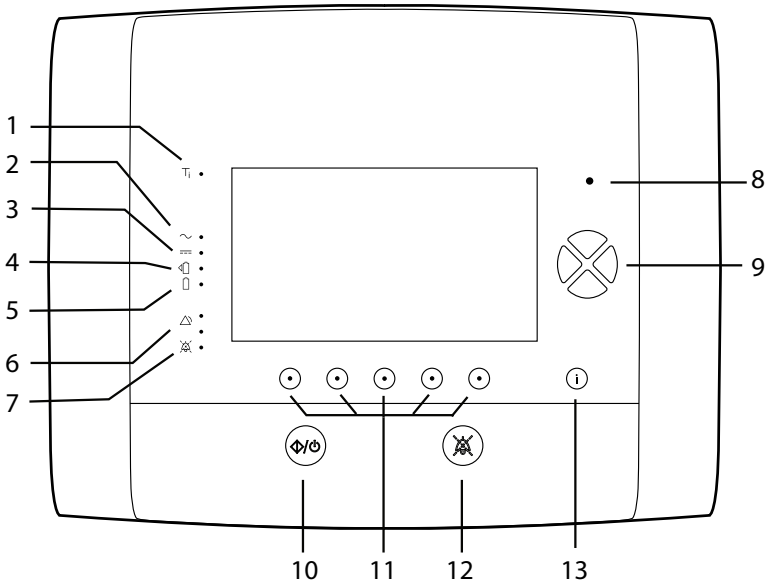


Vivo 55 main unit

The Vivo 55 and its packaging do not contain any natural rubber latex.



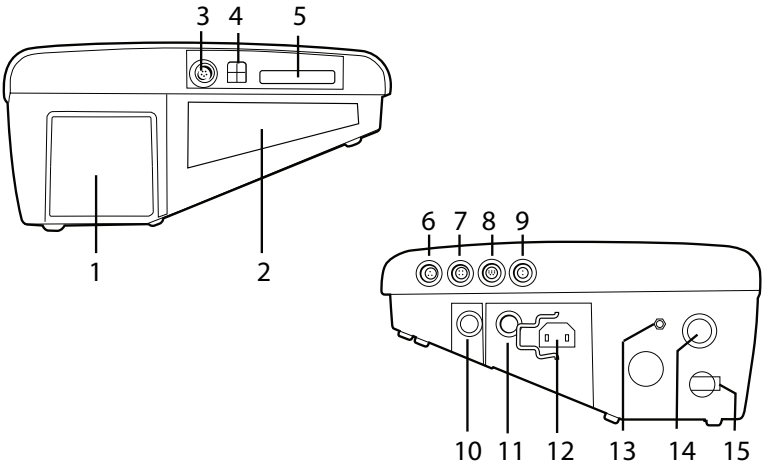
3.2 The Front Panel



No	Item	Function
1	Trigger LED	Patient triggered breath indication
2	AC power (Mains) LED	Power source
3	External DC LED	Power source: External DC
4	Click-on battery LED	Power source: Click-on battery
5	Internal battery LED	Power source: Internal battery
6	Alarm LED	Alarm indication (red or yellow)
7	Audio pause LED	Paused alarm sound indication
8	Sensor	Ambient light sensor
9	Navigation/ Setting	Navigation in current menu selection/Define settings
10	Start/Stop	Start/Stop ventilation treatment

No	Item	Function
11	Function/ Navigation	Function according to display
12	Audio Pause	Pause the alarm sound
13	Information	Show/Hide information

3.3 The Vivo 55's Side Panels



No	item	Function	Colour/Symbol
1	Patient air inlet	Air path in, replaceable filters Make sure that nothing can block the patient air inlet on the side of the Vivo 55. Read 4.2 *Placing the Vivo 55*, page 31 for more information.	
2	Cooling air inlet	Inlet internal cooling, cooling air filter	
3	Nurse call / Remote alarm	Connection for nurse call	
4	USB data connection port	Data connection (PC and the Vivo 55. The data connection port is only to be used by your care provider)	
5	Memory card slot	Ventilator Memory Data download	
6	Remote Start/ Stop	Connection for remote start/stop module	
7	SpO_2 interface port	Connection for SpO_2 module	SP O2

No	item	Function	Colour/Symbol
8	CO_2 interface port	Connection for CO_2 sensor	
9	FiO_2 interface port	Connection for FiO_2 sensor	
10	Standby button	Power on and off	
11	External DC inlet	Connection for external DC power source	
12	Mains inlet	Connection for mains power source. Read the chapter 4.3 *Connecting the Vivo 55 to AC power (Mains)*, page 32	
13	Exhalation valve control pressure outlet	Connection for exhalation valve control pressure tube	
14	Patient air outlet	Connection for patient circuit	
15	Oxygen inlet port	Connection for low pressure/ bleed-in oxygen source	

3.4 Equipment Designation and Safety Labels

Symbol	Description
MD	This product is a Medical Device.
⚠	**Warning!**
	At click-on battery connector: Make sure not to touch this connector while simultaneously touching the patient.
	At Patient air inlet: Make sure that nothing can block the patient air inlet on the side of the Vivo 55. Read 4.2 *Placing the Vivo 55*, page 31for more information
	At internal and click-on battery: Read the chapter 5.7 *Using Batteries*, page 64.
	Battery
REF	Product number
SN	Serial number
	Date of Manufacture
	Read user instructions
	This product must not be exposed to open fire
	This product should be recycled
	Read 7.7 *Disposal*, page 118 for information about recycling and disposal.
IP22	Degree of protection provided by enclosure The Vivo 55 is rated IP22, which means it is protected from touch by fingers and objects greater than 12 mm, and protected from water spray less than 15 degrees from vertical.

Symbol	Description
	Class II equipment; double insulation
	Body floating IEC 60601-1 Type BF, Isolated Applied Part
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.
	Conforms to IEC 60601-1:2012 including ANSI/AAMI ES60601-1:2005 Conforms to CAN/CSA C22.2 No. 60601-1:08.
	CE marking 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.
	Manufacturer

4 Preparing the Vivo 55 for Use

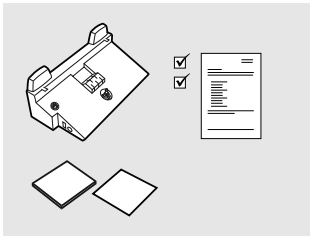
WARNING!

Read the chapter 2 *Safety Information*, page 11 before setting up the Vivo 55.

4.1 Checking the Vivo 55 before First Use

When using the Vivo 55 for the first time, follow the instructions below

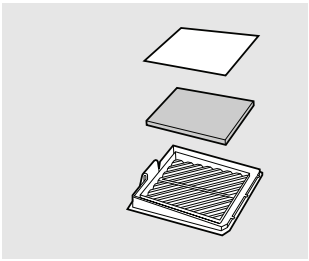
1 Check that all main components and ordered accessories have been delivered. (Refer to the packing note or the invoice, if available.)

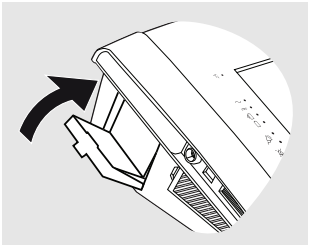


2 Ensure that the equipment is in good condition.

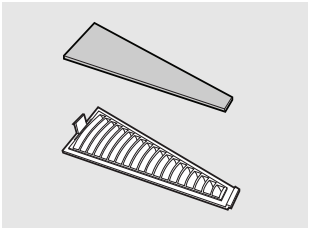
3 If stored more than one month, connect the Vivo 55 to the power supply to recharge the internal battery. (See 5.7.2 *Charging the Batteries*, page 64for further instructions.)

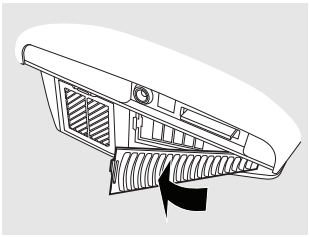
4 Check that the grey and white (optional use) air filters are installed.





5 Check that the grey cooling air inlet filter is installed.





4.2 Placing the Vivo 55

WARNING!

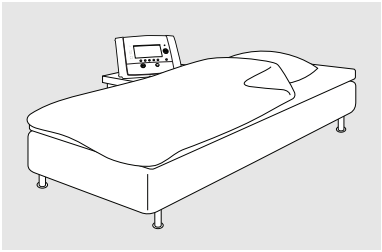
Read the chapter 2.3 *Environmental Conditions*, page 13 carefully to make sure all conditions are met and considered.

Do not place the Vivo 55 on a soft surface that will prevent the air flow underneath the device.

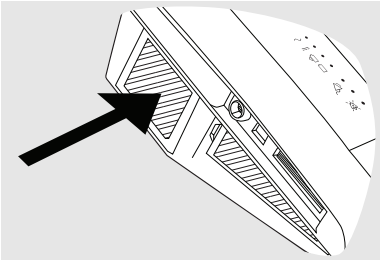
Never cover the device.

Always position the Vivo 55 so that it is easy to remove the power cord from the AC power inlet.

1 Place the Vivo 55 on a solid, flat surface. The Vivo 55 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 inlets on the side of the Vivo 55.

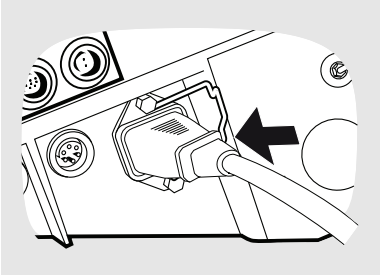


4.3 Connecting the Vivo 55 to AC power (Mains)

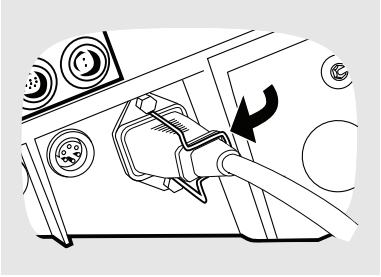
WARNING!

Read the chapter 2.2 *Electrical Safety*, page 13 carefully to make sure all conditions are considered and met.

1 Plug the AC power (Mains) cord into the power inlet of the Vivo 55.



2 Secure the power cord using the restraining clip.



3 Connect the power cord to the AC power (Mains) supply.

To isolate the Vivo 55 from the AC power (Mains) supply, remove the power cord from the AC power inlet.

4.4 Connecting the Patient Circuit

WARNING!

Read the chapter 2.4 *Usage of Patient Circuit*, page 15 carefully to make sure all conditions are considered and met.

NOTE

- Make sure that the correct patient circuit type is selected when connecting a patient circuit.

"Select Patient Circuit Type" is located in the Others section of the Vivo 55 display when the ventilator is in Standby mode.

- In MPV breath mode the patient circuit type setting is not available. Circuit with mouthpiece interface shall always be used in MPV breath mode.

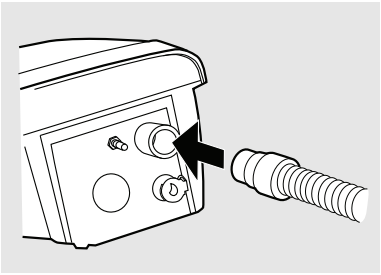
The Vivo 55 can be used with the following circuits:

- Single limb circuit with external active exhalation valve
- Single limb circuit with external leakage port
- Circuit with mouthpiece interface

4.4.1 Connect a Circuit with Leakage Port

The leakage from the mask or leakage port should be at least 12 l/min at 4 cmH_2O, to prevent rebreathing of exhaled air. The recommended leakage is 20 to 50 l/min at 10 cmH_2O pressure.

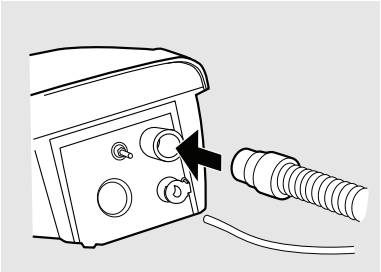
1 Connect the patient circuit to the patient air outlet of the ventilator.



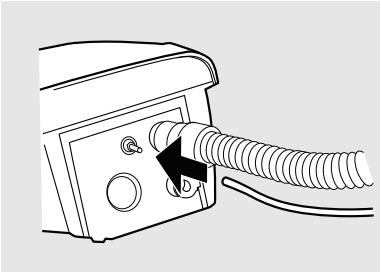
2 Connect the other end of the patient circuit to the leakage port or patient interface.

4.4.2 Connect a Circuit with Active Exhalation Valve

1 Connect the patient circuit to the patient air outlet of the ventilator.



2 Connect the control pressure tubing to the exhalation valve control pressure outlet of the Vivo 55.



3 Connect the other end of the patient circuit to an HME or patient interface.

4.5 Inspecting the Vivo 55 before Use

Inspection of Device

- Check that there is no visible damage.
- Check that the surface is clean.

Inspection of Cables

- Check that all cables are recommended by Breas.
- Check that the cables are undamaged.
- Check that the cables are properly connected.

Inspection of Placement

- The Vivo 55 shall be placed on solid flat surface below the patient level. (See 4.2 *Placing the Vivo 55*, page 31.)
- Make sure that nothing can block the air inlet at the side.

Inspection before Use

Always make the following checks before using the Vivo 55:

1. Connect a patient circuit to the Vivo 55.
2. Connect the Vivo 55 to the AC power (Mains) supply.
3. Turn on the Vivo 55 main power using the Standby button on the side panel.
4. Ensure that the treatment settings and alarm settings are adjusted as prescribed, and that the correct patient circuit type is selected.
5. Perform a pre-use test by following the instructions on the display.

   Note: Pre-use test cannot be performed in MPV breath mode. Skip this step if MPV breath mode is used.
6. Press the Start/Stop button on the front panel until the progress bar is filled.
7. Check that a short double sound signal is heard. If there is no signal, do not use the Vivo 55 and contact your service provider.
8. Disconnect the power cord for more than 5 seconds. Check that the device switches to the internal battery (or click-on battery if connected) and that an information message is shown on the screen together with an audible warning. If this is not the case, contact your service provider.
9. Reconnect the power cord. Check that the device switches to the AC power (Mains) supply and that an information message is shown on the screen together with an audible warning.
10. Connect the patient and adjust and fit the mask if one is used.

4.6 Perform the Pre-Use Test

The pre-use test is used for detecting the type and characteristics of the patient circuit that is connected to the Vivo 55. The resistance and compliance of the patient circuit are measured and calculated. This will be used to compensate for pressure and compliance deviations during treatment.

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

CAUTION!

Always perform a new pre-use test if the patient circuit configuration is modified.

NOTE

If the pre-use test has not been performed, the Vivo 55 will operate with default patient circuit compensation.
Pre-use test cannot be performed in MPV breath mode.

4.6.1 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.

5 How to Use the Vivo 55

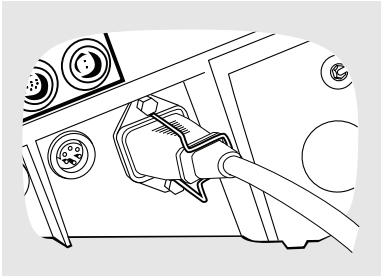
WARNING!

Read the chapter 2 *Safety Information*, page 11 before using the Vivo 55.
When the Vivo 55 is handed over to the patient, the physician in charge or hospital staff must instruct the patient in how the unit works.

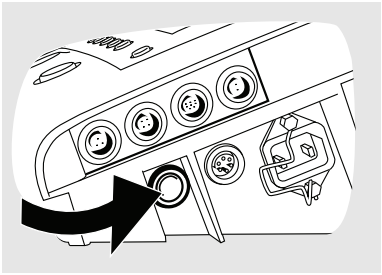
5.1 Turning the Vivo 55 On and Off

5.1.1 Turn On and Enter Operating Mode

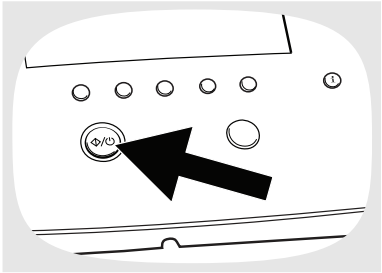
1 Make sure the AC power (Mains) supply is connected and secured by the restraining clip.



2 Turn on the Vivo 55 and enter Standby mode by pressing the Standby button on the side panel.



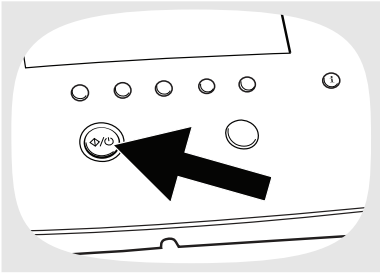
3 To start treatment and enter operating mode first press and hold the Start/Stop button on the front panel.



4 Release the Start/Stop button when the progress bar is filled.

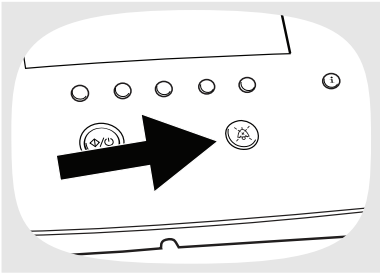
5.1.2 Stopping Treatment and Turning Off

1 To stop treatment and enter Standby mode, first press and hold the Start/Stop button on the front panel.

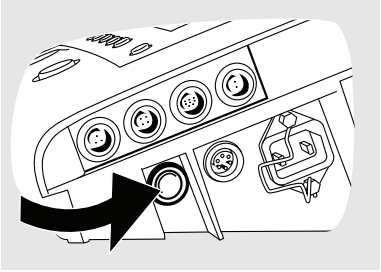


2 Release the Start/Stop button on the front panel when the progress bar is filled.

3 Press the Audio Pause button within 10 seconds. Press the button firmly.



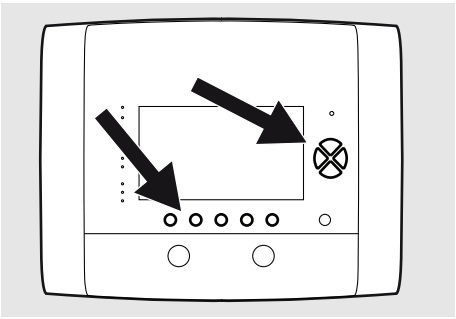
4 When the Vivo 55 is not in an active treatment mode, press the Standby button on the side panel to change the unit to a low power standby state.



5.2 Using the Menu

5.2.1 Navigating with the Buttons

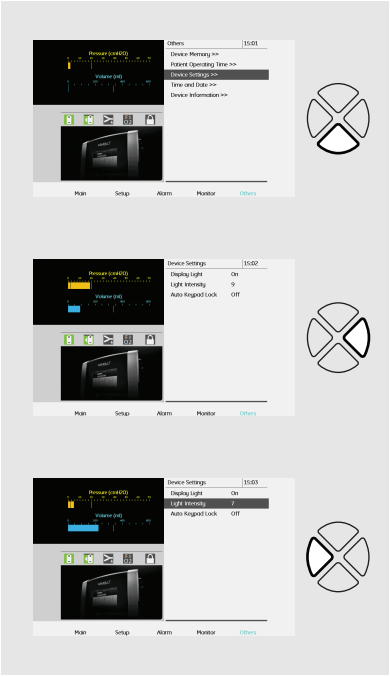
Use the five navigation buttons and the up and down buttons on the panel in order to navigate the Vivo 55 menu.



The navigation buttons are used to view the different sections indicated above each one. The same navigation button can also be used to view additional information in some sections, or it can be designated a temporary function while an event window is active.

NOTE

Use the up or down button to enter the menu list.



Use the arrow buttons (up and down) to navigate up or down in a menu list, or to select different parameters.

Use the arrow buttons (left and right) to alter parameters, or enter and exit sub sections.

5.2.2 Symbols Used in the Menu

Internal battery level

Click-on battery level

Home Mode activated

Leakage circuit selected (Leakage)

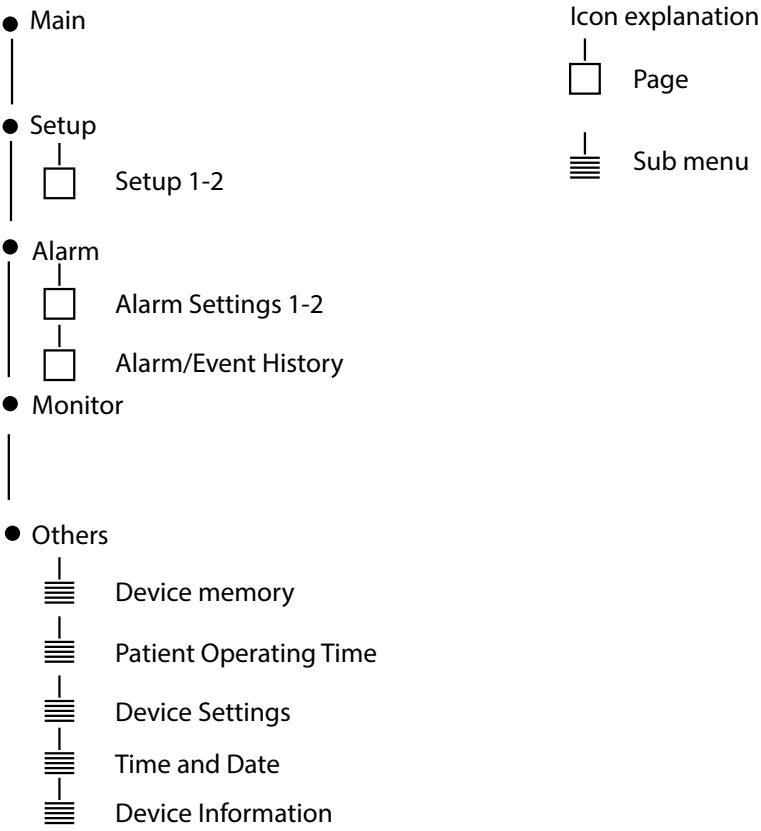
Exhalation valve

Exhalation valve circuit selected (Exh. valve)

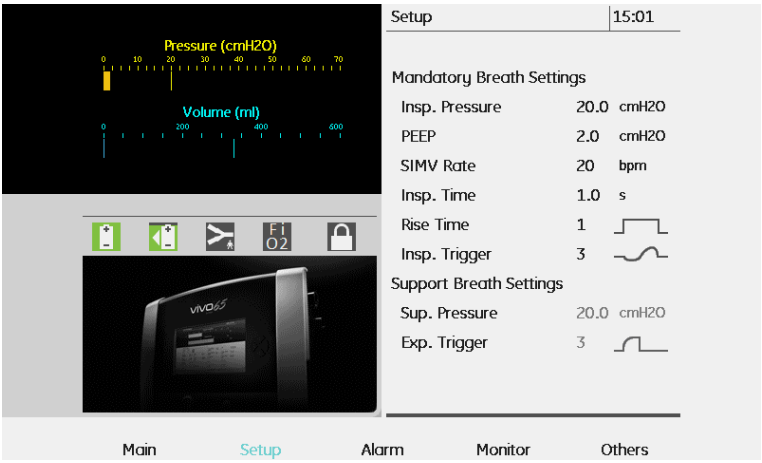
MPV breath mode	
MPV breath mode selected. Circuit with mouthpiece interface shall be used.	
SpO_2 connected	
FiO_2 connected	
CO_2 connected	
Multiple pages	
Multiple content available	
High priority alarm	
High priority alarm event in history list	
Medium priority alarm	
Medium priority alarm event in history list	

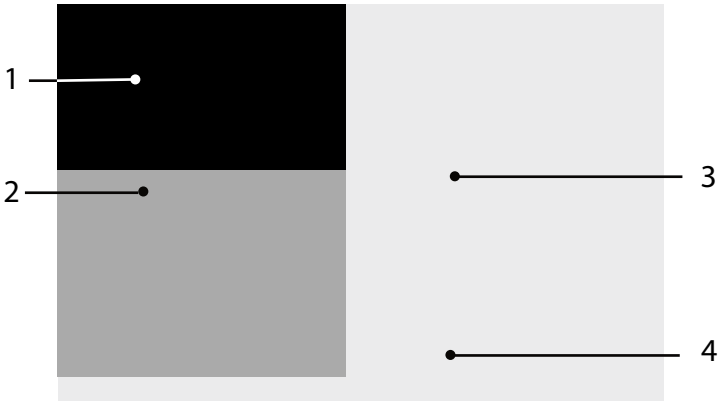
5.2.3 Menu Overview

The Vivo 55 menu has the following section layout:



5.2.4 The Vivo 55 Display





1. **Pressure and Volume Indicators**:

   The bargraphs are used to display current pressure, PEEP, P_{peak}, pressure, and volume alarm limits, and estimated tidal volume .

   The red lines represent the low and high pressure alarms, the low and high tidal volume alarms.

2. **Icon/Alarm Message**:

   Information icons are presented here to give a quick overview of the Vivo 55 basic status. (See 5.2.2 *Symbols Used in the Menu*, page 40.)

3. **Screen, Title and Context Area**:

   Screen title, page number (if more than one subpage exists in the section) and time are displayed.

4. **Navigation Field**:

   This field is mainly used for displaying the section layout of the menu, and determines the function of each navigation button.

   Depending on the current operation, the navigation buttons can be assigned temporary functions such as "Yes" or "Next", depending on which operation is active.

5.2.5 The Setup Section

In the Setup section, treatment parameters can be altered. See 5.4 *Functions and Parameters in the Vivo 55*, page 50.

5.2.6 Home Adjust

The Home Adjust function can be activated by the care provider. When activated, the care provider can unlock treatment parameters and define a limited setting range. The patient and lay care giver can change these settings within the limited range when the Vivo 55 is in Home mode.

Black color indicates that the parameter is possible to adjust within a certain settings range. Grey color indicates that the parameter is locked.

5.2.7 The Alarm Section

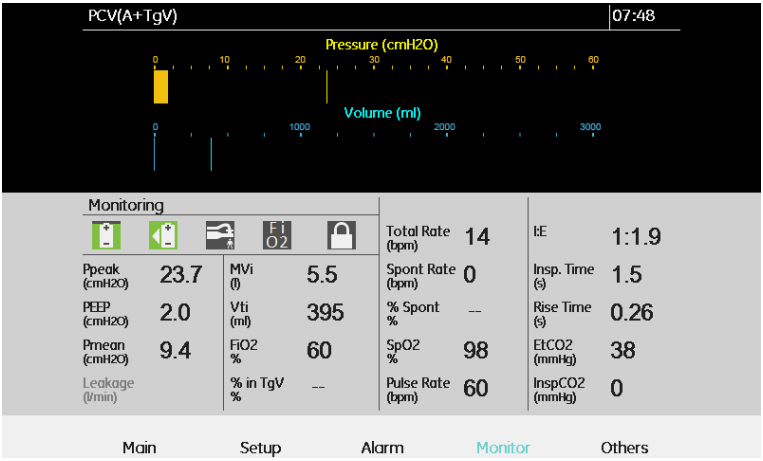
In the Alarm section, the alarm parameters can be altered. (See 6 *Alarms*, page 81 for more information .)

The Alarm/Event History screen displays all events that have been logged, as well as alarms that have occurred. Alarms are coloured according to priority, and are maintained when the Vivo 55 is powered down.

The manufacturer-configured state of physiological alarms may be retrieved by selecting "Reset to basic settings" on the Mode screen in Standby mode.

5.2.8 The Monitor Section

The monitoring section provides display of treatment data.



The monitoring screen contains a bargraph field that displays current Pressure, PEEP and Ppeak, pressure and volume alarm limits, and tidal volume.

The monitoring field displays all available values for the current treatment mode. (In most other screens, except for the curve and trend view, a small monitoring field is displayed with 8 values.) See 5.3 *Monitored Values in the Vivo 55*, page 47 for a description on the monitored values.

5.2.9 The Others Section

WARNING!

For the ventilator to deliver treatment according to settings, it is important that the selection of the patient circuit type is correctly set.

NOTE

Patient circuit type setting is not available in MPV breath mode. In MPV breath mode a circuit with mouthpiece interface shall be used.

- The currently selected profile cannot be turned off.

Device Memory

A memory card can be used for transferring data or settings from the internal memory. See *Transferring Data with a Memory Card*, page 63 for instructions on how to transfer memory data on a card and erase memory data.

Patient Operating Time

Shows the number of hours a patient has been using the Vivo 55 for breathing therapy.

Device Settings

General settings for the Vivo 55:

- Display Light:
  - On — keeps the display lit regardless of use
  - Auto — adjusts the light intensity depending on the ambient light
  - Delayed — dims the display after 30 seconds or more depending on the mode and battery setup. If any button is pressed or any alarm occurs, the display light will return to normal again.

CAUTION!

If the light intensity is set too low, ambient light could cause difficulties in reading the alarm text.

- Light Intensity (setting range: 1-9, where 1 is the lowest and 9 is the highest light intensity setting. In cases where Display Light is set to "Auto", the Light Intensity setting will not be available)
- Alarm Sound Level (setting range: 1-9, where 1 is the lowest and 9 is the highest alarm sound level setting)

CAUTION!

Setting the alarm sound level below that of the ambient sound level can impede recognition of alarm conditions.

- Auto Keypad Lock (On, Off)

Time and Date

- Time (set time: hours and minutes)
- Time Format (choose between 24 h or 12 h am/pm format)
- Date (set date: year, month and day)
- Date Format (choose between yyyy-mm-dd, dd/mm/yyyy, mm/dd/yyyy format)

Device Information

- Device Operating Time (hours)
- Firmware Version
- Language Package
- Lang. Package Version
- AC (On/Off)
- External DC (V)
- Serial Number

5.3 Monitored Values in the Vivo 55

Values monitored by the ventilator can be found in:

- The monitoring screen
- Right hand side field in curve and trend screens

- The monitoring field

5.3.1 Ppeak

Ppeak displays the highest pressure that is recorded during the inspiratory phase.

5.3.2 PEEP

PEEP displays the pressure at the end of the expiratory phase.

5.3.3 Pmean

Pmean displays the calculated mean value of pressure during a complete ventilatory cycle (inspiratory + expiratory phase).

5.3.4 Leakage

Leakage displays the total leakage (intentional and unintentional) as calculated at expiratory pressure level

5.3.5 MVe

MVe displays the expired Minute Volume calculated as expired Tidal Volume multiplied with the Total Breath Rate.

MVe is displayed when a leakage circuit is used.

CAUTION!

When the Vivo 55 is used non-invasively the Mv_e can differ from the exhaled tidal volume from the patient due to leaks around the mask.

5.3.6 MVi

MVi displays the inspired Minute Volume calculated as inspired Tidal Volume multiplied with the Total Breath Rate.

MVi is displayed when an MPV circuit or an active exhalation valve circuit is used.

NOTE

The Vivo 55 is suitable for treatment of patients that require a minute volume between 1 and 30 litres.

5.3.7 % in TgV

% in TgV displays the percentage of breaths where the actual delivered Tidal Volume matches with the set Target Volume (not calculated until 100 breaths are registered).

5.3.8 Vte

Vte displays the Expired Tidal Volume that the patient exhales during each breath.

Vte is displayed when using a leakage patient circuit . Vte is a calculated value.

CAUTION!

When the Vivo 55 is used non-invasively the Vt_e can differ from the exhaled tidal volume from the patient due to leaks around the mask.

5.3.9 Vti

Vti displays the inspired Tidal Volume that the ventilator delivers during each breath.

Vti is displayed when an MPV circuit or an active exhalation valve circuit is used.

5.3.10 FiO_2

The FiO_2 displays the fraction of inspired oxygen as measured in the air channel of the ventilator. An FiO_2 sensor needs to be in place to measure and display this value (see the section on using the ventilator with the FiO_2 sensor.)

5.3.11 Total Rate

The Total Rate displays the actual total breath rate independent of whether the breaths are patient- or ventilator-triggered breaths.

5.3.12 Spont Rate

The Spont Rate displays the actual spontaneous breath rate.

5.3.13 % Spont

% Spont displays the percentage of spontaneous breaths calculated since the ventilator was last started (not calculated until 100 breaths are registered).

5.3.14 SpO_2 (Oxygen Saturation)

The SpO_2 displays the patient's oxygen saturation, if measured with the SpO_2 module accessory.

- When using the ventilator with the SpO_2 sensor accessory, the ventilator displays functional oxygen saturation measured by the sensor.
- The following information concerns the light emitted by the SpO_2 Sensor:

1. Peak Wavelength (red): 660 nm
2. Peak Wavelength (infrared): 905 nm
3. Maximum Optical Output Power: 15 mW
4. 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.

5.3.15 Pulse Rate

Pulse Rate displays the patient's pulse rate as measured with the SpO_2 module.

5.3.16 I:E

I:E displays the ratio between the length of the inspiration and the length of the expiration.

5.3.17 PScalc

PScalc displays the pressure above the PEEP pressure applied to the patient in PCV/PSV mode.

5.3.18 Insp. Time

Insp. Time displays the duration of the inspiratory cycle, measured from the start of inspiration to the start of expiration.

5.3.19 Rise Time

Rise Time displays the duration of the pressure or volume increase, measured from the start of inspiration until the set pressure or volume has been reached.

5.3.20 $EtCO_2$

$EtCO_2$ displays the end-tidal carbon dioxide, measured on the last portion of the exhaled volume that is passing through the $EtCO_2$ sensor.

5.3.21 $InspCO_2$

$InspCO_2$ displays the inspired carbon dioxide.

5.4 Functions and Parameters in the Vivo 55

The parameters used for controlling the breathing by the ventilator are described below.

Depending on the setup for Home mode adjustment, parameters may not be available or have limited ranges when the Vivo 55 is in Home mode.

5.4.1 Parameters' Availability in Different Modes

This table offers an overview of the available parameters in each mode.

Modes Parameter	PCV	PSV	VCV	PCV SIMV	VCV-SIMV	PCV-MPV	VCV-MPV	CPAP
Insp. Pressure	x	x		x		x		
PEEP	x	x	x	x	x			
Breath Rate	x		x					
Insp. Time	x		x	x	x	x	x	
Backup Insp. Time		x						
Sigh Sigh rate Sigh %	x	x	x					
Rise Time	x	x	x	x	x	x	x	
Insp. Trigger	x(2)	x	x(2)	x	x	x	x	
Exp. Trigger		x		x	x			
Min Insp. Time		x						
Max Insp. Time		x						
Backup Rate		x				x	x	

1= Indicated by the (TgV) suffix to the mode description on the display. When activated, *Insp. Pressure* is replaced by *Max Pressure* and *Min Pressure*.
2= Indicated by the (A) suffix to the mode description on the display.

Modes Parameter	PCV	PSV	VCV	PCV SIMV	VCV- SIMV	PCV- MPV	VCV- MPV	CPAP
Target Volume [1]: Max Pressure Min Pressure	x	x						
Tidal Volume			x		x		x	
Flow pattern			x		x	x		
SIMV rate				x	x			
SIMV support pressure				x	x			
CPAP								x
1= Indicated by the (TgV) suffix to the mode description on the display. When activated, *Insp. Pressure* is replaced by *Max Pressure* and *Min Pressure*. 2= Indicated by the (A) suffix to the mode description on the display.								

5.4.2 Insp. Pressure

The Insp. Pressure setting is used to define the airway pressure during the inspiratory phase.

Minimum/maximum working IPAP is limited/achieved by a software control of blower speed vs. measured pressure.

Min	4 cmH_2O
Max	50 cmH_2O
Default	15 cmH_2O
Resolution	0.5 cmH_2O < 10 cmH_2O 1.0 cmH_2O ≥ 10 cmH_2O
Tolerance	± (0.5 cmH_2O+ 5%)

5.4.3 PEEP

The PEEP setting is used to define the airway pressure at the end of the expiratory phase.

Min	2 cmH_2O Off (Off is only for patient circuits with active exhalation valve)
Max	30 cmH_2O For SIMV and pressure ventilation modes: The max setting is also limited by *Insp. Pressure -2 cmH_2O or SIMV Support Pressure - 2 cmH_2O.*
Default	5 cmH_2O
Resolution	0.5 cmH_2O < 10 cmH_2O 1.0 cmH_2O ≥ 10 cmH_2O
Tolerance	± (0.5 cmH_2O+ 5%)

5.4.4 Breath Rate

The Breath Rate setting defines the minimum number of breaths the ventilator will deliver as long as no inspiratory trigger effort from the patient is detected. The cycles will be ventilator-initiated breaths.

The combination of the Breath Rate and Inspiratory Time setting is limited by the I:E ratio range, 2:1 to 1:99.

Min	4 breaths/minute
Max	40 breaths/minute
Default	12 breaths/minute
Resolution	1
Tolerance	± 2%

5.4.5 Backup Rate

The Backup Rate setting defines the minimum number of breaths the ventilator will deliver as long as no inspiratory trigger effort from the patient is detected. The cycles will be ventilator-initiated breaths.

The combination of the Breath Rate and Inspiratory Time setting is limited by the I:E ratio range, 2:1 to 1:99.

Min	4 breaths/minute 0 breaths/minute (MPV)
Max	40 breaths/minute
Default	12 breaths/minute 0 breaths/minute (MPV)
Resolution	1
Tolerance	± 2%

5.4.6 SIMV Rate

The SIMV Rate setting is used in the SIMV ventilation modes, for defining the minimum frequency of mandatory, ventilator-controlled breaths. The mandatory breaths can be either triggered by an inspiratory effort from the patient, or ventilator-initiated. The SIMV Rate setting determines the SIMV cycle time.

The combination of the SIMV Rate and Inspiratory Time setting is limited by the I:E ratio range, 2:1 to 1:99.

Min	4 breaths/minute
Max	40 breaths/minute
Default	12 breaths/minute
Resolution	1
Tolerance	± 2%

5.4.7 Insp. Time (Inspiratory Time)

The Inspiratory Time setting defines the length of each inspiration from start of inspiration to cycling off to expiration.

In the PCV-SIMV and VCV-SIMV modes, this setting is used for defining the inspiration length of the mandatory breaths controlled by the ventilator.

The combination of the Inspiratory Time and Breath Rate or SIMV Rate settings is limited by the I:E ratio range, 2:1 to 1:99.

Min	0.3 s
Max	5 s
Default	1.5 s
Resolution	0.1 s
Tolerance	± (20 msec + 5%) or ± 0.1 s (whichever is smallest)

5.4.8 Backup Insp. Time (Backup Inspiratory Time)

The Backup Inspiratory Time setting defines the length of each inspiration delivered during ventilator-triggered backup ventilation, initiated by the set Backup Rate.

The combination of the Backup Inspiratory Time and Backup Rate setting is limited by the I:E ratio range, 2:1 to 1:99.

Min	0.3 s
Max	5 s
Default	1.5 s
Resolution	0.1 s
Tolerance	± (20 msec + 5%) or ± 0.1 s (whichever is smallest)

5.4.9 Sigh Parameters

With the Sigh function, the ventilator will periodically deliver extended breaths with an increased % of the set pressure or volume.

NOTE

During the sigh breath, the high pressure alarm will automatically be raised (but not higher than the alarm max setting):

- In pressure mode, it will automatically be set 10 cmH_2O above the set sigh pressure .
- In volume mode, it will automatically be increased by the same percentage as the set sigh volume.

When the sigh parameter is on, the following parameters are available:

Sigh	
Min	Off
Max	On
Default	Off
Resolution	—
Tolerance	—
Sigh Rate	The Sigh rate sets the frequency of which breaths with an increased pressure or volume are delivered to the patient. If the High Pressure alarm or the High Tidal Volume alarm is given, the Sigh function will be disabled as long as the alarm condition remains.
Min	1 sigh every 50 breath
Max	1 sigh every 250 breath
Default	1 sigh every 100 breath
Resolution	50
Tolerance	—
Sigh %	Sigh % sets the increased % of the set pressure (pressure mode) or volume (volume modes) is delivered to the patient.
Min	125
Max	200
Default	125
Resolution	25
Tolerance	—

5.4.10 Rise Time

The Rise Time setting controls the speed of the pressure/volume increase from start of inspiration to set inspiratory pressure/tidal volume.

A low setting will give a faster pressure/volume increase and therefore a longer plateau at the set inspiratory pressure/tidal volume. A high setting will give a slow increase and therefore a shorter plateau.

In the VCV-SIMV mode, two different Rise Time settings are made, one for mandatory ventilator-controlled breaths and one for additional pressure support breaths triggered by the patient.

Rise Time in Pressure mode	In pressure control mode (PCV) and pressure support mode (PSV), the rise time is set in steps.
Min	1
Max	9
Default	3
Resolution	1
Tolerance	—

Rise Time in Volume mode	In the Volume Control mode (VCV), the rise time for the support is set as a percentage of the inspiratory time. If using the VCV-SIMV mode, the percentage settings controls the rise time for the mandatory breaths triggered by the ventilator. You can also use step settings as described above, for controlling the rise time for the support breath, triggered by the patient.
Min	50% of set *Insp Time*.
Max	90% of set *Insp Time*. Off
Default	Off
Resolution	10%
Tolerance	± (20 msec + 5%) or ± 0.1 s (whichever is smallest)

5.4.11 Insp. Trigger (Inspiratory Trigger)

The inspiratory trigger defines the patient's effort required to initiate a ventilator assisted breath. When the patient starts a breath, an increasing flow is created in the patient circuit. If the patient's effort reaches the set inspiratory trigger level an inspiration is initiated.

If the patient cannot trigger a breath, the ventilator will deliver breaths according to the set Backup Rate, Breath Rate or SIMV Rate.

Min	1
Max	9 Off (*Off* only available in VCV and PCV modes. *Off* disables the Assist function)
Default	3
Resolution	1
Tolerance	—

5.4.12 Sup. Pressure (SIMV mode)

The Support Pressure setting is used in the SIMV ventilation modes, for defining the inspiratory pressure for the support breaths triggered by the patient.

Min	4 cmH_2O cmH_2O
Max	50 cmH_2O
Default	15 cmH_2O
Resolution	0.5 cmH_2O < 10 cmH_2O 1.0 cmH_2O ≥ 10 cmH_2O
Tolerance	± (0.5 cmH_2O+ 5%)

5.4.13 Exp. Trigger (Expiratory Trigger)

The Expiratory Trigger setting defines the moment when the ventilator will cycle from the inspiratory to the expiratory phase.

In PCV-SIMV and VCV-SIMV modes, this setting is applicable to the pressure support breaths that are triggered by the patient.

Min	1
Max	9
Default	3
Resolution	1
Tolerance	—
Low value is easy to trigger, high value is harder to trigger. (Each step corresponds to 10% decrease from peak flow). Setting 1 cycles off early and 9 cycles off late.	

5.4.14 Minimum Inspiratory Time (Min Insp. Time)

The Minimum Inspiratory Time setting defines a minimum length for each inspiration. If the Minimum Inspiratory Time is set to Off, the length of the inspiration is dependent on the set Expiratory Trigger or the maximum inspiratory time.

Min	0.3 s Off
Max	3 s
Default	Off
Resolution	0.1 s
Tolerance	± (20 msec + 5%) or ± 0.1 s (whichever is smallest)

5.4.15 Maximum Inspiratory Time (Max Insp. Time)

The Maximum Inspiratory Time setting defines a maximum length for each inspiration. If the Maximum Inspiratory Time is set to Off, the length of the inspiration is dependent on the set Expiratory Trigger and/or minimum inspiratory time.

Min	0.3 s
Max	3 s Off
Default	Off
Resolution	0.1 s
Tolerance	± (20 msec + 5%) or ± 0.1 s (whichever is smallest)

5.4.16 Target Volume

CAUTION!

If Target Volume is used with a patient circuit with an active exhalation valve, leakage may be misinterpreted by the Vivo 55 as an increase of tidal volume. This will lead to a decrease of the Inspiratory Pressure (the Inspiratory Pressure will not be lower than the set Min Pressure). This may result in hypoventilation as the true delivered tidal volume will decrease both as a result of the leakage and the decrease in Inspiratory Pressure. This does not occur if a patient circuit with leakage port is used.

The Target Volume setting defines the tidal volume that the Vivo 55 will aim for while ventilating the patient in a pressure mode. To aim for the preset volume, the Vivo 55 will adapt the Inspiratory Pressure between two adjustable pressure limits: Min Pressure and Max Pressure.

When Target Volume is active, the mode field on the Vivo 55 display will indicate "(TgV)".

Min	100 ml
Max	2500 ml
Default	300 ml
Resolution	10 ml < 500 ml 50 ml ≥ 500 ml
Tolerance	± (12ml + 10%) (Valid down to 50 ml breaths with bpm >= 20 and I:E ratio 1:2)

5.4.17 Max Pressure

The Max Pressure setting is only used when Target Volume is activated. Max Pressure defines the upper pressure limit up to where the Vivo 55 can increase the pressure to reach the set Target Volume. If Target Volume is not reached at Max Pressure, the Vivo 55 will continue to ventilate at this Max Pressure setting.

Min	Current *Min Pressure*
Max	50 cmH_2O
Default	15 cmH_2O
Resolution	0.5 cmH_2O < 10 cmH_2O 1.0 cmH_2O ≥ 10 cmH_2O
Tolerance	± (0.5 cmH_2O+ 5%)

5.4.18 Min Pressure

The Min Pressure setting is only used when Target Volume is activated. Min Pressure defines the lower pressure limit down to where the Vivo 55 can decrease the pressure to maintain the set Target Volume. If the actual volume is above Target Volume at Min Pressure, the Vivo 55 will continue to ventilate at this Min Pressure setting.

Min	4 cmH_2O
Max	Current *Max Pressure*
Default	15 cmH_2O
Resolution	0.5 cmH_2O < 10 cmH_2O 1.0 cmH_2O ≥ 10 cmH_2O
Tolerance	± (0.5 cmH_2O+ 5%)

5.4.19 Tidal Volume

The Tidal Volume setting defines the volume that will be delivered by the Vivo 55 for each breath.

In VCV-SIMV mode, this setting is applicable to the mandatory breaths that are controlled by the ventilator.

Min	100 ml
Max	2500 ml
Default	400 ml
Resolution	10 ml < 500 ml 50 ml ≥ 500 ml
Tolerance	± (12ml + 10%) (Valid down to 50 ml breaths with bpm >= 20 and I:E ratio 1:2)

5.4.20 Flow Pattern

The Flow Pattern setting is used to define how the flow will be delivered during inspiration. When a square wave pattern is applied the flow will be constant throughout the rise time of the inspiratory cycle. When a decelerating wave pattern is applied the flow will be higher at the start of the inspiratory cycle and decrease towards the end. The decelerating flow pattern might help to prevent air hunger.

Values	Square Decelarating
Default	Square

5.4.21 CPAP

The CPAP setting defines the pressure that will be applied to the airways.

Min	4 cmH_2O
Max	20 cmH_2O
Default	10 cmH_2O
Resolution	0.5 cmH_2O < 10 cmH_2O 1.0 cmH_2O ≥ 10 cmH_2O
Tolerance	± (0.5 cmH_2O+ 5%)

5.5 Modes

In the Modes section of the display, the operator selects the ventilation mode, breath mode and device mode for the treatment.

5.5.1 Standby and Operating Mode

Standby mode is defined as the state of the ventilator when AC power (Mains) is connected and the Standby button has been pressed, but without starting the ventilator with the Start/ Stop button.

Operating mode is defined as the state of the ventilator when the blower is operating and producing an air flow.

Switch between operating and standby mode by starting/stopping the Ventilator (see 5.1 *Turning the Vivo 55 On and Off*, page 37).

Some operations (such as setting time and date) are only available in Standby mode.

5.5.2 Ventilation and Breath Modes

The ventilation and breath modes are used for controlling the ventilation treatment with the Vivo 55. The ventilation mode selected can be either Pressure, Volume or CPAP. It is used in combination with the Support, Assist/Control, SIMV or MPV breath mode.

The following combinations of ventilation and breath modes can be selected for the Vivo 55:

- PSV – Pressure Support Ventilation
- PSV(TgV) – Pressure Support Ventilation with Target Volume
- PCV – Pressure Controlled Ventilation
- PCV(TgV) – Pressure Controlled Ventilation with Target Volume
- PCV(A) – Assisted Pressure Controlled Ventilation
- PCV(A+TgV) – Assisted Pressure Controlled Ventilation with Target Volume
- PCV-SIMV – Pressure Controlled Ventilation with Synchronized Intermittent Mandatory Ventilation
- PCV-MPV – Pressure Controlled Ventilation with MouthPiece Ventilation
- VCV – Volume Controlled Ventilation
- VCV(A) – Assisted Volume Controlled Ventilation
- VCV-SIMV – Volume Controlled Ventilation with Synchronized Intermittent Mandatory Ventilation
- VCV-MPV – Volume Controlled Ventilation with MouthPiece Ventilation
- CPAP – Continuous Positive Airway Pressure

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, when 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 backup 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 has reached the limit for maximal inspiration time or 3 seconds.
- The limit for the high-pressure alarm is reached.

PSV(TgV) – Pressure Support Ventilation with Target Volume

The PSV(TgV) mode acts as the PSV mode but with an added regulation of the pressure. Target volume is a feature that automatically adapts the pressure to make sure that the ventilator delivers the desired set target volume to the patient. The delivered volume is compared to the set target volume on a breath by breath basis. The delivered pressure for the next breath will be increased or decreased depending on the difference between the delivered volume and the set target volume. Automatic pressure adjustments will be made in between two adjustable limits (min pressure and max pressure) in order to deliver the optimal support to the patient.

See also the section on Target Volume setting above.

PCV – Pressure Controlled Ventilation

In the PCV mode the ventilation is controlled by the ventilator. This is done at the preset pressure, breath rate, inspiratory time, and rise time settings set by the operator.

The inspiration stops and an expiration starts in two cases:

- The inspiration time expires.
- The limit for the high pressure alarm is reached.

PCV(A) – Assisted Pressure Controlled Ventilation

In the PCV(A) mode the ventilation is controlled by the ventilator, but the patient has the possibility to start a breath through the Inspiratory Trigger. This patient triggered breath will be delivered with the inspiratory time, rise time and pressure setting set by the operator.

PCV(TgV) – Pressure Controlled Ventilation with Target Volume

The PCV(TgV) mode acts as the PCV mode, but with an added regulation of the pressure. Target volume is a feature that automatically adapts the pressure to make sure that the ventilator delivers the desired set target volume to the patient. For every breath, the delivered volume is compared to the set target volume. The delivered pressure for the next breath will be increased or decreased depending on the difference between the delivered volume and the set target volume. Automatic pressure adjustments will be made in between two adjustable limits (min pressure and max pressure) in order to deliver the optimal support to the patient.

See 5.4.16 *Target Volume*, page 56 for more information about Target Volume.

PCV(A+TgV) – Assisted Pressure Controlled Ventilation with Target Volume

The PCV(A+TgV) mode acts like the PCV(A) mode, but with an added regulation of the pressure. Target volume is a feature that automatically adapts the pressure to make sure that the ventilator delivers the desired set target volume to the patient. The delivered volume is compared to the set target volume on a breath by breath basis. The delivered pressure for the next breath will be increased or decreased depending on the difference between the delivered volume and the set target volume. Automatic pressure adjustments will be made in between two adjustable limits (min pressure and max pressure) in order to deliver the optimal support to the patient.

See 5.4.16 *Target Volume*, page 56 for more information about Target Volume.

PCV-SIMV – Pressure Controlled Ventilation with Synchronized Intermittent Mandatory Ventilation

In the PCV-SIMV mode, the Vivo 55 synchronizes mandatory pressure-controlled breaths with the patient's breathing efforts.

In this mode, the ventilator delivers mandatory pressure-controlled breaths with a preset breath frequency defined as the SIMV Rate. The SIMV Rate setting determines the length of the SIMV cycle.

For each SIMV cycle, there is an initial mandatory period in which the patient may trigger one mandatory breath. This mandatory period is always 80% of the SIMV cycle time. If the patient does not trigger a breath during this period, the ventilator will deliver one mandatory breath automatically in the end of the period.

Between the mandatory breaths, the patient may trigger spontaneous breaths until the next SIMV cycle begins. The ventilator will respond to the patient's inspiration efforts with additional pressure support breaths. The inspiratory pressure of these support breaths is defined by the SIMV Support Pressure, together with the settings for Rise Time and Expiratory Trigger. The default value for SIMV Support Pressure is the Inspiratory pressure in PCV.

PCV-MPV – Pressure Controlled Ventilation with MouthPiece Ventilation

The PCV-MPV mode is tailored specifically for those patients that uses mouthpiece interface together with pressure controlled ventilation.

In MPV breath mode it is possible to set Breath Rate to zero so that breaths are only initiated when the patient triggers them using the mouthpiece. PEEP setting is not available but always set to Off so that no air blows from the mouthpiece when no breaths are delivered.

As the patient is not always connected to the ventilator several of the surveillance functions are not working in the same way as in other modes:

- Disconnection alarm is not available in MPV mode.
- Low Pressure alarm is only active during breaths.
- Apnea alarm is possible to set to longer times and is an important mean of surveillance to make sure that the patient gets ventilation support regularly.

When switching to MPV mode all alarms, except from High/Low Pressure Alarms, are automatically switched off to avoid false alarm triggering (when changing between profiles the alarm settings does not change to Off, but stays as defined in the profiles).

WARNING!

- The alarm levels must be assessed and adjusted considering the patients condition and treatment settings.
- MPV breath mode shall be used with a mouthpiece interface only.
- MPV breath mode shall not be used with ventilator dependent patients.

VCV – Volume Controlled Ventilation

In the VCV mode the ventilation is controlled by the Vivo 55. This is done with the preset tidal volume, breath rate, inspiratory time, and rise time settings set by the operator.

The inspiration stops and an expiration starts in two cases:

- The inspiratory time expires.
- The limit for the high pressure alarm is reached.

VCV(A) – Assisted Volume Controlled Ventilation

In the VCV(A) mode the ventilation is controlled by the Vivo 55, but the patient has the possibility to start a breath through the inspiratory trigger. This patient triggered breath will be delivered with the inspiratory time, rise time and tidal volume setting set by the operator.

VCV-SIMV – Volume Controlled Ventilation with Synchronized Intermittent Mandatory Ventilation

In the VCV-SIMV mode, the Vivo 55 synchronizes mandatory volume-controlled breaths with the patient's breathing efforts.

In this mode, the ventilator delivers mandatory volume-controlled breaths with a preset breath frequency defined as the SIMV Rate. The SIMV Rate setting determines the length of the SIMV cycle.

For each SIMV cycle, there is an initial mandatory period in which the patient may trigger one mandatory breath. This mandatory period is always 80% of the SIMV cycle time. If the patient does not trigger a breath during this period, the ventilator will deliver one mandatory breath automatically in the end of the period.

Between the mandatory breaths, the patient may trigger spontaneous breaths until the next SIMV cycle begins. The ventilator will respond to the patient's inspiration efforts with additional pressure support breaths. The inspiratory pressure of these support breaths is defined by the SIMV Support Pressure, together with the settings for Rise Time and Expiratory Trigger. The default value for SIMV Support Pressure is the Inspiratory pressure set in PCV or PSV.

VCV-MPV – Volume Controlled Ventilation with MouthPiece Ventilation

The VCV-MPV mode is tailored specifically for those patients that uses mouthpiece interface together with volume controlled ventilation.

In MPV breath mode it is possible to set Breath Rate to zero so that breaths are only initiated when the patient triggers them using the mouthpiece. PEEP setting is not available but always set to Off so that no air blows from the mouthpiece when no breaths are delivered.

As the patient is not always connected to the ventilator several of the surveillance functions are not working in the same way as in other modes:

- Disconnection alarm is not available in MPV mode.
- Low Pressure alarm is only active during breaths.
- Apnea alarm is possible to set to longer times and is an important mean of surveillance to make sure that the patient gets ventilation support regularly.

When switching to MPV mode all alarms, except from High/Low Pressure Alarms, are automatically switched off to avoid false alarm triggering (when changing between profiles the alarm settings does not change to Off, but stays as defined in the profiles)

WARNING!

- The alarm levels must be assessed and adjusted considering the patients condition and treatment settings.
- MPV breath mode shall be used with a mouthpiece interface only.
- MPV breath mode shall not be used with ventilator dependent patients.

CPAP – Continuous Positive Airway Pressure

In CPAP mode the ventilator is applying a continuous positive pressure to the airways. The flow will automatically be adjusted to maintain the set CPAP level. CPAP mode can only be used when a leakage circuit is selected.

Sigh

When the Sigh feature is enabled the ventilator will deliver a Sigh breath as configured by the prescriber at a certain preset frequency. A Sigh is a breath where an increased % of the set pressure or volume is delivered to the patient.

In Volume modes the ventilator can deliver a Sigh using 125%, 150%, 175% or 200% of the set Tidal Volume. The Tidal Volume that will be used during the Sigh for the selected % will be displayed on the Setting screen.

In Pressure modes the ventilator can deliver a Sigh using 125%, 150%, 175% or 200% of the set Inspiratory Pressure. The Inspiratory Pressure that will be used during the Sigh for the selected % will be displayed on the Setting screen.

The Sigh frequency can be set to occur once every 50, 100, 150, 200 or 250 mandatory or assisted breaths.

NOTE

In pressure modes (during the sigh breath), the high pressure alarm will automatically be set 10 cmH_2O above set sigh pressure (max 60 cmH_2O).

In volume modes (during the sigh breath), the high pressure alarm will automatically be increased by the same percentage as the set sigh volume (max 60 cmH_2O).

5.6 Transferring Data between the Vivo 55 and a PC

WARNING!

Read the chapter 2.2 *Electrical Safety*, page 13 carefully to make sure all conditions are considered and met.

CAUTION!

Do not eject the memory card or disconnect the Vivo-PC data cable while the Vivo 55 is transferring data. Doing so may result in loss of data and/or damaged equipment.

NOTE

In order to view and present patient data correctly, the Vivo 55 PC Software must be installed on the PC.

Instructions on how to manage data in the Vivo 55 PC Software can be found in the software help.

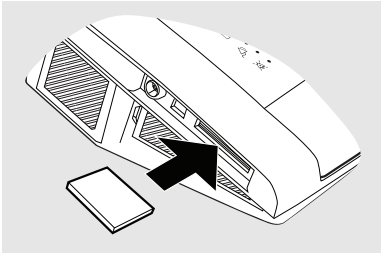
Data can be transferred in two ways:

Transferring Data with a Memory Card

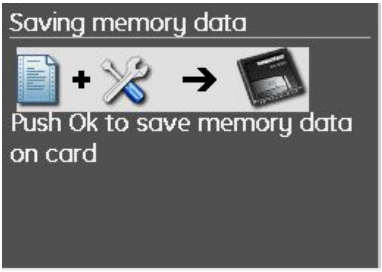
NOTE

The Vivo 55 can copy and transfer data to the memory card.

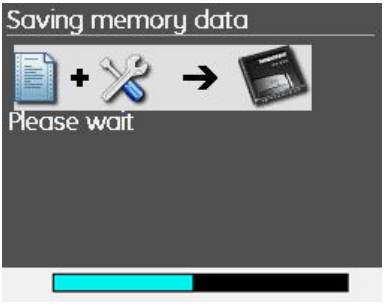
1 Insert the memory card in the memory card slot on the side of the Vivo 55. Make sure the memory card is properly inserted.



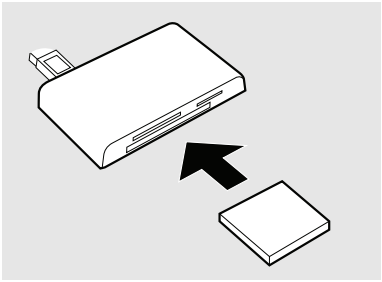
2 When the memory card is inserted, a pop-up window will appear on the Vivo 55's display. Press OK to start saving data on the memory card.



3 Wait while the Vivo 55 is saving to the memory card.



4 Connect the memory card reader/writer to a PC and insert the memory card.



WARNING!

The PC must be placed outside the patient area (i.e. more than 2 meters (7 feet) from the patient).

- Data transmitted over the USB port is not to be relied on for monitoring parameters such as alarms that may require an immediate clinical response. USB data output does not substitute for the ventilator's standard output mechanisms (display, alarm system, visual indicators, accessory interfaces, etc).
- Do not connect wireless devices such as USB wireless dongles to the USB port of the ventilator. Use of wireless technologies may interfere with the operation of the ventilator and other nearby devices.

NOTE

The Vivo 55's USB data connection port is isolated. A USB data cable (part no. 004886) can be used for transferring data if the PC is connected to mains or running on batteries.

5.7 Using Batteries

Since all batteries, in general, degenerate over time, the recommendations below will ensure that the battery capacity of the Vivo 55 is maximized during its lifetime.

The internal and click-on batteries in the Vivo 55 are of the Lithium-ion type, which is a high performance battery. It has long expected lifetime, low weight in relation to its capacity and low self discharge.

See the Vivo 55 Service Manual on how to perform service on the batteries.

5.7.1 Power Source Priority

1. AC power (Mains)
2. External DC
3. Click-on battery
4. Internal battery

When a power source fails or is disconnected, the Vivo 55 will switch to either the external DC (if installed), the click-on battery (if attached) or the internal battery and show a message in the display window.

NOTE

The switchover to internal battery can be tested by disconnecting the AC power cord. Switchover is indicated by power source LED and information message on the screen.

5.7.2 Charging the Batteries

CAUTION!

Do not charge the ventilator while placed in the carry bag or other types of closed or non-ventilated spaces.

The batteries have no “memory effect” (with older battery types it was an advantage to fully discharge and charge the battery, otherwise they will “learn” not to use the full capacity). The new batteries perform best if no complete cycles are made. Therefore it is only an advantage to charge the battery as soon as an opportunity arises.

The internal and click-on batteries are automatically charged when connecting the Vivo 55 to the mains supply. To ensure that the batteries are fully charged, a maintaining charging cycle will be performed. The batteries are not charged when connecting the Vivo 55 to an external DC supply. While charging, the battery level will be animated. The batteries are only charged if the internal temperatures are between 0 to 45°C (32 to 113°F). High power consuming settings in combination with high ambient temperatures may make the battery temperature rise above 45°C (113°F).

Charging Times

BATTERY	CHARGER	TIME*
Internal battery	Vivo 55	3 h
Click-on battery	Vivo 55	5.5 h
Click-on battery	Click-on battery charger	3 h

** Times are based on charging empty batteries.*

5.7.3 Battery Icons

When running on battery, the battery status is indicated by the following symbols:

SYMBOLS	BATTERY STATUS
	Full
	Medium
	Empty/Low
	Disconnected or malfunctioning
	Malfunctioning

5.7.4 Internal Battery

The internal battery is intended as a backup power source if the primary AC power (Mains) source fails. It can also be used as a temporary power source. For example during transportation between one stationary power source to another.

The battery level is displayed in the icon row, monitoring field.

5.7.5 Click-on Battery

WARNING!

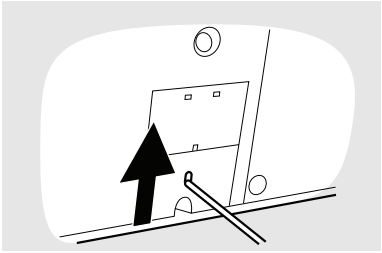
The patient must not remove nor replace the click-in battery during treatment.

The click-on battery is intended as a power source during transportation, or if the primary AC power (Mains) source fails.

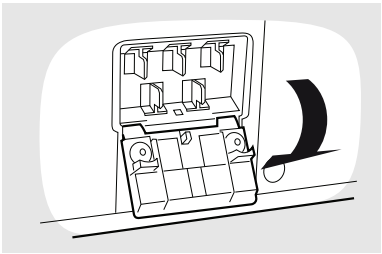
The click-on battery can be replaced during treatment, provided that the internal battery is charged.

Connect the Click-on Battery

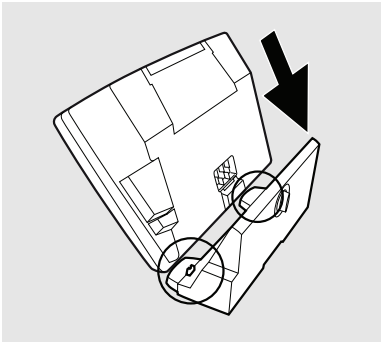
1 Use, for example, a small screwdriver to open the cover for the click-on battery connectors.



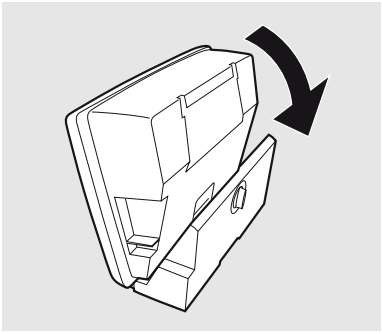
2 Make sure the cover is completely opened.



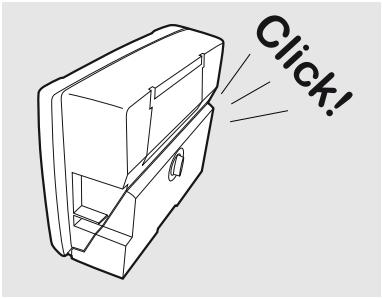
3 Hold the Vivo 55 as shown in the picture, in order to target the click-on battery holders (marked with circles).



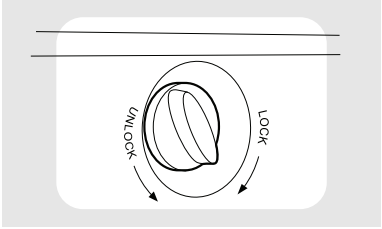
4 Tilt the Vivo 55 into an upright position.



5 Once in position, a clicking sound should be heard.



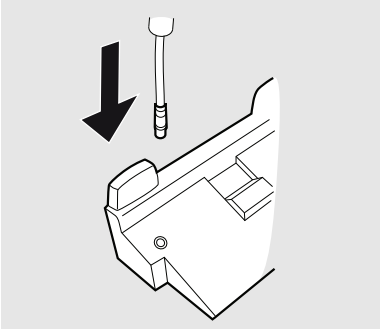
6 Use the screw to secure the click-on battery by pressing it in and turn clockwise.



Remove the click-on battery in reverse order. Make sure the cover is closed after disconnecting the click-on battery.

Charging the Click-on Battery using Click-on Battery Charger

1 Connect the click-on battery charger to the click-on battery.



2 Connect the charger to the AC power (Mains) supply.

To charge an empty click-on battery using the click-on battery charger takes about 3 hours.

5.7.6 Battery Operating Time (Internal and Click-on)

The operation time is dependent on the battery condition, its capacity, the ambient air temperature and the Vivo 55 pressure setting. These data are based on new and fully charged batteries.

PARAMETER	EXAMPLE 1	EXAMPLE 2
Ventilator settings		
Mode	VCV	PCV
Tidal Volume	800 ml	N/A
Inspiratory Pressure	N/A	30 cmH_2O
PEEP	5 cmH_2O	5 cmH_2O
Breath Rate*	20 bpm	30 bpm
Insp. Time*	1 s	0.6 s
I : E (Calculated)	1 : 2	1 : 2.3
Insp. Trigger	Off	Off

PARAMETER	EXAMPLE 1	EXAMPLE 2
Rise Time	Off	4
Flow Pattern	Square	N/A
Display Light*	On	On
Light Intensity*	5	5
Lung Characteristics		
Resistance	5 hPa(l/s)-1 ±10%	200 hPa(l/s)-1 ±10%
Compliance	50 ml(hPa)-1 ±5%	3 ml(hPa)-1 ±5%
Operating Time		
Internal Battery	3.5 h	3.5 h
Click-on Battery	8 h	8 h

* *These ventilator settings affect the operating time significantly.*

5.7.7 Storing the Internal Battery and the Click-on Battery

Storage longer than one month should be initiated with half-charged batteries in order to maintain maximum capacity.

Optimal storage temperature is 5 to 30°C (41 to 86°F).

5.7.8 External DC

WARNING!

Do not connect the ventilator to a wheelchair unless the operating manual for the wheelchair permits this as this can affect the ventilator performance and consequently result in patient death.

CAUTION!

Only use a battery charger compliant to IEC 606011 if you are charging a battery that at the same time is connected to the ventilator.

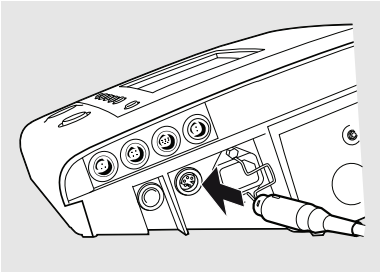
The Vivo 55 can be operated from:

- The Breas XPAC using the XPAC battery cable.
- a 12 V external DC source using the 12/24 V converter.
- a 24 V external DC source using the external battery cable.

See 9.2 *Power Accessories*, page 136 for part numbers and more information.

With an external DC source connected, the Vivo 55 will automatically switch over to the external DC source if the AC power (Mains) cord is removed or if the AC power (Mains) supply fails. The external DC voltage level is shown under “Others”, “Device Information” in the menu.

1 Connect the external DC cable to the Vivo 55. Make sure that it is fitted correctly.

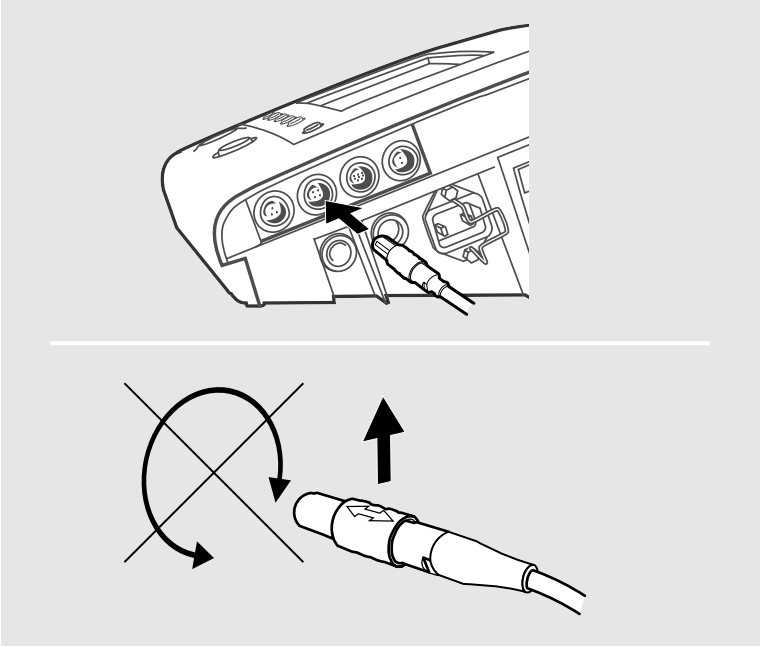


2 Connect the other end of the cable to the DC source.

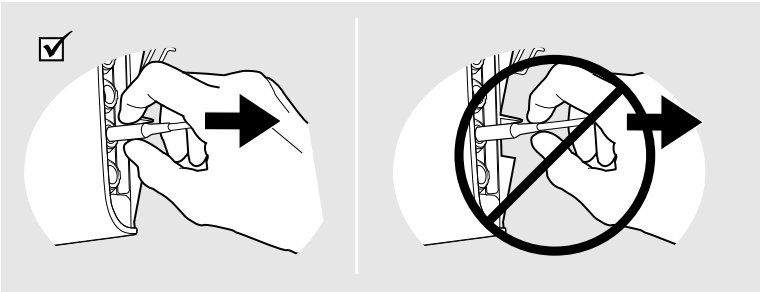
The switchover to external DC can be tested by connecting the external DC source and then disconnecting the AC power cord. The Vivo 55 will automatically switch to external DC as power source. Switchover is indicated by power source LED and information message on the screen.

5.8 Using Accessories

5.8.1 Connecting and Disconnecting the Cables



Insert the connector with the marking pointing upwards.

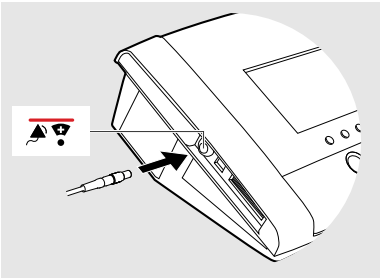


Pull the connector sleeve, not the cable itself or cable restrainer to release the connector.

5.8.2 Using the Vivo 55 with a Nurse Call System

The Vivo 55 can be connected to a nurse call system using the nurse call cable. When connected, the Vivo 55 alarms will also be forwarded to the nurse call system.

1 Connect the nurse call cable on the left side panel of the Vivo 55.



2 Test the connection by triggering an alarm on the Vivo 55 and verify that the nurse call system activates.

5.8.3 Using the Vivo 55 with the FiO_2 Sensor

The FiO_2 sensor can be connected to the Vivo 55 in order to monitor and store FiO_2 measurements. The FiO_2 sensor measures the fraction of inspired oxygen at the air outlet of the Vivo 55. The FiO_2 measurements will be stored in the data memory which can be downloaded to a PC and viewed in the Vivo 55 PC software.

The FiO_2 sensor is not intended to be in contact with the patient's body.

The FiO_2 sensor should be calibrated when first connected and then at least once a month.

NOTE

FiO_2 calibration can be performed by a clinician.

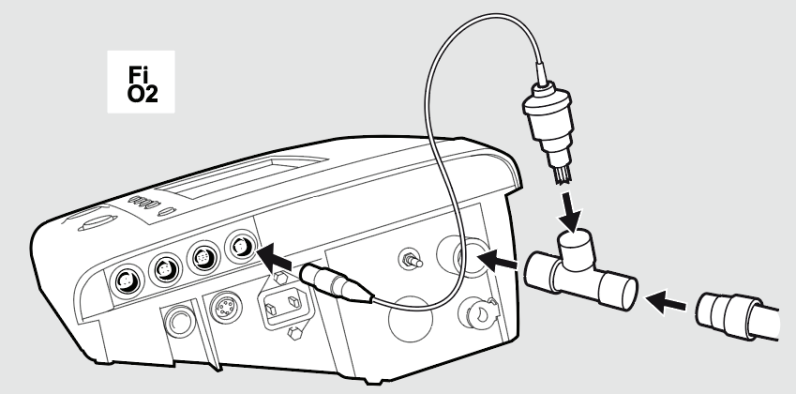
CAUTION!

Note that the operating conditions for the FiO_2 sensor is different from the ventilator system conditions. If the sensor is used outside its operating conditions the FiO_2 measurements might deviate.

NOTE

The FiO_2 monitoring automatically compensates for changes in ambient barometric pressure.

How to Connect the FiO2 Sensor



USAGE	TIME
Operating temperature	10 to 40°C (50 to 104°F)
Operating pressure	700 to 1250 mbar
Response time	<12 s
Expected operating life	<6 years (in ambient air) 1 year (in 100% O_2)
Shelf life	6 months

Cleaning

WARNING!

- Always be careful when cleaning to ensure that you do not damage any equipment.
- Fluid must not be allowed to enter into the FiO_2 sensor.
- Always clean the T-piece with plug when to be used by a new patient. All parts that come into contact with the respiration gas must be cleaned.

1. Remove the FiO_2 sensor with cable from the T-piece and the Vivo 55. Disconnect the T-piece from the Vivo 55 and the patient circuit. Dismantle the plug from the T-piece.
2. Place the T-piece and the plug in hot water containing mild detergent.
3. Remove fouling with a brush.
4. Rinse the parts thoroughly under running hot water.
5. Shake any water out.
6. Dry the T-piece and plug completely.

Disinfection

The T-piece and plug can be disinfected by the following solutions, provided that the disinfectants are used according to the manufacturer's instructions. Do not disinfect the FiO_2 sensor and cable.

Before disinfection, always clean the T-piece and plug as described above.

After disinfection, thoroughly rinse the T-piece and plug in running water for 2 minutes, in order to remove any residue of the disinfectant. Make sure to rinse all surfaces. Dry the parts before use.

Below are listed the disinfectants and recommended periods with regard to disinfection effectiveness and the material durability of the patient circuit parts:

DISINFECTION SOLUTION	FULL EFFECTIVENESS	MATERIAL DURABILITY
Gigasept® FF	5% solution) 15 minutes	10% solution) 15 minutes up to 20 cycles
Steranios 2%	10 minutes	10 minutes up to 20 cycles

Autoclaving

The T-piece can withstand to be autoclaved at 126 °C (258 °F) for 15 minutes. This treatment can be repeated up to 20 times. Do not autoclave the FiO_2 sensor and cable.

WARNING!

The effectiveness of this sterilization method has not been validated. It is recommended with regard to material durability only.

After cleaning

Check that there is no visible damage.

5.8.4 Using the Vivo 55 with the Remote Alarm

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 55 alarms remotely. The Remote Alarm forwards alarms from the Vivo 55. When an alarm sounds, the care provider or clinical personnel must attend to the patient quickly.

5.8.5 Using the Vivo 55 with the CO_2 Sensor

The CO_2 sensor can be connected to the patient breathing circuit and to a Vivo 55 in order to monitor and store CO_2 measurements. The CO_2 measurements will be stored in the Vivo 55 data memory which can be downloaded to a PC and viewed in the Vivo 55 PC software.

5.8.5.1 Safety Information

WARNING!

Read the instructions thoroughly so that you completely understand how the $EtCO_2$ sensor is operated before taking it into use, to ensure correct usage and maximum performance.
Breas Medical reserves the right to make changes to this product without any prior notification.

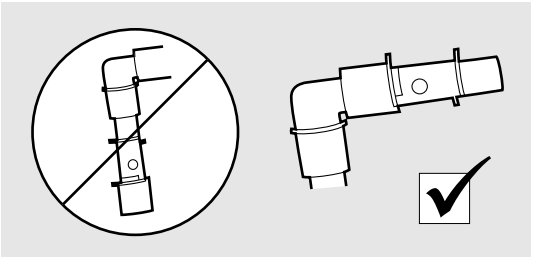
Do not use a damaged CO_2 sensor or adapter.
The CO_2 sensor is intended to be used by authorized and trained medical personnel only.

The CO_2 sensor is intended only as an adjunct in patient assessment. It must be used in conjunction with other assessments of clinical signs and symptoms.

Masks' dead-space, patient's volumes and unintentional leakage may influence the CO_2 measurements.

Used airway adapters shall be disposed of in accordance with local regulations for medical waste.

Measurements can be affected by mobile and RF communications equipment. It should be assured that the CO_2 sensor is used in the electromagnetic environment specified in 8.3 *Emission and Immunity Declaration*, page 127.



Do not place the airway adapter between the endotracheal tube and an elbow as this may allow patient secretions to block the adapter windows and result in incorrect operation.

Incorrect CO_2 zeroing will result in false gas readings.
Replace the airway adapter if rain-out/condensation occurs inside the airway adapter.

Only use airway adapters distributed by Breas Medical.
Do not apply tension to the CO_2 sensor cable.

To keep secretions and moisture from pooling on the windows, always position the CO_2 sensor in a vertical position with the green LED pointing upwards.

WARNING!

Disposable airway adapters shall not be reused. Reuse of the single use adapter can cause cross infection.

CAUTION!

If an intentional leakage port is used, make sure that the CO_2 sensor is placed between the patient interface and the leakage port.
If a patient interface with integrated leakage is used, the monitored CO_2 values may be influenced.

The CO_2 sensor should be placed as close to the patient interface as possible. However, a HME (if used) shall be placed between the patient interface and the CO_2 sensor. This will protect the airway adapter from secretions and effects of water vapour and eliminates the need of changing the airway adapter.

NOTE

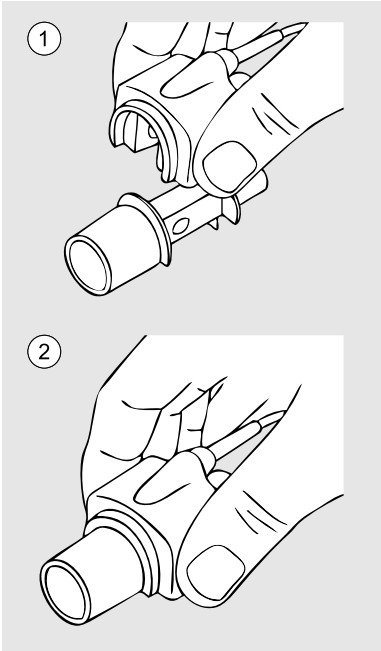
The CO_2 monitoring automatically compensates for changes in ambient barometric pressure. The CO_2 monitor shall fulfil the ISO 80601-2-55 standard (Medical electrical equipment – Particular requirements for the basic safety and essential performance of respiratory gas monitors).

5.8.5.2 How to Connect the $EtCO_2$ Sensor

1 Connect the CO_2 sensor cable to the CO_2 connection port on the ventilator (according to the instruction 5.8.1 *Connecting and Disconnecting the Cables*, page 71).

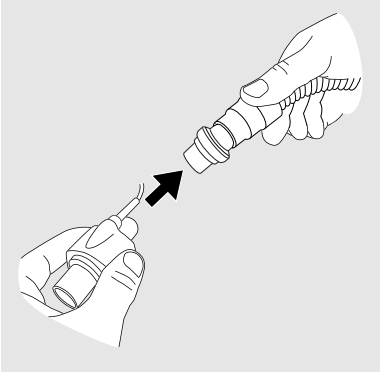
A green LED indicates that the CO_2 sensor is ready to use.

2 Snap the CO_2 sensor probe on top of the airway adapter. It will click into place when properly sealed.

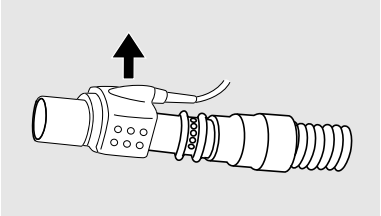


3 Perform a CO_2 zeroing procedure.

4 Connect the airway adapter to the patient circuit.



5 Make sure to position the CO_2 sensor with the LED pointing upwards.



When installed, the ventilator automatically detects the sensor, also after powering off/on or after power failure.

WARNING!

The CO_2 sensor is not intended to be in contact with the patient body.

CO_2 Zeroing

CO_2 zeroing is recommended when changing the airway adapter. Besides from that, zeroing only needs to be performed when an offset in monitored CO_2 values is observed, or when a CO_2 sensor accuracy unspecified message is displayed.

CO_2 zeroing can be performed from the "FiO_2/CO_2 Calibration" page under the "Others" section.

LED Status	Description
Steady green light	System OK
Flashing green light	Zeroing in progress
Steady red light	Sensor error
Flashing red light	Check adapter

Maintenance

No periodical maintenance is required for the CO_2 sensor.

To verify the CO_2 sensor readings, a gas span check shall be performed every year, preferably when the ventilator is sent for service.

See the ventilator service manual for how to perform the gas span check.

WARNING!

Do not under any circumstances attempt to service or repair the CO_2 sensor yourself. If you do so, the manufacturer will no longer be responsible for the performance and safety of the CO_2 sensor.

Cleaning

WARNING!

- Always be careful when cleaning to ensure that you do not damage any equipment.
- Fluid must not be allowed to enter into the CO_2 sensor.
- Always clean the T-piece with plug when to be used by a new patient. All parts that come into contact with the respiration gas must be cleaned.
- Remove the airway adapter before cleaning.
- Do not sterilise the CO_2 sensor.
- Do not autoclave the CO_2 sensor.

Clean the outside of the CO_2 sensor using a lint-free cloth moistened, but not wet, with ethanol or isopropyl alcohol (< 70%).

Disposal

The CO_2 sensor must be disposed of in accordance with the local environmental regulations regarding the disposal of used equipment and waste.

5.8.6 Using the Vivo 55 with the SpO_2 Module

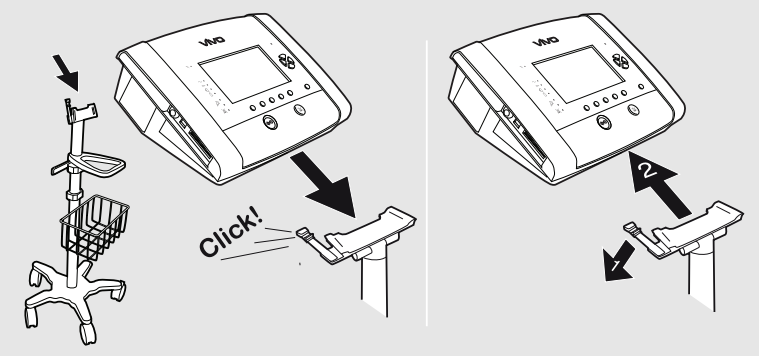
The SpO_2 module can be connected to the Vivo 55 in order to monitor and store SpO_2 measurements. The SpO_2 measurements will be stored in the data memory which can be downloaded to a PC and viewed in the Vivo 55 PC software.

5.8.7 Using the Vivo 55 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.

Mount and dismount the Vivo 55 as shown in the picture:



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 IV-pole is 3 kg (6.5 lbs).
- The maximum load of the trolley rail is 9 kg (20 lbs).
- The maximum load of the E-cylinder holder is 7.9 kg (17.5 lbs).

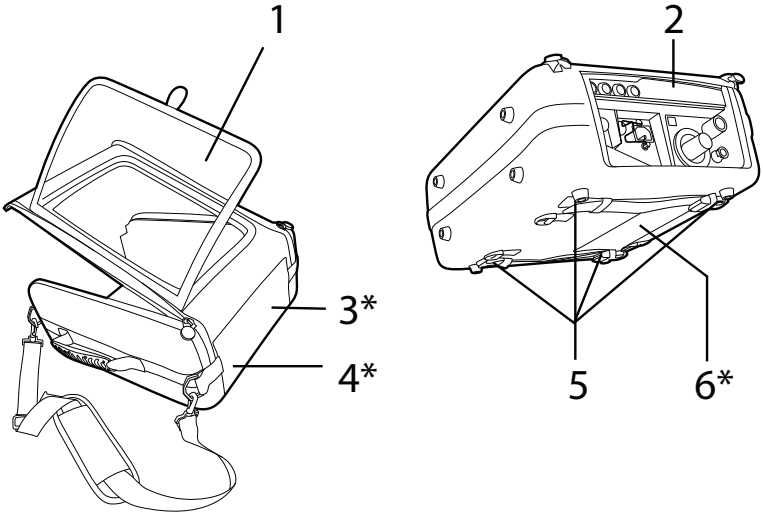
No maintenance is required.

5.8.8 Using the Vivo 55 with the Protective Cover

The protective cover is intended for additional protection of the Vivo 55 during transportation, and in hospital, institutional and home care environments. It can be used while the Vivo 55 is operating, for example mounted on a wheelchair, in a personal vehicle, or carried by hand.

Do not use the Vivo 55 in the protective cover while positioned in a warm place, such as direct sunlight or close to a radiator.

The protective cover has the following functions:



No	Component/Function
1	Transparent window, for accessing front panel and buttons
2	Port for patient circuit, cables, O_2 inlet, standby button
3*	Cooling air inlet
4*	Patient air inlet
5	Straps for safe mounting
6*	Cooling air outlet

CAUTION!

* Do not cover the air inlets or outlets.

6 Alarms

WARNING!

The adjustable alarm settings should be re-evaluated whenever a change in settings is made on the ventilator.

CAUTION!

Never leave a patient unattended during an alarm condition.

Setting alarm limits to extreme values could put the patient at risk.
Permitted distributed alarm systems are Vivo 55 remote alarm with cable and Vivo 55 nurse call cables provided by Breas Medical only.

NOTE

The alarm settings are maintained during an extended power failure.

This chapter describes the alarm functions used for the ventilator.

6.1 Alarm Function

The alarm function of the ventilator consists of the alarm LEDs on the front panel, an audible alarm, and messages on the display (see the front panel section for an overview of the position of the LEDs).

6.1.1 Alarm Indication

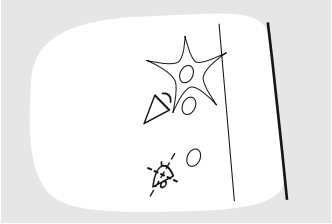
As soon as an alarm condition is detected, the ventilator main unit and the remote alarm unit (if connected) will alarm without delay.

When an alarm condition arises, the alarm is indicated in three ways:

Colour LED on the panel

Indicates the priority of the active alarm condition.

- High priority: red colour, flashing twice per second.
- Medium priority: yellow colour, flashing every 2 seconds.



Alarm text in display

Displays the name of the active alarm condition.

If several alarm conditions have been reached, the alarm descriptions are rolling in the display, displaying the alarms with highest priority first. A ">>" symbol is indicating that more than 1 alarm is set.

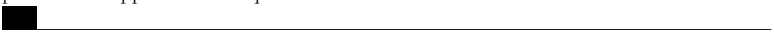
For detailed information about an alarm, press the info button at the lower left corner of the front.

Audible signals

- **High priority:** 3 signals followed by 2 more. The signal sequence is repeated with a 0.5 second pause and thereafter a 3 second pause.

- **Function failure:** Same signal as the high priority alarm or a constant signal, depending on the kind of function failure.
- **Medium priority:** 3 signals, with a lower frequency than the high priority alarm. The signal sequence repeats after a 6 second pause.

- **Information:** 1 signal with a low frequency. The signal is repeated after a 5 second pause and stopped after 5 sequences.



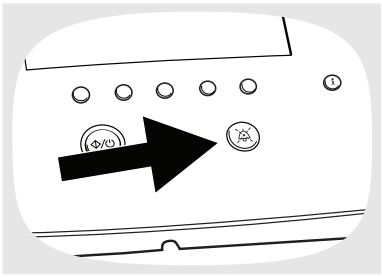
Alarm signal sound pressure: Adjustable from 45 to 85 dB(A) measured at 1 m. Accuracy: ± 5 dB(A).

The power failure alarm sounds in the case of power failure.
If the external DC falls below the warning limit and it is the last power source, the Low External DC warning is displayed.
If a battery that is the last power source falls below the warning limit, the Low Last Power Source alarm is set.

6.1.2 Audible Signal Pause

The audible signal of an active alarm can be paused for 60 seconds by pressing the Audio Pause button. The audible signal can be reactivated by pressing the Audio Pause button again.

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



6.1.3 Audible Signal Presilence

The audible signal can be turned off for the coming 2 minutes.

CAUTION!

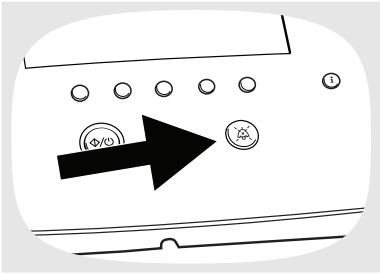
During the presilence period, any new alarms will only be indicated by the visual signals, the audible signal will not be activated.

NOTE

Power Failure and Function Failure alarms are not affected by presilence and, if triggered, will sound during the presilence period.

1 Press and hold the Audio Pause button for about 3 seconds.

⇒A confirmation request is displayed.



2 Press OK to confirm.

6.1.4 Alarm Reset

An alarm will automatically be reset once the cause of the alarm has been corrected.

In the alarm descriptions, read the *Possible cause* information and perform corrective actions, if applicable.

WARNING!

If an alarm condition cannot be corrected, discontinue use and refer the ventilator for service.

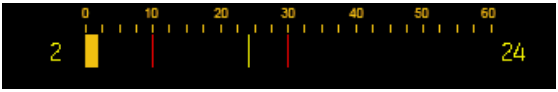
6.2 Operator's Position

To receive the audible part of an alarm, the operator's position should be within audible range from the ventilator, depending on the set audible alarm level.

To receive the visual part of an alarm and its priority, the operator's position should be within a distance of 4 metres (13 feet) from the ventilator, and within an angle of 30° to the normal of the ventilator display.

6.3 Physiological Alarms

6.3.1 High Pressure Alarm

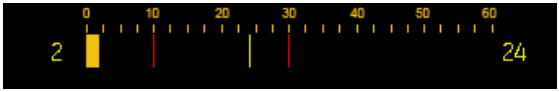
Property	Description
Alarm text	**High Pressure**
Priority	High
Alarm condition	A High Pressure alarm will be given when the patient pressure reaches the set High Pressure alarm limit for three consecutive breaths.
Possible cause	• Mismatch between pressure setting and alarm setting. • Coughing during inspiration. • Changes in airway resistance and or compliance. • Blocked exhalation valve or leakage port.
Reset criteria	A full breath is performed with maximum pressure below the alarm limit.
Ventilator action	The Vivo 55 will continue treatment according to the current settings. The actual breath is however terminated if the High Pressure alarm limit is reached.
Setting range	• 5 cmH_2O to 60 cmH_2O Note that the High pressure alarm cannot be set lower than the value set for the Low pressure alarm.
Setting resolution	Below 10 cmH_2O: 0.5 cmH_2O Above 10 cmH_2O: 1.0 cmH_2O
Setting Display	The High Pressure alarm setting is displayed by a red line in the pressure bar graph. 

NOTE

While sigh function is activated:

- In pressure modes (during the sigh breath), the high pressure alarm will automatically be set 10 cmH_2O above set sigh pressure.
  (Max 70 cmH_2O.)
- In volume modes (during the sigh breath), the high pressure alarm will automatically be increased by the same percentage as the set sigh volume percentage.
  (Max 70 cmH_2O.)

6.3.2 Low Pressure Alarm

Property	Description
Alarm text	**Low Pressure**
Priority	High
Alarm condition	A Low Pressure alarm will be given when the Vivo 55 pressure fails to reach the low pressure alarm limit for 15 seconds. In MPV breath mode the alarm will be given when the pressure fails to reach the limit during inspiration.
Possible cause	• 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 55 will continue treatment according to the current settings.
Setting range	• 1 cmH_2O to 50 cmH_2O Note that the Low pressure alarm cannot be set higher than the value set for the High pressure alarm.
Setting resolution	Below 10 cmH_2O: 0.5 cmH_2O Above 10 cmH_2O: 1.0 cmH_2O
Setting display	The Low Pressure alarm setting is displayed by a red line in the pressure bar graph. 

6.3.3 High PEEP Alarm

Property	Description
Alarm text	**High PEEP**
Priority	Medium
Alarm condition	A High PEEP alarm will be given when the measured PEEP is 30% above the set value for more than 15 seconds
Possible cause	• Blocked leakage port. • Too short expiratory time. • Changes in airway resistance and or compliance. • Malfunction of the exhalation valve. • Blocked exhalation valve.
Reset criteria	PEEP has gone below the alarm limit (lower than 30% above the set value).
Ventilator action	The Vivo 55 will continue treatment according to the current settings.
Setting range	• On • Off

6.3.4 Low PEEP Alarm

Property	Description
Alarm text	**Low PEEP**
Priority	Medium
Alarm condition	A Low PEEP alarm will be given when the measured PEEP is 30% below the set value for more than 60 seconds
Possible cause	• Excessive leakage. • Malfunction of the exhalation valve.
Reset criteria	PEEP has gone above the alarm limit (higher than 30% below the set value).
Ventilator action	The Vivo 55 will continue treatment according to the current settings.
Setting range	• On • Off

6.3.5 High Vt_i (High Inspired Tidal Volume Alarm)

Property	Description
Alarm text	**High Vti**
Priority	Medium
Alarm Condition	A High Inspired Tidal Volume alarm will be given when the monitored Inspired Tidal Volume exceeds the set limit for the High Inspired Tidal Volume alarm for 15 seconds. This alarm is only used if the Vivo 55's patient circuit type is set to Exhalation valve (single limb) circuit or in MPV modes.
Possible cause	• Mismatch between Inspired Tidal Volume and alarm setting. • Pressure settings causing the Inspired Tidal Volume to exceed the set alarm level. • Leakage from the mask or other components of the patient circuit. • Mismatch between selected and used patient circuit.
Reset criteria	When inspired tidal volume is below set alarm limit
Setting range	• 100 ml to 3000 ml • Off
Setting resolution	10 below 600 ml, 100 above 600 ml
Ventilator action	The ventilator will continue treatment with the same settings.

6.3.6 High Vt_e Alarm (High Expired Tidal Volume)

Property	Description
Alarm text	**High Vte**
Priority	Medium
Alarm condition	A High Expired Tidal Volume alarm will be given when the monitored Expired Tidal Volume exceeds the alarm limit for 15 seconds. This alarm is only used if the Vivo 55's patient circuit type is set to Leakage circuit.
Possible cause	• Mismatch between Expired Tidal Volume and alarm setting. • Mismatch between selected and used patient circuit. • Pressure settings causing the Expired Tidal Volume to exceed the set alarm level.
Setting range	• 100 ml to 3000 ml • Off
Setting resolution	10 below 600 ml, 100 above 600 ml
Ventilator action	The ventilator will continue treatment with the same settings.

6.3.7 Low Vt_i Alarm (Low Inspired Tidal Volume)

Property	Description
Alarm text	**Low Vti**
Priority	High
Alarm Condition	A Low Inspired Tidal Volume alarm will be given when the monitored Inspired Tidal Volume fails to reach the set limit for the Low Inspired Tidal Volume alarm for 15 seconds. This alarm is only used if the Vivo 55's patient circuit type is set to Exhalation valve (single limb) circuit or in MPV modes.
Possible cause	• Mismatch between Inspired Tidal Volume and Alarm setting. • Changes in airway resistance and or compliance. • Obstructed or occluded patient circuit.
Setting range	• 500 ml to 2000 ml • Off
Setting resolution	10 below 600 ml, 100 above 600 ml
Reset criteria	A full breath above set alarm limit
Ventilator action	The ventilator will continue treatment with the same settings.

6.3.8 Low Vt_e Alarm (Low Expired Tidal Volume)

Property	Description
Alarm text	Low Vte
Priority	High
Alarm Condition	A Low Expired Tidal Volume alarm will be given when the monitored Expired Tidal Volume fails to reach the set limit for the Low Expired Tidal Volume alarm for 15 seconds. This alarm is only used if the Vivo 55's patient circuit type is set to Leakage circuit.
Possible cause	• Mismatch between Expired Tidal Volume and Alarm setting. • Changes in airway resistance and or compliance. • Leakage around the mask or within one of the components of the circuit. • Obstructed or occluded patient circuit.
Reset criteria	Full breath above set alarm limit
Setting range	• 50 ml to 2000 ml • Off
Setting resolution	10 below 600 ml, 100 above 600 ml
Ventilator action	The ventilator will continue treatment with the same settings.

6.3.9 High MV_i Alarm (High Inspired Minute Volume Alarm)

Property	Description
Alarm text	**High MVi**
Priority	Medium
Alarm condition	A High Inspired Minute Volume alarm will be given when the monitored inspired minute volume exceeds the set limit for 15 seconds. This alarm is only used if the Vivo 55's patient circuit type is set to Exhalation valve (single limb) circuit or in MPV modes.
Possible cause	• Mismatch between Breath Rate, Inspired Tidal Volume settings and the alarm setting. • Increased Breath Rate. • Leakage around the mask or within one of the components of the circuit.
Reset criteria	When inspired minute volume is below set alarm limits
Setting range	• 1.0 to 40 l/min • Off
Setting resolution	0.5 l/min
Ventilator action	The ventilator will continue treatment with the same settings.

6.3.10 High MV_e (High Expired Minute Volume Alarm)

Item	Description
Alarm text	**High MVe**
Priority	Medium
Alarm condition	A High Expired Minute Volume alarm will be given when the monitored expired minute volume exceeds the alarm limit for 15 seconds. This alarm is only used if the Vivo 55's patient circuit type is set to Leakage circuit.
Possible cause	• Mismatch between Breath Rate, Tidal Volume settings and the alarm setting. • Increased Breath Rate.
Setting range	• 1.0 to 40 l/min • Off
Setting resolution	0.5 l/min
Ventilator action	The ventilator will continue treatment with the same settings.

6.3.11 Low MV_i (Low Inspired Minute Volume Alarm)

Property	Description
Alarm text	**Low MVi**
Priority	High
Alarm condition	A Low Inspired Minute Volume alarm will be given when the monitored minute volume does not reach the alarm limit for 15 seconds. This alarm is only used if the Vivo 55's patient circuit type is set to Exhalation valve (single limb) circuit.
Possible cause	• Mismatch between Breath Rate and Inspired Tidal Volume settings and the alarm setting. • Changes in airway resistance and or compliance. • Decreased Breath Rate.
Setting range	• 1.0 l/min to 30 l/min • Off
Setting resolution	0.1 l up to 1.0 l, 0.5 l above 1.0 l.
Ventilator action	The ventilator will continue treatment with the same settings.

6.3.12 Low MV_e Alarm (Low Expired Minute Volume)

Property	Description
Alarm text	**Low MVe**
Priority	High
Alarm condition	A Low Expired Minute Volume alarm will be given when the monitored minute volume is below the alarm limit for more than 15 seconds. This alarm is only used if the Vivo 55's patient circuit type is set to Leakage circuit.
Possible cause	• Mismatch between Breath Rate and Tidal Volume settings and the alarm setting. • Changes in airway resistance and or compliance. • Decreased Breath Rate. • Leakage around the mask or within one of the components of the circuit.
Setting range	• 1.0 l/min to 30 l/min • Off
Setting resolution	0.5 l
Ventilator action	The ventilator will continue treatment with the same settings.

6.3.13 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	• 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 55 will continue treatment according to the current settings.
Setting range	• 10 bpm to 70 bpm • Off
Setting resolution	1 bpm.

6.3.14 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	• 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 55 will continue treatment according to the current settings.
Setting range	• 1 bpm to 30 bpm. • Off
Setting resolution	1 bpm.

6.3.15 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	• Patient stopped breathing. • Patient decreases spontaneous breathing. • Circuit disconnection. • Inspiratory Trigger is set too high.
Reset criteria	Inspiratory effort detected by the Vivo 55.
Ventilator action	The Vivo 55 will continue treatment according to the current settings.
Setting range	• 5 to 60 s. (Non MPV mode) • 15 to 900 s. (MPV mode) • Off
Setting resolution	5 s below 15 s. 15 s above 15 s. MPV mode: 15 s below 60 s. 60 s above 60 s.

6.3.16 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	• 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 55 will continue treatment according to the current settings
Setting range	• On • Off

6.3.17 Rebreathing Alarm

Property	Description
Alarm text	Rebreathing (with leakage circuit) Rebreathing (with active exhalation valve circuit)
Priority	High (with leakage circuit) Medium (with active exhalation valve circuit)
Alarm condition	**Leakage Circuit** A Rebreathing alarm will be given if the intentional leakage is too low for more than 15 seconds. **Exhalation valve circuit** A Rebreathing alarm will be given if the exhalation valve is obstructed for more than 10 consecutive breaths. **MPV circuit** A Rebreathing alarm will be given if air returns into the ventilator for more than 10 consecutive breaths.
Possible cause	• Obstructed or occluded patient circuit. • Incorrect patient circuit. • Patient exhales through mouthpiece. • Obstructed or removed CO_2 port from leakage circuit. • For active exhalation valve circuits: Disconnected pilot pressure line. • For active exhalation valve circuits: The control pressure evacuation outlet at the bottom the ventilator is obstructed.
Reset criteria	The leakage is back within limits.
Ventilator action	The Vivo 55 will continue treatment according to the current settings.
Setting range	• On • Off

6.3.18 Obstruction Alarm

Property	Description
Alarm text	**Obstruction**
Priority	High
Alarm condition	An Obstruction alarm will be given if the inspiratory breathing tube becomes blocked and remains blocked for 2 consecutive breaths.
Ventilator action	With each breath cycle, upon detection of an obstruction the ventilator will reduce the airway pressure to the set PEEP. Treatment will resume with the start of the next breath cycle.
Reset Criteria	When the monitored compliance and resistance become normal after a breath.
Setting Range	• High • Low • Off

6.3.19 High FiO_2 Alarm

Property	Description
Alarm text	**High FiO2**
Priority	Medium
Alarm condition	A High FiO_2 alarm will be given when the measured FiO_2 exceeds the alarm limit for 30 seconds.
Possible cause	• Increased oxygen inflow. • Decreased minute ventilation.
Reset criteria	FiO_2 goes below the alarm limit
Setting range	• 21% to 100% • Off
Setting resolution	1%
Ventilator action	The ventilator will continue treatment with the same settings.

6.3.20 Low FiO_2 Alarm

Property	Description
Alarm text	**Low FiO2**
Priority	High
Alarm condition	A Low FiO_2 alarm will be given when the measured FiO_2 is below the alarm limit for 30 seconds.
Possible cause	• Decreased oxygen inlet. • Disconnection of oxygen inlet. • Increased minute ventilation. • High leakage.
Setting range	• 21% to 100% • Off
Setting resolution	1%
Ventilator action	The ventilator will continue treatment with the same settings.

6.3.21 High SpO_2 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 55 will continue treatment according to the current settings.
Setting range	• 90 % to 100 % • Off
Setting resolution	1 %

This alarm requires a connected SpO_2 sensor.

6.3.22 Low SpO_2 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	• Too low flow of bleed-in oxygen. • Oxygen inlet is disconnected. • Delivered tidal volumes are too small.
Setting range	85% to 100%
Setting resolution	1%
Ventilator action	The ventilator will continue treatment with the same settings.

This alarm requires a connected SpO_2 sensor.

6.3.23 High $EtCO_2$ Alarm

Property	Description
Alarm text	**High EtCO2**
Priority	High
Alarm condition	A High $EtCO_2$ alarm will be given when the measured $EtCO_2$ exceeds the alarm limit for 30 seconds.
Possible cause	• Alarm limit is set too low. • Breath Rate too low. • Delivered Tidal Volume too low. • Excessive dead space between patient and exhalation valve/ leakage port. • Exhalation valve / leakage port is occluded.
Setting range	1 to 99 mmHg Off
Setting resolution	1 mmHg
Ventilator action	The ventilator will continue treatment with the same settings.

This alarm requires a connected $EtCO_2$ sensor

6.3.24 Low $EtCO_2$ Alarm

Property	Description
Alarm text	**Low EtCO2**
Priority	Medium
Alarm condition	A Low $EtCO_2$ alarm will be given when the measured $EtCO_2$ is below the alarm limit for 30 seconds.
Possible cause	• Alarm limit is set too high. • Ventilator disconnection. • Excessive leakage in the Patient circuit/Interface. • Partial obstruction of the airways. • Breath Rate too high. • Delivered Tidal Volume too high. • Self triggering of the ventilator.
Setting range	1 to 99 mmHg Off
Setting resolution	1 mmHg
Ventilator action	The ventilator will continue treatment with the same settings.

This alarm requires a connected $EtCO_2$ sensor

6.3.25 High $InspCO_2$ Alarm (High Inspired CO_2)

Property	Description
Alarm text	**High InspCO2**
Priority	High
Alarm condition	A High Inspired CO_2 alarm will be given when the measured inspired CO_2 exceeds the alarm limit for 30 seconds.
Possible cause	• Alarm limit is set too low. • Excessive dead space between patient and exhalation valve/ leakage port. • Leakage port/valve occluded.
Setting range	1 to 99 mmHg Off
Setting resolution	1 mmHg
Ventilator action	The ventilator will continue treatment with the same settings.

This alarm requires a connected $EtCO_2$ sensor

6.3.26 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	• Insufficient ventilatory support. • Too low flow of bleed-in oxygen. • The PEEP 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 55 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 SpO_2 sensor.

6.3.27 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	• 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 55 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 SpO_2 sensor.

6.4 Technical Alarms

6.4.1 Power Failure Alarm

Property	Description
Alarm text	No alarm text during the alarm. After restart: **Treatment was restarted after power failure.**
Priority	High
Alarm condition	A Power Failure alarm will be given when the last power source is below limits.
Reset criteria	The power is restored
Ventilator action	The Vivo 55 stops treatment and gives alarm for at least 2 minutes. If power is restored within 2 minutes, the Vivo 55 will automatically resume treatment with current settings.

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

Property	Description
Alarm text	**High Patient Air Temp**
Priority	Medium
Alarm condition	A High Patient Air Temperature alarm will be given when the patient air temperature exceeds 43°C (109.4°F).
Possible cause	• Blocked air inlets. • Blocked cooling air outlets. • Too high ambient temperature.
Ventilator action	The Vivo 55 will continue treatment. The ventilator stops treatment and gives alarm for up to 2 minutes.
Reset criteria	The temperature goes below the limit again.

6.4.3 High Internal Temperature (High Internal Temp)

Property	Description
Alarm text	**High Internal Temp**
Priority	High
Alarm condition	A High Internal Temperature alarm will be given when the internal temperature is very high.
Possible cause	• Blocked air inlets. • Blocked cooling air outlets. • Too high ambient temperature.
Ventilator action	The Vivo 55 will continue treatment.
Reset criteria	The temperature goes below the limit again.

6.4.4 Low Last Power Source Alarm

Property	Description
Alarm text	**Low Last Power Source**
Alarm condition	A Low Last Power Source alarm will be given when the last battery source (internal battery or click-in battery) has 15 to 20 minutes of operating time left with current settings.

Property	Description
Priority	Medium
Ventilator action	The ventilator will continue treatment with the same settings.

6.4.5 Lost Mains Alarm

Property	Description
Alarm text	**Lost Mains Power**
Alarm condition	A Mains Power Lost alarm will be given when the ventilator switched from AC power (Mains) to another power source due to AC Power (Mains) is lost.
Priority	Medium
Ventilator action	The ventilator will continue treatment with the same settings. An information message will be shown on the screen.
Reset	Confirmation by user or AC power (Mains) reconnected.

6.4.6 Crit. Low Last Power Source Alarm

Property	Description
Alarm text	**Crit. Low Last Power Source**
Alarm condition	A Crit. Low Last Power Source alarm will be given when the last battery source (internal battery or click-in battery) has 5 minutes of operating time left with current settings.
Priority	High
Ventilator action	The ventilator will continue treatment with the same settings.
Reset	Connection of “higher” power source.

6.4.7 Exhalation Valve Control Error Alarm

Property	Description
Alarm text	**Exhalation Valve Control Error**
Alarm condition	An Exhalation Valve Control Error alarm will be given when the ventilator fails to control the internal /external exhalation valve.
Priority	High
Possible cause	• Exhalation valve occluded • Exhalation valve control tube disconnected • Internal function failure of the exhalation valve controls
Reset	The pilot pressure gets a normal value.

6.4.8 SpO_2/CO_2/Remote Start/Stop Failure Alarm (SpO_2/CO_2 Remote Fail)

Property	Description
Alarm text	**SpO2/CO2/Remote fail**
Alarm condition	An SpO_2/CO_2/Remote Start/Stop Failure alarm will be given when a failure occurs with the patient interface or attached units.
Priority	Medium
Possible cause	• Failure in the Remote start/stop unit. • Failure in the SpO_2 sensor. • Failure in the CO_2 sensor. • Internal failure in the ventilator.
Ventilator action	The ventilator will continue treatment with the same settings.

6.4.9 SpO_2 Disconnected (SpO_2 Sensor Failure/Disconnection Alarm)

Property	Description
Alarm text	**SPO2 Disconnected**
Alarm condition	An SpO_2 Sensor Failure/Disconnection alarm will be given when an error signal or no signal from the SpO_2 sensor has been detected for 2 seconds. Check the SpO_2 sensor.
Priority	High
Possible cause	The SpO_2 electronics cable has been disconnected and subsequently no communication (possibly due to disconnection) for 2 seconds. Failure in the SpO_2 sensor.
Ventilator action	The ventilator will continue treatment with the same settings.
Reset	Confirmation by user or reconnected/changed.

6.4.10 SpO_2 Signal Inadequacy Alarm (SpO_2 Signal)

Property	Description
Alarm text	**SPO2 Signal**
Alarm condition	An SpO_2 Signal Inadequacy alarm will be given when the SpO_2 probe is not able to perform an adequate measurement, due to low perfusion or artefacts. Check the SpO_2 sensor.
Priority	High
Possible cause	• Bad positioning or occlusion of the probe. • Low blood flow in finger.
Ventilator action	The ventilator will continue treatment with the same settings.

6.4.11 CO_2 Disconnected (CO_2 Sensor Failure/Disconnection Alarm)

Property	Description
Alarm text	**CO2 Sensor Disconnected**
Alarm condition	A CO_2 Sensor Failure/Disconnection alarm will be given when communication between the ventilator and the CO_2 sensor has been lost for 2 seconds. Check the CO_2 sensor.
Priority	High
Possible cause	• CO_2 Sensor disconnected. • Failure in the CO_2 sensor.
Ventilator action	The ventilator will continue treatment with the same settings.
Reset	Confirmation by user or reconnected/changed.

6.4.12 CO_2 Sensor Accuracy Unspecified Alarm (CO_2 Accuracy Unspec)

Property	Description
Alarm text	**CO2 Accuracy Unspec**
Alarm condition	A CO_2 Sensor Accuracy Unspecified alarm will be given when an unspecified accuracy in the CO_2 measurement has occurred. Perform a zeroing procedure of the CO_2 sensor.
Priority	High
Ventilator action	The ventilator will continue treatment with the same settings.

6.4.13 CO_2 Sensor Error Alarm

Property	Description
Alarm text	**CO2 Sensor Error**
Alarm condition	A CO_2 Sensor Error alarm will be given when an error in the CO_2 sensor has occurred. Replace the CO_2 sensor. CO_2 monitoring cannot be performed in this condition.
Priority	High
Ventilator action	The ventilator will continue treatment with the same settings.
Reset	OK message from sensor or sensor disconnected by user.

6.4.14 FiO_2 Disconnected (FiO_2 Sensor Failure/Disconnection Alarm)

Property	Description
Alarm text	**FiO2 Disconnected**
Alarm condition	An FiO_2 Sensor Failure/Disconnection alarm will be given when no signal from the FiO_2 sensor has been detected for 2 seconds. Check the FiO_2 sensor.
Priority	High
Possible cause	• FiO_2 Sensor disconnected. • Communication with the FiO_2 sensor failed.
Ventilator action	The ventilator will continue treatment with the same settings.
Reset	Confirmation by user or reconnected/changed.

6.4.15 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 55 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.

6.4.16 Temperature Comp. Lost (Ambient Temperature Compensation Lost Alarm)

Property	Description
Alarm text	**Temperature Comp. Lost**
Alarm condition	An Ambient Temperature Compensation Lost alarm will be given when the automatic ambient temperature compensation is out of order.
Priority	Medium
Ventilator action	The ventilator will continue treatment with the same settings. The accuracy of the volume measurement may be impaired.
Reset	Ambient temperature inside valid range.

6.4.17 Humidity Comp. Lost (Humidity Compensation Lost Alarm)

Property	Description
Alarm text	**Humidity Comp. Lost**
Alarm condition	An Humidity Compensation Lost alarm will be given when the automatic humidity compensation is out of order. 50% relative humidity is used for temporary compensation. If the ventilator is used at other humidities, delivered and measured pressure and flow may deviate.
Priority	Medium
Ventilator action	The ventilator will continue treatment with the same settings. The accuracy of the volume measurement may be impaired.
Reset	Air humidity sensor values (RH and temperature) inside valid range.

6.4.18 LED Failure Alarm

Property	Description
Alarm text	**LED Failure**
Alarm condition	A LED Failure alarm will be given when one or more LED indicators on the front panel are broken.
Priority	Medium
Ventilator action	The ventilator will continue treatment with the same settings.
Reset	Power-on reset of ventilator (or repair).

6.4.19 Low Alarm Battery Alarm

Property	Description
Alarm text	**Low Alarm Battery**
Alarm condition	An alarm for *Low Alarm Battery* will be given if the alarm battery is not charged enough to have power for a *Power Fail* alarm for at least 2 minutes.
Priority	Medium
Ventilator action	The ventilator will continue treatment with the same settings and start charging the alarm batteries.
Reset	When alarm energy storage level is sufficient to give an alarm for at least 2 minutes.

6.4.20 Alarm for Beeper Failure

Property	Description
Alarm text	**Alarm Beeper Fail**
Alarm condition	Failure of the beeper control by the treatment processor.
Priority	High
Ventilator action	The ventilator will continue treatment with the same settings.

6.4.21 Int. Function Failure (Internal Function Failure Alarm)

Property	Description
Alarm text	**Int. function failure:**
Alarm condition	An Internal Function Failure alarm will be given when the ventilator has an internal function failure, followed by an error code for the specific failure. All Internal Function Failure alarm error codes are defined and explained in the ventilator Service Manual.
Priority	High
Ventilator action	The ventilator will stop the treatment and shut down.
Ventilator reset	Restart the ventilator.

6.5 Alarm Test

6.5.1 Instructions

NOTE

- In order to test an alarm it must be activated by your clinician.
- In some cases a setting must be altered.

To perform the alarm test, follow the instructions below:

Low Pressure and Disconnection Alarms

1. Start treatment and disconnect the patient circuit.
2. Wait 15 seconds.
3. The Low Pressure Alarm and/or the Disconnection Alarm will be given.
4. Stop treatment. Test completed.

Low Vti or Low Vte Alarms

1. Start treatment and block the patient circuit completely to simulate an occlusion.
2. Wait 15 seconds.
3. The Low Vti or Low Vte Alarm will be given.
4. Stop treatment. Test completed.

Obstruction Alarm

1. Start treatment; block the patient circuit completely to simulate an obstruction.
2. Wait approximately 10 seconds.
3. The Obstruction Alarm will be given. (If the expiratory path is blocked, a Disconnection Alarm may be triggered.)
4. Stop treatment. Test completed.

7 Cleaning and Maintenance

WARNING!

The Vivo 55 should undergo maintenance, service and control procedures, as well as any applicable upgrades, in accordance with Breas service instructions.

The Vivo 55 shall only be repaired or modified in accordance with Breas service manuals, technical bulletins, and any special service instructions, by service technicians that have been authorised after Breas Vivo 55 service training.

Do not under any circumstances attempt to service or repair the ventilator yourself. If you do so, the manufacturer will no longer be responsible for the performance and safety of the ventilator.

Deviation from these service instructions may lead to risk of personal injury!

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

7.1 Cleaning the Vivo 55

WARNING!

To avoid electrical shock, disconnect the power supply to the ventilator before cleaning. Do not immerse the ventilator into any fluids.

CAUTION!

Always be careful when cleaning to ensure that you do not damage any equipment.

Fluid must not be allowed to enter the ventilator.

Never apply any liquids directly on the ventilator by spraying, splashing or pouring. Use a moistened lint-free cloth when cleaning.

Do not use an excessive amount of liquid when cleaning the ventilator.

Do not autoclave the ventilator.

7.1.1 Main Unit

1 Switch off the Vivo 55 and disconnect the mains supply.

2 Remove the patient circuit.

3 Disconnect all electric cables.

4 Clean the outside of the Vivo 55 using a lint-free cloth with a mild soap solution, and/or ethanol 70% for surface disinfection.

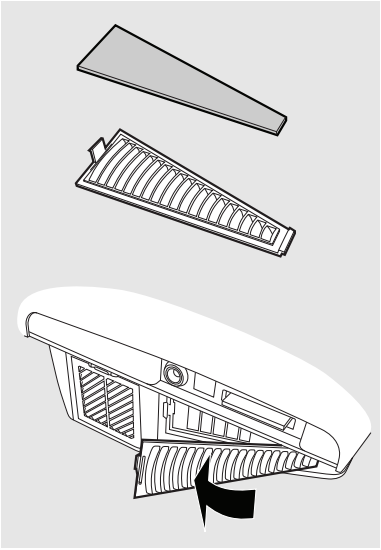
5 Reconnect the patient circuit. Make sure all parts are dry before the Vivo 55 is put into operation.

The Vivo 55 can be cleaned 5 times in a validated ozone-sterilisation process.

Cooling Air Inlet Filter

The cooling air inlet filter is located in the filter cassette at the side of the ventilator. Replace the filter at least once a year. Wash the filter at least once a week.

1 Wash the filter using warm water and a mild soap.



2 Rinse thoroughly.

3 Dry the filter by squeezing it out in a towel. Do not wring the filter.

4 Make sure the filter is completely dry before inserting.

7.1.2 Patient Circuit

The patient circuit should be cleaned and replaced in accordance with the manufacturer's instructions and care provider's instructions, where applicable.

Always use a new patient circuit when used by a new patient.

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

CAUTION!

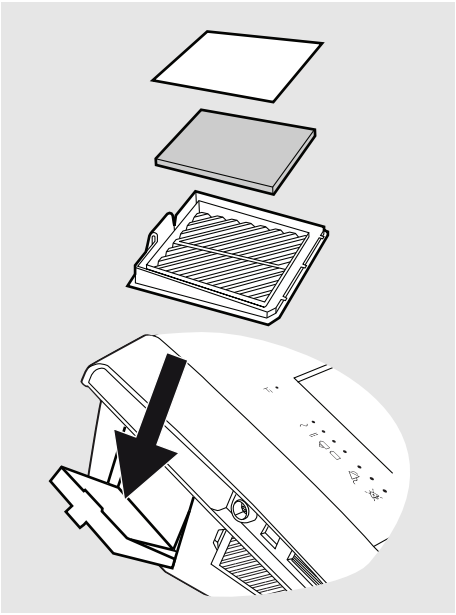
Appropriate personnel should determine the duration of use for the patient circuit based on accepted infection control procedures.

7.2 Cleaning and Replacing the Patient Air Filters

The patient air filters are located in the filter cassette at the side of the ventilator.

There are two types of filters:

- washable filter
- disposable filter



Washable Filter (grey)

Replace the washable filter at least once a year. Wash the filter at least once a week.

1 Wash the filter using warm water and a mild soap.

2 Rinse thoroughly.

3 Dry the filter by squeezing it out in a towel. Do not wring the filter.

4 Make sure the filter is completely dry before inserting.

Disposable Filter (white)

Replace the white filter at least every 4th week, or more frequently when used in high pollution or pollen-rich environments.

⚠ CAUTION!

Do not wash or reuse the disposable filter.

7.3 Change of Patients

If the ventilator is used in a clinic by several patients, a low resistance bacterial filter may be used between the air outlet and the patient tube to prevent patient cross-contamination.

1 Follow the instructions in 7.1 *Cleaning the Vivo 55*, page 114, steps 1 to 5.

2 Replace the patient filters according to 7.2 *Cleaning and Replacing the Patient Air Filters*, page 115.

3 If a low resistance bacterial filter is used, it shall be replaced..

4 Use a new patient circuit when the ventilator is used by a new patient.

7.4 Regular Maintenance

Regular maintenance inspections and checks shall be carried out at least every 24 months, according to the ventilator Service Manual.

WARNING!

Do not use the device and contact your responsible care provider for an inspection of the device in the event of:

- Unexpected patient symptoms during treatment.
- Unexplainable or sudden pressure, performance or sound changes during operation.
- Suspected damage to the device, including the occurrence of Internal Functional Failure alarms.
- Suspected damage to the click-in battery, including evidence of battery cell leakage.

7.5 Service and Repair

The service and repair of the ventilator must only be carried out by authorised service personnel in accordance with Breas service instructions. Service inspections must always be carried out following any repairs to the device.

WARNING!

Do not use the device and contact your responsible care provider for an inspection of the device in the event of:

- Unexpected patient symptoms during treatment.
- Unexplainable or sudden pressure, performance or sound changes during operation.
- Suspected damage to the device, including the occurrence of Internal Functional Failure alarms.
- Suspected damage to the click-in battery, including evidence of battery cell leakage.

Authorised service workshops can order the ventilator Service Manual that contains all technical documentation required for the maintenance and service of the ventilator.

7.6 Storage

Store the Vivo 55 in a dark room, where the temperature range is within -20 to +60°C (-4 to +140°F). For instructions on how to charge the batteries after long time storage, see 5.7 *Using Batteries*, page 64.

CAUTION!

The ventilator must not be stored in a warm place, such as direct sunlight or close to a radiator.
If stored in a cold environment, let the ventilator adapt to room temperature before using the device.

7.7 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.

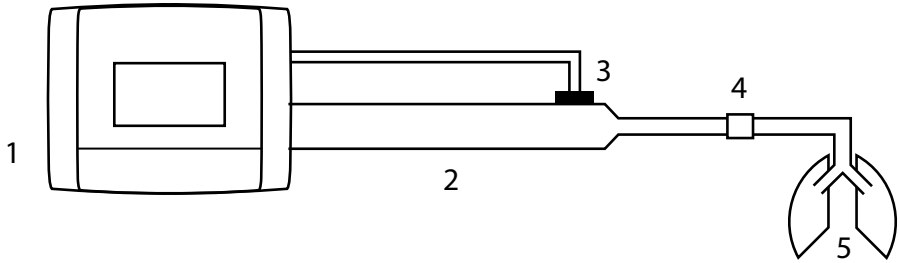
NOTE

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

8 Technical Specifications

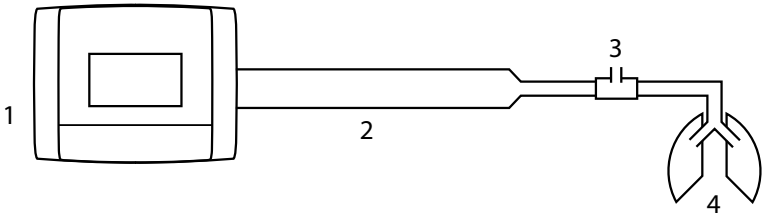
8.1 System Description

8.1.1 Active Exhalation Valve Circuit



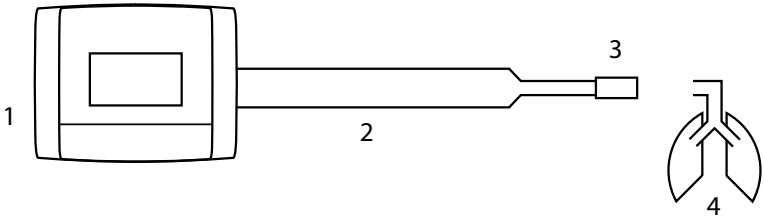
No	DESCRIPTION
1	Vivo 55
2	Tube
3	Active Exhalation valve
4	Patient interface connection
5	Patient

8.1.2 Leakage Circuit



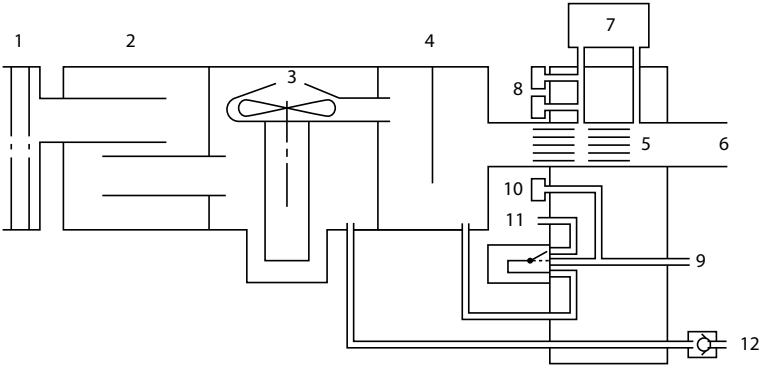
No	DESCRIPTION
1	Vivo 55
2	Tube
3	Leakage port / Patient interface connection
4	Patient

8.1.3 MPV Breath Model



No	DESCRIPTION
1	Vivo 55
2	Tube
3	Mouthpiece interface
4	Patient

8.1.4 Pneumatic Diagram for the Vivo 55



No	DESCRIPTION
1	Air inlet with filters
2	Inlet silencer
3	Blower
4	Outlet silencer
5	Restriction
6	Patient air outlet
7	Flow sensor
8	Pressure sensors
9	Exhalation valve control pressure outlet
10	Exhalation valve control pressure valve
11	Exhalation valve control pressure sensor
12	Low pressure/bleed-in oxygen connection

8.1.5 Worst Case Accuracy

Pressure Control Modes

The worst case Vivo 55 System is the dual limb patient circuit with HCH humidifier, bacterial filter, FiO_2 sensor and CO_2 sensor.

Volume Control Modes

The worst case Vivo 55 System is the dual limb patient circuit with or without HCH humidifier, bacterial filter, FiO_2 sensor and CO_2 sensor.

8.2 Data Parameters

NOTE

All stated tolerances includes measurement uncertainty. The accuracies have been tested with all allowed configurations. Stated tolerances only discloses the maximum tolerance. If a parameter's tolerance is described with both absolute and relative measures, the greater one applies if nothing else is stated. Percent measurements are relative to the set value.

8.2.1 Settings

Please refer to the information in 5.4 *Functions and Parameters in the Vivo 55*, page 50.

8.2.2 Monitored Values

MONITORED VALUE	RANGE	ACCURACY
P_{peak}	4 to 60 cmH_2O.	±10%
PEEP	0 to 30 cmH_2O.	±10%
P_{mean}	0 to 60 cmH_2O.	±10%
Leakage	0 to 100 l/min (BTPS*).	1 l/min, ±10%
MV	0 to 99.9 l (BTPS*).	±10 ml or 10%, whichever is greatest
Vt	0 to 9999 ml (BTPS*).	±10 ml or 10%, whichever is greatest
Vt_i	0 to 9999 ml (BTPS*).	±10 ml or 10%, whichever is greatest
Vt_e	0 to 9999 ml (BTPS*).	±10 ml or 10%, whichever is greatest
FiO_2	0 to 100%.	±2%**
% in TgV	0 to 100%.	±1%
Total Rate	0 to 60 bpm.	1 bpm
Spont Rate	0 to 60 bpm.	1 bpm

MONITORED VALUE	RANGE	ACCURACY
% Spont	0 to 100%.	Not applicable
SpO_2	70 to 100%.	±3 digits. Data update period 1 s. 4-beat average signal processing.
Pulse Rate	18 to 300 bpm.	±3 digits. Data update period 1 s. 4-beat average signal processing.
I:E	1:99 to 10:1.	±0.1 unit
Insp. Time	0.3 to 5 s.	±10%
Rise Time	0.1 to 5 s.	±10%
$EtCO_2$	0 to 25%.	0 to 15%: ±(0.2 vol% + 2% of reading), 15 to 25%: unspecified
$InspCO_2$	0 to 25%.	0 to 15%: ±(0.2 vol% + 2% of reading), 15 to 25%: unspecified

* BTPS (Body Temperature and Pressure Saturated)

** Effects of humidity on FiO_2 accuracy: -0.03% per % RH relative to calibration point

8.2.3 Alarms

Please refer to the information in 6 *Alarms*, page 81.

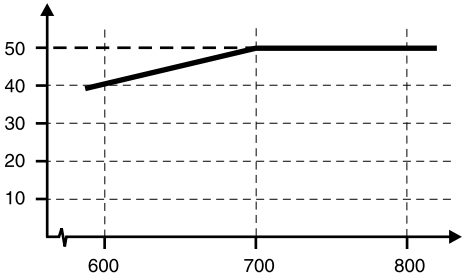
8.2.4 Technical Specifications and Conditions

8.2.4.1 Power Supply

POWER SUPPLY	SPECIFICATION
AC Power (Mains) supply	100 to 240 V AC, tolerance: +10%/-20%, 50 to 60 Hz, max 300 VA.
External battery	24 V DC, tolerance: 24 V ± 6 V.Max 7 A, 140 W.
Click-on battery*	Capacity 5.2 Ah. LiIon. Operational time 8 hours, life-time 3 years.
Internal battery	Capacity 2.6 Ah. LiIon. Operational time 4 hours, life-time 3 years.

*For transportation by air, please observe that the click-on battery capacity is 192 Wh which exceeds stated limits. Always consult your airline company for transportation restrictions.

8.2.4.2 Environmental Conditions

ENVIRONMENTAL CONDITIONS	SPECIFICATION
Operating temperature range	5 to 40°C (41 to 104°F)
Storage and transport temperature	-20 to +60°C (-4 to +140°F)
Ambient pressure range	700 to 1100 mbar, corresponding to ~3000 metres (10000 feet) above sea level to ~700 metres (2300 feet) below sea level, at normal atmospheric pressure.  As seen in the graph above, the Vivo 55 is unable to deliver set max pressure at a very low ambient pressure.
Humidity	10% to 95%, non-condensing

8.2.4.3 Leakage Conditions

LEAKAGE CONDITIONS	SPECIFICATION
Recommended leakage	20 to 50 l/min at 10 cmH_2O (leakage circuit)
Minimum leakage	12 l/min at 4 cmH_2O (leakage circuit)

8.2.4.4 Circuit Resistance and Compliance Conditions

CIRCUIT RESISTANCE AND COMPLIANCE LIMITS	SPECIFICATION
Leakage-port circuit resistance	0 to 8 cm H_2O at 60 l/min 0 to 20 cm H2O at 120 l/min
Leakage-port circuit compliance	0 to 4 ml/cm H_2O

CIRCUIT RESISTANCE AND COMPLIANCE LIMITS	SPECIFICATION
Exhalation-valve circuit resistance	0 to 20 cm H_2O at 60 l/min 0 to 35 cm H_2O at 120 l/min
Exhalation-valve circuit compliance	0 to 4 ml/cm H_2O

8.2.4.5 Oxygen Inlet

OXYGEN INLET	SPECIFICATION
Oxygen inlet port	Maximum flow: 15 l/min (medical oxygen) Oxygen coupling is type CPC MC1602

8.2.4.6 Sound Level

SOUND LEVEL	SPECIFICATION
Sound level at 10 cmH_2O in CPAP mode	Less than 30 dB(A) Measured at 1 m

8.2.4.7 Miscellaneous

MISCELLANEOUS	RESULT AND RANGE
Maximum flow	> 300 l/min
Maximum limited pressure during single fault condition	60 cmH_2O (PCV, PSV & VCV) 30 cmH_2O (CPAP)
Breathing resistance under single-fault	1 cmH_2O at 30 l/min 3.5 cmH_2O at 60 l/min
Bias-flow when using active exhalation valve	8 l/min

8.2.4.8 Vivo 55 Dimensions

DIMENSIONS	SPECIFICATION
W × H × D	348 × 120 × 264 mm (13.7 × 4.7 × 10.4 inch) without click-on battery 348 × 120 × 290 mm (13.7 × 4.7 × 11.4 inch) with click-on battery
Weight	5 kg (11.0 lb) without click-on battery 7 kg (15.5 lb) with click-on battery
Patient air outlet	22 mm male, 15 mm female conical standard connector

8.2.4.9 CO_2 Sensor

CO_2 SENSOR	SPECIFICATION
W × H × D	38 × 37 × 34 mm (1.5 × 1.5 × 1.4 inch)
Cable length	2.4 m (7.8 ft)
Weight	75 g (0.2 lb)
Warm-up time	10 s
Total system response time	<1 s
Interference from medical gases: O_2	<0.1% relative CO_2 per % O_2 (calibrated at 21% O_2)
CO_2 indicator	0 to 25%

8.2.4.10 Filtering/Smoothing Techniques

FUNCTION	TECHNIQUE DESCRIPTION
Pressure	Low pass average time constant 16 ms
Inspiration trigger	Differential mass flow resolution 4 ms
Expiration trigger	Flow low pass filtering with level sensing

8.3 Emission and Immunity Declaration

8.3.1 Vivo 55 Essential Performance

The Vivo 55 will deliver ventilation at the patient-connection port within its published accuracy specifications and within the alarm limits set by the operator, or generate an alarm condition for high pressure, low pressure, high PEEP, low inspired tidal volume, low expired tidal volume, low inspired minute volume, low breath rate, high $EtCO_2$, high and low FiO_2, obstruction, low last power source, or power failure.

The Vivo 55 will provide SpO_2 and pulse rate values within its published accuracy specifications and generate an alarm upon a low SpO_2 condition.

The Vivo 55 will provide indication when the SpO_2 value or pulse rate is potentially incorrect, and generate an alarm condition to indicate when the SpO_2 value update period has exceeded 30 seconds.

The Vivo 55 will provide $EtCO_2$ and FiO_2 values within its published accuracy specifications and generate an alarm condition upon high and low $EtCO_2$ and FiO_2 conditions.

Under the immunity test conditions of IEC 60601-1-2 4th Ed., the following allowances are acceptable:

- Error of delivered volume and PEEP of individual breaths up to 35% and error of the delivered volume and PEEP averaged over a one-minute interval up to 25%.
- Any temporary degradation of SpO_2, $EtCO_2$ or FiO_2 performance following transient immunity test exposure shall recover from any disruption within 30 seconds.

Additionally, the following shall not be allowed:

- permanent damage or unrecoverable loss of function
- changes in programmable parameters or settings
- reset to default settings
- change of operating mode
- initiation of unintended operation

8.3.2 Guidance and Manufacturer's Declaration – Electromagnetic Immunity

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

Immunity Test	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact±15 kV air	The relative humidity should be at least 5 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	AC Power (Mains) quality should be that of a typical commercial, hospital and residential environment.
Surge IEC 61000-4-5	±1 kV line to line	AC Power (Mains) quality should be that of a typical commercial, hospital and residential environment.

Immunity Test	Compliance Level	Electromagnetic Environment - Guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial, hospital and residential environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T, 0.5 cycle (multiple phase analysis); 0% U_T, 1 cycle; 70% U_T, 25/30 cycles (50/60 Hz); 0% U_T, 250/300 cycles (50/60 Hz);	Vivo 55 runs on internal battery during voltage dips, short interruptions and voltage variations on power supply input lines.

U_T is the AC Power (Mains) voltage prior to application of the test level.

WARNING!

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 ventilator, including cables specified. Otherwise, degradation of the performance of this equipment could result.

Immunity Test	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	150 kHz to 80 MHz 3 Vrms ISM and amateur radio bands; 6 Vrms	d=0.35*√P m at 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	d= 1.2*√P m at 80 MHz to 800 MHz d= 2.3*√P m at 800 MHz to 2.5 GHz **Equation description:** P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and, except for portable RF communications equipment, d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with this symbol: 

NOTE

At 80 MHz and 800 MHz, the higher frequency range applies.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ventilator is used exceeds the applicable RF compliance level above, the ventilator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ventilator.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

8.3.3 Guidance and Manufacturer's Declaration – Electromagnetic Emission

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

Emissions test	Compliance Level	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The ventilator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The ventilator is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emission IEC 61000-3-3	Complies	

8.3.4 Recommended separation distances between portable and mobile RF communications equipment and the ventilator

The ventilator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ventilator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ventilator as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to the frequency of transmitter (m)**		
	150 kHz to 80 MHz d= 0.35*√P m	**80 MHz to 800 MHz d= 0.6*√P m**	**800 MHz to 2.5 GHz d= 1.2*√P m**
0.01	0.035	0.06	0.12
0.1	0.11	0.19	0.36
1	0.35	0.60	1.2
10	1.1	1.9	3.6
100	3.5	6.0	12

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE

At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

8.3.5 Recommended separation distances between external power conductors and the ventilator

Rated maximum current in conductor (A)	Separation distance (m)
	50-60 Hz d= I/2πH= I/188
1	0.005
10	0.05
30	0.16

For conductors rated at a maximum current not listed above, the recommended separation distance d in metres (m) can be estimated using the equation d=I/2πH, where I is the maximum current rating of the conductor in amperes (A) according to the transmitter manufacturer; H is the ventilator immunity compliance level to electromagnetic fields in the 50-60 Hz frequency span (30 A/m).

8.4 Default Settings

Default settings: modes and functions

Ventilation Mode: Pressure, PCV(A)

Breath Mode: Assist/Control

Device Mode: Clinical

Home Adjust: Off

Profile 1: Active

Profile 2: Off

Profile 3: Off

Default settings: parameters

Inspiratory Pressure: 15 cmH_2O
PEEP: 5 cmH_2O
SIMV Rate: 12 bpm
Inspiration Time: 1.5 s
Rise Time (ventilation mode: pressure): 3
Inspiratory Trigger: 3
SIMV Support Pressure: 15 cmH_2O
Expiratory Trigger: 3
Maximum Inspiratory Time: Off
Minimum Inspiratory Time: Off
Backup Rate: 12 bpm
Backup Inspiration Time: 1.5 s
Sigh: Off
Sigh Rate: 100 bpm
Sigh %: 125%
Target Volume: Off
Tidal Volume: 400 ml
Max Pressure: 15 cmH_2O
Min Pressure: 15 cmH_2O
Flow Pattern: Square
CPAP: 10 cmH_2O

Default settings: alarms

High Pressure Alarm: 25 cmH_2O
Low Pressure Alarm: 10 cmH_2O
High PEEP Alarm: Off
Low PEEP Alarm: Off
High Vt Alarm: 500 ml
High Vt_e Alarm: 500 ml (Adult), 400 ml (Paediatric)
Low Vt Alarm: 200 ml
High MV Alarm: 8 l
Low MV Alarm: 3 l
High Breath Rate Alarm: 20 bpm
Low Breath Rate Alarm: 8 bpm
Apnea Alarm: Off
Disconnection Alarm: On
Rebreathing Alarm: On
Obstruction Alarm: Off
High FiO_2 Alarm: Off
Low FiO_2 Alarm: Off
High SpO_2 Alarm: Off
Low SpO_2 Alarm: 85%
High $EtCO_2$ Alarm: 51 mmHg
Low $EtCO_2$ Alarm: Off
High $InspCO_2$ Alarm: Off
High Pulse Rate Alarm: Off
Low Pulse Rate Alarm: Off

Default settings: other

Patient operating time: 0 h
Display light: On
Light Intensity: 5
Alarm sound level: 5
CO_2 Unit: mmHg
Auto keypad lock: Off
Patient circuit type: Exh. Valve
Pre-use Test: On

9 Accessories and Parts

WARNING!

Only use accessories recommended by Breas Medical AB. Breas Medical AB cannot guarantee the performance and safety for the use of other accessories with the Vivo 55. To reduce the likelihood of disconnection and to prevent adverse ventilator performance, use only accessories compatible with the Vivo 55.

NOTE

Accessory equipment connected to the analogue and digital interfaces must be certified according to the respective IEC standards (e.g. IEC 60950 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 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.

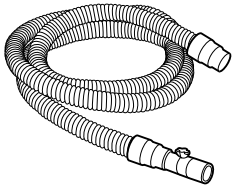
The following Breas accessories are currently available for the Vivo 55:

9.1 Patient Circuits and Air Delivery Accessories

Circuit: 22 mm smoothbore with leak port

Function: Delivers air to the patient, applied part

Part No: 005060

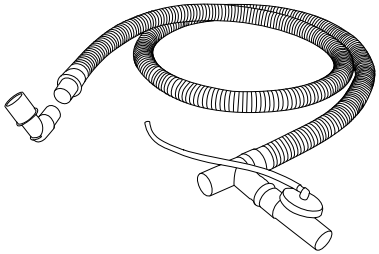


Circuit: Dual Limb with Exhalation Valve

Function: Deliver air to the patient.

Part No:

007616 (disposable)



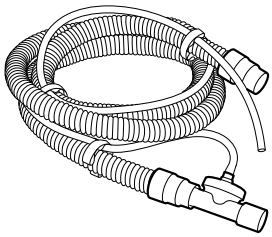
Circuit: Single limb with active exhalation valve

Function: Deliver air to the patient

Part No:

005055 (reusable)

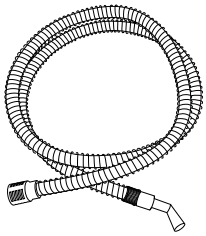
005050 disposable)



Circuit: Single limb for Mouthpiece ventilation (MPV)

Function: Deliver air to the patient

Part No: 006093



Mouthpiece

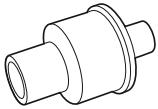
Function: Patient interface for Mouthpiece ventilation (MPV)

Part No: 006094

Hygroscopic Condenser Humidifier (HCH)

Function: Humidifier

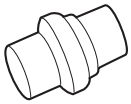
Part No: 003974



Leakage port

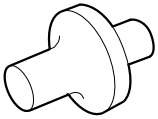
Function: Providing a leakage

Part No: 004426



Low resistance bacterial filter (303 Respirgard-II Filter)

Function: Filter air at ventilator outlet



Characteristics

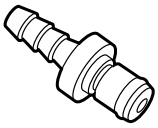
- Resistance: 1.8 cmH_2O @ 60 l/m
- Deadspace: 30 ml
- BFE (Bacterial Filtration Efficiency): 99.9%
- VFE (Viral Filtration Efficiency): 99.8 %

Part No: 004185

Low pressure oxygen adapter

Function: Oxygen tube adapter with connector for the Vivo 55.

Part No: 005032



9.2 Power Accessories

Power cord

Function: Deliver power to the ventilator

Part No:

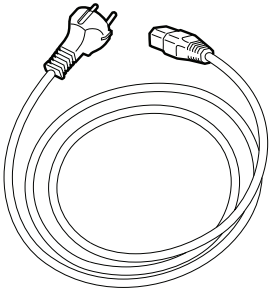
EU: 005336

UK: 005337

AU/NZ: 005049\

JP: 1,8 m:\005338\3,6 m:\007220

US: 1.8 m:\005432\3.6 m:\007219\



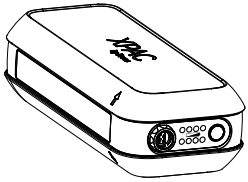
XPAC - External battery with charger

Function: Extends usage time of supported Breas products.

Part No Cable for connection to device: 007804

Part No Charger with cable:
Single: Charger with one battery
Dual: Charger with two batteries

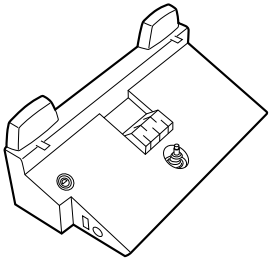
Single: 007995, Dual: 007999



Click-on battery

Function: Power source for transportation

Part No: 004559



Click-on battery charger

Function:

Part No:

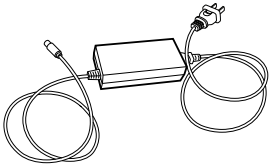
EU: 005186

US: 005189

UK: 005187

AU/NZ: 005188

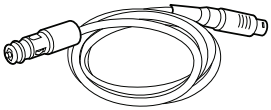
JP: 005190



External Battery cable 24 V DC

Function:

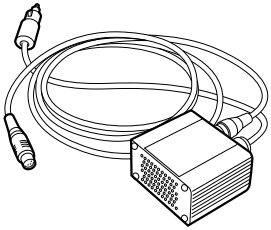
Part No: 004899



12/24 V converter

Function: Convert 12 V DC, in a car for example, to stable 24 VDC.

Part No: 004901

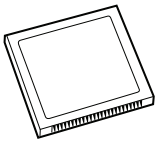


9.3 Monitoring Accessories

Memory card

Function: Vivo 55 settings, patient data and usage data

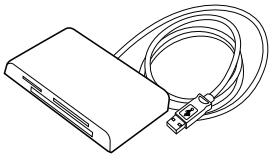
Part No: 003619



Memory card reader/writer

Function: Read/write memory card

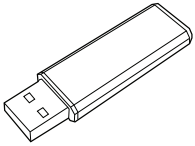
Part No: 002185



Vivo 55 PC software USB

Function: Data monitoring software

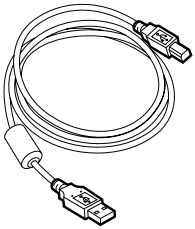
Part No: 005100



Vivo 55 USB cable

Function: Data cable: PC and Vivo 55 (USB to USB)

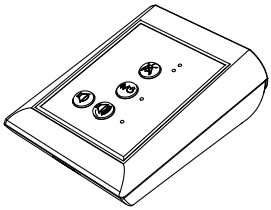
Part No: 004886



Remote alarm with cable

Function: Monitor Vivo 55 alarms remotely

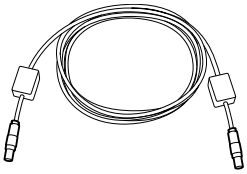
Part No: 10 m: 006348, 25 m: 006349



Remote alarm cable

Function:

Part No: 10 m: 006359, 25 m: 006360, 50 m: 006361



Nurse call cable

Function: Connect the ventilator to a hospital nurse call system

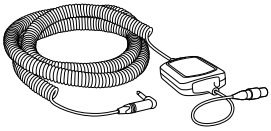
Part No:

NO: 006365

NC: 006364

10 kΩ, NO: 006363

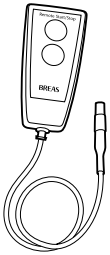
10 kΩ, NC: 006362



Remote start/stop

Function: Start and stop the ventilator remotely. Also, pause audio remotely.

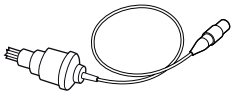
Part No: 006342



FiO_2 sensor

Function: Measure O_2 in the patient air

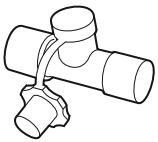
Part No: 006347



T-piece with plug

Function: Connect the FiO_2 sensor to the patient circuit

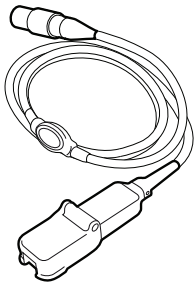
Part No: 005120



SpO_2 module

Function: Connection interface

Part No: 006369



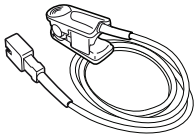
SpO_2 sensor

Function: Finger Clip SpO_2 sensor

Part No:

Adult: 006589

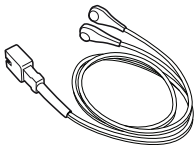
Paediatric: 006590



SpO_2 sensor

Function: Multisite SpO_2 sensor

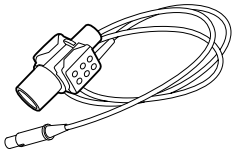
Part No: 006591



$EtCO_2$ sensor

Function: Measure CO_2 in the airflow

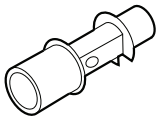
Part No: 006346



Airway adapter

Function: Connects the $EtCO_2$ sensor to the patient circuit

Part No: 005263 (25 pcs)

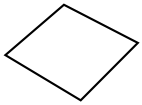


9.4 Ventilator Filters and Detachable Parts

Patient air inlet filter (white)

Function: Inlet air filtration

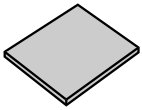
Part No: 004910 (10 pcs)



Patient air inlet filter (grey, washable)

Function: Inlet air filtration

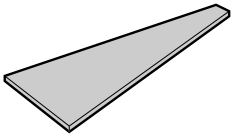
Part No: 004909 (5 pcs)



Cooling air inlet filter (grey, washable)

Function: Inlet air filtration

Part No: 006435 (5 pcs)



9.5 Other Accessories

Manual

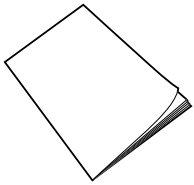
Function: Product and usage information

Part No User manual:

006625

Part No Clinician's manual:

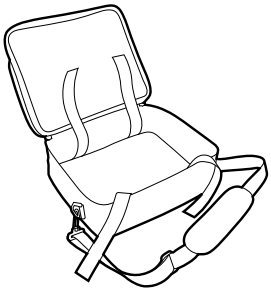
006626



Carry bag

Function: Storage for transportation

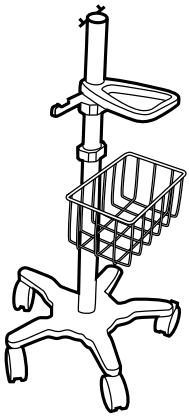
Part No: 006343



Trolley

Function: Mobile use, transportation

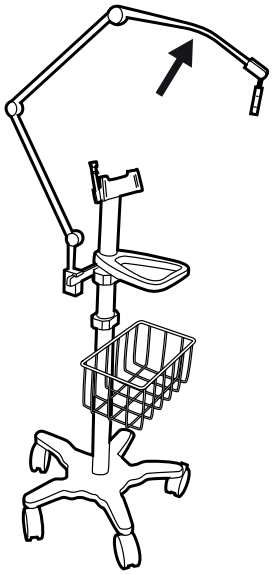
Part No: 007384



Patient circuit arm

Function: To support a patient circuit.

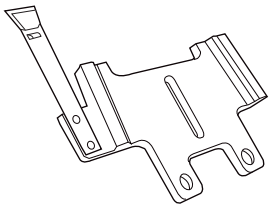
Part No: 007917



Mounting bracket

Function: Mount the Vivo 55 on the trolley or a hospital rail system

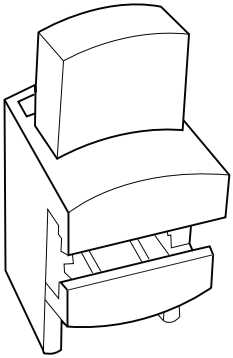
Part No: 007916



Universal rail clamp

Function: Attach a humidifier to a trolley. This accessory is part of the trolley system.

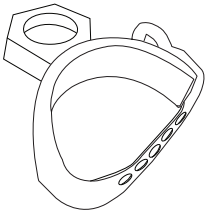
Part No: 007858

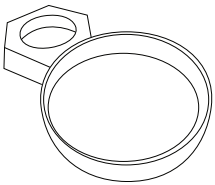


E-cylinder holder

Function: Attach an E-cylinder to a trolley. This accessory is part of the trolley system.

Part No: 005128

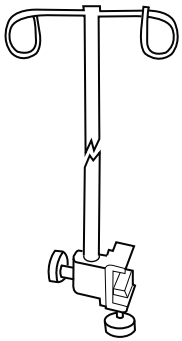




IV-pole

Function: Pole with hooks to hang IV fluid bags.

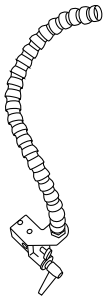
Part No: 007859



MPV Arm

Function: Hold an MPV circuit so Mouthpiece can be mounted close to the patient

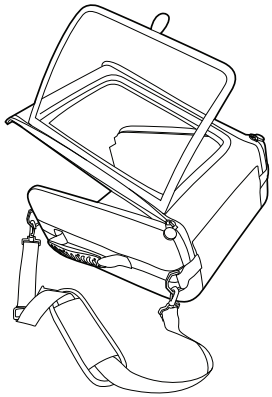
Part No: 006095



Protective cover

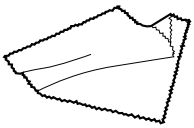
Function: Shock protection

Part No: 006344



Polishing cloth

Part No: 005066



10 Patient Settings

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

Patient Settings - Vivo 55

Patient .....

Date .....

Clinic .....

Set by .....

Ventilation mode:.....

Patient Circuit	Tidal Volume
Pressure	Inspiratory Trigger
PEEP	Expiratory Trigger
Breath Rate	Min Inspiratory Time
Inspiratory Time	Max Inspiratory Time
Backup Rate	Backup Inspiratory Time
Target Volume	Min Pressure
Max Pressure	CPAP
SIMV Rate	SIMV Support Pressure
Flow Pattern	

Notes

.....

.....

11 FAA Compliance

11.1 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.

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