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1 Introduction

WARNING!

Vivo 40 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 shape and only with accessories specified or approved by Breas Medical AB.

Every other use may lead to risk of personal injury!

CAUTION!

Read this operating manual thoroughly so that you completely understand how the Vivo 40 is operated and maintained before taking it into use, to ensure correct usage, maximum performance and serviceability.

WARNING!

Do not use the Vivo 40 for any kind of total ventilatory requirement.

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

1.1 What is the Vivo 40?

The Vivo 40 is a pressure-supported and pressure-controlled ventilator.

It has three modes of operation: PCV (Pressure Control Ventilation), PSV (Pressure Support Ventilation) and CPAP (Continuous Positive Airway Pressure). The PCV and PSV modes have an adjustable inspiratory trigger sensitivity setting which allows the patient to initiate ventilator-assisted breaths.

- In the PCV mode (Pressure Control Ventilation), the ventilator provides assisted or controlled pressure-regulated breathing. In PCV mode, the clinician sets an inspiration time. The inspiratory pressure is set by the IPAP (Inspiratory Positive Airway Pressure) setting. The end-expiratory pressure is set by the EPAP (Expiratory Positive Airway Pressure) setting.
- In the PSV mode (Pressure Support Ventilation), the ventilator's expiratory trigger can also be adjusted allowing the ventilator to more easily match each patient's needs. The inspiratory pressure is set by the IPAP setting. The end-expiratory pressure is set by the EPAP setting.
- In the CPAP mode (Continuous Positive Airway Pressure), the ventilator provides a continuous positive airway pressure.

The Vivo 40 has a pressure sensor that continuously monitors output pressure to the patient and reference ambient pressure, so that the device automatically will compensate for altitude changes.

The internal memory of the Vivo 40 can be downloaded to a PC where you can view the patient compliance data in the Breas Vivo PC Software.

For more information about the Breas Vivo PC Software, please contact your Breas representative.

1.2 Intended Use

The Vivo 40 is an assist ventilator intended to augment the breathing of spontaneously adult patients >66 lbs (>30 kg) suffering from respiratory failure, respiratory insufficiency, or obstructive sleep apnea.

The Vivo 40 is not intended to provide the total ventilatory requirements of the patient.

The Vivo 40 is intended to be used for both invasive and non-invasive applications.

The Vivo 40 is intended to be operated by qualified and trained personnel.

The Vivo 40 is intended for use in clinical settings (e.g., hospitals, sleep laboratories, sub-acute care institutions) and home environments. The Vivo 40 must always be prescribed by a licensed physician.

The CPAP function is intended to deliver continuous positive airway pressure therapy for the treatment of obstructive sleep apnea, via non-invasive nasal or full-face masks.

1.3 Contraindications

The use of the Vivo 40 is contraindicated on patients with severe respiratory failure without a spontaneous respiratory drive.

The use of the Vivo 40 for positive pressure therapy may be contraindicated on patients:

- Incapable of maintaining life- sustaining ventilation in the event of a brief circuit disconnection or loss of therapy.
- Unable to maintain a patent airway or adequately clear secretions.
- At risk for aspiration of gastric contents.
- With a history of allergy or hypersensitivity to the mask materials where the risk from allergic reaction outweighs the benefit of ventilatory assistance.

Therapy with the Vivo 40 should **not** be prescribed when the following specific diseases or conditions are present:

- Bullous lung disease
- Pathologically low blood pressure
- Severe cardiac arrhythmias
- Coronary artery disease
- Unstable angina pectoris
- Decompensated cardiac failure or hypotension, particularly if associated with intravascular volume depletion
- Recent thoracic surgery
- Pneumothorax
- Pneumomediastinum

- Massive epistaxis or previous history of massive epistaxis (risk of recurrence)
- Pneumoencephalus, recent trauma or surgery that may have produced cranio-nasopharyngeal fistula
- Cerebral spinal fluid (CSF) leaks
- Acute or unstable respiratory failure or insufficiency
- Conditions predisposing to a risk of aspiration of gastric contents
- Impaired ability to clear secretions

Caution should be used when prescribing positive airway pressure therapy for susceptible patients, such as patients with abnormalities of the cribriform plate, or prior history of head trauma.

The use of CPAP therapy may be temporarily contraindicated if the patient exhibits signs of a sinus or middle ear infection.

1.4 About this Manual

Always read this manual before setting up and using the Vivo 40 or performing maintenance on the machine, to ensure correct usage, maximum performance and serviceability.

Breas Medical AB reserves the right to make changes to the contents of this manual without any prior notification.

Audience

This manual is primarily intended for care providers, clinical personnel, physicians and others who require a working knowledge of the Breas Vivo 40 system. The manual comprises detailed information on the settings and functions of the Vivo 40 to be handled by trained health care personnel only.

- Patients and other lay users operating the Vivo 40 will find all the information they need in the User Manual.
- Service personnel may order the Vivo 40 Service Manual that contains detailed technical information for maintenance, service and repair.

Icons

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 and serious personal injury.
	**Caution!** Risk of minor or moderate injury. Risk of equipment damage, loss of data, extra work, or unexpected results.
	**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.

2 Safety Information

2.1 General User Precautions

- The Vivo 40 must be switched off and on at least once a day. This is necessary in order for the Vivo 40 to perform a self test.
- U.S. Federal law restricts this device for sale by or on order of a physician.
- The Vivo 40 should not be used for any kind of total ventilatory requirement.
- The Vivo 40 shall only be used by patients with spontaneous breathing.
- Advice contained in this manual should not supersede instructions given by the prescribing physician.
- If the patient is admitted to a hospital or is prescribed any other form of medical treatment, always inform the medical staff that the patient is on mechanical ventilation treatment.
- Vivo 40 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 shape and only with accessories specified or approved by Breas Medical AB.
- Do not use the Vivo 40 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 40 is abnormally hot or emits an odor. Contact your responsible care provider for an inspection.
- Inadequate use of device or accessories may cause loss of treatment or decreased performance.
- The Vivo 40 therapy settings must always be based on medical supervision and must be changed by authorized clinical personnel only. Blood gas measurement should be performed when changing settings or changing to another device.

- Always perform the procedure "Set up the Vivo 40 Before Use" on page 35 before using the Vivo 40.
- Only use accessories recommended by Breas Medical AB.

- Clinical personnel must read the Clinician's manual thoroughly and understand the Vivo 40 operation before setting up and using the machine.
- The user must read the user manual thoroughly and understand the Vivo 40 operation before using the machine.
- All the physiological alarms of the Vivo 40 must be set at safe levels that will effectively warn the user of any risk. The alarm levels should be assessed considering the patient settings. Any change of settings or components may require the readjustment of the alarm levels.
- Handle the Vivo 40 with care.
- Make sure to place and pack the device in a way that prevents unintentional start of the machine. Due to the internal battery, the Vivo 40 may start if the Start/Stop button is pressed even without the AC power being connected.
- Do not use the Vivo 40 while in a carry bag. Attach the rear lid and place the swivel in a down position when placing the Vivo 40 in the bag.
- If using the Vivo 40 for a short intra hospital or vehicle transportation, the following cautions need to be observed:
  - Do not mount the Vivo 40 on a wheelchair or in a vehicle.
  - Make sure that the Vivo 40 stands securely in a upright position and cannot tilt or fall.
  - Do not use the Vivo 40 outdoors during rain or snowfall.
  - If the HA 01 humidifier is attached, make sure that it is not in use and that it is empty.

2.2 Electrical Safety

- Do not operate the Vivo 40 if it has a damaged power cord or casing.
- The Vivo 40 may not work properly if any part has been dropped, damaged or submerged in water.
- To avoid electrical shock, disconnect the electrical supply to the Vivo 40 before cleaning. Do not immerse the Vivo 40 into any fluids.
- The operator shall not touch accessible contacts of connectors and the patient simultaneously.
- When handling the HA 01 humidifier, always turn off the Vivo 40 and disconnect the Vivo 40 from the AC power supply.
- Accessory equipment connected to the analog 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 shall comply with the valid version of the system standard IEC 60601-1-1. Therefore, everyone who connects additional equipment to the signal input part or signal output part configures a medical system is responsible that the system complies with the requirements of the valid version of the system standard IEC 60601-1-1. If in doubt, consult the technical service department or your local representative.

- If an external battery is used, always disconnect it when the Vivo 40 is switched off. Otherwise there is a risk that the battery will discharge.
- If the AC power source fails and the internal or the external battery activates, the HA 01 humidifier will be turned off automatically. It must be activated again manually, if humidification during battery use is necessary.
- Only use the data connection to connect the Vivo 40 to the iCom or a PC.

2.3 Environmental Conditions

- Do not use the Vivo 40 in any toxic environment.
- Do not use the Vivo 40 in environments where there are explosive gases or other flammable anesthetic agents present.
- The air flow for breathing produced by the Vivo 40 can be as much as 10°F (5°C) higher than room temperature. Caution should be exercised if the room temperature is greater that 95°F (35°C).
- If a room humidifier is used, place it at least 6 feet (2 meters) away from the Vivo 40.
- The performance of the Vivo 40 may deteriorate at ambient temperatures below 41°F (5°C) and above 100°F (38°C).

- Do not use the Vivo 40 while positioned in a warm place, such as direct sunlight.
- The device complies with the EMC requirements of standards listed in "Compliance of Standards" on page 95. Necessary measures should be taken in order to assure that field levels exceeding 10 V/m are avoided, since this may impair the safety and performance of the Vivo 40. 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 m to the Vivo 40. Examples include: radio emitting devices such as cellular or cordless telephones, microwave ovens and high-frequency surgery apparatus.
- The Vivo 40, all accessories and replacement 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 40 and treatment of the patient may deteriorate if the operation conditions in "Technical Specifications" on page 89 are not fulfilled. Do not use the Vivo 40 immediately after storage or transport outside the recommended operating conditions.

2.4 Usage of Patient Circuit

- Only use the Vivo 40 with a mask, patient tube and leakage port recommended by Breas Medical AB and your health care professional.
- The Vivo 40 requires an intentional leak port instead of an actively controlled exhalation valve to remove exhaled gases from the patient circuit. Therefore, specific masks and patient circuits using an intentional leakage are required for normal operation. The pressurized air from the Vivo 40 causes a continuous flow of air to exhaust from the leak ports, flushing exhaled gas from the circuit. The Vivo 40 should be turned on and the intentional leak ports should be checked before application.
- Do not breathe in the connected patient circuit unless the Vivo 40 is turned on and operating properly.
- Do not use patient hoses or tubes made of static or electrically conductive material.
- Always use a new mask, tube and leakage port when the Vivo 40 is to be used by a new patient.
- Patient connected parts and filter must be replaced regularly to ensure correct function of the Vivo 40. All replaced parts must be disposed of according to local environmental regulations regarding the disposal of used equipment and parts.
- Periodically check for moisture in the patient circuit. When present, remove the moisture. Before attempting to dry the circuit, disconnect it from the Vivo 40 to ensure no water will flow back into the Vivo 40. The frequency at which these checks must be performed will depend on the patient's own condition and the device used. You should assess this on an individual basis in accordance with the patient's needs.
- If the patient needs assistance to take off the patient interface, the patient shall not be left alone. This is to avoid the risk of re-breathing of CO_2 in case of accidental ventilator failure. If the patient is using a full face mask (covering mouth and nose), the mask must be equipped with a safety entrainment valve.

- Make sure that the ventilation holes in the mask or the leakage ports are never blocked or obstructed. These ports are used to prevent re-breathing of exhaled air. Re-breathing of exhaled gases for longer than several minutes can, in some circumstances, lead to suffocation.
- At low CPAP pressures, the air flow through the ventilation holes in the mask or the leakage ports may be inadequate to clear all exhaled gases. Some re-breathing may occur.
- Do not leave long lengths of air tubing around the top of the bed. It could twist around the patient's head or neck while sleeping.
- Always follow the instructions of the mask manufacturer.

2.5 Invasive Use

- For invasive applications, assure that an intentional leakage port is present in the patient circuit. Install the leakage port as close as possible to the patient connection, to reduce the risk of rebreathing CO_2.
- When using the Vivo 40 invasively the low volume alarm and the low breath rate alarm must be carefully set, to ensure safe use.
- The highest output from the HA 01 humidifier is 30 mgH_2O/litre, which means that it does not fulfill the humidifier standard for invasive use.
- The Vivo 40 is equipped with a low leakage alarm. The low leakage alarm is not a substitute for operator vigilance in ensuring that the leakage ports remains clear at all times. Periodically check the leakage ports during therapy.
- In general as pressure decreases the potential of rebreathing increases. Lower pressures produce less flow through the leakage ports which may not clear all CO_2 from the circuit to prevent rebreathing.
- In general as inspiratory time increases the potential of CO_2 rebreathing increases. A higher inspiratory time decreases the expiratory time allowing less CO_2 to be cleared from the circuit before the next breath. I:E (inspiration time : expiration time) ratios close to 1:1 increase the potential of CO_2 rebreathing.
- Tracheal tubes, oral/nasal tubes etc with small inner diameters increase the resistance in the breathing circuit.
- An external heated humidifier approved for invasive use or an appropriate HME (Heat and Moisture Exchanger, artificial nose)/HCH (Hygroscopic Condenser Humidifier) is recommended.

2.6 Usage of Filters

- Always use the Vivo 40 with patient air inlet filters installed. Only use filters that are specified in this manual.
- Replace or clean the filters regularly to ensure correct function of the Vivo 40, especially when changing patient. Failure to replace or clean a dirty filter may cause the Vivo 40 to operate at higher temperatures than intended.
- When operating the Vivo 40, make sure that the air inlet and filters are not obstructed or occluded.
- If the Vivo 40 is used in a clinic by several patients, a low resistance bacteria filter is recommended between the air outlet and the patient circuit to prevent patient cross-contamination. Breas Medical AB recommends the usage of the Breas filter 004185, see "Breas Accessories List" on page 99. Reuse of mask or bacteria filter may expose patients to contagious agents.
- The use of a high resistance bacteria filter on the output of the device may interfere with the operation of the patient disconnect function. It may also interfere with the device trigger function.
- Do not connect any filter to the HA 01 humidifier.

2.7 Humidification

- The HA 01 humidifier is intended for non-invasive use only.
- Do not place the Vivo 40 with the HA 01 humidifier in a bag.
- When the HA 01 humidifier is installed, the Vivo 40 must be located below the patient and on a flat surface. This is to prevent personal injury from accidental spillage or from excess water or condensation flowing down the patient tube and into the patient's mask. Extra cautions should be taken for patients who are unable to guard their airways or cannot pull off the mask.
- When using an external heated humidifier, it should be located below the Vivo 40 and the patient to prevent injury from accidental spillage.
- 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 condensated water in the patient circuit from running into the patient airways and causing personal injury.

The use of an HME (Heat and Moisture Exchanger, artificial nose) or an external humidifier may require readjustment of the Vivo 40's low-pressure alarm.

- Certain HME's and HCH's (Hygroscopic Condenser Humidifiers) are sufficient to provide humidification when the Vivo 40 is used invasively. Check specific suppliers recommended use.

2.8 Cleaning and Maintenance

- The Vivo 40 should be cleaned and maintained in accordance with this operating manual.
- Do not attempt to autoclave or sterilize the Vivo 40.
- Vivo 40 should be subjected to maintenance, service and control and any applicable upgrades, in accordance with Breas service instructions.
- Vivo 40 shall only be repaired or modified in accordance with Breas service manuals, technical bulletins, and any special service instructions, by service technicians authorized by Breas Medical AB.
- Do not under any circumstances attempt to service or repair the Vivo 40 yourself. If you do so, the manufacturer will no longer be responsible for the performance and safety of the Vivo 40. Furthermore, no warranty will be valid.

2.9 Adverse Patient Symptoms

If the patient experiences discomfort or any of the following symptoms while using the Vivo 40, a physician or responsible clinician shall be contacted immediately:

- Bloated feeling from excessive swallowing of air while awake
- Air continually leaking from the mouth while sleeping
- Dryness of air passages or nose
- Ear pain, runny nose or sinus discomfort
- Day time sleepiness
- Disorientation or memory lapse
- Mood change or irritability
- Skin sensitivity
- Severe headache
- Chest discomfort
- Shortness of breath

The following are potential side effects of non-invasive positive pressure therapy:

- Ear discomfort
- Conjunctivitis
- Skin abrasions due to non-invasive interfaces
- Aero phagia (gastric distension)

2.10 Usage of Oxygen

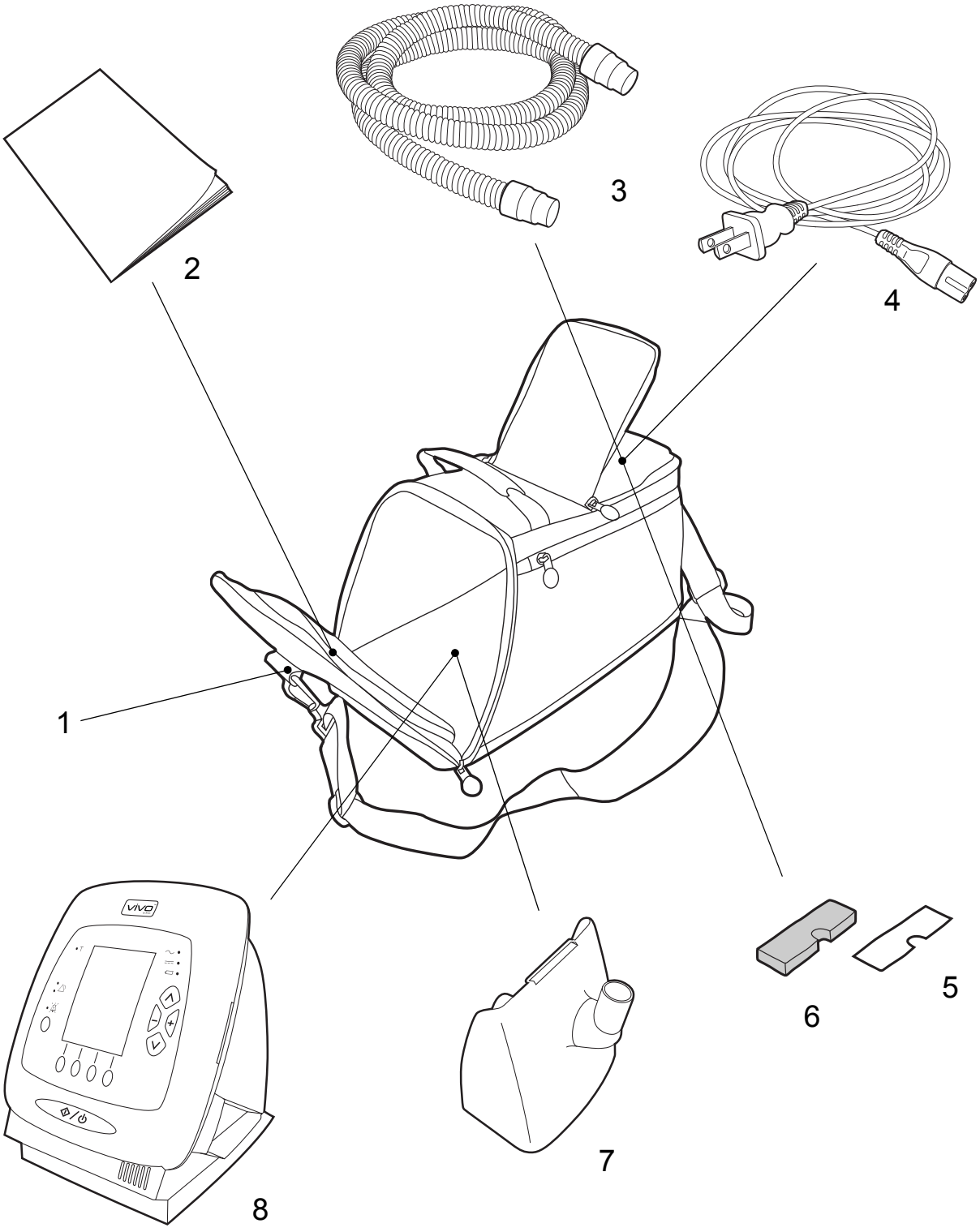
- The presence of oxygen can speed up combustion of inflammable materials.
- If oxygen has been prescribed, connect the oxygen supply tube to the appropriate oxygen port of the nasal mask or breathing system connector.
- At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure delivered, patient's breathing pattern, mask selection, and leak rate.
- When oxygen is used with the Vivo 40, the oxygen flow must be turned off when the Vivo 40 is not operating.
- Ventilate the room adequately.
- Do not smoke in a room where oxygen is being used.
- Naked light bulbs and other sources of ignition must be kept a minimum of 6 feet (2 meters) away from the oxygen cylinder or any part of the patient circuit.
- Do not use aerosols or solvents close to the oxygen supply, even when the oxygen supply is shut off.
- When the Vivo 40 is not in operation, and the oxygen flow is left on, oxygen delivered into the patient tubing may accumulate within the machine enclosure. Oxygen accumulated in the machine enclosure will create a risk of fire.

- Supplemental oxygen may trigger the low leakage alarm prematurely.
- Supplemental oxygen flow may not exceed 15 liter/min.
- Supplemental oxygen affects the accuracy of the volume and flow measurements. It is not recommended to use supplemental oxygen when target volume is active.

3 Product Description

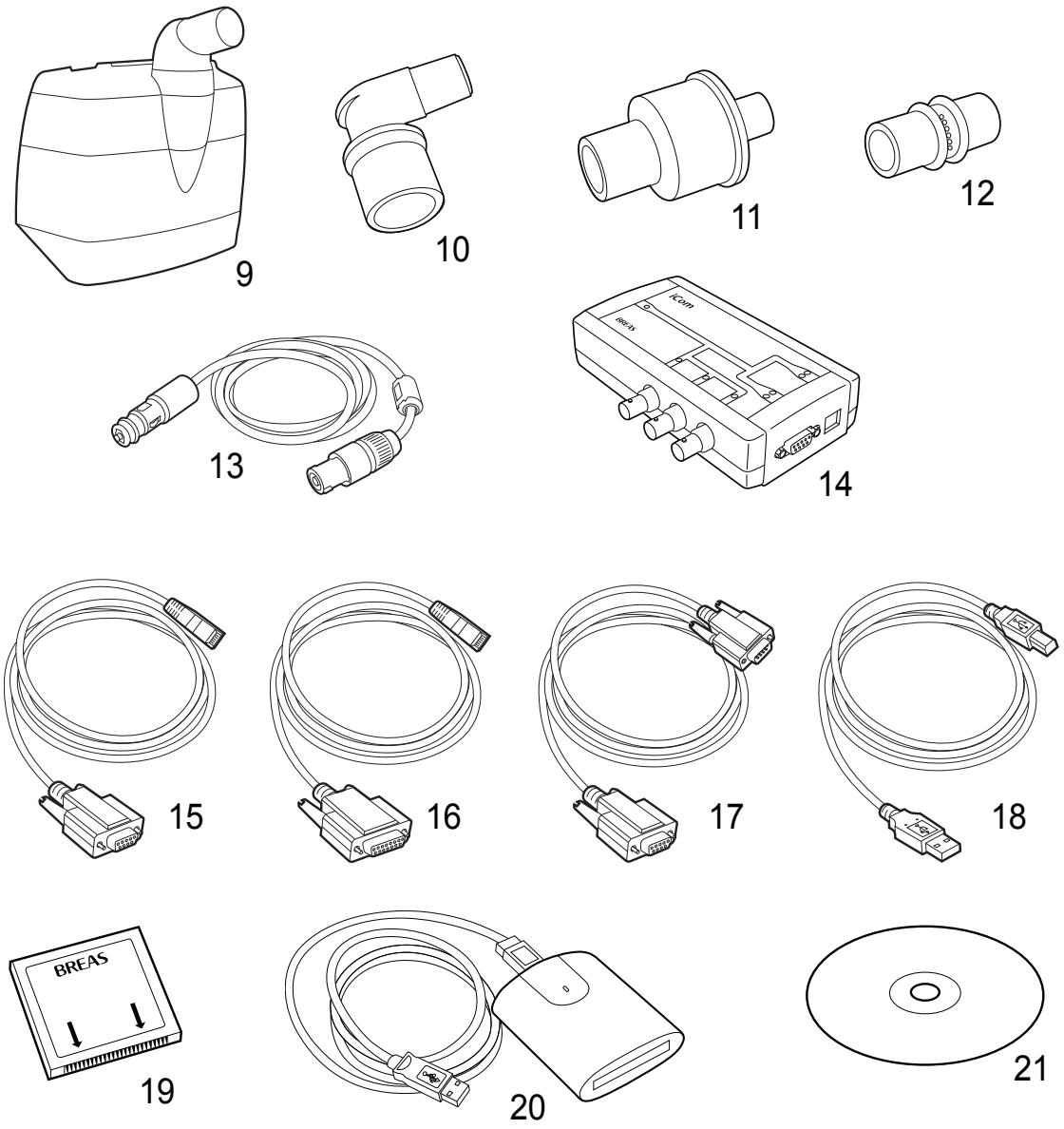
3.1 Main Components

The Vivo 40 system contains the following components:



NO.	COMPONENT	FUNCTION	PART NO.
1	Carry bag	Storage for transportation	003519
2	User manual	Product and usage information	003819
3	Patient tube		004465
4	Power cord		003522
5	Filter (white, disposable)	Inlet air filtration	003526
6	Filter (grey, washable)	Inlet air filtration	003527
7	Rear lid	For usage without the HA 01 humidifier	003591
8	Vivo 40 main unit		

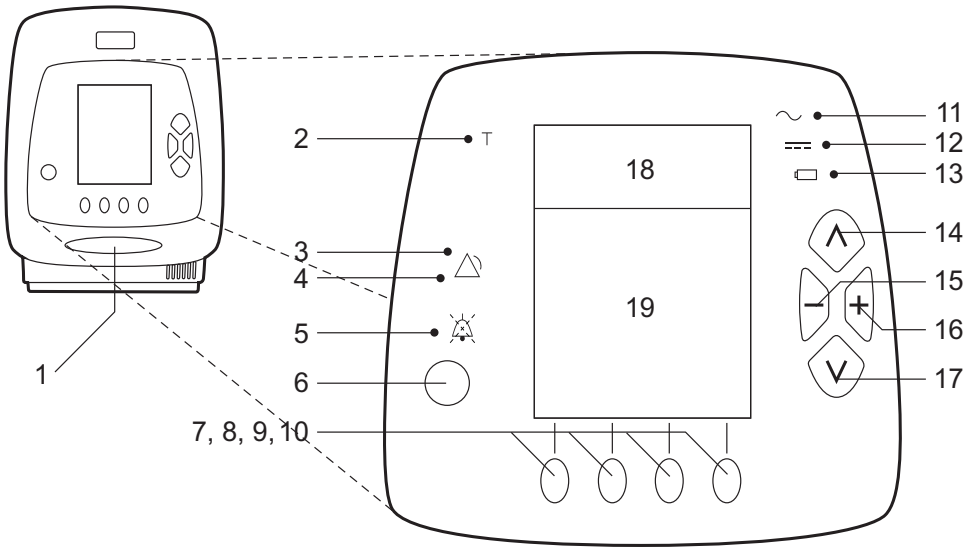
3.2 Accessories



NO.	COMPONENT	FUNCTION	PART NO.
9	HA 01 Humidifier	Humidifies patient air	003530
10	Trach elbow	Trach connection	004810
11	Hygroscopic Condenser Humidifier (HCH)	Humidifier	003974
12	Leakage/Exhalation port	Providing a leakage	004426

NO.	COMPONENT	FUNCTION	PART NO.
13	Battery cable 12/24 V DC		004258
14	iCom kit	Includes: • Isolated communication interface: PC and Vivo • Vivo-iCom data cable • iCom-PC data cable (D-sub) • iCom-PC data cable (USB) • iCom User manual • iCom PC drivers	004143
15	Vivo-PC data cable	Data cable: PC and Vivo 40 (RJ45 to D-sub)	003588
16	Vivo-iCom data cable	Data cable: Vivo 40 and iCom (RJ45 to D-sub)	003574
17	iCom-PC data cable D-sub	Data cable: iCom and PC (D-sub to D-sub)	003721
18	iCom-PC data cable USB	Data cable: iCom and PC (USB to USB)	003722
19	Memory card	Vivo 40 settings, patient data and usage data	003619
20	Memory card reader/ writer	Read/write memory card	002185
21	Vivo PC software kit	Data monitoring software	004145

3.3 The Vivo 40's Front Panel

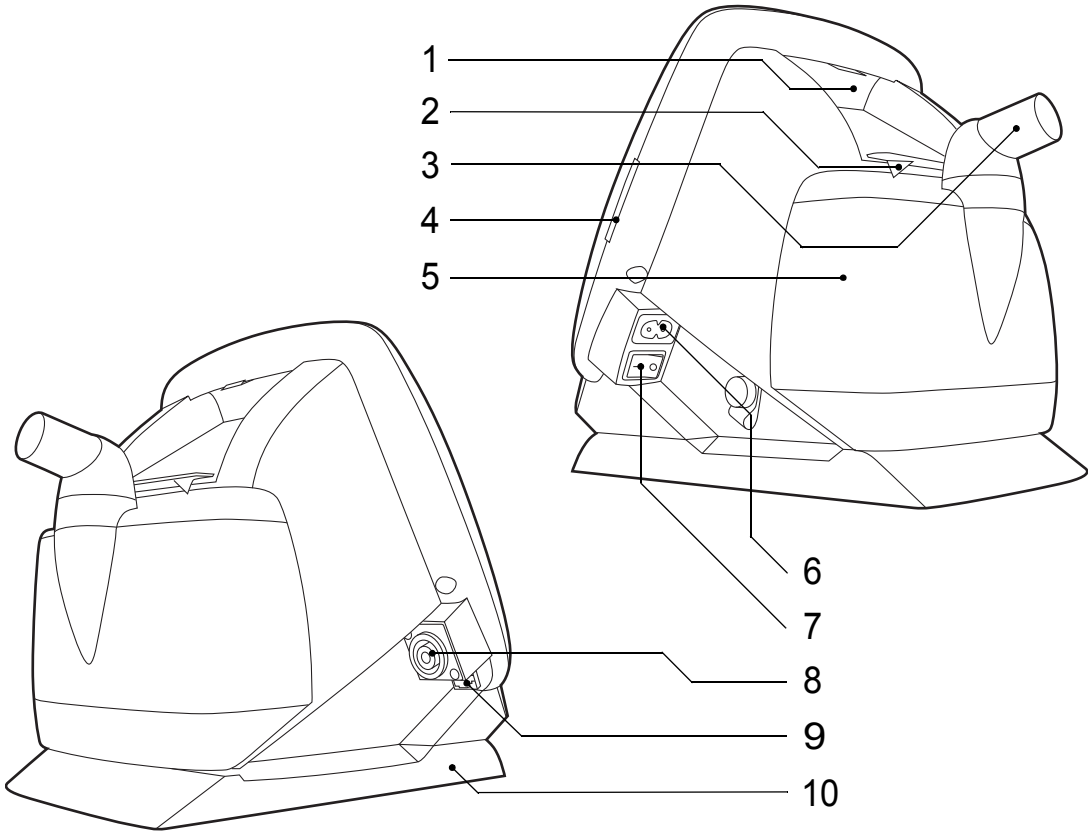


NO.	USER BUTTONS	FUNCTION
1	Start/Stop	Start/Stop ventilation treatment
6	Audio pause	Pause the alarm sound
7-10	Function/Navigation	Function according to display
14-17	Navigation/Setting	Navigation in current menu selection/ Define settings

NO.	LED	FUNCTION
2	Trigger	Patient breath trigger indication
3-4	Alarm (red & yellow)	Alarm indication
5	Audio pause	Paused alarm sound indication
11	AC power	Power source: AC power
12	External DC	Power source: External DC
13	Internal battery	Power source: Internal battery

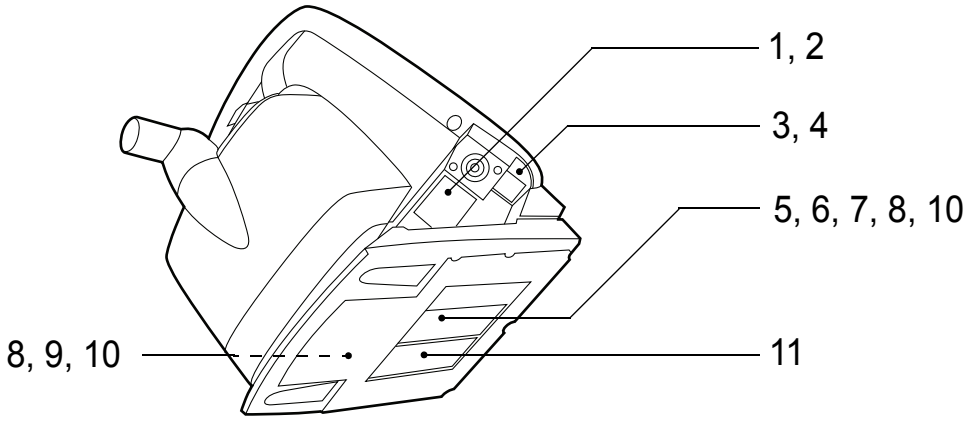
NO.	DISPLAY WINDOW	FUNCTION
18	Monitoring section	Current treatment data
19	Active section	Adjustable settings

3.4 The Vivo 40's Back and Side Panels



NO.	ITEM	FUNCTION
1	Air inlet	Air path in, replaceable filters
2	Locking mechanism	Release and lock the HA 01 humidifier or rear lid
3	Air outlet	Air path out to the patient
4	Memory card slot	Read and write memory card
5	HA 01 humidifier	Patient air humidification
6	AC power inlet	Connection for an external AC power source
7	On/Off	AC power on and off
8	External DC inlet	External DC power source connection
9	Data connection	Data cable connection (iCom/PC and the Vivo 40)
10	Internal battery	Provides power for a limited time in case of AC power disconnect

3.5 Equipment Designation and Safety Label



NO.	SYMBOL	EXPLANATION
1		Model designation
2		Serial number (last seven alphanumeric characters)
3		Data connection port (for iCom or PC)
4		Before using the data connection port, read "Transferring Data between the Vivo 40 and a PC" on page 44 carefully.
5		Class II electrical equipment; double insulation
6		Body floating (IEC 60601-1 Type BF, Isolated Applied Part)
7		Read the clinician's manual thoroughly before connecting the Vivo 40 to the patient.
8	CE 0123	CE marking applies in accordance with the directive MDD 93/42/EEC.
9		Before using the internal battery, read "Using Batteries" on page 49 carefully.
10		Read "Disposal" on page 88 for information about recycling and disposal.
11		Battery instructions

4 Functions and Parameters of the Vivo 40

This chapter includes descriptions of the modes and parameters used for controlling the ventilation of the Vivo 40.

4.1 Ventilation Mode

The following modes can be selected for the Vivo 40:

- PCV mode (Pressure Control Ventilation)
- PSV mode (Pressure Support Ventilation)
- CPAP mode (Continuous Positive Airway Pressure)

4.2 Device Mode

- Clinical
- Home

In order to prevent the patient from changing the settings, the home mode should be activated before giving the Vivo 40 to the user. The home mode hides treatment settings, alarm limits and other selected information.

The clinical mode is used by the clinician to control all mode choices, settings and limits.

4.3 Settings

All the parameters that are used for controlling the breathing by the Vivo 40 are listed below.

Read the chapter "Settings Applicable for the Different Modes" on page 59 for information about the modes and ranges the different settings work with.

IPAP (PSV & PCV only, mandatory)

The IPAP setting is used for defining the patient's airway pressure during the inspiration phase.

EPAP (PSV & PCV only, mandatory)

The EPAP setting is used for controlling the patient's airway pressure during the expiration phase.

Breath Rate (PSV & PCV only, mandatory)

The breath rate defines the minimum number of breaths the Vivo 40 will deliver. If the number of spontaneous patient breaths per minute is less than this number, Vivo 40 will uphold this rate.

In PSV mode the expiratory trigger is inactive during the non-patient triggered breaths, and these breaths are delivered with an I:E ratio of 1:2 (up to maximum inspiration time of 3 seconds). In PCV mode, non-patient triggered breaths are delivered according to settings.

Rise Time (PSV & PCV only, mandatory)

The rise time setting controls the pressure increase to the desired IPAP value. A high setting will give a slow increase and therefore a shorter plateau. A low setting will give a faster increase and therefore a longer plateau.

Min and Max Inspiration Time (PSV only, optional)

If set, the min and max inspiration time setting defines a minimum and maximum length of each inspiration. If the min and max inspiration time are set off, the length of each inspiration is dependent on the set expiratory trigger.

Inspiration Time (PCV only, mandatory)

The inspiration time setting controls the length of each inspiration.

Inspiratory Trigger (PSV mandatory, PCV optional)

The inspiratory trigger setting 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 reaches the set inspiratory trigger level, the increasing flow is registered by the ventilator, and that immediately starts an inspiration. If the patient cannot trigger a breath, the ventilator will deliver breaths according to the set breath rate.

Expiratory Trigger (PSV only, mandatory)

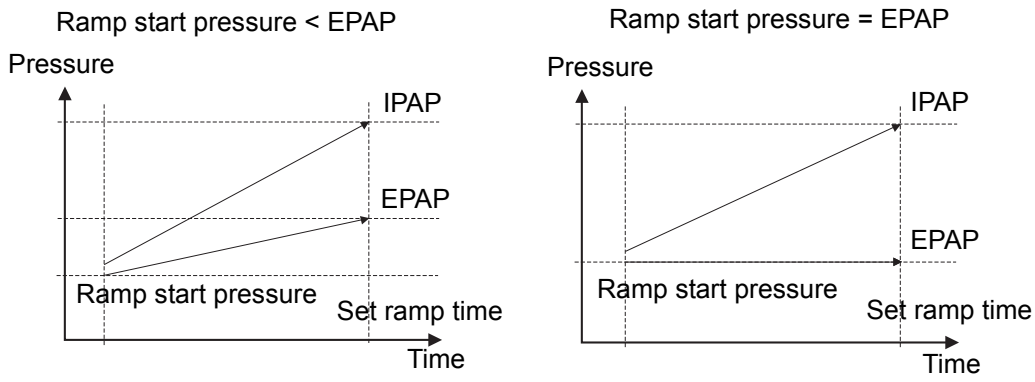
The expiratory setting defines the patient's effort required to terminate an inspiration at IPAP pressure level. To increase or to decrease the set patient effort requirement the expiration trigger level can be set to a number between 1 and 9 where 1 is the lowest patient effort level setting and 9 is the highest effort level.

CPAP (CPAP only, mandatory)

The CPAP setting sets the pressure for the CPAP (Continuous Positive Airway Pressure) mode.

The Ramp Function (optional)

The ramp function is used for increasing the EPAP and IPAP pressure during a set time, the IPAP pressure starts at 2 cmH_2O above the ramp start pressure.



During CPAP mode the ramp function provides a pressure increase from the ramp start pressure to the set CPAP pressure during a set time.

4.4 The PCV Mode (Pressure Control Ventilation)

In the PCV mode, the ventilation is controlled by the Vivo 40. This is done by the pressure, rate, inspiration time, and rise time settings.

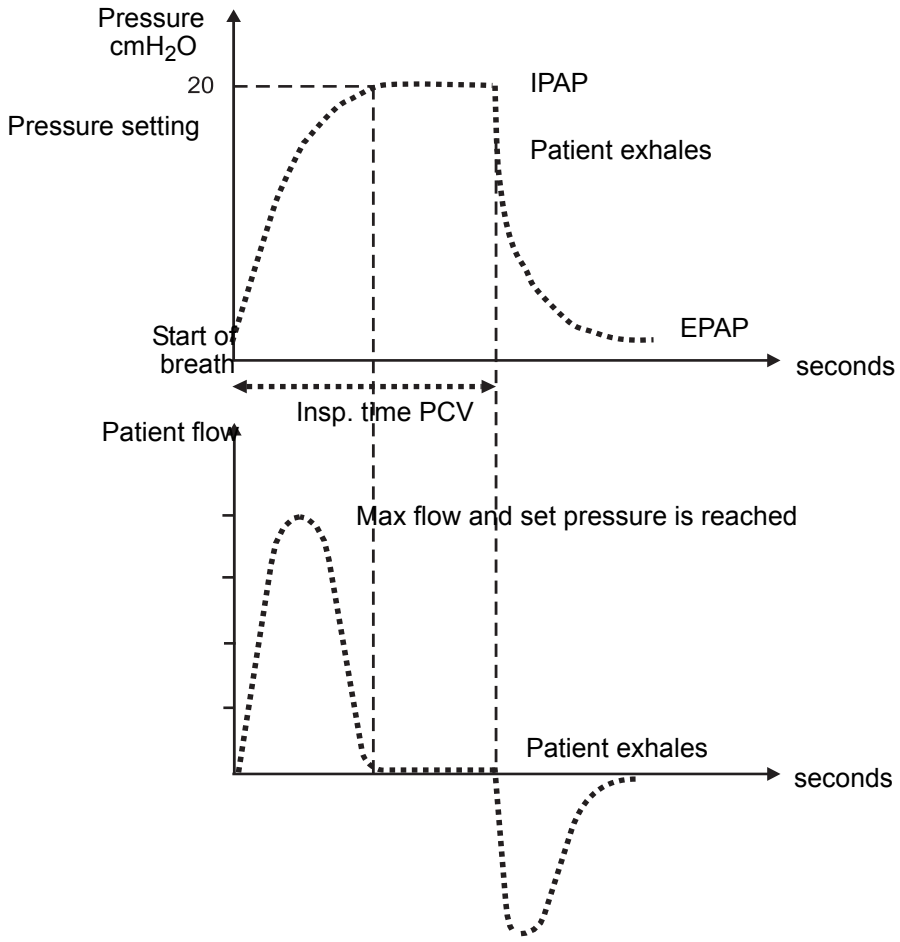
Inspiration is started either when the ventilator initiates a breath, or when the patient triggers a breath (if the trigger function is activated). The ventilator tries to reach and maintain the set pressure until the expiration starts.

The inspiration stops and an exhalation starts in two cases:

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

The figure below shows how the pressure and the inspiration time settings control the ventilator's function in the PCV mode.

The following settings have been used: Pressure 20 cmH_2O, insp. time 1.8 sec.



4.5 The PSV Mode (Pressure Support Ventilation)

In the PSV mode, the patient normally controls both the inspiration through the inspiratory trigger, and the exhalation by the expiratory trigger.

Inspiration is started when either the patient triggers a breath (if the trigger is activated), or when the breath rate setting initiates an inspiration. The ventilator tries to reach and maintain the set pressure until the expiration starts.

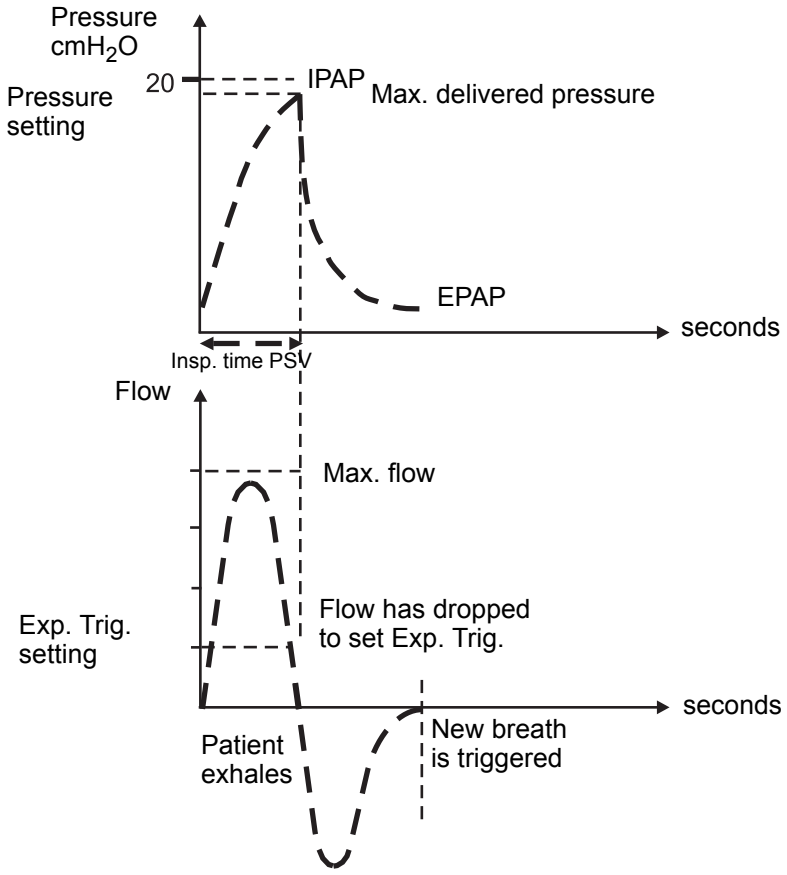
Inspiration stops and an exhalation starts in three cases:

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

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

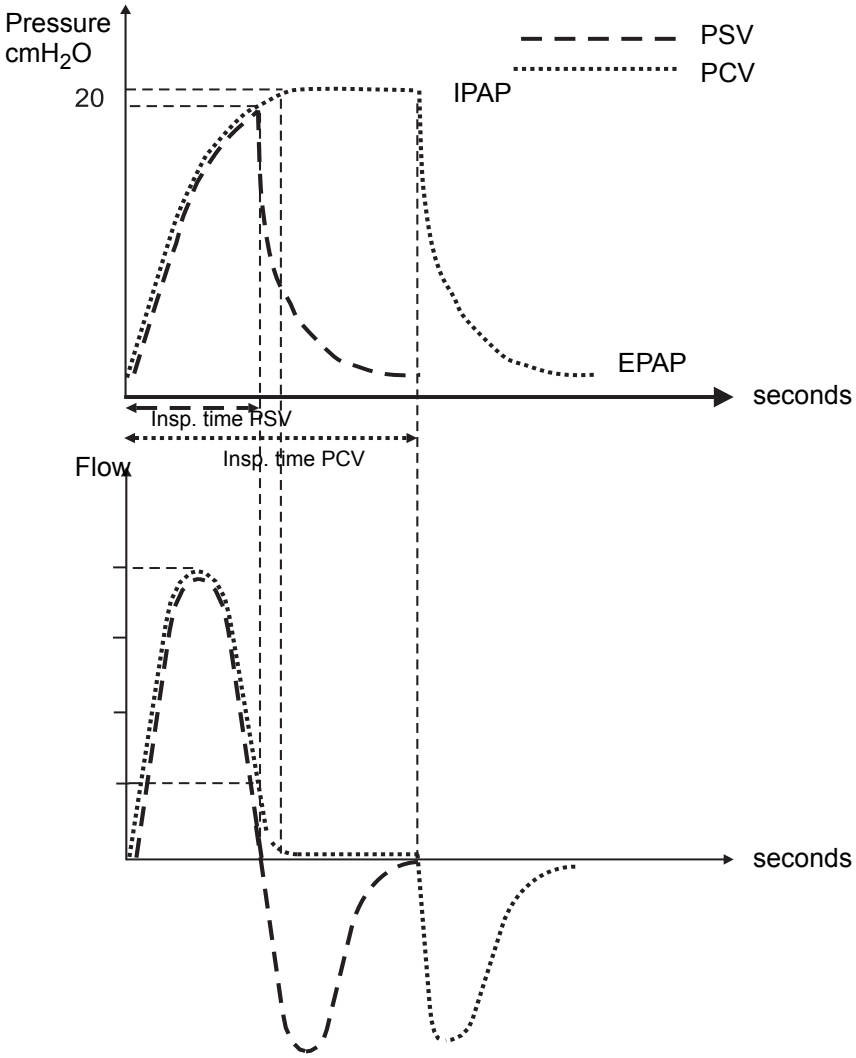
The figure below shows how the pressure and the expiratory trigger settings control the ventilator's function in the PSV mode.

The following settings have been used: Pressure 20 cmH_2O, exp. trigger 8.



4.6 The Difference between PCV and PSV Mode

The figure below shows the previous two examples superimposed to illustrate how the PCV and PSV modes differ.

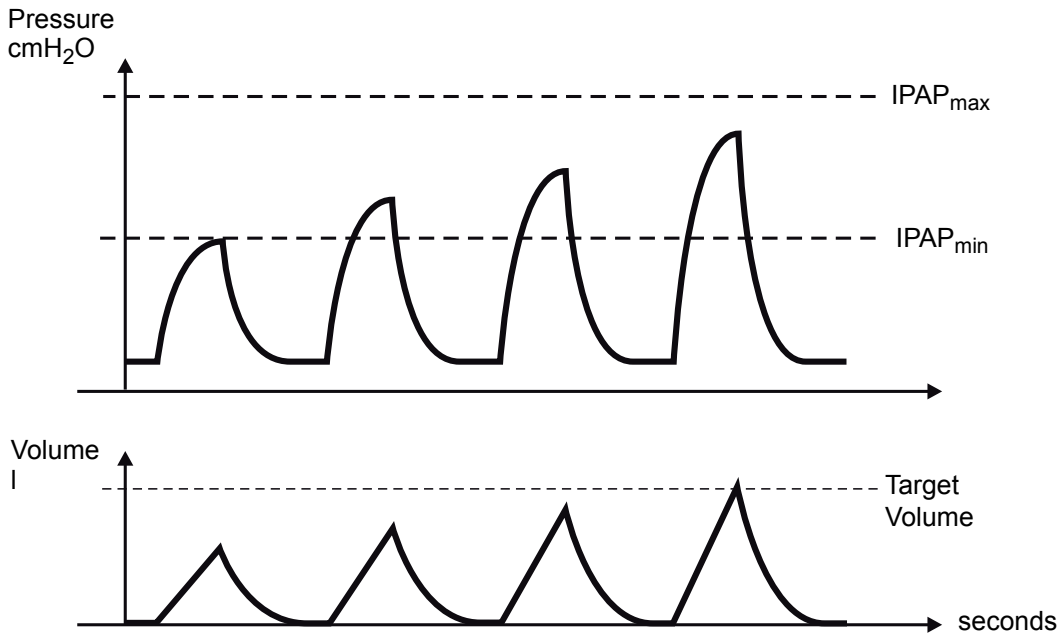


4.7 Target Volume

Target volume is a feature that automatically adapts the IPAP to make sure that the Vivo 40 delivers the desired set tidal volume to the patient.

The delivered volume is calculated and compared to the set target volume on a breath by breath basis. The delivered IPAP for the next breath will be increased or decreased depending on the difference between the calculated volume and the set target volume. Automatic pressure adjustments will be made in between two settable limits (IPAPmin and IPAPmax) in order to deliver the optimal support to the patient.

Target volume can be used both in PSV and PCV mode and shall combine the comfort and leakage compensation of pressure ventilation with the advantages of volume oriented ventilation.



4.8 The CPAP Mode

In CPAP mode, the device delivers a continuous positive airway pressure during operation.

The flow is automatically adjusted to maintain the set CPAP level, within the limitations of the devices flow compensation.

4.9 Standby and Operating Mode

Standby mode is defined as the state of the Vivo 40 when AC power is connected and the On/Off switch is on, but without starting the Vivo 40 with the Start/Stop button.

Operating mode is defined as the state of the Vivo 40 when the fan is operating and producing an air flow.

Enter operating mode by switching the Vivo 40 on (see "Switching the Vivo 40 On and Off" on page 36). Enter standby mode by switching the Vivo 40 off again.

Some operations such as accessing the memory card and setting time and date are only available in standby mode.

4.10 Low Leakage Detection

The Vivo 40 automatically detects if the mask and tubing fitted to the device has sufficient leakage. If the leakage measured is below the recommended level it will generate a Low Leakage Alarm. The Vivo 40 will continue to deliver breaths during the alarm.

Check mask, leakage/exhalation port and tubing and if necessary clean ventilation holes if clogged.

4.11 Humidifier (optional)

The humidifier function is adjustable to provide additional humidity to the patient air.

5 Using the Vivo 40

5.1 Set up the Vivo 40 Before Use

Always do the following before using the Vivo 40:

1 Connect a cleaned or new patient circuit to the Vivo 40.

2 Connect the Vivo 40 to the AC power source.

3 Switch on the Vivo 40 main power using the On/Off switch on the side panel.

4 Press the Start/Stop button on the front panel. Check that a short sound signal is heard. If there is no signal, do not use the Vivo 40 and contact your service provider.

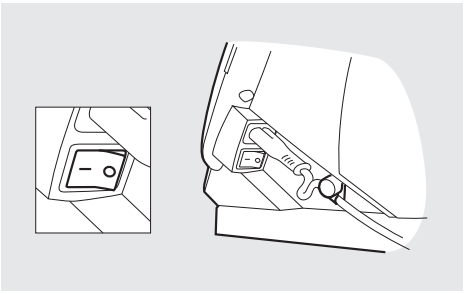
5 Ensure that the settings are adjusted as prescribed.

The Vivo 40 is ready for use.

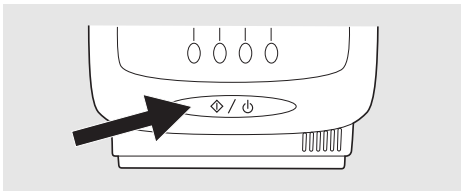
5.2 Switching the Vivo 40 On and Off

Switching On

1 Make sure the AC power source is connected and the On/Off switch is switched on.

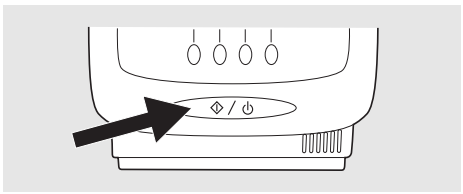


2 Turn on the Vivo 40 by pressing the Start/Stop button on the front panel for 2 seconds. Press for 4 seconds when using an external or internal battery. A short sound signal is heard.

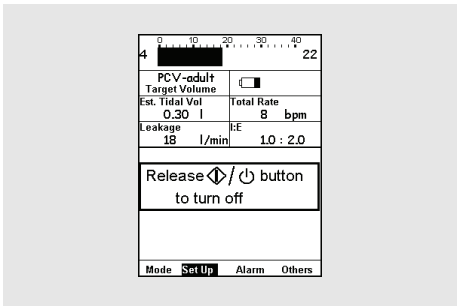


Switching Off

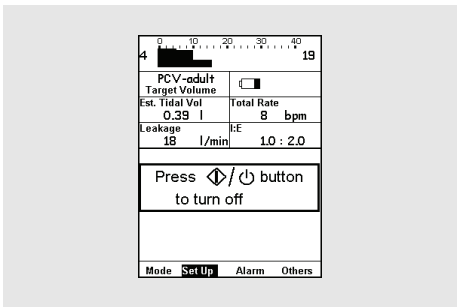
1 Press the Start/Stop button on the front panel for 2 seconds (max 4 seconds).



2 Release the Start/Stop button when the message is shown in the display window.

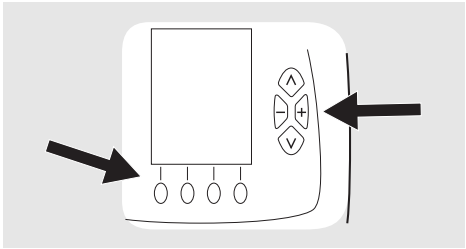


3 Turn off the Vivo 40 by pressing the Start/Stop button again.

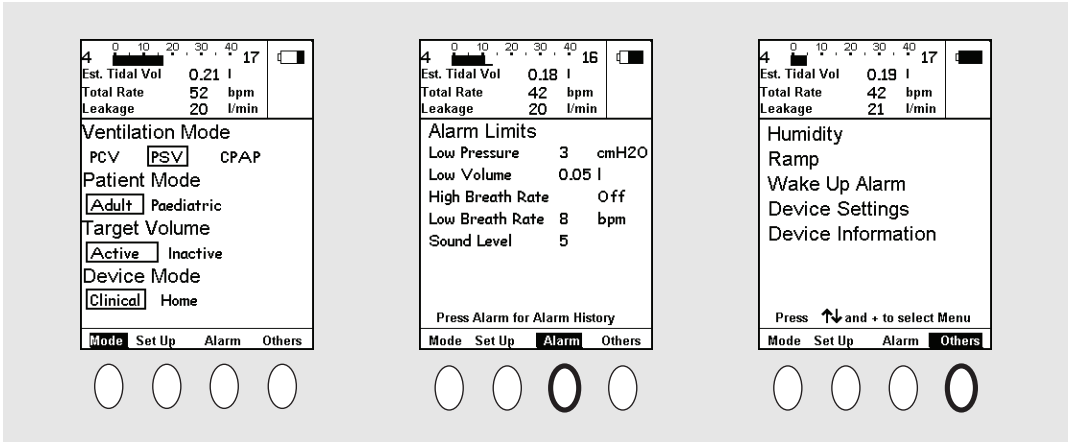


5.3 Using the Menu

Use the four navigation buttons and the up, down, "+" and "-" buttons on the front panel to navigate the Vivo 40 menu.

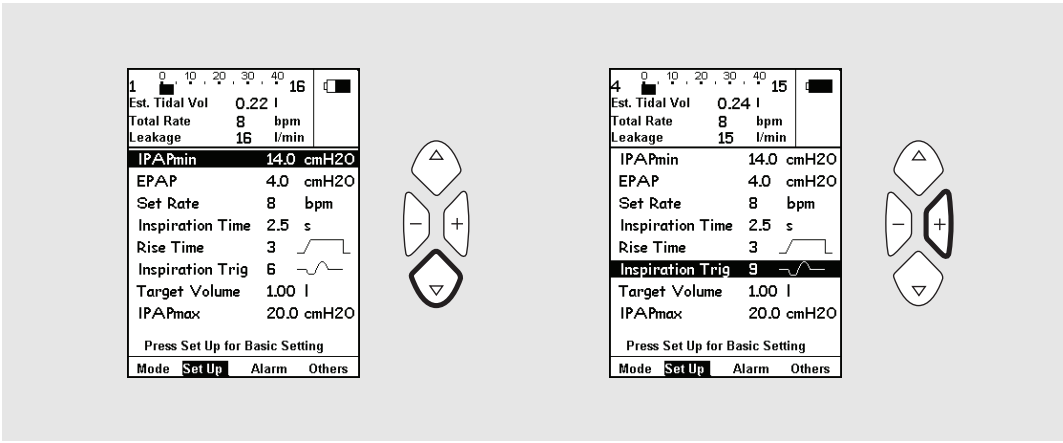


Read chapter "The Vivo 40's Front Panel" on page 24 for exact position of the buttons.



The navigation buttons are used to view the different sections defined above each navigation button. The same navigation button can also be used to view additional information in some sections.

Use the up or down button to enter the menu list.
During operation and when no button has been pressed for 20 seconds, the menu will automatically switch to the clock in home mode and to the simple set-up in clinical mode.



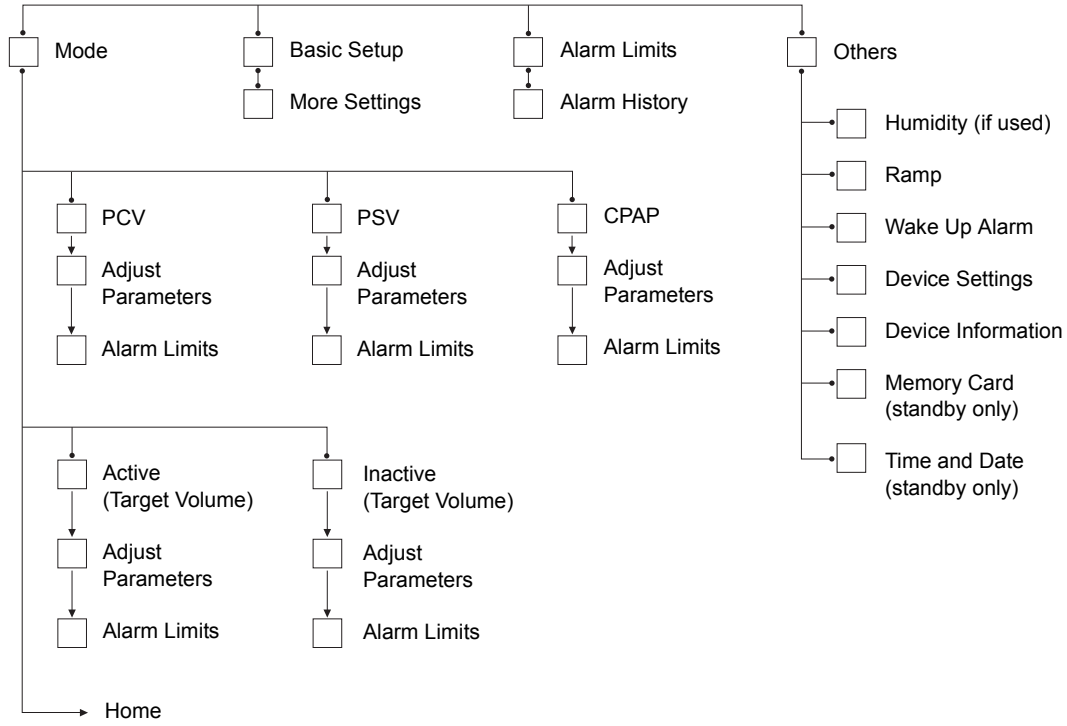
The up and down buttons are used to select values in a section. The plus and minus buttons are used to alter a value.

Symbols Used in the Menu

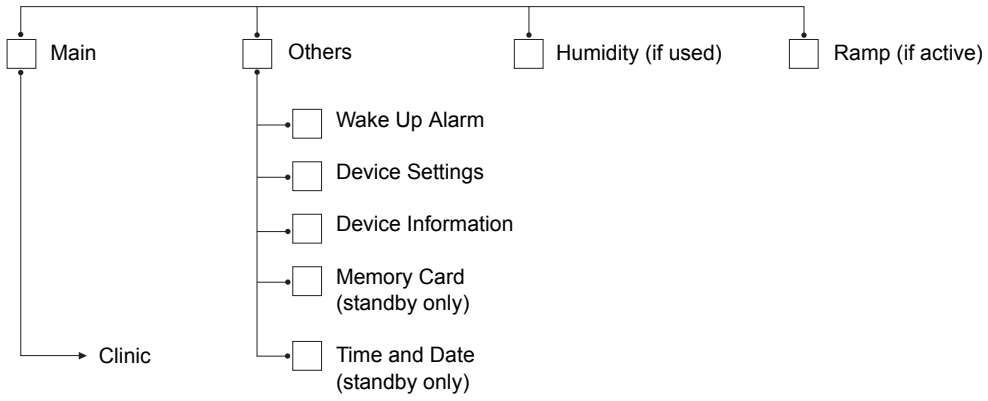
SYMBOL	DESCRIPTION	UNIT
	Battery level	
	Alarm time active	Hour : Minute
	HA 01 humidifier active	1 to 9, Off
	Ramp active	Minute
	Panel locked	On, Off
	Panel locked by the Breas Vivo PC software	On, Off
	Rise time	1 to 9
	Inspiratory trigger	1 to 9, Off
	Expiratory trigger	1 to 9

Overview

The Vivo 40 menu has the following section layout in the clinic mode:

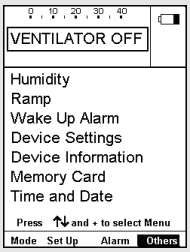


The Vivo 40 menu has the following section layout in the home mode:

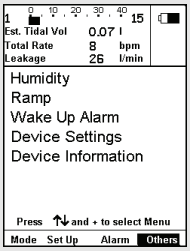


The Others Menu

The menu list for "Others" in standby mode (with HA 01 humidifier connected).

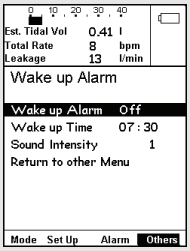


The menu list for "Others" in operating mode.



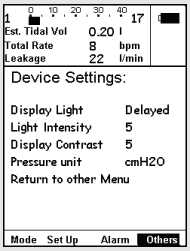
Wake up Alarm

Navigate to the section "Others" and select "Wake up Alarm" to reach the "Wake up Alarm" page.



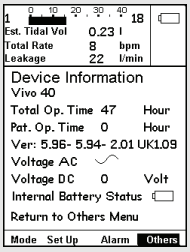
Device Settings

Navigate to the section "Others" and select "Device Settings" to reach the "Device Settings" page.



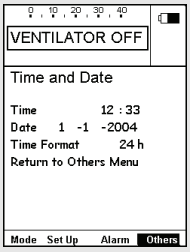
Device Information

Navigate to the section “Others” and select “Device Information” to reach the “Device Information” page.



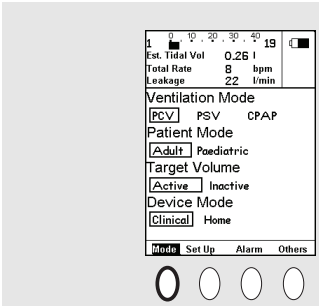
Time and Date

Navigate to the section “Others” and select “Time and Date” to reach the “Time and Date” page.

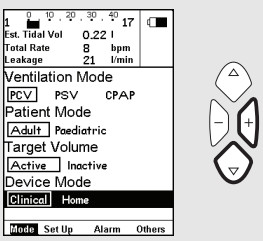


Switching between Clinical and Home Mode

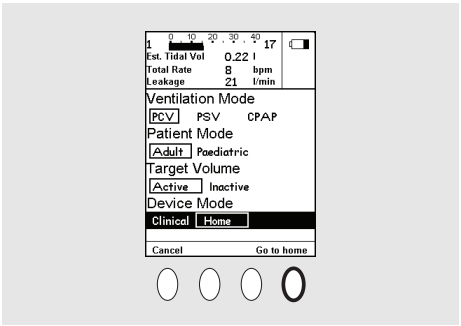
1 Navigate to the “Mode” section.



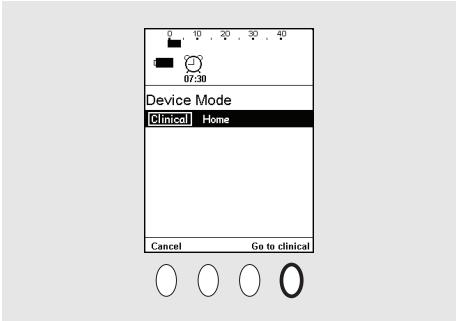
2 Use the down arrow to navigate to the “Device Mode” setting. Select the required mode with the “+” and “-” buttons.



3 Press "Go to home" to change to home mode.



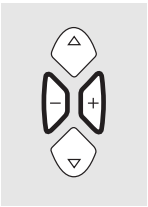
4 In home mode, navigate to the "Main" section and change the "Device Mode" setting back to "Clinical" if wanted.



When handing out the Vivo 40 to a patient, the panel should always be locked.

Locking and Unlocking the Panel

The panel can be locked in order to prevent an accidental change of settings. The panel is locked by pressing the "+" and "-" buttons simultaneously for 5 seconds. When locked, the Vivo 40 enters the home mode. It cannot be switched back to clinical mode by using the menu.



The Vivo 40 is unlocked from the home mode by pressing the "+" and "-" buttons again simultaneously for 5 seconds.

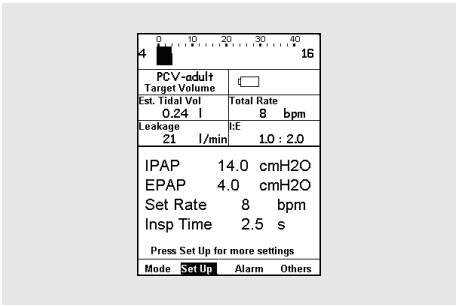
5.4 Monitoring Section

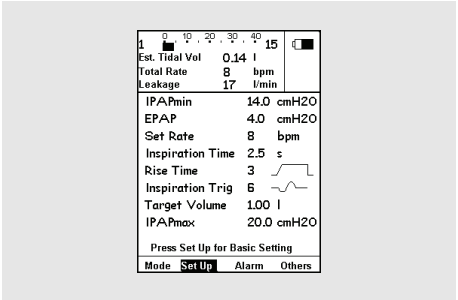
The monitoring section provides a display of the current treatment data. The monitoring section is located in the top of the display window:

Clinical Mode

The monitoring section contains a bargraph to display current pressure, information about max and min pressure, mode, estimated tidal volume, leakage, internal battery status, HA 01 humidifier, remaining ramp time, total rate and the I:E ratio.

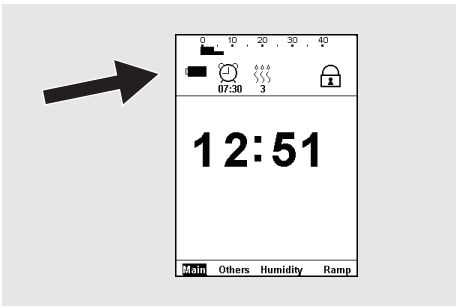
In some screens, the information will adapt in size and amount depending on the page layout.





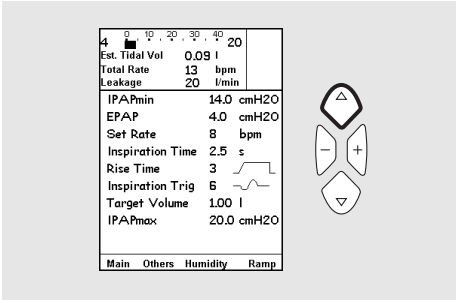
Home Mode

The monitoring section contains a bargraph, information about the alarm time, HA 01 humidifier, remaining ramp time, battery status and the panel lock is shown.

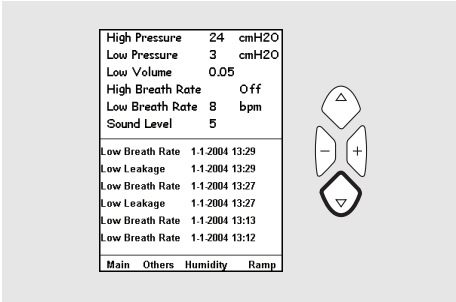


Settings in Home Mode

To show settings in home mode: Enter the main screen and press up button for 3 seconds.



To show alarm history and alarm settings in home mode: Enter main screen and press down button for 3 seconds.



5.5 Transferring Data between the Vivo 40 and a PC

Read the chapter "Electrical Safety" on page 10 carefully to make sure all conditions are fulfilled and considered.

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

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

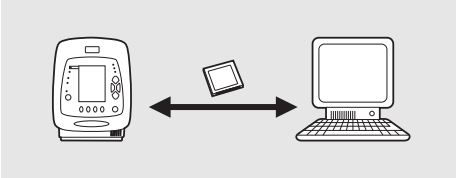
Data can be transferred in three ways:

- Memory card
- iCom communication unit
- Vivo-PC data cable

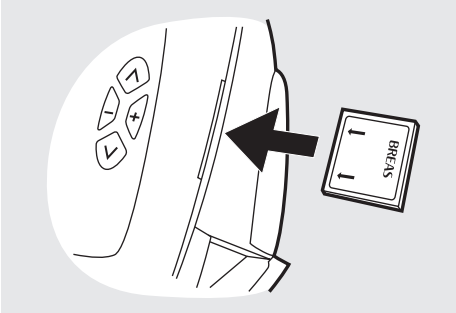
Memory Card

The Vivo 40 can only copy and transfer data to the memory card in standby mode (not operating).

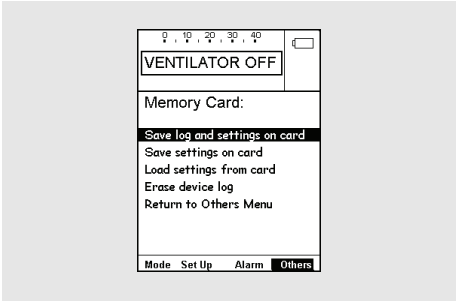
The memory card is used for copying and transferring settings, detail logs, usage logs and breath logs.



1 Insert the memory card in the memory card slot on the side of the Vivo 40. Make sure the memory card is properly inserted.

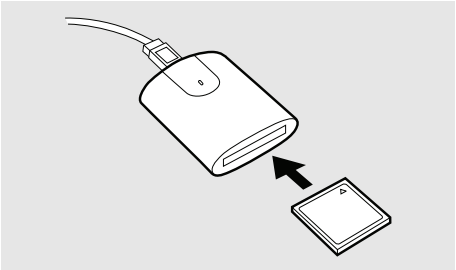


2 In clinical mode, navigate to the "Memory Card" page under the "Others" section.
In home mode, navigate to the "Memory card" page under the "Others" section



3 Select the desired operation and wait while the ventilator load or save to the memory card.

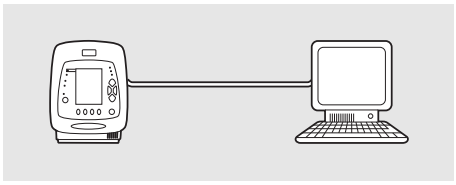
4 Connect the memory card reader/writer to the PC and insert the memory card. The Breas logo should be facing down.



Vivo-PC Data Cable

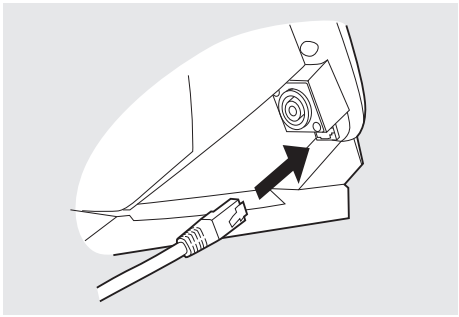
- **The Vivo-PC data cable shall not be used for data transfer while the patient is connected to the Vivo 40. Only a PC that complies to the IEC 60601-1 standards can be used for copying and transferring data during treatment of a patient.**
- **Never connect the Vivo 40 directly to a network port.**

The Vivo-PC data cable can copy and transfer the same data as the memory card. However, the Vivo-PC data cable is considerably slower than the memory card. With the Vivo-PC data cable, real-time data can also be received and sent between the Vivo 40 and a PC.



1 Connect the Vivo-PC data cable to the Vivo 40. Make sure it is fitted correctly.

2 Connect the other end of the Vivo-PC data cable to the PC.

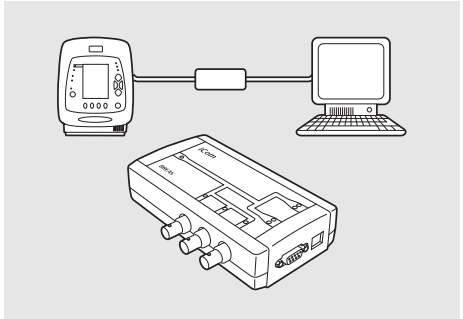


iCom Communication Unit

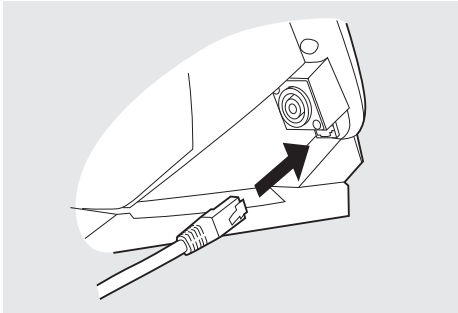
The iCom is an accessory which electrically isolates the Vivo 40 from a PC and other devices (i.e. plotters, printers etc). A common PC, which does not comply with IEC 60601-1, must comply with IEC 60950 and be placed outside the patient area (i.e. more than 2 meters from the patient).

The iCom can copy and transfer the same data as the memory card and the data cable. However, the iCom is considerably slower than the memory card.

With the iCom, real-time data can also be received and sent between the Vivo 40 and a PC.



1 Connect the Vivo-iCom data cable to the Vivo 40. Make sure it is fitted correctly.



2 Connect the other end of the Vivo-iCom data cable to the iCom.

3 Connect the iCom-PC data cable between the iCom and a PC. Do only use either the D-sub cable or the USB cable.

5.6 Using the HA 01 Humidifier

Information about safety, warnings, product description, installation, usage, cleaning, maintenance and technical specifications can be found in the Breas HA 01 Humidifier User manual.

Read the chapter "Humidification" on page 16 carefully to make sure all conditions are fulfilled and considered.

If the AC power source fails and the internal or the external battery activates, the HA 01 humidifier will be turned off automatically. It must be activated again manually, if humidification during battery use is necessary.

The HA 01 humidifier is intended to humidify the patient air. The HA 01 humidifier must be installed in order to access and navigate to the humidifier setting on the Vivo 40 menu, both in clinical and home mode. The HA 01 humidifier can only be activated if the Vivo 40 is operating.

If the HA 01 humidifier is disconnected and reconnected after usage according to the instructions in the HA 01 Humidifier User manual, the Vivo 40 will remember the humidity setting used.

5.7 Using Batteries

A battery is intended as a backup power source if the primary AC power source fails.

Power Source Priority

1 AC power

2 External DC

3 Internal battery

When a power source fails, the Vivo 40 will switch to either the internal or the external battery if installed and show a message in the display window.

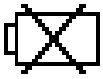
When running on battery, the battery status is indicated by the following symbols:


Full


Medium


Low


Empty


The internal battery is disconnected or malfunctioning.

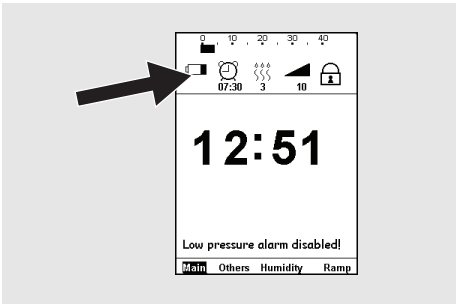
Using the HA 01 humidifier while operating on a battery significantly decreases the battery operation time.

Internal Battery

The internal battery can also be used as a temporary power source for transportation between one stationary power source to another.

Due to the internal battery, the Vivo 40 may start if the Start/Stop button is pressed accidentally, for instance, when packing the ventilator in the carry bag. Make sure to place and pack the device in a way that prevents unintentional start of the machine.

The battery level is displayed in the monitoring section. The estimated internal battery capacity is only shown when the Vivo 40 is operating from the internal battery. This display is for indication only.



Charging the Internal Battery

Each time the Vivo 40 is connected to the AC power supply and the On/Off switch is switched on (standby mode), the Vivo 40 will automatically start a 10-hour charging cycle of the internal battery. This is indicated by a flashing battery indicator in the display. This is done regardless of the internal battery charging status.

To recharge an empty internal battery takes about 14 hours in standby mode. The charging is reduced by 50% during operation. If the temperature inside the Vivo 40 is higher than 113°F (45°C), which is normal during operation, the charging is decreased in order to protect the battery. This will result in longer battery charging time.

Follow the instructions below to ensure that the battery capacity of the Vivo 40 is maximized during its lifetime:

- Exercise the battery every 3 months by discharging it completely and fully recharging it again. Repeat this procedure twice.
- If the Vivo 40 is stored for more than 1 month, connect it to the AC power supply to recharge the internal battery and alarm battery.
- Replace the internal battery every 24 months, after 500 charging cycles, or when necessary to ensure the battery performance.

Internal Battery Operation Time

The internal battery operation time is dependent on the battery condition, its capacity, the ambient air temperature and the Vivo 40 settings.

The following are examples of the operation time with new, fully charged batteries and Vivo 40 running in PCV mode:

SETTING	VALUES		
EPAP	4	8	4
IPAP	10	20	30
Breath Rate	12	15	20
Insp. Time	2.0	1.5	1.5
Rise Time	3	3	1
Insp. Trigger	Off	Off	Off
Delivered Tidal Volume	0.20	0.50	0.75
Total Time	**4 h**	**2 h 45 min**	**1 h 45 min**

ENVIRONMENTAL CONDITIONS	
Ambient temperature	68°F (20°C)
Altitude	Sea level

External Battery

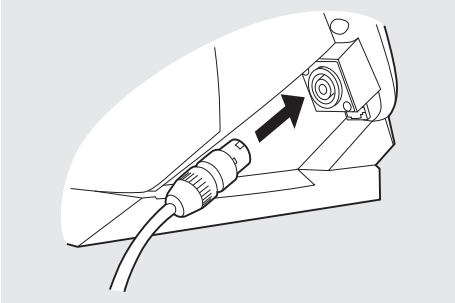
The Vivo 40 can be operated from a 12 V or a 24 V DC external battery.

- Use the battery cable 12/24 V DC and check carefully that the voltage is 12 V or 24 V.
- Check the polarity of the external battery before connecting it to the Vivo 40.

With an external battery connected, the Vivo 40 will automatically switch over to the external battery source if the AC power cord is removed or if the AC power supply fails. The external DC level is shown under "Others, Device information" in the menu.

1 Connect the external DC cable to the Vivo 40. Make sure that it is fitted correctly.

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



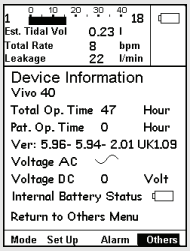
- Only use a Breas external DC cable to connect the Vivo 40 to the external battery.
- An external battery must be disconnected when the Vivo 40 is switched off, otherwise the battery can be discharged.

External Battery Operation Time

The operation time is dependent on the battery condition, its capacity, the ambient air temperature and the Vivo 40 settings.

5.8 Vivo 40 Operating Time

The Vivo 40 records two types of operating times. They can be viewed on the page "Device Information" in the "Others" section.



Total Operating Time

Shows the total number of hours the Vivo 40 have been operating.

Patient Operating Time

Shows the total number of hours a patient have been using the Vivo 40 for breathing therapy.

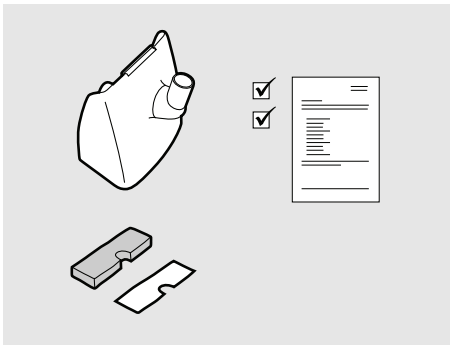
6 Preparing the Vivo 40 for Use

Read the chapter "Safety Information" on page 8 before setting up and using the Vivo 40.

6.1 Installing the Vivo 40

When using the Vivo 40 for the first time, follow the instructions below:

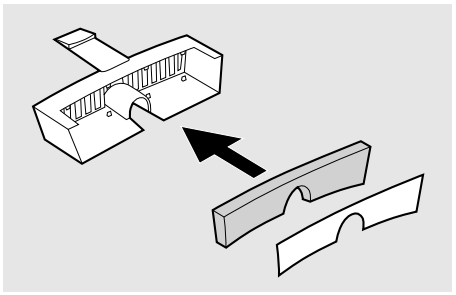
1 Check that all main components and ordered accessories have been delivered (refer to the packing note or the invoice, if available).



2 Ensure that the equipment is in good condition.

3 If stored more than 1 month, connect the Vivo 40 to the AC power supply and switch on the On/Off switch to recharge the internal battery and the alarm battery in standby mode.

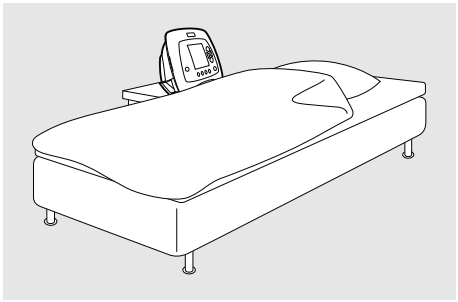
4 Check that the air filters are installed.



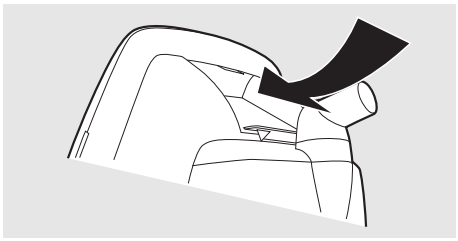
6.2 Placing the Vivo 40

Read the chapter "Environmental Conditions" on page 11 carefully to make sure all conditions are fulfilled and considered.

1 Place the Vivo 40 on a solid, flat surface facing towards the patient. The Vivo 40 should be placed lower than the patient in order to prevent the device from falling on the patient, as well as preventing condensated water to reach the patient.



2 Make sure that nothing can block the patient air inlet at the rear of the Vivo 40.

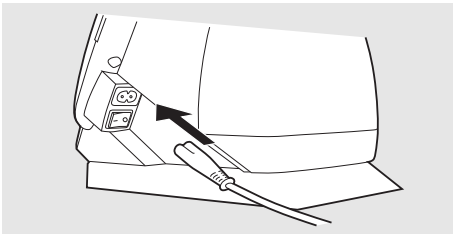


6.3 Connecting the Vivo 40 to the AC Power Source

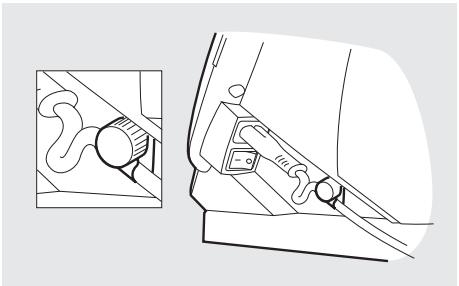
Read the chapter "Electrical Safety" on page 10 carefully to make sure all conditions are fulfilled and considered.

To connect the Vivo 40 to the AC Power Source:

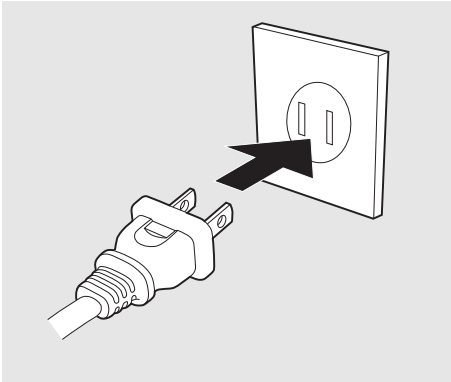
1 Plug the power cord into the power inlet of the Vivo 40.



2 Create a small loop on the cable in order to prevent stretching. Secure the power cord using the cable holder.



3 Connect the power cord to the AC power source.

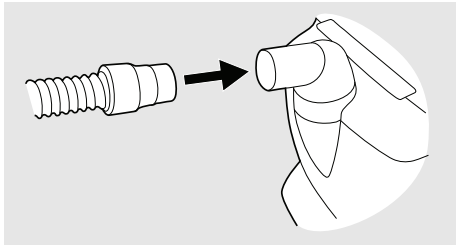


6.4 Connecting the Patient Circuit

Read the chapter "Usage of Patient Circuit" on page 12 carefully to make sure all conditions are fulfilled and considered.

Non-Invasive Use

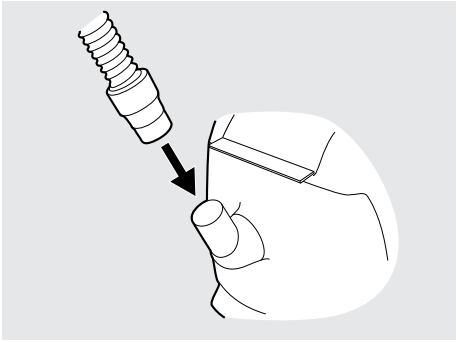
1 Connect the patient tube to the air outlet.



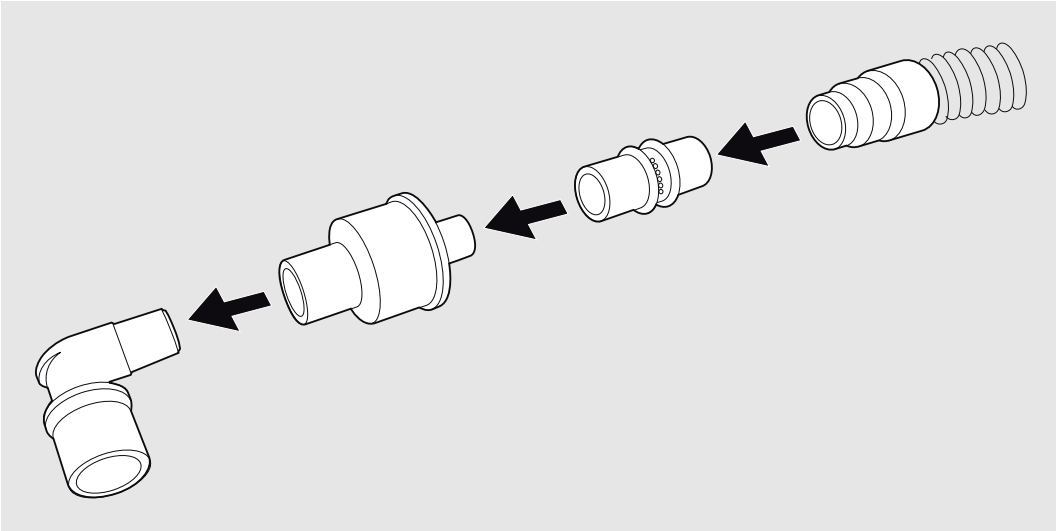
2 Connect the other end of the patient tube to the mask and the leakage port, if applicable.

Invasive Use

1 Connect the patient tube to the air outlet.



2 Connect the other end of the patient tube to the leakage port, a hygroscopic condenser humidifier (HCH) and a trach elbow.



Intentional Leakage

The leakage from the mask or leakage/exhalation port should be at least 12 liter/min at 4 cmH_2O, to prevent re-breathing of exhaled air. The recommended mask leakage is 20 to 40 liter/min at 10 cmH_2O pressure.

This leakage may be achieved by:

- integrated leakage in the mask
- an adjoining leakage port

7 Setting Up the Vivo 40

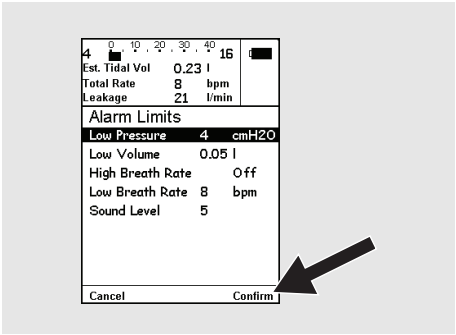
Read the chapter "Safety Information" on page 8 before setting up and using the Vivo 40.

The configuration of the Vivo 40 therapy settings must always be prescribed by a licensed physician and carried out by an authorized health care professional.

This chapter describes how to set the different parameters that are used for controlling the ventilation of the Vivo 40.

Follow the Instructions below when Setting Up the Vivo 40

- Adjust the settings to find the best possible breathing comfort for each patient.
- You must confirm all applicable settings for each of the PSV, PCV, or CPAP modes that are to be used by the patient. See the table matrix in the following section.
- If you have changed the ventilation mode, always consider the settings before pressing "Confirm".



- Always document the set values before the patient returns home.

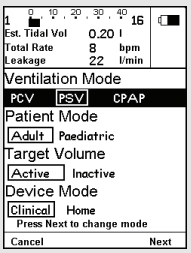
7.1 Settings Applicable for the Different Modes

SETTING	RANGE	PCV	PSV	CPAP
EPAP	2 cmH_2O to 20 cmH_2O or IPAP/ IPAPmin -2 cmH_2O.	✓	✓	
IPAP	4 to 40 cmH_2O	✓	✓	
IPAPmin (Target Volume active)	4 to 40 cmH_2O or to IPAPmax	✓	✓	
CPAP	4 to 20 cmH_2O			✓
Breath rate	4 to 40 BPM (Breaths Per Minute)	✓	✓	
Inspiration time	0.3 to 5 sec	✓		
Min inspiration time	Off, 0.3 to 3 sec		✓	
Max inspiration time	0.3 to 3 sec, Off		✓	
Rise time	1 to 9	✓	✓	
Insp. trigger (PCV)	1 to 9, Off	✓		
Insp. trigger (PSV)	1 to 9		✓	
Exp. trigger	1 to 9		✓	
Target Volume	0.2 to 1.5 l	✓	✓	
IPAPmax (Target Volume active)	4 or IPAPmin to 40 cmH_2O	✓	✓	
Ramp time (PSV, PCV, CPAP)	10 to 60 min	✓	✓	✓
Ramp start pressure	2 cmH_2O to EPAP	✓	✓	
Ramp start pressure	3 cmH_2O to CPAP			✓
HA 01 humidifier	1 to 9, Off	✓	✓	✓

The ventilation modes and setting parameters are described in detail in the chapter "Functions and Parameters of the Vivo 40" on page 27.

7.2 Selecting the Mode

Navigate to the section “Mode” and then to “Ventilation Mode”. Use the “+” and “-” buttons to select the desired mode.
Follow the on-screen instructions and adjust the parameters according to the prescribed treatment.



The ventilator always starts in the mode and with the settings that were active when it was switched off.

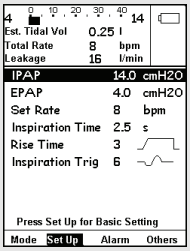
7.3 Setting the Parameters

If the set values are outside the Vivo 40's working range and cannot be achieved, the lines for these settings will flash. Adjust the settings so that the flashing ceases.

For more information about how to use the menu, please read the chapter "Using the Menu" on page 37.
Study the "Overview" on page 39 if a page or section cannot be found.

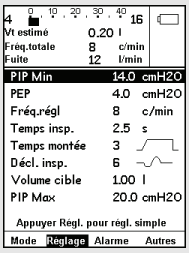
IPAP (PSV & PCV only, mandatory)

Setting range: 4 to 40 cmH_2O.
Navigate to the section "Setup".



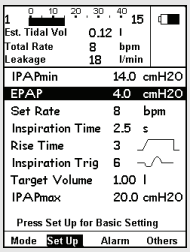
IPAPmin (PSV & PCV only, Target Volume active)

Setting range: 4 to 40 cmH_2O or to IPAPmax.
Navigate to the section "Setup".



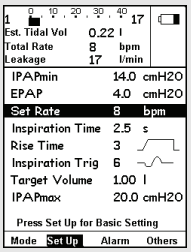
EPAP (PSV & PCV only, mandatory)

Setting range: 2 cmH_2O to 20 cmH_2O or IPAP/IPAPmin -2 cmH_2O.
Navigate to the section "Setup".



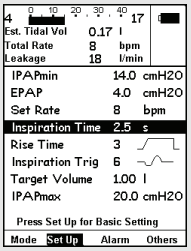
Breath Rate (PSV & PCV only, mandatory)

Setting range: 4 to 40 BPM.
Navigate to the section “Setup”.



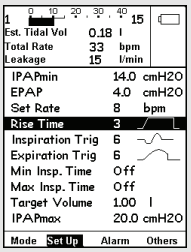
Inspiration Time (PCV only, mandatory)

Setting range: 0.3 to 5 seconds.
Navigate to the section “Setup” and press “Setup” one more time to reach the “More Settings” page.



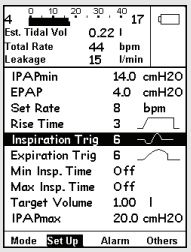
Rise Time (PSV & PCV only, mandatory)

Setting range: 1 to 9.
Navigate to the section “Setup” and press “Setup” one more time to reach the “More Settings” page.
In PSV mode, Rise Time is limited by Min Inspiration Time.



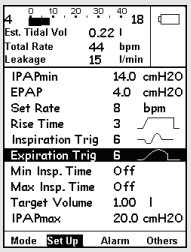
Inspiratory Trigger (in PSV mandatory, in PCV optional)

Setting range: 1 to 9, Off (where 1 is the most sensitive).
Navigate to the section “Setup” and press “Setup” one more time to reach the “More Settings” page.



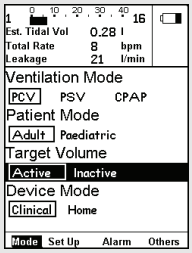
Expiratory Trigger (PSV only, mandatory)

Setting range: 1 to 9 (where 1 is the most sensitive).
Navigate to the section "Setup" and press "Setup" one more time to reach the "More Settings" page.

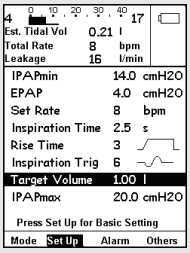


Target Volume (PSV & PCV only, Target Volume active)

Navigate to the section "Mode" and then to "Target Volume". Use the "+" and "-" buttons to select "Active" or "Inactive".
Follow the on-screen instructions and adjust the parameters according to the prescribed treatment.

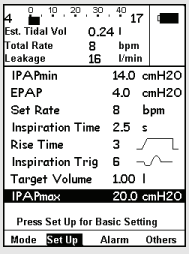


Setting range: 0.2 to 1.5 l.
Navigate to the section "Setup" and press "Setup" one more time to reach the "More Settings" page.



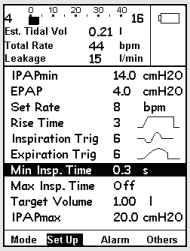
IPAPmax (PSV & PCV only, Target Volume active)

Setting range: 4 or IPAPmin to 40 cmH_2O.
Navigate to the section "Setup" and press "Setup" one more time to reach the "More Settings" page.



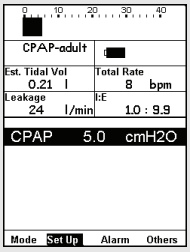
Min and Max Inspiration Time (PSV only, optional)

Setting range: Off, 0.3 sec [min] and 3 sec [max].
Navigate to the section "Setup" and press "Setup" one more time to reach the "More Settings" page.



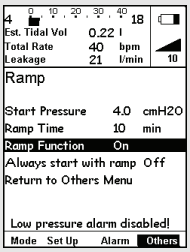
CPAP (CPAP only, mandatory)

Setting range: 4 to 20 cmH_2O.
Navigate to the section "Setup".



The Ramp Function (optional)

Ramp function: On, Off or Disabled (where On and Off turns on and off the ramp function in operating mode. With the ramp function Disabled, it cannot be activated in operating mode).
Ramp time setting range: 10 to 60 min.



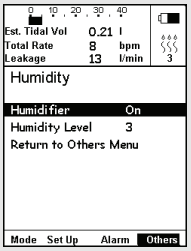
Start pressure setting range: 2 cmH_2O to EPAP (PSV & PCV), 3 cmH_2O to CPAP (CPAP).
"Always start with ramp" setting range: On or Off or Disabled.
Navigate to the section "Others" and select "Ramp" to reach the "Ramp" page.
In home mode the ramp can be activated by pressing the ramp soft key for more than 1 second.

Humidifier (optional)

Setting range: 1 to 9 (where 9 is the maximum humidity), Off.

Navigate to the section "Others" and select "Humidity" to reach the "Humidity" page.

In home mode the HA 01 humidifier can be activated by pressing the humidity soft key for more than 1 second.



8 Alarms

The adjustable alarm settings should be re-evaluated whenever a change in settings is made on the Vivo 40.

This chapter describes the alarm functions used for the Vivo 40, and how to adjust the alarm levels for each ventilation mode.

8.1 Alarm Function

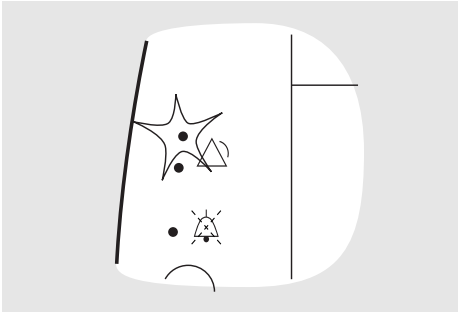
The alarm function of the Vivo 40 consists of the alarm LEDs on the front panel, an audible alarm, and messages on the LCD display (see "The Vivo 40's Front Panel" on page 24 for an overview of the position of the LEDs and the LCD display).

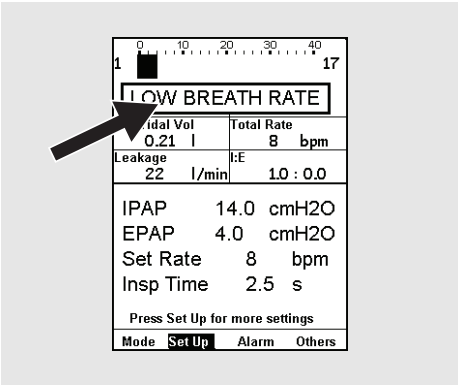
Alarm Indication

As soon as an alarm condition is set, the Vivo 40 will alarm without delay.

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

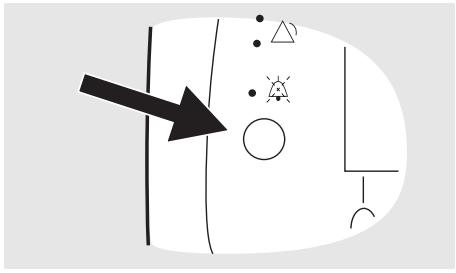
- Color LED on the panel: indicates the priority of the active alarm condition.
  - High priority: Red color, flashing twice per second.
  - Medium priority: Yellow color, flashing every 2 seconds.
- Alarm text in display: displays the name of the active alarm condition.





- Audible signals: indicates the priority of the active alarm condition.
  - High priority: 3 signals followed by 2 more. The signal sequence is repeated after a 0.5 seconds pause.
  - Medium priority: 3 signals only, with a lower frequency than the high priority alarm. The signal sequence is repeated after a 6 seconds pause.
  - Function failure. Same signal as the high priority alarm or a constant signal, depending on the kind of function failure.

Audible Signal Pause and Reactivation



The audible signal can be paused by pressing the Audio Pause button. If the ventilator still registers the same alarm after 60 seconds, and the Audio Pause button was pressed, the audible signal will sound again.

Once the audible signal has been paused, it can be reactivated by pressing the Audio Pause button again for 2 seconds.

If a new alarm condition occur during the silence period, the audible signal will be reactivated.

To ensure the timely detection of any new alarm condition, never leave a patient unattended while the audible signal is paused.

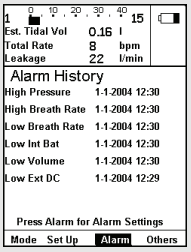
Alarm Reset

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

If an alarm condition cannot be corrected, discontinue use and refer the Vivo 40 for service.

Alarm History Screen

Alarm History will display the 6 last alarms, when the alarm occurred and what type of alarm it was. The latest alarm will be placed in top of the list.

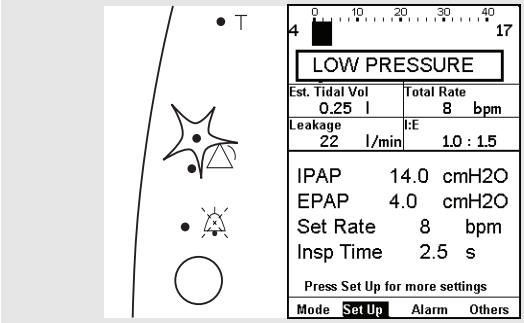


The Alarm History is maintained when the Vivo 40 is powered down.

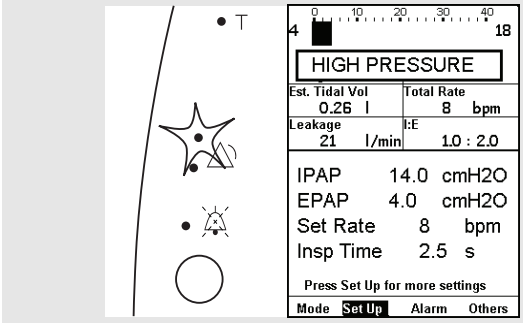
The last set alarm settings are retrieved after power has been off.

8.2 Physiological Alarm

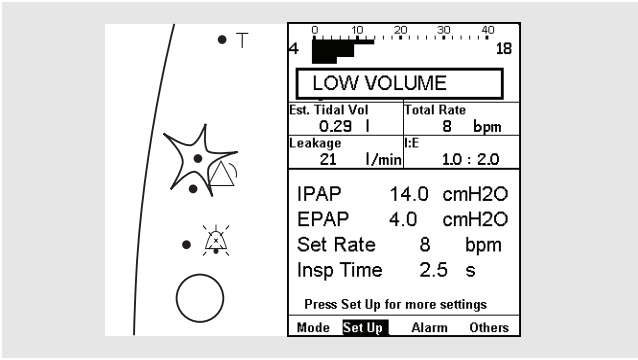
Low Pressure Alarm

ITEM	DESCRIPTION		
Definition	A low pressure alarm will be given when the Vivo 40's pressure fails to reach the low pressure alarm limit for 15 seconds.		
Possible cause	• Disconnection of patient circuit. • Setting is higher than IPAP/IPAPmin. • Leakage from the mask or other components of the patient circuit.		
Setting	Parameter: Low pressure		
	Min:	Max:	Resolution:
	2 cmH_2O	IPAP/IPAP-min	1.0 cmH_2O
Ventilator action	The Vivo 40 will continue to give breaths with the same settings.		
Indication	 The alarm is given audibly with a tone and visibly by the red alarm LED and a display message.		

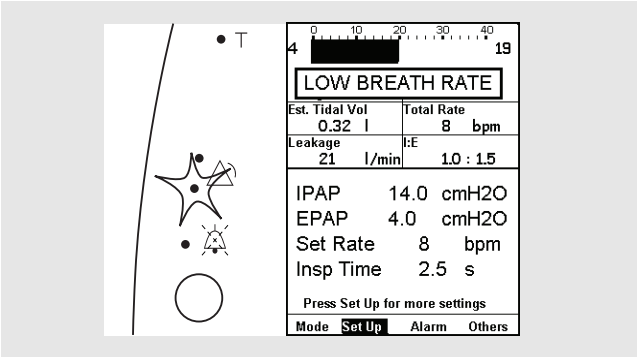
High Pressure Alarm

ITEM	DESCRIPTION
Definition	A high pressure alarm will be given when the Vivo 40's pressure exceeds 10 cmH_2O more than IPAP/IPAPmax, for 3 consecutive breaths.
Possible cause	Only activated under exceptional conditions, such as a strong cough during the ventilator's inspiration phase.
Setting	Self adjusting
Ventilator action	The Vivo 40 will terminate inspiration from the first high pressure breath. The Vivo 40 will then continue to give breaths with same settings.
Indication	 The alarm is given audibly and visibly by the red alarm LED and a display message.

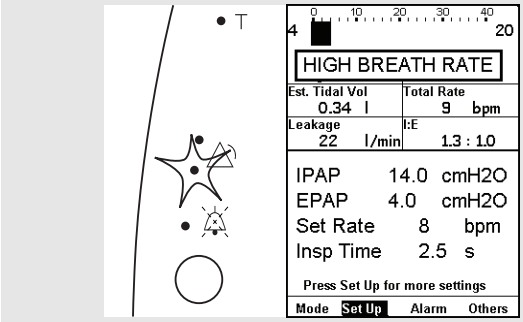
Low Volume Alarm

ITEM	DESCRIPTION		
Definition	A low volume alarm will be given when the Vivo 40's volume fails to reach the low volume alarm limit for 15 seconds (45 seconds after start-up and after cancelling a high leakage alarm).		
Possible cause	• Restrictions in airways. • Obstructed or occluded patient circuit.		
Setting	Parameter: Low volume		
	Min:	Max:	Resolution:
	0.03 l	2.0 l	0.05 l
Ventilator action	The Vivo 40 will continue to give breaths with the same settings.		
Indication	 The alarm is given audibly with a tone and visibly by the red alarm LED and a display message.		

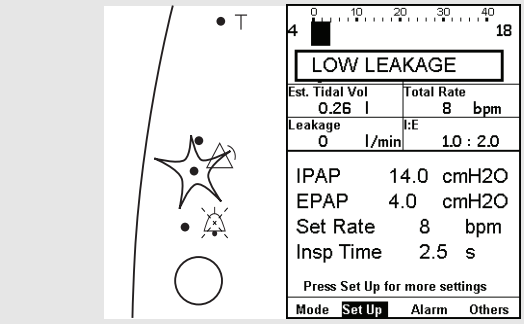
Low Breath Rate Alarm (Apnea alarm)

ITEM	DESCRIPTION		
Definition	A low breath rate alarm will be given when the delivered breath rate is less than the low breath rate alarm limit for 15 seconds.		
Possible cause	• Setting is higher than breath rate. • The patient doesn't trigger any breaths. • Decrease of the patient's spontaneous breathing.		
Setting	Parameter: Low breath rate		
	Min:	Max:	Resolution:
	4 BPM	50 BPM	1 BPM
Ventilator action	The Vivo 40 will continue to give breaths with the same settings.		
Indication	 The alarm is given audibly with a tone and visibly by the yellow alarm LED and a display message.		

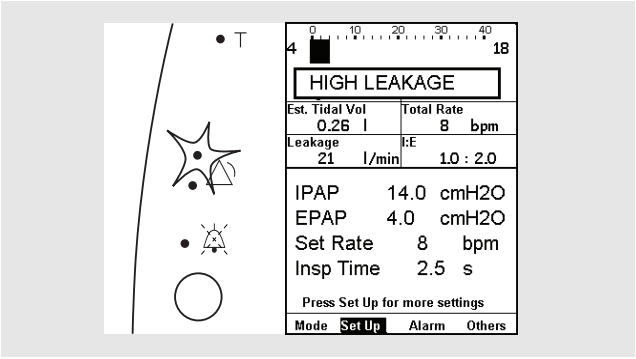
High Breath Rate Alarm

ITEM	DESCRIPTION		
Definition	A high breath rate alarm will be given when the delivered breath rate exceeds the high breath rate alarm limit for 15 seconds.		
Possible cause	The alarm for high breath rate is activated if the patient hyperventilates or if the ventilator starts to self-trigger because of incorrect settings.		
Setting	Parameter: High breath rate		
	Min:	Max:	Resolution:
	10 BPM	60 BPM, Off	1 BPM
Ventilator action	The Vivo 40 will continue to give breaths with the same settings.		
Indication	 The alarm is given audibly with a tone and visibly by the yellow alarm LED and a display message.		

Low Leakage Alarm

ITEM	DESCRIPTION
Definition	A low leakage alarm will be given when the measured flow is lower than the expected leakage flow at set pressure.
Possible cause	• Incorrect patient circuit leakage. • Obstructed or occluded patient circuit.
Setting	Self adjusting
Ventilator action	The Vivo 40 tries to continue delivering breaths according to settings.
Indication	 The alarm is given audibly with a tone and visibly by the yellow alarm LED and a display message.

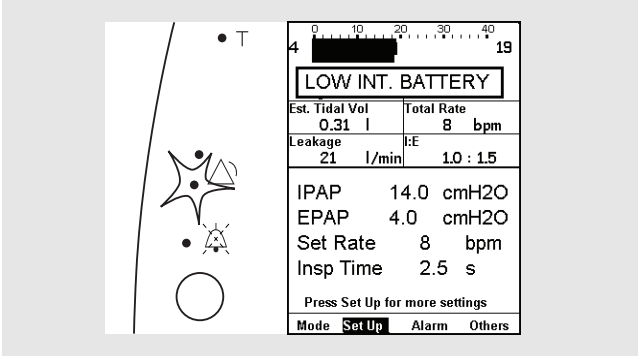
High Leakage Alarm

ITEM	DESCRIPTION
Definition	A high leakage alarm will be given when the measured flow exceeds the expected leakage flow at set pressure during more than 15 seconds.
Possible cause	• Leakage in patient circuit. • The patient has removed the mask.
Setting	Self adjusting
Ventilator action	The Vivo 40 tries to continue delivering breaths according to settings.
Indication	 The alarm is given audibly with a tone and visibly by the red alarm LED and a display message.

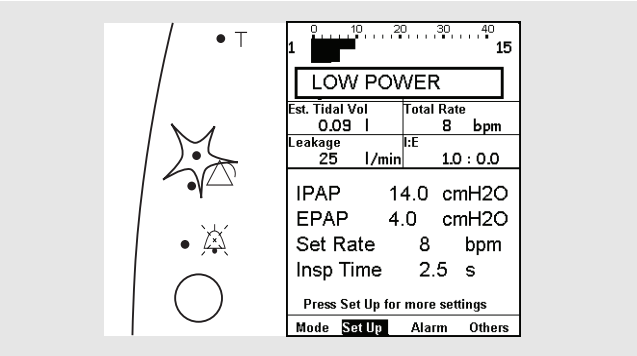
8.3 Technical Alarm

Low Internal Battery Warning

The low battery alarm can be triggered prematurely by a sudden increase in flow, such as an excessive leakage, a large breath or a mask off event. If this should happen, restart the Vivo 40 on internal battery. If the low battery alarm persists, the internal battery needs to be charged.

ITEM	DESCRIPTION
Definition	A low internal battery warning will be given when the internal battery is the last power source, and it falls below the voltage warning limit. Under normal circumstances, the low battery alarm will be activated approximately 15 minutes before shutdown.
Possible cause	A discharged internal battery.
Warning limit	Internal battery: 16.3 V
Ventilator action	The Vivo 40 will continue to give breaths with the same settings.
Indication	 The warning is given audibly with a tone and visibly by the yellow alarm LED and a display message.

Low Power Alarm

ITEM	DESCRIPTION
Definition	A low power alarm will be given when the internal battery source has fallen lower than its voltage alarm limit.
Possible cause	Discharged batteries.
Alarm limits	Internal battery: 14 ±0.75 V
Ventilator action	**The Vivo 40 stops giving breaths and gives alarm for 2 minutes.**
Indication	 The alarm is given audibly with a tone and visibly by the red alarm LED and a display message.

Internal Function Failure Alarms

ITEM	DESCRIPTION
Definition	An internal function failure alarm will be given when the Vivo 40 has an internal function failure.
Ventilator action	The Vivo 40 will continue or stop the treatment depending on the type and priority of the alarm.
Indication	The alarm is given audibly with a tone and visible by a display message at least for 120 seconds.
Ventilator reset	In order to stop the alarm the ventilator must be switched off by the On/Off switch on the side panel.

9 Complete Function Check

This chapter describes the complete function check of the Vivo 40. This function check should be performed after changing the ventilation mode, or if the ventilator function needs to be checked for any other reason.

For information on the short function check, which should be performed once a day, see "Set up the Vivo 40 Before Use" on page 35.

To perform a complete function check, all tasks in this chapter needs to be completed in the written number order.

9.1 Pre-use Check

Inspection of the HA 01 humidifier, if used

1. Remove and open HA 01 humidifier.
2. Check that there is no visible damage.
3. Check that the water container is clean.

Inspection of device

- Check that there is no visible damage.
- Check that the surface is clean.
- Check that the rear lid (or the HA 01 humidifier if applicable) is connected properly.

Inspection of cables

- Check that they are Breas cables.
- Check that the cables are undamaged.
- Check that the cables are properly connected.

Inspection of placement

- The Vivo 40 shall be placed on solid flat surface below the patient level.
- Make sure that nothing can block the patient air inlet at the rear.

9.2 Alarm Check

If an alarm check fails, do not use the Vivo 40 and contact your responsible service provider for an inspection of the device.

Chapter "Alarms" on page 66 has a detailed description of the alarm functions used for the Vivo 40.

Prepare the Vivo 40 for the Alarm Test

1 Connect Vivo 40 to the AC power supply and turn it on.

2 Press the Start/Stop button on the front panel. Check that a short sound signal is heard. Press the Start/Stop button again to switch off the Vivo 40.

3 The Vivo 40 shall be in standby mode (not operating) and the AC LED (see "The Vivo 40's Front Panel" on page 24) shall be lit.

4 Adjust the ventilator settings as follows:

SETTING	VALUE
Mode	PCV
IPAP	14 cmH_2O
EPAP	2 cmH_2O
Set rate	10 BPM
Inspiration time	1.5 sec
Rise time	4
Inspiration trigger	Off
Low pressure alarm	2 cmH_2O
Low volume alarm	0.05 l
High breath rate alarm	Off
Low breath rate alarm	4 BPM

Check the Low Leakage Alarm and High Leakage Alarm

5 Connect the patient circuit to a test lung (<1.5 l) and a leakage connector.

6 Enter operating mode by starting the treatment.

7 Block the leakage port.

8 The low leakage alarm shall occur within 60 seconds.

9 Disconnect the patient circuit from the air outlet.

10 The high leakage alarm shall occur within 30 seconds.

Check the High Pressure Alarm

11 Enter standby mode by stopping the treatment.

12 Connect a patient circuit to the Vivo 40.

13 Enter operating mode by starting the treatment.

14 Create pressure towards the Vivo 40 by blowing air into the mask or patient tube.

15 The high pressure alarm shall be activated after 3 consecutive high pressure breaths.

Check the Low Pressure Alarm

16 Enter standby mode by stopping the treatment.

17 Connect the patient circuit to a test lung (<1.5 l) and a leakage connector.

18 Adjust the IPAP to 12 cmH_2O and the low pressure alarm to 10 cmH_2O.

19 Enter operating mode by starting the treatment.

20 Adjust the IPAP to 5 cmH_2O.

21 The low pressure alarm shall occur within 30 seconds.

22 Adjust the IPAP to 12 cmH_2O.

23 The alarm shall disappear.

Check the High Breath Rate Alarm

24 Adjust the ventilator settings as follows:

SETTING	VALUE
IPAP	15 cmH_2O
EPAP	10 cmH_2O
Set rate	20 BPM
High breath rate alarm	10 BPM

25 The high breath rate alarm shall occur within 30 seconds.

26 Adjust the set rate to 5 BPM.

27 The alarm shall disappear in 30 seconds.

Check the Low Breath Rate Alarm

28 Adjust the ventilator settings as follows:

SETTING	VALUE
Set rate	5 BPM
High breath rate alarm	Off
Low breath rate alarm	15 BPM

29 The low breath rate alarm shall occur within 30 seconds.

30 Adjust the set rate to 20 BPM.

31 The alarm shall disappear in 30 seconds.

Check the Low Volume Alarm

32 Adjust the ventilator settings as follows:

SETTING	VALUE
High breath rate alarm	Off
Low volume alarm	2.0 l

33 The low volume alarm shall occur within 20 seconds.

34 Adjust the low volume alarm to 0.05 l.

35 The alarm shall disappear in 30 seconds.

Check the Switching of Power Source to the Internal Battery

36 Disconnect the power cord from the AC power supply.

37 Treatment continues and the Vivo 40 runs on internal battery with the internal battery LED lit.

38 Reconnect the power cord to the AC power supply.

39 The ventilator shall switch to main supply with the AC LED lit.

10 Cleaning the Vivo 40 and Replacement of Accessories

The patient-connected parts and the filter must be cleaned and replaced regularly to ensure correct function of the Vivo 40. All replaced parts must be disposed of in accordance with local environmental regulations regarding the disposal of used equipment and waste.

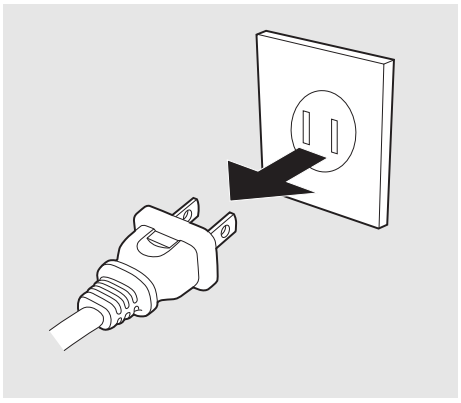
10.1 Cleaning the Vivo 40

To avoid electrical shock, disconnect the ACpower supply to the Vivo 40 before cleaning. Do not immerse the Vivo 40 into any fluids.

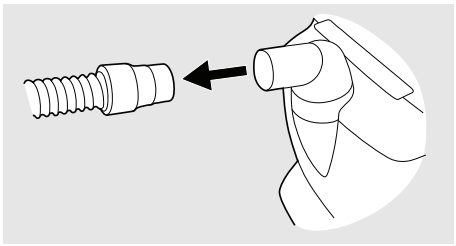
- Always be careful when cleaning to ensure that you do not damage any equipment.
- Fluid must not be allowed to enter into the Vivo 40.
- Do not sterilize the Vivo 40.

Main Unit

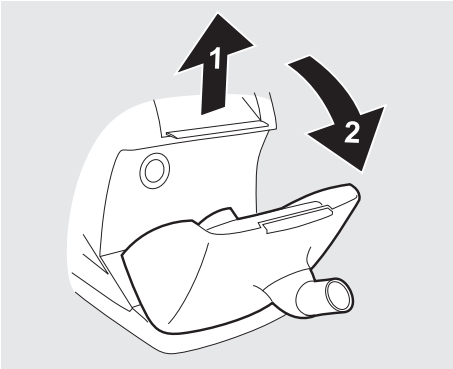
1 Switch off the Vivo 40 and disconnect the power supply.



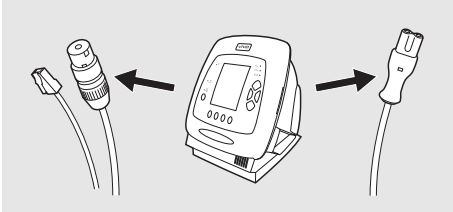
2 Remove the patient circuit.



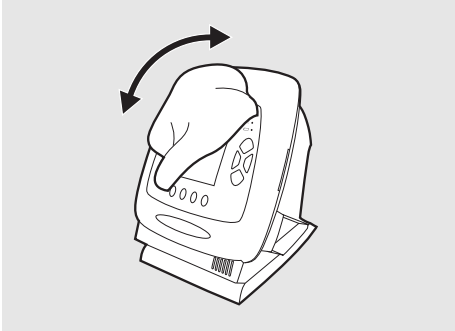
3 At regular cleaning after normal use, keep the rear lid or HA 01 humidifier attached.
In case a more thorough cleaning is needed, detach the rear lid or the HA 01 humidifier.



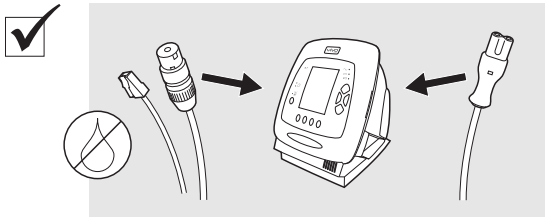
4 Disconnect all electric cables.



5 Clean the outside of the Vivo 40 using a lint-free cloth and a mild soap solution. If the surface of the Vivo 40 needs to be disinfected, this can be done with Virkon® or Gigasept®.



6 Reconnect the patient circuit. Make sure all parts are dry before the Vivo 40 is put into operation.



HA 01 Humidifier

The HA 01 humidifier should be cleaned, maintained and replaced in accordance with the manufacturer's instructions.

For more information, see Breas HA 01 Humidifier User Manual.

Patient Circuit

The patient circuit should always be cleaned, disinfected and replaced in accordance with the applicable manufacturer's instructions.

Always replace the patient circuit with a new one when the Vivo 40 is to be used by a new patient.

All parts that come into contact with the respiration gas must be cleaned as follows:

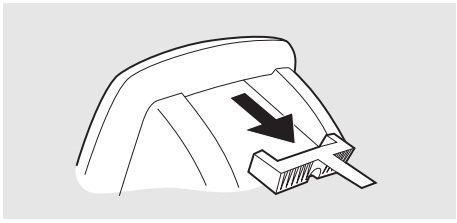
1. Place the dismantled parts in hot water containing mild detergent.
2. Remove fouling with a brush.
3. Rinse parts thoroughly under running hot water.
4. Shake water out of all parts.
5. Dry the parts completely.
6. Store in dust-free location.

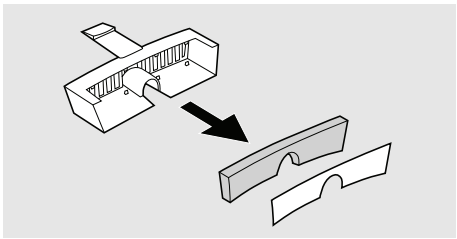
Check the patient circuit for damage regularly. In case of damage, replace the circuit.

If the parts need to be disinfected, this can be done in a bath of disinfectant, for instance Virkon® or Gigasept®. Then rinse the parts well in clear water and dry them thoroughly.

10.2 Cleaning and Replacing the Patient Air Filters

The patient air filters are located in the filter cassette at the rear of the ventilator. There are two types of filters: washable filter and disposable filter.





Washable Filter (gray)

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.

Disposable Filter (white)

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

Do not wash or reuse the disposable filter.

10.3 Change of Patient

If the Vivo 40 is used in a clinic by several patients, a low resistance bacteria filter may be used between the air outlet and the patient tube to prevent patient cross-contamination. However, if a HA 01 humidifier is connected to the Vivo 40, do not use any bacteria filter.

1 Follow the instructions in "Cleaning the Vivo 40" on page 83, step 1 to 5.

2 Clean the HA 01 humidifier according to the Breas HA 01 Humidifier User Manual.

3 Replace the patient filters according to "Cleaning and Replacing the Patient Air Filters" on page 85.

4 If a low resistance bacteria filter is used, it shall be replaced.

5 Use a new patient circuit when the Vivo 40 is used by a new patient.

11 Maintenance

WARNING!

- **Vivo 40 should be subjected to maintenance, service and control and any applicable upgrades, in accordance with Breas service instructions.**
- **Vivo 40 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 authorized after Breas Vivo 40 service training, or have an equivalent technical knowledge on medical device.**
- **Do not under any circumstances attempt to service or repair the Vivo 40 yourself. If you do so, the manufacturer will no longer be responsible for the performance and safety of the Vivo 40.**

DEVIATION FROM THESE SERVICE INSTRUCTIONS MAY LEAD TO RISK OF PERSONAL INJURY!

11.1 Regular Maintenance Control

Regular maintenance inspections and controls shall be carried out at least every 12 months. Maintenance control according to the Vivo 40 Service Manual.

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.**

11.2 Service and Repair

The service and repair of the Vivo 40 must be carried out by authorized service personnel in accordance with Breas service instructions. Service inspections must always be carried out after any repair of the device.

Authorized service workshops can order the Vivo 40 Service Manual that contains all technical documentation required for the maintenance and service of the Vivo 40.

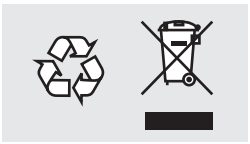
11.3 Storage

Empty, clean and dry the HA 01 humidifier (if applicable) before storage of the Vivo 40.

11.4 Disposal

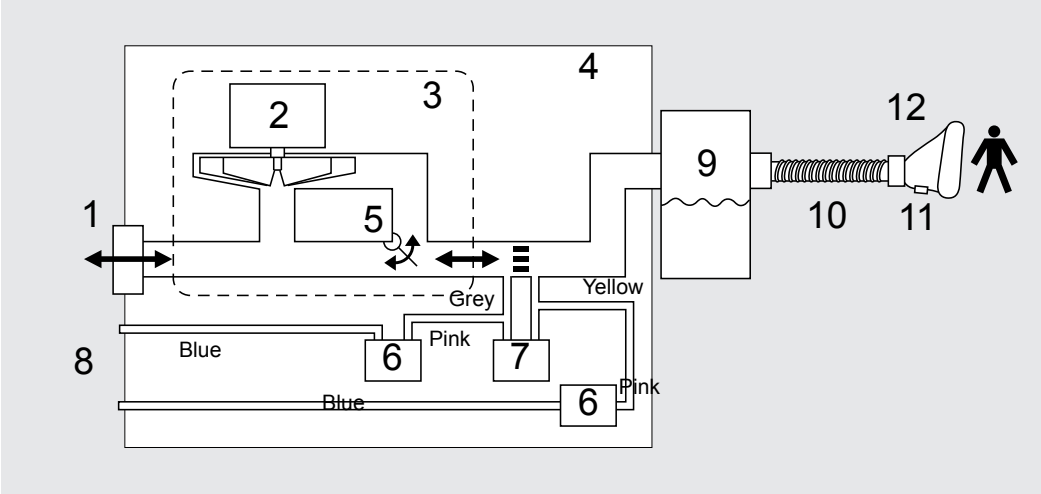
The Vivo 40, any accessories and all replaced parts must be disposed of and recycled in accordance with the local environmental regulations regarding the disposal of used equipment and waste.

Batteries used with the Vivo 40 shall be recycled in accordance with the local environmental regulations.



12 Technical Specifications

12.1 System Description



No.	Description
1	Air inlet filter
2	Blower
3	Silencer box
4	Vivo 40 casing
5	Pressure regulating valve
6	Pressure sensor
7	Flow sensor
8	Ambient
9	Humidifier (HA 01)
10	Patient tube
11	Leak hole
12	Mask

12.2 Data

SETTING/VALUE	RANGE/PERFORMANCE	RESOLUTION
Ventilation modes	• PSV (Pressure Support Ventilation) • PCV (Pressure Control Ventilation) • CPAP (Continuous Positive Airway Pressure)	
Target Volume	• Active • Inactive	
Device modes	• Clinical • Home	
EPAP	2 cmH_2O to 20 cmH_2O or IPAP/IPAPmin -2 cmH_2O Tolerance: ±2% of the maximum value and ±10% of the set value.	0.5 below 10 cmH_2O 1.0 above 10 cmH_2O
IPAP	4 to 40 cmH_2O Tolerance: ±2% of the maximum value and ±10% of the set value.	0.5 below 10 cmH_2O 1.0 above 10 cmH_2O
IPAPmin (Target Volume)	4 to 40 cmH_2O or to IPAPmax Tolerance: ±2% of the maximum value and ±10% of the set value.	0.5 below 10 cmH_2O 1.0 above 10 cmH_2O
Target Volume	0.2 to 1.5 l	0.05 l
IPAPmax (Target Volume)	4 or IPAPmin to 40 cmH_2O Tolerance: ±2% of the maximum value and ±10% of the set value.	0.5 below 10 cmH_2O 1.0 above 10 cmH_2O

SETTING/VALUE	RANGE/PERFORMANCE	RESOLUTION
CPAP	4 to 20 cmH_2O. Tolerance: ±2% of the maximum value and ±10% of the set value.	0.5 below 10 cmH_2O 1.0 above 10 cmH_2O
Breath rate	4 to 40 breaths per minute (BPM), tolerance: ±10% of set value.	1 BPM
Inspiration time	0.3 to 5 sec, tolerance: ±10% of set value.	0.1 sec
Min inspiration time	Off, 0.3 to 3 sec	0.1 sec
Max inspiration time	0.3 to 3 sec, Off	0.1 sec
Rise time	1 to 9	1
Inspiratory trigger effort level	1 to 9, Off.	1
Expiratory trigger effort level	1 to 9, where 1 is the lowest effort and 9 is the highest effort setting.	1
Ramp function	On, Off, Disabled	
HA 01 humidifier	Settings: Off, 1 to 9, corresponds to 10 to 30 mgH_2O/l, <100% RH. Heat-up time from 73°F (23°C): less than 1 hour. Max gas temperature at patient port: 109°F (43°C).	1
Audible alarm level	1 to 9, where 1 is the lowest and 9 is the highest volume setting.	1
Maximum flow	> 200 liter/min	

SETTING/VALUE	RANGE/PERFORMANCE	RESOLUTION
Maximum limited pressure during single fault condition	PCV, PSV: 60 cmH_2O CPAP: 30 cmH_2O	
Maximum steady limiting pressure	Set IPAP + 10 cmH_2O, tolerance: ±10%	
Max flow in CPAP mode	1/3 of max press.: 110 liter/min 2/3 of max press.: 150 liter/min Max pressure: 155 liter/min	
Breathing resistance under single-fault	4 cmH_2O at 30 liter/min 6 cmH_2O at 60 liter/min	
Sound level at 10 cmH_2O	Less than 30 dB(A)	Measured at 1 m

INDICATOR	SPECIFICATION	RESOLUTION
Pressure	0 to 40 cmH_2O	±2% of full scale and ±4% of actual reading
Estimated tidal volume	liter (BTPS, Body Temperature and Pressure Saturated)	±20% or ±20 ml, whichever is the greatest.
Leakage	liter/min (BTPS)	1 liter/min, ±20%
Total rate	BPM (Breath Per Minute)	1
I:E	1:10 to 10:1	0.1 unit, ±1 unit

ALARM	SPECIFICATION	INDICATION
Auditory alarm signal pressure	45 to 85 dB(A)	±5 dB(A). Measured at 1 m.
Low pressure alarm	2 cmH_2O to IPAP/IPAPmin resolution 1 cmH_2O	Red LED, audible alarm and a warning message on the display.

ALARM	SPECIFICATION	INDICATION
High pressure alarm	Self adjusting	Red LED, audible alarm and a warning message on the display.
Low volume alarm	0.03 l to 2.0 l resolution 0.05 l	Red LED, audible alarm and a warning message on the display. Accuracy: 0.05 l.
Low breath rate alarm	4 BPM to 50 BPM resolution 1 BPM	Yellow LED, audible alarm and a warning message on the display.
High breath rate alarm	10 BPM to 60 BPM, Off resolution 1 BPM	Yellow LED, audible alarm and a warning message on the display.
Low leakage alarm	Self adjusting	Yellow LED, audible alarm and a warning message on the display.
High leakage alarm	Self adjusting	Red LED, audible alarm and a warning message on the display.
Low Internal Battery Warning	16.3 V	Yellow LED, audible alarm and a warning message on the display.
Low power alarm	AC power: 65 ±15 V AC Ext. DC 12 V: 10.0 ±0.5 V Ext. DC 24 V: 20.0 ±0.5 V Int. Batt.: 14 ±0.75 V	Red LED, audible alarm and a warning message on the display.
Internal function failure alarms		Red or yellow LED, audible alarm and a warning message on the display.

POWER SUPPLIES	SPECIFICATION
AC power supply	100 to 240 V AC, tolerance: +10%/-20%, 50 to 60 Hz, max 140 VA

POWER SUPPLIES	SPECIFICATION
Internal battery	Capacity 3.8 Ah. NiMH (Nickel-Metal Hydride). Operational time 3 hours, lifetime 3 years.
External battery	12/24 V DC, tolerance: +20%/-15% (10.5 to 15 V/20.4 to 30 V). Max 120 W with Breas external battery.

ENVIRONMENTAL CONDITIONS	SPECIFICATION
Operating temperature range	41 to 100°F (5 to 38°C)
Storage and transport temperature	-4 to +140°F (-20 to +60°C)
Ambient pressure range	600 to 1060 cmH_2O, corresponding to ~4000 metres above sea level to ~375 metres below sea level, at normal atmospheric pressure.
Humidity	10% to 95%, non-condensing

OPERATING CONDITIONS	SPECIFICATION
Recommended leakage	20 to 40 liter/min at 10 cmH_2O
Minimum leakage	12 liter/min at 4 cmH_2O

DIMENSIONS	SPECIFICATIONS
W × H × D	7.48 × 9.57 × 8.78 inch (with rear lid)
Weight	8.8 lbs (with rear lid)
Air outlet	22 mm male conical standard connector

12.3 Compliance of Standards

STANDARD	SPECIFICATION
IEC 60601-1 (1988) A1 (1991) A2 (1995)	Medical electrical equipment - Part 1: General requirements for safety.
IEC 60601-1-2 (2001)	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - requirements and tests.
IEC 60601-1-4 (2000)	Medical electrical equipment - Part 1-4: General requirements for safety - Collateral Standard: Programmable electrical medical systems.
IEC 60601-1-8 (2003)	Medical electrical equipment - Part 1-8: General requirements for safety - Collateral standard: Alarm systems - requirements, tests and guidelines.
ISO 10651-6 (2004)	Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 6: Home care ventilatory support devices.
ISO 17510-1 (2002)	Sleep apnea breathing therapy - Part 1: Sleep apnea breathing therapy devices.
ISO 8185 (2007)	Respiratory tract humidifiers for medical use - Particular requirements for respiratory humidification systems.
CAN/CSA-C22.2 No. 601.1-M90	Medical electrical equipement Part 1: General requirements for safety.
CAN/CSA-C22.2 No. 601.1S1-94	Supplement no. 1-94 to CAN/CSA-C22.2 No. 601.1-M90--Medical electrical equipement Part 1: General requirements for safety CSA 601.1 Amendment 2:1998
UL Std No. 60601-1, 1st Ed.	Medical electrical equipement Part 1: General requirements for safety.

CLASSIFICATION	SPECIFICATION
Class II (IEC 60601-1)	Class II, Type BF. Electrical equipment with dual isolation and body floating (isolated) applied part according to IEC 60601-1.
Class IIb	Classification according to the European Medical Device Directive 93/42/EEC.

The Vivo 40 and it's packaging do not contain any natural rubber latex.

12.4 Delivery Settings

MODES AND FUNCTIONS	SETTING
PSV	On
PCV	Off
Target Volume	Inactive
CPAP	Off
Ramp	Disable
Clinical	On
Home	Off
Humidifier	Off
Wake up	Off

PARAMETERS	SETTING
IPAP	10 cmH_2O
EPAP	4 cmH_2O
Target Volume	0.5 l
IPAPmax	10 cmH_2O
CPAP	10 cmH_2O
Breath rate	10 BPM
Inspiration time	1.5 sec
Inspiration trigger	3
Expiration trigger	3
Rise time	3
Max inspiration time	Off
Min inspiration time	Off
Ramp time	10 min
CPAP ramp start pressure	4 cmH_2O
IPAP ramp start pressure	4 cmH_2O

ALARMS	SETTING
Low pressure	2 cmH_2O
High breath rate	Off
Low breath rate	8
Low volume	0.25 l

OTHERS	SETTING
Time format	12 h AM/PM
Patient operating time	0 h
Pressure unit	cmH_2O
Wake up alarm sound	1
Sound level (alarm)	5
Display light	Delayed
Light intensity	5
Display contrast	6
Wake up time	07:30, Off
Humidity level	6

13 Accessories

13.1 Breas Accessories List

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 40.

The following Breas accessories are currently available for the Vivo 40:

DESCRIPTION	PART NO.
Carry bag	003519
Users manual	003819
Clinician's manual	003886
Patient tube	004465
HA 01 humidifier	003530
Rear lid	003591
Filter (grey, washable)	003563 (5 pcs)
Filter (white, disposable)	003564 (5 pcs)
Leakage/Exhalation port	004426
Trach elbow	004810
Low resistance bacteria filter (303 Respirgard-II Filter)	004185
Power cord (Vivo)	003522
Memory card reader/writer	002185
Memory card	003619
External DC cable	003584
iCom	004143
Vivo-PC data cable, RJ45 to D-sub 9F	003588
Vivo-iCom data cable, RJ45 to D-sub 15F	003574
iCom-PC data cable, D-sub 9M to D-sub 9F	003721

DESCRIPTION	PART NO.
iCom-PC data cable, USB to USB	003722
Vivo PC Software kit	004145

Accessory equipment connected to the analog 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 shall comply with the valid version of the system standard IEC 60601-1-1. Everybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of the valid version of the system standard IEC 60601-1-1. If in doubt, consult the technical service department or your local representative.