Nippy 4, User's

ENGLISH (GB)

Nippy 4 User Manual

Breas Nippy 4
User Manual

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Table of Contents

1 Introduction

WARNING!

Risk of Personal Injury

The Nippy 4 must only be used:

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

Every other use may lead to risk of personal injury!

CAUTION!

Read this manual thoroughly so that you completely understand how the Nippy 4 is operated and maintained before taking it into use, to ensure correct usage, maximum performance and serviceability. Non-professional caregivers (e.g. family members) should consult the medical equipment provider's respiratory therapist if they have any questions about the function, proper use, operation, service or maintenance of the Nippy 4.

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

U.S. Federal law restricts this device to sale by or on order of a physician.

1.1 What is the Nippy 4?

The Nippy 4 is a pressure ventilator capable of delivering continuous or intermittent ventilatory support for patients who require invasive or non-invasive mechanical ventilation. The Nippy 4 is capable of running 24 hours/day.

The Nippy 4 can be operated in the following ventilation modes:

- Pressure Support (PSV)
  May be combined with Auto-EPAP (AE)
- Pressure Support with TgV (PSV+TgV)
  TgV= Target Volume
  May be combined with Auto-EPAP (AE)
- Pressure Control (PCV)
  May be combined with Auto-EPAP (AE)
- Pressure Control with TgV (PCV+TgV)
  TgV= Target Volume
  May be combined with Auto-EPAP (AE)
- Mouthpiece - Pressure (PCV-MPV)
- CPAP

Compatible Patient Circuits

The Nippy 4 should be used with a leakage circuit and a suitable patient interface or an MPV circuit. See 9 *Accessories and Parts*, page 121 for detailed information about compatible patient circuits.

The patient circuit shall comply to ISO 17510. The leakage should be at least 12 l/min at 4 cmH_2O, to prevent rebreathing of exhaled air. The recommended leakage is 20 to 50 l/min at 10 cmH_2O pressure.

Compatible Patient Interfaces

For invasive use, the patient interface may be a tracheostomy tube.

For non-invasive use it may be a mask, or a pillow interface. See the patient interface's instructions for use when selecting the interface to use.

Data Log

The Nippy 4 has an internal memory with a data log that holds the following data:

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

The log data is maintained when device is powered off or in case of power failure. When logs are filled up, the oldest data will be discarded. The data can be transferred to a computer, printed out, and analyzed via Breas software products, see 5.10 *Transferring Data between the Ventilator and a PC*, page 56.

For more information about Breas software products, please contact your Breas representative.

Multiple Use

This is a multiple patient multiple use ventilator. If it should be used by multiple patients, see the cleaning instructions in 7.3 *Change of Patients*, page 106 before assigning it to a new patient. Note that accessories to the ventilator might be for single patient use and should in that case be replaced at change of patient.

Expected Service Life

The expected service life of the Nippy 4 is 8 years.

1.2 Intended Use

Nippy 4 is intended to provide non-invasive or invasive ventilation for adult or paediatric patients weighing over 10 kg (22 lbs) who require long-term support or mechanical ventilation for respiratory insufficiency or respiratory failure, with or without obstructive sleep apnea.

Nippy 4 is intended for spontaneously breathing patients.

1.3 Contraindications

The Nippy 4 is not a life-support ventilator and is contraindicated in patients who are unable to tolerate more than brief interruptions in ventilation.

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

- Untreated pneumothorax
- Pneumomediastinum
- Inability to maintain a patent airway or adequately clear excessive respiratory secretions
- Severe acute systemic complications (shock, unstable arrhythmias, myocardial ischemia)
- Severe bullous lung disease
- Risk of vomiting
- Pathologically low blood pressure, especially if associated with intravascular volume depletion
- Cerebrospinal fluid leak, recent cranial surgery or trauma

The use of the Nippy 4 is contraindicated in an MRI environment.

Adverse Effects

If the patient experiences chest discomfort, pain, severe headache or shortness of breath while using the Nippy 4, a physician or responsible clinician should be contacted immediately.

The following side effects may occur during the course of therapy with the Nippy 4, patients are advised to report any new or changing adverse effects to their physician:

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

1.4 Intended Environment

The Nippy 4 is intended to be used in clinical settings (e.g. hospitals, sub-acute care institutions), public spaces and home environments as well as during portable applications such as wheelchairs, personal family vehicles, ground ambulances and civil aircraft, excluding helicopters.

It is not intended for use during emergency transportation.

1.5 Operation by Lay Users

Day-to-day caregivers, patients, relatives and other non-professional users may operate the Nippy 4 with the *Home mode* activated, after it has been set up according to the prescribed treatment. In Home mode, some settings and controls are locked or hidden.

The lay operator may also perform basic maintenance that doesn't require special equipment or a service environment.

Training

The lay operator shall be trained to basic knowledge of the Nippy 4 and in the specific operations they are assigned to perform. The training shall be based on this user manual and the responsible clinical personnel shall assess the level of training required for each lay operator. This manual shall be available for training and as reference when operating the Nippy 4.

1.6 About this Manual

CAUTION!

Always read this manual before setting up and using the Nippy 4 or performing maintenance on the machine, to ensure correct usage, maximum performance and serviceability.

1.6.1 Audience

This manual is intended for patients and other lay users operating the Nippy 4.

- Care providers, clinical personnel, physicians and others who require a working knowledge of the Nippy 4 will find additional information on settings and functions in the Clinician's Manual. The Clinician's manual should be of the same revision as the User's Manual.
- Service personnel may order the Service Manual that contains detailed technical information for maintenance, service, repair and disposal procedure. The Service manual's revision is independent of the User's Manual revision.

1.6.2 Icons in this Manual

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

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

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

1.7 Manufacturer Information

Legal Manufacturer

CE 2797

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2 Safety Information

2.1 General User Precautions

WARNING!

Risk of Personal Injury

The Nippy 4 must only be used:

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

Every other use may lead to risk of personal injury!

Risk of Insufficient Ventilation

Usage outside the specified operating conditions may cause reduced performance.
The Nippy 4 must only be used in accordance with the operating conditions specified in this manual.

Risk of Reduced Safety and Performance

Accessories that have not been verified to be compatible with the Nippy 4 might affect safety features and performance negatively.
Only use the Vivo with accessories that are compatible with the ventilator. Use of incompatible parts to connect the ventilator to the patient can result in degraded performance and change of pressure gradient.
Breas Medical has verified the compatibility between the Nippy 4 and the accessories listed in the Clinician's manual.
The responsible organization must ensure the compatibility of the ventilator with all parts used to connect to the patient before starting the intended treatment. If incompatible accessories are used, Breas Medical has no responsibility for the safe and effective use of the Nippy 4.

Changes to the patient circuit, like adding or removing accessories or changing type or length of breathing tube, may affect both circuit compliance and alarm triggering conditions.
It's recommended to perform a pre-use test and re-test the alarm function after making changes to the patient circuit.

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

To prevent disconnection of the patient circuit during use, only tubes in compliance with ISO 5367 or ISO 80601-2-74 should be used.

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

WARNING!

Risk of Burns

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

WARNING!

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

Risk of Faulty Treatment
Do not use the Nippy 4 in the event of:

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

Contact your responsible care provider for an inspection.

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

Before starting treatment, always perform the procedure 4.5 *Inspecting the Nippy 4 before Use* , page 35.

The ventilator is not suitable for a ventilator dependent patient.

Risk of Unnoticed Critical Conditions

- All the physiological alarms of the Nippy 4 must be set at safe levels that will effectively warn the user of any risk.

  The alarm levels should be assessed considering the patient's treatment settings.
- Any change of treatment settings or change of components in the ventilation system may require readjustment of the alarm levels.
- The alarm sound level should be set to a clearly audible level. Setting the alarm sound level below that of the ambient sound level can impede recognition of alarm conditions.

CAUTION!

Clinical personnel must read the Clinician's manual thoroughly and understand the ventilator operation before setting up and using the ventilator.

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

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

Ensure that the cooling air intake vents are not blocked. If the vents are blocked, especially in hot use environments, the surface temperature of the patient circuit may rise above 41°C (106°F). In a 40°C (104°F) environment and with the cooling air intake vents blocked, surface temperatures as high as 50°C (122°F) can occur. Before an unsafe temperature is reached, the "High Patient Air Temp" alarm will occur. If this alarm occurs, assure that the ventilator cooling air intake path is free of obstruction and that the patient circuit surface is not heating the patient's skin.

WARNING!

Risk of Electric Shock
Modifying or using the ventilator with accessories that are not compatible may cause cardiac arrhythmia.
The Nippy 4 must only be used in original and unmodified shape and only with compatible accessories.
Inadequate use of device or accessories may cause loss of treatment or decreased performance.

CAUTION!

If you suspect that the device has been mistreated, perform a functional check before taking it to use. A basic functional check can be performed as described in 4.5 *Inspecting the Nippy 4 before Use* , page 35. A complete functional check can be performed by an authorized service technician.

NOTE

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

2.2 Electrical Safety

WARNING!

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

- Do not operate the Nippy 4 if it has a damaged power cord, power supply or casing.
- To avoid electrical shock, only clean the Nippy 4 according to instructions in this manual. Do not soak or immerse the Nippy 4 into any fluids.
- Use the approved power supply units only.

  Use of unapproved power supply units may compromise the electrical isolation and lead to risk of electric shock.
- Do not use more than one multiple portable socket-outlet or extension cord. If a multiple portable socket-outlet is used, it must not be placed on the floor.

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

WARNING!

Risk of Faulty Treatment
Electromagnetic Interference may cause electrical equipment to malfunction.

- The aspects of electromagnetic compatibility must be considered.
  - The Nippy 4 should not be used adjacent to or stacked with other equipment; if adjacent or stacked use is necessary, the Nippy 4 should be observed to verify normal operation in that configuration.
  - Mobile or transportable radio transmitters may interfere with the Nippy 4.
  - Further guidance for safe installation of the ventilator can be found in the chapter about emission and immunity declaration.
- If a portable AC power supply is used, make sure that the voltage variations are within the operating limits of the Nippy 4.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Nippy 4, including cables specified. Otherwise, degradation of the performance of this equipment could result.

WARNING!

Avoid touching the contacts within the ventilator click-in battery compartment. Under certain circumstances touch current limits per IEC 60601-1 may be exceeded.

2.3 Environmental Conditions

WARNING!

Risk of Intoxication
Do not use the Nippy 4 in a toxic environment.

WARNING!

Risk of Fire
Do not use the Nippy 4 in environments where explosive gases or flammable anesthetic agents present.

WARNING!

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

Risk of Faulty Treatment
If a room humidifier is used, place it at least 2 meters away from the Nippy 4.

Risk of faulty Treatment
The performance of the Nippy 4 may deteriorate at altitudes or ambient temperatures outside the operation conditions specified in the chapter *Technical Specifications*.

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

Risk of Faulty Treatment

Do not use or store the Nippy 4 in a magnetic resonance (MR) environment. Use of the Nippy 4 in an MR environment may result in malfunction of the Nippy 4 and pose unacceptable risk to the patient, medical staff or other persons.

Unsteady indicated values for delivered volumes or pressures and the occurrence of alarm conditions without apparent cause may be an indication of loss of performance due to electromagnetic disturbances. Follow the instructions above and the guidance provided in 8.3 *Emission and Immunity Declaration*, page 115 to mitigate the effects of electromagnetic disturbances.

CAUTION!

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

2.4 Usage of Patient Circuit

WARNING!

Risk of Insufficient Ventilation

Insufficient ventilation may cause transient hypoxia.
The Nippy 4 ventilator is intended to be used with patient circuits with intentional leakage and compliant to ISO 17510. Recommended leak rate: 20 to 50 liters per minute at 10 cmH_2O.
Failure to use a mask or accessory that minimizes rebreathing of carbon dioxide or permits spontaneous breathing can cause asphyxiation.

Risk of Insufficient Ventilation

Insufficient ventilation may cause transient hypoxia.
Before use:

- Make sure that the patient circuit and joined parts are undamaged and correctly connected, in order to avoid unwanted leakage.
- The leakage port of the patient circuit or patient interface prevents rebreathing by flushing the exhaled air. It should be located as near the patient interface as possible (this is even more important for treatments with low pressure). Make sure that it is not blocked or obstructed.
- The Nippy 4 should be turned on and the function of the leakage port should be checked before use:

When the patient circuit is replaced or modified, check the alarm settings as changes to the patient circuit may affect the alarm triggering. Also consider performing a pre-use test for optimizing the therapy.

Risk of Suffocation

If the patient needs assistance to remove the patient interface, the patient shall not be left alone. This is to avoid the risk of re-breathing of CO_2 in case of accidental ventilator failure.
Do not breathe through the connected patient circuit unless the ventilator is turned on and operating properly.

WARNING!

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

WARNING!

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

By conducting a pre-use test (see4.7 *Performing the Pre-use Test*, page 36) the compatibility of the complete patient circuit configuration with the ventilator can be verified. If a pre-use test is successfully performed the circuit configuration meets the required characteristics.

Risk of Suffocation
Periodically check for moisture in the patient circuit.
When present, remove the moisture. Before attempting to dry the circuit, disconnect it from the Nippy 4 to ensure no water flows back into the Nippy 4.
The frequency at which these checks must be performed will depend on the patient's condition and the device used. The responsible caregiver should assess this on an individual basis in accordance with the patient's needs.

Risk of Insufficient Ventilation
Insufficient ventilation may cause transient hypoxia.
The use of equipment such as endotracheal tubes, oral/nasal tubes, adaptors etc. with small inner diameters or high resistance filters, humidifiers etc. increase the resistance in the patient circuit which may interfere with the operation of the patient disconnect function. It may also interfere with the device trigger function.
This impact can be reduced by conducting a pre-use test.

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

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

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

WARNING!

Risk of Cross-Contamination
Patient circuits might get contaminated by exhaled gases. To avoid cross-contamination, always use a properly cleaned or a new patient circuit when the Nippy 4 is to be used by a new patient.

NOTE

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

2.5 Usage of Filters

WARNING!

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

Risk of Overheating
Replace or clean the air inlet filters as specified in the *Maintenance* chapter.
Using old or clogged filters may cause the Nippy 4 to operate at higher temperatures than intended.
When operating the Nippy 4, make sure that the air inlet and filters are not obstructed or occluded.

Risk of Insufficient Ventilation
Insufficient ventilation may cause transient hypoxia.
Do not use high resistance bacteria filter at the air outlet of the Nippy 4. High resistance bacteria filters placed between the air outlet and the patient interface may interfere with the operation of the patient disconnect function. It may also interfere with the device trigger function.

When adding, changing or removing any kind of filter, always reassess the settings, including alarm settings. A pre-use test is recommended.

WARNING!

Risk of Cross-Contamination
Deep tissue or mucosal contact with infectious agents may cause infections.
If the Nippy 4 is used by several patients, a low resistance bacteria filter shall be used between the air outlet and the patient circuit, for preventing patient cross-contamination.
Reuse of bacteria filter, patient circuit or mask may expose patients to contagious agents.

2.6 Humidification

WARNING!

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

Risk of Suffocation
When the attachable humidifier is installed, the Nippy 4 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 a humidifier or a nebuliser any patient air filter will need more frequent replacement to prevent increased resistance or blockage.

The ventilator accuracy can be adversely affected by the gas added by the use of a pneumatic nebuliser.

WARNING!

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

WARNING!

The use of a heated wire patient circuit decreases condensation in the patient circuit.

In case of invasive application, the use of an appropriate external heated humidifier or HME is recommended.

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

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

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

Do not add any attachments or accessories to the humidifier that are not listed in the instruction for use of the humidifier or the humidifier might not function correctly affecting the quality of the therapy or injuring the patient.

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

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

2.7 Cleaning and Maintenance

WARNING!

Risk of Electric Shock
Cleaning with excessive water or opening the device's casing without certified training may cause electric shocks.
The Nippy 4 should be regularly cleaned and maintained in accordance with this operating manual.

WARNING!

Risk of Faulty Treatment
Service and Maintenance of the Nippy 4 shall not be performed when the Nippy 4 is in use.

WARNING!

Risk of Electric Shock
High voltage contact may cause cardiac arrhythmia.
Repairs and modifications must be carried out by authorized technicians only and in accordance with instructions from Breas Medical

- The Nippy 4 must not be opened, repaired or modified by unauthorized personnel or interconnected with incompatible equipment. If subjected to unauthorized modifications or operations, Breas Medical is no longer responsible for the device's performance and safety and all warranties will become invalid.

CAUTION!

Do not attempt to autoclave or sterilize the Nippy 4.

2.8 Usage of Oxygen

When using the Nippy 4 with oxygen, always follow the oxygen provider's instructions and use only medical grade oxygen complying with local regulations.

WARNING!

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

It is the responsibility of the responsible organization to ensure that the oxygen source is compatible with the rated range of pressure, flowrate and oxygen concentration as indicated in the instructions for use as this can affect the performance of the ventilator that can consequently result in patient death or serious deterioration of health.

WARNING!

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

Risk of Fire
When oxygen is used with the Nippy 4, the oxygen flow must be turned off when the Nippy 4 is not operating. Oxygen delivered into the patient tubing may accumulate within the machine enclosure. Oxygen accumulated in the machine enclosure increases the risk of fire.

WARNING!

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

WARNING!

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

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

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

WARNING!

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

Risk of faulty Treatment

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

To monitor the oxygen concentration, use the FiO_2 sensor accessory.

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

CAUTION!

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

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

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

3 Product Description

3.1 Main Components

This section describes the components of the Nippy 4 medical electric equipment.

NOTE

- There might be local variations of the main components configuration.
- The standard Nippy 4 and its packaging do not contain any natural rubber latex.

Carry bag

Function: Storage for transportation

Part No: 006469

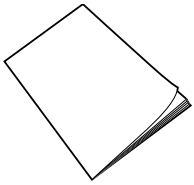
Manual

Function: Product and usage information

Part No:

User's manual: 006553

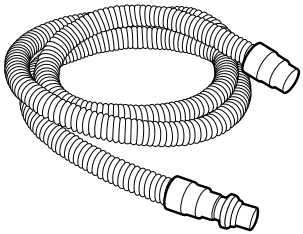
Clinician's manual: 006554



Patient Circuit

Function: Delivers air to the patient (applied part)

Delivered patient circuit depends on the sales configuration. See 9 *Accessories and Parts*, page 121 for compatible patient circuits.



Patient air inlet filter, fine, white, disposable

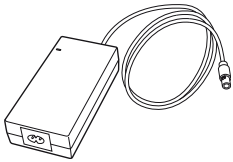
Function: Fine inlet air filtration.

Material: AS 100

NaCl Penetration: (0.65 µm NaCl @ 95 l/min) = <7.35%

Part No: 007103 (5pcs)

Power Supply



Function: Deliver power to the ventilator

Part No: 006396

Power cord

Function: Deliver power to the AC power supply

Part No:

GB: 003521

CN: 005304

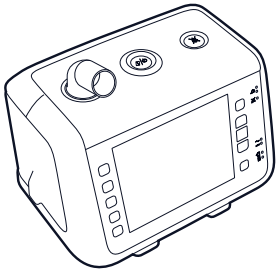
EU: 003520

JP: 004834

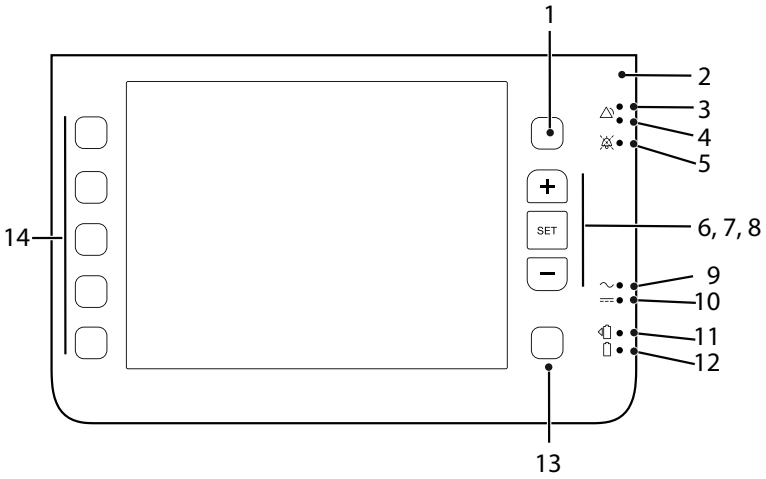
US: 003522

Nippy 4 Main Unit

Main Unit



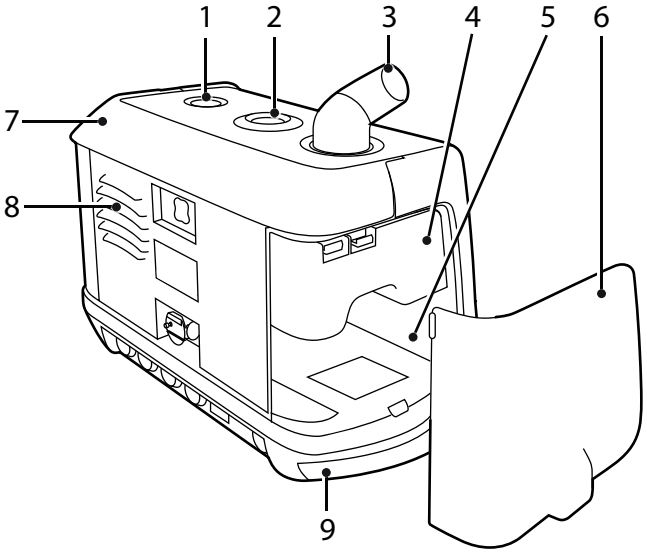
3.2 Front View



No	Item	Function
1	Alarms button	Access to alarm settings
2	Sensor	Ambient light sensor
3–4	Alarm (red & yellow) LED	Alarm indication: Red = High priority Yellow = Medium priority
5	Audio pause LED	Paused alarm sound indication
6-8	Plus, Set, Minus buttons	Function according to display Plus = Increase, go up Set = Enter / Navigation Minus = Decrease, go down
9	Mains LED	Power source indication: Mains
10	External DC LED	Power source indication: External DC
11	Click-in battery LED	Power source indication: Click-in battery
12	Internal battery LED	Power source indication: Internal battery
13	Menu button	Menu/Navigation
14	Settings, Mode buttons	Select settings, modes and profiles

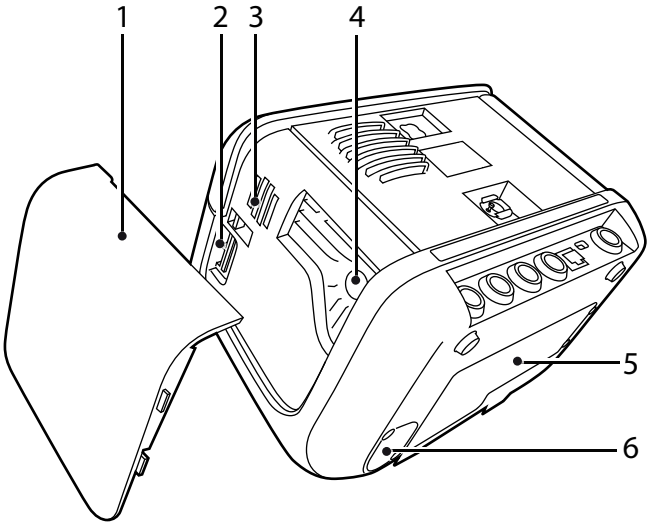
3.3 Side Views

Click-in compartment side



No	Item	Function
1	Audio pause	Pause the alarm sound
2	Start/Stop	Start/Stop ventilation treatment
3	Patient air outlet	Connection for patient circuit
4	Air bypass unit	Click-in airway/silencer for use without the click-in humidifier. (If the click-in humidifier is used, it replaces the air bypass unit)
5	Click-in compartment	Compartment for either of the accessories click-in humidifier or click-in battery.
6	Side panel	Cover
7	Carrying handle	Handle for lifting the ventilator
8	Cooling air outlet	Outlet internal cooling
9	Cooling air inlet	Inlet internal cooling

Filter Side



No	Item	Function
1	Side panel	Cover
2	Memory card slot (SD card)	Memory download
3	Alarm beeper	Alarm Sounds Output
4	Patient air inlet	Air bypass unit in, replaceable filters
5	Internal battery	Compartment for the internal battery
6	FiO_2 sensor hatch	Compartment for the optional FiO_2 sensor

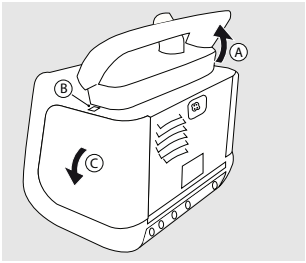
3.3.1 Detaching and Reattaching the Side Panels

Detaching the Filter Side Panel

1 Lift the handle to access the release button (A).

2 Looking from behind, to dismount the filter side panel press the button above the panel (B). The panel is released.

3 Remove the panel. (C)

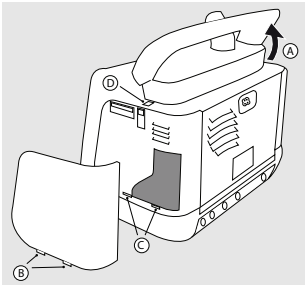


Reattaching the Filter Side Panel

1 Lift the handle to access the release button (A).

2 To mount the filter side panel, insert the tabs (B) on the lower side of the panel into the holes (C).

3 Press the side panel into the casing until it clicks in place at the button (D).



Detaching the Click-in Compartment Side Panel

1 Lift the handle to access the release button (A).

2 Press the button marked "**1**". (B).

⇒The panel is released.

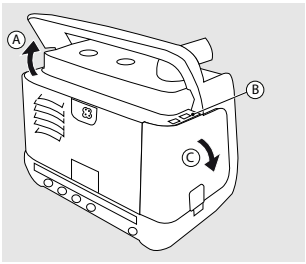
3 Remove the panel (C).

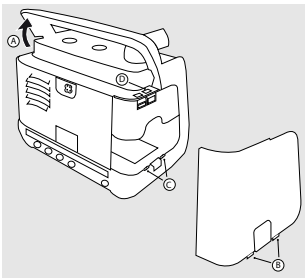
Reattaching the Click-in Compartment Side Panel

1 Lift the handle to access the release button (A).

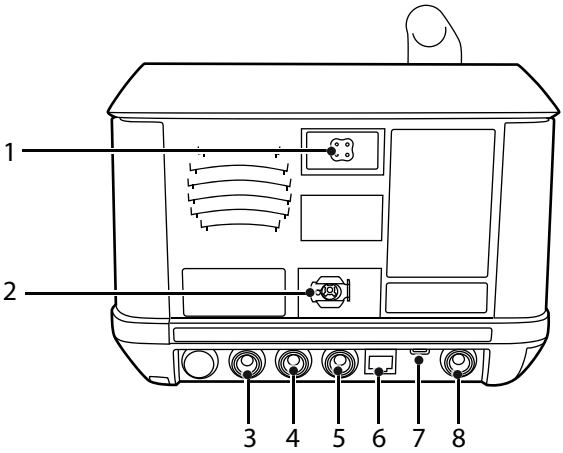
2 To mount the click-in compartment side panel, insert the tabs (B) on the lower side of the panel into the holes (C).

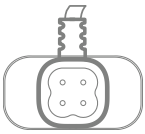
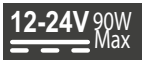
3 Press the side panel into the casing until it clicks in place at the button (D).





3.4 Equipment Designation



No	Item/Symbol	Description	Colour
1		Electrical connector, for power to the heated patient circuit.	
2		Connection for low pressure/bleed-in oxygen source	
3		SpO_2 interface port	
4		Remote start/stop, Audio pause, interface port	
5		Remote alarm and Nurse call interface port	
6		Network connection port	
7		USB data connection port	
8		Mains/External DC inlet	

3.4.1 Additional Symbols

This section describes symbols and markings that might appear on the parts or packaging of the Nippy 4.

Symbol	Description
	Internal battery
	Product number
	Read user instructions.
	Attention: Read the intended use in the manual. Read the Safety chapter in the manual.
	This product must not be exposed to open fire.
	This product should be recycled.
	Read 7.7 *Disposal*, page 107 for information about recycling and disposal.
IP22	Degree of protection provided by enclosure: IP22. See 8.2.6 *Environmental Conditions*, page 114 for detailed information.
	Manufacturer
	Serial number
	This product is a Medical Device.
	Date of Manufacture
	IEC protection Class II: Double insulated equipment.
	Indication of applied parts (IEC 60601-1 Type BF, Isolated Applied Part)
Rx Only	(Symbol only applicable in U.S.) Caution: U.S. Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
CE 2797 CE	Meets all requirements for CE marking according to relevant European health, safety and environmental protection legislation

Symbol	Description
UK CA UK CA 0086	Meets all requirements for UKCA marking according to applicable United Kingdom health, safety and environmental protection legislation.
	Do not obstruct air inlets or outlet.
	Single patient multiple use.
	Single patient multiple use.
	Hot Surface. Do not touch. (Heating plate in click-in compartment.)
	MR Unsafe. The device should not enter a magnetic resonance (MR) environment, such as an MRI scanner room.
	RTCA/DO-160 G categorization. Category M This category is defined for equipment and interconnected wiring located in areas where apertures are electro-magnetically significant and not directly in view of radio reciever's antenna. This category may be suitable for equipment and associated inteconnecting wiring located in the passsenger cabin or in the cockpit of a transport aircraft.

4 Preparing the Nippy 4 for Use

WARNING!

Read 2 *Safety Information*, page 12 before setting up the Nippy 4.

4.1 Checking the Nippy 4 before First Use

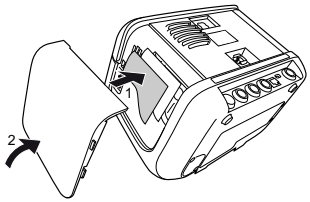
When using the Nippy 4 for the first time, follow the instructions below:

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 Nippy 4 to the power supply to recharge the internal battery.

4 Check that the grey and white air filters are installed.



4.2 Placing the Nippy 4

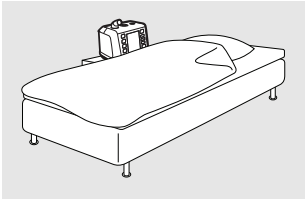
WARNING!

Read 2.3 *Environmental Conditions*, page 15 carefully to make sure all conditions are met and considered.

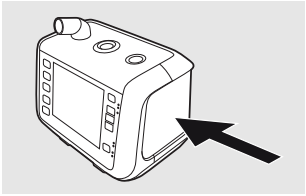
1 Place the Nippy 4 on a solid, flat, and clean surface.

The Nippy 4 should be placed lower than the patient in order to prevent the device from falling on the patient, as well as preventing condensed water from reaching the patient.

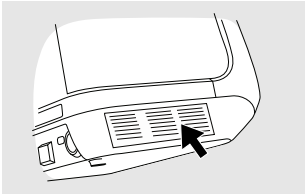
Overnight, the Nippy 4 should be placed close enough to the patient's bedside to allow movements during the sleep without pulling the Nippy 4 of its surface.

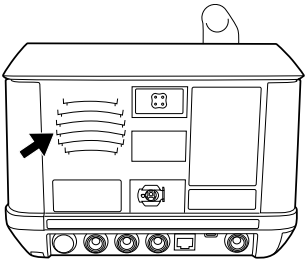


2 Make sure that nothing can block the patient air inlet.



3 Make sure that nothing can block the cooling air inlet or outlet.



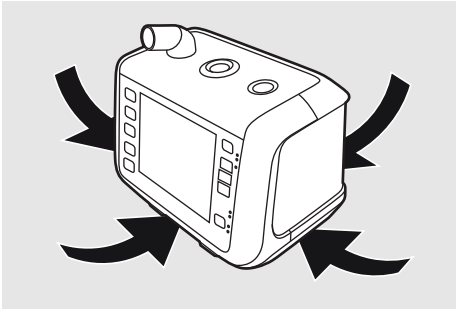


4 Make sure that the controls are accessible for the operator.

CAUTION!

- Do not place the Nippy 4 on a soft surface that will prevent the air flow underneath the device.

  Never cover the device.



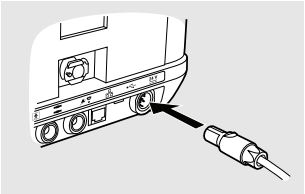
- Always position the Nippy 4 so the power supply lays on a surface without strain to the power cord. The power supply shall be easy to disconnect, if required to isolate the Nippy 4 from the mains.

4.3 Connecting the Nippy 4 to Mains

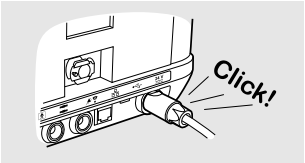
WARNING!

Read 2.2 *Electrical Safety*, page 14 carefully to make sure all conditions are considered and met.

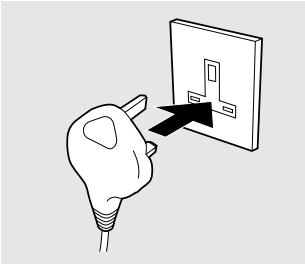
1 Plug the power supply into the power inlet of the Nippy 4.



2 Make sure a clicking sound is heard to ensure the power supply is completely inserted.



3 Connect the power supply's power cord to the mains supply.



To isolate the Nippy 4 from the mains supply, disconnect the power supply.

4.4 Connecting the Patient Circuit

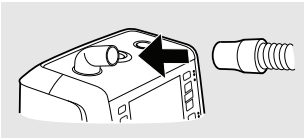
WARNING!

Read 2.4 *Usage of Patient Circuit*, page 16 carefully to make sure all conditions are considered and met.

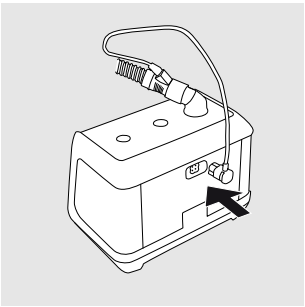
Connect the Patient Circuit

1 Inspect the circuit for damages.

2 Connect the patient circuit to the patient air outlet on the ventilator.



3 If having a heated patient circuit, connect the heated wire electrical plug to the socket on the ventilator.



4 Connect the other end of the circuit to a leakage port or to a patient interface with integrated leakage port.

4.5 Inspecting the Nippy 4 before Use

Inspection of Device

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

Inspection of Cables

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

Inspection of Placement

- The Nippy 4 shall be placed on solid flat surface below the patient level (see 4.2 *Placing the Nippy 4*, page 31).
- Make sure that nothing can block the air inlet at the side.

Inspection at Ventilator Startup

This procedure checks the ventilator's alarm handling and power source handling. If any check fails, take the ventilator out of use and contact your service provider.

1 Connect a patient circuit to the ventilator

2 Connect the power supply to the ventilator. If the power is supply is connected and the ventilator is turned off, press the Start/Stop button.

⇒The ventilator now turns on and enters stand by mode. If it is the first time the ventilator is turned on, you also have to select language.

3 If needed, perform a pre-use test.

4 Press and hold the Start/Stop button until the progress bar is filled to start the treatment.

⇒At the start of the treatment the ventilator performs an alarm test. Check that:

- The alarm LEDs flash
- The ventilator beeps

5 Disconnect the power supply for more than 5 seconds.

⇒The ventilator now switches to the internal battery (or click-in battery, if connected). Check that *Lost mains power* alarm is given.

6 Reconnect the power supply.

Check that the device switches to the mains supply, indicated by an information message and a beep.

7 Ensure that the treatment settings and alarm settings are set as prescribed before taking the ventilator to use.

4.6 Adjusting the Nippy 4 Patient Settings

WARNING!

The configuration of the Nippy 4 therapy settings must always be prescribed by a licensed physician and carried out by an authorised health care professional.

For detailed information about the treatment parameters of the Nippy 4, see 5.6 *Treatment Settings*, page 46.

Follow the instructions below when setting up the Nippy 4:

- Adjust the settings to find the best possible breathing comfort for the patient.
- If you have changed the ventilation mode, press **Select** and review the settings before pressing **Confirm**.
- Always document the patient settings.
- The ventilator always starts in the mode and with the settings that were active when it was switched off.

4.7 Performing the Pre-use Test

The pre-use test is used for detecting the characteristics of the patient circuit that is connected to the Nippy 4.

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

CAUTION!

A pre-user test is recommended if the patient circuit configuration has been changed.

NOTE

If the pre-use test has not been performed, the Nippy 4 will operate with default patient circuit compensation.

Starting the Pre-use Test Manually

1 On the **Menu**, select **Pre-use Test** and then **START PRE-USE TEST**.

Activating the Pre-use Test Prompt

1 On the Menu, select **Pre-use Test** and press the **Set** button.

2 Using the + and - buttons, set **Start Pre-use Test** to **On**.

3 Press the **Set** button to confirm the setting.

Pre-use Test Sequence

When performing a pre-use test, the instructions on the display will guide you through this sequence:

Step	Action
1	Start of pre-use test.
2	Connect the patient circuit.
3	Make sure that nothing is blocking the patient end of the circuit.
4	Wait while the Nippy 4 is checking the patient circuit resistance. If the resistance is not within the limits, the test will end without performing the following steps. The result will be displayed for review.
5	Block the end of the patient circuit with an air tight object.
6	Wait while the Nippy 4 is checking the patient circuit compliance and leakage.
7	Test finished. Review the test result.

4.7.1 Actions At Pre-Use Test Failure

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

Failure Due To Incorrect Leakage

Indication: **Leakage: Fail**

1 Check the ventilator set-up (circuit, filters, humidifier, etc.) for leakage.

2 Ensure that all connectors are tightly fitting.

3 Run the pre-use test again.

4 Replace the circuit if the test is failed repeatedly.

Failure Due To Incorrect Resistance or Compliance

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

1 Check the ventilator set-up (circuit, filters, humidifier, etc.) for blockage or pinched tubing.

2 Run the pre-use test again.

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

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

Ensure that the delivered ventilation is closely monitored.

5 How to Use the Nippy 4

WARNING!

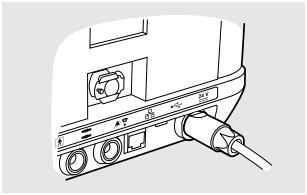
Read 2 *Safety Information*, page 12 before using the ventilator.
When the ventilator is handed over to the patient, the physician in charge or hospital staff must instruct the patient in how the unit works.

5.1 Switch the Nippy 4 On and Off

5.1.1 Switch On and Enter Operating Mode

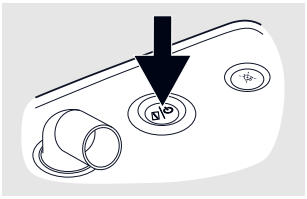
1 If having access to mains power, connect the mains power supply.

⇒The Nippy 4 needs about 15 seconds to power up and enter standby mode.

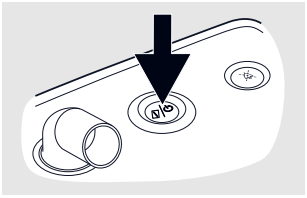


2 If running the Nippy 4 on the internal battery or the click-in battery, press the Start/Stop button.

⇒The Nippy 4 needs about 15 seconds to power up and enter standby mode.

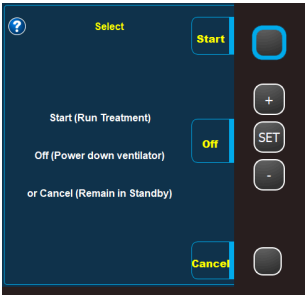


3 To start treatment and enter operating mode, press and hold the Start/Stop button on the Nippy 4.



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

5 You can also press the Start/Stop button shortly and then confirm by pressing the Start button at top right.

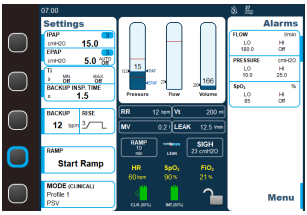


6 Select Yes/No if asked to “Perform Pre-use Test”.

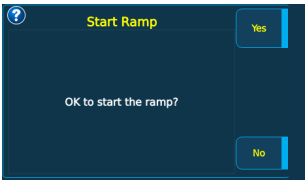
5.1.2 Start the Pressure Ramp

If the treatment has been configured to allow pressure ramp, it can be started or stopped by the ramp button. The ramp buttons are only available after the treatment has started.

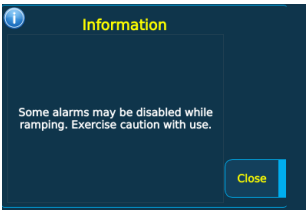
1 Press the **Start Ramp** button.



2 Confirm to start the ramp.

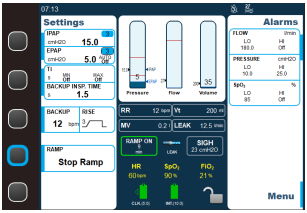


3 Read and acknowledge the information message regarding reduced alarm functionality during the ramp period.

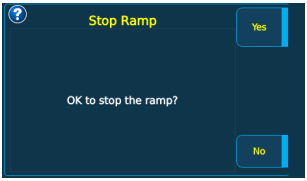


5.1.3 Stop the Pressure Ramp

1 Press the **Stop Ramp** button.

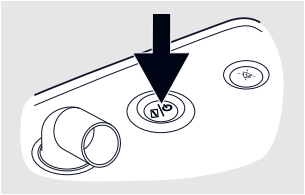


2 Confirm to stop the ramp.



5.1.4 Stop Treatment

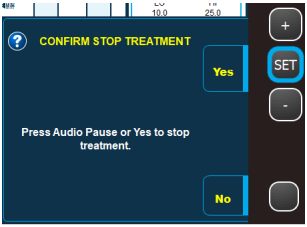
1 To stop treatment and enter standby mode, first press and hold the Start/Stop button on the front panel.

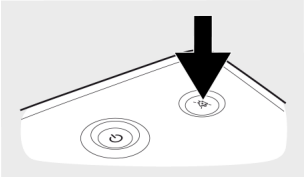


2 Release the Start/Stop button when the progress bar is filled.

3 Press "Yes" to stop the treatment.

You can also confirm to stop the treatment by pressing the Audio Pause button.





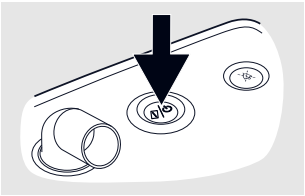
5.1.5 Turn off / Enter Sleep Mode

If the Nippy 4. is running on batteries, this procedure turns it off.

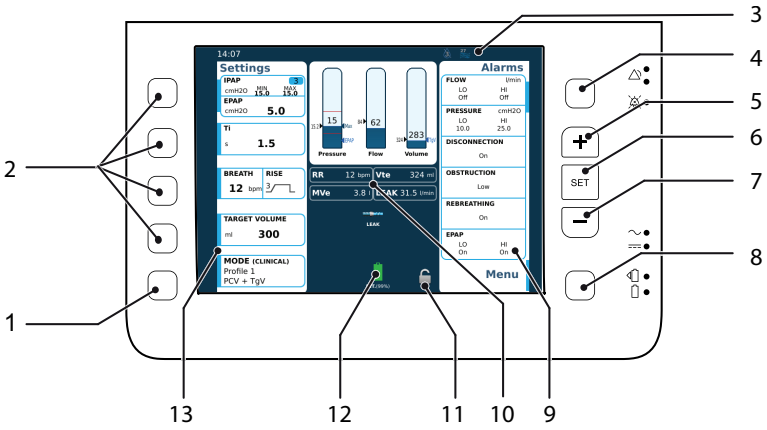
If the Nippy 4. is connected to mains, this procedure puts it in sleep mode (all functions are off, except battery charging)

1 When the Nippy 4 is in standby mode (no treatment is running), press the Start/Stop button on the front panel.

2 When asked to confirm the action, press"Yes".



5.2 Navigating the Display



No.	Item
1	**Mode / Profile** Use this button to select between user profiles (if profiles are configured by your clinician).
2	**Treatment settings** buttons Use these buttons to change the settings in their respective frame on the display. See 5.6 *Treatment Settings*, page 46 for more information.
3	**Accessory/Function** icons Indicates connected or activated accessories or functions.
4	**Alarms** settings button Use this button to change the alarm settings.
5	**+** button Use this button to increase a value when editing a setting, or to move up in the menu or on the alarm settings list.
6	**Set** button Use this button to select a setting to edit and to confirm a change.
7	**-** button Use this button to decrease a value when editing a setting, or to move down in the menu or on the alarm settings list.
8	**Menu**/**More** button Use this button to open the menu for accessing information and settings for the device and for comfort functions.
9	**Alarms** list Displays alarm settings. See 5.7 *The Alarms List*, page 50 for more information. To see an alarms history list, open to the Alarm/Event log from the Menu.
10	**Monitored Values** pane. Displays read outs of monitored values and bar graphs of the current Pressure, Flow and Volume during treatment. Values from connected accessories are displayed with yellow text.

No.	Item
11	**Home mode** lock Indicates whether the settings are locked to Home mode.
12	**Battery** Icon Displays battery charge status by colour and percentage of fully charge. If having the click-in battery, it will have an icon of its own.
13	**Settings** list Displays treatment mode and treatment settings.See 5.6 *Treatment Settings*, page 46 for more information.

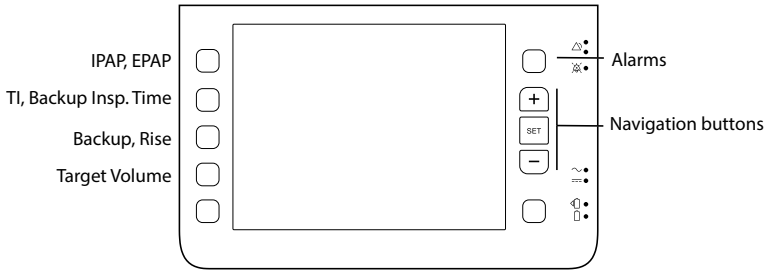
5.3 Symbols Used on the Display

Symbol	Description
	Internal battery For battery level information, see 5.11 *Using Batteries*, page 57.
	Click-in battery (accessory)For battery level information, see 5.11 *Using Batteries*, page 57.
	Keypad lock activated
	Keypad lock deactivated
	Click-in Humidifier (accessory) The number in the drop indicates humidity setting. If the click-in humidifier is connected but not activated, the symbol is stroked through.
	Heated circuit (accessory) The number in the symbol indicates the set temperature for the heated circuit. If the heated circuit is connected but not activated, the symbol is stroked through.
	Multiple pages Press the MORE button to display the next page.

5.4 Display Overview

5.4.1 Home Mode

In Home Mode, the Nippy 4 start screen has the following layout:



Icon explanation:

Page

Sub menu

- Menu
  - Humidification Settings
  - User Preferences
  - Keypad Lock
  - Patient Monitor
  - Compliance Data
  - Alarm/Event Logs
  - Device Information

5.5 Profiles

Three different profiles can be used for storing complete parameter and alarm settings. This function is suitable as a quick selection for a patient using different settings, for example at night or during daytime.

5.5.1 Selecting a Profile

1 Press the **Mode/Profile** button.

2 Press the **-** button to select the profile to use and then press the **Select** button.

The Settings list and the Alarm lists are now displayed. Note that the frames around the settings are red, indicating that the change of profile needs to be confirmed.

3 Review the treatment settings and press the **Confirm** button.

The profile is now saved and applied, indicated by blue frames around the settings.

To revert to the original settings, press the **Cancel** button.

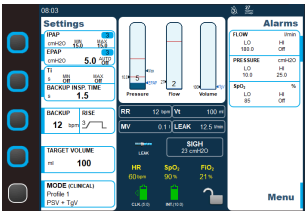
5.6 Treatment Settings

5.6.1 Changing a Setting

1 Make sure the *Home mode* lock is off.

2 Press the **Setting** button for the frame that contains the setting to change.

If the frame contains several settings, press repeatedly until the setting to change is selected.



3 Use the **+** and **-** buttons to adjust the value and then press the **Set** button.

5.6.2 Settings

5.6.2.1 IPAP

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

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

Unit	Min	Max	Default
cmH_2O	4	40	15

5.6.2.2 EPAP

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

Unit	Min	Max	Default
cmH_2O	2 Off	20 (2)	5
(2)= The max setting is also limited by IPAP -2 cmH_2O and Min Pressure -2 cmH_2O.			

5.6.2.3 Breath Rate

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

The combination of the Breath Rate and Inspiratory Time setting is limited by the I:E ratio range 1:9.9 to 2:1.

Unit	Min	Max	Default
1/breath	4	50	12

5.6.2.4 Backup Rate

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

The combination of the Breath Rate and Inspiratory Time setting is limited by the I:E ratio range 1:9.9 to 2:1.

Unit	Min	Max	Default
breath/ minute	4 0 (MPV)	50 40 (MPV)	12 0 (MPV)

5.6.2.5 Insp. Time (Inspiratory Time)

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

The combination of the Inspiratory Time and Breath Rate settings is limited by the I:E ratio 2:1.

Unit	Min	Max	Default
s	0.3	5	1.5

5.6.2.6 Backup Insp. Time (Backup Inspiratory Time)

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

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

Unit	Min	Max	Default
s	0.3	5	1.5

5.6.2.7 Sigh Parameters

With the Sigh function, the ventilator will periodically deliver extended breaths.

NOTE

During the sigh breath, the high pressure alarm will automatically be set 10 cmH_2O above set sigh pressure.

The following parameters are avialable in the menu, after enabling the Sigh function:

Sigh Rate			
The Sigh rate sets the frequency of which breaths with an increased pressure are delivered to the patient. If the High Pressure alarm or the High Tidal Volume alarm is given, the Sigh function will be disabled as long as the alarm condition remains.			
Unit	**Min**	**Max**	**Default**
1/ breath	10	250	50

Sigh %			
Sigh % sets the increased % of the set pressure is delivered to the patient.			
Unit	**Min**	**Max**	**Default**
%	125	200	125

Sigh Inspiratory Time			
Sigh inspiratory time sets the inspiratory time during sigh breaths.			
Unit	**Min**	**Max**	**Default**
s	Current *Inpspiratory Time* or *Backup Inspiratory Time*	5	1.5

5.6.2.8 Rise Time

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

A low setting will give a faster increase and therefore a longer plateau at the set value. A high setting will give a slower increase and therefore a shorter plateau.

Unit	Min	Max	Default
Step	1	9	3

5.6.2.9 Insp. Trigger (Inspiratory Trigger)

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

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

A patient triggered inspiration is indicated by a frame around the trigger setting. 

Unit	Min	Max	Default
Step	1 (1)	9 Off	3
(1)= Low value is easy to trigger, high value is harder to trigger.			

5.6.2.10 Exp. Trigger (Expiratory Trigger)

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

A patient triggered expiration is indicated by a frame around the trigger setting. 

Unit	Min	Max	Default
Step	1 (1)	9 (1)	3
(1)= Low value is easy to trigger, high value is harder to trigger.			

5.6.2.11 Max Insp. Time (Maximum Inspiratory Time)

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

Unit	Min	Max	Default
s	0.3	5 Off	Off

5.6.2.12 Min Insp. Time (Minimum Inspiratory Time)

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

Unit	Min	Max	Default
s	0.3 Off	3	Off

5.6.2.13 Target Volume

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

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

Unit	Min	Max	Default
ml	Off 300 (A) 50 (P)	2000 (A) 500 (P)	Off

Target Volume Parameters

When target volume is on, the following parameters are enabled:

Max Pressure			
Max Pressure defines the upper pressure limit up to where the ventilator can increase the pressure to reach the set Target Volume. If Target Volume is not reached at Max Pressure, the ventilator will continue to ventilate at this Max Pressure setting.			
Unit	**Min**	**Max**	**Default**
cmH_2O	Current *Min Pressure*	40	15

Min Pressure			
Min Pressure defines the lower pressure limit down to where the ventilator can decrease the pressure to maintain the set Target Volume. If the actual volume is above Target Volume at Min Pressure, the ventilator will continue to ventilate at this Min Pressure setting.			
Unit	**Min**	**Max**	**Default**
cmH_2O	4	Current *Max Pressure*	15

5.6.2.14 CPAP

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

Unit	Min	Max	Default
cmH_2O	4	20	10

5.6.2.15 Ramp Time

The Ramp Time setting defines the time during which the pressure will increase from the set Start Pressure to the set Inspiratory Pressure.

Ramp Time can only be set in Clinical Mode.

Unit	Min	Max	Default
Minute	10 Off	60	Off

5.6.2.16 Start Pressure

The Ramp Start Pressure defines the pressure level delivered by the ventilator at the beginning of the Ramp Time.

Unit	Min	Max	Default
cmH_2O	2	Current *IPAP*–2	5

5.6.2.17 Always Start Ramp

The Always Start Ramp determines whether the ramp is started automatically at the beginning of the treatment.

Unit	Min	Max	Default
—	Off	On	Off

5.6.2.18 Humidifier

Humidifier allows the user to start or stop the heated humidification.

The click-in water chamber needs to be connected before the setting can be turned On.

Unit	Min	Max	Default
—	Off	On	Off

5.6.2.19 Humidifier Setting

The Humidifier Setting defines the level of humidity of the air delivered to the patient.

Unit	Min	Max	Default
Step	1	5	3

5.6.2.20 Heated Circuit Temp

Heated Circuit Temp setting will define the temperature of the heated circuit.

Unit	Min	Max	Default
°C/°F	16/61	30/86	27/81

5.6.2.21 Circuit Heating

Circuit Heating allows the user to start or stop the heating of the circuit.

The Heated Circuit needs to be connected before the setting can be turned On.

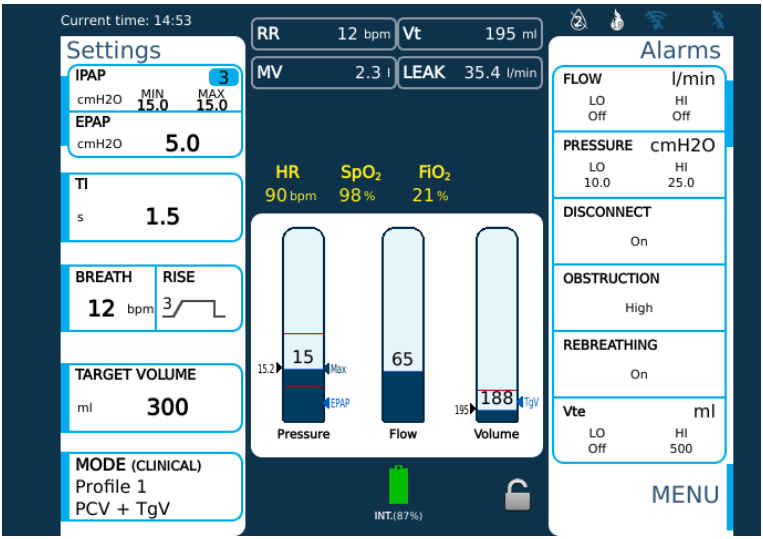
Unit	Min	Max	Default
—	Off	On	Off

5.7 The Alarms List

The Alarms list displays the alarm settings. Which alarms that are available depends on the current treatment mode and settings.

5.8 The Monitored Values Pane

This section describes the monitored treatment values that are displayed on the start screen



Value	Description
RR	Respiratory rate
Vt	Tidal Volume (the volume delivered with each breath)
MV	Minute Volume, calculated as Tidal Volume multiplied with the Total Breath Rate.
LEAK	The total leakage (intentional and unintentional) as calculated at expiratory pressure level.
HR	Heart rate An SpO_2 sensor needs to be in place to measure and display this value.
SpO_2	Displays the patient's oxygen saturation. An SpO_2 sensor needs to be connected to measure and display this value.
FiO_2	Displays the fraction of inspired oxygen as measured at the air outlet of the Nippy 4. An FiO_2 sensor needs to be connected to measure and display this value.
Pressure bar graph	Displays the pressure during treatment. • To the left of the bar a mark discloses the highest pressure during last breath. • To the right of the bar marks discloses the set values for IPAP and EPAP. • Red lines in the bar indicates alarm levels.

Value	Description
Flow bar graph	Displays the flow during treatment. • To the left of the bar, a mark discloses the highest flow during last breath.
Volume bar graph	Displays the air volume delivered during treatment. • To the left of the bar a mark discloses the total volume delivered during last breath. • To the right of the bar marks discloses the set target volume value (if used). • Red lines in the bar indicates alarm levels

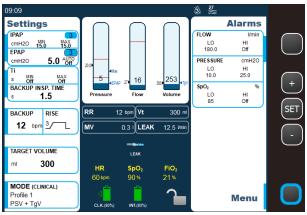
In clinical mode, curves, trends and additional values can be viewed from the Patient Monitor page, see .

5.9 The Menu

This section contains information about the menu and the menu items.

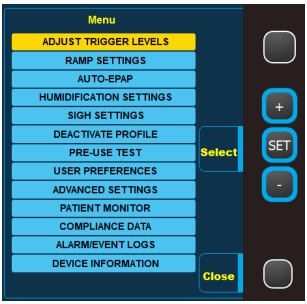
Opening the Menu

1 Press the **Menu** button.



2 In the menu, use the **+** and **-** buttons to select the item to open and then press the **Set** button to open it.

Note that only menu items applicable for the current mode are available.



5.9.1 Humidification Settings

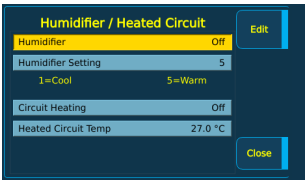
This menu item lets you make changes to the humidifier and the heated circuit settings.

1 Press the **Menu** button and then select **Humidification Settings**.

2 Use the **+** and **-** buttons to select the setting to change and click the **Edit** button.

3 Use the **+** and **-** buttons to change the value and then click the **Edit** button to leave the editing mode for the specific setting.

4 Click **Close** to save the settings when done.



5.9.2 Sigh Settings

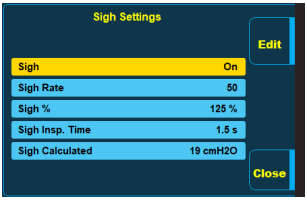
This menu item lets you make changes to the sigh settings.

1 Press the **Menu** button and then select **Sigh Settings**.

2 Use the **+** and **-** buttons to select the setting to change and click the **Edit** button.

3 Use the **+** and **-** buttons to change the value and then click the **Edit** button to leave the editing mode for the specific setting.

4 Click **Close** to save the settings when done.



5.9.3 Pre-Use Test

This menu item is only available in clinical mode and when the Nippy 4 is in standby mode.

This menu item contains:

- Start Pre-use Test On/Off (Selects whether a pre-use test shall be prompted every time the Nippy 4 is powered on).

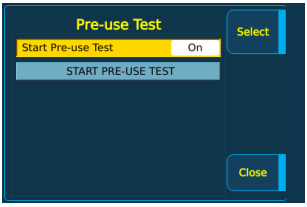
  The default setting for pre-use test is Off.
- START PRE-USE TEST (starts a pre-use test immediately).

1 Press the **Menu** button and then select **Pre-use Test**.

2 Use the **+** and **-** buttons to select the item and then click the **Select** button.

3 If configuring the pre-use test prompt, use the **+** and **-** buttons to change the value and then click the **Select** button to leave the editing mode.

4 Click **Close** when done.



5.9.4 User Preferences

This menu item lets you view or make changes to the user preferences:

- Time and Date
- Display Light

  — On (will keep the display lit up regardless of use)

  — Auto (will adjust the light intensity depending on the ambient light)

  — Delayed (the display is dimmed after 30 seconds or more depending on the mode and battery setup. If any button is pressed or any alarm occurs, the display light will return to normal again).
- Light Intensity (setting range: 1-9, where 1 is the lowest and 9 is the highest light intensity setting).
- AHI (Show/Hide)
  Selects whether to show or hide AHI as part of compliance data. AHI is available for leakage circuits only. This menu item is available in clinical mode only.
- Compliance in Home Mode (Show/Hide)

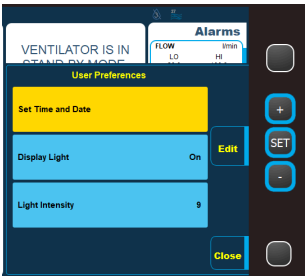
Change User Preferences

1 Press the **Menu** button and then select **User Preferences**.

2 Use the **+** and **-** buttons to select the setting to change and click the **Edit** button.

3 Use the **+** and **-** buttons to change the value and then click the **Edit** button to leave the editing mode for the specific setting.

4 Click **Close** to save the settings when done.



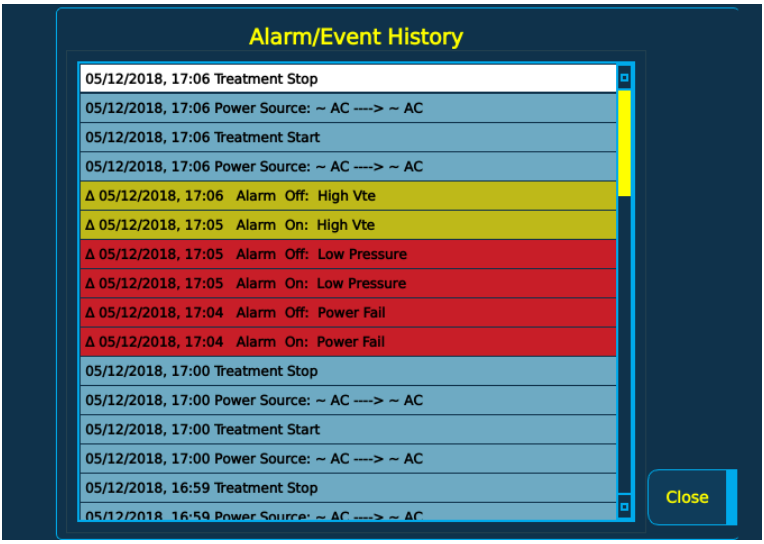
5.9.5 Compliance Data (Optional)

Compliance data is statistics of usage, such as usage hours and days used.

From this menu item you view the compliance data, if the Nippy 4 has been configured to show it.

5.9.6 Alarm/Event Logs

This menu item displays the alarm and event logs.



- Red: High priority alarms
- Yellow: Medium priority alarms
- Blue: Messages
- White: Currently selected row

Click **Close** when done.

5.10 Transferring Data between the Ventilator and a PC

WARNING!

Read the chapter 2.2 *Electrical Safety*, page 14 carefully to make sure all conditions are considered and met.

CAUTION!

Do not eject the memory card or disconnect the USB cable while the Nippy 4 is transferring data. Doing so may result in loss of data and/or damaged equipment.

NOTE

In order to view and present patient data, Breas software must be used.

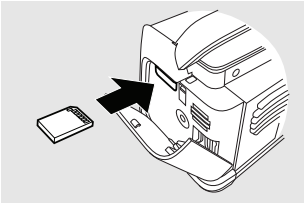
Instructions on how to manage data in the Breas software can be found in the software help.

5.10.1 Transferring Data with a Memory Card

NOTE

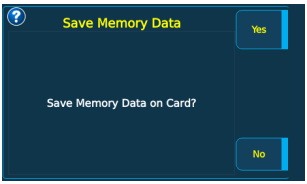
The *Home mode* lock must be off for copying and transferring data to the memory card.

1 Insert the memory card in the memory card slot on the side of the Nippy 4. Make sure the memory card is properly inserted.



2 Press the Menu button and navigate to the Device Memory page. Menu > Advanced Settings> Device Memory.

3 Select **Save Memory Data on Card** and press the **Select** button. Confirm to save the data and wait while the data is being saved.

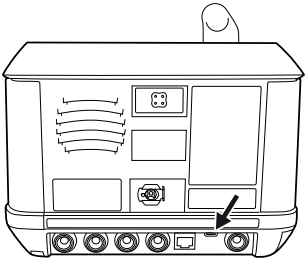


4 Remove the memory card from the ventilator and insert it to the computer You need Breas software to read the data on the card.

5.10.2 Transferring Data with a Data Cable

With a USB cable, real-time data can also be received and sent between the ventilator and a PC.

1 Connect the USB cable to the ventilator. Make sure it is fitted correctly.



2 Connect the other end of the cable to a PC running Breas PC software.

WARNING!

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

5.11 Using Batteries

Since all batteries, in general, degenerate over time, the recommendations below will ensure that the battery capacity of the Nippy 4 is maximized during its lifetime.

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

See the Nippy 4 Service Manual on how to perform service on the batteries.

5.11.1 Power Source Priority

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

If the AC power source fails, the ventilator will switch to either the external DC (if installed), or the click-in battery (if attached) or the internal battery and show a message in the display window.

NOTE

How to test the Internal Battery:
The switch-over to internal battery can be tested by disconnecting the AC power cord, and confirming the behaviour described below is observed.

- Internal battery power source LED will be illuminated
- Medium priority "Lost Mains Power" alarm will be triggered
- Information message "Switched to Internal Battery" will be posted

How to test the Click-In Battery:
The switch-over to click-in battery can be tested by disconnecting the AC power cord while having a click-in battery connected, and confirming the behaviour described below is observed.

- Click-in battery power source LED will be illuminated
- Medium priority "Lost Mains Power" alarm will be triggered
- Information message "Switched to Click-In Battery" will be posted

How to test the External DC ("alternative Supply Mains"):
The switch-over to external DC can be tested by disconnecting the AC power cord while having an external DC source connected, and confirming the behaviour described below is observed.

- External DC power source LED will be illuminated
- Medium priority "Lost Mains Power" alarm will be triggered
- Information message "Switched to External DC" will be posted

5.11.2 Charging the Batteries

CAUTION!

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

Charging of batteries is only started when the state of charge is below 95%.

The internal and click-in batteries are automatically charged when connecting the Nippy 4 to the mains supply. To ensure that the batteries are fully charged, a maintaining charging cycle will be performed.

The batteries are not charged when connecting the Nippy 4 to an external DC supply. While charging, the battery level will be animated. The batteries are only charged if the internal temperatures are between 0 to 45°C (32 to 113°F). High power consuming settings in

combination with high ambient temperatures may make the battery temperature rise above 45°C (113°F).

Behaviour of the Ventilator while Internal Battery or Click-in Battery is Charging

The battery icon will be animated (filling from bottom to top).

Charging Times

Battery	Charger	Time
Internal battery	Nippy 4	2 h
Click-in battery	Nippy 4	4 h
Click-in battery	Click-in battery charger	3 h

Times are based on charging empty batteries.

5.11.3 Battery Icons

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

Symbol	Description
	Internal battery Green symbol indicates over 50 % state of charge.
	Click-in battery Green symbol indicates over 50 % state of charge.
	Medium State of charge (20 % – 50 %)
	Low state of charge (below 20 %)
	Malfunctioning battery

5.11.4 Internal Battery

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

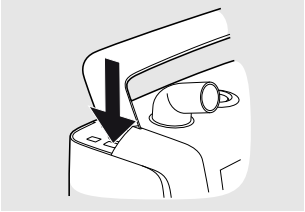
5.11.5 Click-in Battery

The click-in battery is intended as a power source during transportation, or if the primary mains power source fails.

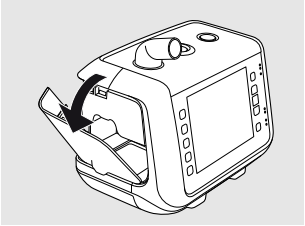
The click-in battery can be replaced during treatment, provided that the internal battery is charged.

Connect the Click-in Battery

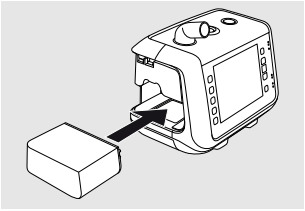
1 Release the side cover by pressing the button under the handle.



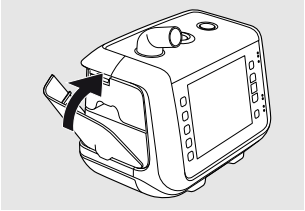
2 Open and remove the side panel.



3 Insert the click-in battery.



4 Close the side panel. Make sure there is a clicking sound to secure the side panel.



When removing the battery, press down the latch at the bottom of the battery compartment and tilt the ventilator sideways. Make sure to close the side panel after removing the click-in battery.

5.11.6 Battery Operating Time (Internal and Click-in)

The operation time is dependent on the battery condition, its capacity, the ambient air temperature and the Nippy 4 pressure setting. These data are based on new and fully charged batteries.

Parameter	Example
Environmental Conditions	
Ambient temperature	20°C (68°F)
Ventilator Settings	
Mode	PCV
IPAP	20 cmH_2O
EPAP	4 cmH_2O
Breath Rate*	20 bpm
Insp. Time*	1.0 s
I:E	1:2
Insp. Trigger	Off
Rise Time	1
Target Volume	Off
Display Light*	Off
Light Intensity*	-
Monitored Value	
Tidal Volume	800 ml
Resistance	5 hPa $(l/s)^{-1}$
Compliance	50 ml $(hPa)^{-1}$

*: These ventilator settings affect the operating time significantly

Battery	Operating Time
Internal Battery	2.5 h
Click-in Battery	6.5 h

5.11.7 Storing the Internal Battery and the Click-in Battery

Storage longer than 1 month should be initiated with half-charged batteries in order to maintain maximum capacity. Optimal storage temperature is 5 to 30°C (41 to 86°F).

5.11.8 External DC

WARNING!

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

CAUTION!

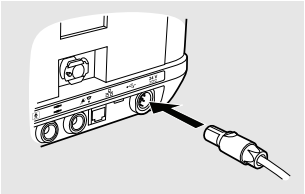
Only use a battery charger compliant to IEC 606011 if you are charging a battery that at the same time is connected to the ventilator.

The ventilator can be operated from:

- The Breas XPAC using the XPAC battery cable.
- A 12 V external DC source using the 12-24 VDC car adapter cable.
- A 24 V external DC source using the external battery cable.
- Both AC power supply and external DC using the Y-cable.

With an external DC source connected, the Nippy 4 will automatically switch over to the external DC source if the mains power cord is removed or if the mains power supply fails. The external DC voltage level is shown under "Device Information" in the menu.

1 Connect the external DC cable to the Nippy 4. Make sure that it is fitted correctly.



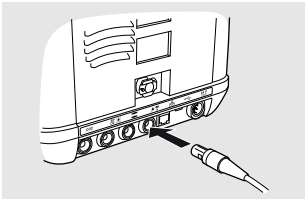
2 Connect the other end of the cable to the DC source.

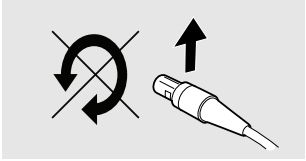
5.12 Using Accessories

5.12.1 Connecting and Disconnecting the Cables

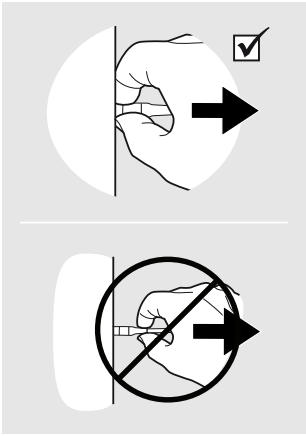
1 Insert the cable in the appropriate port.

2 Make sure to insert the connector with the marking pointing upwards.





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

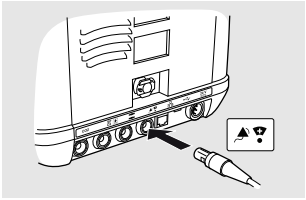


5.12.2 Using the ventilator with a Nurse Call System

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

5.12.2.1 Connect the ventilator to a Nurse Call System

1 Connect the nurse call cable at the back of the ventilator.



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

5.12.3 Using the ventilator with the FiO_2 Sensor

The FiO_2 sensor can be used to monitor and store FiO_2 measurements. The FiO_2 sensor measures the fraction of inspired oxygen in the air channel of the ventilator. The FiO_2 measurements will be stored in the data memory which can be downloaded to a PC and viewed in Breas software.

Usage	Time
Operating temperature	10 to 40°C (50 to 104°F)
Operating pressure	700 to 1250 mbar
Expected operating life	<3 years (in ambient air) or 500,000 Vol.% h, whichever comes first.
Shelf life	< 6 months (recommended)

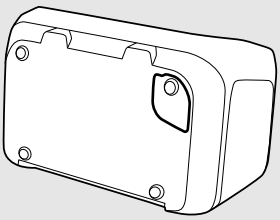
CAUTION!

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

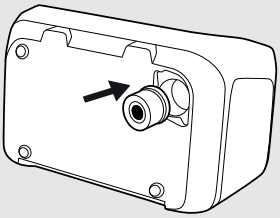
5.12.3.1 Installing the FiO_2 Sensor

1 Place the ventilator so the bottom is accessible.

2 Remove the hatch for FiO_2 sensor. Use a torx TX10 screwdriver.



3 Insert the FiO_2 sensor with the electrical contact side in.



4 Reinstall the hatch.

5 Calibrate the FiO_2 sensor in the advanced settings of the main menu.

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

5.12.3.2 Calibrating the FiO_2 sensor

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

FiO_2 calibration can be performed from the "FiO_2 Calibration" page under the Advanced settings section of the main menu.

5.12.4 Using the ventilator with the Remote Alarm

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

The Remote Alarm enables care providers and clinical personnel to monitor the ventilator alarms remotely. The Remote Alarm forwards alarms from the ventilator. When an alarm sounds, the care provider or clinical personnel must attend to the patient quickly.

When installing a remote alarm system, check that it operates as intended before starting the treatment.

5.12.5 Using the Ventilator with the SpO_2 module

Information about safety, warnings, product description, installation, usage, cleaning, maintenance and technical specifications can be found in the user instruction for SpO_2 module.

The SpO_2 module enables connection to an SpO_2 sensor for measuring of functional oxygen saturation of arterial haemoglobin (SpO_2) and pulse rate. The SpO_2 module can be connected to the Nippy 4 in order to monitor and store SpO_2 measurements.

The SpO_2 measurements will be stored in the data memory which can be downloaded to a PC and viewed in the Breas PC software.

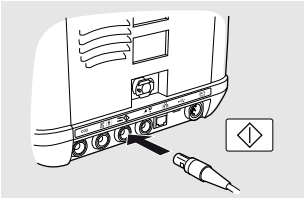
When installed, the Nippy 4 automatically detects the sensor, also after powering off/on and after power failure.

5.12.6 Using the ventilator with the Remote Start/Stop

5.12.6.1 Connecting the Remote Start/Stop

1 Connect the Remote Start/Stop cable to the ventilator.

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

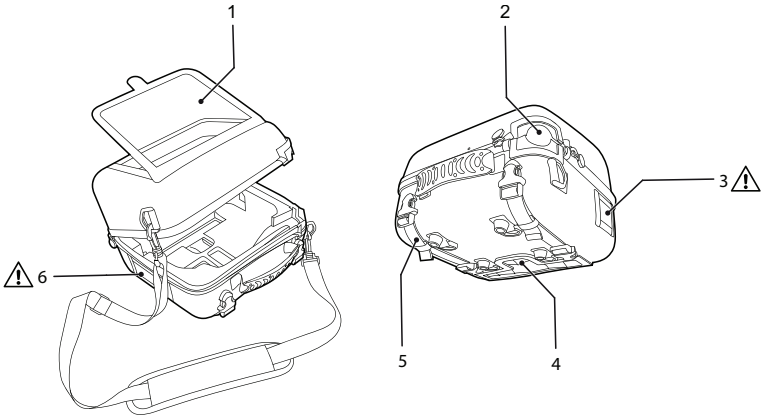


5.12.7 Using the ventilator with the Protective Cover

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

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

The protective cover has the following functions:



1. Transparent window, for accessing front panel and buttons
2. Port for patient circuit
3. Cooling air inlet
4. Port for cables and O_2 inlet
5. Mounting straps
6. Patient air inlet

CAUTION!

Do not cover the air inlets or outlets.

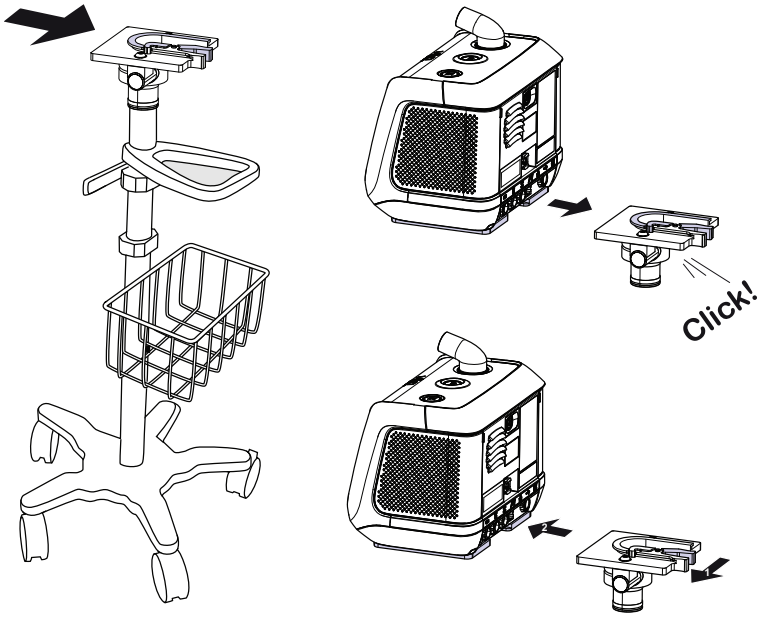
5.12.8 Using the Nippy 4 with the Trolley

Intended Use

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

This section describes how to use the Nippy 4 and a trolley with mounting bracket.

Mount and dismount the Nippy 4 as shown in the picture:



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

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

WARNING!

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

- The maximum load of the trolley basket is 0.9 kg (2 lbs).
- The maximum load of the IV-pole is 3 kg (6.5 lbs).
- The maximum load of the trolley rail is 9 kg (20 lbs).
- The maximum load of the E-cylinder holder is 7.9 kg (17.5 lbs).

No maintenance is required.

5.12.9 Using the Click-in Humidifier

WARNING!

Read the chapter 2.6 *Humidification*, page 18 before using the Nippy 4 with the humidifier.

CAUTION!

The click-in humidifier and the circuit heating operates on the AC power source only. If the AC power source fails and the internal or the external battery activates, the click-in humidifier and the circuit heating will be turned off automatically.

The click-in humidifier is intended to humidify the patient air. It is intended for non-invasive use only. The click-in water chamber is for single patient use only. Reusing a water chamber for a new patient might cause a risk of cross-contamination. The Nippy 4 shall not be moved with a filled water chamber installed.

About the Click-in Humidifier

The information in the table below is applicable to the recommended breathing system configuration, which is the click-in humidifier and the heated circuit.

Property	Value
Humidifier classification	ISO 80601-2-74:2021, Class 2
Rated Flow	Max 50 l/min
Operating Conditions	+5°C to +40°C. Humidity: max 90% RH, non-condensing.
Max humidification output	> 10 mg/l
Duration of Operation between Humidifier refills	Default setting (3): 16 hours and 40 minutes Max setting (5): 8 hours and 40 minutes
Static temperature stability *	±2°C
Measurement uncertainty	±0.5°C

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

5.12.9.1 Adding Water to the Water Chamber

CAUTION!

⚠ Use only distilled or sterilised water or boiled, chilled tap water in the humidifier water chamber. This is to reduce mineral deposits and maximize the life of the water chamber.

⚠ Do not fill the water chamber with hot water.

⚠ Do not overfill the water chamber. Fill only the water chamber to the maximum level indicated on the water chamber.

⚠ Always ensure the lid with seal is properly mounted after filling and reassembling the water chamber. Also check that the water chamber is correctly docked in place and locked to the ventilator.

⚠ Avoid to remove the seal from the lid at normal, daily usage.

⚠ Make sure all parts are dry before the ventilator is connected to the mains and put into operation.

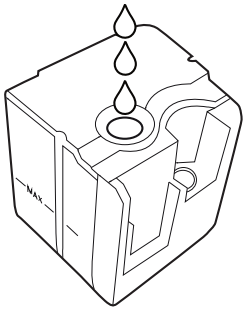
1 Detach the water chamber, see 5.12.9.4 *Detaching the Water Chamber*, page 71.

2 Inspect the water chamber for damages, dirt or deposits. Clean if required, see 5.12.9.6 *Cleaning the Water Chamber*, page 72. If the water chamber is damaged, replace it before use.

3 Fill water to the chamber, by filling through one of the airway connections.

Make sure not to fill above the Max indication. A water chamber filled to the maximum level contains approximately 350 ml

You can also remove the lid and fill water through the top of the chamber.



5.12.9.2 Installing the Water Chamber

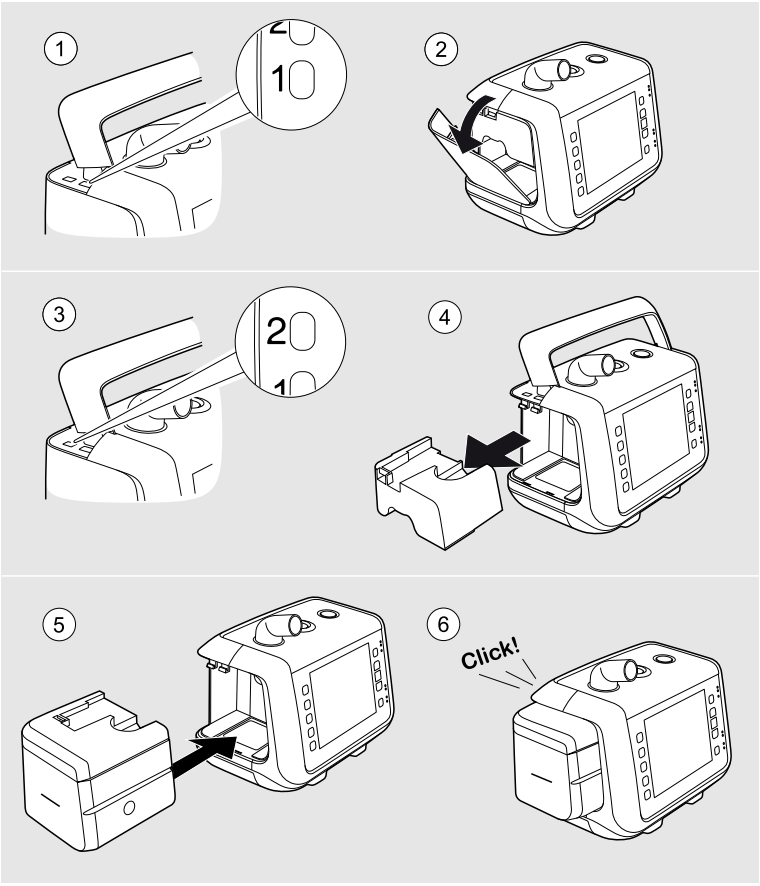
CAUTION!

Do not switch on the humidifier without a filled water chamber in order to avoid burn or damage to the humidifier's electronics.

NOTE

If the ventilator is equipped with click-in battery, remove it before installing the water chamber.

Follow the instructions in the illustration below to install the water chamber to the ventilator



CAUTION!

Always make sure the water chamber is in correct position before use.
Store the airway bypass unit in a clean and dust free environment.

5.12.9.3 Activating the Humidification

The water chamber must be installed in order to access the humidifier setting on the ventilator menu, both in clinical and home mode. If the water chamber is disconnected and reconnected after usage, the ventilator will remember the humidity setting used.

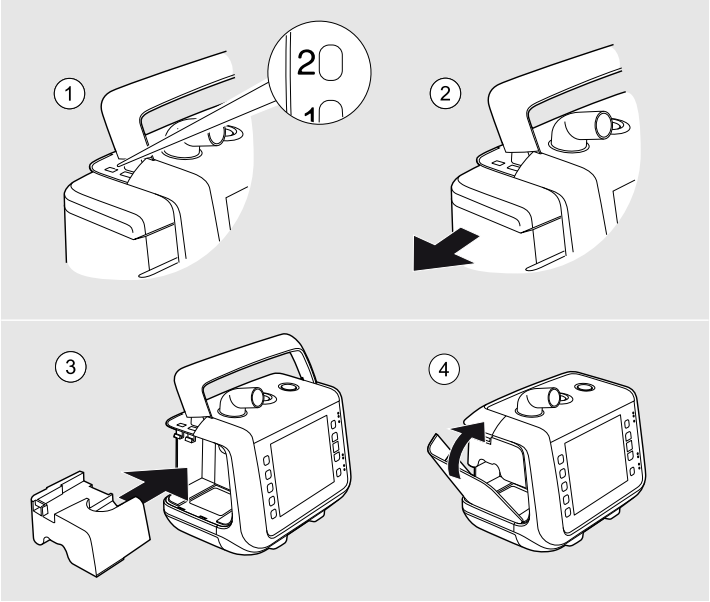
The click-in humidifier only operates during treatment. When the ventilator is in standby mode, the humidification is paused.

Prerequisites

- The water chamber shall be filled with water and attached.
- The ventilator shall be connected to the mains power supply

1. In the **Main menu**, select **Humidification Settings**.
2. Select **Humidifier Setting** and set the level of humidification. 1 is the lowest level 5 is the highest level.
3. Select **Humidifier** and set it to **On**.
4. The humidifier is now activated and will start to operate when the treatment starts.

5.12.9.4 Detaching the Water Chamber



CAUTION!

Always insert the air bypass unit after disconnecting the water chamber.

WARNING!

Always stop treatment before detaching or attaching the water chamber.
Make sure the Nippy 4 with the attached water chamber is placed lower than 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 interface.

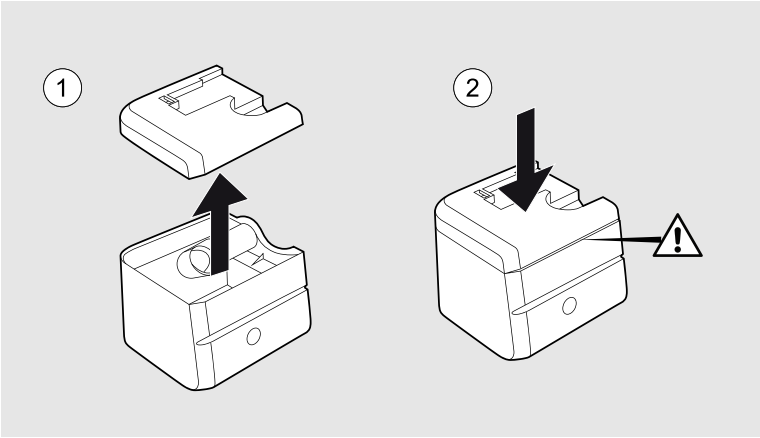
Never add or pour out water from the water chamber when it is attached to the ventilator.
If there is water outside of the water chamber after filling, dry it using a lint-free cloth before reconnecting it to the ventilator.

WARNING!

To avoid burn injury, be careful not to touch the heater plate or the heated water in the water chamber when the humidifier is switched on or has not yet cooled down. Wait 10 minutes for the heater plate and water to cool.

5.12.9.5 Opening the Water Chamber

The water chamber lid shall be opened when manually emptying or cleaning the water chamber



CAUTION!

Always make sure the lid of the water chamber is totally sealed.

5.12.9.6 Cleaning the Water Chamber

The cleaning and disinfection intervals should be established by the care provider, based on the care provider's infection control procedures.

1 Open the water chamber as described in 5.12.9.5 *Opening the Water Chamber*, page 72.

2 Clean the parts of the water chamber either by hand using a mild detergent or in a dishwasher without dishwashing detergent. Max. temperature: 60°C (140°F).

3 If there are mineral deposits inside the water chamber, dissolve them using warm water and citric acid for 30 minutes.

For disinfecting the water chamber, use any of the agents listed below. Follow the provider's instructions. The water chamber will withstand at least 20 disinfections without degradation.

Disinfection Agent	Duration
Gigasept® FF 5% solution	15 minutes
Steranios 2% solution	10 minutes

5.12.10 Using the Patient Circuit with Heated Wire

The ventilator may be used with the accessory *Patient Circuit, Heated Wire with Cable Connector*.

When the heated circuit is used, the time for the patient air temperature to reach the set temperature from a starting temperature of (23±2)°C may be up to 3 minutes.

Prerequisites

The wire heating only operates during treatment. When the ventilator is in standby mode, the wire heating is paused.

Read the User Instruction for the Patient Circuit, Heated Wire with Cable Connector before using the patient circuit.

5.12.10.1 Connecting the Patient Circuit

Connect the circuit as described in 4.4 *Connecting the Patient Circuit*, page 34.

When the circuit is connected, continue with activating the circuit heating.

5.12.10.2 Activating the Circuit Heating

The ventilator shall be connected to the mains power supply

1 In the **Main menu**, select **Humidification Settings**.

2 Select **Heated Circuit Temp** and set the temperature according to the respiratory therapist's prescription.

3 Select **Circuit Heating** and set it to **On**.

The circuit heating is now activated and will start to operate when the treatment starts.

6 Alarms

WARNING!

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

CAUTION!

Never leave a patient unattended during an alarm condition.

Setting alarm limits to extreme values could put the patient at risk.

The Nippy 4 remote alarm with cable provided by Breas Medical is the only permitted *distributed alarm system (DAS)*.

The Nurse call cable may be used for a distributed information system for alarm *conditions (DIS)*. In a DIS, the information about the alarm condition is distributed. The DIS shall not be used for making the operator aware of the existence of an alarm condition as it does not have the required functions for confirming the delivery of the alarm condition.

NOTE

The alarm settings are maintained during an extended power failure.

This chapter describes the alarm functions used for the ventilator.

6.1 Alarm Function

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

6.1.1 Alarm Indication

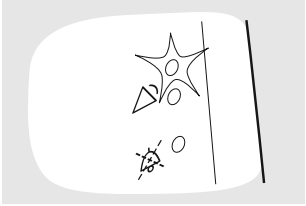
As soon as an alarm condition is detected, the ventilator main unit and the remote alarm unit (if connected) will alarm without delay.

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

Colour LED on the panel

Indicates the priority of the active alarm condition.

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

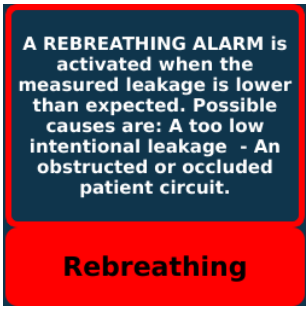


Alarm text in display

Displays the name of the active alarm condition and a guiding text.

The priority of the alarm is indicated by the background colour

- Red = High priority
- Yellow = Medium priority



Audible signals

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

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

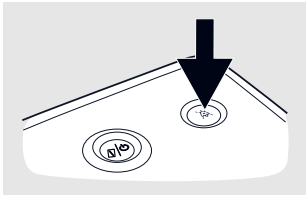
- **Information:** 1 signal with a low frequency. The signal is repeated after a 5 second pause and stopped after 5 sequences.

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

6.1.2 Audible Signal Pause

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

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



6.1.3 Audible Signal Presilence

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

CAUTION!

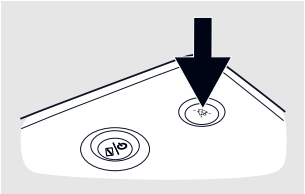
During the presilence period, any new alarms will only be indicated by the visual signals, the audible signal will not be activated.

NOTE

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

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

⇒A confirmation request is displayed.



2 Press OK to confirm.

6.1.4 Alarm Reset

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

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

WARNING!

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

6.2 Operator's Position

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

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

6.3 Physiological Alarms

The ventilator only enables the alarms that are relevant for the used treatment. If changing modes or treatment settings, review the alarm settings.

6.3.1 High Flow Alarm

Property	Description
Alarm text	**High Flow Alarm**
Priority	High
Alarm condition	A high flow alarm will be given when the total flow exceeds the set High Flow alarm limit for 3 consecutive breaths during inspiration. The alarm is reset after a full breath with a flow below the alarm limit.
Possible cause	• Unintentional leaks from the patient interface or breathing circuit • Mismatch between IPAP/CPAP and alarm setting • Coughing during inspiration • Changes in airway resistance and / or compliance
Setting range	• 10 l/min to 200 l/min • Off
Setting resolution	5 l/min
Setting display	The alarm setting is also displayed by a red line in the Flow bar graph.
Ventilator action	The Nippy 4 will continue treatment with the current settings, and try to compensate for unintentional leakages.

6.3.2 Low Flow Alarm

Property	Description
Alarm text	**Low Flow Alarm**
Priority	High
Alarm condition	A low flow alarm will be given when the total flow remains below the Low Flow alarm setting for more than 10 seconds. The alarm is reset when the flow exceeds the alarm limit again.
Possible cause	• An Obstruction in the breathing circuit • Mismatch between IPAP/CPAP and alarm setting • An obstructed CO_2 leak valve, reducing the total flow • Changes in airway resistance and or compliance
Setting range	• 3 l/min to 180 l/min • Off
Setting resolution	Below 40 l/min: 1 l/min Above 40 l/min: 5 l/min
Setting display	The alarm setting is displayed by a red line in the Flow bar graph.
Ventilator action	The Nippy 4 will continue treatment with the current settings.

6.3.3 High Pressure Alarm

Property	Description
Alarm text	**High Pressure**
Priority	High
Alarm condition	A High Pressure alarm will be given when the patient pressure reaches the set High Pressure alarm limit for three consecutive breaths. It will also be given if pressure exceeds 75 cmH_2O.
Possible cause	• Mismatch between pressure setting and alarm setting. • Coughing during inspiration. • Changes in airway resistance and or compliance.
Reset criteria	A full breath is performed with maximum pressure below the alarm limit.
Ventilator action	The Nippy 4 will continue treatment according to the current settings. The actual breath is however terminated if the High Pressure alarm limit is reached.
Setting range	• 5 cmH_2O to 55 cmH_2O Note that the High pressure alarm cannot be set lower than the value set for the Low pressure alarm.
Setting resolution	Below 10 cmH_2O: 0.5 cmH_2O Above 10 cmH_2O: 1.0 cmH_2O
Setting Display	The High Pressure alarm setting is displayed by a red line in the pressure bar graph.

6.3.4 Low Pressure Alarm

Property	Description
Alarm text	**Low Pressure**
Priority	High
Alarm condition	A Low Pressure alarm will be given when the Nippy 4 pressure fails to reach the low pressure alarm limit for 15 seconds. The low pressure alarm is disabled during ramp periods.
Possible cause	• Disconnection of patient circuit. • Mismatch between pressure setting and alarm setting. • Leakage from the mask or other components of the patient circuit.
Reset criteria	The pressure rises above the alarm limit.
Ventilator action	The Nippy 4 will continue treatment according to the current settings.
Setting range	• 1 cmH_2O to 40 cmH_2O Note that the Low pressure alarm cannot be set higher than the value set for the High pressure alarm.
Setting resolution	Below 10 cmH_2O: 0.5 cmH_2O Above 10 cmH_2O: 1.0 cmH_2O
Setting display	The Low Pressure alarm setting is displayed by a red line in the pressure bar graph.

6.3.5 High EPAP Alarm

Property	Description
Alarm text	**High EPAP**
Priority	Medium
Alarm condition	A High EPAP alarm will be given when the measured EPAP is 30% above the set value for more than 15 seconds
Possible cause	• Blocked leakage port. • Too short expiratory time. • Changes in airway resistance and or compliance.
Reset criteria	EPAP has gone below the alarm limit (lower than 30% above the set value).
Ventilator action	The Nippy 4 will continue treatment according to the current settings.
Setting range	• On • Off

6.3.6 Low EPAP Alarm

Property	Description
Alarm text	**Low EPAP**
Priority	Medium
Alarm condition	A Low EPAP alarm will be given when the measured EPAP is 30% below the set value for more than 60 seconds
Possible cause	• Excessive leakage.
Reset criteria	EPAP has gone above the alarm limit (higher than 30% below the set value).
Ventilator action	The Nippy 4 will continue treatment according to the current settings.
Setting range	• On • Off

6.3.7 High Vt_e Alarm (High Expired Tidal Volume)

Property	Description
Alarm text	**High Vte**
Priority	Medium
Alarm condition	A High Expired Tidal Volume alarm will be given when the monitored Expired Tidal Volume exceeds the alarm limit for 15 seconds.
Possible cause	• Mismatch between Expired Tidal Volume and alarm setting.
Setting range	• 100 ml to 2500 ml • Off
Setting resolution	10 below 600 ml, 100 above 600 ml
Ventilator action	The ventilator will continue treatment with the same settings.

6.3.8 Low Vt_e Alarm (Low Expired Tidal Volume)

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

6.3.9 High MV_e (High Expired Minute Volume Alarm)

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

6.3.10 Low MV_e Alarm (Low Expired Minute Volume)

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

6.3.11 High Breath Rate Alarm

Property	Description
Alarm text	**High Breath Rate**
Priority	Medium
Alarm condition	A High Breath Rate alarm will be given when the alarm limit has been exceeded for 15 seconds.
Possible cause	• Mismatch between the Breath Rate setting and the alarm setting. • Increased Breath Rate. • Too sensitive setting of the inspiratory trigger setting.
Reset criteria	The breath rate goes below the alarm limit.
Ventilator action	The Nippy 4 will continue treatment according to the current settings.
Setting range	• 10 bpm to 70 bpm • Off
Setting resolution	1 bpm.

6.3.12 Low Breath Rate Alarm

Property	Description
Alarm text	**Low Breath Rate**
Priority	High
Alarm condition	A Low Breath Rate alarm will be given when the delivered total breath rate is below the alarm limit for 15 seconds.
Possible cause	• Mismatch between the Breath Rate setting and the alarm setting. • The patient cannot trigger breaths because the inspiratory trigger setting is too high. • Decrease in the patient's spontaneous breathing. • Circuit disconnection.
Reset criteria	The breath rate goes above the alarm limit.
Ventilator action	The Nippy 4 will continue treatment according to the current settings.
Setting range	• 4 bpm to 40 bpm • Off
Setting resolution	1 bpm.

6.3.13 Apnoea Alarm

Property	Description
Alarm text	Apnoea
Priority	High
Alarm condition	An Apnoea alarm will be given when no patient-triggered breath is detected for the set period of time. The Apnoea alarm is only available if the Inspiratory trigger is activated.
Possible cause	• Patient stopped breathing. • Patient decreases spontaneous breathing. • Circuit disconnection. • Inspiratory Trigger is set too high.
Reset criteria	Inspiratory effort detected by the Nippy 4.
Ventilator action	The Nippy 4 will continue treatment according to the current settings.
Setting range	• 5 to 60 s. (Non MPV mode) • 15 to 900 s. (MPV mode) • Off
Setting resolution	5 s below 15 s. 15 s above 15 s. MPV mode: 15 s below 60 s. 60 s above 60 s.

6.3.14 Disconnection Alarm

CAUTION!

⚠

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

Property	Description
Alarm text	**Disconnection**
Priority	High
Alarm condition	A Disconnection alarm will be given when the measured flow exceeds the expected leakage flow at the set Pressure for 15 seconds.
Possible cause	• Too high leakage in the patient circuit. • The patient has removed the mask. • Circuit disconnection.
Reset criteria	The leakage is back within limits.
Ventilator action	The Nippy 4 will continue treatment according to the current settings
Setting range	• On • Off

6.3.15 Rebreathing Alarm

Property	Description
Alarm text	**Rebreathing**
Priority	High
Alarm condition	**Leakage Circuit** A Rebreathing alarm will be given if the intentional leakage is too low for more than 15 seconds.
Possible cause	• Obstructed or occluded patient circuit. • Incorrect patient circuit. • Obstructed or removed CO_2 port from leakage circuit.
Reset criteria	The leakage is back within limits.
Ventilator action	The Nippy 4 will continue treatment according to the current settings.
Setting range	• On • Off

6.3.16 Obstruction Alarm

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

6.3.17 High FiO_2 Alarm

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

6.3.18 Low FiO_2 Alarm

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

6.3.19 High SpO_2 Alarm

Property	Description
Alarm text	High SpO2
Priority	Medium
Alarm condition	A High SpO_2 alarm will be given when the measured SpO_2 exceeds the alarm limit for 30 seconds.
Possible cause	Too high flow of bleed-in oxygen.
Reset criteria	The SpO_2 value goes back below the alarm limit.
Ventilator action	The Nippy 4 will continue treatment according to the current settings.
Setting range	• 90 % to 100 % • Off
Setting resolution	1 %

This alarm requires a connected SpO_2 sensor.

6.3.20 Low SpO_2 Alarm

Property	Description
Alarm text	**Low SpO2**
Priority	High
Definition	A Low SpO_2 alarm will be given when the measured SpO_2 is below the alarm limit for 30 seconds.
Possible cause	• Too low flow of bleed-in oxygen. • Oxygen inlet is disconnected. • Delivered tidal volumes are too small.
Setting range	85% to 100%
Setting resolution	1%
Ventilator action	The ventilator will continue treatment with the same settings.

This alarm requires a connected SpO_2 sensor.

6.3.21 High Pulse Rate Alarm

Property	Description
Alarm text	**High Pulse Rate**
Priority	Medium
Alarm condition	A High Pulse Rate alarm will be given when the measured pulse rate exceeds the alarm limit for 15 seconds.
Possible cause	• Insufficient ventilatory support. • Too low flow of bleed-in oxygen. • The EPAP value is set too high. • Bad positioning of the finger probe.
Reset criteria	The pulse rate goes back below the alarm limit.
Ventilator action	The Nippy 4 will continue treatment according to the current settings.
Setting range	30 to 230 bpm (beats per minute) Off
Setting resolution	5 bpm (beats per minute)

This alarm requires a connected SpO_2 sensor.

6.3.22 Low Pulse Rate Alarm

Property	Description
Alarm text	**Low Pulse Rate**
Priority	High
Alarm condition	A low pulse rate alarm will be given when the measured pulse rate goes below the alarm limit for 15 seconds.
Possible cause	• Bad positioning of the finger probe. • Too low flow of bleed-in oxygen. • Insufficient ventilatory support.
Reset criteria	The pulse rate goes back above the alarm limit.
Ventilator action	The Nippy 4 will continue treatment according to the current settings.
Setting range	30 to 230 bpm (beats per minute) Off
Setting resolution	5 bpm (beats per minute)

This alarm requires a connected SpO_2 sensor.

6.4 Technical Alarms

6.4.1 Power Fail Alarm

Property	Description
Alarm text	The alarm is given audibly with a tone and the display is blinking with the alarm message **Power Fail**
Priority	High
Alarm condition	The Power Fail alarm is given if the last power source fails to provide enough power for running the ventilator.
Possible cause	The last available power source cannot deliver power to the ventilator. Battery discharged or battery failure.
Reset criteria	External power supply connected to ventilator.
Ventilator action	The Nippy 4 stops the treatment, and gives the Power Fail alarm for at least 2 minutes. If power is restored within the alarm time, the ventilator will automatically resume treatment with current settings. When powered up again, the power failure will be logged.

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

Property	Description
Alarm text	**High Patient Air Temp**
Priority	High
Alarm condition	A High Patient Air Temperature alarm will be given when the patient air temperature exceeds 43°C (109.4°F).
Possible cause	• Blocked air inlets. • Blocked cooling air outlets. • Too high ambient temperature.
Ventilator action	The Nippy 4 will continue treatment. If a heated circuit or the click-in humidifier is used, these will be turned off.
Reset criteria	The temperature goes below the limit again.

6.4.3 Low Patient Air Temp. (Low Patient Air Temperature Alarm)

Property	Description
Alarm text	**Low Patient Air Temp**
Alarm condition	A Low Patient Air Temperature alarm will be given when the patient air temperature is below the preset limit -30°C (-22°F).
Priority	High
Possible cause	Too low ambient temperature
Ventilator action	The ventilator will continue treatment with the same settings.

6.4.4 Low Last Power Source Alarm

Property	Description
Alarm text	**Low Last Power Source**
Priority	Medium
Alarm condition	This alarm will be given when the last battery source (internal battery) has 15 minutes of operating time left with current settings.
Ventilator action	The Nippy 4 will continue treatment according to the current settings.

6.4.5 Crit. Low Last Power Source Alarm

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

6.4.6 Lost Mains Alarm

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

6.4.7 SpO_2 Disconnected (SpO_2 Sensor Failure/Disconnection Alarm)

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

6.4.8 SpO_2 Signal Lost Alarm

Property	Description
Alarm text	SPO2 Signal Lost
Alarm condition	SpO_2 signal lost.
Priority	High
Possible cause	Signal lost reported by SpO_2 electronics (due to patient removing the probe from finger, or sensor detached from SpO_2 electronics.
Ventilator action	The ventilator will continue treatment with the same settings.
Reset	User presses OK or electronics cable is disconnected by the user, or the sensor is reconnected to the finger.

6.4.9 Poor SpO_2 Signal

Property	Description
Alarm text	Poor SPO2 Signal
Alarm condition	A Poor SpO_2 signal alarm will be given when the SpO_2 signal is not correct. Check the SpO_2 sensor.
Priority	High
Possible cause	Artifact or low perfusion reported by SpO_2 electronics
Ventilator action	The ventilator will continue treatment with the same settings.
Reset	OK message from SpO_2 electronics or SpO_2 electronics disconnected by user or SpO_2 Signal Lost alarm is triggered.

6.4.10 FiO_2 Disconnected (FiO_2 Sensor Failure/Disconnection Alarm)

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

6.4.11 Ambient Pressure Compensation Lost Alarm

Property	Description
Alarm text	**Pressure Comp Lost**
Priority	Medium
Alarm condition	An Ambient Pressure Compensation Lost alarm will be given when the automatic ambient pressure compensation functionality is out of order.
Ventilator action	The Nippy 4 will continue treatment according to the current settings. Normal atmospheric pressure at sea level will be used as approximation for the temporary ambient pressure compensation. If used at other altitude, delivered and measured pressures may deviate.
Reset	Reset of ventilator.

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

Property	Description
Alarm text	**Temperature Comp. Lost**
Alarm condition	An Ambient Temperature Compensation Lost alarm will be given when the automatic ambient temperature compensation is out of order. There is no communication with the air temperature sensor or the value is out of range (less than -30°C (-22°F) or more than 70°C (158°F).
Priority	Medium
Ventilator action	The ventilator will continue treatment with the same settings. The accuracy of the volume measurement may be impaired.
Reset	Ambient temperature inside valid range.

6.4.13 Humidity Comp. Lost (Humidity Compensation Lost Alarm)

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

6.4.14 LED Failure Alarm

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

6.4.15 Low Alarm Battery Alarm

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

6.4.16 Alarm Battery Error Alarm

Property	Description
Alarm text	**Alarm Battery Error**
Alarm condition	Unable to communicate with super capacitor and read super capacitor status.
Priority	Medium
Ventilator action	The ventilator will continue treatment with the same settings.
Reset	When triggering condition is removed.

6.4.17 Internal/Click-In Battery Hot Alarm

Property	Description
Alarm text	Internal Battery — Internal Battery Hot Click-In Battery — Click-In Battery Hot
Alarm condition	An alarm for Internal/Click-In Battery Overheat in Discharge will be given when the internal or click-in battery reaches 55°C (131°F).
Priority	High
Ventilator action	The ventilator will continue treatment with the same settings. Battery discharging will be disabled (by the battery electronics) once the temperature gets to 60°C (140°F). (If the battery is last power source, the ventilator will stop running).

NOTE

The battery electronics by manufacture stops discharge at 60°C (140°F).

6.4.18 Heated Circuit Temp. Alarm

Property	Description
Alarm text	Heated Circuit Temp.
Alarm condition	A Heated Circuit temp alarm will be given when the measured temperature of the heated wire is outside the tolerance.
Priority	Medium
Ventilator action	The ventilator will continue treatment with the same settings.
Priority	Medium
Reset	Heated wire measured temp tolerance is inside limits.

6.4.19 High Humidifier Temp. Alarm

Property	Description
Alarm text	High Humidifier Temp.
Alarm condition	A Humidifier High Temperature alarm will be given if the humidifier heater plate temperature exceeds 76°C (169°F) for more than 2 seconds.
Priority	Medium
Ventilator action	The ventilator will turn off the click-in humidifier and then continue treatment with the same settings. A message with option to turn on the humidifier again will be displayed.
Reset	The alarm is dismissed when the humidifier temperature drops below 76°C (169°F), set humidifier temperature).

6.4.20 Humidifier Fault Alarm

Property	Description
Alarm text	**Humidifier Fault**
Alarm condition	• All humidifier enabling conditions have been satisfied for 10 minutes, and • No humidifier setting changes have been made for 10 minutes, and • Heater plate temperature < 50°C (122 °F) • Humidifier set temperature > Ambient temperature ,and • The heater plate temperature is more than 5°C (41 °F) below the set temperature, or the heater plate temperature < -20°C (68 °F) or greater than 400°C (752 °F)
Priority	Medium
Ventilator action	The ventilator will turn off the humidifier and continue treatment with the same settings. The humidifier must be restarted manually when the cause of the alarm is resolved.

6.4.21 Heated Circuit Fault Alarm

Property	Description
Alarm text	**Heated Circuit Fault**
Alarm condition	A Heated Circuit Fault alarm will be given if a fault in the heated circuit electronics or temperature sensor is detected.
Priority	Medium
Ventilator action	The ventilator will turn off the heated circuit and continue treatment with the same settings. The heated circuit must be restarted manually when the cause of the alarm is resolved.
Reset	The alarm is dismissed when the heated circuit setting is changed to OFF, or the treatment is stopped. The power to the heated circuit is re-enabled when all enabling conditions are satisfied.

6.4.22 Internal Function Failure

Property	Description
Alarm text	**Int. Function Failure**
Priority	High
Alarm condition	Failure of internal function that prevents treatment or normal operation of the ventilator. The error code that follows the alarm text indicates the kind of function failure. All Internal Function Failure alarm error codes are defined and explained in the ventilator Service Manual.
Reset criteria	Restart the ventilator.
Ventilator action	The ventilator will stop the treatment and shut down.
Action to take	Restart the Nippy 4. If the alarm persists or reoccurs: Take a note of the error code and contact your supplier of the Nippy 4.

6.4.23 Air Temp. Sensor Fail Alarm

Property	Description
Alarm text	**Air Temp Sensor Fail**
Alarm condition	The alarm is given in case of swivel boot temperature sensor communication failure or sensor reporting temperatures out of range (below -30°C (-22°F) or above 60°C (140°F).
Priority	Medium
Ventilator action	The ventilator will continue treatment with the same settings.

6.4.24 Internal Error Alarm

Property	Description
Alarm text	**Internal Error**
Priority	High
Alarm Condition	An internal Error alarm will be given when the ventilator has an internal error, followed by an error code for the specific failure. All Internal Error alarm error codes are defined and explained in the ventilator Service Manual.
Ventilator action	The ventilator will continue treatment with the same settings.
Reset action	Power off and restart the ventilator.

6.4.25 Database Integrity Fail Alarm

Property	Description
Alarm text	**Database Integrity Failed**
Priority	High
Alarm Condition	This alarm is given when the database integrity check fails.
Ventilator action	The ventilator will continue treatment with the same settings.
Reset action	Rebuild the database and restart the ventilator.

6.4.26 Cooling Fan Error Alarm

Property	Description
Alarm text	**Cooling Fan Error**
Alarm Condition	The Cooling Fan Error alarm shall be given when the cooling fan runs too slow.
Priority	High
Ventilator action	The ventilator will continue treatment with the same settings.
Reset	When cooling fan speed is above 275 rpm.

6.4.27 Clock Failure Alarm

Property	Description
Alarm text	**Clock Failure**
Priority	High
Alarm condition	The alarm shall be given when the real time clock value is invalid.
Ventilator action	The ventilator will continue treatment with the same settings.
Reset action	Restart the ventilator.

6.4.28 Internal Temp High Alarm

Property	Description
Alarm text	**Internal Temp High**
Priority	High
Alarm condition	The Internal High Temp alarm shall be given when the ventilator internal temperature is high. The internal temp high alarm is triggered when PTU/Sensor board temperature is higher than 65°C (149°F), or main board temperature is higher than 65°C (149°F), or motor temperature is higher than 85°C (185°F).
Ventilator action	The ventilator will continue treatment with the same settings.
Reset	When the triggering conditions are resolved.

6.4.29 Humidifier/Bypass Loose Alarm

Property	Description
Alarm text	**Humidifier/Bypass Loose**
Priority	Medium
Alarm condition	The Humidifier/Bypass Loose alarm shall be given when the air bypass/humidifier latch is stuck in the down position for 5 secs.
Ventilator action	The ventilator will continue treatment with the same settings.
Reset action	Reinsert the air bypass unit/humidifier and make sure the latch closes.

6.5 Alarm Test

6.5.1 Alarm Signal Test

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

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

If the test fails, do not use the Nippy 4. Contact your supplier of the Nippy 4 for a technical check.

6.5.2 Mandatory Alarm Tests

This alarm test should be performed every 24th month or if the ventilator's function needs to be checked for any other reason.

The alarm test should be included in the regular inspections during maintenance.

To perform the alarm test, follow the instructions below:

Alarm Test Preparation

1 Connect the ventilator patient circuit to a test lung.
2 Connect the ventilator to Mains power supply.
3 Start the ventilator.
4 Adjust the settings as follows:

Setting	Value
Ventilation Mode	Pressure Support Ventilation (PSV)
Patient Mode	Adult
IPAP	15 cmH_2O
EPAP	5 cmH_2O
Rise Time	9
Insp. Trigger	9
Exp. Trigger	3
Min Insp. Time	Off
Max Insp. Time	Off
Backup Rate	12 bpm
Backup Insp. Time	2.0 s
Target Volume	Off

5 All alarm settings shall be set to Off if possible.
6 Start the treatment.

6.5.2.1 High and Low Flow Alarm Tests

1 Set the high flow alarm to 20 l/min.
⇒ The high flow alarm shall be given.
2 Set the high flow alarm to Off
3 Set the low flow alarm to 150L/min.
⇒ The low flow alarm shall be given.

6.5.2.2 High and Low Pressure Alarm Tests

1 Set the high pressure alarm to 10 cmH_2O.
⇒ The high pressure alarm shall be given.
2 Set the high pressure alarm to 55 cmH_2O.
3 Set the low pressure alarm to 20 cmH_2O.
⇒ The low pressure alarm shall be given.
4 Set the low pressure alarm to 1.0 cmH_2O.

6.5.2.3 Expiratory Tidal Volume Alarm (Vt_e) Tests

1 Set up the ventilator as described in *Alarm Test Preparation*, page 100.

2 Set the high Vt_e alarm to 150 ml.

⇒ The high Vt_e alarm shall be given.

3 Set the high Vt_e alarm to Off.

4 Set the low Vt_e alarm to 400 ml.

The low Vt_e alarm shall be given.

6.5.2.4 SpO_2 Related Alarm Tests

These tests applies if the SpO_2 accessory is used,

1 Connect SpO_2 sensor to device and to your finger.

2 Set the low SpO_2 alarm to 85%.

3 Set the high SpO_2 alarm to be 90%.

4 Start treatment and wait 30 s.

⇒ High SpO_2 alarm should be given.

5 Stop treatment.

6 Set the high SpO_2 alarm to off.

7 Set the low SpO_2 alarm to be 100%.

8 Start treatment and wait 30 s.

⇒ Low SpO_2 alarm should be given.

9 Stop Treatment.

10 Set the low SpO_2 alarm to 85%.

11 Set the low pulse rate alarm to off.

12 Set the high pulse rate alarm to 30 bpm.

13 Start treatment and wait 30 s.

⇒ High pulse rate alarm should be given.

14 Stop treatment.

15 Set the high pulse rate alarm to off.

16 Set the low pulse rate alarm to be 230 bpm.

17 Start treatment and wait 30 s.

⇒ Low pulse rate alarm should be given.

18 Stop Treatment.

19 Set the low pulse rate alarm to off.

6.5.3 Optional Alarm Tests

In this chapter, methods for additional alarm tests are described. These tests are optional and not needed to ensure safe use of the ventilator.

6.5.3.1 High EPAP Alarm

1 Connect the ventilator patient circuit to a test lung and a CPAP device.
2 Set the CPAP device treatment pressure to 10 cmH_2O.
3 Adjust the ventilator settings as follows:

Setting	Value
Ventilation Mode	
IPAP	15 cmH_2O
EPAP	5 cmH_2O
Breath Rate	12 bpm
Insp. Time	1.5 s
Rise Time	5
Insp. Trigger	Off
Target Volume	Off

4 Start treatment on both the ventilator and the CPAP device.
5 Wait approximately 15 seconds before the High EPAP alarm shall be given.
6 Stop treatment. Test completed.

6.5.3.2 Low Pressure and Disconnection Alarms

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

6.5.3.3 Obstruction Alarm

1 Start treatment; block the patient circuit completely to simulate an obstruction.
2 Wait approximately 10 seconds.
3 The Obstruction Alarm will be given.
4 Stop treatment. Test completed.

7 Cleaning and Maintenance

WARNING!

The Nippy 4 should be subjected to maintenance, service and control and any applicable upgrades, in accordance with Breas service instructions.

The Nippy 4 shall only be repaired or modified in accordance with Breas service manuals, technical bulletins, and any special service instructions, by service technicians that have been authorised after Breas Nippy 4 service training.

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

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

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

7.1 Cleaning the Nippy 4

WARNING!

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

CAUTION!

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

Fluid must not be allowed to enter the ventilator.

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

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

Do not autoclave the ventilator.

7.1.1 Main Unit

1 Switch off the Nippy 4 and disconnect the power supply.

2 Remove the patient circuit.

3 Disconnect all electric cables.

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

5 If the click-in humidifier is used, clean it as described in 5.12.9.6 *Cleaning the Water Chamber*, page 72.

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

7.1.2 Air Pathway Disinfection

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

Condition	Parts
With bacteria filter	• Patient circuit • Bacteria filter
Without bacteria filter	• Patient circuit • FiO_2 sensor (if used) • Patient air outlet/Pneumatic unit • Air bypass unit/water chamber • Blower/Inlet silencer • Air inlet with filters

In case of contamination, the internal air pathways of the Nippy 4 may be disinfected up to 5 times by a maximum 60 minute long validated ozone gas process.

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

7.1.3 Patient Circuit

The patient circuit should be cleaned and replaced in accordance with the manufacturer's instructions and care provider's instructions, where applicable. For safety information, read 2.4 *Usage of Patient Circuit*, page 16.

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

CAUTION!

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

7.2 Cleaning and Replacing the Filters

Patient air filters

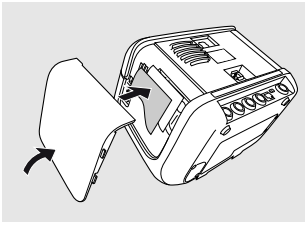
NOTE

- Coarse filter (grey): This is a washable filter, wash the filter at least once a week and replace once a year. See 7.2.1 *Washing a coarse filter*, page 106 for washing instructions.
- Fine filer (white): This is a disposable filter that not shall be washed or reused. Replace the fine filter at least every month, or more frequently when used in environments rich of pollen, pet hair or other particles that might clog the filter.

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

1 Turn off the ventilator and place it on a dust free surface.

2 First Place the filters in the air inlet compartment, with the coarse filter outside the fine filter.



3 Close the side panel carefully for not displacing the filters while closing. For detailed information about closing the side panel, see 3.3.1 *Detaching and Reattaching the Side Panels*, page 26.

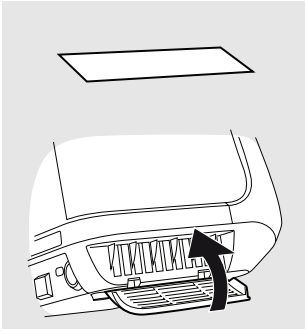
Cooling Air Filter

NOTE

The filter shall be washed at least once a week and replaced every second year. See 7.2.1 *Washing a coarse filter*, page 106 for washing instructions.

The cooling air inlet filter is located at the bottom left side of the ventilator.

1 Open the cooling air filter compartment by pulling at the top of the lid.



2 Remove the filter and wash or replace it.

3 Put back the filter and close the lid.

7.2.1 Washing a coarse filter

1 Wash the filter using warm water and a mild soap.
2 Rinse thoroughly.
3 Dry the filter by squeezing it out in a towel. Do not wring the filter.
4 Make sure the filter is completely dry before inserting.

7.3 Change of Patients

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

1 Follow the instructions in 7.1.1 *Main Unit* , page 103, steps 1 to 5.
2 Replace the patient filters according to 7.2 *Cleaning and Replacing the Filters*, page 105.
3 If a low resistance bacterial filter is used, it shall be replaced. To avoid cross-contamination when no bacterial filter has been used, a validated ozone-disinfection process may be used, see the section on disinfecting the main unit internally.
4 Use a new patient circuit when the ventilator is used by a new patient.

7.4 Regular Maintenance

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

7.5 Service and Repair

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

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

7.6 Storage

Store the ventilator in a dark room, where the temperature range is within -20 to +60°C (-4 to +140°F).

For instructions on how to charge the batteries after long time storage, see 5.11 *Using Batteries*, page 57.

CAUTION!

The ventilator must not be stored in a warm place, such as direct sunlight or close to a radiator. The time required for the device to cool from the maximum storage temperature of +60°C (+140°F) until it is ready for use in ambient temperature of +20° C (+68°F) is 30 minutes.

If stored in a cold environment, let the ventilator adapt to room temperature before using the device. The time required for the device to warm from the minimum storage temperature of -20°C (-4°F) until it is ready for use in ambient temperature of +20°C (+68°F) is 30 minutes.

7.7 Disposal

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

NOTE

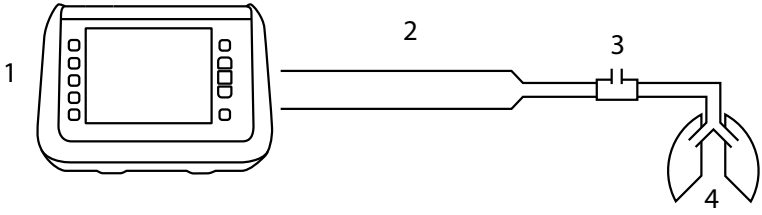
Batteries used with the ventilator shall be recycled in accordance with the local environmental regulations.

8 Technical Specifications

8.1 System Description

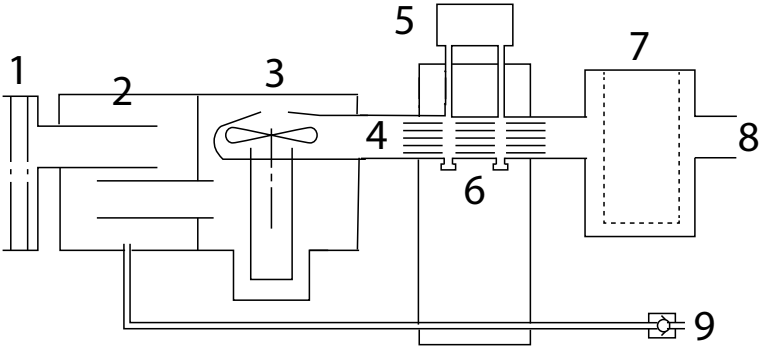
Leakage Port Configuration

This diagram provides an overview of the ventilator system when used with a leakage port patient circuit.



1. Nippy 4
2. Tube
3. Leakage port / Patient interface connection
4. Patient

8.1.1 Pneumatic Diagram for the ventilator



Item	Description
1	Air inlet with filters
2	Inlet silencer
3	Blower
4	Restriction
5	Flow sensor
6	Pressure sensors
7	Air bypass unit/Humidifier
8	Patient air outlet
9	Low pressure/bleed-in oxygen connection

8.2 Data

8.2.1 Worst Case Accuracy

Pressure Control Modes

The worst case Nippy 4 configuration is the 15 mm patient circuit with HCH humidifier and bacterial filter.

8.2.2 Modes Specifications

This section lists the settings that can be made for the ventilator's modes.

Ventilation modes

- Pressure Support (PSV)
  May be combined with Auto-EPAP (AE)
- Pressure Support with TgV (PSV+TgV)
  TgV= Target Volume
  May be combined with Auto-EPAP (AE)
- Pressure Control (PCV)
  May be combined with Auto-EPAP (AE)
- Pressure Control with TgV (PCV+TgV)
  TgV= Target Volume
  May be combined with Auto-EPAP (AE)
- Mouthpiece - Pressure (PCV-MPV)
- CPAP

Device modes

- Clinical
- Home

8.2.3 Parameter Specifications

This section lists the characteristics for the ventilator's parameters.

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

Setting	Unit	Min	Max	Default	Resolution	Tolerance
IPAP	cmH_2O	4	40	15	0.5 < 10 1.0 ≥ 10	±0.5 cmH_2O or ±5%
CPAP	cmH_2O	4	20	10	0.5 < 10 1.0 ≥ 10	±0.5 cmH_2O or ±5%
EPAP	cmH_2O	2 Off	20(3)	5	0.5 < 10 1.0 ≥ 10	±0.5 cmH_2O or ±5%
Breath Rate	bpm(4)	4	50	12	1	±2%
Backup Rate	bpm(4)	4 0 (MPV)	50 40 (MPV)	12 0 (MPV)	1	±2%
Backup Insp. Time	s	0.3	5	1.5	0.1	± (20 ms + 5% of setting) or ±0.1 s,
Inspiratory. Time	s	0.3	5	1.5	0.1	± (20 ms + 5% of setting) or ±0.1 s,
Min Insp. Time	s	0.3 Off	3	Off	0.1	± (20 ms + 5% of setting) or ±0.1 s,
Max Insp. Time	s	0.3	5 Off	Off	0.1	± (20 ms + 5% of setting) or ±0.1 s,
Inspiratory Trigger	Step	1	9 Off (5)	3	1	-
Expiratory Trigger	Step	1	9(5)	3	1	-
Rise Time	Step	1	9	3	1	-
Max Pressure	cmH_2O	Current *Min Pressure*	40	15	0.5 < 10 1.0 ≥ 10	±0.5 cmH_2O or ±5%
Min Pressure	cmH_2O	4	Current *Max Pressure*	15	0.5 < 10 1.0 ≥ 10	±0.5 cmH_2O or ±5%

(1)= 0.5 cmH_2O < 10 cmH_2O , 1.0 cmH_2O ≥ 10 cmH_2O, (3)= Also limited by IPAP- 2 cmH_2O, (4)= breath per minute, (5)= *Off* is only available in Control mode, 6)Values >10 might initially be set with a 0.5 step when turning on Auto-EPAP. When changing the value, whole numbers will be used.

Setting	Unit	Min	Max	Default	Resolution	Tolerance
Target Volume	ml	Off 300 (A) 50 (P)	2000 (A) 500 (P)	Off	10 <500 50 ≥500	±12 ml or ±10%,
Sigh	-	Off	On	Off	-	-
Sigh Rate	1/Breath	10	250	50	10	-
Sigh Inspiratory Time	s	Current *Inpspiratory Time* or *Backup Inspiratory Time*	5	1.5	0.1	± (20 ms + 5% of setting) or ±0.1 s,
Auto-EPAP	-	Off	On	Off	-	-
EPAP Min	cmH_2O	2	20 or Current *EPAP Max*	5	0.5 < 10 1.0 ≥ 10	±0.5 cmH_2O or ±5%
EPAP Max	cmH_2O	2 or Current *EPAP Min*	20 or *Pressure Limit*-2	5	0.5 < 10 1.0 ≥ 10	±0.5 cmH_2O or ±5%
EPAP Step	cmH_2O	0.5	2	1	0.5	±0.5 cmH_2O or ±5%
PS	cmH_2O	2	40–Current *EPAP Max*	10	0.5 < 10 1.0 ≥ 10 (6)	±0.5 cmH_2O or ±5%
Min PS	cmH_2O	2	40–Current *EPAP Max*	Variable(1)	0.5 < 10 1.0 ≥ 10 (6)	±0.5 cmH_2O or ±5%
Max PS	cmH_2O	2	40–Current *EPAP Max*	10	0.5 < 10 1.0 ≥ 10 (6)	±0.5 cmH_2O or ±5%
Pressure Limit	cmH_2O	Current *EPAP Max*+2	40	*High Pressure* Alarm-2	0.5 < 10 1.0 ≥ 10	±0.5 cmH_2O or ±5%
Relax Time	Minute	2	12 Off	5	1	± (20 ms + 5% of setting) or ±0.1 s,
Ramp	Minute	10 Off	60	Off	10	± (20 ms + 5% of setting) or ±0.1 s,

(1)= 0.5 cmH_2O < 10 cmH_2O , 1.0 cmH_2O ≥ 10 cmH_2O, (3)= Also limited by IPAP- 2 cmH_2O, (4)= breath per minute, (5)= *Off* is only available in Control mode, 6)Values >10 might initially be set with a 0.5 step when turning on Auto-EPAP. When changing the value, whole numbers will be used.

Setting	Unit	Min	Max	Default	Resolution	Tolerance
Always Start Ramp	-	Off	On	Off	-	-
Ramp Start Pressure	cmH_2O	2	Current *IPAP*– 2	5	0.5 < 10 1.0 ≥ 10	±0.5 cmH_2O or ±5%
Humidifier Setting	Step	1	5	3	1	-
Heated Circuit Temp	°C/°F	16/61	30/86	27/81	0.5	
Audible Alarm Level	Step	1	5	3	1	-
(1)= 0.5 cmH_2O < 10 cmH_2O , 1.0 cmH_2O ≥ 10 cmH_2O, (3)= Also limited by IPAP- 2 cmH_2O, (4)= breath per minute, (5)= *Off* is only available in Control mode, 6)Values >10 might initially be set with a 0.5 step when turning on Auto-EPAP. When changing the value, whole numbers will be used.						

8.2.4 Monitored Values Specifications

This section describes the ranges and tolerances for monitored values on the Nippy 4.

All stated tolerances include measurement uncertainty. The accuracies have been tested with all allowed configurations. Stated tolerances only disclose the maximum tolerance.

P_{peak}

Range/Performance: 4 to 99 cmH_2O.

Tolerance: ±0.5 cmH_2O or ±10%, whichever is greatest

EPAP

Range/Performance: 0 to 99 cmH_2O.

Tolerance: ±0.5 cmH_2O or ±10%, whichever is greatest

P_{mean}

Range/Performance: 0 to 99 cmH_2O.

Tolerance: ±0.5 cmH_2O or ±10%, whichever is greatest

CPAP pressure

Range/Performance: 0 to 99 cmH_2O.

Tolerance: ± (4% CPAP set pressure + 0.8 cmH_2O)

Leakage

Range/Performance: 0 to 99.9 l/min (BTPS*).

Tolerance: ±10%

MV

Range/Performance: 0 to 99.9 l (BTPS*).

Tolerance: ±10% or (±10 ml × bpm), whichever is greatest

Vt

Range/Performance: 0 to 9999 ml (BTPS*).

Tolerance: ±10% or ±10 ml, whichever is greatest

FiO_2

Range/Performance: 0 to 100%.

Tolerance: ±2%

% in TgV

Range/Performance: 0 to 100%.

Tolerance: ±1%

Total Rate

Range/Performance: 0 to 99 bpm.

Tolerance: ±1 bpm

Spont Rate

Range/Performance: 0 to 99 bpm.

Tolerance: ±1 bpm

% Spont

Range/Performance: 0 to 100%.

SpO_2

Range/Performance: 70 to 100%.

Tolerance: ±3 digits. No motion and flex sensor.

Pulse Rate

Range/Performance: 25 to 240 bpm.

Tolerance: ±3 digits. No motion and flex sensor.

I:E

Range/Performance: 1:10 to 10:1.

Tolerance: ±0.1 unit for I:E < 9.9, ±1 unit otherwise.

Insp. Time

Range/Performance: 0.3 to 5 s.

Tolerance: ±0.1 s

Rise Time

Range/Performance: 0.1 to 5 s.

Tolerance: ±10% or ±0.1 s, whichever is greatest

8.2.5 Power Supply

AC supply: 100 to 240 V AC, tolerance: +10%/-20%, 50 to 60 Hz, 1.0 - 2.0 A.

External DC: 19 V DC, tolerance: 19 V ± 6 V. Max 90 W.

Click-in battery: Capacity: 65Wh. Li-ion.

Internal battery: Capacity: 25Wh. Li-ion. Expected service life: 500 full charging cycles.

8.2.6 Environmental Conditions

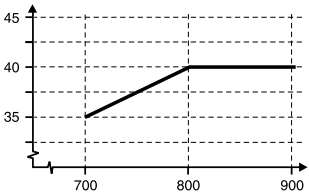
Operating temperature range: 5 to 40°C (41 to 104°F)

Storage and transport temperature: -20 to +60°C (-4 to +140°F)

Ambient pressure range:

700 to 1100 mbar, corresponding to ~4200 metres (13800 feet) above sea level to ~700 metres (2300 feet) below sea level, at normal atmospheric pressure.

As seen in the graph above, the ventilator is unable to deliver set max pressure at a very low ambient pressure.



Ingress Protection:

IP22

Solid particle protection: Hazardous parts are protected from touch by fingers and by objects greater than 12 mm.

Liquid ingress protection: The protection withstands dripping water less than 15 degrees from vertical.

The ingress protection has been tested by water drips equivalent to 3mm rain/minute for 10 minutes (2.5 minutes for each tilting direction).

8.2.7 Other

Patient Circuit Leakage

Recommended leakage: 20 to 50 l/min at 10 cmH_2O (leakage circuit)

Minimum leakage: 12 l/min at 4 cmH_2O (leakage circuit)

Oxygen Inlet

Oxygen inlet port: Maximum flow: 30 l/min (medical oxygen). Oxygen coupling is type CPC PMCD181032.

Start-up Time

Start-up from unpowered state: about 20 seconds.

Sound Power Level

Sound level at 10 cmH_2O in CPAP mode: Less than 30 dB(A). Measured at 1 m.

Alarm sound level : Adjustable 50–80 dB(A), Measured at 1m. Tolerance: ± 5 dB(A).

Miscellaneous

Maximum flow: > 300 l/min

Maximum flow at 20 mbar: > 150 l/min

Maximum limited pressure during single fault condition: 80 cmH2O (PCV, PSV) 30 cmH2O (CPAP)

Breathing resistance under single-fault: <6 cmH2O at 30 l/min, <6 cmH2O at 60 l/min

Nippy 4 Dimensions

W × H × D: 216 × 159 × 152 mm

Weight: 2.4 kg

Patient air outlet: 22 mm male, conical standard connector

Filtering/Smoothing Techniques

Pressure: Low pass average time constant 16 ms

Inspiration trigger: Differential mass flow resolution 4 ms

Expiration trigger: Flow low pass filtering with level sensing

SpO_2: No data post-processing done by the ventilator

8.3 Emission and Immunity Declaration

According to IEC 60601-1-2:2014.

The performance of all functions of the ventilator is considered as essential performance for the purpose of immunity testing.

8.3.1 Nippy 4 Essential Performance

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

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

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

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

Under the immunity test conditions, the following allowances are acceptable:

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

Additionally, the following shall not be allowed:

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

8.3.2 Guidance and Manufacturer's Declaration – Electromagnetic Immunity

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

Immunity Test	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact±15 kV air	The relative humidity should be at least 5 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	AC Power (Mains) quality should be that of a typical commercial, hospital and residential environment.
Surge IEC 61000-4-5	**Input power ports:** 0.5 and 1 kV (Line to Line) 0.5, 1.0 and 2.0 kV (Line to Earth) **Signal Input/Output ports:** 2.0 kV (Line to Earth)	AC Power (Mains) quality should be that of a typical commercial, hospital and residential environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial, hospital and residential environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T, 0.5 cycle (multiple phase analysis); 0% U_T, 1 cycle; 70% U_T, 25/30 cycles (50/60 Hz); 0% U_T, 250/300 cycles (50/60 Hz);	Nippy 4 runs on internal battery during voltage dips, short interruptions and voltage variations on power supply input lines.

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

WARNING!

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

Immunity Test	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 V_{rms} (150 kHz to 80 MHz) 6 V_{rms} (inside ISM/ASR bands)	d=0.35*√P m at 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	d= 1.2*√P m at 80 MHz to 800 MHz d= 2.3*√P m at 800 MHz to 2.5 GHz **Equation description:** P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and, except for portable RF communications equipment, d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with this symbol: 

NOTE

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

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

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

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

8.3.3 Guidance and Manufacturer's Declaration – Electromagnetic Emission

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

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

8.3.4 Frequencies of portable and mobile transmitters for which the recommended separation distance is 30 cm (12 inches)

Band (MHz)	Service	Immunity test level (V/m)
380 — 390	TETRA 400	27
430 — 470	GMRS 460, FRS 460	28
704 —787	LTE Band 13, 17	9
800 — 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	28
1,700 — 1,990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	28
2,400 — 2,570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	28
5,100 — 5,800	WLAN 802.11 a/n	9

8.3.5 Recommended separation distances between external power conductors and the ventilator

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

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

8.3.6 Proximity fields from RF wireless communications equipment

Frequency Range and Level: RF wireless communication equipment		
Test Frequency (MHz)	**Modulation***	**Immunity Level (V/m)**
385	Pulse Modulation: 18 Hz	27
450	**FM ±5 Hz deviation: 1 kHz sine	28
710 745 780	Pulse Modulation: 217 Hz	9
810 870 930	Pulse Modulation: 18 Hz	28
1720 1845 1970	Pulse Modulation: 217 Hz	28
2450	Pulse Modulation: 217 Hz	28
5240 5500 5785	Pulse Modulation: 217 Hz	9
* The carrier shall be modulated using a 50 % duty cycle square wave signal. ** As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used as it would be worst case although it does not represent the actual modulation.		

8.4 Delivery Settings

Delivery settings: modes and functions

Ventilation Mode: Pressure Support

Device Mode: Clinical

Profile 1: Active

Profile 2: Off

Profile 3: Off

Delivery Settings, Alarms

High Pressure Alarm:
25 cmH_2O
Low Pressure Alarm: 10 cmH_2O
High EPAP Alarm: Off
Low EPAP Alarm: Off
High Flow Alarm: 100 l/min
Low Flow Alarm: 20 l/min
High Vt_e Alarm: 500 ml
Low Vt_e Alarm: 300 ml
High MV_e Alarm: Off
Low MV_e Alarm: Off
High Breath Rate Alarm: Off
Low Breath Rate Alarm: Off
Apnoea Alarm: Off
Disconnection Alarm: On
Rebreathing Alarm: On
Obstruction Alarm: Off
High FiO_2 Alarm: Off
Low FiO_2 Alarm: Off
High SpO_2 Alarm: Off
Low SpO_2 Alarm: 85%
Low Pulse Rate: Off
High Pulse Rate: Off

Other

Patient operating time: 0 h
Display light: On
Light Intensity: 9
Alarm sound level: 3
Auto keypad lock: Off
Pre-use Test: Off

9 Accessories and Parts

WARNING!

Only use accessories recommended by Breas Medical. Breas Medical cannot guarantee the performance and safety for the use of other accessories with the ventilator.

NOTE

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

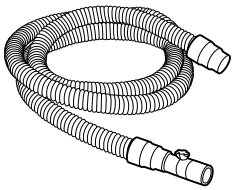
The following Breas accessories have been verified for use with the Nippy 4.:

9.1 Patient Circuits and Air Delivery Accessories

Circuit: 22 mm smoothbore with leak port

Function: Delivers air to the patient, applied part

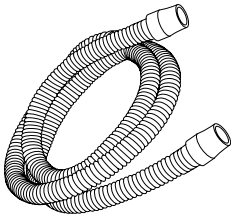
Part No: 005060



Circuit: 1.8m x 22mm Smoothbore disposable

Function: Delivers air to the patient, applied part

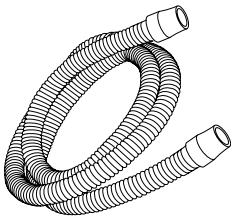
Part No: 009118



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

Function: Delivers air to the patient, applied part

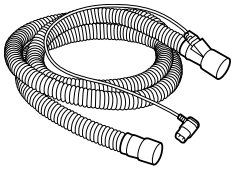
Part No: 008426 (30-pack of 004465)



Circuit: Single limb heated wire 15 mm, disposable

Function: Deliver heated air to the patient, non-invasively

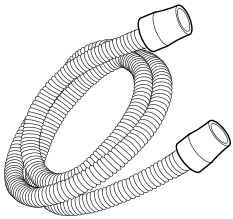
Part No: 006193



Circuit: 1.8m x 15mm Smoothbore Disposable

Function: Deliver air to the patient

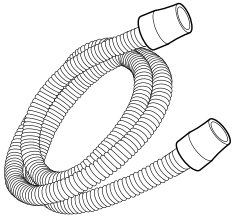
Part No: 009119



Circuit: Single limb 15 mm

Function: Deliver air to the patient

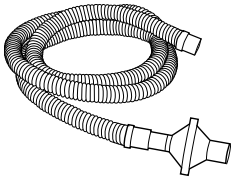
Part No: 008427 (30-pack of 006712)



Circuit: Single limb 22 mm, with bacterial filter, disposable

Function: Deliver air to the patient

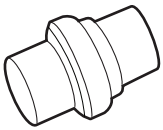
Part No: 007936



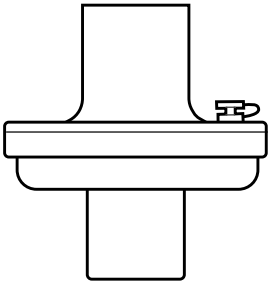
Leakage Port

Function: Providing a leakage for clearing exhaled gases.

Part No: 004426



Low resistance bacterial filter, with CO_2 connector



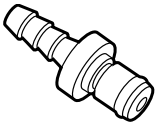
Function: Filter air at ventilator outlet

Characteristics

- Resistance:
  0.5 cmH_2O @ 30 l/m
  1.4 cmH_2O @ 60 l/m
  2.76 cmH_2O @ 90 l/m
- Deadspace: 33 ml
- BFE (Bacterial Filtration Efficiency): 99.9999%
- VFE (Viral Filtration Efficiency): 99.999 %

Part No: 007963

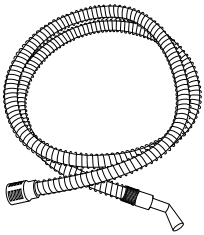
Low pressure oxygen adapter



Function: Oxygen tube adapter with connector for the Nippy 4.

Part No: 005032

Circuit: Single limb for Mouthpiece ventilation (MPV)



Function: Deliver air to the patient

Part No: 006093

Mouthpiece

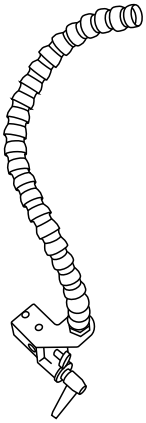
Function: Patient interface for Mouthpiece ventilation (MPV)

Part No: 006094

MPV arm

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

Part No: 006095

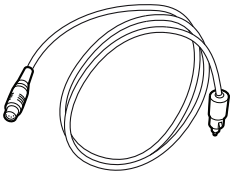


9.2 Power Accessories

Car Adapter Cable

Function: 12–24 VDC car adapter cable.

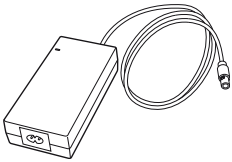
Part No: 007653



Power Supply

Function: Deliver power to the ventilator

Part No: 006396



Power cord

Function: Deliver power to the AC power supply

Part No:

GB: 003521

CN: 005304

EU: 003520

JP: 004834

US: 003522

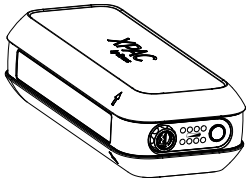
XPAC - External battery with charger

Function: Extends usage time of supported Breas products.

Part No Cable for connection to device: 007671

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

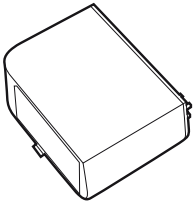
Single: 007993, Dual: 007997



Click-in battery

Function: Power source for transportation

Part No: 006265

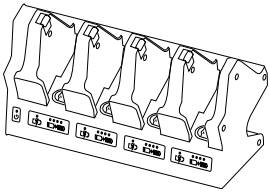


Click-in Battery Charger

Function: External charger for click-in batteries, available with bank for 2 or 4 batteries)

Part no:

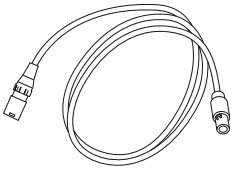
007728 (2 batteries charger)
007729 (4 batteries charger)



Cable, external DC

Function: External DC cable.

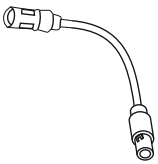
Part No:006709



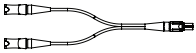
Cable, external DC to Ventilator Adapter

Function: Connect the ventilator to external DC

Part No: 006710



Cable, Y-adapter, Mains AC and External DC to Ventilator

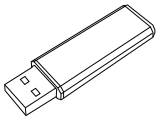


Function: Connects the ventilator to both mains and external DC at the same time. If the Mains power source is available, it will have precedence over the DC power source.

Part No: 006711

9.3 Monitoring Accessories

Breas PC software



Function: Data monitoring software

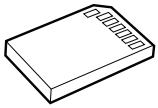
Part No: 007067

USB cable

Function: Data cable: PC to Nippy 4 (USB to USB)

Part No: 005757

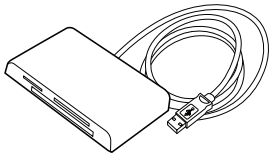
Memory card



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

Part No: 006705

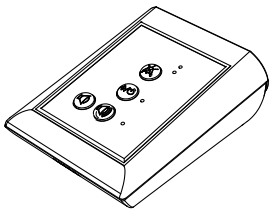
Memory card reader/writer



Function: Read/write memory card

Part No: 002185

Remote alarm with cable



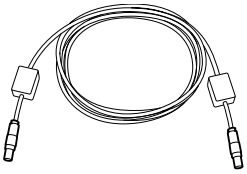
Function: Monitor Nippy 4 alarms remotely

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

Remote alarm cable

Function:

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



Nurse call cable

Function: Connect the ventilator to a hospital nurse call system

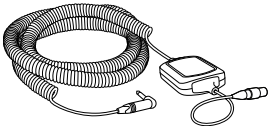
Part No:

NO: 006365

NC: 006364

10 kΩ, NO: 006363

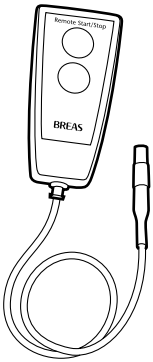
10 kΩ, NC: 006362



Remote start/stop

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

Part No: 006649



FiO_2 sensor

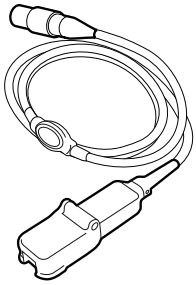
Function: Measure FiO_2 to the patient.

Part No: 006172

SpO_2 module

Function: Connection interface

Part No: 006369



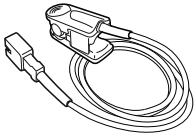
SpO_2 sensor

Function: Finger Clip SpO_2 sensor

Part No:

Adult: 006589

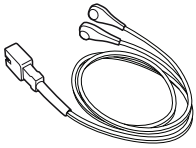
Paediatric: 006590



SpO_2 sensor

Function: Multisite SpO_2 sensor

Part No: 006591



9.4 Ventilator Filters and Detachable Parts

Patient air inlet filter, fine, white, disposable

Function: Fine inlet air filtration.

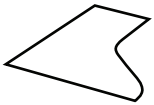
Material: AS 100

NaCl Penetration: (0.65 µm NaCl @ 95 l/min) = <7.35%

Part No: 007103 (5pcs)

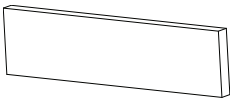
Patient air inlet filter, coarse, grey, washable

Function: Coarse inlet air filtration
Material: Bulpren S 28133
Filter diameter: 1080-1580 Microns
Part No: 007104 (5pcs)



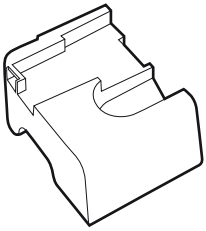
Cooling air filter

Function: Device air inlet filtration, 5 pieces
Part No: 007105



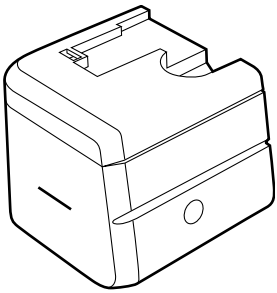
Air bypass unit

Function: Direct the air flow within the ventilator
Part No: 007064



Click-in water chamber

Function: Humidify the patient air
Part No: 006490

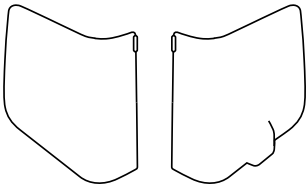


Side panels

Function: Protect the internal ventilator components.

Part No:

Grey: 007065, Blue: 007066, Light blue: 007518

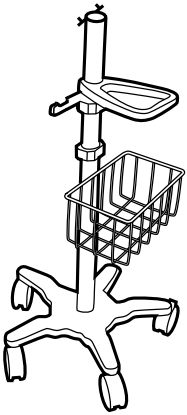


9.5 Other Accessories

Trolley

Function: Mobile use, transportation

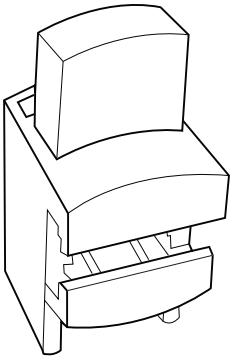
Part No: 007384



Universal rail clamp

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

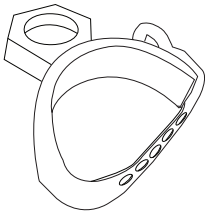
Part No: 007858

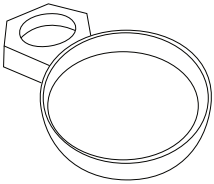


E-cylinder holder

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

Part No: 005128

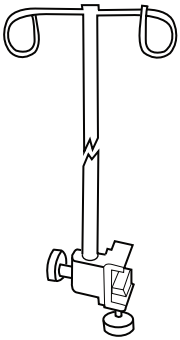




IV-pole

Function: Pole with hooks to hang IV fluid bags.

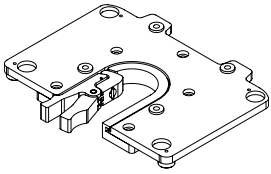
Part No: 007859



Mounting bracket

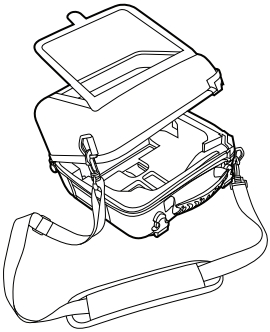
Function: Mount the ventilator to a stand / trolley / rail system.

Part No: 006761



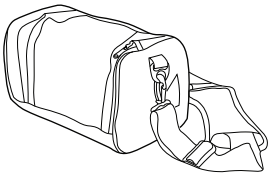
Protective cover

Function: Shock protection
Part No: 006067



Lightweight Mobility Bag

Function: Mobile use
Part No: 007555



Carry bag

Function: Storage for transportation
Part No: 006469

10 Patient Settings

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

Patient Settings - Nippy 4

Patient .....

Date .....

Clinic .....

Set by .....

Ventilation mode:.....

Patient Circuit	
IPAP	Inspiratory Trigger
EPAP	Expiratory Trigger
Breath Rate	Min Inspiratory Time
Inspiratory Time	Max Inspiratory Time
Backup Rate	Backup Inspiratory Time
Target Volume	Min Pressure
Max Pressure	CPAP
Auto-EPAP	EPAP step
EPAP Min	EPAP Max
PS	Pressure Limit)
PS Min	PS Max
Relax Time	

Notes

.....

11 FAA Compliance

To whom it may concern:

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

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

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

FAA Compliance (English text)

To whom it may concern:

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Index

D

E

F

G

H

I

L

M

N

O

P

R

S

T

U

W