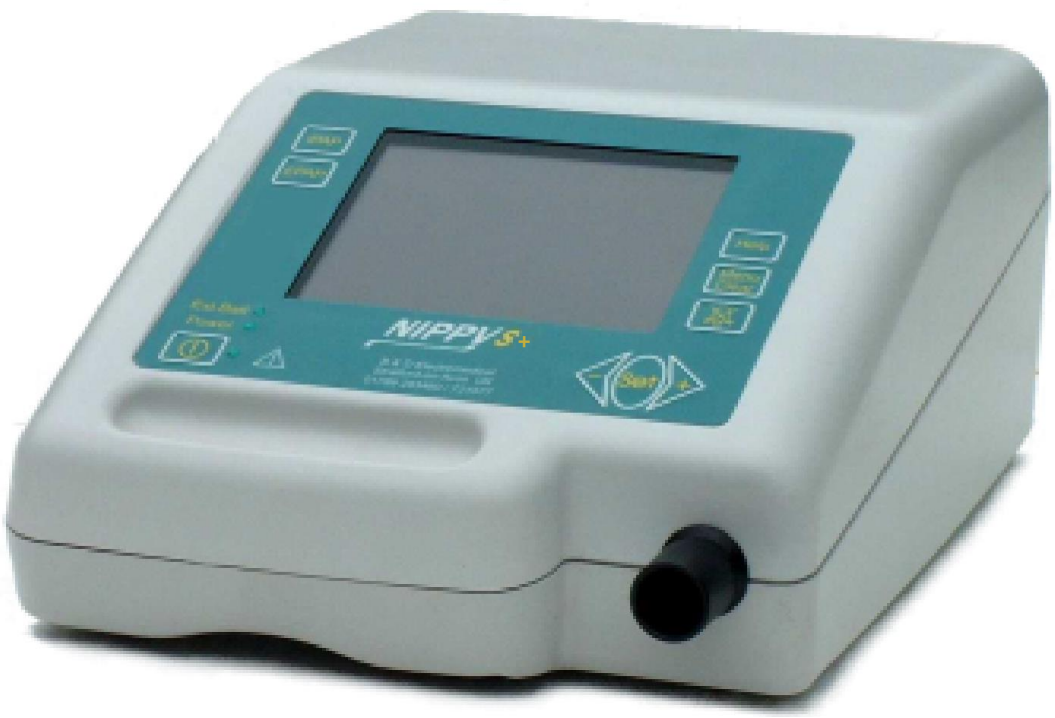
DOC 0918

INSTRUCTION MANUAL FOR THE NIPPY S+ BI-LEVEL VENTILATOR

This book must be kept with the machine



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NIPPY S+

INSTRUCTION MANUAL INDEX

Please note Breas Medical previously traded as B & D Electromedical & some photographs in these instructions still show the name B & D Electromedical.

Introduction

WARNING!

NIPPY S+ must only be used:

• For the intended treatment in accordance with this operating manual and with the instructions given by the responsible clinical personnel.

• In accordance with the operating conditions specified in this operating manual.

• In original and unmodified shape and only with accessories specified or approved by Breas Medical Ltd.

Every other use may lead to risk of personal injury!

CAUTION!

Read this manual thoroughly so that you completely understand how the NIPPY S+ is operated and maintained before taking it into use, to ensure correct usage, maximum performance and service life.

WARNING!

This device is not intended for use as a critical care ventilator, transport ventilator or for dependent patients.

Description

The NIPPY S+ is a pressure controlled, bi-level ventilator. It compresses ambient air and delivers it to the patient through a close fitting nasal mask. The output pressure, can be adjusted by controls on the fascia panel. The Pressure, and all settings are displayed on a colour LCD(Liquid Crystal Display) screen.

The screen can be set to dim after a pre-set time (accessed via the user preferences in the main menu). To restore the display, press any button once .

The basic ventilator settings can be achieved using the two buttons to the left of the display. The three buttons to the right of the display provide access to more advanced features and adjustments (accessed via a menu).

For greater safety and convenience the NIPPY S+ may be equipped with an internal battery. The ventilator is capable of recharging both the internal battery and an external battery when running from the mains electrical supply.

Mode of Ventilation

Pressure Support IPAP (Inspiratory positive airway pressure) and EPAP (Expiratory positive airway pressure) are set by the physician. The ventilator augments the patient's spontaneous breathing. A fixed back-up respiratory rate takes over in the absence of an inspiratory trigger from the patient.

Alarms

Power Fail If the electrical power to the ventilator is interrupted, an audible alarm will sound. This alarm will run for 5 minutes unless cancelled with the mute button. Once cancelled the power fail alarm will not re-activate.

Low Internal Battery When running on its optional internal battery, the alarm will operate when the battery is almost depleted.

The user cannot replace this battery. Refer to qualified technical personnel for battery replacement.

Low External Battery When running on an external battery, the alarm will operate when the battery is almost depleted. Machines fitted with an internal battery will automatically switch to internal battery power without alarming.

Low Pressure A pre-set low pressure alarm is provided. If the control pressure falls to below 50% of the set IPAP level for 10 seconds an audible and visual alarm will operate.

High Pressure A pre-set high-pressure alarm is provided. If the pressure rises above 120% of the working pressure, an audible and visual alarm will operate after a 2 second delay.

Breathing Circuit Disconnect A disconnect alarm is provided. This is activated by analysis of the inspiratory and expiratory flow waveform. An audible and visual alarm will operate.

Fault The alarm may also be operated by an internal fault. In this case the fault will be displayed on screen and stored in the fault log.

These alarms may be muted for approximately 2 minutes to allow for setting up of the ventilator.

Low Alarm Battery An intermittent alarm (short beep) with no onscreen message indicates a depleted mains fail alarm battery. If the ventilator has been stored for more than a few weeks the internal battery will self discharge. In this case the alarm will stop after the battery has recharged.

The user cannot replace this battery. Refer to qualified technical personnel if the alarm operates when the ventilator is in daily use.

Triggering

Inspiratory Trigger

The NIPPY S+ employs flow triggering, detecting the start of the patients inspiratory effort when the flow rate exceeds the level set by the Inspiratory Trigger sensitivity.

Expiratory Trigger

Towards the end of inspiration, when the inspiratory flow rate drops to the baseline (standing flow caused by exhale port leak) minus the expiratory trigger sensitivity the ventilator will cycle into the expiratory phase.

The inspiratory and expiratory effort required to cycle the ventilator can be adjusted via the Trigger option in the Menu.

For simplicity the trigger sensitivity is scaled 1 –10, with 1 requiring the least patient effort and 10 requiring more patient effort.

Intended Use

The NIPPY S+ is intended to provide non-invasive ventilation for non-dependent, spontaneously breathing adult patients with respiratory insufficiency, or respiratory failure.

The NIPPY S+ is not intended for life support or life-sustaining applications or for transport of critical care patients.

The NIPPY S+ is intended for use in clinical settings (e.g., hospitals and sub-acute care institutions) and home environments.

The NIPPY S+ is intended for non-invasive use only.

The NIPPY S+ shall only be used by patients who are spontaneously breathing.

The NIPPY S+ must always be prescribed by a competent physician.

The NIPPY S+ is intended for treatment of adult patients only.

The NIPPY S+ is intended to be operated by qualified and trained personnel only.

IMPORTANT!

NIPPY S+ must be prescribed by, and used only under the supervision of a qualified physician.

This manual is only intended for clinical personnel, physicians and trained users who require a working knowledge of the NIPPY S+.

Alarms must be tested before use and following a change of the breathing circuit as described in the Alarms Conditions/Tests section.

It is the clinicians responsibility to ensure the device is always used with the appropriate breathing circuit, to ensure sufficient CO_2 elimination. All care staff should be trained to ensure that the location of this exhalation port is known and they are aware that this must not be removed, covered or blocked at any time.

Batteries used for power fail back up must be kept in good condition and fully charged at all times. See Battery care section of this manual.

Contraindications

The NIPPY S+ is not a life support ventilator.

The use of the device may be contraindicated in patients with the following:

- Pneumothorax or pneumomediastinum
- Low blood pressure
- Cerebrospinal fluid leak, recent cranial surgery or trauma, or raised Intercranial pressure
- Severe bullous lung disease
- Dehydration
- Risk of vomiting
- An oxygen requirement higher than achievable with 15l/min of entrained low pressure oxygen and the prescribed ventilation settings

Adverse effects

Patients should report any new or unusual chest pain, severe headache or increased breathlessness or increased day time sleepiness to a clinician immediately.

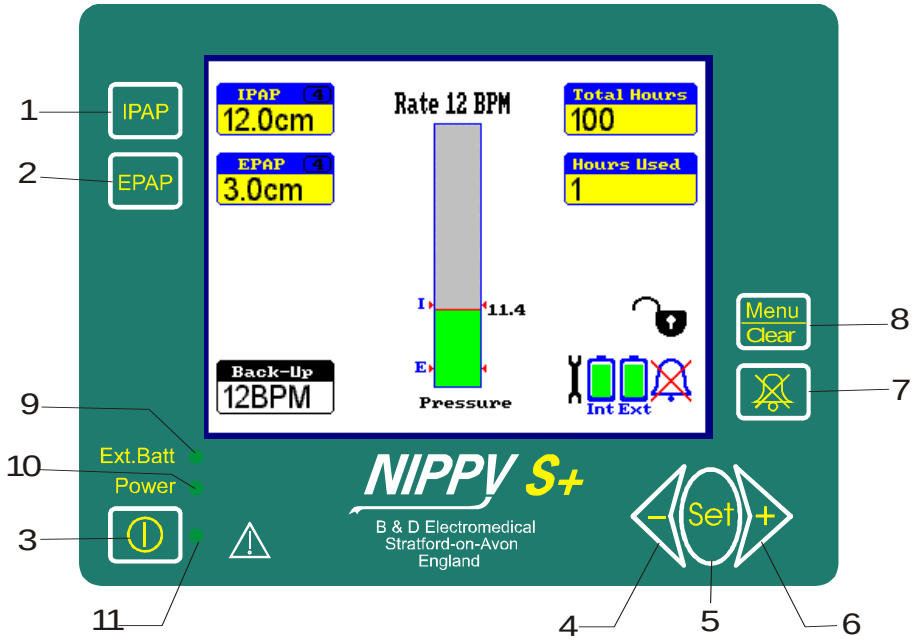
The following side effects may be experienced during the treatment with non invasive ventilation:

- Nasal, mouth or throat dryness
- Bloating
- Ear or sinus discomfort
- Eye irritation from mask leak

Features

1. Comprehensive alarms with mute facility
2. User friendly intuitive user interface
3. Easily understood alarm messages displayed onscreen
4. Universal mains input, operates anywhere in the world without transformers
5. Optional internal battery
6. Adjustable flow triggers with trigger indicators
7. Large, colour LCD display, clearly shows all settings
8. 28 days stored, On-screen compliance data
9. Comprehensive event log stores all adjustments, settings, alarm events and user interventions, for download to PC.
10. Fast trigger response
11. Minimal maintenance requirement
12. Twelve months parts and labour warranty
13. Auto switching to back-up battery
14. Automatic service reminder

Explanation of controls



Fascia Buttons

1. IPAP - Selects the Inspiratory Positive Airway Pressure adjustment (scaled in cm H_2O). Value is displayed on screen adjacent to the switch.

2. EPAP - Selects the Expiratory Positive Airway Pressure adjustment (scaled in cm H_2O). Value is displayed on screen adjacent to the switch.

3. ⏻ - Starts and Stops the ventilator

4. ◄- - Decrements the selected parameter or moves the selection bar down the menu.

5. Set - Selects the current menu function displayed by the selection bar

6. +► - Increments the selected parameter or moves the selection bar up the menu

7. Mute - Silences the alarm for 2 minutes. Press and hold for 2 seconds to cancel alarm mute.

8. Menu - Displays the menu screen

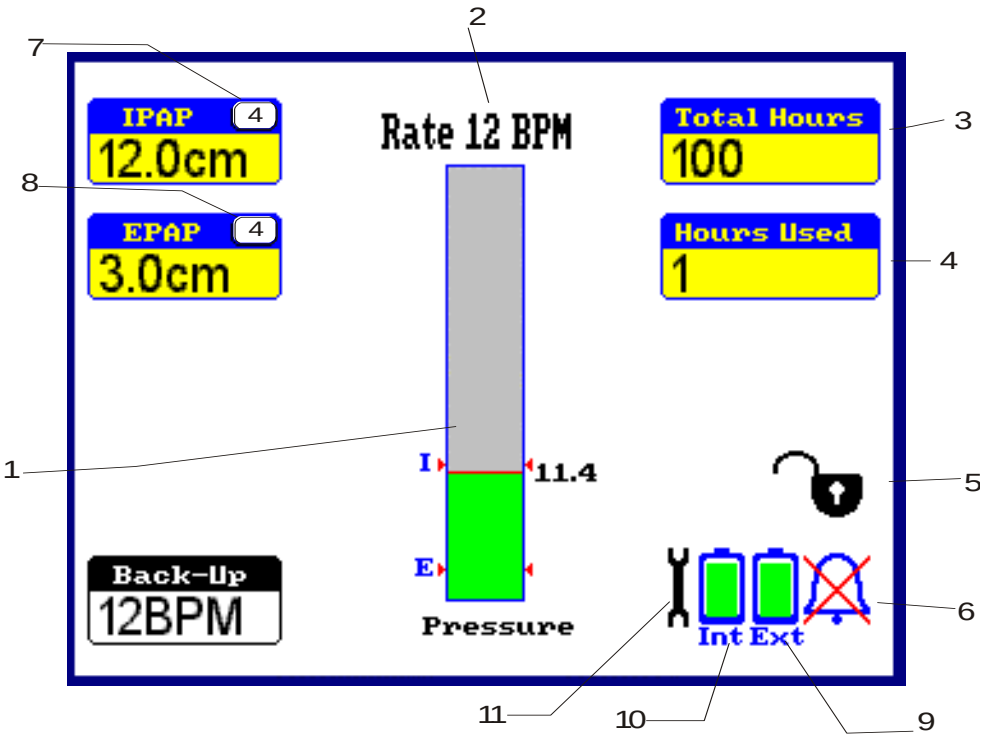
9. Ext. Batt - Indicates that ventilator is running on battery power. This may be internal or external

10. Power - Indicates that external power is connected.

Ext Batt OFF and Power ON = Battery charging

11. Start - Indicates that the ventilator is running.

Fascia Display



1. **Pressure Display** - Indicates airway pressure (scaled in cm H_2O). Changes colour to red in over pressure alarm condition.

2. **Rate Display** - Indicates patient breath rate (scaled in Breaths Per Minute).

3. **Total Hours** - Indicates total time machine has been running.

4. **Hours Used** - Shows total hours of use. (Compliance Hours)

5. **Settings locked symbol** - This symbol shows that the settings are locked.

6. **Alarm Muted symbol** - This symbol shows that the audible alarm has been temporarily silenced.

7. **I Trigger indicator** - “Flashes” each time the inspiratory cycle is initiated by the patient.

8. **E trigger indicator** - “Flashes” each time the expiratory cycle is initiated by the patient.

9. **External battery** - Indicates external battery state of charge, when connected. Red when Discharged.

10. **Internal battery** - Indicates internal battery state of charge. Red when Discharged.

11. **Service Reminder** - Major service due

Ventilator Outlets

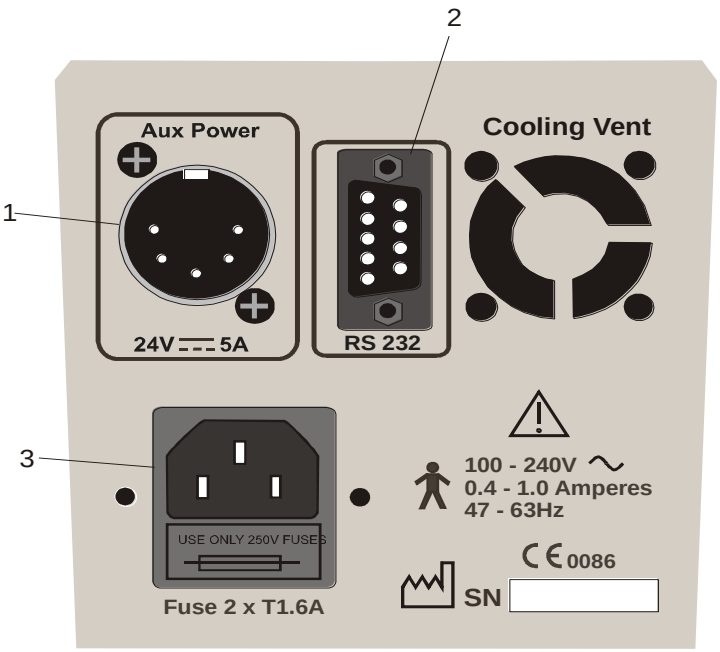
1. **Outlet** - Main Air Outlet to breathing circuit

Rear Panel Layout

1. Power Inlet - Input mains power connector. Double fused and fitted with connector retaining clip.

2. Optional RS232 Port **-** For connection to remote alarm or personal computer. Isolated to 1500 Volts.

3. Optional Aux. Power **-** 24 Volt connection for external battery. Connect only recommended battery, part no 0910



Explanation of Symbols used on NIPPY S+ and Accessories

 - Type B Applied parts to EN 60601-1

 - Alternating Current

 - Direct Current

T - Time Delay Fuse

SN - Serial Number

 - Date of Manufacture

 - Attention. Consult Accompanying Documents

 - Switch ON /OFF

+▶ - Increase Button

◀- - Decrease Button

 - Locked / Unlocked, Purple = total lock, Black = settings locked

 - Alarm Muted

 - Battery charged

 - Battery Discharged

 - Service Reminder

 - Dispose of in Line with Local Authority Guidelines

 - Recycle

 - Batch code

Getting Started

To Switch On

Place the NIPPY S+ on a clean, smooth, hard surface. (NOT carpet)
Connect the power lead to the mains power connector on the rear panel. Plug into the mains power supply.
Press the Start/Stop button.

To Switch Off

Press the Start/Stop button. The “Switch Ventilator Off” message will appear onscreen. Press the Start/Stop button again after 2 seconds. There must be a delay of 2 seconds before each push, to prevent accidental operation.

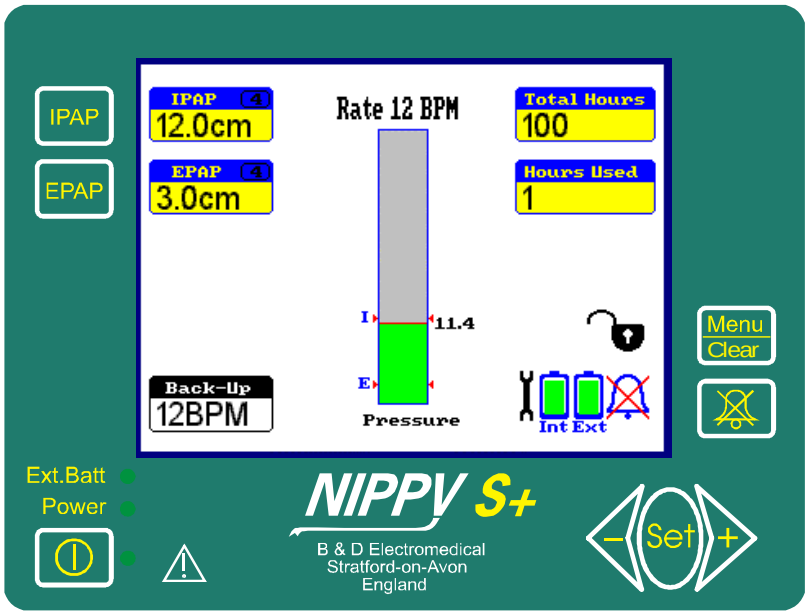
The Main Screen

The Main Screen is divided into 3 areas

The left-hand side shows the basic ventilator settings, IPAP, EPAP, adjacent to its setting button.

The centre section shows the airway pressure and breath rate.

The right-hand side shows the symbols for hours used, alarm, mute and locked settings.

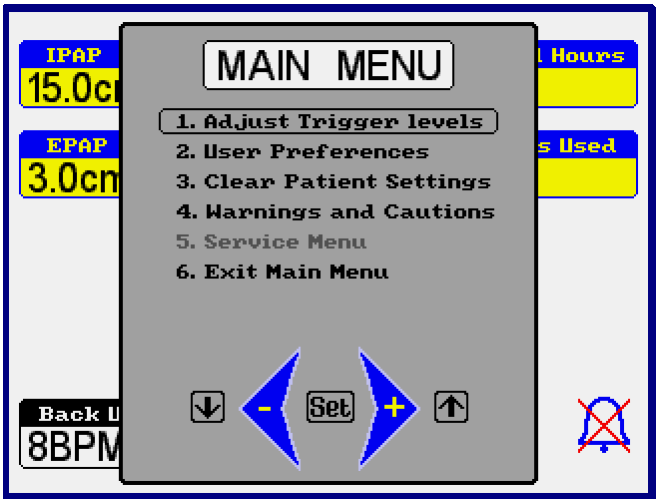


How to adjust the NIPPY S+

Select the desired parameter with the relevant button.
The reading adjacent to the button will be highlighted by a purple flashing box.
Alter it with the ◄- or +► buttons.
When you have finished, move on to the next adjustment or wait a couple of seconds for the flashing box to disappear.
E.g. Press IPAP.
IPAP setting will be surrounded by a purple flashing box.
Press +► to increase the pressure setting.

Menu Window

The Main Menu gives access to further adjustments and allows you to view information relating to the ventilator usage.



How to use the on-screen menu

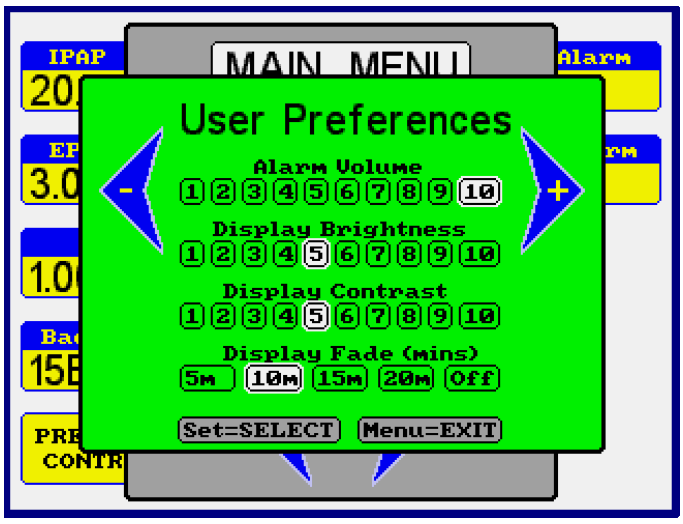
Press the MENU button. The menu window will be displayed in front of the main screen.

Move the selection bar up or down the menu with the ◄- or +► buttons to highlight the desired function and press the SET button.

Follow the on-screen instruction at the bottom of the window

Press MENU at any time to exit and return to the main screen.

Eg.



Press MENU.

Press ◄- button to move the selection bar over “User Preferences”.

Press SET. Press SET again to move the ◄- and +► symbols either side of “Display Contrast”

Press +► to increase contrast - Press MENU to exit.

Structure of the Main Menu

1. Adjust Trigger
   - I Trig — View / Adjust
   - E Trig — View / Adjust

2. User Preferences
   - User Preferences
     - Alarm Volume — View / Adjust
     - Display Brightness — View / Adjust
     - Display Contrast — View / Adjust
     - Display Dimming — View / Adjust

     (Sets time in minutes until display dims, to night time level)
   - Disconnection Alarm — View / Adjust
   - Apnoea Alarm — View / Adjust
   - BPM Alarm — View / Adjust
   - Sigh Settings — View / Adjust

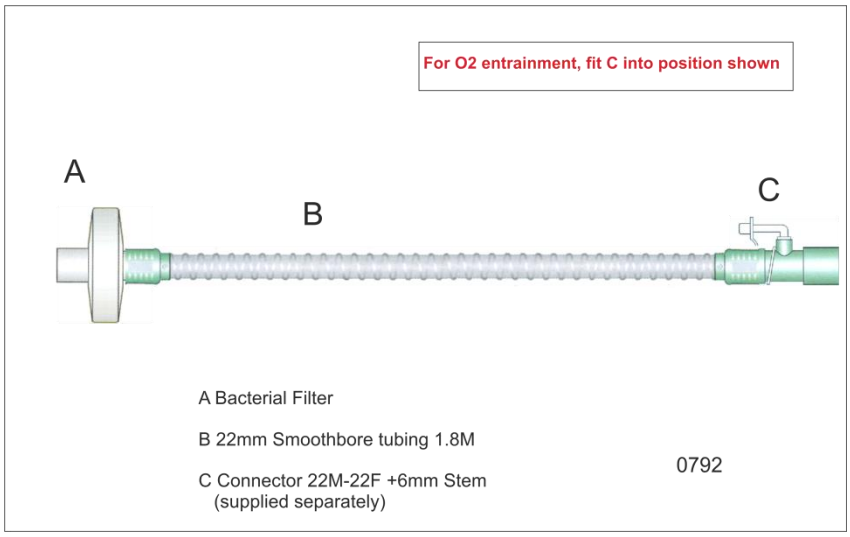
4. Clear Patient Settings — Resets machine to default settings and clears the compliance data, ready for a new patient.

3. Warnings & Cautions — Safety information — View only

4. Service Menu — Service Information — Restricted Access

Breathing Circuits

Breathing circuits to be assembled in the order A-B-C-D from the ventilator end. The NIPPY S+ uses a single limb circuit. Always use a ventilated mask.



Part Number 0792
Breathing circuit volume = 570 ml including filter.

Setting up the NIPPY S+

Before starting to set up the ventilator, assess the patients breathing pattern. You will need to know the breath rate.

1. Place the NIPPY S+ on a clean, level surface.
2. Connect the breathing circuit tube to the outlet. It is recommended that a bacterial filter be fitted between the outlet and the 22mm diameter breathing tube.
3. The breathing circuit must contain an intentional leak to prevent re-breathing of exhaled air. This may be achieved with either an integrated leakage in the mask or a leakage/exhalation port.
4. Connect the mask to the outlet tubing on the breathing circuit.

   Note: Do not fit the mask onto the patient at this point.
5. Press the Start/Stop button.
6. Carry out alarm tests as described in “Alarm conditions / tests”. **Note:** If any of the alarms fail to operate, **DO NOT USE** until the fault has been rectified.
7. Ensure the settings are adjusted as prescribed.
8. The patient or physician may now **hold** the interface to the face.
9. Allow the patient to get used to the interface. Objective assessments should verify the settings are suitable and clinically effective.
10. If the inspiratory or expiratory trigger needs to be adjusted, select “Adjust trigger level” from the menu and adjust to suit the patient and to ensure optimal patient synchrony.
11. Read the rate from the display (top of screen). This should match the value observed when assessing the patient. If the rate has increased, make sure that the trigger is not so sensitive that it is causing “self triggering”.
12. Allow the patient to get used to the interface then fasten the interface to the patient.
13. Check the rate when the patient is asleep. The inspiratory and expiratory trigger indicators should “flash” at the beginning of each breath.
14. Lock the settings to prevent unauthorised adjustment. See back page.

Remove the patient interface or disconnect the patient circuit from the outlet port, before switching off.

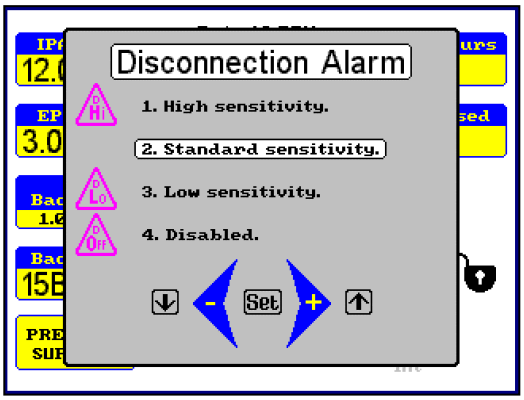
Setting Up Alarms

Disconnection Alarm

The inspiratory and expiratory flow waveform of the patient is analysed. If the waveform indicates that a significant leak maybe present in the breathing circuit an audible and visual alarm will operate after 10 seconds.

There are three different sensitivity levels or it may be disabled if not required. Select the appropriate sensitivity level for your patient. Press SET to store the setting.

It is essential that the disconnection alarm is tested with the circuit and interface/tube used by the patient to ensure the device alarms appropriately -see page 20 testing alarms.



High Sensitivity – The alarm will be activated during the detection of a leak which is less than that required to trigger the standard sensitivity setting. This may be useful for very restrictive breathing circuits or small tracheostomy tubes.

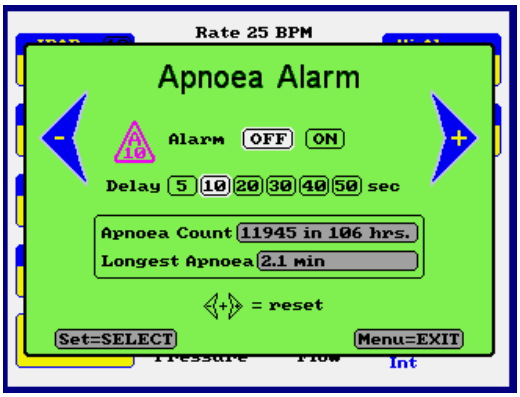
Standard Sensitivity – Default level.

Low Sensitivity – The alarm will be activated during the detection of a leak which is greater than that required to trigger the standard sensitivity setting. This may be useful where mask leaks cause nuisance disconnect alarms. Verify that patient is properly ventilated during these periods before using the Low setting.

Disabled – Disconnect alarm is switched off. Useful where mouth breathing or excessive leak causes nuisance disconnect alarms. Verify that patient is properly ventilated during these periods before using this setting. A full risk assessment must be carried out and documented before activating this setting, and must only be set by the prescribing physician.

Apnoea alarm

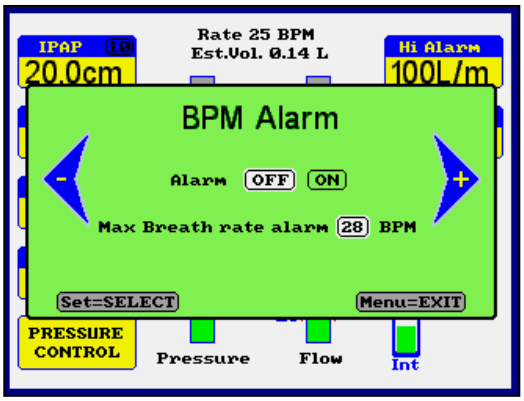
Select USER PREFERENCES from the main menu. From the OPTIONS MENU, select APNOEA ALARM.



To activate the apnoea alarm, select ON and select the required delay.
The total number of apnoeas during the last seven days or since reset, will be displayed along with the time duration of the longest single apnoea.
Press + and – together to reset the apnoea count.

An apnoea is defined as a cessation of spontaneous breathing for the set time delay. Ventilation will continue at the backup rate during apnoea events.

Max Breath Rate Alarm



The max rate alarm will be activated if the patients breath rate exceeds the set level. Select USER PREFERENCES from the main menu. From the OPTIONS MENU, select RATE ALARM. To activate the rate alarm, select ON and set the required max rate.

Alarm Conditions/Tests

Test the alarms prior to use. Before testing alarms, ensure that the alarm is not muted. To cancel the Mute, press and hold the mute switch until a beep is heard (2 seconds)

Disconnect Alarm

If the breathing circuit becomes disconnected, the alarm will be activated.

To Test Switch on the ventilator without a breathing circuit connected and cancel the Mute. After 10 seconds the alarm will sound, accompanied by the on-screen disconnect alarm message.

Mains Fail Alarm

If the mains power to the NIPPY S+ fails, the alarm will operate and continue for approx. 5 minutes. Press the mute button to silence the alarm.

To Test To ensure that the mains failure alarm is operating correctly, start the NIPPY S+ and switch off the mains power at the wall socket. The screen will go blank after a few seconds and the alarm will sound. Press the mute switch or restore the power and re-start the ventilator to silence.

Low Pressure Alarm

If the IPAP pressure falls to less than 50% of the IPAP setting for more than 10 seconds, the alarm will sound and an on-screen message will warn of low pressure.

To Test It is not possible for the user to test this function.

High Pressure Alarm

If the airway pressure exceeds 120% of the IPAP setting for more than 2 seconds, the alarm will sound and the pressure display will turn red.

To Test It is not possible for the user to test this function.

Fault Alarms

The fault alarm indicates a fault in the machine. The on-screen message will indicate the nature of the fault. The message may be temporarily hidden by pressing the Mute button.

To Test It is not possible for the user to test this function.

If you receive a fault message at any time, DO NOT continue to use the ventilator. The machine MUST be referred to suitably qualified technical personnel for investigation/repair.

Sigh Function

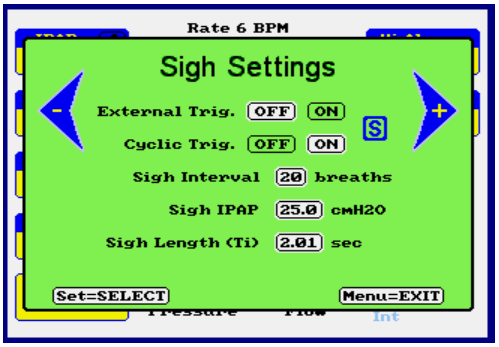
The ventilator can be programmed to deliver an occasional sigh with a larger tidal volume. This prevents collapse of the alveoli (atelectasis) which can result from the patient constantly inspiring the same volume of gas. Sigh is available in all modes except CPAP.

The Sigh function provides a timed inspiration at the IPAP and TI settings specified in the Sigh Settings screen.

Sigh may be set for cyclic operation, sigh breath at the specified interval or an external switch (Manual mode). Or a combination of both, where the cyclic sigh may be supplemented by extra sigh breaths on demand.

Setting the Sigh function

Press MENU and select USER PREFERENCES. In the User preferences screen select SIGH SETTINGS.

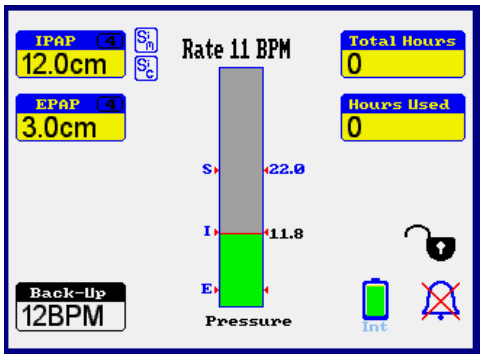


Use the SET button to scroll down the settings, using the +/- buttons to alter the settings.

Sigh Interval sets frequency of cyclic sigh

Ext Trig = manual switched sigh

Symbol S_m shows Manual Sigh function is enabled.
Symbol S_c shows Cyclic Sigh function is enabled.
Blue Symbol = Sigh mode enabled.
Green Symbol = External sigh trigger acknowledged.
Purple Symbol = Sigh breath activated.
Sigh breath pressure (S) is indicated on the pressure bar-graph display.



Note: If the ventilator IPAP is adjusted after the sigh has been set up, this may affect the sigh setting.

If the IPAP is reduced the sigh will be reduced by the same amount, to maintain the difference between IPAP and Sigh. This can be overridden in the Sigh Settings screen.

If IPAP is increased to a value equal to the sigh setting, the sigh value will “track” the IPAP. This effectively makes IPAP and Sigh the same. This is done to prevent accidental increase of the sigh breath. The sigh will need to be reset in the Sigh Settings screen. Sigh is cancelled when Mode is changed.

The IPAP during Sigh cannot be lower than normal IPAP.

Regardless of the back-up rate, a sigh breath is timed with an IE ratio of 1:2. This does not affect triggering.

High flow and disconnect alarm is suspended during Sigh.

No more than 5 consecutive sigh breaths are allowed.

Running the NIPPY S+ on Battery Power

The NIPPY S+ may be powered from the mains, internal or external battery.

IMPORTANT BATTERY CARE RULES

1. Regularly check battery run times for your system at your prescription settings and record in the log.
2. If you have more than one ventilator, check this one too.
3. Never check the on-screen run time estimate when running on mains power.
4. Failure to perform regular battery performance checks could result in failure during loss of mains power. Check Monthly.
5. Know the difference between battery run time and battery state of health. The run time is the running time expected from a healthy battery. The state of health is the condition of the battery in terms of its total service life.

NOTE: Basic models, not fitted with the internal battery have no reserve power unless an external battery is connected.

Power Source Priority

1. - Mains Electricity
2. - External Battery (if connected)
3. - Internal Battery (if fitted)

In order to save battery power, the ventilator will always run on mains electricity if it is present.

If the mains fails or is not connected, the ventilator will select the external battery as the next choice. The external battery, if present, will always be run flat before the internal battery is selected.

If there is no external battery, the ventilator will switch to its internal battery.

If there is no internal battery the ventilator will shut down and alarm to warn of power failure.

Battery Run Times

Battery run times are dependent on the battery age, condition, ambient temperature, ventilator settings and amount of leak. High pressures and /or high breath rates use more power and therefore shorten run times. Large leaks use more power and shorten run times.

Run times will gradually reduce as the battery ages regardless of how much use the battery has had.

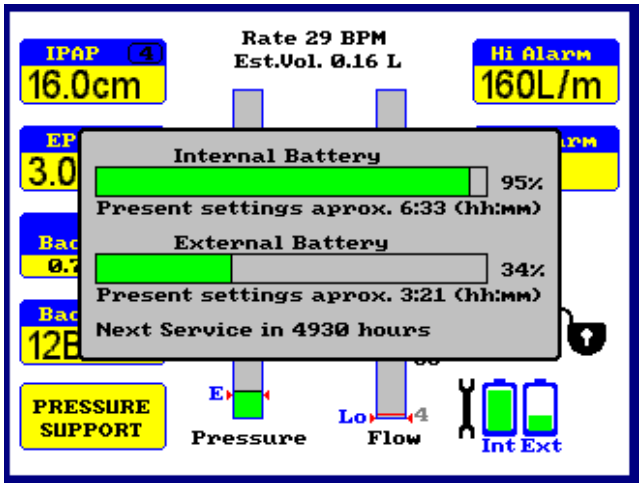
Battery Run Time Estimate Screen

Double press the SET button to display a bar graph of run time. The time for each battery connected will be calculated, according to the ventilator settings, and shown on the screen.

This is an indication of the battery state of charge not its health. For most accurate result, run the ventilator on battery power for 5 minutes prior to this check.

The results shown assume that the connected battery is in good serviceable condition. It is not possible to take into account the state of health of the battery. The only way to determine the state of health of the battery is to perform a run time test.

When checking expected battery run time the ventilator must NOT be connected to the mains.



Low Battery Alarm

Low battery = alarm sound, and on screen message, “Battery Power Running Low” and flashing red battery icon.

Flat Battery = alarm sound and on-screen message “Battery Power Exhausted. About to switch off. Connect to Mains Power Now” and flashing red battery icon.

Critical battery = 10 minutes after battery exhausted warning, alarm sound continuous tone and auto power off.

After auto power off, the constant alarm will continue until the Mute is pressed.

Charging the batteries

Internal and external batteries are automatically charged when the ventilator is connected to the mains supply. Charging takes approximately 8 - 11 hours depending on ventilator settings.

Charging priority is given to the internal battery. Charging of the external battery if connected will begin after the internal battery is charged. When charging is complete the batteries will be monitored to maintain charge.

Battery Care

- ❖ Check the running time of your system regularly.
- ❖ Always make sure batteries are fully charged before use.
- ❖ The battery should be recharged as soon as possible after use.
- ❖ This type of battery does not suffer from the memory effect that is widely talked about and does not need to be fully discharged before charging.
- ❖ Batteries like to be used. A new battery may require several charge/discharge cycles before it reaches its maximum performance. The same applies to a battery that is only used occasionally with long periods in storage.
- ❖ If you have more than one external battery, use them in rotation.
- ❖ If you are in doubt regarding the state of charge, charge for at least 24 hours.

Battery Life

The battery will deteriorate due to age and usage. It is not possible to predict the ageing. The life span of the battery will depend on a number of factors, including:- Age, number of charge cycles, depth of discharge, charge and discharge temperature.

- An internal battery that is not used will age prematurely.
- An internal battery that is heavily used will age gradually and lose its capacity.
- An internal battery that is moderately used will last longest It has been designed to be used.
- When a battery is towards the end of its life, the run times will be much shorter. This is why it is important to carry out a run time check regularly.
- The end of life is defined by the maximum running time falling to 75% of that of a new battery (refer to the Battery Testing section.)
- Service life is 2 years under normal operating conditions. Replace the battery when running times drop below those indicated or after 2 years.
- *If the battery icon remains RED after several hours charging there may be a fault with the battery of the ventilator.*

Battery Storage

- This type of battery is best stored partly charged.
- A battery that is not in use will slowly discharge. This rate of discharge increases with temperature.
- Optimal storage temperature is between -20^{o}C and +20^{o}C. It must be below 40^{o}C.
- After storage in a cold environment allow 24 hours for the battery to reach room temperature before use.
- Fully charge the battery before use.

Battery Run Time Test (Health test)

- Ensure the battery is fully charged.
- Run the ventilator from the battery until the low battery alarm operates and record the running time. Look up the run time in the table. If the battery is not achieving minimum run time replace it.
- If the battery is good, fully recharge it immediately after testing.
- A run time record is provided at the end of this manual.

Table of typical running times

Pressure Support mode with EPAP set to minimum @ 20BPM

IPAP	Run Time (Hours)	Min Run Time (Hours)
15	11	8.25
20	9.5	7.25
25	8.5	6.25
30	6.5	5
35	5.5	4
38	5	3.75

Battery Health Quick Test

If it is not practical to check battery run times, a crude quick test may be performed to identify a battery that is at the end of its life and has not been noticed by the user or for a quick check on a battery that has not been used regularly. This test is not an indication that the battery is good, but is a useful way of identifying *a failed battery.*

This test is not intended to replace regular run time testing used to determine battery state of health.

Quick Test Procedure

1. Remove the external battery from the Aux Power socket if being used.
2. Connect NIPPY+ to mains power supply and fully charge the internal battery overnight.
3. Turn the NIPPY+ on with the patient circuit fitted to the outlet.
4. Disconnect the mains power supply so the NIPPY+ is running on its internal battery.
5. Remove the patient circuit from the outlet and allow the NIPPY+ to ‘free flow’. This will create maximum flow and load on the battery.
6. If the battery symbol turns red or the NIPPY+ shuts down within 2 minutes the battery MUST be replaced immediately.

Disposal of depleted batteries

Depleted batteries may be disposed of in line with local authority regulations.

External Battery

An external battery may be used to increase the running time. This battery will power the NIPPY+ for the same time as an internal battery, depending on settings and leak.

External Battery, part number 0910.
External battery charger, part number 0911
These batteries should never be used to run any other type of equipment.

Instructions for Use

- Connect the battery to the NIPPY+ Aux Power input.
- Switch on the NIPPY+. The Ext Batt light will flash and a “Running on battery power” message will be displayed on the NIPPY+ screen. Press the alarm mute button to hide the message.
- To disconnect a battery: **Always switch off the ventilator first**. Press the plug release button on the connector and withdraw the connector.

To Charge an External Battery

- Connect the battery to the NIPPY+ whilst it is connected to mains electricity.

Alternatively, charge with the battery charger as follows:-

- Place the charger on a smooth flat surface.
- Connect the charger to the battery socket **before switching on the mains power**.
- Connect the mains plug to the AC supply and switch on.
- Leave on charge until the charged / ready indicator lights.
- Batteries may be left connected to the charger until required for use.

Safety

- Warning! High voltages exist inside the charger.
- Do not remove the cover. Return to B & D Electromedical if a fault occurs.
- Do not expose to water or dust.
- Do not cover the charger whilst in use
- Do not use any other type of battery charger. This could lead to damage to the battery and personal injury.
- Do not attempt to connect any battery other than those supplied by the manufacturer. Use of any other type of battery could lead to personal injury and damage to the ventilator.
- Ensure that the mains lead is not damaged.
- Batteries may produce explosive gases during charging. Always charge away from sparks or sources of ignition. Do not smoke near a battery whilst charging.

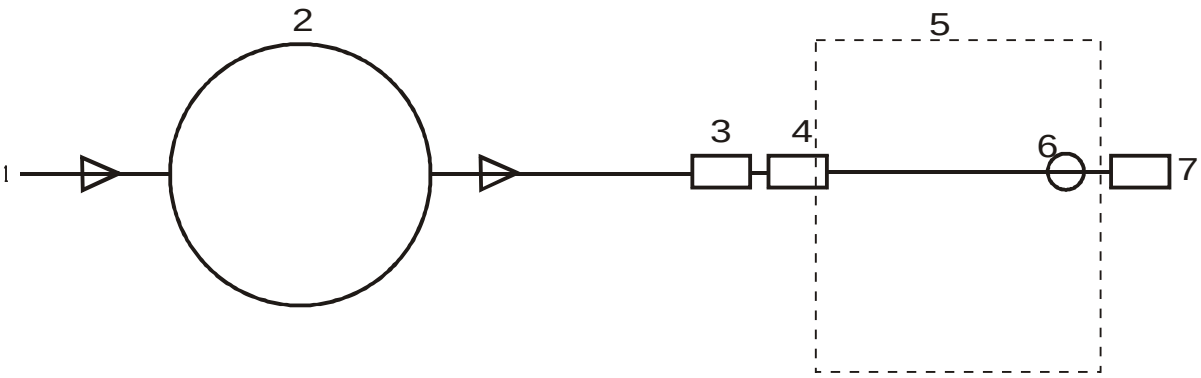
Disconnect from the mains before disconnecting the battery from the charger

Connecting auxiliary monitoring equipment

For monitoring or downloading data the NIPPY S+ may be connected to a PC or Laptop computer. The NIPPY S+ isolated RS232 port is safe for use with any domestic PC or laptop computer. However, when assembling a system, the completed system should comply with EN60601-1 (medical systems). For example, most computers do not comply with this standard, so it should be sited at a distance which makes it impossible to touch the computer and the patient at the same time.

The RS232 port may also be used to run a remote alarm unit.

Ventilator System Pneumatic Diagram



1. Fresh air inlet
2. Blower (compressor)
3. Flow Sensor
4. Outlet connector
5. Breathing Circuit
6. Exhalation Port
7. Patient Connection Port

SPECIFICATIONS

Supply Voltage		-	100 - 240 V alternating current
Supply Frequency		-	47 - 63 Hz
Maximum Input Current		-	0.40 – 1.0 Amperes
Fuse Ratings		-	2 x T 1.6 A 20mm
Dimensions (mm)	Length - 297	Width - 223	Height - 132
Weight		-	3.6 kg (4.5kg with int. battery)
Ambient Operating Temperature		-	40^{O}C, 104^{O}F Max
Digital Output		-	RS232 Isolated to 1500 Volts
All displayed readings expressed as		-	ATPD
Max. Output Pressure		-	38cm H_2O(44cm fault condition)
Calibrated pressure Range		-	0 - 38cm H_2O
Accuracy of pressure reading		-	+/- 3.0% F.S. +/-1% zero
Max. Output Flow		-	200 L/min. (unrestricted)
Max Volume Reading		-	2000 millilitres
Accuracy of volume reading		-	Estimated
Inspiratory Trigger		-	0.14 – 2.21 L/sec^2
Expiratory Trigger		-	0.28 – 1.67 L/sec^2
Inspiratory Time		-	0.7 – 3.0 seconds
Back-up Rate		-	6 - 43 Breaths per minute
Type of protection against electric shock		-	Class 1 equipment
Degree of protection against electric shock		-	Type B to EN 60601-1
Mode of operation		-	Continuous
IP rating		-	X0
Storage environment		-	-20 to 50^{O}C
			5 – 85% RH
			260 – 1100 mBar atmospheric pressure
Internal battery		-	18.75Vdc 116Whr
Running time		-	4 -12 hours depending on settings and leak
External battery		-	18.75Vdc 116Whr
Running time		-	4 -12 hours depending on settings and leak

Protection against flammable anaesthetic mixtures - Not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR OR WITH OXYGEN OR NITROUS OXIDE

International Standards

BS EN60601-1 1990, EN 10651-6 EN 10651- 6 2004

Safety of Electromedical Instruments, General Requirements

Electromagnetic Compatibility (In accordance with the EMC Directive 89/336/EMC)

B & D Electromedical declares that the NIPPY S+ Ventilator complies with the following EMC standards. EN60601-1-2: 1993

Test results available for review from B & D Electromedical

CE 0086

Operation Under Extreme Conditions

Ambient Temperature in the range of +5 to +50 ^{o}C

Between 5 and 40 degrees functioning of the ventilator should not be affected. Extremes of temperature (below 5 ^{o}C, above 40 ^{o}C) may affect the colour of the LCD display. This will return to normal with the temperature.
Operation above 40 degrees is not recommended. The ventilator may overheat at elevated temperatures. An audible and visual alarm will be activated in the event of over temperature. Air conditioning should be employed to keep the room temperature below 40 degrees.

Ambient Relative Humidity in the range of 10 to 100% RH

The ventilator is expected to function correctly at extremes of humidity. High humidity levels may affect the colour of the LCD display. This will return to normal with the humidity.

Atmospheric Pressure in the range of 600mBar to 1100mBar

The ventilator is expected to function correctly between 600 and 1100 mBar.

Supply Voltage Range from –20% to +10% of specified value
The NIPPY S+ will operate normally

Failure of Electrical Power Supply
If a back-up battery is connected, the ventilator will automatically switch to the back-up supply and give an audible and visual indication that it has done so. During total power failure, there will be no output from the machine. The patient will be able to breathe spontaneously through the machine and out through the exhale port. However, some re-breathing of exhaled gas is inevitable. During power/ventilator failure disconnect the patient from the breathing circuit as soon as possible.
The inspiratory / expiratory resistance of the NIPPY S+ and breathing system (NIPPY S+ and circuit) is less than 6cm H_2O @ 60 l/min. This value must not be exceeded when adding attachments or fittings to the breathing circuit.

Accessories and Spares

- A range of nasal and facemasks is available in various sizes. Please contact us for details
- Head Set pt.no. 0563 available in Small, Medium, Large and Extra large. Please add S,M,L OR XL to part number when ordering.
- A range of breathing circuits is available for use with nasal mask, facemask. See Breathing Circuits section, page 17.
- Air Filter Element pt.no. 0584 (pack of 5)
- Inline Bacterial Filter pt.no. 0635. - 99.999% filtration – Resistance, 0.75mB @ 50 l/min – deadspace 55ml – 22mm tapered fittings.
- **These components are for single patient use.**
- External battery, part number 0910

WARNINGS

This ventilator is intended to augment the patient breathing. It **MUST NOT BE USED AS A LIFE SUPPORT VENTILATOR**. It is not intended to provide the total ventilatory requirement of the patient**..**

Do not attempt to pass oxygen into the panel mounted air inlet, or use with flammable anaesthetic agents e.g. Ether etc.

The NIPPY S+ must be connected to a grounded (earthed) electrical supply. The protective earth of the domiciliary electrical installation shall be checked for safe and effective operation

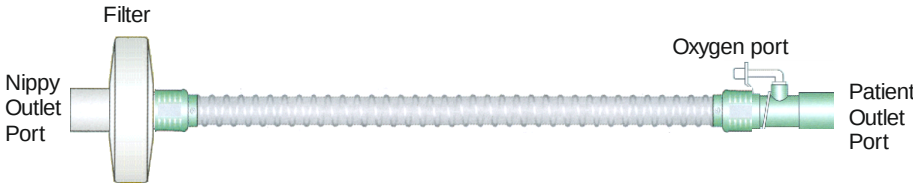
CAUTIONS

- The NIPPY S+ should only be used in accordance with the instructions of the supervising physician. **Personnel using and operating the NIPPY S+ must become familiar with this instruction manual before using the unit.**
- Ensure patient safety through the presence of a trained attendant and an alternative means of ventilation. Consideration should also be given to the use of secondary alarm monitoring.
- The NIPPY S+ should not be placed close to high frequency surgical diathermy, defibrillator or short wave therapy equipment as it may adversely effect the operation.
- The functioning of the ventilator can be adversely affected by electromagnetic interference exceeding the level of 10V/m in the test conditions of EN60601-1-2. . E.g. Mobile telephone operation may adversely affect the operation of the ventilator.
- If the NIPPY S+ is moved from cold surroundings into a well-heated room, condensation may form. Do not operate the unit for at least 2 hours to allow any condensation to evaporate.
- Do not operate the ventilator in direct sunlight.
- Avoid places where there is excessive humidity or dust, which may cause damage to internal parts.
- Keep the NIPPY S+ away from extreme direct heat, such as fires, heating radiators etc., and always allow a 100mm (4.0in) air space around the unit when in use.
- If liquids are allowed to enter the unit, serious damage could occur. If you spill any liquid into the NIPPY S+, consult qualified service personnel.
- Do not place any form of cover over the ventilator, especially near the air intake.
- DO NOT use anti static or electrically conductive tubing.
- Adding extra components / subassemblies to the breathing circuit may cause the pressure, during expiration, at the patient connection port of the breathing circuit to increase.

Using Supplementary Oxygen with the NIPPY S+

If required, supplementary oxygen may be entrained into the breathing circuit up to a maximum of 15 L/minute.

When adding oxygen, fit an entrainment port at the mask / tracheotomy end of the circuit.



Switch on the NIPPY before the oxygen.

When treatment is complete, switch off and **disconnect the oxygen supply**, Switch off the NIPPY and disconnect the breathing circuit. Store the breathing circuit in a clean bag or other suitable container.

DO NOT leave the oxygen connected when not in use. This can cause a build-up of oxygen in, or around the machine

DO NOT block the end of the breathing circuit with oxygen connected.

DO NOT expose oxygen to naked flames.

DO NOT smoke in the vicinity

DO NOT use a gas cooker in the vicinity

DO NOT use a gas, oil or solid fuel heater in the vicinity

Precaution: always follow user instructions when entraining Oxygen.

Maintenance

YOU MUST DISCONNECT THE NIPPY FROM THE MAINS SUPPLY BEFORE ANY MAINTENANCE IS CARRIED OUT

User maintenance is limited to cleaning and visual inspection of the ventilator, the input air filter and the breathing circuit.
The ventilator and the detachable mains cord set should be inspected for signs of external damage weekly. If any damage is evident (particularly to the mains cord set) refer repair to appropriately qualified technical personnel.

DO NOT immerse the ventilator in or spray with water

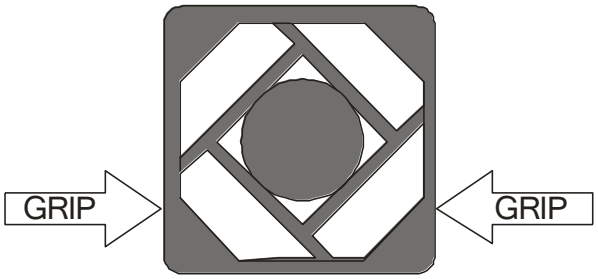
DO NOT use solvent cleaning agents or detergents

DO NOT use abrasive cleaning agents

Mains Power Lead
Before using the NIPPY, inspect the mains lead for damage. Do not use if there is any damage to the plug, socket or the insulation.

Exterior of Case
To clean, wipe the exterior of the case with a soft cloth moistened with water.

Input Air Filter
The input air filter should be inspected weekly. It is located on the rear of the machine.



To remove the filter, grip the filter housing with the thumb and forefinger, across the bottom corners and pull the filter cover away from the ventilator. Remove and inspect the element. If the filter element requires replacement, use only recommended spares (see spares list). The use of any other filtering material may impair the performance of the ventilator.

Never attempt to clean the filter element with solvent cleaning agents.

Do not operate the ventilator unless the input air filter is in place.

User Maintenance Schedule

	Before Use	Daily	Weekly	Monthly
Alarms	Test	Test		
Batteries				Test
Breathing Circuit		Inspect	Replace	
Inlet Filter			Inspect/Replace	
Power Cord	Inspect			

Battery Run Time Test

Perform a run time test as detailed in the battery care section of this manual.

Breathing Circuit Cleaning

The 22mm diameter breathing tube is considered disposable.

Servicing/Repair

Only suitably qualified technically competent personnel should attempt servicing of this ventilator.

To maintain its performance, the ventilator will require periodic servicing at the following intervals: -

Annual electrical safety test, alarm function, calibration, battery condition tests.

10000 hours use. The service reminder symbol will be displayed on screen.

Details of service requirements are contained in the technical manual.

Damage to either the machine or its mains lead must be inspected by competent technical personnel before use.

Technical Information

A technical manual incorporating circuit diagrams and descriptions will be made available, on request, to enable appropriately qualified technical personnel to repair the parts of the equipment designed to be repairable.

Warranty

The NIPPY S+ is covered by a full 12 months parts and labour warranty, provided that the unit is properly operated under conditions of normal use. This warranty does not apply to any unit that has been subjected to misuse or accidental damage, or repaired or modified by unauthorised personnel.

Transportation

When shipping, damage as a result of inadequate packing is the customer's responsibility. Use the original packing materials whenever possible.

In the event of a breakdown or damage to the ventilator, refer servicing or repair to qualified and competent technical personnel.

Factory Service / Repair

Breas Medical Ltd products returned for factory service or repair must have a Return Material Authorisation (RMA) number assigned. This is essential for efficient processing of repairs.

You can obtain your RMA number by calling 01789 293460 with the following information:

1. Unit Model
2. Serial number
3. Your name, address and telephone number
4. Complete description of the malfunction or service required

When the RMA number has been issued, we will arrange for the unit to be collected.

Place the RMA number on the outside of the carton.

The unit must be properly packaged before shipment. Preferably, in the original packaging.

Breas Medical Ltd are not responsible for inbound transit damage.

When enquiring about a returned item, you must quote the RMA number.

Disposal at end of Life

The NIPPY S+ should be disposed of in line with local authority guidelines / regulations.

Spent batteries should be disposed of in line with local authority guidelines / regulations

EMC Information

Guidance and Manufacturer's Declaration – Electromagnetic Emissions:

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Emissions Test	Standard	Electromagnetic Environment- Guidance
RF emissions (radiated) CISPR 11	EN55011	The device 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 (conducted) CISPR 11	EN55011	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network.
Harmonic emissions IEC 61000-3-2	EN61000-3-2	
Voltage fluctuations/Flicker emissions IEC 61000-3-3	EN61000-3-2	

Electromagnetic Immunity:

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment- Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input-output lines	±2 kV for supply mains ±1 kV for input/output lines	Mains power quality should be that of a typical home or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV for common mode	Mains power quality should be that of a typical home or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	>95% dip in Voltage for 0.5 periods @ 230Vac and 100Vac 60% dip in Voltage for 5 periods @ 230Vac and 100Vac 30% dip in Voltage for 25 periods @ 230Vac and 100Vac	>95% dip in Voltage for 0.5 periods @ 230Vac and 100Vac 60% dip in Voltage for 5 periods @ 230Vac and 100Vac 30% dip in Voltage for 25 periods @ 230Vac and 100Vac	Mains power quality should be that of a typical home or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical hospital or home environment.

Electromagnetic Immunity:

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment- Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	**Recommended separation distance:** d = 1.2√P @150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	d = 1.2√P @ 80 MHz to 800 MHz d = 2.3√P @ 800 MHz to 2.5 GHz Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.Where P is the maximum output power rating of the transmitter in watts (W) d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by the proximity of structures, objects, and people.

a: Field strengths from transmitters, such as base stations for radio (mobile/cordless) telephones, 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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as relocating the device.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and This Device:

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

Rated Maximum Power Output of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	d = 1.2 √P	d = 1.2 √P	d = 2.3 √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Typical Power Output of Some Common Transmitters

This list is provided for general guidance. It is not exhaustive or specific. It not intended to replace the findings of an electromagnetic survey.

Power	Notes	Suggested Minimum Separation Distance This is a very approximate guide. If abnormal operation is observed, disregard this figure and take corrective action.
100 kW	Typical transmission power of FM radio station with 50 km range	727m
1 kW = 1000 W	Maximum allowed output RF power from a amateur radio transceiver without special permissions	73m
100 W	Typical maximum output RF power from a amateur radio transceiver	23m
5 W	Typical maximum output RF power from a hand held amateur radio transceiver	5m
4 W	Typical maximum output power for a Citizens' band radio station, (27 MHz) in many countries	4.6m
2 W	Maximum output from a UMTS/3G **mobile phone** (Power class 1 mobiles) Maximum output from a GSM850/900 mobile phone	3.25m
500 mW	Typical cellular phone transmission power Maximum output from a UMTS/3G mobile phone (Power class 2 mobiles)	1.6m
400 mW	Access point for Wireless networking	1m
250 mW	Maximum output from a UMTS/3G mobile phone (Power class 3 mobiles)	1.15m
32 mW	Typical WiFi transmission power in laptops.	400cm
2.5 mW	Bluetooth Class 2 radio, 10 m range	115cm
1.0 mW = 1000 µW	Bluetooth standard (Class 3) radio, 1 m range	7.2cm
100 µW	Typical maximum received signal power (−10 to −30 dBm) of wireless network	2.3cm

NIPPY+ Battery run time test record

Use this table to record the battery run times when performing the monthly battery health test.

Replace the battery when the run time is less than 75% of a new battery or the battery is 2 Years old.

Fully charge the battery, connect the breathing circuit and using your normal settings run the ventilator until the low battery alarm operates. Record the run time in the table.

NIPPY Serial Number:……..

Date	Runtime – Internal battery	Runtime – External Battery If applicable

Locking the settings

Adjustment lock

The settings can be locked to prevent unauthorised adjustment.

To lock	press ◄- and +► buttons simultaneously and hold for 2 seconds.
To unlock	press ◄- and +► buttons simultaneously and hold for 2 seconds.

This prevents adjustment but allows the user to switch the ventilator on and off.

Total lock

The ventilator can be locked to prevent unauthorised adjustment or power off.

To lock	press ◄- and +► and SET buttons simultaneously and hold for 2 seconds.
To unlock	press ◄- and +► and SET buttons simultaneously and hold for 2 seconds.

In this mode, the ventilator must be unlocked before it can be switched off.

This page may be removed before the instruction manual is passed to the user.