

INSTRUCTION MANUAL FOR THE NIPPY VENTILATOR



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NIPPY

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SECTION ONE

FEATURES AND OPERATING GUIDE

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 agent's e.g. Ether etc.

The Nippy 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

Do not use anti static or electrically conductive tubing.

CAUTIONS

General Use

The Nippy should only be used in accordance with the instructions of the supervising physician.

Personnel using and operating the Nippy must become familiar with this instruction manual before using the unit.

High Dependency Patients

Ensure patient safety through the presence of a trained attendant and an alternative emergency unit. Consideration should also be given to the use of secondary alarm monitoring.

Avoid Excessive Electromagnetic interference

The functioning of the Nippy 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.

Avoid High Frequency Equipment

The Nippy should not be placed close to high frequency surgical diathermy, defibrillator or short wave therapy equipment as it may adversely effect the operation.

Avoid sudden changes in temperature

If the Nippy 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.

Avoid Direct Sunlight

Do not operate the ventilator with the unit in direct Sunlight.

Humidity and Dust

Avoid places where there is excessive Humidity or Dust, which may cause damage to internal parts.

Keep away from High Temperatures

Keep the Nippy 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.

Keep away from Magnets

Never bring a Magnet or a magnetised object near the Nippy, as it may adversely affect the performance.

Keep away from Water

Keep the Nippy away from water vessels.

CAUTION: If liquids are allowed to enter the unit, serious damage could occur. If you spill any liquid into the Nippy, consult qualified service personnel.

Do Not Cover the Ventilator

Do not place any form of cover over the ventilator, especially near the air intake.

Mains Cord Set

Only use the Mains Cord Set supplied with the Nippy, as the retaining clip is specially designed for use with the type of connector fitted to this unit.

NIPPY I.P.P.V.

DESCRIPTION

The Nippy is a pressure controlled, intermittent positive pressure ventilator. Ambient air is drawn through a dust filter and compressed by a centrifugal fan. An electronically controlled valve controls output airflow. Air is delivered to the patient through a close fitting nasal mask or a tracheostomy. The output pressure, timing and alarms can be adjusted by controls on the fascia panel. As the airflow is servo controlled, the ventilator is able to compensate for leaks around the nasal mask. If leaks become too great or the patient's mouth opens, and the pressure falls below the pre-set low pressure alarm level, an alarm will sound to indicate the drop in pressure.

Air is delivered to the nasal mask during the inspiratory phase. This may be triggered by the patient's own inspiratory effort or by the ventilator expiratory timer if there is insufficient inspiratory effort. The inspiratory pressure is adjusted with the set pressure control. The inspiratory time is set by the inspiratory time control. At the end of the inspiratory time, the exhalation valve opens and the patient may exhale through the exhalation valve. The next inspiratory effort will trigger the next breath. If the ventilator does not detect an inspiratory effort, the next breath will be initiated by the end of the expiratory time, as set by the exp. time control.

The trigger is activated when the pressure in the mask drops (due to the patient's inspiratory effort) below the level set by the patient trigger control. The inspiratory effort required to trigger the ventilator can be increased by increasing the set trigger level.

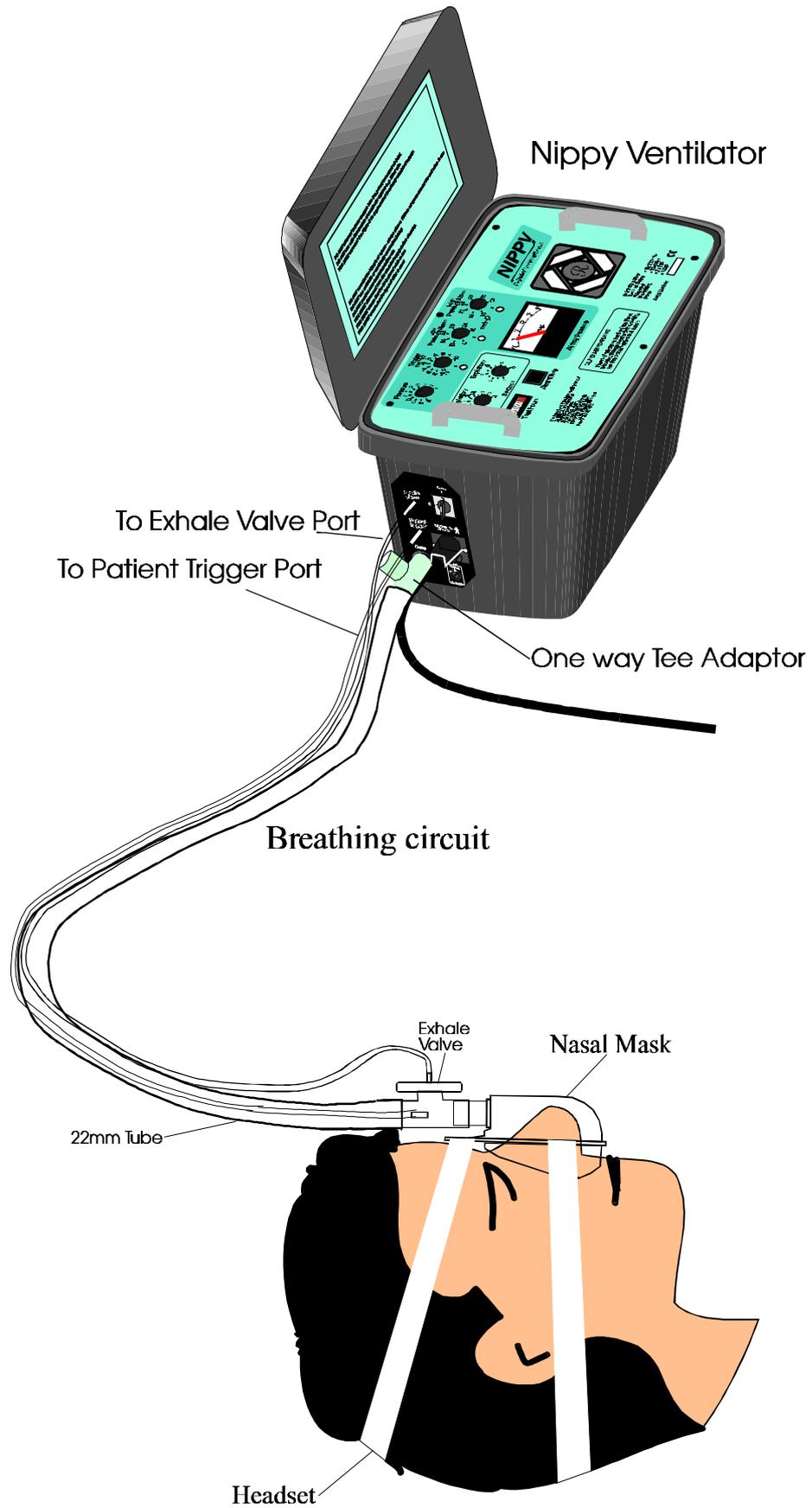
If the electrical power to the ventilator is interrupted, an alarm will sound.

An adjustable low-pressure alarm is provided. The low pressure alarm is activated by the inspiratory pressure failing to reach the level set by the low pressure alarm, due to excessive leakage around the nasal mask, disconnection of the breathing circuit or a malfunction of the machine.

An adjustable high-pressure alarm is provided. If the pressure rises above the set alarm level, due to the patient sneezing etc., the alarm will sound and the excess is vented automatically through the exhalation valve in the breathing circuit.

The high and low-pressure alarms may be muted for approximately 1 minute to allow for setting up of the ventilator.

Nippy Ventilator and Breathing Circuit



Intended Use

The Nippy is designed to augment ventilation in acute or chronic type 2 respiratory failure. **It must not be used for life support.**

Patients who suffer from nocturnal hypoventilation are chiefly those with failure of the respiratory pump, though any concomitant lung disease is also deleterious. The main groups of patients who develop this problem are: -

Patients with respiratory muscle weakness. E.g. diaphragm paresis, myopathies, old polio, motor neurone disease.

Patients with skeletal deformity e.g. scoliosis, thoracoplasty

Improvement of ventilation during sleep by non-invasive techniques in these patients will correct the diurnal abnormalities of blood gases.

Adjustment is carried out by medical staff. The patient only needs to fit the headset and nasal mask and switch on the machine. Patients with special needs, such as disabled or elderly persons, may require assistance when fitting the headset. The medical staff would assess the level of assistance required.

The ventilator is placed by the bedside and plugged into the domestic electricity supply. Providing that a suitable socket outlet exists near the bed, no installation is required.

FEATURES

A. Patient Use

1. Lightweight
2. Quiet
3. Compact fully self-contained unit
4. Designed for long life
5. Battery powered alarm to warn of mains failure
6. Adjustable low and high pressure alarms with LED indicators
7. Alarm mute facility
8. Independent inspiratory and expiratory time settings
9. Electronic control of air valve gives consistent and accurate pressure settings
10. Adjustable patient trigger with trigger indicator
11. Patient trigger sensitivity decreased by a factor of three during the first half of the expiratory period, to prevent accidental re-triggering

B. General Features

1. Operates from domestic 115/230 VAC electrical supply
2. Long life brushless motor
3. Integral analogue pressure meter
4. Trigger response time 60ms

C. Maintenance

1. Minimal user maintenance required. Only checking that the input air filter is clean. Major service at 10,000 hours, therefore maintenance costs are extremely low.
2. Twelve months or 3,000 hour use, parts and labour warranty

SPECIFICATIONS

| | | |
|--|--------------------|--|
| Supply Voltage Switch Selectable | - | 115/230 VAC |
| Supply Frequency | - | 50-60 Hz |
| Maximum Power Consumption | - | 100 V.A. |
| Maximum Input Current | - | 0.43 Amperes @ 230V 0.86 Amperes @ 115V |
| Fuse Ratings- | | |
| | Side Panel mounted | 2 x T 1 A 20mm |
| | Internal | 2 x T 250m A 1 x T 5 A 20mm 2 x 750mA self resetting over current devices |
| Dimensions | | |
| Length | - | 370mm (14.5in) |
| Width | - | 230mm (9.0in) |
| Height | - | 260mm (10.2in) |
| Weight | - | 7.3 Kg (17.5lbs) |
| Ambient Operating Temperature | - | -10° to +32° C (14° to 90° F) |
| Max. Output Pressure | - | 35cm H ₂ O (Working) 40cm H ₂ O (Fault condition) |
| Accuracy of Pressure Reading | - | +/-3% F.S. |
| Max. Output Flow | - | 350 L/min. (unrestricted) |
| Patient Trigger Range | - | -0.5 to -10cm H ₂ O (adjustable) |
| Trigger Response | - | 60 ms |
| Low Pressure Alarm | - | 4 - 40cm H ₂ O (adjustable) |
| High Pressure Alarm | - | 10 - 40cm H ₂ O (adjustable) |
| Inspiratory Time | - | 0.7 - 4 seconds (adjustable) |
| Expiratory Time | - | 1 - 6 seconds (adjustable) |
| Type of protection against electric shock | | Class 1 equipment |
| Degree of protection against electric shock | | Type B applied parts |

| | | |
|----------------------------|---|-----------------------------|
| Mode of operation | - | Continuous |
| IP rating | - | X0 |
| Storage environment | - | -20 to 50°C 10 – 100% RH |

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**

Accessories

1. Soft Series Nasal Mask pt. no. 0565 available in the following sizes:- Small, Medium, Medium narrow, Medium wide, Large, Large narrow. Please add S/M/MN/MW/L or LN to part number when ordering.
2. Head Set pt. no. 0563 available in Regular or Large. Please add R or L to part number when ordering.
3. Breathing circuit consisting of, Lightweight Smoothbore 22mm tubing and two smaller diameter tubes for exhale valve and patient trigger connections pt. no. 0555
4. Exhalation Valve pt. no. 0561
5. 22mm Diameter Tee piece with one way valve pt. no. 0559
6. Air Fiter Element pt. no. 0562 (pack of 5)
7. Inline Bacterial Filter pt. no. 0564

These components are for single patient use.

Operation Under Extreme Conditions

Ambient Temperature in the range of +5 to +50 °C

Between 5 and 40 degrees functioning of the ventilator should not be affected. Operation above 40 degrees is not recommended. The ventilator may overheat and stop running at elevated temperatures. 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.

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

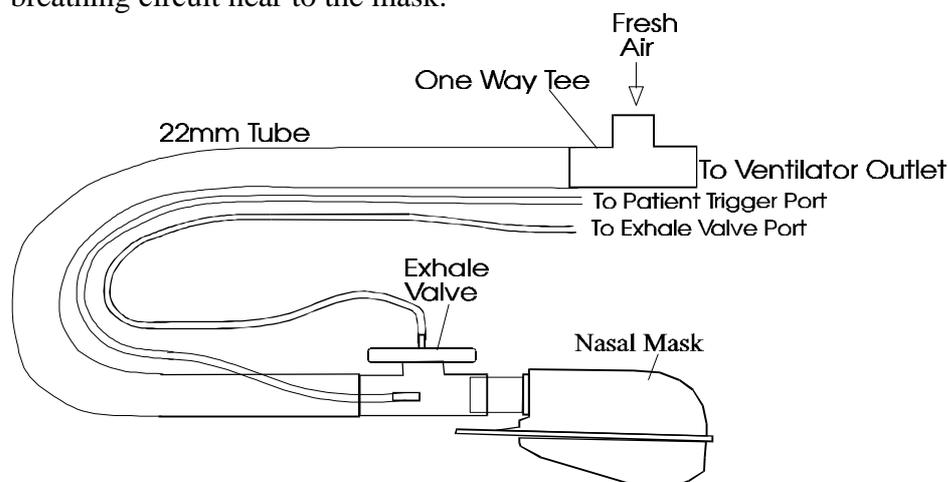
With the voltage select switch set to 230V, the ventilator will function normally at 253 V (Nominal +10%).

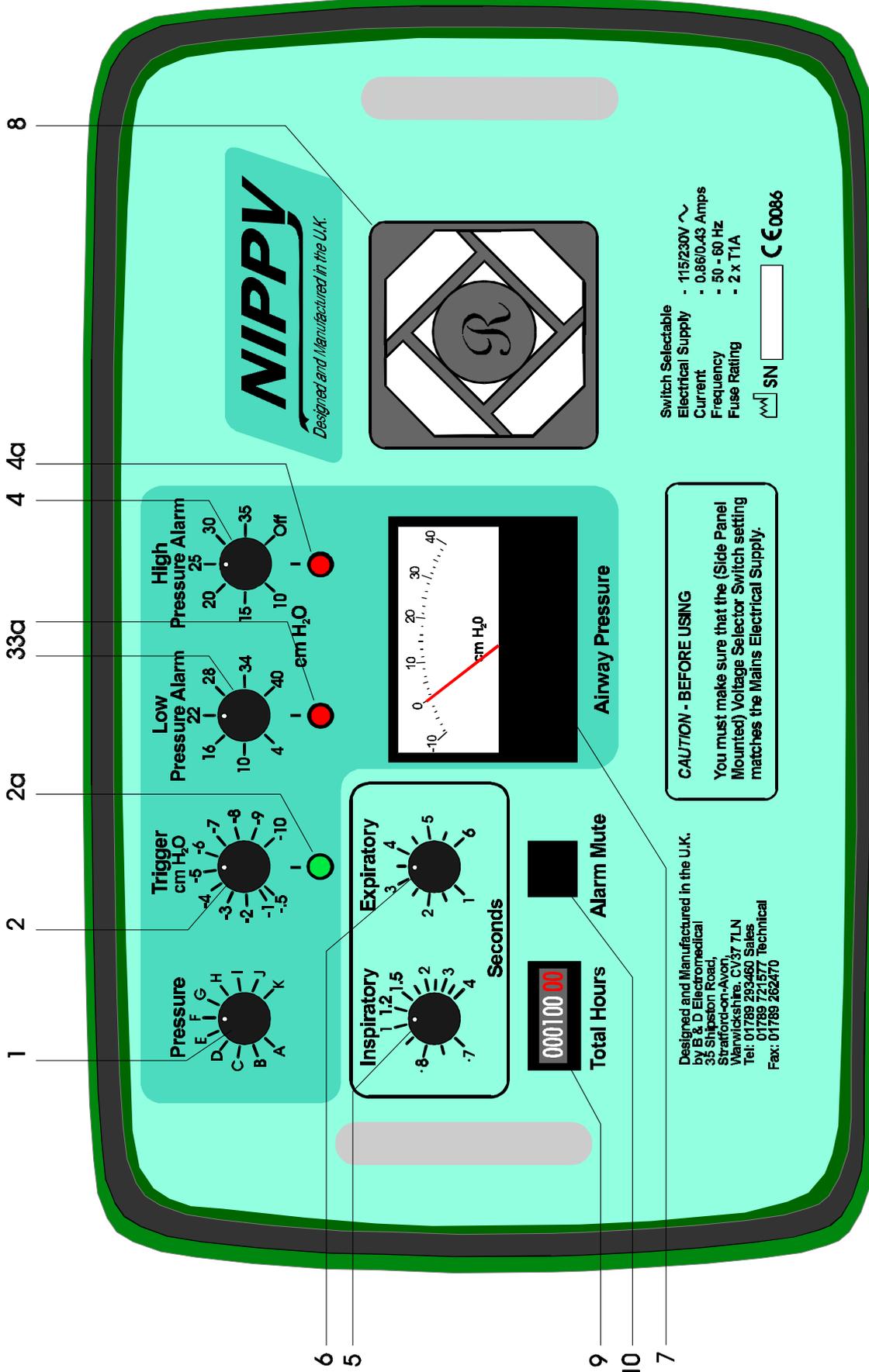
At 207V (Nominal -10%) the maximum working pressure will be limited to approximately 27.5 cm H₂O.

At 184V (Nominal -20%) the maximum working pressure will be limited to approximately 21cm H₂O.

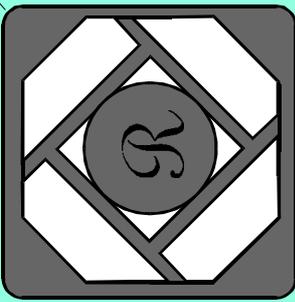
Failure of Electrical Power Supply

During a power failure, there will be no output from the machine. The patient will be able to breathe spontaneously through the mouth and out through the exhale valve. To enable the patient to breathe in and out through the breathing circuit, a “Tee” adapter with a one way valve should be inserted into the breathing circuit. This adapter should be fitted close to the ventilator outlet, with the one way valve arranged such that fresh air can be drawn into the breathing circuit near to the mask.





NIPPY
Designed and Manufactured in the U.K.



Switch Selectable
 Electrical Supply - 115/230V ~
 Current - 0.86/0.43 Amps
 Frequency - 50 - 60 Hz
 Fuse Rating - 2 x T1A

SN 0086

Low Pressure Alarm
 10 16 22 28 34 40 cm H₂O

High Pressure Alarm
 15 20 25 30 35 Off

Airway Pressure
 -10 0 10 20 30 40 cm H₂O

CAUTION - BEFORE USING
 You must make sure that the (Side Panel Mounted) Voltage Selector Switch setting matches the Mains Electrical Supply.

Pressure
 A B C D E F G H I J K

Trigger
 -4 -5 -6 -7 -8 -9 -10 cm H₂O

Inspiratory
 .7 1 1.2 1.5 2 3 4 Seconds

Expiratory
 1 2 3 4 5 6

Total Hours
 000100 00

Alarm Mute

Designed and Manufactured in the U.K.
 by B & D Electromedical
 35 Shipston Road,
 Stratford-on-Avon,
 Warwickshire, CV37 7LN
 Tel: 01789 293460 Sales
 01789 721577 Technical
 Fax: 01789 262470

EXPLANATION OF CONTROLS

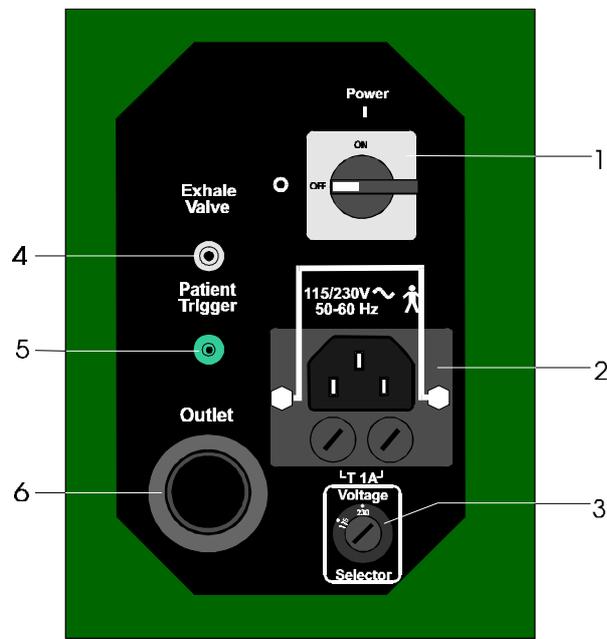
Main Panel

1. **Pressure** - Sets the control pressure. Turn clockwise to increase the pressure (scaled in percentage of maximum).
2. **Trigger** - Sets the negative pressure level at which the patient trigger operates. Turn clockwise to increase the trigger level.
- 2a. **Trigger Indicator** - Green LED indicates when the patient has triggered the ventilator.
3. **Low Pressure Alarm** - Sets the pressure level at which the low-pressure alarm will operate. Turn clockwise to increase the level.
- 3a. **Low Indicator** - Red LED indicates when the low-pressure alarm is activated.
4. **High Pressure Alarm** - Sets the pressure level at which the over pressure alarm will operate. Turn clockwise to increase the level.
- 4a. **High Indicator** - Red LED indicates when the over pressure alarm is activated.
5. **Inspiratory** - Sets inspiratory time (Time to inhale). Turn clockwise to increase the inspiratory time.
6. **Expiratory** - Sets expiratory time (Time to exhale). Turn clockwise to increase the expiratory time.
7. **Pressure Meter** - Reads the pressure of the air in the nasal mask.
8. **Air Filter** - Filters the patient air supply.
9. **Total Hours** - Records the hours in use.
10. **Alarm Mute** - Press to silence the pressure alarm. If the fault condition has not been rectified, the alarm will re-activate after approximately one minute.
11. **Symbols** - See Explanation of Symbols for full details.

EXPLANATION OF CONTROLS

Side Panel Controls/Outlets

1. **Power Switch** - Applies mains power to the unit
O = Off I = On
2. **Power Inlet** - Input mains power connector. Double fused and fitted with connector retaining clip.
3. **Voltage Selector** - Rotary switch 100-120/220-240 VAC. (Operate with a small screwdriver)
4. **Exhale Valve** - Connected to the breathing circuit exhalation valve, to vent the expired gasses.
5. **Patient Trigger** - Connected to the breathing circuit to measure the airway pressure.
6. **Patient Output** - Main airway outlet to breathing circuit/mask.



EXPLANATION OF SYMBOLS

-  - Type B Equipment
-  - Alternating Current
- T** - Time Delay Fuse
- SN** - Serial Number
-  - Date of Manufacture

SETTING UP THE NIPPY FOR NASAL IPPV

Before use Read the Warnings and Cautions on pages 2- 3

YOU MUST make sure that the (side panel mounted) voltage selector switch setting matches the Mains Electrical Supply. If the switch is incorrectly set, the side panel fuses will blow and they will need replacing before the Nippy can be used.

1. Place the Nippy on a suitable firm surface. Open the lid to access the mains cable. Connect the socket to the IEC Connector on the side panel. Plug into the mains power supply.
2. Check that the Input Air Filter is clean in accordance with the instructions in the user maintenance section.
3. Connect the three breathing circuit tubes to the side outlets as indicated. If necessary, a Bacterial filter may be fitted between the patient output and the 22mm diameter breathing tube. The exhale valve control tube is fitted to the silver connector port. The airway pressure pick-off (patient trigger) tube is connected to the green connector port.
4. Connect the mask to the large outlet tubing on the breathing circuit.
Note: Do not fit the mask onto the patient at this point.
5. Carry out alarm tests as described in the user maintenance section.
Note: If any of the alarms fail to operate, **DO NOT USE** until the fault has been rectified.
6. Switch on the Nippy power switch.
The alarm will sound after approximately 12 seconds. Press the mute switch to silence.
7. Set the trigger control to minimum -0.5 cm. (It will only be necessary to increase the trigger setting if used for weaning purposes)
8. It is now necessary to adjust the Inspiratory and Expiratory time controls in order to match the ventilator with the patients breathing pattern. Place your hand over the outlet of the mask and turn the Pressure control clockwise until the Airway Pressure gauge reads approx. 10cm H₂O. Adjust the Inspiratory and Expiratory controls as follows:-

For Adult - Inspiratory 1.2 seconds

Expiratory - 3.0 seconds

For Child - Inspiratory - 0.7 seconds

Expiratory - 1.0 seconds

Position yourself sideways on to the patient, and ensure that the movement of the hand being held over the mask matches the movement of the patient's chest wall as they breathe in and out.

If the patient is breathing more slowly than the ventilator, increase the Expiratory control as necessary

If the patient is breathing rapidly slowly than the ventilator, decrease the Expiratory control as necessary

If the patient's inspiratory time differs from the ventilator, adjust the Inspiratory control as necessary.

9. The patient may now **hold** the mask to the face. Adjust the Pressure control until the patient feels comfortable (the most common setting is 20cm H₂O, unless the patient has a rigid chest wall, in which case the pressure setting would be increased). Fine tune the Inspiratory or Expiratory settings until the patient feels comfortable
10. Having ensured that the patient is comfortable, the mask may now be strapped on using the head set, which can be adjusted to fit by means of Velcro.
11. Finally adjust the Low and High Pressure alarms.

The Low-Pressure alarm should be adjusted to just below the working pressure, as read from the Airway Pressure meter. The alarm will sound if the patient becomes disconnected from the machine.

The High-Pressure alarm should be set by turning the control counter-clockwise until it sounds. Then, very gradually, turn clockwise until the alarm is silenced. (This should be within 1 or 2 cm of peak reading of the airway pressure.)

CAUTION: YOU MUST close the lid when the Nippy is in use to prevent accidental alteration of the control settings and to protect the Nippy from ingress of liquids.

BEFORE SWITCHING OFF always disconnect the patient from the Nippy, to avoid any discomfort from the continuous blowing which lasts for 20 seconds after the unit has been turned off.

Fig 1. Timing Diagram

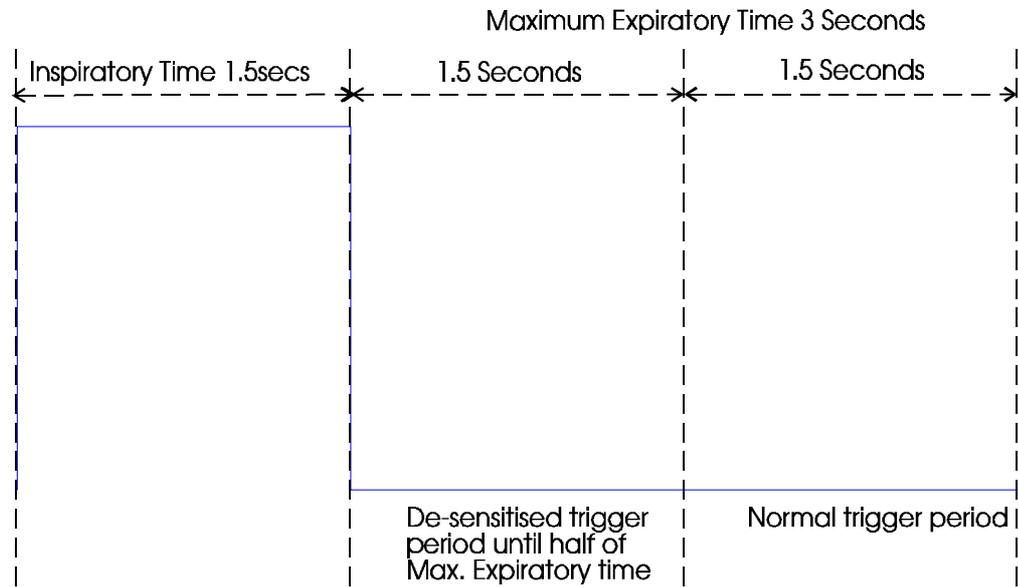
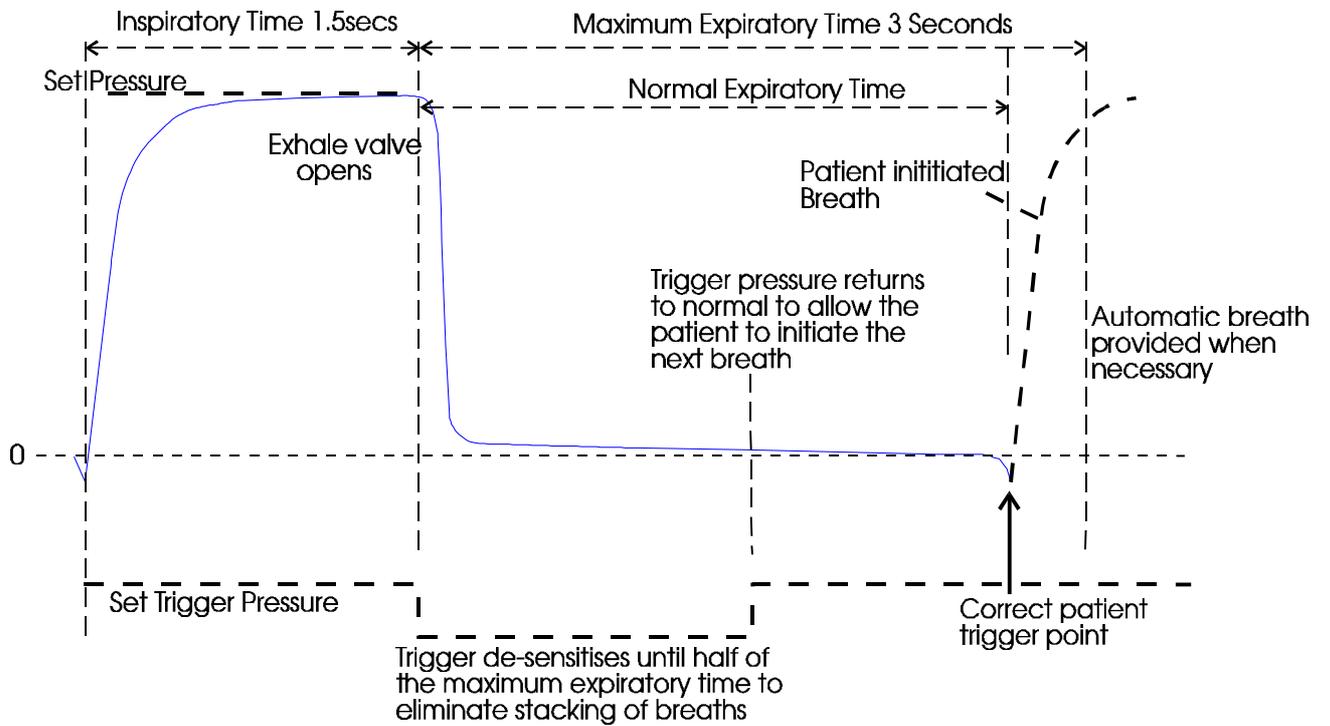


Fig 2. Example of Patient Trigger/Breath Cycle



Patient Triggered Operation See Figs. 1 and 2.

When the patient starts to inhale, the pressure measurement circuit detects the resulting depression in the nasal mask. When the trigger level (as set on the Trigger control) is reached, the ventilator will provide air to the nasal mask at the required pressure (as set by the Pressure control). **If the patient fails to trigger the ventilator, the expiratory timer will 'take over' and the next breath will be initiated at the end of this period (as set by the Expiratory Time control).** To prevent 'stacking of breaths', the trigger level is increased three fold during the first half of the maximum expiratory time.

Example: If the trigger level is set to minus 1cm of water and the Exp Time is set to 3 seconds, the trigger level will rise to 3cm of water for the first 1.5 seconds of the expiratory period, thus making it difficult for the patient to trigger the ventilator accidentally, immediately after inhaling.

The trigger facility is not disabled during this period in case the patient requires a breath.

After half of the expiratory time has elapsed, the trigger level returns to that set by the Set Trigger control and the ventilator is ready to trigger again.

Timed Operation See Figs. 1 and 2.

If the patient trigger is not required, the Set Trigger control should be set to maximum (10 cm) and the Exp Time control to the patients normal expiratory time.

The Expiratory Time Control

The Exp control should be set so that the end of the patient's expiration falls in the middle of the latter half of the expiratory time setting. The patient's normal expiratory time is equal to three quarters of the expiratory time setting.

Example: Patient's normal expiratory time is 2.25 seconds. If the Exp Time control is set to 3 seconds, the trigger level will be high for the first 1.5 seconds and normal for the remaining 1.5 seconds. The patient will therefore be able to trigger the ventilator at his normal time +/- 0.75 seconds.

Alarm Conditions/Tests

Mains Fail Alarm

If the mains power to the Nippy fails, the unit alarm will operate immediately. Turn off the mains switch to silence the alarm.

To Test To ensure that the mains failure alarm is operating correctly, disconnect the Nippy from the mains supply and set the mains power switch to ON. The alarm should then sound, but no LED's will light. After testing the Mains Alarm function, switch off the unit and re-connect to the mains supply, but do not switch on at this stage.

Low Pressure Alarm

When the set airway pressure is not achieved during inspiration or if the breathing circuit becomes disconnected an alarm will sound and the red LED will light.

To Test To ensure that the Low Pressure Alarm is operating correctly, set the high pressure alarm control to 40cm H₂O and the low pressure alarm control to 20cm H₂O. Set the Pressure control to minimum. Switch on the unit and after approximately 12 seconds the alarm and the set low LED will activate. Place thumb in mask partially occluding the inlet, gradually turn up the pressure control until the pressure exceeds 20cm H₂O. The alarm and LED will cease. After testing - switch off.

High Pressure Alarm

When the set airway pressure is exceeded during inspiration the exhale valve will open, the alarm will sound and the red LED will light.

To Test To ensure that the High Pressure Alarm is operating correctly, set the low pressure alarm control to 4cm H₂O, place thumb in mask partially occluding the inlet. **Do not cover completely.** Set the set high pressure alarm control to 20cm H₂O. Switch the unit on and gradually turn up the pressure control until the pressure exceeds 20cm H₂O. The alarm should then sound, and the set high LED will light while the airway pressure is above 20cm H₂O. The exhale valve will open to dump the excess pressure while the alarm is on and close when the pressure falls below 20cm H₂O. Thus having the effect of modulating the pressure at the set high value, and causing the alarm to bleep intermittently as the pressure rises and falls about the set high level.

In both of the above Low and High Pressure alarm conditions, the alarm may be silenced for approximately 60 seconds by pressing the Mute Switch.

SECTION TWO

USER MAINTENANCE

WARRANTY

The Nippy 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 which 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.
See Factory Service / Repair Section**

USER MAINTENANCE

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

User maintenance is limited to cleaning of the ventilator, the input air filter and the breathing circuit.

DO NOT immerse in or spray with water

DO NOT use solvent cleaning agents or detergents

DO NOT use abrasive cleaning agents

Mains Power Lead

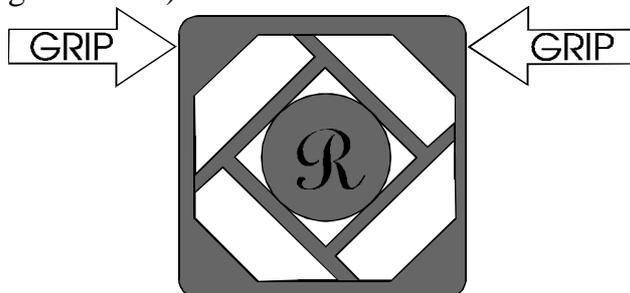
Before using the Nippy, inspect the mains lead for damage. Do not use if there is any damage to the plug, socket or the insulation.

Exterior of Case

To clean, wipe the exterior of the case with a soft moist cloth.

Input Air Filter

The input air filter should be inspected weekly. It is located on the fascia panel (lift lid to gain access).



To remove the filter, grip the filter housing with the thumb and forefinger, across the top corners and pull the filter cover away from the ventilator. Remove and inspect the element.

To clean the filter element, wash gently in tepid, soapy water. Rinse and allow the element to **dry**. When the element is **dry**,

place it back in the filter housing and refit the cover.

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.

Breathing Circuit Cleaning.

The exhalation valve and 22mm smooth-bore tubing may be cleaned by immersing in an anti-microbial sterilising agent or in an autoclave. The exhale valve should be autoclaved at 121°C at 15p.s.i. for 15 minutes and the smooth-bore tubing at 260°C for 10 minutes.

The two small diameter tubes are considered disposable. If required they and the Nasal Mask may be cleaned by immersing in an anti-microbial sterilising agent.

Servicing

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: -

12 months or 3000 hours use, as shown on the hours counter.

2 years or 6000 hours use.

10000 hours use.

Details of service requirements are contained in the technical manual.

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.

Factory Service / Repair

B & D Electromedical 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.

B & D Electromedical are not responsible for inbound transit damage.

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

International Standards

IEC 601-1 1990 / IEC60601-2-12 1988

Safety of Electromedical Instruments, General Requirements

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

B & D Electromedical declares that
the Nippy Ventilator
complies with the following EMC standards

EN60601-1-2 1993

Test results available for review at B & D Electromedical



Notes