0346H

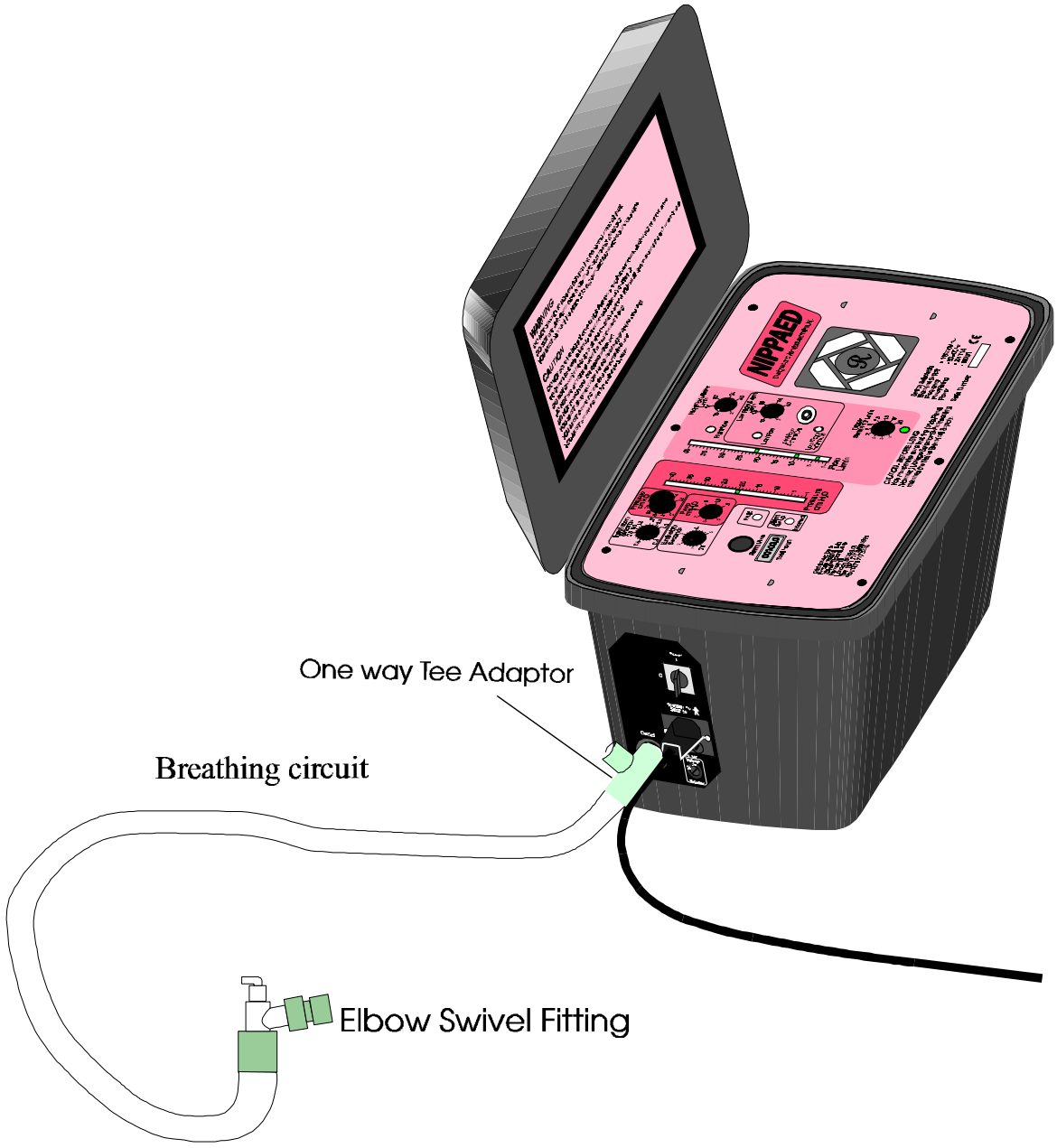
INSTRUCTION MANUAL FOR THE NIPPAED POSITIVE PRESSURE VENTILATOR

Version 9, November 2001

B & D Electromedical
35 Shipston Road,
Stratford–on-Avon,
Warwickshire. CV37 7LN
Tel: 01789 293460 Sales
01789 721577 Technical Support
Fax: 01789 262470

NIPPAED

INSTRUCTION MANUAL INDEX


NIPPAED
One way Tee Adaptor
Breathing circuit
Elbow Swivel Fitting

Nippaed I.P.P.V.

DESCRIPTION

The Nippaed is a pressure controlled, intermittent positive pressure ventilator, for paediatric use. 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 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 in the breathing circuit. If leaks become too great or the patient's mouth opens, and the flow becomes greater than the pre-set high flow alarm level, an alarm will sound. The airway pressure alternates between a set inspiratory level and a standing PEEP level.

Air is delivered to the tracheostomy during the inspiratory phase and at a lower pressure during expiration. Inspiration 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 and the end expiratory pressure (PEEP) is adjusted with the set PEEP control.

The inspiratory time is set by the inspiratory control. At the end of the inspiratory time, the patient may exhale against the PEEP flow. 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 expiratory control.

When the patient makes an inspiratory effort the resulting increase in flow is detected by the ventilator, triggering the inspiratory phase. 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 flow alarm is provided. The low flow alarm is activated by the inspiratory flow failing to reach the level set by the low flow alarm, due to a blockage in the breathing circuit or tracheostomy. The low flow alarm may be switched off if the patient uses a nasal mask. DO NOT switch off the low flow alarm if the patient uses a tracheostomy or full face mask. Once the prescibing physician has selected the appropriate function, the key should be removed, to prevent unauthorised access to this function.

An adjustable high-flow alarm is provided. If the flow rises above the set alarm level, due to leakage or disconnection of the breathing circuit, the alarm will sound.

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

Alarms are also provided for incorrect set-up of alarm levels and machine fault.

<u>Nippaed must be prescribed by, and used only under the supervision of a qualified physician.</u>

Intended Use

The Nippaed is designed to augment ventilation in acute or chronic type 2 respiratory failure. It must not be used for life support.
Patients who suffer form 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.

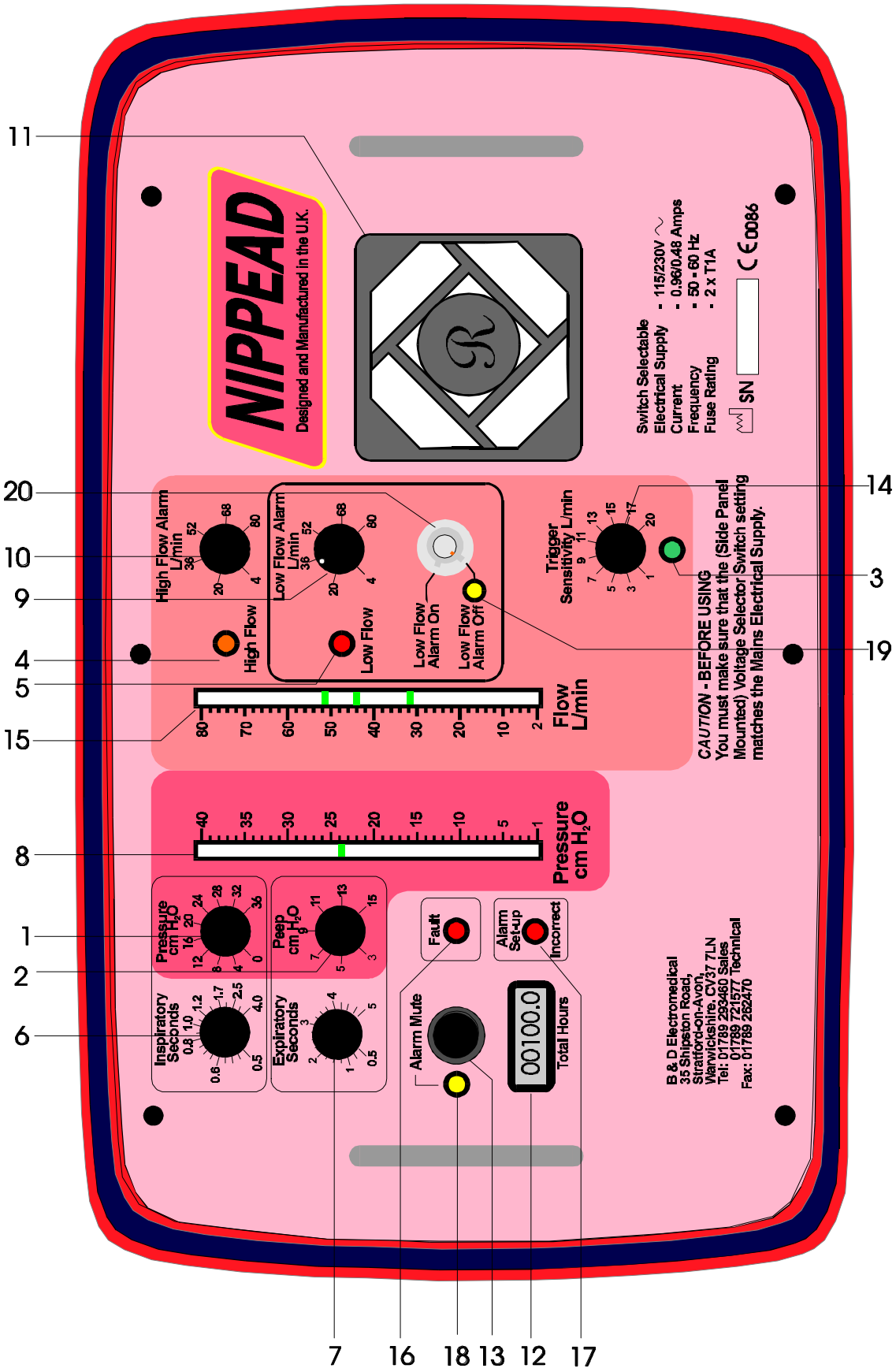
Patients with skeletal deformity e.g. scoliosis, thoracoplasty

Improvement of ventilation during sleep in these patients will correct the diurnal abnormalities of blood gases.

Adjustment is carried out by medical staff. The carer only needs to fit the swivel coupling and switch on the machine. Patients with special needs, such as the disabled, may require assistance. 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

1. Compact fully self-contained unit
2. Mains supply failure alarm
3. High and Low flow alarms with LED indicator (to warn of disconnection or blockage)
4. Alarm mute facility
5. Electronic control of air valve gives consistent and accurate pressure settings
6. Adjustable flow trigger with trigger indicator
7. Operates from domestic 115/230 VAC electrical supply
8. Long life brushless motor
9. Integral dual LED bargraph pressure and flow displays
10. Trigger response typically 25ms
11. Very low maintenance requirements, therefore maintenance costs are extremely low.
12. Twelve months or 3000 hours parts and labour warranty


NIPPEAD
Designed and Manufactured in the U.K.
Switch Selectable
Electrical Supply - 115/230V
Current - 0.96/0.48 Amps
Frequency - 50 - 60 Hz
Fuse Rating - 2 x T1A
SN
CE 0086
High Flow Alarm L/min
Low Flow Alarm L/min
High Flow
Low Flow
Low Flow Alarm On
Low Flow Alarm Off
Trigger Sensitivity L/min
Flow L/min
CAUTION - BEFORE USING
You must make sure that the (Side Panel Mounted) Voltage Selector Switch setting matches the Mains Electrical Supply.
Pressure cm H2O
Pressure cm H2O
Peep cm H2O
Inspiratory Seconds
Expiratory Seconds
Fault
Alarm Set-up
Incorrect
Alarm Mute
00100.0
Total Hours
B & D Electromedical
35 Shipston Road,
Stratford-on-Avon,
Warwickshire. CV37 7LN
Tel: 01789 293460 Sales
01789 721577 Technical
Fax: 01789 262470
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17

EXPLANATION OF CONTROLS

Main Panel

1.	**Pressure**	-	Sets the control pressure. Turn clockwise to increase the pressure (scaled in cm H_2O)
2.	**Peep**	-	Sets the PEEP pressure. Turn clockwise to increase the pressure (scaled in cm H_2O)
3.	**Trigger Indicator**	-	Green LED indicates when the patient has triggered the ventilator.
4.	**High Alarm Indicator**	-	Red LED indicates when the high flow alarm is activated
5.	**Low Alarm Indicator**	-	Red LED indicates when the low flow alarm is activated.
6.	**Inspiratory**	-	Sets inspiratory time (time to inhale). Turn clockwise to increase the inspiratory time.
7.	**Expiratory**	-	Sets the expiratory time (Time to exhale). Turn clockwise to increase the expiratory time.
8.	**Pressure Display**	-	Reads the pressure of the air in the breathing circuit.
9.	**Set Low Flow Alarm**	-	Sets the flow level at which the low flow alarm will operate. Turn clockwise to increase the level.
10.	**Set High Flow Alarm**	-	Sets the flow level at which the high flow alarm will operate. Turn clockwise to increase the level.
11.	**Air Filter**	-	Filters the patient air supply.
12.	**Total Hours**	-	Records the hours in use.
13.	**Alarm Mute**	-	Press to silence the flow alarm. If the fault condition has not been rectified, the alarm will re-activate after approximately one minute.
14.	**Trigger Sensitivity**	-	Controls inspiratory flow required to trigger a breath. Turn clockwise to decrease sensitivity.
15.	**Flow/Alarm Display**	-	Reads the flow rate of the air in the breathing circuit and the high and low alarm levels
16.	**Fault Indicator**	-	Indicates an internal machine fault.
17.	**Set-up Incorrect Indicator**	-	Indicates incorrectly set alarm levels. i.e.:- The Low flow alarm has been set higher than the High level flow
18.	**Mute Indicator**	-	Lights when alarm is silenced by Mute switch
19.	**Low Flow Alarm Off Ind**		Illuminates when Low Flow Alarm is turned off
20.	**Low Flow Alarm Switch**		Switches Low flow alarm on or off

EXPLANATION OF CONTROLS

Side Panel Controls/Outlet

1. Power Switch - Applies mains power to the unit

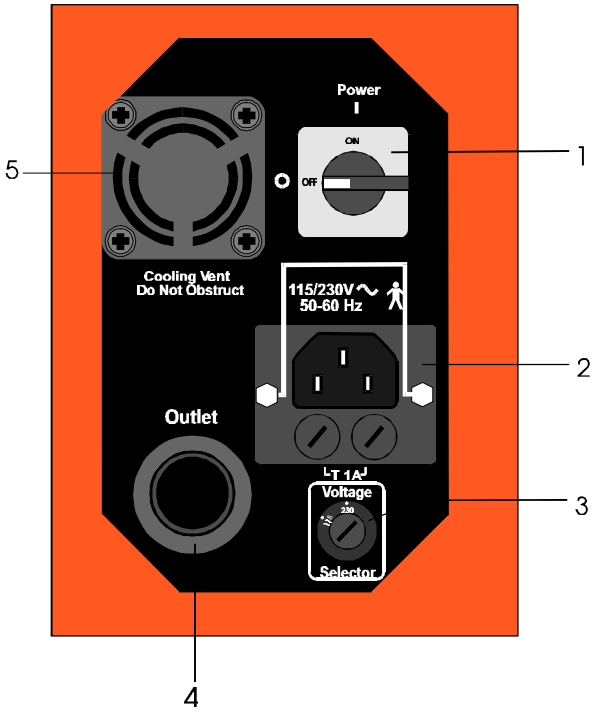
O = Off **I** = On

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

3. Voltage Selector - Rotary switch 115/230 VAC.
(Operate with a small screwdriver)

4. Patient Output - Main airway outlet to breathing circuit/mask.

5. Cooling Fan Reduces internal air temperature.



EXPLANATION OF SYMBOLS

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

SETTING UP THE NIPPAED

FOR IPPV

Before use Read the Warnings and Cautions on pages 17- 18

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 Nippaed can be used.

1. Place the Nippaed on a clean and level 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 on page 18.

3. Connect the breathing circuit tube to the outlet. It is recommended that a Bacterial filter be fitted between the patient output and the 15mm diameter breathing tube.

4. Carry out alarm tests as described in user maintenance section. **Note:** If any of the alarms fail to operate, **DO NOT USE** until the fault has been rectified.

5. Switch on the Nippaed power switch.

6. The alarm will sound after approximately 12 seconds. Press the mute switch to silence the alarm for 1 minute.

7. Turn 'Set Low' flow alarm control to approx. 4 l/min and the Set High flow alarm control to 80 l/min as a starting point.

8. Turn the 'Pressure' control knob clockwise to set the airway pressure and observe the reading on the pressure display. 10 to 20cm H_2O will suit most patients. Set the PEEP control to minimum (3 cm H_2O).

   CAUTION: Avoid starting off with the pressure too high.

9. Set the Inspiratory and Expiratory times to match the ventilator in current use. (In patients without airflow obstruction, it would be reasonable to start with an inspiratory time of 0.5 seconds and an expiratory time of 0.5 seconds, giving a respiratory rate of 60 breaths/min). For the smallest babies, (up to 3 kg) increase of size and weight reduces the breathing rate.

10. Attach the swivel elbow to the tracheotomy fitting on the patient. Connect an oximeter to the patient and observe the Oxygen saturation. Oxygen may be added via the fitting on the breathing circuit.

12. Adjust either Pressure, PEEP, Inspiratory or Expiratory and trigger sensitivity until the ventilator is raising O_2 and decreasing CO_2 Set flow alarms as follows:-

Note the peak flow rate reading on the flow display

Adjust the set High Alarm control so that the reading on the display is approx. 10-20 l/min higher than the peak flow reading. Do not set the high alarm level too close to the peak flow. An allowance should be made to allow the patient to take a deeper breath. Approximately 10-20 l/min is usually sufficient. Once set, remove the mask and ensure that the alarm operates. Refit the mask when you are satisfied that the disconnect alarm is working correctly.

Adjust the set Low Alarm control so that the reading on the display is a little lower than the peak flow rate reading. This setting should be checked when the patient is asleep, as the reduction in flow may cause the alarm to operate.

Low Flow Alarm Switch

Some patients using a nasal mask may experience "false alarms" due to intermittent mouth breathing. In these cases the alarm can interrupt the patients sleep. The alarm may be switched off if it is not required, using the key switch provided. The decision to switch off the low flow alarm is the responsibility of the prescribing physician. *Once set, the key must be removed to prevent unauthorised access to this function.*

NEVER switch off the low flow alarm if the patient has a tracheostomy or a full-face mask or in any other situation where blockage of the airway may cause a safety hazard.

CAUTION: **You must** close the lid when the Nippaed is in use to prevent accidental alteration of the control settings and to protect the Nippaed from ingress of liquids. This also muffles the machine and air noise.

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

Patient Triggered Operation

When the patient starts to inhale, the inspiratory flow is detected and 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 is disabled during the inspiratory period and the first 200 milliseconds of the expiratory time.

The Expiratory Time Control

The control should be set to a value slightly longer than the patients normal expiratory time.

Timed Operation

If the patient trigger is not required, set the Expiratory Time control to the patients normal expiratory time. Adjust the trigger sensitivity control to 20 L/min.

Alarm Conditions/Tests

High Flow (Disconnect) Alarm

If a leak occurs in the breathing circuit or it becomes disconnected the resulting increase in flow will be detected by the high flow alarm circuit and the alarm will be activated.

To Test To ensure that the High Flow alarm is operating correctly, switch on the Nippaed, set the pressure control to 20cm. Turn the set Low Flow control to 40 l /min and turn the set high flow control to obtain a reading of approx. 60 l/min. Whilst reading the flow, partially occlude the outlet so that the flow display reading peaks at approximately 50 l/min. In this condition the alarm should **not** operate.

Reduce the flow restriction so that the flow display peak reading rises above 60 l/min. The alarm and High indicator should operate.

Low Flow (Blockage) Alarm

If the Low flow Alarm has been switched off, there is no need to test this function.

If a blockage occurs in the patients airway or the breathing circuit the resulting drop in flow will be detected by the low flow alarm circuit and the alarm will be activated.

To Test To ensure that the Low Flow alarm is operating correctly, switch on the Nippaed, set the pressure control to 20cm. Turn the set High Flow control to maximum and turn the set low flow control to obtain a reading of approx. 30 l/min. Whilst reading the flow, partially occlude the outlet so that the flow display reading peaks at approximately 40 l/min. In this condition the alarm should **not** operate.

Increase the flow restriction so that the flow display peak reading drops below 30 l/min. After approximately 10 seconds the alarm and Low indicator should operate.

Alarm Set-up Incorrect Alarm

If the flow alarm levels are incorrectly set, in such a way that the low flow level is higher than the high flow level, the alarm and the Set-up incorrect indicator will be activated.

To Test To ensure that the Set-up Incorrect alarm is operating correctly, switch on the Nippaed. Turn the set High Flow control to 40 l/min and turn the set low flow control to 42 l/min. In this condition the alarm should operate and the Set-up Incorrect indicator should light.

In all of the above flow alarm conditions, the alarm may be silenced for approximately 60 seconds by pressing the Mute Switch.

Mains Fail Alarm

If the mains power to the Nippaed 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 Nippaed from the mains supply and set the mains power switch to ON. The alarm should then sound, but no LED 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.

The Mute switch has no effect on the mains fail alarm.

Fault Alarm

The fault alarm indicates a fault in the machine.

If this indicator lights at any time during operation, DO NOT continue to use the Nippaed. The Nippaed MUST be referred to suitably qualified technical personnel for investigation/repair.

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

SPECIFICATIONS

Supply Voltage Switch Selectable	-	115/230 V alternating current
Supply Frequency	-	50-60 Hz
Maximum Power Consumption	-	110 V.A. (Volts. Amps)
Maximum Input Current	-	0.48 Amperes @ 230V
		0.96 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 semiconductor over current devices
Dimensions Length	-	370mm (14.5in)
Width	-	230mm (9.0in)
Height	-	260mm (10.2in)
Weight	-	7.3 Kg (16.5lbs)
Ambient Operating Temperature	-	32^{o} C 90^{o}F Max
Max. Output Pressure	-	36cm H_2O
		(40cmH_2O fault condition)
Calibrated Pressure Range	-	0 - 36cm H_2O
Accuracy of Pressure Reading	-	+/- 3.0% F.S.
Max. Output Flow	-	350 L/min. (unrestricted)
Calibrated Flow Range	-	0 - 80L/min
Accuracy of Flow Reading-	-	+/- 10% F.S.
Trigger	-	1 - 20 L/min (adjustable)
Low Flow Alarm	-	4 - 80 L/min (adjustable)
High Flow Alarm	-	4 - 80 L/min (adjustable)
Inspiratory Time	-	0.5- 4 seconds (adjustable)
Expiratory Time	-	0.5 - 5 seconds (adjustable)

Type of protection against electric shock	**-**	Class 1 equipment
Degree of protection against electric shock	**-**	Type B to IEC 601-1
Mode of operation	**-**	Continuous
IP rating	-	X0
Storage environment	-	-20 to 50^{O}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

International Standards

EN60601-1 1990, IEC 60601-2- 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 Nippaed Ventilator

complies with the following EMC standards

EN60601-1-2: 1993

Test results available for review from B & D Electromedical

CE

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

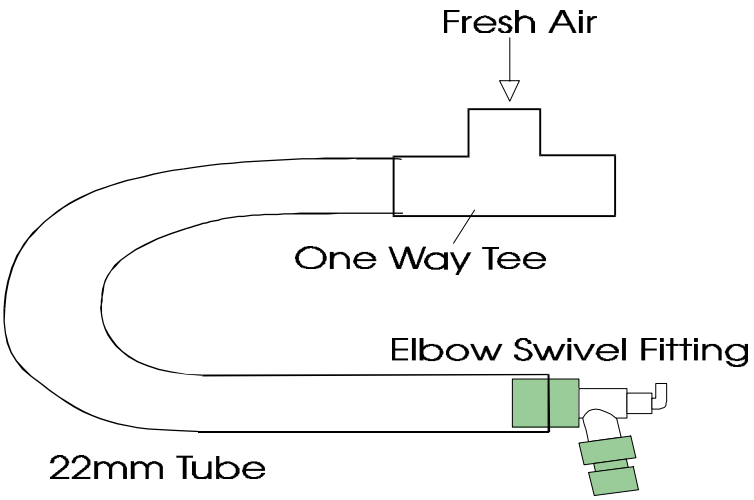
The ventilator is expected to function correctly between 600 and 1100 mBar.

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 28.5 cm H_2O.
At 184V (Nominal –20%) the maximum working pressure will be limited to approximately 19cm H_2O, and the bargraph displays may show an erratic reading.

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 port. 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 with the one way valve arranged such that fresh air can be drawn into the breathing circuit.



Accessories and Spares

1. 15mm Swivel Elbow Coupling pt. no. 0632
2. Breathing Circuit pt. no. 0628, or 0629 (Heated).
3. 22mm Diameter Tee piece with one way valve pt. no. 0634
4. Air Fiter Element pt. no. 0584 (pack of 5)
5. Inline Bacterial Filter pt. no. 0635

These components are for single patient use.

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 Nippaed 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 Nippaed should only be used in accordance with the instructions of the supervising physician. **Personnel using and operating the Nippaed 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 High Frequency Equipment

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

Avoid Excessive Electromagnetic Interference

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.

Avoid Sudden Changes In Temperature

If the Nippaed 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 Nippaed 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 Nippaed, as it may adversely affect the performance.

Keep Away From Water

Keep the Nippaed away from water vessels.

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

Do Not Cover the Ventilator

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

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

input air filter and the breathing circuit.
The Ventilator and the detachable mains cord set should be inspected for signs of

set) refer repair to appropriately qualified technical personnel.

DO NOT

DO NOT use solvent cleaning agents or detergents

use abrasive cleaning agents

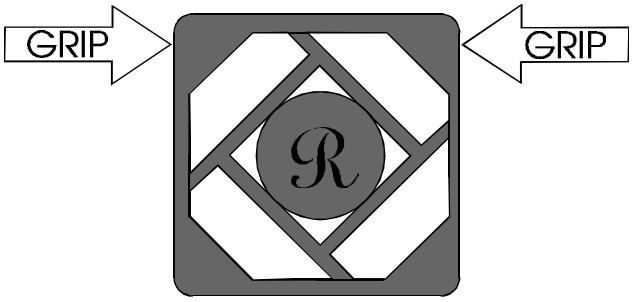
Mains Power Lead

Before using the Nippaed, inspect the mains lead for damage. Do not use if there is

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



To remove the filter, grip the filter housing with the thumb and forefinger,

filter cover away from the ventilator. Remove and inspect the element.

gently in tepid, soapy water. Rinse and allow the element to . When the element is **dry**
housing and refit the cover.
If the filter element requires replacement, use only recommended spares (see

the Ventilator.

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

operate the ventilator unless the input air filter is in place.

Breathing Circuit Cleaning

The 22mm diameter breathing tube is considered disposable. If required it may be cleaned by immersing in an anti-microbial sterilising agent, such as Milton fluid.

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.

5000 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.

WARRANTY

The Nippaed 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

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.