

INSTRUCTION MANUAL FOR THE NIPPY 3+ POSITIVE PRESSURE VENTILATOR

This book must be kept with the machine



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NIPPY 3+

INSTRUCTION MANUAL INDEX

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NIPPY 3+ Positive Pressure Ventilator

The Nippy 3+ is a pressure controlled, positive pressure ventilator. It compresses ambient air and delivers it to the patient through a close fitting nasal mask or a tracheotomy. The output pressure, timing and alarms can be adjusted by controls on the fascia panel. The Pressure, estimated Tidal Volume, Rate 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 four buttons to the left of the display. The four buttons to the right of the display adjust the alarms and provide access to more advanced features and adjustments (accessed via a menu).

For greater safety and convenience the Nippy 3+ 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.

There are 4 modes of ventilation:-

- | | |
|-------------------------|--|
| CPAP | (Continuous Positive Airway Pressure) Constant positive pressure is applied via the mask. No respiratory support is given in this mode. |
| Pressure Support | <p>IPAP (Inspiratory positive airway pressure) and EPAP (Expiratory positive airway pressure) are set by the physician. The ventilator augments the patient's spontaneous breathing. Ti is limited to half of the back-up period, up to a maximum of 1.5 seconds and minimum of 0.7 seconds.</p> <p>If the patient's breathing rate falls to the back-up rate, a timed breath (Ti back-up) is initiated at the back-up rate.</p> |
| Pressure Control | IPAP, EPAP and Ti are set by the physician. A timed inspiration is cycled by the patients inspiratory effort. Adjustable back-up rate takes over in the absence of inspiratory trigger. |
| IPPV | IPAP and Ti are set by the physician. A timed inspiration is cycled by the patient's inspiratory effort. Patient exhales to atmosphere via an exhale valve fitted in the breathing circuit. EPAP is not used in this mode. Adjustable back-up rate takes over in the absence of inspiratory trigger. |

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 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.

Breathing Circuit Malfunction This alarm warns of a malfunction of the exhale valve in the IPPV mode circuit.

High Flow alarm An adjustable alarm is provided to warn of excess inspiratory flow. This is activated when the inspiratory flow exceeds the set high flow alarm level for 5 seconds. An audible and visual alarm will operate.

Low Flow alarm An adjustable alarm is provided to warn of insufficient inspiratory flow. This is activated when the inspiratory flow fails to achieve the set low flow alarm level for 10 seconds. 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.

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

Low Internal Alarm/Memory 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.

Estimated Tidal Volume

The estimated tidal volume is a calculated value, based on time and calibrated flow values. The constant leak through the breathing circuit exhalation port is subtracted from this calculation to give a reasonably accurate estimation of tidal volume. The estimated tidal volume is displayed above the bargraph display.

Inspiratory Trigger

The Nippy 3+ 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

The expiratory trigger is used in Pressure Support mode only. 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 10 being the most difficult.

Intended Use

The Nippy 3+ is designed to augment ventilation in adults with acute or chronic type 2 respiratory failure.

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.

Nippy 3+ may be used to treat patients via:-

- ❖ **Tracheotomy**
- ❖ **ET Tube**
- ❖ **Full Face Mask**
- ❖ **Nasal Mask / Nasal Pillows**

IMPORTANT!

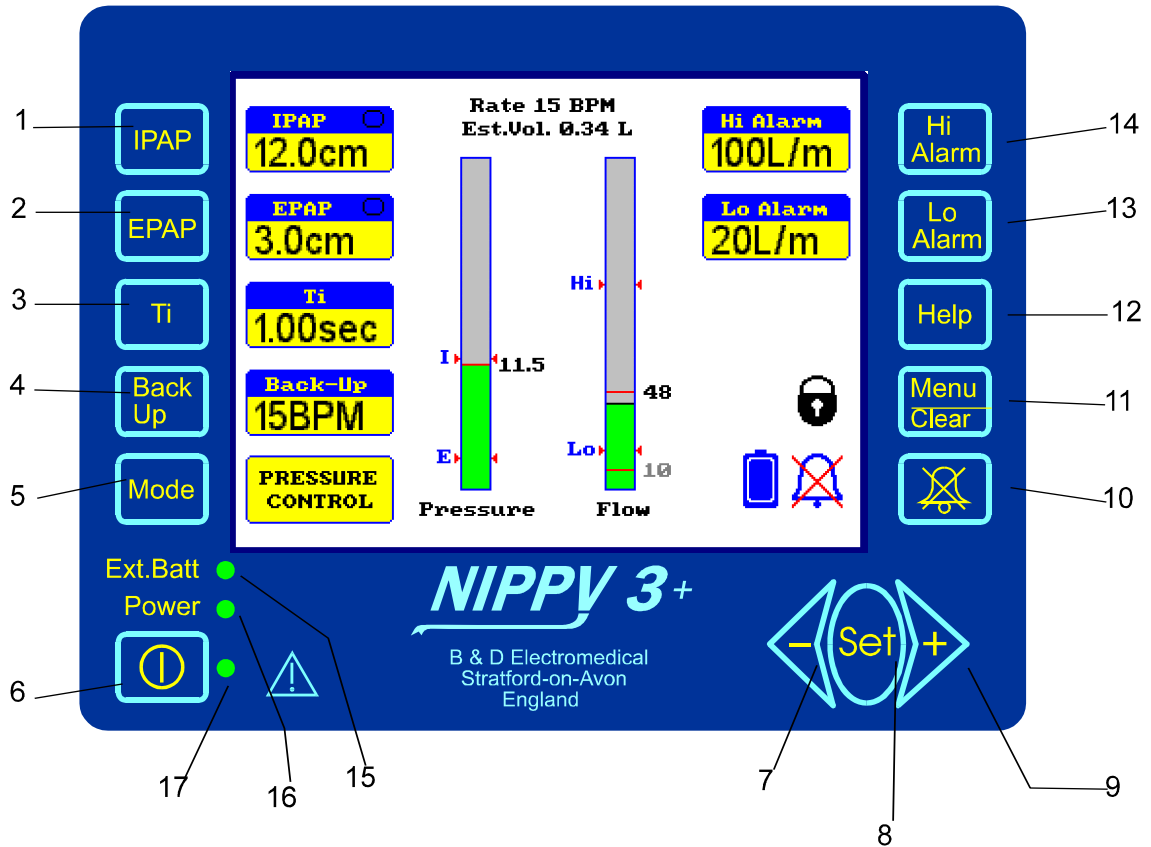
Batteries used for power fail back up must be kept in good condition and fully charged at all times.

Nippy 3+ must be prescribed by, and used only under the supervision of a qualified physician.



FEATURES

1. Lightweight, compact fully self-contained unit
2. Optional internal battery operation
3. Comprehensive, auto setting, alarms with mute facility
4. Can be used with Nasal mask, Full face mask or tracheotomy.
5. User friendly intuitive software
6. Easily understood alarm messages displayed onscreen
7. 4 modes of ventilation
8. Employs state of the art microprocessor control
9. Universal mains input, operates anywhere in the world without transformers
10. Adjustable flow triggers with trigger indicators
11. Large, colour LCD display, clearly shows all settings
12. 28 days stored, On-screen compliance data
13. Comprehensive event log stores all adjustments, settings, alarm events and user interventions, for download to PC.
14. Breath analyser display, showing pressure and flow waveforms
15. Fast trigger response
16. Very low maintenance requirements, therefore maintenance costs are extremely low.
17. Twelve months parts and labour warranty
18. Auto switching to internal or external battery.
19. Automatic service reminder.

EXPLANATION OF CONTROLS

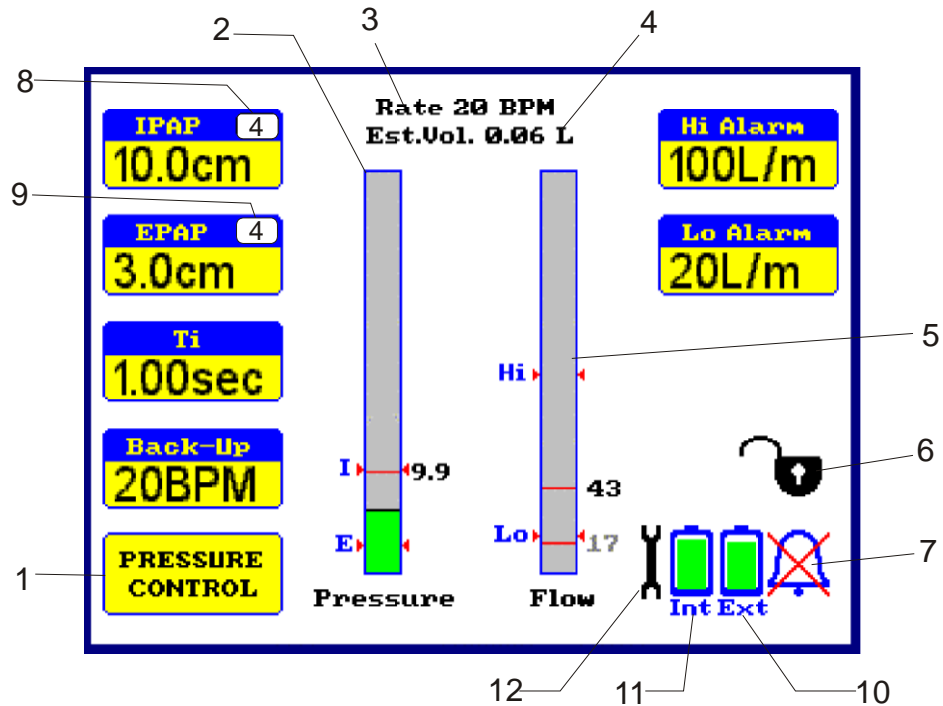


Fascia Buttons

1. **IPAP**
 - Selects the Inspiratory Positive Airway Pressure adjustment (scaled in cm H₂O). Value is displayed on screen adjacent to the switch.
2. **EPAP**
 - Selects the Expiratory Positive Airway Pressure adjustment (scaled in cm H₂O). Value is displayed on screen adjacent to the switch.
3. **Ti**
 - Selects the inspiratory time adjustment (scaled in Seconds). Value is displayed on screen adjacent to the switch.
4. **Back up**
 - Selects the Back-up Rate adjustment (scaled in Breaths Per Minute). Value is displayed on screen adjacent to the switch.
5. **Mode**
 - Displays the mode selection screen
6. 
 - Starts and Stops the ventilator
7. 
 - Decrements the selected parameter or moves the selection bar down the menu.

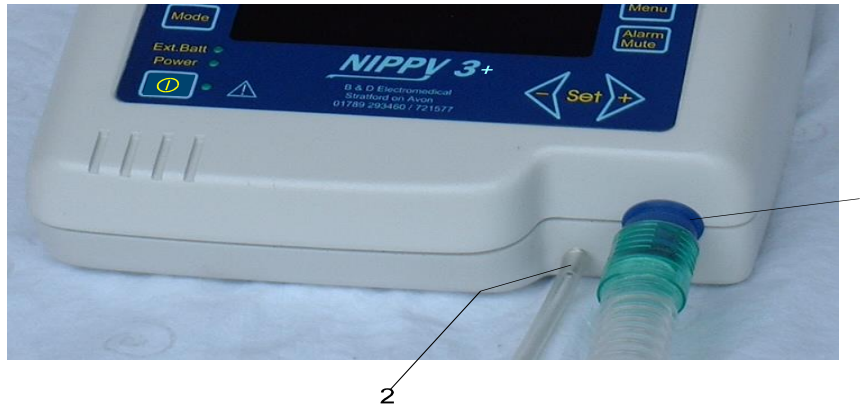
- 8. Set** - Selects the current menu function displayed by the selection bar. OR double press for battery run time and hours till next service.
 - 9. +▶** - Increments the selected parameter or moves the selection bar up the menu
 - 10. Mute** - Silences the alarm for 2 minutes. Press and hold for 2 seconds to cancel alarm mute.
 - 11. Menu** - Displays the menu screen
 - 12. Help** - Displays context sensitive help messages.
 - 13. Lo Alarm** - Selects the Low Flow Alarm adjustment (scaled in litres/minute). Value is displayed on screen adjacent to the switch. Changes colour to red in alarm condition.
 - 14. Hi Alarm** - Selects the High Flow Alarm adjustment (scaled in litres/minute). Value is displayed on screen adjacent to the switch. Changes colour to red in alarm condition.
 - 15. Ext. Batt** - Indicates that ventilator is running on battery power. This may be internal or external.
 - 16. Power** - Indicates that external power is connected.
- Ext Batt OFF and Power ON = Battery charging
- 17. Start** - Indicates that the ventilator is running.

Fascia Display



- | | |
|----------------------------------|--|
| 1. Mode | - Displays current mode of ventilation. |
| 2. Pressure Display | - Indicates airway pressure (scaled in cm H ₂ O). Changes colour to red in under / over pressure alarm condition. |
| 3. Rate Display | - Indicates patient breath rate (scaled in Breaths Per Minute). |
| 4. Volume Display | - Indicates estimated inspiratory tidal volume (scaled in millilitres). |
| 5. Flow Display | - Indicates airway flow (scaled in litres/minute) Changes colour to red in flow alarm condition. |
| 6. Settings locked symbol | - This symbol shows that the settings are locked. |
| 7. Alarm Muted symbol | - This symbol shows that the audible alarm has been temporarily silenced. |
| 8. I Trigger indicator | - "Flashes" each time the inspiratory cycle is initiated by the patient. |
| 9. E trigger indicator | - "Flashes" each time the expiratory cycle is initiated by the patient. |
| 10. External battery | - Indicates external battery state of charge, when connected. |
| 11. Internal battery | - Indicates internal battery state of charge. |
| 12. Service Reminder | - major service due |

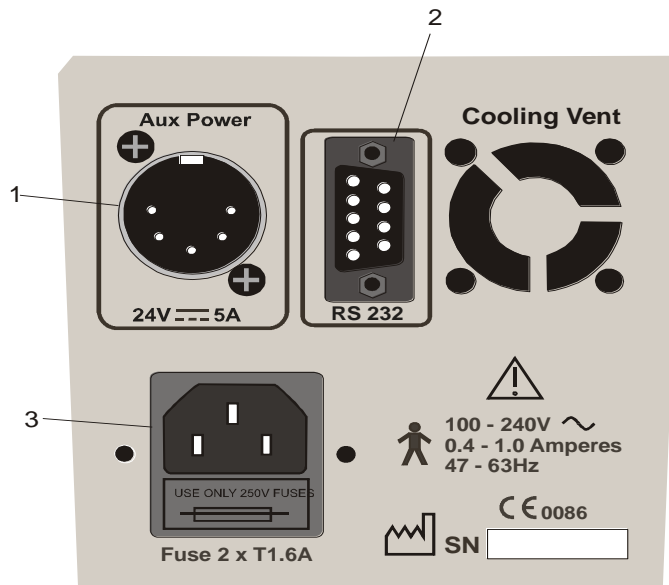
Ventilator Outlets




















- 1. **Outlet** - Main Air Outlet to breathing circuit
- 2. **EVC Port** - Exhale Valve Control outlet
Connected to the Exhalation valve in IPPV mode
Leave disconnected in any other mode

Rear Panel Layout

- 1. **Aux. Power** - 24 Volt connection for external battery. Connect only recommended batteries, part no 0910
- 2. **RS232 Port** - For connection to remote alarm or personal computer. Isolated to 1500 Volts.
- 3. **Power Inlet** - Input mains power connector. Double fused and fitted with connector retaining clip.



Explanation of Symbols used on Nippy 3+ 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 |
|  | - | Do Not Reuse |
|  | - | Batch code |

Getting Started

To Switch On

Place the Nippy 3+ 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.

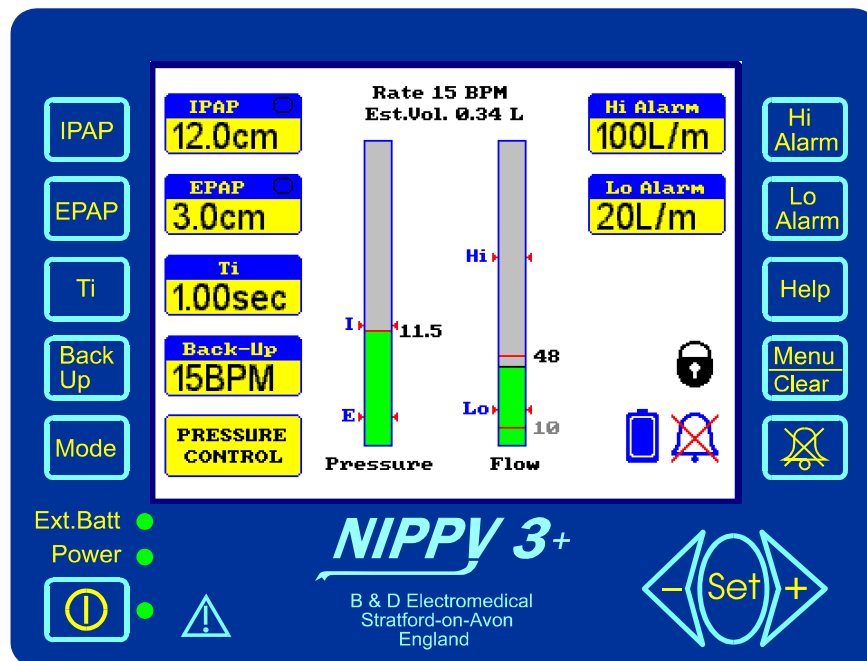
The Main Screen

The Main Screen is divided into 3 areas

The left-hand side shows the basic ventilator settings, IPAP, EPAP, Ti, BACK-UP, and Mode, adjacent to its setting button.

The centre section shows the airway pressure, flow, estimated tidal volume and breath rate.

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



How to adjust the Nippy 3+

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.

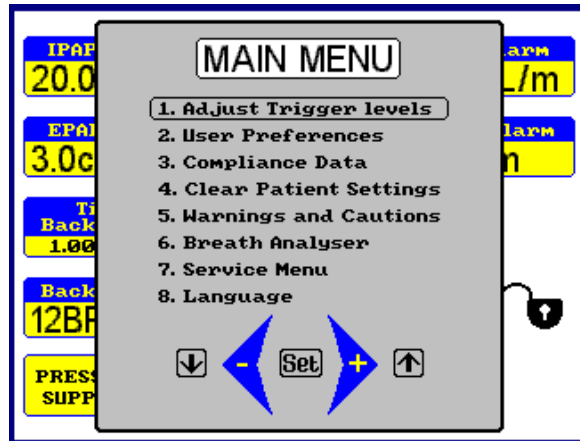
E.g. Press IPAP.

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

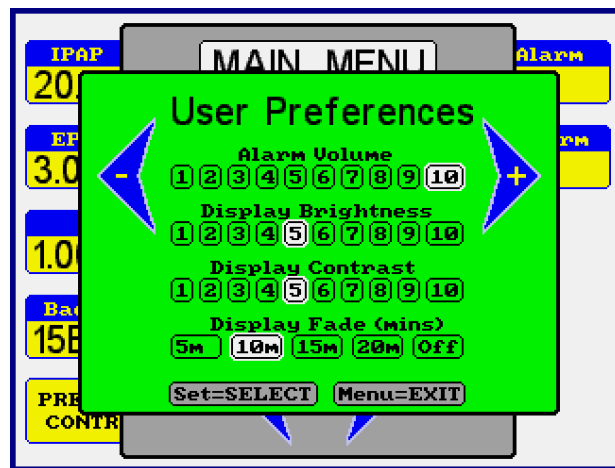
Press the MENU button. The menu window will be displayed in front of the main screen.

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”

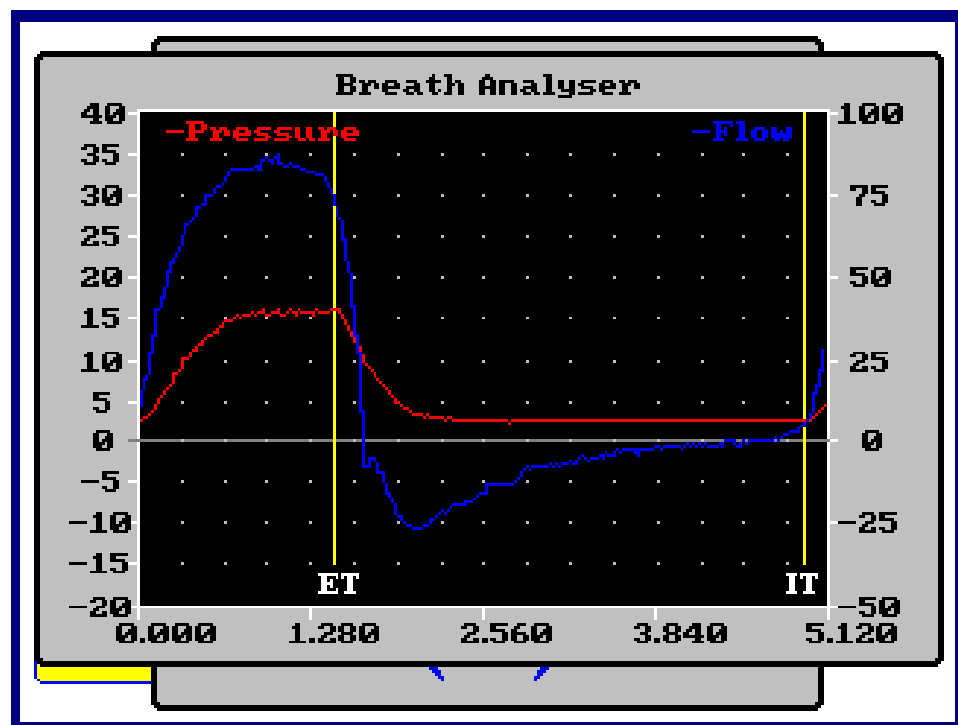
Press +▶ to increase contrast - Press MENU to exit.

Breath Analyser

The breath analyser changes the display to a graphical format, like an oscilloscope. This can be useful to evaluate a patient's breathing pattern and to assess the effectiveness of the triggering.

The pressure and flow waveforms are stored then displayed on the screen.

- The screen displayed shows the stored information from the previous breath.
- The width of the trace is the period of the back up rate, displayed in seconds on the X axis. E.g. if back up rate is set to 10BPM, the trace width represents 3 seconds.
- The pressure in cm H₂O is displayed on the left Y-axis and relates to the RED trace.
- The flow in litres/minute is displayed on the right Y-axis and relates to the BLUE trace.
- The insp trigger (IT) and exp trigger (ET) points are marked along the X-axis as they occur.
- The display may be "frozen" by pressing the ◀ - button. Press the + ▶ button to restart the display.



How to use the On-screen Help

Press the HELP button at any time for a list of help topics. Follow the simple on-screen instructions.



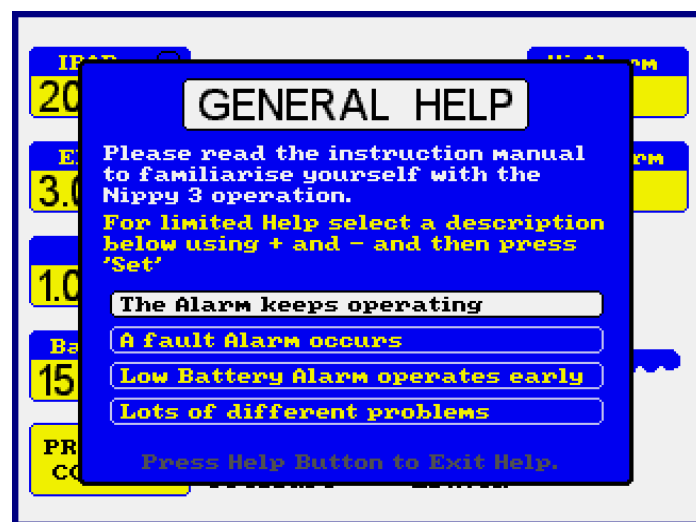
Press HELP again to exit.

If during setting up, you require a description of a particular parameter, select it then press HELP. Press HELP again to clear.

Using Help with settings locked.

When the settings have been locked, help is limited to a list of more common problems that may arise during use and advice on how to deal with them.

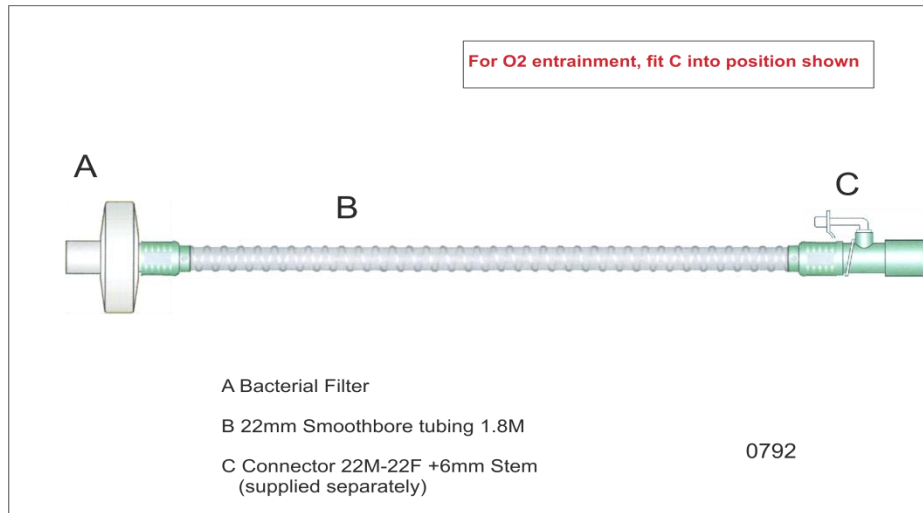
Follow the on-screen instructions



Breathing Circuits

The type of breathing circuit used will depend on the mode of ventilation selected:-
Breathing circuits to be assembled in the order A-B-C-D from the ventilator end.

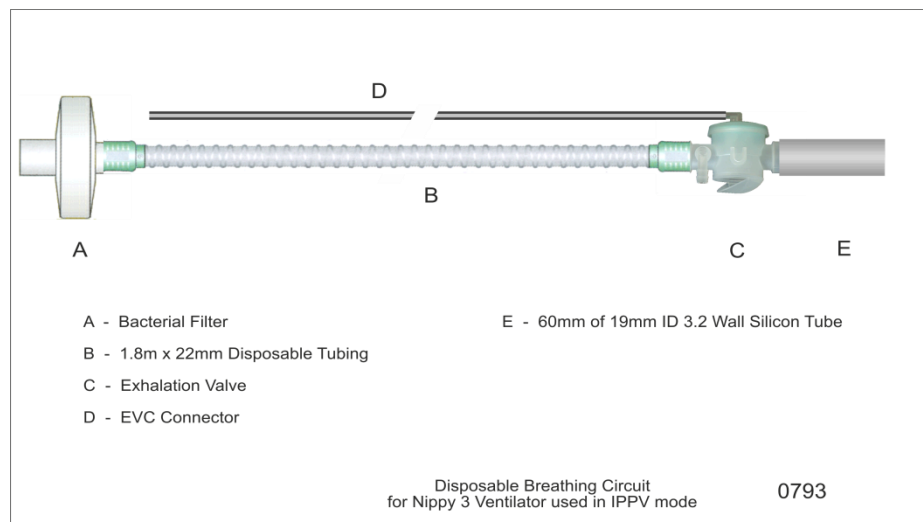
In **CPAP**, **Pressure Support** and **Pressure Control** modes, a single limb circuit with an exhalation port will be required. **DO NOT USE THIS TYPE OF CIRCUIT FOR IPPV MODE**



Part Number 0792

Breathing circuit volume = 570 ml including filter.

In **IPPV** mode a single limb circuit with an exhalation valve will be required. This type of circuit will have a 22mm diameter main tube and a small tube to connect the exhalation valve to the EVC (exhale valve control) port on the Nippy 3+. **THIS IS THE ONLY TYPE OF CIRCUIT RECOMMENDED FOR USE IN IPPV MODE**

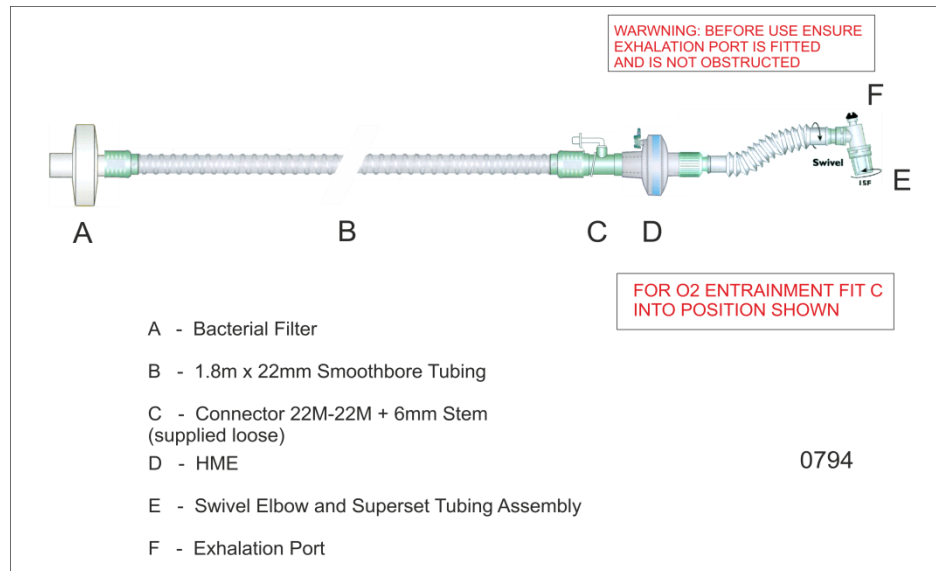


Part Number 0793

Breathing circuit volume = 600 ml including filter.

Using the Nippy 3+ Invasively

The Nippy 3+ is safe for use with a tracheotomy or endotracheal tube. An exhalation port must be fitted between the breathing circuit and the tracheotomy fitting. **DO NOT USE THIS TYPE OF CIRCUIT FOR IPPV MODE**

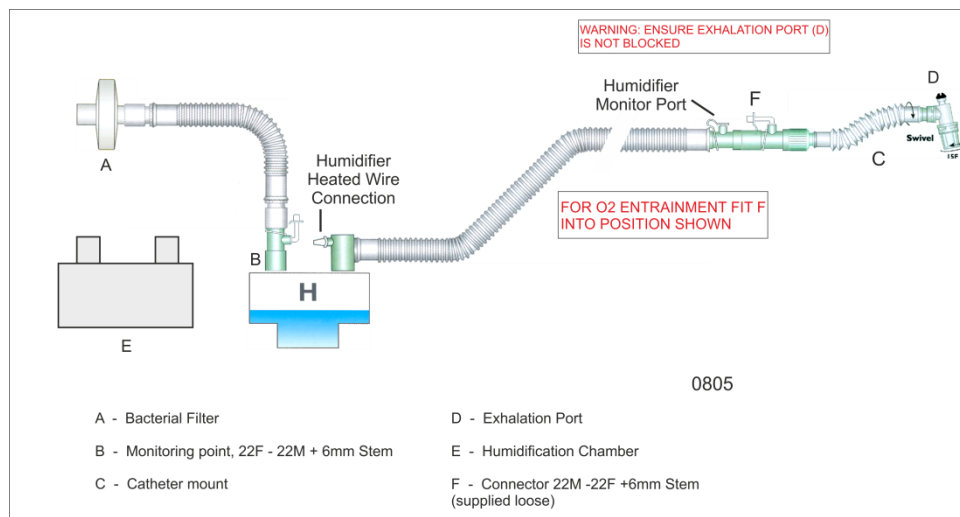


Part Number 0794

Breathing circuit volume = 620 ml including filter.

Using a Humidifier with the Nippy 3+

Heated breathing circuits are available for use with water bath humidifiers. Follow the instructions supplied with the humidifier.



Part Number 0805 for use with a Fischer and Paykel Humidifier

Breathing circuit volume = 1290 ml including filter and water bath.

SETTING UP THE NIPPY 3+ in CPAP MODE

1. Place the Nippy 3+ 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. Connect the mask to the outlet tubing on the breathing circuit.
Note: Do not fit the mask onto the patient at this point.
4. Press the Start/Stop button and select CPAP mode.
5. Set the High Alarm to 160 Lpm and the Low Alarm to 20lpm. This will help to stop the alarm becoming a nuisance during setting up. Alarm settings will be finalised later
6. Set EPAP to the prescribed pressure.
7. The patient may now **hold** the mask to the face.
8. Allow the patient to get used to the mask. Then strap the mask/headset to the patient.
9. Set Up the alarms, as detailed in the “Setting Up the Alarms” section of this manual
 - **Test the alarms as detailed in “Alarm Conditions and Tests” section of this manual.**
10. Lock the settings to prevent unauthorised adjustment. See back page.

Disconnect the patient outlet port, before switching off.

SETTING UP THE NIPPY 3+ in PRESSURE SUPPORT MODE

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

1. Place the Nippy 3+ 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. Connect the mask to the outlet tubing on the breathing circuit.

Note: Do not fit the mask onto the patient at this point.

4. Press the Start/Stop button and select Pressure Support mode.
5. Set the High Alarm to 160 lpm and the Low Alarm to 20 lpm. This will help to stop the alarm becoming a nuisance during setting up. Alarm settings will be finalised later
6. Start with a low pressure to avoid distressing the patient. Set IPAP to around 8cm H₂O (or less for weak, frail patients). Set the EPAP to minimum (3 cm H₂O).

CAUTION: Avoid starting off with the pressure too high.

7. Ensure that the back-up rate is set to a lower value than that observed when assessing the patient.
8. The patient may now **hold** the mask to the face.
9. Allow the patient to get used to the mask. Then **gradually** increase the IPAP setting until the patient feels comfortable and is being ventilated efficiently. 10 to 20cm H₂O will suit most patients.
10. If the inspiratory or expiratory trigger needs to be adjusted, select "Adjust trigger level" from the menu and adjust to suit the patient.
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". It may be due to the patient's anxiety at trying a new treatment. Stay with the patient while he / she settles down. When the rate has settled, set the Back-up to a value a few BPM below the patient's rate. Allowance should be made for a reduction in rate when the patient falls asleep.
12. Set EPAP if required. Then strap the mask/headset to the patient.
13. Set Up the alarms, as detailed in the "Setting Up the Alarms" section of this manual
 - **Test the alarms as detailed in "Alarm Conditions and Tests" section of this manual.**
14. Check the rate and alarms when the patient is asleep. The inspiratory and expiratory trigger indicators should "flash" at the beginning of each breath.
15. Lock the settings to prevent unauthorised adjustment. See back page.
Disconnect the patient outlet port, before switching off.

SETTING UP THE NIPPY 3+ in PRESSURE CONTROL MODE

Before starting to set up the ventilator, assess the patients breathing pattern. You will need to know the breath rate and the approximate inspiratory time (Ti).

1. Place the Nippy 3+ on a clean and 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. Connect the mask to the outlet tubing on the breathing circuit.
Note: Do not fit the mask onto the patient at this point.
4. Press the Start/Stop button and select Pressure Control mode.
5. Set the High Alarm to 160 lpm and the Low Alarm to 20 lpm. This will help to stop the alarm becoming a nuisance during setting up. Alarm settings will be finalised later
6. Start with a low pressure to avoid distressing the patient. Set IPAP to around 8cm H₂O (or less for weak, frail patients). Set the EPAP to minimum (3 cm H₂O).
CAUTION: Avoid starting off with the pressure too high.
7. Set Ti to match the patient. (In patients without airflow obstruction, it would be reasonable to start with an inspiratory time of 1.0 - 1.5 seconds).
8. The patient may now **hold** the mask to the face.
9. Allow the patient to get used to the mask. Then **gradually** increase the IPAP setting until the patient feels comfortable and is being ventilated efficiently. 10 to 20cm H₂O will suit most patients.
10. Fine-tune the Inspiratory time (Ti) to the comfort of the patient.
11. If the Inspiratory trigger needs to be adjusted, select "Adjust trigger level" from the menu and adjust to suit the patient.
12. 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". It may be due to the patient's anxiety at trying a new treatment. Stay with the patient while he / she settles down. When the rate has settled, set the Back-up to a value a few BPM below the patient's rate. Allowance should be made for a reduction in rate when the patient falls asleep.
13. Set EPAP if required. Then strap the mask/headset to the patient.
14. Set Up the alarms, as detailed in the "Setting Up the Alarms" section of this manual
 - **Test the alarms as detailed in "Alarm Conditions and Tests" section of this manual.**
15. Check the rate and alarms when the patient is asleep. The inspiratory trigger indicator should "flash" at the beginning of each breath.
16. Lock the settings to prevent unauthorised adjustment. See back page.
Disconnect the patient outlet port, before switching off.

SETTING UP THE NIPPY 3+ in IPPV MODE

Before starting to set up the ventilator, assess the patients breathing pattern. You will need to know the breath rate and the approximate inspiratory time (Ti).

1. Place the Nippy 3+ 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. Connect the small exhalation valve tube to the EVC outlet.
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 and select IPPV mode.
6. Set the High Alarm to 160 lpm and the Low Alarm to 20 lpm. This will help to stop the alarm becoming a nuisance during setting up. Alarm settings will be finalised later
7. Start with a low pressure to avoid distressing the patient. Set IPAP to around 8cm H₂O (or less for weak, frail patients). **Avoid starting off with the pressure too high.**
8. Set Ti to match the patient. (In patients without airflow obstruction, it would be reasonable to start with an inspiratory time of 1.0 - 1.5 seconds).
9. The patient may now **hold** the mask to the face.
10. Allow the patient to get used to the mask. Then **gradually** increase the IPAP setting until the patient feels comfortable and is being ventilated efficiently. 10 to 20cm H₂O will suit most patients.
11. Fine-tune the Inspiratory time (Ti) to the comfort of the patient.
12. If the Inspiratory trigger needs to be adjusted, select "Adjust trigger level" from the menu and adjust to suit the patient.
13. 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". It may be due to the patient's anxiety at trying a new treatment. Stay with the patient while he / she settles down. When the rate has settled, set the Back-up to a value a few BPM below the patient's rate. Allowance should be made for a reduction in rate when the patient falls asleep. Then strap the mask/headset to the patient.
14. Set Up the alarms, as detailed in the "Setting Up the Alarms" section of this manual

Test the alarms as detailed in "Alarm Conditions and Tests" section of this manual.

15. Check the rate and alarms when the patient is asleep. The inspiratory trigger indicator should "flash" at the beginning of each breath.
16. Lock the settings to prevent unauthorised adjustment. See back page.
Disconnect the patient outlet port, before switching off.

Setting Up the Alarms

Automatic Setting

For convenience, the high and low flow alarms may be set automatically. Varying leak or the patient getting out of synch with the ventilator may disrupt the measurement process. Therefore it is vital that the alarms are tested after setting up.

Low Flow Alarm

- Press and hold the Low Flow Alarm button
- The ventilator will read the peak flow, the inspiratory baseline or leak flow and set the low flow alarm to the mid point between these two values.
- This setting may be further adjusted manually if required.
- **Test the alarm as detailed in “Alarm Conditions and Tests” section of this manual.**

High Flow Alarm

- Press and hold the High Flow Alarm button
- The ventilator will read the peak flow and set the high flow alarm to this value plus 30% or 20 l/min, whichever is greater.
- This setting may be further adjusted manually if required.
- **Test the alarm as detailed in “Alarm Conditions and Tests” section of this manual.**

Warning!

The auto set facility is not infallible. Varying leak can cause erroneous readings.

The settings must be verified and the alarm function tested. If the alarm settings are not correct or the alarms do not operate when tested, proceed to the manual set up.

Manual Setting

Low Flow Alarm:-

- Note the peak flow reading. This is the patient’s peak inspiratory flow.
- Disconnect the breathing circuit at the mask or tracheotomy and occlude the end (do not obstruct the exhale port). Note the peak flow reading. This is the leak flow.
- Reconnect the breathing circuit.
- Set the Lo alarm to a value approximately half way between the leak flow and the peak inspiratory flow.
- **Test the alarm as detailed in “Alarm Conditions and Tests” section of this manual.**
- If the patient is being treated via a nasal mask, this alarm is not required and may be set to minimum.

High Flow Alarm:-

- Note the peak flow reading. This is the patient’s peak inspiratory flow.
- Disconnect the breathing circuit at the mask or tracheotomy end. Note the peak flow reading. This is the disconnected flow.
- Set the Hi alarm to a value a little higher than the peak inspiratory flow. This must be lower than the disconnected flow. Allow for an increase in flow if the patient takes a deep breath.
- **Test the alarm as detailed in “Alarm Conditions and Tests” section of this manual.**

Alarm Conditions/Tests

Test the alarms prior to use or daily for machines that are in constant 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).

High Flow Alarm

If the inspiratory flow exceeds the high alarm value, the alarm will be activated accompanied by the on-screen, high flow alarm message.

To Test Disconnect the breathing circuit at the patient outlet port and allow the flow to exceed the set alarm value. The alarm will be activated after a delay of 5 seconds, accompanied by the on-screen, high flow alarm message.

Disconnect Alarm

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

To Test Switch on the ventilator and cancel the Mute. Disconnect the breathing circuit at the patient outlet port. The High Flow alarm will be activated after a delay of 5 seconds and will be replaced by the disconnect alarm after 10 seconds, accompanied by the on-screen disconnect alarm message.

Low Flow Alarm

The low flow alarm warns of insufficient inspiratory flow. This could be caused by a blockage in the patients' airway or breathing circuit. The resulting drop in flow will activate the alarm.

To Test Switch on the ventilator and cancel the Mute. Occlude the outlet and wait 10 seconds. The alarm will sound, accompanied by the low flow alarm message and the flow display will turn red.

Power Fail Alarm

If both mains and internal power to the Nippy 3+ fails, the alarm will operate and continue for approx. 5 minutes. Press the mute button to silence the alarm.

To Test Machines NOT fitted with an internal battery - start the Nippy 3+ 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.

Machines fitted with internal battery – Power fail alarm will only operate if the internal battery is completely discharged and the mains fails. The only way to test it is to run the ventilator on battery power until the battery is exhausted and the power fails.

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.

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. 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.

Running the Nippy 3+ on Battery Power

Nippy 3+ may be powered from the mains, external battery or internal battery.

When running on mains, the ventilator will recharge its own internal and/or external battery. Charge time is normally around 8 to 11 hours, per battery, depending on the ventilator settings.

Batteries will also be charged when the Nippy is connected to the mains supply but not running. Leave connected to the mains supply in between periods of use to keep the batteries charged or to recharge ready for the next use.

When an external battery is connected to a machine, which has an internal battery, each battery is charged to approximately 90%, starting with the internal one. Then both batteries are fully charged starting with the internal one. When the battery(s) are charged, the charge will terminate and the battery will be monitored to maintain its charge.

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

The ventilator will select its power source, according to the power available, in the following sequence:-

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 external battery as the next choice. The external battery, if present, will always be run flat before the internal battery is selected.

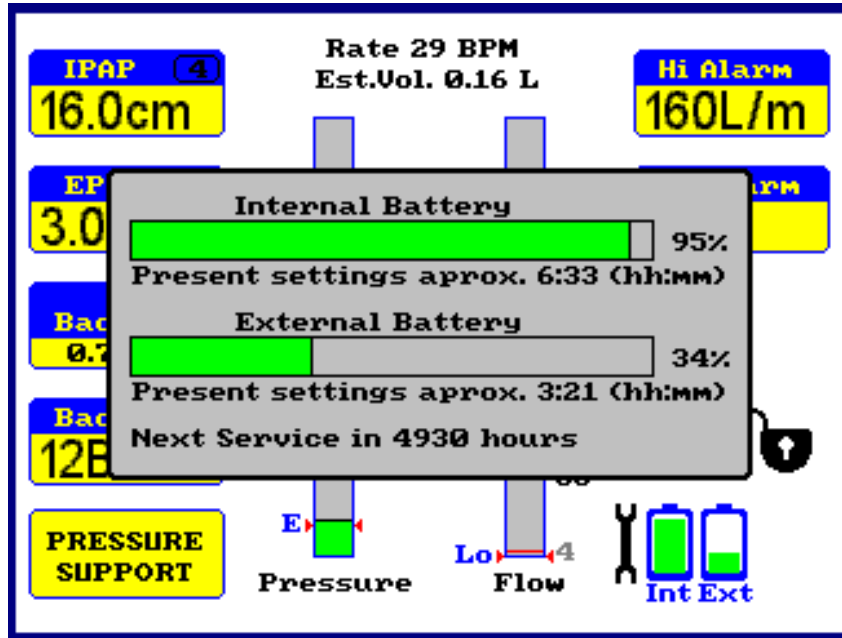
If there is no external battery, the ventilator will switch to its internal battery.

If there is no internal battery the ventilator will shut down and alarm.

Battery Run Times

Battery run times are dependent on the ventilator settings and the amount of leak. High pressures and /or high breath rates use power and therefore shorten run times. Large leaks use power and shorten run times.

The expected run time can be displayed on 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.



The run time may be as long as 12 hours for low values of CPAP with only moderate leak, or as short as 4 hours for Pressure Support at maximum pressure with quite severe leaks. Battery run times will typically be 20% more in IPPV mode because of the absence of the exhale port leak.

Run times will be shortened by higher breath rates and/or higher EPAP levels.

Typical Running Times 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 |

Low Battery Alarm

When the battery is almost depleted the battery icon will flash and change colour to red.

When the battery is depleted an alarm will sound, accompanied by an on screen message, "Battery Power Running Low"

When battery power reaches a critical level, the alarm will change to a continuous tone and the on-screen message will change to "Battery Power Exhausted. About to switch off. Connect to Mains Power Now"

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

Internal Battery (Optional)

Battery Test

Test the battery if the running time seems low, a fault is suspected, or to confirm that the battery is good.

- 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 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.

Hints and Tips For Reliable Operation

- Always make sure that the battery is fully charged before use.
- If you are in doubt about your battery's state of charge, charge for at least 24 hours.
- If running time suddenly seems considerably shorter than normal, make sure that the battery is fully charged.
- Check the running time of your system regularly.
- Most reported problems arise from incorrect battery charging.

Battery Life

The end of life is defined by the maximum running time falling to 75% of that of a new battery. For a battery that is used occasionally service life is 2 years. Replace the battery when running times drop below those indicated or after 2 years.

Internal Battery Replacement

The internal battery should be replaced every 2 years or after 10000 hours use or if the run times are shorter than expected.

The user cannot replace the battery. Refer ventilator to suitably qualified technical personnel for battery replacement.

DO NOT attempt to dismantle the ventilator

DO NOT attempt to fit any battery other than the approved type. Fitting of any other type of battery could lead to personal injury and damage to the ventilator.

Disposal of depleted batteries

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

Recommended batteries for use with Nippy 3+

- Replacement internal battery, part number 0913
- External battery, part number 0910
- Use only the recommended batteries

See "battery care" section for full instructions.

External Batteries

An external battery may be used to increase the running time. This battery is essentially the same as the internal battery and will power the ventilator for the same time, 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. 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.

Instructions For Use

- Connect the battery to the Nippy 3+ Aux Power input.
- The Power light will illuminate.
- Switch on the Nippy 3+. The Ext Batt light will flash and a “Running on battery power” message will be displayed on the Nippy 3+ 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 a Battery

- Leave the battery connected to the Nippy 3+ 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 produce explosive gases during charging. Always charge away from sparks or sources of ignition. Do not smoke near a battery whilst charging.

Disconnect the mains power before disconnecting the battery from the charger.

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

Ensure that the mains lead is not damaged.

Do not attempt to charge any other type of battery with it.

Battery pack cleaning

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

Battery Care

DO NOT use any other type of battery charger. This could lead to damage to the battery and personal injury.

- 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.

Battery Life

The end of life is defined by the maximum running time falling to 75% of that of a new battery. For a battery that is used occasionally service life is 2 years.

Replace the battery when running times drop below those indicated or after 2 years.

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. Ideally the storage temperature should be above -20°C and below 20°C . It must be below 40°C .

After storage in a cold environment allow 24 hours for the battery to reach room temperature before use.

Fully charge the battery every 2 months.

Battery Test

Test the battery if the running time seems low, a fault is suspected, or to confirm that the battery is good.

- 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 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.

Hints and Tips For Reliable Operation

- Always make sure that the battery is fully charged before use.
- Do not switch off charger until battery is fully charged.
- Avoid the temptation to give the battery “a quick boost”. This is of no benefit.
- If you are in doubt the state of charge, charge for at least 24 hours.
- If running time suddenly seems considerably shorter than normal, make sure that the battery is fully charged.
- Do not charge your battery near sources of ignition.
- Check the running time of your system regularly.
- If you have more than one battery, use them in rotation.
- Do not use if any of the cables or components show any sign of damage.
- Most reported problems arise from incorrect battery charging.

Disposal of depleted batteries

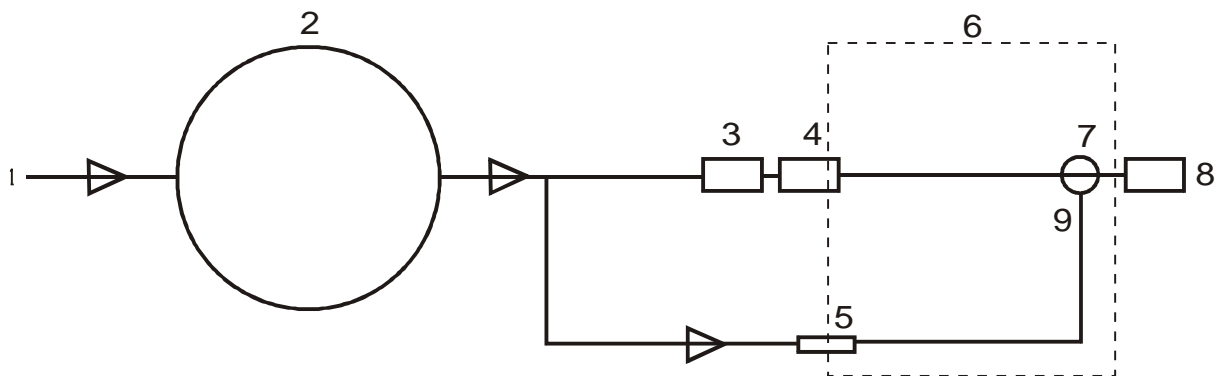
Depleted batteries may be disposed of in line with local authority regulations.

Connecting auxiliary monitoring equipment

For monitoring or downloading data the Nippy 3+ may be connected to a PC or Laptop computer. The Nippy 3+ 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. EVC Port (IPPV mode only)
6. Breathing Circuit
7. Exhalation Port
8. Patient Connection Port
9. Exhalation Valve (IPPV mode only)

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 | - | 4.5 kg |
| Ambient Operating Temperature | - | 32 ⁰ C 90 ⁰ F Max |
| Digital Output | - | RS232 Isolated to 1500 Volts |
| All displayed readings expressed as | - | ATPD |
| Max. Output Pressure | - | 38cm H ₂ O(44cm fault condition) |
| Calibrated pressure Range | - | 0 - 38cm H ₂ O |
| 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 |
| Accuracy of Flow reading | - | +/-10% |
| Inspiratory Trigger | - | 0.14 – 2.21 L/sec ² |
| Expiratory Trigger | - | 0.28 – 1.67 L/sec ² |
| Low Flow Alarm | - | 0 – 200 lpm |
| High Flow Alarm | - | 0 – 200 lpm |
| 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 ⁰ 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 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 3+ Ventilator complies with the following EMC standards. EN60601-1-2: 2001

Test results available for review from B & D Electromedical



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. Extremes of temperature (below 5 °C, above 40 °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 3+ 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 3+ and breathing system (Nippy 3+ and circuit) is less than 6cm H₂O @ 60 l/min. This value must not be exceeded when adding attachments or fittings to the breathing circuit.

Accessories and Spares

1. A range of nasal and facemasks is available in various sizes. Please contact us for details
2. 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.
3. A range of breathing circuits is available for use with nasal mask, facemask or tracheotomy. These can be supplied with a heated wire for use with an external humidifier. See Breathing Circuits section.
4. Air Filter Element pt.no. 0584 (pack of 5)
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.

6. 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 3+ 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

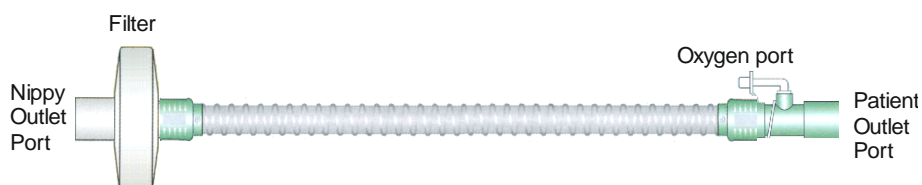
CAUTIONS

- The Nippy 3+ should only be used in accordance with the instructions of the supervising physician. **Personnel using and operating the Nippy 3+ 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 3+ 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 3+ 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 3+ 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 3+, 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 3+, junior+, ST+.

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.

USER 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

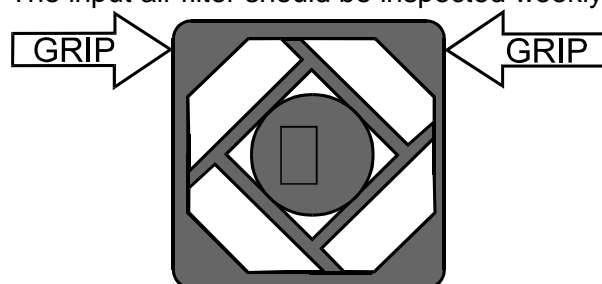
Before using the Nippy, inspect the mains lead for damage. Do not use if there is any damage to the plug, socket or the insulation.

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 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.

User Maintenance Schedule

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

Breathing Circuit Cleaning

The breathing circuit 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

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 3+ 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

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.

Disposal at end of Life

The Nippy 3+ 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 TestLevel | Compliance Level | Electromagnetic Environment- Guidance |
|-------------------------------|-----------------------------|------------------|---|
| Conducted RF IEC 61000-4-6 | 3 Vrms 150 kHz to 80 MHz | 3 Vrms | Recommended separation distance: $d = 1.2\sqrt{P}$ @ 150 kHz to 80 MHz |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2.5 GHz | 3 V/m | $d = 1.2\sqrt{P}$ @ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ @ 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 $d = 1.2\sqrt{P}$ | 80 MHz to 800 MHz $d = 1.2\sqrt{P}$ | 800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$ |
| 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 is 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 |

