USER MANUAL

o_two controlled™ ventilation

o_two e500

AUTOMATIC TRANSPORT VENTILATOR

01EVE500

TABLE OF CONTENTS

1. Safety

⚠ WARNING ⚠

- U.S. Federal Law restricts this device to sale by or on the order of a physician.
- The ventilator shall only be used for the purposes specified under “Intended Use”.
- The ventilator should only be used by qualified personnel trained in its use.
- Strict adherence to all instructions contained within this manual is essential for safe use.
- During use, the patient must be constantly monitored by qualified personnel.
- Alternate means of ventilation such as a manual resuscitator must be available in case of power failure or malfunction.
- Keep away from open flames, sparks and grease/oil. To avoid the risk of fire or explosion this ventilator must not be used with flammable gases or anaesthetic agents. Operating the unit in a confined space will elevate ambient oxygen levels.
- The ventilation setting will turn off during battery replacement while the device is in operational mode and the external power supply is not connected.
- Only use O-Two specified hoses, patient circuits, batteries and external power supplies to avoid affecting the output performance of the ventilator. Antistatic or conductive hoses or tubing are not used in the Ventilator Breathing System.
- Unauthorized modification of this medical device is prohibited. Do not disassemble or modify any part of the ventilator except where described in this manual. Any unauthorized disassembly will void the warranty.
- Do not use this ventilator in toxic environments as entrainment of ambient air during spontaneous breathing or air mix mode may permit toxic gases to be delivered to the patient.

- Do not use this ventilator within a Magnetic Resonance Imaging (MRI, NMR, NMI) suite.

- Do not use this ventilator in hyperbaric (high pressure) chambers.

- Do not use the external electrical power supply outdoors as moisture may affect its function.

- Do NOT allow the power supply plug to contact the patient.

- The performance of this ventilator may be affected if used near portable and mobile RF telecommunication devices (cell phones) within the minimum distance specified in section 9.5 of this user manual.

- The intake and exhaust ports on the patient valve must be left unobstructed for proper function & safety.

- When using a bacterial filter or HME (Heat Moisture Exchanger) connect the bacterial filter or HME to the patient connection between the elbow and the endotracheal tube or face mask, note that this action will increase the dead space. Bacterial filters or HME may increase breathing resistances.

- Use pressure regulators maintaining a minimum output flow of 120 L/min at a dynamic pressure of minimum 45 PSI to ensure the proper functioning of the ventilator.

- Operation of this ventilator outside the environmental condition range specified in this manual may result in a reduction and or failure in the ventilator's performance. In extreme temperature conditions the effect is not noticeable in terms of delivered ventilations but may cause excessive wear in the ventilator or its components over time. Extreme low temperatures reduce the operating time of the battery (Refer to 9.4 battery operating Time).

- Operation of this ventilator outside the supply pressures range detailed in this manual may result in reduction in the ventilator's performance, component failure, low pressure alarm or possible loss of automatic cycling.

- Operation of this ventilator outside the electrical power range detailed in this manual may result in reduction or failure in the ventilator's performance. Component failure, inadequate power of internal components may occur.

- Operation of this ventilator below sea level or above 4,000 m (13,000 feet) may result in reduction or failure in the ventilator's performance, low pressure alarm or possible loss of automatic cycling.

- The ventilator is intended for use in the prehospital, intrahospital, interhospital and ground transport environments only.

- Connecting the patient circuit to a patient prior to turning on the ventilator may cause a calibration error.

CAUTIONS

- When the ventilator is not in use, always turn off the gas supply.

- Never allow oil or grease to come into contact with any part of the cylinder, regulator, or ventilator.

- After use, always ensure that all components are cleaned in accordance with the instructions provided in this manual. (See section 8.1 - Cleaning and Disinfection).

- The use of this device in a carrying case may result in an increase in oxygen concentration or lower than intended ventilation volume when used in the 60 % air mix mode. When air mix mode is being used it is recommended that the ventilator be placed in its normal operating orientation and the air intake on the side of the ventilator is not obstructed.

- Never operate the ventilator without an intake filter being fitted, otherwise particles may contaminate the ventilator and affect its function.

- This ventilator must only be serviced by the manufacturer or its authorized service centers.

- Device, single use patient circuits and battery packs should be safely discarded in accordance with local state and institutional laws and procedures. .

- Spare O-Two patient circuits are recommended at all times.

- The design of this Ventilator does not incorporate a negative pressure phase during either automatic or manual ventilation.

- The external power supply and battery are component parts of the medical electrical equipment system.

- The ventilator is considered as a high flow device as its maximum flow output at pressure of 40.6 PSI is around 100 L/min. It should only be connected to a pipeline system that allows for the indicated high flow to avoid interfering with the operation of adjacent equipment.

- Always ensure that all components are assembled correctly and ready for use.

- When selecting very small tidal volumes during ventilation of infants, take into consideration the dead space in the patient circuit.

2. Intended Use

The e500 is a time-cycled and volume-constant emergency and transport ventilator designed for use in the pre-hospital, intra-hospital, inter-hospital and transport settings. It is intended for use with Adult, child, infant patients with a tidal volume from 100 ml upwards who are in respiratory and/or cardiac arrest or respiratory distress and who require the ventilatory support.

3. Overview

3.1. Control and Display Layout

Figure 01

A	Warning indicator	H	Pause/Resume key
B	Battery operation indicator	I	Lock key
C	External power indicator	J	Waveform selection key
D	Battery charging indicator	K	Cancel key
E	Manual/Inspiratory Hold key	L	Confirmation indicator light
F	Screen brightness key	M	Control Selection Knob
G	Alarm Silence key	N	ON/OFF key

3.2. Function Keys

While all ventilation parameter settings are controlled by the Control Selection Knob (M) in Figure 1, there are a number of key membrane buttons which control additional ventilator functions:

3.2.1. ON/OFF

To turn on the ventilator, Press the ON/OFF button (N) in Figure 01 for one second, during that second the associated green LED will start flashing at a high frequency. After 1 second the ventilator will turn on but without ventilation until the appropriate patient size symbol is selected. If the button is pressed and released for less than a second, the ventilator will remain OFF.

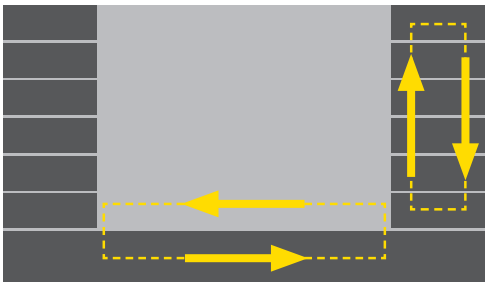
To turn off the ventilator, Press and hold the ON/OFF button for 4 seconds, the green power LED will start flashing at a high frequency. After 4 seconds the ventilator will turn off and all ventilation will stop. If the button is pressed and held for less than 4 seconds, the ventilator will stay ON.

⚠ WARNING ⚠

At approximately 2% of full battery capacity, the ventilator will not start when in the off position or will shut down when operating.

3.2.2. Control Selection Knob

The Control Selection Knob (M) (Figure 01) is used to navigate between parameters, change modes, select primary function change when rotated, and to confirm function changes when pressed. Diagram below illustrates path of cursor when Control Selection Knob is rotated clockwise.



Control Selection Knob rotation contour

Direction for clockwise knob rotation shown

3.2.3. Lock

Lock function will disable all buttons and the Control Selection Knob except for the ON/OFF, Alarm Silence and Day/Night buttons, which are enabled at all times.

To lock the key membrane or cancel the lock function:

1. Press the Lock key (I) (Figure 01). The Lock symbol will be displayed on the screen.
2. To cancel the Lock function, press the Lock key (I) again.

Note: During the Lock function, if any locked key is pressed or the control knob is pressed or rotated, the Lock symbol on the left of the screen will flash with these actions.

3.2.4. Alarm Silence

The Alarm Silence key (G) (Figure 01) will silence the audible alarm for 120 seconds. It could be also selected without an active alarm to silence potential alarms. This function is activated or deactivated by pressing the Alarm Silence key once.

When selected, the Alarm Silence symbol will be displayed on the left of the screen.

CAUTION

Repetitive use of alarm silence without identification of cause of alarm may pose potential harm to the patient.

3.2.5. Waveform

Pressing the Waveform selection key (J) (Figure 01) will switch between the pressure and volume ventilation waveforms.

3.2.6. Screen brightness 

Pressing the Screen Brightness key (F) (Figure 01) will switch between 4 different brightness levels as follows:

1. Light background with dark color text and waveform at 100% light intensity.
2. Light background with dark colored text and waveform at 35% light intensity.
3. Dark background with light colored text and waveform at 100% light intensity.
4. Dark background with light colored text and waveform at 35% light intensity.

Note: This feature is active in ventilation mode screens only.

3.2.7. Cancel 

The Cancel key (K) (Figure 01) allows the operator to return to the previous settings if the last unconfirmed changes in settings are not required.

3.2.8. Pause/Resume 

During activation of the Pause/Resume key (H) (Figure 01), the ventilator will stop ventilating with all un-locked keys kept active except for the Manual/Inspiratory Hold key (E).

To activate the Pause function, proceed as follows:

1. Press the Pause/Resume key (H) (Figure 01). The Pause symbol will flash on the left of the screen along with the confirmation symbol ✓ as well as the Confirmation indicator (L) (Figure 01) to guide users to activate the pause function by pressing the Control Selection Knob (M) (Figure 01).
2. The symbol will flash for 10 seconds and then disappear if the Control Selection Knob (M) (Figure 01) is not selected. Users can also press the Cancel key (K) (Figure 01) to quit this selection before the 10 seconds.
3. Once activated, a flashing yellow pause symbol will be displayed on the screen and the ventilator will pause ventilation.

Note:

A. During Pause, there will be an audible alarm associated with a flashing yellow Warning indicator (A) (Figure 01) every 15 seconds. Users can press the Alarm Silence key to disable the audible alarm for 2 minutes but the yellow Warning indicator will continue flashing every 15 seconds.

B. During Pause, users can change and confirm new ventilation settings but no ventilation will occur until the Pause function is disabled.

4. To cancel the Pause function, press Pause/Resume key (H) (Figure 01) again. The "Resume" symbol ⏵ will flash on the screen along with the confirmation symbol ✓ and the Confirmation indicator (L) (Figure 01) to guide users to resume ventilation by pressing the Control Selection Knob (M) (Figure 01).

5. When ventilation is resumed, the ventilator will recommence ventilation with current settings shown on the screen unless new set-up selections were made.

3.2.9. Manual/Inspiratory Hold Manual

During the exhalation phase, if the Manual/Inspiratory Hold key (E) (Figure 01) is pressed, a mandatory breath will be initiated and either the flow rate or set pressure control parameter will be delivered as long as the Manual/Inspiratory Hold key remains pressed or until the I-time setting is achieved.

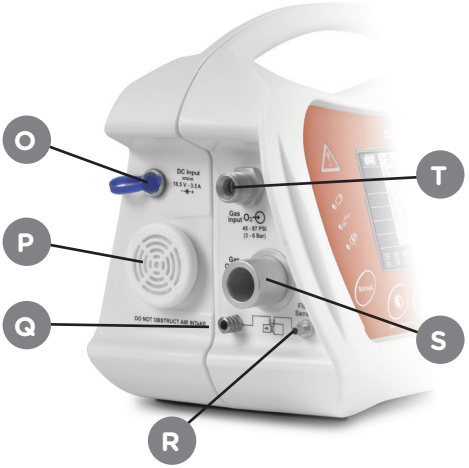
After I-time if the button still pressed, the ventilator will switch to inspiratory hold function in which the ventilator will cut the flow but will keep the exhalation port closed in order to block exhaled gas from going to ambient resulting in the maintenance of lung pressure.

The maximum inspiratory hold time is 6 seconds. After that time, the ventilator will switch to exhalation phase by opening airway pressure to ambient.

Note: Manual/ Inspiratory Hold function exists only in SIMV mode.

3.3. External Connectors

- **O** DC Input connector
- **P** Air Intake filter
- **Q** Sensor connector #1
- **R** Sensor connector #2
- **S** 22mm gas output connector
- **T** Gas supply input



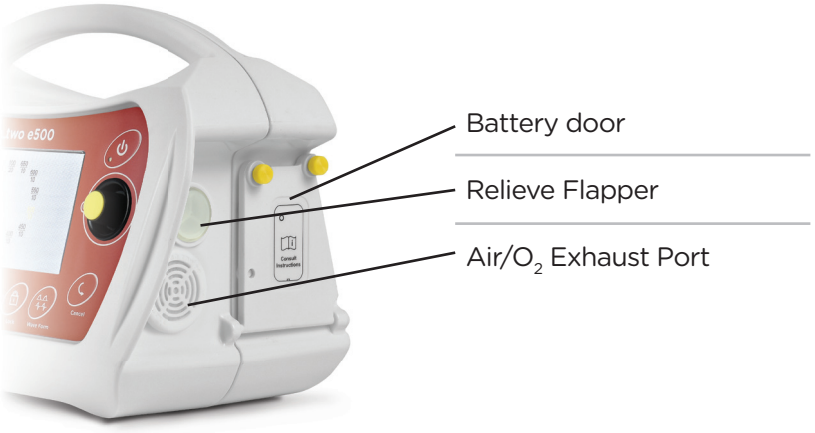


Figure 02

3.4. Patient circuit

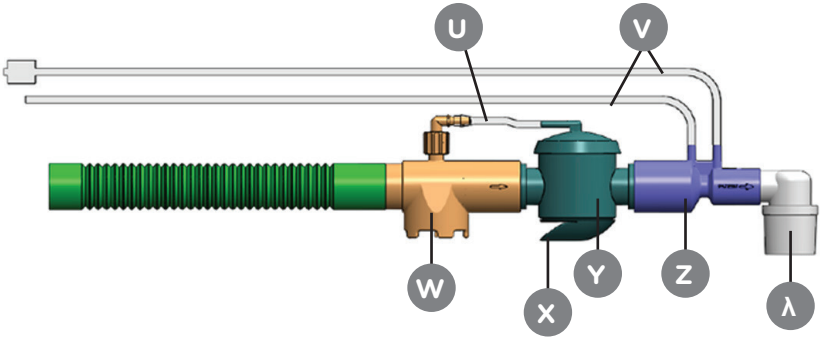


Figure 03

U	Breathing Control Hose	Y	Breathing Valve
V	Sensing hoses	Z	Flow sensor adapter
W	One Way Intake Valve	λ	Elbow
X	Exhalation port		

Specifications

LENGTH	70 in (178cm)
WEIGHT	8.4 oz (260 g)
OPERATING TEMPERATURE RANGE	-18°C to 50°C (0°F to 122°F)
STORAGE TEMPERATURE	-20°C to 60°C (-40°F to 140°F)
RH	15 - 95%

Note: To avoid entanglement of the patient circuit tubing and pressure sensing hoses during movement of the patient, the pressure sensing hoses and the 22mm corrugated hose are contained within in a close fitting, non-woven fabric sheath.

3.5. Display

3.5.1. Screen Layout

The screen is divided into 7 sections as shown below and each section is dedicated to display the following parameters:

Section 1:	Battery status during charge and discharge.
Section 2:	Live ventilation parameters (Vte, Mve, Paw_{peak}, Paw_{AV}, Rate)
Section 3:	Ventilation Modes (SIMV, CPAP & CPR)
Section 4:	Alarms/ Warnings.
Section 5:	Ventilation waveforms.
Section 6:	Set up parameters
Section 7:	Confirmation request/ Patient effort/ Invalid or Conflict setting

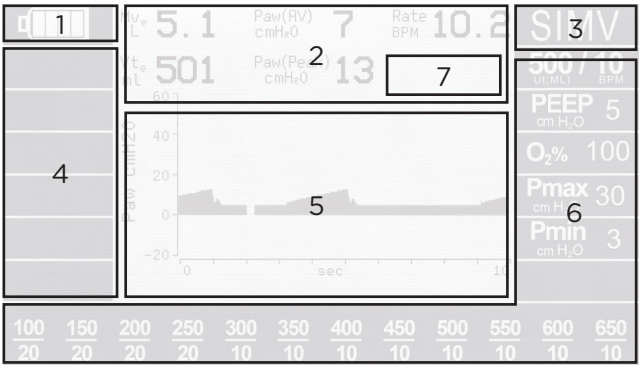


Figure 04

Note: By changing the ventilation mode, section 6 of the display will change accordingly to reflect the default or set up parameters for each mode.

The followings are screen layouts for each ventilation mode:

SIMV screen layout

CPAP screen layout

Masked CPR screen layout

Masked CPR screen layout

3.5.2. Live Monitoring Parameters

The following Live Monitoring Parameters are displayed at the section 2 of the screen:

Paw_{AV} (cmH_2O): Paw AV is the average patient airway pressure measured during the last 60 seconds. This measurement is monitored by the ventilator at all times and modes. The number on the display will be updated every 15 seconds.

Mve (L): Minute volume is the total exhaled volume for the last 60 seconds as calculated using the last 8 breaths. The Mve will constantly change as the value is recalculated and displayed at the end of exhalation phase. When unit is first turned on or resumed after pause or on selecting a new mode, the Mve calculation will be based on first then second then third and so on until the 8th exhaled tidal volume when the above logic will be followed.

Rate (bpm): Rate (BPM) is the rate at which breaths are delivered in one minute. It is the monitored breath rate calculated by measuring the time interval (Tb in seconds) between 2 breaths. Rate (BPM) = 60 / Tb. The number is updated after each breath. This number will be displayed for both mandatory and spontaneous breathing phases.

Vte (ml): Tidal volume is the volume exhaled from the patient in mandatory, spontaneous or PSV (Pressure Support Ventilation) breaths. Vte is calculated by the measurement of the entire expired flow displayed as a volume. Vte display will be updated at the beginning of the next inspiratory phase (The end of exhalation phase).

Paw_{Peak} (cmH_2O): Peak air way pressure is the maximum pressure measured during the inspiratory phase. The displayed number on the screen represents the maximum pressure during mandatory inspiratory phase of SIMV, CPR modes as well as spontaneous inspiratory phase of CPAP mode. This number will be updated at the end of each inspiratory phase.

Note: Mve, Rate and Paw are not active during CPR mode and displayed with "--"

3.6. Symbols and Notations

	Consult instructions for use.
	Warning! Risk of injury and possible negative patient outcome.
CAUTION	Warns of material damage and negative patient outcome.
NOTE:	Offers useful tips to assist in the proper use of the equipment.
	Confirmation Symbol
	Invalid Setting Symbol
	Conflict Setting Symbol
	Keep away from open flames.
	No smoking around ventilator.
IPX4	Ingress protection rating: Splash-proof. Do not immerse.
	Class II equipment. Protection against electric doesn't rely on Basic Insulation only, additional safety precautions such as Double or Reinforced insulation are provided.
	Type BF applied part

4. Preparation for Use

4.1. Setup

4.1.1. Connecting the electrical power supply

The e500 is designed to operate using one of the following power options:

- Internal rechargeable battery pack
- AC/DC external power supply.

CAUTION

- A fully charged battery must always be installed for safety reasons, even when operating from an external power supply, so that continuous ventilation is not interrupted in the absence of external power.
- The use of batteries, other than those specified, may cause the ventilator to fail and/or endanger the patient and operator.
- Connect the ventilator to an external electrical source right away if the “Battery Empty” alarm is triggered.

4.1.2. Installing / replacing the battery

1. Ensure the ventilator is turned off and unplugged from the mains electrical supply.
2. Turn the two screw knobs on the battery compartment cover anticlockwise and open the cover downwards.
3. Disconnect the battery leads and pull out the battery pack using its stand-off.

CAUTION

Always use the battery stand off to pull out the battery pack, never pull the battery by its leads (Figure 05).

4. Insert the fully charged battery such that the battery stand-off is positioned upwards (as per illustration below), attach battery connectors. Close cover and turn screw knob clockwise to secure.

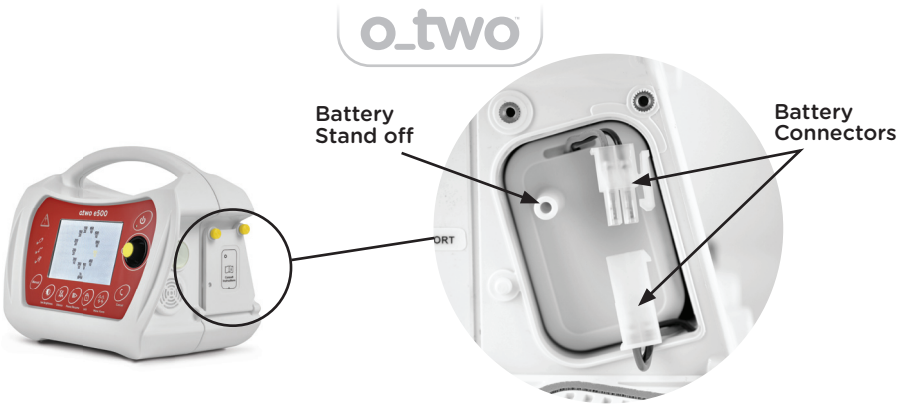


Figure 05

4.1.3. Connecting the Gas Supply

1. Connect the gas supply hose to the gas supply input (T) in Figure 02 of the e500.
2. Connect the other end of the hose to the pressure outlet of the pressure regulator or wall outlet of piped medical oxygen system.
3. Turn cylinder valve slowly and fully.

⚠ WARNING ⚠

Extra care must be taken when handling oxygen:

- The e500 must only be used with medical oxygen.
- Only use approved medical oxygen compressed gas cylinders.
- Always begin use with a full oxygen cylinder.
- Secure oxygen cylinders so they do not fall over.
- Keep away from excessive heat to avoid the risk of explosion.
- Do not grease or lubricate oxygen fittings, cylinder valves and pressure reducers, and do not handle with greasy hands to avoid the risk of fire.
- Only open or close cylinder valves by hand or with the correct cylinder wrench. Open the cylinder valve slowly, at least two full turns, counter clockwise. Do not use any other tools.
- Do not smoke or work in areas where open flames are present. Oxygen supports combustion and exacerbates fires.
- Only use a pressure reducer with an overpressure relief valve to limit the delivery pressure in case of a regulator failure!
- To avoid ventilator malfunction do not attach the ventilator to a flow control valve or flow meter.

4.1.4. Connecting the Patient Circuit

1. Attach the O-Two patient circuit (Figure 03) to the 22mm gas output connector (S) (Figure 02).
2. Connect the sensing hoses (V) (Figure 03) of the patient circuit to their corresponding connectors (Q) & (R) (Figure 02).
3. Attach a face mask to the patient port of the patient circuit. For invasive ventilation, attach an endotracheal tube (ETT) instead. The size of ETT shall be appropriate for the intended patients. It is recommended to use ETT with no cuff for infant patients.

⚠ WARNING ⚠

DO NOT connect the patient circuit to a patient or attach the test lung until the ventilator is turned on (Step 4.1.5) and three solid silhouettes start up figures (Figure 06) are displayed.

4.1.5. Turning the Ventilator ON

To turn on the ventilator, Press the ON/OFF key (N) (Figure 01) for one second. During that second the associated green LED will start blinking at a high frequency. After 1 second the ventilator will turn on but with no ventilation at this point.

If the key is pressed and released for less than one second, the ventilator will remain OFF.

Note: Do not connect the patient circuit to a patient or the test lung before turning on the ventilator. SIMV is the default start-up ventilation mode for e500.

4.2. Pre-use Checks

The following checks must be performed and confirmed by the healthcare provider in the following cases:

- Prior to use
- After replacing hoses, patient circuits or batteries
- At least every 6 months.

1. Visually inspect the ventilator for mechanical damage
2. Ensure that battery is fully charged.
3. Ensure the e500 is connected to a gas supply (Cylinder or piping system) capable of delivering flow of 120 L/min and maintaining a minimum pressure of 45 PSI (3 Bar) and a maximum 87 PSI (6 Bar) output pressure.
4. Ensure that the patient circuit and monitoring hoses have been properly connected.
5. Ensure Performance check (Leak & Function test): To undertake the performance check, you will need the following:

- Full Oxygen cylinder.
- Calibrated test lung (Provided with the unit).
- Oxygen pressure regulator capable of delivering flow of 120 L/min and maintaining a minimum pressure of 45 PSI (3 Bar) and a maximum 87 PSI (6 Bar) output pressure.

A. Connect Input hose to input connector (T) (Figure 02) and the other end of the input hose to the pressure regulator or wall outlet.
B. Connect the power supply to the DC input socket and plug the power supply into the mains electrical supply.
C. Connect the sensing hoses of patient circuit to sensor connectors #1 (Q) and #2 (R) and connect the corrugated hose of patient circuit to output connector (S) (Figure 02).
D. Once the ventilator is started, connect the other end of patient circuit to test lung.

⚠ WARNING ⚠

Prior to use, the operator shall check that the alarm pre-set value is appropriate for the patient being ventilated.

Input Leak Test

Once all connections are verified, open the cylinder valve slowly, at least two full turns, counter clockwise. From the pressure regulator gauge reading, ensure the cylinder pressure is above 650 PSI (45 bar) otherwise replace with new oxygen cylinder.

Once pressurized, turn off the oxygen cylinder and observe the output pressure on the gauge of the regulator. Note that to perform this test, a regulator with cylinder and output pressure readings are needed. If pressure does not drop more than 0.5 PSI every 30 seconds, the system is free from leaks.

To identify and repair the input leak:

1. Release the remaining gas from the system.
2. Tighten all connecters firmly.
3. Open the cylinder valve slowly, at least two full turns, counter clockwise.
4. If leak still present, spray oxygen compatible leak detector on hose and connectors. Turn off the regulator and replace the input hose or regulator if necessary. Repeat from 1. to confirm correction of the leak.

Note: If a leak is still present and no external leak was detected using the above processes, the unit must be returned to the manufacturer or its authorised service center for service or repair.

Output Leak Test

1. Open the cylinder valve slowly, at least two full turns, counter clockwise.
2. Turn on ventilator and select child default setting.
3. Press and hold manual key (E) (Figure 01) and observe the pressure wave form on the screen. If pressure drops immediately, inspect patient circuit connections and ensure all connectors are attached. If the leak is still present replace the circuit and repeat from 1. To confirm correction of the leak.

Note: If a leak is still present and no external leak was detected using the above processes, the unit must be returned to the manufacturer or its authorised service center for service or repair.

Function check

After confirming no leaks are present in the ventilator, input hose and patient circuit, with the mains electrical supply connected, proceed as follows:

1. Turn on the ventilator and select child default setting by depressing the control knob (M) (Figure 01).
2. Let the ventilator cycle a minimum of five (5) breathes and during cycling disconnect power supply, the ventilator should switch immediately to internal battery power. The LED indicators should also switch to show the ventilator is running on the internal battery.
3. Check battery level. Do not run the ventilator if the battery level is low, install a fully charged battery before continuing with the testing.
4. During ventilator cycling, observe the presence of the pressure wave and the live ventilation parameters on the screen.
5. Disconnect the test lung and check for the BCI (Breathing Circuit Integrity) visual alarm associated with yellow warning indicator. The BCI audible alarm associated with red warning indicator will activate with a delay of 15 seconds.
6. Block the patient output completely, the Pmax alarm should be activated.
7. Re-connect the test lung, the BCI visual and audible alarms should be de-activated.
8. Change the tidal volume (Vt) and observe the changes in the lung movement, live ventilation parameters, and the pressure wave form.
9. Change the ventilation rate (bpm) and observe changes in the lung movement, live ventilation parameters and the pressure wave form.
10. Change the I:E ratio or inspiratory time (Ti) and observe the changes in the lung movement, live ventilation parameters and the pressure wave form.
11. Turn off PEEP and observe changes in the lung movement, live ventilation parameters and the pressure wave form.
12. Activate pause, night mode, and flow waveform to ensure proper functioning of each control and observe the changes in the screen display.
13. Turn off the oxygen cylinder and check for low pressure and no pressure audible and visual alarms.
14. Turn off the Ventilator by pressing ON/OFF key for 4 seconds.

5. Operating Instructions

5.1. Start Up and Setting the Ventilation Parameters

A. Turn on the ventilator:

Ensure that the gas supply is turned on before start up to ensure that the calibration process is performed correctly.

To turn on the ventilator, press the ON/ OFF key (N) (Figure 01) for one second. During that second the associated green LED will start blinking at a high frequency. After 1 second the ventilator will turn on but with no ventilation at this point. If the key is pressed and released for less than a second, the ventilator will remain OFF.

B. Start default ventilation:

Once the ventilator is turned on, a selection dial with 12 Vt/BPM pre-set values (Figure 06) will be displayed on the screen. This eliminates the need for a potentially long set up before starting ventilation.

Note: Start-up selection dial is used during start up only and are not active during ventilation.

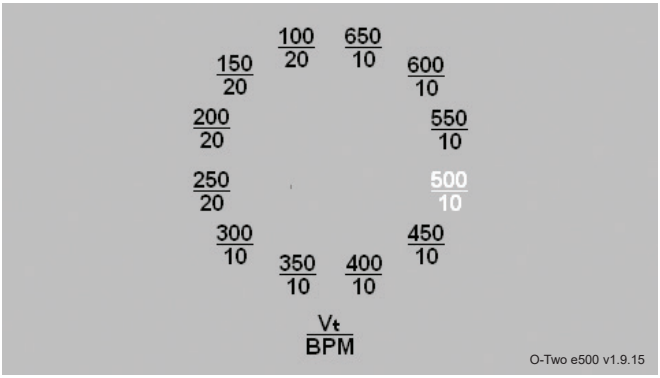


Figure 06 - Start-up Selection Dial

Healthcare providers navigate among these 12 combination settings by rotating the Control Selection Knob (M). The parameter setting will be highlighted if it is selected. Once the desired setting is selected, the user must confirm the selection by pressing the Control Selection Knob (M) to start ventilation. If no selection occurs within 20 seconds, the ventilator will start ventilation with 500/10 setting as its default start-up.

Press the Control Selection Knob (M) to confirm the patient size selection and connect the patient valve to the patient, the ventilator starts SIMV ventilation with the selected Vt and BPM. The default parameters of this mode are listed in Table- 1.

C. Set up the desired ventilation settings:

Health care providers may choose or change the ventilation mode or parameter setting any time during ventilation by the following method:

Rotate the Control Selection Knob (M) and move the yellow cursor (Figure 8) to section 3 of the screen (Figure 4) for ventilation mode setup, or to the parameter to be set up located at section 6 of the screen (Figure 4). The user must confirm the selection by pressing the Control Selection Knob (M). Once confirmed, the selected area will be highlighted with solid contrast background (Figure 9).

Navigate among the available settings by rotating the Control Selection Knob (M). Press the Control Selection Knob (M) to choose the desired setting. The chosen setting will turn yellow with the flashing confirmation symbol ✓ and the Confirmation indicator (L) to guide users to activate the setup by pressing the Control Selection Knob (M) again.

Press the Control Selection Knob (M) to activate the setup. The operator can also press the Cancel button (K) to go back to previous parameters before activation.

TABLE 1
SIMV mode default settings

SIMV SETTINGS	Default
Rate (BPM)	Selected or 10
Vt (ml)	Selected or 500
PEEP (cm H_2O)	5
P max (cm H_2O)	30
P min (cm H_2O)	3
I:E	1:2
O_2 (%)	100%
F trig. (L/min)	3

Figure 07 - SIMV mode screen w/ default parameters (Child setting)

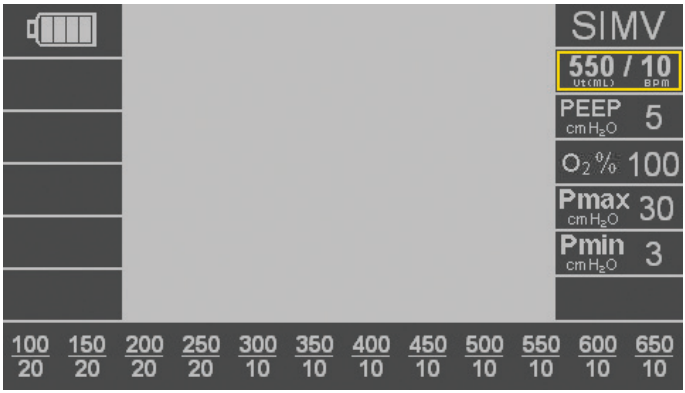


Figure 08 - Showing frame around parameter during selection

Figure 09 - Showing selected parameter with solid contrasting background

5.2. Ventilation Modes

The e500 ventilator is equipped with a number of ventilation modes to enable the healthcare provider to tailor the ventilator settings to the patient's specific respiratory requirements. Ventilation could be delivered invasively (ET tube) or non-invasively (mask).

In all modes, should the patient demand more flow than set by Health care provider, he/she can inhale the required volume from ambient.

Each ventilation mode has a default setting (based on the initial patient size setting selection on startup) which will be initiated on selection of that specific ventilation mode if no changes to the settings are made.

Note: When switching between ventilation modes, any shared parameter will be carried over and any new parameter will be set to default.

5.2.1. SIMV (Synchronized Intermittent Mandatory Ventilation).
In SIMV mode the ventilator will deliver volume ventilation at the set Tidal Volume (Vt) and Rate (Figure 10).

The default trigger for this mode is 3 L/min. If trigger condition is met, the ventilator will deliver synchronized volume controlled mandatory ventilation.

In SIMV mode the selected breathing rate remains constant and the time of spontaneous breathing window will change if patient triggers the synchronized mandatory breath before the normal start of inhalation phase (beginning of Ti).

If no effort was detected during the trigger period, the ventilator will initiate mandatory ventilation at the end of trigger window. Should the patient demand more flow than set by user, he/she can withdraw the excess from ambient.

TABLE 2 - SIMV (Synchronized Intermittent Mandatory Ventilation)

PARAMETER	RANGE	DEFAULT
Tidal Volume/ Rate	100/20,150/20, 200/20, 250/20, 300/10, 350/10, 400/10, 450/10, 500/10, 550/10, 600/10, 650/10	500/10 or selected by user during start-up
I:E ratio	1:2	1:2
PEEP	0, 4, 5, 6, 7, 8, 9, 10, 12, 15, 18, 20	5
Trig.	3 L/min	3
O_2 %	(100% or 60%)	100%
P max.	10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 80	30
P min.	0, 2, 3, 4, 5, 6, 7, 8, 10, 12, 15, 20	3
Manual	Refer to Manual and I-Hold section	ready

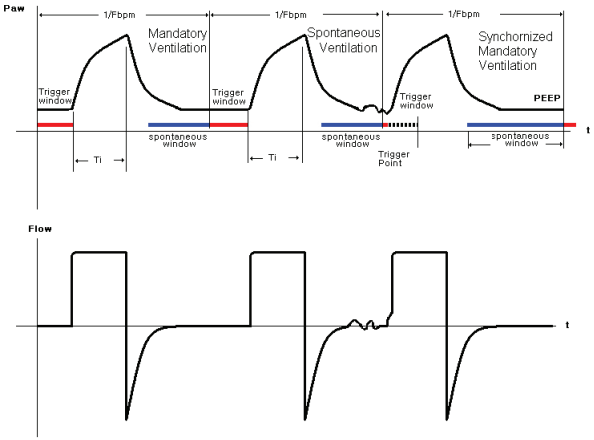


Figure 10 - SIMV waveform

5.2.2. CPAP (Continuous Positive Airway Pressure)
In CPAP mode, the ventilator will deliver a continuous flow rate to generate airway pressure and use the control valve to maintain CPAP levels (Figure 11).

Note: The default trigger in CPAP mode is pressure trigger (P) which is set at 2 cm H_2O below CPAP settings.

In this option the ventilator adjusts the amount of flow internally to maintain average airway pressure close to CPAP setting.

The CPAP mode is equipped with APNEA back up ventilation in which the ventilator switches to SIMV when the ventilator does not trigger patient's spontaneous breathing for a period of time (T APNEA) set by the user. The parameters of back up SIMV ventilation are settable by user.

The trigger changes from pressure trigger (P) to 3 L/min default flow trigger when the ventilator switches to APNEA back up.

TABLE 3 - Default Ventilation Setting- CPAP

PARAMETER	RANGE	DEFAULT
CPAP (cm H_2O)	4, 5, 6, 7, 8, 9, 10, 12, 15, 18, 20	Carry over from PEEP of previous mode
P max.	10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 80	Carry over from previous mode
P min.	0, 2, 3, 4, 5, 6, 7, 8, 10, 12, 15, 20	Carry over from previous mode
O_2 %	(100% or 60%)	Carry over from previous mode
T APNEA (sec)	10, 15, 20, 25, 30, 40, 45, 50, 55, 60	20
Vt/f (A) (ml/BPM)	100/20,150/20, 200/20, 250/20, 300/10, 350/10,400/10, 450/10, 500/10, 600/10, 650/10	Carry over from previous mode

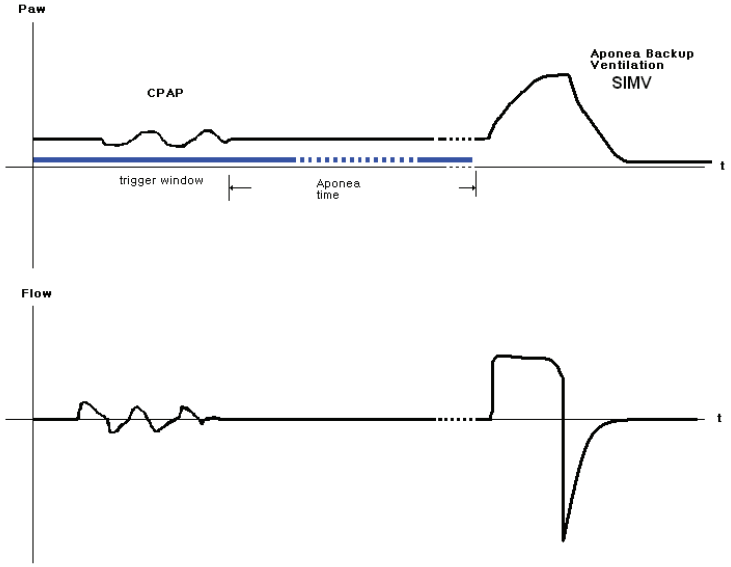


Figure 11 - SIMV waveform with pressure support

5.2.3. CPR mode

The CPR mode consists of timed chest compression audible prompts coupled with automatically delivered breaths for both intubated and mask ventilated patients. There is also a visual animated display to guide the health care provider while performing CPR.

The CPR mode for masked ventilated patients is the default setting for this mode but changes can be made between the 2 sub-modes at any time.

The CPR mode for masked ventilated patients consists of 2 phases, chest compression and ventilation. 30 chest compressions over 18 seconds are synchronized with audible prompts and on screen visual animations, followed by two, 1 second, mandatory breaths within a 5 second ventilation phase. The ratio between chest compressions and ventilations is 30:2 (Figure 12a).

The CPR mode for intubated patients consists of continuous compressions indicated by an audible prompt and visual animation at a rate of 100 compressions per minute plus automatically delivered breath every 6 seconds (Figure 12b).

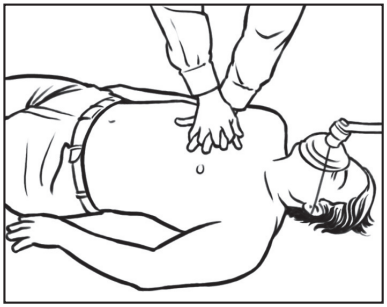
The ventilation in CPR mode is flow controlled ventilation. The tidal volume is user selectable. The O2% is fixed at 100% oxygen during CRP mode.

The ventilator will automatically compensate up to 30% of the required tidal volume Vt in case a leak is detected. Beyond this limit, low Paw visual and audible alarms will be activated to warn rescuer to either re-apply the mask or increase the set tidal volume.

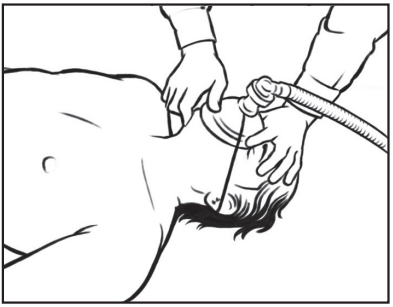
TABLE 4 - Default Ventilation Setting- CPR

PARAMETER	RANGE	DEFAULT
Tidal Volume	100,150, 200, 250, 300, 350,400, 450, 500, 550, 600, 650	Carry over from previous mode
P max.	10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 80	Carry over from previous mode
P min.	0, 2, 3, 4, 5, 6, 7, 8, 10, 12, 15, 20	Carry over from previous mode
O_2 %	100%	100%

CPR FOR MASKED PATIENTS



On screen chest compressing animation



On screen ventilation animation

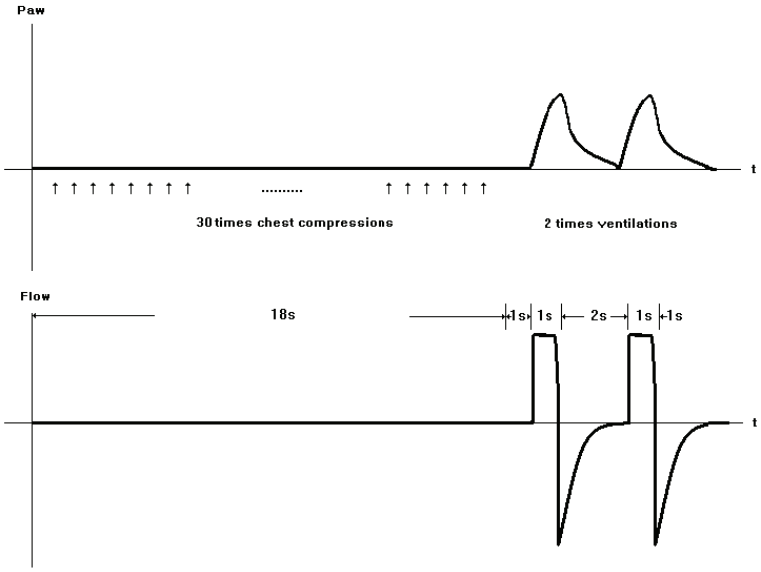
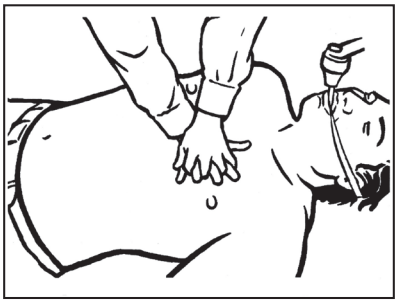


Figure 12.a - CPR waveform for masked patient



On screen intubated CPR animation

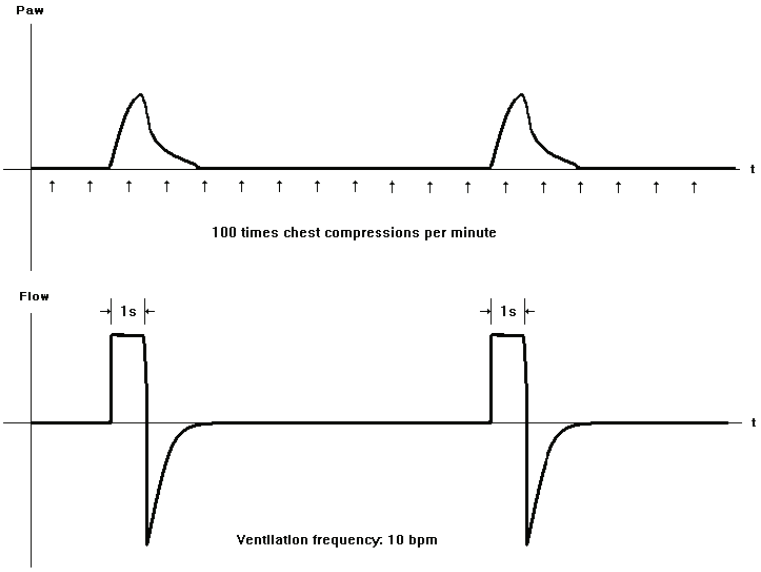


Figure 12.b - CPR waveform for intubated patient

5.3. Turning the Ventilator Off

Press and hold the ON/OFF key for 4 seconds, the Ventilator will turn OFF.

6. Post Use

6.1. Disconnect device after use

A. Turn off gas supply to the ventilator.
B. Disconnect gas supply hose.
C. Disconnect patient circuit from the output connector.
D. Unplug the power cable from mains if no charging is required.
E. Clean and disinfect according to section 8.1 in this manual.

6.2. Storage

Store ventilator within the following environmental range:

- 40°C to +60°C, Rh: 15% to 95%.

Note: The ventilator operates within 5 minutes after being brought back from minimum storage temperature to room temperature;

The ventilator operates within 2 minutes after being brought back from maximum storage temperature to room temperature.

7. Alarms and Indicators

7.1. Ventilation Alarms

Visual and Audible alarms continue until the cause of the alarm is resolved.

During alarm activation the user may press the Alarm Silence key (G) (Figure 01) which will silence the audible alarm for 2 minutes but the visual alarm will continue to flash until the cause of the problem is resolved.

During “alarm silence”, should a new alarm develop, the Alarm Silence function will continue and only the new visual alarm will be shown flashing on the screen.

Alarms will be visible in section 4 or section 7 of the display (Figure 04).

There could be multiple alarm/warning symbols visible on the screen indicating multiple failures occurring at the same time. In this case the visible and audible alarms will be based on highest priority alarm.

All ventilation alarms of e500 are listed in the following Table-5.

TABLE 5 - Ventilation Alarms and Symbols

Symbol	Name	Priority	Visual Alarm		Audible Alarm
			Alarm Symbol	Warning LED	
BCI	Patient Circuit disconnect (Breathing circuit Integrity)	High after 15 seconds	Flashing Symbol	Flashing yellow for 15 seconds, then red	15 sec. delay Two bursts with five pulses
LOW PAW	Low Airway Pressure	High	Flashing Symbol	Red	Two bursts with five pulses
HIGH PAW	High Airway Pressure	High	Flashing Symbol	Red	Two bursts with five pulses
Leak	Leak (at 40% below set Vt)	High	Flashing Symbol	Red	Two bursts with five pulses
O_2	No Oxygen ≤ 20 PSI	High	Flashing Symbol	Red	Two bursts with five pulses
O_2	Low Oxygen ≤ 40 PSI	Medium	Flashing Symbol	Yellow	One burst with 3 pulses
O_2	High input pressure ≥ 90 PSI	High	Flashing symbol	Red	Two bursts with five pulses
APNEA	APNEA	High	Flashing symbol	Red	Two bursts with five pulses

Symbol	Name	Priority	Visual Alarm		Audible Alarm
			Alarm Symbol	Warning LED	
	Empty Battery	High	Flashing symbol	Red	Two bursts with five pulses
	Low Battery	Low	Flashing symbol	N/A	N/A
	Pause	N/A	Flashing symbol	Yellow every 15 seconds	N/A
	Play	N/A	Flashing symbol	N/A	N/A
	Lock	N/A	Solid symbol	N/A	N/A
	Alarm Silence	N/A	Solid symbol	N/A	N/A
	Patient effort	Low	Solid symbol during Patient effort	N/A	N/A
	Invalid setting - Refer to manual	N/A	Solid symbol During invalid selection	N/A	N/A
	Setting Conflict	N/A	Solid symbol During invalid selection	N/A	N/A
	Confirm	N/A	Flash symbol after primary selection	N/A	N/A

Invalid setting is when the ventilator reaches its limits mechanically or physically. In this case users can't make adjustments from and beyond the invalid setting adjustment.

Setting conflict is when the ventilator detects a conflict in the setting like reaching the Pmax level. In this case users can make adjustments from and beyond the conflict point while the symbol will be displayed during the adjustment.

7.2. Battery Status Indicator

Battery status will be displayed in section 1 of the display (Figure 04). There are two different status indicators showing battery discharging (Table-6.1) and charging (Table-6.2) status respectively.

TABLE 6.1 - Battery discharging status

1		Full Capacity	No Alarm
2		Approx. 75% of full capacity	No Alarm
3		Approx. 50% of full capacity	No Alarm
4		Approx. 25% of full capacity. Symbol changes to yellow flashing	On screen symbol change to Yellow color and flashing
5		Approx. 5% of full capacity. Symbol changes to red flashing with associated red colour LED	On screen symbol change to Red color and flashing with associat-ed Red color warning LED.

TABLE 6.2 - Battery charging status

1		Full Capacity	No Alarm
2		95% of full capacity	No Alarm
3		90% of full capacity	No Alarm
4		80% of full capacity	No Alarm
5		65% of full capacity	No Alarm

⚠ WARNING ⚠

At approximately 2% of full battery capacity, the ventilator will not start when it is turned off or will shut down when it is turned on.

Note: The battery capacity level is detected from measured voltages and the capacities shown above are based on results from new batteries tested at room and low temperature. Battery capacity levels are subject to change when old batteries are used.

Fully charged Batteries shall be recharged after 6 months without usage or when battery discharging LED turns orange and flashes.

The battery re-charge time is about 5.5 hours from fully discharged. Batteries have a minimum of 200 discharge and charge cycles.

7.3. LEDs

	Green color LED - Continuous when unit is ON and flashing when unit is OFF.
	Red or Yellow color LED – Flashing during alarm/ warning situation. LED color depends on the severity of the failure.
	Green color LED - Continuous when unit is connected to AC power source during both ON and OFF phases.
	Orange color LED - Continuous when unit is charging and off when battery is fully charged during both ON and OFF phases. During OFF phase this light will start flashing when battery capacity drops to around 90 %.
	Green color LED - Continuous when unit is operated using internal battery.

8. Cleaning, Preventive Maintenance & Servicing

8.1. Cleaning and Disinfection

Disinfect the ventilator housing and supply hose using a damp cloth with a commercially available, legally marketed disinfectant solution which is compatible with the materials of manufacture in accordance with local protocols. Do not use chlorine based cleaning agents. Make sure no liquids enter the ventilator connections or the ventilator.

⚠ WARNING ⚠

Do not immerse the e500 Ventilator or patient circuit or supply hoses in disinfectant or other liquids, serious electric shock hazard and damage to the ventilator may occur. If the Ventilator is accidently submerged in any liquid it must be returned to the manufacturer for factory service.

Do not attempt to clean the intake filter or patient circuit. Using a wet or damp filter may result in inaccurate parameters and potentially damage the ventilator.

⚠ WARNING ⚠

RISK OF EXPLOSION!

Cleaning agents containing alcohol or grease become flammable when combined with compressed oxygen and can cause explosions.

8.2. Charging the battery

1. Connect one end of the external power supply/charger to its supply (100 to 240 Volts or on-board vehicle socket*) and the other end to the DC input socket (O) (Figure 02) located on the side panel of the ventilator. The LED indicators illuminate as follows:

	Green LED - Continuous when unit is connected to external power source during both ON and OFF phases.
	Orange LED - Continuous when unit is charging and off when battery is fully charged during both ON and OFF phases.

2. Turn unit ON and observe battery level (section 1 of the screen), Refer to 7.2 Battery Status Indicator for exact battery charging status. The battery shall be fully charged

CAUTION

The ambient temperature shall be between 0°C and 35°C during battery charge.

Note:

- The Battery pack can be charged during operation.
- The Battery pack may be charged using external power supply supplied with the unit or the optional DC to DC power supply.
- The Battery pack should be replaced after 200 charge/discharge cycles or if the battery pack will not fully charge (as indicated on the battery display on the ventilator) or if the ventilator doesn't run for more than 5 hours on a single charge.

8.3. Ambient Air Entrainment Filter

The e500 entrains ambient air through the internal Venturi system for ventilation when the O_2 concentration is set at 60%. This provides not only decreased oxygen concentration but also increases the ventilator operating time on an oxygen cylinder.

CAUTION

Always keep the ambient air entrainment port clear of obstructions. Always replace the filter after use.

⚠ WARNING ⚠

Avoid particulate and/or gaseous pollutants in the ambient air! The entrainment of pollutants into the ventilator may cause the ventilator to malfunction or cause danger to the patient.

8.4. Preventive Maintenance and Servicing

It is recommended that routine preventive maintenance (PM) and servicing shall be carried out as per the following:

TYPE	DESCRIPTION	PROCEDURE	CRITERIA	SCHEDULE	By
PM	Charging battery	User Manual Chapter 8.2	Battery fully charged	Every 6 months	User
PM	Leak test	User Manual Chapter 4.2	No leak observed	Every 6 months	User
PM	Function check	User Manual Chapter 4.2	No abnormal function observed	Every 6 months	User
Servicing	Level II service	Service Manual	Meet product specifications	Every 2 years	Manufacturer or authorized service center
Servicing	Full service	Service Manual	Meet product specifications	Every 6 years	Manufacturer

Preventive Maintenance
To ensure proper operation of the ventilator, regular inspection and checking of the device and accessories for correct function should be undertaken by a responsible member of staff. It is recommended that a preventive maintenance record be maintained for each unit.

The battery should be charged and the ventilator be checked for leakage and proper function at least every six months, and more frequently in high use applications. Any malfunction unit should be returned to the manufacturer or an authorized service center since this product is not designed for field disassembly or service. Unauthorized repairs will nullify the product warranty.

Level II service
The device shall be returned to the manufacturer or a service center authorized by the manufacturer for Level II service every 2 years.

Manufacturer full service
The device shall be returned to O-Two Medical Technologies for Manufacturer Full Service every 6 years.

⚠ WARNING ⚠
Any malfunctioning unit should be returned to the manufacturer or an authorized service center since this product is not designed for field disassembly or service.

9. Technical Data

9.1. Specifications

DEVICE CLASS PER MDD		II b
CLASSIFICATION PER IEC60601-1	Protection against electric shock	Class II, Type BF
	Protection against water	IP X4
POWER SOURCE (PNEUMATIC)		Compressed Oxygen, 45 to 87 PSI (3-6 Bar)
POWER SOURCE (ELECTRIC)		AC/DC power supply, Rechargeable Lithium Battery
VENTILATION MODES		SIMV, CPAP, Mask CPR and Intubated CPR
TIDAL VOLUME /RATE (ML/BPM)		100/20, 150/20, 200/20, 250/20, 300/10, 350/10 400/10, 450/10, 500/10, 600/10, 650/10 ± (4ml + 15%) BTPS */ (± 10% or ± 1BPM)
MANUALLY TRIGGERED VENTILATION		Yes, set flow rate or pressure will be delivered during I time then Inspiratory hold
MAXIMUM INSPIRATORY HOLD TIME		6 sec.
I:E RATIO		1:2 (± 20%)
PEEP (cmH_2O)		0, 4, 5, 6, 7, 8, 9, 10, 12, 15, 18, 20 (± 10% or ± 2 cm H_2O)
CPAP (cmH_2O)		4, 5, 6, 7, 8, 9, 10, 11, 12, 15, 18, 20 (± 10% or ± 2 cm H_2O)
FiO_2 (%)		60 or 100 (± 15%)
PMAX (cmH_2O)		10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 80 (± 10% or ± 2 cm H_2O)
PMIN (cmH_2O)		0, 2, 3, 4, 5, 6, 7, 8, 10, 12, 15, 20 (± 10% or ± 2 cm H_2O)
TRIGGER SENSITIVITY (L/MIN)		3 L/min (± 10%) or 2 cmH_2O below baseline in CPAP mode only
APNEA BACK UP TIME (SEC.)		10-60 (± 0.5s)
BATTERY OPERATING TIME AT ROOM TEMPERATURE (HRS.)		>18 hrs for default settings (Data obtained using fully charged new battery)
ALTITUDE COMPENSATION		up to 4000 m (13000 feet)
BATTERY HOT SWAP		No
BUILT-IN BATTERY CHARGER		Yes
AC/DC POWER SUPPLY		100-240 VAC/ 19 VDC, 4.74 A
PATIENT CIRCUIT		O-Two Electronic Ventilator Circuit
MOUNTING BRACKET		Smart Mount multi-configuration frame
DISPLAY		4.3" Color TFT
LIVE MONITORING		Mve, Vte, Paw(AV), PAW(Peak), Rate (bpm), Battery level
REAL TIME WAVEFORM		Pressure or Flow
DAY/NIGHT DISPLAY MODE		Yes
PARAMETER SETTINGS		Control Selection Knob
LOCK KEY FUNCTION		Yes
PAUSE FUNCTION		Yes
NOISE LEVEL IN NORMAL USE		Less than 65 dBA
ALARMS (VISUAL AND AUDIBLE)		Gas Supply Pressure, Airway Pressure limits, Battery status, APNEA, Breathing Circuit Integrity, and Leakage
AUDIBLE SILENCE		Yes, 120 second max
DIMENSIONS (MM)		250 x 200 x 155
WEIGHT (KG)		2.4 (w/ Battery), 1.77 (w/o Battery)

INTERNAL VOLUME OF THE COMPLETE RESPIRATORY SYSTEM (REUSABLE AND DISPOSABLE)			approx. 690 ml without mask approx. 800 ml with mask
DEAD SPACE OF PATIENT VALVE WITH ELBOW			Approx. 35 ml
COMPLIANCE (DISPOSABLE) HOSE SYSTEM			16.6 ml/kPa
RESISTANCE OF PATIENT HOSE SYSTEM (INHALATION AND EXHALATION):			Less than 6 cmH_2O at 60 l/min & Less than 6 cmH_2O at 30 l/min
ENVIRONMENT CONDITION	Ventilator	Operating-Continuous	- 18°C to +40°C, Rh: 15% to 95%
		Operating-Transient**	- 20°C to +50°C, Rh: 15% to 95%
		Storage	- 40°C to +60°C, Rh: 15% to 95%
	Battery Pack	Charge	0°C to +40°C
		Discharge	- 20°C to +60°C
		Storage	- 20°C to +35°C, low humidity and no corrosive gas atmosphere.
	Patient Circuit	Operating	- 18°C to +50°C, Rh: 15% to 95%
		Storage	- 20°C to +60°C, Rh: 15% to 95%

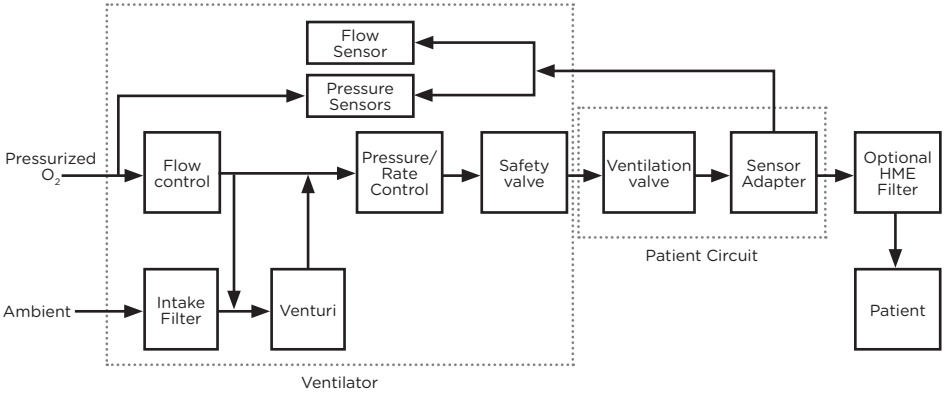
Note: Measurement uncertainty: 5% for volume parameters and 6% for pressure parameters.

* Volume measurements corrected to BTPS (Body Temperature 37°C, barometric Pressure 101.3Kpa under Saturated 100% humidity) conditions.

****Transient Operation**: The e500 is capable to keep its specifications when operated in normal use for a period not less than 20 minutes under - 20°C and +50°C. This ensures a typical long duration for emergency treatment at the scene prior to timely removal of the patient to the next point of care. It is highly recommended that the patient, the ventilator and the operator be moved to a more controlled environment in case of extreme temperatures and humidity levels.

During transient operation, the maximum temperature of the VBS in contact with patient may reach to +50°C. It is advised that patient contact period be limited to as minimum as possible.

9.2. Circuit Description



When a gas source (medical oxygen) is supplied to the e500 ventilator via the gas input connection, the gas will flow into the Flow control valve which is used to control both the flow and rate of ventilation.

The output of this valve is connected to a selector switch which is used to direct the flow path either directly to the ventilator output (if 100% oxygen ventilation is required) or through a Venturi system used to entrain air to provide an oxygen concentration of 60%.

9.3. Battery & Power Supply

Battery Pack	**Type 01**	**Type 02**
Battery Cell Type	Rechargeable Lithium Ion Cell	
Type	4ICR19/65-3	4INR19/66-3
Nominal Capacity	7500 mAh, Min 111 Wh	6000 mAh, 86.4 Wh
Nominal Voltage	14.8 V	14.4 V
Max. Charging Current	3750 mA	5000 mA
Max. Charging Voltage	16.8 ± 0.1 V	
Dimension mm / in	144 x 62 x 42 / 5,66 X 2,44 x 1,65	
Weight	642 g / 1,41 lbs	
Test specification	Meet requirements of IEC62133:2012	Meet requirements of IEC62133:2017

AC/DC Power Supply

Model	PMP90-13-2 01CV0105
Input Voltage	100 - 240 VAC
Input Current	1.06 - 0.45 A
Input Frequency	47 - 63 Hz
Output Voltage	19 VDC
Output Current	4.74 A Maximum
DC Output Plug	2.5 x 5.5 x 11 mm
DC Output Cable Length	6’
AC Power Cord Length	6’
Weight	642 g
EMC performance	Meet requirements of IEC60601-1-2
Safety Standards	Meet requirements of IEC60601-1:2005

Note: Upon disconnecting AC Power supply, Ventilator will automatically switch to Battery operation without affecting ventilator behaviour.

9.4. Battery Operating Time

Battery operation time ranges from 22 hours in normal operating temperature to 16 hours under extreme low operating temperature.

9.5. Electromagnetic Compatibility

O-Two e500 has been tested and complies with IEC 60601-1-2:2007 requirements.

Electromagnetic Emissions
O-Two e500 is intended for use in the electromagnetic environment specified below. The user of O-Two e500 should assure that it is not used in environments outside those specified:

EMISSION TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT -GUIDANCE
RF emissions CISPR 11	Group 1	The O-Two e500 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference with nearby electronic equipment
RF emissions CISPR 11	Class B	The O-Two e500 external power supply is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supply buildings used for domestic purposes
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC61000-3-3	complies	

Electromagnetic Immunity

IMMUNITY TEST	IEC60601 REQUIRED TEST LEVEL	ACTUAL COMPLIANCE LEVEL
Electrostatic discharge (ESD) IEC61000-4-2	± 6 kV contact ± 8 kV air	± 8 kV contact ± 15 kV air
Electrical fast transient/ burst IEC61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines
Surge IEC61000-4-5	± 1 kV line to line; ± 2kV line to earth	± 1 kV line to line; ± 2kV line to earth
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5%U_T for 0.5 cycle 40%U_T for 5 cycle 70%U_T for 25 cycle <5%U_T for 5 s	<5%U_T for 0.5 cycle 40%U_T for 5 cycle 70%U_T for 25 cycle <5%U_T for 5 s
Power frequency (50/60Hz) magnetic field IEC61000-4-8	3 A/m	30 A/m
Conducted RF IEC61000-4-6	3Vrms: 150 kHz to 80 MHz outside ISM bands	3 Vrms
	10Vrms: 150kHz to 80 MHz in ISM bands	10 Vrms
Radiated RF IEC61000-4-3	10 V/m @ 80 MHz to 2.5 GHz	30 V/m

O-Two e500 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the O-Two e500 as recommended below, according to the maximum output power of the communications equipment:

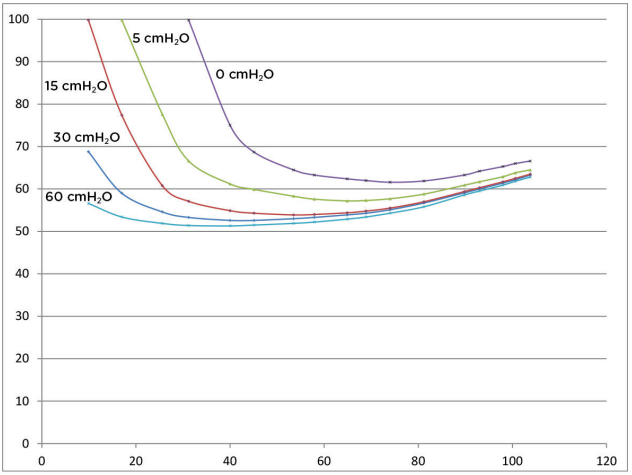
RATED MAXIMUM OUTPUT POWER OF TRANSMITTER W	SEPARATION DISTANCE (M)			
	150kHz to 800 MHz outside ISM bands d = 3.5/3 *√ P	150kHz to 800 MHz in ISM bands d = 1.2√ P	80 MHz to 800 MHz d = 1.2√ P	80 MHz to 800 MHz d = 1.2√ P
0.01	0.12	0.12	0.12	0.23
0.1	0.4	0.4	0.4	0.7
1	1.16	1.2	1.2	2.3
10	3.8	3.8	3.8	7.3
100	12	12	12	23

9.6. Oxygen Consumption

For a "D" size cylinder (capacity of 425 liters), pressurized to 2015 PSI and with the e500 set to the Adult default setting (Vt= 500ml, Rate= 10BPM, 100% Oxygen) the pneumatic operating time is 85 minutes without PEEP (0.2 min/L) and is 39 minutes with maximum PEEP (0.089 min/L).

Duration of consumption of a cylinder in minutes is calculated approximately by dividing the liter content by the minute volume with or without PEEP.

9.7. Oxygen Concentration delivered against different back pressures



10. Troubleshooting

⚠ WARNING ⚠

Please contact the manufacturer if a problem cannot be rectified. For the safety of the patient and the Health care providers DO NOT continue using the ventilator.

Message/ fault	Cause	Remedy
	Leaking mask, ETT, disconnected patient circuit	Make sure mask fits / all patient circuit parts are properly connected./change patient circuit
Low Paw	Low Airway Pressure	Replace hose, check tube position, check ventilation settings and correct
High Paw	High Airway Pressure	Check patient, ventilation circuit, check tube position, adjust Pmax alarm value
	Apnea, spontaneous breathing failed or disconnection, faulty sensor	Switch to Assist Control ventilation, ensure connections tight, Replace patient circuit
	No Oxygen ≤ 20 PSI	Change Oxygen cylinder
	Low Oxygen(40-21 PSI)	Change Oxygen cylinder
	Leakage, measured expiratory volume is 40% lower than set.	Check leakage in breathing system.
	Invalid setting	Resolve parameters conflict by resetting out of range parameters
Battery discharges quickly	No proper charging/Faulty battery	Charge Battery as per instructions/ Replace battery
e500 cannot be switched on	Battery empty/no power supply connected/defective	Change Battery/connect power supply/ send to O-Two for repair or service

11. Abbreviations and Acronyms

TERM	DESCRIPTION
BCI	Breathing Circuit Integrity (Patient circuit disconnect)
CPAP	Continuous Positive Airway Pressure
CPR	Cardio Pulmonary Resuscitation
Rate	Ventilation rate (number of breaths per minute)
I:E	Ratio of inspiration time to expiration time
LED	Light Emitting Diode
Mve	Exhaled Minute Volume
Mv	Minute volume
O_2 (%)	Percentage of Oxygen inspired
Paw (AV)	Average airway pressure
Paw (peak)	Peak airway pressure
PEEP	Positive End Expiratory Pressure
P max	Maximum airway pressure
P min	Minimum airway pressure
SIMV	Synchronized Intermittent Mandatory Ventilation
T APNEA	Apnea Alarm time
Te	Expiratory time
TFT	Thin Film Transistor
Ti	Inspiration time
Trig.	Triggering flow rate
Vte	Exhaled Tidal volume
Vt	Tidal volume

12. Accessories

ITEM	PART	ORDER NUMBER
1	O-Two Single-Use Electronic Transport Ventilator breathing circuit 6′ (1.83 m) - case of 10	01CV8030-cs
2	PVC 6’ (1.83 m) input pressure hose – 9/16” DISS nut fitting	01FV4302
3	Intake filter - case of 10	01CV8040-cs
4	Power supply Cord (Canada and the US)	01CV0106
5	Battery Pack	01CV9100
6	e Ventilator External Power Supply	01CV0105
7	“SMART MOUNT” Mounting Bracket for Road ambulance	01EV7035
8	1L Test lung	01TA1852
9	eSeries Automatic Transport Ventilator Carrying Case – With sling-style shoulder strap	01CV7050

Note: When ordering the ventilator please specify the input hose and power cable connectors required for the country of use.

13. Warranty

O-Two Warrants the e500 ventilator, when used in accordance with the instructions contained within this Manual, for a period of two years from the date of purchase except for the following cases:

1. Using unspecified parts/accessories
2. An attempt to service by unqualified persons/entities
3. Negligence
4. Normal wear and tear (filters, batteries, patient circuits)

Note: O-Two Warrants the battery for a period of one year from the date of purchase.

⚠ WARNING ⚠

It is recommended that the routine preventive maintenance shall be carried out at least every 6 months from date of purchase. Repair and general overhaul of the ventilator must be carried out by trained service personnel. Evaluation of performance against manufacturer's specifications may be undertaken by suitably qualified personnel to determine if the ventilator is functioning within specification. Any ventilators deemed to be out of specification must be returned to O-Two Medical Technologies Inc. (or one of it's approved Service Centers) for service and/or repair.

We recommend that a service contract be obtained with O-Two Medical Technologies Inc. (or one of it's approved Service Centers) and that all repairs also be carried out by them.

Only authentic O-Two Medical Technologies Inc. spare parts must be used for maintenance.

Liability for proper function or damage

The liability for the proper function of the apparatus is irrevocably transferred to the owner or operator to the extent that the apparatus is serviced or repaired by personnel not employed or authorized by O-Two Medical Technologies Inc. or if the apparatus is used in a manner not conforming to its intended use.

O-Two Medical Technologies Inc. cannot be held responsible for damage caused by non-compliance with the recommendations given above.

The warranty and liability provisions of the terms of sale and delivery of O-Two Medical Technologies Inc. are likewise not modified by the recommendations given above.

Your Representative is:

O-TWO MEDICAL TECHNOLOGIES INC.

For your nearest Authorized O-Two Distributor
In North America call Toll Free 1-800-387-3405

SERIAL N°:	

CE 1639

EC	REP

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