USER MANUAL

o_two controlled™ ventilation

eAdvantage®

Electronic Nitrous Oxide/Oxygen Analgesic Gas Mixing and Delivering System

01EQ3000

Made in Canada by O-Two™ Medical Technologies Inc.
Part Number: 15PL1033 Rev. 12, July 2023

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1. SAFETY

⚠ WARNINGS ⚠

- Federal Law restricts this device to sale by or on the order of a physician.
- The eAdvantage® shall only be used by qualified healthcare professionals trained in its use for the purposes specified under “Intended Use”.
- The eAdvantage® system is designed for patient self-administration.
- Never attach the face mask to the patient using a head harness.
- The eAdvantage® shall not be used in oxygen rich nor flammable gases or anaesthetic agents environments. Keep away from open flames, sparks and grease/oil.
- It is recommended to use cylinders that are at least 1/4 full. Always turn ON the cylinder valve slowly and fully.
- The nitrous oxide cylinder should be operated in an upright position. If the nitrous oxide cylinder is in a valve-down position while the post valve is open, liquid may be expelled through the vent passages. This liquid, Nitrous Oxide, can cause burns by freezing on exposed skin.
- Never allow oil or grease to come into contact with any part of the cylinders, regulators or eAdvantage® system.
- Always use the checklist to ensure that all components are reassembled correctly and that all disposable items are replaced.
- Before use on a patient, the settings of the delivered gas should be checked to ensure they are in accordance with the intended use.
- It is recommended to use an oxygen monitor complying with ISO 80601-2-55 whenever the gas mixer is in use by connecting it to the gas outlet on the device between the device and the circuit.
- This device must be used with the O-Two™ Breathing Circuit, 01CV8037. It is recommended to connect the expiratory tubing of the circuit to an Anaesthetic Gas Scavenging System complying with ISO 80601-2-13
- If the alarm sounds continuously, immediately discontinue use and shut OFF the gas supply.
- After use, always turn OFF the cylinders to ensure that gas cylinders with sufficient volume are attached before returning the unit to its normal storage position.
- After use always turn OFF the device.
- Do not disassemble any part of the unit except where described in this manual as any unauthorized disassembly will invalidate the warranty.
- NEVER obstruct the output port nor the scavenging connector outlet.
- DO NOT use the Oxygen Flush function to provide positive pressure ventilations to a non-breathing patient.

℞ Only

- After use, always turn OFF the cylinders and ensure that gas cylinders with sufficient volume are attached before returning the unit to its normal storage position.
- Medical gases must be dry and free from dust and oil. A malfunction in the medical gas pipeline will cause this device to stop working.
- This device and its associated breathing system are compatible for use with N_2O and O_2.
- The patient shall be constantly monitored by trained healthcare professionals while using the eAdvantage.

2. GENERAL INFORMATION

2.1 Intended Use

The O-Two eAdvantage® N_2O/O_2 electronic analgesic gas mixing and delivery systems are intended to administer an operator adjustable mixture of nitrous oxide analgesic/anxiolytic gas and oxygen, on demand, to a conscious, spontaneously breathing patient.

2.2 Environment of Use

The device is suitable for use in hospitals, medical, dental and doctor's offices, where short-term or intermittent inhalation analgesia is required for a wide range of procedures.

2.3 Contraindications

The contraindications for this device include, but may not be limited to:

- Hypersensitivity to the medication
- Head injuries with impaired consciousness
- Maxillofacial injuries
- Artificial, traumatic or spontaneous pneumothorax
- Air embolism
- Middle ear occlusion, ear infection
- Decompression sickness
- Abdominal distension / intestinal obstruction

Note: Nitrous oxide/oxygen (N_2O/O_2) mixtures must never be used in any condition where air is trapped in the body and expansion (up to 3x original size) would be dangerous. For example, it will exacerbate a pneumothorax and increase pressure in any intracranial air. Air in any other cavities such as the sinuses, middle ear and abdomen may also expand.

3. OVERVIEW

3.1 Product Description

The eAdvantage® is an electronically controlled (mains supply or battery), gas pressure operated, self-administered mixing system for the delivery of a variable concentration of a gaseous mixture of nitrous oxide and oxygen (N_2O/O_2), on demand flow to spontaneously breathing, conscious patients via a unique patient circuit with monitoring line.

Note: This device shall be used by the patient under the guidance of qualified personnel trained in its use.

Intended Patient Population:
Conscious, spontaneously breathing patients who are able to comprehend the activity, understand verbal commands and self-administer the set analgesic gas mixture.

3.2 Principles of Operation

The eAdvantage® System utilizes variable flow control and measurement to deliver accurate concentrations of N_2O/O_2 from pressurized and regulated gas supplies (either cylinder or pipeline) at flow rates equivalent to that demanded by the patient. Two input connectors are provided on the device for the connection of pressure regulated gas sources of nitrous oxide and oxygen. The device has only one control for turning ON or OFF as well as adjusting the setting selections. When it is turned ON, and the device auto-calibration is completed, the display changes to the operation screen with Demand Flow mode set at 50%-50% mixture as the default setting. The gas mixture output can be selected on the screen from a range of percentages from 0%/100% (N_2O/O_2) to 70%/30% (N_2O/O_2) in 5% increments.

The gas specific built-in alarm systems will generate both visual and audible alarms should either the nitrous oxide or oxygen input pressure fall below 45 PSI, and the device will be automatically shut OFF should the oxygen input pressure fall below 21 PSI.

An oxygen flush function allows the healthcare professional to provide a constant flow of 100% oxygen to the patient.

Note: The eAdvantage® mixer is considered a critical device, and its components considered critical components. Only those individuals trained in the operation of nitrous oxide/oxygen analgesic gas delivery systems (and this device) should use this equipment. Thoroughly review the instruction manual before use.

3.3 Controls, Connections and Indicators

A	Green LED for battery operation indicator	I	Output Connection
B	N_2O Input Connection	J	LED Confirmation Indicator
C	Power Input Connection	K	Control Knob
D	USB Connection	L	Cancel Key
E	Alarm Buzzer	M	Audio Paused Key
F	Green LED indicator for AC power	N	Oxygen Flush Key
G	Orange LED indicator for battery charging	O	Oxygen Input Connection
H	Airway pressure monitoring port	P	LCD Screen

3.4 Control Functions

Control Knob (K):
The Control Knob is used to turn ON the mixer (by depressing it for 1 second) or turn the mixer OFF (by depressing it for 4 seconds).

It is also used to navigate between the options and settings on the screen, by rotating it in either direction when needed and for confirming the setting selection (by depressing the knob).

Cancel Key (L):
Pressing the Cancel Key will cancel the current selection stage to go back to the previous stage until the main screen with no selection is reached.

Audio Paused key (M):
The eAdvantage® is equipped with an Audio Paused key to silence the Audible Alarm for 2 minutes. The Audio paused function will be activated any time the Audio Paused key is depressed even without an active alarm.

Oxygen Flush key (N):
The eAdvantage® is equipped with the ability to manually deliver a constant flow of 40 L/min of 100% oxygen as long as this key is pressed.

3.5 LED Indicators

	Green LED – Continuously illuminated when unit is ON and flashes when unit is OFF.
	Green LED – Continuously illuminated when unit is connected to an external power source during both ON and OFF phases.
	Orange LED – Continuously illuminated when unit is charging and OFF when battery is fully charged during both ON and OFF phases. During OFF state this light will start flashing when battery capacity drops to around 60%.
	Green LED – Continuously illuminated when the unit is operated using the internal battery.

3.6 Symbols and Notations

	Consult the instructions for use.
	Warning! Risk of injury and possible negative patient outcome.
WARNING	Warns of material damage with potential patient consequences.
NOTE:	Offers useful tips to assist in the proper use of the equipment.
	Keep away from open flames.
	No smoking around mixer.
IPX2	Ingress protection rating: “Dripping Water”. Do not immerse.
	Type BF applied part complying with the specified requirements of IEC60601-1 to provide a higher degree of protection against electric shock.
	Separate selection for waste of electrical and electronic components
	Read the User Manual before use.
	Demanded flow delivery during Patient effort.
	Return for Service
	Audio paused
	Caution: Federal law restricts this device to sale by or on the order of a physician

4. PREPARATION FOR USE

4.1 Component List

Ensure that all the following components have been received:

1. eAdvantage® mixer
2. Single use patient circuit with mouthpiece
3. Oxygen supply hose
4. Nitrous oxide supply hose
5. External power supply with power supply cord
6. Battery pack
7. Operating manual

If any components are missing from the shipping carton, call the supplier immediately.

4.2 Set Up

4.2.1. Connecting the electrical power supply

The eAdvantage® mixer is supplied with a regulated power supply with the customer specified power cord for the country of use. The power supply plugs into the socket on the left hand side of the unit. This socket is protected with a dust cap when not in use. (Fig. 1)

Note: Power supply cords are available for most countries. Please specify the country of use at time of purchase.

Should external power be lost, the device will automatically switch to internal battery power (providing the battery is charged) and the green battery LED on the left of the front panel will illuminate.

⚠ WARNING ⚠

Do not place this device in a position that limits access to the mains power inputs.

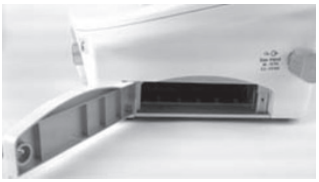
4.2.2. Installing / replacing the battery

The battery is inserted into the battery compartment on the right side of the device by unscrewing the yellow/black knob anti-clockwise and allowing the compartment door to open.

⚠ WARNING ⚠

The replacement of lithium batteries by personnel not specifically trained in the use of this device may be hazardous.

Yellow/black knob



Connector

Insert the battery with the connector on the right hand side.

WARNING

- A fully charged battery must always be installed for safety reasons, even when operating from an external power supply, so that continuous operation is not interrupted in the absence of external power. Never run the device with the battery removed or unplugged.
- The use of batteries, other than those specified, may cause the mixer to fail and/or endanger the patient and operator.
- Connect the mixer to an external electrical source right away if the "Battery Empty" alarm is triggered.

4.2.3. Connecting the gas supply hoses

The eAdvantage® mixer is designed to operate on medical nitrous oxide and oxygen from either pressure regulated medical gas cylinders or "piped-in" systems. The entrance fittings on the device are non-interchangeable fittings specifically for nitrous oxide and oxygen.

The device is designed to operate between 50 – 70 PSI (3.5 - 4.8 Bar) input pressures for both N_2O and O_2 gas supplies.

The nitrous oxide supply hose provided shall be attached to the N_2O input connection on the left side (when facing the device). The oxygen supply hose provided shall be attached to the O_2 input connection on the right side of the device. Tighten the supply hoses.

⚠ WARNING ⚠

"Finger tight" only – DO NOT USE A WRENCH (Fig. 1).

Fig. 1 Connecting the Supply hoses, Patient Circuit and Power Supply

⚠ WARNING ⚠

Using a wrench or applying excessive force in tightening the supply hose may damage the seal or the thread of the connection.

Note: Power supply cords are available for most countries. Please specify the country of use at time of purchase.

Should external power be lost, the device will automatically switch to internal battery power (providing the battery is charged) and the green battery LED on the left of the front panel will illuminate.

4.2.4. Connecting the patient circuit and Sensor line

Connect a new patient circuit (01CV8037) to the 22mm outlet connection port, remove the monitoring line plug and connect to the monitoring line connection port (Fig. 2).

Note: Ensure both the monitoring line and patient circuit are securely connected.

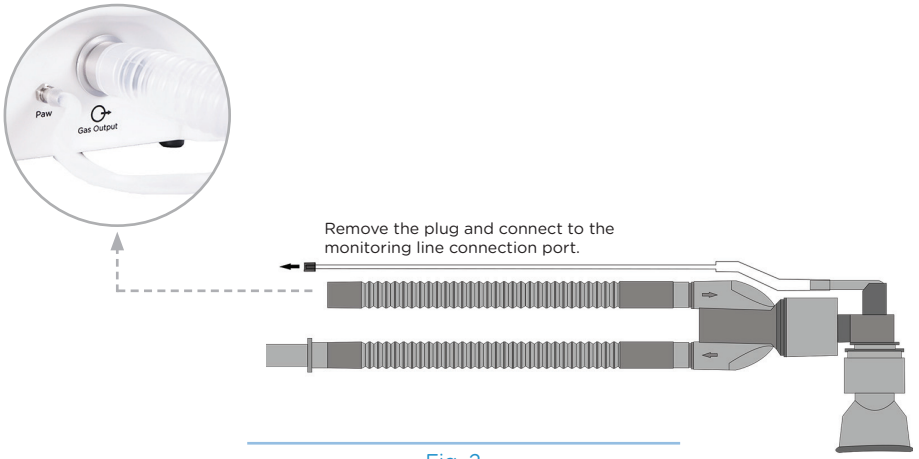


Fig. 2

⚠ WARNING ⚠

The use of patient circuits, other than those approved by the manufacturer, may interfere with the correct operation of this device. Therefore, the use of non-approved circuits with this device will void the product warranty.

⚠ WARNING ⚠

NEVER obstruct the output port nor the scavenging connector outlet.

4.2.5. Turning the Mixer ON

To turn the mixer ON, depress the ON/OFF Control Knob for 1 second.

4.3 Functional Checks Prior to Introduction into Service

Along with the contents of the shipping cartons you will require the following items to enable you to undertake the functional check prior to introduction of the device into service:

1. Nitrous oxide and oxygen pressure sources with 50-70 PSI output capable of providing a minimum of 100 L/min at no less than 45 PSI (3.1 Bar).

2. Vacuum generator with a minimum 30 L/min flow rate.

4.3.1. Input Leak test

Having connected the supply hoses to the device (refer to section 4.2.3 for connection of hoses), ensure that the O-Two™ eAdvantage® mixer is OFF and turn ON the N_2O and O_2 Gas sources. Using a mild soap solution, spray the input connections (B and O) to check for leaks. If any leak is present, tighten the connection and re-test. Once no leakage is confirmed, turn the device ON.

Note: Connections should be “finger tight” only.

4.3.2. Output Leak test

The eAdvantage® is equipped with leak detection feature which will notify the User if a leak is detected inside the device. It is recommended to perform this test before introduction into service:

Connect one gas at a time to the corresponding input connection, spray the other input connectors, no bubbles should be observed coming from either the other connection or the output connector (I).

Testing of the Individual Features of eAdvantage® System

The following features can be individually tested or measured using a calibrated pressure gauge and flowmeter during the pre-use Functional Checks:

4.3.3. Demand Function

Apply a vacuum to the patient connector equivalent to a flow rate of 30 L/min for a minimum of 1 second. The mixer will provide a flow rate equivalent to that demanded. Remove the vacuum from the patient connector; the flow from patient connector should stop.

Note: The vacuum source can be as simple as a 500 ml calibrated syringe.

4.3.4. Low Input Pressure Alarms

Note: To fully test this function it is necessary to have a supply regulator with an adjustable output pressure and a release valve (Not supplied). Checking of the alarm may be undertaken by simply slowly closing the cylinder valve.

With the adjustable outlet pressure regulator set with an outlet pressure of 50 PSI, gradually reduce the outlet pressure of the regulator to around 45 PSI while slowly releasing the gas from the device until the audible and visual Low Input Pressure Alarm is activated.

4.3.5. Low Input Pressure Shut OFF

Continue to decrease the oxygen regulator outlet pressure to around 20 PSI, the device should automatically shut OFF.

4.3.6. Oxygen Flush key

When pressed with the ON/OFF switch set to ON, oxygen should flow from the patient circuit.

4.3.7. Oxygen Concentration

If required, the oxygen concentration of the delivered gas can be determined by:

A. Connecting an oxygen monitor to the output connection of the eAdvantage® using a T-Connector.

B. Utilizing a 1 Liter calibrated syringe connected to the output of the eAdvantage®, draw 5 full breaths (1 Liter each) from the unit.

C. Check the corresponding reading of the oxygen percentage, ensure the reading falls within +/- 5 % V-V of the preset value.

4.4 Pre-use Checklist

When the device is turned ON it will undertake an internal self-diagnostic test protocol to ensure that the device is fully functional (see section 5.1).

Ensure that the patient circuit and monitoring line are securely connected to the device.

Note: It is important that the device is turned OFF after each patient use and turned ON prior to use to allow this self-diagnostic protocol to take place

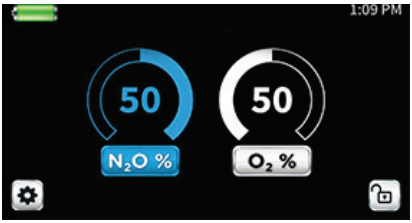
5. OPERATING INSTRUCTIONS

5.1 Start-up and Calibration

To start the eAdvantage®, press the Control Knob (K) for 1 second, the associated green LED (J) will commence flashes at a high frequency. After 1 second, the eAdvantage® will turn ON and begin the calibration process.

A calibration progress bar will be displayed commencing from the left to the right of the screen. The calibration process takes 5 seconds.

Once calibration is completed, the display changes to the operation screen. Demand flow mode is the default mode during start up. The screen will display the concentration of each gas (with 50%-50% mixture as the default setting), the time, battery status and lock status as shown below:



Once this screen is displayed the mixer is ready for operation.

Note: Start Up Calibration Error (Startup calibration results and during use technical failure):

The eAdvantage® will not switch ON if any of the problems listed below are detected:

1. O_2 Valve Failure.
2. N_2O Valve Failure.
3. O_2 Flow Sensor Failure.
4. N_2O Flow Sensor Failure.
5. U12 (Paw) Sensor Failure.
6. U13 (O_2 input pressure) Sensor Failure.
7. U14 (N_2O input pressure) Sensor Failure.

Instead, a new screen will display the cause of the malfunction and request the mixer to be checked or returned for service. At the same time a continuous Audible Alarm will sound.

The above failures will be saved in the events log under specific failure as listed in “Stored History” section

If multiple failures were detected the mixer will switch between the messages related to the failures.

5.2 Selecting the Gas Concentration

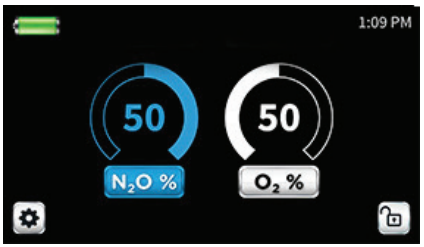
To select (or make changes to) the device settings, rotate the Control Knob (K) and a frame will move around the selected figures following the direction of the Control Knob rotation. Below is an illustration of clockwise knob rotation:

Note: If the screen is locked the selection of the mode, gas mixture and setting will be inactive until the screen is un-locked.

To change the gas concentration, rotate the Control Knob (K) until selection frame surrounds the gas mixture display on the screen as shown below:

Press the Control Knob (K) to activate the selection. At this point the percentages of both O_2 and N_2O will commence flashing indicating that a change is being initiated.

Note: The setting change will be automatically cancelled if no change is made within 10 seconds. The Cancel Key (L) can be also used to exit this mode prior to making any changes.



Rotate the Control Knob (K) to change the concentration as listed below:

0/100, 5/95, 10/90, 15/85, 20/80, 25/75, 30/70, 35/65, 40/60, 45/55, 60/40, 65/35, 70/30.

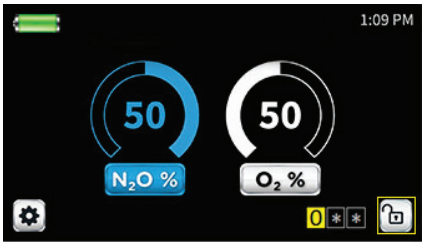
Note: The unit offers 3 settings of concentrations which can be preset by the manufacturer or an authorized distributor. The full range as mentioned above, fixed 50/50% of each gas or a maximum of 50% of nitrous oxide gas according to local protocol or customer request.

Press Control Knob (K) to confirm selection. Once confirmed, the 2 numbers stop flashing and the screen will display the new gas mixture selection.

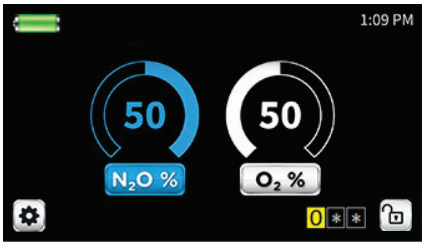
5.3 Lock Feature

The eAdvantage® is equipped with a "lock" feature (protected by passcode) to prevent patients from making changes to the setting selected by their caregivers.

Note: When the lock is activated the mixer will not permit changes to the selected concentration and will inactivate the Setting mode and Oxygen Flush function.



To activate the lock feature, rotate the Control Knob until the selection frame surrounds the lock symbol as shown below:



Press the selection knob (K) to activate the selection. At this point the symbol changes from solid to flashes accompanied by a color change from light grey to yellow.

Rotating the Control Knob (K) in either direction will result in changing the symbol from lock to unlock or vice versa.

Press Control Knob (K) to confirm selection.

Once confirmed, a 3-digit passcode will appear. The default passcode number shipped with each unit is 000. Users may change the passcode in the setting mode (see section 5.6).

To unlock the screen, repeat the same steps required to lock the screen.

5.4 Settings Mode

Within the Settings Mode, Users can set the date & time, change the passcode, display and transfer “Stored event information” or perform software upgrades.

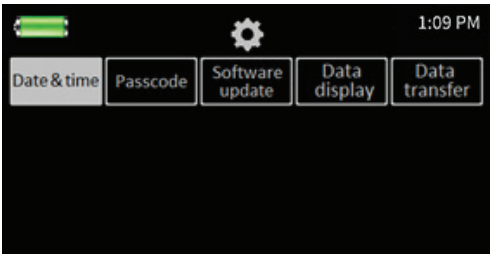
Note: The screen must be unlocked to access this mode.

A. To access the setting mode, rotate the Control Knob (K) until the selection frame surrounds the settings symbol as shown below:

Note: The selection frame will disappear if no action is taken within 10 seconds.

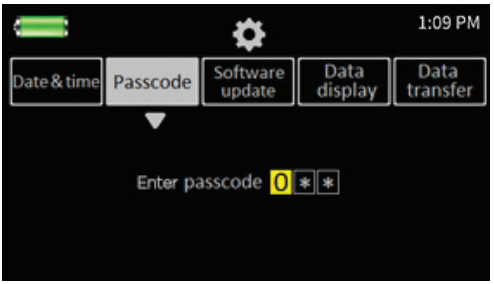
B. Press the Control Knob (K) to confirm the selection.

C. Once confirmed the screen will change to the setting page with a solid reversed color “Date & time” window as shown below.



D. Rotate the Control Knob (K) in either direction and the solid color frame will move between the 5 setting selections until the desired selection is reached. Press Control Knob (K) to confirm selection.

Once confirmed the related setting information will be displayed (as shown in the Passcode setting example below):

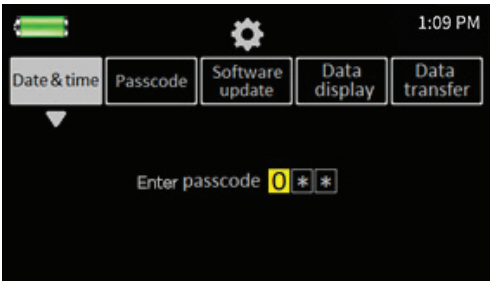


follow the instructions below to change the setting parameters.

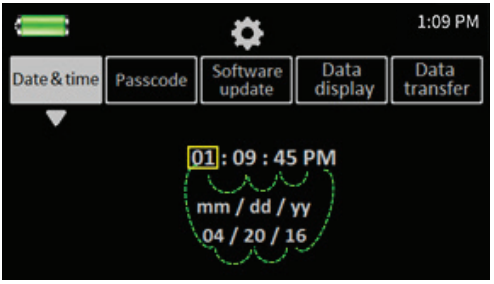
Note: Pressing the Cancel Key at any time within the setting mode will move the process back to a previous step until exiting the setting.

5.4.1. Date and Time

To set the Date & Time, follow the steps detailed in 5.4 above under "Setting mode" to activate Date & Time cell and do the following:

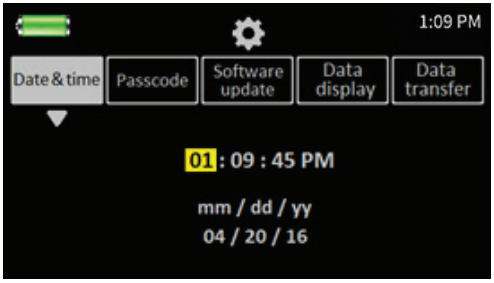


Once the "Date & Time" setting is activated the yellow square frame appears surrounding the hours setting window as shown below.



Using the Control Knob (K) move the square frame to the desired cell to be changed. The green dotted lines shown above indicates the sequence of cell selection based on Control Knob rotation.

At the desired cell, press the Control Knob (K) to activate this cell. The cell now changes to solid color as shown below.



To increase the setting rotate the knob clockwise or counter clockwise to decrease it (except for the AM/PM cell where the information switches in either direction). Press the Control Knob (K) to confirm the change.

Once confirmed, the same cell changes from a solid color back to a square frame.

Move to the next desired cell and follow the same steps to make changes or select the Cancel Button to exit out of this selection change and go back to the main settings screen.

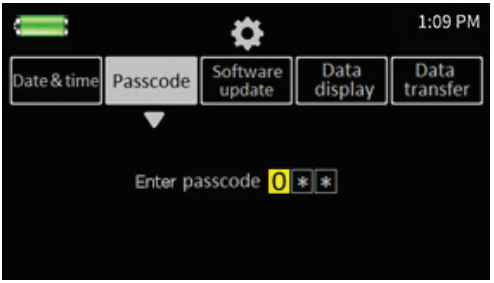
Note: The date and time will need to be reset if the battery and power supply are disconnected for more than 2 months.

If the user does not set up the time and date after connecting the mixer to the power supply or inserting a battery, the device will display the following default settings: 00:00 AM and 01/01/00.

5.4.2. Passcode

To change the Passcode, follow the steps detailed in 5.4 above under “Setting mode” to activate its cell and do the following:

Once the “Passcode” is activated the page below will open requesting users to enter the current passcode.

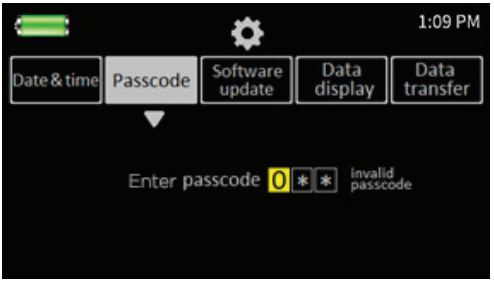


At the desired cell, press the Control Knob (K) to activate this cell. The cell now changes to a solid color as shown below.

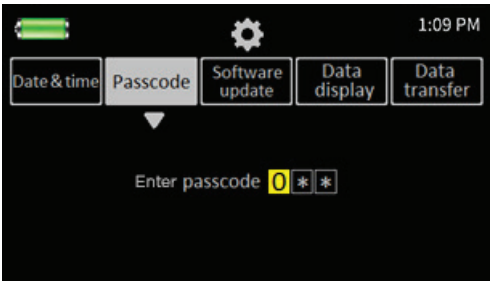
To increase the numbers 0-9 rotate the knob clockwise or counter clockwise to decrease. Press the Control Knob (K) to confirm the change otherwise the selection will be cancelled if no confirmation occurred in 10 seconds.

Once confirmed, the same cell changes from solid color back to a square frame.

Move to the next desired cell and follow the same steps to make changes or select the Cancel Key to exit out of this change and go back to the main settings screen.

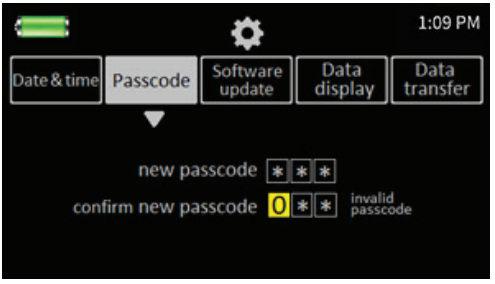


If the entered Passcode is accepted the screen will change to prompt the User to enter the new passcode otherwise it will show “invalid passcode” and the operator must repeat the above steps or may select “Cancel” to exit without changes.



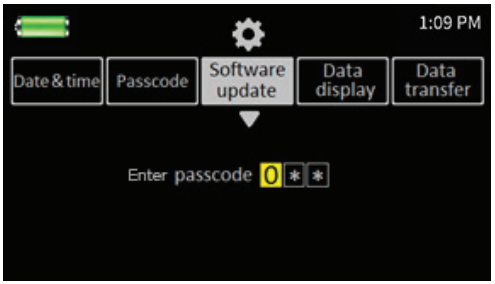
Once the new passcode is entered, another line appears under the first prompting the User to confirm the new passcode.

Once confirmed the screen will revert to the setting screen in the passcode setting mode as shown below:



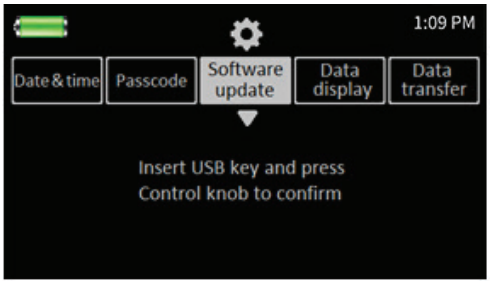
5.4.3. Software Update

To update software, follow the steps detailed in 5.4 above under "Setting mode" to activate its cell and do the following:



After confirming the passcode select software update.

Insert the USB key with the new software revision or select the Cancel Symbol to abandon this process.



Once the boot loader USB key is inserted, the confirmation indicator light (J) will begin flashing indicating the need to confirm the selection manually before the start of the software update.

Once it is confirmed by pressing the Control Knob (K), the boot loader will update the software automatically. During this process the confirmation indicator light (J) will turn on until the new software is uploaded into the device.

Note: If both the software revisions in the device and the USB Key are the same, the device will cancel this process and restart the mixer without writing software from the USB key into the device.

Once the update is completed, the device will shut down and restart automatically. Once it's on, the technician must confirm that the software version shown on the startup page (Fig. 1) is identical to the revision number written on the new USB key.

Note: Should the update process fail to write the new software to the device, note the following:

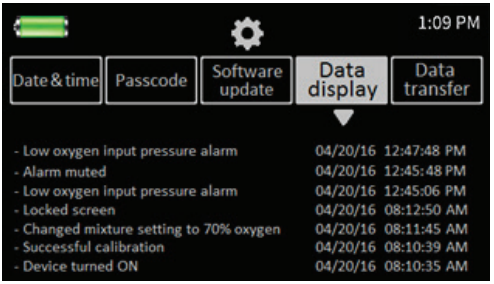
- If the software update failed during the download process – the orange LED light (G) & Buzzer (E) will activate continuously for 3 seconds and then the mixer will shut down and restart.
- If the USB was disconnected during the update – the orange LED light (G) & Buzzer (E) will activate continuously for 3 seconds and then the mixer will shut down and restart.
- If no USB is connected - the following message will appear if the user pressed the Control Knob (K) without inserting the USB key "INSERT THE USB KEY AND PRESS THE CONTROL KNOB TO UPDATE OR PRESS CANCEL TO EXIT". The message will time out in 10 seconds.
- If the wrong USB is connected – both the orange LED light (G) & the battery operation indicator LED (A) will illuminate along with 2x 150 ms bursts followed by 1.5 second continuous Audible Alarm before the mixer shuts down.

Note: If the User correctly connects the USB key within 5 seconds the device will start the software update process mentioned above automatically.

- If the USB key has the wrong software revision – the orange LED light (G) will illuminate along with 5x 150 ms bursts followed by 1.5 second continuous Audible Alarm and the mixer will shut down.
- If the USB key has the wrong or no files – the LED lights (A & G) will flash along with 3x 500 ms ON and OFF audible bursts from the Buzzer (E) and the mixer will shut down.
- If the device loses power during update – the software update process will cease and the device will restore the previous revision until the user updates the software as per the above process.

5.4.4. Stored Events

Note: The “Data display” is not protected by a passcode. To display the stored events, follow the setting mode steps below and press the “Data display” cell and the screen will change to:



The mixer will store any event including all alarms and their related actions, turning the device ON or OFF, pressing the Oxygen Flush key, setting changes after confirmation, activating and canceling the alarm silence, calibration results, software update as well as locking and un-locking the screen.

All stored events are saved, per event, up to a maximum of 2048 events after which the software will start overwriting the older stored data starting from the oldest event. The contents of the stored events can be maintained for about 7 weeks after a total loss of both power supply mains and internal battery.

To view the data, users must turn the control Knob (K) clockwise to move the stored data down and display older events or counter clockwise to display previous events. Scrolling the Control Knob will move the events up or down by one event per turn.

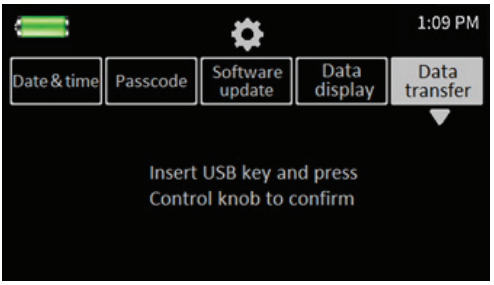
If multi events occurred at the same time, their events will be saved sequentially with no particular priority.

Once completed the user can exit the mode by pressing the Cancel Key.

Note: Individual stored events cannot be deleted by the user.

5.4.5. Stored Events Transfer

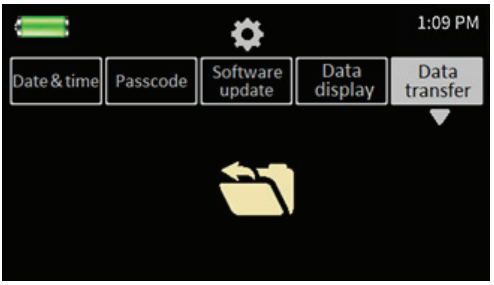
This feature allow the users to transfer and display the stored event on a computer or mobile devices. follow the steps to activate the Data Transfer cell.



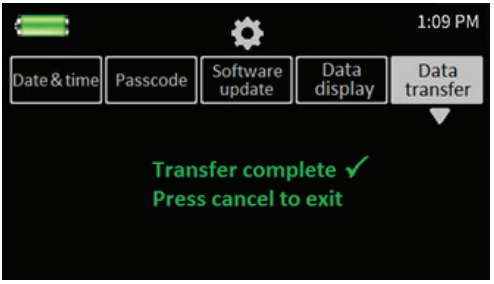
Insert the USB key or press the Cancel Button (L) if the user wishes to abandon this process.

Once the software verifies that the USB key is ready for transfer, the confirmation indicator light (J) will start flashing indicating the need to confirm the selection manually before starting the data transfer.

Once confirmed by pressing the Control Knob (K), the screen changes to the one below with a flashing file transfer symbol until data transfer is complete.

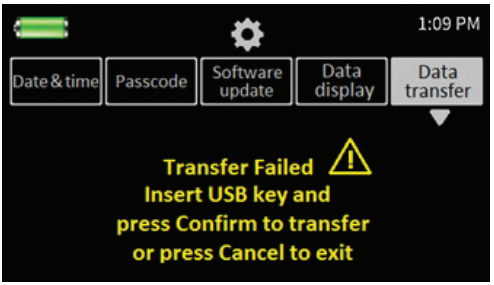


Upon successful transfer the screen will display the following message:



The user can press Cancel to exit and go back to the main screen or it will exit automatically if no action occurs within 10 seconds.

If the Data Transfer failed or the USB key is removed while transferring files or the USB loses its connection during transfer, the message below will be shown:



5.5 Use of Device

The eAdvantage® system is designed for patient self-administration. The nurse/physician in attendance should advise the patient of the following:

5.5.1. You are being provided with pain relief by inhalation analgesia, which is self-administered. By placing the mask or mouth piece over your nose and/or mouth and simply inhaling you will receive a dose of the inhalation analgesic gas mixed with oxygen in a precise concentration.

You should breathe out through the mask so that your exhaled breath is diverted through the tube to the gas scavenging system.

5.5.2. The analgesic gas being provided is a mixture of nitrous oxide and oxygen. Nitrous oxide, commonly known as “laughing gas”, is a colourless gas with a pleasant, slightly sweet odour and taste. It is used in surgery and dentistry for its anaesthetic, analgesic and anxiety reducing effects.

5.5.3. Should you feel it becomes difficult to inhale through the mask, feel nauseous or disorientated, simply remove the mask from your face and inform a member of staff. Simply removing the mask from your face and breathing room air will remove the gas from your system very quickly.

5.6 Turning OFF the Device

To turn OFF the mixer, press and hold the Control Knob (K) for 4 seconds. During this time the green power LED will start flashing at a high frequency. After 4 seconds the mixer will turn OFF. At the same time the Oxygen Valve will open to deliver a 40 L/min flown rate for 1 second to clear the gas pathways of residual gas.

If the Control Knob (K) is pressed and held for less than 4 seconds and then released, the mixer will stay ON.

Note: It is important that the device is turned OFF after each patient use and turned ON prior to use to allow the self-diagnostic protocol to take place.

6. POST USE

6.1 Disconnect device after use

A. Turn OFF the gas supplies to the mixer.

B. Disconnect the gas supply hoses.

C. Disconnect the patient circuit from the output connector and the pressure sensor connection.

D. Unplug the power cable from the mains supply if no charging is required.

E. Clean and disinfect the device and replace the single use circuit in accordance with section 8.1 in this manual.

Note: It is important that the device is turned OFF after each patient use and turned ON prior to use to allow the self-diagnostic protocol to take place.

6.2 Storage

Store the mixer within the temperature and humidity ranges specified in Chapter 9.1.

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

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

7. ALARMS, WARNINGS AND NOTIFICATIONS

7.1 Functional Alarms

Note: Visual and audible alarms will continue until the cause of the alarm is resolved.

During alarm activation the user may press the audio paused key to silence the Audible Alarm for 2 minutes, the visual alarm will continue to flash until the cause of the problem is resolved.

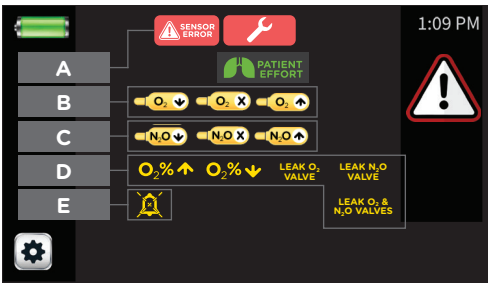
During alarm mute, should a new alarm situation develop the mute function will continue and only the new visual alarm will be displayed on the screen.

Alarms will be visible in the sub-sections A-D associated with a red warning symbol for high priority alarms and yellow warning symbol for medium and low priority alarms as shown below.

The device allows for multiple alarm symbols to be displayed on the screen indicating multiple failures occurring at the same time. In this case, the Audible Alarm will follow the highest alarm priority.

The patient effort cell is located at the center of the screen above the mixtures dials as shown below. This symbol will be displayed during the whole phase of patient demanded breaths.

Note: The dark grey cells shown below are invisible and shown for illustration purpose only.



Alarm/Warning priorities with corresponding visual/ audible alarms

Symbol	Name	Cell #	Priority	Alarm delay	On Screen Visual Alarm	Audible Alarm
	Sensor error (U13 and/or U14 sensors failure)	A	High	Directly	Solid symbol with flashing red warning symbol	1 Burst with 10 pulses each, repeat every 7.5 seconds
	No O_2 gas input ≤ 20 PSI	B	High	Directly	Solid symbol with flashing red warning symbol	1 Burst with 10 pulses each, repeat every 7.5 seconds
	Low O_2 input pressure (45-21 PSI)	B	Medium	Directly	Solid symbol flashing down with yellow warning symbol	1 Burst with 3 pulses each, repeat every 20 seconds
	HighO_2 input pressure ≥ 80 PSI	B	High	Directly	Solid symbol with flashing red warning symbol	1 Burst with 10 pulses each, repeat every 7.5 seconds
	No N_2O gas input ≤ 20 PSI	C	High	Directly	Solid symbol with flashing red warning symbol	1 Burst with 10 pulses each, repeat every 7.5 seconds
	Low N_2O input pressure (45-21 PSI)	C	Medium	Directly	Solid symbol flashing down with yellow warning symbol	1 Burst with 3 pulses each, repeat every 20 seconds
	High N_2O input pressure ≥ 80 PSI	C	High	Directly	Solid symbol with flashing red warning symbol	1 Burst with 10 pulses each, repeat every 7.5 seconds
	Empty Battery		High	Directly	Solid symbol with flashing red warning symbol	1 Burst with 10 pulses each, repeat every 7.5 seconds
	Low Battery		Low	N/A	Solid yellow symbol with fixed yellow warning symbol	N/A

Symbol	Name	Cell #	Priority	Alarm delay	On-Screen Visual Alarm	Audible Alarm
$O_2\%\downarrow$	Low O_2% @ 6% volume lower than setting	D	Medium or highbelow 27% of O_2%	After 3 consecutive breaths	Follow the visual alarm logic depending on the alarm priority	(Medium) 1 Burst with 3 pulses each, repeat every 20 seconds (high) 1 Burst with 10 pulses each, repeat every 7.5 seconds
$O_2\%\uparrow$	High O_2% @ 6% volume higher than setting	D	Medium	After 3 consecutive breaths	Solid symbol flashing down with yellow warning symbol at 0.7 Hz with 50% usage	1 Burst with 3 pulses each, repeat every 20 seconds
LEAK O_2 VALVE	O_2 valve leak during standby	D	High	10 seconds after turning the device ON or the last demanded breath	Solid symbol with flashing red warning symbol at 1.4 Hz with 50% usage	1 Burst with 10 pulses each, repeat every 7.5 seconds
LEAK N_2O VALVE	N_2O valve leak during standby					
LEAK O_2 & N_2O VALVES	O_2 & N_2O valves leak during standby					

7.2 Flow Valve Leak Alarm

The eAdvantage® is equipped with flow valve leak detection when gas is supplied to the unit in either the ON and OFF positions.

When the device is ON, it will monitor the output from the 2 flow sensors during standby mode or 10 seconds after the last demanded breath. Should either of the flow sensors detect any flow the device will display the leak alarms on the screen.

Note: This feature will be disabled when both input gasses are OFF (0 PSI).

7.3 Battery Indicators

Battery status will be displayed on the screen. There are 2 different status indicators, one showing discharge status and the other showing the charging status. Capacities and alarms for charging and discharging are as follows:

Battery discharge status on screen indicators:			
1		Full capacity	No alarm
2		75% at full capacity	No alarm
3		50% at full capacity	No alarm
4		25% at full capacity	Solid yellow symbol with solid yellow WARNING symbol
5		5% at full capacity	Corrected symbol with flashing red warning symbol at 1.4 Hz with 50% usage

Battery charging status on screen indicators			
1		Full capacity	No alarm
2		75% at full capacity	No alarm
3		50% at full capacity	No alarm
4		25% at full capacity	No alarm
5		5% at full capacity	No alarm

Note: At approximately 2% of full battery capacity, if the eAdvantage® is OFF, it will not turn ON. If it is turned ON it will shut down automatically during operation.

Battery levels are detected from measured voltages and the capacities shown above are based on results from new batteries tested at room and low temperatures. Levels are subject to change when old batteries are used.

8. CLEANING, PREVENTIVE MAINTENANCE AND SERVICING

8.1 Cleaning

Routine cleaning of the device shall be undertaken to maintain the device in a clean condition.

The patient circuit with mouth piece (or facemask) is intended for single patient use only and shall be discarded after each patient (in accordance with local protocols) and replaced with a new circuit.

All other components should be wiped clean with a mild soap solution or hard surface disinfectant suitable for the materials of manufacture of the device. Under no circumstances should the complete unit be allowed to be soaked or immersed in cleaning solutions.

Detailed cleaning procedures are as follows:

8.1.1 Ensure that the device is turned OFF and disconnected from the gas supply source.

8.1.2 Remove the single patient use circuit from the device and dispose of safely in accordance with local protocols.

8.1.3 Wipe clean the N_2O and O_2 input hoses with a mild soap or hard surface disinfectant. Ensure no cleaning solution enters the hoses.

8.1.4 The enclosure of the device can be wiped over with a soft cloth and mild soap solution or hard surface disinfectant. Ensure no cleaning solution enters the input fittings.

8.1.5 If there is ingrained contamination a soft bristled brush may be used.

8.1.6 Dry all components thoroughly.

8.1.7 Attach a new patient circuit and connect the unit to the gas supplies prior to use with the next patient.

⚠ WARNING ⚠

Do not attempt to clean and sterilize any components that are designated as single patient use.

8.2 Charging the Battery

8.2.1 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 (C) in Fig. 1 located on the side panel of the mixer. The indicator lights up as follows:

8.2.2 Turn unit ON and observe battery level (section 1 of the screen). Refer to 7.3 battery status indicator for exact battery charging status. The battery shall be fully charged.

WARNING

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

Note:

Battery Life expectancy:

Given normal storage and usage, the battery delivers 75% more of its initial capacity after 300 charge/discharge cycles where the charge phase is CC/CV 3.3A, 16.80 V and the discharge is 3,3A down to 9000-mV pack voltage at 25°C.

Battery Shelf life:

The battery provides a minimum of 6 months shelf-life with its initial charge state of 40%, when stored at 25°C.

⚠ WARNING ⚠

The battery pack should be replaced after its life expectancy or if the battery pack will not fully charge (as indicated on the battery display on the mixer) or if the mixer doesn't run for more than 5 hours on a single charge.

8.3 Preventive Maintenance and Servicing

Service Life
This device has an anticipated minimum service life of 12 years, provided that the service is performed according to the manual.

Note: A failure to undertake the routine preventive maintenance and product service in line with recommendations in the product manual, or misuse and/or abuse of the device, may reduce the operating life expectancy.

To ensure proper operation of the eAdvantage®, 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.

It is recommended that the routine preventive maintenance be carried out, and the eAdvantage® mixer be returned to O-Two™ Medical Technologies (or its authorized service center) for maintenance and service every 2 years as follows:

Monthly checking
This check is to ensure that all of the accessories and device components are present, the nitrous oxide and oxygen cylinders are full and that the device is in working order by turning ON the gas supplies and the device and confirming that the self-diagnostic does not show any issues.

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.

	Description	Procedure	Criterion	Schedule	Factor:
PM	Visual inspection	User Manual Chapter 8.3 Monthly checking	Device in working order, gas tanks are full, no missing item	Monthly	User
Servicing	Level II service	Service manual	Meet product specifications	Every 2 years	Manufacturer/ service center
Servicing	Full service	Service manual	Meet product specifications	Every 6 years	Manufacturer

Note: The manufacturer will make available, on request, factory trained service personnel, circuit diagrams, component part lists, description, calibration instructions, or other information required to undertake service and repair of the device.

Note: Single patient use circuit shall be disposed of in accordance with local protocols.

At the end of their expected service life, the device, power supply, cables and battery shall be disposed of in accordance with local protocols.

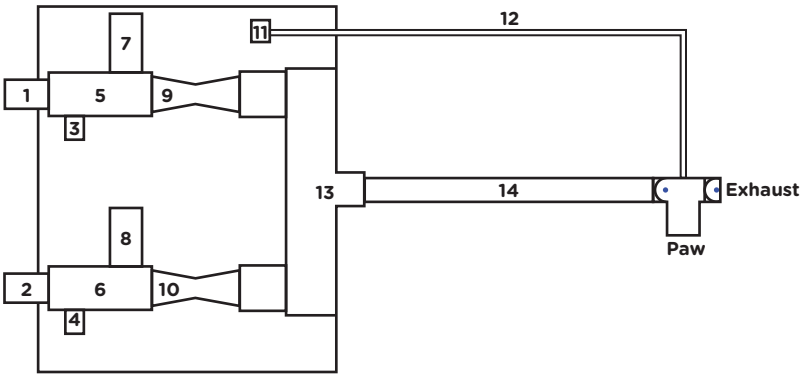
9. TECHNICAL DATA

9.1 Specifications

GAS SOURCE	Compressed oxygen + nitrous oxide	
CIRCUIT CONTROL SOURCE	Electronic	
MAXIMUM FLOW RATE (L/MIN)	>260 combined or 160 from oxygen input only	
OXYGEN CONCENTRATION (O_2 %)	30-100 % continuous adjustment with 5% incremental changes. Accuracy: ±5% V@ min. flow rate of 15 L/min. (+5% V/-3%V for 30% O_2)	
TRIGGER SENSITIVITY (cmH_2O)	Approx. -1.0 (non-adjustable)	
INPUT PRESSURE RANGE (PSI)	50-70	
INHALATION RESISTANCE (cmH_2O)	0 to -6	
EXHALATION RESISTANCE (cmH_2O)	0 to 6	
FLUSH FLOW RATE (L/min)	40 (Oxygen)	
OPERATING TEMPERATURE	5°C to 40°C (41°F to 104°F)	
STORAGE TEMPERATURE	-20°C to 60°C (-4°F to 140°F)	
RELATIVE HUMIDITY	15% to 95%	
ALTITUDE (METERS)	About 4000	
DEVICE EMERGENCY SHUT OFF	• Below 20 PSI O_2 input • Below 25% O_2 output w/ 3 consecutive breaths or below 21% O_2 output immediately • Sensors and/or valves failure	
BATTERY (01CV9200)	Li-Ion Smart Battery	
BATTERY OPERATING TIME (HRS.)	15-24 hrs	
BUILT-IN BATTERY CHARGER	Yes	
A/C POWER ADAPTER	100-240V / 4.74A	
PATIENT CIRCUIT (01CV8037)	Single use patient circuit with monitoring line.	
MOUNTING BRACKET (01CV7040)	Compatible w/ rail mount and standard rolling stand	
DISPLAY	4.3” Color TFT	
DATA STORAGE AND TRANSFER	Yes	
USB	Yes (for data transfer & software update)	
LIVE MONITORING	Alarms and setting only	
PARAMETER SETTINGS	Control Knob	
LOCK KEY FUNCTION	Yes w/ passcode	
ALARMS (VISUAL AND AUDIBLE)	**HIGH, LOW OR NO INPUT GAS SUPPLY PRESSURE**	Yes (O_2 & N_2O)
	LOW BATTERY	Yes
	OUT OF TOLERANCE GAS MIXTURE	Yes
	DEVICE MALFUNCTION	Yes
	VALVES LEAK	Yes
	RETURN FOR SERVICE	Yes
	AUDIO ALARM PAUSED	Yes, 120 second max
	ALARM SOUND PRESSURE LEVEL	60 dB
BUILT-IN SCAVENGING SYSTEM	N/A	
DIMENSIONS (mm)	305 x 210 x 130	
WEIGHT WITH & W/O BATTERY (KG)	2.80 & 2.20	

Note: All values are measured at STPD

9.2 Circuit diagram



1. O_2 Input Connector
2. N_2O Input Connector
3. O_2 Input The Pressure Sensor
4. N_2O Input The Pressure Sensor
5. O_2 Inlet Manifold
6. N_2O Inlet Manifold
7. O_2 Flow Control Valve
8. N_2O Flow Control Valve
9. O_2 Flow Sensor
10. N_2O Flow Sensor
11. Respiratory Pressure Sensor
12. Sensor Hose
13. Removal Kit
14. Patient Circuit
15. 3-Bypass Valve

Note: Always remove the plug from the sensing hose before connecting to the sensor connection port as shown on Fig. 2 page 13.

9.3 Battery and Power Supply

Battery Pack

BATTERY CELL TYPE	Rechargeable Lithium Ion Cell
MODEL	01CV9200
NOMINAL CAPACITY	6600 mAh, Min. 95.0 Wh
NOMINAL VOLTAGE	14.4 V
MAX. CHARGING CURRENT	4.62 A
MAX. CHARGING VOLTAGE	16.8 V ± 0.1 V
DIMENSION	167.2 x 107.5 x 21.5 mm
WEIGHT	590 g

Note: The behavior of the mixer will not be affected while the battery is charging.

AC/DC Power Supply

MODEL	PMP90-13-2 01CV0104
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

Note: Upon disconnecting AC Power supply, Mixer will automatically switch to battery operation without affecting mixer behavior.

9.4 Electromagnetic Compatibility

The eAdvantage® has been tested and complies with IEC 60601-1-2:2014 requirements and is intended for use in hospital environment except near active HF surgical equipment where the intensity of electromagnetic disturbance is high. The user of eAdvantage® should ensure that it is not used in environments outside those specified below:

Electromagnetic Emissions

Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The eAdvantage® 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 CISPR 11	Class A	The eAdvantage® external power supply is suitable for use in all establishments other than domestic and those directlyly connected to the public Low-voltage power supply network that supplies buildings used for domestic purposes. If it is used in a residential environment, the eAdvantage® might not offer adequate protection to RF communication services. The user might need to take mitigation measures, such as relocation or re-orienting the device.
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC61000-3-3	Complies	

Electromagnetic Immunity

Immunity test	Immunity test level
Electrostatic discharge (ESD) IEC61000-4-2	± 8 kV contact ± 2, ±4, ±8, ±15 kV air
Electrical fast transient/ Burst IEC61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines
Surge IEC61000-4-5	±0.5, ±1 kV line to line; ±0.5, ±1 kV, ± 2 kV line to earth
Voltage Dips IEC61000-4-11	0.5 cycle, 1 cycle, 25 (50Hz)/30 (60Hz) cycles
Voltage Interruptions IEC61000-4-11	250 cycle (50Hz), 300 cycle (60Hz)
Power frequency magnetic field IEC61000-4-8	30 A/m (50/60 Hz)
Conducted RF IEC61000-4-6	3Vrms: 50 kHz to 80 MHz outside ISM bands
	6Vrms: 150kHz to 80 MHz in ISM bands
Radiated RF EM fields IEC61000-4-3	3 V/m @ 80 MHz to 2.7 GHz
Proximity fields from RF wireless communications equipment IEC61000-4-3	IEC 60601-1-2 Chapter 8.10 Table 9

⚠ WARNING ⚠

Use of eAdvantage® adjacent to or stacked with other equipment should be avoided because it could result in improper operation of the device.

⚠ WARNING ⚠

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of eAdvantage® could result in increased electromagnetic emissions or decreased electromagnetic immunity of eAdvantage® and result in improper operation.

The eAdvantage® 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 (including peripherals such as antenna cables and external antennas) and the eAdvantage®.

⚠ WARNING ⚠

Portable RF communication equipment should be used no closer than 30 cm (12 inches) to any part of the eAdvantage®.

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 mixer.

Message/fault	Cause	Remedy
High inhalation resistance	Disconnected sensing hose or no input gas	Check input gas valves or sensing hose connection
External leak	Input hoses are not tightened	Tighten input hoses
Extremely high inhalation resistance	Device is OFF	Remove mask from face and ensure the device is ON
No input gas	No gas or input gas pressure below 20 PSI	Change the gas cylinder
Low input gas	Low gas below 40 PSI	Change the gas cylinder
Battery discharges quickly	No proper charging/faulty battery	Charge battery as per instructions/replace battery
eAdvantage® 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. REPLACEMENT PARTS AND ACCESSORIES

PART #	DESCRIPTION	UNIT
01CV8037-CS	O-Two™ Medical Single-Use Relieve / eAdvantage® 6 foot circuit with scavenger Hose and adapter with mouthpiece	Case/10
01FM4999-CS	Universal Face Mask	Case/12
01CV0106*	Power supply cord (Canada and the US)	Each
01CV0104	External power supply	Each
01CV7040-1	eAdvantage® Mounting Bracket w/ C-Clamp	Each
01CV7040-2	eAdvantage® Mounting Bracket w/ Medirail clamp	Each
01CV9200	Li-Ion Smart Battery	Each
02RT1303	Disposable Mouthpiece (Individually Wrapped)	Case/50

OXYGEN HOSES		
PART #	**DESCRIPTION**	**UNIT**
01FV4303-AFNR	O-Two™ 6 Foot (1.85 Meter) O_2 supply hose with AFNOR probe and 9/16" DISS nut device connection	Each
01FV4303-AGA	O-Two™ 6 Foot (1.85 Meter) O_2 supply hose with AGA probe and 9/16" DISS nut device connection	Each
01FV4303-CZCH	O-Two™ 6 Foot (1.85 Meter) O_2 supply hose with CZECH probe and 9/16" DISS nut device connection	Each
01FV4303-DIN	O-Two™ 6 Foot (1.85 Meter) O_2 supply hose with DIN probe and 9/16" DISS nut device connection	Each
01FV4303-DISS	O-Two™ 6 Foot (1.85 Meter) O_2 supply hose with 9/16 DISS nut and 9/16" DISS nut device connection	Each
01FV4303-UNFR	O-Two™ 6 Foot (1.85 Meter) O_2 supply hose with UNIFOR probe and 9/16" DISS nut device connection	Each
01FV4303-BM	O-Two™ 6 Foot (1.85 Meter) O_2 supply hose with BRITISH probe and 9/16" DISS nut mixer connection	Each

NITROUS OXIDE HOSES		
PART #	**DESCRIPTION**	**UNIT**
01FV4303-AFN-N_2O	O-Two™ 6 Foot (1.85 Meter) N_2O supply Hose with AFNOR Gas supply fitting and N2O DISS nut Device Connection	Each
01FV4303-AGA-N_2O	O-Two™ 6 Foot (1.85 Meter) N_2O supply Hose with AGA Gas supply fitting and DISS nut Device Connection	Each
01FV4303-CZCH-N_2O	O-Two™ 6 Foot (1.85 Meter) N_2O supply Hose with Czech Gas supply fitting and DISS nut Mixer Connection	Each
01FV4303-DIN-N_2O	O-Two™ 6 Foot (1.85 Meter) N_2O supply Hose with DIN nut and DISS nut Device Connection	Each
01FV4310	O-Two™ 6 Foot (1.85 Meter) N_2O supply Hose with DISS Gas supply fitting and DISS nut Device Connection	Each
01FV4303-UNF-N_2O	O-Two™ 6 Foot (1.85 Meter) N_2O supply Hose with UNIFOR gas supply fitting and DISS nut device connection	Each
01FV4303-BM-N_2O	O-Two™ 6 Foot (1.85 Meter) N_2O supply Hose with British gas supply fitting and DISS nut device connection	Each

12. WARRANTY

WARRANTY

O-Two™ Medical Technologies Inc. products are manufactured from the finest quality materials. Each individual part is subject to strict quality control tests to ensure exceptionally high standards. The manufacturer warrants to the purchaser of the eAdvantage® N_2O/O_2 Analgesic Gas Mixing and Delivery System that its component parts are free from defects in material and workmanship for a period of two years from the date of purchase. The manufacturer will replace and/or repair all parts of the device at its option for two years from the date of purchase at no cost to the purchaser, upon the notification of the defects, in writing by the purchaser. All shipping costs shall be borne by the purchaser. The manufacturer shall be liable under this warranty only if the device and its parts have been used and serviced in the normal manner described in the instruction manual. There are no other expressed or implied warranties. This warranty gives no specific legal rights. You may also have other rights which may vary according to local regulations.

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

CE 1639

EC REP

MedNet EC-REP IIb GmbH
Borkstrasse, 10
48163 Münster, Germany

SERIAL Nº:	

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