



eAdvantage®

Electronic Nitrous Oxide/Oxygen Analgesic Gas Mixing and Delivering System

01EQ3000

TABLE OF CONTENTS

1. Safety	4
2. General Information	5
2.1. Intended Use	5
2.2. Environment of Use	5
2.3. Contraindications	5
3. Overview	6
3.1. Product Description	6
3.2. Principles of Operation	6
3.3. Controls, connections, and indicators	7
3.4. Control Functions	8
3.5. LED Indicators	8
3.6. Symbols and Notations	9
4. Preparation for Use	10
4.1. Component List	10
4.2. Set up	10
4.2.1. ON/OFF	10
4.2.2. Installing/replacing the battery	10
4.2.3. Connecting the gas supply hoses	11
4.2.4. Connecting the patient circuit and Sensor line	13
4.2.5. Turning the Mixer ON	13
4.3. Testing Prior to introduction into Service	14
4.3.1. Input Leak test	14
4.3.2. Output Leak test	14
4.3.3. Demand Function	15
4.3.4. Low Input Pressure Alarms	15
4.3.5. Low Input Pressure Shut OFF	15
4.3.6. Oxygen Flush key	15
4.3.7. Oxygen Concentration	15
4.4. Pre-use Checklist	16

5. Operating Instructions	16
5.1. Start-up and selecting settings	16
5.2. Demand Mode	18
5.3. Lock Feature	19
5.4. Settings mode	20
5.4.1. Date & time	21
5.4.2. Passcode	22
5.4.3. Software update	25
5.4.4. Stored events	27
5.4.5. Stored events transfer	28
5.5. Use of the device	29
5.6. Turning OFF the device	30
6. Post Use	30
6.1. Disconnecting the Device After Use	30
6.2. Storage	30
7. Alarms, Warnings and Notifications	31
7.1. Functional Alarms	31
7.2. Flow Valve Leak Alarm	33
7.3. Battery Indicators	33
8. Cleaning, Preventive Maintenance and Servicing	35
8.1. Cleaning	35
8.2. Charging the Battery	36
8.3. Preventive maintenance and Servicing	37
9. Technical Data	39
9.1. Specifications	39
9.2. Circuit Diagram	40
9.3. Battery and Power Supply	40
9.4. Electromagnetic Compatibility	41
10. Troubleshooting	43
11. Replacement parts and accessories	44
12. Warranty	46

1. SAFETY



WARNINGS



- Federal Law restricts this device to sale by or on the order of a physician.
- The eAdvantage® should only be utilized by qualified healthcare professionals who have received training as specified in the 'Intended Use' section.
- The eAdvantage® system is designed for patient self-administration, intended to be used under the supervision of a healthcare provider. Never attach the face mask to the patient using a head harness.
- The eAdvantage® shall not be used in oxygen-rich, flammable, or anesthetic 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. Operating it in a valve-down position can result in liquid nitrous oxide being expelled, which can cause freeze burns upon contact with skin.
- Always use the checklist to ensure the correct assembly of all components and replacement of disposable items.
- Always use the checklist to ensure all components are reassembled correctly and all disposable items are replaced.
- Before use on a patient, the settings of the delivered gas should be checked to ensure they are for 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 and ensure that they have sufficient gas volume 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 or the scavenging connector outlet.
- DO NOT use the Oxygen Flush function to provide positive pressure ventilation to a non-breathing patient.

- 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 N₂O and O₂.
- 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® N₂O/O₂ 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 may include, but are not 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 (N₂O/O₂) mixtures must never be used in any condition where trapped air in the body could dangerously expand (up to 3x its original size). For example, it will exacerbate a pneumothorax

and increase pressure in any intracranial air, in addition to the air trapped in other body cavities like the sinuses, middle ear, and abdomen.

3. OVERVIEW

3.1 Product Description

The eAdvantage® system is an electronically controlled, gas pressure-operated mixer, capable of functioning with either mains supply or battery power. It is designed for self-administered delivery, providing an adjustable concentration of nitrous oxide and oxygen (N_2O/O_2) mixture. This on-demand flow system is specifically intended for conscious patients who are breathing spontaneously, and it includes a unique patient circuit with a monitoring line.

Note: The patient shall use this device under the guidance of qualified personnel trained.

Intended Patient Population:

Conscious, spontaneously breathing patients who can comprehend the instructions, understand verbal commands and self-administer the prescribed analgesic gas mixture.

3.2 Principles of Operation

The eAdvantage® system is an electronically controlled, gas pressure-operated mixer, capable of functioning with either mains supply or battery power. It is designed for self-administered delivery, providing an adjustable concentration of nitrous oxide and oxygen (N_2O/O_2) mixture. This on-demand flow system is specifically intended for conscious patients who are breathing spontaneously, and it includes a unique patient circuit with a monitoring line. The device has a single control knob serving a dual purpose. It is used for both powering the device ON or OFF and for navigating and adjusting 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 built-in gas-specific alarm system will trigger visual and audible alerts if either the nitrous oxide or oxygen input pressure drops below 35 PSI. Furthermore, the device will automatically shut off if the oxygen input pressure falls below 21 PSI.

Additionally, the eAdvantage® includes an oxygen flush function, enabling healthcare providers to deliver a constant flow of 100% oxygen to the patient.

Note: The eAdvantage® mixer is classified as a critical device, and its components are considered critical components. Therefore, only individuals specifically trained in operating nitrous oxide/oxygen analgesia gas delivery systems, including this particular device, are authorized to use this equipment. Thoroughly review the instruction manual before operating the device.

3.3 Controls, Connections, and Indicators



A Green LED for battery operation indicator

I Output Connection

B N₂O 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 serves to turn ON the mixer (depressing it for 1 second) or turn the mixer OFF (depressing it for 4 seconds).

Additionally, it is utilized to navigate through options and settings on the screen by rotating it in either direction when needed. Confirming a setting selection is achieved by depressing the knob.

Cancel Key (L):

Pressing the Cancel Key will cancel the current selection stage, allowing the user to return to the previous stage without any active selection. Additionally, this key can be used to navigate back through previous pages sequentially until the main screen is reached."

Audio Paused key (M):

The eAdvantage® includes an Audio Paused key, designed to temporarily silence the Audible Alarm for 2 minutes. This function can be activated at any time by pressing the key, regardless of whether an alarm is currently active.

Oxygen Flush key (N):

This key enables the manual delivery of a constant flow of 40 L/min of 100% oxygen as long as the key is pressed.

3.5 LED Indicators



Green LED – Continuously illuminated when the unit is ON and flashes when the unit is OFF.



Green LED – Continuously illuminated when the unit is connected to an external power source during both ON and OFF phases.



Orange LED – Continuously illuminated when the unit is charging and OFF when the battery is fully charged during both ON and OFF phases. During the OFF state, this light will start flashing when the 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 the mixer.

IPX2

Ingress protection rating: "Dripping Water". Do not immerse.



IEC 60417-5172, Class II equipment



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 in most countries. Please specify the country of use at the 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 main power inputs.

4.2.2. Installing/replacing the battery

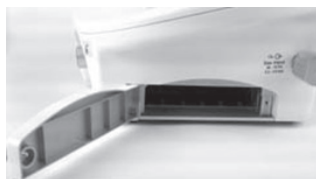
The battery is inserted into the battery compartment on the right side of the device by unscrewing the yellow/black knob anti-clockwise and allowing the compartment door to open.

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 specifically for nitrous oxide and oxygen.

The eAdvantage® mixer is designed to operate with input pressures for both N₂O and O₂ gases ranging from 3.0 to 5.0 bar or 43.5 to 72.5 PSI.

Note: the device labeling indicates 50 to 70 PSI and 3.5 to 5.0 bar. These values are market references and within the device pressure limit range.

The provided nitrous oxide supply hose shall be connected to the N₂O input on the device's left side (when facing the device), and the oxygen supply hose should be attached to the O₂ input on the right side. It is crucial to securely tighten these supply hoses to ensure a stable and leak-free operation.

⚠ 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 compatible with the electrical standards of most countries are available for the eAdvantage® system. It is important to specify the intended country of use when purchasing to ensure the correct power supply cord is provided.

In the event of an external power outage, the device is designed to automatically transition to its internal battery power, assuming the battery has sufficient charge. This switch to battery mode is indicated by the illumination of the green battery LED, located on the left side of the front panel.

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, if applicable, and connect to the monitoring line connection port (Fig. 2).

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

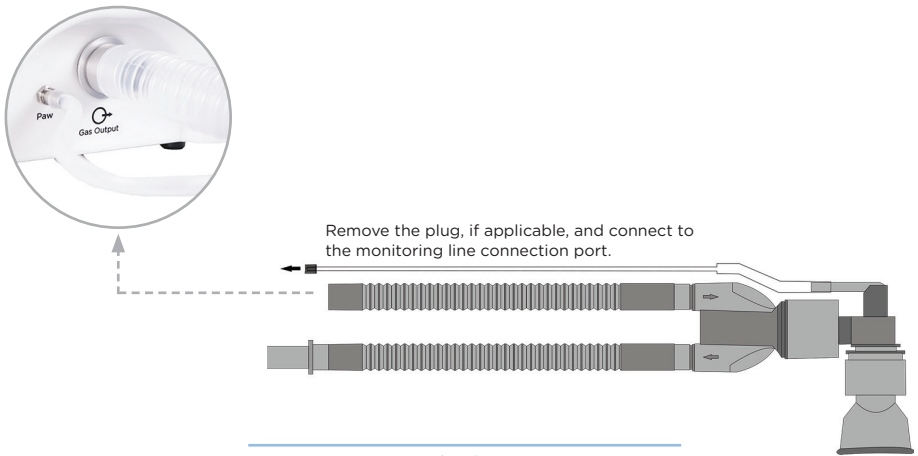


Fig. 2

⚠ 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 or 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

The eAdvantage® is equipped with an internal self-diagnostic test system to ensure the device's full functionality. During this phase, the valves and sensors undergo a check (refer to section 5.1). While this test is optional, a functional check can be performed by following the next steps.

To carry out the functional test, you will need the following items in addition to the contents of the shipping boxes.

1. Nitrous oxide and oxygen pressure sources with 43.5 - 72.5 PSI output capable of providing a minimum of 100 L/min at no less than 35 PSI (2.4 Bar).
2. Vacuum generator with a minimum 30 L/min flow rate.

4.3.1. Input Leak test

After securely connecting the supply hoses to the device (see section 4.2.3 for hose connection guidance). Then, proceed by opening the N₂O and O₂ gas sources. Observe for any signs of leakage. If a leak is detected, tighten the connections.

Note: When attaching connections, ensure they are 'finger tight' only. Avoid using tools or excessive force, as this can lead to over-tightening and potential damage to the connections.

4.3.2. Output Leak test

The eAdvantage® is equipped with an automatic leak detection feature that alerts the user to any detected leaks inside the device. Alternatively, you can manually perform the Output Leak Test.

To conduct the test, connect and turn ON both gases. Attach a closed system pressure gauge to the gas output port; the pressure should not increase by more than 2 cmH₂O in 10 seconds.

Testing of the Individual Features of eAdvantage® System

Various features of the eAdvantage® system can be individually tested or measured. This is done using a calibrated pressure gauge and flow meter as part of the optional functional checks:

4.3.3. Demand Function

To test the Demand Function of the eAdvantage® mixer, apply a vacuum to the patient connector. This vacuum should be equivalent to a flow rate of 30 L/min and maintained for at least 1 second. The mixer is designed to respond by providing a flow rate that matches this demand. Once the vacuum is removed from the patient connector, the flow should stop to that demanded. Remove the vacuum from the patient connector; the flow from the patient connector should stop.

4.3.4. Low Input Pressure Alarms

Note: A complete test of this alarm function requires a supply regulator that has an adjustable output pressure and a release valve. (Not supplied with the eAdvantage® system). However, a basic check of the alarm function can be performed by gradually closing the cylinder valve.

Start with the adjustable outlet pressure regulator set to an output pressure of 50 PSI. Gradually decrease the outlet pressure to approximately 35 PSI, while simultaneously and slowly releasing the gas from the device. Continue this procedure until the Low Input Pressure Alarm, which includes both audible and visual alerts, is activated.

4.3.5. Low Input Pressure Shut OFF

Gradually decrease the oxygen regulator's outlet pressure. Aim for a target pressure of approximately 20 PSI. Observe the device's response to this decrease in pressure. It is designed to automatically shut OFF when the oxygen input pressure reaches around 20 PSI.

4.3.6. Oxygen Flush key

When the eAdvantage® mixer is active and turned ON, press the Oxygen Flush key. While doing so, keep an eye on the patient circuit to confirm if oxygen begins to flow continuously for the duration that the key is pressed.

4.3.7. Oxygen Concentration

To determine the oxygen concentration of the gas delivered by the eAdvantage® mixer, follow these steps:

- 1- Attach an oxygen monitor to the mixer's output connection using a T-Connector.
- 2- Draw a total of 5 full breaths from the unit, each breath amounting to 1 Liter.
- 3- Observe the readings of the oxygen percentage.
- 4- Verify that 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 to turn the device OFF after each patient's use. Before the next use, turn the device ON to enable the self-diagnostic test.

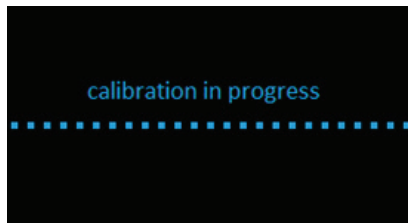
5. OPERATING INSTRUCTIONS

5.1 Start-up and Calibration

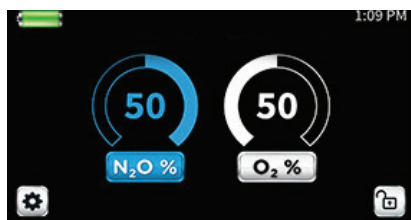
To start the eAdvantage®, press and hold the Control Knob (K) for 1 second. You will notice the associated green LED (J) beginning to flash at a high frequency.

After holding the knob for 1 second, the eAdvantage® turns ON and initiates the calibration process.

A calibration progress bar will appear on the screen, moving from left to right. This process typically takes about 5-10 seconds.



After completing the calibration, the display transitions to the operational screen. This screen presents various parameters, including the gas concentration (defaulted to a 50%-50% N₂O/O₂ mixture), current time, battery status, and lock status, as shown below:



Once the operation screen is displayed with all the relevant parameters, the eAdvantage® 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. O₂ Valve Failure.
2. N₂O Valve Failure.
3. O₂ Flow Sensor Failure.
4. N₂O Flow Sensor Failure.
5. U12 (Paw) Sensor Failure.
6. U13 (O₂ input pressure) Sensor Failure.
7. U14 (N₂O 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.

N₂O FLOW SENSOR
FAILURE!!!
RETURN FOR SERVICE

N₂O VALVE FAILURE!!!
RETURN FOR SERVICE

O₂ FLOW SENSOR
FAILURE!!!
RETURN FOR SERVICE

O₂ VALVE FAILURE!!!
RETURN FOR SERVICE

U12 SENSOR FAILURE!!!
RETURN FOR SERVICE

U13 SENSOR FAILURE!!!
RETURN FOR SERVICE

U14 SENSOR FAILURE!!!
RETURN FOR SERVICE

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

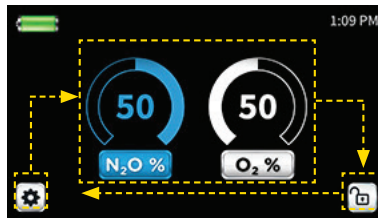
If multiple failures are detected the mixer will switch between the messages related to the failures.

5.2 Selecting the Gas Concentration

To adjust the gas concentration or modify device settings:

Rotate the Control Knob (K) to navigate through settings. The moving frame on the display will highlight various figures or options, following the direction of the knob's rotation.

Refer to the illustration below for an example of clockwise rotation and its corresponding effect on the selection frame:

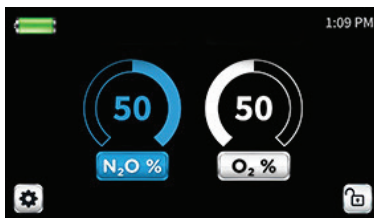


Note: If the screen is locked, the selection or adjustment of modes, gas mixture, and other settings will be disabled. Unlock the screen to enable these changes.

To change the gas concentration, follow these steps:

Rotate the Control Knob (K) until the selection frame highlights the gas mixture display on the screen. Then, press the Control Knob (K) to activate your selection. Upon doing this, the percentage values for both O2 and N2O will begin to flash. This flashing indicates that the process to change the gas mixture has been initiated."

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

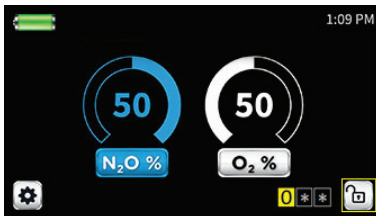
Note: The unit offers 3 preset concentration ranges, which can be pre-configured by the manufacturer or an authorized distributor. These settings include the full range mentioned above, with options for a fixed 50/50% mixture of each gas, or a maximum concentration of 50% nitrous oxide. This customization allows for adjustments according to local medical protocols or specific customer requests.

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

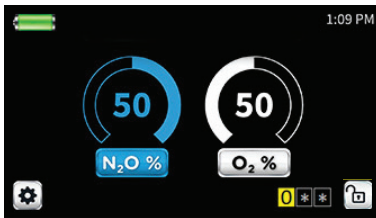
5.3 Lock Feature

The eAdvantage® is equipped with a 'lock' feature, protected by a passcode, to prevent patients from changing the settings selected by their healthcare providers.

Note: Activating the 'lock' feature on the eAdvantage® mixer disables the ability to make changes to the selected gas concentration. Additionally, it inactivates both the Setting mode and the Oxygen Flush function.



To activate the lock feature, rotate the Control Knob until the selection frame on the display screen surrounds the lock symbol, as shown in the picture.



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 the 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).

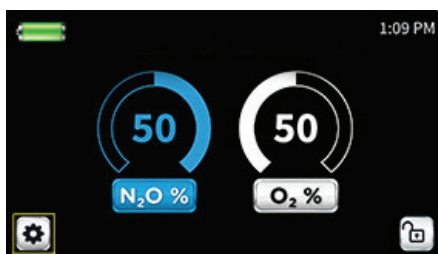
To unlock the screen, repeat the same steps required to lock the screen.

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: To access the Settings Mode, ensure that the screen is unlocked.

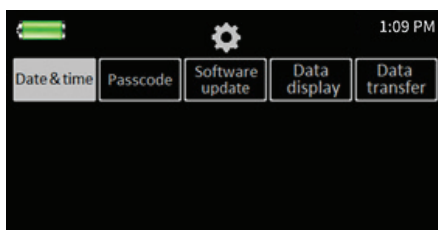
A. To access the setting mode, rotate the Control Knob (K) until the selection frame surrounds the settings symbol as shown below:



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

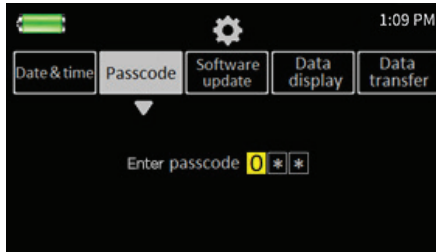
B. Press the Control Knob (K) to confirm the selection.

C. After confirmation, the screen will transition to the settings page, presenting the ‘Date & Time’ window in a solid reversed color scheme, below.



D. Rotate the Control Knob (K) in either direction to navigate through the five setting selections. The solid color frame will move accordingly until you reach the desired option. Once you’ve selected the appropriate setting, press the Control Knob (K) again to confirm your choice.

Once confirmed, the screen will display the specific information related to the selected setting. (as shown in the Passcode setting example below):

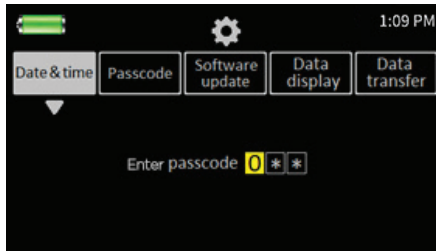


follow the instructions below to change the setting parameters.

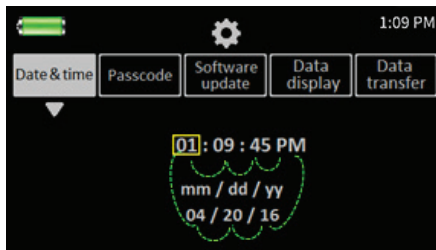
Note: Pressing the Cancel Key at any time within the setting mode will move the process back to a previous step until exiting the setting.

5.4.1. Date and Time

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

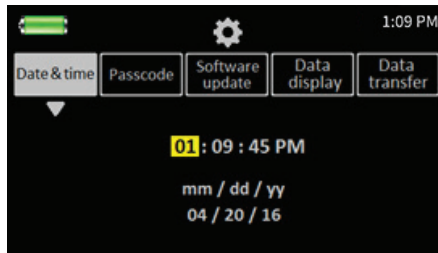


Once the ‘Date & Time’ setting is activated, a yellow square frame will appear around the hours setting window, as shown below.



Use the Control Knob (K) to move this square frame to the particular cell (e.g., hour, minute, day, month, year) you want to change. The green dotted lines shown above indicate the sequence for selecting each cell based on the rotation of the Control Knob.

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 setting, rotate the knob clockwise. Rotate it counter-clockwise to decrease it (except for the AM/PM cell where the direction of rotation does not matter). Press the Control Knob (K) to confirm the change.

After adjusting, the cell will revert from a solid color back to being outlined by a square frame.

To change another cell, move the frame to the next cell you wish to adjust and repeat the above steps.

If you decide not to make any changes, or once you have completed your adjustments, select the Cancel Button to exit this mode and return to the main settings screen.”

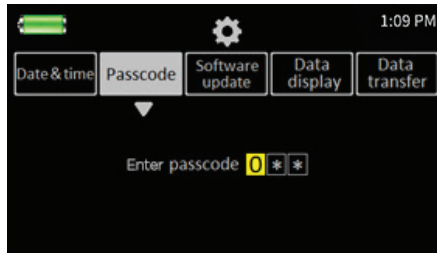
Note: It is important to be aware that if both the battery and power supply are disconnected for a period exceeding 1 month, the date and time settings will need to be reset.

In situations where the user does not configure the date and time after connecting the mixer to a power supply or inserting a battery, the device will automatically default to the following settings: 00:00 AM for the time and 01/01/00 for the date.

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.



To adjust a specific cell in the eAdvantage® system settings, follow these steps:

1 - Press the Control Knob (K) when the desired cell is highlighted. The cell will change to a solid color, indicating it is ready for adjustment, as shown below.

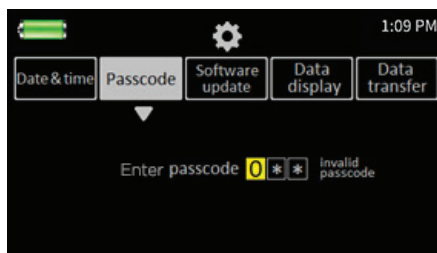
2 - Rotate the knob clockwise to increase the numbers from 0-9, or counter-clockwise to decrease them.

3 - Press the Control Knob (K) again to confirm your change. If you don't confirm within 10 seconds, the system will automatically cancel the selection.

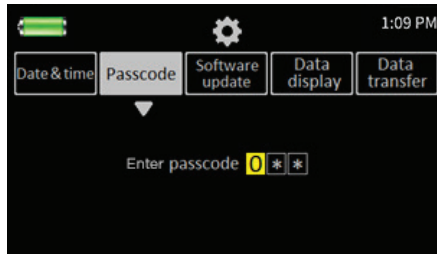
4 - Once the change is confirmed, the cell will revert from a solid color back to being outlined by a square frame.

5 - To adjust another setting, move the frame to the next cell and repeat the above steps.

6 - If you decide not to make any changes, or after you've completed your adjustments, use the Cancel Key to exit this mode and return to the main settings screen.

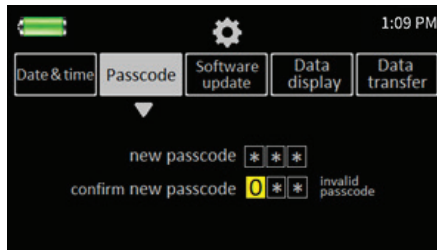


If the entered Passcode is accepted the screen will change to prompt the User to enter the new passcode otherwise it will show "invalid passcode" and the operator must repeat the above steps or select "Cancel" to exit without changes.



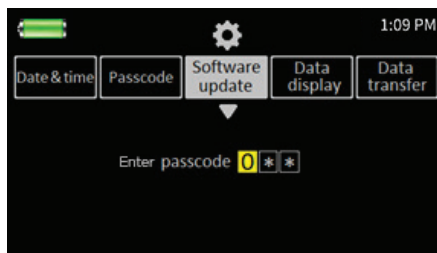
After entering the new passcode, a second line will appear beneath the first, prompting the user to confirm the new passcode.

Once the new passcode is confirmed, the screen will automatically revert to the settings screen within the passcode setting mode, as shown below:



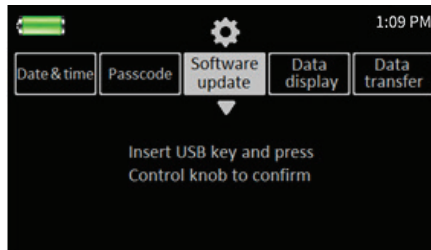
5.4.3. Software Update

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 the software update option.

Insert a USB key with the new software revision to update, or select the 'Cancel' symbol to exit without updating.



Upon inserting the boot loader USB key into the eAdvantage® system, the confirmation indicator light (J) will start flashing, indicating the need to confirm the selection manually before initiating the software update process.

To confirm and start the update, press the Control Knob (K). The boot loader will then automatically proceed with the software update. During this process, the confirmation indicator light (J) will remain ON, signaling that the new software is uploading 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:

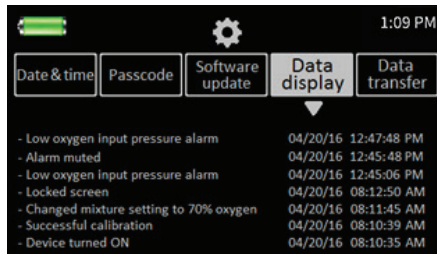
- If the software update fails during the download process - the orange LED light (G) and buzzer (E) will activate continuously for 3 seconds and then the mixer will shut down and restart.
- If the USB was disconnected during the update - the orange LED light (G) and buzzer (E) will activate continuously 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 a 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 a 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 the 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 updates as well as locking and unlocking 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 counterclockwise to display previous events. Scrolling the Control Knob will move the events up or down by one event per turn.

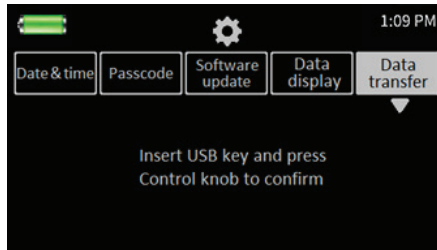
If multiple events occur at the same time, their events will be saved sequentially with no particular priority.

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

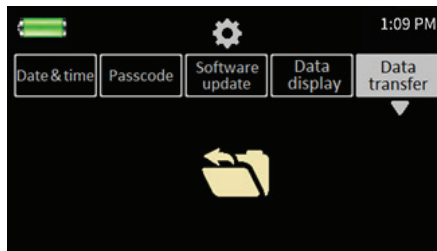
This feature allows the users to transfer and display the stored event on a computer or mobile device. follow the steps to activate the Data Transfer cell.



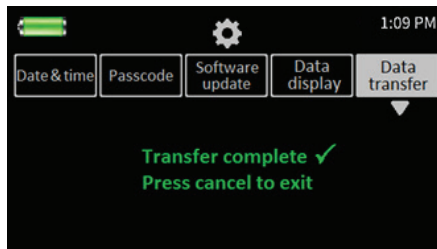
Insert the USB key or press the Cancel Button (L) if the user wishes to abandon this process.

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 the 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 fails; if the USB key is removed while transferring files; or if 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 under the supervision of healthcare professionals. Nurses or physicians attending to the patient should provide the following instructions for use:

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

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

5.5.2. The analgesic gas provided is a mixture of nitrous oxide and oxygen. Nitrous oxide, commonly known as 'laughing gas,' is a colorless gas characterized by a pleasant, slightly sweet odor and taste. It is used in medical settings such as surgery and dentistry due to its anesthetic, analgesic, and anxiety-reducing effects.

5.5.3. If you find it difficult to inhale through the mask, or if you feel nauseous or disoriented, simply remove the mask from your face and inform a staff member. Simply taking off the mask and breathing normal room air will quickly expel the gas from your system.

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 flow 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 essential to turn the device OFF after each patient use and to turn it ON again before the next use. This practice allows the self-diagnostic protocol to be activated, ensuring the device is functioning optimally for each patient.

6. POST USE

6.1 Disconnect the 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 following section 8.1 in this manual.

6.2 Storage

Store the mixer in an environment that adheres to the specified temperature and humidity ranges, specified in Chapter 9.1 of the manual.

Note: When the mixer is brought back to room temperature from the minimum storage temperature, it is designed to operate within 5 minutes.

Conversely, if the mixer is brought back from the maximum storage temperature to room temperature, it will be ready to operate within 2 minutes.

7. ALARMS, WARNINGS AND NOTIFICATIONS

7.1 Functional Alarms

Note: Both visual and audible alarms will persist until the underlying cause of the alarm has been addressed and resolved.

If an alarm is activated, the user can press the audio paused key to temporarily silence the audible alarm for 2 minutes. However, the visual alarm will continue flashing until the problem causing the alarm is resolved.

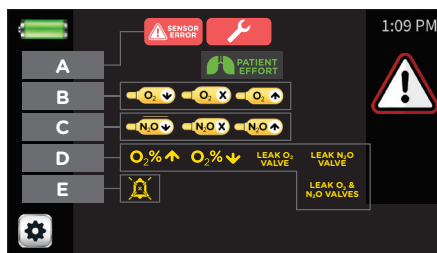
If the alarm is muted and a new alarm situation arises, the mute function will remain in effect. Only the visual indication for the new alarm will appear on the screen.

Alarms are displayed in sub-sections A-D. High-priority alarms are indicated with a red 'Warning' symbol, while medium and low-priority alarms have a yellow symbol.

The eAdvantage® device can display multiple alarm symbols simultaneously if several failures are occurring at the same time. In such cases, the audible alarm will correspond to the highest-priority alarm.

The patient effort cell is located at the center of the screen above the mixture 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 not visible on the actual device screen. They are included in the following illustration for demonstration purposes.



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 (35-21 PSI)	B	Medium	Directly	Solid symbol flashing down with yellow warning symbol	1 Burst with 3 pulses each, repeat every 20 seconds
	High O 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 ₂ O 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 ₂ O input pressure (35-21 PSI)	C	Medium	Directly	Solid symbol flashing down with yellow warning symbol	1 Burst with 3 pulses each, repeat every 20 seconds
	High N ₂ O 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 a flashing red warning symbol	1 Burst with 10 pulses each, repeat every 7.5 seconds
	Low Battery		Low	N/A	The solid yellow symbol with a fixed yellow warning symbol	N/A

Symbol	Name	Cell #	Priority	Alarm delay	On-Screen Visual Alarm	Audible Alarm
O ₂ % ↓	Low O ₂ % @ 6% volume lower than setting	D	Medium or high below 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 % ↑	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 O₂ VALVE	O ₂ valve leak during standby	D	High	10 seconds after turning the device ON or the last demanded breath	A solid symbol with a flashing red Warning symbol at 1.4 Ghz with 50% usage	1 Burst with 10 pulses each, repeat every 7.5 seconds
LEAK N₂O VALVE	N ₂ O valve leak during standby					
LEAK O₂ & N₂O VALVES	O ₂ & N ₂ O valves leak during standby					

7.2 Flow Valve Leak Alarm

The eAdvantage® system includes a flow valve leak detection feature that functions when the unit is supplied with gas.

While the device is ON, it continually monitors the outputs from both flow sensors. This monitoring occurs during the standby mode or for 10 seconds following the last patient-demanded breath.

If either of the flow sensors detects any unexpected flow (suggestive of a leak), the device will promptly display leak alarms on the screen, alerting the user to the issue.

Note: It's important to note that the leak detection feature will be inactive when both input gases are turned OFF (O PSI). This means the detection feature only operates when there is gas pressure present in the system.

7.3 Battery Indicators

The eAdvantage® system provides visual indications of the battery status on the screen. There are two distinct types of battery status indicators:

- Discharge Status Indicator: This displays the current battery level during normal operation of the device, indicating how much charge is remaining.
- Charging Status Indicator: This shows the status of the battery while it is being charged.

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	A solid yellow symbol with solid a 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: When the battery reaches approximately 2% of its full capacity, the device will not turn ON if it is currently OFF. Conversely, if the device is already ON and operating, it will automatically shut down to preserve the remaining battery life.

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, including the mouthpiece or facemask, is designed for single-patient use only. Following each patient use, it should be discarded as per local protocols and replaced with a new circuit.

Other components of the device should be wiped clean using a mild soap solution or a hard surface disinfectant suitable for the device's materials. It is critically important to ensure that the entire unit is never soaked or immersed in any cleaning solutions under any circumstances.

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 following local protocols.

8.1.3 Wipe clean the N₂O and O₂ 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.



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

8.2 Charging the Battery

8.2.1 To charge the battery, connect one end of the external power supply/charger to a power source (ranging from 100 to 240 Volts or an onboard vehicle socket). Then, connect the other end to the DC input socket (C), as shown in Fig. 1 on the side panel of the mixer. Upon successful connection, the indicator light will activate, indicating the beginning of charging.

8.2.2 Turn the unit ON and observe the battery level (section 1 of the screen). Refer to the 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. The same goes 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 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 routine preventive maintenance be carried out, 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 - 2-year interval

Performed by trained and certified technical teams, consisting exclusively of a functional check against the product specifications.

	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	Trained and certified technical teams

Note: Upon request, the manufacturer provides access to factory-trained service personnel and essential technical information. This includes circuit diagrams, component part lists, detailed descriptions, calibration instructions, and any other information necessary for the service and repair of the device.

Note: Single-patient use circuits shall be disposed of under local protocols.

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

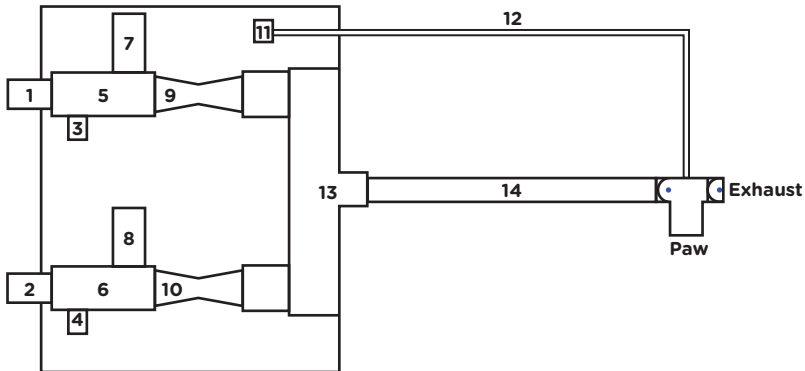
9. TECHNICAL DATA

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 (O₂ %)	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 (cmH₂O)	Approx. -1.0 (non-adjustable)	
INPUT PRESSURE RANGE (PSI)	43.5 - 72.5	
INHALATION RESISTANCE (cmH₂O)	0 to -6	
EXHALATION RESISTANCE (cmH₂O)	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 O₂ input - Below 25% O₂ output w/ 3 consecutive breaths or below 21% O₂ output immediately - Sensors and/or valve 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 settings 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 ₂ O)
	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 | 9. O ₂ Flow Sensor |
| 2. N ₂ O Input Connector | 10. N ₂ O Flow Sensor |
| 3. O ₂ Input The Pressure Sensor | 11. Respiratory Pressure Sensor |
| 4. N ₂ O Input The Pressure Sensor | 12. Sensor Hose |
| 5. O ₂ Inlet Manifold | 13. Removal Kit |
| 6. N ₂ O Inlet Manifold | 14. Patient Circuit |
| 7. O ₂ Flow Control Valve | 15. 3-Bypass Valve |
| 8. N ₂ O Flow Control Valve | |

Note: Always remove the plug, if applicable, 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	O1CV9200
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 the AC Power supply, the 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 environments 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 directly connected to the public Niedrig-voltage power supply network that supplies buildings used for domestic purposes. The eAdvantage® might not offer adequate protection for RF communication services if used in a residential environment. 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 $\pm 2, \pm 4, \pm 8, \pm 15$ 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	$\pm 0.5, \pm 1$ kV line to line; $\pm 0.5, \pm 1$ 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	6Vrms: 150kHz to 80MHz in ISM bands
	6Vrms: 150kHz to 80MHz 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 emission 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 the mask from the 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 35 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 Breathing circuit with Scavenger Hose, Monitoring line, 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 AFNR 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 ₂ O	O-Two™ 6 Foot (1.85 Meter) N ₂ O supply Hose with AFNOR Gas supply fitting and N2O DISS nut Device Connection	Each
01FV4303-AGA-N ₂ O	O-Two™ 6 Foot (1.85 Meter) N ₂ O supply Hose with AGA Gas supply fitting and DISS nut Device Connection	Each
01FV4303-CZCH-N ₂ O	O-Two™ 6 Foot (1.85 Meter) N ₂ O supply Hose with Czech Gas supply fitting and DISS nut Mixer Connection	Each
01FV4303-DIN-N ₂ O	O-Two™ 6 Foot (1.85 Meter) N ₂ O supply Hose with DIN nut and DISS nut Device Connection	Each
01FV4310	O-Two™ 6 Foot (1.85 Meter) N ₂ O supply Hose with DISS Gas supply fitting and DISS nut Device Connection	Each
01FV4303-UNF-N ₂ O	O-Two™ 6 Foot (1.85 Meter) N ₂ O supply Hose with UNIFOR gas supply fitting and DISS nut device connection	Each
01FV4303-BM-N ₂ O	O-Two™ 6 Foot (1.85 Meter) N ₂ O 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 part is subject to strict quality control tests to ensure exceptionally high standards. The manufacturer warrants to the purchaser of the eAdvantage® N2O/O2 Analgesic Gas Mixing and Delivery System that its parts are free from defects in material and workmanship for 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

SERIAL N°:

CE 1639

MD **EU** **REP**

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

o_two controlled™
ventilation

www.otwo.com

45A Armthorpe Road, Brampton, ON, Canada, L6T 5M4
Telephone: +1 905 792-OTWO (6896) N.A. Toll Free: +1 800 387 3405
Facsimile: +1 905 799 1339 Email: resuscitation@otwo.com