



Personal Humidifier

USER GUIDE

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TRADEMARKS

O2asis™ is a registered trademark of Perma Pure, LLC.

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WARRANTY

The O2asis personal humidifier is designed for use with low flow oxygen delivery systems to provide warmth and humidification to patients. Under normal operating conditions, Perma Pure will warrant the base unit to be free from defects of workmanship or materials for a period of one - (1) year, and the replacement water-well unit for a period of thirty - (30) days from the date of receipt provided that the unit is properly operated and maintained in accordance with Perma Pure's operating instructions. Based on Perma Pure's product evaluation, Perma Pure's sole obligation under the foregoing warranty is limited to making replacements, repairs or issuing credit for equipment found to be defective within the stated warranty period. Should the O2asis base unit or the replacement water well fail prematurely, the replacement base unit is warranted for the remainder of the original base unit warranty period, or the replacement water well is warranted for the remainder of the original water well warranty period. This warranty extends only to the buyer purchasing the equipment directly from Perma Pure or through Perma Pure's designated distributors and/or agents as new equipment.

Other replacement parts, consumables, and routine maintenance items are excluded from this warranty. Perma Pure shall not be liable to the purchaser or other persons for incidental or consequential damages or equipment that has been subject to abuse, misuse, misapplication, alteration, negligence or accident.

PATENTS

Covered by U.S. patent: 11071842

Other patents pending

CONTACT INFORMATION

Please contact your care provider, licensed distributor, or Perma Pure if you have trouble setting up or using the O2asis device. Should you need to contact Perma Pure directly, please use the following contact information:

Perma Pure LLC
1001 New Hampshire Ave
Lakewood, NJ 08701 USA

Toll Free: 866-334-2447
www.o2asishumidifier.com



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INTENDED USE

The O2asis Humidifier is a device intended to add moisture to breathing gases before they reach the patient to aid in the comfort of oxygen therapy.

INDICATIONS FOR USE



The O2asis Humidifier is indicated to add moisture and may warm breathing gases for administration to pediatric and adult patients in the home, hospital, and clinical settings. It is used with an external gas source of up to 6 Lpm via nasal cannula.








IMPORTANT

Rx only. ⚠ **Caution:** Federal law restricts this device to sale by or on the order of a physician. In order to receive the safe and proper treatment prescribed for you, only use the parts and accessories that came with the device or were supplied with the O2asis device or its licensed distributors.

WARNINGS

Warnings indicate that possible harm to the operator or user may occur.

- The patient and caregiver should read and understand this entire guide before using the device.
- This device is not intended for life support
- This device has no user serviceable parts.  **Do not** attempt to disassemble the unit as this could cause injury and invalidate the warranty.
-  **Do not** use any parts, accessories, or materials not recommended with O2asis as degraded performance can result.
- Use only power cords and accessories supplied with the O2asis device. Using other power cords and accessories could damage the device and may result in decreased immunity or increased emissions of the system.
- This device is not transit operable.

-  **Do not** pull on or stretch the **heated line**. This could damage the device or cause air leaks.
 - Always route the power cord in a way that will avoid anyone tripping or anything otherwise interfering with it.
-  **Do not** position the device in a way that would make it difficult to access the power supply connection port. Doing so would prevent quick disconnection if needed in an emergency situation.
 - This device is turned on when the power cord is plugged in. There is no on/off switch.
 - Keep the power cord and **heated line** away from sharp objects at all times
 - Inspect power cord and **heated line** for damage or signs of wear before use and periodically during use. If damaged, immediately discontinue use and contact your care provider, licensed distributor, or O2asis Customer Service for a replacement.
-  **Do not** connect any part of the device to any other equipment not described in this user guide.
 - Strangulation hazard! – Keep cords and hoses out of the reach of children. Arrange all tubing so that it will not twist around the head or neck.
 - Choking Hazard – Small parts. Keep away from children under 3 yrs.
-  **Do not** autoclave, gas-sterilize, or immerse any portion of the device. This may create an electric shock hazard or damage internal components.
-  **Do not** cover the breathing tubes with a blanket or subject to any outside heat source. This can affect the quality of treatment or injure the user.
-  **Do not** add any attachments or accessories to the device that are not listed in this user guide as the device may not function correctly affecting the quality of therapy or injuring the patient.
-  **Do not** use the device at an altitude above 3,100 m (10,171 ft.) above sea level or outside of a temperature of 20°C to 35°C (68° - 95° F). Using the device outside of this temperature range or above this altitude can affect the performance of the device which consequently can result in patient harm.

- To prevent disconnection of tubing during use, especially during ambulatory use, only tubes in compliance with ISO 5367 or ISO 80601-2-74 should be used.
- This device contains a heater and should not be used in a situation where prolonged direct skin contact could occur. **Ⓢ Do not** rest any part of the heated portion of device onto exposed skin.
- If the device has been dropped or mishandled, or if you otherwise notice any changes in the performance of the device, disconnect the power cord and discontinue use. Contact your care provider, licensed distributor, or O2asis Customer Service for repair or replacement.
- Inspect all tubing and parts for damage, wear, debris, or occlusion. Discard and replace as necessary.
- No substances other than oxygen shall be administered or delivered while using the device or through the device itself.
- Ⓢ **Do not** attempt to sterilize or reuse the Water Well cartridge. It is labeled as Ⓢ single patient use only and must be disposed of after 30 days of use on a Ⓢ single patient. Reuse of the Water Well cartridge can result in diminished performance and harm to the patient.
- Ⓢ **Do not** attempt to sterilize or reuse the nasal cannulas included with this device. They are labeled for Ⓢ single patient use only and must be replaced after one (1) week of use. Failure to replace the nasal cannulas as recommended can result in diminished performance and harm to the patient.
- Ⓢ **Do not** touch the surface plate while changing the Water Well consumable cartridge.
- Ⓢ **Do not** use organic solvents or abrasive cleaners. These types of cleaners may create toxic gasses when heated and may damage the device.
- Water fill pump is intended for Ⓢ single patient use only. It cannot be reprocessed. If the pump becomes contaminated, discard and replace the pump before filling.
- The Water Fill Pump is only intended for use with the O2asis Humidifier. **Ⓢ Do not** attempt to use with or connect to other medical equipment.
- This device is not intended for connection to a medical pipeline.
- This device is not intended for use with patients whose upper airways have been bypassed.

CAUTIONS

Cautions indicate that the device can be damaged























- Ⓢ **Do not** place the device directly onto blankets, carpets, fabrics, or other flammable materials.
- Ⓢ **Do not** place the device in or on any container that can collect or hold water.
- Ⓢ **Do not** use extension cords with this device.
 - The responsible organization is accountable for the compatibility of the humidifier and all of the parts and accessories used to connect to the patient before use.
 - The included cannula is validated for use with this device. **Ⓢ Do not** use with any other breathing systems.
 - Mobile RF communications equipment can affect medical electrical equipment.
 - Use only distilled water with this device. Use of tap or filtered water will damage the device and impair the quality of therapy it can provide.
- Ⓢ **Do not** use this device near any moisture producing devices such as a tea kettle or nebulizer. Increased moisture will reduce the effectiveness of the device and possibly cause moisture to build up inside of the breathing tube.
- Ⓢ **Do not** place the device on a surface that is above your nose to reduce the chances of moisture build up in the cannula and [heated line](#).
- Ⓢ **Do not** place the device near any sources of heating or cooling such as fire places, radiators, air conditioners, or forced air vents.
- Ⓢ **Do not** overfill the water container. Use only the included Water Fill Pump to fill the device.
 - Keep the device away from any children, pets, or pests as interaction with the device could cause damage and degrade performance.
 - Keep the device free of lint, dust, and dirt as these debris can damage the device and degrade performance.

CONTRAINDICATIONS

- This device should not be used by patients who have undergone nasal surgery within the past three months.
- This device should not be utilized to condition nebulized medicine or any gas with airborne salt/saline.

SYMBOLS AND MARKINGS

The symbols listed in the table below may appear on the device or its labeling:

 Consult Instructions for Use	 Type BF Applied Part
 Catalog Reference Number	 Temperature Limitation
 Manufacturing Lot Number	 AC
 Serial Number	 DC
 Manufacturer	 Ingress Protection Rating (Drip Proof)
 Caution	 Federal Law (USA) restricts this device to sale by or on the order of a physician
 Date of Manufacture	 Warning
 Single Patient Use	 Humidity
 Instructions for Use	 Do not use if package is open or damaged
 Non sterile	 Keep dry
 Expiration	 Pressure



WARNING: This product can expose you to chemicals including acrylonitrile, which is known in the state of California to cause cancer. For more information, go to www.p65warnings.ca.gov

INCLUDED WITH THE SYSTEM

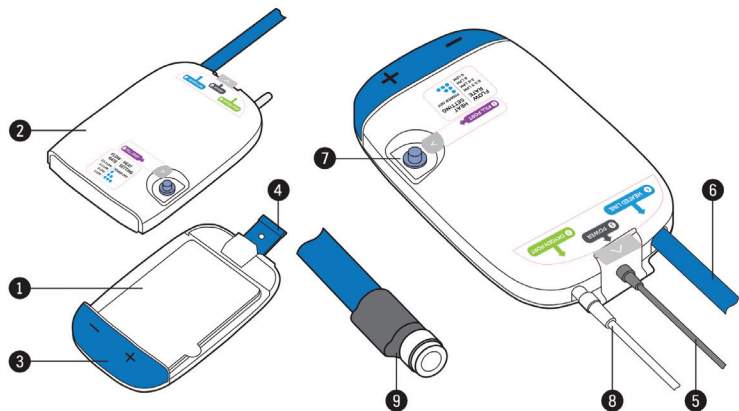
The O₂asis Humidifier comes with the following parts:

- O₂asis Humidifier Base and Water Well
- User Guide
- Consumable Cartridge pre-installed
- Replacing Water Well Guide
- Power Supply
- O₂asis Humidifier Adult Cannula
- Water Fill Pump
- Quick Start Guide
- Reorder Card

NOTE: If any of the items listed above are missing or damaged, please contact your care provider, licensed distributor, or O₂asis Customer Service.

DEVICE OVERVIEW AND FEATURES

The O₂asis personal humidifier is used with low flow oxygen therapy to provide moisture and heat to the oxygen stream. This greatly increases the comfort level of the oxygen therapy as oxygen is often very dry and can lead to discomfort.



FEATURES

- 1 **O₂asis Base Unit** — The base of the humidifier that includes the heat control buttons and the connection to the power plug.
- 2 **O₂asis Water Well Consumable Cartridge** — The top cartridge that includes the water reservoir and **heated line**. The cartridge lasts for 30 days before it needs to be replaced.
- 3 **Heat Control Buttons** — The + and - buttons which allow the user to select from three levels of heat.
- 4 **Cartridge Latch** — The hinged latch that locks the Water Well cartridge in place onto the base unit.
- 5 **Power Cord Connector** — The connector that accepts the male connector at the end of the power cord.
- 6 **Heated Line** — The heated tube attached to the Water Well cartridge that heats the oxygen to prevent water droplets from collecting inside of the tubing.
- 7 **Water Fill Port** — The port on the Water Well cartridge used to fill the water reservoir with distilled water.
- 8 **Oxygen Connection Port** — The port that accepts connection to the oxygen input from an oxygen tank or concentrator.
- 9 **Cannula Connection Port** — The port at the end of the **heated line** where the cannula is connected to.
- 10 **Water Fill Pump** — The pump and tubing set that attaches to a bottle of distilled water to be used to fill the Water Well cartridge reservoir.

SYSTEM COMPONENTS:



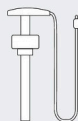
O₂asis Humidifier



Power Supply



O₂asis Humidifier Cannula



Water Fill Pump

Not included:



Distilled Water
(Tap or filtered water will damage device)

SAFETY FEATURES

The O₂asis Humidifier has been designed with the following safety features to limit temperature, power currents, and to cut off power of the device to ensure patient and user safety:

- **Power Supply and Accessories** – Power is supplied to the device when plugged in. The device does not have a Power Switch.
 - Power to the Base Unit is shut off when the Water Well is removed.
- **Water Well consumable cartridge (and Locking Latch)** – Power to the Heating System is terminated when the Water Well consumable cartridge is removed.
- **Main Board PCB** – Controls, Heaters and Settings to device performance and safety specifications
 - Heated Line Power Levels
 - Water Heater Temperature Levels
 - Water Heater power turned off when Heated Line is not detected
- **LED Indicator Lights** – (3) LED Indicator Lights (low, medium, high)
- **User Interfaces:**
 - Temperature Control Buttons - (2) Buttons (plus (+), minus (-)) to control temperature

SETTING UP THE DEVICE

Place the device on a firm, flat surface within easy reach of where you will use it. **Do not** place the device near any sources of heating or cooling such as fire places, radiators, air conditioners, or forced air vents.

Note: If an uncomfortable amount of rainout is occurring, try to place the device above your nose.

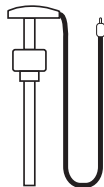
FILLING THE WATER WELL CONSUMABLE CARTRIDGE

To fill the device, complete the following steps:

What You Will Need

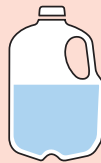


**O₂asis
Humidifier**



**Water Fill
Pump**

NOT INCLUDED



Distilled Water
Tap or filtered water
will damage device

- ⚠ **Warning:** Make sure that the device is not plugged in to an electrical outlet before filling.
- ⚠ **Warning:** Make sure that the Water Well consumable cartridge is secured to the base unit with blue latch closed before filling.
- ⚠ **Warning:** ⚡ **Do not** fill the water reservoir with anything other than distilled water. Adding different water or other substances can damage the device and degrade performance.
- ⚠ **Warning:** ⚡ **Do not** overfill the water reservoir. Use only the included Water Fill Pump to fill the device.
- ⚠ **Warning:** The Water Fill Pump is only intended for use with the O2asis Humidifier. ⚡ **Do not** attempt to use with or connect to other medical equipment.

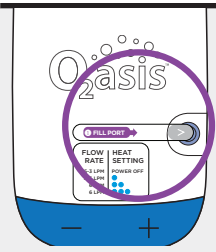
Note: Make sure to position the device on a flat, stable surface before filling.

Note: You should expect a full Water Well reservoir to hold 135 ml (4.6 oz) of distilled water and last 24 hours under normal use at 2 lpm flow rate. For additional reservoir durations, please refer to the Performance section of this manual.

Note: The device will detect when the Water Well is empty and will shut down. The three LED lights will flash until the device is filled.

Color-Coded Port Connections for the Water Fill Pump

The **Water Fill Port** is color-coded to aid the patient/user when connecting the Water Fill Pump to the **Water Fill Port** (1 **COLOR CODED IN PURPLE**).



1 Obtain a one-gallon bottle or jug of distilled water (available at many pharmacies and grocery stores) and set the bottle on a hard, flat, and stable surface.

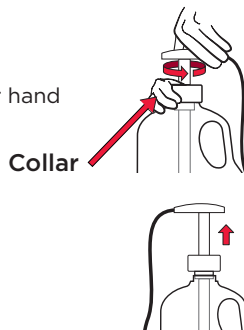
2 Remove the cap from the water bottle and insert the Water Fill Pump into the top of the bottle. The pump can rest on top of the water gallon. You **do not** need to twist the pump collar onto the water gallon.

Note: If the container of distilled water is filled to the top, water may overflow when the Water Fill Pump is inserted. Pour some water into the sink to avoid overflow.



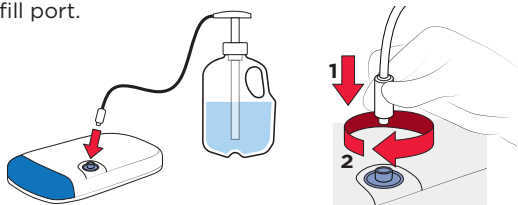
3 The first time using the Water Fill Pump:

Hold the pump collar in one hand. Use the other hand to twist pump head **COUNTER-CLOCKWISE**.



Twist until the pump **SPRINGS UP**.

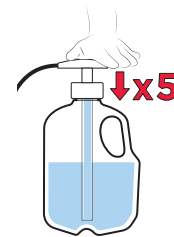
4A Push (1) and then twist (2) the connector at the end of the Water Fill Pump hose to the Water Well fill port.



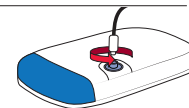
4B Slowly push down on the water fill pump handle 5 times to fill the Water Well.

As needed, remove Water Well to visually check water level, see section Checking for an empty Water Well, page 18. To prevent over-filling, the pump should not be used while the Water Well is disconnected from the Base Unit.

Confirm that the electrical port is dry and reattach the device to an electrical outlet. If the device is overfilled, the soft portion of the Water Well may balloon, create difficulties in closing the blue latch, and cause it to disconnect from the base unit. If this happens, unplug the device and allow it to run for several minutes without power. When the ballooning has subsided, the device can be reconnected to power and used normally.



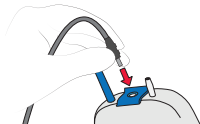
4C Remove the Water Fill Pump hose from the fill port. Set aside the gallon and Water Fill Pump until need to refill.



POWERING THE DEVICE

To connect the device to AC power, complete the following steps:

- 1** Ensure the blue latch is closed.
- 2** Plug the prongs of the power supply into a standard electrical outlet.
- 3** Plug the barrel connector of the power supply into the **2 POWER** cord connector on the latch side of the device.
- 4** When the device is powered on, one or more of the LED lights will be illuminated.



Warning: Be sure to periodically inspect the power adapter cord for signs of damage or wear. Immediately discontinue use and replace if damaged. Contact your care provider, licensed distributor, or O2asis Customer Service for replacement.

Note: Make sure that the Water Well consumable cartridge is securely latched to the base unit before plugging in the power cord.

Note: The O₂asis Humidifier device will continue to humidify the airflow even when disconnected from the power supply. Heating functions will not be available without power. Therefore, without power, it will be possible to get condensation in the breathing tube.

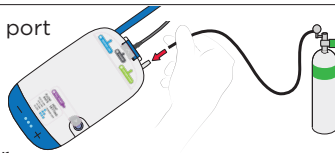
Note: The O₂asis Humidifier device does not have a power button. In the event of a malfunction, unplug the device to disconnect power.

Note: In the event of a power failure, unplug the device from the outlet until power is restored. Then plug the unit back in and check to make sure the device is functioning properly. The device will work to humidify the oxygen supply without power. However, no heat will be supplied to the gas pathway.

CONNECTING THE OXYGEN SOURCE

To connect your oxygen source, complete the following steps:

- 1 Find the connector at the end of the hose or line coming from your oxygen source.
- 2 Push the connector on to the oxygen input port on the latch side of the device until snug.
Note: Make sure that the connector forms a seal around the oxygen input port on the device. If you hear air coming out of that connection, push the connector further onto the port until it seals.



Note: Color-Coded Port Connections for the Oxygen Hose

The table below includes an image of the green color-coded O2asis Humidifier Port Label and an image of the **Oxygen Connection Port**.

Color-Coded Port Connections for the Oxygen Hose

The **Oxygen Connection Port** is color-coded to aid the patient/user when connecting the oxygen input to the **Oxygen Connection Port** (3 **GREEN COLOR CODED**).

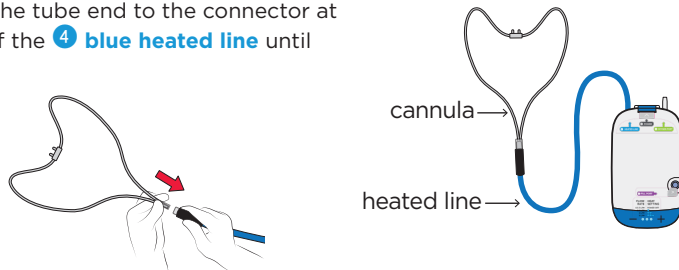


CONNECTING THE CANNULA

To connect the cannula to the device, complete the following steps:

Warning: Use only the cannula included with the device. Use of other cannulas can degrade the performance of the device.

- 1 Remove the cannula from its plastic bag.
- 2 Connect the tube end to the connector at the end of the 4 **blue heated line** until snug.



- 3 Position cannula on face as directed by your care provider.
- 4 Check for appropriate flow rate setting from oxygen source (concentrator, tank, etc.) and confirm that oxygen is flowing through the cannula.

Note: Small amounts of condensation may build up in the device during periods when it is not being used. In these cases, let oxygen flow through the

device for 5 to 10 seconds to clear condensation before positioning on face.

Note: During use, the device status should be checked every 4 hours. If the lights are off or flashing, consult the Troubleshooting section of this guide.

Note: The nasal cannula can be contaminated with discharge from the nose during use and if left unchecked portions of the O2asis tubing within the heating tube and cartridge may also be contaminated. If visible contamination is observed, the nasal cannula and any other contaminated parts should be disposed of and replaced.

ADJUSTING THE HEAT LEVEL

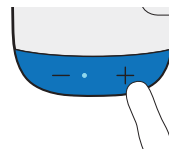
To adjust the temperature level applied to the oxygen flow, complete the following steps:

- 1 Select the appropriate heat level for the prescribed oxygen flow as shown in the table below:

Flow Rate	Heat Setting
0.5 lpm – 2 lpm	Power off
2 lpm – 6 lpm	● – Low
4 lpm – 6 lpm	● ● – Medium
5 lpm – 6 lpm	● ● ● – High

- 2 Above 2lpm of oxygen flow, begin your oxygen therapy on the first level of heat. When the device receives power, the left most LED light will illuminate, signifying that the device is on level one. Try this level first before adjusting to a higher heat level as indicated by the table above.

- 3 The heat level can be adjusted by pressing the '+' and '-' buttons on either side of the LEDs.



1 Light = Low



2 Lights = Medium



3 Lights = High



Note: When the power cord is disconnected, the device will return to the previous heat level when power is restored.

Condensation: Regularly check for visual condensation in the cannula. If excessive amounts of condensation are present, reduce the heat setting to the lowest level or unplug the device. If the problem persists, discontinue use of the O2asis Device.

PEDIATRIC PATIENTS

Setup and use for pediatric patients are consistent with all other instructions within this manual, except as follows:

Adult Caregiver: This device shall only be used with pediatric patients under close adult supervision.

Cannula: For pediatric patients, utilize the appropriate cannula as indicated in the table below, along with the supplied tubing connector

Patient	Age range*	Cannula	Source
Pediatric	2 years to < 21 years	HU412	Separate purchase
Adult	21 years +	HU401	1 pc. Included in kit

**Ages according to the Federal Food, Drug, and Cosmetic Act*

Initial Heat Setting: Follow the instructions in “Adjusting the Heat Level” section of this document.

Condensation: Regularly check for visual condensation in the cannula. If excessive amounts of condensation are present, reduce the heat setting to the lowest level or unplug the device. If the problem persists, discontinue use of the O2asis Device.

USE WITHOUT ELECTRICAL POWER

The O2asis Humidifier will continue to provide humidity even when disconnected from the power supply. For use without power, simply unplug the power supply from the electrical outlet on the wall, then unplug the power adapter cord from the O2asis device.

Without power, the device will not provide warmth, and humidification performance will be diminished. Use without power may also lead to additional condensation, particularly if unplugged after a period of use with electrical power.

REPLACING THE WATER WELL CONSUMABLE CARTRIDGE

What You Will Need



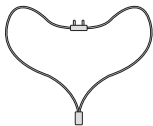
**O₂asis
Humidifier**



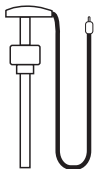
**Replacement
Water Well**



Power Supply



O₂asis Cannula



**Water Fill
Pump**

NOT INCLUDED

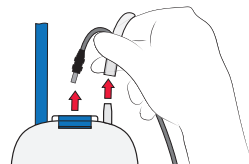


Distilled Water
Tap or filtered water
will damage device

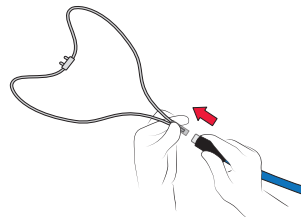
To replace the Water Well consumable cartridge, complete the following steps:

1 Unplug the power adapter cord from the latch side of the device.

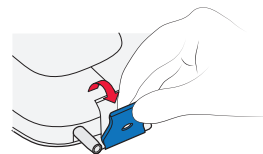
2 Unplug the oxygen source line from the oxygen connector. Leave the blue **heated line** in place.



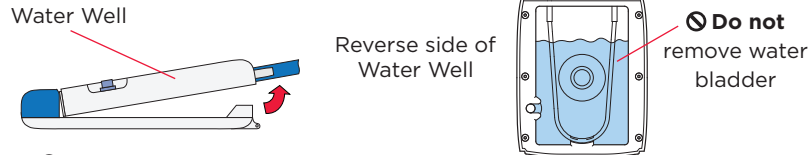
3 Unplug the cannula from the end of the **heated line**.



4 Open the base latch by prying the top of the latch off of the Water Well consumable cartridge and swinging it down.



- 5** Lift the latch side of the Water Well consumable cartridge and rotate out of the base.

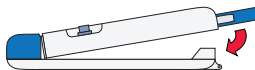


Do Not have any sharp objects around the Water Well consumable cartridge to prevent punctures to bladder.

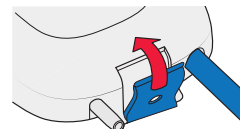
- 6** Dispose of the entire Water Well consumable cartridge in accordance with local plastic recycling guidelines. **Do not** attempt to separate the water bladder from the Water Well.

- 7** Open the new consumable cartridge from its packaging.

- 8** Insert the non-port side of the cartridge into the button side of the base and push in until the cartridge sits flush with the base.



- 9** Swing the base latch up and snap it onto the cartridge to lock it in place.

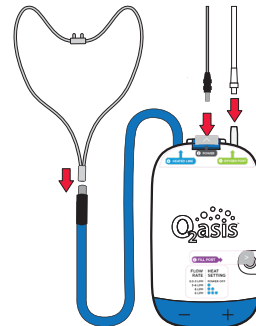


- 10** Fill the Water Well using the Water Fill Pump and distilled water as outlined on pages 9 - 10, Filling the Water Well Consumable Cartridge.

- 11** Plug your cannula into the end of the **heated line**.

- 12** Plug in your oxygen source tubing to the oxygen input port on the cartridge.

- 13** Plug in the power adapter cable to the power input port on the base.



⚠ Warning: You must replace the Water Well consumable cartridge every 30 days to ensure device safety and performance. Failure to replace the cartridge can result in degraded device performance and risk of serious patient injury.

Note: The entire gas pathway is contained within the Water Well consumable cartridge and can become contaminated with bodily fluids. If visible contamination is present or performance degradation is suspected, dispose of and replace the Water Well consumable cartridge.

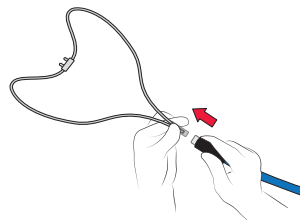
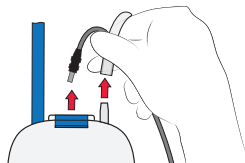
⚠ Warning: **⊘ Do not** touch the surface plate while changing the Water Well consumable cartridge. Surface plate may be hot.

CHECKING FOR AN EMPTY WATER WELL

1 Remove connections:

A: Remove power and oxygen connections (leave blue line in).

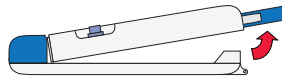
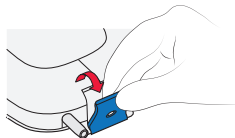
B: Remove cannula from **heated line**.



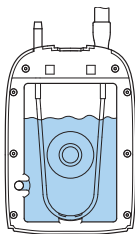
2 Remove Water Well:

A: Open blue latch to unlock.

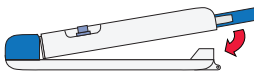
B: Lift up to remove water well.



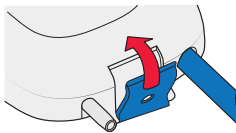
- 3** Check Water in Water Well: If low or empty, refill water well.



- 5** Reinstall Water Well: After ensuring water, install water well into base unit.



- 6** Close Latch: Close blue latch to secure the waterwell



CLEANING AND DISINFECTION

Regular Cleaning

Clean the device periodically and when dirt or debris is visible on the outside of the device. To clean the device base, disposable cartridge, or water fill pump, use a lint free cloth dampened with water and a few drops of dish soap. Wipe all exterior surfaces. If visible soil is present, use a wetted soft nylon bristle brush to remove visible soil, paying close attention to seams and crevices in the device. Wipe again with dish soap and water. Dry with a lint free cloth. Ammonia-free disinfecting wipes, such as Super Sani-Cloth® can be used on the outside of the device or pump.


Note: If the device or pump becomes noticeably dirty and regular cleaning does not remove soil, the device should be discarded and replaced.


Warning: ⚠️ **Do not** try to clean or disinfect the inside of the Water Well consumable cartridge. It is designed and tested to be ② single patient use for 30 days, after which it must be replaced.

Reprocessing and Disinfection Between Patients

The O2asis Humidifier Base must always be cleaned and disinfected between patients. The entire Water Well consumable cartridge, including its blue [heated line](#), is disposable and no disinfection is required. Follow these steps to ensure a clean and disinfected device:

- 1 Unplug the O₂asis Humidifier Base from the power supply.
- 2 Remove and discard the Cannula (Ⓜ single-patient use).
- 3 Remove and discard the Water Well consumable cartridge (Ⓜ single-patient use).
- 4 Examine for visible soil. If visible soil is present, use a wetted soft nylon bristle brush or Super Sani-Cloth® to remove all visible soil, paying close attention to seams and crevices in the device.
- 5 Wet all surfaces of the base unit with another Super Sani-Cloth®. Keep the surface wet for at least two minutes. Use additional Super Sani-Cloth® if needed.
- 6 Allow the device to air dry completely.
- 7 If Power Supply is exposed to the patient, disconnect from the O2asis device and wall. Repeat steps 4 through 6, and let thoroughly dry.

 **Warning: Do not** use organic solvents or abrasive cleaners. These types of cleaners may create toxic gasses when heated and may damage the device.

 **Warning:** Water fill pump is intended for Ⓜ single patient use only. The Water Fill Pump should not be used between multiple patients. It cannot be reprocessed. If the pump may have been contaminated, replace or provide patient with new pump.

The Super Sani-Cloth® Germicidal Disposable Wipe is a premoistened nonwoven durable wipe containing a quaternary ammonium chloride/alcohol-based solution. It is recommended for use in hospitals and other critical care areas where the control of the hazards of cross-contamination between treated surfaces is required, and it is designed to be compatible with hard nonporous surfaces and equipment made of plastic, Formica® laminate, glass and more. Some organisms are removed from the surface by thoroughly wiping the surface with the wipe. Most remaining organisms are killed within two (2) minutes by exposure to the liquid in the wipe.

The Super Sani-Cloth Wipe is registered with the Environmental Protection Agency (EPA) under (EPA #9480-4). In accordance with 21 CFR 880.6890, the Super Sani-Cloth Wipe is regulated by the FDA as a Class I, 510(k) Exempt, General Purpose Disinfectant under Product Code (LRJ).

MOVING THE DEVICE

To move the device to a new location, it is recommended that the power adapter plug be disconnected from the humidifier base. When moving with the device, make sure to secure the unit and route the tubing such that you will not get tangled in or trip on it.

TECHNICAL SPECIFICATIONS

Physical

Dimensions 187 x 102 x 30mm (7.4 x 4.0 x 1.2 in.)
(Not including 1118mm (44 in.) long heated line)
Weight 0.7 lbs. 65lbs. (295 g) empty, 10.95 lbs. (430 g) full
Distilled water reservoir approx. capacity: 135 ml or 4.6 oz (> 115 ml)

Environmental

Ambient Operating Conditions

Temperature 20° to 35° C (68° - 95° F)
Humidity 15% - 90%, non-condensing
Atmospheric Pressure Range 650 hPa - 1060 hPa

Transport and Storage Conditions

Temperature 5° to 40° C (41° - 104° F)
Humidity 15% - 90%, non-condensing
Atmospheric Pressure Range 650 hPa - 1060 hPa

Electrical

The device shall only receive power from the included Globtek GMTM46402-3612 power supply.

AC Power Input 100-240 VAC ~ 50-60 Hz, 1.0 A

DC Power Output 12 VDC, 3.0 A

Power Rating 36W

Fuses There are no user-replaceable fuses.

Use Durations

Component	② Single Patient Use Only?	Duration of Use / Expected Service Life	Shelf Life
Base Unit	No, Reusable	3 Years	3 Year
Water Well Cartridge	Yes, Single Patient Use	30 Days	3 Year
Power Supply	No, Reusable	3 Years	n/a
Cannula	Yes, Single Patient Use	1 Week	n/a
Water Fill Pump	Yes, Single Patient Use	1 Year	n/a

Standards Classification

- This device is an US FDA cleared Class II medical device.
- This device is considered an IEC Class II, continuous operation, ordinary equipment device.
- The heated line with cannula is considered an IEC applied part Type BF. This is a means of classification stating the degree of protection against electric shock.
- This device is classified as **IP22**. This means that the degree of protection against ingress of water is drip proof.
- This device is classified as a Class II humidifier per the ISO 80601-2-74 standard.
- This device is designed for use in professional and home healthcare environments. All parts and accessories included with the device are suitable for use in a patient environment. The patient is an intended operator.
- The power supply is specified as part of the ME equipment.

PERFORMANCE

Startup time to normal use: 30 seconds

Tests automatically performed at startup: Temperature check, sensor check, consumable present check, last setting check.

Passive humidification begins immediately. Full heated humidification performance can take up to 30 minutes at start-up, depending on flow rate.

Units of Measure:

Volume. ml (milliliters)

Flow Rate lpm (liters per minute)

Leakages ml (milliliters)

Oxygen Supply Flow Rate Range. 0.5 lpm to 6 lpm

Maximum Oxygen supply flow rate 6 lpm

ESTIMATED HUMIDIFICATION OUTPUT

Dry Oxygen Flow Rate	Heat Setting	20°C Ambient Temp		35°C Ambient Temp	
		Outlet Dew Point (°C)	Outlet Humidity (mg/l) BTPS	Outlet Dew Point (°C)	Outlet Humidity (mg/l) BTPS
0.5	Unplugged	15	11	26	23
	Low	29	27	36	40
	Medium	30	28	37	42
	High	32	32	40	49
3	Unplugged	12	9	22	18
	Low	26	23	25	21
	Medium	30	28	30	28
	High	34	36	34	36
6	Unplugged	8	7	17	13
	Low	18	14	19	15
	Medium	22	18	23	19
	High	24	20	25	21

Estimated use duration before refilling, based on 135ml initial fill:

Dry Oxygen Flow Rate	Heat Setting	Estimated Use Time Before Refill (Hours)
0.5	Low	57
	Medium	37
	High	25
3	Low	17
	Medium	12
	High	8
6	Low	13
	Medium	11
	High	10

Maximum delivered gas temperature 47°C (116.6°F) at exit of heated line

Maximum operating pressure 45 psia

Maximum pressure drop across device.2 psi at 6lpm

The accuracies of set and monitored humidification are maintained over flow-rates from 0.5 lpm to 6 lpm. Only use standard kink resistant oxygen lines and the included cannula to assure the accuracy of the system.

Maximum rated supply pressure from an external source 45 psia

ELECTROMAGNETIC COMPATIBILITY

The O₂asis Humidifier is suitable for the electromagnetic environment of typical homes, commercial or hospital settings.

During the immunity testing described below the O₂asis Humidifier continued to humidify air

⚠ Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the O₂asis Humidifier System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.”

⚠ Warning: The O₂asis Humidifier should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the O₂asis Humidifier should be observed to verify normal operation. If operation is not normal, the O₂asis Humidifier or the other equipment should be moved.

⚠ Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

⚠ Warning: Avoid exposure to known sources of EMI (electromagnetic interference) such as Magnetic Resonance Imaging (MRI) systems, X-ray, electrosurgery, defibrillation, infrared radiation, diathermy, lithotripsy, electrocautery,

RFID (Radio Frequency Identification), and electromagnetic security systems such as anti-theft/electronic article surveillance systems, metal detectors. Note that the presence of RFID devices may not be obvious. If such interference is suspected, reposition the equipment if possible, to maximize distances.

Emissions

Electromagnetic Emissions		
The O ₂ asis Humidifier is intended for use in the electromagnetic environment specified below. The user of the O ₂ asis Humidifier should assure that it is used in such an environment.		
Emission Tests	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The O ₂ asis Humidifier 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 B	The O ₂ asis Humidifier is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Immunity

Electromagnetic Immunity		
The O ₂ asis Humidifier is intended for use in the electromagnetic environment specified below. The user of the O ₂ asis Humidifier should assure that it is used in such an environment.		
Immunity Test	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8kV contact ± 2, 4, 8, 15kV air	The relative humidity should be at least 5 %
Electrical fast transient / burst IEC 61000-4-4	± 2 kV for power supply lines	Mains power quality should be that of a typical home commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode	Mains power quality should be that of a typical home commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% .5 Periods 0% 1 Period 70% 25 Periods 0% 5 sec	Mains power quality should be that of a typical home commercial or hospital environment. If the user of the O ₂ asis Humidifier requires continued operation during power mains interruptions it is recommended that the O ₂ asis Humidifier is powered from an uninterruptible power supply.

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	Power frequency magnetic fields from common appliances in the home are not expected to affect the device. Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. Keep the O ₂ asis Humidifier away from sources of high levels of power line magnetic fields (in excess of 30 A/m) to reduce the likelihood of interference.”
NOTE: UT is the A/C. mains voltage prior to application of the test level.		

Electromagnetic Immunity			
The O ₂ asis Humidifier is intended for use in the electromagnetic environment specified below. The user of the O ₂ asis Humidifier should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 6 V rms in ISM and amateur radio bands	The O ₂ asis Humidifier is suitable for the electromagnetic environment of typical homes, commercial or hospital settings.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m	

DISPOSAL

- **Base Unit:** This device should be disposed of separately from standard municipal waste. Dispose of in accordance with local regulations for recycled electronic goods.
- **Water Well Consumable Cartridge:** Dispose of the Water Well consumable cartridge in accordance with local plastic recycling guidelines.

TROUBLESHOOTING

Below is a list of possible problems you may have with the device and the actions to take if these problems occur.

Problem	Possible Cause	Action to Take
The three LEDs on the base unit are flashing.	There is an error with the device.	Unplug the device from the wall outlet and then plug back in. Check to see if the water well is empty. If empty, refill with distilled water. Also check to make sure that the consumable cartridge is properly secured to the base and that the hoses and power connector are all properly connected to their respective ports. If you have verified all of the above are correct, unplug the device and then please contact the care provider, licensed distributor, or O ₂ asis to return the device.

Problem	Possible Cause	Action to Take
The device does nothing after providing power. No LED light indicators are on.	The device is unplugged, or the outlet is not providing power.	Check that the AC power adapter is properly plugged in to an electric outlet and that the outlet has power available to it. Also check that the barrel connector at the end of the adapter cord is securely connected to the power input jack on the base unit. If the device still does not power on, or power is intermittent, please contact the care provider, licensed distributor, or O2asis to return the device.
The air flow coming out of the cannula feels too low.	The connection between the oxygen input hose and the device is not secure, or the connection between the cannula and the heated line is not secure.	Check that the oxygen input connector is securely attached to the device's oxygen input port. Push on until the connector is snug with the device. Also check that the cannula connector is secured to the heated line. Push the end of the cannula into the open end of the heated line until snug. If the device still does not provide the proper air flow, please contact the care provider, licensed distributor, or O2asis to return the device.

Problem	Possible Cause	Action to Take
The temperature of the air coming out of the cannula feels colder or warmer than usual	You may be using the device in a colder or warmer environment than usual, or the device could be improperly placed on or near a heater or cooler.	Change the temperature setting on the device to be lower or higher than usual based on your surrounding environment. Also make sure that the device is securely positioned away from any sources of cold, heat or humidity. If the device still does not provide the proper air temperature, please contact the care provider, licensed distributor, or O2asis to return the device.
You are not able to adjust the heat level of the humidifier	There is a malfunction with the control buttons, or the device has no power.	Unplug the device from the wall outlet and then plug back in. If that doesn't solve the problem, check the connection of the power supply barrel plug into the device. Make sure it is securely connected. If you are still not able to adjust the settings on the device, please contact the care provider, licensed distributor, or O2asis to return the device.

Problem	Possible Cause	Action to Take
The LED light indicators are not changing when you press the heat level control buttons	There is a malfunction with the control buttons, or the LED indicator lights.	Unplug the device from the wall outlet and then plug back in. If that doesn't solve the problem, check the connection of the power supply barrel plug into the device. Make sure it is securely connected. If the lights still do not illuminate, please contact your care provider, licensed distributor, or O2asis to return the device.
The water in the Water Well cartridge runs out before waking up.	Conditions are such that the humidifier is using more water than usual to achieve the selected heat level, or the water reservoir was not full before going to bed.	Make sure to fill the reservoir with 5 full pumps from the Water Fill pump in order to completely fill the device. Also, make sure that the device is securely positioned away from any sources of cold, heat or humidity.
The air coming out of the cannula seems too dry.	You accidentally filled the Water Well cartridge with regular or filtered tap water.	Make sure to only fill the device with distilled water. If you accidentally filled the device with tap water and its performance has degraded such that it is not providing comfort anymore, please purchase a new Water Well to restore full comfort.

Problem	Possible Cause	Action to Take
The device does not seem to be operating correctly.	You accidentally spilled water onto the humidifier base unit.	Unplug the device from the wall outlet and then allow the device to completely dry. Plug back in to the wall outlet. If that doesn't solve the problem, check the connection of the power supply barrel plug into the device. Make sure it is securely connected. If the device performance has degraded such that it is not providing comfort anymore, please contact your care provider, licensed distributor, or O2asis return the device.
You hear a leak or whistling sound coming from one of the tubing connections on the humidifier.	The connection between the oxygen input hose and the device is not secure, or the connection between the cannula and the heated line is not secure.	Check that the oxygen input connector is securely attached to the device's oxygen input port. Push on until the connector is snug with the device. Also check that the cannula connector is secured to the heated line. Push the end of the cannula into the open end of the heated line until snug. If the device still does not provide the proper air flow, please contact your care provider, licensed distributor, or O2asis to return the device.

If any of these problems occur again after you perform all suggested actions, contact the care provider, licensed distributor, or O2asis for customer service.



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