

OXYMIZER INFO & FREQUENTLY ASKED QUESTIONS

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Oxymizer Pendant Style (P-224)

Oxymizer Mustache Style (O-224)

Oxymizer & Oxymizer Pendant

Disposable Oxygen Conserving Devices

Description and Rationale

Oxymizer and Oxymizer Pendant devices are simple, disposable oxygen conservers. The use of these products allows healthcare professionals to maintain adequate oxygen saturations in hypoxic patients while using significantly lower oxygen flow rates than required by traditional means.

By reducing the oxygen flow rate necessary to achieve adequate oxygen saturations, these devices reduce by 50% to 75% the amount of oxygen required to treat a patient successfully. The benefits of this conservation include:

- Reduced oxygen costs
- Increased ambulation by making portable systems last significantly longer
- Reduced nasal irritation and dryness, eliminating the need for humidification in most patients
- Use of low flow oxygen concentrators on patients who require higher flow rates than their existing concentrators provide
- Ability to adequately saturate higher flow oxygen patients more comfortably, eliminating the need for an oxygen mask.

These conservers accumulate and store, in a reservoir (20ml – Mustache style, 40ml – Pendant style), the oxygen that is usually wasted during exhalation. A highly responsive membrane within the reservoir acts as a reflux to force the accumulated oxygen, together with the reduced oxygen flow, into the lungs quickly. This occurs at the very beginning of inhalation – the optimal time to deliver supplemental oxygen.

The delivery of this bolus of oxygen at the very beginning of inhalation allows the healthcare professional to reduce the oxygen flow rates required to obtain target oxygen saturations. For example, in the first half second of inhalation (the time period during which all the oxygen that takes part in the gas exchange reaches the distal portion of the lungs), a patient who requires 2 Lpm oxygen by traditional means receives the same amount of oxygen and achieves the same blood oxygen saturations when the oxygen is delivered at .5 Lpm via the Oxymizer devices. One Lpm via Oxymizer is equivalent to 3 Lpm via standard cannula and 2 Lpm is equivalent to 4 Lpm via traditional means. These equivalencies have been confirmed in more than (30) worldwide clinical studies in a variety of circumstances and clinical conditions.

Two versions of the Oxymizer device are available. Both work on the same reservoir principle and provide

similar oxygen saturations and savings. The original Oxymizer places the reservoir directly under the patient's nose. Although patients report that this is the more comfortable of the two styles, its configuration makes it too obtrusive for some patients. The Oxymizer Pendant version incorporates the reservoir system in the cannula tubing and a circular chamber resembling a pendant that rests against the patient's chest. This chamber can be concealed easily under clothing, making it much less obtrusive than the original Oxymizer device; however, it is not quite as comfortable. Many patients use both styles – they wear the original Oxymizer when they are in the privacy of their homes and the Oxymizer Pendant when they go out.

The Oxymizer is a disposable oxygen-conserving device with curved tubular nasal prongs, 6 feet of connection tubing, and one (1) female connector. This disposable reservoir cannula is for use in Oxygen Therapy by prescription only and for single patient use only. It is the simplest conserving device available today, operating without electronics, batteries, switches or flow controls.

These devices are CE marked as well as FDA cleared. This product has been in the market since 1983 and has 30+ clinical studies.

BENEFITS:

If used properly, these devices will provide you with the oxygen needed as well as these added benefits:

- It will take a lower flow rate to get the same amount of oxygen into your body, which can be as much as 75% less (depending on the flow rate) than a standard nasal cannula.
- If you use a portable oxygen system, it will last longer and allow you to be away from your main oxygen source for a longer period of time; or, you may be able to use a smaller, lighter weight portable system.

FEATURES/BENEFITS:

- Delivers up to a 4:1 savings ratio / Reduces oxygen costs by up to 75%
- Does not require batteries
- Allows you to obtain the equivalent of 7.5 liters from a five-liter concentrator
- Features a built-in humidification effect
- Compatible with a wide variety of oxygen sources, including compressed gas, concentrators and liquid oxygen / Accommodates the oxygen delivery requirements of a broad range of patients
- Proven efficacy for use during sleep and exercise / Ensures proper saturation in a wide variety of settings
- Can achieve the equivalent of a 7.5 Lpm setting at 5 Lpm / Accommodates the needs of high liter flow patients
- Pendant model can be used with pursed-lip breathing at all flows & the Mustache model at flows higher than 4 Lpm / Offers improved oxygen saturations and increased conservation
- Provides adequate saturations at higher flows when used in place of a non-rebreather mask / Enhances patient comfort and allows patients to eat, drink and talk in an unobstructed manner
- Achieves adequate saturations at lower flow rates / Reduces nasal irritation associated with higher flows
- Pendant model features a reservoir that can be worn underneath clothing & Mustache-style model features an updated, clear facepiece / Offers less conspicuous oxygen delivery
- Pendant model features soft, flexible cannula tubing and small nasal prongs / Comfortable for all-day use
- Accommodates the use of handheld nebulizers, incentive spirometers and suctioning devices without interrupting oxygen therapy.
- Effectively oxygenates hard-to-saturate patients, including some with refractory hypoxemia

BASIC PRINCIPLES OF OXYMIZER:

The Oxymizer is a disposable conserving device with a built-in reservoir that stores (20mls) of expired air. That air is enriched or replaced with oxygen during the remainder of exhalation.

1) Oxymizer – reservoir cannula that stores air on initial expiration. It enriches that air with oxygen during the remainder of expiration.

2) Diaphragm collapses on initial inspiration, delivering a bolus of highly

oxygen-enriched air to the deepest part of the lungs.

3) Because of this the Oxymizer efficiently delivers supplemental oxygen by:

- a) O2 savings of up to 75%
- b) Reduces nasal irritation
- c) Eliminates need for supplemental humidification

NOTE: The Oxymizer is to be used with continuous flow only. With Gas or Liquid Oxygen

FREQUENTLY ASKED QUESTIONS/TOPICS:

FDA APPROVAL

Question: Is the Oxymizer FDA approved?

Answer: The FDA does not "approve" products. That word is used to freely; what the FDA does it "clears" the product for market. The evidence that the product has cleared is the 510K notification; Number K830009, Class II product.

Also, this product has been in the market since 1983 and has 30+ clinical studies.

EXPIRATION DATE

Question: Is there an expiration date for the Oxymizers?

Answer: The notion of expiration date was determined when the Oxymizers first came out around 1982. There was concern about the membrane not lasting and the possibility of growth of bacteria over time. None of those possibilities were adequately tested. There are no criteria for expiration date. These devices last for months. On the other hand there is nothing written that I am aware of that specifically states that there is no expiration date. Thus, it is basically an unresolved issue. It generally has not been a major issue.

In order to maintain maximum efficiency, items should not be exposed to extreme temperatures. Also, to avoid unnecessary contamination and/or dust particles, it is recommended the product remain stored in its original packaging until time of use.

SHELF LIFE:

Question: How long is the Oxymizer shelf life?

Answer: The Oxymizer and Pendant being a disposable product, like cannulas and supply tubing, are to be used and discarded within a reasonable period of time. It is recommended that inventory supplies be turned periodically to avoid these products from sitting in a warehouse for prolonged periods of time.

It is also important to keep these products in the original package or shell in order to avoid contamination and early material degradation. A common way to check any vinyl product for material degradation is by touch and feel. This should of course be done with clean hands, and if the product feels sticky, do not use.

OXYMIZER REPLACEMENT

Question: How frequently is it recommended that the Oxymizer be replaced?

Answer: The original clinical studies proved that the membrane within the reservoir (the nosepiece on the Mustache style and the disc at the chest on the Pendant style) remained responsive after continuous 24 hour per day use for three weeks. We then concluded and recommended replacement after about three weeks continuous usage, with more frequent change being suggested when needed for reason of hygiene.

Less use would of course allow the membrane to last longer and extend the usage time. In that case, our recommendation is to replace the device whenever it has become too unsightly or the plastic has started to stiffen.

Question: If a patient is using the Oxymizer on a part-time schedule (only during therapy) for 2 hours each session 2-3 times per week should the replacement schedule still be the recommended 3-4 weeks or is it possible to extend that?

Answer: The Oxymizer replacement need not be held to 3-4 weeks. It could be twice that time. It is important that the Oxymizer be kept clean and dry during the off times and that the plastic not become

hardened by the weather

TEMPERATURE RANGE

Question: Is there a temperature range for the Oxymizers?

Answer: Storage tests for these devices is -40 degrees F, 1% humidity for 4 hours.

CLEANING/MINIMIZING PLASTIC ODOR:

Question: Can the Oxymizer be cleaned?

Answer: It is recommended that only the outer surfaces and prongs be cleaned with soap and water, but care must be taken not to allow the membrane within the reservoir to become wet.

Question: How can the plastic odor be minimized when a new Oxymizer is used?

Answer: Sit the Oxymizer in the sun for a day or run oxygen through it for a day. The odor is plasticizer which leaches out over time.

HARDENING OF THE NASAL PRONGS PLASTIC

Question: What can cause the plastic in the nasal prongs to become hard?

Answer: The plasticizer keeps the plastic flexible and "plastic". When the plasticizer leaches out, the plastic loses its flexibility. Age and heat can leach out the plasticizer. Saline nasal gel that is sometimes used to alleviate nasal irritation can also cause the plastic to harden.

CARBON DIOXIDE

Question: When a patient exhales, I understand that a part of the O₂ goes into the reservoir and is "fed" back to him when he breathes in again. This oxygen is enriched with what is generated from their main O₂ source such as the tank, concentrator, etc. However, doesn't a patient also exhale CO₂, and is this safe for the patient to breathe back in?

Answer: CO₂ is not an issue. The reason is that CO₂ comes out at the very end of exhalation. By that time the reservoir has already been filled with oxygen. Under high flow conditions, some of the CO₂ has been "washed out" from the nose.

SLEEPING

Question: Can the Oxymizer be used while sleeping?

Answer: The Oxymizer and Pendant are not recommended for a sleeping patient that is not being monitored as there is potential for the Oxymizer to dislodge from the nose or bend during sleep in which case the patient would not be receiving appropriate oxygenation.

Question: Has the Oxymizer ever been tested/used in a sleep lab?

Answer: A sleep lab is an appropriate place to test a patient using the Oxymizer and adjust the flow according to the patient's needs. If the patient requires oxygen - particularly high flow oxygen, it is a good way to test the patient as the patient is carefully monitored. If the patient breathes via open mouth, the membrane will not cycle, however, with high flow oxygen, the patient should oxygenate well. If the patient has apnea (stops breathing) that would explain hypoxemia at night - even with the Oxymizer.

SHOWERING

Question: I spoke with a patient that is using the Oxymizer. He must use oxygen while showering. He feels like a couple of droplets of water got into the reservoir. He asked me if the product is completely sealed or could it be that the water got into it? Can the Oxymizer be used in the shower or will the patient have to find another method of delivering oxygen while he is showering?

Answer: People have used the Oxymizer in the shower. However, I suggest that they use a standard nasal cannula while in the shower on higher flow and return to the Oxymizer when they come out. The humidifier bottle on the concentrator is no problem. However, it is unnecessary because the Oxymizer humidifies the oxygen going to the patient.

Question: We had a therapist call regarding a patient currently using the Oxymizer Pendant at 8-10 Liters. We advised that it was recommended to not wear it while showering, but to use a standard cannula instead. She then asked if it would be different if she were to use the Moustache style Oxymizer. We told her that the

concern is for moisture accumulation in the reservoir (for either style), which could cause the membrane to stick, and compromise the effectiveness of the device. She is concerned about using a standard cannula with a higher oxygen setting. Please advise.

Answer: It is better not to use the Oxymizers in the shower because of membrane sticking. It is okay to temporarily use the standard cannula in the shower at the higher flows. People use them in swimming pools.

CONDENSATION

Question: Is it normal for an Oxymizer to have some condensation in the Pendant? The patient is on a setting of 2 Lpm and has not showered with the unit, nor is the unit being used with a humidifier.

Answer: It is not unusual to have condensation in the Pendant if the oxygen is humidified going into the Pendant and there is a lot of air conditioning. Air conditioners dry out the air. At flows less than 4 Lpm it is unnecessary to humidify the oxygen. If the moisture has been there a while, it is safer to switch to a newer unit to avoid the affects of bacterial or fungal growth in the condensation.

MEMBRANE MOVING?

Question: Are you supposed to see the membrane moving up and down on the Oxymizer Pendant? If you don't see it moving, does that mean the unit is not working properly?

Answer: At low levels of delivery, the membrane should move in and out. It is sometimes difficult to see what the membrane is doing. At high flows above 4 Lpm, there may be no movement of the membrane and yet the patient is deriving benefit. The bottom line is oxygen saturation. If the saturation is above 90% at rest and exertion, the goal of oxygen therapy is being met.

OXYGEN LOSS

Question: Is any purity in the oxygen lost due to the fact that it sits in the reservoir?

Answer: The Pendant is a cycling device. The concentration of oxygen in the reservoir is nearly 100% if the oxygen is flowing at 1 Lpm or greater. Because it cycles, the oxygen in the reservoir remains about 100% because it constantly replenishes. Conceptually, it is like the concentration of oxygen in the tubing.

OXYMIZER NOISE

Is it normal for the Oxymizer to make noise at a high flow setting?

Question: A patient at a high flow rate (up to 15 liters on liquid oxygen) is sometimes using the Oxymizer up to 12. His wife says that sometimes when the flow is turned up the Oxymizer makes a very loud constant noise and she wants to know if this is normal and if it's okay?

Answer: Both the Oxymizer Mustache and Pendant styles make a lot of noise at high flows - beyond 8 Lpm. This is especially true with the Pendant because it has a "jet". A high flow version is being designed that should make less noise.

USE WITH A TRACHEOSTOMY (TRACH) TUBE?

Question: Can an Oxymizer be used with a patient using a trach tube?

Answer: No, since the Oxymizer operates by nasal delivery.

BREATHING – PURSED LIP BREATHING (PLB)

Pursed lip breathing is one of the simplest ways to control shortness of breath. It provides a quick and easy way to slow your pace of breathing, making each breath more effective.

Pursed Lip Breathing:

- Improves ventilation
- Releases trapped air in the lungs
- Keeps the airways open longer and decreases the work of breathing
- Prolongs exhalation to slow the breathing rate
- Improves breathing patterns by moving old air out of the lungs and allowing for new air to enter the

lungs

- Relieves shortness of breath

- Causes general relaxation

Pursed Lip Breathing Technique:

This technique is useful during the difficult part of any activity such as bending, lifting or stair climbing.

- Relax your neck and shoulder muscles

- Breathe in (inhale) slowly through your nose for two counts, keeping your mouth closed. Don't take a deep breath; a normal breath will do. It may help to count to yourself: inhale, one, two.

- Pucker or "purse" your lips as if you were going to whistle or gently flicker the flame of a candle.

- Breathe out (exhale) slowly and gently through your pursed lips while counting to four. It may help to count to yourself: exhale, one, two, three, four.

With practice, this technique will seem natural to you.

MOUTH BREATHERS

Question: Does the Oxymizer work for a patient who breathes through his mouth?

Answer: The Oxymizer does not work with mouth breathers.

OXYMIZER DETAILS:

MATERIALS

Question: Does the Oxymizer contain neoprene or latex?

Answer: No, the Oxymizer is created using medical grade Polyvinyl Chloride (PVC). The Pendant is also PVC with a hard shell plastic and a silicon membrane.

Question: What is the composition of the materials in the Oxymizer?

Answer: The Oxymizer Mustache is constructed of PVC and has no latex. The Pendant is constructed of PVC for the tubing but a hard plastic for the shell and fluidics and silicon for the membrane. There is no latex.

Question: How much oxygen is stored in the reservoir?

Answer: The Oxymizer Mustache stores 20ml of oxygen. The Pendant stores 40ml of oxygen.

MUSTACHE VS. PENDANT:

The Pendant stores O₂ in the tubing & reservoir (40ml)

The Mustache stores O₂ in the nasal reservoir (20ml)

Mustache style provides shorter travel time of O₂ from reservoir

TUBING LENGTH

Question: What is the length of the tubing for the Oxymizer (both styles)?

Answer: The length of tubing for the Oxymizer was 7 feet and Pendant was 6 feet. The difference is not important except if the patient is on high flow from a concentrator. The driving pressure of the concentrator is about 6 psi as opposed to compressed gas which is much higher. In such an instance, the back pressure becomes important.

EXTENSION TUBING

Question: What is the maximum length of tubing you can use with the Oxymizer cannulas?

Answer: With the Oxymizer, you can use just about any length of tube as long as there is flow and pressure in the line. With most concentrators, you need to be more careful with the length of tube because they only put out about 6 psi of pressure at the outlet. A 25 or 50 ft. tube would work in most cases.

TUBING TRIMMING

Question: Can the nasal pieces on the Pendant be trimmed? Would it change the flow configuration at all? Would it be a problem?

Answer: Minimal trimming (1 mm) will not be a problem. In fact, the manufacturers in China made them too long. The problem is that cutting produces sharp edges that could be irritating. Perhaps even cause nose bleeds. So, that would be a point of caution.

NEBULIZER TREATMENTS

Question: Will an Oxymizer Mustache be affected or become sticky from a patient receiving nebulizer treatments (with an aerosol mask) to 6-8 times a day? It is not possible to remove the oxygen supply for the treatment as the patient is close to the end of life and is already on 10 liters with the Oxymizer.

Answer: The nebulizer can be used alone if driven by oxygen. If not, the therapy can be delivered over the Oxymizer. If it gets sticky, just wipe it with a damp cloth. The membrane is not an issue at 10 Lpm.

AVIATION USAGE

Question: Can an Oxymizer Pendant be used with Aviation grade oxygen for small aircraft operators at altitudes above 10,000 feet and below 18,500 feet?

Answer: Yes

LIQUID OXYGEN

Question: Is the Oxymizer compatible with liquid system?

Answer: The Oxymizer is effective with all oxygen sources: liquid, gas and concentrators.

Question: Is it possible to use either Oxymizer style at 20 psi from the source with liquid oxygen? Is there enough pressure to fill up the reservoir or is a higher source/pressure required?

Answer: The Oxymizer and the Pendant are based on flow and not pressure. That is why they work with the oxygen concentrator which operates at 6-7 psi. The answer is yes, they will work with all sources of continuous flow oxygen.

COMPATIBILITY:

NOTE: When using the Oxymizer with a standard concentrator at 10 Lpm, the back pressure gets very high and the patient will not be able to get the oxygen they were prescribed. For example at 10 Lpm, they may get 8.5 or 9 Lpm.

HIGH FLOW/HIGH PRESSURE CONCENTRATOR

Question: Which is better for a patient using the P-224 on 10 liters – a High/Flow Concentrator or a High Flow/High Pressure Concentrator?

Answer: In general, 10 Lpm through a reservoir cannula will cause the concentrator to work hard, however it does work with the Oxymizer. If there is higher pressure available, that would likely be slightly better dependent on the type of concentrator and its delivery pressure. There may be a small benefit from a high flow/high pressure concentrator, but it might not be measurable.

Question: Can the Oxymizer be used on a 10 liter concentrator and if the concentrator is set at 10 will they get a higher liter flow using the Oxymizer?

Answer: The Oxymizer will work with a 10 Lpm Concentrator although the flow will likely be a little less than 10 Lpm due to higher resistance at that flow rate.

PULSING OXYGEN CONSERVING DEVICES

Question: Can an Oxymizer be used with another conserving device? Are there any problems with doing so?

Answer: It is not recommended using the Oxymizer or Pendant with a pulsing oxygen conserving device. It works via a different mechanism and would not add any benefit to pulsing device. The pulsing device requires an inspiratory signal and the Oxymizer would attenuate that signal.

PULSE DOSE CONSERVER

Question: Can a patient use an Oxymizer with a pulse dose conserver?

Answer: We do not recommend this setup as in most situations this does not work.

CONCENTRATOR PRESSURE

Question: What are the acceptable input pressures from an Oxygen concentrator? Most proved 5psi is acceptable for use with this disposable converter.

Answer: Oxygen concentrators operate on low pressures and are adequate for the reservoir cannulas. Reservoir cannulas operate on flow rather than pressure. Make sure the flow is correct. Most oxygen concentrators have good flow meters that answer that question.

PEDIATRIC USE:

Question: Are there any restrictions for using the Oxymizer Pendant on a

Answer: To date, no studies have been performed on patients in the pediatric age group. The age of the patient is not as important as the size of the face and nostrils. If the patient is the size of a small adult, the Pendant should work. If smaller than that, you may have problems with the size of the prongs, the prong interspace, and how the Pendant lays on the face. If the sizing fits, you can try the Pendant and adjust to keep the oxygen saturation at the therapeutic target – usually around 92% unless there is a shunt.

HUMIDIFICATION:

BUBBLE HUMIDIFIER

Question: Can an Oxymizer be used with a bubble humidifier? Is it necessary since the patient

Answer: The bubble humidifier is not necessary for any oxygen up to 4 Lpm. I don't believe it is necessary at even 5 or 6 Lpm. In regard to the Oxymizer, particularly the Mustache it is not necessary at all. However, there are a lot of clinicians who believe in the bubble humidifier. Using it on the Oxymizer at most flows is not a problem. As the oxygen delivery flow is turned up to 10 Lpm, back pressure is greater and sometimes causes the tubing to pop off the humidifier. Most therapists are aware of this and make sure that the connection is good. Also, at high flows (again because of the back pressure) they should make sure that the humidifier is sealed so there is no leak of oxygen into the room.

Question: Is a bubble humidifier the same as a regular or standard humidifier?

Answer: Yes, they just "bubble" the oxygen through a bottle of water hanging on the oxygen outlet. It is generally provided in the hospital. They mostly stopped using a humidifier in home oxygen.

Question: Can we use humidification with the Oxymizer?

Answer: Yes, however, generally it is not necessary.

Question: What are the parameters as to when we can and cannot use an Oxymizer with humidification? Can it be used with a concentrator?

Answer: At low flows up to 4 Lpm, no nasal cannula (standard or Oxymizer) delivery requires it according to several studies. At the higher flows, bubble humidifiers do not have the contact time in the water to pick up sufficient moisture. In the Oxymizer there is some humidification that comes from the patient exhaling into the chamber at body temperature and moisture that goes back into the nose upon inhalation. The best advice is to titrate the flow of oxygen going to the Oxymizer to sufficient to achieve the target SpO₂.

Question: If at flows lower than 4 Lpm no humidification is required, then is it safe to say that at 5 Lpm and above humidification can be used without it causing any damage to the Oxymizer?

Answer: Humidity should not harm the Oxymizer.

Question: For the patient at 6 Lpm typically but on 3.5 Lpm on the Oxymizer, humidification would not be necessary because there is no proven benefit until after 4 Lpm?

Answer: Correct. Even after 4 Lpm there is probably little or no benefit from bubble humidification. In fact, the patient gets humidification from rebreathing moisture at close to body temperature from the Oxymizer.

HIGH ELEVATION

Questions: Can a patient living at a high elevation area (6200 ft) with extreme dry air use a humidification with an Oxymizer unit in order to help avoid nose bleeds? Are there any risks in doing so? Is one style preferred over the other?

Answer: Humidification is fine, particularly in dryer climates. Additionally, the patient may be helped by Ayr Saline Nasal Gel to keep the nasal passages moist.

DRYING EFFECTS

Question: What are the drying effects to patients using an Oxymizer with

Answer: This is an area where there are no direct studies.

Question: What causes the ball on the liter flow gauge to drop 2 liters when a Pendant Oxymizer is attached to a concentrator? The flow was fine when a regular cannula was used.

Answer: This can happen if the concentrator is running at higher flows near 10 Lpm because of the resistance of the Oxymizer tubing and jet. This is not a problem if they are using gas or liquid oxygen.

SETTINGS/FLOWS FOR OXYMIZERS

NOTE: With an Oxymizer setting past 5.0 Lpm there is not O2 savings. Settings of 12-15 Lpm are used so the patient can eat and communicate.

Question: What is the maximum liter flow that the Oxymizer can be used without causing the membrane to break?

Answer: The liter flow has been set up to 16 Lpm without a problem. There is not a major problem of membrane rupture because the outflow is through relatively wide nasal prongs.

Question: How long should an E-tank last at 3 Lpm?

Answer: It should last at least 11.4 hours.