



voutia™

The Voutia™ system is indicated to provide relief of dry mouth by coating, moistening, and lubricating oral structures thereby relieving the symptoms of xerostomia (dry mouth).

**SAVE THESE INSTRUCTIONS FOR FUTURE REFERENCE.
THE VOUTIA™ SYSTEM IS FOR SINGLE PATIENT USE ONLY
DO NOT SHARE THE DEVICE WITH OTHERS.**

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Operation and Maintenance

Take care to read all of the information contained with this unit before using it. **THE DEVICE SHOULD BE CLEANED BEFORE ITS FIRST USE** and weekly thereafter. This helps to prevent germs from growing in the bottle and the tube. **DO NOT WEAR THE UNIT DURING THE CLEANING PROCESS.**

To clean, follow these steps once per week:

CLEANING

The recommended cleaning protocol is intended to clean the reservoir, tubing, attachment components and pump. These are the only components in contact with the fluid to be delivered to the oral cavity. **Cleaning is essential to ensure safe use of your device.**

1. Users should boil water for 10 minutes and allow it to cool to room temperature before proceeding. Then, safely transfer this water to the 16 oz. reservoir bottle using a measuring cup. If **sterile water** is available, it may be used without the boiling procedure.
2. Add 2 ml of household chlorine bleach to the reservoir. Replace the reservoir cap and tubing.
3. Attach the pumping unit to its included wall power adapter/charger as shown in the setup instructions and plug into a wall outlet.
4. Attach the reservoir to the inlet port and the headset to the outlet port on the main pump housing. **Position the polyimide tube end such that the fluid pumped during this cleaning process is collected and/or disposed of in a manner deemed appropriate by your locality.** Cleaning solutions will not be reused.
5. Power on the device and allow it to run on its maximum setting #9 (0.9 ml/min) for 1 (one) hour. Make sure to collect the cleaning solution in a safe container for disposal. Cleaning solution can damage/stain items if it is spilled. (Please note, not all cleaning solution in the reservoir will be used.)
6. After 1 (one) hour, power the device off and detach the reservoir from the device.
7. Remove the cap and dampen a soft cloth or paper towel with some of the remaining cleaning solution. Use this dampened cloth or paper towel to gently wipe down the outside of the tube that goes into your mouth and allow a minimum of 10 minutes for it to dry.
8. Dispose of all remaining cleaning solution in a manner deemed appropriate by your locality.
9. Rinse the **headset tubing, reservoir bottle and the reservoir tubing/cap section** several times with clean, potable drinking water to remove any residual cleaning solution.
10. Fill the reservoir with potable drinking water, reattach the cap/tubing section and then reconnect the closed reservoir/cap/tubing component to the inlet port of the device. NOTE: PRIOR TO REATTACHING TO THE INLET PORT, USE AN ABSORBANT CLOTH OR PAPER TOWEL TO BLOT OFF ANY VISIBLE CLEANING SOLUTION PRESENT ON THE INLET PORT.
11. Power on the device as before and run the device on its maximum setting 9 (0.9 ml/min) for a minimum of 20 (twenty) minutes. NOTE: **DO NOT DETACH** THE HEADSET FROM THE OUTLET PORT AT ANY TIME DURING THIS PROCEDURE.

The maximum amount of liquid contained in the tubing and pump is less than 1 ml. As all components in the fluid pathway are nonabsorbent, running potable water from the rinsed reservoir/cap/tubing component for a minimum of 20 (twenty) minutes will flush out all tubing and the pump system of any residual cleaning solution with 18 (eighteen) ml of potable fluid.

MAIN UNIT SET UP

ATTACHING THE RESERVOIR BAG/BOTTLE

When looking at the front of the Voutia™, you will notice 2 inlet ports located at the top.

The right port (IN) is where you attach the reservoir. The left port (OUT) is for attaching the headset/tubing. Fluid will flow in from the right port, through the pumping system and exit at the left port.

To attach the reservoir, do the following:

1. Locate the right "IN" port and the small tube coming from the reservoir bag.
2. Attach the reservoir tube to the Voutia™ top right "IN" port. (do not overtighten)
3. When ready for use, remove the reservoir cap and fill the reservoir with the appropriate fluid.
4. Replace the cap and follow the instructions for attaching the headpiece tubing before powering on Voutia™.

SETTING UP THE HEADPIECE

1. Gently hold the flexible ear loop with your fingers.
2. Carefully unwind the tubing attached to it so there are no bends. (do not use much force)
3. Place the flexible ear loop over the ear of your choice with the smallest tube facing your mouth.
4. Take the very small tube and put it in your mouth between your cheek and teeth. Do not chew on the tube.
5. If desired, the thin tube to the mouth can be threaded between the lower teeth and positioned under the tongue.
6. If desired, the larger tube can be run under a jacket or shirt to hide it. Have it come out near where it can hook to the pump. (It is recommended that the tube go between an undergarment and the shirt to avoid rubbing on your skin or catching.)
7. Attach the larger tube's end to the top left "OUT" port, just as the reservoir tube was attached. (Do not over tighten)

PLACE THE UNIT ON A STABLE TABLE/NIGHTSTAND IF YOU ARE GOING TO SLEEP.

DO NOT EXCEED RECOMMENDED FLOW RATES DURING SLEEPING.

IF YOU ARE GOING TO BE WALKING AROUND, ATTACH IT TO YOUR BELT WITH THE BELT CLIP OR USE A PREFERRED CARRY BAG

See photos and video instructions at www.voutia.com



THE VOUTIA™ CONTROLS

On the front of the Voutia™ device, you will notice a LCD display, four (4) directional arrows, and a center button with a circle on it. This is where you will be able to turn on/off the device and make your flow selections.

POWERING ON THE VOUTIA™ USING ITS *INTERNAL BATTERY*

Locate the center button with the round circle.

1. Press and hold the center button for 2-3 seconds.
2. The unit will power on, go through a system check and show the display.
3. If a mode is not selected, the device will enter a sleep mode after 30 seconds.
4. If a flow rate was selected at an earlier use, the system will begin pumping at that setting immediately.
5. If you do not wish the unit to pump, press the “down” arrow until the number “0” is displayed.

POWERING AND CHARGING THE VOUTIA™ SYSTEM FROM *EXTERNAL POWER*

1. Check to make sure the Voutia™ Device is not powered on.
2. Plug in the included wall adapter to a standard home wall outlet (110 volt).
3. Plug in the other end of the power adapter to the power jack on the outside of the Voutia™ Device.
(Do not force the plugs together; slowly rotate the plug as you apply light pressure.
There is only 1 (one) correct position and they will slide together when aligned.)
4. The Voutia™ unit will power on when attached to the wall charger.
5. The unit will go through a system check and show “STANDBY” on the display.

NOTE: If you turn off your Voutia™ while charging, you must disconnect the charger from the unit in order to turn the unit back on.

While connected to an outlet, the Voutia™ System will operate normally and charge the internal Lithium Polymer battery at the same time. You should not need to go without the system while charging.

TURNING THE POWER OFF

To shut off your Voutia™ System, simply locate the center key with the circle on it. Press and **hold down** the center key marked “0” for 4- 5 seconds. The device should power off.

DISPLAY AND DISPLAY LIGHTING

The Voutia™ LCD display will light up to help you read it when you power on the device or adjust a setting. Because this lighting draws extra power from the internal battery, the Voutia™ System is designed to turn off the backlight and display after approximately 30 seconds if no buttons are pressed. Optimizing battery life for pump function is important so you can get maximum use from each charge. To turn the lighting on again, simply press the center button marked "O"

If you power on your Voutia™ System but do not select a mode, after several seconds, the unit will go into "STANDBY MODE." This also protects the battery from excessive drain. To exit the "STANDBY MODE," simply press any one of the keys and Voutia™ will "wake" up.

NAVIGATING THE DISPLAY

Use the left and right arrow keys to move between the preprogrammed modes (shown at the top of the LCD display) depending on your activity and needs.

- SLP** = Sleep mode, (0.1 to 0.3 ml/min recommended, **DO NOT EXCEED**)
- SIT** = Resting mode, (0.5 ml/min recommended)
- DAY** = Daytime mode, (0.4 to 0.7 ml/min recommended)
- EXE** = Exercise mode, 0.7 to 0.9 ml/min recommended)

PLEASE NOTE: EACH PERSON IS UNIQUE AND THE SELECTION RECOMMENDATIONS ARE ONLY GUIDELINES. SELECT THE RATE THAT PROVIDES THE BEST RELIEF, HOWEVER, **DO NOT EXCEED THE RECOMMENDED RATE WHEN SLEEPING.**

A full description of what mode you have selected will appear in the lower left of the LCD display. A battery monitor bar is located in the lower right corner of the display so you will know the Voutia™ battery charge status. Selectable modes are: **Sleep, Sitting, Daytime, and Exercise.**

Once started, your Voutia™ System will begin to pump at the selected rate and save this setting for future use. Make sure you are wearing the accompanying headpiece or fluid spilling will occur.

ADJUSTING THE RATE FOR INDIVIDUAL NEEDS

Each user has unique personal needs and desires. The Voutia™ System understands this and may be adjusted to slightly increase or decrease the rate of each preprogrammed mode. If you find that a slight increase or decrease is desired, please do the following:

1. Locate the up and down arrows on the front of the unit.
2. To slightly increase fluid to the mouth, press the "up" arrow key facing the LCD display.
3. To slightly decrease the fluid to the mouth, press the "down" arrow key.



IMPORTANT CHARGING INFORMATION

- Do not charge the device near flammable materials.
- In any case where the Voutia™ System becomes damaged, hot, or swells, discontinue its use immediately.
- If the housing becomes damaged and internal components of the battery come in contact with your skin, wash the area with soap and water immediately.
- If contact with the eyes occurs, flush eyes with generous amounts of water for 15 minutes and seek medical attention.
- Damaged Voutia™ devices should be returned to the manufacturer for repair or replacement.
- **DO NOT USE A DAMAGED DEVICE.**

STORAGE OF THE UNIT

The Voutia™ Device, Headpiece and Tubing should **not be stored** unless these steps are performed. Storage should be in a **cool dry place**.

1. Pour out all contents of the bottle.
2. Attach the headpiece to the pump and perform the cleaning procedure described above.
3. After the bottle is emptied, run the device **AT ITS MAXIMUM SETTING OF 9** with the headset attached for 10 minutes to clear any liquid out of the tubes.
4. Detach the reservoir and headset from the main pumping unit.
5. Attach the included 3cc syringe to the outlet port using the included adapter and gently pull the plunger up to draw any residual fluid from the pumping system that may remain.
6. Attach the 3cc syringe to the Luer connector on the headset and gently draw back on the plunger to remove any residual fluid in the headset.
7. Disconnect all power sources and store the unit in a cool dry place.

NOTE: Prior to using the unit at a later date, perform the complete cleaning procedure listed above. The unit should then be ready to use again.

DO NOT ATTEMPT TO INJECT AIR OR WATER INTO THE “OUT” PORT OR WITHDRAW WATER FROM THE “IN” PORT. THE PUMPING MECHANISM HAS AN INTERNAL 1 WAY VALVE AND COULD BECOME DAMAGED IF THIS IS DONE.

FREQUENTLY ASKED QUESTIONS AND TROUBLESHOOTING

I set up and turned on my device and nothing is coming out.

- When you first attach the tubing and turn on your device, all the tubes are empty. Because the device does not pump water fast, it can take a few minutes to fill and begin wetting the mouth.
- Check to make sure there is no leak at where the tubes meet the pump. If so, slightly tighten the connection some more.
- Watch the tube to see if the water is moving through it.
- **Perform the priming procedure for the pump shown in figures 3 & 4 below.**
- Apply light suction to the tube in your mouth. This will speed up priming of the pump.

I plugged in my device and pressed the key but nothing happens.

- Check to make sure wall plug is all the way plugged into the outlet.
- Check to make sure the battery is charged on the unit by looking at the lower right display.
- Check the speed setting. Sleeping mode is very slow. The tubing may take more time to fill.

I hear the pump working but no water is coming out.

- Check to make sure the tubes are hooked to the correct ports of the pump.
- Check the tubing to make sure there is no bend stopping the flow.
- Look at the small tube that goes in your mouth to check for any kinks.
- Check the bottle to make sure it is full of water.
- Gently suck on the small tube to help pull fluid from the reservoir to the pump.

The plug came out of the device while I was using it and it cut off.

- If the unit becomes unplugged during use, turn the device off before reattaching the power cord to the unit. The device should not be harmed if this occurs.

How long will my Voutia™ device last?

- By adhering to the recommendations in this document, your Voutia™ device should give you several years of operation. The pump is rated to last > 5000 hours and the battery for 500 charges or approximately 2-3 years.
- In the event your pump stops functioning, or your battery fails to hold a charge, simply return it to the supplier who can replace either for a nominal parts and labor fee. There is no need to purchase a completely new Voutia™ device in these situations.

In the event that you are unable to get the device to run as you need, please contact the manufacturer so arrangements can be made for instruction, a replacement or repair.

DO NOT ATTEMPT TO REPAIR THE DEVICE YOURSELF AS THIS WILL VOID ANY WARRANTIES.

THANK YOU FOR CHOOSING VOUTIA™

Your Voutia™ System is a very versatile device. Used correctly, it is intended to make life more comfortable for individuals suffering from the debilitating effects of dry mouth (xerostomia). Take care to read all of the information contained with this unit before using it.

SAVE THESE INSTRUCTIONS FOR FUTURE REFERENCE.

**For Customer Support please call
804.803.1840 or email support@voutia.com**

Contraindications:

The Voutia™ device should not be used in individuals with an impaired swallow or gag reflex or who have failed a physician prescribed swallow test. The use of fluids other than potable water is not recommended by Virginia Head and Neck Therapeutics, Inc. or the developer. Use of fluids other than potable water should only be undertaken when supervised by a licensed healthcare provider who accepts full responsibility for any consequences arising from such use and indemnifies Virginia Head and Neck Therapeutics, Inc. and its affiliates of any and all liability.

Disclaimer of Liability:

This device is for single patient use and should not be shared amongst others. Virginia Head and Neck Therapeutics, Inc. indemnify themselves in the use of this device by others. Any and all Claims against Virginia Head and Neck Therapeutics, Inc. shall be under the jurisdiction of the Commonwealth of the State of Virginia.

Virginia Head and Neck Therapeutics, Inc. acknowledge and adhere to the United States FDA in imposing the notification and other remedies (repair, replacement, refund) provisions of section 21CFR518 of the USFDA act. Determination of replacement or repair of returned units is at the sole discretion of Virginia Head and Neck Therapeutics, Inc.



Continuous Relief for Acute and Chronic Dry Mouth

Virginia Head and Neck Therapeutics, Inc.
10149 Bon Air Crest Dr. Richmond, VA, 23235
804.803.1840 | www.voutia.com