CAUTION––US Federal law restricts this device to sale by or on order of a physician.

Read and understand these Instructions for Use and all safety precautions it contains. Improper use can cause serious or fatal injury and/or illness.

WARNING

CAUTION—US Federal law restricts this device to sale by or on order of a physician.
REGISTER FIRST

WARRANTY ACTIVATION REQUIRED
Three different options to choose from.

🌐 www.pari.com/register
📞 1.866.335.6943
✉️ Registration card enclosed
INTRODUCTION

These Instructions For Use contain information and safety precautions for the Altera® Nebulizer System for use only with CAYSTON™ (aztreonam for inhalation solution). **DO NOT USE ANY MEDICATION IN THE ALTERA NEBULIZER HANDSET OTHER THAN CAYSTON (aztreonam for inhalation solution) which is the only product to demonstrate efficacy and safety in the ALTERA NEBULIZER HANDSET.**

Before using your Altera Nebulizer System, read and understand these entire Instructions For Use. Save these Instructions For Use for future reference. If for any reason you do not understand any part of these Instructions For Use, please call the toll free number below before proceeding with your treatment.

Take special note of all safety precautions marked DANGER and WARNING.

INDICATIONS FOR USE: ALTERA NEBULIZER SYSTEM

The Altera Nebulizer System is intended specifically for the aerosolization of CAYSTON [aztreonam for inhalation solution] using vibrating membrane technology. The device is intended for adult and pediatric patients who have been prescribed CAYSTON, and may be used in hospitals, hospital-type facilities, nursing homes, sub-acute institutions and home environments.
SAFETY PRECAUTIONS AND IMPORTANT SAFEGUARDS

READ ALL DANGERS AND WARNINGS BEFORE USING

**DANGER**

To reduce the risk of serious or fatal injury from electrocution:

1. DO NOT place or store the Altera Nebulizer System where it can be in water or fall into a bathtub, sink, or other liquid. Do not place or drop into water or other liquid. Do not use while bathing.

2. DO NOT reach for the Altera Nebulizer System if it has fallen into water or other liquid. Unplug immediately. Retrieve the Altera Nebulizer System ONLY after it has been unplugged.

**WARNING**

1. The Altera Nebulizer Handset is for single patient use. DO NOT SHARE your handset with any other people.

2. The Altera Nebulizer Handset is designed specifically for use only with CAYSTON (aztreonam for inhalation solution) (Figure A, on page 4). To reduce the risk of severe or fatal injury/illness from improper treatment, NEVER USE OTHER MEDICATIONS IN THE ALTERA NEBULIZER HANDSET.

3. Read, understand and follow all warnings and instructions in the Instructions For Use prior to using this device.

4. To reduce the risk of serious or fatal injury from electrocution, fire, burns and to reduce the risk of damage and malfunction of the unit:
   a. DO NOT overload wall outlets or use extension cords.
   b. Keep all electrical cords away from heated surfaces.
   c. DO NOT spray liquids onto the housing of the Controller. [See Section C: Getting Started] Liquid may cause damage to the electrical parts and could lead to a malfunction. In the event that liquids enter the Controller, call the number below for examination and repair.
   d. DO NOT drop or insert any object into any opening on the Altera Nebulizer System.
   e. DO NOT operate where oxygen is being administered in a closed environment such as an oxygen tent.

5. Always unplug this product immediately after using and before cleaning.

6. Before use, check your Altera Nebulizer System or Altera Nebulizer Handset for proper assembly. All parts must be connected and firmly in place. Use of an improperly assembled Altera could diminish or eliminate the effectiveness of the treatment.

7. Use ONLY adapters and accessories that are authorized for the Altera Nebulizer System. Use of unapproved adapters and accessories can lead to improper treatment, injury, or damage to the Controller.

8. NEVER operate the Controller if it is improperly or incompletely assembled or damaged. Section G: Taking A Treatment, shows the alerts to these situations when the Altera Nebulizer System is improperly assembled, or might be damaged.

9. NEVER operate this product if:
   a. it has damaged cords or plugs,
   b. it is not working properly,
   c. it has been dropped or damaged, or
   d. it has been exposed to any liquids inside the Controller.

Continued on page 4
10. To reduce the risk of infection, illness, and/or injury from contamination, clean and dry all parts of the Altera Nebulizer Handset after each treatment. Follow the instructions in Section H to clean the Altera Nebulizer Handset properly.

11. Cleaning the Altera Nebulizer Handset properly will help prevent the Aerosol Head from clogging. If the Aerosol Head becomes clogged, the aerosol mist will be reduced or stopped, which may make the treatment ineffective. If clogging occurs, use the instructions in Section H to clean the Aerosol Head.

12. Cleaning the Altera Nebulizer Handset only removes the medication. To reduce the risk of serious or fatal illness caused by contamination of the Altera Nebulizer Handset, YOU MUST ALSO DISINFECT THE ALTERA NEBULIZER HANDSET AT THE END OF EVERY TREATMENT DAY. See Section I for disinfection instructions.

13. This product contains small parts that may present a choking hazard to small children. The Altera Nebulizer Connection Cord also presents a strangulation hazard.

14. DO NOT LEAVE CHILDREN UNATTENDED DURING TREATMENT. ALWAYS USE CLOSE ADULT SUPERVISION WHEN ADMINISTERING A TREATMENT TO A CHILD.

15. Close supervision is necessary when this product is used by or near children or the physically or mentally impaired.

16. DO NOT use your Altera Nebulizer System while driving or in any situation which takes away your full attention.

17. If the Altera Nebulizer System has been damaged or is not operating properly, call the number below for details. If you suspect that the Altera Nebulizer System has been damaged or is not working correctly, run the Functionality Test described in Section J.

18. DO NOT disassemble the Controller at anytime. There are no user serviceable parts inside the Controller. Call the number below for all service needs.
Check your Altera Nebulizer System package to ensure you have the following items.

- Controller
- Nebulizer connection cord
- Carrying case
- AC power supply
- Four "AA" batteries
- Medication reservoir
- Medication cap (Note: The cap seal and cap will come as one assembled part)
- Cap seal
- Aerosol head
- Inhalation valve
- Aerosol chamber
- Mouthpiece with exhalation valve
- Aerosol chamber detail

For use only with Cysteron® (aztreonam) for inhalation solution.
D Using “AA” Batteries

1. The Altera Nebulizer System is designed to be used with “AA” batteries or with the optional AC Power Supply. Four (4) new “AA” batteries will provide approximately 2 hours of continuous treatment. You may also use “AA” rechargeable batteries. Please see “Specifications” on the back cover of these Instructions For Use.

**NOTE: IT IS STRONGLY RECOMMENDED TO HAVE AN EXTRA BATTERY SET WITH YOU AT ALL TIMES.**

2. Open the Battery Door on the Controller by placing your thumb on the tab of the Battery Door and firmly pushing the tab to open the door (Figure 1).

**NOTE: The Battery Door is designed to have a tight fit. Questions? Please call the number below.**

3. Load the batteries.

4. Each battery chamber has a small figure that shows the proper position of each battery (Figure 2). Using the battery “tips” as guides and starting left-to-right, insert the batteries: Tip Out, Tip In, Tip Out, Tip In.

5. To close the Battery Door, push it closed until you hear it “click” into place. **NOTE: Rechargeable and Disposable Batteries vary considerably in terms of storage life and output. Operating life of 2 hours of use is based on disposable batteries that meet the specifications listed in “Specifications” on the back cover of these Instructions For Use.**

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E Using Optional AC Power Supply

1. The Controller can also be used with the optional AC Power Supply. The AC Power Supply is useful as a back-up power supply when the batteries are depleted. If not already attached, insert the Plug Converter into the AC Power Supply as shown (Figure 3).

2. The AC Power Supply (Figure 3) can be used with 100-240V outlet and will automatically adjust to the incoming voltage. It can be used worldwide, but does require “Plug Converters” for use outside the USA. Additional Plug Converters for the Altera Nebulizer System are available as optional accessories. Make sure to use the correct Plug Converter for the AC outlet.

3. To connect the AC Power Supply to the Controller, place the Controller on a flat, stable surface. Push the Plug Insert (the round end of the AC Power Supply cord) into the Plug Inlet Port, located on the under side of the Battery Door. (Figure 4). Do not attempt to insert the AC Power Supply Cord into the front of the Controller.

4. Plug the AC Power Supply into the wall outlet.

---

**Figure 1**

Controller

**Figure 2**

Battery Door

**Figure 3**

Plug Converter

**Figure 4**

Plug Insert

**NOTE: Prior to storing the device over an extended period of time (e.g., over 30 days) we recommend you remove the four batteries from the Controller. Doing so saves the batteries and reduces the risk of battery leakage.**
The Altera Nebulizer Handset is not sterile. Clean and Disinfect the Altera Nebulizer Handset before the first use. (see Section H for Cleaning and Section I for Disinfecting). Inspect all parts to ensure they are clean and are not visibly damaged. Do not use dirty or damaged parts.

1. The Medication Reservoir and the Aerosol Chamber are attached using a “hinge”. First, gently pull up on the tab of the Medication Reservoir (Figure 5a). This will release the Aerosol Chamber so that you may open it (Figure 5b). Ensure that the Inhalation Valve is placed correctly in the Aerosol Chamber. If not, re-insert as shown (Figure 6a-6b).

2. Ensure that the Aerosol Head is inscribed “Altera” (Figure 7, enlargement). Do not use other eFlow® Technology Aerosol Heads in this device. Being careful to touch ONLY the plastic outer ring of the Aerosol Head (Figure 7), press the two flexible plastic tabs on the side of the Aerosol Head while firmly inserting it into the Medication Reservoir (Figures 7a-7b). You should feel the plastic tabs “grab” as you insert it. It is important that you do not touch the metal part of the Aerosol Head (Figure 8).

3. Close the Altera Nebulizer Handset by pushing the Aerosol Chamber together with the Medication Reservoir until you hear a slight “snap” (Figure 9). If you do not hear a slight snap, open the Altera Nebulizer Handset and ensure that the Inhalation Valve is seated properly (Figure 6b).

4. Attach Mouthpiece to Nebulizer Handset with Exhalation Valve facing up (Figure 10).

5. Snap the Altera Nebulizer Connection Cord onto the rear underside of the Altera Nebulizer Handset (Figure 11).

6. Place the Controller on a clean, flat, stable surface.

7. Connect the Nebulizer Connection Cord round end to the front of the Controller (Figure 12).
G TAKING A TREATMENT

1. Make sure the Altera Nebulizer Handset is on a flat, stable surface. See the Patient Instructions for Use (in Canada: Consumer Information) for CAYSTON for instructions on how to mix (reconstitute) CAYSTON [aztreonam for inhalation solution]. Pour only mixed CAYSTON liquid into the Medication Reservoir of the Altera Handset (Figure 13). DO NOT POUR CAYSTON POWDER INTO THE MEDICATION RESERVOIR. DO NOT USE OTHER MEDICATIONS IN THE ALTERA NEBULIZER HANDSET.

2. Align the Tabs on the Medication Cap with the Tab Slots on the Medication Reservoir (Figure 14a). Turn the Medication Cap clockwise until it stops (Figure 14b). Your Altera Nebulizer Handset is now ready, and you can begin your treatment (Figure 15).

3. To begin your treatment, sit in a relaxed, upright position. Press and hold the On/Off button for a few seconds (Figure 16). You will hear one “beep” and the status light will illuminate green. The eFlow Technology logo will appear. This is the START screen. (Figures 16-17a). The Controller is now ON.

4. After a few seconds, aerosol mist will begin to flow into the Aerosol Chamber of the Altera Nebulizer Handset.

5. Your Controller is designed to display the TREATMENT screen (Figure 17b) if the Altera Nebulizer System is assembled correctly and working properly.

6. Place the Mouthpiece on top of your bottom lip and tongue and close your lips around it (Figure 18). Hold the Altera Nebulizer Handset level. If held at an angle over 45 degrees, the Controller is designed to sound two beeps (and two green lights) and shut off after approximately 30 seconds. If this occurs, hold the Altera Nebulizer Handset level and press the Controller’s On/Off Button to resume the treatment.

7. Breathe normally in and out through the Mouthpiece. Continue to inhale and exhale comfortably until the treatment is finished.

8. When all of the medication has been delivered you will hear the Aerosol Head emit 2 beeps, the DOSE COMPLETE screen will appear (Figure 19), and the Controller will automatically shut off.

9. If for any reason you must stop the treatment before completion, press and hold the Controller’s On/Off Button for one full second. A 5-beep alarm tone will sound, the status light on the Controller will flash RED-GREEN, and the TREATMENT INTERRUPTED screens will appear. After 10 seconds the Controller will automatically shut off. To re-start the treatment, you must wait for the Controller to completely shut off. Then, press and hold the Controller On/Off Button for one full second. The START screen will reappear (Figure 17a), and the treatment will resume.

10. After the Controller has shut off automatically at the end of the treatment, open the Medication Cap to ensure that only a few drops of medication remain in the Medication Reservoir. If more than a few drops remain, replace the Medication Cap and resume the treatment until only a few drops remain in the Medication Reservoir (Figure 14).

Once the treatment is complete, disassemble the Altera Nebulizer Handset for cleaning. Refer to Section H for cleaning instructions.
MESSAGE SCREENS & WARNINGS

NOTE: Your Controller has an LCD screen that provides information to you. Think of these screens as “electronic coaching” to ensure proper operation of the Altera Nebulizer System. Symbols on the screen will “alternate” as shown below. In addition, the Controller status light NEAR THE ON/OFF BUTTON will flash red-green and a 5 beep alarm will sound. When the alternating screens appear, follow the text in the “Description/Remedy” to the right of the screen symbols below.

<table>
<thead>
<tr>
<th>SYMBOL (ALTERNATING SCREENS)</th>
<th>DESCRIPTION/REMEDY</th>
</tr>
</thead>
<tbody>
<tr>
<td>START SCREEN</td>
<td>BATTERY LEVEL LOW. Following Treatment, Replace with New Batteries Immediately OR Use AC Power Supply.</td>
</tr>
<tr>
<td>TREATMENT SCREEN (Battery)</td>
<td>INCORRECT ASSEMBLY. Check Nebulizer Connection Cord to Controller. Check Nebulizer Connection Cord to Nebulizer Handset.</td>
</tr>
<tr>
<td>TREATMENT SCREEN (AC Adapter)</td>
<td>NO MEDICATION DETECTED IN MEDICATION RESERVOIR. Fill Medication Reservoir OR Hold The Altera Nebulizer Handset Level and Press The On/Off Button.</td>
</tr>
<tr>
<td></td>
<td>TREATMENT INTERRUPTED. Press “On/Off” Button To Resume Treatment.</td>
</tr>
<tr>
<td></td>
<td>BATTERIES ARE EMPTY. Replace with New Batteries Immediately OR Use AC Power Supply.</td>
</tr>
<tr>
<td></td>
<td>CAUTION SCREEN. Device will shut down. Call 1-866-335-6943.</td>
</tr>
</tbody>
</table>

NOTE: After all fault screens have been remedied, the START screen will re-appear (Figure 17a) and the treatment can resume.
ALTERA NEBULIZER HANDSET CLEANING

WARNING
To reduce the risk of infection, illness, and/or injury from contamination and/or improper use, clean the Altera Nebulizer Handset as soon as possible after your treatment. Do not wash the Controller, Nebulizer Connection Cord, AC Power Supply or Plug Converters. Use liquid soap designed for washing dishes. Do not use “white” liquid dish soaps (e.g. Ivory or Dove) or antibacterial liquid dish soaps as these may contain additives harmful to the Altera Nebulizer Handset.

NOTE: The cleaning instructions described may be used in both home and institutional environments.

1. Disconnect the Altera Nebulizer Handset from the Nebulizer Connection Cord (Figures 20a and 20b).

2. Disassemble the Altera Nebulizer Handset parts:
   a. Remove the Medication Cap from the Medication Reservoir (Figure 21).
   b. Remove the Mouthpiece from the Aerosol Chamber (Figure 22).
   c. Gently pull up on the tab of the Medication Reservoir. This will release the Aerosol Chamber so that you may open it (Figure 23).
   d. Remove the Inhalation Valve from the Aerosol Chamber (Figure 24).
   e. Being careful to touch ONLY the plastic outer ring of the Aerosol Head, press the two flexible plastic tabs on the side of the Aerosol Head and remove the Aerosol Head (Figures 25-26).

   NOTE: There is no need to disassemble the Medication Reservoir from the Aerosol Chamber either for Cleaning or Disinfecting. Doing so may damage the hinge that holds them together.

3. To wash the Altera Nebulizer Handset, start by thoroughly rinsing each of the disassembled parts under warm running tap water for approximately 10 seconds each. Rinse the Aerosol Head for at least 10 full seconds on each side (Figure 28).

   Never use a brush or any other object to clean the aerosol head (Figure 29). THOROUGH RINSING OF BOTH SIDES OF THE AEROSOL HEAD HELPS TO PREVENT CLOGGING AND ENSURE PROPER OPERATION.

4. Add a few drops of clear liquid dish soap to a clean bowl or basin and add warm tap water (Figure 27).

5. Wash all parts of the Altera Nebulizer Handset and rinse thoroughly under running, warm tap water.

If Disinfecting after Cleaning, skip to Section I and follow the steps.

6. Air dry the Altera Nebulizer Handset parts on a clean, lint-free towel.

7. After the Altera Nebulizer Handset parts are completely dry place them in a bag for storage. Re-assemble the Altera Nebulizer Handset just prior to the next treatment. This is to ensure that the silicone seals do not become warped over time.

8. If the Controller needs cleaning, wipe down with a slightly damp, soft cloth. DO NOT allow liquid to get inside the Controller.
WARNING
To reduce the risk of serious or fatal illness caused by contamination of the Altera Nebulizer Handset you must also DISINFECT THE HANDSET AT THE END OF EVERY TREATMENT DAY. In addition, the Altera Nebulizer Handset is strictly FOR SINGLE PATIENT USE ONLY.

NOTE: The disinfection instructions described may be used in both home and institutional environments.

1. Clean the Altera Nebulizer Handset as described in Section H.
2. At the end of every treatment day, disinfect the Altera Nebulizer Handset with a commercially available medical device disinfectant such as Control III®. Follow the disinfectant manufacturer’s directions for use.
3. After the Altera Nebulizer Handset parts are completely dry, place them in a bag for storage. Re-assemble the Altera Nebulizer Handset just prior to the next treatment. This is to ensure that the silicone seals do not become deformed over time.
4. Hospitals and clinics can sterilize the Altera Nebulizer Handset parts by autoclaving at 250° F (121° C) for 30 minutes. Follow the autoclave manufacturer’s instructions for use.

FUNCTIONALITY TEST
A Functionality Test takes only a few minutes and is helpful if you suspect the Altera Nebulizer Handset is not working properly. Follow the steps below and use only 1 ml sodium chloride 0.9% (normal saline) for the Functionality Test.

1. Assemble the Altera Nebulizer Handset as described in Section F, but do not attach the Mouthpiece.
2. Follow the procedure in Section G for taking a treatment. However, for this Functionality Test only, use 1 ml of sodium chloride 0.9% instead of CAYSTON (aztreonam for inhalation solution).
3. Using a stop watch or clock with a second hand, time the complete Functionality Test from when the Altera Nebulizer Handset starts producing aerosol until the Controller automatically turns off.
4. After the Controller has automatically shut off, remove the cap and check the amount of liquid in the Medication Reservoir. Only a few drops of saline should remain in the Medication Reservoir. If more than a few drops remain, clean the Aerosol Head and repeat the test. If, after proper cleaning, there are still more than a few drops remaining in the Medication Reservoir, call the number below for details.
5. If the time to nebulize 1 ml of sodium chloride 0.9% is about 3 minutes, the Altera Nebulizer Handset is functioning correctly. If it takes more than 4-5 minutes to nebulize 1 ml of liquid, call the number below for details. Clean the Altera Nebulizer Handset after this Functionality Test and prior to using CAYSTON (aztreonam for inhalation solution).
FREQUENTLY ASKED QUESTIONS AND TROUBLESHOOTING

QUESTION 1: How much medication should be left in the Medication Reservoir at the end of a treatment?

**Answer:** Only a few drops of medication should remain after the treatment in the Medication Reservoir. If more than a few drops remain, clean the Aerosol Head (Section H). If after proper cleaning, more than a few drops remain in the Medication Reservoir, call 1-866-335-6943.

QUESTION 2: How long should each treatment take?

**Answer:** With normal operation and proper cleaning the Altera Nebulizer Handset should deliver 1 ml of sodium chloride 0.9% within 3 minutes. Follow Functionality Test (Section J). If more than 4-5 minutes are required to deliver 1 ml of sodium chloride 0.9%, call 1-866-335-6943.

QUESTION 3: When I turn on my Altera Nebulizer System, nothing happens. There does not seem to be any power.

**Answer:** If you are using batteries, use the figures in each battery compartment to verify that the batteries are inserted correctly. If the batteries are positioned properly, check to see if the light is blinking on the Controller signaling low battery power. If it is, replace the batteries or use the AC Power Supply.

**Answer:** If you are using the AC Power Supply, check the adapter connection to be sure it is firmly connected to the adapter port located underneath the battery compartment. Be sure that the adapter is plugged into a working wall outlet.

QUESTION 4: How long will a new set of batteries last?

**Answer:** A new set of batteries will provide approximately 2 hours of continuous treatment.

**Answer:** Consider using rechargeable batteries.

QUESTION 5: What if no mist is coming out of the Altera Nebulizer Handset?

**Answer:** First, check that the Controller has power. Secondly, make sure the Nebulizer Connection Cord is correctly attached. Thirdly, check to be sure that the Altera Nebulizer Handset has been assembled properly (Section F). Lastly, check to be sure medication is in the Medication Reservoir. If the Altera Nebulizer System still does not function properly, call 1-866-335-6943.

QUESTION 6: What if liquid is leaking from the Altera Nebulizer Handset during the treatment?

**Answer:** Check to see if the Inhalation Valve has been deformed by storing the Altera Nebulizer Handset assembled.

**Answer:** Be sure the Inhalation Valve is properly attached to the Aerosol Chamber to prevent leaks (Section F, 6a and 6b).

**Answer:** Ensure the Aerosol Head is inserted correctly (Section F, 7, 7a, 7b). Next, ensure the Medication Reservoir and the Aerosol Chamber are closed correctly (Section F, 9).

QUESTION 7: What if my Controller shuts off before my treatment begins, or does not restart?

**Answer:** Press the On/Off button for one full second. If it still shuts off after several (3-4) attempts, call 1-866-335-6943.

QUESTION 8: What if my Controller does not shut off at the end of my treatment?

**Answer:** Press the On/Off button again.

**Answer:** Disconnect the AC Power Supply from the Controller and remove the batteries.

Please note that the Controller has a built-in, automatic shutoff after 20 minutes, and it will turn off at that time. If this situation continues three or four times, call 1-866-335-6943.
SPECIFICATIONS

Weight: Controller and Altera Nebulizer Handset ........................................ 6 oz
Weight: Controller, Altera Nebulizer Handset, and Batteries .... 9.5 oz
Dimensions of Altera Nebulizer Handset .......... 1.93” X 2.5” X 5.5”
Electrical Requirements ......................... 110 V - 240 V, 50 Hz/60 Hz
Power Wattage ............................................. 2.0 Watts under normal load

TRANSPORT / STORAGE
Ambient Temperature .................................................. -4° to 140° F
Ambient Humidity ...................................................... 10% to 95%

RECHARGEABLE BATTERIES
Rechargeable Batteries ........................................ 1.2V-1.5V, min 1500mAh
Rechargeable Battery Operation
................................................................. About 2 hours of continuous treatment
Rechargeable Battery Charge Time ..................... up to 15 hours
[depends on type of battery charger]

DISPOSABLE BATTERIES
Panasonic Power Max 3 or equivalent ....................... 1.5V
Panasonic Power Digital or equivalent ....................... 1.5V

MANUFACTURED IN GERMANY & DISTRIBUTED BY:
PARI Respiratory Equipment, Inc.
2943 Oak Lake Blvd.
Midlothian, Virginia USA
1-866-335-6943

PATENT NOS:
US 5,152,456; US 5,261,601; US 5,518,179; US 6,983,747;
US 6,962,151 Additional Patents Pending
Canadian Patent CA 2,389,936

DESIGN AWARDS: