

Instructions For Use

Rx only

⚠ WARNING

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



eRapid[®]
nebulizer system



178 **G** 1030

General Purpose Electronic Nebulizer

Quick Instructions

(Detailed Instructions Start on Page 5)

1. Familiarize Yourself with the eRapid Parts



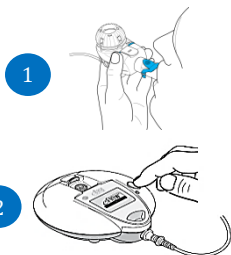
2. Clean and/or Disinfect Your eRapid Handset Before First Use

<p>1) Rinse each Handset component under tap water for 10 seconds.</p> <p>2) Clean by soaking Handset components in warm soapy water for 5 minutes.</p>	<p>3) Rinse all parts.</p> <p>4) Disinfect Handset components by boiling in distilled water for 5 minutes.</p>	<p>5) Air-dry Handset components until dry.</p>
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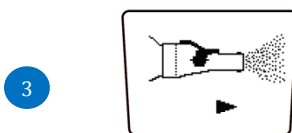
3. Assemble and Fill Your eRapid Nebulizer

<p>1) Power Controller with 4AA batteries or AC Supply.</p> <p>2) Wash and dry your hands.</p> <p>3) Open you're the Handset Body and insert Blue Valve.</p>	<p>4) Insert the Aerosol Head.</p> <p>5) Close the Handset and attach Mouthpiece.</p> <p>6) Pour your medicine into the Reservoir.</p>	<p>7) Attach the Connection Cord.</p> <p>8) Attach the Cap to the Handset and attach the Connection Cord to the Controller.</p>
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4. Begin Your Treatment



- 1) Place the Mouthpiece in your mouth.
- 2) Press and hold the On/Off Controller button for 1-2 seconds.



Controller Running

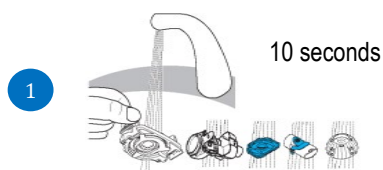
- 3) Take normal breaths in and out while keeping the Handset level. Do not breathe through your nose.



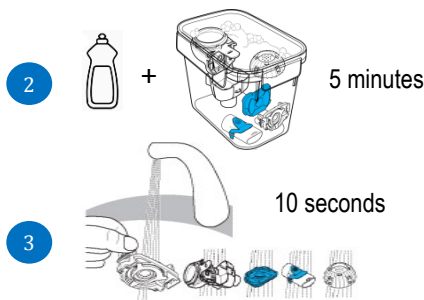
Controller Stopped

- 4) The Controller will turn off once liquid medicine is no longer touching the Aerosol Head, which will leave 1 mL medicine in the Handset. This is normal. Your treatment time depends on the type and volume of your drug.

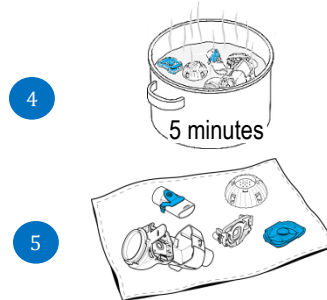
5. Cleaning and Disinfecting Your eRapid



- 1) **Disassemble** the Handset and **Rinse** each Handset component under tap water for 10 seconds. Take special care of the Aerosol Head and rinse both sides for 10 seconds to remove anything that can clog the small holes.

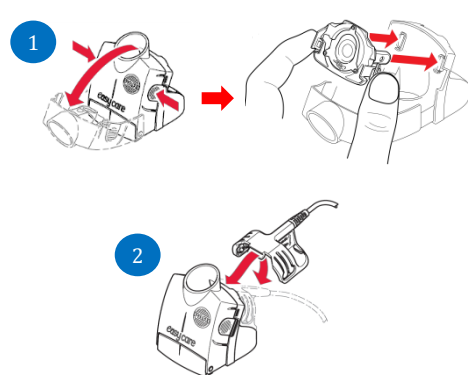


- 2) **Clean** by soaking Handset components in warm soapy water for **5 minutes**.
- 3) Rinse all components to remove residual soap and inspect for dirt. Soak for an additional 5 minutes if necessary.

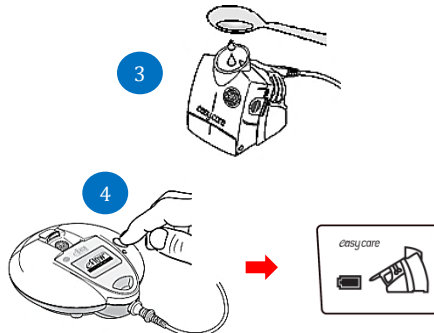


- 4) **Disinfect** by boiling all Handset components in distilled water for **5 minutes**.
- 5) **Air-dry** all parts until dry.

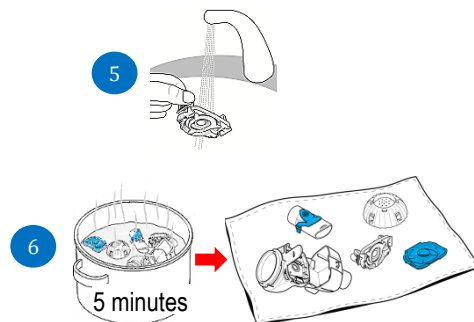
6. (Optional) Unclogging of the Aerosol Head with Easycare



- 1) Open the **Easycare** and insert Aerosol Head so "eRapid" is upside down.
- 2) Use Connection Cord to connect **Easycare** to the Controller.



- 3) Add 1 teaspoon (5 mL) of distilled water.
- 4) Press and hold the On/Off button for 10 seconds until you see **Easycare** on the Controller display. The Controller will turn off once liquid is no longer touching the Aerosol Head.



- 5) Rinse the Aerosol Head and **Easycare**.
- 6) Disinfect the Aerosol Head and Handset components by boiling in distilled water for 5 minutes and then air dry.

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Pour le français voir: www.pari.com/us-en/products

Para español ver: www.pari.com/us-en/products

A. Introduction

The eRapid® Nebulizer System (eRapid) is a lightweight, battery operated electronic nebulizer which will convert your liquid medicine into a fine mist. Your medicine is placed in a reservoir, which feeds to a stainless steel membrane that has been drilled with very small holes. When this membrane is vibrated, liquid is forced through the holes to form a fine mist.

Before using your eRapid Nebulizer System, read and understand all 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, Warning, Caution or Important**.

Safety Precaution Definitions:

Danger indicates hazards, which, without precautionary measures, will result in death or serious injury.

Warning indicates hazards, which, without precautionary measures, can result in serious injury or even death.

Caution indicates hazards, which, without precautionary measures, can result in moderate or minor injury or impair treatment, or damage to equipment.

Important indicates information considered important but not hazard related.

Indications For Use

The eRapid Nebulizer System is to be used with patients for whom doctors have prescribed medicine for nebulization. It is intended for adult and pediatric patients, and may be used in hospitals, hospital-type facilities, nursing homes, sub-acute institutions and home environments.

Read the following Dangers, Warnings, and Cautions before using this device.

DANGER

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

1. **Do Not** place or store your eRapid 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 eRapid if it has fallen into water or other liquid. Unplug immediately. Retrieve your eRapid **Only** after it has been unplugged.

WARNING

1. The eRapid Nebulizer Handset (Handset) is for use only by 1 patient. **Do Not Share** your Handset with other people.
2. The eRapid Handset has a residual volume similar to general purpose compressor-based jet nebulizers and will leave about 1/5 teaspoon (1 mL) of medicine in the reservoir. **Do not use this residual medicine or your dosage will not be accurate.**
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 damage and malfunction of the unit that could result in serious or fatal injury from electrocution, fire, and burns:
 - 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 eBase® Controller (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.
 - d. **Do Not** operate where oxygen is being used in a closed area such as an oxygen tent.
 - e. Always unplug this product immediately after using and before cleaning.
5. **Use Only** AC power supplies and accessories that are authorized by PARI. Use of unapproved power supplies or accessories can lead to improper treatment, injury, or cause (receive) interference leading to damage to the Controller.
6. **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,
 - d. it has been exposed to any liquids inside the Controller, or
 - e. the AC power supply is visibly damaged.
7. This product contains small parts that may present a choking hazard to small children and the Connection Cord (Connection Cord) may present a strangulation hazard. Close supervision is necessary when this product is used near children or the physically or mentally impaired.
8. This Handset has unique performance characteristics and should **Never** be substituted for other eFlow Technology Handsets (e.g. Altera®, Lamira®, Zirela®, or Investigational eFlow Handsets).
9. **Never** use the eRapid Aerosol Head (Aerosol Head) with any other eFlow Technology Handset or eFlow Technology System (e.g. Altera, Lamira, Zirela, Investigational eFlow).
10. **Do Not** use your eRapid while driving or in any situation which takes away your full attention.

11. **Never** operate the Controller if it is not properly and completely assembled. **Do Not** use if the Controller is damaged. See Section I: Troubleshooting, for the alerts that show when the Controller is damaged or not properly assembled.
12. To reduce the risk of infection, illness, and/or injury from contamination, and to maintain the longevity of your Handset, clean and dry all parts of the Handset before you first use it and after each treatment. Follow the instructions in Section E for cleaning your Handset.
13. Cleaning the Handset only removes the medicine and saliva. To reduce the risk of serious or fatal illness caused by contamination of the Handset, **disinfect the Handset daily or as recommended by your physician.** See steps E9 and E10 for disinfection instructions.
14. **Only** use cleaning and disinfecting procedures described in this document. PARI has tested these procedures specifically for eRapid. Use of other methods may not clean or disinfect properly or damage your Handset.

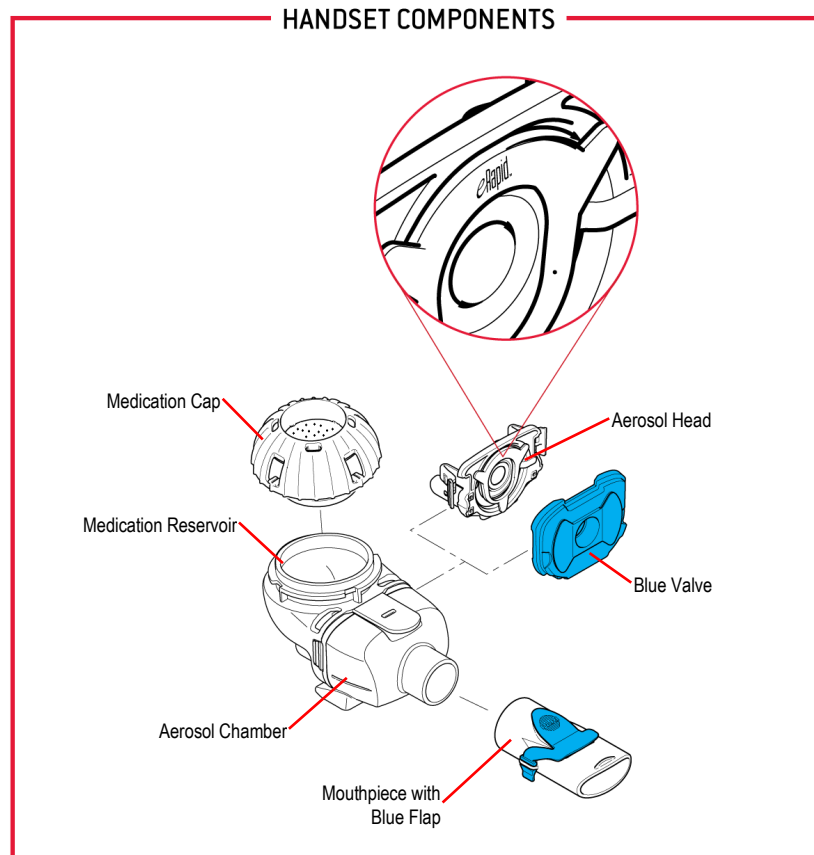
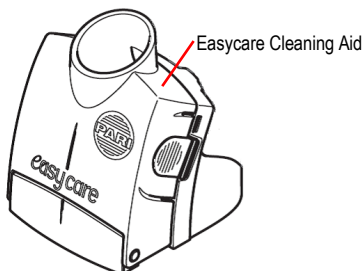
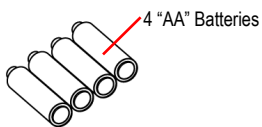
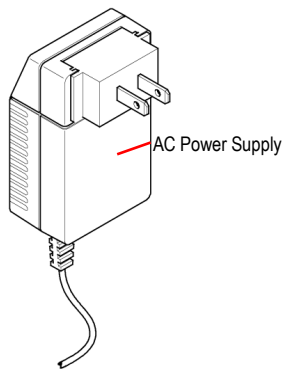
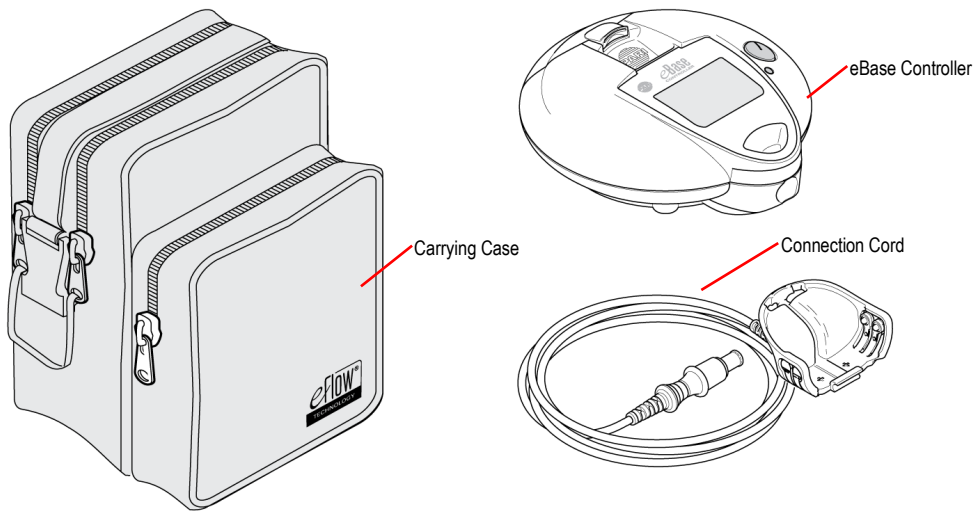
CAUTION

1. Before use, check your Handset for proper assembly. All parts must be connected and firmly in place. Use of an improperly assembled Handset could reduce or eliminate the effectiveness of the treatment.
2. Keep the Handset level when in use. If the Handset is tilted, the dosage may not be accurate. Excessive tilting can cause the Controller to shut off prematurely because medicine may not be covering the Aerosol Head membrane.
3. To reduce the risk of damage and malfunction of the unit, **Do Not** drop or insert any object into any opening of the eRapid.
4. **Do Not** modify this equipment without authorization from the manufacturer.
5. **Do Not** disassemble the Controller at any time. There are no user serviceable parts inside the Controller. Call the number below for all service needs.
6. **Do Not** allow pets (for example; dogs, rodents, rabbits) near the cables.
7. Cleaning the 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 **Easycare** and water to unclog the Aerosol Head as described in Steps E11 through E19.
8. If you suspect that your eRapid has been damaged or is not working correctly, call the number below.
9. **Do Not** use the device in areas exposed to elevated electromagnetic or electrical radiation such as a MRI scanner or high frequency surgical equipment.
10. **Do Not** place near other medical devices during operation unless both devices are monitored constantly to insure both are operating properly.
11. **Do Not** use within 30 cm of portable wireless communication devices such as cell phones or antenna cables or external antennas.
12. **Do Not** use near airplane or train control systems. Do not use aboard aircraft.
13. **Do Not** use the nebulizer near anti-theft systems and Radio Frequency Identification (RFID) readers, which are used in a wide variety of settings, including stores, libraries, and hospitals. **Do not** power on the nebulizer when passing through security screening or theft protection (RFID) systems at entrances or exits of stores, libraries, or hospitals. Note that some entrance and exit security systems are not visible.

Technical electromagnetic compatibility data is available in table form upon request from PARI Respiratory Equipment or on the Internet at <https://www.pari.com/fileadmin/Electromagnetic-compatibility-4.pdf>

Getting Started

Check your eRapid System package to make sure you have the items shown below. Note that the package contains two eRapid Handsets and two eRapid Aerosol Heads. Also note that the **eRapid Handset is not sterile and needs to be cleaned and/or disinfected before you use it for the first time**. Remove one new Handset and one new Aerosol Head from their packaging and proceed to step E2c to begin the cleaning procedure. You can keep the second Handset as a backup or clean it at the same time as you clean the first Handset.



Using Batteries or the AC Power Supply

The Controller is designed to be used with “AA” batteries or with the AC Power Supply.

Using Batteries. Four (4) new “AA” batteries will provide approximately 2 hours of continuous treatment. You may also use “AA” rechargeable batteries.

Step D1: Open the Battery Door on the Controller by placing your thumb on the tab of the grey Battery Door and firmly pushing the tab to open the Door (**Figure D1**). Note that the Battery Door is designed to have a tight fit.

Step D2: Load the Batteries. Each battery chamber has a small symbol that shows the proper position of each battery (**Figure D2**). Using the battery positive (+) and negative (-) markings as guides, match the + and - signs on the battery with the same markings on the Battery Chamber. Starting left to right, insert the batteries: + out, + in, + out, + in.

Step D3: Close the Battery Door. 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 is about 2 hours when using high quality disposable batteries. To reduce the risk of battery leakage, it is recommended to remove the batteries if you plan to store the Controller for more than 30 days.

✓IMPORTANT: It is strongly recommended to have an extra battery set with you at all times.

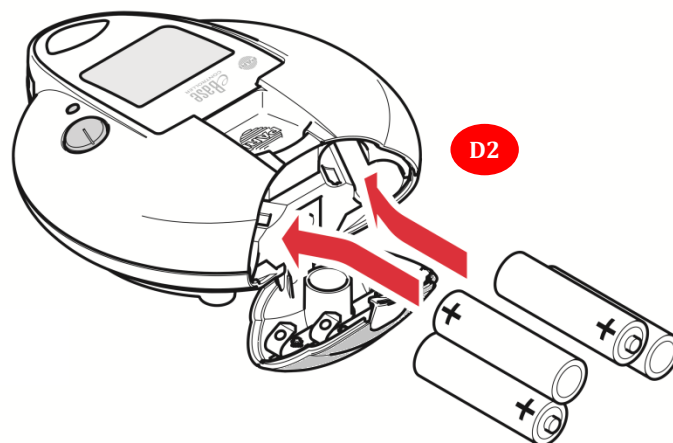
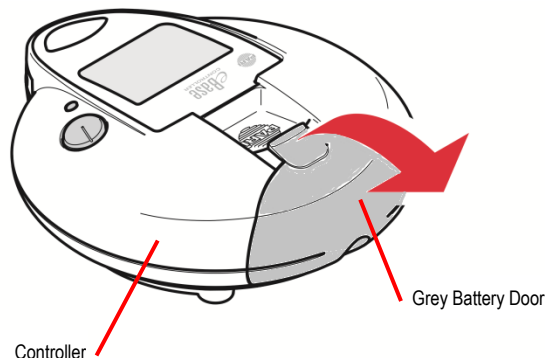
Using the AC Power Supply. The Controller can also be used with the AC Power Supply. The AC Power Supply is useful as a back-up power supply when the batteries are depleted. The AC Power Supply can be used with 100-240V outlet and will automatically adjust to the incoming voltage.

Step D4: If necessary, insert the Plug Converter into the AC Power Supply as shown (**Figure D-4**).

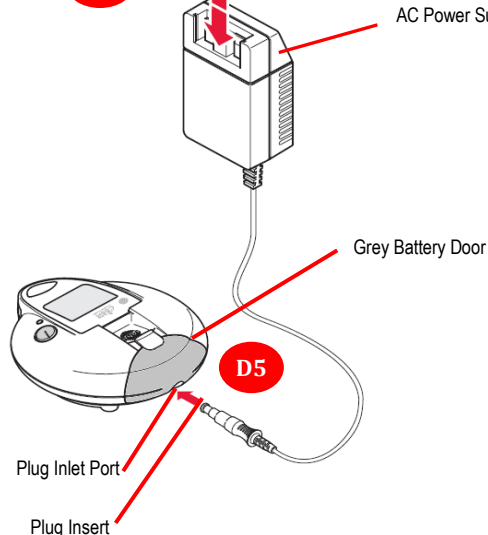
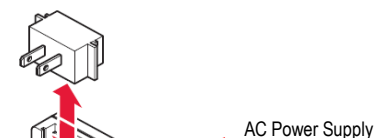
Step D5: Plug the AC Power Supply into the Controller. To connect the AC Power Supply to the Controller, place the Controller on a flat, stable surface. The plug inlet port is located on the underside of the Battery Door. Push the round end of the AC Power Supply cord into the plug inlet port (**Figure D5**). **Do Not** try to insert the AC Power Supply into the front of the Controller.

Step D6: Plug the AC Power Supply into the wall outlet. Note that the AC Power Supply will not charge the Batteries in the Controller.

D1



D4



⚠ WARNING

To reduce the risk of infection, illness, and/or injury from contamination and/or improper use, it is important to:

- Clean and/or Disinfect your Handset Before First Use.
- Rinse and Clean your Handset Immediately after Each Use (see Steps E1-E8).
- Disinfect Your Handset Daily or as Recommended by Your Physician (see Steps E9-E10).

⚠ CAUTION

The Aerosol Head contains very small holes. To reduce the risk of damage to the Aerosol Head and Handset:

- Do Not clean the Aerosol Head in a dishwasher.
- Do Not clean the Aerosol Head with brushes or abrasives.
- Do Not disinfect the Aerosol Head in the microwave oven.
- Do Not apply liquid dish soap directly to the Aerosol Head.
- Do Not use “white” liquid dish soaps or antibacterial liquid soaps as these may contain additives harmful to the Aerosol Head.
- Do Not wash the Controller, Connection Cord or AC Power Supply.
- Use clear liquid soap designed for washing dishes.
- Use only distilled water to disinfect by boiling.
- Follow manufacturer directions when using a chemical disinfectant, such as Control III®.

Handset Maintenance Summary (Details Can Be Found on the Following Pages)

Instruction	When	Parts cleaned	Method	How Long	Comments
Rinse	After each use	<ul style="list-style-type: none"> • Aerosol Head • Medication Cap • Blue Valve • Reservoir and Chamber • Mouthpiece 	Rinse with warm running tap water.	10 seconds	Rinse each side of the Aerosol Head for At Least 10 Seconds .
Clean	After each use	<ul style="list-style-type: none"> • Aerosol Head • Medication Cap • Blue Valve • Reservoir and Chamber • Mouthpiece 	Soak in warm soapy water.	5 minutes	Soak longer if Handset has dried medicine or if visibly dirty.
Disinfect	Daily or as recommended by your physician.	<ul style="list-style-type: none"> • Aerosol Head • Medication Cap • Blue Valve • Reservoir and Chamber • Mouthpiece 	Boil in distilled water or Soak in Control III® disinfectant.	5 minutes 10 minutes	Rinse thoroughly after disinfecting with Control III®.
Unclog	When needed	Aerosol Head	Run the Controller's Easycare cycle with distilled water and the Easycare cleaning aid.	5-10 minutes	Disinfect after completing Easycare cycle. Do not exceed 30 Easycare cycles per Aerosol Head.

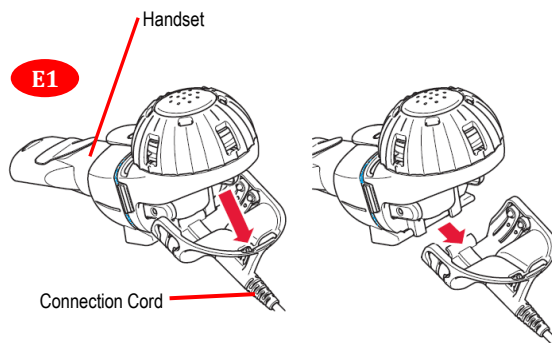
New Handsets

It is important to clean and/or disinfect your Handset before first use. Remove the new Handset and the Aerosol Head from their packaging and proceed to Step E2c to begin cleaning.

Cleaning Your Handset after Treatment

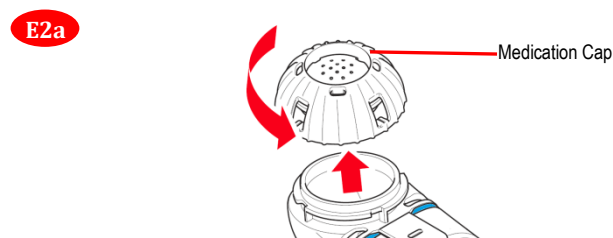
WARNING Contamination and moisture may cause the growth of bacteria and any remaining medicine can clog the small holes on the Aerosol Head and affect performance. It is important to **rinse and clean your Handset right away after every use.**

Step E1: Disconnect the Handset from the Connection Cord (Figure E1).

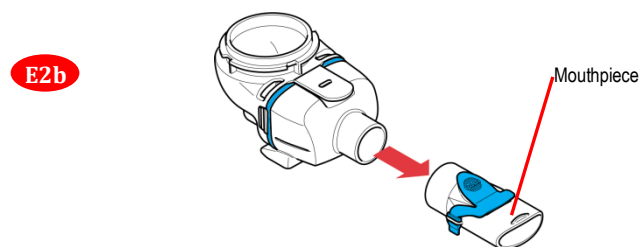


Step E2: Disassemble the eRapid Handset:

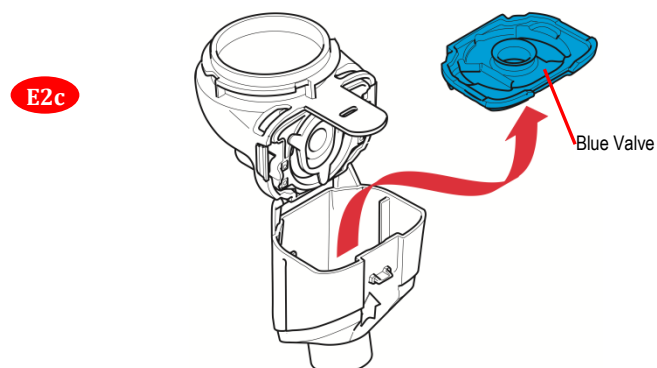
a. **Remove the Medication Cap from the Medication Reservoir (Figure E2a).**



b. **Remove the Mouthpiece from the Aerosol Chamber (Figure E2b).** The valve must still be attached to the Mouthpiece as shown in the picture.

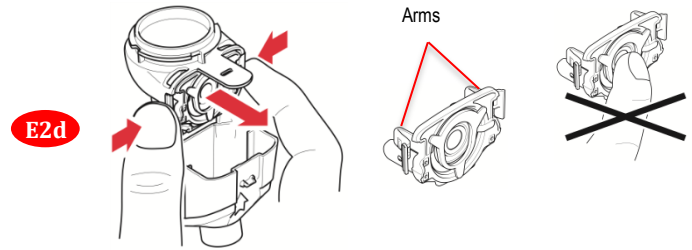


c. **Remove the Blue Valve by gently pulling up on the tab of the Medication Reservoir. This will release the Aerosol Chamber so that you can open it and remove the Blue Valve (Figure E2c).**

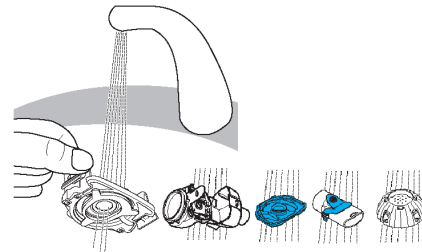


E. How To Clean and Maintain Your eRapid

- d. **Remove the Aerosol Head.** Be careful to touch **Only** the plastic outer ring of the Aerosol Head, press the 2 flexible plastic arms on the side of the Aerosol Head and remove (Figure E2d). **Do Not touch the center metal part of the Aerosol Head.**

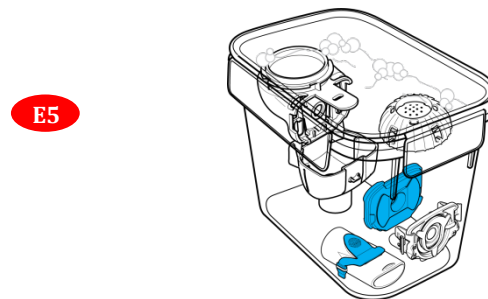


- Step E3:** Rinse each of the disassembled parts under warm (approximately 104°F/ 40°C) running tap water to remove residue (for approximately 10 seconds). **Note: there is no need to disassemble the Medication Reservoir from the aerosol chamber for cleaning.**



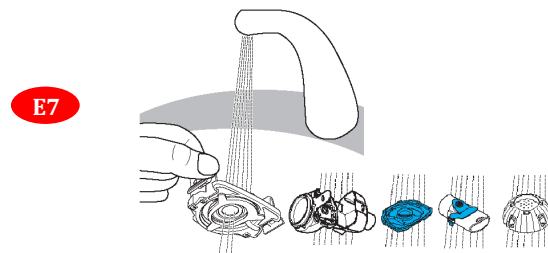
- Step E4:** Rinse each side of the Aerosol Head for at least **10 full seconds** (Figure E4). Never use a brush or any other object to clean the Aerosol Head. **Thorough rinsing of both sides of the Aerosol Head helps with proper operation and prevents clogging.**

- Step E5:** Soak all parts of the Handset in warm soapy water for **5 minutes** made by adding about ¼ teaspoon of clear liquid dish soap and 1 quart of warm tap water to a clean tub or bowl (Figure E5).

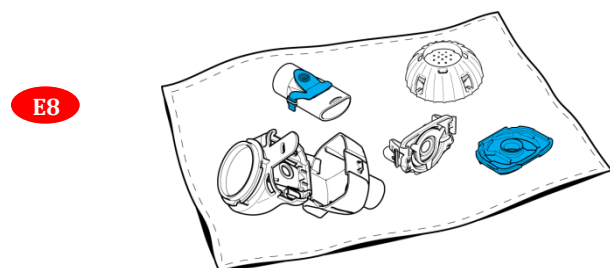


- Step E6:** **Inspect** all parts to confirm they are clean. If they are not clean, soak them in warm soapy water for an additional 5 minutes with gentle agitation.

- Step E7:** Rinse all parts thoroughly under warm running tap water (Figure E7).



- Step E8:** Air dry parts on a clean, lint-free cloth or paper towel (Figure E8). After the parts are completely dry, place them in a bag or cover them with a lint-free cloth or paper towel for storage. Re-assemble just before treatment.



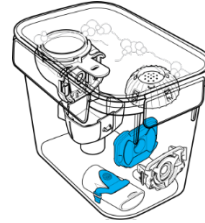
Disinfecting Your Handset

To reduce the risk of serious or fatal illness or injury caused by contamination, it is important to disinfect your Handset daily or as recommended by your physician. Disinfection is more effective if you clean your Handset before you disinfect.

Step E9: Disinfect the Handset with the commercially available medical device disinfectant Control III® or by boiling in distilled water.

- **To disinfect with disinfectant**, mix $\frac{1}{2}$ tablespoon of Control III solution to 1 quart of water in a clean bowl. Immerse the parts in that bowl and soak for **10 minutes (Figure E9a)**. Remove parts from solution and rinse thoroughly with sterile water.
- **To disinfect with boiling water**, immerse and boil the parts, including the Aerosol Head, in a clean pot of **distilled water** for a full 5 minutes (**Figure E9b**).

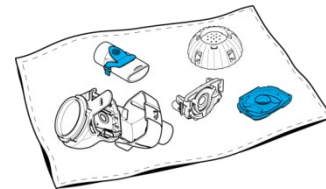
E9a



E9b



E10



Step E10: Dry on a lint-free cloth or paper towel (Figure E10). After the parts are completely dry, place them in a bag or cover them with a lint-free cloth or paper towel for storage. Re-assemble the Handset just prior to the next treatment.

Unclogging the Aerosol Head with Easycare (Optional)

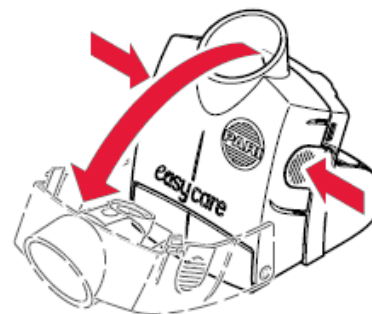
After multiple uses, your nebulization time may slowly increase. If soaking in soapy water does not improve performance, it may be necessary to perform special cleaning of the Aerosol Head. The **Easycare** is used to clean and unclog the small holes in the Aerosol Head by reversing the flow of liquid. The cleaning process takes about 5-10 minutes and uses the **Easycare** powered by the Controller. **It is important Not To Use the Easycare more than 30 times on a single Aerosol Head.**

Clean the Handset as described in Steps E1-E7.

Step E11: Open the Easycare.

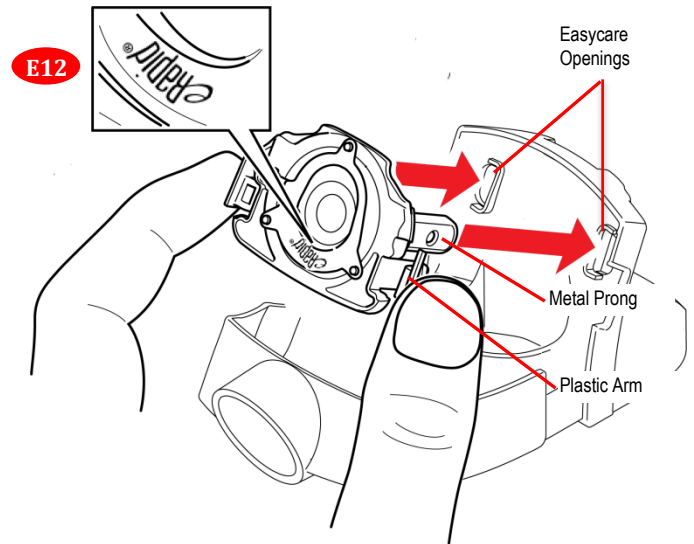
- Press lightly on the side gripping surfaces to release the side engaging hooks (**Figure E11**).
- Gently pull the light gray funnel part outward and down.

E11

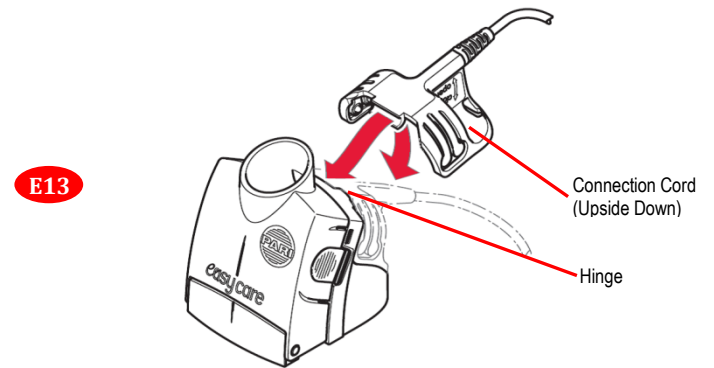


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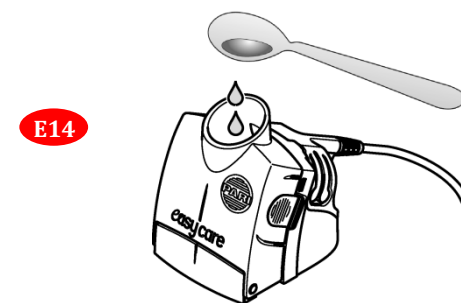
Step E12: Insert the Aerosol Head so the "eRapid" label is upside down (**Figure E12**). Being careful to touch **Only** the plastic outer ring of the Aerosol Head, squeeze the 2 flexible plastic arms on the side of the Aerosol Head together while firmly inserting 2 plastic tabs and 2 metal prongs into the 4 holes of the **Easycare**. The Aerosol Head will snap into place when it has been properly inserted. Then close the **Easycare** making sure that the 2 side engaging hooks snap into place.



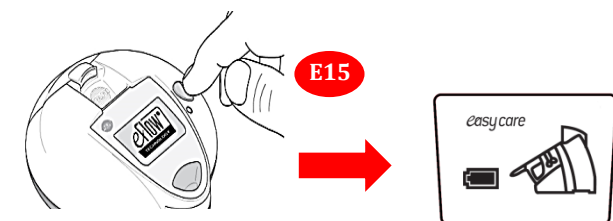
Step E13: Connect the **Easycare** to the Controller using the Connection Cord by attaching the horseshoe-shaped end of the Connection Cord upside down to the hinge of the **Easycare** part and swivel it downwards (**Figure E13**). Make sure that the Connection Cord's metal contacts engage with the Aerosol Head's metal inserts. Connect the other end of the cable to the front of the Controller.



Step E14: Add about 1 teaspoon (5 mL) of distilled water or saline solution to the mark in the **Easycare** funnel opening (**Figure E14**).



Step E15: Start the Controller by pressing and holding the On/Off button for 10 seconds until the Controller beeps and displays the **Easycare** screen (**Figure E15**).



Step E16: After 5-10 minutes, the Controller should beep, display the dose complete screen (**Figure E16**) and then automatically turn off. If liquid is still present in the **Easycare** funnel, restart the Controller in **Easycare** mode by pressing and holding the On/Off button for 10 seconds.

E16



Step E17: Reverse the assembly steps and discard any solution from the **Easycare**.

Step E18: Clean the **Easycare** by soaking in warm soapy water.

Step E19: Rinse and disinfect the **Aerosol Head** as described in Steps E9 and E10.

Cleaning Your Controller and Connection Cord (Optional)

Step E20: **Switch off the Controller.** Remove the Connection Cord and AC Power Supply from the Controller.

Step E21: **Clean the Controller** housing and Connection Cord with a damp cloth.

How to Assemble Your Handset

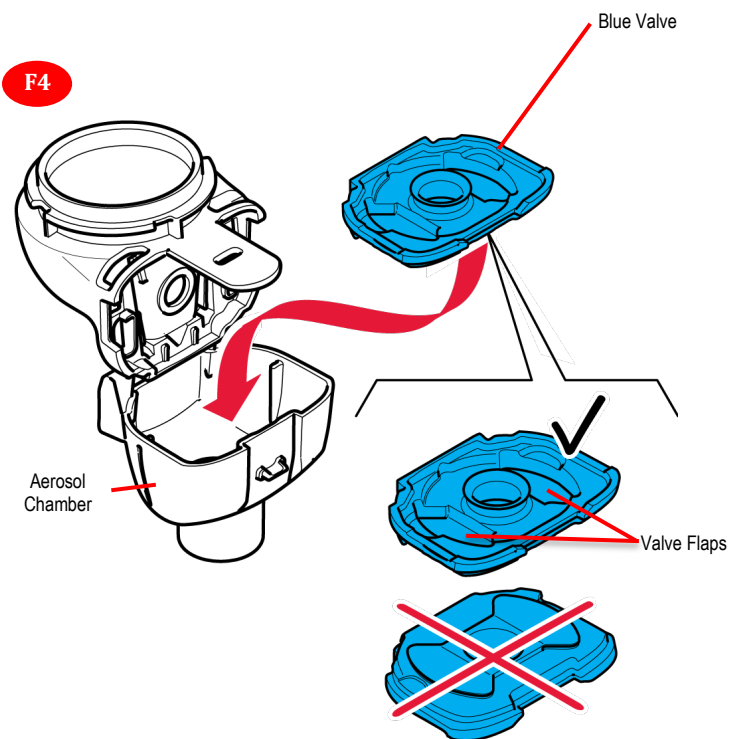
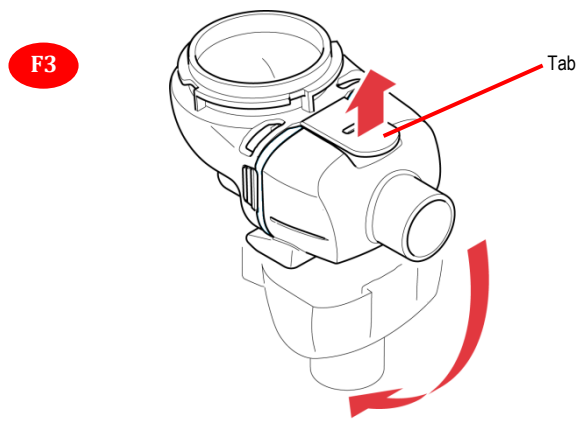
WARNING New Handsets must be cleaned and/or disinfected before you use them for the first time (see Section E).

Step F1. Wash your hands.

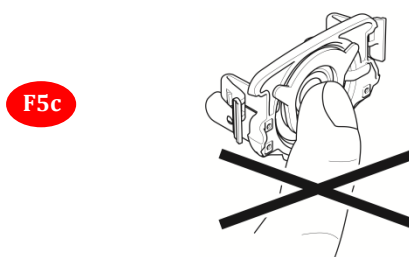
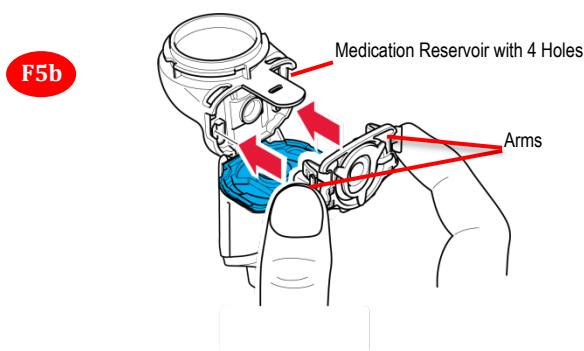
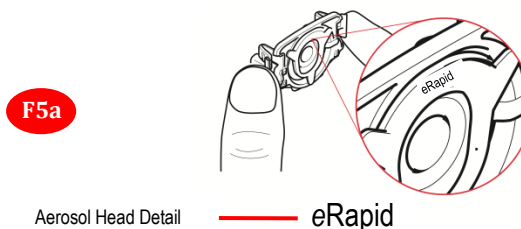
Step F2. Inspect the Handsets parts and confirm they are clean and not visibly damaged. **Do Not** use dirty or damaged parts.

Step F3. Open the Handset. The Medication Reservoir and the Aerosol Chamber are attached using a “hinge”. First, gently pull up on the tab of the Medication Reservoir (**Figure F3**). This will release the Aerosol Chamber so that you may open it.

Step F4. Place the Blue Valve on top of the Aerosol Chamber making sure the 2 valve flaps are pointed down as shown in **Figure F4**.

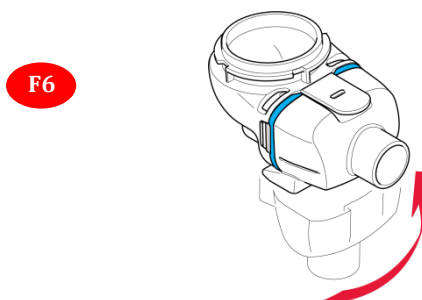


Step F5. Insert the Aerosol Head making sure that it is labeled “eRapid” (Figure F5a, detail). **Do Not use other Aerosol Heads in this device.** Being careful to touch **Only** the plastic outer ring of the Aerosol Head, squeeze the 2 flexible plastic arms on the side of the Aerosol Head (Figure F5b) together while firmly inserting 2 plastic tabs and 2 metal prongs into the 4 holes of the Medication Reservoir. 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 F5c).

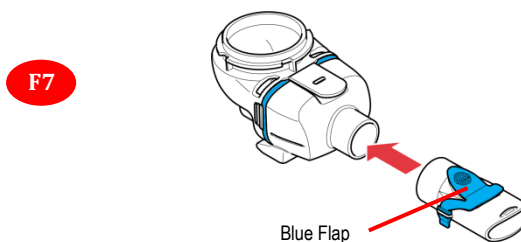


✓IMPORTANT: Do Not touch the metal part of the Aerosol Head.

Step F6. Close the Handset by pushing the Aerosol Chamber together with the Medication Reservoir until you hear or feel a “snap” (Figure F6). If you **Do Not** hear or feel a “snap”, open the Handset and check that the Blue Valve is seated properly.



Step F7. Attach Mouthpiece to Handset. Make sure the Blue Flap is facing up (Figure F7) and is pressed in the slot on the Mouthpiece. Push the Mouthpiece straight onto the Handset. Make sure the Mouthpiece stays attached to the Handset during treatment.



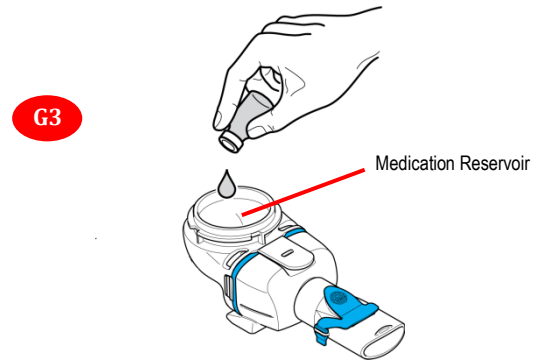
How to Take Your Treatment

Step G1. Confirm your medicine is at room temperature.

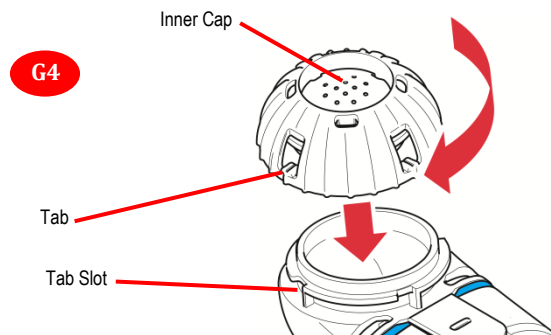
Step G2. Wash your hands.

Step G3. Add your medicine to the Medication Reservoir. Make sure the Handset is on a flat, stable surface. Add your medicine to the Medication Reservoir. (Figure G3).

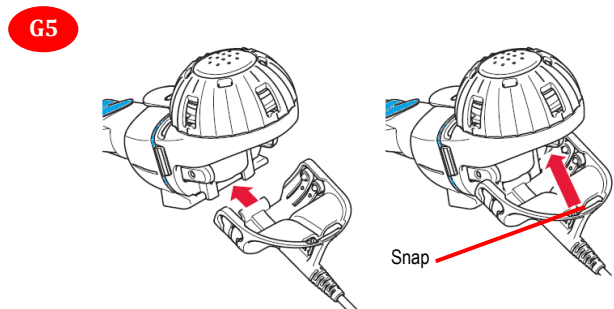
- Do Not Use Medicines Prescribed for Other Nebulizers in the eRapid.
- Do not exceed the maximum fill volume of 6 mL.



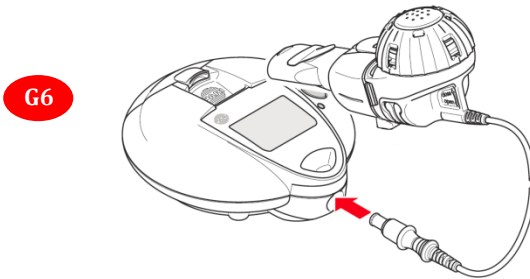
Step G4. Close the Medication Cap by lining-up the Tabs on the Medication Cap with the Tab Slots on the Medication Reservoir and turning the Medication Cap clockwise (to the right) until it stops (Figure G4). As the Medication Cap is turned, the inner part of the Medication Cap should rise.



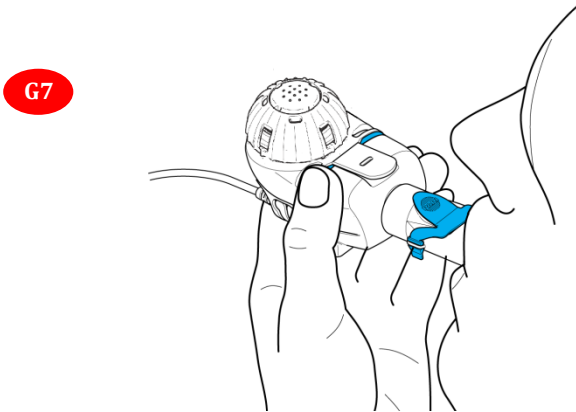
Step G5. Attach the Connection Cord by aligning the bottom of the Connector with the bottom of the Handset and lifting until the Connection Cord snaps into the rear underside of the Medication Reservoir (Figure G5).



Step G6. Attach the Connection Cord to the Controller. Place the Controller on a clean, flat, stable surface. Attach the Connection Cord round end to the front of the Controller (**Figure G6**).

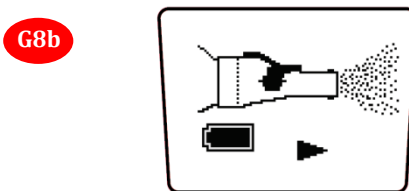
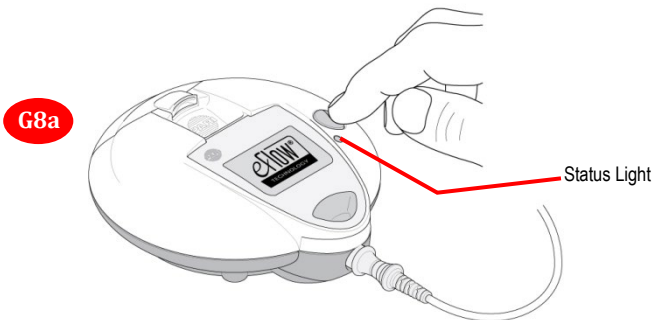


Step G7. Place the Mouthpiece in your mouth. Sit in a relaxed position. Place the end of the Mouthpiece on top of your bottom lip and tongue and close your lips around it (**Figure G7**). Keep the Handset level and **Do Not** cover the Blue Flap with your mouth.



Step G8. Turn on the Controller. Press and hold the On/Off button for 1-2 seconds (**Figure G8a**). The following will happen:

- You will hear 1 “beep” and the status light will turn green.
- The eFlow Technology logo will appear on the screen.
- If your eRapid Nebulizer system is assembled correctly, your Controller will switch and display the **Treatment Screen** (**Figure G8b**). The Controller will continue to show the Treatment Screen throughout your entire treatment. Note that this example screen shows the Controller is powered by batteries.
- After a few seconds, aerosol mist will begin to flow into the Aerosol Chamber of the Handset and out of the Mouthpiece.



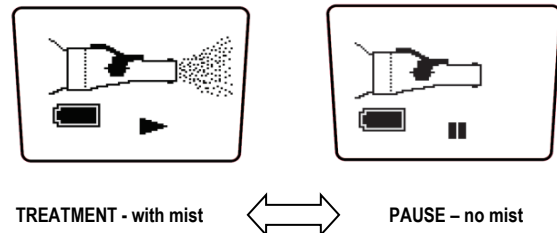
Step G9. Breathe normally in and out through the Mouthpiece but **Do Not** breathe through your nose. Continue to breathe in and breathe out normally until the treatment is finished. If the Handset is tilted over 45 degrees for more than 30 seconds, the Nebulizer system will think your medicine has been consumed and will beep twice, display a check mark (**Figure G9**), and shut down. If this happens, hold your Handset level and restart the Controller by pressing the On/Off button.

Step G10. At the end of Treatment, the Controller will shut off automatically.

- You will hear 2 beeps.
- The Dose Complete Checkmark will appear briefly on the screen (**Figure G9**).
- Then the Controller will automatically shut off.



G9

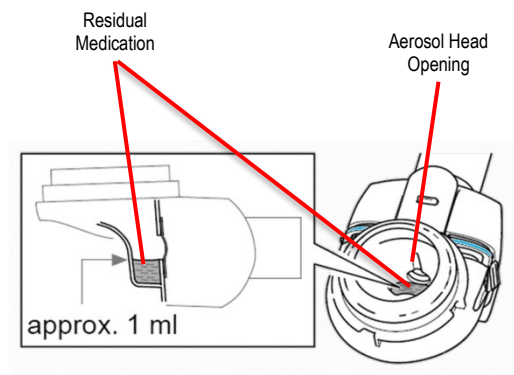


G10

✓IMPORTANT: If, for any reason, you must **PAUSE** your treatment, press the **Controller On/Off Button** for 1 full second. The **PAUSE** function is activated when the LED flashes **green** and the Controller display switches from the **TREATMENT** screen to the **PAUSE** screen (**Figure G10**). When you are ready to resume your treatment, press the **Controller On/Off Button** again for 1 full second. The treatment will resume when the LED remains a steady **green** and the Controller display switches back to the **TREATMENT** screen.

Step G11. Confirm your treatment is complete by removing Medication Cap and seeing if the medicine is below the Aerosol Head opening (Figure G11). To mimic other general-purpose nebulizers, the eRapid is designed to keep 1 mL (1/5 teaspoon) of medicine in the Medication Reservoir. Do not tilt or try to use the residual medicine. If the medicine is above the Aerosol Head opening, replace the Medication Cap and press the On/Off button to restart your treatment.

G11



⚠ WARNING Rinse and clean your Handset after each use!

Step G12. Once the treatment is complete, disassemble the Handset for Cleaning. Refer to Steps E1-E21 for cleaning instructions.

Frequently Asked Questions

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

Answer: Following treatment, about 1 mL of medicine should remain in the Medication Reservoir and the liquid level should be slightly below the opening for the Aerosol Head (Figure G11). If the liquid level is above the Aerosol Head opening, put the Medication Cap back on and restart the treatment. Following treatment, unplug the Aerosol Head by cleaning and then running the **Easycare** cycle on the Aerosol Head. If the problem continues, call the number below.

Question 2: How long should each treatment take?

Answer: Treatment time depends on the volume and type of medicine. With normal operation and proper cleaning the eRapid Nebulizer Handset should deliver 2.5 mL of distilled water in less than 5 minutes. If more than 5 minutes are required, unplug the Aerosol Head by cleaning and then running the **Easycare** cycle on the Aerosol Head. If you are still having a long treatment time, call the number below.

Question 3: When I turn on my Controller, nothing happens. There does not seem to be any power.

Answer: If you are using Batteries, use the symbols 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 connection to be sure it is firmly connected to the Power Supply Port located underneath the battery compartment. Also, be sure that the AC Power Supply 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. You may also use rechargeable Batteries.

Question 5: What if no mist is coming out of the Handset?

Answer: First, check that the Controller has power. Second, check to be sure the eRapid has been assembled correctly (Section F). Third, check the Controller LCD to see if the Pause Function has been activated (Figure G10). Lastly, check to be sure that medicine is in the Medicine Reservoir. If, after cleaning the Aerosol Head, your eRapid still does not function properly, call the number below.

Question 6: How long will my eRapid last?

Answer: The Controller is warranted for 2 years with appropriate care and if you remove the Batteries when storing the Controller for more than 30 days. The Handset should last for 2-6 months but it depends on the number of different medicines used with the Handset, the number of times the Handset is used per day, the amount of salt contained in the medicines, and the prompt and proper maintenance of the Handset. For Medications that are high in salt, it is a good idea to rinse both sides of the Aerosol Head after use if you cannot clean immediately after use.

Question 7: I see many approaches for cleaning and disinfecting nebulizers, which should I use?

Answer: Only use cleaning and disinfecting procedures described in this document. PARI has tested these procedures specifically for eRapid. Use of other methods may damage your Handset.

Question 8: What if liquid is leaking from the Handset during the treatment?

Answer: To prevent leaks, be sure: (1) the Blue Valve is properly positioned in the Aerosol Chamber (Step F4), (2) the Aerosol Head is inserted correctly (Step F5b), (3) the Medication Cap is screwed on correctly (Step G4), and (4) the Medication Reservoir and the Aerosol Chamber are closed properly and *snapped* together (Step F6).

Answer: It is normal to have some liquid accumulate in the Aerosol Chamber. Try to hold the Handset so that liquid medicine does not come out of the Mouthpiece.

Question 9: What if my Controller powers up and then shuts off before my treatment begins, or does not restart?

Answer: Press the On/Off button for 1 full second. Confirm the batteries are good or switch to the AC adapter. If it still shuts off after several (3-4) attempts, call the number below.

Question 10: 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 3 or 4 times and you have been cleaning the Handset, call the number below.












Question 11: What should I do with my old eRapid?


Answer: Clean and disinfect your Handset and then dispose in normal municipal trash. Dispose of the Batteries following your local municipality guidelines. Dispose of or recycle the Controller with other electronic equipment.

Question 12: When I started my Easycare, the EASYCARE screen did not appear on the display and the TREATMENT screen appeared instead. What should I do?

Answer: Press and hold the Controller's On/Off Button for 3 full seconds. After 10 seconds, the Controller will automatically shut off. Restart the **Easycare** cycle as described in Step E16 by holding down the On/Off button for about 10 seconds until the **Easycare** screen appears. If this situation occurs several (3-4) times call the number below.

Troubleshooting

	Fault/Condition	Possible Cause/Solution
1	Steady 	Controller running on AC power.
2	Steady 	Controller running on battery power.
3	Blinking 	Empty battery, replace Batteries or switch to AC power.
4	Blinking  The LED changed from green to red and the battery symbol is blinking during treatment.	Low battery, replace Batteries or switch to AC power.
5	Blinking  Device turns on, but LED flashes green-red and this symbol is blinking.	Bad or missing Connection Cord, check Connection Cord between Handset and Controller. Bad or missing Aerosol Head, correct then press the On/Off button.
6	Blinking  Device beeps 1x, then beeps high to low with the LED flashing red and this symbol is blinking.	No medicine. Add medicine if you have not done so. Not level or medicine is not touching the Aerosol Head. Gently tap the Handset, hold the Handset level and press the On/Off button.
7	Blinking  Device beeps low to high 3x, flashes LED green-red, blinks this symbol on the LCD, and then turns off.	Have reached 20-minute maximum time and will shut down. If more than 1 mL of medicine remains, press the On/Off button. After treatment is complete, clean the Aerosol Head.
8	Steady  Device beeps 1x and LCD shows this symbol.	Misting and working properly.
9	Steady 	Controller has paused and Handset is not misting. To resume treatment, press the On/Off button.
10	Brief 	Functioning properly, eFlow has booted properly.
11	Brief  Device beeps 2x, displays this checkmark symbol then turns off.	Your treatment is complete. If more than 1 mL of medicine is remaining, the Handset may have been tilted. Keep Handset level ($\pm 45^\circ$), gently tap Handset and restart Controller.

	Fault/Condition	Possible Cause/Solution
12	The device cannot be activated – no green LED, no screen, and no beep.	Bad, missing or misloaded Batteries. Bad or missing AC Power Supply.
13	The device beeps 1x and begins to produce a mist, then stops and shuts off with no beep, no LED, and with medicine still present.	Bad Batteries or bad AC Power Supply. Replace Batteries or AC Power Supply and press the On/Off button.
14	The device stops before your treatment is complete.	Lost power. Replace Batteries or use AC Power Supply. Tilted Handset. Keep Handset level ($\pm 45^\circ$), gently tap Handset and press the On/Off button.
15	The device does not stop automatically after your medicine is consumed.	Clean the Aerosol Head. If condition persists, call the number below.
16	Longer than normal nebulization time.	Clean the Aerosol Head and then use Easycare . If condition persists, call the number below.
17	There is more than 1 mL residual medicine remaining in the Handset.	Handset may have been tilted. Keep Handset level ($\pm 45^\circ$), gently tap Handset and restart Controller.
18	Handset leaks.	Confirm the Blue Valve is placed correctly in the Handset and the 2 flaps point into the Handset Chamber (see Step F4). Confirm Aerosol Head is correctly placed in the Handset. It is normal to have some liquid condense in the Aerosol Chamber and Mouthpiece. The amount depends on the volume of the medicine and on your breathing pattern.
19	Steady <i>easycare</i> 	The On/Off button has been pressed for 10 seconds, which activated the Easycare function. The Easycare is an accessory that is used to unclog the small holes in the Aerosol Head. Press the On/Off button briefly to turn off the Controller and discontinue the Easycare function.

Technical Data

Weight: Controller and Handset 6 oz. (170 g)
 Weight: Controller, Handset, and Batteries approx. 9.5 oz. (270 g)
 Dimensions: Handset 1.93 x 2.5 x 5.5 inches (4.9 X 6.4 x 14 cm)
 Electrical Requirements 100 - 240 V, 50/60 Hz
 Power Wattage 2.0 Watts under normal load
 Minimum Fill 2 mL
 Maximum Volume Fill 6 mL
 Residual volume remaining after nebulization about 1 mL

Operation/Storage













Controlled Room Temperature 41 - 104 °F (5 - 40°C)

Batteries

High quality alkaline or lithium 1.5V
 Battery Operation approximately 2 hours of continuous treatment

Device Classification According to IEC 60601-1

Type of electric shock protection (AC Power Supply)..... Protection Class II
 Degree of protection from electric shock of part used (nebulizer) Type BF
 Degree of protection against water ingress per IEC 60529 IP rating (nebulizer)..... IP 21
 Degree of protection when in the presence of flammable mixtures No protection
 Continuous operation Operating mode

	Please follow the instructions for use		Caution: Read all warnings and precautions in instructions for use
	Part number of the device		Protection class II appliance
	Serial number of the device		CE marking: This product is compliant with the requirements set forth in 93/42/EEC (Medical Devices) and 2011/65/EU (RoHS)
	Direct current		Do not dispose in domestic waste
	Indoor use only		Manufacturer
	Protection class of the part used: Type BF		Certification Mark
IP21	Protected from condensation		

Warranty and Disposal

Expected useful life

The Controller is expected to last for at least 2 years with appropriate care. The Handset should last for 2-6 months but it depends on the prompt and proper maintenance of the Handset, the number of medicines used with the Handset, the number of times the Handset is used per day and the amount of salt contained in the medicines.

Disposal

Follow your local municipality guidelines for disposal. The Handset plastic components and Aerosol Head should be cleaned and disinfected before disposal. The Controller, AC Supply and Connection Cord can be disposed or recycled with other electronic equipment.

Warranty.

Register at www.pari.com/register or by calling 1.866.335.6943 or 1.804.253.7274.

PARI Respiratory Equipment, Inc. (PARI) will offer a two (2) year limited warranty on the eRapid and its parts, limited to the Controller, Nebulizer Connection Cord, and Power Supply, to all patients who submit a **Warranty Registration**. THIS LIMITED WARRANTY WILL NOT BE ACTIVATED UNTIL THE WARRANTY REGISTRATION IS COMPLETED. Once this limited warranty is activated, PARI warrants that the eRapid and its parts will be free from defects in workmanship and materials for a period of twenty four (24) months, from the date of first retail purchase of the equipment. This warranty does not cover failures of the Handset, Aerosol Head, or accessories. This warranty does not extend to failures resulting from accident, misuse, abuse, alteration, use of unauthorized service parts, or cleaning solutions, or failure to comply with the Instructions For Use. If the warranted equipment should fail during the warranty period, PARI, at its option, will repair or replace the equipment or parts at issue, provided the claim is bona fide. It shall be the responsibility of the purchaser to pack and return the equipment in a manner to avoid shipping damage. The shipment must be prepaid to PARI. This warranty covers the cost of labor incurred in the removal or replacement of the warranted component parts at PARI. To make a claim under this warranty, notify the authorized service center by calling PARI Patient Connection at: **1.804.253.7274**. THERE ARE NO OTHER EXPRESS WARRANTIES. ALL IMPLIED WARRANTIES ON THE ERAPID AND ITS PARTS, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE LIMITED TO TWENTY FOUR (24) MONTHS FROM THE DATE OF FIRST RETAIL PURCHASE. ALL EXPRESS OR IMPLIED WARRANTIES ON ANY OTHER PARTS, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE DISCLAIMED. Some states do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you. The sole and exclusive remedy under this warranty is to replace the eRAPID and/or its parts at the option of PARI. IN NO EVENT SHALL PARI Respiratory Equipment, Inc. BE LIABLE FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES TO THE PURCHASER OR ANY THIRD PARTY, INCLUDING WITHOUT LIMITATION, DAMAGES ARISING FROM LOST PROFITS, LOSS OF BUSINESS OPPORTUNITY, LOSS OF PROPERTY, ECONOMIC LOSSES, OR STATUTORY OR EXEMPLARY DAMAGES, WHETHER IN NEGLIGENCE, WARRANTY, STRICT LIABILITY OR OTHERWISE. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitations or exclusions may not apply to you. This warranty gives you specific rights, and you may also have other rights which vary from State to State.

For patent information see: www.PARI.com/ip



Manufactured by
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