INSTRUCTIONS FOR USE

RX ONLY

Zirela®
nebulizer system

⚠ WARNING

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

Read and understand the Patient Medication Information Leaflet for information and warnings related to the drug Quinsair. The Patient Medication Information Leaflet is contained in the Quinsair Box.



eFlow® TECHNOLOGY

For use only with Quinsair® (levofloxacin inhalation solution)

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A. INTRODUCTION

The Zirela® Nebulizer System (Zirela®) is a lightweight, battery operated electronic nebulizer which will convert Quinsair® (levofloxacin inhalation solution) into an aerosol mist. Quinsair is placed in a reservoir, which feeds to a stainless steel membrane that has been laser-drilled to form microscopic holes. When this membrane is vibrated, it forces liquid through the holes to form an aerosol mist.

These Instructions For Use contain information and safety precautions for the Zirela Nebulizer System for use with Quinsair only. DO NOT USE ANY OTHER MEDICATION IN THE ZIRELA NEBULIZER SYSTEM OTHER THAN QUINSAIR.

Before using your Zirela 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** and **WARNING**.

INDICATIONS FOR USE

The Zirela Nebulizer System is intended specially for the aerosolization of Quinsair (levofloxacin inhalation solution) using vibrating membrane technology. The device is intended for adults who have been prescribed Quinsair, and may be used in hospitals, hospital-type facilities, nursing homes, sub-acute institutions, and home environments.

READ ALL DANGERS AND WARNINGS BEFORE USING

⚠ DANGER

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

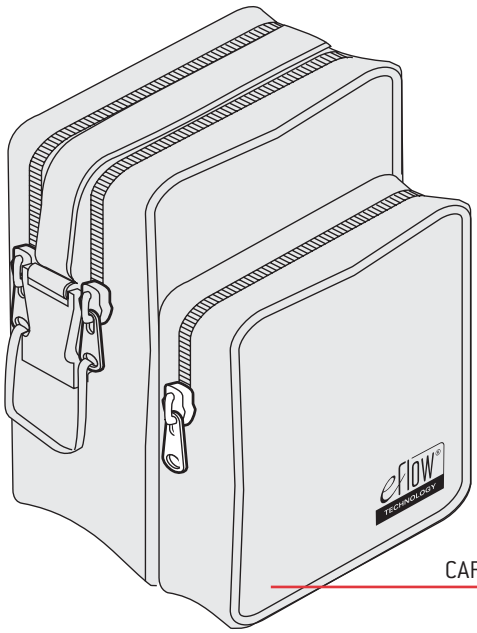
1. DO NOT place or store your Zirela where it can be in water or fall into a bathtub, sink, or other liquid. Do not place or drop into water or other liquid. Do not use while bathing.
2. DO NOT reach for the Zirela if it has fallen into water or other liquid. Unplug immediately. Retrieve your Zirela ONLY after it has been unplugged.

⚠ WARNING

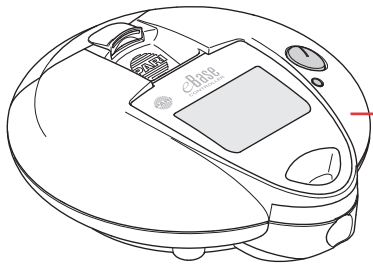
1. The Zirela Nebulizer Handset (Handset) is for use only by one patient. DO NOT SHARE your Handset with any other people.
2. The Handset is designed only for use with Quinsair (levofloxacin inhalation solution). To reduce the risk of severe or fatal injury/illness from improper treatment, NEVER USE OTHER MEDICATIONS IN THE ZIRELA NEBULIZER HANDSET.
3. Read, understand, and follow all warnings and instructions in the Instructions For Use prior to using this device.
   a. To reduce the risk of damage and malfunction of the unit that could result in serious or fatal injury from electrocution, fire, and burns; 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 drop or insert any object into any opening on your Zirela.
   e. DO NOT operate where oxygen is being administered in a closed environment such as an oxygen tent.
4. Always unplug this product immediately after using and before cleaning.
5. Before use, check your Zirela for proper assembly. All parts must be connected and firmly in place. Use of an improperly assembled Zirela could diminish or eliminate the effectiveness of the treatment.
6. Use ONLY adapters and accessories that are authorized for the Controller. Use of unapproved adapters and accessories can lead to improper treatment, injury, or damage to the Controller.
7. This Handset has unique performance characteristics and should NEVER be substituted for other eFlow Technology Handsets (e.g. Altera®, eRapid®) or Investigational eFlow Handsets.
8. NEVER use the Zirela Aerosol Head (Aerosol Head) with any other eFlow Technology Handset or eFlow Technology System (e.g. Altera, eRapid, Investigational eFlow). The Aerosol head has its own unique performance characteristics for Quinsair.
9. NEVER operate the Controller if it is not properly and completely assembled. Do not use if the Controller is damaged. See Section K: Troubleshooting, for the alerts that show when the Controller is damaged or not properly assembled.
10. 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.
11. To reduce the risk of infection, illness, and/or injury from contamination, clean and dry all parts of the Handset before you first use it and after each treatment. Follow the instructions in Section G and H to maintain and clean the Handset properly.
12. 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 the instructions in Section H to clean the Aerosol Head.
13. Cleaning the Handset only removes the medication. To reduce the risk of serious or fatal illness caused by contamination of the Handset, YOU MUST ALSO DISINFECT THE HANDSET AT THE END OF EVERY TREATMENT DAY. In addition, DISINFECT BEFORE FIRST USE. See Section I for disinfection instructions.
14. ONLY use cleaning and disinfecting procedures described in this document. PARI has tested these procedures specifically for Zirela. Use of other methods may damage your Handset.
15. This product contains small parts that may present a choking hazard to small children.
16. The Zirela Connection Cord (Connection Cord) may present a strangulation hazard.
17. Keep the Handset level when in use. Excessive tilting can cause the Controller to shut off leaving unused Medication in the Medication Reservoir.
18. Close supervision is necessary when this product is used near children or the physically or mentally impaired.
19. DO NOT use your Zirela while driving or in any situation which takes away your full attention.
20. If you suspect that your Zirela has been damaged or is not working correctly, call the number below.
21. 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.
22. DO NOT use the device in areas exposed to elevated electromagnetic or electrical radiation such as a MRI scanner or high frequency surgical equipment.
23. DO NOT place near other medical devices during operation unless both devices are monitored constantly to insure both are operating properly.
24. DO NOT use within 12 inches (30 cm) of portable wireless communication devices such as cell phones or antenna cables or external antennas.
25. DO NOT use near airplane or train control systems. Do not used aboard aircraft.
26. 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 Pharma GmbH or on the Internet at https://www.pari.com/fileadmin/Electromagnetic-compatibility-4.pdf

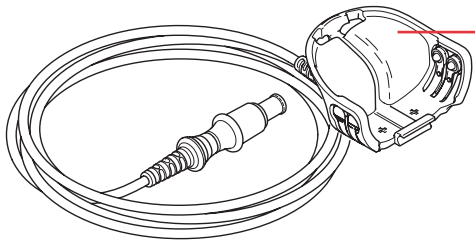
Check your Zirela package. Your Zirela System should have all items shown. Your Zirela Handset will only have the items in the box labeled "Handset Components".



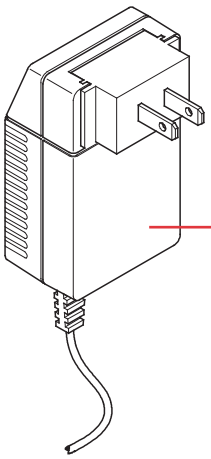
CARRYING CASE



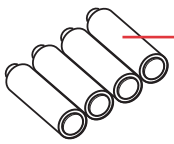
EBASE CONTROLLER



CONNECTION CORD



AC POWER SUPPLY

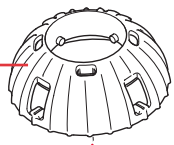


FOUR "AA" BATTERIES

HANDSET COMPONENTS



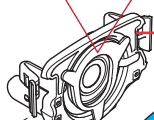
MEDICATION CAP
(NOTE: THE CAP SEAL AND CAP WILL COME AS ONE ASSEMBLED PART)



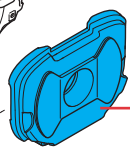
CAP SEAL



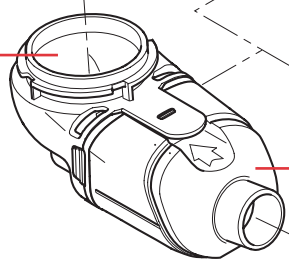
AEROSOL HEAD



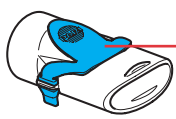
BLUE VALVE



MEDICATION RESERVOIR



AEROSOL CHAMBER



MOUTHPIECE WITH BLUE FLAP

D USING BATTERIES OR THE AC POWER SUPPLY

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

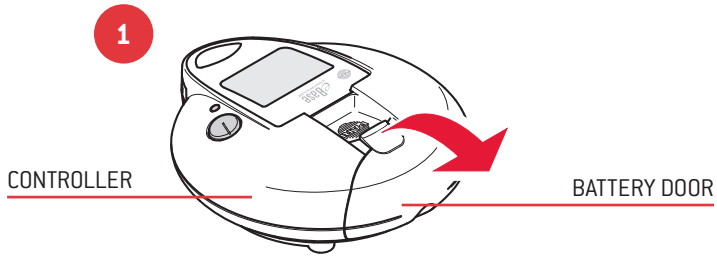
Using Batteries. Four (4) new "AA" batteries will provide approximately 2 hours of continuous treatment. You may also use "AA" rechargeable batteries.

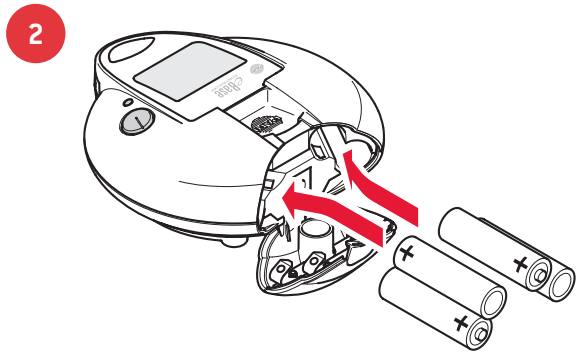
1. **Open the Battery Door** on the Controller by placing your thumb on the tab of the Battery Door and firmly pushing the tab to open the Door (Figure 1). Note that the Battery Door is designed to have a tight fit.
2. **Load the Batteries.** Each battery chamber has a small figure that shows the proper position of each battery (Figure 2). 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.
3. **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 of 2 hours is based on high quality disposable batteries that meet the specifications listed in Section L—Specifications. 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.

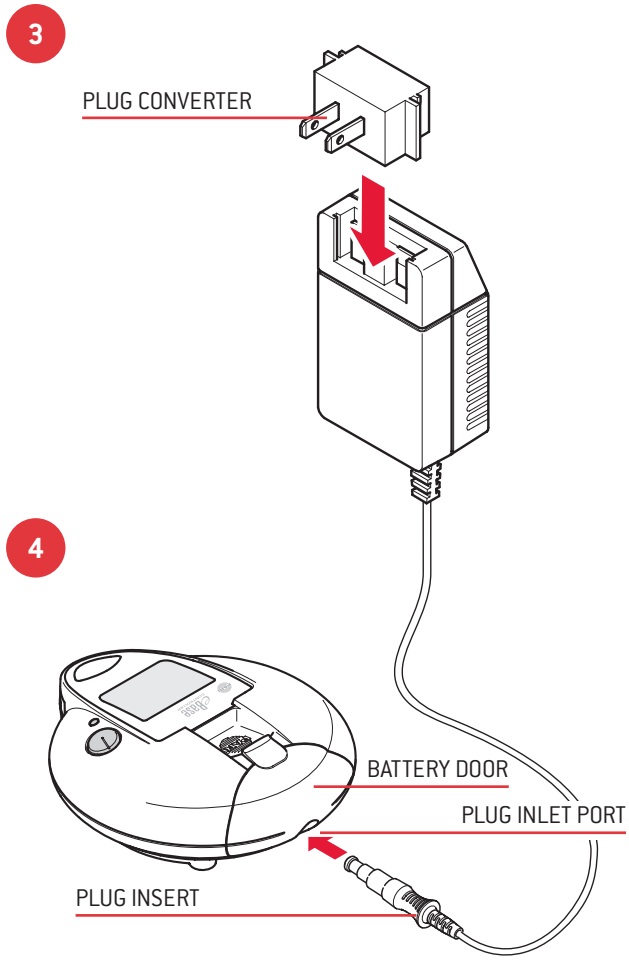
IT IS STRONGLY RECOMMENDED TO HAVE AN EXTRA BATTERY SET WITH YOU AT ALL TIMES.

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 (Figure 3) can be used with 100-240V outlet and will automatically adjust to the incoming voltage.

1. **Insert the Plug Converter** into the AC Power supply if it is not already attached (Figure 3).
2. **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 4). DO NOT ATTEMPT TO INSERT THE AC POWER CORD INTO THE FRONT OF THE CONTROLLER.
3. **Plug the AC Power Supply into the wall outlet.** Note that the AC Power Supply will not charge the Batteries in the Controller.







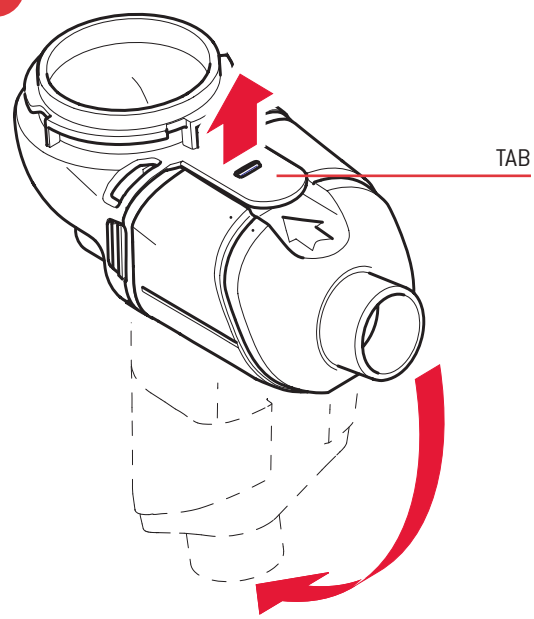
⚠ WARNING

Clean and disinfect your 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.

CLEAN AND DISINFECT YOUR HANDSET BEFORE USE! SEE PAGES 12 - 15.

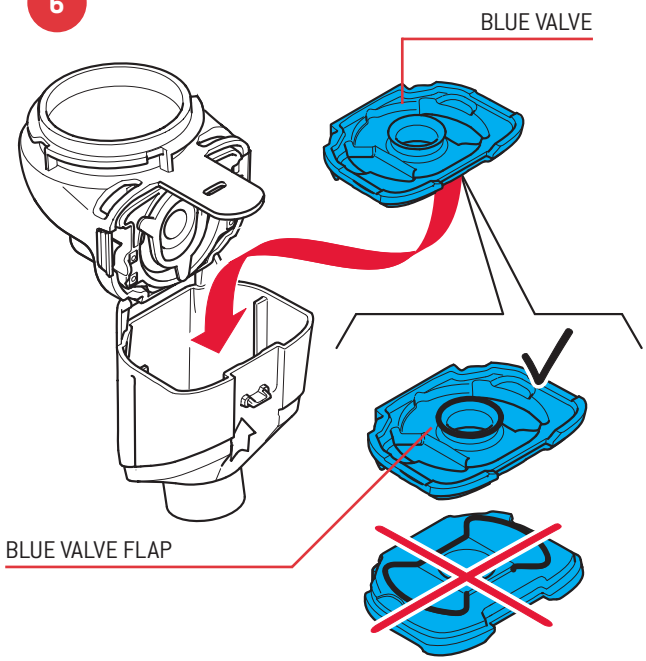
1. **Clean and disinfect** the Handset before first use.
2. **Wash your hands.**
3. **Open the Handset.** The Medication Reservoir and the Aerosol Chamber are attached using a "hinge". First, gently pull up on the tab of the Medication Reservoir (Figure 5). This will release the Aerosol Chamber so that you may open it.

5



4. **Place the Blue Valve** on top of the Aerosol Chamber making sure the two blue valve flaps are positioned down as shown in Figure 6.

6



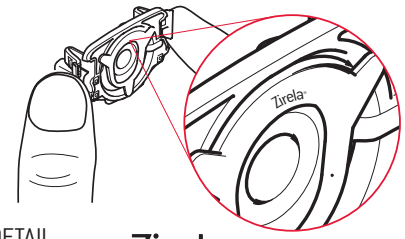
5. **Insert the Aerosol Head** making sure that it is marked as Zirela (Figure 7, detail). **Do not use other Aerosol Heads in this device.** Being careful to touch ONLY the plastic outer ring of the Aerosol Head, squeeze the two flexible plastic arms on the side of the Aerosol Head (Figure 8) together while firmly inserting two plastic tabs and two metal prongs into the four 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 9).

DO NOT TOUCH THE METAL PART OF THE AEROSOL HEAD.

6. **Close the Handset** by pushing the Aerosol Chamber together with the Medication Reservoir until you hear a slight "snap" (Figure 10). If you do not hear a slight snap, open the Handset and check that the Blue Valve is seated properly.

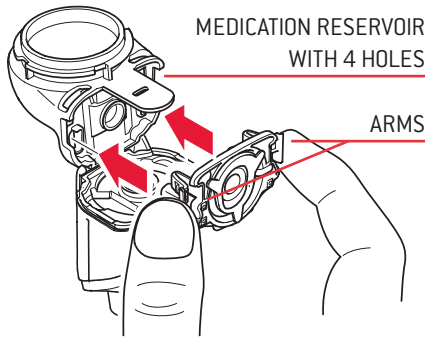
7. **Attach Mouthpiece to Handset.** Make sure the Blue Flap is facing up (Figure 11) and is pressed in the slot on the Mouthpiece.

7

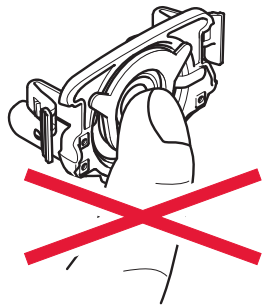


AEROSOL HEAD DETAIL Zirela

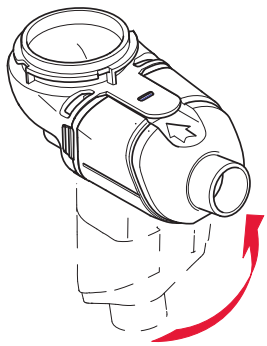
8



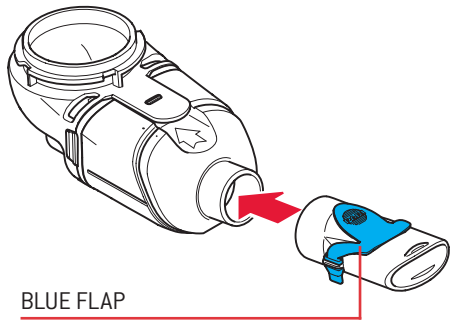
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10

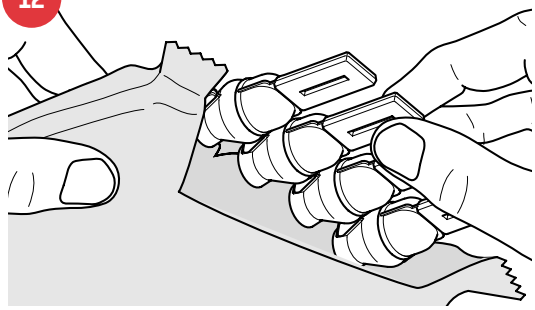


11



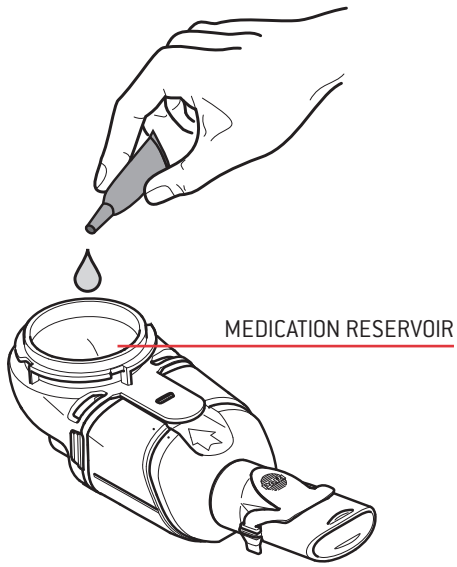
1. **Wash your hands.**
2. **Take Quinsair exactly as prescribed by your doctor.** Quinsair is supplied in ampoules. Inhale the contents of one ampoule (240 mg levofloxacin) twice a day using the Zirela Nebulizer System. It typically takes about 5-7 minutes to inhale the medicine using the nebulizer.
3. **Detach the ampoule from the card** and twist off the top tab (Figure 12).

12



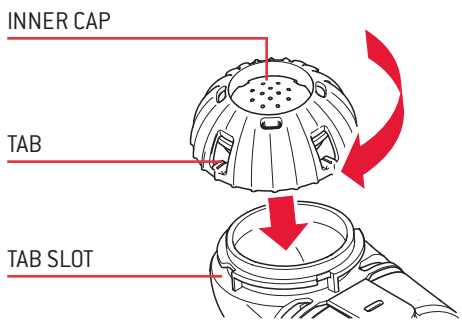
4. **Squeeze Quinsair into the Medication Reservoir.** Make sure the Handset is on a flat, stable surface. Tap the ampoule on the side of the Medication Reservoir if there is any remaining liquid in the ampoule. Pour only Quinsair into the Medication Reservoir of the Zirela (Figure 13). **DO NOT USE ANY OTHER MEDICATION IN YOUR HANDSET.**

13



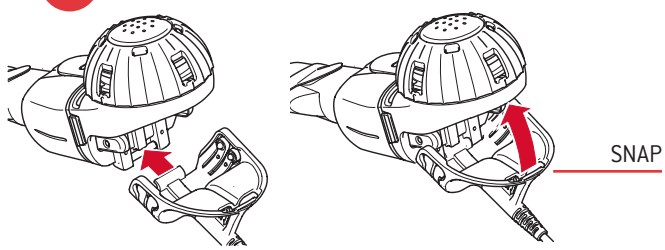
5. **Close the Medication Cap** by aligning the Tabs on the Medication Cap with the Tab Slots on the Medication Reservoir and turning the Medication Cap clockwise until it stops (Figure 14). As the Medication Cap is turned, the inner part of the Medication Cap should rise.

14



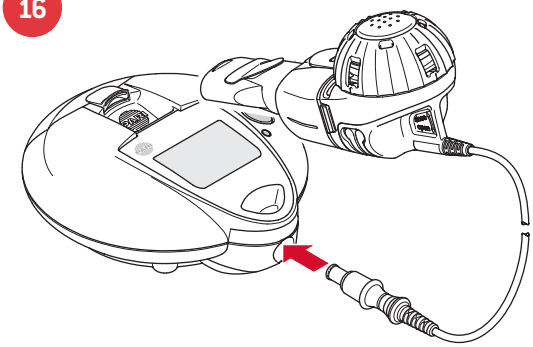
6. **Attach the Connection Cord** by aligning the bottom of the Connector with the bottom of the Handset and lifting until the Connection Cord snaps into the rear underside of the Medication Reservoir (Figure 15).

15



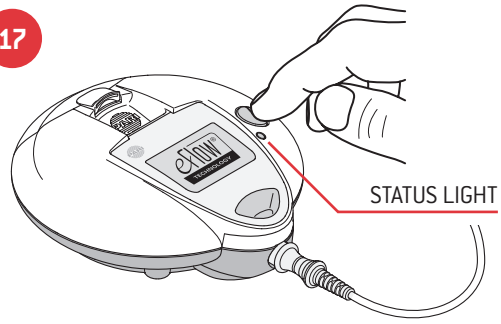
7. **Attach the Connection Cord to the Controller.** Place the Controller on a clean, flat, stable surface. Attach the Connection Cord round end to the front of the Controller (Figure 16).

16



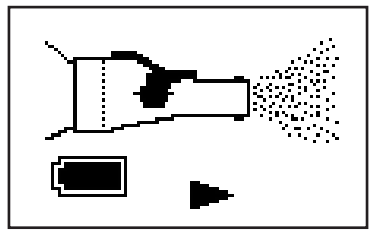
8. **Turn on the Controller.** To begin your treatment, sit in a relaxed, upright position. Press and hold the On/Off button for a few seconds (Figure 17). You will hear one "beep" and the status light will illuminate green. The eFlow Technology logo will appear on the screen. The Zirela Nebulizer system is now running.

17



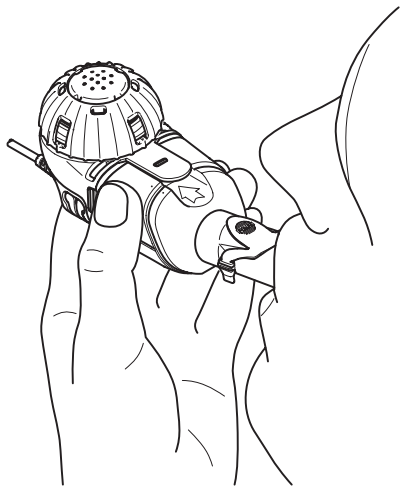
9. After a few seconds
   a. Aerosol mist will begin to flow into the Aerosol Chamber of the Handset.
   b. Your Controller will display the TREATMENT SCREEN (Figure 18) if the Zirela Nebulizer system is assembled correctly and working properly. Note that this example screen shows the Controller is powered by batteries.

18



10. **Place the Mouthpiece on top of your bottom lip and tongue and close your lips around it** (Figure 19). Hold your Handset level. If held at an angle over 45 degrees for more than 30 seconds, the Zirela Nebulizer system will sound two beeps, display a check mark (Figure 20), and shut off. If this occurs, hold your Handset level and press the On/Off Button to complete the treatment.

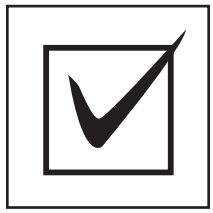
19



11. **Breathe normally** in and out through the Mouthpiece. Do not breathe through your nose. Continue to inhale and exhale comfortably until the treatment is finished.

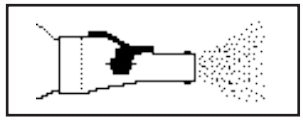
12. **At the end of Treatment, the Controller will shut off automatically.** Do not shut off the Controller during a treatment. When all of the Quinsair has been delivered:
    a. You will hear two beeps
    b. The Dose Complete Checkmark will appear briefly on the screen (Figure 20).
    c. Then the Controller will automatically shut off.

20

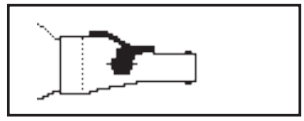


NOTE: If, for any reason, you must PAUSE your treatment, press the Controller On/Off Button for one full second. The PAUSE function is activated when the LED flashes GREEN and the Controller display switches from the TREATMENT screen to the PAUSE screen (Figure 21). When you are ready to resume your treatment, press the Controller On/Off Button again for one full second. The treatment will resume when the LED remains a steady GREEN and the Controller display switches back to the TREATMENT screen.

21



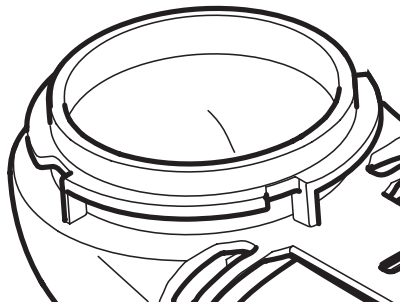
Treatment—With Mist



PAUSE—No Mist

13. **At the end of treatment, check to confirm that no more than a drop of medication remains**. After you have completed the treatment, open the Medication Cap to ensure that no more than a drop of Quinsair remains in the Medication Reservoir (Figure 22). If more than a drop of Quinsair remains, replace the Medication Cap and press the On/Off button to restart your treatment. DO NOT add any more Quinsair to the Medication Reservoir until your next regular treatment time.
14. Once the treatment is complete, disassemble the Handset for Cleaning. Refer to Section H for cleaning instructions.

22



RINSE AND CLEAN YOUR HANDSET AFTER EACH USE!

⚠ WARNING

To reduce the risk of infection, illness, and/or injury from contamination and/or improper use, IT IS IMPORTANT TO:

- **CLEAN and DISINFECT your HANDSET BEFORE FIRST USE.**
- **RINSE and CLEAN your HANDSET IMMEDIATELY AFTER EACH USE (see Section H).**
  a. Do not wash the Controller, Connection Cord or AC Power Supply.
  b. Use clear liquid soap designed for washing dishes.
  c. Do not use "white" liquid dish soaps or antibacterial liquid soaps as these may contain additives harmful to the Aerosol Head.
  d. Use only distilled water to disinfect by boiling.
  e. Follow manufacturer directions when using a chemical disinfectant, such as Control III®.
- **DISINFECT YOUR HANDSET at the end of EVERY TREATMENT DAY (see Section I).**

⚠ CAUTION

- **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.**

HANDSET MAINTENANCE SUMMARY

INSTRUCTION	WHEN	PARTS CLEANED	METHOD	HOW LONG	COMMENTS
Rinse	After each use	• Aerosol Head Medication Cap & Seal • Blue Valve • Reservoir & 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	• Aerosol Head • Medication Cap & Seal • Blue Valve • Reservoir & Chamber • Mouthpiece	Soak in warm soapy water.	5 minutes	Soak longer if Handset has dried or if visibly dirty.
Disinfect	End of every treatment day	• Aerosol Head • Medication Cap & Seal • Blue Valve • Reservoir & Chamber • Mouthpiece	Boil in distilled water *or* ———— Soak in Control III disinfectant.	5 minutes ———— 10 minutes	———— Rinse thoroughly after disinfecting with Control III.

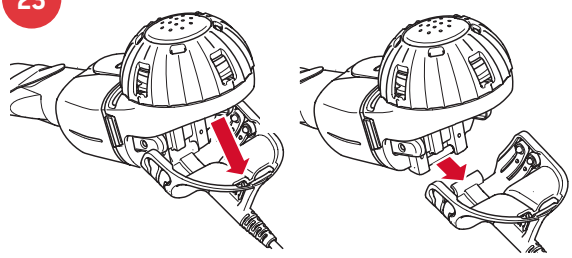
CLEANING YOUR HANDSET

⚠ WARNING

Contamination and moisture may encourage the growth of bacteria and residual medication can clog the small holes on the aerosol head and affect performance. Therefore, it is important to **rinse and clean your Handset immediately after every use.**

1. **Disconnect the Handset** from the Connection Cord (Figure 23).

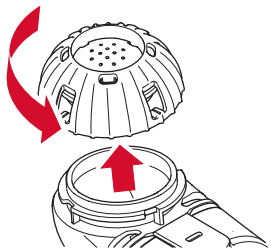
23



2. **Disassemble the Zirela Handset:**

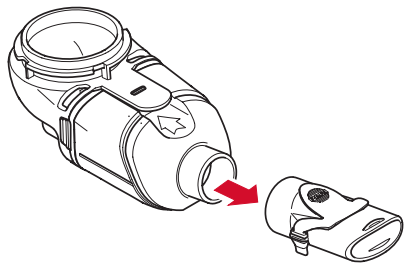
   a. **Remove the Medication Cap** from the Medication Reservoir (Figure 24).

24



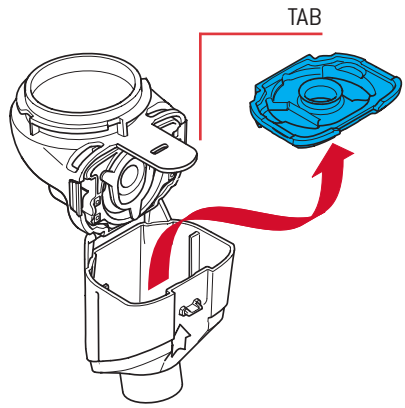
   b. **Remove the Mouthpiece** from the Aerosol Chamber (Figure 25).

25



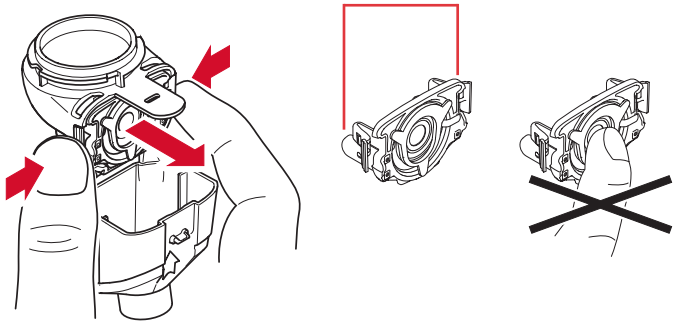
   c. **Remove the Blue Valve.** Gently pull up on the tab of the Medication Reservoir. This will release the Aerosol Chamber so that you can open it and remove the Blue Valve (Figure 26).

26



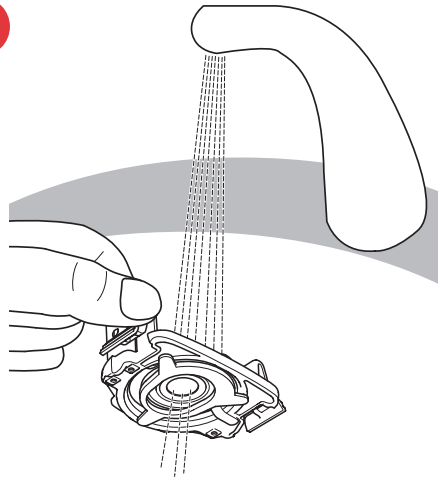
d. **Remove the Aerosol Head.** Be careful to touch ONLY the plastic outer ring of the Aerosol Head, press the two flexible plastic arms on the side of the Aerosol Head and remove (Figure 27). **DO NOT TOUCH THE CENTER METAL PART OF THE AEROSOL HEAD.**

27



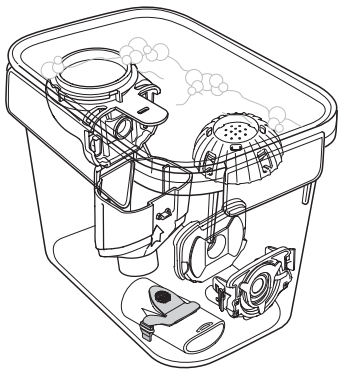
3. **Rinse each of the disassembled parts** under warm (approximately 104°F / 40°C) running tap water to remove residue (for approximately 10 seconds). **Note: THERE IS NO NEED TO DISASSEMBLE THE MEDICATION RESERVOIR FROM THE AEROSOL CHAMBER FOR CLEANING.**
4. **Rinse the Aerosol Head for at least 10 full seconds** on each side (Figure 28). Never use a brush or any other object to clean the aerosol head. **THOROUGH RINSING OF BOTH SIDES OF THE AEROSOL HEAD HELPS TO PREVENT CLOGGING AND ENSURE PROPER OPERATION.**

28



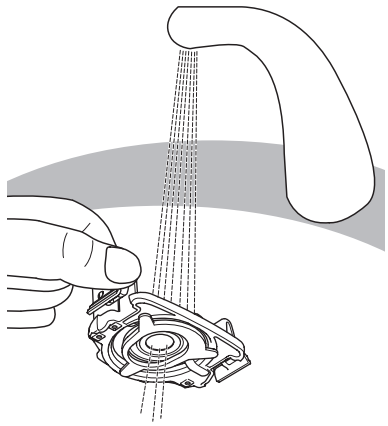
5. **Soak all parts of the Handset in warm soapy water for 5 minutes** made by adding about ¼ teaspoon of clear liquid dish soap and 1 quart of warm tap water to a clean tub or bowl (Figure 29).

29



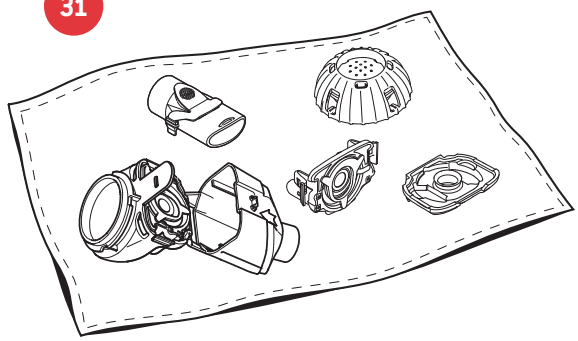
6. **Inspect** all parts to confirm they are clean. If they are not clean, soak them in warm soapy water for an additional 5 minutes.
7. **Rinse all parts thoroughly** under warm running tap water (Figure 30).

30



8. **Air dry parts** on a clean, lint-free cloth or paper towel (Figure 31). 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. This is to ensure the Blue Valve and seals do not become deformed over time.

31



⚠ WARNING

- **Never let the Controller come in contact with water or cleaning agents.**
- **If liquid does get into the Controller, call the number below.**

CLEANING YOUR CONTROLLER AND CONNECTION CORD

9. **Switch off the Controller.** Remove the Connection Cord and AC Power Supply from the Controller.
10. **Clean the Controller** housing and Connection Cord with a damp cloth.

For disinfection, turn to the next page

⚠ WARNING

To reduce the risk of serious or fatal illness or injury caused by contamination, disinfect the Handset at the end of every treatment day.

1. **Clean the Handset at the end of every treatment** with soapy water as described in Section H.
2. **Disinfect the Handset at the end of every treatment day** with the commercially available medical device disinfectant Control III or by boiling in distilled water.
   a. **To disinfect with disinfectant,** mix ½ tablespoon of Control III solution to 1 quart of water in a clean bowl and soak parts for 10 minutes. Remove parts from solution and rinse thoroughly with sterile water.
   b. **To disinfect with boiling water,** boil the parts, including the Aerosol Head, in a clean pot of distilled water for a full 5 minutes.
3. **Dry on a lint-free cloth or paper towel.** 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. This is to ensure the Blue Valve and seals do not become deformed over time.

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

ANSWER: Only a drop of Quinsair should remain in the Medication Reservoir after the treatment. If more than a drop remains, clean the Aerosol Head (Section H). If after proper cleaning, there remains more than a drop in the Medication Reservoir, call the number below.

QUESTION 2: How long should each treatment take?

ANSWER: With normal operation and proper cleaning, the Zirela should deliver Quinsair within 5 to 7 minutes. If your treatment takes more than 10 minutes, clean and disinfect your handset and 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 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 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 Zirela has been assembled correctly (Section E). Third, check the Controller LCD to see if the Pause Function has been activated (Figure 21). Lastly, check to be sure Quinsair is in the Medication Reservoir. If, after cleaning the Aerosol Head, your Zirela still does not function properly, call the number below.

QUESTION 6: 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 Zirela. Use of other methods may damage your Handset.

QUESTION 7: 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 (Section E4), (2) the Aerosol Head is inserted correctly (Section E5), (3) the Medication Cap is screwed on correctly (Section F5), and (4) the Medication Reservoir and the Aerosol Chamber are closed properly and snapped together (Section E6).

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

QUESTION 8: 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 the number below.

QUESTION 9: 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 and you have been cleaning the handset, call the number below.

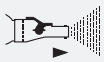
QUESTION 10: How long will my Zirela last?

ANSWER: The controller is warranted for 2 years with appropriate care. Keep your controller until your doctor says you will no longer be on Quinsair therapy. Remove the batteries when storing the controller for more than 30 days. The handset should last for at least one month with appropriate maintenance. A new handset will come with each supply of Quinsair.

QUESTION 11: What should I do with my old Zirela?

ANSWER: Clean and disinfect your handset and then dispose in normal municipal trash. Dispose the batteries following your local municipality guidelines. Dispose or recycle the controller with other electronic equipment.

K 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 is flashing, 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 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 and this symbol is blinking.	No Medication. Add medication if you have not done so. Not level or medication 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, the LED flashes, this symbol blinks on the LCD, and then turns off.	Have reached 20-minute maximum time and will shut down. If Medication 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. 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.	No Quinsair remaining, treatment done. If Quinsair is remaining; the Handset may have been tilted. Keep Handset level (± 45°), 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 medication 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 medication is completely consumed.	Lost power. Replace batteries or use AC Power Supply. Tilted Handset. Keep Handset level (± 45°), gently tap Handset and press the On/Off button.
15	The device does not stop automatically after all medication is consumed.	Clean the Aerosol Head. If condition persists, call the number below.
16	Longer than normal nebulization time.	Clean the Aerosol Head. If condition persists, call the number below.
17	Handset leaks.	Confirm the Blue Valve is placed correctly in the Handset and the two flaps point into the Handset Chamber (see Section E). 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 medication and on your breathing pattern.
18		The On/Off button was accidently pressed for 10 seconds, which activated the easycare function. The easycare is an accessory that is not used on this model. Press the On/Off button briefly to turn off the Controller and discontinue the easycare function.

L SPECIFICATIONS

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	110 - 240 V, 50/60 Hz
Power Wattage	2.0 Watts under normal load
Minimum Fill	0.5 mL
Maximum Volume Fill	4 mL
OPERATION / STORAGE	
Controlled Room Temperature	68 - 77 °F (20 - 25°C)
BATTERIES	
High quality alkaline or lithium	1.5V
Battery Operation	approximately 2 hours of continuous treatment

Expected useful life

The controller is expected to last for at least 2 years with appropriate care. With appropriate maintenance, the handset is expected to last one month. A new handset is provided with each monthly kit of Quinsair.

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 adapter and connection cord can be disposed or recycled with other electronic equipment.

Warranty.

PARI Respiratory Equipment, Inc. (PARI) will offer a two (2) year limited warranty on the Zirela 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 Zirela 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 ZIRELA 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 ZIRELA 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.

Manufactured by:

PARI Respiratory Equipment, Inc.
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Midlothian, Virginia 23112 USA

Online at: www.PARI.com

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