INSTRUCTIONS FOR USE

For single patient use (one person) only



INCLUDES INSTRUCTIONS FOR THE PARI LC® PLUS NEBULIZER IMPORTANT: READ INSTRUCTIONS AND SAFETY PRECAUTIONS BEFORE USE



READ ALL WARNINGS AND INSTRUCTIONS BEFORE USE. USE THE PRODUCT ONLY FOR ITS INTENDED USE AS DESCRIBED IN THESE INSTRUCTIONS FOR USE. IMPROPER USE CAN RESULT IN SERIOUS OR FATAL ILLNESS/ INJURY, IMPROPER TREATMENT OR PROPERTY DAMAGE.





Welcome to the Vios<sup>®</sup> PRO experience! The Vios<sup>®</sup> PRO Aerosol Delivery System is designed from PARI's long legacy of clinically proven products and consists of two important components: a Vios<sup>®</sup> PRO compressor and a PARI nebulizer. Vios<sup>®</sup> PRO was inspired by the Latin and Greek words for "Life" and our goal is to improve your quality of "Life" through the efficient delivery of aerosol.

Your physician has prescribed the Vios<sup>®</sup> PRO to treat your respiratory symptoms because of PARI's reputation for consistent particle size and fast treatments resulting in targeted delivery to the lungs. PARI products have been used in more than 25 clinical trials for new nebulized medications. Designed with the patient in mind, these instructions will help you achieve the best aerosol therapy experience.

We hope the Vios<sup>®</sup> PRO experience allows for a "Life Inspired".

# SAVE THESE INSTRUCTIONS FOR FUTURE USE

#### INDICATIONS FOR USE: LC® PLUS

The PARI LC<sup>®</sup> Plus reusable nebulizer is used to deliver aerosolized medication to the lungs. This nebulizer is used with patients for whom a physician has prescribed medication for aerosol treatments in the home, doctor's office, hospital, or clinic.

# A. SAFETY PRECAUTIONS - LC<sup>®</sup> PLUS

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US Federal Law restricts this device to sale by or on the order of a physician. Use only when prescribed by a physician and with the prescribed medication.

The LC<sup>®</sup> Plus is a handheld nebulizer, designed to aerosolize medication approved for nebulization and prescribed by a physician. The LC<sup>®</sup> Plus is intended for adult and pediatric patients consistent with the indications for the aerosol medication. Improper use can result in serious or fatal illness or injury. Nebulizer is not sterile.

# WARNING

Use only when prescribed by a physician and with the prescribed medication. In order to achieve the specified droplet characteristics the compressor or central air supply must provide 3.5 - 8 lpm at a minimum of 20psi.

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- To reduce the risk of increased bacterial growth, infection, illness, or injury from contamination: thoroughly clean and dry all parts of the nebulizer and thoroughly dry any moisture or condensation in the tubing at the end of every treatment following the instructions below.
- Cleaning the nebulizer after each treatment is not enough---you must regularly disinfect or sterilize the nebulizer between treatments to prevent serious or fatal illness caused by contamination of the nebulizer.
- 3. Never use a nebulizer with a clogged nozzle. If the nozzle is clogged, the aerosol mist will be reduced, altered or stopped, which will diminish or eliminate the effectiveness of the treatment. If clogging occurs, replace with the same model PARI Reusable Nebulizer.
- 4. Close supervision is necessary when this product is used by or near children and physically or mentally impaired. Never use when sleeping or drowsy.
- 5. This product contains small parts that may present a choking hazard to small children. The tubing also presents a strangulation hazard. ALWAYS USE CLOSE ADULT SUPERVISION WHEN ADMINISTERING A TREATMENT TO A CHILD. DO NOT LEAVE CHILD UNATTENDED DURING TREATMENT.
- 6. Patients under the age of 4 or any patients who have special needs should use a facemask instead of the valved mouthpiece.
- Before use, check PARI Reusable Nebulizer for proper assembly. All parts should be seated firmly in place. Use of an improperly assembled nebulizer could diminish or prevent adequate delivery of medication and the effectiveness of the treatment.

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#### INDICATIONS FOR USE: VIOS® PRO AEROSOL DELIVERY SYSTEM

The Vios<sup>®</sup> PRO is a light weight compressor for use with PARI Nebulizers. The Vios<sup>®</sup> PRO Compressor is intended for adult and pediatric patients for use in hospital, clinic, or home environments.

# B. SAFETY PRECAUTIONS - VIOS® PRO AEROSOL DELIVERY SYSTEM

### **WARNING**

Use only with nebulizers and tubing authorized by PARI for this device. Other nebulizers and tubing may result in improper treatment.

When using electrical and medical products, especially when children are present, basic safety precautions must be followed.

### A DANGER

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

- Do not place or store product where it can fall or be pulled into a bathtub, sink, water, or other liquid. Do not place in or drop into water or other liquid. Do not use while bathing.
- 2. Do not reach for a product that has fallen into water or other liquid. Unplug immediately.

## **A**WARNING

To reduce the risk of serious or fatal injury from electrocution, fire or burns and to reduce the risk of damage and malfunction to the product:

- Before use, check the serial number label on the bottom of the PARI Vios<sup>®</sup> PRO Compressor to ensure that the voltage and current indicated on the compressor label correspond to the voltage and current available.
- Never operate this product if it has a damaged cord or plug, if it is not working properly, if it has been dropped or damaged, or if it has been exposed to any liquids inside the case. Return the product to PARI for examination and repair.
- Keep all electrical cords away from heated surfaces. Do not overload wall outlets or use extension cords.
- 4. This appliance has a polarized plug (one blade is wider than the other). As a safety feature, this plug will fit in a polarized outlet only one way. If the plug does not fit fully in the outlet, reverse the plug.
- 5. Never block the air vents of this compressor or place it on a soft surface, such as a bed or couch, where the air vents may be blocked. Keep the air vents free of lint, hair, and similar substances. Blocked vents could cause excessive heat buildup. This product should never be left unattended when plugged in.

### **A**WARNING

- 6. Do not operate outdoors.
- Not suitable for use in the presence of flammable anesthetic mixture with air or oxygen or nitrous oxide.
- 8. Do not operate where oxygen is being administered in a closed environment such as an oxygen tent.
- 9. Never drop or insert any object into any openings.
- 10. Always unplug this product immediately after using.
- II. Be sure the PARI Vios® PRO Compressor is unplugged prior to cleaning.
- Do not open or disassemble the PARI Vios<sup>®</sup> PRO Compressor. Refer all servicing to PARI.

### **WARNING**

To reduce risk that the compressor will fail to operate properly as a result of decreased electromagnetic interference, resulting in improper treatment:

- Portable and mobile radio frequency ("RF") communication devices can disrupt electrical medical equipment.
- 2. Use only with accessories and cables authorized by PARI for this device. Use of this device with unauthorized accessories and cables may result in increased electromagnetic emissions or decreased electromagnetic immunity of the device.
- This device should not be used adjacent to, or stacked with other equipment. If adjacent or stacked use is necessary, this device should be observed to verify normal operation.

# C. GETTING STARTED Check your Vios® PRO package to ensure you have the following items. It is important to have a second PARI Reusable Nebulizer on hand at all times. 105 PRO FILTER Air Filter Air Outlet Power Switch PARI Reusable Nebulizer Holder Nebulizer Replacement Sticker Sheet Nebulizer Replacement Reminder Sticker REPLACE IN REPLACE IN JANUARY PARI Reusable Nebulizer (2 included) REPLACE IN FEBRUARY REPLACE IN AUGUST REPLACE IN MARCH REPLACE IN SEPTEMBER REPLACE IN APRIL REPLACE IN OCTOBER REPLACE II MAY REPLACE IN NOVEMBER Inspiratory Valve Cap REPLACE II JUNE REPLACE IN DECEMBER Nebulizer Insert Nebulizer Semi-Circle Alignment Rings Nebulizer Outlet Mouthpiece with Expiratory Valve Nebulizer Cup Nebulizer Replacement Sticker Suggested Placement Air Intake Vios<sup>®</sup> PRO Tubing



# D. VIOS® PRO SET-UP

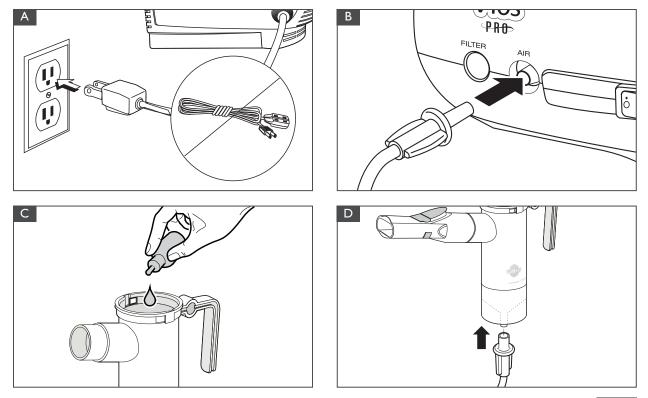
You are 10 Steps away from starting your treatment with  $Vios^{\circledast}\,PRO.$  Please follow step by step.

- Clean/Disinfect Nebulizer Cup: Refer to Sections E-F to properly clean and/or disinfect your nebulizer prior to first use. Re-assemble nebulizer.
- Set-up Compressor: Place the compressor on a flat, stable surface free of dust. Avoid cushioned, upholstered or carpeted surfaces. Make sure power switch is turned to O, the "OFF" position. Plug power cord into wall outlet (Fig A).
- Connect Tubing To Compressor: Insert one end of tubing to the air outlet on the compressor. It should fit snugly (Fig. B).
- 4. Load Medication: Remove the nebulizer insert by twisting counter-clockwise until it stops and lift up. Pour medication into the nebulizer cup. Never fill past the max fill line of 8ml (Fig. C). Replace the nebulizer insert making sure the two alignment rings are lined up with each other.
- 5. Attach Mouthpiece or Mask: If using the mouthpiece, attach the mouthpiece to the nebulizer outlet with the expiratory valve facing up. Then attach the inspiratory valve cap by pressing it firmly into the top of the nebulizer. If using a mask, attach mask to the nebulizer outlet and refer to the mask instructions.
- Attach Tubing To Nebulizer Cup: Firmly press the other end of the tubing to bottom of PARI reusable nebulizer (Fig. D).

- 7. Starting Treatment: Sit in a relaxed, upright position and turn the compressor "ON" (☉).
- 8. Nebulizer Position: Place the mouthpiece on top of tongue and close lips around it. Take slow, deep breaths. As you inhale, the inhalation valve opens.
- 9. *Breathing:* For mouthpiece, inhale and exhale slowly through your mouth. As you exhale, the valve on the mouthpiece opens to allow the exhaled mist to escape. For mask, place mask over nose and mouth and inhale and exhale slowly.
- Complete Treatment: Continue until the medication is gone or you hear a slight "sputtering" sound. Turn compressor off O.

#### A NOTE ON TREATMENT TIME

Please note that many factors affect treatment time, such as a patient's age, condition, breathing pattern, and medication. The Vios<sup>®</sup> PRO was designed for intermittent use to deliver respiratory medications, not continuous use for humidification.



Questions? I.800.FAST.NEB (327.8632) | PARI.com/VIOSPRO EN-4

## E. CLEANING YOUR PARI REUSABLE NEBULIZER

- 1. Disconnect the tubing from the air intake on the bottom of the nebulizer cup.
- 2. If there is any moisture (condensation) in the tubing, let the compressor run with only the tubing attached for 2-3 minutes. The warm air from the compressor will dry out the tubing. Alternatively, you can dry the tubing by removing it from the compressor and hanging it up with the "ends down" to allow any moisture (condensation) to drain out and evaporate. Use a clean damp cloth to wipe the exterior of the tubing.
- 3. Disassemble reusable nebulizer parts as illustrated on page 3.
- 4. Wash all parts with warm water and liquid dish soap. DO NOT WASH THE TUBING.
- 5. Rinse the reusable nebulizer parts thoroughly with warm water and shake out water.
- 6. Air dry or hand dry nebulizer parts on a clean, lintfree cloth. Reassemble nebulizer when parts are dry and store.
- 7. You can also wash all parts of the reusable nebulizer on the top shelf of a dishwasher. DO NOT WASH TUBING. Place the reusable nebulizer parts in a dishwasher basket, then place the basket on the top rack of the dishwasher. Remove and dry the parts when the dishwasher cycle is complete.

# **WARNING**

TO REDUCE RISK OF INFECTION:

- 1. Nebulizer for single patient use (one person) only. Do not share your nebulizer with other patients.
- 2. You must regularly disinfect or sterilize the nebulizer between treatments. Failure to do so could lead to serious or fatal illness.

# F. DISINFECTING YOUR PARI REUSABLE NEBULIZER

- Clean the nebulizer as described in Section E. For low-level disinfection every other treatment day, soak all parts of the PARI Reusable Nebulizer (except tubing and mask) in a solution of 1 part distilled white vinegar and 3 parts hot tap water for 1 hour. You can substitute respiratory equipment disinfectant (like Control III<sup>®</sup>) for distilled white vinegar (follow manufacturer's instructions for mixing).
- 2. Rinse all parts of the PARI Reusable Nebulizer thoroughly with warm tap water and dry with a clean, lint-free cloth. Discard the vinegar solution when disinfection is complete.
- 3. The PARI Reusable Nebulizer parts (except tubing and mask) may also be disinfected by boiling them in a clean pot of water for a full 5 minutes.
- Hospitals and clinics can sterilize the PARI Reusable Nebulizer parts (except mask and tubing) by autoclaving (a maximum of 277° F or 136° C), follow autoclave manufacturer's instructions.
- 5. Dry parts on a clean, lint-free cloth.

CONTROL  $\mathrm{III}^{\circledast}\,$  is a registered trademark of Maril Products, Inc.

VIOS <sup>®</sup> PRO REPLACEMENT ITEMS	
	Part No.
LC <sup>®</sup> Sprint Reusable Nebulizer	023F35-VP
LC <sup>®</sup> Plus Reusable Nebulizer	022F8I-VP
Vios <sup>®</sup> PRO Tubing	041F4594
Vios® PRO Replacement Filter 2pk	085F0012P2
Note: Only use Vios® PRO tubing with the Vios® PRO Aerosol Delivery System	

# G. MAINTENANCE OF YOUR VIOS® PRO

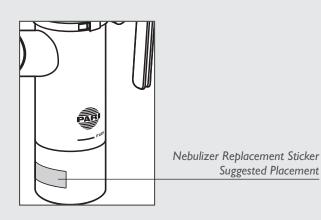
### FILTER

The Clear View<sup>™</sup> Filter on the front of the Vios<sup>®</sup> PRO Compressor was designed to be monitored without removing it. This makes it easy to check without much work. When the filter is new, it is bright white in color. With use, the filter will turn grey, indicating the need for replacement. The filter must be replaced immediately if it gets wet or becomes clogged. A good rule to follow is to replace your filter every 6 months - at the same time as your PARI reusable nebulizer.

For filter replacement, obtain the replacement filter set part # 085F0012P2 which includes the filter and the filter removal tool (Fig. E). Push the filter tool firmly over the filter and rotate the filter removal tool counter clockwise a full 8 turns until loose and pull the filter out (Figs. E and F). Discard the dirty filter and tool. The filter tool prevents unwanted removal of the filter or a lost filter.

Once the filter is removed, tilt the compressor so that the face of the unit is facing the floor. Gently tap on the back of the compressor to remove any unwanted materials from the filter area. Place the compressor on a stable surface and using clean hands, push a new filter into the filter receptacle.

**NOTE:** DO NOT ATTEMPT TO WASH AND REUSE AIR FILTERS. DO NOT USE SUBSTITUTE FILTER MATERIAL COMPRESSOR DAMAGE MAY RESULT.



#### COMPRESSOR

Use a damp cloth to wipe the exterior of your  $\mathsf{Vios}^{\circledast}\mathsf{PRO}$  housing and tubing.

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Never spray fluid into the ventilation slots on your Vios® PRO. Fluid could cause damage to the electrical & compressor parts and could lead to malfunction. In the event fluid enters the unit, please contact PARI Patient Connection at 1.800.FAST.NEB (327.8632).

#### MAINTENANCE & REPAIR

Never operate your Vios<sup>®</sup> PRO if it is improperly or incompletely assembled or damaged. Use only original PARI parts and attachments authorized by PARI for the Vios<sup>®</sup> PRO Aerosol Delivery System. Use of other parts and attachments may damage the unit or cause improper treatment. Do not open or disassemble the compressor unit at any time.

**NOTE:** THERE ARE NO SERVICEABLE PARTS INSIDE THE VIOS® PRO AEROSOL DELIVERY SYSTEM. SERVICE BY ANYONE VOIDS WARRANTY.

#### **! REMEMBER** REPLACE YOUR REUSABLE NEBULIZER CUP EVERY SIX MONTHS

It is very important to replace your PARI reusable nebulizer every 6 months for the most effective treatments.

Advantages of Replacing Your Nebulizer Cup:

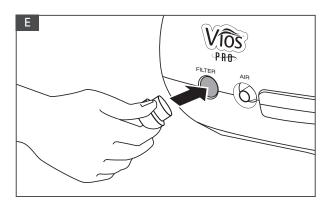
-Consistent medication delivery to the lungs -Fast and efficient treatments -Bacterial contamination can be reduced\*

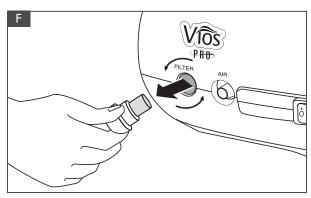
Included in this configuration is a reminder sticker. Place the sticker that corresponds to six months from date of first use to the smooth surface on the bottom of your nebulizer cup as indicated in this picture. Sticker is dishwasher safe.

Allow two hours after label is applied before cleaning.

**WARNING:** The sticker may present a choking hazard to small children-adult supervision is required.

\* Lester, Mary K. Nebulizer Use and Maintenance by Cystic Fibrosis Patients: A Survey Study. Respiratory Care 2004; 49(12): 1504-1508.





# H. SPECIFICATIONS

## **VIOS® PRO SPECIFICATIONS**

Weight:	
Dimensions:	
Electrical Requirements:	
Power Wattage:	
Ambient Operating Conditions:	
Power cord length:	

### TRANSPORT/STORAGE CONDITIONS:

Ambient temperature:40°C to 70°C, (-40°F to 158°F)	
Relative Humidity:	
Atmospheric Pressure:	

A

### EXPLANATION OF SYMBOLS

Attention: Read all "Instructions for Use" before operation:	<u> </u>
Insulation enclosed Class II equipment:	
Type "B" Protection from electrical shock:	Ϋ́
Do not dispose of in unsorted municipal trash. Please consult local laws and regulations for proper disposal:	
Power Switch:	ó o
"On" Position (compressor running):	0
"Off" Position (compressor is not running):	ċ

NOTE: WHEN SWITCH IS IN THE "OFF" POSITION AND THE COMPRESSOR IS NOT RUNNING, THERE WILL STILL BE ELECTRICAL POTENTIAL INSIDE THE COMPRESSOR HOUSING. TO REMOVE POWER FROM THE COMPRESSOR, THE POWER PLUG MUST BE REMOVED FROM THE POWER SOURCE.



# I. WARRANTY & RETURN INFORMATION

#### PARI LC® PLUS REUSABLE NEBULIZER LIMITED WARRANTY

PARI reusable nebulizers include a 6 month limited warranty for home care use. If you have any problems and need to return your PARI reusable nebulizer, contanct PARI Patient Connection at 1.800.FAST.NEB (327.8632).

Please be sure to clean and disinfect your PARI reusable nebulizer and place it in a plastic bag before returning.

#### VIOS® PRO AEROSOL DELIVERY SYSTEM LIMITED WARRANTY

PARI offers a standard five (5) year limited warranty on the Vios<sup>®</sup> PRO Aerosol Delivery System and its parts. The warranty period will be printed on the serial number label located on the bottom of the compressor. PARI warrants that the Vios<sup>®</sup> PRO Aerosol Delivery System and its parts will be free from defects in workmanship and materials for a period of sixty (60) months, from the date of first retail purchase of the equipment. This warranty does not cover failures of the nebulizer, tubing, 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 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 Respiratory Equipment, Inc. This warranty covers the cost of labor incurred in the removal or replacement of the warranted component parts at authorized PARI service centers only. To make a claim under this warranty, notify the authorized service center by calling PARI Patient Connection at: 1.800.FAST.NEB (327.8632), Press 2

THERE ARE NO OTHER EXPRESS WARRANTIES. ALL IMPLIED WARRANTIES ON THE Vios® PRO Aerosol Delivery System AND ITS PARTS, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE LIMITED TO SIXTY (60) 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 warra nty lasts, so the above limitation may not apply you. The sole and exclusive remedy under this warranty is to repair or replace the Vios® PRO Aerosol Delivery System and/or its parts at the option of PARI. IN NO EVENT SHALL PARI 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. You may also have other rights which vary from State to State.

#### Register your Vios® PRO Aerosol Delivery System today with one of these three ways:

Online at pari.com/register

Call I.800.FAST.NEB (327.8632)

Fill out the pre-addressed, postage paid registration card and drop it in any USPS Mailbox.

Failure to register your Vios® PRO does not affect your standard product limited warranty.

If you have any problems and need to return your Vios® PRO compressor, contact PARI Patient Connection at 1.800.FAST.NEB (327.8632).

Manufactured for:

PARI Respiratory Equipment, Inc.

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