

## IV. OPERATION PROCEDURE

The PARI BABY Mask Conversion Kit is designed to work with the breathing pattern of the patient for a more efficient treatment. If the inspiratory flow of the patient is sufficiently high, the inspiratory valve on the nebulizer opens, which increases nebulizer output (for low tidal volumes, the valve will not open). When the patient exhales, the valve remains closed, which minimizes the amount of aerosol wastage. The exhaled mist escapes through the two slots on the side of the Elbow Piece.

1. For the treatment, the baby or child should be in a comfortable position: lying down, reclining, sitting, or standing. Adjust the Elbow Piece and mask for the desired position, while keeping the nebulizer upright (Fig. 6-7).
2. Turn on compressor or air source and gently place the Silicon Mask over the patient's face. Allow the patient to breathe normally.
3. Continue to hold the Silicone Mask gently against the patient's face as the patient exhales.
4. Continue steps 2 and 3 for the length of time indicated by the patient's physician. Turn off the compressor or air supply when the treatment is complete.

### ⚠ WARNING

To reduce the risk of choking and asphyxiation, make sure that the expiratory vents on the side of the Elbow Adapter are not obstructed. If the patient begins to choke, stop treatment immediately and do not continue until condition has been rectified.

## V. CLEANING THE NEBULIZER

### ⚠ WARNING

1. To reduce the risk of infection, illness, or injury from contamination, you must thoroughly clean all parts of the Reusable Nebulizer (including Elbow Adapter or Y-piece and Silicone Mask) as instructed after each treatment.
2. Never use a nebulizer with a clogged nozzle. If the nozzle is clogged, no aerosol mist is produced, which will alter the effectiveness of the treatment. Replace with new Reusable Nebulizer if clogging occurs.

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, 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 PARI Reusable Nebulizer & Mask Conversion Kit parts as illustrated on front page.
4. Wash all parts with warm water and liquid dish soap. **DO NOT WASH THE TUBING.**
5. Rinse the parts thoroughly with warm water and shake out water.
6. Air dry or hand dry parts on a clean, lint-free cloth. Reassemble nebulizer and Mask Conversion Kit when parts are dry and store.
7. You can also wash all parts on the top shelf of a dishwasher. Silicone Masks can be washed safely in a dishwasher. **DO NOT WASH TUBING.** Place the 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.

## VI. DISINFECTING AND STERILIZING THE NEBULIZER

### ⚠ WARNING, TO REDUCE RISK OF INFECTION:

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

For patients with Cystic Fibrosis, the CF Foundation recommends boiling for a full 10 minutes to disinfect.

1. Clean the nebulizer as described in section V. Every other treatment day, soak all parts of the PARI Reusable Nebulizer and Mask Conversion Kit (except tubing) 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®) for distilled white vinegar (follow manufacturer's instructions for mixing).
2. Rinse all parts of the PARI Reusable Nebulizer and Mask Conversion Kit 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 and Mask Conversion Kit parts (except tubing) may also be sterilized by boiling them in a clean pot of water for a full 10 minutes.
4. Hospitals and clinics can sterilize the PARI Reusable Nebulizer and Mask Conversion Kit parts (except tubing) by autoclaving (a maximum of 277° F or 126° C), follow autoclave manufacturer's instructions.
5. Dry parts on a clean, lint-free cloth.

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THE PARI REUSABLE NEBULIZER INCLUDES A 6 MONTH LIMITED WARRANTY FOR HOME CARE USE

## VI. PROCEDURE FOR RETURNING THE PARI REUSABLE NEBULIZER

1. Contact PARI Patient Connection at 1.800.FAST.NEB for shipping instructions. Press 2 for Patient Connection.
2. Clean, disinfect and/or sterilize the PARI Reusable Nebulizer as indicated on the previous page. Dry the nebulizer and place in a plastic bag.
3. In writing, describe the malfunction or symptoms of the nebulizer. Include your full name, address and daytime telephone number.
4. Send written description and nebulizer in a protected box to the address provided by Patient Connection.



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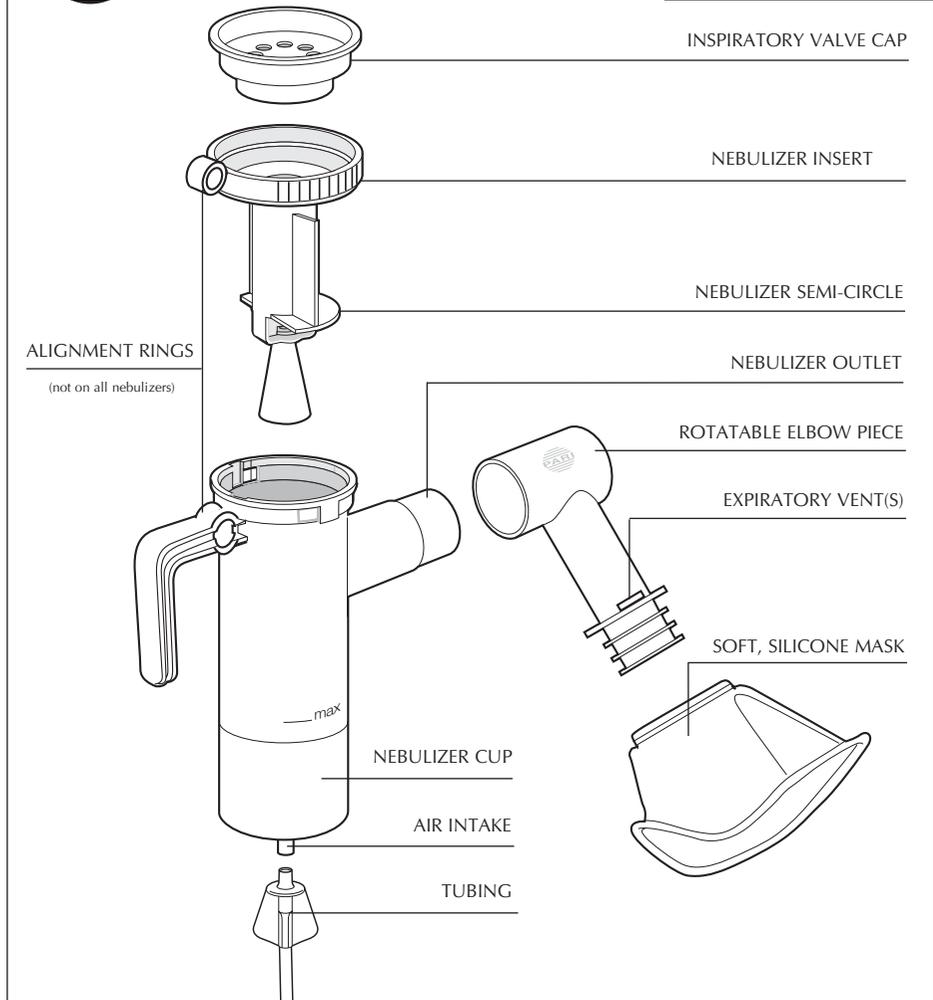


DS-22-940 REV. E 5/05

PARI BABY™ REUSABLE NEBULIZER SET PART# 22F90

INSTRUCTIONS FOR USE

FOR SINGLE PATIENT USE (ONE PERSON) ONLY



### ⚠ WARNING

CAUTION: U.S. 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. Read all warnings and instructions before use. Improper use can result in serious or fatal illness or injury. Nebulizer is not sterile.

## I. SAFETY PRECAUTIONS

### ⚠ WARNING

Use only when prescribed by a physician and with the prescribed medication. Use only with compressors and tubing authorized by PARI. Other compressors and tubing may produce incorrect liter flow, resulting in improper treatment.

### ⚠ WARNING

1. 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.
2. 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.
7. 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.

## II. GETTING STARTED

1. Make sure that you have all components illustrated on the front cover. If you did not receive all components, contact PARI's Patient Connection at 1.800.FAST.NEB.
2. The Silicone Mask should be just large enough to cover the nose and open mouth of the patient. If the mask is not the correct size, contact the dealer where you purchased your PARI BABY™ Mask Conversion Kit. In general, the following guidelines pertain to the mask sizes:  
Mask Size 0.....Age: Neonates  
Mask Size 1 .....Age: 1- 11 Month  
Mask Size 2 .....Age: 1 Year - 3 Years  
Mask Size 3 or mouthpiece.....Age: 3+ Years

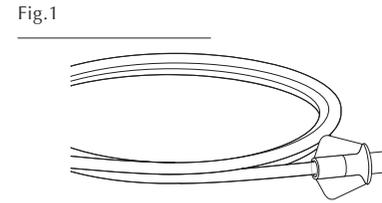


Fig.1

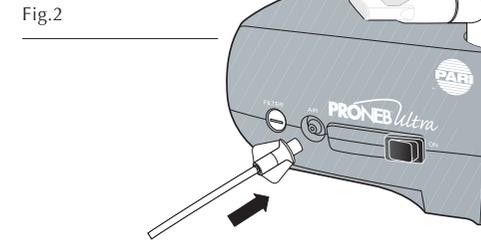


Fig.2

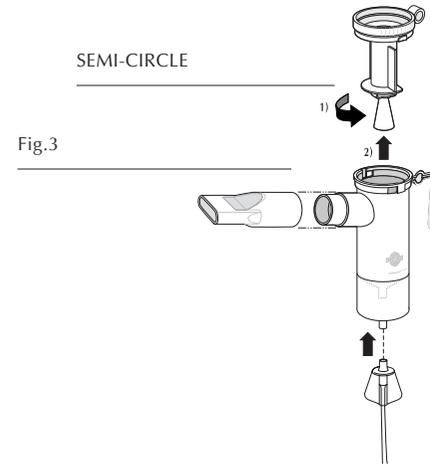


Fig.3

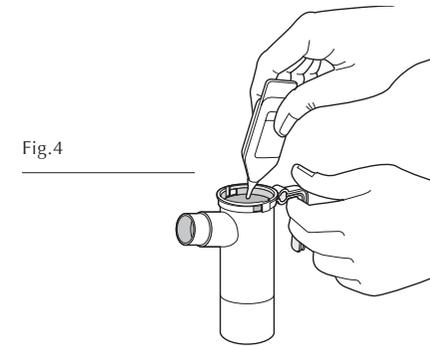


Fig.4

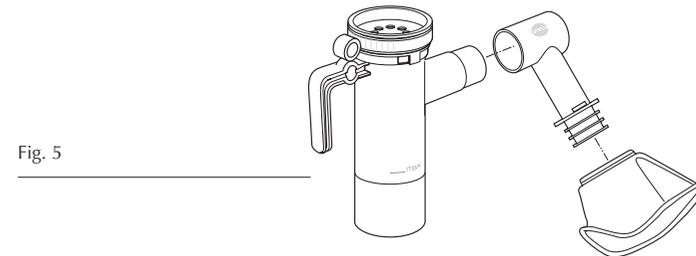


Fig.5



Fig.6

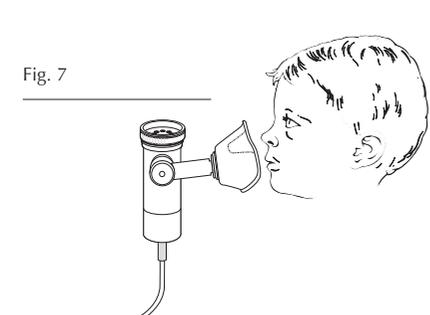


Fig.7

3. Read these Instructions For Use. Make note of all warnings and safety instructions. If you do not understand any portion of these Instructions For Use, please call PARI Patient Connection at 1.800.FAST.NEB, then press 2.

## III. SET-UP

(Consult front cover and figures 1-7)

The PARI BABY™ Mask Conversion Kit will turn your LC® Reusable Nebulizer into the PARI BABY™ Reusable Nebulizer. The PARI BABY™ Reusable Nebulizer was designed to be used with a PARI compressor or with the central air supply in a hospital. In order to achieve the specified droplet characteristics with the central air supply, a liter flow of 3.5 - 8 liters per minute must be selected.

1. Unwind the tubing (Fig. 1).
2. Insert one end of the tubing directly to the compressor air outlet. Make sure the tubing is firmly inserted or attached (Fig 2). **The tubing is designed to fit tightly.**
3. Remove the nebulizer insert by twisting counter-clockwise until it stops and lift up (Fig. 3).
4. Pour prescribed medication into the nebulizer cup (Fig. 4). Do not fill past the maximum fill line. **Caution:** Medication maximum fill for PARI LC® PLUS (part # 22F81) is 8 cc (ml) and the PARI LC® STAR (part #22F51) is 6 cc (ml).
5. Replace the nebulizer insert. (Fig. 3) **The semi-circle should face the nebulizer outlet.** The two alignment rings (not on all nebulizers) should now be lined up with each other.
6. Remove mouthpiece from nebulizer outlet. (Fig. 3) and attach the Elbow Adapter to the nebulizer outlet (Fig. 5), then attach the Silicone Mask by firmly pressing the mask onto the Elbow Adapter as far as it will go (Elbow Adapter and Silicone Mask each rotate 360° to allow flexibility in administering the treatment to the baby or child).
7. Then attach the inspiratory valve cap by pressing firmly into the nebulizer insert. **The inspiratory valve cap is designed to fit snugly.**
8. Connect the other end of the tubing to the air intake on the bottom of the nebulizer (Fig. 3). Press on firmly.

### ⚠ WARNING

Check PARI Reusable Nebulizer for proper assembly. All parts should be seated firmly in place. Use of an improperly assembled nebulizer could prevent adequate delivery of medication.