

en

Instructions for use

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1 IMPORTANT INFORMATION

1.1 General

Please read these instructions for use carefully and completely. Do not discard, so you can consult them at a later date. If you fail to comply with the instructions for use, injury or damage to the device cannot be ruled out.

If symptoms persist or if your condition worsens, discontinue the application and contact your doctor immediately.

1.2 Information about the instructions for use

These instructions for use are intended for the user at home. A separate copy of instructions for use is available for medical specialists.

If these instructions for use are lost, you can request another copy from PARI GmbH [see: Contact, page 49]. The instructions for use for some products can be retrieved on the internet in both German and English. Simply visit: www.pari.com (on the respective product page).

1.3 Structure of safety instructions

Safety-critical warnings are categorised according to hazard levels in these instructions for use:

- The signal word **CAUTION** is used to indicate hazards which, without precautionary measures, can result in minor to moderate injury or impair treatment.
- The signal word **NOTICE** is used to indicate general precautionary measures which are to be observed to avoid damaging the product during use.

1.4 Treatment of babies, children and anyone who requires assistance

Babies, children and anyone who requires assistance must be supervised constantly by an adult during inhalation therapy. This is the only way to ensure safe and effective treatment. Individuals in this group often underestimate the hazards involved (e.g. strangulation with the power cord or the connection tubing), thus resulting in a risk of injury.

The product contains small parts. Small parts can block the airways and lead to a choking hazard. Therefore, make sure that you always keep the compressor, the nebuliser and the accessories out of the reach of babies and infants.

Special masks may be obtained for treating babies and infants who are not yet able to inhale using the mouthpiece.

The nebulisers are only designed for patients who are able to breathe by themselves and are conscious. This is the only way to ensure effective treatment and avoid a choking hazard.

1.5 Treatment of patients with a surgically created opening in the windpipe (tracheostoma)

Tracheostomised patients cannot use the mouthpiece to inhale and therefore need the PARI TRACHEO SET with a special tracheostoma mask for an inhalation session. When the tracheostoma mask is used, the inspiratory valve must not be attached to the nebuliser. This ensures unobstructed expiration and avoids the risk of shortness of breath.

1.6 Hygiene

Observe the following hygiene instructions:

- Do not use product components unless they have been thoroughly cleaned and dried. Contamination and residual moisture encourage the growth of bacteria, which increases the risk of infection.
- Before every use and cleaning, wash your hands thoroughly.
- Make absolutely sure you also carry out cleaning and drying before using the device for the first time.
- For cleaning and disinfection, always use fresh water with reduced calcium content.
- Make sure all components are dried properly whenever you have performed cleaning or disinfection.
- Do not keep the product and accessories in a damp environment or together with damp objects.

2 PRODUCT DESCRIPTION

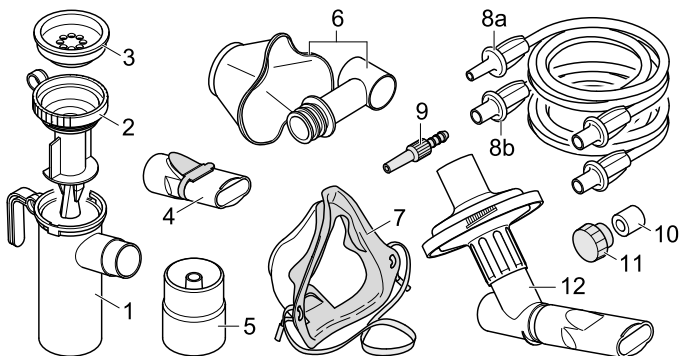
2.1 Components

The components included vary depending on the pack. To find out which components are included in your pack, refer to the following table.

Check that all components of your PARI product are contained in your pack. If anything is missing, please notify the dealer from whom you purchased the PARI product immediately.

Components

Your pack may contain the following components:



- (1) Nebuliser lower section
- (2) Nozzle attachment
- (3) Inspiratory valve
- (4) Mouthpiece
- (5) LC extension ring
- (6) Baby mask with baby bend
- (7) a) Child mask soft
b) Adult mask soft
- (8) a) Connection tubing (f/m)
b) Connection tubing (f/f)
- (9) Tubing adapter
- (10) Filter insert for compressor
- (11) Filter changer
- (12) Filter/Valve Set

Packs

The following components are included in all nebuliser packs:

- (1) Nebuliser lower section
- (2) Nozzle attachment
- (3) Inspiratory valve
- (4) Mouthpiece

The following components may also be included with the product depending on the pack:

Pack no. (REF)	(5)	(6)	(7a)	(7b)	(8a)	(8b)	(9)	(10)	(11)	(12)
022B0113	x	x								
022B0114					x			x		
022B0304										
022B5202			x			x			x	
022B5209				x		x			x	
022G8001	x									
022G8010						x		x		
022G8100					x					
022G8104					x					
022G8107						x	x	x	x	
022G8200										x
022G8740						x	x			

2.2 Intended purpose

The nebulisers of the PARI LC family are medication nebulisers that are designed to be used in conjunction with a PARI compressor for inhalation therapy of the lower and/or upper airways.

Each application generally takes between 5 and 10 minutes (depending on the quantity of medication), but in no case more than 20 minutes.

Only original PARI compressors and PARI accessories must be used. PARI GmbH cannot be held liable for damage caused by using PARI nebulisers with compressors or accessories from other manufacturers.

Please read and follow the instructions for use of the compressor and of the accessories you are using.

2.3 Intended use

The nebuliser is intended exclusively for home use.

For reasons of hygiene, the nebuliser, the mouthpiece and the masks must only be used by a single patient.

This product is only designed for patients who are able to breathe by themselves and are conscious.

Only medication that has been approved for inhalation treatment must be used. Take note of any restrictions in the instructions for use of the medication in question.

2.4 Contraindications

None.

2.5 Product variants and combinations

The nebulisers of the PARI LC family can be operated with all PARI compressors that are available on the market.

The PARI LC Family nebulisers are available in a variety of versions for different age groups and requirements:

- PARI LC (nebuliser without valve system)
With mouthpiece for general treatment of the airways in adults and children aged approx. 4 years and older.
- PARI LC PLUS
For treatment of the airways in adults and children aged approx. 4 years and older.
- PARI LC PLUS Junior
For treatment of infants and children.
If the patients are not yet able to inhale using the mouthpiece, treatment must be carried out using a suitable baby mask.
- PARI LC STAR (nozzle attachment: red)
With mouthpiece for treatment of the deep airways in adults and children aged approx. 4 years and older.

2.6 Material information

Polypropylene	Nebuliser lower section, nozzle attachment, inspiratory valve, mouthpiece, baby bend, child mask, adult mask
Silicone	Baby mask
Thermoplastic elastomer	Nebuliser lower section, nozzle attachment, inspiratory valve, mouthpiece, child mask, adult mask
Polyester	Rubber band
Synthetic rubber (latex-free)	Rubber band

2.7 Operating life

Replace the nebuliser after a year at the latest as changes can occur in the material of the nebuliser over time. This might impair the effectiveness of the treatment.

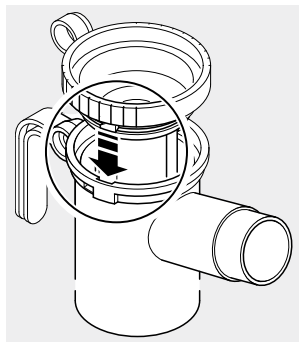
3 INHALATION

3.1 Assembling the nebuliser

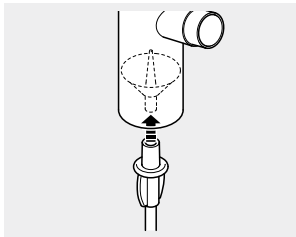
CAUTION

Check all nebuliser components and the accessories before each use. Replace any broken, misshapen or seriously discoloured parts. Please also follow the instructions for assembly given below. Damaged components and/or an incorrectly assembled nebuliser may impair **functioning of the nebuliser** and thus **treatment as well**.

- Insert the nozzle attachment in the nebuliser lower section.
- Gently twist the nozzle attachment clockwise to lock it in place.

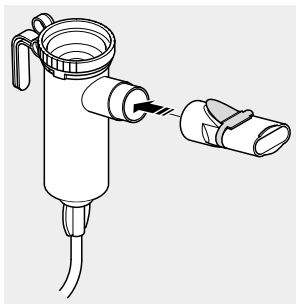


- Attach the connection tubing to the nebuliser.



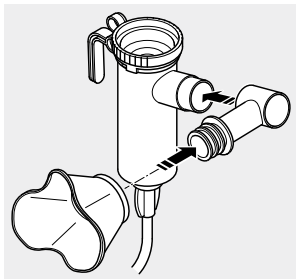
Using with a mouthpiece

- Fit the mouthpiece onto the nebuliser.



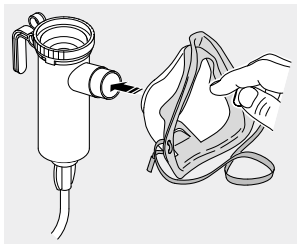
Using with a baby mask and baby bend

- Attach the baby mask to the baby bend.
Use your thumb to press the baby mask from the inside over the first ridge on the baby bend.
- Attach the baby bend to the nebuliser.



Using with a child or adult mask

- Attach the child or adult mask to the nebuliser.



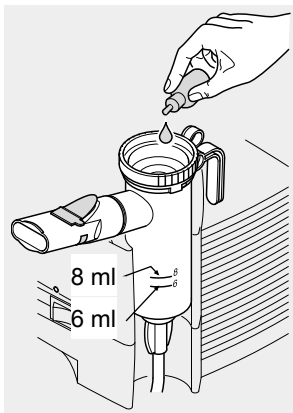
i When using a mask, make sure that the expiratory valve plate is pressed out so you can exhale freely during an inhalation session.

3.2 Filling with medication

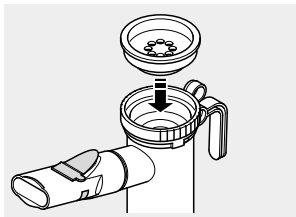
- Insert the nebuliser in the holder on the compressor intended for this purpose.
- Pour the quantity of medication prescribed by your doctor into the nebuliser nozzle attachment.

Info: Take care not to overfill the nebuliser:

LC STAR no higher than the lower scale marking (6 ml), all others no higher than the upper scale marking (8 ml). Overfilling can greatly impair the nebulisation of medication.



- Attach the inspiratory valve to the nebuliser.



If you are to inhale several medications one after the other in one application, rinse out the nebuliser with tap water between inhalations. Remove excess water by shaking the nebuliser and then fill it with the next medication as described.

3.3 Performing the inhalation

Before starting the treatment, ensure that all parts are firmly connected to each other.

Perform the treatment until the aerosol is used up (indicated by a change in the sound of the nebuliser).

i *Several drops of medication will remain in the nebuliser after the treatment has ended.*

- Connect the connection tube to the compressor and switch the compressor on.

Inhalation with mouthpiece or with child or adult mask

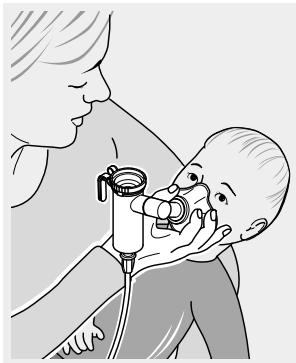
- Sit in an upright position and relax.
- Take the nebuliser out of its holder and hold it upright.
- Take the mouthpiece between your teeth and close your lips around it or press the mask lightly over the mouth and nose.
- Breathe in through the mouthpiece or mask as slowly and deeply as possible, and then breathe out in a relaxed manner.

- Replace the nebuliser in the holder as soon as you have finished inhaling.
- Switch the compressor off.

Inhalation with a baby mask and baby bend

i *The baby mask must only be used in conjunction with the baby bend. The baby or infant can breathe out without obstruction and the risk of shortness of breath is avoided.*

- Adjust the alignment of the bend and the mask according to the position the baby or infant is in.
- Gently press the mask against the face so that it fits snugly over the mouth and nose. Make sure that the nebuliser is upright.




i *Sick infants often struggle when the mask is pressed against their face, and twist their head back and forth. To ensure effective inhalation, hold the mask firmly in your hand and rest your little finger against the child's cheek. This will enable you to follow the movements of the child's head with the mask more easily.*

- Complete the treatment session.
- Replace the nebuliser in the holder as soon as you have finished inhaling.
- Switch the compressor off.

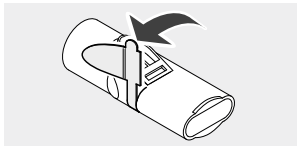
4 CLEANING AND DISINFECTION AT HOME

The nebuliser and the accessories used must be cleaned thoroughly after each application and disinfected at least once a day.

 *The connection tube cannot be cleaned or disinfected.*

4.1 Preparation

- Detach the tubing from the nebuliser.
- Make sure that all medication residues are removed from the nebuliser.
- Dismantle the nebuliser into its individual parts.
- Carefully pull the blue expiratory valve out of the slot in the mouthpiece. The valve must still be attached to the mouthpiece.
- Rinse all components of the nebuliser under running tap water. This must be done especially thoroughly if cleaning and disinfection are not carried out straight away.

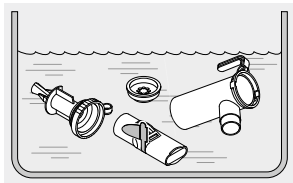


4.2 Care of the connection tube

- Connect the connection tube to the compressor.
- Switch the compressor on.
- Leave the compressor running until any condensation in the tube has been removed by the air flowing into the tube.

4.3 Cleaning

- Place all disassembled components in warm tap water with a little dishwashing liquid for at least 5 min. If necessary, use a clean brush to remove loose dirt (the brush must be reserved exclusively for this purpose).
- Rinse all parts thoroughly in running water.
- You can remove excess water more quickly by shaking all parts.



4.4 Disinfection

After cleaning, disinfect the dismantled nebuliser and accessories used (except for the connection tube). Effective disinfection is only possible if the nebuliser has been cleaned.

i **Information when using masks with rubber bands:**
The rubber band can only be cleaned as it might be damaged by the high temperatures used during disinfection.


CAUTION

A damp environment may encourage the growth of bacteria. Therefore, remove all parts from the pot or disinfectant as soon as disinfection has finished. Dry the parts. The **risk of infection** is reduced when the parts are dried completely.

In boiling water

- Place all the individual parts in boiling water for at least 5 minutes.

Use a clean pot and fresh water with reduced calcium content, if possible.

 *Plastic will melt if it comes into contact with the hot base of the pot. Therefore, make sure there is plenty of water in the pot. This way you will avoid damaging the components.*

- You can remove excess water more quickly by shaking all parts.

Using a standard thermal disinfector for baby bottles (not a microwave oven)

For effective disinfection, use a disinfector with a runtime of at least 6 minutes. Regarding disinfection, the duration of the disinfection procedure and the quantity of water required for this, follow the instructions for use of the disinfector you are using.



CAUTION

Inadequate disinfection encourages the growth of bacteria and thus increases the **risk of infection**. Thorough disinfection has not been completed until the disinfector automatically switches itself off, or the minimum disinfection time specified in the instructions for use of the disinfector has elapsed. Therefore, do not switch the device off prematurely. Also make sure that the disinfector is kept clean and regularly check that it is in good working order.

With a microwave disinfecter

Microwave disinfectors ensure effective disinfection of the product components in a standard commercial microwave oven.

Place the product components in the disinfecter with enough space between them to allow the steam to reach all surfaces reliably.



Maintain the following times when disinfecting:

Wattage	Disinfection time	Cooling time
850 – 950	4 min.	2 min.
600 – 850	6 min.	2 min.

Information about the amount of water required and about the disinfection process is included in the instructions for use of the devices in question (disinfecter and microwave).



CAUTION

The product components must not be exposed to microwave radiation unless they are in a microwave disinfectant. If they are heated in a microwave oven without the protection of the disinfectant, the **individual parts will be damaged**.

Do not use the grill function because this too will **damage the individual parts**.

At the end of the disinfection process, the parts may still be very hot. Therefore, it is essential to wait for the cooling time to pass before taking the parts out, otherwise there is a **risk of burns**.

Inadequate or ineffective disinfection encourages the growth of bacteria and thus increases the **risk of infection**. Disinfection is not completed properly unless both the specified minimum disinfection time and the required power output of the microwave are observed. The disinfectant must also be perfectly clean. Check regularly that the microwave and the disinfectant are functioning perfectly.

Use only water for disinfection, never use chemicals.

Chemical cleaning with disinfection

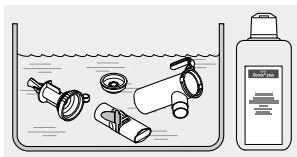
Cleaning and disinfection can be carried out in a single cycle using a chemical preparation process. For this, use the cleaning disinfecting agent Bomix® plus.

To ensure safety when handling chemicals, follow the instructions for use of the disinfecting agent, particularly the accompanying safety instructions.

CAUTION

Inadequate disinfection encourages the growth of bacteria and thus increases the **risk of infection**. Adequate cleaning with disinfection can only be assured if the specified mixing ratio and application time are adhered to, and if all individual parts are completely immersed in the solution for the entire application time. There must not be any air pockets or bubbles.

- Prepare a 2% solution of Bomix® plus by mixing 10 ml of the concentrate with 500 ml tap water.
- Place all the individual parts in the prepared solution and leave them to soak for 5 min.



i *If the application period is exceeded significantly, the plastic parts may take on the smell of the disinfectant.*

- Rinse off all parts thoroughly in running water (residues of the disinfectant can cause allergic reactions or irritations of the mucous membrane).
- You can remove excess water more quickly by shaking all parts.
- Dispose of the used solution (the diluted solution can be got rid of down the drain).

4.5 Visual inspection

Inspect all product components after each cleaning and disinfection. Replace any broken, misshapen or seriously discoloured parts.

4.6 Drying and storage

- Place all parts on a dry, clean and absorbent surface and let them dry completely.
- Wrap the nebuliser in a clean, lint-free cloth (e.g., a tea-towel) and keep it in a dry, dust-free environment.

5 MISCELLANEOUS

5.1 Disposal

All product components can be disposed of with domestic waste unless this is prohibited by the disposal regulations prevailing in the respective member countries.






5.2 Technical data

Aerosol data according to DIN EN 13544-1 is available on request from PARI GmbH.

Operating gases	Air, oxygen
Minimum flow	3.0 l/min.
Corresponding minimum operating pressure	0.5 bar / 50 kPa
Maximum flow	6.0 l/min.
Corresponding maximum operating pressure	2.0 bar / 200 kPa
Minimum fill volume	2 ml
Maximum fill volume	8 ml (LC STAR: 6 ml)

5.3 Explanation of symbols

The following symbols can be found on the product and/or the packaging:

	Manufacturer
	The product satisfies the basic requirements as set forth in Appendix I of Directive 93/42/EEC concerning medical devices.
	Please follow the instructions for use.
	Order no.
	Lot no.

5.4 Contact

For all product information and in the event of defects or questions about usage, please contact our Service Center:

Tel.: +49 (0)8151-279 279 (German-speaking)
+49 (0)8151-279 220 (international)

Spezialisten für effektive Inhalation



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