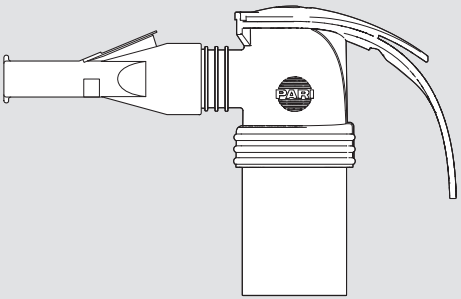
Instructions for use

PARI LC SPRINT® COMPACT

Model: PARI LC SPRINT COMPACT (Type 023)

Nebulisers for PARI Inhalation systems



CE 0123

en

Read the instructions for use

Read these instructions carefully before using the product. Follow all instructions and safety directions. Keep the instructions in a safe place.

Validity of instructions for use

PARI LC SPRINT COMPACT (Type 023)

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Disclaimer

These instructions for use describe the components of PARI products and optional accessories. For this reason, these instructions for use also describe and illustrate features not present in your PARI product because they are, for instance, country-specific and/or optional. When using the systems, products and functions, the applicable country-specific regulations must be observed.

Trade marks

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LC SPRINT®, PARI®

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1 IMPORTANT INFORMATION

1.1 Intended purpose

The PARI LC SPRINT COMPACT nebuliser generates an inhalable aerosol[1] for inhalation for the therapy of the lower airways.

Together with a PARI compressor or the PARI CENTRAL and with PARI accessories, the nebuliser forms an inhalation system.

The nebuliser is suitable for use in treating patients in all age groups.

Only solutions and suspensions that are approved for use in nebuliser treatment may be used.

The nebuliser must only be connected with a PARI compressor or with a central gas supply system. The PARI CENTRAL is intended for the connection with the central gas supply system.

This PARI product can be used in a home environment, as well as in professional health institutions. When used in a home environment, this PARI product is intended for single-patient use only (no patient change). In a professional environment, the device can be used with different patients as long as the corresponding hygiene reprocessing measures are complied with.

This product must be used only by individuals who understand the contents of the instructions for use and are able to use the product safely. Individuals in the following groups must be supervised by a person who is responsible for their safety:

– Babies, infants, and children

– Individuals with limited capabilities (e.g. physical, mental, sensory)

If the patient is not able to use this product safely on their own, then the treatment must be carried out by the responsible person.

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

An application takes approximately 5 to 10 minutes (depending on the quantity of fluid), but in any case no more than 20 minutes. The frequency and duration of use is determined by professional medical staff[2] according to the individual needs of the patient.

1.2 Indication

For treatment of diseases of the lower airways.

1) Aerosol: Small particles of solid, liquid or mixed composition (fine “mist”) suspended in gases or air.

2) Professional medical staff: Doctors, pharmacists, and physiotherapists.

1.3 Contraindication

There are no contraindications known to PARI GmbH.

1.4 Labelling

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

MD	Medical device
UDI	Unique Device Identifier (UDI)
	Legal manufacturer
	Date of manufacture
REF	Item no.
LOT	Production batch number, lot number
CE 0123	This product conforms to the EU Medical Device Regulation 2017/745.
	Consult instructions for use
	Air filter for compressor types 028/085
	Air filter for compressor types 128/130/152
	Tubing adapter
	PARI LC SPRINT nebuliser with nozzle attachment
	Connection tubing
	Mouthpiece with exhalation valve
	LC interrupter

1.5 Safety and warning instructions

The present instructions for use contain important information, safety instructions and precautionary measures. The user must follow these in order to guarantee safe operation of this PARI product.

This PARI product must be used only as described in these instructions for use.

The instructions for use of the compressor and accessories used and the information for use of the inhalation solution used must also be followed.

Labelling and classification of warning instructions

In these instructions for use, safety-critical warnings are categorised according to the following hazard levels:

DANGER

DANGER indicates a hazardous situation which will lead to very severe injuries or death if it is not avoided.

WARNING

WARNING indicates a hazardous situation which can lead to very severe injuries or death if it is not avoided.

CAUTION

CAUTION indicates a hazardous situation which can lead to mild or moderate injuries if it is not avoided.

NOTE

NOTE indicates a hazardous situation which can lead to material damage if it is not avoided.

General

If non-approved solutions or suspensions are used for nebulisation, then nebuliser aerosol characteristics may differ from the information provided by the manufacturer.

This product is not suitable for use in an anaesthetic breathing system or a ventilator breathing system.

Tracheotomised patients cannot inhale using a mouthpiece. To perform inhalation therapy, they require specific equipment. In this case, please contact your doctor for further information.

Skin care products containing oils or fats can damage the soft plastic components. The patient should refrain from using skin care products of this kind while using the device.

If your health condition does not improve or it even worsens as a result of the treatment, seek professional medical advice.

Treatment of babies, infants, and anyone who requires assistance

DANGER

Life-threatening situation from strangulation

For individuals who are not able to perform the therapy session without assistance or cannot appreciate the hazards, the risk of injury is greater e.g., strangulation with the power cord or the connection tubing. Such individuals include, for example, babies, children, and people with limited capabilities.

- Ensure that for these individuals a person responsible for their safety either supervises or implements the application.

Hazard due to small parts which can be swallowed

The product contains small parts. Small parts can block the airways and lead to a choking hazard. Keep all components of the product out of the reach of babies and infants at all times.

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 reprocessing cycle, wash your hands thoroughly.
– Make absolutely sure you also carry out reprocessing before using the device for the first time.
– Always use drinking water for reprocessing in a home environment.
– Make sure all components are dried properly after each reprocessing step.
– Do not keep the product components in a damp environment or together with damp objects.

Reporting serious incidents

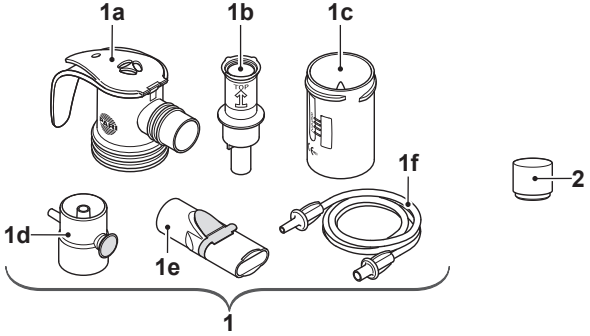
Report serious adverse incidents to the manufacturer and to the competent authority.

2 PRODUCT DESCRIPTION

2.1 Components

Please refer to the package for information on the supplied components.

2.2 Overview and designations



1	**Nebuliser**	
	1a	Nebuliser upper part
	1b	Nozzle attachment
	1c	Nebuliser lower part
	1d	LC interrupter
	1e	Mouthpiece
	1f	Connection tubing
2	**Air filter for compressor**	

2.3 Product variants

PARI LC SPRINT COMPACT (nozzle insert: orange)

– With mouthpiece for treatment of the airways in adults and children aged 4 years and older.
– With PARI baby mask soft for the treatment of babies aged between 6 months and 3 years.
– With PARI child mask for the treatment of children aged 4 years and above.

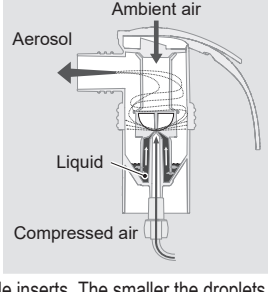
2.4 Product combinations

The PARI nebuliser can be connected to all PARI compressors or to a central medical gas supply system via a PARI CENTRAL.
The nebuliser can be used in combination with a range of PARI accessories.

2.5 Description of function

The PARI nebuliser is part of a PARI inhalation system.

When compressed air is supplied, the nebuliser generates an aerosol from the liquid with which it is filled, for example the medication. This aerosol is breathed into the lungs through the mouthpiece or optionally a mask.



The size of the aerosol droplets is determined by the nozzle inserts. The smaller the droplets are, the farther they can penetrate into the deeper and smaller regions of the lung:

– The orange nozzle insert creates tiny droplets to treat the lower airways in all age groups.

The LC interrupter makes it possible to interrupt aerosol generation while the patient breathes out, thereby optimising medication use.

2.6 Material information

The individual product components are made from the following materials:

Product component	Material
Nebuliser upper part	Polypropylene, thermoplastic elastomer
Nozzle attachment	Polypropylene
Nebuliser lower part	Polypropylene, thermoplastic elastomer
LC interrupter	Polypropylene
Mouthpiece (with exhalation valve)	Polypropylene, thermoplastic elastomer
Connection tubing	Polyvinyl chloride
Tubing connector	Thermoplastic elastomer
Tubing adapter	Polyamide

2.7 Service life

The individual product components have the following expected lifetimes:

Product component	Service life
Nebuliser, connection tubing and accessories	Home environment [see: Processing limits, page 18]
Nebuliser, connection tubing and accessories	Professional environment [see: Processing limits, page 23]

When the expected operating life has been reached, replace the affected component. Nebuliser replacement sets (nebuliser including connection tubing) or PARI spare filter for PARI compressors are available.

3 USE

If the nebuliser is to be connected to a central medical gas supply system via a PARI CENTRAL, the instructions for use of the PARI CENTRAL must be followed.

WARNING

Danger of acute respiratory distress when the nebuliser is operated using oxygen

When the nebuliser is used with the PARI CENTRAL O2, acute respiratory distress can arise through an increased level of carbon dioxide in the blood.

COPD patients with exacerbation may develop acute respiratory distress as a result of treatment which uses oxygen.

- The PARI CENTRAL O2 is no longer sold.
- If you use a PARI CENTRAL O2 which is still on the market, perform the treatment using oxygen only after consultation with, and under the supervision of, a professional.

3.1 Preparing for treatment

Assembling the nebuliser

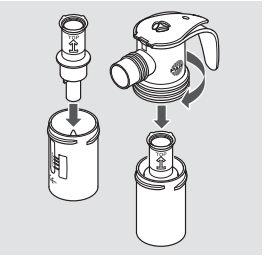
CAUTION

Risk of impaired treatment

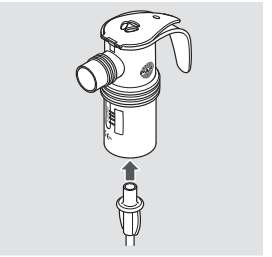
Damaged components and/or an incorrectly assembled nebuliser may impair functioning of the nebuliser and thus treatment as well.

- Check all nebuliser components and the accessories before each use.
- Replace any broken, deformed or seriously discoloured parts.
- Follow the assembly instructions in these instructions for use.

- Press the nozzle insert lightly onto the nozzle in the nebuliser lower part.
  The arrow on the nozzle insert must point upwards.
- Place the nebuliser upper part on the nebuliser lower part and turn it clockwise to lock the two parts together.

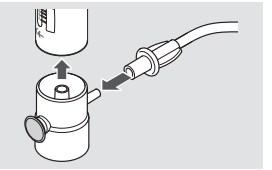


- Attach the connection tubing to the nebuliser.



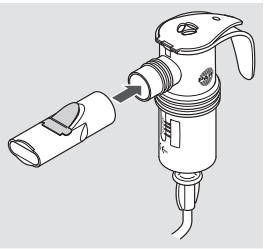
Or:

- Attach the LC interrupter to the nebuliser.
- Insert the connection tubing in the air inlet on the side of the LC interrupter.



Using the mouthpiece

- Fit the mouthpiece onto the nebuliser.



Using accessories

Information on assembling accessories is included in the instructions for use of the respective accessory[3].

3) Instructions for use of accessories are included with the respective accessory. They can also be ordered from the manufacturer or distributor.

Filling the nebuliser

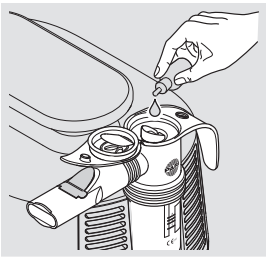
NOTE

Nebuliser lid might break off

If the cap is twisted in the wrong direction, it may break off. The nebuliser will then be unusable and irreparable.

- Never move the lid except in the direction allowed by the hinge.

- Insert the nebuliser in the holder on the compressor intended for this purpose.
- Open the nebuliser lid by pressing your thumb against the underside of the lid.
- Pour the required quantity of inhalation solution into the top of the nebuliser.
  Be sure to follow the instructions regarding the minimum and maximum fill volumes [see: General nebuliser data, page 32]. If the nebuliser contains too little or too much liquid, the nebulisation and consequently the therapy will be less effective.



- Close the nebuliser lid. Make sure that the lid snaps into place.

If several inhalation solutions are to be used one after the other:

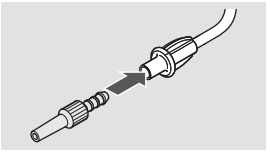
- Rinse the nebuliser out with drinking water between the individual applications.
- Shake excess water out of the nebuliser.
- Fill the nebuliser with the next inhalation solution as described.

3.2 Performing treatment

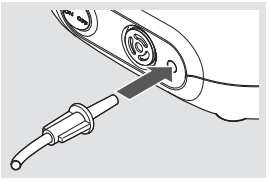
All the safety instructions and warnings in these instructions for use must have been read and understood before any treatment is carried out.

Always hold the nebuliser upright during treatment.

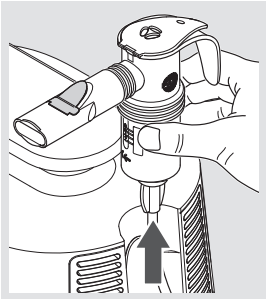
- If necessary, use the tubing adapter to connect the connection tubing and the compressor.



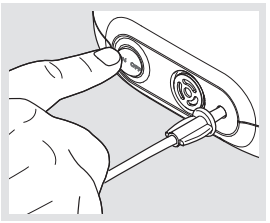
- ⚠ **DANGER! Life-threatening situation if tubes are mixed up!** If tubing systems for other devices are present close by (e.g., for infusions), check carefully to ensure that the other end of the connection tubing connected to the compressor is connected to the nebuliser. Otherwise, there is a danger that different connection options may be confused with each other. Push the connection tubing of the nebuliser with a slight twist into the compressor's air connection.



- Take the nebuliser out of its holder on the compressor and hold it upright.
- Verify that all parts are firmly connected to each other.



- ⚠ **DANGER! Life-threatening situation from electrocution if there is a device fault!** Switch the compressor off immediately, and disconnect the power plug from the mains socket if a fault is suspected (e.g., if the device is dropped, or there is a smell of burning plastic). If there is a device fault, there may be a risk of contact with live parts. This in turn may lead to an electric shock.
  Switch the compressor on by shifting the on/off switch to "ON".



- Check that an aerosol is being generated (a fine mist is escaping from the nebuliser) before you begin the treatment.

Inhaling with the mouthpiece

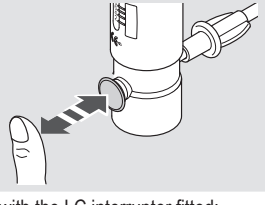
- Sit in an upright position and relax.
- Hold the mouthpiece between your teeth and enclose it with your lips.
- Breathe in as slowly and deeply as possible through the mouthpiece, and out again calmly.
- Carry out the inhalation treatment until the noise in the nebuliser changes.

Some residual fluid will remain in the nebuliser after the end of the treatment.

Using the LC interrupter

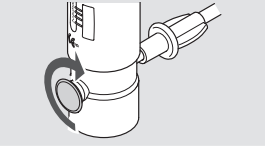
If the LC interrupter is attached, aerosol is not generated until the interrupter button is pressed. Proceed as follows to inhale and to interrupt aerosol generation when breathing out:

- Press the interrupter button to generate aerosol.
  Info: *If the button cannot be pressed, it is locked and the LC interrupter has been set for permanent nebulising. In this case, unlock the interrupter button by turning it counterclockwise as far as it will go.*
- Release the button to interrupt aerosol generation.



If you want to use the permanent nebulising function even with the LC interrupter fitted:

- Turn the interrupter button clockwise as far as it will go.
  ➡ The aerosol is generated permanently (**permanent nebulising**).



Inhaling with accessories

Inhalation with accessories (e.g., masks) is described in the instructions for use of the respective accessory.

3.3 Ending the treatment

- Switch the compressor off by shifting the on/off switch to "OFF".
- Place the nebuliser back in the holder on the compressor.
- Disconnect the power plug from the mains socket.

Complete disconnection from the mains is only certain when the power plug has been unplugged from the socket.

4 REPROCESSING IN A HOME ENVIRONMENT

The product components must be cleaned thoroughly immediately after each use, and disinfected once a week.

The connection tubing cannot be cleaned or disinfected.

Dry the connection tubing after each use [see: Care of the connection tube, page 22].

The maximum operating life of the connection tubing is 1 year.

4.1 Reprocessing cycles

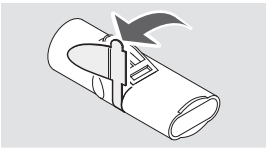
Nebuliser and accessories (e.g. mask)	– Clean immediately after every use – Disinfect once a week

4.2 Processing limits

Nebuliser and accessories, disinfection	300 processing cycles, max. 1 year

4.3 Preparation

- Detach the tube from the nebuliser.
- Detach the mouthpiece from the nebuliser.
- Make sure that all residual volume is removed from the nebuliser.
- Dismantle the nebuliser into its individual parts.
- Carefully pull the blue exhalation valve out of the slot in the mouthpiece. The exhalation valve must still be attached to the mouthpiece.



4.4 Cleaning

Precleaning

All individual parts must be precleaned immediately after use.

EQUIPMENT:

– Drinking water temperature of about 15 °C

PROCEDURE:

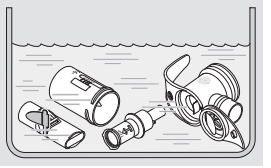
- Rinse all parts used for 2 minutes in running drinking water.

Manual cleaning

EQUIPMENT:

– Drinking water temperature of about 40 °C
– Standard commercial washing-up liquid[4]
– Receptacle with at least 3 l capacity

PROCEDURE:



- Unless otherwise specified by the manufacturer, add about 1 teaspoonful washing-up liquid to 3 l warm drinking water.
- Place all the parts in the washing-up water. Application time: 5 minutes
- Occasionally move the parts back and forth.
- In case of visible soiling, use a medium-soft brush (e.g. a toothbrush) which is used exclusively for this purpose.

RINSING:

- Rinse off all parts thoroughly in running drinking water at about 15 °C for 3 minutes.

DRYING:

- Shake the water out of all of the parts.
- Place all parts on a dry, clean and absorbent surface and allow them to dry completely.

In the dishwasher

The individual parts can be cleaned in a standard household dishwasher provided it is connected to a mains water supply of drinking water quality.

To ensure safety when handling the cleaning agent used, follow the corresponding instructions for use, particularly the accompanying safety instructions.

PROCEDURE:

Do not clean the individual components together with very dirty dishes.

- Place all components in the crockery basket so that no water can collect in them.
- Select a program with at least 50 °C.

DRYING:

Ensure that there is no residual moisture remaining in the components. If necessary:

- Shake the water out of all of the parts.
- Place all parts on a dry, clean and absorbent surface and allow them to dry completely.

4) Validated with Palmolive®.

4.5 Disinfecting

Disinfect all individual parts after cleaning. Only components that have been cleaned can be disinfected effectively. The validated disinfection procedures are described below.

In boiling water

EQUIPMENT:

– Clean cooking pot

– Drinking water

PROCEDURE:

⚠ CAUTION

Risk of infection due to moisture

Moisture encourages the growth of bacteria.

- Remove all parts from the pot as soon as the disinfection process is finished and allow them to dry.

- **NOTE! Risk of damage to plastic parts!** Plastic will melt if it comes into contact with the hot base of the pot. Make sure there is enough water in the pot to prevent the individual parts from touching the pot base.
  Place all the individual parts in water at a rolling boil for at least 5 minutes.

DRYING:

- Shake the water out of all of the parts.
- Place all parts on a dry, clean and absorbent surface and allow them to dry completely.

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

EQUIPMENT:

– Thermal disinfector with a runtime of at least 6 minutes.

PROCEDURE:

CAUTION

Risk of infection due to inadequate disinfection

Inadequate disinfection encourages the growth of bacteria and thus increases the risk of infection.

- Make sure that the disinfector is clean and operating properly before every disinfection process.
- Allow the disinfection to continue until the disinfector switches off automatically or the minimum disinfection time stated in the instructions for use of the disinfector has elapsed. Do not switch the device off prematurely.

CAUTION

Risk of infection due to moisture

Moisture encourages the growth of bacteria.

- Remove all parts from the disinfector as soon as the disinfection process is finished and allow them to dry.

Regarding the performance of the disinfection, the duration of the disinfection procedure and the quantity of water required, follow the instructions for use of the disinfector you are using.

DRYING:

- After the disinfection process is complete, place all parts on a dry, clean and absorbent surface and allow them to dry completely. Or leave all individual parts in the closed thermal disinfector for max. 24 hours until the next use.

4.6 Care of the connection tube

Dry the connection tube after every inhalation session:

- Connect the connection tube to the compressor.
- Switch on your compressor.
- Let the compressor continue to run until all the moisture in the tube has been removed.

4.7 Inspecting

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

4.8 Drying

After each cleaning and disinfection, place all product components on a dry, clean and absorbent surface and let them dry completely.

4.9 Storage

Store this product as described below:

- Wrap all individual components in a clean, lint-free cloth (e.g. a tea towel).
- Store all individual components in a dry, dust-free place.

5 REPROCESSING IN PROFESSIONAL HEALTH INSTITUTIONS

Dry the connection tubing after each use [see: Connection tubing, page 30].

5.1 Reprocessing cycles

Single patient use

Nebuliser excluding connection tubing and accessories (e.g. masks)	– Clean immediately after every use – Disinfect once per week

Before a change of patients

Nebuliser without connection tubing and accessories (e.g. mask)	– Cleaning – Disinfection – Sterilisation
Connection tubing	Mechanical cleaning with disinfection

5.2 Processing limits

Nebuliser and accessories, disinfection	300 reprocessing cycles, max. 1 year
Nebuliser and accessories, sterilisation	100 processing cycles, max. 1 year
Connection tubing	50 reprocessing cycles, max. 1 year

5.3 Nebuliser

Separated parts for processing

CAUTION

Risk of infection due to cross-contamination in the case of a change in patients

If a product is used for more than one patient, there is a risk that germs may be transmitted from one patient to the next.

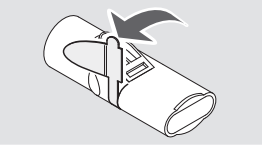
- Clean, disinfect and sterilise all separated parts before every patient change.
- Replace the connection tubing or carry out mechanical cleaning and disinfection of the connection tubing [see: Connection tubing, page 30].

All components of a PARI nebuliser and the PARI accessories used can be cleaned, disinfected and sterilised according to the procedures described below.

The connection tubing must be treated separately.

Preparation

- Detach the tube from the nebuliser.
- Detach the mouthpiece from the nebuliser.
- Make sure that all residual volume is removed from the nebuliser.
- Dismantle the nebuliser into its individual parts.
- Carefully pull the blue exhalation valve out of the slot in the mouthpiece. The exhalation valve must still be attached to the mouthpiece.



Precleaning

All individual parts must be precleaned immediately after use.

EQUIPMENT:

– Drinking water temperature of about 15 °C

PROCEDURE:

- Rinse all parts used for 2 minutes in running drinking water.

Cleaning and disinfecting

Please observe the instructions for use for the chemicals used.

Manual cleaning

EQUIPMENT:

The method has been validated in Europe using:

– pH-neutral cleaning agent:
  Bode Bomix® plus (concentration: 0.1%)
– Application time: 10 minutes

PROCEDURE:

CAUTION

Risk of infection due to growth of bacteria

Inadequate disinfection encourages the growth of bacteria and thus increases the risk of infection.

- Observe the mixing proportions indicated and the specified treatment time.
- Ensure that all components are completely submerged in the solution for the whole of the treatment time. There must not be any air pockets or bubbles.

- Clean all individual parts with a solution prepared according to the manufacturer's instructions.
  In case of visible soiling, use a medium-soft brush (e.g. a toothbrush) which is used exclusively for this purpose.

If the recommended application period is exceeded significantly, the plastic parts may take on the smell of the medium used.

RINSING:

- Rinse off all parts thoroughly in running water at about 15 °C for 3 minutes.

DRYING:

- Shake the water out of all of the parts.
- Place all parts on a dry, clean and absorbent surface and allow them to dry completely.

Cleaning with disinfection

To ensure safety when handling chemicals, follow the instructions for use of the disinfectant.

Mechanical cleaning with disinfection:	EQUIPMENT: The method has been validated in Europe using: – Alkaline cleaning agent: Dr. Weigert neodisher® MediClean forte (concentration: 0.5%) – Deionised water – Cleaning and disinfection device as per DIN EN ISO 15883-1 and 15883-2. ***Info:*** *It may also be necessary to use a neutralising agent. Follow the recommendations of the manufacturer of the chemical.* PROCEDURE: Program (min. A0 = 3000) for cleaning and disinfecting according to manufacturer's instructions. DRYING: Ensure that there is no residual moisture remaining in the components. • Shake the water out of all of the parts. • Place all parts on a dry, clean and absorbent surface and allow them to dry completely.

Chemical cleaning with disinfection:	EQUIPMENT: The method has been validated in Europe using: – Aldehyde-free instrument disinfectant: Bode Bomix® plus (concentration: 2%) Active agent basis: Quaternary ammonium compound – Application time: 5 minutes PROCEDURE: • Clean and disinfect the individual parts in a single work step with a solution prepared according to the manufacturer's instructions. ***Info:*** *If the recommended treatment time is exceeded significantly, the plastic parts may take on the smell of the disinfectant.* RINSING: • ⚠ **CAUTION!** Disinfectant residues can cause allergic reactions or irritation of the mucous membrane. Rinse off all parts thoroughly in running water at about 15 °C for 3 minutes. • Dispose of the used solution. Unless otherwise specified by the manufacturer of the disinfectant, the diluted solution can be disposed of down the drain. DRYING: • Shake the water out of all of the parts. • Place all parts on a dry, clean and absorbent surface and allow them to dry completely.

Chemical disinfection

To ensure safety when handling chemicals, follow the instructions for use of the disinfectant.

EQUIPMENT:

The method has been validated in Europe using:

– Aldehyde-containing disinfectant: Bode Korsolex® basic (concentration: 4%)
  Active agent basis: Aldehyde donor, aldehyde
– Application time: 30 minutes

PROCEDURE:

CAUTION

Risk of infection due to growth of bacteria

Inadequate disinfection encourages the growth of bacteria and thus increases the risk of infection.

- Observe the mixing proportions indicated and the specified treatment time.
- Ensure that all components are completely submerged in the solution for the whole of the treatment time. There must not be any air pockets or bubbles.

- Disinfect the individual parts with a solution prepared according to the manufacturer's instructions.

If the recommended application period is exceeded significantly, the plastic parts may take on the smell of the medium used.

RINSING:

CAUTION

Risk of allergic reactions and irritation of the mucous membrane by disinfectants

Disinfectants can trigger allergic reactions or irritation of the mucous membrane on contact with the skin.

- Rinse the product thoroughly to ensure that no residues of the disinfectant remain on the PARI product.

- Rinse off all parts thoroughly in running water at about 15 °C for 3 minutes.
- Dispose of the used solution. Unless otherwise specified by the manufacturer of the disinfectant, the diluted solution can be disposed of down the drain.

DRYING:

- Shake the water out of all of the parts.
- Place all parts on a dry, clean and absorbent surface, and allow them to dry completely.

Sterilising

CAUTION

Risk of infection by residual germs

If there is dirt on the parts, germs capable of reproduction may remain despite the sterilisation process. As a result, there is a danger of infection.

- Clean, disinfect, and dry all parts thoroughly before sterilising.
- Use only validated procedures for cleaning and disinfection.

EQUIPMENT:

The method has been validated in Europe using:

– Steam steriliser with fractionated pre-vacuum in accordance with DIN EN 285 or DIN EN 13060

– Sterile barrier system in accordance with DIN EN 11607-1

– Temperature: 132 °C / 134 °C

– Holding time: min. 3 minutes

PROCEDURE:

- Pack all the disassembled parts in a sterile barrier system as per DIN EN 11607-1 (e.g. foil-paper packaging).
- Carry out the sterilisation in a steam steriliser in accordance with the manufacturer's instructions.

Sterilisation temperature and holding time:

132 °C / 134 °C, at least 3 minutes.

DRYING:

Ensure that there is no residual moisture remaining in the components. If necessary:

- Shake the water out of all of the parts.
- Place all parts on a dry, clean and absorbent surface and allow them to dry completely.

5.4 Connection tubing

Mechanical cleaning and disinfecting

EQUIPMENT:

The method has been validated in Europe using:

– Alkaline cleaning agent: Dr. Weigert neodisher® MediClean forte
– Neutralising agent: Dr. Weigert neodisher® Z
– Cleaning and disinfection device: RDG G7836 CD (Miele) (conforming to DIN EN ISO 15883)
– Special baskets for Miele instrument dishwasher
– Compressed air source for drying

PROCEDURE:

Vario TD program or comparable valid programs

DRYING:

Dry the connection tubing as described in the section on this topic.

Drying

- Connect the connection tubing to a compressed air source (compressor or central medical gas supply system).
- Switch the compressed air source on.
- Leave the compressed air source running until all the moisture in the tube has been removed.

5.5 Visual inspection and storage

Check all individual components. Replace any broken, deformed or seriously discoloured parts.

Storage location:

– dry
– dust-free
– protected from sources of contamination
optional: Use sterile packaging

6 TROUBLESHOOTING

Contact the manufacturer or distributor:

– in the event of faults that are not listed in this chapter.

– if the suggested procedure does not correct the fault.

Fault	Possible cause	Remedy
No aerosol is coming out of the nebuliser.	The nebuliser nozzle is blocked.	Clean the nebuliser.
	The connection tubing is not connected properly.	Check that the tubing connectors are connected firmly to the compressor and the nebuliser.
	The connection tubing is leaking.	Replace the connection tubing.

7 TECHNICAL DATA

7.1 General nebuliser data

Size[5]	10 cm × 10 cm × 4 cm
Weight[5]	31 g to 33 g
Operating gases	Air, oxygen
Minimum compressor flow	3.0 l/min.
Minimum operating pressure	0.5 bar / 50 kPa
Maximum compressor flow	6.0 l/min.
Maximum operating pressure	2.0 bar / 200 kPa
Minimum fill volume	2 ml
Maximum fill volume	8 ml

7.2 Aerosol characteristics according to ISO 27427

The aerosol characteristics presented in these instructions for use were determined in accordance with ISO 27427 using 2 ml Salbutamol fill volume. If other solutions or suspensions are used for nebulisation, the aerosol characteristics may differ from the values shown (particularly if they have greater viscosity).

The following data is based on tests according to a standard which takes adult breathing patterns as a basis. Therefore, these figures will probably differ from corresponding figures that were calculated for populations of children and infants.

5) Without mouthpiece; unfilled.

Nozzle insert (orange)	Minimum nozzle flow (3 l/min – 0.6 bar)	Nominal nozzle flow (4.1 l/min – 1.2 bar)[6]	Maximum nozzle flow (6 l/min – 1.9 bar)
MMAD [µm][7]	4.0	3.4	2.9
GSD[8]	2.08	2.1	2.05
Respirable fraction [% < 5 µm]	61.7	68.7	76.5
Aerosol fraction [% < 2 µm]	17.4	24.9	28.6
Aerosol fraction [% > 2 µm < 5 µm]	44.3	43.8	47.9
Aerosol fraction [% > 5 µm]	38.3	31.3	23.5
Aerosol output [ml]	0.39	0.52	0.38
Aerosol output rate [ml/min]	0.05	0.15	0.16
Residual volume [ml] (gravimetric)	1.04	1.13	0.96
Percentage of fill volume emitted per minute [%/min]	2.7	8.0	7.9

8 FURTHER INFORMATION

All product components may be disposed of with normal domestic waste. The country-specific disposal regulations must be observed.

6) Operation with PARI COMPACT2 compressor (Type 152).

7) MMAD = Mass Median Aerodynamic Diameter

8) GSD = Geometric Standard Deviation

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