



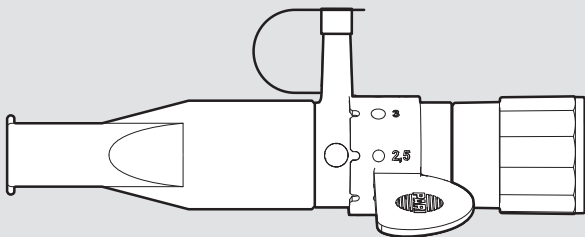
# Instructions for use

## PARI PEP® S System

Model: PARI PEP S System (Type 018)

PEP therapy system

PARI inhalation system accessories for combination therapy



## **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 PEP S System (Type 018)

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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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# 1 IMPORTANT INFORMATION

## 1.1 Intended purpose

The PARI PEP S System is used to mobilise secretion in acute and chronic diseases of the lower airways (**PEP therapy**<sup>1</sup>). It is used together with a PARI nebuliser in **combination treatment** (inhalation therapy and PEP therapy at the same time). The PARI PEP S system can also be used without an inhalation system (PEP therapy only).

The PARI PEP S system can be used:

- by children from about 4 to 10 years of age under the supervision and direction of a competent person
- by children aged 10 and older and adults after informed instruction

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.

The frequency and duration of use is determined by professional medical staff<sup>2</sup> according to the individual needs of the patient.

## 1.2 Indication

Diseases of the lower airways which are associated with increased mucus build up.

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1) PEP = **P**ositive **E**xpiratory **P**ressure














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

## 1.3 Contraindication

The PARI PEP S System must not be used by individuals who are suffering from untreated pneumothorax or massive haemoptysis.

## 1.4 Labelling

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

	Medical device
	Legal manufacturer
	Date of manufacture
	This product conforms to the EU Medical Device Regulation 2017/745.
	Consult instructions for use
	Item no.
	Production batch number, lot number
	Mouthpiece (without exhalation valve)
	Connecting element
	Inhalation valve
	Adjusting ring
	Nose clip
	Connection tubing

## 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.

When the system is used in combination therapy, the instructions for use of the nebuliser and compressor 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

The PARI PEP S system must not be used without first receiving instruction from a healthcare professional <sup>2</sup>.

**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.
- 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

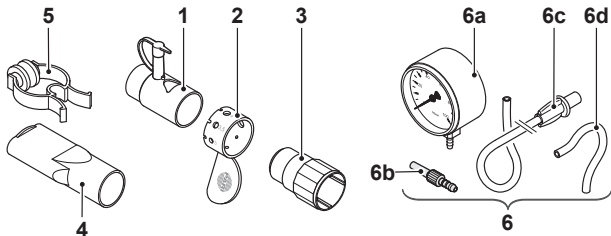
Serious incidents which occur in connection with this PARI product must be reported promptly to the manufacturer and/or the distributor, as well as to the competent authority. Any incident which has led or could lead directly or indirectly to death or an unexpected serious worsening of the health condition of a person is to be considered serious.

## 2 PRODUCT DESCRIPTION

### 2.1 Components

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

### 2.2 Overview and designations



(1)	Connecting element
(2)	Adjusting ring
(3)	Inhalation valve
(4)	Mouthpiece (without exhalation valve)
(5)	Nose clip
(6)	Pressure gauge 0 to 100 mbar
(6a)	Pressure gauge
(6b)	Tubing adapter
(6c)	Connection tubing
(6d)	Pressure gauge connector line

## 2.3 Product combinations

The PARI PEP S system can be used with:

- Nebulisers: PARI LC PLUS, PARI LC STAR, PARI LC SPRINT, PARI LC SPRINT Junior, PARI LC SPRINT STAR, PARI LC SPRINT COMPACT, PARI LC SPRINT SP, and PARI LL
- Pressure gauge
- PARI Filter/Valve Set

The PARI PEP S System **cannot** be used with masks.

## 2.4 Description of function

The PARI PEP S System is used in PEP therapy. It can be used alone (PEP therapy) or together with a nebuliser and a compressor (combination therapy).

### ***PEP therapy***

In PEP therapy, expiratory resistance when exhaling is increased by the different sizes of the holes in the PARI PEP S System (the smaller the hole, the greater the resistance). The increased expiratory resistance has the effect of stabilising the airways and stimulating mucus dissolution.

The hole size must be determined individually for each patient by a healthcare professional <sup>2</sup>.

### ***Combination therapy***

The PARI PEP S System can be used together with a nebuliser and a compressor instead of the mouthpiece (with exhalation valve) or a mask. In this case, PEP therapy is also performed as the patient breathes out during the nebuliser treatment.

## ***Pressure gauge***

When you exhale into the PARI PEP S System, pressure builds up in the tubing system. The pressure gauge measures this pressure and displays it in millibars (mbar) on the scale. The greater the pressure, the greater the expiratory resistance. The pressure gauge makes it possible to adjust the desired expiratory resistance on the PARI PEP S System and to monitor it during PEP therapy.

The pressure gauge is connected to the PARI PEP S System by tubes. The pressure gauge connector line and the tubing adapter prevent any germs from the exhaled air from getting into the connection tubing.

## **2.5 Material information**

The individual product components are made from the following materials:

### ***PARI PEP S System***

<b>Product component</b>	<b>Material</b>
PEP S connecting element	Polypropylene
PEP S adjusting ring	Polypropylene
PEP S inhalation valve	Silicone, polypropylene
Mouthpiece (without exhalation valve)	Polypropylene
Nose clip	Polyacetal, thermoplastic elastomer

## **Pressure gauge**

<b>Product component</b>	<b>Material</b>
Pressure gauge connector line	Silicone
Tubing adapter	Polyamide
Connection tubing	Polyvinyl chloride
Tubing connector	Thermoplastic elastomer

## **2.6 Calibration**

The pressure gauge should be calibrated every three years. For this, please contact PARI GmbH.

## **2.7 Operating life**

The individual product components have the following expected lifetimes:

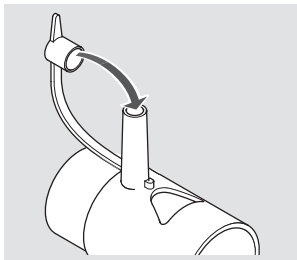
<b>Product component</b>	<b>Service life</b>
PARI PEP S System, connector line, tubing adapter, connection tubing	in home environment [see: REPROCESSING IN HOME ENVIRONMENTS, page 19]
PARI PEP S System, connector line, tubing adapter, connection tubing	in professional environment [see: REPROCESSING IN PROFESSIONAL HEALTH INSTITUTIONS, page 25]
Pressure gauge	The pressure gauge must be disposed of when it is no longer able to be calibrated.

### 3 USE

All the steps described below must be carried out properly.

#### 3.1 Preparing for treatment

- Close the PEP S connecting element securely using the cap.

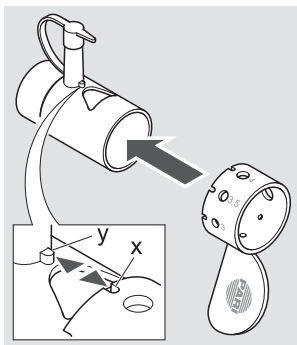


#### Adjusting expiratory resistance

- Push the PEP S adjusting ring onto the PEP S connecting element.
- Align the adjusting ring so that the hole with the diameter recommended by your doctor or therapist is positioned over the hole in the connecting element.

**Info:** *The smaller the hole, the greater the expiratory resistance.*

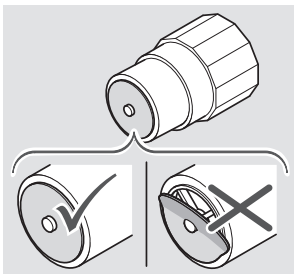
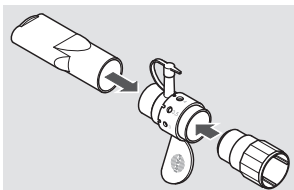
- To prevent the adjusting ring from slipping out of position, engage lug "y" in locking notch "x".



## PEP therapy

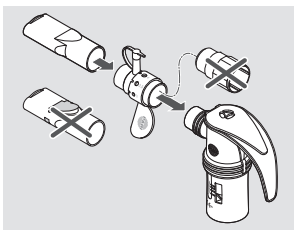
- Insert the PEP S inhalation valve in the connecting element.
- Insert the mouthpiece (**without exhalation valve**) on the other side of the connecting element.

**Info:** Make sure that the blue inhalation valve washer is seated correctly.



## Combination therapy

- Assemble the nebuliser (without mouthpiece) as described in the accompanying instructions for use.
- Attach the PEP S connecting element to the nebuliser.  
**Info:** The PEP S inhalation valve and the mouthpiece with exhalation valve are not needed for combination therapy.

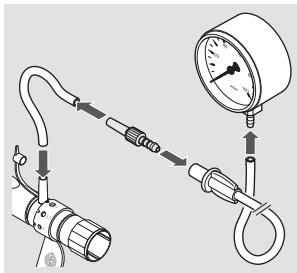


- Attach the mouthpiece (**without exhalation valve**) to the connecting element.

## Connecting the pressure gauge

- Open the cap on the PEP S connecting element.

- **⚠ CAUTION! Risk of infection due to contamination!** If the connection tubing is connected directly to the PARI PEP S System, germs may build up in the tubing. Since the connection tubing cannot be disinfected, use the pressure gauge exclusively with the extra pressure gauge connector line and the tubing adapter, in order to avoid a risk of infection.



- Push the pressure gauge connector line onto the pressure gauge attachment point on the PEP S connecting element.
- Insert the corresponding end of the connection tubing in the pressure gauge.
- Connect the connection tubing and the pressure gauge connector line using the tubing adapter.

## 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.**

Proceed as follows in order to carry out the treatment:

- Before starting the treatment, ensure that all parts are firmly connected to each other.
- Make sure that the expiratory resistance is adjusted correctly [see: Adjusting expiratory resistance, page 14].

**i** *If the breath resistance seems too high or too low to you during the therapy session, stop the session and consult your doctor or therapist.*



### ***When using without a pressure gauge***

- Make sure that the connecting element is closed securely by the cap.

### ***When using a pressure gauge***

#### **NOTE**

#### **Impaired treatment due to damaged pressure gauge**

If the pressure gauge is damaged, the measurement results displayed may be incorrect.

- If the pressure gauge has been dropped or suffered a similar impact, contact the manufacturer or distributor.
- During the therapy session, monitor the expiratory resistance displayed on the pressure gauge. If this is constantly different from the prescribed value, the expiratory resistance must be adjusted [see: Adjusting expiratory resistance, page 14].

### **PEP therapy**

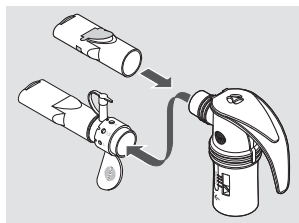
- Block your nose with the nose clip.
- Hold the mouthpiece between your teeth, close your lips tightly around it and breathe in slowly and deeply.
- Exhale through the mouthpiece.  
The exhaled air should pass through the hole in the PEP S adjusting ring.
- Cough to clear any secretion that is loosened during the treatment.  
For reasons of hygiene, avoid coughing into the PARI PEP S System.
- Continue the PEP therapy session for the period recommended by your doctor or physiotherapist.

## Combination therapy

- Block your nose with the nose clip.
- Hold the mouthpiece between your teeth, close your lips tightly around it and breathe in slowly and deeply.
- Exhale through the mouthpiece.  
The exhaled air should pass through the hole in the PEP S adjusting ring.
- Cough to clear any secretion that is loosened during the treatment.  
For reasons of hygiene, avoid coughing into the PARI PEP S System.

If the PEP therapy is to be terminated before the end of the nebuliser therapy, then the combination therapy can be paused and the PARI PEP S System can be replaced by the mouthpiece with exhalation valve or a mask. To do this, proceed as follows:

- Switch the compressor off.
- Disconnect the PARI PEP S System from the nebuliser.
- Attach the mouthpiece **with exhalation valve** or a mask to the nebuliser.
- Switch the compressor on again and resume the nebuliser treatment.



## 4 REPROCESSING IN HOME ENVIRONMENTS

The product components must be cleaned thoroughly immediately after each application and disinfected at least once a week.

The connection tubing cannot be cleaned or disinfected.

Dry the connection tubing after each use [see: Care of the pressure gauge and connection tubing, page 24].

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

### 4.1 Reprocessing cycles

PARI PEP S System	<ul style="list-style-type: none"> <li>– Clean immediately after every use</li> <li>– Disinfect once per week</li> </ul> <p>Cleaning and disinfection can be carried out together with the nebuliser.</p>
Pressure gauge	Care as required [see: Care of the pressure gauge and connection tubing, page 24].

### 4.2 Processing limits

PARI PEP S System, disinfection	300 processing cycles, max. 1 year
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## 4.3 Preparation

If a pressure gauge has been used:

- Detach the pressure gauge connector line from the connecting element.
- Detach the connection tubing from the pressure gauge.
- Detach the tubing adapter from the pressure gauge connector line and the connection tubing.

General:

- If necessary, disconnect the PARI PEP S system from the nebuliser.
- Dismantle the PARI PEP S system into its individual parts.
- Open the cap on the connecting element.

## 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 with a temperature of at least 40 °C
- Standard commercial washing-up liquid<sup>3</sup>
- Receptacle with at least 3 l capacity

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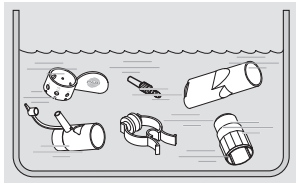
3) Validated with Palmolive®.

#### PROCEDURE:

- 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 all individual parts thoroughly under running drinking water at approx. 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.

If the pressure gauge connector line is visibly soiled, replace it.

### 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:

**i** *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.

## 4.5 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.
- Place all the individual parts in water at a rolling boil for at least 5 minutes. **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.

#### 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 disinfecter for baby bottles (not a microwave oven)

#### EQUIPMENT:

- Thermal disinfecter 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 disinfecter is clean and operating properly before every disinfection process.
- Allow the disinfection to continue until the disinfecter switches off automatically or the minimum disinfection time stated in the instructions for use of the disinfecter 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 disinfecter 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 disinfecter 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 disinfecter for max. 24 hours until the next use.

## **4.6 Care of the pressure gauge and connection tubing**

Wipe the pressure gauge and connection tubing with a damp cloth as necessary.

If the connection tubing is visibly soiled, replace it.

## **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 33].

### 5.1 Reprocessing cycles

#### Single patient use

PARI PEP S System	<ul style="list-style-type: none"> <li>– Clean immediately after every use</li> <li>– Disinfect once a week</li> </ul>
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#### Before a change of patients

PARI PEP S System	<ul style="list-style-type: none"> <li>– Cleaning</li> <li>– Disinfection</li> <li>– Sterilisation</li> </ul>
Connection tubing	Mechanical cleaning with disinfection

### 5.2 Processing limits

PARI PEP S System, disinfection	300 processing cycles, max. 1 year
PARI PEP S System, sterilisation	100 processing cycles, max. 1 year
Connection tubing	50 reprocessing cycles, max. 1 year

## 5.3 PARI PEP S System

### 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 33].

All components of the PARI PEP S System can be cleaned, disinfected and sterilised according to the procedures described below.

The connection tubing and elastic band of the mask must be treated separately.

### **Preparation**

Dismantle the inhalation device into its individual parts.

### **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

### **Manual cleaning**

#### EQUIPMENT

The method has been validated in Europe using:

- pH-neutral, enzymatic cleaner:  
Bode Bomix® plus (concentration: 0.1%)
- Drinking water temperature of about 15 °C
- 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.  
**i** *If the recommended application period is exceeded significantly, the plastic parts may take on the smell of the medium used.*

#### RINSING:

- Rinse all individual parts thoroughly under running drinking water at approx. 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***

Cleaning and disinfection can be carried out in a single cycle using a chemical preparation process.

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

<b>Mechanical cleaning with disinfection:</b>	<p><b>EQUIPMENT:</b></p> <p>The method has been validated in Europe using:</p> <ul style="list-style-type: none"><li>– Alkaline cleaning agent: Dr. Weigert neodisher® MediClean forte (concentration: 0.5%)</li><li>– Deionised water</li><li>– Cleaning and disinfection device: Steelco DS800 in conformance with DIN EN ISO 15883-1 and 15883-2</li></ul> <p><b><i>Info:</i></b> <i>If a different alkaline cleaning agent is used, it may also be necessary to use a neutralising agent. Follow the recommendations of the manufacturer of the chemical.</i></p> <p><b>PROCEDURE:</b></p> <p>Programme for cleaning and disinfecting according to manufacturer's instructions.</p> <p><b>DRYING:</b></p> <p>Ensure that there is no residual moisture remaining in the components.</p> <ul style="list-style-type: none"><li>• Shake the water out of all of the parts.</li><li>• Place all parts on a dry, clean and absorbent surface and allow them to dry completely.</li></ul>
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**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
- Drinking water at approx. 15 °C
- 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 drinking water at about 15 °C for 3 minutes.
- Dispose of the used solution (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
- Drinking water at approx. 15 °C
- 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.
- i** *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 all parts thoroughly under running drinking water at approx. 15 °C for 3 minutes.
- Dispose of the used solution. 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 of the disassembled parts in a sterile barrier system in accordance with 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 FURTHER INFORMATION**

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



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