



## **Identification, validity, version**

These instructions for use are valid for PARI SINUS2 nebuliser systems in the following countries:

Countries outside the EU

Version of these instructions for use: Version F – 2020-02,

Approved version dated 2019-11-21

Information as of: 2019-11

The current version of the instructions for use can be downloaded from the internet as a PDF file:

[www.pari.com](http://www.pari.com) (on the respective product page)

## **Formats available for visually impaired patients**

The instructions for use available in PDF format on the internet can be enlarged for printing.

## **CE conformity**

The product is compliant with the requirements according to:

- 93/42/EEC (Medical devices)
- 2011/65/EU (RoHS)

## **Trade marks**

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# TABLE OF CONTENTS

<b>IMPORTANT INFORMATION.....</b>	<b>7</b>
Intended purpose .....	7
Indication .....	8
Contraindications.....	8
Safety instructions .....	8
<b>PRODUCT DESCRIPTION .....</b>	<b>12</b>
Components .....	12
Working parts .....	13
Description of function .....	14
Material information .....	15
Maintenance .....	15
Operating life .....	15
<b>APPLICATION .....</b>	<b>16</b>
Setting up the compressor .....	16
Preparing for treatment .....	18
Performing treatment.....	21
Ending the treatment .....	24
<b>REPROCESSING .....</b>	<b>25</b>
Single patient use.....	25
Multiple patient use .....	29
Care of the PARI SINUS tubing system .....	30
Replacing the air filter.....	30
Inspecting .....	31
Storage .....	31
<b>TROUBLESHOOTING .....</b>	<b>32</b>
<b>TECHNICAL DATA.....</b>	<b>33</b>
Compressor .....	33
Nebuliser .....	35

<b>MISCELLANEOUS .....</b>	<b>36</b>
Disposal.....	36
Links .....	37
Labelling .....	37
<b>APPENDIX: Reprocessing in professional environ- ments (for only one patient) .....</b>	<b>39</b>
Compressor.....	39
Nebuliser .....	39
PARI SINUS tubing system.....	41

# 1 IMPORTANT INFORMATION

## 1.1 Intended purpose

The PARI SINUS2 nebuliser system consists of a PARI SINUS2 compressor and a PARI LC SPRINT SINUS nebuliser.

The system is used for treatment of the upper airways.

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

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

If the patient is not able to operate the nebuliser system safely himself, the therapy must be carried out by the responsible person.

### ***Compressor***

The purpose of the PARI compressor is to generate compressed air for operating a PARI nebuliser.

The PARI compressor is intended for use with multiple patients. It must only be used for PARI nebulisers. The compressor can be operated by the patient himself and must only be used indoors.

### ***Nebuliser***

The PARI LC SPRINT SINUS nebuliser generates aerosols<sup>1</sup> for respiratory therapy.

For reasons of hygiene, this PARI product must only be used in a home environment by a single patient. It is designed to treat patients from age 6 up to adult.

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

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

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

The frequency and duration of use will be determined by the physician or therapist according to the individual needs of the patient.

## **1.2 Indication**

Diseases of the nose and paranasal sinuses.

## **1.3 Contraindications**

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

Following surgery or where inflammation of the middle ear is present, a risk/benefit assessment for vibrating aerosols must be carried out by the doctor before the start of treatment.

## **1.4 Safety 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 only be used as described in these instructions for use.

The instructions for use of the inhalation solution used must also be followed.

### **General**

Nebuliser aerosol characteristics differ from the information provided by the manufacturer if non-approved solutions or suspensions are used for nebulisation.

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

**If your health condition is not improved, or even worsens as a result of the treatment, seek professional medical advice.<sup>2</sup>**

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

## **Danger of electrocution**

The compressor is an electrical device that is powered by supply voltage. It has been designed so that no live parts are accessible. However, if ambient conditions are unfavourable or if the compressor or power cord is damaged, this protection may no longer be provided. It may then be possible to come into contact with live parts. This in turn may lead to an electric shock. To avoid this danger, follow the instructions below:

- Make sure that the compressor housing, the power cord and the power plug are undamaged every time before use. The compressor must not be operated
  - if the housing, the power cord or the power plug is damaged,
  - if a fault is suspected following a fall or similar.
- Never leave the compressor unattended while it is in use.
- Plug the compressor into an easily accessible socket. It should be possible to unplug the power plug at all times.
- Switch the compressor off and disconnect the power plug from the mains socket immediately:
  - if it is suspected that the compressor or the power cord might have been damaged (e.g., after the compressor has fallen or if there is a smell of burning plastic)
  - if a malfunction occurs during operation
  - before cleaning and maintaining the device
  - immediately after use
- Keep the power cord away from domestic animals (e.g., rodents). They may damage the insulation on the power cord.

## **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.



## **Danger of a device defect**

Comply with the following instructions to avoid a device defect:

- Make sure that the local supply voltage matches the voltage data marked on the compressor identification label.
- To avoid overheating of the compressor,
  - Never operate the compressor while it is in a bag,
  - Never cover the compressor while it is operating,
  - Make sure that the ventilation slits on the compressor are unobstructed at all times while it is operating.
- Always pull the power cord by the power plug, not the cable, to disconnect it from the socket.
- Make sure that the power cord is never kinked, pinched or jammed. Do not pull the power cord over sharp edges.
- Keep the compressor and the power cord away from hot surfaces (e.g., stove top, electric fire, open fire). Direct heat may damage the compressor housing or the insulation on the power cord.

## **Impairment of treatment due to electromagnetic interference**

Use only original spare parts and original accessories from PARI. The use of third party products can result in increased emissions of electromagnetic interference or reduced resistance of the PARI compressor.

## **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.
- It is essential to clean and dry all product components before the first application as well.

- Always use drinking water for cleaning and disinfecting.
- Dry all product components completely after each cleaning and disinfection.
- Do not keep the product components in a damp environment or together with damp objects.

## **Treatment of children and anyone who requires assistance**

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 a tube). Such individuals include for example babies, children and people with limited capabilities. For these individuals, a person responsible for safety must supervise or carry out the application.

## **Identifying and classifying warning instructions**

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

### **DANGER**

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

### **WARNING**

WARNING indicates a hazardous situation which can lead to 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.

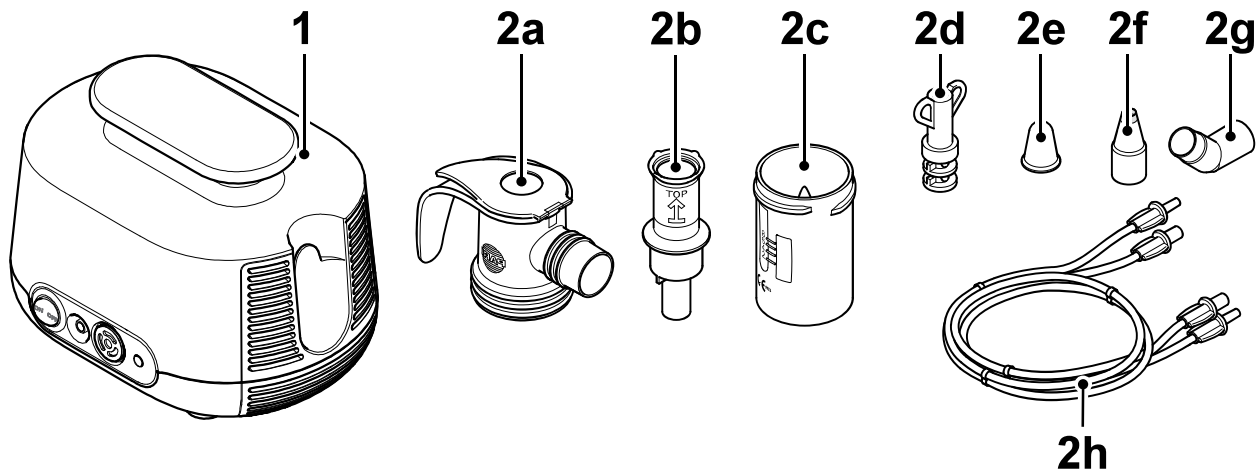
### **NOTE**

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

## 2 PRODUCT DESCRIPTION

### 2.1 Components

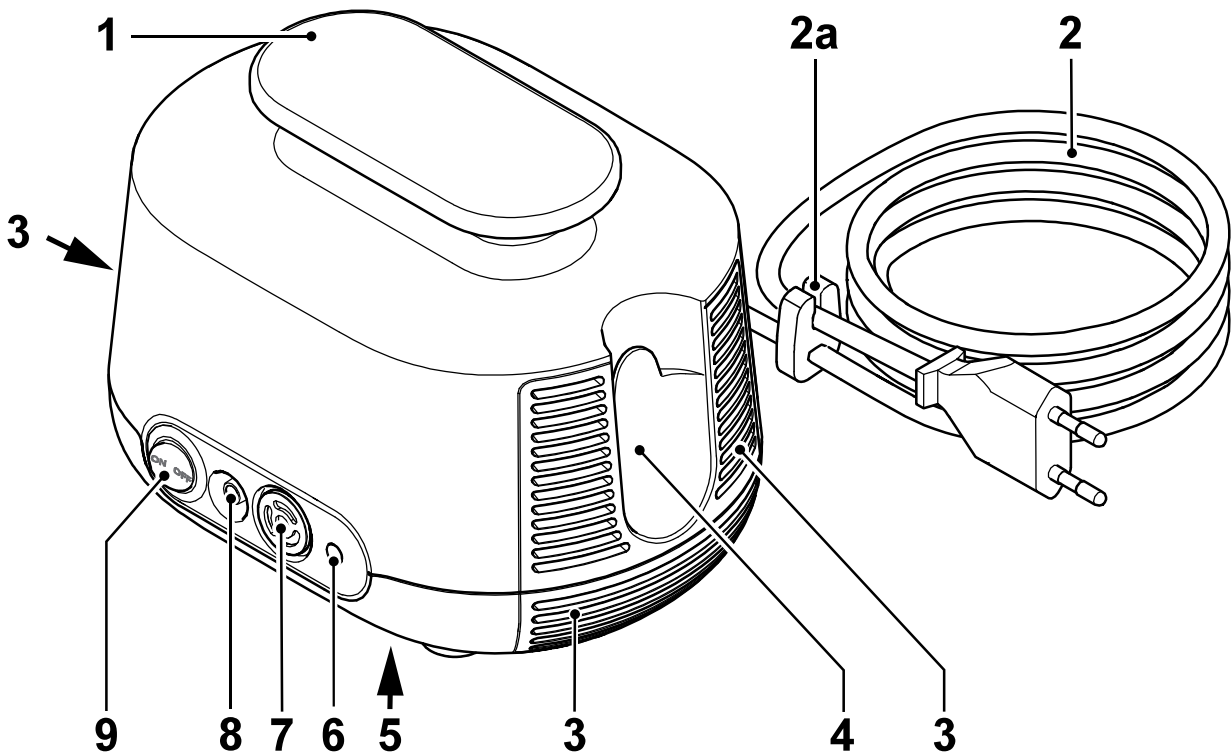
The following components are included in the package (these may differ from the picture on the packaging):



(1)	Compressor
(2)	PARI LC SPRINT SINUS nebuliser
(2a)	Nebuliser upper part
(2b)	Nozzle insert (orange)
(2c)	Nebuliser lower part
(2d)	Adapter for vibration
(2e)	Nasal plug
(2f)	Nasal joining piece
(2g)	Bend
(2h)	PARI SINUS tubing system

## 2.2 Working parts

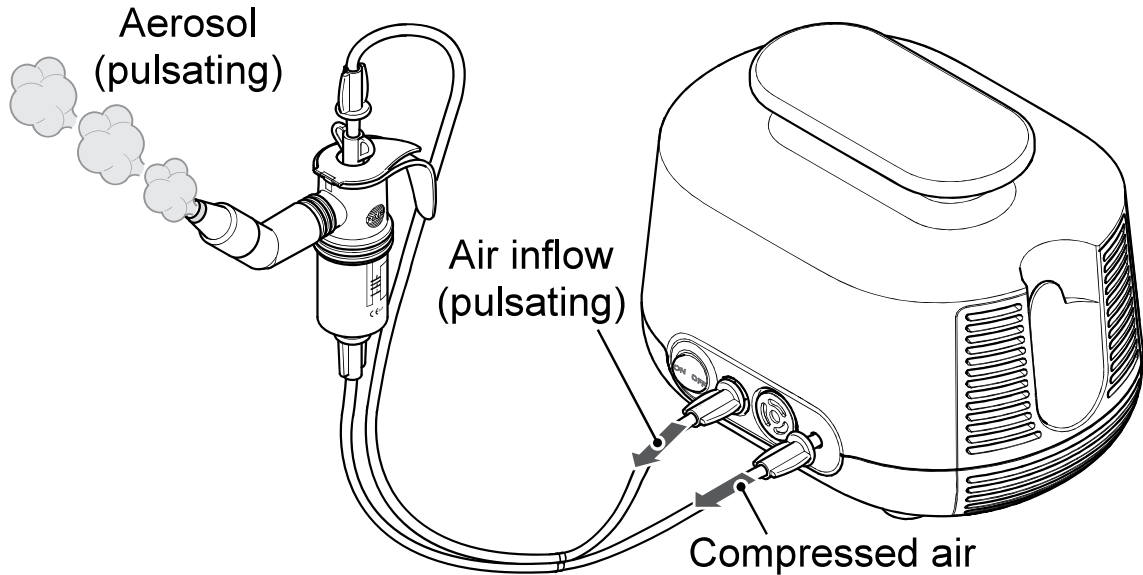
The compressor includes the following working parts:



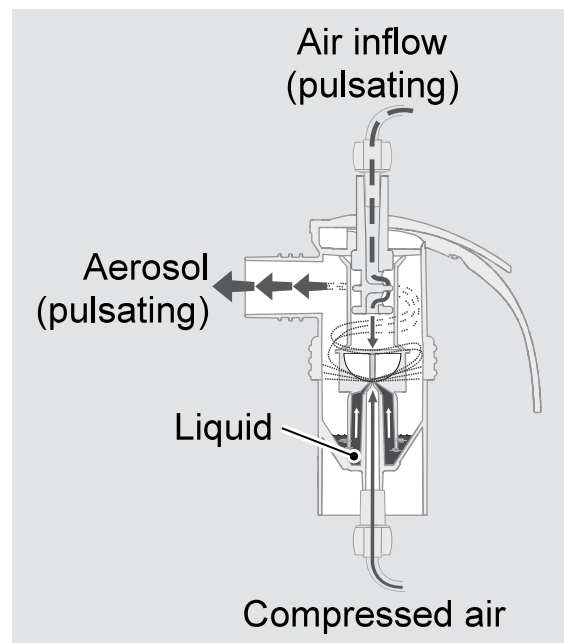
(1)	Carrying handle
(2)	Power cord <sup>3</sup> (connected inseparably to the compressor)
(2a)	Cable holder
(3)	Ventilation slits
(4)	Holder for nebuliser
(5)	Identification label (bottom of device)
(6)	Air connection
(7)	Air filter
(8)	Vibration connection
(9)	On/off switch

3) The power plug type is country-specific. The figure shows the europlug (type "C").

## 2.3 Description of function



The compressor supplies the nebuliser with compressed air. When compressed air is supplied, the nebuliser generates an aerosol from the liquid, for example the medication with which it is filled. This aerosol is delivered to the nose and paranasal sinuses through the nasal insert. The pulsation supports this process.



## 2.4 Material information

The individual product components are made from the following materials:

Product component	Material
Nebuliser upper part	Polypropylene, thermoplastic elastomer
Nozzle insert	Polypropylene
Nebuliser lower part	Polypropylene, thermoplastic elastomer
PARI SINUS tubing system	Polyvinyl chloride
Tubing endpiece	Thermoplastic elastomer
Nasal joining piece	Polypropylene, thermoplastic elastomer
Adapter for vibration	Thermoplastic elastomer
Nasal plug	Silicone
Bend	Polypropylene

## 2.5 Maintenance

The compressor is maintenance free.

## 2.6 Operating life

The individual product components have the following expected lifetimes:

Product component	Operating life
Compressor	Approx. 1,000 operating hours (this corresponds to max. 5 years) If the compressor is still in use after this time, have the compressor tested. To do this, contact the manufacturer or distributor.
Nebuliser (all components except the PARI SINUS tubing system)	300 disinfections, max. 1 year
PARI SINUS tubing system	Max. 1 year

## 3 APPLICATION

People who assist others in carrying out the therapy must ensure that all of the steps described below are carried out correctly.

### 3.1 Setting up the compressor

The room in which the compressor is operated must satisfy certain requirements [see: During operation, page 34]. Furthermore, please note the following warnings before setting the compressor up:



#### **WARNING**

##### **Risk of fire due to a short circuit**

A short circuit in the compressor can cause a fire. In order to reduce the risk of fire in such an event, follow the instructions below:

- Do not operate the compressor close to readily flammable objects such as curtains, tablecloths, or paper.
- Do not operate the compressor in areas where there is a risk of explosion or in the presence of oxidising gases (e.g., oxygen, nitrous oxide, flammable anaesthetics).



#### **CAUTION**

##### **Quality of treatment impaired by electromagnetic interference**

Electrical devices can cause electromagnetic interference. Interference can impair the function of the devices and thus also the effectiveness of the treatment.

- Do not place the PARI device immediately beside or on top of other devices.
- Keep at a minimum distance of 30 cm from portable wireless communication devices (including accessories therefor, such as antenna cables or external antennas).
- If the PARI device has to be placed immediately beside or on top of other devices for operation, all devices must be monitored to ensure that they are working properly.

 **CAUTION**

**Danger of injury from falling compressor**

A compressor placed in a poor position poses a risk of injury.

- Do not place the compressor above head height.
- Make sure that the compressor cannot be pulled down by the power cord or the connection tubes.
- Do not place the compressor on a soft surface such as a sofa, a bed or a tablecloth.

**NOTE**


**Danger of device fault caused by dust**

If the compressor is operated in a very dusty atmosphere, more dust may collect inside the housing. This may cause a fault in the device.

- Do not operate the compressor on the floor, under the bed or in workshops.
- Only operate the compressor in a low-dust environment.

Set the compressor up as follows:

- Place the compressor on a firm, flat, dust-free, dry surface.
- Plug the power plug into a suitable socket.

 **CAUTION!** Route the power cord in such a way that it is not a tripping hazard and no one can become entangled in it. Poorly routed cable connections pose a risk of injury.



## 3.2 Preparing for treatment

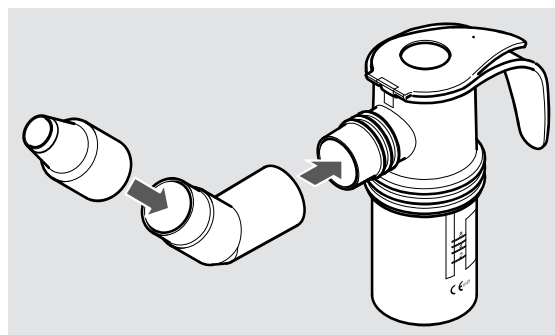
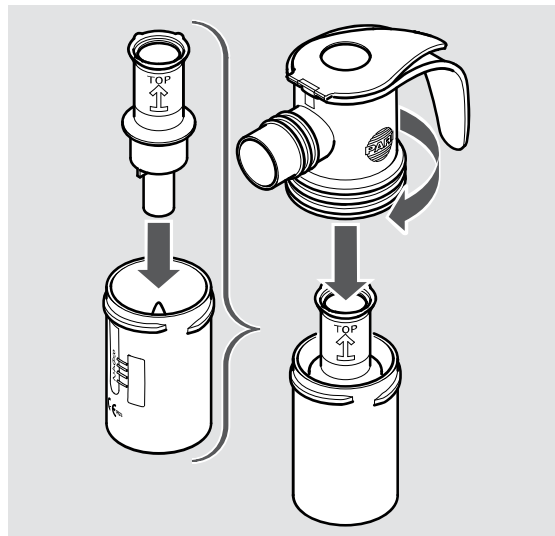
### Assembling the nebuliser

#### CAUTION

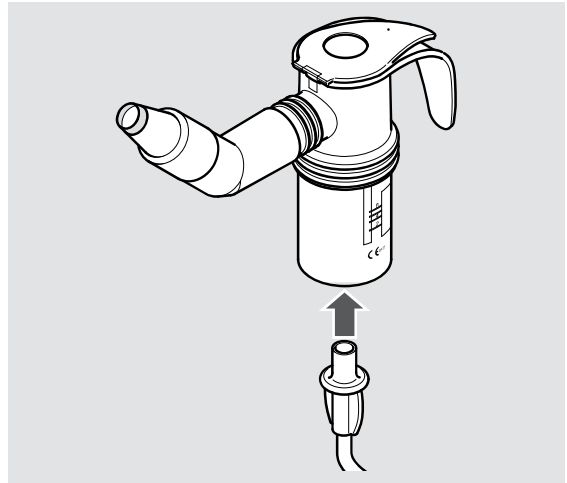
#### Risk of impaired treatment

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, misshapen 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.
- 
- Connect the nasal joining piece to the bend and then connect both to the nebuliser.



- Insert one tubing connector on the PARI SINUS tubing system in the bottom of the nebuliser.



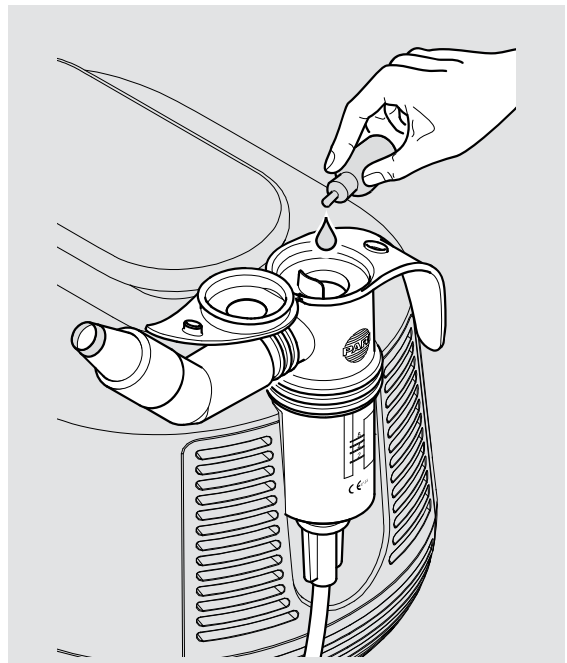
## Filling the nebuliser

### **NOTE**

#### **Nebuliser lid might break off**

If the lid 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.  
Note the minimum and maximum fill volumes [see: General nebuliser data, page 35]. 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:***

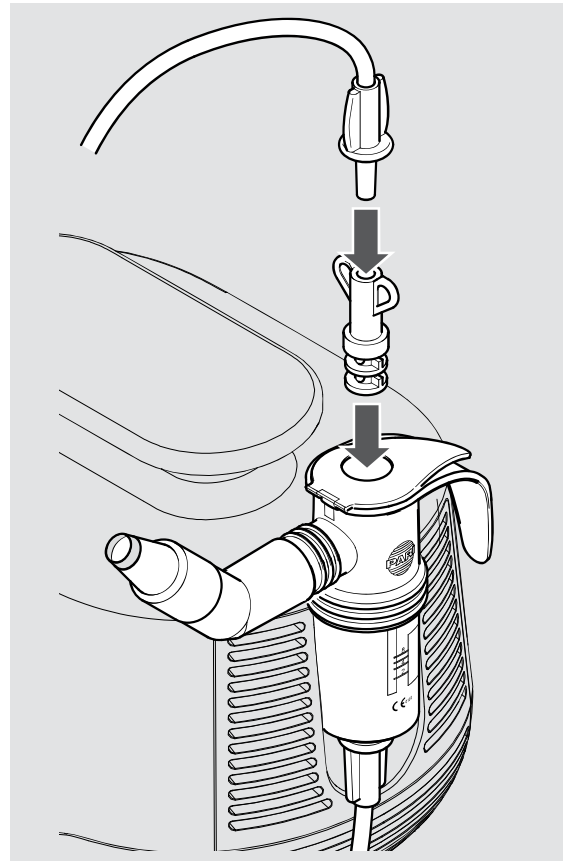
- Rinse the nebuliser out with drinking water between the individual applications.
- Shake excess water out of the nebuliser.
- Fill the nebuliser with the next inhalation solution as described.

## **Connecting the tubes**

The PARI SINUS tubing system consists of two identical tubes. One tube is needed for the compressed air supply, the other helps to generate the vibration.

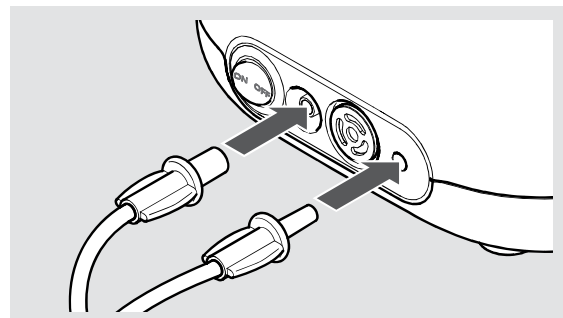
To connect the tubing system up fully, proceed as follows:

- Insert the corresponding connector of the unconnected tube in the vibration adapter.
- Insert the adapter in the nebuliser upper section.



- Insert the free tubing connectors in the corresponding connectors on the compressor.

***Info:*** The tubing connectors can be inserted more easily if they are twisted slightly when inserting.



### 3.3 Performing treatment

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

**i** *Always hold the nebuliser upright during treatment.*

#### General instructions for use

To ensure that the treatment has the desired effect, please follow the instructions below:

- In order for the aerosol to reach all regions of the nose and paranasal sinuses, the nose must be clear. If your nose is blocked, rinse it beforehand using a nasal douche for example. If necessary, use a product designed to reduce swelling.
- The aerosol that is generated during nebulisation should only be delivered to the nose and paranasal sinuses. Therefore, the soft palate<sup>4</sup> – the natural partition between the nasal cavity and the mouth and throat – must be closed.

#### Tips for closing the soft palate

To close your soft palate, say the three letters “ing” as one word for as long as possible. After a short breathing pause, repeat this as often as necessary until the treatment is complete.

**i** *When you make certain sound combinations such as “ing” and when you swallow, the “soft palate” closes and separates the nasal cavity from the mouth and throat automatically.*

Alternatively, you can breathe in and out slowly and deliberately through your mouth, as if attempting to blow a candle out (i.e. do not breathe through your nose). However, this method of closing the soft palate is not easy to perform for everybody, and some practice may be required.

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4) The soft palate is the extension of the hard palate.

While the soft palate is closed and you are holding your breath, the aerosol flows into the paranasal sinuses. Your nostrils will vibrate a little.

**i** *Caution: If the soft palate is not closed properly, some of the aerosol will end up in your mouth and throat. One sign of this is that the nostrils do not vibrate. In this case, it is possible that not enough saline solution or medication is reaching the paranasal sinuses.*

## Procedure

### DANGER

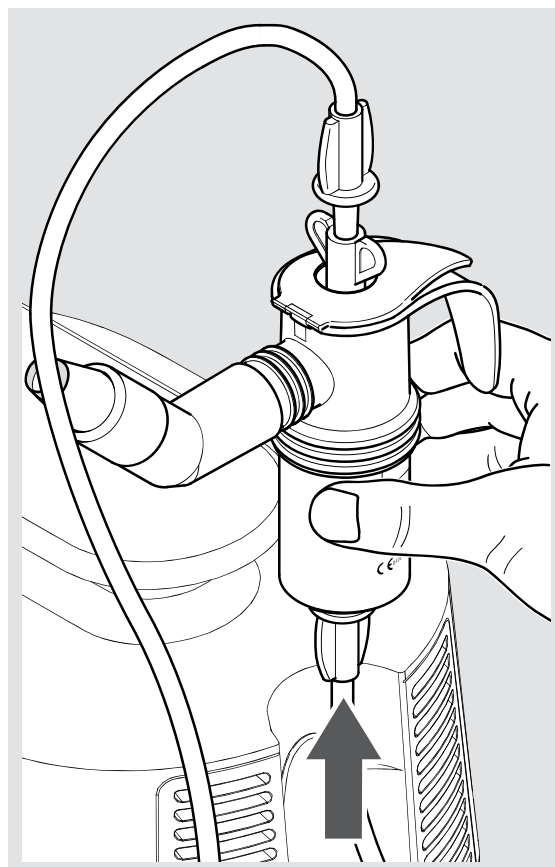
#### **Life-threatening situation due to mixing up tubes**

If tubing systems that belong to other devices are close by (e.g., for infusions), there is a possible danger of mixing up different connection tubes.

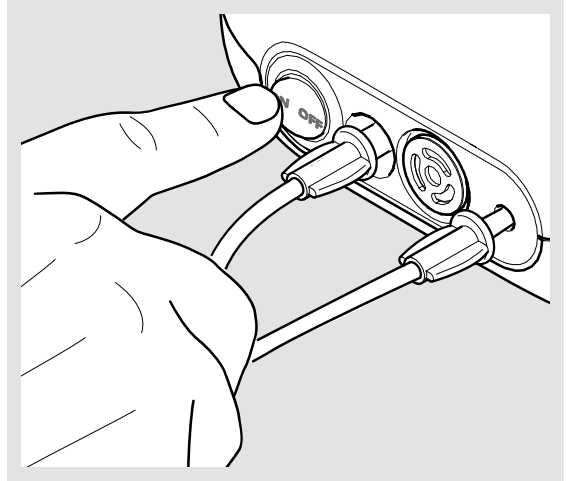
- Make quite sure that the other ends of the tubes connected to the compressor are attached to the PARI nebuliser.

Proceed as follows in order to carry out the treatment:

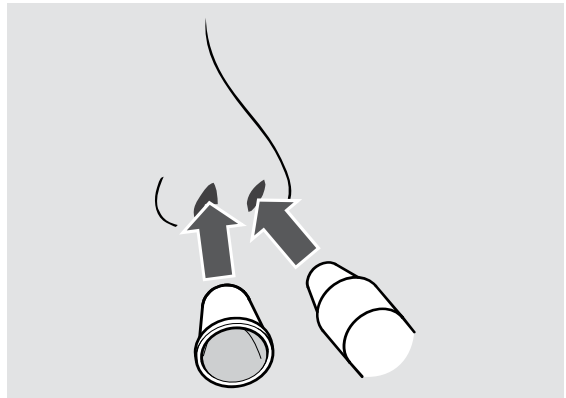
- Take the nebuliser out of its holder and hold it upright.
- Verify that all parts are firmly connected to each other.



- Switch the compressor on.  
**⚠ DANGER! Danger of death by electrocution in the case of device fault!** Switch the compressor off and disconnect the power plug from the mains socket immediately if a fault is suspected (e.g., following a fall or if there is a smell of burning plastic). If there is a fault in the device, it may be possible to come into contact with live parts. This in turn may lead to an electric shock.



- Check that an aerosol is being generated before you begin the treatment.
- Sit in an upright position and relax.
- Constrict one nostril.  
To do this, either press one finger lightly against the side of the nose or use the nasal plug supplied.



**i** Make sure that the nostril is not completely blocked (e.g. by pressing closed with a finger) because this might create a feeling of too much pressure.

*The nasal plug has a small aperture. This aperture reduces the feeling of pressure.*

- Press the nasal joining piece of the nebuliser against the free nostril so that the nostril is closed tightly.
- Close your soft palate [see: Tips for closing the soft palate, page 21].

The aerosol is automatically delivered to the paranasal sinuses. Therefore, you should hold your breath during the treatment. In order to breathe, pause the treatment briefly.

After about 2.5 minutes, carry out the treatment as described for a further 2.5 minutes on the other nostril. The treatment is complete after 5 minutes in all.

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

## Reducing feeling of pressure

If you feel an uncomfortable level of pressure while carrying out the therapy, reduce the pressure:

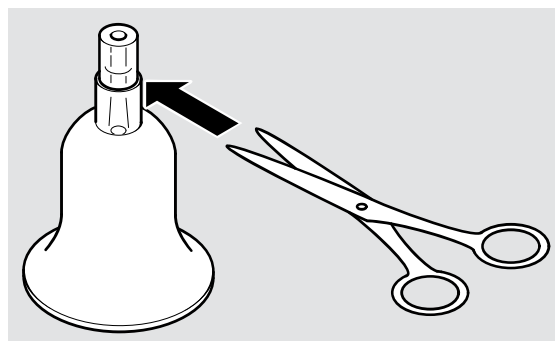
- reduce the pressure on your free nostril and/or
- enlarge the hole in the nasal plug.

To enlarge the hole, proceed as follows:

**i** *The larger the hole, the less the feeling of pressure.*

**i** *Proceed carefully to avoid making the hole too large and reducing the pressure too much. You must be able to feel the vibration all the time during the therapy.*

- Push out the inside of the nasal plug and cut off the tip at the edge indicated using a pair of scissors.
- Push the inside of the nasal plug back in.



## 3.4 Ending the treatment

To end the treatment, proceed as follows:

- Switch the compressor off.
- Place the nebuliser back in the holder on the compressor.
- Disconnect the power plug from the mains socket.

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

## 4 REPROCESSING



### DANGER

#### Danger of electrocution

Liquids can conduct electricity, thereby posing a risk of electric shock.

- Always switch the compressor off and disconnect the power plug from the mains socket before starting to clean it.

If the nebuliser system is used **by only one patient**, follow the instructions for cleaning and disinfecting in the section "Single patient use" [see: Single patient use, page 25].

If the nebuliser system is used **by several patients**, follow the instructions for cleaning and disinfecting in the section "Multiple patient use" [see: Multiple patient use, page 29].

If the nebuliser system is used **in professional environments**, follow the information on reprocessing included in the appendix at the end of these instructions for use.

### 4.1 Single patient use

#### Cleaning and disinfection cycles

Compressor housing	Clean when visibly dirty
Nebuliser (without PARI SINUS tubing system)	<ul style="list-style-type: none"><li>– Cleaning immediately after every use.</li><li>– Disinfection at least once a week. In the case of an acute infection or for high risk groups (e.g., cystic fibrosis patients) at least once a day.</li></ul>
Air filter	Replace after 200 operating hours (approx. 1 year)



## Nebuliser

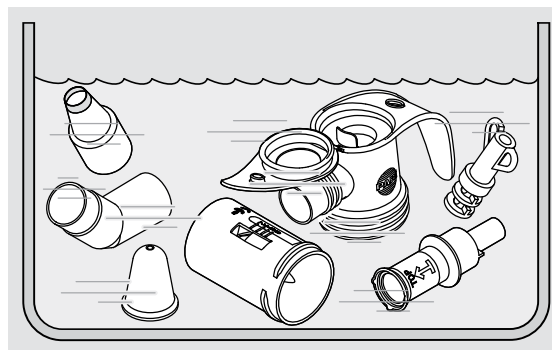
### Preparation

- Pull the two tubes and the adapter off the nebuliser.
- Make sure that all residual volume is removed from the nebuliser.
- Detach the adapter from the tube.
- Dismantle the nebuliser into its individual parts.

### Cleaning

**i** *The PARI SINUS tubing system cannot be cleaned or disinfected. Regarding care of the tubing system, follow the instructions in the corresponding section [see: Care of the PARI SINUS tubing system, page 30].*

- Briefly rinse all parts used in running drinking water beforehand.
- Place all disassembled components in warm drinking water with a little dishwashing liquid for about 5 min.



- Rinse off all parts thoroughly in drinking water.
- Shake the water out of all of the parts.

### Disinfecting

After cleaning, disinfect all of the **disassembled parts** (only parts that have been cleaned can be disinfected effectively). The recommended disinfection procedures are described below. Descriptions of other validated disinfection procedures are available from the manufacturer or dealer upon request.

**i** *The PARI SINUS tubing system cannot be cleaned or disinfected. Regarding care of the tubing system, follow the instructions in the corresponding section [see: Care of the PARI SINUS tubing system, page 30].*

 **CAUTION**

**Risk of infection due to moisture**

Moisture encourages the growth of bacteria.

- Remove all parts from the pot or disinfector as soon as the disinfection process is finished.
- Dry all parts.

**IN BOILING WATER**

- Place all the **individual parts** in boiling water for at least 5 minutes. Use a clean pot and drinking water.

**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.

- Shake the water out of all of the parts.

**USING A STANDARD THERMAL DISINFECTOR FOR BABY BOTTLES (NOT A MICROWAVE OVEN)**

 **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.

Use a thermal disinfector with a runtime of at least 6 minutes. 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 each cleaning and disinfection, place all product components on a dry, clean and absorbent surface and let them dry completely.

## **Cleaning the compressor housing**

### **NOTE**

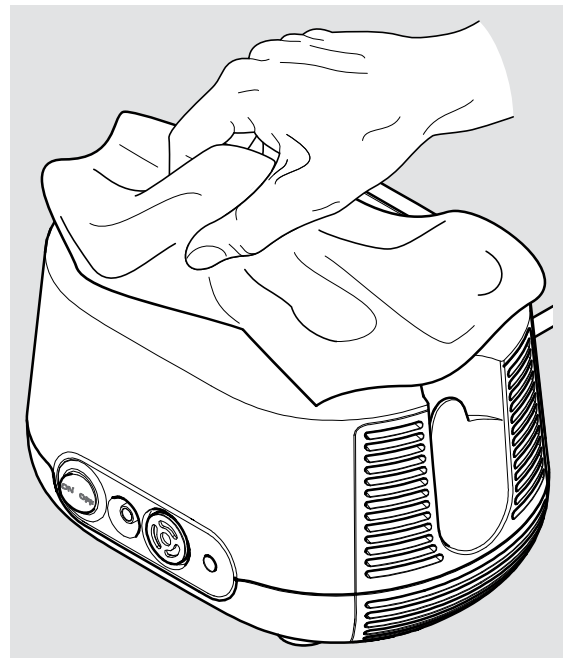
#### **Danger of device fault due to liquid penetration**

If liquids get into the interior of the compressor, this may cause a fault in the device.

- Never immerse the compressor in water.
- Never clean the compressor in running water.
- Never spray any liquids onto the compressor or the power cord.
- If liquid does get into the compressor, it must not be used under any circumstances. Before starting the compressor again, contact the manufacturer or dealer.

Clean the compressor housing as follows:

- Wipe the outer surface of the housing with a clean, damp cloth.



## 4.2 Multiple patient use

### Cleaning and disinfection cycles

Nebuliser with PARI SINUS tube system	Replace before each patient change
Compressor housing	Disinfect before each patient change
Air filter	Replace after 200 operating hours (approx. 1 year)

### Nebuliser

The nebuliser is not suitable for use by more than one patient. Use a separate nebuliser (including connection tubing) for each patient.

### Disinfecting the compressor housing

For disinfection, use a standard, alcohol-based disinfectant (e.g., isopropanol). Regarding the use and quantity of the disinfectant, it is imperative to follow the information for use of the agent used.

Disinfect the compressor as follows:

- If the compressor is visibly dirty, clean the compressor before disinfecting it [see: Cleaning the compressor housing, page 28].
- Moisten a cloth with the disinfectant.

**NOTE! Danger of device fault due to liquid penetration.**

Never spray any liquids onto the compressor or the power cord. If liquid does get into the compressor, it must not be used under any circumstances. Before starting the compressor again, contact the manufacturer or distributor.

- Wipe the outer surfaces of the housing off thoroughly with the cloth.

### 4.3 Care of the PARI SINUS tubing system

Dry the PARI SINUS tubing system after every use:

- Insert the matching tubing connector on the first of the two tubes in the compressed air connector on the compressor.
- Switch the compressor on.
- Allow air to blow through the tube until the air has removed all moisture from the tube.
- Switch the compressor off.
- Disconnect the tube from the compressor, and attach the other tube to the compressed air connection.
- Repeat the process as described for the first tube.

### 4.4 Replacing the air filter

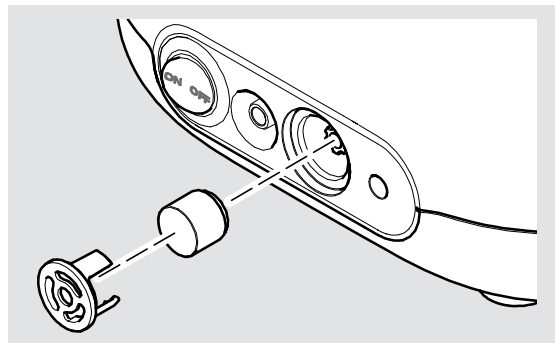
The air filter must be checked at regular intervals (after every 10th application). If it is discoloured brown or grey, or if it is damp or clogged, it must be replaced.

In all cases, it must be replaced after 200 operating hours (approx. 1 year).

**The air filter cannot be cleaned and then reused!**

Take the air filter out:

- Pull the filter holder out of the compressor. Use a small screwdriver, for example, to prise the filter holder carefully out of the compressor.



Replace the air filter:

- Pull the old air filter out of the filter holder and fit the new filter in its place.

**NOTE!** Only use air filters provided by the manufacturer or dealer for operating your compressor. If air filters that are not designed for the compressor are used, the compressor may be damaged.

- Insert the filter holder back in the compressor.

## 4.5 Inspecting

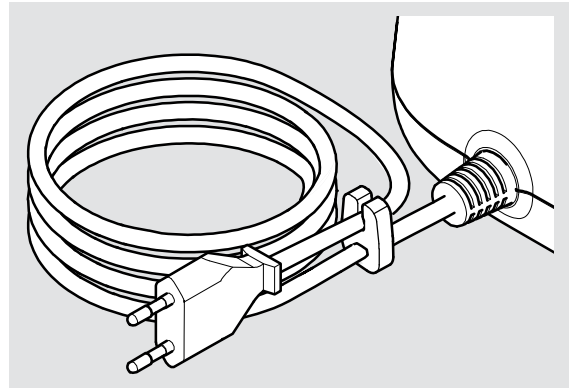
Inspect all product components after each cleaning and disinfection. Replace any broken, misshapen or seriously discoloured parts.

## 4.6 Storage

Store this product as described below:

- Wind the power cord up loosely.

**NOTE!** Do not wind the power cord around the compressor. If the power cord is wound or bent very tightly, the wires inside the cord may break. The power cord will then be unusable.



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

**i** *Unplug the power plug from the socket when putting the compressor away. Electrical devices that remain plugged into the power supply present a potential hazard source.*

## 5 TROUBLESHOOTING

The compressor must not be repaired except by the Technical Service of PARI GmbH or a service center expressly authorised to do so by PARI GmbH. If the compressor is opened or manipulated by anyone else, all claims under the warranty shall be void. In these cases, PARI GmbH will accept no liability.

Fault	Possible cause	Remedy
The compressor does not start up.	The power plug is not plugged into the mains socket properly.	Check whether the power plug is plugged into the socket correctly.
	The supply voltage is not suitable for running the compressor.	Check whether the local supply voltage matches the voltage data marked on the compressor identification label.
No aerosol is coming out of the nebuliser.	The nebuliser nozzle insert is blocked.	Clean the nebuliser.
	The compressed air supply tube is not connected correctly to the compressed air connection on the compressor or the nebuliser lower section.	Check that the tubing connectors are connected firmly to the compressor and the nebuliser.
	The tube attached to the compressed air connection on the compressor is leaking.	Replace the defective tube or the entire PARI SINUS tubing system.

## 6 TECHNICAL DATA

### 6.1 Compressor

#### General compressor data

Supply voltage [V] Mains frequency [Hz] Power consumption [A]	see label on confirmation of purchase
Housing dimensions (W × H × D)	18.5 cm × 13.0 cm × 15.0 cm
Weight	1.7 kg
Pressure <sup>5</sup>	1.5 bar
Compressor flow <sup>5</sup>	4.6 l/min.
Sound pressure level	55 dB(A)
Vibration frequency <sup>6</sup>	43 Hz

#### Classification according to IEC 60601-1 / EN 60601-1

Type of electric shock protection	Protection class II
Degree of protection from electric shock of the applied part (nebuliser)	Type BF
Degree of protection according to IEC 60529 / EN 60529 against penetration by water and solid substances	IP 21
Degree of protection when used in the presence of flammable mixtures of anaesthetics with air, with oxygen, or with nitrous oxide	No protection
Operating mode	Continuous operation

5) Towards nebuliser nozzle (Ø 0.48 mm).

6) Measured according to PARI measurement procedure.



## Electromagnetic compatibility

Electrical medical equipment is subject to special precautionary measures with regard to electromagnetic compatibility (EMC). Such equipment must only be installed and operated in accordance with EMC instructions.

Portable and mobile high-frequency communication devices can disrupt electrical medical equipment. Using accessories, converters and power cords other than those specified (with the exception of converters and power cords that the manufacturer of the medical electrical device sells as spare parts for internal components) can result in higher emission levels or lower the resistance to interference of the device.

The device must not be placed directly beside or on top of other devices for operation. If the medical electrical device must be placed beside or on top of other devices to operate it, it must be monitored constantly to ensure that it is operating properly in the arrangement used.

Technical data on electromagnetic compatibility (EMC information) is available in table format upon request from the manufacturer or dealer or on the internet at the following linked page:

<https://www.pari.com/fileadmin/Electromagnetic-compatibility-5.pdf>

## Ambient conditions

### *During operation*

Ambient temperature	+10 °C to +40 °C
Relative humidity	30% to 75% (non-condensing)
Atmospheric pressure	700 hPa to 1,060 hPa

The compressor is intended for operation in all healthcare situations. It is not permitted to operate it in trains, motor vehicles or aeroplanes.

Use of the compressor in professional healthcare facilities is limited to the inpatient wards and the intensive care unit. Use of the compressor in areas with elevated magnetic or electrical radiation (e.g., close to an MRI scanner) is not permitted.

***During transportation and storage***

Minimum ambient temperature (without monitoring of relative humidity)	-25 °C
Maximum ambient temperature (with relative humidity of up to 93%, non-condensing)	+70 °C
Humidity	max. 93%
Atmospheric pressure	500 hPa – 1,060 hPa

**6.2 Nebuliser**

**General nebuliser data**

Size <sup>7</sup>	10 cm × 10 cm × 4 cm
Weight <sup>7</sup>	31 g to 33 g
Operating gases	Air
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

**Aerosol data**

The aerosol characteristics of the PARI LC SPRINT SINUS nebuliser were determined using the PARI SINUS2 compressor. The particle size was measured with the “Next Generation Impactor” (NGI). The measurement was carried out with

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7) Without bend, nasal joining piece and adapter; unfilled.

an ambient temperature of 23 °C and 50% relative humidity. 2 ml salbutamol (1 mg/1 ml) were nebulised. The Jet Flow was measured to be 4.6 l/min.

Nozzle insert (orange)	Nominal compressor flow (4.6 l/min – 1.5 bar)
MMAD [ $\mu\text{m}$ ] <sup>8</sup>	3.0
GSD <sup>9</sup>	2.18
Aerosol fraction [% > 5 $\mu\text{m}$ ]	66.6
Aerosol fraction [% < 2 $\mu\text{m}$ ]	28.7
Aerosol fraction [% > 2 $\mu\text{m}$ < 5 $\mu\text{m}$ ]	38.0
Aerosol fraction [% > 5 $\mu\text{m}$ ]	33.4
Aerosol output [ml]	0.78
Aerosol output rate [ml/min]	0.15
Residual volume [ml] (gravimetric)	0.95
Percentage of fill volume emitted per minute [%/min]	7.54

## 7 MISCELLANEOUS

### 7.1 Disposal

#### *Compressor*

This product falls within the scope of the European Council Directive on Waste Electrical and Electronic Equipment (WEEE)<sup>10</sup>. Accordingly, this product must not be disposed of with domestic waste. The disposal regulations prevailing in the re-

8) MMAD = Mass Median Aerodynamic Diameter

9) GSD = Geometric Standard Deviation

10) Directive 2012/19/EU of the EUROPEAN PARLIAMENT AND THE EUROPEAN COUNCIL of July 4, 2012 on waste electrical and electronic equipment.

spective member countries must be observed (e.g., disposal by local authorities or dealers). Materials recycling helps to reduce the consumption of raw materials and protect the environment.

### **All other product components**

All other product components included in your PARI inhalation system can be disposed of with domestic waste unless other regulations apply in the country where you are located.

## **7.2 Links**








Warranty conditions:  
[www.pari.com/  
warranty-conditions](http://www.pari.com/warranty-conditions)




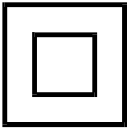


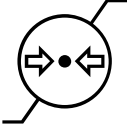



Technical data regarding electro-  
magnetic compatibility:  
[https://www.pari.com/fileadmin/  
Electromagnetic-compatibility-5.pdf](https://www.pari.com/fileadmin/Electromagnetic-compatibility-5.pdf)

## **7.3 Labelling**

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

	This product satisfies the requirements of 93/42/EEC (Medical devices) and 2011/65/EU (RoHS).
	Follow the instructions for use
	Consult instructions for use
	Item number
	Production batch number, lot

	Serial number
ON OFF	On / Off
	Alternating current
	Protection class of the applied part: Type BF
	Protection class II device
<b>IP21</b>	The device is protected against drip water (degree of protection according to IEC 60529 / EN 60529).
	Temperature limit
	Humidity, limit
	Air pressure, limit
	Legal manufacturer

## **APPENDIX: Reprocessing in professional environments (for only one patient)**

### **Compressor**

In general, it is recommended to disinfect the surface of the compressor – if necessary – with a disinfectant which is suitable for use in wipe disinfection of plastics according to the DGHM or VAH list [see: Disinfecting the compressor housing, page 29].

Ensure that no liquid gets into the device, as this might damage the device.

### **Nebuliser**

The following overview of the processing steps in professional environments applies to the following products:

- Nebuliser (all components except the PARI SINUS tubing system)

#### **1. Preparation**

Disassemble the product [see: Preparation, page 26].

Check:

- Expiry date of the cleaning agent/disinfectant
- Processing limits reached?

## 2. Cleaning and disinfection

<p>Manual cleaning:</p>	<p>pH-neutral, enzymatic cleaner, e.g., Korsolex<sup>®</sup> Endo Cleaner (Bode) or Bodedex<sup>®</sup> forte (Bode)          Use: In accordance with manufacturer information, if dirt is visible use a brush if necessary.</p>
<p>Manual disinfection:</p>	<p>With <b>aldehyde-containing</b> instrument disinfectant, e.g., Korsolex<sup>®</sup> Basic (Bode)          Use: In accordance with manufacturer information          Active agent basis:          – Aldehyde donor <sup>1</sup>          – Aldehyde <sup>1</sup></p> <hr/> <p>With <b>aldehyde-free</b> instrument disinfectant          Use: In accordance with manufacturer information          Active agent basis: Quaternary ammonium compound  <i><b>Info:</b> Bomix<sup>®</sup> plus cleans and disinfects in a single work step</i></p>
<p>Mechanical cleaning with disinfection:</p>	<p>Neutral cleaning agent, e.g., neodisher<sup>®</sup> Medizym (Dr. Weigert) or alkaline cleaning agent, e.g., neodisher<sup>®</sup> MediClean forte 0.5% (Dr. Weigert) in conjunction with neutraliser, e.g., neodisher<sup>®</sup> Z (Dr. Weigert)          Equipment: Cleaning device and disinfector in conformance with DIN EN ISO 15883, e.g., RDG G7836 CD (Miele)          Vario TD programme or comparable valid programmes</p>

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1) Additional activity spectra: tuberculocidal, mycobactericidal, fungicidal  
 According to the information supplied by the disinfectant manufacturers, the agents listed are effective against the gram-positive bacteria *Staphylococcus aureus* and *Enterococcus hirae* and against the gram-negative bacteria *Escherichia coli*, *Pseudomonas aeruginosa* and *Proteus mirabilis* as well as the yeast-like fungus *Candida albicans*.

### 3. Steam sterilisation

Equipment:

- Steam steriliser (preferably with fractionated pre-vacuum) in accordance with DIN EN 285 or DIN EN 13060 (Type B)
- Sterile barrier system in accordance with DIN EN 11607

Temperature / Duration:

134 °C for at least 3 min.

### 4. Visual inspection & storage

Check:

Inspect all individual parts. Replace any broken, misshapen or seriously discoloured parts.

Storage location:

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

### Processing limits

max. 300 disinfection cycles, max. 1 year

## PARI SINUS tubing system

### 1. Preparation

Check the product:

- Expiry date of the cleaning agent/disinfectant
- Processing limits reached?

### 2. Cleaning and disinfection

Manual cleaning:	not applicable
Manual disinfection:	not applicable



<p>Mechanical cleaning with disinfection:</p>	<p>Alkaline cleaning agent, e.g., neodisher<sup>®</sup> MediClean forte (Dr. Weigert) in conjunction with neutralising agent, e.g., neodisher<sup>®</sup> Z (Dr. Weigert)</p> <p>Equipment:</p> <ul style="list-style-type: none"><li>– Cleaning device and disinfector in conformance with DIN EN ISO 15883, e.g., RDG G7836 CD (Miele)</li><li>– Special baskets for Miele instrument dishwasher</li><li>– Compressed air source for blowing dry</li></ul> <p>Vario TD programme or comparable valid programmes</p>
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### **3. Steam sterilisation**

not usable

### **4. Visual inspection & storage**

Inspect all individual parts. Replace any broken, misshapen or seriously discoloured parts.

Storage location:

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

### **Processing limits**

max. 50 processing cycles

# **PARI SINUS2 nebuliser system**

## **CERTIFICATE OF GUARANTEE**

We guarantee the compressor for 4 years. The warranty period commences on the date of purchase.



**Barcode**

Proof of purchase:

The product with the serial number stated above was sold in its original packaging by us.

\_\_\_\_\_

Date of purchase

\_\_\_\_\_

Stamp and signature of the dealer



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