

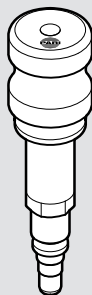
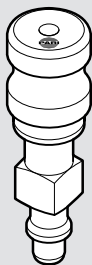


Instructions for use

PARI CENTRAL

Model: PARI CENTRAL (Type 058)

Outlet fitting for connection to a central gas supply system



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 CENTRAL (Type 058)

Contact

Email: info@pari.de
Tel.: +49 (0)8151-279 220 (international)
+49 (0)8151-279 279 (German)

Copyright

©2023 PARI GmbH Spezialisten für effektive Inhalation
Moosstrasse 3, 82319 Starnberg, Germany. Technical and design changes and printing errors reserved. The same applies to illustrations.

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

Registered trade marks of PARI GmbH Spezialisten für effektive Inhalation in Germany and/or other countries:

PARI®

TABLE OF CONTENTS

IMPORTANT INFORMATION	4
Intended purpose.....	4
Indication	4
Contraindication.....	4
Labelling	5
Safety and warning instructions.....	6
PRODUCT DESCRIPTION	8
Components	8
Overview and designations	8
Product variants.....	8
Product combinations	8
Description of function	9
Material information	9
Service life	9
USE.....	10
Preparing for treatment.....	10
Performing treatment.....	11
Ending the treatment	11
REPROCESSING IN PROFESSIONAL HEALTH INSTITUTIONS	12
Reprocessing cycles.....	12
Processing limits.....	12
PARI CENTRAL	13
PARI CENTRAL connection tubing	14
Visual inspection and storage.....	15
TROUBLESHOOTING.....	16
TECHNICAL DATA	17
General CENTRAL data	17
PARI CENTRAL dimensions	17
FURTHER INFORMATION	17

1 IMPORTANT INFORMATION

1.1 Intended purpose

The PARI CENTRAL is an accessory for nebuliser treatment. In professional health institutions, the PARI CENTRAL combined with a PARI nebuliser reduces gas pressure and flow of the central gas supply system.

Together with a central gas supply system, a PARI nebuliser and PARI accessories, the PARI CENTRAL forms an inhalation system.

The PARI CENTRAL is suitable for treating patients in all age groups.

The PARI CENTRAL must only be connected with a PARI nebuliser and the central medical compressed air supply.

The PARI CENTRAL must only be operated in professional health institutions by medical professionals.

This PARI product must only be used in professional health institutions. 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 PARI product is suitable only for patients who are able to breathe by themselves and are conscious.

1.2 Indication
















The indication for the PARI CENTRAL is the same as the indication for the PARI nebuliser used.

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:

	Medical device
	Legal manufacturer
	Date of manufacture
	Item no.
	Production batch number, lot number
	Unique Device Identifier (UDI)
	This product conforms to the EU Medical Device Regulation 2017/745.
	Consult instructions for use
	Humidity limit
	Atmospheric pressure limit
	Temperature limit
	PARI CENTRAL AIR (DIN 13260-2)
	PARI CENTRAL AIR (SS 87 524 30)
	PARI CENTRAL Clip
	PARI CENTRAL 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.

Follow the instructions for use of the nebuliser you are using.

A prerequisite for using the PARI CENTRAL is that the connections of the central gas supply system are designed to the appropriate standard (e.g. DIN 13260-2 or SS 87 524 30).

The PARI CENTRAL is to be used exclusively with the PARI CENTRAL connection tubing and other compatible PARI accessories.

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



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 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.



CAUTION

Danger of damage to health or inefficient therapy from faulty installation.

- The PARI CENTRAL must be installed, removed, and used only by trained or medical staff.

NOTE

After each use, the PARI CENTRAL must be disconnected from the central gas supply system, and stored so that it is inaccessible to the patient.

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.
- 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

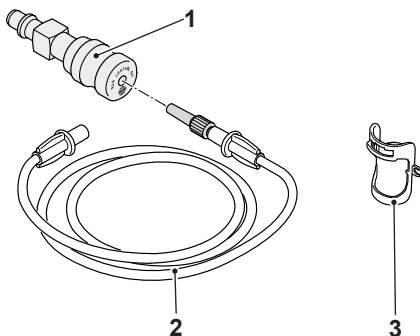
Report serious adverse incidents to the manufacturer and to the competent authority.

2 PRODUCT DESCRIPTION

2.1 Components

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

2.2 Overview and designations



1	PARI CENTRAL
2	PARI CENTRAL connection tubing
3	PARI CENTRAL Clip

2.3 Product variants

Type	Supply type
PARI CENTRAL AIR	Central medical compressed air supply

2.4 Product combinations

The PARI CENTRAL can be used with all PARI nebulisers (except PARI LCD, PARI LC SPRINT SINUS, and membrane nebulisers).

2.5 Description of function

The PARI CENTRAL is an outlet fitting for connection to the central gas supply in the hospital or the doctor's practice. It is used to reduce pressure or flow.

When in use, the PARI CENTRAL ensures that the nebuliser is operated at the intended operating pressure.

In combination with the PARI CENTRAL and the PARI CENTRAL connection tubing, the PARI CENTRAL Clip is a holder for the nebuliser.

2.6 Material information

The individual product components are made from the following materials:

Product component	Material
PARI CENTRAL	Aluminium and stainless steel
PARI CENTRAL connection tubing	Polyvinyl chloride (PVC) and thermoplastic elastomer (TPE), polyamide (PA)
PARI CENTRAL Clip	Polypropylene (PP)

2.7 Service life

The individual product components have the following expected lifetimes:

Product component	Service life
PARI CENTRAL	5 years
PARI CENTRAL connection tubing	[see: Processing limits, page 12]
PARI CENTRAL Clip	[see: Processing limits, page 12]

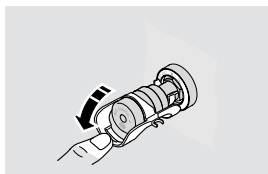
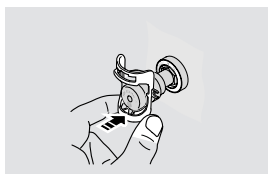
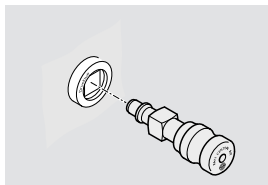
When the expected operating life has been reached, replace the affected component.

3 USE

3.1 Preparing for treatment

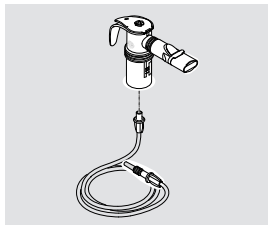
Connecting the PARI CENTRAL

- Connect the PARI CENTRAL to the designated connection outlet of the central gas supply system.
- Carefully push the clip onto the PARI CENTRAL, until it is located completely in the notch.
- Flip the clip downwards until it engages.

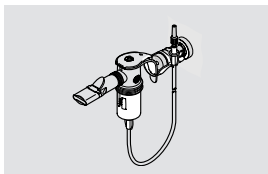


Preparing the nebuliser

- Connect the PARI CENTRAL connection tubing to the nebuliser.

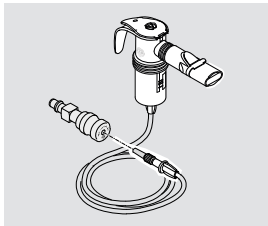


- Attach the nebuliser to the PARI CENTRAL Clip.
- Attach the PARI CENTRAL connection tubing in the side holder.



3.2 Performing treatment

- **⚠ DANGER! Life-threatening situation if tubes are mixed up!** If tubing systems from other devices are close by (e.g. for infusions) check carefully to ensure that the connection tubing connected to the PARI CENTRAL is connected with the nebuliser at the other end. Otherwise, there is a danger that different connection options may be confused with each other.
- Fill the nebuliser as per the appropriate instructions for use.
- Insert the tubing adapter of the PARI CENTRAL connection tubing into the PARI CENTRAL. Attach the tubing adapter by pushing it on while twisting gently. The valve of the PARI CENTRAL opens, and nebulisation starts.



3.3 Ending the treatment

- Remove the PARI CENTRAL connection tubing from the PARI CENTRAL by twisting gently. The air supply of the nebuliser stops.
- Place the nebuliser back in the holder on the PARI CENTRAL.

4 REPROCESSING IN PROFESSIONAL HEALTH INSTITUTIONS

Dry the PARI CENTRAL connection tubing after each use [see: PARI CENTRAL connection tubing, page 14].

4.1 Reprocessing cycles

Single patient use

PARI CENTRAL, PARI CENTRAL Clip	<ul style="list-style-type: none">– Clean when visibly dirty– Disinfect once a week
------------------------------------	--

Before a change of patients

PARI CENTRAL, PARI CENTRAL Clip	<ul style="list-style-type: none">– Cleaning– Disinfection
Connection tubing	Mechanical cleaning with disinfection

4.2 Processing limits

PARI CENTRAL Clip	300 processing cycles, max. 1 year
Connection tubing	50 reprocessing cycles, max. 1 year

4.3 PARI CENTRAL

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 and disinfect all individual parts before every change of patient.



CAUTION

Moisture in the PARI CENTRAL poses a risk to health

If fluid or moisture enters the PARI CENTRAL, this can lead to infection of the airways, allergic reactions, and skin and mucosal membrane irritation.

- Do not immerse the PARI CENTRAL in water.
- Do not clean the PARI CENTRAL in running water.
- Do not sterilise the PARI CENTRAL.
- Do not spray any liquid onto the PARI CENTRAL.
- Do not store and transport the PARI CENTRAL in a moist environment.
- If liquid penetrates the PARI CENTRAL, it must not be used under any circumstances. Before operating the PARI CENTRAL again, contact the manufacturer or distributor.

The PARI CENTRAL and the PARI CENTRAL clip can be cleaned and disinfected as per the procedure described below.

The connection tubing must be treated separately [see: PARI CENTRAL connection tubing, page 14].

Preparation

- Remove the PARI CENTRAL Clip.
- Pull off the PARI CENTRAL connection tubing.

Cleaning and disinfecting

Please observe the instructions for use for the chemicals used.

Cleaning the PARI CENTRAL and PARI CENTRAL Clip

Clean the PARI CENTRAL and the PARI CENTRAL Clip as follows:

- Wipe the outer surfaces thoroughly with a clean, damp cloth and allow the individual parts to dry completely.

Disinfecting the PARI CENTRAL and PARI CENTRAL Clip

Unless otherwise specified by the disinfectant manufacturer, perform a wipe disinfection as described below. Also comply with the information provided by the disinfectant manufacturer.

The procedure was validated in Europe using a disinfectant suitable for use on metals as per the DGHM and/or the VAH list: Quaternary ammonium compound

Validated with Sani-Cloth™ Active

Disinfect the PARI CENTRAL and the PARI CENTRAL Clip as follows:

- Clean the PARI CENTRAL and the PARI CENTRAL Clip before disinfection.
- Remove an already moistened cloth from the dispenser.
- Wipe the outside thoroughly with the cloth, and leave the disinfectant to dry.

4.4 PARI CENTRAL 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 PARI CENTRAL connection tubing as described in the section on this topic.

Drying

- Connect the PARI CENTRAL 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.

4.5 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

5 TROUBLESHOOTING



CAUTION

Danger of damage to health as a result of malfunction

Malfunction of the PARI CENTRAL or of the central gas supply system may result in less effective treatment.

- If the PARI CENTRAL malfunctions, remove it from the central gas supply system immediately.

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
The PARI CENTRAL audibly blows air without the connection tubing being connected.	The PARI CENTRAL is faulty.	Do not use the PARI CENTRAL any more. Send the PARI CENTRAL to the technical service at PARI GmbH.
No air flows through the nebuliser.	The connection tubing is faulty.	Replace the connection tubing.
	The connection tubing is not connected properly.	Check that all tubing connectors are connected firmly to PARI CENTRAL and to the nebuliser.
No air flows through the nebuliser.	The air flow is blocked.	<p>Detach the connection tubing from the nebuliser.</p> <p>Check whether air is flowing out of the end of the tube (can you hear or feel the flow?).</p> <p>Air flows out: The nebuliser may be faulty. Follow the instructions for use of the nebuliser you are using.</p> <p>No air flows out: The PARI CENTRAL is faulty. Send the PARI CENTRAL to the technical service at PARI GmbH.</p>

6 TECHNICAL DATA

6.1 General CENTRAL data

The CENTRAL data was measured using the PARI reference nozzle.

	Minimum	Nominal	Maximum
Inlet pressure:	2.6 bar/260 kPa	5.0 bar/500 kPa	6.0 bar/600 kPa
Outlet pressure/operating pressure	0.6 bar/60 kPa	1.6 bar/160 kPa	1.9 bar/190 kPa
Flow:	3.0 l/min.	5.0 l/min.	6.0 l/min.

6.2 PARI CENTRAL dimensions

	Length	Diameter	Weight
PARI CENTRAL AIR (DIN 13260-2)	86 mm	26 mm	67 g
PARI CENTRAL AIR (SS 87 524 30)	99 mm	26 mm	80 g

7 FURTHER INFORMATION

All product components must be disposed of in accordance with the Ordinance on the European Waste Catalogue (EWC). Where applicable, country-specific disposal regulations must also be observed.



PARI GmbH

Spezialisten für effektive Inhalation

Moosstraße 3

82319 Starnberg • GERMANY

info@pari.de • www.pari.com