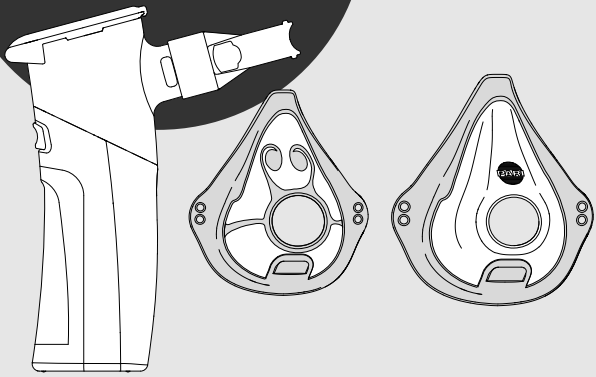
Instructions for use



PARI BOY® Go

- Model: PARI BOY® Go (Type 155)
- Model: PARI mask soft (Type 041)
- PARI inhalation system for the therapy of the lower airways

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CE 0123

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 BOY® Go (Type 155)
PARI mask soft (Type 041)
PARI SMARTMASKs (Type 041/078)

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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

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

Warranty

PARI provides a 3-year warranty on the controller. The warranty period commences on the date of purchase.

TABLE OF CONTENTS

1 IMPORTANT INFORMATION

1.1 Intended purpose

The PARI BOY Go is an inhalation device for therapy of the lower airways.

The nebuliser is suitable for use in treating patients in all age groups, starting with children aged 2 years and above.

The PARI BOY Go is not intended for use with antibiotics for treating bacterial infections of the airways (e.g. for *Pseudomonas aeruginosa*).

The PARI BOY Go may only be used with substances authorised for nebuliser treatment (do not attempt to inhale essential oils).

The PARI BOY Go must be used exclusively for its intended purpose.

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:

– 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 designed for patients who are able to breathe by themselves and are conscious.

This PARI product can be used in a home environment, as well as in professional health institutions.

As provided, the PARI BOY Go inhalation device is non-sterile. Reusability is ensured as long as validated cleaning and disinfection processes are used.

Use only original spare parts and original accessories from PARI.

The frequency and duration of use is determined by professional medical staff [1]according to the individual needs of the patient.

Use of this PARI product in areas with elevated magnetic or electrical radiation (e.g. close to an MRI scanner or in close proximity to HF surgical devices) is not permitted.

Masks

The PARI mask soft is an accessory for inhalation treatment. That enables inhalation of aerosol[2] through the mouth and nose.

The PARI SMARTMASKs are an accessory for nebuliser treatment. They enable inhalation of aerosol[2] through the mouth and nose.

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

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

The different mask sizes are suitable for treating patients in the following age groups:

– PARI child mask soft "Spiggy": Children aged 4 years and above

– PARI adult mask soft: Adults

– PARI SMARTMASK Kids: Children aged 2 years and above.

– PARI SMARTMASK: Adults.

The specified ages are approximate. The actual size of the mask depends on the size and shape of the person's face.

In a lying position, the PARI BOY Go must be used only in combination with a PARI mask soft or a SMARTMASK.

1.2 Indication

For treatment of diseases of the lower airways.

Masks

For patients who cannot inhale using a mouthpiece, or if inhalation via mask is preferred.

Together with an inhalation device, the mask forms a system. The indication for this system is the same as the indication for the inhalation device 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:

MD	Medical device
UDI	Unique Device Identifier (UDI)
	Legal manufacturer
	Date of manufacture
SN	Serial number
REF	Item no.
LOT	Production batch number, lot number
CE 0123	This product conforms to the EU Medical Device Regulation 2017/745.
	Consult instructions for use

IP22	Degree of protection as per EN 60529. Protection against penetration by foreign bodies having a diameter greater than 12.5 mm and protection against dripping water when the device is inclined up to an angle of 15°.
	Humidity limit
	Atmospheric pressure limit
	Degree of protection of the application component: Type BF
	Temperature limit
	Direct current
	Alternating current
	The medical device was distributed commercially after 13 August 2005. **The product must not be disposed of with normal domestic waste.** The symbol of the refuse bin with a cross through it indicates that it must be disposed of separately.
	Mouthpiece without expiratory valve
	PARI BOY Go nebuliser top
	PARI BOY Go controller
	PARI child mask soft "Spiggy"
	PARI adult mask soft
	PARI SMARTMASK Kids
	PARI SMARTMASK for adults
	Elastic band
	Bend piece (45° angle)
	Ampoules

1.5 Safety and warning instructions

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

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

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

Labelling and classification of warning instructions

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

⚠ DANGER

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

⚠ WARNING

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

⚠ CAUTION

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

NOTE

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

General

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

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

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

Hazard due to small parts which can be swallowed

WARNING

Choking hazard from blocked airways
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.

Use the device only for patients aged 2 years and above

WARNING

Risk to health from overdosing
In the inhalation treatment of babies, undesired and potentially serious side effects can arise.
- Use the device only for children aged 2 years and above.

Reporting serious incidents

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

Modifications to the device

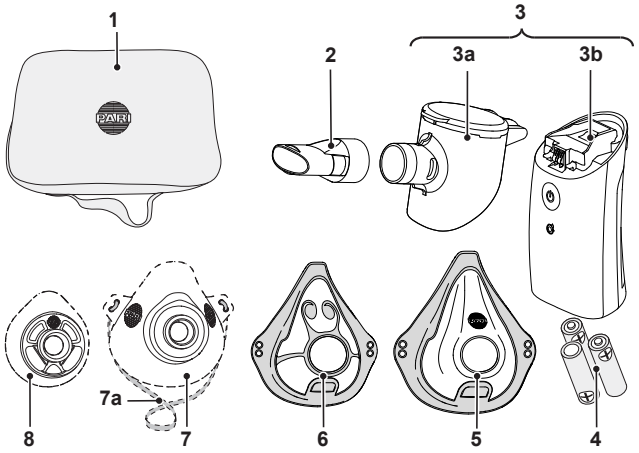
If the device is modified, its safe and effective operation cannot be ensured. Electric shocks and overheating can result. Do not make modifications to the device.

2 PRODUCT DESCRIPTION

2.1 Components

The product components included in the scope of delivery are country-specific, and the contents may deviate from the components described in this instruction for use. For the scope of delivery, therefore please refer to the packaging.

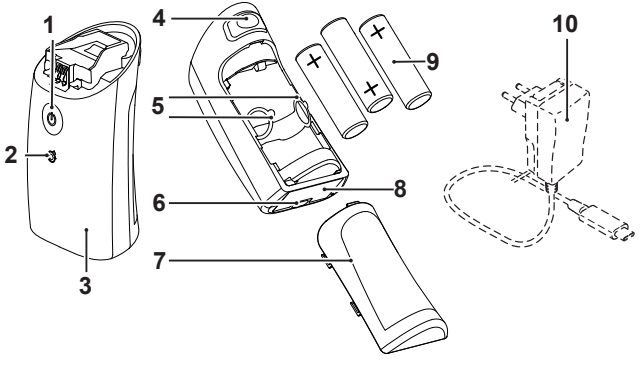
2.2 Overview and designations



1	**Case**	
2	**Mouthpiece**	
3	**Inhalation device**	
	3a	Nebuliser top
	3b	Controller
4	**Batteries**	
5	**Adult mask soft**	
6	**Child mask soft "Spiggy"**	
7	**SMARTMASK** (not included in scope of delivery)	
	7a	Elastic band
8	**SMARTMASK Kids** (not included in scope of delivery)	

2.3 Working parts

The controller has the following working parts:



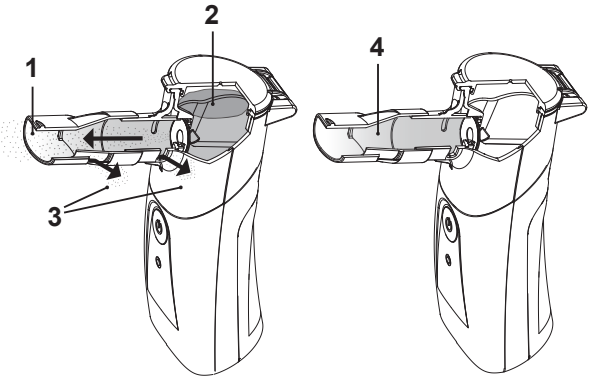
1	On/Off button
2	Care mode LED
3	Controller
4	Release button for nebuliser top
5	Battery strap
6	USB-C socket for power adapter
7	Battery compartment cover
8	Identification label (base of housing)
9	Batteries
10	Power adapter[3] (not included in scope of delivery)

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

2.4 Description of function

The PARI BOY Go consists of a PARI controller, a PARI nebuliser top, a PARI mouthpiece and PARI accessories. The system is used to treat the lower airways.

The PARI BOY Go is a quiet, lightweight, hand-held, battery-operated medical device, which converts your inhalation solution into an aerosol mist for inhalation. The medication is loaded into the nebuliser top, which supplies it to a membrane having small holes. When the device is switched on, the membrane vibrates, thus forcing the inhalation solution through the tiny holes, and creating a fine aerosol mist. This aerosol is inhaled through the mouthpiece or optionally through a mask.



1	When the device is switched on, aerosol passes out of the mouthpiece.
2	Nebuliser top with inhalation solution.
3	During the inhalation process, aerosol passes out of the outlet holes during exhalation.
4	At the end of the inhalation process no more aerosol remains.

2.5 Device signals

The various operating states are represented by illumination of the On/Off button, the care mode symbol beneath it, and by signal tones.

Visual signal		Acoustic signal	Operating state
	On/Off button illuminates green.	1 signal tone	Device is switched on.
	On/Off button flashes green 5 times.	1 signal tone	The therapy was completed successfully.
	Care mode LED flashes blue.	Signal tone sequence	The care mode reminder display is active.
	Care mode LED flashes blue.	No signal tone	Care mode is active. Backflushing is taking place; this cleans the membrane's micropores.
	Care mode LED extinguishes.	1 signal tone	Care mode was performed successfully.
	On/Off button illuminates orange for 5 seconds.	2 signal tones	No medication has been loaded.
	On/Off button illuminates orange for 5 seconds.	No signal tone	The nebuliser top is not connected to the controller. The nebuliser top becomes disconnected from the controller during the therapy. The nebuliser top is faulty.
	On/Off button flashes orange.	No signal tone	Low battery charge.
	On/Off button flashes orange 5 times.	2 signal tones	Battery empty/voltage too low. The battery falls to a low charge level during therapy. The maximum time per operation (20 minutes) has been reached. The therapy was ended/interrupted early.

2.6 Material information

The individual product components are made from the following materials:

Product component	Material
Mouthpiece	Polypropylenes
Nebuliser top	Polypropylenes, thermoplastic elastomer, silicone, stainless steel
Controller housing	Acrylonitrile-butadiene-styrene, polycarbonate, polyoxymethylene, silicone
PARI mask soft	Polypropylene, thermoplastic elastomer
PARI SMARTMASKs	Silicone
Exhalation valve	Silicone
Bend piece (45° angle)	Polypropylene
Elastic band	Synthetic rubber

2.7 Service life

Product component	Max. service life	Processing limits
Controller	3 years	156 disinfection cycles
Nebuliser top	1 year	52 disinfection cycles, 365 inhalation cycles
PARI mask soft	1 year	300 disinfection cycles, 100 sterilisation cycles
PARI SMARTMASKs	1 year	300 disinfection cycles, 100 sterilisation cycles

The product's service life depends on the reprocessing and inhalation cycles. It may be reduced through repeated reprocessing or multiple daily use. The product components are designed for the cycles specified. The individual components should be replaced no later than the maximum service life or the specified reprocessing limits.

3 USE

All the steps described below must be carried out properly.

Do not use product components unless they have been thoroughly cleaned and dried. Wash your hands thoroughly before every use. You must perform cleaning and disinfection before using the device for the first time.

WARNING

Electromagnetic interactions with diagnostic devices

Electrical devices can cause electromagnetic interference. Interference can impair the functioning of other devices, and thus also the therapy.

- The device may be used exclusively in stationary hospital areas and in intensive care units.
- Do not use the device in areas exposed to high levels of magnetic or electrical radiation, e.g. in an MRI scanner.

WARNING

Impairment to quality of therapy caused by electromagnetic interference

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

- Do not place the device immediately beside or on top of other devices.
- If the device must be operated immediately beside or on top of other devices, then all devices must be monitored to ensure that they are working properly.

WARNING

Electromagnetic interactions with control systems

Electrical devices can generate electromagnetic fields. These can impair the functioning of other devices. With the following restrictions, the device can be operated in a motor vehicle, train or aircraft:

- Only use the device in the passenger areas of trains and aircraft.
- Do not use the device close to control systems of aircraft or trains.
- In a motor vehicle, only use batteries to operate the device.

Anti-theft systems and RFID (Radio Frequency Identification) reading devices can impair the performance of the nebuliser system. Do not use the device close to entries to businesses, libraries or hospitals.

Portable wireless communication devices (such as mobile phones or routers) can impair the functioning of the inhalation device, and therefore the therapy. Maintain a minimum distance of 30 cm between the inhalation device and wireless communication devices.

3.1 Preparing for treatment

Assembling the inhalation system

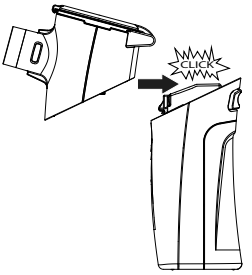
CAUTION

Risk of impaired therapy

Damaged components and/or incorrect assembly can impair the functioning of the inhalation device, and therefore the therapy.

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

1. Connect the nebuliser top to the controller. For this, push the nebuliser top horizontally along the guide to the controller until you hear it click into place.



Inserting and changing batteries

NOTE

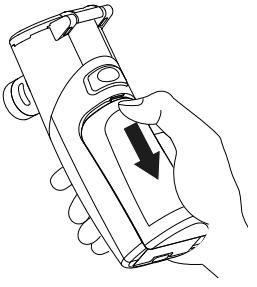
Device damage from leaking batteries

Leaking batteries cause corrosion and damage the device.

- Remove the batteries when it is expected that the device will not be used for an extended period.

Before first use, there are no batteries in the battery compartment.

1. Open the cover of the controller's battery compartment.
2. To remove expired batteries, pull on the battery strap.
3. Insert three new AA batteries. Press the batteries fully into the positions provided for them. Comply with the polarity symbols in the controller's battery compartment and on the batteries.
4. Close the battery compartment cover. The battery compartment cover is securely closed when you hear it click into place.



Operation using a power adapter

Operation is possible using either the batteries or the power adapter. It is not possible to charge the batteries with the power adapter!

WARNING

Danger of injury through strangulation
For individuals who are not able to perform the therapy without assistance or cannot appreciate the hazards, the connection cable increases the risk of injury from strangulation. 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.

WARNING

Electrical devices that remain plugged into the power supply present a potential hazard source
There is a danger of electric shock.
- Keep the power adapter away from liquids and damp environments.
- Do not use a defective device/power adapter (e.g. broken housing).
- Disconnect the USB-C connection from the controller before dismantling the device or reprocessing it.
- Do not use plug-in adapters.
- For mains operation we recommend use of the PARI power adapter (078B7116). Alternatively, third-party power adapters can also be used, as long as they fulfil the technical requirements[see: Power adapter requirements, page 33].

⚠ WARNING

Impairment to quality of therapy caused by electromagnetic interference
Electrical devices can cause electromagnetic interference. Interference can impair the function of the devices and thus also the effectiveness of the therapy.
- Do not operate with a cable longer than 3 m.

NOTE
The charging cable must be kept away from domestic animals, e.g. rabbits. Cables which have been bitten through can cause malfunctions or device damage.

1. Connect the USB-C cable to the controller.
2. Plug the power adapter into a suitable socket.

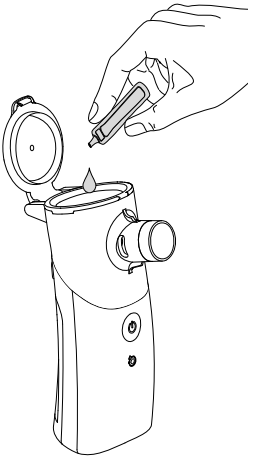
Preparing the inhalation therapy

FILLING THE NEBULISER TOP

⚠ CAUTION

Impaired therapy if overloaded
If the nebuliser contains too much liquid, the nebulisation and consequently the therapy will be less effective.
- Pour the required quantity of inhalation solution into the top of the nebuliser. Comply with the maximum fill volume. For the necessary amount of the inhalation solution, please refer to the medication's instructions for use.

1. Open the nebuliser top by flipping open the nebuliser lid.
2. From above, load the necessary amount of the inhalation solution into the nebuliser top.
   Comply with the maximum fill volume [see: Dimensions/ weight/fill volume, page 33].
3. Close the nebuliser lid. Make sure that the nebuliser lid snaps into place.
4. If you wish to inhale using a mouthpiece [see: Inhaling with the mouthpiece, page 20]. If you inhale using a mask [see: Inhaling with a mask, page 20]



3.2 Performing therapy

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

1. Switch the controller on by briefly pressing the On/Off button. A brief signal tone sounds and the button's LED illuminates green.
2. Check that an aerosol is being generated (a fine mist is escaping from the nebuliser) before you begin the therapy.

Inhaling with the mouthpiece

1. Push the mouthpiece onto the nebuliser top.
2. Sit in an upright position and relax.
3. Hold the mouthpiece between your teeth and enclose it with your lips.
4. Breathe in as slowly and deeply as possible through the mouthpiece, and out again calmly.
5. Carry out the inhalation therapy until a signal tone sounds. The LED flashes green 5 times.

During the therapy keep the inhalation device as vertical as possible in order that the loaded medication is always in contact with the membrane. In this way you ensure that there is no premature switch-off or incorrect dosing.

- *– At the end of the therapy ensure that the medication reservoir is empty.*
- *– If too much condensate or spittle has collected on the outside of the membrane, nebulisation can come to a stop.*
- *– Switch the device off, and remove the moisture by shaking or using a lint-free cloth. Then switch the device on again and continue the therapy.*

Inhaling with a mask

The mask is used instead of a mouthpiece.

1. If necessary, pull the mouthpiece off the nebuliser top.
2. Push the mask onto the nebuliser top.

CAUTION

Impaired therapy due to escaping aerosol

If the mask does not form a seal on the face, aerosol may escape. This may result in medication underdosage.

- Make sure that the mask completely covers both corners of the mouth and the nose.

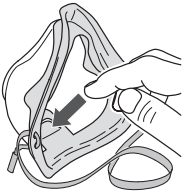
Beware of possible side effects caused by escaping aerosol. These are described in the information for use of the respective medication.

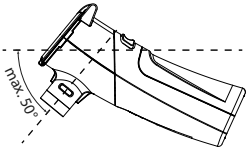
WITH PARI CHILD OR ADULT MASK SOFT

1. Check whether the exhalation valve is pressed outwards, to ensure that the user can breathe out freely during the inhalation session.
2. Sit in an upright position and relax.
3. Gently press the mask snugly over the mouth and nose.

In order to fully nebulise the inhalation solution, ensure that the inhalation device is not tilted more than 50° away from the vertical position (see image). If necessary, set the device upright again.

4. Breathe in as slowly and deeply as possible through the mask, and out again calmly.
5. Carry out the inhalation therapy until a signal tone sounds. The LED flashes green 5 times.





If the "Spiggy" child mask is too large, the baby mask soft for children aged 2 years and older can optionally be used with the PARI BOY Go.

WITH PARI SMARTMASKS

CAUTION

Risk posed by blocked expiratory opening

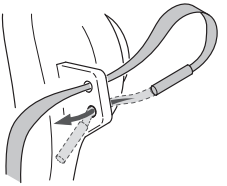
If the expiratory opening is blocked by the exhalation valve, there is the risk of severe injury.

- Make sure the expiratory opening remains unobstructed.
- Make sure the exhalation valve is sitting flush. It may not be caught in the expiratory slits of the mask.

If using the PARI SMARTMASK for adults, secure the blue exhalation valve:

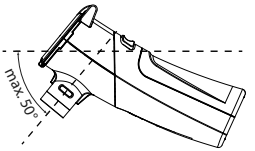
1. Carefully push the exhalation valve onto the mask.
2. Press the exhalation valve over the lip until it is completely seated in the notch.

3. If necessary, attach the elastic band to the mask.

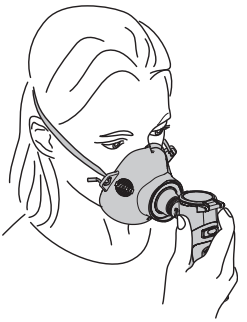


4. Sit in an upright position and relax.
5. Use gentle pressure to place the mask tightly over mouth and nose.
   Ensure that the nebuliser is positioned vertically.

In order to fully nebulise the inhalation solution, ensure that the inhalation device is not tilted more than 50° away from the vertical position (see image). If necessary, set the device upright again.



6. If necessary, use the elastic band to hold the mask firmly in place against the face.
   The elastic band runs along the back of the head.
7. Breathe in as slowly and deeply as possible through the mask, and out again calmly.
8. Carry out the inhalation therapy until a signal tone sounds. The LED flashes green 5 times.



INHALING WITH A MASK - OPTIONALLY IN A LYING POSITION

1. Arrange the inhalation device and the mask position to suit the child's position.
2. Gently press the mask snugly over the mouth and nose.
3. The child should breathe in as slowly and deeply as possible through the mask and out again calmly.
4. In order to fully nebulise the loaded inhalation solution, occasionally bring the inhalation device into a vertical position.
5. Carry out the inhalation therapy until a signal tone sounds. The LED flashes green 5 times.

***Tip for easier use**: Children may struggle when the mask is pressed against their face, twisting their head back and forth. For effective inhalation, support the back of the head by hand. This will enable you to follow the movements of the child's head with the mask more easily.*

In a lying position, the PARI BOY Go should be used with a SMARTMASK without a bend piece (45° angle).

3.3 Interrupting the therapy

If you wish to interrupt the therapy, proceed as follows:

When operating with batteries	When operating with the power adapter
1. Briefly push the On/Off button. 2. Set the device upright.	3. Briefly push the On/Off button. 4. If necessary, disconnect the USB-C connection from the controller. 5. Set the device upright.

If you wish to restart the therapy, proceed as follows:

When operating with batteries	When operating with the power adapter
1. Briefly push the On/Off button. 2. Perform the inhalation as usual.	3. Connect the USB-C cable to the controller. 4. Briefly push the On/Off button. 5. Perform the inhalation as usual.

3.4 Ending the therapy

1. Carry out the inhalation therapy until a signal tone sounds. The LED flashes green 5 times.
   ⇨ The therapy is complete when no more aerosol is generated.
   ⇨ At the end of the therapy, the device switches itself off automatically.
2. If necessary, disconnect the USB-C connection from the controller.
3. Disconnect the power adapter from the socket.

If the care mode LED illuminates blue and a signal tone sequence sounds, perform care mode [see: Procedure, page 31].

4 CLEANING, DISINFECTION AND STERILISATION

The following sections describe reprocessing the PARI BOY Go product and its accessories before first use and after every use. This includes pre-rinsing, manual and machine reprocessing, and sterilisation.

The PARI BOY Go is suitable for patient change/device loan. Please perform the following steps before patient change/device loan:

– Check the functioning of the controller.
– Controller and case: clean and disinfect
– Nebuliser top and mouthpiece: replace
– Mask: clean, disinfect and sterilise. If sterilisation is not possible, replace mask
– Replacing the elastic band

4.1 General hygiene information

– Before every reprocessing, wash your hands thoroughly.
– Medical aids for reprocessing must be clean.
– The product must **be cleaned after every use, and must be disinfected weekly** . **High-risk patients must disinfect once per day.**
– So that the device and its accessories remain clean during use, it must be ensured that cleaning and disinfection processes specifically validated for the respective product are used exclusively. The parameters thus specified must be reliably complied with.
– Please observe the instructions for use for the chemicals used.
– Inspect all product components after each cleaning, disinfection or, where applicable, sterilisation.
– Replace any broken, deformed, calcified or seriously discoloured parts.

4.2 General information about material durability

– The nebuliser top, mouthpiece and controller cannot be sterilised.
– Use only cleaning and disinfection agents approved for the reprocessing of medical devices and accessories.
– To avoid damage to the product, follow the manufacturer's instructions, and prepare the products as per the following instructions.
– Do not use cleaning and disinfection agents which adhere, because residues which contain protein may build up.
– In order not to damage the membrane, do not use brushes or similar when cleaning the nebuliser top.

4.3 Safety instructions

⚠ WARNING

Risk of infection

When products are reused, there is an increased risk of bacterial transmission and infections, especially through cross-contamination, bacterial growth, and residual organisms or moisture

- Be absolutely sure to perform cleaning and disinfection, even before using the device for the first time.
- To avoid residual organisms and cross-contamination, clean, disinfect and, if necessary, sterilise all products as per the reprocessing instructions and the specified reprocessing cycles.
- To avoid bacterial growth caused by residual moisture, it is essential that you ensure complete drying before sterilisation, and also after reprocessing.
- Always use clean reprocessing materials, and ensure that the product is cleaned fully. Contamination which remains affects further reprocessing.

⚠ WARNING

Danger of infection for patients at risk

For patients at risk, respiratory tract infections represent an increased likelihood of a worsening of the general state of health, because they are especially endangered by remaining residual organisms. Patients at risk include cystic fibrosis patients, patients with immunosuppression or immunity deficit, and vulnerable patient groups.

- If you are a patient at risk, clean and disinfect the individual parts once daily after therapy.
- If you are unsure whether you are a patient at risk, you should consult medical specialists before use.

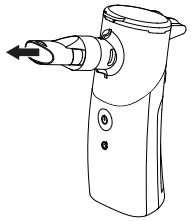
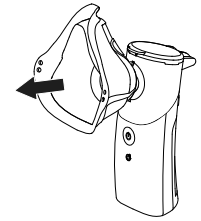
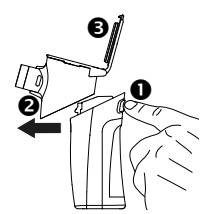
NOTE

Danger of device fault due to liquid penetration

If liquids enters the interior of the controller, this may cause a fault in the device.

- Never immerse the controller in water.
- Never clean the controller in running water.
- Never spray any liquids onto the controller or the power cord.
- If liquid gets into the controller, it may not be used under any circumstances. Before operating the controller again, contact the manufacturer or distributor.

4.4 Preparation

Mouthpiece, mask, nebuliser top			
Dismantling:			
1. Switch the device off. 2. If necessary, disconnect the USB-C connection from the controller. 3. Pull the mouthpiece or mask off the nebuliser top. 4. Pull the nebuliser top off the controller. To do this, press the release button (1) and pull the nebuliser top (2) horizontally forwards. Open the lid of the nebuliser top (3). 5. If necessary, detach the elastic band from the mask.			

4.5 Reprocessing

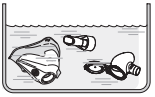
Cleaning

Controller and case
1. Wipe the outer surface of the housing and the case with a clean, damp cloth.

Pre-rinsing

Nebuliser top including mouthpiece/mask		
Rinsing off:	Avoid chemical residues and organic material drying on the device immediately after use. 1. Immediately after use, rinse off all parts (except for the controller, power adapter, batteries and case) in flowing tap water (water temperature ≤40 °C), in order to remove visible contamination.	

Cleaning

Nebuliser top including mouthpiece/mask		
Soaking:	1. Now soak the product components for 5 min. at a water temperature of approx. 38 °C, using clear washing-up liquid (1 teaspoon in 3 l water). 2. Ensure that all parts are covered with water. 3. Avoid air bubbles when placing the parts in the vessel. 4. Occasionally move the parts back and forth. 5. Remove the components and rinse them off under flowing tap water (at least drinking water quality and water temperature ≤40 °C) in order to remove soap residue.	

Elastic band	
Cleaning:	1. Clean the elastic band as necessary with warm drinking water and a little dishwashing liquid. *The elastic band cannot be disinfected or sterilised.*

Alternative method for professional healthcare institutions

Nebuliser top including mouthpiece/mask	
Automatic cleaning:	1. Place the components in a cleaning and disinfection device which fulfils the requirements of EN ISO 15883. 2. Use a suitable push-in rack and instrument holder, and position all components in such a way that they can be cleaned thoroughly all over. 3. Start the programme: Pre-cleaning with cold tap water for 2 minutes. Wash at 55 °C with enzymatic-alkaline cleaner for 5 minutes. Perform an intermediate rinse for 3 minutes, using cold demineralised water.

Disinfection

All parts (except for the power adapter and batteries) must be disinfected once per week - for high-risk patients, disinfect once per day. To ensure a sufficient level of disinfection, you must clean the product components beforehand.

Controller and case	
Wipe disinfection:	For disinfection, use a standard, alcohol-based disinfectant. 1. Moisten a soft, lint-free cloth with the disinfectant. 2. Wipe the outer surface of the housing and the case thoroughly with the cloth. 3. Keep the product moist for the whole of the required application time of the disinfectant. Wipe again if necessary. 4. After the application time of the disinfectant, allow the products to surface-dry completely.

Nebuliser top, mouthpiece and mask		
Thermal disinfection:	1. Place all the individual parts in distilled water at a rolling boil for at least 5 minutes. 2. Ensure that all parts are covered with water, and that there is sufficient water in the vessel. Avoid air bubbles when placing the parts in the vessel. 3. Occasionally move the parts back and forth.	

ALTERNATIVE METHOD FOR PROFESSIONAL HEALTHCARE INSTITUTIONS

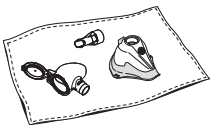
Nebuliser top, mouthpiece and mask	
Cleaning and disinfection device:	1. An A0 value >3000 must be achieved. A temperature of 90 °C for at least 5 minutes is recommended. Use contamination-free water (<10 cfu/ml). *As a rule, automatic disinfection forms part of a cleaning and disinfection device programme which also includes automatic cleaning, e.g.:* *– Pre-rinse with cold tap water for 2 minutes.* *– Wash at 55 °C for 5 minutes, using 0.5 % alkaline-enzyme cleaner.* *– Perform an intermediate rinse for 5 minutes, using cold demineralised water.* *– Thermal disinfection at 90 °C in contamination-free water (<10 cfu/ml) for 5 minutes (A0>3000).*

Drying

Ensure that no residual moisture remains in the components after the cleaning or disinfection. Dry the device as follows.

Device

1. Shake the water out of all of the parts.
2. Place all parts on a dry, clean and absorbent surface and allow them to dry completely.
3. Contact pins must be dry.



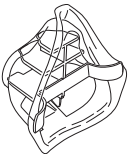
Sterilisation

To ensure sufficient sterilisation, you must clean and disinfect the product beforehand.

The nebuliser top, mouthpiece and controller cannot be sterilised.

Mask

Information on sterilising a PARI mask soft:
Always use the corresponding mask stabiliser[4] when sterilising this mask type, because otherwise the mask may lose its shape under the effects of high temperatures.



1. Insert the mask stabiliser in the mask as shown in the illustration.
2. Pack all the disassembled parts in a sterile barrier system according to ISO 11607-1 (e.g. foil-paper packaging).
3. Sterilise the product as per ISO 17665, using a steam steriliser at the following parameters: Fractionated pre-vacuum at 134 °C for between 3 and 5 minutes.

Information on sterilising a PARI SMARTMASK:
Perform the sterilisation of this type of mask without using a mask stabiliser.

1. Pack all the disassembled parts in a sterile barrier system according to ISO 11607-1 (e.g. foil-paper packaging).
2. Sterilise the product as per ISO 17665, using a steam steriliser at the following parameters: Fractionated pre-vacuum at 134 °C for between 3 and 5 minutes.

4) The mask stabiliser is not included in the scope of delivery.

Storage

Store this product as described below:

Product
– Dry and dust-free (e.g. in the case supplied) – Protected against contamination, where necessary (e.g. using optional sterile packaging)

Further validated procedures for reprocessing

The instructions provided were validated by PARI and were found to be suitable for preparing your medical device for its reuse.

Further validated procedures for reprocessing:
https://www.pari.com/fileadmin/041D0624_Professional_healthcare_institution_Validated_Reprocessing_Methods.pdf

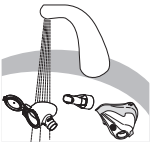
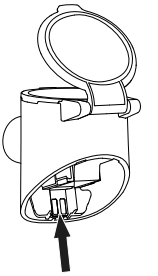
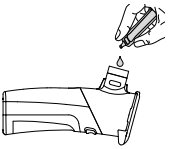
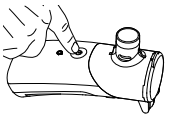
Ensure that the reprocessing actually performed using your equipment, chemicals and personnel achieves the desired result. For this, validation and routine process monitoring are normally required. If you have to deviate from our validated process, pay particular attention that your selected reprocessing method is appropriately effective and that potentially adverse effects are assessed.

5 PARI CARE MODE

5.1 Description of function

The PARI care mode maintains the aerosol head by removing any residues of the inhalation solution from the membrane. So that inhalation periods remain short and the nebulisation performance remains high, perform the care mode after ten therapy procedures. The blue care mode LED and a signal tone sequence remind you about performing it. **The PARI care mode does not replace cleaning and disinfecting.**

5.2 Procedure

Sequence		
Step 1: Rinsing off	1. Open the nebuliser lid. 2. Rinse the nebuliser top with hot drinking water.	
Step 2: Drying	***NOTE*** **Danger of device defect from liquid on the contact surface** If liquids enters the interior of the controller, this may cause a fault in the device. • Ensure that the contact surfaces are dry. 1. Confirm that the contact surface (see arrow) is dry. 2. If necessary, shake the liquid out of the nebuliser top. 3. If necessary, carefully dab the contact surface using a lint-free cloth.	
Step 3: Filling	1. Connect the nebuliser top to the controller. For this, push the nebuliser top horizontally along the guide to the controller until you hear it click into place. 2. Close the nebuliser lid if necessary. 3. Lay the inhalation device down horizontally. 4. Add 15-20 drops of a 0.9 % salt solution or distilled water through the hole into the nebuliser top.	
Step 4: Care	1. In order to start care mode, press the On/Off button until 2 signal tones sound. ⇨ The care mode LED flashes blue (duration approx. 5 minutes). ⇨ Care mode is ended when the blue care mode LED is extinguished,1 signal tone sounds, and the On/Off button flashes green 5 times. *At the end of care mode, aerosol is released from the hole of the nebuliser top. The controller then switches off automatically.*	

Sequence	
Step 5: Reprocessing	Perform the reprocessing of the device: [see: CLEANING, DISINFECTION AND STERILISATION, page 24].

6 TROUBLESHOOTING

Contact the manufacturer or distributor:
– in the event of faults that are not listed in this chapter.
– if the suggested procedure does not correct the fault.

Fault	Possible cause	Remedy
The device cannot be switched on.	The batteries are empty.	Insert new batteries or connect the power adapter.
	The power adapter is not correctly plugged into a socket, or the USB plug is not correctly inserted in the controller's USB connection.	Confirm that the power adapter is correctly plugged into the socket and the USB plug is correctly inserted in the controller.
The device does not nebulise or has unexpectedly stopped nebulising.	No medication was loaded.	Add a suitable medication.
	Inhalation was interrupted.	To continue inhalation, press the On/Off button.
	The maximum operating period per use (20 minutes) has been exceeded.	
Nebulisation is lasting longer than usual.	The aerosol head is blocked.	Perform a care mode.
Some areas of the controller housing can reach temperatures up to 42 °C.	The device is being operated close to the upper limit for the ambient temperature (40 °C).	Change the position of your hand, if it feels uncomfortable to the touch. Conduct the therapy at a lower ambient temperature.
When performing care mode, the cleaning liquid has not run through completely.	The device has switched off automatically after 20 minutes, even though the liquid has not run through completely.	Use the On/Off button to switch the controller on again. The rest of the liquid will then be flushed through.

Only the Technical Service of PARI GmbH or a service location expressly authorised by PARI GmbH is permitted to repair the device. If the device is opened or tampered with by anyone else, all claims under the warranty shall be void. In these cases, PARI GmbH will accept no liability.

7 TECHNICAL DATA

7.1 Electrical connection

Power consumption	< 2.0 W
Input voltage	5 V DC
Connection type	USB-C

Operation with batteries

Batteries	3 × 1.5 V (Mignon AA LR6/alkaline)

7.2 Power adapter requirements

Output voltage	5 V DC
Output current	>1 A
Connection type	USB-C
Normative testing	IEC 62368-1, IEC 60601-1, IEC 60950-1 or IEC 60335-1

7.3 Dimensions/weight/fill volume

Weight of complete device incl. mouthpiece (excl. batteries)	104 g

Controller

Dimensions [W × H × D]	53.5 mm × 99 mm × 46.5 mm
Weight (excl. batteries)	73 g

Nebuliser top (incl. mouthpiece)

Dimensions [W × H × D]	47.5 mm × 60 mm × 112 mm
Weight (incl. mouthpiece)	31 g
Maximum fill volume	8 ml

7.4 Aerosol characteristics according to ISO 27427

The aerosol characteristics presented in these instructions for use were determined in accordance with ISO 27427 using a fill volume of 2.5 ml salbutamol. If other solutions or suspensions are used for nebulisation, the aerosol characteristics may differ from the values shown (particularly if they have greater viscosity).

	Mean value
MMAD [µm][5] (mass median aerodynamic diameter)	4.4
GSD[5] (geometric standard deviation)	1.82
Respirable (lung-accessible) fraction [% <5 µm][5]	58.1
Aerosol fraction [% <2 µm][5]	8.2
Aerosol fraction [% >2 µm <5 µm][5]	49.9
Aerosol fraction [% >5 µm][5]	41.9
Aerosol output [ml][6]	0.80
Aerosol output rate [ml/min][6]	0.21
Residual volume [ml] (gravimetric)	0.41
Percentage of fill volume emitted per minute[6]	8.4

7.5 Classification as per IEC 60601-1/EN 60601-1

Type of electric shock protection (power adapter)	Protection class II
Degree of protection from electric shock from the application component (nebuliser)	Type BF
Degree of protection as per EN 60529 against penetration of solid foreign bodies and dripping water	IP 22
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) Measured using Next Generation Pharmaceutical Impactor (NGI) at 23 °C and 50 % relative humidity. Inspiratory flow: 15 l/min.

6) Measured using breath simulator at 23 °C and 50 % relative humidity. Breathing volume 500 ml, breathing frequency 15 cycles/minute, sinusoidal breathing pattern, inhalation/exhalation ratio 1:1 (for adults; may deviate for children).

7.6 Electromagnetic compatibility

Electrical medical equipment is subject to special precautionary measures with regard to electromagnetic compatibility (EMC). Such equipment must be installed and operated only in accordance with the electromagnetic compatibility 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 reduce the device's resistance to interference.

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

On request, technical data on electromagnetic compatibility (EMC information) is available in table format from the manufacturer or distributor, or on the website [see: Links, page 36]

7.7 Ambient conditions

During operation

Ambient temperature	+5 °C to +40 °C
Relative humidity	15% to 90% (non-condensing)
Atmospheric pressure	700 hPa to 1060 hPa

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

Transport and storage between uses

Ambient temperature	-25 °C to +70 °C
Relative humidity	0% to 90% (non-condensing)
Atmospheric pressure	500 hPa to 1060 hPa

8 FURTHER INFORMATION

8.1 Disposal

This product falls within the scope of the European Council Directive on Waste Electrical and Electronic Equipment (WEEE)[7]. Accordingly, this product must not be disposed of with domestic waste. The disposal regulations applying in the respective countries must be complied with (e.g. disposal by local authorities or distributors). Materials recycling helps to reduce the consumption of raw materials and to protect the environment.

8.2 Links

Terms and conditions of warranty:
https://www.pari.com/int/warranty-conditions

Technical data regarding electromagnetic compatibility:
https://www.pari.com/fileadmin/Electromagnetic-compatibility-2.pdf

PARI inhalation systems in aircraft:
https://www.pari.com/fileadmin/041D0625_Airplane_Certificate_Jet_nebuliser.pdf

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

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