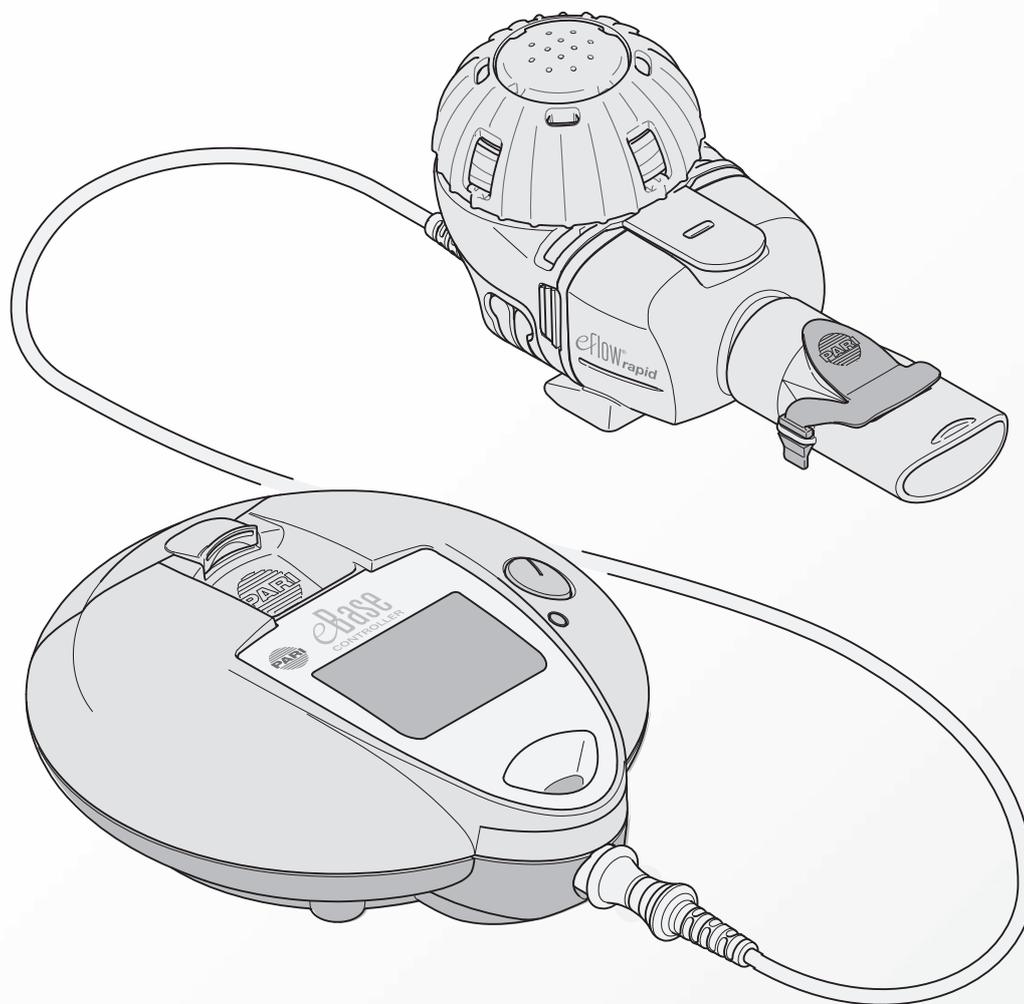




eFlow[®] rapid

nebuliser system



CE 0123

eFlow[®]
TECHNOLOGY

en Instructions for use

bg Инструкции за употреба

cs Návod k použití

el Οδηγίες χρήσεως

et Kasutusjuhend

hr Upute za uporabu

hu Használati utasítás

is Notkunarleiðbeiningar

pl Instrukcja obsługi

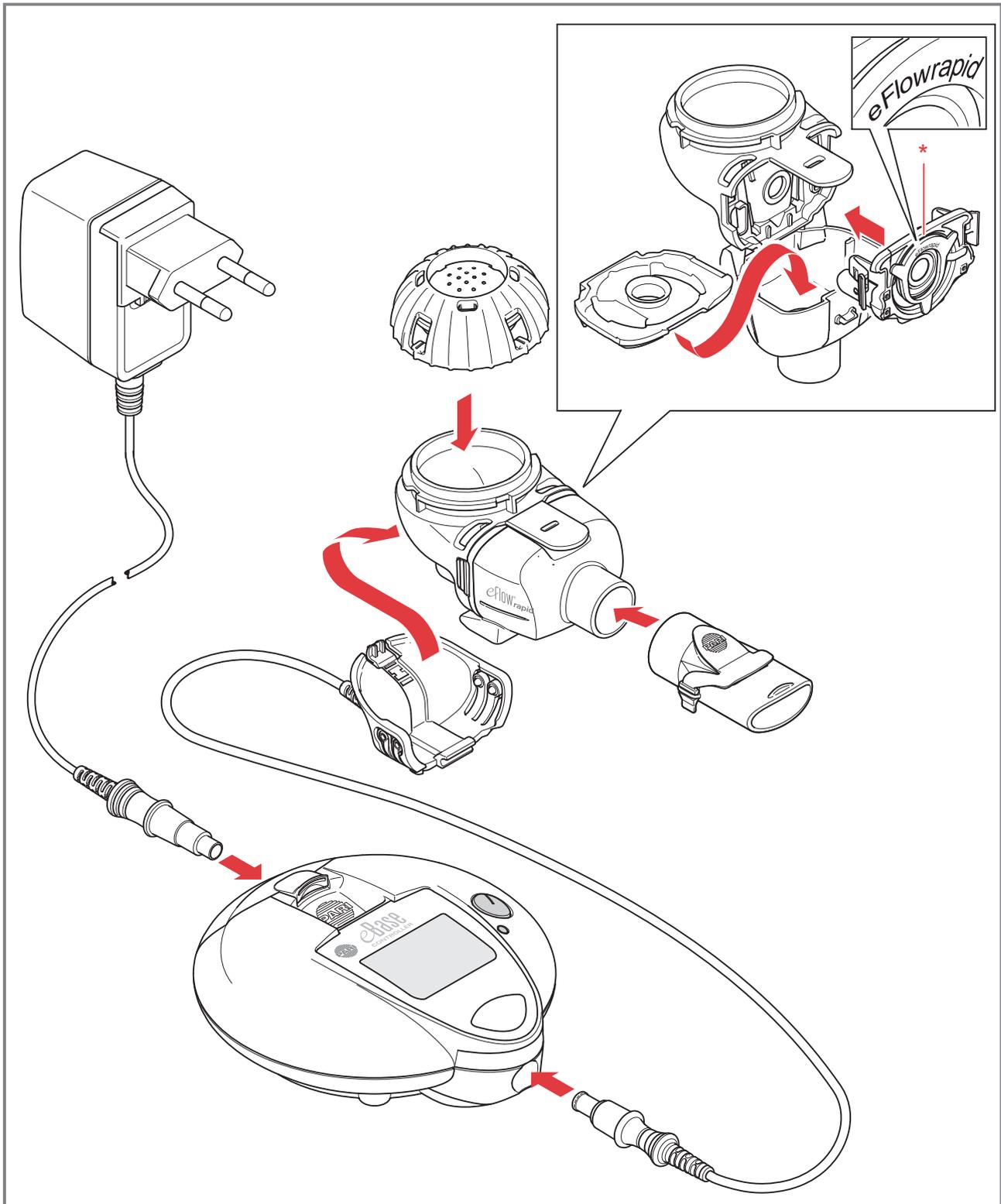
sk Návod na použitie

sl Navodila za uporabo

tr Kullanım talimatları

For full details, please read and take note of the instructions for use.

1 ASSEMBLE



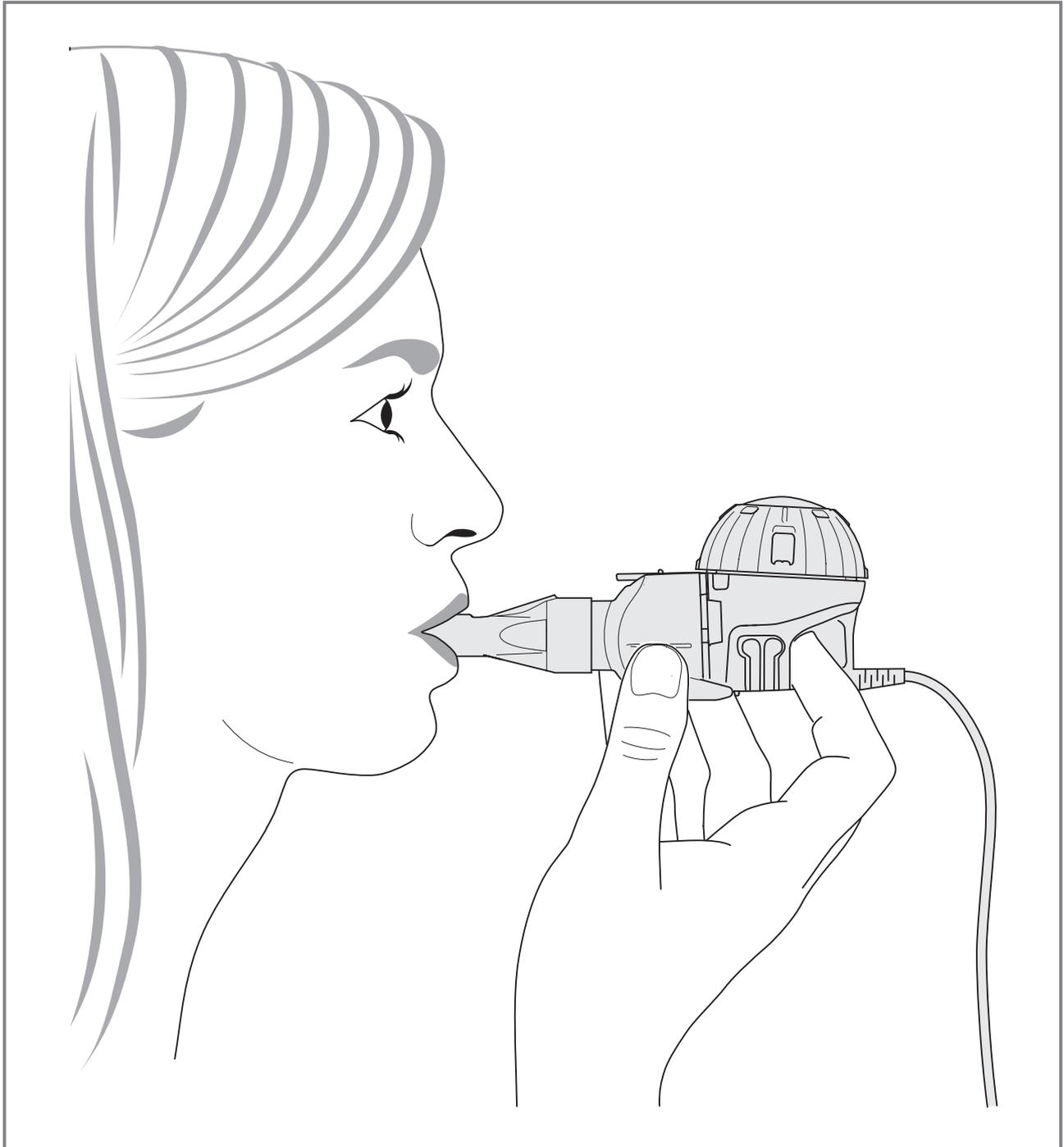
* TouchSpray made under licence from The Technology Partnership plc.

For full details, please read and take note of the instructions for use.

2 INHALE

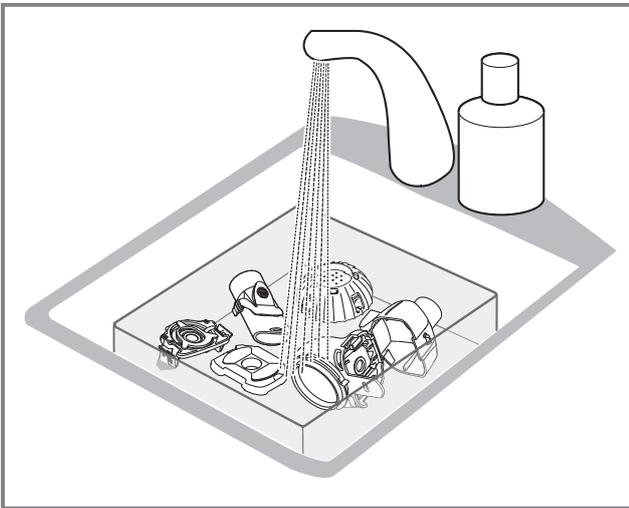


Sit in an upright position.
Hold nebuliser handset horizontally.



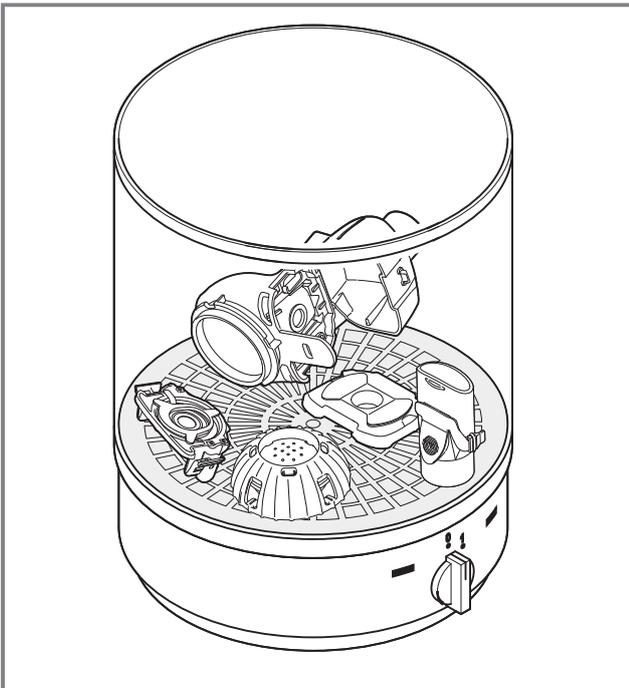
For full details, please read and take note of the instructions for use.

3 NEBULISER HANDSET HYGIENE AT HOME



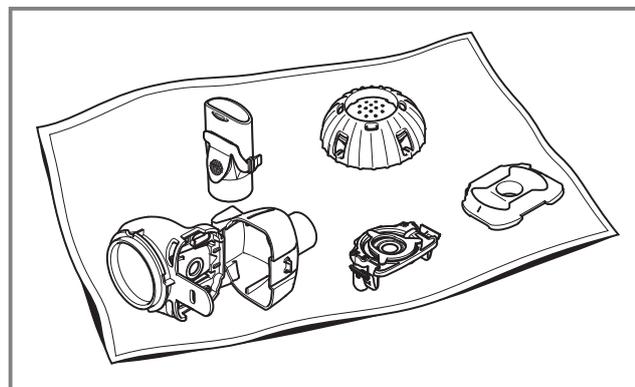
Clean immediately after inhalation

Warm water, washing up liquid



Disinfect

Disinfect in the steam disinfecter for 6 minutes, or boil thoroughly in distilled water for 5 minutes.



Dry

Allow to air dry (for about 4 hours).
Store in a clean, dry place.

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For eFlow[®]rapid Type 178G1005

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1 IMPORTANT INFORMATION

Read these instructions for use and the instructions for use of the accompanying accessories completely before using for the first time. Keep them safe so that you can refer to them again later.

WARNING:

If these instructions for use are not followed, injuries and damage to the product cannot be ruled out.

Report serious incidents to the manufacturer and the competent authority.

You should have a medical examination before beginning treatment for an illness.

Organisation of warnings

In these instructions for use, safety-related warnings are organised according to the degrees of hazard:

- The signal word **WARNING** is used to indicate dangers that may result in serious injuries or even death if precautionary measures are not taken.
- The signal word **CAUTION** is used to indicate dangers that may result in slight to moderate injuries or impair treatment if precautionary measures are not taken.
- The signal word **NOTE** is used to indicate general precautionary measures for handling the product that should be followed to avoid damaging the product.

Handling the nebuliser system

Check the nebuliser system before each use.

CAUTION:

Replace all broken, deformed and heavily discoloured parts. Damaged parts can impair the function of the nebuliser system and thus also affect treatment.

WARNING:

Do not operate the nebuliser system if the power adapter is visibly damaged, since otherwise there is a risk of contact with live parts (e.g., electric shock).

Follow the instructions below in order to operate the nebuliser system safely:

- Always remove the power adapter from the socket to ensure that the power is completely cut off.

WARNING:

Never remove the power adapter from the socket with wet hands. There may be a risk of electric shock.

- Keep the nebuliser system away from hot surfaces (e.g., hob).
- Do not allow pets near the cables.

WARNING:

Do not use the nebuliser system in areas where there is a risk of explosion or in the presence of gases that promote combustion (e.g., oxygen, nitrous oxide, flammable anaesthetics).

- Do not carry out an inhalation session while you are driving a motor vehicle (risk of accident).

Treatment of babies, children and individuals requiring assistance

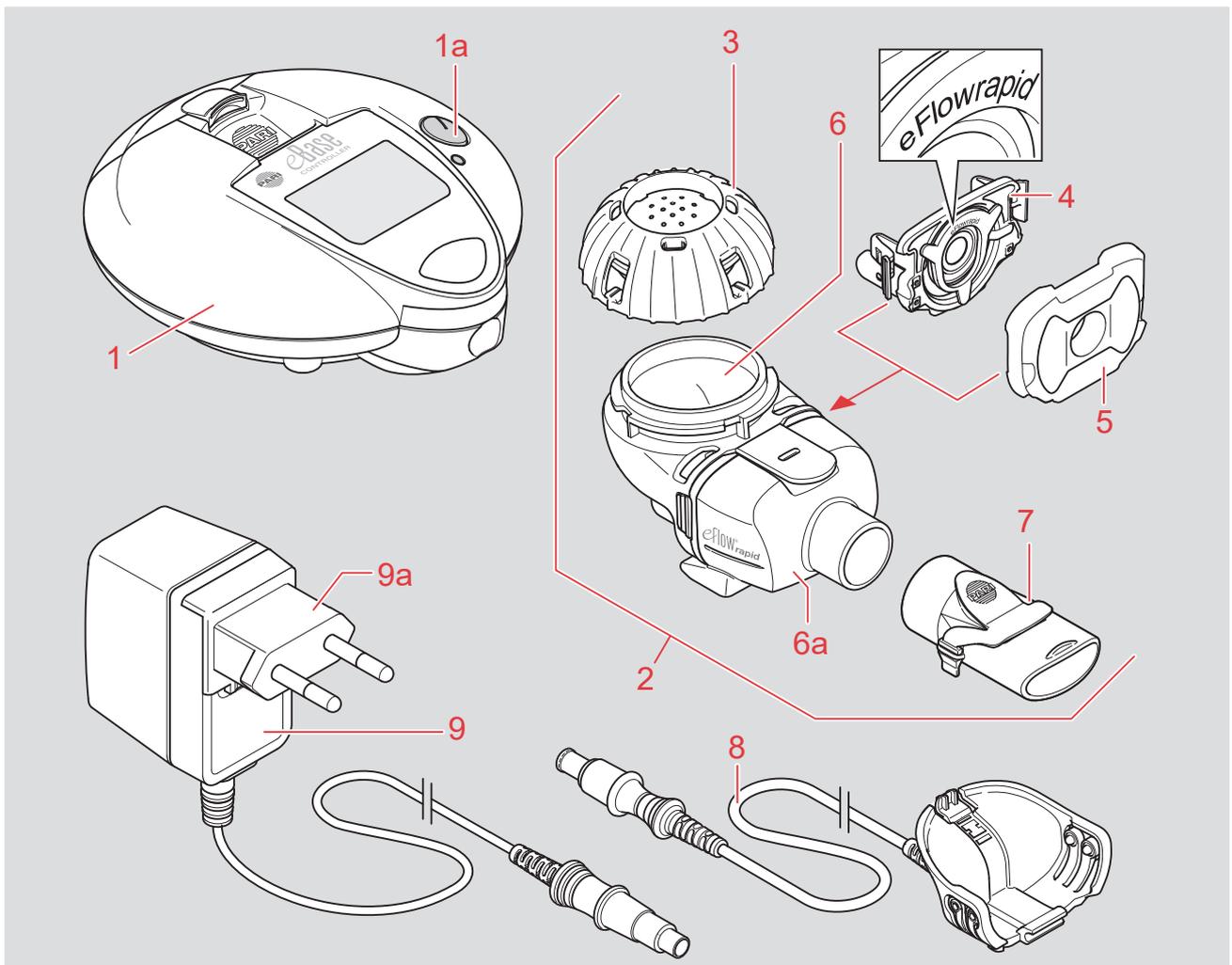
WARNING:

Children and anyone who requires assistance must be supervised constantly by an adult during inhalation therapy. This is the only way to ensure safe and effective treatment. These individuals often underestimate the hazards associated with the equipment (e.g., risk of strangulation with the cable), and this can result in risk of injury.

WARNING:

The product contains small parts. Small parts can block the airways and pose a choking hazard. Therefore, be sure to keep them out of reach of children at all times.

2 PRODUCT DESCRIPTION



1 eBase[®] Controller

1a ON/OFF button

2 Two eFlow[®] rapid nebuliser handsets (incl. aerosol head)

3 Medication cap

4 Aerosol head
eFlow[®] rapid Aerosol Head

5 Inspiratory valve

6 Medication reservoir and

6a Aerosol chamber (preassembled)

7 Mouthpiece with expiratory valve

8 Connection cord (connection between the controller and the nebuliser handset)

9 Power adapter

9a Country-specific adapter (AU, EU, UK, US)

- Carrying case and nebuliser handset bag

- *easy care* cleaning aid for aerosol heads

- Batteries (optional)

Check that all components are contained in your package. If they are not, contact your local service partner (see “Service and manufacturer”, page 32).

Intended purpose

The eFlow[®]rapid nebuliser system is intended to administer solutions or suspensions for a nebuliser handset as an aerosol for inhalation.

Indication

The eFlow[®]rapid nebuliser system is intended to administer solutions or suspensions for a nebuliser handset which are approved for the treatment of diseases of the lower airways.

Intended use

The nebuliser system must only be used in accordance with its intended purpose. The frequency of inhalation sessions may vary depending on the nebuliser solution or suspension used for a nebuliser handset and the clinical picture. Take note of any limitations in the package leaflet accompanying the respective solution or suspension for a nebuliser handset.

WARNING:

For reasons of hygiene and to avoid cross-infections, the eFlow[®]rapid nebuliser handset and the connection cord must be used by one patient only. For patients at greater risk of infection, e.g., with cystic fibrosis (CF) or a weakened immune system, or for those infected with MRSA it is recommended that the eBase[®] Controller and the power adapter are also used by one patient only.



Info:

The eBase[®] Controller can also be used for a drug-specific nebuliser handset (Tolero[®], Zirela[®] and Altera[®]). Follow the instructions for use of the nebuliser handset as well.

CAUTION:

Medications that are approved for inhalation with a drug-specific nebuliser handset must not be used with an eFlow[®]rapid nebuliser handset (risk of incorrect dosage).

CAUTION:

Never attempt to inhale essential oils, as this can cause irritation of the airways (intense coughing).

Only original PARI accessories must be used to operate the system (see "SPARE PARTS AND ACCESSORIES", page 26).

CAUTION:

Using accessories and spare parts other than those supplied by the manufacturer may cause increased electromagnetic emissions or reduced electromagnetic immunity, leading to a malfunction.

PARI Pharma GmbH is not responsible for damage if the system is used improperly or contrary to the instructions.

Contraindications

For the eFlow[®]rapid nebuliser system no contraindication is known to PARI Pharma GmbH. Take note of contraindications of the medicine in the accompanying package leaflet.

Intended patient group

The eFlow[®]*rapid* nebuliser system is suitable for use by all age groups. Inhalation with the mouthpiece is the most effective form of inhalation, since it results in minimum medication losses on the way to the lung. For babies and toddlers who cannot use the mouthpiece to inhale, PARI offers appropriate masks as accessories.

The nebuliser system is only suitable for use by patients who can breathe unassisted and are conscious.

The nebuliser handsets are not suitable for use by patients who are receiving mechanical ventilation or have undergone a tracheotomy.

Lifetime of the medical device

The nebuliser handset with aerosol head is designed for multiple uses. For optimal inhalation therapy with exact dosing and short inhalation time and to ensure the best possible hygiene conditions, nebuliser handsets and aerosol heads must be replaced regularly.

The lifetime of the nebuliser handset depends on the daily number and duration of the inhalation cycles performed, the composition and variety of the nebuliser solutions used, and the cleaning/hygiene processes applied.

Over time, medication residues and microparticles introduced from the environment can partially block the fine pores in the aerosol head and prolong the nebulisation times. When the cleaning instructions are followed regularly and the *easycare* cleaning aid is used, the aerosol head has a possible lifetime of between three and six months. If the nebuliser handset is used frequently (two or more different nebuliser solutions several times a day), the recommended useful life of the aerosol head may be shortened to a period of one to three months due to significantly longer nebulisation times.

It is recommended that the plastic parts (nebuliser handset without aerosol head) be replaced after 12 months at the latest. For drug-specific nebuliser handsets (Tolero[®], Zirela[®] and Altera[®]) and for the eFlow[®]*rapid* nebuliser handset for inhalation of antibiotics, replacement after one month is recommended.

The expected lifetime of the eBase[®] Controller is 3 years.

3 PREPARING FOR INHALATION

Information for the first application

- Wash your hands thoroughly every time before using the nebuliser system.
- To avoid irritation of the airways due to inhaling aerosol when it is too cold and impairment of the aerosol properties, do not use medications straight from the refrigerator.

WARNING:

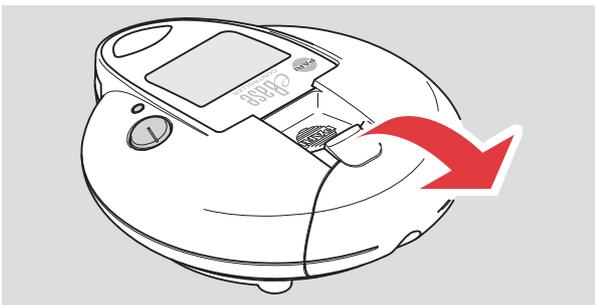
Clean the nebuliser handset and aerosol head before the first application (see “CLEANING AND DISINFECTATION”, page 17).

Preparing the controller

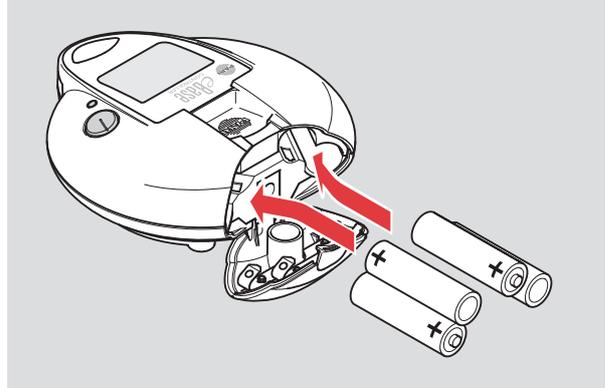
The controller can be operated with batteries or with rechargeable batteries.

i *Info:*
i *Rechargeable batteries cannot be recharged in the controller!*

- Open the battery compartment by lifting the clip.



- Insert the batteries as indicated by the polarity symbols.



- Close the battery compartment.

Operation with the power adapter

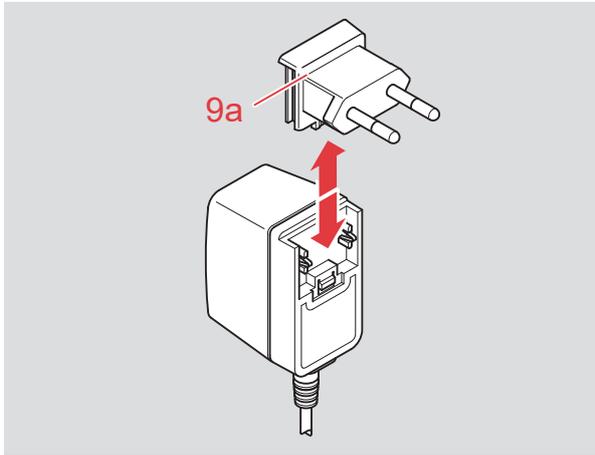
Check that the power adapter is intact before every application.

WARNING:

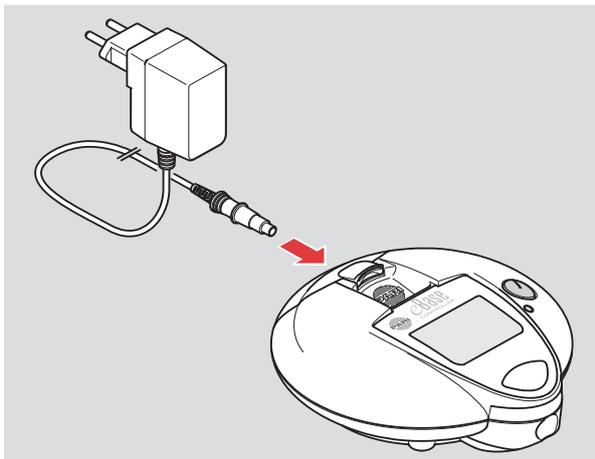
Do not use a power adapter that is damaged or faulty.

The eBase[®] Controller was developed for mobile use. Therefore, insert batteries before use and leave them in the controller during mains operation. This guarantees smooth functionality. This does not deplete the energy reserves of the batteries.

- Replace the country-specific adapters for the power adapter as required. To unlock, press the clip and push the country-specific adapter upwards. When plugging in, make sure that the adapter (9a) engages in the power adapter housing.



- Connect the power adapter to the power cord socket on the controller.



- Plug the power adapter into an electrical wall socket.

Preparing the nebuliser handset

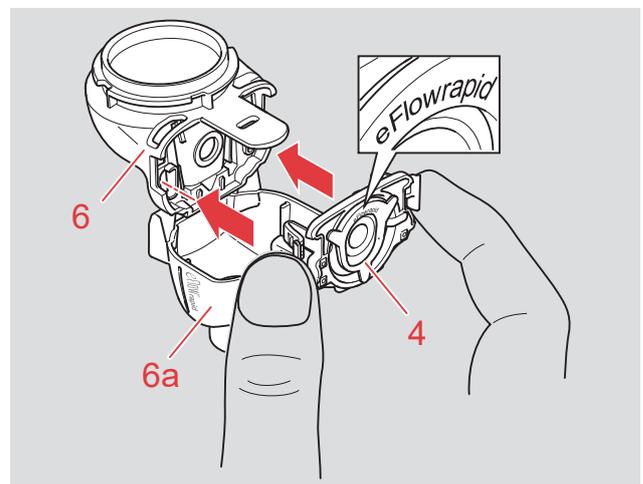
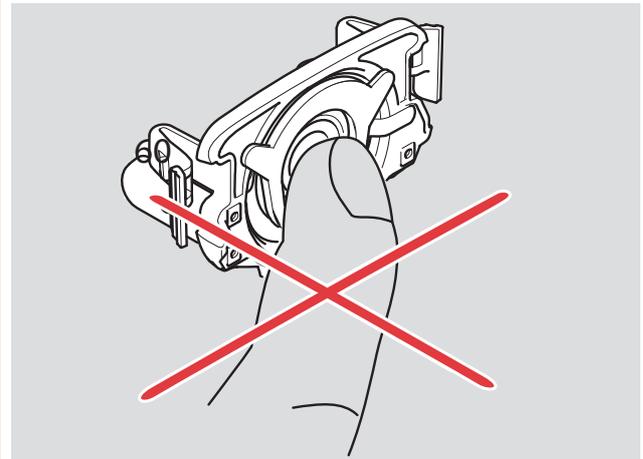
CAUTION:

Check the parts of your nebuliser handset before each use. Replace all broken, deformed and heavily discoloured parts. Damaged parts and incorrectly assembled nebuliser handsets can impair the function of the nebuliser handset and thus also affect the treatment.

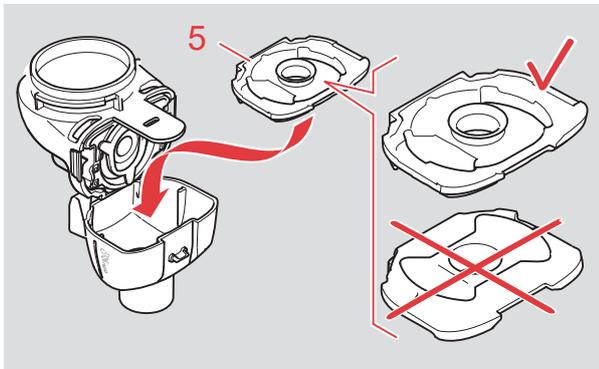
- Insert the aerosol head (4) into the openings on the medication reservoir (6) (opened aerosol chamber (6a)). It must snap noticeably into place.

CAUTION:

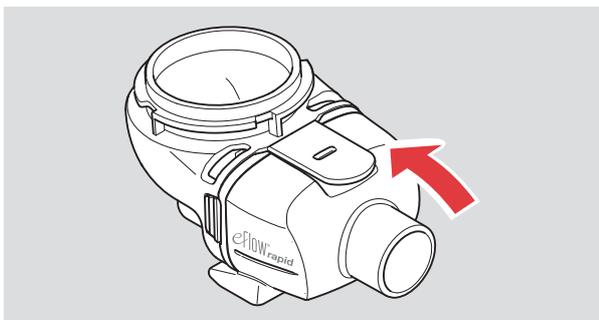
Do not touch the membrane (the curved metal surface in the middle of the aerosol head) to avoid damage.



- Insert the inspiratory valve (5) in the aerosol chamber.
When doing so, check that the two valve flaps are seated correctly. They must lie perfectly flush and face towards the aerosol chamber following insertion.



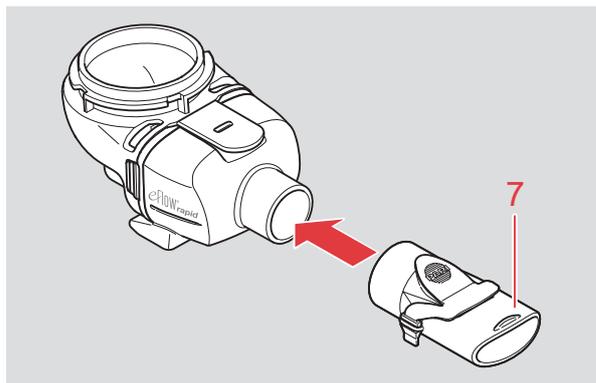
- Close the aerosol chamber.



NOTE:

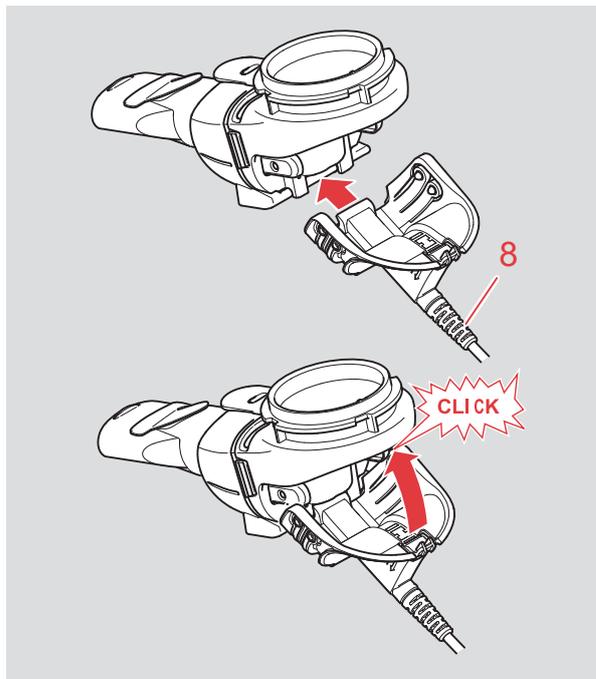
If the snap closure does not close, ensure that the inspiratory valve is seated correctly. It must lie flat against the aerosol chamber.

- Attach the mouthpiece (7) to the aerosol chamber.

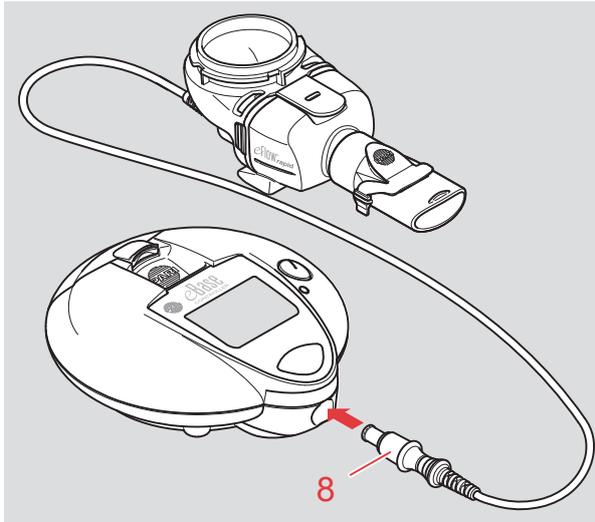


i Info:
For inhalation with a mask, follow the instructions for use of the mask you are using.

- Connect the connection cord (8) to the nebuliser handset.



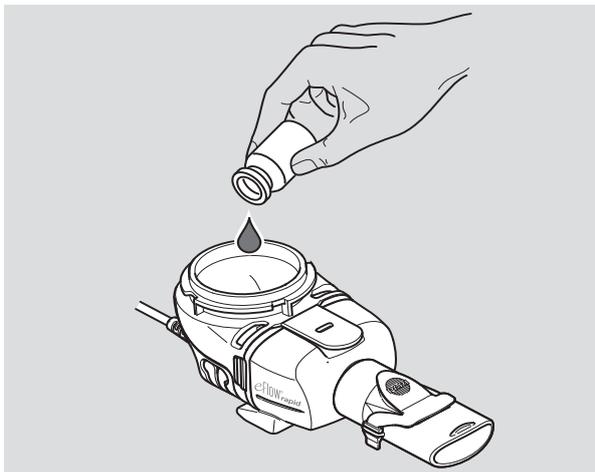
- Connect the connection cord (8) to the controller.



- Place the nebuliser handset on a firm, flat surface.
- Add the quantity of medication prescribed by your doctor to the medication reservoir.

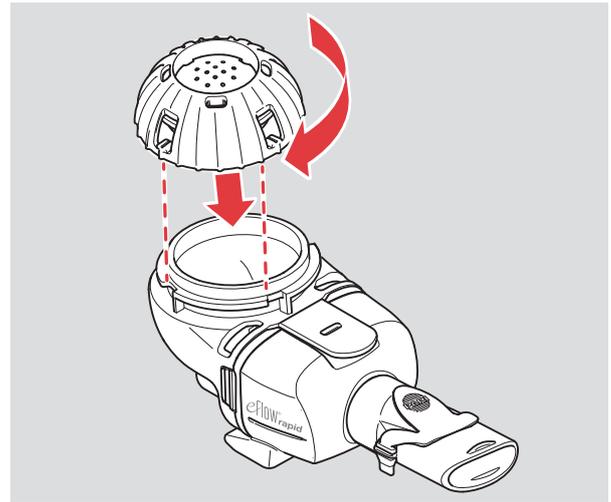
WARNING:

Ensure that the medication is filled no higher than the upper scale graduation mark (6 ml). Do not overfill under any circumstances!

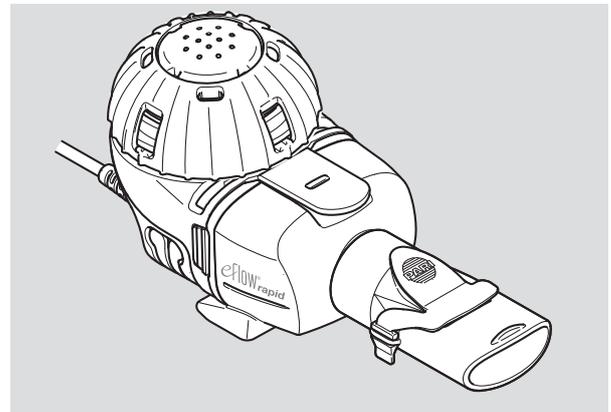


- i Info:**
 If you intend to inhale several medications one after the other, rinse all nebuliser handset parts thoroughly with warm tap water before refilling.

- Close the medication reservoir.



- Check that all parts are connected tightly and that the medication reservoir is sealed.



4 PERFORMING INHALATION

- Sit in an upright position and relax. This makes inhalation easier and improves uptake of the medication in the airways.
- Hold the nebuliser handset in your hand.

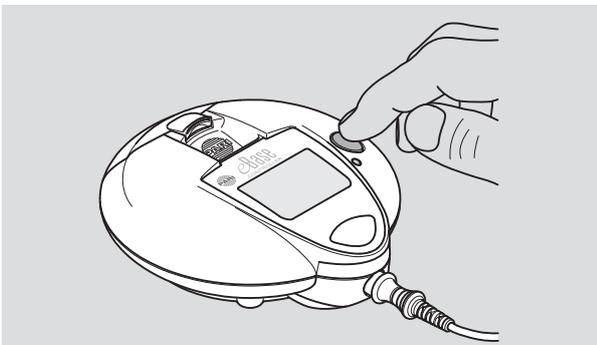
CAUTION:

Hold the nebuliser handset horizontally at all times while performing the inhalation. If the handset is tilted, this may result in the incorrect dosage being delivered.

- Hold the mouthpiece between your teeth and enclose with your lips. The lips must not touch the blue expiratory valve.



- Press the ON/OFF button on the controller to start the inhalation session.



A green LED next to the ON/OFF button lights up and an audible signal (1 beep) is emitted to indicate readiness for use.

- Inhale and exhale slowly and deeply through the mouthpiece. Hold the mouthpiece in your mouth while breathing out as well.

Do not breathe through your nose. You can use a nose clip if necessary.

Info:

i It is normal for aerosol to escape through the expiratory valve in the mouthpiece during exhalation; this is not a malfunction.

Pausing during inhalation

If it is necessary to interrupt the inhalation session briefly, activate pause mode:

- Press the ON/OFF button for approx. 1 second. Pause mode is activated when the LED flashes green.
- Press the ON/OFF button for approx. 1 second again to resume the inhalation session.

Info:

i Pause mode can only be activated after an operating time of a few seconds.

If pausing for a longer time, switch the controller off by pressing the ON/OFF button for approx. 2 seconds.

As long as there is enough liquid in the medication reservoir, nebulisation can be restarted by pressing the ON/OFF button again.

Screens during inhalation

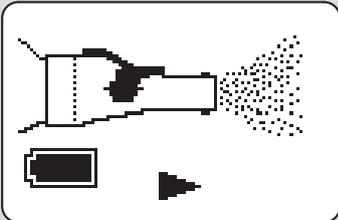
The following screens appear during the inhalation session:

Start

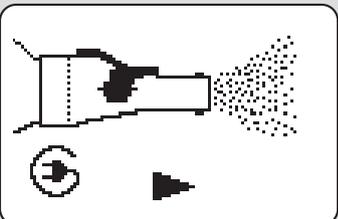


During inhalation

Nebulising with battery power

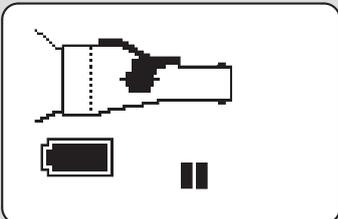


Nebulising with mains power

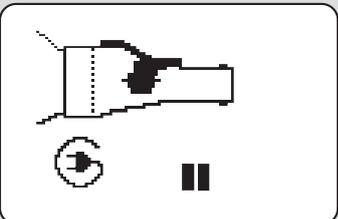


Pause mode activated

Pause mode when operating with batteries

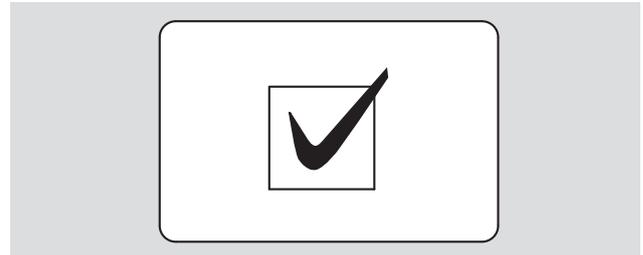


Pause mode when operating with mains power



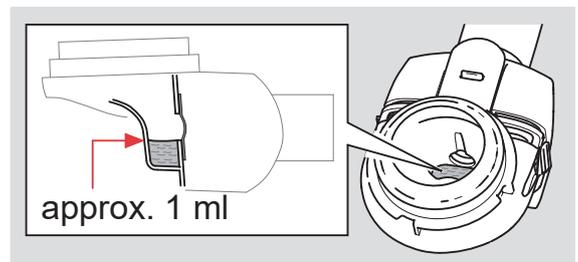
End of the inhalation session

The inhalation session is finished as soon as no more aerosol is generated, and the following screen appears:



The controller switches off automatically. If the controller switches itself off considerably sooner or later than usual, follow the instructions in Chapter “TROUBLE-SHOOTING”, page 22.

i Info:
 Note that about 1 ml of medication cannot be nebulised and remains unused in the medication reservoir of the eFlow[®] rapid nebuliser handset; this residue must be discarded. This is necessary to ensure a safe dosing of medication is delivered and does not constitute a malfunction.



For safe disposal of the leftover medication, follow the information in the medication package leaflet.

i *Info:*
The nebulisation times may gradually become longer with increasing length of use. This does not constitute a malfunction of the nebuliser handset.

- When operating with the power adapter:
When the inhalation session has ended, disconnect the power adapter plug from the socket.
- Carry out the hygiene procedures (see “CLEANING AND DISINFECTATION”, page 17) immediately after the inhalation session has ended.

5 CLEANING AND DISINFECTION

Nebuliser handset

WARNING:

The nebuliser handset (and the aerosol head) must be cleaned immediately after each use and disinfected once a day.

Preparation

Disassemble the nebuliser handset into its individual parts:

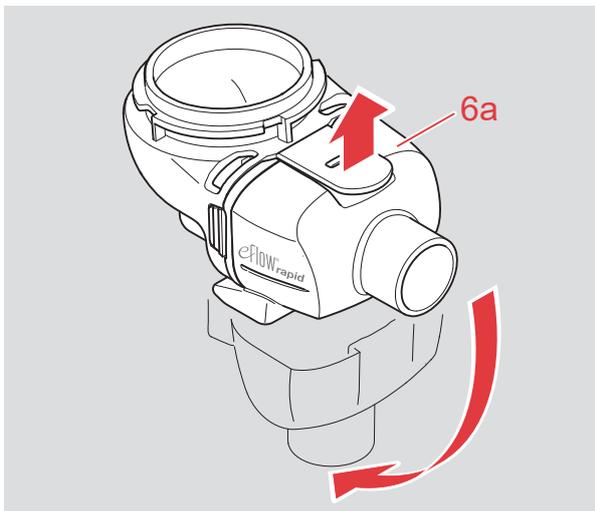
- Pull the connection cord out of the nebuliser handset.
- Remove the mouthpiece from the nebuliser handset.
- Open the medication reservoir and pour out the medication residue.



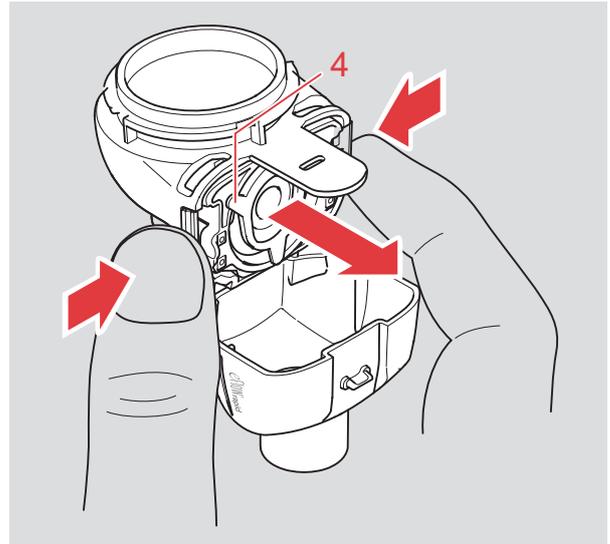
Info:

The medication reservoir and aerosol chamber are already preassembled and must not be detached from one another.

- Open the aerosol chamber (6a).



- Remove the inspiratory valve from the aerosol chamber.
- Remove the aerosol head (4). To do this, gently press the engaging side hooks on the aerosol head together.



CAUTION:

Do not touch the membrane (the curved metal surface in the middle of the aerosol head) to avoid damage.

Hygienic reprocessing at home

Cleaning

WARNING:

Clean the nebuliser handset (incl. aerosol head) immediately after each application.

NOTE:

Rinsing all the parts of the nebuliser handset and the aerosol head in warm tap water straight after use prevents medication residue from accumulating, for example. This helps you to prevent a potential lengthening of the nebulisation times due to partial closure of the pores in the membrane.

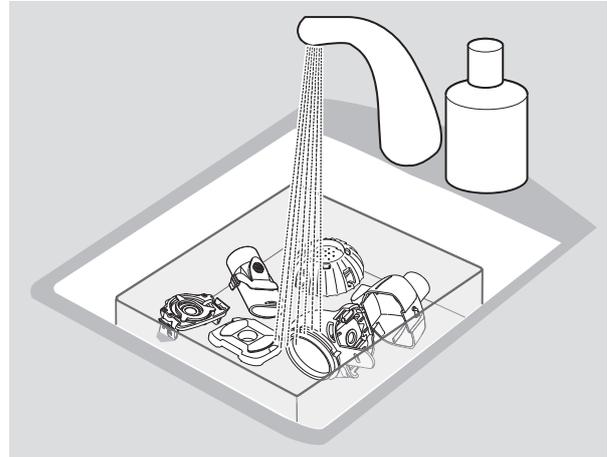
NOTE:

If necessary, clean the aerosol head with the *easycare* cleaning aid (not more than twice a week). Backwashing unblocks the pores in the membrane of the aerosol head by flushing with liquid in the opposite direction to the direction for nebulising. Observe the information provided in the *easycare* instructions for use.

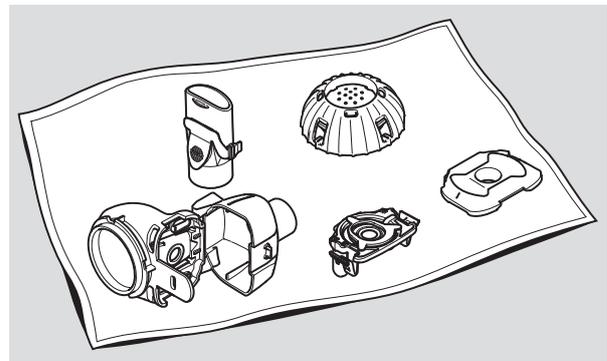
- Rinse each side of the aerosol head for approx. 5 seconds each in warm tap water (water of drinking water quality, temperature up to 37 °C).
- Rinse all parts of the nebuliser handset for approx. 5 seconds.
- Place all nebuliser handset parts and the aerosol head in warm tap water with a few drops of washing-up liquid for 5 minutes. Use a clean bowl for this.

CAUTION:

Do not use a brushes or any other tools to clean the aerosol head as they may cause damage to the product components.



- Rinse all nebuliser handset parts and the front and back of the aerosol head thoroughly under running tap water.
- Shake all parts to remove excess water more quickly.
- Place the individual parts on a dry, clean surface and allow them to air-dry completely.



CAUTION:

Moisture promotes the growth of bacteria. Please ensure adequate drying after each cleaning.

Disinfection

WARNING:

Disinfect the nebuliser handset parts and the aerosol head at least once a day, e.g., immediately after cleaning at the end of the day (a nebuliser handset cannot be disinfected effectively unless it has been cleaned first).

NOTE:

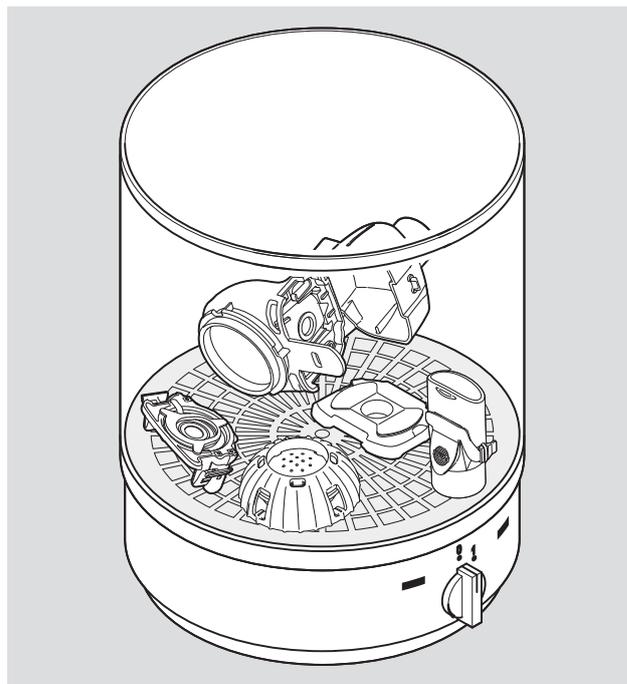
Do not use a microwave to disinfect the aerosol head. The possibility of product components being damaged cannot be ruled out.

With a commercially available disinfectant for baby bottles

- To ensure effective disinfection, use a thermal disinfectant with an operating time of at least 6 minutes. With regard to performing the disinfection, the duration of the disinfection process and the quantity of water required, follow the instructions for use of the disinfectant you are using.

CAUTION:

Inadequate disinfection promotes the growth of bacteria and thus increases the risk of infection. If disinfection is not carried out for the time specified for the device concerned, it will not be effective. Therefore, do not switch the device off before the disinfection cycle is complete. Also, make sure that the device is clean and check it regularly for proper operation.



- Take the parts out of the disinfectant immediately after disinfection is complete. Place them on a dry, clean surface and allow them to air-dry completely.

CAUTION:

Check the nebuliser handset parts after every disinfection. Replace all broken, deformed and heavily discoloured parts.

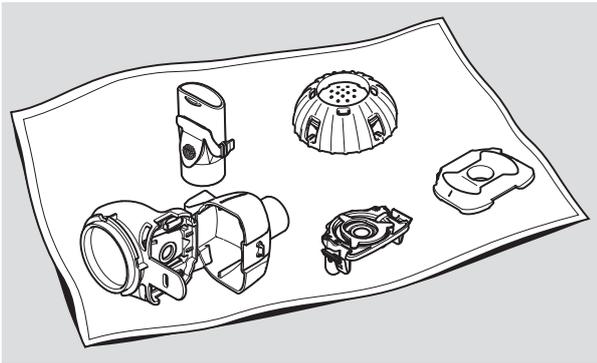
Possible option: Boiling in distilled water

CAUTION:

Plastic will melt if it comes into contact with the hot base of the pot. Therefore, make sure that there is sufficient water in the pot. This will prevent the parts from being damaged.

- Put all parts in boiling water for at least 5 minutes. Use a clean pot and distilled water for this.
- Take the parts out of the pot.
- Shake all parts to remove excess water more quickly.

- Place the individual parts on a dry, clean surface and allow them to air-dry completely.



CAUTION:

Moisture promotes the growth of bacteria. Please ensure adequate drying after every disinfection.

CAUTION:

Check the nebuliser handset parts after every disinfection. Replace all broken, deformed and heavily discoloured parts.

Hygienic reprocessing in the hospital and doctor's practice

Carry out cleaning with disinfection immediately after use. Ideally, a mechanical procedure (instrument dishwasher) should be used.

Prepare for cleaning with disinfection (see "CLEANING AND DISINFECTION", page 17).

Cleaning with thermal disinfection

- Place the nebuliser handset components in the instrument dishwasher.
- Select the 93 °C programme (treatment time: 10 minutes).

The effectiveness of this procedure has been validated using a G7736 disinfectant made by Miele and using neodisher MA (Chemische Fabrik Dr. Weigert, Hamburg) as a cleaning agent in conjunction with deionised water as a neutraliser. Even when the instrument dishwasher is equipped with a drying function, ensure that no residual moisture remains in the nebuliser handset. Remove residual moisture by shaking the parts and allow them to air-dry completely.

Controller, connection cord and power adapter

Cleaning

Clean the controller, the connection cord and the power adapter as necessary with a clean, lint-free, damp cloth.

Allow the controller, the connection cord and the power adapter to dry completely.

CAUTION:

Do not hold the controller, the connection cord or the power adapter under running water and do not use liquid cleaning agents. If liquid gets into these components, the electronics may be damaged and the device may no longer function properly. If liquid does get into them, contact your local service partner immediately.

Disinfection

Disinfect the controller, the connection cord and the power adapter after cleaning. Use an alcohol-based, standard commercial disinfectant wipe for disinfecting.

To ensure safe application, follow the instructions for use of the disinfectant wipe. Effectiveness has been tested using Bacillol Tissues and Clinell Wipes.

Allow the controller, the connection cord and the power adapter to dry completely.

Storage

Between applications, particularly for prolonged breaks in treatment, keep the nebuliser handset in a dry, dust-free place (e.g., nebuliser handset bag).

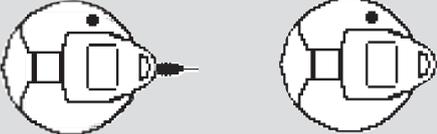
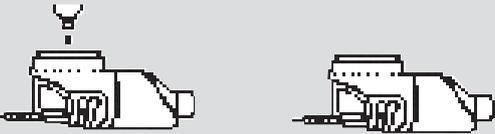
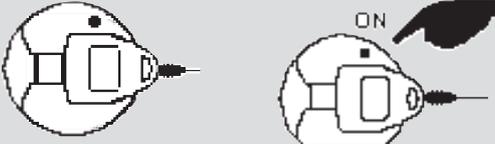
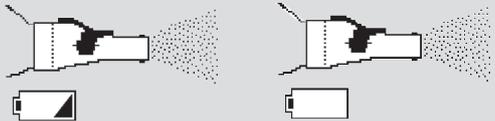
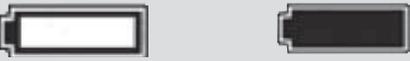
Pack the controller, the connection cord and the power adapter in the case provided for this purpose.

NOTE:

Leaking batteries may cause damage to the controller. Therefore, remove the batteries if the nebuliser system is not expected to be used for a relatively long period of time.

6 TROUBLESHOOTING

You can correct malfunctions that occur during daily operation yourself. The following tables will help you to locate and correct the causes of malfunction.

Screen (flashes alternately)	Possible cause	Solution
	Connection between the controller and the nebuliser handset/ aerosol head interrupted.	<ul style="list-style-type: none"> - Verify that all parts are securely connected. - Replace the aerosol head and/or the connection cord if damaged. If the fault persists, contact your service partner.
	No medication added.	Add medication.
	Inhalation interrupted.	Resume inhalation by restarting the device (press the ON/OFF button).
	The maximum operating time of 20 minutes for an inhalation session has been exceeded.	Resume inhalation by restarting the device (press the ON/OFF button).
	Battery charge level 50%.	Have new batteries ready.
	Battery flat.	Insert new batteries or operate with the power adapter connected.

Fault/Condition	Possible cause/Solution
<p>The controller cannot be switched on (no beep, no orange or green light signal).</p>	<ul style="list-style-type: none"> - To switch on, press the ON/OFF button for approx. 2 seconds. - Is power cord plug plugged into mains and the device (for mains operation)? Does the power adapter LED light up? - Are the batteries inserted correctly? - Check the charge level of the batteries.
<p>After switching the controller on, no aerosol is generated, and/or the controller switches off again after a few seconds.</p>	<ul style="list-style-type: none"> - Has the medication reservoir been filled with medication? - Check the connection between the controller and the nebuliser handset.
<p>The controller switches off even though there is still medication left in the medication reservoir.</p> <p>i <i>Info:</i> <i>Note that about 1 ml of medication cannot be nebulised and remains unused in the medication reservoir of the eFlow[®]rapid nebuliser handset; this residue must be discarded. This is intentional and does not represent a malfunction.</i> <i>With drug-specific nebuliser handsets (Tolero[®], Zirela[®] and Altera[®]) there is no significant volume of residue left in the medication reservoir.</i></p>	<p>If there is still more than 1 ml in the medication reservoir of the eFlow[®]rapid nebuliser handset:</p> <ul style="list-style-type: none"> - Check the charge level of the batteries. - Was the nebuliser handset held horizontally throughout the inhalation session? Hold the nebuliser handset horizontally. - The controller switches off automatically after 20 minutes. Carry out inhalation to the end by pressing the ON/OFF button again, so that you can inhale the prescribed dose of medication. If the maximum operating time for an inhalation session is exceeded repeatedly, the aerosol head must be replaced.
<p>The controller does not switch off automatically even when no more aerosol is being produced and there is no more than about 1 ml of residue left in the medication reservoir of the eFlow[®]rapid nebuliser handset.</p>	<p>The treatment session has been completed successfully and the controller can be switched off by pressing the ON/OFF button.</p>

Fault/Condition	Possible cause/Solution
<p>The nebulisation times have become considerably longer than normal.</p>	<p>If the nebuliser handset is used regularly, the nebulisation time will gradually become longer. This is not a malfunction. However, if you notice that the nebulisation time has become considerably longer (twice as long), this may be due to one of the following:</p> <ul style="list-style-type: none"> - You are inhaling a different medication. - The fill volume has been increased. - The medication cap was not closed tightly. - The aerosol head was not cleaned immediately after the last application (the fine pores of the membrane may be partially blocked) or it is damaged. - You are using the aerosol head for longer or more often than is described in section Lifetime of the medical device. <p>If the causes mentioned above do not apply, use the <i>easycare</i> cleaning aid. The <i>easycare</i> cleaning aid can help to shorten the nebulisation time if the performance of the aerosol head becomes less than optimal.</p> <p>Observe the information provided in the <i>easycare</i> instructions for use.</p> <p>If the nebulisation time is still more than twice as long after cleaning with the <i>easycare</i> cleaning aid, the aerosol head must be replaced.</p>
<p>Aerosol escapes continuously in large volumes from the opening slots in the medication reservoir.</p>	<ul style="list-style-type: none"> • Check whether the nebuliser handset has been assembled correctly. Check that the two valve flaps of the inspiratory valve are seated correctly. When the valve is inserted, they must lie flat and face towards the aerosol chamber.

Fault/Condition	Possible cause/Solution
The medication cap cannot be removed from the medication reservoir after the inhalation treatment.	The negative pressure in the medication reservoir is too high. <ul style="list-style-type: none"><li data-bbox="783 286 1401 405">• Open the aerosol chamber and gently pull the aerosol head so that air can flow in. The medication cap can now be removed easily.

If the malfunction persists, contact your local service partner.

7 DISPOSAL

The live parts (such as the controller, the cable, the power adapter and the batteries) as well as the aerosol head must not be disposed of with domestic waste.

The device components must be disposed of in accordance with local regulations.

8 SPARE PARTS AND ACCESSORIES

Description	Catalogue number
Nebuliser handset (incl. aerosol head)	678G8222
Aerosol head	678B2620
Mouthpiece	078B3601
Power adapter (100 to 240 V~, 50-60 Hz)	078B7114
Connection cord	178G6009
Carrying case	078E8005
PARI Filter valve set ^{a)}	041G0500
PARI SMARTMASK (adults) ^{a)}	041G0730
SMARTMASK Kids (children aged 2 and older) ^{a)}	078G5000
SMARTMASK Baby (babies weighing 2.5 kg and more) ^{a)}	078G5026
<i>easycare</i> cleaning aid for aerosol heads ^{a)}	078G6100

a) The availability of accessories may differ between countries/sales regions.

9 TECHNICAL DATA

General

Technical electromagnetic compatibility data in table form is available upon request from PARI Pharma GmbH or on the Internet under the following link:

<https://www.pari.com/fileadmin/Electromagnetic-compatibility-4.pdf>

Electrical connection	PARI power adapter REF 078B7114 Input: 100 to 240 V~, 50-60 Hz Output: 12 V ---
Batteries	4 x 1.5 V Mignon (AA LR6/Alkaline)
Rechargeable batteries	4 x 1.2 V Mignon (AA rechargeable, at least 2100 mAh)
Controller weight (incl. batteries)	approx. 300 g
Controller housing dimensions	H 4.0 cm, Ø 11.6 cm

eFlow[®] rapid nebuliser handset

Nebuliser handset weight	approx. 55 g
Nebuliser handset dimensions (W x H x D)	5.0 cm x 6.3 cm x 14.5 cm
Min. fill volume	2.0 ml
Max. fill volume	6.0 ml
MMAD ^{a)} (Mass Median Aerodynamic Diameter)	4.7 µm
GSD ^{a)} (Geometric Standard Deviation)	1.7
Respirable fraction ^{a)}	< 5 µm 53.8% < 2 µm 4.7% 2 - 5 µm 49.1%
Aerosol output ^{b)}	0.67 g
Aerosol output rate ^{b)}	0.43 g/min

Aerosol data according to ISO 27427; nebulised medium: Salbutamol 2.5 ml. Measured values may vary depending on the medication used.

Recommended fill volume: see package leaflet for the medication

a) Measurement with Next Generation Pharmaceutical Impactor (NGI) at 23 °C and 50% relative humidity. Inspiratory flow: 15 l/min.

b) Measurement with breathing simulator at 23 °C and 50% relative humidity. 500 ml breathing volume, breathing frequency 15 cycles/minute, sinusoidal breathing pattern, inhalation/exhalation ratio 1:1 (with adults, may vary in children).

Classification according to EN 60601-1

Type of electric shock protection (power adapter)	Protection class II
Degree of protection from electric shock of applied part (nebuliser handset)	Type BF
Degree of protection against ingress of water as per IEC 60529 (IP rating)	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
Environment	- Professional healthcare facility environments - Domestic healthcare settings

Materials used

- Nebuliser handset (incl. aerosol head):
Polypropylene, thermoplastic elastomers, polyoxymethylene, silicone rubber, stainless steel
- Mouthpiece: Polypropylene, silicone rubber

The eFlow[®]*rapid* contains no parts made from natural rubber (latex).

Ambient conditions for operation

- Ambient temperature: +5 °C to +40 °C
- Relative humidity of ambient air: 15% to 93% (non-condensing)
- Air pressure: 700 hPa to 1060 hPa

Users can operate the device both at home and when out and about. Its use on trains and aeroplanes is restricted to passenger areas only. If using the device in a car, it must be operated with battery power.

Within professional healthcare facility environments, the device must only be used in in-patient wards and intensive care units. The device must never be used in areas exposed to elevated magnetic or electrical radiation (e.g. in the vicinity of an MRI scanner).

CAUTION:

When using portable wireless communication devices, you must ensure that a distance of at least 30 cm is maintained between all parts of the nebuliser system and these devices (including their accessories, e.g., antenna cables or external antennas). Otherwise, the performance of your nebuliser system may deteriorate.

CAUTION:

The controller must not be placed directly beside or stacked with other devices for operation. If operation near or stacked with other devices is unavoidable, the controller must be monitored continuously to ensure proper operation.

Ambient conditions for transport and storage

- Temperature: -25 °C to +70 °C
 - Relative humidity of ambient air: 0% to 93% (non-condensing)
 - Air pressure: 500 hPa to 1060 hPa
- These values for transport are valid for the unpackaged product/ the unpackaged aerosol head. The blister packing for the aerosol head will only function properly under the transport conditions described on the system packaging.

NOTE:

Moisture from condensation can impair the controller's functional capabilities. Therefore, you should avoid extreme temperature fluctuations. Wait until the controller has reached room temperature before beginning an inhalation session.

The batteries must be removed if you do not expect to use the device for a lengthy period.

i *Info:* Batteries vary considerably in terms of storage life and output depending on battery quality. The operating time of about 90 minutes can only be achieved with the batteries supplied (4x or batteries with the same quality and performance).

10 SYMBOLS

	Medical device
	Follow the instructions for use
	Single patient – multiple use
	Direct current
	Alternating current
	Lot number
	Item number
	Serial number
	Unique Device Identifier
	Protection class of the applied part: Type BF
	Protection class II appliance
	IP21 The device is protected against dripping water
	Minimum and maximum ambient temperature
	Minimum and maximum humidity
	Minimum and maximum air pressure
	CE marking: This product complies with the European requirements for medical devices (EU 2017/745).
	The medical device was distributed commercially after 13 August 2005. This product must not be disposed of with normal domestic waste. The symbol of a crossed-through refuse bin indicates that separate collection is required.

	Caution
	Manufacturer
	Date of manufacture

11 TERMS AND CONDITIONS OF WARRANTY

PARI guarantees to you that if used for its intended purpose your nebuliser system will be free from defects in material or workmanship caused by the manufacturing process for the warranty period of two years.

However this warranty does not cover wearing parts, that is to say device parts that are exposed to normal wear, such as the nebuliser handset and aerosol head.

The warranty shall no longer be valid if:

- the device has been operated or used in a manner inconsistent with the guidelines in the instructions for use,
- damage is evident that is attributable to external factors such as water, fire, lightning strike or similar,
- the damage has been caused by transporting the device incorrectly, or resulted from a fall,
- the device has been handled or serviced incorrectly,
- the serial number on the device has been changed, removed or rendered illegible,

- repairs, adaptations or modifications have been made to the device by persons not authorised by PARI.
- If, exceptionally, a defect does occur, PARI will replace the device. The device may be replaced with an identically or at least comparably equipped model. Replacement of the device shall not serve as grounds for new claims under the warranty. All exchanged used devices or parts will become the property of PARI. All other claims under the warranty are excluded to the extent permitted by law. In the event of a claim under the warranty, please contact your local service partner. The original purchase receipt from the dealer must be presented as proof of warranty and ownership. This warranty applies solely for the initial purchaser of the device.

Service and manufacturer

Manufacturer	PARI Pharma GmbH Moosstr. 3 82319 Starnberg Germany
Contact for technical problems or questions regarding the device	Local service partner Contact: www.pari.com

The device must only be serviced by PARI Pharma GmbH or a service location expressly authorised by PARI Pharma GmbH.

We reserve the right to make technical changes.
Information as of: 2022-05