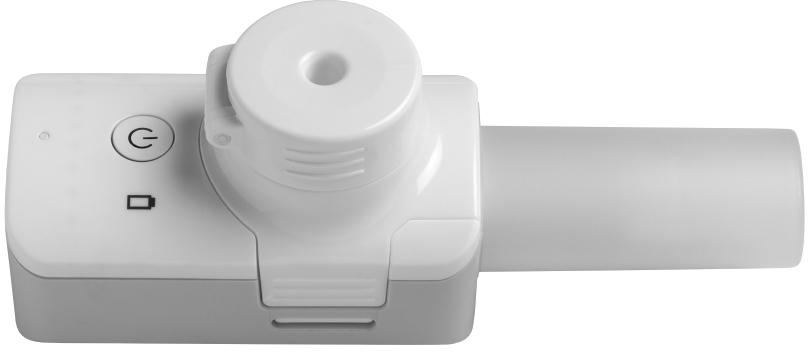
Breelib™

Inhalation System

Instructions for Use



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Definitions

The following definitions are used throughout this document. Please read these paragraphs carefully.

⚠ Warning

▶ Indicates a potentially hazardous situation which, if not avoided, could result in a serious or life-threatening injury.

Caution

▶ Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury or to highlight best practice. This term may also be used to highlight unsafe practices or potential equipment damage.

User Assistance Information

Please report any serious incident that has occurred in relation to the device to the Manufacturer and the Regulatory Authority of the country in which you reside.

To report a serious incident or for any questions relating to your *Breelib*™ Inhalation System please contact:

breelib.complaint@vectura.com

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1. Safety Instructions

Always have these instructions for use ready at hand. It is part of *Breelib*™ Inhalation System and a requirement for the intended use.

⚠ Warning

- Read the entire instructions for use and receive training from your healthcare provider before operating the *Breelib*™. Correct and safe operation can only be achieved if these instructions for use are followed. Incorrect usage may reduce the effect of the treatment.
- Keep these instructions for future reference.
- Do not use the *Breelib*™ if it is damaged or modified. Only use accessories supplied by a service partner.
- Only Vectura Group Ltd or a service partner authorised by Vectura Group Ltd is permitted to repair the *Breelib*™. Vectura Group Ltd is not liable for any damage or malfunction as a result of incorrect use.
- Use the *Breelib*™ only for its intended use as described in these instructions for use (refer to chapter “3. Intended Use“ on page 5).
- Use the *Breelib*™ only when prescribed by a physician and only with the drug prescribed for the *Breelib*™.
- Do not use any drug other than VENTAVIS® for *Breelib*™. The use of other drugs can lead to serious risks to health or can damage the *Breelib*™.
- Do not share your *Breelib*™ with other people. It can lead to infections. The *Breelib*™ is designed for single patient use.
- Do not open or disassemble the base unit. It may cause damage that is not covered by this warranty.
- Keep the *Breelib*™ away from small children to prevent contamination.
- Keep the *Breelib*™ away from small children to prevent strangulation with the charger cable.
- Ensure the *Breelib*™ has been properly cleaned before use.
- Do not use any left-over drug for further therapies.
- Do not use in an oxygen-rich environment.

Caution

- Do not use the consumables of the monthly pack for more than one month to maintain constant performance.
- Always keep the *Breelib*™ unit in the horizontal position to avoid any damage to the unit.

Caution

- ▶ Special precautions are needed for the *Breelib*™ regarding EMC (electromagnetic compatibility). It needs to be used according to the EMC information provided in chapter “11.8. Electromagnetic Compatibility” on page 36.
- ▶ The *Breelib*™ may be affected by portable or mobile RF (radio frequency) communication equipment like mobile phones or computer equipment. In case of a malfunctioning base unit, increase distance to portable or mobile RF communication equipment. For detailed information, refer to chapter “11.8. Electromagnetic Compatibility” on page 36.

2. Terms

Used term	Description
Breelib™	Inhalation system to nebulise the VENTAVIS® inhalation solution
PAH	Pulmonary arterial hypertension
VENTAVIS®	Inhalation solution
Base unit	Component containing the hardware
Mouthpiece	Component for inhaling VENTAVIS®
Nebuliser unit	Component for generating VENTAVIS® aerosol
Monthly pack	Reusable nebuliser unit + mouthpiece
Drug dosing system	System for dosing VENTAVIS®
Membrane	Component of nebuliser unit that generates aerosol of the drug
Pulsing LED	The LED pulses slowly
Blinking LED	The LED flashes quickly
Illuminated LED	The LED is constantly lit
Glass ampoule	VENTAVIS® drug in a glass container
RF	Radio frequency

3. Intended Use

The *Breelib*™ Inhalation System is a breath activated vibrating mesh nebuliser with passive flow and active volume control. It is designed to be used for oral inhalation of VENTAVIS® nebuliser solution.

The *Breelib*™ Inhalation System ensures precise drug dosage and targeting of VENTAVIS®.

The *Breelib*™ is intended to be used by adult, conscious, cooperative patients, who can control their breathing. The patient may use the device outside a professional healthcare facility (home use environment). It is intended for single patient use only.

Guidelines for Reuse

The components of *Breelib*™ can be reused, only if they are handled carefully and free of damage.
Vectura Group Ltd shall not be held liable for any damages or consequential damages, consequences for safety, reliability and performance of the device when using dirty or damaged components.

For hygienic and performance reasons use the nebuliser unit and the mouthpiece of the monthly pack for one month only.

For more details on the cleaning process, refer to chapter “8.2. Cleaning and Disinfection” on page 20.

4. Description

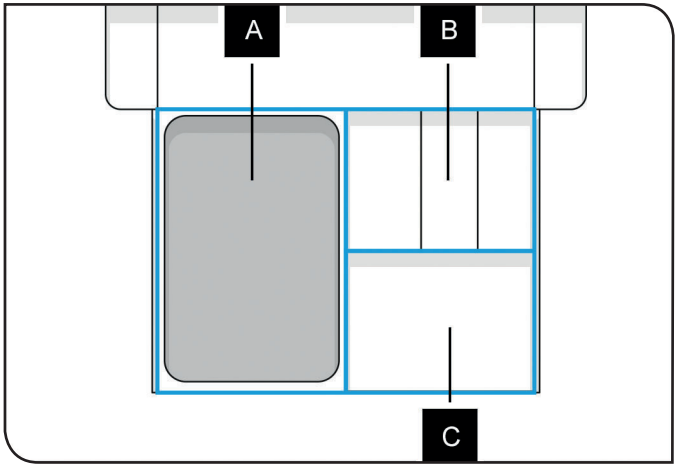
Caution
If any of the components are missing, damaged or incomplete, contact your *Breelib*™ service partner or prescribing physician.

4.1. Package Content

Ensure the starter pack contains:

- Instructions for use
- Quick reference card
- Carry case including base unit
- Charger
- Monthly pack (nebuliser unit + mouthpiece)

Starter pack

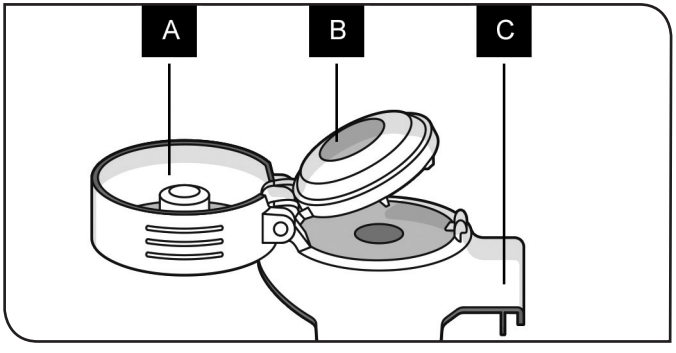


A Carry case including base unit

B Charger

C Monthly pack

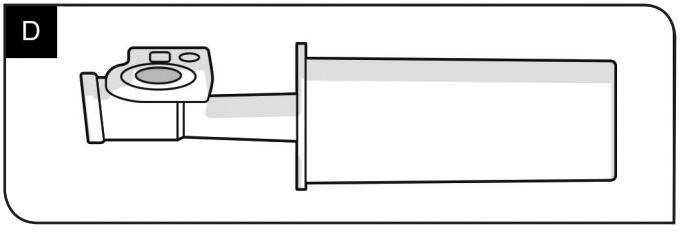
Nebuliser unit



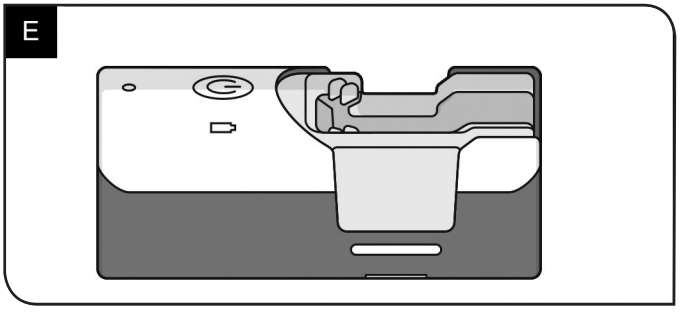
A Cap

B Drug dosing system

C Nebuliser body



D Mouthpiece



E Base unit, battery powered

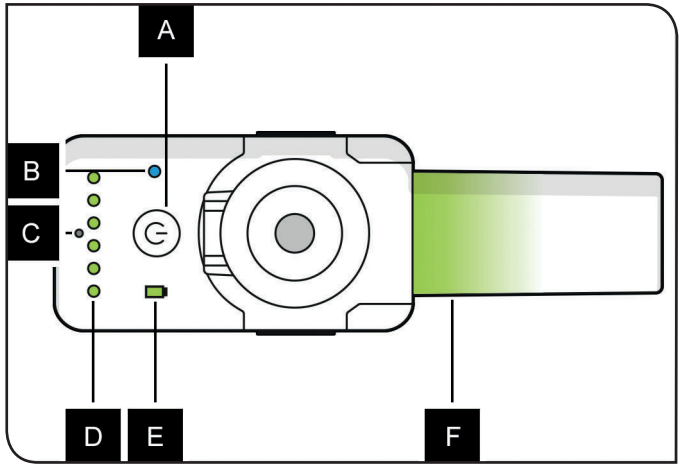
To use the *Breelib*™ you also need:

- ▶ Distilled water for cleaning
- ▶ Washing-up liquid without skin care additives (for example balsam) or disinfectant properties for washing
- ▶ Use washing-up liquid (for manual dish washing, neutral pH between 6 and 8)
- ▶ Clean, dry and lint-free paper towels for drying
- ▶ VENTAVIS®

4.2. LEDs and Buttons

The LEDs on the base unit indicate the current state of the *Breelib*™.
If no LEDs light up, the base unit is either switched OFF and/or the battery is flat.

Patients affected by colour-related vision impairment should seek the advice of their healthcare professional before using this product.



The following table contains a description of all LEDs and buttons.

A ON/OFF button		
For more details on switching the *Breelib*™ ON and OFF, refer to chapter "6.4. Switch the Base Unit ON/OFF" on page 14.		
B Wireless Connection LED		
●	Constant blue	Connection successful.
◪	Blinking blue	Ready for Connection.

C Reset button		
To reset the hardware, refer to chapter "10.2. Resetting the Hardware" on page 33.		
D Auto-test LED		
●	All LEDs are illuminated for a short time	Auto-test is in progress.
E Power LED		
●	Constant green	Battery is fully charged (refer to chapter "6.4. Switch the Base Unit ON/OFF" on page 14).
◕	Pulsing green	Battery is charging.
●	Constant orange	Charge the battery of the base unit after the next treatment.
◕	Slow blinking orange	Charge the battery of the base unit before the next treatment.
F Mouthpiece LED		
●	Constant green	Inhalation mode (refer to chapter "7.1. General Inhalation Guidelines" on page 16).
◕	Blinking green	Treatment is finished (refer to chapter "7.1. General Inhalation Guidelines" on page 16).
●	Constant orange	Operating error: Incorrect use. *Breelib*™ is still powered on (refer to chapter "7.1. General Inhalation Guidelines" on page 16)
◕	Blinking orange	Device error: *Breelib*™ turns off. (refer to chapter "7.1. General Inhalation Guidelines" on page 16)

4.3. Inhalation System

This chapter describes the functionality of the *Breelib*™ and how to correctly take a treatment. The *Breelib*™ is a breath-actuated inhalation system. It controls flow and volume to ensure precise drug dosage and targeting for effective drug therapy.

The device contains a flow-dependent valve, which limits the rate of the airflow.

For a successful treatment you must inhale and exhale several times at a moderate rate.

To ensure that you inhale and exhale at a moderate rate the *Breelib*™ pauses for 1 second between each inhalation. If you pause for more than 5 minutes, the *Breelib*™ turns off. If you have successfully completed a treatment, the mouthpiece LED blinks green for 5 seconds. For a step-by-step instruction on how to correctly take a treatment, refer to chapter “7. Take a Treatment” on page 16.

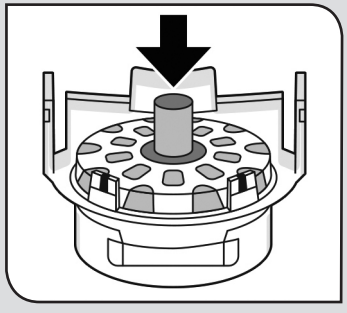
4.3.1. VENTAVIS® Aerosol Generation

The vibrating membrane on the under side of the nebuliser unit generates an aerosol out of the VENTAVIS® inhalation solution. The patient will inhale this aerosol when breathing through the *Breelib*™.

There will be no aerosol generation if the patient is not breathing through the *Breelib*™.

Caution

Do not touch or clean the membrane located on the under side of the nebuliser unit with abrasive materials. Avoid touching the membrane during the cleaning procedure because it is damaged easily. Replace any broken, misshapen or seriously discoloured parts.



4.3.2. Drug Dosing System

In order to correctly dose VENTAVIS®, the nebuliser unit contains a drug dosing system which ensures that the correct amount of VENTAVIS® is released.
When the cap is closed, the integrated piston located in the cap of the nebuliser unit pushes the correct amount of VENTAVIS® through a valve into the lower part of the nebuliser unit. There is a mechanism inside the dosing system that will retain the left-over drug.

5. Before First Use

Caution

- ▶ The first use of the components must not be after the “1st use before” date on the outer packaging.
- ▶ If the “1st use before” date marked on the outer packaging has passed, contact your *Breelib*™ service partner.

- ▶ Unpack all components of the starter pack.
- ▶ Charge the base unit battery completely before using. For further details, refer to chapter “5.1. Charge the Base Unit” on page 9.

5.1. Charge the Base Unit

The base unit battery must be fully charged before using the *Breelib*™ for the first time.

⚠ Warning

- ▶ Do not use any other charger. Using another Charger or Accessory may damage, lead to increased emissions or decreased immunity of the *Breelib*™ Inhalation System.
- ▶ Do not use an outlet, if the voltage on the outlet exceeds the specification on the charger. When travelling, use a suitable power socket adapter.
- ▶ Do not use the charger if it is damaged.
- ▶ You cannot take a treatment while the base unit is connected to the charger.

- ▶ The minimum charging time for one treatment is 10-15 minutes.

▶ Shade the power LED with your hands when in bright light conditions, so that you can clearly see whether the power LED pulses green or is brightly lit.

▶ Charge the *Breelib*™ when the power LED is orange or blinking orange.

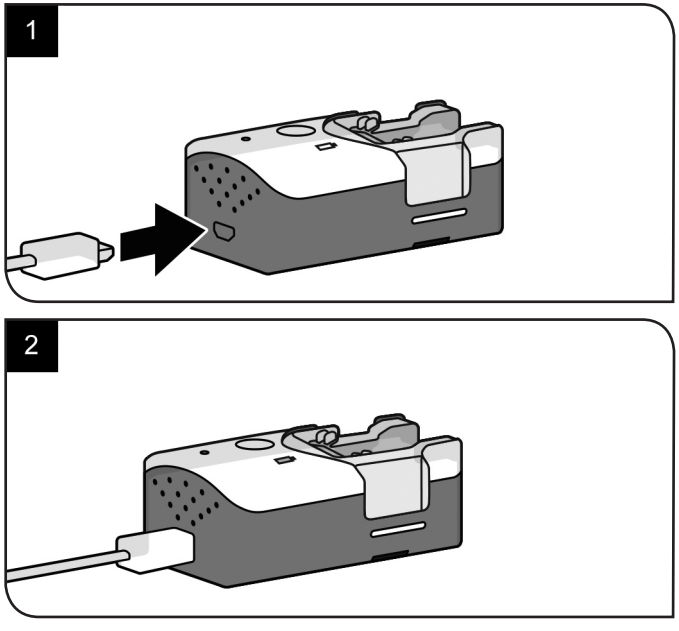
There are five different states of charge indicated by the power LED:

●	Constant green	Battery is fully charged.
◐	Pulsing green	Battery is charging.
●	Constant orange	Charge the battery of the base unit after the next treatment.
◐	Slow blinking orange	Charge the battery of the base unit before the next treatment.
◐	Slow blinking orange and slow blinking orange mouthpiece	After the end of the treatment, low battery state is visible for 2 minutes. Charge the battery of the base unit immediately.

To charge the base unit battery, follow these steps:

▶ Place the *Breelib*™ on a dry horizontal surface.

▶ Plug the connector into the socket inlet of the base unit.

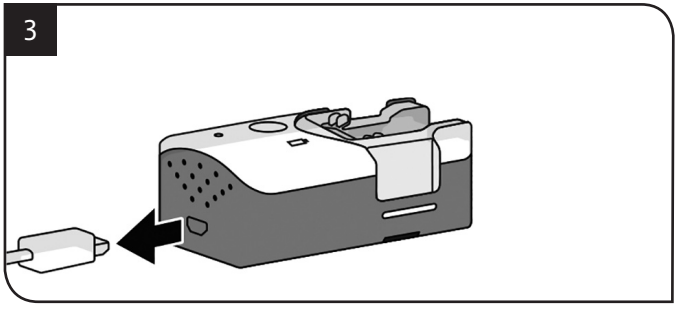


▶ Connect the charger to the power outlet.

▶ The power LED will pulse green when charging.

▶ When the power LED is constantly lit green, the battery is fully charged and you must unplug the charger from the base unit.

▶ Disconnect the charger from the mains.
The *Breelib*™ is now ready for use.



▶ Disconnect the charger from the device and the power outlet. You can not take a treatment while the charger is connected to the device.

▶ The *Breelib*™ is now ready for use.

Continue by preparing the treatment. Refer to chapter “6. Preparing for Treatment”.

6. Preparing for Treatment

6.1. General Treatment Guidelines

Follow these steps sequentially and exactly as described to ensure proper use of the *Breelib*™.

Step	Chapter
▶ Charge the base unit.	"5.1. Charge the Base Unit" on page 9
▶ Assemble the *Breelib*™.	"6.2. Assembling" on page 12
▶ Fill the nebuliser unit with VENTAVIS®.	"6.3. Fill the Nebuliser Unit with VENTAVIS®" on page 13
▶ Switch the base unit ON.	"6.4. Switch the Base Unit ON/OFF" on page 14
▶ Take a treatment.	"7. Take a Treatment" on page 16
▶ Disassemble the *Breelib*™.	"8.1. Disassembling" on page 20
▶ Rinse the components immediately after each use.	"8.2.3. Rinse the Components" on page 22
▶ Clean the components (weekly).	"8.2.4. Clean the Components (Weekly)" on page 24
▶ Disinfect the components (weekly).	"8.2.5. Disinfect the Components (Weekly)" on page 26
▶ Dry the components.	"8.2.6. Dry the Components" on page 28

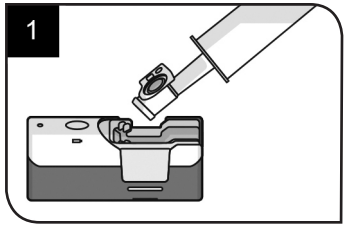
6.2. Assembling

Caution

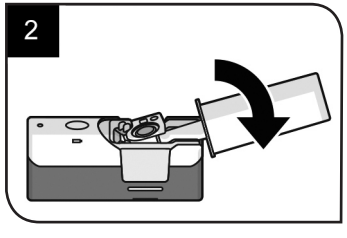
- ▶ Ensure that each component of the *Breelib*™ is clean (refer to chapter “8.2. Cleaning and Disinfection” on page 20), dry and not damaged. Check for misshapen or broken membrane and replace nebuliser unit immediately.
- ▶ If the components feel loose when shaking after assembly, disassemble and reassemble the *Breelib*™. If the problem remains, contact your *Breelib*™ service partner.

To assemble the *Breelib*™, follow these steps:

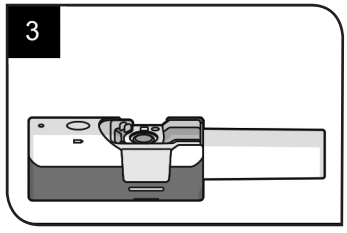
▶ Insert the back end of the mouthpiece into the base unit.



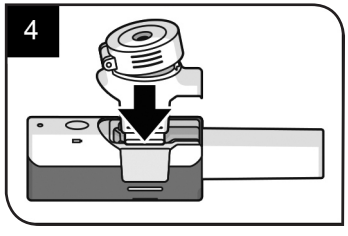
▶ Press the mouthpiece downwards.



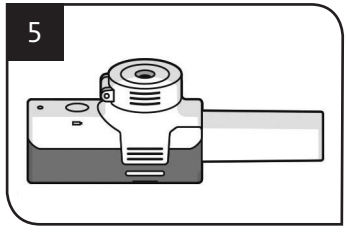
▶ The mouthpiece must be latched into the base unit.



▶ Insert the nebuliser unit into the base unit.



▶ Press the nebuliser unit down until it latches into the base unit.
Ensure that the arms are clipped in on both sides.



▶ Ensure that all components are correctly and firmly connected.

Continue by filling the nebuliser unit with VENTAVIS®. Refer to chapter “6.3. Fill the Nebuliser Unit with VENTAVIS®” on page 13.

6.3. Fill the Nebuliser Unit with VENTAVIS®

⚠ Warning

- ▶ Use a new ampoule of VENTAVIS® for each treatment. Always transfer the whole content of the ampoule into the dosing system.
- ▶ Do not store or transport a filled *Breelib*™.

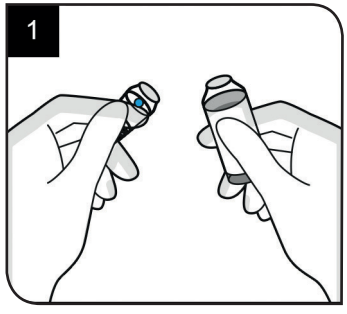
Caution

- ▶ Do not reinject more VENTAVIS® once you have filled the nebuliser unit and closed the cap.

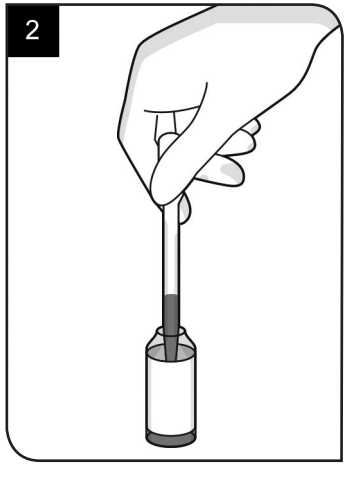
- ▶ Assemble the *Breelib*™ before filling the nebuliser unit with VENTAVIS® (refer to chapter “6.2. Assembling” on page 12).
- ▶ Before filling the nebuliser unit, make sure that the base unit is not connected to the charger.
- ▶ Once you have filled the nebuliser unit, keep the cap closed until the end of the treatment. The drug dosing system can be impaired when the cap is re-opened/closed during treatment.

To fill the nebuliser unit with VENTAVIS®, you will need a single-use pipette. Follow these steps:

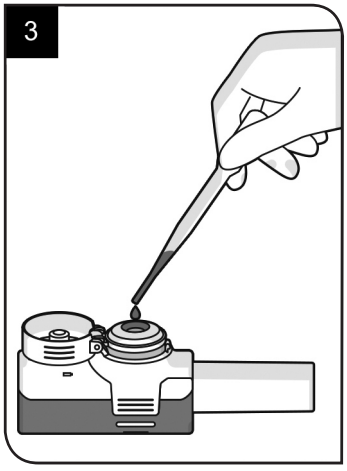
- ▶ Open the glass ampoule.



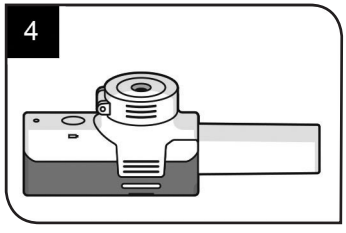
- ▶ Fill a single-use pipette with VENTAVIS®.



- ▶ Doser must be in horizontal position, not tilted for the filling step (see image 3).
- ▶ Transfer all of the VENTAVIS® with the pipette into the centre of the drug dosing system.
- ▶ Avoid splashing liquid into the base unit, especially onto the on-off button.



- ▶ Slowly close the cap of the nebuliser unit. The correct amount of the inhalation solution will be automatically pushed into the nebuliser unit.



Your *Breelib*™ is now filled. Continue immediately by switching the *Breelib*™ on and starting the inhalation procedure. For details on how to switch the base unit on, refer to chapter “6.4. Switch the Base Unit ON/OFF” on page 14.

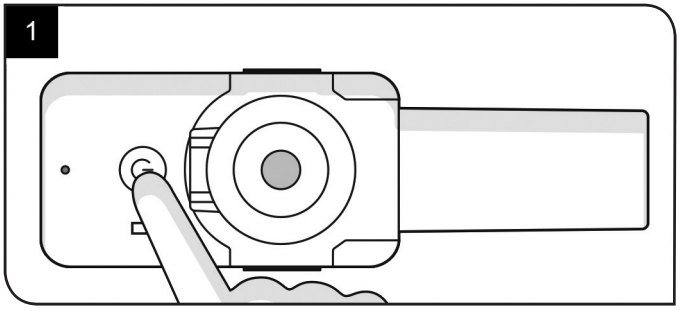
6.4. Switch the Base Unit ON/OFF

If the *Breelib*™ is connected to the charger, disconnect it. Ensure that the nebuliser unit is filled with VENTAVIS®.

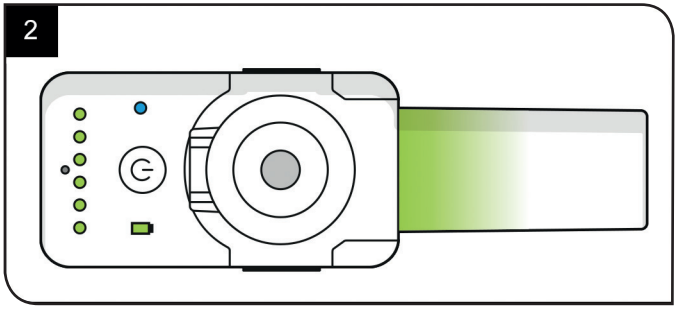
- ▶ Avoid switching the base unit off accidentally. If the base unit is accidentally switched off, press the ON/OFF button again.
- ▶ If the base unit cannot be switched on and the nebuliser unit is filled, dispose of any inhalation solution and rinse the nebuliser unit (refer to chapter “8.2.3. Rinse the Components” on page 22).
- ▶ If the power LED is constant orange charge the battery of the base unit after the next treatment.
- ▶ If the power LED is blinking orange charge the battery of the base unit before the next treatment.
  Please refer to chapter “5.1. Charge the base unit” on page 9 for details.
- ▶ Do not inhale during the auto-test.
- ▶ If the auto-test fails, the mouthpiece will blink orange and a signal will sound (“beep”). The *Breelib*™ will turn off. Please refer to chapter “10.1. Error Messages” on page 30.

To switch the base unit ON, follow these steps:

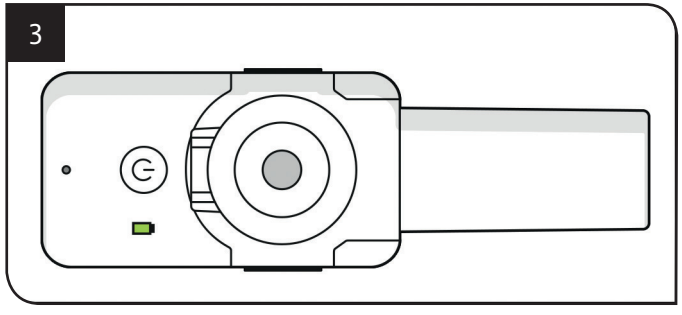
▶ Press the ON/OFF button.



▶ Wait until the auto-test starts.
All LEDs and the mouthpiece are illuminated during the auto-test.



▶ The auto-test is finished when only the power LED is illuminated. The *Breelib*™ clicks twice at the end of the auto-test.



Your *Breelib*™ is switched ON. You can now take a treatment. To continue, read the following chapter “7. Take a Treatment” on page 16.

7. Take a Treatment

A complete treatment session with the *Breelib*™ consists of:

- ▶ The inhalation system preparation,
- ▶ The inhalation itself,
- ▶ And the signal for the end of treatment.

For a detailed description on how to inhale and exhale correctly, refer to chapter “7.1. General Inhalation Guidelines”.

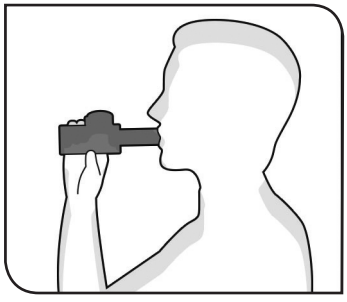
7.1. General Inhalation Guidelines

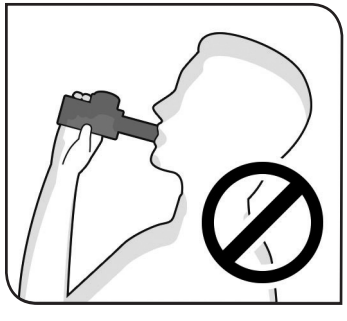
Caution

- ▶ Do not inhale additional air through your nose during inhalation. If necessary, use a nose clip.
- ▶ Do not block the mouthpiece with your tongue during inhalation.
- ▶ Very strong inhalation will cause the *Breelib*™ to decrease the airflow.

- ▶ Breathe slowly to ensure a successful treatment and to avoid inhalation solution waste.
- ▶ Before you take a treatment, the base unit must be switched on and the auto-test must be completed (power LED is green).
- ▶ Check the battery state before inhalation. For further details on battery states, refer to chapter “5.1. Charge the Base Unit” on page 9.

- ▶ Hold the *Breelib*™ horizontally during treatment. Holding the *Breelib*™ at an angle might impair performance. 15° tilt is permitted.





- ▶ To see the mouthpiece LED clearly, avoid direct sunlight.
- ▶ Avoid pressing the ON/OFF button accidentally.
- ▶ Breathe in through your mouth and exhale through your mouth and nose.

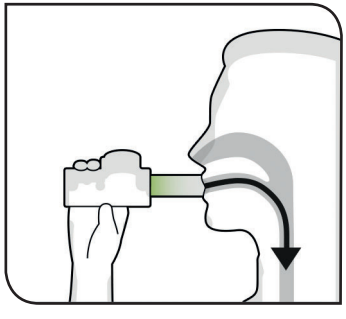
7.2. Inhalation Feedback

During inhalation the mouthpiece LED indicates the inhalation speed. The optimal inhalation speed is reached when the green mouthpiece LED is at full brightness. Beneath and above the optimal inhalation speed (too slow and too fast) is indicated by the low brightness of the mouthpiece LED.

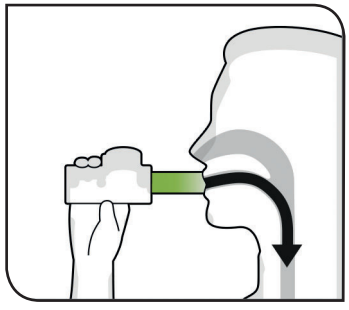
The following pictures describe the four possible states of inhalation feedback:

If the brightness of the green mouthpiece LED is low, this indicates the inhalation speed is too slow.

- ▶ *Increase your inhalation speed until you achieve full brightness of the green LED*

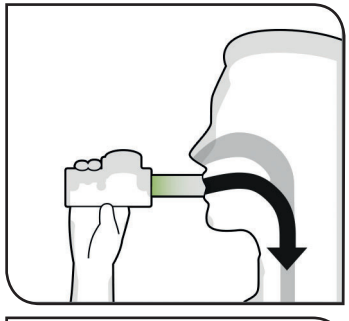


Full brightness of the green mouthpiece LED indicates your inhalation speed is correct.



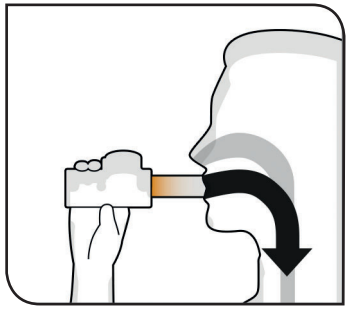
With faster inhalation the low brightness of the green mouthpiece LED indicates you are inhaling too fast.

- ▶ *Decrease your inhalation speed until you achieve full brightness of the green LED*



If the mouthpiece LED illuminates orange you are inhaling far too fast.

- ▶ *Resume inhalation at a lower speed until you achieve full brightness of the green LED*



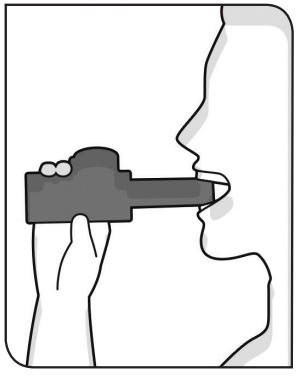
Now you are prepared for your inhalation. Continue by inhaling. Refer to chapter “7.3. Inhaling”.

7.3. Inhaling

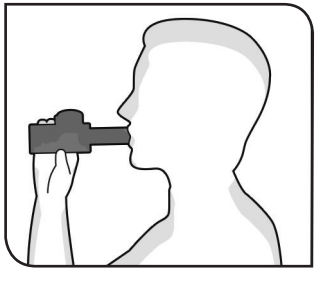
To start the inhalation, follow these steps:

▶ Sit in a relaxed and upright position.

▶ Place the mouthpiece between your teeth.



▶ Enclose the mouthpiece completely with your lips.

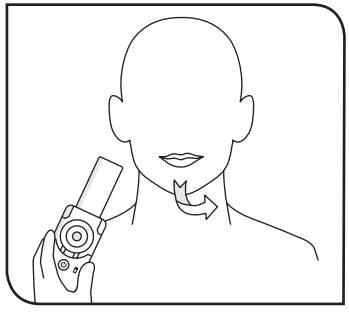


▶ Inhale through the mouthpiece. The air channel opens and you will hear a click.

▶ Continue inhaling for 3 seconds.
While inhaling, watch the mouthpiece LED to ensure correct inhalation speed.

▶ The air channel closes automatically after 3 seconds. You will hear a second click.

▶ Remove the device and exhale normally through your mouth or nose.



⚠ Warning

▶ Do not exhale into mouthpiece. Move device sideways while exhaling

▶ Continue inhaling and exhaling until the *Breelib*™ indicates the end of treatment by the mouthpiece LED blinking green for 5 seconds. The *Breelib*™ will automatically turn off at the end of a treatment.

If necessary, you may pause between breaths. The *Breelib*™ will stay active for 5 minutes and you can continue your inhalation at any time during this time period. Try not to pause longer

than 5 minutes between breaths. In case the *Breelib*™ has switched off, press the ON/OFF button to continue the inhalation session.

Caution

▶ Disassemble and clean the *Breelib*™ components immediately (within 5 minutes) after each use. This ensures full functionality for the next treatment.

In order to clean the *Breelib*™, you will need to disassemble it. For more details on how to disassemble, continue with chapter “8.1. Disassembling” on page 20.

7.4. Automatic Wireless Connection after each Treatment

This chapter describes the automatic wireless connection after each treatment.

The purpose of the wireless connection is for you to be able to send your therapy adherence data to a connected device with a mobile application.

The data flow is unidirectional. Data will only flow from the device to the mobile application through the wireless connection.

If the wireless connection is not required, continue with chapter “8.1. Disassembling” on page 20. For further information about the wireless connectivity, refer to chapter “9. Initial Pairing via Wireless Connection” on page 30.

If the *Breelib*™ has been already paired to a compatible wireless connection device, the wireless connection will start after the device indicates the end of treatment (green mouthpiece LED blinking for 5 seconds). Be sure that your desired partner device is in close range and has a wireless connection activated. The wireless connection LED indicates the connection status (refer to chapter “9. Initial Pairing via Wireless Connection” on page 30).

During the automatic wireless connection you may disassemble the device to clean the mouthpiece and nebuliser unit (refer to chapter “8.1. Disassembling” on page 20). Disassembling will not affect the wireless connection. The *Breelib*™ will automatically turn off after the wireless data transfer has been completed.

If a manual wireless connection is required, follow the same steps as described in chapter “9. Initial Pairing via Wireless Connection” on page 30.

8. Maintenance

8.1. Disassembling

For cleaning and storage purposes the components of the *Breelib*™ must be disassembled.

⚠ Warning

▶ Do not open or disassemble the base unit. It may cause damage that is not covered by this warranty.

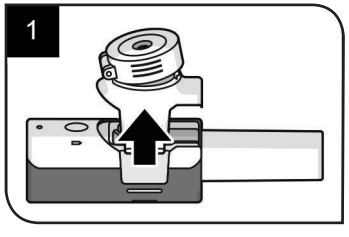
Caution

▶ Do not disassemble the nebuliser unit. Disassembling could affect the dosing accuracy.

To disassemble the components of the *Breelib*™, follow these steps:

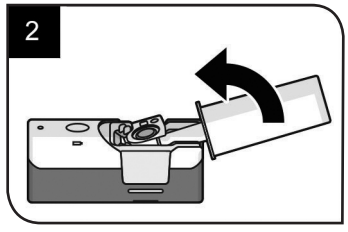
▶ Remove the nebuliser unit from the base unit.

▶ Dispose of leftover inhalation solution as described in chapter “8.2.3. Rinse the Components” (page 22)



▶ Remove the mouthpiece from the base unit.

After disassembling, continue with the cleaning procedure. Refer to the chapter “8.2. Cleaning and Disinfection”.



8.2. Cleaning and Disinfection

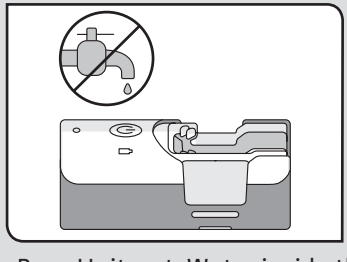
8.2.1. Cleaning the Base Unit

To clean the base unit, wipe the housing with a damp cloth or a disinfecting tissue.

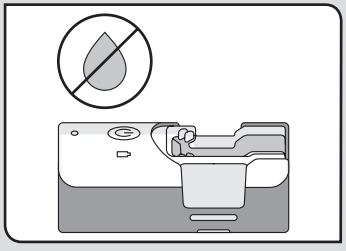
▶ Place the base unit in the carry case after cleaning and move the case away from the cleaning area .

Caution

▶ Do not rinse or wash the base unit.



▶ Do not get the Base Unit wet. Water inside the base unit can seriously affect its performance.



8.2.2. Cleaning Guidelines for the Nebuliser Unit and Mouthpiece

The cleaning guidelines relate to the cleaning of the nebuliser unit and the mouthpiece only. The cleaning procedure consists of:

- ▶ Rinsing after each use
- ▶ Cleaning a minimum of once a week
- ▶ Disinfection once a week

Cleaning procedure		
	After each use	**Once a week**
Rinsing	✓	-
Cleaning	-	✓
Disinfection	-	✓

The instructions provided below have been validated by the manufacturer of the medical device as being capable of preparing a medical device for reuse.

It is recommended to let the components air dry to ensure that they are adequately dried and ready for the next treatment. To avoid risks to health from a contaminated *Breelib*™, it is essential to comply with the following hygiene rules:

⚠ Warning

- ▶ Do not use any methods for cleaning or disinfection other than those described here.
- ▶ Only use a mouthpiece and nebuliser unit which has been cleaned according to the procedures described in this chapter.
- ▶ If the *Breelib*™ has not been used for a couple of days, both the nebuliser unit and mouthpiece must be cleaned and disinfected prior to use.
- ▶ Ensure adequate drying after cleaning and disinfection. Condensation or residual moisture increases the risk of microbial growth.

- ▶ Clean the nebuliser unit and the mouthpiece prior to disinfection. Please refer to chapter “8.2.4. Clean the Components (Weekly)” on page 24.

Caution

- ▶ Do not use an automated washer or disinfector.
- ▶ Use the nebuliser unit and mouthpiece for one month only.
- ▶ Do not use tap water. Any calcification can damage and reduce the lifetime of the nebuliser unit. Use distilled water only.

▶ Thoroughly check the components of your *Breelib*™ regularly and replace any defective components.

For details on how to clean, disinfect and dry the *Breelib*™, refer to corresponding chapters on the following pages.

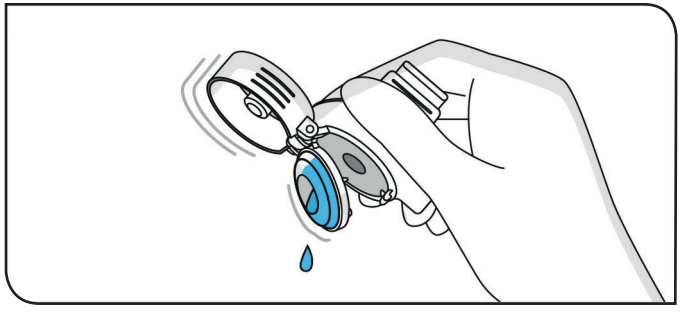
8.2.3. Rinse the Components

After each treatment, immediately rinse the disassembled mouthpiece and nebuliser unit with distilled water.

⚠ Warning

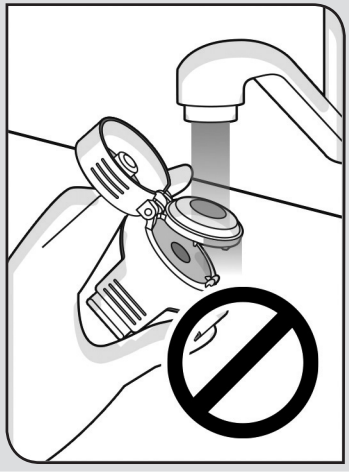
▶ Do not reuse the left over inhalation solution. Safely dispose of all left-over inhalation solution.

▶ To dispose of left-over inhalation solution open the cap of the nebuliser unit and shake gently.



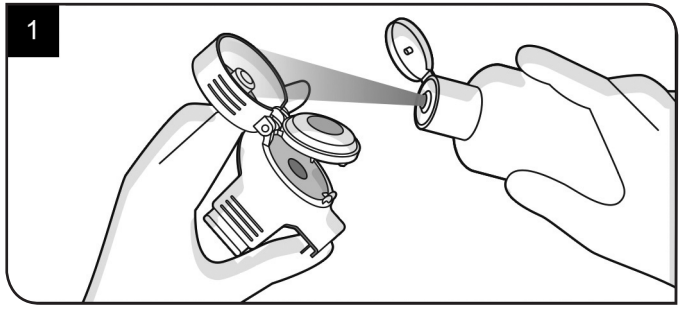
Caution

▶ Do not use tap water. Any calcification can damage and reduce the lifetime of the nebuliser unit. Use distilled water only.

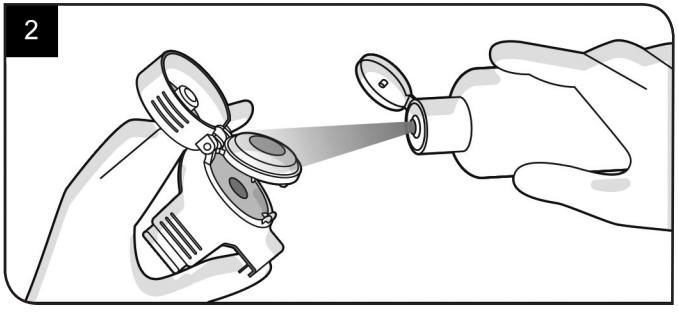


To rinse the nebuliser unit, use at least 100 ml of distilled water. Follow these steps:

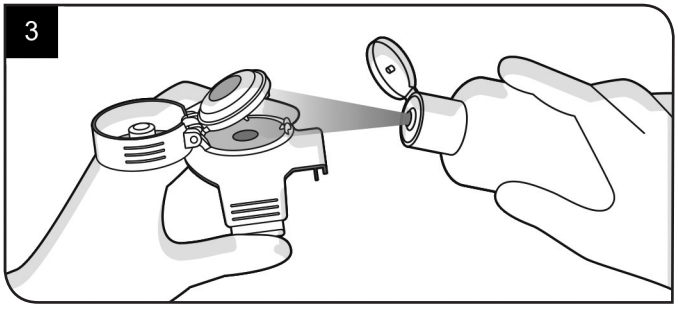
▶ Rinse the cap with distilled water.



▶ Rinse the drug dosing system with distilled water.



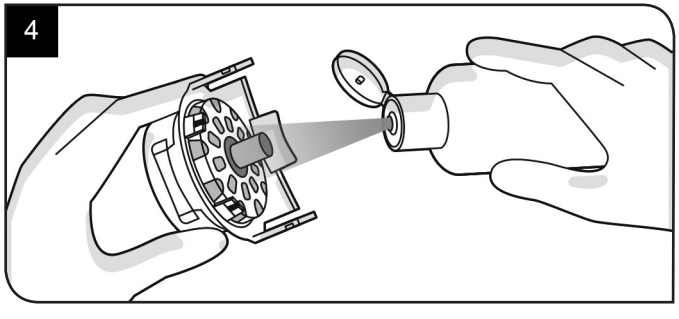
▶ Rinse the area below the drug dosing system with distilled water thoroughly.



Caution

▶ Do not touch or clean the membrane located on the under side of the nebuliser unit with abrasive materials. Avoid touching the membrane during the cleaning procedure as it is damaged easily.

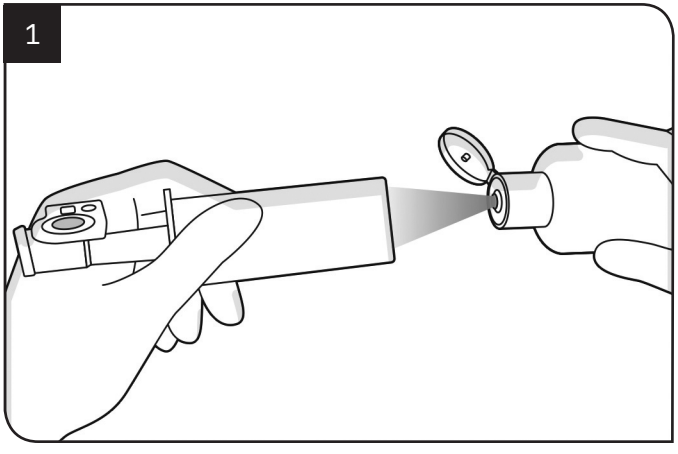
▶ Rinse the membrane with distilled water.

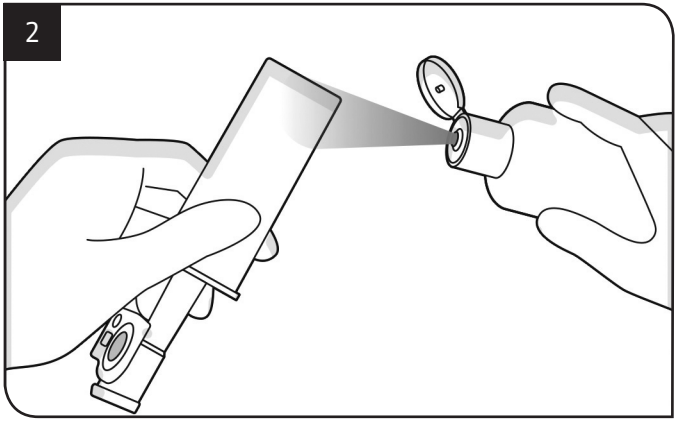


Continue by rinsing the mouthpiece. Use at least 100 ml of distilled water and follow these steps:

▶ Rinse the inside of the mouthpiece with distilled water.

▶ Rinse the outside of the mouthpiece with distilled water.





▶ To air dry, put the mouthpiece and the nebuliser unit on a clean, dry and lint-free paper towel.

Now you have rinsed the components. If necessary, continue with the weekly cleaning. Refer to chapter “8.2.4. Clean the Components (Weekly)”.

If you want to store your *Breelib*™ until the next treatment, continue with storage and transport (refer to chapter “8.3. Storage and Transportation” on page 29.

8.2.4. Clean the Components (Weekly)

The components of the *Breelib*™ must be cleaned at least once a week.

To clean the mouthpiece and nebuliser unit, follow these steps:

▶ Fill a clean bowl with distilled water (room temperature).

▶ Add washing-up liquid to the distilled water. Follow the washing-up liquid manufacturer’s instructions.

▶ Put the nebuliser unit and the mouthpiece into the cleaning solution. The components need to be fully submerged.

⚠ Warning

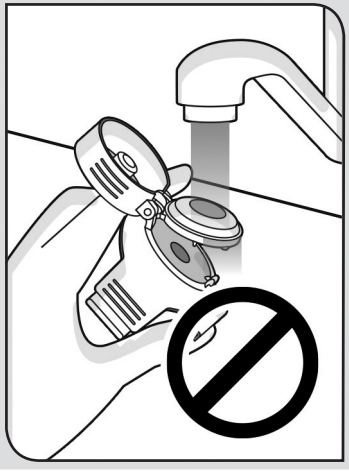
▶ Do not use a washing-up liquid with skin care additives (for example balsam) or disinfectant properties.

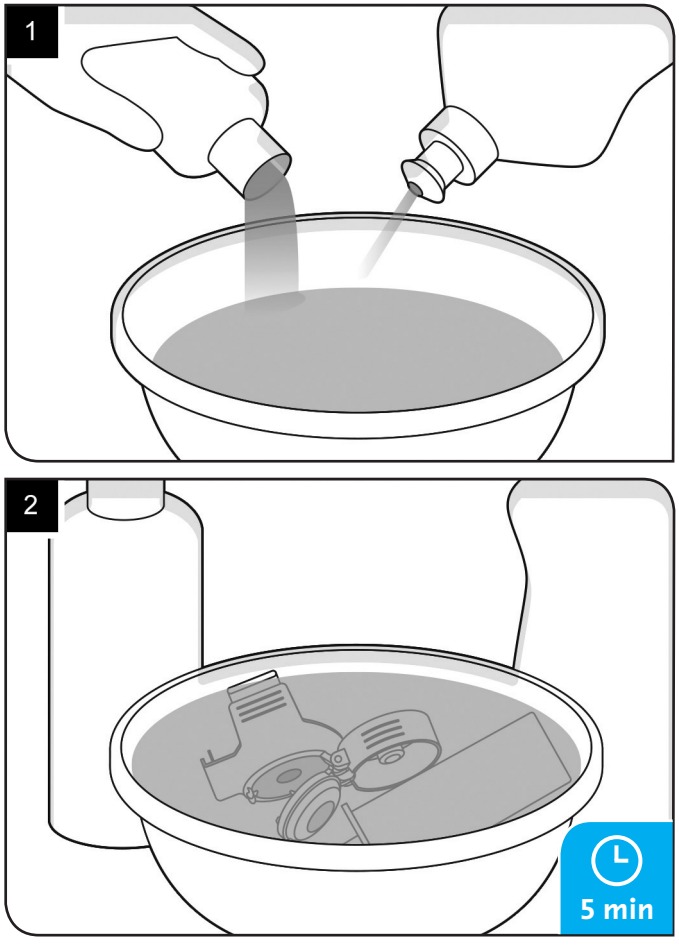
▶ Use of such washing-up liquids may cause severe damage to the *Breelib*™ or result in health hazards.

- ▶ Forbidden substances include: washing-up liquids with disinfectants, detergents with skin care additives, detergents for dish washers, acids, organic solvents, oxidizing agents.
- ▶ Use washing-up liquid (for manual dish washing, neutral pH between 6 and 8).

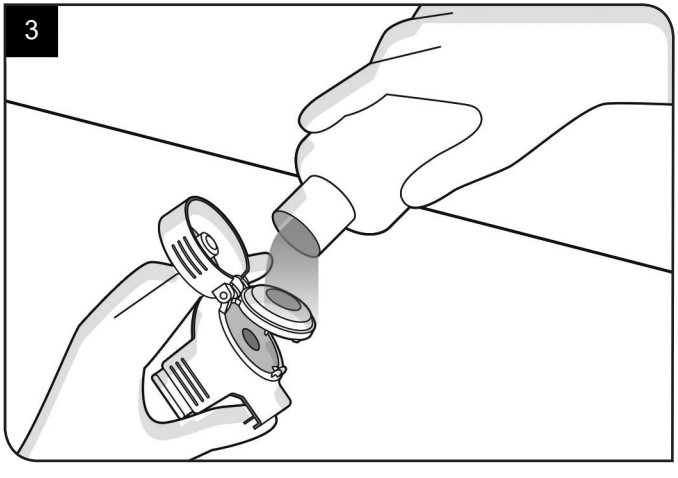
Caution

- ▶ Do not use tap water. Any calcification can damage and reduce the lifetime of the nebuliser unit. Use distilled water only.





- ▶ Open and close the hinged cap twice while submerged to clean the drug dosing system.
- ▶ Make sure that the hinged cap is open.
- ▶ Leave the components in the cleaning solution for at least 5 minutes and agitate gently.
  If necessary, assist by carefully wiping with a soft clean cloth.
- ▶ Remove the components from the bowl.
- ▶ Rinse the nebuliser unit and the mouthpiece with at least 100 ml of distilled water.
  Ensure that the inside of the mouthpiece and the nebuliser unit, including the drug dosing system, are rinsed thoroughly.



After you have cleaned the mouthpiece and the nebuliser unit of your *Breelib*™, disinfect them. Refer to chapter "8.2.5. Disinfect the Components (Weekly)".

8.2.5. Disinfect the Components (Weekly)

- ▶ Clean the nebuliser unit and the mouthpiece prior to disinfection (refer to chapter "8.2.4. Clean the Components (Weekly)" on page 24).

⚠ Warning

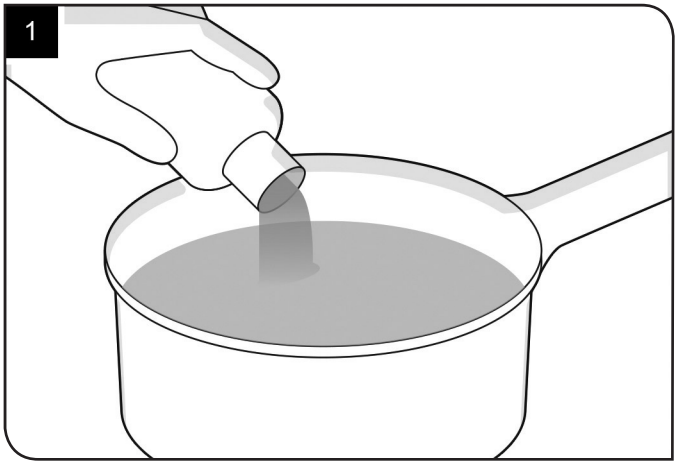
- ▶ Do not use any disinfection methods other than those described.

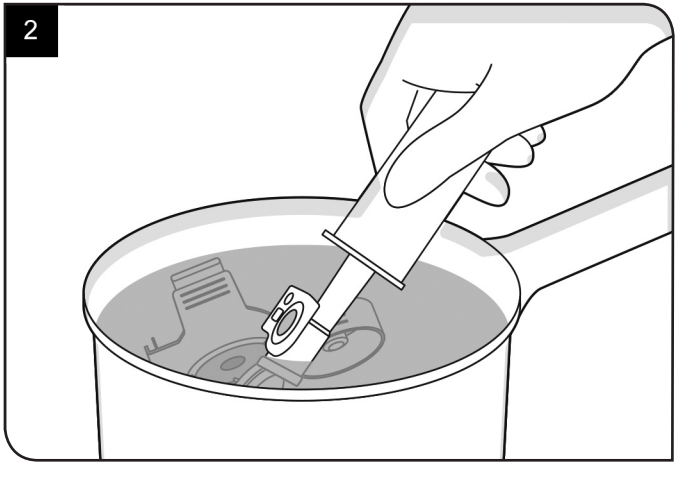
Caution

- ▶ Do not disinfect the nebuliser unit more than once a week. Disinfecting more frequently can damage the nebuliser unit.

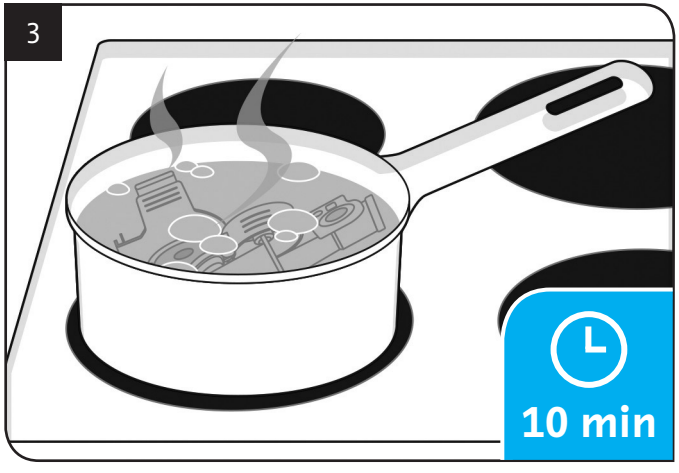
To disinfect mouthpiece and nebuliser unit, follow these steps:

- ▶ Fill a pan with distilled water.
- ▶ Put the nebuliser unit and the mouthpiece into the pan. The components need to be fully submerged.





- ▶ Put the pan on the stove.
- ▶ Turn on the heat.
- ▶ Boil the distilled water with the nebuliser unit and the mouthpiece for 10 minutes.



- ▶ Turn off the heat.

Caution

- ▶ Do not touch the hot components or boiling water. As this can lead to serious scalds.

- ▶ Place the pan on a heat-proof surface.
- ▶ Use tongs to remove the components from the pan.
- ▶ Place hot components on a clean, dry and lint-free paper towel.

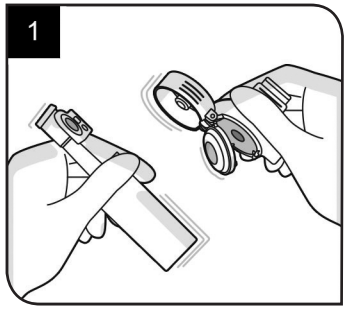
▶ Let the components cool down for 10 minutes.

The disinfection procedure is complete. After you have disinfected the components, continue with drying. Please refer to chapter “8.2.6. Dry the Components”.

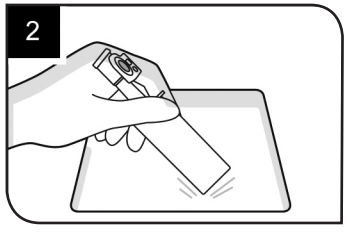
8.2.6. Dry the Components

To dry the nebuliser unit and the mouthpiece follow these steps:

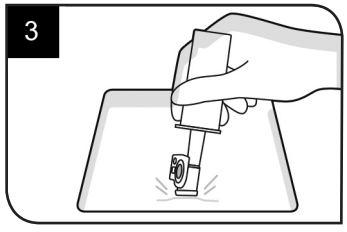
▶ To remove left-over water, gently shake the mouthpiece and the nebuliser unit.



▶ Tap the front end of the mouthpiece carefully on a clean, dry and lint-free paper towel to remove left-over water.

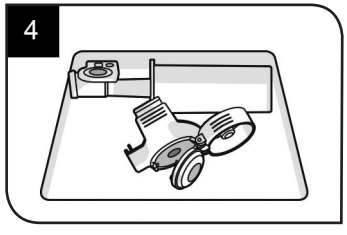


▶ Press the back end of the mouthpiece carefully on a clean, dry and lint-free paper towel to remove left-over water from the filter.



▶ Open the cap of the drug dosing system.

▶ Put the mouthpiece and the nebuliser unit on a clean, dry and lint-free paper towel.



▶ Let the components dry adequately overnight, if possible.

▶ Ensure that the mouthpiece and nebulizer head are completely dry before next usage.

Your *Breelib*™ is now ready for the next treatment or for storage and transportation. For more details on how to store or transport the *Breelib*™, read chapter “8.3. Storage and Transportation” on page 29.

8.3. Storage and Transportation

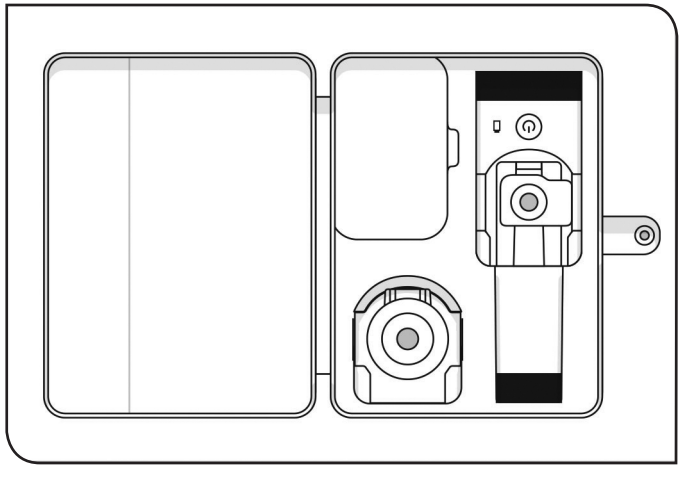
The *Breelib*™ must be rinsed or cleaned before storage (refer to chapter “8.2. Cleaning and Disinfection” on page 20).

For storage and transportation, follow these rules:

- ▶ Store and transport the base unit, mouthpiece and nebuliser unit in the carry case.
- ▶ Store the carry case with the components in a dry and dust-free environment.
- ▶ Do not store the carry case with the components in direct sunlight.
- ▶ Store and transport the components within the temperature range described in “11.5. Environmental Conditions for Storage and Transportation” on page 35.

8.3.1. Carry Case

If you transport the *Breelib*™, use the carry case provided. The carry case has space for the nebuliser unit, the base unit and the mouthpiece. The following graphic shows the components in the carry case:



The carry case can also be used as a surface to assemble the components and fill the nebuliser unit before use.

9. Initial Pairing via Wireless Connection

▶ You cannot take a treatment while your *Breelib*™ is connected to a partner device.

To transfer data, you need a partner device which has the correct encryption protocol included to ensure cyber security. Please talk to your prescribing physician or the patient support program to learn more about the usage of available and suitable partner devices.

To initially pair your *Breelib*™ to a partner device follow these steps:

▶ Press the ON/OFF button until the Wireless Connection LED starts blinking. Be sure your desired partner device is in close range and has a wireless connection activated.

There are two states of the wireless connection indicated by the Wireless Connection LED:

	The Wireless Connection LED blinks blue slowly and the mouthpiece is constantly orange.	Advertising/ Discoverable.
	The Wireless Connection LED is constantly illuminated blue.	Connection active.

Once you have successfully paired your *Breelib*™ to a partner device the connection automatically starts after each treatment. For further information about the automatic wireless connection, refer to “7.4. Automatic Wireless Connection after each Treatment” on page 19.

10. Troubleshooting

10.1. Error Messages

Error	Cause & Remedy
Prior to Start	
The mouthpiece LED is blinking orange when power button is pressed.	It is not possible to take a treatment while charging. ▶ Disconnect the charger from the base unit before inhaling.
The *Breelib*™ cannot be switched on. No LED lights up.	Battery is flat. ▶ Charge the base unit before taking a treatment (refer to chapter "5.1. Charge the Base Unit" on page 9).
During start up	
The mouthpiece LED is blinking orange and an acoustic signal sounds ("beep") after the power button has been pressed. The device shuts down.	▶ Check whether the nebuliser unit and mouthpiece are properly connected to the base unit (refer to chapter "6.2. Assembling" on page 12) and start the base unit again.

Error	Cause & Remedy
	▶ The nebuliser unit is not filled correctly (refer to chapter “6.3. Fill the Nebuliser Unit with VENTAVIS®" on page 13). ▶ Check whether the membrane of the nebuliser unit is damaged. Replace the nebuliser unit if necessary. ▶ Ensure that the components are adequately dry (refer to chapter “8.2.6. Dry the Components” on page 28). ▶ Ensure that the device is used within the allowed temperature range (refer to chapter “11.4. Environmental Conditions for use” on page 35). Allow a few minutes for the device to acclimatise, when transferring from hot or cold conditions.

Error	Cause & Remedy
The *Breelib*™ cannot be switched on. The mouthpiece LED is blinking orange while ON/OFF button is pressed.	Very low battery power. ▶ Charge the base unit before taking a treatment (refer to chapter “5.1. Charge the Base Unit" on page 9).
During Treatment	
The device shuts OFF and the power LED is blinking.	It is not possible to take a treatment while charging. ▶ Disconnect the charger from the base unit and turn the device back on. Continue the treatment.
Mouthpiece LED is blinking orange, but device does not shut OFF.	Check if the nebuliser is attached correctly. ▶ Continue with the treatment.
The mouthpiece feels blocked during inhalation.	▶ Ensure you follow the detailed inhalation instructions (refer to chapter “7.1. General Inhalation Guidelines” on page 16). ▶ Ensure that the mouthpiece is adequately dry (refer to chapter “8.2.6. Dry the Components” on page 28).

Error	Cause & Remedy
The mouthpiece LED illuminates orange during inhalation.	▶ Ensure that you do not block the air inlet at the back end of the base unit. ▶ If the mouthpiece LED illuminates orange during inhalation you are inhaling far too fast (refer to chapter “7.2. Inhalation Feedback” on page 17).
After Treatment	
The mouthpiece LED is illuminated orange and the power LED is blinking orange.	▶ Charge the base unit before next treatment. As soon as you connect the device to the charger the device will turn off and start the charging automatically.
Overly long inhalation time.	Check whether the nebuliser head has been physically damaged (e.g. broken, misshapen or seriously discoloured parts). If this is the case immediately replace the nebuliser head.

Error	Cause & Remedy
Charging	
Charging process does not start.	Please follow charging instructions (refer to chapter “5.1. Charge Base Unit” on page 9). ▶ Ensure that the device is used in an environment within the allowed temperature range (refer to chapter “11.4. Environmental Conditions for use” on page 35). Allow a few minutes for the device to acclimatise, when transferring from hot or cold conditions.
Wireless Communication	
The wireless connection LED is Blinking quickly and the mouthpiece LED is illuminated orange. The device turns off.	Failed wireless connection: To repeat wireless data transfer refer to chapter “9. Initial Pairing via Wireless Connection” on page 30).

Error	Cause & Remedy
Radio Frequency	
The *Breelib*™ does not react as expected.	There may be RF (radio frequency) communication equipment around. Increase the distance from portable or mobile RF communication equipment.

In case all of these actions are ineffective please reset the device (refer to chapter “10.2. Resetting the Hardware”) and contact your service partner if necessary.

Caution

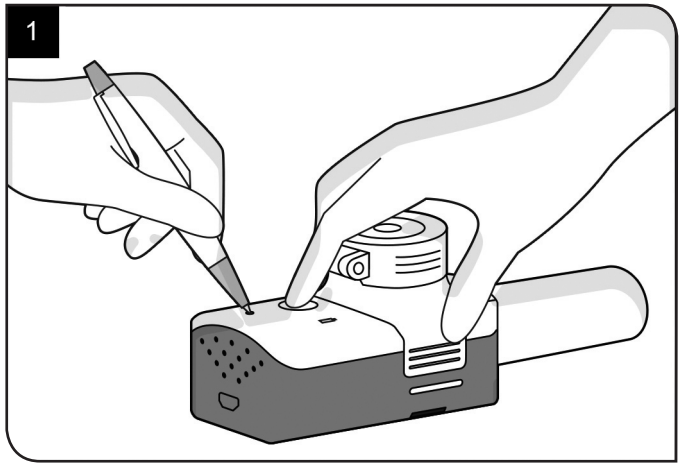
If you follow these instructions and the error still persists, contact your *Breelib*™ service partner for assistance or prescribing physician for assistance.

10.2. Resetting the Hardware

In some cases the base unit may not respond to the ON/OFF button. In this case a hardware reset may be necessary. Make sure that the base unit is charged. A reset will not work if the battery is flat.

To reset the hardware, follow these steps:

▶ Press the ON/OFF and the reset buttons at the same time. Use a pen to gently press the reset button.



▶ Release the buttons.
The reset is completed when you see short green flashes from the mouthpiece LED.

11. Technical Data

11.1. General

***Breelib*™**	
Filling Volume	1.0 ml
Inhalation Flow	15 l/min
Weight	128 g
Dimensions (WxHxD)	154 x 55 x 51 mm
Electrical Protective Class	II Type BF
Ingress Protection Marking (IP Class)	IP22 Solid particle protection: Fingers or similar objects > 12.5 mm Liquid ingress protection: Protected against dripping water when tilted at 15°
Maximum A-weighted sound pressure level	70 dB
Charging interval	Weekly
FCC ID	QOQWT12
Charger	
Manufacturer	XP Power LLC
Type	VER05 VEL05
Model	VER05US050-UB VEL05US050-EU-UB
Power Input	100 - 240 V / 50 – 60 Hz
Power Output	5 VDC / 900 - 1000 mA

Charger (Alternative)	
Manufacturer:	UE Electronics
Type:	UES06WV UES06WNCP
Model:	UES06WV-050100SPA UES06WNCP-050100SPA
Power Input:	100 - 240 V / 50 – 60 Hz
Power Output:	5 VDC / 1000 mA
Internal Battery	
Type	Secondary Battery
Chemistry	Lithium Polymer Battery
Capacity (typical)	1350 mAh
Cycle Life	≥ 500

11.2. Accessories and Spare Parts

Breelib™ Monthly pack.

11.3. Service Life

The *Breelib*™ is intended for repeated use. The service life of the components is given in the following table:

Component	Service life
Base unit	2 Years after 1st use
Nebuliser unit and mouthpiece	1 Month after 1st use

At the end of the service life, replacement is recommended to ensure full device functionality. In the event of visible damage or a noticeably longer nebulisation time per treatment, the nebuliser unit must be replaced immediately.

11.4. Environmental Conditions for Use

The following table describes the ambient conditions required for the use of the *Breelib*™.

Ambient temperature	5 to 40°C
Humidity range	35-85% RH, non-condensing
Ambient pressure	700 hPa to 1060 hPa

After transport or storage of the device at <5 °C, wait 30 minutes for temperature acclimatization.

⚠ Warning

▶ In the event of extreme fluctuations of the ambient temperature, the device can malfunction due to condensation.

Caution

▶ If you need to use your *Breelib™* in an aircraft turn the Breelib™ off and then back on again to recalibrate the pressure sensor to the cabin pressure.

11.5. Environmental Conditions for Storage and Transportation

Caution

▶ If your device is left inside a closed vehicle, temperatures up to 80°C can be reached. Do not expose your device to direct sunlight for extended periods of time (for example on the dashboard of a car).

Ambient temperature during transport	-10 to 35 °C Humidity: 35-85% RH
Ambient temperature during storage	-10 to 35 °C Humidity: 35-85% RH

11.6. Electrical Safety Information

Essential performance is defined according to IEC 60601-1 to be “performance necessary to achieve freedom from unacceptable RISK”.

Considering the intended use of the device, essential performance is not applicable to the *Breelib*™ Inhalation System.

11.7. Radio Frequency Information

Frequency band	2.4 GHz ISM band
Operating Frequency	2400 to 2483.5 MHz
Modulation	Frequency Hopping Spread Spectrum (FHSS) (GFSK)
Nominal Output Power	Max. 4 dBm

The *Breelib*™ may be affected by portable or mobile RF (radio frequency) communication equipment, like mobile phones or computer equipment. In case of malfunction, increase the distance from portable or mobile RF communication equipment.

Detailed information is provided in chapter “11.8. Electromagnetic Compatibility” on page 36.

11.7.1. Radio Equipment Directive

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Chippenham, SN14 6FH
United Kingdom

declares under its sole responsibility that the product *Breelib*™ Inhalation System conforms with the essential requirements of the Radio Equipment Directive (2014/53/EU) and complies with the harmonized standards.

11.7.2. Risks Related to Wireless Connection

Connection of your device mobile application or other equipment could result in previously unidentified risks to patients, operators or third parties; which the manufacturer have identified, analysed and controlled through means of encryption and secured communication protocols and further technical means.

Changes to the wireless connection could introduce new risks which require additional analysis. These include changes to network configuration, connection of additional items, disconnection of items, upgrade/update of equipment.

Supplementary information is kept on file.

11.8. Electromagnetic Compatibility

The *Breelib*™ complies with the electromagnetic compatibility standard, IEC 60601-1-2. The intended environment includes home healthcare and professional healthcare facilities. The device is not intended to be used in military areas, near HF (High Frequency) surgical equipment and RF shielded rooms.

⚠ Warning

- The *Breelib*™ should not be used near to other equipment. If this is necessary, the *Breelib*™ should be checked to verify normal operation in the configuration in which it will be used.

Caution

- Under certain conditions electromagnetic interference can impair the *Breelib*™ performance. Interference can, for example, be caused by mobile telephones or other telecommunication equipment. If you detect such interference, switch the base unit off and increase the distance from possible sources of interference.

Guidance and manufacturer's declaration – electromagnetic emission

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The *Breelib*™ uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The *Breelib*™ is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class B	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

Immunity test	IEC 60601-1-2:2014 Test Condition	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD)	± 8 kV contact	± 8 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
IEC 61000-4-2	± 15 kV air	± 15 kV air	

Immunity test	IEC 60601-1-2:2014 Test Condition	Compliance Level	Electromagnetic Environment - Guidance
Radio-frequency EM fields and Proximity fields from RF wireless communications equipment IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2.7 GHz	Mains power quality should be that of a typical home healthcare or hospital environment.
	10 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2.7 GHz	
	27 V/m 380 - 390 MHz 50% PM at 18 Hz	27 V/m 380 - 390 MHz	
	28 V/m 430 - 470 MHz 50% PM at 18 Hz	28 V/m 430 - 470 MHz	
	9 V/m 704 - 787 MHz 50% PM at 217 Hz	9 V/m 704 - 787 MHz	
	28 V/m 800 - 960 MHz 50% PM at 18 Hz	28 V/m 800 - 960 MHz	
	28 V/m 1700 - 1990 MHz 50% PM at 217 Hz	28 V/m 1700 - 1990 MHz	
	28 V/m 2400 - 2570 MHz 50% PM at 217 Hz	28 V/m 2400 - 2570 MHz	
	9 V/m 5100 - 5800 MHz 50% PM at 217 Hz	9 V/m 5100 - 5800 MHz	

Immunity test	IEC 60601-1-2:2014 Test Condition	Compliance Level	Electromagnetic Environment - Guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Immunity test	IEC 60601-1-2:2014 Test Condition	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the *Breelib*™, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \frac{6}{E}\sqrt{P}$ where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, E is the field strength in
Radio-frequency field IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz		
	6 Vrms ISM/amateur Bands	6V	

Immunity test	IEC 60601-1-2:2014 Test Condition	Compliance Level	Electromagnetic Environment - Guidance
			V/m and *d* is the recommended separation distance in metres (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

Immunity test	IEC 60601-1-2:2014 Test Condition	Compliance Level	Electromagnetic Environment - Guidance
Fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line to line	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
	± 2 kV Line to ground		

Immunity test	IEC 60601-1-2:2014 Test Condition	Compliance Level	Electromagnetic Environment - Guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T for 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T for 1 cycle at 0° 70 % U_T for 25/30 cycles at 0° 0 % UT for 250/300 cycles	0,5 cycle 1 cycle 25/30 cycles 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the *Breelib*™ requires continued operation during power mains interruptions, it is recommended that the *Breelib*™ be powered from an uninterruptible power supply or a battery.
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people. NOTE U_T is the a. c. mains voltage prior to application of the test level.			

Immunity test	IEC 60601-1-2:2014 Test Condition	Compliance Level	Electromagnetic Environment - Guidance

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the *Breelib*™ is used exceeds the applicable RF compliance level above, the *Breelib*™ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the *Breelib*™.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the *Breelib*™

The *Breelib*™ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *Breelib*™ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *Breelib*™ as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

11.9. Recycling and Disposal

This product falls within the scope of the European Council Directive on Waste Electrical and Electronic Equipment WEEE (Directive 2012/19/EU) and is included in annex IA “8. Medical devices”. Accordingly, the base unit must not be disposed with domestic waste. The disposal regulations prevailing in the respective member countries must be observed (for example disposal by service partner).

Used and cleaned components of the monthly pack (nebuliser unit and mouthpiece) can be disposed of with normal household waste.

Please recycle all packaging materials in accordance with local regulations.

12. Warranty

During the warranty period, Vectura Group Ltd or the *Breelib*™ service partners will repair any defects resulting from faults in material or manufacturing free of charge. Claims for redress, depreciation or cancellation are excluded.

Damage resulting from improper use of the device is not covered by this warranty. The warranty becomes void if repairs are carried out on the device by unauthorised persons. Compensation for direct or indirect damage or injury is excluded from the warranty.

If you have a complaint, contact your *Breelib*™ service partner or send the device to Vectura Group Ltd in its original packaging. Consumables are excluded from the warranty.

The warranty period for the base unit is 2 years from the date of purchase.

13. Explanation of Symbols

The following symbols may be used on the under side of the base unit and on the packaging.

Symbol	Indication
	This symbol indicates that this is a Medical Device
	This device complies with the requirements of the Medical Devices Regulation (2017/745/EU).
	Follow instructions for use
	This device is a protection class II appliance
	This device is a Type BF equipment
	Temperature range for storage or transport

13. EXPLANATION OF SYMBOLS

	Humidity Limitations
	This product is compliant with WEEE recycling directives (Directive 2012/19/EU). Refer to chapter "11.9. Recycling and Disposal" on page 42 for further information.
	This device should be stored and used in dry conditions.
	Date of manufacture
	Use By
	Manufacturer
	Device emitting non-ionizing radiation

	Battery status display
	ON/OFF button
	Direct current
	Order Number
	Serial Number
	Importer
	Unique Device Identifier
	EU Representative
	Indicates the packaging material is corrugated fibreboard (cardboard)
	Indicates the packaging material is Non-Corrugated Fiberboard(paperboard)

Single patient multiple use

Vectura Group Ltd reserve the right to make technical changes.