AdheResp™

Smart Breath-actuated Mesh Nebulizer

Instructions For Use

⚠Caution

Read this manual before using the product. Failure to follow the instructions and safety precautions in this manual could result in serious injury or illness.

hcmed

Due to use life of the AdheResp, the medication reservoir is supposed to be replaced with a new one every six months. Write down the date of first use as a reminder to replace the medication reservoir.
Date of first use:_____

Table of Contents

◎To ensure patient safety and proper use of the AdheResp Smart Breath-actuated Mesh Nebulizer, please read this instruction manual carefully.
◎Keep this manual in a safe place for future reference.
◎This manual may be updated following regulatory requirements. For the most current version, contact info@HCmed-inno.com for assistance.

Important Information

The AdheResp Smart Breath-actuated Mesh Nebulizer is a sensitive medical device and should be handled with care. To make sure that your AdheResp Smart Breath-actuated Mesh Nebulizer works properly, and its durability is not compromised, follow the instructions in this Instructions for Use.

The AdheResp Smart Breath-actuated Mesh Nebulizer is a “clean, non-sterile” product for single patient multiple use. The AdheResp Smart Breath-actuated Mesh Nebulizer can only be used with the embedded battery and the supplied power adapter or charging cable.

Do not attempt to disassemble the AdheResp Smart Breath-actuated Mesh Nebulizer main unit or tamper with the software or hardware of this product.

Tested to IEC60601-1 and IEC60601-1-2. Class ll Type B.

Tested to ISO 10993-1 for limited contact duration with skin and mucosal membrane.

This device complies with Part 15 of the FCC rules.

Compliant with the WEEE/RoHS recycling directives.

Intended Use

1. The intended purpose of the AdheResp Smart Breath-actuated Mesh Nebulizer is to nebulize liquid medication approved for use by the means of vibrating mesh technology. Inhalation treatment must be conducted by the patient in an appropriate environment.
2. The intended user of the AdheResp Smart Breath-actuated Mesh Nebulizer is any patient requiring inhalation treatment, such as asthma or chronic obstructive pulmonary disease (COPD) patients. The device is intended for patients ranging from children above 5 years old to adults who can breathe spontaneously, according to the prescribed medication. We recommend that users under 15 years old should be accompanied by an adult during the treatment.

3. The AdheResp Smart Breath-actuated Mesh Nebulizer is for users to breathe through a mouthpiece.

Expected Service Life

◎Main Unit: 2 years after 1st use.
◎Medication container, aerosol chamber, and mouthpiece: Maximum 6 months after 1st use.
◎Note: The service life is of the AdheResp Smart Breath-actuated Mesh Nebulizer is designed to be used for 15 minutes per session, 2 sessions per day. The service life of the components may be shortened if the nebulizer is used with higher frequency or challenging medicinal formulations.
◎Dispose of Main unit, medication reservoir, mouthpiece at the end of their service life.

Warranty Period

HCmed provides a one-year warranty period for the main unit from the date of purchase.

Limited Warranty

HCmed Innovations Co., Ltd. warrants that reasonable care has been used in the design and manufacture of this device. HCmed excludes all other warranties, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness. Handling and storage as well as other factors relating to the patient, diagnosis, treatment, medical procedures, and other matters beyond HCmed's control, may directly affect the device and the results obtained from its use. HCmed shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from the use of this device. HCmed neither assumes nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device.

HCmed Innovations Co., Ltd. warrants the main unit of the device to be free from defects in materials and workmanship under normal use and operation for a period of 1 year from date of purchase from HCmed Innovations Co., Ltd. The warranty is limited to repair or replacement, at HCmed Innovations Co., Ltd.'s sole option, of any component or equipment claimed to be defective when claim is shown to be bona fide by evaluation by HCmed Innovations Co., Ltd.. This warranty does not extend to any components or equipment subjected to misuse, improper operation, accidental damage, or unauthorized repairs, and is not extended to charges of, or for, labor repairs. All items returned must be properly packaged and shipped, prepaid by the product distributor servicing the unit.

⚠Contraindications

The AdheResp Smart Breath-actuated Mesh Nebulizer is not intended for use with Pentamidine.

⚠Precautions

General Safety

◎ The AdheResp Smart Breath-actuated Mesh Nebulizer is a medical device. Only use medications as prescribed and instructed by your physician.

◎ The AdheResp Smart Breath-actuated Mesh Nebulizer is designed for single patient multiple use. Do not share the AdheResp Smart Breath-actuated Mesh Nebulizer with others.

◎ The AdheResp Smart Breath-actuated Mesh Nebulizer is only intended for patients who are conscious and can control their breathing.

◎ The AdheResp Smart Breath-actuated Mesh Nebulizer can be operated by patients themselves, healthcare professionals, or caregivers.

◎ The AdheResp Smart Breath-actuated Mesh Nebulizer is designed for

liquid medication only. Liquid medication includes reconstituted medication but not suspension. Do not attempt to inhale water, essential oils, or any non-medicinal liquids or substances.

◎ Clean and dry your hands before using your AdheResp Smart Breath-actuated Mesh Nebulizer.

◎ Clean and disinfect your AdheResp Smart Breath-actuated Mesh Nebulizer thoroughly before use for the first time.

◎ Clean your AdheResp Smart Breath-actuated Mesh Nebulizer thoroughly after each use and disinfect the medication reservoir weekly or after the last use of the week.

◎ Do not wash the main unit or power adapter with water or any other liquid. If the main unit or the power adapter comes in contact with any liquid, discontinue the operation immediately and wipe off the liquid before use again.

◎ The AdheResp Smart Breath-actuated Mesh Nebulizer will not function normally if the medication reservoir is not properly attached to the main unit.

◎ The mesh attached to the medication reservoir is delicate. Do not touch it or clean it with sharp objects. This could damage the mesh and void your warranty.

◎ Do not use the AdheResp Smart Breath-actuated Mesh Nebulizer on patients who are unconscious or unable to breathe spontaneously.

◎ Patients who need assistance, such as children above 5 years old, must be supervised constantly by an adult or a medical professional when using the AdheResp Smart Breath-actuated Mesh Nebulizer for inhalation treatment. This helps ensure the treatment is safe and effective.

◎ Always keep the AdheResp Smart Breath-actuated Mesh Nebulizer and

all associated parts out of reach of infants and children.

◎ To avoid the risk of degradation or contamination of medication, do not fill the medication reservoir when not in use. Only fill medication into the medication container right before treatment.

◎ Do not drop the AdheResp Smart Breath-actuated Mesh Nebulizer or bump it against any surface as it may cause damage and void your warranty.

◎ Disposal of the entire device, components, and optional accessories is subject to applicable local regulations. Unlawful disposal may cause environmental pollution.

Electrical Safety

◎ The AdheResp Smart Breath-actuated Mesh Nebulizer is powered by an embedded, rechargeable Li-ion battery. The power adapter WILL NOT charge the battery without connecting to a suitable power outlet.

◎ Only use the power adapter or the charging cable supplied by HCmed. Use of any other power adapter or charging cable may damage the AdheResp and void your warranty.

◎ When charged with the charging cable supplied by HCmed, use only a suitable USB Type-C wall charger that is safety certified (e.g. IEC60601) and only with a suitable wall power outlet. Do not charge through a laptop, portable power bank, or on an aircraft.

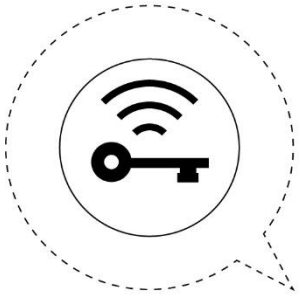
◎ AdheResp cannot be operated while charging.

◎ Do not soak or immerse your AdheResp Smart Breath-actuated Mesh Nebulizer main unit or power adapter in water or any other liquid.

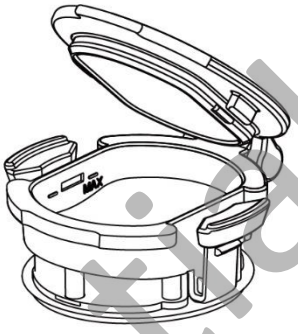
◎ Do not attempt to disassemble or modify any components of the AdheResp Smart Breath-actuated Mesh Nebulizer in any way.

Package Content

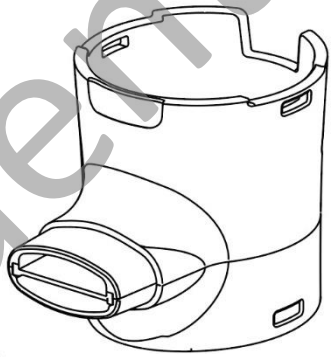
The following items are contained in the package. If any items are missing, please contact your local authorized dealer.



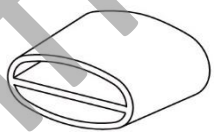
Key tag(s) are supplied with the product package or with the prescribed medication.



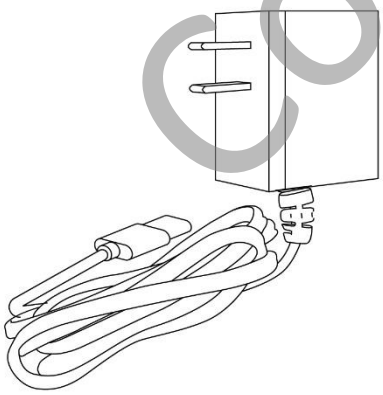
Medication container



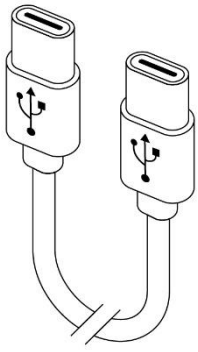
Aerosol chamber



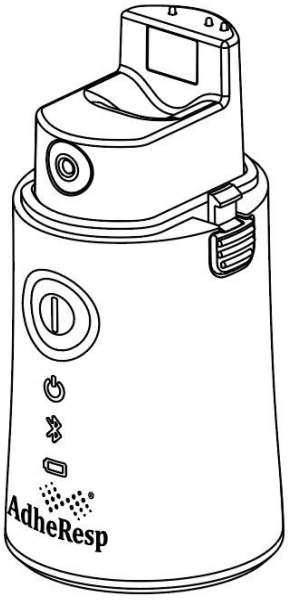
Mouthpiece



Power adapter



Charging cable

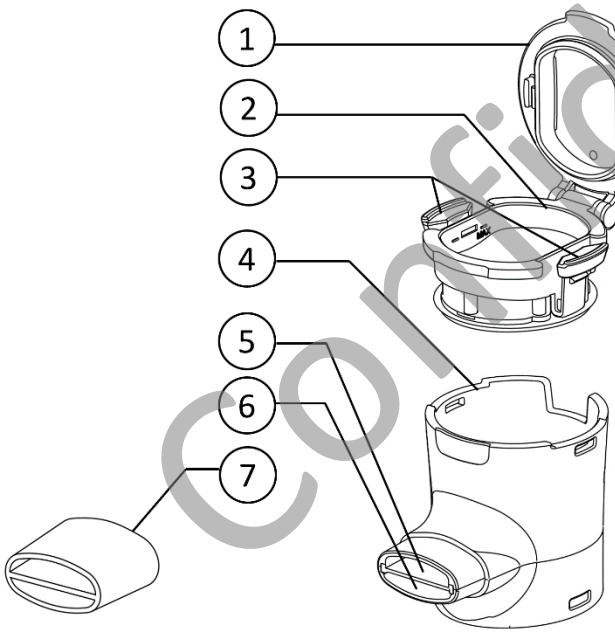


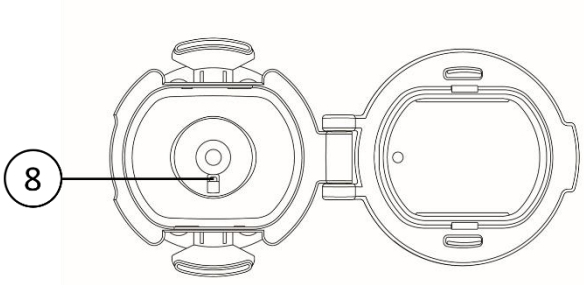
Main unit

Components and features

1. Medication container lid
2. Medication container
3. Medication container release buttons
4. Aerosol chamber
5. Aerosol port
6. Pressure port
7. Mouthpiece
8. Liquid detection pin

The combination of No. 2 and 4 is called Medication Reservoir.

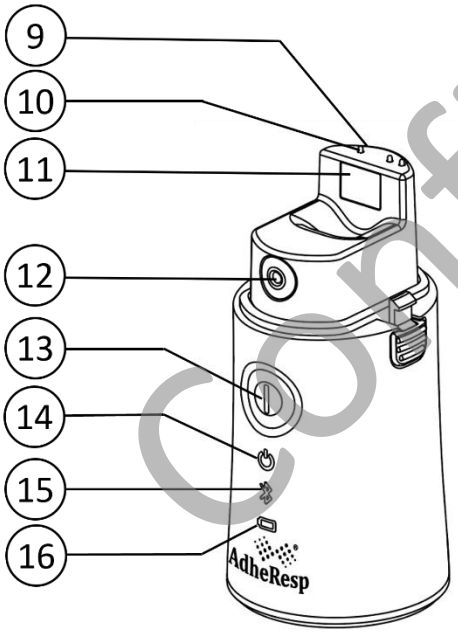




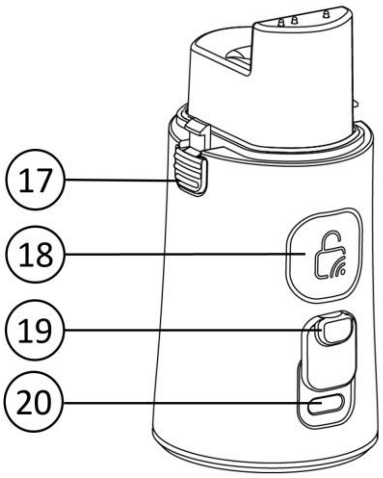
Top view of medication container

Product Composition

9. Main unit
10. Electrodes
11. Optical window
12. Pressure sensor port
13. ON/OFF button
14. Power indicator
15. Bluetooth (BLE) indicator
16. Battery status indicator
17. Reservoir release button
18. Key tag detecting area
19. Charging port cover
20. Charging port (under the cover)



Front view



Back view

Terms

Used Term	Description
Medication container lid	Prevents the liquid medication from spilling out of the medication container.
Medication container	Space to be filled with the prescribed liquid medication for nebulization. There is a MAX marking on the internal surface to indicate the maximum fill volume.
Medication container release buttons	Releases the medication container from the aerosol chamber.
Aerosol chamber	Holds the aerosol generated by nebulization.
Aerosol port	Transports the generated aerosol to the user during inhalation and guides the user-exhaled air to be discharged from the vent holes on the back of the aerosol chamber.
Pressure port	Serves as the channel for air pressure changes when the user breathes through the reservoir.
Liquid detection pin	Detects the level of residual liquid medication.
Electrodes	Supplies power to the medication reservoir from the main unit.
Optical window	Detects the aerosol in the aerosol chamber.
Pressure sensor port	Detects the pressure changes transmitted through the pressure port by the pressure sensor.
ON/OFF button	Turns the nebulizer on and off.
Power indicator	A blue LED indicates whether the nebulizer is on or off.
Bluetooth (BLE) indicator	A blue LED indicates whether the Bluetooth status is to-be-paired or paired with a mobile device.

Product Composition

Battery status indicator	An orange LED indicates whether the battery is only sufficient for one more treatment or requires charging before the next treatment. A green LED Indicates that the battery is charging, fully charged or with sufficient power to sustain more than one treatment.
Reservoir release button	Releases the medication reservoir from the main unit.
Key tag detecting area	Area of main unit to detect the key tag to activate the nebulizer.
Charging port cover	Protects the charging port.
Charging port (under the cover)	USB Type-C connector for the power adapter.

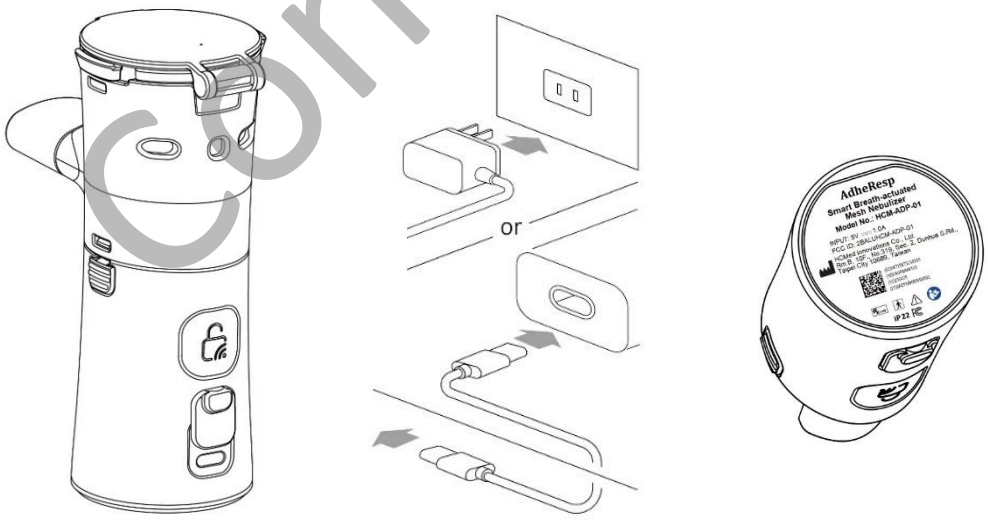
The AdheResp Smart Breath-actuated Mesh Nebulizer is a portable device designed to nebulize liquid medication approved for use by the means of vibrating mesh technology.

The AdheResp Smart Breath-actuated Mesh Nebulizer is capable of providing use and status information to a companion application wirelessly via Bluetooth connection. The companion application is an optional accessory for displaying purposes only and will not allow operation or control of the nebulizer. The companion application is not a medical device.

Connecting to the power adapter or the charging cable

1. Open the charging port cover on the main unit and insert the USB Type-C connector of the power adapter or the charging cable into the charging port.
2. Product package with the power adapter: Insert the region-specific plug of the power adapter into a suitable power outlet.

   Product package with the charging cable: Insert the other end of the charging cable to a USB Type-C outlet on a suitable power source.



For trouble shooting and warranty service, please quote the lot number of the main unit or the unique device identification (UDI) of the nebulizer.

Cleaning

- ◎Before you use the AdheResp for the first time or after long storage, wash, rinse and dry the mouthpiece, aerosol chamber, and medication container. See pages 25-27 for cleaning instructions (step 23 to 26).
- ◎Never wash the AdheResp and its components in a dishwasher.
- ◎Do not place or try to dry the AdheResp and its components in a microwave or regular oven.
- ◎Do not use steam sterilizers to disinfect the AdheResp.
- ◎Do not use bleach or any other cleaning agents to clean the AdheResp.
- ◎Do not use mineral or hard tap water to clean or rinse the AdheResp. Any calcification can damage and reduce the lifetime of the AdheResp. Use soft, distilled, or filtered water only.
- ◎Never remove the rubber seals from the medication container lid.

Use

- ◎Never use the AdheResp to inhale water.
- ◎Never poke the mesh or button with sharp objects. Handle the container lid with care.
- ◎Keep the AdheResp out of reach of small children or infants. Small parts in the AdheResp can be dangerous to children and infants.
- ◎Handle the AdheResp with care. Do not shake or drop the AdheResp.
- ◎Other electrical equipment may be affected by the AdheResp. When using the AdheResp, keep it away from other equipment or turn the equipment off. See pages 45-54 for guidance on electromagnetic compatibility.
- ◎Do not expose the AdheResp to high temperatures, high humidity, or direct sunlight.
- ◎Do not carry the AdheResp with medicine in the medication container. It may spill.
- ◎Do not attempt to take apart or modify the AdheResp.

Battery care

◎Do not wash the power adapter or the charging cable with water.
◎Do not handle the power adapter or the charging cable with wet hands. Only use the power adapter or the charging cable in a dry place indoors.
◎Only use the AdheResp with the power adapter or the charging cable supplied by HCmed.
◎Do not connect the embedded battery to other equipment.
◎Do not short circuit the battery.
◎Do not attempt to remove the battery from the main unit.
◎Do not dispose of the battery in fire. It may explode.
◎Do not drop medication on the charging port of the main unit or ends of the power adapter. Immediately wipe up spills with gauze or a clean cloth.
◎Unplug the power adapter or the charging cable from the port and outlet after charging.

Before taking your first treatment, there are four things you will need to do:

- ◎Charge the internal battery.
- ◎Prepare the key tag for activation.
- ◎Wash and disinfect the mouthpiece, medication container, and aerosol chamber.
- ◎Wash and dry your hands.
- ◎Get used to assembling and handling the AdheResp.

Charging the internal battery

1. Before taking your first treatment, charge the battery for 3-4 hours or at least 30 minutes until the green light of the battery status indicator is constantly on. When the battery is sufficiently charged, the green light of the battery status indicator will be constantly on. Then, you can unplug the power adapter or the charging cable from the main unit and close the charging port cover.
2. Product package with the power adapter: To charge the battery, insert the USB Type-C connecter of the power adapter into the charging port of the main unit and insert the region-specific plug of the power adapter into a suitable power outlet.

   Product package with the charging cable: To charge the battery, insert one of the USB Type-C connectors of the charging cable into the charging port of the main unit and insert the other end of the charging cable into the USB Type-C wall charger connected to a suitable power outlet.

   (When charging the battery, the green light of the battery status indicator will slowly blink along with the BLE indicator for the first 2 minutes. Simultaneously, the AdheResp searches for the mobile device to pair with. After 2 minutes, the BLE indicator will turn off, and the green light of the battery status indicator will continue blinking until the battery is sufficiently charged.)

IMPORTANT: If the orange light of the battery status indicator turns on during the treatment, try to breathe continuously and shorten time of pauses.

⚠Caution

◎When the orange light of the battery status indicator lights up before starting a treatment or when finishing a treatment, charge the main unit for ensuring the power is sufficient for the next treatment.

◎The AdheResp cannot be used for treatment during charging the battery.

◎Close the charging port cover properly after charging the battery.

Prepare the key tag for activation

3. The key tag will be supplied or attached with the prescribed medications. When starting therapy, always use the key tag with the prescribed medication. If you lose your tags, or if you have any questions about which tag to use, please contact customer service.

   IMPORTANT: Frequency of dosing and length of the activation period depend on the key tag provided along with the device package or the prescribed medication. Read through the information attached to the key tag for confirmation.

   IMPORTANT: When you want to start a treatment session after completing the preparation, activate the AdheResp according to the activation instructions (step 12) on page 19-20.

⚠Caution

◎ Place the key tag away from the main unit if you do not intend to start a treatment session.

◎ If you do not activate the AdheResp with the key tag, the AdheResp

will not work.

Wash mouthpiece and medication reservoir

4. Before you use the AdheResp for the first time or after long storage, wash, rinse, and dry the mouthpiece, medication container and aerosol chamber. See pages 25-27 for cleaning instructions (step 23 to 26).

Assembling the AdheResp

Before you take your first treatment, practice assembling and dissembling the AdheResp to get familiar with the device components.

5. Push the mouthpiece toward the aerosol port of the aerosol chamber to attach it.
6. Keep the medication container lid open, then attach the medication container downward to the aerosol chamber. The medication container fits over the rear cave of the upper aerosol chamber. Once in place, push the medication container down and lock it by securing with the slots on the aerosol chamber until you hear the clicks.

⚠Caution

◎If the medication container is not secured on the aerosol chamber, the AdheResp may not work as intended.

7. Attach the medication reservoir to the main unit by pushing the medication reservoir down until you hear the clicks and locking it by securing with the slots on the aerosol chamber.

⚠Caution

◎ Ensure the top surface of the main unit is dry before attaching the medication reservoir to the main unit, or the main unit may be damaged due to short circuit during treatment.

◎ If the medication reservoir is not secured on the main unit, the

AdheResp will not turn on or aerosol may not be produced.

Preparing for treatment

8. Place the AdheResp on a flat surface and open the medication container lid.
9. Add liquid medication into the reservoir according to your prescribed dosage. The volume should be between 0.5 and 8.0 ml.

⚠Caution

◎ When adding medication into the medication reservoir, do not exceed the MAX (8.0 ml) medication indication line on the internal side of the reservoir.

◎ Ensure the medication level is above the liquid detection pin.

◎Do not allow your fingers or hands to come in direct contact with the medication.

◎For reconstituted medication, do not directly put the solid form medication into the container before reconstitution nor carry out the reconstitution process within the container.

10. Close the container lid and make sure the AdheResp remains upright. You are now ready to start your treatment.

⚠Caution

◎ If the container lid is not secure, medication may spill from the container.

Using the AdheResp Smart Breath-actuated Mesh Nebulizer

11. Press the ON/OFF button for at least 2 seconds and release it to turn on the AdheResp. The power indicator will start to blink slowly, indicating the AdheResp is in stand-by mode.

IMPORTANT: If the orange light of the battery status indicator is constantly on after turning on the AdheResp, the battery power may not sustain one last treatment session. If the AdheResp is not in use, charge the battery before next treatment.

IMPORTANT: If the orange light of the battery status indicator is blinking slowly after turning on the AdheResp, the AdheResp will turn off automatically, and the battery must be charged before starting the next treatment.

IMPORTANT: If the BLE indicator is off after the AdheResp is turned on, the treatment still can be completed without the BLE function which is only for transmitting use and status information.

⚠Caution

◎ Make sure the mouthpiece is in place before turning the AdheResp on.

◎ Do not use sharp objects such as pens to turn the AdheResp on. They may damage the ON/OFF button.

◎ If the medication reservoir is not properly attached to the main unit, a long vibration feedback will occur and the AdheResp will not turn on.

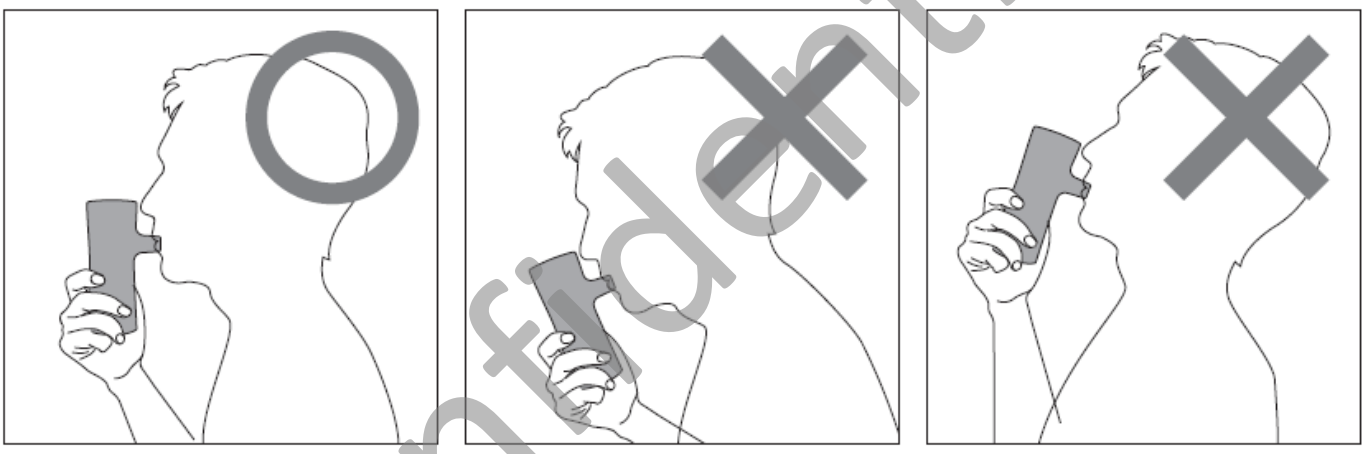
12. Place the key tag within 1 cm of the unlock icon on the back of the main unit to activate the AdheResp for a predefined activation period of a treatment session. When a valid key tag is detected, the AdheResp will

have a medium vibration and produce initial puff of aerosol. Then, the power indicator will be lit up constantly.

IMPORTANT: If an invalid key tag is detected, a long vibration feedback will occur.

IMPORTANT: If there is no correct key tag detected within 2 minutes after turning on the AdheResp, the AdheResp will automatically turn off after a long vibration.

13. Sit in an upright position and hold the AdheResp vertically (see the following illustrations). Seal your lips around the mouthpiece and breathe



normally through your mouth.

Hold the AdheResp vertically during treatment. Holding the AdheResp at an angle might impair performance. Tilting angle less than 10° is permitted.

IMPORTANT: When exhaling, it is normal to see some aerosol coming out of the vent holes on the back of the aerosol chamber if you are breathing rapidly. If it keeps happening, try to slow down your breathing frequency.

IMPORTANT: The breath actuation function can only be triggered by inhalation of sufficient intake force, and you will feel a short vibration for each successfully triggered nebulization. This is an indication to let you know the medication is being delivered.

IMPORTANT: Avoid shallow breathing. Breathe deeply to increase the aerosol reaching your lungs.

IMPORTANT: Breathing through your nose during the treatment will not trigger the breath actuation function. Holding your nose for a few breaths will help you get used to the feeling of breathing through your mouth.

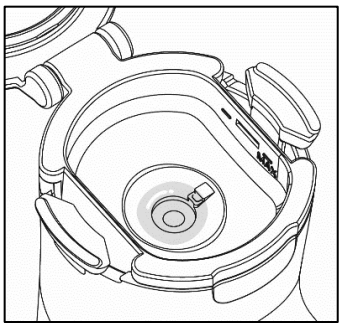
⚠Caution

- ◎ When you breathe through the AdheResp, make sure you hold it vertically.
- ◎ The mesh mechanism could be damaged if no liquid medication contacts the mesh during inhalation.
- ◎ Do not cover the vent holes on the back of the aerosol chamber when holding the AdheResp.
- ◎ Do not press the reservoir release buttons when holding the AdheResp.

14. Continue to breathe through the AdheResp until you feel two consecutive short vibrations. The two short vibrations let you know that your medication has been fully delivered and the treatment is complete. AdheResp will automatically switch off after two short vibrations, and all LED indicators will turn off.

    IMPORTANT: If you hold the AdheResp in a tilted position, that will make medication not contact the mesh and the liquid detection pin at the bottom of the container, causing the AdheResp to turn off automatically to protect the mesh mechanism.

    IMPORTANT: You could open the medication container lid to check the residual volume of medication. If the residual medication level is above the liquid detection pin (as shown in the right figure), you could close the medication container lid and turn



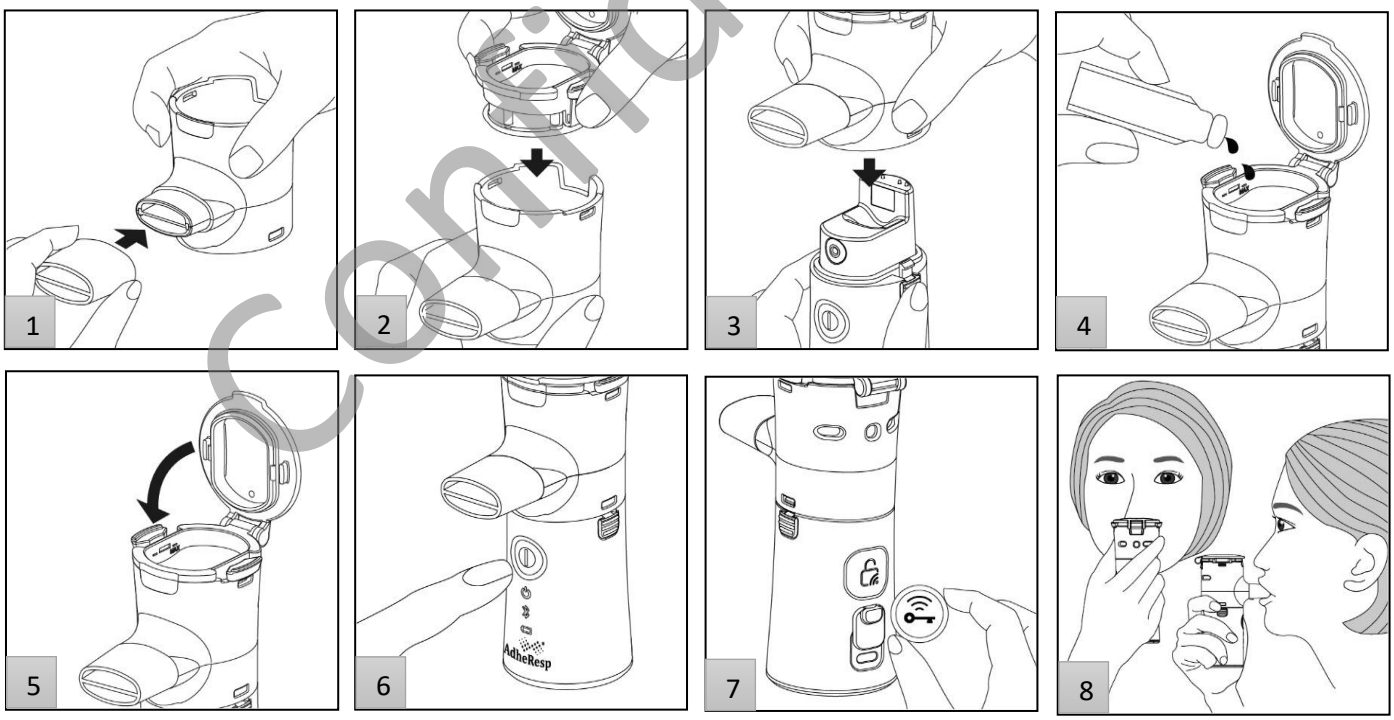
on the AdheResp again to complete the treatment within the activation period after activating the AdheResp with a key tag.

⚠Caution

◎ Complete the treatment within the predefined activation period for one treatment session, or the AdheResp will turn off and return to the inactivated status. You will have to use a valid key tag to activate it again as described in Step 12.

◎ The quantity of the key tag or its valid credits is usually the same as the number of prescribed treatments. Repeating device activation during the same treatment session may result in lacking keys or valid credits to complete all the prescribed treatments.

Illustration of steps from assembling, loading medication, to switching on the AdheResp, activating the AdheResp with the tag to breathing through the AdheResp.



Pausing your treatment

15. You can pause your treatment at any time by stopping breathing through the AdheResp. The AdheResp will stay in the stand-by mode for at most 10 minutes until detecting inhalation. You can restart your treatment by breathing through the AdheResp within 10 minutes from the last inhalation.

IMPORTANT: For safety reasons, if there is no inhalation detected for 10 minutes, the AdheResp will automatically turn off following a long vibration. *You can turn on the* AdheResp *again by pressing the ON/OFF button for 2 seconds and release it within the predefined activation period.*

You can press the ON/OFF button for 5 seconds at any time before the AdheResp automatically turns off, and it will be manually turned off following a long vibration.

IMPORTANT: You can turn on the AdheResp again by pressing the ON/OFF button for 2 seconds and release it within the predefined activation period.

IMPORTANT: If the AdheResp turns off due to treatment completion or reaching the predefined activation period after activating it, the treatment will not be restarted without consuming a new key tag or a valid credit of a key tag.

⚠Caution

◎ The medication might degrade or be contaminated if it is exposed to the environment for more than 1 hour. Please contact your healthcare provider or physician for more information.

16. There will be some medication left in the chamber after the treatment. This is normal. Open the container lid and carefully discard the residual medication in the container.

Disassembling the AdheResp

17. Place the AdheResp on a flat and horizontal surface. Separate the medication reservoir from the main unit by pressing both reservoir release buttons and simultaneously pulling the reservoir away from the main unit.
18. Open the lid and separate the medication container from the aerosol chamber by pressing both container release buttons and simultaneously pulling the container away from the chamber.
19. Pull the mouthpiece forward to separate it from the medication reservoir.

IMPORTANT: Handle the medication container with care. The mesh in the center of the container is vulnerable.

IMPORTANT: If there is liquid medication left but not discarded, it may spill from the container as the container lid needs to remain open during the disassembly.

⚠Caution

◎ Do not re-use any left-over medication.

20. For maintaining cleanliness, the mouthpiece and all the parts in the medication reservoir should be cleaned regularly. To keep the AdheResp working properly, you must wash the mouthpiece and medication reservoir after each treatment. It is also important to disinfect the medication container, aerosol chamber, and mouthpiece on a weekly basis.

Maintaining the main unit

21. Use gauze, an antiseptic wipe or an alcohol pad to wipe away any moisture around the main unit and pressure sensor port.

IMPORTANT: Only wipe the optical window with soft material to avoid scratching the surface.

⚠Caution

◎ Do not scratch the optical window. Scratching the optical window could affect the device function and lead to a malfunction.

22. Press the ON/OFF button for 2 seconds and release it to turn on the AdheResp and check the battery status. If you see the orange light of the battery status indicator blinking or constantly on, follow step 2 to charge the main unit for 3-4 hours or at least 30 minutes until the green light of the battery indicator is constantly on. When the AdheResp is fully charged, unplug the power adapter from the main unit and close the charging port cover properly.

⚠Caution

◎ Do not check the battery status by activating the AdheResp with a valid key tag, or you will use up one credit of the key tag.

Routinely washing the reservoir

23. After each use: place the mouthpiece, medication container, and aerosol chamber in a container filled with warm soapy water (water with a few drops of clear, neutral dishwashing detergent). Gently Clean the surface of the reservoir components mentioned above by finger without touching the mesh for 2 minutes.

⚠Caution

◎ Do not touch the mesh with any objects or fingers.

◎ Do not reuse soapy water.

◎ Use only clear dishwashing soap. Do not use “white” soap or antibacterial soap; these may cause damage to the mesh.

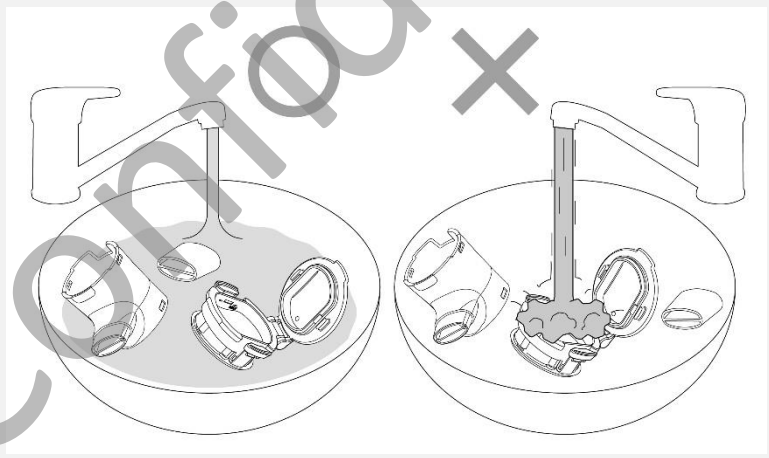
◎ Do not boil or immerse any parts of your AdheResp in water above 40 degrees Celsius during washing process.

◎ Do not attempt to remove any components from the medication container and the aerosol chamber for the purpose of cleaning.

24. Wash off the detergent residue from the components mentioned above thoroughly in running water.

⚠Caution

◎ Do not place the medication container directly under running water.



◎ Do not soak the main unit or the power adapter in any liquid. Clean these electrical components by wiping contaminations off with a clean paper towel or cloth.

◎ Do not scratch the interior surface of aerosol chamber. Scratching the interior surface of aerosol chamber could affect the device function and lead to a malfunction.

25. Rinse the components mentioned in Step 23 and 24 again in soft, distilled, or filtered water. If hard water available only, rinse the components with water that has been boiled and allowed to cool. Shake off excess water carefully and allow components to air dry completely on a clean lint-free cloth before storing.
26. Place the AdheResp components in the storage case or other dry and clean containers. If the AdheResp is stored for a long period, complete the routine wash before using it (see Step 23 to 25).

Weekly disinfection

27. Prior to disinfection at the end of the week's last treatment, ensure all parts are visibly clean and free from dirt following the routine wash process.
28. Disinfect the medication container, aerosol chamber, and mouthpiece by immersing them in liquid 70%-75% medical grade ethyl alcohol for approximately 1-2 minutes. Then, shake off excess liquid carefully and allow to air dry completely on a clean lint-free cloth.

⚠Caution

◎ Do not place the AdheResp components in an oven or microwave for any purposes. If any components of the AdheResp are unintentionally placed in an oven or microwave, replace them with new ones in case of device malfunction during treatment.

◎ Do not use steam sterilizers to disinfect the medication container, aerosol chamber and mouthpiece. If the components mentioned above are unintentionally disinfected by being exposed in the steam or being immersed in water above 40 degrees Celsius, replace the medication reservoir with a new one in case of device malfunction during treatment.

Periodic maintenance

29. If there is liquid spilled on the main unit, wipe it with a clean damp cloth as soon as possible.
30. The pressure sensor port on the main unit is important for ensuring the AdheResp works correctly. Make sure there is no foreign matter blocking the port. If the port is blocked, wipe it off carefully.

⚠Caution

◎ Do not remove the rubber seals from the main unit.

◎ Do not poke the port and avoid sticky materials from blocking the port, or the embedded pressure sensor will be damaged.

Every 6 months

31. Six months after the initial use of the AdheResp Smart Breath-actuated Mesh Nebulizer, throw away the medication container (consisting of the container, lid, and mesh) according to the disposal instructions on page 29 and replace it with a new one.
32. Follow step 22 to check the battery status and charge the main unit when the battery is low.

Disposal Instructions

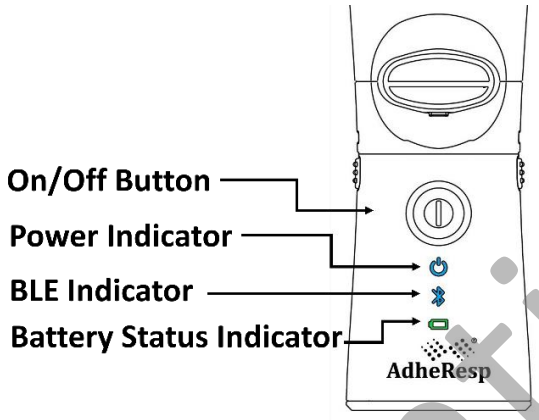
Follow applicable local regulations for disposal. The plastic components, including medication container, aerosol chamber, and mouthpiece should be cleaned and disinfected before disposal. The main unit should not be disposed of with other household wastes at the end of its working life. To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate this from other types of wastes and recycle it responsibly with other electronic equipment to promote the sustainable reuse of material resources.

Users should contact either the retailer where they purchased this product or their local government office for details of where and how they can take this item for environmentally safe recycling.

This product does not contain any hazardous substances.

Indications of AdheResp

Power button, visual and tactile indications equipped by the AdheResp could refer to the following illustration and table. The LEDs on the main unit indicate the current state of the AdheResp. If no LEDs light up, the AdheResp is either turned off and/or the battery is flat.



ON/OFF button		
	When device is off	• Press the ON/OFF button for 2 seconds and release it to turn on the AdheResp Smart Breath-actuated Mesh Nebulizer into BLE pairing and stand-by mode. • Press the ON/OFF button for more than 5 seconds and release it to turn on the AdheResp Smart Breath-actuated Mesh Nebulizer into stand-by mode with BLE in discoverable mode.
	When device is on	• Press the ON/OFF button for more than 5 seconds and release it to manually turn off the AdheResp Smart Breath-actuated Mesh Nebulizer during operation.
Power Indicator (blue LED)		
	Slow blinking	The AdheResp is turned on into stand-by mode.
	Constantly lighting	The AdheResp is activated by the valid key tag

		and ready to start the treatment.
	Light is off	The AdheResp is turned off.
Bluetooth Indicator (blue LED)		
	Slow blinking	Not yet pairing with a mobile device during the first two minutes of charging or when the AdheResp is turned on.
	Rapid blinking	The AdheResp is in discoverable mode.
	Constantly lighting	The AdheResp is paired with a mobile device.
	Light is off	The BLE is off because the AdheResp is not paired with a mobile device during the first two minutes of charging or after the AdheResp is turned on for two minutes.
		The AdheResp is turned off.
Battery Status Indicator (orange LED)		
	Slow blinking (10 sec) and turning off the device	The AdheResp is manually turned off when the battery power is low and the power adapter or charging cable is not plugged. Slow blinking is the reminder that the battery needs to be charged before next treatment.
		The AdheResp is on but forced to shut off automatically due to the flat battery when the power adapter or charging cable is not plugged. Slow blinking is the reminder that the battery needs to be charged before next treatment.
	Constantly lighting	The AdheResp is on and the battery power islow when the power adapter or charging cable is not plugged. The battery power may not sustain one

		last treatment session. If the AdheResp is not in use, charge the battery before next treatment.
	Light is off	The AdheResp is turned off.
Battery Status Indicator (green LED)		
	Slow blinking	The AdheResp is charged with the power adapter or charging cable.
	Constantly lighting	The AdheResp is charged with the power adapter or charging cable, and the battery is fully charged.
		The AdheResp is on when the power adapter or charging cable is not plugged. The battery can sustain more than one treatment session.
	Light is off	The AdheResp is turned off.
Vibration feedback		
	One short vibration (0.3 sec)	Successful nebulization in each breathing cycle.
	One medium vibration (1 sec)	The AdheResp is turned on by pressing the ON/OFF button for 2 seconds.
		Valid key tag is detected after the AdheResp is turned on.
	Two short vibrations and turning off the device	Treatment is completed or no liquid medication contacts the mesh during use if the tilting angle is too large.
	One long vibration (3 sec) and turning off the device	The AdheResp is manually turned off.
		No valid or correct key tag is detected within two minutes after the AdheResp is turned on.
		The treatment is not completed within the

		predefined activation period after the AdheResp is activated by the valid key tag.
		No inhalation is detected from the last inhalation for ten minutes, resulting in the AdheResp to turn off automatically.
		No liquid medication is loaded in the medication container or the medication reservoir is not properly attached to the main unit when turning on the AdheResp.

Troubleshooting

Problem	Possible cause	Solution
The AdheResp shuts off automatically within 2 minutes after power on.	The medication reservoir is not attached to the main unit properly.	Reattach the medication reservoir according to the assembling instruction on page 17, step 5-7.
	Low battery	Charge the battery according to the instructions for charging the internal battery on page 15, step 2. Insert the USB Type-C connecter of the power adapter into the charging port of the main unit and insert the region-specific plug of the power adapter into a suitable power outlet. Or insert one of the USB Type-C connectors of the charging cable into the charging port of the main unit and insert the other end of the charging cable into the USB Type-C wall charger connected to a suitable power outlet.
Low battery indicator is flashing or constantly on after power on	Low battery.	Charge the battery according to the instructions for charging the internal battery on page 15, step 2. Insert the USB Type-C connecter of the power adapter into the charging port of the main unit and insert the region-specific plug of the power adapter into a suitable power outlet. Or insert one of the USB Type-C connectors of the charging cable into the

		charging port of the main unit and insert the other end of the charging cable into the USB Type-C wall charger connected to a suitable power outlet.
Low battery indicator does not flash after connecting the power adapter	The connection between the power adapter / charging cable and the charging port of the main unit is incorrect.	Reconnect the power adapter / charging cable to the main unit by inserting the USB Type-C connector firmly into the charging port.
	The connection between the power adapter / charging cable and the power outlet is incorrect.	Reconnect the power adapter / charging cable to the power outlet correctly.
	The battery is Fully charged.	No action is needed.
	The power adapter / charging cable is damaged.	Replace the power adapter / charging cable.
	The power outlet is not working.	Plug the power adapter / charging cable in another workable power outlet.
Weak or low	The mesh is stained or	Clean and/or disinfect the medication reservoir according to the instructions

nebulization	clogged.	for maintenance on pages 25-27 or replace the medication reservoir which is a consumable part.
	Electrodes on the main unit are wet or dirty.	Power off your AdheResp and detach the medication reservoir carefully without splitting the loaded drug. Wipe off any moisture or dirt around the electrodes on the top of the main unit carefully according to the instructions for maintenance on page 27. Then, attach the medication reservoir back to the main unit and power on your AdheResp again.
Rapid accumulation of aerosol condensation in aerosol chamber	Breathing cycles are too short and fast.	Elongate your inhalation of each cycle to let nebulized drug aerosol be carried into your lungs with the inhaled air flow.
	The vent holes are blocked by fingers or hand.	Hold the AdheResp on the main unit or the medication reservoir without blocking the vent holes on the back of aerosol chamber.
The AdheResp shuts down earlier while there is medicine left in the medication	Electrodes on the main unit are wet or dirty.	Power off your AdheResp and detach the medication reservoir carefully without splitting the loaded drug. Wipe off any moisture or dirt around the electrodes on the top of the main unit carefully according to the instructions for maintenance on page 27. Then, attach the medication reservoir back to the main unit and power on your AdheResp

reservoir		again.
	Poor contact between electrodes on the main unit and medication reservoir.	Power off your AdheResp and detach the medication reservoir carefully without splitting the loaded drug. Remove anything blocking the electrodes on the top of the main unit carefully. Then, attach the medication reservoir back to the main unit and power on your AdheResp again.
	The user changes orientation of the AdheResp held in his or her hand while in use.	Hold the AdheResp vertically as the Figure illustrated on page 20. Tilting angle should be less than 10 degrees.
No aerosol is generated while there is medicine left in the medication reservoir when the AdheResp is on	The medication reservoir is loose or not properly attached to the main unit.	Turn off the AdheResp. Re-attach the medication reservoir as shown on page 17 and power on the AdheResp again.
	The medication reservoir is damaged.	Replace the medication reservoir which is a consumable part.
	The AdheResp does not detect inhalation.	Breath through the AdheResp by mouth when taking the treatment.
Liquid leaks from the medication	The medication container lid is not sealed	Ensure the medication container lid is tightly closed before use.

reservoir.	The lid or the body of the medication container is damaged.	Replace the medication container which is a consumable part.
	The mesh is damaged.	Replace the medication container which is a consumable part.
The AdheResp cannot be activated by the key tag, and it turns off after power indicator flashes for 2 minutes.	There is no valid key tag detected by the AdheResp within 2 minutes after power on, and the AdheResp is not successfully activated.	Use a valid tag which is supplied with the package of the prescribed medication to activate the AdheResp. Place the key tag within 1 cm of the unlock icon on the back of the main unit to activate the AdheResp again.
	The key tag is damaged.	Replace the key tag.
	NFC antenna in the main unit is damaged.	Replace the main unit.
The AdheResp does not shut off automatically when the medicine in the reservoir	The medication reservoir detects an incorrect liquid level caused by the foam produced by medication during	Press the ON/OFF button for more than 5 seconds and release it to manually turn off the AdheResp.

is depleted.	nebulization.	
	Electrodes on the main unit are wet or dirty.	Press the ON/OFF button for more than 5 seconds and release it to manually turn off the AdheResp.
	The medication reservoir is damaged.	Press the ON/OFF button for more than 5 seconds and release it to manually turn off the AdheResp. Replace the medication reservoir which is a consumable part.

If your AdheResp Smart Breath-actuated Mesh Nebulizer still does not function after following the instructions above, please contact your local authorized dealer or HCmed for assistance and quote the unique identification number of the nebulizer (illustrated on page 12)

FCC Part 15

NOTE: This product has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules.

These limits are designed to provide reasonable protection against harmful interference in a residential installation. This product generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications.

However, there is no guarantee that interference will not occur in a particular installation. If this product does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

—Reorient or relocate the receiving antenna.

—Increase the separation between the product and receiver.

—Connect the product into an outlet on a circuit different from that to which the receiver is connected.

—Consult the dealer or an experienced radio/TV technician for help.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and
(2) this device must accept any interference received, including interference that may cause undesired operation.

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the device.

This device meets the government’s requirements for exposure to radio waves. This device is designed and manufactured not to exceed the emission

limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission of the U.S. Government.

The exposure standard for wireless devices employing a unit of measurement is known as the Specific Absorption Rate, or SAR. The SAR limit set by the FCC is 1.6W/kg.

The FCC has granted an Equipment Authorization for this device with all reported SAR levels evaluated as in compliance with the FCC RF exposure guidelines. SAR information on this device is on file with the FCC and can be found under the Display Grant section of www.fcc.gov/oet/ea/fccid after searching on FCC ID: 2BALUHCM-ADP-01

Product Specification

AdheResp Smart Breath-actuated Mesh Nebulizer	
Model	HCM-ADP-01
Dimensions	Approximately 91 mm (L) x 55.5 mm (W) x 133 mm (H)
Weight	Approximately 170 g (including battery)
Power consumption	Approximately 1.2W
Battery voltage	3.5-4.2V
Min. fill volume	0.5 ml
Max. fill volume	8 ml
Contains FCC ID	A8TBM71S2
FCC ID	2BALUHCM-ADP-01
IP Class	IP22
Power Adapter	
Type	The power adapter (Unifive UM305-0510) is with an USB Type-C connector to connect to the main unit and with a region-specific plug to insert into the power outlet.
Input	AC 100-240V, 50/60Hz, 0.16-0.12A
Output	DC 5V 1A 5W
Length	1 meter
Charging Cable (optional)	
Type	The charging cable is with an USB Type-C connector on both ends to connect to the main unit and the USB Type-C wall charger plugged into the power outlet.

Length	1 meter
Battery	
Type	Secondary Battery
Chemistry	Lithium-ion Battery
Capacity (typical)	3450 mAh
Battery life	Up to 300 minutes if used continuously after being fully charged. Expected life cycle is around 300 cycles.
Bluetooth	
Type	AdheResp is equipped with a Bluetooth version 5.0 module. The treatment data can be read out when used with a mobile device with app.
Frequency band	2.402-2.480 GHz
Operating Frequency	32 MHz
NFC	
Type	AdheResp features the NFC module to enable users to verify their identity and unlock the device with a key tag, granting access to use the device.
Frequency band	13.56MHz
Operating Frequency	27Mhz

If the AdheResp Smart Breath-actuated Mesh Nebulizer is expected to be in storage for a prolonged period, place the components in the unit box or store them in a dry and dust-free environment after proper cleaning and disinfection.

Storage and Transport Conditions

◎Ambient Temperature：-20˚C to +50˚C
◎Relative Humidity：maximum 90% (non-condensing)
◎Atmospheric Pressure：50 kPa to 106 kPa

Operation Conditions

◎Ambient Temperature：+5˚C to +40˚C
◎Relative Humidity：15% to 90%
◎Atmospheric Pressure：70 kPa to 106 kPa

Electromagnetic Compatibility

◆ The AdheResp Smart Breath-actuated Mesh Nebulizer conforms to IEC60601-1-2:2014, which describes requirements of electromagnetic compatibility (EMC) of medical devices. This includes not only immunity to radio frequency electric fields and electrostatic discharge, but also the other appliable requirements of the standards.

◆ Essential Performance

The risk management process for this product concludes that there are no functions considered essential to the safety of the patients.

⚠Caution

◎ In compliance with EMC standards **DOES NOT** mean the AdheResp Smart Breath-actuated Mesh Nebulizer has total immunity; certain devices which generate electrical or electromagnetic fields **MAY INTERFERE** with operation if they are used near the AdheResp Smart Breath-actuated Mesh Nebulizer. A high electromagnetic environment generated by such devices **MAY DAMAGE** your device.

◎ Use of power adapters and/or accessories other than those specified or provided by the manufacturer of the AdheResp Smart Breath-actuated Mesh Nebulizer could result in improper operation, increased electromagnetic emissions or decreased electromagnetic immunity of the AdheResp Smart Breath-actuated Mesh Nebulizer.

◎ The device should not be used adjacent to or stacked with other equipment. In case it is necessary to use the device near other equipment, the device should be observed to verify normal operation in the configuration in which it will be used.

◎ Portable RF communications equipment (including peripherals such as antenna cables and external antennas, e.g., cell phones and AM/FM radios) should be used no closer than 30 cm (12 inches) to any part of the AdheResp Smart Breath-actuated Mesh Nebulizer including power

adapter specified by the manufacturer. Otherwise, that would degrade the performance of the AdheResp Smart Breath-actuated Mesh Nebulizer.

◎ The AdheResp Smart Breath-actuated Mesh Nebulizer should not be used in areas where it can be exposed to known sources of electromagnetic interference (EMI) from medical devices, e.g., diathermy, electrocautery, magnetic resonance imaging (MRI), therapeutic radiation, computerized axial tomography (CT/CAT) scans, anti-theft systems, radio frequency identification (RFID), electromagnetic security system, e.g., metal detectors.

◎ Anti-theft systems and Radio Frequency Identification (RFID) readers are used in a wide variety of settings, including supermarkets, shopping malls, libraries, and hospitals. Metal detectors for airport and facility security applications, such as metal detector portals and hand-held metal detector “wands.”

– Be aware that anti-theft systems and RFID readers in commercial buildings can be hidden or camouflaged in entrances and exits invisibly.

– Do not stay near the anti-theft system, RFID reader or metal detector if not necessary. And do not lean against them.

– If you are scanned with a hand-held metal detector, inform the security personnels that you have an electronic medical device and ask them not to hold the metal detector near the device any longer than absolutely necessary; or request other alternative of metal detection.

◎ Refer to further guidance below regarding the EMC environment in which the device should be used.

Electromagnetic Compatibility

<table>
<tr><th colspan="3">Manufacturer's Declaration – Electromagnetic Emissions</th></tr>
<tr><td colspan="3">The AdheResp is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the AdheResp should assure that it is used in such an environment.</td></tr>
<tr><td>Emission Test</td><td>Compliance</td><td>Electromagnetic Environment Guidance</td></tr>
<tr><td rowspan="2">RF Emissions
CISPR 11:2015
+A1:2016
+A2:2019</td><td>Group 1</td><td>The AdheResp uses RF energy only for its internal function. Therefore, its RF-emission is very low and not likely to cause any interference nearby electronic equipment.</td></tr>
<tr><td>Class B</td><td rowspan="3">The AdheResp 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.</td></tr>
<tr><td>Harmonic Emissions
IEC 61000-3-2: 2018+A1:2020</td><td>Class A</td></tr>
<tr><td>Voltage Fluctuations / Flicker Emissions
IEC 61000-3-3: 2013+A1:2017
+A2:2021
+COR1:2022</td><td>Complies</td></tr>
</table>

Manufacturer's Declaration – Electromagnetic Immunity			
The AdheResp is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the AdheResp should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance (for home and professional healthcare environment)
Electrostatic Discharge (ESD) IEC 61000-4-2:2008	Contact: ± 8kV Air: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV	Complies	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/ Burst IEC 61000-4-4:2012	+ 2 kV for power supply lines + 1 kV for input/output lines	Complies Not applicable	Mains power quality should be that of a typical home and professional healthcare environment.
Surge IEC 61000-4-5:2014 +A1:2017	± 0.5 kV, ± 1kV line(s) to line(s) ± 0.5 kV, ± 1 kV, ± 2V	Complies Not	Mains power quality should be that of a typical home and professional healthcare environment.

	line(s) to earth	applicable	
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 :2020 +COR1:2020	Voltage dips: 0 % UT; 0,5 cycle 0 % UT; 1 cycle 70 % UT; 25/30 cycles Voltage interruptions: 0 % UT; 250/300 cycle	Complies	Mains power quality should be that of a typical home and professional healthcare environment. If the user of the AdheResp requires continued operation during power mains interruptions, it is recommended that the AdheResp be powered from an uninterruptible power supply or a battery.
Power Frequency (50, 60 Hz) Magnetic Field IEC 61000-4-8:2009	30 A/m, 50 Hz or 60 Hz	Complies	The AdheResp power frequency magnetic fields should be at levels characteristic of a typical location in a typical home and professional healthcare environment.
Conducted RF IEC 61000-4-6:2013	3Vrms: 150 kHz-80 MHz 6Vrms:	Complies	**Portable and mobile RF communications equipment should be used no closer to any part of the** AdheResp, including

+COR1:2015	In ISM and amateur radio bands between 150 kHz and 80 MHz 80% AM at 1 kHz		cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Interference may occur in the vicinity of equipment market with the following symbol: 
Radiated RF IEC 61000-4-3:2020	10 V/m 80 MHz- 2.7 GHz 80% AM at 1 kHz	Complies	

Note 1: UT is the a.c. mains voltage prior to application of the test level.

Note 2: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 3: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection form structures, objects, and people.

Recommended separation distances between portable and mobile RF communications equipment and the AdheResp

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

Rated maximum output power 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 2.7 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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 higher frequency range applies.

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

Manufacturer's Declaration – Electromagnetic Immunity
Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The AdheResp is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.
The customer or the user of the AdheResp should assure that it is used in such an environment.

Test frequency (MHz)	**Band** [a] (MHz)	**Service** [a]	**Modulation** [b]	**Maximum power** (W)	**Distance** (m)	**IMMUNITY TEST LEVEL** (V/m)	**Compliance LEVEL** (V/m) (for home and professional healthcare)
385	380 – 390	TETRA 400	Pulse modulation b) 18 Hz	1.8	0.3	27	27
450	430 – 470	GMRS 460, FRS 460	FM c) ±5 kHz deviation 1 kHz sine	2	0.3	28	28
710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0.3	9	9
810 870 930	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0.3	28	28
1 720 1 845 1 970	1,700–1,990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0.3	28	28

2 450	2,400 – 2,570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0.3	28	28
5 240 5 500 5 785	5,100 – 5,800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0.2	0.3	9	9

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Manufacturer's declaration-electromagnetic immunity
Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields

The AdheResp is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.
The customer or the user of the AdheResp should assure that it is used in such an environment.

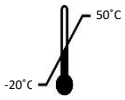
Frequencies	**Test Level [A/m]**	**Modulation**	**Dwell time [s]**	**Compliance LEVEL [A/m] (for home and professional healthcare)**
30 kHz (a)	8	CW	3	8
134.2 kHz	65	Pulse modulation (b) 2.1 kHz	3	65 (c)
13.56 MHz	7.5	Pulse modulation (b) 50 kHz	3	7.5 (c)

Note:
(a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended

for use in the HOME AND PROFESSIONAL HEALTHCARE ENVIRONMENT.
(b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
(c) r.m.s., before modulation is applied.

Symbols

	Follow instructions for use
	Caution: Read all warnings and precautions in instructions for use.
	Manufacturer
	Prescription only
IP22	The device is protected from object ingress and dripping water when tilted at 15 degrees.
	Protection class of the part used: Type BF (mouthpiece)
UDI	Unique device Identifier

	This product complies with part 15 of the FCC Rules.
	Storage and transport temperature range
	Humility limitation
	Atmospheric pressure limitation
	Disposal: separate collection for electrical and electronic equipment
	The AdheResp Smart Breath-actuated Mesh Nebulizer web page: www.HCmed-inno.com

Machine Markings

	On/Off device operation
	Key tag detecting area
MAX	Indication for the maximum fill volume of the medication container
	Green light of the battery status indicator

	Power indicator
	BLE indicator
	Orange light of the battery status indicator

INFORMATION

For further product information, please contact

HCmed Innovations Co., Ltd.:
Rm.B, 10F., No.319, Sec.2, Dunhua S. Rd., Taipei City, 10669, Taiwan
Website: www.hcmed-inno.com
E-mail: info@HCmed-inno.com
Tel: +886-2-2732-6596

Scan the QR code to visit our website at
www.hcmed-inno.com