Instruction Manual

VIB-MESH NEBULIZER

Model No. HL100R

Intended Use

This device is an ultrasonic (vibrating mesh) nebulizer system designed to aerosolize liquid medications for inhalation by the patient.

Intended User

The intended user is for adult and pediatric patients suffer from asthma, Chronic Obstructive Pulmonary Disease (COPD) such as emphysema and chronic bronchitis, or other respiratory diseases that are characterized by obstruction to air flow.

Thank you for purchasing this product.
- ⦿ To ensure safe and correct use of this product, please read the instruction manual carefully before using.
- ⦿ Please keep the instruction manual at a proper place for future reference.
- ⦿ This is a single patient device. Do not allow multiple patients to use the same device.

- A nebulizer is a type of medical device. Please follow a doctor's instructions on choosing the appropriate type, dose, and regimen of medication.
- The nebulization characteristics of the unit differ by the properties of medication. The nebulization rate may vary with using different medicine.

IMPORTANT CAUTION

As with any mechanical device, this product may become unusable due to an electrical outage, battery depletion, or mechanical failure. We recommend that you have spare batteries and a backup device available to you

Safety Precautions

To ensure safe and correct use of this product, please read the instruction manual carefully before using.

Warning

- ◆ Please follow a doctor's instructions on choosing the appropriate type, dose, and regimen of medicine.
- ◆ Do not place any liquid in the medication chamber that is not prescribed by a physician.
- ◆ This is a single patient device. Do not allow multiple patients to use the same device.
- ◆ If you are using the nebulizer for the first time after purchasing it or you have not used it for a long time, please clean the nebulizer parts. (Please see **How to clean after using**)
- ◆ After each use, please clean the medication chamber, protective cap, inhalation mask or mouthpiece and connecting tube with purified water or distilled water (room temperature). Dry the cleaned parts immediately and store in a clean place. (Please see **How to clean after using**)
- ◆ The inhalation mask and connecting tube before use must be cleaned with purified water or distilled water (room temperature) and dried.
- ◆ Do not plug or unplug the AC/DC adapter with wet hands.
- ◆ Do not modify this equipment without authorization of the manufacturer.
- ◆ Not suitable for use in aesthetic breathing systems or lung ventilator breathing systems

Caution

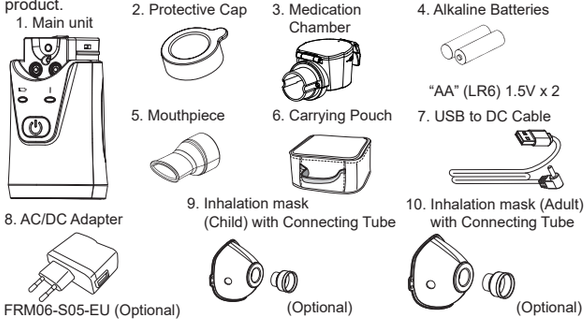
- ◆ If the device does not shut off automatically when medication depleted and foamed, press the "⏻ **START/STOP**" button to turn the power off immediately to avoid the mesh breaking. (Please see **Troubleshooting**.)
- ◆ Please clean the nebulizer parts carefully after each use. Otherwise it may not function.
- ◆ Purified water or distilled water (room temperature) is not applicable for use. The purified water or distilled water (room temperature) can be used for cleaning the medication chamber under "clean mode".
- ◆ Please do not allow q-tips or any foreign objects in contact with the mesh of the medication chamber. Otherwise the unit may not function.
- ◆ Do not drop the nebulizer. Avoid the nebulizer from a severe impact. Otherwise it may not function.
- ◆ Do not use the AC/DC adapter other than the one specifically designed for this product FRM06-S05-EU (Optional).
- ◆ Do not mix different types of batteries.
- ◆ Do not store or carry a nebulizer with liquid medication or water remaining in it.
- ◆ Do not immerse the nebulizer main unit and AC/DC adapter in water.
- ◆ Keep the device out of the reach of infants and children. Children should use only under adult's supervision.
- ◆ The patient is an intended operator. ◆ The applied part is mask or mouthpiece.
- ◆ Do not implement the maintenance procedures for equipment during measurement.
- ◆ When you use the nebulizer with AC/DC adapter, do not position the device to make it difficult to disconnect the adapter plug.

Product Features

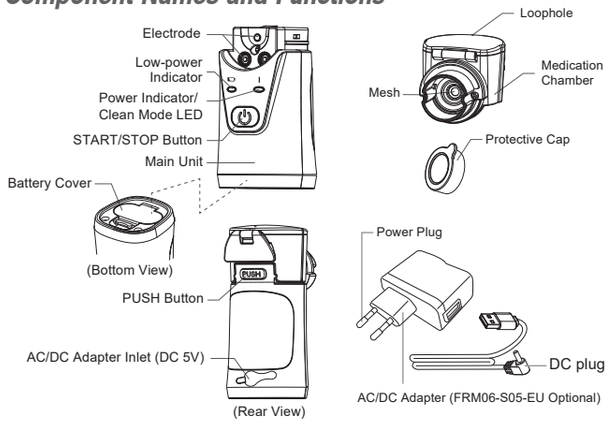
1. Pocket-sized and easy to carry.
2. Low power consumption and low residual medication volume.
3. The nebulizer can function properly for a short time after being rotated to any angle. When the nebulizer is rotated such that the medication does not contact the mesh, it can nebulize properly for about 3~10 seconds. (Time varies depending on specific medication types.)
4. Device information:
   -Not suitable for use in presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide
   -Continuous operation with short-time loading

Components

The package contains the following components. If you find any components missing, please immediately contact the retailer from which you purchased the product.



Component Names and Functions

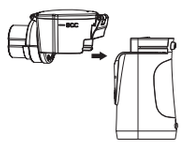


How to assemble the nebulizer

Please clean and dry the nebulizer's parts before using. (See **How to clean after using**)

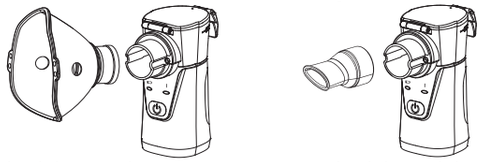
1. Attach the medication chamber to the main unit:

Attach the medication chamber to the main unit until a "Click" sound is heard.



Attention
- Please ensure that the medication chamber is attached correctly; otherwise, it may result in a bad connection and the nebulizer may not function properly.
- Please keep the electrodes of main unit and medication chamber clean; otherwise, the nebulizer may not function properly.
- Keep the small part away from children in case they inhale or swallow it.

2. Attach the inhalation mask or mouthpiece:



- Attach the connecting tube to the inhalation mask.
- Inhalation mask for children is S size.
- Inhalation mask for adults is L size.

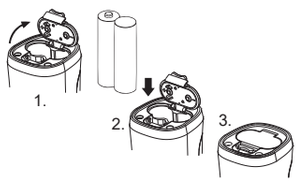
- Attach the mouthpiece. (Under normal conditions, the lifetime of the mouthpiece is approximately 6 months, three times usage per day or 30 minutes per day.)

How to connect to the power supply

This product can use either batteries or an AC/DC adapter (optional) as its power supply.

How to install batteries

Please open the battery cover and insert 2 "AA" (LR6) alkaline batteries.



1. Open the battery cover.
2. Insert the batteries so that the polarities are oriented correctly as indicated.
3. Close the battery cover.

Battery life and replacement

- Brand-new alkaline batteries can last about 3 days. (if used daily for 30 minutes)
- The orange low-power indicator light will blink when battery level is low and will remain on when batteries are completely exhausted.
- If the orange low-power indicator light is on constantly, it means that batteries are completely exhausted and it will cause the nebulizer not to work. Please immediately replace with new alkaline batteries.

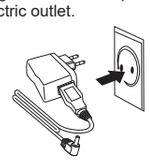
Batteries are hazardous waste. Do not dispose of them together with the household garbage. Please discard worn-out batteries to the recycling site according to local regulations.

Attention
- Do not mix different types of batteries.
- Battery life may be different depending on type of the batteries used.
- To prolong the battery life and prevent damage caused by leakage, remove the batteries from the device if the device is not to be used for a long period.

How to use the AC/DC adapter

1. Plug the AC/DC adapter's DC connector into the main unit's power supply inlet.

2. Plug the AC/DC adapter into an electric outlet.



General Recommendations
- Please purchase the AC/DC adapter specifically designed for this product. (FRM06-S05-EU Optional) Do not purchase and use AC/DC adapters of other brands.
- Please unplug the AC/DC adapter after using. Do not leave it connected to the power supply for a long time.

Attention

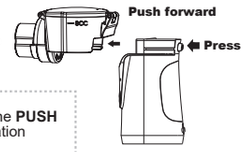
Please connect to the power supply either by installing battery or plugging AC/DC adapter. It is prohibited to replace the power supply when the device is in operation, otherwise the device may suddenly shut down.
When the device connected to the power supply successfully, the LED will flash once.

How to fill the medication

Please remove the protective cap, mouthpiece or connecting tube and inhalation mask first.

1. Remove the medication chamber from the main unit:

Press the **PUSH** button on the rear side of the main unit and push the medication chamber toward the front side of the main unit.



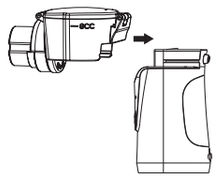
Attention
- To avoid damaging the nebulizer, please ensure the **PUSH** button is pressed down before pushing the medication chamber forward.
- To avoid rupturing the mesh, please do not poke it with your finger or other objects.

2. Fill the medication:
- ◆ Fill the medication as shown in the figure. (Recommended fill volume: Approx. 8 ml maximum / 0.5 ml minimum)
- ◆ Please close the cover of the medication chamber.

Attention
- To prevent the medication leaking from the chamber, ensure the cover is closed securely.
- The medication chamber should be detached from the main unit before the filling process.
- Do not mix medication.

3. Re-attach the medication chamber to the main unit:

Attach the medication chamber to the main unit until a "Click" sound is heard.



Attention
- Make sure the medication chamber is attached correctly or the bad connection may result in malfunction.
- To ensure the nebulizer will function properly, keep the electrodes of the main unit and the medication chamber clean.

4. Attach the inhalation mask or mouthpiece:

- Attach the connecting tube to the inhalation mask.
- Inhalation mask for children is S size.
- Inhalation mask for adults is L size.

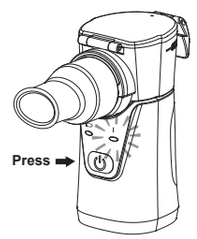
- Attach the mouthpiece.

How to operate the nebulizer

You can also fill a 0.9 % Sodium Chloride solution into the medication chamber and then press the ⏻ **START/STOP** button for a function test after reassembly and before use. If the nebulizer cannot spray out, please see **Troubleshooting**.

1. Turn on the power:

Press the ⏻ **START/STOP** button, and the power indicator (green) will light constantly.



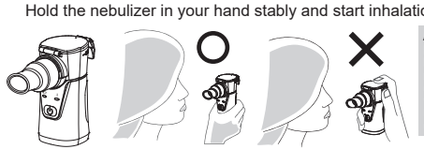
Attention
- If there is no medication inside the medication chamber and the power is turned on, the nebulizer's power indicator (green) will blink for 1 second and switch off automatically.
- The purified water or distilled water (room temperature) can be used for cleaning the medication chamber under "clean mode".
- It is normal for the nebulizer to spray for 1 second then have a 1 second slow down after turning power on. The nebulizer will spray continuously after the 1 second slow down.
- Press and hold on the ⏻ **START/STOP** button to change into the "clean mode", and the device automatically nebulizes. Do not use the "clean mode" for the medication inhalation.

Attention

When nebulizer is filled medication or normal saline, it may give off a high frequency sound during the operation. Please gently shake the device to reduce the chance of this situation.

2. Inhalation :

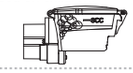
Hold the nebulizer in your hand stably and start inhalation.



Attention

Please do not touch the loophole of top cover of medication chamber, in case the medication and water flow toward the mesh then result in liquid leaking or accumulated water.

Attention
- If the device detects no medication chamber, it will shut down automatically.
- If the device does not shut down automatically when medication depleted and foamed, press the ⏻ **START/STOP** button to turn off the power immediately to avoid the mesh breaking. Please see **Troubleshooting**.
- During the treatment, you may adjust the nebulizer to any angle. However, make sure the medication stays in contact with the mesh; otherwise, the nebulizer will shut down automatically after approximately 10 seconds.
- When the medication is about to be depleted, it is recommended that you tilt the nebulizer (the buttons side) slightly toward you. This allows the remaining medication to contact the mesh to nebulization.
- Do not shake the nebulizer strongly in the usage. Otherwise, the nebulizer may shut down automatically.
- Close adult supervision is highly recommended when the nebulizer is used on children.
- When the foam gathers between the mesh and medication chamber, it may cause mesh vibration and result in mesh breaking. Press the ⏻ **START/STOP** button to turn the power off immediately, and gently shake the device and restart again.



3. Turn off the power :

- ◆ The nebulizer shuts off automatically after the medication is depleted.
- ◆ If you wish to halt the treatment, press the ⏻ **START/STOP** button to turn the power off. The power indicator light will go out.
- ◆ If the AC/DC adapter is being used, please unplug from the wall outlet after turning off the power.

Attention

The nebulizer shut down automatically after 30 minutes.

How to clean after using

After each use, make sure to clean the nebulizer immediately with the purified water or distilled water (room temperature) before storing or carrying.

1. Clean the remaining medication :
- ◆ Detach the medication chamber from the main unit. Soak it in the purified water or distilled water (room temperature) for 15 minutes.
- ◆ The purified water or distilled water (room temperature) is recommended for filling the medication chamber. Securely close the lid, then attach medication chamber to the main unit.
- ◆ Press and hold the ⏻ **START/STOP** button until the blue light is on constantly, the main unit switch to clean mode. The clean mode will automatically stop after approximately 30 seconds.
- ◆ If the mesh is clogged, use purified water or distilled water (room temperature) to clean the medication chamber for 30 seconds. Then go to the above cleaning step and air drying it completely.

Attention
- Do not use other cleaning solution. The purified water or distilled water (room temperature) is the only recommended solution for cleaning.
- Repeat cleaning steps if see residual.

Attention
- If the device gives off the high frequency sound and the purified water or distilled water (room temperature) is depleted, please press the ⏻ **START/STOP** button to turn the power off. Otherwise, the mesh of the medication chamber may be broken.
- Please clean the remaining medication after each use. Otherwise, the mesh of the medication chamber may be blocked.
- It is normal for the nebulizer to spray for 1 second then have a 1 second slow down after turning power on. The nebulizer will spray continuously after the 1 second slow down.

2. Dismantle the nebulizer:

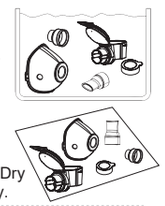
Remove the medication chamber, protective cap, inhalation mask or mouthpiece and connecting tube from the main unit.

Attention

The inhalation mask or mouthpiece and connecting tube, protective cap must be cleaned with the purified water or distilled water (room temperature) and dried.

3. Clean the parts with sufficient amounts of purified water or distilled water (room temperature):

Place the medication chamber, protective cap, inhalation mask or mouthpiece, and connecting tube into purified water or distilled water (room temperature) and soak for 15 minutes. To clean the mesh, press and hold the ⏻ **START/STOP** button to operate the unit. Clean the mesh with 0.5 ml purified water or distilled water (room temperature) solution.

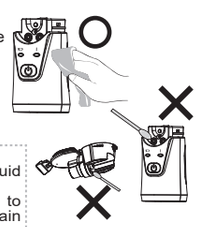


4. Dry the cleaned parts thoroughly:

After cleaning, remove the parts from the cleaning solution. Dry the parts with new gauze and let the parts to air dry thoroughly.

Attention
- Please do not dry the nebulizer with cotton or cloths of other materials; otherwise, dust or cloth fiber may be left on the mesh, causing the nebulizer to malfunction.
- Please do not allow q-tips or foreign objects in contact with the mesh of the medication chamber.

5. Wipe off the main unit with new gauze:



- ◆ Dab a piece of gauze with water and lightly wipe off the stains from the main unit. Then, use new gauze to dry the main unit.
- ◆ Clean the electrodes on the main unit and medication chamber. This ensures a normal electrical conduction and hence a normal nebulization.

Attention
- Please do not clean the nebulizer with a volatile liquid such as benzene or thinner.
- Please do not allow q-tips or foreign objects poke to silicone ring to make falling off from the electrode of main unit.

6. Attach the medication chamber and put on the protective cap. Store all parts in a clean place.

The medication chamber is a maintenance part and does not carry any warranty. Under normal conditions, the lifetime of the medication chamber is approximately 6 months (based on H&L's reliability test results – three times usage per day or 30 minutes per day). However, the nebulization performance may start deteriorating in less than 6 months depending on the way you use it or the use of certain types of medication. If the nebulizer cannot nebulize or the nebulization rate decreases significantly after cleaning, you must replace the medication chamber with a new one. (If you want to purchase a medication chamber, please contact the retailer from which you purchased the product or any nearby retailers.)

7. Accessory Durability and Replacement Recommendations

Medication chamber/ mouthpiece/ inhalation mask are expected to replace every 6 months after unsealing. Accessories are intended to use with device 10 minutes per time / 3 times usage per day.

How to disinfect chamber and accessories

Before disinfecting, please follow the **How to clean after using** section to clean and request that the disinfecting action be performed at the following time.

- Before using the unit for the first time
- After a long period of not used or after use
- Every day during normal use

Disinfection method:

Please put medication chamber, mouthpieces, and other accessories (excluding the main unit) into 70~75% alcohol and soak for about 1 minute, then discard the soaked alcohol, rinse with the purified water or distilled water (room temperature), air drying it on a clean, lint-free tissue or fluff. Or use a lint-free tissue or lint-free cloth to dip in 70-75% alcohol to clean the chamber and mouthpiece and then rinse with the purified water or distilled water (room temperature), place it on a clean lint-free tissue or lint-free cloth.

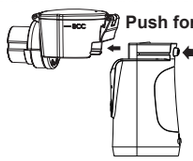
NOTE

1. Due to the complexity of the actual use of drugs and cleanliness, it will still affect the disinfection effect. It is recommended that users replace the relevant accessories depending on the actual use conditions and the recommended use period.
2. If the device is not properly and frequently cleaned and disinfected, microorganisms may remain in the device, posing an infection risk.
3. Alcohol is a highly flammable substance. Keep away from fire when using it.
4. Repeat disinfecting steps if see residual.

How to replace the medication chamber

1. Remove the medication chamber from the nebulizer:

Press the **PUSH** button on the rear side of the main unit, and push the medication chamber toward the front side of the main unit.



Attention

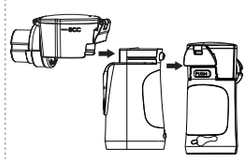
- To avoid damaging the nebulizer, please ensure the **PUSH** button is pressed down before pushing the medication chamber forward.
- To avoid rupturing the mesh, please do not poke it with your finger or other foreign object.

2. Re-attach the medication chamber to the nebulizer

Attach the medication chamber correctly as shown in the figure.

Attention

- Please ensure that the medication chamber is attached correctly; otherwise, it may result in a bad connection and cause the nebulizer to not function properly.
- Please keep the electrodes of the main unit and medication chamber clean; otherwise, the nebulizer may not function properly.
- Please clean the medication chamber before use.

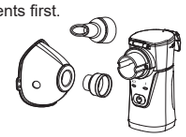


How to carry the nebulizer

Please follow the steps below to dismantle the components first. Then, store them in the carrying pouch for carrying.

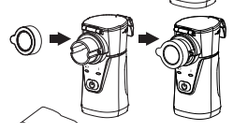
1. Dismantle the nebulizer:

Please remove the mouthpiece or connecting tube and inhalation mask as shown in the figure.



2. Put on the protective cap:

Please put on the protective cap as shown in the figure. This will protect the nebulizer from possible damage during carrying.



3. AC/DC adapter (Optional):

For easy carrying, please bind the AC/DC adapter and its electric wire together with a ribbon band as shown in the figure.

4. Place the main unit and associated parts into the carrying pouch for carrying or storage.

Attention

- Please do not carry the nebulizer that still contains medication or water. The medication may leak and damage or stain the nebulizer.
- Do not store the nebulizer in an area under high temperature or humidity, or in direct sunlight.

Troubleshooting

Please refer to the table below to troubleshoot any problems you may encounter when using the nebulizer.

Problems	Possible Causes	Solutions
Extremely low nebulization.	Medication chamber is not completely attached.	Re-attach the medication chamber correctly and restart the power. (See **How to assemble the nebulizer** section)
	No contact between medication and mesh for more than 10 seconds.	Adjust the nebulizer's angle so the medication can come in contact. (See **How to operate the nebulizer** section)
	Mesh of medication chamber is clogged.	Clean the medication chamber. If it still cannot be used after cleaning, please replace with a new medication chamber. (See **How to clean after using** section)
	Electrodes on medication chamber are clogged with medication or water.	Clear the electrodes of clogged medication or water and restart the power. (See **How to clean after using** section)
	Electrodes on nebulizer and medication chamber are stained.	Remove the stains and restart the power. (See **How to clean after using** section)
After turning power on, power indicator lights for one second and then immediately goes out.	Medication chamber is not completely attached.	Re-attach the medication chamber correctly and restart the power. (See **How to assemble the nebulizer** section)
	No medication in medication chamber.	Fill the medication into the medication chamber. (See **How to fill the medication** section)
	No contact between medication and mesh.	Adjust the nebulizer's angle so the medication can come in contact. (See **How to operate the nebulizer** section)
	Electrodes on nebulizer and medication chamber are stained.	Remove the stains and restart the power. (See **How to clean after using** section)
Power indicator is not lit and nebulizer is not nebulizing.	Batteries installed backwards.	Re-install the batteries in the correct orientation and restart the power. (See **How to connect to the power supply** section)
	Low battery power.	Replace with new batteries and restart the power. (See **How to connect to the power supply** section)
	Incorrect connection of AC/DC adapter to nebulizer.	Re-connect in the correct manner and restart the power. (See **How to connect to the power supply** section)
Power indicator is lit and nebulizer is not nebulizing.	Low-power indicator is lit constantly, insufficient battery power, or battery has run out.	Replace with new batteries and restart the power. (See **How to connect to the power supply** section)
	Rupture of mesh of medication chamber.	Replace with a new medication chamber and then fill in the medication. (See **How to replace the medication chamber** section)
	Electrodes on medication chamber are clogged with medication or water.	Clear the electrodes of clogged medication or water and restart the power. (See **How to clean after using** section)
	Electrodes on nebulizer and medication chamber are stained.	Remove the stains and restart the power. (See **How to clean after using** section)
	Mesh of medication chamber is severely clogged.	If it still cannot be used after cleaning, please replace with a new medication chamber. (See **How to clean after using** section)
Nebulizer shuts off in usage.	Medication chamber is loosened and not completely attached.	Re-attach the medication chamber correctly and restart the power. (See **How to assemble the nebulizer** section)
	Connection of AC/DC adapter to nebulizer is loosened.	Re-connect in the correct manner and restart the power. (Please reference **How to connect to the power supply** section)
	Medication has run out.	Fill the medication into the medication chamber. (See **How to fill the medication** section)
	No contact between medication and mesh for more than 10 seconds.	Adjust the nebulizer's angle so the medication can come in contact. (See **How to operate the nebulizer** section)
	Nebulizer is being shaken in the use.	Hold the nebulizer in the hand stably. (See **How to operate the nebulizer** section)
	Medication chamber is broken.	Replace with a new medication chamber and then fill in the medication. (See **How to replace the medication chamber** section)
	The voltage of the nebulizer drops rapidly	Restart the power.(See **How to operate the nebulizer** section)
Nebulizer does not shut off automatically while medication depleted.	Some type of medications for nebulization maybe cause to produce a lot of foam in the medication chamber.	Clean the foam and restart the power. (See **How to operate the nebulizer** section)
	Electrodes on medication chamber are clogged with medication or water.	Clear the electrodes of clogged medication or water and restart the power. (See **How to clean after using** section)
	Electrodes on nebulizer and medication chamber are stained.	Remove the stains and restart the power. (See **How to clean after using** section)
	Medication chamber is broken.	Purchase and replace with a new medication chamber. (See **How to replace the medication chamber** section)
Nebulizer does not start	Some type of medications for nebulization maybe cause to produce a lot of foam in the medication chamber.	Clean the foam and restart the power. (See **How to operate the nebulizer** section)
	Electrodes on medication chamber are clogged with medication or water.	Clear the electrodes of clogged medication or water and restart the power. (See **How to clean after using** section)
	Electrodes on nebulizer and medication chamber are stained.	Remove the stains and restart the power. (See **How to clean after using** section)
	Medication chamber is broken.	Purchase and replace with a new medication chamber. (See **How to replace the medication chamber** section)
Overflow of medication from medication chamber.	Rupture of medication chamber or ageing of silicone ring.	Replace with a new medication chamber and then fill in the medication. (See **How to replace the medication chamber** section)

If your nebulizer still does not function properly after trying the solutions mentioned above, please contact the retailer from which you purchased the product.

Device Information

Declaration/ Attention

When user(s) wants to verify the overall performance of the device, Saline water is the only recommended liquid to identify our quality responsibility. Any other liquid or medications results may vary.

Repair or service cost will be at the user(s) account if any one of the following conditions happens during the period of warranty:

1. Does not follow the instruction manual and/ or does not operate properly which may cause misuse or abuse circumstances,
2. Alteration and/ or modification to the product,
3. Environmental conditions (e.g. fire, or other natural disasters),
4. Error result/ failure from human factors,
5. Parts or components not produced by original manufacturer.

Specifications

Product Name	Vib-Mesh Nebulizer
Model	HL100R
Method of Operation	Ultrasonic
Dimensions	Approx. 66.6 mm (L) × 41.7 mm (W) × 93.5 mm (H)
Weight	Approx. 82±3g (Exclude batteries)
Power Supply	1. DC 3V, AA "LR6" (1.5V) Alkaline Battery x 2 2. AC/DC Adapter: Input: AC 100~240V, 50/60 Hz; Output: DC 5V, 1.2A
Power Consumption	Approx. 2.5 W
Recommended Fill Volume	Approx. 8 ml maximum Approx. 0.5 ml minimum
Battery Life	Up to approximately 1.5 hours if used continuously. (Use 2 AA "LR6" (1.5V) alkaline batteries)
Warranty	2 years (Excluded medication chamber)
Product Life (Main Unit)	5 years or 5500 times (3 times usage per day)
Medication chamber Life	6 months after unsealing
Mouthpiece Life	6 months after unsealing
Inhalation Mask Life	6 months after unsealing
Operating Conditions	5°C~40°C (41°F~104°F), 15~93%R.H., non-condensing Atmospheric pressure: 700hPa~1060hPa
Storage / Transportation Conditions	-25°C~70°C (-13°F~158°F), ≦93%R.H., non-condensing
Accessories	Protective cap, mouthpiece, alkaline batteries, carrying pouch, instruction manual. Inhalation mask (Child) with connecting tube (optional), Inhalation mask (Adult) with connecting tube (optional), AC/DC adapter (optional)

The nebulizer gives off the high frequency sound and shuts off automatically if the medication is not in contact with the mesh of the medication chamber for more than 10 seconds (time varies for different types of medication) or the medication is depleted.

Technical data

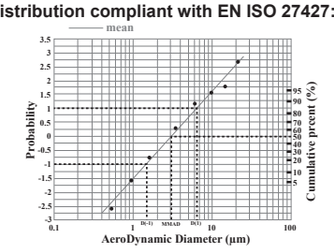
Technical data for Health & Life HL100R nebulizer kit: (According to Test Report_Aerosol output rate pdf.)

Particle Size: MMAD ≦ 5.5 microns (2ml, 2.5% NaF)
Nebulization Rate: 0.2~1.0 ml/min (by weight loss)
Aerosol Output: ≧ 1.2 ml (2ml,1% NaF)
Aerosol Output Rate: ≧ 0.2 ml/min (2ml,1% NaF)

Note:

· Performance may vary with different drugs such as suspensions or high viscosity. See drugs supplier's data sheet for further details.
· The data above is referenced by Health & Life.
· MMAD = Mass Median Aerodynamic Diameter.

Particle size distribution compliant with EN ISO 27427:2019



stage No.	Effective cutoff dia. (μm)	Cumulative fraction (%) Test 1	Test 2	Test 3	Test 4	Mean	Mean collected mass per minute for each stage (μg/min)	Mean mass fraction for each stage (%)
8	0.53	0.45	0.45	0.47	0.52	0.47	3.18	0.48
7	0.93	5.56	6.21	5.56	5.85	5.79	35.65	5.34
6	1.6	22.23	22.72	22.70	22.64	22.57	112.38	16.83
5	3.5	61.44	61.19	61.56	61.34	61.38	260.00	38.95
4	6	88.37	88.19	88.31	88.10	88.24	179.95	26.96
3	9.8	94.29	93.95	94.12	94.01	94.09	39.20	5.87
2	14.8	96.55	96.41	96.63	96.57	96.54	16.40	2.46
1	21.3	99.64	99.62	99.62	99.68	99.64	20.78	3.11
Total							667.53	

Test result of cascade impact or measurements for particle size with Health & Life HL100R.

Accessories / Optional parts

Accessories / Optional parts are shown below. If you wish to purchase any of them, please contact the retailer from which you purchased the nebulizer.

HL100R-MC: Inhalation mask (Child) with Connecting Tube (Optional)

HL100R-MA: Inhalation mask (Adult) with Connecting Tube (Optional)

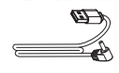
HL100R-MB: Medication Chamber

HL100R-PC: Protective Cap

HL100R-MP: Mouthpiece

AC/DC Adapter (Optional)

USB to DC Cable



HL100R-CP: Carrying Pouch

A testing per EN ISO 27427:2019 demonstrating that the performance of all the components of HL100R shown as above is consistent with the requirements. Also, for those optional accessories are in conformity with the essential requirements of the European Medical Device Directive.

Note:

This Nebulizer complies with the EC Directive (93/42/EEC) and bears the CE mark. CE 0197
This nebulizer also complies with mainly following standards (included but not limited)

Safety standard:
EN 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EMC standard:
EN 60601-1-2 Medical electrical equipment part 1-2: General requirements for safety- Collateral standard: Electromagnetic compatibility- Requirements and tests
Performance standards:
EN ISO 27427:2019 Anaesthetic and respiratory equipment — Nebulizing systems and components
AC Adapter Supplier: FranMar International Inc.

Explanation of Symbols

Symbol	Explanation	Health & Life Information
CE	CE conformity marking	-
0197	Notified Body (NB) number	-
	Refer to instruction manual/ booklet	-
	BF Classification	-Internally powered equipment -BF type applied part -Not suitable for use in presence of flammable anesthetic mixture with air or Oxygen or nitrous oxide -Continuous operation with short-time loading
	Single patient multiple use	-
	To avoid inaccurate results caused by electromagnetic interference	Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the device. Otherwise, degradation of the performance of this equipment could result.
	Waste of electrical and electronic equipment (WEEE)	Discard the used product to the recycling collection point according to local regulations.
	Battery of disposal	Discard batteries to the recycling collection point according to local regulations.
	Manufacturer	HEALTH & LIFE Co., Ltd. 9F, No.186, Jian Yi Road, Zhonghe District, New Taipei City 23553, Taiwan www.healthandlife.com.tw
	Date of manufacture	YYYY-MM
EU REP	Authorized representative in the European Community	EMERGO EUROPE B.V. Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands
SN	Serial number	YYMMXXXXXX
LOT	Batch Code	2YYM0XX
	Importer –if applicable with Name and address	-
	Distributor–if applicable with Name and address	-
IP22	Ingress Protection Rating	Ingress Protection degree provided by IEC 60529
	Humidity limitation	-
	Temperature limit	-
	Atmospheric pressure limitation	-
	Non-ionizing electromagnetic radiation	-
MD	Medical Device	-
	Keep away from sunlight	-
CN	Country of manufacture	-

Manufacturer: HEALTH & LIFE CO., LTD.
9F, No. 186, Jian Yi Road, Zhonghe District, New Taipei City 23553, Taiwan
www.healthandlife.com.tw

Appendix: EMC information

Guidance and manufacturer's declaration – electromagnetic emissions

The device is intended for use in the electromagnetic environments listed below, and should only be used in such environments:

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	RF energy is used only to maintain device's operation. Therefore, its RF emissions are so low that it's not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device 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 A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

The device is intended for use in the electromagnetic environments listed below, and should only be used in such environments:

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact discharge ± 15 kV air discharge	± 8 kV contact discharge ± 15 kV air discharge	In the case of air discharge testing, the climatic conditions shall be within the following ranges: Ambient Temperature: 15°C ~ 35°C, Relative Humidity: 30%~60%.
Power frequency (50 or 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 or 60 Hz	30 A/m 50 or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	AC Power port ±1 KV Line to Line	AC Power port ±1 KV Line to Line	Mains power quality should be that of a typical commercial or hospital environment.
interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% *UT*; 0.5 cycle At 0°,45°,90°, 135°,180°,225°, 270°and 315°.0 % *UT*; 1 cycles 70 % *UT*; 25/30 cycles 0 % *UT*; 250/300 cycle	0% *UT*; 0.5 cycle At 0°,45°,90°, 135°,180°,225°, 270°and 315°. 0 % *UT*; 1 cycles 70 % *UT*; 25 cycles 0 % *UT*; 250 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Conducted RF IEC 61000-4-6	3V rms At 0.15-80 MHz 6V rms At ISM & Radio Amateur Freq.	3V rms At 0.15-80 MHz 6V rms At ISM & Radio Amateur Freq.	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3 (Proximity fields from RF wireless communications equipment IEC 61000-4-3)	10 V/m at 80-2700 MHz AM Modulation And 9-28V/m at 385-6000MHz, Pulse Mode and other Modulation. The system shall be tested as specified in IEC60601-1-2 Table 9 for proximity fields from RF wireless communications equipment using the test methods specified in IEC 61000-4-3	10 V/m at 80-2700 MHz AM Modulation And 9-28V/m at 385-6000MHz, Pulse Mode and other Modulation. The system shall be tested as specified in IEC60601-1-2 Table 9 for proximity fields from RF wireless communications equipment using the test methods specified in IEC 61000-4-3	**Recommended separation distance** Considering to reduce the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation: $E = 6/d\sqrt{P}$ where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVELS in V/m. 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:

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 from structures, objects and people.

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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Test specifications for enclosure port immunity to RF wireless communications equipment.

Test frequency (MHz)	Modulation	IMMUNITY TEST LEVEL (V/m)
385	Pulse modulation 18 Hz a)	27
450	FM ± 5 kHz deviation 1kHz sine b)	28
710 745 780	Pulse modulation 217 Hz a)	9
810 870 930	Pulse modulation 18 Hz a)	28
1720 1845 1970	Pulse modulation 217 Hz a)	28
2450	Pulse modulation 217 Hz a)	28
5240 5500 5785	Pulse modulation 217 Hz a)	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). The carrier shall be modulated using a 50% duty cycle square wave signal.
b). 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.

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