Model **MD631**

Instruction Manual

VIBRATING MESH PORTABLE NEBULISER

Intended Use:

This device utilizes state-of-the-art electrospray technology that sprays liquid medication in aerosol form and delivers it directly to the patient for breathing.

Intended User:

Adult and paediatric patients suffer from asthma, Chronic Obstructive Pulmonary Disease (COPD) such as emphysema and chronic bronchitis, or other respiratory diseases that are characterized by obstruction of 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.

Contents

VIBRATING MESH PORTABLE NEBULISER

- A nebuliser is a type of medical apparatus. Please follow a doctor's instructions on choosing the correct 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.

ATTENTION / WARNING

DO NOT INSERT COTTON BUDS OR OTHER SHARP / POINTED DEVICE OR ANY FOREIGN OBJECTS INTO THE MEDICATION CHAMBER.

Clean the medication chamber after each use.

Use distilled water for cleaning (see page 14 & 15 for further cleaning information).

This nebuliser is designed to automatically shut-off when the medication chamber is empty. If it fails to do so, press the "START/STOP" button to turn the power off to avoid damage to the mesh. (See page 19 for troubleshooting).

The nebuliser may give off a high-pitched sound during the operation. Please gently shake the device which will reduce the noise.

See additional safety precautions on page 4 of the User's Manual.

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 correct 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 nebuliser for the first time after purchasing it or you have not used it for a long time, please clean the nebuliser parts. (Please see page 14-15)
- After each use, please clean the medication chamber, protective cap and mouthpiece with distilled water. Dry the cleaned parts immediately and store in a clean place. (Please see page 14-15)
- The inhalation mask and connecting tube in first use must be cleaned with distilled water and dried.
- Do not plug or unplug the AC adapter with wet hands.
- Do not modify this equipment without authorization of the manufacturer.

Caution

- If the device does not shut off automatically when medication is depleted and foamed, press the "START/STOP" button to turn the power off immediately to avoid the mesh breaking. Please go to page 19 for troubleshooting.
- DO NOT use the device without medication or water in the medication chamber to avoid the mesh breaking.
- Please clean the nebuliser parts carefully after each use. Otherwise it may not function.
- Purified water is not applicable for use. If you fill purified water in the medication chamber, the nebuliser cannot be turned on. Purified water 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 nebuliser. Avoid the nebuliser from a severe impact. Otherwise it may not function.
- Do not use the AC adapter other than the one specifically designed for this product.
- Do not mix different types of batteries.
- Do not store or carry a nebuliser with liquid medication or water remaining in it.
- Do not immerse the nebuliser main unit and AC adapter in water.
- Keep the device out of the reach of infants and children. Children should use only under adult's supervision.

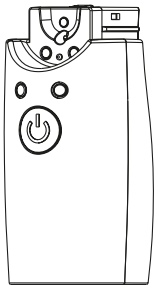
Product Features

1. Pocket-sized and easy to carry.
2. Low power consumption and low residual medication volume.
3. The nebuliser can function properly for a short time after being rotated to any angle. When the nebuliser is rotated such that the medication does not contact the mesh, it can nebulise properly for about 10 seconds. (Time varies depending on specific medication types.)

Components

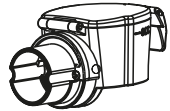
The package contains the following components. If you find any components missing, please immediately contact the retailer from which you purchased the product.

1. Main unit



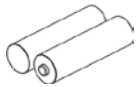
2. Protective Cap

3. Medication chamber

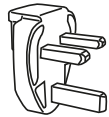


4. Mouthpiece

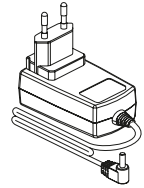
5. Alkaline batteries "AA" 1.5V/LR6 x 2



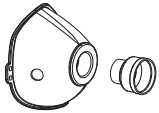
6. 3 Pin Plug



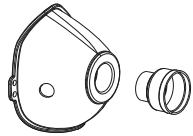
7. AC Adapter



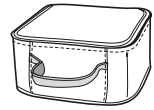
8. Inhalation mask (S) with connecting tube



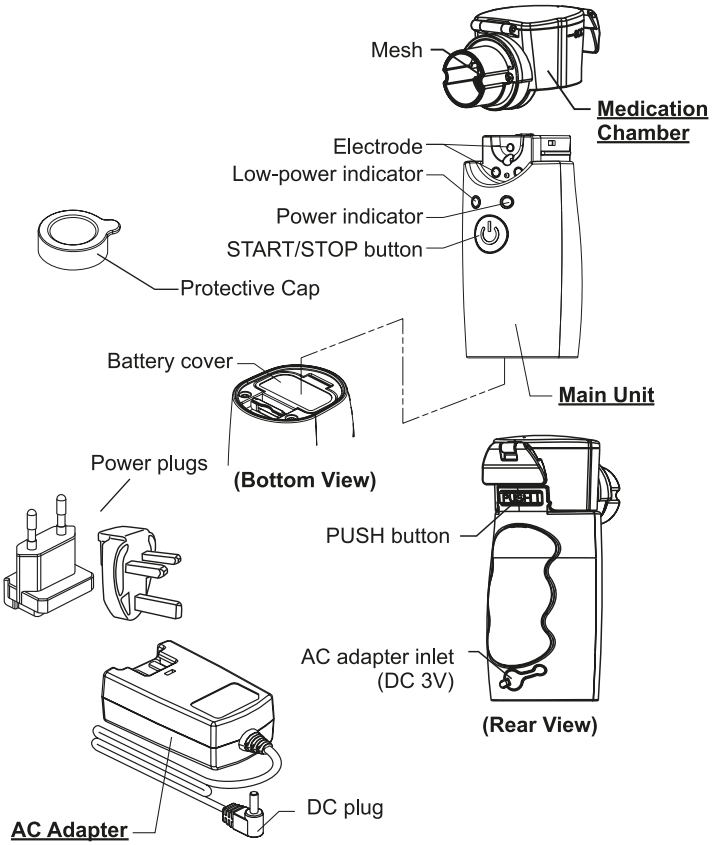
9. Inhalation mask (L) with connecting tube



10. Carrying pouch



Component Names and Functions

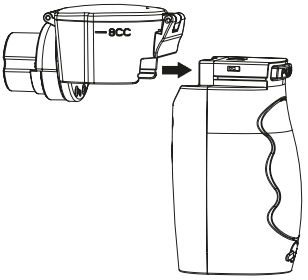


How to assemble the nebuliser

Please clean and dry the nebuliser's parts before using. (See pages 14-15)

1. Attach the medication chamber to the main unit:

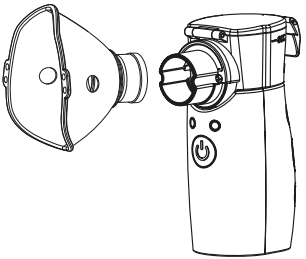
Attach the medication chamber while it gives off a sound "Click".



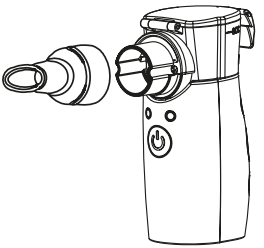
Attention

- Please ensure that the medication chamber is attached correctly; otherwise, it may result in a bad connection and the nebuliser may not function properly.
- Please keep the electrodes of main unit and medication chamber clean; otherwise, the nebuliser may not function properly.
- Under normal conditions the lifetime of the mouthpiece is approximately 2 years, three times usage per day or 30 minutes per day.
- 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.

How to connect to the power supply

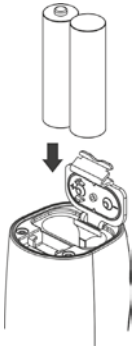
This product can use either batteries or an AC adapter (optional) as its power supply.

■ **How to install batteries**

Please open the battery cover and insert 2 “AA/LR6” alkaline batteries.

1. Open the battery cover.

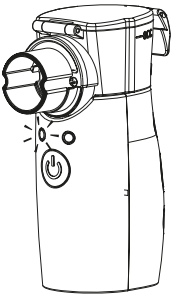
2. Insert the batteries so that the polarities are oriented correctly, as indicated.



3. Close the battery cover.

Battery life and replacement

- Brand-new alkaline batteries can last about 4 days. (if used daily for 20 minutes)
- When the low-power indicator starts blinking (orange color), it means the batteries need to be replaced. Please immediately replace with new alkaline batteries. (Under normal circumstances, the nebuliser can be used for roughly another 10 minutes with alkaline batteries.)
- If the low-power indicator lights on constantly (orange color), it means that extremely low power caused the nebuliser not to work. Please immediately replace with new alkaline batteries.

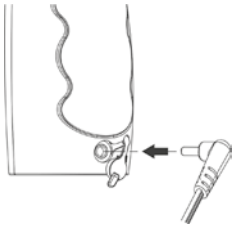


Attention

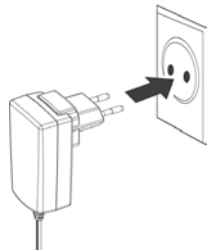
- Do not mix different types of batteries.
- Battery life may be different depending on type of the batteries used.
- To prolong the battery life and prevent damage caused by leakage, remove the batteries from the device if the device is not to be used for a long period.

■ How to use the AC Adapter

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



2. Plug the AC adapter into an electric outlet.



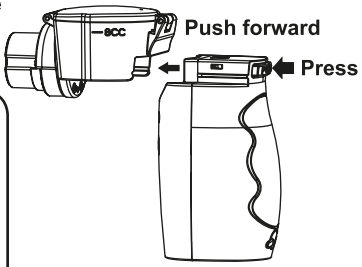
General Recommendations

- Please purchase the AC adapter specifically designed for this product. Do not purchase and use AC adapters of other brands.
- Please unplug the AC adapter after using. Do not leave it connected to the power supply for a long time.

How to fill the medication

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

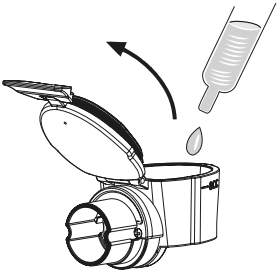
1. **Remove the medication chamber from the main unit:**
   Press the PUSH button on the rear side of the main unit and push the medication chamber toward the front side of the main unit.



Attention

- To avoid damaging the nebuliser, 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.

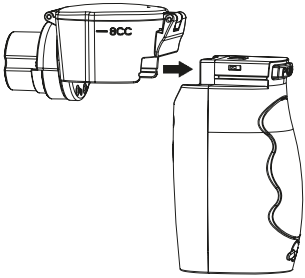
2. **Fill the medication:**
   - Fill the medication as shown in the figure. (Recommended fill volume: Approx. 8 ml maximum / 0.5 ml minimum)
   - Please close the cover of the medication chamber.



Attention

- To prevent the medication leaking from the chamber, ensure the cover is closed securely.
- The filling process should be done while the chamber detached from the main unit.

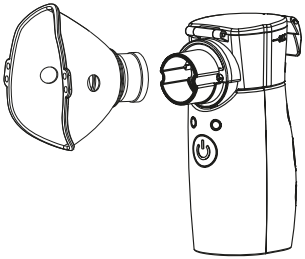
3. Re-attach the medication chamber to the main unit:
Attach the medication chamber while it gives off a sound “Click”.



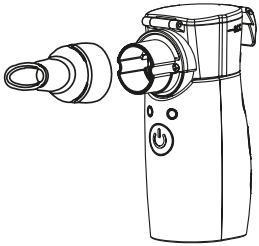
Attention

- Make sure the medication chamber is attached correctly or the bad connection may result in malfunction.
- To ensure the nebuliser 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.

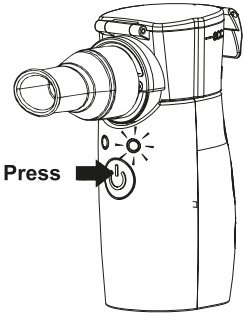
How to operate the nebuliser

You can also fill a 0.9 % Sodium Chloride solution in the medication chamber and then press “START/STOP” button for a function test after reassembly and before use. If the nebuliser can not spay out, please go to page 19 for 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 nebuliser’s power indicator (green) will blink for 1 second and shut off automatically.
- Purified water is not applicable for use. If you fill the water in the medication chamber, the nebuliser’s can be not turned on.
- It is normal for the nebuliser spraying 1 second then having 0.5 second pause after turning power on. However, it will spray continuously after that 0.5 second pause.
- Press and hold on the “START/STOP” button to change into the “cleaning mode”, and the device manually nebulises. Do not use the “cleaning mode” for the medication inhalation.

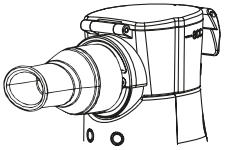


Attention

When nebuliser is filled with medication or normal saline, it may give off a high frequency sound during the operation. Please gently waver the device that will help to reduce the chance of situation happened.

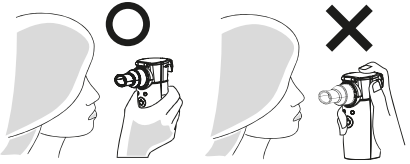
2. Inhalation:

Hold the nebuliser in your hand stably and start inhalation.



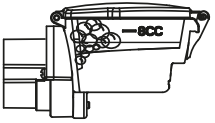
Attention

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



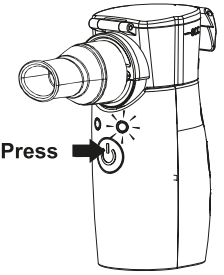
Attention

- If the device detects no medication in medication chamber, it will shut off automatically.
- 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 go to page 19 for troubleshooting.
- During the treatment, you may adjust the nebuliser to any angle. However, make sure the medication stays in contact with the mesh; otherwise, the nebuliser will shut off automatically after approximately 10 seconds.
- When the medication is about to be depleted, it is recommended that you tilt the nebuliser (the buttons side) slightly toward you. This allows the remaining medication to contact the mesh to nebulization
- Do not shake the nebuliser strongly in the usage. Otherwise, the nebuliser may shut off automatically
- Provide close supervision when the nebuliser is used by children.
- When the foam gathers between the mesh and medication chamber, it may cause mesh vibration and result in the mesh breaking. Press the START/STOP button to turn the power off immediately, and gently wave the device and restart again.



3. Turn off the power:

- The nebuliser 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 adapter is being used, please unplug from the wall outlet after turning off the power.
- The unit will give off a high frequency sound and turn off the power automatically when the medication is depleted.



How to clean after using

After each use, make sure to clean the nebuliser instantly with distilled water before storing or carrying.

1. Clean the remaining medication

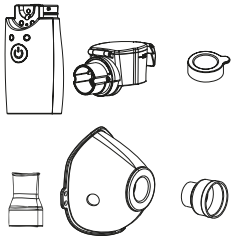
- Open the cover of the medication chamber and discard the remaining medication.
- Pour a small amount of distilled water into the medication chamber and close the cover.
- Press and hold on the “START/STOP” button of the device (until the power indicator lights up in blue) to change into “cleaning mode” and manually nebulise the distilled water for 1 to 2 minutes to remove the residual medication in the medication chamber until the distilled water depleted.

Attention

- If the device gives off the high frequency sound and the distilled water is depleted, please release 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 become blocked.

2. Dismantle the nebuliser:

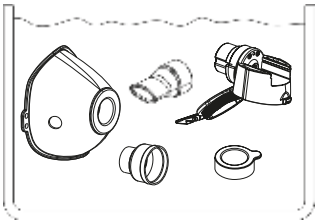
Remove the medication chamber, connecting tube, and inhalation mask or mouthpiece from the nebuliser.



Attention

- Before using the inhalation mask and connecting tube they must be cleaned with distilled water and allowed to air-dry.

3. Clean the parts with sufficient amounts of distilled water: Place protective cap, mouthpiece, medication chamber, inhalation mask, and connecting tube into distilled water and soak for 15 minutes.



To clean the mesh if it is clogged:

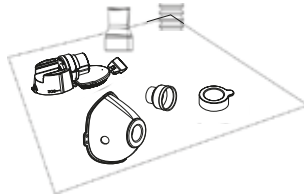
- Pour a solution of 1 part white vinegar and 3 parts water into the medication chamber and close the cover.
- Press and hold on the “START/STOP” button of the device (until the power indicator lights up in blue) to change into “cleaning mode” and manually nebulise the solution for 3 minutes. Then flush the parts with distilled water.

NOTE: Do not use any other cleaning solution. A solution of 1 part white vinegar and 3 parts water is only recommended for cleaning.

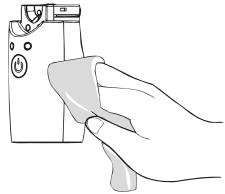
4. Dry the cleaned parts thoroughly:
After the parts are cleaned, remove from the cleaning solution. Pat the parts dry with new gauze and leave to air dry thoroughly.

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

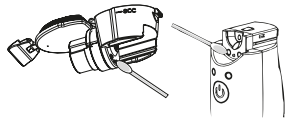
Attention
- If medication chamber nozzle is clogged with a lot of medication or water, it actively turns off
- Clear the electrodes of clogged medication or water and restart the power



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.
- Please 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 nebuliser with a volatile liquid such as benzene or thinner.
- Please do not allow q-tips or foreign objects to poke the silicone ring, this will cause it to fall off from the electrode of the main unit.

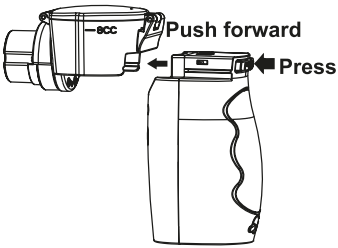


6. Attach the medication chamber and put on the protective cap. Store all parts in a clean place.

How to replace the medication chamber

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 (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 nebuliser can not nebulise or the nebulisation rate decreases significantly after clean, 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.)

1. **Remove the medication chamber from the nebuliser:**
   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.



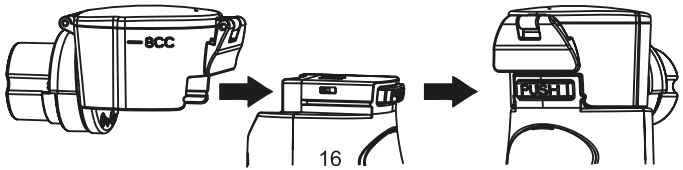
Attention

- To avoid damaging the nebuliser, 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.

Attention

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

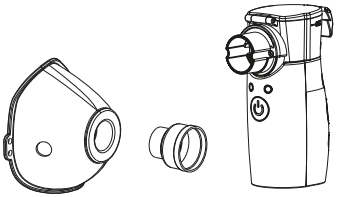
2. **Re-attach the medication chamber to the nebuliser**
   Attach the medication chamber correctly as shown in the figure.

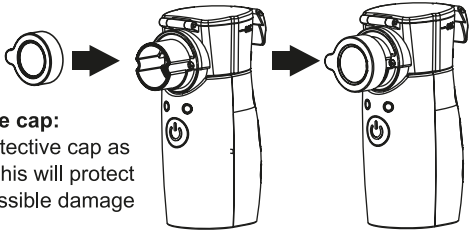


How to carry the nebuliser

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

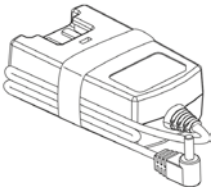
1. **Dismantle the nebuliser:**
   Please remove the mouthpiece or connecting tube and inhalation mask as shown in the figure.





2. **Put on the protective cap:**
   Please put on the protective cap as shown in the figure. This will protect the nebuliser from possible damage during carrying.

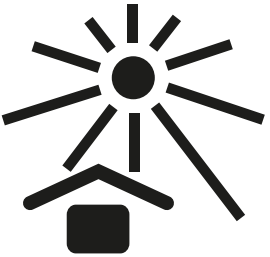
3. **AC adapter:**
   For easy carrying, please bind the AC adapter and its electric wire together with a ribbon band as shown in the figure.



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

Attention

- Please do not carry a nebuliser that still contains medication or water. The medication may leak out and damage or stain the nebuliser.
- Do not store the nebuliser in an area with 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 nebuliser.

Problems	Possible Causes	Solutions
Extremely low nebulization.	Medication chamber is not completely attached.	Re-attach the medication chamber correctly and restart the power. (See page 7)
	No contact between medication and mesh for more than 10 seconds.	Adjust the nebuliser's angle so the medication can come in contact. (See page 12)
	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 page 14~15)
	Electrodes on medication chamber are clogged with medication or water.	Clear the electrodes of clogged medication or water and restart the power. (See page 15)
	Electrodes on nebuliser and medication chamber are stained.	Remove the stains and restart the power. (See page 15)
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 page 7)
	No medication in medication chamber.	Put in the medication in the medication chamber. (See page 10~11)
	No contact between medication and mesh.	Adjust the nebuliser's angle so the medication can come in contact. (See page 12)
	Electrodes on nebuliser and medication chamber are stained.	Remove the stains and restart the power. (See page 15)
Power indicator is not lit and nebuliser is not nebulizing.	Batteries installed backwards.	Re-install the batteries in the correct orientation and restart the power. (See page 8~9)

Problems	Possible Causes	Solutions
Power indicator is not lit and nebuliser is not nebulizing.	Low battery power.	Replace with new batteries and restart the power. (See page 8~9)
	Incorrect connection of AC adapter to nebuliser.	Re-connect in the correct manner and restart the power. (See page 9)
Power indicator is lit and nebuliser 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 page 8~9)
	Rupture of mesh of medication chamber.	Replace with a new medication chamber and then put in the medication. (See page 16)
	Electrodes on medication chamber are clogged with medication or water.	Clear the electrodes of clogged medication or water and restart the power. (See page 15)
	Electrodes on nebuliser and medication chamber are stained.	Remove the stains and restart the power. (See page 15)
	Mesh of medication chamber is severely clogged.	If it still cannot be used after cleaning, please replace with a new medication chamber. (See page 14~15)
Nebuliser shuts off in usage.	Medication chamber is loosened and not completely attached.	Re-attach the medication chamber correctly and restart the power. (See page 7)
	If medication chamber nozzle is clogged with much medication or water, it turns off actively.	Clear the electrodes of clogged medication or water and restart the power. (See page 16)
	Connection of AC adapter to nebuliser is loosened.	Re-connect in the correct manner and restart the power. (See page 9)
	Medication has run out.	Put in the medication in the medication chamber. (See page 10~11)
	No contact between medication and mesh for more than 10 seconds.	Adjust the nebuliser's angle so the medication can come in contact. (See page 12)

Problems	Possible Causes	Solutions
Nebuliser shuts off in usage.	Nebuliser is being shaken in the use.	Hold the nebuliser in the hand stably. (See page 12)
	Medication chamber is broken.	Replace with a new medication chamber and then put in the medication. (See page 16)
Nebuliser does not shut off automatically while medication depleted.	Some type of medications for nebulization may produce a lot of foam in the medication chamber.	Clean the foam and restart the power. (See page 13)
	Electrodes on medication chamber are clogged with medication or water.	Clear the electrodes of clogged medication or water and restart the power. (See page 15)
	Electrodes on nebuliser and medication chamber are stained.	Remove the stains and restart the power. (See page 15)
	Medication chamber is broken.	Purchase and replace with a new medication chamber. (See page 16)
Overflow of medication from medication chamber.	Rupture of medication chamber or ageing of silicone ring.	Replace with a new medication chamber and then put in the medication. (See page 16)

If your nebuliser still does not function properly after taking the solution mentioned above, please contact the retailer from which you purchased the product.

Specifications

Product Name	Vibrating Mesh Portable Nebuliser
Model	MD631
Method of Operation	Ultrasonic
Dimensions	Approx. 71.5 mm(L) × 42 mm(W) × 107.6 mm(H)
Weight	Approx. 101 g (Exclude batteries)
Power Supply	3V DC, AA (LR6) Alkaline Battery (1.5V) x 2 Mains Supply (Input: 100-240 VAC, 50/60 Hz, 0.18 A; Output: 3V DC, 1 A)
Power Consumption	Approx. 2.0 W
Vibrating Frequency	Approx. 120kHz
Recommended fill volume	Approx. 8 ml maximum Approx. 0.5 ml minimum
Battery Life	Up to 1.5 hour if used continuously. 4 days if used daily for 20 minutes. (Use 2 “AA” LR6 alkaline batteries)
Warranty	2 years. (Excluded medication chamber)
Product Life (Main Unit)	5 years. (10 minutes per time/3 times usage per day)
Operating Conditions	5 °C~40 °C (41 °F~104 °F), 15~93%R.H., non-condensing, Atmospheric pressure: 700hPa~1060hPa, non-condensing
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, inhalation mask (Adult) with connecting tube , AC adapter.

The nebuliser 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:

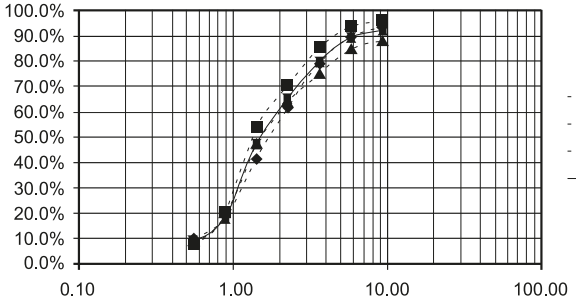
Technical data for MD631 nebuliser kit:

Particle Size:	MMAD 2.1 microns (2ml, 2.5% NaF)
Nebulization Rate:	0.32 ml/min (by weight loss)
Aerosol Output:	0.88 ml (2ml,1% NaF)
Aerosol Output Rate:	0.076 ml/min (2ml,1% NaF)
Sound:	Noise level (at 1 m distance) 50 dB

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 Fleming Medical.
- MMAD = Mass Median Aerodynamic Diameter.

Particle size distribution compliant with EN 13544-1



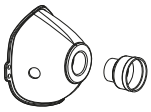
Stage No	Effective Cut-Off Dia. (um)	Cumulative % particle mass of sodium fluoride under size			
		Mean	Test 1	Test 2	Test 3
8	0.00	0.0%	0.0%	0.0%	0.0%
7	0.55	9.0%	10.0%	9.4%	7.7%
6	0.88	19.0%	18.6%	20.6%	17.7%
5	1.41	47.5%	41.4%	53.8%	47.4%
4	2.26	65.3%	61.6%	70.8%	63.4%
3	3.63	80.0%	79.3%	85.5%	75.2%
2	5.81	89.4%	89.5%	93.7%	85.2%
1	9.30	92.5%	93.2%	96.1%	88.2%

Test result of cascade impactor measurements for particle size with MD631

Accessories

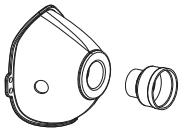
Accessories are shown below. If you wish to purchase any of them, please contact the retailer from which you purchased the nebuliser.

MD631-MS:
Inhalation mask (S) with connecting tube



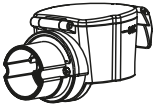
(For Children)

MD631-MS:
Inhalation mask (L) with connecting tube



(For Adult)

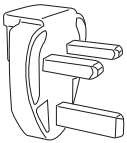
MD631-MB:
Medication chamber



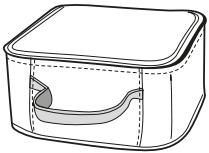
MD631-MP:
Mouthpiece

MD631-PC:
Protective cap

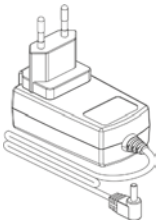
3 Pin Plug:



MD631-CP:
Carrying pouch



AC adapter:



A testing per EN 13544-1 demonstrating that the performance of all the components of MD631 shown as above is consistent with the requirements. Also, the optional accessories are in conformity with the essential requirements of the European Medical Device Directive.

Note:

CE 0197

This Nebuliser complies with the EC Directive (93/42/EEC) and bears the CE mark “CE0197”. This Nebuliser also complies with the following standards (included but not limited):

Safety standard:

EN 60601-1 Medical electrical equipment part 1: General requirements for safety

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 13544-1: Respiratory therapy equipment-part1: nebulizing systems and their components.

BF Classification:

- Internally powered equipment
- BF type applied part
- IP22 Degrees of protection provided by enclosures
- Not suitable for use in presence of flammable anaesthetic mixture with oxygen or nitrous oxide.
- Continuous operation with short-time loading

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 MD631, otherwise degradation of the performance of this equipment could result.

Discard the used product to the recycling collection point according to local regulations.

FLEMING MEDICAL LTD
21/F, Chinachem Tower,
34-37 Connaught Road Central,
HONG KONG

EC REP FLEMING MEDICAL LTD
Limerick, V94 K6W4, Ireland
1800 307777 (IRE) 0800 7314315 (UK)
WWW.FLEMINGMEDICAL.IE

Explanation of Symbols

Item	Explanation
	Follow instructions for use.
CE 0197	This Product complies with the EC Directive 93/42 EEC and bears the CE Mark “CE0197”
SN	Serial number
IP22	**First characteristic numeral**-degree of protection against access to hazardous parts and against solid foreign objects N_1=2 (Protected against solid foreign objects of 12,5 mm and ø greater. **Second characteristic numeral**-degree of protection against ingress of water N_2=2 (Protected against vertically falling water drops when ENCLOSURE tilted up to 15^{O}
	Manufacturer
	Date of manufacturer
	Class II equipment
LOT	Batch code
	No Latex
	Temperature limit
	Atmospheric pressure limitation
	Humidity limitation

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.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
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	± 2 kV Power lines	± 2 kV Power lines	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.

Recommended separation distances between portable and mobile RF communication equipment and the device.

The device is intended for use in an electromagnetic environment where radiated RF disturbances are under control. User can help prevent electromagnetic interference by keeping the device at a minimum distance from portable and mobile RF communications equipment (transmitters). Below table details the maximum output power of transmitter:

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 metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

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

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

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**
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. **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 metres (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: 
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	

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.