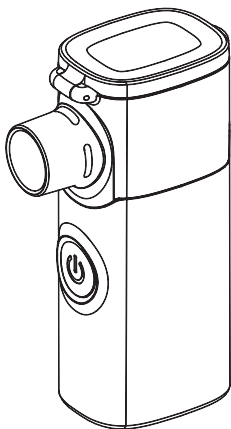


GIO-605

innoGIO



GIO **vital** *mini mesh*

MESH NEBULIZER

INSTRUCTION MANUAL

Manual Version: V1.0.
Date of Issue: 2021/10

Thank you for choosing our INNOGIO Nebulizer

Be sure to read this Instruction Manual before using the unit.
That way you can use it safely and correctly.

- This unit is a medical instrument. Be sure to follow your doctor's instructions and use the unit correctly.
- For the type, dose and regimen of medication, be sure to follow your doctor's instructions. The nebulization characteristics of this unit differ depending on the properties of the medication used.
- Especially with the use of a medication having high surface activity or viscosity such as medication solubilizing agent or expectorant, the nebulization rate may be reduced.
- The nebulization rate may also be reduced when the temperature of medication is low.

Contents

BEFORE USING THE UNIT

| | |
|-------------------------------------|---|
| Uwagi dotyczące bezpieczeństwa..... | 3 |
| Wprowadzenie do produktu..... | 4 |
| Zawartość produktu..... | 5 |
| Nazwy części..... | 6 |

CORRECT USE OF THE UNIT

| | |
|---|----|
| How to Prepare the Power Source..... | 27 |
| How to Fill the Medication..... | 29 |
| How to Inhale..... | 30 |
| How to Clean the Unit after Inhalation..... | 31 |

HOW TO DISINFECT THE UNIT

TROUBLESHOOTING

| | |
|----------------------|----|
| Troubleshooting..... | 34 |
| Specifications..... | 35 |

GUIDANCE AND MANUFACTURER'S DECLARATION

| | |
|-----------------------------------|----|
| A1 Electromagnetic Emissions..... | 34 |
| A2 Electromagnetic Immunity..... | 36 |

Notes on Safety

The warning and the caution shown here are listed to help you use this product safely and correctly as well as to prevent the risk and the damage to you and others.

Warning!

For the type, dose and regimen of the medication, be sure to follow your doctor's instructions.

- Your symptom(s) may worsen. When you use the unit for the first time after purchasing it or after the unit has not been used for a long period of time, be sure to clean and disinfect the Medicine Cup, Inhalation Mask and Mouthpiece. (Refer to Pages 11 to 12)
- Miscellaneous bacteria may propagate and you may get infected. Clean and disinfect Medicine Cup, Inhalation Mask, and Mouthpiece after each use. (Refer to Pages 11 to 12). Be sure to dry the cleaned and disinfected parts promptly, and store them in a clean place.
- Miscellaneous bacteria may propagate and you may get infected. This unit is designed for personal use. It is not appropriate for more than one user. Keep the unit out of reach of children or infants.
- Children or infants may swallow small pieces. The Main Unit may be damaged or may cause injury to children or infants. In case a child swallows small pieces, consult a doctor immediately.
- Do not wash the Main Unit and USB Cable with water or hot water. Do not immerse them in water.
- The unit may experience electricity leakage or you may suffer electric shock.
- The unit will malfunction and its use may become impossible.

Caution

- Do not inhale by using water in the Medicine Cup.
- Your symptom(s) may worsen. Do not spill the medication on the Main Unit. If you do spill the medication, wipe it off with gauze immediately.
- If you use the unit while it is wet, it may malfunction or you may suffer electric shock. Do not poke the Metal Mesh with a cotton swab or a pin.
- The unit may be broken and cannot be used. Do not drop or apply strong shock to the Main Unit or Medicine Cup. They may be broken and cannot be used or you may suffer an electric shock. Do not use any USB Cable other than the one supplied by InnoGIO. Do not use a broken USB Cable. Do not disassemble, repair, or modify the unit.
- The unit may be broken and cannot be used.

Wprowadzenie do Produktu



Symbol for caution. This is a safety symbol that is used to highlight that there are specific warnings or precautions associated with the devices that are not otherwise found on the label. The symbol can also be used to mean “attention, see Instructions for Use.”

IPX2

Protection against ingress of water, it means the device could protected against vertical falling water drop 15°C.



Manufacturer



This symbol indicates that the device includes IEC 60601-1 Type BF Applied Part.



The symbol indicates that the device should be sent to special agencies according to local regulations for separate collection after its useful life.



Indicates the date when the medical device was manufactured.

SN

This symbol shall be accompanied by the manufacturer's serial number.

LOT

Symbol for lot number; Indicates the manufacturer's batch code so that the batch or lot can be identified.

EC REP

Indicates the Authorized representative in the European Community.



Symbol for CE mark. This symbol certifies that a product has met European Union consumer safety, health or environmental requirements.



Refer to user manual

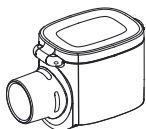
This product is intended for the treatment of respiratory disease such as asthma, allergies, etc.

Working principle: thanks to the self-excited oscillation circuit, the circuit, the ceramic sheets contained in nebulizing head together with the metal mesh are driven successively to oscillate at a high frequency, which makes the liquid flowing through the micromesh of the metal mesh and being ejected and nebulized to form an inhalant aerosol.

Product Contents

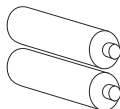
The following items are contained in the box. If any item is missing, please contact the store where you purchased the product or the nearest InnoGIO dealer.

1. Main Unit
2. Medicine Cup
3. Battery AA 1,5V x 2
4. Mouthpiece
5. Storage bag
6. USB Cable
7. Inhalation Mask (Children)
8. Inhalation Mask (Adult)

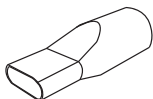
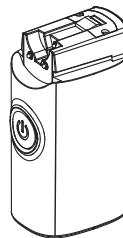


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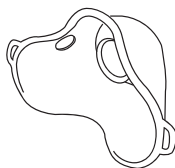
3



1

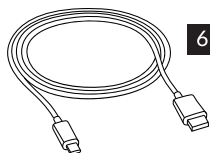


4

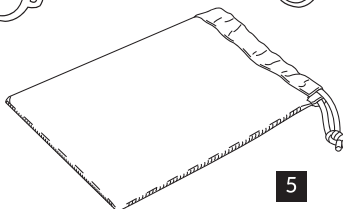


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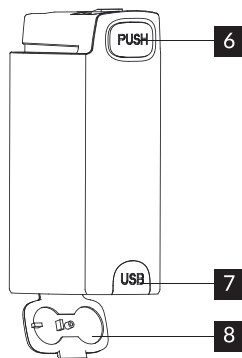
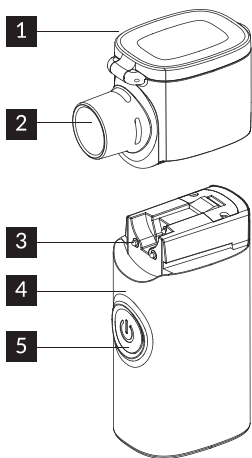


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5

Name of the Parts



- 1** Medicine Cup Cover
- 2** Metal mesh
- 3** Electrode
- 4** Main Unit

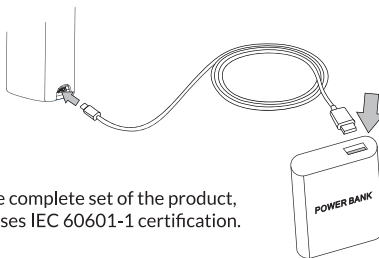
- 5** Power Button
- 6** Medicine Cup Button
- 7** USB Cover
- 8** Battery Cover

How to prepare the Power Source

The Unit uses batteries or USB Cable as the power source.

Please note that this USB Cable is a Micro USB and the designed output voltage is 5V.

Connect the USB cable to the main Unit and power bank as shown in Figure.



The power bank is not included in the complete set of the product, which meets electrical grade and passes IEC 60601-1 certification.

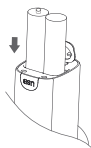
How to Insert Batteries

Please note that rechargeable batteries cannot be used in the Unit.

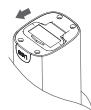
1. Open the battery Cover.



2. Insert batteries correctly by aligning the polarities (+ and -) with the battery indication mark.



3. Close the battery Cover.



How to Prepare the Power Source

Battery life and battery replacement

- When using alkaline batteries
The unit can be used for approximately 3 days
(if it is used for 30 minutes a day).
- When the backlight of the Power Button flashes quickly
(the interval is less than 0.3 second), batteries will be worn out soon.
Replace both batteries with new ones.

General advice

- Immediately replace the worn batteries with new ones.
- If you are not going to use the unit for a long period of time
(3 months or more), remove the batteries.
- If you leave the unit without using while keeping the batteries in it,
the batteries may leak and cause trouble to the unit.
- Do not insert batteries with the polarities (+ and -) in the wrong direction.
- Do not use the batteries other than the ones specified for the unit.
Do not use worn and new batteries together or different types
of batteries together.

How to fill the medication

Open the Medicine Cup and fill the medication.

1. Open the Medicine Cup.



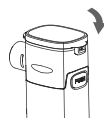
2. Fill in the medication.

Fill the medication as show In the Figure. The maximum capacity of Medicine Cup is 8 mil.



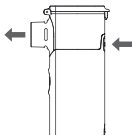
3. Close the Medicine Cup over tightly.

Otherwise the medication may splash out during usages.

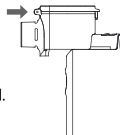


You can fill the medication in the assembled Unit directly or fill the medication in the Medication Cup separately. When you fill the medication in the Medicine Cup separately, please take out the Medicine Cup from the Main Unit and fill the medication in the Medicine Cup, then dose the Medicine Cup tightly and assemble the Medicine to the Main Unit.

- Disassemble the Medicine cup.
- Press the „PUSH“ Button and keep holding on, then Take out the Medicine Cup.



- Assemble the medicine Cup. The Medicine Cup is fixed to the Main Unit only after a clear „click“ is noticed.

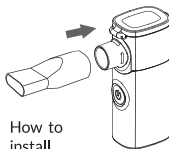
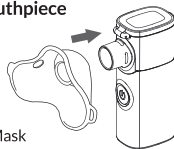


4. Install the Inhalation Mask or the Mouthpiece



Inhalation Mask is recommended when the Unit is used by a child younger than 5 years old.

How to install the Inhalation Mask

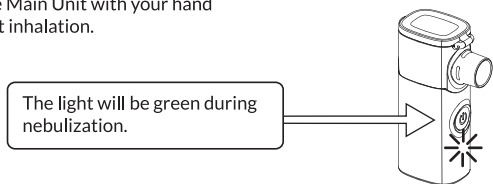


How to install the Mouthpiece

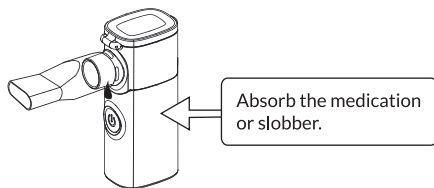
- It is not easy for children to use the Mouthpiece correctly.
- The Mouthpiece or other small parts may be swallowed.

How to inhale

- A** Hold the Main Unit with your hand and start inhalation.



- If medication or slobber collects too much on the internal surface of the head of Medicine Cup, turn off the power and absorb the medication or slobber with a new gauze.
- If a medication has high surface activity, it may exclude from Metal Mesh.



! Caution

Do not poke the Metal Mesh with a cotton swab or a pin.

- The Metal Mesh will be damaged and cannot be used.
- If the medication has high surface activity or viscosity such as medication solubilizing agent or expectorant, the nebulization rate may be reduced.
- A metallic sound may be generated, but it should not alarm you.

- B** When you finish inhalation, push the Power Button to turn off the power

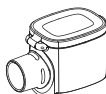
- When the USB Cable is used, unplug the USB Cable from the power bank. (Refer to Page 7)

How to Clean the Unit after Inhalation

! Be sure to clean and store the unit after inhalation.

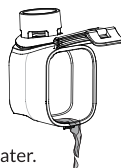
A Remove the parts from the Main Unit

- Remove Inhalation Mask or Mouthpiece, and Medicine Cup from the Main Unit



B Discard the remaining medication

- Open the Medicine Cup and discard the medication.

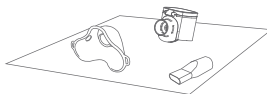
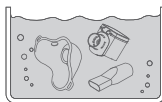


C Wash the parts thoroughly in water

- Wash the Inhalation Mask, Mouthpiece and Medicine Cup in water.
- Carefully rinse the Metal mesh when using a medication with high surface activity or viscosity such as medication solubilizing agent or expectorant because the medication is often left on the Mesh.
- Do not touch the metal mesh directly, otherwise the metal mesh may be damaged and cannot be used.

D Dry the parts thoroughly

- Immediately after washing the parts, wipe off water with a new gauze and dry them thoroughly.



General advice

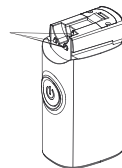
Never try to wipe off water with tissues or cloth.

Dust or lint left on the Metal Mesh may affect nebulization.

How to Clean the Unit after Inhalation

- E** Wipe off the stain on the Main Unit

Keep the Electrodes
clean and dry.

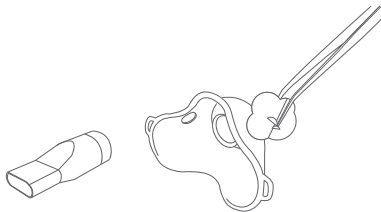


- F** After assembling the unit,
store it in a clean place.

How to Disinfect the product

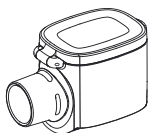
The mouthpiece and inhalation mask have direct contact with the user,
please keep it clean!

Use 75% medical alcohol to scrub the mouthpiece and mask for more than 3 minutes,
then dry the mouthpiece and mask and storage them in the clean area.



How to replace the Medicine Cup

- You can usually use a Medicine Cup for approximately 1 year (if it is used for 30 minutes a day).
- However, the unit may not nebulize even before a year has passed, depending on how often you use it.
- The unit may also not nebulize at all or nebulize with very little force.
- In those cases, replace the Medicine Cup with a new one.



Medicine Cup is a consumable part.

Cautions

Never try to wipe off water with tissues or cloth.

Dust or lint left on the Metal Mesh may affect nebulization.

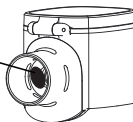
Do not poke the Metal Mesh with a cotton swab or a pin.

The Metal Mesh will be damaged and cannot be used.

Dry the metal mesh naturally.

Strictly follow the instructions in the manual to operate, otherwise you may lose the warranty.

Metal Mesh



Troubleshooting

Jeżeli przy użytkowaniu urządzenia występują jakiegokolwiek problemy, należy najpierw wykonać następujące kroki.

| Trouble | Possible cause | How to correct |
|--|--|---|
| The nebulization rate is extremely low | The batteries are low/ worn out. | Replace the batteries with new ones. (Refer to page 27) |
| | The Metal Mesh is stained. | Clean the Medicine Cup to remove the stain. (Refer to Page 32) If the trouble cannot be corrected by the above-mentioned procedure, replace the Medicine Cup with a new one. (Refer to Page 29) |
| The unit does not nebulize | The polarities (+ and -) of batteries are in the wrong direction. | Insert batteries in the correct alignment. (Refer to Page 27) |
| | The batteries are low. | Replace batteries with new ones. |
| | The USB Cable is not correctly connected. | Remove the USB Cable from the Main Unit and connect it correctly. (Refer to Page 27) |
| | The Medicine Cup is not installed correctly to the Main Unit. | Install the Medicine Cup correctly. (Refer to Page 29) |
| The backlight of Power Button works correctly but the unit does not nebulize | The Metal Mesh is extremely stained. | Replace the Medicine Cup with a new one. (Page 29) |
| | The Metal Mesh is broken. | |
| | Medication or water is collected on the Electrodes of the Main Unit. | Dispose the medication or water. (Refer to Page 32) |
| | The Electrode of the Main Unit is stained. | Wipe off the stain. (Refer to Page 32) |

If the unit does not nebulize normally after following the above-mentioned procedure, contact the store where you purchased the unit or the nearest InnoGIO dealer.

Specifications

| | |
|-----------------------------------|---|
| Product Name | InnoGIO GIOvital Mini Mesh |
| Model | GIO-605 |
| Power Source | 2 x alkaline batteries, Micro USB (5V) |
| Power consumption | Approximately 2 W |
| Nebulization Rate | ≥0,20 ml / min |
| Particle Size | MMAD approximately 5 µm |
| Capacity of Medicine Cup | ≤8 ml |
| Dimensions | 35 mm (S) x 105 mm (W) x 65 mm (G) |
| Weight | Approximately 77g (excluding batteries) |
| Working Environment | Temperature: 10 to 40 °C Humidity: 30 to 85% RH Atmospheric Pressure: 86kPa ~ 106kPa |
| Transport and Storage Environment | Temperature: -20 to 50 °C Humidity: 30 to 85% RH Atmospheric Pressure: 86kPa ~ 106kPa |
| Pollution | Degree 2 |
| Voltage Category | CATEGORY II |
| Altitude | ≤2000 m |

Specifications and appearance may be changed without prior notice for improvement.

Guidance and Manufacturer's Declaration

- 1) This equipment needs to be installed and put into service in accordance with the information provided in the ACCOMPANYING DOCUMENTS;
- 2) IMMUNITY TEST LEVELS for basic safety and essential performance of ME equipment and ME systems should be chosen based on a high probability of maintaining basic safety and essential performance, and shall be according to the professional Healthcare facility environment, home Healthcare environment, and special environment, based on the locations of intended use.
- 3) HOME HEALTHCARE ENVIRONMENT is dwelling place in which a patient lives or other places where patients are present, excluding professional Healthcare facility environments where operators with medical training are continually available when patients are present. Such as schools, outdoors, domiciles, vehicles hotels and pensions.

EXAMPLE: As indicated in Table 6 of IEC 60601-1-2:2014 for ME EQUIPMENT, a typical cell phone with a maximum output power of 2 W yields $d = 3.3$ m at an IMMUNITY LEVEL of 3 V/m.

A1 Electromagnetic Emissions

- For all EQUIPMENT and SYSTEMS

| Guidance and manufacture's declaration-electromagnetic emission | | |
|--|-------------------|---|
| The GIO-605 is intended for use in the electromagnetic environment specified below; The customer or the user of the GIO-605 should assure that it is used in such and environment. | | |
| Emission test | Compliance | Electromagnetic environment-guidance |
| RF emissions CISPR 11 | Group 1 | The GIO-605 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Class B | The GIO-605 is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies building used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations/flicker emissions IEC 61000-3-3 | Complies | |

A2 Electromagnetic Immunity

- For Home Healthcare Environment EQUIPMENT and SYSTEMS

| Guidance and manufacture's declaration – electromagnetic immunity | | | |
|---|---|---|--|
| The GIO-605 is intended for use in the electromagnetic environment specified below. The customer or the user of GIO-605 should assure that it is used in such an environment. | | | |
| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment – guidance |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±8 kV contact ±2 kV, ±4 kV, ±6 kV, ±8 kV, ±15 kV air | ±8 kV contact ±2 kV, ±4 kV, ±6 kV, ±8 kV, ±15 kV air | Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical fast transient/burst IEC 61000-4-4 | ±2 kV for power supply lines | ±2 kV for power supply lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ±1 kV line to line ±2 kV line to ground | ±1 kV line to line ±2 kV line to ground | Mains power quality should be that of a typical commercial or hospital environment. |
| Power frequency (50/60Hz) magnetic field IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| Voltage dips, short 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; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° | Mains power quality should be that of a typical commercial or hospital environment. If the user to the GIO-605 requires continued operation during power mains interruptions, it is recommended that the GIO-605 be powered from an uninterruptible power supply or a battery. |

| | | | |
|---|---|---------------|--|
| <p>Conducted RF IEC 61000-4-6</p> | <p>3 Vrms 150 kHz to 80 MHz</p> | <p>3 Vrms</p> | <p>The MANUFACTURER should consider reducing 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: $E = \frac{6}{d} \sqrt{P}$ <p>Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.</p> </p> |
| <p>Radiated RF IEC 61000-4-3</p> | <p>10 V/m 80 MHz to 2,7 GHz</p> | <p>10 V/m</p> | |

Importer:

Innogio sp. z o.o., Ostródzka street 74H, 03-289 Warsaw, Poland

innogIO

Authorized European Representative:



Share Info GmbH,
Heerdter Lohweg 83, 40549 Düsseldorf



Manufacturer: Vapo Healthcare Co., Ltd.
Address: No99, Yudai West St., Kunshan, Suzhou, P. R. China