

Full User Manual





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1. Foreward

Thank you for choosing the eClear from Elepho Inc. This product is used to clean a baby's nose from mucus which is difficult to extract natually.

This product is for consumer use; it is made up of precise components; please keep it away from high temperature, humid environments, sunlight and dust. For correctly use, please read this user manual. Please keep it for future reference as required.

2. Declaration of conformity

- This product is designed according to the Standard IEC 60601-1: 2012, Medical electrical
 equipment Part 1: General requirements for basic safety and essential performance and ANSI/
 AAMI ES60601-1:2005/IR) 2012+A1:2012+C1:2009/IR)2012+A2:2010/IR)2012.
- This device has been tested in accordance with IEC 60601-1-2:2014 for EMC. This does not guarantee in any way that the device will not be affected by electromagnetic interference. Avoid using the device in high electromagnetic environment.

3. Product type

- · The product is classified as Class II ME equipment when it works with an adapter.
- · The product is internally powered when it is battery operated.

3.1 - Intended Use

The device which is a portable, hand-held, reusable, battery-powered suction device is intended to enable an adult to gently suction and clear excessive mucus from the nasal passages of an infant or child to facilitate easier breathing in a home care environment.

3.2 - Contraindications

Babies or children with the following symptoms should not use this product:

- 1) Nasal bleeding
- 2) Cogaulopathy (condition of excessive bleeding or clotting or any other bleeding disorder)
- 3) Cartilage damage or nose injury
- 4) Acute head, facial or neck injury.

3.3 - Lifespan

The lifespan of the product is 5 years.

4. Important safety information

The warning symbols mentioned in this user manual give guidance of safety and correct method of use to avoid any harm to your body.

The warning symbols are as follow:

| Warning symbol | Meaning |
|----------------|---------------------------------------|
| <u> </u> | It may cause harm to body or article. |

| F© | This device compiles with Part 15 of FCC (Federal Communications Commission) Rules. | A | The device and accessories and the packaging have to be disposed of waste correctly at the end of usage. Please follow local ordinances or regulations for disposal. | |
|----------|---|---------------|--|--|
| <u>†</u> | This symbol means type BF applied part. | LOT | Batch code | |
| | This symbol means the appliance is Class II equipment. | √ RoHS | Restriction of Hazardous Substances. | |
| [Ji] | Read the user manual carefully before using this device. | | Recyclable | |
| | Date of manufacture | *** | Manufacturer | |
| IP22 | IP22: The first number 2: Protected against solid foreign objects of Φ 12.5 mm and greater. The second number 2: Protected against vertically falling water drops when enclosure titled up to 15°. | SN | Serial number | |
| (€ | Product conforms with European health, safety, and environmental protection standards. | | | |

| _ | | _ | | | |
|---|---|---|---|---|--|
| | ı | Æ | ١ | | |
| | / | 1 | 2 | ٧ | |

This product is only suitable for suckina nasal secretions. Please do not use it for other purposes.

Keep the suction nozzle clean and sanitary when in use.

This product should be stored at room temperature, charged to about 40% to 60% of capacity. In case of over-discharge, pack should be charged for one time every 3 months while storing and batteries should be discharge and charge after being stored more than a year in order to activate it and restore energy.

Please keep the nasal aspirator away from the sun or high temperature and humidity, and keep it in a clean, dry place with a temperature of 41°F - 113°F (5°C - 45°C) and a humidity of less than 85%.

Please store this product in the ambient temperature range of -4°F - 131°F (-20°C - 55°C). When the equipment is transferred from the lowest storage ambient temperature to the ambient temperature of 68°F (20°C), it takes 40 minutes to return to normal operation. It takes 40 minutes to return to normal operation from the highest storage ambient temperature to 68°F (20°C).



During storage, please pay attention to the influence of dirt, dust, light (including sunlight); regularly use a damp rag to wipe the external surface of the product, and avoid direct sunlight during storage.

During storage, please keep the product away from pets and children to avoid damaging the product or swallowing. Please pay attention to prevent the contamination of this product by pests.

Please don't service or maintain any parts of the Nasal Aspirator while in use.

If you find any problem, please stop using and contact customer service. Self-repair is prohibited.

When the product cannot be used or discarded, please follow the local regulations to deal with it and avoid environmental pollution.

The nasal aspirator can only use the special accessories provided by the manufacturer and can only be connected to the equipment that does not have external voltage risk and conforms to IEC 60601-1 safety standards.

In order to prevent the water drop from sucking into the pump body and affecting the product performance, it is forbidden to clean the electrode and the air inlet of the nearby pump body when the product is operated

When using this product, please keep your mouth open, do not hold your breath or swallow saliva, so as to avoid unbalanced ear pressure.

It is strictly forbidden to clean or soak the body parts under the nasal aspirator collection container. Please don't immerse it in water or other liquid, and don't flush it to the tap.

Do not drop, disassemble, repair or transform the product.

Keep away from strong electrostatic field or strong magnetic field, so as not to affect the product performance and normal use.

Microwave disinfection and autoclave disinfection are prohibited.

Please read this manual carefully before use. Incorrect use of this product may cause the following symptoms: a. Nasal allergy

b. Bleeding of nasal mucosa



Please keep the nasal aspirator out of the reach of children under 12 years old. Especially care of inhalation or swallowing of small parts or accessories.

Do not put the nasal aspirator into the fire.

Middle and high gears are NOT recommended for newborns.

Do not charge the lithium battery for more than 12 hours otherwise the lithium battery may be damaged or even cause danger.

Do not use USB power supply with external voltage risk that does not conform to IEC 60601-1 safety standards

Contraindications:

- Nose bleeding.
- 2) Coagulation or hemorrhagic disease.
- 3) Nose Injured to cartilage or flesh.

Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation.

5. Technical Data

| Name | Nasal Aspirator (eClear) |
|----------------------------------|--|
| Model | HTD2601US |
| Display LED | |
| | Ambient temperature: 41°F - 113°F (5°C - 45°C) |
| Operating conditions | Relative humidity (RH): ≤85% |
| | Atmospheric pressure: 700 hPa-1060 hPa |
| | Ambient temperature: -4°F - 131°F (-20°C - 55°C) |
| Transport and storage conditions | Relative humidity (RH): ≤93% |
| Conditions | Atmospheric pressure: 700 hPa-1060 hPa |
| Product weight: | 5.9oz (167g) |
| Suction range: | ≤ 65kpa |
| Automatic Power-off | ≤ 65 s |
| Internal power supply | Lithium Polymer Battery: DC 3.7V |
| USB Power Source | Input: DC 5V, ≥1A |

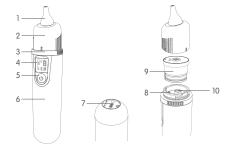
6. Parts identification

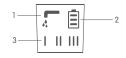
6.1 Parts

- 1. Suction nozzle
- 2. Transparent cover
- 3. Collecting cup base
- 4. Display screen
- Power button
- 6. Plastic shell
- 7. USB charging interface
- 8. Induction electrode
- 9. Collecting cup
- 10. Air inlet of pump body

6.2 Display

- 1. Cleaning prompt
- 2. Battery capacity indicator
- 3. Suction level indicator





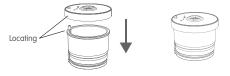
7. Installation and operation instructions

7.1 Installation parts description

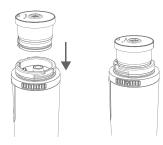
| | Suction nozzle (thick, to clean deep nasal cavity) | Transparent cover |
|----|---|-------------------|
| | Suction nozzle (thin, to clean nostril) | Collecting cup |
| 00 | Seal ring | Silica gel cover |

7.2 How to install

- 7.2.1 Before installation, please check whether the product appearance is good and complete. If there is any defect, please contact the supplier or manufacturer.
- 7.2.2 Component installation:
 - Align the hole position of silica gel cover with the locating column on the cup, cover on the collecting cup, and gently press around the silica gel cover to ensure it is installed in place.



 Install the collecting cup with the locating column and aligne with the gap of the cup base onto the body.

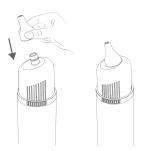


c. Screw the transparent cover on the body.



d. Install the suction nozzle on the transparent cover.

Note: during installation, fingers should be kept away from the tip of the suction nozzle to avoid bacteria pollution.



7.3 Notice before use

- a. If the baby's nose is dry, it should be carefully humidified: Apply a warm towel on both sides of the baby's nose for about 10 minutes. When the nasal mucosa contracts with heat, the nasal cavity becomes smooth, and the viscous nasal mucus will also be hydrated and more easily absorbed. Alternatively gently wet the inner dry area of the baby's nose with a cotton swab dipped in warm soline / sesame oil for about a few minutes, and then use the aspirator to suck out the mucus. Do NOT use excessive force or hard pulling while extracting a 'booger' from the baby's dry nose.
- b. Cleaning and disinfection. Before use, ensure that the suction nozzle is cleaned and sanitized.
- c. Before use, please check whether the suction at the suction nozzle is good if there is air leakage, please check whether the transparent cover is in place, and whether the sealing ring at the bottom of the transparent cover is installed correctly in place with the transparent cover.
- d. On young babies it is not recommended to use the middle and high gear of suction to avoid any discomfort or potential damage to sensitive parts of the inner nose area.

7.4 Using the Optional USB power

Put the USB plug connected to DC 5V power supply into the USB socket at the bottom of the device.

Notes:

- Please choose an adapter that meets the IEC 60601-1-2 standard.
- When the lithium battery power is low, you can connect the USB cable with DC 5V input and continue to use the nasal aspirator. While in use, the nasal aspirator will disconnect the charging of the battery. When the nasal aspirator is turned off it will switch back to the charging mode if still connected to the charger.



7.5 Using the internal battery

After power is turned on, the unit is powered by the internal lithium battery without the use of the USB cable. When fully charged, it can be used for approximately 100 times for one minute each usage. The Lithium battery can charge and discharge for approximately 500 times during the life of the rechargeable battery.

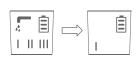
7.6 Operating instructions

7.6.1 - Start up

- In standby mode, press the power button to turn the eClear on at which point all symbols will be briefly displayed on the screen. By default level one operation will be selected.
- Press the button (once) to move to different (higher) suction strengths (between I, II and III).
- To turn off the device keep the button pressed and the device will automatically turn off.
- d. In the charging mode by pressing the power button the device will automatically cut off the charging mode and switch to the working mode of (first suction gear) operation.

The battery power is not displayed at this time.

After use, the nasal aspirator will return to the charging mode if connected to the charger.





7.6.2 - Aspirating the mucus

Please keep the product display screen facing up and gently insert the suction nozzle into the nose for suction

Notes:

- The suction nozzle should be in full contact with the mucus, and the angle between the suction nozzle and the nostril should be about 20-30 degrees;
- During use please make sure the baby's mouth is open to avoid negative pressure entering the ear cavity.



- When using, it is recommended that the baby sit up, or half lie down and raise baby's head.Please do not move baby's head while using the aspirator to avoid damage to the nasal cavity.
- 4. When the liquid is about to enter the gap between the transparent cover and the side wall of the collecting cup, it is recommended to clean the collecting cup and the transparent cover in advance. If the liquid enters the side wall gap and triggers the electrode to enter the alarm mode, the electrode and its surrounding must be cleaned.
- When the cleaning prompt is displayed please dismantle the collection cup and clean it. If the cleaning prompt continues to flash it means the unit needs to be further dried before use.

7.6.4 - Shut down

Automatic shutdown

When the nasal aspirator is not active for more than 65 seconds it will automatically shut down.

7.6.5. - Cleaning

It is recommended to clean the unit and the collection cup after each use to prevent any build-up of bacteria over time. During cleaning process do not use or connect the device to the power supply.

a. Cleaning of suction nozzle, transparent cover and collecting cup - Remove the transparent cover and collecting cup from the host machine, and then remove the suction nozzle when cleaning the transparent cover. It is recommended to clean it with clear water (neutral solvent can be used if necessary). After cleaning, fully dry it and store it in a dry and clean place.

Note: Please make sure that the transparent cover, collecting cup and silica gel cover have been dried without any residual water to avoid the drops triggering the cleaning alarm and shutdown

b. Cleaning of the body surface

Please use a damp cloth to clean the shell of the body. If the electrode on the upper part of the machine body has touched the liquid, please wipe it with a towel or soft cloth until the indicator light " " no longer flashes. If the flashing continued it means the electrode is not completely dry.

Note: it is forbidden to immerse the body in water or wash it under a faucet to avoid the water flow into the air inlet of the pump body. THIS WILL VOID THE PRODUCT WARRENTY.





8. Troubleshooting

| Problem | Possible Cause | Proposed Solution |
|--|--|---|
| No display when you press the power button | The battery may have been depleted if not used for a long time | Please use USB power supply to recharge the lithium battery before using. |
| Cannot suck out the mucus. | Mucus is dry. | Humidify the dry mucus with saline or equivalent and try again a few minutes later. |
| | Wrong angle of use. | Try to adjust the angle during the process of suction. |
| Liquid overfill | The liquid has overfilled from the collecting cup. | Turn off the unit and open the transparent cover, clean the collecting cup and use after all components are completely dry. |
| The first segment of the battery capacity indicator keeps flashing | Low battery. | Connect the USB cable to a charging device. Then connect the micro-USB end of the cable to nasal aspirator. |

9. Care and Maintenance

9.1. Product maintenance and storage

- Every time the nasal aspirator is used, it should be cleaned. Before use, it should also be disinfected to avoid infection.
- 2. If the nasal aspirator is not used for a long time please fully charge the battery before use.
- It is recommended to charge the device at least once every 3-6 months To maintain battery life/ charging capacity.
- 4. Carefully protect the surface of the display from damage.
- 5. Place the nasal aspirator in a dry place to avoid dust, household dirt and direct sunlight.

9.2. Storage and transportation conditions

- 1. Ambient temperature: -4°F 131°F (-20°C 55°C)
- 2. Relative humidity: 10% 93%

WARNING:

- 1. Do not modify this equipment without authorization from manufacturer.
- The device cannot be dismantled by the operators. If you need reassembly, please contact the manufacturer.

10. Warranty and service

The warranty period is 1 year after time of purchase.

Note: if the product is disassembled the warranty is void.

Please keep the sales receipt as evidence of when/where the device was purchased.

11. Contents

- · 2 pieces of silica gel suction nozzles
- 2 pieces of silica gel sealing rings (1 large and 1 small)
- · 1 USB power cable
- 1 Full User Guide
- 1 Quick User Guide

WARNING:

The use of accessories NOT supplied with the purchase of the device is forbidden and will void the warranty.



Manufactured

Manufactured for Elepho Inc by Hetaida Technology Co., Ltd.

Dongguan City, Guangdong Province, P.R. China

12. Disposal

At the end of the product life, the device should not be disposed of in household garbage. It should be disposed of in accordance with local regulations and laws relating to the disposal of battery operated products

13. EMC Guidance

Warning: Don't use near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning: Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 in (30 cm) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

| Guidance and Manufacturer's Declaration – Electromagnetic Emissions | | |
|---|------------|--|
| Emissions test | Compliance | |
| RF emissions CISPR 11 | Group 1 | |
| RF emissions CISPR 11 | Class B | |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Complies | |

| Guidance and Manufacturer's Declaration – Electromagnetic Immunity | | | |
|--|--|---|--|
| Immunity Test | IEC 60601-1-2 Test level | Compliance level | |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±8 kV contact ±2 kV, ±4kV, ±8 kV, ±15 kV air | ±8 kV contact ±2 kV, ±4kV, ±8 kV, ±15 kV air | |
| 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 | |
| Surge IEC61000-4-5 | ± 1 kV line(s) to line(s) ± 2 kV line(s) to earth | ± 1 kV line(s) to line(s) ± 2 kV line(s) to earth | |
| 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', 315', 0 % UT; 1 cycle 70 % UT; 25/30 cycle 0% UT; 250/300 cycle | 0 % UT; 0.5 cycle at 0',45',90', 135', 180', 225', 270', 315', 0 % UT; 1 cycle, 70 % UT; 25/30 cycle 0% UT; 250/300 cycle | |
| Power frequency magnetic field IEC 61000-4-8 | 30 A/m 50Hz/60Hz | 30 A/m 50Hz/60Hz | |
| Conduced RF IEC61000-4-6 | 3 V r.m.s. 150 kHz to 80 MHz 6 V RMS in the ISM and amateur bands between 0.15 MHz and 80 MHz | 3 V r.m.s. 150 kHz to 80 MHz 6 V RMS in the ISM and amateur bands between 0.15 MHz and 80 MHz | |
| Radiated RF IEC61000-4-3 | 10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz | 10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz | |
| NOTE UT is the a.c. mains voltage prior to application of the test level. | | | |

Warranty

The warranty period for device is one year from date of delivery. In case of a warranty claim, the date of delivery has to be proven by means of the sales receipt or invoice.

Repairs under warranty do not extend after the warranty period.

The following cases are excluded under the warranty:

- · All damage due to improper treatment, e.g. failure to follow the user guide.
- · All damage due to repair or tampering by the customer or unauthorized third parties.
- Damage incurred during transport from the manufacturer to the consumer or during transport to the service center.
- · Accessories that are subject to normal wear and tear.
- Battery module is not covered under the warranty.

Liability for direct or indirect consequential losses caused by the unit is excluded even if the damage to the unit is accepted as a warranty claim.

Contact your point of sales representatives and include your product purchase receipt as evidence for service support during the warranty period.



Made in China

Hetaida Technology Company, Ltd, Guangdong Province, P.R. China.

Manufactured for:

Elepho Inc., 466 Central Ave (2nd floor), Cedarhurst, New York 11516, USA

Item/Device #: HTD2601US

Product/model name: eClear

E-mail support: customercare@elepho.com

Telephone support via Elepho Consumer Relations at: 1-833-435-3746 (1-833-4-ELEPHO)

General information regarding Elepho full product line: www.elepho.com

