

REVITIVE

Aerosure User's Manual



**Drug-Free
Clinically Proven
Certified Medical Device**



**Please read the User's Manual
carefully before using this product**

You should also consult with your
healthcare professional before use

- If you have an existing
medical condition
- If you are unsure about the
suitability of Revitive Aerosure or
the cause of your symptoms

USE ONLY AS DIRECTED

If symptoms persist, consult
your healthcare professional

Model number: 3481AJ

BREATHING RELIEF

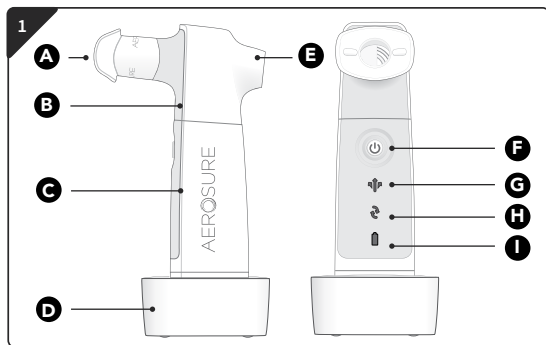
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Parts & controls

Upon opening the carton, please check that the following components are provided.

If anything is missing, contact us free on our helpline number **0845 871 5989** or visit **www.revitive.com**



- A** Mouthpiece
- B** Valve Head
- C** Handle
- D** Charger
- E** Vent
- F** On/Off button and Mode selection button
- G** Mucus Relief Mode Indicator
- H** Breathe Easier Mode Indicator
- I** Charger Indicator

Introduction to Revitive

Indications for Use

Aerosure is indicated to help you breathe easier as follows:

- Reduce breathlessness in healthy people, and patients with asthma and COPD
- Reduce/improve coughing in people with COPD
- Reduce tight chest, associated with breathlessness in people with COPD
- Strengthen (inspiratory) breathing muscles in people with COPD
- Produce beneficial effects in terms of increased respiratory fitness in healthy people and in patients with cystic fibrosis, COPD, and asthma
- Improve sputum clearance in patients with cystic fibrosis and bronchiectasis
- Improve quality of life in patients with COPD, bronchiectasis, asthma and cystic fibrosis

Chronic Obstructive Pulmonary Disease (COPD) is caused by smoking (smokers/ ex-smokers), air pollution, chemical fumes, or dust from the environment



Before operating Revitive Aerosure, please read these instructions in full and save this manual for future reference. Please contact the manufacturer if you require further advice for using or maintaining your device or experience any unexpected issues.

Important safeguards

Do not use if you (contraindications):

- Are pregnant
- Have epilepsy
- Are coughing up blood (Active haemoptysis)
- Have acute sinusitis or an active nosebleed
- Have a broken rib until this is completely healed
- Have recently had thoracic (chest) or upper gastrointestinal tract (duodenum, stomach, oesophagus) surgery or trauma until completely healed
- Currently have or previously had a collapsed lung (Pneumothorax)
- Have abnormally high or low blood pressure, very slow or very fast heart rate (Haemodynamic instability including severe right-sided heart failure with hypotension)
- Currently have a blood clot in the blood vessels in the lungs (Current Pulmonary embolism)
- Have enlarged veins in the oesophagus (Oesophageal varices)
- Had recent dental, head, neck, ear, nose & throat surgery or trauma until completely healed
- Have abnormally high pressure in the skull and brain (Raised intracranial pressure)
- Are experiencing a sudden worsening of breathlessness. For example (but not limited to) exacerbations of asthma.

Warnings

- It is not advised to use this device in the case of users with neurological disorders, respiratory disease in end-stage (incl. COPD and Cystic Fibrosis) **unless under medical supervision.**
- Use of this device does not replace the requirement for any prescribed medication. Do not stop taking your medication or change the dosage without first consulting your doctor
- For hygiene reasons, this product is intended for a single user only. Do **NOT** share the Valve Head or mouthpiece with any other users.
- If you feel light headed, dizzy or pain whilst using Revitive Aerosure, stop using it immediately and rest. If these symptoms persist, consult your doctor.
- In the Mucus Relief mode the mucus is dislodged from the airways and lungs - you must then clear this mucus through effective coughing. In the presence of an ineffective cough, additional assisted coughing devices or techniques may be required and advice sought from a qualified medical practitioner.
- Use this product only for its intended use as described in this manual.
- Swallowing air should be avoided as this may lead to an increased likelihood of vomiting and aspiration

Important safeguards


Warnings (continued)


- If you experience a sore or dry throat, stop using the device until these symptoms go away or try drinking some water. If symptoms persist, consult your doctor.
- Do not use attachments which are not recommended by the manufacturer.
- This product is not intended for use by children or persons with reduced physical, sensory or mental capabilities, unless they are supervised by a person responsible for their safety.
- Keep the product out of the reach of children.
- Clean the Valve Head and mouthpiece prior to first use [see page 17].
- Always unplug before cleaning.
- Do not submerge the handle or charger in water or other liquid.
- Do not place or store the charger where it can fall or be pulled into water or other liquids.
- Do not reach for a charger that has fallen into water or other liquids. Unplug immediately.
- Do not touch the power plug with wet hands. This can cause an electric shock.
- Do not use if the adaptor or cord is damaged. If the cord is damaged, contact your local distributor. The power cord is not intended for repair by service personnel. If damaged the whole charger unit will require replacement.
- Do not modify, repair or disassemble any part of the product. This may cause fire, electric shock or fatal injury. Consult your dealer or contact your local distributor for information and assistance.
- Do not insert any object into the Valve Head or into any opening of the device or charger.
- Ensure no particles or objects are lodged in the valve head and obstructing airflow.

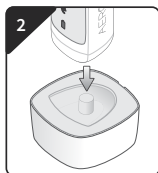
Save these Instructions

Instructions for use

Step 1 : Powering Revitive Aerosure

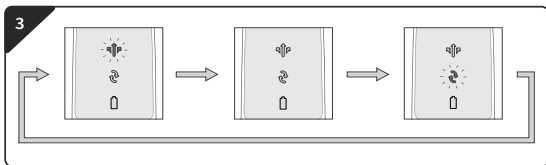
 **IMPORTANT:** Revitive Aerosure will require a full charge prior to first use, approximately 12 hours.

 The charger plug is intended as the means of isolation from the mains supply. Do not position the plug or charger in a position where it is difficult to disconnect from the mains supply.



- Plug the charger (D) into an electrical outlet.
- Place the handle unit (C) onto the charger base [see picture 2].

• The treatment mode indicator lights (G) (H) will flash repeatedly in sequence to indicate the unit is charging [see picture 3].



- Revitive Aerosure is now charging. Once fully charged, the indicator lights will simultaneously flash on and off for ten minutes. After this period the product will turn off automatically to preserve battery life and no indicator lights will be visible.
- A full charge enables approximately one and a half hours of use.

Step 2 : Using Revitive Aerosure

IMPORTANT: Never obstruct the vent (E).



- Hold the product with your hand cupped around the lower section of the handle (C) with the button and mouthpiece facing towards you.
- Place the mouthpiece (A) in your mouth so that your lips cover the outer shield to make a seal.
- Breathe through Revitive Aerosure according to the instructions on the next two pages depending on the Mode you wish to use.

Instructions for use



Breathe Easier Mode:

Turn the product on by pressing and holding the Power Button for 2 seconds [see picture 5].

- Press the power button once more.
- You will also hear the motor and Valve Head begin to rotate.
- The Breathe Easier Mode indicator will now be illuminated [see picture 6].
- Place the Mouthpiece (A) in your mouth.

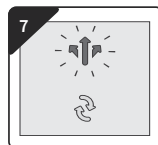


- **Breathe as hard as you are comfortably able to, through the Mouthpiece (A) for five minutes, 3 times per day.**
- Once your session is complete, turn off the product by pressing the Power Button (F) to cycle through the modes until the motor stops.

Note: There is no separate OFF light. The product is off when none of the indicators are illuminated.

Mucus Relief Mode:

Turn the product on by pressing and holding the Power Button for 2 seconds [see picture 5].

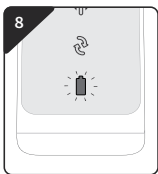


The Mucus Relief Mode indicator will now be illuminated [see picture 7].

- You will also hear the motor and Valve Head begin to rotate.
- Place the Mouthpiece (A) in your mouth.
- **Breathe 15-20 times through the Mouthpiece (A) and then remove the device from your mouth and huff and/or cough to aid the clearance of mucus.**
- It is important that you remove Revitive Aerosure from your mouth before coughing to clear any mucus. Do not attempt to clear loosened mucus by coughing through the Mouthpiece (A).

Instructions for use

Step 3 : Re-charging Revitive Aerosure



- If the rechargeable battery is low, the red low charge indicator light (I) will flash when the product is in use [see picture 8]. Stop using the product and put it on charge. [See Step 2: Powering Revitive Aerosure]
- If the rechargeable battery is empty, the motor will stop. Revitive Aerosure will not respond when the power button is pressed, and will need recharging.
- A full charge will take approximately twelve hours.

Step 4 : Cleaning Revitive Aerosure



It is recommended that after every use the mouthpiece (A) and Valve Head (B) are cleaned according to the instructions below.



It is recommended that users who are currently suffering from a chronic respiratory disease (e.g. Cystic Fibrosis, Chronic Obstructive Pulmonary Disease) or are prone to recurrent chest infections or have an immune deficiency should soak the mouthpiece (A) and Valve Head (B) in a mild disinfectant solution after every use.

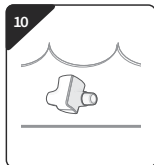


It is recommended that other users should soak the mouthpiece (A) and Valve Head (B) in a mild disinfectant solution at least once a week.

Disinfecting the Head

Prepare an appropriate disinfectant solution in accordance with disinfectant manufacturer's instructions. The disinfectant solution should be suitable for use on equipment that comes into contact with the mouth¹. Remove the mouthpiece (A) and Valve Head (B) from handle (C) and place both the mouthpiece and Valve Head in disinfectant solution. Immerse Valve Head fully and shake it gently to remove any air bubbles [see picture 9].

Instructions for use



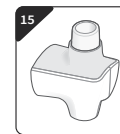
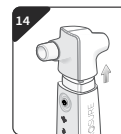
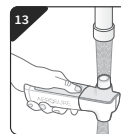
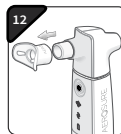
Leave Valve Head to soak in solution for the minimum time specified by the disinfectant solution instructions [see picture 10].

After the specified soak time has passed remove the mouthpiece and Valve Head from solution, rinse with clean water and drain. Allow to air dry for at least 2 hours – to ensure head drains adequately. Ensure that it is standing on the rear vent opening [see picture 11].

¹NOTE: The Valve Head has been tested using disinfectant solutions with the following active ingredient:

- Sodium hypochlorite (CAS: 7681-52-9) 2% w/w diluted and used in line with the manufacturer's directions.
- Sodium dichloroisocyanurate (CAS: 2893-78-9) 19.5% w/w diluted and used in line with the manufacturer's directions.

Cleaning the Head



Remove the mouthpiece (A) from the Valve Head (B) [see picture 12] and rinse under warm running water (approximately 40°C).

With the Valve Head attached to the handle (C) and the Revitive Aerosure switched on, rinse the Valve Head under warm running water to ensure that the Valve Head and its internal components are completely cleaned [see picture 13]. Take care not to put the handle under the running water.

Remove Valve Head from under the water and with the motor still running allow it to drain. Switch off the device and remove the Valve Head [see picture 14]. Shake the Valve Head and mouthpiece to remove any remaining water and allow both to dry fully before reassembling. To help drain any residual water from the Valve Head stand it upright on the vent opening (E) while drying [see picture 15].

The handle and charger (unplugged from mains power supply) should be cleaned as necessary with a damp cloth only.

IMPORTANT: No part of Revitive Aerosure is suitable for dishwasher use.

Instructions for use

Replacement Heads



Replacement Valve Heads are available for your Revivite Aerosure and it is recommended that you replace the Valve Head at least once every 6 months.

Replacement heads are available through your local Revivite Aerosure retailer or distributor, or from the Revivite website.

Please ask for the following part reference.

Revivite Aerosure Replacement Head Item Ref 1377.

Storing Revivite Aerosure

Store in a dry, dust-free location in temperatures between -18°C and 50°C and 25% to 85% relative humidity.

Environmental Notice (Battery)

This product contains rechargeable batteries. In the interest of protecting the environment, please do not dispose of the product in the household waste at the end of its useful life. Disposal can take place by either returning to your local distributor or at approved recycling or disposal locations in accordance with local regulations.

Technical Specifications

Product Model	3481AJ
Software version (shown by V#.#)	See underside of handle.
Charging Voltage	110v-240v
Power supply rating	30mA – 50mA
Battery & Battery Life	Ni-MH / 500 cycles
Fuse	T500mAH250V
Operating Environment	Temperature 0°C to 40°C Humidity 25 to 85% RH Atmospheric pressure 86kPa - 106kPa
Storage and Transportation Environment	Temperature -18°C to 50°C Humidity 25% to 85%RH
Protection rating against ingress of water or particulate matter.	IP45 (Protection against small wires greater than 0.04 in (1.0mm) in diameter and jets of water from all directions.)
Protection against electric shock	Internally powered ME equipment. Class II (for charging unit).Type BF applied part (Valve Head, handle and mouthpiece).
Mode of operation	Continuous

GUIDANCE AND MANUFACTURER'S DECLARATION

Important information regarding Electromagnetic Compatibility (EMC)

With the increased number of electronic devices such as PC's and mobile (cellular) telephones, medical devices may be susceptible to electromagnetic interference from other devices. Electromagnetic interference may result in incorrect operation of the medical device and could create a potentially unsafe situation.

Technical Specifications

In order to regulate the requirements for EMC, with the aim to prevent unsafe product situations, the IEC/EN 60601-1-2 and IEC/EN 60601-1-11 standards have been implemented. These standards define the levels of immunity to electromagnetic interference as well as the maximum levels of electromagnetic emissions for medical devices.

Revivite devices are intended for use in the home setting without the need for involvement of a clinical professional during treatment. On occasion the device may also be used in a hospital environment. In this environment use near the following equipment should be avoided:

- active High Frequency Surgical Equipment
- radio frequency shielded rooms for magnetic resonance imaging (where the intensity of Electro Magnetic 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 and cables other than those specified or provided by Actegy Ltd for this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

⚠ WARNING: Wireless communications equipment such as wireless network devices, mobile phones, cordless telephones and their base stations can affect this equipment and should be used no closer than 30 cm (12 inches) to any part of the Revivite Aerosure, including cables specified by Actegy Ltd. Otherwise, degradation of the performance of this equipment could result.

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Symbols

Contraindications, Warnings and cautions. Make sure you understand these before using Revivite Aerosure	
Type BF medical electrical equipment Parts A, B and C (ref picture 1) are applied parts.	
Medical electrical equipment double insulated	
Complies with European Medical Devices Directive (93/42/EEC)	
The Waste Electrical and Electronic Equipment Directive (WEEE Directive). At the end of the product life-cycle, do not throw this product into normal household waste, but take it to a collection point for the recycling of electronic equipment.	
Legal manufacturer of the device	
EU/EC European Authorised Representative	
UK Conformity Assessed Product conforms to all applicable U.K. legislative requirements.	
Consult instructions for use	
Indicates the LOT number	
Humidity and temperature limit for storage and transportation	
Indicates presence of NiMH battery. (See page 18).	
Not made with natural rubber latex	
Indicates the item model reference number	
Ingress Protection Rating	IP45

Your 2-year warranty

It is important to retain the retailer's receipt as proof of purchase; we suggest you staple your receipt to this manual for future reference.

In the unlikely event of your product proving to be faulty within 28 days of purchase it should be returned to the place where you bought it. If a fault develops after this period we grant a 2-year limited guarantee on the product commencing on the date of purchase.

Within the guarantee period we will eliminate, free of charge, any defects in the product resulting from faults in materials or workmanship, either by repairing or replacing the complete product as we may choose.

To obtain service within the guarantee period contact your local distributor. You will be asked to return the product (in secure, adequate packaging) together with a copy of proof of purchase. Subject to the exclusions set out on page 23 (see Exclusions) the faulty product will then be repaired or replaced within 7 working days of receipt. The guarantee extends to every country where this product is supplied by Actegy or its appointed distributor.

If, for any reason, the product is replaced during the 2-year guarantee period, the guarantee on the new item will be calculated from the original purchase date.

EXCLUSIONS

Actegy Ltd, manufacturer of Revitive Aerosure, shall not be liable to replace or repair the goods under the terms of the guarantee where:

- Damage or the fault is due to improper use, normal wear or use (especially regarding the Valve Head), accidental use, misuse, negligent use or use contrary to the manufacturer's recommendations or where the fault has been caused by power surges or damage carried out in transit
- Defects have a negligible effect on the value or operation of the appliance.
- The device has been used on a voltage supply other than that stated on the product or used with a power adapter other than the one supplied with the product.
- Repairs have been attempted or undertaken by a person other than our service staff (or an authorised dealer) or if original Revitive Aerosure parts are not used
- The device has been used for hire purposes or non-domestic use
- The device is second hand

Actegy Ltd are not liable to carry out any type of servicing work under the guarantee.

This guarantee does not confer any rights other than those expressly set out above and does not cover any claims for consequential loss or damage. This guarantee is offered as an additional benefit and does not affect your statutory rights as a consumer.

REVITIVE®

Aerosure®



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**UK
CA**

BREATHING RELIEF

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