

REVITIVE[®]

AEROSURE

User's Manual



**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

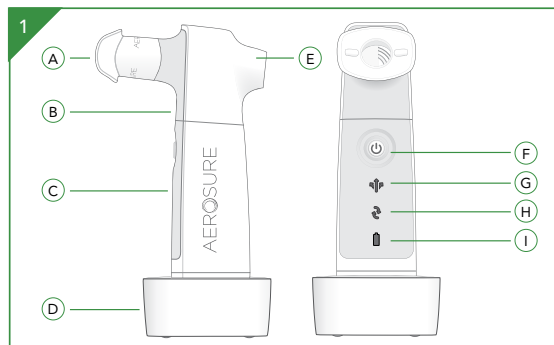
If symptoms persist, consult
your healthcare professional.



Model number: 3481AJ

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- (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

INDICATIONS FOR USE

- Reduce breathlessness in healthy people, and patients with asthma and 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; and
- Improve quality of life in patients with COPD, bronchiectasis, asthma and cystic fibrosis.



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 gastro-intestinal 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)
- You are experiencing a sudden worsening of breathlessness. For example (but not limited to) exacerbations of asthma.

Warnings

- 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.
- Use of this device at excessive pressures may have adverse effects.
- It is not advised to use this device in the case of users with neurological disorders, end-stage respiratory disease (incl. COPD and CF) unless under medical supervision.
- 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.



Warnings (continued)

- Swallowing air should be avoided as this may lead to an increased likelihood of vomiting and aspiration
- 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 16].
- 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.
- Do not reach for a charger that has fallen into water. 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 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 product or charger.
- Ensure no particles or objects are lodged in the valve head and obstructing airflow.

SAVE THESE INSTRUCTIONS

STEP 1 : BEFORE USE

REVITIVE Aerosure has been designed with home users in mind. Please consult the contraindications and warnings prior to use.



Please ensure that **all** of the following checks are carried out before each use of REVITIVE Aerosure.

- Ensure that both the Valve Head (B) and mouthpiece (A) are securely in place.
- Ensure the airway between the mouthpiece (A) and the vent (E) is both clean and dry. If not, please clean the product [see page 16].
- Ensure that there are no obstructions of any kind in the airway between the mouthpiece (A) and the vent (E). If any obstruction is found, please clean the product [see page 16].

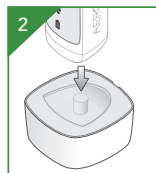
STEP 2 : POWERING REVITIVE AEROSURE



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

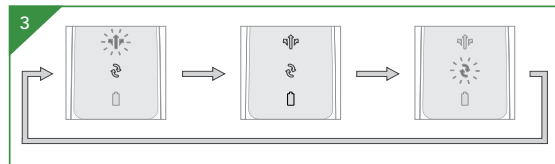


The charger Plug is intended as the means of isolation from the supply mains. Do not position the plug or charger in a position where it is difficult to disconnect from the supply mains.



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

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



Instructions for use

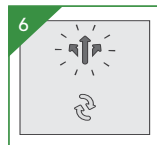
- REVITIVE Aerosure is charging. Once fully charged, the indicator lights will simultaneously flash on and off for ten minutes. After this period the product will turn off automatically to preserve battery life and no indicator lights will be lit.
- The product will require a full charge prior to first use: approximately 12 hours.
- A full charge enables approximately one and a half hours of use.

STEP 3 : 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 buttons 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.



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 lit [see picture 6].

- 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 normally.
- 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).



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 lit [see picture 7].
- Place the Mouthpiece (A) in your mouth.
- Breathe as hard as you are comfortably able to, through the Mouthpiece (A) for five minutes, 2-3 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 lit.

STEP 4 : 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.
- If the rechargeable battery is empty the motor will stop and the REVITIVE Aerosure will not respond when the power button is pressed and will need recharging.
- A full charge will take approximately twelve hours.

STEP 5 : CLEANING REVITIVE AEROSURE



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



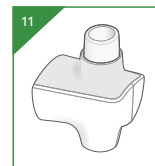
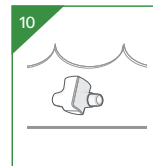
It is recommended that users who are currently suffering from a chronic respiratory disease (e.g. Cystic Fibrosis, Chronic Obstructive Pulmonary Disease) or are prone to recurrent chest infections or have an immune deficiency should soak the mouthpiece (A) and Valve Head (B) in a mild disinfectant solution 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 [\[see picture 9\]](#).



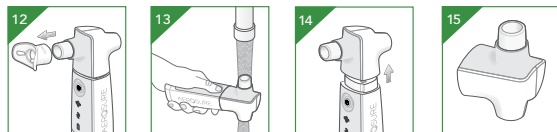
Leave Valve Head to soak in solution for the minimum time specified by the disinfectant solution instructions [\[see picture 10\]](#).

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) and rinse under warm running water (approximately 40°C) [see picture 12].

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 from under the water and with the motor still running allow the Valve Head to drain. Switch off the product 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.

REPLACEMENT HEADS



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

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

Please ask for the following part reference.

REVITIVE Aerosure Replacement Head **Item Ref 1377.**

STORING REVITIVE 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.

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 (protected against small tools and wires >1mm and low pressure water jets)
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

NOTE: Not intended to be sterilised. Not suitable for use in an OXYGEN RICH ENVIRONMENT - if you are on oxygen we recommend you use your REVITITE Aerosure in a well-ventilated room.

Materials have been selected and tested to ensure no irritation or allergic reaction in accordance with biocompatibility standards.

Medical electrical equipment needs special precautions regarding EMC for installation and use according to the EMC information provided in this user manual.

Wireless communication equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations or walkie-talkies can affect this equipment and should be kept at least a distance of 3.3m away from the equipment.

(Note: As indicated in Table 6 of IEC 60601-1-2:2007 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).

Contraindications. This describes situations where you should not use the REVITITE Aerosure	
Warnings and cautions. Make sure you understand these before using the REVITITE 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 lifecycle, 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	
Consult instructions for use	
Indicates the LOT number	
Humidity and temperature limit for storage and transportation	
Indicates presence of NiMH battery. (See page 20).	
Indicates the item model reference number	

Your International Two 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 below (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

Legal Manufacturer



 Actegy Ltd.
Reflex, Cain Road
Bracknell, Berkshire, RG12 1HL
United Kingdom.

Country Distributors:

International and UK:

Tel: +44 (0)845 871 5989

Ireland

Tel: 01677 0164



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