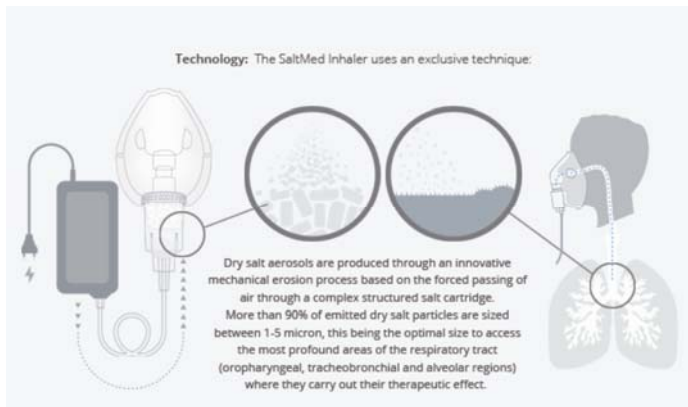


## INTRODUCTION

The SaltMed inhalation device generates dry salt aerosols with salt particles of 1 – 5 micron and has been shown to have significant therapeutic benefits in the treatment of respiratory conditions such as: Acute Bronchitis, Allergic Rhinitis, Bronchiolitis, Asthma, COPD, Cough, Cystic Fibrosis and several other ENT conditions.

SaltMed uses an innovative mechanical erosion process based on the forced passing of air through a complex structured dry salt cartridge.

SaltMed devices are delivered with an L-type cartridge which can be used up to 50 hours. An N-type cartridge is also available which can be used up to 100 hours. N-type cartridges are primarily recommended for hospital / intensive use. Please see [www.saltmed.co.uk](http://www.saltmed.co.uk) for more details.



## TABLE OF CONTENTS

1. Important safety precautions	page 2
2. Product overview	page 4
3. Operation	page 5
4. SaltMed cartridge replacement	page 7
5. SaltMed Inhalation Device in respiratory therapy	page 7
6. Therapeutic recommendations	page 8
7. Troubleshooting	page 9
8. Technical data	page 9
9. Disposal of Unit	page 10
10. Bibliography	page 11
11. Warranty	page 12

### 1. Important safety precautions

When using any electrical appliance, basic safety precautions should always be followed including the following:

- Read all instructions carefully before using any appliance.
- Always ensure that the voltage on the rating label corresponds to the mains voltage in your home. Always connect the air pump to a proper electrical outlet – 230 V AC.
- Incorrect operation and improper use can damage the appliance and cause injury to the user.
- This appliance is not intended for use by persons (including children) with reduced physical, sensory or mental capabilities, or lack of experience and knowledge, unless they have been given supervision or instruction concerning use of the appliances by a person responsible for their safety. Children should be supervised to ensure that they do not play with the appliance.
- Check the power cord and plug regularly for any damage. If the cord or the plug is damaged, it must be replaced by

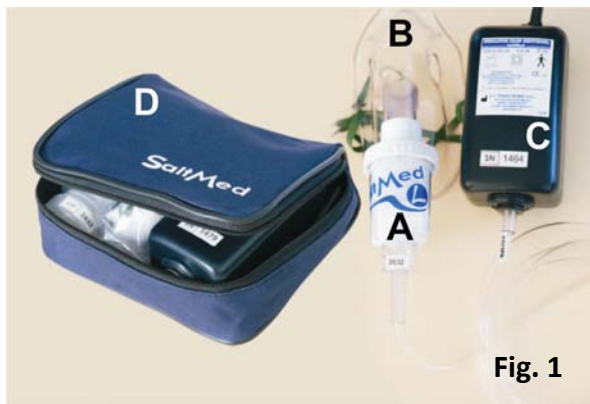
the manufacturer or qualified person in order to avoid an electrical hazard.

- Do not use the appliance if it has been dropped or damaged in any way. In case of damage, take the unit in for examination and/or repair by the authorised service agent.
- Never immerse the unit in water or any other liquid for cleaning purposes.
- Remove the plug from the socket by gripping the plug. Do not pull on the cord to disconnect the appliance from the mains. Always unplug the unit when not in use, before cleaning or when adding or removing parts.
- The use of accessory attachments that are not recommended or supplied by the manufacturer may result in injuries, fire or electric shock.
- Do not use the appliance for anything other than its intended use.
- Do not carry the appliance by the power cord.
- Do not leave the appliance unattended during use. Always unplug the unit when not in use or before cleaning.
- Ensure that the unit is switched off after use.
- The manufacture does not accept responsibility for any damage or injury caused by improper or incorrect use, or for repairs carried out by unauthorised personnel.
- In case of technical problems, switch off the machine and do not attempt to repair it yourself. Return the appliance to the authorised service facility for examination, adjustment or repair. Always insist on the use of original spare parts. Failure to comply with the above mentions precautions and instructions, could affect the safe operation of this product.
- Do not use the appliance on a gas or electric cooking top or over or near an open flame. Keep the device far from heat and hot surfaces.
- Do not block the air exhaust hole.

- The SaltMed cartridge should always be used in the upright/ vertical position.
- Do not use the air pump on surfaces that could clog the air intake filter.
- Never use the device while you are sleeping.
- The supply cord cannot be replaced. If it is damaged, the pump is no longer usable. *Warning* – Using a damaged supply cord can result in electric shocks.
- Do not store or use the device in environments with excessive humidity, dust, oily aerosols or where it can be splashed with water.

## 2. Product overview

The SaltMed device (Fig. 1) includes the salt cartridge 'A', a mask 'B', air pump 'C' and hose 'D' packed in a fabric bag. The air pump is connected to the cartridge with the PVC flexible hose.



SaltMed cartridge 'A' is supplied in a special storage container (Figure 2) which includes in its lower section silica-gel, a drying agent to absorb humidity.

SaltMed cartridges should always be stored in their containers when not in use, to maintain the efficacy. It is important to keep the SaltMed cartridge dry. If the air humidity exceeds 65% due to inadequate cartridge storage, blockage of the salt layer will occur and lead to a loss in therapeutic effect.

### SaltMed cartridge in its storage container

Photo

Cross section



Fig. 2

Description:

- 1 - Container cover
- 2 - Storage container
- 3 - Top cover of cartridge
- 4 - NaCl grain layer
- 5 - NaCl micro-crystals layer
- 6 - Connector (PVC tube to air pump)
- 7 - Storage container filter
- 8 - Silica gel

During use, air from the pump passes through the microcrystalline layer in the lower part of the cartridge and will create the visible appearance of a 'boiling' movement. The air under pressure erodes the salt micro-crystals and generates dry salt particles of 1-5 micron.



Fig. 3

### 3. Operation

1. Place the air pump on a rigid flat surface.
2. Insert the plug into an electrical outlet (voltage 230 V, AC). The pump will create a slight buzzing noise and generate an air flow.
3. Connect the PVC hose to the pump using the end marked 'PUMP'.
4. Take the SaltMed cartridge from its storage container, immediately closing the storage it.
5. Attach the other end of the PVC tube to the connector on the lower part of the SaltMed cartridge. The 'boiling' phenomenon of the lower micro-crystal layer should be observable.
6. Attach the mask 'B' to the SaltMed cartridge. Place the mask on the face so that the SaltMed cartridge is in a vertical position and breathe normally for the duration of the treatment session.
7. At the end of treatment switch off the pump and remove the mask from the face.
8. Detach the SaltMed cartridge and place it back into its storage container.
9. Wipe the mask with cotton and disinfect it with alcohol (ethyl alcohol, max. 70%). It is recommended to periodically wash the mask with warm soapy water and to thoroughly rinse it with clean water.
10. Place all of the components back into the fabric bag for protection and keep the bag in a dry place.

**WARNING:** Moist SaltMed cartridges will produce less salt micro-particles and due to this increased humidity the 'boiling' phenomenon of the lower microcrystalline layer may not appear. This may reduce the therapeutic effect. This situation may be overcome by storing the cartridge in its special container for 10-20 hours. The silica gel will reduce the humidity

of the SaltMed cartridge. After this time shake the cartridge to loosen the microcrystalline salt layer and check its operation using the air pump. If the 'boiling' phenomenon does not appear the SaltMed cartridge will need to be replaced.

#### **4. SaltMed cartridge replacement**

SaltMed devices are delivered with an L-type cartridge which can be used up to 50 hours. To maintain its therapeutic effect a SaltMed L-cartridge should be replaced after 40-50 hours of use and within two months of its first use.

An N-type cartridge is also available which can be used up to 100 hours. N-type cartridges are primarily recommended for hospital / intensive use.

Use original SaltMed cartridges only. Please see [www.saltmed.co.uk](http://www.saltmed.co.uk) for more details

#### **5. SaltMed Inhalation Device in respiratory therapy**

The highly concentrated active salt particles, optimally sized between 1 and 5 microns are inhaled into the respiratory tract. They are dissolved in the mucus layer covering the airway epithelium and attract water from interstitial tissue into the airways. As a result, inflammation is reduced and hydration of the mucus increases.

Reduction of local inflammation improves the symptoms related to airway obstruction and inflammation (such as nasal obstruction, sinus pressure, local pain). Respiratory secretions fluidisation improves the mucus removal and alleviates the stress of an exhausting dry cough by changing it into a productive cough.

Additionally, dry salt aerosols increase protection against respiratory infections and provide anti-inflammatory, immunomodulating and desensitisation effects which are very important in allergic respiratory diseases (asthma, allergic rhinitis).

Consequences of these effects: the SaltMed Inhalation Device assists over time to an elimination of respiratory episodes of infectious (cold, flu) or allergic (allergic rhinitis, asthma) diseases. A reduction in relapses and acute exacerbations in chronic patients may also occur.

## **6. Therapeutic recommendations**

- Administration: the SaltMed Inhalation Device is recommended for daily use (up to three sessions of 30 minutes or more duration), depending on the severity of the disorder and the advice of the physician.
- Use of a SaltMed Inhalation Device is a complementary therapy and does not replace conventional treatment. Do not interrupt or modify the current treatment protocols recommended by a physician.
- The SaltMed Inhalation Device is intended to be used by an individual person. We recommend that you personalise your SaltMed cartridge by filling in your details on the container label.
- Hydrate yourself properly.
- Interactions with other medications: SaltMed may be used together with any other medications.
- Side effects: In isolated cases (e.g. patients lacking vitamin A, E and /or with insufficient hydration) dryness of the pharynx may occur. Administration of Vitamin A, E and normalising the hydration will eliminate this effect.
- Contraindications: none reported.



## 7. Troubleshooting

Disposables (mask, tubing, cartridge) should be checked for damage on receipt and should be returned for replacement within 14 days from the date of receipt. If on inspection they are found to be defective, they will be replaced free of charge.

The pump supplied for the SaltMed Inhalation Device has a warranty of 24 months from date of purchase.

In case of malfunction return the pump to the manufacturer for repair. The repairs shall be free of charge within the warranty period and chargeable after the warranty has expired. No preventive maintenance operations are necessary.

## 8. Technical data

Specifications:

- dimensions (package): 265x185x75 mm
- weight: 0.6 kg
- supply voltage: 230 V AC/ 50 Hz
- air flow: 2 l/min
- absorbed power: 5 VA
- fuse: T32 mA 250 V AC
- noise level: 60 dBA
- air pump: Resun AC 9601 type
- storage temperature: +5 to +40°C
- humidity: 45 to 65 %

Classification:

According to EN 60601-1:2007, Electro-medical devices:

- a) device with AC electrical supply;
- b) class II devices, upon the type of protection against electric shock;
- c) B-type applied part, upon the degree of protection against electric shock;
- d) equipment that can be disinfected;
- e) device that is unprotected for being used in the presence of flammable mixture with air or oxygen or nitrogen monoxide;
- f) protection degree: IP 20;
- g) continuous regime device;
- h) portable device.

Description of the symbols:



Clase II duple  
insulation



Use By



Manufacturer



Apply tipe  
part B



1868

Complying with MDD 42/93 EEC



Date of manufacture

## 9. Disposal of Unit



Disposal instructions for items in accordance with the WEEE directive. Appliances bearing the symbol shown here may not be disposed of in domestic rubbish. You are required to dispose of old electrical and electronic appliances like this separately. Please visit [www.recyclemore.co.uk](http://www.recyclemore.co.uk), or [www.reyclenow.co.uk](http://www.recyclenow.co.uk) for access to information about the recycling of electrical items. The WEEE directive, introduced in August 2006, states that all electrical items must be recycled, rather than taken to landfill. Please arrange to take this appliance to your local Civic Amenity site for recycling, once it has reached the end of its life.

## 10. Bibliography

(1) - Continuous nebulization therapy for asthma with aerosols of  $\beta_2$  agonists Otto G Raabe, PhD; Timothy M Wong, BS; Garrett B Wong; James W Roxburgh, MBA, RRT; S David Piper; and James I C Lee, BS ANNALS OF ALLERGY, ASTHMA, & IMMUNOLOGY VOLUME 80, JUNE, 1998

(2) - Inhaling to mitigate exhaled bioaerosols

David A. Edwards, Jonathan C. Man, Peter Brand, Jeffrey P. Katstra, K. Sommerer, Howard A. Stone, Edward Nardell, and Gerhard Scheuch

Communicated by Howard Brenner, Massachusetts Institute of Technology, Cambridge, MA, November 4, 2004 (received for review July 18, 2004)

## 11. Warranty certificate

Device No: .....Year of manufacture: .....

Cartridge type: ..... Year of manufacture: .....

Invoice no: .....Supplied by: .....

Full name of purchaser: .....

Address: .....

Supplier

.....

Buyer

.....

The pump supplied for the SaltMed Inhalation Device has a warranty of 24 months from date of purchase.

In case of malfunction return the pump to the manufacturer or the manufacturers authorised representative for repair. The repairs shall be free of charge within the warranty period and chargeable after the warranty has expired. Warranty applies only if the device has been used in accordance with the manufacturer's recommendations. No preventive maintenance operations are necessary. Tampering with the device, accidental damage and damage due to misuse or negligence will not be covered by warranty and will be chargeable.

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