TEHNO BIONIC

User Manual
DRY SALT INHALER
SaltMed ®

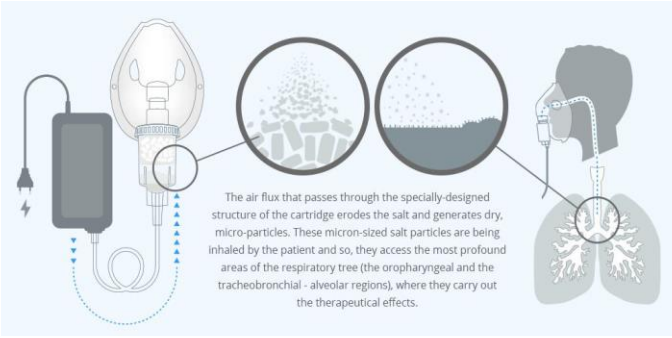
Contents

CE 1370

1. Introduction

The SaltMed inhaler distributes dry micro-particles of NaCl, making it an effective adjuvant therapy in the treatment of various conditions of the upper and lower respiratory pathways: asthma, bronchitis, sinusitis, rhinitis, respiratory allergies etc.
Dry micro-particles of NaCl are created by an innovative process based on the forced passage of air through a uniquely designed cartridge containing dry salt.

Technology: SaltMed is an unique innovation



SaltMed devices are available with either an L-type cartridge or an N-type cartridge.
The L-type cartridge is recommended for home use for individual sessions of up to 90 mins at a time and can be used for up to 60 hours. The N-type cartridge is recommended for hospital or intensive use at home and can be used for sessions of up to 12 hours continuously, and up to 100 hours in total.
For use with high pressures and flows in hospital units, it is recommended to use the Forte type cartridge.

Attention! The SaltMed device must be installed and put into operation according to the information in this manual.

2. SaltMed device in respiratory therapy

Salt micro-particles, with optimum dimensions between 0.3 and 5 microns, are inhaled into the respiratory tract. They are dissolved in the mucus layer that covers the airway epithelium and draws water from the interstitial tissues. As a result, inflammation is reduced and mucus hydration increases, thus eliminating it more easily. In addition, dry salt aerosols increase protection against respiratory infections, providing anti-inflammatory, immunomodulatory and desensitizing effects, very important effects in alleviating allergic respiratory diseases (asthma, allergic rhinitis). As a consequence, the SaltMed Inhaler helps in time reduction of respiratory infectious (colds, flu) or allergic (allergic rhinitis, asthma) episodes. There is also a reduction in relapse and exacerbations in chronic patients.

3. Description of SaltMed device

The **SaltMed** device (Fig. 1) includes the cartridge, an aerosol mask, air pump and oxygen tubing packed in a carton box. The air pump is connected to the cartridge with the flexible tube.

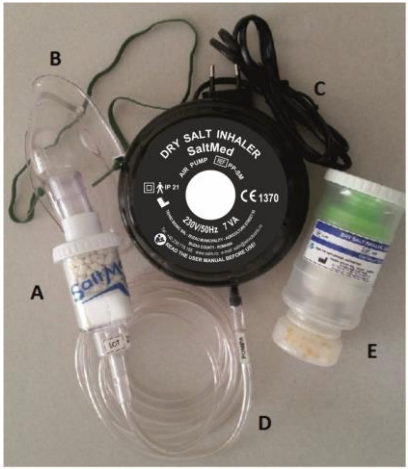


Fig. 1 - The SaltMed Device

A: Salt cartridge;

B: Aerosol mask

(Separate device);

C: Air pump;

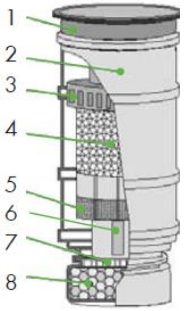
D: Oxygen tubing

(Separate device);

E: Cartridge storage container.

SaltMed cartridge

SaltMed is delivered in a container (Fig. 2) which includes silica-gel in its lower section, to absorb humidity and maintain the optimum functional characteristics. It is very important for the cartridge to be stored only in this container between uses. If the cartridge is not properly stored, adhesion of the salt particles may occur, leading to a decrease in the therapeutic effect. The air from the pump passes through the microcrystalline layer in the lower part of the cartridge (5 – Fig. 2) and creates the visible appearance of a 'boiling' movement (Fig. 3). The air under pressure erodes the salt micro-crystals and generates dry salt particles with dimensions between 0,3-5 microns. The air significantly enriched in sodium chloride micro-particles is then subject to an advanced filtering process and ionization modifications all of which allow high-efficiency treatment of various respiratory disorders.



1 – Container cover
2 – Storage container
3 – Upper cover, mask connection
4 – NaCl extruded grain layer
5 – NaCl micro-crystal layer
6 – Connector (tube to PP-SM air pump)
7 – Container sieve
8 – Silica-gel

Fig. 2 - Filtering cartridge in the storage container

Fig. 3 - 'Boiling' movement

4. Precautions and warnings

Attention!
Do not use the SaltMed device if you are in doubt about its proper functioning or any other problem!

User safety – WARNINGS

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.

- Keep the device out of the reach of children and pets. Inhaling hair or feathers from pets can cause health problems.
- Users should check the device, ensuring that it is clean, before each use, to avoid contamination.
- Do not use the device over a gas or electric cooking top or near an open flame. Keep the device away from heat and hot surfaces.
- Do not block the air exhaust hole.
- Do not kink or strangle the tube as this can cause the device malfunction.
- The cartridge should always be used in upright / vertical position.
- Do not position the air pump on surfaces which could obstruct the air intake filter.
- Never use the device while you are sleeping.
- After using the device, make sure that is turned off.
- The supply cord cannot be replaced. If it is damaged, the pump is no longer usable. Using a damaged supply cord can result in electric shocks.
- The power cord plug is meant for isolating the device from the supply mains, DO NOT place the device in such a way that it is difficult to disconnect the plug from the mains.
- Device is not intended to operate in an OXYGEN RICH ENVIRONMENT, flammable or anesthetic agents.
- Do not store or use the device in environments with excessive humidity, dust, oily aerosols or where it can be water spilled.

The use of a SaltMed device is a complementary therapy and does not replace current medical treatments. Do not interrupt or modify the current treatment! Follow your physician's advice!

Maintaining SaltMed device - WARNINGS

- Do not immerse the device and do not allow liquids to moisten the device or components, so as the liquid pours into the device.
- Disconnect the device from power supply before cleaning.
- Do not attempt to open, disassemble or repair the device; it does not contain parts that can be repaired by the user. Call the qualified service personnel for troubleshooting.
- Examine the presence of defects on the supply cables / connectors and components before every use. In case of any defect, do not use the device until its replacement.
- To reduce the risk of fire or electric shock, use only the recommended accessories and do not expose the device to rain or moisture.
- Use only compatible accessories and spare parts; use of other accessories can reduce the operational safety of the device.
- Changes to the SaltMed inhaler device are not permitted.

5. Indications for Use

Indications for use - WARNINGS

Do not use the SaltMed device for anything other than its intended use.

The patient may be the intended operator.

The SaltMed device is suitable in the treatment of upper and lowers respiratory conditions such as: asthma, bronchitis, sinusitis, rhinitis, inhalant allergies and several other ENT conditions.

- Administration: the device is recommended for daily use (one to three sessions of 30-minute), depending on the severity of the condition and the advice of the physician.

- Use of a device is a complementary therapy and does not replace conventional treatment. Do not interrupt or modify the current treatment! Follow your physician's advice.
- The device is intended to be used by only one person. We recommend that you personalize your cartridge by filling in your details on the container label.
- Hydrate yourself properly.
- Interactions with other medications: No interactions of SaltMed with any other medication have been reported.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

5.1 Mask and oxygen tube compatible with SaltMed Device

Mask and oxygen tube - WARNINGS

- Before the inhalation session, make sure the chosen mask and oxygen tube are compatible with your device.
- Both mask and oxygen tube are single use medical devices, according to the manufacturer's recommendations.

The following masks and oxygen tubes compatible with device can be selected:

Name	Characteristics	Description
Aerosols mask	Medical device - IIa Class	Pediatric or Adult Mask*
Oxygen tubing	Medical device - IIa Class	Length = 2.1 m or other*

*NOTE: Depending on the needs of the patient

6. Contraindications and precautions

6.1 Contraindications

- Contraindications: None reported

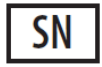
6.2 Precautions

- The SaltMed inhaler is not intended for use by persons (including children) with reduced physical, sensory or intellectual abilities, or lack of

experience and knowledge, unless they are supervised or previously trained for using of the device by a person responsible for their safety.

- It is not recommended to use the SaltMed inhaler for pregnant woman.

7. Symbols

	Manufacturer		Date of manufacture
	The user should read the user manual before using the device		Compliance with European Directive 93/42 / EC
	B-type applied part		Serial number of the Air Pump
	Catalogue number	LOT	Lot Number
	Use by date		For single use only
	II class device		Under normal use, hazardous voltages may be present
IP21	Protection against solid particles > 12.5 mm; Liquid ingress protection: Dripping water		Logo on electrical and electronic waste
	Do not use if package is damaged		Recyclable packaging
	Fragile, handle with care		Keep dry

8. Operating environment aspects

Operating environment - WARNINGS

- Protecting the patient / user is essential in accordance with regulatory requirements.
- Injuries may come from two sources:

■ A short circuit when the current is directed to the ground through the patient

■ Surge or lightning.

Injuries can be avoided by checking the power cord regularly for any damage. If the cord is damaged, it should be replaced by the manufacturer in order to avoid an electrical hazard.

Dust and lint can affect the correct functioning of the device, including blocking the tube.

Powering SaltMed device

PP-SM Pump supply from the mains

Voltage: 230 V (-15%; +10%); Frequency: 50 Hz; Absorbed power: 7 VA; Fuse: T32 mA 250 V AC

Temperature and humidity during use

The SaltMed Inhaler can operate within the limits of 5 - 40^{0}C.

The air relative humidity shall be in the range 15-90%, without condensation.

9. Installing

Please do not install the device before reading the manual.

In the event of problems users may contact TEHNO BIONIC or its representative:

- For assistance on the installation, use and maintenance of device
- To advise on malfunction or unexpected event.

9.1 Unpacking

Carefully unpack the box and check its contents. The packaging has been specially designed to ensure optimum protection of device components during transport; however, if a component is damaged or missing, do not use the device; contact the producer or the supplier.

Keep the package (individual box) to store the SaltMed kit between uses.

Inside the box you will find the following:

Cartridge storage container	1 pc.
Cx-SM; L, N or Forte type filtering cartridge (REF CN-SM, CL-SM, CF-SM)	1 pc.
Mask Aerosol	1 pc.
PP-SM: Air pump	1 pc.
Oxygen tubing	1.pc.

9.2 Cleaning

The device and its accessories are supplied in non-sterile condition.
After use it is disconnected from the socket, wash and disinfect the mask (washing with water and soap, rinse with water and disinfect with alcohol 70%).

9.3 Moving

WARNING: Do not carry the device by the power cord.

Device components (cartridge, mask, air pump, tube) are light and portable. It can be located and conveniently positioned near the treatment area (for example, it can be placed on a table).

Before moving device, make sure the following conditions are met:

- The device is unplugged;
- All accessories and cables are disconnected;
- If you place the device on a table or other support, make sure they are fixed and not subject to shocks, vibrations or other uncontrolled motion.

10. Operating Instructions

WARNING: Incorrect operation and improper use can damage the device and cause injury to the user. Do not pull 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.

1. Place the air pump on a rigid flat surface, near an accessible outlet.
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 tube to the pump.
4. Take the SaltMed cartridge out of its storage container, immediately closing the storage container lid.
5. Attach the other end of the tube to the connector on the lower part of the SaltMed cartridge (Fig. 1) and the 'boiling' phenomenon of the micro-crystal layer should be observable.
6. Attach the aerosols mask to the SaltMed cartridge. Place the mask on the face so that the SaltMed cartridge is in a vertical position and inhale the filtered air enriched with NaCl dry particles.
7. At the end of treatment remove the mask from the face and switch off the pump.

After unplugging, wait 2-3 minutes, then unplug the tube from the cartridge.

8. Detach the SaltMed cartridge and place it back into it storage container with the silica-gel.
9. Place all of the components back into the carton box for protection and keep the box in a dry place.

WARNING: Due to increased air humidity (>70%) the 'boiling' phenomenon of the microcrystalline layer may not appear during use. The moist microcrystalline layer will not produce salt micro-particles and this will nullify the therapeutic effect. This situation may be over come by storing the cartridge in its special container for 12 - 24 hours in a dry place. The silica gel will reduce the cartridge humidity. After that, shake the cartridge to loosen the microcrystalline salt layer and check its functioning using the air pump. If the 'boiling' phenomenon does not appear or is very low, the SaltMed cartridge needs to be replaced.

10.1 SaltMed cartridge replacement

SaltMed devices are delivered with an L-type cartridge recommended for home use and can be used up to 60 hours. To maintain its therapeutic effect,

a SaltMed L-cartridge should be replaced after 50-60 hours of use, but not more than 3 months since opening the original package.
There are also available the N-type cartridge, which can be used up to 100 hours and the Forte-type cartridge, which can be used up to 50 hours. N and Forte-type cartridges are recommended for use in medical facilities or for intensive use at home.

11. Maintenance

- No special maintenance operations are necessary.
- The air pump does not require part maintenance or lubrication.
- In case of malfunction (The pump doesn't work; Damaged filtering cartridge; Punched connection tube; Damaged mask) contact the manufacturer for repair (exceptions are the tube and the mask, which shall be replaced with new ones). The repairs will be free of charge within the warranty period and chargeable after the warranty has expired.

12. Service

12.1 General dates
Repairs should be performed only by qualified personnel that have been authorized by the producer; otherwise, TEHNO BIONIC is not responsible for the safety, reliability and performance of the device.

12.2 Loss of warranty
Any guarantee or warranty claims are void if the user or an unauthorized person tries to repair the device.

12.3 Description of defects
To enable the producer to carry out repairs in a short time, send the device, accompanied by a detailed description of the defect.

12.4 Handling before shipment
For the protection of our personnel carrying out repairs, we request that SaltMed is cleaned and disinfected before returning it for repair. TEHNO BIONIC is entitled to refuse repairs if the inhalers are received in a dirty or contaminated condition.

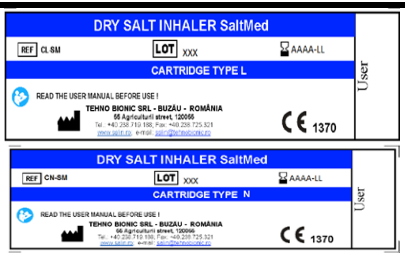
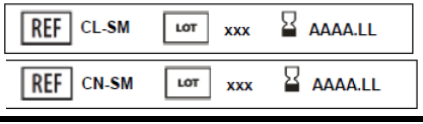
12.5 Shipping
To return a faulty device, please use the original packaging; if this is not possible, pack the device so that it is protected during transport.

13. Specifications

Classification	
MDD 93/42/EC	Medical Device Class IIa, Rule 11
EN 60601-1 Type of protection against electric shock Degree of protection against electric shock Method of sterilization Depending of operating mode	 Class II Part applied Type B Disinfectable device Continuous operation
EN 60529	IP21
Dimensions (mm)	
Box (L x l x h)	280 x 160 x 90
Weight (Kg)	
Box	max. 0.65 Kg
Electrical and operating specifications	
Input Voltage	230 V (196 V – 253 V) /50 Hz
Absorbed power	5VA for 196 V; 7VA for 253 V
Power supply cord	2 x 0.75 mm^2
Air flow	2 l/min - cartridge type L; 2-4 l/min - cartridge type N, Forte
Noise level	max. 60 dB
Environmental conditions	
Operating temperature	5 – 40 ^{0}C
Transport and storage temperature	(– 25) – (+70) ^{0}C
Relative Humidity	15 -90 %, without condensation
Conditions for operation and maintenance	
Average level of service request	90 minutes / day (L); 6 h/day (N)

Normal duration of use Validity	4 years for air pump 2 years for salt cartridge in storage container

14. Labelling

Label	Description	Location
	Identification label PP-SM Air pump	Housing PP-SM Air pump, on the upper face
	Identification label CT-SM Storage Container	On cartridge storage container
	Identification label CL-SM, CN-SM Salt Cartridge	On salt cartridge

Label	Description	Location
SN XXX  AAAA.LL LOT XXX  AAAA.LL	Identification label the boxes	On the boxes

15. Recycling

The device is made of non-biodegradable components, their elimination in the environment is not recommended. At the end of the Saltmed device life, please submit it to an electrical and electronic equipment recycling operator. Recycling is done by licensed operators according to WEEE Directive 2012/19/EU

16. ELECTROMAGNETIC COMPATIBILITY DECLARATION

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">Dry salt inhaler- Saltmed is intended for use in the electromagnetic environment specified below. The customer or the user of the Dry salt inhaler- Saltmed should assure that they are used in such an environment.</td></tr>
<tr><th>Emission tests</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>Dry salt inhaler use 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.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">Dry salt inhaler is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/flicker emissions
IEC 61000-3-3</td><td>Pass</td></tr>
</table>