

# User Manual

## DRY SALT INHALER

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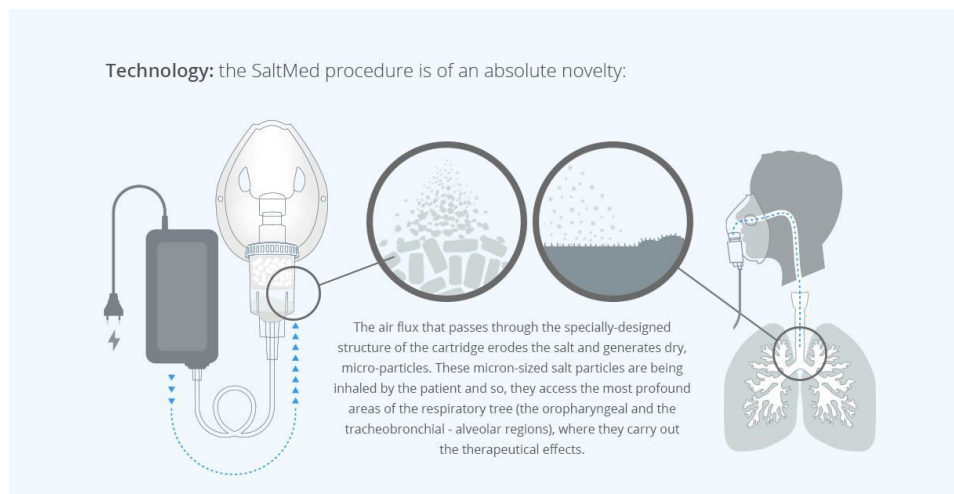


## SaltMed<sup>®</sup> – DRY SALT INHALER – User Manual

### 1 Introduction

The SaltMed<sup>®</sup> 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<sup>®</sup> uses an innovative mechanical erosion process based on the forced passing of air through a complex structured dry salt cartridge.



SaltMed<sup>®</sup> devices are delivered with an L-type cartridge recommended for home, which can be used up to 50 hours. An N-type cartridge is also available which can be used up to 100 hours. N, Forte-type cartridges are primarily recommended for hospital / intensive use.

#### CAUTION!

The SaltMed<sup>®</sup> inhalation device 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 by a person responsible for their safety. Children should be supervised to ensure that they do not play with the appliance.



#### Installation and operation of SaltMed<sup>®</sup> device - Warnings

WARNING: The SaltMed<sup>®</sup> inhalation device must be installed and put into operation according to the information in this manual.

### 2 SaltMed<sup>®</sup> 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

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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, immune-modulating and desensitization effects which are very important in allergic respiratory diseases (asthma, allergic rhinitis).

Consequences of these effects: the SaltMed<sup>®</sup> 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.

### 3 Precautions and warnings

#### CAUTION:

Do not use the SaltMed<sup>®</sup> device if you are in doubt regarding its proper functioning or any other problem!



Do not use the SaltMed<sup>®</sup> device in locations where flammable or explosive substances are found.



#### Patient and user safety – WARNINGS

WARNING: 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.

WARNING: Keep the SaltMed<sup>®</sup> device away from children and pets. Inhalation hair or stains from pet can cause respiratory health problems.

WARNING: Users should check the SaltMed<sup>®</sup> device, ensuring that it is sufficiently clean, before each use, to avoid contamination.

WARNING: Do not use the the SaltMed<sup>®</sup> device on a gas or electric cooking top or over or near an open flame. Keep the device far from heat and hot surfaces.

WARNING: Do not block the air exhaust hole.

WARNING: Do not strangle tube; this can cause the malfunction of device.

WARNING: The SaltMed<sup>®</sup> cartridge should always be used in the upright / vertical position.

WARNING: Do not use the air pump on surfaces that could clog the air intake filter.

WARNING: Never use the device while you are sleeping.

WARNING: 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.

WARNING: Do not store or use the device in environments with excessive humidity, dust, and oily aerosols or where in can be splashed with water ping.

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WARNING: Use of a SaltMed<sup>®</sup> Device is a complementary therapy and does not replace conventional treatment. Do not interrupt or modify the current treatment protocols recommended by a physician.



### Maintaining SaltMed<sup>®</sup> device - Warnings

WARNING: Do not immerse the SaltMed<sup>®</sup> device and do not allow liquids to moisten the device or component.

WARNING: Disconnect the SaltMed<sup>®</sup> device from mains voltage before cleaning.

WARNING: Do not attempt to open, disassemble or service the SaltMed<sup>®</sup> device. Do not crush, puncture, short external contacts, do not dispose them in fire or water. Do not expose to temperatures exceeding 55°C.

WARNING: Examine the presence of defects on the supply cables / connectors and components. In case of any defect, do not use the SaltMed<sup>®</sup> device until its replacement.

WARNING: To reduce the risk of fire or electric shock, use only the recommended accessories and do not expose the SaltMed<sup>®</sup> device to rain or moisture. Do not disassemble; device contains no parts that can be repaired by the user. For troubleshooting, call TEHNO BIONIC SRL service personnel or qualified and authorized by TEHNO BIONIC SRL personnel.

WARNING: Use only accessories and spare parts supplied by TEHNO BIONIC SRL; Use of other accessories can reduce the operational safety of the SaltMed<sup>®</sup> device.

WARNING: Not permitted any change in the SaltMed<sup>®</sup> device.

## 4 Indications for Use



### Indications for use - Warnings

WARNING: Do not use the SaltMed<sup>®</sup> device for anything other than its intended use.

The SaltMed<sup>®</sup> device is indicated on treatment of respiratory conditions such as: Acute Bronchitis, Allergic Rhinitis, Bronchiolitis, Asthma, COPD, Cough, Cystic Fibrosis and several other ENT conditions.

- Administration: the SaltMed<sup>®</sup> Device is recommended for daily use (sessions of 30 minutes or more duration), depending on the severity of the disorder and the advice of the physician.
- Use of a SaltMed<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> may be used together with any other medications.

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## 4.1 Nebulizer mask and oxygen tube compatible with SaltMed® Inhalation Device

**Nebulizer mask and oxygen tube - Warnings**

WARNING: Before making the inhalation session, make sure the mask nebulizers and oxygen tube ctuben are compatible with your device.

WARNING: Both mask nebulizers and oxygen tube are single use medical devices, according to the manufacturer recommendations.

Can be selected following nebulizer masks and oxygen tubes compatible with SaltMed® Inhalation Device:

Name	Characteristics	Description
Aerosol Mask	Medical device IIa Class	Aerosol Mask Pediatric or Adult *
Oxygen Supply Tube (Tubing)	Medical device IIa Class	Length = 2.1 m or other *

\* NOTE: Depending on the needs of the patient

## 5 Contraindications and precautions

## 5.1 Contraindications

- Contraindications: None reported

## 5.2 Precautions

- The SaltMed® Device 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 by a person responsible for their safety. Children should be supervised to ensure that they do not play with the appliance.

## 6 Simbols



Manufacturer



Date of manufacture



Means that it is absolutely necessary for the user to read the user manual before starting the utilization of the device



Compliance with European Directive 93/42 / EEC



Part Type B with application on patient



The serial number of the Air Pump










Catalogue number



Lot Number

SaltMed<sup>®</sup> – DRY SALT INHALER – User Manual

	Use by date		For single use only
	Double insulation		This symbol, adjacent to a terminal, indicates that, under normal use, hazardous voltages may be present
<b>IP21</b>	Protection degree. Solid particle protection >12.5 mm; Liquid ingress protection: Dripping water		The European Union logo on waste electrical and electronic equipment. Allow return for proper disposal
	Do not use if package is damaged		Recyclable packaging

## 7 Functioning environment aspects for SaltMed<sup>®</sup> Inhalation Device



### Environment - Warnings

WARNING: Protecting the patient and the user is essential and a requirement of the laws. Injuries can be caused from two sources:

- A short circuit when the current is directed to the ground by the patient
- Surge and lightning.

Injuries can be avoided by 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.

WARNING: The dust and lint can affect the correct functioning of the device, including blocking the tube.

#### Powering SaltMed<sup>®</sup> device

Pump PP-SM from the mains

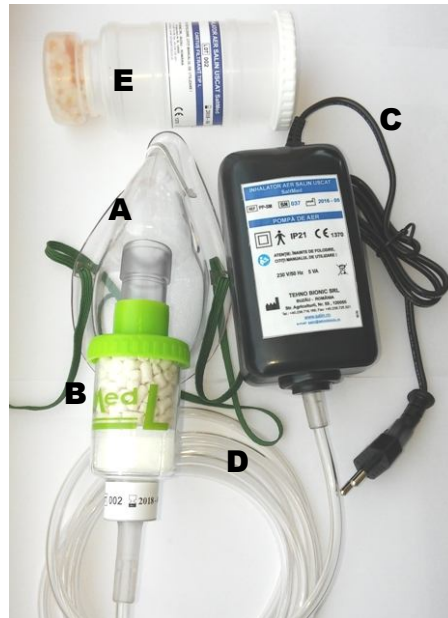
Voltage: 230V (-15%; +10%)  
 Frequency: 50 Hz (+2Hz/-3Hz)  
 Absorbed power: 5 VA

#### Temperatures and humidity during use

The SaltMed<sup>®</sup> Inhalation Device can operate within the limits of 5 - 40°C.  
 The air humidity must be in the range 45-65% at 25°C.

SaltMed<sup>®</sup> – DRY SALT INHALER – User Manual8 Description of SaltMed<sup>®</sup> Inhalation Device

The SaltMed<sup>®</sup> Device (Fig. 1) includes the salt cartridge 'CT-SM', an Aerosol mask, Air pump 'PP-SM' and Oxygen Tube packed in a carton box. The air pump is connected to the cartridge with the flexible tube.



DRY SALT INHALER SaltMed		
Name	Manufacturer	CE mark
1 Storage Container	TEHNO BIONIC SRL	CE1868
1 Salt Cartridge Type N	TEHNO BIONIC SRL	CE1868
1 Face Mask	HUDSON RCI	CE0120
1 Air Pump	TEHNO BIONIC SRL	CE1868
1 Hose	HUDSON RCI	CE1868
1 User Manual		

REF IN-SM

TEHNO BIONIC SRL – BUZĂU – ROMANIA  
56 Agriculturii street, 120055  
Tel.: +40.238.725.321; +40.238.719.166; Fax: +40.238.725.321  
www.saltin.ro; e-mail: salt@tehnobionic.ro

Fig. 1 - The SaltMed<sup>®</sup> Inhalation Device

A: CL-SM, Type L salt cartridge; B: Aerosol mask (separate device); C: PP-SM, Air pump ; D: Oxygen tube(separate device);  
E: RP-SM Container Cover

SaltMed<sup>®</sup> cartridge 'CT-SM'

It is supplied in a special storage container (Fig. 2) which includes in its lower section silica-gel, a drying agent to absorb humidity.

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

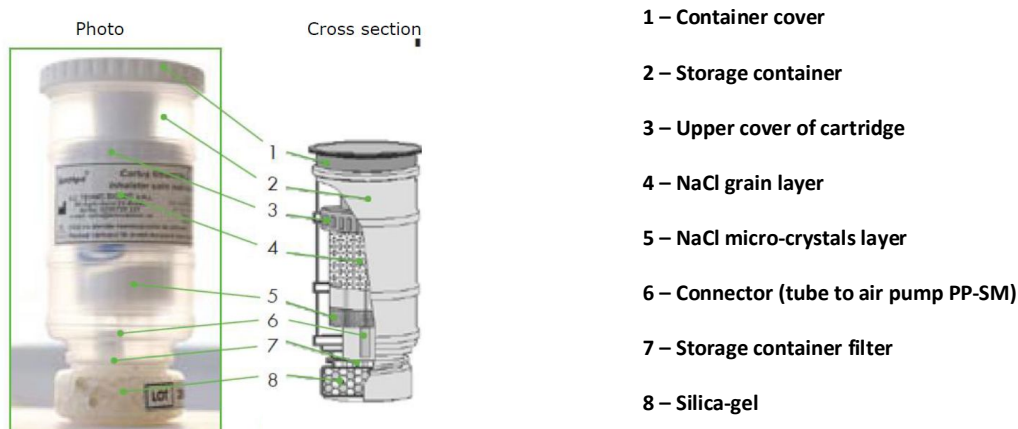


Fig.2 - The SaltMed<sup>®</sup> cartridge in its storage container RP-SM

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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 (Fig.3). The air under pressure erodes the salt microcrystals and generates dry salt particles of 1 -5 micron.



Fig.3 – Boiling movement

### 9 Installing of SaltMed<sup>®</sup> Inhalation Device

Please do not unpack the SaltMed<sup>®</sup> Device package, do not install or adjust the device before reading the present chapter. If you have any questions regarding the installation / adjustment of the device, consult qualified personnel of TEHNO BIONIC SRL.

The user can contact TEHNO BIONIC SRL or its representative:

- For assistance, if necessary, in the installation, use and maintenance of SaltMed<sup>®</sup> Device
- To communicate a not estimated operation or an unexpected event.

#### 9.1 Unpacking

Carefully unpack the box and check its contents. The packaging has been specially designed to ensure optimum protection of SaltMed<sup>®</sup> Device components during transport; however, if a particular component is damaged or missing, do not use the device; contact TEHNO BIONIC SRL. Save the original packaging for possible return of the SaltMed<sup>®</sup> Device, when unforeseen events occur that require service or repairs.

Inside the box you will find the following:

RM-SM; Storage container of salt cartridge	1 pc.
CX-SM; Type Salt cartridge	1 pc.
Aerosol Mask	1 pc.
PP-SM: Air pump	1 pc.
Oxygen Tube (Tubing)	1 pc.
User Manual	1 pc.

#### 9.2 Cleaning SaltMed<sup>®</sup> Device before use

The SaltMed<sup>®</sup> Device and its accessories are supplied in non-sterile condition.



**WARNING:** Use of accessories or cables other than tube supplied by SC TEHNO BIONIC S.R.L., can damage the SaltMed<sup>®</sup> Device



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**CAUTION:** Examine the presence of defects in the power cable and components. In case of a fault, do not use the SaltMed<sup>®</sup> Device, until its replacement.

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.

### 9.3 Moving the SaltMed<sup>®</sup> Inhalation Device



**WARNING:** Do not carry the SaltMed<sup>®</sup> Device by the power cord.

SaltMed<sup>®</sup> Device components ( Salt cartridge; Mask; Air pump, Tube) are light, being portable; it can be located and conveniently positioned near the treatment area (for example, can be placed on a table).

Before moving SaltMed<sup>®</sup> Device, make sure the following conditions are met:

- The device is switched off;
- All accessories and cables are disconnected;
- If you place the SaltMed<sup>®</sup> 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 SaltMed<sup>®</sup> device and cause injury to the user.

**WARNING:** 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.

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 tube to the pump.
4. Take the SaltMed<sup>®</sup> cartridge from its storage container, immediately closing the storage it.
5. Attach the other end of the tube to the connector on the lower part of the SaltMed<sup>®</sup> cartridge. The 'boiling' phenomenon of the lower micro-crystal layer should be observable.
6. Attach the Aerosol mask to the SaltMed<sup>®</sup> cartridge. Place the mask on the face so that the SaltMed<sup>®</sup> 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. Replace the mask and tube used with other new products.
10. Place all of the components back into the carton box for protection and keep the bag in a dry place.



**WARNING:** Moist SaltMed<sup>®</sup> 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

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hours. The silica gel will reduce the humidity of the SaltMed<sup>®</sup> 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<sup>®</sup> cartridge will need to be replaced.

WARNING: Ensure that the SaltMed<sup>®</sup> Inhalation Device is switched off after use.

### 10.1 SaltMed<sup>®</sup> cartridge replacement

SaltMed<sup>®</sup> devices are delivered with an L-type cartridge recommended for home, which can be used up to 50 hours. To maintain its therapeutic effect a SaltMed<sup>®</sup> L-cartridge should be replaced after 40-50 hours of use and within three months of its first use.

N-type cartridge is also available which can be used up to 100 hours; Forte-type cartridge is also available which can be used up to 50 hours. N, Forte-type cartridges are primarily recommended for hospital / intensive use.

**Use original SaltMed cartridges only!.**

## 11 Maintenance

- No preventive maintenance operations are necessary.
- The air pump does not require user maintenance parts inside or lubricating.
- In case of malfunction (The pump doesn't work; Damaged filtering cartridge; Punched connection tube, Damaged mask) contact the manufacturer for repair. The repairs shall be free of charge within the warranty period and chargeable after the warranty has expired.

## 12 Service

### 12.1 Background

SaltMed<sup>®</sup> Device repairs should be performed only by qualified personnel that has been authorized by TEHNO BIONIC SRL; otherwise, TEHNO BIONIC SRL is not responsible for the safety, reliability and performance of the device.

### 12.2 Voided Warranty

Any guarantee or warranty claims to TEHNO BIONIC SRL are void if the user or an unauthorized person tries to repair the SaltMed<sup>®</sup> Device.

### 12.3 Description of defects

To enable TEHNO BIONIC SRL to carry out repairs in a short time, send the SaltMed<sup>®</sup> Device, accompanied by a detailed description of the defect.

The description shall include the following:

- Accurate description of the defect
- Date of delivery
- Copy of invoice (for possible warranty)
- SaltMed<sup>®</sup> Device certificate of Warranty

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### 12.4 Handling of the device SaltMed<sup>®</sup> before shipping

To protect the personnel of TEHNO BIONIC SRL carrying out repairs, before sending SaltMed<sup>®</sup> Device for repair, clean and disinfect it. TEHNO BIONIC SRL has the right to refuse repair SaltMed<sup>®</sup> Devices that are dirty or contaminated, for safety reasons.

### 11.5 Shipping

To send SaltMed<sup>®</sup> defective device, use the original packaging; if this is not possible, wrap the device and its removable parts in films of polyurethane foam and then into a carton box.

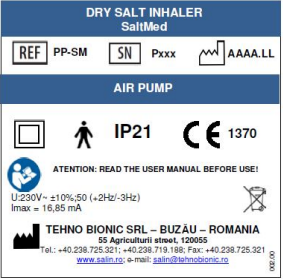
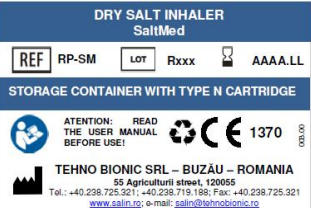


## 13 SaltMed<sup>®</sup> Inhalation Device specifications

Classification	
Directive 93/42/EEC	Medical Device Class IIa, Rule. 11
SR EN 60601 Type of protection against electric shock	Class II
Degree of protection against electric shock	Type B
In accordance with the method of sterilization or disinfection	NA
In accordance with the degree of protection required in the presence of flammable anesthetics mixed with air or oxygen and nitric oxide	NA
Depending on the operating mode	Continuous operation
SR EN 60529	IP21
Dimensions (mm)	
Package (L x l x h)	170 x 160 x 70
Weight (Kg)	
Package	Max. 0,6 Kg
Electrical and operating specifications	
Input Voltage	230 V (-15%; +10%)/50 Hz (+2Hz/-3 Hz)
Absorbed power	5 VA
Air flow	1,8 l/min
Noise level	60 dB
Environmental conditions	
Operating temperature	5 – 40 °C
Transport and storage temperature	(– 25) – (+70) °C
Rated Humidity	30 - 65 % la 25°C, without condensation

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Other requirements	To reduce electrostatic discharge is recommended bare wood, concrete or ceramic
<b>Conditions for operation and maintenance</b>	
Average level of service request	6 hours cumulative / day
The normal duration of use	4 years for air pump 2 years for salt cartridge

14 Labelling of SaltMed<sup>®</sup> Inhalation Device

Label	Description	Location
 <p>Label for PP-SM Air pump. It includes the text: DRY SALT INHALER SaltMed, REF PP-SM SN Pxxx AAAA.LL, AIR PUMP, IP21, CE 1370, ATENTION: READ THE USER MANUAL BEFORE USE!, U:230V~±10%;50 (+2Hz;-3Hz), I<sub>max</sub> = 16,85 mA, and contact information for TEHNO BIONIC SRL – BUZĂU – ROMANIA.</p>	Identification label PP-SM Air pump	Housing PP-SM Air pump , on the upper face
 <p>Label for CT-SM Storage Container. It includes the text: DRY SALT INHALER SaltMed, REF RP-SM LOT Rxxx AAAA.LL, STORAGE CONTAINER WITH TYPE N CARTRIDGE, ATENTION: READ THE USER MANUAL BEFORE USE!, CE 1370, and contact information for TEHNO BIONIC SRL – BUZĂU – ROMANIA.</p>	Identification label CT-SM Storage Container	On storage container of salt cartridge
 <p>Label for CN-SM Salt Cartridge. It includes the text: REF CN-SM LOT Cxxx AAAA.LL.</p>	Identification label CN-SM Salt Cartridge	On salt cartridge
 <p>Label for SaltMed Device. It includes the text: DRY SALT INHALER SaltMed, Name: 1 Salt Cartridge Type N, 1 Face Mask, 1 Air Pump, 1 Tube, CE 1370, REF IN-SM, and contact information for TEHNO BIONIC SRL – BUZĂU – ROMANIA.</p>	Identification Label of SaltMed <sup>®</sup> Device	On SaltMed <sup>®</sup> Device carton box

15 Recycling of SaltMed<sup>®</sup> Inhalation Device

The SaltMed<sup>®</sup> Device is made of non-biodegradable components, the elimination in the environment is not recommended. At the end of the SaltMed<sup>®</sup> Device life, please submit it to a recycling electrical and electronic equipment operator.