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Volcano[®]
MEDIC

INSTRUCTIONS FOR USE

Read carefully before using the device and
save these instructions.



Table of Contents Page

1. Product Overview, Scope of Delivery, Service 6

2. Explanation of Symbols, Safety Recommendations 9

3. Intended Use 13

4. Important Remarks 14

 4.1. Operating Conditions 16

 4.2. Storage and Transport Conditions 16

5. The **VOLCANO MEDIC** Hot Air Generator 17

 5.1. Unpacking 17

 5.2. Installation 17

 5.3. Operation 17

 5.4. Commissioning 18

 5.5. Heating Up 18

 5.6. Temperature Setting 19

6. The Use of Dronabinol (THC)
 dissolved in Alcohol 20

 6.1. The Efficiency of vaporized
 Dronabinol (THC) 20

 6.2. Preparation 21

 6.3. Application 21

 6.4. Inhalation from the Valve Balloon 25

Table of Contents

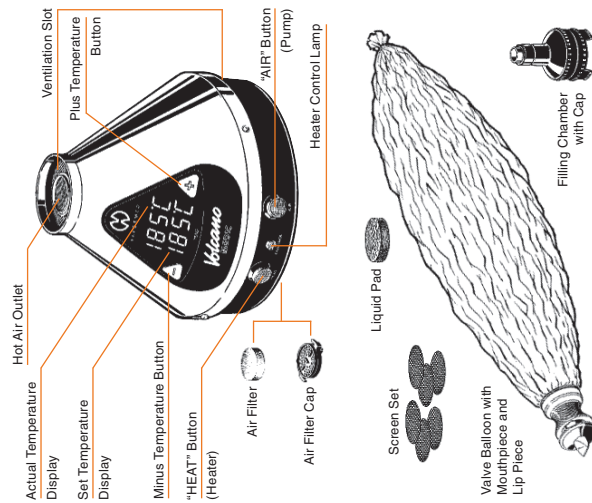
7. The Use of Hemp Flowers (Cannabis Flos)	Page	27
7.1. The Efficiency of Cannabinoids vaporized from Hemp Flowers (Cannabis Flos)		27
7.2. Preparation		30
7.3. Application		30
7.4. Inhalation from the Valve Balloon		33
8. Accessories: Dosing Capsules and Magazine		35
8.1. Filling the Dosing Capsules with ground hemp flowers		35
8.2. Filling the Dosing Capsules with Dronabinol		36
8.3. Inserting the Dosing Capsules		37
9. Hygiene		38
9.1. General		38
9.2. Material Resistance		38
9.3. Disposable MEDIC VALVE Lip Piece for Hygienic Use		39
9.4. Filling Chamber and Valve Balloon		40
- Cleaning of the Filling Chamber, Inspecting/Maintenance of the Filling Chamber, Reusability of the Filling Chamber, Reusability of the Valve Balloon, Storage		42
9.5. Disassembly and Assembly		42
- Filling Chamber, Filling Chamber Cap, Mouthpiece Disassembling the Filling Chamber Cap, Disassembling the Filling Chamber, Drying, Assembly of Filling Chamber Cap, Assembling the Filling Chamber		

Table of Contents

10. Hot Air Generator	Page	45
10.1. Cleaning		45
10.2. Care and Maintenance		45
10.3. Storage		46
10.4. In Case of Problems		46
10.5. Disposal		46
10.6. Troubleshooting		47
10.7. Periodic Safety Checks		48
10.8. Technical Specifications		48
10.9. Guidance and Manufacturer's Declaration – Electromagnetic Emissions		49
11. Spare Parts and Accessories		56
12. Declaration of CE Conformity		57
13. Warranty, Liability, Repair Service		59
14. Prod of the Annual Safety Checks		61

1. PRODUCT OVERVIEW, SCOPE OF DELIVERY, SERVICE

Product Overview



6

1. PRODUCT OVERVIEW, SCOPE OF DELIVERY, SERVICE

Delivery includes **VOLCANO MEDIC** Vaporization System:

- 1 pc. **VOLCANO MEDIC** Hot Air Generator
- 1 pc. Herb Mill (not shown)
- 1 pc. Instructions for Use (not shown)
- 2 pcs. Air Filters
- 1 pc. **MEDIC VALVE** Filling Chamber
- 5 pcs. **MEDIC VALVE** Balloon (standard size 12.5 l) with Mouthpiece
- 3 pcs. Lip Piece
- 1 pc. Cleaning Brush (not shown)
- 6 pcs. Screens
- 1 pc. Liquid Pad
- 3 pcs. Filling Chamber Clips (not shown)
- 1 pc. Cap Ring (not shown)

Please check whether all components have been included.
If not, please inform our Service Center.

7

1. PRODUCT OVERVIEW, SCOPE OF DELIVERY, SERVICE

Operating life:

The Hot Air Generator and the Filling Chamber have an average expected operating life of:

- approx. 1,000 operating hours
- max. 5 to 6 years

Service

Contact in case of technical problems or questions about the device:

Storz & Bickel Service Center

Tel.: +49-74 61-96 97 07-0 · e-mail: info@vapormed.com
For repairs, warranty claims, or disposal, please send the device to the following address:

Storz & Bickel GmbH & Co. KG

Service Center
In Grubenäcker 5-9
78532 Tuttlingen, Germany

2. EXPLANATION OF SYMBOLS, SAFETY RECOMMENDATIONS



Please read the following safety recommendations thoroughly and carefully before using the device.

These Instructions for Use are a significant part of the VOLCANO MEDIC Vaporization System and must be provided to the user.

These instructions given in this Instructions for Use must be strictly observed as they are extremely

important to ensure safety during installation, use and maintenance of the VOLCANO MEDIC Vaporization System.

Please keep this brochure in a safe place for future reference. You may download the current version of the Instructions for Use for the VOLCANO MEDIC Vaporization System on www.vapormed.com

Explanation of Symbols

Please follow these instructions carefully! according to IEC 60601: 2005)



Warning!

In order to avoid injuries to persons and damage to the equipment, it is mandatory to observe instructions marked with this symbol.



Note/Tip!

This symbol always gives you technical information or useful tips regarding the VOLCANO MEDIC Vaporization System.



Symbol for serial number – followed by the serial number of the medical product.



Symbol for the manufacturer – the manufacturer's name and address are next to the symbol



The medical product was introduced after 13 August 2005. The product may not be disposed of in normal household waste. The X on the trash can indicates the necessity of disposing of this product separately.



Safety Category II device

2. EXPLANATION OF SYMBOLS, SAFETY RECOMMENDATIONS

IP 21	Device protected against foreign bodies with a diameter larger than 12 mm and against vertically falling water drops (according to IEC 60529).
CE ⁰¹²³	EU conformity symbol A 4-digit number after the CE marking indicates that a notified body is involved in the conformity assessment procedure.
REF	Symbol for order number – followed by the order number of the corresponding medical product (or part)
	Safety tested and production monitored by TÜEV SÜED according to IEC 60601-1, CAN/CSA C22.2 No. 60601-1.
	Caution! Hot surfaces! Never leave Filling Chamber on the VOLCANO MEDIC Hot Air Generator.
	Keep away from sunlight
	Protect against moisture and humidity
	Contains or presence of phthalate
	Interference may occur in the vicinity of equipment marked with the following symbol.
	Temperature limits of ambient temperature
	Humidity limitation
	Air pressure limitation

10

2. EXPLANATION OF SYMBOLS, SAFETY RECOMMENDATIONS

Safety Recommendations	➤ The packaging material (plastic bags, styrofoam material, boxes, etc.) must be kept out of the reach of children as it is a potential source of danger. ➤ People who require assistance must be supervised constantly during inhalation. Such persons often underestimate the hazards involved (e.g. strangulation with the power cord), so resulting in injury. ➤ The device contains small parts which can block the respiratory tract and lead to choking. Therefore, make sure that you always keep the Hot Air Generator and accessories out of the reach of babies and infants. ➤ Before connecting the Hot Air Generator, make sure that the information given in the type label on the bottom side of the Hot Air Generator corresponds to the mains supply at the place of installation. ➤ If there are any problems during operation, immediately pull out the power plug from the socket. ➤ The power cord must be unwound over its entire length (avoid rolling up and overlapping the cord). It must not be exposed to any impacts and must be kept out of the reach of children. Also, it must not be kept near liquids or sources of heat and must not be damaged.
	Do not wind the power cord tightly, nor pull it over sharp edges and never crush or kink it. If the power cord is damaged, please contact our Service Center to have it replaced. Never try to repair a power cord yourself! ➤ The use of multiple sockets and/or extension cables is not recommended. However, if this is absolutely necessary, only products with a safety certificate (such as UL, IMQ, VDE, +S etc.) may be used, provided the specified power exceeds the power required (A= Amperes) by the devices that are connected. ➤ If you have any concerns, ask a specialist to check whether the electrical system is in accordance with the local safety regulations. ➤ Install the Hot Air Generator on a stable and dry surface at a sufficient distance from sources of heat (oven, stove, fireplace etc.) and in a place where the ambient temperature cannot drop below +5°C (+41°F). Store the Hot Air Generator in a dry place protected against the effects of weather and out of the reach of children or unqualified persons. It must not be installed in damp locations (such as bathrooms etc.). ➤ The Hot Air Generator may only be repaired by our Service Center. In correctly performed repairs without the use of original spare parts can prove dangerous to the user.

11

2. EXPLANATION OF SYMBOLS, SAFETY RECOMMENDATIONS

- Do not operate the Hot Air Generator close to flammable objects such as curtains, tablecloths, or paper.
 - Keep the Hot Air Generator away from pets (e.g. hamsters, mice) and other animals which could damage the power cord insulation.
 - Danger to life when opening the Hot Air Generator as live components and connections are exposed.
 - The Hot Air Generator must never be repaired or transported when the power plug is plugged in.
 - To pull the power plug from the socket, pull the power plug directly, never pull the power cord.
 - The Hot Air Generator must never be operated when the power cord is faulty.
 - Do not put any objects into the openings of the device.
 - Do not leave the Vaporizer unattended during operation. After use, switch off the heater and the air pump.
 - The ventilation slots as well as the hot air outlet of the Hot Air Generator may not be closed, obstructed or blocked while the device is being used nor while it is cooling down.
- Caution! Hot surface!**
- 
- Do not touch the hot air outlet and the Filling Chamber when they are hot.
 - The Filling Chamber may only be placed on the hot air outlet while filling the Valve Balloon. After filling the Valve Balloon, the Filling Chamber must be removed from the hot air generator in order to avoid overheating of the Filling Chamber (Caution! Hot surface!).
 - Do not put any body parts or objects in the hot air stream.
 - Before cleaning, pull out the power cord from the socket. The Hot Air Generator should be cleaned only with a dry cloth - or a damp cloth if absolutely necessary. Never immerse the Hot Air Generator in water or in other liquids or clean it with a direct water or steam jet.
 - The Hot Air Generator must not be used in damp or wet conditions.
 - The Hot Air Generator is protected against falling water drops (IP 21). The device should nevertheless be protected against moisture and rain. Do not use in the bathroom or above water.
 - Never touch the Hot Air Generator with wet or damp parts of the body.
 - Never put containers containing liquids on the Hot Air Generator.

2. EXPLANATION OF SYMBOLS, SAFETY RECOMMENDATIONS

- Never operate the Hot Air Generator when it is wet or damp. If the Hot Air Generator gets wet, it must be checked by our Service Center for damage to electrical components.
- Do not use in an atmosphere with risk of explosion or ignition.
- Never allow the Vaporizer to be used by children or unqualified persons.
- Only use original Storz & Bickel accessories and spare parts.

 The manufacturer is not responsible for any damage or personal injury caused by inappropriate, incorrect or irresponsible use.

3. INTENDED USE

The **VOLCANO MEDIC** Vaporization System is intended for vaporizing and then inhaling dronabinol (THC) dissolved in alcohol or cannabinoids from hemp flowers (cannabis flus).

The goal is the application of the active ingredients in the human body via the alveoli for the appropriate medical indication. It is suitable for the temporary inhalative application of cannabinoids prescribed by a physician for use at home, in a hospital, or doctor's office.

4. IMPORTANT REMARKS

 The **VOLCANO MEDIC** Vaporization System ensures the highly effective, safe, and fast-acting application of cannabinoids. The patient must undergo a medical examination before the beginning of treatment.

The **VOLCANO MEDIC** Vaporization System is not intended for use in children and youth under age 18. Adults may use the device following the Instructions for Use or physician's instructions.

 The device is not to be used if the user has respiratory tract or lung conditions. Depending on the density, the vapor could irritate respiratory tracts or lungs, which can lead to coughing.

The application and inhalation is described in Chapters 6.4 and 7.4, "Inhalation from the Valve Balloon", pages 25 and 33.

 The Valve Balloon with Mouthpiece is intended for only one user and may not be shared among patients. The Valve Balloon can be re-used several times, but only by one person (see Chapter 9, "Hygiene", page 38).

A new Valve Balloon with Mouthpiece may be used for a maximum of 2 weeks.

 At a certain dosage, cannabis can have a psychotropic (mind-altering) effect.

There is thus a potential for abuse, which governments in nearly all countries of the world counteract with corresponding laws.

Use only medicinal hemp flowers (cannabis fls) prescribed by your physician and purchased from a pharmacy. Otherwise you may be at risk of breaking the law.

In case of doubt, ask your physician, pharmacist, or the responsible authorities about the current laws at your place of residence.

Dronabinol is the international non-proprietary name for Delta-9-tetrahydrocannabinol (THC) which is known as the most effective cannabinoid for medical use.

Cannabinoids vaporize at temperatures over 180°C (356°F) and then form aerosols with an average droplet size (MMAD) of 0.64 µm (micrometer) that can be inhaled and respired. The droplets are absorbed in the alveoli and enter the bloodstream (systemic absorption).

When cannabinoids are inhaled, the onset of the effect takes approx. 1-2 min. and the effects last for 2-4 hours.

4. IMPORTANT REMARKS

For application, a distinction must be made between the vaporization of dronabinol (THC) dissolved in alcohol and the vaporization of cannabinoids from hemp flowers (cannabis fls).

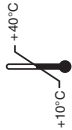
 Our Service Centre is available to answer your questions and receive your comments and suggestion concerning the **VOLCANO MEDIC** Vaporization System.

If questions occur about the medical use of cannabinoids or cannabis, please contact your doctor, pharmacist or manufacturer of medical hemp flowers (Cannabis fls).

4. IMPORTANT REMARKS

4.1. Operating Conditions

Ambient conditions in which the specified aerosol characteristics are guaranteed:



Ambient temperature:
+10°C to +40°C (+50°F to +104°F)

RH

30% - 80%
Relative humidity of ambient air:
30% to 80%

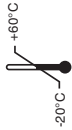
P

700hPa - 1060hPa
Atmospheric pressure:
700 hPa to 1060 hPa

The device features interference suppression acc. to EN 60601-1-2 (see Chapter 10, "Hot Air Generator", page 45).

Radiofrequency emitting equipment (e.g. mobile phones) should not be used in the immediate vicinity of the device. In case of doubt, contact qualified personnel.

4.2. Storage and Transport Conditions



Ambient temperature:
-20°C to +60°C (-4°F to +140°F)

RH

20% - 80%
Relative humidity:
20% to 80%

P

700hPa - 1060hPa
Atmospheric pressure:
700 hPa to 1060 hPa

Do not store or transport any parts of the **VOLCANO MEDIC** Vaporization System in direct sunlight, wet rooms (e.g. bathroom) or near damp objects. Extreme fluctuations in ambient temperature can lead to condensation and damage the device's function.

5. THE VOLCANO MEDIC HOT AIR GENERATOR

5.1. Unpacking

The box contains all components as well as the instructions for Use. Keep the instructions for Use for future reference.

Take out the accessories and the Hot Air Generator from the box. Immediately after unpacking, check whether the Hot Air Generator, the accessories, the power cord and the plug are all included in the delivery and work properly. If you notice any defects, inform the seller or the delivery agent immediately.



The packing material (plastic bags, styrofoam material, boxes etc.) must be kept out of the reach of children as it is a potential source of danger.

Please dispose of the packing material in a proper and environmentally friendly manner.

We recommend keeping the original packaging in case it is required later (transport, Service Center, etc.).

5.2. Installation

Before installing the Hot Air Generator make sure that the information given on the type label on the bottom side of the device corresponds to the local mains supply data.

All parts of the electrical system must comply with currently applicable official regulations.

Put the Hot Air Generator on a flat and stable surface.

Take care that the power cord cannot be damaged through kinking, crushing or pulling.



Improper installation may lead to personal injury or material damages, for which the manufacturer cannot be held responsible.

5.3. Operation



The Hot Air Generator was developed for vaporizing the cannabinoids listed in the instructions. Any other use is inappropriate and potentially dangerous.

For use and maintenance, the user must always follow the instructions given in the instructions for Use.

If you have any concerns, or if there are any problems, immediately switch off the Hot Air Generator and disconnect the power plug from the socket. Do not try to remedy the defect yourself. Contact our Service Center directly.

Allow the device to cool down before it is packed away.

5. THE VOLCANO MEDIC HOT AIR GENERATOR

5.4. Commissioning

Do not leave the device unattended while it is being operated. Put the Hot Air Generator on a flat and stable surface.

Check whether the mains voltage corresponds to the voltage rating stated on the device. The power cord and the plug must be in perfect condition. Only connect the Hot Air Generator to a properly installed socket. The manufacturer will not bear any responsibility whatsoever if this accident prevention measure is not taken.

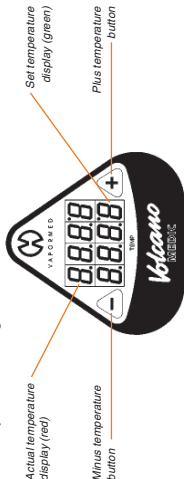
The device is safely disconnected from the mains only when the plug is removed from the socket.

When the power plug is plugged in, the LED display of the device lights up briefly. At the same time, an internal software query is performed. The green dot on the display shows that the Hot Air Generator is connected to the power supply.

5.5. Heating Up

To switch on the heater, push the button labeled "HEAT". The set/actual temperature will light up, signaling that the heater is switched on. At the same time, the yellow control lamp will light up to indicate that the device is heating up. The upper, red display

5.6. Temperature Setting



When you press the plus button, the set value is increased, and when you press the minus button, the set value is decreased.

When you briefly tap on the plus or minus button, the set values are increased or decreased respectively in 1-degree increments.

If you keep the plus or minus button pressed, the set values start running continuously in the corresponding direction.

If you simultaneously tap on the plus button and the minus button, the display changes from degree Celsius to degree Fahrenheit and vice versa.

If the actual value is higher than the set value, you can speed up the cooling down process by switching on the air pump.

30 minutes after the last time a button is pressed, the device automatically switches off.

As long as the heater has a substantial amount of residual warmth, the temperature is displayed until it drops below +40°C (+104°F).

Then the display turns off, and the green dot on the display indicates that the Hot Air Generator is connected to the mains supply.

The device is safely disconnected from the mains only when the plug is removed from the socket.

6.1. Efficiency of vaporized Dronabinol (THC)

Use only approved dronabinol (THC) that is sold to pharmacies for making up prescriptions.

The pharmacy produces an alcohol solution according to your physician's prescription (generally 2.5% THC) for inhalation with the **VOLCANO MEDIC** Vaporization System.

By following the procedure listed in the Instructions for Use the systemic bioavailability of vaporized dronabinol is approximately 40%.

For comparison: The systemic bioavailability of cannabinoids administered orally is below 15%.

When observing the Instructions for Use and with a vaporization temperature of 210°C (410°F) the following reference values are validated in studies:

Drug (Filling Chamber Content)	Cannabinoid content in drug	Cannabinoid content in blood after vaporization with 210°C (410°F)	Cannabinoid content in blood after systemic bioavailability after inhalation
Dronabinol/THC (10 mg)	THC: 10 mg	approx. 6 mg	approx. 4 mg

If dosage is too low increase the amount of dronabinol.
If dosage is too high reduce the amount of dronabinol.

6.2. Preparation

Make sure to use the Mouth-piece only with attached Lip Piece before every operation (see Chapter 9.3. "Disposable MED-IC VALVE Lip Piece for Hygienic Use", page 39)

Turn the Filling Chamber Cap counter-clockwise in order to remove it from the Filling Chamber.



Remove Filling Chamber Cap

When using dronabinol (THC) dissolved in alcohol, the Screens in the Filling Chamber are not needed and should be removed.

The Liquid Pad is inserted in the Filling Chamber instead of the lower Screen.



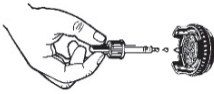
Preparation to use the Liquid Pad

Dronabinol (THC) dissolved in oil is not suitable for vaporization and is intended for oral administration.

6.3. Application

Turn the Filling Chamber upside down and use a pipette to drop the dronabinol (THC) dissolved in alcohol onto the center of the bottom of the Liquid Pad. The Liquid Pad can hold up to 20 drops.

At the beginning of treatment, apply a maximum of two drops and carefully increase to the appropriate dosage. Always follow your doctor's recommendations!



Applying drops with a pipette

Next screw on the Filling Chamber Cap again.

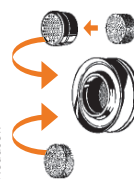
6. THE USE OF DRONABINOL



Screw on Filling Chamber Cap

! Suitable for vaporizing small amounts of dronabinol (THC), the Filling Chamber Reducer, which is available as an accessory, along with the small Liquid Pads and the Dosing Capsules. The Filling Chamber Reducer is inserted instead of the Filling Chamber Cylinder (see Chapter 9.5, "Disassembling and Assembling the Filling Chamber", page 42).

Either the small Liquid Pad (measurements 15 x 5 mm) or the Dosing Capsule containing a Liquid Pad (measurements 13 x 6 mm) are to be inserted into the Filling Chamber Reducer.



Insert either a small Liquid Pad directly into the Filling Chamber Reducer or a Dosing Capsule equipped with a Liquid Pad

Please make sure to not overfill the Liquid Pad. It can contain up to 5 drops.

Dronabinol (THC) is available as an alcoholic solution.

The advantage of this is that the liquid is distributed more equally around the stainless steel wire of the Liquid Pad, yielding a larger surface area that can be vaporized.

However, the alcohol must first be separated from the dronabinol, as alcohol should not be inhaled.

Press the "HEAT" button set temperature to 100°C (212°F) and allow the device to heat up.

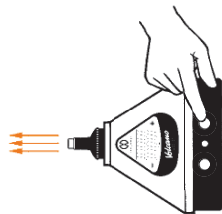
When the temperature has reached 100°C (212°F), place the Filling Chamber with Cap and Liquid Pad onto the Hot Air Generator and make sure it clicks into place.

Then press the "AIR" button to pump air through the Liquid Pad.

The dronabinol does not vaporize at this temperature, but the alcohol evaporates quickly (within 30 sec.).

Since alcohol has a characteristic odor, you can easily determine by smelling whether the Filling Chamber is alcohol free. Dronabinol has neither odor nor taste.

6. THE USE OF DRONABINOL



Separate alcohol

When the Filling Chamber is free of alcohol, press the "AIR" button again to switch off the airflow.

The dronabinol, which evaporates only at higher temperatures – over 157°C (315°F), remains in the Liquid Pad.

Next remove the Filling Chamber, press the heat button again and set the temperature to 210°C (410°F) and continue heating.

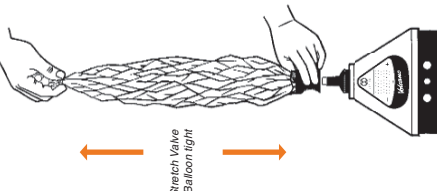
! The dronabinol is vaporized in the first few seconds of filling the Valve Balloon.

However, you should continue filling the Valve Balloon (approx. 35 sec.) as the additional air dilutes the aerosol, which makes inhalation easier, especially for higher dosages.

When the temperature reaches 210°C (410°F), place the Filling Chamber

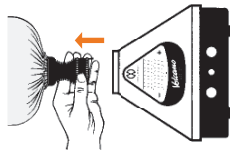
and then the Valve Balloon on and allow them to click in place. This opens the Valve.

Stretch the Valve Balloon tight before setting it onto the Filling Chamber so that when filling, the Valve Balloon sits upright on the Hot Air Generator. Press the "AIR" button. The Valve Balloon will now fill with dronabinol aerosol.



Stretch Valve Balloon tight

When the Valve Balloon is filled, press the "AIR" button and shut off the air pump and remove the Valve Balloon together with the Filling Chamber. To do so, hold the Filling Chamber Cap at the textured grip.



Detach Valve Balloon from Filling Chamber

Do not leave the Filling Chamber on the hot air outlet of the **VOLCANO MEDIC** when "HEAT" is switched on – except for separating the alcohol or filling the Valve Balloon.

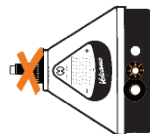
Non-observance may cause the Filling Chamber to overheat and may cause burns.

Remove Valve Balloon with Filling Chamber



Caution! Hot surface!

Do not touch any components of the Filling Chamber (except at the textured grip) until they have cooled down after the Valve Balloon has been filled. Separate the Valve Balloon from the Filling Chamber. The Valve closes automatically after separation and the aerosol in the Valve Balloon cannot escape.



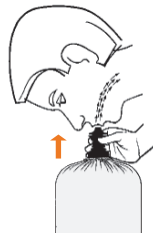
Caution! Hot surface!

6.4. Inhalation from the Valve Balloon

Attach the Mouthpiece with attached Lip Piece to the Valve and allow it to lock in place.



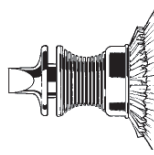
Attach the Mouthpiece with attached Lip Piece onto the Valve Balloon



Press Mouthpiece against lips to inhale



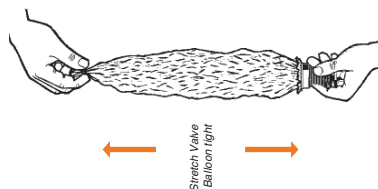
As the content of the Valve Balloon deflates, it may be completely emptied by stretching the Valve Balloon taut and subsequently inhaling the content



Correct position of the Mouthpiece with Lip Piece on the Valve

To inhale, put the Mouthpiece to your lips and lightly press against the Mouthpiece with your lips. By doing

6. THE USE OF DRONABINOL



Breathing Technique

Inhale only half as much as possible. Hold your breath a few seconds and then breathe out slowly.

We recommend consciously concentrating on your inhalation. The cannabinoid aerosol is absorbed by the alveoli and into the bloodstream. The onset of the effect takes approx. 1-2 min.

End of Inhalation

Disconnect the power plug from the socket after inhalation.

! The Valve Balloon is not suitable for storing the aerosol for long periods, as it will condense on the interior surface of the Balloon in time (a few hours). Inhale the contents of the Valve Balloon within 10 minutes.

26

7. THE USE OF HEMP FLOWERS

Use only standardized, medicinal hemp flowers (cannabis flos) that have been tested by licensed producers for authenticity, purity, and pathogens according to the directives of the competent authorities in your country.



Under no circumstances should you use cannabis from the illegal black market or any other cannabis that has not been subjected to recognised quality controls.

The amount of active ingredients in these products is generally unknown, may fluctuate considerably, and they often contain herbicides, fertilizers, bacteria, etc.

7.1. The Efficiency of Cannabinoids vaporized from Hemp Flowers (Cannabis Flos)

By following the procedure listed in the Instructions for Use the systemic bioavailability of cannabinoids vaporized from hemp flowers is approx. 29-40%.

For comparison: The systemic bioavailability of cannabinoids administered orally is below 15%.

The following factors determine the cannabinoid concentration in the Valve Balloon:

- ▶ **Temperature** - Higher vaporization temperatures cause a higher cannabinoid concentration in the Valve Balloon, lower vaporization temperatures cause a lower cannabinoid concentration in the Valve Balloon.
- ▶ **Quantity** - Higher quantities in the Filling Chamber cause a higher cannabinoid concentration in the Valve Balloon, lower quantities in the Filling Chamber cause a lower cannabinoid concentration in the Valve Balloon.
- ▶ **Quality** - Higher cannabinoid concentrations in the plant material cause a higher cannabinoid concentration in the Valve Balloon, lower cannabinoid concentrations in the plant material cause a lower cannabinoid concentration in the Valve Balloon.

To obtain a reproducible dosage with good efficiency, it is recommended to vaporize small quantities (100 mg) in the Filling Chamber at top temperature (210°C/410°F) in a single Valve Balloon only.

27

7. THE USE OF HEMP FLOWERS

When observing the Instructions for Use and with a vaporization temperature of 210°C (410°F) the following reference values are validated in studies:

Drug (Filling Chamber Content)	Cannabinoid content in drug	Cannabinoid content in Valve Balloon after vaporization with 210°C (410°F)	Cannabinoid content in blood stream (systemic bioavailability) after inhalation
Bedrocan (100 mg)	THC: approx. 19 mg	approx. 8 mg	approx. 5.5 mg
Bediol (100 mg)	THC: approx. 6 mg CBD: approx. 7.5 mg	approx. 3.5 mg approx. 4.5 mg	approx. 2.4 mg approx. 3 mg

If dosage is too low increase the amount of cannabis.
If dosage is too high reduce the vaporization temperature.

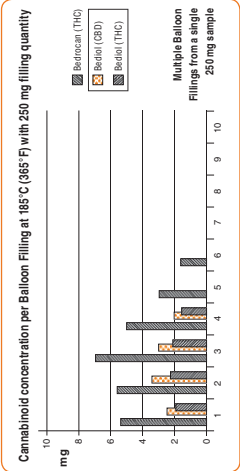
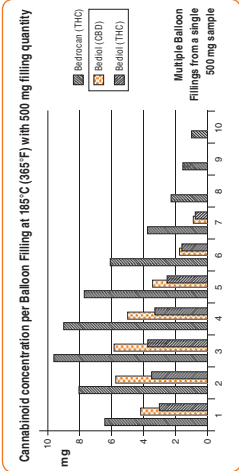
After consulting your physician, if your doctor recommends that you are able to determine your requirement for active ingredients yourself (titration), due to the relatively rapid effect (approx. 1-2 minutes) you may purify higher quantities cannabis (up to 500 mg) into the Filling Chamber and vaporize at lower temperatures.

Thus, you can fill multiple Valve Balloons with vapors of active ingredients with a single Filling Chamber filling.

With this method no reproducible doses are achieved; for this reason, it is only appropriate for experienced users.

When observing the Instructions for Use and with a vaporization temperature of 185°C (365°F) the following reference values are validated in studies:

7. THE USE OF HEMP FLOWERS



The charts show the concentration of active ingredients approx. 5 minutes after the filling of the Valve Balloon. Due to exhalation the actual systematic bioavailability (blood content) is approx. 35% lower than the cannabinoid content in the Valve Balloon.

7.2. Preparation

Make sure to use the Mouthpiece only with attached Lip Piece before every operation (see Chapter 9.3, "Disposable MED-IC VALVE Lip Piece for Hygienic Use", page 39).

Turn the Filling Chamber Cap counter-clockwise in order to remove it from the Filling Chamber.



Remove Filling Chamber Cap

Grind the hemp flowers with the enclosed herb mill. Place a hazelnut-sized amount in the Herb Mill and rotate 4-5 times.

Hemp flowers are ground most easily when they are cooled or frozen. The fridge or freezer are suited for storing hemp flowers.

Depending on the amount of active ingredients and the recommended dosage by a physician, fill the Filling Chamber with ground hemp flowers.

For consistent and reproducible dosage with e.g. 100 mg, use each Filling Chamber portion only once to fill a Valve Balloon.

Other conditions for a reproducible dosage are: using standardized cannabis, consistent amount, consistent temperature, consistent Valve Balloon Size (standard size 1.25 l) and same breathing technique when inhaling.

7.3. Application



Fill Filling Chamber

Next screw on the Filling Chamber Cap again.



Screw on Filling Chamber Cap

Take care that the Screens are not obstructed with plant material. To guarantee optimal results, we recommend cleaning the Screens after each vaporization cycle with the Cleaning Brush supplied with the device.

Suitable for vaporizing small amounts of hemp flowers, is the Filling Chamber Reducer, which is available as an accessory, along with the Dosing Capsules.

The Filling Chamber Reducer is inserted instead of the Filling Chamber Cylinder (see Chapter 3.5, "Disassembling and Assembling the Filling Chamber", page 42).

The Filling Chamber Reducer can be filled with ground hemp flowers directly. Dosing Capsules containing hemp flowers can be inserted into the Filling Chamber Reducer as well.

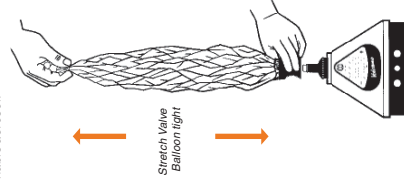


Fill the Filling Chamber Reducer with ground hemp flowers directly or with a filled Dosing Capsule

Press the "HEAT" button to switch on the heater. When the actual tempera-

ture is equal to the set temperature put the Filling Chamber with Cap on the Hot Air Generator and allow it to lock in place. Put the Valve Balloon on the Filling Chamber and allow it to lock in place. This will open the Valve.

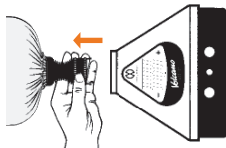
Before putting the Valve Balloon on the Filling Chamber, stretch it tight so that the Valve Balloon is placed vertically on the Hot Air Generator when it is filled. Press the "AIR" button. The Valve Balloon will now fill with the cannabis aerosol.



Stretch Valve Balloon tight

7. THE USE OF HEMP FLOWERS

When the Valve Balloon is filled, switch off the air pump and remove the Valve Balloon together with the Filling Chamber.
To do so, hold the Filling Chamber Cap at the textured grip.



Separate Valve Balloon from Filling Chamber

Do not leave the Filling Chamber on the hot air outlet of the **VOLCANO MEDIC** when "HEAT" is switched on - except for filling the Valve Balloon. Non-observance may cause the Filling Chamber to overheat and may cause burns.

Remove Valve Balloon with Filling Chamber

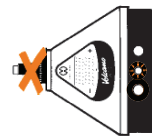


Caution! Hot surface!



Do not touch any components of the Filling Chamber (except at the textured grip) until it has cooled down after the Valve Balloon has been filled.

Separate the Valve Balloon from the Filling Chamber. The Valve closes automatically after separation and the aerosol in the Valve Balloon cannot escape.



Caution! Hot surface!

32

7. THE USE OF HEMP FLOWERS

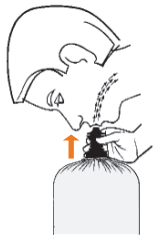
7.4. Inhalation from the Valve Balloon

Attach the Mouthpiece with attached Lip Piece to the Valve and allow it to lock in place.

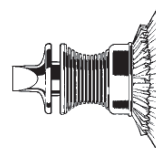


Attach the Mouthpiece with attached Lip Piece to the Valve Balloon

As soon as you remove the pressure from the Mouthpiece, the Valve automatically closes.



Press Mouthpiece against lips to inhale



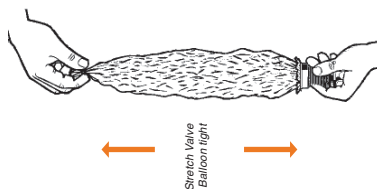
Correct position of the Mouthpiece with Lip Piece on the Valve

To inhale, put the Mouthpiece to your lips and press them lightly against the Mouthpiece. By doing so, the Valve opens and the aerosol can be inhaled from the Valve Balloon.

33

7. THE USE OF HEMP FLOWERS

! When the content of the Valve Balloon is almost emptied, you can empty the Balloon completely by stretching it tight.



! The Valve Balloon is not suitable for storing the aerosol for long periods, as it will condense on the interior surface of the Valve Balloon in time (a few hours). Inhale the contents of the Valve Balloon within 10 minutes.

Breathing Technique
Inhale only half as much air as possible. Hold your breath for a few seconds and exhale slowly. We recommend consciously concentrating on your inhalation. The cannabinoid aerosol is absorbed by the alveoli and into the bloodstream. The onset of the effect takes approx. 1-2 min.

End of Inhalation
Disconnect the power plug from the socket after inhalation. Open the Cap of the Filling Chamber by turning it counterclockwise and discard the used plant material.

8. ACCESSORIES: DOSING CAPSULES AND MAGAZINE



Dosing Capsules with Magazine

ground and have to be portioned and weight out by the patient according to the doctor's directive. In case the hemp flowers are not ground, they have to be ground with the included Herb Mill first.

! Hemp flowers are ground most easily when they are cooled or frozen. The fridge or freezer are suited for storing hemp flowers.

The Dosing Capsules can be filled with e.g. 50, 100 or up to 150 mg ground hemp flowers per capsule and be stored in the Magazine as a reserve.



Dosing Capsule with removed cap

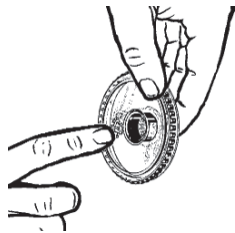
If necessary, grind the hemp flowers. Weight out the amount, which is recommended by the doctor, and fill the Dosing Capsule by using the Magazine Cap (funnel).

8.1. Filling the Dosing Capsules with ground hemp flowers

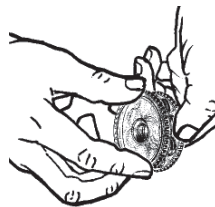
Currently, patients in practically all countries, which allow the use of hemp flowers for medical purposes, get a prescription of a certain amount of dried hemp flowers.

These hemp flowers are delivered either as whole pieces or already

8. ACCESSORIES: DOSING CAPSULES AND MAGAZINE



Dosing Capsule while being filled with Magazine Cap (funnel)



Attaching the Magazine Cap

After filling the Dosing Capsules, attach the Magazine Cap and close it by turning it clockwise.

8.2. Filling the Dosing Capsules with Dronabinol

The Dosing Capsules with inserted Liquid Pad can be filled with up to 5 drops of dronabinol and store them in the Magazine. Please make sure to not overfill the Liquid Pad.



Dosing Capsule with removed cap and inserted Liquid Pad

36

8. ACCESSORIES: DOSING CAPSULES AND MAGAZINE

8.3. Inserting the Dosing Capsules
First, the Filling Chamber Reducer, that is available as an accessory as well, is to be inserted instead of the Filling Chamber Cylinder (see Chapter 9.5, "Disassembling and Assembling the Filling Chamber", page 42). afterwards, insert the Dosing Capsules into the Filling Chamber Reducer.



The Dosing Capsule inserted into the Filling Chamber Reducer

Next screw on the Filling Chamber Cap again.



Screw on Filling Chamber Cap

! The Filling Chamber Reducer can be filled directly as well (without a Dosing Capsule), see Chapters 6.3. and 7.3. "Application", pages 21 and 30.

37

9.1. General



To avoid a health risk – e.g. infection, from a contaminated Valve Balloon – the following hygiene instructions must be followed.

In a physician's practice or in a clinic, the hygiene requirements of the RKI (Robert Koch Institute), the BfArM (German Federal Institute for Drugs and Medical Devices) or comparable institutions in your country, have to be observed.

The **VOLCANO MEDIC** Vaporization System is intended for multiple use.

- Filling Chamber
 - The Filling Chamber must be cleaned if there is visible residue or when a new Valve Balloon is used.
- Valve Balloon
 - The Valve Balloon may be used by one person only.
 - Make sure that the equipment is allowed to dry thoroughly after every cleaning. Condensation or residual moisture may encourage bacterial growth. Please note Chapter 9.2. "Material Resistance" on this page.
 - Inspect the component parts of the Filling Chamber regularly and replace defective (broken, misshapen, discolored) parts. Replace the Valve Bal-

loon after 70 applications or at least 14 days after the first use.



The Lip Piece of the **VOLCANO MEDIC** Vaporization System is equipped with a check valve.

This check valve reduces the danger of a potential contamination inside the Valve Balloon by preventing breathing into the Valve Balloon.

This ensures that the Valve Balloon can be re-used several times.

9.2. Material Resistance of the **VOLCANO MEDIC** Vaporization System

Please ensure that the Mouthpiece, the Filling Chamber, the Lip Piece and the Hot Air Generator do not come in contact with the following chemicals:

- organic, mineral and oxidizing acids (min. permissible pH 5.5)
- strong bases (max. permissible pH 10). We recommend using neutral/enzymatic or slightly alkaline cleaners.
- organic solvents (e.g. aldehyde, ether, ketone, benzene)
- oxidation agents (e.g. hydrogen peroxide)
- halogens (chlorine, iodine, bromine)
- aromatic/halogenated hydrocarbons

- phenol derivatives, amin compounds (in high concentrations)
 - oils and greases
- Clean the parts of the **VOLCANO MEDIC** Vaporization System only with soft brushes, never with metal brushes or steel wool.

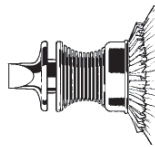
9.3. Disposable **MEDIC** VALVE Lip Piece for Hygienic Use

The Lip Piece will be delivered brand new and in a low-germ, but not fully-sterile state.



The Lip Piece is equipped with a check valve. This check valve reduces the danger of a potential contamination inside the Valve Balloon by preventing breathing into the Valve Balloon.

This ensures that the Valve Balloon can be re-used several times before it has to be disposed (see Chapter 9.4. "Reusability of the Valve Balloon", page 41).



Valve Balloon with Mouthpiece and Lip Piece

The Lip Piece is put on the Mouthpiece, slid until stop and is then ready for operation.

The Valve Balloon with Mouthpiece and the Lip Piece may be used by only one person.

A Lip Piece may be used for max. 4 hours after initial operation if it is undamaged and clean. Afterwards, it must be disposed of in the household waste and a new Lip Piece must be used due to hygienic reasons.

Every further use beyond this or the use of damaged and/or contaminated products respectively is the user's responsibility.

We assume no liability if this recommendation is ignored.



Please note that damaged or brittle Lip Pieces are not to be used.

9.4. Filling Chamber and Valve Balloon

Cleaning the Filling Chamber

- Clean your sink and the surrounding area.
- Disassemble the Filling Chamber (see Chapter 9.5. "Disassembly and Assembly" of the Filling Chamber, page 42).
- Remove stubborn residue inside the Filling Chamber Cylinder and cap cylinder (if necessary, with ethyl alcohol).
- Place all component parts of the Filling Chamber in warm (40-50 °C, 104-122 °F) soapy water for at least 5 min. (Commercial dish soap without disinfectant and with a few additives as possible, used according to manufacturer's recommendations, avoiding excessive foam) and ensure that all parts are completely covered and contain no air bubbles.
- Use a soft brush (bottle brush) or a soft, clean cloth to remove impurities that is used only for this purpose, never metal brushes or steel wool. Clean until there are no visible impurities on the parts.
- Remove the parts from the soapy water and rinse them for at least 1 min. under running water.

- Allow the liquid inside to run out completely and shake any remaining water out of the parts. Avoid any contact with undean surfaces, especially the floor.



Do not immerse any plastic components in ethanol or alcohol for longer than an hour. Extended contact with ethanol or alcohol can lead to discoloration or embrittlement of plastic parts.

Note: If the tap water is very hard, resulting in the formation of a white film on the surfaces of the parts, we recommend replacing the Filling Chamber more frequently.

Possible alternative: The component parts of the Filling Chamber can also be cleaned in a dishwasher using a commercially available dishwasher detergent.

- Put the component parts of the Filling Chamber in a suitable place in the dishwasher. Small parts (e.g. Filling Chamber Clips) can be lost or may damage the dishwasher if improperly placed.

In case of doubt, do not clean the small parts of the Filling Chamber (Filling Chamber Clips, Screens) in the dishwasher.

Inspecting/Maintenance of the Filling Chamber

After cleaning, check all component parts of the Filling Chamber for surface damage, tears, softening or hardening, soiling, discoloration, or excessive limescale and discard damaged Filling Chambers.

Then reassemble the Filling Chamber (see Chapter 9.5. "Disassembling and Assembling" of the Filling Chamber, page 42).

Reusability of the Filling Chamber

The Filling Chamber (incl. Screens and Liquid Pad) is intended for multiple use.

It requires no particular hygienic reprocessing (see Chapter 9.4. "Cleaning the Filling Chamber", page 40).

The Filling Chamber must be cleaned:

- if there is residue (condensate) on the inside of the Filling Chamber,
 - when a new Valve Balloon and Mouthpiece is used,
 - when a new patient uses it.
- Before every use, check the Filling Chamber for damage and wear and tear (see section "Inspecting/Maintenance of the Filling Chamber", page 41). A defective Filling Chamber or part must be replaced immediately.

Reusability of the Valve Balloon

The Valve Balloon is intended for multiple uses without hygienical reprocessing.

It may be used only by one person for a maximum of 70 times and a maximum of 14 days after the initial use.

Then a new Valve Balloon with Mouthpiece must be used.

Before each vaporization, check from the outside whether there is any moisture (condensation) inside the Valve Balloon.

If there is any moisture in the Valve Balloon or if the Valve is damaged, the Valve Balloon may no longer be used and must be disposed of with household waste.

Storage

Store Filling Chamber, Mouthpiece, Lip Piece and Valve Balloon in a dry, dust-free place away from contamination.

9.5. Disassembly and Assembly**Filling Chamber and Filling Chamber Cap**

Please allow the Filling Chamber and the Cap to cool down before disassembling them.

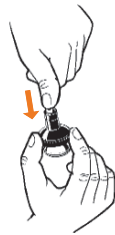
All component parts of the Filling Chamber must be cleaned at the intervals prescribed in Chapter 9, "Reliability of the Filling Chamber", page 41. Disassemble the Filling Chamber as follows:

Turn the Filling Chamber Cap counterclockwise in order to remove it from the Filling Chamber.



Push out the upper Screen with the help of the Cleaning Brush.

Push the cap cylinder downwards out of the cap housing. At the same time the cap ring will be stripped off.



Push the cap cylinder out of the cap housing



Remove Filling Chamber Cap

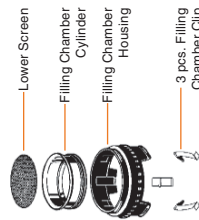
Disassembling the Filling Chamber Cap

Use, e.g., the handle of the Cleaning Brush to press the upper Screen down in order to push it out. No Screens are needed when using dronabinol.



Push the Filling Chamber Cylinder out of the Filling Chamber Housing

When the Filling Chamber Cylinder is pushed out, the three Filling Chamber Clips are loosened and fall out of the Filling Chamber Housing.

**Disassembling the Filling Chamber**

Push the lower Screen or the Liquid Pad upwards out of the Filling Chamber Cylinder.

Push the Filling Chamber Cylinder upwards out of the Filling Chamber Housing.

Drying

All component parts of the Filling Chamber must be completely dry before reassembly.

Put all component parts of the Filling Chamber on a clean, dry, and absorbent pad and allow them to dry thoroughly. A hair dryer may be used for faster drying. Do not dry in wet rooms (e.g. not in the bathroom).

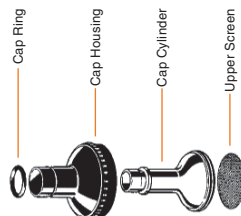
Assembly of Filling Chamber Cap

Slide the cap cylinder into the cap housing until it clicks, then pull the cylinder from above over the cap cylinder to the cap housing.

When using hemp flowers, push the upper Screen from below into the cap cylinder until it clicks into the designated notch.

When using dronabinol solution, the two Screens are not needed. Only the Liquid Pad is inserted instead of the lower Screen.

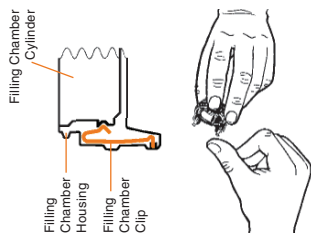
9. HYGIENE



The upper Screen has to be placed carefully into the intended notch. Non-observance may result in plant particles in the Valve Balloon that might be inhaled subsequently.

Assembling the Filling Chamber

Push the Filling Chamber Cylinder from above into the Filling Chamber Housing and allow it to lock in place. Insert the Filling Chamber Clips in the openings provided for them in the foot of the Filling Chamber Housing. Please ensure that the Filling Chamber Clips are placed properly as shown in the illustration.



Insert Filling Chamber Clips

Insert the Screen or the Liquid Pad into the Filling Chamber from above. Screw Filling Chamber Cap on Filling Chamber.

10. HOT AIR GENERATOR

10.1. Cleaning

Before maintenance, the device has to be switched off and the power plug has to be unplugged.

For home use it is sufficient to clean the housing of the Hot Air Generator with a damp cloth. Do not hold the device under running water.

In a physician's office or clinic, the housing of the Hot Air Generator can be cleaned and disinfected with a surface disinfectant.

The surface disinfectant should be certified (e.g. VAH/DGHM or FDA approval or CE marking), be suitable for disinfecting the Hot Air Generator, and compatible with the Hot Air Generator (see Chapter 9.2. "Material Resistance", page 38).

Use only a soft clean cloth for wiping. The cloth may be damp, but not wet. Prevent liquid from entering the Hot Air Generator.

The tests for the material resistance of the Hot Air Generator for surface disinfection were made using the disinfectant "neofarm MED Spray" from Dr. Weigert.

Liquid entering the Hot Air Generator can damage the electrical parts and cause malfunctions.

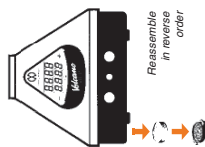
If any liquid does get into the Hot Air Generator, contact our Service Center immediately.

10.2. Care and Maintenance

Before any maintenance work is done, the device has to be switched off and the power plug has to be unplugged.

At the bottom of the Hot Air Generator is an Air Filter.

The Air Filter must be inspected for contamination every four weeks by turning the Air Filter Cap counterclockwise and removing the Air Filter.



10.3. Storage

Store the Hot Air Generator in a dry place protected against the effects of weather and out of the reach of children or unqualified persons.

10.4. In Case of Problems

Immediately unplug the power cord and ensure that no one can connect the Hot Air Generator to the mains supply again without this being noticed.

If there are any faults in the electronics of the Hot Air Generator **VOLCANO MEDIC**, you can perform a reset by pulling out the power plug and plugging it again after waiting for minimum three seconds.

The Hot Air Generator has two internal fuses (F1 and F2). As these fuses are located in case of a defect in the Hot Air Generator, they can be replaced only by our Service Center.

Put the Hot Air Generator in the original packaging or pack it properly in other packing material and take it to our Service Center.

10.5. Disposal

If the Hot Air Generator is irreparably damaged, please do not simply throw it away.

As it is made of high quality, completely recyclable components, it should be brought to a material recycling centre in your town or sent to our Service Center for disposal.

10.6. Troubleshooting

If the device does not function properly when the power plug is connected to the power socket, please check the Hot Air Generator using the tips in the following table:

Problem	Possible cause/remedy
No green light signal visible on the VOLCANO MEDIC display; no activation of the heater or pump possible.	Please make sure that the current is on and that the fuse (in the mains fuse box) is switched on and is not defective. If the Hot Air Generator still does not function, the internal fuses may have been triggered. In this case, send the VOLCANO MEDIC Hot Air Generator to our Service Center.
No aerosol is formed.	Check the set and actual temperature. Make sure the Filling Chamber and/or Valve Balloon were correctly attached. Check whether the dronabinol has been added to the Liquid Pad or whether there is fresh, unused cannabidiol flos in the Filling Chamber.
The Valve Balloon does not fill up.	Check whether the pump is turned on. Check whether the Filling Chamber and/or Valve Balloon are correctly attached.
The device switches off (automatic switch-off of the VOLCANO MEDIC).	No button was pressed in the last 30 minutes – this leads to automatic switch-off. Switch heater or pump on again.
Plant particles in the Valve Balloon (when using cannabidiol flos).	Check whether the Screen in the Filling Chamber Cap is clogged or is not inserted into the notch properly. Check whether the Filling Chamber was cleaned according to the Instructions for Use.

 If the preceding tips do not yield the desired results, or for any other defects or problems not mentioned here, please pull the power plug and contact our Service Center immediately.

 Do not open the Hot Air Generator! Without special tools and specialized knowledge, any attempt to open the device will cause damage to it. Such an attempt will invalidate the warranty claim.
Do not try to remedy the defect yourself. Contact directly our Service Center.

10.7. Periodic Safety Checks

The following safety checks should be performed at least every 24 months by a qualified person who has adequate training, knowledge, and practical experience to perform these tests.

- Inspect the device and accessories for mechanical and functional damage.
- Inspect the safety labels for legibility.
- Verify that the device functions properly as described in the Instructions for Use.

The safety check is to be recorded in a device log and data of control results are to be documented.

If the device is not functioning properly or falls any of the above tests, the device has to be repaired.

10.8. Technical Specifications
VOLCANO MEDIC
Vaporization System

Voltage:
220-240 V / 50-60 Hz (alternatively available with 110-120 V / 50-60 Hz)
The specification is located on the bottom side of the **VOLCANO MEDIC** Hot Air Generator.
Power consumption: 120 VA
Air pump output: 10 VA

Air temperature: adjustable between approx. 40 - 210 °C (104 - 410 °F)
Air flow: approx. 12 l/min
Valve Balloon Size:
approx. 12.5 liters
Size of the Hot Air Generator: 20.0 x 18.0 cm (7.9 x 7.1 inch)
Weight of the Hot Air Generator with power cord, Filling Chamber, and Valve Balloon with Mouthpiece: approx. 1.8 kg (3.9 lbs)
Safety category II
Please unplug to disconnect from the mains current.
Internal fuses F1 and F2: T 1.25 A (applies to 110-120 V and 220-240 V devices)

These fuses may be replaced only by our Service Center.

Subject to technical changes.
Patents and designs:
www.vapormed.com/patents

Manufacturer
Storz & Bickel GmbH & Co. KG
In Gruberlacker 5-9,
79532 Tuttlingen,
Germany

10.9. Information on Electromagnetic Compatibility

Guidance and Manufacturer's Declaration – Electromagnetic Emissions
The **VOLCANO MEDIC** Vaporization System is intended for use in the electromagnetic environment specified below. The customer or the user of the **VOLCANO MEDIC** Vaporization System should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The VOLCANO MEDIC Vaporization System uses 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.
RF emissions CISPR 11	Class B	The VOLCANO MEDIC Vaporization System is suitable for use in all electromagnetic environments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

10. HOT AIR GENERATOR

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The VOLCANO MEDIC Vaporization System is intended for use in the electromagnetic environment specified below. The customer or the user of the VOLCANO MEDIC Vaporization System should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines not applicable: input/output lines are non-existent	Mains power quality should be that of a typical residential, commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical residential, commercial or hospital environment.

50

10. HOT AIR GENERATOR

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Voltage dips, short interruptions and variations on power supply lines IEC 61000-4-11	<5 % Ut (>95 % dip in Ut) for 1 % cycle 40 % Ut (60 % dip in Ut) for 5 cycles 70 % Ut (30 % dip in Ut) for 25 cycles ≤5 % Ut (>95 % dip in Ut) for 5 s	<5 % Ut (>95 % dip in Ut) for 1 % cycle 40 % Ut (60 % dip in Ut) for 5 cycles 70 % Ut (30 % dip in Ut) for 25 cycles ≤5 % Ut (>95 % dip in Ut) for 5 s	Mains power quality should be that of a typical residential, commercial or hospital environment. In the case of the VOLCANO MEDIC Vaporization System requires continued operation during power mains interruptions. It is recommended that the VOLCANO MEDIC Vaporization System be powered from an uninterruptible power supply.
Power frequency magnetic field (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at a level characteristic of a typical location in a residential, commercial or hospital environment.
Note: Ut is the a.c. mains voltage prior to application of the test level.			

51

10. HOT AIR GENERATOR

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The VOLCANO MEDIC Vaporization System is intended for use in the electromagnetic environment specified below. The customer or the user of the VOLCANO MEDIC Vaporization System should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the VOLCANO MEDIC Vaporization System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance : $d = 1,2 \sqrt{P}$ $d = 1,2 \sqrt{P}$ for 80 MHz bis 800 MHz $d = 2,3 \sqrt{P}$ for 800 MHz bis 2,5 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	

52

10. HOT AIR GENERATOR

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Where P is the maximum output power rating of the transmitter in watts [W] according to the transmitter manufacturer and d is the recommended separation distance in meters [m]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey), should be less than the compliance level in each frequency range). Interference may occur in the vicinity of equipment marked with the following symbol:
			
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

53

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **VOLCANO MEDIC** Vaporization System is used exceeds the applicable RF compliance level above, the **VOLCANO MEDIC** Vaporization System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **VOLCANO MEDIC** Vaporization System.

2) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances between portable and mobile RF Communications Equipment and the VOLCANO MEDIC Hot Air Generator

The **VOLCANO MEDIC** Hot Air Generator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **VOLCANO MEDIC** Hot Air Generator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **VOLCANO MEDIC** Hot Air Generator as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]		
	150 kHz – 80 MHz $d = 1,2 \sqrt{P}$	80 MHz – 800 MHz $d = 1,2 \sqrt{P}$	800 MHz – 2,5 GHz $d = 2,3 \sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters [m] can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts [W] according to the transmitter manufacturer.

Note 1
At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2
These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
Medical electrical equipment is subject to special precautions with respect to electromagnetic compatibility. The manufacturer should refer to EN 60601-1-2 is available.

11. SPARE PARTS / ACCESSORIES

REF 01 00 M	VOLCANO MEDIC Vaporization System
REF 05 01 M	MEDIC VALVE Replacement Set
REF 03 01 M	MEDIC VALVE Filling Chamber
REF 03 10 M	MEDIC VALVE Normal Screen Set
REF 03 11 M	MEDIC VALVE Fine Screen Set
REF 03 39 M	MEDIC VALVE Normal Screen Set, small
REF 03 34 M	MEDIC VALVE Liquid Pad Set
REF 06 02 M	MEDIC VALVE Wear & Tear Set
REF 03 03 M	MEDIC VALVE Filling Chamber Housing with Cap Housing
REF 04 05 M	MEDIC VALVE Lip Piece Set, 10 pcs.
REF 03 07 M	MEDIC VALVE Filling Chamber with Reducer
REF 03 06 M	MEDIC VALVE Filling Chamber Reducer
REF 09 32	Magazine with 8 Dosing Capsule
REF 09 33	Dosing Capsule Set, 40 pcs.
REF 09 36 M	MEDIC VALVE Magazine with 8 Dosing Capsule for Liquids
REF 09 38 M	MEDIC VALVE Dosing Capsules for Liquids Set, 40 pcs.
REF 03 35 M	MEDIC VALVE Liquid Pad Set for Dosing Capsules
REF 03 37 M	MEDIC VALVE Liquid Pad Set, small
REF 09 30	Herb Mill
REF 01 10	VOLCANO MEDIC Air Filter Set
REF 01 11	VOLCANO MEDIC Air Filter Cap
REF 09 37	Cleaning Brush Set

All spare parts and other products may be conveniently ordered from www.repormed.com.

56

12. DECLARATION OF CE CONFORMITY

The devices fulfill the requirements of the following directives and standards:

- Medical products: 93/42/EEG
 - UL medical safety testing: UL 60601-1:2003
- Low Voltage Directive: 73/23/EEG
 - Medical electrical equipment: CAN/CSA-C22.2 No. 601.1-M90
- Electromagnetic Compatibility: 89/336/EEG
 - Medical electrical equipment: IEC 60601-1:2005+A1:2012

57

13. WARRANTY, LIABILITY, REPAIR SERVICE

Warranty

Storz & Bickel GmbH & Co. KG as seller hereby guarantees the customer that the product will be free from defects in accordance with the specifications of German law, and pursuant to our General Terms and Conditions (GTC), upon which the purchasing agreement are based. Of course, Storz & Bickel will only be subject to a warranty obligation if the customer has purchased the products directly from us. If products are purchased from third parties, warranty claims may only be asserted against these third parties, and Storz & Bickel cannot provide any information on the content of such claims.

In clarification, we would like to note once again here that the warranty extends only to correcting such initial defects that exist despite proper handling of the product in consideration of the instructions for use and further information provided to users. Normal wear and tear of the products is not covered. If the customer has misused the product, the seller has no warranty obligation. If the customer has neglected the maintenance or repair of the product or if the customer uses external products, Storz & Bickel's warranty obligations will only exist if the customer can prove that the defect was not caused by use of the external service or external product.

Storz & Bickel will decide at its own discretion whether to correct a defect

covered to warranty law through repair or by delivering a new product to the customer.

Any warranty claims must be directed to Storz & Bickel GmbH, In der Hakenacker 3-5, 78532 Tübingen. Please send the complete defective item to us, not disassembled, with invoice. Please use external packaging that would prevent any damage during transportation.

In order to avoid misunderstandings, we would like to note that all information on our products provided in this Instructions for Use or elsewhere does not represent any guarantee of features or durability, unless we have expressly referred to a guarantee for such features or durability.

Liability

Storz & Bickel shall be liable for any damages caused to the customer by our products in accordance with German law and pursuant to our GTC. In said provisions, we are only liable for damages caused by intentional action or gross negligence, unless such damages involve death, personal injury, or injury to health, or if the injury is related to a cardinal contractual obligation. In such cases, we will also be liable to the customer for simple negligence.

13. WARRANTY, LIABILITY, REPAIR SERVICE

Repair Service

In addition to our warranty obligations, we offer competent repair service to our customers. We will promptly repair any defective products made by us after we have informed the customer of estimated costs and obtained customer approval.

Copyright

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13. WARRANTY, LIABILITY, REPAIR SERVICE

14. PROOF OF THE ANNUAL SAFETY CHECKS (SC)

Date	SC Finding	Comments	Signature	Name / Title
	☐ OK ☐ not OK			
	☐ OK ☐ not OK			
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