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Manufacturer and Distributor:

STORZ & BICKEL GMBH & CO. KG

In Grubenäcker 5-9 · 78532 Tuttlingen / Germany

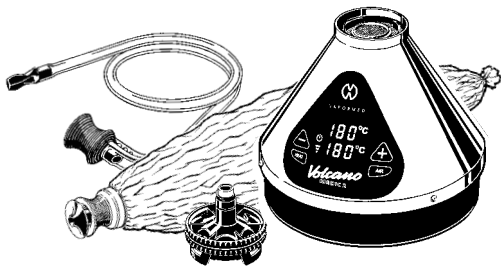
Phone +49-7461-969707-0 · Fax +49-7461-969707-7

e-mail: info@vapormed.com





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Volcano[®]

MEDIC 2

INSTRUCTIONS FOR USE

Read carefully before using the device
and save these instructions.

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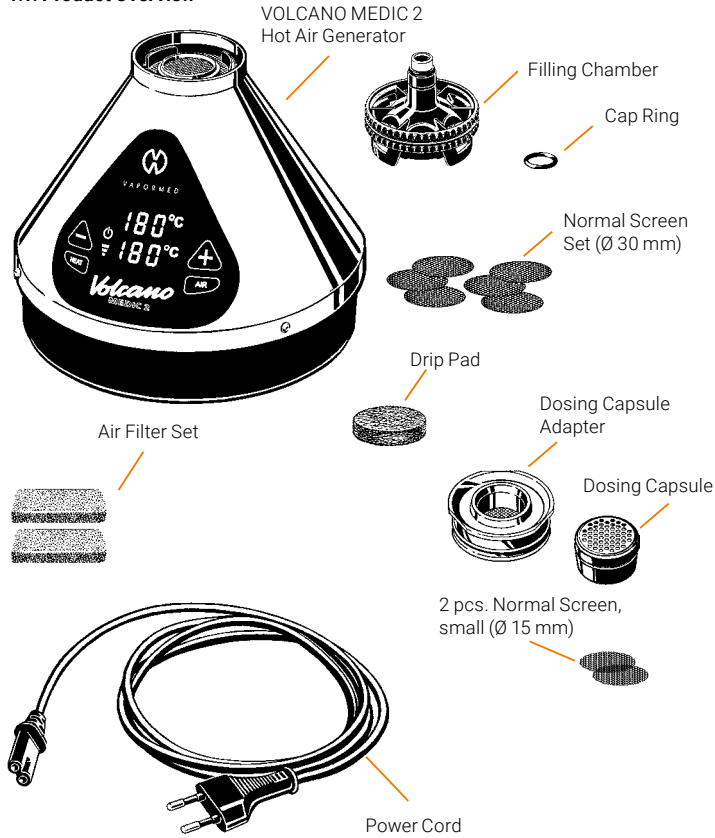
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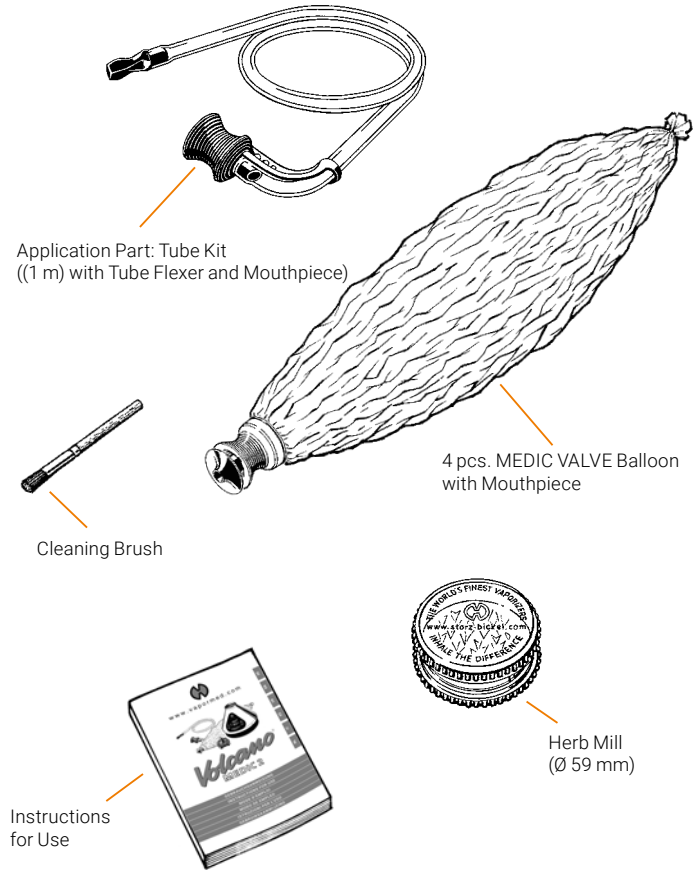
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1. PRODUCT OVERVIEW, SCOPE OF DELIVERY, SERVICE

1.1. Product Overview

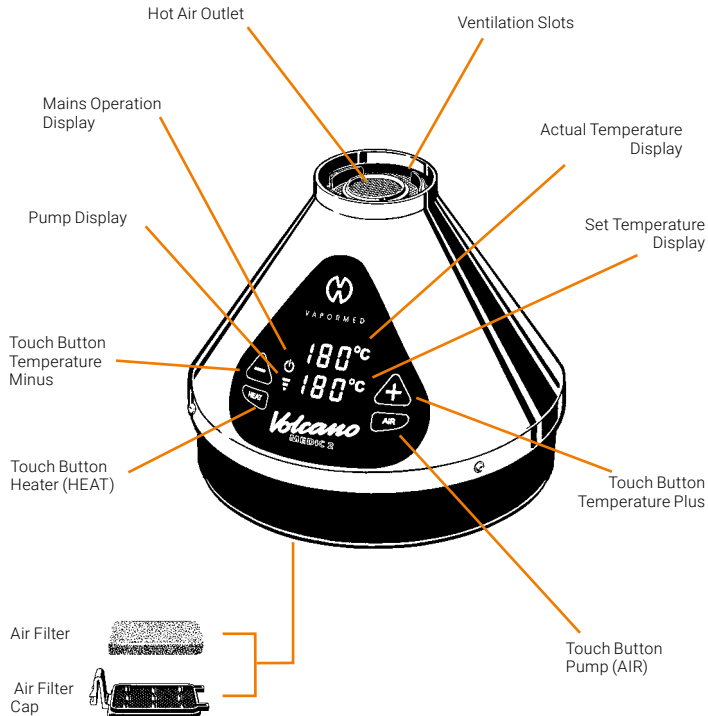


1. PRODUCT OVERVIEW, SCOPE OF DELIVERY, SERVICE



1. PRODUCT OVERVIEW, SCOPE OF DELIVERY, SERVICE

1.2. VOLCANO MEDIC 2 Hot Air Generator Functional Elements



1. PRODUCT OVERVIEW, SCOPE OF DELIVERY, SERVICE

1.3. Scope of Delivery VOLCANO MEDIC 2 Vaporization System

- 1 pc. VOLCANO MEDIC 2 Hot Air Generator
- 1 pc. Power Cord
- 4 pcs. MEDIC VALVE Balloon with Mouthpiece
- Application Part: 1 pc. Tube Kit ((1 m) with Tube Flexer and Mouthpiece)
- 1 pc. Filling Chamber
- 1 pc. Cap Ring
- 1 pc. Normal Screen Set (6 pcs. Screen with regular mesh width)
- 1 pc. Drip Pad (approx. Ø 28 x h 4 mm)
- 1 pc. Dosing Capsule Adapter
- 2 pcs. Normal Screen, small with regular mesh width (approx. Ø 15 mm)
- 1 pc. Dosing Capsule
- 1 pc. Air Filter Set (2 pcs. Air Filter)
- 1 pc. Herb Mill (approx. Ø 59 mm)
- 1 pc. Cleaning Brush
- 1 pc. Instructions for Use

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

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

1.4. 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, WARNINGS AND 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 2 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 2 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 2 Vaporization System on www.vapormed.com

2.1. Explanation of Symbols



Please follow these instructions carefully!
(according to IEC 60601)



Warning!

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



Safety Recommendation!

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



Note/Tip!

This symbol always gives you technical information or useful tips regarding the VOLCANO MEDIC 2 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

2. EXPLANATION OF SYMBOLS, WARNINGS AND SAFETY RECOMMENDATIONS



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

IP 21

Device protected against foreign bodies with a diameter larger than 12 mm and against vertically falling water drops (according to IEC 60529).



EU conformity symbol
A 4-digit number after the CE marking indicates that a notified body is involved in the conformity assessment procedure.



Symbol for order number - followed by the order number of the corresponding medical product (or part)



Safety tested and production monitored by TUEV SUED Product Service GmbH according to IEC 60601-1, CAN/CSA C22.2 No. 60601-1.



Safety tested and production monitored by TUEV SUED Product Service GmbH according to IEC 60601-1.



Caution! Hot surfaces! Never leave Filling Chamber on VOLCANO MEDIC 2 Hot Air Generator.



Protect from direct sunlight.



Protect against moisture and humidity.

2. EXPLANATION OF SYMBOLS, WARNINGS AND SAFETY RECOMMENDATIONS



Application Part Type BF
The class "BF" (Body Float) applies to medical devices (application parts) that come into direct contact with the patient.



Interference may occur in the vicinity of equipment marked with the following symbol.



Temperature limits of ambient temperature



Humidity limitation



Air pressure limitation



Shows a medical device that has not been subjected to a sterilization procedure.

2. EXPLANATION OF SYMBOLS, WARNINGS AND SAFETY RECOMMENDATIONS



2.2. Warnings

- This device may be used by children of 8 years of age and older, and by persons with reduced physical, sensory or mental abilities or lack of experience and knowledge, if they are supervised or instructed in the safe use of the device and understand the possibility of resulting hazards. Do not allow children to play with the device. Cleaning and user maintenance must not be carried out by children without supervision.
- If the Power Cord of the device is damaged, it must be replaced with a special Power Cord available from the manufacturer or its customer service.
- The device has hot surfaces to allow active components to vaporize. These surfaces should not be touched during use.
- The device may only be used for the vaporization of the recommended cannabinoids present in dried hemp flowers or dissolved in an alcohol solution, such as Dronabinol. The use of other substances may cause poisoning or fire.
- The packaging material (plastic bags, polystyrene parts, boxes, etc.) must be kept out of the reach of children as it is a potential source of danger.
- Ensure that all vapors, e.g. from flammable detergents and disinfectants, have evaporated before switching on the Hot Air Generator.
- Ensure that the Valve Balloon with Mouthpiece, and/or the Tube with Mouthpiece are free from inhalable foreign matter.
- People who require assistance must be supervised constantly during inhalation. Such persons often underestimate the hazards involved (e.g. strangulation with the Power Cord or Tube), 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 children.
- Do not operate the Hot Air Generator close to flammable objects such as curtains, tablecloths, or paper.
- The Hot Air Generator may only be repaired by our Service Center.

2. EXPLANATION OF SYMBOLS, WARNINGS AND SAFETY RECOMMENDATIONS

- 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.
- 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.
- When they are hot do not touch the hot air outlet, the Filling Chamber, or the Tube Flexer when using the Tube, whilst they are hot.
- The Filling Chamber may only be attached for filling the Valve Balloon or during use of the Tube Kit. After filling the Valve Balloon or after using the Tube Kit, the Filling Chamber must be removed from the Hot Air Generator to avoid excessive heating (danger of burning) of the Filling Chamber.
- Do not put any body parts or objects in the hot air stream.



Caution! Hot surface!

- The Hot Air Generator must not be used in damp or wet conditions.
- Never touch the Hot Air Generator with wet or damp parts of the body.
- Do not use in an atmosphere with risk of explosion or ignition.



2.3. Safety Recommendations

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

- Do not use the device if the Power Cord is damaged.
- Check the packaging and the housing of the Hot Air Generator. In case the housing appears to be damaged, please send back the device immediately.
- Before connecting the Hot Air Generator, make sure that the information given on the type label on the bottom side of the Hot Air Generator corresponds to the mains supply at the place of installation.
- In case of doubt, or malfunction during operation, immediately disconnect the power plug from the socket.
- If you have any concerns, ask a specialist to check whether the electrical system is in accordance with the local safety regulations.
- The use of multiple sockets and/or extension cables is not recommended. However, if this is absolutely necessary, only products with a quality certificate (such as UL, IMQ, VED, +S etc.) may be used, provided the

2. EXPLANATION OF SYMBOLS, WARNINGS AND SAFETY RECOMMENDATIONS

specified power exceeds the power required (A= Ampere) by the devices that are connected.

- Operate the Hot Air Generator on a stable and flat surface at sufficient distance from heat sources (oven, stove, chimney, 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. It must not be installed in damp locations (such as bathrooms etc.).
 - 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.
 - Keep the Hot Air Generator away from pets (e.g. hamsters, mice) and other animals which could damage the Power Cord insulation.
 - To pull the power plug from the socket, pull the power plug directly, never pull the Power Cord.
 - Do not put any objects into the openings of the device.
 - Do not leave the Hot Air Generator unattended during operation. Switch off the heater and pump after use if applicable.
- The Hot Air Generator should be cleaned only with a dry cloth - or a damp cloth if absolutely necessary. Before cleaning, pull out the Power Cord from the socket. Never immerse the Hot Air Generator in water or in other liquids or clean it with a direct water or steam jet.
 - Do not expose the Hot Air Generator or the power adapter to rain. Do not use in the bathroom or above water.
 - Never put containers containing liquids on the Hot Air Generator.
 - 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.
 - Only use original Storz & Bickel accessories and spare parts.


3. INTENDED USE

The VOLCANO MEDIC 2 Vaporization System is intended for vaporizing and then inhaling dronabinol (THC) dissolved in alcohol or cannabinoids from hemp flowers (cannabis flos).


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 2 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 2 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 are described in Chapters 6.2. and 7.3. "MEDIC VALVE Valve Balloon" (page 30 and 39) as well as 6.3. and 7.4. "Application Part: Tube Kit" (page 34 and 44).


 The Valve Balloon with Mouthpiece and/or the Tube with Mouthpiece are intended for only one user and may not be shared among patients.

 The Mouthpiece of the Valve Balloon and the Mouthpiece of the Tube Kit must be cleaned prior to the first use in accordance

with the instructions in Chapter 9.3. "Filling Chamber as well as Tube Flexer and Mouthpiece of the Tube Kit", page 50.

The Valve Balloon and Tube Kit can be re-used several times, but only by one person (see Chapter 9. "Hygiene", page 49).

The Valve Balloon with Mouthpiece or Tube Kit may be used for a maximum of 2 weeks.

 At a certain dosage, dronabinol (THC) and 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 dronabinol (THC) or medicinal hemp flowers (cannabis flos) 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.

4. IMPORTANT REMARKS


Cannabinoids vaporize at temperatures over 180°C (356°F) and then form an aerosol 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.

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 flos).

Our Service Centre is available to answer your questions and receive your comments and suggestion concerning the VOLCANO MEDIC 2 Vaporization System.

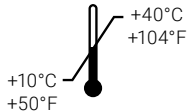
 You may download the current Instructions for Use for the VOLCANO MEDIC 2 Vaporization System on www.vapormed.com. Here you will find the up-to-date information to the current state of research.

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

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)



30% - 80%

Relative humidity of ambient air:
30% to 80%



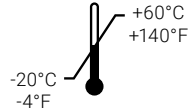
700hPa - 1060hPa

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 57).

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)



20% - 80%

Relative humidity:
20% to 80%



700hPa - 1060hPa

Atmospheric pressure:
700 hPa to 1060 hPa

Do not store or transport any parts of the VOLCANO MEDIC 2 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 2 HOT AIR GENERATOR

5.1. Unpacking

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, polystyrene parts, 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 2 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 device is safely disconnected from the mains only when the plug is removed from the socket.

When the power plug is plugged in, all sequences of the LED display will illuminate briefly before displaying the firmware number. The mains operation display which then appears on the display shows that the Hot Air Generator is connected to the power supply.

5.5. Heating Up

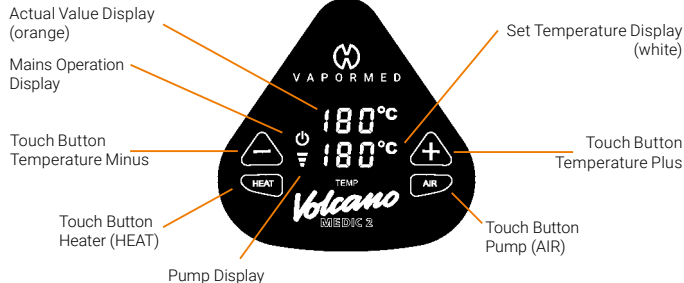
To switch on the heater, press the touch button labeled 'HEAT'. The set/actual temperature will light up, signaling that the heater is switched on. The upper, orange display shows the actual temperature in the Filling Chamber with the air pump switched on, and the lower, white display shows the desired set temperature. The heating process is completed when the set value is equal to the actual value. This is also indicated acoustically when the pump

is switched on briefly. Heating up can take up to two minutes depending upon the chosen temperature. After the heating process is completed, the temperature is constantly maintained at the set value.

 For technical reasons the temperature in the Filling Chamber cannot be measured during vaporization. During operation the temperature is measured at the heat exchanger. The display indicates the reference values for the attached Filling Chamber with the air pump switched on.


5. THE VOLCANO MEDIC 2 HOT AIR GENERATOR


5.6. Temperature Setting



When you briefly tap on the touch button Temperature Plus or Minus, the set values are increased or decreased in the respective direction in 1-degree increments.


If you keep the touch button Temperature Plus or Minus pressed, the set values start running continuously in the corresponding direction. If the touch button Temperature Plus and Minus is activated simultaneously, 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 on the mains operation 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.

5. THE VOLCANO MEDIC 2 HOT AIR GENERATOR

5.7. Keys Combination

The table below gives an overview of commands that can be entered on the display using key combinations:

Key command	Result
Press the touch button ,HEAT'	Switching on the heating
Press the touch button ,AIR'	Switches on the pump
Tap the touch button Temperature Plus	Increases the set value in 1-degree increments
Tap the touch button Temperature Minus	Reduces the set value in 1-degree increments
Keep the touch button Temperature Plus pressed	Continuous increase of the set value
Keep the touch button Temperature Minus pressed	Continuous decrease of the set value
Simultaneous activation of the touch button Temperature Plus and Minus	Changing the display from degrees Celsius to degrees Fahrenheit and vice versa
Press the touch button ,Heat' for 10 seconds while VOLCANO MEDIC 2 is switched on	Carry out the factory reset, which is confirmed by a run sequence on the LCD. This affects the following feature: - Resets the set temperature to 180°C (356°F) Note: the unit previously displayed (°C or °F) is maintained following the factory reset

6. THE USE OF DRONABINOL

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 2 Vaporization System.

6.1. Preparation

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



Preparation to use the Drip Pad

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

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 Drip Pad. The Drip 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.

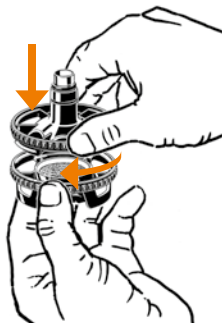
Always follow your doctor's recommendations!

6. THE USE OF DRONABINOL



Applying drops with a pipette

Next screw on the Filling Chamber Cap again.

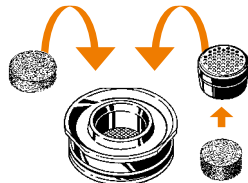


Screw on Filling Chamber Cap



The Dosing Capsule Adapter, available as an accessory, is suitable for vaporizing small amounts of dronabinol (THC) (up to five drops) along with the small Drip Pads and the Dosing Capsules. The Dosing Capsule Adapter is inserted instead of the Filling Chamber Cylinder (see Chapter 9.4. "Disassembly and Assembly of the Filling Chamber", page 53).

Either the small Drip Pad (measurements $\varnothing 15 \times h 5$ mm) or the Dosing Capsule containing a Drip Pad (measurements $\varnothing 13 \times h 6$ mm) are to be inserted into the Dosing Capsule Adapter.



Insert either a small Drip Pad directly into the Dosing Capsule Adapter or a Dosing Capsule equipped with a Drip Pad

6. THE USE OF DRONABINOL



Please make sure to not overfill the Drip Pad. It can contain up to five 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 Drip 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.

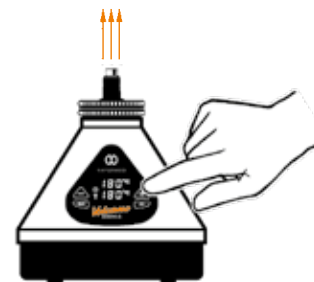
Press the touch button labeled 'HEAT', set temperature to 100°C (212°F) and allow the device to heat up.

When the actual temperature of 100°C (212°F) has been reached, position the Filling Chamber with Cap on the Hot Air Generator and rotate clockwise until it stops.

Then press the touch button labeled 'AIR' to pump air through the Drip 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.



Separate alcohol

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

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

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

6. THE USE OF DRONABINOL

6.2. MEDIC VALVE Balloon

6.2.1. Efficiency of vaporized Dronabinol (THC)

By following the procedure listed in the Instructions for Use the systemic bio-availability of vaporized dronabinol is approximately 46%.

For comparison: The systemic bio-availability 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 Valve Balloon after vaporization with 210°C (410°F)	Cannabinoid content in blood stream (systemic bioavailability) after inhalation
Dronabinol/THC (10 mg)	THC: 10 mg	approx. 7 mg	approx. 4,6 mg

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

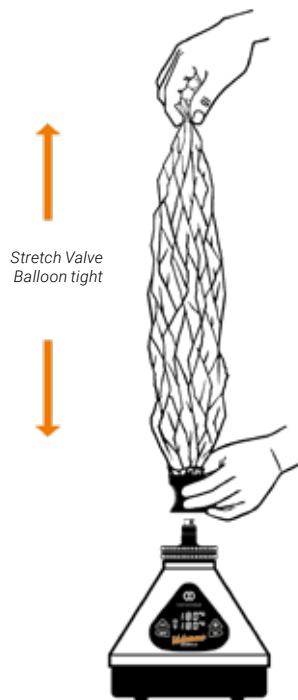
6.2.2. Application

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.

When the actual temperature of 210°C (410°F) has been reached, position the Filling Chamber with Cap on the Hot Air Generator and

rotate clockwise until it stops. Put the Valve Balloon on the Filling Chamber and allow it to lock in place. This opens the Valve. Press the touch button pump (AIR). The Valve Balloon will now fill with dronabinol aerosol.

6. THE USE OF DRONABINOL



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

However you should continue filling the Valve Balloon (approx. 60 sec.) as the additional air dilutes the aerosol, which makes inhalation easier, especially for higher dosages.

When the Valve Balloon is filled, switch off the pump by tapping the touch button pump ('AIR') again - and remove the Balloon together with the Filling Chamber.

To do this, grasp the Filling Chamber by the rotating knobs and unscrew counterclockwise.



6. THE USE OF DRONABINOL



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.

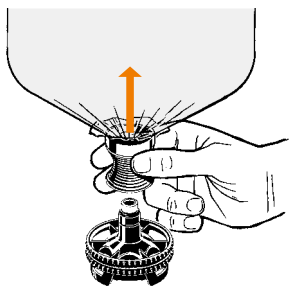
Separate the Valve Balloon from the Filling Chamber. The Valve closes automatically after separation and the aerosol in the Valve Balloon cannot escape.



Caution! Hot surface!

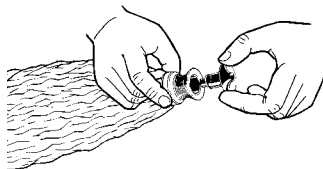
6.2.3. Inhalation

Attach the Mouthpiece to the Valve and allow it to lock in place.



Detach Valve Balloon from Filling Chamber

Do not leave the Filling Chamber on the hot air outlet of the VOLCANO MEDIC 2 when the heater is switched on – except for separating the alcohol or filling the Valve Balloon.

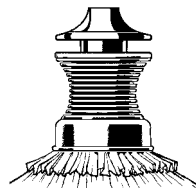


Attach the Mouthpiece onto the Valve Balloon

6. THE USE OF DRONABINOL



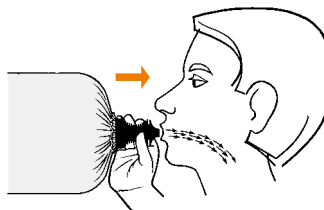
As the content of the Valve Balloon deflates, it may be completely emptied by stretching the Valve Balloon taut and subsequently inhaling the content.



Correct position of the Mouthpiece on the Valve

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

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



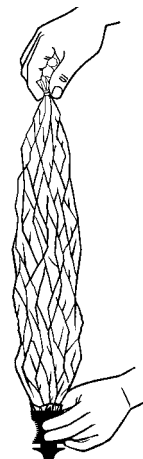
Press Mouthpiece against lips to inhale



To avoid residual moisture deposition in the Valve Balloon, and to minimize the risk of possible contamination, do not blow into the Valve Balloon.



Stretch Valve Balloon tight



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.

6. THE USE OF DRONABINOL

6.3. Application Part: Tube Kit

6.3.1. Efficiency of vaporized Dronabinol (THC)

By following the procedure listed in the Instructions for Use the systemic bio-availability of vaporized dronabinol is approximately 33%.

For comparison: The systemic bio-availability 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 Valve Balloon after vaporization with 210°C (410°F)	Cannabinoid content in blood stream (systemic bioavailability) after inhalation
Dronabinol/THC (10 mg)	THC: 10 mg	approx. 5 mg	approx. 3,3 mg

If dosage is too low increase the amount of dronabinol.

If dosage is too high reduce the amount of dronabinol.

6.3.2. Application



Before using the Tube, switch off the pump by pressing the touch button pump (AIR). When the actual temperature has reached 210°C (410°F), position the Filling Chamber with Cap and then the Tube Kit, and rotate clockwise as far as possible. Put the Tube Kit on the Filling Chamber and allow it to lock in place.

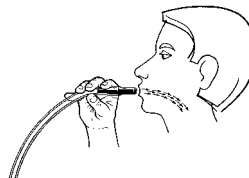
6.3.3. Inhalation



Tube with attached Mouthpiece

6. THE USE OF DRONABINOL

Slowly inhale the vapor from the Tube with the Mouthpiece attached for a few seconds.



Inhale slowly for a few seconds from the Tube with the Mouthpiece attached



Caution! Hot surface!



To avoid residual moisture deposition in the Tube, and to minimize the risk of possible contamination, do not blow into the Tube.



Caution! Hot surface!



Do not touch any components of the Filling Chamber (except at the textured grip) until they have cooled down.

Do not leave the Filling Chamber on the Hot Air Outlet of the VOLCANO MEDIC 2 when the Heater is switched on – except for separating the alcohol or inhaling from the Tube Kit.

6.4. 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.

6.5. End of Inhalation

Disconnect the power plug from the socket after inhalation.

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)

If these Instructions for Use are followed, the systemic bioavailability of vaporized cannabinoids from hemp blossoms is approx. 50% in the Valve Balloon and approx. 43% in the Tube.

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

The following factors determine the cannabinoid content in the Valve Balloon or Tube:

- Temperature - Higher vaporization temperatures cause a higher cannabinoid concentration in the Valve Balloon, lower vaporization

temperatures cause a lower cannabinoid concentration.

- Quantity - Higher quantities in the Filling Chamber cause a higher cannabinoid concentration, lower quantities in the Filling Chamber cause a lower cannabinoid concentration.
- Quality - Higher cannabinoid concentrations in the plant material cause a higher cannabinoid concentration, lower cannabinoid concentrations in the plant material cause a lower cannabinoid concentration.

In order to obtain a reproducible dose with good efficiency, it is recommended to vaporize small filling quantities (100 mg) once in the Filling Chamber at a maximum temperature of 210°C (410°F).

7. THE USE OF HEMP FLOWERS

7.2. Preparation

Turn the Filling Chamber Cap counterclockwise 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.



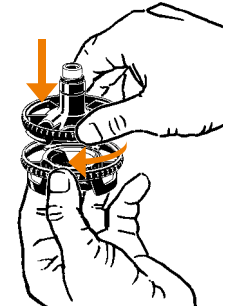
For consistent and reproducible dosage with e. g. 100 mg, use each Filling Chamber portion only once to fill a Valve Balloon.

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.



Fill Filling Chamber

Next screw on the Filling Chamber Cap again.



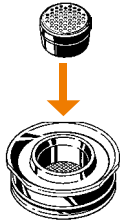
Screw on Filling Chamber Cap

7. THE USE OF HEMP FLOWERS

i 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.

i Suitable for vaporizing small amounts of hemp flowers, is the Dosing Capsule Adapter, which is available as an accessory, along with the Dosing Capsules.

The Dosing Capsule Adapter is inserted instead of the Filling Chamber Cylinder (see Chapter 9.4. "Disassembly and Assembly of the Filling Chamber", page 53). Then the Dosing Capsule filled with ground hemp flowers is inserted into the Dosing Capsule Adapter.



Fill the Dosing Capsule Adapter with a filled Dosing Capsule

7. THE USE OF HEMP FLOWERS

7.3. MEDIC VALVE Balloon

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
drug A (100 mg)	THC: approx. 19 mg	approx. 15 mg	approx. 10 mg
drug B (100 mg)	THC: approx. 6 mg	approx. 5 mg	approx. 3 mg
	CBD: approx. 7,5mg	approx. 6 mg	approx. 4 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 put 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.

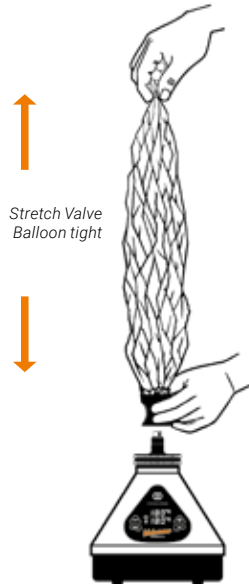
With this method no reproducible doses are achieved; for this reason, it is only appropriate for experienced users.

7. THE USE OF HEMP FLOWERS

7.3.1. Application

Press the touch button labeled 'HEAT' to switch on the heater. 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. When the actual temperature is equal to the set temperature put the Filling Chamber and rotate clockwise as far as possible. Put the Valve Balloon on the Filling Chamber and allow it to lock in place. This will open the Valve.

Press the touch button labeled 'AIR'. The Valve Balloon will now fill with the cannabis aerosol.



When the Valve Balloon is filled, switch off the pump by tapping the touch button labeled 'AIR' again - and remove the Balloon together with the Filling Chamber.

To do this, grasp the Filling Chamber Cap by the rotating knobs and unscrew counterclockwise.

7. THE USE OF HEMP FLOWERS



Remove Valve Balloon with Filling Chamber

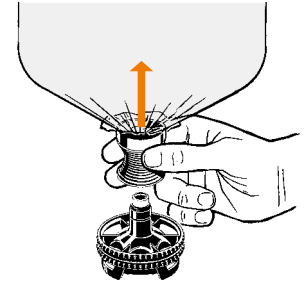


Caution! Hot surface!



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.



Separate Valve Balloon from Filling Chamber

Do not leave the Filling Chamber on the hot air outlet of the VOLCANO MEDIC 2 when the heat is switched on - except for filling the Valve Balloon.

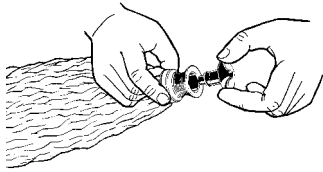


Caution! Hot surface!

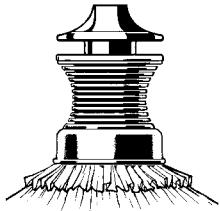
7. THE USE OF HEMP FLOWERS

7.3.2. Inhalation

Attach the Mouthpiece to the Valve and allow it to lock in place.



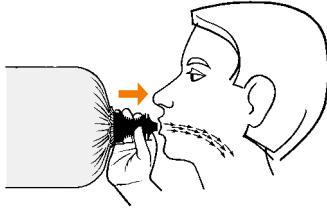
Attach the Mouthpiece to the Valve Balloon



Correct position of the Mouthpiece on the Valve

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

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



Press Mouthpiece against lips to inhale

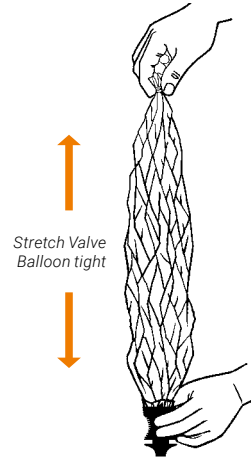


To avoid residual moisture deposition in the Valve Balloon, and to minimize the risk of possible contamination, do not blow into the Valve Balloon.

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.



Stretch Valve Balloon 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.

7. THE USE OF HEMP FLOWERS

7.4. Application Part: Tube Kit

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
drug A (100 mg)	THC: approx. 19 mg	approx. 12 mg	approx. 8,25 mg
drug B (100 mg)	THC: approx. 6 mg	approx. 4 mg	approx. 2,75 mg
	CBD: approx. 7,5mg	approx. 5 mg	approx. 3,4 mg

In order to reach these values, inhalation must be continued until there is no aerosol (vapor) recognizable when exhaling. The Filling Chamber's content is then depleted.

7.4.1. Application



Before using the Tube, switch off the pump by pressing the touch button labeled ‚AIR‘. Press the touch button labeled ‚HEAT‘ to switch on the heater. When the actual temperature is equal to the set temperature put the Filling Chamber with Cap on the Hot Air Generator and rotate clockwise as far as possible. Put the Tube Kit on the Filling Chamber and allow it to lock in place.

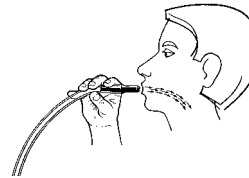
7.4.2. Inhalation



Tube with attached Mouthpiece

7. THE USE OF HEMP FLOWERS

Slowly inhale the vapor from the Tube with the Mouthpiece for a few seconds.



Inhale slowly for a few seconds from the Tube with the Mouthpiece attached



Caution! Hot surface!

7.5. 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 you inhalation. The cannabinoid aerosol is absorbed by the alveoli and into the bloodstream. The onset of the effect takes approx. 1-2 min.

7.6. 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.



To avoid residual moisture deposition in the Tube, and to minimize the risk of possible contamination, do not blow into the Tube.



Caution! Hot surface!

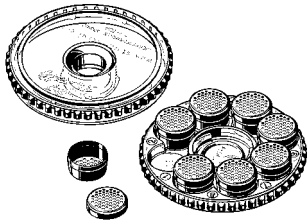


Do not touch any components of the Filling Chamber (except at the textured grip) until they have cooled down.

Do not leave the Filling Chamber on the hot air outlet of the VOLCANO MEDIC 2 when the heat is switched on – except for inhalation from the Tube Unit.

8. DOSING CAPSULES

8.1. Dosing Capsules (for single use) and Magazin



Dosing Capsules with Magazine

With the Dosing Capsules, which are available as accessories, you can fill ground hemp flowers or dronabinol using the Drip Pads into the Dosing Capsules in advance and store them in the Magazine.

This makes usage easy. This way, patients with fine motor dysfunction for example, can have their daily dose pre-filled in Dosing Capsules by the nursing staff.

i The Dosing Capsules are medical disposables, which must be thrown away with your regular household waste after use.

8.1.1. 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 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.

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

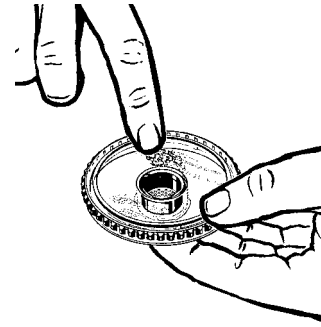
The Dosing Capsules can be filled with e.g. 50, 100 or up to 150 mg ground hemp flowers per capsule and be stored in the Magazine as a reserve.



Dosing Capsule with removed cap

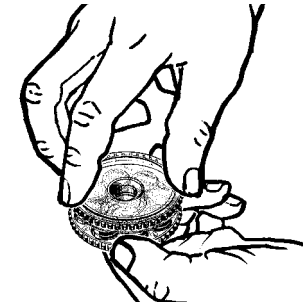
If necessary, grind the hemp flowers. Weight out the amount, which is recommended by the doctor, and fill the Dosing Capsule by using the Magazine Cap (funnel).

8. DOSING CAPSULES



Dosing Capsule while being filled with Magazin Cap (funnel)

Attach the cap onto the Dosing Capsule. Repeat the filling process until the desired amount of Dosing Capsules is filled and insert them into the Magazine. The Magazine can hold up to 8 Dosing Capsules.



Attaching the Magazine Cap

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

8.1.2. Filling the Dosing Capsules with Dronabinol

The Dosing Capsules with inserted Drip Pad can be filled with up to five drops of dronabinol and store them in the Magazine until use.

! Please make sure to not over-fill the Drip Pad.



Dosing Capsule with removed cap and inserted Drip Pad

8. DOSING CAPSULES

8.1.3. Inserting the Dosing Capsules

First, the Dosing Capsule Adapter, that is available as an accessory as well, is to be inserted instead of the Filling Chamber Cylinder (see Chapter 9.4. "Disassembly and Assembly of the Filling Chamber", page 53), afterwards, insert the Dosing Capsules with the cap facing upwards into the Dosing Capsule Adapter.



The Dosing Capsule inserted into the Dosing Capsule Adapter

Next screw on the Filling Chamber Cap again.

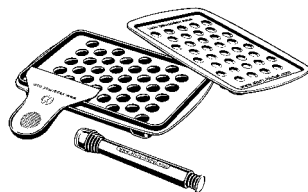


Screw on Filling Chamber Cap

! If the small Drip Pad is used, it can also be inserted directly into the Dosing Capsule Adapter, see Chapter 6.1. "Preparation", Page 27.

8.2. Filling Set for 40 Dosing Capsules

The Filling Set for 40 Dosing Capsules is designed for the simultaneous filling of a larger amount of Dosing Capsules with ground hemp flowers.



Filling Set for 40 Dosing Capsules

9. HYGIENE

9.1. General

If the VOLCANO MEDIC 2 Vaporization System is to be used by other people (patients), the Filling Chamber must be cleaned and a new Valve Balloon with Mouthpiece or a new Tube Kit with Mouthpiece must be used. Further information on the Filling Chamber, Valve Balloon and Tube can be found in Chapter 9.3. "Filling Chamber as well as Tube Flexer and Mouthpiece of the Tube Kit" are described from page 50 onwards.

The Filling Chamber, Valve Balloon with Mouthpiece and Tube Kit with Mouthpiece may only be used by one person.



Caution!

To avoid a health risk, e.g. an infection from a contaminated Filling Chamber, Valve Balloon or Tube Kit, the following hygiene instructions must be followed.

The VOLCANO MEDIC 2 Vaporization System is intended for multiple use.

a) Filling Chamber

➤ The Filling Chamber must be cleaned when a new patient uses it, if there is visible residue or when a new Valve Balloon is used.

b) Valve Balloon / Tube Kit

➤ The Valve Balloon or Tube Kit may only be used by one person.

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 of the VOLCANO MEDIC 2 Vaporization System", on this page.

Inspect the component parts of the Filling Chamber regularly and replace defective (broken, misshapen, discolored) parts. Replace the Valve Balloon or Tube Kit after no more than 70 applications or at least 14 days after the first use.



9.2. Material Resistance of the VOLCANO MEDIC 2 Vaporization System

Please make sure that the Filling Chamber, Mouthpiece, Tube Flexer of the Tube Kit and the Hot Air Generator do not come into contact with the following chemicals:

- organic, mineral and oxidating 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 2 Vaporization System only with soft brushes, never with metal brushes or steel wool.

9.3. Filling Chamber as well as Tube Flexer and Mouthpiece of the Tube Kit

9.3.1. Preparation and Cleaning in medical Practices and Clinics

- The Mouthpieces should be hygienically prepared before the first application and cleaned at least every 12 hours, and/or once a day straight after the last application, in accordance with the generally accepted procedures of hospital hygiene for non-critical or semi-critical A – Products.
- The Filling Chamber and Tube Flexer must be cleaned if deposits of active agents (condensate) on the internal parts are visible, according to the generally recognized procedures of hospital hygiene for non-critical or semi-critical A - Products.

9.3.2. Cleaning at Home

- Mouthpieces must be cleaned before the first application and at least every 12 hours, and/or once a

day straight after the last application.

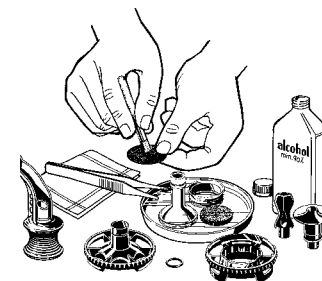
- The Filling Chamber and the Tube Flexer should be cleaned if active substance deposits (condensate) are visible on the inner parts.
- Clean your hands first, and if necessary, cleanse your sink and the surrounding area.
- Disassemble the Filling Chamber (see Chapter 9.4. "Disassembly and Assembly of the Filling Chamber", page 53)
- Disassemble the Tube Kit (see Chapter 9.5. "Disassembly and Assembly of the Tube Kit", page 56).
- Remove stubborn deposits inside the Filling Chamber and Cap Cylinder, as well as inside the Tube Flexer and Mouthpiece.
- Then place all individual parts of the Filling Chamber and Tube Flexer in hot soapy water (40-50°C (104-122°F)) for at least 5 minutes (standard washing-up liquid with as few moisturising additives as possible, dosage in accordance with the manufacturer's instructions, avoid excessive foaming) and make sure that all parts are completely covered and filled (contain no more air bubbles).
- Clean the Mouthpiece separately from all accessories in the same way.

- 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. If necessary, repeat this procedure several times until no remaining residue is visible on the parts.
- Remove the parts from the soapy water and rinse them for at least 1 min. under running water.
- The Filling Chamber parts, Tube Flexer and Mouthpiece can also be cleaned in the dishwasher using a household dishwasher detergent. Place the individual parts in a suitable place in the dishwasher. Small parts (e.g. Filling Chamber Rings or Mouthpieces) can get lost, or could damage the dishwasher, if the parts are not appropriately placed in the dishwasher. Surface changes can occur in the Filling Chamber Cylinder and Dosing Capsule Adapter in a dishwasher.

- After cleaning, allow the liquid inside to run out completely and shake any remaining water out of the parts. Avoid any contact with unclean surfaces.

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

Possible alternative: alternatively, all the Filling Chamber parts, as well as the Tube Flexer, and Mouthpiece, can be cleaned in isopropyl alcohol.



Manual cleaning with isopropyl alcohol (70 %) or detergent



Warning!
Isopropyl alcohol is flammable and may easily ignite.



The safety instructions furnished by the manufacturer of the isopropyl alcohol must be observed!



Do not immerse any plastic parts in isopropyl alcohol for more than half an hour. Prolonged contact with isopropyl alcohol can lead to color changes or embrittlement of the plastic parts. The Herb Mill and Magazin must not be placed in isopropyl alcohol.

9.3.3. Inspecting/Maintenance

After the cleaning, check all individual parts for surface damage, cracks, softening or hardening, soiling, discolouration, excessive limescale and discard any damaged Filling Chamber, Tube Flexer or Mouthpiece.

Then reassemble the Filling Chamber and Tube Kit (see Chapter 9.4. "Disassembly and Assembly of the Filling Chamber", page 53 and Chapter 9.5. "Disassembly and Assembly of the Tube Kit", page 56).

9.3.4. Drying, Packaging and Storage

After the parts are cleaned and completely dry, they must be stored dry and dust-free in a fresh and clean plastic bag (e.g. larger freezer bag). It is not permitted to place individual parts that are still damp into plastic bags; in this case, leave the parts to dry between two fresh and clean cloths.

9.3.5. Reusability of the Filling Chamber

The Filling Chamber (including sieves and Drip Pads) must be filled in accordance with Chapter 9.3.1. "Preparation and Cleaning in medical Practices and Clinics", or 9.3.2. "Cleaning at home", page 50 intended for multiple use.

9.3.6. Reusability of the Valve Balloon and/or Tube

Valve Balloons or Tubes and their Mouthpieces are intended for multiple use without special cleaning. They may only be used by one person and up to a maximum of 70 applications and up to a maximum of 14 days from the first use. Then a new Valve Balloon with Mouthpiece or a new Tube with Mouthpiece must be used. In case of heavy soiling, the Valve Balloon and/or Tube must be replaced earlier.



To avoid confusion, put the patient's name and the date of first use on the Valve Balloon or the Tube Kit. Use a (permanent) marker pen to write on the Valve Balloon or the Tube Kit itself.

Before each vaporization, check from the outside whether there is any moisture (condensation) inside the Valve Balloon or the Tube. If there is any moisture in the Valve Balloon resp. the Tube or if the Valve is damaged, they may no longer be used and must be disposed of with household waste.

9.3.7. Storage

Store Filling Chamber, Valve Balloon with Mouthpiece and Tube Kit with Mouthpiece in a dry, dust-free place away from contamination.

9.4. Disassembly and Assembly of the Filling Chamber**9.4.1. Filling Chamber and Filling Chamber Cap**

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

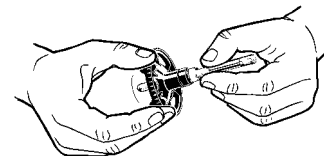
All parts of the Filling Chamber must be cleaned at the intervals prescribed in Chapter 9.3. "Filling Chamber as well as Tube Flexer and Mouthpiece of the Tube Kit", page 50. Disassemble the Filling Chamber Cap counterclockwise in order to remove it from the Filling Chamber.



Remove Filling Chamber Cap

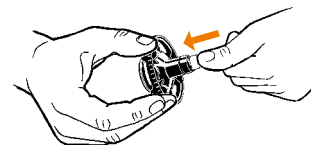
9.4.2. Disassembly of the Filling Chamber Cap

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 out the upper Screen with the help of the Cleaning Brush

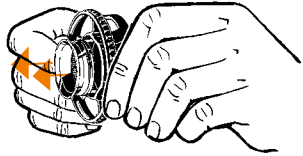
Push the cap cylinder downwards out of the cap housing. At the same time the cap ring will be stripped off.



Push the cap cylinder out of the cap housing

9.4.3. Disassembly of the Filling Chamber

Use Screen, or Drip Pad where applicable, to push the Filling Chamber Cylinder upwards out of the Filling Chamber Housing.

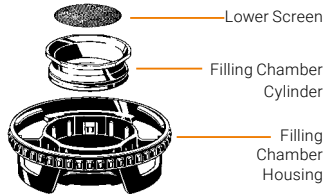


Push the Filling Chamber Cylinder out of the Filling Chamber Housing

Push the lower Screen upwards out of the Filling Chamber Housing.



Push the lower Screen out



9.4.4. 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).

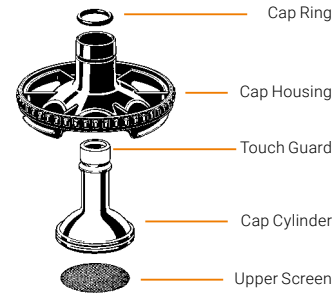
9.4.5. Assembly of the Filling Chamber Cap

Assemble the components in the reverse order:

Slide the cap cylinder into the cap housing until it clicks, then pull the cap ring 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 Drip Pad is inserted instead of the lower Screen.



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.

9.4.6. Assembly of the Filling Chamber

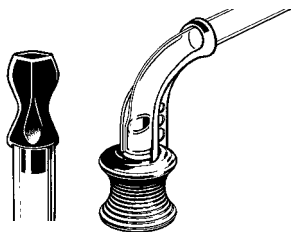
Push the Filling Chamber Cylinder from above into the Filling Chamber Housing and allow it to lock in place. Insert the Screen or the Drip Pad into the Filling Chamber from above. Screw the Filling Chamber Cap onto the Filling Chamber in a clockwise direction.

9.5. Disassembly and Assembly of the Tube Kit

9.5.1. Disassembly

Allow the Tube Kit to cool down before disassembling it.

The Tube Flexer and Mouthpiece must be cleaned at the intervals prescribed in Chapter 9.3. "Filling Chamber as well as Tube Flexer and Mouthpiece of the Tube Kit", page 50. Disconnect the Tube Flexer and Mouthpiece from the Tube. .



Disconnecting the Tube Flexer and Mouthpiece from the Tube

9.5.2. Drying

The Tube Flexer and Mouthpiece must be thoroughly dry before assembling them.

Place these two parts on a dry, clean 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).

9.5.3. Assembly

First, insert the Tube into the Tube Flexer and then insert the Mouthpiece into the Tube.

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.

Alternatively, in domestic applications, the Housing of the Hot Air Generator can be cleaned and disinfected with a surface disinfectant (details are given in the following cleaning and disinfection instructions for use in doctor's surgeries and hospitals).

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 49).

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 "neoform MED Spray" from Dr. Weigert.



If a cleaning spray is being used, it should be applied onto a cloth with which the device is then wiped. Do not spray cleanser directly onto the device.

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

Prior to undertaking any maintenance work, the device must be switched off and disconnected from the power supply.

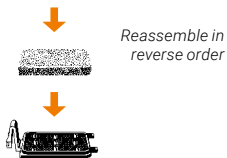
At the bottom of the Hot Air Generator is an Air Filter.

The Air Filter must be inspected for contamination every four weeks, and changed as necessary. To do this, open the rectangular flap on the bottom of the Hot Air Generator and exchange the Air Filter.



Please pay attention to the correct positioning of the Air Filter: it has three large and one small rounded corner.

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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 from the mains supply.

If there are any faults in the electronics of the VOLCANO MEDIC 2 Hot Air Generator, you can perform a reset by pulling out the power plug and plugging it again after waiting for minimum three seconds, or by keeping the touch button labeled "HEAT" pressed for 10 seconds.

The Hot Air Generator has one internal fuse (F1). As this fuse is used only in case of a defect in the Hot Air Generator, it 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.

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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
The VOLCANO MEDIC 2 does not show mains operation on the display; the heater and pump cannot be activated.	Please make sure that the mains supply 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 fuse may have been triggered. In this case, send the VOLCANO MEDIC 2 Hot Air Generator to our Service Center.
Message on the display: Line 1: "ERR" Line 2: number, followed by the letter "r" or "n"	Device faulty. Perform a factory reset if number + "r" is displayed. Display of number + "n" is an irreversible error; the VOLCANO MEDIC 2 Hot Air Generator must be sent to our Service Center.
Possible fault messages:: 01r	Internal communication fault. Restart recommended.
02r	The device is either outside its specified temperature, or internal overheating has occurred. Switch the device off, pull the power plug out of the socket, and leave the device for min. 30 mins at room temperature without operating it. If the fault continues after 30 mins., contact our Service Center.
03r	The device is being operated at the incorrect voltage. Please check which version (115V/230V) of the device you have, and ensure that you are using it at the the correct voltage.
04n	Device is faulty, please send it to our Service Center.

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Problem	Possible cause/remedy
No aerosol is formed	<p>Check whether the set and actual temperatures are the same (at least 180°C (356°F)).</p> <p>Check whether the Filling Chamber and/or Valve Balloon or Tube are correctly attached.</p> <p>Check whether dronabinol has dropped onto the Drip Pad or whether there is fresh, unused cannabis floss in the Filling Chamber.</p>
The Valve Balloon does not fill up.	<p>Check whether the pump is turned on.</p> <p>Check whether the Filling Chamber and/or Valve Balloon are correctly attached.</p>
The device switches off (automatic switch-off).	<p>The automatic switch off has intervened. Switch the heater or pump on again.</p>
Plant particles in the Valve Balloon or Tube (when using cannabis flos).	<p>Check whether the Screen in the Filling Chamber Cap is clogged or is not inserted into the notch properly.</p> <p>Check whether the Filling Chamber was cleaned according to the Instructions for Use.</p>

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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. Technical Specifications VOLCANO MEDIC 2 Vaporization System

Voltage:
220-240 V / 50-60 Hz (alternatively available with 110-120 V / 50-60 Hz)

The voltage specification is located on the bottom side of the VOLCANO MEDIC 2 Hot Air Generator.

Power consumption: 270 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

Automatic switch off after 30 minutes
Please unplug to disconnect from the mains current.

Internal fuse F1: F-T 4 A (applies to 110-120 V and 220-240 V devices)

This fuse 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 Grubenäcker 5-9,
78532 Tuttlingen, Germany

10. HOT AIR GENERATOR

10.8. Information on Electromagnetic Compatibility

10.8.1. Essential Performance

There are no essential performance characteristics according to the risk assessment.

10.8.2. Electromagnetic Environment

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such environment.

Emission test		
Emissions test	Compliance	Electromagnetic environment - Guidance
RF emissions CISPR 11	Group 1	The VOLCANO MEDIC 2 Vaporization System uses RF energy only for its internal function. Therefore, its RF-emission is very low and are not likely to cause any interference in nearby electronic equipment.
	Class B	The VOLCANO MEDIC 2 Vaporization System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Passed	

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Immunity Test			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	Contact ± 8 kV Air ± 15 kV	Contact ± 8 kV Air ± 15 kV	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	5/50 ns, 100 kHz, ± 2 kV	5/50 ns, 100 kHz, ± 2 kV	Mains power quality should be similar to that of a typical residential, commercial or hospital environment. If the user requires continuous function, it is recommended that the VOLCANO MEDIC 2 Vaporization System is operated from an uninterruptible power supply or battery.

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Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – Guidance
Surge IEC 61000-4-5	LtL: ± 1 kV LtG: ± 2 kV	LtL: ± 1 kV LtG: ± 2 kV	Mains power quality should be similar to that of a typical residential, commercial or hospital environment. If the user requires continuous function, it is recommended that the VOLCANO MEDIC 2 Vaporization System is operated from an uninterruptible power supply or battery.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U _T for 0.5 cycles (1 phase) at 0, 45, 90, 135, 180, 225, 270 and 315 angle degrees 0 % U _T for 1 cycle and 70 % U _T for 25/30 cycles (50/60 Hz) single-phase at 0 angle degrees 0 % U _T for 250/300 cycles (50/60 Hz)	0 % U _T for 0.5 cycles (1 phase) at 0, 45, 90, 135, 180, 225, 270 and 315 angle degrees 0 % U _T for 1 cycle and 70 % U _T for 25/30 cycles (50/60 Hz) single-phase at 0 angle degrees 0 % U _T for 250/300 cycles (50/60 Hz)	Mains power quality should be similar to that of a typical residential, commercial or hospital environment. If the user requires continuous function, it is recommended that the VOLCANO MEDIC 2 Vaporization System is operated from an uninterruptible power supply or battery.

10. HOT AIR GENERATOR

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – Guidance
Conducted RF IEC 61000-4-6 Amplitude modulated	3 V at 150 kHz-80 MHz 6 V in ISM and amateur radio bands 80 % AM at 1 kHz	3 V at 150 kHz-80 MHz 6 V in ISM and amateur radio bands 80 % AM at 1 kHz	WARNING: Portable and mobile RF communications devices (including their accessories such as external antennas and antenna cables) should be used no closer than 30 cm (12 inches) to any part of the VOLCANO MEDIC 2 Vaporization System, including cables, specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
Radio-frequency electromagnetic field Amplitude modulated IEC 6100-4-3	10 V/m at 80 MHz - 2.7 GHz - Home Healthcare - Prof. Healthcare - 80 % AM at 1 kHz	10 V/m at 80 MHz - 2.7 GHz - Home Healthcare - Prof. Healthcare - 80 % AM at 1 kHz	WARNING: Portable and mobile RF communications devices (including their accessories, such as external antennas and antenna cables) should be used no closer than 30 cm (12 inches) to any part of the VOLCANO MEDIC 2 Vaporization System, including cables, specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – Guidance
Proximity fields from RF wireless communications equipment IEC 6100-4-3	380 - 390 MHz 27 V/m; PM 50 %; 18 Hz	380 - 390 MHz 27 V/m; PM 50 %; 18 Hz	WARNING: Portable and mobile RF communications devices (including their accessories, such as external antennas and antenna cables) should be used no closer than 30 cm (12 inches) to any part of the VOLCANO MEDIC 2 Vaporization System, including cables, specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
	430 - 470 MHz 28 V/m; (FM ±5 kHz, 1 kHz sine) PM; 18 Hz	430 - 470 MHz 28 V/m; (FM ±5 kHz, 1 kHz sine) PM; 18 Hz	
	704 - 787 MHz 9 V/m; PM 50 %; 217 Hz	704 - 787 MHz 9 V/m; PM 50 %; 217 Hz	
	800 - 960 MHz 28 V/m; PM 50 %; 18 Hz	800 - 960 MHz 28 V/m; PM 50 %; 18 Hz	
	1700 - 1990 MHz 28 V/m; PM 50 %; 217 Hz	1700 - 1990 MHz 28 V/m; PM 50 %; 217 Hz	
	2400 - 2570 MHz 28 V/m; PM 50 %; 217 Hz	2400 - 2570 MHz 28 V/m; PM 50 %; 217 Hz	
5100 - 5800 MHz 9 V/m; PM 50 %; 217 Hz	5100 - 5800 MHz 9 V/m; PM 50 %; 217 Hz		

11. SPARE PARTS / ACCESSORIES

REF 01 01 M	VOLCANO MEDIC 2 (1 pc. VOLCANO MEDIC 2 Hot Air Generator, 1 pc. Power Cord, 4 pcs. MEDIC VALVE Balloon with Mouthpiece, 1 pc. Tube System, 1 pc. Filling Chamber (including: 1 pc. Cap Ring, 1 pc. Normal Screen Set (approx. Ø 30 mm), 1 pc. Drip Pad (approx. Ø 28 x 4 mm), 1 pc. Cleaning Brush), 1 pc. Dosing Capsule Adapter (approx. Ø 15 mm), 2 pcs. Normal Screen, small with regular mesh width (approx. Ø 15 mm), 1 pc. Dosing Capsule, 1 pc. Air Filter Set, 1 pc. Herb Mill (ca. Ø 59 mm), 1 pc. Instructions for Use)
REF 11 38	Power Cord
REF 05 01 M	Replacement Set (6 pcs. Balloon with Mouthpiece)
REF 11 43	Tube Kit (1 m Tube, 1 pc. Tube Flexer, 1 pc. Mouthpiece)
REF 11 44	Tube Set (3 pcs. 1 m Tube, 3 pcs. Mouthpiece)
REF 11 41	Mouthpiece Set (4 pcs. Mouthpiece)
REF 11 31	Filling Chamber (1 pc. Filling Chamber, 1 pc. Cap Ring, 1 pc. Normal Screen Set (approx. Ø 30 mm), 1 pc. Drip Pad (approx. Ø 28 x 4 mm), 1 pc. Cleaning Brush)
REF 11 05	Normal Screen Set (6 pcs. Screen with regular mesh width (approx. Ø 30 mm))
REF 11 09	Fine Screen Set (6 pcs. Screen with fine mesh width (approx. Ø 30 mm))
REF 11 03	Normal Screen Set, small (6 pcs. Screen with regular mesh width (approx. Ø 15 mm))
REF 11 08	Drip Pad Set (2 pcs. Drip Pad (approx. Ø 28 x 4 mm))
REF11 34	Wear & Tear Set (4 pcs. Cap Ring, 1 pc. Normal Screen Set (approx. Ø 30 mm), 2 pcs. Drip Pad (approx. Ø 28 x 4 mm), 1 pc. Cleaning Brush)

11. SPARE PARTS / ACCESSORIES

REF 11 26	Filling Chamber Housing (1 pc. Filling Chamber Housing, 1 pc. Filling Chamber Cap Housing)
REF 11 32	Filling Chamber with Dosing Capsule Adapter (1 pc. Filling Chamber with Dosing Capsule Adapter, 1 pc. Cap Ring, 3 pcs. Normal Screen with regular mesh width (approx. Ø 30 mm), 3 pcs. Normal Screen, small with regular mesh width (approx. Ø 15 mm), 1 pc. Drip Pad, small (approx. Ø 15 x 5 mm), 1 pc. Dosing Capsule, 1 pc. Cleaning Brush)
REF 11 33	Dosing Capsule Adapter (1 pc. Dosing Capsule Adapter (approx. Ø 15 mm), 2 pcs. Normal Screen, small with regular mesh width (approx. Ø 15 mm), 1 pc. Dosing Capsule)
REF 09 32 M	Magazine with 8 Dosing Capsule (1 pc. Magazine, 8 pcs. Dosing Capsule)
REF 09 33 M	Dosing Capsule Set, 40 pcs.
REF 09 34 M	Dosing Capsule Set, 400 pcs.
REF 09 40	Capsule Caddy (1 pc. Capsule Caddy, 4 pcs. Dosing Capsule)
REF 09 36 M	Magazine with 8 Dosing Capsule for Liquids (1 pc. Magazine, 8 pcs. Dosing Capsule, 8 pcs. Liquid Pad for Dosing Capsules)
REF 09 38 M	Dosing Capsules for Liquids Set, 40 pcs. (40 pcs. Dosing Capsule, 40 pcs. Liquid Pad for Dosing Capsule)
REF 09 39 M	Dosing Capsules for Liquids Set, 400 pcs. (400 pcs. Dosing Capsule, 400 pcs. Liquid Pad for Dosing Capsule)
REF 11 22	Drip Pad Set for Dosing Capsules (4 pcs. Drip Pad (approx. Ø 13 x 6 mm))
REF 11 02	Drip Pad Set, small (4 pcs. Drip Pad (approx. Ø 15 x 5 mm))

11. SPARE PARTS / ACCESSORIES

REF 09 41	Drip Capsule Caddy (1 pc. Capsule Caddy, 4 pcs. Dosing Capsule, 4 pcs. Drip Pad for Dosing Capsules)
REF 09 45	Filling Set for 40 Dosing Capsules (1 pc. Filling Device, 1 pc. Spatula, 1 pc. Plunger, 1 pc. Herb Mill XL (approx. Ø 92 mm), 1 pc. Magazine with 8 Dosing Capsules, 40 pcs. Dosing Capsule, 1 pc. Scale)
REF 09 46	Plunger for Dosing Capsules
REF 09 47	Spatula for Filling Set
REF 09 30	Herb Mill (approx. Ø 59 mm)
REF 09 43	Herb Mill XL (approx. Ø 92 mm)
REF 11 20	Air Filter Set (2 pcs. Air Filter)
REF 11 21	Air Filter Cap
REF 11 24	Cleaning Brush Set (3 pcs. Cleaning Brush)

All spare parts and accessories) may be ordered from www.vapormed.com.

12. COMPLIANCE WITH LEGAL AND NORMATIVE REQUIREMENTS

- Council Directive 93/42/EEC concerning medical devices
- IEC 60601-1 - Medical electrical equipment
- Medical electrical equipment CAN/CSA-C22.2 No. 60601

Notified Body:

TÜV SÜD Product Service GmbH
Ridlerstrasse 65
80339 Munich, Germany



Manufacturer:

Storz & Bickel GmbH & Co. KG
In Grubenäcker 5-9,
78532 Tuttlingen, Germany

13. WARRANTY, LIABILITY, REPAIR SERVICE

13.1. 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. In addition, we guarantee that the VOLCANO MEDIC 2 will be free from defects for a period of three years. 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 this Instructions for Use and further information provided to users. Normal wear or tear to the products is not considered a defect under warranty law. If the customer has commissioned third parties with completing 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 & Co. KG, In Grubenäcker 5-9, 78532 Tuttlingen. 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.

13.2. 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. Under 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

13.3. 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.

13.4. Copyright

This document is copyright protected, and may not be used either in whole or in part pursuant to Sections 15 et seqq. UrhG (German Copyright Act) without prior written approval of Storz & Bickel.