



grenco
medical



GRENCO MEDICAL ELITE II

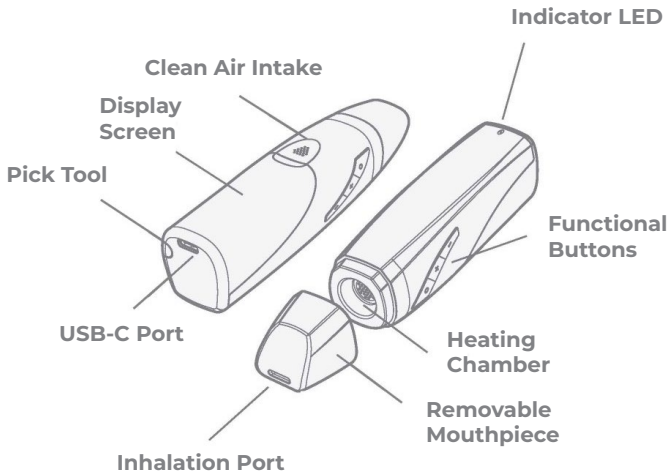
INSTRUCTIONS FOR USE

V2.3



GRENCO MEDICAL ELITE II

EXPLODED VIEW



Throughout the expected lifetime of the medical device, certain components may require replacement. Should any part of the medical device require replacement, please contact our customer support team.

For assistance, contact

North America: GS HOLISTIC, LLC
at support@grencomedical.com or call +1 833-691-3224.

Australia & New Zealand: MOOD STATE MEDICAL
at support@moodstatemedical.au or call 1300 069 385



EXPLANATION OF PACKAGING AND INSTRUCTION MANUAL SYMBOLS



Read instructions symbol. Please read and follow these instructions carefully.



Warning symbol. To prevent harm to individuals and protect medical device, compliance with instructions featuring this symbol is compulsory.



Safety symbol. To prevent medical device damage, it is essential to adhere to the instructions indicated by this symbol.



Manufacturer symbol. The manufacturer's name and address are located adjacent to this symbol.



Serial number symbol. Following this symbol is the serial number of the medical device.



Lot number symbol. Following this symbol is the lot number of the medical device production.



Manufacturing date symbol. Following this symbol is the date that the medical device was manufactured.



For more information, call Mood State Medical 1300 069 385. Device contains a lithium-ion battery contained per UN 3481.



Expiry date symbol. This symbol will be next to the date (year/ month) by which the medical device must be used by.



Do not use the medical device if the box is damaged.



Protect medical device from moisture and humidity.



Protect medical device from direct sunlight.



These are Applied Parts that make direct electrical contact with the patient.



The medical device should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling.



Device Name: Grenco Medical ELITE II



WARNINGS



- The medical device is solely intended for vaporizing the recommended cannabinoids found in dried flowers.
- The device is intended for use with prescribed dry cannabis flower only.
- Individuals requiring assistance must be under constant supervision during application as the medical device contains small components that could obstruct the airway and potentially cause choking. Therefore, always ensure that the medical device and its accessories are kept out of reach of infants and children.
- When charging the medical device battery, exclusively use the provided USB-C cable for the medical device and avoid unsupervised charging.
- The medical device offers a highly efficient and safe method for alveolar cannabinoid application.
- Before commencing treatment, patients must undergo a medical evaluation by a licensed physician.
- Usage is reserved for patients aged 18 or older, after thoroughly reviewing these instructions and following the physician's recommendations.
- Adults can operate the medical device by adhering to these Instructions for Use or as directed by their physician.
- Do not operate or charge the device in enclosed or poorly ventilated spaces, as this may restrict airflow and lead to overheating. Ensure adequate ventilation during use and charging.



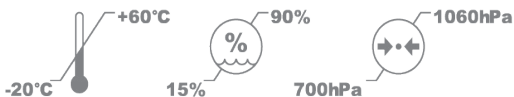
- Do not modify this equipment. Any modification may impair safety and performance.
- If you notice unusual smell, smoke, swelling, excessive heat, or unusual noises, stop using the device immediately. Place it on a non-flammable surface, unplug it from power, and contact customer support.
- Refrain from using the medical device if the patient has respiratory or lung conditions, as vapor exposure may lead to irritation and coughing.
- Only employ medicinal cannabis flowers in the medical device as per your physician's prescription.
- The device allows user selection within the operating temperature range 93-221°C. Scientific literature ^{1,2} suggests a recommended temperature range for cannabinoid extraction between 180°C and 210°C. However, the optimal temperature setting may vary depending on the prescribed cannabis flower, settings, inhalation technique, and individual factors. The device does not deliver a fixed dose per puff or session. Patients should follow prescriber instructions.
- Contains lithium-ion battery. Risk of fire, burn, or explosion if damaged or incorrectly disposed of. Dispose of according to local regulations using an approved recycling program.

¹ Gieringer, D. et al. (2004). Cannabis vaporizer combines efficient delivery of THC with effective suppression of pyrolytic compounds. *Journal of Cannabis Therapeutics*, 4(1), 7-27.

² Eyal AM, et al (2023). Vapor Pressure, Vaping, and Corrections to Misconceptions Related to Medical Cannabis' Active Pharmaceutical Ingredients' Physical Properties and Compositions. *Cannabis Cannabinoid Res.* 2023 Jun;8(3):414-425.



- Do not cover the device with blankets, clothing, or any material during use or charging, as this may block ventilation and cause overheating. Charging must be supervised at all times. Do not charge the device while sleeping.
- Do not block ventilation openings.
- Do not use or charge if damaged, abnormally hot, leaking, or malfunctioning.
- Do not charge while hot or during use.





SAFETY AND CAUTION



- Inspect the packaging and housing of the medical device. If you notice any damage to the medical device housing, refrain from using the medical device and promptly get in touch with customer support.
- When recharging the battery, make sure to exclusively utilize the provided USB-C cable that comes with the medical device.
- Clean the medical device solely with a dry cloth, or if necessary, a damp cloth.
- This device has an IP22 rating and is not protected against water immersion. Do not immerse in liquids or expose to excessive moisture. Exposure to water may result in device malfunction or permanent damage.
- Avoid exposing the medical device to direct sunlight, rain, or extreme temperatures. Drastic fluctuations in ambient temperature can lead to condensation and impair the medical device's functionality.
- Operate the medical device within an ambient temperature range of +5°C to +30°C, maintaining an ambient air relative humidity between 15% and 90%, and ensuring an atmospheric pressure between 700 hPa and 1050 hPa. If the mouthpiece temperature exceeds +43°C, the medical device will auto shut off for 20 minutes to allow mouthpiece to cool to safe operating temperature.
- Charge the device only on a hard, non-flammable surface. Avoid charging on soft or insulated surfaces, which may trap heat.



- The medical device contains no user-serviceable parts. Do not attempt to open, repair, or replace internal components, including the battery. Contact authorized service personnel for servicing.
- Use only the supplied USB-C cable and a certified 5-volt charging adapter. Do not use fast-charging adapters or chargers exceeding the device specifications.



INTENDED USE



THE GRENCO MEDICAL ELITE II VAPORIZER IS INTENDED FOR USE AT HOME, IN A HOSPITAL, OR DOCTOR'S OFFICE FOR VAPORIZING OF CANNABIS FLOWERS AND FOR INHALING CANNABINOIDS DERIVED THEREFROM.

ACTIVE INGREDIENTS IN THE INHALED CANNABINOIDS ARE DELIVERED INTO THE HUMAN BODY VIA THE ALVEOLI FOR THE APPROPRIATE MEDICAL INDICATION AS PRESCRIBED BY YOUR PHYSICIAN. USE IS INTENDED BY PATIENTS WHO ARE OLDER THAN 18 YEARS OF AGE.

CONTRADICTIONS

- The medical device does not have any device-specific contraindications.
- If the user has a pre-existing respiratory tract or lung condition, the medical device should only be employed following consultation with and approval from their attending physician. The vapors may induce irritation in the respiratory tract and lungs, potentially resulting in bouts of coughing, depending on vapor density.

UNPACKING AND COMMISSIONING OF THE MEDICAL DEVICE



- Remove the medical device from the box and all the accessories.
- Register serial number found at the bottom of medical device or packaging at grencomedical.com/register.
- Fully charge medical device using included USB-C Charging Cable.
- Grind medicinal cannabis flowers.
- Remove mouthpiece and load the ground medicinal cannabis flowers into the medical device heating chamber.
- Re-attach mouthpiece.
- Press and hold power button for three seconds to power on/off the medical device.
- Use + and - buttons to set desired temperature.
- Double-click power button to begin/cancel heat session.
- When indicator LED turns green, inhale from the mouthpiece.





DEVICE SETTINGS

- Press power button five times to access medical device Settings Menu.
- Press + and - buttons to navigate menu.
- Press power button to select screen brightness, toggling, haptic feedback, set displaying between °F/°C.
- Access pick tool at bottom of device for packing ground material into heating chamber, stirring of ground material, and removing of spent material from the heating chamber.
- The device utilises two heating methods:
 - Conduction heating: the transfer of heat from the ceramic heating chamber to the cannabis material through direct contact with the heated surface.
 - Convection heating: the transfer of heat through hot air drawn through the cannabis material, without direct contact with the heating surface.
- The device is configured by default to operate in Convection Boost mode, combining both heating methods. The device settings may be adjusted to disable Convection Boost mode in which case the device will operate using Conduction heating only. Device settings should only be adjusted under the direction of a prescribing physician.





RECOMMENDED TEMPERATURE SETTINGS

- The device allows user selection within the operating temperature range (93°C to 221°C). Effect may vary depending on prescribed cannabis flower, settings, inhalation technique, and individual factors. Patients should follow prescriber instructions.
- Heating dry cannabis flower may generate unwanted by-products in the vapor. Vapor composition may vary depending on the cannabis flower used, device settings, and manner of use. Inhaled vapor may cause cough, throat irritation, or respiratory discomfort.
- It is best to consult with your physician for specific guidance on the appropriate temperature range based on your prescription and medical needs.



CONTACT & SUPPORT



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MS

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MEDICAL**

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1300 069 385 | moodstatemedical.au



MANUFACTURED BY

DONGGUAN MEDICA TECHNOLOGY CO, LTD
ROOM 408, BUILDING NO.1
NO.136 GANG JIAN ROAD
CHANG PING TOWN, DONGGUAN
GUANGDONG 523581 CHINA

WARNINGS



Equipment type:

Internally powered medical electrical (ME) equipment.
Type BF Applied part (IEC 60601-1)
IP Rating IP22 medical electrical (ME) equipment.
Type BF Applied part (IEC 60601-1)
Continuous operation (IEC 60601-1)



Expected Service Life:

The expected service life is 2 years

Battery:

Lithium-ion 3.7V DC

Charging Cable:

USB-C

Supply Voltage:

100-240 V / 50-60 Hz Output voltage: 12 V DC

Vaporizer:

Size: 18 x 3 x 3 cm

Weight: approx. 118 g

Chamber size 1064 mm³

Power required by Vaporizer: 29 W

Vaporization Temperature:

Adjustable temperature range approx. 93°C - 221°C

Environmental Limits:

Operating temperature: 5°C - 30°C

Operating humidity: 15 - 90 % RH

Storage and transport temperature: -20°C - 60°C

Storage and transport humidity: 15 - 90 % RH



COMPLIANCE TO INTERNATIONAL STANDARDS:

The Grenco Medical Elite II complies with the following international standards:

IEC 60601-1:2006/AMD1:2013/AMD2:2021 Medical electrical equipment, Part 1: General requirements for basic safety and essential performance.

IEC 60601-1-2:2015/AMD1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electro-magnetic compatibility - Requirements and tests.

IEC 60601-1-11:2015/AMD1:2020 Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

IEC 60601-1-6:2010/AMD1:2013/AMD2:2020 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

IEC 62304:2006/Amd 1:2015 Medical device software - Software life cycle processes

IEC 62366-1:2015/Amd 1:2020 Medical devices – Part 1: Application of usability engineering to medical devices

ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.

ISO 10993-5:2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity.



ISO 10993-10:2021 Biological evaluation of medical devices
Part 10: Tests for skin sensitization.

ISO 10993-18:2020 Biological evaluation of medical devices
Part 18: Chemical characterization of medical device
materials within a risk management process

ISO 10993-23:2021 Biological evaluation of medical devices
Part 23: Tests for irritation.

ISO 18562-1:2024 Biocompatibility evaluation of breathing
gas pathways in healthcare applications Part 1: Evaluation
and testing within a risk management process.

ISO 18562-2:2024 Biocompatibility of breathing gas pathways
– Part 2 Tests for emissions of particulate matter.

ISO 18562-3:2024 Biocompatibility evaluation of breathing
gas pathways in healthcare applications Part 3: Tests for
emissions of volatile organic substances

ISO 18562-4:2024 Biocompatibility evaluation of breathing
gas pathways in healthcare applications Part 4: Tests for
leachables in condensate

UN 38.3 United Nations Manual of Tests and Criteria (Lithium
Battery Transportation Testing).



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