OPERATING INSTRUCTIONS

Venen Engel

VENEN ENGEL 4

ENGLISH

PRELIMINARY REMARK

Congratulations on the purchase of this device! You will enjoy your Venen Engel very much! If you are satisfied with your Venen Engel, we would be very pleased if you submitted a review.

This guide includes details that should be taken into account by the user, to avoid risks, and to enable the safe use of the device.

Should you have any questions about its application, its accessories, or if you have suggestions, please do not hesitate to contact us! We are also happy to help you with any complications that develop during or after using the product.

Telephone: +49 (0) 666 17 48 91 05

Whatsapp: +49 1573 5990084

Mail: service@venenengel.de

Web: www.venenengel.de

HelpDesk: help.venenengel.de

BEFORE YOU GET STARTED

- Please read the operating instructions carefully before using the device.
- Keep this user manual so you can consult it, if necessary.
- Venen Engel may not be used if you suffer from certain health conditions. Please read the list of contraindications carefully on last page.

PRODUCT DESCRIPTION

The air pressure massager consists of a device with a pump, cuffs, air pressure sensor, etc., which work together as one unit. The device is connected to the cuffs via a series of hoses. The compression massage is done by cyclically inflating and deflating the air chambers. The pressure in the cuff is controlled by a sensor and microprocessor.

In medical use, the air pressure massager produces sequential compression from distal to proximal, helping to improve the circulation of blood and lymph, prevent DVT and relieve lymphoedema.

In cosmetic use, the system provides drainage of loosened fat cells and debris through its massage from the feet towards the upper body.

INFORMATION

INTENDED USE

The product is indicated for use by medical professionals and patient at home, who are under medical supervision, reducing swelling and preventing thrombosis in the lower extremities or treatment of truncal or arm breast cancer-related lymphedema. such as: Primary lymphedema, edema following trauma and sport injuries, Postimmobilization edema, Venous insufficiencies, Lymphedema. The system can be used in the home or hospital, using the object (patient) must be over 18 years old of adults.

INDICATIONS

Prevention of:

- Deep vein thrombosis (DVT)
- Chronic venous insufficiency

Treatment of:

- Lymphedema
- Athletic regeneration
- Edema resulting from trauma and sports injuries

KONTRAINDICATIONS

Absolute Contraindications:

- Acute inflammatory skin diseases
- Arrhythmias Erysipelas
- Deep vein thrombophlebitis
- Pulmonary edema
- Acute venous thrombosis Unstable hypertension
- Use of a cardiac pacemaker
- arterial insufficiencies

SIDE EFFECTS

- Feel discomfort when the output pressure is too large
- Redness, itching or discomfort
- Discomfort and pain sensations during treatment with a pressure of 120 mmHg or greater

IMPORTANT SAFETY INSTRUCTIONS AND WARNINGS

It is important that you read all the warnings and precautions in this manual. They are for your safety, to prevent injury and to prevent damage to the unit.

- Do not use this device if you have a pacemaker, implanted defibrillator or other implanted metallic or electronic device. Such use may result in electric shock, bums, electrical malfunction or death.
- Please read the instructions carefully before using the product.
- Keep these instructions near the appliance so that you can read them during use.
- To avoid hazards, ensure safety or prevent non-standard operation, the following are some details that the user should be aware of when using the appliance.
- The unit is not suitable for use in the presence of a flammable anaesthetic mixture with air, with oxygen or nitrous oxide.
- The device is not intended for unsupervised use by patients who are incapable of consenting, mentally disturbed or suffering from dementia.
- Repairs, maintenance and replacement of components must not be carried out during use and only by specialists authorised by the manufacturer. In addition, there is a risk of loss of warranty.
- In case of general discomfort or pain during use, please discontinue use immediately.
- Do not allow water or other materials (e.g. nails, needles and other meta[objects) to get inside the unit.
- lf the unit does not operate correctly, do not open, disassemble or modify the unit in any way as this may result in fire, electric shock or other injury.
- When using for the first time, the application time should not exceed 5 minutes. For subsequent applications, the application duration should be gradually increased according to the user's physical condition. Prolonged applications could cause undesirable side effects.
- The product should not be used by infants or young children.
- Keep the device out of the reach of children.
- Make sure that the plug and your hand are dry when plugging in and unplugging the power plug.
- Use the appliance only with single-phase 220-230V power. After use, you should
- unplug the appliance from the mains socket. Make sure to position the appliance so that you can easily pull out the power plug at any time.
- Make sure that the power cable is not twisted or kinked and do not place heavy objects (e.g. table and chair legs) on it.

- Use the unit only for the specified purpose.
- Do not use the unit on multiple sockets. Do not plug the power plug of this appliance into a socket with other appliances.
- Avoid shaking or dropping the unit during use or transport. Protect the unit from falls and shocks.
- Keep the unit and cuffs away from heat sources (e.g. radiators, cigarettes or direct sunlight) and use only at the intended operating temperature. Use outside the intended operating temperature could cause damage, discolouration and deformation to the cuffs.
- Remain seated during use. With the cuffs on, keep your legs and arms still. Do not run with the cuffs on
- Do not use running water, oil, petrol, alcohol or other chemicals to clean the cuffs and the unit to avoid shortening the product life. Only use a damp cloth to clean the cuff and textile cleaner if it is very dirty. To clean the unit, please use a dry cloth.
- Do not use the device naked. Wear underwear or trousers during use.
- Do not open the cuffs during use to avoid damaging the cuffs.
- When disposing of the device, cuffs, remote control battery or packaging, please follow local disposal guidelines and avoid environmental pollution.
- lf the pressure sensor is damaged, loose or fails, the unit may malfunction. Please
- contact the manufacturer for inspection and maintenance.
- Keep the unit out of reach of pets.
- The unit should be placed so that the plug can be easily connected and disconnected from the power supply.
- Take care not to place heavy objects on cuffs, hoses and other accessories and not to twist or bend them, as this may cause damage to the pressure sensor.
- lf the unit is not used for a long time or is used at low temperatures, the unit may not be usable. Allow the unit to inflate any cuff 3 to 4 times to the highest pressure level before use

WORKING PRINCIPLE

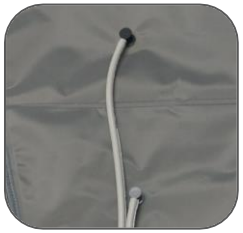
Compression therapy using compressed air is a therapeutic technique used in medical equipment that includes an air pump and inflatable cuffs (gloves, boots, jacket, sleeves). During application, an inflatable cuff envelops the limb to be treated. The cuff is connected to the pump via several pressure pipes. When the pump is activated, it fills the cuff's air chambers, in order to exert pressure on the tissues in the limb, thereby displacing liquids such as blood and lymph from the pressurized area. A short time later, the pressure is reduced, allowing increased blood flow back to the limb.

APPLICATION

STEP 1: BEFORE USE

CONNECT AIR HOSES

Connect the set of hoses to the cuffs, starting with the dark gray connector, and then plugging the other gray connectors onto the appropriate counterparts.



Note: We recommend that you do not detach the connectors afterward.

Note: For users of combination sets with leg cuffs and belly cuff; the two long ends of the tube set correspond to the legs and the short end to the belly.

Device Set-Up

Ensure that the device is securely placed. Also make sure that the device is free standing and not covered by a blanket, or similar. Do not use the device in damp rooms or those with high humidity, such as in saunas or bathrooms.

Tightening Leg cuffs

To prevent contamination, we recommend wearing leggings or sweatpants when using the device. Empty your pockets before application!

The zippers on the cuffs must be completely closed to avoid the cuffs from suddenly splitting open and causing possible damage.

After plugging it into the power plug, putting on the cuffs, and tightening the zipper, the Venen Engel application controls on the control unit can be adjusted.

Information: Always make sure that the hoses are not kinked, and that you are not sitting on the hoses.

Attaching the Multi-plug

Plug the multi-plug into the front of the device as far as it will go. Be sure to insert the multi-plug into the device the right way (the small nippte into the small hole).

Remote Control Batteries

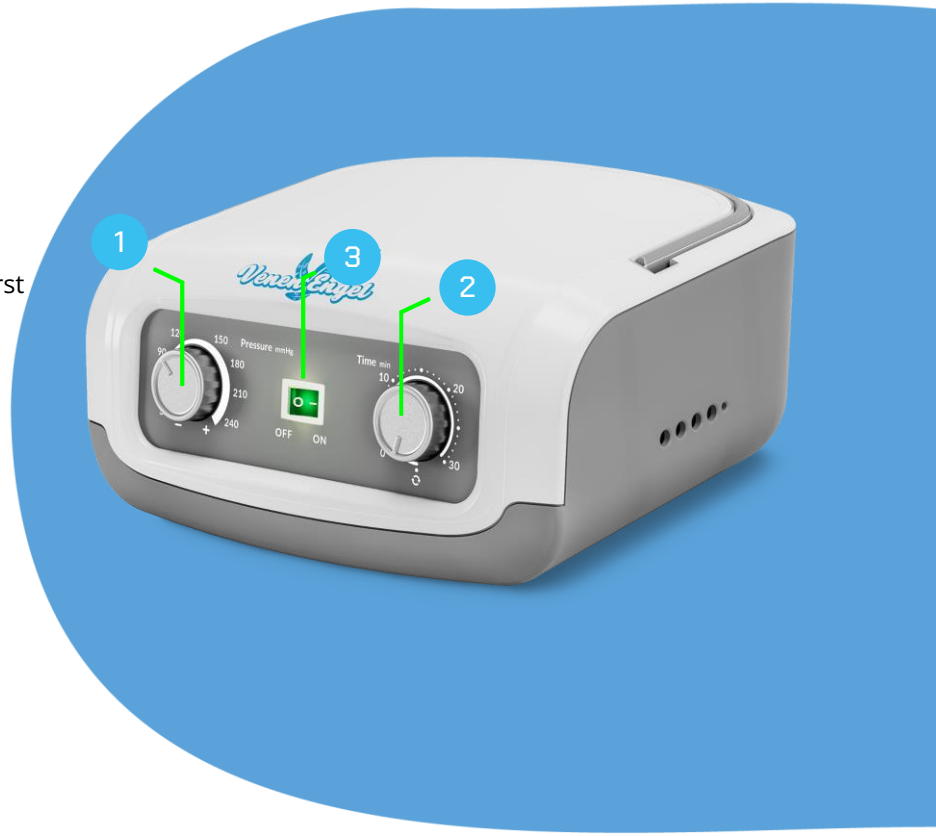
Before the initial use: Remove the battery protection and insert the battery (Type: CR2032; Diameter: 20mm, Height: 2.5mm, Voltage: 3V)!

Due to shipping policies, we are not allowed to provide a battery. We kindly ask for your understanding.
Warning: Keep the remote control and battery out of reach of children as there is a risk of suffocation.

STEP 2: CONTROL UNIT OPERATION

Follow the order as shown:

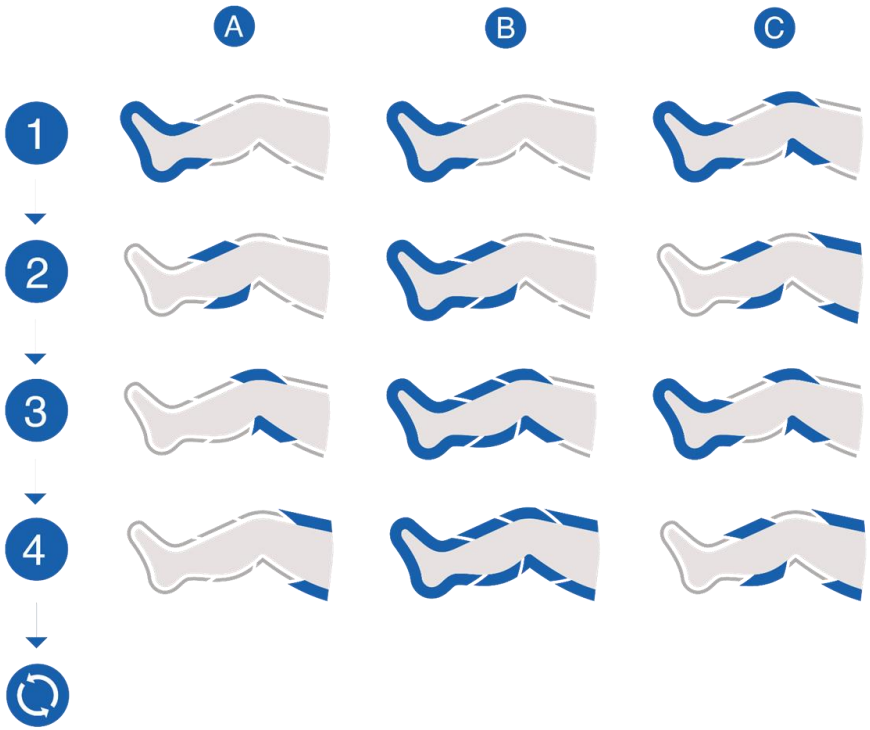
1. Select the pressure (30-240 mmHg). Start with a low setting. During the massage application, you may change the pressure.
2. Select duration of up to 30 minutes (a maximum of 5 minutes the first time, and then increase incrementally)
3. Turn the device on.



STEP 3: ENJOY THE MASSAGE

The leg cuff air chambers inflate one by one.This creates an optimal gliding pressure wave massage for a relaxed feeling in both legs. Duration and pressure can be adjusted, even during the massage.

Massage programs:



STEP 4: COMPLETION & DISMANTLING THE DEVICE

After the set time has elapsed, or after pressing the off switch, you can unplug the multi-plug from the device. If you are not comfortable during the massage, you can also end the massage at any time, as you wish. After that you may open the cuff. To vent the air from the air cushions faster, after application, we recommend pushing the remaining air out of the cuffs with both hands, ensuring that the multi-plug is removed.

After application, we recommend leaving the grey cufflink plugs attached to the cuff and simply removing the multi-plug from the device. For storage, place the cuffs on top of each other and loosely roll them together with the attached hose set.

SCHRITT 5: CLEANING AND STORAGE

Cleaning

To clean the cuffs and the rest of the accessories, we recommend using a damp cloth. In case of heavy soiling, you can also use a gentle textile cleaner. Before cleaning the cuffs, remove the hose plugs and always allow the cuffs to dry thoroughly. When used by different people, we recommend disinfection of the cuffs, using a textile disinfectant spray. Use detergents and disinfectants free of oil, benzene, alcohol, gasoline, and/or chemical agents. Do not wash the cuffs in a washing machine or under running water. Switch off the unit before cleaning. Disinfectants such as Descosept pur or comparable products with a similar composition are suitable for disinfecting the cuffs.

Storage

Store the product at room temperature (minimum 10°c, maximum 40°() and in well-ventilated, dry, and dust-free spaces (minimum 30%, maximum 85% relative humidity). Store the product in places free of frost, or it may damage the product.

Also be careful not to damage the cuffs during storage, especially if stored together with sharp objects such as scissors, or objects with sharp edges.

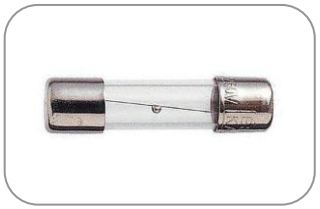
For long-term storage, we recommend that you store the product in the packaging you bought it in.

TROUBLESHOOTING

THE DEVICE DOES NOT TURN ON

If the device does not turn on, please check (A) whether the power plug has been correctly plugged into the socket and/or whether the device is turned on. If the unit is still not turning on, unplug the power plug (B) and unscrew the fuse holder with the inscription "FUSE" on the bottom of the unit (see picture on the left) completely (with a screwdriver or small coin) and check that the fuse inside is intact. (see picture on the right)..

The fuse is located on the bottom of the device



Intact fuse: the wire in the fuse is undamaged.

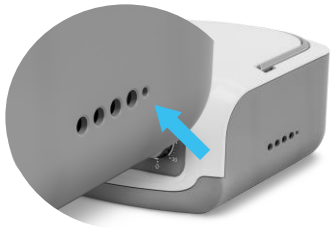
(C) If the fuse is intact, screw the fuse holder with the fuse back into the device completely. If the fuse is damaged, replace the fuse with a commercially-available fine fuse (TR); 3.15 A; 5 x 20 mm). You are also welcome to contact our customer service. (D) Note that the device may only be powered by 220V power.

THE DEVICE IS PUMPING, BUT IT ONLY BLOWS ONE OR NONE OF THE TWO CUFFS

If only one or neither of the two cuffs should inflate after starting the application, please check (A) whether the multi-plug is fully and correctly inserted into the device. Also, make sure (B) that the air hoses are not kinked, for example, because you are sitting on the hoses. Check (C) that the gray cuff plugs are all correctly attached to the cuff.

THE CUFFS ARE INFLATING IN THE WRONG ORDER

Make sure that the multi-plug is correctly inserted into the device. There is a small additional nipple, the multi-plug, which must be inserted into the hole provided for this purpose. If the multi-plug is inserted into the device the wrong way, the multi-plug will be placed crooked.



MY VENEN ENGEL IS VERY LOUD

One should be able to talk or relax and chat with another person, without any issues, during the application. If this is not the case, due to the Venen Engel being too noisy, it is an indication that the transport screw on the bottom of the device has not yet been removed. Open the cover on the bottom and remove the safety screw with the enclosed screwdriver. The screw is only used for securing the de vice during transport, and it can subsequently be disposed of.

YOU CAN HEAR AIR ESCAPING FROM THE DEVICE, HOSES ,OR CUFFS

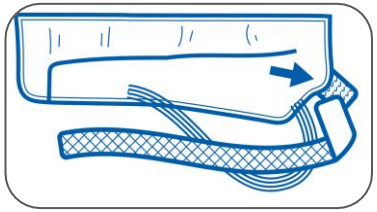
(A) Check the hoses and plugs for damage.
(B) Check that the multi-plug is correctly plugged into the unit.
(C) Check if the hose is bent or has been pulled off.

Instruction for Accessories

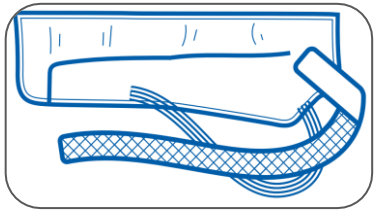
ATTACHING THE EXTENSION FLOP

PUTTING ON THE ARM CUFF

Step 1

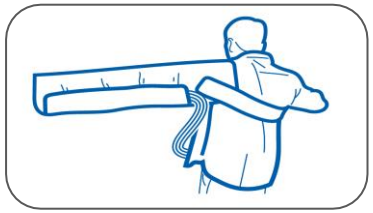


Step 2

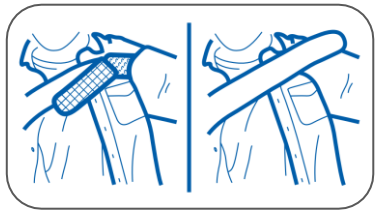


Velcro the strap to the back of the cuff.

Step 3



Step 4



Pull the cuff onto your arm and make sure the end is sitting on your shoulder. Run the strap under your other arm and attach it to the front of the cuff.

COMBINING ACCESSORIES

If you want to use other accessory cuffs, pay attention to the correct number of chambers in the cuff when buying. If you want to use several accessory cuffs at the same time, you can combine them as you like using the Quick Connectors. You can find more information about this at help.venenengel.de.

PLACEMENT OF THE ABDOMEN CUFF

Apply so that it sits in a direct transition to the leg cuffs (top leg cuff bumps to the bottom chamber of the abdominal cuff; "side by side"). Tip: First put on the leg cuffs. Then lay the belly cuff flat behind you on the floor, lounger, or sofa (inside part facing up). Slowly lie down onto the stomach cuff, on your back. After pulling the abdominal cuff to the right height, close it over your stomach.

DISPOSAL

Note that the product contains small amounts of lead. For this reason, please ensure that the disposal carried out by an official electronic waste disposal service. important: Please do not dispose of the product via your general household waste disposal.

Alternatively: we are happy to take care of the disposal of your old Venen Engel free of charge. Just send it to:

Wellcosan GmbH
Bellinger Tor 16a
36396 Steinau a. d. Str.
Germany

Please enclose a note with a request for disposal.

TECHNICAL DETAILS

Programmes	1
Number of chambers	4
Weight	ca. 3 kg
Power output	30 W
Mains Frequency	50-60 Hz
Voltage	220-240 V
Programme Length	up to 30 Min.
Pressure	30-240 mmHg

Pump output	40l / Min.
Fuse	T 0,315 A H
Controller Dimensions	28x28x15 cm
Protection Class	II / ⧈
Temperature range (use and storage)	10-40 °C
Humidity (relative, use and storage)	30-85%

PACKAGE CONTENTS

Control unit

Multi-Plug air hose set

Power plug

Compression boots
The scope of delivery of the boots depends on the set purchased

EXPLANATION OF SYMBOLS USED

Press the button with this symbol to start and pause the application.

Press the button with this symbol to switch on the unit.

Directive 2002/96/EG on electrical and electronic waste: separate collection of electrical and electronic equipment

Only use in enclosed rooms

Protection class II: This icon indicates that the device has an electrical earthing connection (dimension) not needed.

Compliant with the directives of the European Union Collaboration of a nominated agency; Directive 93/42/EEC

Serial number

Lot number

European plenipotentiary

Attention: Please pay attention to this important information regarding health risks

Caution additional information Note - take note of information

Operate only in temperature range+10°C to 40°C

Reference number on the packaging: Protect against liquids and moisture

Follow the instructions for use

Non-sterile

Operate only in barometric pressure range from 500hPa to 1060hPa

Operate only in a humidity range 30% to 85%.

Protect from medium-sized solid foreign bodies (diameter >12 mm) and against perpendicular-dripping water

Manufacturer's symbol

Date of manufacture

Certified medical device

Keep away from sunlight.

IMPORTANT INFORMATION REGARDING ELECTROMAGNETIC COMPATIBILITY (EMC)

1) This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.

1) Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.

1) Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation!

1) Caution: this machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacturer's declaration - electromagnetic emission		
The device is intended for use in the electromagnetic environment specified below. The customer of the user of the device should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11 Harmonie emissions IEC 61000-3-2 Voltage fluctuations / flicker emissions IEC 61000-3-3	Class B Class A Complies	The device 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.

Guidance and manufacturer's declaration - electromagnetic immunity			
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 an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. lf floor are covered with synthetic materi- al, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s)	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70%UT(30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for25 cycles <5% UT (>950/odip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. lf the user of the DEVICE requires continued operation during power mains interruptions, it is recommended that the DEVICE be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	l0V/m	l0V/m	Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: Ur is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
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 an environment.			
Immunity test	IEC 60601 test tevel	Compliance level	Electromagnetic environment - guidance
Radiated RF IEC 61000-4-3	lOV/m & table 9	l0V/m & table 9	Portable and mobile RF communications equipment should be used no closer to any part of the Device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = 1.167 80 MHz to 800 MHz d = 2.333 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. lf the measured field strength in the location in which the Device is used exceeds the applicable RF compliance level above, the Device should be observed to verify normal operation. If normal performance is observed, additional measures may be necessary, such as reorienting or relocating the Device. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [Vii V/m].			

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment (Table 9)						
Test frequency (MHz)	Band •1 (MHz)	Service •1	Modulation bl	Maximum power (W)	Distance (m)	immunity Test Level (V/m)
385	380-390	TETRA400	Pulse modulation bl 18Hz	1.8	0.3	27
450	430-470	GMRS460, FRS 460	FM '1± SkHz deviation !kHz sine	2	0.3	28
710 745 780	704-787	LTE Band 13, 17	Pulse mod- ulationbl 217Hz	0.2	0.3	9
810 870 930	800-960	GSM800/900, TETRA 800, iDEN 820, CDMA850, LTE Band 5	Pulse modulation bl 18Hz	2	0.3	28
1720 1845	1700-1990	GSM1800; CDMA 1900;	Pulse modulation bl	2	0.3	28
1970		GSM 1900; DECT; LTE Band 1,3, 4,25; UMTS	217Hz			
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation bl 217Hz	2	0.3	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation bl 217Hz	0.2	0.3	9

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a)For some services, only the uplink frequencies are included.

b)The carrier shall be modulated using a SO% duty cycle square wave signal.

c)As an alternative to FM modulation, SO% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be the worst case.

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810	800-960	GSM800/900, TETRA 800, iDEN 820, CDMA850, LTE Band 5	Pulse modulation bl 18Hz	2	0.3	28

WARRANTY

We offer a 24-month warranty on the control unit. In the event of malfunction,
it may be necessary to send the device back for inspection. Please ensure that the shipping box is padded to avoid possible damage during transport.
Unfortunately, no claims under the warranty can be brought for defects caused by improper shipping. Terms of warranty: ln sofar as a legal warranty obligation exists, a replacement will either be provided free of charge or the manufacturer shall have the option to repair the device, under exclusion of the right of cancellation or a reduction in the purchase price. lf repeated attempts to effect repair are unsuccessful, or a replacement unit also proves to be defective due to the manufacturers fault, the customer shall be entitled to cancel the purchase or receive a reduction in the purchase
price. Exclusion of warranty: Excluded from the warranty are defects due to
damage caused by the use of force, improper operation, externally applied force, or modifications and repair work performed by third parties, e.g. defects caused by incorrectly rated or short-circuited fuses, or defects attributable to normal wear and tear. Conditions of warranty: The warranty claim exists only in connection with the original proof of purchase (invoice). Please keep the proof of purchase in a safe place. Should you have any problems or questions when using the system, please do
not hesitate to contact us at +49 (0) 666 174 891 05 or service@venenengel.de

OTHER INFORMATION

Xiamen Weiyou Intelligent Technology Co.L,td
Adress: Unit 3 No. 6 Xianghong Road, Torch Hi-Tech Zone Industrial Park, Xiang'an District, Xiamen P.R. China.

DISTRIBUTED BY:
Wellcosan GmbH
Hauptstraße 27
36381 Schlüchtern
Deutschland

The manufacturer declares that the device complies with following normative:

- IEC606011,
- IEC60601-1-2, IEC60601-1-11,
- IEC62304,
- ISO10993-5,ISO10993-10, ISO10993-1,
- ISO 14971

Telefone: +49 (0) 666 17 48 91 05
Mail: service@venenengel.de
web: www.venenengel.de

CE
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Lin Sun

EC REP